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RESEARCH REPORT

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Intra-operative temperature monitoring with cutaneous zero-heat- flux-thermometry in comparison with oesophageal temperature: A prospective study in the paediatric population

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Abstract

Background: Maintenance of thermal homeostasis is of crucial importance in the anesthetized pediatric patient. Gold-standard methods for central core temperature measurement are however inappropriately invasive and impractical in daily practice. The SpotOn sensor uses zero-heat-flux thermometry technology and claims to bypass the invasiveness of classical methods and still accurately display central core temperatures. Up to date no formal analysis of this method in children has taken place.

Aims: The primary objective was to assess the accuracy in comparison with esophageal temperature; the secondary objective concerned the safety of the SpotOn sensor in the pediatric patients.

Methods: Fifty-four children aged 1-12 years with an American Society of Anesthesiology classification I or II scheduled to undergo elective surgical procedures under general anesthesia for a minimum of 30 minutes were included. Exclusion criteria included: fragile forehead skin, procedures impeding proper SpotOn placement, thoracoscopic or gastroesophageal procedures, coagulopathy, hemodynamic instability, or vasoactive medication use. After sevoflurane induction, an esophageal temperature probe was placed in the lower third of the esophagus, and a SpotOn sensor on the lateral forehead. Temperatures were recorded in pairs per 1 minute intervals. Temperatures were subjected to bias analysis with 0.5°C as the a priori established clinical significance cutoff.

Results: Bland-Altman analysis revealed the two methods differed on average 0.14°C (95% limits of agreement: −0.39 to 0.66), with 89.5% of the differences being under 0.5°C. No significant differences could be found between the two methods for the established 0.5°C cutoff. Linear regression analysis determined the following linear regression equation: $0.837x + 5.86$ ($R^2 = 0.738$). Lin's concordance correlation coefficient of 0.83 (95% CI: 0.81-0.84). No complications were observed with the use of the SpotOn sensor.

Conclusion: SpotOn revealed itself as accurate as an esophageal temperature probe when estimating central core temperatures under ideal conditions and over a narrow range of temperatures. No adverse effects were observed with the use of the SpotOn sensor.

KEYWORDS
anesthesia, children, equipment and supplies, equipment safety, general, pediatrics, spoton thermometry, temperature, thermometry, validation

1 | INTRODUCTION

Temperature regulation in the perioperative period is of primary importance in the pediatric population—a population particularly vulnerable to thermal variations. In comparisson to adults, children lose a significant percentage of their core heat through conduction and radiation. Evaporative losses are also significant (up to 20%) and mostly due to the fact that cutaneous heat loss is "grosso modo" proportional to body surface area.[1,2]

This higher thermal vulnerability is aggravated during the perioperative period, both due to the increased exposure of body surfaces, and the impairment of physiologic compensatory mechanisms.[3-8] Core temperature is by definition the temperature measured in the high-perfused central body structures. Although the gold-standard of core temperature monitoring relies on temperature measurement by means of a pulmonary artery catheter, this method remains highly impractical in children not only due to its invasive and costly character in most interventions, but also to its limited clinical use during some cardiothoracic surgery cases.[9]

A panoply of core-temperature surrogate measures have been evaluated for the degree of correlation with core temperature measurement.[10] Pooled data from pediatric studies shows that esophageal, nasopharyngeal, rectal, and axillary temperatures are adequate surrogate measures of central core temperature. Esophageal thermometry is placed blindly and may not be applicable to some pediatric population or type of surgeries, yet it heads the former list in accuracy, although this depends on placement on the distal third of the esophagus.

An alternative thermometry technology called Zero-heat-flux was developed in the 1970s in an attempt to compensate for the limitations of pure skin temperature, while maintaining its practical character.[11-13] It is based on the principle that the temperature 1-2 cm below skin surface reasonably approximates core temperature, and relies on a 4-layered probe with the following deep-superficial (vertical) structure: patient temperature thermistor, insulating foam layer, heating (flex) circuit, and insulating foam. A servo-controlled system actively warms the probe circuit to the point where, theoretically, temperature equilibrium is achieved between the skin and deeper structures and there is zero heat transfer to the surrounding areas. Assuming a good tissue perfusion, dermal temperature will reasonably approximate core temperature.[14-16] In this respect, the skin of the forehead appears to be best perfused and therefore provides most proper results in terms of temperature assessment.

Although the concept is not new, it is still not widely used in clinical practice due to a limited user-friendliness of the first prototypes and a significant time-lag in measuring core temperatures. The SpotOn™ (3M™ Belgium) innovates by using disposable sensors and having a reduced calibration period (up to 3 minutes) due to its reduced thermal mass.[17] It also lacks the hygienic concerns associated with other invasive methods.

Early SpotOn™ tests have shown a good correlation between measurements and core temperatures measured by pulmonary artery thermistors during adult cardiac surgery.[14,17] Similarly, the SpotOn™ showed close correspondence to nasopharyngeal and sublingual temperatures in adults.[18]

Although a systematic adult population validation is underway, no data on the pediatric population exist. Should the probe prove to be accurate in this age range, it can definitely contribute to the improvement of the perioperative temperature measurement and management in children.

Thus, this study aims to assess the accuracy of the SpotOn™ Zero-heat-flux-thermometry sensor in measuring core temperatures in the pediatric population in the perioperative period. This will be achieved by comparing temperature measurements using SpotOn thermometry sensors with those from esophageal temperature probes.

What's already known

- Oesophageal, nasopharyngeal, and rectal temperatures are adequate surrogate measures of central (core) temperature in the pediatric population. Oesophageal temperature affords the greatest sensitivity.
- The SpotOn™ (3M) temperature sensor is well correlated to core temperature measured by a pulmonary artery catheter, oesophageal and nasopharyngeal sensors in adult patients. This temperature measurement technique has not been studied in children.

What this article adds

- In Ideal anesthetic settings, the SpotOn™ (3M) confirms its correlation with esophageal temperature in children with similar intermethod temperature differences as those from adult studies.

2 | MATERIALS AND METHODS

2.1 | Study design

This study was set up as a prospective, interventional, longitudinal, and quantitative clinical trial. This trial was conducted in accordance with the established protocol approved by the IRB of the Universitair

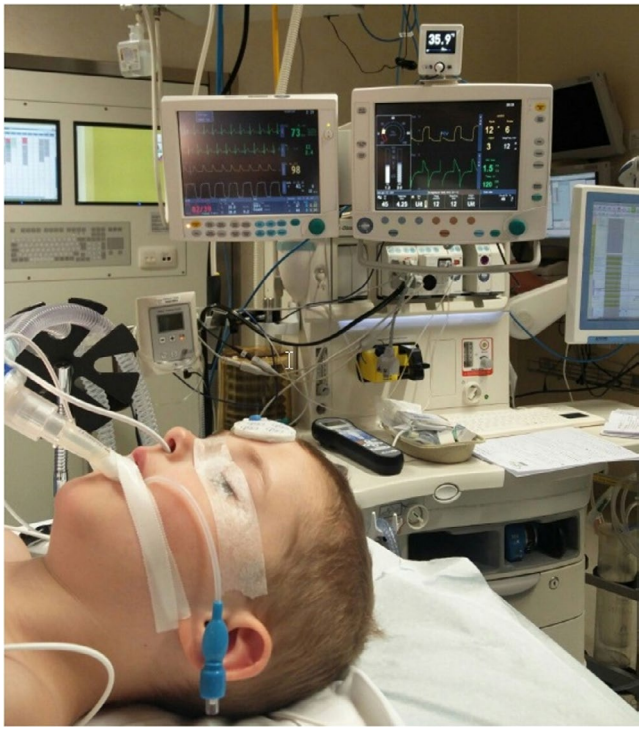

FIGURE 1 Anesthesia set-up. Note the SpotOn sensor on the center-right forehead and the nasally inserted esophageal temperature probe

Ziekenhuis Brussel (reference 2017/0186, UZ Brussel, Brussels, Belgium) and according to the principles of the Helsinki declaration on patient safety in anesthesia. The parents of potential participants were approached for consent for participation in this study. Final inclusion only took place when written informed consent of either parents or legal caregivers was obtained.

The present trial was registered in the Clinicaltrial.gov database (NIH US National Library of medicine) on 19 April 2017 (ClinicalTrials.gov Identifier: NCT03157609; https://clinicaltrials.gov/ct2/show/record/NCT03157609). The first patient was enrolled on 15 November 2017, the last on 23 April 2018.

2.2 | Patient population

2.2.1 | Inclusion criteria included

Children aged 1-12 years with American Society of Anaesthesiology physical status classification I or II scheduled to undergo elective surgical procedures under general anesthesia for a minimum of 30 minutes, according to clinical practice at Universitair Ziekenhuis Brussel.

2.2.2 | Exclusion criteria included

Fragile forehead skin state; known allergy to the probe adhesive or any constituent components; maxillofacial trauma or lesions; procedures impeding proper placement of the SpotOn™ sensor; abnormal esophageal anatomy/gastro-esophageal procedures; coagulopathy; neurologically impaired children with abnormal thermoregulation; hemodynamic instability; need for vasoactive medication; procedures associated with extended use of abdomino/thoracic rinsing fluids; thoracoscopic/thoracotomy procedures; malignant hyperthermia or family history of malignant hyperthermia; patient with fever or infection; all conditions that might be judged to abnormally alter skin perfusion; anatomical variants (overt hydrocephalus …); and calibration/device failure.

2.3 | Protocol

After reviewing the medical records of the child, the patient's legal representative was informed about this study and asked about their desire to participate. A positive answer was followed by signature of the informed consent.

Before transport to the operating room, patients were consistently premedicated with Midazolam 0.5 mg kg^{-1} (max 12 mg) orally as per institutional practice. Operating room temperature was centrally standardized to 24°C (±1°C). In the operating room standard anesthetic monitoring was connected to the patient (plethysmographic oxygen saturation, 3-lead Electrocardiogram, non-invasive blood pressure). Subsequently, anesthesia was induced either intravenously or with inhalational sevoflurane via face mask, followed by a peripheral line cannulation. A balanced crystalloid infusion containing 1% glucose was used as maintenance fluid and administered at room temperature. After deepening the anesthesia plane with a hypnotic (propofol) and opioid (sufentanil), a Laryngeal Mask Airway, orotracheal tube, or nasotracheal tube was inserted. Depending on the selected airway and clinical need, additional administration of a nondepolarizing neuromuscular blocking agent was optional. After reaching a stable and adequate depth of anesthesia, the forehead skin was degreased with ether, followed by attachment of the SpotOn™ sensor (Figure 1).

Nasal insertion of an esophageal temperature probe (DeRoyal Industries Inc) followed. The depth of insertion was calculated according to the formula: "10 + [2 (Age in years)]/3" cm.[19] This aimed the positioning of the sensor on the lower fourth of the esophagus where it most closely approximates pulmonary artery temperatures.[19] After placement, probe position was adjusted in intervals of 1 cm up and down to make sure it is not in the zone of maximum influence of cooling of the anesthetic gases.[20] The temperature probe placement was done either by the principal or supervising investigators.

Esophageal probe was inserted prior to the placement of laryngeal mask airway and in case a nasotracheal tube was used, the esophageal probe was inserted via the contralateral nostril.

Anesthesia maintenance was achieved with sevoflurane in all patients. Boli of opioids and nondepolarizing neuromuscular blocking agents were employed according to need, and ventilatory gas flow was maintained at a nonhypoxic minimum in order to minimize adjacent cooling of esophageal temperature probe. Intraoperative preventive and pre-emptive anti-nociceptive medication administration

was done as per in-house protocol (paracetamol, diclofenac, tramadol according to need, age class, and surgery conditions). Both the esophageal probe and the SpotOn™ sensor were removed before emergence.

Quality measurement was assured by data recording either by the principal or supervising investigator. This was also checked with the electronically collected data (Metavision®, IMDsoft).

No protocol deviations took place during the study.

2.4 | Statistical analysis

An a priori calculated sample size of 63 patients was computed for a study with a Power (1 −β) of 85% and an α error cutoff of 0.05. Power calculation was made assuming a proportion of measuring techniques per patient at a 1:1 ratio, as well as a standard deviation (σ) of 1.[12,15,16] The expected mean inter-measurement difference was of <0.5 degree Celsius (based on previous studies in adults reporting <0.5 degree difference).[14,17,18] After inclusion of 54 patients (corresponding to 1664 data pairs) a *post-hoc* power analysis was done to assess the need of further inclusions. Due to the achievement of a power of 100%, patient inclusion was halted.

The individual demographic parameters as well as their variability in the population were calculated. The main method agreement analysis was based on the "Bland-Altman random effects method for repeated measures data".[21] Prestatistical confirmation of a normal distribution was confirmed recurring to the Kolmogorov-Smirnov test (Univariate variable distribution analysis), after which a paired sample *t* test was used to properly place confidence intervals on the

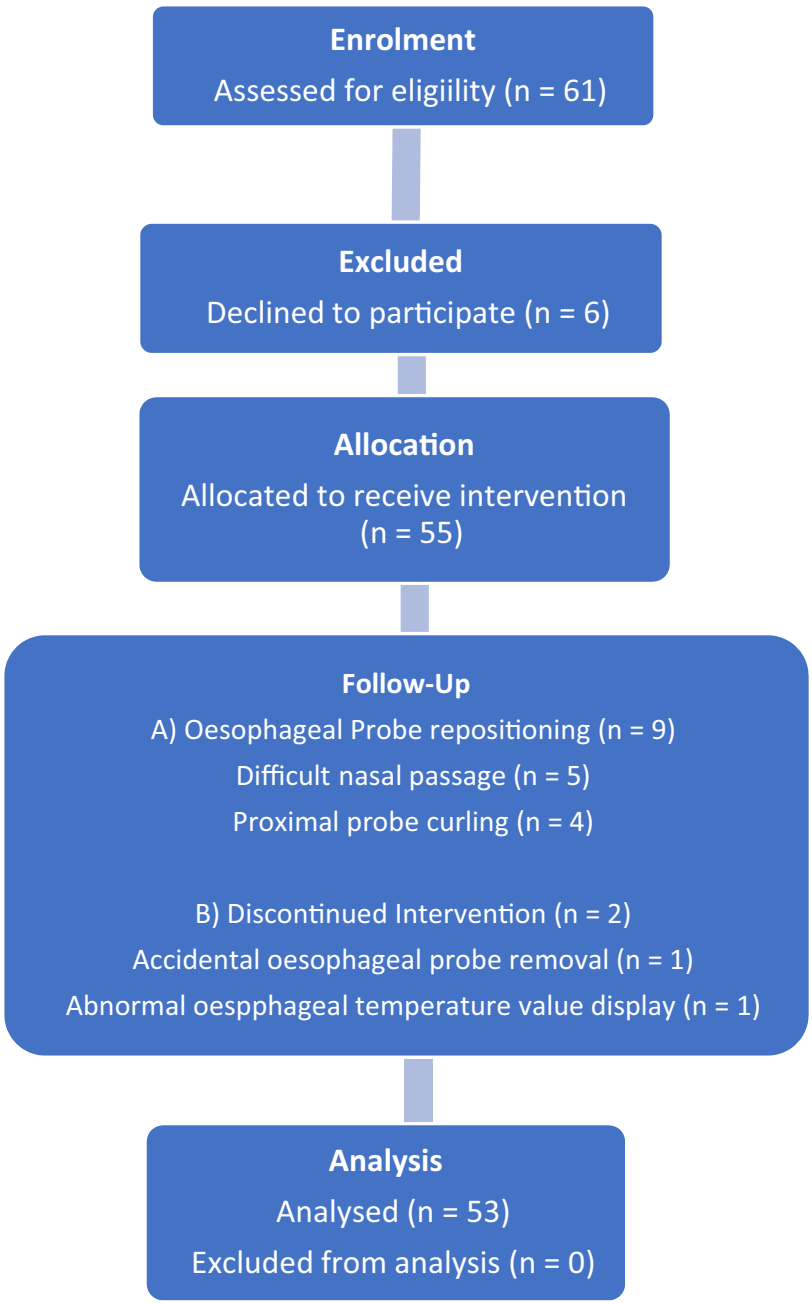

FIGURE 2 Consolidated Standards of Reporting (CONSORT) flow diagram

Bland-Altman Plot. Data analysis was performed with SPSS (IBM Corp. IBM SPSS Statistics for Mac.) per 1-minute intervals in order to obtain a representative dynamic picture of the measurements with both temperature measurement devices. Power analysis was performed both a priori and post-hoc with G*Power (Statistical Power Analyses for Windows and Mac, Release 3.1.9.3, 2018, Heinrich-Heine-Universität Düsseldorf).

3 | RESULTS

The study successfully included a total of 54 patients, corresponding to a sample size of 1664 data pairs. The study's Consolidated Standards of Reporting (CONSORT) flow diagram is displayed in Figure 2. The post-hoc power analysis (Table 1) revealed that for the achieved sample size of 1664 data pairs and a pre-established α value of 0.05, a study power (1-β) of 100% was obtained. The effect size was of 0.52.

The population's demographics and corresponding anesthetic details are displayed in Table 2. The 1664 data pairs were tested through means of a paired sample t-test for means, with an hypothesized mean difference of 0.5°C.[14,17,18] No significant difference between the two temperature measuring methods could be found (P = 0, t-stat = −54.8, t-critical two tail = 1.96, 1663 degrees of freedom). The variance within SpotOn measurements sample was of 0.26, and of 0.25 for the esophageal probe. The Pearson correlation product between the two methods was of 0.86. Lin's concordance correlation coefficient was of 0.83 (95% CI: 0.81-0.84).

Difference analysis between the two measuring methods revealed that the average difference between them was of 0.14°C (Standard deviation 0.27, Upper Limit of agreement 0.66, Lower limit of agreement −0.39, α = 0.05). Based on this difference analysis, a Bland-Altman plot was constructed (Figure 3). The proportion of measurements of which the absolute difference was within the threshold of 0.5°C was of 89.5%.

When analyzing the difference between the beginning and end temperatures, one could observe that the average temperature difference was of −0,54°C within the SpotOn group, and of −0,47°C in the esophageal temperature group. Thirty children (56%) in the SpotOn group had a temperature drop equal or greater than 0,5°C, as opposed to 27 (50%) in the esophageal temperature group.

TABLE 1 Power analysis of the study

Statistical variable	Value
α Error Probability	0.05
Power (1 −β error probability)	1
Total Sample Size	1664
Effect Size (dz)	0.520349
Critical t	1.9613915
Non-centrality parameter δ	21.2261576

4 | DISCUSSION

This method-agreement study shows that in controlled elective anesthetic conditions, there is no significant difference between the SpotOn and the esophageal temperature measurements when used for perioperative temperature monitoring in selected pediatric patients. The SpotOn measurements were in average 0.14°C higher than those from the esophageal probe. This small degree of difference is highly unlikely to be of clinical significance, and lies significantly under the 0.5°C inaccuracy cutoff associated with a higher incidence of morbidity and mortality.[16] It must be recognized, however, that the upper limit of agreement lies slightly above the established 0.5°C cutoff (0.66°C). The SpotOn sensor might thus overestimate temperatures up to 0.66°C in pediatric patients, which must be taken into consideration when defining the acceptable lower temperature limits for each individual.

These results suggest that the SpotOn sensor might be as accurate in pediatric patients as in adults when compared to the most commonly used temperature measuring methods. In fact, when compared to Pulmonary Artery Catheter temperature in the intraoperative setting, the SpotOn has revealed to be in average − 0.08°C (95% limits of agreement of ±0.88) lower.[14] When compared to nasopharyngeal temperatures, the difference has been shown to average 0.07°C (95% limits of agreement from −0.38 to 0.51).[18] The Lin's correlation coefficient between the SpotOn and the esophageal probe

TABLE 2 Study's population Demographics and Anesthetic details

	Patients (n = 54)
Male (n)	42 (78%)
Female (n)	12 (22%)
Average Age (mo)	66.1 ± 46.8
Median Age (mo)	67
Age < 24 mo (n)	9 (16,7%)
Weight (kg)	19.8 ± 8.9
Height (cm)	107.1 ± 23.8
Ambient operating room temperature (°C)	23.9 ± 0.68
Duration of anesthesia (min)	49.0 ± 19.8
Type of surgery (n)	
General surgery	6 (11%)
Nose- ear- throat	14 (26%)
Urology	30 (55%)
Maxillofacial	2 (4%)
Vascular	2 (4%)
Airway instrumentation (n)	
Endotracheal tube	15 (28%)
Laryngeal mask airway	39 (72%)
Anesthesia induction type (n)	
Intravenous	2 (4%)
Inhalational with sevoflurane	52 (96%)

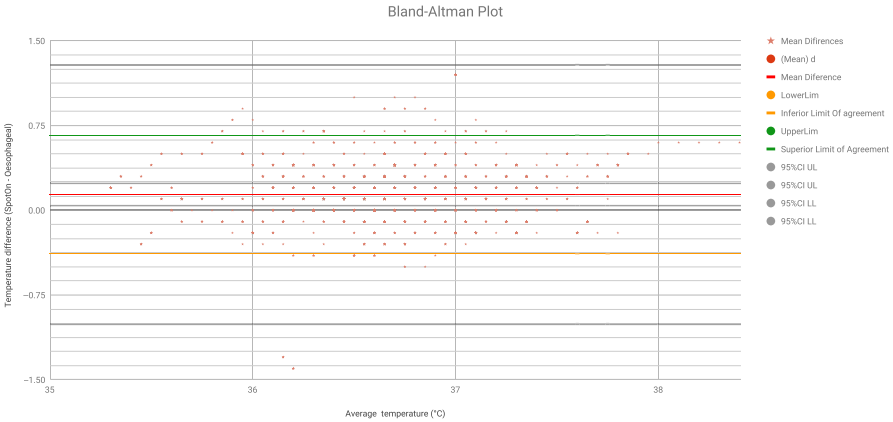

FIGURE 3 Bland-Altman analysis between esophageal and SpotOn thermometry. Lines: *Red:* average difference; *Green* - Upper limit of agreement; *Yellow:* Lower limit of agreement point overlap indicated by increased spot density. Considering the established 0.5°C cutoff, esophageal and SpotOn thermometry differed on average 0.14°C (95% limits of agreement: −0.39 to 0.66) with 89.5% of the differences being under 0.5°C.

(0.83) was higher than the one observed between the SpotOn and the Pulmonary Artery Catheter in the intraoperative period (0.70).[14]

Pearson's correlation product between the SpotOn and Esophageal temperatures was the same as that obtained for the SpotOn and Nasopharyngeal temperatures (0.86). Lin's coefficient is not presented in the study of Iden et al for a comparison with nasopharyngeal temperature [18] whereas Eshraghi et al demonstrated that 89.5% of the differences were under the 0.5°C threshold, versus 84% when compared to a Pulmonary Artery Catheter.[14] The results of our study are thus in line with those derived from adult populations.

In contrast to the study of Eshraghi et al,[14] we did not evaluate either pre or postoperative conditions in order to assess SpotOn`s capabilities outside the intraoperative period, although no immediate reasons suggest that the current correlation would not be applicable.

The device's equilibration and calibration period was quite short and temperature monitoring was possible under 3 minutes after placement of the SpotOn™ probe. This eliminated the earlier concerns of lagging behind significant temperature shifts.

The SpotOn™ sensor also revealed itself as a rather practical and user friendly monitoring device, allowing a continuum of temperature measurement from the operating room, to the post anesthesia care unit, where the sensor could be replugged and resume temperature monitoring without data trend loss. This was however not practically evaluated in this study as the sensor was removed before emergence for comfort of the child.

In the entire evaluation period no side effects associated with the use of the forehead sensor were registered.

This study has important limitations. First, it can only attest SpotOn's accuracy of representation of central core temperature in the pediatric patient by its comparison to a surrogate measure: the lower esophageal temperature. Although the correlation between esophageal and central core temperatures is acceptable in clinical terms, a pure analysis should always be done by comparison to a gold-standard method—in this case, the Pulmonary Artery Catheter temperature, which is ethically hardly acceptable in children. The second limitation concerns the positioning of the esophageal probe, which was done relying on the available anthropometric-based insertion-depth formulas. Unlike in the study of Snoek et al,[22] intraoperative radiographic tip position confirmation was hardly justifiable considering that our study's population underwent procedures not requiring use of intraoperative radiography. Ultrasound confirmation would be ideal, but its use for this specific purpose is technically challenging. Moreover, the restrictive exclusion criteria used in our study impede the generalization of the results to the complicated anesthetic settings with which, to our opinion, overal anesthesiologists are less frequently confronted with. Finally, the observed narrow temperature variation range does not allow to extrapolate the validity of our results to situations of rapid and extreme temperature variations.

Last but not least, our study group was surprised to observe that in a significant proportion of cases, the core temperature dropped more than 0.5°C when compared to the starting temperature (n = 30 with the SponOn sensor, n = 27 with the esophageal temperature probe). This temperature fall occurred even in short procedures, and despite optimal and active perioperative temperature management, actually completely comparable to what has been described in the adult population.[23] This phenomenon again highlights the importance of temperature monitoring in the pediatric population.

5 | CONCLUSION

The SpotOn Zero-heat-flux thermometry sensor and esophageal temperature yielded comparable results when used for temperature monitoring in the selected pediatric population and in controlled anesthetic settings. The SpotOn has been shown to be as accurate as an esophageal temperature probe when estimating central core temperatures over a narrow range of temperatures whilst demonstrating no adverse events. Further analysis of the SpotOn in extremer temperature ranges is needed in order to assert its clinical validity.

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DISCLOSURES

This trial was conducted in accordance with the established protocol after approval by the IRB of the Universitair Ziekenhuis Brussel (reference 2017/0186, UZ Brussel, Brussels, Belgium). No grants were obtained except for institutional funding.

CONFLICT OF INTEREST

All authors declare to have no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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