

THERMOFORMED ANKLE-FOOT ORTHOSES¹

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Clinical and research groups have for many years felt that the use of plastics in orthotics had great potential for the development of improved designs. Attempts to use polyester and epoxy laminates that were adopted by prosthetists in the fabrication of artificial limbs more than 20 years ago largely met with failure when applied to orthoses that were subjected to repeated bending loads, owing no doubt to the relatively short fatigue life of the polyester and epoxy resins.

However, with the availability of thermoplastics such as polyvinyl chloride, polyethylene, and polypropylene in sheet form, and with good resistance to fatigue, a number of new designs emerged in the 1960s (1). Most of the new designs were ankle-foot orthoses for use with "drop foot."

In 1970 the Committee on Prosthetics Research and Development (1) identified 11 ankle-foot-orthosis designs for treatment of "drop foot" that seemed to have advantages over the conventional "short-leg brace" which consisted of two metal uprights and two ankle joints, and were attached to a special shoe or to one that was modified extensively. The Committee requested the Rehabilitation Engineering Center at Moss Rehabilitation Hospital (2) to conduct laboratory and clinical studies of each of the 11 designs in order to provide clinicians with guidance in prescribing and applying the various devices.

The 11 orthoses (Fig. 1) were studied and the origins of their design are listed on page 42.

Where the need for an orthosis was minimal the VAPC shoe-clasp orthosis was found to be the most acceptable, especially in ease of application and cost (2). For more severe cases the TIRR molded polypropylene orthosis seemed to have advantage over the other designs. It is light in

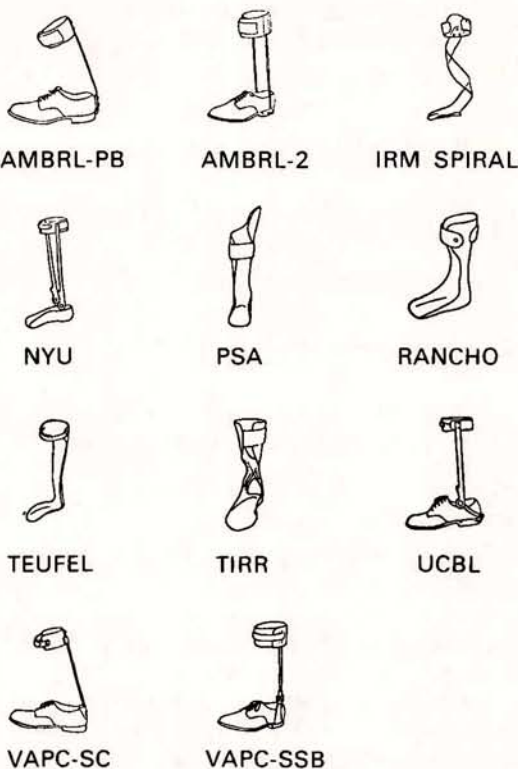


Fig. 1. Sketches of orthoses studied originally by the Research Engineering Center, Moss Rehabilitation Hospital.

weight, almost unnoticeable, requires no shoe modifications, is relatively easy to fabricate and fit, and the amount of control provided about the ankle can be varied (2).

While these studies were being carried out at Moss Rehabilitation Hospital, the Rehabilitation Engineering Center at the Ontario Crippled Children's Centre (Toronto, Canada) was developing methods and equipment for forming sheet thermoplastics for orthotic and prosthetic applications. Because of the encouraging results obtained in the orthosis evaluation project with the TIRR AFO and other molded orthoses, the Rehabilitation Engineering Center at Moss Re-

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AMBRL Posterior-Bar Drop-Foot Orthosis	U.S. Army Medical Biomechanical Research Laboratory
AMBRL Two-Rod Drop-Foot Orthosis	Walter Reed Army Hospital
	Washington, D.C.
IRM Spiral Below-Knee Orthosis	Institute of Rehabilitation Medicine,
Posterior Solid-Ankle Orthosis	New York University, New York, N.Y.
NYU Insert Orthosis	New York University Post-Graduate
	Medical School, New York, N.Y.
RANCHO Polypropylene Drop-Foot Orthosis	Rancho Los Amigos Hospital
	Downey, California
TEUFEL Ortholen Drop-Foot Orthosis	Teufel, 7 Neckarstrasse,
	189-191 Stuttgart, West Germany
TIRR Below-Knee Orthosis	Texas Institute for Rehabilitation and
	Research, Houston, Texas
UC-BL Dual-Axis Ankle Orthosis	University of California, San Francisco
	Medical Center, San Francisco, California
VAPC Shoe-Clasp Drop-Foot Orthosis	Veterans Administration Prosthetics
VAPC Single-Bar Below-Knee Orthosis	Center, New York, N.Y.

habilitation Hospital decided to extend the clinical study to include vacuum-forming of orthoses.

Because of delays in making commercially available the equipment designed by OCCC, a machine manufactured by Plastic Vac, Inc., but not designed specifically for orthotics, was purchased by Moss in 1973. Since that time molded lower-limb orthoses have become standard at Moss Rehabilitation Hospital. Development work is continuing but sufficient experience has been gained so that others can use some of the new designs with confidence.

MOLDED ANKLE-FOOT ORTHOSES

The molded ankle-foot orthosis (Fig. 2) is formed from a single piece of sheet thermoplastic. Polypropylene is usually the material of choice because of its high resistance to fatigue, low cost, and very light weight. It can be worked easily and can be welded, but will not take adhesives.

Molding is carried out over a positive plaster-of-Paris model of the foot, ankle, and shank, usually with the use of a vacuum system.

Although the molded AFO is a single unit, it has two basic components—the posterior calf enclosure and the foot enclosure (Fig. 3).



Fig. 2. Typical molded Ankle-Foot Orthosis.

The perimeter is referred to as the "trimline," and consists of five parts:

1. Proximal trimline
2. Anterior trimline
3. Ankle trimline
4. Foot trimline
5. Metatarsal trimline

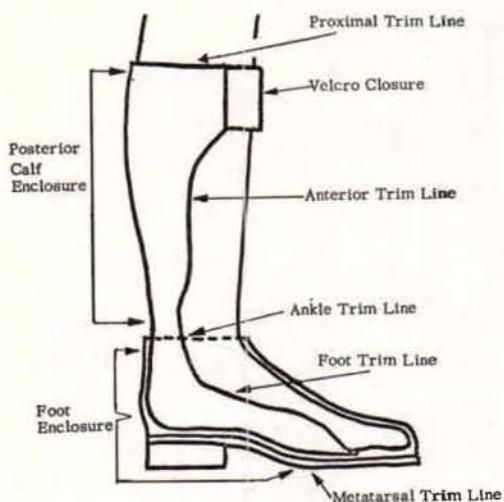


Fig. 3. Lateral view of molded AFO showing the various areas and trimlines.

FUNCTION

The function provided by a molded AFO is largely dependent upon the degree of resistance that is provided to rotation about the ankle joint. The resistance to rotation about the ankle joint, or rigidity of the ankle area, for any given material varies with the amount and distribution of material. Obviously, the thicker the walls the more rigid the orthosis will be for a given cross-

section geometry. Not so obvious is the effect of the shape of the transverse cross-section.

Because the entire inner surface of the molded AFO is in contact with the limb, the shape of the foot, ankle, and calf of the patient dictates the basic geometry of the transverse cross-section. Everything else being equal, rigidity in the sagittal plane varies inversely with the angle between the two sides of the orthosis in the ankle area (Fig. 4).

The rigidity provided by the shape of the anatomy can be modified by: location of the trimline; thickness of the material; and introduction of corrugations.

Thin walls are generally desirable and the orthotist will try to make the walls as thin as possible. They should be no more than 4 mm. thick at the thickest part, tapering down to 2 mm. However, corrugations are seldom needed because the orthotist can usually obtain the desired amount of flexibility by location of the trimlines. The effect of the orthosis on the patient will also depend upon the location of the weight line (Fig. 5, center), which in turn will depend upon the position of the foot part of the orthosis with respect to the shank part of the orthosis for a given heel height.

The location of the weight line must be considered at the time of casting and not left until the time of fitting with the idea that it can be controlled by heel height changes (Fig. 5).

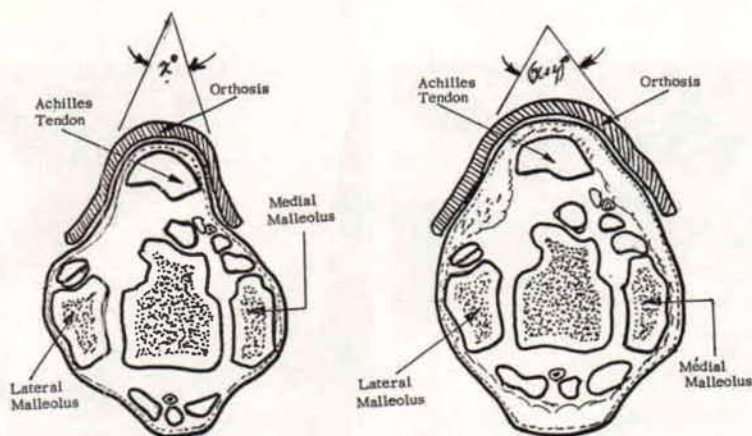


Fig. 4. Transverse sections through the lower shank that demonstrate how the transverse cross-sections of molded AFOs vary. Everything else being equal, rigidity in the sagittal plane varies inversely to the amount of the angle between the two sides.

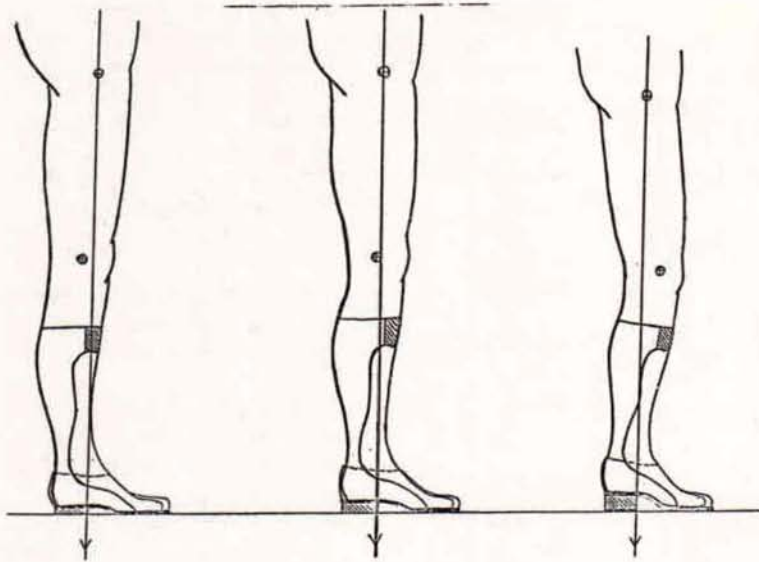
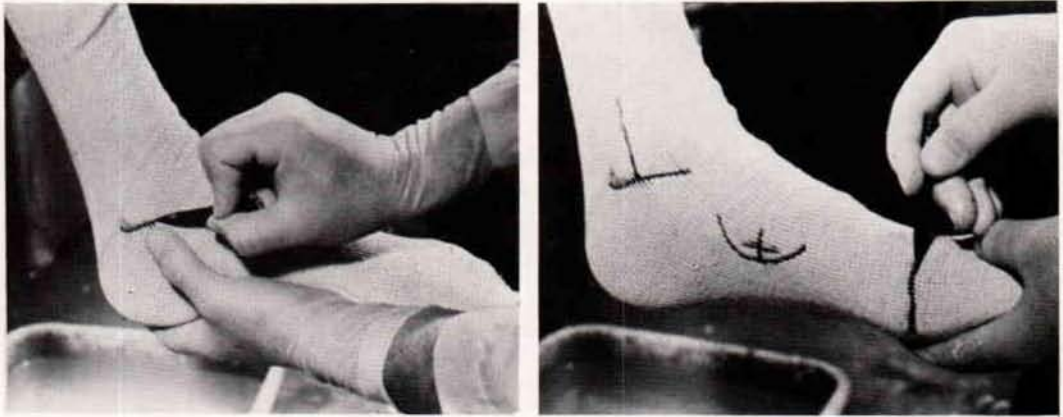
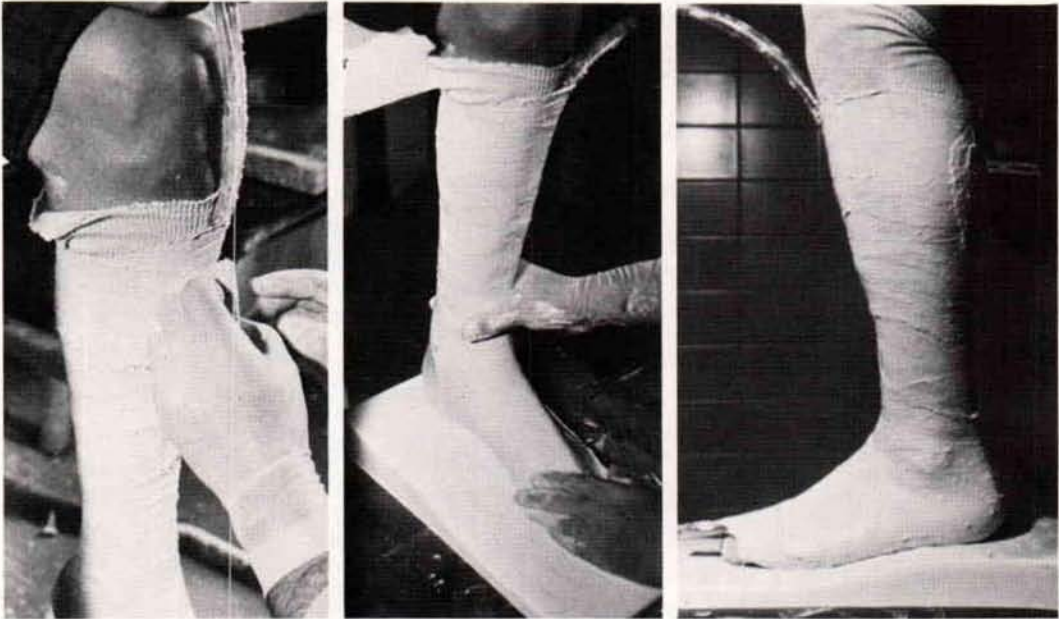


Fig. 5. Schematic drawing to show effect of heel height on function of an ankle-foot orthosis when heel height is changed after orthosis has been made. The vertical lines represent the weight-bearing line in each instance. Proper alignment should be achieved during casting and not by shoe modifications.

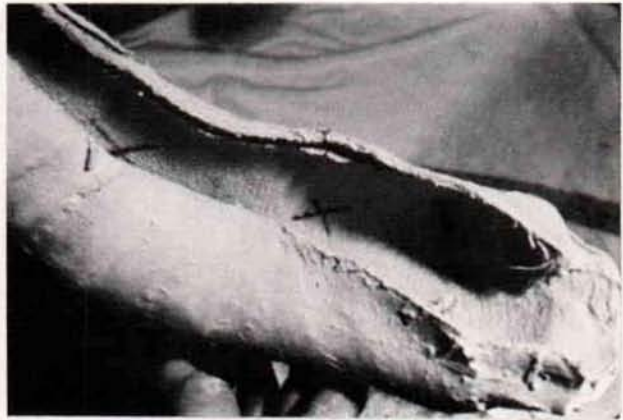
FABRICATION



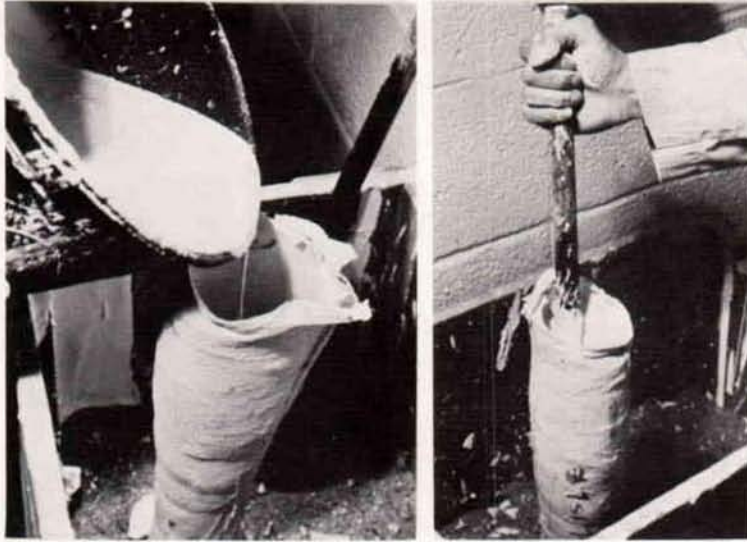
Stockinet long enough to reach the mediotibial plateau is pulled over the foot and leg. Indelible pencil is used to mark the malleoli, the navicular, and the metatarsal heads.



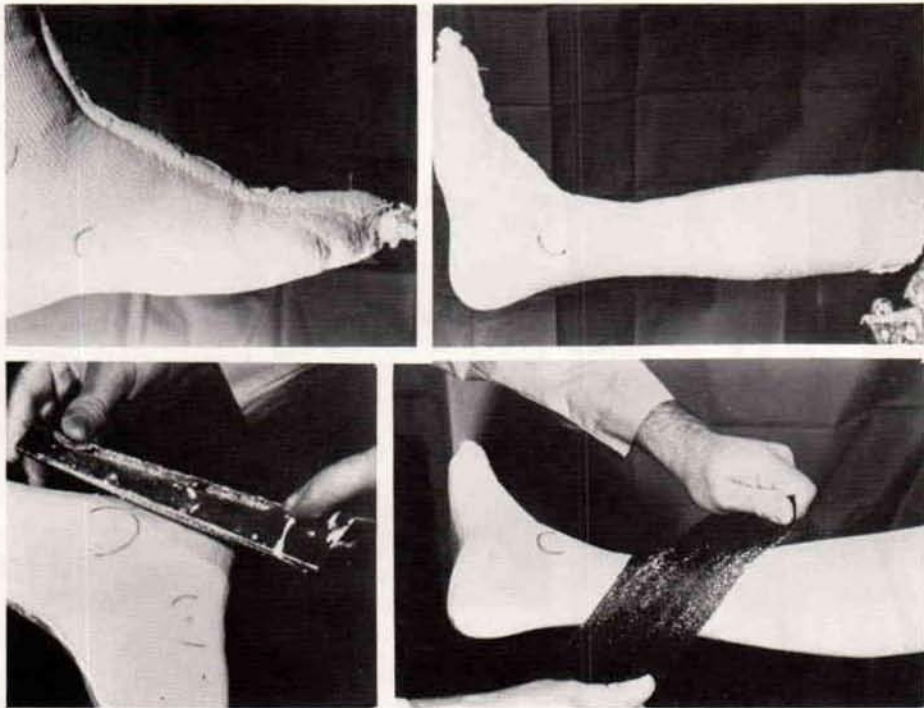
A vinyl or rubber tube is placed along the anterior aspect of leg to facilitate removal of the cast. Elastic plaster-of-Paris bandage is used to wrap the foot and leg. The appropriate size standard casting board is used, and the patient is sitting when the wrapping is carried out.



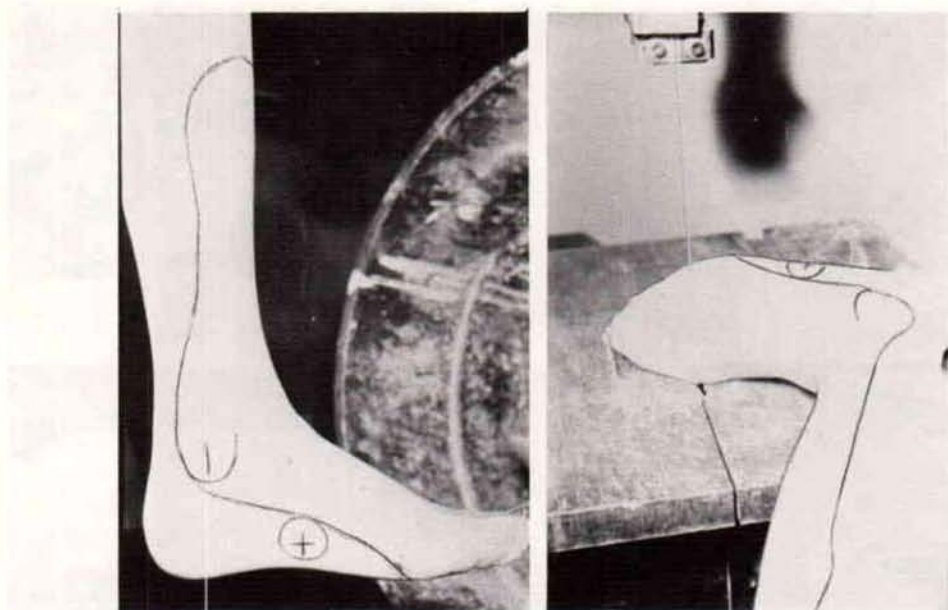
The cast is slit on the anterior aspect over the vinyl tube with a cast cutter, and removed from the patient. The marks showing locations of bony prominences and other points of reference are reinforced with indelible pencil and cast is closed and held together with staples or tape in preparation for pouring of the positive model.



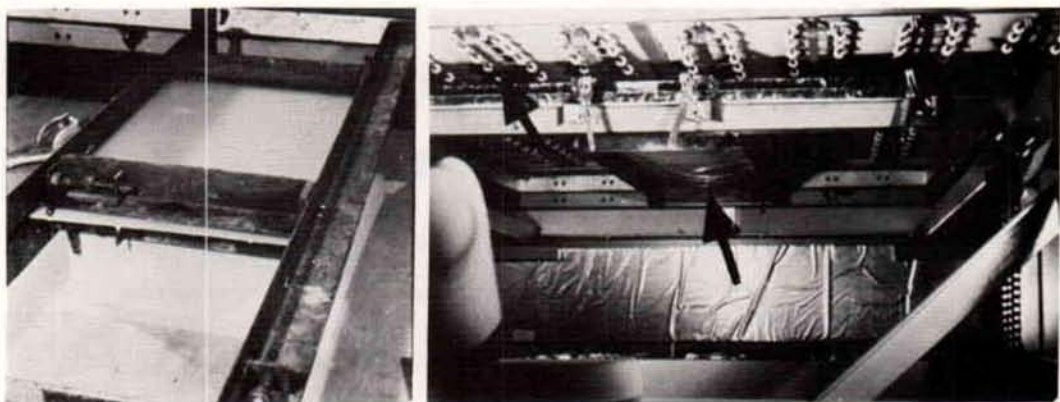
The cast is filled to produce a positive model. A mandrel is placed in the slurry so that it coincides as closely as possible with the centerline of the shank. When a cylindrical rod is used for a mandrel, it can be easily removed later if it is rotated a few times as the plaster hardens.



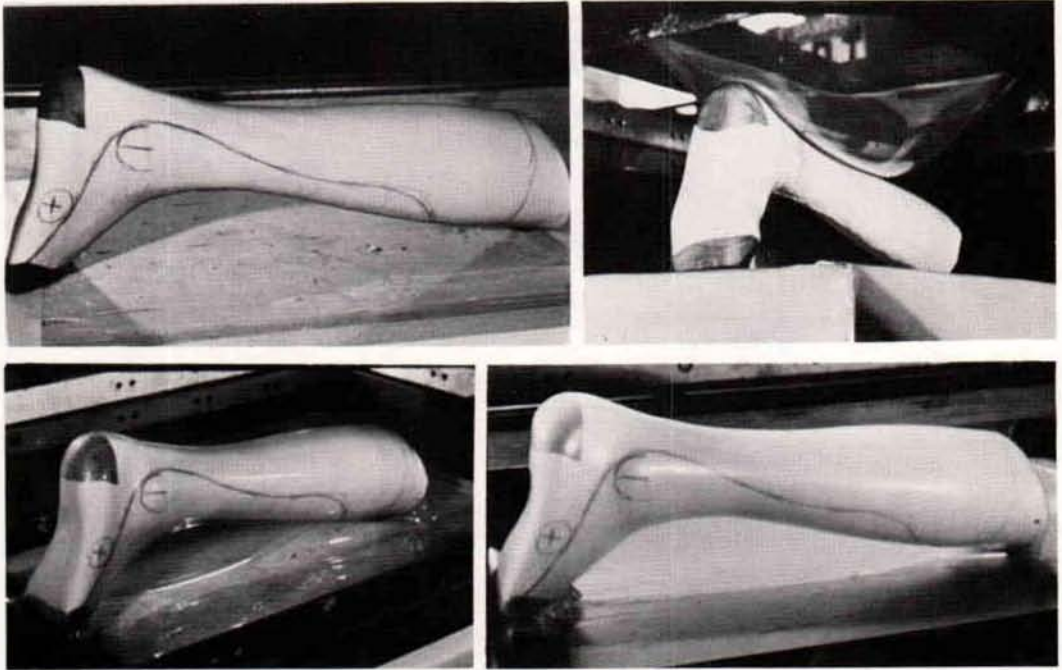
The ridge formed on the positive model as a result of the use of the vinyl tube is removed and the entire surface of the model is made smooth using conventional methods.



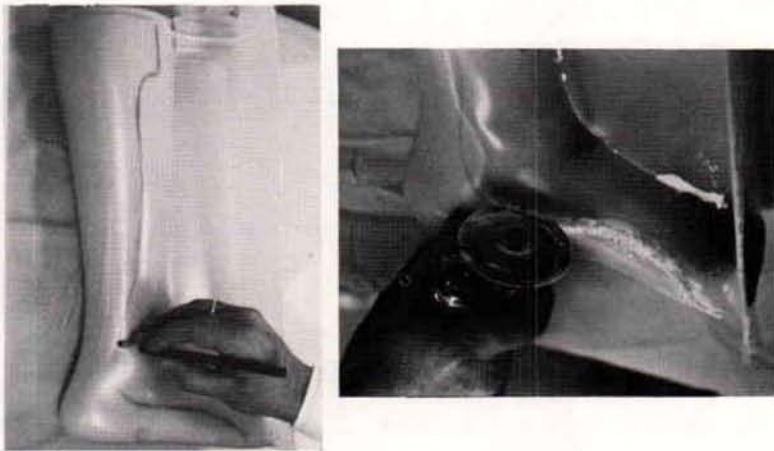
The first trimline is defined with indelible pencil. This line, of course, allows for more material to be left than is thought to be necessary in the finished orthosis. The toe section of the positive model is cut off in order to facilitate mounting the model in the vacuum-forming machine.



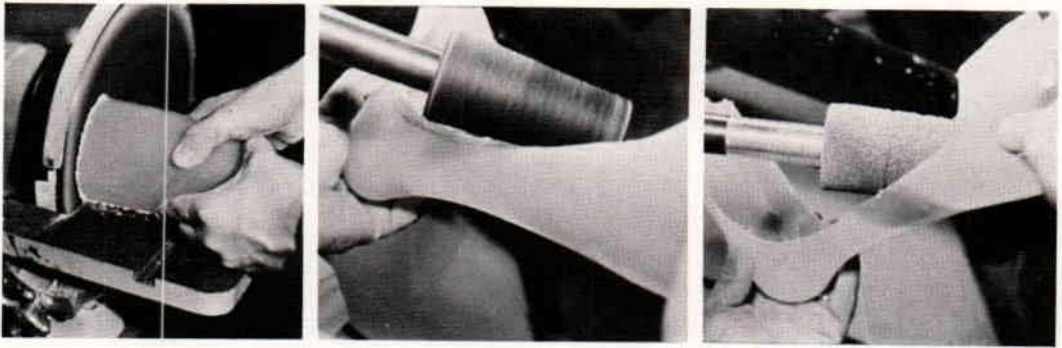
A sheet of polypropylene 12 in. x 24 in. is mounted in the frame of the vacuum-forming machine and subjected to a temperature of +400 deg. F until it sags to a level of about 2/3 the amount of the draw. As a general rule, AFOs for adults require polypropylene 3/16 in. thick; for children, 1/8 in. thick. The time required for heating ranges from 6 to 8 min., depending upon the thickness and temperature.



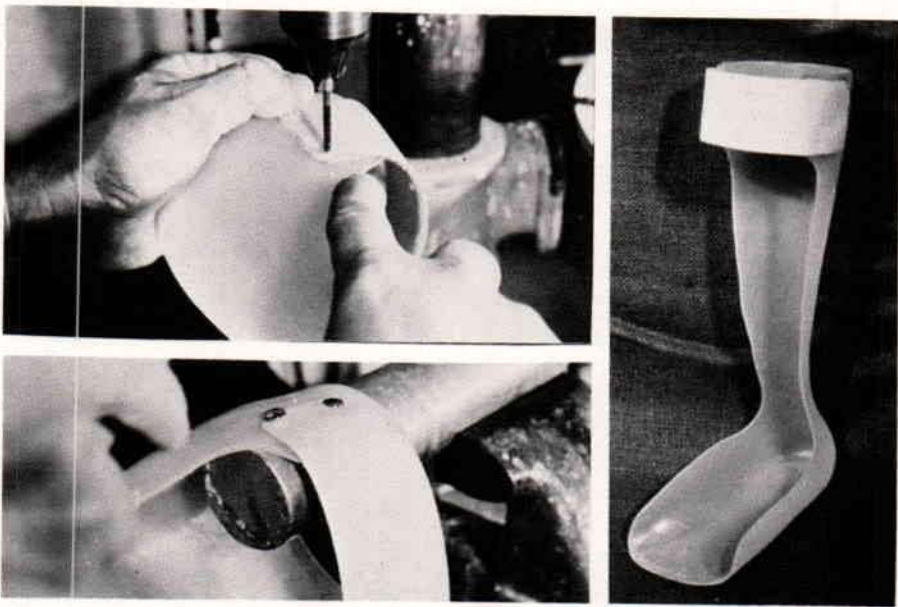
The softened polypropylene is lowered over the positive model and when the periphery of the polypropylene touches the table or platform holding the positive model so as to effect a seal, the vacuum is applied gradually until the model is covered entirely. Leaks caused by breaks can be sealed with molding clay.



The model and molding are removed from the vacuum-forming machine, and the initial trimline is reproduced on the outside of the polypropylene with a grease (china-marking) pencil since the marks on the positive model will not transfer automatically. A cast cutter is used to cut the molding along the trimline and thus permit removal from the model.



The edges of the orthosis are ground smooth using, as appropriate, the disc sander and the cone sander with coarse grit and TYCRO³ cones.



Holes are drilled, Velcro straps are installed with rivets, and the orthosis is ready for initial fitting.

³Minnesota Mining and Manufacturing Co.

THE TRIMLINES

Location of the trimlines will depend upon the results of the assessment of the patient, thus on the patient's individual needs. The following rules apply in general:

- The proximal trimline (Figs. 2 and 6) is located approximately 3.8 cm. (1 1/2 in.) distal to

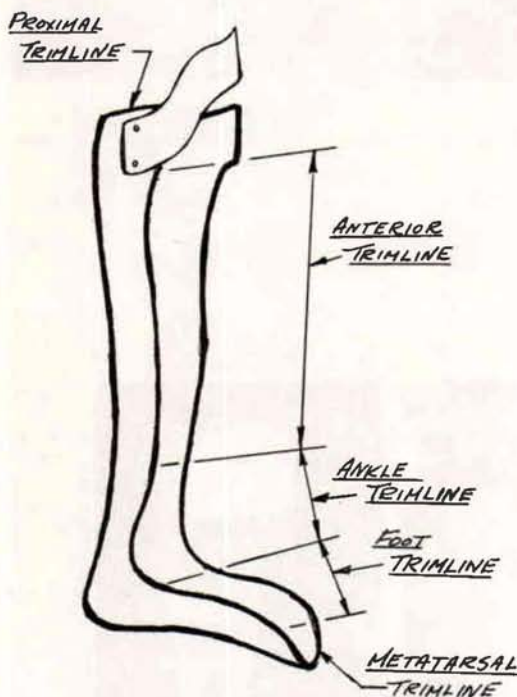


Fig. 6. Drawing to show location of various parts of the trimline of a typical molded AFO.

the head of the fibula so that it will be clear of the peroneal nerve. The proximal trimline should encircle about 3/4 of the calf.

- The anterior trimline extends from the bottom of the junction of the Velcro strap and the orthosis to the midpoint of the shank. The anterior trimline should curve posteriorly as it proceeds distally to the midline of the shank (Figs. 2 and 6).

- The location of the ankle trimline affects the rigidity about the ankle joint more than any other single factor. Obviously, the further anterior that the trimline is located, the more resistance there is to rotation about the ankle.

- The foot trimline on the medial side extends through or slightly above the apex of the navicular. On the lateral side, the foot trimline extends slightly above the shaft of the fifth metatarsal.

- The metatarsal, or terminal, trimline (Figs. 2 and 6) lies along the apices of the metatarsal heads.

- All trimlines should be contoured and blended together smoothly. When a trimline is located slightly below a bony prominence, the area often becomes irritated, but when the trimline is located at the level of or slightly above the apex of a bony prominence, pressure areas do not occur as a rule.

Until more definitive guidelines can be established for arriving at the rigidity desired, the location of the trimlines must be a result of the judgment of the orthotist. Some variations in trimlines to achieve desired effects can be seen in Figure 7. An attempt is being made to develop more definitive guidelines, especially for teaching purposes. Meanwhile, it is felt that competent orthotists will find that, with a little experience, quite satisfactory results can be achieved.

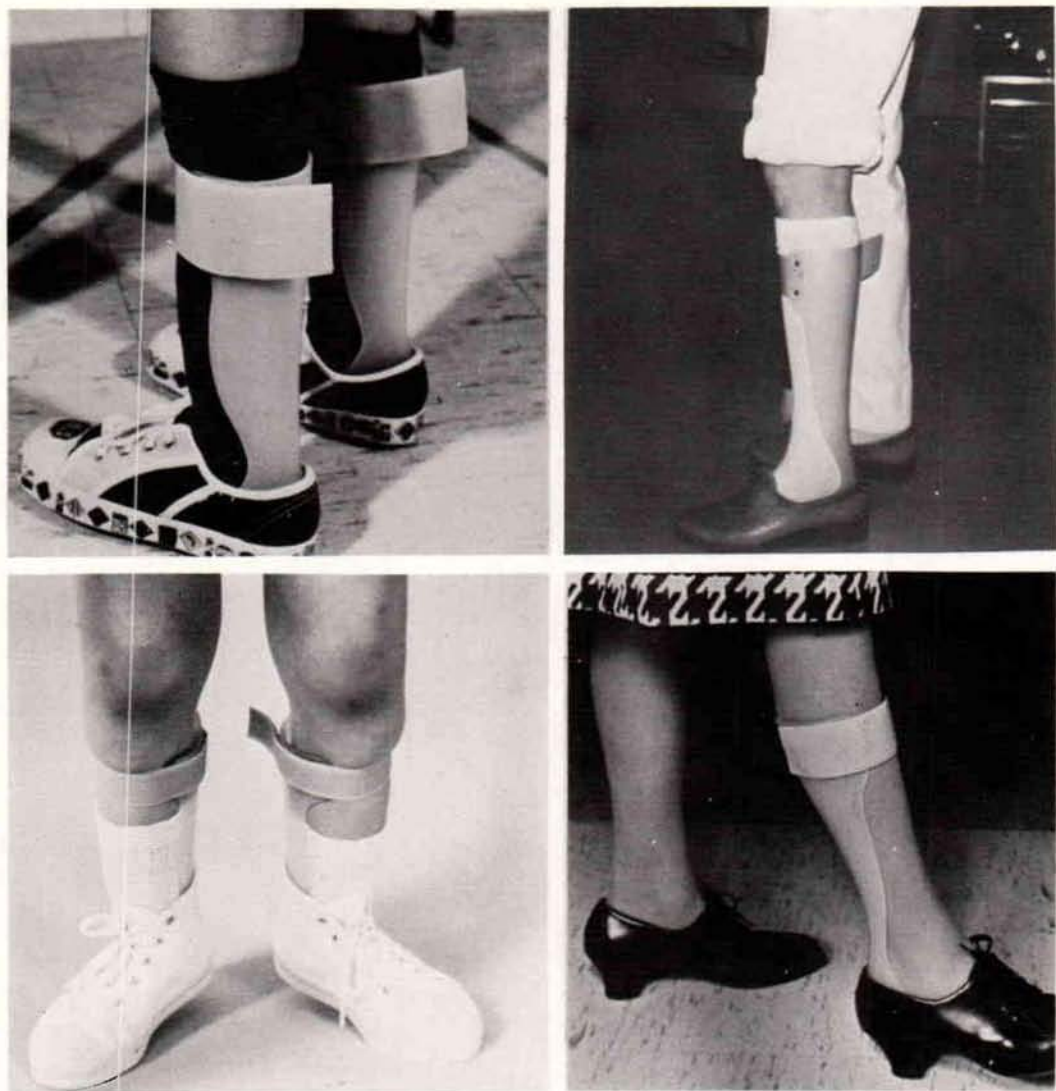


Fig. 7. Views that show variations in the trimline locations made to meet needs of the individual patient.

LITERATURE CITED

1. Committee on Prosthetics Research and Development. *Report of seventh workshop panel on lower-extremity orthotics*. National Academy of Sciences, May 1970.

2. Finley, F. Ray, and Ray G. Wirta. *Rehabilitation biomedical engineering: orthotics design*. Krusen Center for Research and Engineering, Moss Rehabilitation Hospital, Philadelphia, Pennsylvania, May 1972.