Wearable Deep Body Thermometers and Their Uses in Continuous Monitoring for Daily Healthcare

Ming Huang, *Member*, *IEEE*, Toshiyo Tamura*, *Senior Member*, *IEEE*, Takumi Yoshimura, Tadahiro Tsuchikawa and Shigehiko Kanaya

***Abstract*— This paper introduces noninvasive deep body thermometers suitable for continuous deep body temperature (DBT) measurement. On the basis of their features, they were used in DBT monitoring for daily healthcare. A thermometer based on the dual-heat-flux method (T_DHFM), and an aural canal thermistor (ACT), were used in two studies of daily healthcare. The medical device CoreTemp by Terumo, based on the zero-heat-flux method, was also used for a DBT reference. The first study focused on preventing heat stroke in a high-temperature and high-humidity environment, while the other focused on the temperature monitoring of patients with spinal cord injuries. In the first study, CoreTemp and T_DHFM were used, whereas T_DHFM and ACT were used in the second study. Using the results from these two studies, we discuss the availability and performance of each thermometer and indicate the necessity of an appropriate method of measuring DBT.**

I. Introduction

The continuous monitoring of vital signs has revealed an increasing amount of information about the human body. It provides time series data, with which trends in physiological changes can be identified [1, 2]. The shift in measuring vital signs from a hospital setting to an ambulatory setting and in daily life has been propelled by the popularity of wearable devices. Starting with a wearable pulse oximeter, blood pressure and deep body temperature (DBT) can now be measured continuously using lightweight devices.

Among the vital signs, DBT is inherently difficult to measure noninvasively. It refers to the temperature inside the natural cavities of the human body and thus requires invasive measurement. Rectal temperature is generally used as a gold standard in a hospital setting. However, DBT monitoring is needed not only in hospital but also for healthcare in daily life.

For example, the physiological monitoring of construction workers is now becoming increasingly important in order to adhere to strict rules protecting those who work outdoors. In this context, heat strain control is essential, especially in summer. In Japan, workers are required to wear a long-sleeved jacket and trousers while working. This makes heat dissipation more difficult. There are thus strong demands for the close monitoring of thermal regulation. Another example of the use of physiological monitoring is that of people with spinal cord injuries. For paraplegics and quadriplegics, temperature receptors in the body cannot communicate with the hypothalamus, which induces poikilothermia. However, in these individuals, outdoor activities are recommended to improve their quality of life; therefore, when outdoors, their body temperature should be monitored appropriately.

In the above scenarios, only noninvasive methods are applicable. In the present study, we thus focused on the following noninvasive methods: use of the medical device CoreTemp by Terumo, based on the zero-heat-flux method (ZHFM); use of a thermometer based on the dual-heat-flux method (T_DHFM); and use of an aural canal thermistor (ACT). Among these, CoreTemp and ACT have been approved by the Pharmaceuticals and Medical Devices Agency of Japan. These three devices will be briefly introduced later.

We carried out studies on the above two scenarios using practical experiments. For heat stroke prevention, trials were carried out in a high-temperature and high-humidity environment, while the temperature monitoring of paraplegics during outdoor activities was carried out in winter. Using the findings from these two studies, the availability and performance of each thermometer and the necessity of an appropriate method of measuring DBT are discussed.

II. Methods

A. *Wearable Deep Body Thermometers*

DHFM

DHFM is a relatively new method that calculates the DBT based on the heat flux inside a probe. It was originally proposed by Kitamura *et al*. [3]. Using a double heat path inside a probe, it is possible to calculate the DBT using temperature sensors embedded within the probe. The fundamental principle of DHFM is illustrated by Fig. 1. A substrate material with four embedded temperature sensors constitutes the core of the probe. The substrate material has similar physical properties to skin and, when it is attached to skin, the heat flow from the body core due to the difference

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M. Huang and S. Kanaya are with Nara Institute of Science and Technology, Ikoma, Nara 630-0192, Japan ;(e-mail: {alex-mhuang, skanaya}@is.naist.jp).

T. Tamura is with Osaka Electro-Communication University, Neyagawa, Osaka 575-0063, Japan (corresponding author Phone +81-72-824-1131 fax +81-72-824-0014 e-mail: tamurat@isc.osakac.ac.jp).

T. Yoshimura is with Tokyo Metropolitan college of Industrial technology, Tokyo Japan (e-mail. t-yoshim@metro-cit.ac.jp)

T. Tsuchikawa is with University of Hyogo, Shinzaike-honcho, Himeji, Hyogo, 670-0092, Japan (e-mail: tad@shse.u-hyogo.ac.jp)

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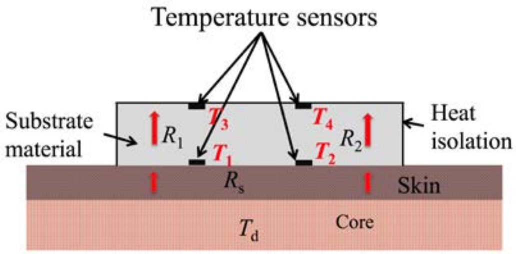

Fig. 1. Illustration of dual-heat-flux method. The substrate material has similar heat conductivity to skin and thus the heat flow is considered to occur vertically from the body into the material

between the DBT and the skin temperature mostly occurs into the substrate material. Additionally, upon implementing heat isolation peripheral boundary conditions, the heat flows longitudinally. Since the two heat paths (T_1–T_3, T_2–T_4) are located transversely close to each other, the thermal resistors in the skin layer of the two heat paths are the same and, thus, one can calculate the DBT using the four sensors (T_1–T_4) by the equation below, where k (= R_1/R_2) is the ratio of heat resistors inside the probe of the two heat paths.

$$T_{\mathrm{d}} = T_1 + \frac{(T_1 - T_2)(T_1 - T_3)}{k(T_2 - T_4) - (T_1 - T_2)}. \quad (1)$$

Regarding the accuracy of the original prototype of this method, its results differ by less than 0.1°C from the reference CoreTemp thermometer; however, it requires an additional urethane sponge cover. This method was improved by Huang *et al.* based on theoretical simulation and experimental validation [4, 5]. By lacking an external heater, its energy consumption is greatly improved, making this method readily implementable in a wearable modality.

Based on the results of DHFM, we recently developed a prototype system and tested its basic performance [6, 7]. For the two studies performed here, as mentioned above, prototypes with a height of 15 mm and a radius of 22 mm were used in the pit of the stomach (Fig. 3).

ACT

The aural canal is a suitable location for body temperature measurement. Using a thermistor set inside the probe, the temperature of the external aural canal can be determined. If appropriate shielding from ambient convection can be achieved, the temperature measured by this device can be regarded as a good approximation of DBT. Additionally, concern over perforation of this kind of thermometer is mitigated by the coating of the thermistor with soft material.

The ACT that we used is manufactured by Nikkiso-Therm

Fig. 2 The aural canal thermistor used in the study of temperature monitoring of a patient with spinal cord injury. The aural canal thermistor that we used is manufactured by Nikkiso-Therm Co.

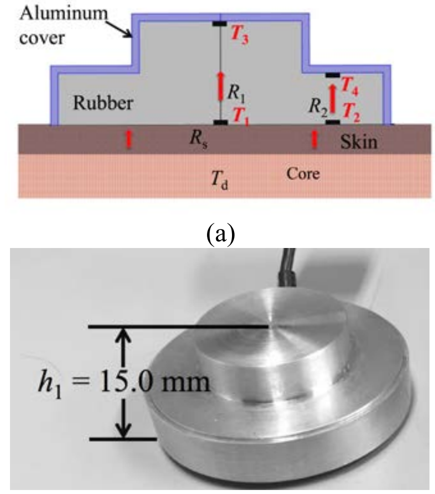

Fig. 2. Design and image of the dual-heat-flux method-based probe used in the studies. The double-cylinder design shown in (a) is used to generate two heat paths with different heat resistors. The prototype (b) is fabricated according to the design shown in (a) with four inlaid temperature sensors

Co. (Tokyo, Japan) and is shown in Fig. 2. Temperature is sampled at a frequency of 1 Hz and then transmitted by Bluetooth to a data logger and saved. The thermistor is embedded in a soft ear-plug and can measure the temperature with an error of less than 0.1°C.

ZHFM

ZHFM was originally proposed in the 1970s by Fox and Solman [8]. It involves the use of a noninvasive deep body thermometer with good traceability and accuracy comparable to those of standard invasive methods. Its fundamental mechanism is based on the fact that, by heating up a cutaneous probe to the extent that there is no temperature gradient inside it, it can be considered that no heat will flow into the probe from the contiguous skin and thus no heat will flow from the interior of the body onto the skin. The DBT will then be equal to the temperature of the probe. This method was subsequently improved by Togawa's group and Terumo Co. (Tokyo, Japan) [9]. The thermometer fabricated by Terumo has been approved as a medical device by the Pharmaceuticals and Medical Devices Agency of Japan and its measurements have been shown to correlate well with blood temperature during cardiopulmonary operations [10]. The convenience provided by this noninvasive thermometer has led to other manufacturers, such as Philips [11,12] and 3M [13], also expending great effort on developing their own sensors based on ZHFM.

Thanks to the adoption of the external heater embedded inside the probe, ZHFM shows a rapid response to the change of DBT with stable readings; however, the power consumption has also restricted this method from being used in daily life. Using this kind of thermometer, it is only possible to perform the continuous monitoring of DBT in a hospital setting.

B. Experimental Studies

The performances and availabilities of these two wearable thermometers were applied to the studies in environments experienced in daily life. The first study focused on the prevention of heat stroke in a high-temperature and high-humidity environment. In this experiment, both CoreTemp and T_DHFM were applied. In addition, the surface temperatures (ST) inside and outside a jacket were monitored and regarded as potential parameters for judging the thermal state of the human body.

Six young male subjects (age: 25.3±8.9 years, height: 169.6±5.2 cm, weight: 64.7±8.6 kg) participated in these experiments. They underwent experiments in an isothermal chamber under conditions of ambient temperature of 40°C and relative humidity of 40%. Each experiment comprised three phases: acclimation (10 min), cycling exercise (20 min, 50 W), and recovery (10 min).

DBT at the forehead and back and ST inside and outside a jacket were measured using a noninvasive thermometer (CoreTemp CM-210; Terumo). CM-210 recorded all of the temperature data at intervals of 2 s. In addition, T_DHFM was applied at the pit of the stomach, with sampling at intervals of 1 s. The set up of the probes is shown in Fig. 4.

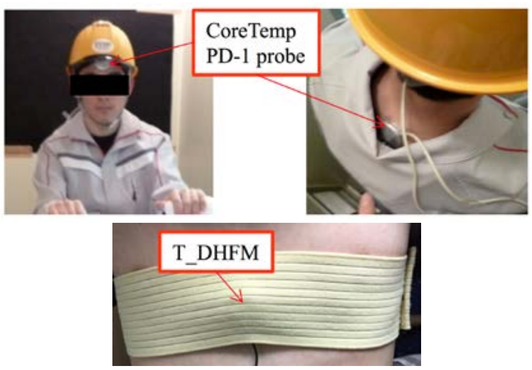

Fig. 4. The set-up of CoreTemp and the dual-heat-flux method. The probes of CoreTemp were fixed with surgical tape, while the device for the dual-heat-flux method was fixed to the pit of the stomach using a supporter belt..

The second study focused on monitoring the temperature of patients with spinal cord injuries, in which T_DHFM and ACT were used. CoreTemp is not suitable here since it is powered by an alternating current. This experiment was carried out based on the conclusion that, by T_DHFM, it is possible to measure DBT change in the thorax and, thus, to compare these two methods experimentally. The experiment lasted 6 h, from 14:00 to 20:00 in late fall, with an average outdoor temperature of 10.2°C. A patient (with a spinal cord injury) and a healthy control underwent the same protocol. In the first phase, both subjects stayed in a room with the temperature at 20°C for 4 h (14:00–18:00), after which they both went out to a park for about 2 h and then returned to the room at 20:00. The experiments were approved by the Ethics Committees of Nara Institute of Science and Technology, Osaka Electro-Communication University, and the University of Hyogo. The informed consents were received from all subjects.

III. Results

Our studies were aimed at examining the performance of the three methods for practical applications in terms of their availability and stability. For the study on preventing heat stroke, we evaluated the availability of T_DHFM in an environment in which the temperature is higher than the DBT. Since CoreTemp has a maximum working temperature of 40°C with 0.1°C error, it was regarded as a reference against which to evaluate T_DHFM. The justification for using the surface temperature as the only criterion representing the thermal state was also examined.

The measurements of ST and DBT by CoreTemp are summarized in Table 1, for which the mean values are shown. For each kind of measurement, two-sample *t*-test was used to test the relationship between two situations, namely, the cycling phase and the recovery phase, whereas the acclimation phase data were not analyzed. From Table 1, it can be seen that there was no significant difference for ST, while the DBTs at the forehead and back were both significantly higher than during the cycling phase.

TABLE I. Summary of the temperature measurement in the study on preventing heat stroke

Situ.	ST (Mean ± SD °C)		CoreTemp (Mean ± SD °C)	
	Inside	***Outside***	***Back****	***Forehead****
DE	38.36 ± 0.19	38.96 ± 0.23	37.04 ± 0.18	37.24 ±0.09
AE	38.39 ± 0.12	38.94 ± 0.13	37.29 ± 0.03	37.38 ±0.03

Situ. is the condition of the subject; DE denotes the situation during exercise by cycling; AE denotes the situation after the exercise; Inside and Outside denote the surface temperatures inside and outside the jacket; SD means the standard deviation and Back and Forehead denote the deep body temperature measurements at the back and forehead. An asterisk denotes that there is a significant difference between the two situations that there is significant difference between the two situation.

The availability of T_DHFM was examined using CoreTemp as a reference. Since T_DHFM is a passive method, it took longer (by ~20 min) to achieve heat equilibrium than

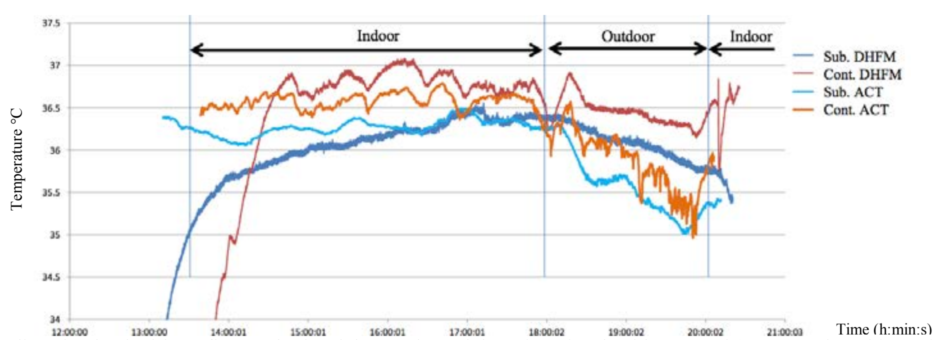

Fig. 5. Time series recordings by the dual-heat-flux method and the aural canal thermistor in a healthy control (Cont.) and a subject with a spinal cord injury (Sub.). The protocol consisted of two phases: indoor monitoring (~4 h) and outdoor monitoring (~2 h)

with CoreTemp. The average difference between the forehead (with CoreTemp) and the pit of the stomach (with T_DHFM) was 0.07°C, while that between the back (with CoreTemp) and the pit of the stomach (with CoreTemp) was 0.14°C.

Regarding the monitoring of patients with spinal cord injury, the availabilities of both thermometers were examined using time series recordings (Fig. 5). As indicated in the first study, T_DHFM required a certain period of time to achieve heat equilibrium, but this period was much longer for the subject with spinal cord injury (>1 h) than for the control (~30 min).

For both thermometers, the outdoor environment influenced the measurements, as shown by the data at around 18:00. The measured values decreased abruptly when the subjects went outside, with the exception of the T_DHFM of the target subject. This may have been due to special measures against getting cold having been taken, which limited the influence of the environment on T_DHFM.

The influence of the outdoor environment was maintained throughout the outdoor activities for ACT, which can be seen from the recordings of both the control and the target subjects. The recordings of ACT decreased to a level (<36°C) that would seldom occur in a thermoneutral person. In contrast, T_DHFM was rather stable for both of them.

IV. Discussion

DBT is considered to be a crucial index for representing the thermal status of individuals. However, owing to restrictions in the methods for measuring it, this parameter is generally only available in a hospital setting. Even for CoreTemp, which has shown satisfactory accuracy when compared with standard invasive methods [9], it is still difficult to extend its range of applications.

Therefore, for the prevention of heat stroke, ST is widely used. However, from the first study in the current work, we determined that the use of this variable alone might be insufficient. When measuring DBT, significant changes were seen; however, the ST neither inside nor outside the jacket reflected these changes. A more reliable index of the internal thermal state is thus needed and the passive DHFM method may be an ideal substitute for CoreTemp, according to the results of this study. Apart from the good accuracy it showed compared with CoreTemp, its low power consumption makes it suitable for a wearable modality.

Temperature measurement in the aural canal is considered a suitable substitute in continuous DBT monitoring. This is especially true for paraplegics, whose skin temperature in the lower limbs differs from that in healthy people. However, our second study showed that ACT is easily influenced by changes in the environment. Using this approach, caregivers would thus have difficulty determining the actual thermal state of the user. On the other hand, the measurements by T_DHFM were stable, which may have been due to clothes acting as a shield against the ambient airflow. It may also have been due to the design mitigating the influence of the environment.

V. Conclusion

By analyzing noninvasive methods for measuring DBT, we attempted to meet the practical need for continuous monitoring of DBT using the CoreTemp medical device, T_DHFM, and ACT. The CoreTemp device provided stable measurements but is not really practical in environments encountered in daily life, while ACT is vulnerable to changes in the environment, such as temperature changes or the wind. On the other hand, T_DHFM is capable of providing good accuracy and is more resistant to environmental influences, potentially making it an ideal substitute for continuous DBT monitoring for healthcare in daily life.

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