Temperature measurement and control system for transtibial prostheses: Functional evaluation

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Abstract:

The accumulation of heat inside the prosthetic socket increases skin temperature and fosters perspiration, which consequently leads to high tissue stress, friction blister, discomfort, unpleasant odor, and decreased prosthesis suspension and use. In the present study, the prototype of a temperature measurement and control (TM&C) system was designed, fabricated, and functionally evaluated in a phantom model of the transtibial prosthetic socket. The TM&C system was comprised of twelve Thermistors that were divided equally into two groups that arranged internal and external to a prosthetic silicone liner. Its control system was programmed to select the required heating or cooling function of a thermal pump to provide thermal equilibrium based on the amount of temperature difference from a defined set temperature, or the amount of difference between the mean temperature recorded by inside and outside Thermistors. A thin layer of Aluminum was used for thermal conduction between the thermal pump and different sites around the silicone liner. The results showed functionality of the TM&C system for thermoregulation inside the prosthetic socket. However, enhancing the structure of this TM&C system, increasing its thermal power, and decreasing its weight and cost are main priorities before its further development.

Keywords: Transtibial amputation, prosthetic socket, residual limb, skin, heat, perspiration, thermoregulatory system

Background:

Heat and perspiration discomfort with prostheses are common complaints in the majority of amputee people regardless of prosthesis type, amputation cause, and amputated limb or side (Ghoseiri & Safari, 2014). However, there are some people with amputation who suffer from cold skin of the residual limb inside the prosthesis, i.e. those with great vascular insufficiency and those who live in cold climate countries (Fairley, 2013; Meulenbelt, Geertzen, Jonkman, & Dijkstra). Improving the thermal comfort with prostheses has received low attention compared to the aesthetic and biomechanical enhancements in the last few years. Some contributing factors of thermal discomfort have been introduced in previous studies. These factors besides insulating feature of the prosthetic wall and decreased skin surface area after amputation, are disturbed blood flow due to vascular insufficiency, existence of comorbidities, and high age in many people with amputation (Charkoudian, 2003; Florez-Duquet & McDonald, 1998; Hachisuka, Matsushima, Ohmine, Shitama, & Shinkoda, 2001; Klute et al., 2009; Klute, Rowe, Mamishev, & Ledoux, 2007). The prosthetic socket and liner act as temperature and moisture insulators that prevent effective thermal transfer mechanisms, i.e. conduction, convection, radiation, and evaporation, from the skin surface of the residual limb (Hachisuka et al., 2001; Klute et al., 2007; Webber, Klittich, Dhinojwala, & Davis, 2014). In addition to the mentioned factors, pressure-sweating reflex plays an important role for thermal discomfort, especially in weight bearing prostheses. Hence, the recurrent loading/unloading on the residual limb during walking generates pressure/relaxation on sweating and blood vessels that causes decreased/increased skin temperature, respectively. Thermal environment inside the prostheses can easily jeopardize skin integrity by increasing skin stiffness and friction as a response to the increased heat and perspiration, In this situation, the risk of ulceration increases mainly due to the decreased skin distortion (Naylor, 1955; Patel, Knapp, Donofrio, & Salcido, 1999). Furthermore, it was proved by Naylor that skin with slight moisture is more susceptible to blister than wet or dry skin (Naylor, 1955). The accumulation of heat inside the prosthetic socket increases skin temperature and fosters perspiration, which consequently leads to high tissue stress, friction blister, discomfort, unpleasant odor, and decreased prosthesis suspension and use (Dudek, Marks, Marshall, & Chardon, 2005; Hagberg & Branemark, 2001; Legro et al., 1999)].

At present, prostheses lack required mechanisms to deal with heat and cold stresses and their threatening sequelae. Recently, the SmartTemp liner (The Ohio Willow Wood Company, USA) has been introduced as a potential solution for heat and perspiration discomfort of the residual limb (Wernke, Schroeder, Kelley, Denune, & Colvin, 2015). This liner has a phase change material in its structure that allows thermal energy storing by solid to liquid phase transition and thermal energy releasing by a reverse transition. (Wernke et al., 2015). Although this liner is commercially available, further studies are required to confirm its effectiveness in resolving thermal discomfort (Wernke et al., 2015). In a proof of concept study, Webber and Davis designed a prototype of an air-based helical cooling channel by modifying the prosthetic socket as a potential solution for heat build-up in the residual limb (Webber & Davis, 2015). The simulation modeling and bench-top evaluation of a prosthetic phantom with unrealistic scales showed promising results for this cooling system. However, their simulated model and evaluation lacked consideration in applying a prosthetic liner inside the phantom. Due to great limitations of their study, further research is warranted to confirm the applicability of this cooling system in a clinical setting (Webber & Davis, 2015). In line with other efforts to find potential solutions to resolve thermal related problems with prostheses, the present study aims to further investigate the functionality of a previously introduced new temperature measurement and control (TM&C) technique/system (Ghoseiri, Zheng, Hing, Safari, & Leung, 2015) by bench-top evaluations.

Methods / Materials:

As a proof of concept study, the prototype of a TM&C system which was a more developed prototype compared to its earlier version (Ghoseiri et al., 2015), was designed and fabricated. Thereafter, it was installed on a phantom model of a transtibial prosthetic socket for evaluation of its functionality.

Design and fabrication of the TM&C system

The TM&C system for transtibial prostheses was a smart mechano-electrical system consisted of twelve analog Thermistors, twelve amplifier boards, a microcontroller board, a thermal pump, a thermal transfer layer, a power supply, and a monitor. The TM&C system was aimed to sense and control skin temperature of the residual limb inside the prosthetic socket. The TM&C system can selectively actuate the heating or cooling function of a thermal pump to provide thermal equilibrium based on different control modes. The component characteristics of the TM&C system were as below:

1- Thermistors: Twelve negative temperature coefficient (NTC) analog Thermistors each with small head dimensions of 0.5x1 mm (NXFT15XH103, Murata Manufacturing Co. Ltd., Japan) were used in this study. Each Thermistor was connected by wire to a small amplifier board (1.5x2.5 cm) and then to an input port of a microcontroller board. Moreover, Thermistors were divided equally into two groups that arranged inside and outside of a prosthetic silicone liner. All Thermistors were calibrated and their sensitivity, resolution, accuracy, and repeatability were determined based on technical notes supplied by the manufacturing company and water immersion tests. The characteristics of Thermistors were as below:

Sensitivity: The nominal sensitivity measure of Thermistors was 3380±1% K based on the technical note released by their manufacturing company. However, it can be determined as the slope of the calibration line for each Thermistor.

Resolution: The analog to digital board of these Thermistors was 12 bits and the maximum voltage for its activation was 3.3 V. Therefore, the amount of resolution was nearly 0.8 mV.

Accuracy: To determine the accuracy of Thermistors, all of them were immersed into water with various temperatures of 20.7, 25, 30.5, 35.5, and 39.2°C. The temperature of water was measured using a thermocouple K-type. The mean value of the recorded temperature by each Thermistor (x) was compared with water temperature (y) for 22 seconds to determine the absolute error (|x-y|), relative error (absolute error/y), and accuracy (1-relative error) of each Thermistor.

Thermistor calibration: Again, all Thermistors were immersed simultaneously into water with various temperatures of 20.7, 25, 30.5, 35.5, and 39.2°C. For each water temperature, five trials each with 22 seconds were conducted to record temperature by each Thermistor. Thereafter, the calibration equation for each Thermistor was determined based on linear regression analysis.

Repeatability: To determine the repeatability of each Thermistor, all of them were immersed simultaneously as a group into water with temperature of 25°C. During three trials each with 45 seconds the temperature of each Thermistor was recorded. Thereafter, the value of intraclass correlation coefficient ($ICC_{3,1}$) was measured for each Thermistor.

2- The microcontroller board: The microcontroller board was an Arduino Duemilanove (Arduino, Italy) prototyping platform that was equipped with supplementary shields for actuation of thermal pump, data monitoring, and data logging. Programming of the microcontroller was based on C/C++ language using IDE software (version 1.5.7). It was a control program based on PID (Proportional-Integral-Derivative) algorithm that was tuned manually to provide three activation modes of (1) temperature recording, (2) temperature recording besides temperature controlling based on comparison of the mean temperature recorded to an adjustable set temperature, and (3) temperature recording besides temperature controlling based on comparison of the mean temperature recorded by internal and external Thermistors. In the first control mode, the temperature measurement system was active to record temperature data with a frequency of 1 Hz from Thermistors that were located inside and outside of the liner. Moreover, the mean value of the recorded temperature was calculated separately for internal and external Thermistors. In the second control mode, the temperature measurement system was active similar to that of the first control mode. In addition, the temperature control system was active to compare the mean value of temperature recorded by internal Thermistors to an adjustable set temperature, e.g. 31°C based on the result of previous study (Klute, Huff, & Ledoux, 2014), to actuate heating or cooling function of a thermal pump in response to required function to provide thermal equilibrium between inside liner temperature and set temperature. In the third control mode, the temperature measurement system was active similar to that of the first control mode. In addition, the temperature control system was active to compare the mean value of temperature recorded by internal Thermistors to that of external Thermistors to actuate heating or cooling function of a thermal pump to provide thermal equilibrium between two sides of the liner. The reference temperature value for activation of thermal pump was the mean temperature recorded by internal Thermistors, i.e. thermal pump cools whenever the mean value of the recorded temperature by internal Thermistors was higher than the mean value of temperature recorded by external Thermistors. Contrary, it heats in the reverse condition.

3- Thermal pump: The thermal pump was constructed from a combination of a thermoelectric Peltier effect module (40x40x3.9 mm, Welfare Electronic Component Ltd, Hong Kong), a heat sink, and a fan. In order to increase heat conduction, a thin layer of thermal grease was rubbed at the interface between the thermoelectric module and the heat sink. The thermal pump had the ability to conduct heat or cold based on its electrical polarity in response to the required function to provide thermal equilibrium. Moreover, two pulse width modulators were used to provide efficient bi-directional current flow to the thermal pump.

4- Thermal transfer layer: A layer was used for thermal conduction between the thermal pump and various regions around the prosthetic liner. Although diverse materials can be applied in the structure of this layer, the selection should be based on thermal conductivity, price, mass, biocompatibility, stiffness, and flexibility. In this study, a flexible, thin, and light layer of Aluminum, 1100-O with 0.4 mm thickness, was cut to have a star shape with eight extensions at each side. Thereafter, this layer was attached to the thermal pump and used for thermal transfer (Figure 1). The Aluminum layer should be formed to follow contours of the inside surface of the phantom model. Moreover, it should directly be kept in contact with the silicone liner (Figure 1).

5- Power supply: The required power for activation of the TM&C system was supplied by a 7-V and 2-A lithium-ion battery with nominal capacity of 2.2 Ah.

6- Monitor: In order to facilitate real-time understanding of the control mode of the TM&C system, finding out the mean value of temperature recorded by internal and external Thermistors, and detecting the defined set temperature of the second control mode, a small monitor with 1.77" diagonal screen and 160x128 pixel resolution (Arduino TFT LCD Screen, Arduino, Italy) was connected to the microcontroller board.

Design and fabrication of a phantom model of a transtibial prosthetic socket

In order to design and fabricate a phantom model, a silicone liner (Parasil Cushion Silicone Liner, ST&G Corporation, South Korea) was attached to a circular cylinder and was hanged in space by mechanical holders and clamps. Thereafter, it was wrapped by plaster bandage to provide a model resembling a total contact socket. Subsequently, the resultant negative impression was used to prepare a positive mold Afterwards, an additional negative impression was prepared by wrapping positive mold with plaster bandage. The second negative impression was used in the next step to provide a space filler cone. Two plastic dummies that were aimed to resemble size and attachment site of thermal pump and microcontroller board, were attached to the positive mold. These dummies were replaced by real components after lamination process.

The installation of the TM&C system on phantom model of the prosthetic socket

Figure 2 shows the installation of the TM&C system on the phantom model of a transtibial prosthetic socket.

Functional evaluations

To conduct functional evaluations, the TM&C system was secured in space. Thereafter, the Thermistors were arranged inside and outside of the silicone liner corresponding to different parts of the Aluminum layer.

1- The amount of temperature change during heating and cooling functions of the TM&C system: It was measured in two situations of with and without pouring water inside the silicone liner. Three trials each with 5 minutes duration were conducted in each situation for both heating and cooling functions. The water with temperature of 24° C was poured incontinuous inside the silicone liner of the phantom model and was kept stagnant during evaluations. Moreover, a thermal shield was used on top of the phantom model during evaluations to prevent conductive cooling by air. The selection of 5 minutes duration for each trial was based on the result of previous study that showed its adequacy to provide 2° C temperature change (Ghoseiri et al., 2015). This amount of temperature change seems to be enough to cause or probably resolve thermal discomfort of transtibial amputees (Peery, Ledoux, & Klute, 2005). The attachment sites of internal and external Thermistors corresponding to the Aluminum layer have been shown in Figure 3.

2- Thermal energy and power of the TM&C system: Thermal energy and power of the TM&C system were determined in a situation of pouring water inside the silicone liner. Water pouring was incontinuous and considered to provide a more realistic situation for functional evaluations of the TM&C system due to the fact that nearly 80% of human skin is comprised of water (Nakagawa, Matsumoto, & Sakai, 2010). Since the thickness of human skin ranges from 0.45 to 2 mm (Krackowizer & Brenner, 2008), the 100 ml water was estimated experimentally to be sufficient to provide a water layer with nearly 2 mm thickness that resembles the skin of the residual limb. During the lamination process, two plies of stockinet each with an approximate thickness of 1 mm were pulled over the positive mold to provide a narrow and constant space around it. Thereafter, this space was filled by water to provide the required water layer for conducting evaluations. Moreover, a space filler medium cone was required to fill the space inside the liner and increase the height of the poured water. The space filler medium cone was fabricated using the second negative impression of the phantom model to resemble its shape and volume. In this regard, the internal walls of this negative impression were isolated by lubricant Vaseline spray. A tube was fixed inside the negative impression mold as housing for thermocouple as well as water pipes. Finally, the rigid polyurethane foam (Rigid Foam 200, Otto Bock Company, Germany) was poured inside the negative impression mold. The selected foam has almost zero thermal conductivity, 0.034 W/m.°K, and can provide a light space filler after setting. After setting the foam, the negative impression mold was opened and the medium cone was taken out. The water was moved directly from a laboratory tap of a reservoir with adjustable temperature to the phantom model using water-in pipe. A syringe was used besides the water-out pipe to move water outside of the phantom model by providing negative pressure. Figure 4 shows the medium cone, syringe, and water-in/-out pipes.

In both heating and cooling activities, during 1192 seconds (~20 mins) the temperature change of all Thermistors was recorded. Moreover, the temperature of the poured water inside the phantom model was 24°C and its fluctuations during both heating and cooling activities was recorded using a thermocouple. A thermal shield was used on top of the phantom model during evaluations to prevent conductive cooling by air. Thermal energy and power of the TM&C system were calculated separately for heating and cooling activities using the mean value of temperature change during the three evaluation trials. Thermal energy and power formulae are $Q = mc\Delta\theta$ (when Q is the thermal energy, m is the mass, c is the specific thermal capacity, and $\Delta\theta$ is the temperature change) and $P = Q/\Delta t$ (when P is the thermal power, Q is the thermal energy, and Δt is the elapsed time of temperature change), respectively.

Results:

The accuracy, repeatability, and calibration characteristics of Thermistors were determined and presented in Table 1.

As can be seen from Table 1, Thermistors A1, A2, and A11 had high accuracy. Furthermore, the lowest accuracy was found for Thermistor A4. In respect to repeatability of Thermistors, although there were significant correlations among their measurements, but most of them had moderate value of ICC. Furthermore, the lowest repeatability was found for Thermistor A5. The last part of Table 1 shows the results of linear regression analysis of the recorded temperature of each Thermistor when all of them were immersed into water with temperature of 25°C. Moreover, this table shows the values of calibration coefficient and intercept for each Thermistor.

Functional evaluations

1- The amount of temperature change during heating and cooling activities of the TM&C system: The mean value of temperature changes of each Thermistor was determined separately for heating and cooling activities (Table 2). As can be seen from Table 2, the mean value of temperature change of all Thermistors was decreased with increasing distance from center of thermal pump.

2- Thermal energy and power of the TM&C system: The mean value of temperature change of all Thermistors during three evaluations of heating and cooling activities, as well as the temperature of the poured water inside the silicone liner during heating and cooling activities of thermal pump are presented in Table 2.

As can be seen from Table 2, in spite of great temperature change at various sites around the silicone liner during heating and cooling activities, the temperature change of the poured water inside the liner was low. Considering the results of Table 2, the thermal energy and power of the TM&C system during heating (1) and cooling (2) activities were calculated as below:

$Q = mc\Delta\theta$, therefore:

(1) $Q = 100 \times 4.1855 \times 0.3 = 125.565$ (2) $Q = 100 \times 4.1855 \times -0.1 = -41.855$

and

P = Q/Δt , therefore:

(1) $P = 125.565/1192 = 0.105$ (2) $P = -41.855/1192 = -0.035$

Discussion:

Drawing attention to the subject of measuring and controlling skin temperature of the residual limb aims to improve the quality of life of people with amputation. The majority of previous temperature measurements of the residual limb were conducted to detect the level of re-amputation surgery and explore vascular integrity and existence of the phantom pain syndrome (Erikson & Hulth, 1962; Hunter, Katz, & Davis, 2005). Prosthetic silicone liners based on the present materials and technologies are thermal insulators. Moreover, due to high flexibility and formability, these liners can attach snugly to the skin of the residual limb. This feature may be considered a benefit of these liners to provide proper prosthesis suspension. However, it can exacerbate thermal discomfort of people with amputation during prosthesis use. Although measuring thermal conductivity of the selected liner material was beyond the scope of the present study, but according to the previous studies, any temperature change at one side of a liner can be conducted in a fraction of time to the other side (Ghoseiri et al., 2015; Klute et al., 2007; Webber et al., 2014). The present study follows the previously introduced idea to design and fabricate a thermoregulatory system for prostheses based on thermal conduction from outside surface of a prosthetic liner. The main advantage of this thermal transfer method is no dependency to vascular structure and blood flow in the residual limb. Therefore, it can be used even in those people who had amputation due to vascular insufficiency. Moreover, indirect control of temperature can decrease the risk of skin damage. The second activation mode of a thermoregulatory system, i.e. based on comparison of mean value of temperature recorded to an adjustable set temperature, for the inside prosthetic socket was introduced previously (Ghoseiri et al., 2015). In the present study, the function of the TM&C system was based on its first and third activation modes. It means that system was recorded temperature data and transferred data to the microcontroller board for analysis, comparison, and decision making of how to derive heating or cooling functions of a thermal pump for providing thermal equilibrium. Finally, the heating or cooling temperature was transferred to various sites around the silicone liner. This TM&C system in comparison to temperature cooling system that was introduced by Fang et al (2004) has equipped with both temperature sensing and controlling systems and provided both heating and cooling functions (Fang, Huang, Chou, & Huang, 2004). Moreover, in the present TM&C system, there is no need to penetrate and damage prosthetic socket for air circulation that consequently can decrease prosthesis suspension on the residual limb. As an advantage of the TM&C system to the newly introduced cooling system (Webber & Davis, 2015), the TM&C system works based on conduction method for thermal transfer. It means there is no need to fluids (air or liquid), pipes, and compressors in the structure of the TM&C system. Furthermore, the risk of fabricating a heavy and bulky socket can be decreased. Moreover, problems associated with fluids such as their leakage can be omitted. The present TM&C system in comparison to the SmartTemp liner has the ability to measure and control temperature based on three activation modes. In addition, the ability of providing heating is another benefit of this TM&C system in comparison to the SmartTemp liner and the cooling system that was introduced by Webber and Davis (Webber & Davis, 2015; Wernke et al., 2015). It can be expected that in future the TM&C system be installed in prosthetic sockets in conjunction with liners which have phase change material in their structure. According to the results, by increasing distance from center of thermal pump, the amount of the induced temperature change due to activation of thermal pump was decreased. Therefore, the selection of material and pattern of thermal transfer layer needs further investigation. Hence, there was just one thermal pump in the structure of the TM&C system, the heating and cooling energies and powers were low. Therefore, choosing the proper quantity and best attachment site of thermal pump to the prosthetic socket needs further investigation. The best design of the TM&C system should consider these issues to decrease its power consumption and total weight (Klute et al., 2014). Two design limitations of this prototype of the TM&C system are its dependence to socket fit and lack of adaptability to volume changes of the residual limb. It can be inferred that the effectiveness of this TM&C system may be unacceptable beyond the ranges of 10% volume loss and 5% volume gain of the residual limb (Fernie & Holliday, 1982). Although not evaluated in the present study, it can be expected that application of a vacuum assisted suspension system can improve the performance of the TM&C system by providing better socket fit. It is worth noting that present study describes functional evaluations of a more developed prototype of the TM&C system compared to its first prototype (Ghoseiri et al., 2015). Of course, the application of this second prototype in clinical settings for thousands of limbs is not possible at the present time. The structure of system needs to be improved by omitting internal Thermistors, minimizing the whole size of the microcontroller board, improving the thermal pump, and selecting an appropriate pattern of thermal transfer layer. A developing process to address these issues is now underway. In order to omit the internal Thermistors, a database should be developed for each liner to collect its material, manufacturing company, thickness, and thermal behaviors. In this regard, several attempts have been made by some researchers (Klute et al., 2007; Webber et al., 2014). It can be expected that by omission of internal Thermistors, the TM&C system can be programmed to activate the heating or cooling functions by estimating the skin temperature inside the liner from temperature data recorded by external Thermistors. Decreasing the whole size of the microcontroller board is the simplest part of the further developing process. In respect to the thermal pump, a custom designed donut-shaped thermoelectric module has been suggested. This design provides the possibility of installing the thermal pump as a modular component directly below the socket in line with other prosthetic components. Therefore, the thermal transfer layer should follow the donut-shaped thermoelectric module. Moreover, due to the heterogeneous structure of the residual limb, the thermal transfer layer should follow the asymmetric pattern of temperature distribution on skin surface of the residual limb. In clinical settings to accelerate designing a thermal transfer layer, the thermographic pattern of the residual limb can be obtained simply by using a standard thermographic camera. It is worth noting that clinical evaluation of efficacy of the TM&C system is underway besides its structural development.

Conclusion:

The functional evaluation of a more developed prototype of the TM&C system was conducted to assess its performance and determine its limitations before further developments. In this line, further investigation on thermal inertia, thermal capacity, and temperature distribution pattern on skin surface of the residual limb are required. These information can be used to further develop the structure of the TM&C system and tune its activation time and power.

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Study concept and design: K. Ghoseiri, Y.P. Zheng, A.K.L. Leung, M. R. Safari, Acquisition of data: K. Ghoseiri, Y.P. Zheng, T.H. Lee, Analysis and interpretation of data: K. Ghoseiri, Y.P. Zheng, T.H. Lee, M. Rahgozar, Drafting of manuscript: K. Ghoseiri, Y.P. Zheng, T.H. Lee, G.R. Aminian, A.K.L. Leung, M.R. Safari

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References

Charkoudian, N. (2003). Skin blood flow in adult human thermoregulation: how it works, when it does not, and why. Mayo Clin Proc, 78(5), 603-612.

Dudek, N. L., Marks, M. B., Marshall, S. C., & Chardon, J. P. (2005). Dermatologic conditions associated with use of a lower-extremity prosthesis. Arch Phys Med Rehabil, 86(4), 659-663.

Erikson, U., & Hulth, A. (1962). Circulation of amputation stumps. Arteriographic and skin temperature studies. Acta Orthop Scand, 32, 159-170.

Fairley, M. (2013). Prosthetic Liners and Sleeves: Reaching New Levels of Comfort, Control, and Suspension. March. Retrieved March 03, 2015, from http://www.oandp.com/articles/2013-03_07.asp

Fang, C., Huang, M., Chou, Y., & Huang, G. (2004). The study of thermal comfort for below-knee prosthesis. Biomed Eng Appl Basis Comm, 16(1), 7-14.

Fernie, G. R., & Holliday, P. J. (1982). Volume fluctuations in the residual limbs of lower limb amputees. Arch Phys Med Rehabil, 63(4), 162-165.

Florez-Duquet, M., & McDonald, R. B. (1998). Cold-induced thermoregulation and biological aging. Physiol Rev, 78(2), 339-358.

Ghoseiri, K., & Safari, M. (2014). The prevalence of heat and perspiration discomfort inside prostheses: Literature review. J Rehabil Res Dev, 51(6).

Ghoseiri, K., Zheng, Y., Hing, L., Safari, M., & Leung, A. (2015). The prototype of a thermoregulatory system for measurement and control of temperature inside prosthetic socket. Prosthetics and Orthotics International, In Press.

Hachisuka, K., Matsushima, Y., Ohmine, S., Shitama, H., & Shinkoda, K. (2001). Moisture permeability of the total surface bearing prosthetic socket with a silicone liner: is it superior to the patella-tendon bearing prosthetic socket? J uoeh, 23(3), 225-232.

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(3), 186-194.

Hunter, J. P., Katz, J., & Davis, K. D. (2005). Dissociation of phantom limb phenomena from stump tactile spatial acuity and sensory thresholds. Brain, 128(Pt 2), 308-320.

Klute, G. K., Huff, E., & Ledoux, W. R. (2014). Does Activity Affect Residual Limb Skin Temperatures? Clin Orthop Relat Res.

Klute, G. K., Kantor, C., Darrouzet, C., Wild, H., Wilkinson, S., Iveljic, S., & Creasey, G. (2009). Lower-limb amputee needs assessment using multistakeholder focus-group approach. J Rehabil Res Dev, 46(3), 293-304.

Klute, G. K., Rowe, G. I., Mamishev, A. V., & Ledoux, W. R. (2007). The thermal conductivity of prosthetic sockets and liners. Prosthet Orthot Int, 31(3), 292-299.

Krackowizer, P., & Brenner, E. (2008). Dicke der Epidermis und Dermis*. Sonographische Messung an 24 Stellen des menschlichen Körpers. Phlebologie, 37, 83-92.

Legro, M. W., Reiber, G., del Aguila, M., Ajax, M. J., Boone, D. A., Larsen, J. A., Sangeorzan, B. (1999). Issues of importance reported by persons with lower limb amputations and prostheses. J Rehabil Res Dev, 36(3), 155-163.

Meulenbelt, H. E., Geertzen, J. H., Jonkman, M. F., & Dijkstra, P. U. (2011). Skin problems of the stump in lower limb amputees: 1. A clinical study. Acta Derm Venereol, 91(2), 173-177.

Nakagawa, N., Matsumoto, M., & Sakai, S. (2010). In vivo measurement of the water content in the dermis by confocal Raman spectroscopy. Skin Res Technol, 16(2), 137-141.

Naylor, P. F. (1955). The skin surface and friction. Br J Dermatol, 67(7), 239-246.

Patel, S., Knapp, C. F., Donofrio, J. C., & Salcido, R. (1999). Temperature effects on surface pressure-induced changes in rat skin perfusion: implications in pressure ulcer development. J Rehabil Res Dev, 36(3), 189-201.

Peery, J. T., Ledoux, W. R., & Klute, G. K. (2005). Residual-limb skin temperature in transtibial sockets. J Rehabil Res Dev, 42(2), 147-154.

Webber, C. M., & Davis, B. L. (2015). Design of a novel prosthetic socket: assessment of the thermal performance. J Biomech, 48(7), 1294-1299.

Webber, C. M., Klittich, M. R., Dhinojwala, A., & Davis, B. L. (2014). Thermal Conductivities of Commercially Available Prosthetic Materials. J Prosthet Orthot, 26(4).

Wernke, M. M., Schroeder, R. M., Kelley, C. T., Denune, J. A., & Colvin, J. M. (2015). SmartTemp Prosthetic Liner Significantly Reduces Residual Limb Temperature and Perspiration. J Prosthet Orthot, 27, 134–139.

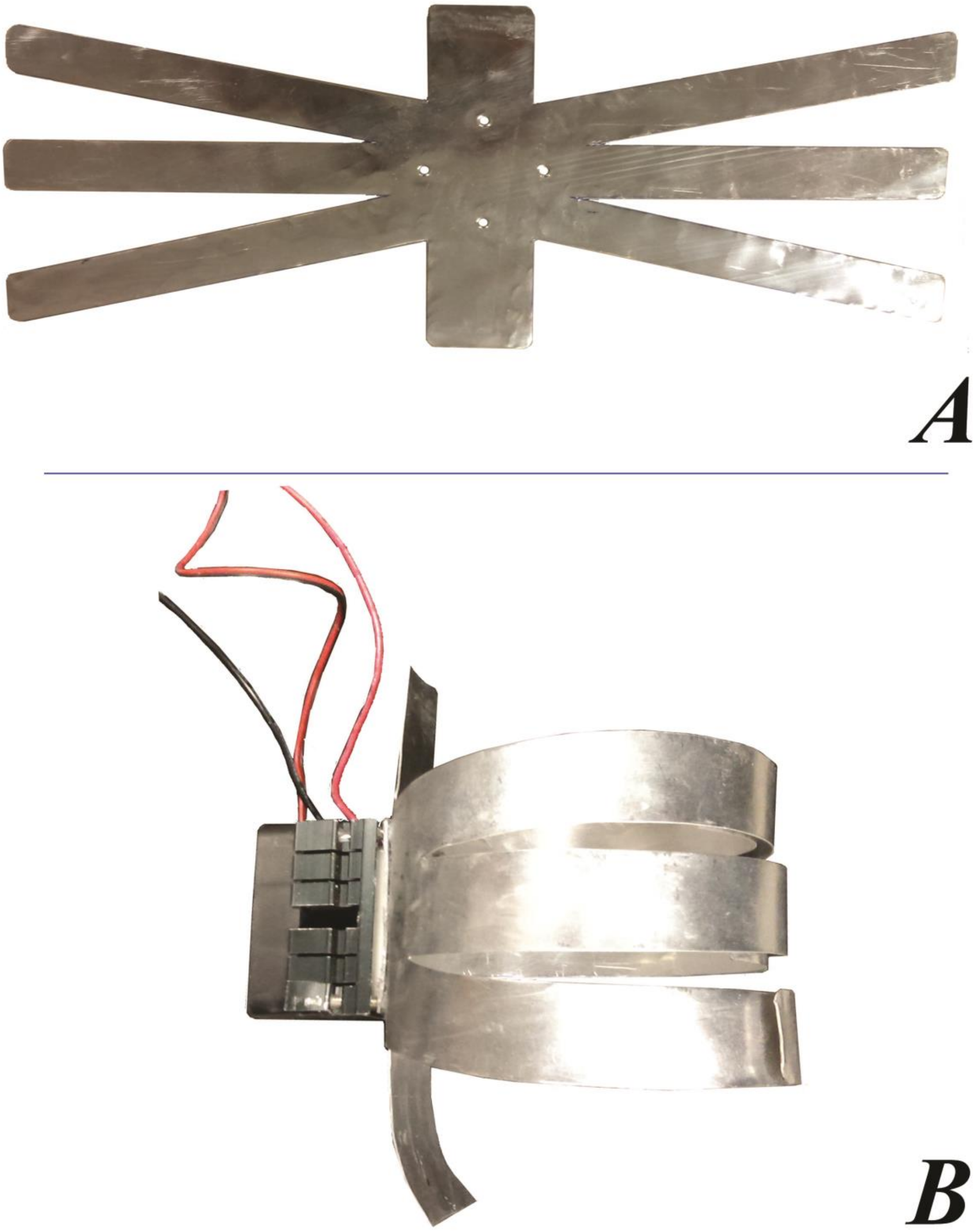

Figure 1. Aluminum thermal transfer layer (A), and its form after attachment of thermal pump (B)

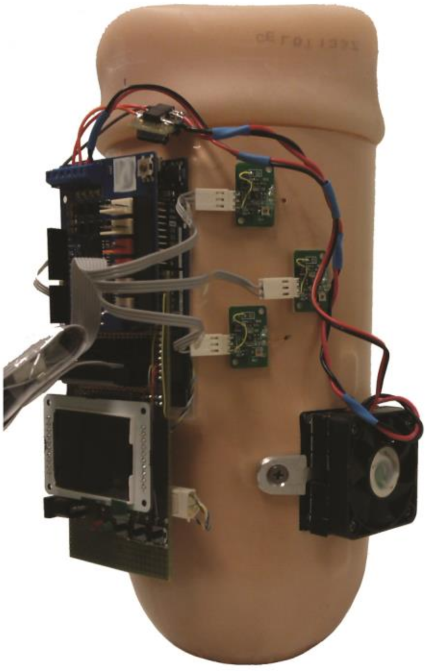

Figure 2. The temperature measurement and control (TM&C) system

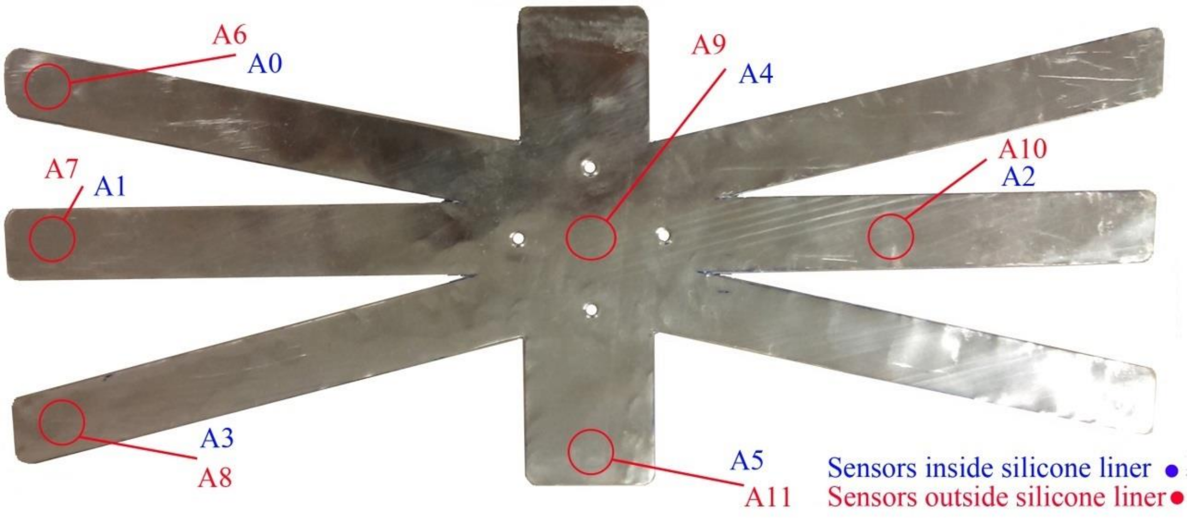

Figure 3. The attachment sites of internal and external Thermistors corresponding to different parts of the Aluminum layer

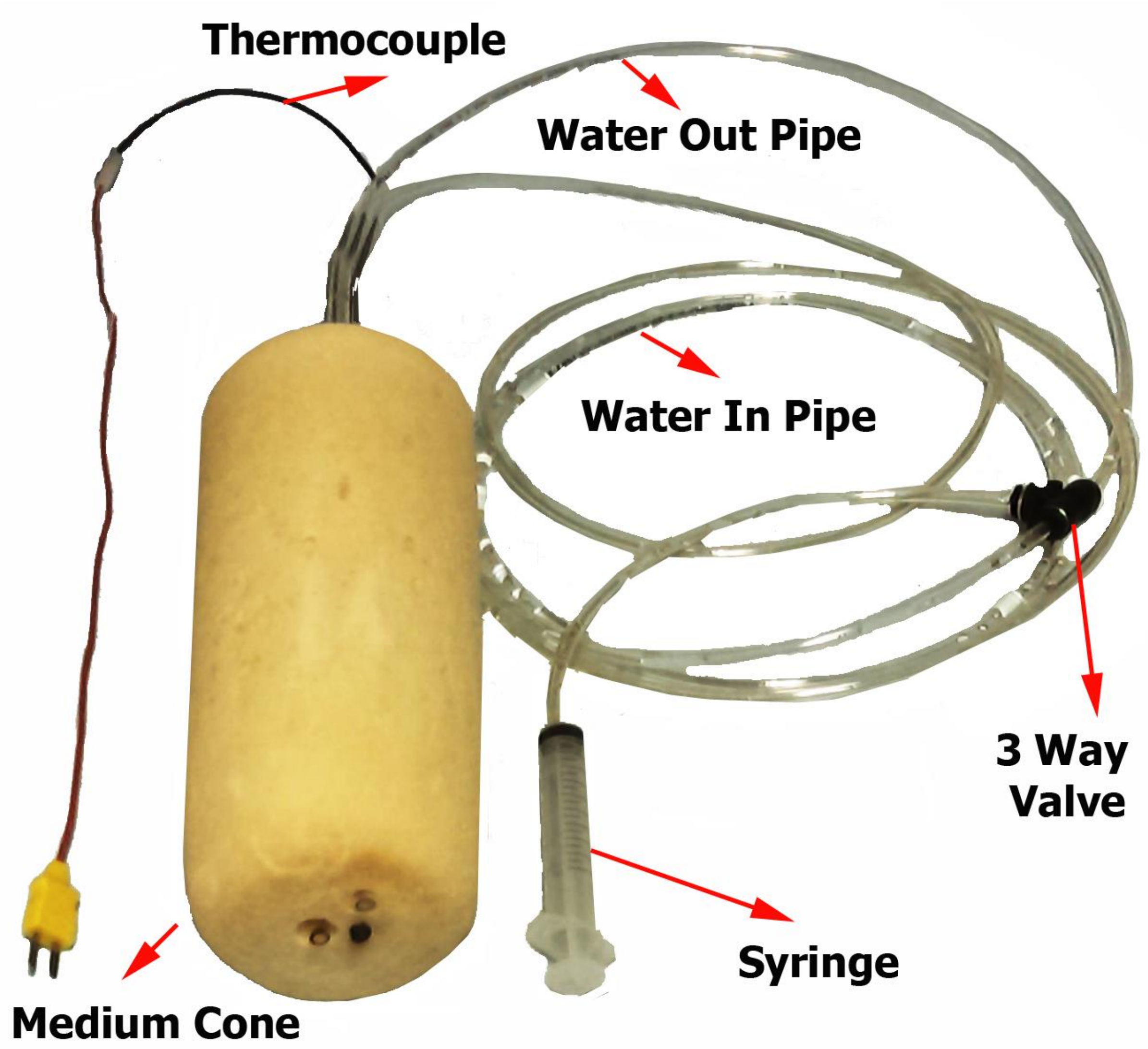

Figure 4. Space filler medium cone with thermocouple and water pipes

Table 1. The characteristics of Thermistors

The accuracy of Thermistors

A0	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	Water Temperature (°C)	
-0.51	-0.08	-0.08	0.11	-1.05	-0.33	0.20	0.15	0.10	-0.24	0.06	-0.19	20.7	Absolute error
-0.43	0.02	0.04	0.24	-0.95	-0.26	0.25	0.24	0.19	-0.16	0.16	-0.08	25	
-0.56	0.01	0.16	0.25	-0.91	-0.24	0.33	0.29	0.26	-0.13	0.14	-0.02	30.5	
-0.49	0.15	0.29	0.38	-0.79	-0.12	0.48	0.45	0.38	0.05	0.22	0.17	35.5	
-0.50	0.18	0.33	0.44	-0.72	-0.12	0.51	0.46	0.45	0.06	0.36	0.21	39.2	
0.02	0	0	0	0.05	0.01	0.01	0.01	0	0.01	0	0.01	20.7	Relative error
0.01	0.00	0.00	0.01	0.04	0.01	0.01	0.01	0.01	0.01	0.01	0.00	25	
0.02	0	0	0.01	0.03	0.01	0.01	0.01	0.01	0	0	0	30.5	
0.01	0	0.01	0.01	0.02	0	0.01	0.01	0.01	0	0.01	0	35.5	
0.01	0	0.01	0.01	0.02	0	0.01	0.01	0.01	0	0.01	0	39.2	
0.97	1	1	0.99	0.95	0.98	0.99	0.99	0.99	0.99	1	0.99	20.7	Accuracy
0.98	1	1	0.99	0.96	0.99	0.99	0.99	0.99	0.99	0.99	1	25	
0.98	1	0.99	0.99	0.97	0.99	0.99	0.99	0.99	0.99	0.99	1	30.5	
0.99	0.99	0.99	0.99	0.98	1	0.99	0.99	0.99	1	0.99	0.99	35.5	
0.99	0.99	0.99	0.99	0.98	1	0.99	0.99	0.99	1	0.99	0.99	39.2	

The repeatability of Thermistors

A0	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11	Thermistors
0.60	0.56	0.40	0.25	0.30	0.19	0.70	0.63	0.48	0.42	0.57	0.32	ICC
0.25	0.22	0.11	0.04	0.06	0.02	0.35	0.28	0.16	0.13	0.22	0.07	Lower Confidence Limit
0.98	0.98	0.96	0.94	0.95	0.92	0.99	0.99	0.97	0.97	0.98	0.95	Upper Confidence Limit
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	P-value

The linear regression analysis to determine calibration equation (y=b+mx)* of each Thermistor

Thermistors	R^2	Sum of square		F (1,53)		Calibration		
		Regression	Residual	Value	P-value	Intercept (b constant)	Coefficient (m)	Equation
A0	1.00	2484.45	0.13	992514.65	0.00	-0.46	1.00	y=-0.46+(1.00*x)
A1	1.00	2559.53	0.05	2867147.91	0.00	-0.35	1.01	y= -0.35+(1.01*x)
A2	1.00	2605.33	0.05	2675781.95	0.00	-0.53	1.02	y= -0.53+(1.02*x)
A3	1.00	2575.05	0.06	2119363.49	0.00	-0.22	1.02	y= -0.22+(1.02*x)
A4	1.00	2578.45	0.06	2192067.05	0.00	-1.41	1.02	y=-1.41+(1.02*x)
A5	1.00	2550.42	0.05	2801538.41	0.00	-0.57	1.01	y= -0.57+(1.01*x)
A6	1.00	2580.93	0.04	3236901.22	0.00	-0.18	1.02	y= -0.18+(1.02*x)
A7	1.00	2579.65	0.05	2694633.38	0.00	-0.21	1.02	y=-0.21+(1.02*x)
A8	1.00	2585.71	0.02	7334038.78	0.00	-0.29	1.02	y=-0.29+(1.02*x)
A9	1.00	2577.25	0.08	1682870.35	0.00	-0.60	1.02	y= -0.60+(1.02*x)
A10	1.00	2558.97	0.12	1097610.26	0.00	-0.22	1.01	y=-0.22+(1.01*x)
A11	1.00	2602.52	0.05	2996681.76	0.00	-0.65	1.02	y= -0.65+(1.02*x)

* y: dependent variable (measured temperature of Thermistor), b: intercept value, m: slope of the fitting regression line, x: independent variable (water temperature)

Table 2. The mean value of temperature changes (°C) for internal and external Thermistors, as well as the temperature change (°C) of water inside the silicone liner during heating and cooling activities

Thermistors sites corresponding to Aluminum layer		Five minutes				Twenty minutes	
		Cooling		Heating		Cooling	Heating
		Air	Water	Air	Water	Water	Water
Center of layer	A4	-4.09	-7.47	6.73	10.38	-12.94	17.46
	A9	-5.20	-10.01	12.87	14.59	-13.56	22.26
Proximal extension	A0	-2.44	-0.73	0.05	0.05	-1.78	1.29
	A6	-2.41	-0.97	0.35	0.36	-2.57	2.23
Middle extension	A1	-2.43	-0.82	0.32	0.16	-2.70	2.55
	A7	-2.44	-1.12	0.54	0.56	-3.22	3.13
Distal extension	A3	-2.40	-0.70	0.18	0.01	-1.97	1.51
	A8	-2.46	-0.97	0.45	0.35	-2.42	1.99
Mid of middle extension	A2	-2.50	-1.42	1.12	1.04	-4.08	2.50
	A10	-2.75	-2.35	2.43	2.44	-5.67	4.51
Distal Part	A5	-3.57	-4.13	4.20	4.97	-8.86	8.44
	A11	-4.25	-6.23	9.80	9.88	-9.45	11.80
Temperature difference of water						-0.1	0.3