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Thermoplastic alignment couplings for prostheses

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Abstract

In the context of modern engineering practice, this paper describes the exploitation of thermoplastic materials for the provision of lightweight, low cost, corrosion free, alignment devices for lower limb prostheses. After setting out design requirements, four newly developed devices are described and discussed. These are respectively a four jack system, a serrated wedge system, a spherical alignment system and a serrated slider.

The level of laboratory fatigue testing and experimental field performance is reported and examples are shown of the application of these systems to tapered column thermoplastic below-knee prostheses.

Introduction

Alignment of a lower limb prosthesis may be defined as the position and orientation of the socket relative to the foot. The purpose of an alignment device is to enable the optimum geometrical relationship between socket, shank and foot unit to be established so as to achieve maximum patient comfort, together with a good gait.

Alignment devices may be classified under two main headings: 'built-in' alignment units such as the Otto Bock device which remain an integral part of the finished prosthesis; and temporary devices which are transferred-out after dynamic alignment using a duplication jig prior to construction of the definitive limb. The Staros Gardner adjustable coupling is an example of the latter type (Staros, 1963) and an alternative is the Berkeley jig (Radcliffe and Foort, 1961; New York University, 1972).

Built-in alignment devices enable the relative position of the socket and foot unit to be altered after the trial stage if necessary without major modification and reconstruction of the prosthesis. This is one of the major advantages of the modular system of artificial limbs over the conventional or crustacean type of limb construction.

Alignment systems may be subdivided into two categories:

1. The neutral or vertical pylon system in which both angular and linear adjustments of the socket relative to the foot are achieved using one alignment unit immediately distal to the socket for below-knee (BK) prostheses and proximal to the knee unit for above-knee (AK) prostheses (Solomonidis, 1975; 1980).
2. 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.

The facility for rotation of the foot unit with respect to shin tube or shank is usually provided in both of these systems.

One of the earliest 'built-in' alignment units is Foort and Hobson's (1964) Winnipeg wedge disc system which is non-neutral. Tilt of the socket and foot unit with respect to the shin tube in A/P and M/L planes is achieved by rotation of wedge discs distal to the socket and proximal to the foot. The alignment procedure is complicated by the fact that socket movements in A/P and M/L planes are interrelated so that it is often difficult to obtain a specific alignment. This alignment coupling is usually attached to the socket and foot unit by a single bolt which makes adjustment inconvenient even when a slot is incorporated in the distal end of the socket. Furthermore loosening of the fixing bolt results in release of the wedge discs from their previous

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position so making controlled adjustments difficult. Advantages of the wedge disc alignment system relate to its small number of component parts, and low overall height.

Design requirements of alignment devices

A clinical and constructional evaluation of various modular prostheses including details of their alignment devices is contained in Solomonidis (1975; 1980). In this context, basic design requirements are enumerated.

1. Any alignment device should possess a wide range of adjustment since bench alignment is then less critical. A follow-up meeting to a conference on Cosmesis and Modular Limb Prostheses at San Francisco in 1971 recommended that alignment units should possess a minimum adjustability of 8° flexion, extension, abduction and adduction and/or 20 mm horizontal movement in M/L and A/P planes (National Research Council, 1971).
2. Importantly for the prosthetist, adjustment should be measurable, independent, controllable and easily accomplished.
3. Effective locking of the alignment device during and after alignment procedures is of course a necessity but in addition, an established alignment condition should preferably be retained on unlocking the device so serving as a reference for subsequent adjustments.
4. Easy access to fixing bolts or locking mechanisms facilitates the alignment procedure thereby reducing inconvenience to patient and prosthetist.
5. From the point of view of manufacture an alignment device should be of simple design, of low overall height and contain few component parts to reduce complexity and cost. It should preferably be produced from corrosion resistant, lightweight materials or combinations of materials.

These objectives set the scene for describing the potential of thermoplastic components as prosthetic alignment devices, both novel and established. The associated inherent properties of light weight, corrosion resistance and low production cost can be used to advantage.

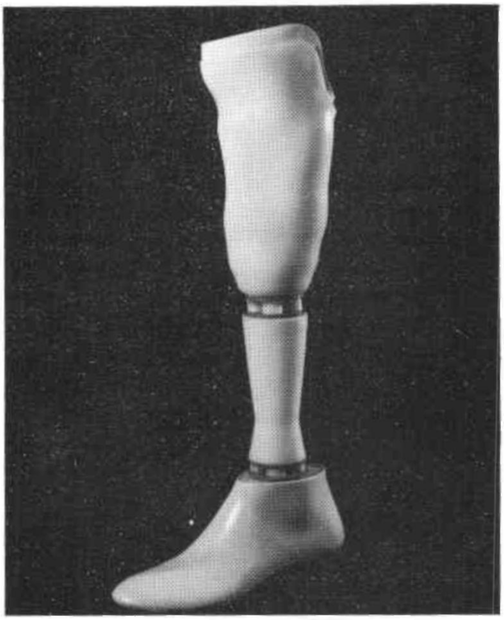

Fig. 1. Tapered column thermoplastic prosthesis with jacked-alignment device.

Thermoplastic jacked-alignment device

The thermoplastic 'jacked-alignment' device is primarily intended for use as a built-in unit with rotationally moulded thermoplastic shank sections (Figs. 1 and 2). It could however be used in conjunction with aluminium alloy shin tubes using appropriately designed adaptors.

The device, used in a non-neutral pylon prosthesis distal to the socket and proximal to the foot, enables rotation of the socket and foot unit relative to the shin tube in A/P and M/L planes. This is accomplished by a tilt action using a system based on four jacking nuts spaced 90° apart. It utilizes the same tilting method as the Staros Gardner alignment coupling for obtaining independent adjustment of socket flexion, extension, abduction and adduction. The jacked-alignment device is both locked and connected to the shank section and socket (or foot unit) by a single bolt.

The component parts of a jacked-alignment device intended for use at the socket/shank interface of a BK prosthesis are shown in Figure 2 (bottom) and consist of:

(a) A base plate which is located by a square boss, in the proximal end of a shank section.

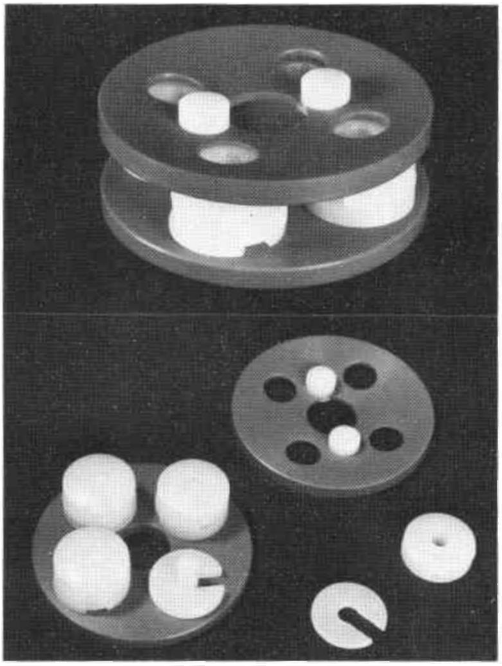

Fig. 2. Top, the jacked-alignment device. Bottom, component parts of the device.

(b) A socket adaptor plate which is located by two cylindrical bosses in a slot at the socket distal end.

(c) Four threaded columns spaced 90° apart which are press fitted into slots in the base plate to act as supports and guides for jacking nuts and snap-in spacers.

(d) Domed jacking nuts. Movement of the appropriate nuts (using an Allen key inserted in a hole in the side of the nut) results in tilt of the socket adaptor plate in A/P or M/L planes. The convex surface of the jacking nut interfaces with a concave surface or radiussed seating in the socket adaptor plate.

(e) Snap-in spacers which are positioned below the jacking nuts once optimum alignment has been established and act in conjunction with them to form a load bearing column. An alignment device intended for use at the foot/shank section interface would be built up from the same basic components, all of which are produced from thermoplastic.

In order to effect a change in alignment, the appropriate fixing bolt is loosened. (Access to the socket fixing bolt is facilitated by a slot at the distal end of the socket). The domed jacking nuts are raised or lowered depending on patient alignment requirements. When optimum alignment and/or prosthesis length has been established, plastic spacers are snapped-in beneath the domed jacking nuts to form four support structures. The fixing bolt is finally tightened.

Independent control over tilt angle in A/P and M/L directions is available with tilt angle variable over 1.6° increments to ± 11.2°. The incremental tilt adjustment is governed by 1 mm increments in spacer thickness. The snap-in spacers, as well as providing a load bearing function in the alignment device, serve as a built-in calibration facility. The fixed position of jacking nuts and spacers corresponding to a particular alignment defines exactly the tilt condition introduced. Subsequent adjustments can be made with the jacked-alignment device relative to a stable and definable reference and a previously established alignment condition is maintained on loosening the fixing bolt. The device can be used to vary the length of the prosthesis by snapping-in four equi-height spacers.

The movement of domed jacking nuts along their threaded support columns initially defines the required tilt angle in A/P and M/L directions during alignment procedures. Load bearing capacity is conferred on the alignment device by snap-in spacers which are positioned below the jacking nuts and act in conjunction with them to give four support pillars. The central threaded columns are thus not used in a direct load bearing role so avoiding a source of stress concentration and weakness due to the screw thread. Resistance to torque loading is achieved on tightening the fixed bolt by contact between the domed surface of the jacking nuts and the spherical seatings in the adjacent adaptor plate.

The jacked-alignment device is produced entirely from thermoplastic giving the advantage of light weight and corrosion resistance. The weight of a unit for incorporation at socket level and foot level (minus fixing bolt) is typically 50 g. In addition the overall height of the device after alignment will probably not exceed 25 mm so resulting in a compact unit. Its simple design and assembly offers the potential for low cost manufacture by injection moulding or batch production by machining.

The main disadvantage of the jacked-alignment device is the relatively poor accessibility of the fixing bolts. At socket level this problem has been reduced to some extent by provision of a slot in the side of the socket at the distal end together with a thermoplastic adaptor for manipulating the fixing bolt from outside the socket. A similar access slot is provided in a thermoplastic, uniaxial foot adaptor currently under development. Use of a laterally slotted SACH foot unit and special bolt obviates the necessity for removal of the shoe before alignment adjustments at the ankle can be carried out. This is subsequently replaced by a standard unit once optimum alignment has been achieved.

Thermoplastic wedge alignment device

Winnipeg wedge disc alignment units, when used in BK prostheses are commonly situated at ankle level and distal to the socket to permit angulation of socket and foot unit relative to the shank. Each unit comprises two wedge discs each having an angulation of 6° giving a possible total angulation in one plane of 12° and 6° each in two planes. When both discs are moved synchronously, angulation occurs in one plane. To provide angulation in two planes, the discs are moved independently of each other.

A major problem encountered with multiple wedge discs in alignment units is that of loosening and consequent slippage under torque loading (Solomonidis, 1975). This limitation was overcome by Breakey (1973) who used a series of one piece wedge adaptors to duplicate the alignment determined with the Winnipeg wedge disc unit. He found that single aluminium wedge adaptors with angulation of 0, 2, 4, 6, and 8° were adequate in meeting the alignment needs of patients and the single adaptor eliminated the problem of wedge slippage. A drawback of Breakey's adaptor system is the need to change the adaptor during dynamic alignment if changes are necessary. Other disadvantages of the Winnipeg wedge alignment coupling are poor access to fixing bolts, tendency for release of the wedge discs from an established alignment position when the fixing bolt is loosened and the interrelationship of A/P and M/L movements which complicates alignment procedures.

Decided advantages of the wedge alignment system however include simple design, low overall height and small number of components which reduce the complexity and manufacturing cost of the device. The development described here is of an easily calibrated thermoplastic version of the wedge alignment system which overcomes several of the disadvantages mentioned above.

An experimental BK prosthesis incorporating a rotationally moulded thermoplastic shank, Rapidform polypropylene socket and 'built-in' wedge alignment devices at ankle level and distal to the socket was shown in Figure 1 of Coombs et al (1985). The shank is connected to the foot unit and socket, via the wedge alignment coupling, by single bolts which engage in moulded-in inserts at either end of the shank. The components making up this particular example are shown in Figure 3. The wedge alignment device currently undergoing evaluation by laboratory testing and service use, comprises:

(a) A thermoplastic socket adaptor shaped to match the curved distal end of a Rapidform polypropylene socket and locked to it by two bosses which protrude from the upper surface of the adaptor and engage in the standard machined

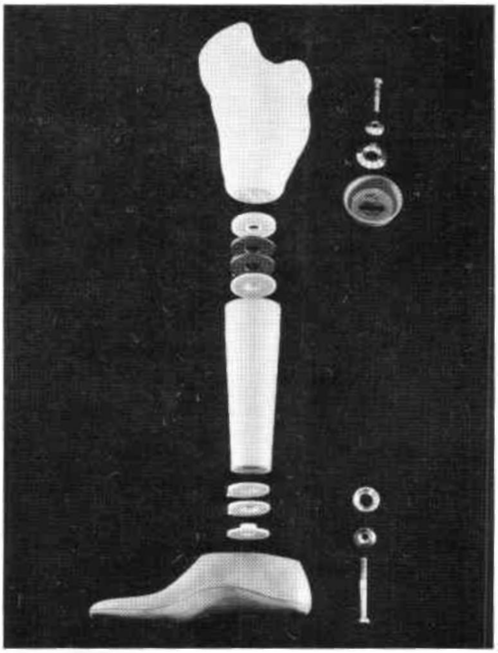

Fig. 3. Exploded view of a tapered column prosthesis with wedge alignment at two locations.

slot at the socket distal end. The base of the adaptor interlocks with the adjacent wedge component by means of a series of grooves radiating from the centre of the adaptor.

(b) Two 6° thermoplastic wedges permit angulation between socket (or foot) and shank. These components display the same pattern of radiating grooves mentioned above which efficiently locks adjacent components preventing slippage under torque loading. The pattern of radiating teeth or grooves form essentially an array of dove tail joints which when located with a similar set, prevent radial movement of engaged components as well as rotation thereby enhancing the locking effect. Wedge adjustment is facilitated by using an Allen screw temporarily attached to each wedge component which also functions as a reference line during alignment procedures.

(c) A thermoplastic shank adaptor is locked to the shank by a square boss and to the adjacent wedge by a pattern of radiating grooves. A central locating bush is incorporated to prevent lateral movement and misalignment of the wedges when the fixing bolt is loosened for wedge adjustment.

Angulation of the foot unit with respect to the shank is accomplished by using a similar arrangement of serrated wedges and adaptors. Movement of fixing bolts from the perpendicular is accommodated within the socket and foot unit respectively by radiussed washers and seatings.

In addition to preventing slippage between components of the alignment device during prosthesis assembly, alignment or service, the serrations introduced on mating surfaces maintain engagement and therefore an established alignment condition when fixing bolts are loosened. The four basic components of the wedge alignment device are produced from thermoplastic giving the advantages of light weight, corrosion resistance and low cost manufacture by injection moulding for instance. The weight of a unit (minus fixing bolts and seatings) is typically 50 g and the overall height of the device including adaptors is 18 mm which enables incorporation in prostheses fitted to long stumps. The poor accessibility of fixing bolts remains one of the main disadvantages of this type of system but the problem has been reduced as mentioned earlier by providing access slots in socket, uniaxial foot adaptor and the SACH foot unit used for alignment purposes.

Importantly for the prosthetist, an alignment device should provide measurable, controllable, easy and preferably independent adjustment in A/P and M/L planes. Although A/P and M/L tilt movements are not independent for the wedge

Resultant angle combination 7 A/P 1 M/L

Some combinations of angles available simultaneously in A/P and M/L planes using double wedge system.

A/P . M/L angle
12 . 0
3 . 3
7 . 1 etc

12.0						
11.1						
10.2	10.0					
9.3	9.1					
8.4	8.2	8.0				
7.5	7.3	7.1				
6.6	6.4	6.2	6.0			
	5.5	5.3	5.1			
		4.4	4.2	4.0		
			3.3	3.1		
				2.2	2.0	
					1.1	
						0

Fig. 4. Addition-subtraction disc for calibrating a wedge alignment device.

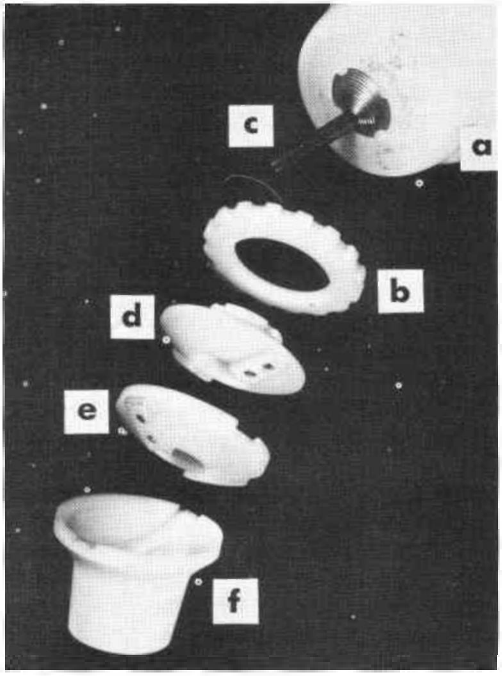

Fig. 5. Exploded view showing the component parts of the spherical alignment system. a) socket; b) jacking ring; c) centre bolt; d) locking unit, e) P.A.L.M. adjustment plate; f) spherical shank adaptor.

alignment system, the relationship between wedge position and resultant angulation can be readily obtained by reference to the calibration disc shown in Figure 4. This has been constructed on the basis of a system put forward by Breakey (1973). The basic combination of angles available simultaneously in A/P and M/L planes is also shown in Figure 4. The calibration disc is positioned below the wedge alignment device and aligned with its main axes in A/P and M/L directions. The resultant alignment conditions are obtained by adding the outer two numbers adjacent to the thin edge of both wedges to give A/P angulation and subtracting the inner two numbers to give the resultant M/L angulation. The wedge configuration shown in Figure 4 for example results in an angulation of 7° and 1° in A/P and M/L planes respectively.

Thermoplastic spherical alignment device

This device combines the light weight, low cost and corrosion resistance of thermoplastics with easy angular adjustment made without removing the prosthesis. A 'C' spanner is used to release a jacking nut allowing independent M/L or A/P angulation which is visually measurable.

Figure 5 is an exploded view of the spherical alignment components. Just below the socket (a) is the jacking ring (b) which pushes against the outer face of the socket to pre-tension the centre bolt (c). The locking unit (d) acts as non-rotatable connection between socket and P.A.L.M. (Posterior Anterior Lateral Medial) adjustment plate (e). The jacking ring screws against the socket to compress all components during the patient trial stage of fitting before alignment is finalised. The P.A.L.M. adjustment plate provides a location dog and at right angles a location groove to prevent the assembled components from turning on the axis. Both dog and groove have a series of teeth pitched at 2° to give angular settings with the number of teeth protruding giving an easy visual measure of set alignment angle. This feature and the assembled unit are shown in Figure 6. The spherical shank adaptor (f) enables mounting onto any suitable shank.

Changes in alignment are accomplished as follows. The device is assembled as shown in Figure 6 with the jacking ring screwed into contact with the bearing face of the locking unit

Fig. 6. Assembled spherical alignment unit.

together with the centre bolt in sufficient tension to hold the assembly together without rotation, but still allowing adjustment of the spherical surfaces. With the initial alignment set the jacking ring is screwed against the socket thereby tensioning the centre bolt and locking all components together allowing the patient to weight bear and walk. If further adjustment is required a 'C' spanner is used to loosen and subsequently tighten the jacking ring externally to the artificial limb. When alignment is satisfactory the limb is removed from the patient and the reference points recorded. The jacking ring is firmly screwed down to its home position on the locking unit and the centre bolt is finally tightened to hold the whole assembly together.

Combination slide and angulation units

In order to provide an option of using any of the above devices in a single alignment unit which permits both angulation and linear adjustments, thermoplastic slide modules have been developed for use in conjunction with the basic angulation module. The construction, locking system and testing of these slide units which are primarily intended for use with rotationally moulded shanks, is described below. Dorsiflexion, plantar flexion, inversion and eversion of the foot unit can of course be retained by providing an angulation module at the ankle.

A combination of slide and angulation modules in a single alignment unit is illustrated in Figure 7. Linear movement is achieved by using a system based on slots and a sliding bolt. The 8 mm single bolt fixing employed to attach socket and shank via the selected alignment device also functions as a locking device in conjunction with the serrated surface of the slide units. The component parts of the slide module are shown in Figure 8 and consist of:

(a) A slotted aluminium alloy insert (not illustrated) which is moulded-in to the proximal end of a rotationally moulded shank to enable linear adjustment in the A/P plane. It incorporates a flanged nut which slides within the insert to provide attachment for the socket fixing bolt. The nut also has machined flats which engage in the slot to prevent rotation under torque loading.

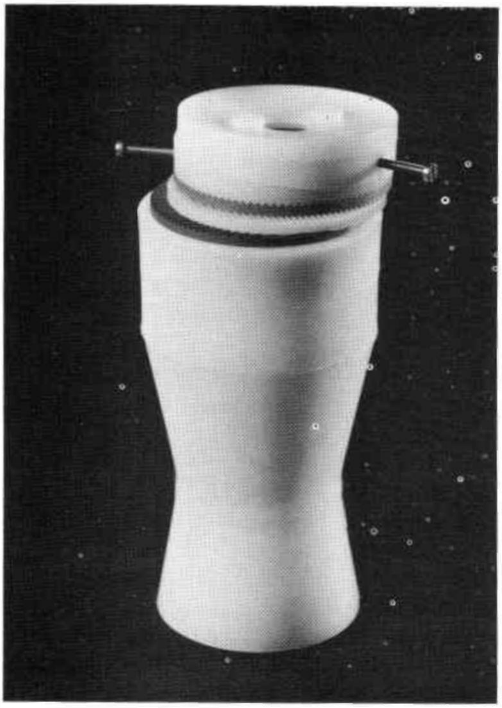

Fig. 7. Alignment coupling incorporating slide units and wedge angulation device.

(b) A slotted shank adaptor which is locked to the slotted insert moulded-in at the proximal end of the shank by a slotted rectangular boss. The upper surface of the shank adaptor displays a pattern of parallel grooves running perpendicular to the slot length which functions as (1) a built-in calibration device for A/P movement, (2) a locking system to

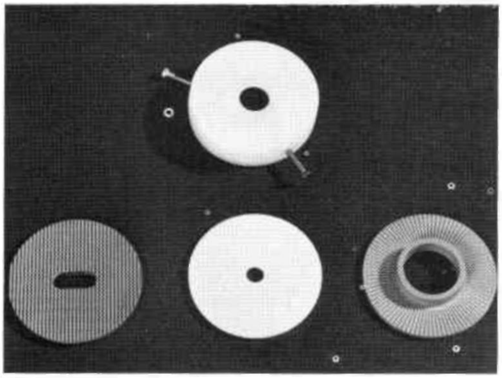

Fig. 8. Component parts of slide alignment unit.

prevent further movement in the A/P direction after an alignment condition has been established, (3) a locking system to counteract movement of the adjacent 'locking disc' under torque loading.

(c) A locking disc having a central hole which provides independent locking of A/P and M/L movements. This is accomplished by arranging that the parallel serrations on one surface of the disc are mutually perpendicular to those on the reverse side. Engagement of the locking disc with the shank adaptor in a particular position locks the A/P movement of the fixing bolt. (M/L movement is prevented by the limited width of the slot). The opposing set of serrations on the reverse side similarly lock M/L movement of the fixing bolt when the angulation module (wedge system or jacked system) and locking disc are engaged.

(d) An angulation module adaptor. The lower surface of the adaptor again displays parallel serrations which lock linear movement when engaged with the locking disc. The upper surface displays a radial pattern of grooves which permits rotation and then locking of engaged wedge discs.

Linear movement of the socket relative to the shank in the M/L plane is accommodated by a slot cut in the distal end of the socket. The slide unit provides ± 7 mm of A/P movement and ± 8.5 mm M/L movement. The parallel serrations provide an in-built calibration facility which defines exactly the amount of linear shift introduced during alignment change. The alignment condition is also retained on loosening the fixing bolt due to the locking effect of the serrations which enables subsequent adjustments to be made with reference to a stable and definable reference. Effective locking of the alignment device after 'optimum' alignment has been achieved is ensured by engagement of the serrations of the shank adaptor and angulation module with those of the locking disc, augmented by constraint of the slots on bolt movement.

Slide units are produced entirely from thermoplastic giving the advantages of light weight and corrosion resistance. In addition the simple component design offers potentially low cost manufacture by injection moulding. The weight of a complete alignment device offering both slide and tilt facility is typically 60 g and the overall height of a complete unit is 25 mm which confers the added advantages of compactness.

The main disadvantage of the alignment device is the relatively poor accessibility of the socket fixing bolt which must be loosened before sliding alignment can be made. This problem can be reduced however by provision of an access slot in the side of the socket at the distal end together with a thermoplastic adaptor for manipulating the bolt from outside the socket.

Laboratory testing and field performance

The first two devices described (jacked and wedge) have been subjected to over one million fatigue loading cycles under an axial load of 1350N with a superimposed bending moment of 140Nm. These tests have been carried out in combination with thermoplastic rotationally moulded shank sections (tapered columns). With the loading at distal and proximal ends of the assembly there was no visible deterioration of the units. Each of these systems has been supplied to two patients to date, again on tapered column prostheses. The four patients are young and active and frequent inspections over the past 5 to 15 months reveal no deterioration in the thermoplastic components. Other patients are being fitted with these experimental systems currently.

The spherical and slide devices also described above are at a slightly earlier phase. Their design and development are complete and laboratory testing has been initiated. Clinical trials will then proceed in order to highlight the major points, both positive and negative, as seen by the patients and prosthetists and also to provide a basis for comparing the new ideas emerging.

Conclusion

Four thermoplastic alignment devices have been designed for use in the new generation of prostheses using modern materials and production techniques. Three provide angulation capability immediately distal to the socket and the ankle and one provides translation capability for use, if desired, in combination with any of the angulation devices.

The devices each weigh in the order of 50 g and occupy less than 25 mm of leg length. This lightness and compactness results from the use of thermoplastic materials and from the simplicity of design. It is intended that the devices described will be produced at low cost by injection moulding methods.

Patients will benefit from the above advances and from the extended life time to be expected as a result of the excellent fatigue properties now being demonstrated and the resistance to corrosion exhibited by thermoplastics.

Acknowledgement

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