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The University College London's Plastic Below-the-Knee Socket and Shank System

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The use of thermoplastic materials in the fabrication of prosthetic sockets has been a goal of the prosthetic profession for many years. In the 1960s, the Veterans Administration Prosthetic Research Laboratory developed a procedure using a thermoplastic material called "polysar" that allows the prosthetist to mold the plastic socket directly onto the residual limb.

In 1975, Tucker and Sullivan[7] used polysar in the forming of prosthetic sockets. In 1978, Compton and Edelstein[1] developed a new thermoplastic material which, reportedly, could be molded directly to the amputee's residual limb.

In 1981, Lawrence and Davies,[6] used polypropylene to form a lightweight prosthetic socket over a modified model. They developed a system of preformed modules which are heated in an oven. A programmed computer assures that the preforms are uniformly heated and are not subject to high stress during the fabrication procedure. This results in a socket capable of withstanding high sheer and extreme rotational forces created when the amputee puts full weight on the prosthesis.

Polypropylene, when combined with other polymers, makes an ideal material for use in prosthetic fabrication. The resulting prosthesis is inexpensive, lightweight, and very durable (Figure 1).

Davies, et al.[4] have developed a Rapidform process for automated manufacture of prosthetic shanks and sockets. This group has conducted an in-depth study of fatigue strength-to-weight ratio of metals, composites, thermoplastic, and thermoset materials. Their study demonstrates that a copolymer of polypropylene and nylon is an excellent material in socket manufacture. Because polypropylene is a semi-crystalline material, some shrinkage does occur during heating and cooling processes. During their investigation, Davies, et al. developed a system for minimizing this shrinkage and have labeled it a "Technique of Double Deformation." The polypropylene is first injected molded into a bell shaped preform (Figure 2). The preform is then heated and vacuum-formed over a positive model of the residual limb.

This group has also developed a computer controlled carving machine designed for making positive residual limb models. This project did not use the carving machine, instead the positive model was designed and modified

Figure 1. Polypropylene:

Density (lb/in)	**0.033**
Tensile Strength Density (in × 10^5)	**1.55**
Tensile Modulus Density (in × 10^8)	**0.15**
Tensile Strength (lb/in)	**5.1**
Comp. Yield Strength (lb/in)	**5.0**
Tensile Modulus (lb/in 2 × 10^3)	**0.16**

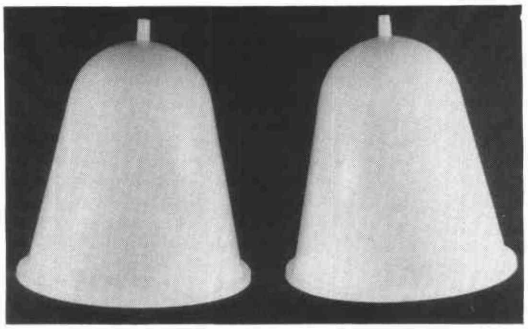

Figure 2. The polypropylene is first injected molded into a bell-shaped preform.

by the REL, then shipped as a negative to University College London for socket fabrication.

The Rapidform, a vacuum forming prosthetic socket manufacturing machine (Figure 3) consists of three sections: a loading bay, an oven with bottom access, and a driving section containing the vacuum system and associated power drives. The procedure consists of the preform being placed in the oven along with the positive model. When heat conditions, which are controlled by a microprocessor, are correct, the positive model is envaginated into the softened preform. Vacuum is applied, forming the plastic around the model, followed by an anneling process. After the process is completed, the model and socket are removed. The rapidform socket machine is almost totally automatic; it requires only that the operator load and unload the preform and positive model.

As part of the system, Coombs, et al. used a rotational molding machine (Figure 4) to make hollow tapered columns, rotational molded, from nylon that can be used for prosthetic shanks (Figure 5).

Shanks produced by rotational molding are inexpensive, lightweight, and very strong. Rotational molding is routinely used by the plastic industry, but this is the first instance of its use in the prosthetic field.

Rotationally molded shank sections are custom made for each prosthesis. Each shank is assembled from two pieces; Metallic inserts are molded in at both ends of the shank for attachment of the foot and alignment unit, and the socket.

Coombs, et al.[3] have also developed the

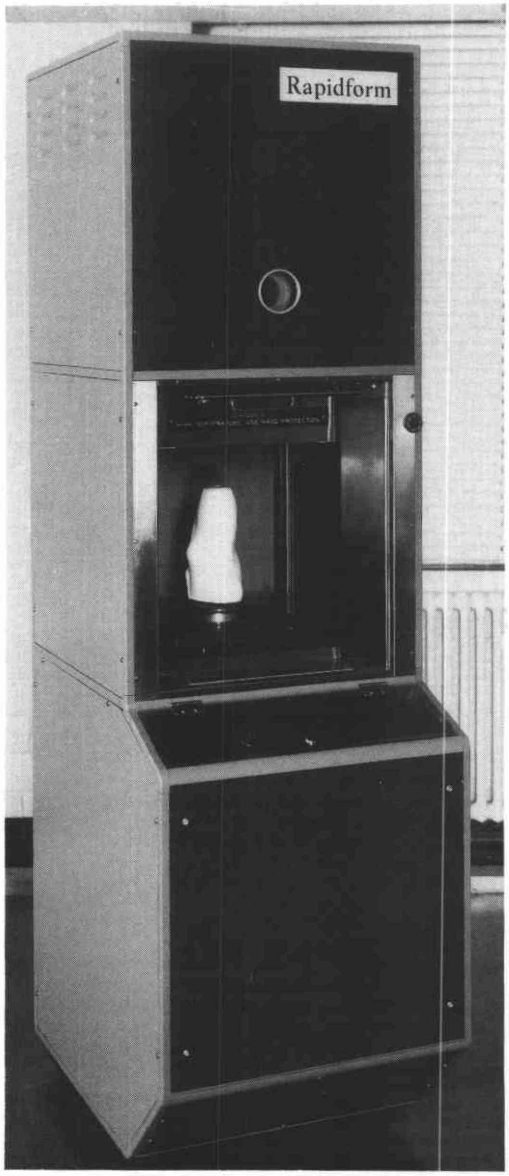

Figure 3. The Rapidform prosthetic socket manufacturing machine.

"jacked-alignment device" (Figure 6) as a companion prosthetic component to the rapidform socket and the rotational molded shank.

The jacked-alignment device is designed primarily to be used with the rotational molded

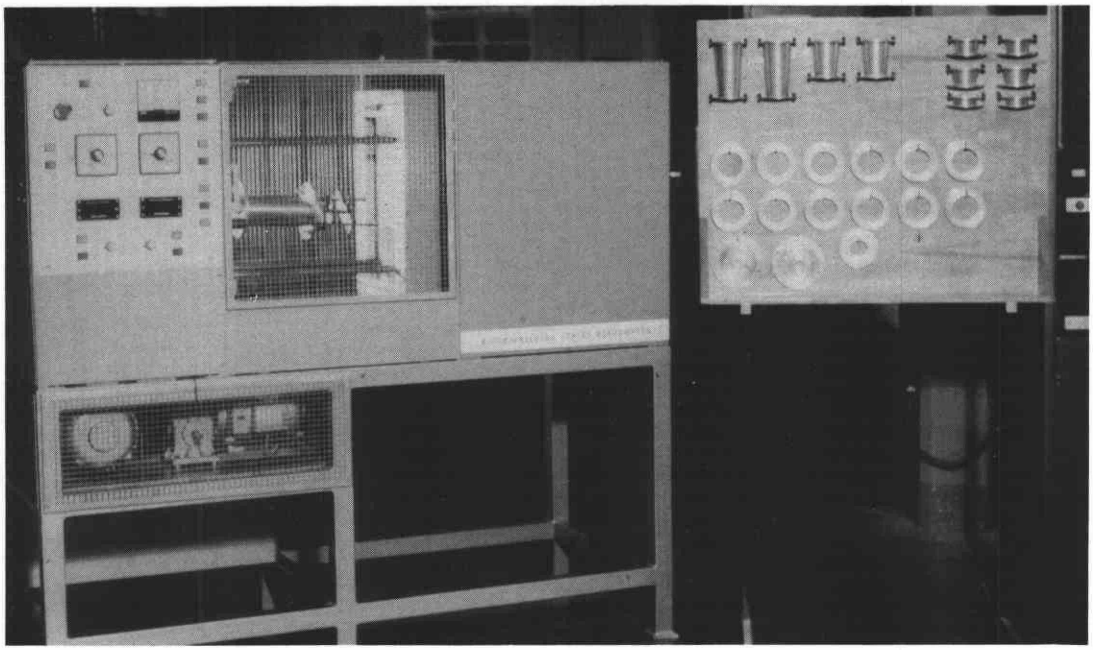

Figure 4. The Rotational Molding Machine.

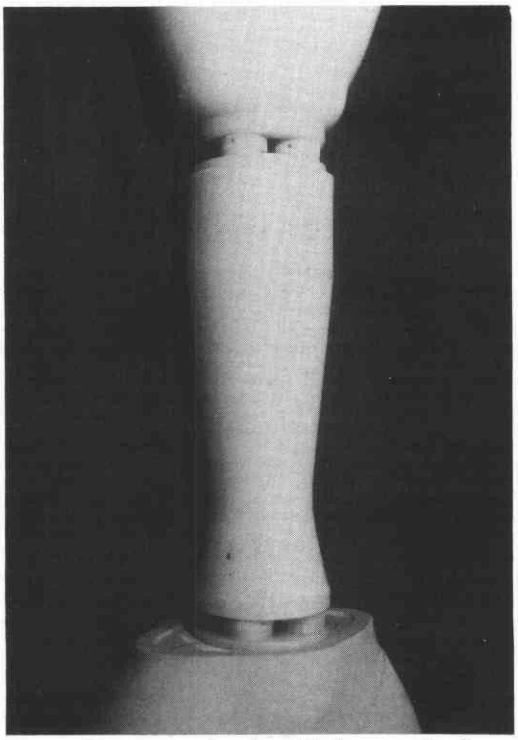

Figure 5A. A rotational molded tapered column made from nylon.

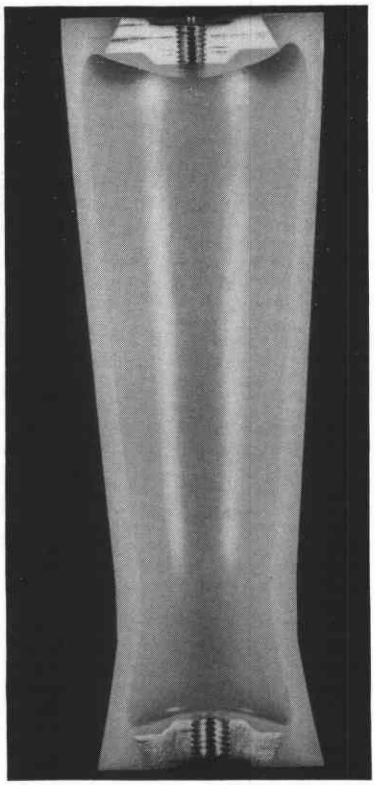

Figure 5B. A cutaway view of the rotational molded tapered column.

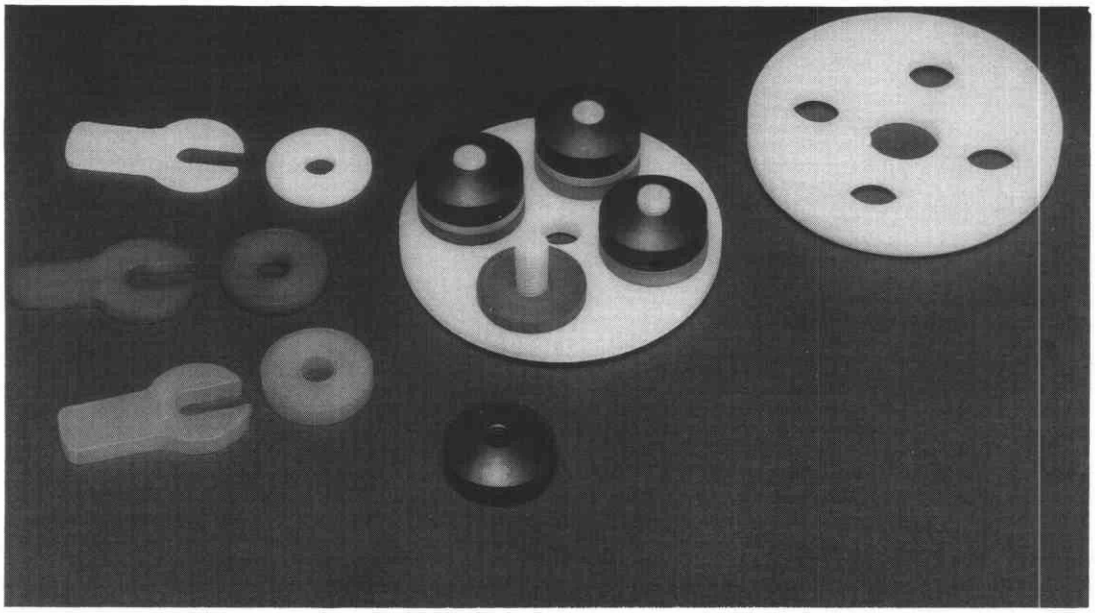

Figure 6A. The UCL's jacked alignment device.

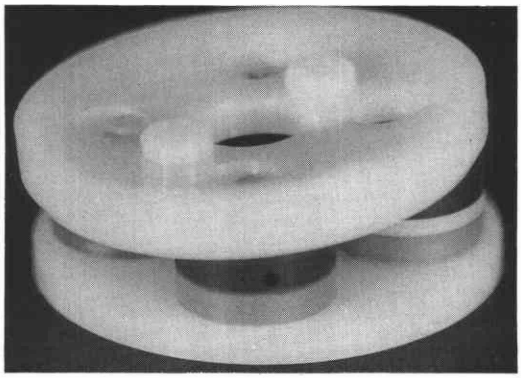

Figure 6B. The UCL's jacked alignment device.

shank, but may be used with other shank systems when appropriately designed. The device allows rotation of both the foot and the socket and allows tilting action in the anterior-posterior and the medial lateral planes. Tilting is accomplished by a series of four jacked nuts spaced 90° apart. The tilting action is accomplished using the same method as in the "Staros Gardner Alignment Coupling."[8]

The jacked-alignment device is made from thermoplastic material and weighs approximately 50 grams.

The Rehabilitation Engineering Laboratory (REL) at the University of Texas Health Science Center San Antonio and The Bioengineering Center at University College London (UCL) designed a cooperative research project to answer the following questions.

1. Can an amputee, cast and measured in the United States, be successfuly fitted with a prosthesis made in the United Kingdom?
2. What fabrication techniques are necessary to design and fabricate the prosthesis?
3. Will the rapidform socket and rotational molded shank with the jacked-alignment device be suitable as components for below-the-knee protheses for veteran amputees?

The REL selected five below-knee veteran amputees that were users of a patellar tendon bearing (PTB) prosthesis and had worn the prosthesis for at least six months prior to being selected for fitting with the new light-weight prosthesis.

Each amputee was cast in the usual manner for producing a negative mold of the residual limb. Each negative mold was used to produce a positive of the residual limb. The positive residual limb model was modified using normal biomechanical considerations for prosthetic socket manufacture. The modified positive model was sent to UCL where a below-the-knee prosthetic socket was made by the Rapidform machine, using a copolymer polypro-

pylene. Each socket produced had a soft thermoplastic liner.

According to preset measurements, a rotationally molded shank was made and attached to the socket with the jacked-alignment unit by UCL. The socket and shank were returned to REL where a Solid Ankle Cushion Heel (SACH) foot was attached to the prosthesis. Each prosthesis was dynamically aligned and properly adjusted for the individual amputee. The aligned prosthesis was secured by placing one roll of fiberglass casting tape around the distal one-fourth of the socket, around the alignment device, down the shank, and around the distal alignment device and the proximal portion of the SACH foot (Figure 7).

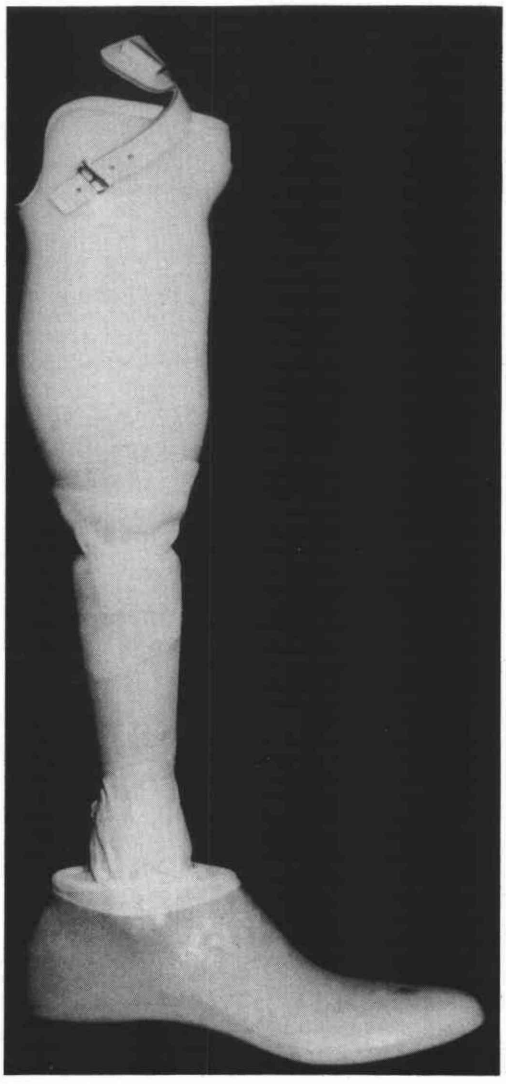

Figure 7. The completed prosthesis.

The prosthesis was delivered to the amputee to be worn for a period of six months. Each amputee wore the lightweight prosthesis for six months. During this time, they returned to the prosthetic lab once each month for visual observation of the prosthesis and their gait while ambulating.

Each amputee wore the lightweight prosthesis for the full term required with no failures of the components.

Four amputees continue to use the new prosthesis. One amputee (a bilateral) discontinued use of the prosthesis, because the research team required him to ambulate with the experimental prosthesis only while using crutches. One amputee experienced fitting difficulties around the fibula head, which was heavily scarred. He has required several adjustments to his socket; however, he prefers the experimental over his regular prosthesis and continues to use it full-time.

This project has proven the feasibility of using a central fabrication facility and the desirability of producing prosthetic sockets by a controlled procedure. The rotational molded prosthetic shanks have proven to be reliable components in this project. The jacked-alignment device does not seem to be strong enough, therefore, it should be reinforced with some material, such as fiberglass casting tape.

It is recommended that the Rapidform process for automated manufacture of prostheses, discribed by Davies, et al., be given a clinical trial over a three year period in the United States. This would require purchase or lease of the entire system as described by Klasson.[5]

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[8] United States Manufacturing Co., 180 N. Gabriel Blvd., P.O. Box 5030, Pasadena, California, 91107.