Case Report: Variably Compliant Transtibial Prosthetic Socket Fabricated Using Solid Freeform Fabrication

Bill Rogers, MS, Gordon Bosker, MEd, CPO, CPED, Mario Faustini, PhD, Gail Walden, MPH, Richard R. Neptune, PhD, Richard Crawford, PhD

ABSTRACT

Achieving and maintaining a comfortable fit in a lower-limb prosthetic socket is an important goal to help ensure a successful rehabilitation. The purpose of this case study was to assess the performance of sockets with compliant features integrated into the socket wall to relieve in-socket pressure during transtibial amputee gait. Two sockets incorporating variably compliant areas over the fibula head and distal tibia were fabricated for a transtibial amputee. The two sockets were designed with different levels of compliance and were compared with a third more conventional socket without compliant areas. All three sockets were otherwise geometrically identical and were aligned identically to eliminate in-socket pressure differences due to alignment. The three sockets were fabricated using selective laser sintering, a form of solid freeform fabrication. The in-socket pressure measurements were acquired during normal walking. Tekscan F-Socket pressure sensors were attached to the amputee's residual limb rather than to the socket wall, which made it possible to measure pressures in the same location on the residual limb upon change of socket. A Vicon motion capture system was used to match in-socket pressures to the subject's gait cycle. The pressure measurements showed that the compliant socket peak pressures over the distal tibia and fibula head were similar for the two compliance levels and nearly 50% and 30% lower than the conventional socket pressures, respectively. This case study showed that selective laser sintering manufactured sockets with variably compliant regions holds great promise for reducing contact pressure in sensitive regions of the residual limb. (*J Prosthet Orthot.* 2008;20:1–7.)

KEY INDEXING TERMS: prosthetic socket, amputees, CAD, CAM, solid freeform fabrication

T he most important aspect of a lower extremity transtibial prosthesis is the socket design. The socket introduces a new interface or a new joint between the human and the mechanical support system. The forces generated through the socket either by body weight or by gait have to be carried by the soft tissue of the residual limb, which when improperly loaded can lead to discomfort or skin breakdown. Ultimately, the design and fit of the socket is what determines patient acceptance, comfort, suspension, and energy expenditure.[1] Achieving and maintaining a comfortable and tissue-tolerant socket fit remains a significant clinical problem. This study explores the use of new manufacturing techniques to fabricate sockets with integrated compliant features specifically designed to improve comfort and fit of the prosthesis.

SOCKET DESIGN

There are two principal socket design strategies, and each is designed to distribute loads to pressure-tolerant tissues and relieve pressure on sensitive areas. The first is the specific weight-bearing socket where loads are distributed over pressure-tolerant areas of the residual limb such as the patella tendon, and pressure relief is provided over sensitive areas such as the fibula head. The second principal design is the total surface-bearing socket with a gel-type liner. Here, the pressure is applied to the entire surface of the residual limb at a tolerable level. In this case, the method of relieving pressure is to provide liner materials that by their nature redistribute the weight-bearing areas by the flow of the material.[2,3] An alternative solution is to locally modify the properties of the socket wall to provide pressure relief; however, very little work has been done in this area, especially in transtibial sockets.

CAD/CAM

Much effort has gone into the development of CAD/CAM systems for designing prosthetic sockets. However, a limita-

BILL ROGERS, MS, is affiliated with the Department of Rehabilitation Medicine, The University of Texas Health Science Center at San Antonio, San Antonio, Texas.

GORDON BOSKER, MED, CPO, CPED, is affiliated with the Department of Rehabilitation Medicine, The University of Texas Health Science Center at San Antonio, San Antonio, Texas.

MARIO FAUSTINI, PhD, is affiliated with the Department of Mechanical Engineering, The University of Texas at Austin, Austin, Texas.

GAIL WALDEN, MPH, is affiliated with PM&R Service, South Texas Veterans Healthcare System, San Antonio, Texas.

RICHARD R. NEPTUNE, PHD, is affiliated with the Department of Mechanical Engineering, The University of Texas at Austin, Austin, Texas.

RICHARD CRAWFORD, PHD, is affiliated with the Department of Mechanical Engineering, The University of Texas at Austin, Austin, Texas.

Correspondence to: Bill Rogers, MS, Research Imaging Center, The University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78229; e-mail: rogers@uthscsa.edu

tion of commercially available prosthetic CAD systems is that they only represent the three-dimensional (3D) shape of the inner wall of the socket with limited ability to design features for pylon attachment. These CAD systems only design a pattern to be machined, which is all that is necessary for conventional fabrication.

A promising alternative to conventional manufacturing is to use Solid Freeform Manufacturing (SFF) technologies, which are a class of technologies that can create 3D objects directly from a geometric database without specific tooling or human intervention.[4] Objects are generally built in layers that are fused by a laser or a binder, or are created by extruded material.

The SFF process used by this study is Selective Laser Sintering (SLS), in which components are built by material addition rather than by material removal using a directed laser beam that fuses powder particles in selected regions of space. The process begins by first depositing a thin layer of powder into the part bed. The powder surface is raster-scanned with a laser beam in much the same way a picture is formed on a television screen by a set of horizontal lines. The intensity of the beam is modulated to melt the powder in the areas that define the cross section of the part. Successive layers of powder are then deposited and scanned until the entire part is complete. In areas not irradiated, the powder remains loose and is removed once the part is completed. A variety of materials can be used in the process including metals, polymers, and wax.

Historically, SFF has been used to make prototype parts for industry, which makes this fabrication technique a good match for use in prosthetics as each prosthetic socket is unique. The entire socket can be directly fabricated at once complete with trimlines and pylon attachment mounting features. Additional features also 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 with the prosthetics industry in many countries.

There are several SFF techniques that have been used to directly fabricate prosthetic sockets under computer control thereby avoiding the intermediate step of pattern fabrication.

The University of Texas at Austin (UTA) and The University of Texas Health Science Center at San Antonio (UTHSCSA) have collaborated to make a number of transtibial sockets using SLS.[5–11]

Stereolithography involves hardening a liquid photopolymer with a laser. This technique has been explored by Northwestern University[12] and Freeman and Wontorcik[13] to fabricate trial prosthetics sockets.

Fused deposition modeling forms 3D shapes by extruding a bead of molten material through a nozzle. Fused deposition modeling has been used by Northwestern[14,15], Lee,[16] and Monash Universities[17] to fabricate transtibial sockets.

3D printing is a method using gypsum or starch and a binder to form 3D parts in layers. Herbert et al.[18] fabricated two prosthetic sockets using this method.

These systems could provide many benefits including sockets with different mechanical properties in different areas of the socket.[10,11,19] Thus, SFF is a promising technology to introduce compliant features in selective regions to reduce contact pressure. The idea is to assure proper rigidity of the socket in load-bearing areas while making 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 labor intensive and expensive. With SFF, the cost of fabrication 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, 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 expensive or even impossible to manufacture using conventional methods.

Early work at UTA and UTHSCSA in using SLS to produce a variably compliant socket resulted in a double-wall socket using cantilever compliant areas.[7] This socket had a rigid outer wall and a thinner more flexible inner wall. In addition, the inner wall had two hexagonal sets of triangular cantilever beams over the distal tibia and fibula head. Some manual steps were required to trim the socket top. Quantitative gait analysis showed little difference between the subject's conventional socket and the cantilever compliant socket. This work led to the development of a spiral compliant area incorporating a diaphragm spring.[11] Two sockets were fabricated using the spiral compliant areas and were tested on an amputee and compared with a socket without compliant areas.[10] This initial test showed lowered socket pressures over the compliant areas. There was no period of acclimation for the sockets between the subject's conventional socket and the SFF manufactured sockets. The only measures taken were in-socket pressures that limited the ability to synchronize in-socket pressure with the gait cycle.

The purpose of this case study was to assess performance of sockets with compliant features integrated into the socket wall to relieve in-socket pressure during transtibial amputee gait. An important aspect of this study is limitation of the number of confounding variables by comparing sockets that are aligned identically and are otherwise geometrically identical. In addition, the subject was well acclimated to the socket design at the time of testing.

METHODS

The subject in this study was a 47-year-old male traumatic transtibial amputee. He weighed 85 kg, was 180 cm tall, and was judged a K4 ambulator. He had been an amputee for 5 years. He was recruited from the University Hospital prosthetic clinic. Informed consent was obtained following local institutional review board protocols.

SOCKET FABRICATION

The residual limb was cast using a fiberglass casting sock. The shape of the residual limb was digitized from the casting sock using a ShapeMaker 2000 scanner. A total surface bearing socket pattern was designed using GordoDesign prosthetic CAD software (GordoDesign. 1.1. 2002, University of Texas Health Science Center, San Antonio, TX). A foam pattern was milled using a Seattle SM2000 carver, and a check socket was fabricated for use with a Harmony VASS suspension system (Otto Bock, Minneapolis, MN, http://www.ottobockus.com). Once the socket was deemed suitable, the socket including trimline, wall thickness, location of pylon adapter, and location of compliant areas was output as a spline surface model in an IGES file (Initial Graphics Exchange Specification, IGES; http://www.eeel.nist.gov/iges/). The IGES file was imported into Rhinoceros (Rhino. 3.0. Robert McNeel and Associates, 2005, http://www.en.na.mcneel.com/.), a 3D CAD program, for final socket design.

Three sockets were designed from the same socket interior shape, and all incorporated the same pylon attachment fitting for a European four-hole adapter. The first socket was a conventional design except for a variation in socket wall thickness over the fibula head and the distal tibia. The other two sockets had integrated variable compliance features over the fibula head and distal tibia. The compliance was provided by an integrated diaphragm spring (Fig. 1).[10] The thickness of the diaphragm spring was varied giving one socket more compliance than the other.

The stiffness of the compliant areas was calculated by finite element modeling (FEM) using the I-deas (UGS, Plano, TX, http://www.ugs.com/) mechanical CAD software package. All values were obtained using FEM models of the compliant sites isolated from the socket; in other words, they are local, not taking into account the overall deformation of the socket. The boundary conditions were designed as follows: the surrounding surface of the detached compliant site was fixed, and a dummy force (1 N) was applied at the center of the inner surface (where it should interface the limb/sock) of the compliant site, pointing outwards (to the outside of the socket). From the results of the FEM analysis, the displacement of the center of the compliant site was obtained, and the stiffness was calculated by dividing the force by the displacement (Table 1).

The sockets were fabricated on a 3DSystems Vanguard HS SLS System (3D Systems, Valencia, CA, http://www.3dsystems.com/)

from Rilsan D80 polyamide powder (Arkema, France), a form of Nylon 11. The sockets with compliant areas required modification to work with the Harmony VASS system. Holes in the external diaphragm cover, which were used to remove excess powder after fabrication, were filled with epoxy putty to seal the sockets for vacuum (Fig. 2). The subject's prosthesis was assembled using the Harmony VASS system initially using the conventional socket without the sophisticated compliant areas. The subject was allowed to wear the socket for the following year and underwent regular evaluations to assure a proper fit.

SOCKET EVALUATION

At the end of the year, a test session was scheduled to evaluate all three sockets via in-socket pressure measurements over the fibula head and the distal tibia as well as kinematic and kinetic gait parameters. In-socket pressure measurements were taken using a Tekscan F-Scan Mobile system (Tekscan, Inc., South Boston, MA, http://www.tekscan.com/). This system utilizes F-Socket Mylar/resistive ink transducers that were attached to the residual limb. F-Socket transducers were trimmed to the appropriate size then calibrated using a flat pressure bladder. To maintain the location of the sensors on the residual limb between tests, the sensors were attached directly to the residual limb rather than to the socket. This ensured that pressure measurements between the three sockets could be directly compared. To attach the sensors to the residual limb, the residual limb was wrapped in a shrink wrap plastic (Fig. 3). The plastic was gently heated to conform to the residual limb. The F-Socket sensors were then glued to the plastic around the residual limb. The regions of the distal tibia and fibula head were marked on the sensors and photographed to aid in identifying those regions in the F-Scan analysis software.

The subject walked using the socket without compliant features for about 5 minutes to condition the sensors. The F-Scan mobile system was used to capture three 30-second walks at a self-selected walking speed in a straight line.

To define the gait cycle and confirm that the overall walking mechanics were similar between sockets, a six-camera, four AMTI force plates (AMTI, Watertown, MA, http://www.amti.biz/), Vicon 370 3D Motion Analysis System (VICON Motion Systems, Tustin, CA, http://www.vicon.com/) was used. Reflective markers were placed according to the Plug-In-Gait marker set. Ground reaction forces were obtained using AMTI force
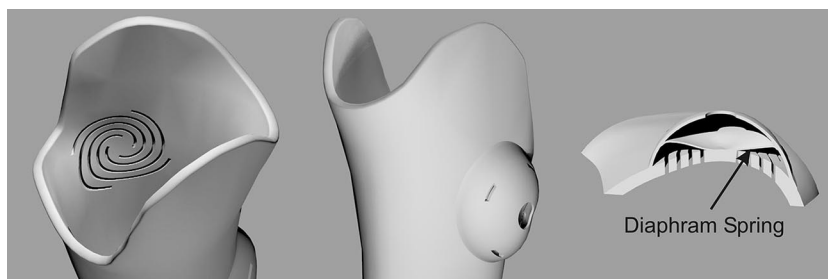

Figure 1. CAD model of compliant socket showing inside, outside, and cross section.

Table 1. FEM calculated stiffness (kN/m)

	Distal Tibia	Fibula Head (terminal stance)
Conventional socket	194.4	112.3
Compliant socket 1	79.5	27.2
Compliant socket 2	58.4	19.8

Figure 2. Assembled prostheses, compliant SLS socket on right.

Figure 3. Tekscan sensor placement on residual limb.

plates embedded into the gait lab floor. The subject walked at his self selected speed through the motion capture area. Enough trials were taken to get five clear hits on a force plate for each foot. At the same time, F-Scan in-socket pressures were captured so that they could be synchronized with the gait cycle.

The socket was then replaced with one of the compliant sockets. Because the pylon attachment was in the same location for all sockets, alignment was not affected. The data capture procedure was repeated for each of the two compliant sockets. At the end of the session, the F-Socket sensors were calibrated again to account for sensor drift.

RESULTS

The sockets with the variably compliant areas showed considerably less pressure over the distal tibia and fibula head than the more conventional socket (Table 2 and Fig. 4). The maximum pressure over the distal tibia occurred during mid stance for all three sockets. The maximum pressure over the fibula head occurred during terminal stance with the conventional socket (Table 2). With the compliant sockets, there were two small pressure peaks over the fibula head during mid stance and terminal stance. There was an additional smaller pressure peak over the fibula head during terminal swing with all three sockets. Vertical ground reaction forces were essentially the same for all sockets (Fig. 5). The cadence and walking speed increased with the compliant sockets. The increase was greatest with compliant socket 2, which had the most compliance (Table 3).

DISCUSSION

The goal of this case study was to assess the performance of sockets with compliant features integrated into the socket wall to relieve in-socket pressure during transtibial amputee gait. An important part of the study was to compare sockets that were geometrically identical except for the compliant areas. This approach limited the number of variables to be managed. Also, being able to switch sockets without changing the alignment was as important to avoid the confounding influence of alignment on in-socket pressure.

The compliant sockets showed considerably less pressure over the distal tibia and fibula head than the more conventional socket. The pressures from the two variably compliant sockets were so close as to be indistinguishable. As can be seen from Table 1, the calculated stiffness of the two compliant sockets is much less than the conventional socket. Also the difference in stiffness between the two compliant sockets is relatively small. Previous work showed a difference in in-socket pressures with two compliant sockets.[10] The earlier work utilized Duraform PA, a type of Nylon-12 (3D Systems), rather than the Nylon-11 used here. A difference in material properties between the two materials may account for the differences observed. In this study, the compliant sockets

Table 2. Peak in-socket pressure (KPa)

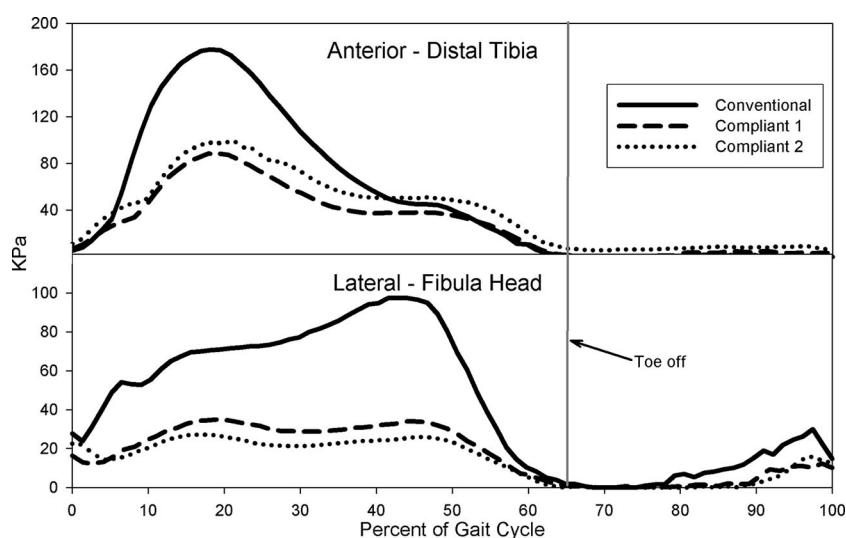|	Distal Tibia (mid stance)	Fibula Head (terminal stance)
Conventional socket	177.8	97.4
Compliant socket 1	88.4	33.9
Compliant socket 2	97.9	25.9

Figure 4. In-socket pressures over distal tibia and fibula head.
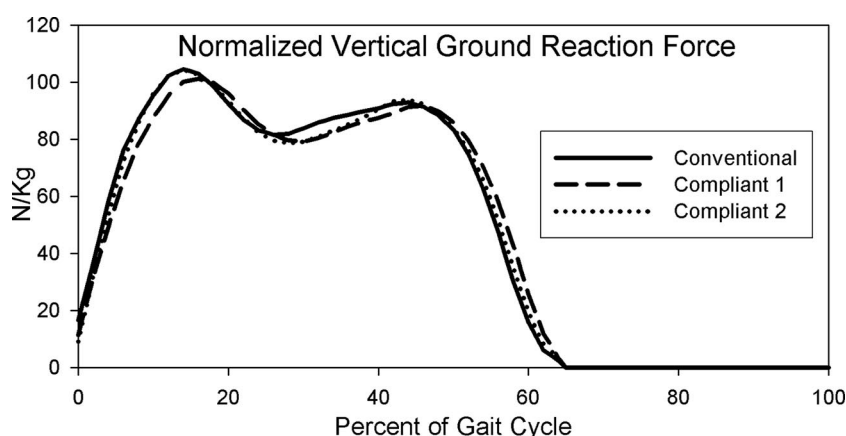

Figure 5. Normalized vertical ground reaction forces.

Table 3. Cadence, stride length, and walking speed

	Cadence (steps/min)	Stride Length (m)	Walking Speed (m/s)
Conventional socket	96.8	1.38	1.12
Compliant socket 1	101.0	1.35	1.14
Compliant socket 2	105.0	1.41	1.23

used a stiffness of less than half the stiffness of the conventional socket. Future tests should use a wider range of socket compliance by using a greater variation in the stiffness of the diaphragm spring including stiffness values closer to that of a conventional socket.

All the pressure measurements were taken during one session, so relative measurements of pressure between sockets were valid. However, quantifying the absolute value of the in-socket pressure was difficult because of specific issues with the F-Socket sensors. The sensors were calibrated using a flat pressure bladder, and it has been reported that the sensor output is affected by the curvature of the surface they are attached to,[20] with areas of higher curvature reporting higher pressures. As the residual limb has a highly contoured surface, the absolute value of the pressure is likely smaller than was recorded.

It should be noted that over the distal tibia, the peak pressure measured in compliant socket 2 was higher than the stiffer compliant socket 1. The difference may be due to the slightly higher cadence and walking speed observed during the compliant socket 2 trials. The difference is small and may also be due to the limitations of the accuracy of the F-Scan system.

There was a slight increase in cadence and walking speed with the compliant sockets (Table 3). It might be expected that the faster cadence and walking speed measured with the compliant sockets would result in higher ground reaction forces though the measured ground reaction forces were essentially identical (Fig. 5). It may be that the cushioning effect of the compliant sockets mitigated any increase in pressure due to an increase in walking speed.

All sockets showed a small pressure peak over the fibula head during terminal swing. The small peak occurred in the

proximal end of the sensor region defined for the fibula head, and the peaks during stance occurred in a more distal location. This suggests that some pistoning of the residual limb within the socket was occurring. Apparently there was enough motion in the socket for the fibula head to contact the proximal end of the relief area during swing.

The appearance of the compliant sockets is unattractive. The bulbous covers over the compliant regions are cosmetically challenging. It should be possible to lower the profile and blend the compliant regions into the socket. For these sockets to be clinically acceptable a more suitable cosmetic appearance will be necessary.

The subject had complained about discomfort in the area of the fibula head with the long-term conventional SLS socket. He felt that the SLS compliant socket 2, which was designed to have more compliance, was most comfortable and relieved the discomfort. The increased comfort may account for the increased walking speed observed.

The inability to predict socket pressures via modeling is a clear limitation of this study. Calculated stiffness values alone will not predict the level of compliance and pressure relief for the site. Compliant features with the same stiffness could lead to different pressure-relieving outcomes due to other factors such as the location of the compliant feature on the socket, and even more importantly, the interaction with the tissues that will contact the feature (how bony is the site or how much soft fat or muscle will be in contact with the feature or with the areas surrounding the compliant feature to where the peak pressures will be redistributed once the feature starts to deform). An initial attempt at studying the response of the entire system (compliant socket + residual limb) was done in a previous case study.[11] This study used computed tomography data of the patient while wearing a prosthetic socket, which is not done in a normal clinical situation.

In conclusion, this case study showed that the SLS manufactured sockets with the variably compliant regions were successful in reducing pressures in sensitive regions of the residual limb. Future work will address the long-term durability of the compliant sockets, improvements in cosmetic appearance, and the evaluation of a large number of subjects.
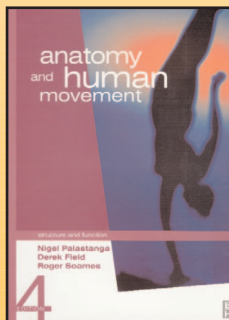
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