

Advanced trans-tibial socket fabrication using selective laser sintering

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Abstract

There have been a variety of efforts demonstrating the use of solid freeform fabrication (SFF) for prosthetic socket fabrication though there has been little effort in leveraging the strengths of the technology. SFF encompasses a class of technologies that can create three dimensional objects directly from a geometric database without specific tooling or human intervention. A real strength of SFF is that cost of fabrication is related to the volume of the part, not the part's complexity. For prosthetic socket fabrication this means that a sophisticated socket can be fabricated at essentially the same cost as a simple socket. Adding new features to a socket design becomes a function of software. The work at The University of Texas Health Science Center at San Antonio (UTHSCSA) and University of Texas at Austin (UTA) has concentrated on developing advanced sockets that incorporate structural features to increase comfort as well as built in fixtures to accommodate industry standard hardware. Selective laser sintering (SLS) was chosen as the SFF technology to use for socket fabrication as it was capable of fabricating sockets using materials appropriate for prosthetics. This paper details the development of SLS prosthetic socket fabrication techniques at UTHSCSA/UTA over a six-year period.

Keywords: Amputees, prosthetics, CAD/CAM

Introduction

Methods of computer assisted design (CAD) and computer assisted manufacturing (CAM) of prosthetics have been available since the 1980s though acceptance has been slow (Brncick 2000). CAD/CAM techniques are just beginning to be widely used to design and manufacture sockets. In one approach, a mechanical digitizer, magnetic digitizer, or a non-contact laser scanner (Walsh et al. 1989) inputs the stump shape into the computer. The prosthetist then uses specialized software to produce the shape of a biomechanically correct socket from the stump shape. A computer controlled milling machine carves a pattern for the socket from plaster or foam. The socket is then made using conventional methods such as vacuum moulding or lamination.

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While digitization technology and prosthetic CAD software have become quite advanced, fabrication technology has not kept pace (Smith and Burgess 2001). A limitation of commercially available prosthetic CAD systems is that they only design the three dimensional shape of the inner wall of the socket with only limited ability to allow for pylon attachment. These CAD systems only design a pattern to be machined, which is all that is necessary for conventional fabrication. This limits the ability to use computer models to evaluate prosthetic limb characteristics especially before prosthetic limb fabrication. The actual wall thickness of the socket and the means of attaching the remainder of the prosthetic limb are determined during the largely artisan manufacturing process.

Solid freeform fabrication (SFF) technologies are a class of technologies that can create three-dimensional objects directly from a geometric database without specific tooling or human intervention. Objects are generally built in layers that are fused by a laser or perhaps extruded. SFF is generally used to make prototype parts for industry which makes it a good match for use in prosthetics as each prosthetic socket is unique. Several manual steps can be eliminated. These include the entire socket fabrication complete with trimlines and the addition of a pylon attachment fitting. Additional features can be included such as variable compliance socket walls and integrated fittings. The SFF industry is largely service bureau based which is a mode common in many countries in the prosthetics industry.

There has been research into systems that use SFF to directly fabricate prosthetic sockets under computer control avoiding the intermediate step of pattern fabrication. These systems could provide many benefits including sockets with different mechanical properties in different areas of the socket (Smith and Burgess 2001).

One area of great promise is to be able to control the flexibility of the socket wall in selective regions. The idea is to assure the socket is properly rigid in load bearing areas but to make the socket wall more flexible over sensitive regions such as bony prominences. This can be achieved to a lesser degree with conventional fabrication with a flexible inner socket and fenestrated rigid outer socket though the conventional approach is labour-intensive and expensive. In fabrication with SFF, the cost is related to the volume of the part rather than its complexity so there is no cost penalty for a more sophisticated design. In addition to that, the freedom of design for parts fabricated with SFF technologies allows the exploration of potentially more elegant and efficient design solutions that would be otherwise prohibitively expansive or even impossible to manufacture using conventional methods.

In selective laser sintering (SLS), the process used by UTHSCSA/UTA, components are built by material addition rather than by material removal by using a directed laser beam that causes individual particles to fuse in selected regions of space. The process begins by first depositing a thin layer of powder into a container. The powder surface is raster-scanned with a laser beam much like the picture is formed on a television screen by a set of horizontal lines. The intensity of the beam is modulated to sinter or fuse the powder in areas to be occupied by the part at that particular cross-section. In areas not sintered, the powder remains loose and is removed once the part is completed. Successive layers of powder are then deposited and sintered until the entire part is complete. A variety of materials can be sintered including metals, plastics, and wax.

Over the last 15 years SFF has been explored as a tool for the fabrication of prosthetics sockets:

• Northwestern University working with Baxter Healthcare made a single trans-tibial socket using stereolithography (SLA) in 1990 (Rovick et al. 1992).

- In 1991, the University of Texas at Austin (UTA) and the University of Texas Health Science Center at San Antonio (UTHSCSA) collaborated to make scaled down trans-tibial sockets (Rogers et al. 1991; 1992). A full sized socket that incorporated a fitting for attaching the pylon followed this in 1992. An amputee in a supervised setting wore this socket briefly.
- In 1992, Rovick from Northwestern developed a rapid prototyping technology called Squirt Shape to address the need for rapidly fabricating prosthetic sockets (Rovick 1992). The process is a form of fused deposition modelling (FDM) where a bead of molten plastic is extruded in a continuous spiral to form a single wall socket.
- In 1998, Freeman and Wontorcik fabricated check sockets suitable for ambulation though they lacked the durability needed for extended use (Freeman and Wontorcik 1998). The cost of the sockets was deemed to high for use as check sockets.
- Also in 1998, Lee et al. (1998) reported on fabricating two prosthetic sockets for amputees using FDM. Gait analysis was performed comparing conventional and FDM sockets. Minimal variations in gait between the two types of sockets were shown.
- In 1999, UTA and UTHSCSA collaborated on a sophisticated double-wall socket fabricated using SLS and compared to a conventional socket (Rogers et al. 2000; Stephens et al. 2000).
- In 2001, UTA and UTHSCSA conducted a pilot study of trans-tibial sockets fabricated by SLS incorporating a pylon adapter and selectively compliant socket walls. The pylon adapter though was a non-standard design that did not use industry standard hardware (Rogers et al. 2001).
- In 2003, Herbert et al. fabricated two sockets using a 3-D printing method using gypsum or starch and a binder (Herbert et al. 2005). The completed sockets were infiltrated with a resin to add strength. The proximal brim was trimmed manually. Due to the limited strength the sockets were reinforced with a carbon fibre wrap.
- Northwestern has updated Squirt Shape to incorporate the pylon adapter with the socket. Alignment is adjusted in software before fabrication. No publications appear to be available though there is a web reference (Northwestern University 2005).
- Monash University has used FDM to integrate sockets with integral cosmetic covers. Alignment is achieved in software. They anticipate using FEM to develop basic design rules. No publications appear to be available as yet though there is a web reference (Monash University 2003). They also appear to have a library of shapes that can be incorporated into a prosthetic limb design via ShapeMaker prosthetic CAD software (BioLogic) (BioLogic, Inc. Bio-Logic, 1134E Ballena Blvd, Suite, Alameda, CA 94501, USA).

It is important to note that little of the above work used SFF for anything except replacing the first manual step in socket fabrication. The remainder of the prosthetic limb had to be attached by conventional manual steps. While UTHSCSA/UTA did incorporate a pylon adapter as part of the design, the adapter did not use readily available hardware.

There is no advantage in using SFF to fabricate a basic socket then use artisan techniques to attach a pylon to the distal end. Since 1999 UTA and UTHSCSA have been developing trans-tibial sockets fabricated by SLS incorporating pylon adapters as well as selectively flexible socket walls. Including these features adds little to the cost manufacturing as the cost is related to the volume of the part, not its complexity. As almost any shape can be fabricated using SLS, socket design is limited only by the limits of CAD software and the imagination.

Methods

The development of techniques for fabricating prosthetic sockets by SLS has been in four stages. The first involved a single socket used for a feasibility test. The second stage was a pilot study to test the clinical acceptability of SLS fabricated socket. The third stage is a test of the long-term durability of SLS sockets and the forth stage involves novel socket construction designed to improve socket comfort.

Commercial mechanical CAD packages are often capable of producing STL files suitable for manufacturing but they are ill-suited for designing prosthetic sockets. Prosthetic CAD packages are tailored to the special needs of the prosthetics industry but as noted before, are only capable of designing the interior of the socket. Therefore, it was necessary to write a certain amount of custom software to make the bridge between the prosthetics world and the mechanical CAD world. In any case, the final output is an STL data file containing the geometric description of the socket. The STL file format is a SFF industry standard. Any facility involved in SFF can use such a file to fabricate a socket.

For all stages the pattern used to fabricate a subject's definitive socket was measured using a laser imager and served as the template for SLS socket fabrication. This was to insure that a comparison could be made between SLS and conventional sockets of identical shape. Trim-lines, load bearing areas, and pressure sensitive areas were marked in black on the pattern. The laser imager captured these marks. The data including the marked locations were saved in an American Academy for Orthotists and Prosthetists (AAOP) data interchange file. This is a non-proprietary file format that is supported by prosthetic CAD/CAM vendors.

All sockets so far have been fabricated using nylon 11 or Duraform (a form of nylon 12). Both of these materials have strength and flexibility characteristics suitable for socket fabrications. The nylon 11 is more flexible while the Duraform can produce a greater level of detail. Both materials have about 90% of the density of extruded nylon and have similar material properties.

Stage 1: Feasibility study

The first trial was to determine the feasibility of using SLS to fabricate a definitive prosthetic socket that included advanced features.

A dual wall socket design was chosen to implement the flexible wall concept. An outer rigid socket wall provided structural integrity and allowed easy incorporation of an integrated pylon-mount fitting. The inner wall of the socket was a thin flexible wall that allowed for regional compliance variability. Regions of maximal flexibility included the distal anterior tibia and the fibula head.

The design process started with an AAOP file exported from a prosthetic CAD program. At this point quite a bit of custom software had to be written to convert the data for use in mathematics and CAD software packages.

A program was written in C to accept data input in the AAOP format and create the double-walled socket by using a perpendicular offset algorithm. The nominal thickness of the outer wall is 3 mm. The nominal thickness of the inner wall is 1 mm with the nominal separation being 6.5 mm.

ACIS 3D Toolkit (Spatial Inc. 10955 Westmoor Drive, Suite 425, Westminster, Colorado 80021, USA) is a solid modelling software package. ACIS used a b-spline socket representation to create a geometric solid model. ACIS was then used to add the rest of the features of the socket.

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For additional flexibility over the fibula head and distal tibia, a hexagonal set of triangular cantilever beams composed of radial slots were added to the inner socket wall. These beams are free to deflect over a certain range. The deflection of the end of each beam is designed to be 2 mm at a pressure of about 140 kps (Figure 1).

There are three stiffened regions. These areas are the antero-lateral area, medial area, and popliteal area. These areas have a wall thickness of about 3 mm. There are additional support struts in these areas connecting the inner and outer walls.

The final design feature is a distal fitting for a nylon pylon adapter. The nylon adapter used two eccentric cylinders to adjust socket alignment. To accommodate high stresses at the pylon to socket interface, the outer wall of the socket was thickened to allow a smooth transition to the cylindrical fitting. The completed socket design was written to an STL file for manufacturing.

The test session involved a quantitative gait analysis using both the subject's conventional socket and the SLS socket. Following an initial test session with the conventional socket, the subject donned the SLS prosthetic limb and was allowed a ten-minute acclimatization period before repeating gait analysis.

Stage 2: Evaluate clinical acceptability

The second stage was to demonstrate clinical acceptability of SLS prosthetic sockets for normal community ambulators.

In Stage 1, the process of taking an AAOP data interchange file and creating a complete 3D socket with an attachment fitting was extremely labour intensive, time consuming and involved several different software packages. The double-wall design was judged too complex for a study involving multiple research subjects. It was decided to provide both flexibility and additional reinforcement by locally varying the socket wall thickness.

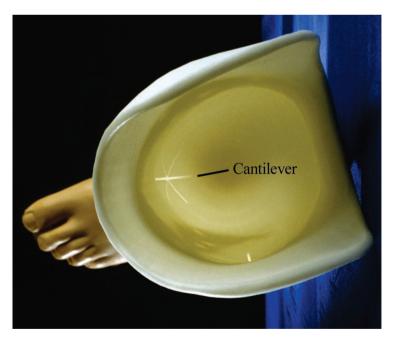


Figure 1. Inside of double-wall socket showing cantilever compliant areas.

In order to produce sockets in a timely manner it was necessary to write custom software to create an STL file from the AAOP file. The UTHSCSA socket design software was written in C++ using the OpenGL graphics API for the Microsoft Windows platform. User-friendly software tools were developed to allow the clinician to design the all aspects of the socket. First it gives thickness to the socket by creating an outer shell from the inner socket shape. The socket trim-line is set interactively using the mouse cursor to select points on the socket shape (Figure 2). Areas of variable wall thickness are interactively drawn on the socket shape. These areas are defined relative to pressure sensitive areas marked on the socket pattern. The nominal wall thickness of the socket is also specified.

A simple cylindrical pylon adapter is added at this time as well. The socket design using variable thickness walls and the cylindrical pylon adapter can be written directly to an STL file suitable for manufacturing.

A conventional patellar tendon bearing socket was designed for each subject using standard CAD/CAM fabrication techniques. The conventional socket was fabricated using carbon fibre lamination. A pylon and prosthetic foot were added to complete the prosthesis. Final alignment of the prosthesis was performed using visual gait analysis and patient feedback. Each subject was given at least two weeks to acclimate to the conventional socket before undergoing quantitative gait analysis.

Each subject was then switched to the SLS socket using the same prosthetic foot as the conventional prosthesis (Figure 3). After at least two weeks to acclimate to the SLS socket a second quantitative gait analysis was performed.

Stage 3: Long-term durability test

In order to evaluate the long term durability, it was decided to let amputees use the SLS sockets over a period of a year. Both total surface bearing sockets and patellar tendon bearing

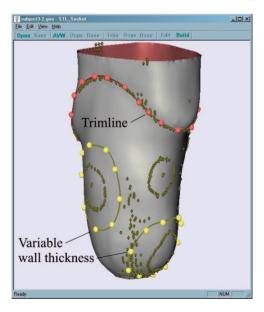


Figure 2. Location of trim-line and variable wall thickness areas.



Figure 3. Components of SLS prosthetic limb.

sockets are used. The sockets incorporate thinner socket walls over sensitive regions such as the distal tibia and the fibula head.

At the same time it was decided to incorporate industry standard hardware for attaching the pylon. The software developed for stage two incorporated a simple cylindrical adapter for pylon attachment. In order to test socket designs using a variety of off the shelf hardware it was decided to use a commercially available CAD package to add the necessary fixtures. These fixture designs will eventually be incorporated in the UTHSCSA socket design software. The basic socket design was exported from the UTHSCSA socket design software as a trimmed NURBS (Non Uniform Rational B-Spline) surface to an IGES (Initial Graphics Exchange Specification) file.

Rhinoceros, a commercially available CAD package was then used to create the design features necessary to use off-the-shelf hardware. The IGES file exported from the UTHSCSA design software is then imported to Rhinoceros and any features needed for pylon attachment are added. The finished socket design is then written to an STL file for manufacturing.

Two basic pylon attachment schemes have been incorporated.

The four holed pyramid adapter is among the most popular components in prosthetics. By incorporating this adapter into the socket design, any prosthetics facility could assemble a limb incorporating an SLS socket.

The initial design for the four holed adapter provided a flat surface on the distal end of the socket to mount a standard pyramid adapter. Two slots are incorporated into the end to accommodate aluminium bars with threaded holes that the pylon adapter will be attached to. The slots are 6 mm beneath the surface. Holes in the SLS socket match up with the threaded holes in the aluminium bars. The pyramid adapter is attached through the holes to the embedded aluminium bars. The disadvantage to this design is that the aluminium bars, while easily fabricated, are not off-the-shelf items.

An updated design incorporates slots in the distal end of the socket to accept commonly available 6 mm flange nuts. The slots are shaped to fit snugly to the hexagonal side of the

flange nuts so that a wrench is not needed to prevent the nuts from turning during tightening (Figure 4). A finite element (FE) model of a socket was used to model the strength of the socket and adapter. Sockets have been tested to destruction in order to validate the model and to verify that the socket/pylon adapter interface was suitable strong (Faustini et al. 2001).

Sockets incorporating internal circular attachment plates (grace plate) are also popular. This is a simple design to incorporate into an SLS socket. The plate fits snugly in the distal end of the socket positioned to match holes in the distal end. This design can also be used with an adapter for pin suspension (Figure 5).

This long-term evaluation is ongoing with the goal of having ten amputees wear a SLS socket for a year. The evaluation criterion for the long-term durability study is simple. Either the socket fails or it does not.

Stage 4: Novel construction for selective control of flexibility

Stage 1 used triangular cantilever beams for controlling flexibility while Stage 2 and Stage 3 use variable wall thickness for control of flexibility. A more sophisticated design has been incorporated for better control of flexibility (Faustini et al. 2005).

Four spiral slots in the socket wall define a compliant region. The centre of each spiral area is backed by a diaphragm spring. The flexibility of the spiral region is varied by changing the thickness of the diaphragm spring (Figure 6).

Stage 4 is in progress. Ten trans-tibial amputees will receive a conventional socket as well as two SLS sockets each having different degrees of flexibility. Each socket will be worn for a month before undergoing a complete biomechanical analysis including Vicon optical motion (Vicon Peak. 9 Spectrum Pointe Drive, Lake Forest, CA 92630, USA) capture and Tekscan in-socket pressure testing (Tekscan Inc. 307 West First Street. South Boston, MA 02127-1309, USA).

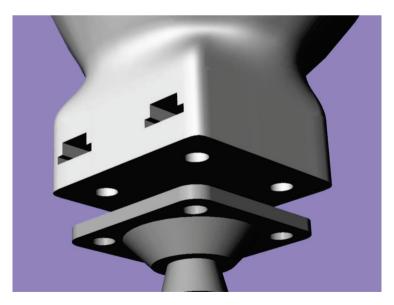


Figure 4. European four holed adapter.

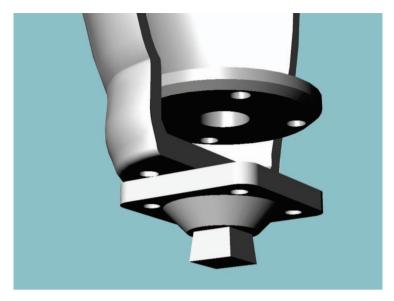


Figure 5. Pylon adapter using grace plate.

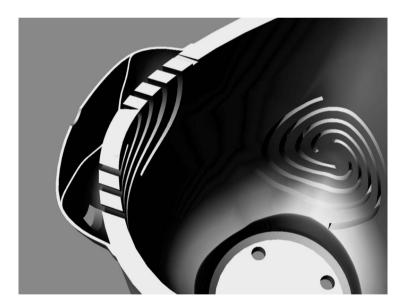


Figure 6. Cross-section of compliant region.

Results

Stage 1 involved one socket for a trans-tibial amputee. The socket was a double-wall socket with cantilever compliant regions over the distal tibia and fibula head. The subject's existing foot was used in conjunction with the SLS socket. The prosthesis was aligned by moving eccentric cylinders in the pylon adapter. An instrumented gait analysis showed little difference

with the conventional socket. The socket was judged acceptable and the encouraging results led to a pilot study.

The Stage 2 pilot study recruited five trans-tibial amputees of whom four participated in the study. The purpose of the study was to see if clinically acceptable for normal everyday use. A conventional socket was fabricated for each amputee. The pattern used for the definitive conventional socket was laser scanned so that the interior shape of the SLS socket would be identical to the conventional socket.

Each amputee wore a conventional socket of the same interior shape for at least two weeks followed by the SLS socket also worn for at least two weeks. A complete biomechanical assessment was performed after each two week period. There were no significant differences between conventional and SLS sockets. It had been hoped that the thinner walls over sensitive regions would provide additional comfort.

There was one notable failure where a socket fractured as one of the amputees stepped off a bus. The socket subsequently broke in two pieces as the amputee continued to walk with the limb. While this caused great concern about the whole project, it led to greater understanding of the whole process. Upon close examination it was revealed a problem with the material was the culprit.

The material problem resulted from the way the Sinterstation 2500 was set up. It was previously noticed that the socket material was quite brittle. This was the result of a trade-off between feature definition and part density. One way of operating an SLS machine is to use a laser power that is less than what would produce the densest possible part. This gives better feature definition and the part is easier to remove from the powder bed. Running the machine at an optimally higher laser power results in a denser part, but with a small loss in accuracy. The denser parts are stronger and have material properties that are closer to an extruded part. The socket that fractured was not fabricated at the highest possible density. All succeeding parts were fabricated at an optimally higher laser power and there were no further failures.

Stage 3 long-term durability testing is ongoing. A total of ten trans-tibial amputees will use an SLS socket for a year. Several months into the test, there have been no durability problems. The SLS sockets are slightly porous so when vacuum is involved in the suspension, it is necessary to coat the exterior of the socket with a water based urethane to avoid leakage. The only problem so far is difficulties with maintaining proper fit with diabetic amputees which is not related to socket fabrication.

The texture of the SLS sockets is slightly rough. Several amputees have noted that the texture of the socket makes donning the socket more difficult. An option is to sand the inside of the socket to make it smoother.

An early test of Stage 4 sockets with advanced compliance features involved one subject and three SLS sockets that were identical except for the diaphragm spring in the compliant areas. Tekscan F-Socket sensors were attached to the stump over the anterior tibia and the lateral fibula using a medical adhesive. By attaching the sensors to the stump, it made it easier to compare the three different sockets. As expected, the pressure was higher where the diaphragm spring was stiffer (Figure 7). A total of ten trans-tibial amputees will participate in the compliance study.

Discussion

SFF offers many advantages for the prosthetics field. One should not look at these technologies as only automating much that is currently done manually. While many artisan steps can be eliminated, the real strength of the SFF technologies is the ability to incorporate features in a socket that cannot be practically produced in another manner. This work has



Figure 7. Compliant socket instrumented with Tekscan sensors.

only looked at the incorporation of selectively flexible regions in the socket and the addition of a pylon attachment.

SLS as used in this study was chosen because of the appropriateness of available materials. The drawbacks have been the texture of the manufactured product and its slight porosity which is a problem with vacuum suspension. Other SFF technologies may also be suitable for prosthetics. Both SLA (Rovick et al. 1992; Freeman and Wontorcik 1998) and FDM (Lee et al. 1998) have been used to produce prosthetic sockets. The same STL data file used to make an SLS socket could be used with these other systems.

The infrastructure for actually manufacturing sockets using SFF is already in place. The service bureau model is well established in prosthetics and hundreds of service bureaux already exist worldwide. Their main business is producing prototype parts for industry and in essence, every prosthetic socket is a custom prototype part. Large prosthetics organizations might be inclined to purchase their own hardware while smaller facilities would use service bureaus.

Cost may or may not be an issue. Some of the sockets in this work were produced at the University of Texas at Austin while others were fabricated by two different service bureaux. The service bureau sockets cost about US\$1000 each. One service bureau indicated that if there was sufficient volume to dedicate a machine to prosthetic sockets, the cost could be around US\$500. While this may seem expensive for a simple socket, it is important to note that a SFF socket could be a much more sophisticated socket than is currently available.

The main barrier to inclusion of SFF as a viable technology for prosthetic fabrication is the lack of suitable software. As discovered in the 1980s, CAD software like AutoCAD is unsuitable for prosthetic socket design. Existing commercial prosthetic CAD software is only able to design socket patterns, not the whole socket. The UTHSCSA socket design software

used in this work allows for inclusion of variable thickness socket walls and the addition of a simple pylon mount adapter but is not currently capable of incorporating industry standard hardware or more sophisticated methods of varying the flexibility of socket walls.

While SFF will not replace conventional fabrication, it can be another tool in the prosthetist's toolbox. Digitizers used with current prosthetic CAD software should work with software designed for SFF fabrication. Manufacturing is not a large issue as a service bureau infrastructure already exists. The cost of the software is the price of entry. The lack of availability of such software is the barrier.

The use of SFF in prosthetics should not stop with the socket. While each socket is a custom part which makes it particularly suitable for SFF, there is no reason that the rest of the prosthetic limb could not fabricated as well. That would change CAD in prosthetics from designing prosthetic socket patterns to designing prosthetic limbs.

Acknowledgements

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