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The Rapidform process for automated thermoplastic socket production

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Abstract

This paper describes the genesis of the Rapidform process and its pioneering place in the new developments leading to complete control of the processes of manufacture of prostheses. The materials and geometric considerations involved in the development of a double deformation process under microprocessor control are described.

Stages in the development of the system show the advance from the initial application to modular below-knee prostheses through extensions to special suspension systems (supracondylar and suprapatellar) to Syme's and above-knee sockets. The clinical and laboratory results are summarized along with an account of the current aspects of the project, ie advanced clinical trials, testing and analysis.

Setting the scene historically for the other computer based modules in this high technology approach to prosthetics, Rapidform has proven to be swift, accurate and economical in its operation. Also, in common with the rest of the suite of equipment, this socket production facility, despite its flexibility and technical sophistication, requires no special services beyond standard single phase mains electricity supply.

Introduction

The Rapidform project, which is now fully integrated into the CAD/CAM systems for prostheses, was the first high technology module to be initiated. It heralded a comprehensive and far reaching research and development programme oriented to radical updating of the state of the art in prosthetics and thus enhancing patient rehabilitation.

The socket was identified as the most serious bottleneck to the manufacture and supply of prostheses to lower limb amputees. The practices in common use at the commencement of the project included: wood carving, sewing and blocking leather, beating/shaping aluminium alloy, and the building up of layers of glass-resin composites over a replica of the stump (Foort et al, 1984). All of these practices are highly labour intensive, costly and time consuming.

The research programme started with an investigation of fatigue strength-to-weight ratios and other key properties of all likely materials, ie metals, composites, thermoplastics and thermosets. Wood was not considered because of its unsuitability for rapid forming techniques and the consequential necessity to employ labour intensive methods. The assessment was most revealing. The outcome was a very short list of suitable materials, those having the most favourable properties being at the top of the list.

One of the aluminium alloys was found to possess the most favourable properties, although it was not the alloy in common use in prosthetics. Rather surprisingly the reinforced resin composite did not come out very near to the top of the list. However, if the reinforcing material (eg glass, boron nitride or carbon fibres) was kept near to the surfaces of the matrix, then the overall properties improved. The improvement thus obtained did not result in bettering the properties of the non-reinforced thermoplastics, which exhibited the next best properties to those of the aluminium alloy. Superplastic metallic alloys were considered but these materials are not yet available for general supply so this line of investigation was shelved.

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In the light of the above it was decided that one of the copolymers of polyproplene offered the most promising avenue for the purposes and objectives of the R & D programme. After a brief investigation into forming thermoplastic sheet, it was decided that a better solution was needed. This led to the Rapidform project.

The process

The investigations revealed that the selected material, a polypropylene, could achieve some remarkably good postformed properties providing the deformation process was closely controlled and carried out with care. Another point that emerged from the early work was the fact that there was a very significant advantage in restricting draw ratios, in order to alleviate severe anisotropy and shrinkage problems that could otherwise occur. Since polypropylene is a semi-crystalline material, some shrinkage occurs but this can be minimized by controlling the cooling.

The research programme pointed to a technique of double deformation (Lawrence and Davies, 1981). The first stage is to injection mould bell shaped preforms which very approximately approach the shape of sockets (Fig. 1). One size of preform was used for all below-knee sockets. The second stage of the process deforms a heated preform and vacuum forms it on to a replica of the stump. The replica was originally a plaster cast which had been rectified in the conventional way. More recently positives have been of wax (or rigid polyurethane foam) as designed in the CASD project and carved automatically by a purpose built CNC carver. A special thermoforming machine was designed and developed for the purpose.

The Rapidform machine

The vacuum forming machine (Fig. 2) consists of three sections: a loading bay in the centre, an oven with bottom access mounted above the loading bay, and a driving section containing the vacuum pump and a ram and associated power drive mounted at the bottom. The oven temperature is servo controlled; the preform is clamped in a carriage and elevated into the oven. The positive cast or model is set on the top face of a ram and the entirety is under microprocessor control. When the thermal conditions are correct, the ram presses the cast into the softened preform. The movement of the ram is servo (rate) controlled in order to optimize the strain rate of the plastic. Circumference and thickness reductions take place simultaneously with longitudinal extension. The rate of deformation and draw ratio (extension) controls the amount of

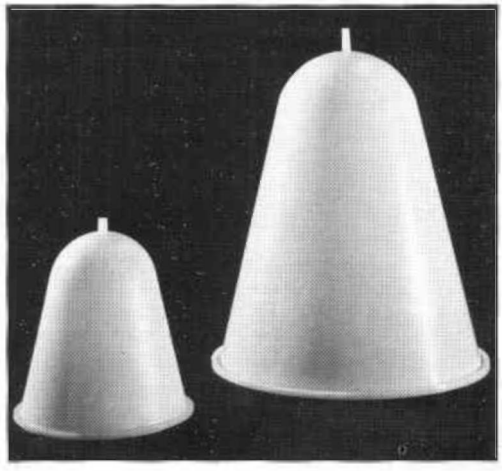

Fig. 1. Thermoplastic preforms.

Fig. 2. The Rapidform machine.

circumference reduction and hence the shape 'taken up' in the initial forming stage. The final socket shape is achieved in the second stage when vacuum is applied causing the plastic to be clamped to the model. There follows an annealing cycle for stress relief and controlled cooling as the socket is lowered from the oven by the ram. The positive is then removed from the socket, which can be finally trimmed and mounted.

Results with the below-knee Rapidform process

Below-knee PTB patient trials were carried out and the result after a year's trial period was most satisfactory. There were no rejections and no structural failures. The sockets were considerably lighter in weight than the alternatives. There was also a very favourable reaction from the patients who liked the slight resilience of the thermoplastic and also its hygienic properties (Davies and Russell, 1979). A total of twelve Rapidform machines are now in use including research applications, private commercial supply and UK limb centres. The latter application is a DHSS (Department of Health and Social Security) provisioning of Rapidform machines in five limb centres, accounting for a rate of supply currently running at 5,000 sockets per year.

Further development

Interfacing of the early Rapidform sockets was by means of a single bolt fixing to a modular prosthesis. However, in the U.K., there is an equal number of conventional prostheses in service and therefore steps were taken to interface the thermoplastic sockets to the microballoon resin used in non-modular constructions.

The chemically inert nature of polypropylene renders it an extremely difficult material with which to form a reliable bond. The research therefore concentrated on modifying the surface of the polypropylene so as to render it suitable for bonding. This was achieved by placing a specially woven interface over the preform at the time it was elevated into the oven. The interface is woven with compatible materials which weld onto the surface of the preform during the thermal cycle and adhere during the subsequent deformation. The final surface is primarily organic woven thread and forms a very good bond with microballoon. After a successful trial was carried out with patients on below-knee PTB conventional prostheses this type of socket became available for clinical use.

As the work has continued, patients have taken delivery of Rapidform sockets of the supracondylar and suprapatellar type of suspension. Syme sockets and very long below-knee sockets have also been fitted, although these have sometimes called for the more advanced techniques described below.

Above-knee sockets

The extension of the Rapidform techniques to the above-knee level has involved a redesign of the machine to encompass the larger positives, an improved oven and a new controller. A new range of preforms was also necessary to cover the extended range of sizes.

The above-knee sockets need their own thermal cycle and deformation control. They also need to be interfaced to modular and conventional prosthetic systems; the former using bolt-through, riveted strut or container systems that are in common use, and the latter using a larger version of the special fabric interface described above.

A method has been developed for attaching valves to suction sockets produced on the Rapidform. A disc is cut from the socket, using a thermal cutter, before removing the plaster. The valve housing machined from polypropylene rod, and scheduled to be injection moulded, is then located and welded in position. The housing required depends upon the valve being fitted.

In parallel with the final technical development, a clinical trial is under way. In the first stage, a number of patients have been fitted in-house and careful control has been exercised over all aspects of the amputees' care and the hardware manufacture.

In addition there is a collaborative trial involving four UK artificial limb companies at separate limb fitting facilities. Cast taking and hardware assembly are the responsibility of the companies whilst the Centre thermoforms sockets and oversees their attachment. The trial, which is expected to encompass up to 50 patients, is being conducted under U.K. quality assurance procedures. A protocol and data forms have been organized and supplied to

ensure consistent feedback on each limb fitted. The trial is of a one year duration.

Preforms

During the development of the thermoforming system it was found that there was a wide variation in the properties of injection moulded preforms when they were manufactured by different moulders even though the raw material was identical.

The manufacturing conditions of the injection moulding machines were investigated and it was found that these were set quite arbitrarily on the basis of a visually pleasing appearance, and the fastest possible throughput. The many variables of the injection moulding machine were therefore instrumented and a set of correct values obtained which optimized the properties of the preforms. A simple, cheap and rapid quality control rig was designed and developed as a means of batch sampling.

Testing and analysis

Throughout the development of the Rapidform process, static and dynamic testing of the samples and sockets has been conducted in the Bioengineering Centre laboratories. This goes some way towards explaining the structural success achieved, with only one defect reported in over 10,000 sockets supplied.

With the above-knee Rapidform socket supply now imminent, the research activities are now two-fold. Firstly, a finite element analysis programme is being undertaken; and secondly, the mechanical testing continues. The set up shown in Figure 3 was developed to allow the internal surface of an AK suction socket to be periodically examined during long term fatigue tests. An AK suction socket produced on the AK Rapidform and tested in this manner was removed after successfully withstanding over three million cycles.

Conclusion

The Rapidform process for socket production is fast, accurate and economical. It can manufacture above and below-knee sockets for all methods of attachment and interfacing and provides the patient with structurally sound, comfortable, light-weight, hygienic sockets. The latest Rapidform machines, in addition to being able to form sockets for all levels under the control of a microprocessor, will select the appropriate heating and deformation cycles for the particular preform loaded. The process requires no more of the operator than correct loading and unloading and does not require tending.

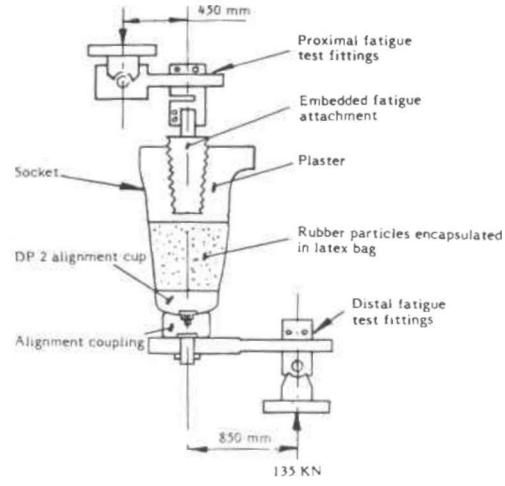

Fig. 3. Fatigue test set-up for AK Rapidform socket testing.

The impact of Rapidform is being seen now and when the other modules in the high technology supply chain reach the same level of proven success, the benefit of the combined projects will be dramatic.

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