

**The prototype of a thermoregulatory system for measurement and control of  
temperature inside prosthetic socket**

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## **Abstract**

**Background and Aim:** Thermal related problems with prostheses are common complaints of amputee people. This paper aims to introduce a thermoregulatory technique as a potential solution for those problems in prostheses wearers.

**Technique:** A smart thermoregulatory system was designed, manufactured, and installed on a phantom model of a prosthetic socket. It captured temperature data from sixteen sensors positioned at the interface between the phantom model and a silicone liner, and used their average for comparison with a defined set temperature to select required heating or cooling functions for thermal equilibrium. A thin layer of Aluminum was used to transfer temperature between thermal pump and different sites around the phantom model.

**Discussion:** The feasibility of this thermoregulatory technique confirmed by its ability to provide thermal equilibrium. Further investigations to improve the design of thermoregulatory system are necessary including temperature transfer element and power consumption based on thermal capacity and thermal inertia of the residual limb.

## **Clinical Relevance**

The smart thermoregulatory system by providing thermal equilibrium between two sides of a prosthetic silicone liner can control residual limb skin temperature and sweating. Consequently, it can improve quality of life in amputee people.

## **Background and Aim**

Considering prosthesis as a machine, the prosthetic socket is a simple type of human-machine interface that transfers loads and motions between the prosthesis and residual limb. A comfortable prosthetic socket can promote an amputee to use prosthesis more but on the other hand, a poor fitting one can decrease prosthesis use and affect the quality of life of an amputee. In spite of great advancement in technology and material science, prosthesis related complaints are still high. The osseointegration approach that aim to exclude the socket and suspension components from the prostheses, due to its high associated risks of infection, loosening, bone loss, bone fracture and high cost, has not been globally accepted. Therefore, using socket is still the most common method for prosthetic connection to residual limb.

Human body has a thermoregulatory system that regulates skin temperature by controlling the blood flow in skin vessels by vasoconstriction and vasodilation in cold and hot environments, respectively. Metabolic heat production and shivering are secondary mechanisms to increase body temperature in cold environment. On the other hand, evaporating moisture produced by skin sweat glands is secondary mechanism to decrease body temperature in hot environment <sup>1</sup>.

Due to the low thermal conductivity and moisture permeability, the prosthetic socket acts as a barrier to decrease of skin temperature of the residual limb <sup>2,3</sup>. In addition, prosthetic liner due to high flexibility and shape adaptability attaches snugly to the skin of the residual limb that exacerbates thermal discomfort by covering perspiration holes, limiting air circulation at skin-prosthesis interface, and promoting pressure-sweating reflex. Based on pressure-sweating reflex, applied pressure on sweating and blood vessels of skin may prevent perspiration and blood perfusion <sup>4</sup>. In a routine manner of weight bearing prostheses, the applied load on skin during activity can decrease skin temperature that will be reversed by

load removal. Therefore, even with little physical activity, e.g. 10 minutes walking, a prosthesis wearer can deal with thermal discomfort<sup>5,6</sup>. Complaints of heat buildup and sweating inside prosthetic sockets are common and their prevalence is nearly 53% in an amputee population<sup>7</sup>. In contrast, cold feeling complaints at the residual limb have been reported by amputees with vascular insufficiency or those who live in cold climate countries, especially during the winter months<sup>8</sup>.

This paper briefly reports a technique to design and fabricate of a thermoregulatory system to monitor and control temperature inside prosthetic sockets.

## **Technique**

### *Design and fabrication of the thermoregulatory system*

The thermoregulatory system was a smart system that sensed and controlled temperature to actuate a thermal pump. It consisted of a mechano-electrical combination of sixteen temperature sensors, a microcontroller board, a thermal pump, a temperature transfer layer of Aluminum, and a power supply.

To sense temperature, sixteen digital temperature sensors (TMP275, Texas Instruments Incorporated, USA), with 0.5° C accuracy and 0.0625°C resolution, were used in this project. Each temperature sensor was mounted on a small amplifier board (1x1.5cm) in series with a pull-up resistance of 2.2 KΩ and a 0.1 μF bypass capacitor. The microcontroller board was an Arduino Duemilanove (Arduino, Italy) prototyping platform that was equipped with supplementary shields for actuation of thermal pump and data logging.

For thermoregulation inside prosthetic socket both heating and cooling functions are required. Therefore, a thermal pump was structured by combination of a thermoelectric Peltier effect module (40x40x3.9mm, Welfare Electronic Component Ltd, Hong Kong), a heat

sink, and a fan. In addition, a thin layer of thermal grease used at interface between the thermoelectric module and the heat sink to increase the amount of temperature transfer. The thermal pump actuation for heating or cooling was controlled based on the polarity of its thermoelectric module. Moreover, two pulse width modulators were used to provide efficient bidirectional current flow to the thermal pump. A flexible and light layer of Aluminum (Figure 1), 1100-O with 0.4mm thickness, was attached to the thermal pump for temperature distribution to/from different distances around the thermal pump. Although some other materials are usable instead of Aluminum for this application but in addition to thermal conductivity the price, mass, biocompatibility, and flexibility of the selected material should be considered. As a comparison, although Copper may be another potential material that its thermal conductivity is 69% higher than Aluminum, but Copper is 230% heavier than Aluminum. The thermal conductivity to density ratio of Aluminum is almost two times higher (96%) than Copper. Moreover, Copper is 70% stiffer than Aluminum <sup>9</sup>.

Programming of microcontroller was based on C/C++ language using IDE software (version 1.5.7). It was a closed-loop control program based on PID (Proportional-Integral-Derivative) algorithm that tuned manually to capture temperature data from sensors to compare their average to a defined set temperature, and then actuate the thermal pump. The required power for activation of the thermoregulatory system was supplied by a 7V and 2A lithium ion battery with nominal capacity of 2.2 Ah. The longevity of battery life depends on temperature difference between measured and set temperatures, as well as the required time span for activity of thermal pump to provide thermal equilibrium.

### Procedure

In order to install the prototype of the thermoregulatory system and to conduct preliminary experiments, a phantom model of a prosthetic socket was fabricated. A silicone liner (Parasil Cushion Silicone Liner, ST&G Corporation, South Korea) was hanged in space by

mechanical holders and clamps and filled with nearly two liters of water. Thereafter, it was wrapped by plaster bandage to simulate a total contact socket. The negative impression was subsequently used to prepare a positive model with the dummies of the thermal pump and the microprocessor board for the lamination process. The real components were attached to the laminated phantom socket afterward.

The sensors were arranged in two vertical U-shaped loops, with eight sensors on each loop, and adhered to the inside wall of the phantom model using double-sided tapes. A thin Aluminum sheet was formed to follow the contour of the inside surface of the phantom socket and directly kept in contact with the silicone liner.

The required time span to provide thermal equilibrium between both sides of silicone liner during heating and cooling functions of thermal pump from baseline temperature of 24°C was measured. In addition, to investigate the amount of temperature transfer through the Aluminum layer, the temperature change from baseline to five minutes after thermal pump activation was measured on both the outside and inside surfaces of the silicone liner. These measurements were done at different distances to the center of thermal pump using a K-type thermocouple.

## **Discussion**

Heat and perspiration discomfort with prostheses are common complaints of amputee patients regardless of level and cause of amputation <sup>7</sup>. This study confirms the feasibility of measuring and controlling the skin temperature inside a prosthetic socket using a thermoregulatory system. Conceptually, it is possible to control sweating by controlling the skin temperature inside the prosthetic socket <sup>11</sup>. Moreover, a proper thermoregulatory system could also provide heating to increase skin temperature for those amputees with cold skin problem.

The thermoregulatory system (Figure 2) captured temperature data with a frequency of 1 Hz from sixteen sensors, transferred data to the microcontroller board, compared their average with a set-temperature of 31°C based on the findings of a previous study <sup>6</sup>, actuated required cooling or heating functions to provide thermal equilibrium, and transferred temperature to different sites around the phantom model using a thin layer of Aluminum.

The benefit of skin temperature control using conduction from outside surface of silicone liner was no dependability to skin blood flow. This feature permits thermoregulation even in vascular insufficient patients. Although tolerable temperature changes can be ranged from above freezing to nearly 45°C <sup>10</sup>, but for safety use of thermoregulatory system especially in patients with insensate limbs, an activation range based on temperature of thermal pump can be defined to alert patient when temperature is close to the limits.

Although thermal conductivity of silicon liners are low, around 0.181-0.266 W/m.°K <sup>2</sup>, but in a fraction of time the temperature change outside the liner could be conducted to the inside of liner. Measuring thermal conductivity for selected liner material was beyond the scope of this note, however the required time to provide thermal equilibrium between outside and inside surfaces of silicone liner, exactly at the center of thermal pump, during heating and cooling functions of thermal pump from a baseline temperature of 24°C was measured and presented in Table 1.

Hence the phantom model was related to transtibial residual limb, and expected range of temperature change during rest and activity in transtibial prostheses is about 1-2°C <sup>5,6</sup>, five minutes activation of thermal pump seemed reasonable to investigate temperature transfer using Aluminum layer. The results of temperature measurements on inside and outside

surfaces of the silicone liner, from baseline to five minutes after thermal pump activation, are presented in Table 2.

The results showed that by increasing distance from thermal pump, the amount of temperature difference between both sides of silicone liner drops rapidly that may suggest that design may not be all that effective, but considering the required small temperature change to provide thermal comfort inside prostheses, it can be suggested that preliminary tests of the thermoregulatory system provide promising results.

The pattern of temperature distribution on skin surface of the residual limb follows an asymmetry pattern due to its heterogeneous structure of different body tissues with different thermal characteristics. To some extent, this pattern may be related to muscle thickness <sup>12</sup>. Moreover, the proximal part of the residual limb has higher temperature comparing to its distal part <sup>5,6</sup>. The thermography map, thermal capacity, and thermal inertia of residual limb need further investigations. In addition, the material and pattern of temperature transfer element, and best attachment site of thermal pump need more investigations. These issues should be considered to improve the design of thermoregulatory system, its power consumption, and total weight <sup>6</sup>. A modular-based design of thermoregulatory system with smaller amplifier and control boards can be suggested to decrease its current weight of 550 g, as well as more wearing comfort for its final design.

The limitations of this technical note were no thermal capacity and thermal inertia evaluations that could help with determining the required time span for activation of thermal pump in real situation, and use of a symmetric pattern for temperature transfer element in contrast to realistic thermography map of residual limb. Further investigations to improve the design of thermoregulatory system and its application in clinical set up are necessary.

## **Key Points**

- The prototype of a thermoregulatory system was designed, fabricated and installed on a phantom model with preliminary investigations.
- This system aimed to keep a thermal equilibrium between the inside and outside surfaces of a silicone liner at a defined range of temperature.
- A thin layer of Aluminum was used for temperature transfer between the thermal pump and different sites around the phantom model.
- Cooling or heating temperature changes could be conducted from the outside surface to the inside surface of a silicone liner in a fraction of time.

## **Declaration of Conflicting Interests**

None Declared.

## **Acknowledgments**

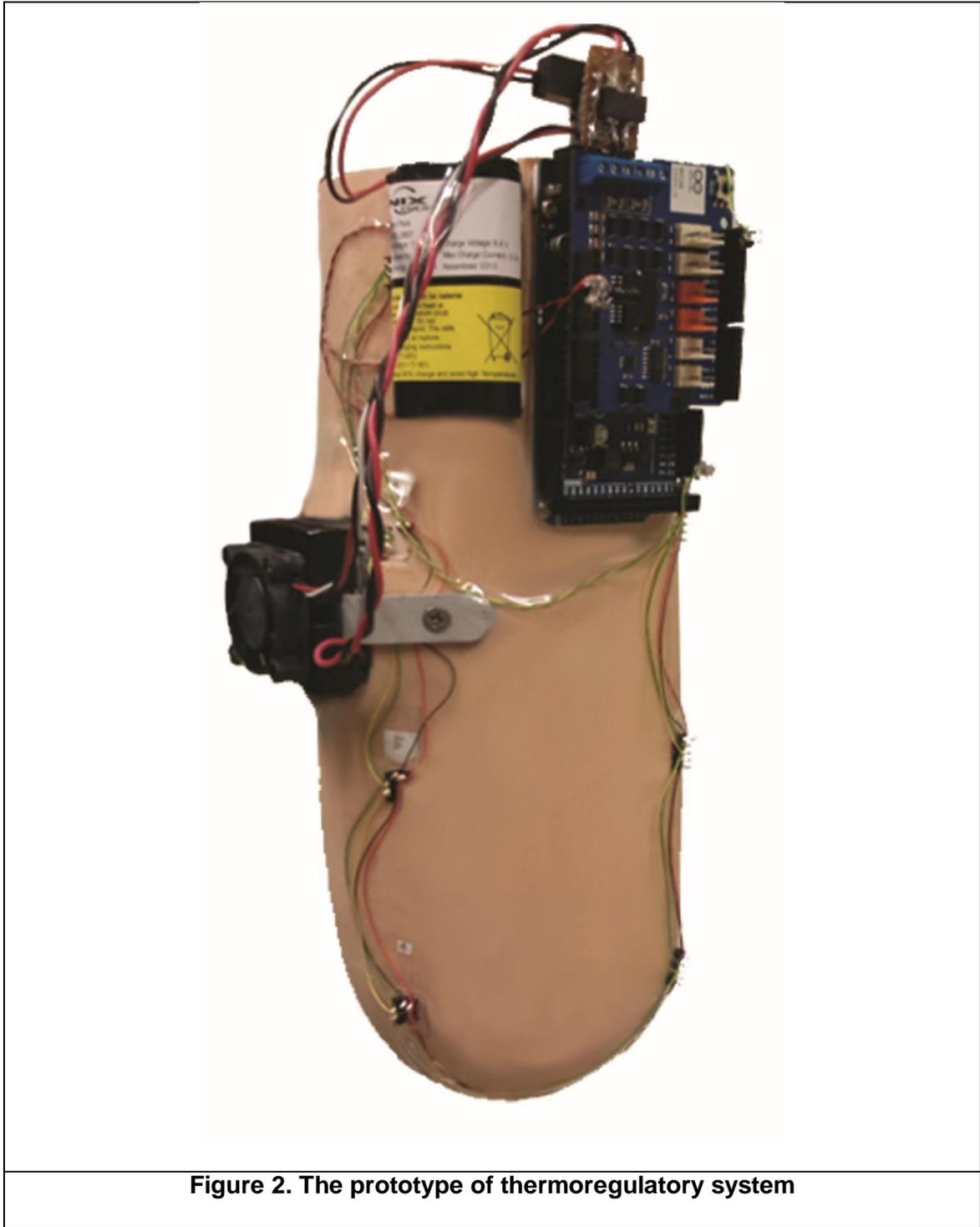
The authors would like to thank Mr. Ho Yip Li and Mr. Hung Yu Chow for their assistance in the fabrication of the phantom model, and ST&G Corporation for donation of silicone liner.

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**Figure 1. The Aluminum temperature transfer layer**



| Table 1. Time span required for thermal equilibrium between outside and inside surfaces of silicone liner during heating and cooling functions from baseline temperature of 24°C |                          |            |                         |
|--|--------------------------|------------|-------------------------|
| Temperature outside liner  | Temperature inside liner | Time (Min) | Thermal Pump Activation |
| 30   | 30                       | 3.4        | Heating                 |
| 29   | 29                       | 2.9        |                         |
| 28   | 28                       | 2.5        |                         |
| 27   | 27                       | 2.2        |                         |
| 26   | 26                       | 1.7        |                         |
| 25   | 25                       | 1.3        |                         |
| <b>Baseline Temperature: 24°C</b>  |                          |            |                         |
| 23   | 23                       | 2.4        | Cooling                 |
| 22   | 22                       | 4.6        |                         |
| 21   | 21                       | 7.5        |                         |
| 20   | 20                       | 9.5        |                         |
| 19   | 19                       | 11         |                         |
| 18   | 18                       | 15.3       |                         |

| Table 2. Temperature difference from baseline to five minutes after thermal pump activation at different distances from the center of thermal pump |   |  |
|--|---|--|
| Distance to Center of Thermal Pump (cm)  | Temperature Difference Outside Liner (°C) | Temperature Difference Inside Liner (°C) |
| 0  | 10.2                                      | 9.9                                      |
| 9  | 1.8                                       | 1.7                                      |
| 14   | 1.6                                       | 1.4                                      |
| 19   | 0.4                                       | 0.3                                      |
| 23   | 0.4                                       | 0.3                                      |