

Validation of an ingestible temperature data logging and telemetry system during exercise in the heat

Gavin J.S. Travers^{a,b}, David S. Nichols^{a,c}, Abdulaziz Farooq^a, Sébastien Racinais^a, and Julien D. Périard^a

^aAthlete Health and Performance Research Centre, Aspetar Orthopaedic and Sports Medicine Hospital, Doha, Qatar; ^bDepartment of Life Sciences, The Centre for Human Performance, Exercise and Rehabilitation, Division of Sport, Health and Exercise Sciences, Brunel University London, Uxbridge, UK; ^cResearch Institute for Sport and Exercise Science, Liverpool John Moore's University, UK

ABSTRACT

Aim: Intestinal temperature telemetry systems are promising monitoring and research tools in athletes. However, the additional equipment that must be carried to continuously record temperature data limits their use to training. The purpose of this study was to assess the validity and reliability of a new gastrointestinal temperature data logging and telemetry system (e-CelsiusTM) during water bath experimentation and exercise trials. **Materials and Methods:** Temperature readings of 23 pairs of e-Celsius (T_{ec}) and VitalSense (T_{VS}) ingestible capsules were compared to rectal thermistor responses (T_{rec}) at 35, 38.5 and 42°C in a water bath. Devices were also assessed *in vivo* during steady-state cycling ($n = 11$) and intermittent running ($n = 11$) in hot conditions. **Results:** The water bath experiment showed T_{VS} and T_{ec} under-reported T_{rec} ($P < 0.001$). This underestimation of T_{rec} also occurred during both cycling (mean bias vs T_{VS} : 0.21°C, ICC: 0.84, 95% CI: 0.66–0.91; mean bias vs T_{ec} : 0.44°C, ICC: 0.68, 95% CI: 0.07–0.86, $P < 0.05$) and running trials (mean bias vs T_{VS} : 0.15°C, ICC: 0.92, 95% CI: 0.83–0.96; mean bias vs T_{ec} : 0.25, ICC: 0.86, 95% CI: 0.61–0.94, $P < 0.05$). However, calibrating the devices attenuated this difference during cycling and eliminated it during running. During recovery following cycling exercise, T_{ec} and T_{VS} were significantly lower than T_{rec} despite calibration ($P < 0.01$). **Conclusion:** These results indicate that both T_{ec} and T_{VS} under-report T_{rec} during steady-state and intermittent exercise in the heat, with T_{ec} predicting T_{rec} with the least accuracy of the telemetry devices. It is therefore recommended to calibrate these devices at multiple temperatures prior to use.

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Introduction

Gastrointestinal temperature, measured via an ingestible telemetry device, has been shown to be a valid index of core temperature,¹ with responses displaying similar profiles as measures made via the rectum or esophagus.^{2–4} Intestinal temperature assessment is also a popular technique in operational and occupational settings.⁵ Such wireless technology (e.g. VitalSense, CorTemp) provides a comfortable and practicable means of monitoring thermal strain. Although an expensive method relative to minimally invasive and reusable alternatives (e.g., axilla, oral or temporal temperatures⁴), intestinal temperature provides greater validity as an index of core temperature.^{3,6} However, in athletic settings the additional equipment that must be carried to receive data from the ingested capsule might impact upon performance.⁷

Moreover, it may be prohibited to carry additional equipment during sanctioned competition, thus limiting the use of such devices to monitoring training.

Recent technological advances have led to ingestible sized capsules that are capable of both live temperature telemetry and data storage. Negating the need for additional cumbersome equipment, the e-CelsiusTM system (BodyCap, Caen, France) presents as a promisingly useful tool for monitoring core temperature within training and competition. Previous studies show the capsules meet standard electrical thermometry performance requirements⁸ and have yielded similar results when compared to existing implantable telemetry systems in rats.⁹ Despite this, intestinal temperature profiles typically display slower responses to rapid body temperature changes in humans when compared to other measurement sites (i.e. pulmonary artery or esophagus) used in

CONTACT Julien D. Périard  Julien.Periard@aspetar.com  Athlete Health and Performance Research Centre, Aspetar Orthopaedic and Sports Medicine Hospital, PO Box 29222, Doha, Qatar.

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clinical settings.^{10,11} Therefore direct comparisons of gastrointestinal telemetry systems to a clinical criterion standard are often used to assess their measurement accuracy during exercise in the heat.

To date, the validity of the e-Celsius™ system as a device for monitoring steady state and intermittent exercising temperature responses in the heat compared to existing invasive and non-invasive methods remains unknown. Therefore, the aim of this study was to first use a water bath experiment to determine the validity and reliability of the e-Celsius™ system compared to another validated commercially available ingestible telemetry system (VitalSense, Philips Respironics, Bend, Oregon, USA),¹² and a criterion standard used in laboratory research; rectal temperature. A secondary aim was to compare the performance of the device during both steady-state cycling and intermittent running in hot-humid conditions. It was hypothesized that the e-Celsius™ system would perform similarly to the existing system and criterion standard, and would therefore be a valid and reliable tool for use in laboratory and field settings.

Materials and methods

Participants

A total of 16 participants took part in the study, which was conducted at the Athlete Health and Performance Research Center laboratories at Aspetar, Qatar. Experiments consisted of low-intensity steady state cycling ($n = 11$) and/or intermittent soccer-simulating treadmill running ($n = 11$) in laboratory conditions. Six participants completed both trials. Cycling participants' average age, height, body mass and maximal oxygen uptake (VO_{2max}) were 33 ± 6 y, 179 ± 6 cm, 78.3 ± 5.3 kg, 54.6 ± 5.4 ml/kg/min, whereas running participants were 33 ± 6 y, 179 ± 6 cm, 78.3 ± 10.2 kg and 56.2 ± 5.4 ml/kg/min. All participants were recreationally trained cyclists and team sport players and provided written informed consent prior to participation. The study was approved by the institute's ethics review committee (Anti-Doping Lab Qatar) and conforms to the declaration of Helsinki.

Ingestible telemetric temperature systems

The e-Celsius™ capsule is 17 mm long and 8.2 mm in diameter. Temperature data is sampled and

transmitted every 30 s, and is displayed in real time on an external receiver (e-Viewer, BodyCap, Caen, France) when within ~ 1 m of the ingested capsule. When not in contact with the receiver, data is stored within the capsule and may be downloaded to the receiver at the end of a data acquisition period for further analysis. The VitalSense capsule is 23 mm in length and 8.7 mm in diameter. Once activated, data can be immediately transmitted by radio telemetry a minimum of every 15 s to a wireless ambulatory chest strap that contains a variety of sensors to monitor physiological status (EquiVital Life Monitor, Hidalgo Ltd. Cambridge, UK). The data collected can be displayed and stored on a laptop via Bluetooth®.

Water bath experiment

Prior to each experimental trial one e-Celsius™ and one VitalSense temperature capsule were activated and assigned to a dedicated data receiver. Receivers were synchronised on activation to ensure temperature measurements of the eCelsius™ (T_{ec}) and VitalSense (T_{vs}) systems occurred simultaneously and data could be later averaged over the course of a 1 min period. All capsules (23 pairs) and rectal temperature (T_{rec}) thermistors underwent a 3-point calibration in a water bath (WNB 14, Memmert GmbH, Swabach, Germany) at 35, 38.5 and 42°C. Temperature of the bath was set according to an uninsulated digital thermistor (MAC flexible probe, Ellab, Hillerød, Denmark) with a temperature variation of $\pm 0.1^\circ\text{C}$ across 15–45°C, which was used as a reference standard. Capsules were lowered into a thin meshed metal container so that they did not touch the interior surfaces of the water bath. The reference temperature and rectal thermistors were secured to the edge of the bath by tape so that they were fully immersed by a minimum of 5 cm and placed in close proximity of the capsules. Care was taken to ensure capsules did not come into contact with each other while water was constantly circulated in the bath. Following a 15 min period of stable reference temperature readings at 35°C, a 20 min measurement period began where temperature readings were sampled every minute from each device (i.e., reference temperature, T_{ec} , T_{vs} and T_{rec}). At the end of this period the process was repeated at 38.5 and 42°C, respectively. Following the water bath experiment each thermistor

temperature could then be manually corrected using raw values in the equation:

$$\text{Corrected Value} = \text{Intercept} + \text{Slope} \times \text{Observed Value}$$

where; the Observed Value is the raw (i.e. uncorrected) data transmitted by the respective device at a given time and the Intercept and Slope are values obtained from regression analysis of the device *vs.* the reference temperature over the 3-point calibration.

Pre-experimental procedures

In an initial visit, participants completed an exercise test to determine $\text{VO}_{2\text{max}}$ on an electronically braked cycle ergometer (Schoberer Rad Meßtechnik; SRM, Jülich, Germany) and/or motorised treadmill (Cosmed T170 DE Med, hp-cosmos, Nussdorf-Traunstein, Germany) in $\sim 20^{\circ}\text{C}$ and $\sim 50\%$ relative humidity (RH) conditions. Participants completing both experimental trials undertook both $\text{VO}_{2\text{max}}$ tests on separate days. They were required to abstain from vigorous physical activity and alcohol consumption for 24 h and caffeine intake for 12 h prior to attending the laboratory.

The cycling test consisted of pedalling at a self-selected cadence while resistance was applied in the order of 5 W every 10 s until volitional exhaustion, or cadence fell below 60 rpm, despite strong verbal encouragement. The treadmill test consisted of running at a speed of 12.5 km/h at a 0% gradient for a 2 min period, after which the gradient was increased by 2% every 2 min until the point of volitional fatigue. During each test heart rate was measured continuously using a telemetry belt strapped to the chest (T31, Polar Electro, Kempele, Finland) and pulmonary gas exchange was measured via on-line analysis of breath-by-breath gases (MasterScreen CPX, Carefusion GmbH, Germany). $\text{VO}_{2\text{max}}$ was defined as the mean VO_2 over the final min of the incremental cycling or running test, while maximal aerobic power output in the cycling test was determined as the highest mean power output over 30 s.

Experimental procedures

Participants reported to the laboratory on the day before each experimental trial. They were provided

with one e-CelsiusTM and one VitalSense telemetry capsule and were instructed to ingest both ~ 8 hours prior to experimentation with water, followed by a standardised light meal to aid transit into the gastrointestinal tract.¹ All trials were completed on separate days with a minimum of 24 h between each visit. In cases where participants completed both the cycling and running trial, separate pairs of capsules were ingested to standardise time between ingestion and experimentation.

On arrival to the laboratory for the experimental trial, nude body mass was measured before participants self-inserted a rectal thermistor (MRB rectal probe, Ellab, Hillerød, Denmark) 15 cm beyond the anal sphincter for measurement of T_{rec} . For the cycling trials, participants wore cycling shorts, socks and cycling shoes, and during the running trials wore shorts, socks and running shoes. During each trial they wore a heart rate monitor and an EquiVital Life Monitor ambulatory belt that housed the T_{VS} receiver. Participants then sat quietly in the laboratory ($22.3 \pm 2.6^{\circ}\text{C}$ and $50 \pm 9\%$ RH) while heart rate and T_{rec} were measured each min over a 5 min period. Participants then moved into an environmental chamber to complete the cycling or running protocol. Average ambient conditions during the cycling and running trials were $35.1 \pm 0.3^{\circ}\text{C}$ and $52.3 \pm 3.5\%$ RH, and $32 \pm 0.8^{\circ}\text{C}$ and $41 \pm 7.8\%$ RH, respectively. Cycling trials consisted of cycling on the SRM ergometer at 30% of maximal aerobic power output for an initial 10 min, followed by a further 50 min at 45% of maximal aerobic power output. The intermittent soccer-specific running task consisted of an initial 10 min self-paced warm up on the motorised treadmill, followed by a 5 min rest/stretching period before the task began. The running task was designed to simulate the typical activity profile of 45 min of soccer.^{13,14} The duration, speed and pattern of the movements of the running task are displayed as a 15 min block in [Figure 1](#), which was repeated 3 times consecutively. Heart rate and T_{rec} were recorded at 5 min intervals, while ambient conditions were recorded every 10 min throughout the trials. Participants were permitted to drink water *ad libitum* during the trial. All water was placed into the environmental chamber ~ 90 min before trial commencement to allow it to equilibrate to the conditions,

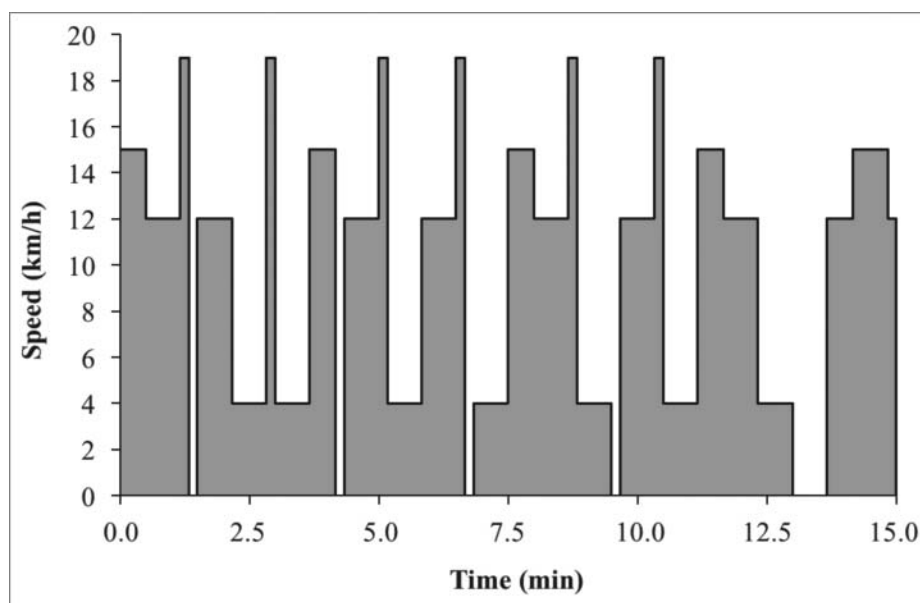


Figure 1. Intermittent treadmill speeds over 15 min of the intermittent running protocol. Each 15 min block was repeated 3 times consecutively. Adapted from Clarke et al.¹⁴ and Drust et al.¹³

thereby minimising any potential confounding effects on telemetry capsule temperature.

At the end of each trial, participants immediately exited the environmental chamber and lay supine in the laboratory ($24.2 \pm 2.3^\circ\text{C}$ and $45 \pm 8\%$ RH) for a period of 20 min. During this time data from the trial in the T_{ec} capsule were downloaded and post-exercise T_{VS} and T_{rec} were monitored. Laboratory and environmental chamber conditions were monitored throughout the trials using a wet bulb globe temperature monitor (Kestrel 4400 Heat Stress Meter, loftopia, LLC, Birmingham, MI, USA).

Statistical analyses

Data was coded and analyzed using computer software (SPSS Version 20, Chicago, IL, USA). Mean difference (bias) and 95% confidence intervals between each thermistor and the reference temperature in the water bath experiment were computed using a 2-tailed paired *t*-test. Mean difference (bias) and 95% confidence intervals between T_{ec} , T_{VS} and T_{rec} in the water bath and laboratory experiments were computed using a 2-tailed paired *t*-test considering T_{rec} as the criterion standard for body core temperature. The differences between each telemetry capsule and T_{rec} recording at each of the 3 temperature points during the water bath experiment were compared using One-way

Analysis of Variance (ANOVA) to establish whether the differences vary at different temperature points. Absolute changes in temperature during exercise and recovery were converted to rates (i.e., $\Delta^\circ\text{C}/\text{min}$) and compared to assess the sensitivity of measurement sites and devices. In order to assess the inter-measure agreement, Intra Class Coefficients (ICC) for agreement and 95% confidence intervals (CI) were reported.^{15,16} Limits of Agreement (LOA) at 95% were computed as the product of the standard deviation of the mean difference between the thermistors and a reference value of 1.96.¹⁵ Standard error of the measurement (SEM)/typical error¹⁷ was estimated from the square root of the mean square residual from the ANOVA output. Data are reported as mean \pm SD unless otherwise stated. The level of significance was set at $P = 0.05$.

Results

Water bath experiment

Both T_{ec} and T_{VS} reported significantly different temperatures compared to the reference temperature across the three calibration temperatures (bias: 0.34°C , 95% CI: $0.31 - 0.37^\circ\text{C}$; bias: 0.18°C , 95% CI: $0.18 - 0.19^\circ\text{C}$; respectively, $P < 0.001$). Although a significant difference was noted between T_{rec} and reference temperature at 35°C (bias: 0.03°C , 95% CI:

Table 1. Reliability statistics for T_{rec} , T_{VS} and T_{ec} thermistors undergoing a three-point calibration in a temperature controlled water bath ($n = 23$).

		Mean Bias (°C) & 95% Confidence Interval	Intraclass Correlation Coefficient & 95% Confidence Interval	Limits of Agreement (95%)	Standard Error of Measurement (°C)
$T_{rec} - T_{VS}$	35.0	0.13 (0.12 - 0.15)*	0.04 (-0.03 - +0.11)	±0.26	0.09
	38.5	0.17 (0.15 - 0.18)*	-0.05(-0.13 - +0.25)	±0.28	0.10
	42.0	0.20 (0.19 - 0.22)*	0.03 (-0.03 - +0.94)	±0.34	0.12
Overall		0.17 (0.16 - 0.18)*	0.99 (0.98 - 0.99)	±0.30	0.11
$T_{rec} - T_{ec}$	35.0	0.19 (0.18 - 0.21)*	0.02 (-0.03 - +0.08)	±0.30	0.11
	38.5	0.24 (0.22 - 0.25)*	0.05 (-0.04 - +0.12)	±0.29	0.10
	42.0	0.26 (0.24 - 0.28)*	0.04 (-0.03 - +0.04)	±0.40	0.14
Overall		0.23 (0.22 - 0.24)*	0.99 (0.89 - 0.99)	±0.34	0.12
$T_{VS} - T_{ec}$	35.0	0.06 (0.05 - 0.07)*	0.54 (0.31 - 0.68)	±0.20	0.07
	38.5	0.07 (0.06 - 0.08)*	0.35 (0.12 - 0.52)	±0.21	0.07
	42.0	0.06 (0.05 - 0.07)*	0.54 (0.37 - 0.66)	±0.23	0.08
Overall		0.06 (0.06 - 0.07)*	0.99 (0.99 - 0.99)	±0.21	0.08

*Significant difference, $P < 0.01$

0.02 – 0.04°C, $P < 0.01$), no difference was observed at 38.5 and 42°C. Both T_{ec} and T_{VS} were significantly lower than T_{rec} across all temperature ranges ($P < 0.001$; Table 1). T_{ec} also consistently under-reported both T_{rec} and T_{VS} ($P < 0.001$). One-way ANOVA indicated that the difference between the reference temperature and both telemetry capsules at 35°C was significantly different to that at 42°C with a mean difference of -0.03°C (95% CI: $-0.05 - -0.01^\circ\text{C}$; $P < 0.01$), while no other differences were observed. The SEM values were increasing with higher calibration temperature points. Relative to T_{rec} , overall T_{VS} showed better performance (95% LOA ± 0.30 and SEM: 0.11) compared to T_{ec} (95% LOA ± 0.34 and SEM: 0.12).

Cycling trial

Prior to cycling exercise, raw/uncorrected temperature values from the capsules reported significantly lower than raw T_{rec} values ($P < 0.05$; Fig. 2A, Table 2). There were no differences in raw T_{rec} and raw T_{VS} during cycling except at 50 and 55 min (0.22°C, 95% CI: 0.02–0.43 and 0.27°C, 0.06–0.49°C, respectively; $P < 0.05$). Raw T_{VS} recordings were also significantly lower than raw T_{rec} during the recovery period following exercise ($P < 0.001$). Raw T_{ec} recordings were significantly lower than raw T_{rec} at baseline and from 5 min of exercise until the end of the recovery period following cycling ($P < 0.05$). Raw T_{ec} was also significantly lower than raw T_{VS} at various time points throughout baseline, cycling and recovery ($P < 0.05$; Fig. 2A).

Corrected temperature values altered the relationship between T_{rec} , T_{VS} and T_{ec} during exercise

(Fig. 2B and 2C). During the recovery period, corrected T_{VS} and T_{ec} were significantly lower than T_{rec} ($P < 0.01$; Fig. 2B and 2C). Corrected T_{ec} and T_{VS} did not differ throughout the trial except at 5 and 60 min during cycling exercise ($P < 0.05$; Fig. 2D). The average increase in the corrected values for T_{rec} ($0.033 \pm 0.006^\circ\text{C}/\text{min}$) during cycling was significantly greater than that of T_{ec} ($0.026 \pm 0.008^\circ\text{C}/\text{min}$; $P < 0.05$), but similar to T_{VS} ($0.028 \pm 0.007^\circ\text{C}/\text{min}$, $P = 1.22$). During the 20 min recovery period after exercise, the temperature change per minute was similar across all 3 measurements ($\sim 0.049^\circ\text{C}/\text{min}$, $P > 0.05$).

Throughout the cycling trial, telemetry devices were significantly biased, under-reporting raw T_{rec} values ($P < 0.01$; Fig. 3A and 3B). Although bias was significantly away from 0 ($P < 0.05$), raw T_{VS} showed excellent reliability during cycling with an ICC: 0.90 (95% CI: 0.84–0.93) and SEM: 0.21°C (Table 2). On the other hand, raw T_{ec} provided significantly greater bias ($P < 0.05$). Moreover, although the ICC was as high as 0.76, it provided wider CI (0.27 to 0.90). Although systematic bias was present for both raw T_{VS} and Raw T_{ec} , this was not proportional (i.e. bias did not increase proportionally with magnitude of the temperature measured; Fig. 3A and 3B) and appears to have been introduced mostly during the recovery period. A significant difference was also noted between telemetry devices ($P < 0.01$; Table 2, Fig. 3C). During exercise, the SEM was 0.24 and 0.29°C for raw T_{VS} and raw T_{ec} relative to raw T_{rec} , respectively ($P < 0.05$). While the SEM decreased during post-exercise recovery, the under prediction of raw T_{rec} by telemetry increased (Table 2). Raw T_{VS} capsules reported significantly higher values than raw

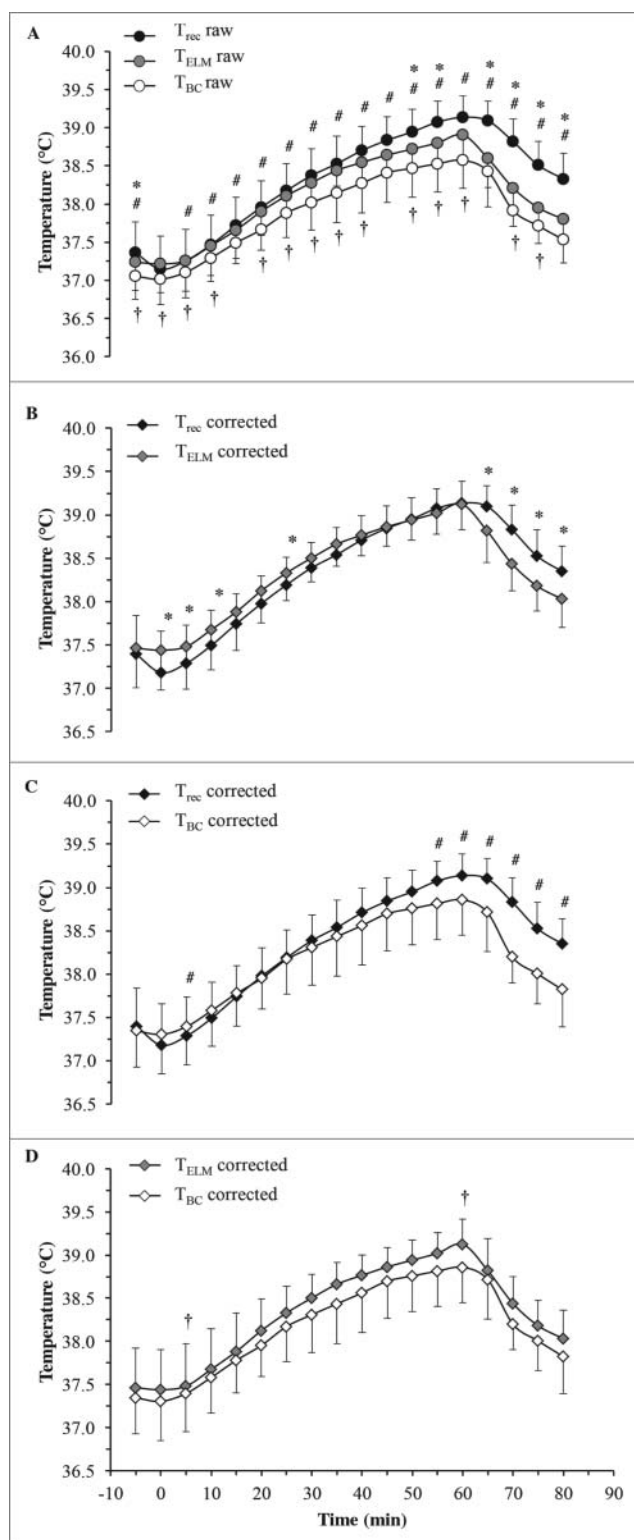


Figure 2. Raw (A) and corrected (B-D) temperature responses to 10 min cycling at 30% of maximal aerobic power output followed by 50 min at 45% of maximal aerobic power output. *Significant difference between T_{rec} and T_{VS} , $P < 0.05$; #Significant difference between T_{rec} and T_{eC} , $P < 0.05$; †Significant difference between T_{VS} and T_{eC} , $P < 0.05$.

T_{eC} throughout the cycling trial, with a mean bias of 0.24 (95% CI: 0.19–0.28°C).

Running trial

One participant had passed the VitalSense capsule prior to commencing the trial. Therefore, data are presented for 10 participants for all T_{VS} running analyses. During the running trial, raw T_{rec} values were significantly higher than raw T_{VS} from 10–35 min ($P < 0.05$), whereas they were higher than raw T_{eC} from 5 to 15 min of exercise and from 30 min to end of the recovery period, except at 5 min post ($P < 0.05$; Fig 4A). Raw T_{eC} were significantly lower than raw T_{VS} until 10 min into the running task and again at the end of exercise ($P < 0.05$).

Corrected temperature values for T_{rec} , T_{VS} and T_{eC} were not different during exercise and recovery (Fig. 4B and 4C), whereas corrected values resulted in a higher T_{VS} compared to T_{eC} at baseline until the beginning of the trial ($P < 0.05$; Fig. 4D). When the increases in corrected temperature were compared, the increase in T_{rec} ($0.031 \pm 0.009^\circ\text{C}/\text{min}$) was significantly greater than that of T_{VS} ($0.027 \pm 0.009^\circ\text{C}/\text{min}$; $P < 0.01$) and T_{eC} ($0.026 \pm 0.009^\circ\text{C}/\text{min}$; $P < 0.01$). Following exercise, T_{VS} decreased at a faster rate than T_{rec} (-0.054 ± 0.021 vs $-0.054 \pm 0.015^\circ\text{C}/\text{min}$; $P < 0.05$), while T_{eC} declined at a similar rate to T_{rec} ($P = 0.12$).

Overall, raw T_{VS} and raw T_{eC} were lower than raw T_{rec} during intermittent running and post-exercise recovery ($P < 0.01$; Table 3, Fig. 4A). Although bias was significantly away from 0 ($P < 0.05$), the ICC for agreement was excellent for raw T_{VS} during the run (ICC: 0.90 (95% CI: 0.70 to 0.96)) and raw T_{eC} (ICC: 0.83 (95% CI: 0.51–0.92)). The data indicated a higher raw T_{rec} bias compared to raw T_{VS} and raw T_{eC} , respectively ($P < 0.01$; Table 3, Fig. 5A and 5B). Although systematic bias was present, as the line of equality lies away from the mean bias, this was not proportional (i.e., bias did not increase proportionally with magnitude of the temperature measured; Fig. 5A and 5B). As with the cycling trial, the bias appears to have been introduced mostly during the recovery period. Furthermore, a mean bias was observed for raw T_{VS} compared to raw T_{eC} throughout (Fig. 5C). During the intermittent running task, a

Table 2. Reliability statistics for T_{VS} and T_{eC} against T_{rec} and for T_{eC} against T_{VS} during cycling in the heat and post-exercise recovery in cool conditions ($n = 11$). Data presented is raw uncorrected values.

		Mean Bias (°C) & 95% Confidence Interval	Intraclass Correlation Coefficient & 95% Confidence Interval	Limits of Agreement (95%)	Standard Error of Measurement (°C)
$T_{rec} - T_{VS}$	Pre	0.13 (0.03 - 0.23)*	0.86 (0.45 - 0.97)	±0.29	0.11
	Cycle	0.11 (0.06 - 0.16)*	0.90 (0.84 - 0.93)	±0.59	0.21
	Post	0.55 (0.47 - 0.62)*	0.45 (-0.08 - +0.79)	±0.50	0.18
Overall		0.21 (0.16 - 0.25)*	0.84 (0.66 - 0.91)	±0.66	0.24
$T_{rec} - T_{eC}$	Pre	0.31 (0.22 - 0.34)*	0.58 (-0.10 - 0.88)	±0.44	0.16
	Cycle	0.34 (0.28 - 0.40)*	0.76 (0.27 - 0.90)	±0.73	0.26
	Post	0.78 (0.68 - 0.89)*	0.27 (-0.08 - +0.63)	±0.69	0.25
Overall		0.44 (0.38 - 0.49)*	0.68 (0.07 - 0.86)	±0.79	0.29
$T_{VS} - T_{eC}$	Pre	0.18 (0.04 - 0.32)*	0.72 (0.11 - 0.92)	±0.41	0.15
	Cycle	0.24 (0.19 - 0.28)*	0.84 (0.50 - 0.93)	±0.58	0.25
	Post	0.25 (0.14 - 0.36)*	0.62 (0.22 - 0.81)	±0.68	0.21
Overall		0.24 (0.19 - 0.28)*	0.82 (0.50 - 0.92)	±0.59	0.21

*Significant difference, $P < 0.05$

significant mean bias for raw T_{rec} was observed between the telemetry devices ($P < 0.01$; Table 3).

Discussion

This study sought to determine the validity and reliability of the e-Celsius™ system from BodyCap as a method for monitoring core temperature during exercise in hot/humid environments. This is the first study to examine the performance of this core temperature data logging and monitoring device in relation to an existing telemetry system (i.e. VitalSense) and medical grade thermistors in both water bath and *in vivo* human exercise experiments. The main findings from this study are that i) both T_{eC} and T_{VS} reported lower temperatures across the three calibration temperatures relative to the reference value and T_{rec} , with T_{eC} also under-reporting T_{VS} , ii) the e-Celsius™ capsules consistently reported lower temperatures than both the T_{rec} and T_{VS} during steady-state cycling, as well as at the onset and termination of intermittent running, iii) and during rapid and large changes in body temperature with exercise in the heat, both T_{eC} and T_{VS} significantly under-reported T_{rec} throughout cycling and intermittent running. However, calibrating the devices significantly attenuated this difference during steady state cycling and eliminated it during the intermittent running task. Hence, it is strongly recommended to calibrate intestinal telemetry systems prior to use.

For evaluating the validity and reliability of devices such as intestinal telemetry systems, an informed decision is required when considering whether the device meets agreement standards. The device must provide low bias, high ICC with the

reference temperature, low SEM and narrow 95% LOA. Moreover, the validity statistics should be consistent across different exercise conditions, like steady-state cycling and intermittent running in hot conditions. The differences between devices during the water bath experiment were not equal across the 3 temperatures. This suggests that the relationship between our reference thermistor and the capsules was not linear. A potential limitation of the present study is that we did not manipulate bath temperature over time and record the responses of devices at discrete intervals. This would allow a non-linear correction to be applied to the raw data. Notwithstanding, the largest difference observed in the relationship between the telemetry devices and reference temperature was 0.03°C (both T_{VS} and T_{eC}). Given this minimal difference and the sensitivity of the rectal thermistor in reporting to the nearest 0.1°C, a calibration of this nature would likely not have made a detectable difference to the corrected data presented.

Chapon et al.⁸ previously calibrated a prototype of the e-Celsius™ system and observed 88% of capsules used reported temperatures within ±0.2°C of their criterion standard. In the present investigation, the 23 capsules used in the water bath experiment reported similar lower (0.23°C) and upper (0.25°C) temperatures when calculated using a 95% limits of agreement. Adjusting these limits to a similar level to that of Chapon et al.,⁸ the lower and upper levels of agreement remain unchanged across the 3 points (35, 38 and 42°C). Despite the differences in sensitivity of the reference probe used in this study (0.1°C) and that of Chapon et al.⁸ (0.01°C), the mean bias and range of T_{eC} values from our water bath

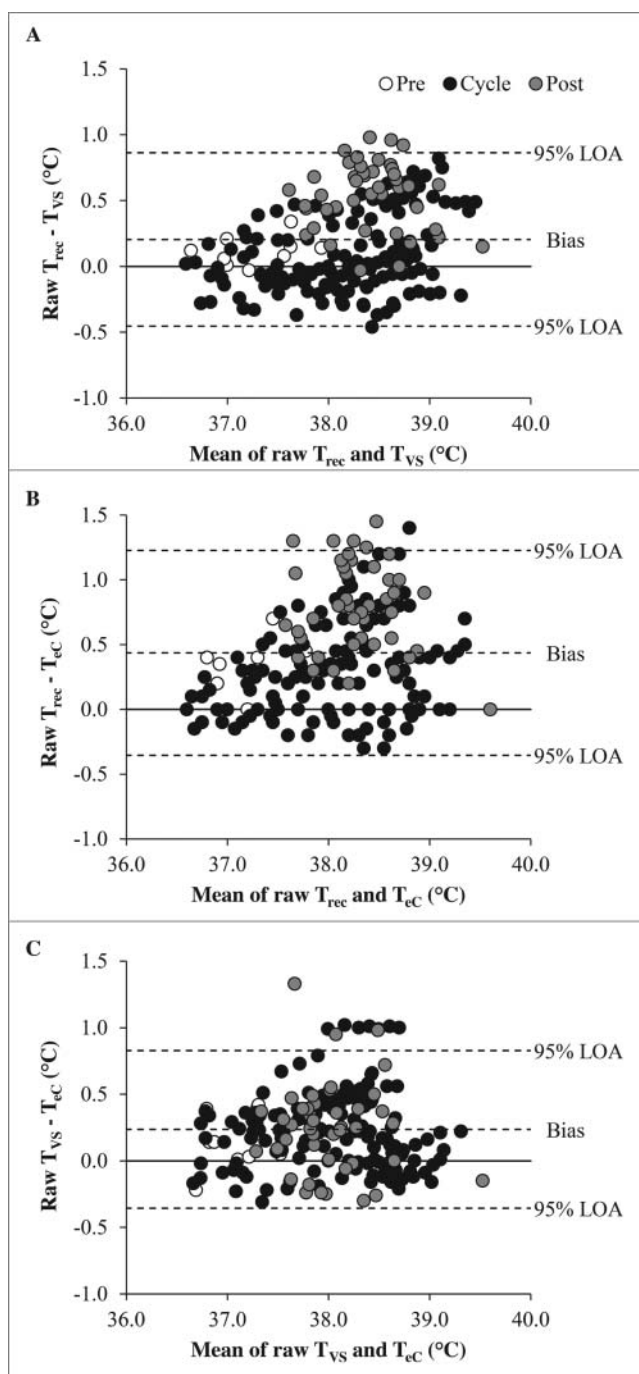


Figure 3. Bland-Altman plots of raw T_{VS} and T_{eC} vs. T_{rec} (A and B) and T_{VS} vs. T_{eC} (C) prior to exercise, during 60 min of cycling and 20 min of post-exercise recovery.

experiment are slightly larger ($0.24 \pm 0.14^\circ\text{C}$). Conversely, the average difference between our reference thermistor and T_{VS} was $0.18 \pm 0.14^\circ\text{C}$, while the difference between the 2 capsules in the water bath experiment is similar to that previously reported.⁹ Therefore, it is recommended that intestinal temperature telemetry capsules undergo calibration prior to use.

Although previous studies report varying relationships, intestinal temperature tends to be higher than that of the rectum during passive rest in temperate environments.^{1,2,18,19} In the present study, both T_{eC} and T_{VS} were lower than T_{rec} prior to cycling, whereas similar temperatures were observed before the running task (Fig. 2A and 4A). When corrected, both telemetry systems reported a temperature similar to that of T_{rec} at rest, which is in agreement with numerous other observations.^{3,4,20} Data from the water bath experiments also indicated a consistent under-reporting of T_{rec} by both T_{VS} and T_{eC} (Table 2). Therefore the differences at rest in the present study compared to previous work are likely due to the inherent difference between both temperature telemetry systems to the rectal thermistor used.

During exercise, a large amount of evidence suggests acceptable agreement between intestinal and rectal temperatures at levels of moderate hyperthermia^{18,20} up to temperatures of $\sim 39.5^\circ\text{C}$.⁴ A review by Byrne and Lim¹ highlighted that the bias between rectal and intestinal temperature varies in magnitude and direction. However, the authors concluded there is an acceptable agreement of $<0.4^\circ\text{C}$ between temperatures. During the running trial, there were no differences in corrected temperatures across all 3 thermistors (Fig. 4B and 4C). However, this is in contrast to the cycling trial, which was conducted under conditions of greater heat stress. At rest and during the first few minutes of cycling, corrected T_{VS} and T_{eC} were similar to T_{rec} . However, after 50 min of exercise T_{rec} was significantly higher than corrected T_{eC} (Fig. 2C). While the average differences between T_{eC} and T_{rec} at this point was within the acceptable limit ($\sim 0.25^\circ\text{C}$), the lower and upper 95% confidence intervals for these time points ranged from 0.03 – 0.51°C , respectively. This suggests a proportional systematic bias and a poor level of agreement when core temperature approaches $\sim 39^\circ\text{C}$ during exercise in the heat (Fig. 3A and 3B). After the cessation of exercise and transfer into cooler conditions, the mean bias increased further as core temperature declined. A more rapid decrease in intestinal temperature compared to T_{rec} following exercise is a typical response, yet these changes tend to be slower than temperature measured via the esophagus.¹ Therefore this should be considered when

Table 3. Reliability statistics for T_{VS} and T_{eC} against T_{rec} and for T_{eC} against T_{VS} during during intermittent running in the heat and post-exercise recovery in cool conditions ($n = 10$). Data presented is raw uncorrected values.

		Mean Bias (°C) & 95% Confidence Interval	Intraclass Correlation Coefficient & 95% Confidence Interval	Limits of Agreement (95%)	Standard Error of Measurement (°C)
$T_{rec} - T_{VS}$	Pre	0.03 (-0.16 - +0.23)	0.73 (0.22 - 0.93)	±0.53	0.19
	Run	0.18 (0.13 - 0.23)*	0.90 (0.70 - 0.96)	±0.48	0.17
	Post	0.14 (0.05 - 0.23)*	0.91 (0.81 - 0.96)	±0.46	0.20
Overall		0.15 (0.11 - 0.19)*	0.92 (0.83 - 0.96)	±0.51	0.18
$T_{rec} - T_{eC}$	Pre	0.17 (-0.06 - +0.39)	0.61 (0.10 - 0.87)	±0.66	0.24
	Run	0.26 (0.20 - 0.33)*	0.83 (0.51 - 0.92)	±0.66	0.24
	Post	0.29 (0.19 - 0.40)*	0.84 (0.47 - 0.94)	±0.70	0.25
Overall		0.25 (0.20 - 0.30)*	0.86 (0.61 - 0.94)	±0.67	0.24
$T_{VS} - T_{eC}$	Pre	0.15 (0.03 - 0.27)*	0.87 (0.34 - 0.97)	±0.32	0.12
	Run	0.11 (0.07 - 0.15)*	0.95 (0.89 - 0.97)	±0.42	0.15
	Post	0.14 (0.03 - 0.25)*	0.89 (0.78 - 0.94)	±0.67	0.24
Overall		0.12 (0.08 - 0.16)*	0.94 (0.88 - 0.96)	±0.48	0.17

*Significant difference, $P < 0.05$

using telemetry devices where it may be necessary to lower an individual's core temperature rapidly.

Kolka et al.²¹ observed intestinal temperature responded more rapidly than that of rectal temperature during moderate and intense exercise in warm conditions (29.5°C). In a more recent study by Teunissen et al.,¹¹ changes in rectal and intestinal temperature were similar (0.75 and 0.8°C, respectively) after 10 min of submaximal exercise followed by 8 min of maximal self-paced cycling in similar conditions to that used by Kolka et al.²¹ Easton et al.⁴ also observed no differences in rectal and intestinal temperature during 40 min of steady state cycling followed by a 16 km time trial. This is in contrast to the raw temperatures noted during cycling trial in the present investigation (Fig. 2A). However when corrected, the relationship between T_{rec} , T_{VS} and T_{eC} during cycling became much stronger, with variations in temperature potentially stemming from the capsules being in different locations. Indeed, the differences in corrected temperatures might indicate the capsules were located differently along the gastrointestinal tract (Figs. 2D and 4D). While it is not possible to know the exact location and movement of the capsules, exercise has been shown to increase peristaltic velocity, which may alter their position along the duodenum and therefore alter the temperature variability of the telemetry devices.^{2,22} Notwithstanding, Domitrovich et al.²³ studied the variation between telemetry capsules consumed 24 h and 40 min prior to 45 min of exercise and showed no differences in temperature between the 2 capsules. This suggests that starting location of the capsule (i.e., upper or lower gastrointestinal tract) may

not necessarily alter the temperature responses during steady-state exercise.

The discrepancy between corrected rectal and intestinal temperatures during the recovery period in cool conditions following cycling in the heat may relate to the distinct redistribution of blood flow during each of these phases. For instance, increases in core and skin temperature during exercise-heat stress result in a constriction of central vascular beds, such as in the splanchnic circulation, resulting in a repartitioning of blood flow to the periphery to dissipate heat.²⁴ This reduction in splanchnic flow occurs in proportion to the level of heat stress and exercise intensity.²⁵ Given the large amount of energy required to alter tissue temperature across the intestinal tract,⁴ the discrepancy in corrected temperature during the cycling recovery phase may be due to a large return of cooled blood from peripheral vascular beds, resulting in altered temperature responses across the intestine and rectum.²⁶ Accordingly, when rapidly moving from a hot/humid to cool environments, as may be necessary following the onset of heat illness symptoms, gastrointestinal temperature may significantly under predict that of the rectum.

Summary

This study investigated the validity and reliability of the e-CelsiusTM temperature data logging and monitoring system from BodyCap compared to an existing temperature telemetry system and a medical precision thermistor. Results of the water bath experiment indicate a large measurement error and

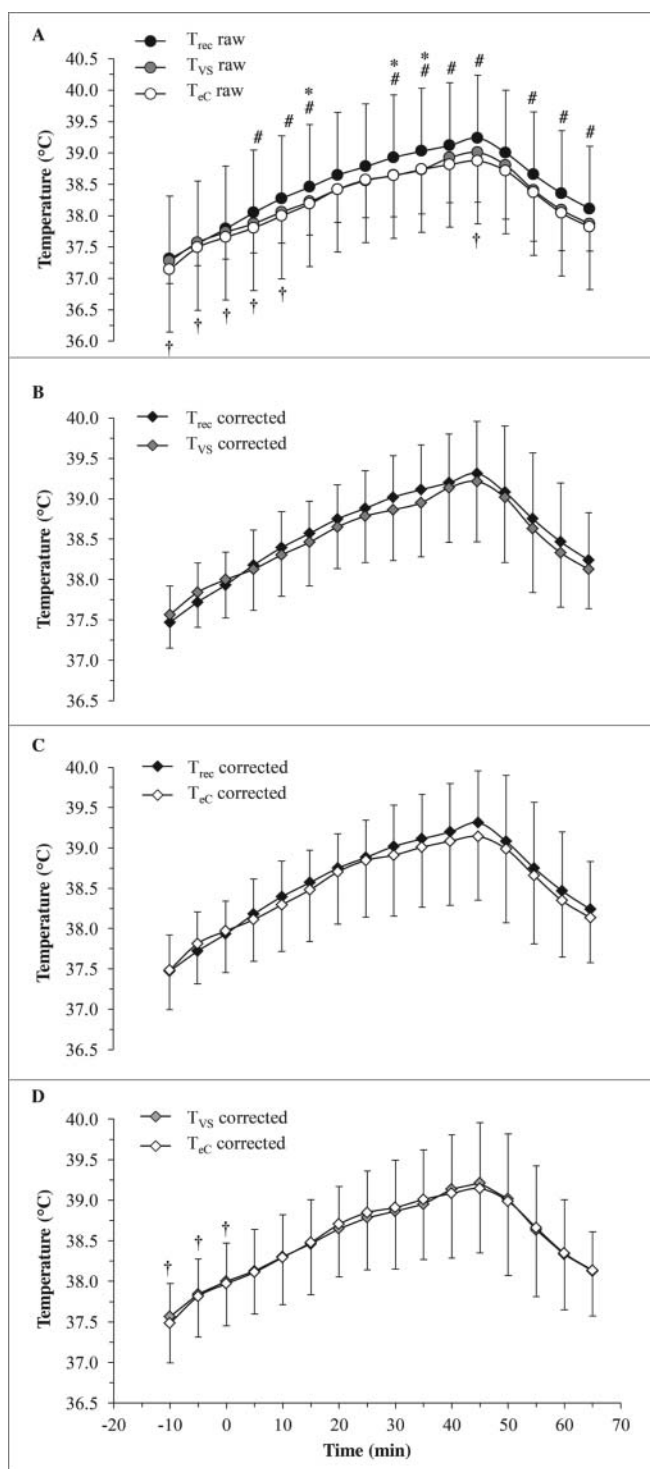


Figure 4. Raw (A) and corrected (B-D) temperature responses to a 10 min self-paced warm up and 45 min of intermittent treadmill running, followed by 20 min of recovery in cool conditions. *Significant difference between T_{rec} and T_{VS} , $P < 0.05$; #Significant difference between T_{rec} and T_{eC} , $P < 0.05$; †Significant difference between T_{VS} and T_{eC} , $P < 0.05$.

variability in both the e-CelsiusTM and VitalSense capsules, with e-CelsiusTM capsules consistently reporting slightly lower values than VitalSense.

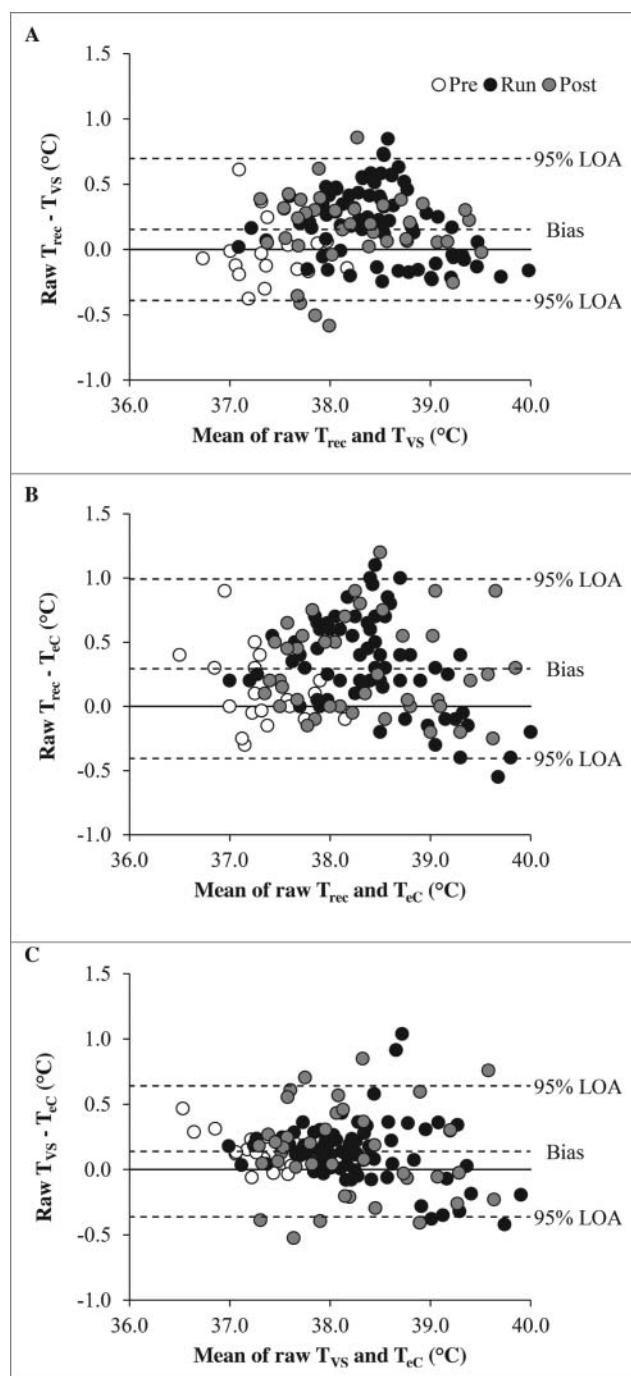


Figure 5. Bland-Altman plots of raw T_{VS} and T_{eC} vs. T_{rec} (A and B) and T_{VS} vs. T_{eC} (C) prior to exercise, during 45 min of intermittent running and 20 min of post-exercise recovery.

This trend was also observed during the cycling and running exercise trials. However, following a correction of the values, both telemetry devices recorded similar temperatures to that of T_{rec} during cycling and intermittent running. Both devices reported lower temperature values during the recovery phase of the cycling trial, which likely relates to rapid changes in whole-body temperature

and blood flow redistribution. It is therefore strongly recommended to calibrate ingestible telemetry devices prior to use, and to consider the possible under prediction of rectal temperature before using intestinal telemetry as a substitute for more obtrusive means of monitoring core temperature.

Abbreviations

CI	confidence intervals
ICC	intra-class correlation coefficient
LOA	limits of agreement
RH	relative humidity
SD	standard deviation
SEM	standard error of measurement
T _{eC}	e-Celsius™ temperature
T _{rec}	rectal temperature
T _{VS}	VitalSense temperature
VO _{2max}	maximal oxygen uptake

Disclosure of potential conflicts of interest

No potential conflicts of interest were disclosed.

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