Prefabrication of knee-ankle-foot orthoses

BACKGROUND

The design of metal leg callipers has not changed for over a hundred years, yet in India they are still commonly used by people who have suffered from polio. Although they can be effective, these callipers (or orthotic braces) are heavy and cumbersome, and have to be worn with boots - inappropriate in a culture where most people walk barefoot. Disabled people, especially children, often reject callipers and as a result their impairment can become more pronounced. The result is isolation, dependence and further loss of mobility.

A well-fitted, lightweight plastic calliper used in early childhood can improve a child’s quality of life immeasurably.

Plastic knee-ankle-foot orthoses (KAFOs) were introduced in India 12 years ago. Unlike metal callipers, KAFOs are lightweight, discreet in appearance and user-friendly. If fitted properly, they have a high acceptance rate amongst children. A well-fitted, lightweight plastic calliper used in early childhood can improve a child’s quality of life immeasurably by making possible everyday activities such as walking to school.

The conventional method of making a KAFO for a polio-affected leg is to take a cast of the whole leg to make a plaster replica. Plastic sheets softened by heat are then hand- or vacuum-moulded over the replica to make braces that fit the contours of the leg and foot, whilst providing support at the same time.
Orthoses for lower limbs are usually made in two parts, the below-knee and the above-knee (thigh) components, which are joined together using metal uprights and knee joints.

The cost and the time needed to produce KAFOs in this way means that they are not widely available. Each orthosis has to be individually crafted, taking up to five days to produce. Additionally, the disabled person may have to make several visits to the workshop for trials.

**THE PROJECT**

This project aims to design a mass-production system to prefabricate low-cost, thermo-plastic KAFOs for rapid production and easy assembly and fitting, based on existing research. These new orthoses are designed to be cheaper and more adaptable. They can be fitted wherever basic workshop facilities are available.

**Mobility India (MI)** is working closely with a large plastics manufacturer, Abhyanta Plastics, to test production techniques for manufacturing orthotic shells of appropriate dimensions and strength. Measurements for ten standard sizes have been obtained by analysing data involving hundreds of individual measurements. Based on this research, a set of blow-moulding dies is being made. There will be 40 dies in total, as four dies (above-knee or below-knee, left leg or right leg) will be made for each of the ten sizes. Orthoses for approximately 8,000 people will be produced and fitted during the life of the project.

Students at national institutes and technicians from rehabilitation centres are involved in fitting and testing the product. User response is being analysed and used to further refine the process. To date (January 2003), metal dies have been created and automated for eight out of ten sizes for the above-knee components, and five out of ten sizes for the below-knee component.
Despite difficulties with suppliers, which have slowed down production of both the dies and orthotic shells, more than 1,800 orthotic components have already been produced. During a first trial, a total of 30 people have been fitted with prefabricated KAFOs.

The project is a unique collaboration between non-governmental organisations, (NGOs) the plastics industry, training institutions and grassroots rehabilitation organisations. Given that there are an estimated four million people in India who need orthoses, the impact of this initiative on post-polio management could be very significant.

**Lessons Learned**

- The project shows how important it is to try out ideas in practice. An example of the value of this is the discovery of shrinkage that occurs in the prefabricated plastic components made from metal dies. The MI team discovered that shrinkage occurs at different rates in different settings, for instance between Bangalore and Calcutta, because of humidity and other factors. When the shells were trimmed to the required size the edges were found to shrink more, therefore the shells are now left uncut until the point of use, which has resulted in the need for more storage space than originally expected.

- There is much to be learned from working with professionals and artisans from diverse settings, in this case, an NGO working on mobility with a commercial plastics company. This collaboration utilised many different skills and was particularly helpful in coming up with the fabrication methods of the special dies, which are now being used to prefabricate the orthoses.

- Using local resources rather than being reliant on imported resources is a valuable practice. It reduces cost, stimulates local industry and is potentially more sustainable. Examples include using jigsaws to cut orthoses rather than expensive, imported plastic cutters, and using a bicycle spoke to ensure that a knee joint is straight and level, rather than using an expensive, imported rig.

- The project illustrates the importance of having good project management skills. In this particular case, the skills have been partially provided by MI, with support from the Jaipur Limb Campaign. This support has included access to funding, the provision of technical expertise, facilitating introductions to other NGOs in the UK and regular support and advisory visits.
**FUTURE PLANS**

Training for M I’s own staff and orthotists is underway as they continue to fit a number of clients as part of the trials. As part of an initial dissemination strategy, further training and demonstrations are planned to introduce the newly adapted prefabricated KAFOs technology and techniques for fitting. These will be aimed at:

- rehabilitation professionals
- trainers from national rehabilitation and professional bodies
- national training institutes
- grassroots rehabilitation NGOs
- commercial orthopaedic workshops.

Patenting agencies have been identified to assist M I in patenting the concept and technology for producing prefabricated KAFOs in this way, as well other ideas such as a low-cost ‘aligner’ to ensure the correct alignment of knee joints.