Orthotics and Prosthetics, Vol. 33, No. 2, pp. 45-53, June 1979

Evaluation of an Ultralight Below-Knee Prosthesis[1]

BRIAN REED, R.P.T.[2]
A. BENNETT WILSON, JR.[2]
CHARLES PRITHAM, C.P.O.[2]

This is a report on experience gained since publication of the article by Wilson and Stills (1) in the March 1976 issue of "Orthotics and Prosthetics" on ultralight prostheses for below-knee amputees made by vacuum-forming sheet polypropylene (Fig. 1). The design resulted in a prosthesis that weighs one-third of the more conventional PTB prosthesis, with essentially the same function, depending upon the treatment of the sole and heel. In addition to offering the possibility of a decrease in energy requirements, suspension problems might be reduced. In the article it was stated that the Rehabilitation Engineering Center would welcome other groups to participate in the development of this concept.

With partial support from the Veterans Administration work on this project was continued and although the original aim of the project was to provide a better prosthesis for the geriatric patient, it was found that the active patient also appreciated advantages offered by the new design. By March 1976 a draft of a manual was sufficiently complete so that it was practical to invite prosthetists from each of the Rehabilitation Engineering Centers, the Veterans Administration Prosthetics Center, and several privately practicing prosthetists to Northwestern University to become acquainted with the technique so that it could be applied in their own setting and provide information useful in making the technique as practical as possible.

With the help of the participants the original fabrication technique was modified to use hand draping of the polypropylene to mold the shank to provide more uniform wall thickness and an anterior seam. An alternate method of fabricating the foot was also introduced (Fig. 2). During the fall of 1976 a fabrication manual (2) was prepared and submitted to the VA with the suggestion that the ultralight below-knee prosthesis be evaluated nationwide through the VA outpatient amputee clinics.

Instead of acting upon this suggestion, the VA requested a proposal from us for the conduct of clinical trials through the Philadelphia Regional Office Amputee Clinic. The proposal was accepted by the VA, and the program was initiated in January 1978.

Method

Seven Philadelphia-area prosthetic firms agreed to participate in the study. The prosthesis design selected was the one using the rigid toe section since it was the lightest of the two designs. The prosthetists were instructed in the fabrication

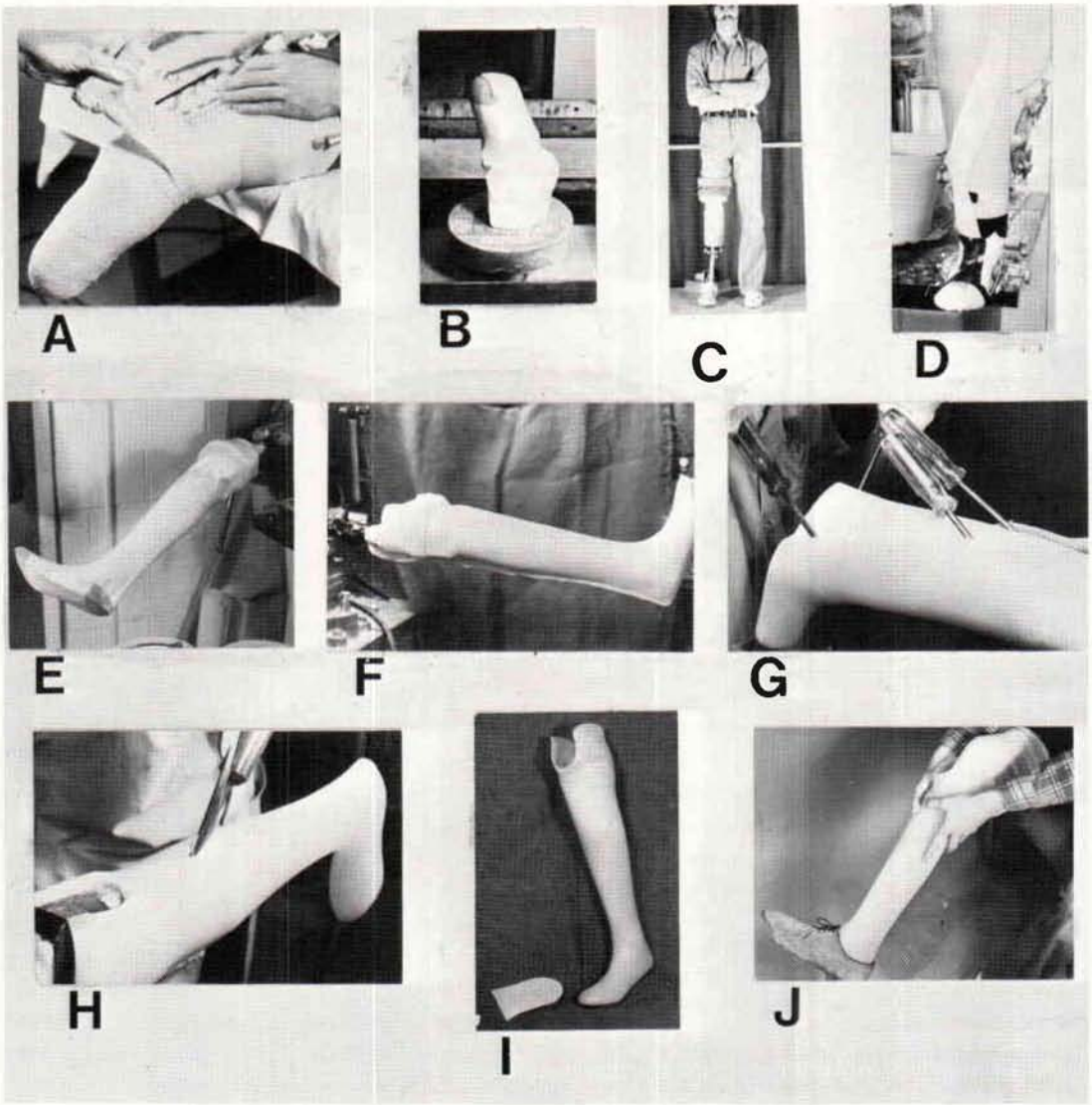

Fig. 1. Steps in fabrication of ultralight below-knee prosthesis from sheet thermoplastic.

and fitting of the ultralight prosthesis in a twelve-hour course at the Rehabilitation Engineering Center of Moss Rehabilitation Hospital in January 1978. The prosthetists then fitted amputees from the VA Regional Office Amputee Clinics, and from their own private practices who were referred to the study from two other local clinics. Amputees who were receiving their first definitive prosthesis as well as amputees who already were successful PTB users were included in the study. Data were collected by means of questionnaires (Appendices A and B). For the former PTB users, one questionnaire was administered before fitting and another one was administered two weeks after a "satisfactory"

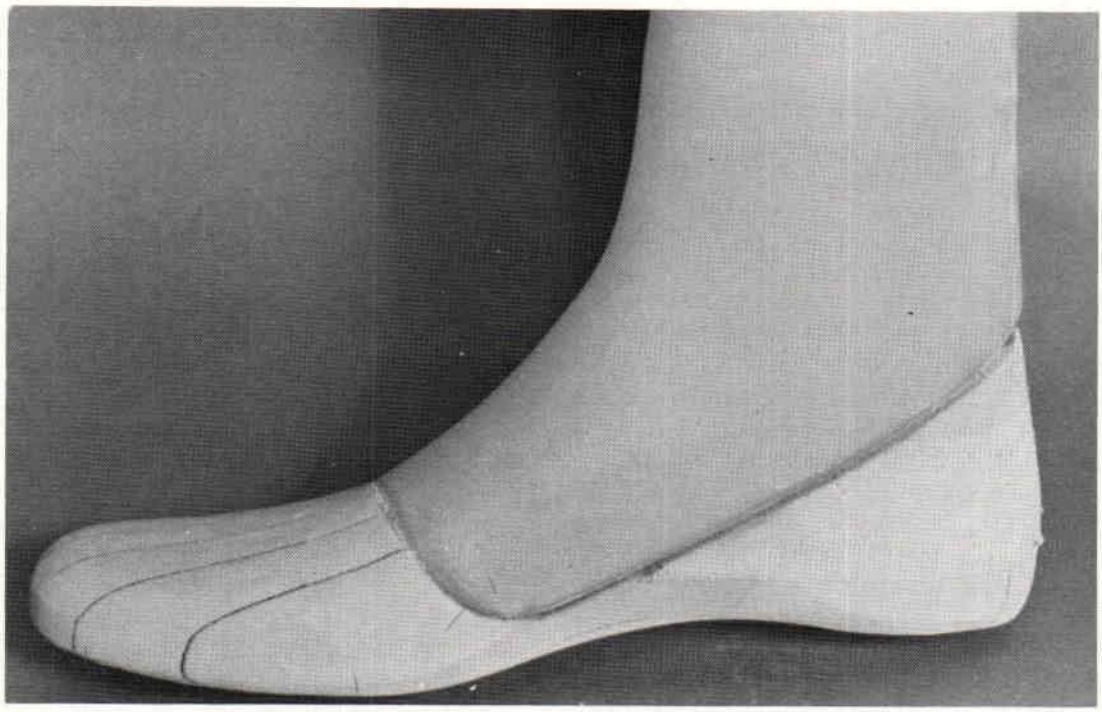

Fig. 2. The foot-and-ankle section of an ultralight below-knee prosthesis when the full function of a SACH foot is desired.

fit was obtained. A "satisfactory" fit was one which was agreeable to both the patient and prosthetist. In addition, an unannounced followup was done one month after the final fitting in order to determine if the subjects were still using the ultralight prosthesis or if they had gone back to their conventional prosthesis. At this time the subjects were also asked whether they liked the lightness of the prosthesis, other factors aside. The prosthetists were given a questionnaire (Appendix C) after all patients had been fitted in order to assess fabrication and fitting problems and the applicability of the device as a first definitive prosthesis versus a PTB replacement. Data in this respect were not collected on the new amputees since they had no prosthetic experience on which to base a comparison.

To date (January 1979), the sample consists of thirty-six patients who have been fitted with the ultralight prosthesis. Of that number, four are receiving it as their first definitive prosthesis. Of the remaining thirty-two patients, complete data have been obtained on fourteen. All but one are male. One patient died during the course of the study from an unrelated cause.

Results

The patient data are presented in Figure 3. The responses of one patient, H.G., need to be considered in light of the fact that shortly after receiving the prosthesis he moved out of state. He then had a structural failure of the foot of the prosthesis which altered its cosmesis, fit, and alignment. He indicated that this was the reason for his unfavorable response to several of the questions. Those responses are circled. He was unable to return to Philadelphia to be fitted

with another ultralight prosthesis.

The following general conslusions can be drawn from this preliminary data:

1. Although wearing time and walking distance do not appear to increase when the lighter prosthesis is used the overwhelming majority of the subjects felt that the lighter prosthesis requires less energy to walk with than a conventional prosthesis.
2. Opinions were mixed regarding which prosthesis is easiest to control and which one was the most comfortable to walk on. In both cases, however, the majority favored the experimental prosthesis.
3. The majority of the subjects felt that conventional prostheses are more cosmetically acceptable than the ultralight (polypropylene) model.
4. For the most part, either there was no difference in ease of donning and doffing, or else the lighter prosthesis was slightly superior in this area.
5. The overall preference was overwhelming for the ultralight prosthesis. The two who preferred their conventional prosthesis both liked the lightness of the experimental prosthesis, but they were very dissatisfied with the foot action.
6. There were six incidences of structural failure. Three were fractures of the polypropylene at the toe area of the foot. Two other cases involved crushing of the internal keel foot. The other failure was a subluxation of the socket within the shank. The first two problems were corrected by using an external keel foot. The socket problem was solved by using a heavier guage polypropylene and meticulous welding at the brim. It may be noted that structural failures occurred with both of the bilateral amputees. Structural failure also occurred most frequently in patients who subjected the prosthesis to extreme stress, as would be expected.
7. All but three subjects were using the ultralight prosthesis at follow-up. Of the three who did not, two gave their reasons as dissatisfaction with the "fit" that they had as a result of the rigid foot. The third subject (H.G.) was not wearing his prosthesis because the crushed foot precluded its use.
8. The subjects were unanimous in their approval of the lightness of the prosthesis.
9. Half of the patients commented that they disliked the rigid foot of the prosthesis, and there were some interesting comments about the light weight of the prosthesis. Two subjects (L.B. and J.C.) commented that the lighter weight noticeably reduced pistoning of the stump in the socket. Two others (A.W. and H.G.) stated that they had found the leg useful for work in and around water. A.W. also Commented that his stump was in better condition than it had ever been before. R.S. felt that the lightweight legs were superior to his conventional ones in every way except durability. Data from the prosthetists's questionnaires has not been compiled yet since some subjects are still undergoing fitting modifications. From informal communication, however, the principal complaints of the prosthetists are: (a) that the ultralight prosthesis is difficult to modify once it is made; (b) structural failures, especially at the foot, pose a problem.

Discussion

The preliminary data seem to indicate that the concept of an extremely

Subject	Age	Stump Length (L) (R)	Sex	Stress on Prosthesis: Extreme	Moderate	Minimal	Wearing Time: Increased	Decreased	No change	Walking Time: Increased	Decreased	No change	Least Energy Required: Light weight prosthesis	Previous prosthesis	So difference	Easiest Control: Light weight prosthesis	Previous prosthesis	No difference	Most Comfortable: Light weight prosthesis	Previous prosthesis	No difference	Most Acceptable Cosmesis: Light weight prosthesis	Previous prosthesis	No difference	Easiest Donning and Doffing: Light weight prosthesis	Previous prosthesis	No difference	Overall Preference: Light weight prosthesis	Previous prosthesis	So difference	Structural Failure: Yes	No	Prosthesis used at follow-up: Light weight	Other	Do you like the lightness?: Yes	No	Specific Complaints
E.W.	49	5¼	M		X				X			X			X		X				X					X			X			X	X	X	X	X	Dislikes rigid foot
C.H.	68	3½	M		X		X				X		X					X	X			X					X				X	X	X	X	X	
J.D.	40	7½	M		X				X	X			X			X			X					X	X			X			X	X	X	X	X	Dislikes rigid foot
G.F.	50	4	M	X					X			X	X			X			X					X			X	X			X		X	X	X	Dissatisfied with fit (new limb being made)
H.S.	30	4 8½	M	X				X				X	X			X			X			X			X			X			X			X	X	
L.B.	54	7½ 7½	M	X					X			X	X					X			X			X			X			X			X	X	Dissatisfied with fit (rigid foot)
A.W.	53		M	X					X			X	X			X			X			X			X			X			X		X		X	
H.S.	53	5½	M		X				X			X	X			X			X			X			X			X			X		X		X	
J.C.	23	5½	M	X					X			X	X				X				X	X			X			X				X	X		X	Dislikes rigid foot
H.G.	31	11	M	X				X		X			X					X		X			X			X			X			X		X	Poor fit after major structural failure
F.S.	31	3½	M	X				X				X		X		X				X			X		X			X			X		X		X	Dissatisfied with fit (rigid foot)
A.J.	60	5½	M		X				X			X			X		X			X		X				X			X			X		X		X	Dislikes rigid foot
A.R.	71	4½	F			X			X		X		X			X			X			X			X			X			X		X		X	
A.B.	64	7	M		X				X			X	X				X		X					X	X			X			X		X		X	Dislikes rigid foot
				TOTALS			1	3	10	2	1	11	11	1	2	7	4	3	8	4	2	3	8	3	5	1	8	12	2		6	8	10	3	14	

Fig. 3. Chart showing interim results of clinical trials of ultralight below-knee prosthesis.

light below-knee prosthesis is valid. The model used for this study seems to be inferior to conventional below-knee prostheses only in the areas of adjustability, durability, and, in some cases, function of the foot. Half of the patients sampled complained about action provided by the rigid foot. Most frequently the complaint was that heel-strike was jarring, and that it was hard to walk up inclines because of difficulty in "rolling over" the foot. The complaints about the rigid foot may be simply a matter of "getting used to it," especially after being used to a SACH foot. Nevertheless, the rigidity of the foot as well as its structural weakness can probably be solved by the incorporation of an external keel foot, a possibility now being considered by the REC. It is estimated that an external keel foot would add about 8 oz. to the prosthesis. Regarding cosmesis, the REC is now investigating the use of prosthetic skins that have been developed elsewhere. The current model is probably best used with patients who do not subject the prosthesis to extreme stress. It is of potential benefit to amputees of all ages, but it may be particularly indicated for patients with cardio-vascular impairments.

A final report on this project will be issued toward the end of 1979. Meanwhile a new fabrication manual will be published, and it is hoped that the American Academy of Orthotists and Prosthetists will undertake a nationwide clinical evaluation of this technique on behalf of the Veterans Administration.

The authors wish to express the sincerest of appreciation for the cooperation and assistance provided by Dr. Howard Zeidman, Chief, Prosthetics Clinic Team, VARO, Philadelphia, Edward Vargo, Prosthetics Representative, VARO, and the following prosthetists:

Joseph Botkin, J.E. Hanger of Philadelphia
Frank N. Cocco, Cocco Brothers
Virgil Faulkner and Amin K. Hajj, INA O&P Research Laboratory, University of Pennsylvania Hospital
Harry J. Lawall, Harry Lawall and Son
Harry J. Lawall, Jr., Harry Lawall and Son
Frank J. Malone, Jr., Frank Malone and Son, Inc.
Edward F. Moran, Cocco Brothers
Blondell Smith, Nu-Way Limb and Brace, Inc.
Thomas Sulima, Modern Limb and Brace Co.
John Swoyer, Modern Limb and Brace Co.
Charles Wright, J.E. Hanger of Philadelphia
Without their unselfish help and open minds this study could not have been carried out.

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2. Wilson, A. Bennett, Jr., Charles Pritham, and Melvin Stills, Manual for an ultralight below-knee prosthesis, Rehabilitation Engineering Center, Moss Rehabilitation Hospital-Temple University-Drexel University (1977).

[1]This work was carried out with fiscal support from the Veterans Administration under Contract V101(134)P-576.

[2]Rehabilitation Engineering Center, Moss Rehabilitation Hospital-Temple University-Drexel Hospital, Philadelphia, Pa. 19141.

APPENDIX A

Questionnaire I – (For amputees who have previously used a definitive prosthesis)

Name: _____ Date: _____

1. How many hours a day do you wear your present prosthesis?
   a. 0-4 hours
   b. 4-8 hours
   c. 8-12 hours
   d. more than 12 hours

2. Are you presently satisfied with your prosthesis?
   a. Yes
   b. No

3. If not, why?
   a. because of the way it fits
   b. because of the way it looks
   c. because it's worn out
   d. other – please explain

4. How far can you walk on your prosthesis without resting?
   a. up to ½ block
   b. ½ block to 1 block
   c. 1 to 2 blocks
   d. more than 2 blocks

5. How long have you had your current prosthesis?

6. How do you like the fit of your prosthesis?
   a. excellent
   b. good
   c. fair
   d. poor

APPENDIX B

Questionnaire II—(For amputees who have previously used a definitive prosthesis)

Name:_____ Date: _____

Instructions: Please answer the following questions as objectively as possible.

1. How many hours a day do you wear the light-weight prosthesis?
   a. 0-4 hours
   b. 4-8 hours
   c. 8-12 hours
   d. more than 12 hours

2. How far can you walk on the light-weight prosthesis without resting?
   a. up to ½ block
   b. ½ block to 1 block
   c. 1 to 2 blocks
   d. more than 2 blocks

3. How do you like the fit of your light-weight prosthesis?
   a. excellent
   b. good
   c. fair
   d. poor

4. Overall, which prosthesis do you prefer?
   a. the light-weight one
   b. your original one (the one you used before entering this study)
   c. no preference

5. Which of the two prostheses do you feel requires less energy to walk with?
   a. the light-weight one
   b. your original one
   c. they both require the same amount of energy

6. Which prosthesis is easier to control when you are walking on it?
   a. the light-weight one
   b. your original one
   c. there is no difference

7. Which of the two prostheses do you feel is more comfortable to walk on?
   a. the light-weight one
   b. your original one
   c. there is no difference

8. In your opinion, which prosthesis looks better?
   a. the light-weight looks better than your original prosthesis
   b. the original prosthesis looks better than the light-weight one
   c. there is no difference

9. Which one is easier to put on and take off?
   a. the light-weight one
   b. your original one
   c. there is no difference

10. If you have found any particular advantages or disadvantages of the light-weight prosthesis as compared to your original one, please describe them here.

APPENDIX C

Questionnaire III – (for prosthetists)

Name: _____ Date: _____

Instructions: Based on your professional experience, and your recent exposure to the light-weight BK prosthesis, please answer the following questions as objectively as possible.

1. Which type of prosthesis is easier to fabricate?
   a. light-weight
   b. conventional
   c. no difference
2. Which type of prosthesis is easier to fit as a first definitive prosthesis (new amputee)?
   a. light-weight
   b. conventional
   c. no difference
3. Which type of prosthesis is easier to fit to an amputee who is already experienced at walking on a prosthesis?
   a. light-weight
   b. conventional
   c. no difference
4. Do you feel that the ultra light-weight prosthesis is a feasible device for your private clinical practice?
   a. Yes
   b. No
5. Do your feel that there are any particular age groups that the light-weight prosthesis is especially appopriate or inappropriate for? Please explain.
6. Do you feel that there are causes of amputation which are especially appropriate or inappropriate to use the light-weight prosthesis? (i.e., traumatic, vascular, etc.) Please explain.
7. Do you feel that the ultra light-weight prosthesis is most useful as:
   a. a first definitive prosthesis
   b. a replacement prosthesis (replacement for a conventional prosthesis)
   c. both
   d. neither
8. What specific difficulties have you encountered in fabricating the ultra light-weight prosthesis?
9. What specific difficulties have you encountered in fitting the ultra light-weight prosthesis?
10. Please give any additional comments that you feel are relevant to the feasibility of the ultra light-weight prosthesis.
11. What method have you used for forming the foot of the ultra light-weight prosthesis?
    a. by vaccu-forming an old sach foot
    b. by vaccu-forming a plaster foot
12. Have you used a flexible forefoot or a rigid forefoot on the ultra light-weight prosthesis?
    a. flexible
    b. rigid
13. What type of suspension system have you used for the light-weight prostheses you have made?