AN ULTRALIGHT BELOW-KNEE PROSTHESIS

A. Bennett Wilson, Jr.

Charles Pritham, C.P.O.

Brian Reed, R.P.T.

Melvin Stills, C.O.

Synopsis

A method of fabrication of an ultralight below-knee prosthesis is presented. Experiences with eight subjects in the experimental study are included.

The report of virtually every workshop and conference since 1960 concerned with the problem of the "geriatric amputee" has included a statement to the effect that weight reduction of prostheses for lower-limb amputees is highly desirable (Committee on Prosthetics Research and Development, 1961, 1971, 1973). Yet, very little effort has been made through the years in making lightweight lower-limb prostheses available for general use.

The use of the crustacean type of prostheses with very thin walls is obviously the most promising method for achieving the lightest system possible.

Murphy (1954) has pointed out that careful attention in carving out the interior of wooden shanks of BK prostheses to form thin walls will result in very light prostheses of satisfactory strength, but to achieve the ultimate strength-weight ratio by this method requires an inordinate amount of labor.

Wollstein (1972), in attempting to avoid the high cost of importing

SACH feet into India, devised a method of fabricating a hollow BK prosthesis (figure 1) by laminating fabric and polyester resin over a plaster-of-Paris model and applying the sole and heel of a SACH foot to the distal end. The result was a very light prosthesis with all of the functions afforded by a SACH foot, but the fabrication time (which was not a problem in India) was considerably more than the time required in conventional practice in Europe and America.

Vacuum forming of sheet thermoplastics introduced into orthotics relatively recently seemed to offer a method of fabricating very light below-knee prostheses at a reasonable cost.

With financial support from the Veterans Administration, the Rehabilitation Engineering Center, Moss Rehabilitation Hospital-Temple University, has undertaken the development of a practical system for fitting, fabrication, and alignment of very light below-knee prostheses.

Initial efforts consisted of making the foot-shank section by molding separate anterior and posterior parts of sheet polypropylene and welding them together along overlapping seams, thus providing extra strength (figure 2). The primary purpose of this approach was to determine patient reaction to weight reduction, as well as the value of utilizing conventional vacuum forming equipment. In addition, patient reaction to a socket made of polypropylene was determined.

To provide a model for the ankle-foot section of the finished prosthesis, sheet polypropylene was molded over a replica of a SACH foot with the heel cushion removed.

The overlapping seams provided more than adequate strength, but the appearance was unacceptable.

As a result of comparing notes with the Prosthetics and Orthotics Group at Rancho Los Amigos, we experimented with a technique for forming the shank-foot section in one piece. In this method, a sheet of polypropylene, 18 in. (45.5 cm) x 24 in. (61 cm), is heated to a moldable temperature, draped by hand over a positive model of the shank-foot and pulled into place by a vacuum source introduced through a longitudinal seam created in the posterior section. (figure 3).

The result is a prosthesis (figure 4) that provides functions identical to those of the conventional patellar-tendon-bearing prosthesis, but the weight is reduced by approximately 65 percent. Obviously, this drastic reduction in weight reduces the suspension problem. Weight reduction, coupled with the inherent properties of the plastic used, often makes it possible to produce a prosthesis that requires no straps, wedges, belts, or other auxiliary means to provide suspension (figure 5).

The prosthesis consists of three components: the socket, the shank-foot section, and the sole and heel cushion (figure 4). The socket is made by vacuum forming polypropylene over a positive model of the stump, after the model has been modified in the conventional manner. The shank is molded from a single sheet of polypropylene over a form that is compatible with the alignment determined by the prosthetist. The sole and heel cushion can be exactly the same as that used on any conventional SACH foot, or as on any design preferred by the prosthetist.

The basic fabrication steps are:

1. Casting the stump and modifying the positive model.
2. Molding the socket.
3. Attaching the socket to an adjustable leg.

4. Alignment of the prosthesis.
5. Removal of the adjustable leg and replacement with a carved foamed filler to provide a positive model for molding a shank.
6. Molding the shank-foot section.
7. Welding the shank-foot section.
8. Removal of the foam.
9. Attachment of the sole and heel cushion.

Two methods are offered for fabrication of the foot section of the shank: a temporary hollow foot piece can be made of polypropylene, or the components of an exposed-keel type of SACH foot can be used. The first method results in the maximum amount of weight reduction, about 2/3 when compared to the conventional PTB, and is especially useful in those cases where a special foot design is needed. The second requires slightly less time if the foot-piece of the first method has to be fabricated in the prosthetics facility. It is anticipated that manufacturers will make available inexpensive components that will reduce the time required in both methods.

A fabrication manual, describing both methods, has been prepared and made available to prosthetists that are currently participating in a clinical study.

A report on our experiences with the amputee subjects fitted in the course of our experimental work follows.

SUBJECTIVE FOLLOW-UP OF PATIENTS FITTED IN THE EXPERIMENTAL STUDY

The Population

Eight amputees have been fitted with the ultralight weight below-knee prosthesis. Of that number, six have been available for follow-up. One

of these patients is pediatric (6 ½ years), two are young adults (23 and 31 years), and three are geriatric (58, 61, and 70 years). All the patients are male. All of the amputations were due to trauma, except for two geriatric patients for whom the cause was vascular insufficiency. Both of these vascular are bilateral amputees: one is an AK-BK; the other is a bilateral BK.

Method

A questionnaire was developed and administered with the intent of comparing the ultralight prosthesis to a conventional BK prosthesis (PTB). Some problems are associated with this approach. The bilateral BK amputee had never had conventional definitive prostheses, so he could compare the experimental prostheses only with his training pylons. The AK-BK amputee has not worn his experimental prosthesis because of poor socket fit and because the new prosthesis, in combination with his conventional AK prosthesis, makes him feel "lopsided." Consequently, his answers regarding wearing time and durability were not used, but his opinions in the remaining categories were included. One other patient uses an ultralight prosthesis, but not the one which was fabricated for him at our Center. It is a "hollow" PTB prosthesis, which was made especially for him, and which he wears almost exclusively. His answers were used to compare this prosthesis to his old conventional PTB prosthesis, except for opinion categories regarding the ultralight prosthesis (cosmetics and donning/doffing). For the above reasons, different numbers of responses will be seen in the various categories (table 1).

Results

1. Wearing time - Four out of five patients stated that wearing time increased with the ultralight prosthesis. One patient stated that there was no difference between the ultralight prosthesis and his PTB prosthesis.
2. Comfort - Four out of six patients felt that comfort was improved with the ultralight prosthesis. One patient felt that there was no difference, and one felt that the ultralight prosthesis was not as comfortable as his conventional prosthesis.
3. Cosmesis - Three out of five patients felt that there was no particular difference in cosmesis. One of these three had had his prosthesis painted, while the other two felt that they could cover the prosthesis with trousers and stockings. One person favored the ultralight prosthesis, cosmetically, because less suspension was required than with his conventional prosthesis. The pediatric patient liked his PTB prosthesis better, both because of its flesh color and because it does not have "wings" from the supracondylar suspension when he sits as does the ultralight prosthesis.
4. Endurance - All six amputees unanimously agreed that a properly fitted ultralight prosthesis would allow them to walk further or longer than a conventional prosthesis.
5. Ease of Walking - Five out of the six amputees agreed that an ultralight prosthesis is easier to walk with and to control. The AK-BK subject felt that his previous prosthesis was easier to walk with because of a better fit.

6. Donning/Doffing - There was a 50/50 split in opinions regarding donning/doffing. Three patients felt that the new prosthesis was easier to don and doff, while three thought that their conventional prosthesis was easier.
7. Durability - Of the four appropriate patients surveyed, all rated the experimental prosthesis as having good durability thus far. However, length of use of any one prosthesis varies from one to six months only. There has been only one failure, that being breakage of a shank while the wearer was playing street hockey.
8. Overall Function - When asked which prosthesis they preferred overall, five amputees responded that they liked the ultralight prosthesis best. The AK-BK subject preferred his conventional PTB.
9. Rating - The amputees were asked to rate the ultralight prosthesis on a scale of one to five regarding how well they liked it. The categories were "very good", "good", "fair", "not too much", and "not at all". Four people rated it "very good", one rated it "good", and one rated it "fair" (the bilateral AK-BK).
10. Miscellaneous comments - Three patients stated that they thought the rigid foot of the new leg made it more difficult to roll-over the prosthesis than is the case with a SACH foot. This is especially a problem when going up inclines.

One patient mentioned that he felt he had "better sensation" with his ultralight prosthesis than with a conventional prosthesis, i.e., he could feel the terrain better.

One patient, who is quite athletic, found that the ultralight prosthesis made running easier than was the case with his conventional prosthesis.

In summary, the ultralight prosthesis appears to offer a potentially good solution, for all age groups. As one would expect, the prosthesis must fit well to be effective. Patients subjectively feel that it takes less energy to walk with the ultralight prosthesis than with a conventional prosthesis. Cosmesis is acceptable, at least in our all-male sample. It is interesting to speculate, as a result of one of the comments, that perhaps there is more sensory feedback with the ultralight prosthesis than there is with a conventional one.

The Veterans Administration is currently supporting a clinical study involving seven prosthetics facilities. The study is scheduled to be completed in October 1978.

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PATIENT	Wearing Time			Comfort			Cosmesis			Endurance			Ease of Walking			Donning/ Doffing			Overall Preference			Rating of U.L. Prosthesis				
	Increased	Decreased	No Change	Increased	Decreased	No Change	U.L. Prosthesis	Previous Prosthesis	Don't Care	U.L. Prosthesis	Previous Prosthesis	Nc Difference	U.L. Prosthesis	Previous Prosthesis	No Difference	U.L. Prosthesis	Previous Prosthesis	No Difference	U.L. Prosthesis	Previous Prosthesis	No Difference	Very Much	Good	Fair	Not Too Much	Not At All
P.M. (Age 6½)	X			X			X			X			X				X		X			X				
D.M. (Age 23)			X			X	X			X			X			X			X				X			
J.E. (Age 31)	X			X					X	X			X			X			X			X				
H.T. (Age 58;Bilateral BK)	X			X					X	X			X				X		X			X				
B.C. (Age 61;AK-BK)					X				X	X				X			X			X				X		
J.B. (Age 70;Uses his own U.L. Pros.)	X			X						X			X			X			X			X				

TABLE I.

LEGENDS

Figure 1. Schematic cross-section of the Wollstein below-knee prosthesis.

Figure 2. Initial design incorporated overlapping lateral seams.

Figure 3. Molding the shanks and foot using the drape method.

Figure 4. Cross-section of foot and lower part of the shank.

Figure 5. Finished prosthesis.

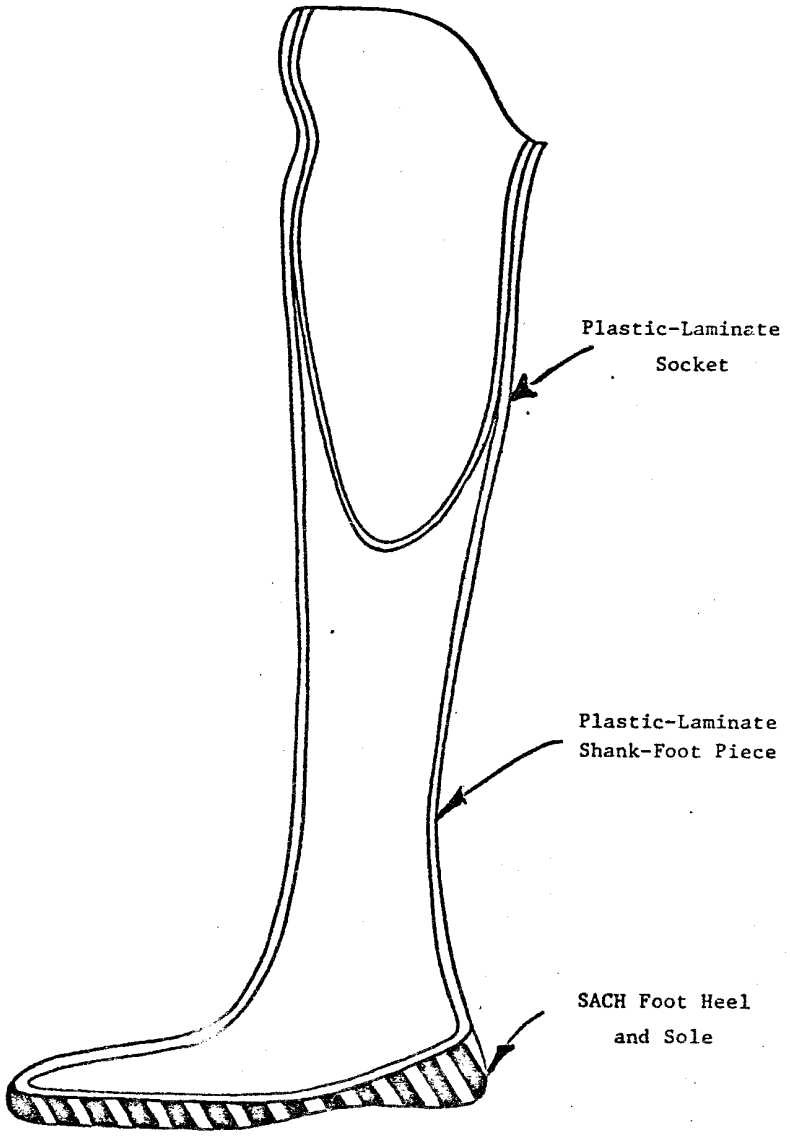

Fig. 1. Schematic cross-section of the Wollstein below-knee prosthesis.

Fig. 3

Fig. 4