Medical Engineering and Physics 000 (2017) 1–8

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

Technical note

Instrumented socket inserts for sensing interaction at the limb-socket interface

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ARTICLE INFO

Article history:
Received 10 May 2017
Revised 18 August 2017
Accepted 22 November 2017
Available online xxx

Keywords:
Lower-limb amputee
Prosthetic socket
Residual limb
Socket fit
CAD/CAM
Interfacial sensors

ABSTRACT

The objective of this research was to investigate a strategy for designing and fabricating computer-manufactured socket inserts that were embedded with sensors for field monitoring of limb-socket interactions of prosthetic users. 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 clinical tests and two days of 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 the 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.

1. 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 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 toward 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.

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https://doi.org/10.1016/j.medengphy.2017.11.006
1350-4533/

Please cite this article as: E.C. Swanson et al., Instrumented socket inserts for sensing interaction at the limb-socket interface, Medical Engineering and Physics (2017), https://doi.org/10.1016/j.medengphy.2017.11.006

2. Methods

2.1. 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]. First, 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 normal socket. The new 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 outer surface was the scanned socket shape, which ensured that the final socket shape would mimic that of the participant's current socket. The inner surface was created by uniformly projecting inward normal from the model's outer 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.

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, described previously [7], 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.

2.2. Clinical studies

Inclusion criteria required the participant to have had a transtibial 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 test; 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 s 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 s of data beginning 1 s 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 s 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 (FWB) (all weight on prosthetic limb) (Fig. 3B). Each condition was held for 10 s and the protocol was repeated three times. Means of all data points from each 10 s 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 s 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.

Please cite this article as: E.C. Swanson et al., Instrumented socket inserts for sensing interaction at the limb-socket interface, Medical Engineering and Physics (2017), https://doi.org/10.1016/j.medengphy.2017.11.006