*Prosthetics and Orthotics International, 1984, 8, 21–28*

# Potential problems of manufacture and fitting of polypropylene ultralightweight below-knee prostheses

P. CONVERY, D. JONES, J.HUGHES and G. WHITEFIELD*

*National Centre for Training and Education in Prosthetics and Orthotics, Glasgow*
**Orthopaedic Department, Southern General Hospital, Glasgow*

**Abstract**
The clinical evaluation of an ultralightweight polypropylene below-knee prosthesis conducted by the University of Strathclyde identified a number of potential problems which can arise from the use of polypropylene. This paper describes the problems associated with manufacture, loss of alignment and fitting, and indicates handling techniques to minimize these problems.

## Introduction

The concept of an ultralightweight below-knee (BK) prosthesis was developed at the Moss Rehabilitation Hospital (MRH) (Wilson and Stills, 1976; Wilson et al, 1978) and at the Rancho Los Amigos Hospital (RLAH) (Quigley et al, 1977). The original MRH design incorporated a completely hollow polypropylene foot extending to the toes and a SACH type heel wedge. In the RLAH design, an external keel SACH foot was chosen with the keel portion replaced by a hollow polypropylene shell. Other institutions around the world have introduced modifications to these designs.

The primary expectation when these ultralightweight limbs are prescribed is that the metabolic energy requirement of the amputee will be minimized whilst keeping a high quality of individual limb supply. With persons who became amputees due to peripheral vascular disease, a reduction in energy expenditure would be desirable. However, the significance of the weight saving has not been demonstrated in clinical results so far. Furthermore, these designs have not gained widespread acceptance because of difficulty in fabrication and doubts regarding durability and strength (Leimkuehler, 1982).

All correspondence to be addressed to Mr. P. Convery, National Centre for Training and Education in Prosthethics and Orthotics, Curran Building, University of Strathclyde, 131 St. James' Road, Glasgow G4 0LS, Scotland.

The National Centre for Training and Education in Prosthetics and Orthotics has been conducting a clinical evaluation of an ultralightweight BK prosthesis. Before providing these limbs to evaluate their relative merits, it was essential to be able to manufacture them to acceptable standards. An array of manufacturing problems delayed progress to the clinical trial phase. This paper describes the method of problem identification of the currently used design and outlines the potential problems which can arise from the use of polypropylene, indicating the necessary handling techniques.

## Problem identification

As will be described, the final limb design incorporates a supracondylar, polypropylene socket with a soft Pe-Lite liner. The socket is mated to a hollow polypropylene calf and keel which is bonded to the flexible soleplate of an Otto Bock IS19 foot. A cosmetic cover is fitted.

"Success" of manufacture was judged by the quality of socket fit, and a patient gait and fitting described as satisfactory. The dimensional stability or "alignment" of each test limb was monitored by using a three dimensional measurement jig (Berme et al, 1978). This jig (Fig. 1) was used to track the positions, in three dimensions, of reference points placed in arbitrary positions on the limbs. By observing the relative movement of these points at every stage of manufacture, the factors contributing to loss of alignment were identified and systematically dealt with.

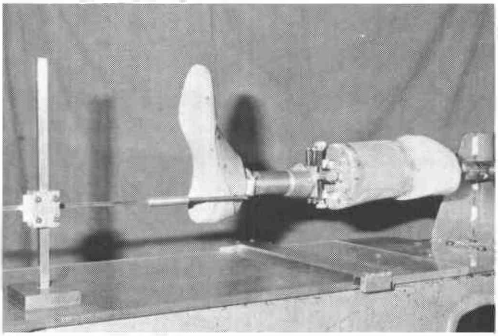

Fig. 1. Alignment measurement jig.

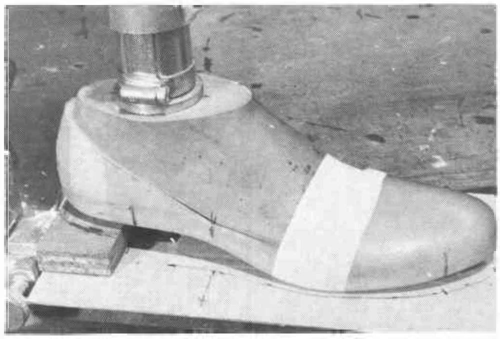

Fig. 2. Transfer jig base with profile plate in position.

**Manufacture of the final limb design**

The process starts with a suitably rectified supracondylar BK cast over which a Pe-Lite liner is formed. The socket is formed by draping a hot polypropylene sheet over the cast and liner with vacuum assistance. Any excess material is trimmed off leaving a web of about 3cm. The result of this process is a socket with a posterior seam and a Pe-Lite liner. Build-ups on the liner in the supracondylar area provide for suspension of the limb.

A Pedilen foam extension is formed on the end of the socket ready for the attachment of the alignment unit. An Otto Bock IS19 foot is used. The keel and soleplates are separated, the breakpoints are marked and matched up and the soleplate is then reattached. The limb is now ready for fitting.

Following fitting, the limb minus the keel and soleplate is secured in a Hosmer vertical transfer jig at the ankle adaptor. A mandrel is inserted in the socket parallel to the axial guide and fixed in place with plaster of Paris. All the jig adjustment screws can be locked and the overall axial length of the limb can be read on the jig scale. The ankle adaptor can then be released, the foot temporarily replaced and a profile plate positioned as shown (Fig. 2). The soleplate and keel positions, and in particular the keel breakpoints, are traced onto this plate. The profile plate is then removed. The keel is removed and the ankle adaptor is reattached to the jig base. Transfer out of the alignment unit and tube can now take place.

The foaming of the calf section can now proceed and is facilitated by the use of an ankle block with a steel reinforcing tube. As will be described later, this was required to prevent loss of alignment. The effective length of the prosthesis is increased by some 4 to 5mm to compensate for problems created by polypropylene drape of the calf and keel. The foamed calf is dressed and realigned with the keel.

A 5mm sheet is introduced between the keel and soleplate to allow for the polypropylene drape. The keel trim line is marked in preparation for the dressing of the anterior and dorsal portion of the keel. The final shaping of the foam calf allows for the additional thickness of the polypropylene which can now be draped over it with vacuum assistance. As will be described later the hot polypropylene creates a shrinkage of the foam calf section. The increased axial allowance of 4 to 5 mm referred to earlier was chosen after monitoring the shrinkage of a number of sample prostheses.

The cool polypropylene prosthesis can now be split at the posterior seam and the foamed calf removed. The socket and liner are thereby recovered. The vertical transfer jig is now used with the profile plate repositioned to minimize alignment errors during welding of the socket to the hollow polypropylene calf (Fig. 3). Tack welds are first used in anterior and posterior, followed by medial and lateral positions. Welding of the plantar and posterior seam can now be completed. The profile plate is used as a final check of the alignment.

After dressing the weld areas, it remains to match and bond the keel to the soleplate. The reference marks for the breakpoint are used to achieve this. Some care must be taken because a small error here has a significant effect on the final alignment.

The process which has been briefly described

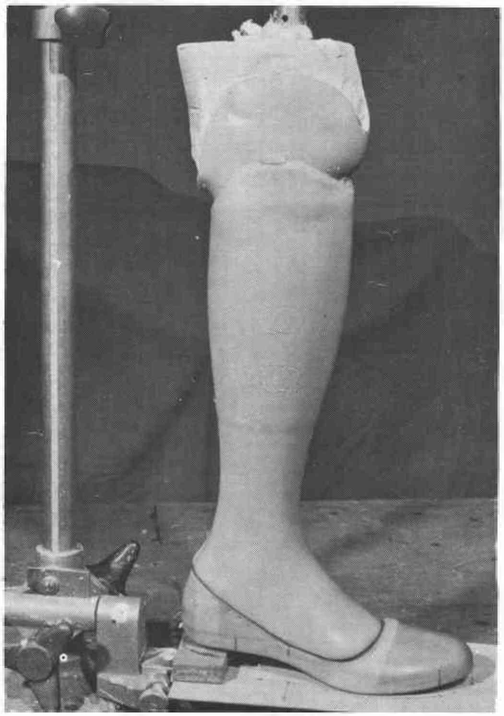

Fig. 3. Calf section tack welded to socket in vertical transfer jig.

evolved from a systematic identification and elimination of errors.

A detailed manual of the manufacturing method is available from the authors (Ballantyne et al, 1983).

**Manufacture and fitting problems**

*Socket brim flexibility*

Initially the ultralightweight BK prosthesis was manufactured with a 3mm thick polypropylene socket and a 4.5mm thick polypropylene calf. These dimensions were based on satisfactory static load tests. However, during fittings of the first amputees, the clinic team noted that the excessive flexibility of the medio-lateral brim of the supracondylar socket prevented the completion of an adequate dynamic alignment. All subsequent prostheses were manufactured with a 4.5mm thick polypropylene socket.

*Short keel*

The keel of a standard SACH foot extends forward to the toe-break. If 4mm is removed from the total surface of the keel to allow for the drape of the 4.5mm thick polypropylene, the keel no longer extends so far forward. Initially the prostheses for alignment were supplied with an undersize keel on a normal size soleplate. Alignment problems were encountered with the first three prostheses in that the prosthetist had to compensate for the short keel by alignment adjustments.

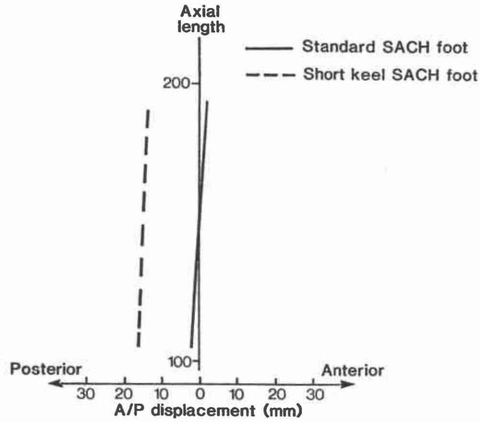


Fig. 4. Socket axis displacement. Standard and short keel SACH foot compared.

To confirm these alignment adjustments, the alignment measuring jig was used to monitor the positions accurately, in three dimensions, of reference points placed on the prosthesis. The first three amputees were aligned first with a standard SACH foot and then with a SACH foot with an external short keel. Figure 4 illustrates a typical alignment adjustment necessary to compensate for the short keel. The clinic team considered the external short keel foot unacceptable for a clinical evaluation of an ultralightweight prosthesis.

The Otto Bock external keel IS19 foot has a keel of suitable length and all surfaces of the keel are 3mm undersize except the surface in contact with the soleplate. All subsequent prostheses were aligned with Otto Bock IS19 feet.

*Poor socket fit*

The next manufacturing problem occurred at delivery of the finished prostheses. Amputees were unable to don the prostheses due to shrinkage of the medio-lateral socket brim dimensions. The slight flexibility of the socket brim at the alignment stage apparently concealed the problem at that point. However, welding the polypropylene calf section to the socket around the socket brim created a very rigid socket. Medio-lateral socket brim shrinkage was of the order of 3mm.

Using a series of casts and adopting different manufacturing procedures, the socket dimensions were monitored to establish potential causes of the shrinkage problem. Two factors were observed to contribute to medio-lateral socket brim-shrinkage:

(a) a high vacuum,
(b) quickly quenching the draped polypropylene in cold water.

The manufacture of all subsequent prostheses was modified by:

1. reducing the applied vacuum from 560mm (22in) Hg to 400mm (15in) Hg,
2. excluding the cold water quench from the manufacturing process,
3. welding the polypropylene calf section to the polypropylene socket at the patellar bar level, rather than around the supracondylar brim.

The socket dimensions of the next six amputees were monitored and found to be consistent throughout the manufacturing process.

*Shrinkage of polyurethane foam*

Shrinkage of polyurethane foam occurs when this is draped with polypropylene. A test model consisting of two steel discs, 130mm dia and 80mm dia connected with a 270mm length of aluminium tubing and jubilee clips was used to investigate this problem.

The Metrology Department of the University of Strathclyde scribed 10 reference marks on the outer faces of both discs. Ten axial dimensions were recorded.

The model was then clamped in the vertical transfer jig to enable the aluminium tubing to be transferred out. The cavity between the discs was filled with Otto Bock Pedilen 200 foam and the ten axial dimensions were recorded.

Prior to draping, the polypropylene foam adjacent to both discs was undercut to provide a good key between the polypropylene and the discs. The model was draped with 4.5mm thick polypropylene and allowed to cool overnight. The outer faces of the polypropylene were trimmed to expose the ten reference marks and ten axial dimensions were recorded.

The polypropylene was then split along its seam and removed from the model (a visual comparison between the polypropylene model and the foam model revealed a polypropylene shrinkage of approximately 2mm). The foam was removed from the model and the two discs were repositioned in the polypropylene grooves. The cut polypropylene edges were then dressed and welded along the axial seam. The final ten axial dimensions were recorded. The results of this investigation are shown in Figure 5. All recorded dimensions were measured accurately by the Metrology Department. The problem of foam shrinkage during transfer out of the alignment unit is now anticipated and an additional amount of foam is used to compensate.

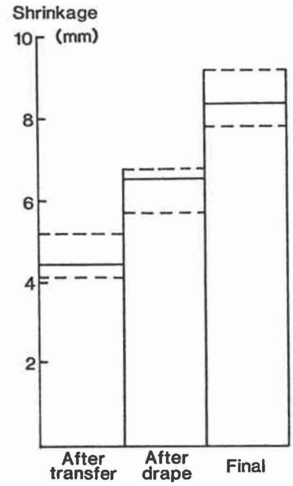


Fig. 5. Shrinkage of test model.

*Heating of polypropylene*

The temperature and rate of heating of the polypropylene sheet was found to be critical. This problem was investigated by welding thermocouples to the upper and lower surfaces of the polypropylene sheet while other thermocouples were free within the oven to monitor oven air temperature. The rate of heating in a convection type oven was found to be more satisfactory than that of an infra-red oven. An oven temperature of 175°C is recommended with a temperature control of ±3°C. The period of time for the polypropylene to be within the oven is dependent upon a number of factors:

a) the room temperature,
b) the thickness of polypropylene sheet,
c) type of polypropylene.

It is recommended that a small sample of similar thickness natural polypropylene is placed in the coolest spot in the oven; when this small sample becomes transparent then the polypropylene sheet is ready for drape. This technique is especially recommended when tan coloured polypropylene sheet is used since there is no observable change in the tan coloured polypropylene when it is ready for drape.

*Grade of polypropylene*

Difficulties arose due to the lack of consistency of the polypropylene sheets supplied. Once a suitable grade of polypropylene is identified all future sheets ordered must correspond to that grade. In the present study extruded sheet of ICI block copolymers to grade GPE 102 with a tan coloured additive provided a suitable polypropylene.

*Soleplate/keel adhesive bond*

The bond between the flexible soleplate and the polypropylene keel of the first 18 polypropylene prostheses supplied during the clinical evaluation were found to be loose after a few weeks. This was particularly noticeable in the case of active amputees. The sole of the polypropylene keel was coated with a polypropylene primer and the bond was achieved with standard Evo-Stik contact adhesive.

The flexible soleplate and polypropylene keel of the last six polypropylene prostheses supplied during the clinical evaluation were bonded with a multipurpose hot melt adhesive, Evo-Stik Thermaflo 6820. This polypropylene based adhesive provides excellent adhesion initially with a degree of flexibility. However the combination of cyclic compressive loading together with the flexibility of the adhesive results in extrusion of the adhesive between the surfaces and subsequent breakdown of the bond.

This problem developed during the latter stages of the clinical evaluation and as a result has remained unsolved. The amputees participating in the clinical evaluation were transferred to conventionally manufactured prostheses.

**Loss of alignment**

*Hosmer vertical transfer jig (VFJ–100)*

This type of transfer jig is not commonly used in the U.K. The vertical transfer jig is recommended for manufacture of the ultralightweight BK polypropylene prosthesis because:

a) foaming of the calf section is easier,
b) with ankle plate modifications, loss of alignment is minimized.

A comparison of the vertical transfer jig and a horizontal transfer jig was carried out with respect to undesirable movements. Familiarity with the horizontal transfer jig may have minimized discrepancies in its use. In the vertical transfer jig the clamps are further apart, socket mandrel to ankle adaptor, compared with distal socket to ankle adaptor in the case of the horizontal transfer jig. Very large discrepancies can occur with the vertical transfer jig if at any one time more than one clamping screw is released and then tightened.

The following technique is recommended when using the vertical transfer jig:

a) the socket mandrel must be located parallel to the vertical column,
b) once the mandrel has been positioned inside the socket on the transfer jig, the transfer jig should only be disturbed for axial movements, i.e. only one clamping screw is released.

*Distortion of polyurethane foam*

The problem of shrinkage of polyurethane foam was discussed as a manufacturing problem. During alignment checks with the alignment measuring jig (Fig. 1) it was established that loss of alignment occurred.

Six alignment reference marks on the keel, 3 medial and 3 lateral, were monitored at each stage. Four types of polyurethane foam were investigated:

a) Otto Bock Pedilen 200 foam (Density: 150kg/m$^3$)
b) Otto Bock Pedilen 700 foam (High Density: 600kg/m$^3$)
c) Otto Bock Pedilen 200 foam with a steel strenthening tube between the ankle block and the polypropylene socket.
d) Baydur 6130V foam.

The results of this investigation (Fig. 6) indicate minimum distortion with Pedilen 2000 Foam with the steel tube. The steel tube was introduced to strengthen the foam calf.

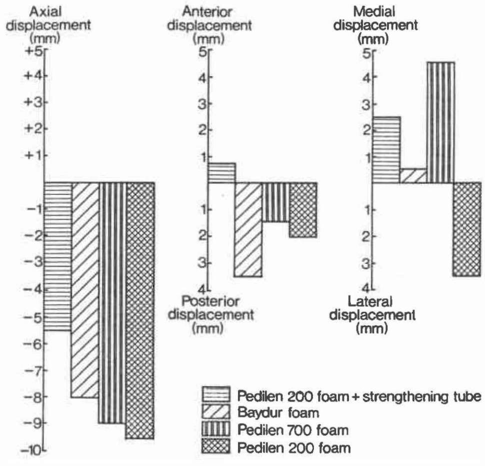


Fig. 6. Loss of alignment due to distortion of polyurethane foam.

*Mating of polypropylene calf and socket*

Although the polypropylene calf section has been draped over the socket, errors can occur when the calf and socket are relocated together for welding after removal of the polyurethane. A small error, eg one degree, produces approximately a 7mm displacement of the foot relative to the socket.

The following technique is recommended:

1. Reference marks are identified between Polyurethane keel and soleplate of the IS19 Sach Foot prior to alignment.
2. Immediately after alignment, with the mandrel located in the socket and clamped to the vertical transfer jig, the Otto Bock IS19 SACH foot is reattached to the prosthesis. A profile template (Fig. 2) is mounted on the base of the transfer jig by means of a bolt and dowel pin. The prosthesis is lowered onto the template and the profile is accurately traced on to the template with a modified set square.
3. The prosthesis is raised off the template. The soleplate is removed from the keel and the prosthesis is again lowered on to the template. The profile of the keel is likewise traced on to the template. The reference mark on the front of the keel is transferred to the profile template.
4. In order to correctly position the socket in the hollow polypropylene calf section, the socket mandrel is relocated in the vertical transfer jig and the polypropylene calf section is positioned on the profile template such that the polypropylene keel can be matched to the previous keel profile. The calf section is then tack-welded to the socket.
5. The plantar and posterior seam of the polypropylene calf section are initially tack welded. The plantar and posterior seam are finally welded and the weld areas dressed.
6. With the mandrel relocated in the vertical transfer jig and the soleplate accurately positioned on the profile plate, the prosthesis is lowered on to the soleplate. If the soleplate and the polypropylene keel do not match the tack welds connecting the socket and calf are broken. The calf section is finally welded to the socket with the soleplate and keel matching.
7. After completing weld of the socket and calf section, and attaching the soleplate, any loss of alignment can be checked by locating the mandrel in the vertical transfer jig and noting the position of the soleplate relative to the soleplate profile on the template.

The final alignment of the next three prostheses were checked with the alignment measuring jig to establish the accuracy of this technique. A total of 12 alignment reference marks, 6 keel and 6 soleplate on the medial and lateral sides of the foot were monitored at each stage. Figure 7 compares the alignment of these three prostheses with the average of those obtained from earlier prostheses. It must be noted that the 6 alignment reference marks on the keel will indicate an axial shrinkage of approximately 4mm. This caters for a 4mm thickness of polypropylene on the sole of the keel.

*Mating of keel and soleplate*

During the investigation of the socket/calf location the mating of the keel and soleplate was also investigated. If the sole of the polypropylene prosthesis is not a perfect match with the soleplate, a plantar or dorsiflexed foot can result. The external keel Otto Bock IS19 Foot, although 3mm undersize on the dorsal part of the keel, is supplied with the sole of the external keel matching the upper surface of the

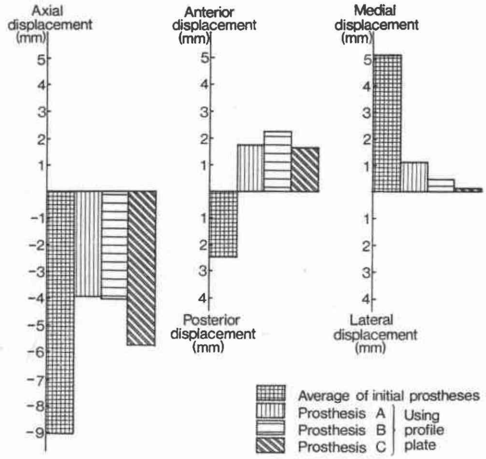


Fig. 7. Improved alignment during manufacture as a result of fabrication modifications.

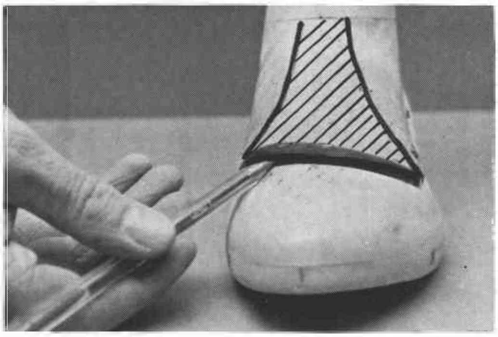

Fig. 8. Modification to polyurethane external keel prior to polypropylene drape.

flexible soleplate. The keel requires to be carefully modified such that when draped with 4.5mm thick polypropylene the sole of the polypropylene matches the upper surface of the flexible soleplate.

The following technique is recommended:

i) The polyurethane keel is not always located accurately in position on the soleplate on receipt from the manufacturers. Separate the keel and soleplate and then reposition the keel centrally on the soleplate. It may be that once positioned centrally the break points on the keel and soleplate do not coincide. If the keel break point is anterior to the soleplate break point, dress material off the sole of the keel. If the keel break point is posterior to the soleplate break, dress material off the sloping underside of the keel. Once keel and soleplate are mated correctly the two surfaces should be bonded.

ii) The polyurethane keel should be modified prior to draping by placing a 5mm thick sheet of Pe-Lite between keel and soleplate, marking the excess of foam as shown in Figure 8, and dressing the excess of foam on the dorsal surface of the keel.

iii) Careful attention must be paid when bonding the polypropylene calf section to the soleplate to ensure that the medial and lateral breakpoints match.

The correct mating of the keel and soleplate can be monitored by recording the anterior socket brim position relative to the toe of the soleplate immediately after alignment, and again at delivery. If the optimium position of the keel/soleplate is not achieved a plantar or dorsiflexed condition results. Moving the soleplate forward by 2mm relative to the keel introduces dorsiflexion which results in the anterior socket brim moving forward approximately 10mm relative to the soleplate toe. Conversely, moving the soleplate posterior 2mm relative to the keel introduces plantarflexion which results in the anterior socket brim moving posteriorly approximately 10mm relative to the soleplate toe.

## Conclusion

The level of interest in ultralightweight prosthesis designs is high but most designs which utilise polypropylene have proved difficult to manufacture to the satisfaction of the prosthetist. However steps can be taken to overcome these problems.

This paper identifies the problems which have led to the revised manufacturing technique.

The results of the clinical evaluation of this ultralightweight BK prosthesis will be published at a later date.

## Acknowledgement

The authors recognise the support of the Scottish Home and Health Department in conducting this work.

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