Management of Skin Temperature and Perspiration Using a Prosthetic Liner Incorporating Phase Change Material

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Abstract

Elevated skin temperatures and increased perspiration are common complaints by amputees wearing prosthetic limbs and create a harsh environment for the residual limb. Typical prosthetic socket and liner materials insulate the limb and do not allow heat to escape. A liner incorporating phase change material (PCM) was developed to regulate skin temperature and perspiration. The purpose of this study was to evaluate the effectiveness of a PCM liner to control these two outcomes compared to a non-PCM liner. The results found the PCM liner exhibited lower temperatures and reduced perspiration. Improvements to the testing apparatuses are also presented.

Introduction

Heat and perspiration are common problems in the prosthetic socket environment. Common liner and socket materials have low thermal conductivity [1] and therefore insulate the residual limb. Qualitative reports presented by Hagberg [2] found that heat/sweating in the prosthetic socket was the most frequently reported problem leading to reduced quality of life. It is also cited that excessive perspiration can negatively affect suspension of the prosthesis [3]. The increased temperature and moisture environments the residual limb is subjected to within the prosthetic socket may be responsible for infections [4] and formation of blisters [5-7]. Improving the thermal properties of socket and liner materials can increase comfort and promote a healthier limb environment for the amputee.

One approach to changing the thermal properties of the liner is to increase the heat capacity. Recent advancements in material science have produced PCMs, which have the ability to store and release thermal energy as it transforms from a solid to liquid and back to a solid material. In an effort to better manage the thermal environment of the prosthetic socket, prosthetic liner materials were modified with PCMs to increase heat capacity.

Qualitative claims of patients wearing a PCM liner reported a more comfortable temperature environment and less moisture buildup. The purpose of this study was to quantitatively evaluate the effectiveness of a silicon liner incorporating PCMs (PCM liner) to regulate skin temperature and moisture buildup on the residual limb compared to standard liner (non-PCM liner).

Methods

Design: A randomized crossover design was used to compare a PCM liner to a non-PCM liner. Six unilateral transtibial amputees participated in the testing protocol. Participants were divided into two groups to determine which liner they wore first during the testing procedures.

Apparatus: Skin temperature was measured using an Omega k-type thermocouple probe plugged into a signal amplifier and a hand-held digital multimeter. The particular temperature apparatus used in the study only allowed for discrete sampling of temperature data. Skin surface moisture was measured using skin surface electrical capacitance (SEC). In this technique, an array of electrically conductive probes is placed on the skin with one probe in the array excited by a small electrical current (Figure 1). The induced current is measured in the other probes in the array to quantify the conductivity of the surface of the skin. The conductivity increases as moisture on the skin surface increases. Skin moisture measurements were collected at the distal end, posterior calf, back of the knee, medial, and lateral.

Figure 1: SEC probe used to collect skin moisture data at 5 sites of the residual limb.

Procedures: Temperature measurements were taken pre-activity, during activity, and post-activity where the activity was defined as walking on a treadmill at two self-selected paces. SEC measurements were also taken pre-activity prior to donning the liner and post-activity after doffing the liner. Several pre-activity skin temperatures were taken under the following conditions: 1) Atmospheric with no prosthetic liner or socket donned; 2) Immediately after donning the liner; 3) Steady-state with the liner donned; and 4) Steady-state with the liner and socket donned.

Only temperature measurements were taken during the activity period under the following conditions: 1) Standing; 2) After 5 minutes walking at a slow pace; 3) After 5 minutes walking at a fast pace; 4) After 5 additional minutes (total 10 minutes) walking at a fast pace; and 5) After 5 minutes walking at a slow pace.

Post-activity temperature measurements were taken 1) Sitting down immediately after finishing the treadmill walk; and 2) After 15 minutes at rest in a seated position. Skin moisture measurements were then taken immediately after doffing the socket and liner. There was a 30-minute rest period between testing the two liners to allow for the residual limb to re-acclimate with atmospheric air.

Data Analysis: A one way paired t-test was performed on the data to determine if there was a statistically significant difference between the two groups. It should be noted that with a sample size of six, the study is underpowered and the data may not have a normal distribution.

Results

Evaluating the complete temperature data for all six patients indicated the following general trends (Figure 2A): 1) Donning either liner initially reduced the skin temperature. 2) Activity increased the skin temperature. 3) Both types of liners exhibited similar temperature curves; however, the PCM liners demonstrated lower skin temperatures especially during activity. The rate of temperature increase associated with the PCM liner was reduced 30% compared to the non-PCM liner. At the end of the activity period, there was an average 1.34°C difference in temperature. This difference is believed to be clinically significant. Peery [8] deduced a temperature increase of 1° or 2° is responsible for reports of thermal discomfort. 4) Temperature associated with the PCM liner was relatively stable post activity.

For 5 of the 6 patients, use of a standard liner correlated to a larger increase in skin temperature for each activity condition. Data for one of these five patients exhibited a considerable decrease in temperature associated with the PCM liner, indicating that the PCM liner was assisting in buffering the increase in temperature. The data for the 15-minute rest period post-activity displays minimum change for the PCM liner, signifying the PCM's material's ability to maintain a steady temperature environment. Several of the standard

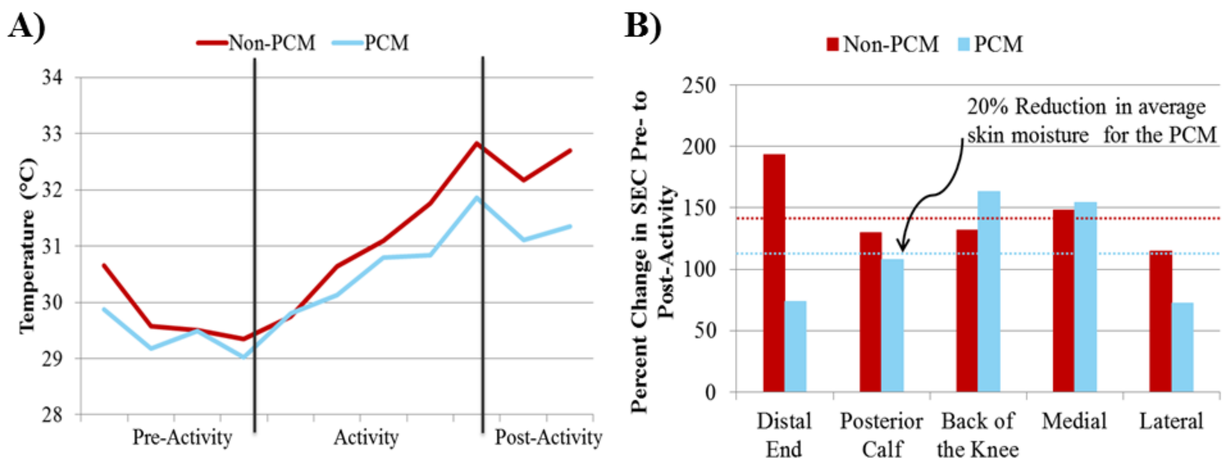

Figure 2: A) Average temperature results for the PCM and non-PCM liner; B) Average skin moisture (SEC) results at each of the residual limb sites tested.

liners exhibited an increase in temperature during this rest period. The results from the paired t-test indicated that the change in temperature during activity and post-activity periods were not statistically significant ($p=0.105$ and $p=0.153$ respectively). However, a statistically significant difference in temperature change was found from the beginning of the activity to the end of post-activity ($p=0.0015$). Comparison of the SEC data found that only 7 out of 30 comparisons resulted in a greater buildup of moisture on the skin after testing the PCM liner. A binomial expansion indicated that there is less than a 1% probability of such an occurrence without the PCM liner having caused reduced levels of perspiration. On average, the change in skin moisture was reduced by 20% while using the PCM liner (Figure 2B). However, the t-test results did not find a significant difference between the two liners ($p=0.161$).

Discussion

Overall, the results from the testing indicated that: 1) The PCM liner buffered the temperature increase during activity, exhibiting a lower temperature increase during activity compared to the non-PCM liner. 2) The PCM liner stabilized the temperature post activity. 3) There was less moisture buildup for the PCM liner compared to the non-PCM liner. One influencing factor may be the lower skin temperatures experienced while testing the PCM liner.

While the statistical analysis found one result to be significant, a larger sample size is needed to increase the power of the study. This is particularly true for the skin moisture data collected by SEC. There is a wide variance in this measurement between individuals.

Apart from the results of the study, improvements to the testing apparatuses were discovered. First, the temperature probe configuration used only allowed for discrete sampling of temperature data. There may be differences in the temperature curve between the PCM and non-PCM liners (i.e. non-linear increases or decreases) that exist. Employing a temperature probe configuration allowing continuous sampling will improve the results. Second, the thermocouple probe used had a very rigid wire, and care had to be taken to route the wire around the knee to avoid snapping the wire during knee flexion. A more flexible probe will increase patient comfort. Third, the temperature probe was sensitive to motion requiring the participant to step onto the side boards of the treadmill and remain still while the measurements were taken. This was intrusive to the activity. Finally, the SEC probe used was very contact sensitive and took upwards of 60 seconds to stabilize. This frequently required researchers to recollect data at a test site due to unintentional movement of the patient or probe resulting in lost contact between the skin and probe. Identifying a new thermocouple configuration and SEC probe to overcome these shortcomings will improve the testing procedures.

Conclusion

The results support continuing the evaluation of a PCM liner as a potential means of regulating prosthetic socket temperature. Regulating the temperature in the socket and reducing the amount of perspiration can lead to improved comfort, health and quality of life for amputees.

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References

1. Klute GK, Rowe GI, Mamishev AV, Ledoux WR. The thermal conductivity of prosthetic sockets and liners. Prosthet Orthot Int. 2007;31(3):292-99.
2. Hagberg K, Branemark R. 2001. Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. Prosthet Orthot Int 25:186–194.
3. Legro MW, Reiber G, Del Aguila M, Ajax MJ, Boone DA, Larsen JA, Smith DG, Sangeorzan B. 1999. Issues of importance reported by persons with lower limb amputations and prostheses. J Rehabil Res Dev 36:155 – 163.
4. Kohler P, Lindh L, Bjorklind A. 1989. Bacteria on stumps of amputees and the effect of antiseptics. Prosthet Orthot Int 13:149 – 151.
5. Naylor PFD. 1955a. Experimental friction blisters. British J Dermatol 67:327 – 342.
6. Naylor PFD. 1955b. The skin surface and friction. British J Dermatol 67:241 – 248.
7. Akers WA, Sulzberger MB. 1972. The friction blister. Milit Med 137:1 – 7.
8. Peery, J, Ledoux, W, Klute, G. Residual Limb Skin Temperature in Transtibial Sockets, Journal Rehabilitation Research and Development, 2005, 42 (2), 147-154