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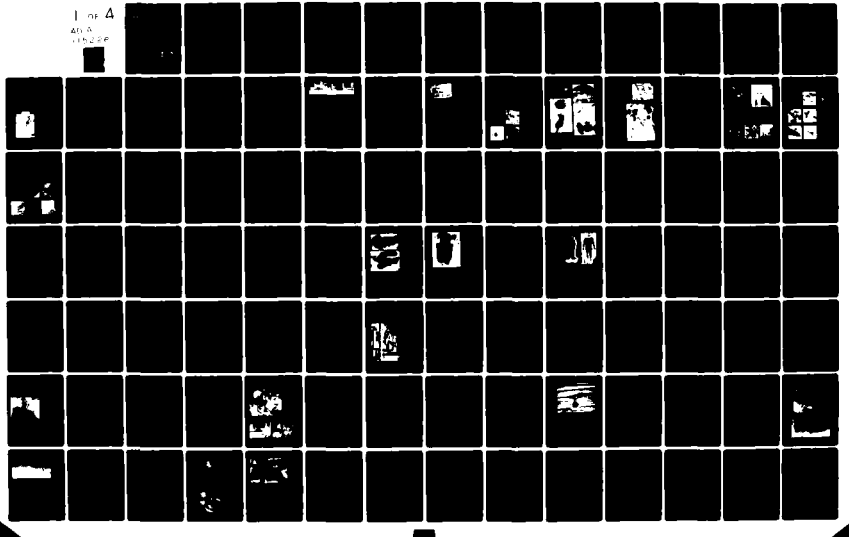

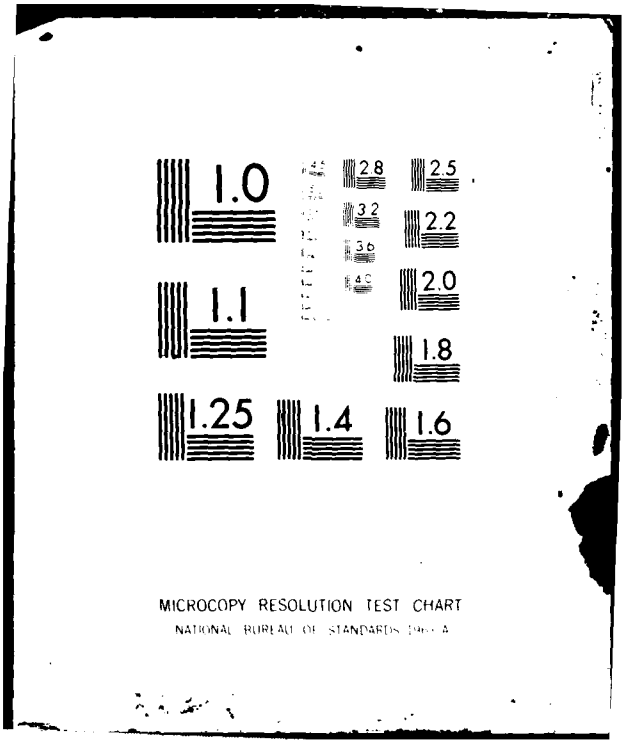
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Bulletin of Prosthetics Research

Rehabilitative Engineering Research and Development

Fall 1981

Department of Medicine and Surgery

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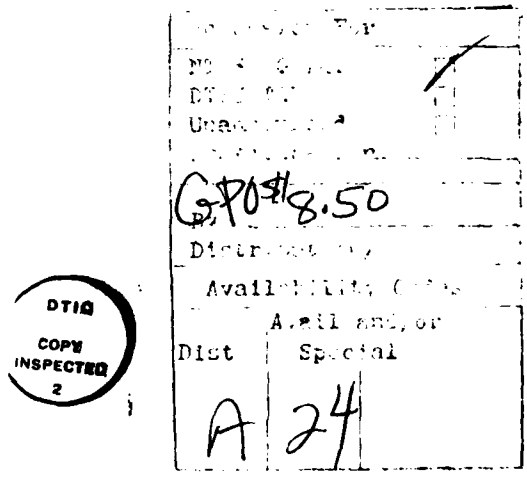

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Simplicity (an editorial)

EUGENE F. MURPHY, Ph. D.[a]
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Consumers of research results sometimes complain of complex, fragile designs and yearn for simplicity; equally, they desire simplicity of function. Some developers are proud of "sophisticated," "state-of-the-art" designs—even if untried. Organizations tend to become increasingly complex, promulgating additional regulations in efforts to promote efficiency and prevent fraud. Advertising often promotes self-gratification, or pride, not a simple life. What are some elements of simplicity?

Finley Peter Dunne's "Mr. Dooley in Peace and in War," published in 1898, is a collection of weekly columns from the Chicago Journal. The saloonkeeper-sage comments satirically on the Spanish American War, its aftermath, and on local, national and international affairs. He displays the prejudices of the time and place, and sometimes movingly discusses human nature, aspirations, and bravery in peace and war. Dunne's Preface describes the Irish immigrants among whom Mr. Dooley was supposed to live as "a simple people." "Simple, says ye!" remarks Mr. Dooley. "Simple like th' air or th' deep sea. Not complicated like a watch that stops whin th' shoot iv clothes ye got it with wears out!"

In this era of environments, aeronautics, space shots, and sea labs, we realize all too profoundly the complexities, costs, and problems of air, blue sky, and deep sea. The Space Shuttle illustrates the value of meticulous care yet also the nagging problems of scheduling, reliability, costs, and reusing a device time after time. On a much smaller scale (and budget), rehabilitative engineering has long faced similar difficulties in developing innovations to improve the quality of daily life for severely disabled persons—with minimal maintenance.

In mechanism, everyone desires simplicity of design. It should bring rapid development, high reliability, low costs, suitability in all cultures and climates, minimal training, and aesthetic satisfaction. But even a simple device may fail to meet a need or may break if overloaded or misused. (Sometimes it should, to avert greater catastrophe.)

A first principle is to eliminate devices or components where possible; why solve a problem that can be avoided? The massive locked hip joint, molded leather socket, and medial tracks and rollers of the "tilting table" hip disarticulation prosthesis, for instance, were heavy, cumbersome, subject to breakage, and awkward to use. Walking with the usual stiff artificial knee joint was difficult and tiresome. In contrast, the free hip joint, plastic socket, and free knee joint of the Canadian hip disarticulation prosthesis permit a lighter and more sanitary prosthesis, reduced clothing wear, and better gait with less energy consumption.

In 1947, the most expensive repair category under the unique VA prosthetics service card program was repair of broken hip joints or pelvic bands of above-knee limbs. The **absence** of hip joint and

[a]Dr. Murphy is Editor of this publication.

pelvic band from the suction socket prosthesis introduced that year totally eliminated part of the problem, and greater understanding of biomechanical principles so greatly reduced stresses in hip joints and bands, when used, that wear is reduced and failures rarely occur.

The SACH (Solid Ankle, Cushion Heel) foot likewise eliminated the mechanical ankle joint and rubber bumpers controlling dorsiflexion and plantar flexion. In 1947, though, cleaning and oiling the ankle joint and replacement of bumpers had been the most common repair charge.

Compromises occur. The Bowden cable simplified construction of artificial arms by replacing pulleys, guards, and thongs. Self-contained, self-suspended myoelectrically controlled below-elbow artificial arms offer freedom from shoulder harness, and simplicity in donning and removal, but they use more complex mechanisms, require recharging, and thus far lack the limited feedback of force and position provided by a Bowden cable and harness.

The whole field of electronics, for many applications, has moved rapidly toward greater simplicity and reliability at lower cost, provided sufficient numbers of identical items are involved. Everyone recognizes the trends from hand-wired vacuum tube circuits through printed circuit boards and transistors to integrated circuit chips. These changes brought great reductions in bulk, weight, power consumption, and vulnerability to vibration and shock.

Increasing use of versatile microprocessors should allow a single type of compact, mass-produced, low-cost hardware to be used for control of many different devices and functions by button-touching or a change in software. The Johns Hopkins Applied Physics Laboratory search, with grant support from the National Science Foundation and Radio Shack and participation of many other organizations and individuals, was designed to stimulate interaction between disabled persons and "computerniks." Attention again is called to IEEE Computer Society's magazine "Computer", Vol. 14, No. 1, January 1981, whose theme was Computing and the Handicapped. Numerous papers at the IEEE/EMBS and the RESNA meetings, and many of the progress reports in this Bulletin, also illustrate applications of computers to simplify the problems of the disabled. Clearly there remain vast opportunities.

Simplicity of function has often been attained by tolerating **reliable complexity** within mechanism. The elimination of the clutch pedal and of many motions through use of the automatic transmission, which simplifies driving for both normal and disabled individuals, is an outstanding example. Our essay in BPR 10-32 also traced many others. The Mauch S-N-S hydraulic knee control has increased the safety, confidence, and function of many thousands of above-knee amputees by allowing recovery from stumbles and simplifying descent of hills and stairs and changes of cadence.

Greater independence simplifies the life style of a disabled person, allowing greater freedom of choice and more flexible scheduling. Technical aids, low-force inputs to environmental controls, power mobility aids, communication systems, and (increasingly) manipulators and robotic aids are devices and systems offering such improved independence. Though there is a spectrum of increasing mechanical and electrical complexity, careful design, evaluation, quality control, and maintenance should lead to reliable, unobtrusive assistance.

Even organizations require careful design and prudent monitoring. The satires of Parkinson's Law and the Peter Principle are amusing but distressingly possible. Nevertheless, detailed controls to prevent waste and to account for costs may themselves become wasteful. Numerous health care plans, for example, will pay for substantial periods of expensive hospital bed occupancy (where costs supposedly can be audited) but will not pay for modest preventive measures or for much less expensive (though less supervised) home care, for an additional temporary prosthesis or for a modest premium price to ensure faster delivery of a definitive prosthesis. Unit-dose drug delivery offers greater control against drug abuse and more precise billing but seems intrinsically expensive.

Simplicity, too, offers a measure of each individual's **expectations** and manner of living. Modesty, decency, generosity, and thoughtfulness are more attractive than pomposity, arrogance, selfishness, and contempt. To quote Mr. Dooley again, "Whin Father Butler wrote a book he niver finished, he said simplicity was not wearin' all ye had on ye'er shirt-front, like a tin-horn gambler with his di'mon' stud. An' 'tis so."■

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Digital Approaches to Myoelectric State Control of Prostheses[a]

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ABSTRACT

The design of a new three-state myoelectric control system is presented. This controller determines its operating state from the initial rate of increase of the myoelectric signal, and the concept is realized in great measure through digital logic techniques. Proportional control of both active states (same dynamic range) is a unique feature of the controller.

A microcomputer was interfaced in a simple way with myoelectric potentials to simulate the three-state controller described and to simulate various other state-determined control methods (some multifunctional). This was found to be a valuable method of evaluating control schemes without building the actual devices.

INTRODUCTION

Since the introduction of myoelectric or electromyographic (EMG) control to limb prosthetics, there have been many attempts to use myoelectric signals for the control of prostheses with multiple degrees of freedom, and to do this with a limited number of muscle sites. These attempts have been prompted because arm amputees with high-level amputation locations frequently need multifunctional artificial arms but have limited muscle sites that are practical as myoelectric signal sources.

The most successful myoelectric artificial limbs, below-elbow myoelectrically controlled hands, may be considered to be wasteful of muscle sites because two sites (finger extensors and flexors) are usually used to control one degree of freedom (hand opening-closing). Dorcas and Scott (1) introduced the three-state single-site control concept in 1966; the method is more conserving of muscle sites because one muscle site controls one degree of freedom. Five-state single-site control (2) has also been used. These, and other state-determinant methods, often lack strong physiological underpinnings. Nevertheless, state approaches have been successful from a clinical viewpoint (e.g., Scott (3), Schmidl (4)) and probably will be used for some time to come.

Graupe (5,6) has introduced the idea of multifunctional control from one muscle site using computer-based signal analysis techniques. However, this concept awaits further development before it can be determined how it will impact the clinical problem.

This paper first presents a digitally-based circuit design for a three-state, rate-sensitive[c] single-site controller, and then presents ideas on how various multifunctional, multistate concepts may be investigated and evaluated through microcomputer approaches. A simple method of interfacing myoelectric inputs with microcomputers is presented. This interface concept may have future applications in microcomputer-based myoelectric limbs.

[a]This work is supported by Veterans Administration Contract V101(134)P–326.

[b]Dept. of Clinical Neurophysiology, Regional Hospital, S–701 85 Orebro, Sweden. Mr. Philipson spent 1980 as a Visiting Engineer at the NU Prosthetics Research Laboratory.

[c]Rate-sensitive, as used in this paper, refers to circuits or devices that set their state in a manner dependent upon the rate of change of the input signal or some function thereof.

THREE-STATE MYOELECTRIC CONTROL

In a three-state controller the myoelectric or electromyographic (EMG) signal from the control muscle is classified as belonging to one of three groups. The classifying parameter can, for example, be the root-mean-square (RMS) amplitude of the EMG, or it can be the rate at which the RMS amplitude is changing (7). By detecting three different states of the EMG signal from one muscle site it is possible to control one degree of freedom (*off, forward, reverse*) in a prosthesis.

A three-state controller that is amplitude sensitive may have the characteristics shown in Figure 1. When the EMG level is below level T1 there is no output from the controller. For an EMG level that stays between levels T1 and T2 longer than time t_d, output **A** is activated. Output **A** will stay *on* until the EMG level is no longer in the region between T1 and T2. When the EMG level goes above level T2, output **B** is turned *on*. Output **B** will continue until the EMG level drops to a value less than T2. A time delay, t_d, makes it possible to directly activate or deactivate output **B** without activating output **A**.

The amplitude-sensitive three-state controller seems to work best with an on-off output characteristic. It is possible to let the amplitude of the EMG level above T2 proportionally control output **B**, but because the zone T1-T2 may occupy a large part of the dynamic range of the EMG signal, this may not be an effective approach. High levels of EMG may be required for full output from **B** in this semi-proportional arrangement, and this may result in muscle fatigue.

The rate-sensitive three-state controller is an alternate approach that some users find more desirable than the amplitude approach. A three-state controller that is rate-sensitive can have the characteristics shown in Figure 2. Childress (8) designed an early rate-sensitive three-state controller based on an idea of Colin Ruch. (The idea was conveyed in conversation by the late Colin Ruch, a biomedical engineer from South Africa, during the ACEMB Conference in Houston in 1968.) That controller used the natural rate-sensitive characteristics of a silicon-controlled rectifier (SCR) as the rate-detection circuit. Dillner & Hagg (7) first suggested the approach described here; their approach is easily realized with digital circuitry, and offers the added advantage of permitting proportional control, although they did not implement a proportional feature.

The general principle of the approach is illustrated in Figure 2. The block diagram of Figure 3 shows how we implemented this approach with a digital-type processing scheme.

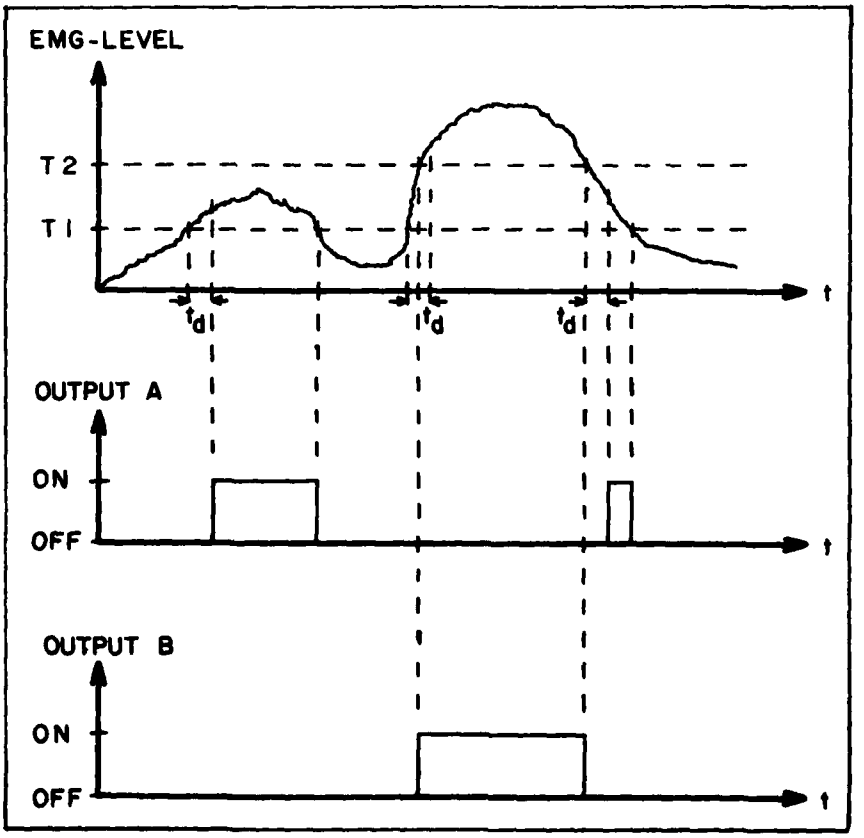


FIGURE 1.
Diagram showing three-state characteristics of an amplitude-sensitive controller. A rectified and integrated EMG signal (EMG-level) in the interval T1 to T2 will activate output **A** and an EMG level in the interval above T2 will activate output **B**. Time-delay t_d makes it possible to activate output **B** without activating output **A**.

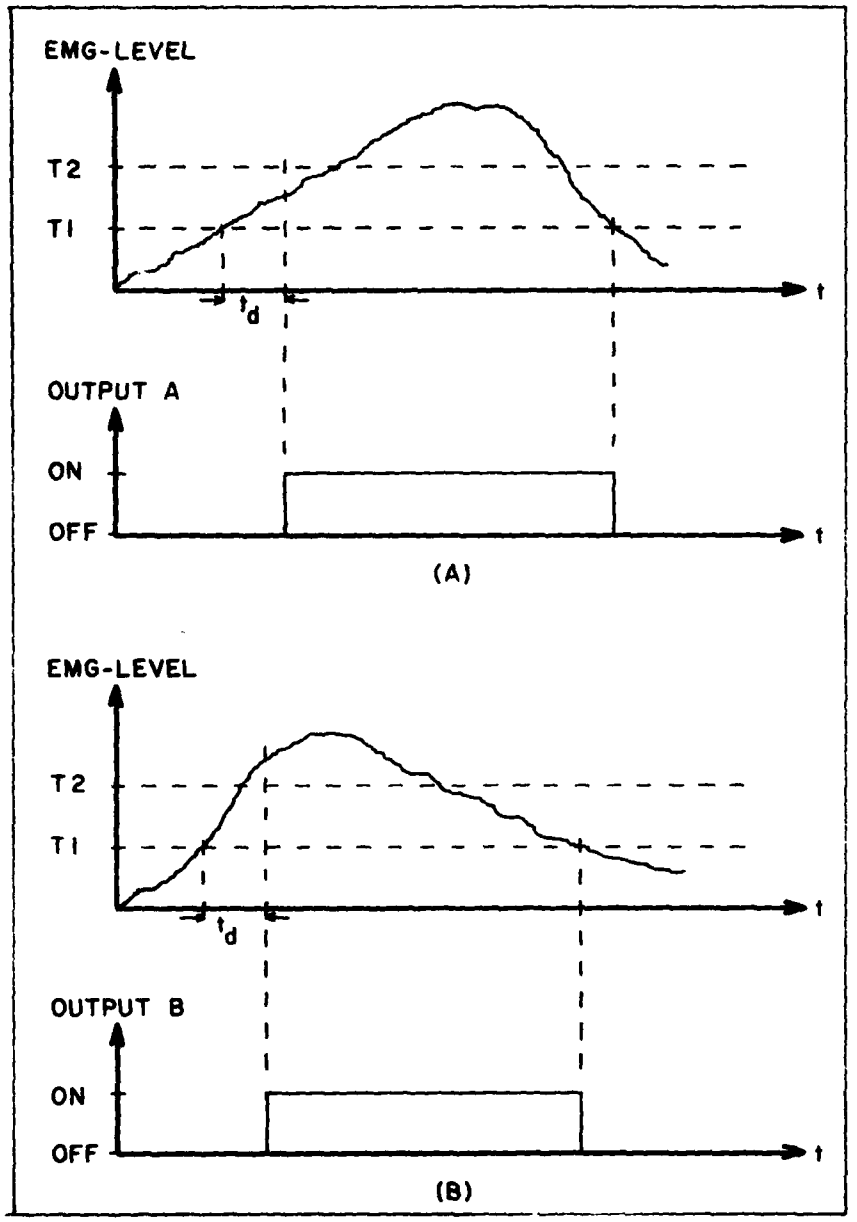


FIGURE 2.
Drawings showing the characteristics of a three-state rate-sensitive controller. The upper drawing, A, shows that a slowly rising EMG level will activate output A. The lower drawing, B, shows that a relatively faster rising EMG signal will activate output B, if threshold window is traversed in an interval less than t_d. The activated output will remain on until the EMG-level drops under level T1.

The principle of operation is based on the average rate of change of the processed EMG signal over a specified time period, t_d. If at t_d seconds after the signal crosses threshold T1 the signal is greater than threshold T2 (T2>T1), then the average rate of change over t_d is greater than (T2-T1)/t_d. Otherwise it is less than this value. The state decision is based on this averaged rate of change of the signal, not on an instantaneous value of the somewhat noisy signal. It is possible to control the output in a quasi-proportional way by letting the EMG control the output (myo-pulse) drive, after the rate-based decision has been made.

Description of Operation of Three-State Proportional Myoelectric Control Circuit

The new three-state proportional myoelectric controller that we have developed is shown in block-diagram form in Figure 3 and diagrammed in detail in Appendix A. The amplified EMG signal is converted to a pulse-type signal in the myo-pulse processor. Figure 4

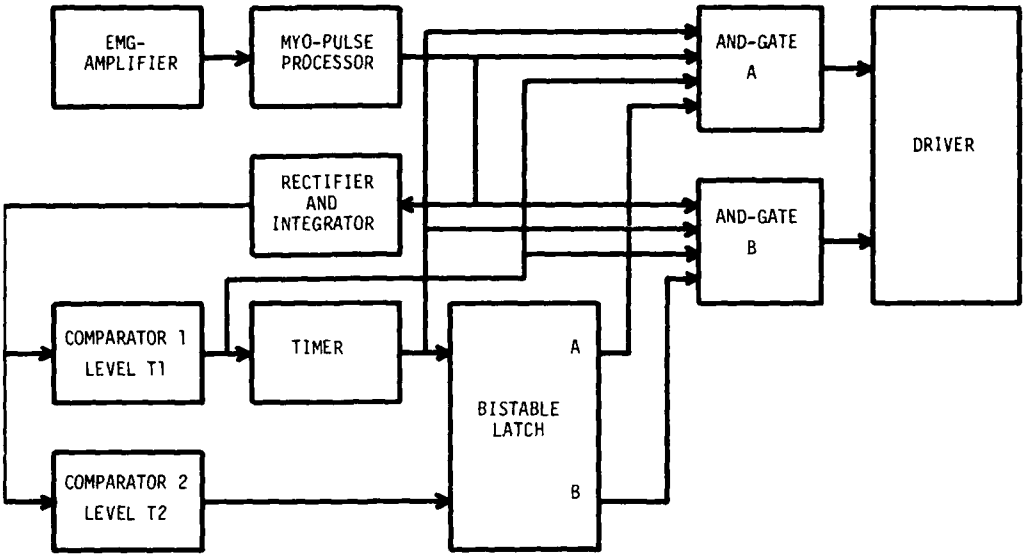
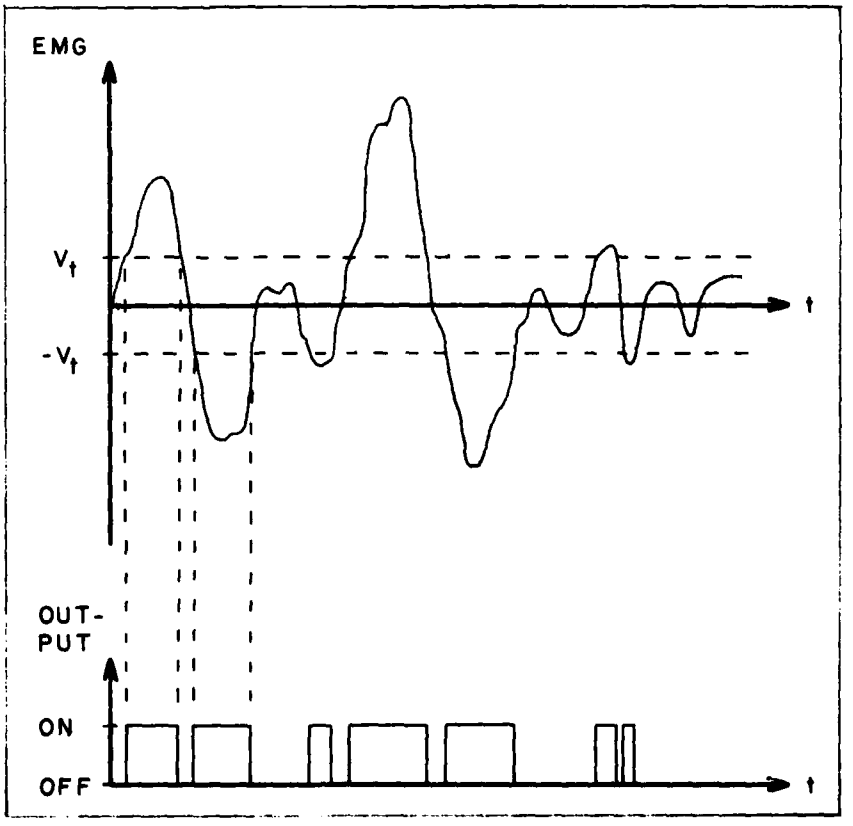


FIGURE 3.
Block diagram of a three-state myoelectric control circuit. The function is described in the text.

FIGURE 4.
Illustration of the myo-pulse processing technique. The upper record represents a typical band-pass filtered electromyographic signal (EMG). When the absolute value of the EMG exceeds a threshold V_t, the output (lower record) saturates. The output will have a duty cycle related to the EMG amplitude.



illustrates this conversion. This so-called "myo-pulse" processing technique has been described elsewhere (9) and has proved to be a practical processing technique in myoelectric control. The power output to a drive motor may be driven directly with this signal, without electrical filtering. The digital-like myo-pulse signal is "gated" to the driver according to the decision made about initial rate of EMG increase.

The rectifier and integrator supplies the two comparators with a DC level that is proportional to the EMG level. When the EMG level reaches level T1 the output from comparator *1* goes *on*, this transition starts the timer. When the timer times out, after the t_d, the bistable latch is clocked[a]. If, when the bistable latch is clocked, the output from comparator *2* is *off*, the latch will be set with output **A** on and output **B** *off*.

If, when the bistable latch is clocked, the output from comparator *2* is *on* (the output of comparator *2* will go *on* when the EMG-level exceeds level T2), the latch will be set with output **A** *off* and **B** *on*.

In other words, a low-rate contraction will open AND-gate **A** at the end of the time-interval t_d and a high-rate contraction will open AND-gate **B** at the end of the time interval t_d (~80 msec).

When either gate is open, pulses from the myo-pulse processor can pass through the gate to the actuator, providing proportional-like control of the prosthetic device.

AND-gate **A** or AND-gate **B** will remain open until the EMG-level drops to a value lower than T1. The driver circuit, when activated, provides power to the motor in the prosthetic device and provides damping to the motor.

The circuit as physically realized is shown in Figure 5. This circuit is identical in size to the two-site circuit used in the VANU myoelectric hand system. Therefore, it can be substituted for the two-site circuit when single-site control is required.

We have successfully used the system with three below-elbow amputees. Each was originally fitted with the SCR rate-sensitive circuit and subsequently changed to

[a]This time out signal also enables the two AND-gates. In this way unwanted outputs are avoided while the timer is running.

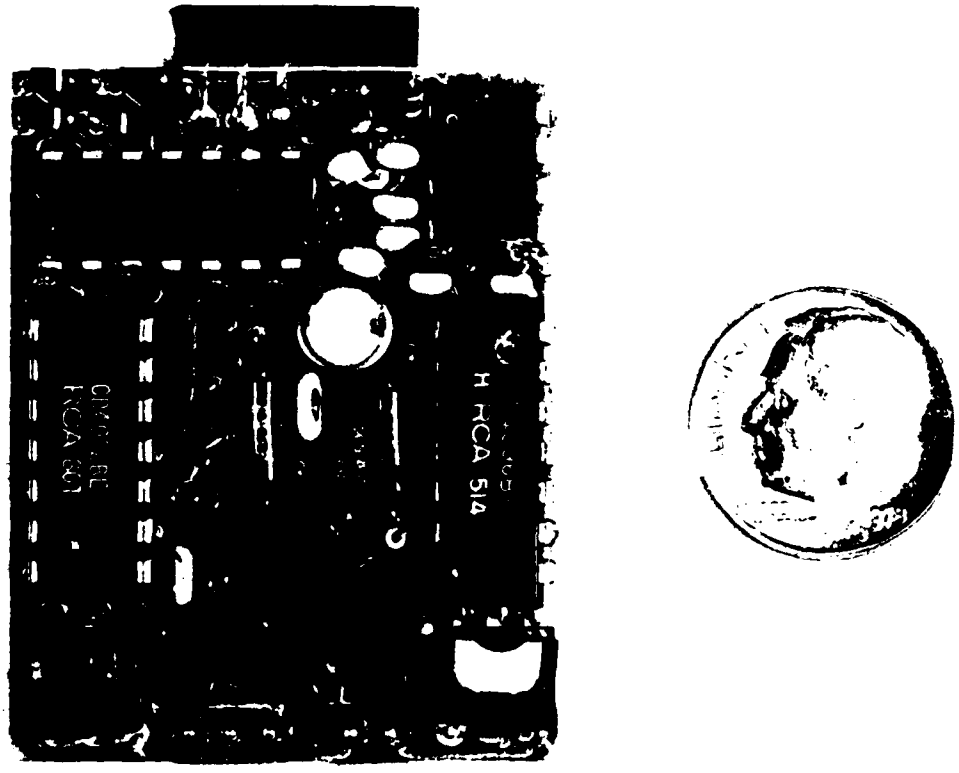


FIGURE 5.
Photograph of a three-state rate-sensitive myoelectric control circuit. The printed circuit board measures 3.5 · 4.4 cm.

the circuit described here because this circuit was simpler (less expensive, more reliable, and easier to adjust) and had proportional control of both hand opening and hand closing.

Clinical Experience

R.S. is a 34-year-old bank executive (Right B/E, electrical burns) first fitted with rate-sensitive myoelectric control of a hand prosthesis in 1968, when he was a college student. He could use only single-site control from wrist extensor muscles because the remaining flexor muscles cramped when contracted. He was converted to the single-site system described here in 1977 and used it daily until 1979 when he was converted to a two-site system, as the muscle cramping problem had gone away. R.S. operated the system easily, and rarely activated the wrong mode, although he found the single-site system required more attention to operate than the two-site system. It also could not be cycled between output states as quickly.

D.M. is a 31-year-old businessman who first received a single-site myoelectric hand system as an immediate postsurgical fitting in 1970. A punch press injury during summer work from college had resulted in a B/E amputation of his right arm. All flexor muscles of the forearm were lost in the injury and subsequent surgery. D.M. was converted to the system described in this paper in 1977 and continues to use the system daily.

W.V., a 47-year-old securities broker (Left B/E, Trauma), was referred to our laboratory in 1971 because he had only one below-elbow myoelectric site. Fitted that year, his system was upgraded in 1978 to contain the three-state system described. He continues to use this system.

All the amputees described operated the three-state system without difficulty on their first trial. Training sessions were not necessary. Quick muscle contractions are easily separated from slow ones. Because the users rarely made incorrect control commands it was not thought necessary to make laboratory measurements of accuracy. The systems clearly gave good control of a prehension prosthesis, although the control was not as automatic or quick as with two-site control of the same kind of prostheses. Experience indicates there is a small percentage of below-elbow amputees who cannot use two-site control for whom the circuit described is beneficial. The system can be used for higher-level amputations, but our experience has been limited to below-elbow amputees.

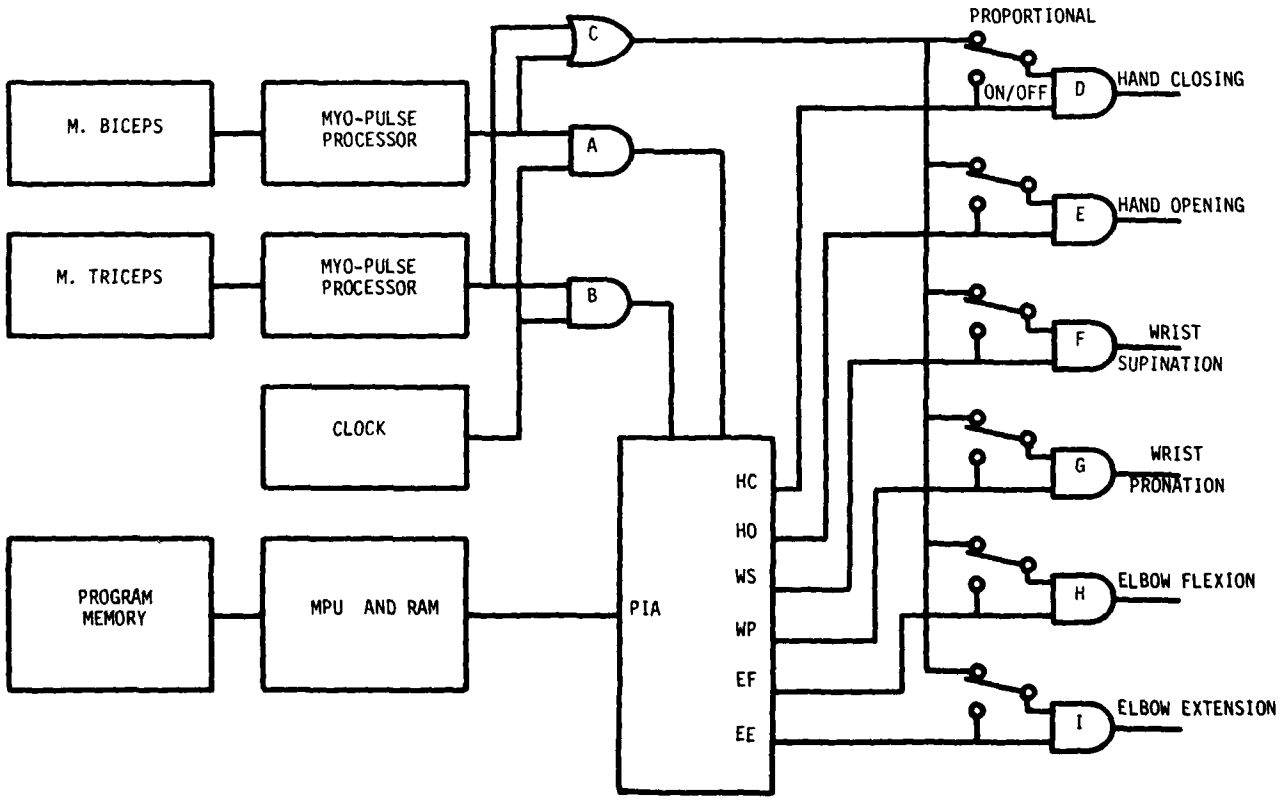


FIGURE 6.
Block diagram of a microcomputer-based myoelectric control system that can utilize one or two electrode inputs and produce up to seven output modes in ways determined by the control program. RAM (Random Access Memory), MPU (Microprocessing Unit), PIA (Peripheral Interface Adaptor), D,E,F,G,H,I, (AND-gates).

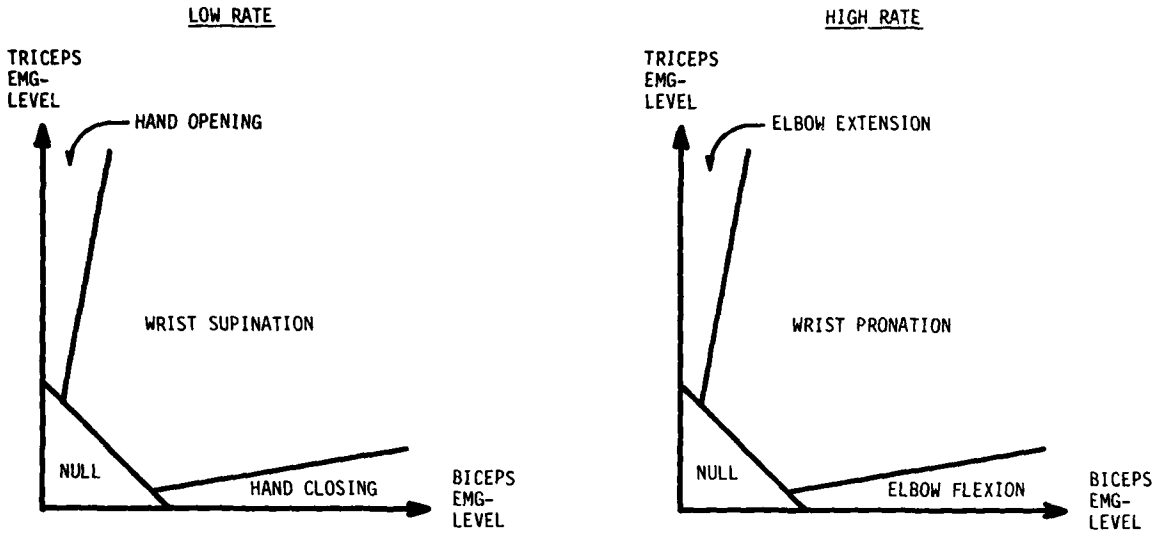


FIGURE 7.
Figure showing state relationships of a possible control method for an A/E prosthesis (two muscle sites controlling three degrees of freedom). Table 1 also describes this state relationship.

Multi-State Proportional Myoelectric Control Using Microcomputer Techniques

One of the problems associated with "state" approaches to prosthesis control, particularly multifunctional control, is that, frequently, various concepts need to be experimentally evaluated. Evaluation may be expensive and arduous if new circuitry must be designed for each new concept. Our goal has been to develop a microcomputer-based device which would allow different control algorithms to be examined by changes in computer program rather than by hardware changes.

The system was developed to handle up to two myoelectric signal inputs, although this could be expanded to any desired number. Proportional or on-off output drives have been provided.

Figure 6 shows the control system in diagrammatic form. Although the system was developed for rapid laboratory evaluation of control concepts, it has potential for future use in actual prostheses. The use of a microcomputer-based controller in a self-contained battery-powered prosthesis should become common in the near future. In fact, a generalized hardware system compatible with a wide variety of control schemes and prosthetic designs seems possible. In that way one hardware system could easily be used for many control techniques commonly used today. Standardized hardware could reduce cost of electronic controllers for artificial limbs.

Description of Operation

The EMGs from two muscle sites are processed as described in Figure 4. The outputs from the processors are logically AND-ed with a high-frequency clock in gates **A** and **B**. By letting the microprocessor count the number of pulses coming from gates **A** and **B** during a fixed time interval, a measurement of the EMG level in the muscles is obtained. The technique of letting the output from the EMG processor gate pulses from a high-frequency clock has been described previously in a paper by Ichikawa et al. (10).

With information concerning the EMG level in the two control muscles, the microprocessor can make a decision on what motion the user wants the prosthesis to perform. This decision can be made according to a resident control algorithm. When the decision is made, the appropriate gate in the gate-array (**D** through **J**) will be opened by the peripheral interface adaptor (PIA). The outputs of the gates may be operated in either an on/off mode or in a proportional, pulse-width-modulated, mode, depending on the setting of switches in front of gates **D** through **I**. The outputs from the two myo-pulse processors are logical OR-ed by gate **C**, producing a signal that is proportional to the boolean sum of the outputs from the myo-pulse processors. This signal can be gated to drive the actuators in a proportional way if the switches are set in the proportional mode.

Several control algorithms have been laboratory-tested. One successful algorithm tested (based upon subjective laboratory experiments with amputee and non-amputee subjects) was a seven-state controller that employed two muscle sites. The state relationships are shown in Figure 7. Table I summarizes that approach.

The muscle space may be partitioned in many other ways (e.g. see Childress (11) et al.). The computer permits rapid experimental examination of various parti-

tioning schemes and allows rapid adjustment of parameters within a particular scheme. Software changes, as opposed to hardware changes, make this possible.

TABLE 1.

rate of contraction	principal muscles	output function
low	triceps	hand opening
low	biceps	hand closing
low	triceps and biceps (co-contraction)	wrist supination
high	triceps	elbow extension
high	biceps	elbow flexion
high	triceps and biceps	wrist pronation

CONCLUSIONS

Several illustrations of the use of digital components and microcomputer technology in the design of some control systems for limb prostheses have been presented.

Extended clinical experiences with three below-elbow amputees indicates rate-sensitive three-state control to be an effective alternative to two-site control. The rate-sensitive circuit described offers proportional control over a wide dynamic range of EMG. The circuit is simple and realizeable with few digital components. The authors believe that digital techniques will play an increasingly important role in the control of future limb prostheses, in the same way that these techniques are influencing so many other fields today.

We have demonstrated that the microcomputer is a powerful tool for empirical evaluation of various prosthesis control ideas. The laboratory trials have elucidated simple techniques for interfacing myoelectric signals with computers and have demonstrated how micro-computers may be used in future prostheses as all-purpose, generalized controllers■

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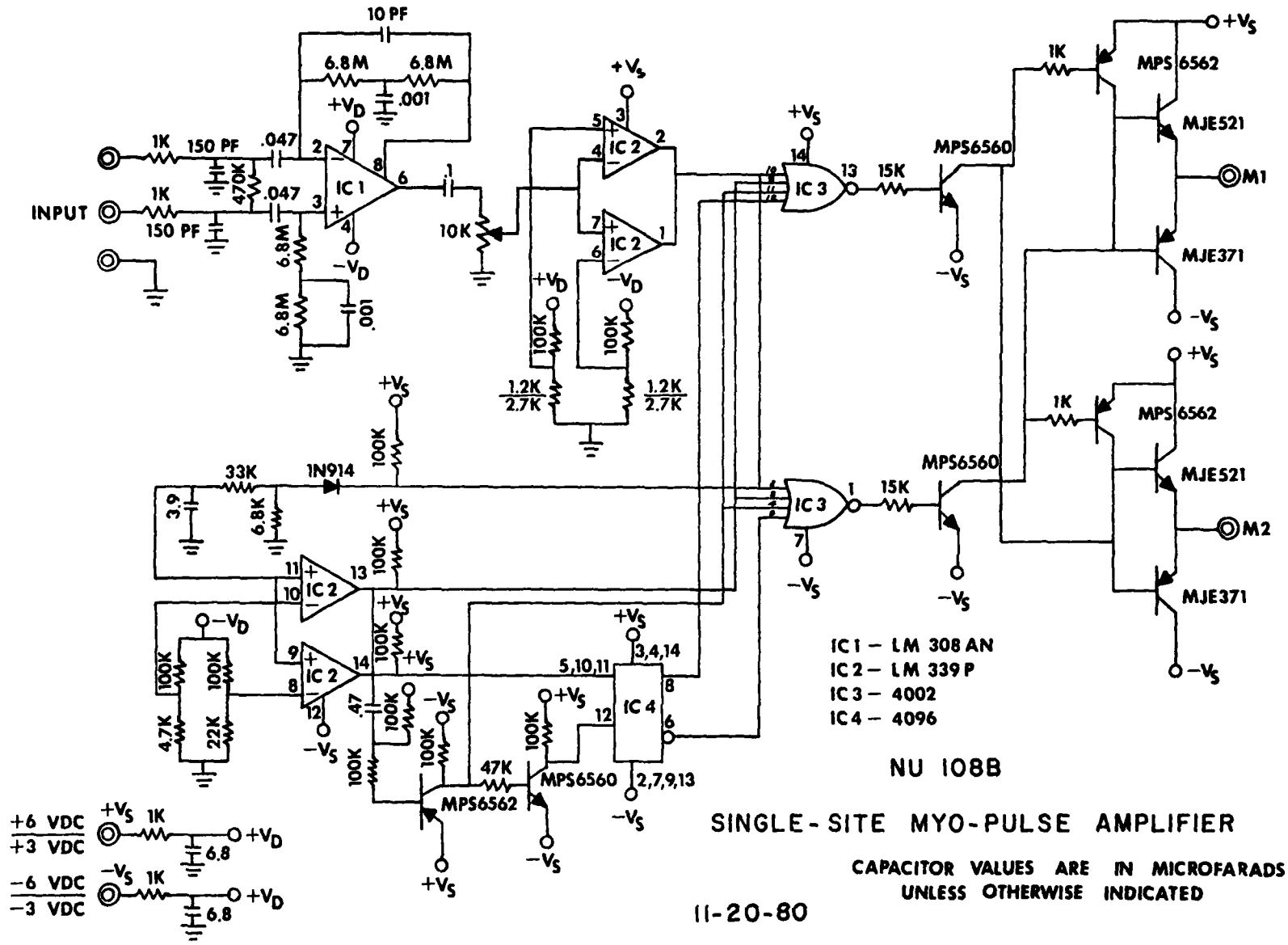
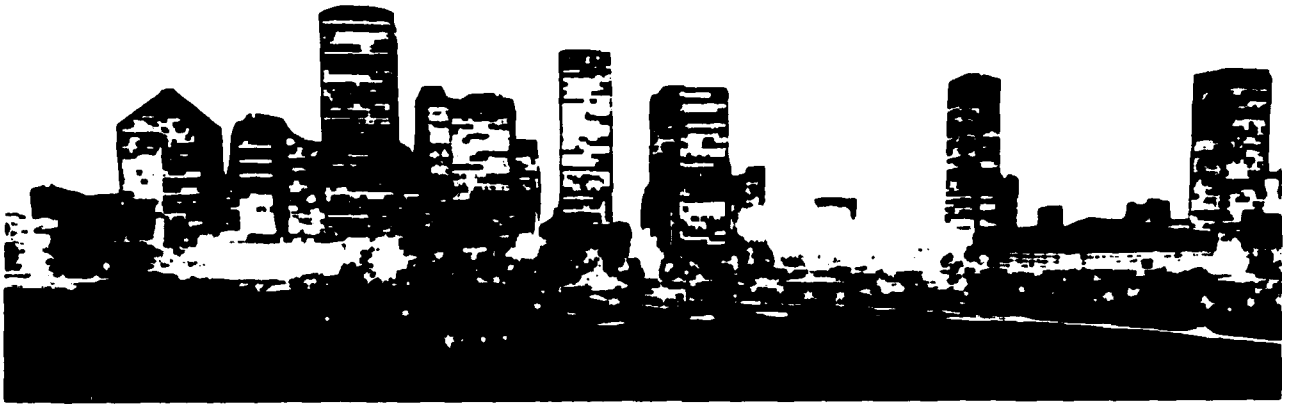


APPENDIX A

New three-state proportional myoelectric controller. Also shown in block-diagram form in Figure 3.

Note: 4-input NOR gates (4002) were used in the actual implementation as diagrammed above. However, the block diagram which appears as Figure 2 showed AND gates for descriptive purposes. With the AND gate configuration all inputs are required to go high before the gate output will go high. In contrast, NOR gate output goes high when all inputs go low.



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TECHNICAL NOTES

"Technical Notes" in BPR originated when certain Progress Reports went beyond the usual scope to present a wealth of detail about some single aspect of the research, typically a matter of instrumentation or materials or procedure.

With the establishment of the category, authors have been finding the department a useful channel of communication. Material available has tended to grow in intellectual and technical stature. BPR's editorial posture has changed in response, so that the earlier informal verification by staff and occasional external review has tended to give way to a more formal procedure which involves reviewers from the publication's Editorial board, ad hoc reviewers, or both, as may be appropriate to deal with complex or wide-ranging subject matter. This "double-anonymous" review effort frequently equals that given to all regular feature articles in this publication.

Therefore, while these more ambitious Technical Notes may lack the number of subjects, weight of data, and discovery of or replication of new knowledge required for a traditional scientific article, they have been handled with the greatest possible respect for the authors' devotion and the readers' requirements.

The Wear Particles of Synovial Fluid: Their Ferrographic Analysis and Pathophysiological Significance[a]

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Abstract—This article reviews recent progress in our investigations into the wear particles which accumulate in prosthetic and natural diarthrodial joints. Ferrographic analysis of these particles is providing new insight into the manner in which joints undergo wear in situ. It also has the potential to serve as a diagnostic and prognostic technique, with special application to monitoring very early changes in the wear status of joints and distinguishing the various arthritides. Wear particles interact with periarticular cells and tissues, provoking the release of lytic enzymes and eliciting other biochemical changes, which exacerbate the destruction of the joint.

Introduction

Recently a novel analytical tool, ferrography, has enabled us to undertake a non-invasive study of the very early deterioration that accompanies various arthritides when applied to an aspirated sample of synovial fluid. The method permits a critical separation of diverse types of biological wear particles generated from the bearing surfaces of an articular joint.

[a]This investigation was supported by the Veterans Administration and by NIH Grant AM20697.

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Ferrography is a technique devised originally for the analysis of wear particles in machines. Ferrous wear particles are retrieved from a sample of the lubricating oil under the influence of an external magnetic field. Microscopic examination of the particles thus retrieved permits accurate diagnosis of the wear status of the machine (q.v.).

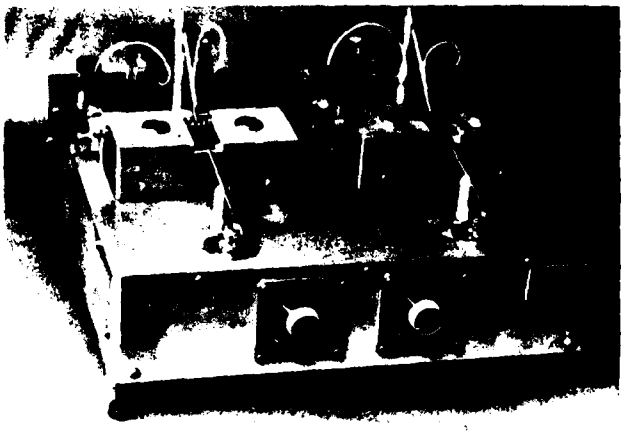
Given the success of the ferrographic technique with machines, it was suggested that ferrography could be profitably applied to the analysis of wear particles contained in the synovial fluid of natural and artificial joints. For prosthetic joint replacements, this would allow a non-surgical, sophisticated analysis of the rate and type of wear of the implant and prognostication of its future performance. With natural joints, there is the enticing prospect of vastly improving the differential diagnosis of arthritis. Particularly important is the potential of ferrography to facilitate an early diagnosis, before the disease has progressed to conspicuous radiological manifestations, by which time potentially prophylactic treatments may not longer suffice and surgical procedures remain the only solution.

Wear particles in joints are of additional significance. By influencing the metabolism of cells in the surrounding tissues, particles eroded from prosthetic devices could contribute to various of the adverse reactions which result, for example, in loosening of the implant, or infection. In natural joints, the wear particles may be mediators of tissue destruction during arthritis, in which case their investigation should provide insights into the disease process itself.

In this article, we review progress made here and at Foxboro Analytical, Burlington, MA, in the application of ferrography to the study of wear particles derived from human and prosthetic joints, and in establishing their possible role in the initiation and progression of arthritis.

The Analysis of Wear by Ferrography

Ferrography is a technique of proven worth in evaluating tribological processes by studying the wear particles they produce. Developed by Vernon Westcott of Foxboro Analytical, Burlington, Massachusetts, ferrography is based upon the magnetic retrieval and separation of wear particles



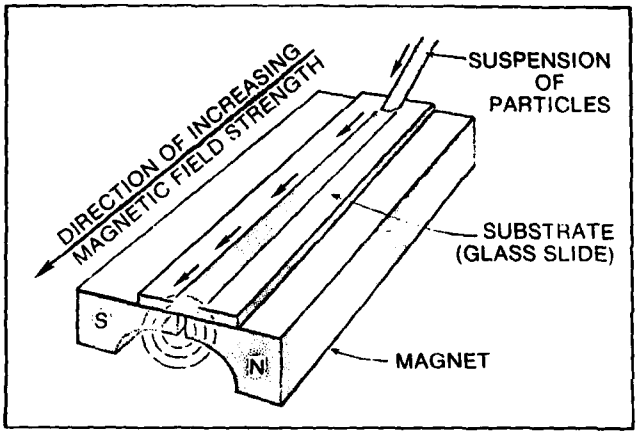


FIGURE 1
The ferrograph analyser. The photograph at the top of the page shows a "dual" analyser capable of processing two samples simultaneously. The diagram illustrates the interaction of the suspension of wear particles with the magnetic field during the ferrographic analysis.

FIGURE 2
A ferrogram. This ferrogram has been deliberately overloaded with cartilaginous wear particles and stained to illustrate the technique. The substrate is 60 mm long. The entry point is at the left of the photograph, and contains the highest concentration of particles.

from lubricating fluids (1). It was originally designed to monitor wear in machines, where the particles are typically ferrous and thus intrinsically susceptible to an external magnetic field. Most biological materials are, of course, diamagnetic, so, as described later, special techniques have had to be developed to enable their magnetic separation.

With machines, a small volume (usually 1–3 ml) of lubricating oil is slowly pumped along a thin glass microscope slide (the substrate) which lies in a high-gradient magnetic field (Fig. 1). The substrate is raised slightly at the point where it first comes into contact with the sample (the entry point), so that particles encounter a perpendicular magnetic force which is weakest at the entry point and which increases progressively down the length of the substrate. Consequently, for particles of the same unit volume susceptibility, the largest particles deposit nearest the entry point, with a grading of particles according to size down the length of the substrate. A washing solution is pumped over the particles on the substrate, which is then allowed to air dry. The resultant ferrogram (Fig. 2) can then be examined by various optical and electron microscopic techniques.

Particles are classified on the basis of their size, shape and other morphological features, to indicate the operation of certain wear modes in the machine from which the sample was drawn. Once the "running-in" period of the machine is over, it is normal to find a moderate number of elongated particles (Fig. 3) indicative of rubbing wear. Abnormal conditions are indicated by increased numbers of particles of greater size and of distinctive morphology indicative of cutting wear, fatigue, or other disturbances (Fig. 3). These particles appear on ferrograms **before** adverse symptoms affect the machine (2): As different components of engines are made from different alloys, identification of the constitution of the wear particles permits the **site** of excessive or abnormal wear to be located.

The ferrographic analysis of engine oil has been extensively reviewed (2,3).

Ferrographic Analysis of Human Joints

With the foregoing background, ferrography seemed of potential value in studying wear in human artificial and natural joints. Wear particles accumulate in synovial fluid in much the same way as they do in engine oil. Non-invasive, objective, diagnostic and prognostic, this technique yields important information pertaining to the rates of wear, types of wear and reasons for failure of prosthetic joint replacements. This information may greatly aid the development of improved implants, and would permit convenient, non-invasive, serial assessment of the progress of implanted prostheses with minimum discomfort to the patient. Ferrography also has potential application to studies of osteoarthritis, where mechanical wear of the joint surfaces occurs.

Ferrographic analysis of prosthetic joint replacements—Ferrography was first applied to the examination of synovial fluids and washings obtained from replacement joints. Such metal-on-metal or metal-on-plastic arthroplasties constitute a type of machine confined within the body, and provide the

opportunity for a logical extension of the original ferrographic technique.

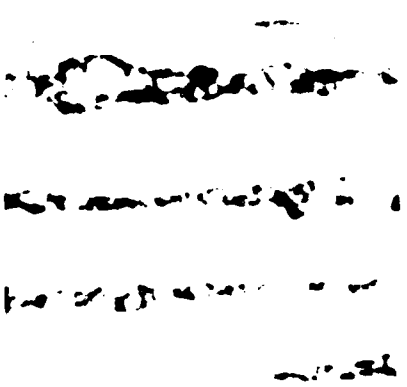
Synovial fluids, or saline washings, from these sources can be processed by a method analogous to that used to make ferrograms from engine oil. This is so because the tiny metallic particles become embedded in the surrounding materials, thereby imparting a magnetic susceptibility which is sufficiently high for normally diamagnetic wear particles to be retrieved under the influence of the magnet of the ferrograph. Under these conditions, wear particles of cartilage, bone, plastic, polymethylmethacrylate and synovium can be analyzed without the need for artificial means of magnetisation (4).

Synovial fluid is obtained by sterile needle aspiration from joints after arthroplasty. If synovial fluid is unobtainable, the joint can be flushed with sterile saline. About 2 ml of the synovial fluid are pumped over the substrate as described below.

Following washing and drying, the ferrogram is first examined by optical microscopy. A useful instrument in this context is the bichromatic microscope, providing both reflected and transmitted illumination (1). Using the appropriate filters, the transmitted light is green and the reflected light red. Under the bichromatic microscope metallic wear particles appear red, due to their attenuation of the green transmitted light and reflection of the red, direct light. Non-metallic materials appear green, yellow or pink, depending upon their density or thickness. Polarized light is advantageous when examining particles of bone, cartilage, methylmethacrylate and plastic.

Following optical inspection, particles can be examined with greater morphological precision using the scanning electron microscope (SEM) and their elemental composition can be determined by energy dispersion X-ray analysis.

Ferrographic analysis of saline washings of failed prostheses (Fig. 4) reveals the presence of metallic, plastic and polymethylmethacrylate particles in synovial fluid (Fig. 5). The relative proportions vary with the type of prosthesis and the severity and type of wear which has occurred. Thus, larger numbers of metallic particles are found when both articular surfaces are composed of metal. With metal rubbing on polyethylene, most of the particles are plastic, and range from 1–10 μm in diameter up to shredded fibres several hundred micrometers long. Metallic particles range in size from under 0.25 μm where wear is relatively small, to 1 mm in length where fatigue or abrasive wear has occurred. Polymethylmethacrylate particles are generally cuboid with large variations in size from 1 μm to 1 mm or more. Sometimes, these particles adhere to metallic fragments. Particles of bone, cartilage and synovial tissue are also found. Histological examination of synovium demonstrates the presence of embedded wear particles,



3-A

3-B

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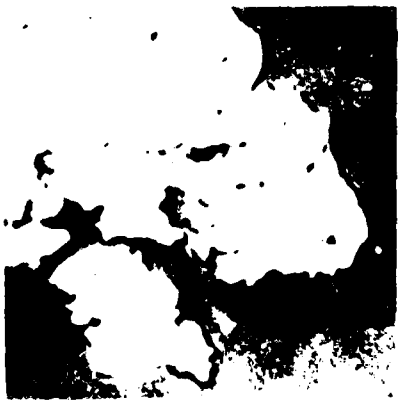


3-D

FIGURE 3
Wear particles from engine oil. (A) Normal rubbing wear particles, mag. 450×. (B) Cutting wear particles, scanning electron microscopy, 225×. (C) Fatigue wear particles, mag. 450×. (D) Laminar wear particle, mag. 1000×.

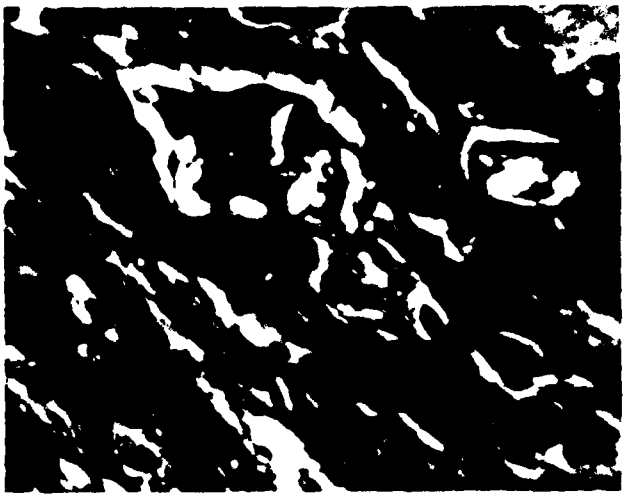
FIGURE 4
Macroscopic appearances of wear in failed prosthetic joint replacements. At top of page, erosion of the polyethylene surface of a failed total knee replacement is seen; the depressions are filled with polymethylmethacrylate. Above, a failed total hip replacement. Again, there is pitting of the polyethylene surface with polymethylmethacrylate infilling. Note that the metallic component is less severely eroded.

FIGURE 5
Wear particles from prosthetic joints, recovered by ferrography. At top, metallic wear particles, mag. 1000 ×. Center, polyethylene wear particle under polarized light, mag. 400 ×. Immediately above, polymethylmethacrylate particles under polarized light, mag. 400 ×.

while phagocytic cells containing endocytosed wear debris can be retrieved from the synovial fluid of affected joints (Fig. 6).

X-ray elemental analysis of the metallic particles confirms that they originate from both the arthroplasty and the surgical instruments, most especially haemostats, scissors, and osteotomes (4).

This study revealed interesting and encouraging similarities to the ferrographic analysis of the lubricating oil of machines. In both cases, excessive wear is signalled by an increase in the numbers and sizes of particles, and the presence of wear particles representing altered and abnormal modes of wear. Thus, ferrography appears to offer the same advantages to studying wear in prosthetic joints as it presently does to studying wear in machines. The presence of wear debris embedded in the synovium (Fig. 6) indicates how rapid prosthetic wear could provoke a painful,



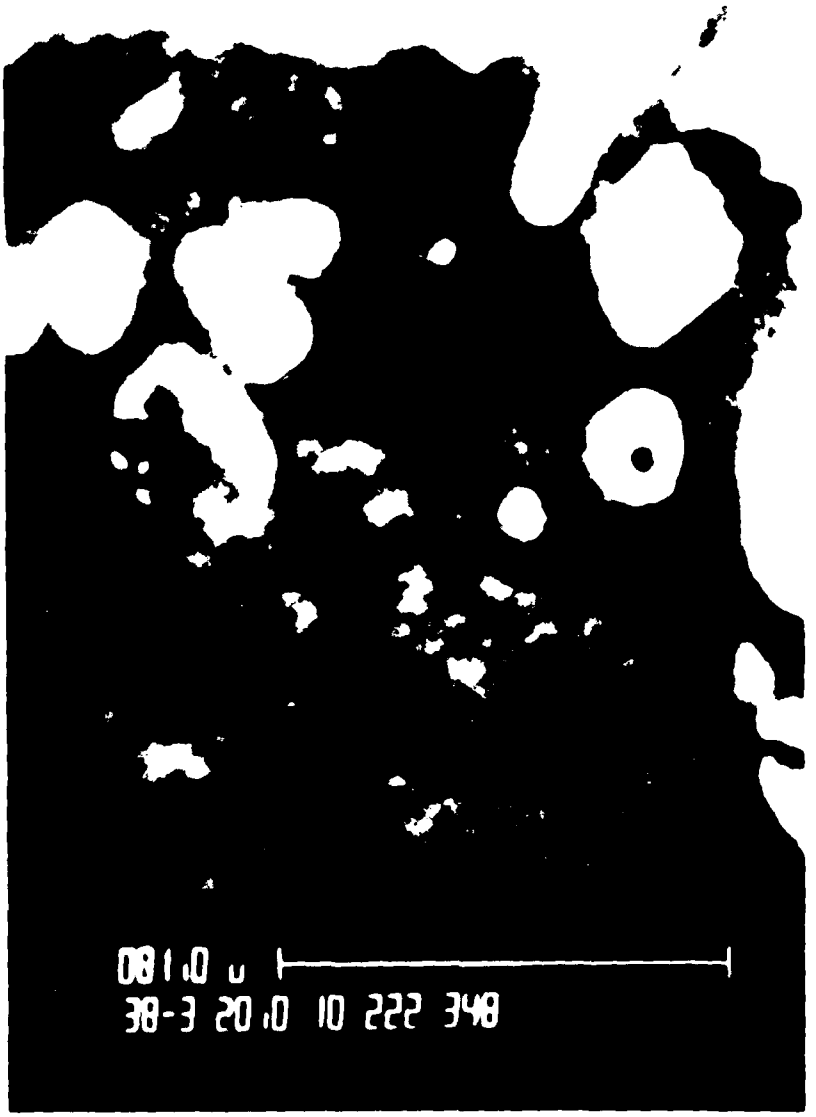


FIGURE 6
Interaction of wear particles with surrounding cells and tissues. Above, right: a polarized light micrograph of synovium shows embedded wear particles. Mag. 100×. At right, a transmission electron micrograph of a polymorphonuclear leukocyte retrieved from the synovial fluid. Engulfed particles occur in intracellular vesicles. Mag. 38,300×.

proliferative synovitis. Such information has stimulated further modification of implant design, and it has indicated one other pathogenesis of a painful joint replacement.

Ferrographic analysis of wear in natural joints—Before the biological wear particles present in the synovial fluid of natural joints can be analyzed effectively by ferrography, it is necessary to make them susceptible to external magnetic fields. Research conducted at Foxboro Analytical has produced methods of achieving this (5). The 'magnetisation' process is based on the sorption of paramagnetic cations of the rare earth element erbium (III) to particles of bone and cartilage (6). Because Er^{3+} interacts strongly with many other substances in synovial fluid, producing troublesome precipitates, the particles are first collected by centrifuging and washed three times by resuspension and recentrifuging in saline (0.9% w/v). Even this may be insufficient to adequately remove hyaluronic acid, a sticky macromolecule which may pose problems by tenaciously coating the particles. For this reason, the washed particles are treated mildly with a highly specific hyaluronidase before analysis. (That step is usually unnecessary for particles obtained through saline washings of joints.)

Bloody samples are difficult to process. If the degree of contamination is slight, the erythrocytes can be lysed in distilled water prior to ferrography. This leaves a residue of cellular debris which, in modest quantities, is not a problem. Samples of synovial fluid quickly form gelatinous precipitates. For this reason, all such specimens must be centrifuged, washed and resuspended in saline before storage. Sodium azide (final concentration 0.02% w/v) should be added to stored saline suspensions of wear particles to prevent microbial contamination.

Peculiarities of "biological" ferrography—Although biological particles achieve considerable positive magnetic susceptibilities on treatment with magnetising solutions containing Er^{3+}, the induced susceptibilities are many times less than those of corresponding metallic particles. For this reason, it is necessary to position the substrate flat against the magnet (Fig. 1) to ensure adequate recovery of the biological material. Unfortunately, this arrangement reduces the longitudinal gradient in magnetic force that is exerted on the particles as they flow along the substrate, thereby interfering with the size-grading of particles along the ferrogram. This is exacerbated by the chemical heterogeneity among the wear particles themselves which influences their uptake of Er^{3+} and thus their individual magnetic susceptibilities. Such heterogeneity results from intrinsic variations in chemistry at different locations within the cartilage, from different mechanisms of wear, and from alterations produced by the disease. (Eventually, the resultant change in ferrographic behaviour of such particles may prove of diagnostic value.)

Dust-free work area—When making and examining ferrograms, it is necessary to work in an environment which is free from dust. Particles of dust are often optically active and in many cases resemble cartilaginous wear particles. Extraneous particulates can be prevented by situating the ferrograph analyser and the bichromatic microscope in a laminar flow hood.

Notes on Optical Analysis—Examination of the ferrograms is first undertaken with the bichromatic microscope, as described in the previous section. Ferrograms made from synovial fluid aspirates reveal a variety of deposited materials, not all of which are yet completely understood.

As bone and cartilage are both optically active, **polarized light microscopy** is especially useful. Whereas most cartilaginous and osseous wear particles are conspicuous under polarized light, soft tissue components such as synovium or other cellular material are not. Osseous particles usually have high optical activity and a compact, chunky appearance; much of this is due to the scattering of light when it encounters the polycrystalline mineral of bone. Consequently, osseous particles remain bright as the direction of prolongation is changed while maintaining crossed polars. On the other hand, materials exhibiting birefringence, in which the molecular structure of the particle is organized over a period of several micrometers, will exhibit a change in light intensity as a function of the direction of prolongation. Cartilaginous particles vary greatly in their optical activity—some resemble bone in having high optical activity, while others are barely visible under crossed polars. This may reflect their degree of mineralization, the extent to which the collagen fibres are oriented along a single axis, and the thickness of the particles.

Occasionally, especially in the larger cartilaginous particles, one can observe lacunae which, in life, contain the chondrocytes. Phase contrast microscopy facilitates such observations.

Histological and chemical notes—Various histological techniques have been brought to bear on the complex problem of particle identification. It would seem, at first sight, that these various types of particle could be elucidated by standard histological techniques, many of which have been specifically devised for differentially staining the tissues of the joint. This, however, has not proved as straightforward as it appears.

The reasons for this are several.[c] The chemistry of the wear particles probably differs from that of the intact tissue. Specifically, metachromatic staining of articular cartilage is markedly reduced in early osteoarthritis, reflecting a loss of the proteoglycans which are responsible for many of the staining properties of cartilage. Also, once released into the synovial fluid, further biochemical modifications of the minute articular particles may occur. However, some success has been obtained with a modified Movat's pentachrome stain (7).

X-Ray analysis of materials—Particles of bone and cartilage which have not undergone excessive degradation can be distinguished readily by energy dispersion X-ray analysis. As shown in Figure 7, cartilaginous particles give a strong sulphur emission from their sulphated glycosaminoglycans. Bone provides strong calcium and phosphorous peaks (Fig. 8), while mineralized cartilage

[c]Procedures required to avoid staining problems, when Er^{3+} has been employed to impart magnetic susceptibility to tissue particles, are discussed in (7).

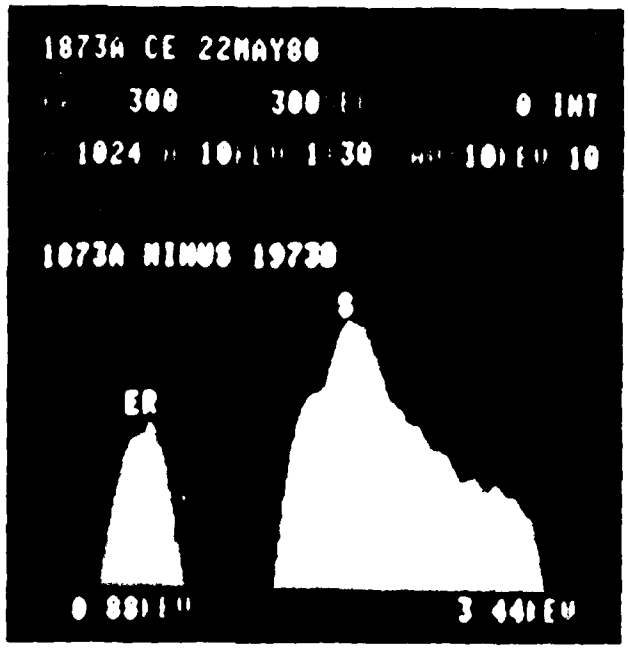


FIGURE 7—cartilaginous wear particle (arrowed), mag. 200×, with (at right) its energy dispersion X-ray analysis spectrum. The analysis shows the presence of sulphur, from the sulphated glycosaminoglycans of cartilage, and erbium, which is used to magnetize the particles. The sulphur peak is irregular due to subtraction of the background spectrum produced by the glass substrate.

contains both of these and sulphur. Figure 8 compares part of the elemental spectrum of bone (background) with soft tissue (foreground). The bone gives a major peak of calcium, while the soft tissue has only a small calcium peak, which is dwarfed by that of potassium. A difference in their relative amounts of chlorine is also seen.

While this technique is rather tedious for routine use, it serves to resolve the identity of enigmatic particles and to cross-check the various other methods tested in the search for improved identification techniques.

Comments on an Analysis of 50 Synovial Samples

Having developed a technique for the ferrographic analysis of synovial fluid aspirates, its applicability was investigated by an analysis of about 50 synovial samples. This survey yielded encouraging results (7). A variety of different particles deposited on the ferrograms, indicating that discrete wear particles do indeed exist in human synovial fluid, and that they are susceptible to ferrographic analysis. It was also encouraging to observe that wear particles were not pieces of random detritus, but that many of them fell into one of several different, identifiable morphological categories.

On the basis of that preliminary work, we are beginning to appreciate the different types of wear particle in joints, the wear conditions that produce them, and their significance. In the work outlined below, the ferrographic analysis was compared to radiographic, arthroscopic, and physical

8-A 8-B 8-C

FIGURE 8—Osseous particles under (A) unpolarized and (B) polarized light, mag. 200×, with (C) their energy dispersion X-ray analysis. The background spectrum is that of bone showing a marked calcium peak. In the foreground is, for comparison, non-osseous tissue which has only a little calcium.

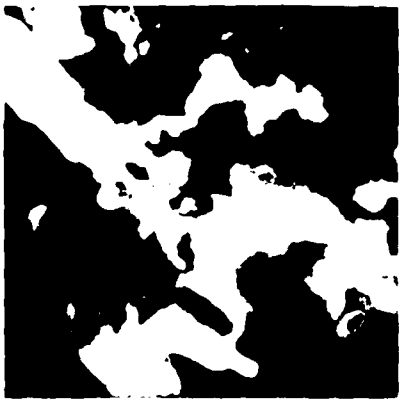
examination of the joint from which the sample was obtained.

Ferrograms made from the wear debris of joints with even modest degrees of articular erosion often contain a sizable and varied population of wear particles. Some of these are indicated in Figures 9 (a, b) and 10 (a, c). The array shown in Figure 9a is the entry deposit, viewed under polarized light at 100x magnification, of a ferrogram made from the synovial fluid of a patient with chondromalacia patella. Closer examination of samples such as these enables many of the particles to be categorized.

FIGURE 9
Types of cartilaginous wear particles are shown in the photographs at right and below.

(a) Entry deposit on ferrogram from chondromalacia patella, polarized light, mag 100 ×.

(b) Thin, angular lamellae of superficial cartilage, unpolarized light, mag 200.



(c) Cartilaginous wear particles from a moderately eroded knee joint. Mag. 200 ×, polarized light.

(d) Fibrous cartilaginous wear particle, mag 200 ×, polarized light.

(e) Spherical cartilaginous particles. Mag 400 ×, unpolarized light.

(f) Triangular fragment of cartilage and cartilaginous sphere, polarized light, mag 400 ×.

(g) Cartilaginous wear particles retrieved from osteoarthritic joint, mag 200 ×, polarized light.

(h) Large cartilaginous wear particle from osteoarthritic joint, mag 100 ×, unpolarized light.

Benign forms of low-grade wear in joints appear to generate small (< 40 μm) flakes of thin, angular lamellae of cartilage with weak optical activity. These occur on most ferrograms, even where damage is light, and they are likely to originate from the superficial layers of the cartilage. An SEM micrograph of one such particle is shown in Figure 9b.

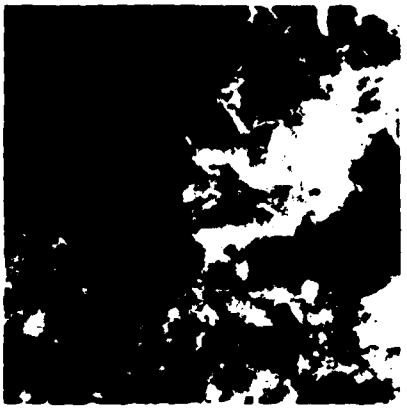
More severe damage—When damage to the articulating surfaces is more severe, the lamellae are larger (~ 80 μm) more numerous, and sometimes give the impression of being laminate. More severe wear also produces larger particles of higher optical activity and a more compact appearance, as shown in Figure 9c under polarized light. Possibly, these are derived from the deeper zones of the cartilage or are produced by different wear mechanisms, or both. Other cartilaginous wear particles are elongate rods, some of which have a coarse fibrous nature (Fig. 9d). (We suspect that many of the latter are derived from the meniscus.)

Spherical particles—Under certain conditions, spherical cartilaginous particles occur. The ones shown in Figure 9e are about 5 μm in diameter and were retrieved from the knee of a patient with chondromalacia patella. The sphere shown by SEM in 9f is larger (~ 25 μm diameter) and of stronger optical activity.

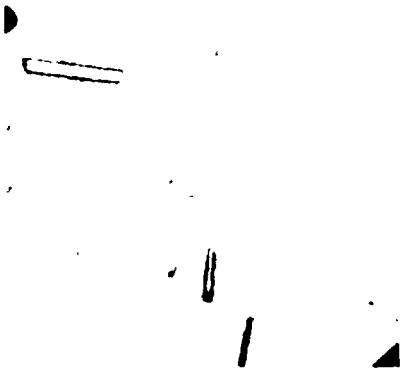
The mechanism of production of cartilaginous spheres remains to be determined. In machines, spherical wear particles are shaped by their rolling in minute cracks in the surface of one of the components of the machine. Spherical particles in synovial fluid may be formed from non-spherical precursor particles in an analogous manner, or they may have been spherical to begin with. In the latter case, an unusually precise wear process must have carved them out of the cartilage, or, more probably, pre-existing spheres within the cartilage might have been released by the wear process. In several examples, there was evidence of some degree of mineralization associated with the spheres (7). This tentative suggestion may bear some relationship to the observations of Pautard (8) on the morphology of crystallized material within bone. In one instance, a high concentration of mineralized spheres of diameter 25–30 μm was seen on a ferrogram made from the synovial fluid of a patient with bursitis and primary osteoarthritis (Fig. 10e). McCarty has observed slightly smaller spheres of hydroxyapatite in the shoulder joint of certain patients (9).

(a) Optically inactive membrane, mag. 100×, unpolarized light.

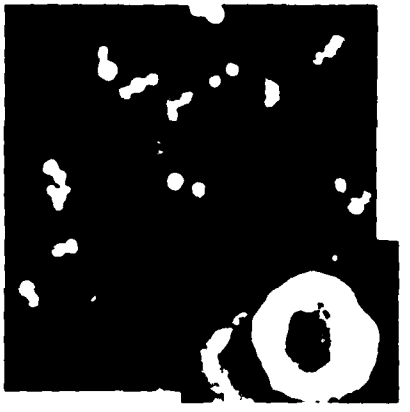
(b) Amorphous debris, mag. 100×, unpolarized light.



(c) As (b), polarized light.



(d) Crystals, mag. 400×.



(e) Crystalline spheres, mag. 200×, polarized light. (Inset shows SEM of one sphere, mag. 1000×.)

FIGURE 10
Photographs (a) through (e) show examples of other types of deposits encountered on ferrograms.

Other evidence of crystal deposition in osteoarthritic joints is growing. This would provide an ideal mechanism for the generation of the "cutting wear particles" of cartilage we have observed on ferrograms made from the fluid of osteoarthritic joints. (Wear particles could conceivably serve as foci for the deposition of minerals.)

When articular erosion is severe, larger particles are produced which do not fall into distinct morphological categories such as the lamellae, spheres, and rods mentioned earlier. The triangular particle shown in Figure 9f is one such example. Others are shown in Figures 9g and 9h. Lacunae are visible in the particle shown in Figure 9g. Part of another large cartilaginous particle is shown in Figure 9h under polarized light, again, lacunae are evident. In some cases, cartilaginous wear particles have a blue-grey sheen under polarized light (7).

Ferrograms contain other types of wear particle in addition to the cartilaginous ones described above. Thin, amorphous membranes without optical activity (Fig. 10a) probably represent fragments of synovium. In contrast, amorphous debris of the type shown in Figure 10b has appreciable optical activity (Fig. 10c). Preliminary energy dispersion X-ray analysis suggests an appreciable level of associated sulphur, indicating the presence of cartilage proteoglycans. These deposits may thus constitute a degraded form of cartilage, possibly that subjected to enzymic attack. In agreement with this interpretation, the few samples of rheumatoid synovial fluid which we have analysed by ferrography, and where the enzymic mode of degradation of cartilage would be expected to be operative, have high amounts of this material (7).

Minerals in the form of crystals (Fig. 10d) or spheres (Fig. 10e) also occur on ferrograms. Those containing phosphate become especially magnetic (6) as Er^{3+} has a high affinity for phosphate groups.

The sizes of the synovial wear particles are generally much larger than their metallic counterparts. Even in joints where the damage is light, wear particles reached 20–30 μm in size, with fibres being larger than this. As with machines, increased severity of wear produced particles of increased size, particles up to 2 mm in length often appearing on ferrograms. Even larger fragments occur in severely arthritic joints. (The upper size limit for detection by ferrography is set by the gauge of the hypodermic needle used to aspirate the sample, and the bore of the turret tube used in the ferrographic analysis (Fig. 1).) Along with the increased size which accompanies more advanced degeneration, there is increased morphological variety among the particles, which thus become difficult to classify.

Studies of Selected Patient Groups

The preliminary survey already described has confirmed the applicability of ferrography to synovial fluid analysis: the wear particles fell into a number of unique categories which varied from one patient to another; the sizes and morphologies of the particles altered with the severity of wear. However, no clear-cut differences could be found between the various groups of diseases studied (chondromalacia patella, torn meniscus, osteoarthritis, rheumatoid arthritis) (7). From these findings, it became clear that realising the diagnostic and predictive potentials of ferrography would require close scrutiny of selected groups of patients whose medical histories and arthritic conditions were minutely detailed.

To develop that phase of the project, in collaboration with Dr. Carl Stanitski of the University of Pittsburgh Health Center, we are presently limiting ourselves to ferrographic analysis of saline washings of knee joints recovered during arthroscopic examination of the knee. This eliminates many variables—we are dealing with only one joint (the knee) and with a limited number of disorders. Most patients suffer from a torn meniscus, chondromalacia patella, or early osteoarthritis. On occasion, arthroscopic examination will reveal no joint abnormalities, thus providing valuable "normal control" samples, which are otherwise difficult to obtain. Arthroscopy also has the advantage of permitting close visual examination of the articulating surfaces and synovium, thus providing the detailed information needed in a study of this kind. Ancillary historical data, physical examinations, and radiological assessments can be correlated with the ferrographic analyses and arthroscopies.

The most interesting group of patients in this study have been those whose arthroscopic examinations revealed essentially no damage to the cartilaginous surfaces of the joint. One illuminating subset contained three patients of equivalent age (11, 12, 14 years). The initial arthroscopic examination classified each of these as normal. However, ferrographic analysis revealed marked differences between one of these patients, whose knee contained very little wear debris, and the two others, whose ferrograms contained evidence of cartilaginous damage. On arthroscopic re-evaluation, one of the latter two patients was found to have a possible slight softening of the patella, and the other a barely detectable softening of the femoral condyle. Thus, ferrography seems much more sensitive than arthroscopy to subtle changes in the integrity of the cartilage.

Examination of five patients with torn anterior cruciate ligaments reinforced that conclusion. Ferrograms made from saline washings of the affected knees contained an appreciable amount of wear debris. Although the number of wear particles was elevated, their size remained small; some were rounded particles only 1–5 μm in diameter. In each case, arthroscopy failed to detect this 'micro-damage' to the cartilage. The suggestion has been made that such damage may arise from the alteration in biomechanical forces within the joint as a result of the ligamentous injury. With ligamentous laxity, sliding of the articular surfaces may supplement the normal rolling motion and greatly alter the wear pattern. In the presence of peripheral ligamentous injury (or with abnormal joint congruity perturbed by traumatic, congenital, or arthritic change) the local sites of linear or point contact on the bearing surfaces might result in excessive forces on those bearing surfaces, so that abnormal wear modes ensue. This suggestion finds support in the analysis of the wear particles in the knees of two patients in which the torn cruciate ligamentous injury was superimposed on another defect; in one of these this was softening of the articular cartilage and in the other it was a slightly "ragged" meniscus. In both cases, the numbers and types of wear particle revealed damage in excess of that caused by torn ligaments or the other injuries alone.

Patients with articular damage of sufficient severity to be detected by arthroscopy yielded elevated numbers of wear particles of large size and varied morphology.

These studies illustrate the extreme sensitivity of ferrography to articular damage. Its superiority over arthroscopy has two aspects. First, there is the magnification factor; ferrograms are routinely examined under the optical microscope under magnifications of 100x–400x. With the electron microscope, much higher magnifications are possible. Arthroscopy, however, scans for articular damage at magnifications of only 3x–5x. A second aspect is the greater resolution permitted by the means used for examining the wear particles, in contrast to that used to view the bulk material, when searching for evidence of damage.

It appears, then, that even grossly normal knee joints do contain some wear particles. This observation raises questions about normality. Preliminary analysis of a few samples seems to indicate that the "background" wear debris of asymptomatic joints increases with age. This ties in with the observation that most, if not all, joints degenerate with age, even though only a fraction suffer from clinically overt arthritis. We are presently trying to analyse ferrographically a sufficient number of samples from asymptomatic knee joints to permit an accurate assessment of this matter.

The Pathological Significance of Wear Particles: Observations and Hypotheses

Specialized phagocytic cells exist for the removal of particulate matter from the body. Most active in this respect are macrophages and polymorphonuclear leucocytes, both of which are derived from the stem cells in the bone marrow. Their phagocytic activities are thought to feature in defense against invading microorganisms. Several other types of cell are able to internalize particulate materials. Of relevance to arthritis is the ability of synoviocytes to do this.

Phagocytosis has a number of biochemical and physiological consequences. One is the release of various hydrolytic enzymes, several of which degrade cartilage. A variety of particulate stimuli have been shown to elicit this response, including inert substances such as latex beads (10), asbestos (11), minerals (12), precipitated immunoglobulins (13) and collagen (14). Putting these two observations together synthesises the hypothesis that phagocytosis of wear particles provokes the release of lytic enzymes which attack the articular surfaces. This would "soften" them, thus potentiating the mechanical release of more particles. Such circumstances could alter the wear modes in operation, thus producing particles of altered morphology. These "secondary" particles could also differ chemically from bulk cartilage as a result of the enzymic attack which had facilitated their production. Such particles might have an altered propensity to provoke the phagocytic cells into releasing enzymes. From these considerations, it is easy to appreciate the possibility of complex interactions between mechanical wear, cellular and biochemical events, and arthritis.

In initial experiments to examine these possibilities, macrophages and synovial cells were grown in tissue culture and exposed to wear particles retrieved from synovial fluid aspirates. The conditioned culture media were then examined for various proteolytic enzymes of relevance to the breakdown of cartilage (15). The results are summarized in Table 1. Both macrophages and synovial cells released proteinases in response to the wear particles. Collagenase may be important in breaking down the collagenous component of cartilage. It is interesting to note that synovial cells released more collagenase than macrophages; cultures of rheumatoid synovium are a rich source of this enzyme (16). This difference is reflected in the inability of macrophages to liberate as much hydroxyproline from cartilage as synoviocytes. Both types of cell produced equivalent activities of the other proteinases tested and were able to release quite large amounts of degraded proteoglycan from cartilage (Table 1).

In every case, mild trypsinisation of the media revealed enzyme latency (Table 1). From these data it is not possible to determine to what extent the newly synthesised enzymes are latent, as their autoactivation occurs during concentration and storage of the conditioned media.

With these initial observations, attention is being turned towards delineating which features of the wear particles are responsible for producing the cellular effects. Wear particles are very heterogeneous in size and shape. Their precise chemical make-up also varies depending on whether they are of meniscal or articular cartilage, or osseous, and to what extent they have been subject to enzymic attack.

The first of these variables to be investigated was size. Synovial fluid aspirates were not used as a source of particles for these experiments, as the yield of particles of any one size range is small. Furthermore, even particles of one size may be chemically heterogeneous. Thus, to minimize the number of variables, meniscal cartilage was used as a source of particles. This was powdered and added to cultures of cells. The response of cells exposed to cartilaginous particles of this type was compared to that elicited by latex beads of diameter 1 μm and 45 μm. From the results of such experiments (Table 2), it was concluded that internalization of particles by the cells was not a necessary condition for enzyme release. Particles which are too large for endocytosis adhere to the cell surfaces and promote the release of enzymes (17). This observation ties in with the demonstration by Harris et al. (18) that urate crystals need not be internalized by synovial cells to stimulate the production of collagenase. Thus it seems that, qualitatively, the observed tissue response is not limited to one particular size of wear particle, although there may well be qualitative differences due to variations in surface area to volume ratios, etc.

Cartilaginous particles provoked a greater release of neutral proteinases than did latex beads (19), which are assumed to be biochemically inert. It thus appears that chemical, as well as physical, stimuli are involved in the effects produced by cartilaginous wear particles on cultures of macrophages.

Chondroitin sulphate is a major component of cartilage, which appears to be one of these chemical stimuli (19). Purified chondroitin sulphate produced a marked elevation in the secretion of both lysosomal hydrolases and neutral proteinases by cultured macrophages (Table 3). The effect is

TABLE 1.
Rates of production of proteinases by cells in the presence or absence of wear particles.

Cell Types	Conditions	Production[a] of Proteinases (mU[b]/10^6 cells/day)			
		Collagenase	Gelatinase	Azocaseinase	Pz-Peptidase
Murine Peritoneal Macrophages	without particles	0.73 ± 0.06	2.37 ± 0.18	1.53 ± 0.18	1.92 ± 0.17
	without particles, trypsinised	0.97 ± 0.10	2.87 ± 0.21	2.18 ± 0.20	2.41 ± 0.21
	with particles	1.52 ± 0.21	4.84 ± 0.25	2.91 ± 0.23	3.53 ± 0.28
	with particles, trypsinised	1.91 ± 0.52	6.56 ± 0.43	4.28 ± 0.35	5.08 ± 0.46
Human Blood Mononuclear Phagocytes	without particles	0.33	2.52	2.05	1.83
	without particles, trypsinised	0.83	3.15	3.10	2.42
	with particles	1.61	4.72	3.22	3.69
	with particles, trypsinised	1.85	5.98	4.86	5.11
Human Synovial Cells	without particles	1.31 ± 0.14	3.00 ± 0.21	1.33 ± 0.21	2.64 ± 0.19
	without particles, trypsinised	2.38 ± 0.21	5.19 ± 0.46	2.56 ± 0.30	3.82 ± 0.30
	with particles	5.52 ± 0.35	6.52 ± 0.53	2.84 ± 0.38	5.31 ± 0.42
	with particles, trypsinised	9.95 ± 0.89	11.56 ± 1.03	5.20 ± 0.51	8.18 ± 0.78

[a]Results shown for murine peritoneal macrophages are the means ± SEM of six replicate experiments; for synovial cells, four replicates; and for human blood phagocytes, the average of two replicate experiments.

[b]1 unit of collagenase, gelatinase or Pz-peptidase degrades 1μg substrate per min at 37°. 1 unit of azocaseinase degrades 1mg azocasein per hour at 37°.

reversible; within three days of changing the cultures of macrophages back to a medium which does not contain chondroitin sulphate, the production of neutral proteinases and lysosomal hydrolases returns to normal.

Certain lines of evidence suggest that these effects are not limited to the artificial conditions of tissue culture. Wear particles exist in considerable amounts in many osteoarthritic joints (7). Observations such as those shown in Figure 6 demonstrate the interaction of these particles with periarticular cells and tissues, which may explain the synovitis and other signs of inflammation that often occur in osteoarthritic joints. Furthermore, the activities of several of the enzymes measured in the work described here are also elevated in tissues taken from osteoarthritic joints (20).

Animal Model: Preliminary Results—We have recently employed laboratory animals to determine, in a more direct manner, whether wear particles have arthritogenic properties (21). Intra-articular injections of particles of rabbit articular cartilage into the knees of recipient rabbits provoke an intense inflammatory arthritis. After 3–4 months of receiving 3 mg of articular cartilage per week, the recipient knees become swollen and inflamed. Histological examination of the synovium reveals a marked cellular infiltrate and the presence of cartilaginous wear particles, presumably from the injected material. Organ cultures of the synovium from knees receiving wear particles secrete much higher levels of both neutral proteinases and lysosomal hydrolases than do cultures of control synovium. The cartilage of particle-injected knees is discoloured and its metachromatic staining properties are attenuated. These changes are much more marked than those reported by Chrisman et al. (22) who conducted similar experiments with dogs. In certain rabbits, the synovium appears to have

TABLE 2.
Production of extracellular proteinases by macrophages in response to particles of cartilage and latex beads of different sizes.

	Enzyme Production (munits/10^6 cells/day)			
	Collagenase	Gelatinase	Azocaseinase	Pz-Peptidase
Control Macrophages	0.57	2.1	1.62	1.85
Macrophages and Cartilaginous Particles	1.26	5.9	3.83	4.52
Macrophages and Small Latex Beads	0.92	4.3	3.21	3.93
Macrophages and Large Latex Beads	0.63	2.9	2.03	2.16

One unit of collagenase, gelatinase or pz-peptidase breaks down 1 µg subsubstrate/min at 37° C. One unit of azocaseinase breaks down 1mg azocasein/hr at 37°C. Enzyme assays on conditioned media were usually incubated for 18 hr. Small latex beads were added to cultures at a concentration of 100 beads/cell; the same weight of large latex beads was added to parallel cultures. Powdered meniscus was added at a concentration of 5mg/75 cu cm culture vessel containing approx. 10^7 cells.

formed an invasive pannus, as found in human rheumatoid arthritis and in symptomatic artificial knee joints.

Experiments are underway to determine whether an immune response has been mounted to the injected material, or whether the effects can be accounted for by the cellular release of catabolic enzymes, and other factors, provoked by the particles. Preliminary results suggest that a systemic response to the injected particles has not occurred; the recipient rabbits give a negative skin test and attempts to demonstrate circulating IgG antibodies against the particles have failed. Furthermore, the timing and severity of symptoms is remarkably constant between animals, a feature which is not normally seen in experimental diseases that rely on an immune reaction.

Evidence that chondroitin sulphate elicits cellular responses in vivo comes from experiments in which purified chondroitin sulphate was injected into the peritoneal cavities of mice (19). After 4 days, peritoneal macrophages were harvested, counted, cultured and their release of acid and neutral lytic enzymes measured. Chondroitin sulphate elicited a concentration-dependent increase in the production of all enzymes measured except lysozyme; this finding agrees with previous reports that the production of lysozome by macrophages is not greatly affected by their state of activation.

It is noteworthy that this stimulation of enzyme production occurred without any increase in the number of cells per mouse. That is unusual, as most agents which activate peritoneal macrophages, such as thioglycollate, recruit additional cells, so that the yield of macrophages per mouse is greatly enhanced. Chondroitin sulphate is not antigenic (23). It may, however, have the important property of reversibly stimulating the local secretion of lytic enzymes, without triggering a full-blown inflammatory response. Workers in Sledge's laboratory (24) have found that the ability of anionic polysaccharides, such as chondroitin sulphate, to provoke synovitis in rabbit knees increases with their molecular weight and charge density. Chondroitin sulphate was shown to produce a transient inflammation; 4 weeks after the termination of the chondroitin sulphate

TABLE 3.
Effect of chondroitin sulphate on the production of acid hydrolases and neutral proteinases by cultured macrophages.

Concentration of Chondroitin Sulphate in culture medium (mg/ml)	ENZYMIC ACTIVITY OF CONDITIONED MEDIUM* Release from cartilage of: Chondroitin Sulphate (pH 7.2)	Hydroxyproline (pH 7.2)	Azocaseinase (pH 5.1)	ß-glucuronidase (pH 5.1)
0.0	4.40	1.04	84	54.7
0.1	7.47	3.09	98	73.6
1.0	8.65	4.67	126	94.9
10.0	9.14	4.77	142	98.3

*Figures quoted are µg of substrate (azocasein, phenolphthalein-glucuronic acid) degraded, or µg of product (chondroitin sulphate, hydroxyproline) released per 10^6 macrophages per hour.

injections, the synovium continued to produce slightly elevated amounts of catabolin-like activity, but the production of lysosomal marker enzymes equalled that of controls (25).

General Discussion

Despite its long history and widespread debilitating effects, osteoarthritis remains a problematic disease. It is difficult to diagnose at an early stage, and it resists effective treatment. Diagnosis relies largely on patient symptoms and X-ray data supplemented, in certain instances, by techniques such as arthrotomy and arthroscopy. But the occurrence of symptoms is peculiar. Pain, for instance, is not directly related to the progression of osteoarthritis. A roentgenographical survey of Americans over the age of 75 years revealed an 85% incidence of articular degeneration (26). Yet the incidence of arthritic symptoms is much less than this. Under such circumstances, osteoarthritis is frequently diagnosed when it is too late to initiate the appropriate anti-inflammatory regime or undertake the optimal reconstructive procedures, such as osteotomies to realign the joint or to restore joint congruity. Treatment is unsatisfactory, in that symptoms rather than the underlying disease processes receive attention. Thus, an arthritic patient with advanced disease may be treated by resort to a walking aid, while the pathophysiological undertow flows unchecked. Alternatively, an unnatural replacement joint of limited anticipated functional period may be the only realistic method of treatment. This, of course, reflects an ignorance of the aetiology and mode of progression of osteoarthritis. Of the existing treatments for severe osteoarthritis, prosthetic hip replacements are outstandingly successful for a period of 5 to 10 years. Much effort is presently being directed towards extending the range of such prostheses to include knees, fingers and elbows and other types of joints. An important determinant is the biomechanical properties of the materials forming the prosthesis. In particular, it is essential that the articulating surfaces have the appropriate rheological and tribological properties. Accurate evaluation of these functions, especially when the implants are performing in situ, is needed.

From the findings reviewed in this paper, we feel that the ferrographic analysis of wear particles and studies of their biochemical and cellular properties can aid the resolution of many of these problems.

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Automated Retrieval of Information on Assistive Devices (ARIAD)

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Introduction

Application of new technology to the problems of rehabilitative engineering and physical medicine is producing new kinds of assistive devices, as well as new versions of familiar devices. In some areas of the field the advances occur so rapidly that individual doctors and related health care professionals have difficulty keeping their information up to date. A result can be the risk of failing to prescribe the most appropriate aids for patients. Consumers or their families have similar problems when they try, independently, to learn about the aids that are now available for their various needs.

The situation has prompted a number of efforts to categorize and systematize information about assistive devices, and to make relevant information available to those needing it.

The U.S. Government's Department of Education publishes a resource guide called Rehabilitation Engineering and Product Information: Resource Guide (1) which lists major sources of rehabilitation information available from private and federal agencies. This is an indirect information source and its main strength is the completeness of its listings of places to go for detailed information. (Among the sources listed are the VA's Office of Technology Transfer, Smithsonian Science Information Exchange, the National Technical Information Service of the U.S. Department of Commerce, the National Library for the Blind and Physically Handicapped, NASA's Technology Utilization Program, the American Foundation for the Blind, National Rehabilitation Information Center (NARIC), and the Trace Research & Development Center for the Severely Communicatively Handicapped.) Another resource guide, from the Department of Health, Education, and Welfare, lists more than 50 data banks containing information on assistive devices for the disabled (2).

Prominent among the computerized data systems intended for widespread accessibility in the field of rehabilitation aids and assistive devices is a commercial effort called Accent on Information. It is a proprietory computerized system developed by Raymond Cheevers (3). The National Institute for Handicapped Research has been sponsoring ABLEDATA, which has been designed to be used through persons called information brokers who accept, interpret, and process requests for information. Data held by ABLEDATA may be accessed through either computer and/or manual searches. ABLEDATA is presently in the pilot stage, with brokers located at Charlottesville, Virginia, and in California at Palo Alto, Downey, and Sacramento (4). A pilot course for the training of additional brokers was planned for November 1981, with expansion of the training program intended in 1982. The ABLEDATA System is now based with NARIC[b].

Other systems also exist, or are believed to exist, but it is characteristic of the situation that few details are available and information about them tends not to be widely circulated. Of the systems reviewed, Accent on Information (AOI) and perhaps ABLEDATA appear able to meet the generally accepted goal of providing easily accessible, relevant, complete, and rapid information on assistive devices that could satisfy a need. But it could not be said that a survey of existing conditions finds a satisfactory choice among well established, convenient to use, and easily accessible services, in place and available. This seems to be the case whether the seeker is a disabled consumer or a provider of direct rehabilitation services.

In light of the existing situation, the Biomedical Engineering Department at Louisiana Tech University has developed a set of computer programs to achieve Automated Retrieval of Information on Assistive Devices (ARIAD). The goals of ARIAD are:

1. To provide a systematic and expandable method of storing information on assistive devices;
2. To provide computer-aided matching between the end-user's functional abilities and limitations versus the operational requirements and capabilities of a particular device;
3. To provide relevant, usable, and up-to-date information quickly to the requestor, whether an end-user or a rehabilitation service provider; and
4. To provide an information service that minimizes staffing requirements (i.e. as few high-salaried professionals as briefly as possible) and computer hardware requirements (i.e. implementable on a modest sized mini-computer).

The accomplishment of the above goals, especially the second, is what makes ARIAD different from information systems reported in the literature.

The remaining sections of this paper discuss how ARIAD functions with the outside world (e.g., with computer operators, rehabilitation personnel, and requestors of information); the coding scheme used to allow efficient storage, matching, and retrieval of information on assistive devices with regard to the nature of the request; the software algorithms that form the inner workings of ARIAD;

[a]All reprint requests and inquiries should be directed to Dr. Szeto.

[b]A press release received early in October 1981 at the Bulletin of Prosthetics Research announced that the National Rehabilitation Information Center (NARIC) has received from the California Department of Rehabilitation a $73,467 contract to continue development work on the ABLEDATA System. The release described the ABLEDATA System as "Rehabilitation product information and a network of information brokers . . . a service of the National Rehabilitation Information Center." Development work under the contract was said to include increase of the database from the then current 3,000 to more than 4,000 items by December 1981. The ABLEDATA letterhead bore the address of The Catholic University of America, 4407 Eighth St. N.E., Washington, D.C. 20017. Those wishing further information were referred to Marian Hall at NARIC, telephone number 202-635-5826.

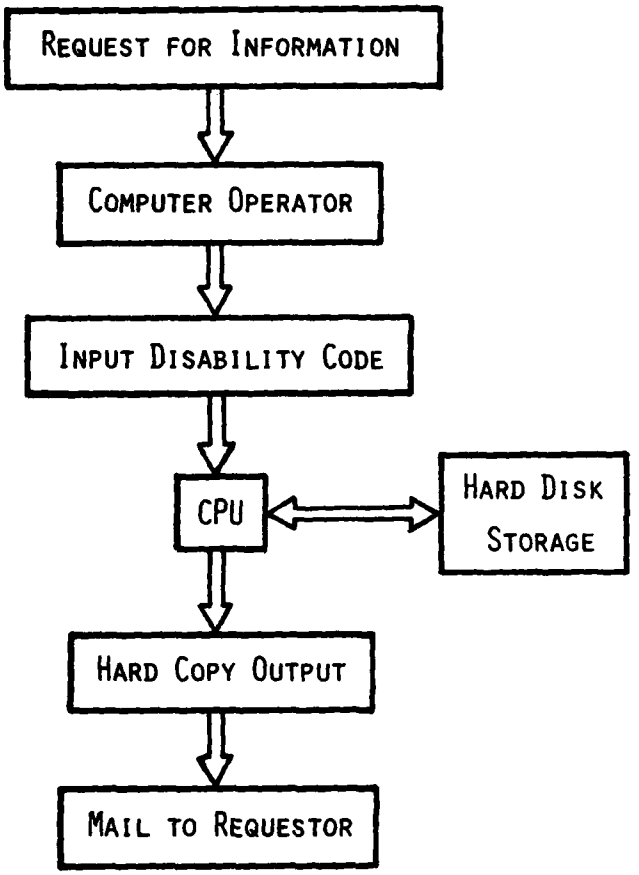

FIGURE 1.
A block diagram of the ARIAD system implemented on a Digital Equipment Corp. minicomputer PDP 11/34, with hard disk storage and 256 bytes of MOS memory.

the type of information available from ARIAD; and finally its present status. For potential users of such a system, the front and later portions of this paper will be of primary interest. For those using or developing information retrieval systems, the sections that discuss the coding scheme and software may be of primary interest.

This paper has been written for two main aims: (i) to propose a coding scheme which will reliably match a handicapped person's functional limitations with the operational characteristics of an assistive device; and (ii) to publicly describe an information retrieval system that is presently serving the people of Louisiana and surrounding states.

Overview of ARIAD

Figure 1 shows a block diagram of the ARIAD program. A doctor, physical therapist, occupational therapist, or rehabilitation counselor would write to the department requesting information on available devices to help his patient—a quadriplegic person, for example. Using information about the patient's functional disabilities as supplied by the requestor, the computer operator would generate an input disability code which would be used by ARIAD. The computer would then search through its files, selecting only data on those assistive devices that could meet the needs of that disabled person. A listing of the device information would then be sent back to the requestor who then makes the final choice.

ARIAD has been designed to suggest potentially suitable devices rather than to prescribe devices, for two reasons: (i) The computer operator generally would not have a complete background on the patient nor be as well-trained in rehabilitation as the requestor; and (ii) The requestor knows the patient intimately and is fully aware of the patient's disabilities and his present or desired lifestyle. The responsibility for prescribing any particular aid would therefore be best handled by the person having direct contact with the patient. ARIAD has been designed to function in a manner similar to that of the computerized searches for bibliographic information used in libraries.

Description of Coding Scheme

A suitable device for a handicapped person must not require control actions nor perceptual abilities outside the residual capabilities of that person. Therefore, some type of classification of both the disabilities and the device characteristics is necessary. After considerable research and study, a single coding scheme has been developed to denote three key parameters: (i) the physical dysfunctions of the person, (ii) the physical abilities needed to operate an assistive aid, and (iii) the disabilities for which that aid was designed. The first parameter is contained in the disability code, and the last two are contained in the device code. ARIAD uses these codes to generate three arrays and then compares them to ascertain which assistive devices are suitable and which ones are not. Details of how the computer program performs these comparisons are given in the next section of this paper.

Information about the disabilities of the person for whom a search is being conducted is entered into ARIAD using a specially designed disability code. In designing this code, the various dysfunctions which can result from medical disorders such as spina bifida, spinal-cord injury, cerebral palsy, amputation, etc., were reviewed. It was decided that a code describing the actual physical disabilities, rather than the medical aspects of the disorders, would be best. A code which describes the functional disabilities is unique and unambiguous, whereas a code denoting medical disorders might not accurately reflect a person's actual condition, especially if there are atypical problems. Nevertheless any coding system inevitably involves generalizations.

Since the quality of ARIAD depends heavily on accurate coding of the devices, a rehabilitation engineer and an occupational therapist do that coding. Then an operator uses the interactive computer programs to add to or edit the existing data bank.

Disability Code—Based on a survey of various disabling disorders, six major categories of deficiencies have been defined: AMPUTATION which covers surgical, traumatic, and congenitally missing body parts; MOTOR which covers motor dysfunctions; TACTILE which covers dysfunction in perceiving touch, pressure, vibration, and temperature via

the skin; BOTH which denotes motor and tactile dysfunctions in the same part of the body; SENSORY which covers any dysfunctions in senses other than tactile; and VISCERAL which covers dysfunctions in major organs of the viscera such as the heart, kidney, and bladder. These categories of deficiencies and the aids for them have been respectively abbreviated and cataloged as follows:

Major Categories	Catalog No. (in octal)
A–Amputation	10,000–17,777
B–Both motor and tactile	20,000–27,777
M–Motor	30,000–37,777
S–Sensory	40,000–47,777
T–Tactile	50,000–57,777
V–Visceral	60,000–67,777

Within the major dysfunction of "Sensory", four subcategories have been defined.

Components of the Sensory Category

B–Blindness
H–Hearing loss
S–Smell
T–Taste

Under the "Visceral" category, the following subregions are used:

Visceral Subregions

H–Heart
K–Kidney
P–Pancreas
B–Bladder

More visceral subregions can be added to the above list when the applicable devices become available.

Ten anatomical subregions have been defined so that the site of a particular dysfunction, complete or partial, can be designated. These subregions are used in conjunction with the major categories of "Amputation," "Motor," "Tactile," and "Motor/Tactile."

Anatomical Subregions

1–Head	6–Pelvis
2–Neck	7–Whole leg
3–Whole arm	8–Below knee
4–Below elbow	9–Foot
5–Hand	0–Mouth

The above categories and subregions are used as follows: The first character of the disability code designates one of the six major categories while the successive characters designate the dysfunctional anatomic or visceral subregions. Periods serve to set off the different major categories and to separate the various subregions associated with each major category.

For example, the patient disability code B.37. indicates that there are both motor and tactile losses (B) in his arms (3) and legs (7). Such a code might designate a quadriplegic. It is important to note that a disability code does not necessarily indicate that a complete dysfunction exists, but rather some significant degree of dysfunction is present. To further illustrate, someone with a weak heart might be coded as V.H., where (V) indicates the visceral category and (H) refers to the heart. Someone who is blind would be coded as S.B. where (S) represents the sensory category and (B) represents the loss of sight.

A person having dysfunction in more than one major category would have codes for each of his separate dysfunctions strung together in a series. For example, a blind person who has lost motor control in his hands and neck and also has a kidney problem could be coded as M.25.S.B.V.K. where M.25. represents motor losses (M) in the neck (2) and hands (5); S.B. represents a sensory loss (S) in the eyes (B); and V.K. represents a visceral dysfunction (V) in the kidneys (K).

An important feature of this disability code is that the major categories and the subregions within them do not need to be listed in any particular order. It is required only that the appropriate anatomic subregions be listed following each category and that periods be used to delineate the categories and subregions. For instance, the previous code could have also been written as follows:

S.B.V.K.M.25.
V.K.S.B.M.25.
V.K.M.52.S.B.

Device Code—Each assistive device stored in ARIAD is assigned a device code. Based on available information, the two main sets of characteristics of the device are ascertained: (i) the types of disabilities which the device is intended to help, and (ii) physical capabilities required for its use. The device code uses the same major categories of dysfunction and anatomical subregions that the disability code uses except that the alphanumeric symbols carry a slightly different meaning. In a device code, the presence of a "D" in front of any major dysfunction category signifies that the device was designed specifically for such a disability. All major categories in the device code not preceded by a "D" delineate those functional abilities needed to operate the device. The presence or absence of the D-prefix allows the device code to reflect accurately the key characteristics of any assistive aid.

For example, the familiar Optacon, which displays printed letters via vibratory reeds that can be sensed by a blind person's fingertips, would be assigned the device code DS.B.B.5. The first part of this code (DS.B.) signifies that the Optacon was designed for persons with visual impairments. The second part of this code (B.5.) signifies that a user must have both motor and sensory capabilities in his hands in order to effectively use the Optacon.

In another example, the device code DS.B.M.3.S.H.B.5. would be assigned to an aid that would help a blind person (DS.B.) who must be able to control his arms (M.3.), be able to hear (S.H.), and who has both motor control and tactile sensation in his hands (B.5.). An assistive device which could help such an individual is the laser cane. This electronic travel aid for the blind combines a long cane with built-in secondary electronics plus laser detection capabilities. Warnings of overhead projections and surface

irregularities are presented as auditory tones of high and low frequencies, respectively. Warnings of straight ahead obstacles are presented tactually by means of a vibratory reed or electrocutaneous stimulation sensed by the index finger; see reference (5).

Description of Software

ARIAD was written using the FORTRAN IV-Plus Scientific Programming Language. FORTRAN was chosen primarily for its speed and ease in programming. ARIAD has been divided into five phases: (i) the initialization phase, (ii) the patient array set-up phase, (iii) the device data set-up phase, (iv) the comparison phase, and (v) the output phase.

The main program, MARIAD, forms the foundation upon which these phases are built. MARIAD coordinates the data transfers between the individual subroutines, indicated in Figure 2, and also provides the necessary control statements to bind the subroutines together. In this way MARIAD serves as the root from which all the subroutines branch.

The initialization phase is handled by the subroutine QUEST. During initialization the following interactive questions guide the computer operator in providing the necessary background information:

1. What is the date?
2. How many different requests for information do you wish to make?
3. What is each requestor's name and address?
4. What is each patient's name (or some other identifying information)?
5. What is each patient's disability code?
6. What type of device is desired for each patient?

The "type of device" asked in question 6 refers to one of the following classifications:

aids for daily living
mobility aids
recreational aids
eating aids
hygiene aids
occupational aids
all aids.

Inclusion of such classifications permits a more focused selection of suitable aids for the intended user. If "all aids" is selected, a general output of all suitable aids for the intended patient is generated. Additional classifications can be added to ARIAD as needed.

The computer operator's answers to the questions are stored as alphanumeric data because alphanumeric formatting has the desirable characteristic of processing data which contains both letters and numbers. Answers to questions 5 and 6 are used to determine which devices are most suitable for the patient. Answers to the other questions appear in the final output.

The second phase begins when MARIAD calls PARRAY to generate the patient's disability matrix. This matrix defines the functional disabilities of the patient and is used for selecting suitable assistive devices during the comparison phase of MARIAD. Each row of the matrix corresponds to a particular category of disability. The first row denotes the disabilities related to amputation; the second row denotes both motor and tactile deficiencies; the third row denotes only the motor dysfunctions; the fourth row denotes only

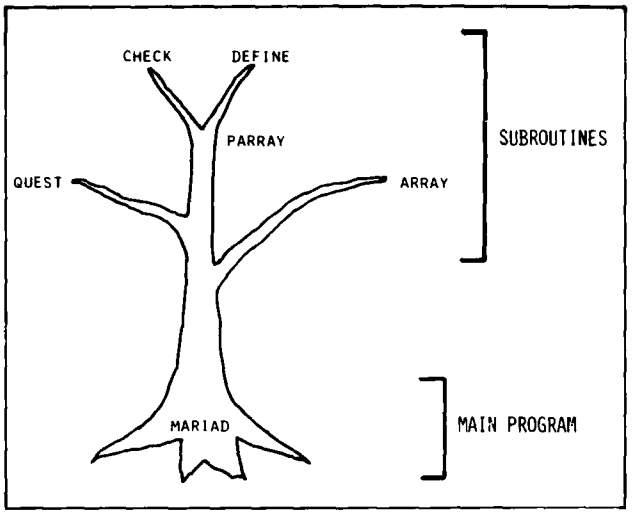

FIGURE 2.
Overall program structure of MARIAD.

the sensory dysfunctions; the fifth row denotes tactile dysfunctions; and the sixth row denotes dysfunctions in the organs of the viscera. The columns of the matrix contain the alphanumeric designations for the affected body parts. For example, the matrix for the disability code S.B.V.K.M.257.* would be

11	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0
2	5	7	8	9	11	0	0	0	0
B	11	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0
K	11	0	0	0	0	0	0	0	0

Each row of the above matrix ends with the number "11" which acts as the terminating symbol. (When there are no dysfunctions in a particular category, the corresponding row begins with the number "11" as is the situation for rows 1, 2, and 5 above.)

The third or motor disabilities row contains the numbers "2,5,7,8, and 9." The numbers "8" and "9" are not explicitly listed in the disability code of S.B.V.K.M.257., but they are implied by the frequent patterns of physical disability. In this example "7" signifies movement difficulties in the upper leg. In general, a person who is unable to move the upper leg also cannot move his lower leg or his foot. Therefore, when the number "7" is specified, PARRAY generates the code for the other most-probably-affected areas. The same general pattern of disability is assumed for the case of the upper limb.

When the subroutine PARRAY ends, the device data phase begins with MARIAD storing data on each of a group of 25 assistive devices in a two dimensional array named IDV. MARIAD now uses IDV and the subroutine ARRAY to create two more matrices for each device—one matrix describing

*Sensory loss in eyes, visceral dysfunction (kidneys), motor losses in neck, hands, and whole leg.

the disabilities for which the device was designed to help (IDES) and the other matrix describing the abilities required to operate the device (INOTD).

The matrices that would be generated for the device code—DS.BH.B.5—is shown below as an example.

(IDES) (disabilities designed for)	33	0	0	0	0
	33	0	0	0	0
	33	0	0	0	0
	B	H	33	0	0
	33	0	0	0	0
	33	0	0	0	0
(INOTD) (abilities required)	22	0	0	0	0
	22	0	0	0	0
	5	22	0	0	0
	5	22	0	0	0
	22	0	0	0	0
	5	22	0	0	0
	22	0	0	0	0

The row terminators for these matrices are '33' and '22' respectively. Again, each row represents a disability category, and each column represents an affected body area or sensation. Since there are 25 devices in each group processed, ARRAY generates 50 matrices (25 IDES matrices and 25 INOTD matrices).

Before MARIAD compares the patient's disability array (IDIS) with the device arrays (IDES and INOTD), each device is checked to see if it corresponds to the device-type selected during question 6 of the initialization phase. For example, if the type selected earlier was hygiene, then only those devices which apply to hygiene will be compared.

The next comparison is between the IDIS and INOTD arrays. If the device was not designed to help such a patient, it is deleted from further considerations by MARIAD and the next device is compared. If no conflict occurs between IDIS and INOTD for a particular device, IDIS is then compared with IDES of that device for compatibility. When compatibility with both INOTD and IDES is found, this device is deemed to be potentially suitable and the information about it is printed out. After all 25 devices have been compared against the patient's disability matrix, MARIAD returns to the device data phase and reads in 25 more devices. This process continues until all device information stored in ARIAD has been examined for each search request.

In order for MARIAD to operate at peak efficiency, two support programs, FILMOD and SEARCH, have been implemented to permit easy inputting and editing of new device data. FILMOD reads in new data, checks for errors in the device codes, and sorts the new and old devices according to preassigned catalog numbers. If any errors are found in the data, the errors are printed on the CRT for correction by the computer programmer. Periodic updating of information is made possible through SEARCH which enables the programmer to either update (or delete) a range of assistive devices or to update just one specific device.

Information Available from ARIAD

Information provided by ARIAD covers a wide scope of devices, from mobility aids for the blind to recreational aids for the immobile. Such a broad spectrum of devices is expected to benefit a maximum number of potential requestors and/or their patients. Practical limitations prohibit storing information on every item listed in every catalog of aids. Only representative aids and their main accessories are incorporated into ARIAD. The decision on whether to include or exclude an item depends on the soundness of its design and its expected usefulness. These admittedly somewhat subjective judgements are necessarily based on available descriptions of the device. A degree of professional objectivity is contributed by the combined expertise of the rehabilitation engineer and occupational therapist, with their access to evaluation literature both at the research and the clinical application levels. The final determination of a device's soundness, as well as its suitability for a specific application with a specific individual user, must remain the responsibility of the person using the system: ARIAD provides information, not a prescription.

The information sources upon which ARIAD is based are as varied as the devices they describe. Almost 100 catalogs and references have been abstracted for information. A brief illustrative list of typical sources is given below:

International Guide to Aids and Appliances for Blind and Visually Impaired Persons
Everest & Jennings Distributor Catalog
The Maddak Catalog
The Beok Catalog
The Green Pages
The Non-Vocal Communication Resource Book.

Manufacturer's releases on new products are also utilized, thus providing information on the latest devices that are available. Magazines and catalogs also permit periodic updating of information about existing devices. When a new catalog comes out, the information in it is checked against the stored information to insure accurate and current data. Any new aids are evaluated for possible addition to the data bank.

Information about a potentially suitable assistive device appearing in the computer printout includes a description of the device, the manufacturer's and/or distributor's names and addresses, the cost of the devices, the printing date of the information source, and the date of the most recent update (Fig. 3). A covering letter attached to the output suggests how the requestor should interpret and use the information provided in response to his oral or written request.

Present Status

The advisory service of ARIAD is fully operational and available on a no-cost basis. More than 30 formal and informal requests for information were processed during the first 6 months following an announcement made to the vocational rehabilitation counselors of Louisiana regarding the availability of ARIAD. The request rate has steadily risen since then, as more and more vocational rehabilitation counselors, physical and occupational therapists, and physiatrists in Louisiana and nearby states have become aware of ARIAD's utility. However, the request rate for ARIAD

is not expected to reach the numbers that the proprietary system of Accent on Information has or will reach, simply because ARIAD is a local system designed to serve the needs of the region.

Periodic reviews of the device classifications and the coding scheme are being performed. Eight to 10 new devices are added weekly, and updating of the information on previously stored devices is done as new information is received through retail catalogs and advertisements in magazines for the physically handicapped. There are now more than 900 representative aids for which data is stored in a readily retrievable format.

ARIAD was originally intended to advise rehabilitation counselors and other direct service providers in Louisiana. The request rate of 4 to 6 per month is not surprising or indicative of nonacceptance by the intended users. Although the service was announced only regionally, a number of out-of-state requests have been processed with favorable results. Approximately 70% of all requests have come from direct rehabilitation service providers, and about 25% have come from disabled persons or their families. Feedback from users of ARIAD has been generally positive. Several suggested changes are being implemented.

In summary, ARIAD as described in this report appears to be a helpful service for persons involved with prescribing or ordering assistive devices for the physically handicapped. The information stored, the coding scheme used to mechanize the matching of handicaps with various aids, and the supporting software to keep ARIAD current and growing have all proved to be very workable and cost effective. Only one full-time-equivalent person is needed to maintain ARIAD and respond to requests, and the entire information system has been implemented on a minicomputer of modest size and capability.

FIGURE 3.
Sample output of ARIAD.

DISABILITY CODE — CATALOG NUMBER
DS.B.M.57. — 40012 — M
TELESCOPING FIBERGLASS CANE
MADE IN 6 SECTIONS FROM WHITE, TUBULAR FIBERGLASS. CANE SECTIONS TELESCOPE INTO HANDLE WHEN CASE IS CLOSED. CLOSED LENGTH IS APPROXIMATELY 11 IN. VERY LIGHTWEIGHT AND SENSITIVE TO PRESSURE OR TOUCH. NOT FOR USE BY PERSONS NEEDING SUPPORT IN WALKING. MADE IN ANY LENGTH DESIRED BY PURCHASER.

MODEL NUMBER: UNAVAILABLE
MANUFACTURER/DEVELOPER:

MR. WALTER L. CRANDELL
7693 LAKEVILLE HIGHWAY
PETALUMA, CA 94952 USA

AVAILABILITY STATUS: COMMERCIAL

PRICE: $10.00

MOST RECENT UPDATE: 06/28/79

DATE OF INFORMATION SOURCE: 1977

. . . . . .

DISABILITY CODE — CATALOG NUMBER
DS.B.S.H.M.12. — 40013 — M
AUDIBLE PHOTOCONDUCTIVE LIGHT PROBE
GENERAL-PURPOSE POCKET-SIZE INSTRUMENT DESIGNED TO DETECT AND CONVERT LIGHT DIRECTLY INTO SOUND, FREQUENCY OF WHICH RISES PROPORTIONATELY WITH INTENSITY OF LIGHT; NO SOUND IN TOTAL DARKNESS, SHRILL WHISTLE UNDER MAX. ILLUMINATION. HAS POTENTIALLY GREAT NUMBER OF USES: DETECT AND LOCATE SOURCE OF LIGHT IN ROOM, PINPOINT SIGNAL LAMPS SUCH AS THOSE FOUND ON COOKERS AND ELECTRIC BLANKET CONTROLS, LOCATE LEVEL OF LIQUIDS IN TRANSPARENT CONTAINERS, DETECT DIFFERENCE BETWEEN LIGHT AND DARK MATERIALS. AID HAS BEEN DESIGNED AS SHORT-RANGE INSTRUMENT AND IS NOT SUITABLE AS GUIDANCE AID. SIZE: 5 X 3.4 IN. WEIGHT: 3 OZ
MODEL NUMBER: 9432
MANUFACTURER/DEVELOPER:

ROYAL NATIONAL INSTITUTE FOR THE BLIND
224 GREAT PORTLAND STREET
LONDON, W1N 6AA, ENGLAND

AVAILABILITY STATUS: COMMERCIAL

PRICE: AVAILABLE UPON REQUEST

MOST RECENT UPDATE: 06/28/79

DATE OF INFORMATION SOURCE: 1977

. . . . . .

Acknowledgment

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EDITOR'S NOTE

The importance of prompt access to current, accurate, and reasonably comprehensive information on assistive devices for disabled persons has been stressed repeatedly by both professionals and groups of disabled individuals. Nevertheless there seems to be very little literature in either rehabilitative engineering or information science on the different users, the types of information each category of user needs, or the variety of approaches available or being developed. Objective evaluations are needed of the effectiveness of the different approaches of dedicated and enthusiastic workers.

Workers in research and development certainly do not want to duplicate efforts or "re-invent the wheel." Treatment teams, counsellors, and agencies or other third-party payers would like to be aware of the rapidly growing array of devices available, their sources of supply, the respective indications and contraindications, durability, purchase and life-cycle costs of each, and the expanding body of reports on user experience. Manufacturers, too, need feedback on such user experience. Disabled individuals would like to feel confident that they are using satisfactory, economical devices and that they somehow learn of genuine improvements. Legislators, budgeters, and many others seek demographic data on numbers and characteristics of actual and potential users of assistive devices.

Realistically, such ambitious goals are not fully attained even in fields with mass markets, though many sources of information exist. Various elements are provided for drugs by such sources as the Physician's Desk Reference for Consumer Products for "over-the-counter" items and the companion Physician's Desk Reference for prescription drugs plus the PDR Supplements for the main volume. There is also a Guide to Prescription Drug Costs. The magazine Consumer Reports, certain government reports on foods, drugs, automobiles, or other products, and columns or departments in magazines on sports, photography, boating, etc., report on various consumer products. Recently announced sources include a Directory of Biologicals and a New Product/Technology Sourcebook of inventions in health care, pharmaceuticals, cosmetics, and toiletries.

In the specialized yet very diversified area of rehabilitative engineering, a variety of publications (and in some cases their advertising) provide portions of the information needed on assistive devices for the disabled. Some are published by groups of disabled individuals. A few examples may suggest the range that is available. Examples of commercial ventures are the magazine Accent on Living, edited by Raymond C. Cheever, and the annual compilation The Green Pages (which is being continued by Mrs. John Erving—see BPR 10-35). The newsletter Inform, numerous pamphlets, and the looseleaf Information Sheets are published by ICTA (the International Committee on Technical Aids, Housing, and Transportation of Rehabilitation International). Each annual Rehabilitation Gazette provides information on numerous devices and publications. Specialized periodicals like Archives of Physical Medicine and Rehabilitation, or Orthotics and Prosthetics, or Journal of Speech and Hearing Research provide valuable information, primarily for professionals. The American Foundation for the Blind publishes an annual revision of its catalog of technical aids. Unfortunately, none of these inkprint documents enjoys the circulation it deserves, and that would be needed to reach the widespread body of professionals and disabled consumers.

The existing services provided by libraries, and

by abstracting and indexing services, help to store, diffuse, and retrieve information. A useful recent survey is presented in the April 1980 issue of the Drexel Library Quarterly, which has the theme "Information Services to Disabled Individuals." The final paper describes international activities.

Major texts (like Lowman and Klinger's Aids to Independent Living—Self-Help for the Handicapped) take years of devoted effort to compile; they can provide wise advice and define stable principles, but editions quickly become incomplete and even obsolete on specific devices. Each individual consumer typically owns a few useful catalogs, but widespread diffusion to all concerned by constantly revised "hard-copy" texts or catalogs seems utterly impractical and uneconomical.

Because of the mass of data, the frequent changes, and the numerous modifiers or limitations, computers seem appealing. Computer systems include Cheever's Accent on Information (a private venture), the newly emerging NIHR-supported ABLEDATA, the University of Washington STORPROD system serving Federal Region 10, and certain computerized aspects of the National Rehabilitation Information Center (NARIC) compilation (primarily of RSA and NIHR reports). The Clearing House on the Handicapped specializes in referring inquiries to the most appropriate agency or reference center. There are numerous other clearinghouses and data banks which include devices for the disabled, though usually incidentally in connection with primary coverage of some other aspects.

The rapid evolution of information science and technology parallels that of computers. Decreasing costs of computers and of memory are encouraging. Increasingly sophisticated programs should reduce the load on the user and sharpen the focus on devices particularly relevant to a clearly stated need.

Though answers to many questions are simple, an intermediary expert may often be needed to interpret or rephrase lay questions and technical output, to use imagination in finding sources or simply in trying synonyms, and to winnow potential useful information from a large body of partially irrelevant information retrieved by inevitably incomplete coding systems. Re-entry with other coding may sometimes be needed. Interested therapists, reference librarians, engineers, and the "information brokers" in the ABLEDATA system function in the role: ABLEDATA's brokers "also develop supplemental local information resources" according to an October 1981 information release issued by The National Rehabilitation Information Center (NARIC). But the seeker of information, too, must be active and ingenious.

The substantial sources, plus the challenges, have led to an attempt to organize an Information Roundtable. Informal meetings were held in 1980 and 1981 in conjunction with the President's Committee on the Handicapped.

Past history has shown that some publications cease, texts rapidly become obsolete but are rarely revised, and projects tend to disintegrate when contracts or grants terminate. A major concern is to preserve easy retrieval of expensive information through accessible, stable, self-supporting systems.

The paper by Szeto, Tingle and Cronk describes the purpose, concepts, software, and early results with a specific system that is now serving an area in and around a single state. The presentation of that paper in BPR is intended not only to record that particular project but to encourage descriptions of other systems. Reports of past experiences and discussions of the respective realistic and economic roles of individual experts with memory and judgments, collections of printed (or manuscript) data, and computerized systems are needed. Probably all variants will coexist for years to come.

Juvenal, millenia ago, asked, "Quis custodiet ipsos custodes"—"Who will watch the watchmen themselves?" Similarly we may need to ask, "Who will serve as clearinghouse for the clearinghouses?"

EDITOR

Aid for Training and Evaluation of Handicapped Drivers

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Abstract

An indoor driver-evaluator and trainer-aid vehicle, developed to quantify students' ability and progress in learning to drive, is described. In general, the instrumentation for each control was built to measure operating force and elapsed time. The system consists of functional ignition and gear shift control, instrumented steering wheel, hand controls for brake and acceleration, and elapsed response time meters for each control. The controls allow the major driving functions to be evaluated in their interactive mode and the subjects to be taught using variable mechanical resistance elements. Pilot tests were made on nine tetraplegic subjects, spaced over a 4-week period for a subject. Evaluation results by the third test agreed with road evaluation for all six of the subjects who thus far have attempted licensing examinations.

Introduction

Through technology, persons with severe disability have been able to achieve mobility independence. An important measure of their independence is the ability to drive a personal licensed vehicle (automobile, van, or truck) (1, 2).

The Occupational Therapy Department at Woodrow Wilson Rehabilitation Center has been evaluating drivers for several years. All persons requiring medical authorization for driving are being evaluated. Many disabilities are involved. In evaluation, those persons with partial or complete quadriplegia (C-5 or below) requiring hand controls have become a particular challenge. The Keystone Vision Equipment, the AAA Driver Education System, and the Aetna Drivotrainer Simulator are used to evaluate clients. Reaction time and night vision are easily tested, but the Drivotrainer had to be modified to accommodate driving from a wheelchair. Recently, the evaluation program has been upgraded by the addition of an occupational therapist as a driver-education instructor who is also an evaluator and trainer. Fifty percent of her time is spent providing on-the-road evaluation and training for the severely disabled clients.

Although these tools are alternatives, and adequate for some clients, they did not provide enough information to predict the abilities of the more severely disabled clients such as the quadriplegic. The simulator, although more interactive than the others, became more useful as an exercise device rather than an evaluation tool. In particular, the above equipment failed to evaluate the simultaneous functions required by "on the road" driving. A new system was needed which would allow the quantification of the major physical variables of driving functions in their interactive mode. In addition to evaluation, the instrumentation would have to be capable of monitoring patient progress.

The resulting design criteria called for (i) a realistic method of testing and monitoring driver performance in braking, steering and acceleration, (ii) training within the spatial restrictions of the driver compartment, and (iii) provision of visual or auditory feedback during testing and training.

Following these criteria, the instrumentation should provide the guidance to establish levels of human performance necessary to permit a severely disabled individual to operate a personal licensed vehicle safely.

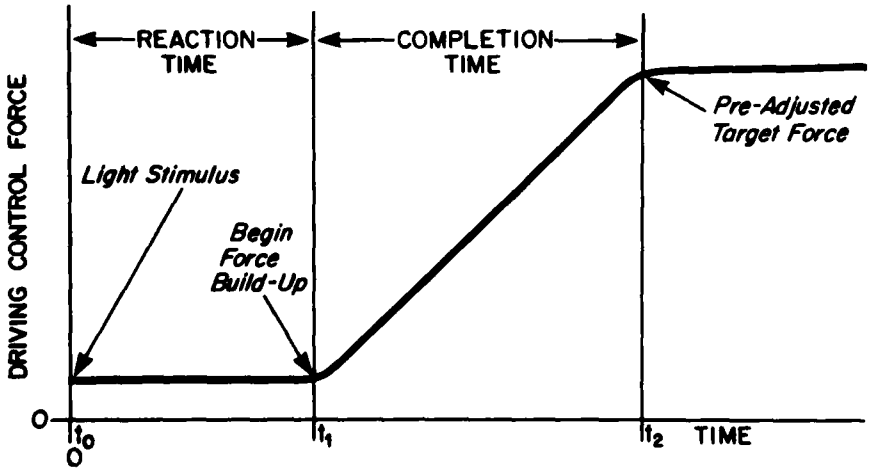

FIGURE 1.
Idealized force-response curve generated by the driver in the course of a driving task.

Controls and Instrumentation

During vehicle operation, the driver's ability to apply the necessary forces to accelerate, to brake, and to steer are not sufficient by themselves as evaluative tools. The completion of any of these driving tasks within a time interval and the ability to maintain a force level over that interval are fundamental to proper handling of the vehicle. The basis of our instrumentation is the simultaneous measurement of exerted force and duration, since driving relies strongly on the interdependence of control force, displacement, and timing.

Force monitoring of the driver's use of the vehicle controls indicates the course from onset to completion of the driving task. An idealized force/response curve as it is experienced in the acts of braking, steering, or other control tasks is shown on Figure 1. The time from a visual stimulus (at t_0) to the beginning of force build up (at t_1) is a well-defined measure of the initial reaction time ($RT=t_1-t_0$). The end point is taken when the pre-adjusted target force is reached. The time to this end point (t_2) is that for reaction plus complete force build up, and the difference is the measure of the task completion time ($CT=t_2-t_1$).

The instrumented controls were installed in an A.M.C. Pacer[a] located indoors and adapted with push-right angle pull (Gresham Slimline) hand controls and interchangeable steering adapters (Steering ball, V-grip, and wrist stabilizer adapter). An overview of the system is shown on Figure 2. The engine and automatic transmission were removed and the steering system was disconnected from the wheels, allowing space for modifications. The speedometer was modified to be controlled by a D-C motor drive, and the speed indicator was controlled from the accelerator pedal. A tri-color traffic light simulator, positioned on the front hood of the car and controlled by the tester, was added to initiate the testing sequences. Also visible on the front hood is a pressure meter, to indicate the force, in pounds, applied to the brake pedal. The implemented controls are enabled by the modified key-activated ignition system (S1) while movement of the gear shift from N to D closing switch S-2 as shown in Figure 3, is used to energize the speedometer motor through the accelerator potentiometer R1.

The task of braking involves two phases, reaction and completion. The time from the appearance of the visual stimulus to the initiation of the brake application is the reaction time. The completion time spans the period from initiation of braking to achievement of a pre-set braking force. Timers to measure these two task phases, in tenths of seconds, have been installed in the car. The reaction timer is started by the appearance of the red light controlled by the therapist at switch S_4, which is the stimulus to slow or brake the car. This counter is stopped by the initiation of braking via the brake relay K_2 through activation of brake pedal S_8. Switch S_4, held in the therapist's hand, is located out of the client's vision. To measure the completion time, there is another timer, which commences counting when braking has been initiated. The completion timer is "stopped" when the variable pre-adjusted force level on the hydraulic pressure switch S_9 is attained. This corresponds to applying a specific level of force at the brake pedal. For example when the hydraulic pressure switch is set at 200 psi, the cutoff pedal force is 40 pounds. This pedal force is registered on a meter on the front hood of the car.

Using the mode selector switch S_7, the tester can evaluate the time required for a complete turn of the steering wheel in either direction. When the steering wheel is rotated from the zero position, S_5 closes and the reaction timer starts.

[a]The Woodrow Wilson Rehabilitation Center gratefully acknowledges the American Motors Corporation's donation of this automobile used in the program.

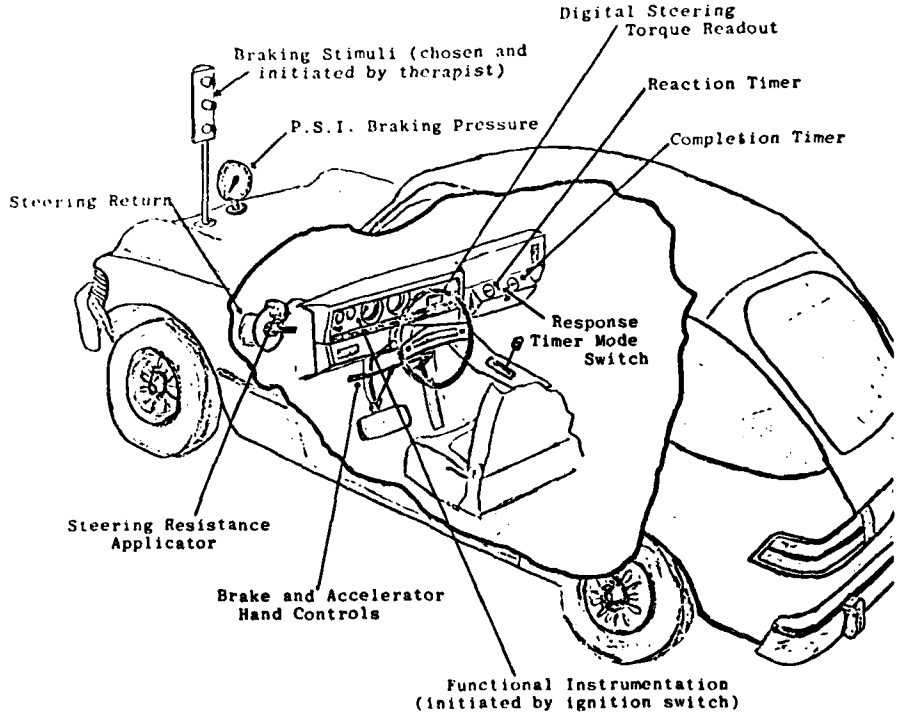

FIGURE 2.
The instrumented driver evaluator-trainer aid vehicle used for assessment of handicapped driver performance.

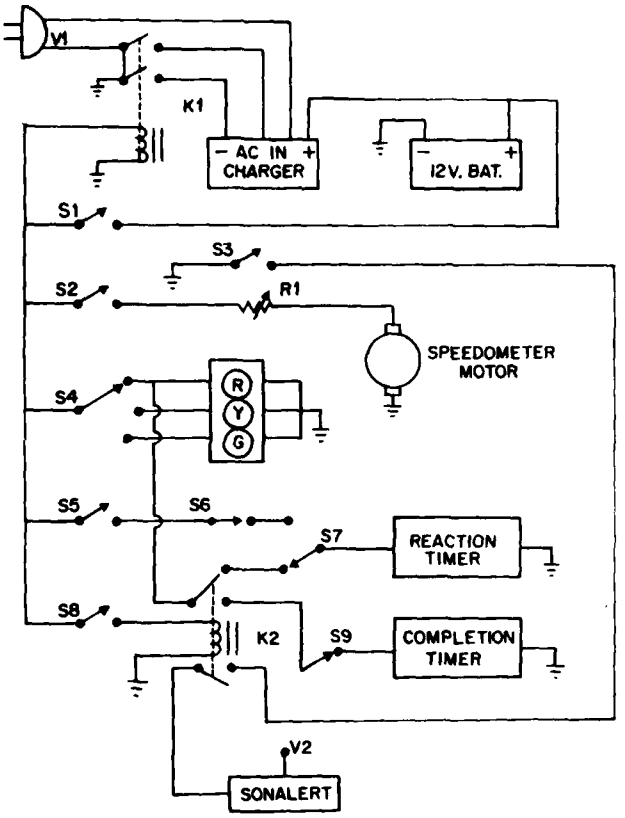

FIGURE 3.
Instrumented driver evaluator-trainer aid. Switches and relays are shown in their normal positions.
V1: 110 V a c power
V2: 4.5 V Battery
R1: Accelerator rheostat
K1: Ignition relay
K2: Brake relay
S1: Ignition switch
S2: Gearshift switch
S3: Accelerator pedal switch
S4: Stimulus selector switch
S5: Initiated steering switch
S6: Steering completion switch
S7: Mode select switch
S8: Brake pedal switch
S9: Hydraulic pressure switch

Completion of a 360 degree steering wheel turn then stops the timer by opening S_6. The tester is also able to assess the potential driver's ability to maintain constant equivalent speeds, utilizing the functional speedometer of the auto.

The potential driver's performance at steering can be evaluated by an added friction-drag torque meter. With a mechanical resistance, adjusted by the therapist on the steering column, the required steering torque applied by the driver can be increased or decreased. Visual display of the applied torque level has not been implemented on the system.

Since a common difficulty in learning to drive with push-right angle pull hand controls is the inadvertent dual application of brake and throttle, an error warning has been included to indicate when this situation occurs. When both the accelerator and brake pedals are simultaneously depressed (S_3 and S_8 are both closed), the circuit to the Sonalert ™ is completed and the audio alarm is sounded. Relays, battery, and other instruments are located under the hood. The mode selector, timers and Sonalert were placed in the glove compartment for easy access by the therapist.

Mode of Operation

Orientation, evaluation, further driving training, and supportive therapy if necessary, are the sequential elements of the training program utilizing this instrumentation.

After appropriate transfer into the auto and proper positioning with application of seat belts (activities which act as screening procedures in themselves), the driver was given a short preliminary orientation to the car. This procedure involved acquainting the driver with the ignition, accelerator, brake, and steering controls. Orientation was followed by a primary test of base-time assessment of driver performance given in a sequence:

1. The ability to maintain constant speed at 40 and 50 mph;
2. The reaction time and completion time involved in braking after the appearance of the red cue; and
3. The time required for a complete turn in either direction.

This testing sequence was performed on three occasions within a 4-week period in an attempt to establish the effectiveness of the system. Each occasion was separated by 7–10 days, the variability being introduced by driver illness, and other delays. At the end of the testing period, the clients were again evaluated for their isolated braking performance simulated at 40 and 50 mph. Throughout the testing period, all of the clients were undergoing occupational and physical therapy. It should be noted that this Driver Evaluator-Trainer aid is limited to evaluation of physical capability and it was not designed to measure mentation, perception, and cognition which are also important factors in safety and good driving performance.

Results

A small pilot series of 9 clients with traumatic tetraplegia of 5 to 41 months duration was tested. The injury levels represented were: 3 clients with C-5-6, 2 with C-6, 3 with C-7 and 1 client with C-8 level of injury.

Preliminary data showed that brake reaction times for all clients were near or below the mean normal value of

0.75 sec given by the National Safety Council (3). Reaction times, as a function of injury level for simulated 40 mph speed (Fig. 4) indicate only a weak dependence of the brake reaction time on the level of injury. On the other hand, brake completion time (as shown in Table 1) confirms the suspicion that it is a more meaningful indicator of driving capability. For Table 1 a target brake pedal force of 40 lb was selected from "on the road" tests with similar cars at 40 and 50 mph. This 40 lb brake pedal force was found to be adequate to stop the car within the braking distance prescribed by the National Safety Council (3) at either speed. The results tabulated by injury level affirm that the brake completion time is slower—as either elbow extension or shoulder rotation or both are diminished to "fair" or poorer values.

Optimal steering performance has also been evaluated for a complete left and right turn of the steering wheel with the rating of the corresponding movement. A group of 10 non-handicapped drivers were tested, each several times, and the less than 1.1 sec average turning time they produced was accepted as the control value. Similar results are shown in Table 2 for most of the patients tested, using plain steering wheel if possible or a knob if necessary. Seven of the clients showed turning performance times of 1.1 sec or less when good-to-normal shoulder function was demonstrated. Diminished shoulder function resulted in longer turning time.

How well the system can predict if an individual will be licensed is illustrated by Table 3. The results of the isolated braking and steering tests for each occasion have been converted to "ready" or "not ready" on the basis of the individual's performance. "Ready" denotes a reaction time of 0.4–0.8 sec, the ability to apply 40 lb of force within 2.5 sec, and the time for a complete turn within 1.1 sec. "Not ready" denotes a poorer performance on these tests. The results of the client's on-the-road evaluations, if conducted, have also been included. For three of the six cases in which road tests have been given, there is agreement between the results of tests on occasion one and the road evaluation. With the second test, the correlation exists for a different three of the six clients. By test occasion number three, the results of the tests agree with the road evaluations for all six cases. Thus the ability of this new evaluation tool to predict driver performance appears to be optimal after three test occasions, which in this series were spaced over a 4-week period of continuing therapy.

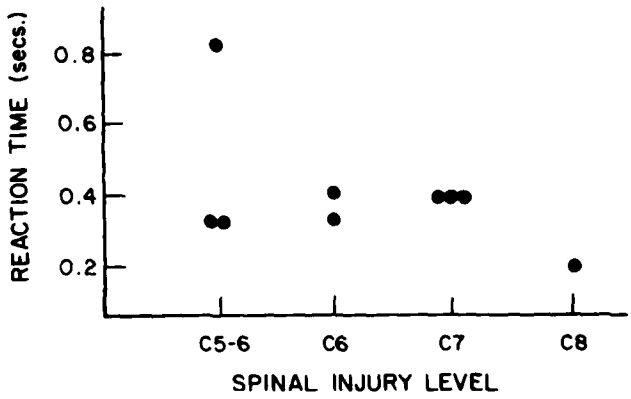

FIGURE 4.
Brake reaction time as a function of spinal cord injury level.

Conclusion

An efficient use of this system relies on the services of the therapist and on-the-road training, as well as the dual nature of the system as evaluator and trainer. It is recommended that this system be used for primary screening to access base-line performance levels, and to determine what muscles/functions need strengthening or substitution. Then, with therapy and repeated use of the testing system, it is recommended that the client be taken on the road for evaluation when he is able to apply 40 pounds of force to the brake within 2 seconds and complete a turn within 1.1 seconds. These specifications are tighter (more conservative) than the minimum conditions found earlier for the control of similar cars. An on-the-road evaluation provides the necessary performance stimuli which are required for driving progress. The indoor system could then be used to monitor further task progress or indicate therapy requirements, while on-the-road training continues.

References

1. Gurgold GD and Harden DH: Assessing the driving potential of the handicapped. Am J Occ Ther 32(1):41–47, 1978.
2. Long CH: Handicapped driver, a national symposium. J of Rehab 40:34–38, 1974.
3. Defensive Driver's Manual: 6th Edition, National Safety Council, 1971.

TABLE 1.
Isolated braking completion times and joint function by levels of spinal injury, at Occasion 3.

Client No.	Completion time (Sec.) 50 MPH	40 MPH	Target pedal force achieved (lb)	Shoulder rotation grade	Elbow extension grade	Injury level
9	0.4	0.4	40	Good–	Good –	C8
8	0.5	0.5	40	Good	Good	C7
7	0.5	0.5	40	Fair	Normal	C7
1	0.8	0.4	40	Fair +	Poor	C5–6
6	0.9	0.8	40	Good +	Fair +	C7
5	1.6	1.9	40	Good	Zero	C6
4	2.0	2.3	40	Normal	Poor	C6
3	2.2	4.4	25	Good –	Zero	C5–6
2	—	5.6	35	Poor –	Zero	C5–6

TABLE 2.
Steering performance and muscle function by levels of spinal injury, at Occasion #3.

CLIENT	COMPLETE TURN		MUSCLE				
No.	time (sec) Left	Right	Ant. deltoid	Post. deltoid	Pector. major	Bicepts and brachiorad.	INJURY LEVEL
9	0.7	0.7	G+	G+	G+	G+	C8
8	0.8	0.7	G	G	G	G+	C7
5	0.8	0.9	G	G	G–	G–N	C7
7	1.0	1.0	N	N	N	N	C7
6	1.0	1.1	F+	G+	G+	G+	C7
1	1.1	1.0	G+	G+	G+	G+	C5-6
4	1.1	1.0	N	N	N	N	C6
3	1.4	1.4	G–	G–	G–	G	C5-6
2	3.2	5.4	F–	F	F–	G	C5-6

TABLE 3.
Evaluation of client's driving potential: isolated steering and braking tests

Client No.	Occs. #1	Occs. #2	Occs. #3	On-the-Road
9	Ready	Ready	Ready	No road test
8	Not Ready	Not Ready	Ready	**Licensed**
7	Not Ready	Not Ready	Ready	No road test
1	Not Ready	Not Ready	Ready	**Licensed**
6	Not Ready	Not Ready	Ready	No road test
5	Ready	Not Ready	Ready	**Licensed**
4	Not Ready	Not Ready	Ready	**Licensed**
3	Not Ready	Not Ready	Not Ready	Not Ready
2	Not Ready	Not Ready	Not Ready	Not Ready

Scotchcast® P.V.C. Interim Prosthesis for Below-Knee Amputees

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Adoption of newly available materials and knowledge, through trial and error experiment, sometimes can result in an increase of productivity as well as improvement of quality. This is often true in industry in general, and can also be true in the prosthetic field. This paper describes a fabrication system combining many widely used techniques (2,4,5,6) and accepted principles (3) and a few new time-saving approaches in making a below-knee interim prosthesis. Using this approach, a skillful prosthetist can fabricate an interim prosthesis in less than 2 hours.* The goals are to improve service to new amputees by speeding provision of interim prostheses and reducing visits to prosthetics facilities. These techniques can also increase the productivity of prosthetists.

Details of the Procedure

A. Making the PTB Socket

1. When the residual limb is healed and no longer edematous, (though further shrinkage will be expected from weight-bearing exercise) usually two to three weeks after surgery, a tube sock (with the elastic band removed) is worn over the residual limb. A tube sock is similar to an athletic sock but without a shaped heel, and is commercially available at low cost at many department stores. Patches of cotton padding, three layers thick and tapered at the edges, are applied over the bony prominences of the tibial tubercle, the tibial crest and the fibular head. Eight to ten layers of tapered cotton padding are also used over the distal end of the tibia (Fig. 1-A). The cotton padding, differing from the felt used in the immediate postsurgical fitting (IPSF) (1), is used as a "spacer." It will be removed after the PTB socket is made to provide graded pressure relief over the bony prominences, as was used in the removable rigid dressing technique (5,6).

2. Cover the tube sock and the cotton paddings with a 5-ply wool stump sock to a level above the knee. Mark on the wool sock the patella and the trim line of the socket to be made.

3. Apply a strip of 10-cm-wide Scotchcast tape (by 3M Co.) or similar casting tape, longitudinally around the stump starting from the patella, down over the tibial tubercle and the tibial crest, and turned under the distal end and upward to the popliteal trim line. This strip provides a smooth inner surface of the socket over the bony prominences. After this longitudinal layer, apply the rest of the Scotchcast tape evenly over the entire stump following the routine bandaging technique. Exert moderate manual tension to the Scotchcast tape to ensure firm adhesion between the layers. Cut along the postero-medial and postero-lateral corners, so that a flared posterior edge can be formed by asking the patient to flex the knee.

4. While waiting for the Scotchcast tape to set, manually apply extra pressure between the posterior wall and the patellar tendon area to form a PTB bar and control A-P diameter for weightbearing. After the tape is set, in about 10 minutes, remove the socket, cut along the trim line, and fold the wool sock outward for a smooth edge (Fig. 1-B).

B. Determining the "Axis" and "Height" of the Socket (Fig. 2)

The patient is then asked to wear his usual sock and shoe on the remaining foot, and two to three tube socks and the socket (with cotton padding removed) on the residual limb. He then stands in the parallel bars with the bottom of the slightly flexed socket resting on a padded adjustable automobile jack. The jack is adjusted until the anterior superior iliac spines are even. The patellae and the patient's subjective feeling are checked. While bearing full weight, the patient adjusts the socket axis to the most comfortable position. Then, the end of a small spirit level is attached with putty to the lateral surface of the socket, and adjusted so that the air bubble is maintained in the center (Fig. 2,3). In addition, another spirit level is attached to the anterior wall, leveled, and is adjusted so that its long axis is parallel to the line of progression. A mark, arbitrarily 18 inches from the ground for adult males, is made on the wall for control of the height of the socket. The shoe on the remaining foot is traced on cardboard or heavy paper.

C. Assembling the Pylon-Foot-Shoe Unit

For the pylon unit, 1½ inch inside diameter, thermoplastic polyvinyl chloride (PVC) pipe is used. The pipe is softened on one end with a heavy-duty hot air blower (heat gun), then snugly fitted to the metal plug attached to the top of the SACH foot. The junction of pipe over plug is further reinforced with a hose clamp. The proximal end of the PVC pipe is then sliced longitudinally (preferably to small holes as crack-stoppers) into four sections, softened, and bent outward into X-shaped bars. The height of the pylon-foot-shoe unit is now slightly lower than that of the adjusted jack (Fig. 3).

*The "less than 2 hours" refers to direct fabrication time only, and does not include travel to and from the hospital, patient evaluation, subsequent adjustments, or overhead activities such as billing and bookkeeping.

NOTE: This Technical Note is partially based on a paper presented at the annual meeting of the American Academy of Physical Medicine and Rehabilitation, Washington, D.C., October 1980.

Please address reprint requests to Yeongchi Wu, Research Department, Rehabilitation Institute of Chicago, 345 East Superior St., Chicago, Illinois 60611. A videotape which supplements the text is also available. Tape may be obtained directly from Dr. Wu at the above address, or by writing to the Editor, Bulletin of Prosthetics Research, VA Office of Technology Transfer (153D), 252 Seventh Ave., New York, N.Y. 10001.

FIGURE 1.
Application of cotton padding (A) for casting the Scotchcast PTB socket (B).

D. Alignment of the Socket and the Pylon-Foot-Unit (Fig 4)

1. Sketch a prosthetic shoe print symmetrical about the axis of progression to the tracing of the shoe on the remaining foot (Fig. 2). Identify the "alignment reference center" at the junction of posterior and middle thirds on the longitudinal axis of the prosthetic shoe print. Place the print on the work table of a vertical alignment fixture, so that the "alignment reference center" is under the plumb line (on the alignment axis) (Fig. 5A.) Place a thumbtack to fix the "reference center" to the work table top. This permits turning the cardboard (Fig. 5B) if needed for adjustment of degree of toe-out without displacing the alignment reference center.

2. The following steps are then taken to position the wool-sock-lined socket in the clamp of the alignment fixture.

a) adjust the mediolateral tilt until the bubble of the lateral spirit level is centered;

b) adjust the socket flexion according to the anterior spirit level;

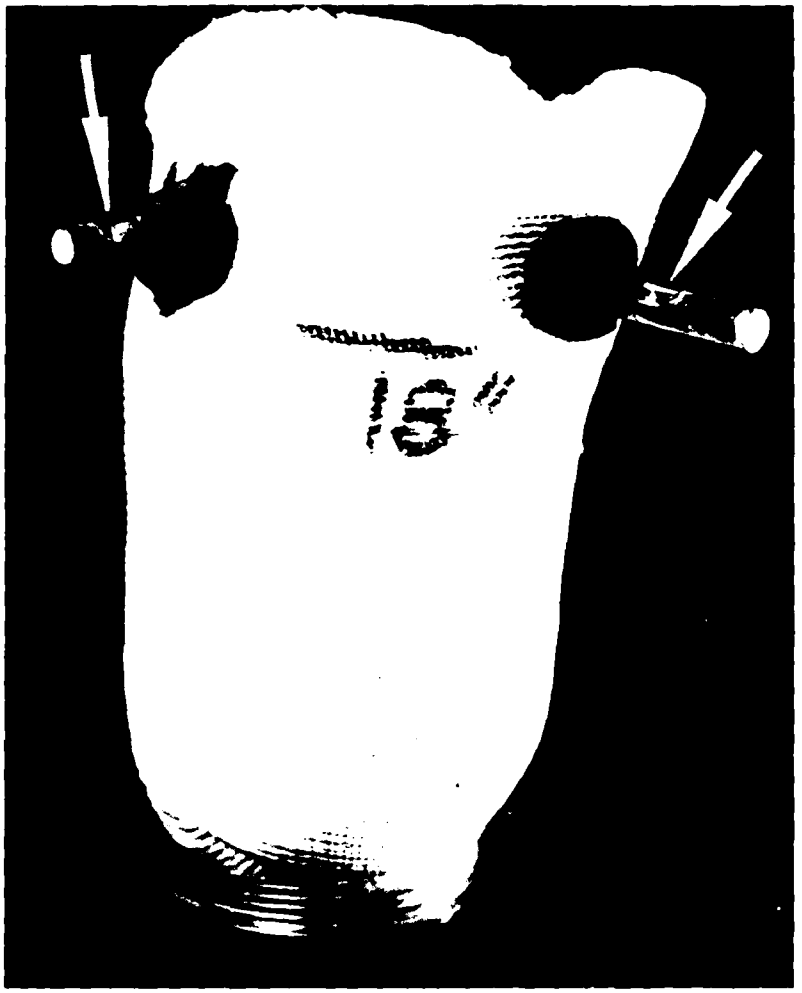
c) adjust the height so that the mark on the socket wall is 18 inches from the table top (Fig. 2,5C);

d) determine the "center" of the socket at the midpoint of the AP axis from the center of the PTB bar (Fig. 4);

e) adjust the clamp and socket so that the vertical plumb line (alignment axis) points at the "center" of the socket (Fig. 4,5B); and finally,

f) if necessary, rotate the cardboard about its vertical axis through the alignment reference center (thumbtack) to provide the desired amount of toe-out in relation to the line of progression guided by the long axis of the anterior spirit level on the socket wall (Fig. 5B).

3. The next step is to bring the pylon-foot-shoe unit into position (Fig. 5D) and to connect the PVC pylon to the socket by softening and molding the four x-shaped bars on the outer surface of the socket (Fig. 5E). This step is facilitated by using double-sided mounting tape between the PVC bars and the socket wall. Then, remove the levels and apply another roll or two of Scotchcast tape to reinforce the



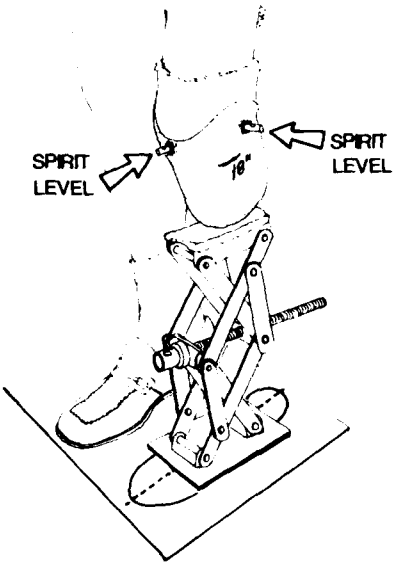


FIGURE 3.
Determine the position (axis and height) of PTB socket by the patient during full weight bearing. Use the anterior and lateral spirit levels to maintain and monitor the medio-lateral tilt, flexion of the socket. The height of the socket is monitored by a mark at a specific height, from the ground, 18 inches for a typical male adult.

FIGURE 2.
The lateral spirit level is used to control medio-lateral tilt while the anterior level is used to control flexion of socket and degree of toe out.

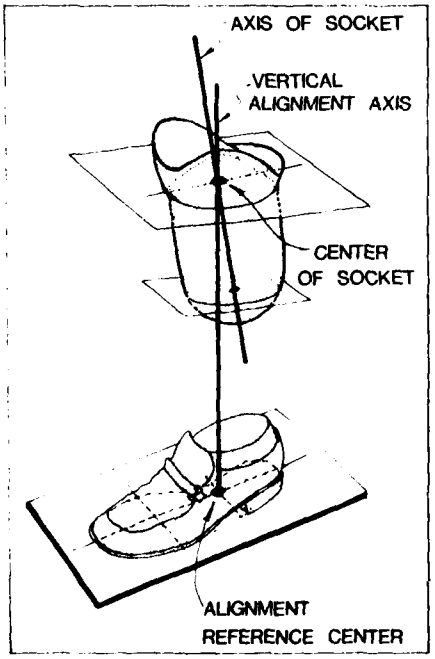


FIGURE 4.
Relationship between the PTB socket and pylon-foot-shoe unit.

attachment of the PVC pipe on the socket. Place Scotchcast in the V-shaped gaps between bars in an effort to reduce stress concentration. Finally, attach the supracondylar strap (and sometimes a waist belt as in Fig. 6) for suspension. Although re-alignment of the prosthesis can be done by softening the PVC pipe with a heat gun (2), it has rarely been necessary.

Sometimes, the interim prosthesis can be foamed and laminated to form a definitive one.

Discussion

For preparatory prosthesis, the use of Lightcast for PTB socket (4) and the use of PVC pipe as part of the pylon unit (2) were reported earlier. Yet, the combination of the two approaches was not described in those articles. The purpose of our approach, initially, was to try a simple preparatory prosthesis, for gait training while the patients were waiting (often many weeks) for the standard VA temporary

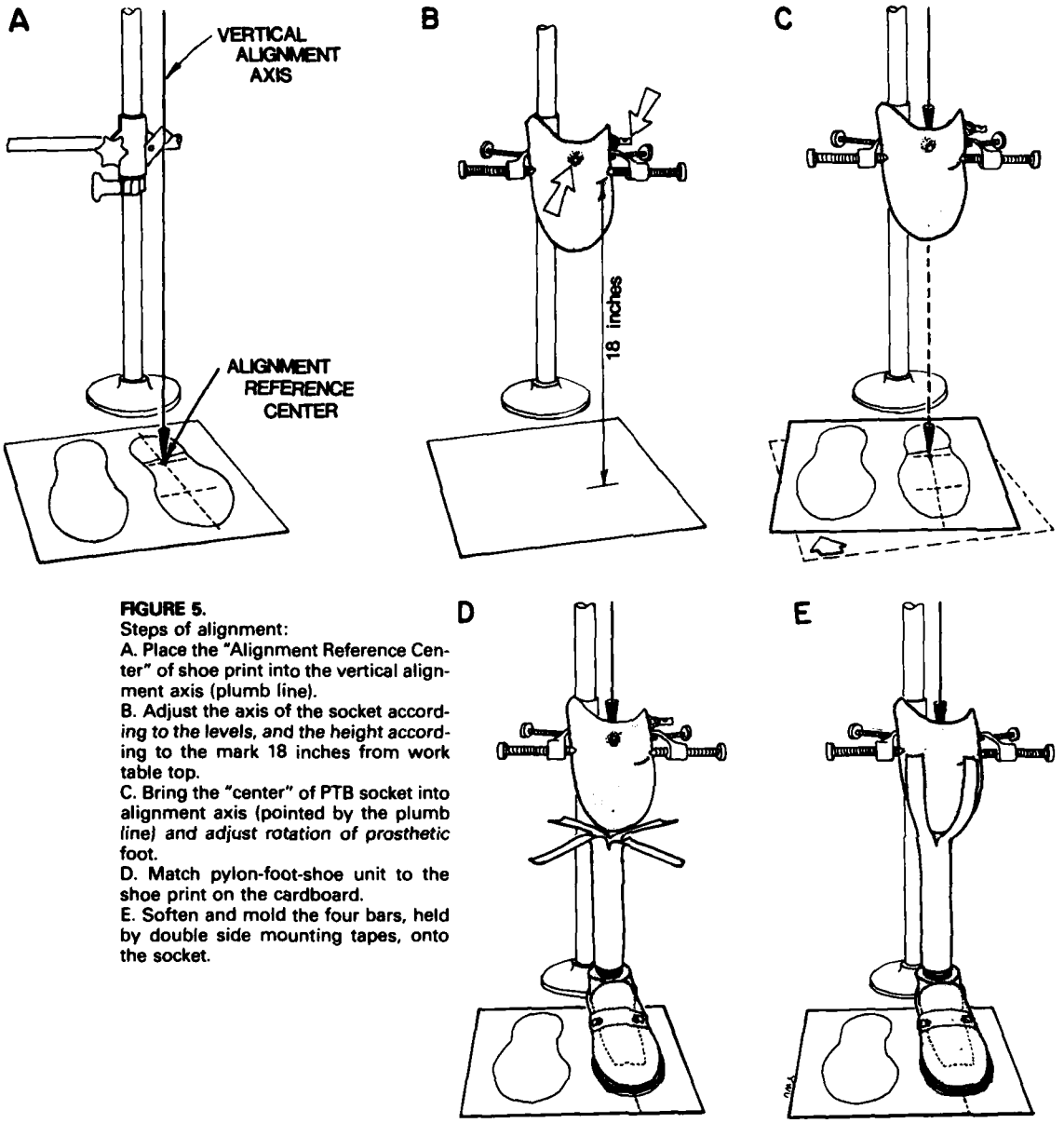


FIGURE 5.
Steps of alignment:
A. Place the "Alignment Reference Center" of shoe print into the vertical alignment axis (plumb line).
B. Adjust the axis of the socket according to the levels, and the height according to the mark 18 inches from work table top.
C. Bring the "center" of PTB socket into alignment axis (pointed by the plumb line) and adjust rotation of prosthetic foot.
D. Match pylon-foot-shoe unit to the shoe print on the cardboard.
E. Soften and mold the four bars, held by double side mounting tapes, onto the socket.

prosthesis from the regional laboratory at another medical center.

Since 1979, we have used this system on 25 patients including two bilateral BK amputees. Mechanical failure of the system has never happened. The longest period of use was 90 days until the patient received his VA training prosthesis. On a patient with 330 pounds body weight, a total of 5 rolls of Scotchcast tape were used—with excellent results.

An advantage of this technique, besides light weight, comfortable fitting, and only rare need for realignment, is the reduction of fabricating time, often to less than 2 hours. This is achieved by the following: (i) direct formation of the socket on the residual limb using the new casting material and simple pressure relief technique, (ii) use of wool sock lining as the soft insert, and (iii) precise static alignment of the socket to prosthetic foot to replace the conventional dynamic alignment procedure.

Direct formation of the socket on the residual limb, using the cotton padding (spacer) method (5,6) provides a graded pressure relief over the bony prominences, and in some cases sensitive areas, while uniform pressure is distributed over the rest of the stump and a desirable higher unit pressure exerted over the patellar tendon for weightbearing (3). The use of a thick wool sock as the liner for a smooth inner surface, and the wearing of tube socks, replace the need for a soft insert in our system. Both direct casting on the residual limb and elimination of the soft insert are effective time-saving approaches in making the PTB socket.

Alignment techniques used are also markedly simplified, although they do follow common principles (3). To connect the socket (upper section) and the prosthetic foot (lower section), three independent factors are involved: (i) the position of the prosthetic foot; (ii) the position of the socket; and (iii) the relationship between the socket and the prosthetic foot. Since the prosthetic foot is the foundation

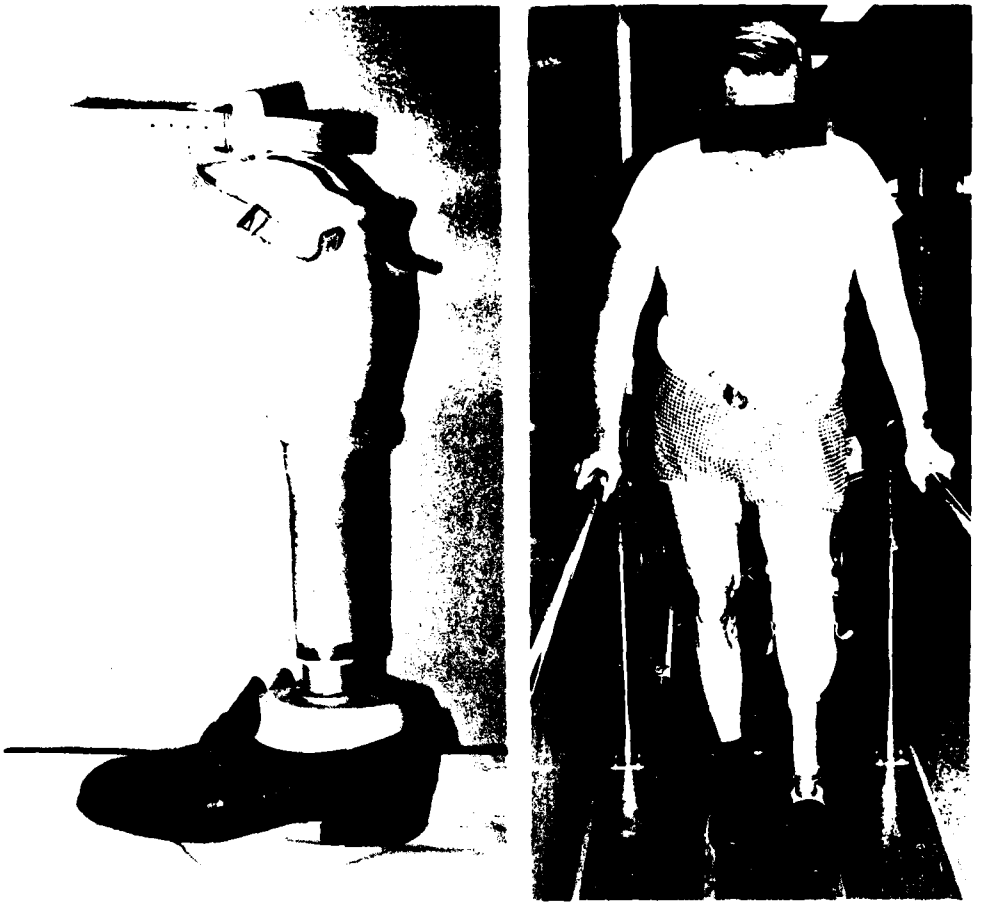


FIGURE 6.
Gait training using Scotchcast-PVC prosthesis.

for the alignment, all that is required is the stability of the pylon-foot-shoe unit on the floor (or work bench). The position for the socket, however, involves the "height" as well as the "axis" (a result of mediolateral tilt and flexion) of the socket. This position can be readily and accurately determined by the patient while standing with the socket on. While bearing full weight, the patient adjusts the socket to the most comfortable position. Once this is achieved, with no excessive pressure to any certain area of the residual limb experienced by the patient, the exact "axis" (i.e., the mediolateral tilt and flexion) of the socket is maintained by temporarily attaching two spirit levels. The exact "height" is defined by a mark on the socket wall. During the transfer from the residual limb to the alignment fixture, the degree of mediolateral tilt, flexion and rotation of the socket is monitored accurately by the spirit levels.

While the patient determines the position of the PTB socket, it is possible to make certain that the socket fits comfortably as in the check socket procedure, thus avoiding later time-wasting in correcting a poorly cast, improperly modified, or otherwise faulty socket normally discovered only after attachment to the pylon unit.

The relationship between the socket and the pylon-foot-shoe unit in the conventional approach is determined by dynamic alignment. Since the "center" of the socket at PTB bar level was found to fall vertically at or very close to the "alignment reference center" in our 20 definitive or temporary below-knee prostheses aligned by conventional dynamic technique, we believe that simply bringing the "center" of the PTB socket onto the same vertical axis with the "alignment reference center" would approximate the same goal as the dynamic alignment process. This has been proved by the fact that realignment in our system was rarely necessary in 25 consecutive cases. Two cases aligned by eye (to test the need for the spirit levels) were inadequate: they were then refitted with the recommended techniques, leading to perfect results.

The "center" and the "axis" of the socket are two independent factors, and must be considered separately. The "center" of the socket must be in the alignment axis (Fig. 4) and the "axis" of the socket should be flexed to match the most comfortable position of the residual limb determined by the patient during full weightbearing. From a practical viewpoint, establishment of the most comfortable position (axis) of the socket by the patient while standing on the jack is a modified form of dynamic alignment, while alignment of the "center" of the socket to the prosthetic foot is a precise and simple method of static alignment.

From our experience, using Scotchcast casting tape and PVC tubing along with a simplified alignment technique by a nearby certified prosthetist-orthotist (M.D.B.) has resulted in improved patient care at this VA Medical Center where no

prosthetic workshop is available and where delay in obtaining a standard training prosthesis has been a problem. To this date, we have had no major complications associated with its use except for two earlier patients who developed very mild superficial skin breakdown over the tibial end. Those incidents led to the application of thicker distal cotton padding and the wool sock lining in making the PTB socket.

This interim prosthesis is very practical and effective. It has been well received by the patients and the staff ■

Acknowledgement

The authors wish to express their thanks to Mr. Simon Kahn for his generous donation that made this study possible, and to Phillip T. White, M.D., Henry B. Betts, M.D., Gunter Gehl, C.P. and John Sankey, C.P.O. for their invaluable support and advice.

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INDEX OF PROGRESS REPORTS

The Bulletin's Progress Report section has outgrown the style of presentation that worked well in the past. The section at one time carried only about 20 reports in 100 pages or less, and only VA-sponsored work was reported. If we grouped them "logically" and retained the same order from issue to issue, the regular reader had very little need for a special index. (The complete BPR title, author, and subject index, provided on a 5-issue and 10-issue basis in recent years, provided all the help that was needed. Incidentally, a 5-issue index covering BPR 10-31 through BPR 10-35 will be found in this issue.)

Progress Reports in this issue number more than 160 reports covering almost 150 pages and listing 301 investigator-authors. Personnel are listed, with initial page numbers, on this and the facing page. An experimental format for an investigator/subject/institution presentation will be found on the following pages, followed by an effort to present, by page numbers, the major subject areas covered in the reports.

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VETERANS ADMINISTRATION REHABILITATIVE ENGINEERING RESEARCH AND DEVELOPMENT SERVICE PROGRAMS

Margaret J. Giannini, M.D., Director

Development and Evaluation of a New Artificial Larynx

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Continuation and modification of the prototype artificial larynx is still underway. There are no new developments to report at this time.

Development of a Communication Control Aid Using Electromagnetic Tracking Technology

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Jack Scully

Polhemus Navigation Sciences, Inc. (PNSI) of Vermont, a subsidiary of The Austin Company, has continually been developing SPASYN (SPAce SYNchronization), a company-patented electromagnetic position and orientation measurement technique. The SPASYN concept has been successfully employed as a head-tracking device which is used by military pilots as a helmet-mounted sight system. PNSI has begun to design and develop a new application of this technology: a communication aid for the handicapped called SPA-SYN-COM. Originally conceived by James Krieg, a PNSI systems engineer, SPA-SYN-COM is envisioned to be a portable direct-selection device enabling even the more severely disabled person to communicate by either small natural movements of the head or by some other controllable part of the body.

When fully developed, SPA-SYN-COM would offer disabled persons the possibility of operating a number of useful devices, ranging from electric typewriters and voice synthesizers to telephonic communication systems and environmental controls.

In practice, the user points a head-mounted sighting device at an adjacent target board that contains blocks of letters, numbers and symbols for various control functions. The user's line-of-sight to the target board is measured through the spatial relationship between two electromagnetic dipole antennas: a fixed source mounted behind the head and a sensor mounted on an eyeglass frame. Measurements of the position and orientation of the user's head-mounted sensor can thus be converted into locations on a passive target board.

SPA-SYN-COM was successfully demonstrated at the DeGoesbriand Unit of the Medical Center Hospital of Vermont in Burlington the week of May 19, 1980.

Based partially on the results obtained in that demonstration, the Rehabilitative Engineering Research and Development Service of the Veterans Administration, operating through its Medical and Regional Office in White River Junction, Vermont, decided to support the PNSI proposal to develop the communication aid. A three-phase program was proposed: in the first phase a research-grade instrument is being configured; the second phase will involve the clinical evaluation of the instrument at Trace Research and Development Center at the University of Wisconsin; and the third phase will provide for the prototype development and testing.

At present, the VA views successful completion of the first phase of the program as a requirement for additional funding authorizations. Work on Phase I began in earnest at PNSI on June 29, 1981 and will continue for one year, at which time the clinical instrument will be available for evaluation and testing.

The Phase I technical plan calls for the development of a clinical evaluation instrument, which will not reflect the final prototype configuration in appearance, power consumption, portability or size. Functionally, however, the SPA-SYN-COM instrument will perform in an identical manner to the envisioned prototype.

Essentially, a straight-forward engineering approach is planned to develop the research-grade communication aid. There are four major steps to the approach: System Design, Hardware/Software Design, Unit Testing and System Integration and Test. The System Design process defines the functional elements of the instrument in terms of their input, output, transfer, and interface parameters. This effort will result in specification documentation sufficient to design the exact hardware and soft-modules for system implementation. The modules will be integrated and the resulting instrument tested for compliance with the specifications.

In conjunction with the design process, equal attention will also be given to the Cost Benefit Analysis segment of the program. Any areas of design that represent cost trade-offs will be noted and justified. For example, the size requirement of the microprocessor memory for the research instrument is a function of software development rather than of the computational and/or operational requirements. Notation and justification of such cost trade-offs will enable a more accurate assessment of the cost of a final configuration. Other critical areas which will be carefully assessed for cost versus benefit will include: manufacturing techniques, power consumption, component availability and future interface requirements such as environmental controls, telephone modems, speech modules, etc.

Documentation of the total engineering effort and the Cost Benefit Analysis will be included in the final report for Phase I of the program.

Studies of Normal and Abnormal Motion

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Mary Patricia Murray, Ph. D.

During the period from January 1 to June 30, 1981, the Kinesiology Research Laboratory continued its investigations into the nature, rate, and extent of change in functional performance in patients with total joint and other reconstructive procedures in the lower extremities.

To help determine the duration of benefits in functional performance resulting from total hip arthroplasty, kinesiologic testing was completed over a 4-year period on 58 patients with 72 Charnley and Müller total hip replacements (1). The patients, who averaged 62 years of age with a range from 22 to 78 years, were tested before surgery and 2 and 4 years after surgery. None of these patients had complications related to the total hip replacement, such as loosening or infection, and none of the patients had any neurological disease or major problems with other joints in the lower extremities.

The study showed that, on the average, men and women with these replacements were significantly improved 2 years after as compared to before surgery. Improvement was measured in almost all of the components of function tested, including range of hip motion, hip abductor and adductor muscle strength, weight distribution between the feet during standing, and multiple components of walking performance. During the period from 2 to 4 years after surgery, the patients tended to maintain the 2-year level of performance, particularly as regards range of hip motion and walking performance measurements (Fig. 1). Average hip muscle strength measurements in the men showed slight, but not statistically significant, declines from 2 to 4 years after surgery (Fig. 2). For most patients, the 2 and 4 year levels of performance were still below the normal limits of variability for comparable age and sex groups.

Preoperatively, we had tested 110 patients. Of this original sample, 52 did not meet the criteria for this long-term study, either because of inability to follow-up, complications related to the hip replacement, or severe arthritis of other joints. From information gathered on these patients, an estimate was made that approximately 70 percent of the patients in the original sample of 110 were still functioning better 4 years after surgery than before surgery.

Two studies to assess the effect of different surgical procedures in groups

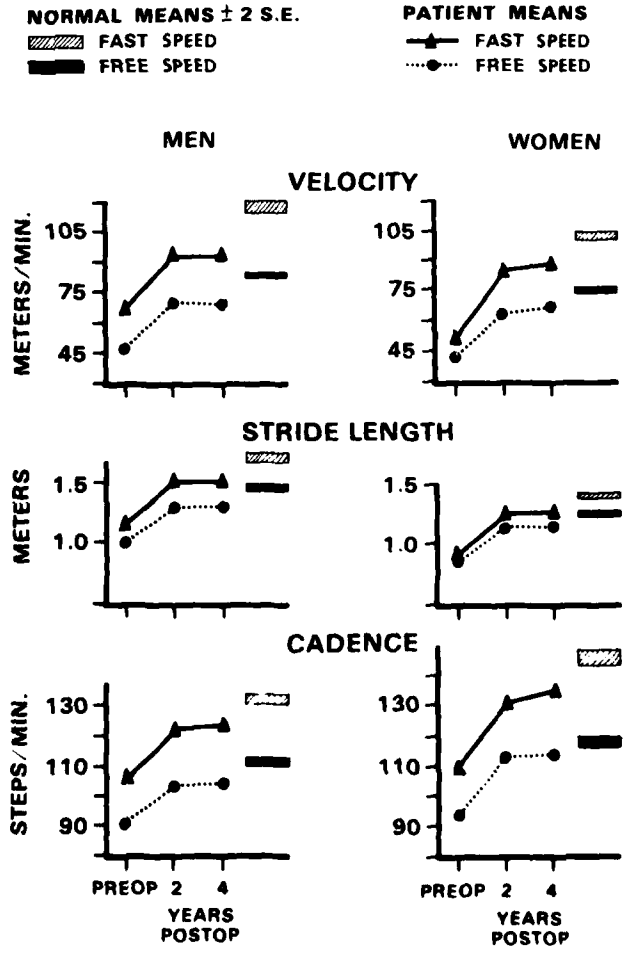

FIGURE 1.
Mean free-speed and fast-walking velocity, stride length (2 successive steps) and cadence for 25 men and 33 women before total hip replacement and 2 and 4 years afterward. All patients were walking without support. Range of normal variability defined by 2 standard errors above and below the mean is indicated by shaded horizontal bars for free-speed walking and diagonally striped horizontal bars for fast walking for men and women. Reprinted with permission from Clinical Orthopaedics and Related Research, No. 147, June 1981, p. 122.

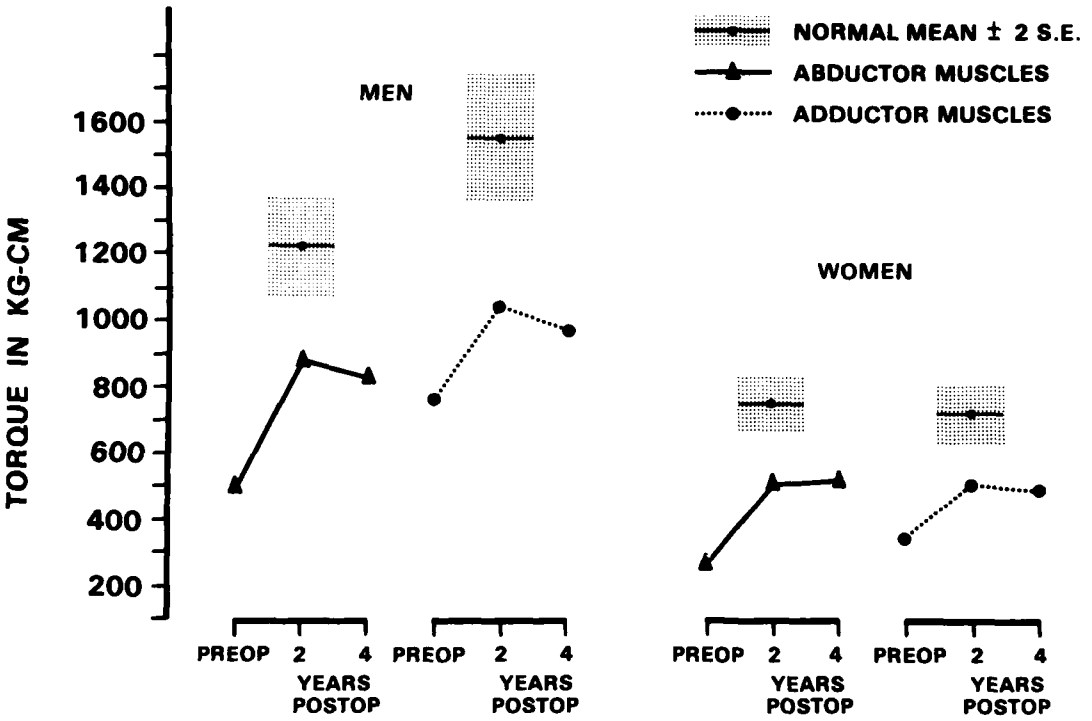

FIGURE 2.
Mean maximum isometric hip abductor and adductor muscle strength before surgery and 2 and 4 years afterward for 30 hips replaced in men and 42 hips replaced in women. The shaded area bisected by the horizontal line represents the normal mean and 2 standard errors above and below the mean for normal men and women. Reprinted with permission from Clinical Orthopaedics and Related Research, No. 147, June 1981, p. 121.

of patients with the same type of hip replacement are near completion. These include a study comparing functional performance of patients with and without osteotomy of the greater trochanter, and a study comparing functional performance of patients operated through an anterolateral as opposed to a posterior approach to the hip.

During the period covered by this report, the Laboratory also published a book chapter in a text, Clinical Biomechanics: A Case History Approach (2). This book chapter, written on request, combined information from two previous works done at the Kinesiology Research Laboratory on the antalgic maneuvers in the gait of patients with hip pain and the compensatory maneuvers in the gait of patients with hip fusion. In the text, gait information from these two studies was synthesized with biomechanical principles in order to elucidate the relationships between gait deviations, hip-joint loading, and the mechanical energy cost of walking.

The Laboratory also collaborated with Dr. Gore in analyzing and interpreting data and publishing a manuscript on a project in which 7642 girls and 751 boys were screened for spinal deformity in a Wisconsin county of approximately 100,000 persons (3). Two hundred forty-three girls and 13 boys had scoliotic curves of ten degrees or greater. Determination of curves which would progress was found to be unpredictable. Identification of progression was possible only by repeated examinations.

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Remote Control Writing

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T. Burn, B.S.

This is a pilot study to assess the feasibility of generating "handwriting" by inputting the motion with the chin. This may be of particular value to the quadriplegic, whose only other method of written communication is by mouthstick or typewriter or video with special keyboard controls. The advantages of the system would be speed, versatility, simplicity and the satisfaction of producing script. Funding sources for this work, in addition to the VA, are the Paralyzed Veterans of America, and Howmedica, Inc.

Both mechanical and electronic systems have been made for the evaluation process. The former employs a system of linkages and has been used for on-site tests where the individual is asked

to trace standard shapes representing script, as well as make script which is compared with a pre-injury sample. A computer program is now being written to evaluate tests in terms of accuracy and speed at the time of the test. A joystick into an a/d converter will be used. The other electronic tests are to measure the frequencies and accuracy of up and down and side to side motions, based on the coupled oscillation model of handwriting. A sample of "chin writing" from a patient is shown (Fig. 1).

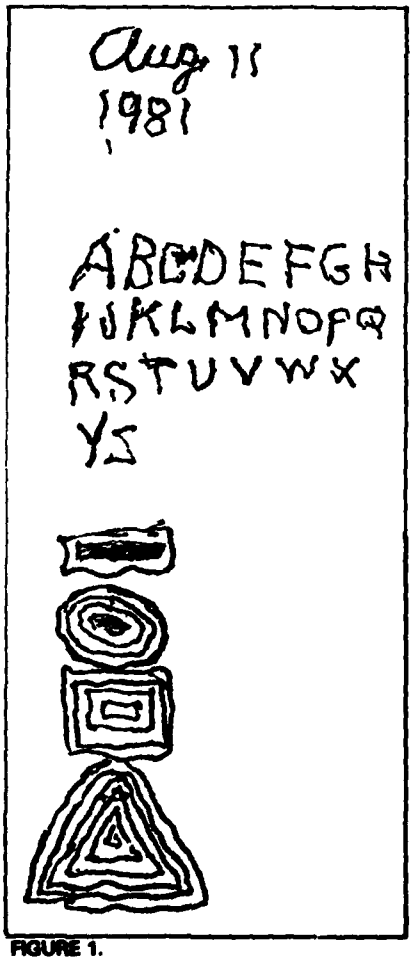

FIGURE 1.
This "handwriting" was generated by a patient who input the motion with his chin. The possibilities of both mechanical and electronic systems are being evaluated.

Quantitative Analysis of the Effect of Total Hip Arthroplasty on Stress and Strain in the Human Pelvis

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The present project is a continuation of an earlier study (1) investigating the changes in the strain field in the human pelvis after implantation of the acetabular component of a total hip arthroplasty. The previous investigation utilized three strain gage rosettes (with three gage elements each) glued to a hemipelvis which was loaded to simulate conditions during stance phase of gait while pelvic strain data were recorded on a strip chart recorder. Comparative results using an Austin Moore hemiprosthesis and subsequent implantation of a conventional acetabular component load with matching Charnley type prosthesis were obtained. Processing of the data from 12 such tests required a minimum of three weeks due to the complexity of the computations involved.

In order to expand the scope of the project and allow for consideration of many variables inherent in the placement of acetabular components, a microcomputer-based data acquisition system is being developed to increase the number of strain gage readings that can be made from each specimen and to provide for real-time analysis of the acquired data. This system is described schematically in the flow chart of Figure 1.

Cadaveric hemipelves and their matched proximal femurs are being procured. Each hemipelvis will be instrumented with five strain gage rosettes, for a total of 15 gage elements on each hemipelvis. Corresponding gage elements for each hemipelvis will be connected into a half-bridge in the "bridge completion and calibration" box, which will also contain the resistors necessary to complete the 15 Wheatstone Bridges. The signals generated by each of the 15 strain gage bridges, as well as the load cell used to monitor the ac-

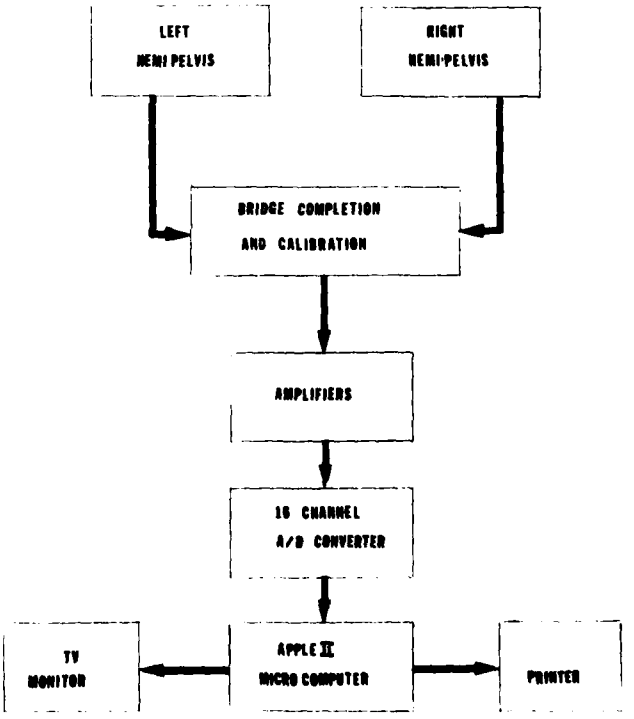

FIGURE 1.
Schematic of microcomputer-based data acquisition system developed to provide real-time data processing and display.

quired load, are amplified by a bank of amplifiers which have been especially designed and custom-built for this application. The amplifier outputs are fed into a 16-channel, eight-bit A/D converter, which feeds the digital representation of the strain gage signals into the Apple II/Plus microcomputer in real time. In order to accelerate execution time and provide real time representation of the strain fields, software is being written in PASCAL rather than the more customary BASIC language used on most microcomputers. The specially designed program allows calibration and scaling of all the data channels. Offset and scaling will be handled by the software rather than by manual adjustment. The program provides for scanning all channels periodically, translating the strain readings from each rosette into the principal strain values and their orientation, and displaying these strain data on a TV monitor as the test is being run. Hard copy of the acquired data will be available via a printer. As of this writing, all computer hardware has been acquired and/or constructed. Software designs have been initiated.

Redesign and fabrication of the loading arm assembly (Fig. 2) is being carried out to allow for more efficient control of loading parameters. Development of the system described above is intended to allow the evaluation of the strength and stiffness of the bony pelvis-acetabular complex under various situations. These include observation of strain readings:

1. When there has been no cortical reaming as compared to reaming through the outer cortex of the acetabulum—leaving the inner or medial pelvic cortex intact.
2. Comparison of the use of three large keying holes as opposed to the use of no keying holes, and also comparing these techniques to the use of multiple small keying holes.
3. Determination of the effectiveness of a uniform mantle of cement, established by spacers, between the bone and prosthetic acetabulum in improving the strength and stiffness of the bone-prosthesis complex.
4. Comparison of the use of pressure injection techniques for insertion of acetabular cement to that of hand insertion of cement.
5. Comparison of the use of surface replacement acetabular components which have a larger diameter and thinner wall to the smaller diameter, thicker wall, conventional acetabular components.
6. Comparison of the use of metal-encased polyethylene acetabular components to the standard acetabular component.
7. Determination of the effect of various reinforcing techniques used to enhance support of the acetabular components, when there is a deficient medial wall (these include the use of protrusio ring, protrusio ring with femoral head bone graft, and wire mesh reinforcement).

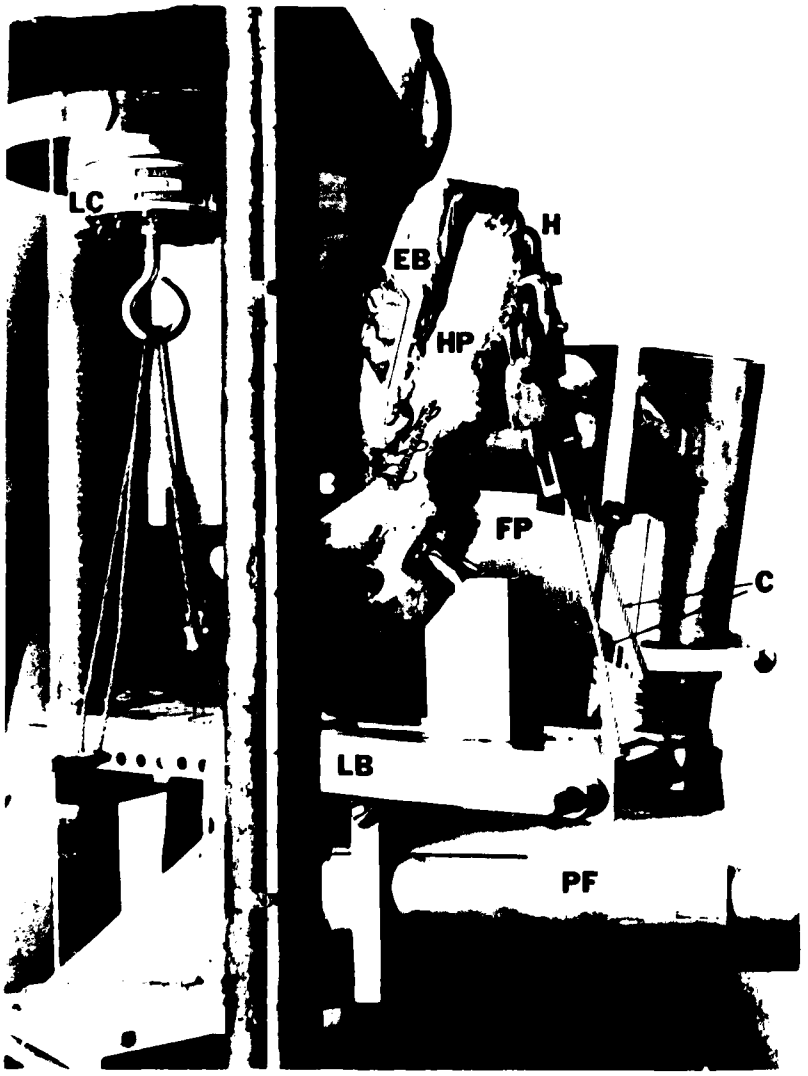

FIGURE 2
Lateral view of hemipelvis (HP) bolted, through epoxy block (EB), to the positioning fixture (PF). A Charnley femoral head prosthesis (FP) is mounted on the loading bar (LB), along with cables (C) and hooks (H) which simulate the abductor muscle pull. The load cell (LC) monitors the simulated ground reaction, applied to the other end of the loading bar.

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The Effect of Partial Versus Full Weightbearing on Late Loosening After Total Joint Replacements in the Lower Extremities

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The objective of our study is to measure and document in vivo motion of the cement-bone interface in total hip and total knee replacements. Four spherical (1.6 mm) markers are inserted in cortical bone near each component of the implant and used as references. From three to six markers (2.39 mm) are embedded in cement. A Biplane Radiographic Technique (1) is used to measure the distance from cement markers to the bone reference markers. Simultaneous Biplane X-Rays in non-weightbearing (20 kG force or less) and full weightbearing are taken on the affected side. These are taken post-operatively, before discharge, and 2, 4, 6, 12, 18, and 24 months postoperatively. We generate, by computer, a report on the Biplane Analysis for each film set taken. Reported data are the coordinates for bone and cement markers, intermarker distances for bone and cement markers, and any relative motion of the cement markers with respect to bone (i.e., loosening and migration). Additionally, we generate a two-dimensional plot of cement marker motion with respect to time, as well as a clinical correlation report that is placed in the patient's chart for permanent reference.

To date, there have been 50 patients in our study; of these 17 have been Total Knee Replacements (TKR's) and 33 Total Hip Replacements (THR's). There are two bilateral TKR's and two bilateral THR's.

We have had 14 patients with measured cement loosening (range: 0.4 to 6.3 mm) and clinical evidence of loosening (radiolucent line on x-ray and symptoms); 6 of these have gone to surgery for revision or fusion (one case of septic loosening). In all cases the prosthesis was found to be grossly loose at surgery, thus supporting our Biplane Radiography findings. To date, 13 of the patients studied (out of a total of 50) have shown no loosening on all studies conducted. Thus approximately ⅔ of all patients studied have shown some motion at the bone-cement interface at some time during our study.

Conclusions

Cement-bone interface motion is more common than not, even in those patients who do not present with clinical symptoms.

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Evaluative and Corrective Techniques for Neuromuscular Deficits

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Richard Shiavi, Ph. D.

and

Biofeedback in Rehabilitation for Hemiplegia

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The same facilities are utilized for locomotion studies in both projects. Computer software has been recently developed which enables on-line data acqusition and subsequent compilation, averaging, and plotting of information. This report briefly outlines the functioning of the data measurement, acquisition, and processing systems.

The data handling system is a Digital Equipment Co. PDP 11/23 central processing unit (CPU) with 32K memory, 16 channel A/D converter, 16 bit parallel line unit, 2 RLO1 5Mb discs, high-speed printer, and digital plotter.

Data Measurement and Acquisition—Data are measured using standard commercial equipment and conditioned with filters and integrators designed and fabricated locally. Electromyograms (EMG) are measured using a Biosentry telemetry system incorporating surface or wire electrodes. Bandpass filters eliminate noise and motion artifacts. They have a fourth order, one-half dB ripple, Chebyshev high-pass section with a cutoff frequency of 40 Hz and a second-order Butterworth low-pass section with a cutoff frequency of 400 Hz. They are a state variable realization (1). Integrated EMGs are formed from the filtered EMG with linear integrators. An integrator consists of an active rectifier and a third order Paynter integrator with a 6-ms time constant (2). Canes or devices requiring force measurement are instrumented with a strain-gage bridge. The bridges are powered and forces measured by the telemetry system. All other analog signals, such as goniometric measurements, are hardwired. All analog signals are acquired by the computer via the A/D converter.

Foot contact patterns are measured using a B&L Engineering telemetry system incorporating sensitive switches that can be taped to feet or footwear. This system senses the contact of the heel, fifth and first metatarsals and large toe of both feet. A special interface has been built which encodes the on-off contact information into 8 bits of 16-bit computer word. This pattern is acquired by the computer via the parallel line unit.

The data acquisition program samples all of the data at 250 Hz during the measurement session and stores this on a disc file. The start and end of a measurement run are triggered by electronic eyes which demarcate a 5-meter section of walkway. Immediately after a run, the data are displayed on an oscilloscope and scanned for accuracy. The measurements may be remade if necessary.

Averaging and Plotting—A second program forms an average gait pattern from the sampled data file in several stages. First, the foot channels are scanned and the onset and offset times detected. These channels are displayed on a video terminal with cursors indicating the detected foot events. An optional editing mode is available to correct any detection or recording errors. The average foot patterns and stride information such as speed, etc. are then calculated. The average patterns of all analog channels are calculated by first demarcating the interval of activity in a full stride, second,

interpolating this single stride data at 256 points, and third, averaging it with other interpolated data from that channel (3). The averaged data are then stored.

A third program plots the signals and prints the information from the averaged data file. Figure 1 shows an average gait pattern from a postoperative gait study of a patient who underwent a split posterior tibial tendon transfer: the stride information is included in the legend of Figure 1.

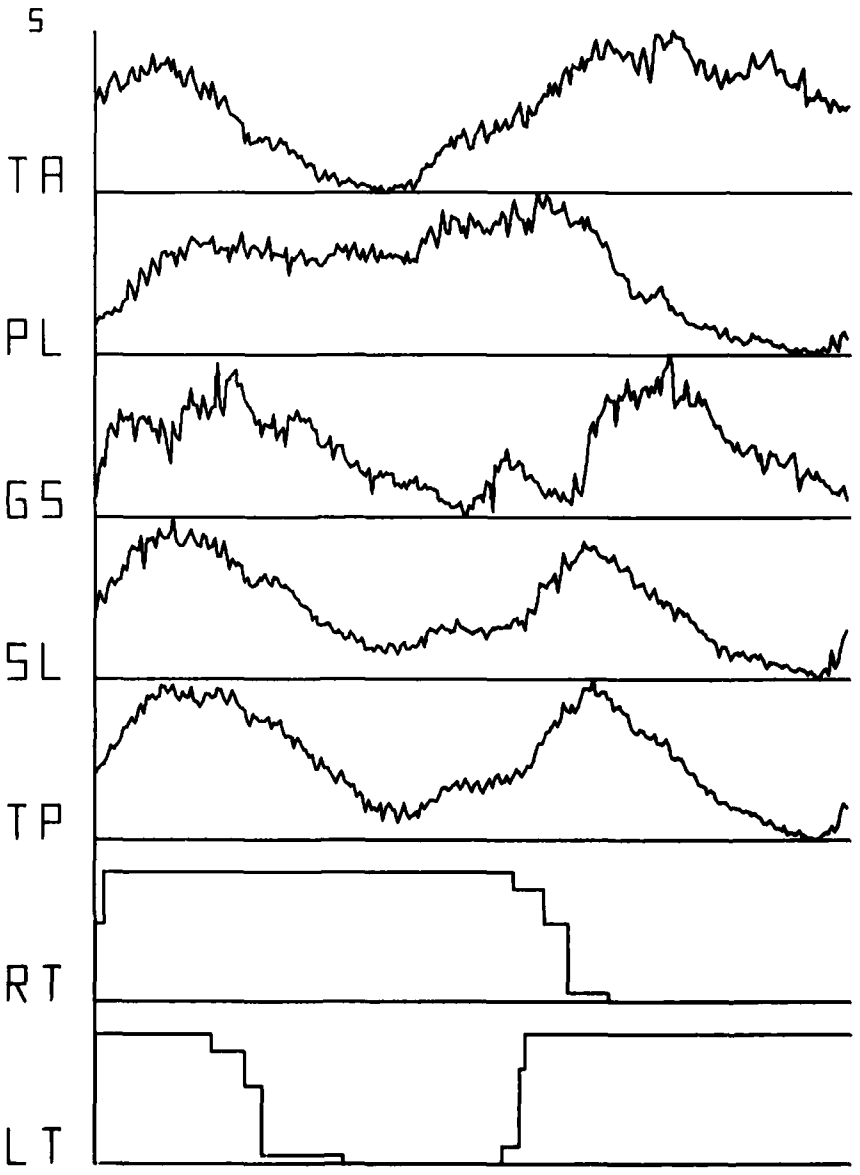

FIGURE 1.
Average integrated EMG from the tibialis anterior (TA), peroneus longus (PL), gastrocnemius (GS), soleus (SL), and tibialis posterior (TP). Right (RT) and left (LT) foot contact patterns. The step sizes are: 1 unit = large toe contact; 2, heel; 4, fifth metatarsal; 8, first metatarsal.
Stride information for Figure 1.
STRIDE TIME=1.1760S: STANCE PHASE=68 percent.
SINGLE LEG SUPPORT PHASE= 21 percent: number of strides=9.
STRIDE LENGTH=0.4113 METERS, VELOCITY=0.3497 m/s.

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Development of Upper Extremity Orthoses Employing Electrical Stimulation

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Introduction—The purpose of this project is to develop and evaluate an upper-extremity orthotic system, employing functional electrical stimulation of paralyzed muscle, to provide control of grasp and release. Palmar prehension-release or lateral pinch-release is elicited by electrical excitation of forearm and hand muscles. Eight C5 or C6 quadriplegic outpatient subjects are currently evaluating this system. Various aspects of these studies are carried out in conjunction with the Applied Neural Control Laboratory, the Engineering Design Center, and the Rehabilitation Engineering Center at Case Western Reserve University.

Laboratory Development—A flexible laboratory stimulation system has been developed to provide versatility in stimulation and control functions. This system allows us to specify stimulus parameters and the type of controller for a specific patient to be used with the present portable stimulation hardware. The system is capable of processing patient-generated input commands from a number of sources, and of regulating the output stimuli to provide the desired coordinated movement in the electrically stimulated muscle. Ongoing studies of these techniques employing the computer to furnish the laboratory with greater flexibility will allow us to design, model, and specify the criteria for future stimulation units. This system is in routine usage in our FES laboratory for establishing proper stimulation parameters

and coordination algorithms, described below. This aspect of the project is supported in part by NIH–NINCDS Neural Prosthesis Program for software development and the VA RER&D program and NIHR for aspects of the hardware development.

Wrist-Hand Orthosis Development—Orthoses are under development to stabilize wrist position for the C5 quadriplegic to use in conjunction with the FES system. The objective is to fabricate a cosmetic appliance which serves the function of conventional devices, but does not encumber the subject during movement generated by FES. Designs of two alternative devices have been completed and are being evaluated. They are fabricated from polypropylene and utilize either a spiral design or a more conventional structure positioned along the radius.

Electrode Evaluation—The percutaneous wire electrode is used exclusively in these studies for excitation of paralyzed muscle. This electrode is fabricated from 10 strand Teflon-insulated wire, as described in previous reports.

Over the period of the past 28 months, 75 multistrand wire (MSW) electrodes have been implanted, and previous to that 103 of a single strand configuration. Of the MSW electrodes, 72 percent are still intact. Of the remaining 28 percent, only eight electrodes were broken (three in one subject after less than 100 days); the remainder were removed intact because of a change in the contractile response which rendered them nonfunctional. Of 24 implanted for at least eighteen months, 17 (71%) were operational, 3 (13%) broken, and 4(17%) removed intact.

The use of percutaneous electrodes has been a safe, reasonably reliable, and extremely valuable technique for excitation of paralyzed muscle for periods of up to several years. This technique enables one to develop functional stimulation systems for subjects to utilize outside the hospital, and for research and development of new concepts of functional electrical stimulation. In the future, we anticipate that the percutaneous electrode will continue to play an important role: (i) in the investigation of new systems, which can be implemented in human subjects without surgery; and (ii) for enabling subjects to utilize functional systems as outpatients to insure that they are candidates for a totally implanted system. Ultimately, in an appropriate subject, the percutaneous system will be replaced by a totally implanted stimulator, as described below.

Electrode Connector Development—A new electrode connector has been developed for covering the site at which the electrodes enter the skin. The connector serves a dual purpose of protecting the area where electrodes pass through the skin and for electrical connection to external apparatus (see previous reports).

The new connector has been in use for the last year with all of our subjects. The new design enables the patient's attendant to maintain the electrode site without technical supervision. Changing the connector at 2 to 3 week intervals results in a clean, long-lasting site, which can now be accomplished without need for the patient to return to the hospital for routine connector maintenance.

***Outpatient* Evaluation of Functional Systems**—Functional electrical stimulation systems have been developed to supply functional control of grasp and release in nine C5 and C6 quadriplegic subjects. The type of grasp provided was either lateral pinch (key grip) or palmar prehension (three jaw chuck grip). The patient obtained proportional control of grasp/release via one of the several available sources. Eight of nine subjects who have been fitted with this system continue to utilize it on an outpatient basis.

The systems that we have developed for control of hand function utilize a single proportional command signal, generated by the patient, to grade the coordinated movement of four electrically stimulated muscles. In our systems, we have developed a special purpose controller/stimulator which receives external inputs from one of a variety of sources and delegates appropriate strength stimuli to the muscles at the appropriate time. The controller/stimulator is configured modularly to provide for versatile use of the basic system with minimal hardware variations to tailor it specifically to individual subjects (see previous reports).

Six C5 and three C6 quadriplegic patients have been supplied with this system. Only three systems have exactly the same control figuration, demonstrating the individuality, based on the subject's performance and/or preference, that must be provided. To produce the same general type of grasp in different subjects, different muscles frequently were used. These differences enabled us to correct for problems such as unstable joints and denervated muscles.

C5 subjects were required to wear an external orthosis. For lateral prehension, this orthosis stabilized the wrist only. For palmar prehension, the splint was used for wrist stabilization only in one subject, with finger and thumb coordination supplied by the stimulated muscle; in two different subjects the splint stabilized the thumb and finger interphalangeal joints as well. C6 subjects required no orthosis. This enabled them to use the grasp generated by muscle stimulation as an adjunct to their tenodesis grasp, which generally is weak.

Our subjects have been involved in evaluation of the systems, primarily on an outpatient basis, for up to 2½ years. We have a total of 146 patient months of experience with the system. Of the nine subjects fitted with the system, eight are still in the evaluation program. Three use their system regularly; three use it irregularly, primarily for special functions; two are less than four months with the system; one was discontinued. Generally the most active subjects utilize their system more frequently.

Donning of the systems requires less than two minutes if put on while dressing; otherwise lead wires must be threaded beneath the clothing. The patient must have assistance in putting on the system.

The primary problems encountered generally have not been technical in origin. In response to patient suggestions, new command sources have been modified or generated to solve specific problems. Generally the electrodes produce sufficiently reproducible response so that modification of stimulation parameters is rarely required. Thus, no adjustments of any kind are available externally on the patient stimulator. Battery lifetime (approximately two months) is generally sufficient for intervals be-

tween visits by users to the hospital; batteries are not changeable by the user.

Implantable Stimulator Development—The purpose of this study is to develop and evaluate a multi-channel implantable stimulator for electrical stimulation of paralyzed muscle. The implantable unit has been specified to be sufficiently versatile for use in applications in the upper or lower extremity. The implant is a slave receiver/stimulator which processes information received from an external transmitter and directs the appropriate strength stimulus to the proper electrode at the desired time. Two models of the implant have been developed. Both models are totally powered and controlled by an externally induced radio-frequency (RF) signal. This design provides for long life expectancy, since no battery is utilized. The original model of the stimulator is a four-channel device which generates stimuli in a format identical to the present generation patient stimulator (see previous reports). This stimulator has been fabricated using thick-film hybrid circuit technology. A packaging technique utilizing a glass-ceramic material (Macor) has been developed. The package consists of Parylene coating of the circuit, hermetic feedthrough connections provided by a solder/glass seal, and an epoxy seal between the capsule lid and body. Three stimulators have been implanted in animals to evaluate circuitry, packaging, and electrode performance.

The implant circuitry has been redesigned to increase its versatility of operation and its reliability. The second generation has been designed and implemented in a semi-custom CMOS integrated circuit (Monochip-Interdesign). This revision has doubled the number of output channels to eight and allows independent activation of each channel, while substantially reducing the component count. A pulse-coded RF signal provides the implant with (i) power for circuit operation and stimulation; and (ii) coded information regarding channel selection and stimulator output parameters.

Major support for this aspect of the project has been through the NIH-NIGMS, and work is performed in conjunction with the Engineering Design Center at Case Western Reserve University.

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A Single Unit Study of Muscle Afferents in Human Movement

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In the past 6 months, a laboratory at the McGuire V.A. Medical Center has been established with electrophysiological capabilities to monitor and record single unit afferent nerve potentials from muscle receptors in the awake, unanesthetized human. The major receptor presently recorded is the muscle spindle, most specifically the primary sensory receptor, although cutaneous receptors such as touch and pressure, and joint receptors, are readily recorded. Potentials are recorded from the median nerve at the elbow and mid-upper arm and the posterior tibial nerve in the popliteal space.

Electrical stimulation through the recording electrode allows for muscle afferent nerve fascicle isolation, which results in a more rapid muscle spindle nerve fiber location.

Single unit action potential activity is recorded using manually inserted electrodes of insulated tungsten wire, electrolytically tipped and impedance measured at 35–50 kΩ at 1.0 kH. These electrodes are superior to electrodes with an impedance of 100–150 kΩ as originally reported. Electrodes are fabricated by Frederick Haer and Co., Brunswick, Maine.

Preliminary recordings in normal subjects allow criteria to be developed for receptor identification and basic unit activity during rest, passive stretch, muscle twitch, reflex activity and voluntary movement. Techniques for recording and quantitation of range and velocity of movement are being developed, as is a system for computer evaluation of results. Recording devices are being custom designed in cooperation with the Bioengineering and Orthotics Departments.

Monitoring muscle afferent activity in patients with hyperactive syndromes and phasic movements (especially cerebral vascular accident and Parkinsonian patients) is projected for the immediate future. The overall objective of the program is to study the role of the alpha motor-fusimotor system in human normal and pathological movement.

Functional Spinal Cord Regeneration

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In order to investigate the capacity of the adult mammalian spinal cord to recover function after injury, it is imperative that an understanding of the central segmental (spinal cord) synaptic organization of motor control is accomplished. Since the last progress report (BPR 10-35) substantial progress in this laboratory has been made in understanding the organizational principles of the monosynaptic projections of spindle afferent fibers onto spinal motoneurons.

Mammalian muscle spindles (muscle stretch receptors) give rise to two groups of afferent fibers, both activated by muscle stretch: (i) rapidly conducting group Ia fibers and (ii) slowly conducting spindle group II fibers. Since the introduction of the powerful technique termed spike-triggered computer averaging (STA), the central synaptic actions of single group Ia and group II spindle afferents have been the subjects of considerable experimental interest (11, 13–16, 18–20, 22, 25, 26). However, few studies have directly examined the general principles of organization observed

by these two muscle spindle afferent systems. In recent studies of this laboratory, the synaptic actions of single medial gastrocnemius (MG) group Ia and spindle group II afferents in triceps surae motoneurons have been compared in great detail leading to new hypothesis regarding the organization principles of the spindle afferent system (17, 24).

Using STA methods and intracellular micropipette electrodes, the monosynaptic excitatory actions of 67 MG Ia and spindle group II afferent fibers on 1,027 triceps surae motoneurons were investigated in cat lumbar spinal cord. The results of these studies allowed comparisons of both Ia versus spindle group II afferents, and rapidly versus slowly conducting fibers, within each spindle afferent group with respect to conduction velocity in the dorsal funiculus, projection of major collateral branches to triceps surae motoneuron pool, ramification of major collateral branches within the pool, functional connectivity with triceps surae motoneurons, and parameters of monosynaptic excitatory postsynaptic potentials (EPSPs) elicited in triceps surae motoneurons.

Based on these data, the functional organization of the MG groups Ia and II spindle afferent projections to the triceps surae motoneuron pool is summarized in the schematic diagram of Figure 1. The stem axons in the dorsal funiculus (including the caudally directed branches) of both groups Ia and II spindle afferent fibers give up to nine major collateral branches into the triceps surae motoneuron pool (13, 14). These major collateral branches descend from the stem axon into the motoneuron pool at about 1.0 to 1.5 mm intervals. Within the motoneuron pool, terminal branches extend both rostally and caudally (13, 14). These rostro-caudal terminal arborizations are much more extensive for group Ia afferents than for group II afferents. Moreover, our evidence indicates that the spindle group II afferents with faster conduction velocities have more extensive terminal arborizations than spindle group II afferents with slower conduction velocities.

The samples of group Ia and spindle group II single fiber EPSPs were each divided into a fast conducting subgroup and a slow conducting subgroup using the observed mean conduction velocities of the respective spindle fiber groups: fast group Ia afferents ($\geq$ 98 m/s); slow group Ia afferents ($<$ 98 m/s); fast spindle group II afferents ($>$ 52 m/s); slow spindle group II afferents ($<$ 52 m/s). Functional connectivity was found to be greater with homonymous than heteronymous motoneurons (group Ia; 86% vs. 57%; group II: 50% vs. 17%); greater for the combined Ia sample than the combined group II sample (78% vs. 42%); and greater for fast than for slow afferents of each type (group Ia: 84% vs. 75%; group II: 57% vs. 23%). The mean amplitude of single fiber EPSPs elicited by spindle afferent fibers was also found to be greater in homonymous than heteronymous motoneurons (group Ia: 88 μv vs. 67 μv; group II: 24 μv vs. 17 μv, not significantly different at the 0.01 level); greater for the combined group Ia sample than the combined group II sample (82 μv vs. 23 μv); and greater for fast spindle afferents than slow spindle afferents (group Ia: 97 μv vs. 74 μv; group II: 24 μv vs. 21 μv, not significantly different). The 10–90% rise time and half-width of single fiber EPSPs elicited by group Ia afferents were not significantly different from those elicited by spindle group II afferents. These data are taken as evidence that the distribution of active terminals of single spindle afferent fibers on the surface of the motoneuron is largely unrelated to the type or size of the afferents. The mean EPSP latencies (measured from the terminal potential) were significantly longer for single fiber EPSPs elicited by spindle group II fibers (0.57 ms) than group Ia fibers (0.50 ms). However, amplitude-matched subsamples of single fiber EPSPs elicited by Ia and group II spindle afferents demonstrated no significant difference in EPSP latency. Rise time and half-width also did not differ between these subsamples. These data lend further support to the hypothesis that Ia and spindle group II afferent fibers have similar distributions of active terminals on the motoneuron soma-dendritic membrane. Overall, these findings indicate a similarity in the central organization of Ia and spindle group II afferents.

Of the variables studied which may discriminate between the central actions of spindle groups Ia and II afferents, single fiber EPSP amplitude may be the most significant, since virtually all spindle group II single fiber EPSPs are less than 70 μv whereas only about one-half of group Ia single fiber EPSPs are less than 70 μv. The differences between the actions of the two spindle afferent systems appear to be largely quantitative (peripheral conduction velocity, functional connectivity and single fiber terminal potential (TP) and EPSP amplitude). Based on our analysis of the central actions of slowly and rapidly conducting fibers of the two spindle afferent groups, it appears that these measured differences are strongly related to peripheral afferent conduction velocity and, hence, to the diameter (size) of the afferent fiber.

Identification of abiding general principles of organization in the central nervous system has been exceedingly difficult. Henneman and colleagues (3, 4, 10, 21, 27) have found evidence that the neural "energy" necessary to discharge a cat lumbar motoneuron, the energy the motoneuron transmits and releases through the muscle cells it innervates, the motoneuron's mean firing rate, and its excitability and inhibitability are all correlated with the motoneuron's size. Based on such correlations, Henneman and colleagues (3) developed the concept of "the size principle" to describe the influence of cell size on the functional properties of motoneurons. More recently, Lüscher et al. (7) have extended the application of the size principle to the Ia and spindle group II afferent systems. Our data lend strong support to the hypothesis that the distribution and density of functional connections of both groups Ia and II spindle afferents are dictated, in part, by afferent size. The larger the spindle afferent fiber, the greater the functional connectivity and the magnitude of the monosynaptic excitatory effect on spinal motoneurons. Contrary to the conclusions of Lüscher et al., however, our data indicate that the size of the sensory neuron bears no relation to the location of its active synaptic terminals on the soma-dendritic membrane of spinal motoneurons.

Relationship of M and S boutons to group Ia and spindle group II terminals:—The present data indicate that the two central actions that best distinguish between group Ia and spindle group II afferents are single fiber EPSP ampli-

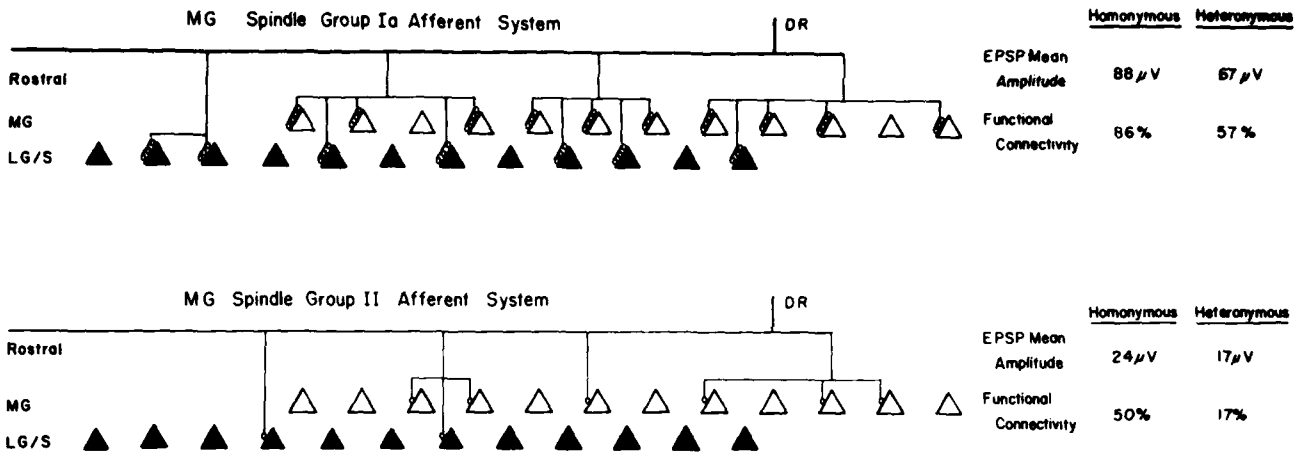

FIGURE 1.
A schematic model of the functional organization of the overall projection of single medial gastrocnemius (MG) group Ia fibers (above) and single MG spindle group II fibers (below) to homonymous and heteronymous motoneurons. Open triangles represent homonymous motoneurons, and filled triangles represent heteronymous motoneurons. The relative density of active terminals (open circles) is estimated, based on the mean amplitude of single fiber EPSPs. DR refers to dorsal root. (Reproduced from ref. 24; copyright 1980 J. Neurophysiol., The American Physiological Society.)

tude and single fiber TP amplitude. Single fiber EPSP and TP amplitudes of group Ia and spindle group II fibers are significantly different. The mean group Ia EPSP amplitude is about three times as large as the mean spindle group II EPSP amplitude and the mean group Ia TP amplitude is about twice as large as the mean spindle group II TP amplitude. Only group Ia fibers appear to be capable of generating large amplitude single fiber EPSPs ($> 150\ \mu v$) and large amplitude single fiber TPs ($> 20\ \mu v$) (14, 16). In contrast, spindle group II afferents appear to elicit many more small amplitude single fiber EPSPs ($< 10\ \mu v$) and TPs ($< 5\ \mu v$) than do group Ia afferents (13). Furthermore, in single fiber EPSP amplitude-matched samples, a significant difference persisted in the mean amplitude of single fiber TPs of the two spindle afferent types (13). In fact, the amplitude difference between group Ia and group II-elicited TPs in the matched samples was almost as great as in the parent samples. It is possible that these physiological differences may reflect anatomical differences in the central terminations of group Ia and spindle group II afferent fibers.

Conradi (1) has shown that two types of presynaptic boutons terminating on spinal motoneurons disappear following dorsal rhizotomy in cats: type M boutons and a subclass of S boutons which are characterized by their relatively large size and by the apposition of P boutons. Certain evidence is consistent with the hypothesis that group Ia fibers may terminate as M boutons and spindle group II fibers may terminate as S boutons. Firstly, the rapid disappearance of both bouton types following dorsal rhizotomy indicates that both are primary afferent terminals that monosynaptically contact motoneurons. Secondly, these large S boutons are smaller than M boutons. Although there are no anatomical data on the relative number of terminals ending on motoneurons from Ia and spindle group II fibers, this difference in bouton size is consistent with our findings that spindle group II single fiber EPSPs and TPs are generally smaller than those of group Ia fibers. Finally, the majority of both M and S boutons are located on the proximal parts of the motoneuron dendrites often close to the cell body (1). This anatomical finding predicts that M and S boutons should elicit EPSPs with similar temporal parameters. Our observations for group Ia and spindle group II afferent single fiber EPSPs are consistent with this prediction. Critical testing of this hypothesis must ultimately depend on ultrastructural examination of labelled (e.g. horseradish peroxidase) and physiologically identified group Ia and group II spindle afferent terminals in contact with alpha motoneurons.

Spindle afferents: One system or two?—In working with these data on the central actions of spindle afferent fibers, one is struck more by the unity of the two spindle afferent systems than by their divisibility. Peripherally, the anatomical and functional properties of the primary and secondary spindle afferent endings are clearly distinguishable (2, 5, 8, 9, 12, 23). Both receptors are sensitive to tonic stretch of the host muscle, but primary and secondary spindle afferents are differentially responsive to the dynamic aspect of muscle stretch. Even dynamic sensitivity, however, has been found under certain experimental conditions to exist as a continuum, progressively increasing from fast group II through slow Ia spindle afferents (8). Interestingly, Loeb and Duysens (6) have characterized one spindle afferent conducting at 70 m/s as a group Ia, and another conducting at 85 m/s as a spindle group II. Like Matthews (9), these authors consider conduction velocity unreliable for spindle afferent classification in the range from about 65 m/s to 85 m/s.

Single-fiber EPSP amplitude and functional connectivity for the spindle afferent systems decrease according to afferent conduction velocity, from fast group Ia through slow group II afferents. There are no systematic differences in the location of afferent terminals on the motoneuron that are related to the major spindle afferent

classification. Since both afferent systems observe a number of common organizational principles in their monosynaptic excitatory connections with motoneurons, differing in the number of motoneurons contacted and the amplitude of the EPSPs generated, group Ia and II spindle afferents may comprise one continuous functional system that is organized in adherence to a size principle (17).

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Studies for the Design of a New System for Stabilization of the Cervical Spine

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The initial aim was to determine the forces and moments acting in the currently used halo-vest systems. As a preliminary study, to determine the upper bounds of linear forces, an apparatus was constructed to immobilize the torso of a seated subject. Force transducers were used to measure maximum head forces. Normals produced 177 Newtons (N) to the right, 161 N to the left, 126 N forwards and 148 N backwards.

An axis system was defined in the halo-vest, which specified the three forces and three moments acting on each side at the halo vertical rod connections (Fig. 1). To determine some of these forces and moments, clip-on inductance type strain gages (Hottinger-Baldwin) were used. Use of a clip-on system allowed versatility in dealing with the various designs of halo-vest, and avoided permanent attachment. The gages were connected to carrier demodulator units (Celesco), thence to a chart recorder (Gould) for recording and amplification, and finally through an a/d converter to an Apple Plus II computer. An intrumented halo device is shown in Figure 2.

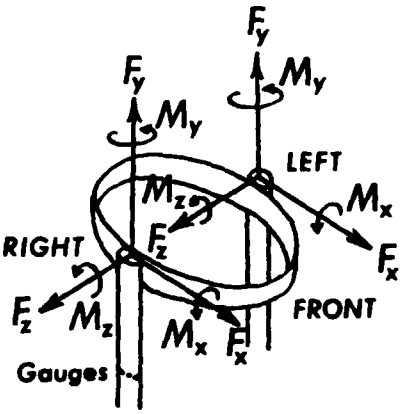

FIGURE 1.
Axis system defined in the halo-vest, specifying the three forces and three moments acting on each side at the halo vertical rod connections.

Equations were written to relate the strains, at points on the various metal rods connecting the halo and the vest, with the forces and moments and with various dimensional constants and materials properties.

Computer programs were produced for various locations of the four gages on the rods of the different halo-vest designs. (The designs included the Ace MKI, MKII and MKIII and the Pope). At the start of each test session, the gages were attached, their locations measured and keyed into the computer, along with the material (steel or aluminum). The test subject then relaxed and the gages were balanced.

The particular activity was then carried out while the computer continuously sampled and stored the strain data. The program computed the forces and moments for each set of data, and determined the maximum values. (The maxima did not necessarily occur at maximum strains). These maximum values were then displayed and printed. When they were satisfactory, the next activity was carried out.

A selection of the maximum values obtained from three normals (using rubber pads between the head and the halo ring instead of pins into the skull) and four patients is shown in Table 1. Note that the values obtained are for one side of the apparatus. Assuming symmetry, the total F_y would be double, while F_x would be double, or plus and minus in turning activities. The limited data available show patients to be similar to normals. Activities not shown in the table, such as walking up and down steps, gave generally lower forces. The force values are all relative to the relaxed position and do not necessarily represent absolute forces relative to zero frame loading. Forces in the horizontal direction F_x were significant as well as the vertical forces F_y.

It appeared that the most important factors in generating large forces were gravity (the weight of the head) and geometrical changes of the body such as when pushing upwards from seated, or shrugging. Muscle forces and inertia forces were probably contributory but apparently to a lesser degree.

Our studies are providing the data to enable an analysis of new design configurations, which will be the next phase of the work.

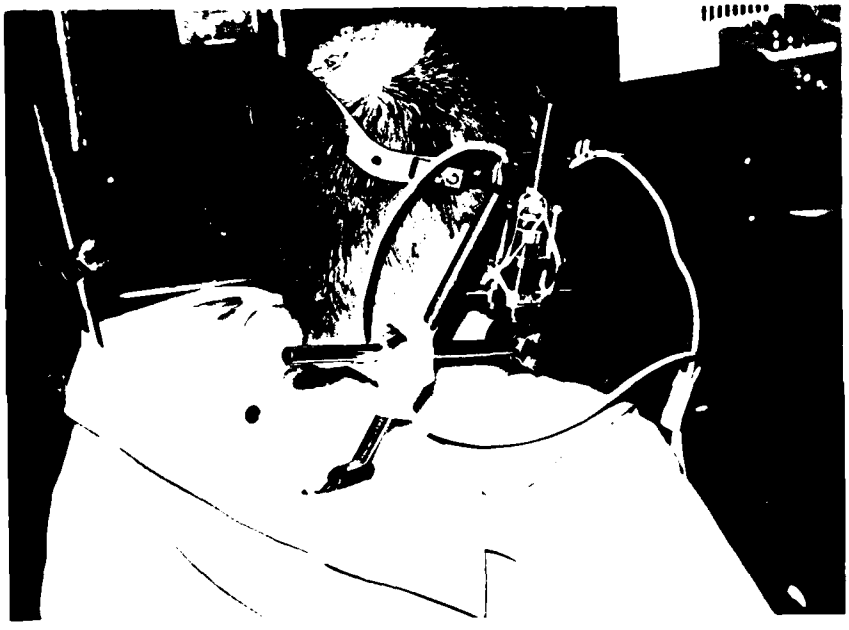

FIGURE 2.
Clip-on strain gages in use. These allowed versatility in dealing with various designs. Computer programs were produced for the differing locations of the four gages on the rods of the various halo-vest designs tested.

TABLE 1.
Maximum forces (in Newtons) obtained from 3 normals and 4 patients for various activities. Forces, shown for one side of the halo-vest, are not absolute relative to zero frame loading, but are relative to those at the "relaxed" position.

Activity	Normals		Patients	
	F_x	F_y	F_x	F_y
Reaching forwards or upwards	40	10	26	—
Reaching arms across chest	43	46	—	51
Bending to floor from seated	28	17	18	93
From lying to seated or vice versa	80	45	40	—
Looking left to right	—	—	25	60
Looking up and down	47	14	18	—
Crouching down	42	—	19	—
Pushing up from seat	60	—	—	79

Development of a Wheelchair Using a Myolectric Control System

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Progress has been made in both: (i) the investigation of the rate at which information can be transferred over a single myoelectrical channel with temporal patterns of minute all-or-nothing pulses, and (ii) the development of a myoelectric command code for wheelchair control. The requirement for automated experimental facilities to perform the myoelectric information rate investigation was presented in the last progress

report (BPR 10-35). This equipment is now fully functional. It monitors the temporal pattern of myoelectric activity and provides on-line feedback that displays the different types of errors made by an experimental subject when attempting to generate specific myolectric patterns. The two patterns currently used are a single myoelectric pulse (P1) and two distinct sequential pulses (P2). This equipment makes possible attempts to train subjects to generate such patterns in time frames that are too short for conscious attention to the generation of the fine structure of the patterns. For example, P2 is to be generated in a time duration that is too short for two distinct attention states, one corresponding to the generation of the first pulse and the other corresponding to the generation of the second pulse. Initially a pulse-pair spacing of 500 milliseconds (easily generated with conscious attention to each of the distinct pulses) is used to familiarize the subject with the feedback for different types of errors and then the pulse spacing is decreased in steps to 50 milliseconds. Experimentation to obtain data pertaining to human error rate when generating such pulse pairs in a short time frame is currently underway. The ability to use either P1 or P2 in a time frame that is less than twice the time that is normally required for a simple myoelectric response will increase the rate of information flow over a single myolectric channel.

The myoelectric command code for wheelchair control that was described in the last progress report (BPR 10-35) has been implemented. A microprocessor program has been written to provide the required decoding for the experimental myoelectric wheelchair in operation at the West Roxbury VA Medical Center. The program resides in an EPROM, an integrated-circuit memory that is capable of storing computer programs. The EPROM is installed in the microcomputer that has been especially designed for operating the wheelchair. This decoding system is in operation and performs well. The decoded myoelectric signals activate relays that perform functions identical to the functions performed by the microswitches in the joystick assembly of the Everest and Jennings type 34 control unit.

Experience with myolectric wheelchair control has led to the conception of a technique for upgrading the myoelectric system from switched control (E&J type 34) to proportional control. This technique will be implemented before extensive testing of the current system with patients. Two myoelectric channels will be used. The right and left occipitofrontalis muscles have been chosen for the initial experimentation. In high level quadriplegics these muscles are both fully innervated and not spastic. They can be used conveniently with electrodes that are built into a headband.

Right occipitofrontalis muscle myolectric activity will operate the right wheelchair drive motor. The speed of this motor will increase with the firing rate of motor units of the muscle. The left occipitofrontalis muscle will be used for similar control of the left drive motor. A specific combination of activity levels in the two occipitofrontalis muscles will map into the coordinates of a corresponding position for the joystick of a proportional control system. This mapping covers all possible joystick locations that correspond to various forward speeds for the two drive motors.

Provisions are also made to cover all joystick locations that correspond to various reverse speeds for the two drive motors. A rapid twitch of the right occipitofrontalis muscle will change the state of the right motor reversing relay. A rapid twitch of the left muscle will reverse the direction of the left drive motor. The reversal mechanism will be automatically disabled during operation at moderate and high speeds to avoid accidental whiplash. The wheelchair can be rotated in place by reversing only one of the motors.

Preliminary experimentation has been performed to assess the practicality of using the occipitofrontalis muscles for the proportional control technique described above. Both myoelectric activity of the right occipitofrontalis muscle and myoelectric activity of the left occipitofrontalis muscle were simultaneously observed on a two-channel oscilloscope. It is apparent that a large percentage of wheelchair operators will require practice in order to directly control their right and left occipitofrontalis muscles with adequate selectivity to make sharp turns. A technique has been found to achieve the desired control indirectly, eliminating the need for such practice. This technique is based upon the neural interconnection that results in activation of the occipitofrontalis muscle when the eye is closed tightly. Closing the right or left eye independently activates the corresponding occipitofrontalis muscle.

The following example illustrates the use of this indirect but independent control. An operator is initially traveling forward. He desires to make a very sharp left turn. He transfers control of the right occipitofrontalis muscle to the indirect mode by closing his right eye. This allows him to keep the right wheel turning at any desired speed while reducing or eliminating left wheel drive in order to execute the sharp left turn. Note that the code is structured in such a way that the left eye is open when making the sharp left turn. If the code had been structured so that the left occipitofrontalis muscle controlled the right wheel, this sharp left turn would have been made with the left eye closed.

Rotating in place represents another case where the high right-left selectivity that is easily achievable with eye closure can be used. Rotating in place, with the wheels turning in opposite directions, corresponds to a sidward movement of the joystick of a manually operated wheelchair. A rapid closure of one eye will result in reversal of only one drive motor. As a result, an operator not proficient at independently activating his right and left occipitofrontalis muscles could rotate in place. It has been observed that normal automatic eye blinks do not produce significant occipitofrontalis activity, thus they will not interfere with this mode of myoelectric wheelchair control.

Seat Cushions for the Paralyzed

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An evaluation of the skin loads during sitting, and corresponding blood flows as measured in geriatric hospitalized patients, has been published in the Ar-

chives of Physical Medicine and Rehabilitation.

A similar evaluation of paraplegic subjects is currently in progress. Results to date suggest that the paraplegic sitter resembles the geriatric. Sitting loads can be far higher than those developed by the normal, and associated skin blood flows (in the vicinity of the ischial tuberosity) can be considerably smaller. Thus we conjecture that the high rate of pressure sore incidence in paraplegic and geriatric patients reflects not only lessened mobility and insensitivity to load, but also a decreased perfusion capability.

Foot Biomechanics: Force and Pressure Distribution in Health and Disease

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We have submitted our study on the stress distribution on the plantar aspects of the foot for publication. The study used a finite element analysis of the foot within the shoe to determine the effects of shoe sole elastic properties upon pressure. This revealed a significant dependence of the stress on the stiffness of shoe sole material. Shoe soles of intermediate stiffnesses lowered stresses.

We have calibrated thin pressure transducers and are starting to apply them to the feet of healthy subjects and those with foot diseases and disorders.

We have developed a lighted walkway in the floor to record pressure images during gait, and this is ready to use on patients with a variety of foot disorders both before and after treatment.

Interdisciplinary Development and Evaluation of Externally Powered Upper-Limb Prostheses and Orthoses

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The research program at Johns Hopkins for the Veterans Administration continues to be focused on the development and evaluation of assistive devices for the high spinal-cord-injured person. Improvement of interface devices, and clinical evaluation of the robotic arm/worktable system and chin controlled wheelchair, were the principal activities of the project during the reporting period. Progress and accomplishments during the January–June 1981 period are summarized below.

Chin Controller for Wheelchairs

Evaluation is continuing on the low-profile chin controller compatible with the E&J Model 3P Wheelchair. Seven E&J wheelchairs equipped with this system are currently being evaluated by volunteer quadriplegics. Testing periods range from a few months to over 3 years in daily living environment. Test models include both open-loop torque control and closed-loop velocity control. Overall results to date indicate that, while closed-loop control with its self-braking characteristics and adjustable velocity limits contributes to wheelchair safety, such features are important only in an outdoor environment. The features do not appear to be required in indoor or institutional environments.

The latest volunteer to receive a chin-controlled wheelchair is a well-educated 35-year-old quadriplegic with neuromyelitis optica of 16 years duration. His only useful upper-limb function derives from a small unilateral remnant of active shoulder musculature. This musculature produces a very weak and limited motion of the hand when appropriately supported. Residual head-neck motion is about ⅔ of normal and is also weak and poorly coordinated.

Prior to participation in this project, this individual had been provided with an E&J non-proportional electric wheelchair with a conventional hand-operated joystick controller and a wrist-hand orthosis designed to assist joystick contact and manipulation. With this equipment he was able to travel independently about the unobstructed corridors of the nursing home in which he resided. His wheelchair control was jerky and erratic. He was obliged to travel very slowly. He could not negotiate narrow places or back up without risk of collision. He could not handle elevators, inclines, irregular surfaces or outdoor terrain. Due to these problems, a non-motorized wheelchair propelled by an attendant was frequently used in preference to the motorized one in order to move him about.

This individual was invited to participate in this program in order to compare his performance using the older wheelchair, manual joystick and control system with that using the new wheelchair with advanced chin controller and closed loop velocity control system. Following equipment delivery and patient orientation, he used the new equipment exclusively for several weeks.

At the end of the test period it was felt by the operator and various knowledgeable observers that his performance with the new system approximated that with the old one and offered no significant advantages. Due to his poorly coordinated head and neck motions, he operated the new proportional wheelchair in a non-proportional mode. He had difficulty switching between reverse and forward. He could not use the high-speed capability or handle the wheelchair safely on ramps or outdoors, regardless of the closed-loop velocity control feature.

It was felt that evaluation by this quadriplegic had enabled better identification of the limits of usefulness of a high technology wheelchair controller. With due consideration of this operator's limited cervical spine range of motion and his poor coordination, it was decided that further testing by him would be unproductive. The test equipment was therefore withdrawn for further evaluation by other types of quadriplegics.

In contrast, during 3 years of evaluation of the chin controller in which the majority of instances have yielded highly successful results, most of the users have possessed better cervical spine range of motion and reasonably good coordination of head and chin motion (see BPR 10-34). Accordingly, discus-

sions are being held with potential manufacturers to try to bring these wheelchair controllers to the market place.

Robotic Arm/Worktable System

Research on the robotic arm/worktable system during the reporting period was primarily concentrated on evaluation testing by a quadriplegic volunteer in his home environment which is also used for the family-owned business. This individual was furnished a complete system which consisted of a dual-purpose chin controlled wheelchair and a robotic arm/worktable system. For a detailed description of each of the subsystems, see BPR 10-35, 10-34 and earlier issues.

The worktable was configured with a low-cost personal computer system located in the main work area of the table and a self feeding arrangement at one end of the table. This quadriplegic volunteer is shown in the self feeding location in Figure 1. Food is placed in three bowls and the robotic arm is programmed to allow self feeding capability with minimal assistance. A typical meal required 30 to 40 minutes to complete.

On the left side of the worktable, a personal computer system is set up to allow handicapped individuals to use a computer with minimal additional help. One feature of this equipment arrangement is the tilted keyboard to allow good mouthstick accessibility. The robotic arm is utilized to insert into and remove the program diskettes from the disk drive. A reading stand permits use of written materials (mouthstick used for page turning) when working with the computer. A telephone located on the table is manipulated with the robotic arm. Figures 2 and 3 show the quadriplegic volunteer in his wheelchair located in the normal work position in front of the computer.

The worktable is designed to permit self docking so that the individual may come to or leave this work area without assistance from an attendant. This feature has worked very well. All control inputs to the robotic arm are via the wheelchair chin controller inputs. Shown in Figure 2 is the robotic arm placing a diskette into the disk drive under robotic arm program control. Provisions are made to store four diskettes in the rack above the disk drive. Figure 3 shows the telephone held in position for conversation.

In the 6 months of evaluation in this environment, this volunteer has verified the capabilities of this system to perform the designated functions in a reliable manner. The chin controller interface was easy to learn to use and it worked reliably. The combination of robotic arm capability and mouthstick capability gives the user flexibility to carry out many tasks on his own. The system has exhibited excellent reliability with only one failure (broken wire) during the 6 months continuous test period. The one attribute which appears to need improvement is speed of response in the use of the telephone and of the self feeding modes. A second advanced model robotic arm, now being completed, operates with simultaneous motion in three axes and is expected to reduce the time to accomplish these tasks to acceptable levels. This individual has taken full advantage of the opportunity over the past 6 months to learn how to use a personal computer, including learning BASIC language and use of some disk programs, and plans to continue working with a computer when these tests are completed during the summer of 1981.

Pseudo Morse Code Interface for Computers

During the course of the evaluation of this robotic arm/worktable system, the mouthstick was found to be generally adequate for keyboard entry except for the multiple key input requirement for key shift and for some word processing programs. Fatigue is also another problem if continuous inputting with the keyboard is required (more than one-half hour at a time). In order to solve these problems, a new technique was evolved as an alternative to keyboard entry to the computer. The requirements for this alternative to the keyboard were that it had to provide standard computer keyboard functions, including upper and lower case, multiple key entry, as well as the capability to operate at an input rate of 10–20 words per minute, and it should permit sustained work at the computer without fatigue. The new system evolved from this program makes use of a standard Morse code high-speed paddle mounted on an adjustable bracket. Minute (less than 1/16 inch) chin motion is required to generate the code. A series of dots or a series of dashes are generated by depressing and holding down one side or the other of the paddle, thus minimizing chin motion input.

The output of the keyer device is sent to a single chip microprocessor which translates the Morse code into ASCII code and serially transmits this signal at 300 baud to the computer terminal via a standard RS-232 input system. Standard Morse code characters are used for the alphabet and numerics and some additional codes are created to complete all keyboard functions including shift, space bar, control, repeat, and other special keys. In order to maximize the character entry rate for a given physical motion capability, a pseudo Morse code is utilized. The code system selected for this purpose utilizes dots and dashes having equal dwell time but distinguishable from each other by utilizing high pitch tones for dots and low pitch tones for dashes. This pseudo Morse code improves the throughput speed by about 30 percent for a given physical capability.

Since this system can contain the full ASCII set and outputs via a standard RS–232 signal, it is compatible with a wide variety of computers, including the Apple II, Radio Shack TRS–80, and many commercial time-sharing terminals. Operation with each of the above models has been demonstrated in the Laboratory. In demonstration testing with an Apple Computer, word processing with Applewriter was shown to be a practical task. Writing programs in BASIC, including use of a disk drive for data storage and retrieval, is readily accomplished. A steady rate of 60 characters per minute for long periods was demonstrated to be feasible.

The system as presently configured is a stand-alone system comprised of a commercial high-speed Morse code paddle mounted on a bracket, a single microprocessor chip to perform the Morse-to-ASCII conversion and tone generation, and a RS–232 connector to the host computer. In application programs such as Applewriter (word processor program), additional special codes were added in the microprocessor to simplify the mechanics of calling up such commands as "delete word, delete paragraph, change the cursor to move to a specified portion of the text, return to BASIC, etc."

It is anticipated that this system may

FIGURE 2.
Robotic arm (foreground) is programmed to permit precise tasks, such as placing a diskette into the mini disk drive, to be carried out on command.

FIGURE 1.
Quadriplegic evaluates self feeding capability of robotic arm system

FIGURE 3.
Multiple-task capability is made possible by worktable layout and by the combined use of the robotic arm and a mouthpiece.

have a broad application to a wide class of handicapped persons including quadriplegics, persons with minimal hand or arm function, and certain non-vocal persons who need flexible communication means. It is a low-cost device and we are actively contacting potential manufacturers to try to make the system available to potential users.

Powered Upper Limb Prosthesis

During previous years of research, this project team developed and evaluated motor units and control systems for powered upper-limb prostheses (see various articles in BPR 10-13 through 10-22). This design concept uses a single drive motor and a cable drive system to power a VO Dorrance series 5 hook and/or elbow motion. Although experimental models were highly successful in clinical trials, attempts in previous years to find a manufacturer were unsuccessful.

Dankmeyer Inc., a Baltimore manufacturer of artificial limbs, expressed interest early in 1981 to manufacture and distribute a motor unit and control system for upper-limb prostheses based on this concept. This firm has enlisted an electronics manufacturing company to make the electronics and battery pack. Engineering prototypes are presently being developed. If the prototype models are successful, it is expected that Dankmeyer will make the unit available commercially.

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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Work during this period continues to be devoted largely to defining the role of surface area in granuloma formation in response to the presence of divinyl copolymer beads (Biobeads SX-8, BioRad) in the lung (see BPR 10-35).

The area of the granulomas, formed in mouse lungs perfused with a fixative, was measured by tracing the outline of the granuloma and bead projected on the ground glass of a light microscope, and the total area of the granuloma determined with a Numonics Electronic Graphics Calculator by substracting the area of the bead from the total.

Other studies—Studies are continuing to use the bead model with sieved 45–53 μm beads to measure the effectiveness of anti-inflammatory drugs. We have tested six anti-inflammatory drugs to date (acetyl salicylic acid, ellagic acid, polyanetholsulfonic acid, hydrocortisone, azathiaprine and bacterial levan (prepared with Erwinia herbicola)), and preliminary results indicate that this model bead system provides a consistent and reproducible method for assessing the anti-inflammatory activity of these drugs.

Publications not previously reported

Coleman SE, Hood CI, Schoen FJ, Robinson M: Electron microscopic study of the effect of anti-inflammatory agents on the foreign body response in mouse lung. Absts. of Southeast Electron Microscopy Society, 1980.

Wilson J, Pigott GH, Schoen FJ, Hench LL: Toxicity testing of Bioglass. World Congress on Biomaterials, Vienna, Austria, 1980.

A Grommet Bone Liner for Flexible Implant Arthroplasty

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Surgical Implantation and Harvesting

As of March 5, 1981, all surgical implantations at the Veterinary Clinical Center at Michigan State University of the textured full grommets and shim grommets were completed. A total of 17 proximal and 17 distal textured full grommets, and 18 proximal and 18 distal textured shims were implanted. Harvesting has been accomplished as close to the proposed dates of sacrifice as possible (See Table 1, pp. 112–113, in BRP 10-35, Spring 1981, Vol. 18, No. 1).

Biomechanics

As of May 31, 1981, fourteen full grommets and twelve shims were submitted to the Biomechanic Department of Michigan State University for testing. Partial results from these tests are included in this report (Table 1).

Histology

As of May 31, 1981, sectioning and microscopy has been done on all samples which were submitted to the Histology Department at Michigan State University. Because of the imminent retirement of the pathologist on this project, another source of the processing and microscopy for the textured samples has been procured. Samples will be processed by Gerry H. Kenner, Ph. D., Associate Professor of Bioengineering, Clemson University, South Carolina.

Specimen retrieval, trimming, and initial fixation in buffered formalin will be done at Michigan State University. After the samples are received at Clemson University, they will be processed through a graded series of daily alcohol changes (once 70%, twice 95%, once 99%) followed by two daily changes of polymerized thin methylmethacrylate resin. Final embedding will be in thick, prepolymerized methlymethacrylate resin.

The polymerized block will be trimmed to approximately a 0.5 in cube. Five or more sections, each 250-500 micrometers thick, will be cut from the block using a diamond saw blade (metal) or a

TABLE 1.
These figures are results from the more recent tests that have been run by the Department of Biomechanics.

	RIGHT SIDE	LEFT SIDE	REMARKS
Rabbit #27 Test 13 tested 8/28/80 Material SSS	Implanted 7/8/80 **Distal Femur** Max. load 10.14 lb.	No implant.	Only one side was implanted (right distal femur). Test went well.
Rabbit #45 Test 14 tested 2/4/81 Material TCG	Implanted 12/22/80 **Prox & Distal** No test results.	No implant.	Animal died from a broken back. Tried test: no results due to grommet falling out during the setup.
Rabbit #42 Test 15 tested 3/11/81 Material TCG	Implanted 11/17/80 **Distal:** Bad angle but the results are Max. load 35.7 lb. **Prox:** Good alignment. Max. load 14.80 lb.	Implanted 1/14/81 **Distal:** Good alignment. Max. load 23.7 lb. **Prox:** Pulled out during setup. Approx. load 2 lb.	Good test series from this specimen. Some trouble with the angle on some femur grommets.
Rabbit #47 Test 16 tested 4/27/81 Material TCG	Implanted 12/23/80 **Distal:** Very little bone around the grommet. Max. load 2.1 lb. **Prox:** Good test. Clamp slipped but grommet did not move. Max. load 16.4 lb.	Implanted 3/2/81 **Distal:** No test result. Fell out during prep. **Prox:** Good test results. Max. load 11.3 lb.	Good tests. Heavy wear on the Silastic implants from both sides.
Rabbit #48 Test 17 tested 4/27/81 Material TCG	Implanted 12/23/80 **Distal:** No test. Fell out during prep. No bone around grommet for support. **Prox:** Good test. Max. load 18.0 lb.	Implanted 3/2/81 **Distal:** Good test results. Max. load 16.0 lb. **Prox:** Good test even though the load is low. Max. load 4.5 lb.	Tests went well.
Rabbit #55 Test 18 tested 4/27/81 Material TCS	Implanted 12/29/80 **Distal:** Good test results. Max. load 8.6 lb. (Clamp slipped. Little bone around grommet.) **Prox:** Test results, Max. load 4.5 lb.	Implanted 3/4/81 **Distal:** Tried a new clamp. Max. load 3.4 lb. **Prox:** No test; bone badly fractured, could not get a grip on it.	Test went well but had some trouble with fractured bones. This was our first test on the new shims. We are trying a new method of clamping and it seems to work.
Rabbit #56 Test 19 tested 4/30/81 Material TCS	Implanted 12/30/80 **Distal:** No test. Load less than .5 lb. **Prox:** Tested at a Max. load of 1.2 lb.	Implanted 3/5/81 **Distal:** Good test. Max. load 10.54 lb. **Prox:** Good test. Max. load 5.6 lb.	Used the new clamps (upper). The test procedure is still the same as before.
Rabbit #57 Test 20 tested 4/30/81 Material TCS	Implanted 12/30/80 **Distal:** Good test. Max. load 6.7 lb. **Prox:** Good test again; Max. load 7.0 lb.	Implanted 3/5/81 **Distal:** Same, very good test. Max. load 10.26 lb. **Prox:** Good. Max. load 11.90 lb.	These tests went very well even though the results seem a little "backwards," in that the grommets that were in the shortest time carried the highest loads.
Rabbit #34 CONTROL ANIMAL No grommets were used.	Implanted 8/14/80 No load. These were tested by a different method and the loads were very low. Max. load 2–4 g.	Implanted 9/22/80 No load. The results were the same on this and all other tests run on Control Animals.	
Rabbit #36 CONTROL ANIMAL	Same	Same	
Rabbits 38, 39, 40 CONTROL ANIMALS	Same	Same	

jeweler's blade (plastics) mounted on a Gillings-Bronwill thin sectioning machine. After the sections are cut they will be labeled according to their position and medial-lateral, dorsal-ventral will be indicated on the specimen. Five specimens from each block will then be finally ground to 200 micrometers or less with graded series of grinding papers using petrographic lapping wheels.

The sections will be microradiographed for 10 minutes at 12 milliamps at 55 kilovolts on a General Electric model XRD–6 X-ray machine using Kodak High Resolution Professional Film type SO-343.

After microradiography, the sections will be stained with Paragon (basic fuchsin and toluidine blue). The sections will be placed on microscope slides on a slide warmer at 50 degrees C. Several drops of Paragon stain will be placed on the sections and allowed to dry. After 20 to 30 minutes, the dried stain will be removed with distilled water, the sections rinsed with alcohol, lightly abraded with a tooth brush and allowed to dry. Finally, a glass coverslip will be mounted with synthetic resin.

Histology will consists of checking the microradiographs and stained sections to determine the tissue apposition at the bone-implant interface. Specifically, the presence or absence of a collagenous membrane and mineralization in the implant-tissue interface will be studied.

During the next quarter, harvesting of the implantations will continue on the proposed dates for sacrifice. Four samples will be harvested and submitted to Clemson University for histology studies. Twenty-four samples will be harvested and submitted to the Biomechanics Department at Michigan State University.

Textured Grommets for Flexible Implant Arthroplasty of Finger Joints

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Grommets made of Co-Cr-Mo alloy (Vitallium) have been ion-textured using a modified 30-centimeter-diameter ion source. The figure (Fig. 1) shows a schematic drawing of the apparatus. The grommets are attached to rods that allow the grommets to be placed inside the discharge chamber. Grommets for the distal and proximal stems of a No. 4 Swanson finger joint have been textured. The sputtering conditions are 1000 volts ion energy and approximately 1.2 mA/cm² current density for 30 minutes. Total grommets, which encircle the stem, and grommet shims, which cover 3 sides of the stem, have been ion-textured. These grommets are presently being evaluated at the Michigan State Small Animal Clinic by Dr. James McGehee.

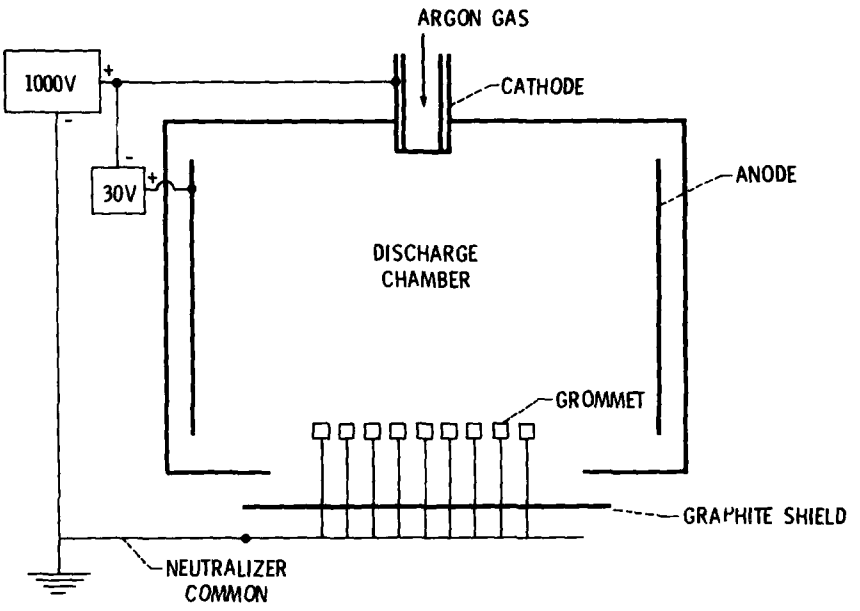

FIGURE 1.
Ion source configuration for grommet texturing is shown in this schematic. Grommets textured by means of this sputtering technique are currently being evaluated.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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Clinical application has demonstrated vascularized diaphyseal bone grafts to be reliable in bridging osseous defects. In theory, the vascularized bone grafts eliminate the need for long-term bone remodeling and creeping substitution of nonviable bony tissue. The vascularized bone grafts retain viable osteocytes which permit the vascular graft to heal to adjoining bone as if it were segmental fracture. We continue to investigate the biological properties of vascularized bone grafts. Our progress report describes in additional detail our findings. Our continuing studies will permit us to correlate the biological healing characteristics of vascularized bone grafts with their mechanical properties.

A segment of diaphyseal canine ulna 4 centimeters long is mobilized, the vascular pedicle cut, and then the vascular pedicle reanastomosed using microsurgical technique. Reanastomosis is accomplished with micro-instruments, the operating microscope with 25 power, and the use of 10–0 nylon suture. The 19 dogs studied to date had undergone bilateral forelimb procedures. A 4 centimeter autograft of ulna has been elevated with its vascular pedicle on one side and a nonvascularized graft on the opposite side. In this way each dog has acted as its control with a vascularized and a nonvascularized 4 centimeter ulna graft. In the vascularized bone graft the ulna was elevated out of its tissue bed

along with its vascular pedicle and then reduced anatomically. Its vascular pedicle was reanastomosed and soft tissue closure was accomplished in the routine manner. The contralateral ulna had a similar procedure without anastomosis of the vascular pedicle and with stripping of the periosteum.

Re-exploration of the dogs was performed according to the following schedule: 4 at one week, 5 at 6 weeks, 4 at 3 months, and 6 at 6 months. In the convalescent period after the initial surgery, animals were periodically labelled with tetracycline to permit, at sacrifice, analysis under the microscope of viable osteocytes. Re-exploration was performed to visualize the vascular pedicle and to determine whether the pedicle was patent. Specimens were then obtained for bone histology including frozen bone, tetracycline labelling, and decalcified bone, H + E labelling. Bone scans were done in the immediate postoperative period in all dogs using technetium labelling. X-rays were done at the time of the original procedure, at the time of the bone scan, and at sacrifice.

All animals survived the experiment and were sacrificed on schedule. Of the 19 vascularized bone grafts at re-exploration, 63 percent were patent. X-rays taken at the time of sacrifice showed healing of both the vascularized and nonvascularized bone grafts at the distal osteotomy but most specimens showed nonunion of the proximal end of the osteotomy. Bone scans were unreliable in permitting us to evaluate in the immediate postoperative period whether the vascularized bone grafts had adequate blood flow. Histologically, the vascularized bone grafts showed preservation of osteocyte in 80 percent of the specimens. In the 20 percent of the vascularized bone grafts where the pedicle was not patent and osteocytes were not present in lacunae, we did see creeping substitution apparent in the subperiosteal section of some specimens. In the nonvascularized bone graft controls, we did see some osteocytes in lacunae but the number of these osteocytes was markedly less than what was seen in the vascularized specimens.

The biological behavior of vascularized canine ulna autografts results in preservation of osteocytes in the vascularized bone graft and supports the theory that bone grafts taken with the vascular pedicle intact can function without the need for long-term creeping substitution. Our subsequent experiments will address the issue of mechanical properties to determine whether these grafts can provide immediate mechanical behavior comparable to adjacent bone upon healing of both ends of the vascularized bone graft to recipient bone.

Student Projects in the Development of Replacement Ligaments and Tendons Using Polylactic Acid/Filamentous Carbon Composites

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This project started April 1, 1981. The work involves two graduate students: one from the Department of Mechanical and Aerospace Engineering, Rutgers University, and the other from the Department of Anatomy, the Graduate School of Biomedical Sciences. Over the past 4 years, the overall objective of a project pursued at the New Jersey Medical School has been to provide a class of synthetic ligaments and tendons for use as long-term implants. This work has resulted in the development of a particular material candidate, a composite of polylactic acid polymer (PLA) and filamentous-carbon. The composite acts as a rate-controlled mechanically degrading scaffold for the development of new tissue. This candidate material is currently in clinical trials. There remain a number of areas that require additional research. The specific projects of the engineering and biomedical students will be to further refine a three-dimensional kinematic model of the human knee in preparation for human patient analysis, and to develop an in-vitro fibroblast cell culture system to study the modes of cell attachment to the implant materials and of extrusion of new collagen, respectively.

It is expected that the first (kinematic model) project will be useful in a number of ways. For example, analytical methods may be used to establish design parameters for a replacement ligament. This is accomplished by analytically and experimentally determining the forces to which the ligament is subjected. In addition, such methods may be used to determine the mechanical response of the knee to replacement of a given ligament. The effect on motion and force distribution of the inevitable change in ligament properties and exact attachment sites introduced by the use of a substitute ligament can be investigated. Finally, such analytical techniques will clearly provide a more detailed understanding of knee mechanics.

The mechanics of the knee joint involves kinematic and force analyses. Prior to kinematic analysis, information on the bony landmarks of the patella, the distal femoral condyle, the tibial plateau, and the tibiofibular joint must be obtained. Likewise, the soft tissue landmarks, attachments of tendons and ligaments to the bony surfaces and the location of muscle groups must be evaluated. Usually this is performed experimentally and the biomechanical information, such as surface contact area, lengths of tendons and ligaments, and strains in tendons and ligaments, can be calculated.

A computer assisted tomography (CAT) scan system was utilized to obtain the geometry of the knee. A cadaver knee was examined and slices of the knee at 5 millimeter distances apart were recorded. These slices were projected in the computer to generate data bases for the tibia and the femur. Computer aided design and three-dimensional graphics programs were utilized to view individual slices and three-dimensional views of the tibia and the femur. The development of the computer programs for the kinematic analysis has been facilitated through the use of a RAMTRAK-PDP 11 minicomputer system provided through the courtesy of Dr. Paul A. Frost, Xybion Corp., Cedar Knolls, New Jersey.

The second project facilitates the study

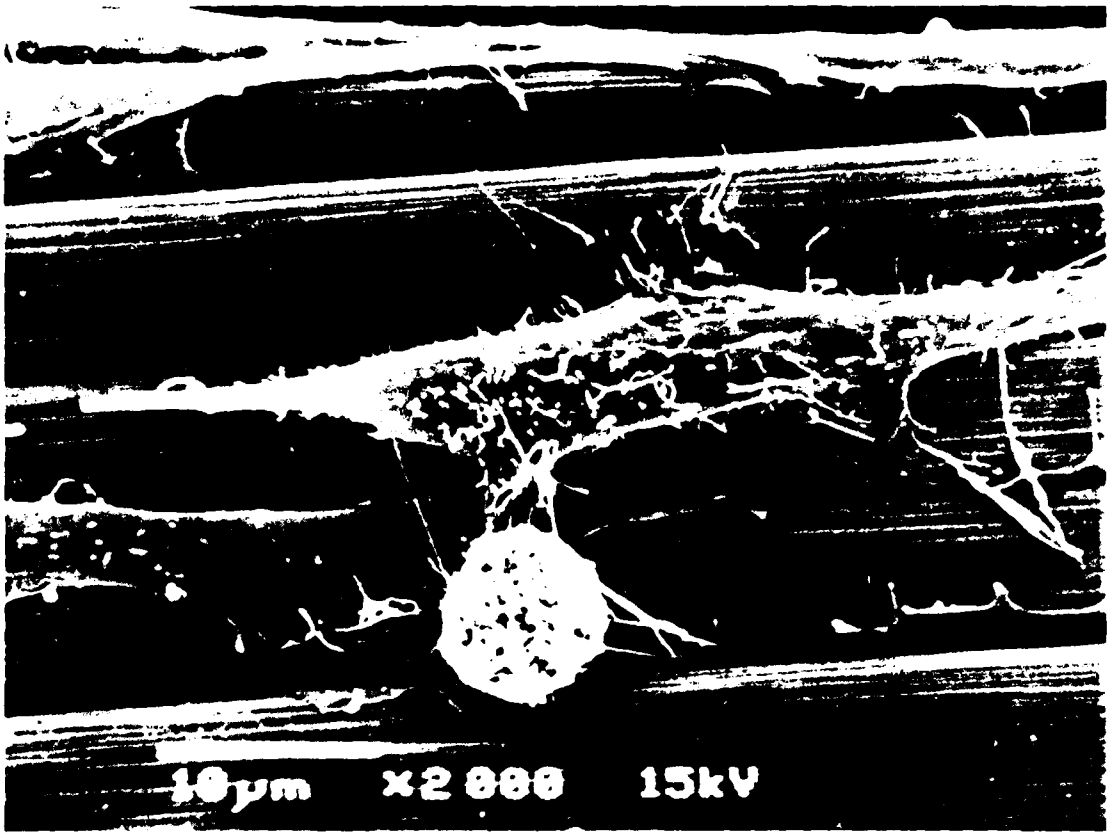

FIGURE 1.
Scanning Electron Micrograph of Fibroblasts attached to carbon fibers in cell culture.

of degradation rate and tissue regrowth rate control. With a fibroblast cell culture system, the degradation of the implant can be quantified and the various methods of acceleration of tissue growth, i.e. growth hormones, Vitamin C, can be studied in an in-vitro model.

The experimental model utilizes 14-day-old Sprague-Dawley rat tendon fibroblasts. The extensor tendons have been removed from the hind legs of the young rats and grown as explants on implant surfaces. To date, cell dynamics alone have been studied. However, in the near future, collagen formation will be stimulated by the addition of ascorbate into culture media.

It has been found that the cells do not adhere to PLA sheets since the surface is continually dissolving away. This property of PLA may become an advantage in gliding tendon repair and replacement. However, when the tendon explants are placed on a sheet of 10 μm carbon fibers, cells rapidly migrate out along the fibers. Within 1–3 days after the start of the explant culture, fibroblasts from the explant begin migrating out of the tissue onto the carbon fiber substrate. These cells migrate away from the explant and along the length of the carbon fibers. They are often seen 1–2 mm away from the explant after 2–4 days in culture.

Tendon cells grown on carbon fiber range in shape from rounded cells about 12 μm in diameter to long, spindle-shaped, 1–2 μm thick cells that align along the length of the fibers. The rounded cells are thought to be undergoing division. The spindle-shaped cells, when viewed with the scanning electron microscope (SEM) (Fig. I), show tooth-like attachments on the carbon substrate. Transmission electron microscope (TEM) pictures are being attempted in order to determine the ultrastructural nature of these attachments. Many of these cells also show microvilli. After 5–7 days in culture, these cells form colonies which may completely envelope individual fibers, form bridges between fibers, or envelope bundles of fibers. Often, one cell is observed to form attachments to several fibers.

This work is continuing during the next quarter with a quantification of the rate of cell migration and an investigation of the effect of fiber type and diameter. A method for determining, in culture, the amounts of DNA, RNA, and total protein is being adapted to this experimental model in order to determine the growth rate of cells on the carbon substrate as opposed to the growth rate of cells on normal culture dishes or on Dacron fibers. By changing certain culture conditions and supplementing the nutrient media with ascorbate, fibroblasts may be stimulated to secrete collagen. Several methods are available for determining the amount and type of collagen produced under these conditions. In the future, the synthesis of col-

lagen, by cells cultured on these substrates, will be investigated to determine the effect of cell-substrate interactions on cell function.

Development of Hydrogel Surfaces for Dental and Orthopedic Implants

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A soft, porous polymer of hydroxyethyl methacrylate (PHEMA), containing connective tissue and plasma proteins is under development as a candidate for eventual use as a surface coating of endosseous dental implants. The implant is an oral prosthesis which is partially submerged in a surgically prepared alveolar bone bed, with the protruding portion serving as an anchor for full or partial dentures. Thousands of these much-needed devices have been placed during the last 30 years, but recent surveys have revealed an overall survival rate of only 49 percent after 6 years in situ (1-3). The major cause of failure is the lack of an attached tissue interface to prevent the entry of oral flora into the bone bed with consequent inflammatory bone destruction (4). The protein-containing polymer under investigation is intended to effect the required tissue attachment, thereby providing a barrier to microbial invasion. What follows is a report of progress of an ongoing animal study to evaluate tissue and cell responses to the polymer.

The proteins being studied are plasma fibronectin and type III collagen. Molecular collagen has been shown to promote cell differentiation (5,6) and cell attachment to a substratum (7) in vitro. Attachment of cultured cells, however, requires the presence of a serum protein, fibronectin. The binding of fibronectin to cell surfaces, demonstrable by immunofluorescence (8), restores certain normal surface properties to transformed cells, such as adhesiveness and contact inhibition of movement (9). The addition of fibronectin to cells in culture induces the formation of actin bundles and a flattened cellular morphology, suggesting a close association between cytoskeletal actin and membrane-associated fibronectin (9,10). A transmembrane linkage between actin and fibronectin during cell attachment has recently been proposed on the basis of immunofluorescence and ultrastructural findings (11,12).

Under laboratory conditions, fibronectin binds readily to collagen, alpha chains and to the cyanogen bromide peptide alpha-1(I)-CB-7 (13). A collagen-fibronectin meshwork has been demonstrated on the external surfaces of attached cultured fibroblasts which disappears after dissociation with trypsin and reappears after reattachment (14).

In view of these reported findings, the proteins selected for incorporation into the polymer were complexes of fibronectin and collagen. Tissue reactions were studied in dogs, using autogenous proteins to avoid allergic phenomena. Proteins were obtained as follows.

A skin specimen 1 cm wide and 10 cm long was surgically removed from the shaved midback under intravenous Nembutal anesthesia, and the wound closed with resorbable sutures. During the same intervention, 100 to 120 ml of whole blood was drawn from the jugular vein and collected in anticoagulant citrate dextrose solution. Plasma was obtained by centrifugation of whole blood (1500 × g), and fibronectin (FN) extracted by affinity chromatography with gelatin coupled to CNBr-activated Sepharose 4B (Pharmacia Fine Chemicals, Piscataway, N.J.). Figure 1 contains a typical chromatogram of dog plasma. FN was eluted with 6M urea and the peak eluate was pooled and dialyzed against acetate buffer (pH 3.6) at 4 degrees C. From 175 to 200 μg of FN per ml of whole blood are routinely extracted by this method. Part of the FN was coupled to Sepharose 4B with the intent of selecting, by affinity chromatography, a subpopulation of skin collagen with fibronectin-binding properties.

Skin specimens (1.5 to 2.0 grams, wet weight) were trimmed free of subcutaneous fat and soft tissues, diced, homogenized in 0.5M acetic acid (HAc) and digested at 4 degree C with pepsin (hog stomach mucosa, Sigma Chemical Co., St. Louis, MO.) at final concentrations of 5 mg (wet weight) of skin per ml of 0.5M HAc and 0.02 mg pepsin per ml of di-

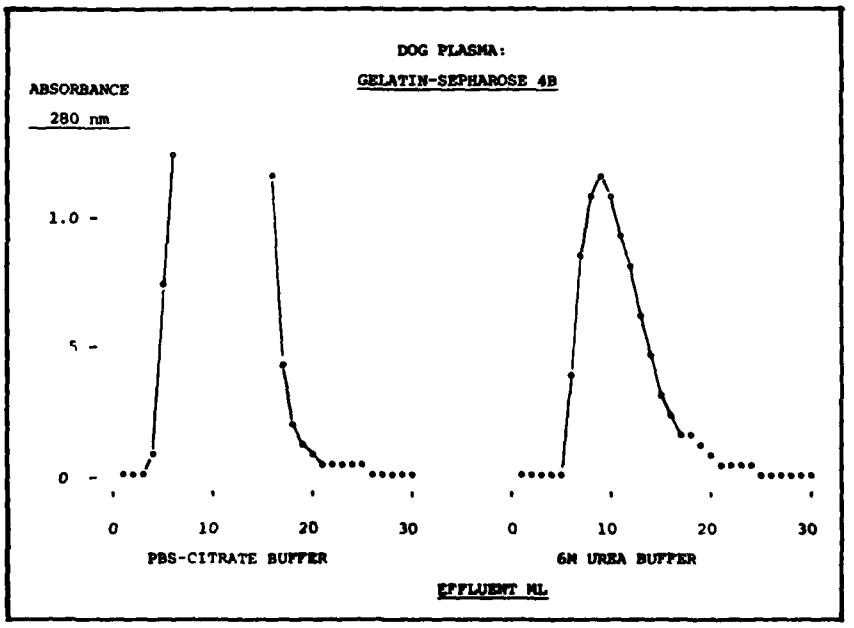

FIGURE 1.
Affinity chromatography at room temperature of fresh dog plasma. The column bed was CNBr-activated Sepharose 4B to which gelatin (Swine skin type I denatured collagen) had been coupled. Plasma fibronectin selectively binds to gelatin while all other plasma proteins are eluted with the column buffer: PBS/.01M sodium citrate, pH 7.2. Fibronectin is eluted with 6M urea/.05M tris, pH 7.5.

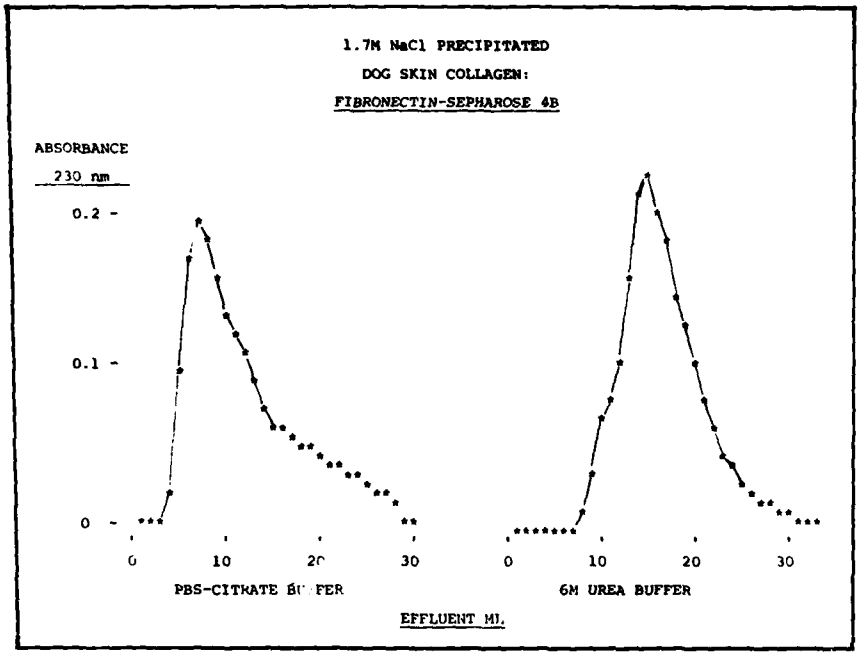

FIGURE 2.
Affinity chromatography at room temperature of acid soluble, pepsin digested, salt precipitated (1.7 M NaCl) type III dog skin collagen. The column bed was CNBr-activated Sepharose 4B to which dog plasma fibronectin had been coupled. Approximately one half of the salt precipitated collagen was eluted with column buffer (PBS-citrate). 6M urea eluted the remaining collagen with fibronectin-binding properties.

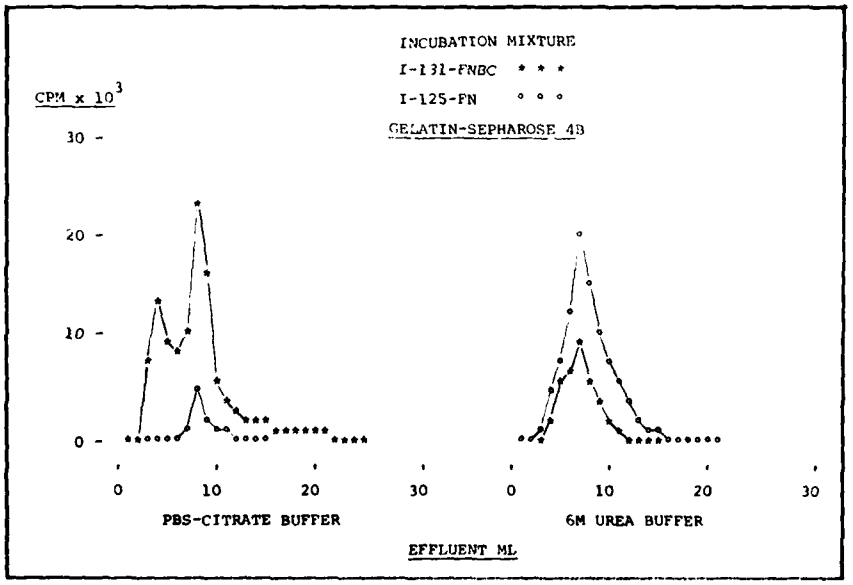

FIGURE 3.
Affinity chromatography with gelatin-sepharose 4B of an incubation mixture containing 50μg I-131-labelled fibronectin-binding collagen (FNBC) and 10μg I-125-labelled fibronectin (FN). The proteins were incubated for one hour at 37 degree C prior to chromatography.

gest. Digestion was stopped after 18 hours by elevation of the digest pH with 3M tris-base, after which type III collagen was precipitated by the addition of NaCl to 1.7 molar. The precipitated collagen was collected by centrifugation (48,000 × g), resuspended in 0.5M HAc, reprecipitated and washed two more times. The final washed precipitate was resuspended in 0.5M HAc, desalted by dialysis versus 0.1 percent HAc and lyophilized. A portion of the lyophilized collagen was solubilized and further purified by affinity chromatography with FN-Sepharose 4B. A collagen affinity chromatogram is plotted in Figure 2 showing the elution with 6M urea of a subpopulation of type III skin collagen with fibronectin-binding properties, comprising roughly one half of the crude salt precipitated preparation.

The formation and composition of complexes were studied with I-125-labelled FN and I-131-labelled fibronectin-binding collagen (FNBC) as follows. Radioiodination was by the chloramine-T method (15). Mixtures of various weight proportions of the labelled proteins were incubated for 1 hour at 37 degrees C and then chromatographed on gelatin-sepharose 4B. Figure 3 is a chromatogram of a mixture containing 50 μg FNCB and 10 μg FN. The plot showed that a portion of the I-125-FN did not bind to gelatin and was eluted with column buffer (PBS-citrate) together with I-131-FNBC. These eluates were presumed to represent complexes in which FN binding sites were totally saturated with FNBC. The urea buffer eluted several fractions containing both radionuclides at differing proportions. These were presumed to contain complexes of partially saturated FN with some sites available for binding to gelatin.

The presumptive complexes were examined by polyacrylamide gel electrophoresis analysis of selected elution fractions containing both I-125 and I-131 activity. Two aliquots each from elution fractions containing both isotopes were electrophoresed on 5 percent phosphate gels, with and without pretreatment with 2 mercaptoethanol (2ME). Thereafter the gels were cut into 2-mm slices and each slice counted for both radionuclide activities.

The results of one such analysis are plotted in Figure 4. The data for the ali-

quot not treated with 2ME show that the highest concentrations of either radionuclide are associated with molecular species greater than 200,000 molecular weight. Pretreatment with 2ME resulted in a decrease of high molecular weight radioactivity and the reappearance of I-125 activity at the molecular weight of FN (200,000). The decrease in I-125 and I-131 activity resulting from 2ME treatment was presumed to represent the disassociation of FN-FNBC complexes. Estimates of FNBC:FN weight ratios were calculated from the differences, due to 2ME, in high molecular weight radioactivity.

The results indicated that complexes eluted with PBS-citrate buffer consisted of from 19 to 23 parts FNBC to 1 part of FN, by weight. Complexes eluted with 6M urea produced a range of proportions from 9 to 0.6 parts FNBC to 1 part FN. Overall, the data showed that regardless of the starting proportions in an incubation mixture, a family of complexes was formed varying in the proportions of the two proteins.

Radiolabelled proteins were also used to determine whether collagen and fibronectin were firmly bound to the polymerized hydrogels. The polymers were prepared in the usual volume proportions of 6 parts hydroxyethyl methacrylate, 0.6 parts ethylene glycol, 0.2 parts each of ammonium persulfate and sodium metabisulfite, and 3 parts protein solution. Sucrose powder, sized from 100–250 micrometers (μm), was added after 10 minutes of initial polymerization and dispersed by vortexing. Fifty mg of sucrose was added per ml of PHEMA formulation.

After polymerization in siliconized glass test tubes was complete, the hydrogels were removed, sliced into several small wedges, counted for radioactivity and then dialyzed for three days versus 200 volumes of saline, with daily changes of dialysate. At the end of dialysis, the wedges and aliquots of the three dialysates were counted. Dissolution of the sucrose by dialysis produced porosity throughout the polymer. The amounts of labelled protein added ranged from 5 to 100μg/ml of hydrogel mixture. The results revealed that regardless of the amounts added, the percent protein retained by the polymer remained constant for each type of protein. The average percents retained were, I-125-FN: 92.5 percent, and I-131-FNBC: 80.7 percent.

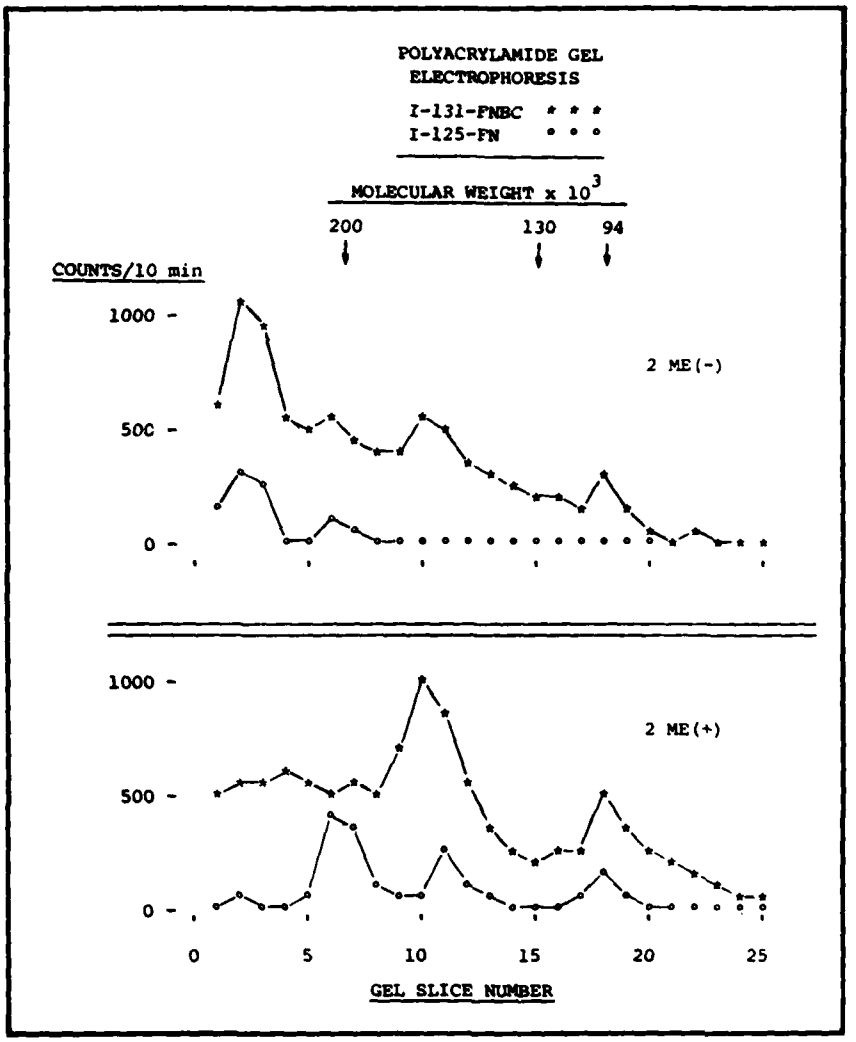

FIGURE 4.
Polyacrylamide gel electrophoresis on 5% phosphate gels of a 6M urea eluate from the affinity chromatogram of Figure 3. The gels were cut into 2mm slices and each slice was counted for 10 minutes. Simultaenously electrophoresed molecular weight standards are indicated. An aliquot of the eluate not pretreated with 2-mercaptoethanol (2ME –) contained a molecular species greater than 200,000 with high count rates of both radionuclides. Pretreatment with mercaptoethanol (2ME +) reduced the high molecular weight associated radioactivity, presumably through disassociation of FN-FNBC complexes. The increase in I-125 activity with 2ME treatment at the molecular weight of FN (200,000) supports this presumption.

Based on the above findings, hydrogels were prepared for in vivo assessment in dog jaws. Porous hydrogels with and without protein were cut into several discs measuring 4 mm in diameter by 2 mm in thickness. These were placed in bone beds prepared as follows. Vertical incisisions were made of the mandibular buccal gingiva and mucosa and full thickness flaps retracted to expose the buccal alveolar bone plate of right and left posterior teeth. Circular beds were prepared with rotary carbide instruments approximately 5 mm inferior to the alveolar crest. The bed dimensions were made comparable to those of the discs to produce a relatively snug fit. The buccal tissues were replaced and the incisions closed with resorbable sutures.

FIGURE 5.
Four micron thick cross-section of a polymer disc (clear area) and its alveolar bone bed. The porous polymer contained no proteins and was encapsulated by a thick layer of fibrovascular connective tissue.

A total of 40 discs were placed in 2 dogs, 20 per dog. During a 2 month period of observation only three discs produced chronic inflammatory responses with fistula formation. Four groups of porous hydrogels were tested, containing the following μg of protein ml of hydrogel:

1. No protein, control.
2. 100 μg FN.
3. 100 μg FNBC.
4. 10 μg FN and 50 μg FNBC, incubated for one hour at 37 degrees C.

The discs were removed after 2 months as follows. Vertical incisions were made as before and the soft tissues were retracted. Teeth within the area were extracted and the interradicular septa removed. Block sections of buccal bone, each containing one disc, were cut, fixed in formalin, decalcified, and prepared for light microscopy.

Figures 5 to 7 are representative micrographs of the specimens. The major observations were:

1. Discs without proteins (Fig. 5) were encapsulated with fibrous connective tissue which separated them from the healing bone bed.

2. Discs with either protein alone (fibronectin, Fig. 6) had little or no inter-

FIGURE 6.
Discs containing either fibronectin alone, as in this figure, or collagen alone, had little or no fibrous connective tissue separating the discs from healing bone beds.

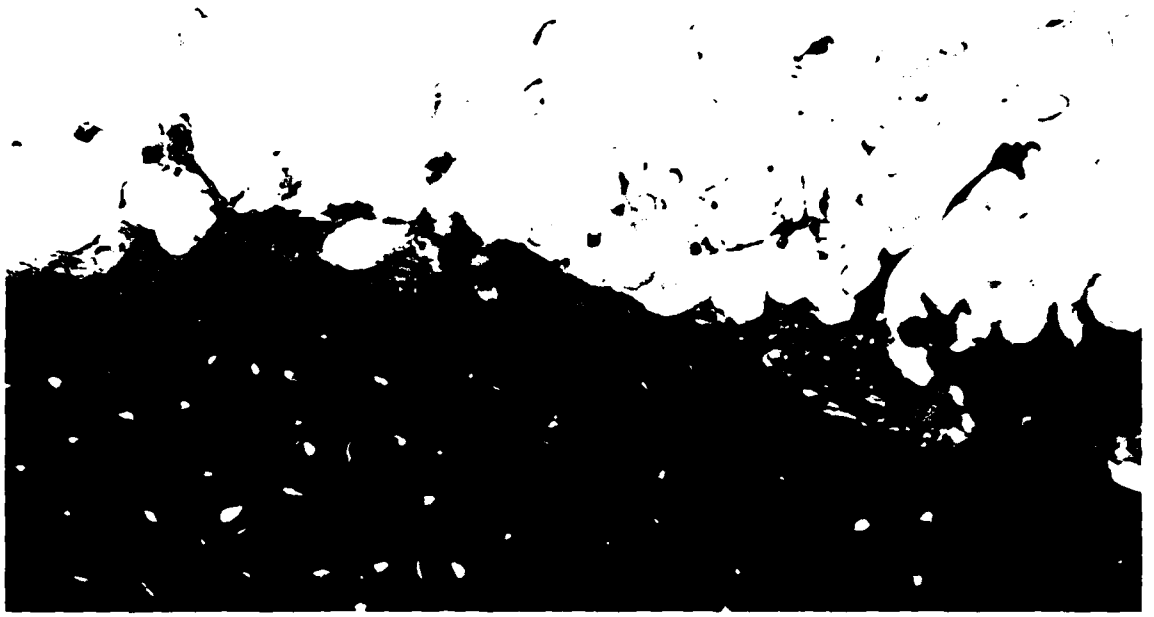

FIGURE 7.
Discs containing incubation mixtures of FN and FNBC contained numerous penetrations of cells and tissues from adjacent healing bone beds.

posed fibrous connective tissue between healing bone and the polymer.

3. Discs with the incubation mixture (Fig. 7) were also without fibrous capsules, but the disc-bone interfaces showed numerous deep penetrations of cellular elements into the polymer.

The results to date support the concept that attachment of a tissue bed to an implanted prosthesis can be obtained through the incorporation of connective tissue proteins whose normal biological function is to provide a substratum for cell attachment. Studies are in progress to test this concept in the form of polymer-coated dental implants inserted in fresh dog molar extraction sites

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Bone Strength: In Vivo Stress and Strain

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MICROMINIATURE STRAIN GAGE PREPARATION, IN VIVO IMPLANTATION, AND IN VITRO MATERIAL PROPERTY EVALUATION

Introduction

During the past 10 years, foil and semiconductor strain gages have been used to analyze the mechanical responses of bone during normal skeletal locomotion, enabling biomechanics researchers to make correlations with simplified static models. Many authors (1,2,3) have described "state of the art" techniques for fabrication, implantation and insulation of foil and semiconductor type strain gages in large experimental animals, but there appear to be no published reports on the use of microminiature strain gages for investigating the in vivo response of small laboratory animals with rapid bone turnover.

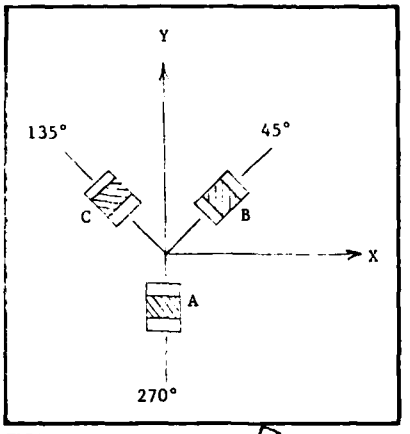


FIGURE 1.
Rosette gage configuration.

This report will present a technique for the preparation of microminiature rosette strain gages that can be installed in laboratory animals as small as 150 grams. One such animal, the rat, has undergone extensive biochemical, histological and metabolic research, but there have been no reports on the mechanical behavior of rat bone in vivo and very little in vitro information is available. Such information is invaluable in assessing the mechanical response of bone, and can provide new insight into the link between changes in the function of bone and bone architecture—the adaptive remodeling response of bone (Wolff's Law).

Gage Description

Male Holtzman albino rats ranging from 150 to 650 grams were instrumented with microminiature three-element 45-degree rosette strain gages (Micro-Measurements EA-06-015RJ-120). The gages were the electrical resistance type consisting of a grid of constantan foil on a thin polyimide backing. Figure 1 shows schematically the configuration of the three-element rosette, which when implanted is oriented so that the abscissa is along the long axis of the bone. Each gage is 120±1% ohms, with a gage factor of 2.00±1%, and self-temperature compensation of 6 ppm/deg F.

The gages were employed in a quarter bridge with excitation from a constant current source. Constant current was used to minimize noise from poor or faulty electrical connections. An excitation voltage of 0.25 volts (2.1 milliamperes) was chosen for each gage element. This excitation level was based on a power density for bone of 0.5 watts/in² and a gage grid area of 0.0003 in². A total of six bridges and current sources enabled recordings from six single gages or two rosette gages. The constant-current source and bridge circuitry for one channel are shown in Figure 2.

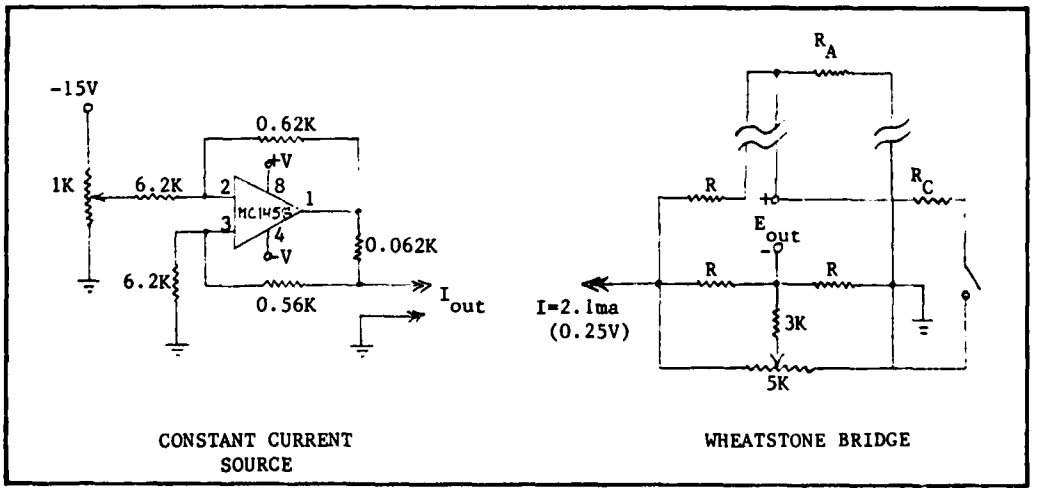


FIGURE 2.
Circuit diagrams of constant current source (left) and Wheatstone bridge (right). Circuitry at left supplies 0 to 20 milliamps excitation. Circuitry at right consists of three precision (0.02%) resistors (R) and a gage or active resistor (R_A) forming a full bridge. Note that a three lead-wire system is used to compensate for differences in pathway resistance. Resistor, R_C, provides a known strain level for calibration, while the 5K potentiometer initially balances the bridge.

Gage Preparation

The gage units were constructed using 38-gage polytetrafluorethylene (PTFE) insulated lead wires soldered directly to the grid solder tabs. Strain relief tabs at the gage were not used owing to the small size of the gage and implantation site. Waterproofing and mechanical protection were achieved by applying a thin base coat of toluene-thinned acrylic (Micro-Measurements, M-Coat D) followed by a coating of polysulfide/epoxy waterproofing compound (Micro-Measurements, M-Coat G). A 2.5 mm section of the lead wires was also potted using the Type G coating. The gage unit was then trimmed resulting in a prefabricated, encapsulated, wired unit with a maximum overall area of 10 mm^2 (2.5 × 4.0 mm) and overall thickness of 0.5 mm. A miniature multipin connector (Amphenol, 222–11N07) interfaced with a three-wire resistance compensation system to the Wheatstone bridge. Figure 3 shows the completed gage unit with attached lead wires, connector, and jacket support.

Surgical Implantation

Femurs of anesthesized rats were exposed and then isolated with cotton-tipped wood applicators. The exposed bone surface was scraped free of periosteum and alternately degreased-dryed with xylene-cotton tipped applicators until a clean dry surface was obtained. After neutralizing the surface with ammonium solution and drying, the gage was introduced subcutaneously from the dorsum to the bone site and methyl 2-cyanoacrylate (Permabond 101) was applied to the back of the gage (Fig. 4). A pre-shaped implement that contoured to the bone surface was then used to bond the gage to the bone. The portion of the lead wires encapsulated with M-Coat G was bonded to the bone in a similar fashion (Fig. 5). The gage and a portion of the surrounding bone was then covered with a very thin layer of fast-drying epoxy for additional mechanical and electrical insulation. A loop was introduced in the lead wires and sutured into the subcutaneous tissue for added stress relief (Fig. 6). The wound was then sutured closed and the plug assembly taped to the rat's back (Fig. 7).

Verification of Strain Gage Readings

During the course of development of this technique, 18 healthy male rats were instrumented. Following a recovery period of 4 to 6 days, the in vivo strains of the rats were recorded during normal locomotion on exercising wheels.

At sacrifice, the gages were visually examined for insulation failure and/or debonding and both femurs were removed. Of the 18 instrumented rats, in vivo recordings were obtained from all but 4 rats that had chewed off their jackets before recordings could be made. In every case, however, visual examination confirmed insulation and gage adhesion integrity. Two rats were kept instrumented until debonding occurred (as evidenced by erratic readings) and the gages were found to give good readings for 12 days.

In order to quantitatively assess the in vivo performance of the gages, in vitro tests were performed on three freshly excised rat femurs. The proximal end of each bone was embedded in methyl methacrylate and securely anchored. To the free or distal end a series of static loads were attached and recordings made of each of the three gages (Fig. 8). The original gage was then removed, with care taken to mark its exact location, and a new gage was installed in exactly the same manner as the original gage. The replacement gages agreed closely (6–10%) with the original gages.

Material Property Evaluation

In vitro static, non-failure cantilever beam and dynamic failure torsion tests were performed on eight freshly excised femurs from health "normal" rats ranging in age from 43 days to 122 days (166 to 490 grams). With respect to the cantilever beam tests, the proximal end of each bone was embedded in methyl methacrylate and anchored and loaded as in the procedure for gage verification described previously (Fig. 8). For these experiments the gage was bonded to the anterior or tensile surface of the bone. A simple state of stress was assumed and the axial Modulus of Elasticity (E_{xx}) was determined by the following equation:

$$E_{xx} = \frac{WLd}{I_{xx}\epsilon_{xx}}, \text{ where}$$

W is the load in Newtons,
L is the distance from the load to the center of the gage in meters,
d is the distance from the bone surface to the centroid in meters,
I_{xx} is the moment of inertia about the X-axis in m^4, and
ϵ_{xx} is the axial strain from the gage readings.

Several different loads (W) were used and the slope of the plot of W vs. ϵ_{xx} was calculated using a linear regression by the least squares method. These tests yielded values for the axial modulus of 15.3 GPa (43 days) to 32.6 GPa (122 days) or an overall mean of 26.8±7.7 GPa. In addition, an average value of 0.41±0.11 for Poisson's ratio (transverse strain/axial strain) was obtained.

A torsion device developed by Burstein and Frankel (5) and shown schematically in Figure 9 was used to calculate the shear modulus, G. In this case both ends of the rat femur were potted in methyl methacrylate and the bone then held by the small grips (F and H) shown in Figure 9. A rosette strain gage was bonded to the center of the unpotted portion of the femur in order to record the strain of failure. A typical torque (T) vs. angle of twist (θ) curve is shown in Figure 10. Based on the formula:

$$T = GK\theta \text{ where}$$

G is the shear modulus in Newtons/m^2,
K is a property of the bone cross-section in m^4, and
θ is the maximum angle of twist per unit length in radians/m,

the following information was determined. Shear modulus ranged from 1.1 GPa (69 days) to 3.3 GPa (122 days) or an overall mean of 2.5±0.8 GPa. Furthermore, the in vivo shear strain ($\gamma_{xy} = 500\mu\epsilon$) was 6.5% of the shear strain at failure for 74-day-old rats in contrast to 3.4% for 122-day-old rats. These results indicate that the mechanical properties of rat bone vary with age and/or maturity and hence remodeling is occurring. The trend is toward an increase in strength as evident by both mechanical properties and in vivo shear strain vs. in vitro shear strain at failure.

Discussion

In vivo recordings for a typical rat are shown in Figure 11 along with the cor-

FIGURE 3.
Micro-miniature rosette strain gage unit. Gage with attached lead wires interface to recording apparatus via miniature multi-pin connector. Connector is protected by syringe container, both of which are bonded to moldable expanded polyethylene jacket support to provide strain relief for wires.

responding axial (ϵ_{xx}), transverse (ϵ_{yy}), and shear (γ_{xy}) strains. Axial strain magnitudes of 250–300 microstrain ($\mu\epsilon$) were characteristic of most of the recordings. This strain level is in agreement with other authors (1,4). The techniques presented in this paper, however, differ somewhat from classical strain gage preparation and implantation as reported by (1,2,3). Some changes resulted from the miniature nature of the gage unit and test animal, but others such as the final epoxy insulation are unique. Basically, though, a strain gage unit for in vivo implantation should meet the following requirements: (i) durability (mechanical, chemical and electrical), (ii) size—small enough to permit placement on the bone surface of at least three gages or one rosette, and (iii) sterilizability (autoclave or gas).

In vitro mechanical testing can evaluate material properties of bone using relatively simple models, although in the future more complex models will be used to fully characterize rat bone with respect to properties in all directions, since bone is really an anisotropic material. Average or mean values for Modulus of Elasticity and Shear Modulus should be limited to groups of rats of similar age and maturity, since the material properties of the bone change significantly with time. Average values or

FIGURE 4.
Left femur of rat exposed, isolated, and cleaned; gage ready for implantation.

FIGURE 5.
Gage bonded to anterolateral surface of rat femur.

FIGURE 6.
Close-up of implantation site with fast drying epoxy encapsulation.

magnitudes, however, are useful in comparing rat-bone material properties with other animal models as well as with humans, and therefore have been included in this report. Mechanical testing techniques such as those presented in this report, used to investigate the physiological and pathological actions of vitamins and hormones on skeletal tissue, will prove invaluable in assessing bone remodeling and bone disease. Experiments of this nature are currently under investigation, as well as histological studies.

Conclusions

Micro-miniature rosette strain gages are available that can be fabricated into units capable of in vivo implantation on very small test animals. These units are rugged and permitted strain recordings for up to 12 days. Other authors (1,2,3) have reported obtaining readings for 3 to 5 weeks, but were not dealing with an animal model with rapid bone turnover such as the rat. Experimental stress analysis techniques applied in vivo represent a step forward for the biomechanics researcher, who until recently was limited to in vitro studies of bone behavior. In vitro mechanical testing,

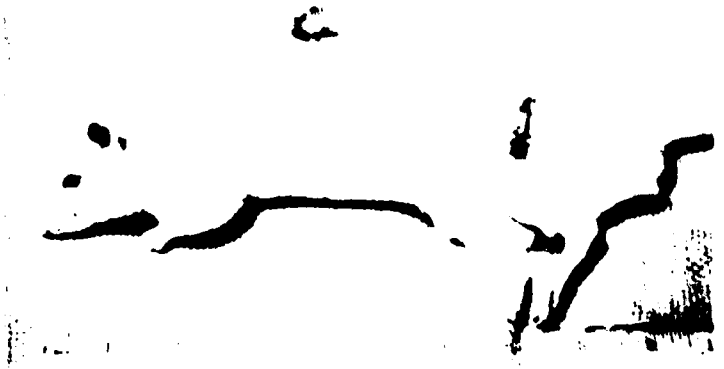
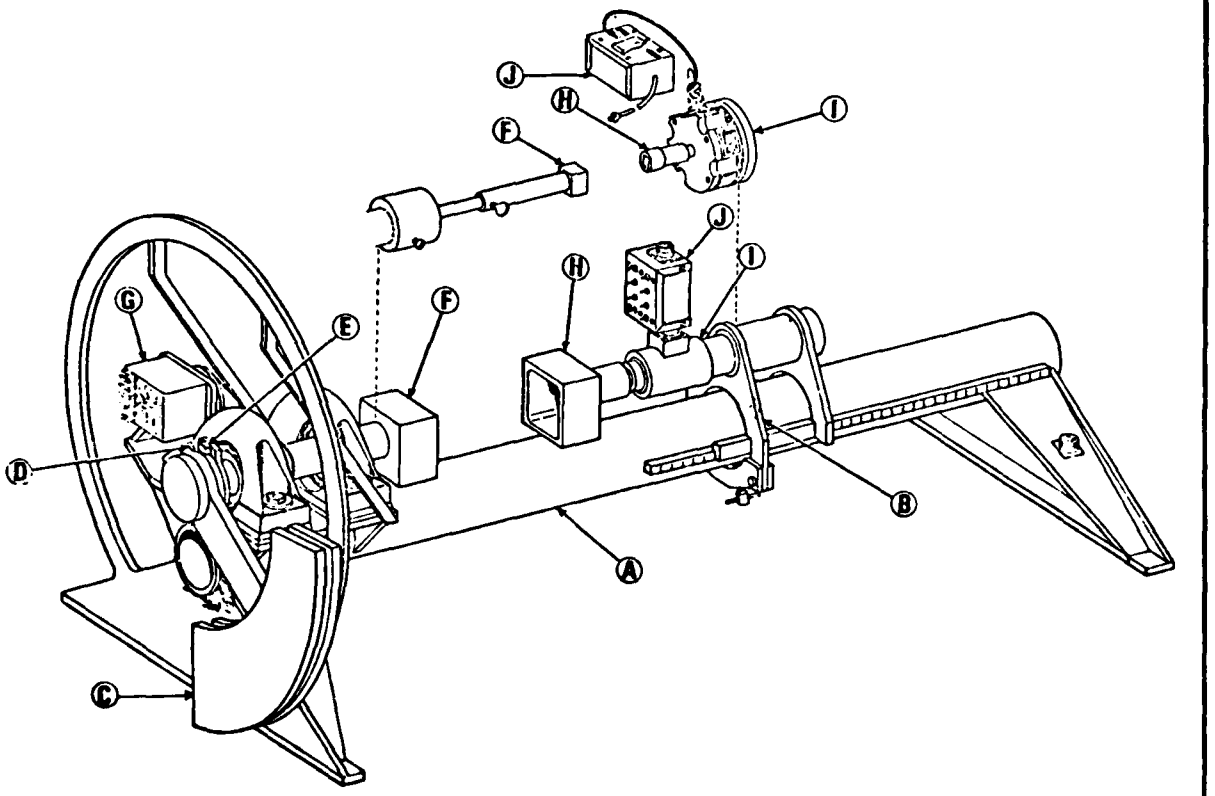


FIGURE 7.
Gage installation complete; plug assembly secured to rat; wound sutured closed and coated with sterile surgical dressing.



The components of a Standard Torsion Testing machine are: A. Frame; B. Tail stock; C. Pendulum; D. Dog clutch in pendulum; E. Dog clutch on rotating shaft; F.* Rotating grips; G. Angular deformation transducer; H.* Stationary grips; I.* Torque transducers; J.* Self calibration system;. *Two sizes shown.

FIGURE 9.

however, is an important aspect of bone biomechanics research, but should be interpreted carefully. In addition, using rats as a model could prove invaluable in assessing the factors responsible for bone remodeling and bone disease, since the biochemical, histological, morphological and metabolic information on rats is extremely well documented.

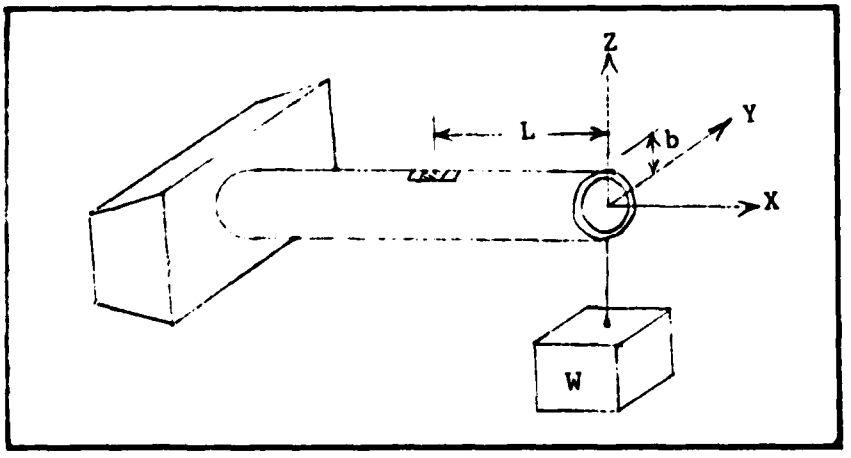


FIGURE 8.
Loading geometry for gage function verification and cantilever beam tests, with bone represented as a hollow elliptical tube.

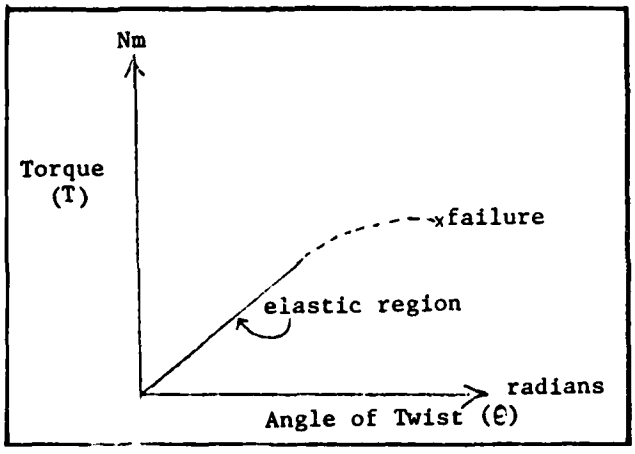


FIGURE 10.
Torque (ordinate) vs. Angle of Twist (abscissa) for a typical normal rat femur obtained from the loading device illustrated in Figure 10.

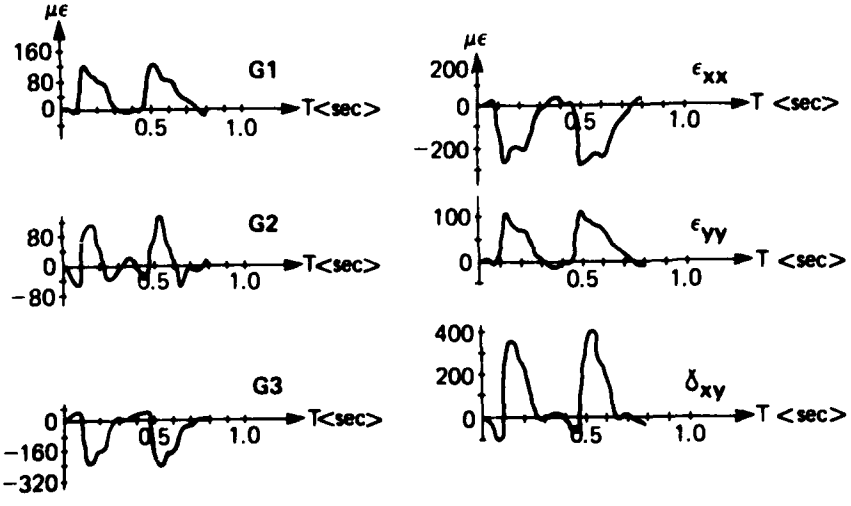


FIGURE 11.
In vivo strain recordings from gages A, B, and C and corresponding axial (ϵ_{xx}), transverse (ϵ_{yy}), and shear (γ_{xy}) strains for two gait cycles.

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In Vivo Loading of Knee Joint Replacements

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Background

Since our previous report, work has proceeded well in the two required areas: the development of a suitable mechanical telemeterizable total-knee joint, and the development of the necessary telemetry electronics. Although, as in any applied research project, many unanticipated problems have arisen in the course of this development, no insurmountable problems have been encountered.

Mechanical Development

As previously reported, it is the goal of this project to instrument the tibial portion of a total knee joint replacement to determine the loads and forces borne by such devices in-vivo. The commercial design chosen as the basis for our development is the total condylar total knee joint replacement. Development of such a device allows standard femoral components to be employed, and the entire telemeterized total knee assembly can be installed using standard clinical surgical procedures. That is, our goal is to reproduce as closely as possible the overall geometry of commercially available total condylar total knee joints systems. An exploded view of our basic instrumented tibial design is again shown in Figure 1 for reference.

With the exception of the actual plateau assembly, the entire device is fabricated using 6 Aluminum – 4 Vanadium extra-low iron (ELI) titanium alloy, and fabricated in the University's precision machine shop. The tibial plateau articulating surface is a standard ultra-high-molecular-weight polyethylene tibia plateau, which is machined for us by Howmedica Corp. from their standard tibial component blanks. Therefore, when implanted this device will be mated with a standard Howmedica femoral component.

Load Cell Design—Reference to Figure 1 shows that the actual load path in

this design is from the tibia plateau through the plateau tray, then through the load cell which resolves the three forces and three moments. In order to resolve all force and moment components with seven data channels, the tray is pinned to only two arms of the load cell. On the other two arms it rests on titanium stems with polyethylene film interfaces. The pins are pressfit into the arms of the load cell. The tray is placed on top and then electron-beam (EB) welded to the pins. The load cell, in turn, is attached to the housing by means of a central stud which is passed through the housing and then also EB welded. Because of this load path, the stems of the pins inserted into the load-cell arms are subjected to bending moments which are difficult to specify for the purposes of analysis. Furthermore, as the beams with the welded pins undergo bending, they try to warp the floor of the tray locally. This loading induces a stress state which is very difficult to predict theoretically.

Because of the inability to define completely the constraints and loading on the ends of the pins that are inserted into the beams, classical beam analysis was accepted as being inadequate, but at least it provided a starting point for the design. This analysis predicted that there would not be any problems from fatigue due to bending. This was substantiated by subsequent axisymmetric finite element analysis. Fatigue testing of the assembled unit has shown that compressive loading of the assembled implant should result in no failures of the pins. Classical analysis also indicates that there should be no failures in fatigue due to shear loads on the implant, especially at the load range that we expect to encounter in the knee. However, fatigue testing in pure shear, or pure shear combined with compression, have not been performed to date. Although it is our belief that the shear loading on the pins (induced by bending deformation in both the load cell beams and tray due to compression loading) is a sufficient test of the pin strength in fatigue, we plan to perform a number of fatigue tests which emphasize the effects of shear loads. Our laboratory has a Model 1230 Instron Dynamic Test Machine which is capable of producing the desired compressive and shear loads at any frequency up to 100 cycles per second.

Mechanical Testing—The fatigue testing that was performed on the implant was carried out with a load that varied in magnitude from 100 to 900 lbs. in compression at a frequency of 65 cycles per second. We had set a limit of five million cycles as an acceptable life in fatigue at those loads. This criterion is somewhat harsh, since the 900 lb. maximum limit is six times the body weight of an average male. Fatigue testing of the implants has shown that the pins, load cells and housing would withstand this five million cycle limit. However, the tray was developing a small fracture in the wall section in the region of the pin at or just slightly beyond the five million cycle limit. To find the solution to this problem, a series of tests were conducted where 4 different pin collar profiles were used in 2 different diameters with 2 trays of different floor thicknesses, which led to a total of 16 possible combinations. Each tray had rosette strain gages located over the areas where the fractures had been occurring. They were loaded to their maximum level and the strains recorded. The results of these tests indicated that by increasing the floor thickness of the tray and using a slightly different collar profile than had been originally used, stresses could be reduced by a factor of two in the regions where the fractures had occurred originally.

The next best possible combination was to keep the same floor thickness as originally used and increase the collar diameter by .075 inches. This, likewise, reduced the stresses by almost a factor of two. A subsequent finite element analysis also showed very comparable results and predicted that there should be no fatigue failures in the trays in the regions of the walls where they had been occurring. At the conclusion of these tests, a new tray design was fabricated. A series of fatigue tests were run on the revised implant and it succeeded in surviving more than 11.7 million cycles before the test was concluded. Although this was in excess of our criterion of five million cycles for an acceptable implant, it was decided to see if any fractures could be produced in either the tray, the pins or the load cell. At the 11.7 million mark the test was concluded and a careful examination of these three critical components showed no signs of excessive wear or any microfractures.

This last implant prototype subjected to fatigue testing was uninstrumented except that a fully wired load cell was used. At the end of the test there was no indication that any of the strain gauges had debonded from the titanium substrate or had failed from fatigue. The current plans for further testing include the shear fatigue test previously mentioned, as well as taking a fully instrumented telemetering implant prototype and installing it in a knee simulator to which we have recently obtained access. By means of this knee simulator, known loads in compression and shear in both the AP and lateral directions, as well as axial torques, can be applied at any level desired. The output from the device will be reduced using the full data acquisition system and then compared with the known simulator inputs for accuracy.

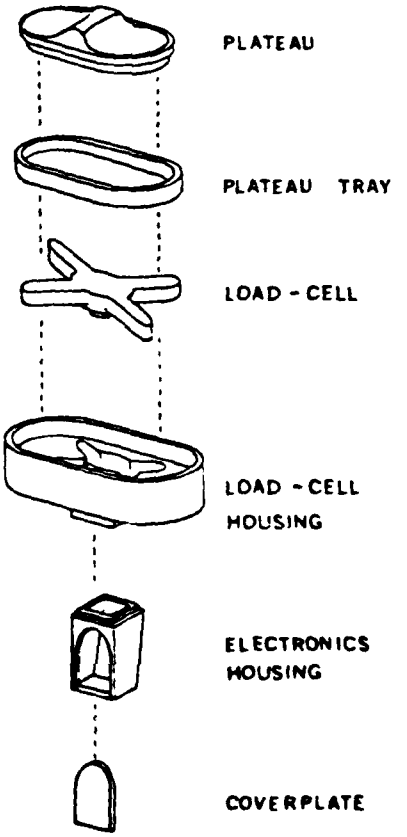

FIGURE 1.
Exploded view of telemeterizable total knee tibial system

Telemetry Development

Strain Gage Bonding—One of the unanticipated technical problems that has arisen relative to this project was the

difficulty associated with getting a good strong bond between the strain gages and the titanium. Because the titanium oxide formed so rapidly on any processed implant, we found it was not possible, using standard techniques, to reliably bond the strain gages to the titanium load cell. Therefore, a new technique for bonding strain gages to 6-4 ELI titanium was developed in our laboratory in conjunction with the Lord Corp. to improve the bonding reliability of the strain gages to this metal by eliminating the titanium oxide coating prior to bonding. The technique utilizes a special etching protocol, then a pre-treatment with a biocompatible conditioner (Chemlock 205) from Hughson Chemical Division of Lord Corp., which is then set after the gages are mounted. Use of this procedure has resulted in much better strain gage bonding and should prevent any problem in this area.

The steps in this procedure start with the machined part receiving a sandblasting. This is followed by a methyl ethyl ketone (MEK) ultrasonic 3-bath cleaning, followed by 10 minutes at 77 deg C in a mild alkaline solution, with stir agitation. After a water rinse, the MEK 3-bath ultrasonic cleaning is repeated, followed by an acid etch for 2 minutes at 45 deg C, with stir agitation. After a water rinse, the part is blown with dry air and when dry is given a spray-on coat of Chemloc 205.

Transmitter Circuitry—During the previous project period, two separate telemetry circuits (a single and a dual transmitter version) suitable for incorporation in the stem of this device have been assembled and tested. To insure against the possibility of intermodulation due to the housing of two separate micro-transmitters in the same stem, a series of laboratory tests were performed. These tests consisted of physically encapsulating two separate microtransmitters with associated subcarriers into the actual stem geometry and receiving and analyzing the output from each on a Tektronix spectrum analyzer. Results showed no difference between a received pattern from a single transmitter or from that same transmitter when a second transmitter was active in the same housing. While the single transmitter version is lower in power, it employs more tightly spaced information channels. In contrast, the dual transmitter version, although consuming slightly more power, allows for greater channel separation and, therefore, greater sensitivity per channel. For this reason, our current plan is to use the dual transmitter version, since the increased current drain is acceptable for the batteries now used and the possibility of using some of the new high-energy density batteries would more than compensate for the power loss with this version.

Telemetry Reception—As part of this evaluation, two McIntosh Laboratories FM tuners were aligned, matched and tested in our laboratory and found to be in agreement within plus or minus 1 db over the full range of frequencies projected for use in this project. These tuners are utilized because they have a fixed-gain output which emanates prior to the standard stereo de-emphasis circuitry found in all modern FM tuners. This capability is essential, since the de-emphasis circuitry would, of itself, serve to decrease the received signal as a function of the subcarrier frequencies. It was these matched tuners that were utilized in conducting the above dual transmitter tests.

Also, as part of this telemetry receiver evaluation, the fidelity of the tape recorder (Technics Model 1500) being utilized in this project was analyzed. To this end, a number of record/playback tests were conducted at different frequencies using different types of recording tapes. As a result of this testing and evaluation, it was found that adequate fidelity and accuracy (tape drop-out and distortion due to flutter, wow, and tape tension) could only be guaranteed if the dual-channel tape system was aligned specifically to a high-quality instrumentation-grade tape on precision reels. Therefore, the tape system that is currently committed to this project has been aligned by an audio laboratory in Cleveland and matched to 3M-301 instrumentation tape. As a result of this procedure, the tape recorder is now capable of accurately recording the output of the dual McIntoshes without any perceptable loss in sensitivity.

Telemetry Demodulation—Since early in the project, when the very real possibility of having to utilize a single transmitter to broadcast all seven channels of data from the implant had to be considered, it was decided that a demodulator system based on the utilization of phaselock loop techniques would give the best possible channel separation. For this reason, a major portion of the electronic development in the early project period was devoted to developing the necessary phaselock loop demodulators. While these original demodulators were found to work reliably under the controlled conditions of the laboratory, they were also found to have a significant temperature instability compensation problem when moved from location to location. This was primarily due to our inability, in the early stages of the project, to obtain commercially a stable voltage-controlled oscillator which not only covered the audio range of our subcarriers, but also supplied the highly accurate quadrature output required for good phaselock loop AM demodulation. As a result, the original design utilized a heterodyning technique and a hybrid voltage-controlled oscillator circuit operating an order of magnitude higher than the subcarrier frequencies. Empirical analysis of the operational circuit showed that this heterodyning technique, although theoretically sound, tended to amplify any thermal non-linearities in the circuitry.

For this reason, commercial manufacturers were again queried, and a suitable low-frequency, high-precision voltage-controlled oscillator (VCO) with quadrature output was found to be on the market now at a reasonable cost. The demodulation circuitry has since been re-designed, based on this new VCO. With the use of this new voltage-controlled oscillator circuitry and its associated balanced multipliers, the required phaselock loop now operates in the same frequency range as the subcarriers, allowing direct lock onto the desired channel. It also allows for more accurate alignment of the tuning range of the individual demodulating units. In fact, this new design also has the additional bonus of increasing the overall reliability of the demodulation system because it actually results in fewer components necessary for implementation of the circuitry. Re-design of this system also greatly improved its ability to track the individual subcarrier channels over a much wider range.

Telemetry Packaging—As can be seen from Figure 1, the implant contains a

stem of standard external geometry which is in fact a hollow cavity accessible through a mating dovetailed sliding coverplate. It is this compartment which contains the actual energy cells and microcircuitry necessary to telemeter out the loading data.

Since our assembly protocol calls for pre-sterilization of the electronic circuitry prior to final assembly, our first investigation concerned itself with the effect of ethylene oxide sterilization on the microcircuitry components. To this end, a microcircuit consisting of an FM transmitter, three subcarrier oscillators, and a set of energy cells was assembled and tested in our laboratory. This initial testing documented the basic transmission parameters of subcarrier amplitude, center frequency and spectral purity as analyzed on a spectrum analyzer, the transmitter sensitivity and transmitter center carrier frequency, as well as the transmitter's signal strength. Following this test, the microcircuitry was then double wrapped and sent over for standard gas sterilization at University Hospitals. The circuitry was then retested in the laboratory. As a result of this testing, it was determined that the temperatures and gas utilized in the sterilization procedure did indeed have a slight effect on almost all the above-mentioned circuit parameters. Therefore, following the second documented test, the circuitry was again sent to the hospital for a second sterilization. Following this second sterilization, retesting demonstrated that no further changes had occurred from the parameters documented following the first sterilization. For this reason, prior to final setting of the implant microcircuitry parameters, all associated components are first cycled through a gas sterilization procedure at least once. However, similar testing of the strain gages utilized on the load cell showed them to be essentially impervious to any effects of the sterilization procedure.

Summary

As stated previously, we currently anticipate no insurmountable technical problems in the successful completion of this project. The required telemetry capability is fully developed and tested. The basic mechanical design has also been extensively tested and shown to meet the mechanical requirements for a fully functioning total knee joint replacement. The only remaining aspect of this project currently under development is the finalization of the packaging of the whole implant system. This aspect of the project is being given considerable attention, since implantation of a total joint replacement gives long-term biocompatibility a whole new meaning. That is, anything that is implanted as a total joint replacement must be considered a permanent implantation. Therefore, the packaging and sealing techniques utilized in this device must be adequate to function for the anticipated long-term period.

Orthopaedic Implant Device Retrieval and Analysis

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This report covers the period 1 January 1981 through 30 June 1981. Two aspects of our retrieval and analysis effort dealing with total knee replacements are being reported.

The first aspect is the results of a surgeon survey, conducted in Louisiana, to provide more specific information concerning the selection and use of total knee arthroplasty.

The second aspect is the results of a continuing followup study of the polycentric knee arthroplasty.

Surgeon Survey

Purpose—The survey of orthopaedic surgeons in Louisiana was conducted in order to determine both the type and frequency of total-knee prostheses currently being inserted. It was further intended that this survey would examine the sentiments of practicing surgeons toward this procedure and possibly identify any common problems being encountered.

Method—A list of orthopaedic surgeons in Louisiana was compiled, using records obtained from the Louisiana Orthopaedic Society supplemented with a check of the telephone directories of the seven largest metropolitan areas of the state. A total of 159 orthopaedic surgeons were identified as practicing in Louisiana, and each was mailed a questionnaire in July of 1979. In December 1979, a revised questionnaire was prepared, which could be completed more easily, and those surgeons not replying to the initial mailing were contacted a second time. The requested information included the number of total knee replacement procedures performed, the types or designs of prostheses for total knee replacement (TKR) utilized, designs which had been abandoned, and comments about TKR.

Results—31 replies to the initial questionnaire and 48 replies to the second questionnaire were received for a final response rate of 50 percent. Of the surgeons who replied, 48 (61 percent) stated that they were currently using total knee arthroplasty as a treatment for rheumatoid and degenerative arthritis. These 48 surgeons claimed a total annual insertion of 487 devices.

In Table 1, the different designs of total knee prostheses have been characterized by their frequency of insertion according to the replying surgeons. Clearly,

TABLE 1.
Number of Each Total Knee Design Being Inserted in Louisiana in 1979.

Device	No. Surgeons* Using Each Device	Total No. Used Annually
Total condylar	35	302
UCI	11	59
Noiles	8	48
Townley Anatomical	5	21
Marmor Modular	2	19
GUEPAR	7	16
Polycentric	1	8
Stabilo-Condylar	2	6
Spherocentric	3	5
Cruciate condylar	1	1
Gustillo	1	1
Zimmer Offset Hinge	1	1
Annual Total		487

*Number of surgeons does not total to 79 because some surgeons do not perform total knee arthroplasty and some surgeons use more than one design.

the total condylar design has been most frequently inserted by this group, with 62 percent of all insertions and 73 percent of the replying surgeons who performed total knee arthroplasty using this design.

Also included in the questionnaire was a request for information concerning the reason why a particular device was chosen. The result clearly illustrated that the surgeon considered the design to be the most important. Other criteria noted as important were a device's usefulness in varied diagnoses, instrumentation associated with the prosthesis, availability, and finally previous training with a specific device (Table 2). The number of total-knee replacements performed each year per surgeon ranged from one to forty, with the average being ten.

TABLE 2.
Selection criteria used by Louisiana orthopaedic surgeons in choosing a prosthesis

Criterion	Number Noting
Design of prosthesis	12
Usefulness in varied diagnosis	9
Instrumentation	7
Availability of the device	6
Received specific training	4

The responses concerning devices no longer utilized by a surgeon, and the reasons for changing, were also investigated. The reason most often noted referred to the design of the prosthesis. Several surgeons noted that a newer design appeared to offer an advantage over an earlier design. Complaints concerning particular devices appeared consistent with those reported in the literature, such as the inadequate range of motion with a Geometric (1), and the loosening and disintegration of the UCI tibial component (2). Individual Louisiana orthopaedic surgeons also reported discontinuing use of the GUEPAR, ICLH, Noiles, total condylar, and the cruciate condylar prostheses.

Discussion

For the reporting year 1979, the survey revealed a general lack of enthusiasm with total-knee prostheses among Louisiana orthopaedic surgeons. Although several surgeons expressed apparent satisfaction with the knee arthroplasty, most did not. Several commented that they discouraged total-knee arthroplasty for fear of "disaster," while three surgeons noted that they had ceased using the procedure entirely. These reactions are very similar to the sense of dissatisfaction noted by Hori (3) in his study of orthopaedic surgeons at the major joint centers in Illinois in 1976. Hori further inquired as to how many additional patients would have been treated with TKR if reliable designs were available and found that an additional 60 percent more procedures would probably have been performed if a better system had been available.

On the basis of the 50 reply rate, it is possible to estimate that the total number of knee prostheses inserted in Louisiana in 1979 was between 489 and 987. The lower of these figures would apply where none of those surgeons who did not reply inserted any total knees, while the higher figure would apply if the surgeons who did reply were fully representative of the whole—obviously, a situation somewhere between the two extremes may be expected. In order to examine the validity of the survey, all of the manufacturers of these devices were contacted to obtain their sales data in Louisiana in 1979 for both total condylar and other designs. These figures indicate that the sales of all total-knee prostheses were 610, of which 306 (50 percent) were total condylar designs. These figures for total sales are in broad agreement with the survey. While the somewhat low percentage of total condylar knees is surprising, this may reflect an over-generalized use of the term by the replying orthopaedic surgeons.

If the 609 figure for the manufacturers' sales is accepted as accurate and complete, then it becomes possible to estimate more accurately the overall usage of total knee arthroplasty. If the 79 surgeons who replied are inserting 489 protheses, then those 80 surgeons who did not reply should be inserting only 121 prostheses. This lowers the average number of insertions per surgeon from the figure of 10 (per surgeon replying and inserting) to 3 (per surgeon in the state)—while implying that a large percentage of all insertions are being performed by a comparatively small number of orthopaedic surgeons.

It would be of great interest to compare these findings with a similar study for total hip prostheses if one were available; certainly a more even distribution of insertions would be expected. It is intended, however, that a similar study be conducted in future years for total knee prosthesis in order to examine any changes which occur with time.

Polycentric Total-Knee Arthroplasty Followup

Purpose—A continuing followup of the polycentric knee affords the longest experience of any non-constrained total knee replacement. In this particular study, a maximum followup period of 93 months was available, with more than one-half of the 56 devices in use for at least 48 months. Although the polycentric total knee is no longer widely used, continuing accumulation of long-term results of its application provides valuable information in the continuing development of a more reliable arthroplasty.

Methods—A questionnaire containing 103 items regarding the preoperative, operative, and immediate postoperative condition of each patient was completed (Table 3). Each patient was contacted, those available were examined, and a form (Table 4) was completed describing each patient's current condition. The questionnaire and followup data form, Tables 3 and 4, are not shown; the two tables which occupy seven pages are available on request to Dr. Weinstein or to this publication. If the patient was not available for re-examination, the followup data form was completed from records of the latest available examination. A thorough radiographic analysis was performed regarding device placement, wire marker migration, and evidence of device settling for all radiographs available throughout the period of implantation, along with weightbearing anterior-posterior and lateral views taken at the time of the followup visit.

In order to define the outcome for the patient population, two knee rating scales were utilized. The first was the modified Larson Knee Score (4) (Table 5) which is a complex, multiple entry rating scale with a 0 to 100 point range of scores. The second was a simpler function rating scale, Table 6 (5) in which the

TABLE 5.
Modified Larson Knee Score

Function (40 points)		Anatomy (10 points)	
Limp:			
none	12	**Genu Valgum or varum:**	
slight	8	0-10	4
moderate	6	10-25	2
severe	2	over 25	0
not walking	0	**Flexion contracture:**	
Support:		none	2
none	12	over 10	0
cane, occas.	8	**Patellar abnormality:**	
cane, always	6	none	1
crutch	4	lateral pos	0
2 canes	1	high riding	0
2 crutches	1	inc. mobility	0
not walking	0		
Distance walked:		**Swelling:**	
unlimited	12	none	3
6 blocks	8	slight	2
2-3 blocks	6	moderate	1
indoors only	2	marked	0
bed, chair	0	**Pain (40 points)**	
Stairs:		none	40
normally	4	slight	35
use bannister	2	mild	25
any method	1	moderate	20
not able	0	severe	10
		disabled	0

Range of motion (10 points)
0 to 45 degrees
Deduct 1 for each 10 of loss. Max. 5 points.
45 to 90 degrees
Deduct 1 for each 15 of loss. Max. 3 points.
90 to 130 degrees
Deduct 1 for each 20 of loss. Max. 2 points.

TABLE 6.
Simplified point system for assessment of function

		Points
Pain	None	50
	Mild	40
	Moderate	15
	Severe	0
Walking ability	Outdoors, 30+ minutes	20
	Outdoors, 0-30 minutes	15
	Indoors	5
	Unable	0
Range of movement	80 +	30
	60-79	20
	30-59	5
	0-29	0
Acceptable Function	Pain	40-50
	Walking	15-20
	Movement	30
If acceptable in all 3 Add 10		

TABLE 7.
Summary of patients

Patients Reviewed	51
Total number of knees	56
Age	mean: 58 years (range: 41–81)
Males	46
Females	3
Weight	mean: 178 pounds (range: 128–260)
Diagnosis	
Rheumatoid	9
Osteoarthritis	32
Post-Traumatic	14
Other	1
Followup	mean: 50 months. (range: 0–93)

TABLE 8.
Operative data

Tourniquet Time	1.5-2.0 hours	(range: 1 to 4)
Blood Loss	150 cc.	(range 100 to 500)
Hospital Stay	23 days	(range 7 to 60)
Healing Time	2 weeks	(range 1 to 6)

Operative Occurrences

Procedure	No. of Patients	% of Population
Patellectomy	0	0
Medial Facetectomy	5	9.6
Lateral Facetectomy	7	13.5
Patellar Shaving	11	21.2
Osteotomy of Posterior Femoral Condyle	26	50.0

Early Complications

Intraoperative deaths	0
Pulmonary embolism	1
Myocardial Infarction	1
Delayed wound healing	1
Infection	0

individual was evaluated using only three parameters. A bonus was provided if an individual were acceptable for all three measurements. The simplified rating scheme has a range of values from 0 to 110.

Overall evaluation to determine the success rate for the arthroplasty utilized the simplified rating scheme and the degree of satisfaction as reported by the patient during the interview. Additionally, any individual who underwent reoperation was classified as a failure.

Anterior-posterior radiographs from patients in the study were subjected to a more detailed analysis than called for in the general study, in order to determine the degree and significance of any settling that had occurred. Only the tibial components were evaluated in this manner, with the lateral and medial components studied separately.

Radiographs of an individual were examined in the following manner (Fig. 1):

1. A line (L1) was drawn determined to be the joint line using bone tissue not removed by the procedure as the landmark.
2. Another line parallel to L1 was drawn tangent to the most distal region of the bone cement for the medial component (L2).
3. A similar line was drawn for the lateral component (L3). (Not shown in figure)
4. The distance between the lines L1 and L2, and between lines L3 and L4, were measured and recorded as the distances (H1 or H2).
5. The width of the joint was measured at its widest point (W).
6. A length-width ratio was calculated and recorded for each component (Settling ratio - R).

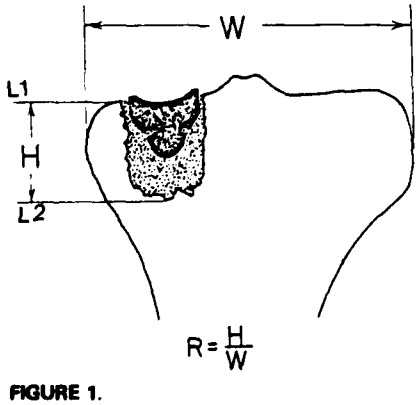

FIGURE 1.
Settling Ratio Determination.

The width measurement was utilized in order to compensate for any magnification variation between the different radiographs of a particular individual. When any region was unclear, several radiographs from the same individual were examined to insure that the same landmarks were chosen. No attempt was made to analyze the data as the measurements were being taken.

The calculated settling ratio was plotted versus time from implantation and a linear regression was performed in order to determine the slope of the best fit line. This slope for the time rate of change of the settling ratio was recorded as the settling indices for the medial and lateral components.

In order to determine the actual number of individuals present in the study during a given time interval, and to determine the probability for failure during any given interval, survival analysis was performed on the data. The 93-month interval for the study was subdivided into 10 periods. Survivorship of the arthroplasty was measured from the date of insertion. Although individuals entered the study at different times, for the purpose of these calculations, every participant entered the first interval and continued through all intervals until the time of followup for a given individual was reached. Individuals removed from the study were then marked as either "failed" or "withdrawn." An individual was marked as withdrawn if the study ended or the patient was lost to observation. This technique allows the use of data from cases for which the response (failure) had not yet occurred by the end of the study. The major restriction is the assumption that withdrawals occur randomly, not in anticipation of failure (6).

Results—The patients who were followed represent 58 consecutive polycentric arthroplasties (Table 7). Two arthroplasties were lost to followup because of unobtainable medical records—therefore 56 of the arthroplasties are included in the study. Of the knees included in the study, 33 were evaluated during an examination which occurred during March, 1980, through May, 1980. The remaining 23 knees were evaluated using the most recently available medical records.

The earliest arthroplasty was performed in April 1972; the most recent included in the study was performed in March, 1979. Approximately 10 arthroplasties per year were performed from 1972 through 1976 when the rate dropped to 2 per year through 1979.

Unique to this population is the male-to-female ratio. Other published studies of total knee arthroplasty involve predominately females, but only three arthroplasties of this study were performed on females, because the majority of the patients were treated at the Veterans Administration Medical Center, New Orleans.

The patient population represents a carefully selected group with the following preoperative indications identified as necessary for success:

1. minimal deformity,
2. minimal ligamentous laxity, and
3. good bone quality

Overall, the preoperative complaint common to all individuals was pain, with every individual complaining of moderate to severe pain on weightbearing. Additionally, 60 percent complained of moderate to severe night pain. The average range of motion for the group was 106 degrees (range 30 to 140) with 37 percent of the individuals demonstrating a flexion contracture of 5 degrees or greater. Disability severe enough to prevent an individual from working was claimed by 46 percent of the population.

Preoperative radiographs indicated only two individuals with normal joint spacing of the medial compartment, with 45 percent of the population rated as having severe loss of medial joint spacing. Only 15 percent of the population demonstrated severe loss of lateral joint space. Irregularities of the tibial surface were noted for 60 percent of the population with 86 percent demonstrating femoral surface irregularities.

The data obtained from the operative reports are given in Table 8.

Prophylactic antibiotics were administered intravenously to all patients with approximately 50 percent of the population receiving Cephalosporin (used prior to 1976) and 50 percent receiving Methicillin (used exclusively in 1976 and later). Cultures were recorded for 52 procedures with 6 (11.5 percent) identified as positive. In five of the six cultures the organism encountered was Staphylococcus epidermidus, with anaerobic diphtheroid in the other. The individual whose arthroplasty cultured the anaerobe had been treated with Cleocin. Three of the individuals with cultures

positive for the Staphylococcus had been treated with Cephalosporin and two with Methicillin.

Anticoagulant therapy was not routinely utilized with aspirin administered to ten individuals (19.2 percent) and Warfarin for one.

Early complications following the surgical procedure resulted in the deaths of two individuals. A 57-year-old male died from a pulmonary embolism on the second post-operative day. An 89-year-old female died during the second post-operative day following a myocardial infarction. No further complications developed during the immediate postoperative period except for one individual who suffered delayed wound-healing. That problem resolved without a skin graft.

Examination of the operative radiographs of 44 knees (12 unavailable) disclosed lucent lines present in nine knees (20 percent) immediately after implantation. Valgus placement was noted for one medial and one lateral tibial component. Twelve knees (27 percent) were noted as having an anterior tilt (anteroversion) of the tibial component with one individual demonstrating a posterior tilt (retroversion). Valgus placement was noted in two medial femoral and two lateral femoral components with two lateral femoral components placed in varus orientation. One individual was noted as having a flexion placement of the femoral components.

Six individuals underwent manipulation under anesthesia following surgery. The mean time for manipulation was 24 days postsurgery (range 14 to 35). The individuals underwent manipulation because they demonstrated a limited range of motion (mean value 50 degrees.) With one exception, all manipulations were performed prior to 1975. (The surgeon in charge became convinced that individuals would gain adequate range of motion in time without the added trauma of additional anesthesia.)

The results of this review are presented initially as tables showing the state of each case before surgery and at followup for various parameters. A cross-tabulation grid was formed with possible preoperative values of a given parameter marked on the vertical axis and possible followup values on the horizontal axis. Any block within the grid corresponds to a unique pairing going from a given preoperative to a certain followup condition as listed in each particular block of the table. In Table 9, Pain Rating, the horizontal row labeled "severe" includes the 25 individuals who suffered severe pain preoperatively. Of those individuals, one suffered disabling pain at followup, and four suffered severe pain. Thirteen individuals went from severe preoperative pain to mild pain at followup, with seven individuals demonstrating no pain at followup after having severe preoperative pain. Presentation of data in this manner indicates both the final quality of results and the degree of change between the two periods. A diagonal line is drawn intersecting cases showing no change in value from the preoperative to the follow-up condition (four knees in Table 9). Cases lying above the diagonal correspond to those that have improved following surgery; those lying below it have deteriorated. The general quality of the results in a group of knees can be seen by their distribution about the diagonal "no change" line. In order to simplify the presentation, a chosen value is defined as "acceptable" for each parameter, and a vertical line is drawn at this point crossing the horizontal axis. Only cases falling to the right of the vertical line are considered acceptable at followup. Further, a summary expressed as percentages is presented below each table. Each table includes every individual from the study for whom both preoperative and postoperative values for the indicated parameter were available.

Referring to Table 9, pain relief at followup represented the most dramatic improvement offered by the procedure, with only one individual worsened and four unchanged. The lower rate of improvement in walking ability (Table 10) resulted from the general condition of the participants of this study; no attempt was made to alter or exclude the rating of an individual whose limited walking ability was unrelated to the arthroplasty.

Three individuals demonstrated a passive range of motion (Table 11) of less than 70 degrees at followup. Two of the individuals with reduced range of motion were short-term, with the device in place for 16 months or less. One died of gunshot wounds 3 months after surgery, and the other died 16 months after surgery following a pulmonary embolism. The third individual continues as a marginal success after 56 months. The average range of motion for the population was 106 degrees with 37 percent of the population demonstrating 110 degrees of motion or greater. Extension contracture of greater than 5 degrees was present in seven individuals, with one individual demonstrating an extension deformity of 30 degrees.

Medial/lateral instability was not a major problem for this patient population, with moderate medial instability more prevalent than lateral instability, and no individual suffering from severe instability in either compartment.

The radiographs of 46 arthroplasties were available at followup and examined for the presence of lucency. Nineteen knees demonstrated slight lucency associated with at least one component of the arthroplasty. The most common site of the lucency was the medial tibial component (in 16 arthroplasties) with the lateral tibial component suggesting slight lucency in 13 arthroplasties. Lucency around femoral components was much less common, present in only four medial and three lateral components.

Moderate lucency was noted in a total of three arthroplasties, in two medial tibial components and one medial femoral component.

Sclerosis beneath one or more tibial components was identified radiographically in 51 percent of those reviewed. Breakage of the wire marker was identified in the radiographs of six individuals. This breakage was thought to follow a loss of bony support beneath the central portion of the component, which permitted a flexing of the polyethylene and the encased wire.

The number of items necessary for completion of the Larson Knee Rating Scale left many individuals with an incomplete rating. Of the 54 knees in the study, only 36 could be rated with the Larson rating. Utilizing the simpler scale suggested by Freeman, 45 knees were rated postoperatively but only 44 could be rated preoperatively.

The minimum rating considered acceptable, using the Freeman scale, was 75. In order to attain an acceptable rating an individual could have no worse than mild pain on weightbearing, 80 degrees of motion, and the ability to walk indoors. (The cross-tabulation of the Freeman rating is presented in Table 12.) One individual demonstrated a drop in rating following the surgery, with seven individuals identified with unacceptable knee ratings at followup.

In order to check the effect of time on

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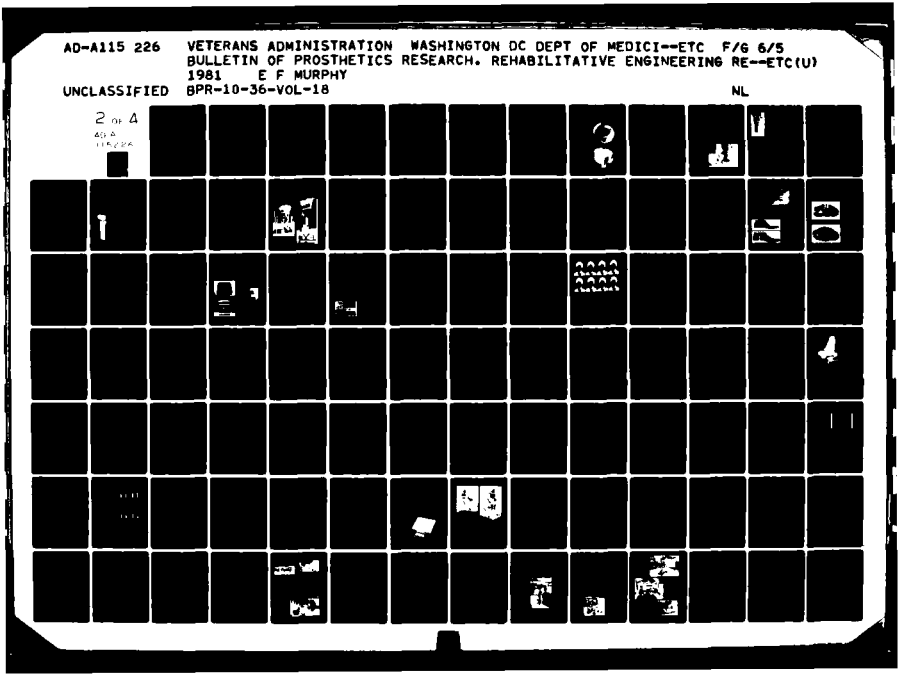

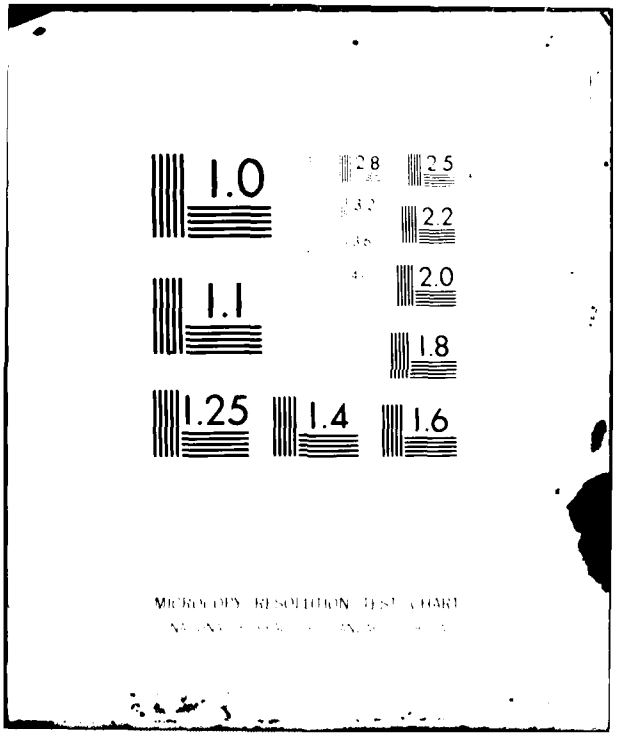
1.0
2.8
2.5
2.2
2.0
1.1
1.8
1.25
1.4
1.6
MICROCOPY RESOLUTION TEST CHART

TABLE 9.

PAIN RATING

PRE-OP \ FOLLOW-UP	Disabled	Severe	Moderate	Mild	Slight	None
Disabled	0	4	0	12	0	8
Severe	1	4	0	13	0	7
Moderate	0	0	0	0	0	0
Mild	0	0	0	0	0	0
Slight	0	0	0	0	0	0
None	0	0	0	0	0	0
	Unacceptable			Acceptable		

SUMMARY

Acceptable	81.6%
Unacceptable, improved	8.2
Unacceptable, unchanged	8.2
Unacceptable, worsened	2.0
Total reviewed	49

TABLE 10.

WALKRATE

PRE-OP \ FOLLOW-UP	Unable	Severe df.	Mod. dif.	No limit
Unable	0	1	1	0
Severe diff.	1	3	4	3
Moderate df.	1	2	9	9
No limit	0	0	0	0
	Unacceptable		Acceptable	

SUMMARY

Acceptable	76.0%
Unacceptable, improved	3.0
Unacceptable, unchanged	9.0
Unacceptable, worsened	12.0
Total reviewed	34

RANGE OF MOTION (degrees)

PRE-OP \ FOLLOW-UP	<70	70-90	90-100	>100
<70	1	0	0	2
70-90	1	3	3	4
90-100	0	3	2	0
>100	1	6	4	21
	Unacceptable		Acceptable	

SUMMARY

Acceptable	71.0
Unacceptable, improved	0.0
Unacceptable, unchanged	7.0
Unacceptable, worsened	21.0
Total reviewed	52

TABLE 11.

SIMPLIFIED KNEE RATING SCALE

PRE-OP \ FOLLOW-UP	Disab	Severe	Prob	Fair	Ok	Excel
Disabled	0	1	0	6	0	0
Severe	0	1	4	13	6	9
Problem	0	1	0	2	1	0
Fair	0	0	0	0	0	0
OK	0	0	0	0	0	0
Excellent	0	0	0	0	0	0
	Unacceptable			Acceptable		

SUMMARY

Acceptable	84%
Unacceptable, improved	14
Unacceptable, unchanged	22
Unacceptable, worsened	0
Total reviewed	44

TABLE 12.

knee-rating value, a plot with linear regression was performed (figure 2). It should be noted that, twice, two knees had identical ratings and times of followup (*rating* = 60, *followup* = 51 months; rating = 95, followup = 84 months).

Although the rating of individuals with a followup of 60 months or greater is somewhat lower than that for short-term arthroplasties, the trend is slight. The average knee rating at different followup periods is almost constant.

A total of 11 knee prostheses were identified as failures. Six knees have undergone reoperation. Three of these knees were revised to a more constrained device, while revision for the others involved replacement of one or more of the polycentric components, leaving the patient with a polycentric arthroplasty. One of the polycentric revisions was subsequently fused. The five remaining were classed as failures based on functional result (knee rating and patient assessment) but have not at this date undergone reoperation. Moderate to severe pain on weightbearing was associated with every failure.

Analysis for settling was performed on 27 individuals from the study. This sub-group represents those individuals on whom three or more readable radiographs were available covering the implantation time of the device. This population contains most of the failures (10 of 11). This was not a conscious choice, but a result of the higher frequency of examination for individuals having difficulty.

The average number of radiographs

read per individual was 6 (range 3 to 13) covering an average period of 50 months (range 18 to 93).

The time rate of change of the settling ratio was determined for both the medial and lateral tibial components. Table 13 reports the values for each individual in the analysis, arranged for medial and lateral compartments. Each set is subdivided into three categories, based on a sharp break in the settling index value. The group labeled "definite" demonstrates what is felt to be definite settling, the second group is identified as "questionable" for settling, with the third having no evidence of settling. Thus, for the medial component, a slope of 0.085 or greater is taken as definite evidence of settling, a range of 0.030 to 0.084 is questionable, and less than 0.030 is classed as not settling. (A negative slope probably represents an indeterminant value rather than actual rising of the device, and is most likely a result of measurement inaccuracies.)

The trends in the settling index values for lateral compartment (Table 14) are less clear than for the medial, with three numerically large negative values well beyond the assumed "indeterminant" range. Whether or not such values represent rising of the prosthesis is not clear.

Table 15 describes the settling ratio for the 10 of the 11 knees described clinically as failures. Every individual classed as a failure demonstrated at least questionable settling on radiographic analysis, with 50 percent of the failures

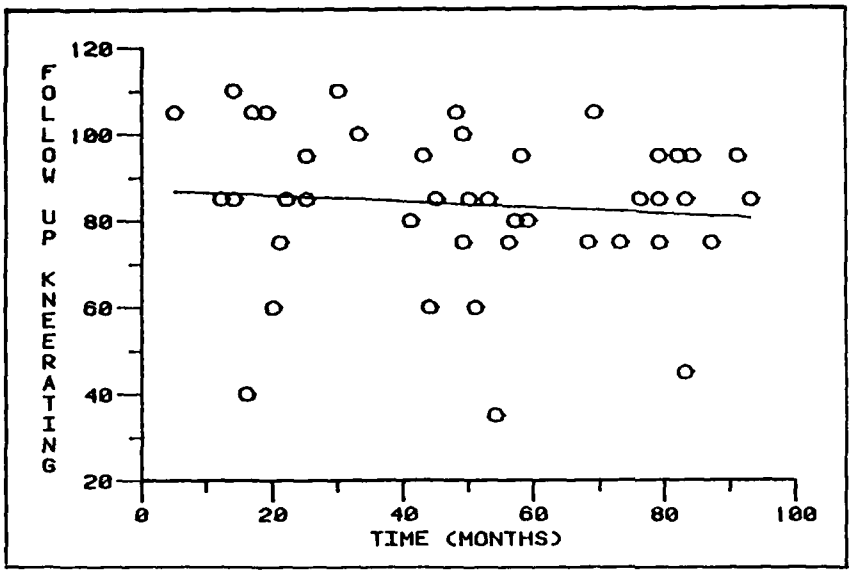

FIGURE 2.
Knee Rating versus Time at followup.

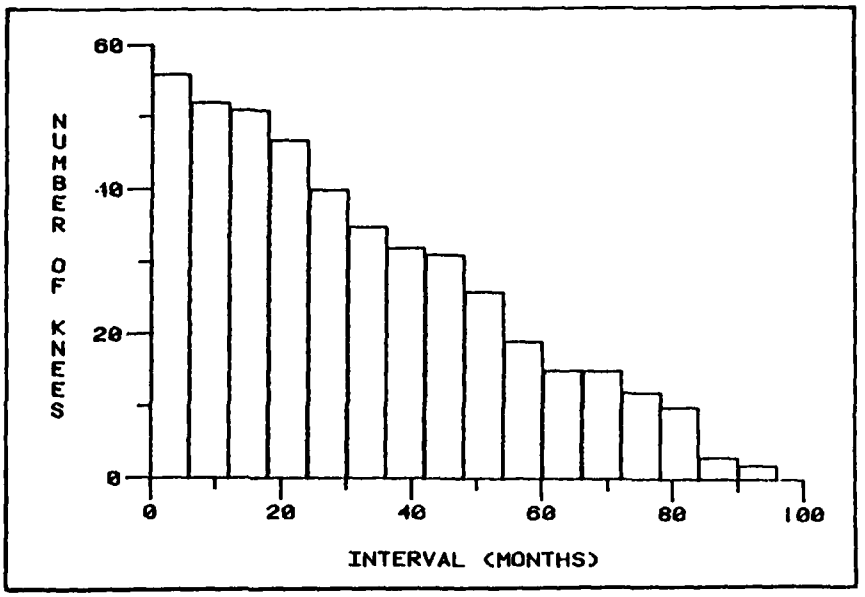

FIGURE 3.
Number of knees exposed versus Time.

MEDIAL SLOPE VALUES

ID	SLOPE	TIME (months)
DEFINITE SETTLING		
366L	0.583	26
401L	0.290	37
698R	0.146	45
828L	0.143	28
443L	0.113	23
924R	0.094	44
210L	0.087	55
434L	0.086	35
QUESTIONABLE SETTLING		
633L	0.068	35
083L	0.052	23
635R	0.047	62
504R	0.041	35
551R	0.034	68
337R	0.030	53
NO SETTLING		
698L	0.027	43
147L	0.024	49
265R	0.018	57
510L	0.011	18
720L	0.006	50
874R	0.004	77
701R	-0.002	60
930R	-0.004	72
044L	-0.020	89
266L	-0.027	59
269L	-0.043	93
038L	-0.085	67
965R	-0.093	36

TABLE 13.

demonstrating definite signs of settling. Also listed are the values of the settling ratio for the 17 non-failures. Of this group, eight (47 percent) demonstrated a suggestion of settling with four (24 percent) of these individuals having definite settling.

Of the four individuals who demonstrated definite settling, two are short term (23 months or less) and warrant a close examination. It is felt that these two individuals are at risk, and some conservative response by the clinician may be called for. One of the remaining is marginally successful; the individual has a rating of 75 (minimally acceptable) after 55 months. The rate of settling and current quality of result suggests that clinical failure may occur shortly. The remaining individual rates 105 on the Freeman scale (excellent) with only slight pain; this individual does demonstrate moderate medial ligamentous laxity and is currently in twenty degrees of varus, which would be consistent with medial settling.

The life table for survival analysis is presented in Table 16. It is important to note that, during the later intervals of the study, the number of arthroplasties exposed or "at risk" is drastically reduced as individuals are withdrawn. With a mean followup period of 50 months for this study, only 15 arthroplasties are exposed to 5 years or longer use. Thus, even with this study, only a small portion of the population has an exposure time suitable for a long-term study. The number of knee arthroplasties exposed is plotted versus the interval of the study, in Figure 3.

LATERAL SLOPE VALUES

ID	SLOPE	TIME
DEFINITE SETTLING		
510L	0.377	18
434L	0.272	35
366L	0.103	26
828L	0.098	28
QUESTIONABLE SETTLING		
698R	0.060	45
720L	0.058	50
265R	0.052	57
266L	0.042	59
NO SETTLING		
337R	0.017	53
701R	0.014	60
965R	0.010	36
210L	0.087	55
874R	0.010	77
504R	0.010	35
635R	0.001	62
147L	0.001	49
038L	0.001	67
924R	-0.012	44
698L	-0.015	43
551R	-0.017	68
044L	-0.020	89
083L	-0.028	23
633L	-0.047	35
269L	-0.068	93
443L	-0.185	23
401L	-0.270	37
930R	-0.628	72

TABLE 14.

FAILURES

ID	Medial Settling Index	Lateral Settling Index	Status or Knee Rating
266L	-0.027	0.042	45
337R	0.030	0.017	Reoperation
366L	0.583	0.103	60
401L	0.290	-0.270	Reoperation
434L	0.086	0.272	Reoperation
504R	0.041	0.010	45
551R	0.034	-0.017	Reoperation
720L	0.006	0.058	60
828L	0.143	0.098	Reoperation
924R	0.094	-0.012	60

NON-FAILURES

ID	Medial Settling Index	Lateral Settling Index	Status or Knee Rating
038L	-0.085	0.001	85
044L	-0.020	-0.023	75
083L	0.052	-0.028	?
147L	0.024	0.001	75
210L	0.087	0.010	75
265R	0.018	0.052	95
269L	-0.043	-0.068	95
443L	0.113	-0.185	110
510L	0.011	0.377	?
633L	0.068	-0.047	95
635R	0.047	0.001	85
698L	0.027	-0.015	95
698R	0.146	0.060	105
701R	-0.002	0.014	85
874R	0.004	0.010	85
930R	-0.004	-0.628	?
965R	-0.093	0.010	110

TABLE 15.

Figure 4 presents a plot of the proportion of the population failing versus time in situ. In this study the time of greatest danger of failure occurred between the 48th and 54th months, with 12.5 percent of the exposed population failing. The interval of highest proportion of failing was immediately preceded by the interval with the second highest failure proportion (6.8 percent). An earlier interval of elevated failure occurred between months 18 and 24, with 6.7 percent of the individuals at risk during the interval failing.

A plot of the overall probability of survival versus time is presented in Figure 5. The final level of survival was 0.705. The estimated time at which 25 percent of the population would fail was 51.3 months.

The population was subdivided into two groups according to preoperative weight of the individual, with 200 pounds at the cut-off value. The probability of failure versus time for the two subgroups is plotted in Figure 6.

In comparing the two groups, the cumulative probability of survival at 96 months was 0.80 for the knees in individuals weighing less than 200 pounds, and 0.50 for individuals weighing more than 200 pounds.

Discussion—With no consensus in the literature on what constitutes a success, assessing the results of total-knee arthroplasty is difficult. A procedure may be said to have failed if it does not meet the goals established for it. A successful total-knee arthroplasty must provide stability, mobility, and freedom from pain. The simplified knee-rating scale utilized for this study provides a semiquantitative measure rating level-of-pain, range-of-motion, and the ability of the patient to ambulate, with 50 percent of the rating weighted toward pain, 30 percent toward range of motion, and 20 percent toward walking ability.

During the patient interview, the most common expression of satisfaction was about freedom from pain, the most common complaint was about the presence of pain associated with the knee. Thus the 50 percent weighting of the scale for pain is probably justified. The large drop in rating between mild pain (40 points) and moderate pain (15 points) made that single observation determine whether the rating was a success or failure. An "acceptable" rating (75 points) was unobtainable if the observer noted moderate pain at followup. The distinction between mild and moderate pain is not clear; the necessity for such distinctions limit the usefulness of this and other semi-quantitative rating schemes. The Larson knee score assigns 40 percent to pain rating, with an additional category which reduces the abrupt drop in points but requires distinction between slight, mild and moderate pain—thus making the subjective decision more difficult.

The multiple factors influencing the walking ability of an individual limit its usefulness in a rating system. The simplified rating scale utilizes only the distance the individual can walk. The Larson scale rates, in addition to the distance walked, the presence of a limp, use of aides, and the ability to maneuver on stairs. Again, none of the additional parameters identify knee function problems alone. The 20 percent weight of the simplified scale assigned to walking ability is justified.

As described earlier, the minimally acceptable rating of 75 represented an individual with mild pain, greater than 80 degrees of flexion-extension motion, and the ability to walk indoors. When asked how they would rate their knee, of the individuals who subsequently were rated as minimally acceptable (75 points) two felt their knee was very good, two felt

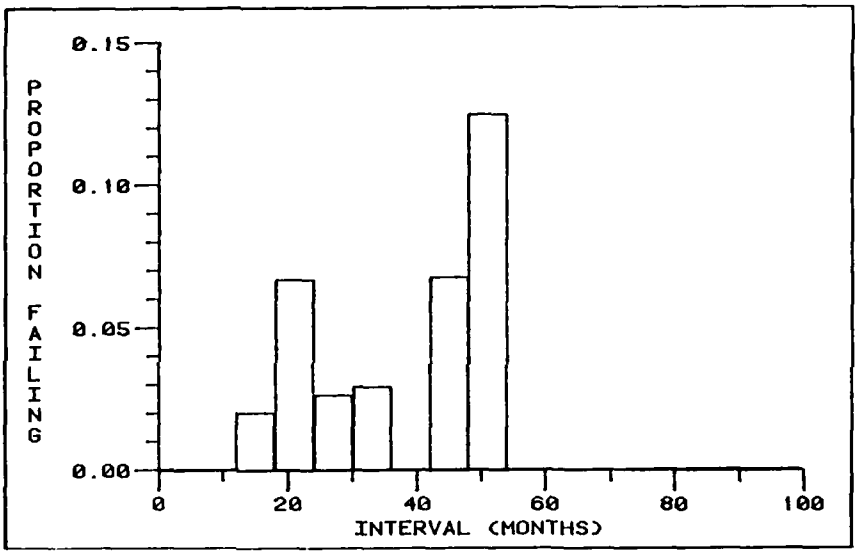

FIGURE 4.
Proportion Failing versus Time.

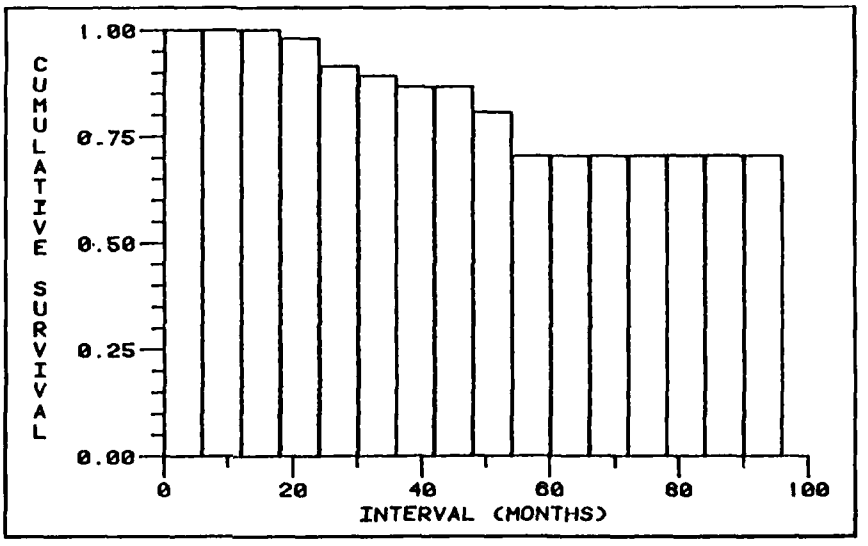

FIGURE 5.
Cumulative Survival.

Life Table

Interval (months)	Entered	Left	Failed	Proportion failed	Cumulative survival
0 - 6	56	4	0	0.00	1.00
6 - 12	52	1	0	0.00	1.00
12 - 18	51	3	1	0.020	1.00
18 - 24	47	4	3	0.067	0.980
24 - 30	40	4	1	0.026	0.914
30 - 36	35	2	1	0.029	0.890
36 - 42	32	1	0	0.000	0.864
42 - 48	31	3	2	0.068	0.864
48 - 54	26	4	3	0.125	0.806
54 - 60	19	4	0	0.000	0.705
60 - 66	15	0	0	0.000	0.705
66 - 72	15	3	0	0.000	0.705
72 - 78	12	2	0	0.000	0.705
78 - 84	10	7	0	0.000	0.705
84 - 90	3	1	0	0.000	0.705
90 - 96	2	2	0	0.000	0.705

TABLE 16

the knee was good and two felt that it was fair. Of the individuals rating 95 points or greater, all identified the results as good (3 individuals) or very good (14 individuals).

The knee rating serves to distinguish a "success" from a "failure" by the independent evaluation of selected parameters rather than a single subjective decision. Marginal scores are the least dependable, and the single step of the pain evaluation from mild to moderate essentially selects the failures.

The eleven individuals identified as failure either because of reoperation (6 patients) or knee rating (5 patients) were grouped for separate analysis to identify factors associated with the failure.

With such a small total number of failures, statistically significant inferences concerning factors predisposing an individual to failure were not possible. Ten of the 11 failures occurred in individuals with a diagnosis of primary (eight failures) or secondary (two) osteoarthritis, with one rheumatoid individual classed as a failure. The individual with rheumatoid arthritis complained of moderate pain on weightbearing, but had an excellent range of motion and was able to ambulate four to six blocks.

The population was examined to determine if any individual failed to meet the preoperative indications. In checking preoperative deformity, six individuals exhibited 10 degrees of varus and one had failed. Of the 6 individuals with 15 degrees of varus preoperatively, also one had failed. Two knees had 20 degrees of varus preoperatively, one could not be rated as the patient died shortly after surgery, and the other failed. One individual demonstrated 10 degrees of valgus preoperatively, and failed. One individual began with 28 degrees of valgus, is currently classed as a success, but has reverted to 20 degrees of valgus at last followup. Though no clear conclusions can be drawn, there appears to be the suggestion that greater than 15 degrees of varus or valgus may predispose a knee to failure.

Evaluation of preoperative instabilities (an indication of ligamentous laxity) revealed 17 individuals with moderate medial instability and one failed. Among the two knees with severe medial instability, none had failed. Only one knee demonstrated moderate lateral instability, and it was not a failure. Three knees demonstrated moderate to severe bilateral instabilities and none of these have failed.

A qualitative estimate of bone quality was determined using preoperative radiographs. Four individuals were rated as having severe loss of bone density, or osteopenia, with no failures among them. One failure was recorded among the two knees rated with moderate osteopenia.

Though not mentioned as a preoperative contraindication, 6 failures occurred among the 24 individuals who had undergone knee surgery prior to the arthroplasty. The types of previous surgery in the failed knees demonstrated no pattern, with one patellectomy, one tibial plateau prosthesis, and one each with osteotomy and synovectomy.

Excess weight has been implicated in the failure of total knee arthroplasty. The mean preoperative weight of the entire population was 174 pounds; of

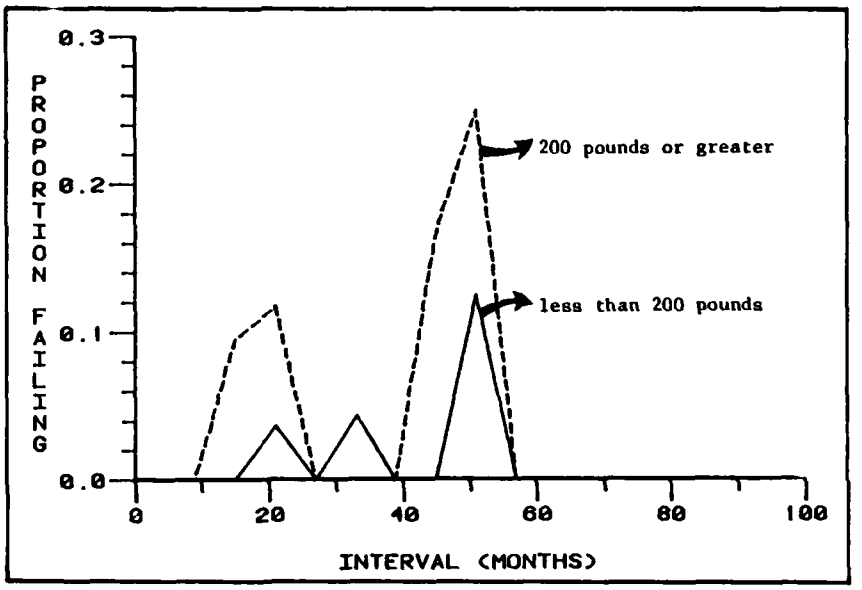

FIGURE 6.
Proportion Failing versus Time.

the non-failures, 172 pounds, and of the failures, 190 pounds. The difference was not statistically significant ($p < 0.20$). Twenty-seven percent of the individuals 190 pounds or greater (4 of 15) failed, while 14 percent (4 of 28) of those individuals weighing less than 190 pounds failed.

No relationship was noted between the presence of lucent lines postoperatively (in nine cases) and later failure. Of the three individuals displaying marked lucent lines at followup, two were classed as failures. The large number of individuals (19) with only slight lucency demonstrated no tendency toward failure.

The effect of individual component placement as noted in the operative radiographs was evaluated. The one individual with retroversion placement of the tibial components, and the one individual with a flexion placement of the femoral components, each failed and underwent revision. No association was noted between varus or valgus placement of the components and subsequent failure.

The relationship between device placement and success of the arthroplasty could not be verified with this population. In his evaluation of Geometric total knee arthroplasty, Lotke (7) noted varus positioning in four of the five instances of mechanical failure of the prothesis. Illstrup (8) suggested that a common sequence of failure for the Polycentric knee involved a good initial result with slight residual varus which would be followed by a gradual sinking of the medial tibial block increasing the varus. At followup, 5 knees of the 56 were in varus with one failure—and 5 were in valgus with 1 failure.

The settling index was the evaluated parameter most closely associated with failure, suggesting settling as the primary mode of failure. Bryan (9) mentioned failure due to settling as an infrequent occurrence. Lax ligaments and unexplained pain which were reported as causes of failure in the Bryan study could have been caused by implant settling.

The initial attempts at identifying settling using a qualitative impression of radiographic changes was not adequate. The quantitative measurement procedure provided a strong indication of the presence or absence of settling and the rate of settling, for most cases. The difficulty in evaluating certain cases could be eliminated if a standardized radiographic technique were utilized.

Because of the increased risk to the device associated with individuals weighing 200 pounds or more, a linear regression was performed between the values for the settling index (once for medial and once for lateral) and the weight of the individual. No trend was present between weight and either of the index values. The slope of the regression line in each case was near zero. The results are not unexpected; time in situ of the device should alter the influence of the individual's weight on the settling index.

The method for determining the settling ratio as described would be applicable only to Polycentric arthroplasty. Other knee arthroplasty procedures require the removal of the entire surface of the tibial condyles, and no bony landmarks remain to identify the joint line. For such devices, another landmark would have to be selected, possibly the head of the fibula.

Actuarial methods (life tables) are commonly used when measuring the time to occurrence of some event or response. They have been used in epidemiological studies and in the engineering analysis of the failure of manufactured components. Dobbs (10) suggested the use of actuarial methods to compensate for the differences in length of followup between different studies of hip arthroplasty, one factor which limits the comparison of such studies. The method can be applied with little difficulty, allowing periodic and overall failure rates to be determined for a group of patients with varying followup.

Survival analysis generates a more conservative estimate of survivorship than the conventional method of reporting the proportion failing within a given population. With 11 failures identified among the 56 knees that underwent Polycentric total knee arthroplasty in the present study, the simple failure rate would be 19.6 percent. The cumulative survival as determined by survivorship methods for the same population was 70 percent, or a failure rate of 30 percent. The computations produce a higher and more realistic failure rate because the probability of failure is calculated for successive intervals by dividing the number of failures by the number of devices at risk during the interval. Successive multiplication of the probability of survival produced the cumulative probability of survival.

The effect of weight on the probability of survival is profound, with a drop from 0.8 to 0.5 as preoperative weight exceeds 200 pounds. The curves of the proportion failing appear similar for both groups displaying only a difference in magnitude. (Figure 6) In both curves there appear two periods of peak failure, with no failures after the 55th month. In his study of long-term followup of Polycentric arthroplasties, Bryan (11) noted a continuing incidence of failure between the 5th and 7th years. At present, no such failure has occurred in the population under study, and a 5-year survival at present appears to insure a 7-year survival. As the number of individuals exposed during the 5 to 7 year period increases, failures may and probably will occur.

Dobbs suggested extrapolation of the survival probability to predict failure at some future time. Such a prediction would be valid only if the future behavior could be defined by the past. In the current study, if the first 30-month interval had been used to predict failure in the second 30-month interval, the high incidence of failure at 50 months would not have appeared. The causes of failure of a joint arthroplasty are not constant in time; for example, infection can occur early, while wearing out of the prosthesis usually occurs late. Extrapolations of survival data, especially when the patterns of failure are irregular and of varying causes, are not valid. Actuarial methods provide many advantages in analyzing the effects of time on a population. They serve to limit the influences of differing followup periods when two or more studies are compared. They do not however, provide a view of the future.

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Development of Hindfoot Joint Resurfacing Prosthesis

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Introduction and Background

This project is based on the hypothesis that established total joint replacement technology can be employed for implants for acquired deformities of the hindfoot joints (subtalar, talonavicular and calcaneocuboid). If properly designed, these implants will restore normal hindfoot position and allow hindfoot joint motion, thus providing nearly normal function. It is planned to develop implant components which resurface the joint with the need to remove only minimal amounts of bone. This strategy will make it possible to remove the implants to perform an arthrodesis if necessary for any reason. Outside of reports of the work being performed in this laboratory (and previously by one of the investigators with M.A.R. Freeman and M. A. Tuke in England) there are no publications in English describing such prostheses.

Initial project tasks have been to establish methods for determining whether prototype prostheses (i) provide adequate range and type of motion, (ii) maintain normal forces in surrounding ligaments and (iii) provide adequate component base cross-sectional areas to prevent collapse of supporting bone. Other design considerations such as articular wear resistance are not being investigated, but will be satisfied by using materials with proven clinical performance. It is necessary to use human cadaver specimens to perform the types of tests described.

This report covers the second half of the first project year. During this year, efforts have been directed chiefly at establishing test methods and performing tests to assess the adequacy of a prototype talonavicular prosthesis already available at the beginning of this project.

Talonavicular Joint Surface Geometry

Determining the surface geometry of the normal talonavicular joint was among the first project activities and was described in this Bulletin (BPR 10-35, Spring 1981). As mentioned at that time, the report was submitted for publication in Foot and Ankle, the journal of the American Orthopaedic Foot Society. During the present reporting period the article was published (1). Specimens are now being gathered for similar assessments of joint surface geometry for the subtalar joints and the calcaneocuboid joint.

Talonavicular Compressive Force Measurements

It is necessary to determine forces transmitted across prosthetic joint components under anticipated tibial loads for two purposes. First, it is possible (especially in the case of polymeric components) that the force per unit area on one of the components will be sufficient to cause damage to the component or alteration in its shape, thus impairing its function. In addition, the intra-articular force results in a compressive stress (force per unit area) in the supporting bone. The magnitude of the stress depends both on the force transmitted across the joint and the cross-sectional area of the base of each of the supporting, articulating components. If the compressive stress under normal joint loads exceeds the compressive strength of the supporting bone, it is possible that the joint components will subside into the bone and thus change their function. In this regard, measurements were made of the compressive strengths of the supporting bone in both the talus and navicular (reported in the immediately previous issue of BPR).

Determining the actual force transmitted across the prosthetic talonavicular joint under applied tibial loads in cadaver specimens has been a more difficult task. This is because it is necessary to incorporate force measurement elements in one of the talonavicular joint components, thus effectively turning it into a force transducer.

Initial efforts to produce a talonavicular prosthesis instrumented to read intra-articular force were documented in the immediately previous issue of BPR. February 1981 marked the completion and utilization of a special talonavicular joint prosthesis, incorporating a fiber optics force transducer, into the talar component. This prototype device was capable of reading moderate (up to 30 kgf) talonavicular loads over a normal range of foot positions relative to the tibia in human cadaver specimens. A complete description of the transducer and its performance was published (2) as a project report in completion of the research project requirement for the degree of Master of Engineering in Bioengineering at the University of Utah.

Subsequent to the development of that prototype force-reading talar component, various methods were explored to allow the component to respond to a higher range (over 100 kgf) of talonavicular force. Essentially, it was necessary to develop or obtain a small, but extremely stiff, low-hysteresis spring which would fit inside the talar component of the joint prosthesis. The prototype configuration of six small coil springs could not be reworked to obtain the required stiffness. A number of spring materials and spring-type devices were explored and evaluated. Finally we were able to incorporate a pair of Belleville springs into the device, as

shown in Figure 1. Belleville or disc springs are essentially precision-made washers which, instead of being flat, have a raised inner rim relative to the outer rim. A wide variety of these springs is available (National Disk Spring Division, Rolex Company, Hillside, New Jersey). In addition, these springs may be stacked in series, parallel or combinations of series and parallel configurations to give a broad spectrum of spring performance. Two springs in series configuration are now used in the talar component, providing a useful force range up to 200 kgf. Figure 2 shows a calibration curve for the prosthesis with the new spring components.

Ankle Ligament Tension Measurements

Little work has been reported in the field of laboratory determination of ligament forces, and most ligament function studies of any type have been concerned with the knee. Other investigators in this laboratory recently developed a novel method for simultaneous determination of the forces in ligaments in statically loaded cadaver specimens, and have applied this technique to biomechanical studies of the knee (3). The technique is now being applied to the ligaments surrounding the ankle-hindfoot joint complex in this project (Fig. 3).

In the technique under development, stress in intact ligaments is sensed by utilizing strain gage transducers placed on the surface of the bone near ligamentous attachments. The strain readings can be converted to force by subsequently severing the ligaments and applying a series of known loads to develop calibration curves. Multiple gage sites with sequential recording of data allow simultaneous static measurements of resultant ligament forces at known positions under known external loads, before and after introducing prosthetic ankle, talonavicular joint, or other hindfoot implants.

Ligamentous function in the ankle region is varied and complex, since some of the ligaments stabilize both the ankle joint and the hindfoot joints. The purpose of this initial study was to define further these anatomical interactions in the deltoid, anterior talofibular, and calcaneofibular ligaments in normal specimens. Embalmed cadaver ankle specimens are being used for protocol development. As techniques are refined, fresh specimens will be studied as they become available. A test platform has been designed and built which allows the specimens to be positioned with known amounts of dorsiflexion/plantarflexion, varus/valgus, and rotation relative to the vertically held tibia. Known loads are then applied to the tibia with an Instron testing machine.

Three specimens have been tested to date, following a detailed protocol involving three tibial force levels (4, 40 and 70 kgf), five positions of varus/valgus, and seven positions of flexion. Data obtained showed reproducible trends in strain patterns. Initial observations are as follows:

1. The anterior portion of the deltoid

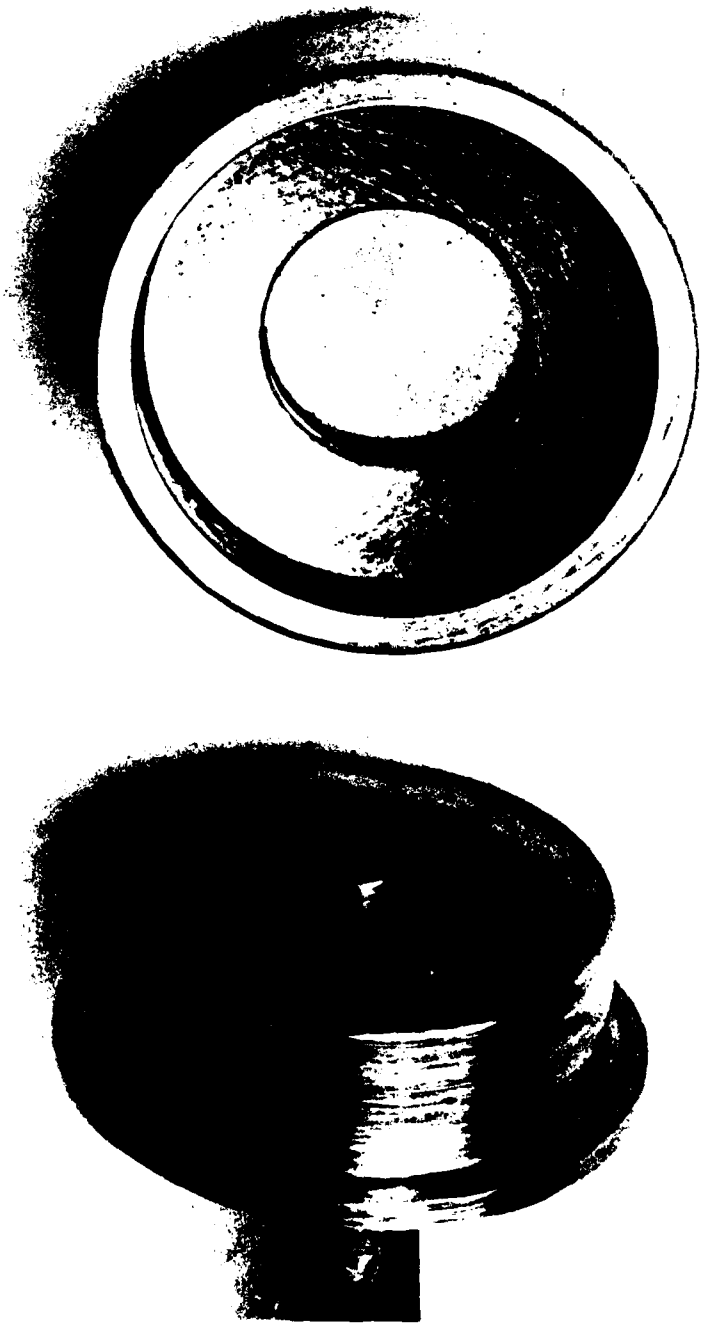

FIGURE 1.
Interior view of improved talar component force transducer showing location of Belleville (disc) springs. Scale is approximately 4 2/3 X life size.

ligament becomes more taut as the ankle goes from dorsiflexion to plantarflexion. Ligament tensions as high as 14 kgf were recorded in a neutral varus/valgus position with 70 kgf tibial axial load applied. Trends were reversed for the posterior portion of the deltoid ligament. Force measurements of 23 kgf were obtained at the maximum dorsiflexion level studied (30 degrees) for this ligament. This was the highest ligament force recorded in our initial studies. Both portions of this ligament were stressed in valgus positions. However, the posterior portion of the deltoid ligament showed increased tension with varying degrees of varus combined with dorsiflexion. This is thought to be secondary to the subtalar motion causing tightening of this ligament in the aforementioned position.

2. Progressing from dorsiflexion to plantarflexion, the **anterior talofibular ligament** showed steadily increasing tension. Varus/valgus positioning had little effect on forces observed.

3. As the ankles were placed in dorsiflexion, the tension on the **calcaneofibular ligament** increased. This occurred with varus positioning also. The forces were small compared to those seen on the medial side of the ankle.

4. In general, as tibial loads were increased a general increase in ligament tension was seen. However, ligament tensions at 4 kgf of tibial force were already 80 to 90 percent of the values observed at 70 kgf.

This initial study has shown that the technique described appears useful in determining the relative tensions in the ankle ligaments. The findings emphasize the need for critical evaluation of these functional interactions. For example, the contribution of subtalar joint movement to ligament tension, especially in causing the posterior portion of the deltoid to be under increased load, is contrary to previously accepted descriptions of ligament function. This work should provide a baseline which will allow evaluation of changes in ligament function related to prosthetic replacement of the ankle and/or hindfoot joints.

Quantifiable and reproducible positioning of the foot relative to the tibia is important in producing and understanding both ankle ligament tension measurements and talonavicular compressive force measurements. A device of simple but unique design, al-

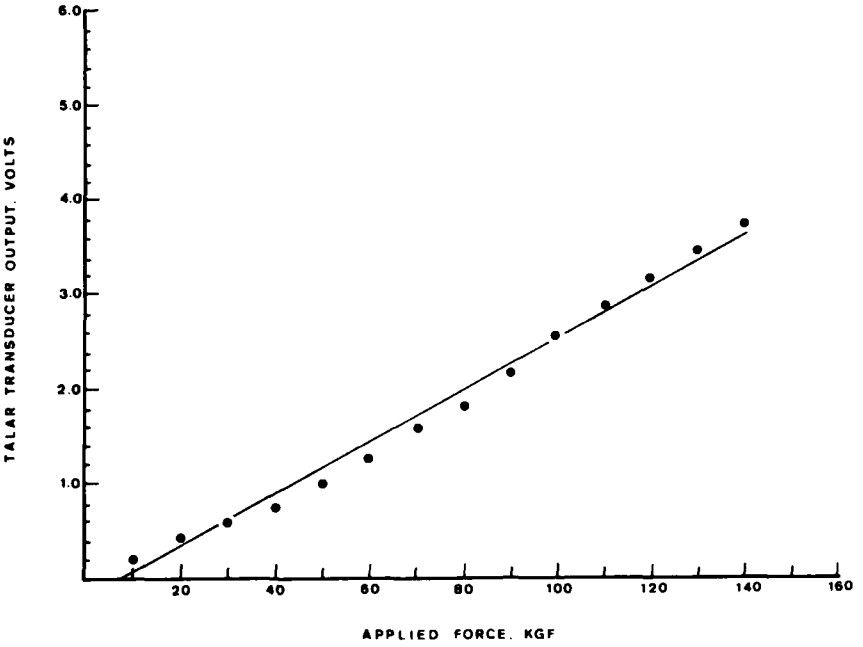

FIGURE 2.
Voltage output of improved talar component force transducer as a function of applied load.

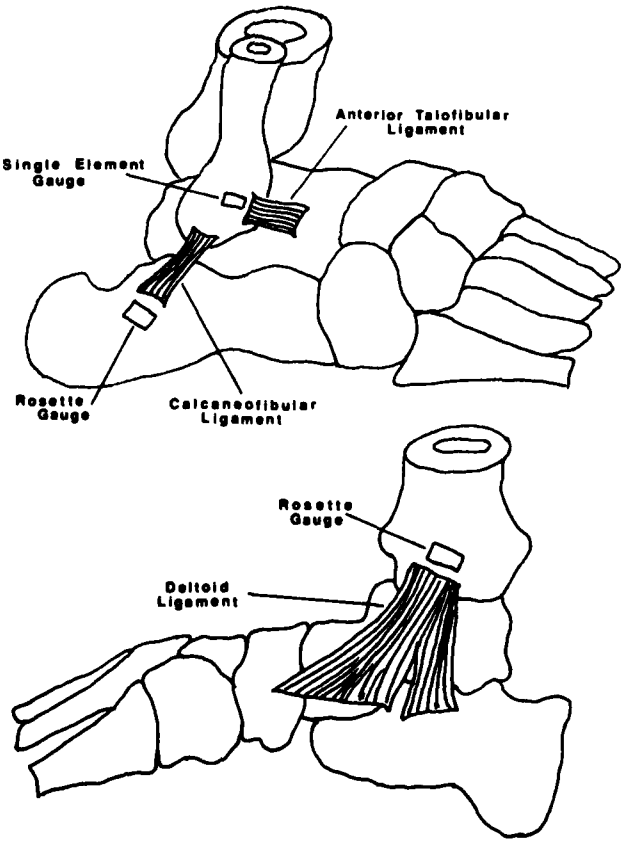

FIGURE 3.
Location of strain gauges for measurement of ligament tension in the ankle-hindfoot joint complex.

lowing positioning of the foot relative to the tibia in any combination of dorsiflexion/plantarflexion, rotation and pronation/supination, is under construction. It will be described in subsequent reports.

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Stimulation of Repair of Cortical Bone Transplants by Implantation of Piezoelectric Materials: A Pilot Study

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Work is continuing in dogs with several types of implants, and evaluation of an initial series of implantation at 20 sites in 5 dogs is currently underway. In the coming year, the effect of the implants on graft incorporation will be studied using quantitative histological techniques with the aid of an Optomax (semiautomatic image analyzer). The project is complicated by the fact that the large specimens of radius and ulna require in vivo fixation techniques to adequately preserve the tissue.

Engineering Applications in Orthotic and Prosthetic Treatment of Musculoskeletal Defects

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In a major development for the Motion Study Laboratory, a 57-year-old nonwalker, for whom all conventional means of ambulation assist had been tried at a major rehabilitation center, became a walker through the use of functional electrical stimulation. A pharmacist who suffered a bilateral stroke approximately 3 years ago, he was paralyzed from the neck down and for 6 months was unable to move at all. He gradually regained function of most of his body. Presently he is able to use his left hand well, his right hand to some degree. There is decided weakness in the left leg, and in the right leg he has no function of the hip flexors or the lateral trunk muscles to "hike" the hip. This limitation interferes with his forward progress in walking, because he is unable to bring his foot through. The patient has a double upright ankle-foot orthosis on the right, but he says it doesn't help much. He does have some selective control of the extension of the right knee, though very little at the ankle. He has some control at the hip on the right but it is not as good as the knee. The patient can stand independently—but can only walk backwards. With the assistance of a therapist who advances his right leg for him, he is able to walk forward.

The patient was implanted with intramuscular electrodes in the right iliopsoas and the rectus femoris. A stimulator was made which is turned on with a heel switch. A timer then activates the rectus after an appropriate delay (Figs. 1 and 2). The patient has been given a stimulator for his personal use at home and is clearly able to walk unassisted with the stimulator and a walker frame, though he is totally unable to walk without the stimulator. We believe that this is a type of patient who may greatly improve with electrical stimulation.

Two other patients are currently in the program. Work is continuing in conjunction with Case Western Reserve University and Dr. Hunter Peckham on an implanted version of the stimulator.

A Master's Thesis (1) resulted in the demonstration of ankle, knee, and hip

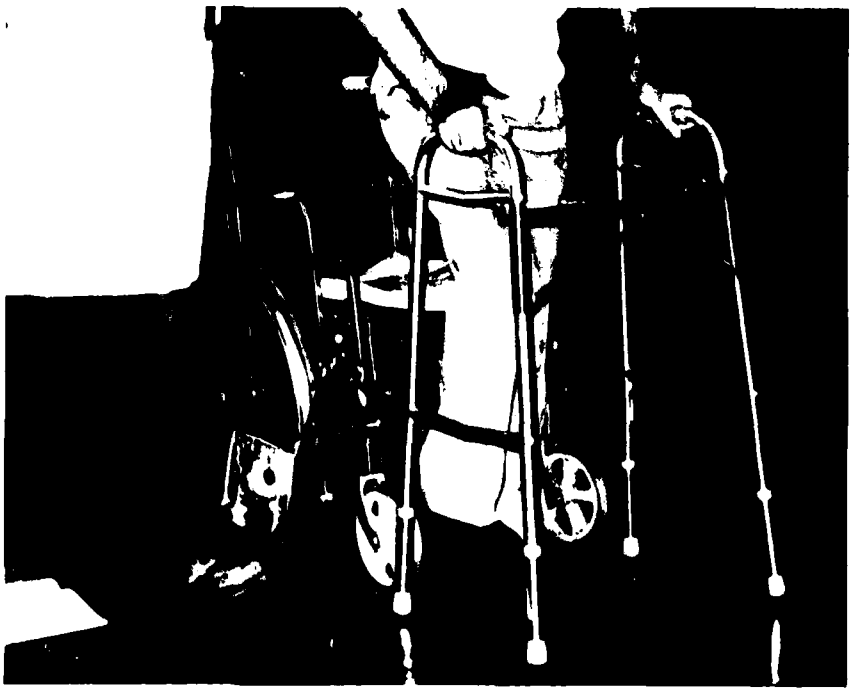

FIGURE 1.
Patient walking with Functional Electrical Stimulator. Right iliopsoas stimulated (hip flexed; knee remains flexed).

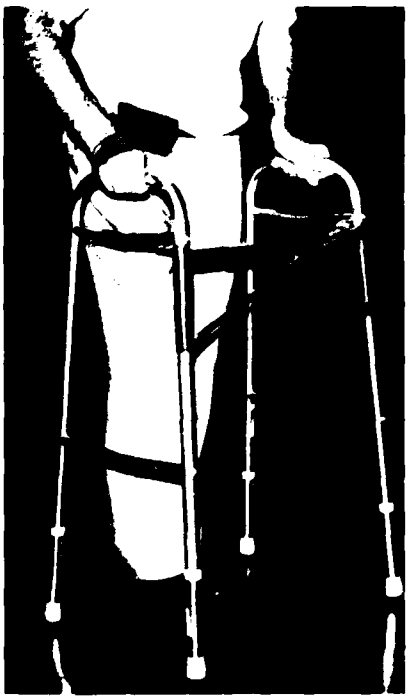

FIGURE 2.
Patient walking with Functional Electrical Stimulator. Right rectus femoris stimulated (hip flexed and knee extended).

kinematics by Selspot with acceptable accuracy. A second Master's Thesis (2) resulted in the upgrading of the joint force estimation capability of the laboratory.

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Prosthetics Research

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Below-Knee Preparatory Prostheses

Direct-casting methods are still being investigated, with continuing experience gained through clinical use of preparatory below-knee prostheses.

Interesting observations are coming to our attention in the comparison of direct-formed (on the patient) socket shape with sockets which have been refined from a number of check socket fittings.

Socket shape and cast modifications are now among the main areas which are under investigation regarding the concept of "total contact" fit.

Clinical use of preparatory below-knee prostheses is progressing. Modifications for Syme's amputation levels have been developed and look promising.

Powered Arm for Shoulder Disarticulation Levels

Work is continuing on a total arm prosthesis for shoulder-disarticulation amputees that utilizes unbeatable position-servo control effected by shoulder motion. A preliminary investigation, analyzing the ability of the normal subject to control the physiological arm and shoulder, has been completed. The results of this investigation have indicated the viability of using shoulder elevation/depression and protraction/retraction to control prosthesis elbow flexion and wrist rotation.

An experimental prosthesis has been built to allow further evaluation of unbeatable position-servo control of prosthesis function. In this system, unbeatable position-servo relationships have been effected by implementing direct cable linkages between the prosthesis activators and a shoulder motion transduction system. The activators incorporated in the prosthesis are the Northwestern University wrist rotator and Liberty Mutual/Boston elbow. Actuator control signals are derived from strain gage force transducers, attached to the linkage cables, that are sensitive to forces derived from shoulder motion. Evaluation of this system is currently in progress.

Hip-Disarticulation Ambulation

A master's thesis has been completed entitled "Pendular Models of the Swing Phase During Gait: The Canadian-type Total Limb Prosthesis." Ambulation data was collected from a vigorous amputee who walked on a Canadian-type prosthesis with a hydraulic knee and on a similar prosthesis with a constant friction knee. Comparisons showed substantial differences in the kinematics of walking with these two prostheses. The amputee under study walked about 10 percent faster on the prosthesis with the hydraulic knee than with the constant friction unit. Angle-angle diagrams (hip angle vs. knee angle) were determined for both conditions.

Pendular models (mathematical) were made of the limbs, and the model response under gravitational influence was compared with walking responses. The results indicated that the swing time of the prosthesis as used by the amputee was much shorter than the swing-time of the model under gravitational influence. This result is consistent with conventional wisdom which states that the prosthesis is forced considerably during gait by the hip flexion stop and by accelerations in the hip region.

Redistribution of prosthetic mass in the models indicated that such attempts in prostheses would probably not be practical for reducing natural oscillation periods.

Models showed that the knee flexion achieved during swing-through by the amputee during gait was not sufficient to produce toe clearance of the floor. Consequently, compensatory floor clearance actions were necessary during gait.

Lower-Extremity Amputation: Immediate Postoperative Fitting of Prostheses

Vascular Surgery Section
VA Medical Center
Tucson, Arizona 85723

James M. Malone, M.D., Wesley S. Moore, M.D., and Joseph M. Leal, C.P.

Due to funding changes and hiring freezes, there was a large lag time for active research productivity in our project. We have just recently recruited a new research prosthetist and have added several new areas of investigation to our prior work. In addition to continuing to evaluate use of Xenon isotope to measure skin blood flow for amputation level selection, and the use of immediate postoperative prostheses for amputation rehabilitation, we are also beginning to evaluate (i) skin temperature as it relates to prosthetic design and environmental factors, and (ii) new prosthetic materials which may contribute to more durable lightweight prostheses, especially needed by geriatric amputees.

We have begun preliminary evaluation of Scotch-cast® (water-activated

polyurethane on fiberglass) for construction of immediate postoperative and temporary lower-extremity prostheses. This material has a large amount of promise, both with respect to prosthetic costs and for rehabilitation of patients with limited physical strength.

We are beginning our evaluation of the feasibility of a regional referral amputation center within the VA system of medical centers.

Upper-Extremity Amputation: Immediate Postoperative Conventional, Electric and Myoelectric Prostheses

Vascular Surgery Section
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James M. Malone, M.D., Joseph M. Leal, M.D., and Sandra J. Childers, B.A.

Since our last report, we have tripled the number of amputees treated with immediate postoperative prosthetic devices after traumatic or elective upper-extremity amputation. Although our group of patients is still small, our initial conclusions would suggest significant improvement in patient prosthesis use and two-handed function, and a decrease in pain and phantom limb problems. In addition, for those patients who were working prior to their injury, we have been extremely successful in returning them to a working environment.

We have been working with manufacturers of various powered prosthetic devices in order to incorporate changes which will allow many of the components to be interchangeable.

Due to funding changes and hiring freezes there was a lag in our program; however, we have just hired a new research prosthetist and expect to be back in full swing very shortly. At the present time, we are making plans to formulate a prospective randomized study which will compare conventional and externally powered components when applied as immediate postoperative prostheses after upper-extremity amputation.

Evaluation of Peripheral Vascular Disease by a Real-Time Multispectral Imaging System

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Victor J. Anselmo, Ph. D.

Scope and Goals

The goal of this research is the development of an imaging system for diagnostic and prognostic evaluation of peripheral vascular disease associated with inadequate limb circulation. As described in our previous report, we are developing a television display technique that utilizes up to three separate simultaneous images of the affected limb, each taken through a photographic filter selected to optimize display of specific deficiencies in selected elements of the cutaneous and subcutaneous vascular arborizations.

At this point, we are approaching completion of photographic data that will provide a baseline suited to the selection of these filters, and at the same time, engineering specifications are being prepared for the electronic data acquisition and image processing system. Final specifications of the electronic processing will be based upon analyses of the baseline data acquired in normal subjects and patients with vascular disease.

Accomplishments in Reporting

Two photographic protocols have been tested. In each case, black-and-white film images have been subjected to initial computer evaluation. Enlarged prints of each negative have been prepared to provide a complete library of the negatives taken with green, red, and infrared filters. These prints are useful in preliminary data evaluation and in controlling lighting parameters.

Photographic Protocol A—This protocol has been used for the study of eight normal subjects and nine patients with vascular disease. It involves the following sequence:

1. Sphygmomanometer cuff placed at midthigh (deflated).
2. Patient rests for 15 minutes.
3. Reference photos taken with green, red, and infrared filters.
4. Cuff pressurized to 50 mm Hg above systolic blood pressure. Pressure maintained for 5 minutes.
5. Reference photos taken before release of cuff.
6. Upon release of cuff, photographic sequence started with pictures at 0, 5, 10, 15, 30, 45, 60, 90, 120, 150, 180 . . . to 300 sec; 1 picture/min to 10 min; 1 picture every two minutes from 10 to 20 minutes.
7. Take Doppler records of systolic pressure and wave from recordings at knee and ankle (elapsed time 5 min).
8. Take photographs of dependent leg at 30, 45, and 60 sec after sitting up.

This sequence demanded excellent coordination on the part of the photographer to secure three images with three cameras at short intervals in the first 5 minutes of the sequence after deflation of the cuff.

Photographic Protocol B—Following preliminary data analyses, it became apparent that vascular changes following the ischemic challenge were periodic in character, with a solitary change in the optical density (reflectance) as a fraction of time over the 20 minutes of the photographic sequence. These first analyses have suggested that a faster photographic sequence would be desirable, and a modification of Photographic Protocol A has now been tested. In most aspects, the sequence is the same as in Protocol A, but the photography is confined to the green filtered image. After the reference sequences preceding and following the cuff inflation for 5 min, photographs are taken every 10 sec for 20 min. To accommodate all the picture frames (totaling approximately 140) on a single roll of film, a motorized camera back is used. There have been four subjects in the initial group using this protocol, two controls and two patients.

Preliminary data analyses of records from Protocol A, using reflectance from the region of the knee and from the lower portion of the leg, shows strong

periodicities that decrease in amplitude and frequency with the passage of time to the completion of recording at 20 min. However, the large changes in sampling intervals between the beginning and the end of these records under Protocol A carry a major risk of aliasing of high frequency data, particularly for sequences between 10 and 20 min. We are therefore making a major effort to complete similar analyses from film sequences under Protocol B, where the 10-sec sample interval will be adequate to evaluate high and low frequency components of these reflectance records from the beginning to the end of the recording epoch.

Plans and Goals

Spectrophotometry and correlated photography through special filters will be performed on blood samples transillumined with light identical with sources to be used in operating the TV data acquisition system. These blood samples will first be equilibrated with a series of gas mixtures having progressively lower oxygen tensions within the expected physiological tissue oxygenation range. This study is necessary in the selection of the vidicon tube to be used in the video converters.

A further baseline of normal subjects and patients with arterial disease will now be established using Photographic Protocol B, extended to a trispectral photographic imaging already tested under Photographic Protocol A.

Progress in baseline data acquisition is now approaching a point where adequate information will be available for the implementation of the electronic engineering phase of the project. This will require a substantially higher level of scientific effort in coordination of biochemical, biophysical, and engineering phases of the project. This expanded commitment will be the subject of a further research proposal in the next 90 days.

Instrumentation for Clinical Investigative Engineering Center

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Work was started to design and construct instrumentation for the Clinical Investigative Engineering Center. The laboratory will be used to conduct clinical investigations, the immediate technical focus of which will be in the area of locomotor impairments. The primary goal is to enable clinicians to employ objective techniques to (i) help make choices in prosthetics and orthotics treatment and methods, (ii) measure progress and efficacy of therapy, and (iii) evaluate new and untested components, appliances, and treatment techniques. The secondary and longer-range goal is to enable development of clinically deployable instrumentation to measure variables associated with gait and having an impact on improvements in locomotory function. To reach these goals, engineering objectives include the provision of instrumentation which (i) is reliable and relatively trouble free, (ii) is convenient to use, and (iii) presents data derived from measurements shortly after testing, formatted in a manner easy to interpret and understand.

The first phase instrumentation is modest in scope and is patterned after successful designs employed at various facilities engaged in locomotion studies. Four categories of gait variables were chosen. They include: (i) detection and indentification of joint movement deviations occurring bilaterally, using electrogoniometry, (ii) limb loads and loading rates using load-sensing sandals, (iii) instantaneous forward velocity using a tachograph, and (iv) mechanical work done during walking using accelerometers. Signal processing and data display will be done using a Commodore Business Machine "PET" microcomputer.

Substantial progress has been made. An electronics technician was hired after certain restrictions from the Federal hiring freeze were eased. Mechanical designs were prepared and fabrication of the mechanical components is about 70 percent complete. Orders were processed for electrical supplies and for equipment; received to date are about half of the supplies but none of the equipment. The construction of a barograph was completed. Experience is being gained in the acquisition of plantarbarograms of patients having foot disorders secondary to diabetes.

Evaluation of Physiologic Suspension Factors in Below-Knee Amputees

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Our work to date has identified physiologic suspension factors at the below-knee level of prosthetic substitution, has established protocols for their measurement, and has begun to investigate their significance. (See our progress reports in BPR 10-33, 10-34, 10-35.) Muscle activity properly captured in this socket design can enhance the physiological components of suspension and stability. Physiologic suspension, between the residual limb and the prosthetic socket, results directly in improved proprioception. Better proprioception provides better control of the limb particularly at night or on uneven ground or during any situation where visual feedback is limited. The goal is not necessarily to produce suspension by the physiologic factors alone but to improve the existing suspension and proprioception through a sustained intimateness of fit.

We are studying below-knee amputees in order to determine the statistical significance of the various suspension factors. A multiple regression analysis has been performed to establish the relationship between the measured suspension factors and the suspension performance. These analyses will enable us to identify which factors are most important to suspension performance, which factors are improved by training, and finally, what final suspension performance can be predicted for an amputee based on measurements of his suspension factors before training.

Methods

At this time we are measuring all below-knee amputee patients who are ambulatory in their prostheses without skin

problems, in conjunction with the prosthetics clinic at the Seattle VA Hospital. Using our protocol, we have evaluated both conventional and myoplastic residual limbs.

Our evaluations consist of an activity profile questionnaire to establish the level of activity available to each individual (Appendix A), a series of measurements of socket and residual limb suspension factors, and measurement of the suspension performance of the prosthesis. Selected patients are also measured stereophotogrammetrically for limb and socket contours.

The socket and residual limb suspension factor measurements are as follows:

1. Limb length, L in centimeters, from the distal aspect of the patella to the distal tip of the residual limb.
2. Gastrocnemius circumference, G in centimeters, measured at the apex of the distal medio-lateral muscle bulge.
3. Medio-lateral expansion, E in centimeters, measured in the distal stump, upon contraction of the residual gastrocnemius muscle mass.

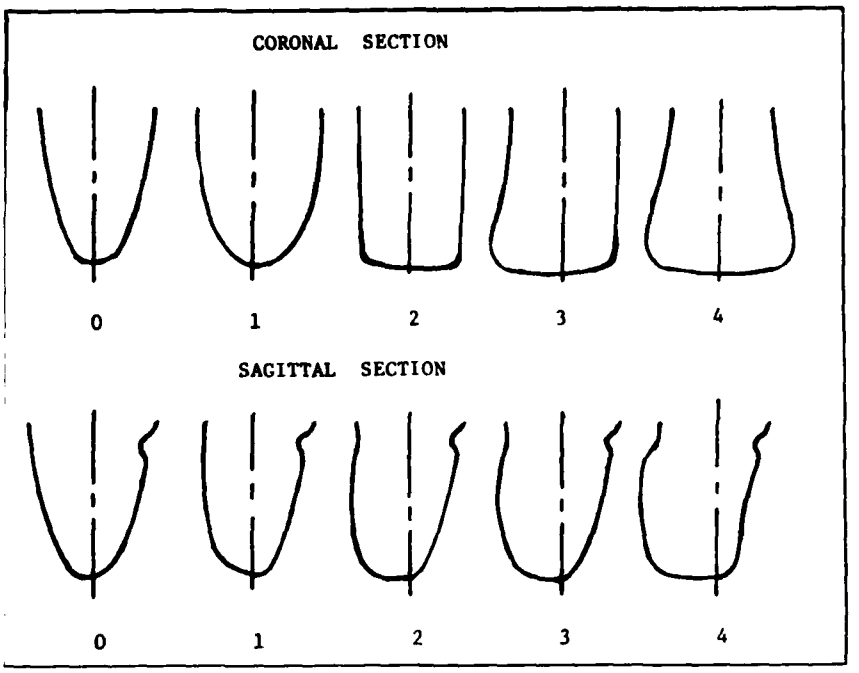

FIGURE 1.
Limb contour factor subjective rating scale.

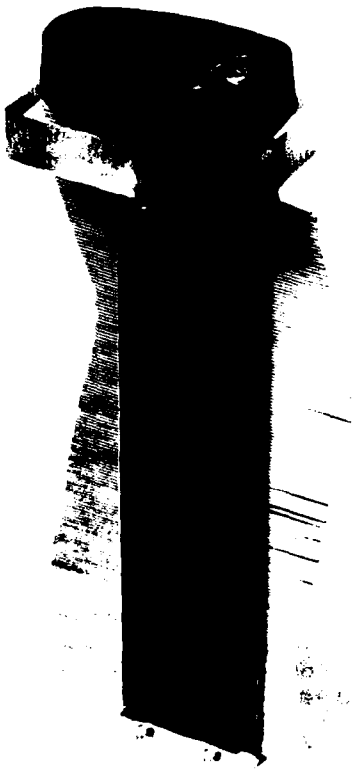

FIGURE 2.
Socket contour replication device.

4. Compliance (the amount of compression), F in centimeters, induced when the contracted muscles at the point of the expansion measurement are subjected to a compressive force. The amount of compression is inversely proportional to the firmness of the contracted musculature.

5. Skin motion, M in centimeters, the maximum amount of vertical motion possible between the skin and the bony structure of the residual limb. It is measured by palpation of the anterior medial face of the tibia.

6. Limb contour (the degree of taper or bulbousness in the shape of the residual limb). Two methods are used for the evaluation of this parameter. One approach matches contour tracings of the limb to weighted cases, and sums the resulting scores to produce a contour factor C_1 (Fig. 1). The other approach fits a third-order polynomial curve to photogrammetrically derived contours of each aspect of the residual limb, and produces a contour index C_3 from the sums of the resulting slopes.

7. Socket contour, similarly to the limb contour index, the qualitative judgement C_2 is based on tracings of the socket made with a special tool adapted for that purpose (Fig. 2). A mathematical description is fitted to the contours of a positive model of the socket to produce contour index C_4.

8. Interference D (a measure of the relative fit in the distal medio-lateral dimension between the residual limb and the prosthetic socket). It is expressed in centimeters, with a plus value indicating tightness.

9. Interference P, similar to above except that it relates to the narrowest place existing in the socket, usually between the levels of the distal muscle bulge and the fibular head.

The suspension performance of the prosthesis is evaluated from measurements of pull-off force versus displacement as the subject pulls straight up. The device used to make these measurements was previously reported in BPR 10-33. Figure 3 illustrates the following characteristics:

1. Suspension stiffness, S in Newtons/cm., is a measure of the effectiveness of the interface between residual limb and prosthesis. This factor is measured at the point where the force passes from weightbearing to tensile in nature.
2. Maximum retention force, P in Newtons, is an indication of how the muscle contours interact with the contours of the socket in their most advantageous position. This force occurs at an average slippage of 3 cm.

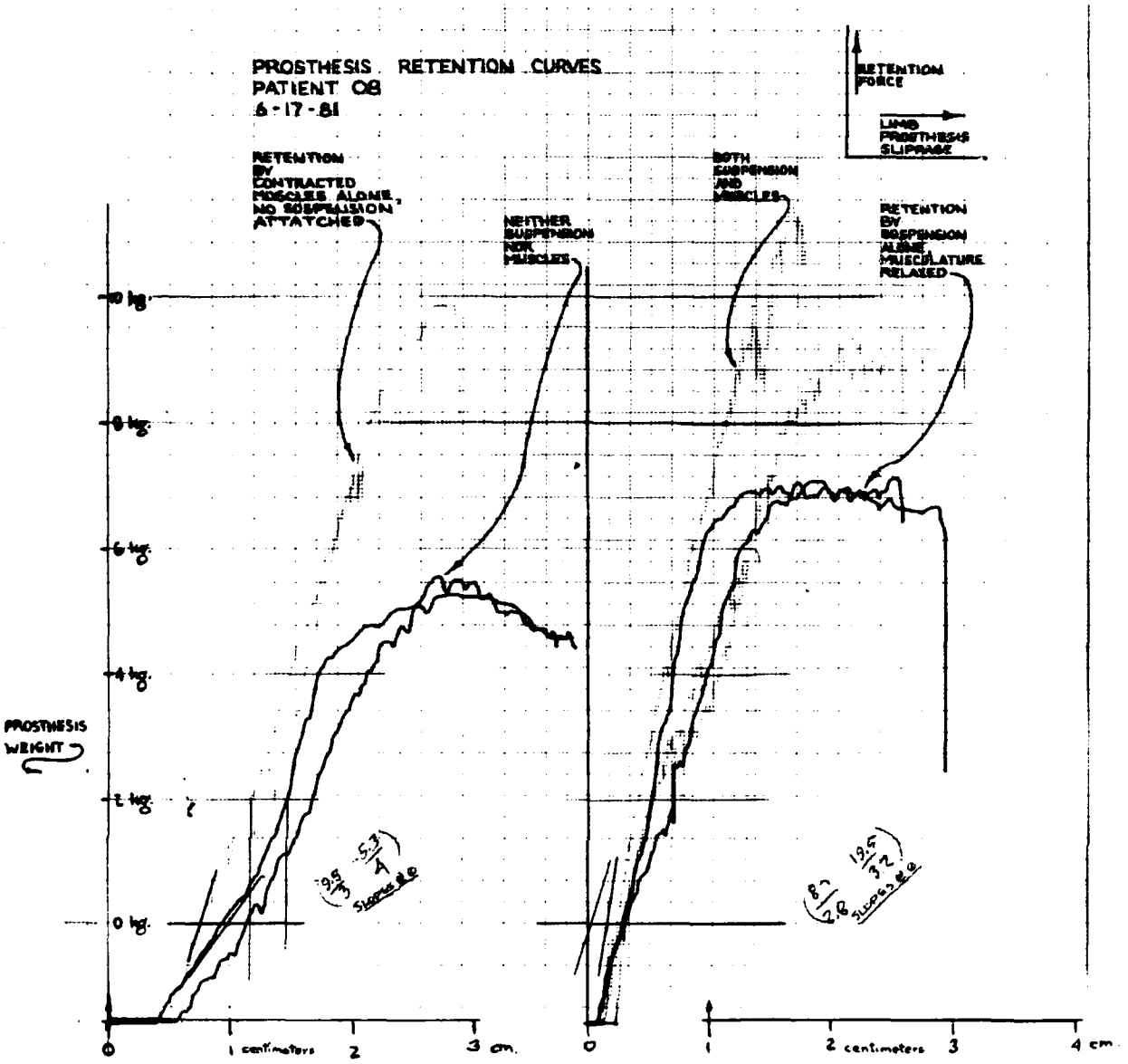

FIGURE 3.
Retention-testing device, data output curves.

Figures 4 and 5 illustrate a subject's suspension performance being evaluated. The device on which his foot rests measures the forces, and the linear displacement transducer is strapped to his leg.

Results

Data collected on 17 subjects are presented in Table 1. These subjects were randomly selected from the prosthetics clinic and received no special training or prosthesis modifications in order to maximize their physiologic suspension. The purpose was to develop methods for evaluating suspension factors and performance, and to fit preliminary multiple linear regression equations to the data. The blanks in the table indicate subjects who were measured early in the program and were unavailable for re-evaluation as more suspension factors were added to the study.

In the statistical treatment of the data, the measured suspension performance (i.e., the stiffness or maximum force values) is assumed to be a dependent variable which is a function of the independent variables (the suspension factors). A computer program generates the coefficients for an equation of the form:

$$S = A_0 + A_1 L + A_2 G + A_3 E + A_4 F + A_5 M + A_6 C_1 + A_7 C_2 \quad [1]$$

(where S, L, C, etc. are as defined in Table 1.)

This is a linear equation because none of the suspension factors are raised to a higher power. The coefficients A_0, A_1, etc. are determined so as to give the smallest difference between the value for suspension stiffness predicted by the equation and the actual measured value. The magnitude of this difference is indicated by the standard error of the estimate, s, which is calculated for each equation. The degree to which suspension performance is linearly related to the suspension factors is called the coefficient of multiple correlation, R^2. This term has a value of 0 if there is no linear correlation at all, and a value of 1 if there is perfect linear correlation. A low value indicates that possibly a non-linear relationship exists between the variables.

Using patients 1–11 the following

equations were determined:

$$S=(-316.5 + 3.47\,L + 9.22G - 8.06\,E + 89.5\,F - 15.96\,M + 1.4.02C_1 - 5.40\,C_2)\ N/cm \quad [2]$$
$$s = \pm 29.4\ N/cm,\ R^2 = .887$$

and,

$$P= (83.9 + 1.29L - .27G - 24.0\,E - 53.2F - 11.57\,M - 12.84C_1 + 20.58\,C_2)\ Newtons \quad [3]$$
$$s = \pm 23.4\ N,\ R^2 = .873$$

Equations [2] and [3] indicate some interesting facts about the sample population. Limb length correlates positively with both suspension stiffness, S, and maximum axial force, P. Gastrocnemius circumference has a large positive correlation with stiffness and a small negative correlation with maximum force. Expansion correlates negatively with performance, with a larger reduction to the maximum axial force. We feel this is due to the prosthetic sockets' lack of modification to take advantage of the muscle expansion, causing an "ejection socket" effect. Compliance contributed positively to suspension stiffness, but correlates negatively to maximum force. Skin motion has a negative correlation with performance (the less, the better). Finally the contour factors apparently have contradictory effects on performance. We feel this is because the socket

SUBJECT NUMBER	L Limb Length cm.	G Gastroc. Circum. cm.	E Expansion cm.	F Compliance cm.	M Skin Motion cm.	ID Interference D - cm.	IP Interference P - cm.	C_1 Limb Contour Subj.	C_2 Socket Contour Subj.	C_3 Limb Slope Photo-gram cm/m	C_4 Socket Slope Photo-gram cm/m	P Max. Axial Force N	S Suspension Stiffness N/cm
1	15	28	.5	.3	2.0	-	-	5	5	-	-	80	52
2	22	26	-.3	.6	3.5	-	-	5	5	- 1.8	-5.0	60	34
3L	12	29	.3	.8	1.5	-	-	4	7	1.5	-	110	50
3R	17	25	0	.3	1.5	-	-	4	7	.6	-	110	63
4	19	32	.6	.6	3.8	-.2	-.5	5	5	2.2	-3.1	50	78
5	14	34	0	.9	5.0	-.2	-.2	4	4	4.8	-	30	83
6	18	26	.2	.5	1.4	.3	.3	5	6	-	-	150	52
7	15	27	.3	.5	3.0	1.3	.9	4	3	-	-	30	11
8	16	29	.6	.5	1.0	-.2	-.1	4	5	-	-	90	35
9	16	23	.4	1.0	2.3	2.6	.4	1	1	-	-	20	1[illegible]
10	21	31	.6	.7	0.5	-.8	-.5	5	5	1.0	-	80	142
11	13	28	.9	.6	2.0	.9	1.9	6	5	-	-	40	52
12L	14	28	.7	.2	2.4	-	-	-	-	4.9	-	120	162
12R	22	25	.4	.4	2.5	-	-	-	-	2.6	-	160	131
13L	11	27	0	.2	2.4	-	-	-	-	-13.7	-	55	18
13R	16	27	.4	.6	2.7	-	-	-	-	- .8	-	55	13
14	-	-	-	-	-	-	-	-	-	9.0	.6	-	120
15	-	-	-	-	-	-	-	-	-	8.6	-.3	-	95
16	-	-	-	-	-	-	-	-	-	2.4	4.6	-	50
17	-	-	-	-	-	-	-	-	-	1.1	9.7	-	45

TABLE 1.
Master Data Record

contours have not been designed to optimize either suspension stiffness or maximum force.

Patients 2–5, 10, 12 and 17 were used to investigate the relationship between suspension stiffness and the photogrammetric limb contour factor;

$$S = (90.3 - 20.0\,E - 56.4\,F + 5.77\,C_3)\ \text{N/cm} \quad [4]$$
$$s = \pm 22.0\ \text{N/cm}$$

In considering equations 2–4 one should appreciate that they reflect correlations of each factor, not cause and effect relationships, and do not account for other possible factors which might have had an effect. Because each factor in the equation is derived from a different set of dimensions, the magnitude of the coefficients cannot be compared directly. The large standard error is assumed to be caused by the lack of specificity in patient selection and prosthetic modification.

Discussion

The results thus far, even though they lack large numbers, seem to indicate that the initial hypotheses regarding important stump and socket factors are correct. On the basis of the regression analysis, skin motion and socket and stump contour correlate highest with the socket retention factors. This situation suggests that special attention to surgical and prosthetic contouring might further enhance an amputee's physiologic suspension capability. We have referred to this concept previously. Still to be tested is the effect of the specific retention training, using the testing devices described in this report. Later, we

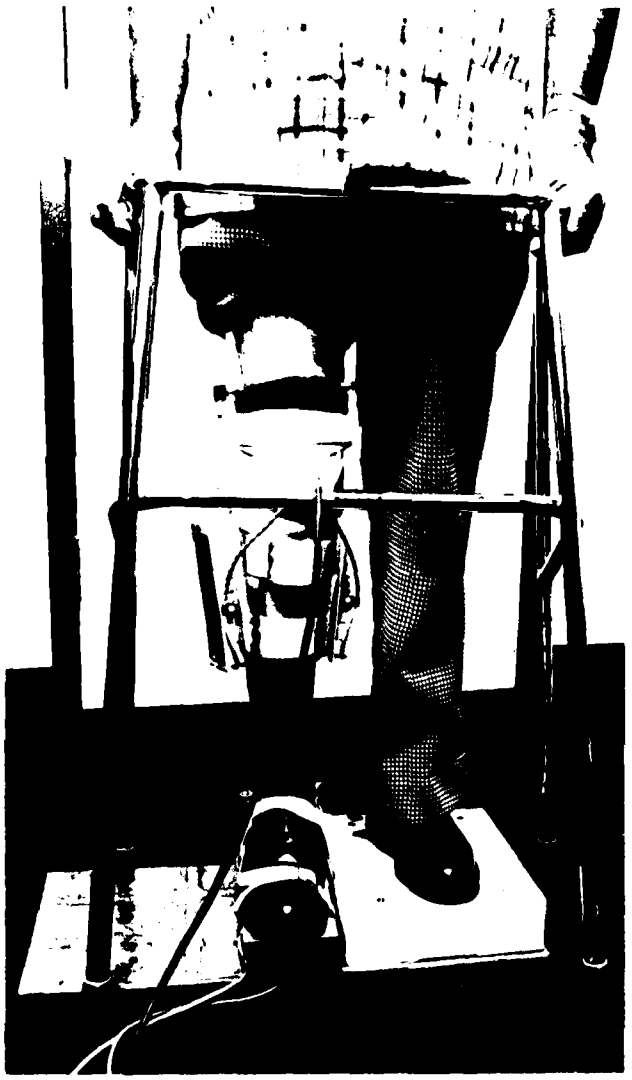

FIGURE 4.
Retention-testing device, front view.

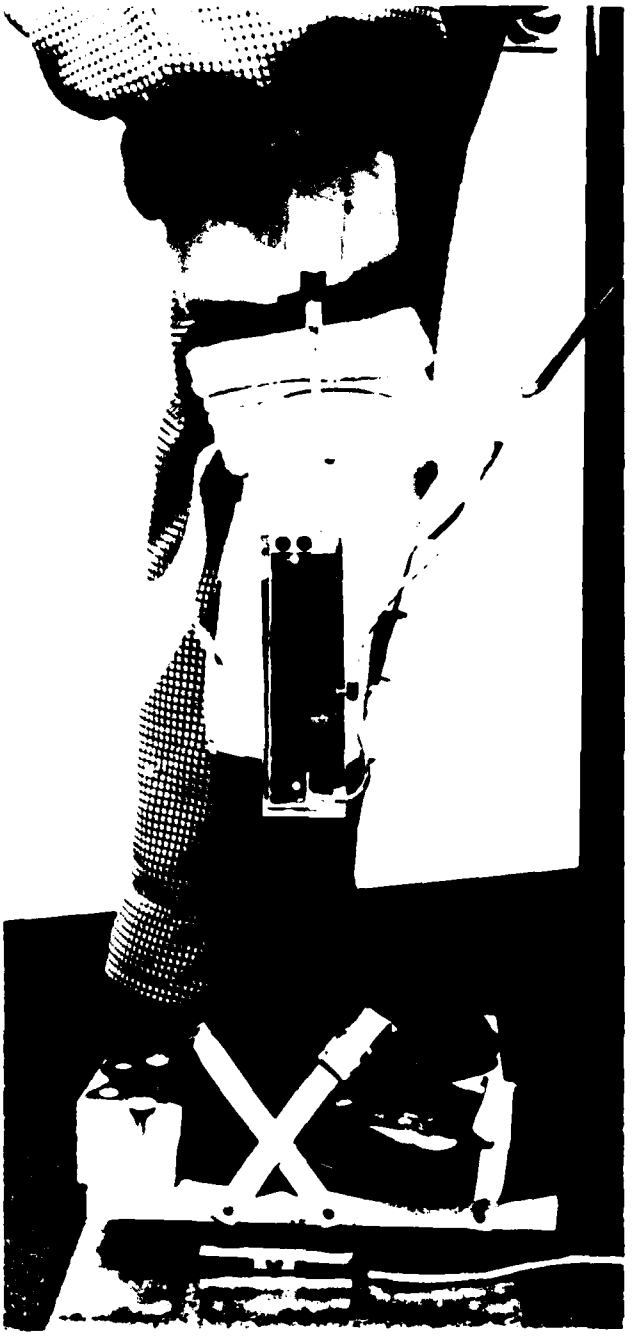

FIGURE 5.
Retention-testing device, side view.

will also explore surgical and prosthetic modifications. Meanwhile, we plan to continue the present study using the protocol described, to gain a larger number of patients and a greater statistical validity. In addition, the activity questionnaire (Appendix A) combined with assessment of gait in the clinic, will establish the relationship of measured suspension performance to real-life performance.

The practical application of these studies is in pinpointing the key suspension factors, especially those that are controllable, which are contributing to physiologic suspension, and in providing a performance protocol which can be used during clinic to follow the amputee's progress.

Summary and Conclusions

1. Suspension factors in below knee amputees have been defined, measured and correlated with suspension performance.
2. The data collection protocol is feasible for outpatient clinic evaluation.
3. Continued refinement of existing data-gathering techniques, and specific attention toward the effects of training and of surgical and prosthetic modification, would appear to be promising.

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APPENDIX: Questionnaire and Consent Form.

UNIVERSITY OF WASHINGTON
Consent Form
Evaluation of Physical Characteristics of Below Knee Residual Limbs to Study Prosthetic Suspension

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Chief, Department of Orthopaedics—206-762-1010 (Extension 396)

Sandor A. Veress, Ph.D., Department of Civil Engineering—206-543-7613

The purpose of this study is to determine those factors which contribute to better prosthesis suspension and thus improved function to you as an amputee. Suspension refers to the attachment of your prosthesis and includes belts, cuffs, wedges, lacers and the action of your residual limb against the walls of the socket. Your participation in this study will be of direct benefit to you in that it will provide an analysis of the function of your own suspension and thus reveal possible ways of improvement.

To obtain this information we use several techniques and types of measurement apparatus. First, you will be asked to complete a questionnaire which provides us with a profile of the activity level, comfort and stability provided to you by your prosthesis. Second, we will measure both your stump and your prosthesis. All measurements cause no discomfort beyond standing on crutches and contracting the musculature in your residual limb. The first measurement utilizes a device which traces the contour of your residual limb to obtain its profile. The second measurement consists of immersing your limb in a water bath to determine its volume. The third measurement requires you to pull upward while wearing your prosthesis which is attached to a force plate to determine the effectiveness of your suspension. The other measurements of your stump and socket will be made with tape measure and calipers to check your fit.

The overall time involved will be about one hour plus, if it is convenient for you, fifteen minutes to stop at the University of Washington so that we can take a three dimensional photograph of your residual limb. (See map attached)

You may decide to omit any questions or any part of this study or not, at your own discretion.

In order to participate, you should be able to keep your balance while standing on your opposite leg, using a walker support, for short periods of time. The risks of the study are possible discomfort and fatigue, and the possibility of a fall. You will be able to rest any time you feel necessary during the course of the measurements. In the unlikely event that a physical injury occurs as a direct result of a study procedure, you will be treated at no cost at the V.A. Hospital.

All information provided by you will remain confidential and you may withdraw from participation at any time without penalty and without jeopardizing your future care. Subjects who drive to the hospital or clinic for the purpose of participating in this study will be compensated on a mileage basis.

_____ _____
Signature of Investigator Date

Copies: Subject
File

SUBJECT'S STATEMENT:

I voluntarily consent to participate in this activity. I have had an opportunity to ask questions. The study as described above has been explained to me.

_____ _____
Signature of Subject Date

VAMC PROSTHETICS RESEARCH
FUNCTIONAL CAPABILITIES QUESTIONNAIRE
PLEASE COMPLETE

NAME_____
SOCIAL SECURITY NUMBER _____ DATE_____
SIDE AMPUTATED?:_____

1. Do you have any medical complications of which we should be aware? (Those which affect your balance, stability, or sensation would be of significance)_____

2. **What is your occupation?**_____

3. **How many hours per day are you on your feet?**_____

4. **How far would you say you walk on an average day?**_____ Blocks/Miles/Kilometers

5. **What percent of your walking is done on smooth surfaces?**
None Very Little Some A lot All

On uneven terrain?
None Very Little Some A lot All

On rough terrain?
None Very Little Some A lot All

In the dark?
None Very Little Some A lot All

6. **How much do you use a cane?**
None Very Little Some Frequently Always

How much do you use crutches?
None Very Little Some Frequently Always

How much do you use a walker?
None Very Little Some Frequently Always

How much do you use a wheelchair?
None Very Little Some Frequently Always

7. **How much difficulty would you say you encountered going up curbs?**
None Very Little Some A lot

How much difficulty would you say you encounter going up stairs?
None Very Little Some A lot

How much difficulty would you say you encounter going up ramps?
None Very Little Some A lot

How much difficulty would you say you encounter going down curbs?
None Very Little Some A lot

How much difficulty would you say you encounter going down stairs?
None Very Little Some A lot

How much difficulty would you say you encounter going down ramps?
None Very Little Some A lot

8. Please assign an **approximate value in hours per week** that you engage in the following activities (if zero, leave blank):
A. RECREATIONAL WALKING_____
B. RUNNING_____
C. SWIMMING_____
D. DANCING_____
E. GOLF_____
F. FISHING_____
G. HUNTING_____
H. SKATING_____
I. ROLLER SKATING_____
J. SKIING_____
K. VOLLEYBALL_____
L. BASKETBALL_____
M. FOOTBALL_____
N. BOWLING_____
O. HORSEBACK_____
P. HIKING_____
Q. OTHER_____

9. **Do you use ladders?**_____ **Do they pose a problem going *up?*_____ *Going down?*_____**

10. **Do you experience phantom sensations in your amputated leg(s)?**_____ **Do you use these sensations when you walk?**_____

11. **Are any areas of your stump(s) usually tender to touch?**_____ **How about right now?**_____

12. **What is the condition of your other leg?**
Normal_____
Some Cramping_____
Limits Activity?_____
*Open sores?*_____
Any pain?_____
*Amputated also?*_____

13. **On a scale of 1 to 10 where 10 is best, how would you rate:**

	Left	Right
A. Your prosthesis	_____	_____
B. The weight of your prosthesis	_____	_____
C. The suspension of your prosthesis (Can you walk with your prosthesis unattached? _____)	_____	_____
D. The intimateness of the fit of your prosthesis	_____	_____
E. The comfort of your prosthesis	_____	_____
F. The stability of your prosthesis	_____	_____
G. The ease of walking with your prosthesis	_____	_____
H. Your ability to tell where your prosthesis is without looking	_____	_____

14. **Do you ever contract the muscles in your stump itself:**
A. To help hold the prosthesis on?_____
B. To make yourself more stable in difficult situations?_____
C. When on stairs?_____
D. When landing on the prosthesis?_____
E. Any other time?_____ Describe_____

15. **Which of the following descriptions best describe your feelings about the foot of your prosthesis?**
A. It is very good
B. It is not as stable as it should be
C. It doesn't walk very smoothly
D. It's not good on uneven terrain
E. It's too heavy
F. It is not very versatile
G. Other

For each of the following areas, select the category or categories which **best** *describe your personal experience.*

1. **With regard to my suspension, when wearing my prosthesis, I feel:**
   A. Very Secure—as if the prosthesis were always a part of me. Even on stairs.
   B. Moderately Secure—The prosthesis feels firmly attached except when walking fast or using stairs.
   C. Somewhat Insecure—Although the prosthesis feels poorly attached, sometimes I can compensate for it.
   D. Quite Insecure—As if I lose contact with the prosthesis, whenever I lift it off the ground, the suspension never gives me a sense of security.

2. **When I bear weight on my prosthesis, I feel that it is:**
   A. Very Stable—It feels stable even on stairs, on uneven terrain, and walking in the dark.
   B. Moderately Stable—It feels stable except on uneven terrain or in darkness.
   C. Slightly Unstable—The leg never gives me a real feeling of stability, even indoors.
   D. Very Unstable—The leg is only moderately stable on smooth surfaces and is very unstable on uneven terrain so that it wobbles and makes balance difficult.

3. **I have the feeling that the prosthesis is a part of me:**
   A. All of the time—I always know where the prosthesis is and rarely if ever have to look at it.
   B. With only some exceptions—I find that in some activities I must watch the foot to avoid tripping.
   C. Sometimes—I find that I frequently look at the foot for safety and would probably not want to walk in the dark.
   D. Not at all—I find myself constantly watching where I put the foot for safety, to avoid tripping, and because there is no other way to judge where it is.

4. **Due to the fact that I wear a prosthesis, I find that in my activities I experience:**
   A. No increase in difficulty, I even feel confident at night and on uneven ground.
   B. Slightly increased difficulty, depending on the situation but nothing that I can't cope with.
   C. Moderate increase in difficulty, the prosthesis requires a significant increase in attention and energy expenditure.
   D. Decidedly more difficulty, the prosthesis causes wobbling, tripping, knee buckling, and/or problems in balance which makes many activities too difficult to consider.

5. **In your own words, please say anything which you would have done differently about your own prosthesis.**_____

_____

_____

_____

_____

A Program to Improve Efficiency and Reduce Risks for Wheelchair Locomotion

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We have recently completed three studies which relate to the physiological stresses of wheelchair locomotion and wheelchair design. One study compared the metabolic and cardiopulmonary responses of eight geriatric ($\bar{x}$ = 62 yr) wheelchair-dependent (WD) and 10 geriatric ($\bar{x}$ = 58 yr) ambulatory (AMB) patients during locomotion (1). WD subjects propelled their wheelchairs, and AMB subjects walked, on a level tiled surface for 5 minutes at their preferred velocities. During the last minute of each locomotive bout, oxygen uptake ($\dot{V}O_2$), pulmonary ventilation ($\dot{V}E$), and heart rate (HR) were determined (2). These procedures were repeated twice for a total of three trials.

Mean results for the two groups of patients were as follows: velocity = 2.0 and 3.1 km•hr^{-1}; $\dot{V}O_2$ = 0.535 and 0.814 l•min^{-1}; $\dot{V}E$ = 19.4 and 26.2 l•min^{-1}; and HR = 95 and 92 bpm during wheelchair locomotion and walking, respectively. Similar HR values for wheelchair locomotion and walking tend to suggest comparable relative stress for these activities. When taking into consideration that wheelchair locomotion (arm exercise) elicits peak $\dot{V}O_2$ values that are approximately 30 percent lower than those for walking (leg exercise), it appears that both groups performed at a similar percentage of their peak aerobic power. The 37 percent lower velocity for wheelchair locomotion as compared to walking should be taken into consideration when scheduling activities for these patients.

The second study compared metabolic and cardiopulmonary responses of geriatric patients during wheelchair propulsion utilizing conventional handrim stroking and arm cranking (3). Seven volunteers ($\bar{x}$ = 61 yr) each operated their own conventional handrim wheelchair as well as a wheelchair incorporating an arm-crank propulsion system. During three 5-minute test bouts on a level tiled surface, their preferred velocities were determined by an electronic speedometer. $\dot{V}O_2$, $\dot{V}E$, and HR were determined during the final minute of each test (2). Mean preferred velocity was found to be 2.1 and 2.8 km•hr^{-1} for the conventional and arm-crank wheelchairs, respectively. During locomotion at these velocities, respective $\dot{V}O_2$ was 0.555 and 0.560 l•min^{-1}; $\dot{V}E$ was 20.3 and 20.8 l•min^{-1} and HR was 94 and 90 bpm. When the arm-crank wheelchair was operated at the same velocity as the conventional wheelchair (2.1 km•hr^{-1}), $\dot{V}O_2$ and $\dot{V}E$ were 11 percent lower and HR was 8 percent lower. The equality of $\dot{V}O_2$ for operating these wheelchairs at the preferred velocities suggests that the selection of velocity was based upon absolute metabolic demands. The 33 percent higher velocity for the arm-crank wheelchair and the lower HR values at this velocity indicate that this form of locomotion is more efficient. This is further supported by the lower physiological responses observed during operation of the arm-crank wheelchair at the same velocity as the conventional wheelchair.

It is also interesting to note that the WD subjects using the arm-crank wheelchair had preferred velocities that were similar to the AMB subjects during walking in the above study.

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The third study compared the physiological responses of 9 AMB and 7 WD volunteers to conventional and arm-crank wheelchair propulsion (4). Both wheelchairs were operated for 5 minutes at 3.0 km·hr^{-1} on level tiled and carpeted surfaces. The arm-crank-propelled wheelchair was operated in 3 gear ratios—low, medium and high. During the final minutes of each test $\dot{V}O_2$, $\dot{V}E$ and HR were monitored (2). These physiological responses were significantly lower during arm-crank wheelchair propulsion for all gear drive ratios on each surface. Average percent differences were as follows: 30 percent and 33 percent for $\dot{V}O_2$; 27 percent and 34 percent for $\dot{V}E$; and 16 percent and 19 percent for HR, on the tiled and carpeted surfaces, respectively. In absolute terms, these responses were lower for the arm-crank wheelchair on the carpeted surface than for the conventional handrim wheelchair on the tiled surface. As with the aforementioned study, these results indicate that arm-crank wheelchair propulsion is less stressful than conventional handrim wheelchair propulsion at given velocities. Both of these studies suggest that arm-crank propulsion systems could be used to improve wheelchair design and thereby improve patient rehabilitation.

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The Mechanical Properties of Porous Coated Orthopaedic Alloy

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Objectives

Although existing designs of total joint replacement have proved extremely successful, it is generally recognized that the chances of failure increase with time. Foremost among the causes is a loosening of the prosthesis, causing pain and ultimately necessitating reoperation. In order to avoid this, a great deal of research has been conducted upon improving the fixation of orthopaedic implants to their surrounding bones. The most favoured approach involves the use of a porous surface upon the implant to allow the bone to mechanically interlock with the implant. Even though this method has been demonstrated to produce good fixation, very little attention has been directed towards the effect that applying a porous coating to a solid substrate has upon the mechanical properties of that material. This question is obviously important if failure of a prosthesis by loosening is not to be replaced by mechanical failure. From an engineering standpoint, the application of a thin porous coating may affect the substrate in two ways—(i) the introduction of surface flaws enabling fatigue cracks to be more easily initiated, and (ii) the high temperature typically required to attach the porous coating to the substrate may severely impair the mechanical properties of that alloy.

This research project is designed to investigate the extent to which the application of a porous coating compromises the mechanical properties of a cobalt-base alloy. In this way, it is intended that the long-term aim of producing orthopaedic implants capable of extended service lives will be furthered.

Background

The use of metallic prostheses in the treatment of degenerative diseases, together with their use in the reconstruction of joints in trauma victims, has increased greatly in the last 10 to 15 years. A survey of Total Hip Replacement (THR) operations indicates that in the United States in 1976 approximately 80,000 total hip joints were implanted (1). At the same time, however, it is becoming recognized that the current designs offer only a limited service life, after which a reoperation may be necessitated. For this reason, many younger patients are being urged to forgo treatment until a later age.

In an attempt to improve upon this situation, a great deal of research has been concerned with developing a truly permanent prosthesis. That research has concentrated upon the areas of implant design and fixation. To be successful, a prosthesis must not only be able to withstand the stresses imposed upon it by the body but must also be able to impose upon the body stresses compatible with the maintenance of adequate bone stock. In this way, the surrounding bone continues to support the implant and thereby minimizes the danger of mechanical failure.

At present, orthopaedic implants are attached to the skeletal system by either a tight fit or use of a polymethyl methacrylate grouting agent. The latter technique has gained widespread acceptance, since it offers the possibility of immediate fixation for a large range of applications. It is generally considered a slowly-failing system, however, due to eventual failure of the cement resulting in implant loosening. The most promising new approach to implant fixation is the use of a porous coating upon the solid implant, a system which allows bone to grow into the surface and thereby provide a mechanical interlock.

The concept of using a porous surface to aid fixation of an implant is not new, having been introduced by Klawitter (2) in the late 1960's. Since then, the efficacy of this approach has been demonstrated by frequent clinical trials. These have shown that, provided a suitable pore structure is available, viable bone will grow into the implant (3). Indeed, at least two designs of THR are available commercially in which a porous surface is provided for implant fixation. Both of these, however, are of a comparatively simple shape and unlikely to find widespread acceptance.

The optimum pore structure for implants has been examined by a number of authors (4–6). Clemow et al (6) has indicated that, from a mechanical strength standpoint, the optimum pore size lies with the range 100—200 μm.

A large number of candidate materials have been examined for use as po-

rous implants, including ceramics (3), carbons (7), polymers (8, 9), and metals (6, 10, 11). Within this latter category, only two major groups of alloys, titanium and cobalt-based alloys, have been found to satisfy the major criteria of corrosion resistance, mechanical strength and biocompatibility. Stainless steel, although used extensively as a surgical implant material, is not suitable for porous coatings due to its insufficient corrosion resistance associated with the increased surface area of the metal (10).

Of all those materials which may be categorized as biomaterials, possibly the most successful (apart from the precious metals) is that alloy known variously at Vitallium, HS21, or Co-Cr-Mo Alloy. The alloy was developed in 1929 for use in dentistry where its excellent corrosion resistance and ease of casting could be utilized. Since that time, Co-Cr-Mo alloy has been used in jet engines and, more recently, in the field of orthopaedics. Surprisingly for an alloy with such a long life, a basic understanding of its physical metallurgy has only recently been achieved.

For the majority of purposes, Co-Cr-Mo alloy is fabricated by investment casting since this technique offers the advantage of excellent dimensional accuracy. The resultant product is generally referred to as being in the as-cast condition. As such its microstructure consists of a cored dendritic structure with an interdendritic dispersion of carbides. Until recently Co-Cr-Mo alloy was used in this as-cast condition. However, it was found that, by subjecting the alloy to a short high-temperature heat treatment, its ductility could be increased sufficiently to ensure passage through ASTM standard F-75. The reactions extensively studied by Clemow and Daniell (12), have been shown to consist of a series of carbide transformations preceding their dissolution into the matrix phase. As a result, a number of varied microstructures may be observed depending upon the time and temperature employed.

Due to its inherent importance with regard to the performance of total joint prosthesis, the mechanical properties of Co-Cr-Mo alloy have been examined by a number of investigators (13). The fatigue properties of the alloy have been examined by Miller, Rostaker and Galante (13) and Devine and Wulff (14). The former authors derived S-N curves to show that there existed, at the 95 percent confidence level, a chance that 0.1 percent of the specimens would fail when stressed for 5×10^7 cycles within the cyclic range of 6,900–46,500 p.s.i. This corresponds very closely with the results of Devine and Wulff (14) even though different techniques of testing and environments were used. Both reports, however, stress the importance that non-metallic inclusions and gas porosity have in determining the true fatigue strength of a specimen.

The influence of heat treatment upon the mechanical properties of Co-Cr-Mo alloy is confusing, with diverging results being reported.

Hollander and Wulff (15) have shown that by using a solution treatment program of 1280 degrees C for 2 hours, a substantial improvement in elongation, together with a slight improvement in yield and ultimate tensile strengths may result. Later work at the same institution, reported by Cohen, Rose and Wulff (16), indicates that by judicious use of heat treatment, a substantial improvement in all three properties may be obtained. Unfortunately, no fatigue properties are available for comparison.

Dobbs (17) found that the use of a solution treatment of 1250 degrees C for 2 hours caused a substantial decrease in mechanical properties. A probable explanation for this behavior is that the higher temperature used caused complete dissolution of the carbides and allowed extensive grain growth to occur once the grain boundaries were freed of any obstacles to motion. A similar anomaly was reported by Clauss, Garrett, and Weeton (18) in the early 1950's, when Co-Cr-Mo alloy was still being used in jet engines.

It is this danger of excessive grain growth, caused by a solution treatment at temperatures high enough to allow carbide dissolution, which constitutes the basis of this research project. Should this growth occur during the attachment of a porous coating, then the mechanical properties of the substrate would be severely compromised, and the possibility of fatigue failure in vivo increased.

As stated earlier, in order to obtain satisfactory growth of bone into a coating, it is necessary that a pore structure of at least 100 μm be provided. In order to achieve this, three methods of fabricating coatings have been used:

1. Gravity compaction in which spherical powder is allowed to settle around the substrate while being held in shape by a ceramic mold. The whole assembly is then heated to ensure proper sintering of the powder (19).

2. A binder technique in which an organic binder such as methyl cellulose is used to adhere the particles to the substrate. The binder is burnt off at high temperature when, as above, sintering of the particles occurs (11).

3. Thin wires of the desired material are mechanically kinked, pressed into the desired shape and sintered together (20).

An obvious similarity between all three methods is the use of a high temperature sintering period to achieve mechanical integrity. The temperature needed was found by Klawitter, Weinstein and Peterson (19) to depend upon the size of the particles being used—the larger the particles, the higher the temperature. For particles of 104–149μm diameter, a temperature of 1310 degrees C for 3 hours was required, while for particles of 420–595 μm diameter it was necessary to raise the temperature to 1330 degrees C. This is consistent with the results of Weloch, Pilliar, and McNab (11), who sintered Co-Cr-Mo alloy particles at 1200 degrees C, but in their case the diameter of the sphere was only around 4.4 μm. Such a size is unlikely to result in a pore structure large enough to allow adequate bone ingrowth.

It is apparent, therefore, that in order to produce a porous surface having a large enough pore size, it is necessary to use a sintering temperature in excess of 1300 degrees C. Since carbide dissolution in Co-Cr-Mo alloy occurs at 1210 degrees C and above, the sintering process introduces a substantial danger of complete carbide dissolution leading to massive grain growth and a substantial alteration in mechanical properties of the material.

The objective of this research project is to examine the extent to which the application of a porous surface influences the fatigue properties of implant grade Co-Cr-Mo alloy.

This work will consist of the following four stages—(i) Examination of the influence upon the microstructure of the addition of a porous Co-Cr-Mo alloy coating to a solid substrate, (ii) Determination of the fatigue properties of as-cast and heat treated Co-Cr-Mo alloy, (iii) Determination of the fatigue properties of porous coated Co-Cr-Mo alloy, and (iv) Examination of the relationship between microstructural changes and fa-

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Rehabilitative Engineering Research Program

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Amputee Survey

The objective is to define the population of amputees served by the San Francisco VAMC and identify the nature of any problems they are experiencing in obtaining prosthetics care.

To date questionnaires have been received from 176 (70 percent) of the original 251 amputees sampled. Of the nonrespondents, 12 were deceased, 22 could not be reached by mail or phone, and 41 did not respond for reasons unknown. Analysis of the available date yields the following statistics:

Type of Amputation	Number	Percent
Below Knee	98	55.7
Above-Knee	46	26.1
Syme	4	2.3
Knee Disartic.	1	0.6
Hip Disartic.	1	0.6
Bilateral	26	14.8
BK/BK	13	7.4
BK/AK	10	5.7
AK/KD	1	0.6
AK/AK	2	1.1
Cause of Amputation		
Trauma	129	73.3
Vascular	44	25.0
with Diabetes M.	17	9.7
without Diabetes	27	15.3
Tumor	3	1.7

Thirty-four of these respondents have been evaluated in the laboratory, with a goal of 50 evaluations to be completed by October 1981. The survey evaluation includes a physical examination, short medical history, prosthetic evaluation, subjective and objective gait analysis, videotaping, and discussion of the amputee's problems and needs regarding his prosthesis.

Evaluation of these 34 amputees indicates that a significant number of amputees experience deficiencies in prosthetic functioning and gait resulting from inadequate prosthetic fitting, fabrication, and alignment techniques.

The three most serious deficiencies encountered were: (i) poor socket fit, (ii) poor foot plantarflexion function and rollover, and (iii) faulty prosthetic alignment.

Employment post amputation	Dysvascular	Trauma	Tumor	Total,	%
Unable to work due to amputation	9	13	0	22	12
Unable to work for medical reasons	9	5	2	16	9
Changed occupation due to amputation	4	67	1	72	41
Retired	17	11	0	28	16
Unemployed	1	4	0	5	3
Part-time work or school	0	9	0	9	5
Same occupation	4	20	0	24	14
Daily Walking					
No Response	0	1	0	1	1
None	6	3	0	9	5
In House only	9	6	1	16	9
1 to 6 Blocks	24	58	2	84	47
Over 6 Blocks	4	29	0	33	19
Unlimited	1	32	0	33	19

46% of the 176 respondents feel they have socket fit problems, 35% feel their limbs are too noisy, and 73% identify additional activities or recreation they would like to perform but are unable.

The following results are based on 34 evaluations including 19 below-knee, 12 above-knee, and 3 bilateral amputees (22 BK limbs and 15 AK limbs).

The questionnaire responses from these same 34 amputees indicate that 55 percent of the BK amputees and 40 percent of the AK amputees felt that they had socket problems. The BK figure agrees well with the assessment of the clinic team, but the AK figure is markedly different. This suggests that the AK amputees often may not realize how poor the fit and function of their prostheses actually are! Since most of the socket problems were identifiable and correctible, there is hope for a significant improvement in the prosthetics care of this group of amputees.

	22 BK Limbs			15 AK Limbs		
Socket Problems		59%			80%	
Suspension Problems		59%			40%	
Knee Problems		—			60%	
Foot Problems		82%			60%	
	Good	Fair	Poor	Good	Fair	Poor
Alignment	45%	35%	20%	27%	60%	13%
Cosmesis	73%	27%	0%	67%	27%	6%

Problem-Case Referrals

The objective is to provide specialized prosthetics treatment for amputees referred to the program because of unusual problems.

The research staff has become involved in the care of problem amputees referred for evaluation both from within this facility and from outside of it. Six problem cases of veterans with lower limb disabilities have been referred to the RERP during this report period. Three of these were unilaterial BK amputees with longstanding fitting problems and skin breakdown, one was a bilateral BK amputee with multiple epidermoid cysts, one was a quadrilateral amputee with AK and BK leg amputations and one was a diabetic with structurally collapsed foot and ankle secondary to osteoarthritis. All the BK amputations were successfully fitted with lightweight PTS prostheses incorporating removable wedge suspension air-cushion sockets with soft insert liners. The AK amputation was fitted with a quadrilateral socket with hip joint and pelvic belt. The patient with foot problems was fitted with a PTB fracture brace.

Prosthetic Device Evaluation

The purpose of the evaluation projects is to evaluate the safety, durability, and functional value of new lower-limb prosthetic devices, and to gather all the information necessary to manufacture, prescribe, fit and fabricate (and teach the use of) the tested devices. More details are to be found in the previous progress report, in BPR 10-35. The initial object of testing is the UC-BL Four-Bar Linkage Polycentric Knee.

Since the initiation of this evaluation project on July 1, 1980, a total of 32 above-knee veteran amputees have been evaluated as potential candidates for clinical trial of the Four-Bar Linkage polycentric knee unit. Of the 24 subjects who have been included in the study, 18 have undergone followup evaluations after using the Four-Bar Knee Unit for periods ranging from 4 to 11 months. Thus the evaluation project is progressing steadily—but not at the projected rate of 25 six-month follow-ups by June of 81. (That goal is now projected for November 1981.)

Preliminary clinical experience with the Four-Bar Knee Unit indicates that, with few exceptions, it has been well received by the amputees. Factors such as the more "natural" behavior of the linkage during level walking, and the unusually large knee flexion angle allowed by the design, have received especially favorable comment. A few subjects have reported feeling that less total energy is required for daily ambulation with their research limbs compared to previous ones.

Subjects who previously had worn hydraulic knee units have frequently noted some initial difficulty in getting used to the characteristics of the pneumatic swing-phase control of the Four-Bar Knee Unit. At the three-month examinations and later follow-up examinations, however, reactions generally have been favorable.

Early problems were encountered with excessive noise due to loose bearings, erratic swing-phase-control action due to leaks in the damper piston seals, and deformation of the cosmetic cover resulting from improper shaping. These problems with the prototype devices have been solved by minor modifications, which have been duly noted in the instructions for manufacture.

Occasional problems in achieving adequate socket fit and optimal alignment have been experienced by local prosthetists, resulting in some amputee dissatisfaction. Solutions to these problems have been worked out on an individual basis with the assistance of the RERP research prosthetist, and descriptions of the improved fitting/alignment procedures have been included in the prosthetist's instruction manual.

Design and Development of Lower-Limb Prosthetic Devices

The objective is to develop new concepts, methods, and devices for improved prosthetics care. The Biomechanics Laboratory of the University of California at Berkeley conducts engineering development projects for the RERP under VA contract. Current projects include prosthetic foot design and experimental studies of knee stability control in above-knee amputees.

Metal Keel—SACH Foot—Six production prototypes, as shown in Figure 1, have completed a 1,000,000 cycle accelerated toe-flexion testing program at Kingsley Manufacturing Co. with no externally visible signs of damage. A slight delamination of the foam material from the metal keel was apparent after sectioning of the feet, but all test specimens were considered fully functional at the end of the test.

Microcomputer Control of an Above-Knee Prosthesis—Improvements to the servo-valve that controls the hydraulic swing-control damper were completed during this report period. Amputee tests of the latest prototype prosthesis have shown excellent control of swing phase and have demonstrated the advantages of individual programing of the table-look-up system for generating the resistance pattern desired by the amputee. The control program is being modified to allow true adaptive control that will

respond automatically to changes in walking speed. Tests of the stance phase control mode have shown the need for an improved servo-valve design which can be isolated from the compliance of the accumulator in the modified U.S. Manufacturing Co. Dyna-Plex unit. The present valve provides good control for flexion resistance but is ineffective in controlling the rate of knee extension. A new valve under construction will provide identical control of flexion and extension resistance, which is important in allowing for control of knee extension at heel contact, followed by control of knee flexion prior to push off.

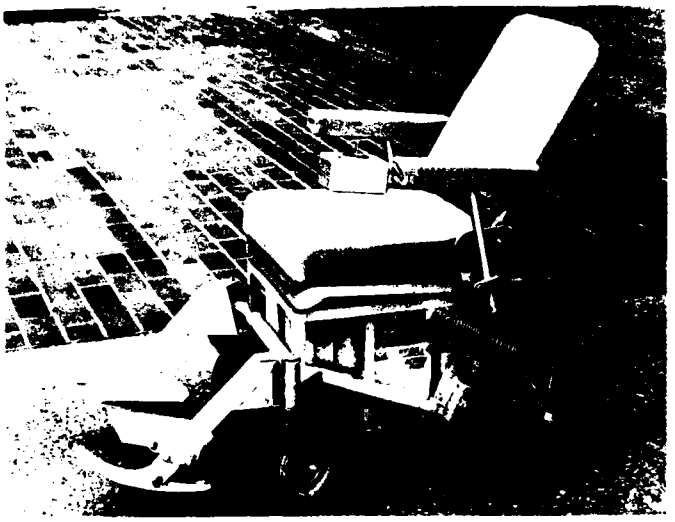

FIGURE 2.
The UC-BL powered spring-suspension wheelchair.

Mobility Aids for the Severely Disabled

The objective is to develop mobility aids for people with severe locomotor disabilities.

Powered Spring Suspension Wheelchair—Components for five wheelchairs less seats and footrests were delivered in December 1980, and two units have been assembled, as shown in Figure 2. A new seat was designed with a contoured backrest and simple body-compatible recline kinematics suitable for use in either a powered or manual recliner. A simple linkage-type latch mechanism allows easy adjustment of armrest length to any of three positions, plus a fourth position folded back out of the way for transfers in and out of the chair. The armrests follow the recline motion in any of the three normal armrest positions. Footrests were further developed for increased strength and improved impact resistance. A new dead-man switch was designed, with a thin, lightly spring-loaded music-wire activator that is easily held in the "on" position while driving but readily released to shut down the controller and apply the chair's fail-safe brakes. One chair has been fitted with the new seat, footrests, and dead-man switch, and has performed well in extensive driving by project staff. Daily use testing of the chair is beginning.

Solid State Controller—Five Bowman UC-BL controllers were delivered in October 1980, and the units fitted to the first two powered spring-suspension wheelchairs have performed flawlessly.

Spring Suspension Caster Forks—Parts for twenty forks were delivered in December 1980, and the eight units assembled so far have performed very well on three different kinds of electric wheelchairs.

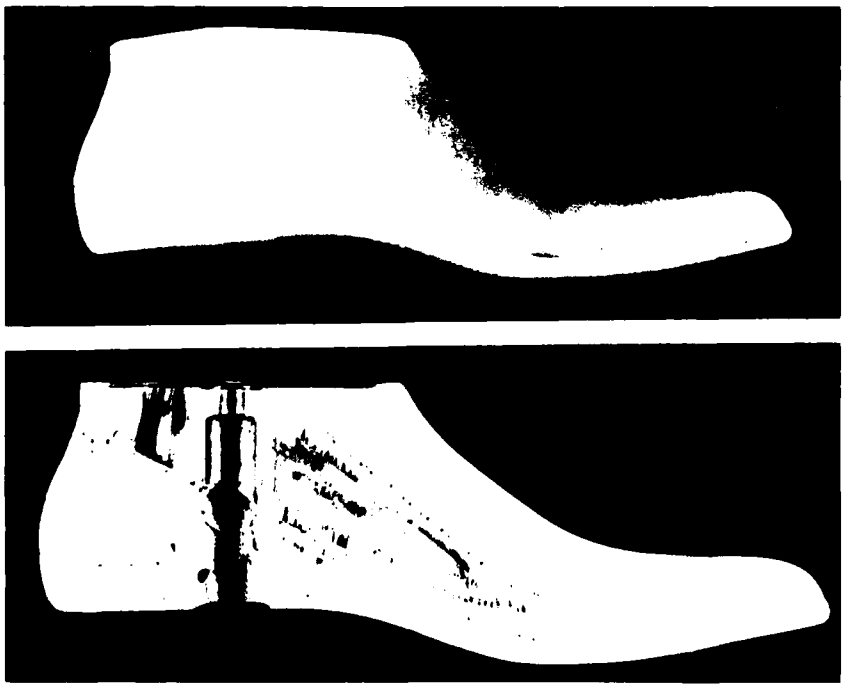

FIGURE 1.
The UC-BL/Kingsley metal keel SACH foot.

Total Hip Joint Loosening

The objective is to examine the causes of loosening in implanted total hip joint prostheses. Working under a VA contract, researchers in the Department of Radiology at the University of California Medical Center in San Francisco (UC-SF) have adapted the algebraic reconstruction technique (ART) to the imaging problem in computed tomography (CT) created by the presence of metallic prostheses in the reconstruction field. The filtered back-projection methods currently employed by commercial scanners are unable to eliminate the artifacts that arise from x-ray opacity of

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the prosthesis, as shown in Figure 3. In the case of bilateral femoral head replacements, the severity of these artifacts is compounded. Since the image in the ART approach is reconstructed iteratively ray-by-ray, it can be reconstructed without using the rays that are severely attenuated by passing through the metal object.

In the present application of ART, the location of the prosthesis within the slice is determined using the software provided by the manufacturer of the CT scanner. After the rays which pass through the prosthesis are flagged, the image is reconstructed by an iterative process consisting of: (i) constructing a set of pseudo-projections based on an estimation of the image, (ii) comparing these pseudo-projections with the corresponding real projection data, and (iii) back-projecting onto the pixel matrix the appropriately weighted differences between the real and the pseudo-data. For the flagged rays in the region of "hollow" data created by the opacity of the prosthesis, the differences between the real data and the pseudo-data are set to interpolated values that insure a convergence to an artifact-free image.

Figure 4 shows an ART reconstruction of the same data used to generate Figure 3. The CT numbers are accurate in the part of the image that shows the cement-bone interface, the region of primary interest for this prosthesis loosening study. At present, the additional calculations required for such a reconstruction procedure require a significant additional expenditure of computer time, but the procedure is now suitable for limited application as a research tool in the study of hip-joint loosening.

FIGURE 3.
A conventional Computed Tomography (CT) scan through the distal pelvis of a total hip patient. When standard CT reconstruction algorithms are used, the presence of metal in the plane of the scan results in a so-called "STAR" artifact that obliterates much of the information in the reconstructed image.

FIGURE 4.
The Algebraic Reconstruction Technique (ART) can be used to eliminate or greatly reduce the STAR artifact and thereby permit the use of CT scans in the study of total hip joint loosening.

Total Knee Implant—Biotelemetry

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During the previous report period, continual evaluation of clinical results involving various knee designs has remained a primary emphasis. Proposals for companion total hip and total knee implant biotelemetry studies have been generated and are currently under review. The total hip biotelemetry project represents a continuation of a joint venture between the UCLA Biomechanics research section and the Jet Propulsion Laboratory to fabricate and test in vitro several laboratory prototypes. The companion knee project requests resources for the initial design and debugging phase of the project. In conjunction with anticipated funding for the projects, a computer system has been installed and the elimination of installation related problems is underway. Several general programs for data acquisition and display are also under development.

Numerous commercial prosthetic designs are currently being evaluated as suitable recipients for the necessary electronic assemblies, but no such unit has been found to date. Total component redesign as well as modifications to only the tibial component are alternatives currently being contemplated. Clinical, developmental and manufac-

turing considerations have served as deterrents to a design consensus to date.

Finally, a few customized tibial components have been implanted for problem cases, and short and long term followups will be evaluated relative to their standard component counterparts.

Program for Evaluating and Monitoring the Disvascular Patient

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This program (initially reported in BPR 10-35, Spring 1981) concerns the development and use of a technique for polarographic monitoring of local hydrogen gas desaturation for measuring myocutaneous perfusion in rehabilitation of the amputee and in evaluating the effects of lumbar sympathectomy in the management of atherosclerotic occlusive disease. This report concerns completion of initial work in the application of the technique of polarographic monitoring of local hydrogen gas desaturation for measuring myocutaneous perfusion rates in the dog (Fig. 1).

To study the effect of lumbar sympathectomy on myocutaneous perfusion, four dogs underwent unilateral lumbary sympathectomy (right) with the contralateral limb (left) serving as a control. Local hydrogen gas desaturation was monitored at the gastrocnemius muscle. Anesthesia was established and maintained throughout the procedure using a 0.2% intravenous drip of sodium thiopental. After anesthesia was induced, the dog inhaled a mixture of 3 percent H_2 gas in room air until full tissue saturation was achieved. The hydrogen gas concentration was monitored using hydrogen-sensitive polarized needle electrodes inserted into the gastrocnemius muscle. Once full tissue saturation was achieved, the dog's inhalation of the H_2-room-air mixture was stopped and normal ventilation of room air was initiated. Simultaneous bilateral recordings of the hydrogen gas washout were made on a stripchart. The hydrogen gas concentration in the muscle tissue gradually falls to zero; the local desaturation of the hydrogen gas follows an exponential decay in accordance with Fick's Law of indication dilution. A total of 47 hydrogen gas washout curves were analyzed. Obtained myocutaneous perfusion rates ranged from 7.42 to 24.15 ml/min/100 g tissue with an average myocutaneous perfusion rate of 12.57 cc/min/100 g tissue obtained for the nonsympathectomized limb. At approximately one week intervals following right lumbar sympathectomy, follow-up bilateral myocutaneous perfusion measurement was done. A representative tracing (shown in Fig. 1) demonstrates an almost three-fold increase in myocutaneous perfusion of the sympathectomized gastrocnemius muscle as compared to the non-sympathectomized contralateral muscle.

These initial data demonstrate an increase in myocutaneous perfusion following lumbar sympathectomy. Additional studies will be made to evaluate repeatability of flows and to establish a trend in myocutaneous perfusion changes following lumbar sympathectomy.

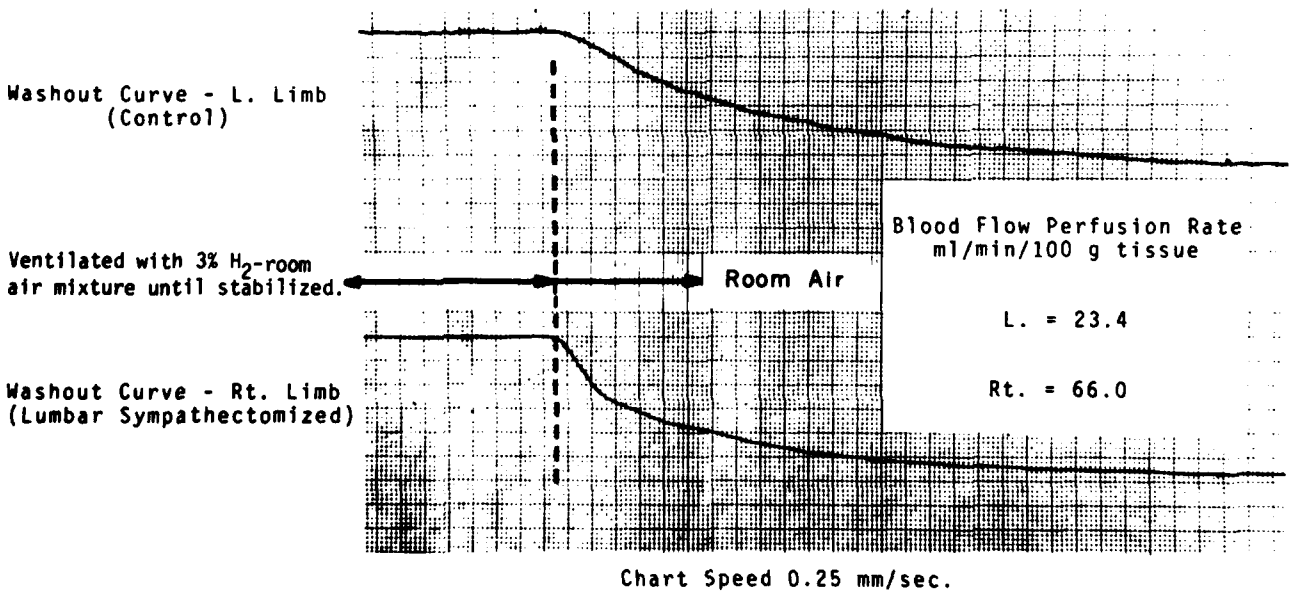

FIGURE 1.
Myocutaneous perfusion measured by hydrogen washout. Curves were obtained from electrodes inserted into gastrocnemius muscle (Canine). Dales: Rt. Lumbar Sympathectomy 2/10/81; Perfusion Study 2/19/81.

Seating Systems for Body Support and Prevention of Tissue Trauma

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To date, 57 prototypes of the Veteran's Administration Seating Interface Orthosis-Paraplegic (VASIO–P) have been evaluated by patients with spinal cord injuries between T1 and T12.

After a minimum of 3 months on the cushion, responses of the patients have reinforced originally favorable comments relating to comfort, balance, posture, practicality, and cleanliness. One noticeable and frequently cited advantage of VASIO–P is a continual increase in the patients' sitting tolerance.

Highly active patients, those involved in sports, gardening, or farming, have presented problems concerning accelerated deterioration of the cushion with constant use. This difficulty could be alleviated by distributing two cushions to the patients for alternate use.

Transfers remain difficult for many due to height of the cushion. Solutions to this problem are being investigated. Data obtained in clinical testing is being used in the formulation of prescription guidelines for clinicians.

Research and development on a seat cushion for quadriplegics, designated VASIO–Q (Q–quadriplegic), is now complete. In this model the surface features have been modified to accommodate the special biomechanical and pressure-reduction needs of patients with quadriplegia who cannot perform pressure reliefs independently. Clinical testing of VASIO–Q is scheduled for July 1981. A lap tray, and leg and trunk supports, will also be designed as accessories to this total body support system.

Design of a third cushion, specific for patients with a cauda equina injury, will permit the increased movement and postural changes exhibited by these patients. Research and development on this cushion will start after clinical testing of VASIO–Q.

Test data on VASIO–P indicate that it performs quite satisfactorily in reducing sitting pressures to acceptable levels. This research further shows that modular seating systems can meet the orthopedic and pressure reduction needs of a wide population of spinal-cord-injured or otherwise asensory persons. Steps are underway to make VASIO–P commercially available.

Clinical and Laboratory Study of Amputation

Prosthetics Research Study
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Limb Viability—Elective amputations were performed on 52 patients at VA Medical Center, Seattle, during the 6-month period. An additional number of patients were included from other hospitals within the University system. This smaller group of patients was selected for their specific research value. Following up on earlier double-blind investigation using transcutaneous pO_2 determination at several limb sites, this test is now included as a routine preoperative amputation determination. The surgeon is informed of the perfusion levels prior to the amputation. This rapidly increasing statistical base will establish the value of noninvasive gas perfusion measurements for limb viability and preoperative determination of correct amputation level.

The **microwound research** is now actively underway. A small standardized and carefully controlled microwound is made on the threatened limb at a predetermined site distal to the level of amputation. The wound is harvested from the amputated limb, then subjected to a variety of histological and biochemical observations. This "in vivo" examination uses the clinical wound healing at the amputation site as a control and also forms a yardstick against which other non-invasive tests carried out at the same site can be measured.

Preoperative tissue viability is also being studied experimentally using a laser Doppler and multispectral reflectometry. These objective laboratory parameters are non-invasive, inexpensive, without hazard or discomfort to the patient, and potentially valuable. We have not, during the time covered in this progress report, used radioactive isotope measurements (Xenon 133). An excellent study of that test continues at VAMC Tucson (Malone et al). The Seattle facility is in regular communication with science persons at Tucson and at other limb viability laboratories in this country and abroad.

Significance of these studies extends well beyond the more accurate preoperative determination of amputation level in the ischemic limb. There is very little current information about the nature of wound healing in the presence of ischemia. This work is directed to more fully understand this process.

Prosthetics Research—A synthetic composite energy-storing foot has been developed in conjunction with the Boeing Technology Services. It is designed to improve functional performance for active lower-extremity amputees. Prototypes have been bench tested and stress analyzed. Design and materials are now standardized. The foot is undergoing testing on ten selected amputees. Performance evaluation will be reported within the next few months.

The Prosthetics Research Study has enlarged its Amputee Evaluation Group to include fifty subjects. These individuals have been carefully selected from a larger volunteer group and are available for field testing of new and modified lower-extremity prostheses and components. The majority of these individuals are from the veteran amputee population.

Surgical and Immediate Postsurgical Amputation Research—Clinical research continues concentrating on distal levels of amputation in the ischemic lower limb. Of particular investigative concern are amputations through the forefoot and midfoot. This area of lower limb amputation is least well understood. Healing failure following surgery is frequent requiring higher secondary amputation. A more precise knowledge of the healing capability, as measured by preoperative studies of the type PRS is investigating, and innovative surgical techniques, are urgently needed.

PRS continues to evaluate statistically all amputations carried out by its staff. These data form a base for inhouse critique and comparison with other services.

Education—A list of current publications is as follows:

1. Burgess EM: *Postoperative Management.* Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 19–23, 1981.
2. Burgess EM: General Principles of Amputation Surgery, Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 14–18, 1981.
3. Burgess EM: Principles of Amputation Surgery in the Upper Limb. Atlas of Limb *Prosthetics, Surgical and Prosthetic* Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 92–94, 1981.
4. Kegel B: Prostheses and Assistive Devices for Special Activities. Atlas of Limb Prosthetics, Surgical and Prosthetic Principles. American Academy of Orthopaedic Surgeons. The C.V. Mosby Co., pp. 423–434, 1981.
5. Burgess EM: Principles of Amputation Surgery in the Lower Limb. Atlas of Limb Prosthetics, Surgical and Prosthetic *Principles. American Academy of Orthopaedic Surgeons.* The C.V. Mosby Co., pp. 272–276, 1981.

A list of publications submitted for publication is as follows:

Enoka R, Miller DI, Burgess EM: *Below-knee* amputee running gait. Accepted by Amer J Phys Med.

Burgess EM, Matsen FA: Current concepts for determining amputation levels in peripheral vascular disease. Accepted by J Bone & Joint Surg.

Johansen KH, Burgess EM: Improvement of amputation levels in limb revascularization. Accepted by Surg Gyn Obstet.

Kegel B, Burgess EM, Starr TW, Daly WK: Effects of isometric muscle training on residual limb volume, strength, and gait of *below-knee amputees. Accepted by* Phys Ther.

Burgess EM & Forsgren SM: The Prosthetist. Chapter in Orthopedic Rehabilitation edited by V.L. Nickel. New York, Churchill Livingstone. In Press.

Burgess EM: Amputations of the Lower Extremity. Chapter in Orthopedic Rehabilitation edited by V. L. Nickel. New York, Churchill Livingstone. In press.

Burgess EM: Amputation Surgery and Postoperative Care. Chapter Three in Rehabilitation Management of Amputees, *edited by S. N. Banerjee and J.V. Basmajian.* Baltimore, Williams and Wilkins. In press.

There were two **presentations** in this time period:

1. Dr. Ernest M. Burgess: Instructional Course, "Advances in Amputations," American Academy of Orthopedic Surgeons Annual Meeting, Las Vegas, Nevada. March 1, 1981.
2. Shirley M. Forsgren: "Prosthetic Foot for Active Sports—Preliminary Studies" American Orthotics and Prosthetics Association Region IX and California Orthotics and Prosthetics Association *Combined Meeting, Monterey, California,* June 5–7, 1981.

The Prosthetics Research Study staff supported by an excellent national faculty is conducting a Continuing Education workshop in Seattle, September 11–12, 1981. This course is entitled "Modern Amputation Surgery and Prosthetic Rehabilitation" and is sponsored by the American Academy of Orthopaedic Surgeons.

Transcutaneous Oxygen Tension as Predictor of Wound Healing

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Ernest M. Burgess, M.D.

This project is directed at exploring the use of transcutaneous oxygen measurements as a means of evaluating noninvasively the severity of peripheral vascular disease and the effect of therapeutic measures. Five separate studies are in progress: (i) prospective evaluation of transcutaneous PO_2 before amputation for peripheral vascular insufficiency; (ii) a longitudinal evaluation of transcutaneous PO_2 values over time in a patient population at risk for peripheral vascular disease; (iii) pre- and post-vascular-reconstruction measurements of segmental transcutaneous oxygen values; (iv) measurement of transcutaneous oxygen during and after exercise on a treadmill in patients with claudication; and (v) development of a multi-probe transcutaneous PO_2 monitor for mapping transcutaneous oxygen over the extremities.

A preliminary paper has been submitted covering a double-blind study of 58 amputations with respect to the prospective evaluation of amputation success or failure using transcutaneous oxygen measurement at the proposed site of amputation. Of 38 below-knee amputations, all patients having prospective transcutaneous PO_2 values greater than 40 mm Hg healed primarily; 15 of 19 patients having transcutaneous PO_2 values greater than zero but less than 40 mm Hg healed primarily, 2 after local revision but 2 failed after intercurrent thrombosis. All three patients having prospective transcutaneous PO_2 values of zero failed to heal and required revision to an above-knee amputation. There were only 3 primary above-knee amputations and the balance of this group were various types of foot amputations. Patients are being added to this data pool continually.

Patients appropriate for longitudinal study, pre- and post-vascular-reconstruction, and exercise testing are picked up as they appear on the vascular or amputation services at the Veterans Administration Hospital. For the longitudinal study, limbs contralateral to an amputation are studied at 6-month intervals when patients return for checkups. Segmental transcutaneous oxygens are measured in patients scheduled for vascular reconstruction and then are measured again about 1 week after their surgery to evaluate the effectiveness of the treatment. Patients who come into the vascular lab for exercise testing are measured with transcutaneous oxygen electrodes just above the ankle cuffs (used for evaluating ankle blood pressure); these patients are followed during and after exercise, and results are compared to the ankle pressure measurements.

Development of the multi-probe transcutaneous oxygen sensor is in the prototype stage and will be completed in about nine months. This multi-probe sensor will be used to measure simultaneously a number of skin sites for mapping out prospective amputation flaps and for monitoring the changes in transcutaneous oxygen that attend exercise over the extremities of patients experiencing claudication.

References

1. Matsen FA, Wyss CR, Simmons CW: The effects of compression and elevation on the circulation to the skin of the hand as reflected by transcutaneous PO_2. Plast. Reconstr. Surg. In press.
2. Burgess EM, Matsen FA: Current concepts for determining amputation levels in peripheral vascular disease. (Editorial) Accepted by J Bone Jt Surg.

Maxillofacial Restorative Materials and Techniques

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Introduction

The research and development effort continues with five project efforts integrated into a comprehensive development plan (1) from basic science and technology to clinical servicing throughout the VA system and interested non-VA maxillofacial clinics. Inasmuch as small maxillofacial prosthetics attracts very little commercial interest or shows the prospect of profitable venture opportunity because of low market volume (2), the development plan has been extended in the direction of large prosthetic devices. Accordingly, special effort, as will be recounted in the succeeding five project sections, has been imposed on producing more flowable modification of PDM siloxane without changing the inherent chemistry, and devising or inventing a stone mold reinforced and stabilized with metal framing to protect the stone mold, despite its hardness, from fracturing and breaking into pieces during the pressuring operation. Salient progress and success have been achieved in this.

Although not extensively reported at this time, the project section on human-safe aspects continues to engage a major portion of the effort in support of a biocompatibility test protocol which has already been submitted for panel review in a committee of the American Society for Testing and Materials. The most pressing task is in separating and specifying the factors in cell growth medium that are in accord with current developments in cell growth. The major burden of this obligatory work is the detailing, fine-tuning so to speak, of the specified testing media and procedures to assure reproducibility of the test results by other tissue culture laboratories.

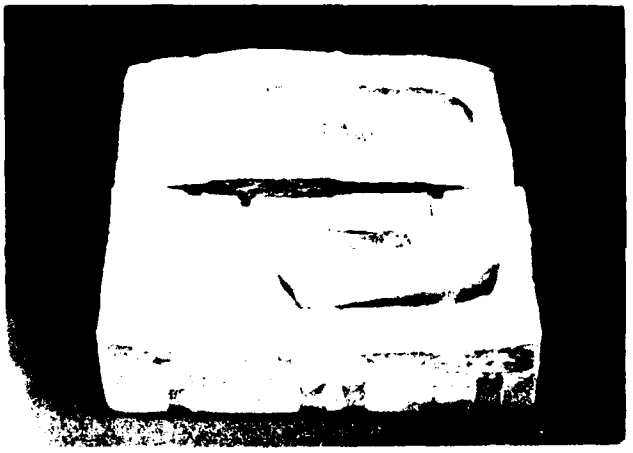

Figure 1(a)—Starting two-part split mold of dental stone. Dimensions are: Length: 11 inches; Width: 7 inches; and Height: 5 inches. Weight is 16.5 lb. (7.49 Kg.).

Figure 1(b)—Extended display introducing the rectangular angle iron reinforcing case to encase the two-part components of the stone mold.

FIGURE 1.
Simplified, inexpensive Design B of large dental stone mold for fabricating large prosthetic devices, beyond current limits with conventional dental stone molds, using angle-iron encasing to stabilize the stone mold against fracture from imposed-pressure molding and from thermal stresses during polymerization at 100 C.

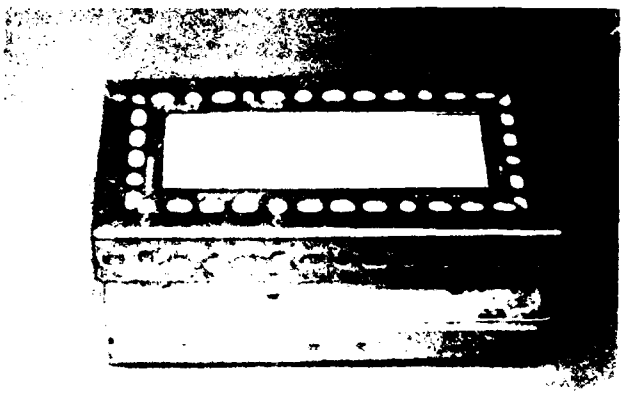

Figure 1(c)—Assembled, closed arrangement of stone mold with the reinforcing case ready for filling in with additional stone, set from water slurry, to lock the rectangular reinforcing case to the two-part stone mold.

Product Development

Of the tentative Performance Standards as required by FDA regulations (1) and listed in a recent BPR (3), that of the elastic modulus is being particularly scrutinized for the 18 production campaigns (to supply the VA-wide needs) for effects of milling schedules, shelf life, and applied tensile straining rates. These effects constitute the essential features for quality and uniformity which increasing clinical acceptance of oligomerized PDM siloxane depends upon.

It has been observed that the specified range of 60–80 lb/sq in (0.41–0.55 MPa) in tensile modulus has been increasing with consequent production campaigns to 100–140 lb/sq in (0.69–0.97 MPa). This is tentatively ascribed to more efficient blending of the prepolymer and oligomer, based on longer milling time in combination with elevated milling temperatures. These milling adjustments have been observed to produce a more tractable, more moldable stock.

The milling adjustments have been undertaken as one aspect of the Comprehensive Development Plan (1) to attain lower viscosity (plastisol) oligomerized stocks, with increased oligomer content, for large prostheses molding in dimensions beyond those limited by the 5-inch diameter dental stone molds (4). As recounted in the ensuing fabrication project section, this task effort proved highly successful. The new 70/30 (prepolymer/oligomer) composition is programmed for studies on effect of oligomer unit dimethylsiloxane lengths in combination with a range of catalyst levels on the extensile properties as was done with the 80/20 composition.

Fabrication

Maxillofacial restorations heretofore have been limited to cross-sectional areas of 16 square inches with a maximum circular width of 4 inches and a maximum depth of 2.5 inches, using the largest (Hanau Giant) dental stone mold. These dimensions preclude the fabrication of a significant number of facial and cranial reconstructions, of functional and cosmetic augmentation of congenital amputated limb defects, and of various cosmetic implants. These enlarged reconstructions are served by prosthetic forms made from a variety of undefined, often untraceable ingredient sources, compounded forms of unspecified, proprietary grades of latex rubber, acrylics, and polyvinylchloride plastisols, etc. Presently available proprietary compositions have one or more serious consumer (end-use) deficiency, among these being age-cracking (rubber), detergent and solvent gumming (acrylic terpolymers), tear rupture (RTV silicones), shrinkage and stiffening (polyvinyl chloride), and gradual elastic distortion or set. In general, the proprietary formulations, usually left to the particular skill or preference of the prostheses technologist, are deficient in mechanical endurance, especially tear resistance and sustained elasticity. All or most of these deficiencies can be eliminated or substantially reduced in the larger prostheses by use of PDM siloxane (5), with the availability and use of a new series of molds larger than the current dental stone mold sizes. Consequently, in this project section, several developments have been undertaken to (i) provide simple, inexpensive mold frames to reinforce the fracturable stone mold compounded from gypsum, (ii) develop a modified form of the current PDM siloxane (80/20 prepolymer/oligomer ratio) for increased viscous flow, and (iii) work out the technical details for thermal schedule for polymerization to performance standards. During this period of these three tasks, initiated as reported in the previous BPR, each has been advanced to the point at which the first successful right-foot prosthesis has been made (and accepted by the client for consumer end-use testing) using the new 70/30 prepolymer/oligomer PDM siloxane composition.

The initial trial of pressure-forming of a 11 in × 7 in (77 in^2 area) rectangular mold was carried out in the fabrication of an internally pigmented (SY–2) form of a prosthetic forward toe section of a right foot, measuring seven inches in length with an area of approximately 21 square inches extending to the back of the client's heel. Repeating the model foot molding described in a previous BPR (5), the new rectangular box mold, depicted in Figure 1, withstood successfuly without any fracturing the 2000 lb applied forming force with the new 70/30 prepolymer/oligomer PDM siloxane composition and the ensuing 3 hour thermal polymerization schedule. This first molded cosmetic foot prosthesis, endowed with substantial tear resistance (lacking with RTV silicones) has been accepted by the client with satisfaction. A series of replicate moldings are in progress for the purpose of (i) retrieval, client-wear evaluation (tear resistance, comfort, hygienic maintenance, and signs of dermal sensitivity) and (ii) ascertaining pressure limits of the new rectangular box mold design with the specified hardware. The client wear evaluation will include a series of 3, 6 and 12 months usage with selected tests for elastomer deterioration.

Pigmentation (Internal Shade Stocks)

The current standard six-shade internal pigmentation has been augmented with a melanin replicating color for which Monastral Gold (DuPont) has been selected from a series of dry pigments resistant to color fading and to hygienic (sodium hypochlorite) disinfecting.

Unlike most darkening or red-surpressing artist's chars or carbon, Monastral Gold has imposed less than a 5 percent diminution in the arterial red/carotene yellow ratio (Hunter DCD b/a as described in (6)). The first of a series of production runs (Shade SY–2A) of internally pigmented PDM siloxane has been sent to outside maxillofacial prosthetics clinics for esthetic replication of Afro cosmetic skin coloration to augment the current standard 6-shade range, from carotene (yellow) dominant to arterial (red) dominant shades of stock material.

Toxicity and Potential Tumorigenicity

Under the regulatory provisions of the Medical Devices Act (7), the protocol for testing and demonstrating non-toxicity of PDM siloxane has been formally submitted to the American Society for Testing Material (ASTM) Committee F04, Medical and Surgical Materials and Devices, at the Spring meeting, May 13–15, 1981, at Phoenix, Arizona, and assigned the ASTM Designation F04.20.06.52. Under the title, Standard Practice for Assessment of Orofacial Materials and Devices by Culturing with Human Excised Donor (HED) Tissues, the proposal now undergoes study by a committee of panelists representing producers, users and general interest reviewers from whom comments will be forthcoming, ranging from constructive modifications to challenges for various reasons of rationale, relevance, and so on. Thus a series of committee reviews are expected with prospects of modifications and experimental verifi-

cation of changes obligated to attain ultimate ASTM approval (8). It is expected this may take from 2 to 3 years at the ASTM level serving as the voluntary agency (7) for FDA approval.

The principal components of the HED tissue biocompatibility testing procedure for nontoxicity include (a) specifications for chemically defined medium, (b) augmentation with minimal and specific human serum protein factors for attachment, viability, and division, and (c) provision for preliminary (7 day) qualification of selected (a) and (b) components with an established HED cell line followed by extended (7 and 30 day) testing with specific HED primary tissue for rated (specification) biocompatibility. This protocol provides ample options and flexibility to the proposed recommended practice for favorable panel review.

Present emphasis is accorded to the separation of the Holmes alpha-I-protein growth factor (AGF) from human serum and blood fractions (9) and establishing an appropriate activity titer for the above qualification test. It is expected that as the proposing laboratory for the biocompatibility test, this project will provide samples of the qualified AGF to reviewing participants of the ASTM F04 Committee. At present there are three biocompatibility test proposals under review by the F04 Committee relating to other medical and surgical prosthetic biomaterials of which only the HED has the highest degree of human relevancy.

Field Participation

The total number of participants, based on requests for starter sets (kits) of PDM siloxane, has reached a total of 52 VA and non-VA maxillofacial clinics. This number represents only a fraction, by about one-fifth, of expected participants as the initial program was set up. Despite the drop-out of an estimated one-fourth of the participants starting in 1978, there is evidence that private clinics, especially those furnishing artificial eyes, are coming into the program.

The principal problem continues to reside first in the lack of professional or technical job classification and secondly, on the fulltime commitment of a prosthodontist or D.D.S. clinician. The latter in most of the participating clinics has to undertake the time-consuming burden of the non-dental tasks of (i) maxillofacial, sculptural replicating from hydrogels to stone molds, followed by (ii) thermal molding, and by (iii) external painting for cosmetic matching, tasks which more properly can and should be carried out by skilled technicians, particularly medical sculpturists. These tasks require special laboratory devices and supply items. Except for the devices, notably forming molds, press, and oven (or autoclaves), the supply items are furnished in the starter kit shown in Figure 2 with a complete array of pigments for external cosmetic matching and items special to molding along with a manual of procedure.

In the meantime, inquiries continue to come for non-pigmented PDM siloxane to be constructed into implants, an area that would give a new impetus to medical or surgical sculpturists. This area is being purposely restrained until the biocompatibility test procedure now under review by ASTM is formally adopted. Although normal laboratory, environmental and personal cleanliness in an isolated room is the practice in the production of PDM siloxane, it is necessary and planned to set up a clean room normally required for medical or surgical grade devices meeting Federal guidelines.

To continue the availability and competent utilization of PDM siloxane, this project program continues to report on the research and development and clinical utilization at conferences of several national professional organizations. Additionally, a workshop similar to that organized in the Spring of 1979 is planned for the Fall of 1981.

Production

A total of 18 production campaigns and over 600 one-pound units of PDM siloxane have been produced since inception of the program in 1979. Each campaign is specific to repeated lots of prepolymer (General Electric SE4524U), oligomer (Dow DC 200 silicone fluid), catalysts (CST and AST), and modifications of processing procedures. The modifications are related to the product development tasks, mentioned in the earlier section of this report, specifically to extend the milling time and temperature range of operation and to incorporate higher levels of oligomer. Each production campaign is monitored by quality control on expected product performance, especially tensile constants and tear resistance, and biocompatibility quality assurance.

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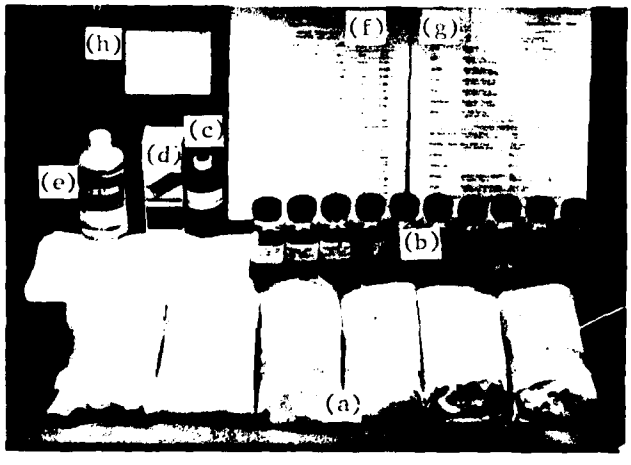

FIGURE 2.
Starter kit of internally pigmented PDM siloxane in six (6) internally pigmented shade with accessories for external, cosmetic painting to match patient skin coloration. The kit includes:
(a) 6 one-pound stocks of PDM siloxane,
(b) 10 pure pigments for external cosmetic painting,
(c) xylene thinner for vehicle (d),
(d) adhesive vehicle (Silastic Type A Adhesive),
(e) separator (foiling over stone mold) compound,
(f) product description list by chemical types,
(g) accessory list with sources of commercial supply, and
(h) manual (draft) of procedure for molding and painting.

BPR 10-32 Fall 1979; see Table 1, pages 378–379 detailing the six project efforts with defined tasks (specific objectives) integrated and consolidated toward the goal of providing a standard, continuing supply of safe and effective prosthesis stocks and their derived prosthetic devices.

2. Ibid BPR 10-32 Fall 1979; see pages 401–402, Clinical Services and Cost Advantage.
3. Ibid BPR 10-34 (Vol. 17, No. 2) Fall 1980; see Table 2, page 105.
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5. Ibid BPR 10-35 (Vol. 17, No. 3) Spring 1981; see the project section II (Fabrication), molding a foot prosthesis.
6. Ibid BPR 10-27 Spring 1977; see pages 162-164, section on digital color difference indices on human skin. Also BPR 10-28 Fall 1977; p. 195–186.
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Rehabilitative Engineering Support for the Atlanta VA Medical Center

Georgia Institute of Technology

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Gary W. Kelly

A Manual Wheelchair Wheel with Integral Anti-Rollback (Gary Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

The first prototype of the wheelchair wheel was developed and tested. Among the problems appearing in the design were: the unit weighed too much, rolling friction was too high, spacing of the push rings was inadequate, a lock-out was needed to disable the anti-rollback feature, and surfaces needed to be smoother with fewer prominences to catch the user's hands.

The efforts this year have been in two directions: to determine further user suggestions as to improvements in design, and to begin designing a wheel that would meet as many of the known criteria as possible.

Work is continuing on gathering as much user input as possible, in order to obtain enough information to rank-order the preferences in design changes. At present, it appears that the highest preference is the reduction of friction, followed by need for a lock-out, reduced weight, cleaner surfaces, etc.

Design modification will continue, taking into consideration the preferences and the intent of providing future options such as forward dynamic braking, 2-to-1 or 1-to-2 gearing, and other options.

It is anticipated that within the next 6 months the design decisions will be made, and the second prototype with reduced weight and friction as well as many other human-factors improvements will be constructed. In addition, alternate construction methods are being considered to reduce the cost and enhance the manufacturing feasibility of the wheel.

An Alternate Vehicle for the Physically Handicapped. (Gary W. Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

At this time the authors are completing an analysis of the proposed vehicle's stability and other operating parameters. All studies to date indicate that the proposed vehicle will successfully meet all of the established design criteria. Work will continue on analysis of the control design and this is expected to evolve into a major project in itself. The control system presently designed may offer some surprising advantages compared with present wheelchairs. The addition of a microprocessor and the innate capability of self-leveling provides the additional attraction of programmable weight-shifting and control of accessories that is far superior to that of any system presently offered or proposed, as far as is known.

Some new accessories have been perfected for use in power chairs (including the proposed vehicle) by the research staff at the Georgia Institute of Technology. Among these are the automatic leg-bag evacuator complete with a robotic arm which would allow the independent use of restroom facilities. This student project is nearing completion of a first prototype for use on conventional power chairs. Research is continuing on other accessories that would be useful in promoting independence of the vehicle user. It is intended that the final design be a system design rather than a model with add-ons; each component will be a modular unit integral to the whole, which is expected to reduce production costs.

Mr. Ken Morgan has been the graduate student who carried the majority of the work to its present state. This report draws upon his graduate thesis for the Master's Degree in Mechanical Engineering. The study will be carried on by a new team who will further develop a clear description and graphics presentation that will be used in additional discussions with wheelchair users, to gain more insight into their needs and also to involve them further in the design process.

In addition, the planning for the electronic control system will continue along with studies of vehicle dynamics, structure, and human-factors design. It is estimated that this study is approximately 2 years from completion of detailed engineering drawings—from which a prototype can be built.

Sonic Orientation and Navigational Aid (SONA) (Gary W. Kelly, Principal Investigator, Robert D. Atkins, Research Scientist, and Theresa Ackerman, Research Technologist.)

The present design of the sonic orientation and navigational aid (SONA) has reduced the size of the packaging required for the transmitter. Efforts at reduction beyond this point may not make sense, since the limits of available touch-tone keyboard sizes is being reached. Tests with present units demonstrate the packaging to be satisfactory, though much more actual evaluation is needed.

With the addition of the new General Instruments music board to the receivers, the tone quality problems have been solved. Virtually all the technical problems associated with this project seem to have been eliminated.

The receivers have been improved by the addition of new tone synthesizer chips. The best version is the programmable General Instruments board. This promises to provide an infinite variety of tones at low cost and with high quality. Similar boards are appearing on the market with highly attractive low costs. This problem appears solved with even greater simplicity than was initially anticipated.

This project now intends to address the utilization of more complex transmitters and receivers. These new devices are replacing the older ones rapidly and have considerably more coding possibilities. Future plans for SONA include the use of the device for elevator control, a decentralized environmental control system, and (coupled with speech output) an information system for blind travelers. The hardware will be updated to provide the capability for these uses later.

Special consideration will be given over the next 18 months to coding. Adoption of reasonable standard codes and location for SONA must be determined. Efforts will continue to involve other centers in testing and evaluating this unique orientation aid which allows the visually impaired traveler to identify and locate specific kinds of known elements within his environment, such as entrances and exits, elevator call buttons, etc.

Electronic Typewriter for the Visually Impaired (Gary W. Kelly, Principal Investigator, Lawrence Moriarty, Research Scientist, and Theresa Ackerman, Research Technologist.)

A typewriter for the visually impaired, designed to meet the needs of persons with usable residual vision who could utilize large print, is based on word-processor technology. It consists of a keyboard, a processor with memory, cassette storage of information, and a large character display.

The philosophy of the device's construction has changed in the last 6 months, and the attempt has been to modularize the entire device into electronic subsystems that are compatible with almost any TTL circuitry. At this time the video board, the RS232 serial interface, the display, the display software, and the cassette interface board are separate operational subsystems interrelated through the central 1802 processor.

The research team is developing a system that is not tied to one processor or mainframe word-processing/text-editing system. This may have some unique design advantages.

The decision to modularize the entire device into electronic subsystems was made to accommodate the newly emerging word-processors, which may ultimately be readily modified to meet the needs of this device—rather than requiring the specialty manufacture of a dedicated device for the visually impaired. At present, the research staff is studying several new word-processors that are portable and have the capability of being modified with one or more of the presently developed subsystems to allow their performance as cassettes to a large-print reading machine for the visually impaired. This effort is expected to be successful, and technical discussions have begun with one large electronics manufacturer to modify one of their machines for the purpose of demonstrating this capability.

The users would aid in evaluating this approach over that of continued construction of a dedicated system. We expect that the piggy-back approach of loading additional subsystems onto existing devices will provide, at lower cost, a device superior to the present prototype. We anticipate having the first successful system operating in 12 months.

A Musical Language Computer Terminal for the Visually Impaired (Gary W. Kelly, Principal Researcher, and David Ross, Graduate Research Assistant.)

The most recent accomplishments in the project have been the development of improved software which allows more versatility, including use as a preliminary training tool. The tone-generating software for the ALF Products music board has been improved to allow use of the nine-voice board. This board, while lacking some of the features of the earlier three-voice boards, is still suitable for this use at a significantly reduced cost.

In addition, improvements have been made in the teaching programs to allow for an increased vocabulary. These programs have been useful in the preliminary work done with a small sample of blind students.

It is expected that, over the next 6-to-9 months, additional software will be developed to allow this musical language to be used with a text editor package available for the Apple II Plus. It is anticipated that even better software for teaching the language will also be available. Efforts will continue to obtain the cooperation of other facilities to evaluate the language and its uses.

Communicator for the Speech Impaired (Gary W. Kelly, Principal Investigator, and Theresa Ackerman, Research Technologist.)

This portable battery-operated device consists of a Morse Code entry system, a microprocessor, memory, and a display. It is designed to permit the user to input any phrase or set of characters into the Morse entry system for translation into normal alphanumeric text appearing on the display.

The Communicator has undergone several design alterations since the construction of the first prototype, each adding versatility and cost effectiveness. The most recent design, initiated in May 1981 and rapidly approaching fruition in the form of a fully working prototype, is technically state-of-the-art and gives the power and versatility to make the communicator an extremely useful device to the widest possible user population.

There are now two models, one with the Morse Code input and one with a pushbutton keypad input. With the ex-

ception of the input, the two models are functionally and operationally identical. All of the software and 95 percent of the hardware is identical between them, thus giving added versatility without losing economies of scale.

The microprocessor is Intel's 8748, which has become the industry standard for one-chip microcomputers. We have designed the device using a slow clock (3.6 MHz) which cuts the cost of the microcomputer to as low as $19.00 in volume. This can be less, if the projected volumes justify mass programming. The use of Intel's revolutionary 2816 EEPROM, just introduced, gives the user the capability to program his own messages. Message capability has been increased to 112 programmable lines which are linkable to any length. The use of a liquid crystal display insures that the display will be visible even in direct sunlight and, when coupled with an increased use of CMOS components, promises 6 or more hours of continuous operation per charge.

We believe that the present configuration represents the final iteration in the design process, as all major shortcomings of the previous designs have been addressed and eliminated. It is still possible, however, for some minor "fine tuning" to be required as we continue to get feedback from potential users of this device.

The new model will feature 112 user-programmable messages. A good redesign providing an improved housing of the model, of optimal shape and size, is expected to be completed within the next 6 months.

SENSORY AIDS IN THE VA RER&D SERVICE PROGRAMS

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Development of the Autocuer Speech-Analyzing Lipreading Aid

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Introduction

Numerous approaches have been made to facilitate communication with hearing-impaired and profoundly deaf persons. A number of methods and variants are widely used. An extensive summary has been prepared by Garmon (1). Various forms of sign language, finger spelling, lip reading, oral gestures, cued speech, and amplification constitute elements of total communication. Instead of competition between elements, some now believe that combinations may be effective.

Cued speech is a very effective technique for facilitating speech communication with people who are deaf. Developed by Orin Cornett, cued speech makes use of eight hand shapes held at four different positions near the face by the speaker. These manual syllable cues, in combination with lipreading, can enable realtime speech perception by a deaf person with accuracy comparable to that of an individual with normal hearing (2). Not a form of sign language, cued speech is described as a code designed to take the guesswork out of lipreading. For it to enable clear communication, of course, the speaker must know and use cued speech.

Recognition of the limitations inherent in any communication method for deaf people that requires each speaker to learn a special code led to the establishment, in 1971, of a collaborative research effort between Gallaudet College and Research Triangle Institute (RTI). The objective of this project was and is the development of a wearable device, now called the automatic cuer or Autocuer, which through electronic speech analysis can present to the deaf wearer visual cues equivalent to those of manual cued speech.

Research demonstrating the feasibility of an autocuer—that such a hypothetical device could remove ambiguities from lipreading—was performed during the period 1973–76 with support primarily from the National Institute of Neurological and Communicative Disorders and Stroke. Gallaudet College trained deaf subjects, then tested them on their ability to perceive speech presented via computer-cued videotapes. RTI developed the hardware and software for this effort, including a minicomputer-based speech analyzer for automatic generation of cues. The results of this work are reported in (3).

Figure 1 illustrates how the Autocuer display will appear to the user. The display shows, on a syllable-by-syllable basis, the results of the speech analysis. Consonant ambiguity is removed by visual symbol shape; each shape represents one of nine groups of visually contrastive consonants. Vowel ambiguity is removed by visual symbol location; each of four locations represents one of four groups of visually contrastive vowels. As seen in the figure, the symbols and locations are produced using two seven-segment displays. The wearable Autocuer will incorporate two seven-segment light-emitting diode (LED) displays built into one lens of eyeglasses, to produce the symbols superimposed on the user's visual field; the user will move his head to position the cue symbols beside the speaker's mouth.

Initiation of VA and NASA Involvement

By 1978 sufficient progress in speech science and integrated circuit technology had been made to justify undertaking the development of the wearable Autocuer. RTI and Gallaudet began discussions with the Veterans Administra-

FIGURE 1.
"He can go" and "Get a coat" appear similar to the lipreader. The Autocuer analyzes the speech signal and displays visual symbols to clear up such ambiguities. Wearer can position eyeglass-mounted display so that symbols appear near speaker's mouth.

tion and with NASA concerning such an undertaking. Key technology required for the wearable Autocuer was identified in the results of NASA R&D programs, and a 3-month study funded by NASA was begun in March 1979 to examine all aspects of Autocuer feasibility. The study results did verify technical and commercial feasibility of the wearable Autocuer. A group of older deaf adults (primarily veterans) were trained and tested at Gallaudet to verify that older adults typical of the VA deaf population can accurately receive speech syllables through Autocuer cues plus lipreading.

The joint VA-NASA project to develop and field test a modest number of wearable Autocuers began in August 1979. Because of the active technical role to be played by NASA in transferring its technology to the project, the decision was made that NASA would be the contracting agency.

Project Status

Project key accomplishments through June 1981 include the following:

1. Autocuer and Autocuer Display patent applications were filed with the U.S. Patent Office in October 1980.

2. An exclusive license agreement (based on the above inventions) and a no-cost contract for the commercialization of the Autocuer were signed by RTI and Gallaudet with Telesensory Systems Inc. (TSI) of Palo Alto, CA in December 1980. Under the terms of the contract, TSI will build 24 wearable Autocuers for use in the field test.

3. Using output from the Autocuer speech analyzer, deaf subjects at Gallaudet College scored 77 percent correct word recognition accuracy as compared with 57 percent accuracy on equivalent uncued speech and 86 percent accuracy on error-free computer-cued speech. These tests were completed in April 1981.

4. As of June, 1981, the design of the wearable Autocuer was nearing completion, and construction of prototypes was under way at RTI. The first demonstration of wearable units to NASA and the VA was planned for November, 1981.

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Effect of Auditory Cues in Computer-Assisted Instruction in Lipreading

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Sensorineural hearing loss in adults is frequently accompanied by a problem in speech discrimination, that is, difficulty in phonemic differentiation at suprathreshold sound levels. Since the mere use of amplification does not alleviate the problem of reduced speech discrimination ability, instruction in lipreading becomes an important component of the aural rehabilitation program. Although the literature abounds in methods, materials, and approaches in lipreading instruction, very little reference is made to quantification of improvement resulting from lipreading instruction.

Communicative efficiency of a hearing-impaired person results from hearing and seeing others talk. However, the use of bisensory input in lipreading instruction has not been examined as a part of aural rehabilitation procedures. The application of computer-assisted instruction in lipreading with an auditory-visual interactive device, such as the David Instructional System (Vontech, Inc.), lends itself appropriately to a more scientific examination of the effects of auditory-visual stimulation than has been available in the past.

The goal of this project is to provide new information on the effectiveness of computer-assisted instruction as a supplementary procedure for drill and practice in a program of lipreading instruction for post-lingually hearing-impaired adults. The first-year objectives include the development, construction, and video-tape production of 12 lists of 25 sentences each which are sequentially and progressively more difficult as lipreading stimuli. These sentences will be used as drill and practice material in a program of lipreading instruction at Olin E. Teague Veterans' Center (OETVC).

Beginning the second year, 12 lipreading lessons will be developed. Twenty-four patients at OETVC will be given audiological evaluations, the Utley Lipreading Test, and the Hearing Performance Inventory which measures the degree of hearing handicap. These subjects will be given 12 1-hour group lipreading lessons. During the interval between group lipreading lessons, these subjects will receive supplementary drill and practice with computer-assisted instruction in lipreading provided by the David Instructional System. For one group of subjects, **linguistic** redundancy will be systematically increased to the degree necessary for correct identification of drill and practice sentences. For another group of subjects, **auditory** redundancy will be systematically increased to the degree necessary for correct identification of drill and practice sentences. Data will be analyzed to determine (i) whether the magnitude of the change in Utley lipreading scores in the Linguistic Redundancy group and the Auditory Redundancy group is significantly different, (ii) whether changes in the Hearing Performance Inventory profiles are related to Utley lipreading scores, and (iii) whether there are significant changes in the degree of hearing handicap as measured by the Hearing Performance Inventory following lipreading instruction.

The probable impact or long-term significance of this research will lie in a number of interdependent outcomes: (i) increased understanding of the effect of systematic use of auditory-visual stimulation on the development of lipreading skill, (ii) quantification of improvement in lipreading skill as a function of instruction and type of practice, (iii) the development of a more scientific basis for construction of lipreading stimulus materials that vary from easy to difficult, (iv) identification of the utility of computer-assisted instruction in lipreading for post-lingually hearing-impaired adults, and (v) a better understanding of the effects of lipreading instruction in terms of how improved lipreading skill relates to a person's degree of hearing handicap.

The Clinical and Acoustic Parameters of Hearing Aid Effectiveness

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Clinical evidence and experience indicate that there is a wide range of communicative (auditory) performance in persons whose thresholds range from normal to the limits of the audiometer. Even persons having similar audiograms with respect to severity and configuration can demonstrate varying abilities to extract meaning from speech and environmental stimuli. To measure this performance clinically, we must seek those tests whose scores reflect such a range of disability. It is most likely that no single score can adequately represent a hearing handicap.

In the continued search for a satisfactory discrimination test, it is necessary to compare existing tests and their properties to the test in question. Since the CID W-22 Auditory Test (Hirsh et al., 1952) is still commonly used in clinical settings and its performance is well-known, it is customary and proper to use it for comparison purposes. The basic underlying construction of the CID W-22 Test is phonetically balanced lists of monosyllabic words. In contrast, a phonemic balancing scheme was followed by Lehiste and Peterson (1959) and Peterson and Lehiste (1962) in the formation of the CNC (consonant-nucleus-consonant) Test. One of the outgrowths of the CNC Test has been the Northwestern University Auditory Test No. 6 (Tillman and Carhart, 1966), more commonly referred to as the NU 6. The present study utilizes these three auditory discrimination tests in a quest for information regarding the equivalency, reliability, and future utility of the NU 6 Auditory Test as it is presently recorded.

The commercially available recordings of the CID W-22 Test were used in this study. The CNC lists were recorded by a young male graduate student in broadcast communications. In an effort to incorporate the effects of coarticulation, a carrier phrase in which the test word was embedded was used. The phrase is "say the _____ again." A female speaker with considerable experi-

ence in radio and stage productions was employed to record the NU 6 lists. The carrier phrase "say the word _____" was utilized. Both talkers had general American speech with absence of regional dialect.

It was the purpose of the following experiments to (i) determine the performance-intensity (P-I) function of the NU 6 Auditory Test with normally-hearing subjects, (ii) determine the P-I function of the NU 6 with hearing-impaired subjects, (iii) determine the equivalency of the four lists of the NU 6, (iv) determine the reliability of the NU 6, and (v) compare performance scores on this test with those obtained on the CID W-22 and CNC Tests.

Experiment 1

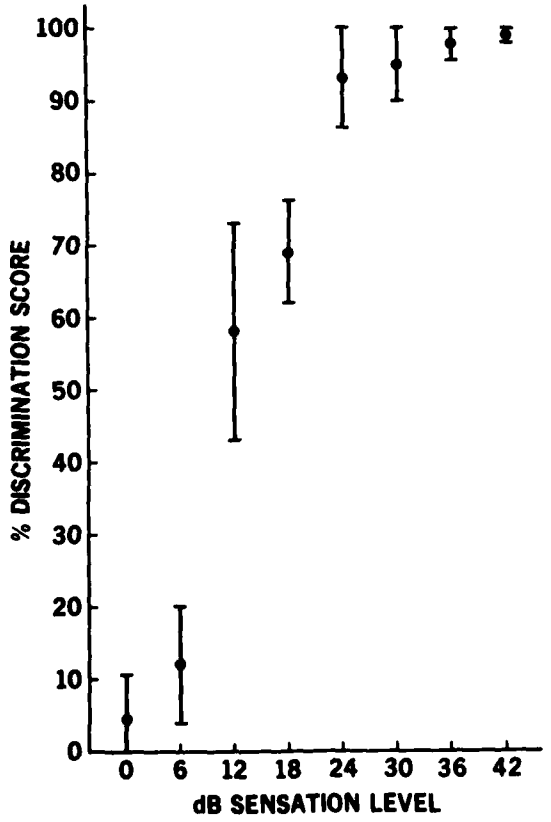
Procedure. Forty college students with normal hearing (thresholds < 20 dB HL from .25 to 8 kHz) and negative otological histories were used as subjects. The subjects ranged in age from 19 to 29 years with a mean age of 24 years. All subjects were tested in an IAC Series 1200 sound suite, using a Sony TC 353D tape recorder and the speech circuit of a Grason-Stadler 1701 audiometer. Test materials were administered via monaural earphone. Each subject was instructed to write his response and guess if not sure of the exact word.

A speech reception threshold (SRT) was established for each subject and used as the basis for administering the four lists at different sensation levels. The first 10 subjects received lists 1 through 4 at decreasing sensation levels of 42, 30, 18, and 6 dB. The second group of 10 subjects received lists one through four at increasing sensation levels starting with 6 dB and progressing to 18, 30, and 42 dB. The methods of presentation for the third and fourth groups replicated those for groups 1 and 2 except with different sensation levels: 36, 24, 12, and 0 dB. An equal number of right and left ears were used to minimize possible ear effects.

Results and discussion. The data were examined at eight different points along the P-I function with 20 subjects at each level. A mean and standard deviation were computed for each of the eight levels of presentation. These data points are plotted in Figure 1. The knee of the function occurs at a sensation level (SL) of 24 dB. The slope of the linear portion of the function was found to rise approximately 4.7 percent per decibel increase in intensity. This was determined using the mean scores at sensation levels of 6, 12, and 18 dB. This rise compares favorably with 5.6 percent per decibel increase reported by Tillman and Carhart (1966) for a different recording of the same test. The mean threshold of intelligibility for these subjects occurred at approximately 12 dB SL. This is somewhat higher than the 50 percent point on the function established by Tillman and Carhart. For their sample, the mean threshold of intelligibility was approximately 8 dB SL.

Experiment 2

Procedure. The subjects consisted of 40 male veterans ranging in age from 34 to 74 years, with a mean of 53 years. Each veteran received a complete hearing evaluation at the Audiology Service of the Veterans Administration Medical Center in Washington, D.C., immediately prior to participation in this inves-



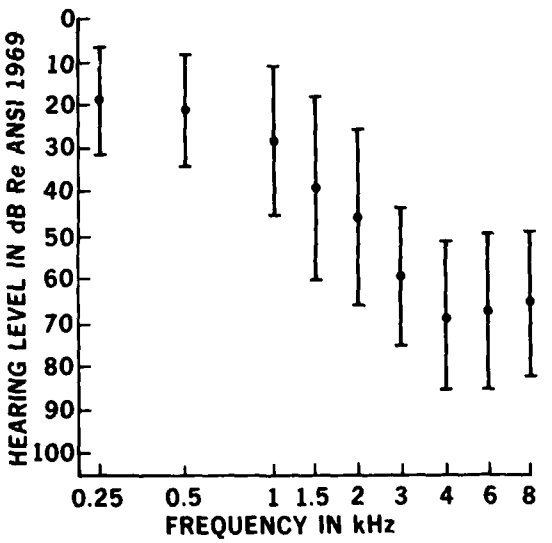


FIGURE 2.
Mean audiogram with standard deviations for the 160 sensorineurally-impaired subjects used in Experiments 2, 3, and part of 4.

FIGURE 1.
Performance-intensity function of 40 normally-hearing adults on the NU 6 Auditory Test and limits of one standard deviation.

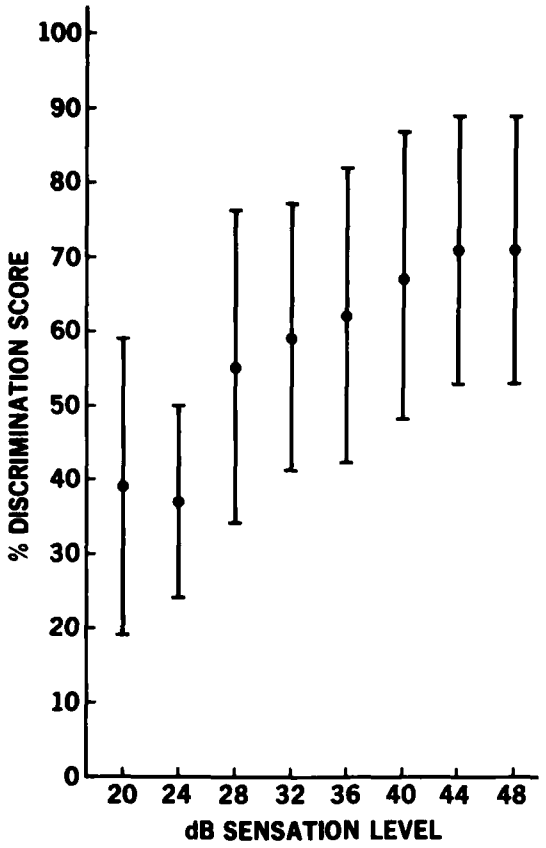


FIGURE 3.
Performance-intensity function of 40 sensorineurally-impaired adults on the NU 6 Auditory Test and limits of one standard deviation. Twenty scores were used to obtain each mean.

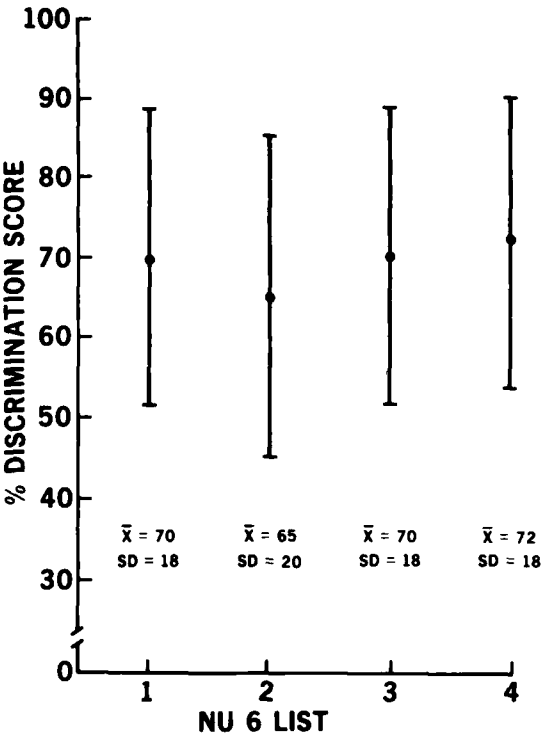


FIGURE 4.
Means and standard deviations of scores of 40 sensorineurally-impaired adults on each of the four lists of the NU 6 Auditory Test.

tigation. Only patients exhibiting hearing losses greater than 20 dB from 1 to 8 kHz were used as subjects. None had air-bone gaps greater than 10 dB, abnormal acoustic reflex thresholds, PI-PB rollover, or positive results on acoustic reflex decay measurements. The mean audiogram for these subjects is displayed in Figure 2.

All subjects were tested in an IAC Series 1200 sound suite, using a Grason-Stadler 1702 clinical audiometer with a Presto A908 tape recorder. Subjects were provided with answer sheets and instructed to write their responses and encouraged to guess if unsure of the exact word. Test materials were presented via monaural earphone and, to prevent lateralization at the higher sensation levels, appropriate masking was used in the nontest ear. The NU 6 Test, Lists 1 through 4, were presented in a counterbalanced manner. Eight presentation levels were employed to obtain eight data points along the function with 20 subjects receiving test stimuli at 20, 28, 36, and 44 dB SL (re SRT) and the other 20 at 24, 32, 40, and 48 dB SL.

Results and Discussion. Figure 3 displays the mean discrimination scores at the eight chosen sensation levels. Discrimination scores were better at an SL of 20 dB than at an SL of 24 dB without explanation. On the linear portion of the slope, there is approximately a 1 percent per decibel increase in performance in the range of 28 through 44 dB. The knee of the function occurs at a sensation level of 44 dB. This is somewhat higher than the 40 dB sensation level generally considered appropriate for achieving PB Max.

Experiment 3

Procedure. Forty male veterans ranging in age from 30 to 81 years with a mean of 54 years served as subjects. Each veteran met the previously-established criteria for sensorineural hearing loss. The test environment remained the same as in the previous experiment.

Each subject was administered all four lists of the NU 6 Test via monaural earphone at a sensation level of 48 dB (re SRT). The order of presentation of the lists was counterbalanced to avoid possible order effects.

Results and discussion. The results of the equivalency study are displayed in Figure 4. A repeated measures analysis indicated that a significant difference ($p < .001$) exists among the four lists. Pairwise comparisons were made among the means using the Tukey procedure (Winer, 1971). Results of these comparisons showed no significant difference ($p < .05$) between Lists 1, 3, and 4. However, List 2 does differ from each of the other lists (Table 1) by being more difficult. List 2 might be better utilized as a practice list while Lists 1, 3, and 4 can be considered equivalent.

Experiment 4

Procedure. Ten of the subjects who participated in the equivalency study returned for a second administration of the test in order to evaluate test-retest reliability. An average of 5 weeks elapsed between the first and second tests. Correlation coefficients comparing test and retest scores for each of the four lists were calculated.

Results and discussion. Results indicated that a significant correlation ($p < .001$) between test and retest scores does exist, thus demonstrating good test-retest reliability and stability of this

discrimination measure over time (Table 2).

Experiment 5

Procedure. Another group of 83 male veterans who met the previously-established criteria for sensorineural hearing loss served as subjects. As part of the routine audiological examination, PB Max was obtained using the CID W-22 Auditory Test. In all cases, the sensation levels necessary to achieve the optimum scores were greater than 44 dB.

Each subject was administered one of the two CNC Lists (1–4, and 1–10) and one of the three NU 6 Lists (1, 3, and 4), which are known to be equivalent, at the level of PB Max for the W-22 Test. The same clinical equipment was used for all measures. Results appear in Figure 5.

A repeated measures analysis indicated that a significant difference exists among the three discrimination texts ($p < .001$). Pairwise comparisons (Tukey procedure) among the test differences showed no significant difference between the NU 6 and CNC Tests (Table 3). However, the W-22 Test was shown to differ quite significantly from the other two measures. Examination of the data shows that the W-22 scores are much higher and have less variability.

Figure 6 was generated from data obtained from selected subjects included in the previous comparisons and from additional subjects with hearing loss isolated to higher frequency regions. These data demonstrate the conspicuous difference between the W-22 and CNC and NU 6 Tests as a function of hearing loss configuration. With one exception, the CNC and NU 6 Tests perform remarkably alike. That one exception is with subjects who have normal hearing only at 0.25 kHz. In that category, the difference in mean scores between the two tests is approximately 23 percent with the CNC Test scoring better.

An analysis of a selected portion of each of those two tests was conducted to determine if there were any obvious differences in spectrum. There appears to be much more energy in the region 0.3 to 0.6 kHz in the CNC Test than in the NU 6 Test, attributable to the difference between the talkers. This may have produced the performance distinction between the two tests in subjects with normal hearing at 0.25 kHz and impaired hearing at all other frequencies.

TABLE 1.
Differences between mean scores for the four lists of the NU 6 Auditory Test for 40 male veterans with sensorineural hearing loss.

List	1A	2A	3A	4A
1A	—	4.60*	.15	2.10
2A	—	—	4.45*	6.70*
3A	—	—	—	2.25

*$p < .05$

TABLE 2.
Mean discrimination scores for the lists of the NU 6 Auditory Test obtained on test and retest, differences between means, and correlation coefficients for 10 male veterans with sensorineural hearing loss.

List	Test	Retest	Difference	r
1A	74.20	78.00	3.80	.96*
2A	71.00	74.00	3.00	.92*
3A	76.00	77.20	1.20	.93*
4A	77.80	79.60	1.80	.95*

*$p < .001$

TABLE 3.
Differences between mean scores for W-22, CNC, and NU 6 speech discrimination tests for 80 ears with sensorineural hearing loss.

Test	W-22	CNC	NU 6 (female speaker)
W-22	—	13.63*	14.40*
CNC	—	—	0.77

*$p < .05$

Summary

As Kruel, Bell, and Nixon (1969) and Hood and Poole (1980) point out, speech discrimination tests should be thought of not as lists of words but as recordings of those words. The particular circumstances of a recording, i.e., talker, equipment, environment, etc., impart a set of characteristics to the recordings that are unique. Therefore, it should be understood that the results described herein pertain to a particular recording of the NU 6 by a female voice.

With regard to the ability to understand monosyllables in quiet surroundings, it is felt that the data on the NU 6 (female voice) demonstrates a decided advantage over the CID W-22 Auditory Test. The data on test-retest reliability and equivalency, the degree of relationship to the CNC Test, and the distinctions the NU 6 makes between individuals with varying degrees of high frequency loss, strongly support its use clinically. Further investigations of this recording of the test are warranted.

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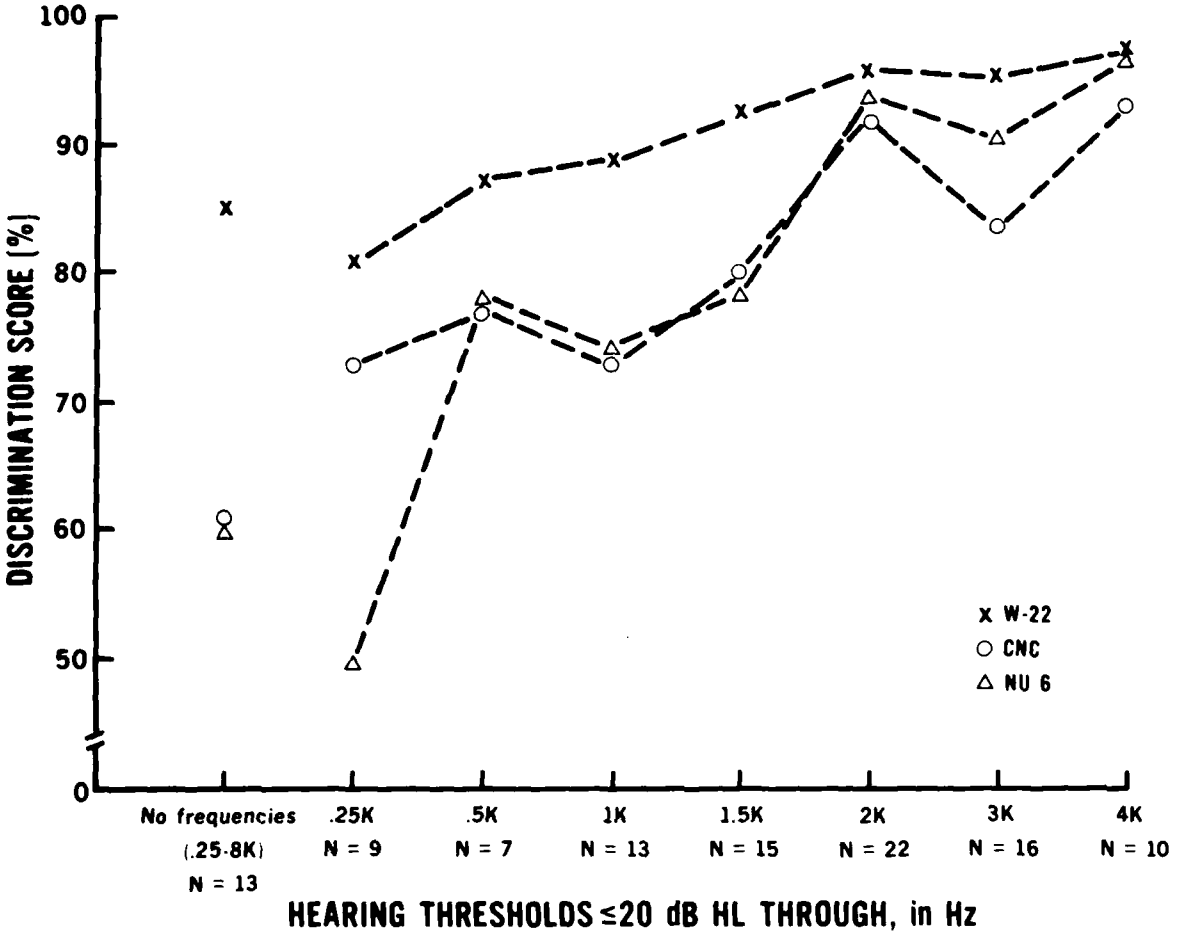

FIGURE 6.
Comparison of performance on W-22, CNC, and NU 6 Tests for groups that differ in region of normal hearing sensitivity.

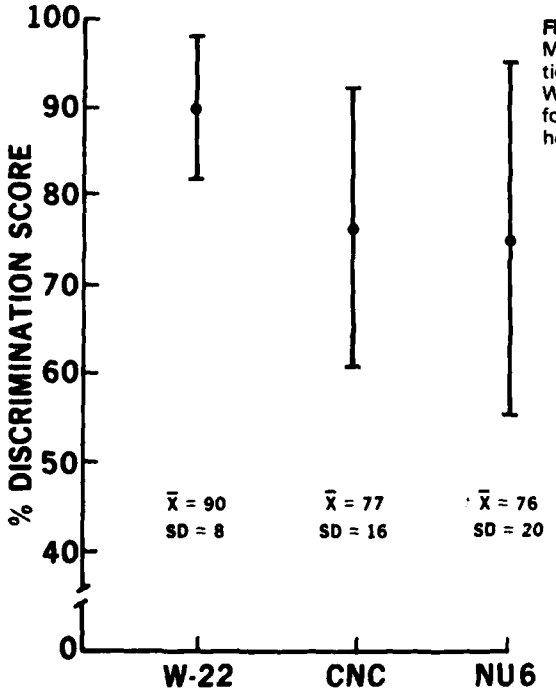

FIGURE 5.
Means and standard deviations of scores obtained on W-22, CNC, and NU 6 Tests for 80 ears with sensorineural hearing loss.

A Tactile Aid for the Treatment of Sensorineural Hearing Loss and Aphasia

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This investigation is designed to test the efficacy of Teletactor, a wearable electrotactile sensory aid, as a treatment for speech discrimination deficit in severe sensorineural hearing loss, and for auditory comprehension deficit in severe aphasia. Worn as a belt across the abdomen, Teletactor converts the frequency, intensity, and temporal information of an auditory signal into electrical pulses and presents these as

electrotactile patterns on the skin. A 16-week controlled treatment trial is being conducted with patients with severe sensorineural hearing loss and patients with severe aphasia to compare performance when wearing Teletactor with their performance when not wearing Teletactor.

During the period from January 1, 1981 through June 30, 1981, the computer system to generate and present acoustic stimuli and record subject responses was designed and ordered. In addition, screening for patients to identify those who meet selection criteria was initiated. Individual treatment programs have been written for four pilot subjects, three with aphasia and one with sensorineural hearing loss. These pilot subjects have been entered into a treatment trial that utilizes "live voice" stimuli while we await the arrival and assembly of our computer system.

Development of a Camera for Application in Sensory Aids for the Blind

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Introduction

The purpose of this project is to develop a hand-held camera for use in a reading machine for the blind. With this reading machine a user should be able to scan printed material using a hand-held camera and hear spoken English output. The new camera will provide good quality images for input to a character recognition module which identifies the images as individual characters and words. This stream of characters will serve as input to a text-to-speech module which produces the spoken output heard by the user. The camera will have high enough resolution and a large enough field of view to allow the reading of print sizes between 6 pt. and 20 pt. type, which roughly corresponds to type with a capital letter height between .05 inches and .2 inches and includes most common reading material.

The camera will be compatible with the Optacon, a tactile reading device which is a product of Telesensory Systems Inc (TSI), and with the Voice Output Reading System, HS-2, which will be developed by TSI. The currently used Optacon camera limits the potential performance of the Voice Output Reading System. The details of the problems which arise when this camera is used were discussed in the previous issue of the Bulletin of Prosthetics Research. It is expected that the improved quality of the images from the new camera, as well as the larger field of view for each character, will increase the accuracy of the character recognition software, which will in turn improve the quality of speech output.

Design Goals

The new camera is intended to offer improved performance over the current Optacon camera which is used in both the Optacon and the Voice Output Reading System, HS-1. It will contain a moderately high resolution solid state retina which will provide high resolution input images for an image preprocessing stage. This stage will simultaneously determine both the size and the orientation of the printed text. The resulting information will be used to automatically track a line of text, even if skewed, and to extract individual character images which will be transformed to a uniform size. This automatic control of line tracking will make camera positioning and movement much less critical. In addition, the automatic magnification control will replace one critical adjustment now required of the user. The result of both these features will be that much less skill, effort, and training will be needed in order to operate the reading system.

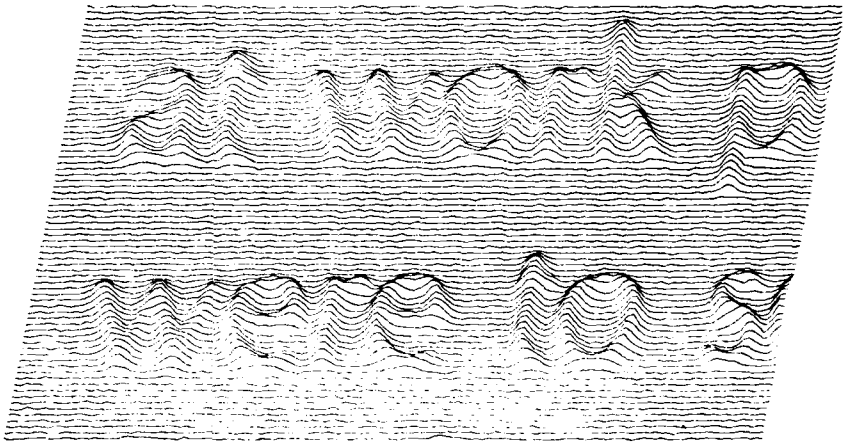

FIGURE 1a.
This image was digitized to 6 bits of grey level from a half inch strip of text printed in 14 point (rather large) type.

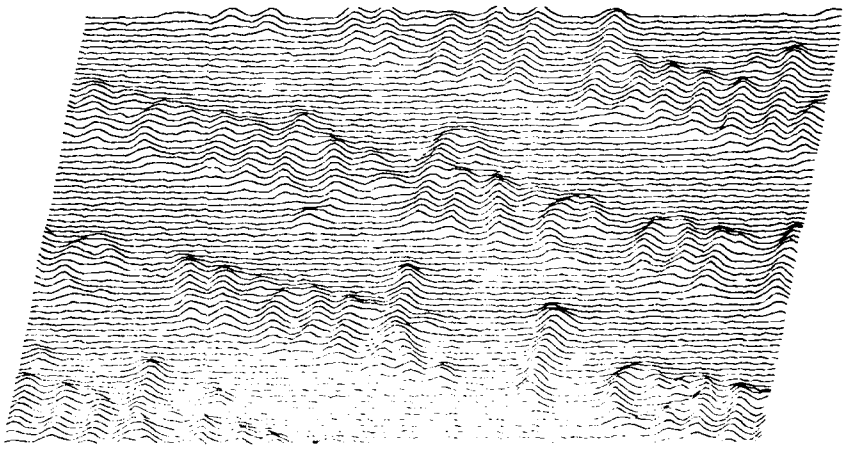

FIGURE 1b.
This image was digitized from text printed in 10 point type (a commonly used size) with about 12 degrees of line skew. This skew is slightly exaggerated by the display angle.

The larger images and improved signal-to-noise ratio are expected to improve the performance of the character recognition software. In addition, the new camera will allow increased reading speeds because the new retina can be sampled at a faster rate than the Optacon retina. The new camera may also contain a 6x24 Optacon retina for motion detection and tactile feedback. This would allow camera motion to be detected by image cross correlation so that no external encoders which might hamper camera movement would be needed.

Summary of Previous Work

An experimental camera with a 1024 point linear array was built and evaluated by TSI. The images from this camera were superior to the images obtained from the currently used Optacon camera. Motion detection software, which uses cross-correlation of sequential 6x24 Optacon images, is currently operating in the HS-1 prototype systems which are now under evaluation under a separate merit review contract.

Current Status

During the past six months an investigation of threshold, orientation, and magnification detection algorithms was begun at the Palo Alto RER&D Center. Images of pages printed in a variety of fonts were digitized to 8 bits of grey level. The image size was 512x512 and the spot size was about .006 inches. The type size varied from 6 point to 14 point, and a line skew of up to 12 degrees was tested.

A small section of 14 point type, set in the Optima font which is a sans-serif style, is shown in Figure 1a. Sampled horizontal scans through the image, which would subsequently be thresholded, are shown for a strip of the original text which is a little less than .5 inches deep. Although the image was digitized to 8 bits, the limited dynamic range made effective use of only 6 bits. With this resolution a digitized small letter ("x-height") would be 15 picture elements tall. This can be observed by counting the number of horizontal traces through a character. Even though this resolution is 25 percent greater than the minimum recommended by earlier studies using the Optacon input for character recognition, the problem of choosing a thresholding algorithm that resolves the crossbars of the two "t" 's shown is readily apparent.

A sample of 10-point Caledonia type with a 12-degree line skew is shown in Figure 1b. In this case the x-height is 11 which is within the recommended range for Optacon use with the reading machine. An image of 6-point type with this resolution was appropriate for magnification and orientation detection, but it was not as easily interpreted by visual observation as the two figures shown.

Preliminary work shows that orientation-dependent line integrals through segments of the digitized image yield a reliable magnification and orientation estimate. This method will be further investigated to establish performance limits. Filtering algorithms suitable for automatic thresholding to reduce the image to one bit of grey level per picture element will be tested using these images.

Three prototype cameras will be designed and built under contract by TSI. Blind subjects will test and evaluate the Voice Output Reading System, HS-2, using the new camera. This work will begin upon completion of contract negotiations.

Development of an Advanced Optical Character Recognition Speech-Output Accessory for Blind People

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Telesensory Systems, Inc. is developing a family of devices intended to meet the print reading needs of blind people. One of these devices, the Optacon, was introduced in 1971. There are now over 7,000 in use throughout the world. Two additional devices are under development. One is an accessory for the Optacon that recognizes printed characters and speaks words intelligibly in a synthetic voice as the reader scans print by hand. The other is a speech-output reading system that automatically scans print under the control of a blind user. The research and development leading to the new devices is partially supported by an inter-agency contract from the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration. Over a 30-month period, it is intended to implement low-cost Optical Character Recognition (OCR) techniques suitable for use with an Optacon, low-cost high-quality text-to-speech techniques, and a means for automatically scanning a bound book.

Results of the first 27-month effort (starting September, 1978) were previously reported. By the end of 1980 five hand-scan prototype units had been built and successfully demonstrated to representatives of the sponsoring agencies. During the first months of 1981 these units were used daily by blind TSI employees. In June 1981, TSI received a contract from the Veterans Administration to conduct a design evaluation of the hand-scan prototypes. Three additional units were built and will be subjected to a formal field evaluation at private sites.

During the final months of the project much effort went into refining the breadboard unit of the automatically scanned reading system. New optical elements were introduced to reduce reflection and to increase reliability. New circuitry for signal detection and thresholding was added. Distortion correction hardware and software were implemented. Software to deal with format and read pages was moved from the mainframe computer to the breadboard hardware.

The result of these efforts is a stand alone system which, under operator control, can scan a single sheet of material. The breadboard scanner can perform a low-resolution "format" pass over the page to locate and identify page features such as columns, titles, and page numbers. The results of this pass can be displayed in real time on a graphics terminal attached to the breadboard. It can also perform a high-resolution "read" pass to collect image data which is then enhanced and formatted for input to an OCR (Optical Character Recognition) program. The enhanced data can either be displayed locally or written on a floppy disk for transmission to the OCR program which runs in a mainframe computer.

A number of tasks have to be accomplished before this breadboard system can become a manufacturable product. Packaging will have to be designed to allow the system to read bound books. The optical and mechanical systems must be further designed for improved

reliability and ease of production in volume. The electronics will have to be expanded to include interfaces to an OCR and TTS (Text to Speech) computer. The page-formatting software should be developed further to handle complex formats. A set of user controls must be integrated and subjected to human factors evaluations. The current breadboard system proves that most of the technical problems have been solved; many practical problems remain.

Design Evaluation of the Hand-Scan Voice Output Reading System

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There is a need for a thorough design evaluation of the Telesensory Systems, Inc. (TSI) Voice Output Reading System based on the Optacon. This initial Hand-Scan Voice Output Reading System has been developed at TSI, in part utilizing funds from the VA, The Bureau of Education for the Handicapped, and the Rehabilitation Services Administration. Extensive consumer feedback is needed in order to review the design and performance of this system, which could substantially overcome the print handicap of blindness for many individuals.

The TSI Hand-Scan Voice Output Reading System prototype (HS-1) will be evaluated through a period of extensive field trials. These trials will involve the placement of four units in diverse evaluation sites for use and review by blind people with a variety of reading needs. The units will be placed in the VA Blind Rehabilitation Centers in Palo Alto, California and Hines, Illinois, in a public school system in DeKalb County, Georgia, and a series of individual employment settings in the San Francisco Bay Area near TSI. In addition, three units apart from these VA systems have been placed at The Cleveland Society for the Blind Sight Center, The Braille Institute of America in Los Angeles, and the American Council of the Blind national office in Washington, D.C.

Each evaluation site will be managed by a site coordinator, trained by project staff concerning HS-1 operation, training techniques and research protocol. Site coordinators will assess individuals for the requisite skills needed to successfully operate the system, train screened individuals, test for reading speed and comprehension, and interview participants concerning response to the system following training. They will also provide following-along support for participants as needed, schedule the system for independent use training, and report performance problems to project staff.

The project Principal Investigator will interview all participants in depth concerning their use of the system and response to it, and compile data concerning the following areas: system features (user controls, optical character recognition, text reformatting), the system's tracking aid, general system performance, and the device's applications and limitations.

All data will be compiled and reported to the VA and to TSI for the purpose of recommending design changes for a future production unit.

Status.—A training program for site coordinators was held during the week of July 20, 1981. Site coordinators were brought to TSI for the 3-day program concerning all aspects of the evaluation project. Following the training, units were shipped to the various sites.

An Auditory Prosthesis for Sensorineural Hearing Loss

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Hearing loss is conventionally classified into two main categories—conductive and sensorineural. In the first, the hearing loss (as measured by elevation in threshold of detectability) can be attributed exclusively to a lowered efficiency in the transmission of acoustical energy to the cochlea. The use of hearing-aid amplifiers to compensate for such conductive hearing losses has proved to be of great value. The second category, "sensorineural" hearing loss (SNHL), represents what might be called "all other" forms of hearing loss. Although threshold elevations are usually present, amplification of the acoustic energy is not often of any significant benefit to such patients and, even worse, frequently results in further deterioration of the patient's ability to process acoustic information—particularly speech information. It would be fair to say that at the present time most patients with a significant degree of sensorineural impairment will derive limited or no benefit from contemporary hearing-aids (1).

The central idea of this research project is the analysis of SNHL, specifically cochlear pathology, in individual patients in terms of the consequences to the patient's ability to process spectral or pitch information. From this point of view, the more peripheral stages of the neural auditory pathways become a system that introduces spectral and/or intensity distortion into the signals it transmits to higher auditory centers. Recent research in this laboratory as well as others indicates that it may be possible to characterize the distortion produced in an SNHL patient by means of simultaneous dichotic pure-tone stimuli. Within the context of a theoretical model of pitch processing (2), the SNHL distortion can not only be characterized, but it is also possible to compute a compensatory signal distortion for each patient, which when combined with his SNHL distortion will tend to normalize the neural signals reaching the higher auditory centers. To the extent that these central neural signals are normalized, the patients' ability to deal with auditory stimuli, especially with spectrally complex ones like speech, should be greatly improved. Indeed, the overall goal of this research is to specify the design of a signal-distorting hearing aid which compensates for the hearing deficits produced by damage to the sensorineural mechanism.

During the period from January 1 to June 30, 1981, six subjects with varying degrees of SNHL have begun the series of monaural and dichotic tests necessary to characterize each of their hearing losses. Four normal-hearing controls have also begun the same series. The results obtained thus far are restricted to frequencies at 1000 Hz and below and must be considered preliminary at this time, but it is clear now that the techniques (used previously only in subjects with normal hearing) can be applied successfully to SNHL subjects. Of par-

ticular interest is the stage of the theoretical model (the intensity-response or I-R function) which corresponds to the ear's ability to determine the intensity of a sound and generate the appropriate neural response for that intensity (3). Of course, it is well known that the ear with SNHL is not operating normally with respect to its intensity-response transduction mechanism—threshold elevation alone established that—but no techniques have been available previously to measure the shape of the I-R function throughout the intensity range in either SNHL or normal-hearing subjects. Previous work in this laboratory has led to an innovative method of measuring the I-R function in normal-hearing subjects. One major aspect of the current study is to perform similar measurements with SNHL subjects.

The I-R functions of normal-hearing subjects tend to have a constant slope in the range of 50-to-90 dB SPL, and when the slope does change, it changes in a gradual, regular way. In contrast, the I-R functions measured so far for hearing-loss subjects at 1000 Hz have shown somewhat more rapid and irregular changes in slope than those of control subjects. Although it is much too early to draw conclusions concerning the significance or utility of these measurements, such abnormalities in the intensity-response transduction mechanism could account for some deterioration or loss of information in the processing of complex acoustic signals (e.g. speech). Further testing will continue on these and other subjects, and tests will be added as computer hardware acquisition and software development progress. The first test of a computer simulated hearing-aid for one of the current hearing-loss subjects will probably occur in about 1 year. It is such hearing-aid simulation tests which will determine the significance and utility of the measurement of the I-R function in subjects with sensorineural hearing loss.

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Communication Aids Research for the Blind

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(The studies and evaluations covered in this report are not funded as research by the Rehabilitative Engineering Research and Development Service.)

Communication aids research at the Central Blind Rehabilitation Section is conducted by Harvey Lauer and Leonard Mowinski. It includes some basic research, testing, evaluation, and dissemination of information.

The urgent need for some blind people to use computers if they are to compete with their sighted peers has given rise to several instruments. An example is the VersaBraille made by Telesensory Systems, Inc. As a stand-alone device it can serve for braille reading, composing, editing, and personal filing. The model we have acquired for an evaluation project being done by VAREC, New York, serves also as a computer terminal. A formal protocol has been written in New York: however, all aspects of VersaBraille (except for extensive reading) have already been experienced by subjects eager for familiarization.

It was found that braille users can easily read the "soft copy" braille output and that professionals who would have need for such an instrument can readily learn to use it as a stand-alone device. Though the manual is very good, those who have not had experience with computing machinery would be best advised to receive personal instruction. Use as a computer terminal was successful in many instances. The Model P2 VersaBraille was interfaced with computers, modems, a printer, and the Kurzweil Reading Machine for interacting, editing, and the production of hard-copy print. Initial instruction and installation can be complex and may require special skills and even a site visit.

Electronic technology for the sighted is undergoing yet another revolution, and many of the results are especially useful to the visually impaired. Even more surprising is the fact that fewer adaptations are needed. The staff, therefore, attended a computer convention and an exhibition on consumer electronics, and contacted dealers and distributors for information and demonstrations. Following is a list of items and categories about which Lauer and Mowinski can supply information and some written reports: talking clocks and watches, speech compressors, talking calculators, musical calculators, new features of tape machines such as indexing or tabulation, digitally-tuned radios, new radios with TV audio bands, personal stereo radios and tape machines with miniature headsets, computer games blind people can play, and making music with synthesizers and computers. Talking tools including microwave ovens, thermometer, currency identifier, multimeters, computer terminals, etc., and dictating machines with microprocessors.

Two of those items deserve special mention. The revolutionary design of new miniature headsets is very welcomed by blind people because it combines comfort, high fidelity, and minimal reduction of sounds from the environment. The Type N' Talk, made by Votrax, is a text-to-speech converter which can be plugged into many computer systems. Its small size, low cost and clear speech may revolutionize talking terminals and computers.

The Voxcom is a module which attaches to a modified cassette recorder. It is a card reader permitting recordings of fifty seconds or more to be stored on a single card. Because it may serve as a filing medium for those who cannot use braille, it is being tested in the Blind Center. (The Voxcom is being tested at the CBRC in a project supervised by the research staff and conducted by an intern in Rehabilitation Teaching, Shif Toda.) The popular APH player/recorder has been modified to work well with the Voxcom.

The staff is working with researchers at the Hines RER&D Center who are conducting a project to evaluate performance of blind people with reading aids and with braille. Basic research into the value of the tonal output for the Optacon described in the previous report is also underway.

The evaluation of the Hand Scan-1 (HS-1), an optical character recognition speech-output system for the Optacon reading machine has begun. The Central Blind Rehabilitation Center is one of six sites where this prototype unit from

Telesensory Systems, Inc., will be evaluated. Development of this unit was supported by an interagency contract from the Veterans Administration, the Bureau of Education for the Handicapped, and the Rehabilitation Services Administration.

Mr. Mowinski attended a 3-day training seminar at Telesensory Systems to learn the function and operation of the HS–1. The unit was delivered on July 29. Protocol for the evaluation was supplied by TSI. The Blind Center will provide the manufacturer with documentation on system reliability, optical character recognition, user controls, tracking accuracy, training and training materials, and application of the system. The veteran population tested will consist of experienced Optacon users as well as veterans with no reading machine experience.

In June, Mr. Lauer served on an advisory panel for the American Foundation for the Blind. It concerned the development and evaluation of a full-page "soft copy" braille display for which the AFB has a National Science Foundation Grant.

Mr. Lauer was selected as one of several consumer respondents at the 1981 conference of the Rehabilitation Engineering Society of North America in Washington, D.C. Two of his papers to be published in the proceedings deal with the role of consumers in rehabilitation engineering, and the rationale for employing several communication media or channels for the blind.

Clinical Application Study of Reading and Mobility Aids for the Visually Impaired

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(The studies and evaluations covered in this report are not funded as research by the RER&D Service of the VA. The period covered here is from January 1, 1981, through June 30, 1981.)

HS-1 Evaluation—The HS-1 (Hand Scan 1 or "Talking Optacon"), a reading machine for the blind, is currently being developed by Telesensory Systems, Inc. (TSI). Under a contract from the VA, prototypes are presently being evaluated at the Braille Institute of America in Los Angeles, The Cleveland Sight Center, and our own site, the Western Blind Rehabilitation Center (WBRC) in Palo Alto. Other sites soon to be added to this evaluation are the DeKalb County schools in Atlanta, The American Council for the Blind in Washington, D.C., and the Central Blind Rehabilitation Center at the Hines VA facility.

The unit has three components. The CPU (central processing unit) is about 17 inches wide, 20 inches deep, and 13 inches high, and weighs about 55 pounds. The operator's console (into which a standard Optacon is inserted) measures approximately 8 inches wide, 8 inches deep, and 4 inches high. The tracking aid, about the size of a clipboard, provides the surface onto which the reading material is clipped and the Optacon camera is attached for easier tracking. The entire unit weighs about 66 pounds.

The controls are simple, conveniently located, and few in number. On the CPU are the on/off switch, jacks for a tape recorder and earphones, the volume control, and the rate control with settings for 60, 100, 180 and 300 words per minute. The operator's console has the intensity and threshold controls—which are on the inserted Optacon—plus three other switches for controlling the system. There are two 3-way switches. The first has settings for record, ready (normal voice output code), and Optacon mode (tactile reading only). The second switch has settings for spell speech only, normal spoken word output, and spell last word. There is also a paddle switch to control the memory (which holds 1000 characters). On the camera there is the magnification control.

The synthetic speech is of high quality, clear, and easy for all students to understand after a listening time of 1 to 3 hours.

The system is programmed to recognize 12 major type fonts, and does well with many of the variations on these fonts. It recognizes many of the common symbols, but there is a need for additional ones, such as the percent (%) symbol. Some consideration is being given to making it possible for the user to choose the types of symbols to be recognized—mathematical, scientific, and other specialized symbols. The programming is on tape, so it is easy to change, but it takes 6 minutes to download.

Evaluation of the optical character recognition error rate is an area where more research is needed. At present, it is difficult to separate this error rate from the human error rate when tracking with the hand-scanned camera. Tracking is one of the more difficult skills needed to operate the system, and hours of training are required before it is mastered. The present tracking aid allows for too much vertical movement of the camera, and a very tight tracking tolerance is required before individual characters are recognized accurately. The general error rate varies greatly, depending upon the tracking skill of the individual user. However, if the tracking can be mastered, it allows the user to read material with a more complicated format than an automatic scanner could deal with.

Thus far, maintenance has not been a major problem. There have been only two problems requiring the attention of a TSI engineer. On one occasion, with the use of a telephone MODEM, the problem was diagnosed from TSI and the appropriate action was taken.

There are many questions yet to be resolved about reading machines in general and this one in particular. It is hoped that we can begin to find answers to some of these during the next year's evaluation.

Night Vision Aid and Wide Angle Mobility Light (Evaluations)—The WBRC has completed its study evaluating the effectiveness of the Night Vision Aid (NVA) and Wide Angle Mobility Light (WAML) in reducing the mobility problems of people with night blindness. An explanation of the operation of the aids and the research methodology have been included in a previous issue of the Bulletin of Prosthetics Research (BPR 10-33, Spring 1980).

Thirty-five subjects participated in the study over a 15-month period, and 24 of them completed all phases of the project. The remaining 11 subjects did not complete the study because of scheduling conflicts, visual acuity and/or visual fields which did not warrant the need of a night mobility aid, discharge from the rehabilitation program prior to completion of the research project, or further loss of vision during the project.

Twenty-one of the subjects were vet-

erans who were either enrolled in the WBRC program at the time of their participation in the study, or were formerly in the WBRC program. The remaining three subjects were nonveterans from local communities who were referred to the project by VA optometrists and ophthalmologists. The participants were between 25–82 years old, with an average age of 52. Of the 24 subjects, there were 21 men and 3 women.

The results of the study have been summarized and analyzed, and a complete description of the study is being prepared for publication. The data showed that, on the average, the subjects' night mobility with the WAML more closely approximated their daytime mobility than did their night mobility with the NVA. This was true for both of the objective measures used: (i) measurement of time to complete the evaluation routes and (ii) number of errors counted during the routes. The results showed that the subjects averaged approximately the same number of errors when using the NVA as when traveling at night without the aid. The average time to complete the route was slightly greater when employing the NVA than when negotiating the environment at night without any aid. In all, 20 subjects had better times and scores with the WAML and 3 performed best with the NVA. One individual had a better time with the NVA but a better score with the WAML.

In addition to the objective results, participants' subjective comments regarding both devices were recorded. Seventeen subjects stated that they preferred using the WAML and seven preferred the NVA. Subjects who preferred the NVA gave such reasons as its size and portability, inconspicuousness and acceptable cosmetic appearance. A few subjects preferred the NVA because the maximum focal range extended to infinity, and they could therefore see for greater distances with the NVA than with the WAML. Although the majority of the subjects preferred the WAML, they cited drawbacks such as weight, size and conspicuousness.

The Central Blind Rehabilitation Center (CBRC) in Hines, Illionis, and the Eastern Blind Rehabilitation Center (EBRC) in West Haven, Connecticut, are conducting evaluation projects following the same protocol.

Mowat Sensor Study—A follow-up study was begun on the Mowat Sensor, an electronic mobility aid designed for the visually handicapped. The operation of the device and the evaluation protocol for this study were described in the previous issue of the Bulletin of Prosthetics Research (BPR 10-35, Spring 1981). A preliminary followup study had previously been conducted by the authors and was reported in the Journal of Visual Impairment and Blindness (Morrissette, Goodrich and Hennessey, 1981).

The start-up date for the project had been delayed due to a delay in completion of a monitoring device which is to be added to the Mowat to gather additional project data. (The monitoring device is being developed by the Palo Alto VAMC RER&D Program.) Since the monitor will not be completed for approximately 6 more months, the project has been modified to accommodate for the delay.

Wide Angle Mobility Light Followup Study—A followup study of the Wide Angle Mobility Light (WAML) has been completed. The purpose of the study was to ascertain the effectiveness of the WAML as a night mobility aid for people with night blindness, as well as determining its maintenance reliability, usage rates, limitations, and user-suggested modifications.

A telephone survey was conducted of all known professionals and visually handicapped individuals who had either purchased the device or had it purchased for them. The names of the purchasers were supplied by the manufacturer, Farallon-Oceanic Industries in San Leandro, California, and the distributor, Innovative Rehabilitation Technology, Inc., in Los Altos, California.

Thirty-two visually handicapped individuals and 23 professionals in the field of low vision were contacted. All individuals who were contacted agreed to answer the survey questions, and each interview required 15–45 minutes. The data are presently being summarized and analyzed, and when this is completed the results will be submitted for publication.

Head-High Obstacle Detector—The WBRC is working cooperatively with the VAMC Palo Alto RER&D Center to develop an object detector to aid in the safe mobility of the visually handicapped. Visually limited and totally blind people who negotiate the environment with the long cane receive advance information and protection from the cane. The cane protects the user from waist height and below. Even with perfect cane skills, however, the cane does not offer any protection to the user above the waist. As a result, the visually handicapped traveler is not protected from contacting overhanging tree branches, bent poles, head-high signs attached to poles and similar hazards. A head-high obstacle detector has been proposed which would act as a warning system for such hazards.

The goal of the project is to develop a small, lightweight, cosmetically acceptable aid which would provide the user with consistent, reliable information regarding the presence of obstacles located at head level. Other goals specify a device which is simple to operate, inexpensive, and usable by visually impaired individuals with additional handicaps.

A first-generation prototype has been developed by the project engineer, Dan Pliskin. The device employs two 40 kh crystal transducers which emit ultrasonic bursts. Reflected signals are then converted into a tactile output. The aid is worn like a medallion around the neck, and tactile feedback to the user is provided by a vibrator located in the neckstrap. The body of the prototype measures approximately 3¼ inches wide, 3¼ inches high and 1 inch deep. With the neck strap, the device measures 10½ inches long. One of the project goals is to design an aid which is smaller and less conspicuous.

The design criteria call for a beam which extends horizontally from 1 to 2 inches beyond the shoulder width of the user and, vertically, covers from the upper chest area to a point 1 to 2 inches above the head. The precise range has yet to be determined, but the objective is to enable the user to detect obstacles in the immediate area and still allow the individual sufficient time to react to the signal.

A second-generation prototype, presently being devised, will be tested with subjects prior to further development and evaluation on a larger scale.

Investigations of Acoustic Reflex in Elderly Persons

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The human acoustic reflex is a brainstem-mediated system that produces contraction of the middle-ear muscles upon presentation of an appropriate acoustic stimulus to an ear. Certain aspects of the acoustic reflex have clinical application, and investigations in recent years have provided useful data for prediction of hearing loss from reflex thresholds (Popelka, 1981) and for assessment of certain auditory pathology (Borg, 1976).

The primary goal of this research program is provision of quantitative information on the effect of aging on the human acoustic reflex. Subject samples for most studies are composed of normally-hearing persons in the 20–79 year age range. Data are gathered with an aural acoustic-immittance[a] instrument, which is the basic instrument in a noninvasive procedure for analysis of the acoustic reflex.

The initial phase of the project is centered around interfacing and calibration of computer hardware and analog instrumentation, development of software for acquisition and analysis of aural acoustic-immittance measures, and location of suitable subjects in the 50-to-80-year age range. The major activity during the reporting period has been the development of an efficient algorithm for computer-controlled measures of perstimulatory adaptation of the acoustic reflex. Written on a Nicolet MED–80 computer, these programs control stimulus generation, direct memory acquisition of data in 4 kbyte segments, and routines for direct-memory-access of data for absolute measurement of quantitative characteristics. This program set is the first of a family of programs for automated measurement of aural acoustic-immittance measures, including tympanogram, acoustic-reflex threshold, and the input-output function of the acoustic reflex.

Other activities have included work on a report on transcranial conduction of signals used for contralateral activation of acoustic reflex, and the development of graphics software for representation of acoustic-reflex measures.

[a]Refers to measures of acoustic impedance or acoustic admittance acquired in the (human) ear canal (ANSI Standards for Aural Acoustic-Immittance Instruments, Draft 1980A).

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1981 is the International Year of Disabled Persons, by resolution of the General Assembly of the United Nations. The expressed purpose of the International Year of Disabled Persons is to "undertake to further full participation of disabled persons in the life of their society." The efforts of this center have focused upon heightening public awareness of the large disabled community, and reducing the number of barriers faced by many of these individuals because of physical limitations.

This year, the RERanD Center has undertaken a program directly attuned to public education regarding rehabilitation research. The Center hosted a public Open House on Saturday, April 11, 1981, presenting current research of the RER&D staff as well as rehabilitation-oriented projects by Stanford University engineering graduate and undergraduate students. A high degree of interest and enthusiasm was evident throughout the 4-hour event. The Center continues to receive requests for tours and presentations from individuals as well as professional and service-oriented groups interested in rehabilitation. An average of 4 such groups per month are accommodated.

In addition to such public education endeavors, a weekly seminar series has been initiated for the purpose of educating both investigators and support staff at the Center. Experts from various rehabilitation-related fields of research and clinical service conduct seminars in their area of expertise at the Palo Alto RER&D Center, facilitating an exchange of information and ideas.

Toward the goal of reducing the number of barriers encountered by disabled persons, Center personnel continue research on the design and development of rehabilitative devices using high technology. It is expected that these efforts, both short and long term, will facilitate the increased integration of physically limited persons into the mainstream of society.

The following summaries represent work that has been accomplished on the various projects under way at our Center during the period January–June, 1981. An additional seven proposals are being prepared for submission to the Fall 1981 VA RER&D Merit Review, and another has been submitted for consideration to the Paralyzed Veterans of America Technology and Research Foundation.

Toward Better Methods of Nerve Repair and Evaluation

Personnel: **Vincent R. Hentz, M.D.** (VA); **Larry J. Leifer, Ph. D.** (VA); and **Gordon S. Abraham, M.S.** (VA).

This is a new VA Merit Review project.

Need—Further investigation of better methods of nerve repair and regeneration must address two fundamental and interrelated problems: (i) the inability to surgically restore normal anatomical configuration at the repair site; and (ii) the present lack of objective techniques to evaluate the results of repair and subsequent regeneration.

Background—Previous investigations of nerve repair techniques have utilized either suture methods at the epineurial or perineurial level, or sutureless methods applied at the epineurial level. Inconsistent results have been obtained,

both because objective methods to measure return of function in clinical and laboratory studies have not existed and because the repair methods mentioned above failed to restore normal anatomical configuration at the severance site.

Goals—This project is designed to test the following two hypotheses: (i) sutureless repair techniques utilizing newly developed biodegradable membranes at the perineurial level can better restore anatomical configuration at the repair site than conventional suture methods, and can increase the number of axons proximal to the repair site making functional distal connections; (ii) recently developed computer derived methods that permit mapping of mixed and motor nerves by axon conduction velocity distributions (NCVD) can provide a quantitative evaluation of functionally connected axons.

Method

Following preoperative nerve conduction velocity distribution studies, controlled injuries will be created in the median and ulnar nerves of a previously developed primate model, the macaca fascicularis or cynomolgus monkeys. Tensionless nerve anastomoses will then be performed, using either standard repair techniques such as epineurial or perineurial suture methods, or perineurial tubulization techniques utilizing several newly developed biodegradable materials (including hypoantigenic collagen and polyglycolic acid membranes). Early events will be studied by standard histologic methods. Serial nerve conduction velocity distribution studies will be used to observe changes in the nerve proximal to the repair site. At varying postoperative intervals, regeneration across the repair site will be assessed using conventional electrophysiologic techniques and newly developed computer-derived nerve conduction velocity distribution methods and methods to integrate the area under the compound action potential. This information will be correlated with standard histologically derived axon histometrics. These studies of repairs performed in a tensionless manner will be modified in a nerve gap model to study the effects of tension on nerve repair and regeneration in the primate.

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Measurement of Muscle Mechanical Properties in vivo Using a Buckle Transducer

Personnel: **Parvati Dev, Ph. D.** (VA); **Michael R. Zomlefer, Ph. D.** (VA), and **Vincent R. Hentz, M.D.** (VA, Stanford)

This new project is supported through the RER&D Center core budget.

Need—Tendon transfer surgery for reconstruction of the upper limb is based on knowledge of the force and maximum excursion of the muscle whose tendon is transferred. The changes in muscle tension with changes in muscle length during contraction are not well-known, but will significantly affect the performance of the transferred muscle at different joint angles. There is a need to know the length-tension relation for all muscles used in reconstruction of the upper limb.

Approach

A small (2 cm × 1 cm) E-shaped chromium-steel buckle has been developed, based on a design available in the literature, which can be slipped onto the tendon. As the tendon is tensed, the buckle is stressed and the corresponding strain is measured by strain gauges glued to the buckle. During surgery, when the tendon to be transferred is exposed, the buckle can be slipped onto the tendon before it is cut to determine the muscle's resting tension (which is often the tension at which it is reattached at its new insertion). Once the tendon is cut, the muscle's length-tension relation can be measured for both passive muscle and muscle that is electrically stimulated. During reattachment, tendon tension is monitored so that the desired tension can be precisely established.

Status—A working prototype of the buckle transducer has been tested on the cat's Achilles tendon. A larger version, suitable for use on human wrist and finger tendons, is being developed. Permission for the experiment is being sought from the Human Subjects Committee.

Pending—Once the required permission for experimentation is obtained, the buckle will be used in the operating room during elective surgery for hand reconstruction. The informed consent of the patients will be sought.

Talking Computerized Bulletin Board

Personnel: **Gregory L. Goodrich, Ph. D.** (VA); **David L. Jaffe, M.S.**; **Sue Melrose** (VA); **Douglas H. Williams** (Psycho-Linguistics Research); **Carol A. Simpson** (Psycho-Linguistics Research), and **Susan H. Phillips** (Sensory Aids Foundation).

Support for this new project is provided from RER&D core budget.

Need—Therapists, physicians, researchers, consumers, manufacturers, and engineers are all a part of the rehabilitation community. Many local, state, national, public, and private organizations participate in providing aid for the disabled. Despite conferences, newsletters, and local meetings, the diverse nature of rehabilitation makes it difficult for segments of the community to keep abreast of research activities, new products, new services, events, and current information.

Approach:

A similar lack of efficient information transfer prompted computer hobbyists to implement "Computerized Bulletin Board Systems." Using terminals, modems, and the telephone, they were able to access a centralized computerized communication node to send and receive messages regarding club meetings, new programs or hardware, equipment for sale, or just gossip. These

systems have multiplied to over 200 and now exist in all parts of the country. Systems have also been developed to meet the specialized needs of amateur radio operators and some non-technically-oriented common-interest groups.

A computerized bulletin board system would provide an ideal information node for the rehabilitation community. Its advantages are:

1. It removes the temporal and spacial coincidence requirement from the information transfer. The sender transmits information to the computer at his convenience. The computer stores that message digitally until the recipient is ready to access the system and read it.
2. Both private and broadcast modes are implemented. Message senders can specify a specific person as the destination or they can designate the message open to "all interested parties."
3. "To," "From," "Date," and "Subject" fields are an integral part of the message. Users can perform a computerized keyword search on these fields to read only messages in which they have interest.

The main disadvantage of the above system, for rehabilitation use, is that a user must access the system using a terminal and a modem. Many members of the rehabilitation community do not have this type of equipment at their disposal. Others, such as vision-impaired individuals, would find such a system difficult to use unless they employ an Optacon.

To overcome this problem, a "talking bulletin board" is proposed. In this system, a computer-operated speech synthesizer is used to convert the digitally stored messages to audio speech for transmission over the telephone lines. (Digital communication would still be supported.) The system would prompt the user for the various modes of operation. These would include: (i) Enter a message, (ii) Request help, (iii) Read a message, (iv) Scan messages for keywords, (v) Enter 'expert' mode, and (vi) Hang up.

For the purpose of entering text and performing mode changes, the user would use the Touch-Tone pad to communicate with the system. A $40 commercial adapter that fits over the telephone would make non-Touch-Tone phones compatible with the bulletin board system.

Among the uses contemplated for the completed system are:

1. Generalized information mode: information relevant to the rehabilitation community can be exchanged without the need for personal phone conversations, newsletter publications, or periodic meetings.
2. On-Line Evaluation: prescribed rehabilitation devices can be evaluated systematically by requiring users to fill out a computerized form message on a regular basis. Problems with those devices can be communicated via this system as well.
3. Employment: a 'Position Wanted' and 'Jobs Available' section can be incorporated into the message scheme. The system can then act as an automated clearing house for employment opportunities for the handicapped.
4. Consumer feedback: comments in regard to the usefulness or modification of specific rehabilitation devices can be made.

Status—A prototype version of the above system is being implemented. The initial hardware includes a Votrax Type-N-Talk speech synthesizer, a Z80 microprocessor, a telephone interface, and a Touch-Tone decoder. Software is written in BASIC for ease of testing and development. A stand-alone system will subsequently include large off-line disk storage and be supervised by a human system operator.

Pending—Funding for this project will be sought from the Veterans Administration.

Publications

Goodrich, Gregory; "Consideration of Standards for Computer Sensory Aids for the Handicapped," Conference at Western Blind Rehabilitation Center; Feburary, 1980. Bull Prosth Res BPR 10-34, Fall 1980 17(2):201–205, 1980.

Ultrasonic Head Control Unit for Smart Wheelchair

Personnel: **David L. Jaffe, M.S.** (VA).

Support for this continuing project is provided by RER&D core budget and by the Paralyzed Veterans of America.

Need—The lack of mobility is a disability that an estimated 50,000 quadriplegic individuals encounter. It is their top priority to be able to personally command any mechanical mobility they do acquire, and thereby achieve a higher level of independent living.

Approach

Although the use of an electric wheelchair provides the most obvious means of providing mobility to quadriplegics, attempts to produce a compatible vehicle have involved a mechanical user/device interface such as a chin or head controlled joystick. These interface devices are far from ideal, since intimate contact with them must be maintained and critical positioning is required to accommodate the user. Limited chin extension and marginal control of those movements aggravate the control problem and prove frustrating in use, for many. Additionally, chair motion tends to be quite jerky due to the acceleration feedback effect of the chair motion on the user's chin position. Other chair control designs, such as pneumatic switch control, suffer from similar disadvantages as well as increased difficulty in mastering control and sanitation problems (aesthetic factors frequently have been overlooked in the design of wheelchair systems for quadriplegics).

By utilizing ultrasonic distance-ranging technology to track the user's head position and proportionally control the chair's movement in joystick fashion with this head position, many problems that plague current designs for quadriplegic individuals can be overcome. Minimal motion of the user's head to the front directs the chair to move forward, while positioning the head to the left, right, or to the rear produce corresponding motions. Combinations of those orthogonal positions allow smooth turns, while the magnitude of motion defines the speed of travel. Since very minimal motion is required to use this system, and the control is easy to learn; this non-contacting, remote-sensing ultrasonic method of wheelchair control offers the possibility of an improved method of quadriplegic control of electric wheelchair.

Status—Currently, work is focused on producing a flexible independent ultrasonic head control unit which will be a stand-alone transducer of head position. Information acquired by this unit would then be used for electric wheelchair navigation and also for robotic arm control and communication board input.

Pending—Hardware and software are currently being developed to implement the ultrasonic head control unit. Once operational, the unit will be integrated

with an electric wheelchair and the robotic arm.

On the wheelchair, DC bridge controllers will be used for increased efficiency as well as the elimination of the bulky and noisy motor relays used in the existing configuration. These controllers will feature motor current sensing circuits and a regenerative system that recharges the batteries during braking. In addition to its superior performance, the DC bridge circuit has the advantage that it can be directly driven by a computer-generated pulse-width-modulation output signal.

To increase the overall gain of the wheelchair system, an inertial frame will be employed. This will serve to minimize the effects of acceleration on performance. Additionally, this feature will indicate the approach of vehicle instability as well as inform the user of an attempt to climb a grade that is too steep. Low-battery alarm, computer watch-dog circuits, and a user-accessible panic switch will be required for a reliable system.

The microcomputer systems for the wheelchair and the ultrasonic head control unit will be designed to dynamically adjust to the user. In such a design, the microcomputer will 'learn' the user's range of motion as well as his rest position. The final design will attempt to capture the above features on a single circuit board that can be fitted onto an existing commercial electric wheelchair at a cost of less than $500.

Publications:

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Epstein, Richard; Gerding, Leslie; and Jaffe, David L., "Head-Controlled/Smart Wheelchair," ASME Design Engineering Conference; April 1981.

La, Bill; Koogle, Tim; and Jaffe, David L., "Microcomputer Controlled Omnidirectional Mechanism for Wheelchairs," EMBS, Houston, Texas; September 1981.

La, Bill; Koogle, Tim; and Jaffe, David L., "Toward Total Mobility: An Omnidirectional Wheelchair," Fourth Annual Conference on Rehabilitation Engineering, Washington, DC; August 1981.

Development/Evaluation of Recreational Bicycles for the Disabled

Personnel: **Douglas F. Schwandt, MSME** (VA), **Peter W. Axelson, BSME** (VA), and **Larry J. Leifer, Ph. D.** (VA, Stanford).

Support for this continuing project is provided by RER&D core budget and the Northern California Charpets of the Telephone Pioneers of America.

Need—As a recreational activity engendering both physical and emotional vitality, bicycling is particularly appropriate for an individual endeavoring to overcome difficulties involving mobility and participation. Existent cycling equipment does not meet this need.

Approach

Our continuing approach focuses on: (i) improving the Para-Bike, a hand-pedaled prototype bicycle initially developed under VA support in the Stanford University Design Division Master's Program; (ii) developing a tandem version of the Para-Bike (for able-bodied and disabled to ride together); and (iii) identifying appropriate manufacturers and ways to move the Para-Bike concepts into the marketplace for the direct benefit of disabled riders.

Status

Two working prototypes of the Para-Bike have been developed: One is the Para-Bike with adjustable steering geometry, the result of a VA funded student pilot project in the Stanford University Design Division Master's Program (completed June 1980). The other is the competition version of the Para-Bike, which demonstrated the versatility and potential of the concept by allowing a paralyzed veteran (within one year of spinal injury), and a recently paralyzed 54-year-old individual, to participate in the Annual International Human Powered Vehicle Championships (Pomona, California, May 2–3, 1981) and ride the Para-Bike to the arm-powered world record speed of 24 mph. This latest prototype has advanced and simplified the Para-Bike design (with improvements in efficiency, compactness, ridability and manufacturability) as a recreational bicycle for the disabled.

The first prototype with adjustable steering geometry has proved to be a valuable ongoing resource in the optimization of steering and drive performance in subsequent design and prototyping. The seating has also been found to be a very important aspect of the vehicle design, as it is the rider/vehicle interface combined with the steering configuration which present the greatest influence on the performance of the Para-Bike for a particular rider.

Pending—Further refinements in the design of the Para-Bike are underway to prepare for the transition into production. A tandem version of the Para-Bike (for able-bodied and disabled individuals to ride together) is on the drawing board. A cooperative effort with the University of British Columbia will involve tandem prototyping and placement of the first production prototypes of the Para-Bike into a comprehensive disabled physical educational curriculum in the spirit of this International Year of the Disabled Person.

Publication

Schwandt, Doug, "Para-Bike," Sports 'n Spokes, Phoenix, Arizona, November/December 1980, pp. 18–19, 21.

Patterns of Conduction Of Impulse Trains in Myelinated Fibers

Personnel: **Sally L. Wood, Ph. D.** (VA); **Kenneth L. Cummins, Ph. D.** (VA); **Stephen G. Waxman, M.D.** (VA, Stanford), and **Jeffrey D. Kocsis, Ph. D.** (Stanford).

Support for this continuing project comes from the RER&D core budget.

Simulations of collision neurography techniques have been run [1] in which two stimulus pulses are applied at different points along a nerve. The minimum time required for the initiation of a propagating response from the second (test) stimulus in each direction is used as a measure of the stimulus-parameter-dependent forward and reverse refractory characteristics. This time was adjusted for the conduction delay from the first (conditioning) stimulus site. The refractory period was examined as a function of the conduction velocity (CV), depth of the axon, and amplitude of the test stimulus pulse.

These results showed the expected variation of refractory period with CV at small depths and low stimulus intensities. As stimulus intensity and depth increased, the forward and reverse refractory periods began to differ due

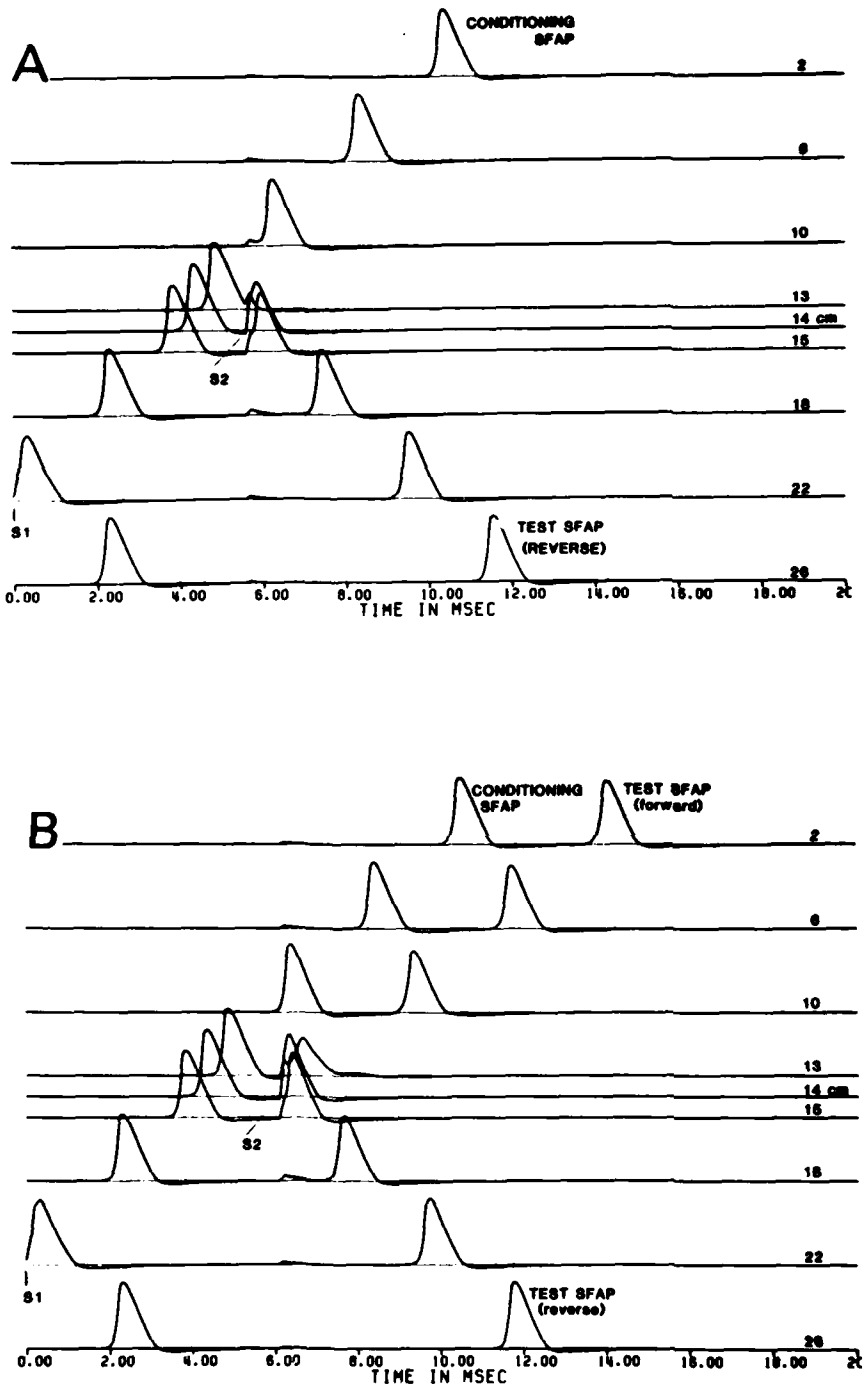

FIGURE 1.
This figure shows an example of the differences in forward and reverse refractory periods. Each horizontal trace is a time waveform "recorded" at a specific position along a 28 cm length of axon. The vertical axis represents distance along the axon. At time t=0 a conditioning stimulus (S1) is applied at the 22 cm point. At some time later a test stimulus (S2) is applied at the 14 cm point.

In Figure 1a the test stimulus was sufficient to excite a propagating response in the reverse direction only. In Figure 1b the increase in IBI (interval-between-impulses) allows the test stimulus to generate a propagating response in both directions. The propagating response in the forward direction travels at a much slower velocity than the reverse direction as can be seen by the arrival time of the second impulse at a distance of 12 cm on either side of S2

to virtual cathode effect of the spatial spread of the stimulus (Fig. 1). These effects reduced the effective interval-between-impulses (IBI) in the forward direction while increasing the effective IBI in the reverse direction. Similar patterns of forward and reverse refractory period behavior were observed at all CV's tested, although the specific depths and intensities at which a particular type of behavior was observed were CV dependent. These results provide one explanation for previously reported discrepancies in experimental findings regarding the CV dependence of refractory period.

Pending—The simulation program is being modified to include recently available empirical data on ionic channels in mammalian CNS and a more general temperature dependence. It will be restructured to allow easier and more direct interaction with the user, so that extensive previous computer experience is not required. The program will be used to study propagation in single axons under normal, and a variety of pathological, conditions. Results of the simulations can be combined to give estimates of compound responses recorded remotely. For example, the new program will be used to study the effects of reduced diameter in demyelinated segments of a myelinated axon. The amount of reduction required in order to promote conduction into and through a demyelinated region will be examined under a variety of conditions. The effect of the demyelinated segment on the conduction characteristics of the total fiber will be investigated with respect to relative refractory period and entrainment. The effects of the absence of potassium conductance, in conjunction with modified sodium and leakage conductances, will also be simulated.

Publications

Wood SL, Cummins KL: Bidirectional nerve refractory characteristics: simulations of conduction resulting from direct and remote stimulation. Proc. 3rd Annual Conf. of the IEEE Engineering in Medicine and Biology Society, Houston, Texas, Sept. 19–20, 1981.

Spinal Injury Patient Transport System

Personnel: **Eric E. Sabelman, Ph. D.** (VA); **Timothy A. Koogle, Eng. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Connel Wilmot, M.D.** (Santa Clara Valley Medical Center).

This continuing project is supported by RER&D core budget.

Status—Two of these transport systems have been completed in a prototype configuration and are currently being used at the Santa Clara Valley Medical Center for transporting patients. Feedback to date has been very positive. We will be using inputs from the SCVMC to produce production prototypes in which we will be using more advanced materials and more convenient fixation systems.

(Note: the device, previously described and illustrated, is a stretcher-like transporter incorporating a traction device and lateral head, axial shoulder, and torso-strap restraints. Editor)

Analytical Modeling of the Human Lumbar Spine

Personnel: **Lyle W. Swenson, Jr., Ph. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Timothy A. Koogle, Ph. D.** (VA).

Support for this continuing project is provided by RER&D core budget.

Status—This project has continued to develop general capabilities in numerical methods appropriate for spinal modeling and general modeling of the human musculo-skeletal system. The project is currently awaiting appropriate data to test the performance of the model. It is anticipated that this will be completed in the next six months.

(Note: among the features of the analytical model developed by this project is the use of non-linear spring force-deflection data in accounting for ligamentous and intervertebral disc interactions. Editor)

The Mechanics of Human Cancellous Bone

Personnel: **Lyle W. Swenson, Jr., Ph. D.** (VA); **Robert L. Piziali, Ph. D.** (VA, Stanford), and **Kil-Soo Kim, M.S.** (Stanford).

Support for this continuing program is provided by RER&D core funding.

Status—Work in this project area has been continuing. The static two- and three-dimensional problems have been completed and work is underway on the dynamic problem.

Improved Predictive Filtering Techniques for Non-Invasive Analysis of Neuromuscular System

Personnel: **C. C. Boylls, Ph. D.** (VA), and **F. E. Zajac, Ph. D.** (VA).

Support for this continuing project is provided by RER&D Center core budget.

Need—The evaluation of therapies for human neuromuscular disease processes benefits from the replacement of invasive assessment techniques by noninvasive methods of comparable sensitivity. We thus have examined the feasibility of extracting the contractile properties of motor-units in muscle using indirect predictive filtering methods as a replacement for muscle biopsy.

Approach

Following the discharge of a motor unit, the fibers of the unit contribute a small increment to the tension in a muscle. If one records (with a needle electrode) both the time-series of motor-unit discharges and the corresponding whole-muscle tension, then a filter can be mathematically constructed which tries to predict the time-course of tension change following each motor-unit volley. If accurate, then this time-course allows the unit to be identified according to its twitch-contraction properties.

The construction of an accurate predictive filter, however, is made difficult by such factors as: (i) nonlinearities and time-dependence in the unit's twitch-contraction behavior; (ii) statistical nonstationarity in the motor-unit discharge train and nonuniformity of the frequency representation within that train; and (iii) the presence of correlated activity (e.g., synchrony) in other motor-units within the muscle. We have been evaluating the sensitivity to these sources of error of predictive filters constructed by various methods.

Status—The behavior of the "simplest" predictive-filter technique, Wiener's least-squares linear predictor, has been studied with reference to motor-unit models derived from Hill's equation. For a linearized Hill's-equation model, the filter predicts tension exactly, provided that the unit's time-series of discharges contains all frequencies (not necessarily uniformly) within the bandpass of the model. However, for the nonlinear model, the extracted twitch-contraction profiles nearly always underestimate both the time-to-peak and the duration of the twitch. The underestimates, in many instances, fall below 70 percent of the actual values. We believe, therefore, that a considerably more sophisticated predictive-filter technique will be required before the goal of accurate twitch-contraction estimation can be achieved.

Pending—This project has been **suspended** until a suitable filtering technique can be found. We expect to consider both Volterra-series estimators and methods based upon model-referenced system identification in making that choice.

Development and Evaluation of an Omnidirectional Wheelchair

Personnel: **William H. T. La, Ph. D.** (VA); **Timothy A. Koogle, Eng. D.** (VA); **David L. Jaffe, M.S.**, and **Larry J. Leifer, Ph. D.**, (VA, Stanford).

Support for this continuing project is provided by RER&D Center core budget.

Need—Conventional wheelchairs have limited mobility, requiring a large area in which to maneuver. Homes, buildings and public transportation systems have to be modified at great costs in order to accommodate these chairs. There is a need for a wheelchair that has no maneuvering constraints beyond the mobility limitations of its physical size.

Approach

Total mobility of a vehicle on the ground plane requires three degrees of freedom of motion: forward-backward translation, left-right translation and rotation on the vertical axis. This total mobility can be achieved in the simplest way with three independently driven wheels that provide positive traction along three lines of action forming a well-defined triangle. The wheels have to be capable of moving sideways without binding or slipping, and must therefore be fitted with idle peripheral rollers.

Status—An experimental prototype of the three-wheel-drive, omnidirectional wheelchair has been built, using mostly

FIGURE 2
Experimental Prototype of the Omnidirectional Wheelchair

available components (modified E&J frame, automobile bucket seat, Solo motors and controller, and Bowman controller (Bowman Electronics, San Anselmo, CA.)). An analog translator converts the inputs from a three-axis joystick and feeds them into the Solo and Bowman units. The three omnidirectional wheels were built by graduate students at Stanford University under the sponsorship of Unimation. The 24-volt electrical system is powered by two Gel Cell batteries.

The prototype exhibits some imprecision in direction control. Pure low-speed translation in odd directions is difficult to achieve, due to the dead zones in controller and motor response. The wheelchair also has a tendency to veer when accelerating or braking. The three-axis joystick requires some adaptation on the part of people who are used to the operation of a conventional electric wheelchair. The present wheels give a rather rough ride due to their limited size and the lack of resilience of the rollers (Fig. 2).

Pending—Different designs of the frame and wheels are being studied. Shaft encoders will be mounted on the motors to implement feedback control. A microprocessor-based digital controller is being assembled; it will enable us to test various control schemes and will help us investigate the dynamics of this wheelchair.

Publication

La, H.T., "Omnidirectional Vehicle," U.S. patent no. 4,237,990. 1980.

Experimental and Theoretical Study of Mammalian Movement

Personnel: **F. E. Zajac, Ph. D.** (VA), and **W.S. Levine, Ph.D.** (University of Maryland).

Support for this continuing project is provided by the RER&D Center core budget and by National Institutes of Health (NS 11971).

Status—Since our last report we have solved the optimal control problem for a human subject jumping to his maximum height using only his calf muscles for propulsion. When these computer and analytical results are compared with experimental data, we find good agreement even for simple muscle models. Critical to this agreement, however, is accurate specification of the properties inherent to these models. Future work will concentrate on more complicated jumps so that we can understand the interaction of externally-imposed and internal body constraints on the biomechanics and neural control of movement.

Development and Evaluation of *a Downhill Ski-Sledding* System for Persons with Disabilities

Personnel: **Peter W. Axelson, B.S.** (VA); **Larry J. Leifer, Ph. D.** (VA, Stanford), and **John J. Csongradi, M.D.** (VA, Stanford).

Support for this project is provided by RER&D Center core budget.

Status—User and Instructor questionnaire information was used to develop the Arroya V ski-sled which incorporates user feedback and suggested modifications from the 1979-80 ski season. (During that ski season, 15 Arroya IV ski-sleds were field-tested at nine ski areas, including Winter Park Ski Area in Colorado and Snoqualmie Ski Summit near Seattle, Washington). Users indicated that, while turns were easy to complete, they were difficult to initiate. This suggestion led to the use of four edges on the Arroya V, two forward edges which allow skiers to initiate turns and two rear edges which allow completion of a turn.

RERanD Center core budget funded the construction of ten Arroya V prototypes which were ready in March of the 1980–81 ski season. These sleds were used in slalom and giant slalom com-

petitions, at the 1981 National Handicapped Ski Championships at Winter Park Ski Area in Colorado, by 35 skiers with varying disabilities. (The freestyle event was eliminated this year. However, an official downhill event was added.) The competition was close and exciting for all of the racers involved. The all-around top male and female Arroya competitor will represent the United States at the World Handicapped Ski Championships in Switzerland in March 1982.

Representatives from all of the RER&D evaluation centers and other ski-sledding programs met to discuss the various issues associated with downhill ski-sledding programs. The issues covered were (i) tethering vs. nontethering, (ii) ski area insurance problems, (iii) and ski area personnel involvement with chair-lift loading and unloading procedures.

Pending—This RER&D Center will seek to locate a manufacturer capable of producing the Arroya in its current state of development. The Center also plans to continue to monitor the evaluation of Arroya V ski-sleds, to publish a user/instructor manual for downhill ski-sledding, to monitor the certification of Level I, II, and III ski-sledding instructors and the certification of advanced users.

Study of Upper-Limb Biomechanics Using Ultrasound Transmission Imaging

Personnel: **Vincent R. Hentz, M.D.** (VA, Stanford); **Parvati Dev, Ph. D.** (VA), and **Kenneth W. Marich, M.B.A.** (S.R.I. International).

Support for this continuing project is provided by the RER&D Center core budget.

Need—Modern functional, and especially biomechanical, analysis of living hands has been restricted because, until now, no safe non-invasive method for studying bone and soft tissue relationships has existed. Ultrasonic transmission imaging combines the advantages of X-ray laminography and fluoroscopy, and permits risk-free visualization of soft tissues and bone in real time.

Approach

One major objective of this study is to extend the capabilities provided by ultrasonic transmission imaging to the study of upper-limb function. Another major objective is to develop mathematical models of hand biomechanics for the eventual evaluation of specific abnormalities and for the selection of optimal rehabilitative measures including reconstructive surgery.

Status—Those areas of the project that deal with ultrasound transmission imaging, and require collaboration with SRI International, are **suspended** while awaiting the evaluation of a research proposal resubmitted to VA RERanD merit review.

In-house development of a mathematical model, and computer simulation of a single joint, the wrist, is **ongoing**. The wrist is modeled as a universal joint with two degrees of freedom. Tendons around the joint are acted on by simulated muscles with specified length-tension properties. The simulation is an interactive one, allowing the user to insert or delete muscles and to alter tendon moment arms and insertion points. The data for the model are derived from the literature and from anatomical measurements (Brand, Paul W.: Orthopedic Clinics of North America, Symposium on Tendon Transfer in the Upper Extremity, Vol. 5, No. 2, April 1974).

Instrumentation for the measurement of muscle mechanical properties is under development (see project by Dev, Zomlefer and Hentz).

Pending—The kinematics of the model will be compared with the kinematics of a cadaver wrist and the model will be refined as necessary. The model will then be made accessible to hand surgeons to determine its acceptability and level of usefulness.

Nerve Conduction Velocity Distributions: Clinical Research Applications

Personnel: **Kenneth L. Cummins, Ph. D.** (VA); **Leslie J. Dorfman, M.D.** (VA, Stanford); **Larry J. Leifer, Ph. D.** (VA, Stanford); **Gordon W. Abraham, M.S.** (VA).

Support for this continuing project is shared by the Muscular Dystrophy Association, the RER&D Center core budget, and the VA Merit Review research program.

Need—There is a need for sensitive non-invasive electrophysiologic techniques for the study of the dynamics of peripheral nerve growth, development, damage, disease, healing and response to treatment.

Status

Initial studies of DCVs (2-CAP method, Cummins et al.) in mixed motor/sensory median nerves suggest that DCV analysis, when controlled for stimulus intensity and temperature, provides a reliable measure of nerve-bundle conduction characteristics that can detect subtle peripheral nerve abnormality, even when conventional electrophysiologic techniques yield normal findings (see BPR 10-35, Spring 1981, VA RER&DS Progress Reports, pp. 131–132.)

We are continuing our study of diabetic patients in an effort to follow the course of diabetic neuropathy in response to dietary control and drug treatment. That study is principally an evaluation of the ability of our DCV methods to detect and follow the course of subtle peripheral neuropathy.

Also, patients with MS, hemiplegia, and spinal cord injury are being studied, in order to investigate the possible correlation of peripheral neuropathy with lesions of the central nervous system.

Our method for studying motor nerve DCVs (collision method, Leifer et al.) has shown an undesirable sensitivity to stimulus intensity. This sensitivity has been isolated to the intensity dependence of refractory period and its relationship to conduction velocity (CV) (Cummins and Abraham, 1981). The nature of the relationship between refractory period and CV has been studied via computer simulation (Wood and Cummins, 1981).

The refractory characteristic which is important in collision neurography is the minimum time interval between the arrival of an action potential at a specific point along a nerve and the time when a second (propagating) action potential can be elicited at that point (IBImin—minimum interval-between-impulses). This interval is, in general, dependent on CV, remoteness of the stimulus site from the nerve, and stimulus intensity. In fact, for high stimulus intensities this interval depends on the direction of propagation being considered ("forward" or "reverse," see Figure 3). This result may well account for the inability of many investigators to demonstrate a

clear inverse relationship between refractory period and CV for "forward" refractory period studies in humans (Hopf and Lowitzsch, 1975 and Betts et al., 1976).

For the collision paradigm, both empirical evidence and computer simulations indicate an inverse relationship between "reverse" IBImin and CV. Therefore any attempt to characterize the range or distribution of motor CVs in humans should take this relationship into account. Ignoring this fact results in errors on the order of 20–40 percent for the estimated range of CVs.

Pending—Development of a stand-alone system for estimating DCVs will begin in the near future. This computer-based instrument will be centered around a commercially available system for electrophysiological analysis of averaged evoked potentials and compound action potentials (Pathfinder II, Nicolet Instrument Corp.).

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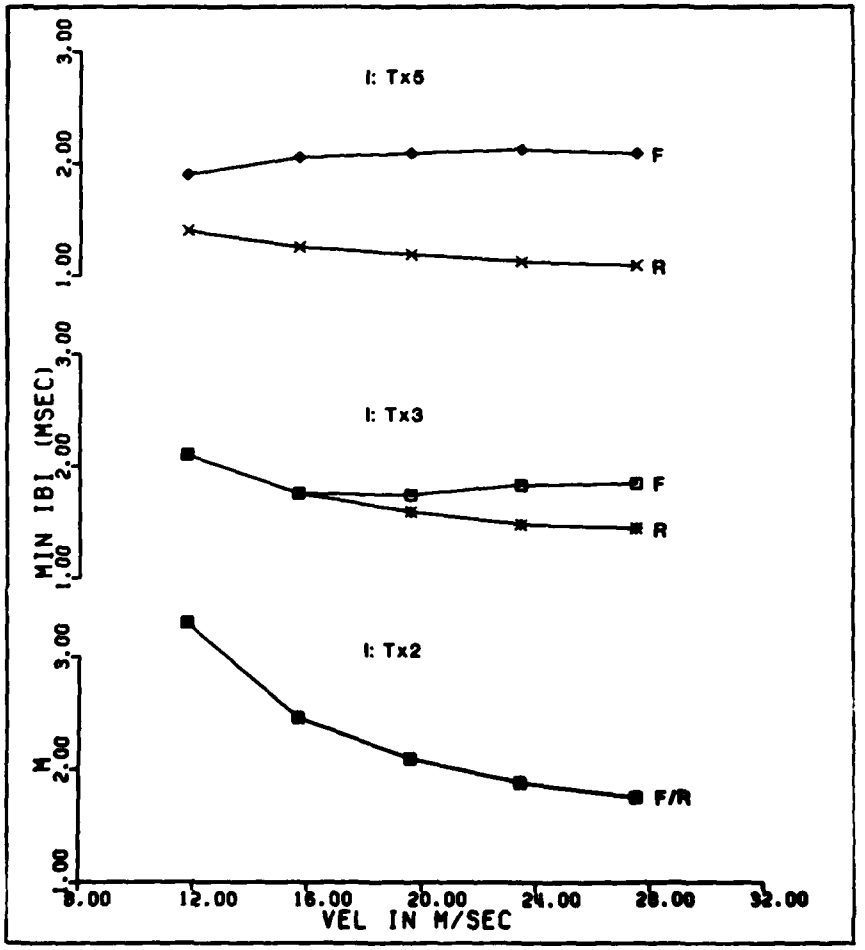

FIGURE 3.
Minimum interval between impulses (IBImin) as a function of conduction velocity (CV) for three different stimulus intensities. Results obtained from computer simulation of a myelinated nerve fiber. Forward (F) IBImin's, which represent conduction of the test action potential in the SAME direction as the conditioning action potential, are indicated by boxes or diamonds. Reverse (R) IBImin's, which represent conduction of test action potentials in the OPPOSITE direction of the conditioning action potential, are indicated by stars or X's. Nerve Depth is 0.5 cm.

For a Stimulus intensity of twice threshold (I: T×2) the forward and reverse IBImin's are identical; IBImin varies inversely with CV. When stimulus intensity is increased to five times threshold (I: T×5) the forward IBImin becomes greater than the reverse IBImin, and no longer varies inversely with CV. The transition in the relationship between forward IBImin and CV occurs at an intensity of three times threshold and a CV of 16 m/sec.

Internal and External Stabilization of the Disrupted Dorsal Lumbar Spine

Personnel: **Inder Perkash, M.D.** (VA); **Donald A. Nagel, M.D.** (Stanford); **Timothy A. Koogle, Eng. D.** (VA); **Robert L. Pizia!i, Ph. D.** (VA, Stanford), and **John J. Csongradi, M.D.** (VA, Stanford).

Support for this continuing project is provided by the Veterans Administration.

Status—This project has tested two cadavers using Harrington distraction rods, Harrington distraction rods with segmental wiring, Harrington compression rods, and the Luque segmental stabilizing system. These tests have been successful and will be part of the data base to compare the four different approaches. In addition, two cadavers have been tested with simulated cervical fracture dislocations. The normal Luque segmental wiring technique was investigated, followed by a study of a variation of the Luque rod developed by our research group. This latter system has performed better than the normal Luque approach and we are in the process of establishing an experimental protocol to fully evaluate the two approaches.

A completely instrumented Harrington rod has been received and is now being mated with a telemetry package appropriate for implantation. The current system has three channels and we are checking the performance of the system in the laboratory. Plans are underway for a complete telemetry package for the rod. In addition, initial contacts have been made with the NASA/Ames Research Center to con-

Rehabilitative Engineering Research and Development Center Hines VA Medical Center Hines, Illinois 60141

Wilton H. Bunch, M.D., Ph. D., Director
John Trimble, Ph. D., Engineering Director

This report of the VA Rehabilitative Engineering Research and Development Center points out existing and new affiliations, functions, and facilities of core laboratories in applied biomechanics, applied neurophysiology, communicative and sensory aids, and systems evaluation and research design. It then gives samples of continuing and proposed work in the several laboratories, and a bibliography.

New affiliations include Northwestern University, University of Illinois, Rush-Presbyterian St. Luke's Medical Center, Rehabilitation Institute of Chicago, Field Electronic Publishing, and four additional Services within VA Hines Hospital.

Current work is reported as follows:

APPLIED BIOMECHANICS AND KINESIOLOGY CORE LABORATORY

Biomechanical Study of Spinal Fusion and its Effect on the Free Segments

Avinash Patwardhan, Ph. D., Ray Vanderby, Ph. D., and Wilton Bunch, M.D., Ph. D.

*The **objectives** of the research are:*

1. To perform a parametric study to generate quantitative data describing the range of motion of the spine and the magnitude and location of peak forces and moments acting on the fused segments, as well as on the free-motion segments above and below the level of fusion. The effects of the following parameters will be investigated: (i) the number of fused segments; (ii) the location of fusion along the length of the spine; (iii) the amount of residual motion at the fusion segment; (iv) the load-deformation properties of the motion segments; (v) the geometric configuration of the spine; and (vi) the applied loads.

2. To investigate the stress distribution within the fused as well as adjacent free-motion segments subjected to the segmental loads obtained as described above, as functions of the various parameters.

In order to meet these objectives, the following **activities** will be undertaken:

1. Experimental study to obtain the load-deformation properties of the motion segments of human spine;

2. Experimental study to obtain data describing the geometric configuration of the spine;

3. Formulation and validation of the motion simulation model of the spine;

4. Experimental study of residual motion in fused segments of canine spines and instrumented human spine segments;

5. A parametric study, using the validated motion simulation model of the spine, to generate data describing the range of motion of the spine, and the peak values of segmental loads acting on the fused as well as adjacent free-motion segments;

6. Experimental study of human articular facets to obtain force/deflection data;

7. Development and validation of a three-dimensional model of human articular facets;

8. Experimental study of effects to ligaments on spinal stiffness using transection approach to obtain individual ligament stiffness;

9. Formulation and validation of a three-dimensional finite element model of a human spinal motion segment incorporating the effects of ligaments and facets;

10. Comparative study of stress distributions in normal spinal motion segments versus fused segments, and also versus normal segments adjacent to fused segments when abnormal loading or motion is indicated.

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duct a cooperative effort using monkeys as test specimens. This will allow us to collect data on the performance of Harrington type instrumentation during the incorporation of bone grafts following fracture dislocation in an upright animal.

Development of a Camera for Application in Sensory Aids for the Blind

Personnel: **Sally L. Wood, PH. D.** (VA). This new VA merit-reviewed project was funded in Fiscal Year 1981.

The initial report will be found elsewhere in this issue of BPR, in the "Sensory Aids" section of the VA RER&DS Progress Reports.

APPLIED NEUROPHYSIOLOGY LABORATORY

An Animal Model for Spinal Cord Injury

John Trimble, Ph. D., Sami Dughman, M.D., Talat Khan, Ph. D., and Wilton Bunch, M.D., Ph. D.

At present, there is considerable conflict over the pathophysiological changes following experimental spinal cord injury. There is also conflict regarding the relationship between these changes and measures of spinal cord function. It is possible these conflicts result from the lack of reproducible and quantifiable injury models, as well as inaccuracies in the physiological and pathological measurements following experimental trauma. There is also the problem that the most commonly used experimental injury models are not directly relevant to clinical injuries.

The proposed project will attempt to resolve these conflicts and to create an experimental injury model which is closely relevant to clinical injuries. This will be done by developing reproducible and quantifiable injury models for both open and closed experimental injuries. In addition, accurate simultaneous measurement of physiological, histological, and functional variables will allow correlation between pathophysiological measurements and measures of spinal cord function.

An open contusion injury and a closed flexion injury will be used for experimental studies. In addition to vital signs and arterial blood gases, we will also measure tissue blood flow, tissue oxygen tension, somatosensory evoked response, monosynaptic reflex, and edema. Correlation of these measure-

ments following both types of experimental injury will be done to obtain a complete temporal description of pathophysiological and functional changes.

Psychophysical and Electrophysiological Measures of Somesthetic Function

John Trimble, Ph. D., Don Dallman, P.E., Don Stewart, R.EEG.T., and Wilton Bunch, M.D., Ph. D.

Most current electrophysiological measures of somesthetic function in humans involve the use of evoked potentials to electrical stimuli. Although these measures have proved clinically useful, their functional significance remains obscure. The primary reason for this problem is the lack of neuroanatomical specificity of electrical stimuli. The goal of this study is to produce electrophysiological or psychophysical measures of somesthetic function which provide an indication of the functional integrity of specific neuroanatomical pathways in humans.

This goal will be accomplished by comparing psychophysical and electrophysiological responses to both electrical and mechanical stimuli. Since the mechanical stimuli are mediated by well-defined receptor types as well as neuroanatomical pathways, comparison of electrophysiological responses to the different stimuli may provide information regarding pathways mediating the responses to electrical stimuli. In addition, comparisons of the psychophysical responses to both stimuli may provide an indication of the functional significance of the response to electrical stimuli.

Effects of Nerve Growth Factor on Functional Recovery After Spinal Cord Injury

Talat Khan, Ph. D.

Previous studies have shown that nerve growth factor (NGF) enhances regenerative growth of dorsal column axons following acute spinal-cord injury in cats. Functional recovery coincident with this regeneration was confirmed with evoked potential measures. The objective of this study is to further define the role of NGF in regeneration, as well as to expand knowledge of the morphological and functional changes induced by NGF.

Experimental contusion injuries will be produced in cats. The forces involved in the injury will be quantified using instrumentation constructed in this laboratory. Following injury, an implantable osmotic pump will be placed in the intramedullary grey matter for infusion of NGF. Infusion will be continued for six to twelve weeks following injury.

Following the recovery period, the functional recovery of the spinal cord will be assessed with kinesiological and electrophysiological measures. In addition, a quantitative histological study of the cord will be made to accurately describe the nature and extent of regeneration.

Preliminary results suggest NGF causes regenerative changes in both the dorsal funiculus (as reported previously) and also in the ventral funiculus. Future studies will be directed to determining the functional significance of the observed changes, and to quantification of the histological changes.

COMMUNICATIVE AND SENSORY AIDS *LABORATORY*

Factors Affecting the Use of Reading Aids by the Blind

B.L. Zuber, Ph. D., John Trimble, Ph. D., Harvey Lauer, Len Mowinski and Dave Hislop

This study embodies a quantitative and rational approach to the development of performance measures for three methods of reading by the blind: audible-output and tactile-output electronic aids, and braille.

A non-contact monitoring method allows recording of manual tracking patterns during reading by blind subjects, and provides both hand position and hand velocity information. The information available from these tracking patterns should allow identification of the major constraints on information processing during reading by the blind, and should indicate whether these constraints are physiologically or mechanically based.

Crucial to this study is the use of a controlled input. Subjects will be read texts which have been quantitatively graded and rank ordered along a scale of difficulty level. Such a controlled input allows separation of test-related effects from those reflecting the performance of the reader. This technique, and others to be utilized in this study, have proved effective in elucidating the nature of information processing by sighted readers.

Within the framework of the approach and methods outlined above, the major objectives of the proposed study are:

1. Development of baseline values for rational performance measures of reading by the blind;
2. Identification and localization of the major constraints in the man-machine system represented by the blind reader and the reading aid;
3. Elucidation of some fundamental characteristics of information processing mechanisms utilized by blind readers; and,
4. Extrapolation of experimental results to provide improved approaches to the training of blind readers, and to the development of future reading aids.

Measuring the Performance of Blind Travelers

John Trimble, Ph. D. and Rebecca Hollyfield, Ph. D.

Because limitations on independent travel impose serious handicaps on blind travelers, improvements in travel skills have been a major part of the rehabilitation effort. These efforts have taken two general forms: mobility training programs and electronic travel aids. Neither of these approaches, however, has been as effective as had been anticipated. Improvements in both of these areas depend upon increased knowledge about the tasks performed by the blind traveler, the information required to do them, and the cognitive and perceptual abilities that are the bases for successful mobility. Such a research program would require a quantifiable measuring system that is sensitive to the safety, efficiency, and stress of the blind pedestrian. While there have been problems associated with measuring the stress placed upon the blind traveler by the mobility task, safety and efficiency have proved useful in performance measurement. The measures used up to this time for these two variables have been averaged scores which do not permit an assessment of the responsiveness of those measures to particular environmental variables and thus do not permit a detailed task analysis of the mobility task. A continuously measured variable would permit such a correlation

between environment and mobility behavior. The project in progress concerns the development of such a measuring system. A position determining device, combined with time measures, will permit the estimation of such variables as speed and acceleration of walking, the proximity of the traveler to environmental objects, and the continuity and veering of the traveler's walking.

Such a measuring system will be created by placing a matrix of conductive tape on the floor and a piece of conductive material on the shoe of the subject who will be walking over the surface. By means of a special-purpose electronic circuit, the position of the pedestrian will be determined on each footfall based upon the coordinates of the two axes that are connected by the conductive material on the subject's shoe. This position, combined with previous position measures and time measures, will provide estimates of the distance and direction traveled, the speed and acceleration of travel, and proximity to predetermined environmental objects. While the resolution and linearity of the measures will be tested prior to subject involvement, the sensitivity of the system will be ascertained by comparing these measures for two groups of travelers, one of which will be trained cane users and the other naïve cane users.

SYSTEMS EVALUATION AND RESEARCH DESIGN CORE LABORATORY

A Study of the Effectiveness of a Blind Rehabilitation Program

Ross W. Lambert, Jr., M.D., Selwyn Becker, Ph. D., Ben Wright, Ph. D., Shelia Courington, M.S., and John Malamazian

The objective of this study is to discover ways of improving the effectiveness of blind rehabilitation training so that blind persons can develop a greater degree of personal and financial independence. We propose to do this by assessing the degree of effectiveness of the Central Blind Rehabilitation Center in bringing about positive changes in the lives of blind patients, and by developing means of predicting individual success in the rehabilitation training.

This broad goal of improving rehabilitation treatment can be subdivided into several key questions, each of which must be addressed by a specific research objective:

1. To what degree does the CBRC effect changes in a patient's life-state?

   The dimensions of life-state have been defined during the course of pilot studies preparatory to this study. We will use the scales derived from these pilot studies to assess patients' life-states prior to rehabilitation treatment, and again after treatment. This will permit us to measure the amount of change in patient's lives which is due to rehabilitation treatment. This process will demonstrate both strengths and weaknesses in the existing program, and thus lead to ways of improving that program.

2. How can we measure the outcomes of rehabilitation treatment and how can we measure the patient variables which predict positive and negative outcomes?

   The objective here is to create measuring instruments or scales which can be used to evaluate any blind rehabilitation program, and thus improve the quality of treatment and the efficiency of service allocation in all such programs. We will use a method of test design which permits an unusual degree of validity, reliability, and generalizability—and which allows a great precision in specifying the amount of a given skill or characteristic possessed by the individual patient.

3. Which personal, psychological and social factors seem to be associated with positive changes in life state subsequent to rehabilitation?

   We need to be able to predict which patients are more likely to succeed in being rehabilitated, and which are less likely to succeed. To accomplish this, we must examine the patterns of demographic, psychological, and social characteristics of individual patients to determine which patterns are related to positive outcomes. Once this is done, we can then use those patterns to predict the success of future patients, and therefore improve the degree of success, and increase the probability of successful outcomes.

The Effectiveness of Differing Outpatient Treatments of Low Back Pain

John Fisk, M.D., Ross Lambert, M.D., Selwyn Becker, Ph. D., Phyllis Dimonte, R.P.T., and Shelia Courington, M.S.

The basic purpose of this research is to assess rigorously the relative effectiveness of Back School as a treatment for low back pain (LBP), as compared to more traditional treatments. In order to do this we will execute a controlled experiment in which selected participants will be randomly assigned to the various treatments. Participants will be selected on the basis of criteria that ensure that they are LBP sufferers, and that the outcome variables are appropriate to the sample.

Although we are primarily interested in the treatment of veterans with LBP, there are no established outcome criteria for the purpose of assessing treatment effectiveness with this population. Therefore, the experiment will be carried out on a more general population of essentially healthy, employed persons. By doing this, we can determine the usefulness of a variety of other outcome variables in assessing treatment efficacy with the veteran population.

Patients who meet our selection criteria will be randomly assigned to one of the following treatments: (i) management with medication and therapy, (ii) Back School with personal instruction, (iii) Back School with audio-visual instruction only, (iv) diathermy placebo treatment, and (v) no treatment (control group).

These five treatments will be compared on two basic outcome variables: time from onset to remission of symptoms, and amount of time lost from work at 6 and 12 months after treatment. But we will also assess the usefulness of other outcome variables that are more appropriate to the veteran population. These are: (i) functional ability on specific tasks, before and after treatment, (ii) frequency of post-treatment medical attention for LBP, (iii) the patient's perception of discomfort and limitations of activities, (iv) psychological state and social adjustment, and (v) levels of medication for LBP.

Thus, the five possible treatments will be compared in terms of their effects on seven outcome variables. Data analysis

will serve two purposes: to assess the relative effectiveness of the treatments on all seven outcomes, and to correlate the two established outcome criteria with the five suggested criteria. This will permit us to define appropriate outcome criteria for persons who are not expected to return to work after treatment or remission of symptoms.

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DEPARTMENT OF EDUCATION
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This is a report of the current activities and recent progress in the 14 projects conducted at this REC. The long-term objectives of the projects were described in earlier issues of the BPR.

The core area for this REC's research is neuromuscular control using sensory feedback systems. In addition, this REC has a long-standing record of concern for and contribution to communication disorders.

Monitoring, Modifying, and Testing Anterior Spinal Instrumentation

Project responsibility: Derek Rowell, Ph. D., and John Hall, M.D.

Research is proceeding in an effort to improve the results of surgical procedures for scoliosis correction. An accepted technique for handicapped children with certain types of spinal deformities is anterior spinal fusion stabilized by implantation of a Dwyer Cable. It is important to reduce, or preferably eliminate, postsurgical complications consisting of breakdown of the cable system and failure of fusion, which result in a loss of the correction. This might be accomplished if adequate biomechanical data were available with regard to the forces acting on the cable and the fusing spine. To obtain such data, a passive telemetry system has been designed for implantation at the time of the spinal fusion procedure.*

Current work is concerned with the assembly of devices for implantation and the design and construction of the associated telemetry receiver and analyzer.

*Reilly RD: An Implantable Biotelemetry *System for the Dwyer Scoliosis Instrumentation*. Master's Thesis, M.I.T., 1981.

Neurophysiological Feedback from Extremities

Project responsibility: Neville Hogan, Ph. D.

The object of this project is to enhance the intimacy of the union between an amputee and his prosthesis by providing as natural a means of control as possible given the limitations of current prosthesis technology. An essential subgoal is to implement in a prosthesis the most accurate transmission of commands which can be achieved using myoelectric signals. To this end, a microprocessor-based technique for improved myoelectric signal processing has recently been implemented. This microprocessor implementation has retained the high fidelity of the improved processing techniques reported previously in the Fall 1979 issue of BPR, and the convenience of digital implementation, while containing the entire processor in a package which is small and portable. In its current form, the processor could be readily applied to the control of assistive devices such as a powered wheelchair or a medical manipulator, but is as yet not small enough to be contained inside a prosthesis. Efforts continue to make this device as small and as practical as possible.

Use of a New Biofeedback and Gait-Analysis System in Conjunction with the Microcomputer-Controlled Above-Knee Prosthesis

Project responsibility: Woodie Flowers, Ph. D.

Efforts are continuing to develop more versatile A/K prostheses through research on microcomputer-controlled knee mechanisms which allow prostheses to be custom tailored to their user. The activities range from clinical application of new prostheses and instrumentation systems for immediate postoperative training to evaluation of the efficacy of powered multimode A/K prostheses.

Three unique electronically-controlled prostheses have been built and used by amputees. The most versatile prosthesis, which is restricted to studies in the laboratory because of its electrohydraulic umbilical, was recently used to demonstrate that an A/K amputee could perform tasks such as foot-over-foot stair and ramp climbing, and could make smooth transitions through automatic gait mode changes using relatively straightforward knee controllers. Another of the new prostheses was used to show that electronically-augmented biofeedback can aid postoperative training.

Immediate goals include completion of smaller and more sophisticated controllers for the existing prototype prostheses, and completion of an all-new, passive-powered, regenerative, selfcontained microcomputer-controlled prosthesis.

Evaluation of Gait and Posture in Selected Groups of Children with Cerebral Palsy, Myelomeningocele and Scoliosis

Project responsibility: Sheldon R. Simon, M.D.

Segmental Energy Analysis—The energy cost of gait is being measured to help determine how functional a patient will be as an ambulator or how effective a particular treatment (operation, orthoses, therapy program) has been in making gait more efficient. The change in mechanical energy per distance walked in one gait cycle is being used as the indication of energy cost. The potential and kinetic energies of 12 different segments of the body are calculated for the entire gait cycle from high-speed films taken of the patient walking. From this segmental information, the total body energy change during the gait cycle is calculated.

Our studies show that healthy subjects and patients tend to walk at a speed that minimizes their change in mechanical energy per distance walked. This is similar to the findings of other investigators which show that metabolic energy used per distance walked tends to be minimized at the chosen speed of walking. The exact relationship between these two parameters is yet to be defined. As efficiency increases, the amount of transfer of energy taking place within and between segments increases, reducing muscle energy needed. Our investigations of patients have demonstrated that improvement in gait, as shown by increases in efficiency, may not coincide with improvement in other commonly used measures of gait such as changes in velocity, or joint angles. This raises the question of whether gait improvement has multiple definitions.

Limb Segment Inertial Properties—During the past year the development of regression equations to determine the moment of inertia of lower-extremity limb segments has been completed. In a series of 13 normal adults, the moment of inertia of the combined thigh, shank and foot and the combined shank and foot were measured using the free oscillation technique of Hatze. Moments of inertia were measured about an axis perpendicular to the sagittal plane and passing through the proximal joint of the system being considered. In addition, on each subject the limb diameters in the sagittal and coronal planes, and limb circumferences, were measured at six locations along the lower extremity, as were segment lengths and subject weight.

A linear multivariable correlation analysis was performed to determine which of the measured anthropometric parameters were the most effective predictors of the moment of inertia determined from the free oscillation. For the thigh-shank-foot system, the leg length squared and body mass were found to correlate most highly with the moment of inertia. For the shank-foot system, the shank length squared, body mass and the knee circumference were found to correlate most highly with the moment of inertia.

Relationship Between the Wire-Electrode Electromyographic Signal (EMG) and the Physical Behavior of Muscles—In the past year we have explored relationships between muscle activity as measured by the electromyographic signal (EMG) and readily identifiable muscle mechanical variables: muscle lengths, lengthening velocities and joint moments.

Based on muscle length, lengthening velocity and EMG data, the following conclusions for normal gait were drawn: (i) The tibialis anterior and hamstrings begin their electrical activity at their peak lengthening velocity. (ii) Two-joint muscles show less changes in length per unit length during gait than do one-joint muscles, due to the interaction of joint rotations. (iii) Motion of the knee joint is less influential than those of the ankle or hip joints to the length changes in two-joint muscles. (iv) Before the period of weight acceptance, vasti muscles are fully active and ready to work as a spring; functionally, the vasti are helping to smooth the impact of the foot at heel strike and could conceivably be storing energy (as a stretched spring) for release at a later time in the gait cycle. (v) The muscle lengths show differences as a function of walking speed, especially when muscles are actively shortening.

From the study of the relation between muscle activity and external joint torques, the fact that two-joint muscles showed electrical activity in phase with the external joint torques at the distal joint was observed. Co-contraction appeared to be present whenever needed for stability of posture. Co-contraction across the hip and knee was found whenever the joint moments were small, i.e., whenever there was a possibility of a change from a flexion (extension) to an extension (flexion) moment even if the moment does not actually change direction. An exception is when the vasti muscles are preparing for weight acceptance by activating before heel strike.

Similar relationships have been investigated for three spastic patients: a 9-year-old female with left hemiplegic cerebral palsy; a 3½-year-old male with asymmetrical spastic quadriplegic cerebral palsy, and a 14-year-old male with left spastic hemiparesis secondary to early encephalopathy. In these subjects with equinus gait, reflex activity in the calf muscles after heel strike could be determined, i.e., as the calf muscles were rapidly lengthened the ankle joint torque increased with a 50 millisecond latency. Additionally, the spring action at the knee joint during the period of weight acceptance, as in the normal subject, was not seen. The knee joint was steadily extending from the beginning of this period by the extending torque at the hip joint.

Interactive Graphic Display of Gait—In order to provide an increased understanding of the complex pattern of gait, an interactive graphics system has been developed and added to the central computer system. Segmental relationships can be examined at any point in the gait cycle or the motion of the whole body or specific segments can be displayed dynamically. The operator has interactive control of the display through computer terminal input. An analog control in the form of a "joystick" is being added to allow the operator to sweep through motions or stop the display at any particular position or viewing angle. This type of representation will provide a means of examining the gait pattern that has been unavailable through film or hard-copy graphics.

EMG System—The evaluation of available techniques for recording electromyographic signals has continued. In the past year, electrode-preamplifier packages from other laboratories as well as those commercially available were extensively tested. No single type was found ideal for clinical purposes. The muscle examined and long leads without preamplification were the greatest factors generating noise, rather than postamplification cable motion. Many of the devices were unacceptably large, awkward to use, fragile, and expensive for use in a clinical setting. This led to the development of a miniaturized preamplifier system, which is located at the electrode site and provides greater flexibility in less than one fifth the volume and cost of commercially available units. Several prototypes of this device are now undergoing clinical trials with considerable success. Final versions, providing further size reduction with increased noise rejection, appear extremely easy to use—and inexpensive.

Motion System Modifications for Upper-Extremity Function—In the past year, the Gait Laboratory System has been modified to examine the kinematics of upper-extremity motion. In the current project, normal subjects were filmed as they reached to pick up objects from a table in front of them with their right hand. This research will provide important information about the motor control of the upper extremity and will serve as a foundation for the development of a clinical evaluation protocol. The software available in the laboratory has been used to derive and analyze the film data and determine the shoulder, elbow, and wrist joint angular changes and angular velocities. Other software was developed to examine the trajectory of the reach and the phasing of the grasp. The adaptation of the system for film analyses was successfully completed. Minimal intra- and inter-subject variability was found in most reaches to a particular object in a particular location. This consistency in normal performance is important for the evaluation of abnormal patterns of movement.

In the near future, we will begin developing a clinical evaluation protocol for teenagers and adults. Reaches to pick up objects and other tasks which represent the spectrum of activities of daily living, will be filmed. EMG activity of several arm and hand muscles will be collected simultaneously. Pilot testing of an adaptation of this methodology with infants has also been initiated.

Statistical Analysis of Gait of Persons with Cerebral Palsy—The objective of this ongoing study is to utilize mathematical pattern recognition programs for the evaluation of kinematic gait data. In the past year, a clustering procedure developed by Professor A. Wong (Sloan School of Management, M.I.T.) has been applied to the kinematic gait data of a random sample of 120 patients with cerebral palsy. Using the kth nearest neighbor clustering procedure, five subpopulations were identified from the modes of a uniformly consistent estimate of the underlying measurement-space density. Graphical profiles and F-ratios were used to identify individual measurements, which were most useful in distinguishing the membership of the various observed clusters.

It was found that the five resulting clusters can be identified with different severeness levels of abnormal gait. Walking velocity and patterns of hip and ankle movements were seen to be markedly different for each cluster rather than related to age (2–15) or to subdiagnosis (hemiplegia, diplegia, etc.). Traits associated with patients in two of the clusters were identified with severe gait pathologies, while the remaining three clusters exhibited characteristics more closely approximating normal gait. Most of the patients in the two poorest-walking groups (clusters 1 and 3) were diagnosed as having quadriplegia, while none of the patients in the best-walking group (cluster 2) had the same diagnosis. On the other hand, a patient diagnosed as having diplegia can be in any one of the five identified clusters; from these results the conclusion was reached that the present clinical diagnosis system is not suitable for indicating the functional status of a. cerebral palsy patient.

The Friedman recursive partitioning decision rule was used to construct a classification scheme based on the groupings obtained by the clustering method. Use of this classification rule demonstrated that the effects of corrective measures such as surgery or assistive devices on the gait patterns of individual patients can be examined.

Accurate Prediction of Individual Muscle Action[a]

Project Responsibility: Robert W. Mann, Sc. D. and Sheldon R. Simon, M.D.

The construction of a system to gather information on the physiologic function of individual muscles about the ankle is nearly complete. The mechanical apparatus at M.I.T. has been integrated with the hydraulics and with the control circuitry to form a functional unit which can either generate torque or control the orientation of the subject's ankle. The frequency response has been measured and found to be adequate for projected experimental needs. Programs have been implemented, and a cable run to the system to allow versatile computer control. The force plate part of the apparatus has been constructed and calibrated. It can measure accurately the force vector and center of pressure during any experimental run. The electronics of the myoelectric processing system are complete and can monitor and store signals from 14 channels through either surface or needle electrodes. Goniometers and the associated electronics to measure the orientation of the limb segments have been integrated into the system. Some final calibration and the substitution of a new hydraulic power supply are needed before experiments can actually begin.

[a]These two projects were collaborative research between the M.I.T. Facility and the Children's Hospital Medical Center Gait Analysis Laboratory.

Dynamic Analysis of Myoelectrical Activity during Gait[a]

Project responsibility: Neville Hogan, Ph. D., and Sheldon R. Simon, M.D.

Recent efforts have focused on a deeper understanding of the transmission of surface myoelectric signals from their origins deep in the muscle to their detection at the electrodes. Analysis and experiments have shown that the anisotropy of muscle due to the parallel arrangement of the muscle fibers and the inhomogeneity due to the difference in the electrical properties of muscle, fat, and skin have a large effect on the amplitude and frequency content of the detected myoelectric signal. An extremely useful aspect of this research has been the description of these effects as analogous to the familiar phenomena of optical distortion and refraction. These insights promise to be of great value in the design of improved electrode arrays. The results were presented at the Third Annual Conference of IEEE Engineering in Medicine and Biology Society, Houston, Texas, in September 1981.

Objective Measurement of Spasticity

Project responsibility: Mark Hallett, M.D.

This project has focused on the nature of the short- and long-latency stretch reflexes produced in the triceps surae by phasic dorsiflexion stretch of the ankle. In the last 6 months we have completed an analysis comparing our normal subjects, 17 patients with rigidity from Parkinson's disease, and 47 patients with spastic increase in tone from a variety

of etiologies. These results are being prepared in manuscript form and for presentation at the World Congress of Neurophysiology in Kyoto, Japan in September, 1981. The results show that there are clear physiological differences between spasticity and rigidity and between different types of spasticity. Additionally, it is possible to quantify objectively certain aspects of the increased tone using phasic stretch reflexes. Our current plans are to incorporate this very interesting set of measurements into a more comprehensive battery of tests to analyze motor capability at the ankle joint.

Suppression of Abnormal Involuntary Movements by Application of Mechanical Loads and Biofeedback

Project responsibility: Michael J. Rosen, Ph. D.

WRIST TRACKING STUDIES

Data taken during pursuit tracking tasks performed by tremor-disabled subjects have been analyzed to establish implications for clinical management and theoretical mechanisms of tremor. Results show, in particular, the following:

1. Abnormal tremor measures based on peak power density or cumulative power were reduced by a statistically, and often clinically, significant amount by application of viscous damping loads.

2. This tremor alteration is selective in the sense that it is achieved, on average over all subjects, with insignificant decrease in voluntary tracking fidelity (with respect to amplitude and phase).

3. For two of three subjects who were tested in isometric force tracking as well as displacement, average tracking performance was substantially better for force production, suggesting the possible utility of isometric joysticks as tremor-adaptive interfaces to systems and vehicles.

4. Unlike normal physiological torque variance, pathological tremor torque oscillations under isometric conditions remained at a **constant** amplitude when the torque required for tracking was increased, so that signal-to-noise ratio was improved.

5. Tremor spectra of tremor-disabled subjects of diverse etiology were found uniformly to include one or two small peaks in the normal tremor range near 10 Hz in addition to the low frequency of pathological peak. This suggests coexisting but distinct mechanisms for physiological and abnormal intention tremor.

6. The difference between the two mechanisms is further indicated by the consistent observation that the peak torque of high frequency tremor increased proportionally to required voluntary torque, in contrast to the invariance of the peak torque at low frequency described above.

7. Abnormal tremor torque is also observed to be constant with respect to the change in experimental conditions from unloaded movement to isometric force production. This suggests a mechanism other than reflex instability since this change should radically alter reflex loop gain.

8. Abnormal tremor peak **frequency** is also invariant over unloaded, damped, and isometric conditions. This finding, that manipulation of peripheral parameters apparently leaves tremor frequency unchanged, strongly suggests a central oscillator as the source of the tremors observed in our subjects.

COMPLIANT ANKLE ORTHOSIS

Work has progressed considerably toward applying viscous or other compliant loading as a means of controlling manifestations of spasticity in gait. Specifically, the goal is to reduce equinus in cerebral palsied children by using an articulated brace (foot-ankle orthosis) which applies torque in opposition to ankle extension/flexion. If the clinical impression that hyperactive stretch reflexes induced by foot dorsiflexion have an abnormally accentuated rate dependence can be verified objectively, then a viscous loading function which limits the angular velocity of the ankle should reduce equinus-inducing reflexes. A gait improvement with respect to that allowed by rigid or elastically constrained orthoses is hypothesized.

At this point, a prototype orthosis has been fabricated with a small magnetic particle brake as the source of restraining torque. Control circuitry and on-line computer programs are being developed to allow for simulation of a variety of passive loading functions. The orthosis is instrumented to transduce standard gait timing events as well as applied torque. It permits adjustment for foot size and ankle axis location, and weighs approximately 2½ lb. including the shoe.

Testing of our first candidate for use of the prototype orthosis is complete. A spastic paraparetic juvenile subject has been monitored using the torque measurement capability of the ankle stretch instrument used in the Measurement of Spasticity project during ramps of dorsiflexion applied at rates ranging from 25 to 200 deg/sec. Preliminary data show a discontinuity in the torque vs. angular velocity curves at 75–100 deg/sec for one leg and 150–200 deg/sec for the other. Unrestrained gait testing of this subject with and without the prototype orthosis will begin shortly.

Automated Muscle-Fatigue Indicator

Project responsibility: Carlo J. De Luca, Ph. D.

A series of pilot studies have recently been initiated to obtain a variety of basic data directed at augmenting our understanding of the process of muscle fatigue. The pilot studies have specifically asked how muscle force, subject handedness, subject sex, and muscle fiber type relate to the process of localized muscle fatigue. Thus far, 31 normal subjects have been studied. The preliminary results show that the initial value of the median frequency of the EMG signal is apparently not directly correlated with the muscle force output. However, the initial median frequency for the same muscle was found to be significantly smaller in females than in males, and slightly smaller in the dominant limb than in the non-dominant limb. The results also show that muscles containing a relatively larger percentage of fast-twitch fibers display a relatively larger percentage change in the value of the initial median frequency during a contraction.

Application of objective measurement of localized muscle fatigue to disabled subjects has begun. Thus far, 8 patients with either Duchenne's Muscular Dystrophy or peripheral nerve injuries have been tested. Preliminary results are highly favorable and indicate that substantial changes in the initial median frequency can in fact be measured in both clinical conditions.

Communication Systems for the Severely Motor Handicapped

1. UNICOM

Project Responsibility: Derek Rowell, Ph. D.

The UNICOM (*UNI*versal *COM*municator) project has progressed with respect to new system features, evaluation by new handicapped users, and objective measurement of user performance. Examples are as follows:

1. The UNICOM scanning mode has been expanded from a system with a single "page" video character menu to one which permits scanning of multiple pages. The additional pages include one with a character matrix containing the necessary control commands and special characters. A third page was added as a transfer page and to assemble and send computer log-on messages and passwords. The original page was left intact with all UNICOM functions except that the cursor command "home" was replaced by the page selection command.

2. A new strategy—direct selection with a joystick controller—has been implemented.* An input matrix is displayed as in the scanning or encoding modes, but the input cursor is directly controlled by a joystick. When the user steers the input cursor to the desired character and closes the "enter" switch, the character is added to the message display. This system will soon be tested by a disabled person.

3. During the past year a UNICOM used as a scanning communication device by a severely involved cerebral palsied high school student has been extended into a computer terminal. He has used it with the school's computer to take a programming course.

4. Four UNICOM users have had their "typing" speed measured, three using encoding and one with directed scan. Two of the encoding users used the sip and puff "harmonica" interface and typed familiar passages at 15 and 17 words per minute. Both are high quads. The other encoding user has spastic paralysis of all extremities with useful function in only the right arm. With the eight-key keyboard he typed at 1.9 words per minute. The fourth person tested can move only his left arm, which is paretic and ataxic. With the directed scan joystick, he can type at 1.1 words per minute.

*Porat RL: An Analog Interface for the UNICOM. B.S. Thesis, M.I.T., 1980.

2. Analysis of Factors Influencing Rate of Non-Vocal Communication

Project responsibility: Michael J. Rosen, Ph. D.

In collaboration with Dr. Cheryl Goodenough Trepagnier, a linguist at Research and Training Center 7 at Tufts-New England Medical Center, a number of theoretical studies have been conducted on non-vocal communication (NVC). Specifically, factors influencing the **rate** of communication of a NVC system user have been analyzed to provide a unified approach to diverse devices, to attempt clinically useful predictions, and to suggest further work. These analyses have been collected in a manuscript to be submitted under joint authorship. Selected results are listed below:

1. A simple formula has been derived which expresses average time per word, Y, as a product of three terms—

C ≡ the average "cost" in linguistic units (letters, phonemes, syllables) of composing a word;

L ≡ the average number of motor acts required to encode a unit (equal to 1 for direct selection systems);

and T ≡ the average time required for a single motor act.

This formula applies broadly to all encoded and direct selection NVC systems.

2. The form of the equation Y = CLT and the dependence of individual terms on the independent variables N (number of units provided by a system menu) and B (number of distinct motor acts recognized) indicates two unavoidable tradeoffs. Larger inventories allow more efficient word formation, i.e., smaller C, but require longer act sequences for coding, i.e., larger L. Similarly, more switches in an interface allow shorter code sequences—while the necessity for smaller switches or large switch arrays implies more time per act, i.e., larger T.

3. A clinical implication of this is that, for a given non-vocal patient for whom a system is being prescribed or designed, selection of an optimal interface and an optimal language menu cannot be undertaken independently.

4. An algorithm has been outlined which operates on time and accuracy data taken during abstract target acquisition tests and predicts the communication rate to be expected with available or hypothetical NVC systems.

5. It can be demonstrated mathematically that codes relating sequences of acts to selection of language units will invariably have reduced L if sequences of multiple length (as opposed to three acts required for every unit, for example) are permitted. This is true in spite of the necessity for an independent "enter" command to notify the system that an act sequence is complete.

6. Expressions are derived for the average number of additional acts required for indication of word boundaries under conditions of different delimitation techniques. These expressions provide a rational means of choosing a technique, depending on the system code and characteristics of the inventory.

Evaluation and Application of Myoelectric Biofeedback

Project Responsibility: Carlo J. De Luca, Ph. D.

During the past 6 months, the myoelectric biofeedback project has entered a termination phase. We are currently in the process of compiling all previously accumulated data and performing the analysis in preparation for final evaluation. Emphasis is on a search for an appropriate manufacturing group to produce our version of the myoelectric biofeedback device. These latter efforts are proceeding very favorably; several groups have displayed and demonstrated active interest.

Refreshable Braille Data Display System

Project responsibility: Derek Rowell, Ph. D.

The two TSPS (Traffic Supervision Position System) refreshable braille displays, installed at the Southwestern Bell Telephone Company, Little Rock, Arkansas (BPR 10-33, pp. 108-110, Spring 1980), continue in service and enable two blind operators to be fully employed and competitive. The performance of one operator is just above the office average. That of the other is significantly above.

These two displays have accumu-

lated over 11,000 operator hours with primary maintenance being an occasional cleaning of the mechanical parts of the braille display. The microprocessor software has been updated as the operating system of TSPS was changed to include new features added to the Bell system. The most recent change in the braille display software was to include handling overseas calls. Work is being done now to include "busy line verification" and "emergency interruption" features.

A system using both braille and synthetic speech will soon be available to telephone companies within the Bell system.

Clinical Engineering in Rehabilitation

Project responsibility: Philip A. Drinker, Ph. D.

A new non-vocal communication technique and display board, Eye-Link, that uses direct selection by eye contact between disabled sender and nondisabled receiver has been developed. The primary use of Eye-Link is seen in the early phases of hospitalization; however, it may also find application in the chronic-care setting as a low cost, indestructible backup to electronic communication systems. The advantages of Eye-Link include simplicity, ease of comprehension, and speed relative to scanning and encoding techniques.

The technique embodied in Eye-Link is based on the use of a transparent board on which the selections are displayed in a rectangular matrix. The receiver holds the board, facing the sender, so that they can see each other through it. The transmission technique is as follows:

1. the receiver asks the disabled sender, "word or spell?"
2. the sender responds with an eye movement to the upper left or upper right.
3. the receiver then instructs the sender to fix on the desired letter/word.
4. the receiver, watching the sender's eyes, moves the board until eye contact is made through an individual square, indicating the desired selection. (For the sender with disconjugate gaze, the receiver must ascertain and follow the dominant eye.)

Results of this research by Philip A. Drinker and Susan Kropoff were presented at the Rehabilitation Engineering Society of North America Conference in Washington, D.C. in August, 1981.

Mobility Aids for the Blind and Severely Visually Handicapped

Project responsibility: Robert W. Mann, Sc. D.

With undergraduate student support from the Eloranta Summer Fellowship Program, work has progressed towards the development of a Computerized Travel Aid (CTA) for the blind. The core of the CTA is the transducer and associated electronics from Polaroid's One-Step Camera which, by transmitting ultrasonic pulses and receiving the reflected echoes, can determine the distance of obstacles. By arranging two transducers to set up interference patterns, an extremely narrow ultrasonic beam (less than 6 inches wide at 6 feet, as opposed to the previous 22 inches) has been created. Current work is to interface this narrow beam to the unit's microprocessor to allow for field testing. Work has also begun on a Monopulse Ranger which will treat the transducers as an array of antennae to pin-point the location of an obstacle.

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Introduction

In July, 1976 the Bureau of Education of the Handicapped of the Department of Education awarded a 3-year demonstration grant to the Memphis City Schools—Division of Special Education. The primary objective of the project was to demonstrate that severely physically handicapped children could participate more meaningfully in their educational programs as a result of assistance from technical aids in the areas of seating, communication, mobility and personal care. The secondary objective was to evolve service delivery concepts that could be incorporated into a model that could be used for replication in other educational settings.

The need for this study was illuminated by the fact that more than half of the approximately 8 million handicapped children presently in the United States do not have access to quality educational opportunities. The BEH award permitted the formation of the cooperative agreement with the NIHR-sponsored Rehabilitation Engineering Center at the University of Tennessee, which has provided the technical consultation, device design, fabrication, and maintenance support. The cooperative effort was termed project TEACH—Technical Educational Aids for Children with Handicaps.

Three major need areas were identified for immediate study; (i) specialized seating and positioning to prolong attentive upright postures, (ii) augmentative communication aids to facilitate communication between teachers and students, and (iii) the refinement of educational goals to include the acquisition of skills of daily living, such as toileting, feeding, fine motor skills, and mobility.

Previous experience of the project staff, as well as those of colleagues working with handicapped children in other areas of the country, has led to the subjective observations that technical aids can make a significant contribution to the level of participation of severely handicapped children within educational settings. However, these most significant accomplishments have rarely been documented using quantitative measures, thereby diminishing their impact in terms of justifying the expendi-

tures involved. Therefore, it was deemed important that the methodology attempt to document quantitatively the individual results within the three aforementioned areas of priority.

It is the intent of this report to present in summary form the results of Project TEACH with emphasis on the Rehabilitation Engineering component.

Methodology

The core area of research focus at the University of Tennessee—Rehabilitation Engineering Center has been specialized seating and mobility for severely handicapped children. Therefore, Project TEACH was able to benefit from the dissemination of this research experience and results, as well as from the direct technical services provided by the center service staff on a contractual basis. The cooperative staffing assigned to the project were a Speech Pathologist (50% time), Occupational Therapist (75% time), Rehabilitation Engineer (50% time), Technician (50% time), Parent Trainer, and a Project Coordinator.

The sample population consisted of 10 children, each exhibiting some form of cerebral palsy. All were nonverbal as a result of extensive motor damage to the speech mechanism. Each child also demonstrated serious motor impairments which affected their functioning in addition to speech; i.e., trunk instability, absence of head control, limitation in personal care skills, or dependency in mobility.

After selection of the study sample, the next step was to develop an assessment protocol which was used to obtain baseline data related to existing functional levels and needs for each child. It then became the challenge of the technical members of the team, working in cooperation with the therapists and educators, to derive solutions to meet the needs defined.

A significant number of diverse variables can affect the successful delivery of technical services in an educational setting. Therefore, a further goal reflected in the methodology was to identify the most significant steps and incorporate them into a generalized flow chart that could be refined to meet the needs of a unique educational setting. This was accomplished by empirically creating a delivery model which was refined as a result of experiences gained throughout the project.

Results

The following results emphasize the technical aspects of the project. However, it does not do justice to the less-tangible contributions of the therapists, educators, evaluators, parents, parent trainers, and children. Their efforts in the areas of needs assessment, fine and gross motor level assessment and training, parent and child intervention, coupled with the guidance necessary to keep the technical staff on course, are contributions that were essential elements for effective technical intervention. A more comprehensive publication on Project TEACH, which elaborates on these non-technical aspects of the project, is available from the Rehabilitation Engineering Center (1). Also, a sound/slide production, available on a loan basis, provides a general description of the project activities (2).

The Effects of Seating and Positioning Supports—In measuring the effects of therepeutic seating systems, three areas were considered: (i) maintaining head control, (ii) maintaining trunk control, and (iii) a student's ability to use the arms in a gross functional manner. Eight of the 10 students required custom fitted seating systems (Two students were ambulatory and therefore not included in this component of the study). Each child was therapeutically positioned by a seating support. Measurements were taken at three intervals within an 18-month period while performing activities with and without the seating systems. The results obtained in (i) and (ii) above are summarized in Figure 1.

When the students were pulled from lying supine to sitting, they were able to maintain their heads in alignment with their trunks (head control) for an average of 51.6 sec; they were able to hold their heads in alignment with their trunks, when prone on a wedge, for 106.9 sec; and when prone standing were able to hold their heads in alignment with their trunks for 19.24 min (1154 sec). However, when they were in their therapeutic seating systems, the students' ability to hold their heads in alignment with their trunks increased most significantly to at least 7 hours, which was the end of the school day. After use of therapeutic seating, most children continued to maintain upright alignment for varying periods during bus transport and also at home.

In measuring trunk control, defined as the ability to maintain the trunk in an upright midline posture, students were seated in four different positions—sitting crosslegged on the floor, sitting on a wedge, sitting on a standard chair, and sitting in a therapeutic seating system. The average time they could maintain trunk control in each position was recorded. The average time sitting crosslegged on the floor was 6.46 min; sitting on a wedge was an average of 10.7 min; they were able to sit unsupported on a standard chair for an average of 5.96 min; and in their seating system they were able to maintain the trunks in alignment for an average of at least 7 hours which again was the termination of the measurement period.

Arm control was measured by suspending a ball with an eight-inch diameter from the ceiling with a rope. The number of times a student could bat it in a 1-minute period was recorded. While in their seating systems students were able to bat the ball an average of 19.3 times in a 1-minute period. When not in their seats they had insufficient control to bat the ball at all. An obvious further step would be to initiate a study in which a comparison is made between seating support and changes in fine motor skills.

Mobility—Four students were chosen as candidates to be given powered mobility, which was compared with the baseline mobility performances using manual wheelchairs, or in one case ambulation with a walker. In the powered situation, one used an ABEC chair, two used E & J 3P Chairs, and the fourth used a modified Amigo Cart. Comparative tests were run and measures were taken by recording the time required for the student to traverse a distance of 125 feet (38.1 meters), first using manual propulsion when possible and then a powered device. The second series of tests involved the use of revolution counters added to both the manual and powered chairs to record the total distance covered in a normal 6-hour school day averaged over a period of a typical school week.

Three of the four children were unable to complete the manual propulsion speed test within an acceptable time frame due to the extent of their physical disabilities. The fourth child could walk the 125 feet distance with a modified walker in 89 seconds. Using their pow-

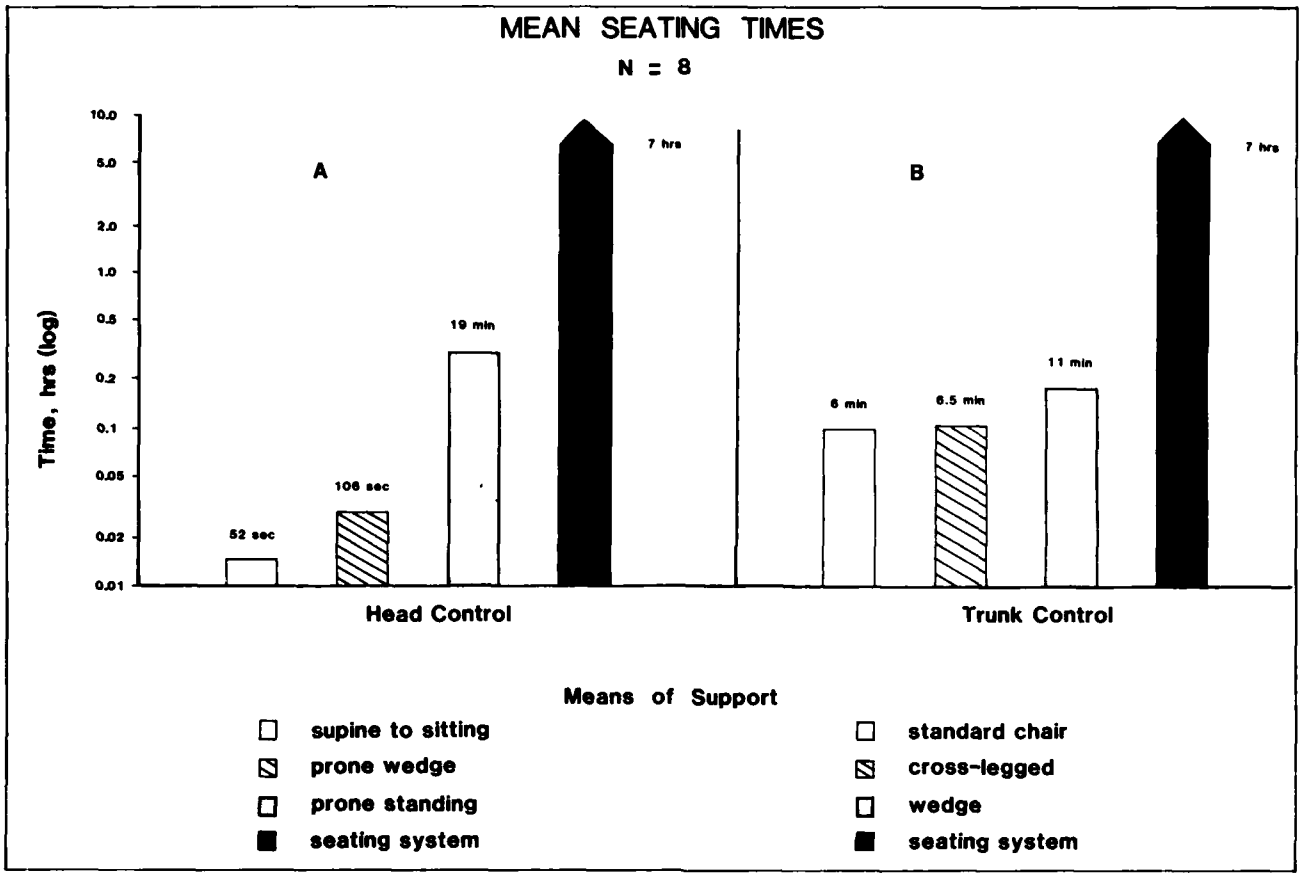


FIGURE 1.

ered devices, all four children could traverse the test track in less than one minute. Individual variations were due to the control ability of each child and the type of powered chair and control system each was using.

The distance test revealed that the average distance traveled by each of the four children dependent on manual propulsion was 1184 feet (388.1 meters) over a typical 6-hour period; three of the children relied on random propulsion by others and the fourth ambulated with the use of a walker. Using powered mobility the average distance traveled within the 6-hour period was 2231 feet (680 meters).

Based on the subjects studied, it can be concluded that children with zero or very limited mobility can be given sufficient control over a powered device in order to permit them to safely mobilize themselves within a school environment within a practical time frame; i.e., traverse 125 feet in less than one minute. Secondly, when given the opportunity through powered mobility, the test *subjects increased their overall mobility* distance approximately two times the distance traveled when dependent on others for propulsion; or in one case on stressful ambulation with a walker.

Communication—Rate of communication is an important variable when considering which alternative communication system to prescribe. The slower the system, the less likely the listener will *choose to wait for the complete mes*sage, resulting in frustration for both the sender and receiver (3). In the educational setting, the rate of communication has a direct bearing on the quality and quantity of time spent between student and teacher, and on the quantity of time required for students to complete work assignments that require output responses.

Directly bearing on the rate of communication *is the rate of accessing the* communication aid. In order to evaluate the relationship between alternate communication devices and speed of accessing the devices, it was decided to use symbolic units as a measure of comparing access rates between six different systems. That is, the selection of a Blissymbol by finger pointing, or an alpha-numeric character by eye gaze, or selection of keys on a keyboard were all given an equal value of one symbolic unit. All students were assessed by the Speech Pathologist as being functionally unintelligible as a result of Cerebral Palsy. Most could communicate only *through facial expression and gross* gestures. Two attempted speech but were almost never understood.

Three children used a lap tray incorporating a symbol board and pointed to the symbols with their hands. Three children used an eye gaze chart and pointed to symbols with their eyes. Two children used the Proscan, which was activated by an optical sensor mounted on the head (4). One child (LM) used a *developmental device also activated by* a head-mounted optical sensor but with an improved feedback panel. Measures were taken with the commercially available TRS-80 pocket computer and the

Canon Communicator, both of which required finger function. All measures were obtained after at least 7 months of training (with the exception of the new optical headpointer (LM) which was only used for 3 months and the TRS-80 which had been used only 2 months).

As shown in Table 1, mean access rates with lap trays and eye gaze charts using symbols were 7 and 8.45 symbolic units, respectively. The optical head pointer, the TRS-80, and the Canon yielded means of 38.8, 25.5, and 39.5 symbolic units respectively. Caution must be exercised in interpreting these results, especially since comparisons are being drawn between individuals with varying degrees of control ability. Also, the eye gaze and lap board devices communicate the equivalent of whole words through the use of symbols, while the remaining systems communicate only alpha-numeric characters, or word units. However, the cluster of access rates within a single device used by children with varying degrees of control ability is significant.

If one assumes that a symbol (Blissymbol) communicates the equivalent of a five-letter word, then the eye gaze and lap board approaches would have equivalent rates of 35 and 42.2 symbolic units respectively. However, the limitation of the simplified eye gaze and lap board approaches is in the practical size of the vocabulary that can be displayed, especially when portable configurations are required. However, the approach is certainly valid for young beginners, since at that stage size of vocabulary is usually not a priority factor. Electronic devices using alphanumeric characters have no limit to the vocabulary size. With the addition of stored words and whole-phrases prediction strategies, user program ability, etc., (features which are now available with microprocessor based systems) the communication rates have been drastically improved, especially when activated by direct access input modes. (The experimental prototype used by L.M. in this study has the stored word/phrases features, but was not used during the testing sessions.) It is further noted that Rosen and Trepagnier have recently published a suggested standardized methodology for measuring access rates for the purposes of comparing direct selection and encoding systems (3).

TABLE 1. Rate of Accessing the Communication Aid.

Device	Means of access/input	Child	Symbols (units) per minute	Mean value
Eye gaze chart	Direct eye gaze/symbols	TR	7	x = 7
		SR	6	(35)
		JM	8	
Lap board	Direct pointing/symbols	AE	9.67	x = 8.45
		BK	7	(42.2)
		HR	8.67	
Proscan	Direct optical pointer/alphabet	DD	18.5	x = 38.83
		LM	34	
*New optical pointer	Direct optical pointer/alphabet	LM	64	
TRS-80	Keys/alphabet	WM	26	x = 25.5
		FN	25	
Canon	Keys/alphabet	WM	39	x = 39.5
		FN	40	

*Experimental prototype

TABLE 2. Feeding Skills Data.

Student	Without equipment unassisted	Without equipment assisted (fed)	With equipment unassisted	with equipment assisted
D.D.	cannot eat	20 min.	30 min.	
H.R.	cannot eat	15 min.	25 min.	
S.R.	cannot eat	25 min.	cannot eat	17 min.
B.K.	cannot eat	20 min.	10 min.	

In summary, other things being equal, faster communication is better communication. These preliminary results suggest that electronic devices, especially when expanded to include stored words/phrases or symbols accessed through direct selection, can be an effective means of providing faster communication. However, it should be also stressed that the more simple (non-electronic) aids can be equally effective, especially for beginners who are at the stage of learning the prerequisite skills necessary for the effective use of more sophisticated (and expensive) electronic communication aids.

Personal Care—Feeding—Feeding was chosen as a personal care activity for documentation, since it has obvious significance for the child and also cost-saving implications within the educational setting.

Feeding skills measurement was taken with four students, all of whom were totally dependent in feeding, but possessed the potential for independence with the assistance of a technical aid. Since the technical solutions provided were so individualized, each will be briefly described.

1. DD was provided with a Winsford Feeder, a powered feeding device he operated with chin control with his arms restrained under his tray.

2. HR was provided with a C.P. feeder, as she has sufficient gross motor arm placement to hit the levers required to operate this mechanical feeder.

3. SR had a modification to her tray which restrained her arms, giving her more upper trunk stability during feeding.

4. BK was provided with a swivel plate because he could not reach the food at the far side of his tray. A built up spoon handle helped sustain grasp.

The time required for a teacher's aide to feed a randomly selected school lunch was recorded. Then the feeding device was provided, a proficiency level obtained, and the time recorded for each child to eat independently; or in one case (SR) to be fed with the arms restrained.

As indicated in Table 2, feeders allowed three of the children to become independent during mealtime and to accomplish this within a practical time period (30, 25, and 10 minutes). Although in two cases the feeding time was increased by 10 minutes, it obviated the need for salaried aid through-

out mealtime. The arm restraint allowed S.R. to be fed in a shorter time (17 vs 25 minutes).

Educational Achievement—The primary purpose for technical intervention was to assist handicapped children to reach their potential in education and personal care skills. Five of the Project children were in a developmental program, with the remaining in an academic program. The developmental program is designed to develop pre-academic skills such as basic vocabulary and language concepts, arm/hand and head control, and perceptual motor skills utilizing environmental stimuli and normal experiences.

In the academic group, one student, who is hearing impaired as well as nonverbal, participated in a specially designed language-based program coordinated between the multiply handicapped hearing-impaired program and the Shrine School Physically Handicapped program. The remaining four children were in non-graded elementary classes.

In order to evaluate the educational achievement of the Project children, an examination was made of each student's performance in their classroom from Fall 1979 to Spring 1981, the period after which technology had been prescribed and secured for each child complete with adequate usage training. Student growth was compared to that of a control group that did not have the benefit of the intervention of technology and other support services the Project provided. However, because of the vast differences between the children, it was virtually impossible to make a completely valid evaluation of comparative growth.

For the academic group, progress was measured in terms of the mean growth of children in reading and mathematical skills. For the developmental group, progress was measured by a percentage of correct responses in color recognition (reading readiness) and matching numerals. (See Figure 2.)

Results indicate that the mean reading achievement score for the project children in the academic group was 7 months as compared to 6 months for the control group for the two consecutive school years. Mathematic scores indicate that all children in the academic group progressed during the 1979–1980 school year with a mean growth of 9 months as compared to 7 months for the control group of four children. In the 1980–1981 school year the mean score was 12 months growth as compared to 8 months for the control group.

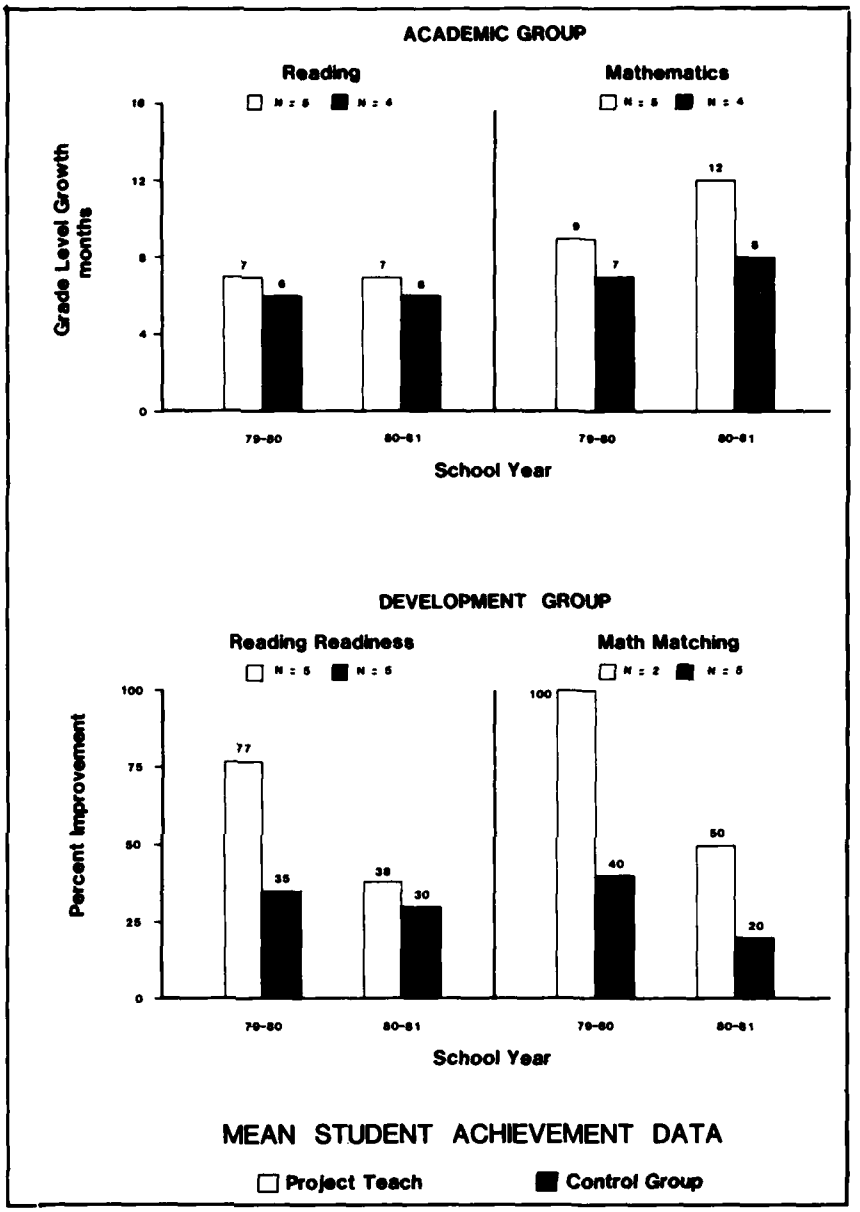


FIGURE 2.

In the developmental group, all children progressed during the 1979–1980 school year in pre-academic skills with a mean growth of 77% as compared to a mean growth of 34.5% for the control group of five non-project children. In the 1980–1981 school year the mean progress in color recognition was 38% as compared to the control group of 30%. In matching numerals all students went from zero ability at the beginning of the 1979 school year to recognizing 100% of the numerals at the year's end; the next year, the same group made 58% progress in matching numerals as compared to 20% for the control group.

As can be noted, the project children made significant gains during the first year when the technology and training were first introduced and then tended to level off in growth, while still performing at higher levels than the control

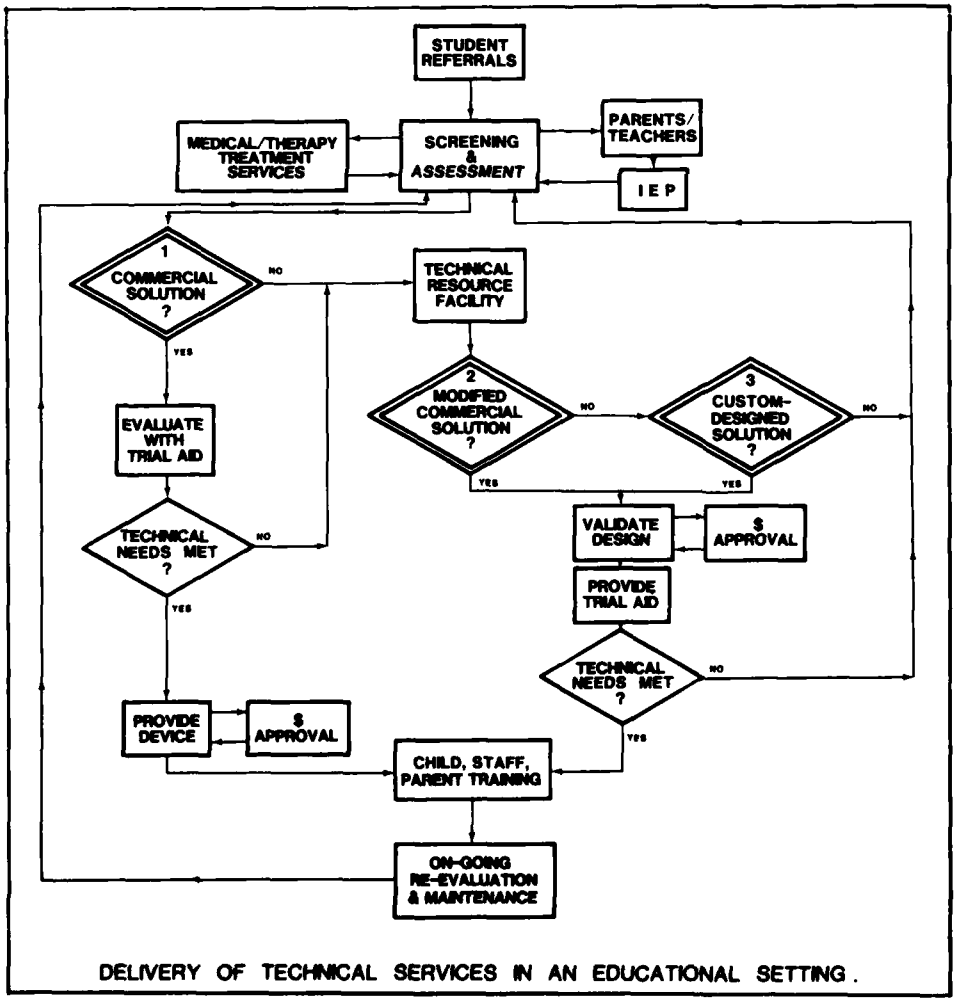
group. Four students from the academic group were mainstreamed on a part-time basis during the course of the project. Teacher interviews revealed that this was accomplished largely as a result of the technical devices and support provided to the students and teachers by the project staff.

It is not evident from the data which specific aspects (i.e., seating, communication, mobility, or ADL) of the technical support were the most effective in supporting educational objectives. Parent, student and teacher interviews suggest that the achievement of effective student-teacher communication is of the highest priority. Further, it can be deduced that the functional accessing of communication devices is highly dependent on good head and trunk control. This suggests that provision of communication aids should be preceeded by the availability of adequate seating support systems. In the academic study group, the final step to mainstreaming was facilitated as a result of powered devices that allowed independent mobility. This permitted transfer between classrooms within an acceptable time frame without any special assistance. Achievements in the area of personal care were particularly important to the morale of the parents as they witnessed the children acquiring skills that were previously considered to be life-long impossibilities. Reduction of staff time required to fulfill the personal care needs of the children during the school day was also a secondary benefit.

Provision of Technical Services—The Delivery Model

Figure 3 is the generalized flow model that was developed for the delivery of the technical services within an educational setting. Upon receipt of student referrals the first essential step is a thorough screening and evaluation process by a multidisciplinary team. Our experience suggests that an occupational therapist, a speech pathologist, the parent and an educator should form the nucleus of the team with other specialists being available as required. A vital part of the assessment process is coordination with the child's ongoing medical and therapy treatment program to insure compatibility of management goals and the receipt of the background information necessary for decision making. Communication with the parents and classroom teachers is most essential, since the ultimate plan must by law be incorporated into the child's Individual Educational Plan (I.E.P.)

In general, four alternatives are avail-



DELIVERY OF TECHNICAL SERVICES IN AN EDUCATIONAL SETTING.

FIGURE 3.

able to the assessment team relative to the provision of a technical aid. These options are (i) provide a commercial device, (ii) provide a modified commercial device, (iii) provide a custom designed device, and (iv) acknowledge that a solution does not exist within the current resources available to the team.

The first option (a commercial device) is usually one that can be purchased directly from a supplier and provided to the child without any significant technical support required. In most cases this is the most practical approach and therefore, as indicated in the flow chart, should be the first route investigated. Risk is diminished if access to trial aids is possible so that an evaluation with the proposed aid can be carried out prior to the commitment of financial resources.

Failure of the "as supplied" commercial aid to meet the needs of the child leads to the two remaining technical options. These options usually require the availability of technical resources in order that modifications to commercial devices can be accomplished, or that custom designed unique solutions can be conceived and produced. If possible, modification of a commercial device is usually the next most practical approach. These modifications are usually concerned with such things as wheelchair mountings, alterations to the input controls, connections without display modes, and interpretations of technical data from the suppliers.

For reasons of cost and time delay, custom designed solutions are the technical approach best reserved for the last resort. Once the modification on prototype design has been validated and the devices fabricated, they should be subjected to usage trials. Failure to meet the needs at this point suggests a complete reassessment of the problem in light of the overall priorities and resources of the program.

In all cases, once a successful device is working under the supervision of the technical resource team, training of others associated with the child's daily environment is the next vital step. The importance of providing detailed instructions and support to educators during the transition phase into the classroom cannot be overstressed. Maintenance and repair of technical aids in a timely manner to minimize "down time" is vitally important in order to maintain student motivation and supportive teacher involvement.

Finally, the technical needs of most children change with time. Therefore, periodic re-evaluation and assessment of the needs is necessary to review the appropriateness of the aid relative to the child's current needs.

In 1980 the National Association of State Directors of Special Education published a delivery model, complete with cost figures and listings of resource facilities (5). This reference is recommended reading to those considering establishing technical resource facilities to serve educational environments.

Cost Distribution

The cost of technical support provided to Project TEACH is summarized in bar graph format (Fig. 4). Cost analysis was related to the five component areas of technical support: seating, mobility, communication, aids to daily living, and evaluation and training aids. The cost within each category has been subdivided into the following three types of aids: commercial, modified commercial, and custom designed.

Technical aids available to children from commercial sources progressed rapidly during the course of the three year project. A number of the children in Project TEACH received custom designed equipment that presently could be provided through commercial channels. To provide cost data more useful for planning and budgeting, the cost distribution data have been adjusted to reflect current (1981) commercial costs of these devices where applicable. Although certain aids are now commercially available, provision is normally through professional consultant channels. In these cases, cost of the aids has been included under the commercial breakdown, while the professional time involved in the prescription and fitting of such aids has been distributed between the modification of commercial equipment and the custom designed solution.

The results in Figure 4 indicate that average seating costs per child were $620, with $330, $40 and $250 distributed between commercial, modified commercial and custom designed solutions, respectively. These costs did not include the wheeled base. Powered mobility costs were the highest with an average of $2,000 per child, with increments of $1,150 for commercial, $200 for modified commercial, $650 for custom design devices. Further analysis of the graph will result in the cost figures for communication aids, ADL devices, and evaluation and training equipment for the 10 Project TEACH children.

The cost distribution does not include the cost of routine maintenance and repair of the aids provided. Over the course of the 3-year project, it was determined that the cost of maintenance, local repair, and repair of aids by commercial suppliers resulted in additional annual expenditures of approximately 10% per year above the cost of the provision of the aids.

Concluding Comments

The provision of appropriate technical aids within an educational setting can have a profound impact on improving the educational achievement experienced by severely handicapped children. In some cases, the support of technical services can lead to the mainstreaming of children that otherwise would not be candidates.

The provision of most aids should be preceeded by a multidisciplinary evaluation in which the abilities, the potential, and the comprehensive needs of the child are clearly defined.

A multidisciplinary engineering service team can be a most effective resource for the selecting and providing of specialized technical services, especially those related to the provision of modified commercial aids and/or custom designed devices.

Due to the need for additional head and trunk control, severely handicapped children should be provided specialized seating systems as a prerequisite for the provision of communication, mobility and personal care aids.

The more sophisticated the technology, the more essential the need for liaison personnel to explain the operation and features of each device to teachers and parents. Failure to provide this liaison support will almost invariably lead to rejection of the device.

Breakdowns with lengthy delays can severely interrupt a student's program: therefore, durability of equipment should be a major consideration in the evaluation and equipment selection process. Repairs to equipment must be provided in a timely manner to assure continuing

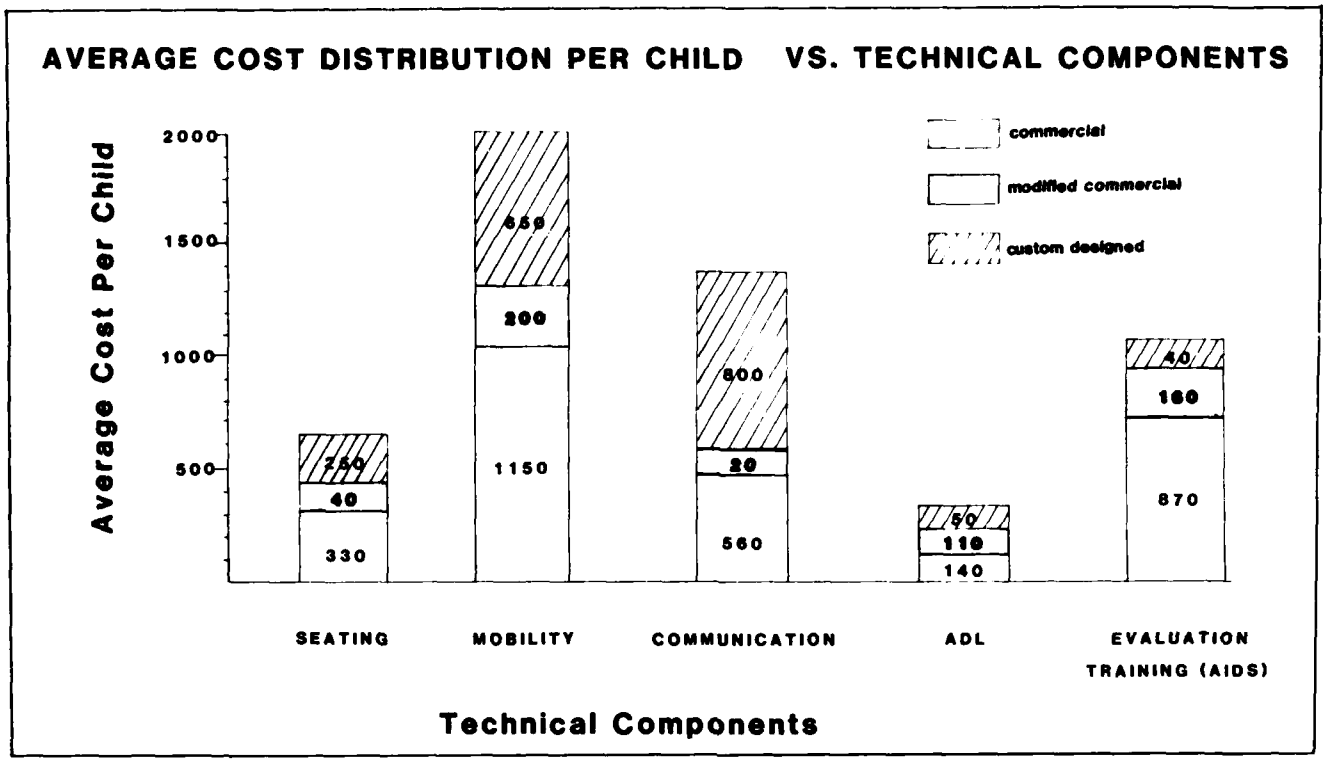


FIGURE 4.

student and teacher participation.

Technical aids should be provided within an educational setting according to a logical plan. The proposed model (Fig. 3) suggests a generalized operational approach which can be restructured to meet the needs of a specific locality. However, it is recommended that none of the components of the model be sacrificed if results as reported are to be achieved.

Continuing research on technical aids to supplement educational objectives is urgently required to improve the quality and effectiveness of devices available within special education classrooms. These studies should include expanded statistical evaluations with larger populations to better confirm the effects on student progress than has been possible in this preliminary effort.

Federal and state policy makers need to be made aware of the potential of technical resources to supplement the goals mandated by Public Law 94-142—Education of the Handicapped Act, so that these resources can be planned into budgetary allocations for implementation in the future.

Acknowledgement

The Directors of the University of Tennessee—Rehabilitation Engineering Center wish to acknowledge the support and guidance provided by the Memphis City Schools—Special Education staff assigned to Project TEACH under the direction of Mr. Harold Perry. The interest and encouragement of the parents and students were also instrumental to the success of the project.

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The 6-month period to June 30, 1981, has seen several promising developments in our REC programs. Rather than giving an exhaustive account of developments in all our projects, a brief description of the areas in which major advances have been made is given below.

Orientation and Mobility

Talking Signs. The present reporting period has seen the formation of a private company, Love Lights, Inc., to pursue the manufacturing and marketing of the Talking Signs Orientation System for the Blind. This company has redesigned the Talking Signs receiver to incorporate a wider angle of acceptance and the ability to operate outdoors, even in bright sunlight. Further development and evaluation efforts are proceeding under a collaborative arrangement between Love Lights, Inc. and Smith-Kettlewell Institute REC.

Experiments designed to evaluate the efficiency of the Talking Signs system in assisting the orientation and navigation process for the blind have been conducted at Smith-Kettlewell. The results of these experiments indicate that the speech quality of the existing version of the Talking Signs is adequate to insure intelligibility, and that use of the Talking Sign system allows blind persons to find locations in an office building faster than does the use of raised print labels on doorways.

In collaboration with Love Lights, Inc., we are investigating the application of Talking Signs technology to elevator speech modules. A local manufacturer of elevator controls has constructed a prototype using our designs, and is investigating the feasibility of production.

Collapsible Cane. As a result of the success of our prototype rigid collapsible long cane, we are investigating the possibilities of having 10 evaluation prototypes constructed by a local manufacturing company. These prototypes will be evaluated by selected long-cane users around the country. One result of our initial evaluation of the first prototype was recognition of the need for extra reinforcement of the lower sections of the cane. The 10 evaluation prototypes would incorporate two or more different methods of achieving this reinforcement.

Educational Aids

Our major project in this category has been the continuing development of the Auditory Arcade, described in earlier reports. We have now fabricated a second "Problem Panel" for this device, enabling it to be used to teach different skills.

Our next step will be to fabricate a talking version of this microprocessor-based game.

Vocational Aids

During the current reporting period, we have developed the use of the Smith-Kettlewell Technical File as a tool for the dissemination of vocational aids developed at our Center. Through the publication of circuits and fabrication instructions in this magazine, we have enabled many blind individuals to construct simple electronic aids for themselves.

We have initiated an ongoing followup program to evaluate the vocational aids developed in our laboratories during previous years. Of the first 23 users questioned in this survey, 21 were still using the various aids and devices in their daily vocational tasks. Of the two who were not, one had regained his sight since receiving the equipment.

We are now assembling a complete catalog of vocational devices developed at our Center, to facilitate our research utilization efforts. This catalog will contain complete details of all of the devices, including information as to how the device can be obtained, and will be circulated to prospective users, vocational counselors, purchasers, etc.

Low Vision Research

Our review of flat panel display technology for possible application to a lightweight, affordable, electronic low-vision reading aid is now complete. A summary of this survey will appear in our 1980/1981 Annual Report, of which published copies will soon be available. We are now ready to purchase examples of the most promising types of display for initial experimentation on a small scale, before beginning the design of an aid using a full-sized display.

Training

Our Technical Training Program for blind technicians has thus far proved most successful, in terms of benefit both to the trainees and our researchers. The 4 blind students who have so far participated in this program have received practical experience in electronics which is not available for them elsewhere, while the interaction between the trainees and our staff have produced a number of innovative methods of electronic circuit fabrication applicable to individuals with visual handicaps. These methods are being published through the Smith-Kettlewell Technical File, with a view to encouraging other blind individuals to become involved in electronic technology.

Braille Communications

We have initiated two new projects in the area of braille communications. While the use of synthetic speech is becoming widespread, we are confident that, for many applications, braille will continue to be a primary form of communication for the blind in the future. Consequently, we have turned our attention to developing less expensive methods of braille production and the realization of volatile braille displays.

Both of the new methods under development utilize different plastic materials as the base upon which the braille is printed. Details of both the approaches will be contained in our 1980/1981 Annual Report. One of our special concerns is the development of low-cost braille output methods for computers. We have conceived a technique whereby the output from a conventional computer printer can be converted into braille without modifying the printer hardware. A prototype system is currently being developed.

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This report (April 1–June 30, 1981) is a followup of the research and development report which appeared in BPR 10-35, Spring 1981. The core area of the Ljubljana REC is functional electrical stimulation (FES) of human extremities and of urogenital mechanisms. Institutions collaborating within the Ljubljana REC are: Rehabilitation Institute, the Faculty of Electrical Engineering and the Jožef Stefan Institute at Edvard Kardelj University, and the Urologic Clinic, all in Ljubljana. This current status report includes only the results and achievements of research tasks which we believe could be of broader interest to other researchers.

Multichannel FES of Lower Extremities for Gait Rehabilitation of Paretic Patients

Resp. for task: U. Stanič, D. Sc., R. Ačimovič, M.D., M. Maležič, Dipl. Ing., J. Krajnik, Dipl. Ing., P. Strojnik

The results of a controlled study performed during the last 2 years, comparing the effectiveness of multichannel electrical stimulation with classical methods of rehabilitation, were analysed. For this purpose two similar groups of hemiplegic patients (9 patients each) were formed. The rehabilitation process of both groups was evaluated by different qualitative and quantitative methods. The former included clinical analysis of gait, evaluation of walking abilities, and test of motor functions; while the latter comprised the measurement of ground reaction by measuring shoes and crutch, measurement of goniograms of the hip, knee, and ankle joints of both legs in sagittal plane, measurement of stride length and gait speed, and recording of EMG activities over six muscle groups of both legs. The measuring techniques and computerized data processing were implemented in our laboratory.

Considering the results of different methods of gait evaluation, no positive answer can be given in favour of the existence of the so-called "long-term" therapeutic effects in gait caused by electrical stimulation. Unfortunately, the groups were too small, and too heterogeneous in several important parameters, to prove statistically possible significant differences in the evaluated parameters between the two groups.

However, it is evident that therapy including multichannel electrical stimulation is more intensive and efficient; namely, the rehabilitation period is shorter and higher levels of improvement can be achieved. "Short-term" therapeutic and orthotic effects of stimulation are well established.

A microprocessor-controlled six-channel surface stimulator (Fig. 1) was developed as a result of experiences gained with previous multichannel stimulators. A microprocessor accommodates stimulation sequences to the gait cadence of the patient, and also gives some basic statistical parameters of the gait.

FES of Spinal-Cord-Injured Patients —Fundamental Locomotion Patterns

Resp. for task: A. Kralj, D. Sc., R. Turk, M.D., T. Bajd, D. Sc.

The wheelchair-attached supporting frame, which enables the patient to balance and partly support himself while standing up and maintaining the erect position by means of FES, was redesigned in Spring 1981 with the goal of improving cosmesis, functionality, and stability. In Figure 2a the frame is shown while collapsed, and in Figure 2b it is shown as used by a T–5 patient during standing by means of FES. Next, this standing frame together with the stimulator will be evaluated and particular efforts made for stimulator improvements in regard to size, electrodes,

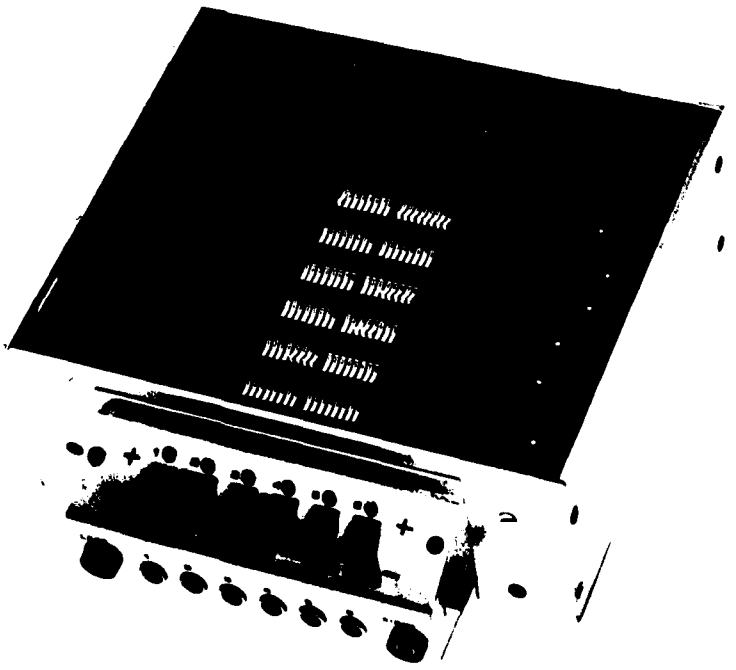

FIGURE 1.
Six-channel microprocessor controlled stimulator.

FIGURE 2a.
The collapsible wheelchair-attached supporting frame does not interfere with the normal use of the wheelchair.

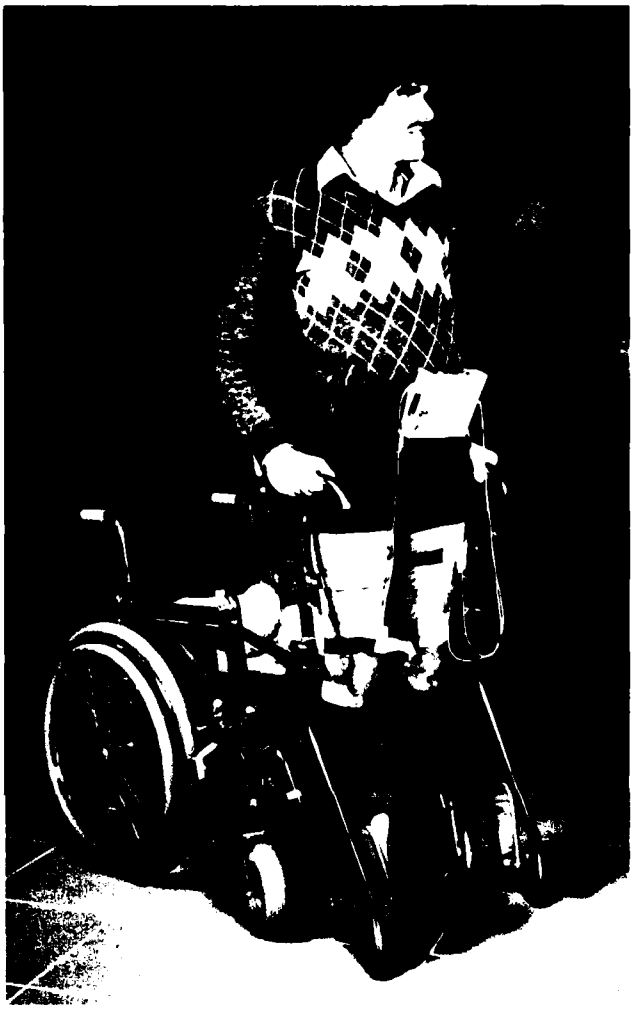

FIGURE 2b.
Patient (T-5) while standing by means of two-channel FES of M. quadriceps using the W/C attached supporting frame.

properties, and fixation means.

In April of this year a four-channel electrical stimulator suitable for the FES of incomplete paraplegic patients was completed. This stimulator provides different triggering possibilities and, according to the patient's voluntary control, can be adapted to the patient's needs. The second important advantage of the stimulator is that different stimulation frequencies can be pre-set and if needed partly controlled by the patient. The parameters of electrical stimulation are selected in such a manner that flexion reflex movement of the entire leg can be evoked during the gait. This provides a one-channel control of the entire swing-phase movement.

Figure 3 shows the hip angle dependence of various stimulation parameters for a T-4-6 paraplegic patient. The described stimulator is used for achieving primitive biped gait patterns in paraplegic patients suffering from complete lesion, too.

One paraplegic patient T-5 uses a roller-walker for support and the four-channel stimulator described. The controls for stimulation are mounted on the handles of the walker. The patient, while walking by means of FES, controls the stimulator via hand switches and this way ensures proper coordination of his upper trunk movements and provides the timing (beginning, duration, and ending of the stimulation). Up to now, this patient has been able to walk more than 100 m on even surfaces.

Functional Electrical Stimulation of Denervated Muscles

Resp. for task: L. Vodovnik, D. Sc., S. Reberšek, M. Sc., V. Valenčič, D. Sc., F. Gračanin, D. Sc.

Electrical stimulation of the nervous tissue has found clinical use in a wide variety of orthotic and therapeutic applications in patients with central nervous system injuries. It is generally believed that the denervated muscle may be directly excited by a special range of electrical wave-forms, all of which elicit a non-tetanic physiological response. Typical parameters are: pulse duration of a few tens of milliseconds and frequency from 0.5 to 10 Hz and relatively strong currents (10-40 mA). The reaction of the skin under a surface electrode, however, shows a marked depen-

dence on the parameters of the stimulating waveforms.

The major goals of our investigations are:

1. Detailed study of the phenomena which arise from electrostimulation of the denervated muscle;
2. Development of a clinically useful functional electrical stimulation (FES) method for a patient with lower motor neurone lesions;
3. Optimization of electrotherapy for a patient with denervated muscles;
4. New knowledge about electrophysiology of denervated muscle; and
5. Minimization of the various waveform parameters which are related to electrically induced redness—such as current and voltage levels, energy, power, injected electrical charge, and timing parameters of electrical stimuli.

The goal of the preliminary experiments on the denervated muscle was to obtain a minimum functional movement by means of electrical excitation on denervated muscle. Surface electrodes were applied and a voltage source of the stimulating pulses was used. The results reported here present a comparative study of the skin response, torque, and angle of the ankle joint to four different waveforms: simple monophasic, simple biphasic, chopped monophasic, and chopped biphasic. Time and current parameters have been fixed. The current was 5 mA, pulse duration T_1 = 30 ms, pulse frequency f = 16.6 Hz, and chopping frequency 500 Hz (Fig. 4). The measurements were performed on 6 normal subjects and 5 subjects with complete denervation of the muscle tibialis anterior.

The redness of skin was estimated visually in three levels. The investigation of problems of electrical stimulation for patients with lower motor neurone lesions shows some possibilities of optimization of electrotherapy and defining the FES to these patients. The redness and the movements are related to the waveforms of stimulation pulses. The stimulation response was better at simple monophasic and simple biphasic waveforms. The redness was essentially diminished at chopped biphasic stimulation pulses. There is also a possibility that the generator of source stimulation pulses is current. Investigations in that direction are running at present.

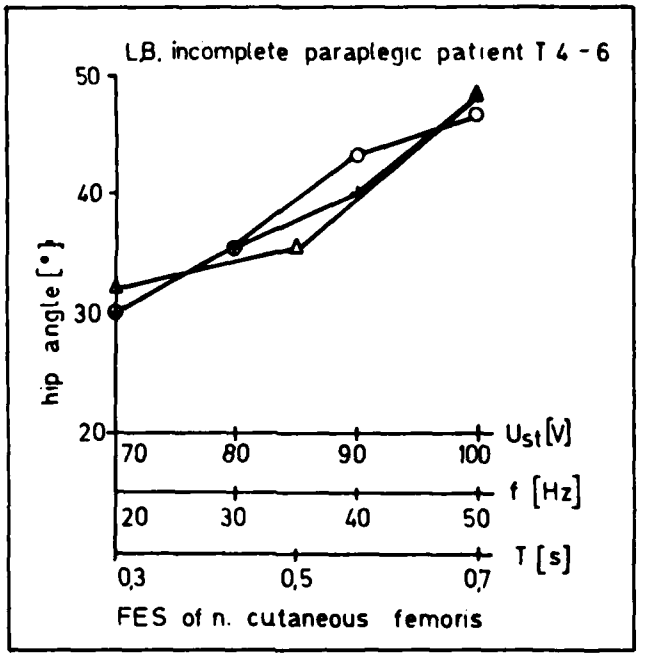

FIGURE 3.
Hip flexion angle change in relation to different FES parameters.

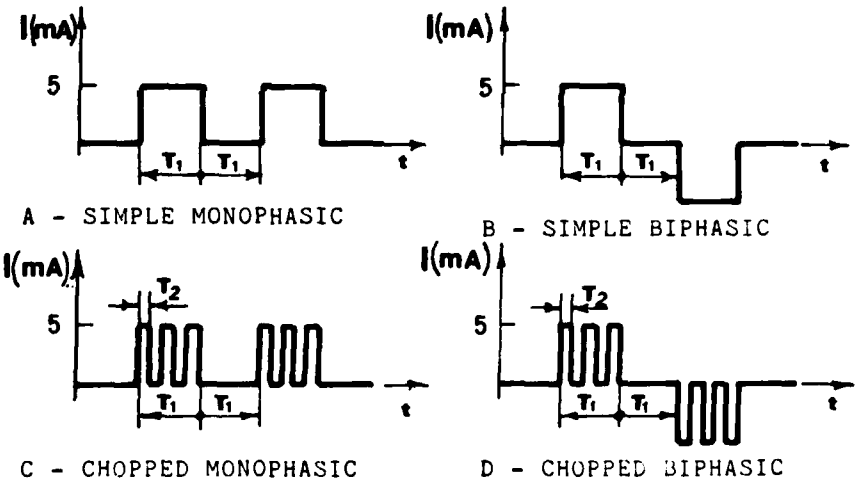

FIGURE 4. *Waveforms of stimuli.*

Neurophysiological Investigations of Improvements in the Pathological Motor Activity Due to FES and other Rehabilitation Methods

Resp. for task: F. Gračanin, D. Sc.

It was shown that by FES of peroneal nerve a motor response (M-wave) is not constant and changes its amplitude depending upon some phases of the gait. Current research is directed to the study of M-wave behaviour using continuous stimulation and an off-on control of FES in normal persons and patients suffering from spastic hemiplegia. Our aim is to analyze the related mechanisms (central and peripheral of the neuromuscular system) of uncontrolled changes in the conditions of FES application together with the influence of the electrodes moving, topographical changes of anatomical structures when the leg is in different positions, etc. Results of this research will be helpful to numerous researchers, clinicians and patients who are using FES. Our measurements

are performed by using the system FEPA 10 for off and on control and simultaneously the AM-5 system for continuous stimulation during the patients' walking. The M-Wave is analyzed with the help of a HP-2100 minicomputer.

The second topic of this task is the analysis of paravertebral and abdominal muscles activity in children attending elementary school. They are frequently wearing school bags, weighted up to 5.5 kg. The goal of this research is to recognize different patterns of motor activity and statiokinesiological changes in respect to foreseen possible development of bad posture and deformation of the spine. Such recognition is important for prevention of functional impairment and disability.

FES of Urogenital Mechanisms (FESUM)—Design of Orthotic Aids and Special Measuring Systems—Electronics

Resp. for task: P. Šuhel, D. Sc., M. Sc.

The Vagicon-X AMFES stimulator design and prototype manufacturing is completed and these stimulators are at present being evaluated in use. The collected results up to now are promising for the usefulness of the device for providing patients home therapy. It is suitable in cases of recurrent urge incontinence.

Up to now the application of clinical hypersuggestion for the cure of urge incontinence has proved to be efficient. In four patients the urodynamical parameters have been positively modified after using hypersuggestion for treatment.

The AMFES stimulator for clinical use, with complete galvanic stimulation channel selection and incorporating automatic programming possibilities is already developed in a laboratory model. Following the line of our basic studies of the urogenital mechanisms by help of EMG of the urethra and the anal sphincter, a new measuring system was developed making use of refined electronic techniques for obtaining great improvement regarding the signal-to-noise ratio of the measured parameters. Results of these better and more accurate measuring techniques will be used later in the development of our microcomputer-controlled diagnostic system.

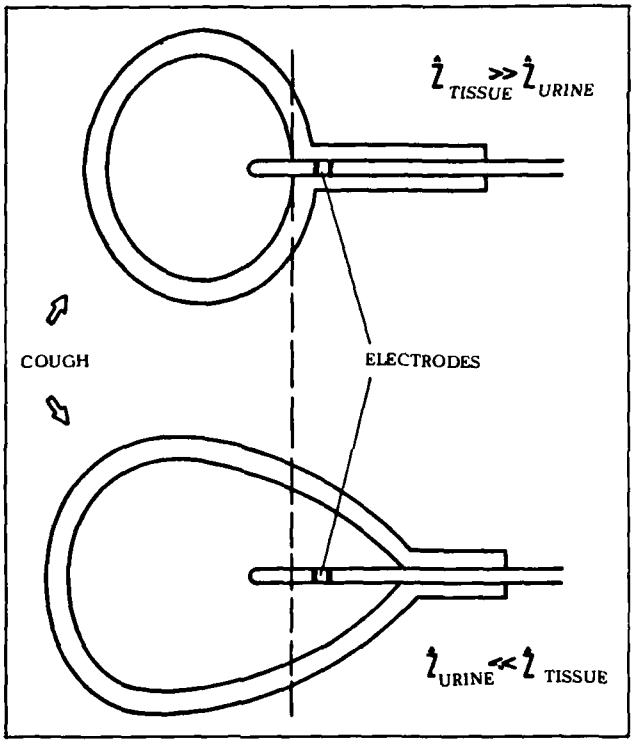

FIGURE 5.
Schematic diagram of electric fluid bridge test for detection of opening of urethra and objective test of incontinence.

FES of Urogenital Mechanisms: Physiology, Techniques of Stimulation, and Methods of Urodynamic Evaluation

Resp. for task: S. Plevnik, M. Sc., J. Janež, M.D., S. Rakovec, M.D., D. Sc., P. Vrtačnik, Dipl. Ing., L. Ravnik, M.D.

In the first half of the year 1981, the research in this particular subarea was directed to treatment of urinary retention using maximal electrical stimulation and to development and testing of the new technique of evaluation of urinary incontinence using an electric fluid bridge test.

Nonimplantable short-term maximal electrical stimulation (MES) benefited the patients with upper motor neuron lesion having urinary retention. In the preliminary study, treatment with MES was successful in paraplegics with longstanding as well as recent lesions who had not developed reflex bladders, as well as in paraplegics with longstanding lesions who had well-developed reflex bladders and in whom retention occurred afterwards.

An electric fluid bridge test was designed and successfully evaluated. The new test allows the most simple and reliable detection of the opening of the urethra during stress (e.g., a cough) and thus objective evaluation of incontinence. The introduction of the urine into the urethra which may occur during stress is detected as a change in impedance, since the urine has much greater conductivity (or lower impedance) as compared with the tissue of the urethral walls (Fig. 5).

FES of Urogenital Mechanisms—Studies of Urodynamics and Evaluation of Orthotic Aids

Resp. for task: L. Ravnik, M.D., D. Sc., J. Janež, M.D., S. Plevnik, M. Sc., P. Vrtačnik, Dipl. Ing., S. Rakovec, M.D., D. Sc.

During the first part of the year 1981, the investigations in this subarea were devoted to basic research of the effects of maximal electrical stimulation on the detrusor muscle in experimental animals.

The dose response relations for acetylcholine and isoprenaline were deter-

mined on isolated strips of the urinary bladders of six control and seven stimulated rabbits.

Electric pelvic floor stimulation produced increased beta-adrenergic activity in detrusor muscle, while the activity for cholinergic receptors was decreased. From the method used, it is not possible to draw conclusions about the nature of these changes (increased number of receptors, altered affinity) but it is possible to explain to a certain extant bladder inhibition and long-term effects of electrical stimulation.

Rehabilitation Engineering Center
The Institute for Rehabilitation and Research
1333 Moursund Avenue, Houston, Texas 77030

Thomas A. Krouskop, P.E., Ph. D., Program Director,
Jesse H. Dickson, M.D., Co-Director, and Laura Winfrey

The Texas Rehabilitation Engineering Center in Houston, Texas, continues its efforts to effectively manage and treat the long term effects of pressure on soft tissue which result in pressure sores. It also studies materials for percutaneous implants.

Recognizing that soft tissue breakdown can dramatically disrupt the rehabilitation progress of spinal cord injured individuals, Texas Rehabilitation Engineering Center developed and established the Tissue Pressure Management Clinical Program in 1977 in an effort to alleviate pressure problems for the severely disabled. Located in the Medical Center at The Institute for Rehabilitation and Research (TIRR), the Tissue Pressure Management Clinical Program provides patient-oriented services to the severely disabled through a comprehensive program of clinic, research, and education.

In the clinic, patients are provided with services in which existing or potential problems in tissue breakdown are identified and corrected. Through the cooperative efforts of physicians, therapists, engineers, orthotists, and nurses, patients receive treatment ranging from extremely conservative to the most dynamic. Staff members evaluate patients and their problems to provide immediate solutions such as providing conservative medical treatment to existing sores, positioning recommendations, referral for cushion evaluation, adjustment of body jackets, referral for surgery, etc. If the problem requires more intensive study, staff members confer to determine the best solution e.g., design of a custom pressure-relief device or design and fabrication of special adapted equipment.

The Program allows patients to participate in the evaluation of new diagnostic instrumentation and pressure relief materials. This participation aids the Center in collecting useful data concerning the functional longevity of pressure relief devices and materials, the methods of preventing and treating pressure related tissue breakdown, and the techniques to modify existing materials and devices to render them more capable of relieving pressure.

Rap sessions are offered to patients and their families instructing them in the latest methods of preventing and managing skin problems. Workshops, lectures, and seminars that include information on the prevention and treatment of tissue trauma and breakdown are conducted to train nurses, physicians, therapists, and counselors.

Success of Clinical Program—In a recent Rehabilitation Engineering Center update, data collected during the 5-year period of the Program's existence were analyzed to determine the success of the Tissue Pressure Management Clinical Program. The statistics indicate that, prior to the Program, patients risked developing a second pressure sore at the recurrence rate of 88 percent. However, since the Program started the recurrence rate of individuals developing a second pressure sore has been reduced to 36 percent. These statistics demonstrate the successful implementation and utilization of a comprehensive, multidisciplinary program that significantly reduces the risk of tissue breakdown.

A Commercial Introduction—Currently the Texas Rehabilitation Engineering Center is working with Palm Beach Medical in Boston, Massachusetts, to introduce commercially and implement the hardware of the Pressure Evaluation Pad (PEP) unit, a cushion life monitor, and the educational/instructional materials to prevent tissue breakdown. Using the Tissue Pressure Management Clinical Program established at the Texas Rehabilitation Engineering Center as a guide, Palm Beach Medical is developing a preventative Tissue Management System which will provide a means for making a comprehensive client evaluation and for prescribing the proper support system and health care regimen to avoid tissue breakdown. This endeavor will make a better comprehensive tissue management program commercially available to hospitals, institutes, and rehabilitation centers concerned with the prevention and treatment of pressure-induced tissue breakdown.

To ensure maximum reliability of patient evaluations using the Pressure Evaluation Pad unit, the Center has completed a second study analyzing the transducer pad made of polyurethane film. Statistics from this study show that the pad introduces a maximum error of less than 10 mm of mercury (usually about 5 mm of mercury) when compared to a single-cell pneumatic-type spot transducer.

The Texas Rehabilitation Engineering Center is also proceeding in the development of materials for improved implant-tissue compatibility. Implant studies using laboratory animals have demonstrated the biocompatibility of such materials as porous vitreous carbon, pyrolytic carbon, and carbon coated titanium buttons with dermal tissue. Preliminary findings on porous vitreous transcutaneous devices show that transcutaneous passage is stable for 4 years. Recent studies suggest that titanium implants induce a more fibrous reaction in subcutaneous tissues. Further studies will determine how large a cannula or tube can be implanted through the skin surface with long term stability.

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Clinton L. Compere, M.D., Project Director

ANALYSIS OF RETRIEVED TOTAL JOINT PROSTHESES

Total joint replacement has proved to be a highly successful procedure for the rehabilitation and restoration of persons disabled by severe arthritis. Total joint replacement (TJR) however, is not yet a perfected procedure, particularly for joints other than the hip. Prosthesis design, and surgical procedures used to implant TJRs, continue to evolve to meet perceived current or potential problems. Monitoring and evaluating the usefulness of these changes is difficult because of the lack of data on both frequency and types of TJR failure.

One approach for monitoring TJR performance is the retrieval and examination of removed TJR implants. The study of each retrieval, when coupled with surgical observations at the time of arthroplasty revision, and the clinical history of the patients, can yield detailed information on the in vivo function of the implant and the conditions which led to its ultimate removal.

		Hips		Knees	
AGE:		Number	Percent	Number	Percent
	less than 40	9	15%	0	
	40 - 49	3	5%	2	5%
	50 - 59	11	18%	5	11%
	60 - 69	25	41%	24	55%
	70 - 79	8	13%	11	25%
	greater than 80	5	8%	2	5%
		61		44	
SEX:		Hips		Knees	
	males	26		11	
	females	35		33	
WEIGHT:		Hips		Knees	
		Number	Percent	Number	Percent
	normal	27	44%	16	36%
	overweight	33	54%	25	57%
	unknown	1	2%	3	7%
		61		44	
DISEASE:		Hips		Knees	
		Number	Percent	Number	Percent
	osteoarthritis	27	44%	29	66%
	rheumatoid arthritis	7	11%	11	25%
	traumatic arthritis	8	13%	4	9%
	CDH	3	5%	0	
	other	16	26%	0	
		61		44	
PRIOR REVISION:		Hips		Knees	
		Number	Percent	Number	Percent
	yes	15	25%	8	18%
	no	46	75%	36	82%
		61		44	
SYMPTOM DURATION:		Hips		Knees	
		Number	Percent	Number	Percent
	less than 1 yr	48	79%	27	61%
	1 - 2 yrs	11	18%	12	27%
	greater than 2 yrs	2	3%	5	11%
		61		44	

TABLE 1.
General patient data.

Materials

Over a period of 6 years, 130 prostheses were retrieved, including 75 hips and 52 knees; all were removed for clinical failure. The original participants of the study were six surgeons associated with the Northwestern University Medical School Hospitals. The study was then gradually expanded to encompass eight hospitals in Metropolitan Chicago area with 21 contributing surgeons; no new contributors have been added since 1978. The surgeons agreed to contribute all removed components so that, to the best of our knowledge, all the TJRs removed by these physicians during their participation are included.

Of the 130 prostheses, 61 hips were of the type made up of a metal femoral component and an ultra-high-molecular-weight (UHMW) polyethylene acetabular component. In addition, 44 knees were of the type where 1 or 2 metal femoral components articulate on 1 or 2 UHMW polyethylene tibial components. Results from a close examination of the data on these particular 61 hips and 44 knees are presented (Table 1). The specific prosthesis types are given in Table 2.

Of the 61 hips, 44 (72%) were originally implanted by the participating surgeon, 16 (26%) were referrals, mostly from the Chicago area, and one case was of uncertain origin. Of the 44 knees, 26 (59%) were originally implanted by the participating surgeon and 18 (41%) were referrals.

Methods

The study of the removed components included (i) examination of patient medical records, (ii) analytical review of patient roentgenograms, (iii) observations at the time of revision surgery, and (iv) postoperative examination of the removed components. The protocol followed for each patient was that all pertinent medical records and X-rays were reviewed by a member of the project team, usually a biomedical engineer, who, when this was practical, attended removal surgery to record all surgical findings. When possible, the patient was later interviewed to complete the medical history.

Data from all medical records and analyses, summarized on the coding forms, are transferred to magnetic tape for storage and later computer analysis.

Results and Discussion

Cause of Removal—The most frequent cause of total hip joint revision was idiopathic loosening of one or more of the prosthetic components, Table 3. One third of all the removed hips were so classified. The other major causes of total hip removal were trauma (21%) and sepsis (15%). Iatrogenic factors were re-

sponsible for only 11% of the revisions.

By contrast, one third of the total knee revisions were performed for iatrogenically induced reasons. The other major reasons for total knee removal were idiopathic loosening (30%) and trauma (11%).

The knee joint is an anatomically intricate joint, consisting of three separate articulations, multiple constraining ligaments, and complex geometries. The relationships between the multiple knee motions of rotation, antero-posterior sliding and flexion-extension, and knee joint structures are not yet fully understood. Accordingly, knee joint prosthesis design is a somewhat imprecise art with new designs and surgical procedures continually evolving. All these factors are reflected in the high incidence of technical problems leading to total knee revision.

Time Between Surgery and Revision—The total time period, grouped by years, for which the prostheses were implanted before removal is plotted in Figure 1 for hips and knees. Both histograms seem to indicate a greater portion of the removals occurred within 3 years after the original arthroplasty. However, if the removal cases which were prejudiced toward early failure at the time of surgery, namely those cases involving early sepsis or technical problems, are eliminated, the rate of total hip removal appears to be approximately constant for at least 8 years. In particular, there is no increasing loosening rate with time.

On the other hand, the incidence of total knee removal remains elevated for the initial 2 or 3 year postoperative time period even after the iatrogenic and early-sepsis cases are removed. Thus, total knee patients may be at increased risk of joint failure during the short-to-intermediate postoperative time period. There were insufficient total knee cases retrieved after long-term use to be able to make any predictions on the long-term survival rates of knees, although no evidence of any upsurge of late loosenings was observed.

Total hip replacement has remained relatively unchanged with regard to overall design concept for the past decade, and substantial numbers of patients have been receiving total hip arthroplasty at least since 1972. Thus, the rate of hip removal is probably not influenced by recent rapid changes in

NUMBER OF CASES: hips - 75; knees - 52; other - 3; 130

PROSTHESIS TYPE:

HIPS		KNEES	
Aufranc-Turner	19	Duo-Patellar	5
Charnley	4	Geomedic	28
Charnley-Muller	36	Marmor	5
T-28	1	Polycentric	2
CAD	1	St. Georg Sled	2
		Total Condylar	1
		UCI	1
	61		44
McKee-Farrar	7	Others	8
Others	7		
	75		52

TABLE 2.
Types of retrieved prostheses.

PRIMARY PREOPERATIVE INDICATION FOR REMOVAL OF TJR:

	Hips		Knees	
	Number	Percent	Number	Percent
loosening with pain	35	57%	20	45%
pain only	1	2%	12	27%
sepsis	8	13%	4	9%
dislocation/subluxation	9	15%	5	11%
bone fracture	1	2%	1	2%
prosthesis fracture	7	12%	1	2%
other	0		1	2%
	61		44	

REVISION PROCEDURE:

	Hips		Knees	
	Number	Percent	Number	Percent
replace component	34	56%	14	32%
new prosthesis	17	28%	21	48%
suction-irrigation	6	10%	3	7%
pseudo-arthrosis	3	5%	0	
arthrodesis	0		5	11%
other	1	2%	1	2%
	61		44	

SUMMARY, REASONS FOR TJR REMOVAL:

	Hips		Knees	
	Number	Percent	Number	Percent
iatrogenic	7	11%	14*	32%
sepsis-early	4	7%	2*	5%
sepsis-late	5	8%	1	2%
trauma	13	21%	5	11%
idiopathic loosening	20**	33%	13***	30%
prosthesis fracture	6**	10%	1***	2%
pain only	2	3%	3	7%
other	3	5%	5	11%
	61		44	

* 2 early sepsis listed as iatrogenic
** 1 prosthesis fracture listed under trauma
*** 3 prosthesis fractures listed under idiopathic loosening

TABLE 3.
Summary clinical data for retrieval patients.

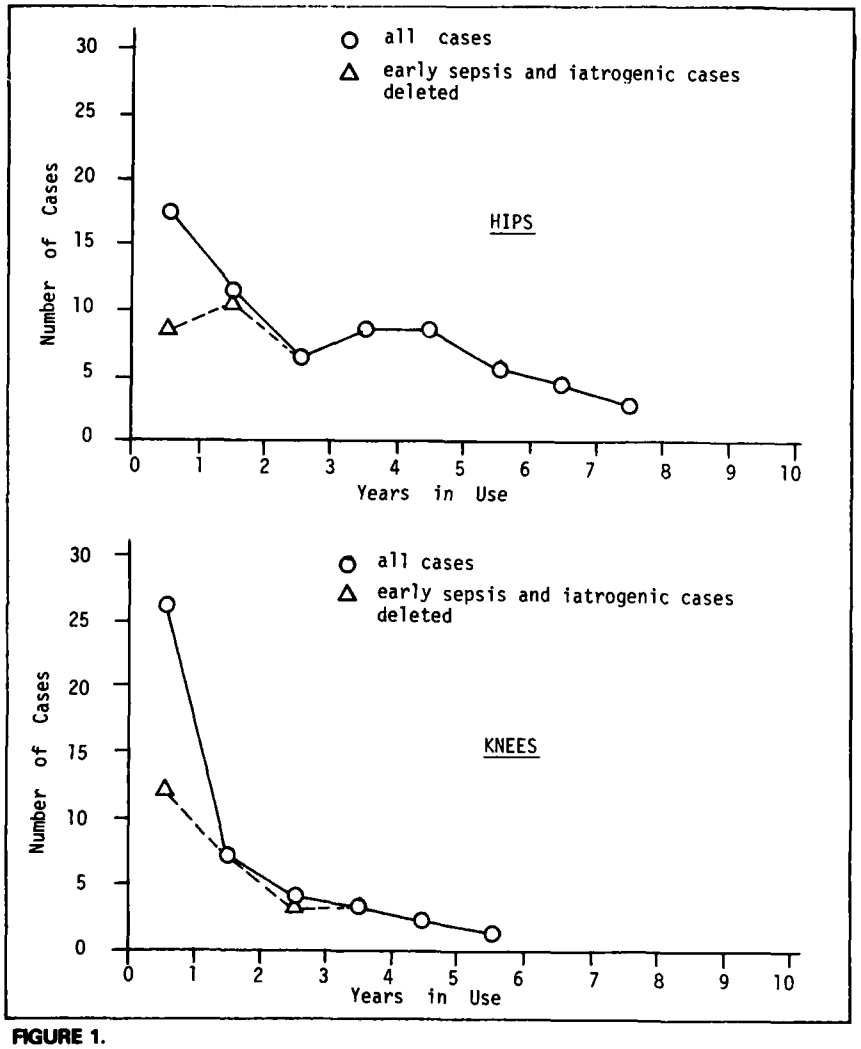

FIGURE 1.
Symptom-free time period of TJR use.

COMPONENT	LOOSENED INTERFACES BONE-PMMA	PMMA-COMPONENT	BOTH	NOT LOOSE
HIP-FEMORAL	0	20	9	18
HIP-ACETABULAR	4	3	4	36
KNEE-FEMORAL	7	1	1	22
KNEE-TIBIAL	12	4	10	10
	47 ASEPTIC HIPS 36 ASEPTIC KNEES			

TABLE 4.
Loosened interfaces of aseptic retrieval cases.

the total hip population. However, the number of patients receiving total knee replacement has been rising in recent years. The lack of long-term total knee data is, in part, a reflection of the relatively few patients with total knee arthroplasties of long duration.

Loosened Interface and Loosening Etiology—The loosened interface varied with prosthetic component. Since this observation may be important in understanding the etiology of the failure process, the nature of the failed interfaces were recorded. Interface failure was classed as one of three: (i) bone-cement interface only, (ii) cement-component interface only, and (iii) at both interfaces. The results are shown in Table 4.

A significant observation from these data is that all (29/29) loose total hip femoral components were loose at the cement-component interface. This finding is at odds with the data for the other three components which were loose more frequently at the bone-cement interface and less often at the cement-component interface. The most frequently observed failed interface might be expected to be the one which failed first. If failure occurred first at the bone-cement interface, which in turn led to cement-component interface failure, a significant number of failures only at the bone-cement interface should be seen.

The implication of this observation is that the hip stems are failing first at the cement-component interface and that this is the weak element in the system. This implication does not have direct data to support it; other processes are possible. However, it agrees with other studies which show that failure of this interface leads to high PMMA cement stresses, implying subsequent PMMA cement fracture and bone-cement interface failure. This observation also supports the need for more research on this interface regarding failure processes and prosthesis design.

Another observation from this data is that the metal femoral components of the knee rarely loosen, and that when they do (or when a firmly fixed component is removed) the PMMA cement is firmly fixed to the component and there is no PMMA fracture. This observation implies that if the PMMA cement remains fixed to the metal, there will be no cement fracture.

The converse is observed with the UHMW polyethylene components, i.e., the acetabular cups and the knee tibial components. Although there were several cases where only the bone-cement interface failed, the more frequent observation in these cases was failure at both interfaces with pieces of PMMA cement remaining firmly fixed to both bone and component. This situation implies cement fracture without total failure of cement-component interface and perhaps even without total failure of the bone-cement interface. Thus, either failure of the bone-cement interface or cement fracture is more likely to be the initial factor in the loosening process in these cases.

Summary

Our implant retrieval program has the inherent problems of a retrospective study and data collection from multiple institutions. Results of high statistical significance are difficult to obtain. Also, retrieval studies cannot give absolute failure rates, since the patient population from which the sample is drawn is unknown, but TJR failure modes and their relative rate can be determined. Finally, not all implants which may be classified as clinical failures come to removal so that retrieval studies do not monitor all failure modalities.

Nevertheless, retrieval analysis provides an efficient means of obtaining detailed information on the in vivo behavior of implants, particularly the failed implants, which are of greatest interest, and is a good means of monitoring and evaluating the failure modes of TJRs in use.

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MOBILITY RESEARCH

Wheelchair Propulsion Studies

Task leaders, Clifford E. Brubaker, Ph. D., Gregory B. Shasby, Ph. D.

The task objective is to determine the conditions for optimum efficiency and effectiveness of wheelchair propulsion for the various populations using wheelchairs. These include type of propulsion system (lever, rim, crank), position of system interface relative to size, and proportion of users. Limitations including the effects on maneuverability posed by the various propulsion systems for different populations are also considered.

A static lever device will be used to study the interplay of lever length and spinal lesion level on isometric lever-pushing at each of a range of positions. The incorporation of the EMG telemetry equipment, recently acquired, will offer evaluation of muscle function and thereby provide useful information with regard to the variation in prime movers as a function of lever length, arc length, and lesion level. Next will be a study of the effects of hand supination and pronation on predicted propulsive power, as well as the effect of lever shape. In the latter case, the current data should give an indication of an optimal lateral distance between lever handgrips. Plainly, the lateral distance between the handles and the lateral distance between the lever mounting points on the drive mechanism need not be the same. The levers could be bent either towards or away from the mid-sagittal plane. Thus, it will be necessary to assess what effect various bent positions might have, first in terms of isometric lever pushing, and then in terms of dynamic activity.

Once the static tests have reached fruition and the results have been incorporated into a lever drive design, dynamic testing will be launched. These studies will center on the evaluation of metabolic efficiency. Incorporated into these studies will be the EMG telemetry system and a motion analysis system. These two devices, operating simultaneously under microcomputer control, should provide biomedical analyses previously unavailable for wheelchair propulsion.

Microcomputer-Based Paper Transport Mechanism

Task leader, James H. Aylor, Ph. D.

The purpose of this project was to design a system capable of aiding the handicapped programmer in handling large amounts of computer printout. Specifically, a low-cost system of hardware and software was developed to provide for moving the printout back and forth between critical locations, while requiring that the only user input be through a mouthstick-operated keyboard. A prototype was built and is being evaluated. No future work is planned on this project, but we feel that the overall scheme applied to the paper handler could very well be extended to book page-turners in the future.

Electric Wheelchair Control System

Task leader, James H. Aylor, Ph. D.

The objective of this project was to develop an electronic controller for an electric wheelchair with the central element of the controller being a commercially available microcomputer. The principal advantages of using a microcomputer were (i) reduction in the number of components required, and (ii) the extensive flexibility that was provided by the resulting system. Also investigated is the application of digital transducers to the design of joysticks for wheelchairs. The advantages of this aspect of the project are (i) that digital transducers are normally wear-free, and (ii) the normally required analog-to-digital conversion process for the microcomputer may now be eliminated.

A very flexible wheelchair controller has been developed and future research will be geared towards utilizing the full

potential of this controller. Automatic battery monitoring is already being investigated, as is the potential of sophisticated automatic guidance and automatic collision-avoidance techniques.

One problem that will need to be investigated in future research is that of fault detection and fault tolerance of the microcomputer systems.

Electric Wheel

Task leader, J.J. Kauzlarich, Ph. D.

The objective is to design an electric motor, transmission, and brake to fit in the hub of a powered wheelchair wheel. One of the goals is higher efficiency through the use of a new type of disk motor.

All of the tests so far show that the electrical wheel of the Mark I design meets the design specifications and demonstrates the advantages for the design. A Mark II design has been considered which will significantly reduce the costs of the motor. Assuming success with the Mark I design, and demonstrated interest by the wheelchair community, we plan to consider implementing the Mark II design.

Due to the cost of the $SmCo_5$ permanent magnet material, which has been severely affected by the rising price of cobalt, it would be most beneficial to pursue a Mark II version of the electric wheel motor that has a smaller volume of magnet material. This will happen if the motor can operate at a higher speed. The proposal is based on using a gyratory gearbox with a ratio of 22:1 plus a 4:1 epicyclic input stage, at a motor speed of 10,720 rpm/min. The epicyclic unit is needed because, although a gyratory unit alone could provide a ratio of 88:1, it could not tolerate this high an input speed.

The overall weight is considerably reduced, the permanent magnet volume is 28% of the Mark I value, and the armature resistance is reduced to 22% of the Mark I design. A similar reduction in the I^2R power loss is anticipated.

Wheelchair Dynamics

Task leader, John G. Thacker, Ph. D.

This study involves the collection of information on the forces influencing wheelchair motion and power requirements.

The intent of this work is to predict the power and torque necessary to propel a manual chair over a particular surface at varying velocities. Torque and power are mainly influenced by the type of wheels used on the wheelchair. Once the simple wheel/surface rolling resistance equations are modeled, more generalized situations such as power/torque necessary to negotiate building ramp entrances and to cross streets can be simulated on a computer to optimize patient utilization.

Three different types of drive wheels will be evaluated over four surfaces: (i) Solid tires (spoked wheels), (ii) Pneumatic tires (spoked wheels), and (iii) Solid tires (magnesium wheels).

The surfaces to be investigated will include concrete, tile, pile carpet and shag carpet. The pneumatic tire pressure will be varied at 70, 50, 30 and 20 psig. The speed ranges will vary from 0 to 6 km/min. The patient weight to be added to the chair weight will range from 400 to 1,000 N over 200-N increments. The chair frame and front casters will remain constant throughout the test. The alignment of the wheels will be monitored and corrected if necessary.

A second study will be performed on the front caster wheels. Pneumatic and solid tires will be studied, with the rear wheels remaining constant. An in-depth study and comparison of all data will be made.

Also a study is being made on the dynamics of wheelchairs with soft suspension systems. The two important elements that are being studied during this analysis are ride quality and propulsion efficiency.

Design parameters will be optimized and centered on propulsion efficiency and ride comfort. A computer-based analysis will be performed and critical chair parameters will be indicated.

Wheelchair Design

Task leader, Colin A. McLaurin, Sc. D.

The objective is to develop, construct, and demonstrate design concepts for wheelchairs. Promising designs are pursued through various changes and prototypes until significant advantages can be shown. It is then hoped that they can be made commercially available by working in cooperation with manufacturers. Four specific design problems are under investigation, the center of gravity wheelchair (grasshopper), the airchair, a lever propulsion system, and the beach wheelchair.

Wheelchair design will become an increasingly active part of the University of Virginia program, working closely with industry. Specific activities are planned as follows:

1. NASA Langley cooperation project. A cooperation project with NASA Langley is in the planning stage. The computer analysis methods and the composite materials experience of NASA and Hercules Corp. will be utilized in developing stronger, lighter wheelchairs. As an initial step, the airchair will be used as an example with manufacturing as the realistic goal. If this indicates the effectiveness of a cooperative program, then the process will be applied to a wheelchair design for the major market, possibly using the grasshopper or some other innovative configuration.

2. Sidewinder. Kinetic Concepts, of San Antonio, Texas have acquired the North American rights to the Swedish wheel concept that allows a wheelchair to move in any direction. The design is based on four independently powered wheels each with eight free-turning rollers set at 45 degrees around the rim of the wheel. Discussions are now under way to formalize a plan whereby the University of Virginia Rehabilitation Engineering Center will work with Kinetic Concepts in the design, development, and evaluation of a wheelchair embodying this concept.

3. Grasshopper. This chassis configuration appears to be meeting the major design requirements. The next step is to build a folding model, based on sketches that have already been made. When the model(s) are satisfactorily made, user testing will be initiated. Further concepts have been considered whereby the weight distribution will be automatically changed to optimize curb climbing without sacrificing level ground traction and performance. Working models of this concept will be made for testing.

4. Lever Drive. The present model will be completed and mounted on a wheelchair for testing. Further development will be based on the results.

5. Beach Wheelchair. Development of this item will continue to decrease the cost and enhance performance and durability. When levers are available (see 4 above) these will be tried.

6. Dynamic Brake. Hub brakes, based

on Sturmey Archer bicycle brakes, will be fabricated to test the concept.

SPINAL RESEARCH

Spinal Cord Monitoring

Task leader, Steven I. Reger, Ph. D.

The objective has been to develop the equipment and techniques for monitoring the electrical activity in the spinal cord. Spinal evoked responses will be used in the operating room and in clinics to show changes with spinal cord obstruction and other trauma.

Work has begun to assemble, test and begin to operate the spinal cord monitoring instruments for intraoperative use at the University of Virginia Hospital. Work will continue to quantitatively describe the effect of spinal cord contusion, compression, cooling and nerve root block on the evoked responses in the cat.

Spinal Stabilization

Task leader, Gwo-Jaw Wang, M.D.

This project has presently emphasized static flexion tests of canine cervical spines. Our ultimate objective is to conduct mechanical load tests on reconstructed cadaver cervical spines. Before testing cadaver specimens (of limited availability), this research will focus on other facets of spinal stability in order to converge on the critical aspects of spinal stability. To that end, we propose to:

1. Improve our data collection and recording techniques by developing an on line capability of recording and displaying the data from the mechanical load tests.

2. Examine the fatigue capability of the constructs (simulate one year of a patient flexing his neck) to determine if cyclic stress on the various constructs produces a different pattern of relative strengths from those recorded from static tests.

3. Continue static tension tests on the wire loops used in some of the fixation procedures to obtain baseline data concerned with the metal grade and size of wire used as well as the strength of the wire-tying procedures.

4. Possibly examine the feasibility of using other metals (i.e. age-hardening coated aluminum that would be kept in a very pliable state during surgery but which achieves a doubling or tripling of strength after a few hours of "aging") or other non-metallic materials as competitors to the present stainless steel and Vitallium wires used in assembling a construct.

COMMUNITY RESEARCH

Community Engineering Program

Task leader, Ronald C. Gordon

Note: This task is primarily supported by grants from the Commonwealth of Virginia's Governor's Employment and Training Council, Employment Commission (CETA Division), and Developmental Disability Unit.

In the Spring of 1979, the Community Engineering Program (CEP) was established to design, establish and optimize a demonstration rehabilitation engineering system at the community level. It was proposed that the engineering technology services be offered through local organizations. It was envisioned that once the program was established, continuous re-evaluation and research would optimize the model system for increased positive impact, minimum cost, and efficiency of operation.

The identification of the disabled population and the needs assessment study in the target community is expected to be completed in fiscal year 1981. After completion of the study, the registry of the population will be maintained and updated so that it will be available for future research.

Small pilot service projects will continue to be operated in fiscal year 1981-82 contingent on availability of funding sponsors. The purpose of these pilots will be to develop procedures for assessing needs of individuals for engineering technology and acquiring data on potential community and agency support structures for the handicapped.

EDUCATION AND PRACTICE

Rehabilitation Engineering Education

Task leader, John G. Thacker, Ph. D.

Note: This task is funded separately by a grant from NIHR to the Department of Mechanical and Aerospace Engineering.

Formal educational programs have been developed in rehabilitation engineering for both engineers and persons from other disciplines involved in rehabilitation engineering activities.

The objectives of the present dual-track 5-year graduate traineeship program at the University of Virginia is to attract and train a minimum of 35 students with engineering and clinical science backgrounds in the general field of rehabilitation engineering. Particular emphasis will be placed on practical training through internship activities at the University of Virginia Rehabilitation Engineering Center. Field experience is available at the Woodrow Wilson Rehabilitation Center and the University of Virginia Children's Rehabilitation Center.

Students participating in the program will complete a 2-year program of study organized to provide sufficient engineering and clinical background necessary to permit graduates to enter employment in the field of rehabilitation engineering. Students will take existing graduate courses offered by the Department of Mechanical and Aerospace Engineering, Electrical Engineering, and Biomedical Engineering in the School of Engineering and Applied Science. Internship and thesis activities will be conducted through the Rehabilitation Engineering Center. Graduates of the program will obtain a Master of Science or Master of Engineering degree in one of the engineering fields, with emphasis on biomechanics and rehabilitation engineering.

Rehabilitation Engineering Practice

Task leader, James R. O'Reagan, M.S.

Rehabilitation Engineering Practice serves as a mechanism by which Rehabilitation Engineering graduate students participate in clinical practice. This endeavor provides customized engineering for rehabilitation needs for the physically disabled and serves as a nucleus for a comprehensive rehabilitation engineering service program on a fee-for-service basis.

During the summer months, the graduate engineering students were involved in approximately 23 client cases. Under the supervision of a staff engineer, the students participated in problem solving whether it was report consultations or device fabrication and subsequent fitting. The approach to this effort took the commonly used ap-

proach that commercially available equipment was recommended whenever possible as the first course of action. The second choice was to modify a commercially available item and, if neither one of these choices were available, design and fabricate a custom device.

Rehabilitation Engineering Practice has established a fee for rehabilitation engineering consultations, and design and fabrications in the areas of seating, mobility, communications, daily living, school and job applications, home modifications, and medical devices.

This direct service to clients will continue to keep the REC staff in touch with the disabled and their specific needs.

EVALUATION

Battery Testing

Task leader, J.J. Kauzlarich, Ph. D.

The objective of this task is to establish typical demand cycles for electric wheelchairs and to test batteries designed for powered wheelchairs.

An electric wheelchair has been instrumented with a recording wattmeter, inclinometer (grade meter), and tachometer, and has been operated over a number of typical days of use to establish simulated demand cycles. The simulated demand cycles are played back through a pulse-width-modulated wheelchair type controller into a suitable load. The discharge and charge cycle are monitored to establish battery performance.

Foam Block Seating

Task leader, Colin McLaurin, Sc. D.

The objective is to clinically evaluate the foam block seating from Tumble Forms. This design originated with UVa REC; but all fabrication and product development is now undertaken by Tumble Forms who will eventually manufacture and market the product if the evaluation proves to be positive.

Staircat Evaluation

Task leader, Colin McLaurin, Sc. D.

Since July 1979, a multidisciplinary team has been conducting a 1-year evaluation of the Staircat Mark IV Prototype Wheelchair, a stair-climbing wheelchair produced by Staircat Incorporated of Nashua, New Hampshire. The Staircat Wheelchair was designed primarily to be used by paraplegics to overcome their inability to climb stairs both within and without their living environment.

The purpose of the investigation has been to evaluate the wheelchair's suitability both as a stair climber and as a standard wheelchair—from functional, safety, and acceptance point-of-view. The ultimate goal was to collect mechanical and metabolic efficiency data, performance data, and paraplegic user impressions.

The Staircat Mark IV prototype was found to be somewhat mechanically and metabolically inefficient, unreliable in its stair-climbing performance, and questionable as a standard wheelchair. If the Staircat can overcome its deficiencies it will attract a potential market of consumers who desire a second wheelchair that can climb stairs.

Orthoses

Task leader, Steven I. Reger, Ph. D.

A simple adjustable orthosis to prevent (or help correct) contractures at the elbow has been designed and prototypes fabricated in three sizes for use by therapists.

The usefulness of the elbow extension brace is now being evaluated by the Occupational Therapy Departments at Rehabilitation Institute of Chicago, Harmerville Rehabilitation Center (Pittsburgh), and Craig Hospital (Denver).

Powered Chair Performance Testing

Task leader, J.J. Kauzlarich, Ph. D.

The objectives for this task are to establish performance criteria for powered wheelchairs.

A set of standard tests to determine the operating characteristics of powered wheelchairs will be established. These tests will determine electrical efficiency, rolling resistance, turning radius, etc. A wheelchair route will be used to determine subjective performance characteristics such as stability, braking, holding, ease of control, etc. A variety of terrain will be used to determine such things as control on wet grass, sand, etc.

Laboratory measurements of powered wheelchair performance are conducted on a slider bed conveyor (treadmill) specially designed and constructed by Yankee Engineering Co., Inc. of Baltimore, Maryland, under Rehabilitation Engineering Center supervision.

The treadmill was placed in operation during September, 1980, and initial testing of the first powered chair with a 200 lb. load has been highly satisfactory. So far, studies have been carried out on (i) rolling resistance, (ii) castered wheel flutter, and (iii) effect of a bump on ride acceleration and shock with and without a seat cushion. Future studies will include (i) range per battery charge, (ii) overall efficiency, (iii) speed under load, and (iv) stall thrust.

Future plans involve testing the available powered wheelchairs for rolling resistance, efficiency, speed, etc. Also, the test procedures will be modified and refined toward simplicity and reproducibility.

Access to the Skies

Task leader, Colin A. McLaurin, Sc. D.

In response to government regulations concerning accessibility for the disabled, the airlines and the aircraft manufacturers are examining varicus means for conveying disabled persons into aircraft and, while on board, providing access to lavatories. The "Access to the Skies" program is headed by Rehabilitation International and TARC 218–2, a committee of aircraft manufacturers appointed for this purpose. A technical advisory committee, with Colin McLaurin as chairman and including engineering and rehabilitation experts from several countries, reports to both these groups. The role of the University of Virginia Rehabilitation Engineering Center is to introduce new concepts in wheelchair design and to formulate and to assist in evaluation procedures.

The University of Virginia wheelchair and sliding toilet seat are currently being evaluated at Boeing in a mock-up of their new 767.

Complete details of the aforementioned projects are available from this REC.

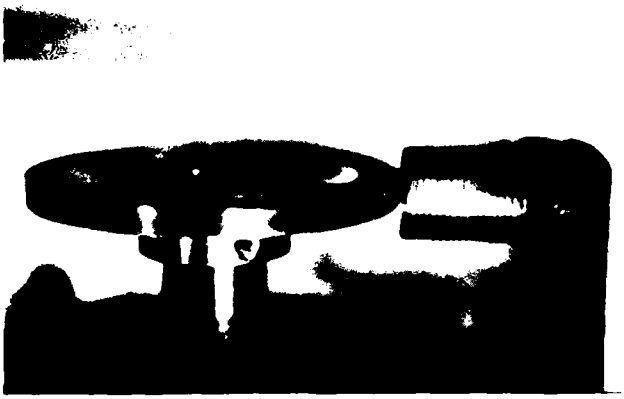

FIGURE 1.
Multipolar ring magnet (on left) is mounted on drive motor shaft. Hall effect velocity sensor (on right) is shown mounted in proximity to the rotating magnet.

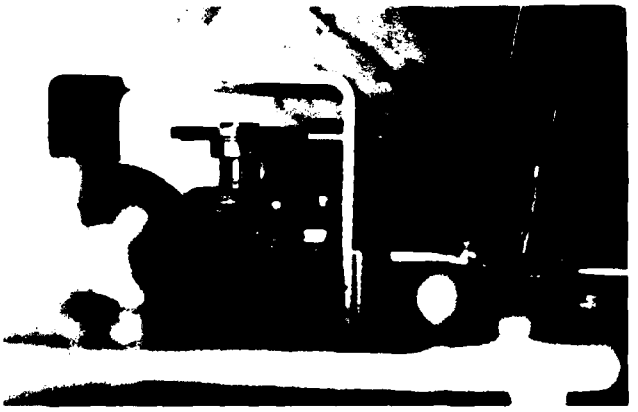

FIGURE 2.
Magnet-sensor assembled onto wheelchair motor and frame. Guard prevents magnet and sensor from being struck by road debris.

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Joseph Goodgold, M.D., Director,
Myron Youdin, M.E.E., and
Theobald Reich, M.D., Co-Dir.

A Proportional Speed Pneumatic (Breath) Control System for Powered Wheelchairs with Automatic (Closed Loop) Speed Control (New Research)

M. Clagnaz, B.E.E., H. Louie, A.A.S., and M. Youdin, M.E.E.

An automatic (closed loop) speed control compatible with the IRM pneumatic (breath) proportional speed control for powered wheelchairs has been developed. The system enables a severely disabled user to vary the speed of the chair over its entire range, and to maintain any speed while travelling up or down sloping terrain. The system is adaptable to all powered wheelchairs utilizing permanent magnet motors. The rotary speed signal to the feedback loop is produced by Hall effect sensors. No mechanical linkage is required between the rotating drive wheel and the sensor. See Figures 1 and 2.

Vocational Rehabilitation of the Severely Disabled: Voice Controlled Computer Programming (New Research)

G. Markowsky, IBM Watson Research Center, M. Youdin, T. Reich, NYU Medical Center

Speech recognition technology has developed to the point where many activities can be controlled by voice. In recent years, this technology has been used to help the disabled achieve better control of their environment. A prototype voice-controlled programming system has been developed to make programming easier for the severely handicapped. The system is now undergoing clinical evaluation. See Figure 3.

Evaluation of Electronic Self-Help Devices for Use by Severely Disabled Persons

Ruth Dickey, M.A., O.T.R.

The purpose of this project, begun in October 1974, is to conduct comprehensive clinical evaluation of selected commercially available electronic assistive devices on a long-term basis, in order to determine their usefulness for diag-

FIGURE 3.
A severely disabled patient being taught APL language.

nostic populations of persons with severe physical disabilities. Various diagnostic populations are included in the sample with primary emphasis on individuals with high-level spinal cord injuries and progressive neuromuscular disorders.

Seven general categories of electronic assistive devices are currently under evaluation: environmental controls, electronic telephones and controls, mobility controls for powered wheelchairs, audio recorder controls, powered door openers, electric page turners, and alphanumeric communications aids. New devices under evaluation reflect microprocessor technology for telephone and environmental control including Prentke-Romich ECU-3, Basic Telecommunication Corp. AbilityPhone, and MED MicroDEC. The evaluation of alphanumeric format-aids now includes computer-assisted word processing and text editing for application to the personal and vocational writing needs of the severely disabled.

Evaluations are conducted in the occupational therapy electronics laboratory, in various rehab. center locations, at bedside, home, school and job-site.

Current data collected on equipment advantages and disadvantages and any cost-benefit relationships are available for any single device or device categories by writing to Project Co-ordinator, RR–310.

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Charles H. Herndon, M.D., Project Director

The activities of the Rehabilitation Engineering Center at Case Western Reserve University are directed toward restoration of function in patients with mobility disorders. Studies are directed toward development of a program for evaluation of the control of movement and restoration of upper extremity function involving tendon transfer, functional electrical stimulation, sensory augmentation, and command control signal generation. Mobility studies include development of control sources for powered wheelchairs, and evaluation of the therapeutic effects of functional electrical stimulation in gait.

1.

Restoration of Upper Extremity Function through Functional Electrical Stimulation

Principal Investigators:
R. Hunter Peckham, Ph. D.
Alvin A. Freehafer, M.D.
Michael W. Keith, M.D.

These studies are the core area of research in the center. The purpose of the project is to develop and evaluate systems employing functional electrical stimulation to provide control of hand movement. Eight quadriplegic subjects with C-5 or C-6 level motor function continue to be involved in outpatient evaluation of these systems. These studies are being performed in conjunction with the VA Rehabilitative Engineering R & D program, and the current status is detailed elsewhere in the Bulletin (See "Development of Upper-Limb Orthoses Employing Electrical Stimulation" under VA RER&D Service Programs).

2.

Restoration of Upper Extremity Function through Tendon Transfer

Principal Investigators:
P. Hunter Peckham, Ph. D.
Alvin A. Freehafer, M.D.
Michael W. Keith, M.D.

Tendon transfer provides a viable means of restoring motor control to paralyzed limbs. The purpose of this study is to investigate techniques for improving upper-extremity function in spinal cord injury patients through the use of tendon transfers. We are presently monitoring function of the transferred muscle during surgery to establish proper functioning of the transferred muscle tendon unit, and monitoring changes in the activity patterns of the muscle following the transfer.

Intraoperative monitoring of muscle properties. The intraoperative monitoring of muscle properties is an ongoing project. The purpose of this project is to evaluate the available excursion and length-tension properties of the muscle-tendon during tendon transfer surgery. The methodology was reported in BPR 10-35. These tests were performed on 73 muscles in 46 subjects.

The results of the excursion studies were reported in the previous report.

The length-tension characteristics of a muscle showed differences from subject to subject and from muscle to muscle. The brachioradialis muscle usually was measured after soft tissue dissection. This muscle showed active properties which were generally quite flat over a 15 mm length centered approximately 5 mm longer than the reference marker. (The reference marker is the point of tendon cut, and is described in the methodology).

The pronator teres muscle showed length-tension characteristics similar to the brachioradialis. Six of seven muscles demonstrated flat active properties over at least a 10 mm length.

The flexor carpi radialis muscle showed a more peaked length-tension curve. In three of five muscles studied, there was a peak at the reference point, and in one muscle at 5 mm longer than that point.

The extensor carpi radialis longus muscle was similar to the FCR. Each of four muscles had a peak active force curve, with three muscles peaked at 5 mm longer than the reference length and one peaked at the reference point.

The posterior head of deltoid showed generally quite flat active force characteristics. A slight peak occurred at 15 mm beyond the reference length or longer in four of eight muscles, at 20 mm or longer in three muscles, and 5 mm in one muscle.

The following procedure is used to establish the correct muscle length at surgery. It incorporated the results of the excursion and length-tension measurements as determined intraoperatively.

The required excursion is measured by moving all joints across which the transfer will act through the full range of motion. Secondly, the available amplitude of the motoring muscles is measured. The decision for the pairing of motor and insertion is then based on providing sufficient excursion for the required function(s). Other factors, such as synergistic activity patterns and mechanical linkages, may be important in this decision as well. The appropriate length is determined by the length-tension characteristics. The arm and hand are placed in the posture at which maximal force is required, and the length of the motoring muscle is set at the length of peak active force. If the active characteristics are flat, approximately mid-range of the flat portion is used.

The technique of electrical stimulation of the muscle provides a measure of confidence of the function of the transfer. Following tendon transfer and suture, a low level of stimulation was delivered to the muscle to observe the movement of the joints. If appropriate movement was not obtained, then adjustments were made before final closure. This technique, combined with traditional passive ranging of the joints, provided a simple, effective method for evaluating the function of the transferred unit.

Postoperative changes in activity of transferred muscles. The objective of this project is to assess changes in the myoelectric activity of muscles which have undergone tendon transfer, in order to establish more rigid criteria for specification of muscles to be used in transfer.

Experiments are under way to test the hypothesis that muscles do not change their phasic activity following tendon transfer, but that individual control of the muscle can be achieved by conscious effort provided that antagonistic function is provided.

Three different tendon transfers are being studied in spinal cord injury patients. They are transfer of the posterior head of deltoid to provide elbow extension, and transfer of the brachioradialis and pronator teres to provide finger flexion or thumb opposition. These transfers are those most commonly performed in our center for restoring upper-extremity control in C-6 quadriplegic patients. Under static conditions, measurements are made of joint position, contractile strength (pinch or elbow extension), and myoelectric activity of the principal muscle under study and its synergists and anatagonists.

Through these studies, we expect to be able to determine (i) the ability of a muscle to assume a new function and the conditions required, (ii) at what point the new function appears, and (iii) whether or not the transfer functions in an automatic sense.

3.
Evaluation of Abnormal Motor Control

Principal Investigators:
Patrick E. Crago, Ph. D.
George H. Thompson, M.D.

This project is a study of the control of movement with the objectives of characterizing normal and abnormal mechanisms of motor control, and to use this characterization to develop improved methods of evaluation and diagnosis of movement disorders. Subjects are mostly cerebral palsy patients, and for comparison purposes, normals.

One of the most productive methods of evaluating motor function is to measure the mechanical and electromyographic (EMG) responses to externally applied loads. If torque loads are applied at a joint, the rotation magnitude and time course are determined by: (i) the mechanical properties of the muscle fibers that are active prior to the load change; (ii) the reflexively induced changes in muscle activation; and (iii) the voluntary changes in activation that the subject produces in reaction to the load. Other fixed parameters such as the initial torque and angle, and the disturbance magnitude and time course also affect the response.

A comprehensive study has begun of these dependencies both in patients with movement disorders and in normal subjects.

In order to obtain reproducible measures of motor function, it is imperative to control these parameters, and to know exactly how they influence the results. A comparative study can only be carried out when these factors are understood and controlled.

Work began this year on establishing a data base for responses to load change in the flexor pollicus longus muscle. This muscle was chosen because it is the only flexor acting across the interphalangeal joint of the thumb. The dependence of responses on the amplitude of a torque disturbance and the initial values of torque and angle are presently being studied. Torque, angle, and EMG are recorded as a function of time—before, during and after a torque disturbance.

The change in angle elicited by a step torque disturbance was also steplike, with the majority of change taking place before any reflex was detectable in the EMG response. Position and EMG became stable after approximately 250 msec.

For fixed values of initial torque and angle, the magnitude of the steady-state angular change increased more than proportionally with the torque disturbance. Thus, the incremental stiffness (defined as the amplitude of the disturbance divided by the change in angle) decreased as the amplitude of the disturbance increased. The greatest effects were seen with angular changes less than one degree.

Steady-state stiffness was measured as initial torque was varied with a constant amplitude disturbance. For torque less than approximately 15 N-Cm, stiffness was nearly proportional to initial torque. For larger torques, stiffness increased less than proportionally.

Major emphasis in the next year will be placed on expanding the data base for both normal subjects and patients with movement disorders.

4.
Command Controller Development and Evaluation

Principal Investigators:
Dennis D. Roscoe, Ph. D.
Michael W. Keith, M.D.

Work is proceeding on a multichannel command system which provides proportional control signals for functional electrical stimulation systems or powered prostheses. The system consists of two subsystems: an implantable electrode array in conjunction with a telemetry device, and a receiver myoprocessor unit. Designs are being reviewed for the telemetry device with consideration being given to a device completely RF powered and to one with a rechargeable battery source. The telemetry will consist of four channels of EMG signals with a bandwidth of 400 Hz per channel.

Electrode array configurations will be evaluated in an animal model (1) within the next several months. Basically, the

array will consist of stainless steel electrodes embedded in a thin Silastic sheet sutured to the control muscle. In quadriplegic patients, arrays will be placed over the upper and lower portions of the trapezius muscle, and in amputees, over the appropriate residual stump musculature.

A single-channel myoprocessor (2) has been implemented with a laboratory digital computer and its performance is presently being evaluated. A multichannel version is concurrently being developed. The real-time bandwidth of the single channel system is 660 Hz and 560 Hz for the projected four-channel system. Once the myoprocessor design is finalized, a microprocessor-based unit will be developed for outpatient usage.

A joint endeavor has been initiated with a leading wheelchair manufacturer to develop commercially our **two-axis proportional position transducer** described in previous reports (BPR 10-33 and 10-34). A universal controller scheme is being considered which engages the fundamental design of the position transducer into a hand, chin or shoulder controller. This scheme has the obvious advantage of providing patients with a variety of powered wheelchair controlling techniques to best suit their handicap, while simplifying the interface problem between controller and wheelchair electronics. A powered wheelchair will be modified to be used to evaluate the universal control scheme.

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5.

Sensory Substitution Using Electrocutaneous Stimulation

Principal Investigators:
Ronald R. Riso, Ph. D.
Michael W. Keith, M.D.

Studies are in progress to develop feedback devices which will provide patients having asensory hands (or prosthetic hands) with an awareness of the extent of their hand opening and the amount of prehensile force applied to a grasped object.

Electrical stimulation of the skin has been demonstrated by others to be an effective means for providing a variety of information to sensory-impaired individuals. An initial coding which is being evaluated is as follows: the spatial extent of hand opening is represented by the relative separation of two simultaneously activated electrodes from a linear array of 6 electrodes mounted along the skin of the upper arm on the same body side as the sensory-impaired limb or prosthesis. The amount of prehensile force developed is signaled to the patient by modulating the burst-repetition rate of the electrical stimuli of the activated electrodes.

Concentric surface mounted electrodes, and subdermal fine wire electrodes are being investigated. The former would be utilized when an externally worn hand prosthesis is employed. The latter are being studied to serve patients whose natural hands will be instrumented for sensory augmentation, with the long-range goal of developing totally implantable sensory feedback systems.

In order to evaluate objectively the performance of the sensory feedback coding scheme and electrode displays, computer generated tracking tasks, similar to those suggested by Szeto et al. (1979), are being utilized. Because these studies have only recently begun, no results are reportable at this time.

Reference

1. Szeto AY, Prior RE and Lyman J: Electrocutaneous tracking: a methodology for evaluating sensory feedback codes. IEEE Trans Biomed Eng, Vol. BME-26, No. 1, Jan. 1979.

6.

Control of Abnormal Muscle Contractions

Principal Investigators:
Ronald R. Riso, Ph. D.
John T. Makley, M.D.

The objective of these studies is to assess the effects of functional electrical stimulation (FES) of muscles on neuromuscular control. As a model, the effects of stimulation of the ankle dorsiflexors in hemiplegic or diplegic cerebral palsy children having either drop-foot or spastic ankle extensors are being studied. A few other children having these same motor disorders, but whose brain damage occurred in later childhood, are also being studied.

Clinical gait analysis, including foot-to-floor contact patterns, ankle joint goniometry and dynamic electromyography of the ankle flexor and extensor muscles is being employed to determine; (i) to what extent the dorsiflexion produced during the period of application of the FES continues after the stimulation is turned off and (ii) whether ankle extensor hyperactivity can be diminished by the periodic application of FES to the ankle flexor muscles. Evaluations for "carry-over" effects after short-term use of FES are performed immediately after the FES has been applied to the peroneal nerve for 20 minutes. Effects due to chronic treatment using FES are evaluated after 2 weeks use of the FES, and then at monthly intervals thereafter.

For all of the eight patients who have been tested several times for short-term-usage effects, the dorsiflexion and eversion of the foot concomitant to the electrical stimulation was not sustained with the stimulator turned off.

Seven patients have been evaluated after being given daily FES for at least 5 months to more than 1 year with the following results: (i) no consistent changes in the patient's gait performance could be demonstrated for five of these patients; (ii) a very favorable therapeutic effect has been unequivocally demonstrated for one hemiplegic child whose abnormal toe-first stance was converted to a normal heel-strike-first stance; (iii) for one diplegic child who previously walked exclusively on his toes, heel contact during walking could be observed after several months use of the FES.

Additional patients will be evaluated in the future to establish the incidence of therapeutic effects that may be expected to occur in a given population of patients.

The scope of the investigation will also be increased to include a different class of patients who walk with crouched gait due to excessive hamstring activity. For these patients, electrical stimulation will be applied to their quadriceps muscles as they pedal on an exercise (stationary) bicycle. Therapeutic effects which will be sought are increases in quadriceps strength and decreases in dysphasic hamstring hyperactivity. A bicycle is presently being instrumented for use in this new protocol.

Rehabilitation Engineering Center
2021 North Old Manor
Wichita, Kansas 67208

Cerebral Palsy Research Foundation of Kansas, Inc.
and
Wichita State University, College of Engineering

Co-Directors: Jack F. Jonas, Jr., John H. Leslie, Ph. D., and Roy H. Norris, Ph. D.

The Rehabilitation Engineering Center, Wichita, Kansas, was established on July 1, 1976, under the joint research auspices of the Cerebral Palsy Research Foundation of Kansas, Inc., and the College of Engineering, Wichita State University. The core area of research is the development of vocational opportunities for severely disabled persons through engineering.

The most frequently occurring functional description of disability is hemiplegia, the incapacity of one side of the body. Therefore, in an occupational setting a pervasive problem in designing modifications for a disabled worker group is the accommodation to hemiplegia. Any engineering solution to the problem of hemiplegia has the potential of applicability to a large number of similarly disabled workers.

Center Industries Corporation has two large numerically controlled lathes. Either may be operated using only one hand except for securing stock in the jaws of the lathe chuck. That operation requires the use of one hand to hold the material while the other hand actuates the control which opens or closes the chuck.

Center Industries had an employee who had use of only one hand. He had performed a variety of tasks competently. It was felt that if the part of the lathe operation which required two hands were modified, the hemiplegic employee might be able to perform the operation. A bracket was suspended above the worker's head. A round padded surface was placed at either side connected to a switching apparatus. The operator could cause the chuck jaws to open by moving his head to the left and cause them to close by moving the head to the right (Fig. 1). The switches on the adaptation were wired in parallel with those on the machine itself so that, with the bracket swung back out of the way, the lathe could be operated in the usual manner. A second lathe was similarly modified; the interface with the chuck controls was carried out somewhat differently as its controls were pneumatic rather than electrical.

The hemiplegic worker performs a variety of operations on the lathe at rates similar to those of his nondisabled fellow employee. It is anticipated that this format of actuation modification can be applied to a variety of machines to accommodate a similarly incapacitated worker.

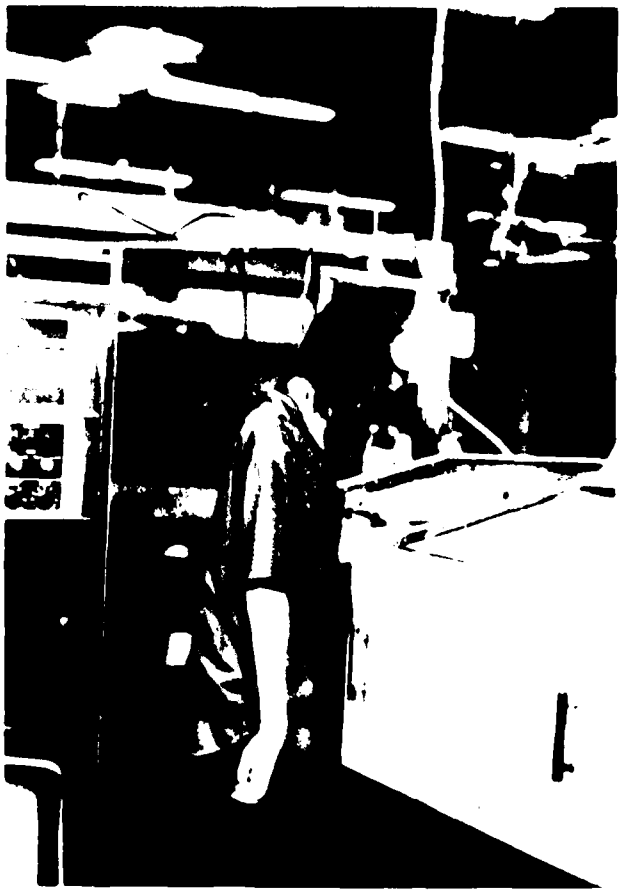

FIGURE 1.
Adaptation for lathe puts duplicate chuck-jaw switch control within reach of hemiplegic worker's head, allowing the worker to deal successfully with a "two-handed" portion of the job.

Rehabilitation Engineering Center
University of Michigan
Department of Mechanical Engineering
W.E. Lay Automotive Laboratory
Ann Arbor, Michigan 48109

J. Raymond Pearson, M. Sc. M.E., Director

Design and Development of Vehicle Adaptive Devices and Systems

Task Leaders:
Robert C. Juvinall,
Mohamed Y. Zarrugh,
David H. Harden

The concept of a prototype wheelchair that uses a General Motors X-body (2-door sedan) was presented in the Bulletin of Prosthetics Research, Fall 1980 (BPR 10-34, p. 182) and the construction of a prototype of that system is nearing completion. The basic criteria for a satisfactory wheelchair-modified car combination were outlined in BPR 10-33 (Spring 1980, p. 138). The feasibility and cost advantage of such a system over the van system have been clearly demonstrated.

The "door-mounted chair" system developed by the University of Michigan Rehabilitation Engineering Center provides access for a specially built wheelchair through the door on the driver's side of an Oldsmobile Omega. The "door-mounted" entry concept is quite simple; the wheelchair acts as its own transfer device, and additional lifting equipment is unnecessary. The chair is driven onto a special bracket that is mounted on the open door. With the seat supported by the door, the seat height adjustment mechanism raises the undercarriage of the wheelchair. This action reduces the overall height of the wheelchair and its occupant so that they will fit through the door opening.

A compact wheelchair with adjustable seat height (Fig. 1) was specifically designed with an automobile door opening in mind. When the seat is in its lowest position, the bottom of the sling seat is almost at ground level; this allows for maximum head clearance at the door opening. The overall length of the chair is restricted by the width of the door opening.

The chair consists of four major sections: (i) seat, (ii) chassis including a cross member and seat guides, (iii) wheel-suspension assembly and (iv) footrest. A ball screw actuator moves the seat along two 5/8-inch vertical guides via four linear ball bearings. The seat frame is made of 3/4-inch (outside diameter) round tubing over which the sling seat and the backrest are stretched in a manner similar to that of a standard wheelchair. A backing plate (Fig. 2) behind the backrest provides a means of mounting the linear ball bearings and transferring seat loads to the screw.

The two rods for the seat guides are supported at their base by the cross member. Two bars extend from the top of the guide rods and attach to the frame behind the guide rods (Fig. 2). These bars reduce the deflection of the top end of the guide rods (Fig. 2).

The cross members and attachments (i.e., chassis) are connected to two leaf springs. The cross member is shaped in such a way that the seat is lowered almost to ground level between the leaf spring and in front of the cross member. (With the leaf springs, the ride is very soft. An experimental structure that is more rigid will be installed to produce a firmer ride.)

The armrests enclose the springs when the seat is in its lowermost position (Fig. 3). The left armrest also serves as a bracket to attach the chair to the support frame inside the door cavity (Fig. 4).

Two caster wheels are fastened to the front end of the springs. The two 8-inch driving wheels with their drive units (Everest and Jennings 3N motor drive) are mounted at the back ends of the springs (Fig. 2).

The adjustable footrest is supported by an A-shaped 3/4-inch round tubing frame pinned to the front of the seat section. The position of the footrest is adjustable by a cable pulled by a screw placed inside the seat-frame tubing at the armrest. The screw is rotated by a chain drive from a motor mounted on the backing plate.

The nature of the loads the chair applies to the car door during lifting necessitated stiffening the door and strengthening the hinges (Fig. 4). This was accomplished by replacing the hinges and by providing a separate frame within the door cavity to support the chair. That frame is bolted directly to the hinges and bypasses the door shell itself. Deflections occurring in the door frame will have little effect on the door; misalignment between the door and the car (i.e., door opening) is minimal. A ball screw actuator opens and

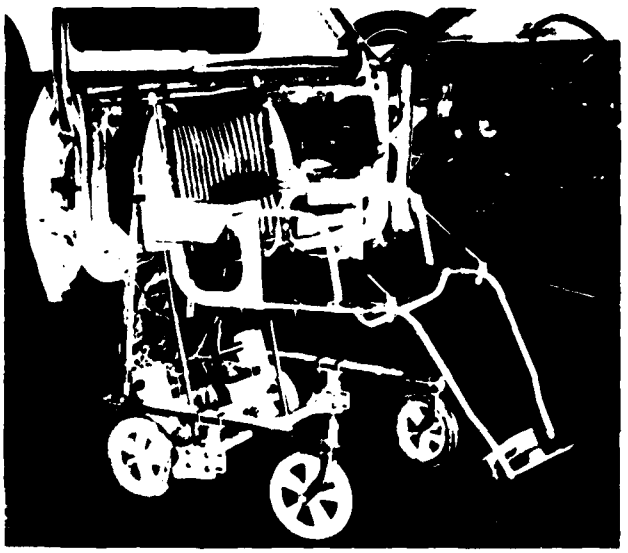

FIGURE 1. Wheelchair with seat fully raised.

closes the door under the remote control of the driver. One end of the actuator is bolted to the dash; the other is bolted to the door above the chair support frame. The operation of the actuator is augmented by a latching device during the last few degrees of door closing, so that a force large enough to compress the door seals and latch the door is exerted.

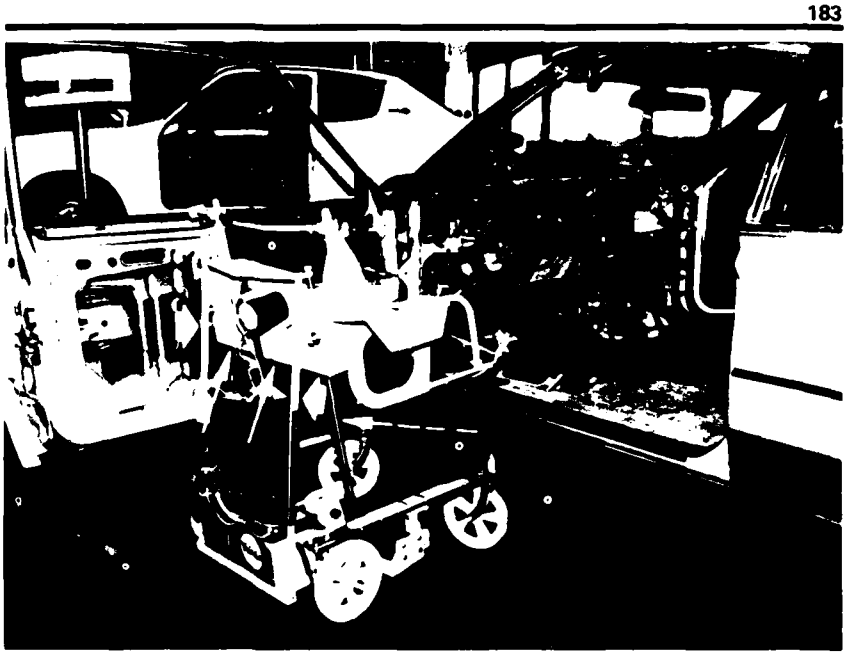

FIGURE 2.
Caster wheels are fastened to the front end of the springs and the driving wheels are mounted at the back end of the springs. Thin arrow indicates backing plate. Each broad solid arrow points to one of the support bars. Broken arrow identifies guide rod.

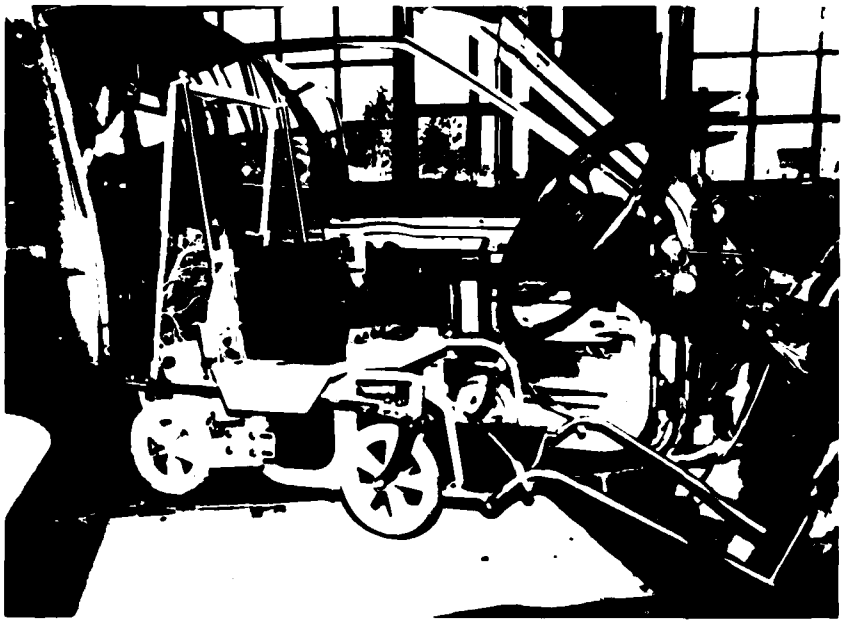

FIGURE 3.
Wheelchair is brought into driving position inside the vehicle. Note how the armrest encloses the leaf spring.

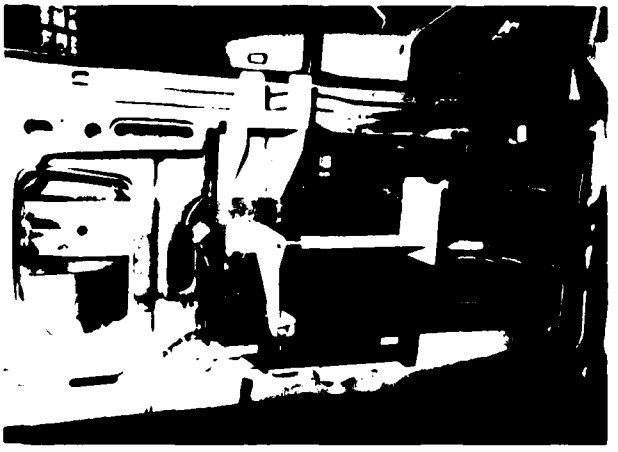

FIGURE 4.
Support frame inside the door transfers chair loads directly to door hinges bypassing the door shell itself.

DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES, PHYSIOLOGY AND BIOMEDICAL ENGINEERING PROGRAM*

Americo Rivera, Ph. D., Program Administrator

Bone-Implant Interface Analysis

Regular Grant: 7 RO1 GM 29785
Cleveland Research Institute
Cleveland, OH 44115

A. Seth Greenwald, D. Phil. (Oxon), Principal Investigator

This project seeks to evaluate the use of microporous coated implant materials which allow bone tissue ingrowth into the pores to anchor the device, as an alternative to bone cement. Previous long-term animal studies have demonstrated sufficient fixation capability of the microporous system. Studies are to be performed to demonstrate the stabilizing ability of low and high modulus microporous systems, in weightbearing and non-weightbearing animal environments, over short-time periods (0,1,2,3 and 4 weeks). Early implant stabilization which allows early mobility would be of immense clinical importance. The group will also study in vitro bone cell cultures to elucidate the initial cellular responses to the microporous materials.

Structural and Mechanical Properties of the Spine

Regular Grant: 5 R01 GM 20201
Wayne State University
Detroit, MI 48202

Albert I. King, Ph. D., Principal Investigator

The aim of this research project is to extend the finite-element model of a vertebra to that of a vertebral segment. To this end, it is proposed to continue the measurements of end-plate and intradiscal pressure at various locations of the vertebral segment. It is also proposed to document the mechanical properties of vertebral cortical and spongy bone. These data are to be incorporated in the finite-element model of the vertebral segment and used to simulate those conditions which would fracture the vertebra or portions thereof.

Development of a Microporous Tracheal Prosthesis

Regular Grant: 2 R01 GM 24300
University of California Los Angeles Medical Center
Torrance, CA 90509

Ronald J. Nelson, M.D., Principal Investigator

The objective of this project is the development of a microporous tracheal prosthesis that will be permanently bioincorporated by the host and lined with epithelium. The prosthesis is fabricated from the negative replication of the naturally occurring microporous exoskeletons of coral and sea urchins in biomedical polymers. The project is divided into three interrelating phases which will be addressed simultaneously by the group: (i) the biology of ingrowth of tissue cells into a matrix will be studied by implanting porous test cylinders in experimental animals; (ii) the influence of primary variables (polymer and pore characteristics) and secondary variables (site of implantation, biodegradable porous phase filler, antibiotic dispersion in polymer, and "wrapping") on ingrowth of tissue will be evaluated quantitatively and qualitatively in dogs and rabbits; (iii) favorable combinations of variables will be tested in 3-cm prostheses implanted in the thoracic tracheae of dogs for 1 to 2 months. The healing processes will be followed by bronchoscopic and biopsy examinations.

Finally, those designs which show excellent healing in 1 to 2 months will undergo long-term evaluation in 8-cm lengths.

Biomedical Engineering Center for Polymeric Implants

Program Project Grant: 2 P01 GM 24487
University of Utah
Salt Lake City, UT 84112

Donald J. Lyman, Ph. D., Program Director

The objectives of this program project are the acquisition of a basic understanding of events occurring at the interface between polymers and living systems. To this end, the group develops and synthesizes new or modified polymers for specific implant applications. The core facility provides for in-depth basic and applied studies of the polymers in relation to their use as implant materials. Bulk and surface chemical and physical properties and morphology are studied, to determine how these are affected by fabrication variables. Polymer-protein and polymer-biological molecule surface interactions and polymer degradation in vivo and in vitro are to be studied. Small-diameter vascular prostheses and nerve prostheses are being prepared and studied. These prosthetic devices have been implanted and their outcomes have been correlated with the bulk and surface, physical and chemical properties of the polymers. Ureter, bladder, bile duct, and esophageal repair prosthetic devices have been studied.

The Traumatology of the Head and Spine

Regular Grant: 5 R01 GM 26608
University of Iowa
Iowa City, IA 52242

Y. King Liu, Ph. D., Principal Investigator

The objective of this project is the construction of a structural finite-element computer model of the head and neck of the rhesus monkey during direct head impact, based on the in vivo constituent and gross mechanical response data. The experimentally measured pressure and acceleration will serve to

*Leo H. von Euler, M.D., is the Acting Director. W. Sue Badman, Ph. D., is the Chief, Biomedical Engineering and Instrument Development Section. NIGMS is located at Bethesda, Maryland 20205.

validate this class of computer models for simulation purposes. The dynamic in vitro material properties and failure characteristics of the spine will be measured, with special emphasis on the cervical region. These studies will provide information for the validation of a human head and spine model to be used to investigate, through computer simulations, the prevention of head and spine injuries.

Porous Polyethylene—Tissue Tracheal Prosthesis

Regular Grant: 5 R01 GM 26963
University of Mississippi Medical Center
Jackson, MS 39216

Barry W. Sauer, D.V.M., Principal Investigator

The objective of this research is evaluation of three different types of composite tracheobronchial prostheses developed by the principal investigator. The prostheses will be used to reconstruct 5-cm-long circumferential defects in the cervical region of the canine trachea. The clinical performance of the prostheses will be determined by physical, radiographic and bronchoscopic examinations. These devices and bronchial sections will be removed after 6, 12 and 24 months and subjected to gross and microscopic examination. Postmortem examination of all animals will be performed. The results of all examinations will be correlated with the clinical studies, and comparisons of performance will be made among the three types of devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, NIH, MUSCULOSKELETAL DISEASES PROGRAM[a]

Stephen L. Gordon, Ph. D., Program Director

BONE HEALING

Study of Internal Fixation Devices for Fracture Healing

University Hospital of San Diego
La Jolla, California 92103

Wayne H. Akeson, M.D., Principal Investigator

The objective of this research is to determine whether significant advantages can be achieved in internal fixation plates of diaphyseal fractures through the use of internal fixation devices of improved design.

One hypothesis being tested is that internal fixation of plates of reduced axial stiffness are superior with respect to the late complication of stress-protection-induced decrease in bone density (osteopenia) usually observed with traditional management. Advantages exist with respect to biomechanical properties of canine radii and femora internally fixed with plates that have large reduction in bending and axial stiffness. These results are confirmed by quantitative histological and biochemical measurements.

Early versus late plate removal is a controversial question. The second objective of this project is to study the effects of plate stiffness on the ability of fracture repair to withstand physiological loads. The hypothesis being tested is that early plate removal will prevent stress bypass osteopenia and facilitate more normal bone remodeling.

Techniques used in this study include periodic X-rays to evaluate fracture healing in the plated canine femoral midshaft osteotomies. Nondestructive and destructive bioengineering tests, quantitative histological measurements using UV light microscopy to evaluate tetracycline labeling and microradiography and biochemical analysis of the organic and inorganic matrix of bone are being used to evaluate the influence of the different internal fixation devices employed.

Study of Bioelectrical Phenomena Controlling Bone Growth

Columbia University College of Physicians and Surgeons
New York, New York 10032

C. Andrew L. Bassett, M.D., Sc. D.

This project addresses several problems in which an expanded base of applied experiments serves to improve the scope of clinical usefulness of pulsing electromagnetic fields (PEMF's).

PEMF's are currently in use for ununited fractures and fusions. Time required by treatment and degree of disability can be reduced by increasing pulse effectiveness to speed mineralization of gap tissues and to augment the osteogenic phase of repair. In this study, effects of PEMF's on improving bone graft incorporation and fresh fracture healing are assessed. Return of mechanical stability in the nonunion, grafting, and fracture studies is monitored by a new, nondestructive, noninvasive sonic frequency testing method. These results are then correlated with mechanical testing and strain gage data to determine the ability of this new frequency analysis (via Fourier transformations) to predict the quality (strength) of bone repair.

PEMF effects in reducing stress-relief osteoporosis in plated dog radii also are being studied, along with their ability to affect longitudinal growth rates in epiphyses and apophyses. Furthermore, this phase of the project is focussing on the potential of induced pulsing currents to alter growth patterns in the immature spine and, thereby, to correct experimental scoliosis. Finally, one mechanism of PEMF action is being studied by following PEMF-induced changes in the calcium content of chondrocytes by isotype, transmission electron microscopy, and ion probe techniques.

[a]A program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Westwood Building, Room 407, Bethesda, Maryland 20205.

Study of Acceleration of Fracture Healing by Electrical Fields

University of Pennsylvania
Medical Education Building
Philadelphia, Pennsylvania 19104

Carl T. Brighton, M.D., Ph. D.

The object of this research is to continue investigating the effects of applied electrical fields on the acceleration of fracture healing in laboratory animals.

This project is designed to determine (i) the optimum parameters of applied (exogenous) electricity for accelerating fracture healing, (ii) the role of stress-generated (endogenous) electricity in fracture healing, and (iii) the mechanism of electrically induced osteogenesis at the cell level.

Methods used include the comparison of the osteogenic response of in vitro fetal rat tibia and in vivo healing rabbit fibula to constant direct current, to various pulsed unidirectional electric fields, and to various electromagnetic fields. Osteogenesis and bone healing are evaluated by incorporation of tritiated thymidine, Ca^{45}, and $^{35}SO_4$, as well as by maximum resistance to bending as determined by an Instron Testing Machine. The mechanism of action of electrically induced osteogenesis is sought by determining (i) pO_2 and pH changes in the vicinity of a cathode, (ii) changes in surface charge of cell membrane, (iii) mitochondrial release of calcium, (iv) cellular proliferation and migration, and (v) collagen and proteoglycan biosynthesis and processing.

Study of Electrical Augmentation of Bone Formation and Ingrowth

Battelle Memorial Institute
Columbus Laboratories
Columbus, Ohio 43201

Craig R. Hassler, Ph. D.

The purpose of this research project is to continue the study of the basic phenomena of electrically augmented bone healing.

Previously, this study has shown that within reasonable limits of power dissipation, or current density, waveform or frequency seem to have little effect upon optimization of the augmentation phenomena. Experiments with anodized tantalum electrodes have shown that oxidation-reduction reactions occurring at the electrode surface are of little importance to the augmenting phenomena. The augmentation process seems to be effective throughout the healing period: no triggering phenomenon is observed.

Several areas require further research for understanding and correct utilization. The variables responsible for best stimulating bone growth are not known. The variability between animals is not understood: Why is it more effective in certain animals? The biochemical alterations which occur in vivo need to be understood and investigated in the in vivo situation. The comparison between electrode stimulation and electromagnetic coils needs to be performed within the same animal model so that a direct comparison between the two methods can be made. Further development of the promising phenomena of stimulating ingrowth into porous titanium and ceramic substrates needs to be continued.

This study employs a standard protocol and a previously developed animal model (the rabbit). Coils are produced and positioned to externally stimulate the same osteotomy system used for implanted electodes. Biochemical analysis involving hydroxyproline, proline cyclic AMP, cyclic GMP, and calcium levels is being continued. Electrochemistry of porous titanium surfaces is being assessed. The investigator is developing a mathematical model to assist in explaining the behavior of bone ingrowth into pores during electrical stimulation.

Study of Investigations of Electrically Induced Osteogenesis

Battelle Memorial Institute
Columbus Laboratories
Columbus, Ohio 43201

Craig R. Hassler, Ph. D.

The purpose of this project is to test the hypothesis that electrically enhanced osteogenesis is the result of changes in ion fluxes, alterations in membrane lateral diffusion rates, or changes in cell potential acting at the cellular membrane.

The two modes of electrostimulation being studied are the use of internal direct-current electrodes and the application of external electric fields. During these modes, variations in ion flux, cell potential, and rates of membrane protein lateral diffusion can be determined. This investigator is studying the effects of these changes on the membrane-bound enzyme adenylate cyclase, an enzyme whose activity responds to electrical stimulation.

The project uses an in vitro cell model consisting of clonal cell lines with osteoblast-like activity derived from a rat osteogenic sarcoma. Direct measurements of physiologically important ion efflux and influx are made during stimulation. In addition, cell potential is determined with fluorescent cation cyanin dyes. Modulation of adenylate cyclase activity during electric stimulation or without stimulation is studied using a combination of ionophores, ions, and drugs to change cell potential and ion fluxes.

The information derived from this program will be used for a scientific comparison between the two modalities used clinically for enhancement of osteogenesis. In addition, information gained concerning the mechanism of electrically induced osteogenesis may be used eventually for improvement of the presently used clinical modalities or development of new methodologies for enhancement of osteogenesis and bone repair.

A New Method to Measure the Rate of Fracture Healing

Louisiana State University
Department of Orthopedics
Shreveport, Louisiana 71130

Subrata Saha, Ph. D.

Radiographic examination is often inadequate for an exact evaluation of the state of union of a healing fracture and to detect early stages of osteoporosis. Therefore, there is a definite need for additional noninvasive means to measure the rate of fracture healing and to determine the mechanical integrity of bone in vivo. Ultrasonic and vibration tests have been attempted before as diagnostic tools to determine the degree of union of healing fractures. However, effects related to the soft tissue make such tests less reliable and therefore clinically less useful.

A noncontacting electromagnetic device has been developed which can detect the propagation of stress waves in a bone (produced by a piezoelectric

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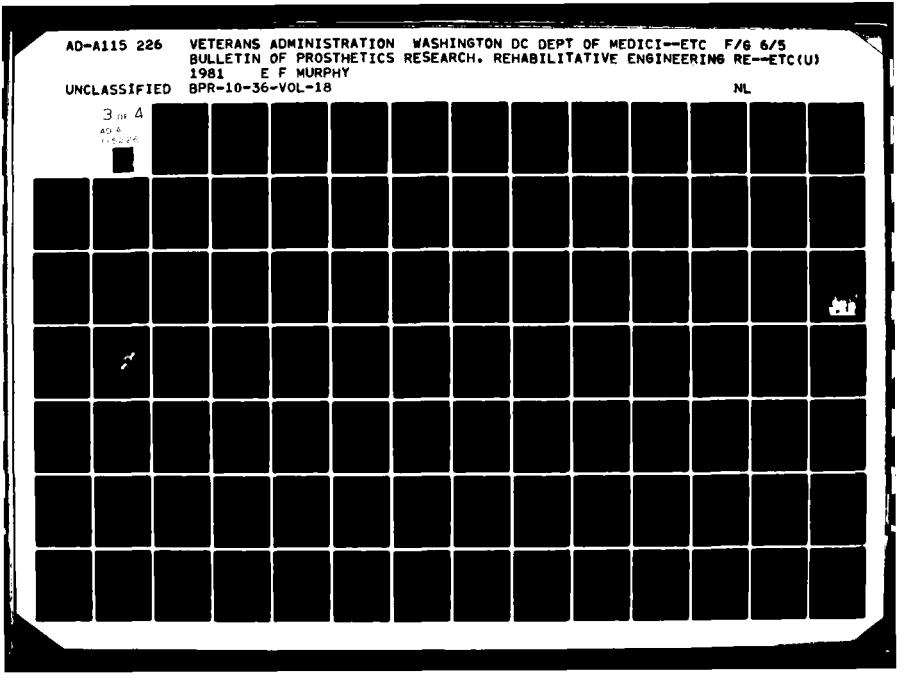

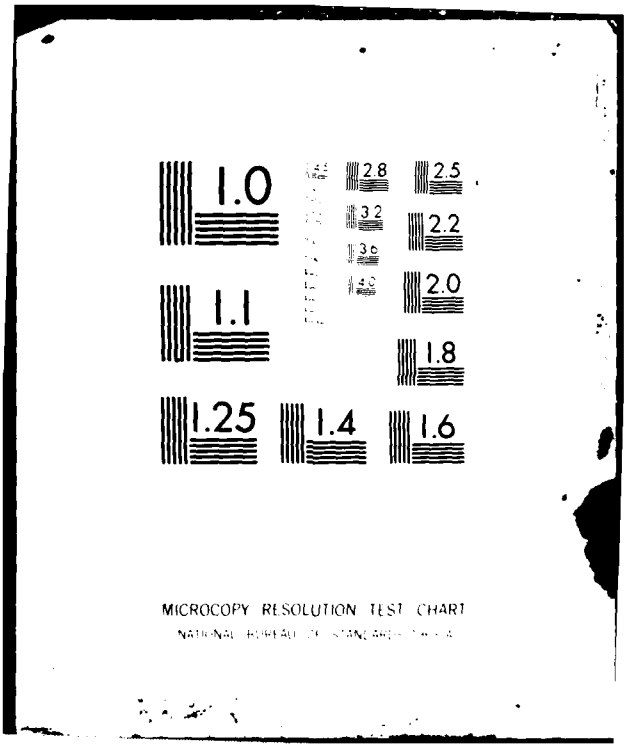
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MICROCOPY RESOLUTION TEST CHART

transducer or by a small impact) in a manner independent of the mechanical properties of the soft tissue. This device monitors the magnetic field produced by the piezoelectric charge associated with a stress wave propagating along a long bone. The stress waves in bone have also been monitored with the use of a vibrating traction pin placed in a magnetic field. Both of these methods have been used to record stress waves proximal and distal to the site of a partial fracture in excised human long bones. The study has found that transmission coefficients of the wave, the degree of simulated fracture healing, and microstructural variables such as porosity of the bone are correlated to a significant degree.

This investigator is conducting fracture healing experiments on dogs so that characteristics of the transmitted wave pulse can be calibrated to indicate the state of healing as evaluated by clinical observation, histological and X-ray examination, and mechanical testing. The sensitivity of the electromagnetic detector is also being improved so that it can be used easily to monitor the rate of fracture healing in patients. It is expected that development of such a method will result in improved health care of patients with fractured bones or other bone lesions. Such a method would also make it possible to detect osteoporosis at an early stage.

ARTIFICIAL JOINTS

Intermediate Organometallic Corrosion Products

University of Pennsylvania
Philadelphia, Pennsylvania 19174
Johnathan Black, Ph. D.

Metallic implants are used in large numbers in the practice of orthopedic surgery. All metals in use have finite corrosion rates. Possibly associated with release of metal by corrosion or other reactions, there have been a variety of clinical problems involving metabolic, immunologic, bacteriologic and carcinogenic responses. Research to elucidate the possible connections has been hampered by a lack of knowledge of the molecular form that the corrosion products take and the concentrations in which they are present in patients. In particular, it has been proposed that a variety of biologically active organometallic intermediate compounds exist as a result of corrosion in vivo.

The object of this research project is to detect, isolate, quantitate, and partially identify the bloodborne organometallic compounds that arise from the corrosion of the two most common orthopedic metallic alloy systems: stainless steel and cobalt-chromium.

These studies involve column fractionation of serum and treated tissue fragments, followed by atomic absorption spectroscopy. The studies have two important elements:

1. The use of a small animal/microsphere implant model to examine the effects of implant area/animal body weight ratio on the production of organometallic complexes and to predict the possible findings in patients.

2. The use of several longitudinal studies in patient populations to determine changes in blood levels of metallic and organometallic substances as sequelae to various orthopedic implant procedures.

Contact Stress Distributions in the Hip and Knee

University of Pittsburgh
Pittsburgh, Pennsylvania 15261
Thomas D. Brown, Ph. D.

This study addresses the direct measurement of the contact stress distributions characteristic of the normal hip and knee. Since this important problem has not lent itself to conventional measurement techniques, only indirect estimates and simplified models are currently available.

Pilot work in this laboratory has shown that highly compliant miniature transducers incorporating piezoresistive elastomers are well suited for articular contact stress measurements. The signals from arrays of 20 such transducers, mounted in the articular cartilage of fresh autopsy specimens (40 hips and 40 knees), are processed by a computer and assembled into contour maps of the contact stress distributions. Cyclic (1 Hertz) loading of the joints to physiological levels is performed in an Instron unit.

The immediate results promise to be of significance in the areas of cartilage pathomechanics, prosthetic joint resurfacing, and stress analysis; the transducers themselves are potentially applicable to a wide range of current biomechanical measurement problems.

Total Surgical Replacement of the Human Hip Joint

Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois 60612
Jorge O. Galante, M.D.

This project is designed to study the fixation of prosthetic devices with porous materials and the wear characteristics of artificial joints.

The ability of a fiber metal composite to obtain bone ingrowth is being studied as it relates to: manufacture of the composite using titanium and cobalt chrome alloy; the long term biocompatibility and the problem of accumulation of metallic elements around the site of fixation and in distant organs; the possible carcinogenic effects of this material; and the application of this material to a model of total hip joint replacement, surface replacement and total knee replacement in experimental animals. Wear studies are being performed to investigate the characteristics and reliability of a wear-resistant titanium surface and the possibility of inducing changes and improvements in the wear characteristics of ultrahigh molecular weight (UHMW) polyethylene as a function of changes in its structure and physical properties.

A Study of Friction and Wear of Prosthetic Bearing Materials

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Keith L. Markolf, Ph. D.

A reliable method for laboratory testing of candidate materials for use in total joint replacement is essential to prevent the type of disasters that have occurred in the past when unproven materials have been introduced into patients.

The multichannel screening device and test protocol developed in the first two years of this project have been used to evaluate a variety of candidate materials with greater accuracy and reliability than has been previously possible. The test method used to date has involved adhesive-abrasive testing of materials in a flat-on-flat configuration, an analog of conforming-type total joints. A main objective of the project at this point is to expand the wear model to include round-on-flat testing as an an-

alog for certain low-conformity joints. Both wear models then will be employed to evaluate high priority candidate materials under conditions that accurately simulate the intended in vivo application.

Evaluation includes testing of new high-strength metal alloys (titanium 6-4, FHS cobalt chrome, Endocast cobalt chrome), ceramics (Alumina, Sialon, Macor) and polymeric materials (compression-molded ultrahigh molecular weight (UHMW) polyethylene, Poly II carbon fiber reinforced polyethylene and Delrin 150 polyacetal), with in-depth correlation of wear properties to critical test parameters. Emphasis is also being given to collaboration with other wear study groups in defining standard wear test criteria (ASTM, BSI, ISO).

Study of Wear Particle Analysis in Human Artificial Joints

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Dana C. Mears, Ph. D.

As diarthrodial joints wear, they produce particles of wear. In this project the technique of ferrography has been adapted to the study of these wear particles, aiming to improve the early diagnosis of different arthritides and to provide a noninvasive, objective means for assessment and prognostication of natural joints and prosthetic joint replacements. Another goal of this project is to identify the wear modes operating in diarthrodial joints, and to contribute to the better understanding of joint rheology and tribology. To this end, the investigators are performing ferrographic analyses of saline joint washings provided by arthroscopic examinations of the knee. They are then comparing and integrating the ferrographic data with detailed medical histories of the patients.

The cellular responses to wear particles are being studied with cell cultures in vitro and with entire animals, thereby affording an insight into their role in the pathophysiology of arthritis. Particles are added to cultures of macrophages and synovial cells, and the conditioned medium assayed for extracellular proteases which degrade cartilage and for catabolic activity. Particles are then chemically and physically fractionated to determine which of their physical properties and chemical components contribute to which of the overall cellular responses. Particles, or certain of their components, are injected intra-articularly into rabbits. The animals are subsequently examined for possible arthritis changes, using radiographic, histological, cellular and biochemical criteria. Comparison of the data obtained from cells in culture with the results from animal studies permits assessment of the physiological relevance of the effects observed with the in vitro system.

The Significance of Allergy to Orthopedic Implants

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Katherine Merritt, Ph. D.

The aims of this interdisciplinary research program are to develop a better understanding of three aspects of allergic reactions to metallic orthopedic implants, and to demonstrate the effectiveness of an in vitro macrophage-inhibiting factor (MIF) test for patient screening and diagnosis of metal allergy. The three aspects being examined are: the influence of preexisting allergy on the outcome of the implantation, the consequence and prevalence of the development of allergy after implantation, and the importance of the metallurgical properties of implants on the development of allergic reactions.

A prospective study is being conducted to determine which patients are allergic to metals prior to insertion of a metallic implant, which acquire an allergy after implant surgery, and what effect the allergy has on the results of the surgery.

Patients admitted for metallic implant removal are also being studied to ascertain if there is a correlation between metal allergy and morbidity. An in vitro test for the production of leucocyte migration inhibition factor in response to metal salts is used to detect the allergic condition. The reliability of the MIF test is being determined in a study of patients with diagnosed metal contact dermatitis, and correlated with the results of a blast cell transformation test. The implants removed are examined for gross evidence of abrasion and corrosion and then for microporosity, casting voids, inclusions, and reactive grain boundaries, using standard metallographic methods. The results of the implant analysis are then compared to the results of the allergy test, to determine if the nature of the implant is an important feature in the development of allergy and of complications in these patients.

An animal study is also being conducted to more clearly define the time of development of metal allergy and its effect on the implant site. Rabbits receive stainless steel finger screws in the proximal humerus. One group serves as control, a second group is made allergic to nickel by injection prior to insertion of the screws, and the third group is made allergic by injection after the insertion of the screws.

Mechanical Evaluation of Total Knee Arthroplasty

Mayo Foundation
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Richard B. Stauffer, M.D.

This is a continuation of a biomechanical evaluation study of patients with disabling knee joint disease before and after total knee arthroplasty. The objectives of this phase of the study are: (i) to complete the number of patients previously proposed, and (ii) to perform objective analysis of the completed patient data to answer a series of specific clinical and biomechanical questions.

Previously 128 preoperative patients were studied, 41 of whom have returned for 1-year postoperative evaluations. Altogether, evaluation of 250 patients is being completed for different study periods because: (i) there has been a drastic change in the types of prostheses used in the last 2 years and the number of each type of prosthesis in the study must be kept at a significant level, and (ii) the clinical results have shown that the functional status of patients with total knee replacement is not stabilized at one year, so that followup study beyond that period must be conducted.

The project employs the goniometric method with computerized data collection and reduction capabilities. Based on a discriminative analysis technique, the eight most significant gait parameters have been used to establish a per-

formance index to grade the gait quality of total knee patients.

Two additional methods based on waveform analysis and phase relationship are being applied to differentiate refined gait variations. These results are presented on a graphic terminal, for visual inspection before hard copy is made as a permanent record. A gait evaluation summary has been developed to report to the surgeons the functional status of their patients.

PMMA-Precoated Intramedullary Implants

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This is a feasibility study of intramedullary implants precoated with an acrylic bone cement. The femoral component of a hip prosthesis is precoated with polymethylmethacrylate (PMMA) and cured. Using the canine animal model, the prosthesis is implanted using the same PMMA and tested for 6, 12, and 24 months. The entire femur with implant is then removed and subjected to mechanical and morphological studies of the implant-bone interface.

This precoating method reduces the amount of PMMA used during the actual implanation procedure, and thus reduces some problems inherent to the use of PMMA, including increased temperature during polymerization which has adverse effects on tissues. The method also improves the transmission of load from implant to bone, improves intramedullary centering of the prosthesis, and increases interfacial shear strength over that of the same prosthesis implanted with conventional methods. The new method does not seem to induce any new risks, as no new materials are introduced into the body and no changes of the actual implantation procedure are proposed.

LOCOMOTION

Joint Contracture: Biomechanical-Chemical Correlates

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Wayne H. Akeson, M.D.

This project is a continuation of a study directed toward the elucidation of the joint contracture process in biochemical, bioengineering, and morphologic terms, and toward the development of therapeutic programs to minimize contracture formation.

Major changes in the composition of fibrous connective tissue have been demonstrated in experimental joint contractures as a result of immobilization. These changes were uniformly observed in ligaments, tendons, fascia, and capsular tissue of the knee joint. Significant correlations were shown between measures of strength of contracture and reduction in content of total hexosamine, water, and hyaluronic acid in the connective tissue matrix.

A working hypothesis has been constructed to explain these observations: that the loss of water and glycosaminoglycans in the periarticular connective tissue of immobilized joints contributes to changes in the physical characteristics of the affected joints. Presumably, this role is a permissive one, allowing a closer proximity of critical intercept points in the immobilized fibrous connective tissue mass which allows cross-links through one of two mechanisms: (i) random disposition of newly synthesized collagen or (ii) covalent cross-links between preexisting fibers. Significant increases of dihydroxlysinenorleucine (DHLNL), hydroxlysinenorleucine (HLNL), and histodinohydroxymerodesmosine (HHMD) in immobilized connective tissue have been demonstrated. Under this formulation, the fixed posture at the intercept points translates into restriction of motion in the joint composite.

In this next phase of the project, collagen turnover studies are being conducted using the Klein proline prelabeling technique to determine mass differences of new and old collagen in immobilized joints. This information is required to interpret the cross-link changes, as increases in reducible cross-links may simply reflect increased collagen synthesis.

The investigator is doing pilot projects to search for myofibroblasts in joint contracture tissue and to determine ratios of Type II to Type III collagen.

Therapeutic agents which hold promise in the prevention of contracture include penicillamine, estradiol, hydrocortisone, indomethacin (an inhibitor of prostaglandin) $CaNa_2$ EDTA. A pilot screening program is evaluating potential drug and hormone applicants for this purpose with in-depth evaluation of the most effective agents. It is possible to reduce the strength of contracture by penicillamine and by estradiol in pharmacological doses.

New Hip Prosthesis and Fixation Modes (In Vivo Study)

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Harlan C. Amstutz, M.D.

This project is designed to evaluate the feasibility of long term fixation of prosthetic joint components by means of bone ingrowth into porous surfaces without the use of acrylic bone cement. Three porous metal systems are being evaluated: sintered cobalt chromium beads, sintered titanium 6-4 beads, and sintered titanium 6-4 wire mesh (alloy of 90% titanium, 6% aluminum, 4% vanadium).

A canine hip surface replacement is used which was developed during the first 2 years of an ongoing 3-year project. Highly successful surgical procedures and histological techniques were developed and were used to evaluate numerous prosthetic fixation modes in 60 animals. With cement prostheses, cellular membranes invariably formed at the acrylic bone interface, a phenomenon associated with progressive loosening of the components. In contrast, the porous systems showed good bone ingrowth with no membrane formation in up to 6 months followup. The problems that were encountered were primarily related to the overall design of the components.

The investigator is now evaluating optimized design of both the femoral and acetabular components of the joint with the three porous metal systems in the canine model, with followups ranging from 1 month to 2 years. Analysis

includes combined techniques of microradiography, fluorochrome labeling, electron and light microscopy and specially developed histological procedures.

Loosening of cemented prosthetic joint components is currently the major cause of clinical failure. If the short-term promise shown by porous ingrowth fixation is fulfilled in this long-term project, application of these techniques to humans would be justified—to alleviate the rapidly growing number of clinical failures experienced with cemented joint replacements.

Static Force and Stability Analysis of Human Elbow

Mayo Foundation
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Kai-Nan An, Ph. D.

The objectives of this research project are to demonstrate a new technique in order to solve the indeterminate problem of static joint force analysis and to apply this technique to the study of the forces about the elbow joint, one of the most neglected joints in biomechanics research.

The components of the analysis consist of: (i) examining the electromyographic (EMG) activities and calculating the tensions of all the elbow muscles during various elbow functions; (ii) determining the forces on various articular surfaces of the elbow joint; and (iii) assessing the function of various ligamentous restraints in the elbow joint.

The methods of analyses include: (i) obtaining detailed three-dimensional information on the functional anatomy of all the elbow muscles and ligaments through cross-sectional dissection and biplanar X-ray investigations; (ii) developing three-dimensional mathematical models of the elbow for the calculation of muscle forces, joint contact, and ligamentous forces during elbow functions; (iii) performing in vitro ligamentous function tests by examining the load through the joint under sequential cuts of surrounding ligaments; and (iv) verifying the theoretical results by quantitative EMG analysis.

The results of this study are providing detailed three-dimensional force distribution data which have, up to now, been unavailable. These date have both far-reaching and immediate application to such pressing clinical problems as how the total elbow arthroplasty can be improved to decrease loosening, and what is required of the design to be in concert with the forces generated at the elbow. In addition, this information may help to explain the ever-increasing athletic injuries to the elbow, as well as provide a rational basis for surgery and rehabilitation.

Biomechanical Study of Total Knee Replacement

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The objective of this investigation is to obtain an improved understanding of the underlying biomechanics associated with total knee replacement design. The methodology is divided into three areas: experimental observation of net knee joint kinematics and kinetics; analytical determination of internal force distributions at the knee; and stress analysis of implanted prosthetic components. These three areas of study are integrated as follows: data generated on net joint reactions are used as input to a model for internal force calculations; internal force distributions are then input to the stress analysis models.

The basic questions addressed in this study include the following: (i) the relationship between patient variables and prosthetic design criteria; (ii) the extent to which patient knee mechanics varies among groups treated with different knee replacements designs and normals; (iii) the minimum mechanical requirements for an interface free from potential loosening.

Findings resulting from this study should aid in improved usage and design of total knee replacements.

Locomotion: Idling Metabolism and Gait Dynamics

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Richard C. Taylor, Ph. D.

This project has two main objectives:

1. To determine the manner in which muscles and populations of fibers within muscles are recruited during locomotion: (i) as animals increase speed and change gaits; and (ii) as animals use their muscles for different tasks, i.e., positive mechanical work and elastic storage of energy.

2. To investigate the contribution of skeletal muscle to total resting metabolism.

The following techniques are used: electromyography (EMG) synchronized with high-speed movies to determine the activity and length changes of active muscles; glycogen depletion to determine the cross-sectional area of active muscles, populations of active fibers, and the power of active muscles; measurement of the length changes of tendons (using high-speed movies) as a means of determining force exerted by muscles during locomotion; and evaluation of blood flow to muscle groups together with oxygen extraction from the blood to measure oxygen consumption of muscles.

Processes Underlying Arm Trajectory Formation

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Emilio Bizzi, M.D.

This is a study of human motor control through measurement of free arm movements.

A commercially available movement monitoring system, the Selspot System produced by Selcom Corporation, provides for the first time the capability for fast accurate measurements of free arm movements. The advantage of accurate measurements is the richness of the set of trajectories that can be measured, revealing corresponding insights into motor control issues such as joint coordination, space-time tradeoffs in movement computation, and adaptation of learned movements to new situations.

The context for the experimentation has been developed from adapting theories of mechanical manipulator control to biological arm control. The notion of an incomplete tabular representation of movement parameters (i.e., sparse lookup tables) is put forth to solve the problems of intractable equations of motion and of mechanical modeling inaccuracies. The implication of a sparse

lookup table, namely that a relatively small number of movements can be executed accurately, has led the investigators to test experimentally (i) for human arm movements that are executed less accurately than others, and (ii) how a sparse lookup table can be used to generate more complex arm trajectories. Experiments with monkeys are revealing the extent to which feedback is required for proper execution of these strategies.

Influence of Wrist Pathomechanics on Hand Function

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The objectives of this project are:

1. To continue basic biomechanical investigations to further improve understanding of normal and pathomechanical states of the rheumatoid wrist and its influence on hand function.
2. To develop reliable methods for the evaluation of patients with abnormal states of the wrist by using existing technology to quantitate the kinematic behavior of the wrist joint.
3. To evolve better methods of treating deformed wrists by providing the basic biomechanical information about their motions and forces needed to intelligently evaluate and prescribe surgical options, define requirements for potential prostheses, and determine optimal treatment modalities.

Methods are clinical and experimental; patients and cadaver specimens are used.

Clinical studies are emphasizing anatomical and surgical findings relating to carpal and wrist joint ligaments and correlating these findings with the experimental studies.

Experimental studies are largely concerned with developing and analyzing simulated rheumatoid wrist joint deformities in the cadaver and with developing optimum mechanical design criteria for a total wrist prosthesis.

This project should produce information of sufficient reliability for proper planning of the clinical and rehabilitative care of patients with wrist deformities.

Biomechanics of Hip and Knee

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This project is the continuation of a study of the biomechanical environment of the hip. The major objective of the original grant was to improve the surgical treatment of patients with arthritic hips by estimating the three-dimensional loading on the hip and then identifying ways, through surgical geometry and implant design, to reduce loading.

A sophisticated, reliable method to estimate the three-dimensional loading of the hip during gait and activities of daily living has been developed. The method involves the use of biplanar photography to record body segment displacement histories. Foot-floor reactions are measured with a force plate. Body segment inertial properties are determined from anthropometric measurements. The kinematic, kinetic, and inertial property data are combined in a Newtonian model to predict the intersegmental resultant forces and moments. The resultant forces and moments are then "distributed" to the muscles and articular surfaces of the hip using a linear optimization scheme. This method has been applied to study loading in the human hip and to identify ways to decrease loads and stresses with treatment.

This project is also a continuation of studies of the hip, extending them to the knee joint. A refined three-dimensional model of the lower-extremity muscle and ligament anatomy is being developed which is being followed by an investigation of new schemes to distribute the resultant hip and knee forces and moments to the muscles and ligaments. Validation procedures on the various distribution schemes are carried out for normal and pathologic gaits and other activities of daily living. Those schemes which are most appropriate are used to collect data on the mechanical function of normal and diseased hips and knees. These data are being analyzed in forms useful for designing treatment modalities.

Study of In Vivo Loading on Total Knee Replacement

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The purpose of this project is to determine the in vivo loading data from total knee joint replacements. These new joint replacements have enough telemetry circuitry incorporated within the body of the tibial components to provide seven channels of loading data. These are being used to record the loads on the device, allowing for the determination of the three forces and the three moments on the tibial components.

Three-Dimensional Analysis of Knee Motion

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The purpose of this project is to determine the kinematics of adult knee joints and postarthroplasty joint replacements using a system of three-dimensional radiographic analysis of in vivo bony structures. Implanted markers are utilized to determine the kinematics of both normal and prearthroplasty deranged knees. The normative data are for adults of both sexes and varying ages. The resultant postarthroplasty kinematics of constrained, semiconstrained, and totally constrained prosthetic types are being determined. The sensitivity of this analysis technique to detect joint loosening is evaluated also.

Pressure Distribution Under the Foot

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This project involves a novel clinical technique for the measurement of the pressure distribution beneath the normal and abnormal foot during locomotion. This technique provides the orthopedist or physiatrist, for the first time, both a quantitative measurement and a graphic representation of the tem-

poral and spatial variations of the stresses generated on the plantar surface of the foot. Preliminary work with a related technique, impractical for clinical applications, has demonstrated the feasibility and potential of this approach.

The first phase of this study involves development of a measurement system consisting of flexible piezoelectric transducer arrays of varying geometries and a common supporting data acquisition and graphic display package. In the second phase, a study will be made of the variabilities in the pressure distributions within and between normal subjects walking and running over a range of speeds. Techniques will also be developed for presenting these data in a form that shows both the mean stresses and their variations as functions of time and position.

Finally, in the third phase, the device will be applied to the study of several well-defined groups of patients exhibiting a variety of lower-extremity pathologies. The aims of this phase are: (i) to determine the pressure distributions characteristic of each pathology and the way in which these deviate from the norms established in the second phase; (ii) to investigate computer-aided diagnosis of these pathologies using pattern-recognition techniques; (iii) to explore the use of the technique in the prescription and evaluation of orthotic devices; and (iv) to provide a reference data base for use of the technique in clinical practice.

Functional Forces in Normal and Abnormal Fingers

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This is the continuation of an analysis of normal finger force performed by the technique of optimization. A graphical method has been used to present the results for a better understanding of the redundant force analysis problem. Normative models for the fingers were developed to perform simulation studies of abnormal hand conditions. Accurate instruments were fabricated and tested for patient evaluation. Important data have been produced.

The present extension of the project attempts to: (i) expand the study to analyze normal and abnormal thumb forces, (ii) determine capsuloligamentous forces of the joint, (iii) analyze the pathomechanics of finger and thumb deformity by simulation studies, (iv) perform objective patient evaluation, and (v) obtain qualitative validation of the analytical results based on quantitative electromyography (EMG) analysis.

A normative thumb model is being developed following the same technique, optimization, as was applied to the fingers. When the muscle strength is reduced due to pathological conditions, the functional forces are calculated in a reverse manner by treating the external applied force as an additional unknown.

Detailed cross-sectional studies are performed to construct the capsuloligamentous model, and its force components are determined by equipollent force analysis technique. Cadaver finger specimens are tested under bending and torsion to assess the role of the ligaments and capsule in maintaining joint stability. Patients with pathological conditions are evaluated biomechanically; integrated EMG's of extrinsic and intrinsic muscles are measured while the hand is performing isometric functions. These values are being correlated with theoretically predicted forces for qualitative comparison.

Medial Gastrocnemius Muscle Function in Locomotion

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Traditionally, considerations of the roles played by the medial gastrocnemius (MG) muscle during stepping have been limited to extension of the ankle joint, either as an active force during the late swing phase or as an elastic body during the stance phase. The main objective of this study is to consider the ankle extensor function of MG in more detail than reported previously and to consider possible roles for MG other than simple talocrural extension.

Normal locomotor function is examined in the cat using a combination of biplanar high-speed cinematography, force platform analysis, and multichannel electromyography. Limb movements (joint angle changes and body segment motions) and activity patterns in MG and all of its possible synergists are studied before and after partial and total denervation of MG. Analysis of this kinetic and kinematic data permits an accurate correlation of biomechanical events of abnormal step cycle and the roles of MG as elaborated by the central nervous system.

Results of preliminary pilot studies indicate that MG functions (i) to produce acceleration of the talocrural joint during the swing phase of stepping so that the foot is moved with a large average velocity, (ii) to decelerate extension of the knee joint just prior to foot placement, (iii) to stabilize the talocrural and subtalar joints during the early stance phase, and (iv) to extend the foot and provide forward thrust via an elastic stretch-shorten mechanism during the stance phase.

The applicability of studies of both peripheral and central aspects of the locomotor system in cats to humans has a long and well-established history. This project should contribute information as to the roles played by individual synergistic muscles during stepping, provide valuable peripheral correlates of the central program for stepping, and provide information on normal muscle function which can be used by specialists in rehabilitation medicine and other fields.

In Vivo Loading in Total Hip Joint Replacements

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The purpose of this project is to determine the in vivo loading data from total hip joint replacements. These hip joint replacements have incorporated within the neck of the femoral component all the circuitry required to provide, by telemetry, three channels of loading data. One channel is used to record the axial load on the neck, the other two to record the bending moments about two orthogonal axes normal to the neck axis.

Development of a Clinically Applicable Model of Gait

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Joseph M. Mansour, Ph. D.

This project is developing a biomechanical model of human gait. The model is constructed as a multilinked open chain system whose motions are governed by the principles of dynamics and kinematics in conjunction with known elements of the physiology and functional anatomy of gait. The model is employed for the analysis of both normal and pathological gait. Using this model the relative influence of both active muscular contraction and passive tissue constraints on motion is evaluated.

For pathological gaits, the investigator is evaluating the response to a treatment modality by analytically describing the mechanical response to treatment and comparing this to the actual patient response observed in the gait laboratory. In this way the effects of treatment and the mechanical compensatory mechanisms that arise secondary to the treatment may be evaluated.

Ballistic Walking: Normal and Pathological Gaits

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These theoretical and experimental studies are devoted to the question of whether or not a model of human gait is realistic in which the muscles of the swing leg are silent after the end of the double support phase.

The studies examine both normal and pathological gaits at both fast and slow speeds. Pathological gaits addressed include Trendelenburg, gluteus maximus, ankylosis of the knee, instability of the knee, equinus, spastic plantar flexion of the ankle, and dropfoot in paralysis or muscular weakness. The predictions of the model, to be tested against new and existing experimental and clinical observations, will allow a simple criterion to be established within each gait pathology, marking the boundary between mild and severe handicaps to progression.

Kinematic Studies of Normal and Abnormal Locomotion

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M. Patricia Murray, Ph. D.

This project is a continuation of kinematic studies of multiple simultaneous displacement patterns of walking in patients with specific arthritic and neurological disabilities, comparing their disordered walking performance with standards of normal variability which have been established previously. The project is also measuring the nature and amount of assistance required for walking, utilizing force-recording canes and crutches.

Methods have been developed to obtain quantitative measurements of basic mechanisms which are operative in causing gait abnormalities. These mechanisms include muscle weakness, muscle rigidity and spasticity, joint immobility, and postural unsteadiness and upright instability. Ranges of normal variability for these mechanisms have been established which serve as baselines for comparing deficits in disabled patients.

Using a multifaceted approach, the investigator is studying patients with severe arthritis before and after various types of major reconstructive surgery. She is comparing the effect of different types of total hip and knee arthroplasties on various components of function such as walking performance, cane force, muscle strength, joint mobility, and weight-supporting activity.

This project also continues studies of the interrelationship between: (i) muscle spasticity, rigidity, or weakness; (ii) postural steadiness and upright stability; and (iii) walking performance in patients with Parkinson's disease and hemiparesis following stroke. Measurements are being made of the effects of various drugs on reducing spasticity, and of various braces on improving walking performance.

Influence of Skeletal Implant Materials on Infection

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The incidence of infection after skeletal implant surgery is low, but the disastrous results make postimplant infection a major complication. In vitro experiments have suggested that some implant materials adversely affect immune mechanisms against infection. The clinical significance of in vitro impairment of immune mechanisms is not known, but can be determined in an in vivo experimental model.

In this project, an implant of polymethylmethacrylate (PMMA), high density polyethylene, stainless steel, or chrome-cobalt alloy is placed in the surgically prepared femoral canal of a dog following the instillation of low dose diluations of bacteria. Occurrence of infection is determined by wound evaluation and bacterial culture; incidence of infection is expressed as the infectious dose-50 (ID-50). Incidence of infection with the various implant materials is being compared.

It is expected that, in the presence of bacteria, all implant materials, as compared to no implant, enhance the development of infection. The purpose of the project is to determine if the bone cement PMMA enhances infection development more than the other commonly used implant materials, and to determine if any commonly used implant materials enhance development of infection to a greater extent than the others.

Further experiments are determining the efficacy of various treatment methods in increasing the ID-50 (that is, in decreasing the incidence of infection) in musculoskeletal wounds in which implants are used. Systemic antibiotics, irrigation of wounds with antimicrobial solutions, and use of PMMA containing antibiotics are being evaluated.

The results of these experiments will have direct clinical application by determining the most effective means of preventing infection when bacteria contaminate wounds in which musculoskeletal implants are used.

Studies of Synovial Joints

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The objectives of this project are: to develop a general instrumentation system for the measurement of joint forces, motions, and intra-articular pressures of living synovial joints; to verify the precision and accuracy of these measurements; and to study the functioning of living synovial joints using this instrumentation. Data obtained are being correlated to various theories of joint lubrication in order to determine the role of various joint constituents, particularly synovial fluid and cartilage, in the functioning of synovial joints.

Diagnosis of Loose or Damaged Total Joint Replacement

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Because of the increasing use of total joint replacements and the need to correctly diagnose mechanical degradation of such implants, the goal of this project is to develop a technique of in vivo joint monitoring by means of acoustic emission.

To accomplish this goal, the acoustic emission signatures of implant metals, the bone cement polymethylmethacrylate (PMMA), and bone are being developed under appropriate loading conditions. Composite in vitro structures consisting of cadaver bone, PMMA, and appropriate implanted total joint replacements are monitored for their acoustic emissions while subjected to heavy static and cyclic loads. A two-microphone technique is used, so that the locations of the emission sources may be detected in two-dimensional space. A finite element analysis is provided, using appropriate material properties and geometries, so that correlations between predicted high-stress areas and regions of acoustic emissions may be performed.

When sufficient accuracy and repeatability has been achieved in the in vitro studies, an in vivo program will be initiated using the identical available equipment. Patients at high risk for mechanical degradation of implants on clinical variables such as weight, bone size, and level of activity will be monitored, and correlations between continued clinical findings and acoustic emission findings will be performed.

EXERCISE PATHOPHYSIOLOGY

Disuse and Exercise in Conditions of Muscular Atrophy

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The primary objective of this research is to better delineate the nature of the molecular events which cause the early decline in the rate of protein synthesis in skeletal muscle after hindlimbs of rats are immobilized with plaster casts. Answers to the following related questions are being sought: (i) Do increased glucocorticoid levels play a role in inhibiting protein synthesis? (ii) Does the development of insulin resistance by the muscle cause a decline in protein synthesis activity? (iii) Is the decline in protein synthesis related to a decreased ability of the cell-free ribosomal preparation to synthesize polypeptide chains? and, (iv) Do calcium pool levels change in such a manner as to contribute to a decline in protein synthesis?

The second major objective is to determine whether insulin resistance plays a role in the atrophy of skeletal muscles. Muscular atrophy and insulin resistance occur in diabetes and obesity, as well as in other diseases such as cancer, cystic fibrosis, acromegaly, Cushing's syndrome, and myotonic dystrophy. Using normal animals as a control, this study is determining whether protein synthesis activity is less for a given dosage of insulin during the in vitro incubation of skeletal muscles from diabetic-obese animals. These findings will then be related to the glucose uptake per insulin concentration and to the insulin binding characteristics in skeletal muscles.

Physical exercise is known to improve glucose tolerance and to decrease insulin requirements in diabetic humans. In this study, diabetic-obese animals are exercised. Subsequently, data will be compiled to determine whether glucose uptake by skeletal muscle increases per dosage of insulin, and whether the affinity of insulin receptors in muscle increases after a single bout of exercise.

Alterations in Skeletal Muscle with Use and Disuse

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It is well established that the motor activity pattern regulates physiological and molecular processes in skeletal muscle. The objective of this study is to perform the first comprehensive and integrated analysis of the adaptive responses that occur with muscle use and disuse in all three mammalian skeletal muscle fiber types.

Wistar female rats have been divided into groups to characterize the effects of (i) hindlimb immobilization produced by casting, (ii) chronic electrical stimulation of hindlimb muscles, and (iii) exercise-training. A novel approach is being used in a separate series of experiments to assess the effects of chronic electrical stimulation (i.e. motor activity) on rat hindlimb muscles during and following immobilization. The effects of exercise-training (treadmill running) on muscle recovery from immobilization is also being studied.

At selected time periods after the initiation of the above experiments, muscle function is evaluated by studying the isometric and isotonic contractile properties of selected muscles representative of the three mammalian fiber types. Biochemical studies are also performed on myosin and the sarcoplasmic reticulum (SR). Myosin and the SR are extracted from Type I, IIA, and IIB muscle samples. The myosin light and heavy chains are analyzed using polyacrylamide gel electrophoresis; functional studies are conducted on myosin ATPase. The SR is evaluated to determine Ca^{++} uptake, binding kinetics, and the ATPase activity of this membrane system. Fiber type differences in the myosin and SR structure and function are evaluated, the effect of use and disuse determined, and the results correlated with the physiological findings.

NATIONAL SCIENCE FOUNDATION
1800 G STREET, WASHINGTON, D.C. 20550
SCIENCE AND TECHNOLOGY TO AID THE HANDICAPPED

James C. Aller, Sc. D., Program Manager

Adaptation of Muscle to High Intensity Exercise

University of Texas
Health Science Center
Dallas, Texas 75235

William J. Gonyea, Ph. D.

The objectives of this research project are to further define the process whereby skeletal muscle adapts to high-intensity (weight-lifting) exercise and to elucidate the mechanisms which control this process.

In this project, adult cats are operantly conditioned to flex their right wrist against increasing resistance to receive a food reward. This procedure has the advantage of inducing significant hypertrophy in the muscles of one limb, while the muscles of the opposite limb can be used for comparative studies. This exercise regimen has been shown to increase the number of fibers in the muscles of the exercised limb. The mechanism for this increase has been shown to be fiber splitting.

In this study, the structural and histochemical features of muscle fibers that are undergoing division by splitting are characterized, and the adaptive changes that occur in the exercising muscle that contribute to fiber splitting are investigated. Alterations in the contractile properties of the exercised muscle are explored, and pharmacological blocking drugs (d-tubocurarine and decamethonium) are used to evaluate the component parts of mixed muscles. Electromyography (EMG) is used to assess adaptive changes in the function and recruitment of exercising muscles.

This study will further elucidate the dramatic structural and functional alterations that occur in skeletal muscle that is adapting to high-intensity exercise, and will define the mechanisms that control these adaptive processes.

Microprocessor-Based Integration of Artificial Reflexes and Sensory Feedback for Prosthetic Control

Scientific Systems, Inc.
54 Rindge Avenue Extension
Cambridge, Massachusetts 02140

Wolfram Jarisch, Biomedical Engineer

This is a final project report, award number PFR-80-09412, based on work supported by the Small Business Innovation Research Program from 9/1/80 to 2/28/81.

This project seeks to improve the performance and usefulness of a microprocessor-based prosthetic arm so that the requirements for continuous visual supervision of prosthetic movements are lowered.

Artificial reflexes and sensory feedback in a prosthetic device have been recognized as important factors for improving prosthetic performance. Associated with the loss of a limb a variety of reflexes and senses are lost. If these are to be substituted, the question arises which are most relevant for a given lost limb function, and for a particular individual.

By way of a literature review of psychometric measurements and current neurophysiological models, the nature of the problem is identified as an optimization problem. In the particular setting the problem presents itself as a stochastic problem in a high dimensional parameter space. Conventional experiment designs and regression techniques are inadequate to acquire the information necessary for optimization with a reasonable experimental effort for a given individual.

In order to cope with these difficulties, a novel stochastic optimization algorithm is developed based on hybridization of ideas from stochastic function minimization, conjugate gradient methods (orthogonal projections), and other statistical concepts. The concept of "high dimensionality" is developed and is cast into a probabilistic framework.

The algorithms can be utilized to construct on-line, for a particular amputee, the necessary artificial reflex laws and sensory feedback codes. These laws and codes may then be placed in a microprocessor controlling the prosthetic device.

Use of Voice-to-Text Conversion in Deaf-Hearing Dialogues

SRI International
Telecommunications Science Center
Computer Science and Technology Division
Menlo Park, California 94025

Earl Craighill, Ph. D.

This is the first year of a 3-year continuing award, proposal number ECS 80-23527, fiscal year 1981.

This research explores methods of coupling voice-to-text (VTT) conversion technology with speech synthesis devices to allow better communication between the deaf and the hearing.

The research specifies, demonstrates, and evaluates VTT systems that are practicable and useful in dialogues between a hearing person talking over a phone to a deaf person who is typing.

Specific tasks are to: (i) Define the necessary system parameters of a usable VTT system, including the level of recognition performed by machine, the degree of accuracy of machine operation, and the amount of training required by deaf and hearing persons; (ii) Demonstrate an operational system coupled to the phone network; (iii) Determine the extent to which deaf users can provide their own syntactic and semantic analyses; and (iv) Identify key research problems that require solution.

Experiments are conducted to simulate communication between deaf and hearing persons and include simple information-transfer tasks as well as fully interactive representative dialogs.

Voice Response Aids for the Handicapped—An Innovative Technique

Signal Technology, Inc.
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Santa Barbara, California 93101

David Y. Wong, Ph. D., Electrical Engineer

This is a final project report, award number PFR-80-09724, based on work supported by the Small Business Innovation Research Program from 9/80 to 2/81.

The usefulness of voice response devices for the handicapped, especially the blind, is a well acknowledged fact. As an example, it would be much easier for the blind to operate a computer if the machine could respond to the operator with voice. This study involves a technique for storing speech in a highly efficient manner based on recent advances in the information theoretic coding of speech signals. The technique allows the vocabulary of a voice response device to be expanded by factors of two or better at little additional cost. The development of these coding techniques will allow speech sounds to be stored digitally in a highly efficient manner in a portable device. Without such coding techniques, voice response devices would simply be too bulky and expensive for general use.

Although the technique of vector quantization is still in its theoretical state of development, it offers significant advantages (32,000 bps) over conventional digital coding (2400 bps) techniques.

The feasibility of a voice response system based upon an efficient linear predictive coding (LPC) primitive approach is studied in this project. The LPC primitive approach is a direct application of the recently developed vector quantization theory of speech coding. Primitive sets of various sizes were generated to encode the speech signal. Rate distortion performance with respect to the training data and the primitive set size was investigated. Quality of the synthetic speech samples was also evaluated by qualified researchers as well as handicapped persons. From these evaluation studies, it is concluded that natural-sounding synthetic speech can be produced from LPC models encoded with only 128 primitives. With such coding efficiency, speech storage cost can be reduced to only one-third to one-fourth of existing voice coding techniques. As the approach is compatible with LPC synthesizers, commercially available microelectronic components can be readily utilized in applying the technique.

Applications of the proposed speech storage technique are to expand the vocabulary of prosthetic talking devices, cut the cost and weight of reading machines for the blind, aid the development of voice response computer terminals and equipment at minimal cost, and greatly enhance the development of computer-based educational programs for the handicapped.

Hearing Aids for Spatial Perception and Localization

Vibrasound Research Corp.
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Denver, Colorado 80236

George F. Kuhn, Ph. D.

This research is proposal number ECS 80-22377, fiscal year 1981, based on work supported under the Small Business Research Initiation Program Solicitation (PFR 79-17067).

This research develops numerical and analytical models for the localization cues for normally-hearing subjects and for those using hearing aids. These models are compared to experimental results measured on an anthropomorphic manikin as well as to models based on regular geometries, such as cylinders and spheres. New hearing-aid design concepts are developed which simulate or reproduce the localization cues available to the normally hearing subject. Thus, the aided subject would, using these new hearing aids, have available the same localization cue as the normally hearing subject. It is expected that these new hearing-aid design concepts will not only improve the aided listener's ability to localize cues, but also improve intelligibility when worn in the presence of background noise.

In addition to the design of the hearing-aid input stage, analyses are made of the "transfer function" from the hearing aid to the eardrum. This research project is primarily aimed at a reproduction of the normal acoustic signal at the output stage of the hearing aids. The technique can then be applied to ensure a good, predictable, and tractable transfer function for the hearing aid.

Low-Cost, High-Performance Speech Recognizer for the Handicapped, Phase II

Threshold Technology, Inc.
1829 Underwood Boulevard
Delran, New Jersey 08075

Phillips B. Scott

This is proposal number ECS 80-22376, fiscal year 1980, based on work supported under Phase I of the Small Business Innovation Research Program Solicitation (Award No. PFR 79-17038).

This research involves analyses of techniques leading to the development of low-cost, high-performance speech recognition devices suitable for use by the handicapped. Such devices will permit physically handicapped individuals to communicate with and control their environment. Existing low-cost speech recognition devices are not adequate for this application. The research studies techniques whereby existing high-quality speech recognition devices can be modified or adapted so that they can eventually be produced at a low cost while maintaining high performance. The techniques studied include simplification of speech preprocessing, restructuring of classification hardware architecture, and improving classifier software for persons with speech handicaps.

Electrodes to Aid the Handicapped

Annex Research
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Santa Ana, California 92705

John A. R. Kater, Electrochemist

This is proposal number 80-09361, fiscal year 1980.

Individuals suffering from chronic renal failure are severely handicapped. A reliable and low cost method to measure potassium (K^+) and calcium (Ca^{2+}) blood electrolytes during hemodialysis is needed. Imbalance of these electrolytes can cause cardiac arrythmias, irreversible complications, and death. The thrust of this research is to study the feasibility of solid-substrate technology in the development of disposable K^+ and Ca^{2+} electrodes and simple, portable, dedicated digital meters suitable for bedside monitoring during dialysis.

These steps would result in lowering the cost of hemodialysis treatment while providing better care.

Described are cost-effective miniature ion-selective electrodes (I.S.E.'s) suitable for the intermittent bedside measurements of potassium ion and free ionized calcium in whole blood. Solid-substrate potassium and calcium ISE's have been fabricated and evaluated in-vitro. Results also indicate that the use of miniature solid-substrate ISE's for direct measurements of electrolytes in whole blood with portable, battery-operated ion analyzers has many other useful applications in the treatment of the critically ill. Simple and rapid measurements are also very useful in the management of patients during surgery, intensive care, diabetic shock, and in the emergency room. Applications in pediatrics are anticipated.

Analysis and Design of Implants for a Fractured Femur

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Victor I. Weingarten, Ph. D.

This is proposal number ECS 80-18270, fiscal year 1981.

Clinical management of femoral fractures has been generally based on an empirical approach. There exists a need to develop a rational basis for fracture healing improvements which will eliminate abnormal stress distributions in the healing fracture area that cause either disuse atrophy with osteoporosis and bone resorption, or overload hypertrophy.

Research investigators in the Department of Civil Engineering and the School of Medicine at the University of Southern California are collaborating on a project to develop and experimentally verify a mathematical model of stress distributions in the upper part of the human femur. This model will be employed to study the design and effect of internal fixation devices used to fix the fracture elements and promote healing.

A mathematical model using a nonlinear finite element computer program is being developed to consider the effects of substructuring, contact elements, healing phenomena, as well as new nonlinear material law models. The initial study models both the intact human femur and intertrochanteric fractures stabilized by condylocephalic nails. For validation and refinement of the analytical model, the Universal Scientific Computerized Test System simulator is being employed to load cadaveric femurs with and without implants. Multiple-channel strain gage data from sensors located in the specimen are used to describe the behavior of both the femur and the fixation devices. The stress-strain behavior of the composite system can then be used to refine and develop a practical computer model for analysis of fracture healing.

Visual Feedback Speech Training for the Deaf—Phase II: Speech Analysis Using Acoustic and Glottal Sensors

Integrated Sciences Corp.
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Walter C. Gish

This is a summary of a completed project, award number PFR78-21347, for the period from 3/1/79 to 1/31/81.

A previous NSF study of visual feedback speech training aids concluded that an effective aid must be capable of extracting the speaker-invariant features of speech. This project is the second of four proposed phases leading to the development of a useful visual display of speech. The research in this phase focused on fundamental problems in speech analysis. The problems addressed were the separation of periodic and random components of speech sounds and the accurate estimation of formants, particularly for high-pitched voices. Theoretical considerations suggested that the necessary speech analysis capability was possible only if the analysis was restricted to the closed-glottis interval. Extensive experiments with synthetic speech and studies of the speech of four adult males, two females, and two children (one male and one female) were conducted. The results suggest that analysis over the closed glottis interval yields extremely accurate formant estimates, no degradation with high-pitched voices, immunity to source-tract interactions, and improved modeling of nasals, voiced fricatives, and fast formant transitions.

The Effect of Chemical Modification of Bone Cements on Their Young's Moduli

Polysciences, Inc.
Paul Valley Industrial Park
Warrington, Pennsylvania 18976

B. David Halpern, Ph. D., Chemical Engineer

This is proposal number 80-09941, fiscal year 1980.

As prosthetic procedures are used on increasingly younger and more active patients, the functional life of the prosthetic system must be extended. The present cement used in fixation of prostheses in vivo has been the principal cause of orthopedic failures. Gross modulus mismatches in mating bone to prosthesis by cement has led not only to prosthesis failure but to bone resorption, tissue necrosis, and deterioration and/or movement of the implant devices and other complications, particularly as the implants age.

The specific objective of this research is a study of the effect of systematic variations in the composition of a proposed bone cement. To be useful as a cement, the rheological properties of compositions of polymer and monomer have to be suitable, and rates of polymerization at room temperature have to be within a certain time frame. The research approach consists of two stages—a material synthesis stage during which several acrylate and methcrylate polymers are being prepared, and a physical testing stage to determine the Young's moduli of the "cured" composition of these cements.

Improved bone cement would significantly reduce medical care cost, improve surgical techniques, and allow patients to lead more active and productive lives.

It was found that varying the composition of the polymer powder has only a minor effect on altering the physical properties. The nature of the monomer did influence the compressive strengths and moduli. A correlation between the second order transition temperature of the homopolymers of the lower monomeric cement component and Young's moduli was found. An unexpected discovery was the observation that cements made with isobutyl methacrylate had higher compressive strengths and moduli than those based on the isomeric n-butyl methacrylate.

This feasibility study has shown that the compression parameters of orthopedic cements may indeed be controlled by the modification of the composition of the monomer phase. The matching of the moduli of the cements with the static and dynamic requirements of the prosthesis-bone interface is expected to lead to the design of materials which will exhibit improvements in their long-term performance as bone cements.

Usefulness of Auditory Cues for Spatial Perception in Blind Populations

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Donald H. Mershon, Ph. D.

This is proposal number ECS 80-23787, fiscal year 1981.

The goal of this research is to examine some of the ways in which individuals, both sighted and blind, can use naturally occurring cues to perceive the distance of objects which make their own sounds (e.g., other people, machines, animals, etc.) and to determine the quantitative relationships between physical and perceived distance in different acoustical settings.

Physical analyses of sound presented from different distances are compared with judgments of perceived distance. Both blind and blindfolded observers are used. Different types of stimuli and acoustical settings are studied.

The identification of just how common sounds can achieve a clear distance localization should allow similar kinds of physical variation to be produced electronically as a means for communicating more effectively about the distances of objects detected by mobility devices.

The results may assist the development of mobility aids by allowing such devices to present information to the wearer in a more readily assimilated form. Increased knowledge may also make possible more rapid training of newly blinded individuals in the full use of their normal hearing as a basis for mobility.

Enhancement of Speech Intelligibility for the Hearing Impaired

Signatron, Inc.
12 Hartwell Avenue
Lexington, Massachusetts 02173

James M. Kates, Electrical Engineer

This is award number PFR-8009372, from 9/1/80 to 2/28/81.

Project summary—Conventional hearing aids are inadequate for people with sensorineural hearing loss. A truly effective hearing aid would be one that would work in a noisy environment. A substantial improvement in hearing aids may be possible by designing signal processing that takes into account the properties of speech generation, perception, and the characteristics of sensorineural hearing loss.

The goal of this research was to enhance speech intelligibility by removing pitch irregularities and by emphasizing perceptually important speech features. By removing pitch irregularities, the effects of noise are further reduced through adaptive filtering of the speech waveform. The use of signal processing in the hearing aid is leading to a significant improvement in the quality of hearing aids.

Final report—In this feasibility study, Signatron has tested a set of computer programs that can noticeably improve speech intelligibility for the hearing-impaired. The processing first emphasizes the speech features by removing noise and pitch irregularities from vowels and by adaptively enhancing the characteristic frequency content of consonants. This is followed by dynamic-range compression and a high-frequency emphasis that helps overcome aspects of the sensorineural hearing loss. The processing was tested on the perception of stop consonants through a simulated hearing impairment; intelligibility improved, from an average of 32% of the phonemes identified correctly without any processing to 68% correctly identified when the full processing was used.

Potential commercial applications of this research lie in the area of processors to enhance speech intelligibility. The applications of signal-processing hearing aids are of special interest, since conventional hearing aids are often inadequate for people with sensorineural hearing loss. Additional applications include a larger processing unit that could be added to a telephone, radio, or television to allow the hearing-impaired to make full use of modern telecommunications.

NOTE: Dr. James C. Aller has replaced Dr. Donald R. McNeal as Program Manager. A reorganization of March 8, 1981, transferred the Science and Technology to Aid the Handicapped program in a new Division of Electrical, Computer, and Systems Engineering.

Abstracts of Recent Articles

The following articles have been abstracted by Joan E. Edelstein, R.P.T., who is a Senior Research Scientist, New York University Post-Graduate Medical School, Prosthetics and Orthotics, 317 East 34th Street, New York, N.Y. 10016.

Kinematics of the Elbow: James T. London (San Pedro, California) Journal of Bone and Joint Surgery 63-A:529–535, April 1981.

Kinematic analysis of the normal elbow can define the axis or axes of rotation and the type of motion occurring at the joint surfaces. Previous studies produced conflicting results, such as a locus of instant centers, a pathway of instant centers, and changes in the carrying angle following either linear or oscillatory patterns. Disparities may be related to the analytic techniques.

This study used a refinement of Reuleaux's technique, based on the concept that as two bones move in relation to one another in a single plane, there is at any instant an axis of rotation that has zero velocity where joint motion is pure rotation. Using X-rays in lateral view, for each increment of elbow flexion the instant centers of rotation of the radiohumeral and the ulnohumeral joint are superimposed on each other. The two points define a line that is the axis of rotation. Previous measurements of 50 cadaver elbows revealed considerable variation in size of the distal end of the humerus, but minimal variation in shape. The sulcus of the trochlea forms a nearly complete circle from the center of the coronoid fossa to the center of the olecranon fossa. The plane of the trochlear sulcus defines the plane of elbow flexion.

Eight elbows were x-rayed, four from cadavers and four from healthy individuals. Flexion and extension occur about a single axis and are of a sliding type, except at the extremes of the range, when the axis moves and rolling occurs. The axis passes through the center of the arcs formed by the trochlear sulcus and the capitellum. The axis of elbow rotation is internally rotated 3 to 8 degrees from the plane through the epicondyles. The carrying angle remains constant throughout the range of flexion.

The Role of Joint Load in Knee Stability: Keith L. Markolf, William L. Bargas, Stephen C. Shoemaker, and Harlan C. Amstutz (Division of Orthopedic Surgery, University of California, Los Angeles, California) Journal of Bone and Joint Surgery 63-A:570–585, April 1981.

The effects of tibiofemoral contact force on knee stability and the role of the menisci were investigated in eight cadaver knees. They were tested on a servohydraulic materials-testing machine, subjecting the joints to varus-valgus stress, tibial torsion, anterior-posterior drawer testing, and mediolateral shear testing.

In each test mode, the knees stiffened with applied joint loading, indicating the protective mechanism afforded by the ligaments. Unloaded knees resisted applied forces internally by the ligaments and capsule. Displacements and rotations caused by external loads were converted to internal ligament strains. The increases in stiffness and decreases in laxity when compression is applied indicate that less tibial displacement and rotation result from a given force and that ligament strains will be reduced, especially when varus-valgus stress is applied. Joint congruency, a function of the contours of the tibial plateaus and femoral condyles, contributes to the stabilizing effect of joint loading. Menisci did not resist medio-lateral tibial movements at full extension very much. The menisci stabilized against antero-posterior displacement and torsion somewhat more. Their greatest effect was evident in varus-valgus tests when the knees were not loaded. Compression is generated by superincumbent body weight and the knee muscles. The neuromuscular control system in vivo can stabilize a flexed knee in stance.

Burns Following Application of Plaster Splint Dressings: Samuel S. Kaplan (Scottsdale, Arizona) Journal of Bone and Joint Surgery 63-A:670–672, April 1981.

Arabs were probably the first to use plaster in the ninth century, mixing calcium oxide and egg whites to make a rigid dressing for fractures. Calcium sulphate was introduced in 1798, a less irritating but more difficult mixture to apply. In 1852, Antonius Mathysen impregnated cotton bandage with plaster. In 1900 a loose-coated bandage became commercially available. In 1927 binders such as starch and gum were added to create the hard-coated bandage.

The basic chemical reaction when plaster reacts with water to create gypsum is exothermic. Two patients who sustained second- and third-degree burns are described—one of these cases resulted in litigation with settlement in the plaintiff's favor. Both patients' burns healed spontaneously. Both had had plaster splints, rather than cylindrical casts.

References to elevated temperatures are cited. Temperatures of 50 degrees Celsius have been recorded ten minutes after plaster application. A third-degree burn can result if such temperature is sustained for five to 15 minutes. Second-degree burns occur with high temperature lasting 12 minutes, and seven minutes of heat causes burn blisters. The temperature generated from heat of crystallization varies from 32.2 to 82.2 degrees Celsius. Thicker dressings increase more in temperature because plaster dries from the outside to the inside. Covering plaster with cotton bandage or other insulation slows heat transfer, allowing higher temperatures within the plaster. Immersing plaster too briefly may cause rapid, intense

local heat, as can squeezing water too thoroughly before application of plaster; water has a high capacity for specific heat absorption. Water temperature should remain cooler than 40 degrees Celsius.

Idiopathic Scoliosis: Stuart L. Weinstein, Donald C. Zavala, and Ignacio V. Ponseti (Department of Orthopedic Surgery, University of Iowa Hospitals and Clincs, Iowa City, Iowa) Journal of Bone and Joint Surgery 63-A:702–712, June 1981.

One hundred ninety-four patients with untreated adolescent idiopathic scoliosis were evaluated. Of these, 33 had died; the average age of the living patients was 53 years. Eighty-four percent were women. About a third had thoracic curves, a quarter had lumbar curves. Approximately one-quarter of the group had curves less than 50 degrees, and half had curves greater than 75 degrees. Most patients are homemakers or gainfully employed. A fifth of the group had mild psychological reactions to their deformity, but none required psychiatric treatment. Backache was reported by about 60 percent of the population, particularly those with thoraco-lumbar curves. Osteoarthritic changes were found in X-rays of the spines of approximately one-third of the patients who had recent X-rays. Twenty-nine percent complained of shortness of breath that limited their activities, particularly those with thoracic curves. Diminished vital capacity correlated well with severity of the thoracic curve.

Nearly all of the group were married, a finding contrasting with other studies. The mortality of the current group is similar to that of the general population, but differs significantly from the findings of other investigations. Inasmuch as a relatively small number of patients complained of back pain, surgery is seldom indicated; surgery may not have a beneficial effect on pulmonary function. Patients whose curves are unresponsive to bracing are treated surgically, sacrificing spinal mobility. Those with double major or lumbar curves that are not severe should be braced, so that with aging they will not be limited by pulmonary dysfunction or backache.

The Effect of Prolonged Physical Training on the Properties of Long Bone: A Study of Wolff's Law: Savio L.-Y Woo and others (Division of Orthopedic Surgery, University of California, San Diego, California) Journal of Bone and Joint Surgery 63-A:780–787, June 1981.

Mechanical and geometric properties of bone were studied following long-term exercise. These properties were correlated with biochemical composition of bone including density, ash content, and calcium content.

Nine swine were subjected to 12 months of exercise training on a treadmill and track. The animals ran an average of 40 kilometers per week. Four animals were kept sedentary as controls. The animals were killed and their femora sectioned. The bony samples were subjected to materials testing.

Exercise had a more pronounced effect on the posterior part of the femur. The mechanical properties, represented by the modulus of elasticity and ultimate bending stress, were similar for the control and exercised animals. Bone from exercised animals had a third more maximum load and maximum energy stored. Biochemical analysis of bone composition showed no difference between the groups. The experiment showed that exercise increases the internal stresses in bone which responds by increasing cortical thickness and narrowing the medullary cavity, although the quality of bone was unchanged. Cortical thickness in the exercise group increased by 17 percent.

Case Note—A Combined End-Bearing and Patellar-Tendon-Bearing Prosthesis for Chopart's Amputation: N. M. Mustapha, F. McCard and A. T. Brand (Artificial Limb and Appliance Centre, Liverpool, England) Prosthetics and Orthotics International 4:156–158, December 1980.

A 42 year old woman had a "verruca" removed from her right foot 11 years ago. An ulcer developed which led to partial foot ablation at the Chopart level. Sepsis postoperatively delayed healing, but the end result was a mobile ankle with neutrally positioned calcaneus. The amputation limb was too short and bulky for ladies' footwear, and was tender on the plantar surface and at the anterior scar which was adherent.

A blocked leather prosthesis was fabricated combining socket, shin, heel and sole attached to a wood forefoot. The socket is a patellar tendon bearing design permitting partial end-bearing on a distal pad. The prosthesis opens posteriorly. An elastic stocking closes the split and suspends the prosthesis.

The patient walks well and performs a full day's work as a housewife, wearing the prosthesis 5 hours a day. Although most patients with a Chopart amputation can be fitted with the "Ortholen" prosthesis which assumes a good end-bearing sole pad and neutral foot, the present prosthesis is an alternative combining end-bearing and proximal-bearing in a cosmetically and functionally acceptable manner.

Reproducibility of Gait Measurement Using the Lamoreux Goniometer: E. Jansen and H. Orbaek (Department of Orthopaedic Surgery T-2, Gentofte Hospital, Copenhagen, Denmark) Prosthetics and Orthotics International 4:159–161, December 1980.

A self-aligning goniometer was designed by Lamoreux in 1971 at the University of California and is now manufactured by Een-Holmgren, A.B., Uppsala, Sweden. Four goniometers were mounted on an aluminum exoskeleton, part of a self-aligning system of parallelogram linkage and a sliding rod. The goniometers use potentiometers of conductive plastic. The subject walked on a treadmill at an average speed of 4 km/hour. The system was applied 10 consecutive times by the same operator; 60 seconds of continuous recordings were used in each test.

None of the tests was significantly different from the others, indicating that the self-alignment of the goniometers functioned well when measuring hip and knee flexion and extension. There was no difference between the right and left side recordings.

The goniometers are thus suitable for basic gait studies, as aids to alignment of lower limb prostheses, and as a tool of control following surgical or medical procedures.

The standard deviation of maximum flexion/extension was approximately 5 percent at the hip and 10 percent at the knee.

A Clinical Study of Amputations of the Lower Limb: A. K. Agarwal, M. K. Goel, R. K. Srivastava, and S. Rastogi (Re-

habilitation and Artificial Limb Centre, K.G.'s Medical College, Lucknow, India) *Prosthetics and Orthotics International* 4:162–164, December 1980.

A retrospective study of 525 lower limb amputees treated from January 1976 to March 1978 was conducted. Nearly all were men. Half were between 21 and 40 years of age. Approximately two-thirds of the amputations were due to trauma, particularly train and automobile accidents. Fifty-seven percent of the cases were below-knee amputations. Three-fourths were suitable for prosthetic fitting with either a standard or modified prosthesis.

On first attendance in the outpatient department approximately 10 percent required amputation limb preparation and preprosthetic management. Less than 3 percent had infection, which was treated with local dressing.

Other causes of amputations in the group of 343 traumatic amputees were crush injuries, firearm injuries, and miscellaneous trauma, such as falls. In the smaller group of nontraumatic amputees, approximately 20 percent had vascular disease. Less than 10 percent had neoplastic lesions.

Other than below-knee amputations, a third had above-knee amputations, and fewer than 5 percent had foot amputations, Syme's, through-knee, and through-hip amputations. Twelve percent of the entire group required surgical correction prior to prosthetic fitting. Approximately one-fourth of the below-knee amputees had short and very short amputation limbs, and fewer than 18 percent of the above-knee amputees had short or very short limbs.

An Integrated Biomechanical-Bioenergetic Technique for Evaluation of Human Locomotion: D. N. Tibarewala, A. K. Ghosh, and S. Ganguli (Bioengineering Unit, University College of Medicine, Calcutta University, India) Journal of Medical Engineering and Technology 4:241–246, September 1980.

Level walking characteristics of 10 normal subjects and 10 individuals with various lower-limb paralyses and amputations were analyzed to determine temporal, kinematic, and kinetic factors, and energy expenditure simultaneously. The instantaneous velocity of each subject's center of gravity was recorded, together with analysis of expired air, as subjects walked at comfortable and fast speeds. These data were used to construct a gait abnormality index, a measure of temporal gait asymmetry.

The investigators derived a walking efficiency factor by dividing the energy expenditure by the product of body weight times distance traversed. This factor ignores the pace and pattern of walking, which are components of the gait abnormality index. Normal and handicapped locomotion can therefore be evaluated in terms of walking efficiency factor, walking velocity, and the gait abnormality index. Statistical correlation theory demonstrates that the cumbersome energy expenditure measurement can be avoided, because this ergonomical parameter can be estimated from the biomechanical parameters of gait abnormality index and velocity.

The Changing Pattern of Scoliosis Treatment Due to Effective Screening: Gunnar Torell, Anders Nordwall, and Alf Nachemson (Department of Orthopaedic Surgery I, Sahlgren Hospital, Goteborg, Sweden) *Journal of Bone and Joint Surgery* 63-A:337–341, March 1981.

The effect of early detection and treatment of scoliosis was assessed in a stable population in Sweden between 1968 and 1978. The study was done at the only center for referral in the western district of Sweden. All patients younger than 20 years who were referred to the center were studied—a sample of 725 individuals. They were followed with regard to development of curve, chronological and skeletal age, and treatment. The mean age at referral was 14 years, and more than 90 percent were female. For the first 5 years of the study, all with curves between 25 and 45 degrees were treated with a Milwaukee brace. Those with smaller curves were observed, and larger curves were operated on. In 1976 the maximum thoracic curve braced was 40 degrees. Since 1977 the minimum curve braced was 30 degrees. Since 1976 the Boston brace has been used for all curves between 25 and 40 degrees with an apex at or below the tenth thoracic vertebra. In 1968 a scoliosis information campaign was launched, but no specific training in screening was provided.

Although a constant number of children had been born during the study period, many more referrals were noted, almost a fivefold increase, with the mean age of referral decreased, and the size of the curve decreased from 46 to 28 degrees at referral. Fewer patients with severe curves were noted. Early in the study, 32 percent had surgery; later only 12 percent required operation.

The Anterior Aspect of the Knee Joint: Bruce Reider, John L. Marshall, Bert Koslin, Bruce Ring, and Fakhry G. Girgis (Hospital for Special Surgery, New York, New York) Journal of Bone and Joint Surgery 63-A:351–356, March 1981.

Forty-eight cadaver knees were dissected, approximately half from men. Knees were from subjects ranging from 40 to more than 80 years of age.

The four-part structure of the quadriceps was identified. The four bellies become aponeurotic at the anterior aspect of the knee. The rectus femoris is a long fusiform muscle, which narrowed to a tendon from 5 to 8 centimeters above the superior aspect of the patella. The tendon fans distally as it approaches the patella, and continues over the anterior surface of the patella into the infrapatellar tendon. Most subjects had continuity of tendinous fibers.

The vastus medialis obliquus showed wide range of angular variation. The vastus lateralis approaches the patella at an average 31 degree angle. Its fibers terminate more proximally than do those of the vastus medialis. The vastus intermedius fibers insert directly into the superior border of the patella, never continuing over the anterior surface. The articularis genu and fascial investments of the knee were also measured, as were the patella and infrapatellar tendon. Negative correlation exists between the length of that tendon and the width of the medial patellofemoral ligament, as seen in patella alta with lateral patellar deviation. Much variability exists on the lateral side of the knee, associated with patellar deviation and chondromalacia patellae. Lateral tethering of the patella restricts patellar mobility.

The Biomechanics of Control in Upper-Extremity Prostheses: Craig L. Taylor (University of California, Los Angeles, California) Orthotics and Prosthetics 35:7–28, March 1981.

This article appeared originally in "Artificial Limbs," September 1955. Structural replacement of the missing hand and arm is comparatively easy. Functional replacement by remote control and substitute mechanisms is much harder. The man-machine combination determines performance.

Bony landmarks enable accurate positioning of prosthetic components. Typical measurements of the male torso were derived from Army personnel. They establish harness patterns and control paths, and the basis for sizing prostheses for unilateral and bilateral amputees. The motions of the arm are simplified, stated in terms of the three spatial planes, rather than as intermediate angular excursions.

The shoulder girdle consists of the scapula and clavicle, although the proximal humerus contributes to coordinated activity of the girdle. Muscular control of the various joints of the girdle is described in terms of the motions produced. The humerus and its glenohumeral joint comprises the arm. Muscular control of the arm and of combined arm and shoulder movements are illustrated, as are control mechanisms of the forearm.

Musculoskeletal mechanisms are analyzed in terms of bony structure, synovial characteristics, and muscle fiber arrangements. Maximum torques at each joint are charted. Prosthetic sockets obtain purchase on the limb and must bear weight axially and laterally, as well as serving as attachment for mechanical components. Single, dual, cineplasty, and triple control systems for all amputation levels are analyzed.

New Casting Material and Improved Functional Design for Lower Femoral Fracture Bracing: T. Vaughan-Lane and B. F. Meggitt (Orthopaedic Department, Addenbrooke's Hospital, Cambridge, England) Prosthetics and Orthotics International 4:145–149, December 1980.

Cast bracing combines the advantages of safe conservative treatment with early mobilization associated with internal fixation, without risk of infection and other surgical problems. Crystona, white alumino-silicate polyacrylic acid in a bandage, is activated by immersion in tepid water. It has a longer setting time than plaster, up to 12 minutes, and is more adhesive. The resulting cast is twice as strong, allowing full weightbearing within 1 hour of application. The cast is porous, unaffected by water, and can be removed with plaster shears.

The knee hinge cylinder brace has been used in treatment of over 200 distal femoral fractures since 1973. The older brace had a quadrilateral thigh section joined by polycentric hinges to a below-knee walking cast. It functions as an antibuckling tube, with leg loading limited by the fracture load itself, rather than the cast. Thus, weight transference through the foot cast was unnecessary. The newer brace has adjustable three-point suspension from a waist belt to studs in the thigh section, polycentric hinges, a calf enclosure, and no ankle or foot components. A foot section is needed by patients with conical thighs where suspension would be difficult otherwise.

The brace is applied at 5 to 7 weeks when early callus has formed. The patient walks with crutches one hour later, initially with knee locked, then with locking screws removed permanently. The brace is removed when the patient can place full weight for 10 seconds steady standing on the leg.

Selected Factors Influencing Job Satisfaction of Attendants of Physically Disabled Adults: Madelyn Stelmach, Jan Postma, Steven Goldstein, and Katherine F. Shepard (Ralph Davies Medical Center, San Francisco, California) Rehabilitation Literature 42:130–137, May–June 1981.

Forty attendant care workers were interviewed, with data entered on demographic collection forms, a standardized interview schedule consisting of eight open-ended questions, a modification of Locke's Action Tendency Interview Schedule for job satisfaction, and a five-point self-rated scale developed by the investigators. The study was prompted by the comments of many disabled people that attendants are difficult to retain.

Three-fourths of the sample were women. The group ranged from 18 to 65 years of age, most being younger than 30. The disabled cared for by these attendants were approximately 50 percent male; 70 percent were older than 30. Most needed more than 25 hours per week of care. Two-thirds of the disabled required multiple attendants. The disabled person was the most often-cited source of information about disability and specific skills needed for the job. Health professionals were mentioned by 30 percent of attendants as a source of skill training. The most often-cited positive factors, according to attendants, were doing worthwhile work, having a satisfactory schedule, and friendship with the disabled person. Attendants least-liked aspects of the work schedule: wages and benefits, and attitudes of the disabled person toward the attendant.

Inasmuch as the independent living movement (which makes disabled people, rather than health professionals, responsible for control of their own medical and personal needs) is increasing in importance, disabled people should be prepared to supervise, educate, and train their attendants. The most satisfied attendants were those who had held five or more previous attendant jobs, and those caring for persons needing less than 25 hours weekly care.

Hip Hinge Thigh Brace for Early Mobilization of Proximal Femoral Shaft Fractures: B. F. Meggitt and T. Vaughan-Lane (Orthopaedic Department, Addenbrooke's Hospital, Cambridge, England) Prosthetics and Orthotics International 4:150–155, December 1980.

Conventional cast bracing cannot control the position of upper femoral shaft fractures, primarily lateral bending. The new brace controls varus buckling by lateral support at the fracture site with medial support at the pelvis and at the distal femur. The distal fixation is provided by a thigh cast extending to just above the knee. Knee hinges and a calf section are unnecessary. Proximal fixation consists of a quadrilateral thigh cast attached to a metal uniplanar hip hinge and rigid pelvic band unit. The band continues to a waist belt and is suspended by a shoulder strap.

The hip hinge thigh brace was introduced in 1976, and in 1978 was made of Crystona, a lighter material than plaster. It is applied when the fracture is at the stable callus state, by 7 weeks. After 1 hour, the patient can walk with crutches, moving the hip and knee actively with maximal weight-bearing. The brace is removed when the limb tolerates full body weightbearing for 10 seconds.

After skeletal traction is removed, the patient sits on a firm

support with the thigh held by an assistant. The hip axis is marked at the greater trochanter. Stockinette is applied from groin to below knee, then an elastic bandage above knee to ankle, covered by an elastic knee support. Felt is placed around the groin and also above the patella. Crystona is wrapped on the thigh, and a quadrilateral thigh mold is positioned to shape the plastic; then the mold is removed. The rigid pelvic band and hinge are positioned with the leg abducted 20 degrees and fixed firmly with Crystona. Shoulder and waist straps are attached.

A Terminal Question: Robert Radocy and Ronald E. Dick (Therapeutic Recreation Systems, Boulder, Colorado) Orthotics and Prosthetics 35:1–6, March 1981.

Upper limb prosthetic terminal devices have remained unchanged for more than a quarter century. Most hooks are voluntary-opening split hooks. Such hooks are inadequate, for they provide forceps pinch with grip strength limited by the power provided by rubber bands or springs (approximately 4 pounds per rubber band.) These hooks are suitable for light use by bilateral amputees, but tools tend to be forced out when pressure on the hook fingers exceeds the capacity of the rubber bands.

The voluntary-opening system uses relative motion between parts of the human body through a harness and cable system to open the fingers by overcoming a closing force. The voluntary-closing system is one in which the amputee closes the fingers by overcoming an opening force. The merits of each system should be evaluated in relation to the needs of specific segments of the amputee population. Unilateral below-elbow amputees, the majority of the population, wear the same terminal device as bilateral and above-elbow emputees, although the unilateral below-elbow amputee has more leverage. This patient needs a useful option. Earlier analyses concluded that the voluntary-closing principle is the most desirable if engineering problems can be solved.

Many designs are improvements on the split hook. Amputees should be involved in design efforts. Interviews with below-elbow amputees reveal strong opposition to myoelectric control because of its fragility and lack of feedback. Weight, size, locking, appearance, versatility, and reliability are important factors in terminal device design.

Cardiovascular Stress of Crutch Walking: Robert Patterson and Steven V. Fisher (Department of Physical Medicine and Rehabilitation, University of Minnesota Hospitals, Minneapolis, Minnesota) Archives of Physical Medicine and Rehabilitation 62:257–260, June 1981.

Eight healthy young men ambulated with underarm crutches using the three-point gait pattern at six speeds on level surfaces; they also walked up a 5 percent incline and climbed 19-cm-high steps at two speeds. Each task was performed twice, and most runs were performed for 6 minutes. Not more than three runs were performed on a given day. Respiratory gases were collected and analyzed. The subjects also had upper-extremity and lower-extremity stress tests.

The slope of the heart rate response compared with oxygen uptake parallels the response for the upper-extremity stress test; this slope is much steeper than for the lower-extremity stress test. Thus, upper-extremity work causes a significantly higher heart rate than does lower-extremity work. A continuous increase in heart rate was observed at all speeds. Heart rate does not achieve steady state during upper extremity activity except at light workloads or after 6 minutes. The rise in the ventilatory equivalent at relatively faster crutch speeds suggests the development of anerobic metabolism.

The average energy requirements of level crutch walking at 60 meters per minute is approximately two-thirds of the maximal upper-extremity stress test values. The rise in heart rate may be due to shift from fat to carbohydrate metabolism, balance between hyperventilation and hypoventilation, central response to arterial acidosis, and response due to stimulation of peripheral receptors where specific muscles are heavily loaded. A subject with pulse rate limit of 140 beats per minute could either crutch walk at 60 meters per minute or run at 134 meters per minute.

Disabled and Nondisabled Persons' Satisfaction with Conditions in the World of Work Before and After the Rehabilitation Act of 1973: Stanford E. Rubin, Charles E. Worth and William G. Emener (Rehabilitation Institute, Southern Illinois University, Carbondale, Illinois) Rehabilitation Literature 42:138–142, May–June 1981.

Section 503 of the Rehabilitation Act of 1973 mandates federal contractors with a contract of more than $2500 to actively employ and advance qualified handicapped persons. Section 504 of the act requires employers to make reasonable accommodations for handicapped persons. One hundred fifteen questionnaire respondents from the National Association of the Physically Handicapped, Inc., and from Mobility on Wheels participated. Most were male, older than 40 years, and had been disabled for an average of nearly 30 years. Half used a wheelchair. A random sample of 250 individuals from the general population was also surveyed. Both groups compared working conditions during the periods 1968 to 1973 and the period 1974 to 1979.

The only significant difference between work perceptions before and after 1973 was in the way the supervisor treated those confined to a wheelchair who were younger than 39 years. The 1973 law apparently has not affected employment conditions for able-bodied workers. The disabled noted a significant positive change in supervisors' attitudes, and satisfaction with salary, as well as in the attitudes of co-workers.

Energy Cost of Ambulation with Crutches: Steven V. Fisher and Robert P. Patterson (Department of Physical Medicine and Rehabilitation, Saint Paul-Ramsey Medical Center, Saint Paul, Minnesota) Archives of Physical Medicine and Rehabilitation 62:250–256, June 1981.

Eight healthy young men ambulated with underarm crutches on a level surface, walking with three speeds; they also walked on a 5 percent ramp, and climbed stairs at several speeds. Four also ambulated with forearm crutches on level surfaces and up stairs. All subjects also ambulated on all surfaces without crutches. An electrocardiogram was recorded continuously and oxygen consumption and ventilation were monitored with an Oxylog portable oxygen consumption device. Expired gas samples were obtained in meteorologic bags. Stress test-

ing was conducted with an upper-extremity maximum bicycle ergometer and a lower-extremity maximum treadmill. Speed, oxygen consumption and ventilation, calories, heart rate, cadence and step length were recorded for each ambulatory situation. The data were compared with figures published in four other studies by other investigators.

The current subjects had a twofold increase in oxygen consumption when crutch walking compared with normal gait. At the slowest speed, consumption was 40 percent of the maximum upper-extremity stress test; at the comfortable walking speed of normal ambulation, consumption was 90 percent of maximum upper-extremity stress. Heart rate was always greater when crutch walking, even at the slowest cadence, than when walking without crutches. Crutch walking is one-third as efficient as normal walking at slow speeds, in terms of energy used per unit body weight per unit distance traveled. Use of underarm crutches was not statistically different from use of forearm crutches.

Parapodium Redesigned for Sitting: Martha Gram, Edwin Kinnen and James Brown (Department of Pediatrics, University of Rochester, Rochester, New York) Physical Therapy 61:657–660, May 1981.

The original design of the parapodium is successful in allowing children with meningomyelocele lesions of L3 to T12 to stand and walk, but sitting is very difficult. Difficulties are due to the knee- and hip-lock design of the Motloch design which requires two hands for locking or unlocking. Sitting required leaning backward against a chair, then collapsing into a partial sitting position which is frightening. Standing required full body extension in order to engage the locks, a precarious and space-consuming requirement.

The new design allows separate hip and knee locking which can be accomplished with one hand. The locks do not project from the sides of the parapodium, so the wearer can engage the locks in a restricted space, such as in a wheelchair. In order to stand, the wearer draws a knee-extension-assist rod out and downward, causing the knee joints to extend and lock automatically. The patient then turns over and pushes to extension, causing the hip locks to engage automatically.

Ten patients have been fitted with the new design. A case report of a 10-year-old boy with a T10-12 lesion illustrates the improved function obtained with the device. The youngest patient to sit and stand unaided was 3 years old. All wearers swivel with greater speed and agility, greater leverage being provided by the forward rigidity and lateral flexibility of the side bars of the redesigned parapodium.

Recent Patents[a]

Device for Air-Massage: Katsumasa Hara. The device may be manufactured as a shaped article (e.g., a boot), a wraparound for an arm or leg, or a mat for the entire body. It consists of an elastic element which contacts the skin and is affixed to an air bag. Cycling a small volume of compressed air in the air bag produces the massage effect in the elastic element. Hot or cold water, or a heating and cooling gel, may be used in the device to enhance the massage effect. (Patent No. 4,231,355, Nov. 4, 1980; filed Sept. 15, 1978; Appl. No. 942,709; 8 claims.)

Electrically Heated Surgical Cutting Instrument: George D. Lipp, assignor to Corning Glass Works, Corning, New York. The heating element is printed or deposited along the cutting edge of the blade. It sterilizes the blade and cauterizes tissue, to reduce infection and hemorrhage and promote rapid healing. The blade is thermally insulated from the instrument handle and detachable. (Patent No. 4,231,371, Nov. 4, 1980; filed Nov. 16, 1978; Appl. No. 961,191; 6 claims.)

Gripping Device for Handicapped Persons: Willem D. van Zelm. Operable with one hand by a wheelchair occupant, the invention employs a mechanically-operated hinged arm and double-acting jaws, to lift and move objects or bring them directly to the operator. The device is lightweight and has a relatively long reach span. (Patent No. 4,231,603, Nov. 4, 1980; filed Feb. 15, 1979; Appl. No. 12,336; 9 claims.)

Inflatable Supports: Aubrey E. Corbett, Siu L. Ho, and Ronald J. Clark, assignors to Glynwed Group Services Ltd., Birmingham, England. A ripple bed helpful in preventing bedsores is described. It consists of upper and lower inflatable layers and a source of controllable compressed air. The upper layer has separate air passages independently inflatable and deflatable for the rippling effect. It may include air bleed apertures for evaporating moisture and cooling the patient. The lower layer is separately inflatable to support any area of the upper layer which is deflated. (Patent No. 4,225,989, Oct. 7, 1980; filed Oct. 5, 1978; Appl. No. 948,798; 9 claims.)

Insert Travel Chair and Method of Transporting the Handicapped: Frederick L. Day. The chair width is normally between only 12 and 16 inches. The chair and occupant can be transferred from an automobile, bus, or plane, pushed down an auditorium or theatre aisle and, by unlocking and dropping the back of the chair, transferred to an assigned seat. It may also be inserted in a conventional chair or wheelchair. The front wheels are easily removed and the chair folds compactly for storage. A head restraint is provided. (Patent No. 4,229,039, Oct. 21, 1980; filed Sept. 11, 1978; Appl. No. 941,253; 28 claims.)

Method for Recording the Walking Ability of an Individual: David F. Webster. A continuous form of multiple sheets is described, the top sheet blank, the middle an inking element, and the bottom an ink receiving element. The top and bottom sheets are moisture-resistant. Laid on a floor or other firm surface, the form permanently records the footprints of an individual walking on it, e.g., a stroke patient or a drug or alcohol user. In the case of a patient, the method may be repeated at intervals to record recovery progress. (Patent No. 4,228,599, Oct. 21, 1980; filed Sept. 28, 1978; Appl. No. 946,769; 4 claims.)

Method of Measuring Blood Perfusion: Arye Rosen, William P. Santamore, assignors to RCA Corporation, New York, New York. As a means of determining if tissue is normal or ischemic, the method measures temperature decay in a given volume of the tissue which has been heated by microwaves of known rate,

amplitude, and frequency. The procedure may be used to determine the rate of flow of any fluid used for diagnostic purposes moved or moving through a volume of tissue. (Patent No. 4,228,805, Oct. 21, 1980; filed Nov. 8, 1978; Appl. No. 958,605; 4 claims.)

Orthopedic Device: Renald A. Cote. An improvement in the treatment of congenital and acquired deformities of children's legs and feet is claimed. The device consists of two foot plates on either end of an adjustable bar, and a pair of children's shoes. A fastener such as Velcro connects the shoes to the plates. The assembly allows continuous adjustment of the shoes (as opposed to incremental adjustment), easy positioning of the shoes on the plates, and quick removal of the shoes from the plates if necessary. Indicia on the plates enable exact repositioning of the shoes. (Patent No. 4,230,103, Oct. 28, 1980; filed Nov. 30, 1978; Appl. No. 966,192; 7 claims.)

Portable Therapeutic Water Massage Mechanism: Donnie R. Lindsey. The device consists of a pump, an electric power control switch, and several nozzles fitted along each of two conduits placed ordinarily on the bottom of a conventional tub near the tub walls. The nozzles create turbulence, using water pumped from the tub, and may be adjusted to direct jets of water selectively, e.g., to the ankles or feet. An in-line heater may also be used to maintain optimum therapeutic water temperature. For travel, the invention can be disassembled and packed in a luggage-size container. (Patent No. 4,225,984, Oct. 7, 1980; filed Apr. 5, 1979; Appl. No. 27,526; 10 claims.)

Pressure Sensor: Warren C. Lyon and William H. Hayes, Jr., assignors to Hittman Corporation, Columbia, Maryland. The sensor transmits pressure data from a body cavity to minimal reading equipment outside the body without lead wires or tubes. It employs radioactive material in movable shielding. The shielding is connected to a bellows and moves with the reaction of the bellows to sensed pressure. Made of biologically-inert materials, the device is fully implantable and, using long-lived radioisotopes, can be left in place for the patient's lifetime. The radiation dosage is negligible. The device is said to be accurate to within several millimeters of water pressure and unaffected by ambient temperature variations. (Patent No. 4,231,376, Nov. 4, 1980; filed Aug. 7, 1978; Appl. No. 931,526; 8 claims.)

Surgical Immobilizing Bandage and the Like: Koji Usukura, assignor to Tokyo Eizai Lab. Co., Ltd., Tokyo, Japan. The bandage is formed of an elastic base material, such as tricot or rubber-threaded fabric, impregnated with an immobilizing preparation. It becomes soft and adhesive in hot water (50° to 100° C.) and can be deformed by partial heating. Other desirable features named are: excellent molding properties, durability, water resistance, lightness, and X-ray transmittance. (Patent No. 4,231,356, Nov. 4, 1980; filed Oct. 25, 1978; Appl. No. 954,467; 7 claims.)

Training Apparatus for Visually Impaired Person: James D. Hajduch. The apparatus enables a visually impaired person to improve his use of a cane, his mobility, and self-confidence without a sighted supervisor in attendance. It employs two light beams in parallel, each aligned with a photo-electric cell, and a special cane. The trainee walks between the beams, using the cane. If he veers from a substantially straight line a light beam is interrupted and an audio signal tells him which side he has veered to. Running may also be practiced. (Patent No. 4,212,116, Jul. 15, 1980; filed Feb. 5, 1979; Appl. No. 9,740; 10 claims.)

Vehicle Control System for the Handicapped: Robert J. Appley. The device enables a wheelchair occupant, who may lack normal hand and/or arm dexterity, to drive a motor vehicle. A unique hand system controls both the braking and throttle functions by a single lever. The driver pulls the lever toward himself to move the vehicle and pushes it away to brake or stop. Body momentum also aids the braking function. The lever may be shaped to accommodate particular hand and/or arm handicaps. (Patent No. 4,228,865, Oct. 21, 1980; filed Aug. 7, 1978; Appl. No. 931,613; 4 claims.)

Viscous, Flowable, Pressure-Compensating Fitting Compositions Having Therein both Glass and Resinous Microbeads: Jack C. Swan, Jr., assignor to Hanson Industries Inc., Boulder, Colo. Composed of microbeads and suitable waxes and oils, the material is lightweight and has low density. Used in envelopes as fitting pads, or with or without envelopes in cavities of such articles as medical devices, orthopedic and prosthetic appliances, footwear (e.g., ski boots), hand grips, and cushioning structures, it provides comfort, support, and protection against pressure, impact, and shock. The material's properties may be altered for particular uses by varying the proportions of the ingredients, or by adding ingredients such as oil-soluble soaps. (Patent No. 4,229,546, Oct. 21, 1980; filed Jul. 27, 1978; Appl. No. 928,563; 39 claims.)

Wheelchair: Gene B. Shaffer. The device moves a handicapped occupant from sitting to standing and vice versa, without assistance. The movement causes the occupant no anxiety because the lever system is designed to move his legs, seat and torso coordinately. A single switch controls electric power. Reliability, relative simplicity, and low cost are also featured. (Patent No. 4,231,614, Nov. 4, 1980; filed Oct. 27, 1978; Appl. No. 955,391; 17 claims.)

[a]Patents may be ordered by number from the Commissioner of Patents, Washington, D.C. 20231, at 50¢ each.

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Standardization

INTERNATIONAL PROGRESS ON WHEELCHAIR STANDARDS, THE NORTH AMERICAN CONTRIBUTION

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Background

Standards writing is an effort to bring some uniformity of understanding to the diverse points of view of the manufacturer, the researcher, and the user of a product. The potential benefits include: (i) improvement in quality and reduction in cost, (ii) avoidance of duplication in testing, and (iii) improvement in communication and problem-solving.

In this country, the Veterans Administration has played a major role in developing a uniform approach to the specification and selection of rehabilitation devices. In 1968, the VA finished development and published a set of standard test methods to be used in selection of manually propelled wheelchairs. For several years thereafter, other agencies and individuals concerned with the purchase of wheelchairs looked to the VA standard for guidance in making their selections. The VA has recently completed a draft standard for electrically powered wheelchairs which will probably serve also as a model document for other agencies.

In 1974, the American Society for Testing and Materials (ASTM) formed the Committee on External Prosthetics, Orthotics and Mobility Aids (designated Code F–19). The ASTM is an internationally recognized organization which manages the development and publication of voluntary consensus standards. Recognizing the need for a consensus format relating to wheelchair standards, ASTM F–19 elected to begin a process of standards development which could be offered to the Food and Drug Administration for consideration.

In September of 1978, ASTM F–19 assembled a group of persons with broad-ranging knowledge and experience to conduct in-depth review of the 1968 VA standard on manual wheelchairs. The purpose of that review was to determine the general applicability of the VA standard toward the perceived needs of the non-veteran population. A report of that meeting was submitted voluntarily to the VA (1). Then in December of 1979, the ASTM group reconvened at the Wheelchair II conference (2), to discuss a plan of action for the development of more generally applicable standards for all forms of wheelchairs used in the public arena. That group recommended the following three-pronged approach to standards development—

1. Design a **classification system** for wheelchair products according to use pattern and user size.

2. Conduct an objective **site visit** to the facilities of American wheelchair manufacturers to observe the methods currently being employed for product quality assurance and response to service problems.

3. Collect **service data** from recognized wheelchair service facilities across the country to determine the most frequent forms of wheelchair and wheelchair component breakdown.

Early in 1980, the Canadian Standards Association (CSA) recognized the efforts of ASTM and invited a joint meeting to pool the Canadian and American efforts toward wheelchair standards development. At a meeting in Toronto in June of 1980, the two organizations agreed to cooperate and share resources for wheelchair standards development and to send delegates to a subcommittee meeting of the International Standards Organization (ISO) which was working to develop international wheelchair standards. In early October of 1980, Subcommittee (SC) 8 (Wheelchairs) of Technical Committee (TC) 136 (Hospital Furniture) met in West Berlin and was joined by the official Canadian representative and two official visitors from the United States.

International Standards Organization

ISO is an international body based in Geneva, whose representation is made up of the official standards-setting agency of each of the member countries (3). In the United States, that organization is the American National Standards Institute (ANSI). ANSI assigns its expert representation for each area of specialization to a Technical Advisory Group (TAG). The designated TAG in this country, for TC136, had no interest in standards activity relating to wheelchairs. Consequently, ANSI authorized two representatives to attend the ISO meeting as non-voting observers: Sam McFarland, the author, representing ASTM; and Keith Rodaway, Everest and Jennings, representing manufacturing interests in the United States.

The meeting of TC136/SC8 was held at the German Standards Institute (DIN) in West Berlin on October 2–3, 1980. Designated representatives to the sub-committee are listed in Table 1. Representation on TC173/SC1 will continue to be the same as on the former TC136/SC8. There were two key business items. First were the reports from the Working Groups (WG) and action on their recommendations. Second, and equally as important, was the vote to transfer the activities related to wheelchair standards from TC136 to TC173, Technical Systems and Aids for Disabled or Handicapped Persons, which had been formed in late 1979. It was announced at this meeting that future efforts toward wheelchair standards development would be conducted under Subcommittee 1 of TC173, and that the directorate for the subcommittee would continue to be Sweden (SIS). The chairman of former TC136/SC8, now TC173/SC1, Mr. S. Holmstedt from Sweden's Handikappinstitutet, was re-elected to another 3-year term of office.

All of the ISO work in drafting and revising drafts of wheelchair standards documents is carried on in specific working groups. Three working groups reported to the subcommittee their activities of the year.

1. **WG 1—Test Methods for Wheelchairs** is chaired by the

TABLE 1
Representation to ISO/TC136/SC8[1], Berlin, West Germany, October 2–3, 1980.

Country	Agency	Membership[2]
Sweden	Swedish Standards Institute (SIS)	P
France	Association Francaise de Normalization (AFNOR)	P
Denmark	Dansk Standardiseringsvaad (DS)	P
Netherlands	Nederlands Normalisatie-instituut (NNI)	P
United Kingdom	British Standards Institute (BSI)	P
Germany, F.R.	Deutsches Institut für Normung (DIN)	P
Canada	Canadian Standards Association (CSA)	P
United States	American National Standards Institute (ANSI)	O
Japan	Japanese Industrial Standards Committee (JISC)	O

[1]The same representation will continue on ISO/TC173/SC1.
[2]P—Participating (voting)
O—Observing (non-voting)

representative from the United Kingdom Department of Health and Social Services (DHSS), Mr. Eric Burnett. Much of the work under consideration by this group was drawn from extensive test methods developed by the British DHSS. However, significant contributions toward testing procedures were offered by the German and French delegations, each of which has its own functioning test methods.

2. **WG 2—Type Classification of Wheelchairs** is chaired by Ake Hansson, Swedish vendor. Not unlike the American model proposed by ASTM, the Swedish delegation has fostered a classification scheme based on a combination of chair size, user size, and use pattern. A significant contribution has been made to this effort by a member of the Dutch delegation (GMB) (4) which has, like the Veterans Administration in this country, a standards development and purchasing specification authority under the government of the Netherlands.

3. **WG 4—Dimensions for Transport and Storage** is chaired by Dr. C. P. Dubbelman from the Netherlands and has been responsible for determining the important measurements needed to describe a folded transportable wheelchair. Of course this dimensioning becomes a significant part of the other standards development for classification and test methods. WG 4 has completed its work and the draft standard for dimensioning will be submitted to an exhaustive series of voting procedures designed to achieve ultimately an official document.

Since the October meeting of ISO/TC136/SC8, the Health Industries Manufacturing Association (HIMA) has been assigned as the administrator of the USA TAG to TC173/SC1. The administrator provides a focal point for national effort. The next annual meeting of TC173/SC1 will be November 5–6, 1981, in Zeist, The Netherlands, immediately following meetings of the working groups. The working groups also have met from time to time throughout the year to continue development and preparation of draft standards documents to be submitted to the subcommittee for official debate and revision.

HIMA will be represented by a large delegation at the working group meetings and at the ISO/TC173/SC1 meeting in the Netherlands. In addition to providing direct representation by manufacturers, consumers, and general interest factions, the U.S. delegation will invite the Secretariat to schedule the 1982 meeting in the U.S.

TABLE 2
European Wheelchair Manufacturers

Company	Country
Carters	**United Kingdom**
Everest & Jennings, Ltd.	
Newton Aids, Ltd.	
Rehab Invacare, Ltd.	
Remploy, Ltd.	
Vessa, Ltd.	
Zimmer Orthopaedic, Ltd.	
Deutsche Orthopädische Werke (DOW)	**Germany, F.R.**
Orthopaedia	
Wilhelm Meyer (Meyra)	
Poirier, S.A.	**France**
Annastolen	**Netherlands**
Oostwond	
R. T. C.	
Vermeiren	
Saab (Permobil)	**Sweden**

Resource: Basisboek Voorzieningen
Gemeenschappelijke
Medische Dienst
Bos en Lommerplantsoen 1
Postbus 8071
1005 AB Amsterdam

European Wheelchairs

Table 2 is a listing of major wheelchair brands manufactured and sold in Western Europe. European wheelchairs are not unlike those known to Americans except that use patterns in Europe demand certain characteristic variations. Many wheelchairs, for example, have placed the large drive wheels at the front and casters at the rear because of the need for better indoor and small space maneuverability. Dynamic hand brakes on manual wheelchairs are frequently seen in response to the hilly environment of many European cities. Electric wheelchairs tend to be more elaborate, more expensive vehicles capable of use on village streets and in limited competition with automobile traffic. In keeping with the European love of

bicycles and motorcycles, electric wheelchairs tend to be larger, more powerful, and include such vehicle trappings as headlights, turn indicators and horn. The vast majority of wheelchairs purchased in Europe are provided by government health programs. Thus, government agencies tend to be very active in developing standards and quality assurance tests.

Domestic Standards (Recent Developments)

Now that HIMA has been selected by ANSI to administer the TAG for TC173/SC1, there will be an official focal point for comments and developments on wheelchair standards. Several groups have expressed their interest in the subject and have been officially acknowledged by HIMA. Each group represents a unique point of view, which helps assure that all persons who may be affected by the development of standards will have an opportunity to contribute to that development process.

U.S. Veterans Administration Rehabilitation Engineering Center (VAREC)—Responsible for evaluation and approval of wheelchairs supplied to individual disabled veterans by the VA, VAREC evaluates products available for purchase, sets minimum criteria of performance, writes test methods, performs compliance tests, and maintains an up-to-date perspective on quality assurance measures.

U.S. Food and Drug Administration, Bureau of Medical Devices (FDA)—Mandated by the Medical Devices Amendment of 1976, FDA assembled a panel of experts to classify a vast list of medical devices according to the perceived need for regulatory activity. According to that panel, wheelchairs for chronic users were appropriate candidates for standards development. Whenever possible, FDA will monitor consensus standards development rather than undertake to write its own.

Health Industries Manufacturers Association (HIMA)—Composed of members who manufacture a vast variety of products for medical and home care markets, HIMA represents the capabilities and concerns of the wheelchair manufacturers. In its role as the administrator of the ISO/TC173/SC1 TAG, however, it is constrained by ANSI to operate within strict procedural guidelines which insure a balance of participating viewpoints.

American Society for Testing and Materials, Subcommittee F-19.40 on Mobility Aids (ASTM)—Internationally recognized as an enabler, manager, and publisher of developing standards, ASTM offers an unbiased forum for assuring full consensus input to the standards development process.

Paralyzed Veterans of America, Incorporated (PVA)—The largest single coalition of chronic wheelchair users, PVA is active in its advocacy for assurance and development of improved products and services for disabled consumers.

Rehabilitation Engineering Society of North America (RESNA)—Organized in 1979 to create a forum for rehabilitation professionals who deal with technology, engineering, and assistive devices, RESNA includes wheelchair designers, prescribers, manufacturers, vendors, testers, and users among its members.

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CURRENT TRENDS IN AURAL REHABILITATION IN AUSTRALIA

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July 1980.

The following is a report on a study visit to Australia during the summer of 1980. The study visit was concerned primarily with the system of hearing-aid delivery and supporting audiological services, personnel preparation and research in Australia. The study was supported by a fellowship from the World Rehabilitation Fund under a grant from the Research Services Administration, U.S. Department of Health, Education, and Welfare.

While this account does not focus explicitly on the subject of "Standards" as the subject is usually meant by the heading of this department of BPR, any such thorough description of an advanced nation's manner of dealing with a universal problem makes implicit comparisons with the details of other nations' efforts to do (presumably) as good a job of it. And value judgements based on comparisons are, clearly, the necessary first step in the process that ultimately produces formal, practical standards. Editor.

Background

The National Acoustic Laboratories (NAL) is the major provider of hearing aids and audiological services in Australia. Almost half of the total Australian population is covered by the services offered by NAL. Services provided outside of the NAL framework are heavily influenced by NAL procedures, and in most cases are designed to supplement the services offered by NAL. In order to review current trends in aural rehabilitation it is first necessary to understand relevant aspects of the geographic, demographic, and governmental structure of Australia and how the National Acoustic Laboratories operate.

Australia occupies a land area of just under 3 million square miles with a population of roughly 15 million. The

population density is thus quite low (5 persons per square mile on the average; the corresponding figure for the United States is more than 13 times as large, approximately 66 persons per square mile). More than 80 percent of the Australian population is concentrated in urban areas, most of these being located on the southeastern seaboard. The two major population centers are Sydney in the State of New South Wales (population approximately 3 million), and Melbourne in the state of Victoria (population approximately 2.5 million). Other major cities are Brisbane (Queensland), Adelaide (South Australia), and Perth (Western Australia), each of which has a population approaching 1 million. With the exception of Perth, all of the above cities are within about 600 miles of Canberra, the capital of Australia. Perth is situated on the western coast and is over 2,000 miles away from the other major population centers. Two other major cities are Hobart, the capital of Tasmania (population approximately 200,000) and Darwin, capital of the Northern Territory (population approximately 50,000).

The government has a federal structure. The country is divided into seven states (New South Wales, Northern Territory, Queensland, South Australia, Tasmania, Victoria, and Western Australia). Each state elects its own government which is responsible for internal state affairs; these include education, social services, and certain health services.

The federal government is concerned with national affairs, such as defense, foreign policy, taxes, and various federal authorities such as the Commonwealth Department of Health. The distribution of power between the federal and state governments is similar to that of the United States; services provided by the federal government are often supplemented by state-supported services. The seat of the federal government is Canberra which, like Washington, D.C., is not subject to the jurisdiction of any one state but occupies a small self-governing area, the Australian Capital Territory (ACT).

Despite the vast distances involved, the uneven distribution of population, and the complex interplay between state and federal areas of jurisdiction, the delivery of audiological services in Australia is remarkably good and is reasonably consistent between states. The backbone of this system is the national hearing-aid delivery system developed and operated by the National Acoustic Laboratories (NAL).

The National Acoustic Laboratories is a branch of the Commonwealth Department of Health. Previously known as the Commonwealth Acoustic Laboratories, it was formed immediately after World War II to look after children born following the maternal rubella epidemic in the early 1940's as well as war veterans with hearing impairments. The Commonwealth Acoustic Laboratories developed its own hearing aids and methods of prescribing these aids. A network of hearing centers was established, beginning with a regional center in each state capital and a main research center in Sydney. The centers were staffed initially by psychologists who were then given additional training in audiology. In due course, an audiology training program was established at the University of Melbourne. That program is now the major program of its type in Australia.

The Commonwealth Acoustic Laboratories (which became the National Acoustic Laboratories in 1975) increased steadily in size and scope over the years. A major expansion came in 1968, when pensioners and their dependents were included among those Australians eligible to receive hearing aids and supporting audiological services.

The primary functions of National Acoustic Laboratories (NAL) are—

1. To undertake in hearing, acoustic amplification for the hearing-impaired, and the effects of noise on man;
2. To provide hearing aids and supporting audiological services to eligible Australians; and
3. To provide consultative service to other federal authorities, particularly to the armed services, on noise-related problems.

In order to achieve these objectives, a network of hearing centers has been established throughout the country. In addition, a large central research and engineering laboratory has been established in Sydney. At this center research is conducted on hearing, on acoustic amplification for the hearing-impaired, and on the effects of noise on man. In addition, these researchers work closely with the engineering staff in designing and developing new hearing aids. And as already noted, the research and engineering center also provides consultative services to other government authorities.

The NAL Hearing-Aid Delivery System

The audiological and hearing-aid services provided by the National Acoustic Laboratories are available to all Australians under 21 years of age, to eligible pensioners and their dependents, and to members of the armed services and veterans with service-related hearing impairments. Almost half of the Australian population is eligible for these benefits. Persons not covered are typically working adults between 21 and 65 years of age, who obtain their hearing aids commercially either by direct purchase or through an employee benefit program. Adults not eligible for hearing aids under the NAL system and who are in financial need receive hearing aids under state-supported social welfare programs.

The hearing-aid service provided by NAL includes the initial audiological assessment, prescription and fitting of the hearing aid, followup to monitor effective usage, servicing of the hearing aid and, finally, replacement of the instrument with a technologically more advanced aid after several years (typically, after about 5 years of service). The National Acoustic Laboratories also design and develop their own hearing aids and supervise their production by industry. Two commercial hearing-aid types are used for special cases in which there is a low demand.

The audiological assessment, hearing-aid prescription and fitting, follow-up evaluation, and maintenance of the hearing aids are all performed at hearing centers operated by NAL. There are 27 such centers located in major towns and cities throughout Australia. Since over 80 percent of the population is located in urban areas, these centers are easily accessible to the large majority of the population. A visiting service is provided for persons living in remote areas.

The Four-Appointment System

The method of hearing-aid prescription differs between adults and children. For adults, the process begins with a referral for an evaluation at a NAL hearing center. A four-appointment system is used at present.

The first appointment involves a 45-minute assessment in which basic audiological measurements are obtained, e.g., air and bone-conduction thresholds. From these data a decision is made as to whether a hearing aid would be helpful and if so, which type of aid is likely to be most effective in terms of amplification characteristics and whether the aid(s) should be fitted monaurally, binaurally or CROS. About 95 percent of the prescribed aids are post-auricular and about 1 percent are in-the-ear aids. The balance are body aids. Binaural hearing aids are more likely to be prescribed for children than for adults. Depending on which type of aid is selected, appropriate earmold impressions are made.

The frequency response and maximum power output of the prescribed aid are determined using the method developed by Byrne and Tonisson (1976). Basically, the method is designed to place the spectrum of the amplified speech signal at a comfortable level at all frequencies. Research is currently in progress on refining and extending this procedure.

The second appointment lasts about an hour, during which the hearing aid is fitted and several basic aided measurements are obtained (e.g., aided thresholds). Additional measurements may be obtained if these aided measurements are unusual in any way.

The third session consists of a followup in which the fitted hearing aid is checked. This session is usually fairly brief (½ hour) if no problems are identified. Basic performance measures are used as a check (e.g., aided speech discrimination) but additional tests will be administered if performance is poorer than expected.

The fourth and last appointment takes the form of a group orientation session lasting about 1¼ hours. The group typically consists of six newly-fitted hearing-aid users who describe their experiences with the aid and, with guidance from the audiologist, discuss tactics for measuring the effectiveness of their aids.

A five-appointment schedule is currently being considered (Upfold and Smither, 1981). The major difference between the existing system and the possible new system is that more detailed performance measures (primarily speech tests) will be obtained, coupled with more intense counselling and followup procedures. For example, a questionnaire on how well the hearing-aid user functions at home is being developed. Similarly, methods for training and testing the new hearing-aid user in manipulating the controls of the aid are being considered.

The services provided to children are more extensive than those provided to adults. The basic approach, however, is the same. After a child with a possible hearing problem has been identified (e.g., by an infant screening program), a more detailed audiological assessment is provided in which air and bone conduction thresholds and other basic measurements are obtained using techniques appropriate for the child's age (e.g., play audiometry, conditioned-response methods). From this information a hearing aid is selected, using either the Byrne and Tonisson (1976) approach or the Byrne (1978) method for severely hearing-impaired children.

The followup procedures for children depend on the age of the child. They are most extensive for very young children. Typically children under 11 years of age are seen 1 month after the initial fitting and then at 6-month intervals. The NAL center also provides counseling to the parents and some habilitative training to the children.

The number of hearing aids fitted each year by the National Acoustic Laboratories is substantial. During the year ending June 30, 1980, some 28,000 Australians were fitted with hearing aids. Of these, roughly 9,000 were binaural fittings requiring two instruments. The total number of hearing aids provided by the National Acoustics Laboratories is thus roughly 37,000 instruments per year. Of these, approximately 6,000 are fitted to children (primarily binaural fittings), 25,000 to pensioners, and 6,000 to veterans. In addition, a small number of hearing aids (about 200) are fitted to federal employees. A more detailed breakdown of the number of hearing aids fitted during the period July 1979 to June 1980 is shown in Table 1. The upper half of the table shows the number of new cases examined, the lower half shows the number of hearing aids fitted. The columns show the breakdown by state; the rows show the breakdown by user group. The majority of new cases are young children of whom roughly 800 are fitted with hearing aids. The average age of fitting for children is 7 years. Most children with losses greater than 90 dB are fitted by 2 years of age. For the pensioners and veterans there are fewer new cases, but more hearing aids are prescribed. This is because many of the fittings are for replacement hearing aids. (As noted earlier, hearing aids are replaced after about 5 years of service.)

By far the largest number of hearing aids are fitted in New South Wales, which is the most populous state. Victoria and Queensland are the second and third most populous states, respectively. The number of hearing aids fitted in Victoria exceeds that for Queensland by a corresponding amount. In contrast, more children are seen by the National Acoustic Laboratories in Queensland than in Victoria. This difference reflects the greater role played by the state of Victoria in providing state-supported services for the early detection and diagnosis of hearing impairment.

The cost to the National Acoustic Laboratories of fitting a hearing aid is A $167.00[a]. This includes both the cost of the instrument (approximately A $65) and the cost of testing and prescribing the hearing aid. These costs are relatively low compared to those in the United States. The low cost is due in large measure to the size and efficiency of the Australian system. Because of the large number of hearing aids fitted, the National Acoustic Laboratories designs and manufactures its own hearing aids. The engineers responsible for the design of the hearing aids work in close co-operation with researchers involved in basic research on acoustic amplification and methods of prescribing hearing aids. Consequently, the cost of the intrument is low, and the prescriptive fitting procedures are relatively efficient. Typically, a staff member fits about 7 hearing aids per week.

Another positive aspect of this close co-operation between the research, design, manufacture, and prescriptive fitting of hearing aids is that the hearing aids appear to be of high quality, particularly with respect to those qualities which are of importance for effective communication. (Most hearing aids produced commercially place considerable

[a]These figures apply to mid 1980. At the time, A $1.00 was roughly equivalent to US $1.15.

emphasis on cosmetic considerations.) Further, the hearing aids have been designed to facilitate the prescriptive fitting procedure that will be used, with the result that they are relatively flexible in terms of shaping frequency response and controlling maximum power output.

The National Acoustic Laboratories, among its other activities, also maintains detailed statistical records on the incidence of hearing impairment and the fitting of hearing aids. Table 2 shows a typical set of statistics for the State of Queensland. The table shows the number of children under 17 years of age who have been fitted with hearing aids in the state of Queensland as of March 31st, 1980. The rows of the table show year of birth. The columns show, for each year, the number of live births in the state, the age at which the hearing aid was fitted, the total number of children fitted, the rate of fittings per 1,000 live births, the number of cases attributable to maternal rubella, the degree of hearing loss, and the number of children fitted in the 12-month period ending March 31, 1980.

Regular record keeping of the type described provides a valuable quantitative overview of current trends, the effectiveness of prevention programs, and the impact of specific events such as the rubella epidemic of 1963. Thus, for example, the data show a systematic downward trend in the incidence of hearing impairment, particularly with respect to impairments due to rubella. An analysis of the data also shows that the proportion of children fitted with hearing aids during the first 2 years of life has increased steadily over the years, from less than 10 percent in 1963 to over 30 percent from 1973 on. These figures reflect the impact of a well organized national program of hearing-aid prescription and associated audiological assessment procedures. For additional information on the distribution and use of hearing aids in Australia, see Upfold and Wilson (1980).

State-Supported Services

The hearing-aid delivery and audiological services provided by the National Acoustic Laboratories are supplemented by state-supported programs. These typically involve educational and social services. Thus, the provision of schools and training programs for the hearing impaired vary between the states, as do hospital-based audiology services and state-wide screening procedures for the early detection of hearing impairments.

State-supported services for the hearing impaired vary widely between the states. A good idea of the extent of this variation, and how the states supplement the services offered by the National Acoustic Laboratories, can be obtained by comparing supplementary services provided by the states of Victoria and Queensland, respectively. These two states have been chosen for this comparison since Victoria probably provides the most extensive supplementary services—whereas Queensland provides the least.

Victoria vs. Queensland: a comparison—the state of Victoria, for example, provides hospital-based audiological services, community health centers which provide audiological screening as well as full audiological assessments, and infant welfare centers which provide audiological screening, among other services. Children who

TABLE 1.
New Cases Examined and Hearing Aids Fitted by NAL for 1979/80

NEW CASES EXAMINED

		NSW & ACT	VIC	QLD	S.A. & N.T.	W.A.	TAS	AUST.
Persons under 21 yrs	(a)	9,257	4,989	5,392	1,881	1,482	1,153	24,154
Pensioners	(b)	5,804	3,749	2,677	1,708	1,102	638	15,678
Veteran's Affairs	(c)	1,194	926	556	477	428	222	3,803
Others		728	311	849	291	151	130	2,460
TOTAL		16,983	9,975	9,474	4,357	3,163	2,143	46,095

HEARING AIDS FITTED

Persons under 21 yrs	(a)	2,143	1,560	964	632	426	166	5,891
Pensioners	(b)	10,783	5,574	3,744	2,251	1,563	739	24,654
Veteran's Affairs	(c)	2,410	1,362	808	602	712	235	6,129
Others		82	48	26	18	26	2	202
TOTAL		15,418	8,544	5,542	3,503	2,727	1,142	36,876

(a) All persons under 21 years of age included in this category irrespective of referral.
(b) Pensioners and their dependents are defined in the National Health Act.
(c) Persons referred by Department of Veteran's Affairs.

Abbreviations
NSW = New South Wales
ACT = Australian Capital Territory (Canberra)
VIC = Victoria
QLD = Queensland
S.A. = South Australia
N.T. = Northern Territory
W.A. = Western Australia
TAS = Tasmania
AUST = Australia

FIGURE 2—*Children fitted with hearing aids in the State of Queensland: details of deaf children known as at 3.31.81*

Year of Birth	No. of Live Births	Age at Fitting in Months							Total Fitted	Rate per 1000	Rubella	3 Freq. Avg. H'L			Number fitted in last 12 months
		0-2 12	3-5 12	6-8 12	9-11 12	12-14 12	15-17 12	18-23 12	24+ 12	Unknown				≤60 dB	61-90 dB	91+	
1963	35,934			1	1	2	2	3	99		108	3.01	8	73	19	16	2
1964	34,972		1	5	4	12	10	21	195		248	7.09	128	115	66	67	4
1965	33,551				2	2	4	6	146		160	4.77	22	107	33	20	9
1966	32,843			3	5	3	3	5	92		111	3.38	34	62	26	23	8
1967	34,692				7	4	8	3	120		142	4.09	36	75	35	32	9
1968	35,190		2		3	2	1	1	109		117	3.32	11	83	15	19	6
1969	36,576		4	5	9	6	11	11	112		147	4.02	43	74	30	43	10
1970	37,530		3	10	6	5	4	17	107		152	4.05	45	75	41	36	5
1971	39,971	1	5	3	3	3	6	4	107		132	3.30	28	73	38	21	11
1972	39,251	1	3	2	1	1	3	5	78		94	2.39	4	62	22	10	5
1973	38,067			5	2	2	3	9	46		67	1.76	17	28	18	21	8
1974	37,904		2	3	1	5	5	8	44		68	1.79	8	29	19	20	12
1975	36,402	1	1	1	4	5	8	7	30		57	1.57	19	16	18	23	10
1976	35,246			2	4	3	6	10	26		51	1.45	15	10	16	25	12
1977	34,963			2	2	3	4	4	9		24	0.69	5	7	4	13	12
1978	34,620			1	3		2				6	0.17	0	1	2	3	3
1979	27,162 To Sept.		3	2	1						6	0.17	0	1	4	4	6
1980																	
TOTAL	613,927	3	18	46	53	61	75	114	1320		1690	2.75	423	891	403	396	133

fail screening tests are typically referred by their family doctor to ENT specialists or hospital-based specialists. In regional hospitals with audiologists on staff, children assessed with a social handicap loss may be referred to the hospital ENT specialist before referral to NAL for prospective hearing-aid fitting. There are, in addition, many children who are referred directly to NAL hearing centers. These referrals may come from medical sources (most frequently pediatricians) as well as other sources, including self-referrals.

Infants who fail the Infant Welfare tests, carried out by Nursing Sisters, are referred increasingly to Victorian Health Commission Audiologists for secondary assessments. If a child is found to have a potential hearing-aid loss he is then referred directly and quickly to a NAL Hearing Centre. The family doctor is still the anchor in the overall continuous Hearing Health Care and is kept fully advised.

Initial counseling is provided to the parents and an ascertainment committee is notified. The main metropolitan ascertainment committee consists of an educational psychologist, an ENT specialist and a speech pathologist. The committee has the power to co-opt other examining professionals who may be of help in the ascertainment process. Regional ascertainment committees are of similar structure and in recent years greater use has been made of speech pathologists and audiologists, when appropriate.

The role of the ascertainment committee is to review the child's situation and recommend placement, e.g., at a special school or nursery. Reports and opinions are obtained from all relevant examining and other sources prior to a decision being made. The ascertainment committee works closely with the parents on post aid-fitting care, and provides long-term guidance and help in placing the child in an appropriate school. This system of providing the family with individualized long-term advice and guidance is modelled on the Manchester or Ewing-type approach.

The schools for the deaf and special units in regular schools are well staffed and well equipped. Auditory training is supported by the Department of Social Security whereas the hearing aids and technical services are provided by the National Acoustic Laboratories. There is a close liasion between the NAL hearing centers and the schools for the deaf.

In Queensland, the identification of hearing impairment in young children is left primarily to otologists and audiologists based on referrals from pediatricians, family members, and others in direct contact with the child. Once a hearing impairment has been identified, the child is sent to a pre-school for the hearing impaired. The pre-school will accept hearing-impaired children of any age. Once the child has been accepted, a decision is made as to the extent that the pre-school can be helpful and how often the child should be seen. The parents are also advised regarding the child's subsequent schooling. The pre-school is usually staffed by teachers, speech therapists, and physiotherapists. In at least one case (the main pre-school in Brisbane) staffing includes occupational therapists as well. There is a pre-school in each major town. There are two such units in Brisbane, plus an additional parochial unit which follows the cued speech philosophy.

The decision as to where to place a school-age child is

made by the parents on the advice of a guidance officer from the Special Education Branch of the State Education Department. The recommendations are reviewed regularly and are based on assessments from teachers and others on the child's intelligence and rate of progress in the child's current setting. A hearing-level criterion is not used.

The choice in placement is typically between a school for the deaf, a regular school with a special unit for the hearing impaired, or integration into classes of normal-hearing children in regular schools which do not have a special unit. Those who are attending regular schools include a signficant number of severely deaf children as well as many with lesser degrees of impairment.

Hearing-impaired children who attend regular schools receive support from the State Education Department Advisory Visiting Teachers for the Hearing Impaired. The visiting teachers are based all over the state, with more of them concentrated in areas of greater population.

The state-supported schools for the deaf follow the Total Communication philosophy of education. The special units at regular schools typically follow the Oral philosophy. The Cued-Speech approach has been adopted in at least one parochial unit.

Queensland thus provides fewer state-supported services than Victoria, although the basic services are provided. Perhaps the most important difference is the network of screening services available in Victoria for the early detection of hearing impairment. It is probably because of this difference that there is much greater use of the NAL hearing centers for the detection of hearing impairments in Queensland. As shown in Table 1, the ratio of number of new cases examined to number of hearing aids fitted is considerably higher in Queensland (for persons under 21 years of age) than for any other state.

The services offered by the states and by NAL complement each other rather well, although there are more support services offered in some states than in others. A potential problem is that if resources become more restricted, any reduction of services offered by NAL will be felt especially keenly in those states with a less well-developed network of state-supported services.

Preparation of Professional Personnel

The major training program for audiologists in Australia is run by the Department of Otolaryngology at the University of Melbourne. Audiology is taught as an area of specialization at the postgraduate level. A bachelor's degree in a related scientific area (e.g., psychology, physics) is a prerequisite. The 1-year, full-time training program leads to the Diploma in Audiology, but the student can continue for a Master of Science in Audiology.

The course covers six subjects: audiology, acoustics, anatomy and physiology, biophysics, otolaryngology, and psychology. Audiology, being the largest component of the training program, is subdivided into seven units: general audiology, geriatric audiology, educational audiology, hearing aids, industrial audiology, pediatric audiology, and speech and language. The topics covered by these units are as follows:

General Audiology: Pure tone audiometry, masking, speech audiometry, differential diagnosis of deafness, impedance audiometry, non-organic hearing loss, evoked response audiometry, brain-stem audiometry, central auditory problems, history taking and clinical examination, interpretation of results, ethics, psycho-acoustics, and instrumentation and calibration.

Geriatric Audiology: The aging process, hearing aids for the elderly, aural rehabilitation, speech reading, clinical assessment of the elderly and presbycusis.

Educational Audiology: Psychology of deafness, role of the family, the deaf child at home and at school, parent guidance, auditory training, educational guidance and school placement, vocational guidance for the deaf, hearing aids for home and school, language assessment in the classroom, educational management of the hearing-impaired child, the multiple-handicapped deaf child and sensory approaches to speech and language development.

Hearing Aids: The design and operation of hearing aids, hearing-aid characteristics, selection and evaluation of hearing aids, binaural listening, hearing aids for home and school, counseling and aural rehabilitation, and the rationale for hearing-aid fitting.

Industrial Audiology: Instrumentation, noise abatement, hearing conservation programs, acoustic trauma, hearing handicap, noise and communication, and medico-legal aspects.

Pediatric Audiology: Development of the infant and young child, emotional and social development of children with impaired hearing, causes of deafness, hearing assessment in infants and children, registers of those at risk, genetics, communication disorders and auditory information processing, mental retardation, cerebral palsy, autism and psychoses, central language disorders, psychogenic deafness, deprivation, and the multiple-handicapped deaf child.

Speech and Language: Anatomy, physiology, pathology of the vocal tract, acoustic phonetics, linguistics, psycholinguistics, normal speech and language development, language of the deaf child, speech pathology, and rehabilitation.

Each of the above units involves between 20 and 30 hours of lectures, demonstrations, and clinical work. Each student is required to attend roughly four ½-day clinical sessions per week. Clinical experience is provided at several locations, including the Royal Victorian Eye and Ear Hospital, the Royal Children's Hospital, the State Health Department, and the National Acoustic Laboratories. Each student's clinical work is assessed during training and by clinical examinations in general audiology and pediatric audiology; the latter also involves assessment in aural rehabilitation.

The seven units in audiology comprise about 60 percent of the curriculum. The remaining five subjects deal with the scientific and medical underpinnings of audiology and are made up of 1 unit each. Each unit involves between 20 and 30 hours of lectures plus additional demonstrations and practical work. The topics covered by these supporting units are as follows:

Acoustics: Wave motion and vibrations in gases, liquids and solids, sound absorption and reflection, acoustical impedance, room acoustics, sound fields and noise, the measurement of sound, and psychoacoustics.

Anatomy and Physiology: Anatomy of the ear, the

histology and ultrastructure of the inner ear, middle ear function, cochlear physiology, psychoacoustics, vestibular neuroanatomy, auditory and vestibular neuro-physiology.

Biophysics: Instrumentation, electroacoustical transducers, basic electronics, electrical safety, data acquisition and processing in biology.

Otolaryngology: Pathology of the ear, methods of clinical examination, diseases of the external ear, diseases of the middle ear, diseases of the inner ear, congenital deafness, otosclerosis, presbycusis, acoustic neuroma, Meniere's disease, vestibular disorders, otoneurology.

Psychology: Cognitive development, personality, neuropsychology, psychophysics and the rehabilitative counselling of the sensorily deprived.

In addition, a course in basic statistics is required for those candidates without training in statistics. Students who meet this requirement take an advanced unit in communication disorders.

TABLE 3.
The Bachelor of Speech Therapy Course; subject codes and credit point values of courses

Year 1

SUBJECTS	C.P.V.	Semester
Anatomy	20	Y[a]
Linguistics IA	10	1
Linguistics IB	10	2
Psychology IA	10	2
Psychology IB	10	1
Psychology IC	5	2
Speech Pathology & Therapeutics (1)	15	1
Speech Pathology & Therapeutics (2)	13	2
Total Credit Points	93	

Year II

SUBJECTS	C.P.V.	Semester
Mammalian Physiology I	10	1
Mammalian Physiology II	10	2
Advanced Neurophysiology	3	2
Applied Psycholinguistics	10	1
Experimental Design and Anaylsis	10	2
Acoustic and Practical Phonetics	10	1
Speech Pathology & Therapeutics (3)	10	1
Speech Pathology & Therapeutics (4)	10	2
Clinical Practice[a]	18	Y[a]
Total Credit Points	91	

Year III

SUBJECTS	C.P.V.	Semester
Medical Specialties (STIII) 1	10	1
Medical Specialties (STIII) 2	10	2
Psychology electives[b]	15	1;2
Audiology (1)	12	1
Audiology (2)	12	2
Language Learning Disorders (1)	12	1
Language Learning Disorders (2)	12	2
Speech Pathology & Therapeutics (5)	10	1
Speech Pathology & Therapeutics (6)	10	2
Clinical Practice[a]	23	Y[a]
Total Credit Points	126	

[a]Extends into vacation period.
[b]A candidate must obtain credit for 15 credit points of advanced Psychology subjects, approved by the Head of the Department of Speech and Hearing. All students must have a minimum of 60 credit points taken in the Department of Psychology over the three years of the Speech Therapy Course.

Training in speech and language pathology (still referred to as speech therapy in Australia) is, for the most part, provided by colleges of advanced education. Queensland is the only state that provides university-level training in speech therapy. The Department of Speech and Hearing at the University of Queensland offers an undergraduate program leading to the Bachelor of Speech Therapy Degree. The department also offers a postgraduate course in speech therapy and audiology leading to the postgraduate Honours degree. Students can also continue for Master's and Doctoral level degrees.

The course work in speech and hearing at the University of Queensland covers relevant areas in several disciplines including psychology, physiology, and linguistics. A summary of the courses for the Bachelor of Speech Therapy degree is given in Table 3. Two-thirds of the courses shown (plus clinical practice) are in the area of speech and hearing. The remaining courses are equally divided between linguistics, physiology and medically-oriented courses (1 in anatomy, and 2 interdisciplinary medical courses).

Clinical experience is obtained by placement in clinics under the supervision of senior clinicians. The level of clinical training is systematically increased over the period of study. The amount of clinical training varies between the programs. At the University of Queensland, for example, the course in clinical practice is taken for four consecutive semesters, including portions of the intervening vacation periods. On completion of the training program the new graduate is expected to obtain additional full-time clinical experience before being considered a fully trained professional.

Training programs typically work in cooperation with several different clinics in order to provide their students with a broad range of clinical experiences. These include hospital clinics, child welfare centers, and both state and federal health centers.

The National Acoustic Laboratories (NAL), because of its large network of hearing centers, plays a major role in providing clinical training facilities. The cooperation between NAL and clinical training programs is mutually beneficial. NAL assists in providing clinical experiences to students in training and is the major employer of the graduates of these programs. The programs, in turn, are cognizant of the needs of the National Acoustic Laboratories and have geared relevant portions of the curriculum towards those needs.

In summary, the training of professional personnel in audiology and speech pathology is strongly interdisciplinary with a distinct emphasis on psychology. This approach is not very different from that at several leading speech and hearing programs in the United States where students in speech and hearing take a minor in either psychology or linguistics. In contrast to the American model, there is a marked disparity between the academic status of audiology and that of speech pathology. Audiology is accorded university status and is taught at the postgraduate level. In contrast, training in speech therapy (as it is called) is typically provided at colleges of advanced education. The gap between the two fields is gradually being narrowed and in one state (Queensland), it is now possible to study speech therapy at the university level. The program at the University of Queensland, which is the first of its type, has many similarities with the American model.

Research on Acoustic Amplification, Audiological Techniques, and Innovative Prosthetic Aids.

Two major research efforts on prosthetic aids for the hearing impaired are currently in progress in Australia. The National Acoustic Laboratories is concerned with research and development on conventional hearing aids, and the University of Melbourne has a major ongoing project on the development and evaluation of a cochlear implant prosthesis.

The research effort at the National Acoustic Laboratories covers three broad areas: hearing, acoustic amplification for the hearing impaired, and the effects of noise on man. The second of these three areas was of primary interest in the study visit. The NAL group most directly concerned with research on acoustic amplification for the hearing impaired and on associated audiological procedures is the Audiology Development Section under the direction of Mr. Denis Byrne. This group is currently working on hearing-aid selection procedures, the validation of these procedures, binaural hearing aids, group amplification systems, and a programmable multi-channel hearing aid.

The work on hearing-aid selection procedures includes the development and refinement of the Byrne and Tonisson (1976) procedure for selecting the frequency-gain characteristic of a hearing aid. The technique requires the measurement of hearing threshold levels from which is estimated the frequency-gain characteristic that will place the speech signal at close to the most comfortable level across the frequency range. The procedure has been extended to the case for severely hearing-impaired children (Byrne, 1978). Refinements and more detailed validation of these procedures are currently in progress. These include an analysis of preferred listening levels for different frequency bands of speech (Christen and Byrne, 1980 a) and the problem of test-retest variability in measuring most comfortable level directly (Christen and Byrne, 1980 b).

A major concern of the National Acoustic Laboratories is whether or not to prescribe binaural hearing aids. Consequently, the Audiology Development Section has engaged in what is probably the largest study yet on the relative advantages of binaural hearing aids (Byrne, 1980). During a trial period of 28 months, approximately 2,500 children were fitted with binaural hearing aids. The children were seen routinely at one month and 6 month intervals after fitting. The information obtained on each child included: a case history (e.g., onset and cause of deafness, stability of hearing levels, other handicaps); aided thresholds (left, right, binaural); history of hearing-aid experience; details of current hearing-aid use (e.g., settings normally used, and measured gain at these settings for selected frequencies); and questionnaire information from the parents on the child's acceptance of the hearing aids and the degree of benefit observed. In addition to the field trials with children, just over 100 hearing-impaired adults participated in several experiments designed to measure a binaural summation, auditory localization, and speech discrimination with binaural hearing aids.

The results of these studies showed a consistent pattern of improvement for the binaural over the monaural hearing aid. Binaural summation on the order of 3 to 5 dB was obtained at sensation levels of 10 to 40 dB (Dermody and Byrne, 1975a). A loudness-balance technique with narrow

bands of noise was used. Auditory localization was also found to be superior for binaural as opposed to monaural hearing aids. (Dermody and Byrne, 1975 b). The advantage in auditory localization was found to be greatest at low sensation levels. At higher sensation levels auditory localization with the monaural hearing aid is improved significantly because of the contribution of the unaided ear at these high levels. The studies also showed that the binaural advantage can be obtained with body-worn hearing aids as well as with earlevel aids, provided the microphones are spaced 7 to 10 inches apart.

The study on speech discrimination showed advantages for the binaurally aided case for most subjects. Test-retest variability on speech discrimination tests is relatively high, however, and the binaural advantage is not as easily measured as in the other experiments. A number of incidental advantages of binaural hearing aids were also observed in these experiments. These include the reduction of head shadow and body baffle effects, and the "cross-over" effect. The latter effect applies to the case where one ear is better than the other for certain frequencies only; a properly prescribed binaural hearing aid makes most effective use of the available hearing at all frequencies, thereby allowing the better ear at each frequency to carry the bulk of the auditory input.

The body of data that provided the strongest support for the binaural hearing aid came from the questionnaire studies. These studies show a preference by the majority of users for the binaural hearing aid except under conditions of speech in noise. Similar results were obtained in questionnaire studies involving parents and teachers of deaf children.

An important practical advance (in the Field Service Section) has been the development of a new earmold-impression technique that reduces acoustic feedback significantly (Fifield, Earnshaw and Smither, 1980). An important feature of the technique is that the impression is built up in stages. A primary impression is made using a heavy bodied silicone rubber material. A thin coating of a medium-bodied silicone is then applied to the surface of the primary impression. The impression is re-seated in the ear. The silicone coating, while soft, flows into those regions not forming a good seal between the impression and the canal wall. The material is allowed to set and the seal is tested by increasing the air pressure in the ear canal using the air pump on an impedance meter. A good seal is expected to maintain a maximum pressure of 200 mm water for 5 seconds without any discernible loss in pressure. A third layer is then added, this time using a thin-bodied silicone material. In this way the fine detail of the ear's structure is recorded on the impression.

The work on group-amplification systems has been geared to the refinement and more efficient utilization of radio transmission systems (e.g., in a classroom or lecture hall). A set of practical guidelines has been developed (Christen and Plant, 1976) which provides for immediate improvements in the utilization of existing systems. Techniques for more efficient use and allocation of available transmission channels have also been developed (Burgess, Christen, Donald and Lowe, 1979). The new infra-red transmission systems (Leshowitz, 1979) have recently been introduced to Australia.

Work on a programmable, multi-channel, amplitude-compression hearing aid is currently in progress (Byrne and Walker, 1979). The main thrust of the project is to develop a digitally programmable system in which gain, amplitude compression, and limiting can be controlled independently for each channel and matched to the individual requirements of each user. The system offers advantages not available in conventional hearing aids. It should be particularly useful for sensorineural impairments in which the ear's dynamic range is severely limited by recruitment.

Other ongoing research includes mathematical modelling of the sound transmission characteristics between hearing-aid receiver and eardrum, and the development of a wide-band hearing aid. A conventional hearing-aid receiver is coupled to a miniature acoustic horn designed to extend the high-frequency of the hearing-aid receiver. Bandwidth up to 18,000 Hz can be obtained (Macrae, 1980). Methods of improving sound localization by placing the hearing-aid microphone in the ear, at the entrance to the ear canal, are also being investigated.

Cochlear Implant Study—One of the most exciting ongoing research projects is the cochlear implant study currently in progress in the Department of Otolarnygology at the University of Melbourne. The project, under the direction of Dr. Graeme Clark, has developed a multiple-channel electrode array for insertion in the cochlea (Clark and Hallworth, 1976). Two subjects have been implanted thus far, with good results. Test scores, before and after implantation, show improved speech communication skills with the potential for even greater improvements.

A major strength of the project is the use of 10 independent channels to deliver the coded speech signal. A crucial limitation of previous attempts at developing an effective cochlear prothesis is that, until very recently, only one channel has been used. A single-channel cochlear implant is highly unlikely to produce intelligible speech, since it is well known that the specch signal contains important information in many different frequency bands (Levitt, Pickett, and Houde, 1980). The important question is not whether a single-channel cochlear implant will be effective, but rather how many channels are necessary for an effective implant. The choice of 10 channels by Clark and his research team appears adequate, since intelligible speech can be obtained from a well designed 10-channel Vocoder.

The present electrode array consists of 20 platinum bands around the outside of a silicone rubber tube. Each band is welded to a Teflon-coated platinum wire which passes down the center of the tube. The spacing between electrodes in the array has been designed to produce independent stimulation of adjacent groups of nerve fibers in the cochlea (Clark, et al., 1978).

The array is inserted surgically through the round window (Clark, Pyman, and Bailey, 1979). The unit is stabilized by seating it in a Silastic mold. A receiver coil is placed in a bed created in the mastoid part of the temporal bone. The transmitter coil is placed externally just behind the pinna.

The 10-channel electrode array is stimulated by a coded speech signal. The fundamental frequency of the voice is extracted from the acoustic signal as well as the frequency and energy of the dominant spectral peak in the mid-

frequency range; the latter serves as an estimate of the second formant. The electrodes are stimulated by bipolar pulses. Fundamental frequency is coded as the rate of stimulation. The frequency of the estimated second formant determines which electrode is stimulated (according to the tonotopic organization of the cochlea); the intensity of the spectral peak determines the current level.

The assessment of the cochlear implant includes clinical evaluation of the ear and balance mechanism, radiological evaluation to check for anatomical variations or pathologies prior to and after surgery, a detailed audiological and psychoacoustic evaluation (pre- and post-surgery), and a basic psychological evaluation (Clark et al, 1977, Tong, et al., 1979). The medical, radiological and psychological evaluations showed no adverse effects resulting from the surgery. The audiological and psychoacoustic evaluations showed significantly improved pure-tone thresholds, and an ability to perceive pitch and loudness changes. Subjects were also able to identify differences in vowel spectra, the electrodes being stimulated according to the tonotopic organization of the cochlea.

Results on a word identification task showed significantly improved scores between multiple-channel and single-channel stimulation (48.5 percent vs 15.2 percent), the latter score being typical of that obtained without the implant. After some training, additional improvements were obtained—from a discrimination score of 48.5 percent to 52 percent, averaged over two tests (Clark, Tong, and Martin, 1980). More detailed testing on a variety of speech and psychoacoustic tests is currently in progress.

In summary, the multiple channel cochlear implant developed at the University of Melbourne appears particularly promising. All major aspects of the problem have been taken into account, including the technological problems of creating a suitable flexible array, the signal processing necessary to encode the speech signal in an intelligent way, the physiological problem of stimulating independently separate groups of nerve fibers, the medical, audiological and psychological factors involved in assessing the effect of the implant and, of course, the surgical procedures to implant the device safely.

Great strides are being made in Australia in the development of more effective prosthetic aids for the hearing-impaired. The approaches used and the methods of practical implementation, including the delivery of services, should serve as models for comparable programs in the United States and elsewhere.

Acknowledgement

I am grateful to the World Rehabilitation Fund, Inc., for their support and to the National Acoustic Laboratories for allowing me to spend my study visit with them. I particularly wish to thank Lawrence J. Upfold, Denis Byrne, and their colleagues at the Laboratories for their gracious help and interactions. I am also thankful to Dr. Graeme Clark, Mr. Field Rickards, Dr. Neil Lewis, Dr. P. Murphy, Mrs. Sue Foster, and Mr. William Tonisson for their hospitality and many useful discussions. Acknowledgement is also made to the Department of Speech and Hearing, University of Queensland, for allowing me to reproduce Table 3 from their departmental handbook, to the University of Melbourne, Department of Otolarngology, for allowing me to summarize their course offerings in audiology, and to the National Acoustic Laboratories for reproducing some of their published data (Tables 1 and 2).

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Conference Reports

Conferences sponsored by the VA Rehabilitative Engineering Research and Development Service, or by individual VA Medical Centers in cooperation with VA RER&DS programs, will be reported in this new regular section of the Bulletin. In some cases we hope to publish the complete proceedings of important conferences, when other facilities for timely publication are lacking. In most cases, more brief accounts should be expected, with emphasis on subjects, contributors, and the availability of papers or a "Proceedings".

Conference Title:

INVESTIGATING SPINAL STABILITY—AN ENGINEERING AND CLINICAL WORKSHOP

Loyola University, Maywood Illinois

October 15-18, 1980

The Rehabilitative Engineering Research and Development Service, through the Hines VA Medical Center, sponsored and funded an open forum for free exchange of data, feelings, and questions concerning clinical problems and basic biomechanical and physiological problems in the investigation of spinal stability. John R. Fisk, M.D., assistant professor and co-director of the RER&D Center at Loyola University Medical Center, coordinated the workshop.

Speakers began with an uncertainty of what was desired of them, but were able to generate interesting and profitable discussions. Short presentations were followed by equal time for discussion from the floor. Discussions were informal and allowed to continue in whichever direction seemed most appropriate. There was an opportunity to visit the RER&D Center at Hines VA Hospital, which is in a very exciting development stage.

Presentations were grouped under these headings: Anatomy, Spine Fractures, Acceleration, Biological Material, Instrumentation, Computer, Providing Stability, Implant Testing, Spinal Orthotics, Bony Fusion, and Spinal Injuries.

The titles of the presentations and their authors were: Spinal Stability (Clinical Concerns), **S. Stauffer**; Spinal Stability (Bioengineering Concerns), **A. Schultz**; Structure vs. Motion, **J. Fisk**; Bone Ligament Interface, **R. Little**; Phylogeny of Lower Cervical Spine Fractures and Dislocations, **B. Allen**; X-Ray Versus CT Scanning in Evaluation of Spinal Trauma, **P. DiMartino**; Biomechanics of Fractures, **J. Mazur**; Seatbelt Injuries, **D. Nagel**; Cephalocaudal Loads, **L. Kazarian**; In Vitro Techniques, **R. Jacobs**; The Canine as an Experimental Model, **K. Metz**; Sheep as an Experimental Model, **G. Lewinnek**; Cadaver Studies in Spinal Stability, **J. Laborde**; Intraoperative Applied Loads, **D. Smith**; Loading Machines for In Vitro Investigation of Spinal Stability, **R. Vanderby**; Transducer Instrumentation, **A. Patwardhan**; The Computer as a Clinical Tool, **D. Smith**; Spinal Modeling and Finite Element Analysis, **R. Brown**; Validity and Future Potentials, **C. Moseley**; Clinical Spinal Stability, **E.S. Stauffer**; Implants Present and Future, **J. Lonstein**; Design Versus Material in the Design of Spinal Instrumentation, **G. Shen**; Laboratory Studies of Spinal Implants, **K. Markolf**; Biomechanics of Implant Utilization, **J. Mayfield**; Comparative Mechanics of Segmental Spinal Instrumentation Versus Traditional, **D. Wenger**; The System Post Time and Stress, **R. Jacobs**; Force Measurements, **T. Stonecipher**; Spinal Stability—Orthotic Design, **M. Carlson**; Orthotic Effectiveness, **J. Mayfield**; Fusion—When and How, **V. Mooney**; Internal Fixation, **J. Lonstein**; Bone Healing, **M. Cole**; Effect of Bony Fusion on the Mobility of Spine, **A. Patwardhan**; Surgical Indications and Contributions, **B. Allen**; Vertebral Body Replacement—Its Clinical Indications and Requirements, **M. Schafer**; Laboratory vs. Clinical Data, **K. Markolf**; Assuring Validity of Test Conditions, **L. Kazarian**.

Proceedings of the workshop will be available from the Continuing Medical Education Office, Loyola University, probably in the summer of 1981.

Notes and News

The Bulletin of Prosthetics Research welcomes contributions to this department. Receipt of clippings, meeting programs listing speakers and titles, or other material that calls our attention to a newsworthy event, will be appreciated.

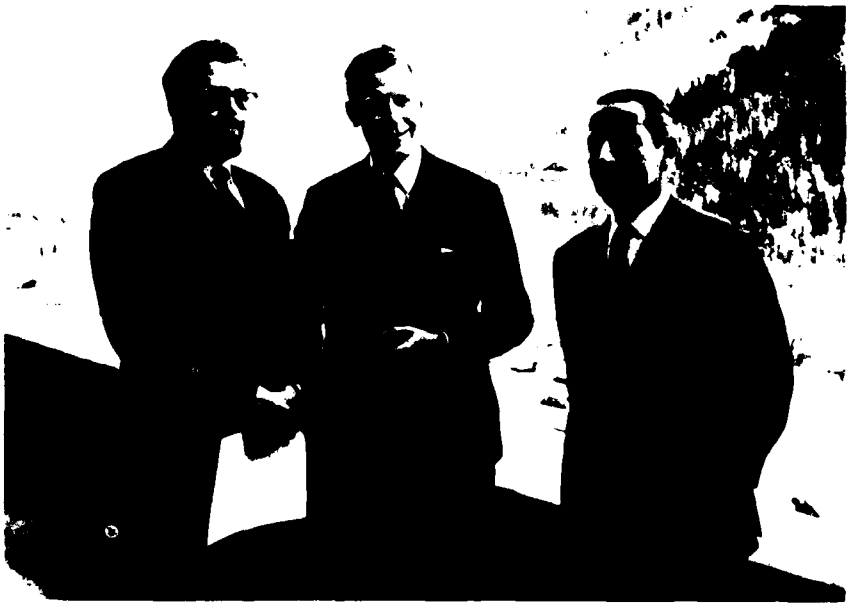
MARIAN WEISS, M.D. 1921–1981

Among one's friends, there are those few individuals who have a certain sense of eternity about them. They radiate a joy of life, a contagious enthusiasm for their work, seemingly boundless energy, a spiritual uplift, inspiration to others. Marian Weiss, M.D., was this sort of person. Because he exhibited a sense of timelessness, it was with unusual sorrow and heartache that we received a telegram from Warsaw on July 20, 1981, notifying us of his unexpected death three days earlier in his beloved city.

Although Dr. Weiss traveled extensively throughout the world organizing, teaching, encouraging and challenging those of us in the field of orthopaedic surgery and rehabilitation, he was best understood and appreciated in his own setting at the great Metropolitan Rehabilitation Center, Konstancin, Poland, in the outskirts of Warsaw. Over the years following World War II he built and developed Konstancin to accommodate 760 patients, many of whom are children. Sitting with him in his spacious office, where by telecommunications he could monitor at any time the activities throughout the entire institution, one could not help but be caught up in the love and enthusiasm with which he worked. He spoke with pride of his and his staff's accomplishments, nonetheless, there was always a sense of impatience, a chafing at bureaucracy, a certain humility engendered by the recognition of so much yet to be done. Marian Weiss was a visionary and a planner, but also a realist who tempered his dreams and his plans by humanitarian pragmatism.

He enjoyed taking visitors on rounds and about the grounds of the institute accompanied by members of his staff. He particularly delighted in spending time with the patients in the gymnasium and with those participating in outdoor recreational activities when the weather permitted. His interest in physical conditioning by therapeutic and recreational exercise was in evidence everywhere. Children with cerebral palsy and scoliosis could be seen riding and training horses. Ambulatory in-patients also carried out well-disciplined routines in setting-up exercises, and by assisting in some of the housekeeping tasks on an organized basis. If the hospital stay involved any length of time, well-planned education was pursued. His patients respected and idolized him; they were comfortable in his presence since he had the happy quality of making each patient feel himself or herself the center of concern. I shall never forget making rounds one day when one of the patients, upon learning that I came from the United States, asked Dr. Weiss to translate to me a personal message to his brother who lives in Chicago. He said "You'll have no trouble finding him, Doctor, for he has the butcher shop there."

Marian Weiss revealed little of his early background and professional life, other than to state that after internment during World War II he returned to Warsaw to face the almost unbelievable physical and human devastation which that bitter struggle had visited on his homeland. He was



Dr. Marian Weiss of Warsaw, Poland, is at left in this photo taken during an "international summit meeting" on lower-extremity prosthetics at Crystal Mountain, Washington, February 6–9, 1966. With him are other active conference participants Knud Jansen (center) of Copenhagen, Denmark, and Pedro Prim of Madrid, Spain.

particularly challenged by the thousands of amputees wandering through Warsaw's rubble without even the most primitive replacement devices. Not only did they have no substitute limbs, but draining infected stumps and severe joint contractures were the rule rather than the exception. As he set about providing for their basic care and rehabilitation, the experience progressively encouraged his innovative mind. Physiological amputation, immediate prosthetic fitting, neurophysical restoration, were his concepts. All were not original—like most of us he built to some degree on the work of others—but his bold imagination, capacity to work, and ability to organize produced striking results.

At a Copenhagen conference in 1963 he startled those attending with a presentation of his amputee work. Many in the international community literally disbelieved his results or wondered if they misunderstood his words. Time has substantiated his veracity—and practice has improved his ability in English. His work has ignited and catalyzed worldwide progress in the field of amputation surgery and prosthetic rehabilitation. That progress continues to this time.

Dr. Weiss' other special professional interests were concentrated on spinal cord injuries, congenital and acquired spinal deformity, and research into electrophysiology. "Weiss springs" for the correction and stabilization of spinal deformity are used throughout the world. In the last 10 years, the surgery and rehabilitation was extended to involve cerebral palsy, muscular dystrophy, and remaining cases with residual effects of poliomyelitis, all from a wide area of referral. The in-patient scoliosis unit at Konstancin as developed by Dr. Weiss and his staff is particularly impressive. All of the distraction equipment for operative treatment is made in Poland, modified from the Harrington techniques. There are very few institutions in which the treatment of deformity is approached in a more holistic way than at Konstancin. One aspect of this approach is contained in a letter from Dr. Weiss, in January of 1980: "I was happy enough to carry within my own institution a comprehensive center for children where I have treatment, social evaluation, professional school, and normal school. Studies on special education program, as well as on professional one are carried on. Our school of special profession education for children is mainly occupied by teenagers in wheelchairs (meningomyelocele, polio, muscular dystrophy, etc.)."

Dr. Weiss' professional work took him to many parts of the world. His influence was appreciated equally in the medically underdeveloped areas as in the most advanced centers of medical knowledge. He was fluent in six languages. When asked how he became such a linguist he said he was too busy to study languages formally but would place language tapes under his pillow at night, turn them on and "learn languages while I was sleeping." An incurable romanticist, he enjoyed music, art, and poetry.

Many of us, his international friends and colleagues, last saw him in Bologna, Italy, in the fall of 1980 at the International Symposium organized by ISPO and INTERBOR. He seemed radiantly happy and in apparent good health, despite serious injuries sustained in an automobile accident in 1977. He had in that same year undergone surgery to his mandible for treatment for a cyst and subsequent pathological fracture. He was married in that same year and was particularly demonstrative at Bologna about his young son, Bartek, whose picture he showed to all around him and whom he obviously idolized.

A Chinese philosopher once said that the parting from a special friend is like a cup half-filled; the loss reflects the unfilled portion, the memories and the joy of association represent that part filled. A totally positive man, Dr. Marian Weiss dreamed, then accomplished. He looked up and reached for the stars—more often than not he grasped them.

Ernest M. Burgess

VA NAMES THOMAS SHIPP, PH. D. AS ONE OF NEW RESEARCH CAREER SCIENTISTS

Among 13 new Research Career Scientists named by the VA in recognition of their achievements as non-clinician doctors engaged in basic research was Thomas Shipp, Ph. D.

Dr. Shipp works in basic and applied research in physiologic and acoustic phonetics. He uses sophisticated computerized instrumentation to describe the process of producing speech sounds. Among applications for this information is help for individuals learning to talk after having had laryngectomies. Dr. Shipp is a member of the Editorial Board of the Bulletin of Prosthetics Research.

DENNIS WYANT RECEIVES AMVETS AWARD

Those honored by the American Veterans of World War II and Korea (AMVETS) in 1981 included Dennis Wyant, former Deputy Secretary of Labor, who received the Rehabilitation Award. Prior to his appointment to the Department of Labor Mr. Wyant was Special Assistant to the Administrator of Veterans Affairs. He is currently Program Analyst, Prosthetic and Sensory Aids Service, VA Central Office. Mr. Wyant is a blinded veteran of the Vietnam Era.

A MANUAL FOR BELOW-KNEE AMPUTEES

A concise illustrated manual, intended to assist individual below-knee (or Syme) amputees, has been prepared and privately published by Alvin L. Muilenburg, a prosthetist, and A. Bennett Wilson, Jr., an engineer. Both authors have had extensive experience in prosthetics research.

According to the foreword, the objective is to make information readily accessible to "below-knee" amputees, including persons who have had Syme's amputation. The amputation, immediate post-operative period, bandaging, types of preparatory and definitive prostheses, fabrication, training, care of the stump, and maintenance of the prostheses are among the topics presented.

The booklet is available from the authors, P.O. Box 8313, Houston, Texas 77044, at $1.00 per copy, with discounts for quantities of 100 or more.

SECOND ANNUAL MEETING SET FOR BIOELECTRICAL REPAIR AND GROWTH SOCIETY

As a result of the growing interest in the electrical mediation of osteogenesis, chondrogenesis, peripheral nerve repair, regeneration, and other soft tissue effects at the cellular level as well as the clinical level, a new international society, the Bioelectrical Repair and Growth Society, has recently been formed. It provides a forum for clinicians, biological scientists, physical scientists, and engineers who have an interest in the field, through annual meetings and publications. The society has an international membership and broad statutory representation of the disciplines involved.

Its first annual, international scientific meeting was held November 9–11, 1981, in Philadelphia, Pennsylvania. The second annual meeting will be held September 20–22, 1982, in Oxford, England. The third meeting will be held in the United States, and the fourth in Japan.

For futher information regarding membership and annual meetings, or for obtaining copies of the transactions of the first annual meeting, (or of abstracts for the 1982 program) contact:

Nancy A. Thiede, Executive Secretary
Bioelectrical Repair and Growth Society
425 Medical Education Building
36th and Hamilton Walk
Philadelphia, Pennsylvania 19104

VA PERSONNEL HONORED

Inder Perkash, M.D., Chief of the Spinal Cord Injury Service, VA Medical Center, Palo Alto, California, was named to the Chair of Spinal Cord Injury Medicine at Stanford University, Stanford, Palo Alto, California, a post established by the Paralyzed Veterans of America.

The Blinded Veterans Association awarded Certificates of Appreciation to the following VA personnel:

Herbert Rainwater, Director, VA Regional Office, San Diego, California;

Fausto Padilla, Visual Impairment Services Team (VIST) Coordinator, VA Outpatient Clinc, El Paso, Texas;

James Cochran, VIST Coordinator, VA Medical and Regional Office Center, Wichita, Kansas;

Edward Lay, VIST Coordinator, VA Medical Center, Indianapolis, Indiana; and

Walter Needham, Ph. D., Clinical Psychologist, VA Medical Center, West Haven, Connecticut.

The College Federal Council of Southern California presented a plaque to Jim Sheridan (Chief, Corrective Therapy) and Herbert Kent, M.D. (Chief, Rehabilitation Medicine Service) VA Medical Center, Long Beach, California, for furthering cooperation between the Center and California State University, Long Beach, in developing a course for teaching driver training instructors from VA Centers nationwide.

PRESSURE SORE PAMPHLET AVAILABLE

Intended for people affected by partial or total loss of sensation or movement, and their families, an 11-page illustrated pamphlet titled "How to Prevent or Treat a Pressure Sore" is available from:
Rehabilitation Engineering Center
Children's Hospital at Stanford
530 Willow Road, Palo Alto, California 94304

Single copies are free of charge. A cost sheet on prices for large orders is available. Tel. 415-327-4800.

INTERNATIONAL DEAFNESS SYMBOL ADOPTED

The World Federation of the Deaf officially endorsed a graphic design to symbolize deafness at its meeting in Paris, France, in 1980. The symbol in its official form is printed in blue and white. It was conceived by the American Task Force, International Symbol for Deafness, and revised by Jack Weiss Associates of New York.

Some examples of how the symbol may be used are: as a card used in wallet next to driver's license . . . as a symbol shown prior to a telecast captioned or interpreted for the deaf . . . or in TV and movie listings to indicate that a program is captioned or interpreted for the hearing-impaired . . . as a symbol showing a centralized emergency TTY number in telephone directories . . . or on poster cards in airports and libraries designating TTY accessibility. The symbol can be used on road signs near deaf schools or where deaf children play . . . plastic symbol cards to be given to the hotel management so that in the event of fire or other emergency, the deaf person could then be specially notified by the hotel management. A small symbol lapel pin, the size of the NAD lapel pin emblem, was expected to be available.

1981 MIGEL MEDAL WINNERS

Eleanor E. Faye, M.D., George O. Hellinger, O.D., and Martha B. Clifford were the 1981 winners of the American Foundation for the Blind Migel Medal. The awards were made at ceremonies held in New York City on October 22. The date also marked the Foundation's 60th anniversary.

IMMIGRATION SERVICE OFFICIAL HONORED FOR WORK WITH DISABLED

James R. Duell of the Immigration and Naturalization Service received last year the John E. Fogarty Public Personnel Award from the President's Committee on Employment of the Handicapped.

Mr. Duell's efforts resulted in the hiring of more than three times the projected number of disabled people listed under the Immigration central office's selective placement program goals.

Mr. Duell, 34, is a graduate of Mississippi State University.

AAWB AWARDS TO BLASCH, WELSH, AND BLASCH

The American Association of Workers for the Blind included, among its 1981 awards for distinguished service, the Shotwell Award to Donald Blasch, and the Bledsoe Award to the book, Foundations of Orientation and Mobility, which was edited by Richard Welsh and Bruce Blasch.

The book, copyright 1980 by the American Foundation for the Blind, packs into fewer than 700 pages what has been described as the first comprehensive textbook for students of this broad and complex field.

Dr. Welsh is Superintendent, Maryland School for the Blind, Baltimore, and Dr. Bruce Blasch (nephew of Don Blasch) heads a program to train Mobility Specialists (for all handicaps) at the University of Wisconsin, at Madison. Don Blasch is Professor and Director of the Rehabilitation Program in the Center for Orientation and Mobility of the Blind at Western Michigan University, Kalamazoo.

DREXEL QUARTERLY Vol. 16, No. 2 DISCUSSES INFORMATION FOR DISABLED

The April 1980 issue of *Drexel Library Quarterly* (Vol. 16, No. 2) focuses on information centers and the information needs of the disabled.

Titled "Information Services to Disabled Individuals," the issue contains a number of articles by distinguished professionals in the fields of information science and of rehabilitation. The articles address the problems and concerns of improving and furthering the services of information centers on behalf of the disabled—an estimated 30 million adults plus eight million children, in the total population of the United States. International information agencies based in the United States are also discussed, as well as information services to the disabled in several foreign countries.

Guest editors are Judith J. Senkevitch (former director) and Joan R. Appel (information specialist) of the National Rehabilitation Information Center (NARIC). Copies of the issue may be ordered from Drexel Library Quarterly, School of Library and Information Science, Drexel University, Philadelphia, Pennsylvania 19104. The price is $6.00 per copy, postage included.

Copies may also be ordered from NARIC, 4407 Eighth Street, N.E., Washington, D.C. 20017, also at $6 per copy.

Calendar of Events

OFC '82 (Optical Fiber Communication) Meeting, Phoenix, Arizona, April 13–15, 1982. (For information: Optical Society of America, 1816 Jefferson Place, N.W., Washington, D.C. 20036.)

CLEO '82 (Conference on Lasers and Electro-Optics), Phoenix, Arizona, April 14–16, 1982. (For information: Optical Society of America, 1816 Jefferson Place, N.W., Washington, D.C. 20036.)

IRMA—4th World Congress of the International Rehabilitation Medicine Association on theme: "New Findings that Influence Disease and Rehabilitation," San Juan, Puerto Rico, April 18–24, 1982. (For information: Dr. Herman J. Flax, IRMA IV, P.O. Box 11696, Caparra Heights Station, Puerto Rico 00922.)

BMES—Biomedical Engineering Society, Annual Meeting, New Orleans, Louisiana, April 21–23, 1982. (For information: Dr. Yoram Rudy, Dept. of Biomedical Engng., Case Western Reserve University, Cleveland, Ohio 44106.)

Society for Biomaterials, 8th Annual Meeting and 14th International Biomaterials Symposium, Orlando, Florida, April 24–27, 1982. (For information: Dr. Myron Spector, Biological and Physical Sciences, Medical University of South Carolina, Charleston, S.C. 29425.)

International Conference on Disability and Communications, Washington, D.C., April 25–30, 1982. (For information: The President's Committee on Employment of the Handicapped, Suite 600, 1111 20th St., N.W., Washington, D.C. 20210.)

ASA—Acoustical Society of America, 103rd Meeting, Chicago, Illinois, April 27–30, 1982. (For information: Howard Schechter, IIT Research Institute, 10 West 35th St., Chicago, Illinois 60616.)

International Conference on "Communications and Disability: A Global Perspective," April 27–30, 1982. (For information: President's Committee on Employment of the Handicapped, Washington, D.C. 20210.)

IEEE International Conference on Acoustics, Speech and Signal Processing, Palais des Congres, Paris, France, May 3–5, 1982. (For information: C. Gueguen, Chairman, E.N.S.T., 46 Rue Barrault, F 75013, Paris, France.)

2nd European Meeting of Cardio-Respiratory Kinesitherapy, Charleroi, Belgium, May 6–8, 1982. (For information: Secretariat dees Deuxiemes Journees Europeennes de Kinesitherapie Carrdio-Respiratoire, Centre Sportif, social et cultural pour Handicapes rue de'l Ancre, la, B - 6000 Charrleroi, Belgium.)

International Federation for Automatic Control, Symposium on Control Aspects of Prosthetics and Orthotics. Held jointly with **7th Midwest Biomedical Engineering Conference** (with participation of IEEE Control Engineering Society and IEEE Engineering in Medicine and Biology Society) Columbus, Ohio, May 7–9, 1982. (For information: Prof. Herman Weed, Biomedical Engineering Center, Ohio State University, 2015 Ned Ave., Columbus, Ohio 43210.)

Society of Photographic Scientists and Engineers, 35th Annual Conference, Rochester, N.Y., May 9–14, 1982. (For information: SPSE, 7003 Kilworth Lane, Springfield, VA 22151.)

Below-Knee and Through-Knee Amputations and Prosthetics, Advanced Course, Copenhagen, Denmark, May 10–13, 1982. (For information: International Society for Prosthetics and Orthotics (ISOP), Borgervaenget 5, DK 2100 Copenhagen O, Denmark.)

OSA—Spring Conference on Applied Optics, Rochester, N.Y., May 17–21, 1982. (For information: Optical Society of America, 1816 Jefferson Place, N.W., Washington, D.C. 20036.)

World Confederation for Physical Therapy, 9th International Congress, Stockholm, Sweden, May 23–28, 1982. (For information: LSR Apelbergsgatan 50, Stockholm 111 37, Sweden, or WCPT, 16/19 Eastcastle St., London W1, United Kingdom.)

International Congress of Audiology, Helsinki, Finland, end of May or early June, 1982. (For information: Dept. of Audiology, Helsinki University, Central Hospital, Helsinki, Finland.)

26th Annual National Rehabilitation Conference, Las Vegas, Nevada, June 1982. (For information: Mr. Jack Tomich, Chmn-b9581 Scotstoun Dr., Huntingon Beach, California 92646.)

ASME—American Society of Mechanical Engineers, Summer Annual Meeting, Hyatt-Regency Hotel, Dearborn, Michigan, June 6–10, 1982. (For information: ASME, 345 East 47th St., New York, N.Y. 10017.)

First Southern Biomedical Engineering Conference, Louisiana State University Medical Center, Shreveport, Louisiana, June 7–8, 1982. (For information: Dr. S. Saha, Conf. Chairman, First Southern Biomedical Engineering Conf., Dept. of Orthopaedic Surgery, Louisiana State University Medical Center, P.O. Box 33932, Shreveport, Louisiana 71130. Tel. 318-674-6187.)

Canadian Physiotherapy Association Annual Congress, Halifax, Nova Scotia, Canada, June 9–12, 1982. (For information: Ms. N. Christie, CPA, 25 Imperial St., Toronto, Ont., Canada M5P 1B9.)

8th International Congress of the World Federation of Occupational Therapists, Hamburg, Federal Republic of Germany, June 13–18, 1982. (For information: World Federation of Occupational Therapists, Occupational Therapy Dept., Tauranga Hospital, Tauranga, New Zealand.)

APTA—58th Annual Conference of the American Phyyical Therapy Association, Anaheim, Calif., June 19–24, 1982. (For information: APTA, 1156 15th St., N.W., Washington, D.C. 20005.)

American Society for Engineering Education, Mechanical Engineering Division Annual Conference, Texas A&M Univ., College Station, Texas, June 20–24, 1982. (For information: Dr. George T. Craig, TIME '82, Dept. of Mechanical Engineering, College of Engineering, San Diego State University, San Diego, Calif. 92182.)

AGBAD—International Convention of Alexander Graham Bell Association for the Deaf, Toronto, Canada, June 22–27, 1982. (For information: Sue Romano, AGBAD, 3417 Volta Pl., N.W., Washington, D.C. 20007.)

BEMS—Bioelectromagnetics Society, 4th Annual Meeting, Los Angeles, California, June 28–July 2, 1982. (For information: **BEMS**, 1 Bank Street, Suite 307, Gaithersburg, Maryland 20878.)

Mechanics in Medicine and Biology, 3rd International Conference, Compiegne, France, July 10–13, 1982. (For information: Prof. M. Jaffrin, Universite de Compiegne, Genie Biologique, BP 233, 60206 Compiegne Cedex, France.)

International Conference on Biomedical Polymers, Durham, United Kingdom, July 12–14, 1982. (For information: Mr. Keith Copeland, Biological Engineering Society c/o Royal College of Surgeons, Lincoln's Inn Fields, London WC2A 3PN, UK.)

Acoustical Imaging '82, London, UK, July 19–22, 1982. (For information: Acoustical Imaging '82, IEE, Savoy Place, London WC2R OBL, UK.)

Electronic Image Processing, International Conference, York, UK, July 26–28, 1982. (For information: Conference Dept., IEE, Savoy Place, London WC2R OBL, UK.)

9th Canadian Medical and Biological Engineering Conference and Exhibition, University of New Brunswick, Fredericton, N.B., August 15–18, 1982. (For information: Conference Secretariat, Bio-Engineering Institute, University of New Brunswick, P.O. Box 4400, Fredericton, N.B. E3B 5A3, Canada. Tel. 506-453-4966.

RESNA—Rehabilitation Engineering Society of North America, 5th Annual Conference on Rehabilitation Engineering, Houston, Texas, August 22–26, 1982. (For information: P. J. Horner, 4405 East-West Highway, Suite 210, Bethesda, Maryland 20814.)

International Ergonomics Association, 8th Congress, Tokyo, Japan, August 23–27, 1982. (For information: Dr. Masamitsu Oshima, The Medical Information System Development Center, Akasaka Park Bldg. 3-4 Akasaka, 2 Chome, Minato-Kw, Tokyo, Japan.)

13th International Conference on Medical and Biological Engineering and the 6th International Conference on Medical Physics, Hamburg, W. Germany, Sept. 5–11, 1982. (For information: Hamburg Messe und Congress GmbH, Postfach 30 23 60, D-2000 Hamburg 36, Federal Republic of Germany.)

IEEE Engineering in Medicine and Biology Society, 4th Annual Conference, Philadelphia, Pennsylvania, Sept. 20–21, 1982. (For information: Dr. Alfred R. Potvin, IEEE/EMBS Conference, P.O. Box 19138, The University of Texas at Arlington, Arlington, Texas 76019.)

Bioelectrical Repair and Growth Society, 2nd Annual Meeting, Oxford, England, Sept. 20–22, 1982. (For information: N. Thiede, Executive Secr., Bioelectrical Repair and Growth Society, 425 Medical Education Bldg., 36th and Hamilton Walk, Philadelphia, PA 19104.)

Engineering in Medicine and Biology, 35th Annual Conference, Philadelphia, Pennsylvania, Sept. 22–24, 1982. (For information: Alliance for Engng. in Medicine and Biology, 4405 East-West Highway, Suite 311, Washington, D.C. 20014.)

AOPA—American Orthotic and Prosthetic Association, National Assembly, Houston, Texas, Oct. 17–24, 1982. (For information: AOPA, 717 Pendleton St., Alexandria, VA 22314.)

ASME—American Society of Mechanical Engineers, Winter Annual Meeting, Hyatt-Regency Hotel, Hotel Adams, Phoenix, Arizona, November 14–19, 1982. (For information: ASME, 345 East 47th St., New York, N.Y. 10017.)

1983

International Confederation for Plastic and Reconstructive Surgery, 8th International Conference, Montreal, Canada, June 26–July 1, 1983. (For information: Dr. Jean Paul Bosse, 3875 St. Urbain, Suite 602, Montreal H2W 1V1, Canada.)

AAAS—American Association for the Advancement of Science, Detroit, Michigan, Jan. 3–8, 1983. (For information: AAAS, 1776 Massachusetts Ave., N.W., Washington, D.C. 20036.)

3rd Mediterranean Conference on Medicine and Biological Engineering, Opatija, Yugoslavia, Sept. 1983. (For information: Dr. Stanko Tonkovic, Elektrotehnicki Faculteit Sveucilista U Zagrebu, 41000 Zagreb, Unska ul. 17, Yugoslavia.)

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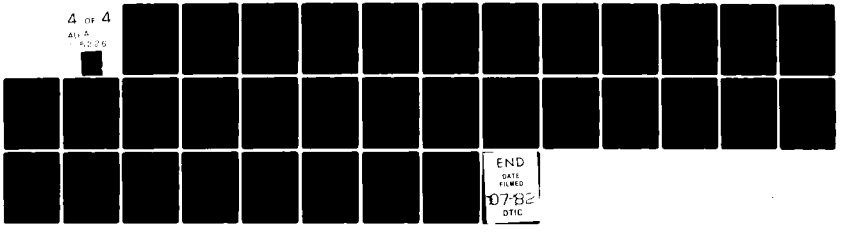

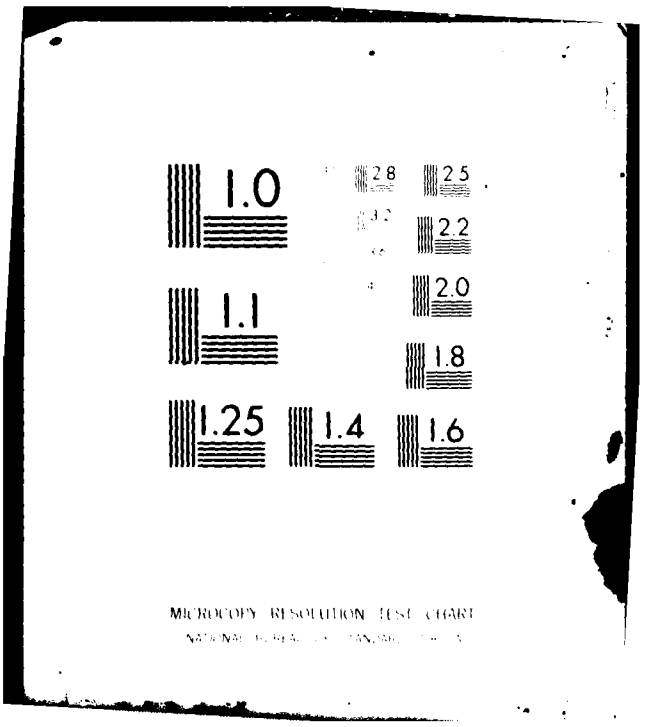
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