Prosthetics and Orthotics International, 1985, 9, 31–36

Rotational moulding in the production of prostheses

A. G. A. COOMBS, R. B. LAWRENCE and R. M. DAVIES

Bioengineering Centre, University College London

Abstract

This paper discusses the place of rotational moulding in the provision of prosthetic shanks and shank sections. It covers the selection of thermoplastic material, the moulding conditions and their automation in a machine process, and the development of a suitable range of moulds. Also covered is the question of interfacing between the moulded shank sections and other limb components, fatigue strength as tested to date and early results of patient field trials.

The most developed of the possible prosthetic options available consists of a hollow tapered column having inserts at each end by which it is clamped through alignment couplings to the socket and foot respectively. For a below-knee application, the complete tapered column prosthesis weighs typically 1 kg. Static and fatigue testing of representative samples by the simultaneous application of compressive and bending loads to the maximum values specified by international standards exposed no failures by the time a million cycles had been reached.

This method of fabrication has the merit of being capable of implementation locally on an "as required" basis. Additional advantages include the low cost of the mould tooling and the flexibility to mould a variety of shapes. Prosthetic feet are a possibility as are special shoes and orthotic parts. These may require other materials and experimentation is proceeding using structural and resilient foams.

Introduction

The potential for mouldable thermoplastics in the production of prostheses goes well beyond the socket which has been well proved and accepted since the early work on Rapidform (Davies and Russell, 1979). The theme of local manufacture, in or near the amputee clinics, is extended by another engineering process—rotational moulding. Shanks or shank sections produced in this way are inexpensive, light weight and very strong., Furthermore, these advantages are consistently available since the laboratory based process variable settings are built into the microprocessor controlling the Bioengineering Centre rotational moulding machine. This in turn can be operated by semi-skilled labour. Once the prosthetist has assessed and recorded the patient's prosthetic requirements, rotational moulding of the shank can be initiated so that production is taking place automatically and simultaneously with the processes described in the previous papers for automated socket production.

Up until now few examples exist of thermoplastic materials playing a direct load bearing role in prostheses by replacing either the cosmetically shaped hollow aluminium shells which characterize the structural members of exoskeletal prostheses, the wood/resin shank of conventional glass laminate PTB prostheses, the aluminium alloy shin tubes of modular prostheses or carbon fibre reinforced resin shanks. Two designs for ultra-lightweight 'crustacean' type BK prostheses can however be mentioned in this context. One was developed by Wilson et al, (1976) at Moss Rehabilitation Hospital and is produced by drape forming heated polypropylene sheet over a cosmetically shaped and aligned low density foam core which contains the socket. Excess polypropylene is cut away and the sheet welded to give the final continuous plastic sheath (without foam core). This procedure is however time consuming in

All correspondence to be addressed to A. G. A. Coombs, Bioengineering Centre, University College London, Roehampton Lane, London SW15 5PR, United Kingdom.

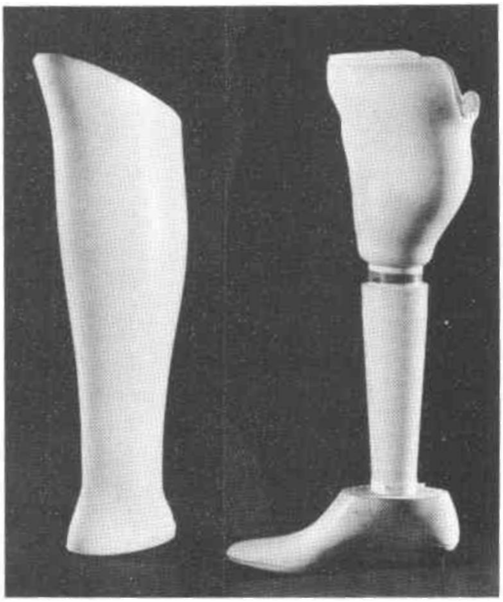

Fig. 1. Left, nylon leg-shaped rotational moulding. Right, endoskeletal prosthesis with nylon shank.

manufacture, requiring work with a high skill content (Convery et al, 1984). Realignment of the finished limb would be extremely difficult, since there is no built in alignment system necessitating modification of the load bearing shank itself. The Rancho Ultralight BK prosthesis developed by Quigley et al, (1977) uses the same drape forming technique as above. Indeed both methods stem from the same source, namely Wollstein's hollow BK prosthesis which was produced by laminating fabric and polyester resin over a plaster of Paris mould and then applying the sole and heel of a SACH foot (Wollstein, 1972).

Examples exist of PVC pipe and pipe fittings being used as stuctural components in temporary endoskeletal prostheses for immediate post operative fitting and alignment (Lehneis, 1974; Pritham, 1974; Pritham et al, 1976) and polycarbonate being used as household ambulator prostheses but thermoplastics have not been used to date for extended-use, definitive, endoskeletal prostheses. The object of this paper is to introduce rotational moulding as a general technique for producing thermoplastic load bearing components for artificial limbs, both exoskeletal and endoskeletal (Fig. 1) and to describe in particular the development of a shank section for modular prostheses whose attachment to other limb components is facilitated by a single bolt fixing. They offer a potentially superior combination of lightness, low cost, corrosion resistance, improved shock absorption and resilience compared to aluminium alloy or carbon fibre reinforced plastic tubing. Their use in modular prostheses would provide an alternative to the alloy shin tube/adaptor system commonly used and would obviate the need for a separate casting to attach shin tube to socket and foot unit respectively.

Rotational moulding

Rotational moulding is widely used in the plastics industry for producing relatively small numbers of hollow components such as footballs and storage vessels. It is a low cost production method making use of simply fabricated moulds and inexpensive moulding machinery. The conventional rotational moulding process can be divided into four stages:

1. A mould is filled with the required amount of thermoplastic powder and is clamped shut.
2. In the conventional method of rotational moulding the mould is heated in an oven for a predetermined time whilst rotated about 2 perpendicular axes. The object of this 2-axis rotation is to tumble the powder over all the mould surfaces so that a layer of molten polymer forms at the mould wall.
3. After the heating stage, the mould is removed from the oven and cooled generally by water and air spray.
4. The final stage involves removal of the finished moulding from the mould.

Rotational moulding of thermoplastics is characterized by relatively long production times—30 minutes is not uncommon—so that it is better suited to the production of small quantities of components. There is also only a limited range of polymers which can be used for moulding. The advantages of rotational moulding, in addition to the low cost of moulding equipment, include the facility to vary wall thickness of mouldings easily. For shank production this allows tailoring to suit an individual patient's weight and activity level. Material wastage is minimal and moulds are of low cost and simple in construction so design changes can be easily incorporated. Finished mouldings are usually stress free.

Materials selection

The thermoplastics currently available for rotational moulding include plasticised PVC, polyethylene (including cross-linked type), ethylene vinyl acetate copolymer, nylon 11, polyester elastomer, cellulose acetate butyrate (CAB), polycarbonate and ethylene chlorotrifluoroethylene. Grades of polypropylene are under development.

Nylon 11, CAB, polyethylene and polycarbonate give rigid mouldings and so are potentially suitable for producing load bearing structural members for prostheses. The remaining thermoplastics listed above are flexible materials more suitable for cosmetic or cushioning applications in prosthesis manufacture.

CAB and to a lesser extent polycarbonate have been used for lighting globes and street signs for example because of their optical clarity and rigidity. Question marks must hang over the suitability of such materials for a cyclic load bearing role in prostheses since they are not renowned for their fatigue characteristics. Polycarbonate in addition is noted for its sensitivity to certain organic chemicals. Investigations thus centred on nylon 11 and polyethylene as the most promising materials for production of load bearing shanks. Emphasis was finally placed on nylon 11 which exhibits greater strength and rigidity compared with polyethylene mouldings. This material is also noted for its good flex fatigue properties, surface hardness and resistance to chemical attack. It retains high impact strength at low temperatures and is far less hygroscopic than the conventional nylons such as nylon 66 so that retention of rigidity and dimensional stability is consequently greater.

Moulding machine

Shank sections were initially produced using the conventional rotational moulding technique in which a mould is rotated about two perpendicular axes. Subsequent investigations revealed however that a modification of the 'tilt and turn' rotational moulding technique was adequate for producing shank sections. This

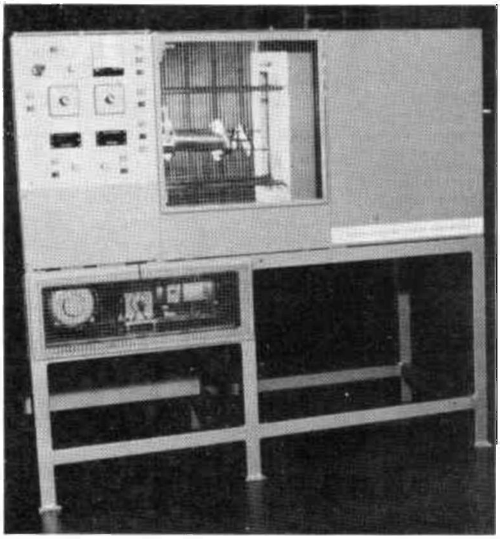

Fig. 2. Purpose built rotational moulding machine.

enabled construction of a compact, semi-automatic, electrically heated moulding machine giving accurate control over temperature, heating time, rotation and tilt speeds, tilt angles and cooling times (Fig. 2). No particular operator skills are required. Mould cooling is completed by electric fan and the heating and cooling cycle takes about 34 minutes.

Overall the process is clean and the space requirements for moulds and moulding machine are low so that the production facility can be operated as designed on a local basis close to patient treatment areas. Storage requirements are minimal since shank sections can be produced on demand and the 'self contained' aspect of the manufacturing system offers a high degree of independence of outside suppliers.

Moulds for shank production

Rotationally moulded shank sections are tailor-made to suit individual patients using a set of low cost aluminium alloy mould segments (Fig. 3, top). Each mould is assembled from two end plates (which carry the inserts for subsequent attachment of the shank to other limb components) a conical section and parallel spacer segments which enable mould length to be varied from approximately 70–250 mm and above in 1 mm increments. An assembled mould

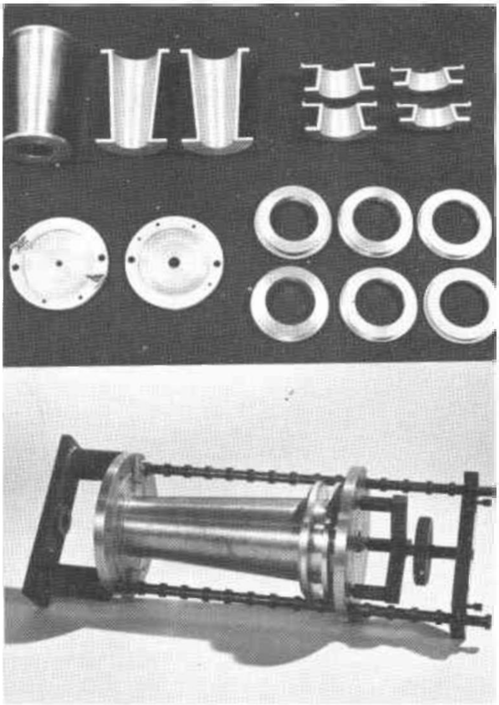

Fig. 3. Top, mould segments. Bottom, assembled mould.

of 200 mm length is shown in Figure 3, (bottom) illustrating the stacking arrangement of mould segments which permits rapid mould assembly and breakdown. This would contain a specified amount of powdered thermoplastic to give the required wall thickness of moulding dependent on patient weight and activity level.

Moulded shank sections are shown in Figure 4. The flared ankle section on the left of Figure 4 (top) shows how highly stressed areas in the ankle region can be obviated by increasing load bearing area. A simple split mould was used to produce this sample, demonstrating the scope for and relative ease of incorporating design changes. Figure 4 (bottom) shows a moulded shank of 400 mm length intended for use in AK experimental prostheses, highlighting the range of shank lengths available.

A sectioned moulding is shown in Figure 5 to indicate the degree of control which may be exercised over wall thickness. It is possible to keep wall thickness variation throughout the moulding to between 0.5 and 1 mm if required. The smooth internal surface of the moulding is also to be noted.

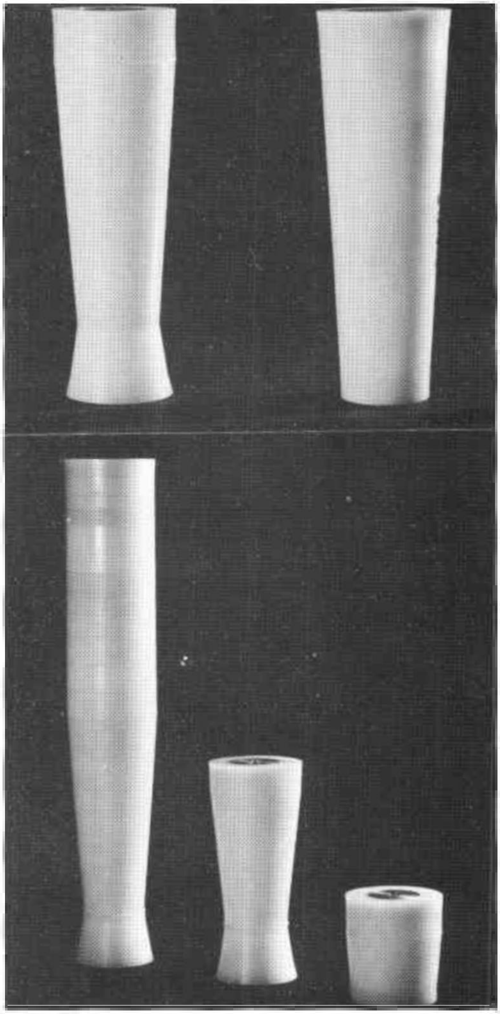

Fig. 4. Moulded shank sections (see text).

Interfacing of shank sections with other limb components

Metallic inserts are moulded in at the distal and proximal ends of each shank to allow attachment to other prosthetic components such as socket and foot unit by a single bolt fixing. Insert design must satisfy two requirements—

1. The shape must allow powder movement around the insert to give complete encapsulation by thermoplastic. In rotational moulding only the tumbling action of powder is available for coating mould walls and inserts.

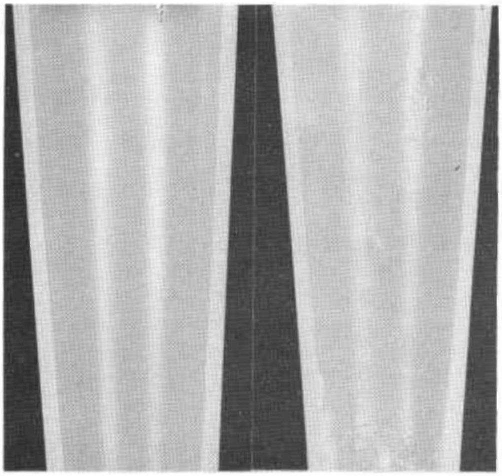

Fig. 5. Cross sections of complete shanks.

2. Inserts must withstand forces tending to pull them from the moulding during fatigue testing and service use.

Specific insert designs have been developed to meet the above requirements so that the need for the traditional and separate tube adaptor is avoided. Experimental prostheses incorporating a rotationally moulded shank, Rapidform polypropylene socket and a thermoplastic wedge alignment device typically weighs less than 1 kg. An alternative insert can be moulded-in at the proximal end of the shank to permit attachment of an alternative alignment device.

Testing of shank sections

Rotationally moulded shanks have been tested using an arrangement whereby pivoted extension bars attached to the proximal and distal ends of the shank enable a combination of compressive loads and AP bending moments to be applied to the test sample. Nylon shanks have withstood static testing to a load of 2500N with a superimposed bending moment of 250Nm applied at both ends. Laboratory fatigue testing using a combination of compressive (1350N) and bending loads (140Nm) recommended by an international meeting in Philadelphia in 1977 demonstrated that mouldings of various lengths from 70 mm to 220 mm containing specific insert designs to resist pullout exhibited fatigue life in excess of a million cycles.

Patient trials

Experimental prostheses incorporating rotationally moulded shank sections, thermoplastic double wedge alignment devices and Rapidform polypropylene sockets have been in service use for times ranging from three months to nine months, including a week's skiing exercise in North America for one of the limbs, with no component failure being recorded to date. In addition, four experimental prostheses incorporating polypropylene sockets, rotationally moulded shanks and jacked alignment devices (currently being developed in the Bioengineering Centre) are undergoing evaluation abroad. These are described in the next paper in this series (Thermoplastic alignment couplings for prostheses). No adverse comments or notification of component failure have been received to date. These limbs have been in service use for almost a year.

Summary

Rotational moulding presents a method for producing definitive lightweight, low cost, corrosion and fatigue resistant thermoplastic shank sections for prostheses. An advantage of the technique is the simplicity and low cost of associated moulding equipment and moulds. This enables shank design to be quickly and readily modified at the prototype stage if required to suit highly stressed areas of the prosthesis. Moulding wall thickness can be varied by adjusting the amount of starting material to match patient weight and activity level.

The moulded nylon shank sections are attached to other limb components such as socket and foot unit by a single bolt fixing onto moulded-in metalic inserts at distal and proximal ends of each shank.

Laboratory fatigue testing and limited patient trials have highlighted the reliability and durability of nylon rotationally moulded shanks which recommends them as a potential alternative to those produced from aluminium alloy and carbon fibre reinforced resin.

Acknowledgements

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.

REFERENCES

CONVERY, P., JONES, D., HUGHES, J., WHITEFIELD, G. (1984). Potential problems of manufacture and fitting of polypropylene ultralightweight below-knee prostheses. *Prosthet. Orthot. Int.* **8**, 21–28.

DAVIES, R. M., RUSSELL, D. (1979). Vacuum formed thermoplastic sockets for prostheses. In: Kenedi, R. M., Paul J. P., Hughes, J. (eds). Disability. London: Macmillan, P.385–390.

LEHNEIS, H. R. (1974). A thermoplastic structural and alignment system for below knee prostheses. *Orthot. Prosthet.* **28(4)**, 23–29.

PRITHAM, C. H. (1974). Development of a thermoplastic below-knee prosthesis with quick-disconnect feature. *Orthot. Prosthet.* **28(4)**, 31–35.

PRITHAM, C. H., LETNER, I. E. (Jr.). KNIGHTON, D. (1976). Use of thermoplastic components in temporary prostheses: a progress report. *Orthot. Prosthet.* **30(4)**, 31–34.

QUIGLEY, M. J. IRONS, G. P., DONALDSON, N. R. (1977). The Rancho ultralight below-knee prosthesis. Downey, CA: Rancho Los Amigos Hospital.

WILSON, A., B. (Jr.), PRITHAM, C., STILLS, M. (1976). Manual for an ultralight below-knee prosthesis. Philadelphia, P.A.: Moss Rehabilitation Hospital, Rehabilitation Engineering Centre.

WOLLSTEIN, L. V. (1972). Fabrication of a below-knee prosthesis especially suitable in tropical countries. *Prosthet. Int.* **4**, 5–8.