Orthotics and Prosthetics

A Thermal Management Device for Active Heat Removal from a Prosthetic Limb Socket

Improvised explosive devices encountered in modern warfare have caused a significant rise in traumatic amputations in the military population and an increased clinical need for prosthetics (*Stansbury et al. 2008*). Commonly used prosthetic liners limit air circulation and evaporation at the prosthetic socket interface. Inadequate heat and moisture management within the prosthetic socket often result in residual limb skin irritation, bacterial growth, and patient discomfort. Sweating and skin irritation can lead to skin diseases like dermatitis, ulceration, and psoriasis, among others. Although these conditions can be successfully managed by care providers, they frequently result in reduced use of the prosthesis and a consequent reduction in patient's activity levels. Several attempts have been made to monitor and maintain lower skin temperatures within the prosthetic socket to reduce sweating. Unfortunately, most sensors and devices have proven to be excessively irritating to the skin, have limits to the amount of cooling they can provide, and/or can cause the socket/liner interface to fail to maintain a secure fit.

Researchers at Vivonics, Inc. (Bedford, Massachusetts) and Liberating Technologies, Inc. (Holliston, Massachusetts), focused on developing an active cooling system that could be incorporated into lower-limb prosthetic sockets. The developed cooling system, Intra-socket Cooling Element (ICE), was designed to contain a heat pumping mechanism for active heat removal that would fit into the prosthetic limb socket. Results from initial human use studies (Figure 1) showed that the custom-fabricated cooling sockets (Figures 2 and 3) were able to decrease the temperature of the residual limb after exercise by an average three to five degrees Celsius, a clinically significant value when compared with subjects who did not have ICE (*Peery, Ledoux, and Klute 2005*). Users noted that ICE was as comfortable as their normal prosthesis and added that they would use ICE if it were available to them.

Promising early clinical results allowed Vivonics, Inc. to file for a provisional patent in May 2016 and subsequent utility patent application in May 2017 ("Cooling System and Method for a Prosthetic Socket", Application Number 15,590,679) (*LeRoy et al. 2017*). Ongoing efforts are underway to further develop and commercialize the ICE active cooling system for lower limb prosthetic sockets. The aim is to refine and optimize the system's conceptual design, finalize the design under U.S. Food and Drug Administration Quality Systems Regulations with ISO 13485 (Quality Management Systems) compliance, perform further validation testing of ICE, and prepare for its commercialization.

In conclusion, the ICE active cooling system can reduce residual limb surface temperatures and has the potential to markedly reduce skin irritation, breakdown, sores, and infection experienced by individuals who wear prosthetic devices and thereby improve quality of life for Service members, Veterans, and Civilians.

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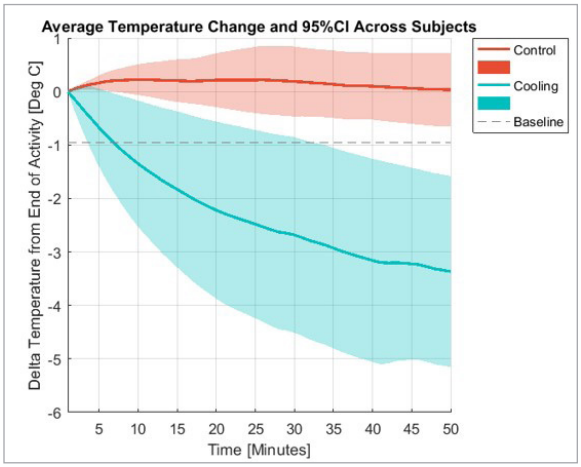

FIGURE 1: Average Temperature Change of Five Subjects with and without cooling for 50 minutes after walking (Figure used with permission from the authors)

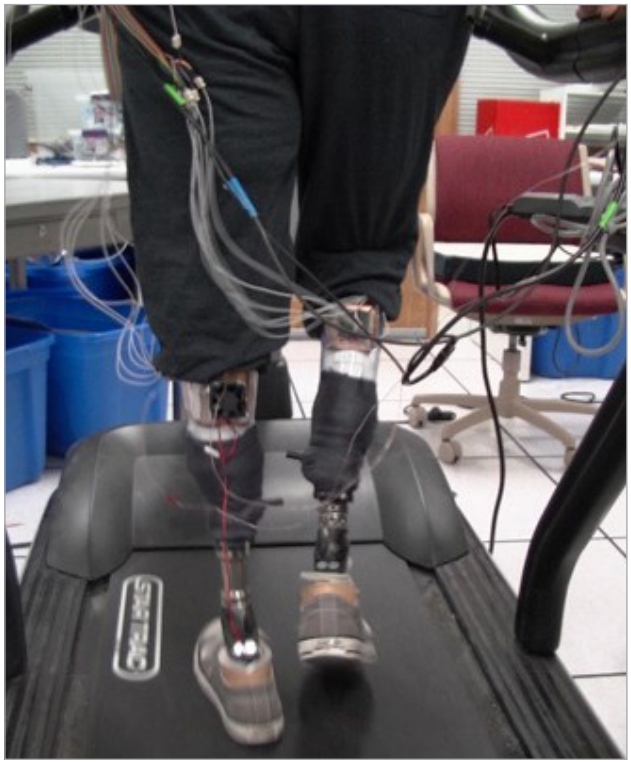

FIGURE 2: Bilateral Amputee during Walking Test (Figure used with permission from the authors)

FIGURE 3: Above Knee Amputee during Sitting Phase of Test (Figure used with permission from the authors)

REFERENCES:

LeRoy, K., Cohen, I., Hirschman, G. B., Hunt, T. R., Keough, K. E., Luna, C. M., Farrell, T. R., Johansson, J. L., and LaBrecque, B. 2017. "Cooling System and Method for a Prosthetic Socket." US Patent Application 15/590,679, filed May 9, 2017.

Peery, J. T., Ledoux, W. R., and Klute, G. K. 2005. "Residual-Limb Skin Temperature in Transtibial Sockets." J Rehabil Res Dev 42 (2):147-54.

Stansbury, L. G., Lalliss, S. J., Branstetter, J. G., Bagg, M. R., and Holcomb, J. B. 2008. "Amputations in U.S. Military Personnel in the Current Conflicts in Afghanistan and Iraq." J Orthop Trauma 22 (1):43-6. doi: 10.1097/BOT.0b013e31815b35aa.