Clinical Evaluation of Prosthetic Sockets Manufactured By Selective Laser Sintering

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Abstract

A pilot study was undertaken to evaluate the clinical acceptance of prosthetic limb sockets manufactured using solid freeform fabrication (SFF). The fabrication of sockets for amputees is a natural application for SFF. The socket is the part of the prosthetic limb that fits onto the amputee's residual limb. Each socket is custom manufactured for each individual amputee. Four amputees were successfully fit with sockets created using selective laser sintering. The scope of the study included software development, finite element analysis, materials testing, and clinical evaluation. This paper discusses socket design issues and clinical testing results.

Purpose

The purpose of this pilot study is to demonstrate the feasibility of Solid Freeform Fabrication (SFF) using Selective Laser Sintering (SLS) to fabricate variable compliant wall prosthetic sockets for trans-tibial amputees. The study includes an engineering design component and a clinical case controlled comparison of variable compliant wall prosthetic sockets with conventionally fabricated prosthetic sockets.

The overall long-term objective of this project is to develop a system to fabricate variable wall compliant prosthetic sockets directly from digital residual limb shape information using freeform fabrication techniques. These sockets are expected to improve prosthetic socket comfort, improve tissue-loading characteristics, reduce skin discomfort and breakdown, and reduce fabrication time and cost compared to conventional socket fabrication techniques.

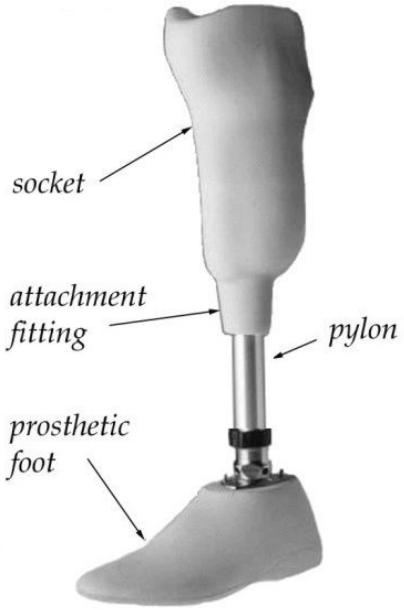

Fig. 1 Prosthetic limb

Introduction

There are approximately 400,000 lower limb amputees in the United States with 60,000 new major lower extremity amputations performed yearly. The majority of these amputees are fit with a prosthetic limb as part of their rehabilitation and return to independence. Because of changes in the shape and volume of the residual limb following amputation, the typical amputee will require a new prosthesis every two or three years.

A prosthetic limb for a transtibial amputee consists of several components (Fig. 1). First there is a socket that fits over the residual limb that is custom fit for each amputee. A fitting is

attached to the lower end of the socket to attach a pylon. The pylon connects to a prosthetic foot and is sized to the proper length for the prosthetic limb.

The most important aspect of a lower extremity prosthesis is socket design. The socket is the interface between the human and the mechanical support system. Ultimately, the design and fit of the socket is what determines patient acceptance, comfort, suspension, and energy expenditure[1]. All of these factors in unison determine the real utility of the final product.

The traditional method for designing sockets requires a skilled prosthetist and time consuming manual steps[2, 3]. First, the patient's residual limb is wrapped with plaster to acquire the shape. The plaster wrap is used to create a plaster positive. The prosthetist empirically modifies the plaster positive of the residual limb to distribute weight bearing to tissues that can tolerate the required forces. The socket is molded over the biomechanically corrected pattern. It is usually necessary to destroy the pattern in order to remove it from the socket. Making a new socket involves repeating all the steps if the pattern is destroyed.

CAD and Computer Assisted Manufacture (CAM) techniques are beginning to be widely used to design and manufacture sockets. A mechanical digitizer, magnetic digitizer, or a non-contact laser scanner[4] inputs the residual limb shape into the computer. The prosthetist then uses specialized software to produce a biomechanically correct socket from the limb shape. A computer controlled milling machine carves the pattern for the socket from plaster or foam. The socket is then made using conventional methods such as vacuum molding or lamination.

A limitation of currently available prosthetic CAD systems is that they only design the shape of the inner wall of the socket, which is all that is necessary for conventional fabrication. These CAD systems do not actually design the three dimensional shape of the socket. The actual wall thickness of the socket and the means of attaching the remainder of the prosthetic limb are determined during manufacturing. This is still largely an artisan process.

SFF techniques are a good match for use in prosthetics. Several artisan steps can be eliminated. These include trimming the final molded socket and the addition of a pylon attachment fitting. Additional features can be included such as variable compliance socket walls and integrated fittings. Due to the nature of the manufacturing process, an increase in socket sophistication does not lead to increased cost. The SFF industry is largely service bureau based which is the mode in which many prosthetic facilities operate.

Previous Work

Over the last ten years there have been several attempts to use SFF in the manufacture of prosthetic sockets for amputees.

Northwestern University working with Baxter Healthcare made a single transtibial socket using Stereolithography (SLA) in 1990[5].

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 transtibial

sockets[6, 7]. 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[8]. The process is a form of Fused Deposition Modeling 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[9]. The cost of the sockets was deemed to high for use as check sockets.

Also in 1998, Lee et al reported on fabricating two prosthetic sockets for amputees using FDM[10]. 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[11, 12]. This work led to the current clinical pilot study.

It is important to note that none of the above work with the exception of the UTHSCSA/UTA collaboration used SFF for anything except replacing the first manual step in socket fabrication. The remainder of the prosthetic limb had to be attached by artisan means and no advanced features such as variably compliant walls were incorporated.

Methods

The previous work involving the double wall socket was extremely complicated and was burdened by the extra weight of the double wall configuration. It was decided to use a simpler approach for this pilot study using a single wall configuration with variable wall thickness. The approach was to vary the wall thickness to provide thinner more flexible socket walls over sensitive areas of the residual limb.

The clinical feasibility of using SLS for socket fabrication was evaluated by comparing conventional and SLS sockets for comfort, stump-socket interface pressures and gait function in four transtibial amputees. Three were vascular amputees and one was a traumatic amputee. Their ages ranged from 31-62 and all would be considered community ambulators. Informed consent was obtained following local institutional review board protocols.

A conventional patella tendon bearing socket was designed for each subject using standard CAD/CAM fabrication techniques. The residual limb of the amputee was cast at the UTHSCSA using a ShapeMate[13] casting sock. This sock hardens in minutes after being put in water. A laser imager was then used to measure the outside shape of the ShapeMate sock. The sock has a uniform thickness so that by measuring the outside of the sock then subtracting the sock thickness, the correct residual limb shape can be calculated. The socket was designed using ShapeMaker[13] prosthetic CAD software. A socket pattern was then milled from urethane foam. The conventional socket was fabricated using carbon fiber 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 gait analysis. Reflective markers were placed on the sacrum, bilateral ASIS, knee, ankle, and 2nd metatarsal phalangeal heads. Ground reaction forces were obtained using AMTI[14] force plates embedded into the gait lab floor. Combined joint kinematic and kinetic data was collected at a sampling rate of 60 fps for three representative strides as the subject walked at his self-selected speed. Using VICON Clinical Manager software[15], basic temporal and spatial features of the gait patterns and lower extremity joint angles were determined. Using inverse dynamics, net joint moment (torque) was calculated. For the prosthetic limb hip and knee joints this represented the net muscular generated joint moment that is developed in response to external forces and loads. For the prosthetic ankle, the joint moment is the resultant internal moment developed at the foot/pylon junction that mirrors the location of the intact limb ankle joint.

At the time of the gait analysis each subject filled a questionnaire regarding limb use, wearing schedule and rated socket comfort using a visual analog scale.

The urethane foam pattern used to fabricate the definitive socket was measured using the laser imager and served as the template for SLS socket fabrication. This was to insure that the comparison was between 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 AAOP data interchange file. This is a non-proprietary file format that is supported by prosthetic CAD/CAM vendors.

In previous efforts at UTHSCSA/UTA[9, 10], the process of taking an AAOP data interchange file and creating a complete 3D socket with an attachment fitting was extremely labor intensive, time consuming and involved several different software packages. In order to produce sockets in a timely manner it was necessary to write custom software to create the final STL file from the AAOP file. This software was written in C++ using the OpenGL graphics API for the Microsoft Windows platform. The software performs four main functions. First it gives thickness to the socket by creating an outer shell from the inner socket shape. The nominal socket wall thickness was set to 6 mm. The socket trimline is set interactively using the mouse cursor to select points on the socket shape (Fig. 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 minimum thickness of regions over sensitive areas was set to 1.3 mm. Finally a fitting for a pylon adapter is added to the bottom of the socket. The fitting has a key that matches a keyway in the pylon adapter. The completed design is saved in an STL file (Fig 3).

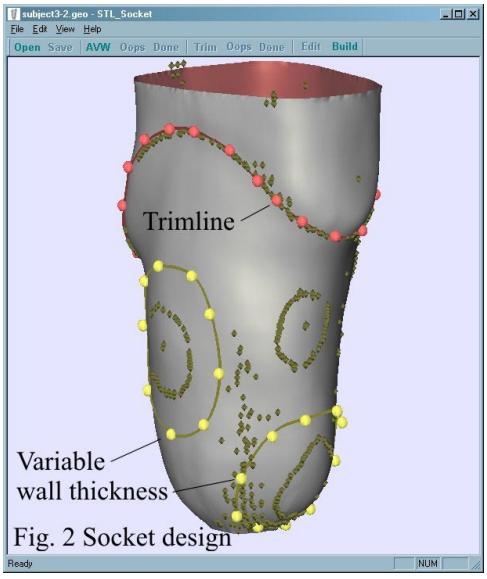

Fig. 2 Socket design

Each STL files was emailed to Accelerated Technologies Inc.[16], a service bureau, for fabrication. The parts were built using Duraform on a Sinterstation 2500[17]. The sockets were coated with cyanoacrylate for a better surface finish after sanding. The finished sockets were sent back to UTHSCSA for final assembly.

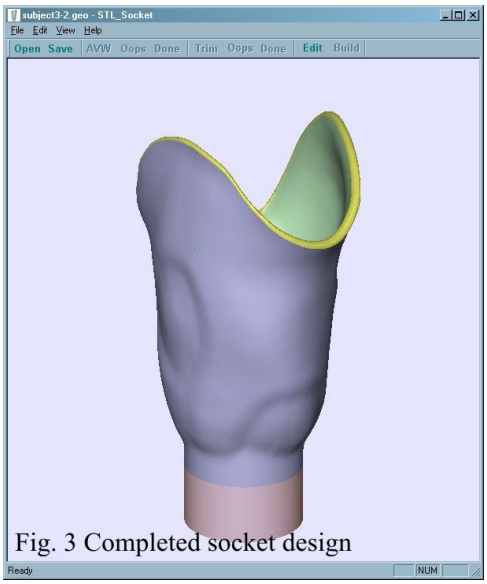

Fig. 3 Completed socket design

Epoxy was used to glue the nylon pylon adapter into the keyed fitting on the socket even though there was already a snug fit. The pylon and a prosthetic foot were added to complete the prosthetic limb (Fig. 4). The pylon adapter has two eccentric cylinders that are used to set the proper alignment angle of the pylon relative to the socket.

The gait analysis and subjective evaluation was repeated using the SLS prosthesis. In addition, measurements were made using the FSCAN[18] system to compare stump-socket interface pressures in the conventional socket and the SLS socket. The FSCAN system uses pezioresistive pressure sensitive plastic strips that were attached to the skin of the residual limb at sites that corresponded to the thinned regions of the SLS socket wall. Interfaces pressures were recorded and averaged over 10 strides. Pressure measurements were first conducted while wearing the conventional socket and then repeated with the SLS socket without changing the location of the sensors.

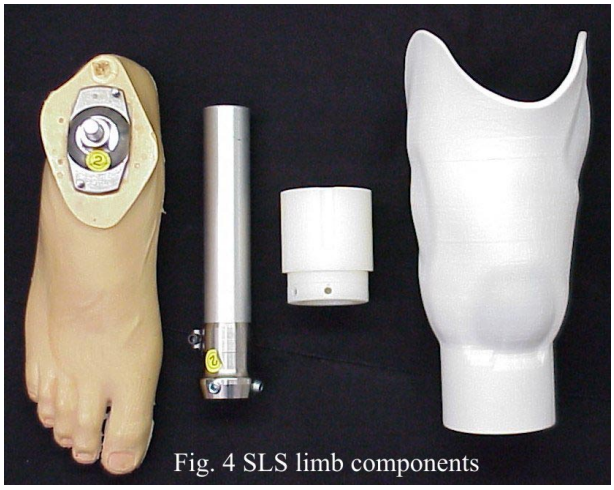
Fig. 4 SLS limb components

A finite element model of the socket was developed at UTA during the same time period though it was not ready to use during the socket design phase. Using IDEAS from SDRC[19] the socket volume is meshed with solid elements (parabolic tetrahedra), generating the final FE model that can be associated with selected material properties, undergo the appropriate boundary conditions and be simulated to generate structural analysis results. This finite element model proved to be valuable during the clinical part of the study.

Materials' testing was also done at UTA. Sample Duraform coupons fabricated at UTA were subject to a uniform pressure and the deflection was measured. It was necessary to verify that the material properties of the parts produced by SLS were the same as used in the finite element model.

Results

A clinically acceptable fit was achieved in all subjects with both sockets. All subjects were satisfied with the fit of the SLS socket and expressed a willing to use it to meet their ambulation needs. Informal feedback from the subjects suggested that overall socket function was nearly identical in three subjects who had a history of satisfactory socket fit and prosthetic use. The fourth subject had a long history of stump pain and poor tolerance to prolonged prosthetic use. This subject displayed the greatest degree of improvement in comfort and use of his prosthesis when using the SLS socket. Using the visual analog scale (0-10 range) comparison of socket comfort between the sockets ranged from the same to 15% improved with the SLS socket. Average daily wearing time remained the same in three subjects and increased by 5 hours in the fourth subject.

Gait analysis showed no significant differences between SLS and conventional sockets in self selected walking speeds or knee joint torques.

Attempts at measuring interface pressures were problematic. The difficulties were related to sensor movement between test sessions and bucking and wrinkling of the sensors during the loading/unloading cycle associated with each step. The resulting measurements contained spurious errors and the data needs to be interpreted cautiously. Considerable variability in the data existed but some trends were observed. Average peak pressures during the stance phase of gait showed no differences in the lateral aspects of the socket but were decreased by 11 psi in the anterior aspects of the SLS socket compared to the conventional socket.

There was one notable failure where a socket fractured as one of the amputees stepped off of a bus. The socket subsequently broke in two pieces as the amputee continued to walk with the limb (Fig. 5). While this caused great concern about the whole project, it led to greater understanding of the whole process. Upon close examination it was revealed that there were both design and materials components to the failure.

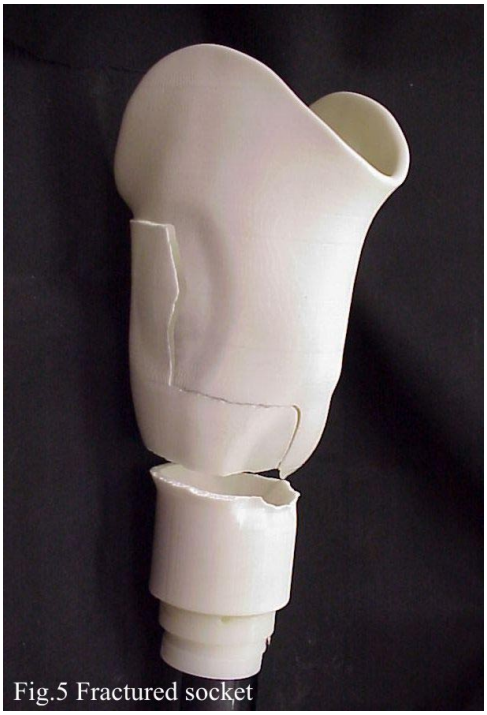

Fig.5 Fractured socket

The materials 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 tradeoff between feature definition and part density. The traditional 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 a 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 a higher laser power and there were no further failures.

The design problem came from the desire to provide the maximum compliance at the distal end of the socket. This resulted in a notch between the pylon adapter and the socket. This was the region where the fracture started. The socket was redesigned to blend the socket and pylon smoothly together.

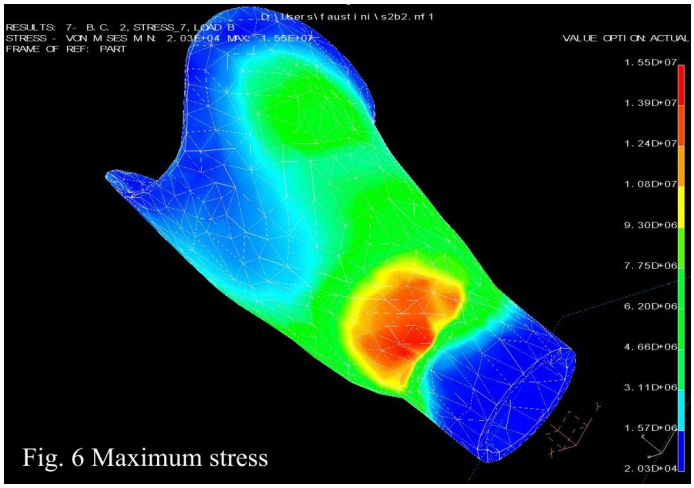

Fig. 6 Maximum stress

The finite element model of the failed socket showed that at the point of failure was the location of maximum stress (Fig 6 in red). The revised socket showed reduced stress at the junction of the pylon and socket. In neither case did the maximum stress in the model approach the (theoretical) ultimate limit of Duraform.

Discussion

This study showed that the SLS sockets were clinically acceptable and that they can be fabricated in a timely manner.

The desired amount of compliance hoped for was not achieved by thinning the socket wall. It was judged that a minimum wall thickness of 1.3 mm was necessary for structural integrity and even at that thickness there was little flexibility.

The pylon adapter chosen for this study presents an obstacle to clinical acceptance. The eccentric cylinder pylon adapter was chosen as it was simple to incorporate into the design. To be accepted by the prosthetics profession it will be necessary to accommodate conventional pyramid adapters.

Future Work

Larger scale clinical studies are planned. In the future, sockets will be designed directly from scan data eliminating the pattern fabrication step. One important addition will be incorporation of industry standard hardware into the socket design. New methods for providing additional compliance for sensitive areas of the residual limb will be employed. It is planned to use finite element modeling of the sockets during the design phase to minimize the possibility of failure as well as testing new methods of varying the socket compliance.

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