Prosthetics and Orthotics International, 1988, 12, 19–40

Development and testing of thermoplastic structural components for modular prostheses

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Abstract

The wider use of thermoplastic structural components in modular artificial limbs would enable their general properties of low density, corrosion resistance and mouldability and more specific properties of certain thermoplastics such as shock absorption, fatigue and wear resistance to be used to the advantage of patients and manufacturers. They provide an alternative to metal and carbon fibre reinforced resin systems.

Emphasis has been placed on the development of rotationally moulded Nylon 11 shank sections, using Philadelphia recommended load levels as the design criteria for structural integrity. Laboratory testing underlined the importance of fatigue testing of thermoplastic components since structural deterioration due to creep—a time dependent mechanical property of thermoplastics—can be ascertained in fatigue testing but would not be evident on the shorter timescale of the static test. Experimental below-knee prostheses incorporating suitably designed plastic shanks and alignment devices can withstand high static loads and exhibit long fatigue lifetimes in excess of 2 million cycles.

The shank design offered an opportunity for testing under service conditions the validity of the Philadelphia Static Load level (2.5 kN) since shank failure loads are around this figure. Patient trials of experimental prostheses based on various combinations of plastic shanks and alignment devices and conducted over 33 months indicate that the Static Load Level along with fatigue testing is a satisfactory test criterion for general service use of thermoplastic prosthetic components.

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Introduction

Although thermoplastics are accepted for socket production, relatively little use is made of them for the structural components of modular prostheses where their properties of lightweight, corrosion resistance, easy mouldability and shock absorption could be used to the advantage of patients and manufacturers. There are some notable exceptions such as the Seattle foot (Hithenberger, 1986) which incorporates an Acetal keel. The good spring characteristics of this material are used to advantage to provide an energy return function which has been welcomed enthusiastically by patients. An experimental prosthesis featuring several of the thermoplastic components which will be considered in the following text will illustrate further the scope for thermoplastics usage in artificial limbs (Fig. 1). Rapidform polypropylene sockets of the type shown have been described by Davies and Russell (1979). They have established an impressive service record in terms of patient comfort and durability. The experimental uniaxial ankle unit shown in Figure 1 was produced by machining from Nylon 66 with the eventual aim of production by injection moulding. Medial and lateral slots allow access to the fixing bolt for alignment adjustment while the good bearing properties of nylon enable a simple circlip fastening to be used for spindle retention. Magnesium alloy uniaxial ankle units on the other hand require the spindle to be locked to the unit to prevent wear. The four-jack alignment device at socket and foot level is produced from Nylon 66 and glass filled nylon. It is based on the Staros-Gardner alignment

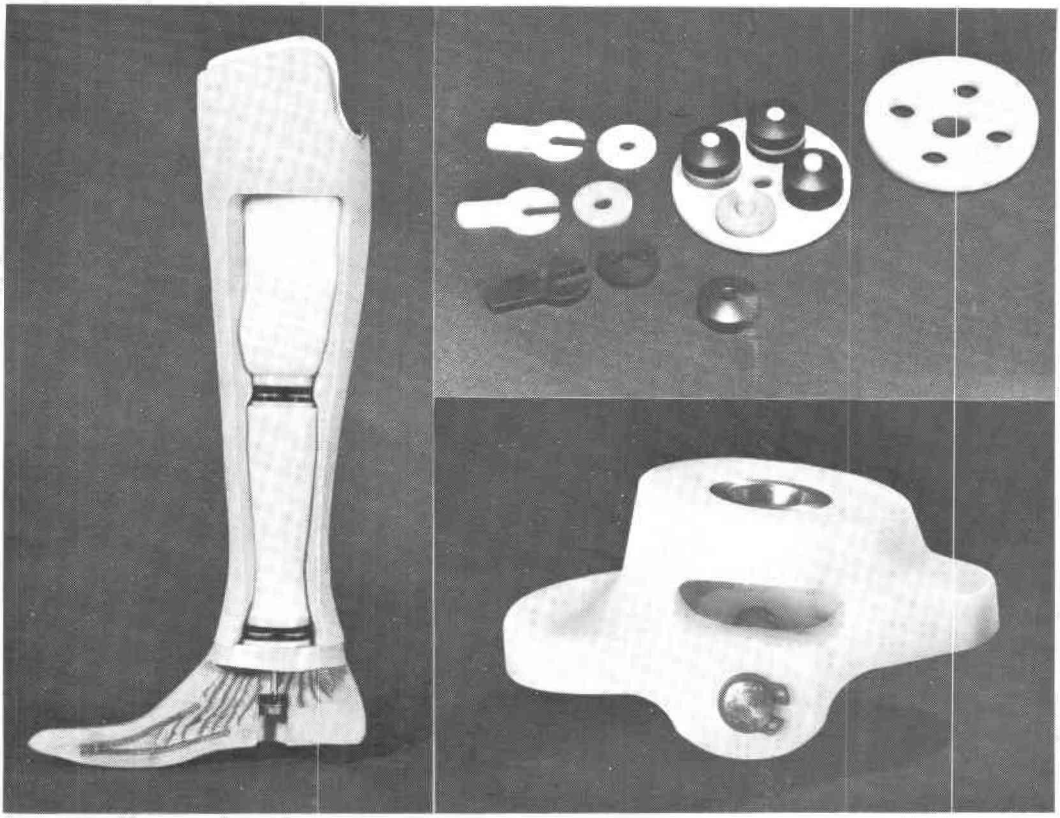

Fig. 1. Left, experimental prosthesis incorporating Rapidform polypropylene socket, rotationally moulded Nylon 11 shank and 4-jack alignment devices. Top right, 4-jack alignment device—component parts. Bottom right, uniaxial ankle unit produced from Nylon 66.

coupling, using the vertical travel of threaded jacking nuts along support columns to accomplish socket tilt. Colour coded spacers inserted below the nuts enable the alignment condition to be established and recorded with certainty. The 4-jack angulation device and slide module for linear adjustment of socket position relative to the shank have been described in detail elsewhere (Coombes et al, 1985a).

Rotational moulding is one production option for thermoplastic shank sections (Coombes et al, 1985b). The type shown in Figure 1 is hollow, rotationally moulded in Nylon 11 and incorporates metallic inserts at distal and proximal ends for single bolt fixing of socket and foot unit via the selected alignment device. These inserts are moulded in during processing and so avoid the need for a separate tube adaptor. The rotational moulding process is characterized by low costs of moulds and moulding machinery. This is advantageous since shank design changes can be readily accommodated at both prototype and production stages. A further advantage is that the wall thickness of mouldings can be varied to suit patient weight and activity level by simply adjusting the weight of starting material. Drawbacks of the method include long production times—30 minutes is not uncommon—and the limited range of thermoplastics which are suitable for rotational moulding.

The first part of this paper will detail the rotational moulding conditions found satisfactory for Nylon 11 shanks and the quality control procedure adopted for the product. The shank geometries used in both laboratory and service testing will be described together with the insert designs which gave long fatigue lifetimes. The successful insert designs which evolved are generally applicable to other thermoplastic structural components used in artificial limbs such as knee units, ankle and foot units.

Testing of shank sections, prosthesis sub assemblies and complete prostheses together with the results of patient trials are documented later with particular reference made to the applicability of Philadelphia standards (ISPO, 1978) as design criteria for structural integrity.

General process conditions for rotational moulding

Production of Nylon 11 shank sections by rotational moulding was outlined by Coombes et al (1985b). During the moulding operation, the shank mould containing a predetermined amount of thermoplastic powder is heated in an oven and rotated about two perpendicular axes in the conventional method so that the powder is tumbled over all mould surfaces. A layer of molten polymer forms at the mould wall and solidifies during the mould cooling stage to give the finished moulding. The system of rotational moulding developed at the Bioengineering Centre provides shank sections for patients on an individual basis. A mould is assembled from a set of low cost aluminium alloy mould segments which enable mould length to be varied by 1mm increments. The resultant mouldings are hollow and incorporate metallic inserts moulded-in at distal and proximal ends of the shank (Fig. 2).

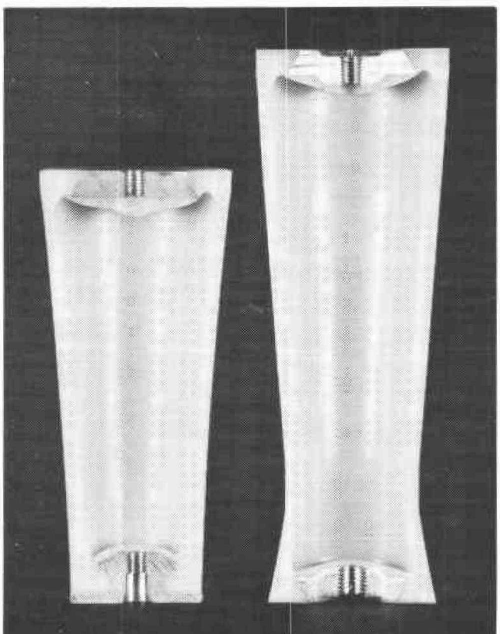

Fig. 2. Sectioned shank mouldings.

Double axis technique

The Bioengineering Centre's 'Autoform' rotational moulder is based on the conventional moulding method where rotation of the (shank) mould occurs on two perpendicular axes; the speed of rotation on both axes being controllable. The oven is electrically heated and thermostatically controlled. After the heating cycle, the oven retracts and the mould is cooled by an air blast of certain duration. Mould rotation continues during the cooling cycle. Typical process conditions are shown in Table 1. The rotation ratios listed (X is the rotation speed about the horizontal axis and Y is the rotation speed about the vertical axis) have been found to give an even wall thickness distribution and good insert encapsulation as illustrated in Figure 3. As a guide to powder weight requirements for the shank geometries under consideration, one subtracts 10g from the figure for shank length i.e. for a 200mm flared ankle shank, the weight of powder would be 190g. For the shorter more cylindrical shanks 20g is added to the figure for shank length.

The minimum shank length produced was 70mm using a nearly cylindrical mould (Fig. 3)—to increase the weight of starting powder.

Single axis technique

During the course of development of nylon shanks, it was found that a modification of the

Table 1. Recommended processing conditions for rotationally moulded nylon 11 shanks

Conventional double-axis technique			
Oven temperature		275°C	
Heating time		24 mins.	
Cooling time		14 mins.	
Mould rotation rate (rpm)	X-axis (horizontal)	Y-axis (vertical)	Shank length (mm)
	9–12	11	70–100
	10–13	11	100–180
	11–14	11	180+
Single-axis technique			
Oven temperature	360°C		
Stage 1 heating time	22 mins		
Stage 2 heating time	3 mins		
Cooling time	12 mins		
Mould rotation rate	50 rpm		
Mould tilt speed	10 cpm		
Tilt angle	12°–shank length 78–120mm		
	9°–shank length 120+		

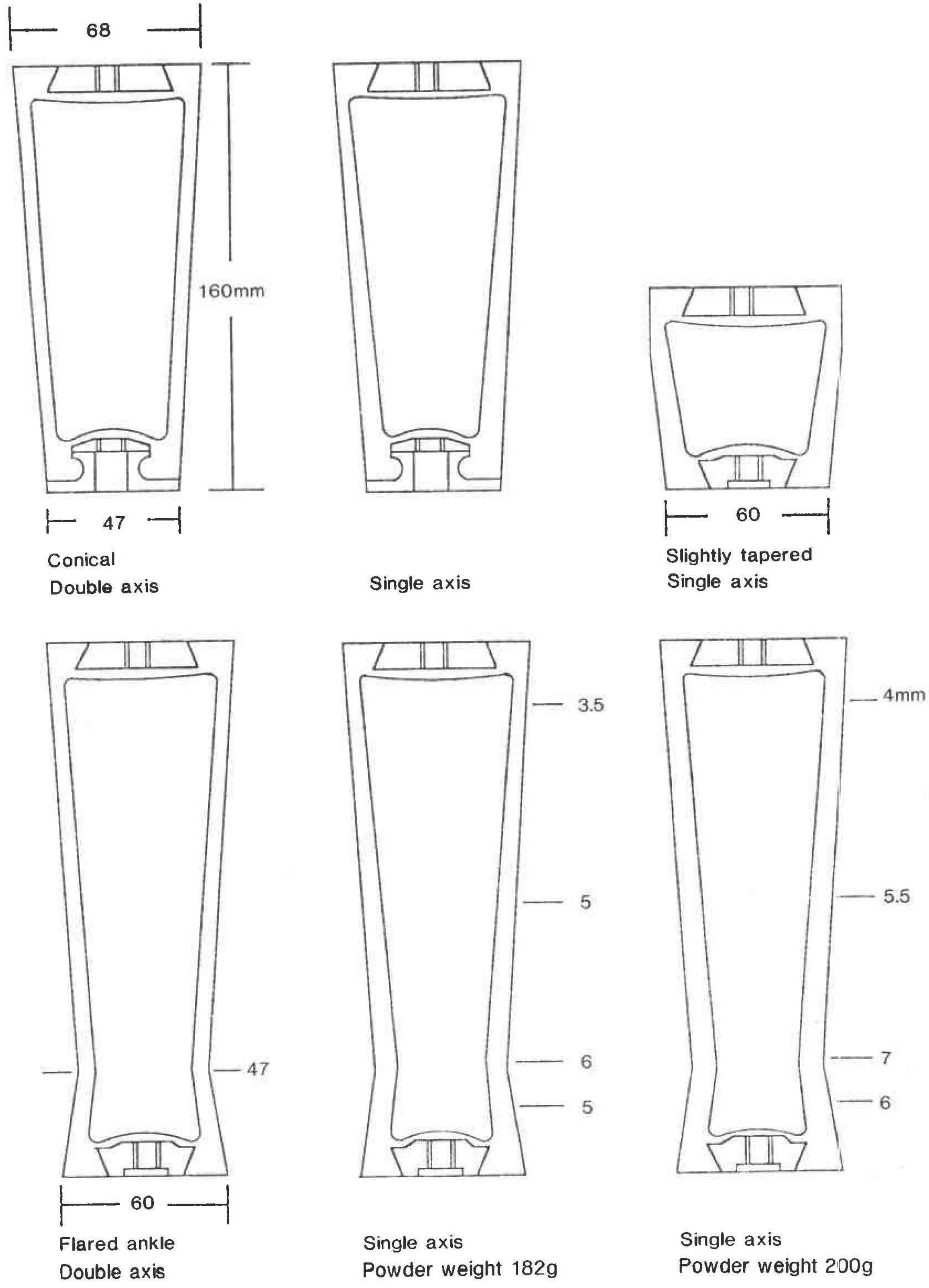

Fig. 3. Shank designs and material distribution.

simpler 'tilt and turn' rotational moulding technique was adequate for producing shank sections. A semi-automatic, compact moulding machine was constructed giving accurate control over oven temperature, mould heating and cooling time, mould rotation, tilt speeds, and tilt angles (Coombes et al, 1985b).

Mould rotation (about the shank axis) coupled with continuous oscillation (or tilt) of the mould in the vertical plane does not yield satisfactory mouldings. Only a thin coating of plastic is obtained on the surface of distal and proximal inserts rather than complete embedding of the insert in plastic.

A two-stage tilt technique was developed for producing nylon shank sections in lengths ranging from 78 to 220mm. This involves continuously rotating the assembled mould containing a predetermined weight of powder in an oven. The mould is inclined at a particular angle below the horizontal to coat the proximal end of the mould first (Stage 1). After a certain heating time the mould is automatically tilted by the same angle in the opposite direction to coat the distal end of the mould. The mould is then cooled in the Stage 2 attitude to solidify the plastic.

The process conditions found satisfactory for producing nylon shank sections of length ranging from 78 to 220mm are listed in Table 1. and the following guidelines apply for the two-stage moulding technique.

1. Mould residence time in Stage 1 and Stage 2 must be optimized to ensure satisfactory embedding of inserts and wall thickness distribution.
2. Material distribution throughout the moulding can be varied by altering the weight of powder, mould residence time in each moulding stage and tilt angle.
3. The distal end of the shank is moulded in the second stage of the process since more control is available over thickness distribution at this point. A gradually increasing wall thickness towards the base of the moulding is achieved which is advantageous for the highly stressed ankle region of the shank (Fig. 3).

Maximum shank length is governed by the existing machine dimensions. The minimum length of shank produced by the 2-stage tilt method was 78mm. Mould and inserts volume limit the amount of nylon powder which can be packed into the shorter moulds. In extreme cases overpacking of the mould prevents free movement of powder to the mould walls and results in a solid core of plastic bridging the gap between proximal and distal insert attached to the mould end plates. It should be noted that shank sections less than 120mm are produced from larger volume moulds to ensure that sufficient nylon powder is available to meet insert embedding and wall thickness requirements. This feature is a disadvantage of rotational moulding for shank production since the increased diameter of short mouldings could cause problems of cosmetic finishing of the prosthesis.

A useful feature of rotational moulding is the ability to vary moulding wall thickness if required to match patient weight and activity level by adjusting the amount of starting material. As a guide to powder weight requirement for the shank geometries under consideration, one subtracts between 0 and 20g from the figure for shank length i.e. for a 150mm flared ankle shank, the weight of powder would be between 130 and 150g. For the shorter, more cylindrical shanks below 120mm in length, 20g is added to the length figure. A typical wall thickness distribution for rotationally moulded shanks used in laboratory testing and service is shown in Figure 3. Wall thickness tapers from approximately 6mm at the distal end to 4mm at the proximal end.

Rotationally moulded nylon shanks—quality control aspects

A quality control system was set up to monitor the following features of rotationally moulded shanks.

1. Moulded appearance-mouldings were examined for the presence of voids and large bubbles (millimetre scale) in the moulding wall, satisfactory insert encapsulation, and evidence of over-heating during processing indicated by the presence of a fine grained 'bubble' effect in the moulding surface.
2. Moulding wall thickness.
3. Moulding deflection under static loading conditions.

Moulding Appearance

Since nylon materials are hygroscopic, Nylon 11 powder was routinely stored in an oven maintained at a temperature of 30°C to prevent moisture pick-up from the atmosphere. Excessive moisture content of the rotational moulding powder could result in large bubbles in the moulding wall. These defects are revealed by visual inspection sometimes aided by internal illumination of mouldings. The extent of insert encapsulation can also be assessed using internal illumination. The thicker wall section around the insert appears darker than the rest of the moulding. Poor encapsulation in one area for example may be revealed by rotating the moulding and observing a corresponding increase in intensity of the transmitted light.

Ultrasonic testing using a Panametrics 5222 thickness gauge based on the 'pulse-echo' principle was also used in quality control procedures. Scattering of sound energy from internal surfaces such as pores reduces the ability of the sensor to discriminate a valid return echo from the back face of the material. The ability to gauge the material ultrasonically is thereby limited. In a few cases moulding wall thickness was not registered ultrasonically despite a visually satisfactory surface appearance. These mouldings were rejected on the basis of unacceptable porosity.

Mouldings exhibiting rough internal surfaces or powder remnant due to poor material coalescence or densification were rejected. This characteristic of rotational mouldings is a result of insufficient heating time or low moulding temperatures and results in brittle failure of the moulding at low loads on static testing.

Wall thickness measurement

Investigations of the behaviour of rotationally moulded shanks under cyclic loading indicated that the minimum wall thickness should be set at 3mm to withstand fatigue loading to a million cycles. Wall thickness of mouldings was determined prior to laboratory testing and patient trials by means of a Panametrics 5222 ultrasonic thickness gauge. A flared ankle shank section fatigue tested to over 2 million load cycles for example had a wall thickness of 4.3mm at the proximal end and 7.3mm at the distal end. These wall thickness figures are also applicable to rotationally moulded shanks which can withstand static testing to the Philadelphia Static Load level.

Moulding deflection characteristics under static loading

Static testing of shanks was carried out using an offset, compressive loading arrangement to apply a bending moment to the test sample. Shank deflection measured in terms of tensometer crosshead movement at 1.35kN axial force was used for quality control purposes and to characterize shanks prior to patient trials and fatigue testing. For example an 'allowed' deflection of 6mm could be assigned to a 70mm shank (Table 3). Repetition of the test after rotating the shank by 90, 180 and 270° enables the homogeneity of the moulding to be assessed. This procedure, in combination with a visual examination, was used to reveal any incidence of poor insert encapsulation.

Shank and insert design

The shank section designs used in the evaluation programme of rotational moulding as a programme production technique for load bearing components were based on three types namely a conical form, flared ankle design and a slightly tapered cylindrical type (Fig. 3).

Conical type shanks offer production advantages since mould construction is simple and they permit easier cosmetic finishing of the limb at the ankle.

Flared ankle shanks were produced to enable highly stressed areas in the ankle region to be obviated by increasing load bearing area. The base diameter of the flared ankle section (60mm) was based on the largest dimension which could be blended cosmetically with SACH feet. They were produced using a split mould and give a good illustration of the relative ease of incorporating design changes in rotationally moulded components.

Slightly tapered, cylindrical shanks This shank design was necessarily adopted for shorter mouldings (<120mm) to ensure that an adequate volume of starting powder was available to meet insert embedding and wall thickness requirements. The increased diameter of these mouldings is a disadvantage as far as cosmetic finishing of the prosthesis is concerned.

The rotationally moulded Nylon 11 shanks in question are hollow and contain threaded metallic inserts moulded-in at distal and proximal ends to provide attachment points for socket and foot unit by means of single bolt fixings. Inserts were generally produced by machining from aluminium alloy, grade HE30TF, which offers lightweight and rapid heat conduction to assist polymer encapsulation of the insert during moulding. This particular grade of aluminium alloy is a medium strength wrought alloy which is recommended for structural purposes and displays good fatigue resistance and corrosion resistance. The design of these inserts must satisfy three requirements: –

1. The shape must allow powder movement around the insert during moulding to give complete encapsulation by thermoplastic without voids.
2. Insert anchorage in the shank must be adequate to withstand forces tending to pull them from the moulding during service.
3. Insert strength must be sufficient to resist failure by overload or fatigue during service.

Insert design for encapsulation by plastic during moulding

In rotational moulding, only the tumbling action of powder is available for coating mould walls and inserts unlike injection moulding of thermoplastics for example where high pressures force the molten plastic into the mould cavity and around inserts. Rotational moulding trials established the insert geometry necessary for complete coverage by thermoplastic at particular mould rotation ratios. Minimum flange height or flange separation (h) and span (s) for top-hat type inserts for example were established as 5mm × 5mm as shown in Figure 4. The minimum distance between mould wall and insert to achieve encapsulation without bridging of thermoplastic and voiding occurring was also established during the course of moulding trials as 7.5mm. Unfavourable insert geometry and/ or rotation ratio can result in large voids, ranging from 0.5 to several millimetres, in the moulding. Pin-hole voids can be formed in the angle of top hat type inserts for example unless the insert is radiussed in this region. Careful

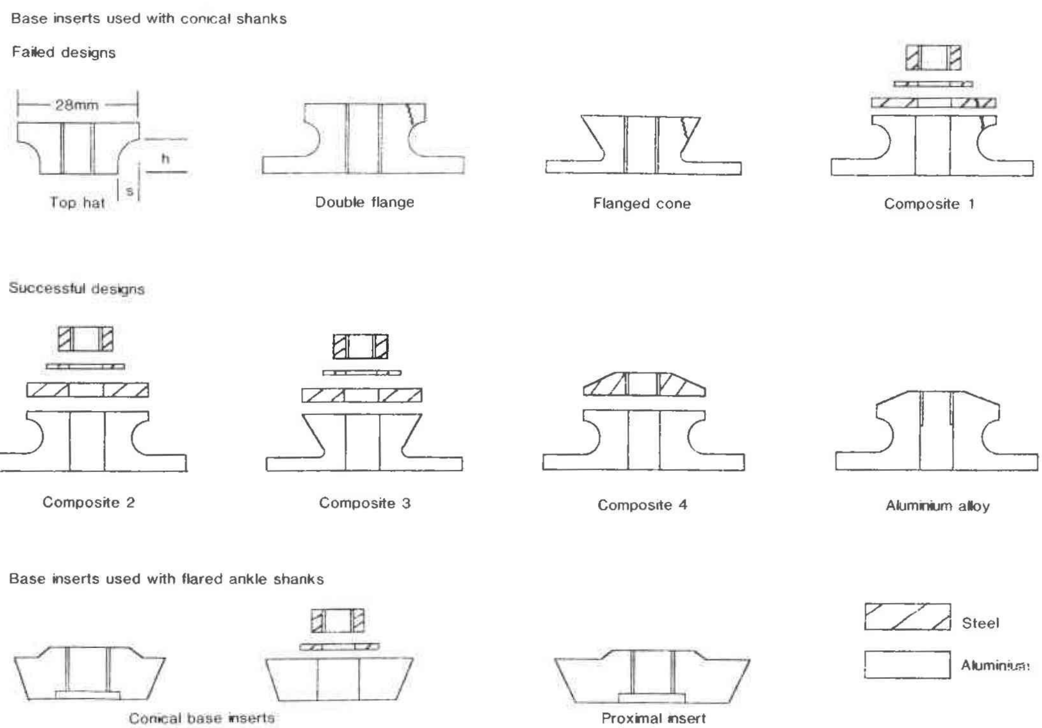

Fig. 4. Metallic inserts for rotationally moulded, Nylon 11 shanks.

choice of insert design and rotation ratios do however result in good encapsulation of inserts as illustrated in Figure 2.

Mechanical testing

An investigation of the mechanical performance of various designs of rotationally moulded Nylon 11 shanks containing specific types of inserts was instigated to test the behaviour of the shank/insert interface under load, and to provide information on the load-deflection characteristics of various shank geometries. Philadelphia recommended load levels for below-knee (BK) prostheses were selected as the design criteria for structural integrity (ISPO, 1978). Two loading regimes are of interest.

1) *The cyclic loading condition.* Where a 1350 N compressive force is applied to the limb structure to generate a bending moment at the knee of 120Nm and a bending moment at the ankle of 140Nm.

2) *The static loading condition.* A STATIC LOAD LEVEL was defined during the Philadelphia proceedings such that application of a compressive force of 2500N which produces a bending moment at knee and ankle of 230Nm and 250Nm respectively should not produce permanent deformation of the limb structure. In addition a MAXIMUM STATIC LOAD or FAILURE LOAD was discussed of 1.5x and twice this value for ductile and brittle-type failure of the limb structure respectively.

Static testing is used to reveal structural or design weaknesses associated with severe loading conditions while fatigue testing aims to simulate prostheses loading under normal service conditions.

Specimen preparation and test procedure

Nylon 11 shanks containing inserts of various designs (Fig. 4) were produced initially using the Bioengineering Centre's 'Autoform' double-axis rotational moulder and subsequently using the single-axis technique described earlier. Before testing, samples were inspected for satisfactory insert encapsulation moulding quality and wall thickness distribution as detailed earlier. Moisture conditioning (apart from exposure to laboratory conditions) was not carried out on samples and these were usually tested within one week of production.

Static testing

The mechanical testing procedure followed the Philadelphia recommendations. Moulded shank sections were static tested using a Zwick Universal Testing machine and an arrangement whereby pivoted extension bars were attached to proximal and distal ends of the shank to give equal offsets of 100mm from the load axis. This system of offset loading enabled AP bending moments to be applied to the test sample. The extension bars were bolted directly to the shank by means of the threaded, moulded-in inserts. Samples were characterized on the basis of deflection and failure mode by loading them to 1350N axial force and recording the resultant crosshead movement and then testing to failure.

Static tests were also carried out on assemblies of rotational moulded shank, plastic alignment devices and plastic uniaxial ankle unit (socket and foot unit are not included in the test). Shanks were confined to the Flared Ankle type containing conical metallic inserts. For SACH foot systems the shank was bolted to the test fixture via the selected alignment device using 8mm, high tensile, socket cap head bolts in combination with a spherical washer/seating arrangement. Offsets from the load axis were measured, as previously, with respect to the distal and proximal fixing bolts. When a plastic uniaxial ankle unit formed part of the test assembly it was connected to the test fixture using a Hangers standard T-bolt fixing, cradle and spherical foot nut. An aluminium alloy replica was substituted for the instep rubber. In this case the bottom offset from the load line was measured with respect to the ankle unit pivot.

Fatigue testing

Shank designs selected for fatigue testing were those which exhibited the least deflection under static loading conditions. As for static testing, pivoted extension bars were attached to each end of the moulding to give equal offsets from the load axis. In this case offsets of 103mm were arranged at distal and proximal ends of the shank to generate bending moments of 140Nm under an axial force of 1350N. Samples were first characterized by loading to 1350N axial force using the Zwick tensometer and measuring the resultant crosshead movement. They were subsequently fatigue tested to investigate the effect of insert design and moulding wall thickness on shank fatigue performance.

The bulk of the cyclic testing programme on rotationally moulded shanks was carried out using a pneumatically powered fatigue rig which applied a force of 1350N to the specimen at a frequency of 52 cpm for five minutes followed by one minute at zero load then 40 cpm for five minutes and so on. In this way the cyclic test procedure aimed to simulate patient activity to a certain extent by varying the loading rate (a minimum loading time of one minute is available on the present rig, one load level can be programmed and two loading frequencies (apart from zero) may be selected up to a maximum of 1 Hz). A Si-plan servo hydraulic testing machine was used for fatigue testing limb assemblies consisting of alignment devices, shank and socket. See 'Systems Testing'. Computer control of loading frequency, maximum and minimum loads, time of loading etc., is available so that patient activity may be simulated in greater detail than is possible using the pneumatic fatigue rig.

Results of static and cyclic testing

The results of characterizing by static testing rotationally moulded Nylon 11 shanks of various lengths and insert designs are presented in Table 2. Shank deflection under load as reflected by the values for tensometer crosshead movement at 1.35kN axial force are recorded in Table 3. Although the effect of shank geometry and wall thickness has not been investigated systematically, there is in general an expected trend for shank deflection to increase with length of moulding representing a tendency for 'bowing' of the longer columns under load. Static test results for limb

Table 2. Static testing of rotationally moulded shanks
Speed of testing 100 mm/min.

Shank type	Conical	Flared ankle ———				
Moulding technique	Double axis ———			single axis ———		
Shank length (mm)	175	200	205	163	188	216
Power weight (g)	–	190	180	165	198	207
Wall thickness range (mm)	5.2–6.1	4.9–6.4	4.9–5.6	4.5–6.4	–	–
Shank base insert	Top hat	Composite 4	Composite 4	Composite 4	Conical	Conical
Maximum axial force (kN)	3.3	4.6	3.1	3.3	3.1	2.5
Failure mode	——— Brittle shank failure ———				Base insert pull-out	

Table 3. Fatigue testing of rotationally moulded nylon 11 shanks

Shank type	Conical ———					Flared ankle ———		
Moulding technique	Double axis ———						Single axis ———	
Shank length (mm)	70	70	205	205	205	220	172	207
Power weight (g)	75	75	160	160	160	200	178	208
Wall thickness range (mm)	3.5–4.5	3.2–4.6	–	3–4	3–4.5	4.3–5.5	–	4.6–7.2
Shank base insert	Flanged cone	Composite 3	Top hat	Double flange	Composite 2	Conical	Compsite 4	Conical
Ankle fixing bolt (mm)	8	8	8	8	8	8	8	10
Cross head movement (mm) at 1.35 kN	–	5.6	–	–	10.5	12	7.6	7.7
Cycles completed	91.000	964.500	60.000	90.000	1.189.000	1.867.000	705.800	2.035.000
Failure mode	Base insert shear	Shank cracked in ankle region	Ankle bolt failure	Base insert shear	Shank cracked in ankle region	Shank cracked at base–excessive insert pull-out	No failure	Excessive base insert pull-out

Shank deflection measured in terms of tensometer crosshead movement at 1.35 kN axial force was recorded at a test speed of 100mm/min.

Table 4. Static testing of limb assemblies—combined compressive and bending loads

	Speed of testing 10mm/min.				Speed of testing 20mm/min.				
Shank type	Cylindrical	Flared ankle			Flared ankle				
Shank length (mm)	116	163	208	208	202				
Power weight (g)	136	165	215	215	182				200
Thickness of base insert (mm)	10	10	10	10	7	8	9	10	9
Alignment device	4-jack	Double wedge	4-jack	4-jack	4-jack				
Plastic uniaxial ankle unit	—	—	—	Yes	Yes				
Max. axial force applied (kN)	2.3	2.9	3.3	2.6	2–2.4	2.1–2.3	2.3–2.6	2.3–2.5	2.6–2.8
Failure mode	Pull-out of shank's base insert				Pull-out of shank's base insert				

Shank proximal insert–conical type, Figure 4.
Shank base insert–conical type, Figure 4.
The same type of alignment device is located at both proximal and distal ends of the shank.

assemblies are presented in Table 4. The failure characteristics of the shank dominate those of the assembly.

Shank failure characteristics can be categorized as follows:—

1. Brittle failure of the shank occurs between 3.1 and 4.6kN when insert pull-out is restricted by using flanged type inserts.
2. Insert pull-out loads for the isolated shank containing conical inserts have ranged from 2 to 3.3 kN depending on embedded insert depth and shank wall thickness.
3. Poor quality rotationally moulded shanks showing powder remnant will fail in a brittle manner at low loads.

Although Philadelphia Static Load Levels can be exceeded, the failure loads do not meet U.K. Department of Health test requirements for safety/structural purposes. These state that in the case of ductile failure, failure loads should exceed 1.5x Philadelphia Static Load Levels i.e. 3.75kN. For brittle failure 2× Philadelphia Static Load Level is required i.e. 5kN.

Insert pull-out from rotationally moulded shanks

Pull-out of conical inserts on overload from rotationally moulded shanks (Fig. 5) is preferable as a failure mechanism to brittle failure since it is progressive and can be detected at prosthesis inspection. Conical inserts are gradually pulled from the shank giving the type of load-deflection curve shown in Figure 5. Insert pull-out can provide a useful indication of the actual loads applied to a prosthesis in service by building in a particular failure load. It provides a convenient method for testing the validity of the Philadelphia Static

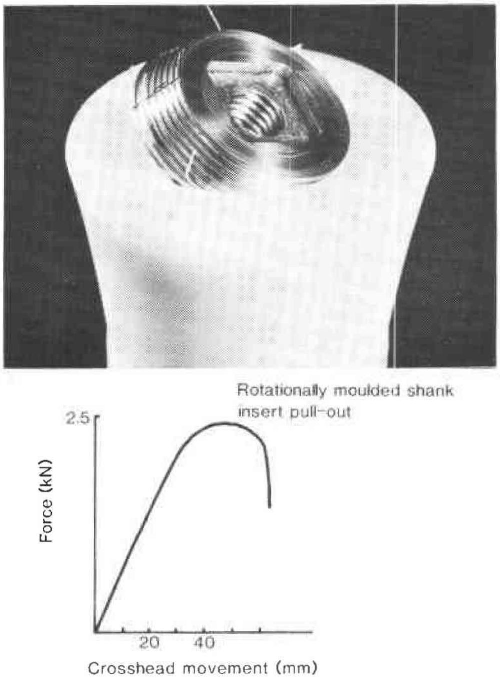

Fig. 5. Pull-out of a conical base insert from a rotationally moulded, Nylon 11 shank and typical force-deflection curve.

Load Level in patient trials for example if pull-out strength can be confined to a load range about this level.

The effect of certain shank design variables such as embedded insert depth, on insert pull-out force was investigated by static testing BK limb assemblies. The same system of offset loading was employed as described above to apply bending loads to a test assembly consisting of:

1. 4-jack angulation modules at distal and proximal ends of the shank.
2. Rotationally moulded, nylon shank section (202mm long, flared ankle type).
3. Plastic uniaxial ankle unit.

Embedded insert depth was varied by altering the height of the insert so maintaining the cone angle constant. The effect of reduced insert diameter on pull-out strength has been assumed to be negligible. Insert pull-out force is presented in Table 4 in terms of the applied compressive force. The results reveal that:—

1. The depth embedding of the insert in plastic at the shank base over 7–10mm has relatively little effect on pull-out strength. Pull-out strengths ranged from 2–2.6kN with an expected tendency to increase with increased depth of embedding.
2. Pull-out strength appears more sensitive to the wall thickness in the shank base i.e. the resistance to spreading of the shank base by the insert is increased with increasing wall thickness in this area. Pull-out strength was raised to 2.6–2.8 kN by increasing the starting powder weight and consequently the wall thickness in the ankle region. Typical wall thickness distributions for 182 and 200g powder weight are illustrated in Figure 3 to emphasize this point.
3. Insert pull-out from the shank may be confined to a fairly narrow load range of 2.3–2.6 kN for test assemblies by suitable control of insert dimensions and moulding conditions.

Only one example of insert pull-out from the proximal end of the shank has been recorded during laboratory testing. In this case the standard conical insert was embedded to a depth of 6mm by plastic and the pull-out force was 2.3kN.

Factors influencing the fatigue performance of rotationally moulded shanks

The results of cyclic testing rotationally moulded shanks of various lengths and containing various insert designs are presented in Table 3. It must be emphasized that each type of shank had been tested to the Philadelphia Static Load Level without failure occurring. Early fatigue failure (i.e. before 700,000 cycles) can be assigned to three main factors namely:—

1. Creep of the thermoplastic resulting in early flexural fatigue failure of ankle fixing bolts.
2. Insert shear.
3. Buckling of the shank.

The types of observed fatigue failure are analysed below since they highlight some of the factors influencing the fatigue behaviour of thermoplastic shanks.

Creep of the thermoplastic during fatigue loading

Conical type shanks (Fig. 3) containing 'top-hat' base inserts and conical proximal inserts (Fig. 4) can withstand static loading to Philadelphia Static Load Levels. Both inserts were machined from aluminium alloy and had tapped 8mm holes to enable attachment to the test machine (and ultimately the socket and foot unit) by single bolts. Fixing bolts were of the socket cap head type, high tensile steel, grade 12.9.

Under fatigue loading conditions frequent ankle bolt failure occurred generally at the threaded section within the shank insert. In all, eight bolts sheared during the course of testing to 319,500 cycles. Deformation of the shank base away from the planar form was also significant. The proposed mechanism for repeated fixing bolt failure is outlined below and illustrated in (Fig. 6).

1. Compressive creep of the shank base occurs in the region x on each loading cycle removing the planar form. Creep may be defined as increasing deformation of a plastic material with time under constant load and is a result of the viscoelastic nature of plastics materials (Powell, 1974).
2. The test fixture or base plate (ultimately the foot unit) is now allowed to pivot about the edge of the insert base. This

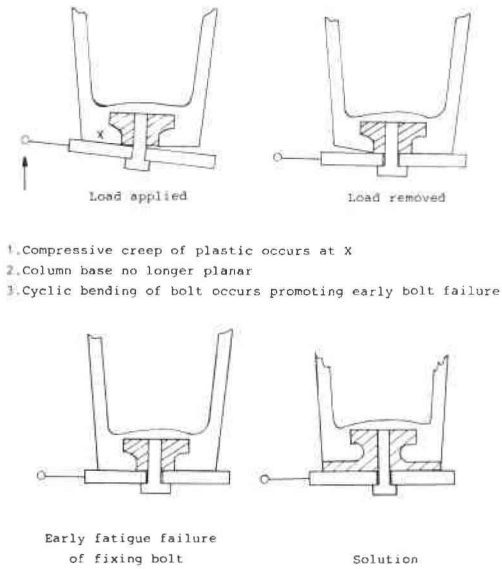

Fig. 6. Proposed mechanism for frequent ankle bolt failure due to creep of thermoplastics.

mechanism is aided by the small area of the insert in contact with the base plate.

3. Repeated bending or flexural loading of the fixing bolt results leading to early fatigue failure.

To avoid early fixing bolt failure by this mechanism, bending or flexing of the bolt must be minimized. This was accomplished by ensuring that shank insert and test fixture (or foot unit in service) were locked together rigidly by the bolt thereby behaving as a single unit under load. A large diameter base flange was added to the insert (Figs. 4 and 6) to satisfy this requirement. The larger insert clamping area prevents pivoting of the test fixture about the insert so that polymer creep and flexure are allowed while fixing bolt flexure is minimized. The effect of this modification is to raise the fatigue lifetime of shank sections to over a million load cycles as illustrated by Sample 5 in Table 3.

Insert shear under fatigue loading

During static and fatigue testing of shank sections there is a tendency to pull the distal and proximal inserts from the moulding. Under the conditions of offset loading employed the shank tends to pivot on its leading edge thereby concentrating the load over a reduced base area (Fig. 6). This condition would result in 'toppling' of the shank in the absence of restraining tensile forces (Gordon, 1978) generated by the top anchoring flange of the insert and the plastic below it as they flex to counteract the bending moment applied to the shank. The incidence of ankle insert fatigue failure by shear, typical fatigue lifetimes and the insert designs prone to this type of failure are listed in Table 3 and illustrated in Figure 4.

Shank fatigue failure due to buckling

Buckling of the shank during fatigue testing generally occurred at extremely low numbers of cycles i.e. less than 50,000 and has been observed under two conditions:

1. Insert failure which results in a marked shift of load onto the shank's leading edge.
2. Poor insert encapsulation or void formation below the insert anchoring flange which reduces the surrounding polymer section thickness.

In both cases the magnitude of forces due to polymer flexure which oppose toppling or pivoting of the shank on its leading edge are reduced. Compressive loads are consequently localized over a smaller area of the shank base promoting buckling. A combination of voids in the moulding wall, low wall thickness or hysteresis losses during cyclic testing causing material softening (Hertzberg and Manson, 1980) will accentuate the problem.

Guidelines for insert design

Certain design features of metallic inserts are necessary if rotationally moulded shanks are to exhibit extended fatigue lifetimes under combined compressive and bending loads. The guidelines for insert design which have evolved are generally applicable to thermoplastic load bearing components for prostheses. Successful and unsuccessful insert designs, as far as the present fatigue loading study is concerned, are shown in Figure 4.

Conical aluminium alloy inserts have been used exclusively at the proximal end of rotationally moulded shanks satisfying both criteria of polymer encapsulation during moulding and resistance to static and fatigue loading. Moulded-in inserts at the ankle interface of rotationally moulded nylon shanks constitute the more difficult design problem due to the high stresses generated in this area during service and the reduced load bearing area occasioned by the need to accommodate cosmetic finishing of the limb. Conical inserts have been used successfully at the distal end of flared ankle shanks. Successful ankle inserts for conical shanks in particular, classed as those which survived fatigue testing to over 700,000 cycles, have several features in common.

1. A large diameter base flange counteracts creep of the shank base to minimize fixing bolt flexure. Early fatigue failure of the bolt is thereby avoided.
2. The top anchoring flange of aluminium alloy inserts is braced against flexural loading by suitable dimensioning or the use of steel reinforcing washers (composite type inserts) to improve fatigue resistance.

   Adequate clearance is essential between the fixing bolt and bolt hole in the aluminium alloy component of composite type ankle inserts to prevent the threaded section of the bolt digging into the softer aluminium component during testing. This condition can result in loading of the thin aluminium alloy top flange independently of the steel reinforcing washer leading to early fatigue failure of the flange.

Moulding wall thickness for extended fatigue lifetimes

A minimum recommended wall thickness of 3mm has been assigned to rotationally moulded nylon shanks to confer resistance to cyclic loading under laboratory conditions. This figure is based on wall thickness data obtained from Sample 5 in Table 3 which survived over a million loading cycles before failure. Failure of the plastic moulding was observed prior to insert failure when the shank wall thickness was 2mm and below. In general shank wall thickness is above 4mm.

Systems testing—fatigue loading conditions

Fatigue testing of rotationally moulded shanks in combination with other prosthetic components such as plastic alignment devices and plastic uniaxial ankle units was carried out to determine the mechanical response of the prosthetic system to simulated service loading. Data was required for instance on the structural integrity of the interfaces between components.

The fatigue test procedure was as described earlier for shank sections. For SACH foot systems the shank was bolted directly to the fatigue machine's test fixtures via the selected alignment device using a single bolt fixing and a spherical washer/seating arrangement mentioned and illustrated in an earlier publication (Coombes et al, 1985a). Bending moments of 140Nm were arranged at positions corresponding to the ankle fixing bolt and top shank fixing bolt respectively. When plastic uniaxial ankle units formed part of the test assembly, they were attached to Hanger moulded foot units using the standard T-fixing and foot nut. A simplified spindle and circlip arrangement is used with the plastic uniaxial ankle unit as previously described (Fig. 1). The instep or heel rubber of the foot unit was replaced by a uPVC replica during testing to limit the deflection of the system. Offsets at proximal and distal ends of the test assembly were arranged such that an applied force of 1350N produced a bending moment of 140Nm at positions corresponding to the ankle unit pivot and top shank fixing bolt respectively.

The results of fatigue testing various combinations of rotationally moulded shank, plastic alignment devices and plastic uniaxial ankle unit are presented in Table 5. An enhanced fatigue performance and a more preferable failure mode are apparent for systems based on flared ankle shanks.

Socket–shank interface

The structural integrity of the socket interface was investigated by fatigue testing a limb assembly incorporating a Rapidform polypropylene socket with soft PElite polyethylene foam liner (Fig. 7). The socket contained a Blatchford cup (Manufacturer's code DP 11) at the distal end for single bolt attachment to the shank. A 200mm long, flared ankle, rotationally moulded shank and 4-jack angulation modules distal to the socket and at ankle level completed the assembly; 10mm fixing bolts in high tensile steel, grade 8.8 to BS3692 were used to connect shank to socket and shank to test fixture via the alignment device. Bolts were Cadmium plated but not passivated or de-embrittled, Aluminium alloy spherical washers completed the socket fixing and ankle fixing.

Table 5. Fatigue testing of limb assemblies

Shank type	Conical			Flared ankle		
Moulding technique	Double axis			Single axis		
Shank length (mm)	118	180	190	128	211	200
Power weight (g)	125	165	175	138	216	210
Wall thickness range (mm)	4.5–5.8	4.5–6.5	4.4–5	4–5	–	4.3–7.3
Shank base insert	Composite 4	Composite 4	Alum. alloy	Conical	Conical	Conical
Alignment device (socket)	Double wedge	Double wedge	4-jack	Double wedge/ slide unit	–	4-jack
Alignment device (ankle)	–	Double wedge	Double wedge	–	Double wedge	4-jack
Plastic uniaxial ankle unit	–	–	–	Yes	Yes	–
Ankle fixing bolt (mm)	8	8	8	10	10	10
Cycles completed	817,000	710,900	1,057,000	1,466,000	947,000	2,023,000
Failure mode	No failure	Ankle bolt failure	Ankle bolt failure	Excessive base insert pull-out	Excessive base insert pull-out	Partial proximal and base insert pul -out

Test Procedure

Testing was carried out in accordance with UK Department of Health procedure and supervised by officials of that department. Philadelphia recommended load levels for dynamic testing were applied to the test assembly using an offset loading arrangement such that a bending moment at the knee and ankle of 120Nm and 140Nm respectively were produced by an axial compressive force of 1350N. Loading was transmitted to the socket by means of a loading bar embedded in a stump replica, produced from microballoon (castable polyester resin filled with hollow phenol formaldehyde spheres) incorporating a 70mm diameter thick pad of Plastazote polyethylene foam at the distal end. The test assembly was set-up on the fatigue testing machine such that the following offsets from the load line applied.

Offset at knee	89mm
Offset at ankle	104mm
Offset at alignment device distal to socket	104mm

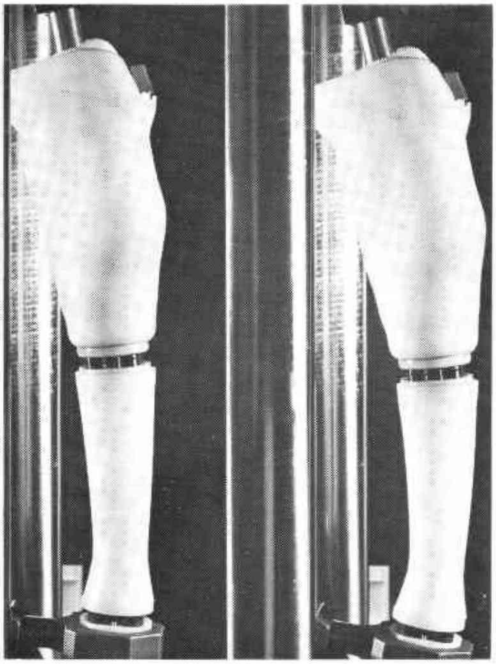

Fig. 7. Bowing distortion in a test assembly after two million loading cycles. Under zero load (left). Under 1.35 kN load (right).

In accordance with the Department of Health test procedure, the knee centre reference for BK test limbs (used for measuring the offset) was taken 19mm above the centre of the patellar tendon bar on the centre line of the loading bar. The ankle centre for SACH base is taken 12.5mm below the base (i.e. below the angulation module at the ankle in this case) on a vertical line through its centre. Offsets were measured under an applied load of 1350N. The length of the limb from knee centre to ankle centre was 435mm which is above the recommended length of 370–420mm. The test frequency was 1Hz and the test machine used was a 'SI-PLAN' servo hydraulic, programmable model.

Test Results

The limb assembly completed over 2,023,000 loading cycles without failure and the test was terminated at this point. 2 million cycles is deemed equivalent to a service life of 5 years by the UK Department of Health. A small amount of wear debris from the spherical seatings of the 4-jack angulation device had collected on the surface of the jacking nuts. No visible signs of deterioration were recorded for the remaining plastic components of the alignment device nor was any joint loosening discernible in the structure.

Bowing distortion of the prosthesis occurred in the AP plane as illustrated in Figure 7 coupled with pull-out of the proximal insert and distal insert to the extent of 0.5mm and 1mm respectively in the posterior region of the shank. Insert pull-out results in progressive 'gap opening' between the shank and alignment devices as the test proceeds. This effect coupled with bowing of the shank account for bowing of the complete structure under load with the resulting increase in offsets at the end of the test to 94mm at the knee (89 initially) and 120mm at the socket alignment device (104 initially).

Patient trials

Laboratory based fatigue and static testing of sub-assemblies incorporating thermoplastic shank and alignment devices to Philadelphia test levels demonstrated that such components could be expected to exhibit long service life. Patient trials were initiated both in the UK and abroad to generate data on the mechanical behaviour of components and the response of patients and prosthetists to the system as a whole.

Limb build

The limb build of experimental prostheses based on thermoplastic structural components is shown in Table 6. Patient weight, age and occupation for each of the patients involved in the trial is also included.

Rotationally moulded nylon shanks were confined to the flared ankle type or slightly tapering cylindrical form dependent on length requirements (Fig. 3). These incorporated conical aluminium alloy inserts (10mm thick) at distal and proximal ends of the shank. As well as increasing load bearing area in the highly stressed ankle region by using flared ankle shanks, the conical inserts are pulled from the moulding under overload conditions so avoiding brittle failure of the shank.

All trial patients were fitted with Rapidform polypropylene sockets. The experimental prostheses were mainly based on the non-neutral pylon system where angular adjustments in the antero-posterior (A/P) plane and mediolateral (M/L) plane are carried out at two levels immediately distal to the socket and at ankle level respectively. Alignment devices used were either a plastic serrated double-wedge device or the 4-jack angulation module

Table 6. Patient trial results

Patient Details					Prosthesis construction						
	Age	Weight (kg)	Occupation	Prosthesis service use (months)	Alignment device Double wedge	4-jack	Shank length (mm)	Plastic ankle unit	Foot unit	Fixing bolts (mm) Socket	Ankle
A	22	74	Student	31	/				Otto Bock SACH	–	8
B	37	89	Soldier	22	/				Hanger SACH	–	10
C	37	75	Soldier	16	/		69		SACH	8	8
D	25	**82**	**Hotel Work**	**9**	/		**74**		**Modified Pirogoff**	**8**	**10***
	..	..	.. ..	**2**	/		**74**		**Modified Pirogoff**	**8**	**10**
	..	..	.. ..	15		/	74		Modified Pirogoff	8	10
E	65	84	Surveyor	9	/		171		Hanger SACH	10	10
F	41	**75**	**Businessman**	**15**		/	**107**		**Hanger SACH**	**8**	**8**
G	66	81	Retired	15	AK		124	/	Hanger Uniaxial (wooden)	–	10
H	66	105	Retired	7	/	/	200	/	Hanger Uniaxial (wooden)	10	10
J	77	**78**	**Retired**	**5**		/	**166**	/	**Hanger Uniaxial (moulded)**	**8**	**10***
K	65	75	Retired	19		/	168		SACH	8	8
L	68	79	Retired	6		/	145		SACH	8	8
M	60	113	Retired	11		/	183		SACH	8	10
N	36	71	Unemployed	11		/	193		SACH	8	10
P	69	76	Retired	4		/	158		SACH	8	10

* Ankle bolt type – hex. head, high tensile steel, grade 8.8
Data in bold type refers to those patients who experienced prosthesis failure.

described previously (Coombes et al, 1985a). Thermoplastic uniaxial ankle units were incorporated in two BK modular systems and one AK prosthesis.

In two cases (patients A and B) the patients involved had very long amputation stumps. Their experimental prostheses consisted simply of a 'long draw' Rapidform PP socket, wedge angulation device, SACH foot unit and a nylon spacer, machined to patient requirements (Fig. 8). A single bolt fixing joined socket to foot unit. The low overall height of the plastic alignment device (less than 25mm) means that an alignment capability can easily be incorporated in prostheses for long stump amputees. In one case, (patient D) height restrictions were such that the prosthesis incorporated a rotationally moulded shank of minimum mouldable length (78mm–single axis technique), one angulation module distal to the socket and a low-profile foot unit based on a modified Otto Bock Pirogoff unit.

One above-knee amputee (patient G) was involved in the trial. His prosthesis was based on the British Modular Assembly Prosthesis (MAP) system having a plain uniaxial knee unit

Fig. 8. Prosthesis fitted to patients with long amputation stumps incorporating Rapidform PP socket, wedge alignment device and Nylon 66 spacer.

with an internal calf spring (kicker spring) and back check. A rotationally moulded shank was attached to the knee cradle by means of a machined, aluminium alloy tube adaptor. The adaptor was connected to the shank by a 10mm bolt onto the moulded-in insert at the proximal end. The tube adaptor was pinned to the knee cradle using the standard method of attachment for alloy shin tubes in the British MAP prostheses namely by using a 5mm dia. roll pin in conjunction with engineering adhesive applied to the joint surfaces.

For patients K-P involved in the American part of the trial, 'Lightcast' Fibreglass casting tape was wrapped around the distal end of the socket, alignment device and top of the shank. The tape was wound loosely down the shank and then wrapped around the distal end of the shank, ankle alignment device and the top 10mm of the proximal part of the foot unit. The efficiency of this extra support structure and its influence on the service performance of the primary structure is questionable but nonetheless should be borne in mind when analysing the results of the patient trial.

Spherical aluminium alloy seatings and washers were used in conjunction with fixing bolts within the socket and foot unit of each prosthesis to allow angulation between these units and the shank. Socket fixing bolts are M8, hex.hd.bolts, 60mm long, high tensile steel, grade 8.8 unless otherwise stated. Ankle fixings were either 8mm or 10mm bolts, socket cap head type, high tensile steel, grade 12.9 unless otherwise stated. The 10mm bolts were incorporated in prostheses fitted to patients over 76 kg (168 lb). Ankle fixing bolts used with plastic ankle units were 10mm, hex.hd. bolts, 50mm long, high tensile steel, grade 8.8.

The SACH foot units incorporated in experimental prostheses were modified to allow a) some degree of linear movement of the fixing bolt within the bolt hole b) adequate angulation of the fixing bolt c) incorporation of a spherical seating and washer arrangement. The modifications involved increasing the bolt hole diameter to 15mm and the counterbore to 30mm.

Results

Although patients expressed an appreciation of the light weight of their trial prostheses, the limb systems, particularly those incorporating

SACH foot units, are unsatisfactory as far as alignment procedures are concerned. Access to fixing bolts at socket and ankle level for alignment adjustment necessitates removal of the prosthesis from the patient. The provision of medial and lateral slots in the uniaxial ankle unit eliminates this problem at ankle level.

Experimental prostheses incorporating various thermoplastic structural components have been in use for the time shown in Table 6. The main results have been tabulated as follows:—

Patients	14
Age range (years)	22–77
Weight range	75–113kg
Service use	5–33 months
Prosthesis failures	4
Type of failure	3 ankle bolt failures 1 partial pull-out of the proximal shank insert
Duration of use prior to failure	5 months–patient J 9 months–patient D 2 months–patient D (insert pull-out) 18 months–patient F

In the three cases of ankle bolt failure, flexural fatigue loading of the bolt, which is known to be detrimental to service performance, is considered the most likely cause of failure. In case 1 (Patient J) this condition was accentuated by the stress raising effect of the thread run-out at the point of failure and possible loosening of the shank-ankle unit joint in service.

It should also be noted that the type of high tensile fixing bolt (grade 8.8) used in this prosthesis, although Cadmium plated for corrosion resistance is not usually de-embrittled after plating. Commercially used ankle fixing bolts are generally socket cap head types produced from grade 12.9 high tensile steel. These are recommended by the DHSS to be Cadmium plated, de-embrittled and passivated to BS3382 since hydrogen absorption by steel can occur on plating or acid cleaning leading to lowered ductility—hydrogen embrittlement (Larrabee & Mathay, 1963). A time delay is necessary for embrittlement to occur and this delay may be related to a critical or threshold amount of stress. The high tensile stresses generated in the surface of a bolt in flexure must focus attention on the possibility of hydrogen embrittlement contributing to early failure of the fixing bolt under conditions of flexural loading.

The second prosthesis failure (patient D) also occurred by ankle bolt failure at the thread run-out. In this case the thread run-out coincided exactly with the foot/shank interface which is known to emphasize stress-raising effects. It is recommended that the thread run-out is kept remote from component interfaces.

Crushing of the wood keel of the Pirogoff foot unit observed in the anterior region of shank/keel contact corresponding to the 'toe-off' walking phase is considered the main factor contributing to failure of this particular prosthesis. Joint loosening results and the bolt is thereby subjected to flexural loading during service precipitating early fatigue failure. Parallels can be drawn with the case of frequent ankle bolt failure under laboratory fatigue loading where compressive creep of the shank base away from the planar form resulted in flexural loading of the fixing bolt and its early failure (Fig. 6). It should also be noted that the Pirogoff foot unit used in this prosthesis is usually laminated to a prosthesis rather than fixed by a single bolt so distributing loads over a large area of the keel's surface. Foot units of this type fitted to experimental prostheses were subsequently modified by adding a hardwood top layer to reduce the tendency for crushing. The merit of this approach has been demonstrated by the fact that Patient D has worn his present prosthesis for 15 months without failure occuring.

Another factor contributing to early failure of the limb structure in service is the high activity level of Patient D which includes five-a-side football, hill walking, running, skiing, water skiing and badminton. These activities would be expected to impose much higher stresses on the prosthesis than is normally experienced and would promote early failure. While this prevents a rigid analysis of the effect of 'normal service use', on the experimental prosthesis it does mean that trial components are being severly tested in this case and that any real improvement can be expected to lead to an overall benefit if transferred to other prostheses at the design and development stage.

The same patient was responsible for partial pull-out of the proximal insert from the shank, fitted to his second prosthesis. Insert pull-out occurred from the posterior region of the shank indicating that large forces were developed on 'toe-off'. This particular shank had been in service for just over two months. A similar shank moulding incorporated in the patient's original prosthesis functioned satisfactorily for nine months without insert pull-out occurring. Partial pull-out of the proximal shank insert has not been noted in the remaining prostheses undergoing patient trials. This behaviour is also rarely observed in laboratory fatigue and static testing—pull-out of the base insert being more usual. Proximal insert pull-out has been observed in one case in fatigue testing but only after two million loading cycles (generally assumed equivalent to five years service use). Proximal insert pull-out in static testing has been observed in one case at 2.3 kN due to unsatisfactory insert encapsulation by the polymer.

A further illustration of the heavy usage imposed on a prosthesis by the patient in question (D) is presented by the occurrence of failure in a British MAP prosthesis two months after issue. A helicoil insert in the ankle tube adaptor of this system was dislodged.

Prosthesis failure for patient F occurred after 18 months, again due to ankle fixing bolt failure. An 8mm high tensile bolt, grade 12–9, was used at the ankle, Cadmium plated, passivated and de-embrittled in accordance with DHSS recommendations. The patient is also highly active, participating in a range of sporting activities such as skiing and cycling using his experimental prosthesis. The DHSS recommend that 10mm ankle fixing bolts are used for male amputees while 8mm bolts are said to perform satisfactorily in prostheses fitted to women patients. The result for patient F tends to support this recommendation, the 8mm ankle fixing bolt proving inadequate for resisting the type of loading imposed by this particular patient on his prosthesis.

Discussion

The continuing increase in thermoplastics usage in all sectors of engineering, underlines the advantages to be gained on both a structural and economic level. While thermoplastics are accepted for socket production little use is made of them for other structural components of modular prostheses. Although emphasis in this paper has been placed on the production of Nylon 11 shank sections by rotational moulding the test results and observations can be used as design guidelines for thermoplastic shanks produced by other methods such as injection moulding.

Shank sections have been produced on an individual basis using a segmented mould, taking advantage of the simplicity of mould construction and the low cost of moulding equipment associated with rotational moulding. Development of a single-axis moulding technique for shank sections has further simplified and scaled down the process and moreover allows greater control over wall thickness in the highly stressed ankle region compared with the conventional double-axis method. Process conditions and quality control procedures have been recommended in the text for Nylon 11 shank production by rotational moulding. Although the process is simple it is characterized by long production times. Mould heating and cooling time is about 34 minutes for instance. In addition it has been found that shank sections less than 120mm in length need to be produced from larger volume moulds to ensure that sufficient material is available to meet wall thickness and insert coverage requirements. The large diameter of these shorter shank sections can cause problems of cosmetic finishing of the prosthesis. The minimum length of shank produced by the single-axis and conventional technique was 78mm and 70mm respectively. The minimum value of wall thickness recommended for a fatigue life in excess of a million load cycles is 3mm. Samples static tested to the Philadelphia Static Load Level typically tapered from 4mm at the proximal end to 6mm at the distal end resulting in lightweight components. A 195mm shank weighs 270g for instance.

The Nylon 11 shanks are hollow and contain metallic inserts moulded-in at distal and proximal ends to provide attachment points for socket and foot unit by single bolt fixings. Moulding trials established optimum insert dimensions to ensure complete encapsulation by plastic during moulding while the mechanical testing programme identified the design features of shanks/inserts which are essential for good fatigue performance and for resisting large static loads. Conical type inserts are preferred. The design is simple, manufacturing costs are low, encapsulation by thermoplastic is facilitated and the strength of insert anchorage in the components can be readily adjusted to give a progressive pull-out type of failure mode if required. The design of the ankle insert for rotationally moulded, Nylon 11 conical type shanks presents greater problems due to the high stresses generated on the prosthesis in this region accentuated by the requirement for good cosmetic finishing which reduces load bearing area at the ankle. Flanged inserts increase the fatigue performance of this type of shank by reducing bolt bending caused by creep of the shank base. Insert anchorage is secure but as a result failure is transferred to the plastic component under overload conditions which is undesirable if brittle failure characteristics are exhibited by the material. Although emphasis has been placed on shank production the insert designs which have evolved are generally applicable to load bearing prosthetic components such as foot and knee units which could be produced for example by injection moulding.

The structural integrity of shank sections was assessed using the Philadelphia recommended Static Load Level and cyclic loading conditions. Laboratory fatigue testing in particular highlighted the pronounced effect which creep of thermoplastics could have on the service performance of shank sections unless offset or minimized by suitable design or choice of materials. Creep is a time dependent property of thermoplastics defined as increasing strain or deformation with time at constant stress. Specifically, deterioration due to creep can be ascertained over the long time scale of a fatigue test but would not be evident in the shorter time scale of a static test.

The role of component design in mitigating the effect of creep on the fatigue behaviour of rotationally moulded shanks is well illustrated by the case of conical type shanks containing a top hat type ankle insert. Compressive creep of the shank base induced bending of the ankle fixing bolt and joint loosening which precipitated fatigue failure of the bolt. Fatigue performance was increased by a factor of almost 20 to over a million cycles by adding a large diameter base flange to the insert. In this case creep of the plastic is tolerated but flexure of the bolt is minimized by locking the insert rigidly to the test fixture or foot unit.

The increase in fatigue performance of flared ankle shanks relative to the conical type may simply be attributed to reduced creep of the shank base due to increased load bearing area in the ankle region. The stress is reduced locally with a consequent reduction in the magnitude of the creep strain (Powell, 1974).

A drawback of rotational moulding is the limited range of thermoplastics which are suitable for processing by this technique. Nylon 11 for example can be considered a relatively weak thermoplastic with the same stiffness as polypropylene ~ 1 GN/m^2 and strength of 57 MN/m^2 which is double that of polypropylene. There is therefore limited scope for varying the material to reduce creep unlike injection moulding for instance. Glass fibre reinforcement of thermoplastics substantially increases creep resistance (Powell, 1974) but these materials are not suitable for rotational moulding. A further advantage of fibre reinforced thermoplastics is the attendant increase in material stiffness and strength (5 GN/m^2 and 160MN/m^2 respectively for 30% glass reinforced Nylon 66) which presents opportunities for reducing the component wall thickness and radial dimensions—the latter being important for cosmetic finishing of the limb.

Despite being limited to an unfilled grade of Nylon 11, optimization of shank and insert design does result in fatigue resistant shank sections. A fatigue life in excess of two million cycles was recorded for an experimental prosthesis incorporating Rapidform polypropylene socket, 4-jack alignment devices and rotationally moulded shank. The scope for improvement based on material variation or speed of processing is extensive.

The results of the patient trials focus attention again on the deleterious effect of ankle joint loosening on the service performance of prostheses. The resultant flexural loading of ankle bolts leads to early fatigue failure of the bolt. Joint loosening in service is clearly indicated in the case of the highly active patient where crushing of the wood keel under the anterior region of the shank occurred. Parallels can be drawn in this case with the fatigue behaviour of conical shanks containing top hat type inserts where creep distortion of the shank base away from the planar form resulted in flexural loading of the fixing bolt and its early failure. A further illustration of the effect of joint loosening on the fatigue behaviour of prostheses is given by the test results of Durance and Wevers (1986). Frequent ankle bolt failure occurred unless the bolt tightening torque was maintained during dynamic testing. Deterioration of the ankle joint was not noted for the third patient indicating that indadequate bolt size is the primary cause of failure.

Apart from one case of service failure due to insert pull-out (which could be caused by overload and/or cyclic loading), all prosthesis failures resulted from fatigue failure of the ankle fixing bolt and not from overload which would result in insert pull-out. This behaviour emphasizes the importance of fatigue testing components and systems at an early stage of development, which could be neglected in an attempt to attain the required static strength figures. Static testing is used to reveal the behaviour of the prosthesis under overload or severe loading conditions but it is worth repeating that static testing will not reveal design weaknesses associated with compressive creep of thermoplastics since this is a time dependent characteristic of these materials. The ability of conical shanks containing top hat ankle inserts to withstand Philadelphia Static Load Levels and yet exhibit early ankle bolt failure as a result of creep of the shank base is a case in point.

Pull-out of conical type inserts from rotationally moulded shanks on overload is preferable as a failure mechanism to brittle failure since it is progressive and can be detected at prosthesis inspection. Moreover pull-out loads are in the region of 2.5kN which provides a convenient method for testing directly the validity of the Philadelphia Static Load Level as a design criterion in patient trials. It should be noted that failure loads recorded due to insert pull-out are well below the UK Department of Health test requirements for safety/structural purposes. These state that in the case of ductile failure, failure loads should exceed 1.5×Philadelphia Static Load Level, i.e. 3.75 kN. For brittle failure 2×Philadelphia Static Load Level is required, i.e. 5kN.

It is significant that partial insert pull-out in service from rotationally moulded shanks was only observed in one case, after two months use, and that for a particularly active patient who also broke a British MAP after two months. A similar shank functioned satisfactorily for nine months without insert pull-out occurring. Partial pull-out of the proximal insert occurred. This is unusual, occurring in laboratory testing after two million fatigue loading cycles for one experimental prosthesis and during static testing at approximately 2.3kN applied axial force due to poor insert encapsulation in a second case. Pull-out of ankle inserts from rotationally moulded shanks in combined compressive/bending tests is more usual between 2.3 and 3.3kN applied axial force. The patient trials indicate then that in general such forces are not applied to limbs in service. These findings fit the pattern of prosthesis loading established during laboratory based ambulation tasks (Biomechanical Research and Development Unit, 1978) and more recent investigations of prosthesis loading by amputees on various types of terrain outside the laboratory. A limited study of prosthesis loading on different surfaces outside the laboratory conducted by Boenick et al, (1977) is also of interest. An instrumented pylon system was used in each case to record the values of prosthetic loading. Maximum values of axial load and ankle AP bending moment recorded during the three studies for BK amputees have been reproduced in Table 7. These can be considered the most damaging loads on a prosthesis.

The most recent Strathclyde study which

Table 7. Maximum recorded values of axial load and ankle AP bending moment

Maximum axial load (kN)	Terrain	Maximum ankle bending moment (Nm)	Terrain	Source/reference
2.2	Up, ramp	220	Up ramp	BRADU/Bioengineering Unit
1.46	Up, pavement	138	Up, gravel	Bioengineering Unit University of Strathclyde (S. Solomonidis)
1.2	Level, rubble	140	Level, rubble	Boenick et al.

recorded prosthetic loading patterns outside the laboratory is more representative of normal service. Their findings tend to confirm the applicability of Philadelphia cyclic load levels as a design criteria for use of a prosthesis under normal service conditions. The Philadelphia Static Load Level is 71% higher than the maximum axial load recorded at Strathclyde indicating that a prosthesis designed to the Static Load Level can be considered to have a safety factor of 1.7.

The present findings indicate that prostheses able to withstand static loading only to the Philadelphia Static Load Level and fatigue testing to Philadelphia cyclic load levels generally function satisfactorily over extended time periods without failing by overload. In only one case was partial insert pull-out noted during routine inspection but whether due to overload or fatigue loading cannot be ascertained. The DHSS Maximum Static Load for definitive limbs is 5kN for brittle failure and 3.75 kN for ductile failure. This test standard appears excessive on the basis of the findings presented here and the amputee loading studies mentioned above. Restrictions are thereby imposed on weight reduction in prostheses and design progress. It is proposed that the Philadelphia Static Load Level is an adequate test requirement for safety-structural purposes when accompanied by a ductile or progressive failure mode of the prosthesis.

Summary and conclusions

The wider use of thermoplastic structural components in artificial limbs would enable their general properties of low density, corrosion resistance and mouldability and more specific properties of certain thermoplastics such as shock absorption, fatigue and wear resistance to be used to the advantage of patients and manufacturers.

Rotational moulding has been investigated in depth for producing thermoplastic shank sections as an alternative to the metal and carbon fibre reinforced resin systems currently available. Moulding conditions have been established which will yield shank sections capable of withstanding Philadelphia recommended static and fatigue loads. The resulting wall thickness distribution has been indicated for various shank geometries and minimum values recommended to ensure mechanical performance to the Philadelphia recommended Static Load Level coupled with long fatigue life. Quality control procedures applied to shanks prior to laboratory and service testing have also been listed.

The design of the metallic inserts moulded-in at distal and proximal ends of the shank to provide attachment points for the shank to other components of the prosthesis has been detailed. Final recommended designs ensure satisfactory encapsulation by plastic during moulding, long fatigue life and a progressive shank failure mode under overload conditions by insert pull-out. The insert designs which have evolved over the course of the investigation are generally applicable to load bearing prosthetic components such as foot and knee units.

Static and fatigue testing of experimental prostheses incorporating plastic shanks and alignment devices demonstrated that they could withstand static loading to Philadelphia Static Load Levels and exhibit long fatigue lifetimes in excess of two million cycles. Laboratory testing underlined the necessity for both fatigue and static testing of thermoplastic components since a high static test value is not necessarily indicative of long fatigue life. Specifically, deterioration due to time dependent mechanical properties such as creep, can be ascertained in fatigue testing. Whilst this property of thermoplastics can exert a major influence on service performance of components its effect would not be evident in the shorter timescale of the static test.

Fourteen patients have been fitted with experimental prostheses based on various combinations of plastic shanks and alignment devices. The longest period of use is 33 months. Four service failures occurred at 2, 5, 10 and 18 months respectively, three due to ankle bolt failure, one due to partial pull-out of the proximal shank insert. Flexural fatigue failure of the fixing bolt is indicated due to distortion and loosening of the ankle joint in two cases. Poor selection of fixing bolt size (i.e. 8mm rather than 10mm for a highly active male patient) is proposed as the dominant reason for failure in the third case.

The shank design gave the opportunity for testing the validity of the Philadelphia Static Load Level for prostheses by building-in failure loads around this figure (2.5kN) based on insert pull-out. Patient trials revealed only one case of insert pull-out although whether due to overload or fatigue loading cannot be ascertained. This finding focuses attention on the ability of prostheses designed to Philadelphia Static Load Levels and cyclic load levels to withstand service loading over extended periods. In addition it indicates that the DHSS static test standards for prostheses are probably excessive. It is concluded that the Philadelphia Static Load Level along with fatigue testing is a satisfactory test criterion, at least over the timespan of the present patient trials, for general service use of thermoplastic prosthetic components.

Acknowledgements

Thanks are due to Professor Vergil Faulkener, CPO of the Audie L. Murphy Memorial Veterans Hospital, San Antonio, Texas for fitting the patients involved in the American based trial and monitoring the performance of the prostheses. Thanks are also due to Professor G. Bentley of the Royal National Orthopaedic Hospital, Stanmore for providing medical supervision and to Mr. L. Bass for finishing off the prostheses.

This work was funded in part by the U.K. Department of Health and Social Security as part of the programme of the Bioengineering Centre. Funding was also provided by the British Limbless Ex-Service Men's Association and by the Mechanical Engineering Department of University College London.

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