

Experimental Investigation of Possible Warmth Perception from a Head Exposure System for Human Provocation Studies with TETRA Handset-like Signals

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An experimental investigation of warming and warmth perception caused by handset EMF exposure was performed in order to examine its possible impact on blinding. Healthy male participants (15) were exposed to three different exposure conditions: sham and Terrestrial Trunked Radio (TETRA) handsets with maximum 10 g averaged SAR values of 1.5 and 6 W/kg each on three days. The study followed a randomized, double-blind design. TETRA signals simulated exposure from a handheld device consisting of a 385 MHz carrier modulated with a pulse length of 14.17 ms and a pulse period of 56.67 ms (i.e., duty cycle 25%; 17.65 Hz pulse modulation). A body worn antenna was used and fixed at the left ear. In addition to subjective ratings, skin temperatures at two locations close to the radiating element of the body-worn antenna were measured. The measurements revealed a temperature rise proportional to the supplied RF power with an average temperature increase measured at the two locations of 0.8 °C following the high exposure level of 6 W/kg. However, subjects were not able to distinguish between exposure conditions based on their subjective perception and thus the double-blinding was ensured. *Bioelectromagnetics* 35:452–458, 2014.

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INTRODUCTION

In human provocation studies on the biological effects of electromagnetic fields (EMF) a double-blind design where neither the participants nor the investigators know which exposure condition (real or sham) is a prerequisite to getting reliable results [Regel and Achermann, 2011]. Participants who are not blinded may give biased psychological and physical responses, which can further affect the outcome [Schulz and Grimes, 2002]. A critical issue that might compromise the blinding of participants in radiofrequency (RF) EMF studies is the sensation of heating. In general, there are two different sources of heating under RF exposure: RF induced heating of the tissue itself and power dissipation of the device or antenna. The covering of the skin surface by the device or antenna results in an additional temperature rise as a consequence of reduced convection in the air, even without RF exposure.

There are several options to deliver RF–EMF in experimental human studies, varying from a real or

manipulated phone [Croft et al., 2010], over specially designed antennas [Bahr et al., 2006; Danker-Hopfe et al., 2011; Schmid et al., 2012a] to patch antennas [Schmid et al., 2012b]. These devices may lead to different degrees of skin temperature rises due to specific thermal losses of the antenna or electronics, or different thermal properties of head-worn devices.

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In an experimental approach, Straume et al. [2005] pointed out that while RF did not induce heating, electrical power dissipation within the phone and insulation lead to statistically significant rises in skin temperature after 15 and 30 min of exposure with real mobile phone use. Anderson and Rowley [2007] reported similar temperature rises even after 6 min of continuous exposure to different mobile phone models and they suggested that the effect of direct RF heating on the temperature rises is rather small. By using numerical analysis methods, Schmid et al. [2007] showed that RF exposure leads to increases in skin temperature at the ear and head of approximately 0.1°C for Universal Mobile Telecommunications System (UMTS), Global System for Mobile Communications (GSM), and Terrestrial Trunked Radio (TETRA). Overall, the increase in skin temperature was slightly higher for TETRA exposure as compared to GSM and UMTS for a given maximum 10 g averaged specific absorption rate (max.SAR_{10g}) of 2 W/kg.

In volunteer studies of a recent research program, possible effects of TETRA exposure on the central nervous system during waking and sleep were investigated by using a specially designed printed circuit board (PCB) based body-worn antenna. In spite of using a design minimizing the internal power dissipation of the antenna structure (i.e., sufficient width of the conducting elements, using a low loss double layered PCB with structures in both layers in parallel) pre-experimental phantom measurements yielded a temperature rise of the applied antenna itself and of a phantom head in proximity of the antenna. In the steady state, after approximately 15 min, a constant temperature distribution is reached and the heat generated inside the antenna causes an elevated temperature on the antenna surface and consequently, a heat flow to the immediate area, the subject's skin. The resulting temperature distribution depends on thermal resistances inside the antenna and transmission resistances to the surrounding air or other matter. The temperature rise due to RF induced heating of the tissue itself is determined by the specific absorption rate (SAR), by thermal resistances, and by the leveling effect of blood circulation. Cooling by both convection and evaporation are reduced because relevant parts of the skin are covered by the antenna cushioning.

Since the temperature differences due to RF exposure were small in the mobile phone studies mentioned above, it can be assumed that this contribution was not perceivable. However, in experiments using sufficiently high SAR values (e.g., max.SAR_{10g}: 6 W/kg) a noticeable warming could result. Hence, there is an urgent need to study whether the subjects are able to perceive the heating and to differentiate the

various exposure conditions. If so, the blindness of the subjects would be compromised and additional measures would have to be introduced to mask the differential sensation of warming.

MATERIALS AND METHODS

Subjects

A total of 15 male subjects, age range between 23 and 36 years (mean age $\pm$ standard deviation (SD): 28.4 ± 3.7 years), participated in the present study. All volunteers gave written informed consent and were paid for participating. Withdrawal from the study was possible at any time. The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of the Charité—University Medicine, Berlin.

Study Design

The subject's perception was tested three times per exposure condition (sham and TETRA with max. SAR_{10g} values of 1.5 and 6 W/kg) resulting in a total of nine sessions on different days. The assignment of the exposure conditions was carried out following a randomized cross-over design and the study was performed double-blind by using an automated control system. Time of day of the measurement was kept constant for each subject.

Exposure took place in a comfortably air-conditioned, electrically shielded chamber. Wooden furniture was used. EMF reflections from other surfaces were negligible due to the close position of the antenna to the head. There was no perceptible airflow at the position of the subject. The room temperature was around 22°C . Personal electronic devices were strictly prohibited inside the room as these can impose a significant risk of unblinding due to RF interference. Study equipment was specifically selected, designed, or modified for the same reason. While being exposed, the participants were seated in a comfortable armchair and were asked to read. Communication with the investigator was ensured via an intercom system. Each session lasted approximately 1 h and included a short resting period after arrival, a 5 min interval without exposure, a 30 min exposure period and subsequent completion of a questionnaire concerning possible heat sensations. During the resting condition, a body-worn antenna with foam spacers and a textile cover [Schmid et al., 2012a] was attached at the left side of the subject's head. The position was the same as in the main experiment and simulated the exposure of a TETRA device (Fig. 1). Immediately after fixing the antenna, skin temperature was measured for the next 35 min.



Fig. 1. Position of the antenna. The antenna was fixed to the left side of a subject's head using a common cloth headband.

Temperature Measurement

Temperature was recorded via a pair of fluoro-optical glass probes of 0.8 mm diameter connected to a Luxtron 790 electronic thermometer (Santa Clara, CA). Due to the lack of any conductive materials and due to their small outline, the probes' impact on the RF or temperature fields was negligible, and vice versa, the RF could not interfere with the measurement. Both probes were stuck to the radiating upper part of the antenna (Fig. 2) enabling simultaneous temperature measurements at two different skin locations.

The electronic thermometer produced up to six averaged temperature values per minute for each sensor.

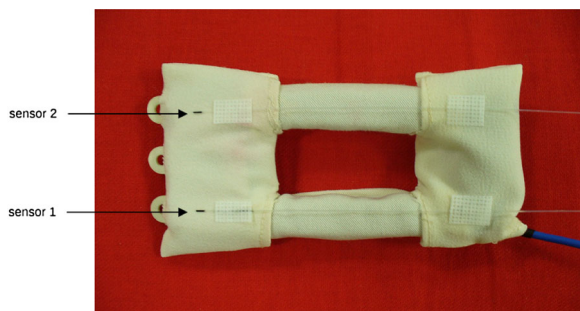


Fig. 2. Body worn antenna. The antenna was equipped with a textile cover and the temperature sensors were fixed at the interior side (touching the subject's skin surface during measurement) by means of small pieces of sticky tape.

The temperature measurement was calibrated using comparisons to gauged medical thermometers with a precision of $\pm 0.1^\circ\text{C}$. Without calibration, temperatures measured by means of the used electronic thermometer would contain an additive error of up to 2°C .

Subjective Evaluation

Subjects were asked to fill in a questionnaire on their subjective sensation immediately after exposure. The degree of warming on the left and on the right side of the head had to be marked on 10 cm visual analog scales (VAS) [Bond and Lader, 1974], with 0 cm representing “not warmer at all” and 10 cm “much warmer.” Additionally, subjects were requested to answer whether the left and/or right side of the head felt warmer, not different or colder compared to the last experimental session. Remarks concerning physical sensations other than warming were also noted.

Data Processing and Statistics

To further reduce random variance, averages of all available temperature values within 1 min intervals (-30 to $+29$ s) were calculated for each sensor separately; the midpoint of the interval was the reference time point. In a second step, temperature data was standardized to zero due to slightly different temperature values under each exposure condition at baseline and was additionally pooled (average) by exposure condition for further analyses. Minute-by-minute values were used for illustration, while the statistical analyses were based on the temperature changes 10, 20, and 30 min after exposure onset. Subjective data, however, was not pooled because even single deviating observations could point to a possible subliminal perception of the heating.

All variables were tested for normal distribution using the Kolmogorov–Smirnov-Test. Standardized temperature changes differing from zero were investigated by means of one sample test (either Student's *t*-test for normally distributed data or Wilcoxon matched-pairs signed-rank test for non-normally distributed data). Moreover, temperature changes were analyzed by using a two-factor repeated measures analysis of variance (rmANOVA) within the subject variables exposure (sham, 1.5 and 6 W/kg) and time (10, 20, and 30 min) for each sensor separately. If sphericity was violated, a Greenhouse-Geisser correction for degrees of freedom was applied. If the rmANOVA yielded a significant result, individual differences between the factor levels were calculated pair wise and, depending on their normal distribution, either Student's *t*-tests for dependent variables or Wilcoxon matched-pairs signed-

rank tests was performed for post hoc analyses. Subjective data was examined by using a separate Friedman test for each side of the head. Relations between categorized data types were tested for significance using the likelihood ratio χ^2 -test. A Bonferroni correction for multiple testing was not considered in this study in order not to miss any risk of compromised blindness of the investigation of possible EMF effects. All tests were performed with a double-sided significance level of $P < 0.05$ except for the tests on normal distribution ($P < 0.01$). Data was statistically processed using SAS Version 9.3 (SAS Institute, Cary, NC).

RESULTS

The temperature curves measured under the three experimental conditions for both sensors are depicted in Figures 3 and 4, respectively. Sensor 1 showed a mean monotonic temperature increase under 6 and 1.5 W/kg exposures of 0.9°C and 0.4°C , respectively, over the measurement interval of 30 min. However, only the increase under the highest exposure condition was statistically significant (Table 1). The monotonic increase for sensor 2 under 6 and 1.5 W/kg exposures was 0.7°C and 0.3°C , respectively, over the measurement interval of 30 min. Again, only the increase under the highest exposure condition differed significantly from zero (Table 1). In addition, Figures 3 and 4 showed that the thermal time constant is below

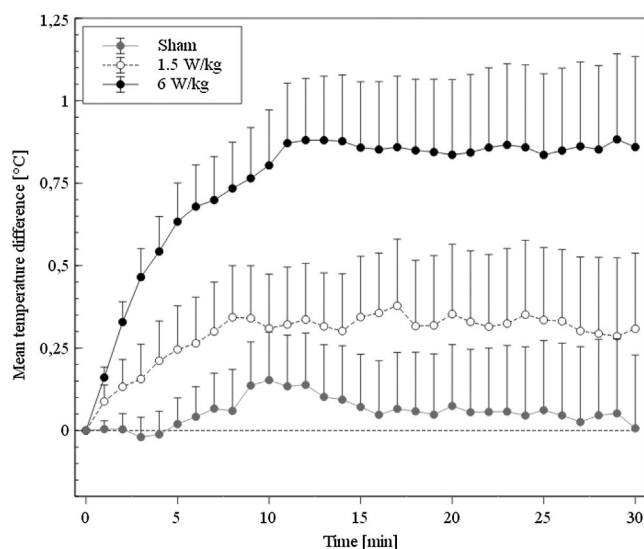


Fig. 3. Changes in temperature during the 30 min measurement interval (Sensor 1) for each of the three exposure conditions. Each measurement point was standardized by subtracting it from the basic value at time point zero. Temperature was repeatedly measured every minute. Values are given as means $\pm$ SEM ($n = 15$).

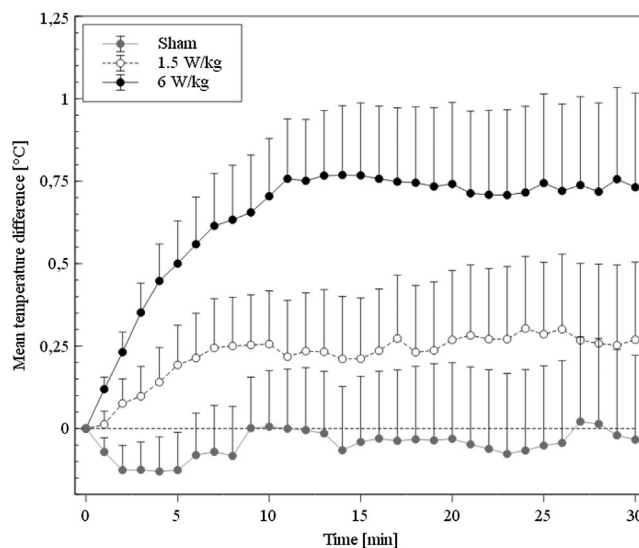


Fig. 4. Changes in temperature during the 30 min measurement interval (Sensor 2) for each of the three exposure conditions. Each measurement point was standardized by subtracting it from the basic value at time point zero. Temperature was repeatedly measured every minute. Values are given as means $\pm$ SEM ($n = 15$).

10 min and that subsequently, there are no substantial changes. Sham exposure led to chance fluctuations of approximately 0.2°C (Table 1, Figs. 3 and 4).

For both sensors, the rmANOVA revealed a significant main effect for exposure (Sensor 1: $F_{(1.85, 25.96)} = 10.58$, $P < 0.001$; Sensor 2: $F_{(1.88, 26.39)} = 13.49$, $P < 0.001$ (both Greenhouse-Geisser-corrected)) but neither a main effect for time nor an exposure $\times$ time interaction effect. Post hoc pair wise analyses showed that at all points of time the temperature differences were statistically higher under 6 W/kg exposure condition when compared to sham exposure. Temperature changes varied between 6 and 1.5 W/kg exposure conditions except for sensor 1 at time point 20 min after exposure onset. Differences between 1.5 W/kg exposure condition and sham were, however, not significant at any of the three time points (Table 1).

While skin surface temperature increases were observed for the measured data, subjective assessments, however, did not show differences in perception as revealed by non-significant results of the Friedman tests (Fig. 5).

Subjective assessments of warming perception compared to the previous session did not reveal statistically significant differences even for situations where sham was followed by a 6 W/kg exposure or vice versa. There was neither a significant relation for the left nor for the right side of the head (Fig. 6).

TABLE 1. Temperature Changes at Time Points 10, 20, and 30 min After Starting Exposure at Both Sensors

Exposure (compared to zero)	Sham	1.5 W/kg	6.0 W/kg
Sensor 1			
10 min after exposure onset	n.s.	n.s.	$P < 0.001$
20 min after exposure onset	n.s.	n.s.	$P = 0.003$
30 min after exposure onset	n.s.	n.s.	$P = 0.008$
Exposure differences (pairwise comparisons)	1.5 W/kg–Sham	6 W/kg–Sham	6 W/kg–1.5 W/kg
Sensor 1			
10 min after exposure onset	n.s.	$P < 0.001$	$P = 0.003$
20 min after exposure onset	n.s.	$P < 0.001$	n.s.
30 min after exposure onset	n.s.	$P < 0.001$	$P = 0.016$
Exposure (compared to zero)	Sham	1.5 W/kg	6.0 W/kg
Sensor 2			
10 min after exposure onset	n.s.	n.s.	$P = 0.001$
20 min after exposure onset	n.s.	n.s.	$P = 0.012^*$
30 min after exposure onset	n.s.	n.s.	$P = 0.023$
Exposure differences (pairwise comparisons)	1.5 W/kg–Sham	6 W/kg–Sham	6 W/kg–1.5 W/kg
Sensor 2			
10 min after exposure onset	n.s.	$P < 0.001$	$P < 0.001$
20 min after exposure onset	n.s.	$P < 0.001$	$P = 0.008^*$
30 min after exposure onset	n.s.	$P = 0.002$	$P = 0.001$

The table shows the results of the one-sample tests and the P -values of the post hoc analyses for individual pair wise differences between the exposure levels at each point of time.

*Wilcoxon matched-pairs signed-ranks test.

DISCUSSION

Though a temperature rise proportional to the supplied RF power was demonstrated, the subjective

data showed that the different degrees of warming, dependent on exposure condition, could not be distinguished by the subjects, indicating that blindness is not compromised.

These results are supported by theoretical thermo-physiological models for heat perception in the skin. In Schmid et al. [2008], numerical computations based on simplified skin models were carried out in order to investigate if the warming perception sometimes reported by mobile phone users in the ear region is a consequence of RF absorption inside the tissue or rather a consequence of heat moving from the mobile towards the skin.

For the assessment of a possible heat perception, the model of Hendler and Hardy [1960] and Hendler et al. [1963] was used. According to this model, heat perception in the skin is based on two different types of thermo receptors located at two different depths (0.2 and 1 mm) inside the skin. Heat perception (sensory reaction) occurs when the natural temperature gradient between these different skin layers is shifted beyond a certain threshold. Shifts of this temperature gradient, as low as approximately 0.01°C , were reported as the threshold for heat perception.

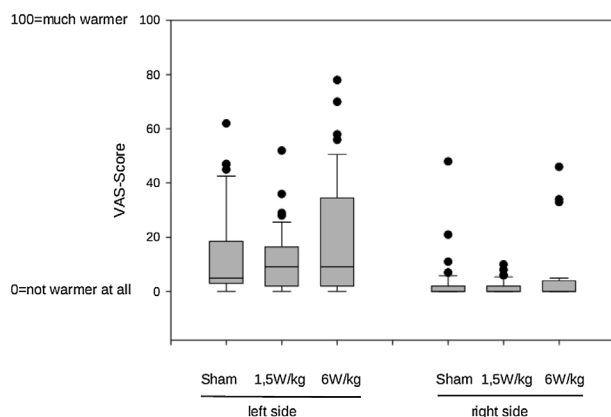


Fig. 5. Subjective heat perception. Box plots indicate the subjectively perceived degree of warming following each of the three exposure conditions on the left and on the right side of the head (The antenna was placed on the left side). The visual analog scale consisted of a 10 cm line with the endpoints 0 cm representing “not warmer at all” and 10 cm “much warmer.”

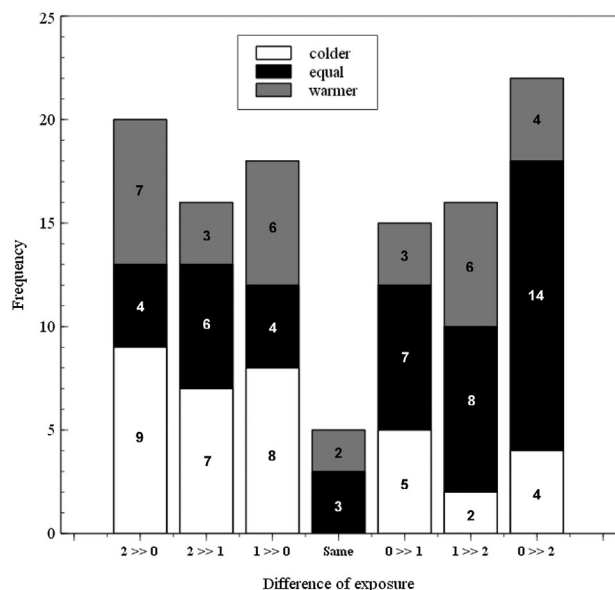


Fig. 6. Subjective rating of warming difference between consecutive sessions for the left side of the head. 0 = sham exposure; 1 = exposure level of 1.5 W/kg; 2 = exposure level of 6 W/kg. X-axis ranges from “2 >> 0” (i.e., 6 W/kg exposure was followed by a Sham exposure) to “0 >> 2” (i.e., sham exposure was followed by a 6 W/kg exposure). “Same” denotes same exposure level in consecutive sessions (e.g., 6 W/kg exposure was followed by 6 W/kg exposure).

The results reported by Schmid et al. [2008] showed that the tissue heating due to RF absorption in the frequency range 400 MHz (very close to the frequency of 385 MHz used in the present study) leads to a temperature increase on the skin surface of approximately 0.1–0.2 °C per W/kg (maximum SAR_{10g}). Moreover, it was shown that a skin temperature increase of 0.8 °C due to 400 MHz RF absorption causes a shift of the temperature gradient between the two thermo receptor layers of about 0.005 °C, that is, clearly below the perception threshold of 0.01 °C.

As reported above, the temperature increase on the skin surface in the present study was approximately 0.8 °C on average for the high exposure level of 6 W/kg (max.SAR_{10g}) and must be seen as a consequence of three factors: RF-absorption inside the tissue, heat transport from the antenna (getting warm due to electric loss) towards the skin, and the restriction of natural convection due to the contact between the skin and antenna. The latter (restriction of convection) is the same for all test subjects and conditions and therefore does not contribute to a different heat perception of subjects during sham and exposure. Thus, it will be neglected for further considerations. With the mentioned simplification, the observed 0.8 °C skin surface temperature increase in the present study is caused by

RF absorption and heat transport from the antenna towards the skin. The skin temperature increase due to heat transport from the antenna towards the skin was measured on three different subjects and yielded approximately 0.2 °C. For these measurements, in order to distinguish between skin temperature increases due to RF absorption or heat transport from the antenna, the electric losses inside the antenna were simulated by a resistor placed at the antenna feeding point and heated by a DC current flow. The required DC current for correctly mimicking the antenna’s temperature increase due to RF losses inside the antenna was determined in preliminary experiments during which the antenna radiates RF power corresponding to the 6 W/kg exposure level. The temperature increase at the antenna feeding point as well as the temperature distribution along the antenna was measured. Finally, the required DC current through the resistor with heat conducting lubricant provides efficient heat flow from the resistor to the metallic antenna structure which, in turn, causes a temperature distribution along the antenna as in case of an RF radiating antenna.

As the skin temperature increase due to heat transport was experimentally determined to be 0.2 °C, the remaining approximately 0.6–0.7 °C are assumed to be caused by RF absorption. Based on the results of Schmid et al. [2008], a temperature increase of 0.6–0.7 °C at the skin surface caused by 400 MHz RF absorption should not shift the temperature gradient between the two thermo receptor layers more than 0.004 °C, clearly below the perception threshold of 0.01 °C. Moreover, from the results regarding heat transportation from a mobile phone towards the skin reported in Schmid et al. [2008], a shift of the temperature gradient of no more than 0.006 °C can be derived for a skin surface temperature increase of 0.2 °C, when linear extrapolation is used as a first approximation. In summary, a maximum shift of the temperature gradient between the two thermo receptor layers responsible for heat perception close to but not beyond the threshold of 0.01 °C can be expected even for the high exposure level used in the present study.

CONCLUSIONS

Although the measurements yielded a temperature increase proportional to the supplied RF power with a statistically significant temperature rise under the high exposure level of 6 W/kg, subjects were not able to distinguish between exposure conditions based on their subjective perception. Thus, the double-blinding of the EMF exposure study was ensured.

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