

Temperature measurement and control system for transtibial prostheses: Single subject clinical evaluation

Kamiar Ghoseiri^{a,b,d*} (Assistant Professor, PhD), Yong Ping Zheng^b (Professor, PhD), Aaron K.L. Leung^b (Associate Professor, PhD), Mehdi Rahgozar^c (Associate Professor, PhD), Gholamreza Aminian^d (Assistant Professor, PhD), Mehdi Masoumi^e (MD), Mohammad Reza Safari^d (Assistant Professor, PhD)

- a) Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences, Hamadan, Iran
- b) Interdisciplinary Division of Biomedical Engineering, Faculty of Engineering, Hong Kong Polytechnic University, Kowloon, Hong Kong
- c) Department of Biostatistics, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
- d) Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
- e) Janbazan Medical and Engineering Research Center (JMERC), Tehran, Iran

***Corresponding Author:** Dr. Kamiar Ghoseiri, Assistant Professor, Department of Orthotics and Prosthetics, School of Rehabilitation Sciences, Hamadan University of Medical Sciences, Hamadan, Iran, 6517838736, Tel: (+98) 81-38381571, Fax: (+98) 81-38381572, Email: Kamiar_g@yahoo.com , K.ghoseiri@umsha.ac.ir

Abstract

The snug fit of a prosthetic socket over the residual limb can disturb thermal balance and put skin integrity in jeopardy by providing an unpleasant and infectious environment. The prototype of a temperature measurement and control (TM&C) system was previously introduced to resolve thermal problems related to prostheses. This study evaluates its clinical application in a setting with reversal, single subject design. The TM&C system was installed on fabricated prosthetic socket of a man with unilateral transtibial amputation. Skin temperature of the residual limb, without prosthesis at baseline, and with prosthesis during rest and walking was evaluated. The thermal sense and thermal comfort of the participant were also evaluated. The results showed different skin temperature around the residual limb with a temperature decrease tendency from proximal to distal. The TM&C system decreased skin temperature rise after prosthesis wearing. The same situation was occurred during walking; but the thermal power of the TM&C system was insufficient to overcome heat build-up in some regions of the residual limb. The participant reported no significant change of thermal sense and thermal comfort. Further investigations are warranted to examine thermography pattern of the residual limb, thermal sense, and thermal comfort in people with amputation.

Keywords: Transtibial amputation, prosthetic socket, residual limb, skin, perspiration, temperature measurement, temperature control, thermoregulatory system

Background and Aim

The socket is the main component of a prosthesis that acts as an interface to transfer loads and motions between the residual limb and prosthesis. The snug fit of a prosthetic socket over the residual limb is essential for proper prosthesis function; however, it can disturb the thermal balance of the residual limb and put the skin integrity of the residual limb in jeopardy. Commonly available materials for the fabrication of prosthetic sockets and liners have low thermal conductivities which decrease their ability to transfer heat between the skin surface of the residual limb and the environment (Klute, Rowe, Mamishev, & Ledoux, 2007; C.M. Webber, Klittich, Dhinojwala, & Davis, 2014). The heat accumulation can be followed by increased perspiration inside the prosthetic socket and liner. This situation provides an unpleasant and infectious environment inside the socket that endangers skin integrity by intensifying irritation and blister formation (Dudek, Marks, Marshall, & Chardon, 2005; Hagberg & Branemark, 2001; Legro et al., 1999). Thermal discomfort with prostheses is a prevalent phenomenon (nearly 53%) in people with amputation (Ghoseiri & Safari, 2014). In this regard, Hansen et al reported 66% incidence of hyperhidrosis inside the lower limb prostheses (Hansen, Godfrey, Wixom, & McFadden, 2015). While simply wearing a prosthesis is enough to cause skin temperature rise inside the socket and liner, an activity such as walking can exacerbate the situation (Klute, Huff, & Ledoux, 2014; Peery, Ledoux, & Klute, 2005). It was shown that 2°C increase in skin temperature is enough to cause thermal discomfort inside the transtibial prosthetic socket (Peery et al., 2005). Furthermore, thermal discomfort can negatively affect the activity time and prosthesis use. Although heat is the main source of thermal discomfort inside the prosthetic socket and liner, in some people with amputation, due to vascular insufficiency, and in those living in cold-climate environments, thermal discomfort may be due to feeling cold in the residual limb (Fairley, 2013; Meulenbelt, Geertzen, Jonkman, & Dijkstra). Some efforts have been made to deal

with temperature increase and thermal discomfort inside the prosthetic sockets; however, no commercially available thermoregulatory system can be found. In this regard, Wernke et al has recently introduced the SmartTemp liner (The Ohio Willow Wood Company, Ohio, USA) as an effective device for temperature and perspiration control (Wernke, Schroeder, Kelley, Denune, & Colvin, 2015). This liner is made from phase change material with the capability to interchange between solid and liquid states, which permits thermal energy storing and releasing, or vice versa (Wernke et al., 2015). However, further research is required to confirm the effectiveness of this liner for temperature and perspiration control with prostheses (Wernke et al., 2015). In another effort, as a proof of concept study, the prototype of an air-based helical cooling channel was designed (C. M. Webber & Davis, 2015). This cooling system showed promising results in prosthetic simulated model and bench-top evaluation. As the phantom prosthetic model lacks prosthetic liner inside the socket, further research is required to confirm its applicability in real situations (C. M. Webber & Davis, 2015). The prototype of a temperature measurement and control (TM&C) system was designed, fabricated, and evaluated in another study (Ghoseiri, Zheng, Hing, Safari, & Leung, 2015). The present study was aimed at exploring the functionality of a more developed prototype of that TM&C system (Ghoseiri et al., 2016) during its application in a clinical setting.

Methods

A single subject research design was chosen for this clinical investigation due to the difficulty of matching subjects for thermography studies. Moreover, in a single subject research design the behavior of a participant during different phases of the study can be more efficiently investigated. This investigation had reversal, single subject design of A₁-B-A₂-C with three

distinct phases: (A₁, 2) temperature recording at rest without prosthesis (baseline), (B) temperature recording at rest with prosthesis, and (C) temperature recording during walking with prosthesis. Each phase was conducted with four repetitions during four consecutive days. Following an advertisement in a public Prosthetic and Orthotic Service Center, a volunteer participant with transtibial amputation was selected based on his compatibility with study criteria. The inclusion criteria were (1) a man with unilateral transtibial traumatic amputation, (2) use of a silicone liner prosthesis, (3) complaint of heat and perspiration discomfort with prosthesis, (4) age between 18-60 years old, (5) wear the prosthesis more than 4 hours per day, (6) more than 2 years' experience of prosthesis use, (7) no existence of skin problem or ulceration based on medical examination. The exclusion criteria were (1) existence of any orthopedic, cardiovascular, respiratory, and metabolic disease or disorder, (2) alcohol and medication use during experiment days, (3) impaired thermal sense of the residual limb based on medical examination, (4) use of any antiperspirant spray, powder, and lotion during experiment days.

All aspects of this clinical evaluation were approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences. A written informed consent was also obtained before enrolling the participant in the study.

In the first session, prior to gathering demographic data, the skin integrity of the residual limb was examined by a physician. Thereafter, the thermal sense was examined through the standard method of detection; in a closed-eye situation, the participant immersed his residual limb in two different pots, one with cold water (25°C) and another with hot water (40°C), to discriminate pots and estimate water temperature (Mumenthaler & Mattle, 2006). The length and circumference of the residual limb were measured to choose the correct size of silicone locking liner with 3mm thickness for the participant. Then, the residual limb of the participant was cast to fabricate a new prosthetic socket. The negative impression mold was

filled with liquid plaster to provide the positive mold. After rectification process, the dummies of thermal pump and microcontroller board were attached to the positive mold. Finally, the lamination of prosthetic socket was performed and dummies were replaced by their real components. Other components of the TM&C system were also installed on the fabricated transtibial prosthetic socket (Figure 1). In order to make the prosthesis ready for clinical evaluation, the socket was connected to other prosthetic components, i.e. the lock, modular shank, and foot-ankle complex.

All clinical investigations were conducted during four consecutive days. The participant was asked to attend the experimental laboratory at a specific time (about noon), at least one hour before evaluations. The ambient temperature was kept constant (23-24°C) for all phases on consecutive days. The participant was instructed to remove his prosthesis and sit for about 30 minutes before evaluations in order to adapt to laboratory temperature. Six sites, which were previously identified to have greater temperature fluctuations, were marked on skin surface of the residual limb for attachment of Thermistors (Peery et al., 2005). Thereafter, Thermistors were taken in place with small tapes. Figure 2 shows the attachment sites of internal Thermistors during all phases of clinical evaluations. Corresponding to the internal Thermistors and exactly at the same place, six Thermistors (external Thermistors) were attached to the outer surface of the silicone liner.

During A phases, the skin temperature was recorded within 10-minute rest without wearing prosthesis. At the first 10-minute of B and C phases, the read control mode of the TM&C system, the prosthesis was worn and the skin temperature was recorded during rest and walking situations, respectively. The second 10-minute of B and C phases, the run control mode of the TM&C system, was similar to the first 10-minute, except the activation of temperature control system to provide thermal equilibrium between both sides of the silicone liner. There was a 15-minute rest period between each phase and a 2-minute familiarization

walking with the new prosthesis before the C phase. Before the two phases of B and C, the quality of socket fit was subjectively assessed using socket comfort scale. Moreover, a certified prosthetist examined the quality of socket fit and resolved any existing problems. These assessments were done to decrease the confounding effect of socket fit on temperature measurements during B and C phases.

In addition to temperature recordings, two subjective evaluations were conducted before and after the prosthesis wearing phases; i.e. B and C, to assess thermal sense and thermal comfort of the participant. The participant was asked from participant to rate his thermal sense and thermal comfort based on ASHRAE (American Society of Heating, Refrigerating and Air-conditioning Engineers) and Bedford scales, respectively. In data analysis, the participant was considered both as a control and a case to compare the results of his evaluation. The visual methods to investigate the level, variability, trend, slope, two standard deviation bands, and C-statistic were used for analysis (Nourbakhsh & Ottenbacher, 1994).

Results

The participant was a 54-year-old man with a left transtibial amputation caused by war trauma 33 years ago. He used his prosthesis nearly 12 hours per day and one of his major complaints was thermal discomfort inside the prosthetic socket and liner, especially in summer months. The findings of skin thermography of his residual limb were derived from A phases. These results are presented in Table 1.

To show the level and variability during all phases, the mean \pm standard deviation (SD) value of temperature change was determined between the first and the tenth minutes after phase beginning. The results are presented in Table 2.

The slope and trend of the mean temperature change can be visually assessed by inspecting the best fit line for temperature graphs of all phases during consecutive days. The split middle

method was used to illustrate the median of temperature change for each Thermistor. The results are presented in Appendix 1.

A two-standard deviation band was calculated for B and C phases during consecutive days to compare mean temperature change during read and run control modes. The two standard deviation bands (see Appendix 2) show the activation effect of temperature control system on mean value of the recorded temperature by each Thermistor.

The C-statistic is a simplified type of time-series analyses used to determine whether there were significant or out of chance trends in A₁-B-A₂-C order of phases during read and run control modes of the TM&C system. The results are presented in Table 3.

The results of thermal sense and thermal comfort before and after wearing prosthesis in phases of B and C are shown using box and whisker plots in Figure 3.

Discussion

The findings of temperature recording in A phases were in line with the existing literature (Klute et al.; Peery et al., 2005). There were different skin temperatures around the residual limb, probably because of the heterogeneous structure of the residual limb that is made of tissues with unequal thickness and thermal property. Similarly, the proximal part of the residual limb had a higher temperature compared to its distal part. Furthermore, the hottest and coldest regions of the residual limb were located at its anterolateral and posterior distal parts, respectively (Klute et al., 2014; Peery et al., 2005). In this study, the mean±SD of eight temperature recordings in A phases was 29.08±0.60 °C, which was lower than that reported by Peery et al, i.e. 31.4±1.3 °C, probably due to the different methods used in two studies (Peery et al., 2005).

In agreement with the results of previous studies (Klute et al.; Peery et al., 2005), wearing the prosthesis, even in rest situation, increased the residual limb skin temperature. However, a

short walking trial can further increase the skin temperature of the residual limb (Klute et al., 2014). The Thermistors that were located close to the thermal pump recorded higher temperature change and variability during thermal pump activation. At the run control mode of B and C phases, i.e. the second 10-minute of temperature recording, the temperature variability was higher than that of the read control mode, i.e. the first 10-minute of temperature recording, due to the activation of temperature control system to provide thermal equilibrium. The best fit trend line was dropped for all Thermistors during run control mode in comparison to that of read control mode at phase B. Similarly, for the majority of Thermistors, the mean temperature change decreased in the run control mode compared to the read control mode, except for Thermistors A2, A7, A8, and A10 (Appendix 1). The comparison of read control mode between the B and C phases showed a lower temperature rise for C phase, which might be because of pressure-sweating reflex during walking activities. The comparison of run control mode between the B and C phases revealed that temperature control system could better overcome skin temperature rise at phase B. It seems that power of the TM&C system was insufficient to adequately decrease heat build-up at some regions of the residual limb during walking. The C-statistic results confirmed the existence of significant and out of chance trends in order of A₁-B-A₂-C phases during read and run control modes of the TM&C system.

Although the materials being used in the structure of prosthetic liners and sockets are great insulators, they can conduct temperature from one side to the other side in a fraction of time (Klute et al., 2007; C.M. Webber et al., 2014). As Klute et al reported, the thermal conductivity ranged from 0.085 – 0.266 W/m.°K for prosthetic liner materials, and from 0.148 – 0.150 W/m°K for prosthetic socket materials (Klute et al., 2007). Therefore, the TM&C system can be applied to a variety of liner materials by compromising between thermal conductivity of the liner material and time span for thermal transfer. Considering

constant thermal power of the TM&C system, it can be concluded that the time span for thermal transfer is greater in Polyethylene liner (0.085 W/m²K) compared to that of the silicone (0.225 W/m²K) or gel liners (0.202 W/m²K) (Klute et al., 2007). The great attention that has been recently given to the thermal characteristics of the liner and socket materials caused great evolutions in liner production technology. Although the application of phase change material in the structure of the prosthetic liner is in its infancy, it seems to be a great progress (Wernke et al., 2015). It can be expected that in future the developed TM&C system be used in conjunction with highly developed prosthetic liners.

With respect to thermal sense, there were some differences before and after B and C phases. However, due to overlap of error bars in each phase, it cannot be confidently stated that these differences were significant (Cumming, Fidler, & Vaux, 2007). Even small temperature change of the residual limb is important. It has been shown that as little as 1 °C muscle temperature change can affect the muscle performance, blood flow in underlying tissues, and neural drive (Bergh & Ekblom, 1979; Racinais, Gaoua, & Grantham, 2008; Winkel & Jorgensen, 1991). Cold receptors are more sensitive to the amount of temperature change rather than the absolute value of temperature (McCleskey, 1997). These receptors detect even small temperature change (0.5 °C) and send signals to brain. On the other hand, warm receptors start to fire action potentials to brain when skin temperature rose up to 30 °C. The frequency of sending signals by these receptors increases with temperature rise up to nearly 45 °C, which is the temperature point at which nociceptors start sending pain signals (McCleskey, 1997). Although thermal receptors can detect small temperature changes, the person may never feel the changes. This was occurred in our case; the participant could not feel those small temperature changes. Accordingly, this finding is in agreement with the results of another study that showed some elderly people might never feel small temperature changes even up to 4 °C (Florez-Duquet & McDonald, 1998). The participant also reported

lower thermal comfort in phase C compared to that of phase B. This result is in line with the result of a previous study; people with amputation have greater thermal discomfort during walking (Klute et al.). The lowest variability of thermal comfort was found after phase C, which probably is the result of the inability of participant to detect small temperature changes.

It is worth noting that the weight and bulk of a thermoregulatory system can increase thermal sense and decrease thermal comfort (Klute et al., 2014). Although this prototype of the TM&C system was light (nearly 550 g), but decreasing its weight and further developing its structure should be considered in future. In the same way, omitting internal Thermistors, minimizing the whole size of the microcontroller board, improving thermal pump structure, and selecting an appropriate pattern for thermal transfer layer can improve its performance.

The main limitation of this study was conducting the clinical evaluation based on a single subject design. Although the selected design was favorable for thermography evaluation, it could decrease the generalizability of the results. Moreover, in our case, we examined the functionality of the TM&C system based on cooling function. The functional evaluation of the TM&C system is warranted based on heating function.

Conclusion

The functionality of a prototype of the TM&C system was investigated in a clinical setting to detect the limitations of its application in real situation before further developments. The results of thermography showed different skin temperatures around the residual limb with a temperature drop tendency from proximal to distal regions. Wearing the prosthesis even in rest situation increases residual limb skin temperature. However, a short walking trial can further increase residual limb skin temperature. The TM&C system could actively decrease skin temperature during prosthesis wearing and walking; but its power was insufficient to

overcome heat build-up in some regions of the residual limb at phase C, i.e. walking trial. Although no significant difference was detected, the thermal comfort and thermal sense were decreased and increased, respectively. Further investigations are warranted to examine thermography pattern of the residual limb, thermal sense, thermal comfort, and appropriate outcome measures for thermal sense and thermal comfort in people with amputation.

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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, Analysis and interpretation of data: K. Ghoseiri, Y.P. Zheng, M. Rahgozar, Drafting of manuscript: K. Ghoseiri, Y.P. Zheng, G.R. Aminian, A.K.L. Leung, M. Masoumi, M.R. Safari

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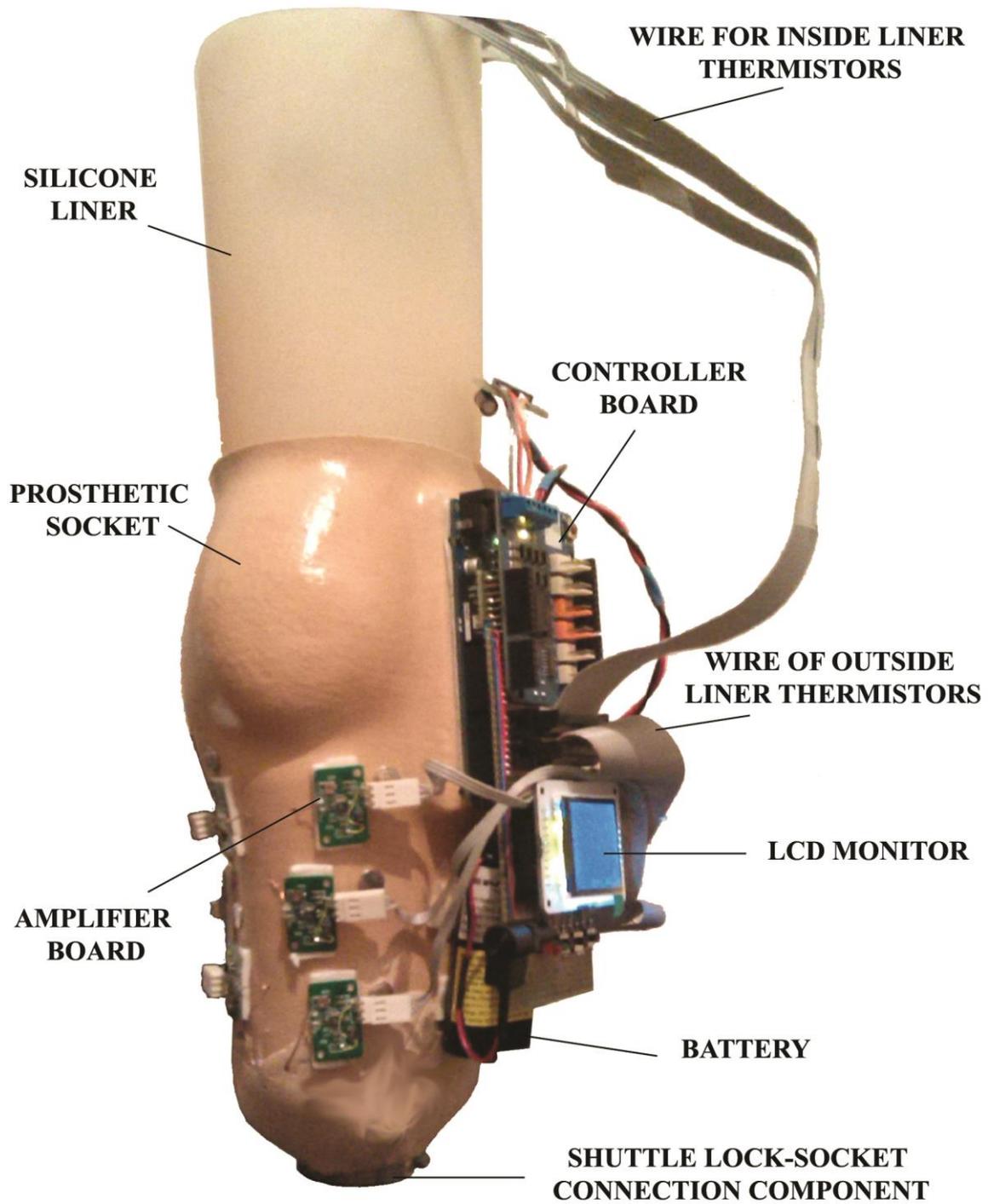


Figure 1. The temperature measurement and control (TM&C) system that was installed on the fabricated prosthetic socket

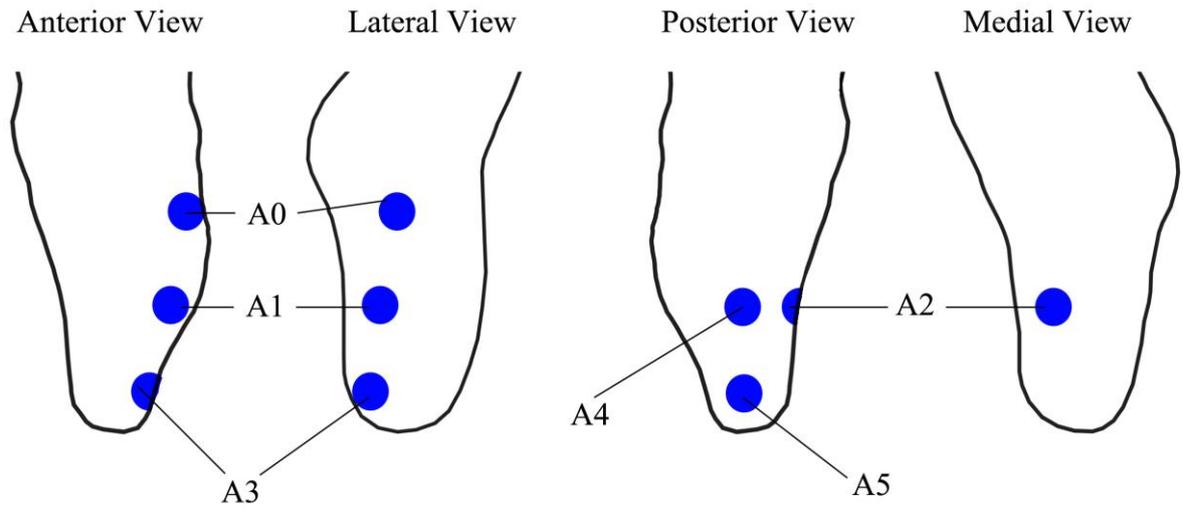


Figure 2. Arrangement of Thermistors around the residual limb during clinical evaluation

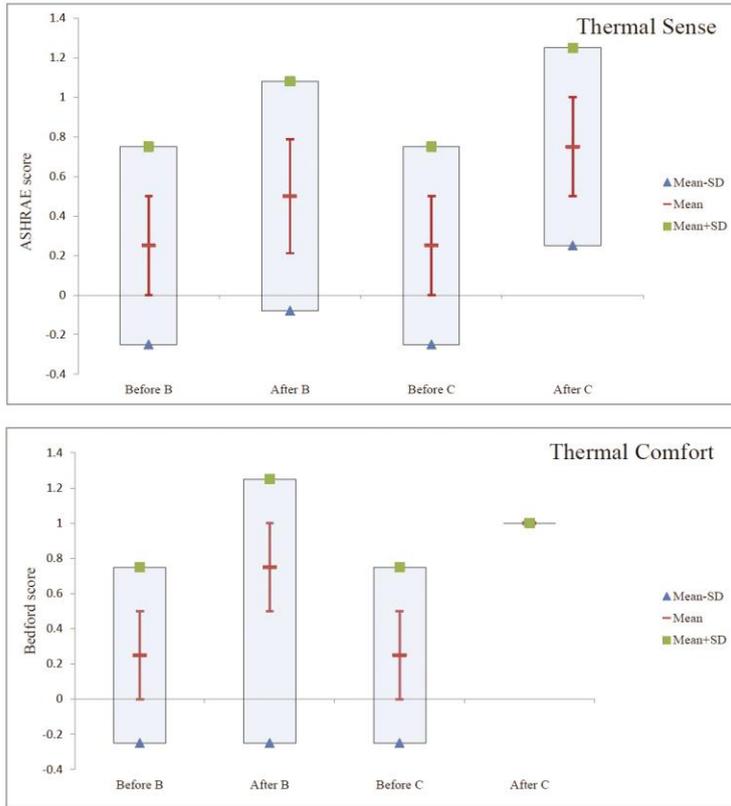


Figure 3. The results of thermal sense and thermal comfort assessments before and after of the B and C phases

Table 1. The residual limb skin temperature at six recording sites at A phases during four consecutive days

Thermistors	The first A phase (A ₁)					The second A phase (A ₂)				
	1 st	2 nd	3 rd	4 th	Mean±SD	1 st	2 nd	3 rd	4 th	Mean±SD
A0	28.93	29.94	29.97	30.01	29.72±0.52	28.82	29.26	29.24	29.16	29.12±0.20
A1	28.44	30.58	31.15	31.48	30.41±1.36	28.09	29.09	29.52	29.75	29.11±0.73
A2	28.71	30.40	29.87	30.01	29.75±0.73	28.20	28.74	28.76	28.62	28.58±0.26
A3	27.46	30.15	30.40	30.95	29.74±1.56	27.49	28.39	28.83	28.94	28.41±0.66
A4	28.30	30.05	30.27	30.45	29.77±0.99	29.21	27.70	28.20	28.56	28.42±0.64
A5	26.18	30.14	28.96	29.75	28.76±1.79	26.71	27.13	27.21	27.78	27.21±0.44

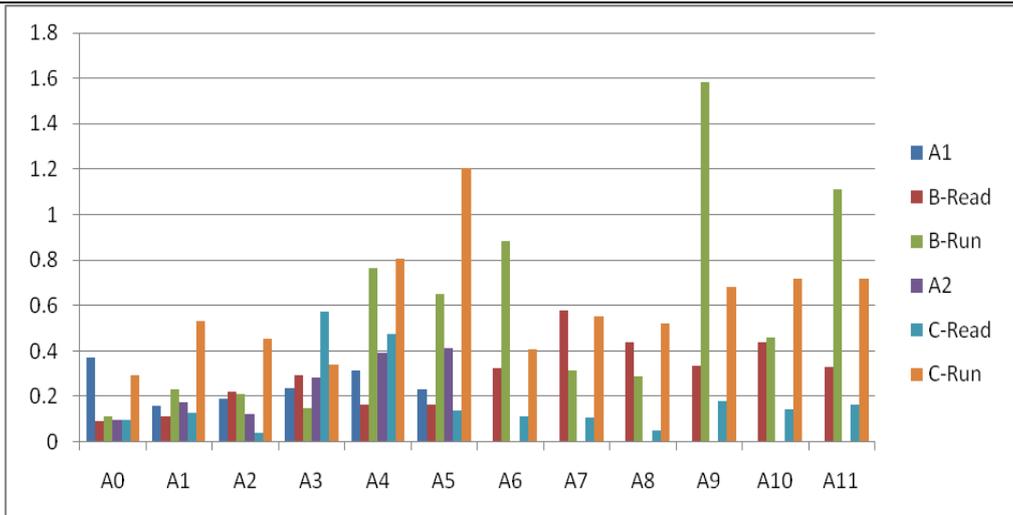
Table 2. The level±variability (Mean±SD*) of temperature change for each phase during 10-minute activation of the TM&C system

Thermistors	The first A phase (A ₁)	B-Read [†]	B-Run [‡]	The second A phase (A ₂)	C-Read	C-Run
A0	-0.25±0.37	0.20±0.09	0.10±0.11	-0.28±0.09	1.09±0.1 0	0.85±0.2 9
A1	-0.17±0.16	- 0.15±0.11	- 0.31±0.23	-0.02±0.17	0.93±0.1 3	0.97±0.5 3
A2	-0.33±0.19	0.21±0.22	- 0.29±0.21	-0.22±0.12	0.70±0.0 4	0.99±0.4 5
A3	-0.57±0.24	- 0.12±0.29	- 0.31±0.15	-0.06±0.28	1.61±0.5 7	0.96±0.3 4
A4	-0.32±0.31	- 0.14±0.16	- 1.47±0.77	0.10±0.39	1.57±0.4 7	0.52±0.8 0
A5	-0.37±0.23	0.05±0.16	- 1.68±0.65	0.07±0.41	1.22±0.1 4	0.60±1.2 0
A6		1.11±0.32	0.04±0.89		0.89±0.1 1	0.61±0.4 1
A7		1.16±0.58	- 0.60±0.32		0.60±0.1 1	0.62±0.5 5
A8		1.19±0.44	- 0.65±0.29		0.64±0.0 5	0.58±0.5 2
A9		1.35±0.33	- 2.05±1.58		1.04±0.1 8	0.51±0.6 8
A10		1.19±0.44	- 0.99±0.46		0.74±0.1 4	0.62±0.7 2
A11		1.43±0.33	- 1.44±1.10		0.78±0.1 6	0.52±0.7 2

Level



Variability



*SD: Standard deviation, †Read: 1st 10-minute of temperature recording, ‡Run: 2nd 10-minute of temperature recording

Table 3. The results of C statistic for internal Thermistors during read and run control modes of the TM&C system at A₁-B-A₂-C order of phases

Thermistors	Read (A ₁ -B-A ₂ -C)				Run (A ₁ -B-A ₂ -C)			
	Mean	C Score	Standard Error	Z* Score	Mean	C Score	Standard Error	Z* Score
A0	0.12	0.60	0.25	2.44	0.06	0.61	0.24	2.53
A1	0.11	0.81	0.25	3.27	0.06	0.84	0.24	3.49
A2	0.04	0.55	0.25	2.22	-0.03	0.81	0.24	3.37
A3	0.14	0.76	0.25	3.08	-0.06	0.86	0.24	3.57
A4	0.24	0.68	0.25	2.73	-0.34	0.65	0.24	2.70
A5	0.18	0.79	0.25	3.18	-0.41	0.62	0.24	2.59

*Z Score is significant at the 0.01 level when its value is > 2.17