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A new non-invasive device to monitor core temperature on earth and in space

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Abstract

Accurate measurement of the core body temperature (cbt) is fundamental to the study of human temperature regulation. As standard sites for the placement of cbt 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 cbt 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.

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3 Herr Gunga hat uns die im Inhalt gleiche englischsprachige Version des Vortrags zur Verfügung gestellt. Sie ist als Kongressmitteilung publiziert in: *SpaceMAG 2011, no.5, pp39-41 reports on the Congress in Naples (December 1-2, 2011)*. (Die Redaktion)

Introduction

Fundamental to the study of human temperatures regulation is the accurate measurement of deep body core temperature. Under experimental conditions the core temperature is usually recorded by inserting a thermo sensor in the esophagus, rectum or auditory 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 in field studies and under clinical settings (Wartzek et al., 2011). The requirements for such a method serving to record body 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 changes in arterial blood temperature, and vi) last but not least, the response time of the thermo sensor to temperature changes 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 body 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, as 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 body core temperature heat flux sensor ("Double Sensor") - which is different from previous heat flux sensors proposed by Fox and Solman (1971) and Danielsson (1980) - aiming to meet the measurement requirements described above (Gunga et al. 2008). Based on this experience we decided in a next step to use the Double Sensor 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 body 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

Study 1

The first study (study 1) was performed at the laboratory of occupational physiology in Trondheim (Norway). 20 male subjects (39.5 ± 10.2 years, height 1.80 ± 0.06 m, 83.8 ± 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 body core temperatures changes due to circadian rhythms at ambient room temperatures (23.0 ± 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 (arith. mean ± SD): age 33.2 ± 7.9 years, body mass 80.6 ± 5.2 kg, height 1.81 ± 0.06 m, body mass index (BMI) 24.6 ± 2.3 kg/m². 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 body 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 (O2C). 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 VO2 ergometer testing 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.

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 two 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

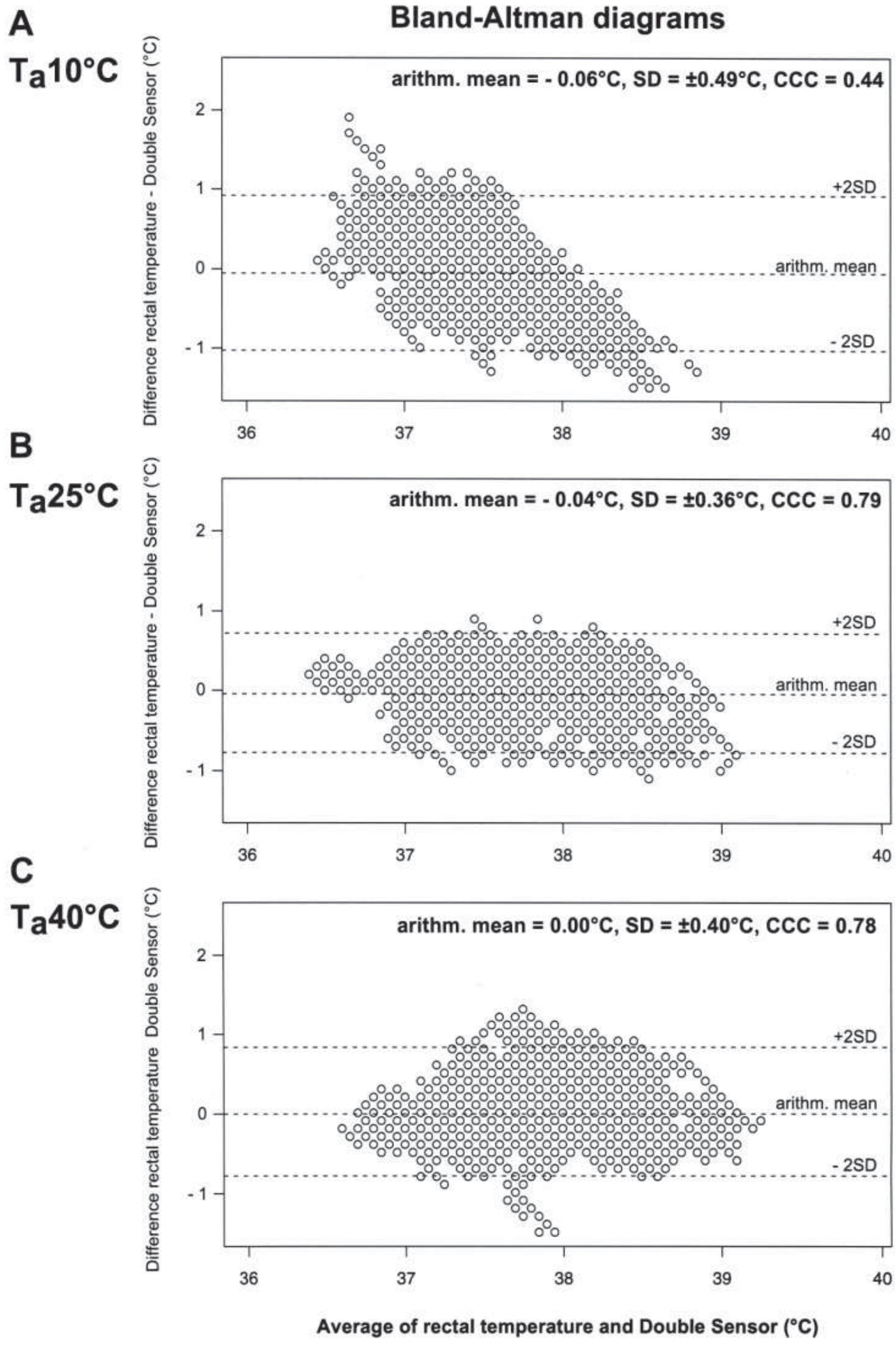

Figure 1A-C: Mean differences (± 2 SD) between the rectal temperature and the device under test as compared to the mean of rectal temperature and device under test according to Bland and Altman (1999) during all working and resting periods at 10 °C, 25 °C, and 40 °C ambient temperature as well as Concordance Coefficient Correlations (CCC) calculated according to formulas given by Li and Chow (2005) (adapted from Gunga et al. 2008)

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°C from the average of the rectal temperature and the Double Sensor, ii) showed with increasing ambient temperatures increasing concordance correlation coefficients (CCC) (10°C:0.49; 25°C:0.69; 40°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).

Study 2

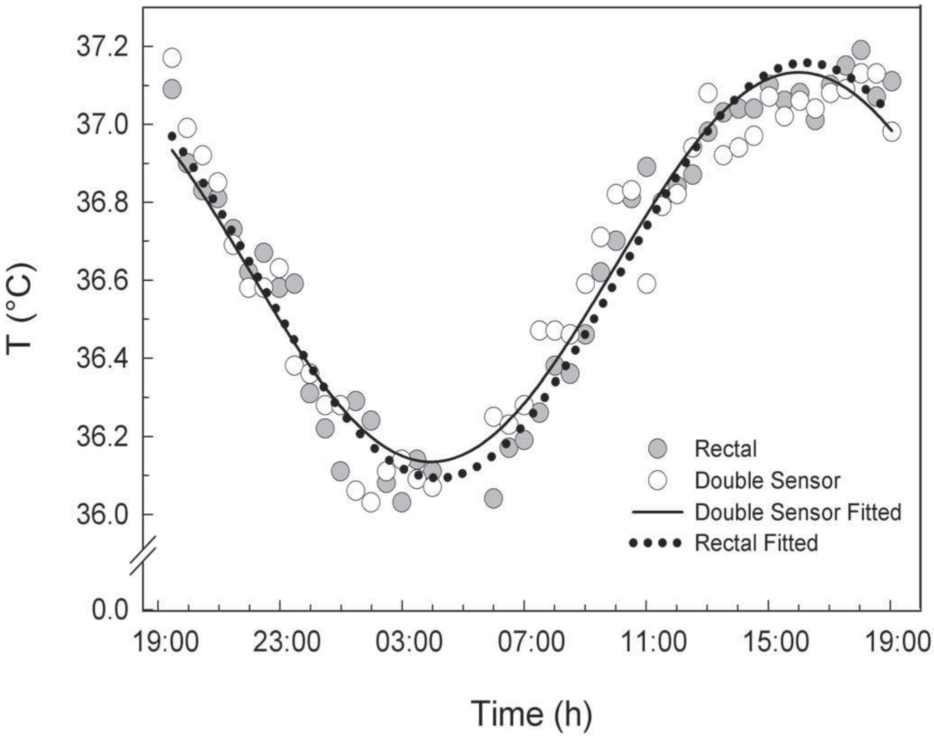

Figure 2: This graph shows a scatter plot and regression lines obtained from cosinor analysis for rectal (black dots, dotted line) and Double Sensor (white dots, solid line) temperature data as a function of time from a single subject. (Adapted from Gunga et al. 2009).

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 degrees C. Further details are given in 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.

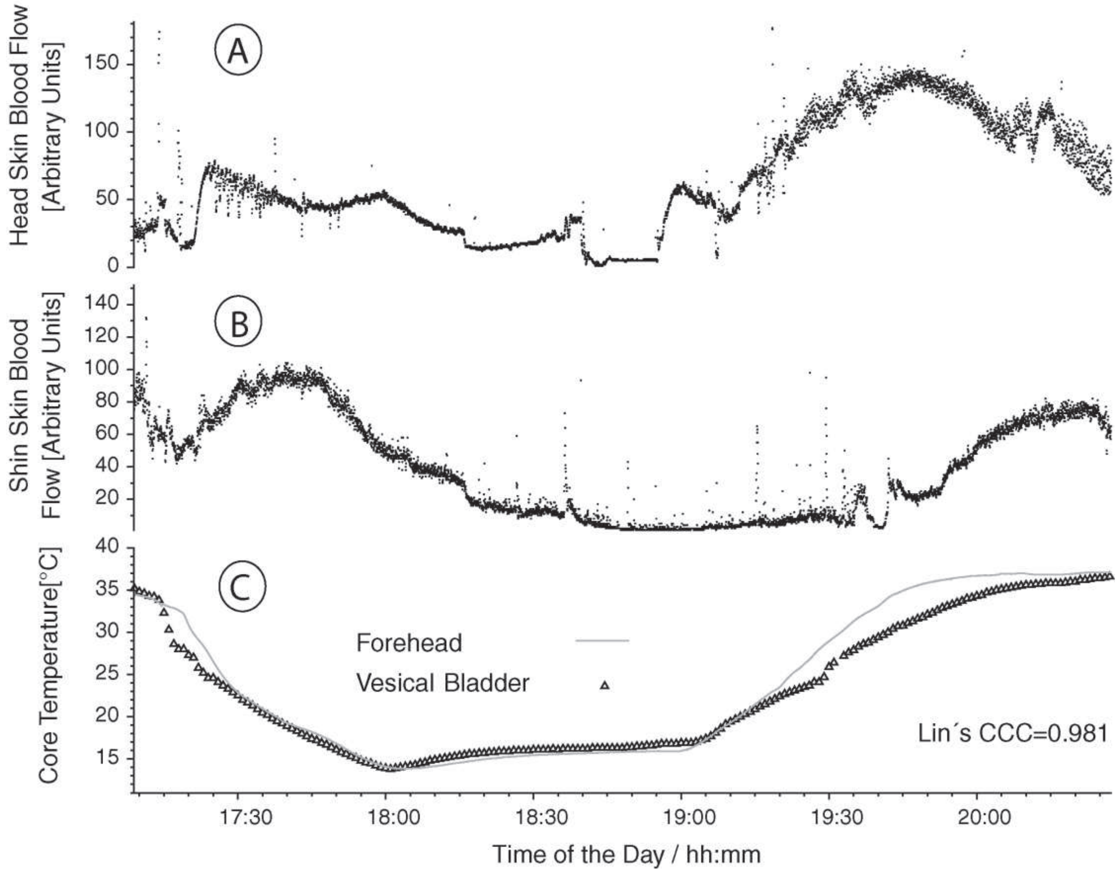

Figure 3: Core temperature changes (vesical and double sensor temperature) and skin blood perfusion changes during operations in a clinical setting under deep hypothermic conditions (14-16 °C). (Adapted from Opatz et al. 2010).

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 astronaut (preliminary data). It was found in this astronaut i) showed a large scatter in core temperature profiles inflight and ii) prolonged decreases of core temperatures in the recovery phase after the exercise was finished.

A -
preflight

L - Before launch

B -
inflight

FD - Flight day

C -
postflight

R - Recovery phase

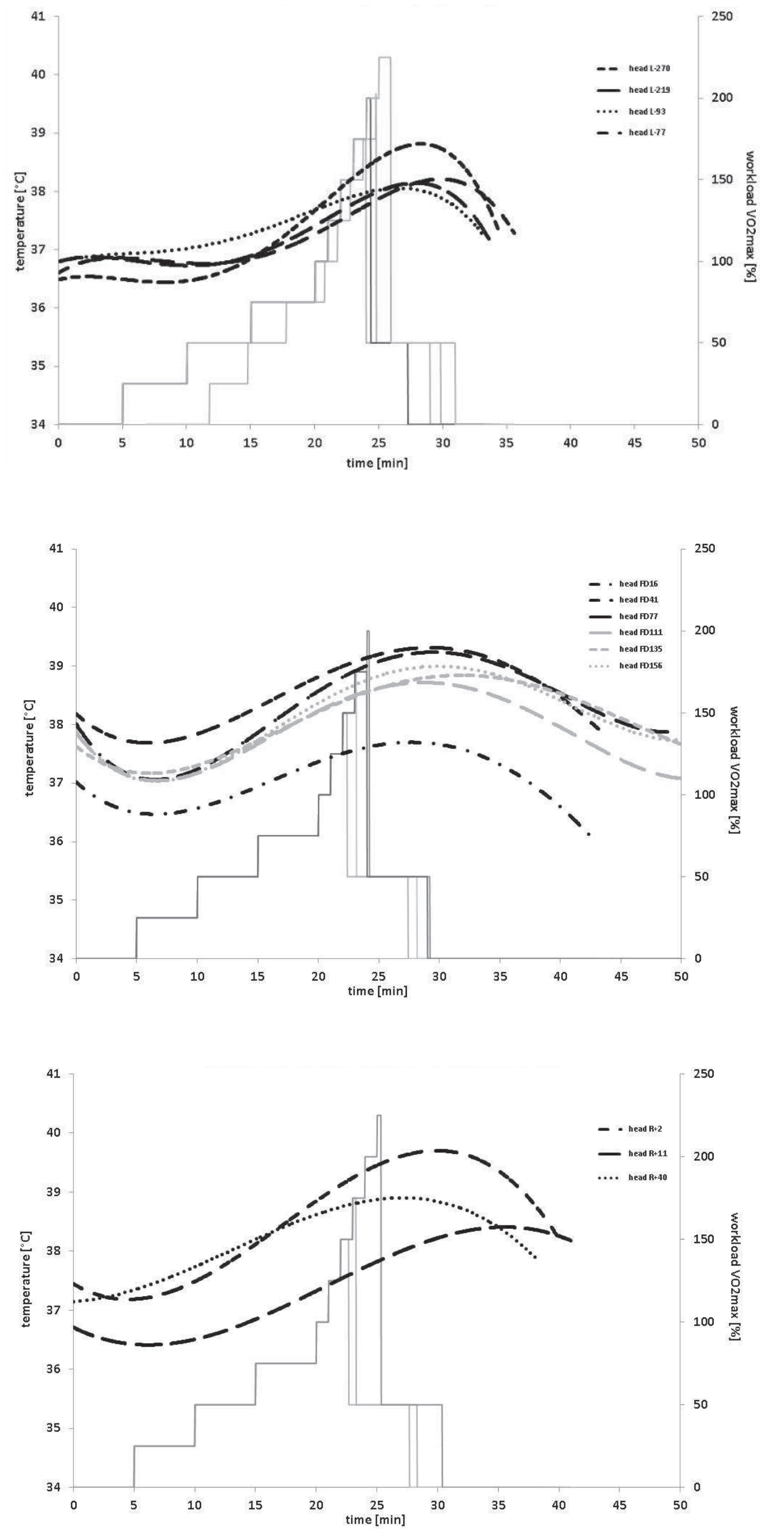

Figure 4A-C: Preliminary core temperature changes measured at the head during an exercise test during a long-term spaceflight preflight (A), inflight (B), and postflight (C) in space in a single astronaut (changing workloads during the different tests are indicated by step profiles, data not completely evaluated).

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 °C (Gunga et al., 2009). 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 body 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 ~14-16 °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 applicable in the field, i.e. for example on site non-invasive core temperature measurement at the front (head) 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 larger 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 much too early to draw any definite further conclusion. The full set of experiments has to 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.

Acknowledgments

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