JRRD
Volume 42, Number 2, Pages 141–146
March/April 2005
Journal of Rehabilitation Research & Development

A preliminary investigation into the development of 3-D printing of prosthetic sockets

Nicholas Herbert, MPhil;[1] David Simpson, MSc;[2*] William D. Spence, MSc;[3] William Ion, BSc
[1]Design, Manufacture and Engineering Management, [2]National Centre for Training and Education in Prosthetics and Orthotics, [3]Bioengineering Unit, and [4]Rapid Design and Manufacture Centre, University of Strathclyde, Glasgow, Scotland

Abstract—The socket is considered an element of major importance in the makeup of a prosthesis. Each socket is a tailor-made device, designed to fit the unique geometry of the patient's residual limb. The design and manufacture of a prosthetic socket traditionally has been a manual process that relies on the use of plaster of Paris casts to capture the shape of the patient's residual limb and then artisan fabrication techniques to manufacture the socket. Computer-aided design and manufacturing technologies have overcome some of the shortcomings of the traditional process, but the final manufacture of the prosthetic socket is still performed manually. Rapid prototyping (RP), a relatively new class of manufacturing technologies, creates physical models directly from three-dimensional (3-D) computer data. Previous research into the application of RP systems to the manufacture of prosthetic sockets has focused on expensive, high-end technologies that have proven too expensive. This paper investigates the use of a cheaper, low-end RP technology known as 3-D printing. Our investigation was an initial approach to using a technology that is normally associated with producing prototypes quickly, some of which could not be manufactured by alternative means. Under normal circumstances, these printed components are weak and relatively fragile. However, comfortable prosthetic sockets manufactured with 3-D printing have been used in preliminary fittings with patients.

Key words: amputee, CAD/CAM, lower limb, manufacture, materials, prosthetic socket, rapid prototyping, rehabilitation, 3-D printing, upper limb.

INTRODUCTION

All major lower-limb prostheses are constructed with three main parts: the socket, the leg section, and the foot. During walking, the forces generated between the foot and the ground are transferred to the anatomical skeletal system via the soft tissue interface within the prosthetic socket. The socket may be considered the most important of the three components, for if it is uncomfortable, the patient may not wear the prosthesis [1].

Advances in prosthetics and orthotics have always been achieved as a result of advances in other fields. Over the last 40 years, materials have been introduced to

Abbreviations: CAD/CAM = computer-aided design and manufacturing, CNC = computer numerically controlled, FDM = fused deposition modeling, PU = polyurethane, RDM = Rapid Design and Manufacture, RMM = Rapid Manufacturing Machine, RP = rapid prototyping, SLS = selective laser sintering, 3-D = three-dimensional, 3DP = 3-D printing, UV = ultraviolet.

This material was based on work supported by the University of Strathclyde, Glasgow, Scotland.

*Address all correspondence to David Simpson, MSc; National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde, Glasgow, G4 0LS; 0141-548-3426; fax: 0141-552-1283. Email: d.simpson@strath.ac.uk

DOI: 10.1682/JRRD.2004.08.0134

replace wood, leather, and steel long after such materials had been introduced into other areas of product manufacture. New manufacturing technologies have been developed to incorporate these materials as they have been introduced.

Currently, production of a prosthetic socket starts by creating a wrap cast of the patient's residual limb using plaster of Paris bandages to capture its geometry. The prosthetist uses his or her experience and judgment to apply pressure with the hands to key areas of the residual limb while the plaster bandage sets. This pressure is intended to change the shape of the residual limb to produce a better fitting socket and reduce the need for modifications later in the process. When the plaster is set, the wrap cast is carefully removed. Next the wrap cast of the residual limb is filled with plaster of Paris slurry. Once this slurry has set, the plaster bandages are removed, leaving a positive mold of the patient's residual limb.

One important note is that the original wrap cast is destroyed in this process; however, most researchers accept that the primary data set is transferred to the positive mold without distortion. The positive mold or cast of the residual limb is usually modified before a socket is formed over it. The prosthetist usually performs such cast rectification (as the modification is called) to produce the perceived distribution of residual limb/socket interface pressures during usage. This rectification destroys the original data set and thus also has the effect of creating a modified set of data. The socket is formed over the rectified cast with the use of either fiber-reinforced resin or sheet thermoplastic materials. Destroying the plaster mold during socket production during removal from the manufactured socket is standard procedure; thereby, the modified data set is also lost.

Occasionally, modifying the socket at the fitting stage may be necessary, in which case, even the rectified model data set is lost. This method of design and fabrication is able to produce comfortable sockets in reasonable timescales that perform well in service. However, the process has several drawbacks. The wrap-casting process can be messy, and no permanent record remains of the patient's residual limb geometry, since both the wrap cast and the positive mold are destroyed during the process. Thus, should another socket be required, the entire process has to be repeated and one cannot guarantee that the second socket will be identical to the first.

In recent years, the introduction of industrial computer-aided design and manufacturing (CAD/CAM) tools has gone some way to bring the prosthetic manufacturing process into the twenty-first century. A number of systems are now available for purchase. Although systems vary, most follow the same basic stages. The process begins with the digital acquisition of three-dimensional (3-D) geometric data from the patient's residual limb. Data are acquired with either a touch probe, a laser, or a photographic-based 3-D scanning system. The digital model of the shape of the residual limb is stored on a computer. Rectification is performed on-screen with the use of software developed for this purpose, and the modified data set is stored on the computer as a separate file. Such rectification can be performed many times without the loss of the primary data. A precise record of the rectification process and modifications is kept and a number of socket shapes, each with different rectifications, may be produced and stored. The prosthetist uses the rectified data set to control the cutting of a plaster of Paris or polyurethane (PU) foam blank by a computer numerically controlled (CNC) milling machine to produce a model, over which the socket is created in the traditional way. Although the socket is still created today by artisan methods and techniques, the attractions of CAD/CAM technologies remain. A permanent digital record of the patient's residual limb is created that can be rectified any number of times without loss of the original data. A record can be kept of changes made to the original data during the rectification process. The need for plaster of Paris bandages for casting of the residual limb is eliminated, and the reproduction of an identical socket is possible.

Several drawbacks exist to currently available CAD/CAM systems. A plaster of Paris or PU foam blank, over which a socket may be created, is still required. The fabrication of the socket, still performed manually, remains a labor-intensive process. The positive mold is destroyed during fabrication and so the production of each socket requires the manufacture of a new mold by a CNC milling machine. CAD/CAM equipment (the 3-D scanner, software and, particularly, the CNC milling machine) is expensive. Thus, one might say that, despite the use of some automated machinery, the CAD/CAM processes currently available for use in the prosthetic industry for socket production are actually only semiautomated [2].

RAPID PROTOTYPING

Rapid prototyping (RP), a relatively new class of manufacturing technology, has the potential to create a prosthetic socket directly from the 3-D CAD data. RP eliminates the need for a plaster of Paris or PU foam cast.

Although a number of different RP technologies exist, they are all based on the common principal of building parts layer by layer. Unlike traditional manufacturing technologies, in which material is removed, RP adds material to create the finished component. Computer software splits the 3-D CAD data into a series of thin horizontal cross-sections (slices). These slices are then sent sequentially, starting with the bottom slice, to the RP machine. Each slice is fabricated on top of the previous one and the slices are bonded together.

Traditionally, RP has been viewed as a quick and cost-effective method of making nonfunctional prototypes with limited mechanical properties. However, advances in both process capabilities and RP materials have led to the possibility of rapid manufacture, the manufacture of finished components directly from 3-D CAD data. A number of RP technologies have been developed, and some attempts have been made to use them to produce prosthetic sockets.

Stereolithography uses a liquid, photosensitive resin that hardens when exposed to ultraviolet (UV) light. The stereolithography apparatus holds a vat of this resin, which contains a platform that descends vertically through the liquid resin as the model is built. Stereolithography was used to manufacture prosthetic sockets in 1990 by a research group based at Northwestern University Medical School (Chicago, IL) [3]. The process was found to be slow and the resulting socket had limited strength, but the experiment demonstrated the potential of the technology. Later, Freeman and Wontorcik concluded that production times and high capital and operating costs must be reduced significantly to make stereolithography practical [4].

Selective laser sintering (SLS) uses a CO_2 laser to fuse a layer of powdered polymer material. Materials currently available include nylons, polycarbonates, and specially prepared metals, which allow a wide range of components to be manufactured. Initial research into the use of SLS technologies in prosthesis manufacture focused on the development of custom software that would manipulate the data generated by a laser scanning system and transform it into a socket design ready for manufacture with SLS technology [5]. Both scaled and full-size sockets were produced, and they successfully demonstrated the viability of the process [6]. Researchers developed SLS further and investigated ways of controlling the rigidity of the socket in selected areas to improve patient comfort [7]. Trials were limited, but the patient reported that the socket was comfortable and found the performance of the device comparable to traditionally manufactured prostheses. However, the design was complicated, was heavier than a traditional socket, and required the use of several software packages in a time-consuming and labor-intensive design process [8]. As a result, researchers more recently focused on a single-wall design, varying the wall thickness in an attempt to control the rigidity of the socket wall [9].

Fused deposition modeling (FDM) requires a machine that has a vertically descending build platform that is housed inside a heated oven chamber. Located above the build platform is an extrusion head capable of moving in the *x*- and *y*-directions. A polymer material, typically acrylonitrile-butadiene-styrene, is fed into the head, where it is heated and extruded in semimolten form through a nozzle. The head moves over the build platform and deposits the polymer where needed to create a cross-section of the component. The polymer material solidifies immediately after it is deposited and bonds to the layer below. Collaborative research between the Institute of Materials Research and Engineering Singapore, Temasek Polytechnic Singapore, and The National University of Singapore has investigated the use of FDM technology for the manufacture of transtibial sockets. Initial work demonstrated the technical feasibility of the process with the building of two transtibial sockets [10]. Subsequent research verified the biomechanical performance of these FDM sockets [11]. During refinement of this FDM fabrication process, concerns were raised about the long fabrication times and potentially high costs of the process. However, transtibial sockets do not require a high level of dimensional accuracy. With this in mind, the research group built a customized machine to manufacture transtibial sockets, called the Rapid Manufacturing Machine (RMM) [12–13]. The RMM was based on the FDM process, but it features a wider extrusion nozzle and higher working temperatures that help reduce the build time. Currently, sockets made with the RMM system are undergoing clinical and biomechanical testing.

Squirt-shape manufacture is a customized RP process that was developed specifically for the manufacture of prosthetic sockets at Northwestern University (Chicago, IL) [2]. The process is based on FDM technology. A bead of semimolten polypropylene material is extruded onto a platform in a continuous helix, following the contours of the socket design. In this manner, the socket is created layer by layer. The polymer solidifies as it cools and bonds the layers together. Subsequent research raised concerns over the layered nature of the socket and the anisotropic nature of the material [14]. Transtibial sockets manufactured using squirt-shape technology were fitted to three patients in long-term clinical trials. In the most successful case, the socket was used exclusively by an active patient for more than 34 months.

All this research has demonstrated that producing prosthetic sockets directly from 3-D CAD data using RP technology is possible. These sockets may be comparable in terms of comfort, strength, and performance to those manufactured with the use of traditional or CAD/CAM techniques. However, the machines have both high capital and operating costs, and they require special installation and support facilities.

3-D printing (3DP) creates components from powdered materials, usually starch or gypsum. The process begins by the spreading of a thin layer of powder over a build platform. An inkjet printing head then selectively prints a binder solution onto this layer of powder to form a slice of the 3-D CAD file. Once the layer is complete, the build platform is lowered by a layer thickness and the process repeated until the component is complete. 3DP lacks the accuracy and mechanical properties of such higher-end rapid prototyping systems as stereolithography and SLS. However, the process is attractive because it has low capital and operating costs, and it does not require special facilities for its operation. These qualities have led to 3DP being chosen predominantly as a concept modeling system and to its producing multiple iterations of a design both quickly and economically. Raw 3DP components have poor mechanical properties and are generally unsuitable for handling. However, after production, the components may be infiltrated with wax or a range of resins to improve their strength. With careful resin selection, the mechanical strength of a 3DP component has been shown to increase to an extent that would make it suitable for use in prosthetic devices.

METHODOLOGY

The Rapid Design and Manufacture (RDM) Centre—a multitechnology RP research and education facility, the first of its kind in Scotland—is jointly managed by the four higher education institutions in Glasgow. The RDM Centre's aim is to provide cost-effective access to RP for both research and education across academia and industry. The center runs a wide range of RP-related activities across a broad platform of application areas. In the center is a Z Corporation (Burlington, MA) Z402 3-D printer. We wanted to investigate if clinically acceptable prosthetic sockets could be made with the use of this technology. The maximum print volume of this printer limited the size of prosthetic socket that could be produced to that for a transtibial or a transradial patient.

We scanned the residual limbs of two patients, one transtibial and one transradial, using the TracerCad Premier Prosthetic system marketed by OrthoEurope (Oxfordshire, UK). Each scan produced a set of digital data representing the surface of the patient's residual limb. These data were exported from the TracerCad software as a 3-D surface in DXF for further processing. We opened each DXF file using SolidView Pro, a CAD package developed by Solid Concepts, Inc. (Valencia, CA, www.solidview.com). This package is widely used in the rapid prototyping industry for preparing data prior to manufacture. One can use this software to add a uniform wall thickness to a 3-D surface. Thus the scan data can be transformed from a surface with zero thickness into a solid object that can be manufactured. We gave both sets of scanned data an external wall thickness of 4 mm, leaving the original data as the inner surface of each socket. Finally, we exported the data in the STL file format required for 3DP. Both sockets were manufactured with the Z Corporation Z402 3-D printer. Once the sockets were built, we dried them in a low-temperature oven and then infiltrated them with PU resin to increase their mechanical properties. The proximal brim of each socket was trimmed manually after the resin had cured.

The patients were of the opinion that the sockets created with RP technology were as comfortable as those made by traditional methods. **Figure 1** shows the transradial patient wearing the socket created for him, and **Figure 2** shows the other patient standing on the transtibial socket. However, because the strength of the material remained

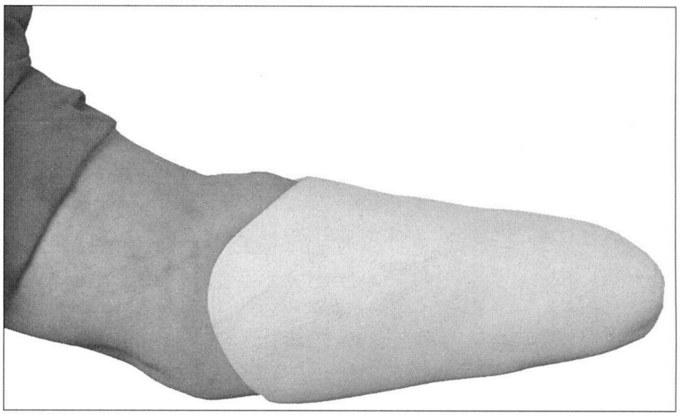

Figure 1.
Transradial patient wearing socket created with three-dimensional printing technology.

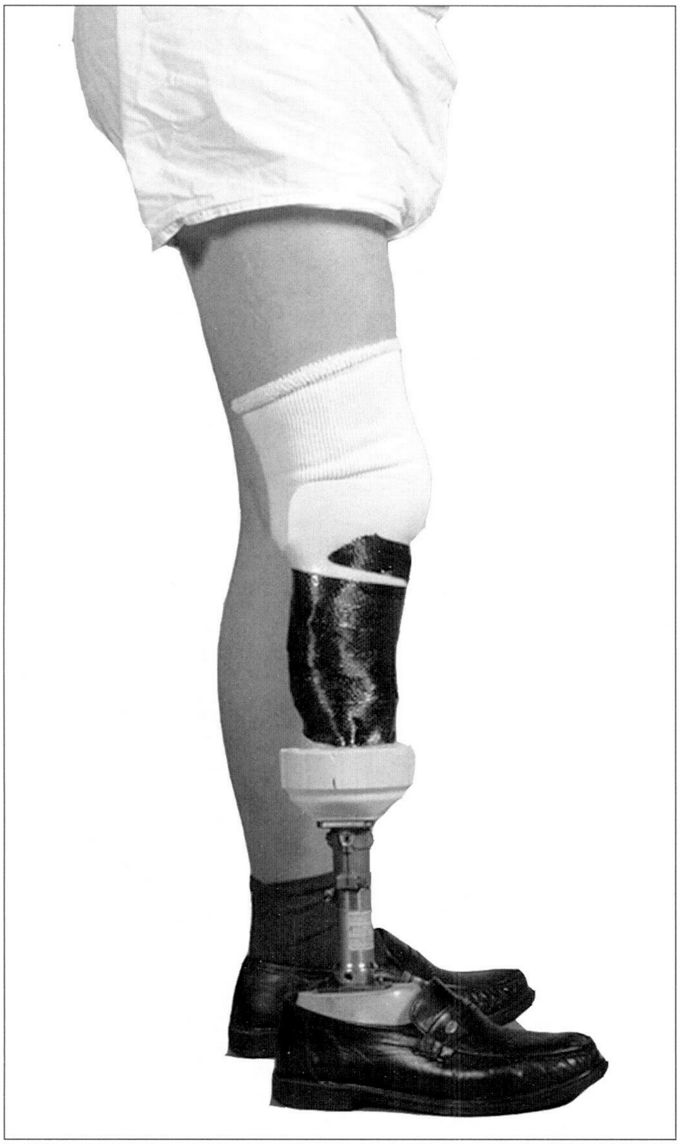

Figure 2.
Transtibial patient standing on socket created with three-dimensional printing technology and wrapped with carbon fiber-reinforced resin material.

unproven, we decided to reinforce the transtibial socket with a wrap of resin-reinforced carbon fiber material before the patient was allowed to bear weight on the prosthesis (**Figure 2**).

The capital and operating costs of this RP technology are relatively modest. We manufactured the sockets described in this paper using a Z Corporation Z402 3-D printer. This printer has been superseded by the Z Printer 310 System, which may be used in an office environment and, by comparison, would currently cost 20 percent less than the OrthoCarve™ CNC carver supplied by Ortho Europe. The Z Printer 310 System creates physical models directly from digital data with a build volume of 8 in. × 10 in. × 8 in. (203 mm × 254 mm × 203 mm) and a layer thickness of 0.003 in. to 0.010 in. (0.076–0.254 mm). The equipment dimensions are 29 in. × 32 in. × 43 in. (74 cm × 81 cm × 109 cm), and it weighs 250 lb (113 kg) (http://www.zcorp.com). The prospect of producing an entire prosthesis with this RP technology has been recognized by Childress [15], and in January 2003 the New Scientist published a report about work under way in California to print fully assembled and functional electric and electronic products, such as a television remote control [16].

CONCLUSION

We have demonstrated that 3DP printing technology may be used to fabricate prosthetic sockets that patients find comfortable. Faster than other RP technologies, the 3DP printing equipment is straightforward to install and does not require special facilities to ensure operator safety. It is simple to use and should allow prosthetists to exploit all the advantages offered by CAD/CAM technologies.

Currently, the strength and durability of sockets produced with this technology remain unproven. However, having demonstrated here that the technology may be used for prosthetic applications, we will be conducting further studies to assess the dimensional accuracy of the process and the mechanical characteristics of the products compared to the mechanical characteristics of currently used materials. The results of our studies will be the subject of future publications.

REFERENCES

1. Lee VSP, Solomonidis SE, Spence WD. Stump-socket interface pressure as an aid to socket design in prostheses for trans-femoral amputees—a preliminary study. Proc Inst Mech Eng. 1997;211(H):167–80.
2. Rolock J, Tucker K. Development, evaluation, and use of a computer aided manufacturing technique based on "rapid prototyping" principles. Capabilities. 1998;7(1):1–2,8–10.
3. Rovick JS, Chan RB, Van Vorhis RL, Childress DS. Computer-aided manufacturing in prosthetics: various possibilities using industrial equipment. In: Zupko JP, editor. Proceedings of the 7th World Congress of the International Society for Prosthetics and Orthotics; 1992 Jun 28–Jul 3;

Chicago (IL). Alexandria (VA): International Society for Prosthetics and Orthotics; 1992. p. 22.
4. Freeman D, Wontorcik L. Stereolithography and prosthetic test socket manufacture: a cost/benefit analysis. J Prosthet Orthot. 1998;10(1):17–20.
5. Rogers WE, Crawford RH, Beaman JJ, Walsh NE. Fabrication of prosthetic sockets by selective laser sintering. In: Bourell DL, Beaman JJ, Crawford RH, Marcus HL, Barlow JW, editors. Proceedings of the 2nd Solid Freeform Fabrication Proceedings; 1991 Aug 12–14; Austin (TX). Austin (TX): University of Texas; 1991. p. 158–63.
6. Rogers WE, Crawford RH, Faulkner VF, Beaman JJ. Fabrication of an integrated prosthetic socket using solid freeform fabrication. In: Zupko JP, editor. Proceedings of the 7th World Congress of the International Society for Prosthetics and Orthotics; 1992 Jun 28–Jul 3; Chicago (IL). Alexandria (VA): International Society for Prosthetics and Orthotics; 1992. p. 23.
7. Stephens S, Crawford R, Rogers W, Gitter A, Bosker G. Manufacture of compliant prosthesis sockets using selective laser sintering. In: Bourell DL, Beaman JJ, Crawford RH, Marcus HL, Barlow JW, editors. Proceedings of the 11th Solid Freeform Fabrication: 2000 Aug 7–9; Austin (TX). Austin (TX): University of Texas; 2000. p. 565–77.
8. Rogers B, Gitter A, Bosker G, Faustini M, Lokhande M, Crawford R. Clinical evaluation of prosthetic sockets manufactured by selective laser sintering. In: Bourell DL, Beaman JJ, Crawford RH, Marcus HL, Barlow JW, editors. Proceedings of the 12th Solid Freeform Fabrication Proceedings; 2001 Aug 6–8; Austin (TX). Austin (TX): University of Texas; 2001. p. 505–12.
9. Lokhande M, Crawford RH. Testing of compliance in a prosthetic socket fabricated using selective laser sintering. In: Bourell DL, Beaman JJ, Crawford RH, Marcus HL, Barlow JW, editors. Proceedings of the 12th Solid Freeform Fabrication Proceedings; 2001 Aug 6–8; Austin (TX). Austin (TX): University of Texas; 2001. p. 513–26.
10. Tan KC, Lee VSP, Tam KF, Lye SL. Automation of prosthetic socket design and fabrication using computer-aided-design/computer-aided-engineering and rapid prototyping techniques. In: Goh JCH, Lee VSP, editors. Proceedings of the First National Symposium of Prosthetics and Orthotics; 1998 Nov 28; Singapore. Singapore: The Institute of Materials Research and Engineering; 1998.
11. Lee VSP, Tan KC, Tam KF, Lye SL. Biomechanical evaluation of prosthetic sockets fabricated using fused depository method. In: Goh JCH, Lee PVS, editors. Proceedings of the First National Symposium of Prosthetics and Orthotics; 1998 Nov 28; Singapore. Singapore: The Institute of Materials Research and Engineering; 1998.
12. Tay EH, Liu L, Lee VSP, Tan KC, Ng P, Goh JC. Refinement of prosthetic socket fabrication process with the FDM technology. In: Lee WB et al., editors. Proceedings of the 9th International Manufacturing Conference; 2000 Aug 16–17; Hong Kong (China). Hong Kong (China): The Hong Kong Polytechnic University; 2000. p. 97–100.
13. Ng P, Lui L, Lee VSP, Tan KC, Tay EH, Goh JC. Rapid manufacturing machine (RMM) for prosthetic socket fabrication. In: Goh JCH, editor. Proceedings of the 10th International Conference on Biomedical Engineering; 2000; Singapore. Singapore: National University of Singapore and Biomedical Engineering Society of Singapore; 2000. p. 417–18.
14. Rovick JS. An additive fabrication technique for the computer-aided manufacturing of sockets. In: Zupko JP, editor. Proceedings of the 7th World Congress of the International Society for Prosthetics and Orthotics; 1992 Jun 28–Jul 3; Chicago (IL). Alexandria (VA): International Society for Prosthetics and Orthotics; 1992. p. 24.
15. Childress DS. Computer-aided design and manufacture (CAD-CAM). J Rehabil Res Dev. 2002;39(3):15–16.
16. Graham-Rowe D. 'Gadget printer' foreshadows a new industrial revolution. New Scientist. 2003 Jan;11:12.

Submitted for publication August 26, 2003. Accepted in revised form April 20, 2004.