

Direct Forming of Below-Knee Patellar-Tendon-Bearing Sockets with a Thermoplastic Material

by
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INTRODUCTION

Research and development groups especially in Toronto, Miami, and New York have recently been using thermoplastic material which when softened can be applied on the body to form orthotic or prosthetic sockets. Sockets for both fracture braces and artificial limbs have been made with these materials.

Noted has been the particularly successful employment of tubes

and sheets made from a material called POLYSAR* X-414 synthetic rubber, a resin available from the Polymer Corporation of Sarnia, Ontario, Canada. Johnson & Johnson of New Brunswick, New Jersey, has made this thermoplastic available in sheet form. Recently, Delford Industries of Middletown, New York has been extruding tubes made from Polysar X-414; such tubes are now available from the U. S. Manufacturing Company of Glendale, California.

¹This article was submitted by Mr. Anthony Staros, Director of the VA Prosthetics Center, New York, N. Y., on behalf of his staff who performed the research and development work underlying the procedure described.

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Presented in this article is a description of the use of tubes made from this particular synthetic balata (rubber) in direct forming of sockets on below-knee amputation stumps. An evaluation of this procedure and of the material is now being conducted by the Committee on Prosthetics Research and Development, National Academy of Sciences—National Research Council. In addition, five clinic teams in the United States are fitting patients following the described procedure. New York University's Prosthetic Research Study is evaluating the use of the thermoplastic tubes in forming below-elbow sockets directly on amputation stumps. It is expected that these evaluations will proceed expeditiously and that sometime during 1969 results can be made available to clinicians and practitioners throughout the world.

Mr. Henry Gardner of the VA Prosthetic Center presented a demonstration of direct forming at the 1968 National Assembly of the American Orthotic and Prosthetic Association and it was felt desirable to support that presentation with the material presented here. Eventually, after the evaluations described above are completed, step-by-step manuals will become available. Hopefully, university and college educational programs will consider presenting this or a similar technique in their curricula.

In the meantime we should like prosthetists and orthotists to give some consideration to the information contained in this article.

We believe that this procedure or one like it with the same material can expedite the provision of prostheses for patients who now sometimes have to wait an excessively long time for a limb. The prosthesis as described seems to offer improvements over present types of temporary prostheses; we also believe that there are possibilities for using this type of device in "semi-permanent" and definitive prostheses. Most important, however, is the fact that amputee rehabilitation may be realized at a much faster rate.

SIGNIFICANCE OF THE METHOD

Our experience suggests that use of tubes made from Polysar X-414 synthetic rubber in the direct forming of below-knee sockets will expedite prosthetic care of patients. The presently described method of direct forming can be used at least for temporary below-knee sockets in conjunction with a metal skeletal (pylon) structure. Moreover, it seems possible to use the same plastic in forming sockets for definitive prostheses, provided a reasonably simple cosmetic treatment can be applied to the skeletal structure.

With cases for whom so-called temporary prostheses may be used, it is often desirable to render a cosmetic treatment to the limb either while a permanent or definitive prosthesis is being formed or for the period when prescription of a definitive limb is questionable. The method of fin-

ishing described here might be used for such situations.

Some researchers are interested in the possibility of using the socket-forming method described here, or a modified method with the same material, to form sockets at some point in the immediate postsurgical prosthetic fitting routine. We are certain that attempts will be made to use this particular synthetic rubber or a material like it at the time of the first rigid dressing change. Indeed several research groups are interested in the possibility of using this material in tubular form for the first rigid dressing. Careful and very deliberate technique development is certainly required before such applications become routine.

The possibility therefore exists of developing a thermoplastic rigid dressing which could gradually be modified to a below-knee weightbearing socket for early ambulation. Then it can be subsequently altered as needed for the definitive socket. The same "pylon" structure can be used throughout, from time of surgery up to and including employment of the definitive prosthesis. Because of the ability to alter the contours of a thermoplastic socket through post forming, and also because the "pylon" structure contains alignment adjustability, practitioners may eventually have available a reasonably adjustable prosthesis as amputee stump changes take place and as amputee capability improves. The prosthetist can thus alter

the biomechanics of the prosthesis as needed through changes both in fit and alignment. And later during the use of the definitive prosthesis, the ability to adjust both fit and alignment would be beneficial in allowing simple corrections to overcome some of the socket comfort problems normally seen in clinics.

Thus, forming sockets directly on amputation stumps is a potentially valuable procedure offering possibilities for improved socket fit, easier socket modification, and substantial reduction in fabrication time. The techniques may also be more readily mastered than those used for fabrication in the conventional manner, as when an intermediate plaster-of-Paris replica must be formed.

The direct-forming process depends on the use of a material which: (a) is plastic at temperatures moderately above ambient but requires reasonably high temperatures to soften subsequently; (b) is easily worked under conditions found in most limb shops; (c) has a "poor memory", i.e., once set, it should not change its shape; (d) exhibits minimum "creep" or deformation under load even at temperatures slightly above body temperature; (e) is non-toxic; (f) has a reasonable strength-to-weight ratio; and (g) is reasonably flexible in its "hardened" state.

THE MATERIAL, POLYSAR X-414

POLYSAR X-414, a synthetic similar to natural rubber, pos-

sesses most of the necessary properties listed above. At temperatures between 160 degF and 180 degF it becomes plastic. It doesn't give up its heat readily and thus can be applied to the amputation stump within a minute or two after softening. It remains reasonably plastic after its surface temperature drops twenty to thirty degrees. When plastic, it exhibits extraordinary cohesive properties.

Laboratory tests indicate that after it cools and becomes non-plastic, it maintains its shape even under stress and subsequent heating to temperatures 120 degF. Other tests have shown that conventional fastenings, rivets, and screws are adequately retained so that it is possible to use all conventional components and accessories with sockets made using this particular synthetic rubber.

Clinical findings indicate that the sockets will remain durable provided excessive heat exposures are avoided. Leaving the limb in the sun, in the trunk of a car on a hot day, or leaning against a house radiator can cause distortions. Amputees should be cautioned about such situations.

Excessive exposure to perspiration may also cause erosion of the material after about a year. Normally, stump socks will act as adequate barriers.

The synthetic rubber is quite flexible, not presenting the rigid, unyielding socket chamber typical of most plastic laminates. Indeed, this characteristic of the thermo-plastic used in this procedure may be one of its major advantages.

THE DIRECT-FORMING METHOD

Using tubes made from this resin, forming of a socket directly on the stump is reasonably simple. One step with this material is equivalent to the whole process of fabricating a conventional socket, thus making it unnecessary to: (a) make a plaster-of-Paris wrap cast; (b) pour a positive cast; (c) modify the positive cast; and (d) laminate. These steps with modified stump replicas are certainly error prone, based on hand-formed contours. It seems desirable to eliminate these and the lamination process in forming artificial limbs.

Regardless of the material used, obtaining a perfect replica of the below-knee stump is extremely painstaking. Even if it were simple, such a replica would not represent the best biomechanical shape for sound weight-bearing and control. When casting the stump, consideration must be given not only to the distortions caused by pressures upon the passive stump mass but also to the special requirements of weight-bearing and control during ambulation.

When using conventional hand-casting procedures, the stump is subjected to pressures of unknown magnitude and distribution yielding a contour which may provide the proper forces for prosthesis control and support of body weight in the socket. However, when the stump is subjected to equal pressure as in the method described here, deformations will

take place as a function of the resistive characteristics of the underlying tissues. The bony tissues of the stump will tend to protrude more as the soft tissues are compressed. (The pressure on the fleshy tissues will tend to reduce any edema present; the socket contour so determined will then maintain some control of edema.)

By employing uniform pressure application, maximum advantage can be taken of the more stable (less resilient) areas of the stump by a concentration of the higher portion of the required support and control forces in these areas, on surfaces such as the ligamentous structures of the patella and the condylar flares of the tibia. Then, during ambulation, the horizontal control forces acting about the stump will be combined vectorially with the vertical support forces. The resultant forces act roughly normal (at 90 deg) to the broad sloping condylar surfaces of the stump, a desirable condition which minimizes the shear forces.

Experimentation with various pressure-casting methods has been carried on for several years. In 1958, Mr. Paul Leimkuehler of Cleveland, Ohio used a vacuum system for casting below-knee stumps. His system was based upon the "dilatancy" principle. In 1960, Mr. Colin McLaurin then at Northwestern University experimented with a hydraulic method of pressure casting. In 1963, Mr. T. Meyer of Detroit, Michigan also used a hydraulic

method of casting. All of these methods required the use of a canister or rigid pressure chamber and a casting stand. The complexity of the techniques discouraged further development. With the availability of materials such as Polysar X-414, a renewed effort was made to develop an adequate pressure-casting method. This led to the design and application of a pneumatic pressure system.*

The pneumatic pressure-forming apparatus presented here is designed to control the external pressures used to form the plastic socket over the below-knee amputation stump. Although wide-scale clinical results of pressure molding are not yet available, limited experience suggests that the pneumatic pressure method is a great improvement over current socket forming and casting methods since (1) pressures are better controlled, (2) variations in hand and finger pressure of the prosthetist are eliminated, (3) replicas or sockets need very little modification, (4) the system can be used with the patient seated or even supine, as on a postsurgical recovery table, and (5) the results are reproducible.

In this procedure, a synthetic rubber tube is heated to a temperature of 180 degF and pulled over the protected stump (Fig. 1). The pneumatic pressure sleeve, when placed over the plastic socket material and inflated under

* Actually a (partial) vacuum system yielding the same pressure differential could be used as well.



FIGURE 1—Softened Plastic Socket Material on Stump Before Pressure Application.

a controlled pressure, applies the compression needed to form the plastic material intimately about the stump contours.

FORMING EQUIPMENT

The pneumatic pressure sleeve is a double-walled cone of small taper which is large enough to fit over the largest knees and stumps. The inner and outer walls are connected at the top forming an airtight closed-end conical sleeve 18 in. long (Fig. 2). Air is introduced into the pressure sleeve chamber by means of a bicycle pump. An air gauge with valve is inserted in the line for observation and control of the pressure magnitude. When air is introduced

into the sleeve, the diameter of the outer wall enlarges only slightly with expansion further restricted by a 5-ply wool stump sock placed over the pressure sleeve. The inner wall however moves inward freely thereby tending to close the conical opening and applying pressure on the synthetic rubber tube on the stump.

PREPARATION OF THE PATIENT FOR SOCKET FORMING

A careful evaluation of the stump must be conducted prior to forming the socket. All stump characteristics, especially conditions which require special considerations for socket comfort,

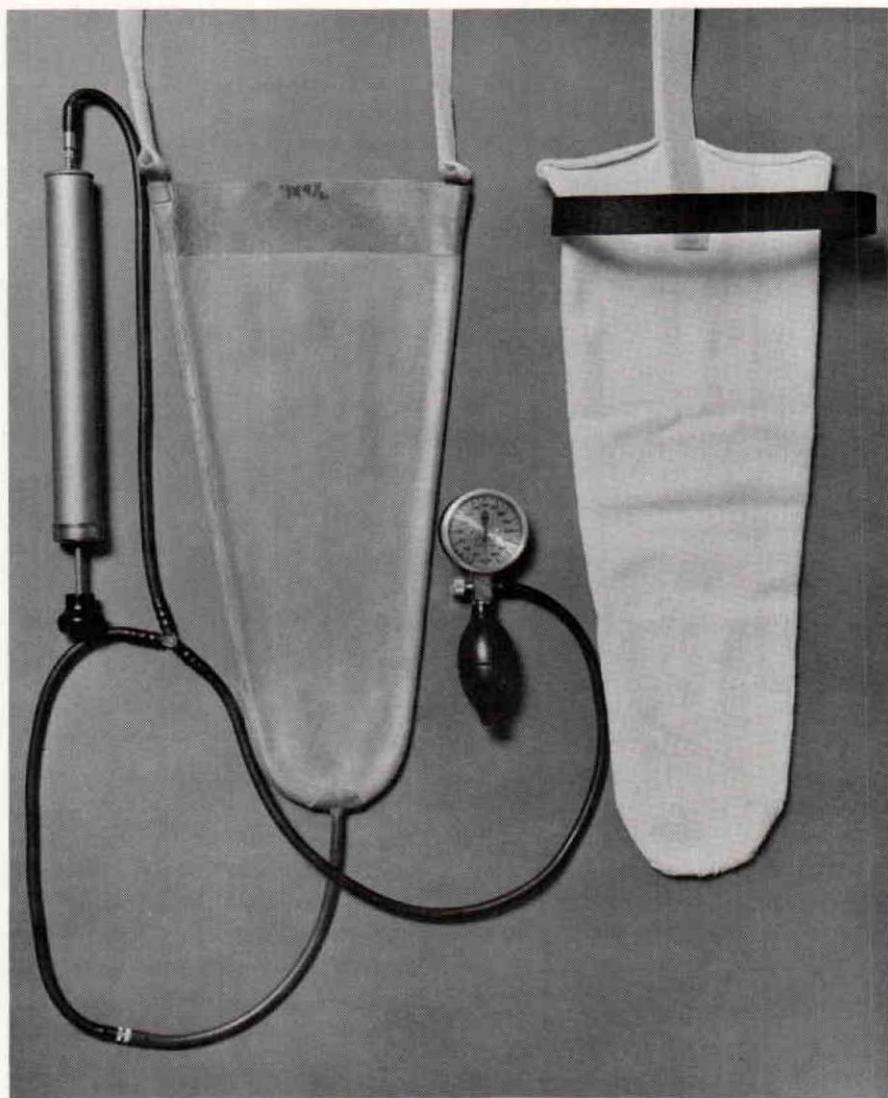


FIGURE 2—Pneumatic Pressure Forming Apparatus. On the right, the rubber inner sleeve over which the synthetic rubber tube is placed. On the left, the pressure sleeve with pump and gauge.

must be noted. Other usual prosthetic data such as the measurements required for the fabrication of the prosthesis are also essential.

With the patient seated, a lightweight cast sock is applied

snugly (Fig. 3). To maintain tension, the top of the sock is clamped to elastic straps equipped with Velcro loops for attachment to a mating section of Velcro hooks fixed to the back of the patient's

chair. The clamps are attached medially and laterally at the top of the sock.

The stump end is capped with a $\frac{1}{2}$ -inch thick soft-felt pad to form an extension (Fig. 4). The edges of the pad are skived; it is also split radially for easy contouring over the stump end. A series of pads ranging in diameter from 3 to $4\frac{1}{2}$ inches in $\frac{1}{2}$ -inch increments will accommodate the various stump-end sizes. Regardless of the size, an uncut center of at least one and one-half inches diameter is left.

The pad should not be perfectly circular. A slight anterior projection should extend beyond the circular contour to cover the anterior distal tibia. The anterior

border of the cap is then positioned to provide a distal continuation of the tibial crest line and form a relief for the end of the tibia.

A strip of felt cut to form a tibial crest relief is positioned from the superior border of the tibial tubercle extending distally *over the capped end of the stump* (Fig. 5). The portion of the tibial relief pad over the tubercle is made approximately $1\frac{1}{4}$ inches wide and tapered down to a $\frac{5}{8}$ -inch width for the entire length of the tibial crest relief. All edges are carefully skived. The felt pads are attached to the cast sock with medical adhesive. A second lightweight cast sock is pulled snugly over the tibial relief and extension



FIGURE 3—Application of Lightweight Cast Sock.



FIGURE 4—Application of the distal pad. Medical adhesive spray is used to form the bond of pad to cast sock.



FIGURE 5—Placement of the Relief for the Tibial Tubercle and Tibial Crest.

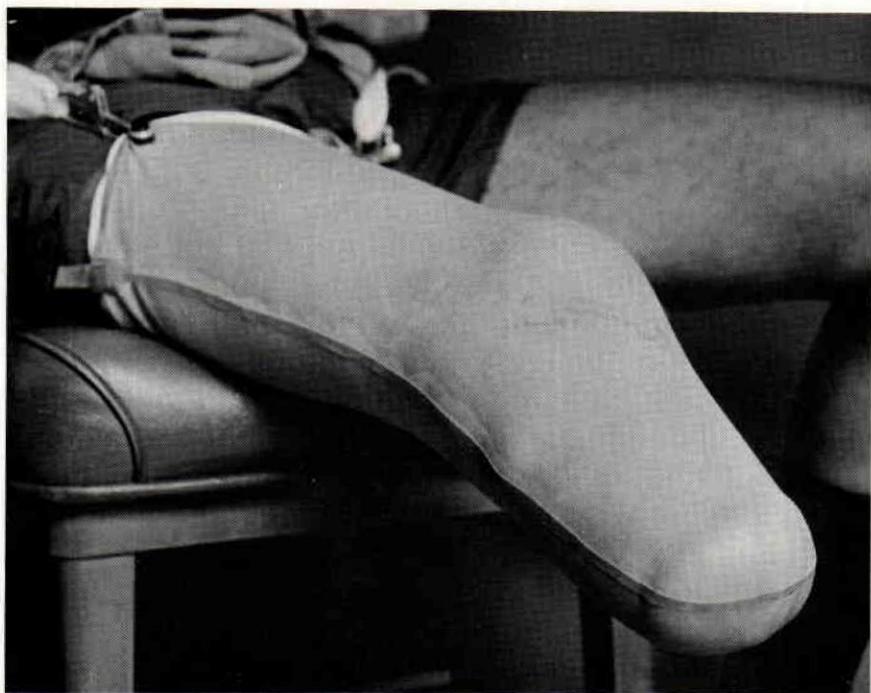


FIGURE 6—Stump with Rubber Sleeve Applied.

and fastened in the same manner as the first sock.

A rubber sleeve is then pulled over the stump (Fig. 6). The top edges of the rubber sleeve are attached to the waist belt to hold the rubber and stockinette under a constant tension. The end of the rubber sleeve must be pulled up into firm contact with the stump end. At this point, the stump is covered by two lightweight cast socks and the rubber sleeve, a total thickness equivalent to that of the five-ply wool stump sock the patient is expected to wear with the socket.

The anterior-to-posterior knee measurement is recorded at the level of the patellar tendon using

the VAPC knee calipers (Fig. 7). The medial-to-lateral dimensions of the epicondyles of the femur are measured in the same manner. These dimensions are useful in determining the accuracy of the socket. The maximum depth of the patellar ledge is determined by the measurement made at this time.

SOCKET FORMING

A suitable section of $\frac{1}{4}$ -inch wall synthetic rubber tubing is selected. Its length should be approximately $1\frac{1}{2}$ times the distance measured *from the top of the knee to the end of the extension cap* (Fig. 8). The diameter of the tube selected should be

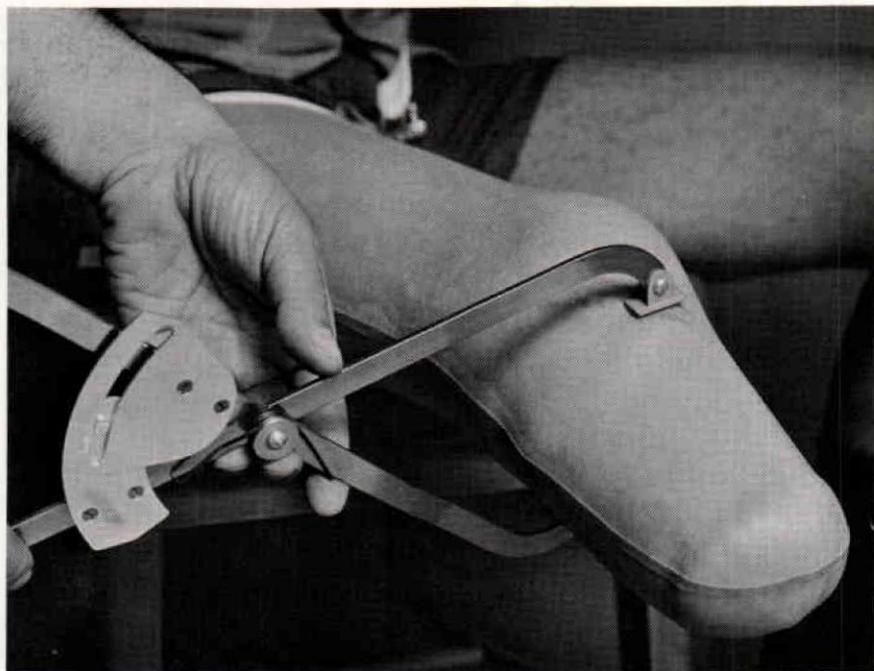


FIGURE 7—Measuring Stump Dimensions with the VAPC Calipers.

one-third of the mid-stump circumference.

The tube end is capped prior to direct forming (Fig. 9). The end of the tube is made plastic with a heat gun and shaped into a round cylinder. When cooled, the end of the tube is sanded even on a disc sander. The sanded surface of the tube end is then cleaned with trichloroethylene to promote bonding. Also the surface of a flat piece of $\frac{1}{4}$ inch synthetic rubber is cleaned so that it may be bonded to the tube end. The flat section is heated in an oven or with a heat gun to approximately 180 degF. The tube end and the flat section are placed together which produces a bond. A $\frac{1}{8}$ -inch hole is drilled in the center of the tube

cap to permit air escape during direct forming. The cap is trimmed to match the outer contours of the tube. The inside surfaces of the tube are carefully cleaned to remove all plastic dust created by cutting and drilling. *When heated, the dust will cohere to the inner walls causing undesirable irregularities in the surface.*

The capped tube thoroughly free of dust is softened by immersing it completely in water heated to a temperature of 180 degF. or just under the boiling point for 4 to 6 minutes. *The inner walls of the heated tube must be prevented from touching since they will cohere instantly.* This may be prevented by standing the tube on the end in the water container.

After heating, the tube is removed from the container. The exterior surface of the rubber sleeve on the stump and the interior surface of the thermoplastic sleeve are lubricated with I.M.S. silicone spray.

Part of the tube is preshaped into a cone prior to placing it over the stump. With the hands together (palms out), the upper half of the tube is stretched into a cone to facilitate slipping it over the knee (Fig. 10). With a light grip on the tube sides (with the palms of both hands), the tube is pushed onto the stump and carried up over the knee (Fig. 11).

The upper socket borders are trimmed with a pair of bandage shears leaving the posterior bor-

ders approximately $\frac{1}{2}$ inch higher than required, for later rolling out of the material to form a relief for the ham strings. The anterior socket border is cut above the superior pole of the patella leaving the medial and lateral walls 1 in. higher (Fig. 12). It is desirable to wait a few minutes, permitting the temperature of the tube to drop slightly, before pulling the pressure sleeve over the plastic tube.

The pressure sleeve has two straps attached to its proximal border. The straps are made from the "loop" part of the Velcro, and when passed around behind the patient's chair, are mated with a "hook" strap of Velcro, affixed to the back of the chair. To main-

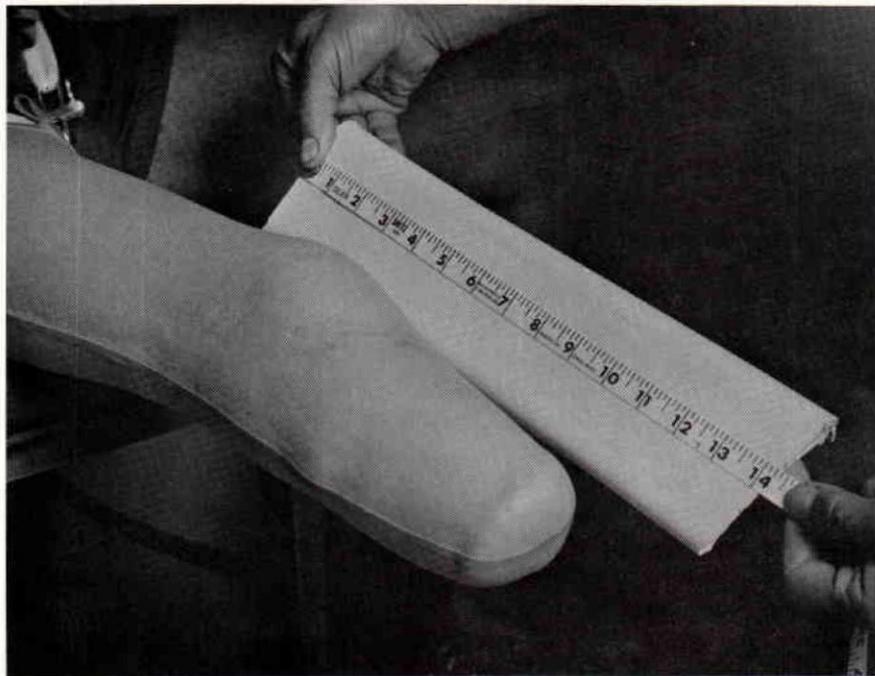


FIGURE 8—Selecting the Proper Length of Tubing.

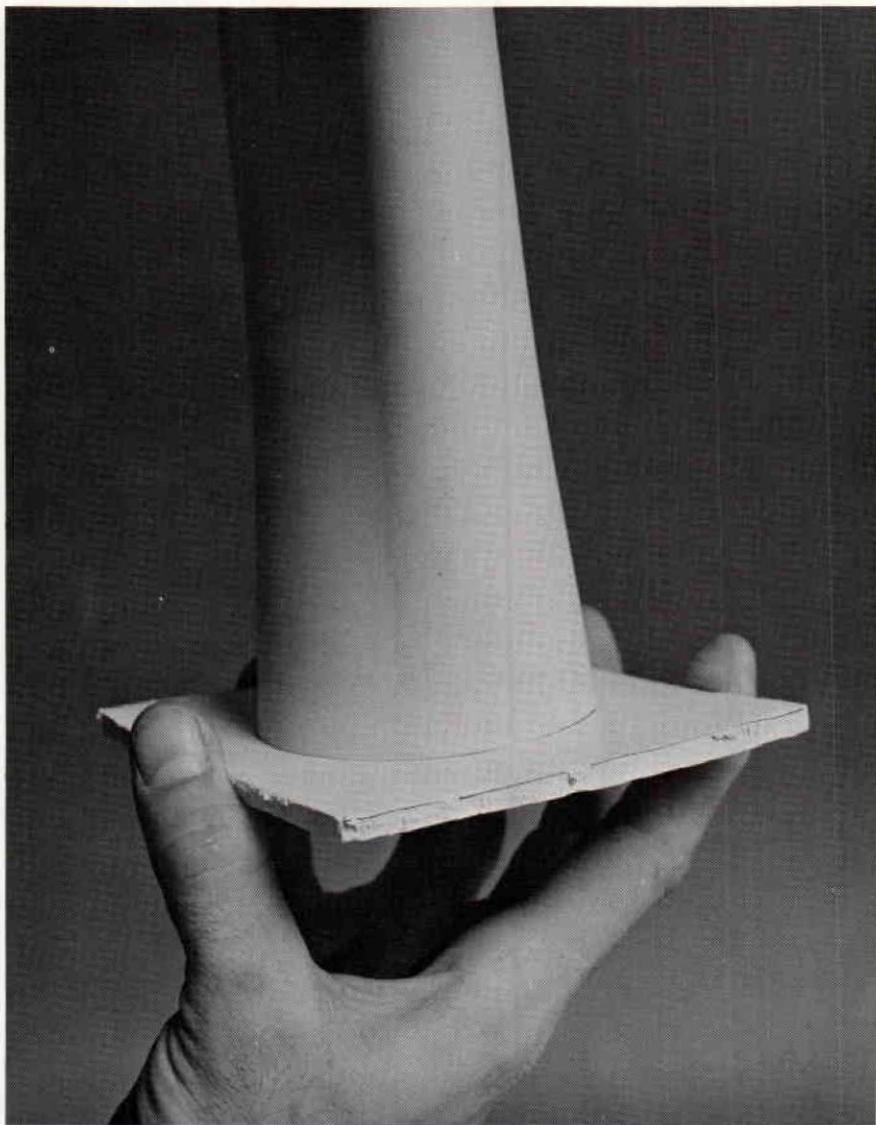


FIGURE 9—Tube end capped prior to direct forming.

tain tension on the strap, the patient must be seated as far back as possible on the chair.

The conical pressure sleeve is pulled up over the stump and knee to touch the end of the capped tube. The pressure sleeve straps are placed around the chair

back and fixed to the mating Velcro. The pressure sleeve cover (a 5-ply wool stump sock) is pulled snugly over the pressure sleeve and fixed by straps to the Velcro on the back of the chair. A loop of Velcro material is wrapped around the top of the stump sock

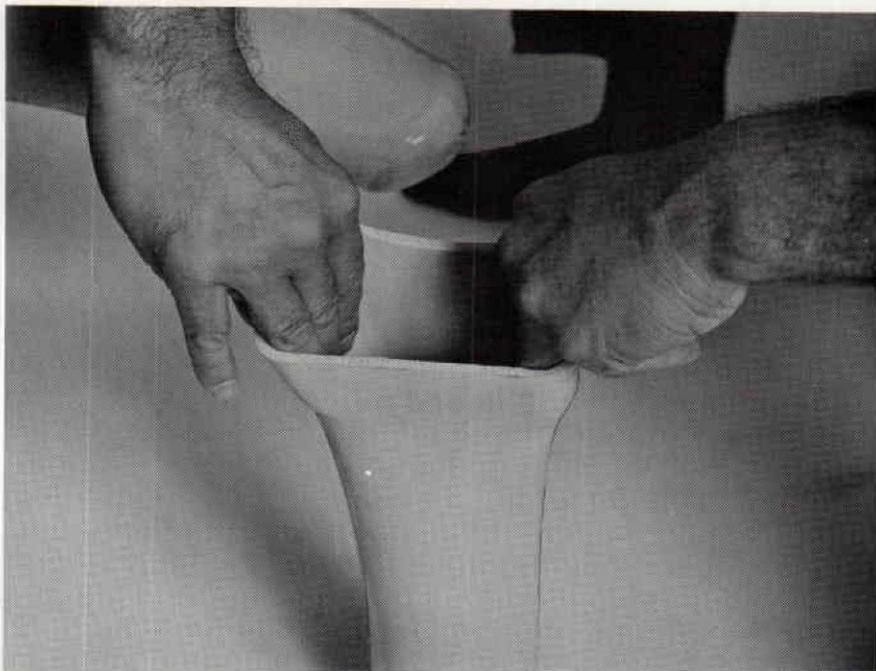


FIGURE 10—Stretching One End of the Tube into a Conical Shape.

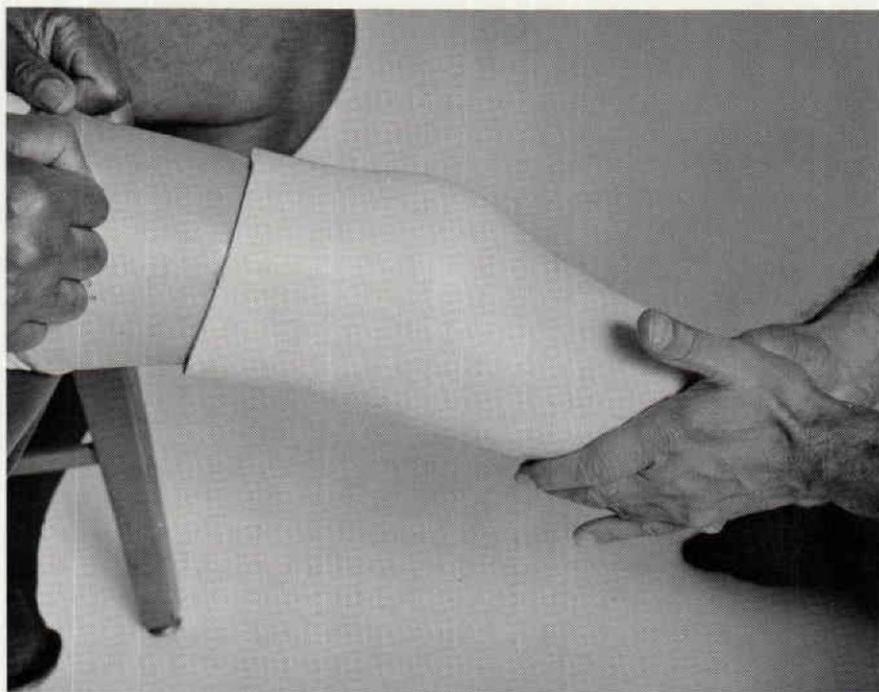


FIGURE 11—Application of the Tube to the Lubricated Sleeve on the Stump.

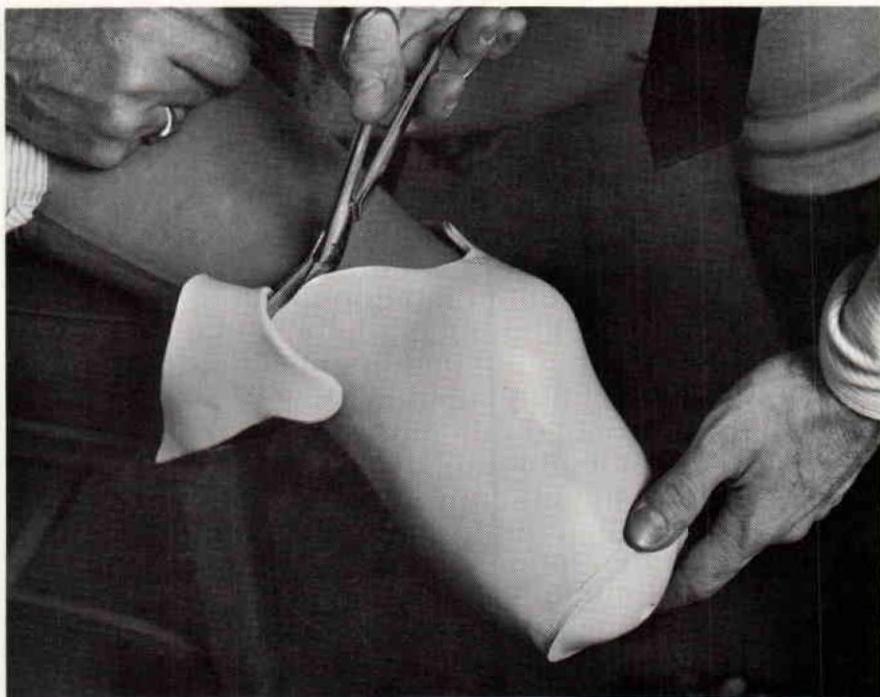


FIGURE 12—Trimming the Upper Socket Borders Before Pressure Molding.

to hold the sock snugly against the thigh. The pressure sleeve is then inflated (Fig. 13). Pressure of $1\frac{1}{2}$ psi or 80 mm Hg is maintained for approximately 15 minutes before removal of the sleeve and the socket.

An adjustable pylon is prepared with a wood socket attachment block $1\frac{1}{2}$ inches thick and 3 in. in diameter. The wood block is tapered to form a slightly smaller diameter around the bottom. Then the wood block is fastened permanently to the pylon with bolts and cement.

Before the socket is mounted upon an adjustable pylon with a foot for dynamic alignment and walking trails (Fig. 14), a 6-inch long section of 3 in. diameter

plastic tubing is heated and bonded around the lower socket following the same procedure used in bonding the tube end. Before bonding, the end of the thermoplastic tube is stretched to provide a generous clearance about the lower socket. Inadvertent touching of the tube to the socket will result in a weld preventing the proper placement of the tube on the socket. This placement is critical to achieve the planned initial socket flexion between socket and pylon.

The plastic tube extending distally from the socket is fitted over the wood pylon attachment block. The tube is taped tightly to the wood block and permitted to cool. Any excess tubing extend-

ing below the wood can be trimmed while the plastic is still soft (Fig. 15). After it hardens, the tube is fastened permanently to the wood block with four wood screws set through the plastic into the wood at 90 deg. angles to one another.

SOCKET MODIFICATIONS

A heat gun is used to modify the socket. To focus the output of the heat gun, a metal cone is made to fit over the end of the gun (Fig. 16).

The hand should be placed inside the socket against the surface to be modified. Heat is directed to the *immediate area from close range* until the heat is

sensed by the fingers through the socket wall. *Large areas should not be heated nor should heat be directed against the socket for a prolonged period of time.*

Excessive temperature will cause the plastic to boil and discolor. When molding for a pressure point, one finger should press from inside the socket, and the surrounding areas should be supported on the outside of the socket with the fingers of the other hand. After the molded area has cooled sufficiently to retain its shape, the socket should be chilled with cold water or refrigerated for a short period of time to re-set the plastic. *Caution must be exercised to avoid heating the entire*

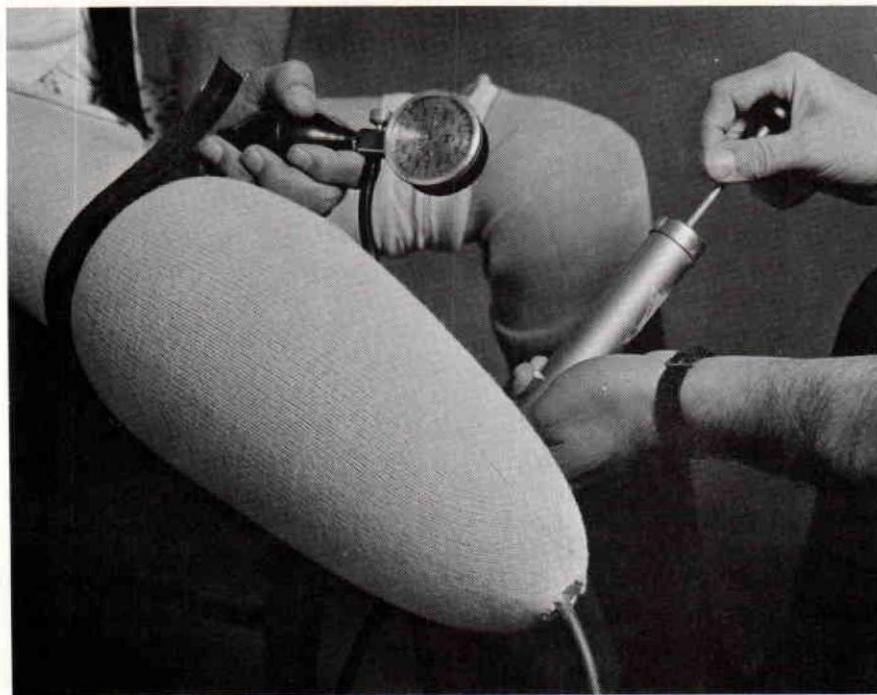


FIGURE 13—Application of Pressure to Pressure Sleeve Which Has Been Covered with a 5-Ply Wool Stump Sock.



FIGURE 14—Socket and Pylon with Connecting Plastic Tube.

socket by holding the heat gun near the intended spot to be molded. The heat should be concentrated on the one spot until the pressure applied with the fingers on the hand inside the socket causes the material to yield.

A similar procedure should be followed if a more pronounced patellar-tendon ledge is required. The previously obtained A-P measurement will determine the depth of the patellar ledge. For patients who have previously worn prostheses, the A-P measurements obtained by caliper are used to determine the depth of the ledge. For patients who have had recent amputations, the patellar-tendon ledge is not molded to the maximum depth in one adjustment.

Instead 3 or more adjustments at intervals of one month should be made until the recorded A-P dimension is reached.

The posterior socket border is heated and rolled out to form a smooth radius for comfortable knee flexion (Fig. 17). The posterior socket level is maintained approximately $\frac{1}{2}$ inch above the patellar tendon level.

Several kinds of PTB suspension can be provided with this socket. The socket can be trimmed at the regular PTB level and a separate cuff used above the knee. Or a suprapatella and strap suspension combined with supracondylar suspension can be provided as follows: the patient's stump is covered with a cast sock and a snug fitting

rubber sleeve. The medial and lateral socket walls above the level of the upper border of the patella are softened by holding the socket bottom up in hot water to this depth. The socket is placed on the patient; then the patient is seated in a chair with his knee flexed at approximately 45 deg. and his stump pushed firmly into the socket. The plastic

is molded firmly against the thigh over the condyles (Fig. 18).

If during the molding process a line of demarcation develops between the soft and hard areas, that edge should be warmed with a heat gun.

To accommodate the suprapatellar strap, two rectangular slots with their long axes parallel to the socket's long axis are placed in the socket on each side of the quadriceps tendon and at right angles to the intended path of the strap. To increase the effectiveness of the suprapatellar strap, the elastic strap is positioned so that its inferior border passes across the upper edge of the patella (Fig. 19). The slots should be angled slightly forward at the bottom to permit the strap to rest flatly against the anterior of the thigh.

After the patient has been fitted and the prosthesis aligned, the bottom of the socket chamber should be foamed to obtain a total-contact fitting. Three $\frac{1}{8}$ in. holes are drilled through the socket wall where the extension was blended into the stump contour. A P. V. A. cap is formed over the stump sock-covered stump end. A foam mixture is prepared and poured into the socket (Fig. 20). The patient's stump is inserted into the socket and then the patient stands in the socket until the foam has set. The foam mixture may vary, depending upon the type of stump and condition of the distal tissues. Usually, a combination of foam and R.T.V. rubber is used. To avoid difficulty in

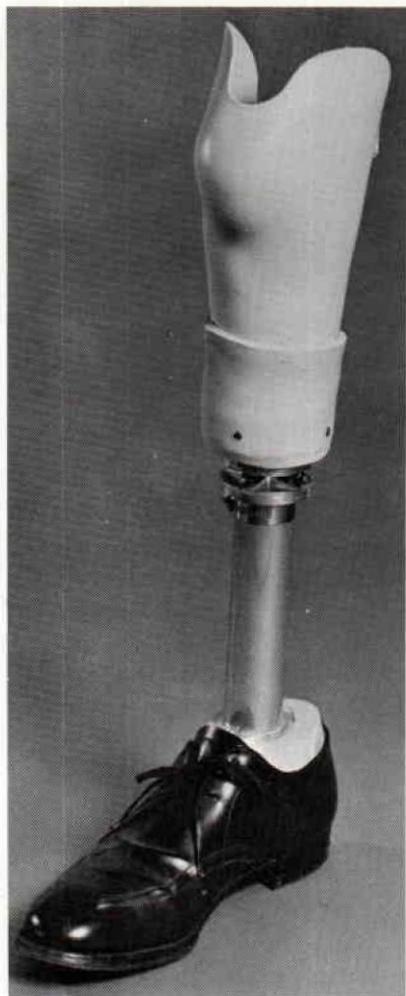


FIGURE 15—Socket Joined to Pylon by Bonded Plastic Tube.

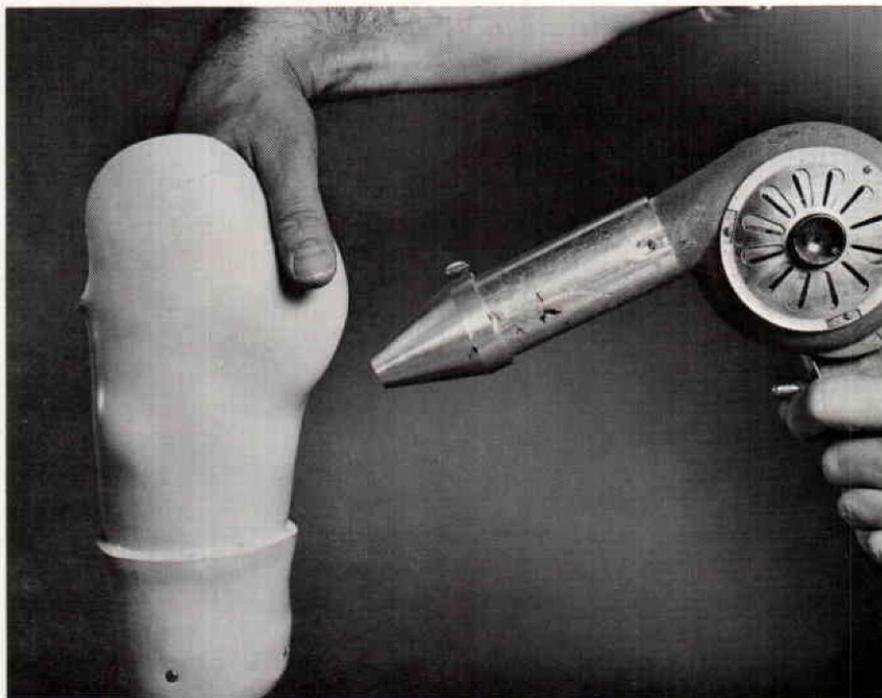


FIGURE 16—Heat Gun with Modified Cone for Control of Heating Area.

quickly inserting the P.V.A.-covered stump into the socket, the patient should wear a light weight sock and the P.V.A. should be powdered.

SHAPING AND FINISHING

A semi-rigid foam leg shape can be made from pre-fabricated sections of a B.F. Goodrich Co. foam product called Koroseal "Spongex."

Beginning at the level of the patella, a paper pattern is cut to fit around the socket at this level. The pattern is traced upon the first foam section (Fig. 21). The foam is carefully sanded to form a hollow for the socket. It is necessary to obtain a tight "gap-free"

fitting of the foam to the socket. Best results are obtained from a *slight stretch fit*. For this, the foam is heated in an oven at 180 deg. and then placed over the socket.

To cover the remaining part of the pylon, a foam block is cut long enough to match the distance between the bottom of the foam surrounding the socket and the top of the foot *plus* $\frac{1}{4}$ in. A hole is made through the length of the foam large enough to receive the pylon tube. Since the foam is semi-rigid, the cut out areas for the alignment coupling and ankle plug of the pylon are made slightly undersize to form a *snug fit about the pylon* (Fig. 22).

A $\frac{1}{2}$ -inch hole is bored trans-

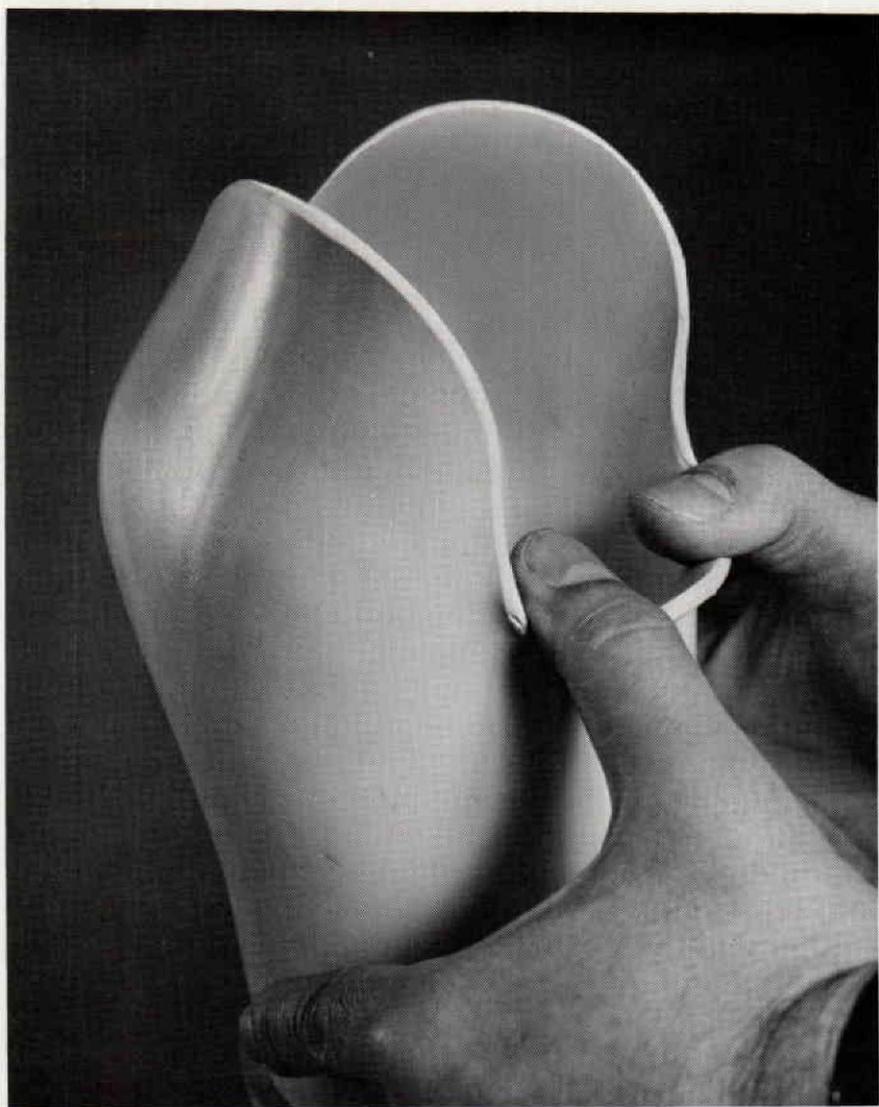


FIGURE 17—Rolling out the softened posterior socket wall.

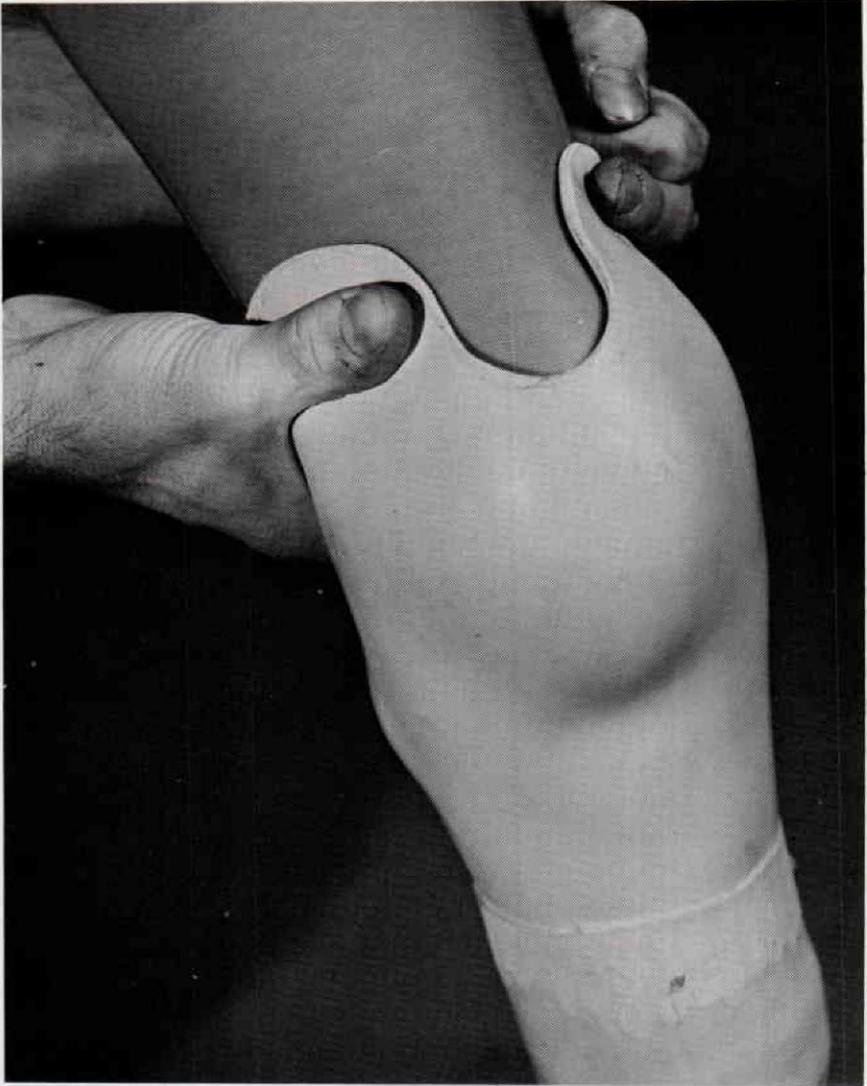


FIGURE 18—Molding the Supracondylar Contours of the Upper Socket.

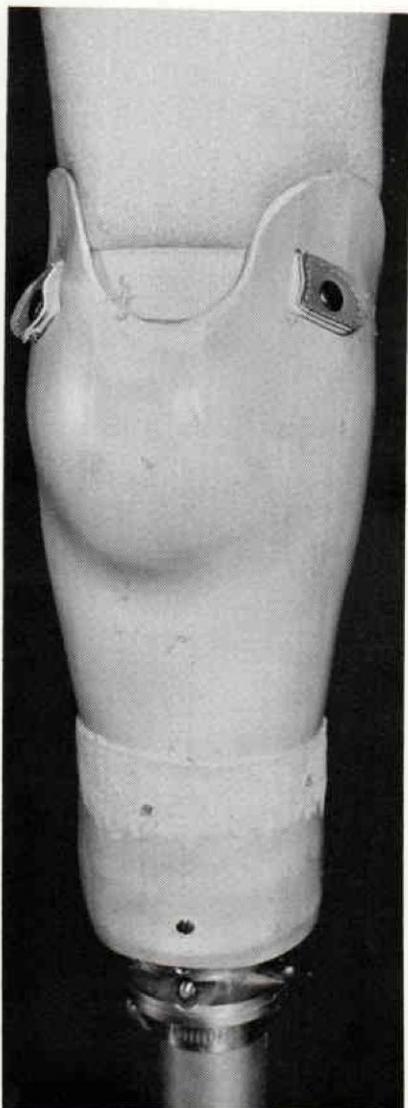


FIGURE 19—The Suprapatellar Strap Rests Firmly Against the Quadriceps Tendon.



FIGURE 20—Pouring Foam Mixture to Form Total Contact Socket Bottom.

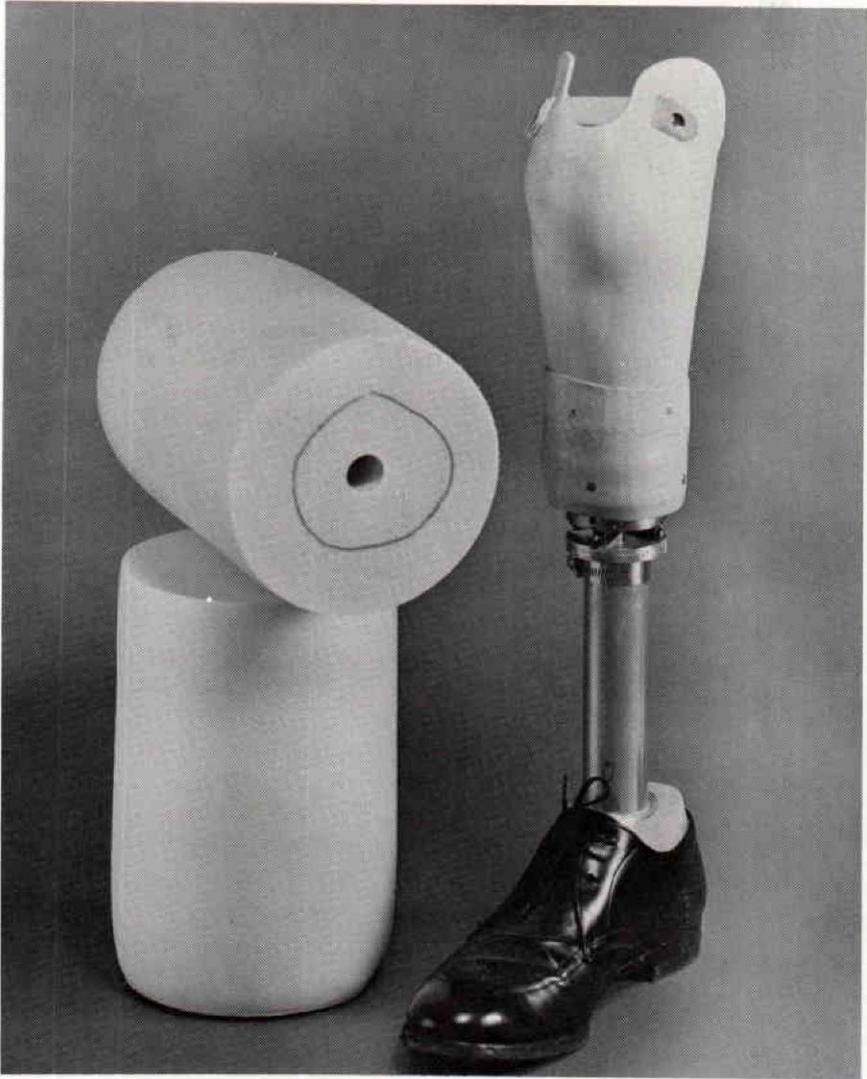


FIGURE 21—Foam Blocks Prepared for Fitting Over the Pylon and Socket.



FIGURE 22—Cutaway of Shaped Foam Cover Showing Close Fitting to Pylon and Socket.



FIGURE 23—Finished Prosthesis with Stocking over Foam.

versely through the foam block to permit entry of a screw driver to fasten the tube clamp. The bottom foam block is not glued to the top foam block. Compression of the extralength foam block between the socket base and the foot will prevent any movement

of the foam and permit easy removal for alignment adjustments.

Shaping is done by a band saw or knife and final sanding with a drum or cone sander. A flexible polyurethane coating over the foam or a stocking cover is recommended for cosmesis (Fig. 23).