An Evaluation of a Zero-Heat-Flux Cutaneous Thermometer in Cardiac Surgical Patients

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BACKGROUND: Although core temperature can be measured invasively, there are currently no widely available, reliable, noninvasive thermometers for its measurement. We thus compared a prototype zero-heat-flux thermometer with simultaneous measurements from a pulmonary artery catheter. Specifically, we tested the hypothesis that zero-heat-flux temperatures are sufficiently accurate for routine clinical use.

METHODS: Core temperature was measured from the thermistor of a standard pulmonary artery catheter and with a prototype zero-heat-flux deep-tissue thermometer in 105 patients having nonemergent cardiac surgery. Zero-heat-flux probes were positioned on the lateral forehead and lateral neck. Skin surface temperature probes were attached to the forehead just adjacent to the zero-heat-flux probe. Temperatures were recorded at 1-minute intervals, excluding the period of cardiopulmonary bypass, and for the first 4 postoperative hours. Zero-heat-flux and pulmonary artery temperatures were compared with bias analysis; differences exceeding 0.5°C were considered to be potentially clinically important.

RESULTS: The mean duration in the operating room was 279 ± 75 minutes, and the mean cross-clamp time was 118 ± 50 minutes. All subjects were monitored for an additional 4 hours in the intensive care unit. The average overall difference between forehead zero-heat-flux and pulmonary artery temperatures (i.e., forehead minus pulmonary artery) was −0.23°C (95% limits of agreement of ±0.82); 78% of the differences were ≤0.5°C. The average intraoperative temperature difference was −0.08°C (95% limits of agreement of ±0.88); 84% of the differences were ≤0.5°C. The average postoperative difference was −0.32°C (95% limits of agreement of ±0.75); 84% of the differences were ≤0.5°C. Bias and precision values for neck site were similar to the forehead values. Uncorrected forehead skin temperature showed an increasing negative bias as core temperature decreased.

CONCLUSIONS: Core temperature can be noninvasively measured using the zero-heat-flux method. Bias was small, but precision was slightly worse than our designated 0.5°C limits compared with measurements from a pulmonary artery catheter. (Anesth Analg 2014;119:543–9)

Perioperative core temperature perturbations are common, and unwarmed surgical patients nearly always become hypothermic. Hypothermia may lead to complications including myocardial events,[1] surgical site infections,[2,3] coagulopathy,[4] and prolonged recovery.[5] It is thus the standard of care to monitor temperature and maintain core normothermia perioperatively.

The ideal core temperature thermometer should be noninvasive, accurate during large changes in physiological conditions, independent of operator and technique, easy to use, and provide continuous measurements. Invasive core temperature can be measured at the pulmonary artery, tympanic membrane, nasopharynx, or distal esophagus. Among these, the esophagus is perhaps the most widely used in patients whose tracheas are intubated. However, it is challenging to measure core temperature in unintubated patients, and it is challenging postoperatively.[6]

The skin surface has been used to estimate core temperature; however, skin temperature is several °C lower than core temperature, and the relationship between core and skin surface temperature varies among individuals, as well as over time within individuals.[7] Furthermore, skin temperature poorly reflects the rapid increase in core temperature as may occur with patient rewarming during cardiopulmonary bypass (CPB) or that associated with malignant hyperthermia.[8] An alternative to uncorrected skin surface temperature is transcutaneous zero-heat-flux thermometry, a technique that was developed in the early 1970s.[9,10] Zero-heat-flux thermometers consist of a thermal insulator adjacent to the skin, which is covered by an electric heater. The heater is servo-controlled to eliminate the flow of heat through the insulator, at which point heater and skin temperatures are equal. Ignoring lateral convection of heat by blood, tissue temperature at the skin surface and just below the monitor must also be the same as subdermal temperature to avoid accumulation of heat. Zero-heat-flux thermometers, thus, effectively measure tissue temperature approximately 1 to 2 cm below the skin surface. At least in well-perfused parts of the body, tissue temperature slightly below the skin surface reasonably approximates core temperature.

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Reprints will not be available from the authors.

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Abundant experimental and clinical evidence confirms that zero-heat-flux thermometry reliably and accurately estimates core temperature.[9–24] There have also been many studies comparing zero-heat-flux estimates to standard invasive and noninvasive thermometric techniques in surgical and nonsurgical settings.[6,25–34] These results are summarized in 4 reviews.[15,35–37]

The only currently available zero-heat-flux thermometer is primarily sold in Japan and, even there, has seen limited use.[15,38] One reason is that the system uses a heavy nondisposable probe that takes a long time to reach thermal equilibrium. Recently, a new zero-heat-flux system was developed that uses a lightweight, disposable probe. Our goal was to compare temperature measured with this novel system against reference core temperature measured in the pulmonary artery. Specifically, we tested the hypothesis that zero-heat-flux temperatures are sufficiently accurate for routine clinical use.

METHODS

With approval from the Cleveland Clinic IRB and after receiving written informed consent, we enrolled 105 patients having elective cardiac surgery with CPB and a pulmonary artery catheter. Patients were excluded when deep hypothermic cardiac arrest was planned, as were patients with forehead or neck skin rash or infection.

Clinical Care

Demographic and morphometric characteristics were recorded, as were surgical details. Temperature probes and pulmonary artery catheters were placed before the induction of general anesthesia. The later was accomplished using etomidate 20 mg, fentanyl 5 mcg/kg body weight, and rocuronium 100 mg. After initiation of CPB, temperature was allowed to drift down to 34°C. Before separation from bypass, patients were actively rewarmed to 37°C over a minimum of 10 minutes, maintaining an arterial inflow-to-patient blood temperature gradient ≤6°C.

Prototype Equipment Description

The zero-heat-flux temperature probes were built around a flexible circuit board that contained a heater and 2 precision thermistors (Fig. 1). A layer of insulting foam was positioned between the 2 thermistors, and another layer of foam adhered to the top of the probe to minimize heat loss. The cutaneous face of the assembled probe was covered with an adhesive layer that held the probe assembly to patient's skin.

The control and display software for the prototype system was developed in LabVIEW 8.5 (National Instruments, Austin, TX). The software computes the temperature at the heater and skin thermistor sites and activates the heater to maintain a very small (essentially zero) temperature difference between the 2 sites. The software always limits the power to the heater to maintain skin temperature to a value <41°C. Thereafter, a proportional-integral-derivative scheme was used to maintain the zero-heat-flow condition across the probe. Both temperatures and heater power settings were recorded electronically.

The external hardware provided: (1) heater control and current-limiting circuitry and (2) voltage-regulation and measurement circuitry for 3 zero-heat-flux probes and 2 standard clinical thermistor probes. The heater current-limiting circuitry prevented skin temperature beneath the probe from exceeding 41°C in the event of a software or hardware failure.

Figure 1. The SpotOn Prototype™ zero-heat-flux cutaneous thermometer. The cutaneous sensor consists of 2 thermometers, separated by an insulator, and covered by a heater. The heater is servocontrolled to keep the 2 temperatures identical. At that point, an isothermal tunnel develops below the skin surface so that surface temperature is about the same as subcutaneous temperature. In many parts of the body, subcutaneous temperature is similar to core temperature. Reproduced with permission © 3M 2013. All rights reserved.

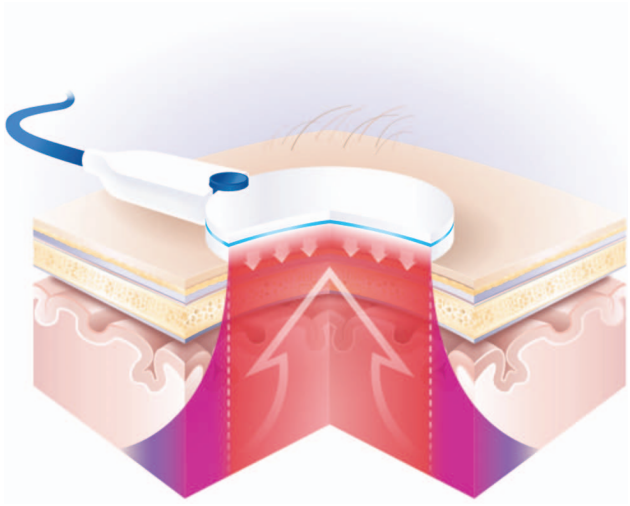

Figure 2. Cartoon of SpotOn Prototype™ zero-heat-flux cutaneous thermometer on a subject.The heater is servocontrolled to keep the 2 temperatures identical. At that point, an isothermal tunnel develops below the skin surface so that surface temperature is about the same as subcutaneous temperature.

Temperature Monitoring

After the induction of anesthesia, the SpotOn Prototype™ (3M, St. Paul, MN) zero-heat-flux temperature monitoring probe was positioned on the skin of the forehead. Another was positioned on the lateral neck contralateral to the site of internal jugular vein cannulation for the pulmonary artery

catheter, which was used for core temperature monitoring. The probe at the neck was positioned above the carotid artery, a few centimeters below the lower edge of the ear lobe.

In both cases, the probes were carefully positioned against the skin surface, and adequate positioning was confirmed at intervals throughout the study. The single-use probes are 40 mm in diameter and attach to the skin with a pressure-sensitive adhesive. The probes are flexible and just 6 mm thick. Each probe is connected by cable to the data acquisition system. Figure 2 is a cartoon showing the probe positioned on the skin surface and the isothermal tunnel below.

Uncorrected (routine) skin surface temperature was measured at the forehead with a self-adhesive skin probe (Covidien, Dublin, Ireland). Ambient temperature was measured at the level of the patient, at least 30 cm from any heat-producing equipment. Temperatures were recorded electronically at 1-minute intervals throughout surgery and for 4 postoperative hours with an electronic data acquisition system that obtained values from clinical monitors.

The initial 10 minutes of zero-heat-flux measurements were discarded to allow for instrument and tissue equilibration because the prototype system did not have a tissue prewarming capability.[39] Analysis was restricted to the intraoperative period, excluding bypass, and then for 4 postoperative hours. The CPB period was excluded because zero-heat-flow thermometery is not designed for the rapid thermal perturbations that are typical during bypass. Also, because there is no pulmonary artery blood flow during most of the bypass period, the pulmonary artery catheter thermistor does not produce an accurate estimate of core temperature.

Data Analysis

We a priori set the acceptable agreement (i.e., 95% limits of agreement) between pulmonary artery (core) and zero-heat-flux measurements to be 0.5°C.[40–42] This limit was chosen because: (1) normal human circadian temperature variation is at least this large[40,41,43]; and (2) no randomized trials demonstrate adverse postoperative consequences from temperature differences <0.5°C.

Agreement was assessed using the Bland and Altman random effects method for repeated measures data.[44] Limits of agreement, which account for the repeated nature of the data, were constructed based on the within- and between-subject variance components from a random effects model, including patient, time of measurement, and baseline temperature. Mean bias, standard deviation of the bias, and limits of agreement for both were estimated using the same random effects model and resampling algorithm, considering the varying number of observations for each patient and their correlation.

The proportion of zero-heat-flux measurements that were within ±0.5°C of the corresponding pulmonary artery measurement were computed using bootstrap resampling (with replacement) to account for the within-subject correlation. Finally, Lin's concordance correlation coefficient was computed.[45] The limits of agreement for the concordance was estimated using the same bootstrap percentile method to determine the proportion within ±0.5°C. Results are presented as means ± SDs or means (95% limits of agreement).

After data on the first 30 subjects were recorded, the initial assumptions of within-subject correlation and the related standard error for the proportion of differences within ± 0.5°C were reanalyzed, and the sample size was recomputed to provide enough subjects expected to create a 95% limits of agreement for the proportion of measurements within ±0.5°C of the reference temperature with a width no greater than ±0.05. We thus enrolled 105 patients to provide reasonable assurance of acceptable estimates of the limits of agreement and the proportion of core temperature differences within ±0.5°C.

RESULTS

Temperature data were obtained from all 105 patients. The duration of surgery averaged (mean ± SD) 279 ± 75 minutes, and the mean cross-clamp time was 118 ± 50 minutes. The patients were (mean ± SD) 67 ± 9 years old, weighed 88 ± 19 kg, and were 172 ± 10 cm tall; 64% were men.

Two patients were excluded from analysis because of sensor failure. Data were also excluded from analysis when temperature of the sensor heater and skin surface thermometer exceeded 0.4°C, indicating a sensor or software problem, which occurred in 6 of the subjects. There remained 35,717 sets of matched zero-heat-flux and pulmonary artery temperatures, with 39% being intraoperative and the remainder postoperative. Pulmonary artery temperatures ranged from 32.0°C to 39.3°C.

The average overall difference between forehead zero-heat-flux and pulmonary artery temperatures (i.e., forehead minus pulmonary artery) was −0.23°C (95% limits of agreement of ±0.82); 78% of the differences were ≤0.5°C. The average intraoperative temperature difference was −0.08°C (95% limits of agreement of ±0.88); 84% of the differences were ≤0.5°C (Fig. 3). The average postoperative difference was −0.32°C (95% limits of agreement of ±0.75); 84% of the differences were ≤0.5°C (Fig. 4).

The average overall difference between lateral neck zero-heat-flux and pulmonary artery temperatures (i.e., neck minus pulmonary artery) was −0.30°C (95% limits of agreement of ±0.88); 75% of the differences were ≤0.5°C. The average intraoperative temperature difference was −0.15°C (95% limits of agreement of ±0.84); 81% of the differences were ≤0.5°C. The average postoperative difference was −0.40°C (95% limits of agreement of ±0.84); 81% of the differences were ≤0.5°C (Table 1).

The body mass index distribution is shown in Figure 5. Results for obese patients (body mass index exceeding 35 kg/m^2) were similar to the entire group. The average difference between forehead zero-heat-flux and pulmonary artery temperatures in obese subjects was −0.24°C (95% limits of agreement of ±0.76°C). The average difference between forehead zero-heat-flux and pulmonary artery temperatures in all subjects was −0.23°C (95% limits of agreement of ±0.82°C). Lin's concordance correlation coefficient for all patients was 0.69 and for obese patients was 0.62. Table 1 provides a summary of the results.

Uncorrected forehead skin temperatures were 3.2°C ± 1.4°C lower than pulmonary artery blood temperature. Furthermore, as illustrated in Figure 6, the negative bias of uncorrected skin temperatures increased as a patient's core temperature decreased.

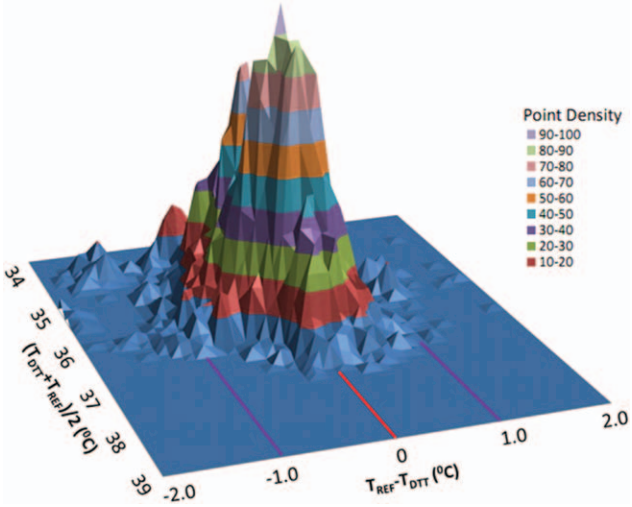

Figure 3. The difference between zero-heat-flux temperature and pulmonary artery temperatures plotted against the average of the 2 temperatures. The conventional Bland and Altman plot was expanded to 3 dimensions because there was considerable overlap, especially for differences near 0°C. The average intraoperative difference between zero-heat-flux at the forehead and pulmonary artery temperatures (bias) was −0.08°C (95% limits of agreement of ±0.88), as indicated by purple lines. In 84% of the measurements, zero-heat-flux temperatures were within 0.5°C of pulmonary artery temperature.

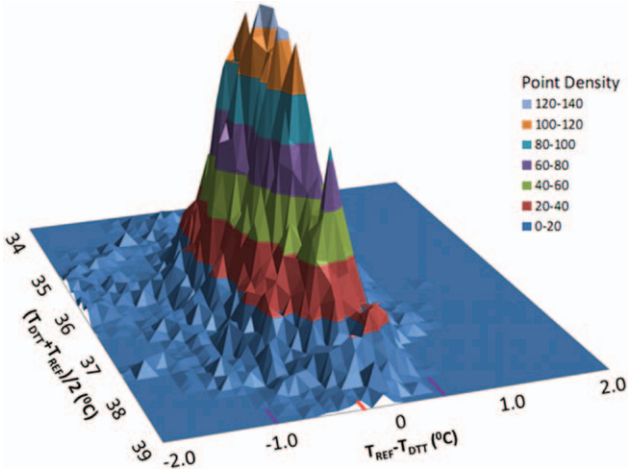

Figure 4. The difference between zero-heat-flux temperature and pulmonary artery temperatures plotted against the average of the 2 temperatures. The conventional Bland and Altman plot was expanded to 3 dimensions because there was considerable overlap, especially for differences near 0°C. The average postoperative difference between zero-heat-flux at the forehead and pulmonary artery temperatures (bias) was −0.32°C (95% limits of agreement of ±0.75), as indicated by purple lines. In 84% of the measurements, forehead zero-heat-flux temperatures were within 0.5°C of pulmonary artery temperature.

DISCUSSION

Core temperature is defined as the mass-weighted mean temperature of tissues within the body's highly perfused core. In practice, the thermal core is composed of the deep tissues of the trunk and head, which represent approximately half the body mass. Brain and liver temperatures are typically about 1°C higher than the rest of the core. However, the remaining core tissue temperatures are homogeneous, rarely differing by more than a few tenths of a °C even during rapid thermal perturbations. Consequently, temperature at any core location reasonably represents the entire mass of the core.

In contrast, the peripheral thermal compartment (mostly the extremities) is typically 2°C to 4°C cooler than the core and varies considerably, depending on the current and previous thermal environments and thermoregulatory vasomotion. While core, peripheral, and skin temperatures all contribute to thermoregulatory control, core temperature contributes most. Core temperature is thus generally considered the single most representative body temperature. We therefore considered the pulmonary artery as our reference temperature.

To adequately test zero-heat-flux temperatures measured at the forehead or neck, it is important to have a range of core temperatures among and within subjects. Cardiac surgical patients are allowed to become mildly or moderately hypothermic during CPB, they require rewarming, and they are often hypothermic after bypass. An additional benefit of studying patients having cardiac surgery is that, even during non-bypass periods, the rate of core temperature changes is as fast as or faster than during noncardiac operations. On the contrary, the limited or absent blood flow in the pulmonary artery during cross-clamp renders pulmonary artery temperature unreliable during this period. We therefore eliminated the bypass period from our analysis.

Forehead and neck zero-heat-flux measurements using the prototype system reflected core temperature in the pulmonary artery with a mean bias of −0.23°C (95% limits of agreement of ±0.82) and −0.30°C (95% limits of agreement of ±0.88), respectively. This limit of agreement was greater than our a priori acceptable limit of 0.5°C; specifically, 95% of the SpotOn Prototype measurements were within 0.82°C of the pulmonary artery temperature. The average intraoperative difference between forehead zero-heat-flux and pulmonary artery temperatures (bias) was −0.08°C (95% limits of agreement of ±0.88). In 84% of the measurements, zero-heat-flow temperatures were within 0.5°C of pulmonary artery temperature. The average postoperative difference between forehead zero-heat-flux and pulmonary artery temperatures (bias) was −0.32°C (95% limits of agreement of ±0.75). In 84% of the postoperative measurements, forehead zero-heat-flux temperatures were within 0.5°C of pulmonary artery temperature. Zero-heat-flux measurements at the forehead and neck thus appear to reasonably estimate core temperature, even during the relatively rapid thermal perturbations associated with the non-bypass portions of cardiac surgery. Presumably, this approach is at least equally reliable during noncardiac surgery when core temperature changes are slower and there is thus more time for tissue thermal equilibrium.

Previous studies of temperature measurement based on zero-heat-flow have consistently shown this approach to be reliable. For example, Harioka et al.[33] showed that "deep-forehead" temperature correlated well with pulmonary artery temperature, with the determination coefficient (r^2) being 0.85. The bias for the deep-forehead temperature was 0.0°C, which was the same as tympanic membrane temperature and smaller than rectal and esophageal temperatures. The standard deviation of the differences for the deep-forehead temperature was 0.3°C, which was the same as rectal temperature. In addition, Akata et al.[33,46] demonstrated a satisfactory

Table 1. Comparisons Between Thermometry Methods and Sites

Comparison (indicated minus reference temperature)	Mean (SD) (°C)	95% limits of agreement (°C)	Proportion of differences within 0.5°C (95% CI)	LCCC (95% CI)	T_{Low} (°C)	T_{High} (°C)
Operating room						
Forehead – PA	−0.08 (0.45)	−0.96, 0.80	0.84 (0.80–0.88)	0.70 (0.65–0.76)	32	37.7
Neck – PA	−0.15 (0.43)	−0.99, 0.69	0.81 (0.77–0.85)	0.60 (0.54–0.68)		
Skin – PA	−3.1 (1.62)	−6.27, 0.07	0.00 (0.00–0.01)	0.06 (0.04–0.08)		
Obese forehead – PA	−0.05 (0.42)	−0.89, 0.78	0.83 (0.71–0.95)	0.69 (0.58–0.82)		
Obese neck – PA	−0.18 (0.44)	−1.04, 0.68	0.79 (0.65–0.92)	0.63 (0.44–0.82)		
Obese skin – PA	−3.31 (1.93)	−7.09, −0.48	0.01 (0.00–0.04)	0.06 (0.02–0.11)		
Neck – forehead	0.07 (0.48)	−0.88, 1.02	0.80 (0.75–0.85)	0.62 (0.55–0.68)	32.8	37.8
Cardiac intensive care unit						
Forehead	−0.32 (0.38)	−1.06, 0.42	0.84 (0.80–0.88)	0.69 (0.63–0.75)	34.5	39.3
Neck	−0.40 (0.43)	−1.24, 0.44	0.81 (0.77–0.85)	0.65 (0.59–0.71)		
Skin	−3.2 (1.14)	−5.44, −0.96	0.00 (0.00–0.00)	0.06 (0.04–0.07)		
Obese forehead	−0.35 (0.44)	−1.22, 0.51	0.69 (0.49–0.88)	0.54 (0.40–0.69)		
Obese neck	−0.40 (0.41)	−1.21, 0.41	0.71 (0.51–0.90)	0.56 (0.42–0.72)		
Obese skin	−3.26 (1.11)	−5.44, −1.08	0.00 (0.00–0.00)	0.03 (0.01–0.05)		
Neck – forehead	0.07 (0.52)	−0.95, 1.10	0.74 (0.67–0.80)	0.70 (0.64–0.76)	33.4	39
Overall (OR and CICU)						
Forehead	−0.23 (0.42)	−1.06, 0.60	0.78 (0.73–0.82)	0.69 (0.65–0.73)	32	39.3
Neck	−0.30 (0.45)	−1.18, 0.58	0.75 (0.71–0.79)	0.62 (0.58–0.67)		
Skin	−3.2 (1.35)	−5.84, −0.56	0.00 (0.00–0.01)	0.09 (0.05–0.07)		
Obese forehead	−0.24 (0.39)	−1.00, 0.52	0.76 (0.65–0.87)	0.62 (0.53–0.71)		
Obese neck	−0.28 (0.42)	−1.10, 0.55	0.75 (0.64–0.86)	0.60 (0.49–0.71)		
Obese skin	−3.39 (1.47)	−6.27, −0.50	0.00 (0.00–0.00)	0.05 (0.02–0.07)		
Neck – forehead	0.07 (0.51)	−0.92, 1.06	0.77 (0.73–0.81)	0.66 (0.61–0.70)	32.8	39

The 95% limits of agreement were computed using the method of Bland and Altman for repeated measures. The 95% confidence intervals were estimated using the reflection method based on 10,000 bootstrap resamples.

Forehead = forehead zero-heat-flux thermometer; Neck = neck zero-heat-flux thermometer; Skin = forehead skin surface thermometer (thermistor); PA = pulmonary artery blood temperature from the thermistor at the tip of the Swan-Ganz catheter; LCCC = Lin's concordance correlation coefficient; T_{low} = lowest reference temperature measured within the indicated comparison interval; T_{high} = highest reference temperature measured within the indicated comparison interval.

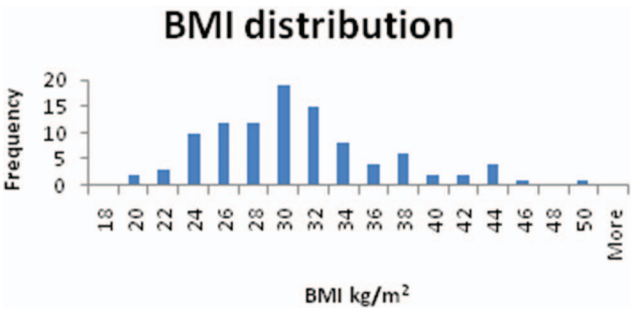

Figure 5. Distribution of body mass index (BMI) among enrolled subjects. Results for obese patients (BMI exceeding 35 kg/m^2) were similar to those for the entire group.

correlation of the forehead deep-tissue temperature with the nasopharyngeal temperature ($r = 0.76$, $n = 300$). In their study, the difference between nasopharyngeal and forehead temperatures was +0.26°C with a standard deviation of 0.34°C.

SpotOn Prototype differs from previous zero-heat-flux systems in being disposable and having a low thermal mass that reaches thermal equilibration quickly. Furthermore, the SpotOn Prototype system connects to routine hospital monitoring systems, which allow zero-heat-flow temperatures to be electronically recorded and included in standard automated anesthesia record-keeping systems.

As illustrated in Figure 6, uncorrected forehead skin surface temperatures were >3°C less than pulmonary artery temperatures, and the difference between the temperatures was inconsistent. These results are similar to those reported previously[7,20,47] and once again show that simply adding a constant to uncorrected skin temperature is an unreliable way to estimate core temperature.

Any surface temperature monitor depends critically on tight adhesion to the skin. Even small air gaps between probes and the skin surface markedly degrade temperature estimates. We thus took great care to assure that the SpotOn Prototype probes were firmly attached to the skin surface throughout the study period.

Unlike pulmonary artery and esophageal temperatures, zero-heat-flux systems require some equilibration time since they depend on zeroing out heat flow across the skin surface. With older systems, this process could easily take 10 minutes. The SpotOn Prototype system is considerably faster since it has a small thermal mass; however, the equilibration time is dominated by the tissue equilibration rather than the instrument equilibration. We did not evaluate the equilibration time in this prototype system, but instead deleted the initial 10 minutes from our analysis.

Unlike uncorrected skin temperature that varies with ambient temperature,[7] zero-heat-flux measurements should remain accurate over a broad range of ambient temperatures. However, we did not specifically evaluate the effect of ambient temperature variation on the accuracy of zero-heat-flux measurements. The observed 95% limits of agreement of 0.82°C is close to our predefined limit of 0.5°C; it is likely that many rapid thermal perturbations during cardiac surgery contributed to this variability. Results may well be better in noncardiac patients.

In summary, SpotOn Prototype is a novel noninvasive continuous measure of core temperature based on a well-established zero-heat-flux technology.

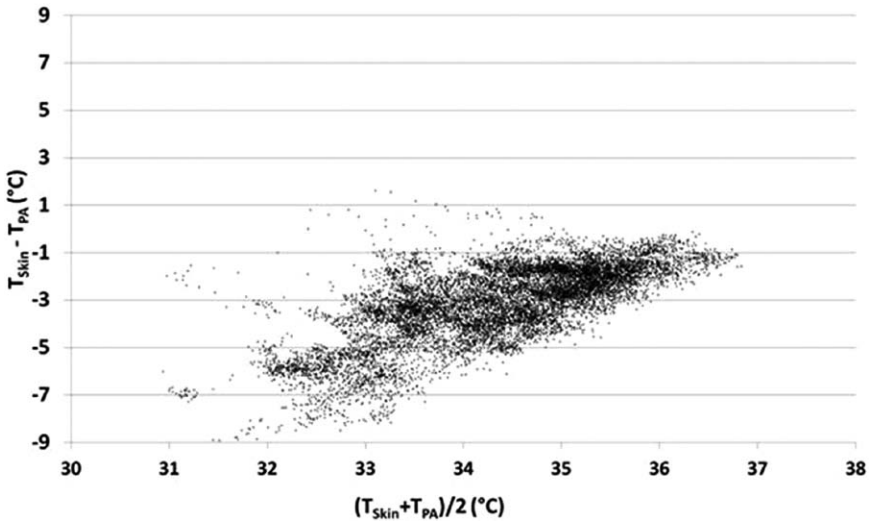

Figure 6. Bland-Altman chart of intraoperative forehead skin and pulmonary temperatures. Uncorrected forehead skin temperatures were 3.1°C ± 1.8°C lower than pulmonary artery temperature. Furthermore, uncorrected skin temperatures varied considerably within and among patients.

DISCLOSURES

Name: Yashar Eshraghi, MD.
Contribution: This author helped conduct the study and write the manuscript.
Attestation: Yashar Eshraghi has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
Conflicts of Interest: The author has no conflicts of interest to declare.
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Contribution: This author helped design the study, conduct the study, and write the manuscript.
Attestation: Daniel I. Sessler has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
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