SmartTemp Prosthetic Liner Significantly Reduces Residual Limb Temperature and Perspiration

Matthew M. Wernke, PhD, Ryan M. Schroeder, BS, Christopher T. Kelley, MS, Jeffrey A. Denune, CP, James M. Colvin, MS

ABSTRACT

Introduction: Common materials used for prosthetic liners and sockets have poor thermal properties, thus insulating the residual limb resulting in thermal discomfort and increased perspiration. The purpose of this work is to compare the temperature increase and amount of perspiration between traditional silicone liners and the SmartTemp liner, which incorporates phase change material to improve the thermal properties and mitigate perspiration.

Materials and Methods: Sixteen individuals with transtibial amputations participated in a double-blind, randomized clinical trial. Participants were asked to cycle on a stationary bike for 25 minutes followed by a 10-minute rest period. This activity was completed once for each treatment with a 1-hour rest period between treatments. Temperature and perspiration data were collected as outcomes, and a paired 1-way Student *t*-test was used to compare the data.

Results: The SmartTemp liner resulted in significantly reduced mean skin temperature and perspiration during the activity and postactivity periods when compared with the placebo liner.

Conclusions: Use of the SmartTemp liner can positively impact the internal socket conditions. Reducing temperature and moisture within the socket can improve comfort and suspension, and reduce the risk of skin injury for persons with amputation who use a prosthesis. (*J Prosthet Orthot*. 2015;27:134–139.)

KEY INDEXING TERMS: phase change material, prosthesis, socket, interface, heat, amputation, lower limb

Elevated skin temperature and perspiration are commonly associated with wearing and using prosthetic limbs. Results from questionnaire responses[1] from prosthesis users have documented heat and perspiration as the leading complaint resulting in a reduced quality of life. These conditions may also negatively impact the health of the person with amputation's residual limb.

Confining the residual limb in a warm and moist environment may be responsible for infections[2] and the formation of blisters.[3–5] Furthermore, Legro et al.[6] noted that excessive perspiration can negatively affect suspension of the prosthesis.

The poor thermal environment is a result of the poor thermal properties of common prosthetic socket and interface materials. Klute et al.[7] quantified the thermal conductivity (a measure of how freely heat passes through a material) of various prosthetic materials. The results of this work found that both liner and socket materials have poor thermal conductivity. A recent work reported by Webber et al.[8] supports these earlier results. Both authors suggest that improvements to the thermal properties of prosthetic socket and interface materials can improve the comfort and quality of life and promote a healthier limb environment for individuals with amputation.

To improve the thermal properties of the prosthetic liner, the SmartTemp liner (The Ohio Willow Wood Company, Mount Sterling, OH, USA) incorporates phase change material (PCM) into a traditional silicone liner. Phase change material has the ability to store and release thermal energy as it changes physical state from a solid to a liquid (latent heat of fusion) and back to a solid, maintaining the conditions of the surrounding environment for longer periods. The purpose of this work is to compare the residual limb skin temperature inside the liner and amount of perspiration produced by individuals with amputation wearing the SmartTemp liner and a placebo liner. The hypotheses state that the SmartTemp liner will reduce the internal liner temperature as well as the amount of perspiration during activity and during postactivity rest periods.

MATTHEW M. WERNKE, PhD; RYAN M. SCHROEDER, BS; CHRISTOPHER T. KELLEY, MS; JEFFREY A. DENUNE, CP; and JAMES M. COLVIN, MS, are affiliated with the Ohio Willow Wood Company, Mount Sterling, Ohio.

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Correspondence to: Matthew M. Wernke, PhD, 15441 Scioto Darby Rd, PO Box 130, Mount Sterling, OH 43143; email: mattw@owwco.com

METHODS

DESIGN

A double-blind, randomized, crossover design was used to compare outcomes between the SmartTemp liner and placebo SmartTemp liner (Figure 1). Sixteen individuals with transtibial amputation (Table 1), all with signed test-subject agreements, were recruited to participate in the study procedures. Eligibility criteria stated that subjects had to be 6 months after amputation or after revision surgery, must be able to ride a stationary bike continuously for 30 minutes, must be older than 18 years, and able to consent without assistance. Upon agreeing to participate, subjects were randomly allocated to determine the treatment order, such that subjects in group A began testing with the placebo SmartTemp liner and group B with the SmartTemp liner before crossing over to the other treatment (Table 1). The allocation schedule was managed by an individual independent from subject recruitment, data collection, and data analysis. During the testing visit, this individual would deliver two visually identical liners in visually identical boxes, one labeled "treatment 1" and the other labeled "treatment 2" on the box. The subjects and

Figure 1. A SmartTemp liner and a placebo liner worn by one of the subjects with a transtibial amputation.

the research team remained blind to the treatments until the data were processed. Note, one of the subjects was an individual with a bilateral transtibial amputation and thus participated as two subjects, where the placebo and real SmartTemp liner were tested at the same time. The liners were worn on the opposite limb for the second data collection period.

PROCEDURES

Data were collected during one testing day for each subject. The data collection room was maintained at 26.7°C using a space heater. The room temperature was monitored by a T-type thermocouple (GE Sensing; Billerica, MA, USA), and the space heater was adjusted to maintain a consistent temperature. Four additional thermocouples were placed at the following measurement sites directly on the residual limb: medial-anterior, medial-posterior, lateral-posterior, and lateral-anterior. Thermocouple placement was approximately 1.5 inches proximal to the distal end of the residual limb at each location. Once the thermocouples were in place, there was a 15-minute rest period to allow the residual limb to equilibrate with the environment. The equilibrium temperature was recorded ("end of equilibrium" temperature).

After 15 minutes, the subject donned the treatment 1 liner and the prosthesis. Once the subject was on the stationary bicycle and ready, the subject was instructed to begin pedaling at a self-selected pace, and the temperature recording (frequency, 0.5 Hz) began. The researcher matched a metronome beat to the pedaling cadence of the subject. The metronome beat was recorded and used to maintain consistent pedaling effort during the remainder of the first treatment and the second treatment. After 25 minutes, the subject transferred to a chair and doffed the prosthesis and liner. The amount of perspiration was measured and recorded by wiping the residual limb and internal liner surface with a laboratory towel and placing the laboratory towel in a sealed plastic bag and weighing on a digital scale. The weight was compared with the weight of the laboratory towel and sealed plastic bag before wiping the limb, and the difference in weight was recorded as the amount of perspiration.

Immediately after the residual limb and liner were wiped, the subject redonned the liner and was instructed to rest seated in a chair. Temperature data were collected for 10 minutes while the subject rested. After the 10-minute postactivity rest, the subject doffed the liner and the amount of perspiration was collected and recorded.

Table 1. Subject demographics

ID	Group	Age	Sex	Amputated Limb	Suspension	Etiology	Years with Amputation
1	A	63	Male	Right	Pin-locking	Trauma	11
2	A	47	Male	Left	Pin-locking	Trauma	4
3	B	63	Male	Right	Vacuum	Infection	10
4	B	69	Male	Right	Suction	Trauma	16
5	A	57	Male	Left	Suction	Trauma	10
6	B	66	Male	Left	Vacuum	Congenital	66
7	B	53	Male	Right	Vacuum	Trauma	10
8	A	42	Male	Right	Pin-locking	Trauma	16
9	A	78	Male	Right	Pin-locking	Trauma	17
10	A	53	Male	Right	Pin-locking	Congenital	39
11	B	48	Female	Bilateral	Vacuum	Vascular	2
12	B	49	Male	Right	Suction	Trauma	13
13	B	58	Male	Right	Suction	Vascular	5
14	A	48	Female	Bilateral	Vacuum	Vascular	2
15	B	42	Male	Left	Pin-Locking	Diabetes	6
16	A	32	Male	Left	Vacuum	Trauma	9
Mean		54.3					14.8
σ		11.7					16.2

Table 2. Mean (SD) temperature across all subjects and all measurement sites

	End of Equilibrium	Start Activity	End Activity	Start Rest	End Rest
Placebo	29.4°C (1.4°C)	30.0°C (1.8°C)	31.2°C (2.0°C)	30.8°C (1.8°C)	31.2°C (2.0°C)
SmartTemp	29.2°C (1.6°C)	29.4°C (1.6°C)	30.4°C (2.3°C)	30.4°C (1.8°C)	30.7°C (1.9°C)
P value	0.57	<0.001	0.001	0.048	0.005

The subjects were instructed to drink an entire 0.5-L bottle of water during an hour intermission before returning to repeat the procedures with the treatment 2 liner. The intermission occurred out of the testing room, and subjects were given a similar 15-minute acclimation period in the testing room after the intermission before starting the second part of the data collection.

DATA ANALYSIS

The end of equilibrium skin temperature (end of equilibrium) before donning the liner and socket was calculated as the average temperature across all measurement sites for the final 20 seconds of the equilibrium period. Similarly, the starting ("start activity" and "start rest") and ending ("end activity" and "end rest") temperatures for the activity and postactivity rest periods were calculated as the average temperature during the initial and final 20 seconds (10 data points) of each period, respectively, across all four measurement sites. The temperature increase during the activity and the postactivity rest were calculated as the difference between the start and end temperatures. A 1-way paired Student *t*-test was performed on the average data as well as the individual measurement sites to determine if there was a statistically significant difference between the two groups. *P* values less than 0.05 were considered statistically significant.

RESULTS

Wearing the SmartTemp liner reduced internal liner temperatures and the amount of perspiration when compared with wearing the placebo liner. The mean residual limb skin temperature after the 15-minute equilibrium period and before donning a liner was not statistically different ($P = 0.57$) between the two treatments (Table 2). The mean residual limb skin temperature across all sites increased by 0.6°C between the mean pretest and the start of activity temperatures when subjects donned the placebo liner and their prosthesis (Table 2). When subjects donned the SmartTemp liner, the mean temperature increase during the same period was reduced to 0.2°C. Therefore, the mean skin temperature across all measurement sites at the start of activity was significantly reduced ($P < 0.001$) when wearing the SmartTemp liner (Table 2). The mean residual limb skin temperature across all measurement sites increased from the start to end of activity for both liner treatments (Table 2), but the mean increase associated with wearing the SmartTemp liner was 0.2°C lower relative to the increase while wearing the placebo liner (Table 2). This difference in temperature increase during activity was not significantly different ($P = 0.09$). However, the mean temperature at the end of activity was significantly lower by 0.8°C when wearing the SmartTemp liner (Table 2). Perspiration measured after the activity was significantly reduced ($P = 0.02$) when wearing the SmartTemp liner (Figure 2). For 12 of the 16 subjects, wearing the SmartTemp liner resulted in less perspiration. The remaining four subjects did not sweat in either liner.

Postactivity temperature and perspiration results were also found to improve with the SmartTemp liner. The beginning postactivity rest skin temperature was significantly lower ($P = 0.048$) when wearing the SmartTemp liner compared with the placebo liner. During the rest period, the mean skin temperature increased 0.4°C and 0.3°C when wearing the placebo and SmartTemp liner, respectively. The mean skin temperature at the end of the 10-minute rest period was significantly lower ($P = 0.005$) when wearing the SmartTemp liner compared with the placebo liner. Perspiration, while small in quantity, was also significantly (statistically) reduced with the SmartTemp liner during the postactivity rest (Figure 3). Many of the subjects (n = 9) did not sweat with either liner during this period; however, of the seven subjects that did have sweat during this period, only one of these subjects had sweat while wearing the SmartTemp liner (subject 4). The amount of sweat while wearing the SmartTemp liner was less than the amount of sweat this subject produced while wearing the placebo liner.

Inclusion of one subject with bilateral transtibial amputation enabled a unique case study within the larger study, where both treatments could be tested within the same activity period and then tested on the opposite limb during the second activity period. Regardless of the limb the SmartTemp liner was worn on, the temperature increases for both activity periods

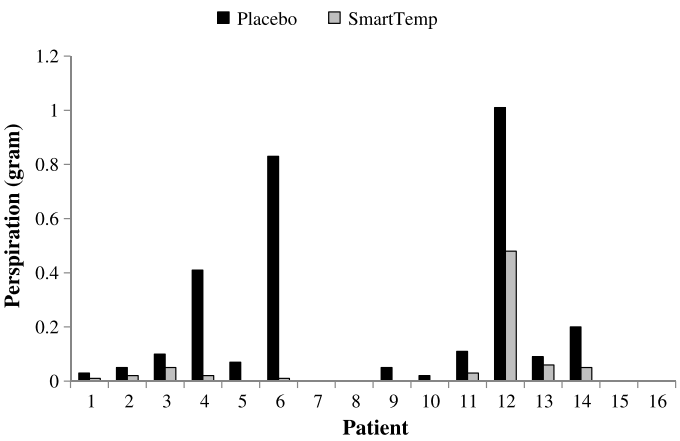

Figure 2. Amount of perspiration on the residual limb and liner for each subject and treatment after activity.

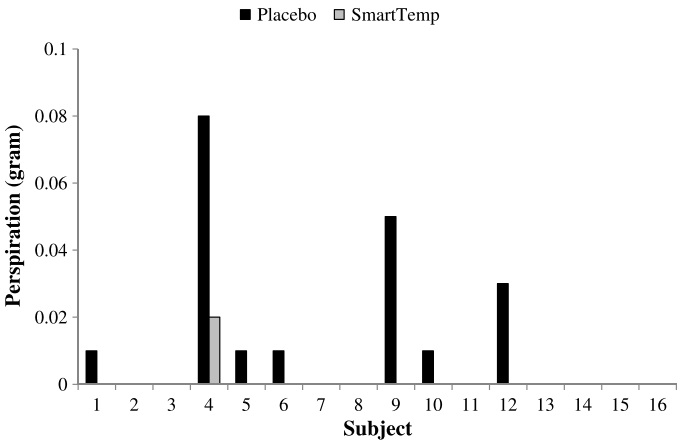

Figure 3. Amount of perspiration on the residual limb and liner for each subject and treatment after postactivity rest.

associated with that limb were lower when wearing the SmartTemp liner compared with the placebo liner. Figure 4A shows the mean start and end temperature for each liner during both activity periods. A reduction in perspiration for the limb wearing the SmartTemp liner was also found during both activity periods compared with the placebo liner (Figure 4B).

DISCUSSION

In 2005, there were 1.6 million persons living with limb loss in the United States.[9] While the anticipated projections for an increasing population of persons with amputations are lower than anticipated,[9] the number of amputation cases continues to grow. A major contributing factor to this increase includes the growing health impact of diabetic complications.[10] For instance, from 1990 to 2010, the yearly number of amputation cases increased by 22,703 due to diabetic complications alone.[11] However, the prevalence of diabetic-related complications resulting in amputation in adults younger than 45 years of age does not surpass amputations due to traumatic injury.[12] Recent military conflicts have shed light on a unique subset of the community of persons with amputation in that these individuals are younger and lead highly active lifestyles, which place increased demands on the prosthetic components. Regardless of amputation cause and functional needs, the prosthetic interface is a critical factor to overall success of a prosthetic device.

Heat and perspiration are common complaints among individuals with amputation when using a prosthesis[1,13] due to the poor thermal properties of common prosthetic interface materials.[7,8] Apart from being uncomfortable for a person with amputation, evidence suggests that warm and moist socket conditions expedite the formation of blisters.[3–5] Moist skin may also reduce the adherence between the skin and limb and negatively impact suspension and result in injury of the soft tissues. The most common skin problem clinically presented by individuals with lower-limb amputations is ulcers.[14] For individuals with traumatic lower-limb amputations, the incidence of chronic or chronic recurrent ulcers can reach 50%.[15] Furthermore, persons with diabetic and dysvascular conditions who have undergone limb amputations are at an increased risk for ulceration. The standard of care for ulcers typically requires disuse of the prosthesis, which negatively impacts rehabilitation efforts and quality of life for the individual. In extreme cases, chronic ulcers necessitate surgical revision of the residual limb. In that light, there is a clear need to improve upon the interface materials traditionally used for prosthetic applications to reduce risk and best protect the comfort and health of individuals with amputation.

The results of the double-blind clinical trial support the use of the SmartTemp liner to reduce skin surface temperature and perspiration within the prosthetic liner. The authors attribute this result to the increased latent heat of the SmartTemp material, which provides a pathway to remove heat away from the residual limb, thereby reducing perspiration. Indeed, the SmartTemp liner resulted in a consistently lower residual limb skin temperature compared with the placebo liner and was particularly effective at reducing or even eliminating perspiration within the liner. Localized cooling of the skin surface has shown to impact sweat rate through the delay of cutaneous vasodilation.[16,17] In addition, it has been suggested that local cooling may mitigate neurotransmitter release associated with perspiration.[17] Peery et al.[18] suggests that a change in temperature of 1°C or 2°C is clinically significant. The results in this

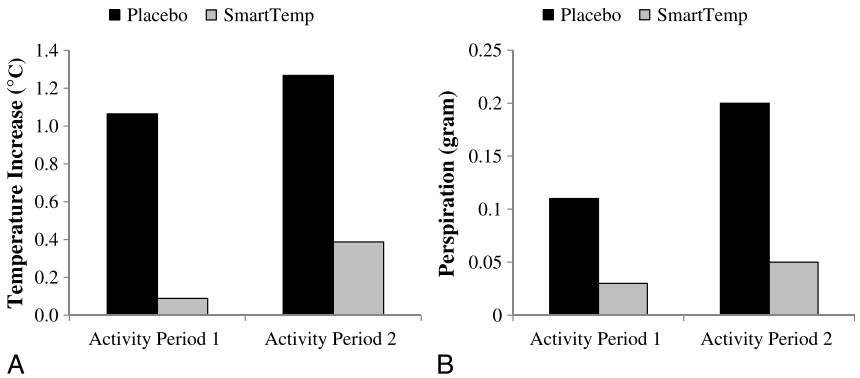

Figure 4. Temperature and perspiration results for the bilateral subject. SmartTemp liner reduced temperature (A) and perspiration (B) during both activity periods compared with the placebo liner regardless of the limb wearing the SmartTemp liner. Note, the opposite liner treatment configuration was implemented between activity periods.

study support the hypothesis of Peery et al.[18] The average temperature change for the placebo treatment of 1.2°C (31.2°C–30.0°C) is within the range specified by Peery et al.[18] and resulted in higher average perspiration compared with results for the SmartTemp treatment. The average temperature increase for the SmartTemp treatment of 1°C (30.4°C–29.4°C) is near the lower boundary of the range suggested by Peery et al.[18] Qualitative reports from persons with amputation wearing the SmartTemp system in the field over longer periods report a perceived reduction in residual limb perspiration during activities of daily living even though the PCM may become saturated (i.e., has reached the limit of heat capacity where all PCM has undergone a change in physical state) during the course of wearing the liner. These qualitative reports suggest that establishing a pathway for heat to move out of the socket may result in reduced perspiration beyond local cooling. Further research is warranted in this regard.

Previous work[19] found temperature increased on average 3.1°C during a 30-minute continuous walk and an average maximum of 34°C. Another study found an average temperature increase of 1.7°C during a 10-minute walking activity.[16] While individual patients from this the current study had temperature increases similar to these studies, the average temperature increases in the current study for both the placebo and SmartTemp liners are lower than that in the previous studies. The authors believe the difference in activities had the biggest impact on this outcome. The activity of walking may be more vigorous than riding a stationary bike as in this protocol. The stationary bike ride was chosen for this study over a walking task as an additional safety measure to reduce the risk of thermocouple wire failure and to limit subject withdrawal due to difficulty completing the task. Other factors that may have had an impact are the subject population and the season during data collection. The study by Klute et al.[19] also found that skin surface temperatures varied depending on the location measured, suggesting that the development of location-specific technology would be advantageous to regulate subject-specific areas that could benefit from additional heat removal. The results of this work also found that skin surfaces temperatures for each of the sites varied among individual subjects with no clear trends presented. This suggests that any attempts to optimize interface design would need to be done on an individual basis. Further research is needed to better understand these differences.

The testing protocol sought to determine the amount of sweat produced during activity and postactivity periods separately. This required the socket system to be doffed immediately after activity and redonned before collecting postactivity temperatures. Interestingly, the temperatures associated with wearing the placebo liner reduced during this period (31.2°C at the end of activity and 30.8°C at the start of postactivity) while the temperatures associated with wearing the SmartTemp remained the same. This may be an indication of the SmartTemp liner not only storing but also releasing thermal energy and protecting against thermal fluctuations.

The design of clinical research trials that includes blinding of subjects and researchers is not a trivial endeavor when investigating prosthetic devices. Often, it is very difficult to camouflage the appearance or function of a prosthetic component to the individual with amputation, researcher, or both parties. In this study, a placebo liner was successfully made that replicated the appearance and feel of a real SmartTemp liner. Qualitative feedback was collected from the subjects by asking which of the two liners they believed to be the real SmartTemp liner. Surprisingly, 65% of persons with unilateral transtibial amputations correctly chose the real SmartTemp liner. However, the bilateral subject correctly chose the real SmartTemp liner for both activities when asked the same question. This result for unilateral subjects may be influenced by the long break between activity periods, the mind-set of performing the activity for the first or second time, and the ability to perceive changes in temperature. The latter point could be particularly relevant for four subjects that did not perspire with either liner as well as the four to five additional subjects who had very little perspiration (approximately <0.01 g). However, analyzing the responses of the unilateral subjects did not reveal any trend related to treatment order and correct/incorrect responses.

CONCLUSIONS

The SmartTemp liner is the first commercially available liner to address the prominent problem of excessive heat and perspiration for persons with amputation using a prosthesis. The results presented demonstrate the ability of the liner to reduce temperature and perspiration before and after a 25-minute exercise period and 10-minute postactivity rest period, and corroborate clinical feedback from individuals with amputations and prosthetists. Further work is needed to fully understand the impact this liner will have on the health of the residual limb by reducing factors that accelerate injuries to the soft tissues.

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