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Evaluation of the Temple Touch Pro, a Novel Noninvasive Core-Temperature Monitoring System

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BACKGROUND: The Temple Touch Pro (TTP) is a novel system that estimates core temperature from skin over the temporal artery. We tested the hypothesis that this noninvasive system estimates core temperature to an accuracy within 0.5°C.

METHODS: Core temperature was continuously monitored in 50 adult and pediatric surgical patients by positioning the sensor patch of a TTP over one temporal artery. The sensor consists of a thermistor array near the skin surface, another set of thermistors above an insulator, and a second insulator between the upper unit and the environment. The sensor measures skin temperature and heat flux, from which the monitor unit estimates core temperature from a proprietary algorithm. Reference core temperature was measured from the esophagus or nasopharynx. We conducted agreement analysis between the TTP and the reference core temperature measurements using the 95% Bland-Altman limits of agreement for repeated measurement data. The proportion of all differences that were within 0.5°C and repeat measures concordance correlation coefficient (CCC) were estimated as well.

RESULTS: TTP and the reference core temperature measurements agreed well in both adults and pediatric patients. Bland-Altman plots showed no evidence of systematic bias or variability over the temperature from 35.2°C to 37.8°C. The estimated 95% lower and upper limits of agreement were −0.57°C (95% confidence interval [CI], −0.76 to −0.41) and 0.57°C (95% CI, 0.44 to 0.71), indicating good agreement between the 2 methods. Ninety-four percentage (95% CI, 87% to 99%) of the TTP temperatures were within 0.5°C of the reference temperature. Good agreement was also supported by an estimated repeated measures CCC of 0.82 (95% CI, 0.66 to 0.91). The TTP core temperature measurements also agreed well with nasopharyngeal reference temperatures.

CONCLUSIONS: The noninvasive TTP system is sufficiently accurate and reliable for routine intraoperative core temperature monitoring. (Anesth Analg 2017;125:103–9)

Core temperature in humans is normally maintained within about ±0.5°C of 37°C. General and regional anesthesia impair thermoregulatory control and thus perturb core temperature homeostasis.[1] Even just a degree or two of hypothermia substantially augments the risk of surgical bleeding and surgical wound infection, and delays recovery from anesthesia.[2–5] Hyperthermia is potentially even more serious and can result from fever, allergic reactions, excessive warming, or malignant hyperthermia.[6,7] Intraoperative core temperature monitoring is thus standard-of-care because prompt diagnosis and management of thermal disturbances may prevent complications.[8]

Intraoperative core temperatures are most often measured in the distal esophagus or nasopharynx, but both are at least somewhat invasive sites that usually require general anesthesia. Core temperature can also be reliably measured from the pulmonary artery or tympanic membrane with a direct-contact sensor. Other sites that estimate core temperature but are less reliable include the axilla, mouth, rectum, and urinary bladder.[9–14] Infrared skin temperature measurements at the temple above the temporal artery and liquid-crystal measurements over the forehead and neck poorly estimate core temperature.[15–17]

In intubated patients, the distal esophagus is an excellent site for core temperature measurement because the site is accurate and resistant to artifact. However, in patients managed with supraglottic airways or having neuraxial anesthesia, intraoperative monitoring of core temperature remains challenging. Accurate postoperative temperature monitoring is even more difficult since few patients tolerate esophageal or nasopharyngeal probes. A system that reliably estimates core temperature both intraoperatively and postoperatively would be clinically useful.

The Temple Touch Pro (TTP) is a new thermometer that estimates core body temperature from the temple. We thus evaluated intraoperative performance of the TTP system in adult and pediatric patients, and compared it with reference esophageal or nasopharyngeal measurements.

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Specifically, we tested the hypothesis that the TTP noninvasive temperature measurement system estimates core temperature to within 0.5ºC of reference values.

METHODS

The study was conducted with IRB approval from the Helsinki Committee of Wolfson Medical Center, Holon, Israel (IRB approval number 0077-10-WOMC) and approval from the Israeli Ministry of Health (Ministry of Health approval number HT-5776) to test a new medical device. Written consent was obtained from patients or from both parents of children

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We enrolled 50 patients having elective surgery under general anesthesia that was expected to last longer than an hour. Patients' ages ranged between <1 and 73 years and the ASA physical status was I to IV. We excluded patients having operations on the forehead, women who were pregnant, patients with systemic or forehead infections or other local cutaneous inflammation, and patients with pharyngeal or esophageal pathology.

Protocol

Anesthetic technique and agents, fluid and blood administration, monitoring, and vasoactive medications were used per clinician preference. Except during cardiac surgery, patients were warmed with forced air (Gaymar Industries, Orchard) and ambient temperature was maintained near 21ºC. Heating blankets were kept well away from the forehead.

Measurements

Demographic and morphometric characteristics were recorded, along with anesthetic and surgical details.

A TTP sensor (Medisim, Neve Ilan, Israel) was attached over the temporal artery shortly after induction of anesthesia. The sensor consists of 2 units: a sensor patch and an external monitor-connecting unit with an optional data logging system. Communication between the 2 units can be wired or wireless. For the wired version used in this study, the components are connected by a sensor unit cable (Figure 1).

The sensor consists of a thermistor array near the skin surface, another set of thermistors above an insulator, and a second insulator between the upper unit and the environment. These readings are transmitted to the monitor-connecting unit, where core body temperature is estimated from a proprietary algorithm and can be displayed on routine clinical monitoring systems.

Reference temperature probes were inserted shortly after induction of general anesthesia. Core temperature was measured in the distal esophagus at the level of maximal heart sounds (Novamed, New York, NY). In patients having cardiac surgery, those requiring transesophageal echocardiography and in patients where esophageal temperature measurement proved to be technically difficult, reference core temperature was measured with a nasopharyngeal probe (DS Medical, Hampshire, UK) inserted to a depth equal to the length between the base of the ipsilateral nostril and the earlobe.

Recording from the TTP and reference sites started immediately after induction of anesthesia and continued at 30-second intervals throughout surgery except in the cardiac surgical patients in whom temperatures were only considered until onset of bypass. Temperatures from the TTP system were recorded by the monitor-connecting unit that was connected to a Vital Signs monitor, which displayed the patient's temperature. After surgery, data were downloaded for subsequent analysis.

Statistical Analysis

We conducted agreement analysis between the TTP and an invasive reference method on core temperature. We estimated the 95% Bland-Altman limits of agreement using the Bland-Altman repeated measurement data formula to adjust for within-patient correlation.[18] The 95% limits of agreement were estimated by average difference in temperature measurements between 2 methods ±1.96 standard deviation of the difference, within which 95% of the differences are expected to fall. If the limits are not clinically different, then 2 methods may be used interchangeably. Also, a Bland-Altman plot of individual differences between the 2 methods versus the average of the 2 methods was generated to show agreement with the reference method as a function of the range of mean temperature. It also allows us to visually investigate the existence of any systematic difference between the 2 methods. The 95% confidence intervals for the lower and upper limits of agreement were estimated using bootstrap percentiles (2.5th and 97.5th percentiles) based on 10,000 resamples obtained by replacement from our original data, where the entire content of patient's data was resampled to account for within-patient correlation.

We also calculated the proportion of all differences that were within 0.5ºC and the repeat measures concordance correlation coefficient (CCC). A range of ±0.5ºC was selected because it is the smallest difference shown to be associated with hypothermia-induced complications.[19] The CCC summarizes both bias from the 45° line of equality and the correlation between the 2 variables. The 95% confidence interval for the proportion was estimated using bootstrap percentiles (2.5th and 97.5th percentiles) based on 10,000 resamples. The 95% confidence interval for the repeat measures CCC was estimated using the R function "ccclon" from "cccrm" package.[20]

The agreement analysis was performed within 4 subgroups according to the reference type and the age group: (a) nasopharyngeal reference; (b) esophageal reference; (c) pediatric patients (age <5 years); and (d) adults (age ≥5 years). The age cutoff was 5 years old according to ISO 60601-2-56, an international standard for the thermometers accuracy evaluation. For each subgroup, the same statistical methods were used as described above.

Sample size consideration: Our primary analysis is to estimate the Bland-Altman limits of agreement, for which an a priori power analysis is not necessary. The sample size was initially set up to 800 patients by sponsor, Medisim Ltd (Neve Ilan, Israel). We analyzed the first 50 patients. With

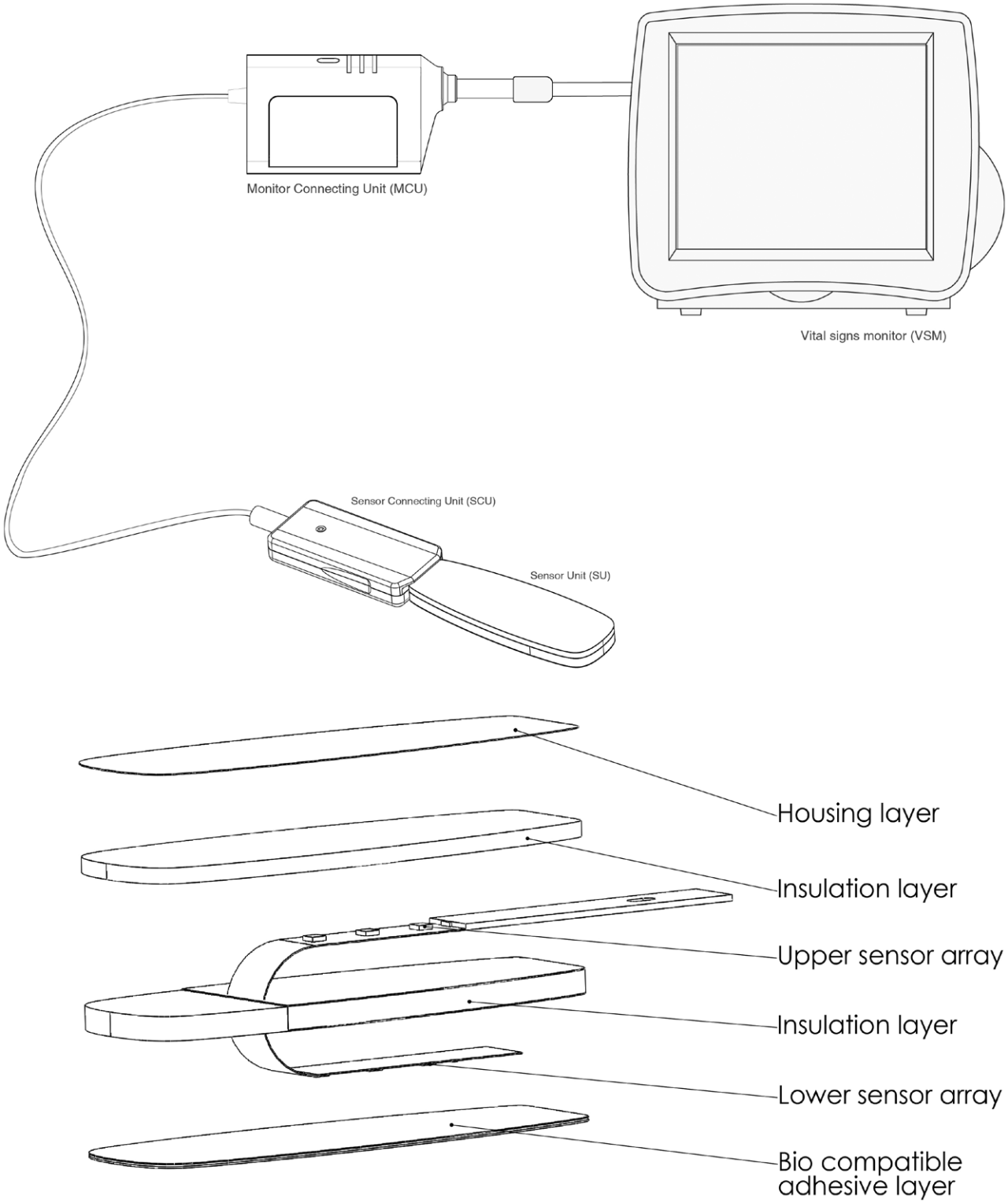

Figure 1. Illustration of the Temple Touch Pro system, with close view on the sensor layers.

these patients, we were able to show a reasonably good agreement between TTP and the reference method. Thus, we decided to stop the study. Analyses were completed using SAS version 9.4 (SAS Institute, Carey, NC) and R version 3.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Of 56 enrolled patients, 6 were excluded because of poor reference measurements or nonconformity to the protocol. Among the 50 patients analyzed, 24 (48%) were male, and the median [quartile] ages were 9 [2, 37] years, 68% of the patients were adults (29 [9, 44] years) and 32% were children

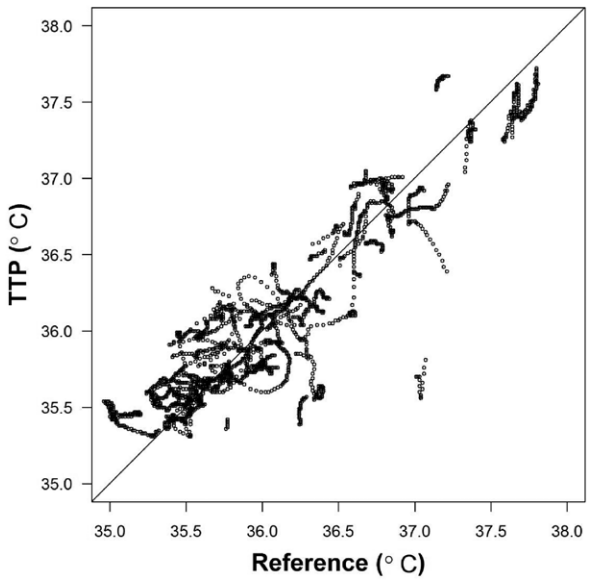

Figure 2. Scatter plot of core-temperature measurements using the Temple Touch Pro (TTP) system versus an invasive measurement system as a reference. The line of equality is shown (N = 50).

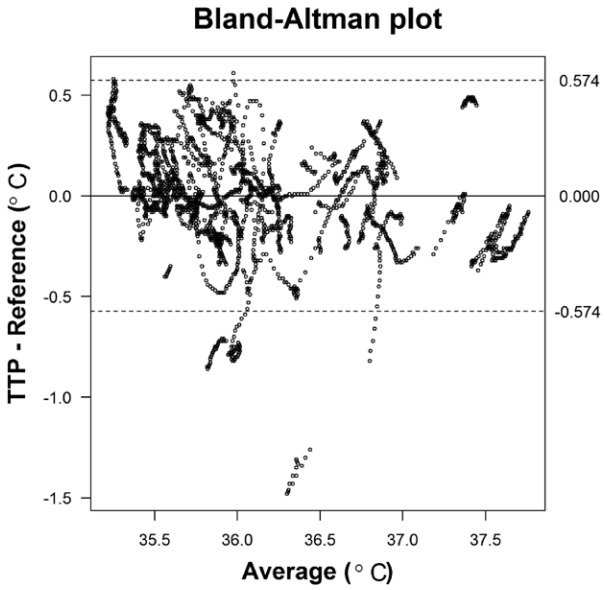

Figure 3. Bland-Altman plot of core-temperature measurements using the Temple Touch Pro (TTP) system versus an invasive probe. Limits of agreement (dashed lines) on the plot indicate where 95% of differences between the 2 methods are expected to fall.

Table 1. Summary of the Agreement Analysis in All Patients, and Divided by Reference Temperature Site and by Age

	Reference Temperature Site		Age[a]		
	Nasopharyngeal (n = 25)	Esophageal (n = 25)	< 5 (n = 16)	≥5 (n = 34)	All Patients (N = 50)
Lower limit of 95% LOA[b] (95% CI)[c]	−0.58°C (−0.79 to −0.40)	−0.58°C (−0.89 to −0.30)	−0.62°C (−0.97 to −0.30)	−0.57°C (−0.80 to −0.37)	−0.57°C (−0.76 to −0.41)
Upper limit of 95% LOA† (95% CI)[c]	0.64°C (0.44 to 0.84)	0.53°C (0.34 to 0.71)	0.60°C (0.36 to 0.89)	0.57°C (0.41 to 0.74)	0.57°C (0.44 to 0.71)
Repeat measures CCC[d] (95% CI)	0.82 (0.66 to 0.91)	0.81 (0.65 to 0.90)	0.77 (0.47 to 0.91)	0.78 (0.60 to 0.88)	0.82 (0.66 to 0.91)
Range of mean temperatures	35.2–37.8	35.2–37	35.2–37.8	35.2–37.4	35.2–37.8
Percent of TTP temperatures that were within 0.5°C (95% CI)‡	96% (90% to 99%)	92% (79% to 100%)	97% (91% to 100%)	93% (84% to 99%)	94% (87% to 99%)

Abbreviations: CCC, concordance correlation coefficient; CI, confidence interval; LOA, limits of agreement; TTP, Temple Touch Pro.

[a]The age cutoff was 5-years old according to ISO 60601-2-56, an international standard for thermometers accuracy evaluation.

[b]The 95% confidence intervals for both the LOA and proportions were estimated using the bootstrap percentile method (2.5th and 97.5th percentiles) based on 10,000 resamples with replacement from our original data, where entire patient's data resampled together to account for within-patient correlation.

[c]95% Bland Altman limits of agreement, using the Bland Altman repeated measurement data formula.[18]

[d]CCC summarizes both the bias from the 45° line of equality and the correlation between two variables.[20]

(0.8 [0.4, 1.6] years). Patients in ASA functional categories I to III underwent orthopedic (24%), general (20%), gynecologic (18%), cardiac (14%), urologic (12%), and other (12%) procedures. Core temperature was measured from the esophagus in one-half the cases and from the nasopharyngeal in the other half. The total number of measurements on the 50 patients was 3205. The median number of measurements per patient was 51 [Q1, Q3: 28, 88]. Duration of surgery ranged from 1 to 4.6 hours, with a median of 1.4 hours.

As shown in the scatter plot (Figure 2), the TTP and the reference core temperature measurements agree well. A Bland-Altman analysis (Figure 3) shows that the limits of agreement are reasonably narrow. The estimated 95% lower and upper limits of agreement were −0.57°C (95% confidence interval [CI], −0.76 to −0.41) and 0.57°C (95% CI, 0.44–0.71), respectively, within which 95% of the difference is expected to fall, indicating good TTP minus reference agreement across the observed range of mean temperatures from 35.2°C to 37.8°C. There was no significant evidence of increasing or decreasing systematic bias or variability between the TTP and the reference measurements with increasing temperature. As shown in Figures 2 and 3, one patient had low TTP values compared with the reference, which was due to a contact problem of the sensor patch on patient skin. Good agreement between the TTP and the reference measurements is also supported by the estimated repeated measures CCC of 0.82 (95% CI, 0.66–0.91) and proportion of differences within 0.5°C of 94% (95% CI, 87%–99%) (Table 1).

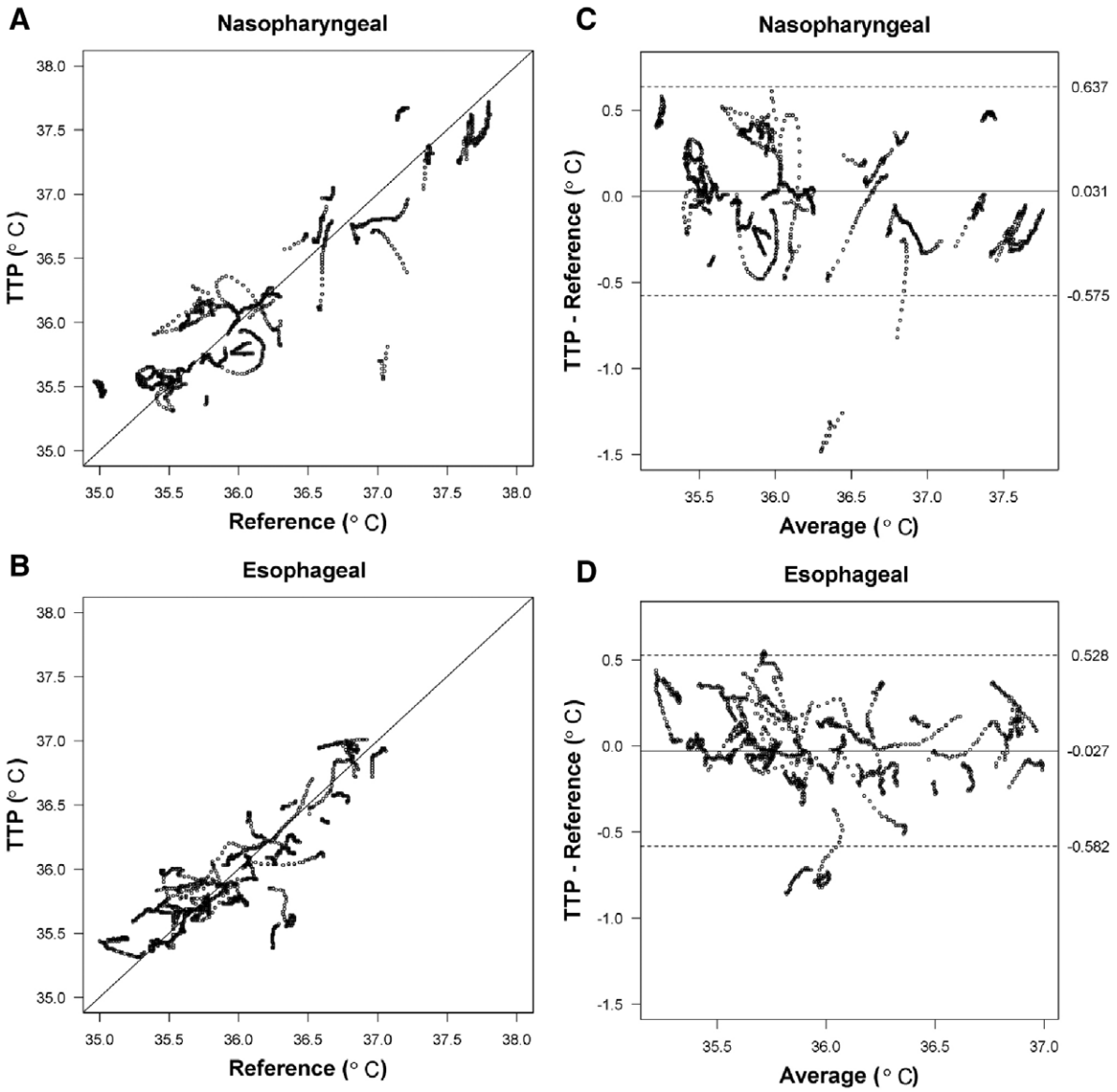

Figure 4. A and B, Scatter plot of core-temperature measurements using the Temple Touch Pro (TTP) system versus an invasive measurement system as a reference by the reference temperature site (A) Nasopharyngeal (n = 25) and (B) Esophageal (n = 25). The line of equality is shown. C and D, Bland-Altman plot core-temperature measurements using the TTP system versus an invasive probe by the reference temperature site (C) Nasopharyngeal (n = 25) and (D) Esophageal (n = 25). Limits of agreement (dashed lines) on the plot indicate where 95% of differences between the 2 methods are expected to fall.

Core temperature measurements agree well between the TTP and the nasopharyngeal reference as well as the esophagus reference (Figure 4A and B). A Bland-Altman analysis shows that the limits of agreement are reasonably narrow (Table 1 and Figure 4C and D). There was no significant evidence of increasing or decreasing systematic bias (mean difference) or variability (spread) between the TTP and the nasopharyngeal reference or esophageal reference measurements with increasing temperature. The estimated repeated measures CCC was 0.82 (95% CI, 0.66–0.91) for nasopharyngeal reference and 0.81 (95% CI, 0.65–0.90) for esophageal reference. The proportion of differences within 0.5ºC was 96% (95% CI, 90%–99%) for nasopharyngeal reference and 92% (79%–100%) for esophageal reference (Table 1).

The agreement analysis results for the children subgroup shows strong agreement between the TTP and the reference (Figure 5A). The estimated repeat measures CCC was 0.77 (95% CI, 0.47–0.91). Ninety-seven percentage (95% CI, 91%–100%) of the TTP temperatures were within 0.5ºC of the reference temperature (Table 1). The calculated limits of agreement were (–0.62ºC, 0.60ºC), as shown in Figure 5C. There was no significant evidence of increasing or decreasing systematic bias or variability between the TTP and the reference measurements with increasing temperature.

The results for the adult patients also indicate a reasonably good agreement between the TTP and the reference measurements (Figure 5B). The estimated repeat measures CCC was 0.78 (95% CI, 0.60–0.88) and proportion of differences within 0.5ºC was 93% (95% CI, 84%, 99%) (Table 1). The estimated limits of agreement were similar to that in children (–0.57ºC, 0.57ºC, Figure 5D).

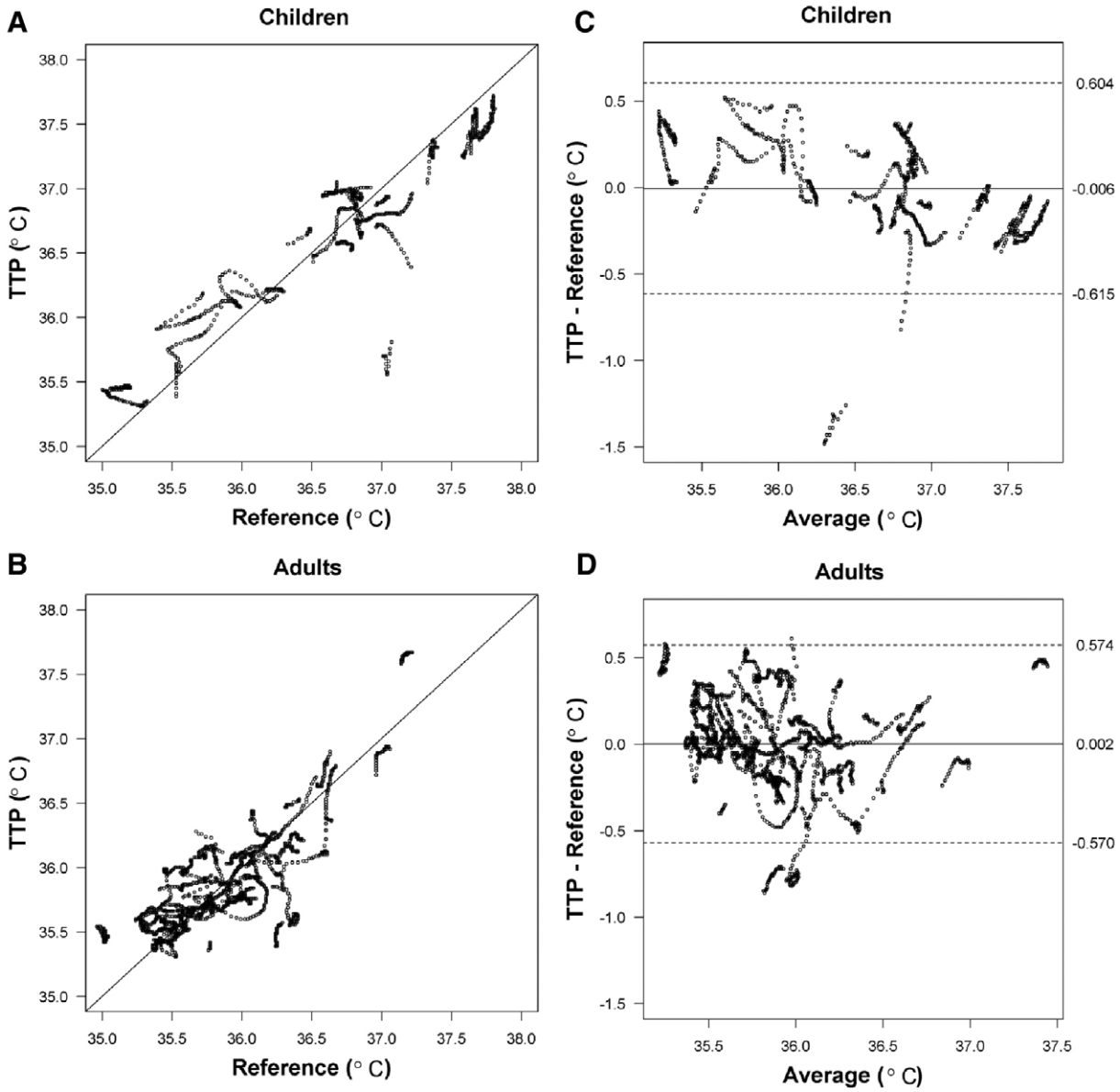

Figure 5. A and B, Scatter plot of core-temperature measurements using the Temple Touch Pro (TTP) system versus an invasive measurement system as a reference by age group (A) children (< 5, n = 16) and (B) adults (≥ 5, n = 34). The age cutoff was 5 years old according to ISO 60601-2-56, an international standard for thermometers accuracy evaluation. The line of equality is shown. C and D, Bland-Altman plot of core-temperature measurements using the TTP system versus nasopharyngeal probe by age group (C) children (n = 16) and (D) adults (n = 34). Limits of agreement (dashed lines) on the plot indicate where 95% of differences between the 2 methods are expected to fall.

DISCUSSION

Among all enrolled patients, the TTP cutaneous thermometer had a bias (TTP minus reference) of only 0 ± (SD) 0.29ºC with 95% of the difference are expected to fall within ±0.57ºC; furthermore, 94% of all measurements were within ±0.5ºC. The results did not differ appreciably as a function of age or core-temperature reference site. The TTP system thus appears to be sufficiently accurate for routine clinical use.

In operating room environments, exposed skin temperature is typically about 2ºC below core temperature. However, the difference between skin and core temperature varies among individuals and over time. Among the most important determinants of skin temperature is ambient temperature,[17] which often varies by several degrees in the course of an operation. Core temperature, therefore, cannot be reliably estimated simply by adding a constant to skin temperature.

In the 1970s, an accurate method of measuring core temperature from the skin surface was developed by Fox and colleagues.[21] Such systems, which are well validated, are based on nulling thermal flux across the skin surface.[22] Heat flux measurements are based on the Second Law of Thermodynamics, which states that heat can only flow down a temperature gradient. Consequently, the temperature difference across a known insulator quantifies heat flow. A corollary is that if temperatures are identical on the skin and alternate sides of an insulator, there is no flow of heat.

In practice, zero heat flow thermometers combine a thermal flux transducer with a covering heater that is servo-controlled to null heat flux. With zero heat flow, the device becomes a perfect

insulator and heat that would normally escape from the skin surface to the environment is reflected back toward deeper tissues. The result is a column of tissue at nearly core temperature just below the insulator. Temperatures above and below the insulator — which by definition are identical — are thus also good approximations of deep tissue temperature. In practice, some heat is lost by lateral blood-borne convection so the system works best in places such as the forehead where tissue temperature is normally near-core just a centimeter or so below the skin surface. Until recently, the only commercial deep temperature thermometer was restricted to Japan. But a new version of the system with a disposable transducer is now widely available.[23,24]

The TTP is loosely based on zero heat flow thermometry, but differs in lacking a servo-controlled heater. (The heater consumes considerable power, which precludes prolonged battery-powered operation.) Instead, the system uses a proprietary algorithm to estimate core temperature from temperature measurements from the cutaneous and environmental sides of a known insulator. Presumably, the algorithm augments the assumed core-to-skin gradient skin temperature as a function of heat flux (which increases at lower ambient temperatures). Whatever the algorithm, it appears to work since temperatures recorded by the TTP system were similar to core temperature over a reasonable range of core temperatures in men, women, and children having a broad range of procedures.

We excluded the bypass period in cardiac surgical patients because the temperature changes during bypass are extreme and it is unrealistic to expect any surface-based thermometer to compensate for the consequent large core-to-skin gradients. We avoided exogenous warming of the temporal temperature measurement site. We thus did not evaluate the extent to which TTP measurements might be affected by artifactual warming, but the effect may be substantial.

In summary, cutaneous temporal TTP temperatures were sufficiently accurate for routine clinical use, with 94% of all measurements across a range of ages and types of surgery being within ±0.5°C of reference distal esophageal or nasopharyngeal reference core temperatures. The device may be especially useful in patients having neuraxial anesthesia or general anesthesia with a laryngeal mask airway, and has the advantage that monitoring can continue with the same device into the postoperative period. ■

DISCLOSURES

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