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Design of a novel prosthetic socket: Assessment of the thermal performance

Christina M. Webber, Brian L. Davis*

Department of Biomedical Engineering, The University of Akron, United States

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A B S T R A C T

Prosthetic liners and sockets insulate the residual limb, causing excessive sweating and concomitant skin maceration. When coupled with atypical loading conditions, further dermatologic problems can arise. This can significantly reduce the quality of life of an amputee patient. Improving the design of the prosthetic socket has been proposed as a means of reestablishing a normal thermal environment around the residual limb. In this study, a prosthetic socket was modified by incorporating a helical cooling channel within the socket wall using additive manufacturing techniques. Two sockets were modeled: a control socket, and a modified socket containing a 0.48 cm diameter cooling channel. Computer simulations and bench-top testing were used to assess the design's ability to create a greater temperature differential across the socket wall. A greater temperature drop across the socket wall suggested that the socket could provide cooling benefits to the residual limb by allowing for heat to be drawn away from the limb. The temperature difference across the socket wall was calculated for both sockets in each aspect of the study. Both socket type ($p = 0.002$) and location on the socket ($p = 0.014$) were statistically significant factors affecting the temperature difference between inner and outer socket walls. Compared with the control socket, the modified socket containing a helical cooling channel exhibited greater temperature differences across its wall of 11.1 °C and 6.4 °C in the computer simulations and bench-top testing, respectively. This finding suggested that socket modifications, such as the cooling channel presented, could provide a beneficial cooling effect to an amputee patient's residual limb.

1. Introduction

Many research efforts have been devoted to improving the foot, ankle, and knee units for transfemoral prosthetic components. While improving the mechanical functionality is critical, an equally important area of prosthetic design, the thermal environment, is often overlooked.

Current commercially available prosthetic liners and sockets are insulators, trapping heat around the residual limb (Deans et al., 2008; Huff et al., 2008; Klittich et al., 2013; Klute et al., 2007). An unnatural environment is created around the residual limb by this trapped heat, often causing the residual limb to sweat excessively. Because of this, numerous dermatologic conditions can arise, such as allergic contact dermatitis, microorganism infections, and verrucous hyperplasia (Huff et al., 2008; Klute et al., 2010; Levy, 1980; Meulenbelt et al., 2007; Peery et al., 2006). Atypical loading conditions experienced by a residual limb can exacerbate these skin problems, often reducing the quality of life for the amputee patient. Furthermore, amputee patient rehabilitation is hindered by the physical and psychological burdens caused by these conditions (Deans et al., 2008; Dudek et al., 2005; Levy, 1980). Efforts to improve the thermal properties of the prosthetic liner and socket could therefore benefit the amputee community. This study utilized a design-based approach to alleviating the issue of heat trapped within a socket. Through computer simulations and bench-top testing, the feasibility of a modified prosthetic socket with a built-in cooling channel was assessed.

The prosthetic environment is complex, making it difficult to model without making numerous assumptions and simplifications (Klute et al., 2007; Peery et al., 2006). Nevertheless, studies have been conducted to model residual limb temperature under various conditions. Some researchers have assumed heat generation by the residual limb to be uniform across the surface, however, this does not represent typical in vivo conditions (Klute et al., 2007). Furthermore, it is difficult to quantify what "cool" means to individual amputee patients. Regardless, by making efforts to understand how various sockets affect the thermal performance of the prosthetic

* Correspondence to: Department of Biomedical Engineering, Auburn Science and Engineering Center, West Tower, Room 275B, The University of Akron, Akron, OH 44325-0302, USA. Tel.: +1 330 972 6977; fax: +1 330 972 3939.
E-mail address: bdavis3@uakron.edu (B.L. Davis).

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system, future studies can then be directed toward developing new iterations of commercially available prosthetic components that do not significantly insulate the residual limb.

Klute et al. used a multilayered approach when analyzing the prosthetic assembly, taking into account the thermal conductivity and thickness of each component (2007). They examined the effect of different prosthetic components on the temperature difference between the limb and environment. This model assumed a uniform heat flux across the entire limb.

To account for the reality of non-uniform heat generation across the residual limb, Peery et al. constructed a 3-D finite element model of the limb and prosthetic socket to predict skin temperatures (2006). In this model, elevated skin temperatures were observed over areas where muscles were present, even though muscles were not modeled individually (Peery et al., 2006). Decreased skin temperatures were found over bones and towards the distal end of the residual limb. These results corroborated with previous clinical testing Peery et al. conducted, and are subsequently described (2004).

Peery et al. monitored the temperature of five patients' residual limbs before, during, and after exercise (2004). The temperature differences between the testing phases were approximately 1.5 °C. Although this temperature difference seems minimal, patients reported that their residual limb felt significantly warmer after the activity, suggesting that only a small increase in temperature may be responsible for the discomfort reported by amputee patients (Peery et al., 2004).

In this study, it was proposed that improving the design of the prosthetic socket could help reestablish a normal thermal environment around the residual limb. A prosthetic socket was modified by adding a helical cooling channel into its wall – a design that is now possible to manufacture due to advances in 3D printing. To evaluate the effect a cooling channel has on the temperature difference across the socket wall, computer simulations were conducted using two sets of residual limb temperature data: steady residual limb temperature and clinical temperature data from the Peery et al. (2004) study. Two variants on a proof-of-concept prosthetic socket were studied: a control socket and a modified socket. The designs were then manufactured using 3D printing and bench-top testing was conducted to assess the effect of a cooling channel on the temperature difference across the socket wall.

2. Methods

It was proposed that modifications to a prosthetic socket could provide a cooling benefit to the residual limb by establishing a greater temperature drop across the socket wall. To assess this, the temperature difference across the socket wall was observed in both computer simulations and bench-top testing for two proof-of-concept sockets. The first set of computer simulations were conducted using a steady temperature input on the inner socket wall to represent the residual limb. Residual limb temperature data from Peery et al. (2004) was used in the second set of computer simulations to represent a more clinically relevant scenario. The socket designs were then manufactured using 3D printing, and tested using a bench-top testing protocol. Detailed procedures for each of the above assessments of the socket design follow.

2.1. Modeling: steady temperature input

To determine if a cooling channel affects the temperature difference across the socket thickness, sockets were modeled using SolidWorks (Dassault Systemes, Waltham, MA). Both proof-of-concept sockets were modeled with the following scaled dimensions: 12.7 cm height, 1.0 cm wall thickness, and 7.6 cm outer wall diameter. Each socket model contained a cooling channel inlet port (Fig. 1a) and an outlet port (Fig. 1b). The final design for clinical use may have ports in different locations compared with the prototype. In preparation for bench-top testing, the sockets were designed with an outer flange (Fig. 1c), allowing for the socket to be constructed as two interlocking halves. Flange holes (Fig. 1d) were included on the flange for the tightening of the socket halves together around a gasket. In a prosthetic system for clinical use, it is unlikely that the socket would be made of

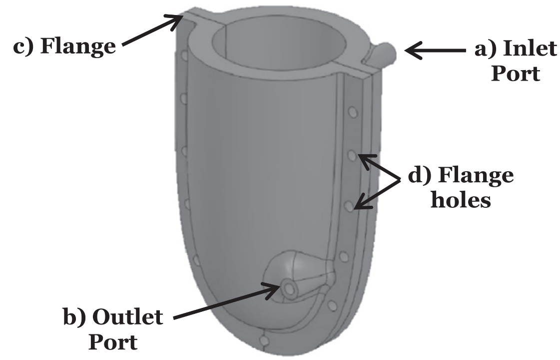

Fig. 1. Details of proof-of-concept sockets including: (a) inlet port, (b) outlet port, (c) flange and (d) flange holes. In an actual prosthetic socket, there would be no need for the flange.

two separate halves. However, this approach allowed for easy cleaning of the cooling channel and straightforward assembly of the proof-of-concept socket.

The modified socket contained a helical cooling channel 0.48 cm in diameter with eight revolutions (pitch = 1.1 cm, 2.6° inward taper) (Fig. 2). This was the maximum number of revolutions that could be included in the socket wall given the chosen dimensions. The control socket did not contain a helical cooling channel. Steady-state thermal analyses were performed using ANSYS Workbench 14.5 (ANSYS, Cannonsburg, PA) to determine if a cooling channel affected the temperature difference between the inner and outer socket wall.

The socket material was assigned a thermal conductivity of 0.16 W/m K based on average literature values for plastics typically used when making sockets (Bertels and Kettwig, 2011; Klittich et al., 2013; Klute et al., 2007). A prosthetic liner was not included in the model for this study. As such, it was assumed that the residual limb was in direct contact with the socket, so the inner wall of the socket was modeled as the same temperature of the residual limb skin. Based on the average of literature values (Peery et al., 2004), the limb was modeled as a steady 32.2 °C over a period of 28 min. Convection acted on the outer surface of the socket with an ambient room temperature of 21.9 °C. For the modified prosthetic socket, the inner channel temperature was fixed at 21.9 °C to represent room temperature air flowing through the channel, corresponding to the conditions to be used in the bench-top testing.

The default mesh generator in ANSYS Workbench was used to mesh each socket using the medium smoothing feature, which was determined to be appropriate for use in the current study after conducting a convergence study. There was less than a 2% difference in the temperature differentials of the coarse, medium, and fine meshes tested in the convergence study. The mesh of the control socket contained 36,786 elements and 60,302 nodes. The modified socket's mesh had 54,948 elements and 90,628 nodes. The simulation duration was 28 min, corresponding with the Peery et al. (2004) study. Time stepping was controlled using the automatic time stepping function in ANSYS.

Temperature profiles for each socket were generated. Inner and outer socket wall temperatures were recorded for proximal and distal locations on both sockets. The proximal temperatures were measured 4.1 cm from the top rim of the model sockets. This was the optimal location that was directly over a cooling channel. Furthermore, this location was 1 cm above the heating element that was to be used in the bench-top testing. The distal temperatures were measured 1 cm above the distal flange to avoid any influence of the flange on the temperature of the socket.

2.2. Modeling: clinical temperature input

The modeling procedure described above was repeated for both sockets using a dynamic and more physiologically relevant temperature input from Peery et al. (2004). For each socket, the simulation was run five times, corresponding to the temperature data from five patients collected by Peery et al. (2004). The residual limb temperature varied with time. All other aspects of the simulation remained the same as in the steady temperature input simulation described previously, including assuming that the residual limb temperature was uniform across the entire surface of the limb. The temperature differentials for each patient (1–5), socket type, and location (proximal or distal) were analyzed for statistical significance ($\alpha = 0.05$) using Minitab 16 (Minitab, State College, PA) to perform an analysis of variance.

2.3. Bench-top testing

Prototype sockets were constructed from the SolidWorks™ models using an Eden 360 3D printer with VeroWhitePlus rigid opaque printing material (Stratasys, Eden Prairie, MN). This material was impermeable to water and mechanically suitable for the testing of prototype sockets as described in this manuscript.