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Instrumented Socket Inserts for Sensing Interaction at the Limb-Socket Interface

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Abstract

The objective of this research was to investigate a strategy for designing and fabricating computer-manufactured socket inserts for prosthesis users that were embedded with sensors for field monitoring of limb-socket interactions. An instrumented insert was fabricated for a single trans-tibial prosthesis user that contained three sensor types (Proximity Sensor, Force Sensing Resistor, and Inductive Sensor) and the system was evaluated through a sequence of laboratory tests and two days of clinical field use. During in-lab tests 3 proximity sensors accurately distinguish between don and doff states; 3 of 4 force sensing resistors measured gradual pressure increases as weight-bearing increased; and one inductive sensor indicated that as prosthetic socks were added the limb moved farther out of the socket and pistoning amplitude decreased. Multiple sensor types were necessary in analysis of field collected data to interpret how sock changes affected limb-socket interactions. Instrumented socket inserts, with sensors selected to match clinical questions of interest, have the potential to provide important insights to improve patient care.

Keywords

Lower-Limb amputee; Prosthetic socket; Residual limb; Socket fit; CAD/CAM; Interfacial sensors

INTRODUCTION

Custom stiff plastic inserts that snap together to fit within prosthetic sockets have previously been made using 3D additive fabrication methods [1]. They may be useful to practitioners as a temporary solution for lower limb prosthesis users who have lost excessive limb volume. Unlike socks or pads, custom plastic inserts are stiff and provide mechanical support similar to a prosthetic socket. By placing custom inserts within sockets to reduce size and adjust

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shape, practitioners reduce the patient's sock thickness and improve limb-socket coupling and stability. Given today's reimbursement environment that provides new sockets at time-based intervals rather than need-based intervals, custom stiff plastic inserts may offer a useful new strategy to maintain socket fit until a new prosthetic socket can be made.

Custom inserts also have the potential to serve as sensor platforms for field monitoring. Out-of-clinic monitoring of limb-socket interactions is of interest in external prosthetics [2–4]. Field-collected data has the potential to provide helpful information to practitioners towards componentry selection, socket design, and limb health [2]. Continually collected field data may help identify when a user's prosthetic fit has changed and socket modifications are needed.

Instrumented inserts offer advantages over taping or affixing sensors to the inside of the socket. By positioning sensors, wires, and circuitry within the inserts, we minimize distortion to the measurement of interest, damage to the instruments, and irritation of residual limb tissues, and maximize flexibility since an old insert can easily be swapped for a new insert. Some sensor measurements are affected by temperature changes of the limb, for example from heating that occurs when a person exercises [5]. Donning may also overstress and mechanically damage sensors, particularly if the socket is tight and induces high shear stresses during donning and doffing. Practitioners may not want to make permanent changes to the socket, such as drilling holes or applying adhesives to hold sensors in place, so that the socket can be re-used by the patient when the sensors are removed. These problems are minimized by positioning sensors in the inserts with their sensing surfaces flush with the limb-insert interface, and making the inserts of a plastic with appropriate thermal conductivity.

The purpose of this technical note is to present a strategy for instrumenting custom prosthetic inserts to provide field data meaningful to patient care. An instrumented insert that included three sensor types was fabricated for a single below-knee prosthesis user. The utility of the system was evaluated through a set of laboratory tests and 2 days of continuous data collection out of the lab.

METHODS

Instrumented Insert and Socket

The insert was designed and fabricated as previously described except with recesses and channels for installation of sensors and wires [1]. Briefly, the recipient's current socket was digitized using a mechanical coordinate measuring machine (FaroArm Platinum, FARO Technologies, Lake Mary, Florida). The digitally captured point cloud was then transformed into a surface mesh and then a solid three-dimensional CAD model of the insert, using specialized software (Geomagic, Design X, 3D Systems, Rock Hill, South Carolina). The model's inner surface was the scanned socket shape, which ensured that the final socket shape would mimic that of the participant's current socket. The outer surface was created by uniformly projecting outward normal from the model's inner surface. In this research, inserts were 1.8 mm thick (approximately the sum of the thicknesses of a 5-ply, 1-ply, and 1-ply

sock under stance phase weight-bearing [6]) since that was the minimum thickness necessary to adequately mechanically support the sensors of interest within the insert.

Recesses and channels were designed into the insert using 3D CAD software (Inventor, Autodesk, San Rafael, California). The design ensured the sensors (described below) were flush with the inside surface (Proximity Sensor, Force Sensing Resistor) or embedded just beneath the surface (Inductive Sensor). Once designed, the insert was fabricated using a tabletop additive fabrication system (Objet30 Pro, Stratasys, Eden Prairie, Minnesota) and a rigid clear polymer (VeroClear RGD810, Stratasys). The polymer had an elastic modulus of 2000–3000 MPa and Shore D hardness of 83–86. Inserts were manufactured in four sections (anterior, lateral, medial-posterior, and distal end) so as to reduce the amount of supporting material required during manufacturing, reducing cost.

A new socket was fabricated for the participant that was uniformly 1.8 mm larger so that the socket could accommodate the instrumented insert and match the shape and dimensions of the user's original socket. The assembled instrumented insert was installed into the enlarged socket using two-sided adhesive tape (SpeedTape, FastCap, Ferndale, Washington) at the brim and a few select points on the seams. The tape introduced minimal socket shape error, as demonstrated previously [1]. Wires exited the insert-socket interface together at the socket brim in two bundles, one at the medial brim and one at the lateral brim. The two bundles of wires were routed along the external surface of the socket to a custom-designed portable data acquisition device, described in detail in Supplement 1. Self-adherent medical tape was then wrapped around the socket to protect the wires and data acquisition device. The completed instrumented socket is shown in Fig. 1.

Proximity Sensors to Identify Limb Presence or Absence within the Socket

Proximity sensors were used to distinguish among different socket wear states, including donned, partially donned, and doffed. Three proximity sensors were placed in-line down the lateral side of the socket (brim, mid limb, distal) (Fig. 2A), with one additional sensor placed at the patellar tendon that was available as an alternate. Sensors were potted using a polyamide hot melt to provide electrical and mechanical isolation of the sensors from the surrounding insert (where connections to the wires were located) and the socket wall. Technical details are described in Supplement 2.

Force Sensing Resistors to Quantify Interface Pressures

A common force sensing resistor (FSR) model employed in prosthetics research was used here (FSR 402, Interlink Electronics, Camarillo, California; dimensions 18.28 mm diameter, 0.48 mm thickness) [8,9]. Although FSRs are known to have poor precision and also to suffer from drift problems [10,11], they are useful as general indicators of pressure levels and are well-suited for installation into prostheses due to their low profile, low cost, and ease of implementation. In this study four FSRs were used: two in regions believed to be areas of high interface pressure (anterolateral distal and posterior proximal) and two in regions believed to be areas of low interface pressure (anteromedial proximal and posterior distal) (Fig. 3A) [12,13].

FSRs were installed in 0.48 mm deep recesses, the thickness of an FSR. The FSR tail was passed through a slit to the outer surface of the insert for wire routing. The FSR head was affixed using the adhesive backing layer of the FSR. Technical details are provided in Supplement 3.

Inductive Sensors to Measure Limb-to-Socket Distances

The inductive sensor was a custom-designed flexible coil antenna (diameter 32.0 mm, thickness 0.15 mm) which acted as a resonant LC tank (parallel inductor and capacitor). The antenna was placed slightly anterior of the high curvature distal end region of the socket (Fig. 4A). The conductive target was a custom-fabricated patch comprised of conductive fabric layers (Nora Dell and MedTex180, ShieldEx, Palmyra, New York). The conductive patch (9.0 mm diameter), was adhered directly to the outside of the participant's elastomeric liner using two-sided adhesive tape (SpeedTape). Technical details are provided in Supplement 4.

Clinical Studies

Inclusion criteria required the participant to have had a trans-tibial amputation at least 18 months prior to the study, to currently use a definitive prosthesis, and to be at an activity classification level of at least K-2 (a limited community ambulatory or higher per the Medicare Functional Classification Level scale). Candidate participants were excluded if they presented with skin breakdown at the time of the study. All study procedures were approved by a University of Washington Institutional Review Board and informed consent was obtained before any test procedures were initiated.

The participant conducted three in-lab procedures (don/doff tests; variable weight-bearing test; and sock test) and then underwent field data collection.

Don/Doff Test

The participant was asked to wear his or her prosthesis under each of the following conditions for 5 seconds in the following order: fully doffed, half donned, fully donned, half doffed, fully doffed, and resting the residual limb on top of the socket brim. The latter position is a common doffed resting position for individuals with lower limb loss.

For each don/doff state, a single value was calculated for each sensor by averaging 3 seconds of data beginning 1 second after the transition to the new state. Data were inspected to determine if a proximity count threshold existed such that for all doffs (OFFs) all sensors were above the threshold, and for all dons (ONs) all sensors were below the threshold. The threshold was then used to convert proximity sensor data from all tests to OFFs or ONs (Fig. 2B).

Variable Weight-Bearing Test

For this test the participant began by standing on a scale to record full body weight. He or she then walked for 60 seconds to ensure the limb was fully settled into the socket. The participant then stood on a level platform with a scale beneath the prosthetic limb and shifted his or her weight until each of four weight-bearing conditions was reached: no

weight-bearing (**NWB**) (all weight on contralateral limb); quarter weight-bearing (**QWB**) (scale reading 1/4 of full weight); equal weight-bearing (**EWB**) (scale reading 1/2 of full weight); full weight-bearing () (all weight on prosthetic limb) (Fig. 3B). Each condition was held for 10 seconds and the protocol was repeated three times. Means of all data points from each 10 second stand period were reported. For walking data, the peak pressure during each step was determined and the mean of all of those peaks for each walk cycle was calculated.

Sock Test

The participant walked for 90 seconds wearing each of three different sock thicknesses, sitting to change sock ply in between walks. The order was as follows: 1 ply, 3 ply, 5 ply, 3 ply, 1 ply. Sock thickness was measured under pressure (101.2 kPa) for each of the socks tested using a tabletop sock thickness measurement tester previously described [6].

A maximum (peak), minimum (trough), and peak-to-peak amplitude were determined for each step and means calculated for each of the 5 walking bouts. Pistoning amplitude was calculated as the difference between the mean peak and mean trough. These three variables were assessed for correlations with sock thickness (Fig. 4B).

Field Data Collection

The participant left the laboratory setting wearing the instrumented insert, going about his or her normal daily routine for the next 2 days as data were continuously collected at a 10 Hz sampling rate from the sensors. The participant was asked to write down the start time and end time of prosthesis use each day and to log all sock changes. The participant was provided with four new socks (1, 2, 3, and 4-ply) and asked to use only those socks for the next 2 days. Upon returning to the lab after 2 days, all sensor data were downloaded. Data were analyzed to characterize matches between user log data and sensor data for nightly doffs and sock ply changes. Sensor signal changes from 10 minutes before to 10 minutes after each sock change were visually inspected.

RESULTS

Test Participant

The test participant was male, 74 years of age, 81.6 kg, and had undergone a trans-tibial amputation 38 years prior as a result of trauma. He did not have any known comorbidities. He was a K-3 level ambulator and wore a total surface bearing socket with a vacuum suspension and a dynamic response prosthetic foot. The instrumented insert socket had the same shape as the total surface bearing socket and was held on using a suspension sleeve.

Don/Doff Test

The threshold proximity count for which all sensors were above the threshold for all doffs (OFFs) and below the threshold for all dons (ONs) was set to 63,000. Proximity counts changed differently for different locations as the limb transitioned from doffed to partially doffed to partially donned to fully-donned status (Fig. 2B). During every half don and half doff, the brim and mid limb sensors were ON, though the distal sensor varied (Fig. 2C),

presumably due to inconsistent placement of the limb during these states. As expected, resting the limb on top of the socket did effectively cause the brim sensor to trigger the ON state and the mid limb and distal sensors the OFF state.

Variable Weight-Bearing Test

For three of the four FSRs, the sensor measurements agreed with the expected relative magnitudes based on their selection as high or low pressure regions of the limb. The anterolateral distal FSR reported the highest stresses for every condition tested, with a mean peak walking pressure of 57.6 kPa. The posterior distal and anteromedial proximal sensors followed with 29.2 kPa and 22.2 kPa mean peak pressures during walking, respectively (Fig. 3C). The posterior proximal FSR, anticipated to be a high pressure region, did not register any pressure throughout this test despite recording small magnitude pressures later in the field test. The posterior distal sensor remained unloaded during NWB and QWB and the anteromedial proximal sensor remained unloaded during NWB.

Sock Test

Thicknesses of 1, 3, and 5-ply socks were 0.54, 1.30, and 2.34 mm, respectively. Data collected during this test agreed with the expectation that the addition of socks caused the limb to position progressively farther away from the distal end of the socket (Fig. 4B). It was also demonstrated that pistonning amplitude decreased as socks were added (Fig. 4C). Pistoning amplitude was comparable for both walk cycles while the participant wore the 1-ply sock. It was lower for the first walk cycle wearing the 3-ply sock than the second walk cycle wearing the 3-ply sock.

Field Data Collection

Thicknesses of the 1, 2, 3, and 4-ply socks at the start of the 2-day test were 0.54, 1.04, 1.30, and 1.84 mm, respectively. All sensors within the instrumented socket gathered data throughout the entire 2-day field test without interruption. A summary of sensor behavior change following each of three sock changes the participant executed is shown in Table 1. The mid limb and distal proximity sensor data matched self-reported data for all sock changes and both nightly doffs (Fig. 5A). The lateral brim sensor, however, remained below the OFF threshold for the sock change from 2 to 3 ply during the first day and for both nightly doffs.

Sensor data from the three distal sensors (lateral distal proximity, posterior distal FSR, and inductive sensor) were qualitatively assessed in the period 10 minutes before to 10 minutes after each sock change. During the first sock change (1 to 2 ply) (Fig. 5B) the proximity sensor showed a clear decrease in proximity after the sock thickness increase, the inductive sensor showed a clear increase in socket-to-liner distance, and the pressure sensor showed minimal change. This result suggests that the sock change caused the liner and limb to be lifted farther out of the socket, but the additional sock thickness filled in more of the space at the distal end of the socket.

During the second sock change (2 to 3 ply) (Fig. 5C) the three distal sensor readings did not appear significantly altered. The mid limb proximity sensor, however, showed a decrease,

indicating that the increased sock thickness resulted in excess space being filled at the mid limb even though the distal end remained largely unchanged. The mid limb proximity sensor did not display this trend during the other two sock changes.

The third sock change (3 to 4 ply) (Fig. 5D) showed similar trends to the first sock change for the three distal sensors. Following the sock addition, the sock moved closer to the socket wall and the liner moved farther away from the distal end. The posterior distal FSR displayed a large decrease in pressure, indicating the sock addition lifted the limb out of the socket far enough such that the distal end became largely unloaded. The increased frequency content of sensor data following sock addition suggests that the participant added a sock in anticipation of increased activity.

DISCUSSION

This study demonstrated a method for designing and manufacturing sensor-instrumented plastic inserts for prosthetic sockets, and that such a system can be used to obtain clinically relevant information for trans-tibial prosthesis users. By designing the inserts with recesses to enable sensor and wire placement within the insert, we ensured the contour remained smooth and the sensors were well-protected.

To distinguish periods when the socket was donned from when it was doffed, a single mid-limb proximity sensor was demonstrated to be sufficient for the single participant tested in the present study. Monitoring when a prosthesis user partially doffs the socket or rests his or her residual limb on the brim may also be of clinical interest, since these actions may facilitate limb fluid volume recovery and obviate the need for sock accommodation [14]. The present study demonstrated that additional proximity sensors would be needed to track these behaviors, increasing power consumption but providing a richer data set.

We note that in the present study the lateral brim proximity sensor behaved differently in the field than in the lab, remaining below the OFF threshold during multiple known doff scenarios, whereas the other sensors performed well using the same threshold determined by in-lab tests. The lateral brim sensor was more exposed than sensors at other locations, and this exposure likely affected field test results. When the doffed socket was stored the sensor may have been partially covered by an object such as a liner or a sock. Incident sunlight or another infrared-containing light source may also have altered the signal.

FSR data from anterior sites in the present study in general demonstrated gradual pressure increases with greater weight-bearing (Fig. 4C), in agreement with a prior study by Zachariah and Sanders [15]. The researchers were able to approximate peak stresses during walking in two individuals with trans-tibial limb loss by measuring standing socket interface stresses at multiple levels of weight-bearing. Unexpected in the present study, the posterior proximal FSR did not record high magnitude pressures, or increases in pressure with greater weight-bearing. After further investigation we determined this result was due to the contour of the socket at the FSR placement site. The FSR was placed in an overhanging region, which limited its exposure to increased force with greater weight-bearing. In future research efforts this result should be anticipated and sensor placement adjusted accordingly.

During in-lab tests, the inductive sensor measured increases in superior-inferior limb position as the participant added more socks, as expected; however, the change in position measured was not equal to the change in sock thickness. It is likely that other variables affected the data during these tests and contributed to this lack of agreement, in particular limb volume and distal end bearing. A prior study showed that when individuals with trans-tibial limb loss added socks, limb fluid volume decreased by a moderate to large amount [16]. When a sock is added, distal end bearing may increase from an increase in sock thickness at the distal end of the socket, or it may decrease if the added socks provide better support proximally.

Using several sensor types simultaneously helped to clarify some of these confounding variables, and to gain a more complete understanding of the participant's interaction with his prosthesis (Table 1). Each sensor type provided unique information. Ultimately the data that are collected with an instrumented socket insert and the analysis that is performed depend on the specific questions that the researcher or clinician asks regarding patient care. Perhaps one of the more clinically important questions one can ask is if any set of sensors could be used as a real-time indicator of degrading socket fit, and therefore be used to inform an intervention, such as a sock change. This is an exciting area for future research.

Currently the design and fabrication of the instrumented inserts takes a significant amount of time. As such, instrumented inserts are currently only valuable for research efforts. However, if the process were streamlined, made more user-friendly, and became integrated within socket scanning and fabrication methods, the system could provide clinicians with a feasible means of gaining important clinical insights that could significantly improve the care they are able to provide their patients.

CONCLUSION

A method for designing and fabricating custom, sensor-instrumented, plastic inserts for lower limb prosthetic sockets was demonstrated. The instrumented inserts did not disturb the normal fit of the socket and protected sensors and associated electronics from being damaged within the socket. Three sensor types were employed in an instrumented socket insert and demonstrated an ability to detect don/doff state and changes in limb mechanics and position from weight shifting and sock thickness changes. In a two-day field test, combining data from multiple sensors helped to clarify how the participant adjusted to sock additions. Efforts to advance the technology could lead to a novel clinical diagnosis system to enhance patient care.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- A means to create sensor-embedded prosthetic socket inserts is described
- Proximity sensors, force sensing resistors, and an inductive sensor were included
- In clinical testing three proximity sensors well-distinguished don and doff states
- The sensor embedded insert performed without error during a two-day field test
- Understanding sock addition effects required data from multiple sensor types

Fig. 1. Instrumented insert installed into the enlarged socket
(A) Close-up of socket interior, arrows pointing to 1 sample sensor of each type (not pictured: posterior proximal FSR). (B) Completed test prosthesis, with wires and data acquisition device (DAQ) protected by medical wrap.

Fig. 2. Proximity sensor don/doff test

(A) Proximity sensor locations in socket. (B) Representative data set from 1 cycle, after processing mean values at each don/doff condition. Threshold of 63,000 shown to indicate which sensors were considered ON versus OFF. (C) Following threshold application, ON/OFF status of each sensor during each condition.

Fig. 3. FSR variable weight-bearing test
(A) FSR placement in socket and expected high vs low loading at each location. (B) Representative pressure waveform of 1 cycle. (C) Test results for three FSRs (mean $\pm$ SD). Posterior Proximal not included since it was unloaded during this test. **NWB** = No Weight-Bearing; **QWB** = Quarter WB; **EWB** = Equal WB; **FWB** = Full WB.

QWB = Quarter WB; **EWB** = Equal WB; **FWB** = Full WB.

Fig. 4. Inductive sensor pistoning test

(A) Inductive sensor placement at distal end, shifted slightly anteriorly. (B) Raw data of entire test after conversion to mm. Key measures illustrated (Peak, Trough, and Pistoning Amplitude). (C) Pistoning amplitude during each 90s walk with varying sock thicknesses shows distinct decreases as thickness increased, and increased as thickness decreased.

Fig. 5. Field data

(A) Proximity sensors for don and doff status during field test. Black and white triangles indicate self-reported sock changes and self-reported start-of-day, respectively. High sensor values match closely with self-reported doff data. (B–D) Sensor measurements 10 min before and after each of 3 sock changes during field test, indicated by circles. (B) 1 to 2 ply sock change induced an increase in proximity of sock to socket and increased liner distance from the socket, but did not noticeably change pressure. (C) 2 to 3 ply sock change did not induce significant changes in sensor measurements at the distal end, but the mid limb

proximity sensor measured a distinct increase in proximity of the sock to the socket wall.
(D) 3 to 4 ply appears similar to B, with a notable pressure decrease following the change.

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Table 1

Summary of sensor behavior change following each sock change. “No” indicates that no clear change in sensor data occurred.

Sensor	Location	Sock Change		
		1 to 2 ply	2 to 3 ply	3 to 4 ply
Proximity – Proximity	Lateral Brim	No	No	No
	Lateral Mid Limb	No	Yes (Closer)	Minimal
	Lateral Distal	Yes (Closer)	Minimal	Yes (Closer)
FSR – Pressure	Anteromedial Proximal	No	No	No
	Anterolateral Distal	No	No	No
	Posterior Proximal	Yes (Increase)	No	No
	Posterior Distal	Minimal	Minimal	Yes (Decrease)
Inductive – Distance	Anterior Distal	Yes (Farther)	No	Yes (Farther)