

## A NEW NON-INVASIVE DEVICE TO MONITOR CORE TEMPERATURE ON EARTH AND IN SPACE

Hanns-Christian GUNGA<sup>1</sup>, Andreas WERNER<sup>1</sup>, Oliver OPATZ<sup>1</sup>,  
Alexander STAHN<sup>1</sup>, Karl KIRSCH<sup>1</sup>, Frank SATTLER<sup>2</sup>, Jochim KOCH<sup>2</sup>

<sup>1</sup> Charité University Medicine Berlin, Department of Physiology, Center for Space  
Medicine Berlin, Berlin-Dahlem, Germany

<sup>2</sup> Draegerwerk AG, Lübeck, Germany

Corresponding author:

Hanns - Christian GUNGA

Charité University Medicine Berlin, Department of Physiology,  
Center for Space Medicine Berlin, Thielallee 71, 14195 Berlin-Dahlem, Germany  
e-mail: hanns-christian.gunga@charite.de

### ABSTRACT

*Accurate measurement of the core temperature (T<sub>c</sub>) is fundamental to the study of human temperature regulation. As standard sites for the placement of T<sub>c</sub> measurement sensors have been used: the rectum, the bladder, the esophagus, the nasopharynx and the acoustic meatus. Nevertheless those measurement sites exhibit limited applicability under field conditions, in rescue operations or during peri- and postoperative long-term core temperature monitoring. There is, indeed, a high demand for a reliable, non-invasive, easy to handle telemetric device. But the ideal non-invasive measurement of core temperature has to meet requirements such as i) a convenient measurement site, ii) no bias through environmental conditions, and iii) a high sensitivity of the sensor regarding time shift and absolute temperature value. Recently, together with the Draegerwerke AG we have developed a new heat flux measurement device (so-called "Double Sensor") as a non-invasive T<sub>c</sub> sensor aiming to meet the requirements described above. Four recent studies in humans will be summarized and discussed to show the applicability of this new non-invasive method to monitor core temperature under different environmental and clinical settings on Earth and in Space.*

**Keywords:** non-invasive marker, core temperature, measurement, Earth, Space

## NOVA NEINVAZIVNA NAPRAVA ZA SPREMLJANJE TEMPERATURE SREDICE TELESA NA ZEMLJI IN V VESOLJU

### IZVLEČEK

*Natančno merjenje temperature sredice človeškega telesa (Tc) je poglavitno za preučevanje uravnavanja telesne temperature. Običajna mesta za namestitev senzorjev za merjenje Tc so rektum, mehur, požiralnik, nosni del žrela in sluhovod. Vendar pa ta mesta kažejo omejeno uporabnost v različnih pogojih, reševalnih operacijah ter med pred- ali pooperativnem dolgotrajnem spremljanju temperature sredice telesa. Tako obstaja velika potreba po zanesljivi, neinvazivni telemetrični napravi, ki bi bila enostavna za uporabo. Vendar pa mora najbolj primerno neinvazivno merjenje temperature sredice telesa ustrezati naslednjim zahtevam: i) ustrezno in priročno mesto za opravljanje meritve, ii) nepristranski pogoji v okolici in iii) visoka občutljivost sensorja glede na časovne spremembe in absolutno temperaturno vrednost. Tako smo nedavno skupaj z družbo Drägerwerk AG razvili novo merilno napravo s toplotnim pretokom (t. i. „dvojni senzor“), ki je neinvazivni senzor za merjenje Tc, ki ustreza zgoraj opisanim zahtevam. Povzeli in razpravljali bomo o štirih študijah, ki so bile nedavno izvedene na ljudeh in ki dokazujejo uporabnost te nove neinvazivne metode za spremljanje temperature sredice telesa v različnih okoljskih in kliničnih pogojih na Zemlji in v vesolju.*

***Ključne besede:*** neinvazivni marker, temperatura jedra, merjenje, Zemlja, vesolje

## INTRODUCTION

Fundamental to the study of human temperatures regulation is the accurate measurement of deep core temperature. Under experimental conditions the core temperature is usually recorded by inserting a thermo sensor in the rectum, the bladder, the esophagus, the nasopharynx and the acoustic meatus (Gunga 2005; Wartzek et al. 2011). The relative advantages and disadvantages of these and other recording sites including the time response of the sensor have been intensively discussed ever since the first benchmark investigations by Claude Bernard in 1876 (Cooper and Kenyon, 1957; Cranston et al., 1957; Aikas et al., 1962; Nielsen and Nielsen, 1962; Saltin et al., 196; Braeuer et al., 1977; Mairiaux et al., 1983; Sawka and Wenger, 1986; Brengelmann, 1987; Deschamps et al., 1992; Moran and Mendal, 2002; McKenzie and Osgood, 2004; Easton et al., 2007; Low et al., 2007; Wartzek et al., 2011). However, none of these methods is really applicable during daily routines because the current methods are hard wired, difficult in cleaning (sanitation), not easy reusable, and uncomfortable.

There is a clear demand for an alternative method that eliminates the shortcomings of current technologies and which is applicable for multiple hours during daily activities and under clinical settings (Wartzek et al., 2011). The requirements for such a method serving to record core temperature are demanding: the new technique has to be i) non-invasive, ii) easy to handle, iii) must fulfill basic hygiene standards, iv) not influenced towards various environmental conditions, while on the other site v) changes should quantitatively reflect small temporal in core temperature, and vi) last but not least, the response time of the temperature sensors should be as short as possible (Cooper et al., 1964; Shiraki et al., 1986; Moran and Mendal, 2002; Easton et al., 2007; Lawson et al., 2007; Wartzek et al., 2011).

These requirements are essential because several terrestrial studies in humans have shown that if high environmental temperature and humidity prevail, especially in combination with heavy physical workloads and fluid loss (sweating) with inadequate re-hydration, the heat load will lead to a rapid rise in the core temperature, subsequently resulting in heat stress related injuries such as heat strokes (Shibolet et al., 1976; Wenger, 2001; Sandsund et al., 2005). Furthermore, it has been frequently hypothesized by different authors that a lack of gravity impairs in a sustained manner the natural share of convective heat transfer from the body surface. This is because gravity, as the driving force for this convective heat transfer, ceases to apply at the body surface along the body axis under microgravity conditions (Blanc et al., 2000; Kuhlmann, 2000; Yu et al., 2000; Zhang et al., 2000). This results in changes in the thermal comfort of the astronaut/cosmonaut under these specific environmental conditions (Novak et al., 1979; Novak and Genin, 1980; Novak et al., 1988; Novak, 1991; Qui et al., 1997; Qui et al., 2002), especially during extravehicular activities (EVA) (Clement, 2003). Therefore, we recently reported a new non-invasive core temperature heat flux sensor ("Double Sensor (Gunga et al. 2008) which is different from previous heat flux sensors proposed by Fox and Solman (1971) and Danielsson (1980).

In a next step we decided to use the technology at bedside during a long-term bed rest study (Berlin Bed Rest Study, BBR2) conducted by the European Space Agency (ESA) to establish whether rectal temperature recordings in humans could be replaced under those circumstances by the Double Sensor to monitor circadian core temperature changes in humans. Then we conducted a pilot study to determine whether this kind of sensor could be used also in a clinical setting during deep hypothermia (14–16°C) to monitor core temperature in the course of heart transplantation. Finally, we will show here first preliminary data of core temperature changes due to physical exercise in a single astronaut before, during and after a long-term spaceflight. Taken together, these four studies - which are partly still on-going - will be used to document the applicability of this new non-invasive method to determine core temperature in humans under different clinical and environmental setting including space.

## METHODS

The Double sensor is placed at the front of the head by an adhesive tape, Further details are given in Gunga et al. (2009).

### Study 1

The first study (study 1) was performed at the laboratory of occupational physiology in Trondheim (Norway). 20 male subjects (arithmetic mean  $\pm$  SD)  $39.5 \pm 10.2$  years, height  $1.80 \pm 0.06$  m,  $83.8 \pm 11.0$  kg) participated in the study. Thermal (rectal, nasopharyngeal, skin temperatures, Double Sensor temperatures) and cardiovascular data were collected continuously before, during and after the different experimental set-ups from 25–55% maximal intensity work load at 10, 25, and 40°C environmental temperatures. Further details are given in Gunga et al. (2008).

### Study 2

The objective of the second experiment (study 2) was to establish whether rectal temperature recordings in humans could be replaced by the Double Sensor to monitor core temperatures changes due to circadian rhythms at ambient room temperatures ( $23.0 \pm 2.0$  °C). To achieve this goal, rectal and Double Sensor data were collected continuously, starting at 19:30 h in the evening until 6:30 h the following morning. The study was conducted by the Centre of Muscle and Bone Research and performed at the University Hospital Charite Campus Benjamin Franklin in Berlin during the years 2007–2008. In total 9 male subjects participated in the experiment. The anthropometrical characteristics of the subjects were as follows ((arithmetic mean  $\pm$  SD) age  $33.2 \pm 7.9$  years, body mass  $80.6 \pm 5.2$  kg, height  $1.81 \pm 0.06$  m, body mass index (BMI)  $24.6 \pm 2.3$  kg/m<sup>2</sup>. Further details are given in Gunga et al. (2009).

### Study 3

In the third setting (study 3), which was performed in collaboration with the German Heart Institute Berlin, we determined the core temperature by the Double Sensor technology in a single patient during a cardiac operation and compared it to a concomitantly taken vesical core temperature. The patient was cooled down to 14–16°C (deep hypothermia). After the operation was finished the patient was heated again up to the physiological temperature. In addition to the standard monitoring we recorded in this patient the skin blood flow using a Laser-Doppler-Tissue-Oxymeter (O<sub>2</sub>C). Further details are given in Opatz et al. (2010).

## Study 4

In the fourth experimental setting (study 4), the Double Sensor was used during a regular  $\text{VO}_2$  ergometer testing (each step 25 Watt) before, several times in space on the ISS, and after spaceflight in a single male long-term astronaut. This study (called “Thermolab”) is still on-going in close co-operation with NASA scientists (Exercise Lab, PI Dr Alan Moore, JSC, Houston) and will be finished in 2012. Please note, all data presented here have to be taken as preliminary and not final.

## Statistics

As statistical methods descriptive statistics as well as GLM (general linear model) and paired t-Test were applied, and  $P < 0.05$  was considered for statistical significance. To show the correlation between the three methods we used Lin’s Concordance Correlation Coefficient (CCC). For specific statistical methods used in the different studies, such as Bland-Altman diagrams (Bland and Altman, 1999), details are given in the specific publications mentioned above.

## RESULTS

The main results of the different studies performed with the new Double Sensor technology on Earth and in space are summarized in the figures 1–4.

## Study 1

The specific results of study 1 are shown in figure 1 A–C. This study revealed that i) the device under test differed between  $-0.16$  to  $0.1^\circ\text{C}$  from the average of the rectal temperature and the Double Sensor, ii) showed with increasing ambient temperatures increasing concordance correlation coefficients (CCC) ( $10^\circ\text{C}:0.49$ ;  $25^\circ\text{C}:0.69$ ;  $40^\circ\text{C}:0.75$ ), and iii) exhibited (data not shown here) a faster temperature decrease at all resting periods at all ambient conditions as compared to rectal temperature ( $P < 0.01$ ) (Gunga et al., 2008).

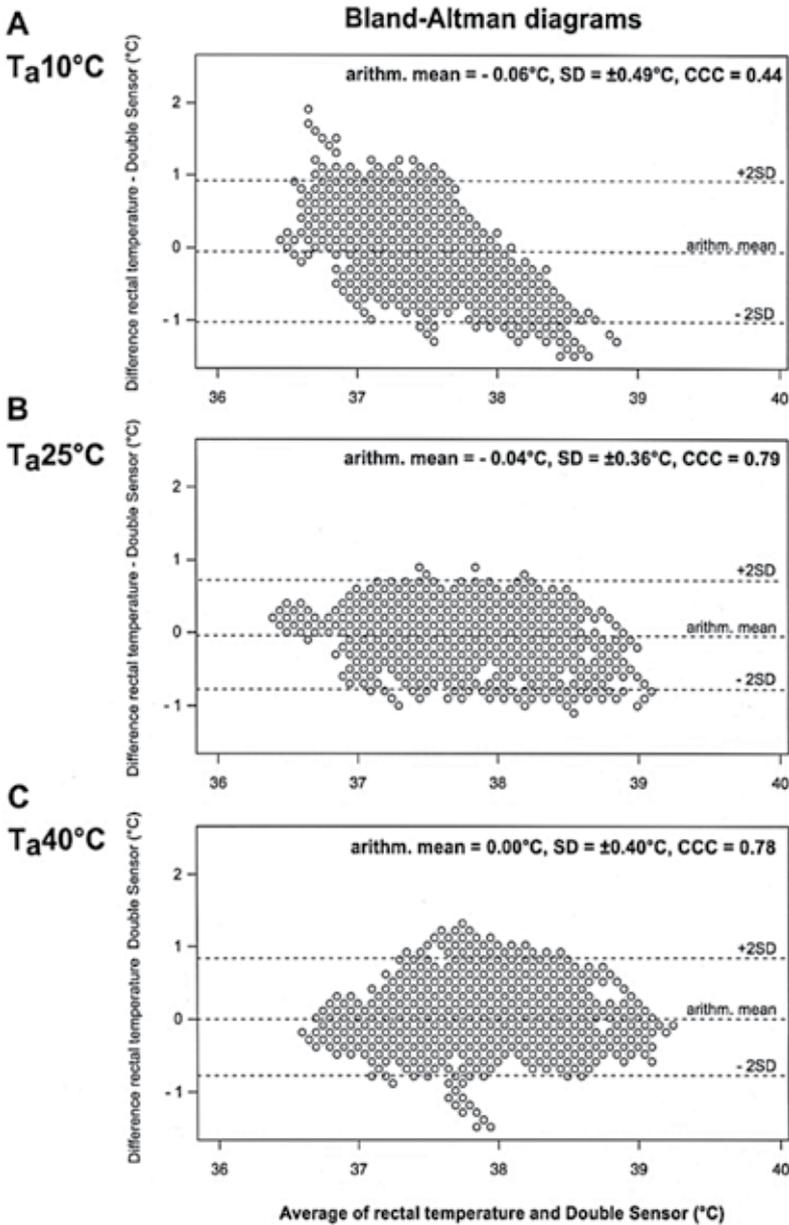


Figure 1A–C: Bland and Altman plots comparing the rectal and Double Sensor temperature during all working and resting periods at 10°C, 25°C, and 40°C ambient temperature as well as Concordance Coefficient Correlations (CCC) calculated according to formulas given by Li and Chow (2005) (adapted from Gunga et al. (2008)).

## Study 2

Figure 2 shows a scatter plot and regression lines obtained from cosinor analysis for rectal (black dots, dotted line) and Double Sensor (white dots, solid line) temperature data as a function of time from a single subject. The complete group analysis showed that the individual differences between the two techniques varied between  $-0.72$  and  $+0.55^{\circ}\text{C}$ . Further details are given in Gunga et al. (2009).

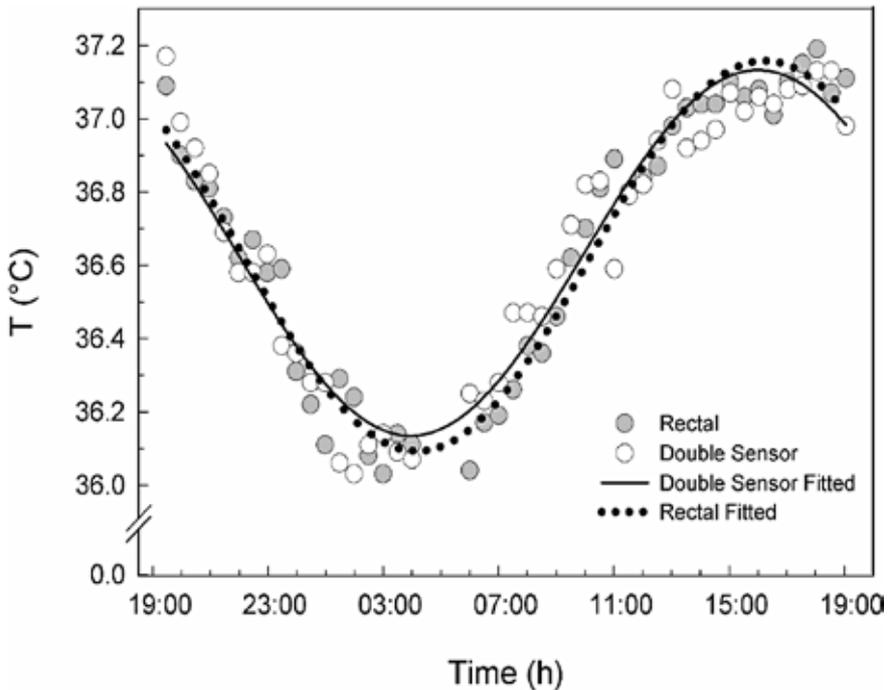


Figure 2: This graph shows a scatter plot and regression lines obtained from cosinor analysis for rectal (black dots, dotted line) and Double Sensor (white dots, solid line) temperature data as a function of time from a single, representative subject. (Adapted from Gunga et al. (2009)).

### Study 3

Figure 3 shows core temperature changes (vesical and Double Sensor) changes in a clinical setting in which a patient had to be exposed to deep hypothermia (preliminary data). The measurements depicted that the Double Sensor showed great accuracy (Lin's CCC=95%). Further details are given in Opatz et al. (2010).

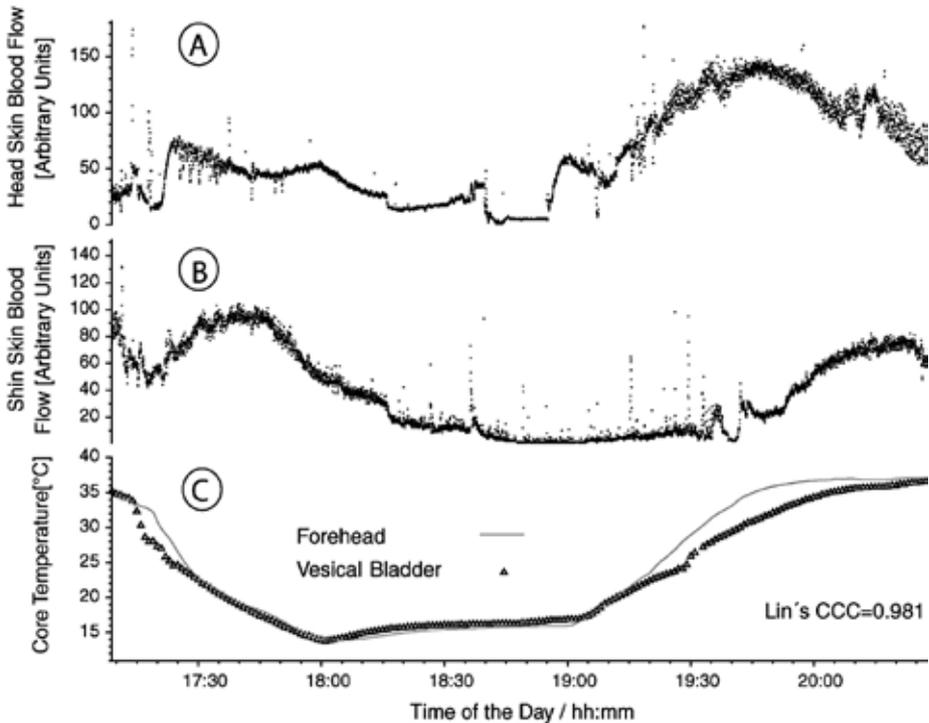
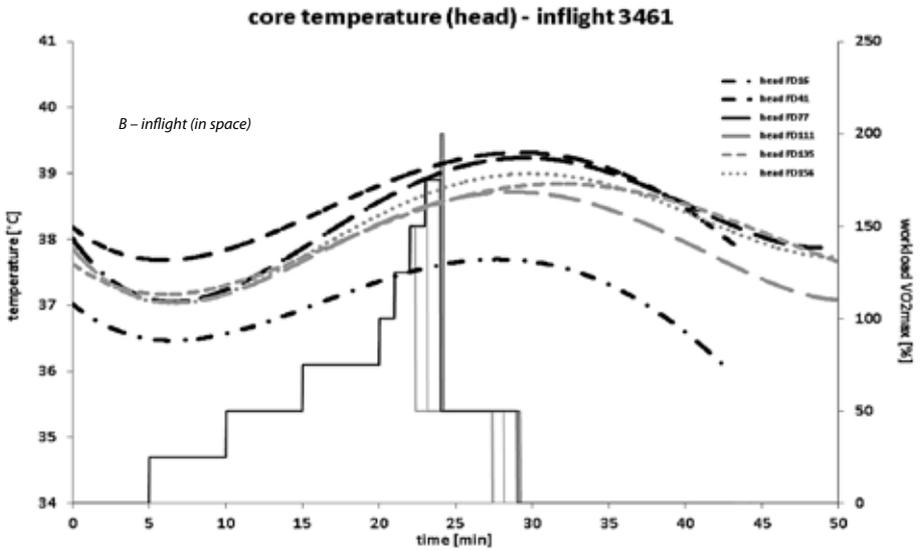
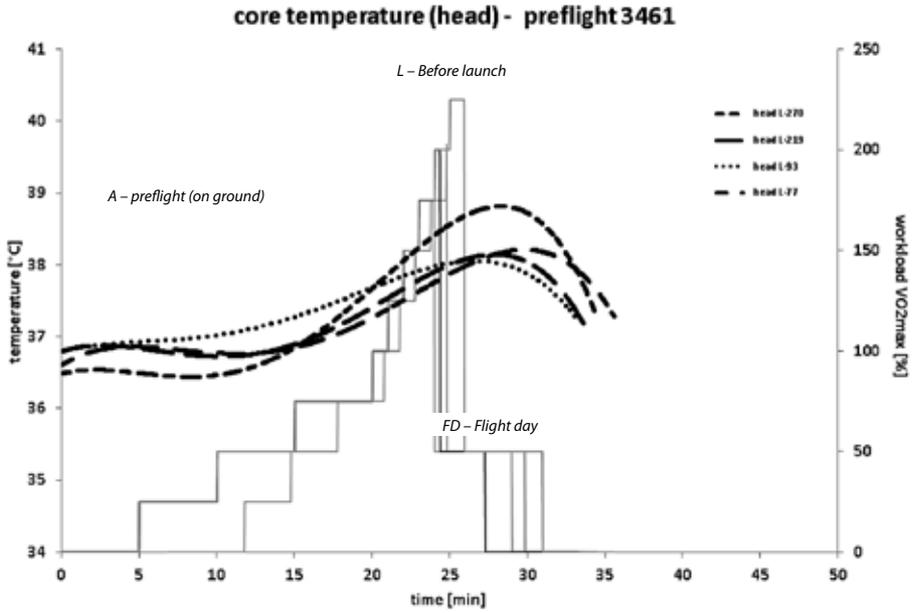


Figure 3: Core temperature changes (vesical and Double Sensor temperature) and skin blood perfusion changes during operations in a clinical setting under deep hypothermic conditions. (Adapted from Opatz et al. 2010).

### Study 4

Figure 4 A–C shows core temperature changes during an exercise test before, during and after a long-term spaceflight in a single, male astronaut (preliminary data). The core temperatures were only measured at the head (front) with the Double Sensor technology. It was found i) a large scatter in core temperature profiles inflight and ii) prolonged decreases of core temperatures in the recovery phase after the exercise was finished.



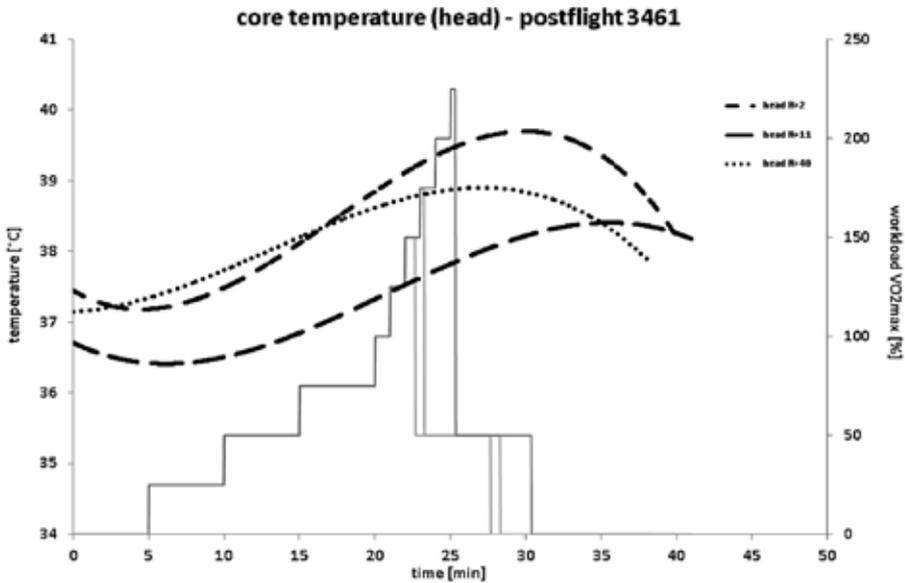


Figure 4A–C: Preliminary core temperature changes measured at the head during an exercise test during a long-term spaceflight preflight (A), inflight (B), and postflight (C) in space in a single astronaut (changing workloads during the different tests are indicated by step profiles, each step 25 Watt).

## DISCUSSION

In particular study 1 revealed that for strenuous physical activity during heat exposure, the device under test appears to be a reasonably reliable method to assess core temperature and therefore might be useful as well in occupations in which individuals are exposed to thermally challenging environments. However, it is clear that this new sensor system cannot completely replace rectal or radio pill core temperature recordings under all circumstances. In the study reported here the Double Sensor system was integrated into a helmet system. As outlined and discussed earlier, lateral heat loss can also occur from the sensor, especially in cold environmental conditions below 0°C (Gunga et al., 2008). Therefore, it remains to be investigated whether this concept can be used reliably in other outdoor environmental conditions as well.

In the course of the study 2 it could be observed that the individual differences between the two techniques varied between  $-0.72$  and  $+0.55^{\circ}\text{C}$  (Gunga et al., 2009). The reasons for the differences are currently unclear. Nonetheless, when temperature data were approximated by cosinor analysis in order to compare circadian rhythm profiles

between methods, it was observed that there were no significant differences between mesor, amplitude and acrophase ( $P > 0.310$ ). It was therefore concluded that the Double Sensor technology in this specific setting is presently obviously not accurate enough for performing single individual core temperature measurements under resting conditions at normal ambient room temperature, but it seems to be a valid, non-invasive alternative for monitoring circadian rhythm profiles.

The study by Opatz et al. (2010) revealed that even during deep hypothermia (core temperature  $\sim 14\text{--}16^\circ\text{C}$ ) the Double Sensor technology might be applicable in such a clinical setting. Furthermore, it could be shown that heat flux measurement – as one would expect – are closely linked to skin perfusion changes as indicated by concomitantly performed near infrared spectroscopy measurements (Opatz et al., 2010). This special topic, the link between skin blood flow and heat flux measurements, has definitely to be examined in a larger group of deep hypothermic patients. Such kind of research is currently on-going and it has to be tested whether this kind of method might also be applicable in the field, i.e. for example on site non-invasive core temperature measurement at the forehead in avalanche victims which, indeed, would be very helpful for a rescue team operating in the field. Finally, in this context it is interesting to note, that recently other researchers could confirm our first results on the applicability of the Double Sensor in a clinical setting to monitor peri- and post-operative core temperature in a clinical study as well (Kimberger et al., 2009).

The preliminary data of the case report in study 4 indicates that obviously under micro-g conditions heat exchange between the human body and the environment is altered in space. Especially, the time span to decrease core temperature after exercise in the recovery phase seems to be prolonged in comparison to pre- and post-flight measurements. However, it is too early to draw any definite further conclusion. The full set of experiments has to be evaluated, i.e. 10 astronauts are anticipated to conduct the studies during long-term missions (6 months) to ISS until the end of 2012.

## CONCLUSION

In general, the new developed heat flux sensor (“Double Sensor”) seems to be a new reliable method of assessing core temperature changes under different environmental and clinical conditions, and an especially promising method to determine non-invasively circadian core temperature profiles for chronobiological research.

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