AD 669 998

DEVELOPMENT OF AN EPOXY FOOT MOLD AND A LIGHTWEIGHT FOAM ARTIFICIAL FOOT

Charles Asbelle

Navy Prosthetic Research Laboratory
Oakland, California

15 March 1968

DEVELOPMENT OF AN EPOXY FOOT MOLD AND A LIGHTWEIGHT FOAM ARTIFICIAL FOOT

FINAL REPORT
15 MARCH 1968

NAVY PROSTHETIC RESEARCH LABORATORY
NAVAL HOSPITAL, OAKLAND, CALIFORNIA

71

DEVELOPMENT OF AN EPOXY FOOT MOLD
AND
A LIGHTWEIGHT FOAM ARTIFICIAL FOOT

FINAL REPORT
15 MARCH 1968

NAVY PROSTHETIC RESEARCH LABORATORY
NAVAL HOSPITAL, OAKLAND, CALIFORNIA

12ND P867 (REV. 4-68)

NAVY PROSTHETIC RESEARCH LABORATORY

THIS REPORT DEALS WITH TWO INTERRELATED DEVELOPMENTS -- THE CONSTRUCTION OF A SPECIAL THICK SECTION EPOXY ARTIFICIAL FOOT MOLD WHICH PERMITS THE PRODUCTION OF A MOLDED, POLYURETHANE PROSTHETIC FOOT.

BOTH THE MOLD AND THE FOOT HAVE BEEN TESTED AND USED SUFFICIENTLY TO PROVE BOTH TO BE WORTHWHILE.

THE WORK NOTED WAS PERFORMED ENTIRELY BY THE STAFF OF THIS LABORATORY. TWO COMMERCIAL FIRMS ARE PRESENTLY ENGAGED IN THE PRODUCTION OF THIS FOOT FOR THE CIVILIAN POPULATION.

Prepared by:	Approved by:
Charles Asbelle B.S., C.P.& O Research Director	LCDR D. W. Rohren MC, USN Medical Officer-in-Charge

BLANK PAGE

SECTION I

INTRODUCTION

A. General

This report describes and discusses the development of a particular kind of artificial foot. The foot provides advantages of light weight and simplicity of construction and manufacture over other commonly available prosthetic feet.

A lightweight foot is of considerable advantage to all amputees. The above-knee subject may thus use his limb over an extended period of time, the below-knee will have reduced piston action, the geriatric patient will have reduced load on his heart and those with circulatory dysfunctions will subject their circulatory apparatus to minimal strain.

To achieve the lightweight advantages it has been necessary to trade off some life expectancy of the foot; however, the foot is quite durable and will wear similarly to the life of a good pair of shoes.

The simplicity of construction allows a low manufacturing cost.

Outwardly, the foot is a one-piece, molded, flexible polyurethane foam which encases a maple wood and three or four ply canvas belting keel assembly. The wood keel provides structural integrity to the foot and also allows the secure attachment to the shin section. The canvas belting extends into the toe section and serves to stiffen the toe and to also distribute the walking loads over the sole of the foot, improving the life of the polyurethane foam.

Functionally, the polyurethane foam foot approaches its human counterpart in such actions, motions and combinations of motions as plantar and dorsal flexion and to a reduced but apparently adequate extent, the motions of medio-lateral and transverse rotations.

B. Biomechanics

Casual study of the human leg and ankle during walking gives the initial illusion of ease and simplicity in their respective functions. During walking the several leg segments perform intricate motions and patterns with timeliness and precision. Actually, the feat of walking involves an incompletely understood series of interrelated, yet interdependent, actions. The general pattern of walking is subject to individual variations. Even more severe variations may occur with a wide variety of medical, surgical or neurological conditions including physical loss of a leg, or legs, by amputation.

The skeletal structure of the leg, the bones, functionally serve in three distinct ways, e.g., support, mobility and stability for the body. Mobility between the bones of the leg is provided by the different types of articulations of the hip, knee, and ankle joints. Loss of the ankle joint by amputation can usually be so compensated for by the amputee that the individual will have a normal appearing gait. This is accomplished by the remaining joints taking over some of the functions of the ankle and the elastic deformations of the polyurethane foam foot.

The ankle joint is subjected to a variety of complex forces arising from the ground reactions of normal walking. In the human ankle these forces are balanced by muscle action and the geometry of the skeletal and ligamentous structures of the ankle. When the amputee is deprived of the ankle joint it is necessary for him to learn a new pattern of walking so as to have a normal appearing gait. The remaining muscles of the amputation stump will, of course, have extra duties to perform to compensate for the loss of the musculature and skeletal structures of the foot and ankle.

Because of its distal position, the foot and ankle are subjected to considerable accelerative and retarding forces during walking. All of the forces required to achieve these accelerations and decelerations must be transferred through the shin and ultimately to the amputation stump. The lightest possible weight on the end of the mechanical lever, represented by the shin, reduces the magnitude of the forces acting on the stump and reduces the amount of work the individual's muscles must perform as he goes about his daily activities.

The sequelae of amputation naturally includes some degree of necessary trauma and general debility with individually variable effects. Ordinarily the partial muscles remaining, or those with disturbed nerve supply, tend to lose their original functional abilities; sometimes become soft, edematous and lose their tone. They sometimes become flaccid, deposited with fatty tissues and present a typical pattern of atrophy of disuse. Degenerated tissues of that type frequently complicate the later problems of prosthetic fitting. An operative procedure called myodesis, or myoplasty, in which the involved muscles are virtually tied together and secured to the bone during amputation surgery is intended to reduce or eliminate tissue degeneration of this kind. The intent is that the remaining musculature will remain under slight tension and actively engage in the function of supporting, moving and stabilizing the involved bone and thus the body. This muscle activity also assists in venous blood return and lymphatic circulation.

Amputation of the leg thus primarily affects the fundamental mechanics of walking by upsetting the pre-amputation leverages and biomechanics then in effect. Secondarily, the problem is compounded by removal of muscle and muscular attachments and the natural deterioration which takes place in the remaining soft tissues.

C. Human Walking Cycle

Considerable clarity may be provided by describing the basic "walking cycle." The term refers to the typical movement pattern described by one leg as it moves in coordinated sequence (Fig. 1) from heel strike to heel strike. By heel strike is meant the moment the heel first touches the ground. The walking cycle may be divided into two phases; one in which no weight is borne, the other in which weight is borne. They are called the Standing and Swing Phases. Approximately thirty-three percent of the cycle is required for the Swing Phase.

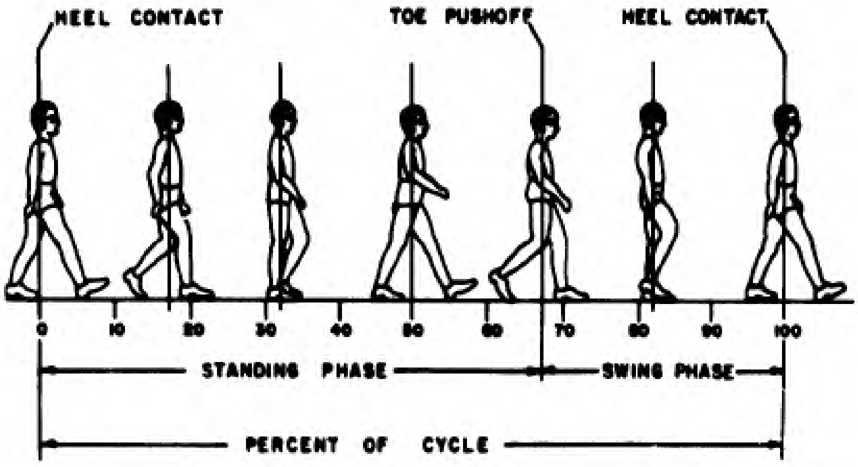


Fig. 1 HUMAN WALKING CYCLE

The Walking Cycle is divided into Standing and Swing Phases for purposes of discussion. The arbitrary starting point for the right leg in the figure is the moment of heel contact with the walking surface. Note that approximately one-third of the cycle is required for the Swing Phase while the remaining two-thirds involve weight-bearing.

The moment of heel contact may be arbitrarily considered as a starting point. As the non-amputated subject normally walks on a level surface, about two-thirds of the total cycle involves weight-bearing by the foot. Beginning at heel contact, the body weight is progressively and rapidly assumed by the foot. Immediately after heel contact the ankle joint moves into plantar flexion as the shank arcs forward toward a vertical position over the ankle joint. At that point the foot, for all practical purposes, bears full weight of the body because at the same moment the opposite leg is in its Swing Phase and has no contact with the ground. Also, immediately after heel contact the knee flexes slightly and then extends so that full extension coincides with the action of the tibia as it reaches its vertical position. As the tibia continues its path forward from the vertical position, the ankle joint moves into slight dorsal flexion. The diminishing body weight shifts to the ball of the foot as the heel rises from the floor. In rapid sequence the knee flexes as the ankle joint returns to a neutral position, midway between plantar and dorsalflexion. At that moment the heel of the opposite foot contacts the floor. The Standing Phase ends with the moment the toe leaves the floor. As noted, the Swing Phase occupies about one-third of the cycle and begins with the moment the toe leaves the floor and ends at the moment of heel contact. The Swing Phase includes three sequences, acceleration, swing-through and terminal deceleration. During these sequences the foot and ankle move through space, at first accelerating rapidly, swinging through, and then decelerating rapidly just before heel contact.

SECTION II

DEVELOPMENT OF EPOXY MOLDS

A. Sculpturing (Fig. 2)

The mold-making process begins with a master model of the foot. This master model is the result of research, experience, artistry and a high level of technical skill. For this laboratory, no usable models or even dimensional data existed and so development started at the very beginning.

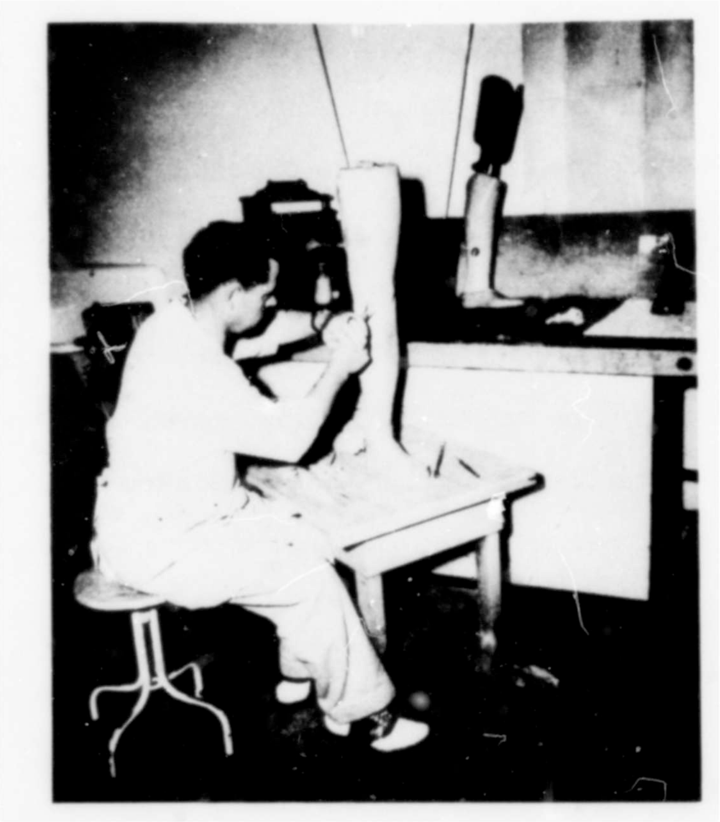


Fig. 2 SCULPTURING THE LEG/FOOT/ANKLE

Epoxy molds are locally made from plaster foot models themselves made with a combination of artistic and anatomical knowledge with the understanding that the human foot is a matched component of the lower extremity.

From available hospital personnel, people with shoe sizes from 5 to 13 male, 3 to 9 female, 1 to 4 juvenile and 4 to 13 children, were selected and wrap casts were made of their feet. Ultimately a total of 52 usable molds were thereby produced. The wrap casts were taken on a contoured foot board, made to duplicate the heel height of military last shoes for the man and woman and standard commercial shoes for the children. These wrap casts were merely used as a convenient means of obtaining rough models and in no case were these used for the purpose of defining the foot contours.

Male models of plaster were prepared from these wrap casts. The complete series of casts (male models) were then lined up on the bench from the smallest to largest and firmly secured to a board that provided the correct heel height. All contours were then faired in and all dimensions were checked so that the models provided regular graduated sizes from the largest to the smallest . This procedure was used on all series of feet so that graduated sizes were developed. In addition, the left and right models were checked and adjusted to the exact same size. The final check of these master models was to evaluate the fit in a new pair of shoes.

B. Special Modifications

From the foregoing it is seen that a set of standardized foot models had evolved which were based on human contours but with standard graduations in size. While these models were good approximations of the human foot they were not suitable to define the required contours for an artificial foot, especially if the foot is of the solid ankle cushion heel type.

The most obvious difference between the human foot and the "SACH" foot is the absence of an ankle joint in the prosthetic member. This limits such natural motions as plantar and dorsal flexion, lateral and medial motion, transverse rotation and combinations of such motions. Such of these motions remaining are dependent on elastic deformation of the foot materials, sliding movements of the foot within the shoe, or both. In most cases, this apparently presents acceptable performance.

An excellent discussion of desirable modifications adding substantially to success of the solid ankle cushion heel concept is contained in the manual on "The Patellar-Tendon-Bearing Below-Knee Prosthesis," by Radcliffe and Foort.

C. Duplication of Master Models

It will be appreciated from the foregoing that the master models become valuable because of the labor required to produce them. To ensure the safety of the master models, they are themselves reproduced and the reproductions serve as the working patterns for fabricating the molds. In order to produce the working patterns it is necessary to make a split mold of plaster using the master model to form the cavity.

To avoid undercuts and to have a smooth parting line, the split mold has the parting line in the anterior-posterior plane. On the finished epoxy mold the parting line is located along the sole of the foot. The plaster split mold is formed in a simple wooden box made in halves to correspond to the parting line of the plaster mold. The lower section of the box is filled with sand to within 1/4 - 3/8 inches of the parting line surface with the master model in place. The parting line is sealed with plaster applied over the sand to fill the box exactly to the parting surface which corresponds to the top of the lower half of the box. The plaster surface is carefully smoothed and sealed and a parting agent applied.

We now have the upper half of the master model projecting from the lower half of the box and a smooth parting surface in the anterior-posterior plane. The upper half of the box is then fitted into place and the plaster is poured to completely fill the wooden box. After the plaster has hardened the wooden box is turned over and the sand and plaster seal is removed. Once again we have one-half of the master model projecting from a smooth parting surface. After the plaster has completely set up (overnight), indexing holes are drilled through both halves of the split mold and indexing pins are fitted. The split mold is then opened and the master model is carefully removed.

Any number, up to 15 to 20, of copies may be produced by using this split mold. These working copies are required because the epoxy molds have undercuts that make it necessary to break out the patterns. These undercuts are the contours of the malleoli and when the molded urethane foam foot is removed from the mold the elasticity of the materials allow removal of the molded part without damage. The plaster being rigid requires breaking out for removal.

D. Epoxy Molds

The artificial foot described is shaped by means of a negative mold in which a model of the foot is used to form its inner shape.

For quantity molding of such devices as the artificial foot, an expensive, high quality mold is ordinarily used, a separate mold for each foot size, right and left. Handmade molds produced by toolmakers can result in a very heavy investment when an array of molds is required.

In this instance the use of epoxy molds is introduced for the production of artificial feet which present certain conveniences at quite moderate cost. Because of the value of the epoxy molding technique here and in other instances in the prosthetic shop, the procedure will be described in some detail.

The molds, of course, are made from models therefore it is necessary to have a set of foot models. The foot models require some artistic knowledge of anatomy of the foot. The models are made of a high grade plaster of Paris or dental stone in appropriate sizes in rights and lefts as follows:

	Left	Right
Size	5 1/2 - 6	5 1/2 - 6
Size	6 1/2 - 7	6 1/2 - 7
Size	7 1/2 - 8	7 1/2 - 8
Size	8 1/2 - 9	8 1/2 - 9
Size	9 1/2 - 10	9 1/2 - 10
Size	10 1/2 - 11	10 1/2 - 11
Size	11 1/2 - 12	11 1/2 - 12
Size	12 1/2 - 13	12 1/2 - 13

The sizes indicated fulfill practically all adult, male needs.

Shapes and contours of the foot models, as indicated, were determined after considerable study of available commercial artificial feet and shoes made on military lasts. Sole thickness was considered to be 3/8", heel height 1". Models of feet in high grade plaster of Paris were thus produced in which spaces for the ankle bolt and recess were molded in place.

When the foot models were ready for use they were pre-heated in a 140° - 150°F. oven to eliminate all traces of moisture. They were then finished over all surfaces with a high gloss lacquer and then waxed and buffed to a very glossy finish. A glossy finish assures a smooth surface for the mold and thus a smooth surface and external "skin" for the molded foam of the foot to be produced.

At the end of this section the exact materials found to be satisfactory are listed. Until experience is gained, no variations, however slight, should be made. In addition, drawings of all fittings and fixtures required are likewise included.

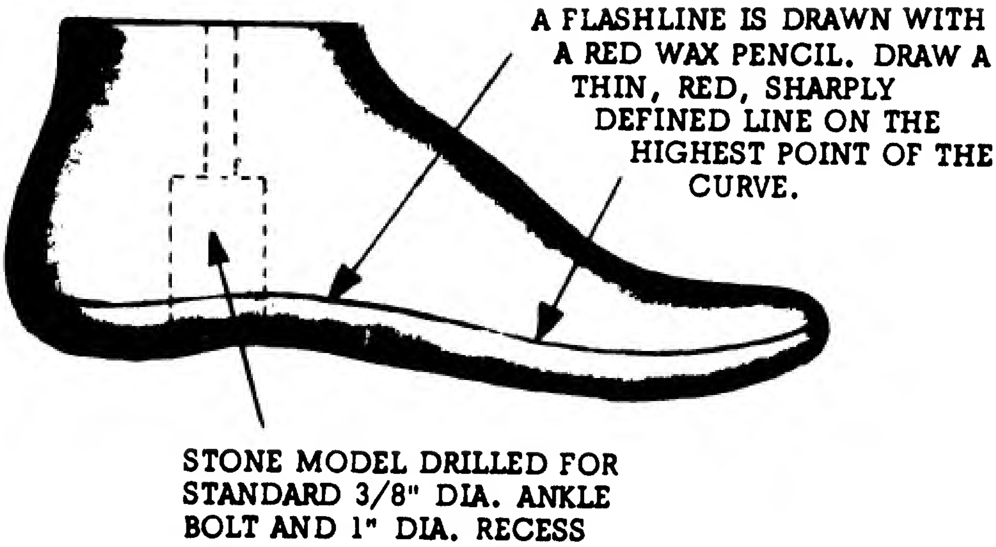


FIG. 3 PLASTER FOOT MODEL

The foot model, or pattern, may be made of dental stone or high grade plaster of Paris. The model, before use, should be oven-dried for several hours at 140° - 150° F. to eliminate all trace of moisture. A high gloss lacquer is applied then waxed and buffed to a high, smooth finish.

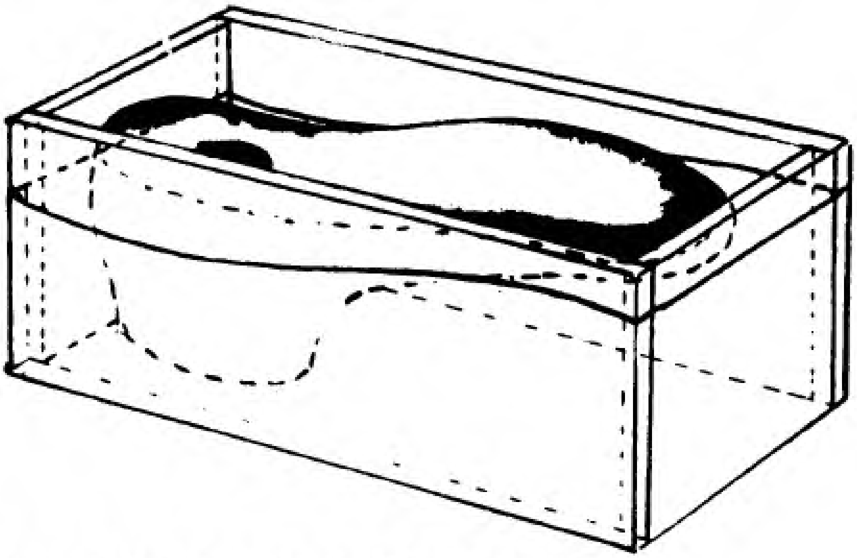


FIG. 4 FOOT MODEL IN PLYWOOD BOX

Using 1/2" exterior plywood, a box is made to contain the foot model and extend 2" beyond its largest dimensions. The foot is inverted and attached and the red lines previously inscribed on the model are duplicated on the box. The box is then sawn into plantar and dorsal sections as illustrated.

The following method for making foot molds for the production of molded foam feet is the result of an experimental study made in cooperation with Mr. M. K. Young, associated with U. S. Gypsum Company, during a visit to this laboratory. The U. S. Gypsum pamphlet titled, "Report on Epoxical Casting Resins Systems," contains important fundamental information in this field and is highly recommended.

The U. S. Gypsum thick section epoxy casting resin is identified as No. 301. This resin plus hardener and aluminum grain are used in the following proportions by weight:

No. 301 Thick Section Epoxy Casting Resin	100 parts
Aluminum Grain	80 parts
Hardener	12 parts

The following steps are followed:

1. As shown, a flashline is drawn as a thin, red, sharply defined line on the highest point of the curve at the sole level (Fig. 3).

2. Using one-half inch exterior plywood, a box is constructed with dimensions 2" longer, 2" wider and 2" higher than the stone model. The model (Fig. 4) is placed in the box and secured to the lid by means of a standard ankle bolt. Lines are marked on the box exactly as those of the red flashline noted above. The box is then sawed into two sections along the marked line. This divides the box into a plantar section and a dorsal section.

3. As noted when the foot model is attached to the dorsal base, the model has spaces for a standard 3/8" diameter ankle bolt and a 1" diameter recess. These spaces, as shown in Fig. 3 may be either molded or drilled out when the model is made.

4. When the inverted foot model is securely bolted to the dorsal base the box is nearly filled with common builder's sand which is compacted and contoured

as shown, Fig. 5. A layer of smooth plaster of Paris, about 3/4" thick, is spatulated onto the sand and smoothed to the contour of the red line on the model. This will form the separating line between the dorsal and plantar sections of the box.

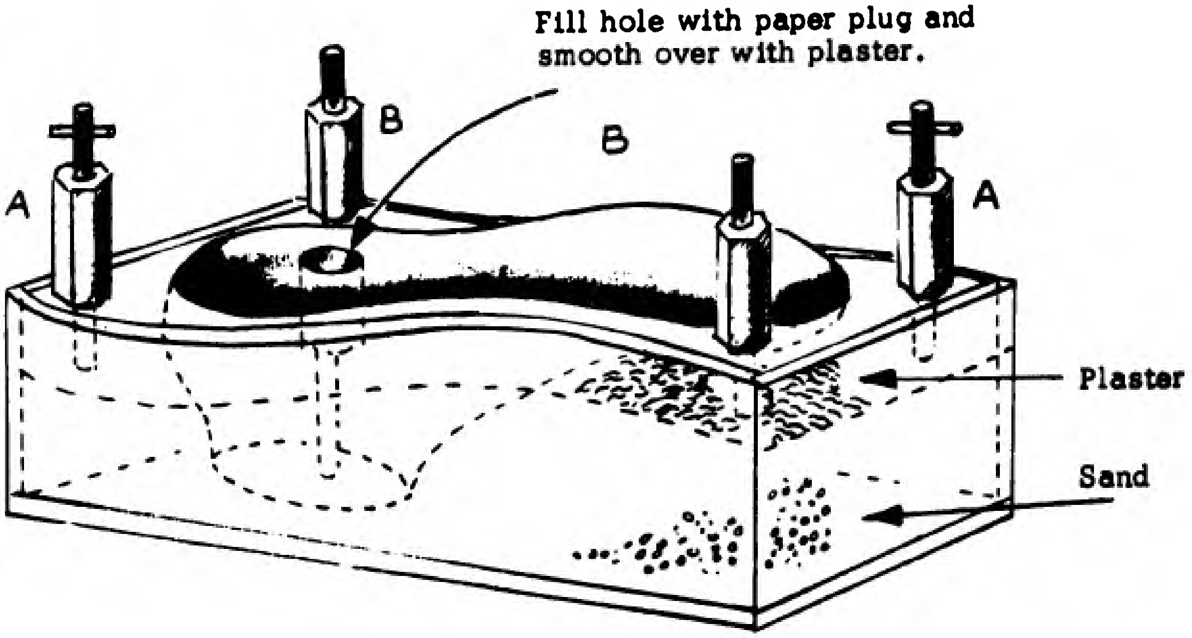


FIG. 5 APPLICATION OF PLASTER LAYER OVER SAND

With the foot bolted into position, partially fill the dorsal box section with sand, as shown. Spatulate onto the sand a 3/4" layer of smooth plaster of Paris up to the red line. On hardening of the plaster, 3/8" diameter holes are drilled 1" deep in each corner. Positions A-A are threaded for pushout pins while Positions B-B are alignment pins. The ankle bolt hole is filled with crumpled paper to prevent fouling.

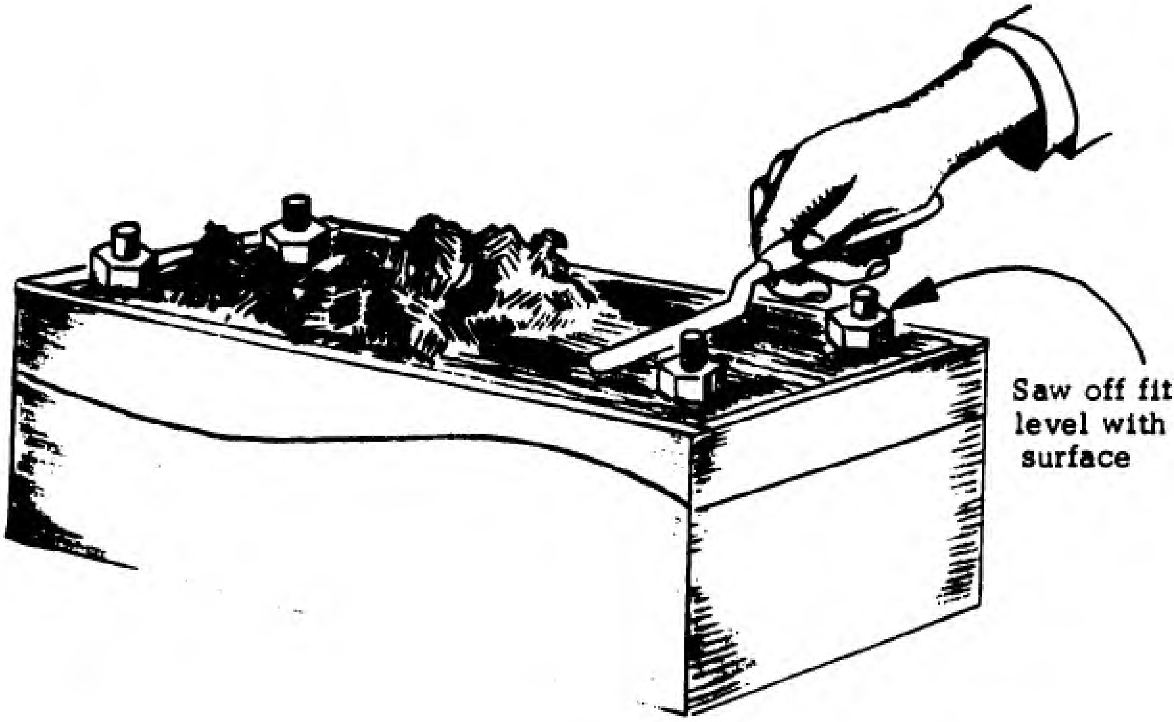
5. On each corner, centered 3/4" from either side, vertical 3/4" holes are drilled 1" deep. Two are for alignment pins and two for pushout pins, the latter used to separate the two mold halves when the foam plastic foot has been cured. Details of both are shown in Fig. 7.

6. Paper is used to plug the recess hole at the ankle bolt position. A light coating of wax ("Trewax") is applied followed by a coating of release agent

(Astrolite Release Agent No. R800).

7. As shown in Fig. 5, the alignment and threaded pushout pins are set in place followed by the plantar half of the box mold.

8. Mix a quantity of #301 Thick Section Epoxy Casting Resin and Hardener and apply over the surface of the stone model and presenting inner surfaces of the mold. After 4 minutes add the aluminum grain and stir for 4 minutes, pour into the box and smooth off (Fig. 6) uniformly with a spatula. This mixture sets up hard in approximately twelve hours.



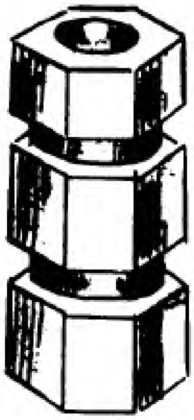
Saw off fittings level with plastic surface

FIG. 6 APPLICATION OF EPOXY AND ALUMINUM GRAIN

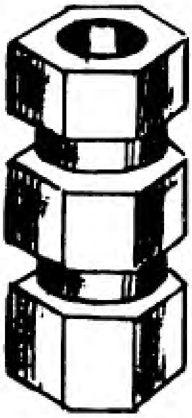
Reposition the plantar half of the mold and brush an even coat of #301 Resin and Hardener over the presenting stone surfaces and inner surfaces of the mold. Wait 4 minutes. Add aluminum grain to the mixture consisting of 100 parts resin plus 80 parts aluminum grain. To 12 parts resin add 1 part hardener.

FITTINGS NEEDED FOR ONE FOOT MOLD

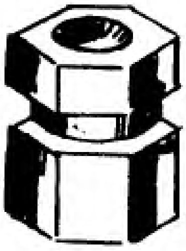
8 Hexagonal fittings	1 Keel holder
2 Alignment pins	2 Threaded pushout pins



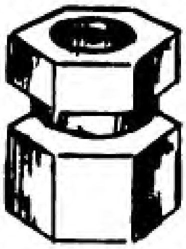
2 Long threaded fittings



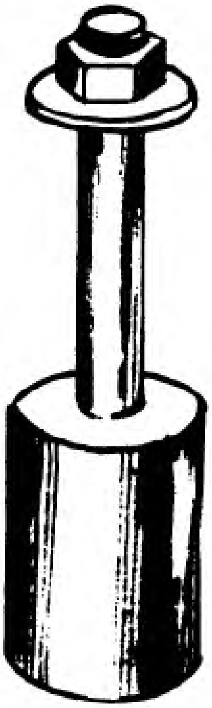
2 Long, smooth bore fittings



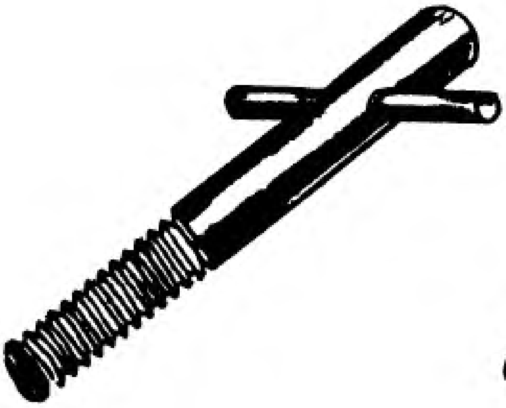
2 Dimpled fittings



2 Smooth bore fittings



Keel holder
3/8" dia. bolt
#16 N.C. thread



2 Threaded
pushout pins

2 Smooth alignment pins

FIG. 7 MOLD FITTINGS

9. On setting of plastic in the plantar side of the box, remove the lid and pour out the sand. Carefully remove the layer of plaster that formed the flash-line and also held the hexagonal alignment and pushout pins in position.

10. Remove stone model, examine surfaces and smooth off if necessary. Apply smooth, even, coat of clear lacquer, (Fig. 8) wax and release agent (Astrolite R-800).

11. Lift off dorsal side of box. Insert two 1" diameter aluminum rods across inside box as shown in Fig. 9 so that they rest about 3/4" from the model. These are held in place by small nails driven into drill holes in the end of the rods. The rods act as heat sinks to help discharge heat from thick sections during the exothermic reaction of polymerization.

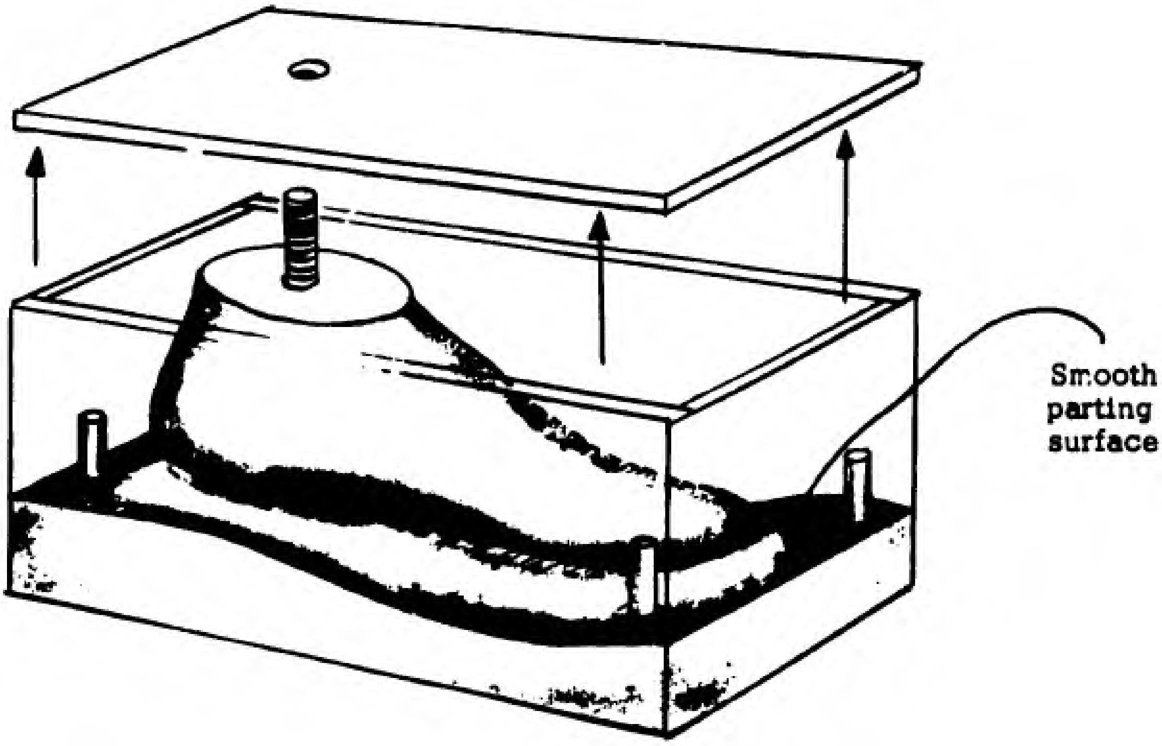


FIG. 8 REFINISHING PARTING SURFACES - PLANTAR SIDE

Remove lid of plantar side of box then sand. Carefully remove plaster layer. Remove stone model and refinish parting surfaces with lacquer, wax, then polyvinyl alcohol coating.

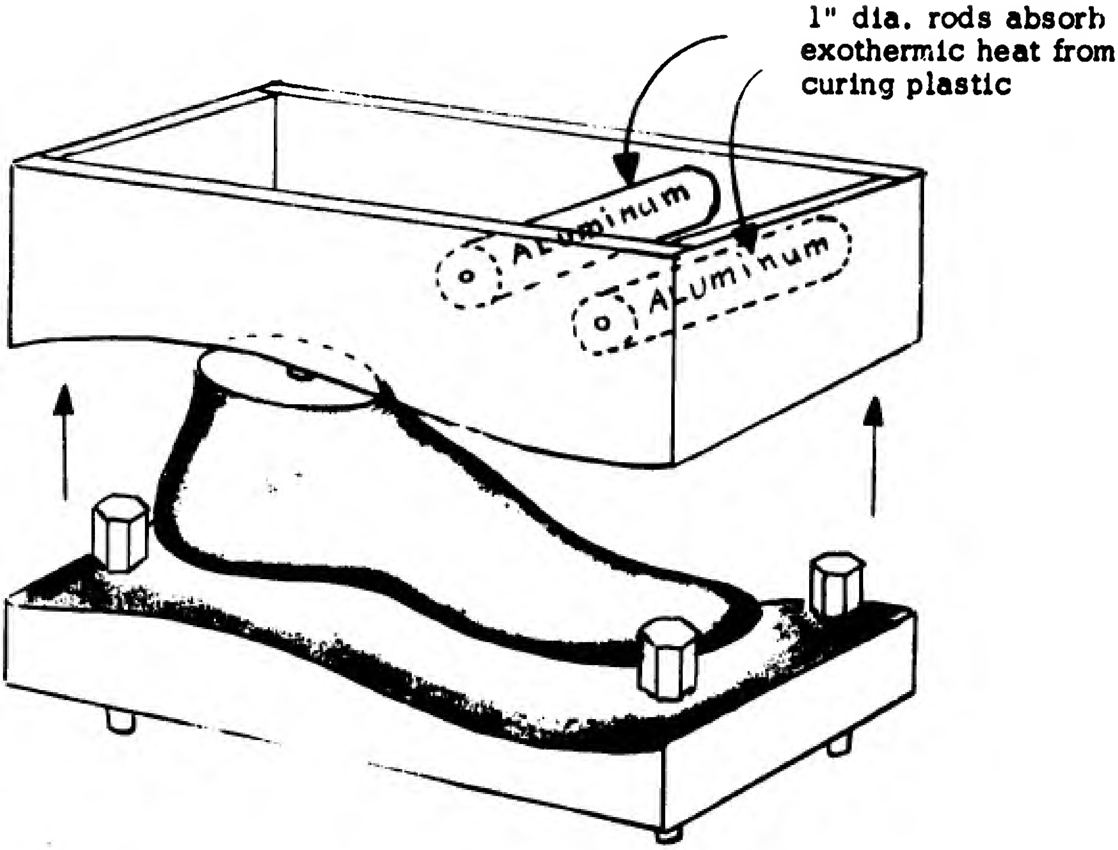


FIG. 9 INSTALLATION OF HEAT SINKS

Lift dorsal section of box and insert two 1" diameter aluminum rods about 3/4" away from actual model surface. Attach with small brads driven through the wood sides. The rods act to help release exothermic heat from thick section plastic. Install the four hexagonal fittings.

12. As shown in Fig. 10, place the dorsal section of the box into position with the aluminum rods in place. Be sure the foot model is in the same position as it was when the plantar section was poured. Use a piece of 1/2" x 2" x 6" plywood to support the ankle block as shown. Tap in two tapered wedges to prevent movement. Brush coat the model and inside the mold surfaces with #301 and let stand for 3 minutes. Then add the aluminum grain, pour into the mold and level off with the spatula.

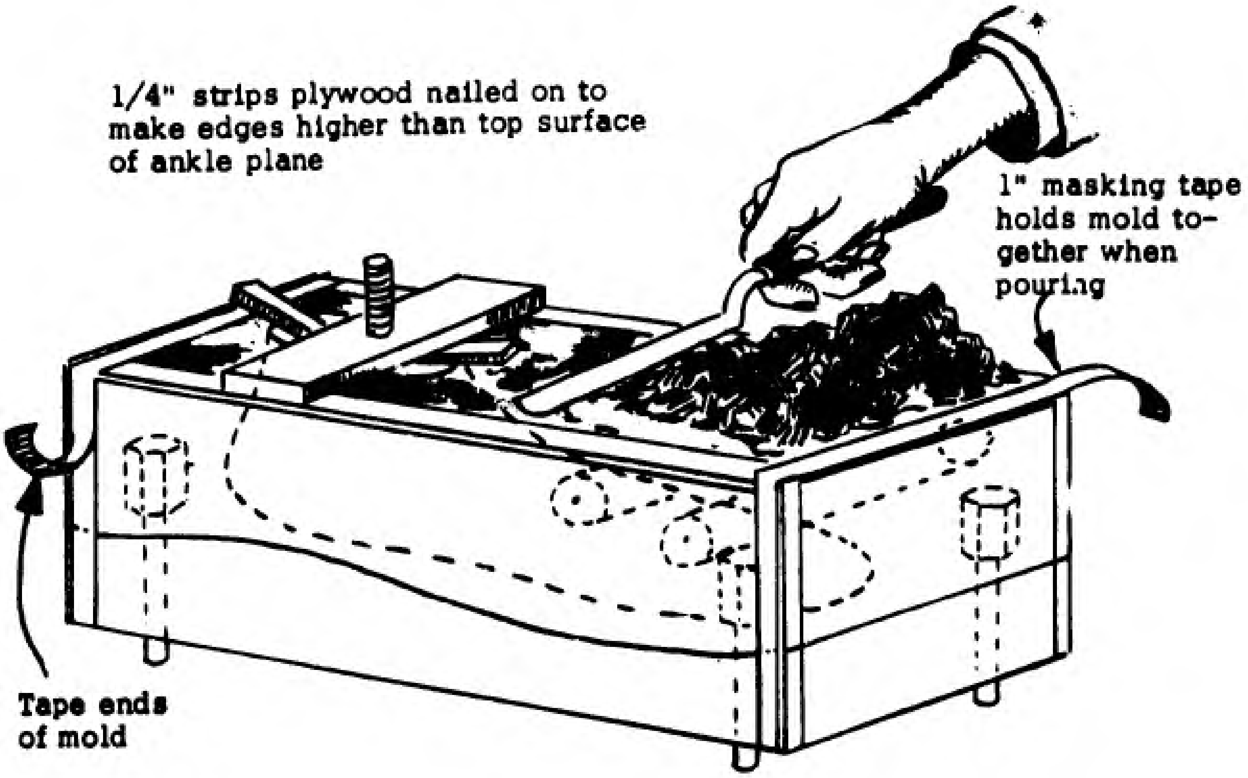


FIG. 10 APPLICATION OF EPOXY AND ALUMINUM GRAIN - DORSAL SIDE

Position foot model into proper position. Support ankle bolt, as shown, with small board. Wedge to prevent movement. Apply brush coat of #301 Resin and Hardener to model and inner mold surfaces. After 3 minutes pour in aluminum grain and level with spatula.

13. All surfaces coming into contact with the resin must be prepared. The following procedure is used. First, give the surface an even coat of clear lacquer. Use a soft sable or camelhair brush. Thin the lacquer down, two thin coats insure an even finish. When the lacquer is completely dry, give the surface an even coat of "Trewax." Buff the surface to a high gloss. Then take the soft brush and brush on an even coat of liquid polyvinyl alcohol.

14. Drill 1/8" holes as shown to vent entrapped gas during curing. Install aluminum plates as shown in Fig. 11.

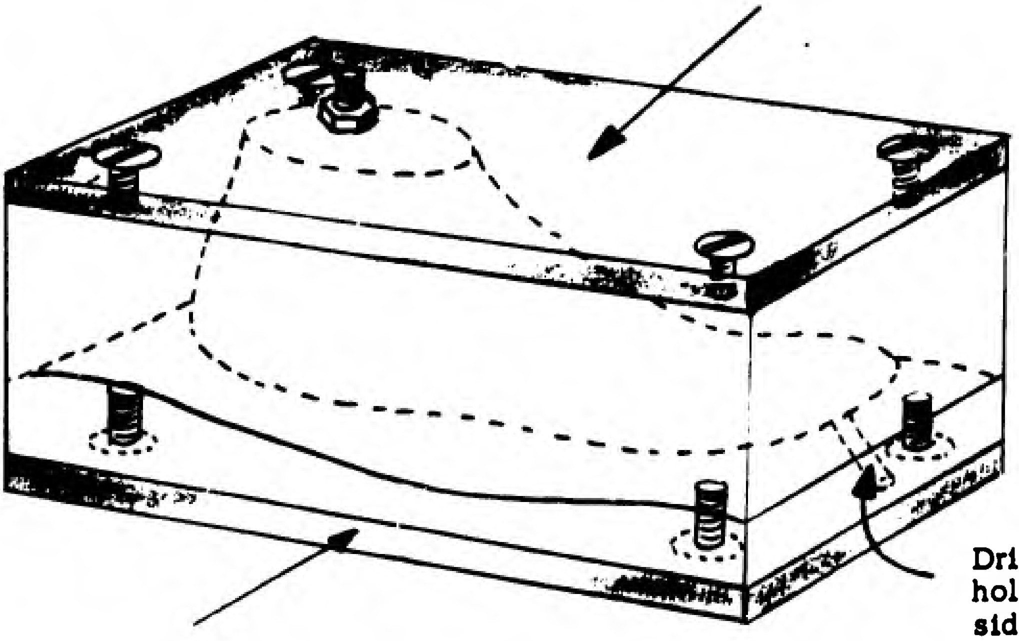


FIG. 11 INSTALLATION OF ALUMINUM PLATES

All surfaces coming in contact with this resin must be properly prepared. The following procedure is used. First, give the surface an even coat of clear lacquer. Use a soft sable or camelhair brush. Thin the lacquer down, two thin coats insure an even finish. When the lacquer is completely dry give the surface an even coat of "Trewax." Buff the surface to a high gloss. Then take the soft brush again and brush on an even coat of liquid polyvinyl alcohol.

15. Using ankle bolt and 1" plug, the maple keel with its canvas belting section attached, is secured as shown in Fig. 12.

16. The sand and plaster barrier is removed and all auxiliary metal inserts put in place and the second half of the mold is poured. When the epoxy has completely cured, the plaster pattern is removed from the mold.

17. Aluminum plates are fastened to the top and bottom surfaces of the epoxy mold to distribute the clamping loads. These plates are held on by means of four flat head screws, one in each corner, with the female threads being

tapped directly into the epoxy. The epoxy molds are surfaced in a shaper to insure a close fit with the reinforcing plates.

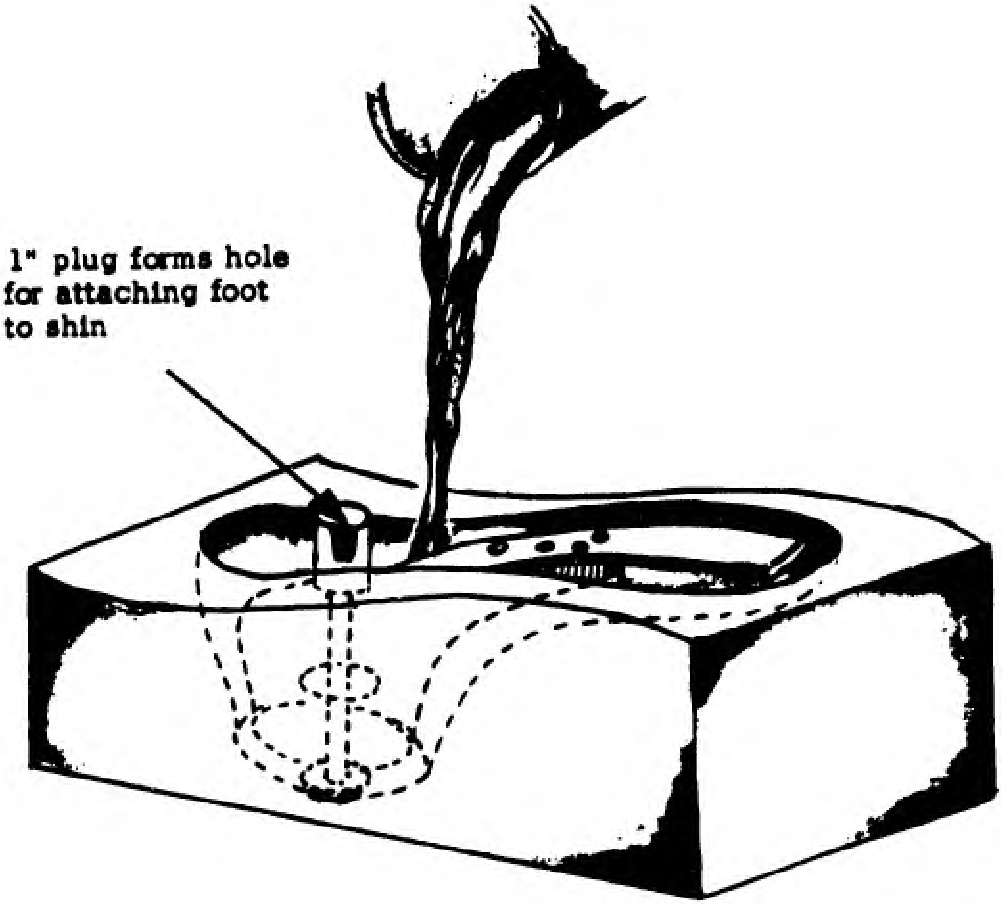


FIG. 12 MIXING/POURING POLYURETHANE FOAM

Components of the polyurethane foot material are carefully mixed, then poured into the mold from the plantar side with the keel bolted in place. After adding the catalyst the working time is 30 seconds. Within 20 seconds the plantar section of the mold must be gently placed in position with the alignment pins in place. The mold is quickly positioned, placed into the press and secured solidly to prevent loss of the rapidly expanding plastic inside.

E. Low-Cost Molds

Perhaps the single factor contributing most to practical development of the foam foot is the design and construction of comparatively low-cost molds. The local estimate for producing epoxy/aluminum grain molds required to produce right and left feet in most used male sizes is about $3,200.00 for labor and materials.

As in any other mold, these plastic molds should be handled carefully and not abused, especially the inner surfaces. With care, the epoxy mold should produce eight to ten thousand feet before requiring replacement. The replacement mold itself may be made in a few hours within the shop, using easily procured materials.

MATERIALS

Epoxy Thick Section Casting Compound with Catalyst (#301)	U. S. Gypsum Co., Attn: Mr. Young 101 S. Wacker Dr., Chicago, Ill.
Aluminum Grain (only in one size)	Industrial & Foundry Supply Co. 2401 Poplar Street, Oakland, Calif.
High Gloss Lacquer ("Hi-Glo") #L-785	Western Specialty Coating Co. 4400 E. Washington Blvd., Los Angeles, California
Polishing Wax (Clear Trewax)	Trewax Company, Culver City, Calif.
Liquid PVA - Astrolite #R-800 Release Agent	Industrial Plastics & Chemicals 4425 Linden St., Oakland, Calif.
CPR #2018 Foam Component "C" & "R"	Upjohn Co., 555 Alaska Avenue Torrance, California 90503
RAM Pigment Concentrate, Flesh 44-51	RAM Chemicals, 210 Alondra Blvd. Gardena, California
Red China Marking Pencil	
Assorted Drills	
Alignment and Pushout Pins 3/8" x 4"	
Spatula - 5" Blade	
Brass Flat Head Screws 1/4" x 1"	
Plaster of Paris or White Dental Stone	
Trimming Scissors	
Wood Skewers - 3/16 x 5"	
1/2" Exterior Plywood	
Common Builders Sand	
Aluminum Rod - 1" diameter	
Aluminum Plate - 3/8"	
Small Camelhair Brush	
Hand Tools	

Note:

Oven not needed since Epoxy Resin #301 cures at room temperature

SECTION III

DETAILS OF MOLDING POLYURETHANE FOOT

A. Description of Present Foot

1. Structure

The foot consists of a shaped, rock maple keel sawn from board stock at the proper angle to assure the wood grain runs along the keel length, the canvas belting extension at the toe, the encasing polyurethane foam and the bolt for attachment to the ankle block. Shaping of the keel is achieved by a locally made pantographic apparatus (Fig. 13) holding a small router motor and tool. Both keels and belting are cut to shape and size. Each section of belting, 4-ply canvas/rubber construction, is attached to the keel with five stainless steel screws. The forward extension of the belting adds slight stiffness and strength to the completed foot, acting as a flexible core to the toe section.

The outer surface of the completed foot presents a "skin" - a thin, condensed and solid layer of the foam which seals the foam from entrance into its structure including water and other foreign materials.

2. Heel Stiffness Options

The need for differing heel durometers occurs because of different weights and heights of patients, different lengths and alignments of prosthetic legs, different walking patterns among individuals and special requirements of individual patients. Such requirements functionally link the hip, knee and ankle axes together commensurate with the age and infirmity of the individual patient being fitted.

The firmness of the heel becomes evident when one observes the unilateral below-knee amputee walking. On heel contact the compressible heel section of the artificial foot controls the timing and degree of plantar flexion, and may be too late (or not at all, if excessively hard) if too hard, or too early if too soft. In both events the walking pattern becomes unnatural and inefficient, frequently requiring far more energy than should be required of the patient.

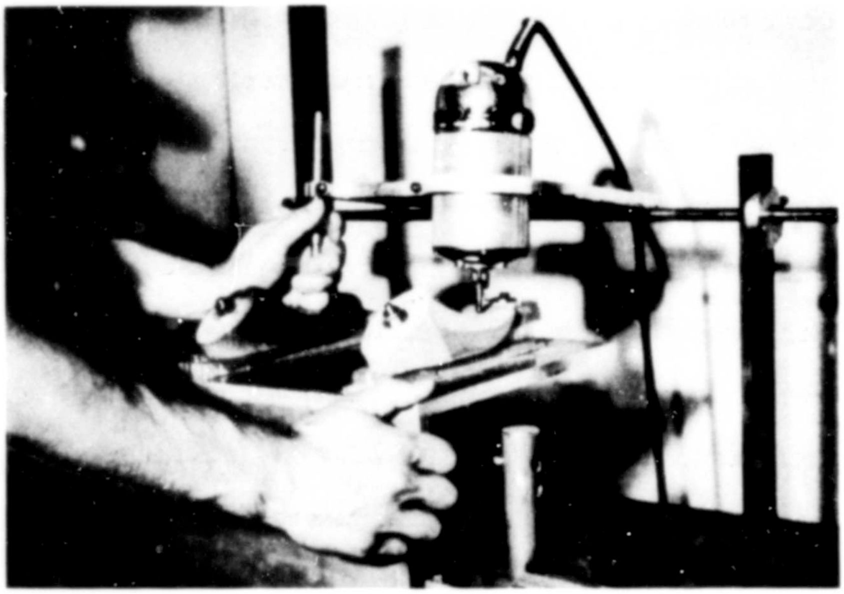


FIG. 13 DUPLICATOR FOR PRODUCING IDENTICAL WOODEN KEELS

Pantographic device consists of hinged, commonly attached router and guide constraining movement to vertical plane. Wood model and blank are likewise attached to common plate resting on captive ball bearings allowing easy movement in the horizontal plane.

The need for some means for varying several degrees of resistance to compression at the heel thus becomes evident . Along with others, we have experimentally provided wedges and cylindrical inserts of differing durometers to modify the heel compressibility. Especially in view of the fact that we are presently unable to anticipate the proper heel durometer, given a set of known factors, we feel this method to be not entirely valid.

Our present approach, which appears to work with some success, is to manipulate the quantity of plastic, catalyst and keel size so that the overall durometer of the foot is modified.

For instance, the Size 9 foot is composed of the indicated components to produce the indicated overall durometers.

Durometer	Foam Wt.	Catalyst	Keel Size
15-20 Soft	236.0 gms.	14.2 gms.	36
20-26 Med.	255.0 gms.	15.3 gms.	36
26-30 Hard	270.0 gms.	16.3 gms.	36

Any proposed design considerations for the artificial ankle joint or foot must duly consider possible affects of its planned functions upon the other limb components. As a practical example the function of the prosthetic ankle may severely affect the function of the prosthetic knee joint and thereby the stability of the knee.

It is desirable for the artificial foot, on heel contact during walking, to undergo plantar flexion readily, assuring proper traction of the foot on the walking surface. The action should not be so easy, however, as to allow the foot to slap the ground with an unpleasant sound. Balanced and desirable action is achieved by proper selection of the heel durometer, a measure of its deformation on bearing weight. If the durometer of the heel is too high, then resistance to plantar flexion is excessive to create still other problems. On heel contact, with the high durometer heel, not only does the forefoot fail to grip the ground properly, but forces are transferred through the shin, tending to force the knee axis forward beyond the weight bearing line. The leg prosthesis is then unable to support the weight of the amputee and buckling of the knee frequently occurs.

As is commonly known among prosthetists, the greater the distance the artificial knee axis is positioned posterior to or the ankle axis anterior to the weight-bearing line, the less efficient the system of levers represented by the artificial leg becomes. While such alignment thus provides for greater relative stability and less tendency for buckling at the knee, operation of the system demands greater energy output from the amputee and is therefore a less efficient system.

It is therefore important that safety from buckling be assured by aligning one or both joint axes in proper relation to the weight-bearing line compatible with safety for the individual wearer but not so distant as to require inordinate energy demands from the amputee. As a routine technique here the ankle axis in the standing position is placed 1/8" anterior to the weight-bearing line while the knee axis is aligned so that its actual center is 1/4" posterior to that line.

Alignment of the below-knee artificial leg is achieved in virtually the same way as in the above-knee limb. The axis of the knee joints are aligned at right angles to the line of progression so that their centers, also aligned, lie slightly posterior to the weight-bearing line.

3. Life Expectancy

Traditionally, we tend to measure the competency and quality of our manufactured items on a basis of how long the unit will last. This generally continues to hold, but not as regards artificial feet.

The weight of the foot, particularly in view of its attachment on the end of the shin, is exaggerated because of its attachment on the end of a lever, represented by the shin. Obviously more energy is required to lift, move and stop the heavier foot so it will seem the use of a lighter foot would be beneficial.

The foot herein described is expected to wear well for a time approximating that of a medium-priced pair of shoes. It may then require replacement.

B. Precautions for Technicians Handling Epoxies

1. All individuals working with plastics should be carefully instructed in the hygienic requirements. Scrupulous working habits are required.

2. Contamination from plastics occurs mainly from inhaling the fumes or from contact directly to the skin.

3. Good ventilation is absolutely required in the work space.

4. The work bench should be covered with heavy wrapping paper which should be renewed twice daily.

5. The workroom should be provided daily with new, unused cleaning rags. Gloves should be worn during cleaning. The safest and most effective protection of the skin is afforded by the wearing of gloves. The disadvantages and possible skin irritations connected with permanent wearing of rubber gloves can be avoided if leather gloves with knitted upper cuffs are worn during manipulation of resin and hardener. Wearing cotton gloves under rubber or plastic (polyethylene) gloves is advantageous in certain cases. Finger stalls offer a certain amount of protection in the case of delicate work which renders the wearing of gloves impossible. The gloves should be washed daily with soap and warm water, preferably while they are still on the hands of the technician. They should then be dried and kept in a clean place. Powdering the inside with talc is recommended. In any case, the fundamental rule also applies here, that wearing of gloves does not eliminate the need to observe absolute cleanliness.

C. Mold Preparation and Molding Procedures

1. Pre-Heating Molds

The epoxy molds (Fig. 14) being discussed are classified as thick section molds, therefore any treatment such as heating or cooling requires time.

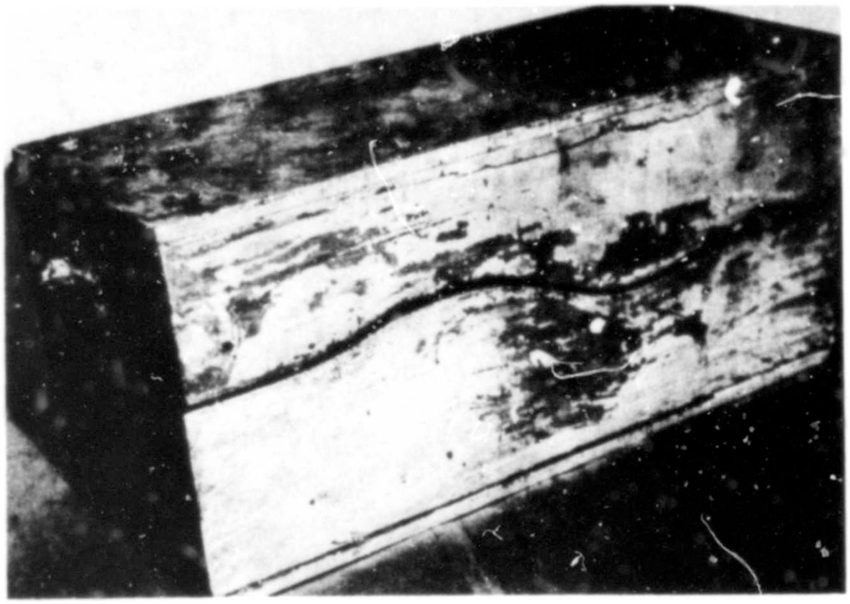


FIG. 14 THE EPOXY/ALUMINUM GRAIN FOOT MOLD

Equipped with heavy aluminum upper and lower plates to distribute compressive forces evenly, the complete Size 9 mold weighs only 25 1/2 pounds.

If the temperature of the environment is changed substantially and rapidly there is always the danger of cracking or crazing due to build-up of internal stresses within the thick plastic.

2. Application of Parting Agent

Spray all inside (Fig. 15) surfaces, including the apposing areas, with Mold Release Agent ("Ram Mold Release #225") available from Ram Chemicals, 210 E. Alondra Blvd., Gardena, Calif.). Wipe thoroughly with paper towel. Repeat, wiping excess gently from mold with clean paper towel.

3. Mounting Keel Assembly in Mold

Insert main shaft with round rubber gasket through countersunk hole in proper size keel. Put rubber gasket on top of keel and cut to outer dimension of wood. Insert keel (Fig. 16) in prepared mold using care that belting attached to keel is not touching dorsal surface of mold. Place mold in press. Spray relief

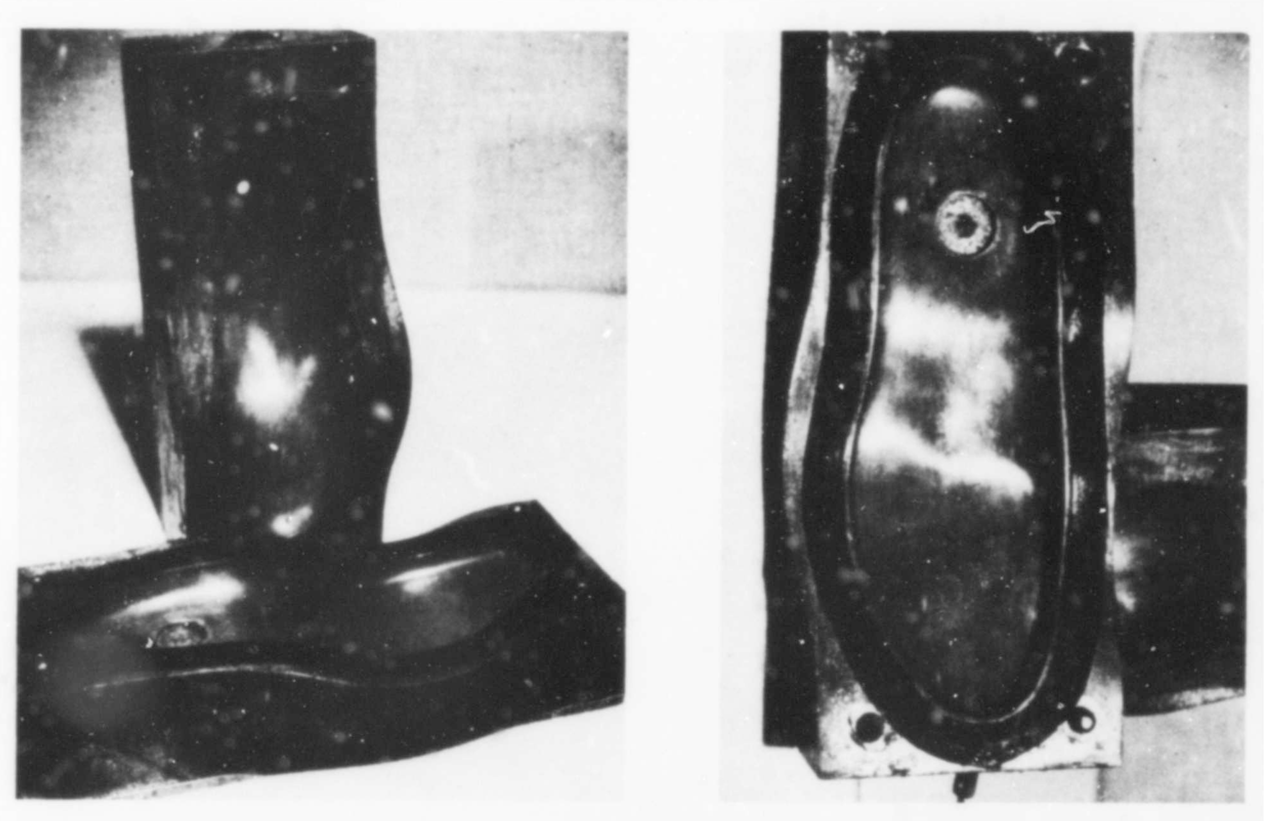


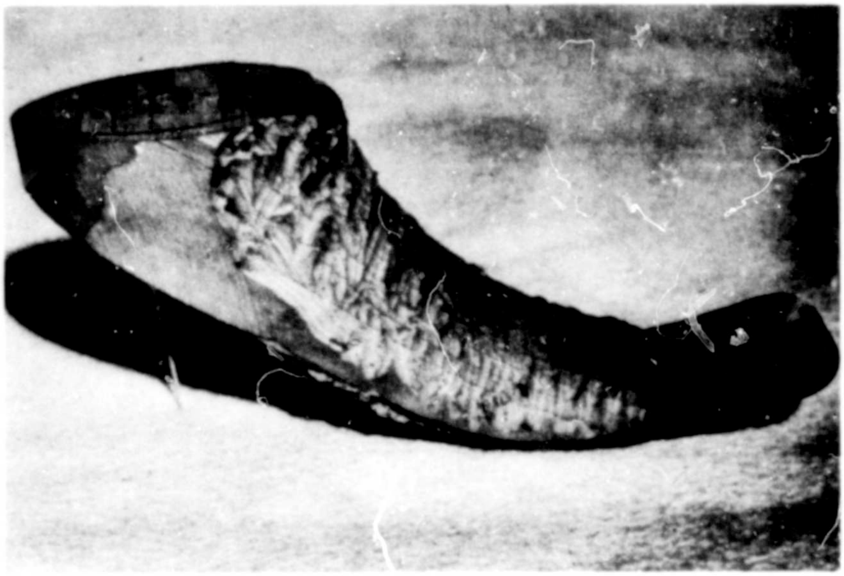
FIG. 15 INTERIOR OF THE EPOXY/ALUMINUM GRAIN FOOT MOLD

Mold is constructed so that flash line, if any, will fall in about position of sole welt. Smooth, shiny interior results from similar prepared surface on plaster model. The two halves are fitted with alignment pins on diagonal corners with threaded pins for separating the two halves on opposite corners. A thin rubber gasket is used between the two halves.

valve (Fig. 17) with Ram Mold Release and insert in relief hole in top of mold.

4. Measure Foam Materials

Prepare proper amounts of foam and pigment, mixing thoroughly with a propeller type (Fig. 18) mixer. Place into refrigerator for ten minutes. Measure catalyst and with other items in readiness, resume mixing of foam and catalyst in high speed mixer and pour in catalyst while mixer is running. Mix for six seconds and immediately pour (Fig. 19) into mold onto keel starting at just past belting location then moving along length to the heel.



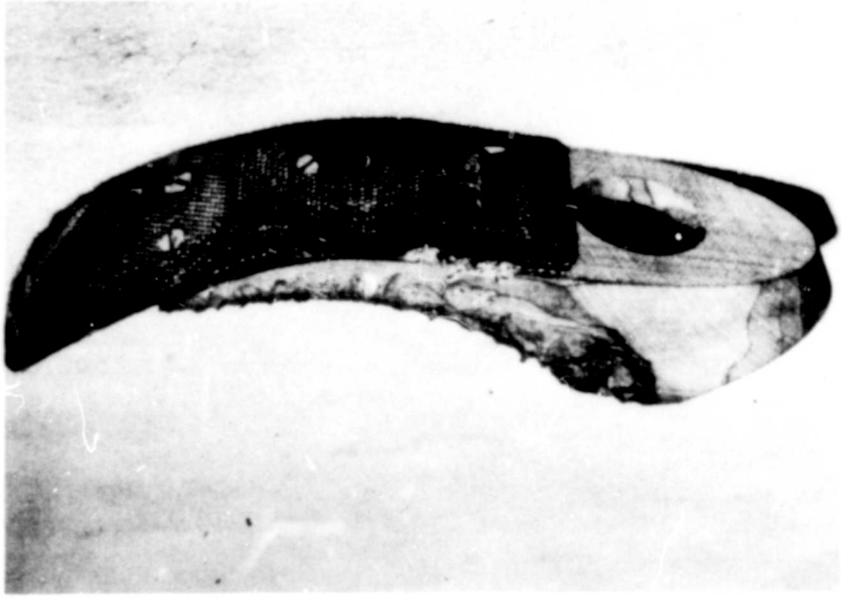


FIG. 16 WOODEN (MAPLE) AND CANVAS BELTING KEEL

Rock maple wood stock serves as keel. It is sawn into sections with grain oriented to length. Its antero-superior rounded surface is achieved by rough shaping with a homemade router-duplicator. A section of canvas belting is attached to bottom of wood as shown with five stainless steel screws. The canvas toe extension is three-ply to stiffen the toe and prevent curling upward tendencies.

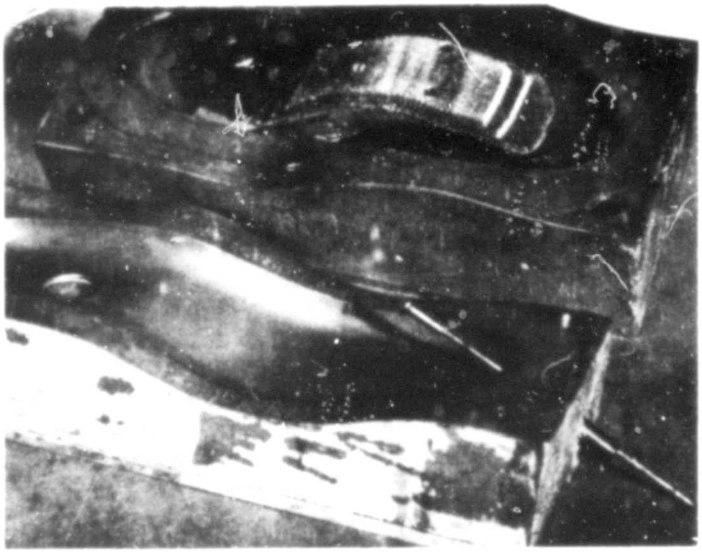


FIG. 17 KEEL ATTACHED TO INTERIOR OF EPOXY MOLD

Attachment of keel is means of fitting which also molds cavity in completed foot for attachment of ankle bolt. Vent and valve for escape of air is also shown. Entire unit, as illustrated, is pre-heated in warm oven for two hours prior to actual pour.

5. Clamping Mold

A simple clamping jig has been constructed (Fig. 20) to permit application of sufficient pressure, holding the charged mold in proper position and performance of this procedure very rapidly.

The clamping jig consists of a large metal plate hinged to the work table which holds an ordinary auto hydraulic jack. Actual clamping requires the operator, on completion of the pouring process, to apply the top section of the mold. He then slides the mold under the pressure plate and pumps the hydraulic jack, applying pressure to the top section of the mold. When this pressure is sufficient the entire unit is tilted to about a sixty degree angle with the toe uppermost. This is done to promote escape of any entrapped air inside the closed mold.

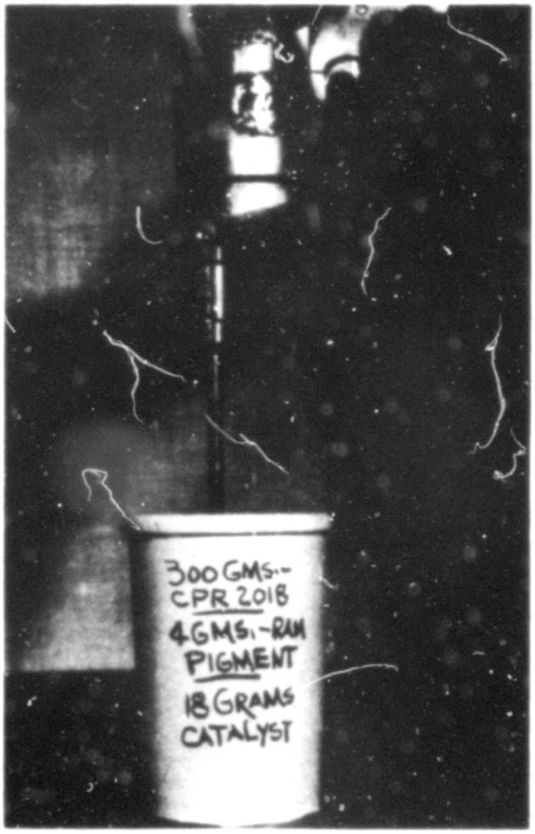


FIG. 18 MIXING OF FOAM INGREDIENTS

A slow speed mixing blade is used to mix plastic, catalyst and color. An air powered or electrical drill may be used if speed of 800 to 1,000 rpm is available. Major objective is to mix rapidly yet avoid introduction of air into mixture.

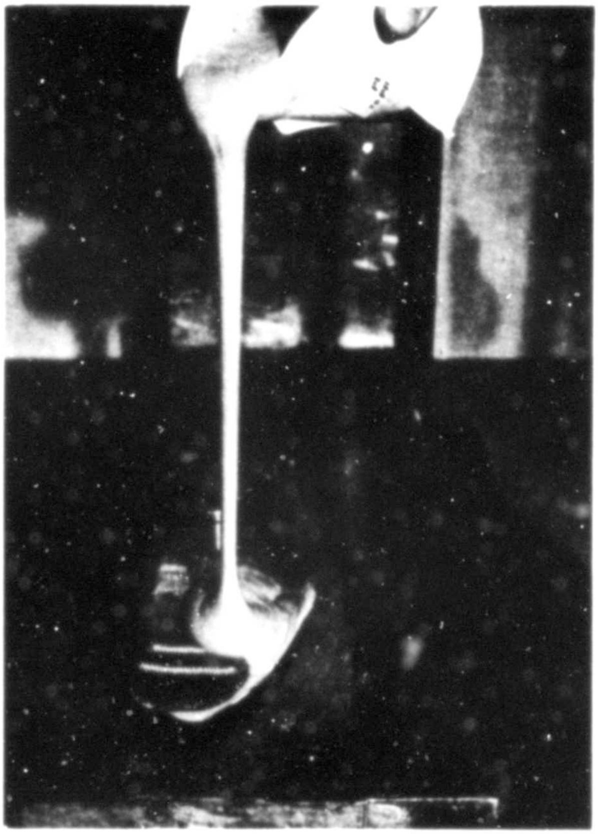


FIG. 19 POURING THE POLYURETHANE PLASTIC INTO MOLD

Time elements are vitally important to successful production of the foot. Pouring must be done immediately on mixing and in such a way that the least exposed parts of the keel and mold interior are poured first.

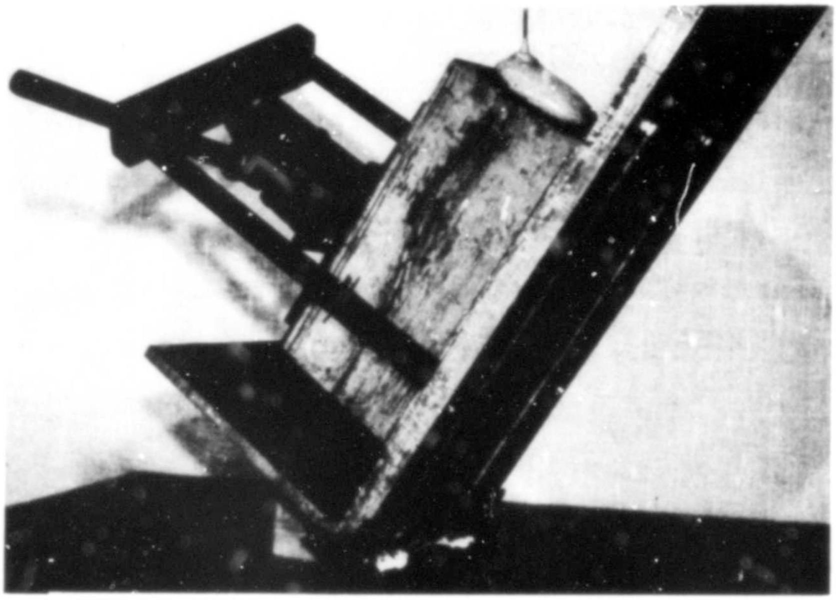


FIG. 20 POLYMERIZATION/EXPANSION

On completion of pour the top of mold is applied, using care with aligning pins. Hydraulic jack is used to apply pressure closing mold and entire unit is tilted to 60° from horizontal. Air is expressed through vent followed by foam. A ball of foam about like golf ball is allowed to escape at which time valve is closed.

6. Venting Requirements

A simple valve is used to control venting of the entrapped air. The valve is manually held open to allow "bleeding" of a small quantity of foam, when it is closed. The mold is left in the tilted position and undisturbed for at least one-half hour.

7. Removal from Mold

When ready to open, remove mold from clamping jig and separate the two sections (Fig. 21) by means of the two built-in jack screws. Under no circumstances should a screwdriver or other wedging tool be inserted between the two halves of the epoxy mold. In the same vein great care must be taken to avoid spoiling the surface of the mold proper.

Removal is accomplished by first pulling the "skin" surface away from the mold surface (Fig. 22) by means of the fingers. Removal imposes no problem. (Figs. 23 & 24)

FIG. 21 SEPARATION OF THE MOLD SECTIONS

Threaded pins fitted into diagonal corners of mold are used to initially separate the two mold sections. When the two sections are "broken" apart the separating process becomes easy. Use no prying tools.

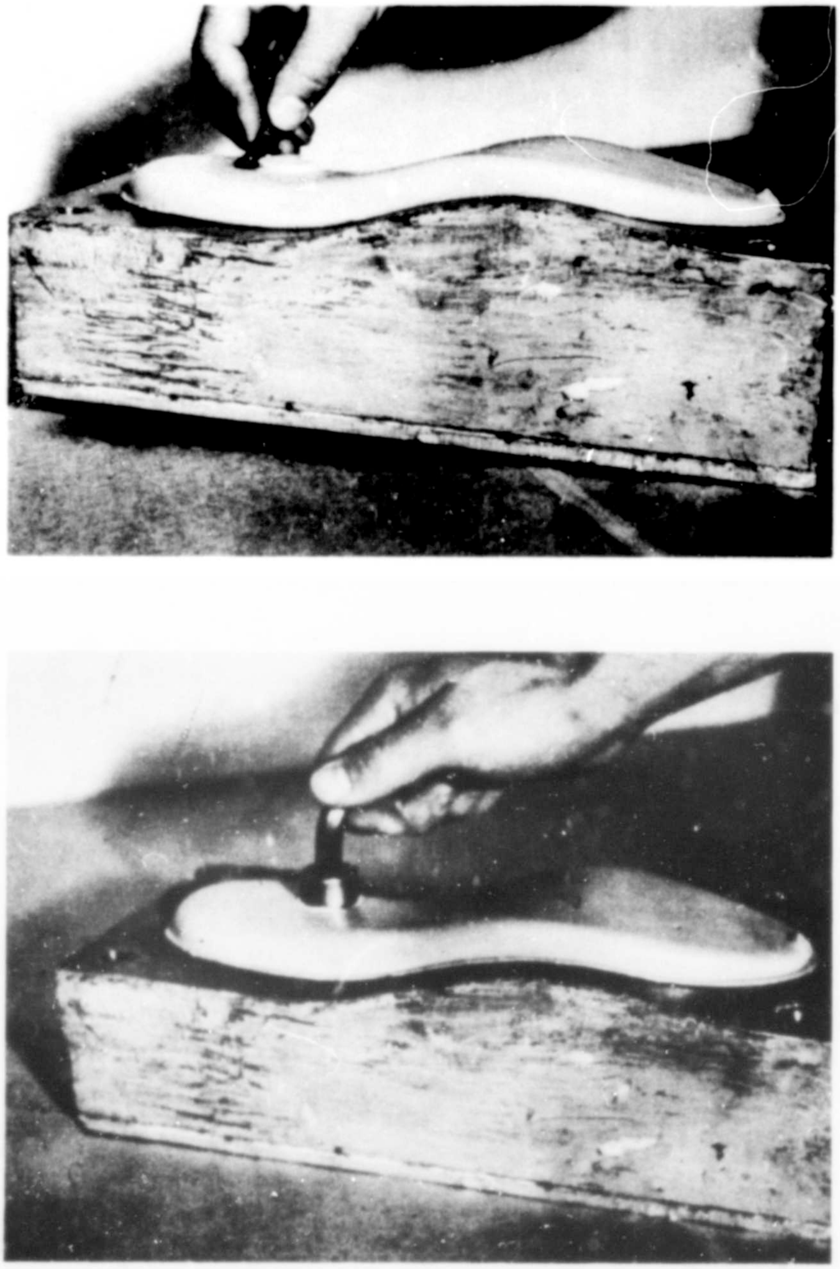


FIG. 22 REMOVAL OF TOP HALF OF MOLD

The overlying flash of foam is trimmed away to permit insertion of ankle bolt and ankle bolt wrench.

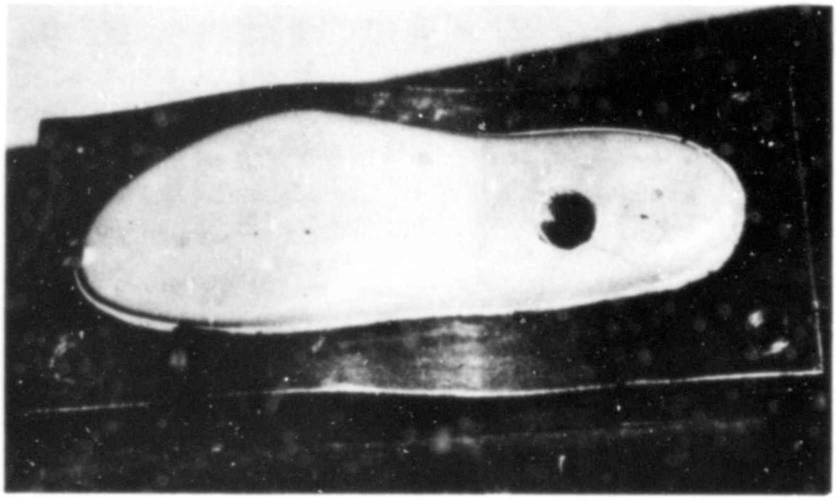


FIG. 23 FLASH LINE ABOUT WELT SECTION

Due to the fairly high internal pressures and in spite of the use of gasket material, some expansion into the spaces between the two mold sections generally takes place.

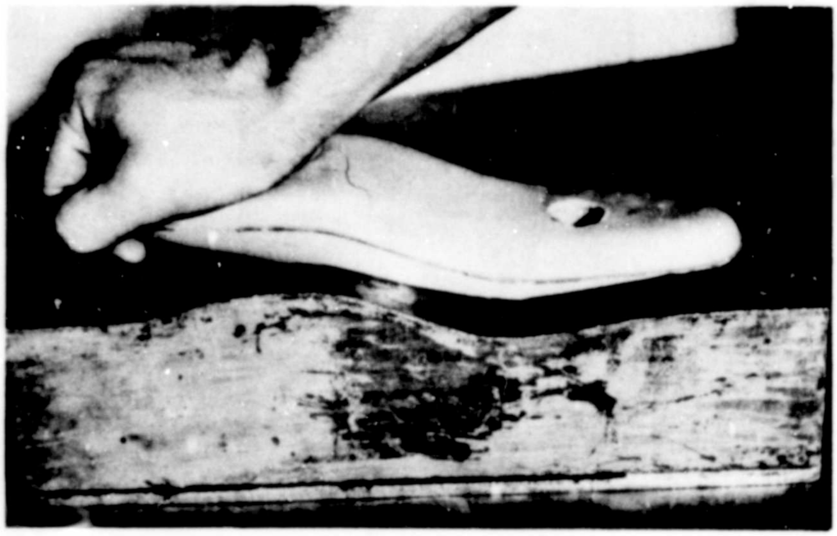


FIG. 24 REMOVAL OF FOOT FROM MOLD

Foam material, being compressible, is carefully manipulated from the mold with the fingers. Use no metal tools!

D. Finishing

1. Trimming Flash Line

Internal pressures built up in the mold during the foaming process cause a flow of the foam material into the area between the two mold sections. On polymerization and separation of the mold sections the thin waste material is carefully trimmed away (Fig. 25) with scissors. Foot is shown in cross-section in Fig. 26.

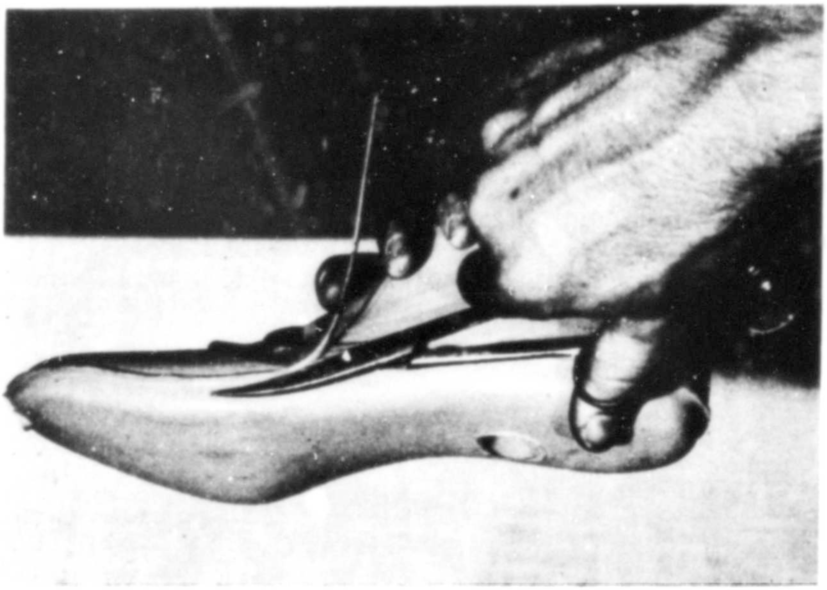


FIG. 25 TRIMMING AWAY THE FLASH LINE

The material making up the flash is peripherally solid. The foamed structure is only apparent when the flash is trimmed away. The flash should not be trimmed too closely.

2. Check Fit in Shoe

The actual fit of the foot inside the shoe is carefully checked. (Fig. 27). Special attention is paid to the surface atop the artificial foot, to the arch area and to the heel section. Compression of the polyurethane foam is not unlike pressure applied to hydraulic fluid. When the foam is displaced or

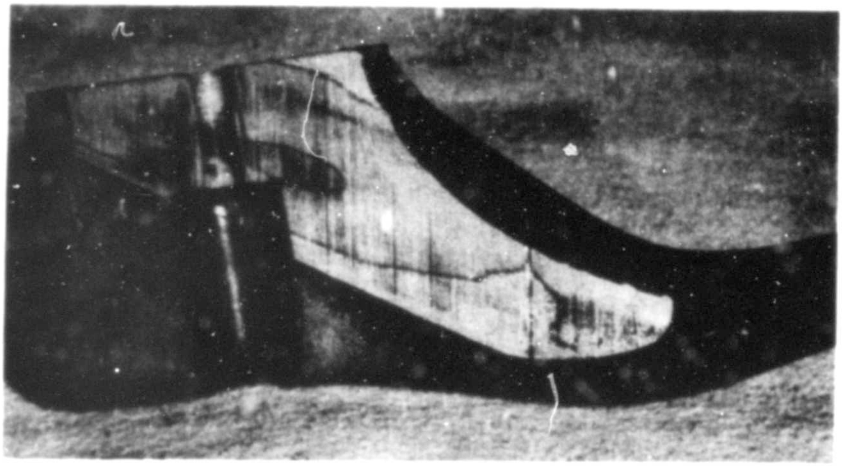


FIG. 26 COMPLETED MOLDED POLYURETHANE FOOT

In cross-section, maple keel shows attached canvas toe extension. Molded hole in heel section facilitates installation, removal and/or adjustment of foot from shin through access to the ankle bolt.

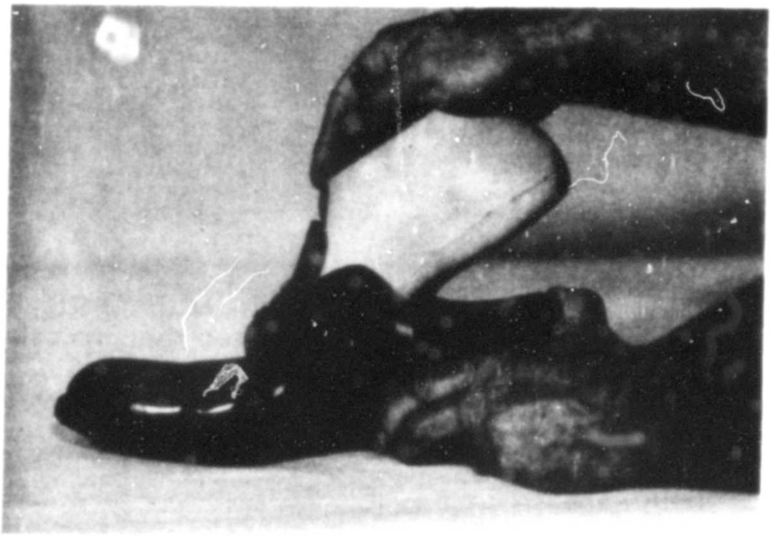


FIG. 27 CHECK FIT IN SHOE

Proper fit in the shoe attempts to obtain very slight compression of the foam. This, in turn, avoids frictional forces on the "skin," spoiling that surface. A sock should always be worn over the artificial foot.

compressed there must be allowances made for movement of the foam material. In the artificial foot the areas noted are more critical than others.

In the event the "skin" of the foam must be ground away in order to achieve a correct fit in the particular shoe to be used, then the surface defect may be painted with flesh-tinted "Hypalon," which re-establishes a seal and a skin-like surface.

3. Storage

While the effects of ageing on the foam structure of the prosthetic foot are basically known and recognized, they do not appear to be particularly severe. It is our impression that the durometer of the foam increases slightly with age, the degree of increase is not sufficient to interfere with alignment of the leg or its functional characteristics and efficiency.

One unresolved problem relates to color instability of the finished foot as modified by time, exposure to light and storage. At time of molding the Caucasian foot is pinkish-white in color as a result of the color paste used. This color slowly changes to a tan to brownish shade over a period of several weeks unless it is exposed to daylight/sunlight. In the latter case the discoloration may require only a few days.

A second problem is the moderately offensive odor from the freshly molded foot. Warming the foot accelerates the loss of the odor as does storing in a well-ventilated container for 1 - 2 days.

Both problems, in a preliminary way, appear to be essentially corrected by post-molding warming for two hours then wrapping the foot loosely (not sealed) in a light opaque plastic film.

Completed assembly is shown in Figs. 28 and 29.

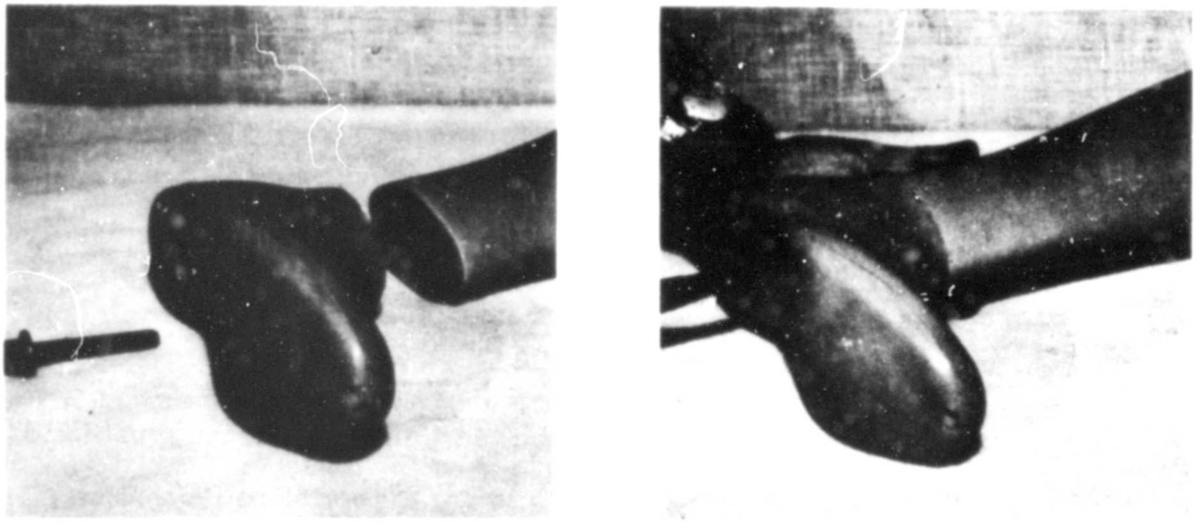


FIG. 28 ASSEMBLY OF FOOT ONTO SHIN WITH ANKLE BOLT

Foot is attached by Allen-head Cap Screw to threaded and flanged sleeve installed in wooden ankle block above. The apparent imperfection on the tip of the toe is due to the mold vent valve and has no effect on the function or life of the foot.

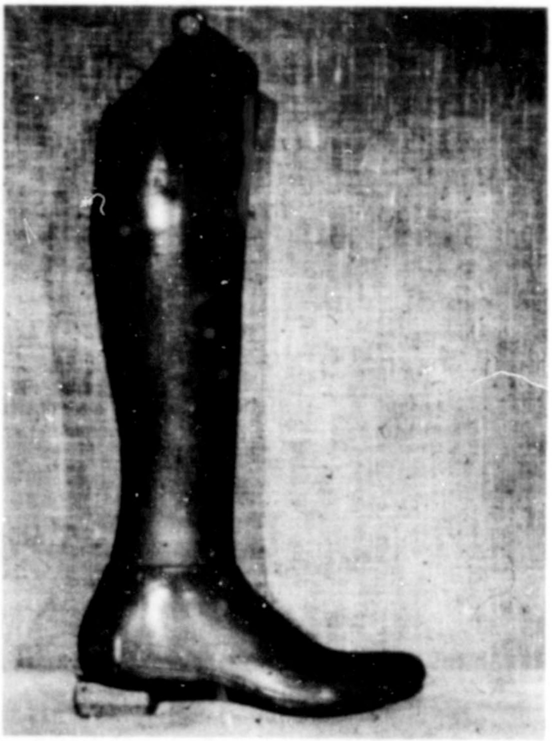


FIG. 29 COMPLETED FOOT, ANKLE AND SHIN

The molded, lightweight, polyurethane foot nicely matches the laminated plastic shin intended for an above-knee amputee. Its lightweight feature becomes especially notable by above-knee wearers because of the reduced effect of weight when compared with others during the swing phase of walking.

SECTION IV

CONCLUSIONS

The subject artificial foot, in a complete range of sizes, has been designed, developed, produced and tested by this laboratory. The foot is considered to offer a well-balanced set of characteristics which provide advantages for both the amputee wearer and for the prosthetic manufacturer seeking a competitive element.

As with other artificial feet made on the solid ankle cushioned heel principle, the subject foot appears to be functionally adequate. Presently, the polyurethane foam structure is varied by modifying the amounts of the chemical elements, a procedure which appears to control the softness or hardness of the heel compression to a satisfactory degree. At the toe section the flexibility of that part may also be modified by altering the plys of the rubberized canvas belting which extends from the maple wood keel.

Local testing as to durability of the device has consisted of laboratory tests followed by use by pilot wearers and then to routine use in fitting all lower extremity patients requiring an artificial foot. This use and experience has been successful. Additional tests including those of a mechanical nature and long term storage in a warm, humid environment performed by others have also been satisfactory.

Cosmetically, the foot is produced in the required color by means of an included color paste. The untreated Caucasian color is, however, affected by light and tends to turn a light brown color over a period of months. To avoid this occurence, before use the feet are stored in opaque polyethylene bags until ready for installation. An earlier noted unpleasant odor from the freshly molded foot is now avoided by holding same in a warm oven overnight prior to use.

Obviously, it is very important to reduce the weight of the foot, not only to increase the efficiency of its function but to reduce the tendency toward "piston" action of the stump in the below-knee socket and reduce the load being borne by possibly the cardiac patient. The subject foot is considered to be one of the lightest feet made.

Parallel development of the epoxy foot molds represents a possible breakthrough in producing artificial feet at relatively reduced costs. The epoxy molds are adequately durable, relatively inexpensive to reproduce and may be made in any fairly well-equipped limb shop.

Finally, the subject foot is presently found to be acceptable by the Veterans Administration and for the past two years has been used routinely by the limb fitting facility at Naval Hospital, Philadelphia.

REFERENCE

1. Page 4 "Fundamental Studies of Human Locomotion and Other Information Relative to Design of Artificial Limbs." Vols 1 & 2, University of California, School of Engineering, Berkeley, California, 1947

2. Page 8 "The Patellar-Tendon-Bearing Below-Knee Prosthesis," Radcliffe and Foort. School of Medicine, University of California, San Francisco, California, and Dept. of Engineering, University of California, Berkeley, California. 1961

3. Page 10 U. S. G. Epoxical Resin Systems. "IGL Bulletin #400, 401, 402, 405, 406, 407, 408, 409, 411, 412, 414, 422, 425, 426, 428, 429, 430, 431, and 434. "Report on Epoxical Casting Resin Systems." United States Gypsum, Industrial Sales Division, 101 South Wacher Drive, Chicago, Illinois. 1965

BLANK PAGE

ADDENDUM

EARLY EXPERIENCES IN DEVELOPING MOLDS AND MOLDED FEET

A. Foot Models

The models were made of yellow dental stone, ideally suited because it is strong and the texture is quite uniform. The material may be sanded very smoothly and will not flake off after oven drying at 150° F. for 12 hours. After so drying the models were finished with an automotive type lacquer finish and buffed to a high gloss with "Trewax".

Personnel of the hospital, both male and female, were asked to participate by allowing us to make impressions of their feet. All necessary sizes were selected and both lefts and rights were taken. A positioner was made of willow wood for the donor to stand on while the impression was being made. This device was band-sawed on a curve to represent the inner curve of a good fitting military shoe having a 1" regulation heel in the men's sizes.

A positioner was made also for women's feet, shaped to the plantar surface of an oxford. A Wave's shoe with a 1 3/4" heel was used for this project.

The donors stood on the positioner while the foot was wrapped with 3" plaster bandages. The bandage was applied firmly but not tightly in order to avoid deforming the underlying tissues. The plaster was extended to a level about 1" above the medial malleolus. A strip of thin metal was placed along the dorsum to permit cutting the cast off following a waiting period of 8 - 10 minutes to allow setting of the plaster.

Male sizes from 5 to 15, female sizes 4 to 10, were used.

A set of military shoes, both male and female, were obtained. A cut was made on each shoe down through the leather tongue to the sole line opposite a point at the second toe. This split permits checking the fit of the stone model to the shoe.

The model was smoothed off and filled in wherever necessary. A smooth contour was desired to fit a military shoe. The plantar side of the foot rested evenly on the sole plate with the weight distributed on the heel surface and the first and fifth metatarsal area. The upper surface of the model was planed off parallel to the floor. The convex curve of the heel was altered to correspond to the concave surface of the shoe. This close heel fit prevented the heel of the foot from slipping out of the shoe at the push-off phase of walking.

The shaping of the feet was not intended to show the bony prominences except for the malleolus, nor the individual toes and nails, although in the case of open-toed Grecian sandals this might be desirable. The models were shaped in a stylized manner to fit the shoe and for strength and good balance. Effort was not made to represent accurate anatomy of the foot. A strong foot which would withstand great forces which represented a reasonable copy of the foot was considered to be sufficient.

All the models were placed on a level bench with the surfaces of the heels at the same height that they would be in their respective shoes. The contours and measurements were then graduated from the smallest to the largest - Size 5 to Size 14. A gradual tapering from the largest to the smallest was employed. The models were then drilled to accommodate the 3/8" ankle bolt after which they were lacquered and polished, ready for forming the epoxy mold.

B. Laminated Plastic Molds

A foam rubber compound was obtained and considered in the design of a foot which would use a section of aluminum bar stock for the keel and whose upward extension was used to attach the foot to the ankle block. The aluminum material was square and so resisted movement of the foot on the shin and ankle block in the transverse plane.

By means of sculpture, a set of feet, made up of plaster, was used to construct split molds for use in molding. The molds were made of laminated plastic (Fig. 1), and the two halves joining each other in the anterior-posterior plane. At the junction line each half included liberal sized flattened lips to enable the two halves to be securely clamped together with conventional hand clamps. The foot shape generally resembled its human counterpart, however, the toe section was somewhat elongated in order to fill the toe section of the shoe completely.

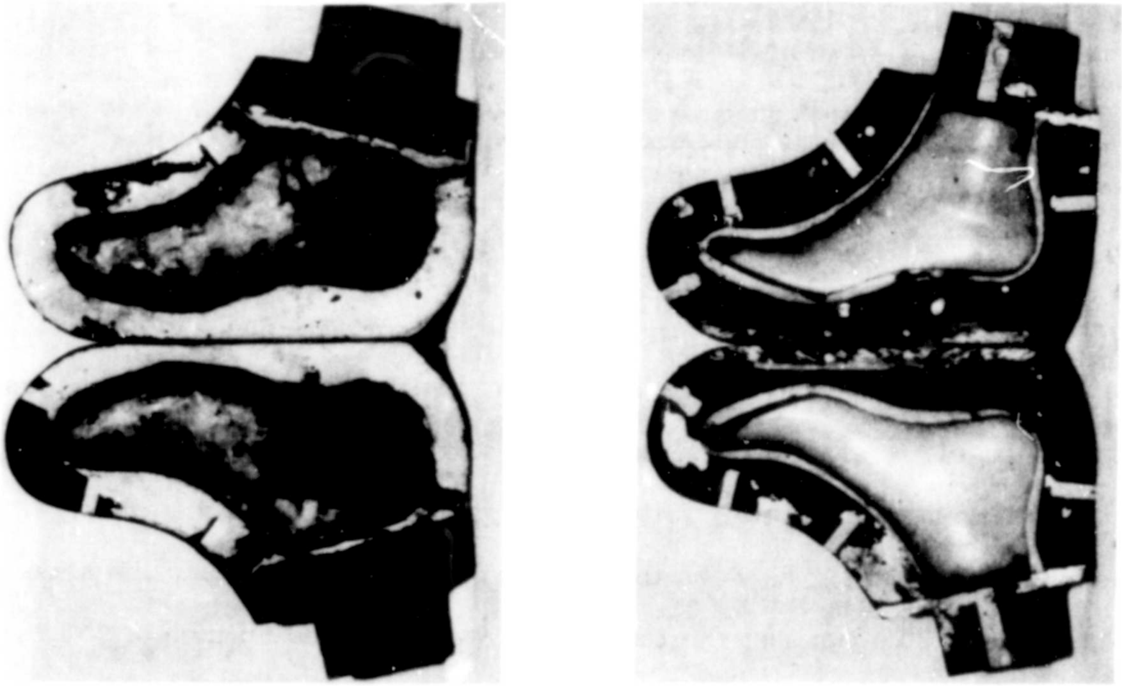


FIG. 1 ORIGINAL LAMINATED PLASTIC FOOT MOLDS

Hinged along the base with piano hinging, the left figure shows the external appearance of the laminated plastic mold; the right figure, the internal surfaces. The mold proper is made of an unsaturated polyester ("Selectron 5003") and cotton stockinet, formed over plaster models.

Different kinds of foams were used. At one time the problem of mixing and pouring was compounded in that five components required mixing under rather rigid conditions of degree and timing and the actual mixing and pouring procedure verged on the frantic.

Though steps were taken to properly stiffen the walls of the laminated plastic molds, there still occurred wall deformities caused by the internal pressures of the expanding foams. The molds likewise tended to leak around the junction of the two halves, a condition disturbing the planned and anticipated ratios of materials and densities of the foams produced.

In an attempt to improve the situation outlined, we discarded the laminated plastic molds in favor of cast aluminum split molds.

C. Cast Aluminum Molds

As a result of experiences and observations during use of the original laminated plastic molds, the decision was made to procure cast aluminum (sand) molds and contacts were made with a local producer. Before actual production measurements were made of a fairly large number of men, women and children which were applied to new foot models. As compared with earlier models, changes were made in the heel, forefoot and toe sections. At the heel the shape was rounded somewhat to more accurately follow the typical shoe last so that during walking the relative movement between the heel of the artificial foot and the shoe might be reduced. In like manner, the toe section was extended an inch or so, graduated according to size, to fill the shoe in the toe section. Finally, the top of the forefoot was reduced somewhat in order to allow the proper lacing and closure of the shoe.

All plaster models were completed and delivered to the mold-maker who promptly delivered the molds (Figs. 2&3) which were made in halves, along the

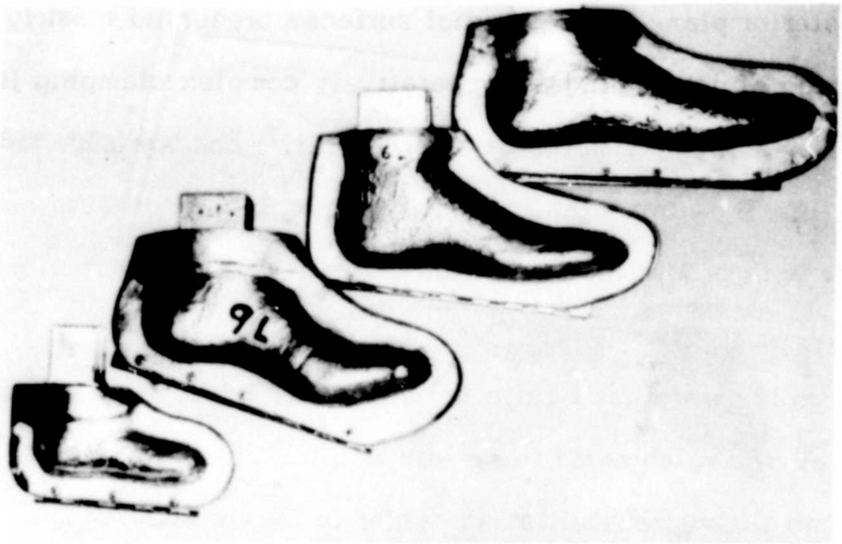


FIG. 2 ALUMINUM MOLDS - EXTERNAL ASPECT

Representative foot sizes were reproduced in cast aluminum molds. The molds were made in lateral and medial halves in which the opposing peripheral surfaces were machined. Closure is achieved with piano hinging.

FIG. 3 ALUMINUM MOLDS - INTERNAL ASPECT

Keels were machined sections of aluminum plate. The proximal ends were threaded for proper attachment inside the mold and to the ankle block. The finished aluminum bar was encased in black rubber of 60 durometer.

anterior-posterior plane. The internal surfaces presented a fairly reflective sheen.

Instead of developing a comparatively complex clamping jig, the mold halves were machined for close closing tolerance and were hinged together with piano hinging. The hinge was installed in machined undercuts so they would not interfere with proper closure of the molds. Ordinary "C" clamps were used for closure.

The molds were used quite satisfactorily for several years. During this period the laboratory engaged in certain helpful measures devoted to establishment of a limb fitting/rehabilitation center in Mexico City. The Mexican Center obtained a set of the cast aluminum foot molds from the local manufacturer which they continue to use successfully.

With time and use, the aluminum molds began to show signs of deterioration. The hinges became sprung and the inner surfaces scratched and sometimes gouged by careless or inexperienced personnel and the tendency for the expanding foam to leak from the molds increased. Locally, we managed to polish the mold surfaces but this turned out to be a long-term, tedious and expensive process in time and labor. It was during the time of these problems that the possibilities of epoxy molds became known.

D. Foot Structures

1. Wood Ankle Blocks

Traditionally used for construction of ankle blocks, wood remains one of the best materials for that purpose. When wood is used, one requirement is that it be sealed from moisture because of its possible deterioration under such conditions.

2. Machined Aluminum Ankle Blocks

Experimental ankle blocks of aluminum (Fig. 4) were produced and did lend themselves particularly to experimental limbs which were adjustable in length. They were not otherwise better than those of other materials and despite attempts at reducing their weight we were never able to achieve weight lighter than wood.

3. Phenolic Spheres

Ankle blocks were molded of this relatively lightweight material (Figs. 5&6) which was chemically bonded together with an unsaturated polyester. This proved to be perhaps the best of the synthetic ankle blocks from the standpoint of weight and strength but was still not remarkably superior to wood.

4. Polyester + Fibers

An additional combination of unsaturated polyester plus cut fibers, including fiberglass and nylon, was found to be too heavy, as well as too expensive, when compared with wood.

FIG. 4 METAL (ALUMINUM) ANKLE BLOCKS

Experimental metal ankle blocks worked well but were dropped in favor of plastic or wood because of the weight and relative expense of manufacture.

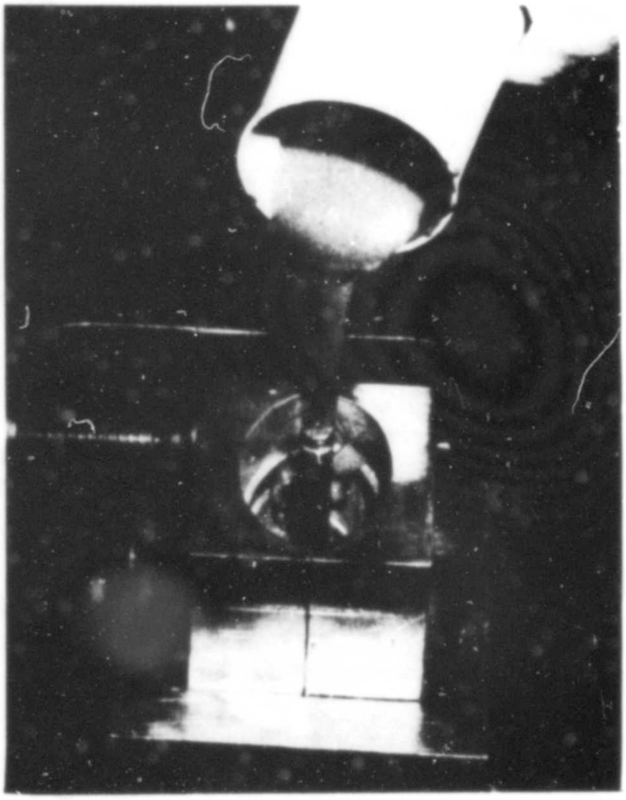


FIG. 5 POURING ANKLE BLOCK MOLD WITH PHENOLIC SPHERES

Locally produced ankle block mold for forming blocks of phenolic spheres which are unaffected by moisture and other environmental conditions.

FIG. 6 COMPLETED PLASTIC ANKLE BLOCKS

Four sizes of the phenolic ankle blocks were found to serve the need. They are neuter in shape, thus useful for either right or left sides. Note the grooves which allow tying first few layers of laminated shin to ankle block during construction of the shin and prior to polymerization of the plastic.

5. Keels

Numerous keel designs and keel materials have been locally developed and used, all seeking to reduce the weight, yet maintain strength of existing artificial feet. Some success has been achieved, as described:

a. Machined/Molded

Several such keels have been produced and tested, some of somewhat sophisticated construction, including one of steel (Fig. 7) and one of molded magnesium alloy. Practically all such keels proved to be structurally adequate but were considered too expensive to fabricate and use. General keel placement is shown in half-section (Fig. 8).

b. Aluminum

Sheet stock, 1/2" thick, aluminum was used for the early aluminum keel. Keel shapes were sawed from sheet stock (Fig. 9) and the upper end was machined to permit rigid attachment to the ankle block, here a permanent part of the laminated plastic shin.

Two problems arose. There was a considerable increase in incidence of broken keels and a tendency for the distal end of the keel to punch through the underlying rubber foam. The latter condition resulted from concentration of forces at the tip of the keel onto the foam thickness between the keel tip and the plantar surface of the artificial foot, which was relatively thin. A rubber sole was made a part of the foot structure by insertion of same into the mold at time of pouring. This helped but did not eliminate the problem and also added significantly to the weight of the foot.

c. Aluminum and Rubber

Through arrangements with Mare Island and Alameda Naval Air Station Rubber Laboratories, the aluminum keels (the part actually embedded

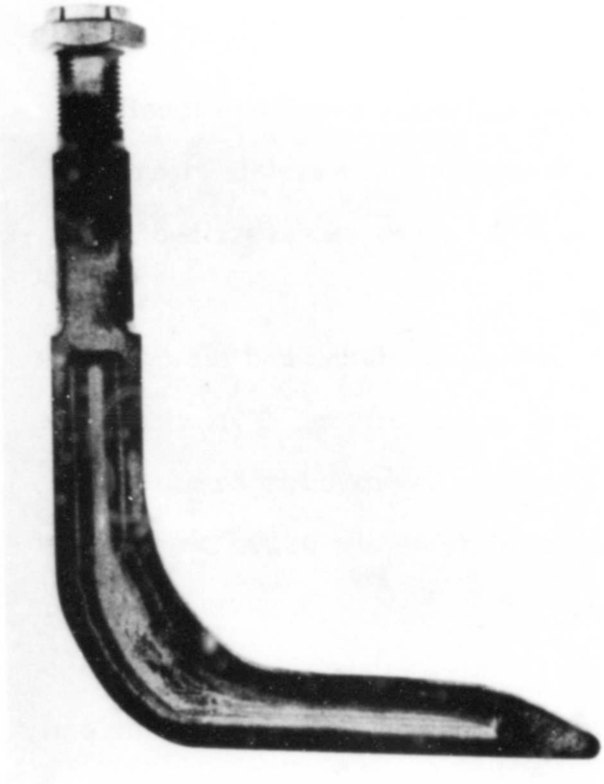


FIG. 7 EARLY STEEL KEEL - NPRL

Machined from flat stock, the early steel keel bolt weighed 211 grams. The bolt was quite satisfactory from the standpoint of strength, but considerably too heavy.

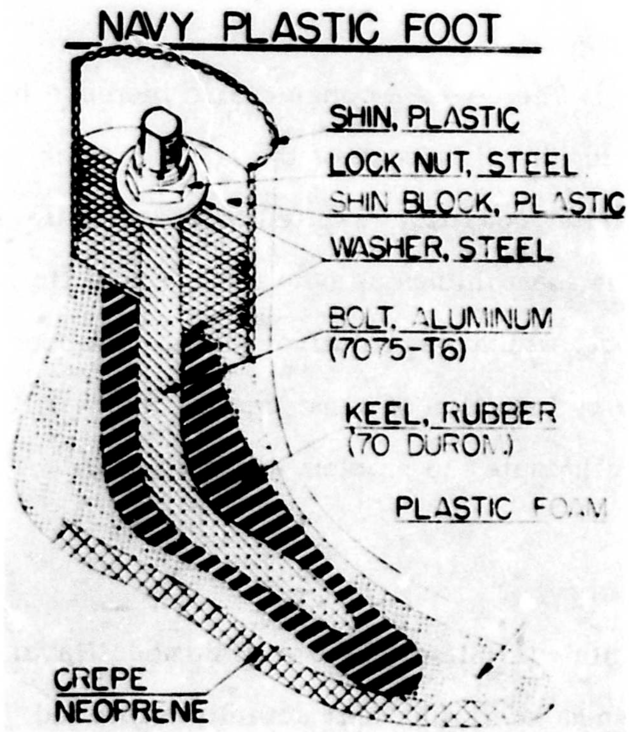


FIG. 8 HALF-SECTION OF EARLY NPRL MOLDED FOOT

Half-section illustrates the several elements and components of the early molded foam foot. Included is the plastic ankle block made of phenolic spheres.

in the foot) were combined with a thick overlay of black rubber (Fig. 10). The rubber toes section was tapered and extended somewhat to add resilience and progressive resistance to bending to the forward section of the keel. The broadened rubber base likewise almost entirely eliminated the previous tendency to punch through the rubber sole.

On occasion there still occurred a break in the keel, now embedded in black rubber of about 80 durometer. On occasion, also, there were also failures of the foam rubber to properly combine with the keel rubber. Most important, however, was the heavy weight of the foot and increasing concern with the limited life of the foam rubber then in use.

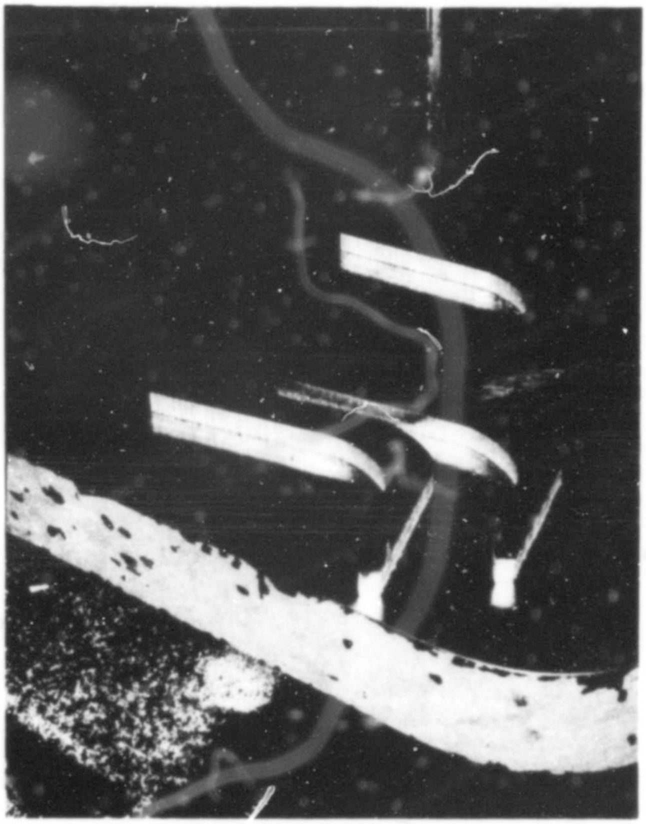


FIG. 9 BANDSAWING ALUMINUM KEELS

Thick aluminum sheet stock was sawed, according to sized patterns, from flat stock to form the core of the keel. Size and shape variations were made to accommodate female and children's feet as well as special prosthetic requirements such as the Syme prosthesis.

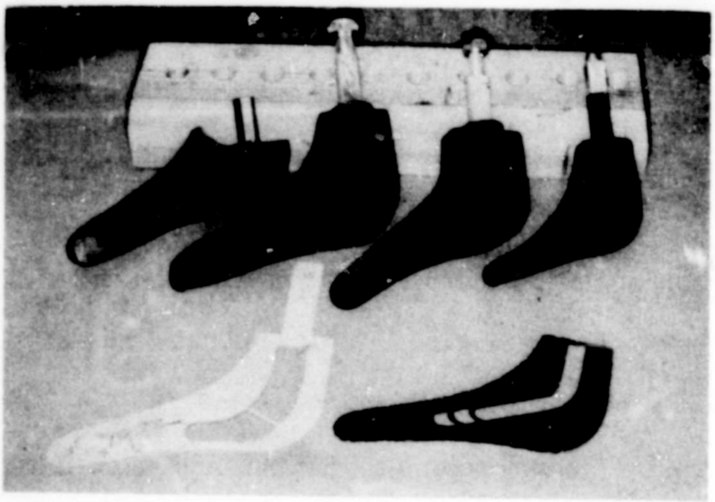


FIG. 10 SIZING OF EARLY ALUMINUM/RUBBER KEELS

The metal section was appropriately threaded then invested in and vulcanized to a black rubber section to form the keel proper. The toe section extended beyond the tip of the metal to add resilience and smoothness to the transfer of weight from the standing position to toe-off during the walking cycle.

d. Wood

Experimental wood keels have been used over the past several years with good success. Keels constructed of relatively soft woods, those with hidden defects in their inner structure or those whose grain was not oriented to this particular use, have rarely required replacement. To standardize their uniformity and production, rock maple has been chosen for use in all keels.

e. Other Experimental Keels

Two experimental keels were designed, constructed and used experimentally but were both dropped because of their high potential construction costs.

One (Fig. 11) combined sheet aluminum sides connecting two wooden elements and the other (Fig. 12) combined a machined element combined with a lightweight plastic ankle block with an interposed rubber fairing.

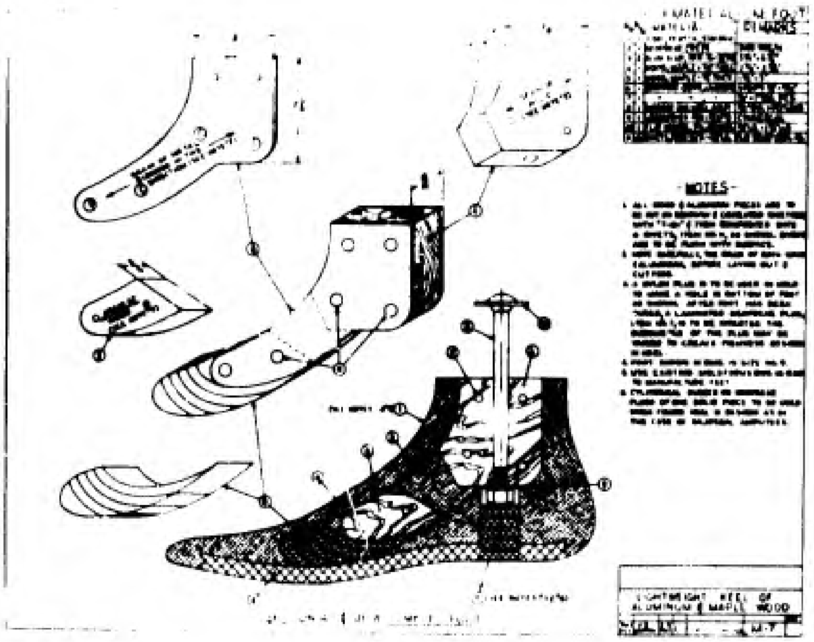


FIG. 11 EXPERIMENTAL ALUMINUM/WOOD KEEL

Experimental foot combines aluminum sides connecting proximal wood block with neoprene toe extension, as shown. Structure provides hollow central section for "Stafoam" material of molded foot. Basic tests indicated functional worthiness but manufacturing costs were too high.

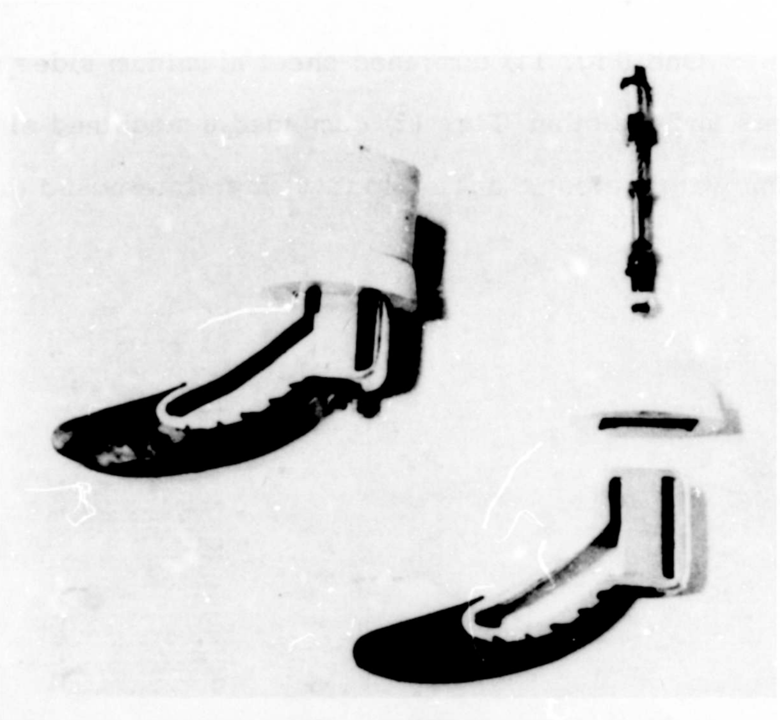


FIG. 12 EXPERIMENTAL ALUMINUM/PLASTIC KEEL

An experimental aluminum keel machined from solid stock, this device proved to be too expensive to produce. As shown, the phenolic spheres ankle block rests above a soft rubber fairing which was inserted between the shin and top of the foamed foot. The fairing also encircles a flexible steel cable forming part of the "ankle bolt," designed to permit life-like action of the foot, including transverse rotation.

C. Original Foam Foot ("Stafoam")

1. Development of the Solid Ankle Cushioned Heel Concept

Along with others, this laboratory began development of a relatively simple foot structure which would employ a solid ankle cushioned heel arrangement. An exceptionally simple approach was used in trying to develop a foot employing a keel encased in a molded rubber structure. Development of a suitable mold was presumed to be a problem in itself - a presumption which has proved to be correct on several occasions.

Use of the solid ankle cushioned heel concept accepts that the foot will be attached to the ankle block, usually attached to the shin piece in a permanent manner, by means of a rigid bolt in a way to allow detachment or re-attachment of the foot from the bottom of that member in a convenient and simple manner. The concept allows for means of providing a resilient cushioning effect on the heel section such as occurs on natural heel contact during the walking cycle. Compression of the heel section should be sufficient to give the proper walking pattern.

The original foot was a one-piece molded unit made of a "foam-in-place" polyether called "Stafoam." The foot was resilient, flexible and generally simulated the skin in color and texture and was considered to be waterproof.

All size requirements, including rights and lefts, for adult males, females, juveniles and children, including infants, were served to a total of fifty-two molds. Special molds for producing female feet, enabling those patients to wear other than low heel shoes, were included.

Structurally, the foot, internally, consisted of a keel and a sole pad, both within the foamed plastic structure. The latter material was considered to give the artificial foot its natural and characteristic shape and appearance. Keels, sole pads and/or fully fabricated feet, in standard sizes, might thus be made up as stock items.

The keel consisted of two parts, a central shaped metal bolt and its rubber investment. The bolt provided proper stiffness to support body weight and also allowed for secure attachment of the artificial foot to the plastic shin by means of the threaded proximal end. The bolt was permanently encased in a shaped rubber section of 70 durometer black rubber by means of vulcanization.

Adult male and female keel bolts were sawed from one-half inch sheet aluminum, following standard patterns. Child and infant sizes were formed from standard bar 1/2" stock through use of a simple bending jig, produced locally for the purpose.

The sole pad was made of "Neoprene" crepe rubber and cut from sheet stock, using patterns. The pad acted to stiffen the sole of the prosthetic foot and provide a long-wearing surface for that member.

The relative positions and dimensions of both the keel and sole pad were based upon careful study, experimentation and use by this laboratory. The keel bolts were made of 7075-T6 aluminum alloy. They were made in three configurations, for adult male, female and child sizes, respectively. They differ in the angulations between their upright and forward sections. Flat metal patterns were used for the adult male and female sizes - each appropriately notched to produce three lengths for the forward projection of the unit, one for the male and two for the female sizes. The child size, made of bar stock as noted, allowed for three lengths of the forward section.

An angle of 120 degrees was used with the female pattern for use in the foot with elevated heel. Female feet for use with flat heels employed the smaller male sizes.

The proximal ends of the metal keel sections were threaded (5/8" SAE 18) and secured in appropriate molds for the rubber vulcanization process. When vulcanized, forward projections of the rubber were easily shortened by trimming away small, rounded sections of the completed keel to the size and length desired.

The rubber sole pad was cut to pattern, according to foot size, to provide a long-wearing, durable surface for the sole of the artificial foot. Two thicknesses of Neoprene crepe rubber was used, 15 and 21 iron in thickness, respectively. (1 iron = 1/48 inch). The thinner material was used for child, juvenile and female sizes, the thicker for adult male sizes. A V-shaped groove was cut around the outer edge of the cut pad in order to increase its surface bonding effectiveness with the foam plastic when molding the foot.

In forming keels and sole pads there was no differentiation between rights and lefts. The keels were neutrally shaped for universal use while the sole pads allowed either surface to be uppermost in the molded foot.

2. Molding the Plastic Sponge Foot

Briefly stated, the foot was formed by first fixing the keel and sole pad in proper position within the open mold (Fig. 13), pouring a measured amount of the mixed chemical substances in and around the keel and sole pad (Fig. 14), after which the mold was closed and clamped tightly shut. The liquid plastic reacted inside the mold to form tiny, flexible bubbles of plastic which rapidly filled the mold cavity until constrained by the inner mold surfaces. As the expansion process continued the plastic filled all cavities within the mold, packing slightly against the mold surface to form a "skin" over the entire outer surface of the foot. The skin, therefore, is a slightly more dense surface layer of the plastic. The molding process permanently encases the positioned keel and sole plate in a non-reversible formed spongy structure.

a. Steps in the Early Foot Molding Technique.

The foam materials were available in three separate containers labeled Component R, C and A, respectively (Fig. 15).

The manufacturers stated that Components R and C. should be stored in tightly sealed containers at 65° to 80° F. with protection from moisture. Component A, alone or when mixed with Component C., contains a highly volatile ingredient and must be stored in tightly sealed containers at temperatures

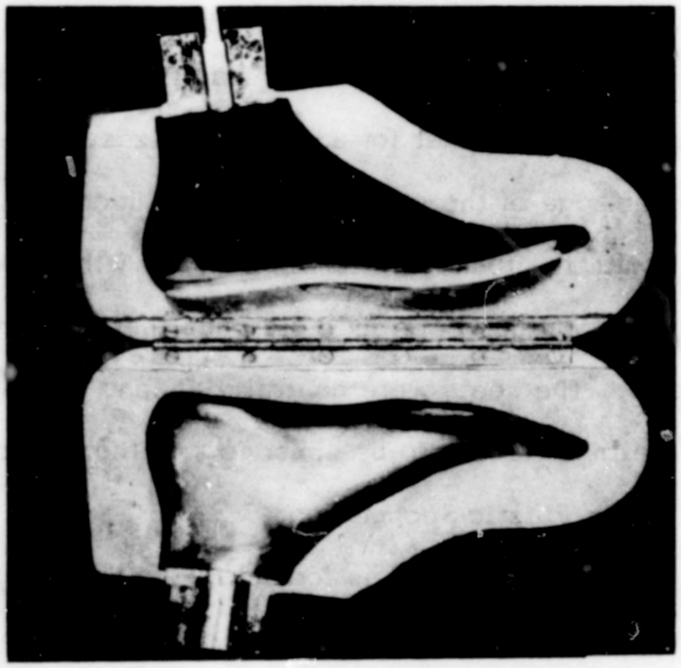


FIG. 13 RUBBER KEEL AND SOLE PLATE IN PLACE

The interior of the cast aluminum mold is moderately polished to produce a smooth "skin" on the molded foot. Shown is the keel and "Cats Paw" rubber sole in place, ready for the pour.

FIG. 14 POURING ALUMINUM FOOT MOLD

Pouring the mixed polyrubber about the keel and rubber sole must be done carefully to avoid entrapping air bubbles and must be completed quickly before significant foaming commences.

FOOT MOLD SIZE	COMPONENT "R"	COMPONENT "C"	COMPONENT "A"	PIGMENT
Child				
4	200 gms.	21.0 gms.	2.0 gms.	2.0 gms.
6	"	"	"	"
8	"	"	"	"
10	250 "	26.75 "	2.5 "	2.5 "
12	"	"	"	"
13	"	"	"	"
Juvenile				
1	300 gms.	31.5 gms.	3.0 gms.	3.0 gms.
2	"	"	"	"
3	350 "	36.75 "	3.5 "	3.5 "
4	"	"	"	"
Female				
3	250 gms.	26.75 gms.	2.5 gms.	2.5 gms.
4	"	"	"	"
5	300 "	31.5 "	3.0 "	3.0 "
6	"	"	"	"
7	350 "	36.75 "	3.5 "	3.5 "
8	"	"	"	"
9	400 "	42.0 "	4.0 "	4.0 "
Male				
5	400 gms.	42.0 gms.	4.0 gms	4.0 gms.
6	"	"	"	"
7	"	"	"	"
8	450 "	47.2 "	4.5 "	4.5 "
9	"	"	"	"
10	"	"	"	"
11	500 "	52.5 "	5.0 "	5.0 "
12	"	"	"	"
13	550 "	57.7 "	5.5 "	5.5 "

FIG. 15 MIXING CHART - "STAFOAM" COMPONENTS

ranging from 60° to 70° F. They finally advise that Component R. should not be used at temperatures greater than 75° F.

All components should be between 60-75° F. before containers are opened since high temperatures will vaporize certain elements increasing the density of the foam produced.

Mixing is conveniently done at relatively low speed or about 600 revolutions per minute. The purpose is to mix thoroughly without beating or introducing air into the mixture.

Components C. and A. are mixed until completely homogenous. Component R. is added when mixing and should be carefully timed for 15 to 30 seconds or until the mixture is smooth, creamy and easy flowing. From that point chemical reaction of the components takes place promptly.

Quantities of each component used, including the pigment, were based on study and experimentation, were closely related to the mold sizes and followed the following sequence:

Step 1. Clean mold thoroughly, using soft cloth and methylethylketone (MEK).

Step 2. Spray all interior surfaces of mold with mold release agent ("Stafoam #3).

Step 3. Inscribe bottom surface of sole pad with straight pencil line dividing it into lateral and medial halves.

Step 4. Apply first of two thin coats of adhesive (Stabond T-161) to upper surface and edges of sole pad. Similarly coat all surfaces of rubber keel. Allow to dry.

Step 5. Weight appropriate quantity of Component R. into one-quart paper container.

Step 6. Weigh indicated amount of pigment and mix thoroughly in Component C.

Step 7. Repeat application of adhesive to keel as in Step 4. Position keel into mold slot.

Step 8. Apply about one-inch stripe of T-161 adhesive along pencil line inscribed in Step 3. Insert pad into open half of mold, align line with mold edge and press into position, thus anchoring into proper position. Apply second coat of adhesive to upper pad surface as in Step 4. Check for proper positions of keel and sole pad in open mold.

Step 9. Weigh Component A. Combine Components R, C and pigment. Add Component A and mix for 15-30 seconds.

Step 10. Immediately pour mixture into mold. Pour lower areas first to avoid entrapping air. Include thin stream along groove of sole pad.

Step 11. Close mold immediately and clamp shut (Fig. 16). Avoid bumping or vibration and suspend with toe downward at about 60°. Do not move or otherwise disturb for three hours.

Step 12. Remove foot from mold. If present, trim away "flash" sections (Fig. 17). Allow plastic foot to complete curing for period of sixteen additional hours before foot is used on prosthetic leg.

3. Testing

Dynamic testing of the foot has taken three forms, involving cyclic mechanical test on a "walking" machine, use by pilot wearers and field tests, as follows:

a. Mechanical

Commonly referred to as a "walking machine (Fig. 18) because the pattern of its movement roughly resembles the walking cycle, the test foot is

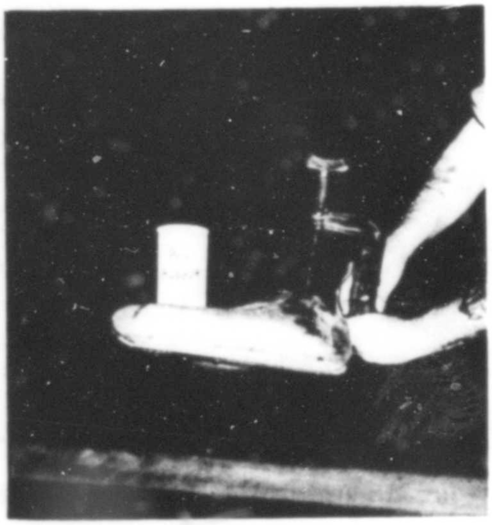


FIG. 16 CLAMPING ALUMINUM MOLD

Immediately, on completion of the pour, the mold is closed and clamped shut. In spite of clamping pressure the material flows somewhat between the matching edges of the mold forming a "flash."

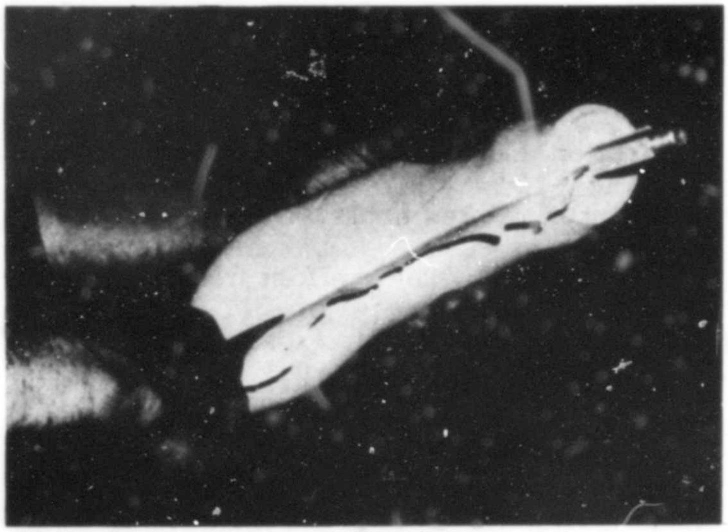
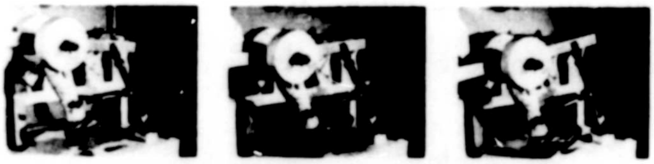


FIG. 17 TRIMMING FLASHLINE OF MOLDED FOOT

Flash material is relatively solid, rather than foamy. It is neatly trimmed away with scissors taking care to avoid cutting into the foot "skin."



1. TERMINAL PORTION OF SWING PHASE

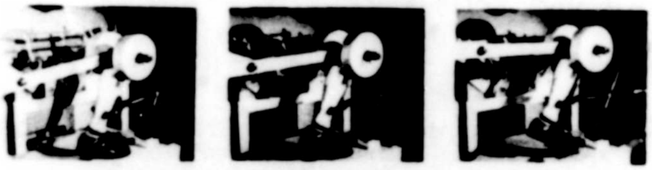
2. IMMEDIATELY PRIOR TO HEEL CONTACT- NO LOAD

3. HEEL CONTACT- BEGINNING PLANTER FLEXION- PARTIAL LOAD

4. FULL LOAD- SLIGHT PLANTER FLEXION

5. FULL LOAD (150 POUNDS) -FOOT AT 90° TO SHIN

6. FULL LOAD- BEGINNING HEEL RISE



7. TOE PUSH-OFF

8. IMMEDIATELY PRIOR TO SWING PHASE

9. SWING PHASE

FIG. 18 ACCELERATED TEST MACHINE

Machine operates with 150 pound load at 37 cycles per minute. During each cycle the foot, in relation to the shin, describes 19 degrees in plantar flexion and 28 degrees in dorsal flexion for a total of 47 degrees under indicated load. The machine permits equivalent of one year use of the foot as regards loading and unloading and plantar and dorsiflexion in about nineteen days.

subjected to repeated plantar and dorsal flexion some thirty-two times per minute as the foot is loaded and unloaded during each cycle with 150 pound loading. Such tests commonly develop defects in elements such as the keel or the foam materials in short order. One million cycles on the machine is arbitrarily considered to be equivalent to one year of actual use.

b. Selectivity in choosing pilot wearers generally consists of using those individuals who live in the area to permit frequent inspection of the test unit and/or those individuals who will subject the device to moderate to severe test experiences. An example of the latter would be an overweight, bilateral leg amputee who is physically very active.

c. Field Tests

On successful completion of the first two phases, the unit is adapted for routine use by all lower extremity amputees fitted by this laboratory. In that way a wide spectrum of uses under diverse environmental conditions is used. In this way we discovered the premature deterioration of an earlier foam due to the environment on Guam, where the foot was used over an extended period. On the other hand, one of our test amputees used the same type foot during short visits to both the North and South Poles, without undue problems.