Evaluating Accuracy of Digital Thermometers Using a Tissue Phantom Mimicking Normal and Fever Environments[1]

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1 Background

Body temperature monitoring is an important tool for helping clinicians diagnose infections, detect fever, monitor thermoregulation functions during surgical procedures, and assess postsurgery recovery. Commercially available ("store brand") fast read thermometers have been developed to predict body core temperatures based on the first few seconds of temperature recordings either orally or under the arm. Our recent clinical study [1] demonstrated temperature variations from one body site to another and their deviations from the true body core temperature. Our study was the first where temperature transients were recorded in a clinical setting by a fast responding reference thermometer—based on a thermistor bead sensor—at two body sites. It is also the first time the reference thermometer was placed simultaneously with a store brand digital thermometer to evaluate the digital thermometer's algorithm-based temperature predictions. There was a large temperature measurement variation between the reference and store brand thermometers during the initial 10 s of measurement. Compared to the measurements from the reference thermometer after 120 s, the store brand thermometers routinely overestimated or underestimated the actual temperature by up to 2 °C in both healthy and sick patients. The predictive algorithm apparently does not capture the initial temperature variations; therefore, the accuracies of the store brand thermometers used were questionable. The objective of this study was to develop a tissue-equivalent human upper arm phantom as a system to simulate different clinical thermal conditions of a human body to evaluate the performance of store brand digital thermometers.

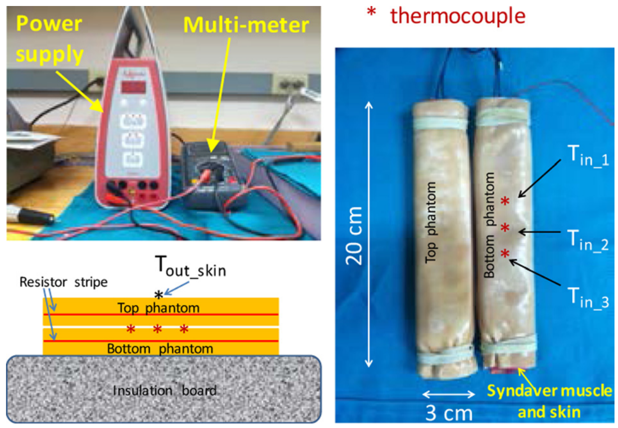

Fig. 1 Experimental setup of arm phantoms

2 Methods

Artificial muscle and skin were purchased from SynDaver™ Labs (skin and muscle plates, fatty, Caucasian, SynDaver™ Labs, Tampa, FL). The 20 cm × 20 cm sheet of artificial muscle (2 mm thickness) was rolled to form a cylinder and then covered by the artificial skin sheet (1 mm thickness). Flat resistor strips (SRFG-108/5 Silicone Rubber Heater, Omega Engineering, Inc., Stamford, CT) were used as heating elements, since they were easily embedded in the SynDaver™ muscle. A DC power supply (PS300B, Hoefer, Inc., Hilliston, MA) provided controllable incremental adjustments in the voltage to the flat resistors. Two identical tissue-equivalent phantoms were constructed and stacked together. The interface of the two phantoms mimics the thermal environment of the axillary temperature measurement site, i.e., under the arm (Fig. 1). Thermal properties of the SynDaver™ tissue were measured to evaluate whether they were similar to those of human tissue. Based on a 3D whole body heat transfer simulation [2], the flat strip resistors were imbedded into the arm phantom and the power supply was adjusted to establish temperatures at the arm and torso interface similar to those seen in vivo.

Twenty-five digital thermometers each of three store brands were used in this study. Each store brand thermometer was inserted into a disposable sheath simultaneously with the reference thermometer (Fig. 2). Three different interface temperatures were tested to simulate (1) normal conditions, (2) modest fever conditions, and (3) high fever conditions. The power level was selected to achieve the

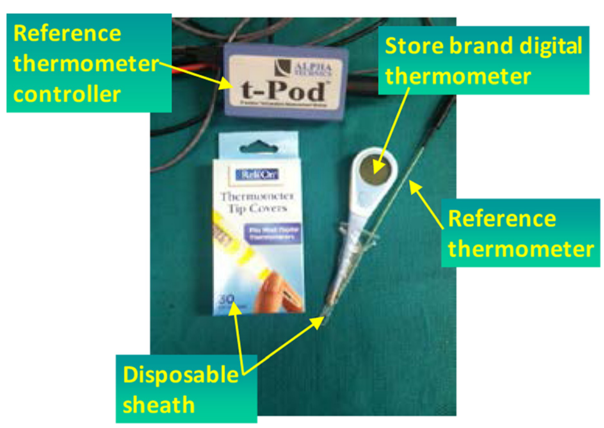

Fig. 2 A store brand thermometer and a reference thermometer are placed together inside a disposable sheath

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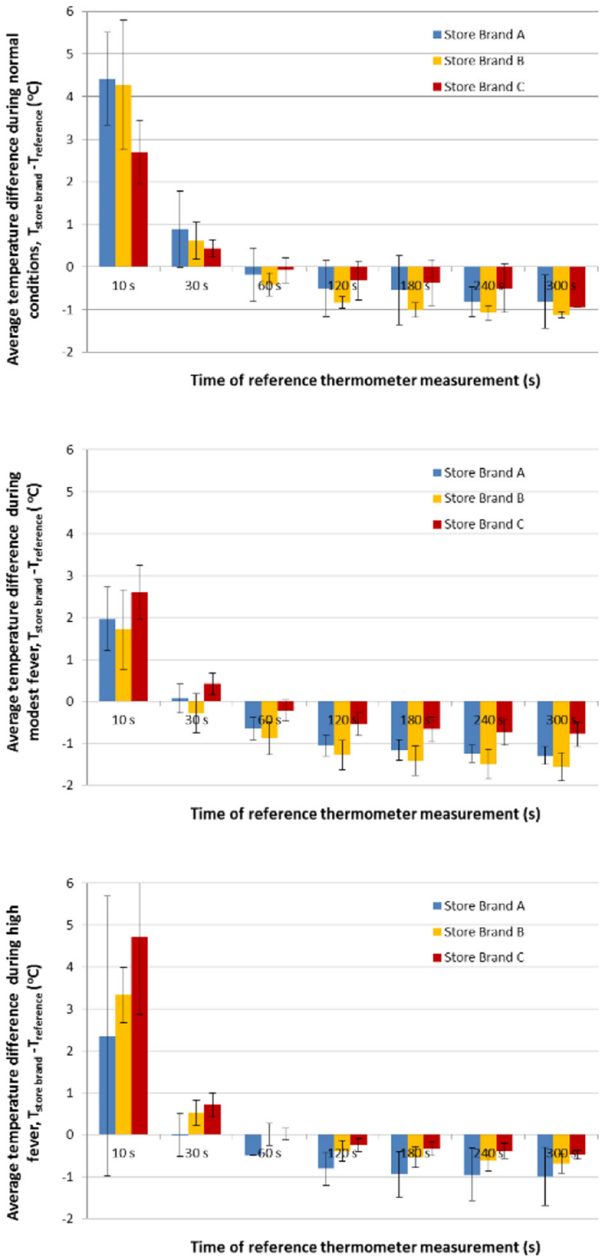

Fig. 3 Temperature difference between the store brand thermometers' prediction and that by the reference thermometer at different times, ($T_{\text{store brand}} - T_{\text{reference}}$). Top: normal, middle: modest fever, and bottom: high fever.

desired temperature at the interface based on our preliminary evaluations. Once the steady-state temperature field was established in the arm phantom, the store brand digital thermometer and the reference thermometer were placed side-by-side in the disposable sheath. The store brand thermometer was prepared for measurement following the manufacturer's instructions. The pair of thermometers was then inserted between the two tissue phantoms. It usually only took a few seconds for the store brand thermometer to complete its measurement. The pair remained between the phantoms for approximately another 5 min, allowing the reference thermometer to record the temperature transients at the interface.

3 Results

The tested SynDaver™ muscle had thermal properties ($k = 0.452$ W/m K and $a = 1.12 \times 10^{-7}$ m^2/s) similar to that of human tissues [2]. Figure 3 shows the temperature difference between the store brand thermometer's prediction of the body temperature and that by the reference thermometer. Note that the store brand thermometer only predicts once, while the reference thermometer measures the temperature at the interface continuously for 300 s. The temperature measured by the reference thermometer at $t = 300$ s was considered to be the thermal equilibrium temperature at the site. All the three store brand thermometers constantly underestimated the thermal equilibrium temperature at the site by up to 1.8 °C.

All the store brand thermometers state that the thermometer should be turned on before it is inserted into the measurement site. Since the temperature of the thermometer will respond to the warm environment of the interface of the phantoms, we performed a subsequent test to investigate how the timing of when the store brand thermometer is turned on affects the predicted equilibrium temperature by the digital thermometer. We randomly selected eight store brand A [1] thermometers to evaluate the effect. Following the previously described experimental procedures, each thermometer was turned on with three different timings and subsequent measurements: (1) before the insertion, (2) 30 s after the insertion, and (3) approximately 300 s after the insertion. Figure 4 shows that when the thermometers were turned on before the insertion, the average temperature predicted was barely 37.32 °C, resulting in an indication of "false negative" since the actual thermal environment is the modest fever conditions (∼39 °C). However, only 30 s after the insertion, the thermometers predicted a much higher average temperature of 38.36 °C, which was only approximately 0.5 °C below the thermal equilibrium temperature by the reference thermometer at 300 s. It was not surprising to see that the store brand thermometers predicted an average value of 38.91 °C when the thermometers were turned on 300 s after insertion, very close to the average thermal equilibrium temperature by the thermistor bead sensor.

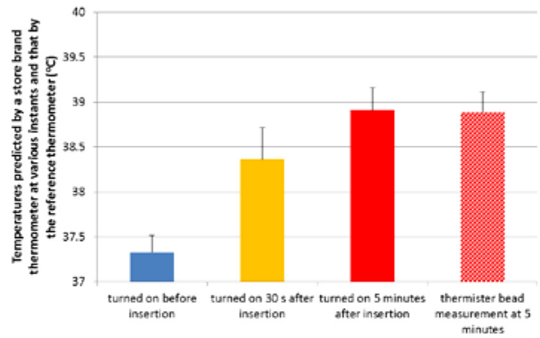

Fig. 4 Thermal equilibrium temperatures measured by the reference thermometer and the temperatures predicted by store brand A thermometers when measured at different time instants

4 Interpretation

A human arm phantom constructed using SynDaver™ muscles was capable of simulating the thermal environment in a human arm and its thermal interaction with the torso and the colder ambient environment. Based on the average measured temperatures, the three store brand thermometers consistently underestimated the thermal equilibrium temperature measured at $t = 300$ s, with a discrepancy ranging from 0.6 to 2.0 °C lower than the equilibrium temperature. The values of these discrepancies are consistent with the discrepancies measured in our previous clinical study [1]. However, the results here were only underestimates of the reference temperature (after 60 s), while in the clinical study, the store brand thermometer both under- and overestimated the reference temperature (at 120 s). Among the three thermal environmental conditions, all the store brand thermometers were the least accurate under the modest fever conditions. All the store brand thermometers appear to produce reasonable measurements to evaluate the body temperatures of patients when their body temperatures are normal. When the patients have a high fever (∼40 to 41 °C), the store brand thermometer will still indicate fever, although they underestimate the actual temperature by 0.5–1.0 °C. Under modest fever conditions (∼38.5 to 39.5 °C), all the store brand thermometers may fail to indicate fever, thereby potentially resulting in misdiagnosis and delays in treatment. One recommendation to improve the accuracy of the store brand thermometers is to insert the thermometer into the measuring site for more than 30 s before the actual measurement is executed.

Acknowledgment

The mention of commercial products, their sources, or their use in connection with materials reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services.

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