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A Clinical Evaluation of an Ultralightweight Polypropylene Below-Knee Prosthesis

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INTRODUCTION

This paper presents the results of a clinical evaluation of an ultralightweight polypropylene below knee prosthesis recently completed at the National Centre for Training and Education in Prosthetics and Orthotics, Strathclyde University, and its prosthetic clinic at the Southern General Hospital in Glasgow. The evaluation was funded by the Scottish Home and Health Department. The ultralightweight polypropylene prosthesis will be referred to as UP in subsequent discussion; similarly, the amputees' previous resin laminated prosthesis will be referred to as OP (original prosthesis) for brevity.

The concept of UP was developed at Moss Rehabilitation Hospital[1] and at Rancho Los Amigos Hospital.[2] A report of an evaluation in Philadelphia of a UP was published in *Orthotics and Prosthetics*, Vol. 33, No. 2, June, 1979.[3] Information from questionnaires completed during this evaluation indicated an overall preference for the UP by the amputees compared with their previous prosthesis, although half of the amputees disliked the rigid polypropylene foot of this type of prosthesis. A revised fabrication manual was subsequently produced, recommending an external keel foot.

The design utilized in this evaluation incorporated a supracondylar suspended polypropylene socket with a soft Pelite liner® (Pelite is the trade name of a closed cell polyethylene foam material). The socket is welded to a hollow polypropylene calf and keel, which is bonded to the flexible soleplate of an external keel Otto Bock SACH foot. A stockinette cosmetic cover is applied.

In the early stages of the Glasgow evaluation of a UP, manufacturing problems—resulting from particular combinations of materials and handling techniques—were encountered, resulting in loss of alignment. Techniques to compensate for these difficulties were identified and reported in *Prosthetics and Orthotics International*, Vol. 8, No. 1, April, 1984. The clinical evaluation was delayed until such time as the clinician and prosthetists were satisfied with the UP alignments and that differences between UP and OP were minimized. A detailed manual of the manufacturing method adopted is available from the National Centre for Training and Education in Prosthetics and Orthotics, in Glasgow, Scotland (Ballantyne et. al., 1983).[4]

- The five aims of the Glasgow evaluation were to
  - —Monitor amputees' response to this modified UP via questionnaires similar to the Philadelphia evaluation
  - —Assess activity level changes with a step counter
  - —Note comments of the clinic team
  - —Record the weights of the UP and the OP
  - —Note the manufacturing times and material costs of the UP

A total of 24 active male amputees were supplied with a UP. Figures 2 and 3 provide amputee demographics.

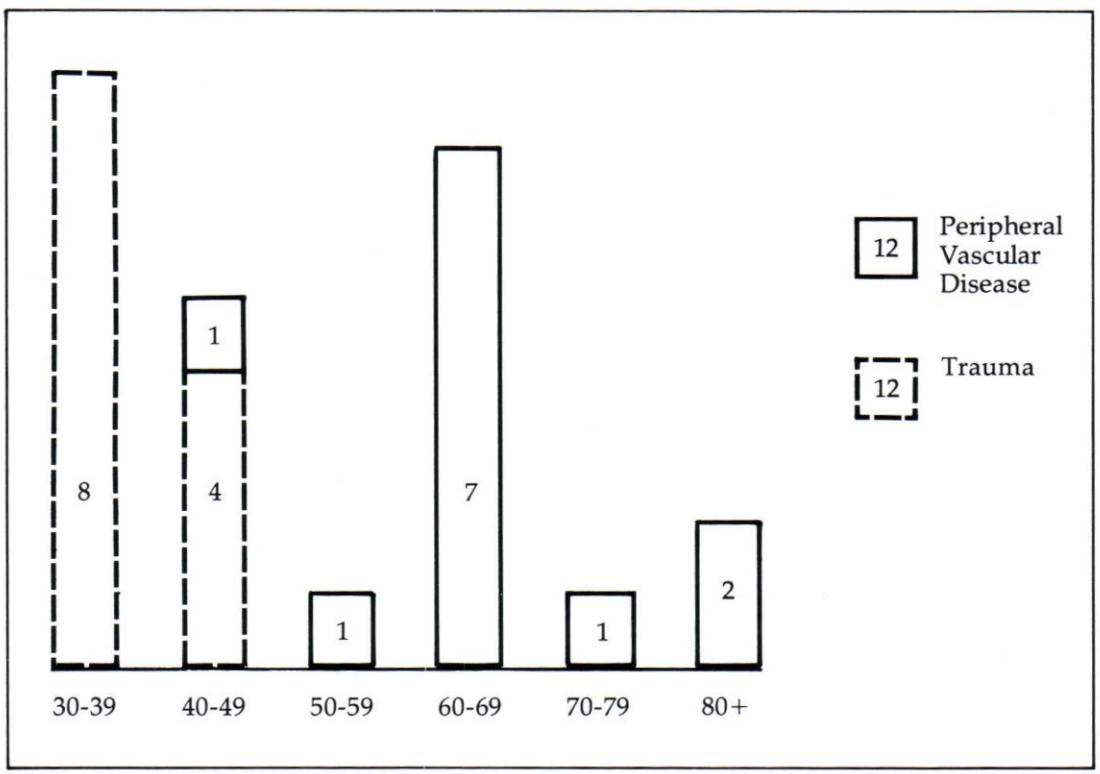

Figure 2. Amputees' Age Groups (years)

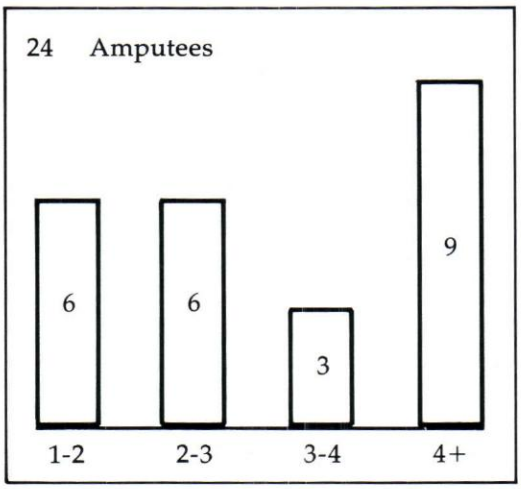

Figure 3. Years Wearing Prostheses

The 24 amputees all previously wore a resin laminated prosthesis with a soft Pelite® liner and SACH foot. Twenty-one of the OP had supracondylar suspension, the other three OP were cuff suspended. Two prosthetists were involved in the fittings.

RESULTS OF CLINICAL EVALUATION

• Monitoring Amputee Response

The amputees were informed that the material of the prosthesis was changed and their comparable views of the OP and the UP were required. Questionnaires were completed by the amputees and clinic team at periodic intervals. During the first visit, when a negative impression was taken for the UP, the amputee was asked his opinion of his current prosthesis (OP) (Table 1).

	Good	Acceptable	Poor
Socket Fit	16	7	1
Suspension	17	7	
Cosmesis	17	7	

Table 1. Amputees' opinion of old prosthesis

The amputees were also asked how many hours per day they wore their OP and also how far they walked. The wearing time ranged from seven to 16 hours, with an average of 14 hours. The walking distance ranged from 200 yards to four miles, with an average of 1½ miles per day. The information from this first questionnaire provided data that constituted a starting point.

The second and third questionnaires were completed two weeks and three months, respectively, after delivery of the UP. The amputees were asked to compare their OP and UP with respect to a number of factors.

• Questions

—Do you wear your polypropylene prosthesis *less/same/more* hours per day than your original prosthesis?
—Compared with your original prosthesis, do you walk *less/same/more* with your polypropylene prosthesis?
—Are you *less/same/more* tired walking with the polypropylene prosthesis vs. original prosthesis?
—Do you have *less/same/more* control of the polypropylene prosthesis vs. original prosthesis?
—With the polypropylene prosthesis, what activities do you participate in?
—Is the socket fit of polypropylene prosthesis vs. original prosthesis *worse/same/better*?
—Walking comfort of polypropylene prosthesis vs. original prosthesis: *worse/same/better*?
—Do you think your polypropylene prosthesis is *heavier/same/lighter* than your original prosthesis?
—Overall, which prosthesis do you prefer: *original/no preference/polypropylene prosthesis*?

The final questionnaire was completed by the amputee one month after reverting to his OP. This procedure enabled the amputee to familiarize himself with his OP again before being asked to compare both prostheses.

—Which prosthesis do you prefer *original/no preference/polypropylene*?

Amputees' Response

Question	Time since ultralightweight prosthesis (UP) delivery			
		Less	**Same**	**More**
Wearing time of UP vs. old prosthesis (OP)	2 weeks	1	18	1
	3 months		14	4
Walking distance UP vs. OP	2 weeks		19	1
	3 months	2	12	4
Energy expenditure UP vs. OP	2 weeks	9	10	1
	3 months	3	15	
Control of UP vs. OP	2 weeks		10	10
	3 months	2	10	6
Social activities UP vs. OP	2 weeks		18	2
	3 months	1	15	2
		Worse	**Same**	**Better**
Socket fit UP vs. OP	2 weeks	5	5	10
	3 months	1	3	14
Walking comfort UP vs. OP	2 weeks	4	3	13
	3 months	1	5	12
		Heavier	**Same**	**Lighter**
Weight UP vs. OP	2 weeks		3	17
	3 months		3	15
		OP	**No Preference**	**UP**
Overall preference UP vs. OP	2 weeks	3	4	13
	3 months	2	1	15
Overall preference UP vs. OP	One month after reverting to OP	2		16

Table 2.

Table 2 represents the amputees' response to specific questions comparing the UP and OP. Some amputees did not complete all questionnaires due to either the rejection of the ultralightweight prosthesis, failure to attend specific clinics, illness, or death during the evaluation. Twenty amputees completed the two week questionnaires and 18 amputees completed the three month questionnaire and the final questionnaire.

Sixteen of the 24 amputees preferred their UP. This may have been due mainly to a better fitting socket and a general improved feeling of comfort.

Five of the 24 amputees rejected their UP for the following reasons:

- One amputee considered the UP socket brim to be too flexible. This created a feeling of insecurity. The clinic team considered this amputee to be "confused."
- One UP was rejected due to loss of alignment detected by the clinic team at delivery. A quality control check had been conducted during the manufacture of this prosthesis, but this did not detect the problem.
- One amputee experienced excessive pressure within the socket at the tibial tubercle. This problem was also experienced by two other amputees, but minor socket rectification produced acceptable sockets in their cases. This socket pressure discomfort was thought to be due to socket distortion during manufacture.
- One amputee complained of excessive pressure on the lateral aspect of his residual limb with the UP. The prosthetist had attempted alignment compensation in the UP to correct a poor gait observed with his OP.
- One amputee experienced discomfort with the supracondylar suspension of the UP and complained that the foot of this prosthesis was "too rigid." This amputee's OP was cuff suspended.

The views of the remaining three amputees are inconclusive. One amputee failed to attend clinics after delivery of his UP, one amputee became a bilateral amputee during the evaluation, and the other amputee died during the evaluation.

Activity Level Assessment Results

In parallel with the questionnaire approach, a quantitative assessment of walking activity was carried out by fitting a pressure switch and step counter between the prosthetic foot and shoe. Subjective assessments of walking distance via questionnaires are unreliable. The pressure switch was positioned on the heel or ball of the foot, dependent on the fit of the prosthetic foot within the shoe. The pressure switch and step counter were worn for a two week period when wearing both types of prostheses to monitor the number of steps taken during these periods.

Failure of the pressure switch during the two week period or failure of the amputee to attend appropriate clinics prevented a comprehensive study. Step count data relative to both types of prostheses was recorded for eight amputees. The average active amputee accumulated 4,800 steps/day (2½ miles) whereas the average inactive amputee accumulated 1,500 steps/day (<1 mile). No increase or decrease in step count with these amputees could be attributed to activity level changes introduced by either the OP or UP.

Summarized Comments of Evaluation Team

No detailed comments from the prosthetists were reported in the Philadelphia evaluation report. The role of the clinic team was to assess this type of UP compared with the laminated prosthesis supplied at present.

- The cosmesis of the UP was considered to be unsatisfactory. This would have been particularly important for females. Specifically, a relatively larger calf diameter and a tendency to damage the cosmetic stockinette were noted. The calf diameter was found to increase by 2.5 cms. on average when using the techniques inherent in the

UP design. The amputees—all males—participating in the study did not appear to be concerned about cosmesis.

- Compared to a resin laminated prosthesis, more minor socket adjustments of the UP were necessary. This was thought to be due to slight local distortion of the polypropylene. A particular problem area would appear to be the tibial tubercle. Socket discomfort problems were not detected at delivery of the prosthesis, but were identified at the review stage. Concern was expressed that if supply of such prostheses were conducted on a nationwide scale, with many prosthetists involved, then potential residual limb problems could pass undetected.
- A favorable impression of the UP may have been created by the new socket which provided a better fit. This could have been avoided by supplying the amputee with a laminated prosthesis whose socket could have been duplicated from a master to provide the UP with an identical socket. This would have extended the evaluation period considerably as amputees became accustomed to their new laminated prosthesis.
- The soleplate attachment to the polypropylene keel was considered unsatisfactory, as it was susceptible to failure.
- Different technician skills were needed than those required for the manufacture of the laminated prosthesis designs. The technician compensated for the shrinkage of Pelite,® polyurethane foam, and polypropylene during manufacture. New skills were needed to perform the polypropylene welding.
- No skin reactions were noted.
- The prosthetists noted that the inner surface of the polypropylene socket is rougher than that of a resin laminate socket. The result of this rough surface was that some of the elderly subjects had difficulty in withdrawing the residual limb and Pelite® liner from the socket when doffing the limb.
- The technician recommended that some form of alignment "quality control" should be used before the UP is supplied to the prosthetist for delivery. This is needed because the method of manufacture creates an increased likelihood of alignment loss compared with lamination methods. Significant loss of alignment occurred during manufacture of some UPs in the early stages of the evaluation. These manufacturing problems were overcome by the introduction of modifications to the manufacturing technique. However, the prosthetist continued to have a reduced confidence in the prosthesis. The prosthetist's confidence in the UP would be restored with more experience.
- Children's growth spurts may be more difficult to accommodate with the UP.

Weights of the Ultralightweight Prostheses

The weight of the 24 OP ranged from 2.6 lbs (1180 gm) to 4.4 lbs (2020 gm) with an average of 3.2 lbs (1450 gm). The weight of the 24 UP ranged from 1.9 lbs (884 gm) to 3.0 lbs (1370 gm) with an average of 2.2 lbs (1005 gm). This represents a typical weight reduction of 30 percent.

The weight of presently available designs of modular below knee prostheses is approximately 4.4 lb (2000 gm).

Manufacturing Costs

The times for manufacture were noted for each of the 24 UP. The first UP to be manufactured was completed in a total of 22 hours. Approximately six hours were required to manufacture the prosthesis to the fitting stage and a further 16 hours were needed to complete it. The manufacturing time, which steadily decreased during the supply of subsequent prostheses, averaged 13 hours—consisting of 4½ hours to the fitting stage and a further 8½ hours to completion.

The typical manufacturing times in the same workshop for a resin laminated prosthesis—3½ hours to the fitting stage and a further 4½ hours to completion—demonstrate the significant increase in manufacturing time required to complete the UP when compared with a lamination approach. The amount of time required by the prosthetist would be comparable for the UP and the laminated prosthesis.

The material cost of the UP was £78 ($116*) compared with £76 ($113) for a laminated prosthesis. The minimum cost of equipment necessary for the manufacture of the UP is approximately £1600 ($2,380), based on production by one technician.

RECOMMENDED DEVELOPMENTS

Polypropylene has been widely used in orthotics for several years. Experience gained during this evaluation identified that shrinkage and distortion of polypropylene after draping does occur. This is not such a major problem in orthotics, where the orthosis does not encapsulate the limb and the interface forces are smaller. It can, however, present a major problem in prosthetics, since the polypropylene encapsulates the limb and an accurate fit is important to minimize interface forces.

In the manufacture of the UP it must be recognized that shrinkage occurs when hot polypropylene is formed over a rigid model. Tests with polypropylene on conical plaster casts confirmed that shrinkage occurs. The hot expanded polypropylene formed over a solid model cannot contract on cooling, creating stresses in the polypropylene. These stresses are relieved and shrinkage occurs when the polypropylene is removed from the model. A shrinkage of 1.5 percent could be anticipated in a socket resulting in circumference shrinkage of ¼ in. and socket length shrinkage of approximately ⅛ in.

*based on exchange rates of late August, 1986.

The external keel SACH foot was not designed for the UP, and, as a result, the soleplate of this foot is difficult to mate with the polypropylene keel of the UP. In particular, the adhesive bond at the interface between the flexible soleplate and the polypropylene keel is susceptible to failure. The incompatibility of these materials and the cyclic compressive load, applied during walking, results in the adhesive extruding between the surfaces.

The excessive calf diameter of the UP was noted by the prosthetists and consultant. This problem cannot be solved with the current UP design. The appearance of the cosmetic cover could be improved, however. During this evaluation the male amputees expressed little interest in cosmesis and no major effort to improve it was undertaken. Therefore, further research and development of the UP is deemed necessary before it is acceptable for routine supply.

DISCUSSION

Twenty-four amputees were fitted with a prosthesis, which was on average 30 percent lighter than their previous prosthesis. The majority of the amputees noticed that the UP was lighter and stated a preference for it. Care must be taken in interpreting the reason for this preference. The weight reduction was not the only factor which changed in supplying the UP. Amputees for this evaluation were selected from those attending review clinics. As a result, although the amputees were satisfied with the socket of their laminated prostheses, the clinic team might have recommended a socket change irrespective of the type of prosthesis supplied. The time since delivery of their laminate sockets varied from four months to four years, with an average of 14 months. These amputees may have been stating a preference for the improved fit of the new socket rather than the UP in general. It is suggested that an amputee supplied with a prosthesis which is comfortable with a well fitted socket will consider the prosthesis to be lighter than his previous poor fitting prosthesis, even if

both prostheses are of similar weight. This pitfall should be avoided in future evaluations of lightweight prostheses. Standard fitting procedure was followed. After alignment, the prosthesis was manufactured for immediate delivery. No intermediate alignments were undertaken with the amputee.

The response of the amputees were similar to those involved in the Philadelphia evaluation, apart from the Philadelphia amputees' dissatisfaction with foot function. In practice, the UP did not extend the range of activities of the amputees involved in the evaluation. There was no significant increase in the amount of time the amputees wore the UP or significant change in their activity patterns. This may be because this group of established amputees have adopted a lifestyle which is not influenced by the weight of the prosthesis. The weight of shoes worn by normal subjects does not affect their lifestyle. The UP might, however, provide an increased potential which would benefit the very inactive amputees.

Following the completion of the clinical evaluation, all amputees were supplied with comfortable resin laminated prostheses.

Questionnaires, irrespective of careful phrasing of questions, are not an ideal way to undertake a clinical evaluation. Extensive scientific studies of energy consumption and activities need to be completed to confirm the philosophy of a lightweight prosthesis.

Field trials of a UP have been completed satisfactorily in England. This particular UP differs in manufacturing procedure from the UP evaluated in Glasgow and also in that cuff suspension was adopted. There have been no published detailed comments from the clinic teams involved in these field trials.

CONCLUSIONS

Two conclusions are evident:

- The amputees preferred the UP
- The clinic team considered the UP inferior to the resin laminated prosthesis.

The second conclusion may have been influenced by the significant manufacturing problems encountered at the start of this evaluation. The clinic team considers the obvious weight reduction of the UP and acceptability to the amputee overshadowed by its poor cosmesis, possibility of socket shrinkage, poor attachment of flexible soleplate to the polypropylene keel, and general lack of confidence in the repeatability of production.

AUTHORS

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