A Thermoplastic Endoskeletal Prosthesis

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INTRODUCTION

With the advent of new materials and improved surgical techniques, new types of prosthetic devices are being developed. Despite these recent improvements, however, the basic needs with regard to prosthetic design have stayed the same. Comfort, function, and, to a lesser degree, adjustability, durability, cosmesis, weight, and expense have all become factors in prosthetic design and their prescription. To continually strive for such basic improvements, and to give both the patient and prosthetist an alternative from which to choose, the following system has been developed.

This system incorporates components that have been used before in other prostheses but never before in this combination to provide a prosthesis that can be modified for temporary, definitive, or extra-ambulatory use.

Briefly, the system consists of an endoskeletal prosthesis made of polyvinyl chloride (PVC) tubing, a thermoplastic total contact socket, and a prosthetic foot.

The advantages of such a system are as follows:

Adjustability: changes in alignment, foot placement, and socket contour can be accomplished by heating the PVC tubing or socket in the desired location to modify it as needed.

Weight: The socket and pylon together weigh on the average of one and one-half pounds and the average finished prosthesis weighs between two and three pounds, depending on the foot used.

Expense: The cost of materials required is less than that of a conventional endoskeletal prosthesis and fabrication time is reduced by 50 percent.

Adaptability: The system can be modified to meet the patient's needs whether they be for temporary or definitive use, and because of the waterproof components, can be adapted for water activities.

DESCRIPTION OF COMPONENTS

The success or failure of any system depends in part on its components. The components in this system have been used before in other prostheses but never in this combination.

The socket is made of a thermoplastic material called colyene.[1] Colyene is a copolymer made of 85 percent polypropylene and 15 percent polyethylene. Colyene has the same working characteristics as polypropylene, but is more durable be-

cause of added polyethylene. This allows the copolymer to flex, thereby increasing its impact resistance.

The reasons behind the incorporation of thermoplastic materials in socket design are: (1) adjustability—the socket can be modified with a heat gun or eliminate the need to grind or add filler to the inside of the socket in order to make adjustments; (2) ease of fabrication—since conventional layup procedures are not required, this reduces the fabrication time and materials cost; and (3) flexibility—the socket is flexible proximally, which makes it more comfortable for the patient, yet remains rigid enough to distribute the pressure in the desired weightbearing areas.

The endoskeletal pylon is made of schedule 40, 1¼" ID tubing commercially available at most plumbing supply stores. The PVC tubing can be heated to change the alignment and foot placement. The tubing is held to the socket and foot using PVC plugs[2] in combination with hose clamps to secure it in place. THe PVC is then reinforced with fiberglass to prevent breakage.

Conventional foam and lamination procedures can be followed or a cosmetic cover can be applied if desired. If a conventional system is desired, a ¾" wooden block is added distal to the foot plug and foamed in the conventional manner. If a cosmetic cover is desired, Ethafoam or an Otto Bock cover can be used.

FABRICATION

Conventional alignment procedures are followed using a vertical alignment fixture.[3] Once the angular relationship between the socket and foot is established, the socket is filled with plaster. When set, the socket is removed to obtain a positive mold. The cast is then smoothed and sealed with ambroid varnish or spray sealer to eliminate moisture.

Since all thermoplastics (i.e., polypropylene and polyethylene) shrink after foaming due to the stress put in the plastic during fabrication. A three ply prosthetic sock must first be applied over the cast before the plastic is pulled, otherwise the socket will be too small.

A distal end pad is fabricated by heating a 6" × 6" × 3/16" thick piece of pelite and two 6" × 6" × 1" thick pieces of Plastazote™ and formed to the distal end of the cast. The pieces are glued together using Barge® cement and applied temporarily to the three-ply sock using rubber cement. The pad is tapered proximally so there is a smooth transition from the cast to the distal end pad (Figure 1). If this is not done, a ridge will form on the inside of the socket along the proximal border of the distal end pad causing irritation.

To find the angle at which the distal end pad is to be trimmed, the cast is placed back in the vertical alignment fixture. A piece of PVC tubing is cut according to

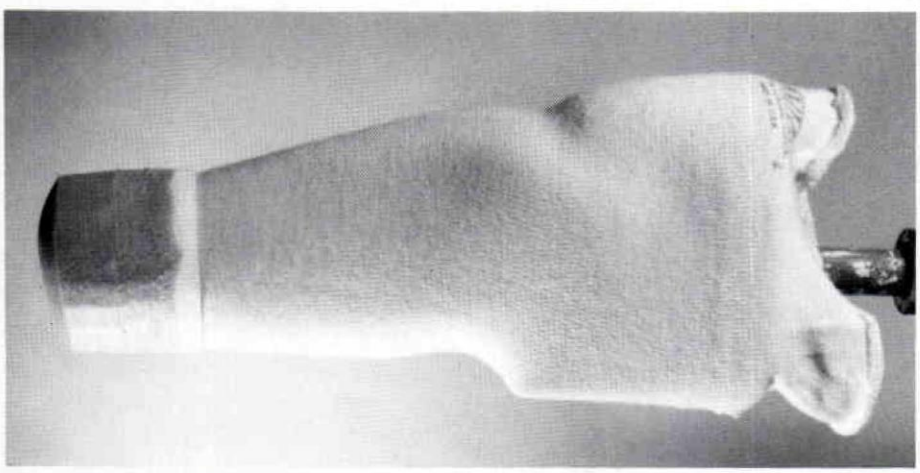

Fig. 1. Distal end pad trimmed flush with cast.

Fig. 2. Determining angle of distal end pad.

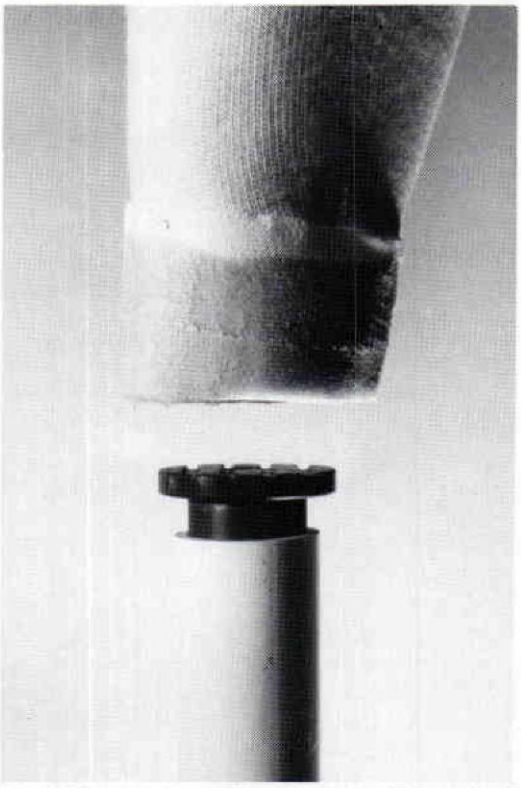

Fig. 3. Distal end pad trimmed flush with proximal PVC plug.

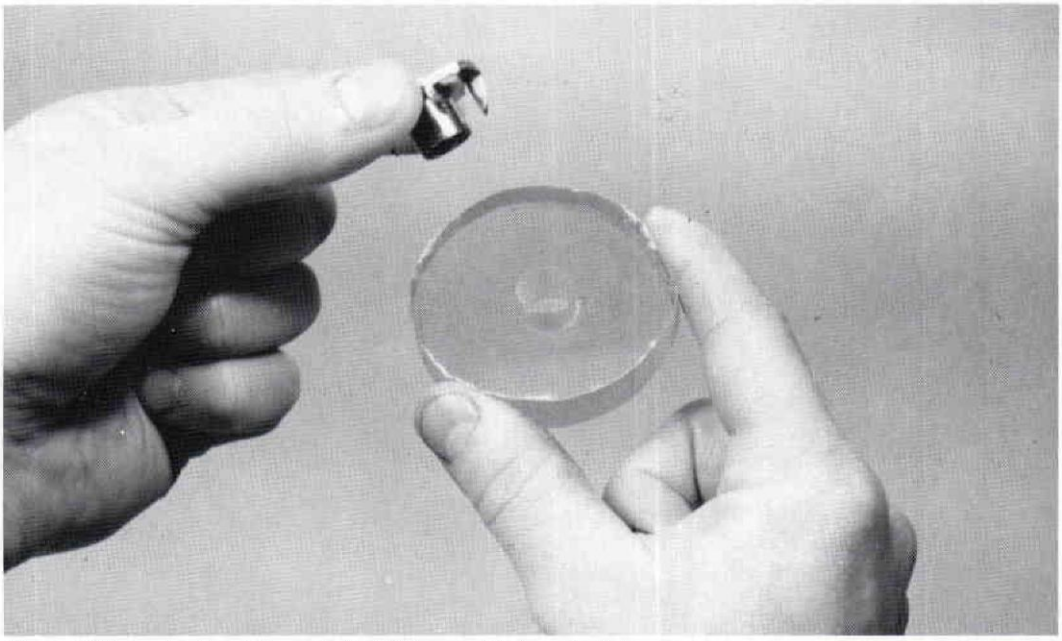

Fig. 4. 3/8" T nut is placed through the 1/2" Lexan attachment plate.

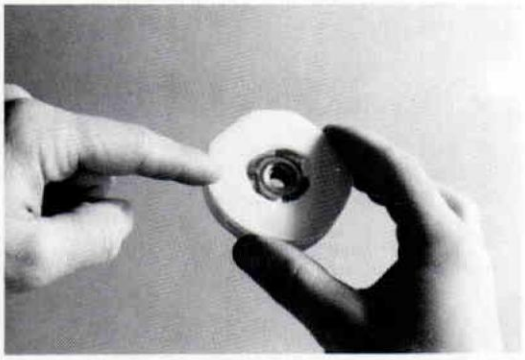

Fig. 5. 1/16" Pelite is added to the attachment plate to make it flush proximally so it can be glued to the distal end pad.

length, and with two PVC plugs placed on either end of the tube, is secured to the foot plate (Figure 2). The distal end pad is then trimmed so it can lay flush against the proximal PVC plug (Figure 3).

A semi-circular attachment plate of 1/2" Lexan is fabricated. Cut just larger than the proximal border of the PVC plug, it is drilled in the middle using a 15/32" drill. Do not make the attachment plate perfectly round because it may rotate within the socket and cause loosening. A 3/8" T nut is placed through the hole after the prongs have been removed, so it can lay flush against the Lexan plate (Figure 4). After sanding the T nut and Lexan to roughen the surfaces, the two pieces are epoxied together. A good bond is critical, otherwise rotation and loosening of the pylon occurs.

To make the attachment plate flush proximally so it can be glued to the distal end pad, a 1/16" piece of Pelite is added to the same side of the Lexan as the T-bolt head. The pad is circular in configuration and extends past the top of the T nut (Figure 5). The attachment plate is then glued to the distal end pad and static alignment checked before the socket is fabricated (Figure 6).

Conventional drape molding procedures are followed because it assures maximum and uniform material thickness throughout the socket. Using a vacuum adapter[4] (Figure 7) to hold the cast, a 1/2" wide piece of 3/16" thick Plastazote™ is wrapped proximally around the cast and taped in place to facilitate easy socket removal. A nylon hose is pulled over the entire cast and taped to the mandrel, then a one inch wide piece of dacron felt is wrapped around the mandrel next to the cast and secured in the adapter. The dacron felt keeps the plastic from pulling inside the tube which causes the plastic to break and eliminates suction (Figure 8).

A piece of colyene of an appropriate size is heated in an oven at 450 degrees for eight to ten minutes or until clear. It is then removed from the oven and pulled over the cast and sealed along the posterior section of the socket and to the vacuum adapter tube after which 20 to 25 inches of mercury vacuum is applied (Figure 9).

Once the plastic has cooled sufficiently, it can be removed from the cast by cutting along the proximal Plastazote™ trim strip. Only cut into the Plastazote™; any deeper and the sock cannot be reused. The cast is broken out in the conventional manner. The socket is trimmed and then finished as desired. Do not trim the posterior seam until it has been removed from the cast

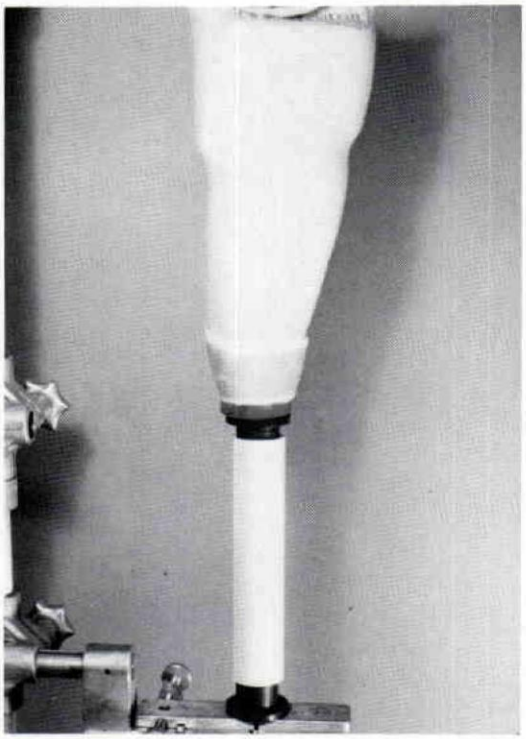

Fig. 6. The alignment is checked before the socket is fabricated.

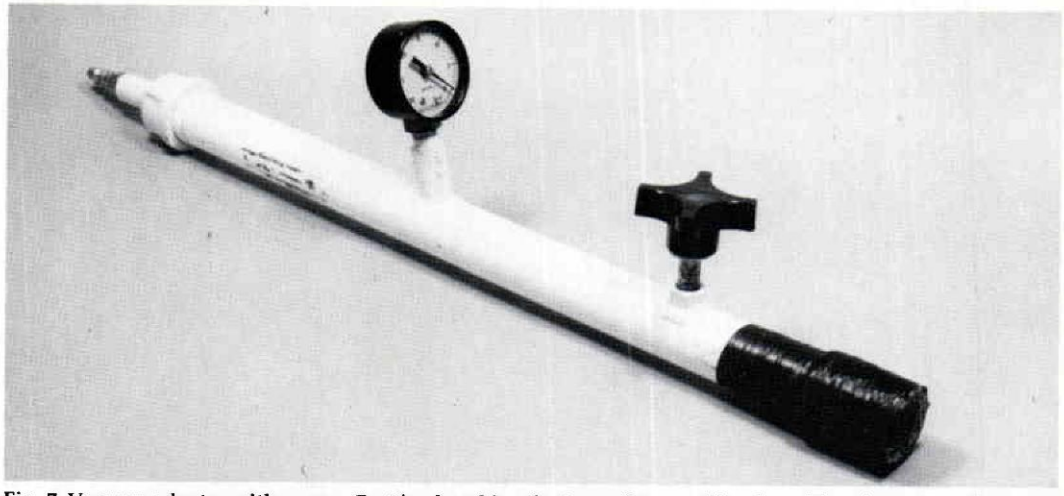

Fig. 7. Vacuum adapter with gauge. Cast is placed in adapter and secured in place. The plastic is sealed to the electrical tape while the vacuum is drawn from the other end.

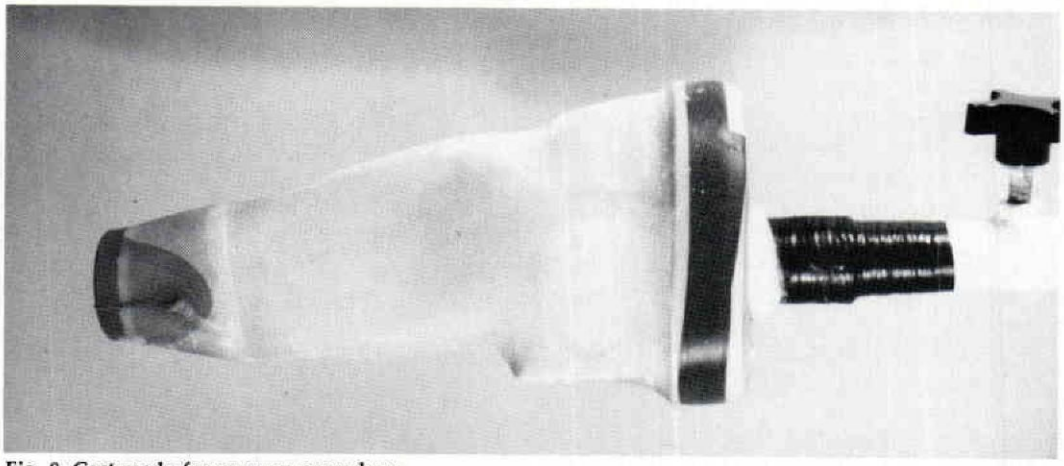

Fig. 8. Cast ready for vacuum procedure.

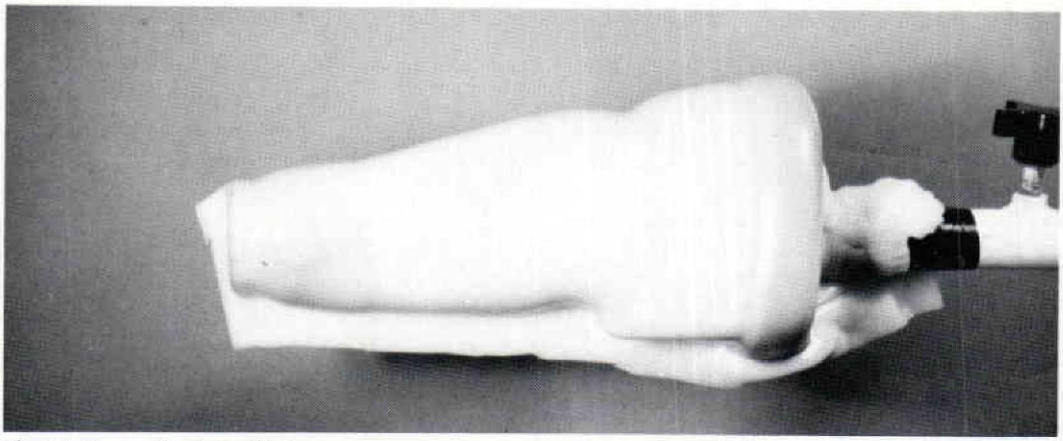

Fig. 9. Thermoplastic molded over cast.

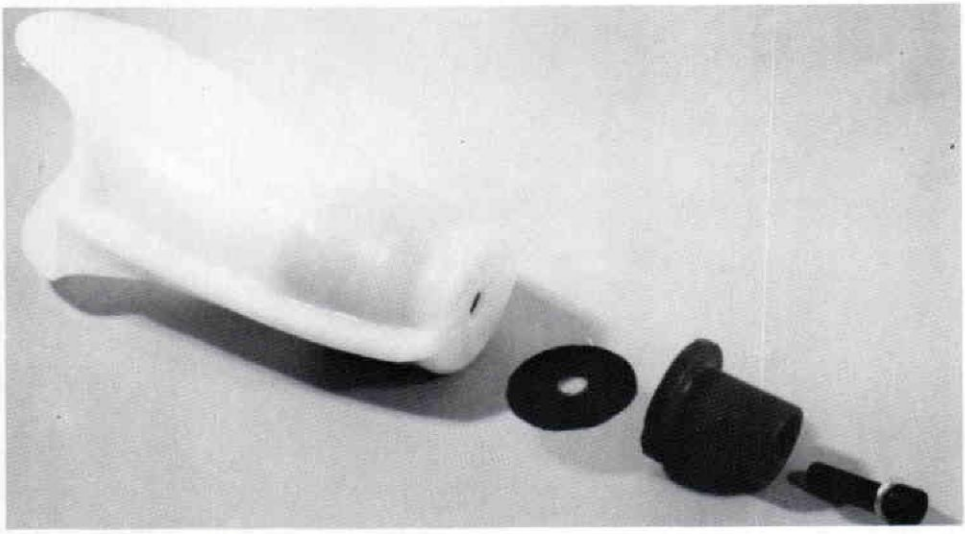

Fig. 10. Socket assembly.

because it has a tendency to split. When trimming the posterior seam, leave 3/8" to 5/8" of the seam exposed. This ensures good adhesion if welding is not possible and makes riveting feasible if necessary. Distally, grind the plastic flat so that the PVC plug can lay flush against the socket and drill a 3/8" hole for the socket bolt. Do not drill past the plastic into the metal threads on the T nut.

Assembly is straightforward. The socket and foot components are assembled as shown in Figures 10 and 11. During the trial fitting, abrasive screen washers are used to eliminate rotation. But because of the rotational forces, they will tear with extended use. Therefore, once the initial fitting is complete, remove the screen washers and epoxy the PVC plugs in place.

A 3/8" × 1 1/2" hex bolt is used on the socket and a 3/8" × 3" hex bolt in combination with a 3/8" T nut is used on the foot. When securing these hex bolts, care must be taken not to overtighten them. Optimal wrench torque is 15 ft/lbs (Figure 12).

The PVC tubing fits snugly over the PVC plugs and is held in place with 1 1/4" stainless steel hose clamps (Figure 13).

DYNAMIC ALIGNMENT

Any alignment changes can be accomplished by heating the PVC tubing and bending it to the desired location to adjust either foot position and/or alignment. Difficult changes in alignment can often be solved by putting the prosthesis back in the vertical alignment fixture to find some point of reference. When heating the PVC tubing, heat a large section to contour the adjustment. Do not make sharp bends in the tubing because this promotes breakage.

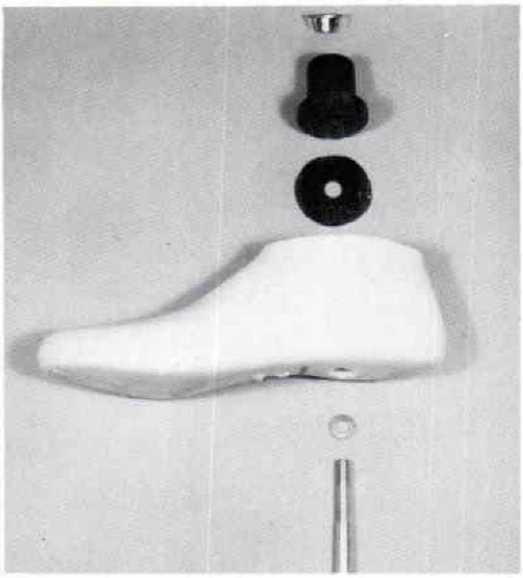

Fig. 11. Foot assembly.

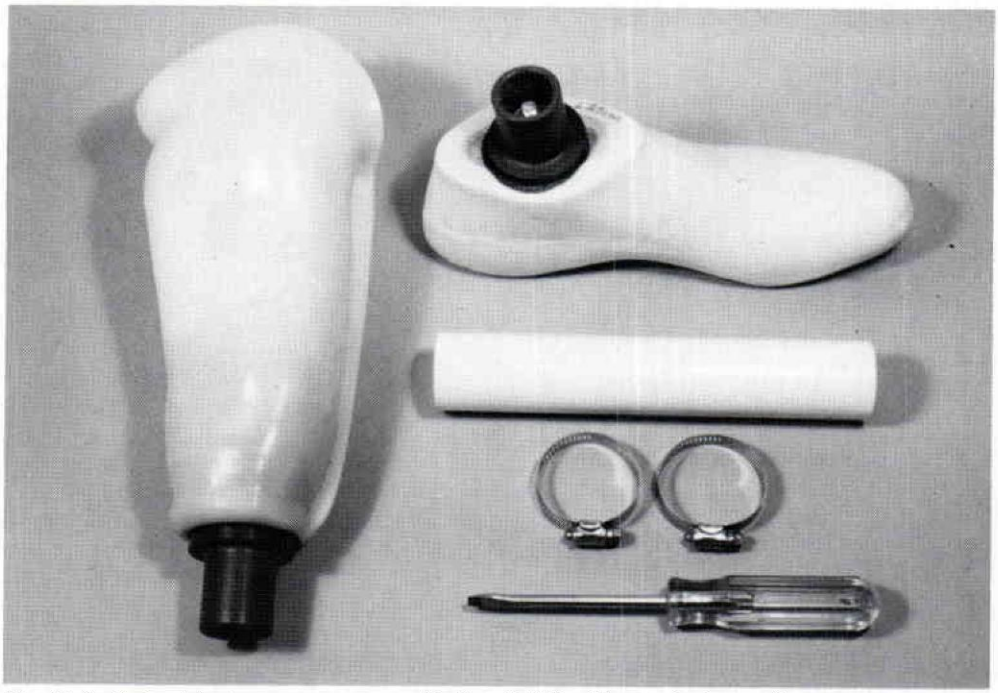

Fig. 12. Socket and foot components assembled and PVC tubing ready for application.

Fig. 13. Prosthesis complete and ready for dynamic alignment.

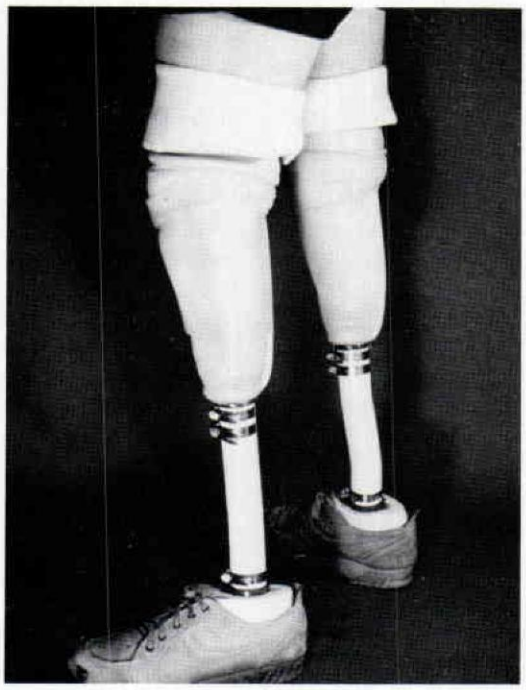

Fig. 14. Bilateral below knee prostheses, incorporating SAFE feet and rubber latex suspension sleeves for water activities.

FINISHING

Once the prosthesis has been dynamically aligned, the PVC tubing must be reinforced with fiberglass. After making proximal and distal reference lines on the PVC tubing and plugs, the tubing can be removed. Roughen the tubing and reinforce it with four to six layers of fiberglass cloth. The PVC plugs are then glued back in place using PVC glue. Before gluing PVC plugs, make sure all alignment changes have been made because once the PVC plugs are glued and PVC reinforced, any further adjustments cannot be made. A cosmetic cover or conventional lamination may then be added if desired (Figure 14).

DISCUSSION

Designed as a temporary/preparatory prosthesis, the system works well for the newer amputee because it accommodates changes in the socket due to residual limb atrophy and changes in alignment from improved gait patterns. While this system was designed to be lightweight, adjustable and inexpensive, other factors, including durability, should also be considered in its prescription. Because it was designed to be temporary, careful attention needs to be directed towards reinforcing the system to prevent breakage and/or limiting the prosthesis to the less aggressive amputee. When wearing this prosthesis, the patient must be able to come in for regular checkups (every 4–6 weeks). If he is unable to do this, or shows an unwillingness to follow the recommendations of the prosthetist or physician, this prosthesis should not be prescribed.

When using this system, its adaptability should also be considered. This system can be made waterproof, depending on the type of foot used, so that the patient can use the prosthesis in the shower or for water related sports activities. Various types of other mechanisms can also be attached to the PVC tubing and foot for prototype development or patient evaluation before a definitive prosthesis is made.

CONCLUSION

The level of prosthetic care can increase only as the result of incorporation of new ideas and technology. It is through this mix that the above temporary endoskeletal prosthesis was developed. Based on the needs of amputees, this system provides the patient with a lightweight, adjustable, inexpensive and adaptive prosthesis that can be used by patients to increase their level of rehabilitation.

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Evanston, Illinois 60202

[3]Hosmer Dorrance Company
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