Effectiveness of the SmartTemp Prosthetic Liner to Reduce Residual Limb Temperature and Perspiration

Matthew Wernke, PhD, Ryan Schroeder, BS, Christopher Kelley, MS, Alexander Albury, CPO, James Colvin, MS WillowWood Global I.I.C. Mt. Sterling, OH



Background

Results from questionnaire responses¹ 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 infections² and the formation of blisters³⁻⁵. 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 and Weber et al⁸ quantified how freely heat passes through various prosthetic materials. The results of these works found that both liner and socket materials very good insulators.

Methods

A double-blind, randomized, crossover design was used to compare outcomes between the Alpha SmartTemp® Liner and placebo SmartTemp Liner (Figure 1). Sixteen individuals with transtibial amputation participated in the study procedures. One subject was a bilateral transtibial amputee, and therefore tested both liners simultaneously.

Subjects entered a room heated to 80°F and temperature sensors were placed on their skin. The liner and socket were then donned over the temperature sensors and the subjects rested for 15 minutes to acclimate to the new room environment. After the rest period, subjects completed a 25 minute exercise bout on a stationary bicycle inside the heated room. Immediately following the exercise period, sweat measurement was completed by wiping the limb with a light towel and weighing the towel. The difference in towel weight after the wipe to before the wipe was equal to the amount of sweat collected from the limb. The subjects then redonned their liner and rested for 10 additional minutes before another sweat measurement was collected.



Figure 1: The study liners for a single subject. Neither the subject or the researcher collecting data knew which was the real SmartTemp and which was the placebo.

Results

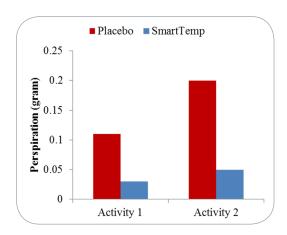
Wearing the SmartTemp Liner reduced internal liner temperatures and the amount of perspiration when compared with wearing the placebo liner. At the start of the activity, there was not a significant difference in skin temperature, suggesting an equivalent starting point between conditions. However, each timepoint thereafter showed a significant reduction in skin temperature when using the SmartTemp Liner.

Table 1: Average skin temperature over the testing period. The Alpha SmartTemp Liner significantly lowered skin temperature throughout the test period.

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

Perspiration was also reduced when using the SmartTemp Liner compared to the placebo (Figure 2).

On average, there was a 25% reduction in perspiration across the 16 subjects in the study. The one bilateral subject in the study always had less perspiration on the limb that was wearing the SmartTemp Liner compared to the placebo (Figure 3).



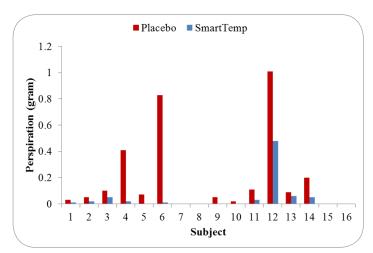


Figure 2: Perspiration results showed the Alpha SmartTemp Liner always reduced the amount of perspiration for those who had measurable sweat compared to the placebo condition.

Figure 3: The Alpha Smart-Temp Liner also results in less perspiration compared to the placebo for the bilateral subject.

Conclusion

The Alpha SmartTemp Liner has shown to be effective at reducing temperature, and more importantly perspiration within a prosthetic socket. Reducing perspiration will reduce the potential for injury to the skin tissues²⁻⁵.



References

- 1. Hagberg K, Branemark R. Consequences of non-vascular transfemoral amputation: a survey of quality of life, prosthetic use and problems. Prosthet Orthot Int 2001;25:186-194.
- 2. Kohler P, Lindh L, Bjorklind A. Bacteria on stumps of amputees and the effect of antiseptics. Prosthet Orthot Int 1989;13:149–151.
- 3. Naylor P. Experimental friction blisters. Br J Dermatol 1955;67: 327–342.
- 4. Naylor P. The skin surface and friction. Br J Dermato 1955;67:239-246.
- 5. Akers WA, Sulzberger MB. The friction blister. Mil Med 1972;137:1-7.
- 6. Legro M, Reiber G, Del Aguila M, et al. Issues of importance reported by persons with lower limb amputations and prostheses. J Rehabil Res Dev 1999;36:155–163.
- 7. Klute G, Rowe G, Mamishev A, LedouxW. The thermal conductivity of prosthetic sockets and liners. Prosthet Orthot Int 2007;31:292–299.
- 8. Webber C, Klittich M, Dhinojwala A, Davis B. Thermal conductivities of commercially available prosthetic materials. J Prosthet Orthot 2014;26:212–215.