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13. ABSTRACT *(Maximum 200 words)*

The Assistive Technology Research Center is responsible for identifying promising technologies within DOD, NASA, and federal labs that may have an impact on the rehabilitation field. The ATRC is responsible for conducting the necessary research to transfer that technology for application to the field of clinical rehab. The Center's work comprises two sections that of Assistive Technology Transfer and Cognitive Studies. During year 2, the ATTP section continued its development in the assessment of unilateral spatial neglect in a virtual reality environment; the development and the evaluation of alternate educational strategies for UNS. The Interactive Rehab Tele-Assistants/Portable Evaluation System software system developed by the ATTP section is now complete and will allow remote access to patient files for clinical assessment. The orthotic projects have been developed and successfully tested both mechanically and clinically. Future research will focus on biomechanical analyses of these devices. In the Cognitive Studies Section, many clinical trials were conducted to determine the efficacy of pharmacologic agents for enhancement of cognition; a consensus conference was held to identify ways to share and generalize research findings from different labs and to adapt the ANAM for alternative uses. The ANAM database is currently in the testing phase and in the future will be expanded to include additional ANAM tasks. The sports concussion studies to assess neuropsychological function after concussion continues and participants have been successfully recruited. In year 3, the study will be expanded to include female athletes.

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10/25/96
PI - Signature Date

10/28/96

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A. INTRODUCTION

In this report, we provide status information on a number of projects that began and/or were carried out by the National Rehabilitation Hospital's Assistive Technology Research Center (ATRC) in year two of our cooperative agreement # DAMD17-94-V-4036. This document also contains revised plans for year three activities which were provided to our designated project officer, Fred Hegge, Ph.D., in a meeting that took place August 2, 1996.

ATRC activities are directed by a senior management team comprising Joseph Bleiberg, PhD, and William Peterson, MS, co-principal investigators; John Toerge, DO, medical director of the ATRC; Jack Winters, PhD, director of Catholic University support for the ATRC; and Sabrina Smith, MHA, administrative coordinator of the ATRC. This group meets regularly to review progress on ATRC goals and objectives.

The ATRC is divided into two main components: the Assistive Technology Transfer program and the Cognitive Studies program. This report will reflect upon activities carried out by each of these programs and will discuss future projects earmarked for year three.

B. SENIOR MANAGEMENT CHANGES

The senior management team changed recently as a result of two team members leaving NRH. Richard Materson, MD, resigned his position as Medical Director of NRH and Ruth Brannon, MSPH, resigned her position as Administrative Director of the NRH-Research Center. Subsequently, Joseph Bleiberg, PhD, and William Peterson, MS, have replaced Dr. Materson as co-principal investigators and Sabrina Smith, MHA, replaces Ms. Brannon as the administrative coordinator for the ATRC.

Dr. Bleiberg and Mr. Peterson have been involved with the ATRC from the outset. Over the past two years, Dr. Bleiberg and Mr. Peterson have directed the day-to-day activities for the Cognitive Studies program and Assistive Technology Transfer program respectively. Ms. Smith is new to the ATRC but brings with her a strong background in health care administration.

Another newcomer to the ATRC senior management team is John Toerge, DO, Acting Medical Director of NRH. Dr. Toerge has provided medical direction for the ATRC since Dr. Materson's departure and is also very active in administrative decisions.

C. ASSISTIVE TECHNOLOGY TRANSFER PROGRAM
Year 2 - Progress Report

Introduction

The Assistive Technology Transfer Program (ATTP) within the ATRC is responsible for identifying promising technologies within DOD, NASA, and federal labs which may have an impact on the rehabilitation field and for performing the necessary research to transfer that technology. In order to meet those objectives, the ATTP has four full-time engineers who work with staff and students from The Catholic University of America (CUA). ATTP staff are quick to pull in other allied health professionals to assist on various projects as needed including physicians, physical and occupational therapists, speech pathologists, and psychologists. Also during the course of this past year, six college interns and two volunteers have assisted on Assistive Technology Transfer projects which include utilizing advanced materials, advanced fabrication techniques, virtual reality systems, and "intelligent" expert systems.

Internal Review Board Issues

Most ATRC projects require up to three independent Internal Review Board (IRB) approvals. The process for submitting ATRC proposals is as follows:

1) All proposals are first submitted to the NRH Research Review Committee for approval prior to being sent to any IRB.

2) Once approved by the Research Review Committee, the proposal is forwarded to the Medlantic Research Institute (MRI) Internal Review Board for approval.

3) If any portion of the project will be conducted at CUA, the proposal must also be approved by the CUA-IRB.

4) Once the MRI-IRB (and CUA-IRB, if appropriate) approves the project, the proposal is submitted for DOD IRB approval.

Step four of this process caused major delays early on. There were times where it took up to 8 months to get DOD-IRB approval. A number of factors contributed to these delays including differences in IRB language requirements and the simple fact that some of the projects being proposed were unfamiliar to those responsible for overseeing the IRB process.

The ATRC was site visited in June, 1996 by Catherine Smith, a Human Use Review Specialist from the Army's Human Use Review Command and her assistant, Keena Conner. The site visit lasted two days thus allowing Ms. Smith and Ms. Conner to observe many of the projects now underway. It also provided an opportunity for ATRC senior management to learn more about the DOD-IRB process and to discuss ways in which to expedite the process. We are pleased to

announce that all projects submitted for DOD-IRB approval since that visit have been dealt with expeditiously. A copy of the site review report is included with this report (Appendix) Progress on these and other ATTP projects is detailed below.

Virtual Reality (VR) Projects

Study #1: Assessment of Unilateral Spatial Neglect in a Virtual Reality Environment

The aim of this project is to develop and assess the efficacy of a VR based diagnostic tool for unilateral spatial neglect (USN). Two elements of USN are being investigated in this study: 1) overt attention to hemispace on a cylinder bisection task, and 2) covertly assessed attention to hemispace implicit in performance on a block-stacking task. These elements are being assessed under three different saliency conditions (high, low, and no saliency). Initially, the study included four subject groups: 1) 15 adult patients with evidence of left hemispatial neglect, 2) 15 matched controls, 3) 10 right temporal lobectomy patients, and 4) their respective matched controls. However for logistical reasons the scope of the study has been reduced to two subject groups: patients with USN and controls. The initial proposal has been revised to indicate this change. Data from this study will address the following questions: 1) Can unilateral visual neglect be adequately assessed in a VR environment?, 2) Can tasks designed to take advantage of the VR environment better assess USN than current practices?, 3) Can the effects of USN be exacerbated or attenuated by manipulating certain stimulus qualities within the VR environment?, and 4) Are those elements of USN assessed and manipulated within the VR environment more apparent on overt or covert tasks of hemispatial attention?

Progress in Meeting Project Objectives/ Status

- This project was approved by the MRI IRB (after amendments) in November, 1995.
- The proposal was subsequently forwarded to the DOD IRB for approval.
- The project received final DOD approval in March 1996.
- Meanwhile, development of the simulation programs continued at the ATRC.
- Data collection commenced in May 1996.
- Data has been collected on a total of ten subjects (two subjects with symptoms of USN, and eight controls).

Barriers in Meeting Project Objectives

- There was a delay in getting the DOD IRB approval.
- Jack Spector, listed as Co-PI on this study was unable to commit the time and effort required to actively participate in this study. Therefore Dr. Spector's name has been deleted from the list of investigators and the size of the study reduced.

Course Corrections

The protocol has been revised to reflect the elimination of two subject groups from this study. However, the testing protocol for subjects remains the same.

Status: Ongoing

Study #2: ***The Development and Evaluation of Alternate Educational Strategies for Unilateral Spatial Neglect***

Unilateral spatial neglect (USN) is a complex disorder frequently observed in patients following stroke or traumatic brain injury. Current methods for educating family members about the USN phenomenon are limited by the lack of educational tools. Available educational tools are general in nature and do not specifically address unilateral neglect and its impact on daily function. Some clinicians currently employ techniques like "blacking out" eyeglasses to simulate the phenomenon of USN for family members of patients with USN. However, such an approach more accurately simulates a sensory field cut rather than USN.

This study compares current methods for family education about USN with two newly developed educational tools: 1) a videotape that explains and shows examples of the effects of USN; and 2) an interactive, immersive virtual reality (VR) based educational experience. The videotape presentation is an edited version of a professionally produced video which uses a combination of graphics and illustrations, clinician and family member interviews, and actual footage of patients with USN. Three VR programs have been developed which simulate the effects of USN on activities of daily living.

The primary subject group for this study consists of family members or significant others of patients admitted for inpatient rehabilitation with a confirmed diagnosis of unilateral neglect. Patient participation is limited to the mapping of their visual field using customized VR software and equipment. The visual perception map obtained for each patient is used to customize the VR experiences for their respective family member. Subjects are randomly assigned to either one of the three groups: the videotape group (VT), the VR group (VR), or the control group. Participants must complete a questionnaire within three days after their family member has been admitted into a rehabilitation program. Subjects in the VT and VR groups will undergo their respective educational experiences at least 12 days post admission. The questionnaire will be administered one day after these experiences and for those in the control group, at least twelve days after admission of their family member. The questionnaire will once again be administered to the same individuals three months later. The questionnaires will help us objectively evaluate the effect of the respective educational schemes on the subject's awareness of USN.

This study will be useful in determining effective methods for educating family members on the disorder of unilateral neglect. Data collected will answer the following questions: 1) What is the initial level (at three days post admission) of family member understanding of USN?; 2) Do the alternate educational strategies developed during the course of this study enhance a family member's understanding of USN and its impact on the patient's daily function?; 3) Does an interactive VR based educational experience enhance a family member's perception of USN?; and

4) Do the alternate educational tools developed in this study provide improved long term retention of knowledge (at three months post discharge) when compared to traditional method?

Current Status:

- The project was approved by the MRI-IRB in January, 1996.
- The proposal was subsequently forwarded to the DOD-IRB for approval.
- Developed software for the VR based simulations
- Received notification of required changes to the proposal in May, 1996.
- Submitted changes based on DOD-IRB comments in June, 1996.
- Received verbal approval for this project in July, 1996.
- Developed initial version of videotape to be used for the study.
- Awaiting IRB approved consent forms.

Status: Ongoing

Therapeutic Applications of Virtual Reality

A number of therapeutic applications have been developed since the program started in April 1995. These include:

1. Virtual "Soccer" (for patient with RSD and minimal limb movements)
2. Pick, Drag and Drop routines for ROM
3. Pick and Flip routines (for supination/pronation)
4. Motorcycle ride through a city block (flexion/extension of wrist)
5. Virtual "Art Gallery" (for wrist based exercises)
6. Flight simulator (wrist based exercises)
7. Tank Simulator (for wrist based exercises)
8. Car driving game (using knee or wrist flexion/extension)

These therapeutic applications of VR have served as a basis for developing custom routines that allow the scaling of position/orientation records from the sensors. Consequently, a library of functions have been developed to allow scaling and resetting of sensor data to allow the measurement of rotations along any arbitrary axis in space. These are custom-built routines (not available commercially) and should serve us well in the development of other therapeutic routines.

Status: Ongoing

Biofeedback Studies

The biofeedback program developed out of a need expressed by Dr. Katherine Alter, a PM&R physician at the Hospital for Sick Children (HSC) and the Washington Hospital Center (WHC).

The primary goal was to develop instrumentation that will allow patients to conduct therapeutic exercises in a more motivational manner. Initially, the VR system was used to develop therapeutic games for patients. Sensor mounts were fabricated to allow the mounting of motion sensors on the limb of interest. Special routines were developed to measure the movement of sensors around any of the three axes (X, Y, and Z). This sensor data was then used to control actions in a virtual world. Several software programs were developed to cater to the needs of such children.

1. "What's behind this door?": In this program, a toy was hidden behind each of 5 virtual doors. The door opened only when the user (patient) performed a prespecified task to a level of proficiency (target). For example, the task could be wrist extension as measured by a sensor mounted on the hand. A prespecified target level (e.g. 20^0 wrist extension) could be interactively set for this task based on a therapeutic goal. The achievement of the therapeutic goal results in the door being raised and a toy rolling out (as an incentive). This game was developed for a 4 year old girl.

2. A car driving game was adapted to accept sensor input so that the users' actions could control the car's throttle. Collision detection was added to the simulation with sound to indicate car crashes. These features were added to increase the realism of the simulations and help catch the attention of young subjects.

3. After further discussion, it was decided to design and implement a biofeedback system using a home-entertainment system. A Super-NES system was adapted to accept EMG signals measured by a custom-built EMG processing system. The system includes an EMG processing/filtering box, a Relay/Comparator box, and the adapted controller. Using the system, the user can access one or more of the functions on the Super-NES controller (left, right, jump, etc.). This system allows for adjustable target setting. Using this feature, the degree of difficulty for an exercise can be adjusted to match the ability of the user. This system has been successfully used by children with both lower and upper extremity muscle weakness and spasticity. Children have responded very well to this type of therapy. The system was also used by an adult SCI patient at NRH for shoulder abduction exercises. The muscle groups of interest were the anterior deltoid and the trapezius. In the first two weeks of therapy, the patient demonstrated a 40^0 increase in his ability to shoulder abduct (from 35^0 initially to 75^0.)

Status: Ongoing

Presentations/Publications:

Sukthankar, S.M., "Virtual Reality Research at the NRH-ATRC," *Technology in the Twenty First Century*. Conference at Ft. Detrick, MD (1110th Signal Battalion), December, 1995.

Sukthankar, S.M. and Reddy, N.P., "The Use of EMG as the Controlling Modality for Simulation of Virtual Object Squeezing," *Journal of Medicine and Virtual Reality*, accepted for publication January, 1996.

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Sukthankar, S.M., "Research at the National Rehabilitation Hospital's - ATRC," *Technology at Work and Leisure*, NASA Session at the Third Paralympic Congress, Atlanta, Georgia, 1996.

Interactive Rehab Tele-Assistants / Portable Evaluation System

Motivation and Background

Advances in telecommunication, computer, and sensor technologies are gradually transforming society. An area that is attracting considerable private and public investment, and spans many fields and applications (including telemedicine), is that of "tele-assistants." Our focus is on concurrent research within our niche: interactive, "intelligent" evaluation in rehabilitation. This includes developing efficient data calibration and analysis capabilities, studying and refining human-computer interfaces, and developing appropriate "expert" rehab data synthesis of multiple channels of objective, sensor-based, information with standard clinical assessment measures. Within this context, we utilize technologies that we anticipate will be part of the evolving larger picture: portable computers, state-of-the-art sensors, multimedia technologies, and expert systems.

The purpose of this project is to develop portable, "intelligent," user-friendly evaluation tools that can be used to quantitatively assess a patient's cognitive, neuromotor and biomechanical function using an appropriate battery of tests. Evaluation would be based upon synthesis of: multiple channels of objective sensor-based information; multiple tasks within a test battery; and standard clinical assessment measures. The PES utilizes exclusively portable technology, including a laptop computer, Flock of Birds portable motion analysis system, EMG electrodes, and a miniature force sensor[1-3].

The scope of the PES project has been expanded to include telemedicine capabilities, hence the name Rehab Tele-Assistant (RTA). The concept of the RTA is to develop a user-friendly system that allows a clinician or experimenter to accomplish a variety of tasks, from searching through patient files, viewing data charts or graphs, viewing or editing text comments associated with patient files, or running experiments with Labview and creating new patient files. Functionality is

achieved with standard software packages like Fuzzy Clips, MS Word, MS Excel, Labview and Visual Basic. Visual Basic serves as the front-end, and the link between all of the packages, using OLE communication. The patient database could foreseeable be connected to the Internet to allow remote access by authorized users.

Software Development for RTA / PES

The entire data acquisition software system is complete. It is a robust, easy-to-use, flexible system. On the various front panels, the user is guided through the setup for each test including entry of subject information and selection of the test to conduct. On the data acquisition front panel, the user can select which combination of the three instruments to measure from, the type and format of the data transmitted, the type of data displayed, and whether to save data to a file.

The efficiency of the data acquisition systems has been substantially improved. The data acquisition mode for all three instruments has been switched from single-scan, simultaneous acquisition, to concurrent, nearly simultaneous batch acquisition. That is, each instrument is initialized, and primed to begin data transmission. Then each instrument is commanded to begin sending streams of data which are collected in respective serial port and DAQ Card buffers and are periodically retrieved in batches by Labview into memory. The batch acquisition approach has increased acquisition rate capabilities to 100 Hz for EMG, 20 Hz for force and torque, and 35 Hz for the Flock-of-Birds (position and orientation). The change in data acquisition mode from single scan to batch scans necessitates that all data processing of force/torque and position/orientation be done off-line, after the data acquisition for that particular test is completed. The force sensor and Flock-of-Birds data is thus displayed on the front panel 5-10 seconds after each test is completed. However, EMG data can still be displayed in real-time.

Software has been written in Labview for post-experiment data viewing. The programs include user-friendly interfaces which allow a researcher or clinician to select which data files to view and which subset of the data files to be plotted together on the screen. Comparisons can then be made between different calibration tasks or reaching tasks of the same subject or between the same tasks performed by multiple different subjects.

System Hardware Components

Force Transducer Mount:

The design and fabrication of the second generation force transducer door-mount apparatus was completed. The door-mount consists a 3 inch square aluminum channel, 1/4 inch thick, with another aluminum plate attached via bolts to the channel. The clamp is designed to grip the door firmly when the bolts are tightened by hand-turnable knobs. The force transducer is mounted directly to the mounting device with three small bolts. The force transducer interfaces with different apparatus that have been custom designed. One apparatus, designed and built in the first year of the ATRC, is a rigid aluminum handle that is grasped by the subject's hand. A

second apparatus is a flexible-length cable with a loop and strap that couples the user's body segment (hand, forearm, or upper arm) to the force transducer. The padded strap is designed to loop around a limb segment of the upper extremity, either at the hand, the forearm, or the upper arm, depending on the task being performed. The user applies a pulling force to the strap, which is directed primarily along the z-axis of the force transducer, the axis with the greatest maximum allowable force. The strap design allows greater flexibility in positioning of the subject relative to the door, as well as the orientation of the subject's arm. With this design, the force transducer measures only three directions of force. Torque is non-existent. The force measurement of the x, y, and z axis components allows precise determination of the line of action of the force applied and therefore the position and orientation of the subject's arm (if the subject's position relative to the door mount is known).

EMG filter circuits:

The EMG analog filtering hardware has been completed. Aggressive filtering is accomplished with a RMS to DC converter chip circuit (from Analog Devices - AD736), which outputs a DC equivalent of the raw EMG signal input and generates a rms value of the raw EMG signal. The circuit has acceptable rise-times and settling times, and is thus adequate for our purposes. With this circuit, no additional filters or amplifiers are needed and a low sampling rate can be used. Two portable circuit boxes were constructed with 8 RMS to DC filter circuits per box providing for a total of 16 EMG circuits. Each box contains one anti-aliasing filter circuit, a low pass circuit with a cutoff frequency of 400 Hz which provides the experimenter with the capability of acquiring a raw EMG signal from one channel at a time. The boxes are small and lightweight and contain a front panel with switches to control how many channels of EMG to acquire and to select the raw signal option. Ribbon cables connect from the circuit boxes to a 50-pin cable that plugs into the PCMCIA DAQ card.

Arm support:

Trial runs from Pilot Test 1 have revealed that the subject's arm fatigues quickly during the test and that simple gravity support should be provided. An adjustable arm support with 6 degrees of freedom (by Ablenet ®) that simply clamps to the arm of the subject's chair has been a very successful solution to this problem. An added benefit of the arm support is that by positioning the arm on the small support platform, extraneous movement of the proximal limb segments can be more easily detected and prevented, thus achieving better muscle calibration data.

Computer Hardware:

The system computer was upgraded with a new hard drive of 540 MB, and RAM expanded to 20 MB. These upgrades have significantly improved computer speed and performance.

Pilot Study 1

Test Protocol Revision:

The protocol for the first pilot study was refined to more closely approximate procedures for isometric strength tests for upper limbs used in physical and occupational therapy. Several trial runs were conducted at CUA, with the assistance of an occupational therapist from NRH, in order to refine and improve the test protocol. The orientation of each subject and direction of force applied to the force transducer during each exercise was more specifically defined. It was especially important to constrain the direction of applied force along the z-axis of the transducer during calibration tasks to prevent overloading and damaging the force transducer. Detailed, step-by-step, instructions have been written to assist the experimenter conducting each test. These explicit instructions help to ensure greater consistency between subjects without restricting each subject's freedom to perform movements naturally. One key area of focus has been on efficient calibration so that all EMG signals are scaled to an estimate of "maximum" thus facilitating the synthesis of information. Through correlation and fuzzy inference, the objective is to minimize the number of tests that need to be performed to adequately calibrate all the EMG channels for one subject. Thus the subject testing time is long (2-3 hours) relative to what we expect for subsequent testing.

Progress of Testing:

All 10 subjects have been tested. A cursory review of the test data has revealed that all of the sensor instruments are operating correctly, that the data from the different sensors are being acquired synchronously, and that the information on all channels is reasonable. The data is now being analyzed in considerably greater depth with a focus not only on the data itself but also on aggressive data synthesis process both within and across tasks.

Status: Ongoing

Related Activity

A number of other activities are evolving as a consequence of the RTA/ICA thrust. First, the project has been well received at conferences[1-3] and both the biomechanics and telemedicine communities seem intrigued by the possibilities. Ties have been with both the *Imaging Science and Information Systems* Center of *Georgetown University Medical Center* (ISIS-GUMC) and with the Army telemedicine group at Ft. Detrick. A proposal to establish a *National Center for Tele-Rehabilitation Engineering (NC-TRE)* is pending with the Whitaker Foundation ($815,170 over 3 years), with CUA as the main (Dr. Winters as PI) and NRH and ISIS-GUMC as subcontractors. Perhaps most importantly, considerable cross-fertilization is occurring between the PES/ICA and Virtual Reality (VR) thrusts, and it is becoming clear that these approaches and technologies need to more fully converge. In particular, integrating quantitative evaluation within "fun" therapeutic interventions is emerging as a priority area[5-6].

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Orthotics Projects

One of the key areas of innovation in DOD and NASA labs has been in advanced and smart materials. The ATRC is interested in identifying appropriate materials, fabrication techniques, and design methodologies that can have the impact on the rehabilitation field and performing the appropriate research necessary to transfer the technologies into the private sector. This involves developing or obtaining prototypes, then utilizing our resources to evaluate and refine these prototypes with the ultimate aim of producing deliverable products. This deliverable can take one of two forms: I) the transfer of a process (e.g., a published technique that can be replicated with manuals and some type of support infrastructure); or ii) the delivery of a device into the marketplace.

Composite Leg Brace Project

The National Rehabilitation Hospital has been committed for some time to develop, test, and commercialize a new generation of composite leg braces for persons with physical disabilities. The ATRC has committed some of its resources to continue with these efforts to see this project

to fruition. The following is a brief description of tasks worked on over this past year and a status report on each:

Development of a Composite Ankle Joint Using an Injection Molding Process
A composite ankle joint has been developed and successfully tested both mechanically and clinically. However, the cost of manufacturing this joint is prohibitive in today's market. Preliminary test results indicated that an injection modeling process for manufacturing composite ankle joints could be accomplished and still stay within acceptable safety margins. Using this type of manufacturing process would reduce manufacturing costs dramatically thus making the NRH Composite Ankle Joints more affordable. Therefore, NRH contracted with SPARTA, an aerospace contractor, to develop and test an injection molding process for manufacturing composite ankle joints. Subsequently, a new generation of injection molded composite ankle joints were developed. These joints successfully passed dynamic fatigue and static load tests and are now awaiting clinical trials to determine whether or not the injection molded composite ankle joints can withstand the stresses applied to them in a structured clinical environment. Results are expected in march, 1997.

Clinical Trial of Composite Knee Joints
Newly developed composite knee joints have been incorporated into a pair of Scott-Craig long leg training braces typically worn by paraplegics learning to ambulate. The knee joints were bonded to aluminum uprights using a non-reversible epoxy bonding agent. The purpose of the clinical trials is to determine whether or not the composite knee joints can withstand the stresses applied to them in a structured clinical environment. The goal is to subject the braces to a minimum 50 hours of clinical trials during which various ambulatory and functional tasks will be realized including swing through gait; sit to stand transitions; ambulating up and down steps; standing from a prone position; ambulating up and down a ramp; and falling.

After 42 hours of clinical use, one of the composite knee joints failed at the drop ring. The failure was not catastrophic. The test braces were immediately removed from clinical use and the failed composite knee joint removed and sent to SPARTA for tests. After careful scrutiny and an assay test for fiber content, it was determined that the failure was the result of poor manufacturing, not design. Subsequently, a new composite knee joint has been bonded into the training braces and they were recently put back into clinical trials for an additional ten hours of clinical use. Upon completion of these trials, the composite knee joints will be removed from the training braces and returned to SPARTA for another battery of dynamic fatigue and static loading tests to determine whether structural integrity of the joints has been compromised due to clinical use. Based upon results from the clinical trials and mechanical tests, a determination will be made about the future marketability of this design. Results are expected in December, 1996.

Reversible Bonding Agent
The composite joints designed for this project (ankle and knee joints) all incorporate 1/4 by 5/8 inch "pockets" used to couple the joints with uprights. In order to make this a modular system, it

is necessary to identify a bonding agent capable of being reversed thus allowing an orthotist to dismantle a brace and rebuild it whenever necessary. NRH contracted with SPARTA, Inc. to assist in the identification of a reversible bonding agent capable of withstanding the stresses of daily use. Four agents were identified and tested as possible candidates. All four candidates failed. A chemist from Locktite Corporation was then called in for consultation purposes. He felt that a reversible bonding agent was possible and set out to develop one which meets predetermined specifications. In June 1996, the chemist demonstrated a bonding agent that reversed itself in a solution of alcohol and phosphoric acid within 20 minutes. However, the solution slightly damaged the outside surface of the composite material. The chemist is now working on refining the reversible solution to ensure that the integrity of the composite material is not compromised in the reversible process. If successful, it will be identified as the reversible bonding agent of choice for this project. However, if it fails, further research will continue and will probably include engineers and chemists from various Department of Energy labs since representatives from these labs have expressed an interest in working with the ATRC on these and other issues. Results are expected December, 1996.

Postformable Composite Uprights

An important component when making an entirely composite bracing system is the development of a composite upright that is both postformable and strong. Orthotists routinely postform uprights to make them biofidelic and cosmetically appealing. Composite materials inherently are not good candidates for postforming and therefore present a problem with respect to traditional methods of assembly by orthotists. Because of this, efforts have been made to overcome these challenges but have proved fruitless thus far.

Becker Orthopedic, Inc. has been successful in developing a postformable composite upright prototype and NRH contracted with this company to manufacture ten feet of this material using a 1/4 by 5/8 inch rectangular geometry so that we may test its postformability and mechanical integrity. The rectangular geometry is necessary in order to integrate the upright with the composite knee and ankle joints already designed which incorporate 1/4 by 5/8 inch "pockets" for coupling the upright to the joint. Upon delivery of the upright material, NRH postform the material to the likeness of typical uprights and sent the test pieces to SPARTA for mechanical and fatigue tests. The postformed composite uprights passed all mechanical tests and are now awaiting clinical trials to determine whether or not the composite uprights can withstand the stresses applied to them in a structured clinical environment. Results are expected March, 1997.

Composite Footplate

A major component of long leg braces is the footplate. This component couples both uprights with the shoe. Footplates are also subjected to enormous stresses and have a tendency to fail in normal braces more than any other component. ATRC and SPARTA engineers consulted on a new composite footplate design that appears to be both strong and modular. SPARTA is currently developing a mold for manufacturing the newly designed composite footplates and is expected to have test samples in November 1996. The test samples will then be subjected to a

battery of mechanical tests to determine their structural integrity. Results are expected January 1997.

Publications:

White, M. And Peterson, W., "Advance Materials for Orthotic Applications: An Example of Technology Transfer," *Advancement of Materials and Process Engineering*, accepted for publication March. 1996.

Posture-Assist (Anti-Gravity) Shoulder-Arm Orthoses

Background.

Several years ago the Rehabilitation Engineering Research Center on Rehabilitation Robotics in Delaware had identified a significant need for orthoses that help hold up the arm while a person used their hand and developed a prototype "anti-gravity" device that could attach to a chair or wheelchair. This passive device uses springs within parallelogram structures to counterbalance the weight of the arm. The purpose of this project is to develop a more low-profile, streamlined system that can be mounted to the torso, then evaluate customized versions of the device for several target populations of persons with disabilities who we believe could benefit from this technology (candidate populations include persons with muscular dystrophies, brachioplexus injury, multiple sclerosis, and worksite injuries). Our intent is for the system to be miniaturized and conforming, such that it can fit with relative ease under most clothing. The design now consists of three parts:

1. A 3-chain parallelogram link "gravity-assist" structure which forms a miniature "crane" that pulls up on a distal contact location, with the most proximal link mounted reasonably close to the origin of the clavicle (near the base of the lateral neck) and the most distal link coupled to an elbow orthosis that approximates the center of mass location of the arm. Due to the arrangement of the springs within the parallelogram sections, the amount of pull is a function of the configuration of the arm (i.e.,the system automatically pulls harder when the arm is out from the body).

2. A spring-loaded elbow orthoses, which serves as an attachment location for the gravity-assist orthoses, and additionally approximates the center of mass of the arm. This orthoses attaches between the upper and lower arms with a spring-loaded sliding mechanism between the attachment sites.

3. Thermoplastic attachment cuffs for the upper and lower arm and for mounting the gravity-assist linkage to the upper right chest (using a modified halo vest).

In order to keep the design small and streamlined, we have designed our own miniature joints consisting of a double ball-socket design which uses small steel balls and ultra-high-molecular-

weight-polyethylene (UHMWPE) for the socket. The socket is formed by heating the UHMWPE within a custom-designed fixture and then indenting it to an appropriate depth. A lubricant is also added to help lower friction. Due to the challenges of working with UHMWPE, and the desire to have a high range of motion (e.g., 100°) yet avoid having the steel balls "pop" out of the UHMWPE sockets, a good deal of iteration (and engineering bench testing) has been required to refine the fabrication technique. Another engineering challenge has been to find an appropriate material to serve as a "spring" across the upper and lower bars of the linkage – this is where the "gravity assist" potential energy is stored. Mathematical analysis and a computer model was used to define our needs. The engineering criteria for this material spring proved challenging: a small size with reasonably high stiffness, at least 80% strain over a reasonably linear region, and low cyclic hysteresis and creep/relaxation. These stringent criteria managed to eliminate most candidate materials and, indeed, after testing a range of materials it became clear that a new strategy was required. It was then decided to machine a set of deep grooves along the parallelogram bars and place a set of urethane rubber "gaskets" along the length of these bars. Given that they are located structurally in parallel, their forces (and thus stiffness) add.

Plans For Year III

The prototype mechanism is nearing completion and is scheduled to go through human subjects evaluation (human subjects approval is now in place, through CUA, NRH and the Army) during early November of 1996. The testing protocol includes a wide range of tracking and postural tasks in which EMGs are used to document "effort" levels, with and without the orthoses, and for some tasks to provide biofeedback to the subject whenever effort crosses certain thresholds. The PES is being adapted for this evaluation. After data analysis has been completed, the ATRC intends to put together a ½-day workshop during January 1997 (which would include several clinicians and other professionals) to evaluate the initial system and the results of the pilot study. The goal is to prioritize future directions and target populations for this technology. We will then customize the design for the specific (prioritized) target population, improve on the design as necessary, and perform a Phase II controlled study.

Leg-Powered Shoulder-Assist Orthoses

Motivation.

Body-powered upper-limb prostheses, designed primarily during the 1940's, have proved to be a remarkably robust technology with low rates of abandonment versus "higher-tech" powered prostheses. At the foundation of this technology is the use of Bowden cables to transmit power and information (force, length, velocity) from one region of the body to another. This concept has also been used to design a leg-controlled feeder. The success of these technologies appears related to the intimate contact between the device and the person which allows the part to essentially become an extension of the body. This phenomena has been coined Extended Physiological Proprioception (EPP). Given the effectiveness and simplicity of this class of technologies and its ability to be combined with the artificial muscle that several members of the

research team have considerable experience with[1], we had felt that it was worth further investigation.

The purpose of this pilot project was to develop and evaluate a prototype system to test the EPP concept for new applications. Erika Sagranichiny, a biomedical engineering graduate student, had helped formulate the plan and chose to design and implement this project as her master's thesis, with assistance from ATRC personnel on an as-needed basis. She coined the orthoses ROMULO (range-of-motion upper limb orthoses). While the prototype was designed to be evaluated by a normal population, the target population has been hemiplegic stroke patients who, while seated, could utilize the uninvolved leg to help move, or stabilize, the involved arm. This could be useful for therapy and/or for performing daily activities. Thus the focus was on a shoulder-assist orthoses in which three shoulder degrees-of-freedom and one elbow degree-of-freedom (DOF) are mapped to corresponding contralateral leg DOFs: arm elevation (via knee extension), forward-backward arm rotation (via hip adduction-abduction), humeral rotation (via thigh axial rotation), and elbow flexion-extension (via ankle dorsi-planter flexion). The design includes shoulder-arm cuffs (including a scapular component that is to move roughly with the underlying scapular), leg cuffs, Bowden cables, and a chair. The chair was custom-designed, with part of the seat rotating with the leg. Nine Bowden cables are used to transmit motion and force between the leg and arm. The mapping locations were initially set by using a computer program written in Matlab which helped establish causality between leg motion and loading to arm motion and loading through various plots of key variables. The various shells for the system were fabricated with the assistance of the orthotics staff at NASCOTT. There are extensive interface fasteners for attaching the 9 cables to the orthotic shells and for interactively adjusting the system to users of various sizes. The prototype was refined during the Spring of 1996, and was judged to be completed during the Summer of 1996 (after considerable iteration to try to improve the ranges of motion).

The ROMULO prototype is currently under evaluation for a group of normal subjects using an approved human subjects protocol that includes EMG calibration tests (using isometric contractions) followed by sets of ROM, tracking and postural tasks. LabView VIs developed for the PES data acquisition system were adapted for this purpose. The experiments involve acquiring eight EMG signals, as well as analog signals from electrical switches that are activated by the subject during the tracking tasks. These switches are used to assess the accuracy of the upper limb trajectory during a specified task and to signal the start and finish of such task. Tests are underway and the thesis of Erika Sagranichiny is expected to be turned in by November of 1996. Despite considerable iterative design, it has been clear since the Spring of 1996 that the friction within the cables and movement at the skin interface prevent full range of motion. Especially challenging has been humeral (internal-external) rotation of the shoulder. Additionally, elevation is only to about 90 deg. Part of the evaluation process involves documenting the extension and excursions within the cables so that we can better understand the nature of the current limitations. While we have already decided to postpone further development of this technology at this time, of note is that it will remain available as a testbed for other projects.

Other Advanced Fabrication/Materials Projects

In the plans for Year 2 there were several areas where we proposed to initiate planning activity. One was related to utilization of the toroid bonder (a NASA Langley technology, sold by a company called Inductron). This technology, which was procured during the Spring of 1996, allows fast, very localized, selective internal heating near the site of suceptors within an appropriately planned application. It will be evaluated for several possible applications which could profoundly impact on the orthotics field: **I)** reversible bonding for modular orthoses (e.g., composite-metal, composite-composite surfaces coated with a thermoplastic adhesive with an embedded susceptor); and **II)** selective "on-the-fly" Hardening of drapable (form-fitting) orthotic shells (while on the person, finished within minutes).

Currently a group of four biomedical engineering undergraduate students are utilizing the toroid bonding gun as part of their Senior Design project, supervised by Dr. Winters and with collaboration from ATRC engineers. Their goal is to fabricate multi-layered postformable theromoplastic composite shells, then perform engineering bench tests on these fabricated structures. The layers include thermoplastics, susceptors (e.g., aluminum foil), composite fabrics (e.g., graphite), light-weight filler (if needed), and insulators at the bottom and top surfaces. A motor-controlled mounting system is being developed by the students that will allow us to precisely control the depth and rate of advance of the torobonder along the surface. Both flat and cylindrical steel sections will be fabricated. If it turns out that strong, post-formable shells can be dependably and safely created by "on-the-fly" techniques, this technology could have a profound impact on the orthotics field. The student design project is scheduled to be completed and presented in December of 1996. Subsequent development will depend in part on their results.

There has also been a strong desire to pursue the area of "smart materials" -- materials with intrinsic electrical-mechanical-thermal coupling that allows them to function as either an actuator or a sensor. There are two classes on intriguing applications: First, there are lower-frequency "shape memory" materials could function as *static orthoses* that are pre-designed to slowly change conformation (below rates sensed by muscle spindles), triggered simply by body temperature. This could be used, for instance, for management of contractures. Second, there are thin, higher-frequency materials that have been used to vibration management in DOD applications. These could be used for management of tremor and other forms of oscillation due to neuromotor impairment. During Year 2 Dr. Winters went to the SPIE Smart Structure and Materials conference[4,5] to help plan a possible thrust in this area. We anticipate a small pilot study in this area.

References:

1. Winters, J.M. and Sagranichiny, E.S., "Why Braided Pneumatic Actuators in Rehabilitation Robotics? Principles, Properties, and Suggested Applications," *Int. Conf. on Rehab Robotics,* pp. 201-208, Wilmington, June, 1994.

2. Winters, J.M. "Consider Neuromusculoskeletal Redundancy and Extended Proprioception When Designing Smart Structures to Interface with Humans", SPIE Smart Sensing, Processing and Instrumentation: *Smart Sensors and Actuators for Neural),* Vol. 2718, pp. 469-480, San Diego, February, 1996.

3. Winters, J.M. "Intelligent Synthesis of Neuromusculoskeletal Signals Using Fuzzy Expert Critics", abstract accepted, *SPIE Smart Sensing, Processing and Instrumentation: Smart Sensors & Actuators for Neural Prosthesis, Vol. 2718,* pp. 456-468, San Diego, 1996.

Biomechanical Analysis of Scott-Craig Long-Leg Type Braces During Ambulatory Tasks

The aim of the "Biomechanical Analysis of Scott-Craig Type Long Leg Braces During Ambulatory Tasks" project is to obtain a quantitative understanding of the overall mechanical loading of the Scott-Craig type long leg braces during various ambulatory and functional tasks. A goal of this study is to provide information to the orthotics industry to address the issue of over design that results in excessive safety margins, and increased weight and bulk. Results from this study will also assist us in the future development of nonmetallic composite brace components.

Progress in Meeting Project Objectives

- A proposal was submitted to the MRI IRB June 1995 and the project was approved on July 1995.
- The proposal was then forwarded to the DOD IRB for approval.
- The project received final DOD approval in March 1996.
- Meanwhile, all the hardware (electronic circuitry) and software (Virtual Instruments or Vis) needed to collect the data from the strain gages was built, tested and debugged for both a desktop and a laptop computer on January 1996.
- Three pilot tests were conducted on normal subjects to test and refine the protocol, software and hardware components.
- Data collection commenced in April 1996.
- Data has been collected on a total of three subjects.

Barriers in Meeting Project Objectives

- There was a delay in DOD IRB approval.
- Since no commercially available collections systems are suited for our collection needs, all electronic hardware had to be designed and handmade.
- Recruitment of test subjects has proven to be more difficult than originally anticipated.

Strategies to Overcome Barriers

- Because of the tedious process of constructing the data collection boxes, two ATRC research interns were enlisted to assist.
- Recruitment process has been expanded to the local metropolitan area.

Status Ongoing

Proposed Future Projects

Future Biomechanical Analyses of Orthoses

During the past year, our experiences with the brace instrumentation project has been useful in enhancing our internal knowledge and developing an expertise in biomechanics testing. When the brace instrumentation project was proposed, it quickly became evident that the Orthotics and Prosthetics (O & P) industry lacked objective information on the types and amounts of actual loads subjected to a brace during actual normal daily use. As a result, most of the orthotic designs are based on subjective information. This approach can result in over design, excessive safety margins and an increase in weight and bulk. Conversely, there is also the possibility that orthoses can be under designed, and catastrophic failure could occur. Thus, there exists a need and a desire for quantitative studies to determine the overall mechanical loads on various components of orthoses. These quantitative studies have proven to be a difficult task due to the various complexities of planning experimental protocols. Our experiences from the brace instrumentation project has resulted in expertise in mechanical strength testing and the development of a testing software and hardware which can be used for future biomechanical analyses.

Balance Testing Project

Deficits of balance control can limit activities of daily living. Such deficits also can lead to falls, a major source of morbidity and mortality in the elderly and disabled population. Over the years, balance tests have been developed using force platforms and some measure of center of pressure (CoP) movement called postural sway. These tests have been used to measure and quantify balance control. Treatment for balance deficits have been traditionally based on subjective means used by therapists. We feel that balance testing can be enhanced by incorporating virtual reality technologies, as part of the ATRC. By using VR technologies and coupling them with the Performance Diagnostic Laboratory, a balance testing system will be developed for two purposes. The first objective would be the use of visual stimuli via VR to provide insights into how the bodies balance control mechanism is working. The last purpose would be the incorporation of visual stimuli towards the actual treatment of the patients via biofeedback.

Evaluation of the efficacy of Biofeedback Strategies in Children with Lower Extremity Spasticity

The biofeedback program developed using a combination of VR and Nintendo technologies has shown promise, and has generated interest amongst clinicians. Many parents have expressed an interest in a similar take-home system, if one were so developed. Clinicians at NRH have discussed the possibility of using the biofeedback systems in their daily therapy routines. Dr. Alter has expressed an interest in conducting formal research investigating the effects of biofeedback therapy on performance enhancement. The incorporation of performance assessment

features in such biofeedback systems will also help enhance the applicability of these systems in clinical and research settings. Such a study will essentially involve the selection of a model system (for e.g., lower extremity), the measurement of their baseline performance scores using the PDL, the conducting of biofeedback therapy, and then a post-biofeedback PDL evaluation to help quantify the progress in the subject. Of particular interest could be a study of the relative progress in two subject groups: one receiving biofeedback therapy using the Nintendo style system discussed earlier, and a second group receiving target tracking therapy using a specially developed PC based system.

The use of Motion Analysis to study differences in task-completion strategies in real-world and VR based tasks

While VR applications in various fields are growing, there are still lingering questions regarding the applicability of VR based simulations in real-world situations. In this study, biomechanical performance of subjects (described in terms of pattern to target) can be measured for certain real-world tasks (e.g. pointing to back-lit targets on a checker board). The motion of the subject's body segments would be measured concurrently during this task (kinematics only). Subjects would then be asked to perform the VR analog of this real-world task. Changes in the patterns of task performance would be recorded and would yield information about the extrapolability of VR based simulations. The results of this study would help gain an insight into the applicability of VR as a training tool for individuals with disabilities.

Distributed Interactive Surgical Simulation and Modeling (DISSM)

The DOD with its SIMNET technology has for a long time been conducting virtual warfare using a combination of ultra-high speed wide area networks and high speed graphics rendering. With the introduction of Virtual Reality Modeling Language (VRML) 2.0 specification (*Moving Worlds*), the Internet is now ready to accept the transfer of dynamic 3-D data-sets images across the web. Such DIS (Distributed Interactive Simulation) technology can make a major impact in the field of teleradiology, telesurgery, and telemedicine. One such possible application could involve the development of a DISSM system that would preclude the need for resident computing horsepower in a clinician's office or operating room. The idea would involve the development of a VRML based API (Application Program Interface) that would allow the clinician to access simulation and modeling capabilities at a central resource through a standard VRML browser. Such technology could, for example, allow surgeon's remotely interact with patient specific graphic models, and practice their surgical procedures. A biomechanical processing widget embedded within the VRML API could also allow the surgeon to preview the biomechanical outcomes of his actions in real-time. Such development can be performed using a SGI platform and VRML development using a application with Java bindings such as Cosmo from SGI.

D. COGNITIVE STUDIES SECTION

Year 2 - Progress Report

Currently ongoing research, related activities, and some ideas for Year 3 projects to be conducted by the Cognitive Studies section of the ATRC are listed below:

1. Medication Trials with Neurologic Illness
2. Outcome of and follow-up to Consensus Conference
3. Adaptive Testing
4. ANAM Database
5. Concussion Care
6. Nootrope Database
7. Sports Concussion
8. ANAM Task Analysis

Brief descriptions of each of these items, any applicable methodological issues as well as their current status are discussed in the following sections.

1. Medication Trials with Neurologic Illness

Years one and two of the grant have involved considerable emphasis on carrying through clinical trials of efficacy of pharmacologic agents for enhancement of cognition following TBI. Thus far these trials have been in the form of single-subject, blinded placebo-crossover designs, using ANAM performance as the primary measure of change in cognition. Ideally a subject would begin to display a stable baseline of ANAM performance following 1-2 days of initial training, following which a medication could be introduced. It was expected, based on prior single-subject experience (e.g., Bleiberg, Garmoe, Cederquist, et al, 1993) that changes in cognition as a function of the medication would be reflected in changes in ANAM performance. A large volume of single subject medication trials were planned for years one and two of the grant. However, following approximately the first eight trials, it became evident that TBI subjects were not achieving a stable baseline of ANAM performance, even after as many as 20-30 trials over three days. Absence of stable baseline makes it virtually impossible to detect the potential effects of a medication on cognition, because day to day ANAM performance is so variable or unstable. Controlled trials to assess efficacy of medications with potential efficacy in enhancing cognition continues to be an important goal, and will be pursued in the following ways:

a) Single subject medication trials with TBI subjects will continue, but other methodologies will be considered; for example, shorter daily baseline periods, longer medication trials (two weeks on a medication versus one day), etc.

b) Assessment of normal control subjects using the same baseline procedures as used with TBI subjects. This will help r/o the possibility that baseline instability is a function of ANAM or the methodology used. Preliminary observations suggest that normal controls

produce a much more stable baseline acquisition pattern, and this needs to be studied in a more deliberate and controlled manner.

c) Group studies of medication trials. Study of pharmacologic enhancement of cognition will be expanded to a between groups study in addition to ongoing single subject trials. The most likely candidate for a between-groups study (e.g., active medication versus placebo effects in matched samples) would involve a geriatric sample at risk for development of cognitive impairment as a function of vascular disease. Potential cognitive enhancers are being explored through an existing database and consultation with a research psychiatrist and geriatrician.

2. Consensus Conference Outcome and Follow-Up

In May 1996 a group of approximately 12 researchers who largely form the core of people across the country using ANAM for research into mental performance/cognitive impairment gathered for a consensus conference. The conference was stimulated by recognition of several challenges that affect ability to generalize and share research findings from different labs. These include the use of different forms of ANAM and methodologies across labs, adapting ANAM to new subject samples/groups, and the above-noted difficulties in obtaining stable baseline patterns with TBI subjects. All participants had the opportunity to give an update of current ANAM research activities and results, to problem-solve conceptual and methodological challenges, consider alternative ways to analyze and structure data, and develop some consensus regarding future directions and challenges. From this conference the following priorities were identified:

* Establish a common ANAM data-base which will provide qualified researchers opportunity to contribute data to a larger pool, and to query for cases/samples that meet current research requirements, which will facilitate further studies and development.
* Develop ANAM to be Windows95 compatible.
* Pursue collaborative projects where relevant to research pursuits.
* Publish an edition of the journal Neuropsychology Review, which will serve to summarize the current state of the field of computerized performance assessment batteries (e.g., ANAM), and develop critical conceptual issues that will be the focus of ongoing research.

An important goal for year three will be to support writing and editing of the Neuropsychology Review issue, and to stimulate follow-up on many of the conceptual and methodological issues identified during the conference.

3. Adaptive Testing

Adaptive tests are those which are flexible in that performance criteria for subsequent trials are adjusted as a function of prior trials. For example, if a subject is performing with a high level of accuracy and speed, an adaptive test may adjust difficulty level on subsequent trials to increase the level of challenge. Conversely, if a subject is performing with frequent errors or slow speed, the difficulty level may be adjusted downward. Little or no research and application of adaptive tests has been done with brain injured subjects, though there are several reasons why they may be

beneficial. Adaptive tests may have potential for helping solve the problem of the unstable baseline, since the initial trials on a given day may be used to determine difficulty level for later trials, potentially resulting in a smoother pattern. Adaptive tests have shown early promise in identifying certain characteristics of performance among normal samples, and may also help to further conceptual understanding of cognitive models of brain injury.

Either as a stand-alone project or embedded in one of the areas outlined above, a study of the feasibility of an existing adaptive performance test will be pursued, comparing performance of normal controls to TBI subjects.

4. ANAM Database

Research using ANAM as a repeated measures test generates enormous quantities of data. Arranging the data for sophisticated data reduction and analysis has been a rather arduous and time-consuming task. It was determined during year one that a centralized ANAM database could greatly facilitate the data reduction and analysis process and facilitate collection of data from colleagues in the ANAM research community. At the first ANAM Consensus Conference, in May 1996, the current state of ANAM methodology was uncovered and recommendations were made to improve both the use of ANAM and communication about its use. In the latter portion of year two, a Microsoft Access database was designed and developed to store the raw ANAM data and associated demographic and neuropsychological test data collected by researchers here at NRH. Reading in raw ANAM data files has been automated. Data may be accessed for analysis via the database package directly or through SPSS (or any program which has an ODBC interface). The database is currently in the testing and demonstration phase, in preparation for distribution to other ANAM users in our group. Documentation of the database to this point includes a User's Manual, Database Administrator's Manual, and Design Description. In year three, the testing and demonstration phase will continue. The database will be expanded to include additional ANAM tasks from the Tester's Workbench as needed. Copies of the database will be distributed to ANAM collaborators. Once the database has been fully tested and is in a stable form, preparations will be made to make it available on a server and ultimately on a web page. A protocol will be developed to allow the larger ANAM research community to add data to the database and to access the data of others. Final versions of all documentation will be completed.

5. Concussion Care Treatment Protocol

Mild brain injury is a major civilian and military health care issue. There currently are no widely accepted treatment guidelines or protocols and there is no way to determine efficacious and cost-effective treatment. We propose to convene a panel of experts in all phases of concussion management to develop a coordinated treatment protocol that will cover all aspects of concussion management from a holistic framework that includes neurologic care but also incorporates management of musculoskeletal injury and pain, sleep disturbance, affective and stress disorders, and fitness enhancement. The protocol will incorporate "expert systems" software for appropriate protocol components. The protocol will include appropriate diagnostic and outcome

measurements so that a concussion treatment program will also, as a byproduct, be a concussion research program.

6. Nootrope Database

In addition to the traditional pharmacologic agents used to enhance cognition following TBI, the international literature suggests that there are many other agents which are beginning to be used in this way. These nootropes are being tested and used overseas with some success in enhancing cognition in many patient groups. Some of these substances are available in non-regulated forms in health food stores throughout the US, but studies with them have not been done here. During year two, an extensive search of the literature for cognitive enhancing agents was performed and documented, producing a searchable database. In year three, this database will be updated regularly and used to develop proposals for drug trials with clinical groups (as described in 1. Above).

7. Sports Concussion

During year two, a proposal to study patterns of recovery from sports-related concussion was approved. A collaboration with the athletic department of a local high school, Gonzaga College High School (private, Jesuit), was arranged. Baseline neuropsychological and ANAM testing of Varsity football players began in September. In year three, follow-up assessments will be done during and after the football season. Concussed players and matched controls will be measured at shorter intervals until return to baseline is detected.

In year three, a collaboration with a local girl's school will be sought for the purpose of studying sports concussion in adolescent women. To date, there are no published findings of studies of concussion recovery in this population; there appears to be no published evidence that any research in sports concussion has been done with this population. A proposal will be developed similar to that being used at Gonzaga, with the findings from Gonzaga being used to adapt the measures and procedures to improve understanding of concussion recovery.

8. ANAM Task Analysis

Research in cognitive processing comparing brain injured with non-brain injured subjects indicates that some functions are apparently more susceptible to disruption after brain injury. The ANAM battery has proven to be an adequate tool for differentiating clinical from non-clinical subject groups in processing speed and variability of performance. As described in (1.) above, this variability makes it hard to get a stable baseline performance against which to test pharmacological interventions. Preliminary analysis of individual tasks suggests that there may be certain types of items in some of the ANAM tasks and interactions across items that may disproportionately influence the overall score for a trial. By examining this data more closely, it may be possible to construct an instrument more sensitive to specific cognitive deficits. In turn, this instrument might be more sensitive to the effects of cognitive enhancing agents as well.

During year three, a thorough, theory-driven, analysis of existing data, both our own and that which we can obtain from others in the ANAM community, will be performed. Patterns of response will be identified and specialized tasks will be constructed to maximize the potential for

finding differences between brain injured and non-brain injured. Testing of these specialized tasks will done in two phases. First, an appropriate number of non-brain injured subjects will be assessed with these new tasks to support and replicate the findings of the task analysis. Then, if the task analysis is supported, a comparable group (N, age, gender, time of day) of mild to moderately brain injured subjects will be assessed. Tasks which clearly differentiate the TBI from the non-TBI will be considered for inclusion in subsequent drug trials.

DEPARTMENT OF THE ARMY
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REPLY TO
ATTENTION OF

June 27, 1996

Deputy Chief of Staff
For Regulatory Compliance
and Quality

Richard Materson, M.D.
National Rehabilitation Hospital
102 Irving Street, NW
Washington, DC 20010-2949

Dear Doctor Materson:

A staff assistance visit was conducted at the National Rehabilitation Hospital, Cooperative Agreement Number DAMD17-94-V-4036, on June 13-14, 1996, by Mrs. Catherine Smith, Human Use Review Specialist, and Ms. Kenna Conner, Human Use Review Assistant.

The following contacts are listed in order of visit:

Ruth Brannon, M.S.P.H., ATRC Administrative Director
William Peterson, M.S., Director, Rehabilitation Engineering, NRH-ATRC
Chris Ruffin, Administrative Secretary, Rehabilitation Engineering, NRH-ATRC
Anthony Fu, Electronics Technician, Rehabilitation Engineering, NRH-ATRC
Sujat Sukthankar, Ph.D., RE, Senior Research Engineer, Rehabilitation Engineering, NRH-ATRC
Tom Dang, M.S.E., RE, Senior Clinical Research Engineer, NRH-ATRC
Loretta Polite, Research Administrator, MRI, NRH
Raymond Waters, Ph.D., Pschometrist, Psychology, NRH
Ellen Halpern, Ph.D., Post Doctoral Psychology Fellow, NRH
Naomi Lampert, Doctoral Student, NRH-Consultant

The studies reviewed and discussed during the staff assistance visit were:

"Assessment of the Efficacy of Methylphenidate and Dextroamphetamine in Enhancing Cognitive Functioning Following Mild and Moderate Traumatic Brain Injury," Submitted by Joseph Bleiberg, Ph.D., National Rehabilitation Hospital (Log No. A-6907).

Appendix

Staff Assistance Visit

"Biomechanical Analysis of Scott-Craig Type Long Leg Braces During Ambulatory Tasks," Submitted by Tom Dang, M.S.D., National Rehabilitation Hospital (Log No. A-7040).

"Assessment of Unilateral Spatial Neglect in a Virtual Reality Environment," Submitted by Sujat Sukthankar, National Rehabilitation Hospital (Log No. A-7092).

Dr. William Peterson provided an overview of the concept of assistive device technology. The Technology Demonstration Center's capabilities were demonstrated and just a few of the heartwarming success stories were presented. The primary focus of the center is to provide the greatest amount of mobility possible for those people with catastrophic disabilities. These individuals are provided a means to continue in life as functionally independent as possible. The center uses products on the market that are adapted in the center to meet the needs of the handicap. Included in the demonstration were: the Kurzwell Voice Center demonstration which allows voice-activated/controlled computer typing, as well as voice activation of television, doors, fans, and other electrical devices. This would allow an immobile individual complete access to devices within the person's work area and home environment.

The Biomechanics Laboratory was viewed. This computerized lab is designed to view how the body moves. The computer records movement with output shown on a camera attached to the computer. This allows a handicapped individual's physician to determine where the weaknesses are in the individual's prosthesis and make necessary adjustments. In the past, the physician had to rely on the eye to attempt to determine where the adjustments needed to be made. This was a time-consuming process for both the physician and for the handicapped individual. This new process allows for determination within a matter of minutes.

The Virtual Reality Workstation was demonstrated. Ms. Smith and Ms. Conner were involved in the demonstration. The purpose of using virtual reality for handicapped individuals is to assess the elements of unilateral spatial neglect.

All study records were reviewed. Nine consent forms were reviewed from studies A-6907 and A-7040. Seven subjects have been enrolled in A-6907 and two subjects have been enrolled in A-7040. Study records for A-7092 were at a separate building and not available. Three of the consent forms did not have the address block completed. There were no other deficiencies noted. The study records were in exceptional condition. All appropriate approvals were filed, in order.

Discussion took place regarding the lengthy process each protocol must endure. The NRH Research Committee performs an exhaustive review which includes assessment of scientific merit, risk/benefit to patient, scientific design, adequacy of consent form, etc. The committee consists of department heads and senior researchers. This committee works as the Institutional Review Board (IRB) with respect to ensuring the protocol, consent form, and related documentation are in the final form. Only upon review and approval of the NRH Research Committee, does the protocol package go to the Medlantic Research IRB which does a cursory review and final approval. The protocol is then sent to the Human Use Review and Regulatory Affairs Division (HURRAD) for review and recommended revisions. Once the revisions are made, the protocol then must go back to the Medlantic Research IRB for approval. It was decided that the process was too lengthy and that it could be simplified by having HURRAD provide review comments after the protocol is approved by the NRH Scientific Committee. The final package would then be sent to Medlantic Research IRB for approval. That approval letter would then be provided to HURRAD. Any changes made by Medlantic Research IRB would need to be reviewed by HURRAD.

Discussion took place regarding changes to existing protocols. An addendum is working its way through the review process and would be sent to HURRAD as soon as possible. Most studies ongoing at this point are pilot studies. Upon year's end, the projects will be reviewed and NRH will make the decision whether to terminate or expand the protocols into phase II.

Discussion took place regarding HURRAD review comments, requirements, and additional protections.

Ms. Polite then met with Ms. Smith and Ms. Conner to discuss IRB requirements. A copy of the Investigator's Guide was provided for information. The streamlined review

process discussed above was presented, and Ms. Polite indicated that this would work very well. The scheduling of the various committees was discussed. Ms. Smith indicated that a copy of the Human Subjects Research Review Board (HSRRB) meeting schedule would be sent to NRH so they can plan appropriately. The continuing review process was discussed. A copy of National Institute's of Health IRB Information sheets was presented. Ms. Polite outlined her continuing review policy.

The issue of non-english speaking individuals was brought up. Ms. Polite indicated that for those who do not understand English their policy is to have the individual bring an English-speaking friend or relative whom they trust and who can translate on site for them. Ms. Polite also discussed research with children. Because this is not a common occurrence at NRH, she indicated that two consent forms must be provided in the event a minor is enrolled. A consent document to be signed by the parent or guardian and an assent document to be signed by the minor.

Dr. Waters and Dr. Halpern discussed the cognitive functioning study using methylphenidate and dextroamphetamine. The protocol includes male and female subjects currently under treatment by a physician for mild or moderate traumatic brain injury. The study will determine whether or not these drugs will improve cognitive functioning in this patient population. Sixteen candidates have been interviewed. At this point, six subjects have met the study criteria, have been enrolled and have completed. Subjects have 2 days baseline testing on the Automated Neuropsychological Assessment Metrics (ANAM). After medication or placebo is taken on the third day, the same series of ANAM tests are conducted. The investigator is blinded to what medication or placebo the subject is taking. A pseudo-random order is generated so that the subject will not take the same medication/placebo on 2 consecutive assessment days. A total of 6 to 8 days will complete the testing. A demonstration of the ANAM test was provided. It was mentioned that the test terminal has a special password access only so that non-study personnel can enter the system. It was suggested that some improvement has been shown in a few subjects in this study but that it is too early to determine the overall benefit.

The day's visit ended at 1800 hours on 13 June 1996.

On 14 June 1996, an attempt was made to observe a subject testing in the leg brace project. The subject, however, was uncomfortable with the additional people in the room. It was decided to view the virtual reality project which was also in progress. The virtual reality project is designed to see if virtual reality can be used in the assessment of unilateral visual neglect.

The consent process for the virtual reality project was witnessed by Ms. Smith and Ms. Conner. Ms. Lampert introduced the subject (normal) to the study and outlined the objectives and the procedures. The subject was then asked a series of questions regarding her medical history (screening process). Upon determination of eligibility, Ms. Lampert then asked the subject if she wanted to participate at this time. The subject indicated she would like to participate and was presented a consent form to read and sign. Each page was read, and initialed and dated, by the subject. The subject was then presented the Volunteer Registry Data Sheet, USAMRDC Form 60-R, to complete. The study began with a series of pen and pencil tests. Continually throughout the consent process, the subject was asked if she had any questions. All questions were answered to the subject's satisfaction and there was exceptional rapport between the subject and Ms. Lampert.

The subject then was brought to the virtual reality test site where she was introduced to Dr. Sukthankar, who proceeded to discuss the process and procedures involved in the study. A practice session was allowed to familiarize the subject with the system. The testing then began with a series of tasks using a head mounted display. The study required a number of trials under three conditions: 1) equally salient stimuli presented to the right and left visual fields; 2) visually enhanced stimuli presented to the affected hemispatial field, and; 3) visually degraded stimuli presented to the otherwise intact visual field. The study took approximately 30 minutes.

Ms. Smith then met in the conference room and presented an outline of the HURRAD to interested individuals. This presentation included a flow-chart of the Army's human use review process, the USAMRMC's extramural proposal review process, The Army's medical care clause, samples donation clause, and the volunteer registry requirements. Also provided were information papers on the Army's requirements for human volunteers in research, the

HSRRB, and the HURRAD's history from 1974 through the present. A question and answer period followed. The visit was wrapped up at 1200 hours.

CONCLUSION: All human use documentation for the above studies are complete and accurate. Continuing review and approval of all active protocols are up-to-date. There were no deficiencies noted.

We would like to thank your colleagues for their time and cooperation in assisting Ms. Smith and Ms. Conner during this very educational and rewarding staff assistance visit.

Point of contact for all questions is Mrs. Catherine Smith, Human Use Review Specialist, 301-619-2607.

Sincerely,

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