

## Memory plastics for prosthetic and orthotic applications

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### Abstract

Shrink forming prosthetic sockets from memory plastics offers several advantages over existing techniques. The manual skill requirement is reduced relative to drapeforming flat sheet while compared with the Rapidform process, the requirement for a purpose-built vacuum forming machine is eliminated.

Two methods for producing thermoplastic sockets from heat shrinkable preforms are described. One uses established heat shrink technology and crosslinked thermoplastics. The second based on blowmoulding simplifies preform manufacture relative to existing techniques by reducing it to a single stage operation. Shrink formed sockets have been produced for three application areas concerned with the lower limb namely load bearing sockets, flexible ISNY type and rigid transparent check sockets. Static testing has demonstrated the ability of shrink formed, load bearing sockets to surpass Philadelphia Static Load Levels (ISPO, 1978) while fatigue testing has indicated a capability for long service life.

### Introduction

Several recent advances in prosthetic practice and hardware have been achieved through innovative use of thermoplastics materials. In England and Wales for example thermoformed polypropylene (PP) load bearing sockets are gradually replacing the traditional types based on fibre reinforced thermosetting plastics (FRP). Manufacturing time is reduced and the overall process is simpler and cleaner since use of liquid matrix resins such as acrylic and polyester, with their associated problems of

storage and handling, are avoided. Patients have welcomed the increased comfort of polypropylene sockets arising from their greater flexibility relative to FRP sockets. The establishment of ISNY type sockets and fitting techniques for below-knee (BK) (Fishman et al, 1986) above-knee (AK) (Kristinsson, 1983; Pritham et al, 1985) and below-elbow (Supan, 1987) prostheses has further extended thermoplastics usage. In the ISNY system a flexible thermoplastic socket made from low density polyethylene (LDPE) or clear Surlyn lonomer is supported in a load bearing laminated frame which transmits patient loading through the prosthesis to the floor. The advantages of the ISNY system over conventional sockets are said to include enhanced patient comfort and sensory feedback due to the lightness, flexibility and coolness of the thin socket. Impact loading on the residual limb during stance phase is also reduced by deflection of the flexible socket (Fishman et al, 1986). A third and expanding area of thermoplastics application in prosthetics practice is the use of Transparent Check Sockets to improve socket fit and thereby patient comfort (Abrahamson et al, 1987).

One of the earliest investigations of socket fabrication from thermoplastics was carried out in 1970 at Rancho Los Amigos Hospital by Mooney and Snelson (1972). A vacuum forming technique using heat softened polycarbonate sheet was used to produce transparent check sockets over a rectified plaster cast of a patient's amputation stump. Vacuum forming of sheet thermoplastic is a widely used long established technique for producing thin walled formings from positive moulds. However socket production over plaster casts requires extensive stretching or drawing of heated sheet which can cause problems of web formation and thinning in the finished socket. The interesting point about the

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technique developed at Ranchos Los Amigos, which is different to conventional vacuum forming is that the hot plastic sheet (9mm thick) was allowed to sag under its own weight to a distance of approximately 2/3rd the length of the positive cast forming a cone or bubble. This was then inverted resulting in a preform which was drawn down over the positive model before vacuum was applied. The preform is of course closer in dimensions to the positive stump model than the sheet form and the act of drawing the bulbous preform down over the cast further adjusts the shape so that it is even closer to the finished product. The result of this approach is that webbing due to excess material associated with the drawing process from flat sheet is reduced. This technique is termed drape forming in the prosthetics industry and is widely used nowadays for producing thermoplastic sockets in a variety of materials. (In conventional thermoforming the problem of large draw ratios is often approached by using "plug assist" or "bubble assist" to pre-stretch the hot plastic sheet into a preform using a solid intermediate former or air pressure respectively.)

The preform approach to thermoplastic socket production lies at the centre of three manufacturing techniques which have been developed over the last few years namely the Rapidform technique (Knox et al, 1982) Otto Bock's Orthoglass cone system (Pike and Black, 1982) and latterly the heat shrink technique (Hagglund, 1983; Otto Bock; Bertelee, 1986). All represent attempts to control more precisely the process variables which can affect socket performance to reduce or eliminate the manual skill content associated with socket forming from flat sheet and to reduce socket fabrication times.

The Rapidform technique makes use of a bell shaped plastic preform "substantially corresponding to the (socket) moulding" (Knox et al, 1982). This preform is securely clamped and heated in the oven of a semi-automatic purpose built Rapidform vacuum forming machine. A plaster cast of the patient's stump is then driven into the softened preform by means of a mechanical ram after a preset heating time. The preform is invariably shorter than the cast so that stretching of the preform occurs during the forming operation. Vacuum is then applied to draw the preform material into contact with

the cast and is maintained during cooling and solidification of the plastic. The plaster is removed to leave a semi-finished socket. The Rapidform process overcomes the problems associated with large scale deformation of plastic sheet by stretching a standard shaped, heated preform by means of the plaster cast itself to effect an intermediate shape change. In this way the dimensions of the original preform are adjusted during stretching and conform more closely to each individual plaster cast before vacuum is applied. Web formation due to excess material around the cast is thereby reduced. Otto Bock Orthopaedic Industries use a similar technique based on conical acrylic preforms for producing check sockets (Pike and Black, 1982). The cone is heated to soften it, then pulled by hand over a plaster model before vacuum is applied to ensure good following of the contour by the thermoplastic.

It is well known that certain thermoplastics have "memory properties" such that on stretching under certain conditions and cooling in the stretched form they will retain the stretched form until heated to a particular temperature whereupon shrinkage will occur unless the plastic is restrained. Heat shrink techniques for thermoplastic socket production have attracted the attention of commercial organisations such as LIC (Hagglund, 1982) and Otto Bock and researchers in the prosthetics field (Bertelee, 1986). In the LIC method a positive cast of a patient's stump is positioned inside a heat shrinkable plastic preform which is subsequently heated to soften it and to cause it to shrink so that it conforms closely to the cast contours. Final shaping is performed by applying a vacuum so that the hot plastic is drawn into contact with the cast and is maintained while the plastic cools and hardens. Otto Bock have recently started marketing a Pedilon thermoplastic socket-shaped preform which is shrunk directly onto the patient's stump to produce a temporary above-knee (AK) socket without vacuum application.

The production of thermoplastic sockets using shrink fit techniques is not new, A UK patent was granted to C. H. Davis in 1932 which describes the production of sockets from tubes of cellulosic material which had been softened in hot water, expanded over a mandrel and cooled to retain the expanded form. This conical open ended preform was subsequently



shrunk onto a plaster replica of the patient's stump by re-immersing it in hot water. Vacuum application was not recommended to ensure good contour following presumably since the author mentions that the shrunken preform "becomes an exact duplicate of the cast element". The author also reminds the reader of perhaps the very first use of shrink fit techniques for producing sockets for artificial limbs. Leather was saturated with water and stretched around the cast, hammered to bring out indentations essential to the fit of a socket then dried. On drying the leather contracts to provide good socket fit. LIC's method updates, only in its use of modern thermoplastics and final vacuum shaping, that described by C. H. Davis in 1932 who must be credited for his innovative use of the reversion shrinkage characteristics of plastics.

The manufacture of thermoplastic sockets for artificial limbs from heat shrinkable preforms is potentially simpler than drape forming from flat sheet as well as reducing the manual skill content of the process. In addition, heating time could be reduced since preform thickness is less than the sheet thickness used in drapeforming and the resulting socket should exhibit greater uniformity of wall thickness.

Compared with the Rapidform process shrinkforming eliminates the requirement for a purpose built vacuum forming machine.

The aim of this paper is to describe two methods for producing heat shrinkable, thermoplastic preforms for socket manufacture, to identify their heat shrinkage behaviour and to display the performance of heat shrink sockets under laboratory testing conditions. One method uses established heat shrink technology and crosslinked thermoplastics. The second technique based on blow moulding simplifies preform manufacture by reducing it to a single stage operation. Existing techniques first involve production of an intermediate moulding which is then reheated and expanded to give the heat shrinkable preform.

### **Manufacture of heat shrink preforms**

#### *Crosslinked thermoplastic preforms*

Semi-crystalline thermoplastics consist of crystalline and non-crystalline (amorphous) phases. When heated above the crystalline melting point, the polymer softens and flows readily. However, if the same polymer is

subjected to ionizing radiation, crosslinks form between the individual polymeric molecules. When the crosslinked polymer is heated above the crystalline melting point, the crystalline areas melt but the polymer itself does not flow since it possesses form-stability due to the presence of crosslinks. At this stage the polymer is similar to an elastomer. If the shape of the material is changed, it will return to its original shape. However, if the polymer is held in a new shape whilst above the crystalline melting point, and then allowed to cool in this condition, crystalline areas will re-form. Crystalline forces will then keep the crosslinked polymer from returning (shrinking) to its original shape. Once the polymer is reheated above its melting point, thereby eliminating the crystalline forces, the elastic forces will cause it to recover back to its original form.

Thermoplastics suitable for radiation crosslinking are initially moulded to give an "intermediate" preform using standard manufacturing processes such as extrusion, injection moulding and blow moulding. The material is next subjected to high energy electron-beam irradiation. This causes some molecules to break down (chain scission) and crosslinks to form between molecules. The former is detrimental to the mechanical properties of the polymer and is suppressed in a limited number of polymers with additives. For this reason, the materials available are generally limited to grades of polyethylene, PVC and fluoropolymers. The crosslinked intermediate preform is then heated above the melting point, expanded to the required diameter (generally 2 to 3 times the original diameter), and cooled to room temperature in the expanded form. When the object to be covered is placed inside the heat-shrinkable moulding and the moulding heated, it will shrink around and conform to the object as it attempts to return to its original crosslinked shape.

A heat shrink preform suitable for BK sockets was produced by Raychem, the size being based upon the largest IPOS casting brims (Fig. 1). These preforms are also suitable for small AK sockets, the development of an exoskeletal prosthesis and some orthotic applications. A smaller intermediate preform was first blow moulded, irradiated and then expanded to the final preform shape.

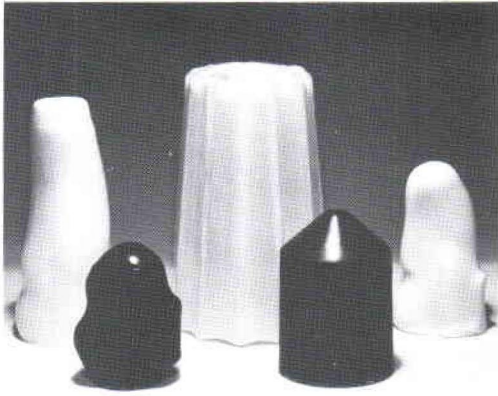


Fig. 1 Crosslinked HDPE preforms and shrink formed sockets

A grade of High Density Polyethylene (HDPE) was selected for load bearing structure. Potentially suitable thermoplastics are available for flexible socket applications (such as ISNY).

#### *Shrink forming technique*

Generally, an object to be covered by heat shrinking plastics is simply inserted inside the preform which is then heated to cause it to shrink and conform to the contours of the object. The simplest method for producing heat shrink sockets is to place a preform over a plaster cast of the stump and insert the set up into an oven maintained at a particular temperature. This approach when applied to PELite foam lined plaster casts caused unacceptable thinning of the liner due to the large forces of retraction developed by the preform, aggravated by softening of the polyethylene foam liner itself during the heating process. Direct forming onto wet plaster casts increased preform heating time to an hour due to a "cooling by evaporation" effect. A particular shrink forming technique was therefore developed for crosslinked HDPE preforms which eliminated excessive thinning of the PELite liner and at the same time yielded significant process time savings by increasing the efficiency of heat transfer to the preform. In addition the technique established could be applied to wet casts.

The preform is positioned over an open ended, conical, thin sheet metal former for heating to translucency in an oven. The metal former restrains the preform from shrinking

and also reduces heating time to approximately seven minutes. Shrink forming is performed outside the oven by locating the metal former/preform system over a "cold" lined cast then withdrawing the metal former so that the heat softened preform shrinks onto the cast. Vacuum application improves replication of the cast contours by the thermoplastic. The plastic is allowed to cool to room temperature before removing the plaster to leave a semi-finished socket. By this means, the lined cast is not itself heated during the preform heating stage and excessive thinning of the liner is avoided. Wet unlined casts can therefore also be used without the need for barrier coatings to prevent water vapour transmission.

Some examples of sockets produced from crosslinked HDPE are shown in Figure 1. The small black socket in the foreground was produced from a Raychem End Cap and illustrates the scope for size and colour variation using this heat shrink process. As mentioned above heating time has been reduced to seven minutes a significant time saving compared with the time for drapeforming structural PP sockets (22 minutes) and shrink forming of "reversion" type preforms (15 minutes) mentioned below.

#### *Reversion type preforms*

The hot drawing behaviour of thermoplastics such as polypropylene, polyethylene, polystyrene and ABS is sensitive to process conditions such as temperature and draw speed. Large and uniform sample extensions can readily be obtained if the draw temperature is controlled. Upon reheating the stretched samples also exhibit high shrinkage — reversion shrinkage. Basically low draw temperatures limit the extent of draw and increase the required extensional force while too high a temperature results in non-uniform or neck draw and frequent sample fracture. Sample extension is limited by the decrease in melt viscosity or melt strength at elevated temperatures and by reduced chain mobility at low temperatures. The visco-elastic character of the thermoplastic at "optimum" draw temperatures, described in terms of a chain entanglement model, promotes chain extension and orientation during draw and consequently high recovery or shrinkage when the stretched and cooled sample is reheated.



Blow moulded preforms have been produced under a set of conditions which promote orientation and chain extension, so that associated large scale reversion shrinkage can be used to produce a socket or load bearing shank for instance over a positive model (Figs. 2-5). Existing methods for producing heat shrinkable preforms include two or more stages comprising production of a smaller intermediate preform by injection moulding (Hagglund, 1983) followed by a separate reheating and expansion stage to give the final heat shrinkable preform. In the case of crosslinked preforms mentioned earlier, the intermediate preform also undergoes a crosslinking process prior to reheating and expansion to the finished form. Production of heat shrinkable preforms by blowmoulding — designated reversion type preforms in this document — is a single stage operation which markedly simplifies preform production. The parison (or extruded tube of molten plastic) produced by the blowmoulding machine is expanded to the final preform dimensions defined by the mould cavity and cooled by contact with the mould surface to retain the moulded geometry. Cooling of an intermediate preform to room temperature then reheating prior to expansion is eliminated.

#### Shrink forming

Two types of blow moulded thermoplastic preforms have been produced for BK and AK socket applications respectively, exhibiting a degree of reversion shrinkage which enables them to be heat shrunk over positive models of the residual limb (Figs. 2-5). Process conditions and materials have been investigated for the three main socket application areas mentioned earlier namely flexible sockets, structural or

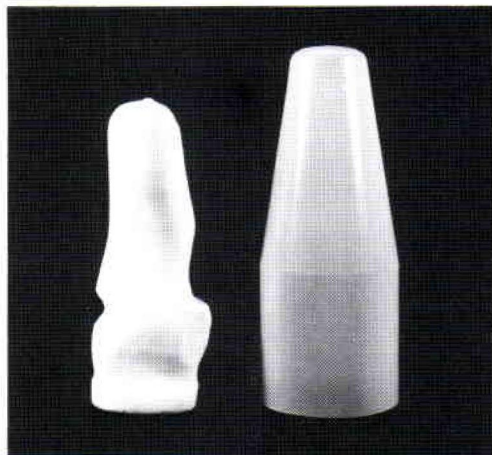


Fig. 2 LDPE reversion type preform and socket forming

load bearing sockets and rigid, transparent check sockets. Typical shrink forming conditions are presented in Table 1.

Shrink forming is a relatively simple operation. A preform cut to the required length is placed over the rectified cast and the assembly is placed in an oven maintained at the required temperature. In general the preform is observed to shrink once melting or adequate heat softening has occurred and conforms closely to the cast surface aided by an element of drapeforming of the softened thermoplastic. Replication of the cast contours is improved by vacuum application. Once the thermoplastic has cooled sufficiently to retain the thermoformed shape, the plaster cast is removed to leave the semi-finished socket.

For polypropylene preforms in particular, casts must be dry or a suitable barrier layer must be applied to the cast to prevent water

Table 1. Typical shrink forming and drapeforming conditions

Material	SHRINK			DRAPE			Reference
	Preform wall thickness (mm)	Oven temp (°C)	Heating time (minutes)	Sheet thickness (mm)	Oven temp (°C)	Heating time (minutes)	
Polypropylene	2	210	15	12	240	22	Charles A. Blatchford
Crosslinked HDPE	—	210	7	—	—	—	
LDPE	1.4	170	8	6	165-177	8-10	New York University
Surlyn	1.4	170	8	6	175-204	7	Stills and Wilson
Rigid, transparent	2	210	8	3-4.5	150	6	Durr-Fillauer Medical Inc.

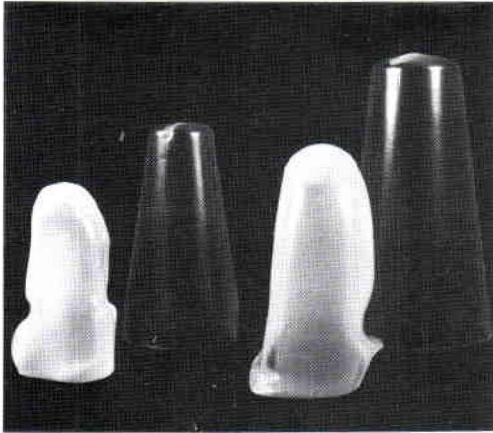


Fig. 3 Surlyn reversion type preforms and shrink formed sockets

vapour transmission during the heating process and consequently preform cooling as mentioned above.

LDPE and Surlyn preforms intended for socket applications of the ISNY type are shown (Figs. 2 and 3). Three grades of Surlyn have been investigated spanning a range of Flexural Modulus from  $90\text{MN/m}^2$  to  $380\text{MN/m}^2$ . The prosthetist could therefore be offered a selection of materials of different flexibility. It will be noticed that the Surlyn socket formings are not clear like the starting preform. This is due to the stockinette impression on the inner surface of the forming and slow cooling of the thermoplastic which promotes the development of larger crystals. Nonetheless the formings are translucent and still enable observation of the

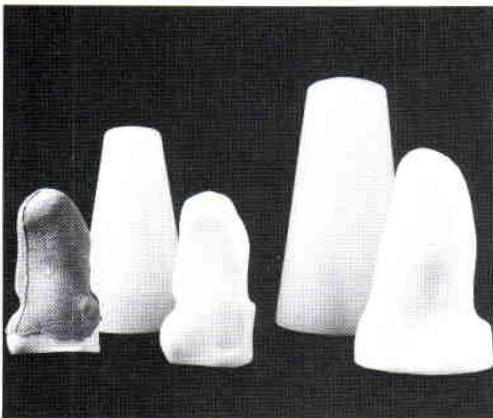


Fig. 4 Polypropylene reversion type preforms and shrink formed sockets

patient's stump through the socket wall for checking socket fit.

The long BK forming in LDPE shown in Figure 2 was produced over a computer rectified and machined cast, illustrating the size and shape range of sockets which can be produced using reversion type preforms. This particular forming is to be incorporated in a BK, ISNY socket.

Shrink formed polypropylene sockets produced from reversion type, blow moulded preforms are shown in Figure 4 and are intended for load bearing socket applications. To the left in Figure 4 is a polypropylene socket with a bonded fabric covering which was applied to the molten surface of the shrink forming. This technique, based on bicomponent fabrics described in an earlier publication (Coombes et al, 1985) enables shrink formed polypropylene sockets to be adhesively bonded to artificial limb systems if required.

Reversion shrinkage preforms suitable for rigid transparent check socket applications are shown in Figure 5 with examples of BK and AK socket formings.

The process conditions listed in Table 1 indicate typical heating times for shrink forming reversion type preforms compared with drape forming. Significant time savings are achievable for polypropylene. The main advantages of shrinkforming over drapeforming for Surlyn,



Fig.5 Rigid, transparent check sockets and reversion type preforms



LDPE and rigid transparent materials would be the reduced manual skill requirement which could also result in greater uniformity of socket wall thickness. For example Kawamura and Kawamura (1986) quote a wall thickness range of 1.2–2.5mm for LDPE, AK sockets. Measurements of wall thickness taken from a shrink formed LDPE, AK socket generally ranged from 1.7–2.3mm although the thickness at the extreme distal end of the socket increased to 3.4mm. A further advantage of reversion type preforms is that the pre-shrink wall thickness can be easily adjusted during processing so that a minimum value of post shrink wall thickness can be assured in the socket.

### Mechanical testing

The mechanical testing procedure followed the Philadelphia recommendations (ISPO, 1978). A Static Load Level was defined during the Philadelphia proceedings such that application of a compressive load of 2.5kN which produces a bending moment at knee and ankle of 230Nm and 250Nm respectively should not produce permanent deformation of the limb structure. Shrink form sockets were tested using an offset loading arrangement to apply AP bending moments to the test sample. Equal offsets of 100mm from the load axis were arranged at proximal and distal ends using pivotted extension bars. At the distal end the test fixture was bolted directly to the socket via an alignment base using a single M10 bolt fixing. Loading was transmitted to the socket by means of a loading bar embedded in a plaster of Paris stump replica. A 20mm thick pad of Plastazote polyethylene foam was located below the plaster to simulate the foam build-up which is normally bonded to the distal end of soft foam socket liners. (This blends the cast contours

with the metallic cup incorporated in socket systems based on bolt fixings.) Sockets were static tested using a Zwick Universal Testing Machine and a loading rate of 100mm/min.

Fatigue testing was also carried out on shrink formed sockets attached to Roelite alignment bases. The same system of offset loading described above was used to apply an AP bending moment of 140 Nm at distal and proximal ends of the test sample. The Philadelphia recommended bending moments for testing BK prostheses are 140 Nm and 120 Nm at ankle and knee respectively generated by a 135kN compressive force. The test frequency was 1Hz.

### Crosslinked HDPE sockets

Static failure loads obtained for crosslinked HDPE sockets connected to Roelite and Endolite alignment systems are shown in Table 2. Maximum loads are limited by buckling of the socket wall in the anterior aspect and distortion of the distal end of the socket at the alignment device/socket interface which results in a levelling off of the load/displacement curve. Static failure loads vary from 2 to 5.5 kN depending on preform thickness and socket geometry. The effect of the latter variable is highlighted by the test results for sockets containing a 65mm and 75mm Roelite cup respectively where increased load bearing area at the socket distal end results in an increase of approximately 30% in failure load. The Philadelphia recommended Static Load Level for BK prostheses is 2.5 kN and the test results listed indicate that this value can be exceeded by sockets produced from crosslinked HDPE heat shrinkable preforms.

Fatigue testing of experimental sockets carried out under offset loading conditions to Philadelphia recommendations demonstrated

Table 2. Static failure loads for shrinkformed crosslinked HDPE sockets

Preform designation	Maximum recoverable wall thickness (mm)	Alignment system	Static failure load (kN)
Medium	3.5–3.7	Ultra Roelite: 65mm cup	2.08
Medium	3.5–3.7	Ultra Roelite: 75mm cup	2.62
Thick	4–4.5	Ultra Roelite: 65mm cup	2.76
Ultra thick	6.1–8.9	Endolite	5.52

#### Ultra Roelite system

65mm Roelite cup, Hanger code 202–U8 766  
75mm Roelite cup, Hanger code 204–U8 768  
Alignment base, Hanger code 50–U9 111

#### Endolite system

Socket plate/bolt assembly, Blatchford code 189305  
Upper alignment coupling, Blatchford code 189505

the long term durability of this particular memory plastic. Two sockets withstood cyclic loading to 1.4 and 1.9 million cycles respectively before cracking was observed at the distal end of sockets corresponding to the perimeter of the alignment device. Socket load bearing ability was not impaired despite crack growth over approximately 50% of the socket circumference.

#### *Reversion type PP sockets*

Test samples consisted of a shrink formed PP socket incorporating a 75mm diameter Roelite metal cup (Hanger Code 204-U8768) at the distal end. The socket was in turn attached to a Roelite alignment base (Hanger Code 50-U9111) using the four fixing bolts supplied with the kit.

Socket distortion in the anterior aspect limited the applied load to 2.4 kN in one case for polypropylene copolymer (nominal preform thickness of 2mm). A socket produced from polypropylene homopolymer (nominal preform wall thickness of 2mm) withstood a static load of 3.8 kN before distortion of the socket at the distal end produced a levelling-off of the load displacement curve. The higher static load value attained in the latter case reflects the higher flexural modulus of the homopolymer (1.7 GPa) relative to the copolymer (1.1 GPa). In the case of polypropylene copolymer there is scope for improvement of static test performance simply by increasing the preform wall thickness.

A fatigue of 2.4 million cycles was achieved for a PP copolymer socket attached to a Roelite base without visible deterioration of the socket. The test was terminated at this point. Two million loading cycles represents an expected service life of 5 years on the basis of Department of Health (England) test guidelines.

#### **Summary and conclusions**

The production of thermoplastic sockets from heat shrinkable preforms or memory plastics offers several advantages over existing techniques. Compared with the Rapidform process, shrink forming eliminates the requirement for a special purpose, thermoforming machine. Greater control over socket manufacture is achieved using heat shrinkable preforms relative to hand draping

from flat sheet since the degree of manual skill required is reduced. The two heat shrink techniques described in this paper extend both the range of manufacturing options and materials options which can be considered for prosthetic and orthotic applications. The use of crosslinked HDPE preforms for structural sockets offers significant time savings over drapeforming PP sheet (seven minutes compared with 22 minutes) and the potential range of materials available means that alternatives to LDPE and Surlyn could also be provided for flexible socket applications. The production of reversion type preforms in one operation by blowmoulding simplifies preform production with concomitant time and cost savings. Existing methods for producing heat shrink preforms, are based on reheating then expanding a smaller intermediate moulding. Production of crosslinked HDPE preforms also involves a crosslinking stage prior to reheating and expansion which increases further the cost of the preform. The versatility of the reversion method is underlined by its extension to flexible socket applications based on Surlyn and LDPE and rigid, transparent check sockets as well as PP load bearing sockets.

Mechanical testing to date has demonstrated that Philadelphia recommended load levels can be surpassed by shrink formed sockets produced from both crosslinked HDPE preforms and reversion type PP preforms albeit when attached to Roelite limb systems which employ a four bolt socket fixing. These shrink fit sockets can also be expected to exhibit long service life. Further laboratory and service testing are planned to assess patient acceptance and to evaluate the performance of shrink formed, load bearing sockets attached to prostheses by bolt fixings and adhesive bonding respectively. In addition other categories of shrink formed sockets namely flexible sockets and transparent check sockets are to be subjected to evaluation under laboratory and service conditions in collaboration with UK limb manufacturers. The results of these trials will be the subject of a future publication. Socket manufacture for the lower limb represents just one application of the heat shrink preforms described here to which can be added the production of load bearing shanks (Convery et al, 1984), orthoses such as drop foot splints, and spinal jackets and sockets for



upper limbs (Berger et al, 1986; Supan, 1987). The heat shrink technique is suited to all existing commercial operations and the emerging technologies based on Computer Aided Design/Computer Aided Manufacture (CAD/CAM).

### Acknowledgement

This work was funded by the U.K. Department of Health and Social Security as part of the programme of the Bioengineering Centre.

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