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The Flek-shin: a composite material for use in flexible shank below-knee prostheses

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Introduction

Conventional below-knee prostheses are manufactured of rigid materials for durability and stability. The use of glass fibre and resin composite materials to form the rigid shank of the below-knee prosthesis is well established in many countries and forms part of the modern practice of cosmetic prosthesis manufacture.

While these materials are strong, durable, easily worked and cosmetically acceptable, there are a number of disadvantages. Mechanically they are essentially inert. The finished limb resists compressive and bending forces and as a consequence running, jumping and even vigorous walking are performed only with difficulty and certainly at high energy cost to the wearer.

A new material has been developed at the Wellington Artificial Limb Centre and the Wellington School of Medicine which is semirigid but sufficiently flexible to allow its energy storing properties to be utilized in amputee gait. No data on the suitability of this new composite material for use in artificial limbs exist. As part of the development of this material it was essential to determine its fatigue strength and durability before further development of this exciting new concept could proceed.

Method

A composite material was fabricated by laminating glass fibre, carbon fibre and Kevlar™ in a mould, without prestressing the tensile elements, and then incorporating a methyl methacrylate resin (70% rigid Orthocryl®, 30% flexible Orthocryl®). The laminate was compressed during curing of the resin. The resulting composite material was then aligned and mounted on a custom-made socket and a standard Otto Bock S.A.C.H. foot.

a. Deformation tests The deformation of a shank during normal use was measured by fixing a foot plate in the shoe to which was attached a blade, orientated in the sagittal plane, and bearing a piece of white card. On to the proximal end of flexible shin segment of the prosthesis, a stylus was mounted and adjusted so as to record the displacement of the upper end of the composite shin on the white card. The subject then donned the prosthesis and executed a number of vigorous runs. This recorded the bending in the shin relative to the foot of the prosthesis.

b. Fatigue tests Base-line stress/strain data were recorded on an Instron before fatigue testing (Fig. 1, top).

Each shank was then mounted on a test rig comprising a pneumatic cylinder driven by compressed air and controlled by valves for cyclic loading (Fig. 1, bottom). The rig was capable of applying variable bending loads to the flexible shin at a variable frequency. The frequency of loading for these tests was one Hz as recommended by Wevers and Durance (1987). The number of cycles was recorded by an IVO (model H200) event counter. Failure of any of the prosthetic components resulted in the test material falling away from the test rig and the cessation of counting.

Each flexible component was tested initially for the equivalent of three months use. It was then retested on the Instron to determine if there had been change in the mechanical properties of the composite material. The cyclic loading was repeated in three months use equivalents and tested to the equivalent of two

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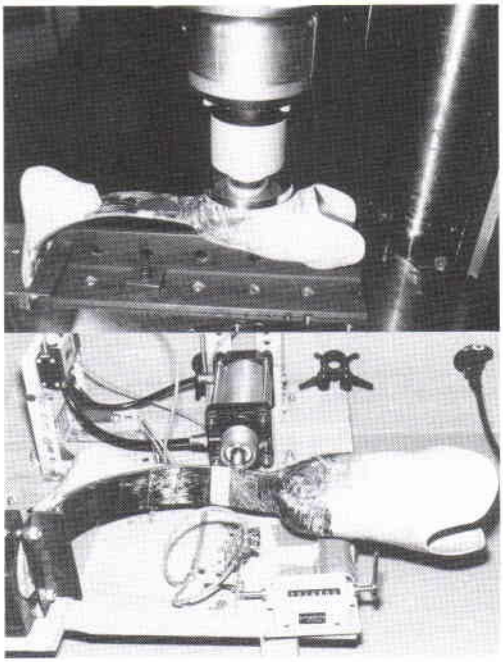

Fig. 1. Top, below-knee prosthesis with the flexible composite material of glass fibre, carbon fibre, Kevlar™ and synthetic resin with the cosmetic cover removed, mounted on the Instron for testing. Bottom, fatigue testing rig showing the Flek-shin mounted by the toe. The pneumatic cyclinder applies a cyclical bending force to the proximal end of the prosthesis. The counter records complete cycles.

and a half years of use or until fatigue failure of the composite material occurred.

From the stress/strain graphs for each "three months equivalent" stage, the degradation of the mechanical properties of the new composite shank material became evident and on the basis of these results the suitability of the material for incorporation into below-knee prostheses for selected patients was assessed.

Height and weight considerations for patients of different body habitus were not incorporated at this stage.

c. Field tests Prostheses each incorporating a flexible shin (Flek-shin) of this composite material were fitted on three patients for subjective assessment. Patients were asked to use the new Flek-shins regularly for a period and then to report back on their impressions of the new material.

Results

Fatigue testing of the material was continued until failure or to the equivalent of two and a half years of vigorous use. Of the samples tested none failed during testing and all endured for the equivalent of two and a half years.

The stress/strain characteristics of the samples showed no statistical change over the period of testing. Typical stress/strain graphs for one specimen tested at 0, and 30 months are shown in Figure 2. The apparent hysteresis effect is accounted for by movements in the test instrument between compressive and tensile modes.

The subjective tests carried out by the three patients all produced favourable reports. Each agreed that the new prosthesis felt "alive" and that running was almost a new experience. When each patient was being observed there was an obvious difference in running gait between using a standard, rigid shank prosthesis and the Flek shin.

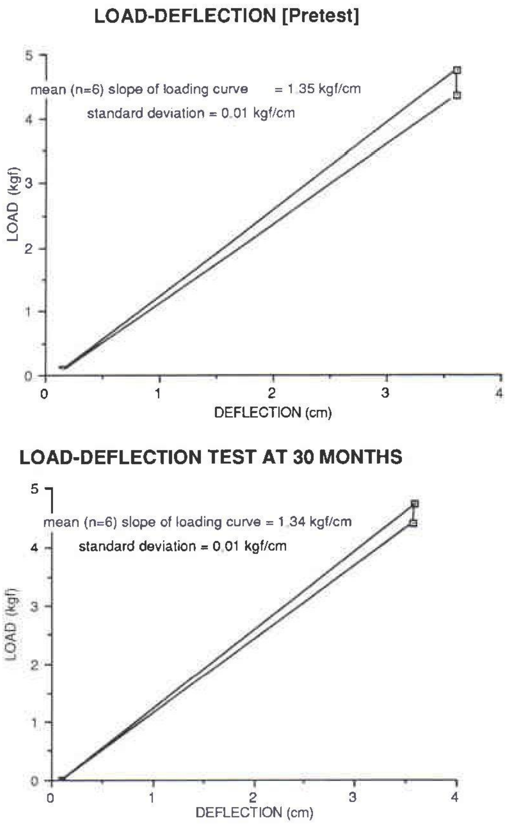

Fig. 2. Stress/strain graphs for one sample of the composite material tested after the equivalent of 0, and 30 months of vigorous use. No statistical difference exists between these recordings.

Discussion

Energy utilization in amputee gait is increased over that in non-amputee gait. In an attempt to gain a relative reduction in energy expenditure in vigorous physical activity in amputees the use of flexible components in below-knee prostheses has become widespread.

The inclusion of a semi-rigid, shank connecting the socket with the terminal device (foot) has been shown to improve greatly the functional abilities of the amputee as far as vigorous activity is concerned. The basis of the improved function is the bending of the shank during the flat foot to toe-off phase of the gait cycle. This stores potential energy within the shank which is released as kinetic energy as "active" plantar flexion of the prosthetic foot at toe-off. The effect is similar to the active plantar flexion of the foot brought about by the sural triceps and the long toe flexors during normal gait.

Various examples of flexible feet and shank components are available commercially. The authors have found that it is possible to fabricate, without sophisticated equipment, a laminated composite of glass fibre, carbon fibre, Kevlar™ and synthetic resin which fulfils the requirements of an energy storing component for use in below-knee prostheses. This material is easily modified to suit individual patients in that by changing the composition of the composite material the relative flexibility, and thus the energy storing capacity, can be tailored to each patient's needs.

The material has been fatigue tested using bending loads to an equivalent of two and a half years of vigorous use without significant deterioration in its elastic deformation properties. At this stage it would have outlasted many of the other components of a standard below-knee prosthesis. The material is recommended for the younger active patient committed to vigorous sporting activities.

Acknowledgements

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