Finnish Institute of Occupational Health

WIRECOM – Wireless Communication Devices and Human Health

NATIONAL RESEARCH PROGRAMME INTO THE HEALTH EFFECTS OF MOBILE PHONES

FINAL REPORT

Tommi Alanko
Maila Hietanen
(eds.)

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YHTEENVETO

Matkapuhelinten ja muiden langattomien viestintälaitteiden yleistyminen on lisännyt väestön altistumista radiotaajuisille (RF) sähkömagneettisille kentille. Vaikka matkapuhelimien ja tukiasemien lähettämien RF-kenttien aiheuttama altistus ei ylitä väestölle tai työympäristölle annettuja turvallisuusrajoja, julkinen keskustelu ja muutamat tutkimustulokset ovat herättäneet huolta käyttäjiin kohdistuvista mahdollisista terveysvaikutuksista.

Vuosina 1994 - 2007 neljä kansallista tutkimusohjelmaa toteutettiin Suomen yliopistoissa ja tutkimuslaitoksissa, joissa päärahoittaja oli TEKES - teknologian ja innovaatioiden kehittämiskeskus. Ohjelmat pyrkivät vastaamaan kysymyksiin matkapuhelinten mahdollisista terveyshaitoista, ja ne olivat osa kansainvälistä yhteistyötä RF-kenttien terveysriskien arviomiseksi. Vaikka ohjelmat tuottivatkin paljon tietoa, avoimia kysymyksiä on edelleen. Sen vuoksi tammikuussa 2009 käynnistettiin uusi kansallinen tutkimushanke WIRECOM (Langattomat laitteet ja terveys). Tavoitteena oli täydentää tutkimuslaitosten ja yliopistojen laaja-alaista ja luotettavaa tutkimustietoa ja siten varmistaa tulosten julkinen hyödynnettävyys.

WIRECOM-yhteishanke koostui neljästä osaprojektista. Hankkeet kohdistuivat radiotaajuisen sähkömagneettisen säteilyn mahdollisiin vaikutuksiin pään alueella sekä terveysvaikutusten tutkimiseen kansainvälisen epidemiologisen kohorttitutkimuksen osana. Hankkeiden käsittelemät tutkimusongelmat sisältyivät Maailman terveysjärjestön (WHO) prioriteetteihin ja siten edistävät WHO:n tulevaa RF-kenttien terveysriskien arviointiprosessia.

Työterveyslaitoksen (TTL) osaprojektissa selvitettiin voiko koehenkilöiden altistuminen RF-kentille aiheuttaa sellaisia lämpövaikutuksia pään alueen kudoksissa, että niistä voisi aiheutua käyttäjälle terveyshaittoja. Tutkimukseen otettiin 59 koehenkilöä, joista 26 oli 14 - 15 v. poikia ja 33 nuoria miehiä. Koehenkilöitä altistettiin sekä tavallisen että suurempitehoisen GSM-matkapuhelimen lähettämille RF-kentille. Teini-ikäisten poikien tutkimuksessa korvakäytävän lämpötilat eivät nousseet merkittävästi eikä havaittu muutoksia aivojen verenvirtauksessa käytettäessä suurinta yleisölle sallittua puhelimen lähetystehoa (2 W / kg) 15 minuutin altistumisen aikana. Myöskään aivojen merkittävään lämmönnousuun sopivia muutoksia perifeerisessä lämmönsäätelyjärjestelmässä tai verenkierron autonomisessa säätelyssä ei löytynyt.

Nuorille aikuisille tehdyissä altistuskokeissa käytettiin SAR-arvoa 4 W / kg. Se on korkeampi kuin väestölle sallittu GSM SAR-arvo 2 W / kg, mutta selvästi alle radiotaajuussäteilystä annettujen turvallisuusrajojen. Otsalohkon verenvirtauksessa todettiin 20 min altistuksessa laskeva suuntaus. Tämä havainto on yhdenmukainen Turun yliopiston PET tutkimuksen tulosten kanssa. Korvakäytävän lämpötila nousi noin 0,5 °C 20 min altistuksen aikana. Aikuisten ryhmältä otettiin verinäytteet ennen altistusta että sen jälkeen. S100B proteiini oli yksi tutkituista merkkiaineista ja sitä tuottavat aivokudoksessa lähinnä astrosyyttisolut. Sitä on ehdotettu keskushermoston vaurioitumisen merkkiaineeksi. Altistuksen aikana koehenkilöiden veren S100B pitoisuus pieneni merkitsevästi (p < 0,01). Tasot olivat kuitenkin fysiologisen vaihtelun normaalirajoissa sekä ennen altistusta että sen jälkeen. Muissa biokemiallisia merkkiaineissa ei havaittu merkittäviä muutoksia.

Turun yliopiston (UTU) tutkimuksessa selvitettiin mahdollista yhteyttä RF-altistumisen ja aivokudoksen aineenvaihdunnan muutosten välillä. Samoin tutkittiin toiminnallisia muutoksia neurobiologisten mekanismien ja kognitiivisien toimintoja välillä. Tutkimus toteutettiin yhteistyössä kansallisen PET-keskuksen kanssa. Matkapuhelimen säteilyn vaikutusta aivojen glukoosiaineenvaihduntaan ja aivojen verenvirtaukseen (CBF) tutkittiin kahdella positroniemissiotomografia (PET)-tutkimuksella, joissa käytettiin fluorodeoksiglukoosia ([18F] FDG) ja radioaktiivista vettä ([15O] H2O). Tärkein havainto FDG-PET:ssä oli, että aivojen sokeriaineenvaihdunta väheni merkittävästi altistuneella (oikealla) aivopuoliskolla. Altistuksen aikana aivojen suurin SAR-arvo oli 0,2 W/kg ja vastaavasti pään suurin SAR-arvo oli 0,7 W/kg.

Säteilyturvakeskuksen (STUK) vastuulla oli koko yhteishankkeen altistumislaitteistot ja altistumisen arviointi (RF dosimetria). Käytetty numeerinen malli havaittiin laadullisesti riittävän hyväksi vertaamalla mitattuja ja simuloituja SAR-arvoja homogeenisessa nestemäisessä phantomissa. Altistusjärjestelmien korkealaatuinen dosimetrinen arviointi on keskeinen edellytys luotettaville ihmisen altistumista koskeville tutkimuksille.

Neljäs osahanke, prospektiivinen kohorttitutkimus matkapuhelimen käyttäjistä ja terveydestä (COSMOS) tehtiin myös STUK:ssa. Tutkimuksen tavoitteena on selvittää yhteyttä matkapuhelimen käytön ja erilaisten sairauksien ja oireiden kuten neurologisten sairauksien, aivokasvainten ja päänsäryn välillä. Suomalainen COSMOS tutkimus on osa laaja-alaista kansainvälistä COSMOS-yhteistyötä, jolla on yhteinen tutkimussuunnitelma. Suomen lisäksi kansallinen COSMOS tutkimus on käynnistetty Ruotsissa, Tanskassa ja Iso-Britanniassa (30,000-66,000 osallistujaa kussakin maassa), ja parhaillaan käynnistämistä valmistellaan Alankomaissa ja Ranskassa. Kansainvälinen yhteistyö lisää aineiston kokoa ja parantaa tutkimuksen tilastollista voimaa (power). Tutkimukseen pyydettiin osallistumaan aikuisia, jotka käyttävät matkapuhelimia eri määriä. Heihin otettiin yhteyttä puhelinoperaattoreiden kautta. Rekrytointivaiheessa osallistujat täyttivät kyselyn, joka koski aikaisempaa puhelimen käyttöä, terveydentilaa ja tutkimusta sekoittavia tekijöitä. Yhteensä 15 800 henkilöä on suostunut osallistumaan tutkimukseen (9,6% kutsutuista). Noin 13 000 on myös täyttänyt kyselyn (8,0% kutsutuista). Tutkimuksessa kyselyyn osallistujista useimmat kertoivat aloittaneensa matkapuhelimen käytön 1990-luvun puolivälissä. Noin 15 % katsoi terveytensä olevan tavanomainen tai huono. Tutkittavat ilmoittivat puhuvansa yleensä 1-3 tuntia viikossa (38%). Korkeimpaan luokkaan (> 6 h viikossa) kuului 6 % ja alimpaan luokkaan (< 5 min viikossa) kuului alle 1 % vastanneista. Päänsärky oli ainakin joskus rajoittanut tavanomaista päivittäistä toimintaa 12% tutkimukseen osallistuneista. Noin 24% vastaajista raportoi valoilmiöistä päänsäryn aikana. Lähes 15 %:lla vastaajista esiintyi tinnitusta ja 10%;lla osittaista kuulon heikkenemistä matkapuhelimen käyttöön liittyen. Harvinaisin oire oli pahoinvointi (3%) ja tavallisin polttava tunne korvassa (49%).

Kaikki kolme Suomen tärkeintä operaattoria (DNA, Elisa ja TeliaSonera) suostuivat antamaan tiedot osallistujien puheluista. Operaattorin tiedot on saatu vähintään kolmen kuukauden ajalta vuodessa. Tutkittavat pidetään ajan tasalla tutkimuksen etenemisestä uutiskirjeen (lähetetään sähköpostitse) ja internet-sivun (www.cosmostutkimus.fi) avulla. Suomalainen COSMOS-hanke on nyt siirtymässä seurantavaiheeseen. Seurantalomakkeet

pyritään lähetetään vuonna 2013. Tutkimuksen odotetaan jatkuvan ainakin vuoteen 2020.

Avoimia kysymyksiä ja suosituksia

Sekä Työterveyslaitoksen ja Turun yliopiston tutkimukset osoittivat, että altistuminen matkapuhelimen RF-kentille voi vaikuttaa aivojen aineenvaihduntaan ja aivojen verenkiertoon. Vaikutuksista etenkin sokeriaineenvaihduntaan on julkaistu ristiriitaisia raportteja tuoreessa kirjallisuudessa. Tämän vuoksi on tarpeellista toistaa tutkimukset ja määrittää annos-vaste-suhteet käyttäen erilaisia RF-altistumisen tasoja. Koska muutoksia aivoissa on hyvin vaikea mitata, tutkimuksissa tulisi käyttää riippumattomia menetelmiä (esim. PET ja NIRS). Suomalaisen tutkimusohjelman jatkumisen kannalta suurin uhka tulevaisuudessa on riittävän rahoituksen varmistaminen.

WIRECOM-hankkeen rahoitus

WIRECOM - ohjelman päärahoittaja oli Tekes. Ohjelman osarahoittajia olivat Nokia, TeliaSonera ja Elisa sekä hankkeeseen osallistuneet tutkimuslaitokset. Työterveyslaitos toimi hankkeen koordinaattorina.

EXECUTIVE SUMMARY

The rapid spread of mobile phones and other wireless communication devices has increased the population's exposure to electromagnetic fields at radio frequencies (RF). Even though the electromagnetic fields emitted by mobile phones and base stations are weak compared to safety limits, public discussion and some research findings have raised concern about possible health effects.

During the years 1994 – 2007, four national research programmes were carried out in Finnish universities and research institutes, funded mainly by TEKES. The programmes attempted to respond to citizens' concerns about the possible adverse health effects of mobile phones, and they were part of international cooperation to evaluate the health risks of electromagnetic fields at radio frequencies. Although these Finnish and foreign studies generated a lot of information, there remain still some open questions. Therefore, in January 2009, a new national research project into the health effects of mobile phones' RF fields was started. The objective was to enable large-scale and reliable research in independent research institute, hence ensuring public benefit from the findings.

The joint project WIRECOM (Wireless Communication Devices and Human Health), was made up of four different projects, containing a large-scale international cooperation that includes epidemiological monitoring research as well as provocative projects focussing on possible effects on the head area. The projects dealt with the research questions that were the highest priority for the World Health Organisation (WHO), thus supporting the WHO's planned evaluation of the health risks of RF fields.

The focus of the Finnish Institute of Occupational Health's (FIOH) sub-project was to clarify whether the exposure of trial subjects to the RF fields from GSM phones produces levels of temperature change in the tissues of the head area which could be detrimental to the health of the phone user. The results of the volunteer tests by preadolescent boys and young adults indicated no significant increase in local ear canal temperatures or superficial cerebral blood flow. Alterations in peripheral thermoregulatory or circulatory autonomic reflexes typically related to the increase in the temperature of brain thermostat were neither found. With the preadolescents boys the used phone transmitting power was the maximum allowed for the general public (2 W/kg).

In the adult group, the SAR value of 4 W/kg was used in the experiments. It is higher than the normal allowed maximum GSM SAR value of 2 W/kg, but clearly below the safety limits for RF exposures. During the exposure time of 20 min, a slight decrease in the blood flow indicators of the frontal area was found. This finding is in accordance with results of Turku University's Centre for Cognitive Neurosciences PET study. The ear canal temperature increased about 0.5 °C during the 20 min exposure time. The blood samples were taken only in the adult group before and after the session. The protein S100 B is mainly produced in the brain by astrocytes. and it has been suggested to serve as a screening tool of CNS injury. During the exposure the S100B concentration decreased significantly ($p < 0.01$). The levels, however, were within biological normal range both be-

fore and after the exposure. Any other significant changes were not found in other bio-chemical markers.

The primary interests of the Centre for Cognitive Neuroscience of University of Turku (UTU) were in the possible link between RF exposure and metabolic changes in brain tissue, as well as in the link between functional changes in neurobiological mechanisms and cognitive functions. The research was carried out in cooperation with the national PET Centre. Two positron emission tomography (PET) studies were conducted to investigate the effects of mobile phone radiation on brain glucose metabolism and cerebral blood flow (CBF) using fluorodeoxyglucose ([18F]FDG) and radioactive water ([15O]H2O), respectively. The main finding of the FDG-PET study was that the brain glucose metabolism was significantly reduced in the temporoparietal junction and anterior temporal lobe of the exposed (right) hemisphere. The SAR value during the exposure was 0.25 W/kg.

The Radiation and Nuclear Safety Authority (STUK) was responsible for the construction of the exposure device for the subjects and for measuring exposure (dosimetry) in the other sub-projects. The quality of the numerical source model used was found adequate by comparing the measured and simulated SAR values in a homogeneous liquid phantom. Also the simulated return loss and center frequencies agreed well with the measured values. The high quality dosimetric assessment of the exposure systems is essential requirement for reliable human exposure studies.

The fourth sub-project was also carried out by STUK, consisting of monitoring research into mobile phone users as part of a large-scale European project. The Finnish COSMOS study is a part of international collaborative COSMOS study with a common study protocol. Besides Finland, national COSMOS study components have been launched in Sweden, Denmark, and the UK (30,000-66,000 participants in each country), and are being prepared in the Netherlands and France. International collaboration increases the statistical power of the study considerably, which is essential particularly for rare diseases such as brain tumours (glioma, meningioma) and Parkinson and Alzheimer disease.

People who use mobile phones at different levels were invited to take part in the research and were contacted through their service providers. In the monitoring phase, data about the participants' incidence rate of illness were collected, and the question as to whether there is a link between use of mobile phones and the risk of illness was evaluated. A total of 15,800 persons have agreed to participate in the study (9.6% of those invited) and about 13,000 have also filled in the study questionnaire (8.0% of those invited). In the study questionnaire participants reported most often having started their use of mobile use in the mid-1990s. Study participants usually reported having called their mobile phone 1-3 hours per week (38 %); 6 % belonged to the highest category of call time (> 6 h per week) and < 1 % belonged to the lowest category (< 5 min per week). About 60 % had used one mobile phone and some 5 % had used at least mobile phones during the preceding three months. Headache had at least sometimes limited usual daily activities for 12 % of the study participants and about 24 % had been bothered by light when having a headache. On average 15 % considered their health being fair or poor. In addition, participants reported any symptoms occurring in relation to mobile phone use. Almost 10% of the respondent reported headache, 15% tinnitus and 10% partial hearing loss in conjunction with mobile phone use (always, often or sometimes vs. never). Nausea was the

least common (3%) and burning sensation in the ear was the most common symptom (49%).

All three major Finnish operators (DNA, Elisa and TeliaSonera) agreed to deliver operator data for the participants upon researchers' request. Operator data have been received from all the operators at least for a three month period each year. Study participants are being kept up to date about the progress of the study through a newsletter (sent by email) and through the study web page (www.cosmostutkimus.fi). After the recruitment period, the Finnish COSMOS is now entering the follow-up phase. We aim to send the first follow-up questionnaires in 2013 to those recruited in 2009. The study is expected to continue until at least 2020 or beyond.

OPEN QUESTIONS AND RECOMMENDATIONS

Research findings of both FIOH and UTU indicated that the RF exposure from the mobile phone can affect the brain metabolism and cerebral blood flow. However, conflicting reports have been published from other research groups on the brain glucose metabolism after the RF exposure. There is a need for replication of the present results and to determine possible dose-response relations using different RF exposure intensities. It is one important way to evaluate the causality of the events. As the changes in the brain are very difficult to measure, the research should be designed to use independent methodologies (e.g. PET and NIRS) on the same physiological function. Similar results by independent methods would give more credibility to the results.

The effect of local SAR on brain glucose metabolism could be studied in the future with a setup delivering smaller and better defined and targeted exposed volume. With a dipole or planar antenna the exposure could be targeted to a certain brain lobe. Higher SAR values could be used to study the dose-dependence of the changes in metabolism.

A major threat for the future of the Finnish research programme is the lack of continued funding.

FUNDING

The main funder of the WIRECOM - programme was Tekes – the Finnish Funding Agency for Technology and Innovation. The programme received funding also from Nokia, TeliaSonera and Elisa as well as from the participating research institutes. The Finnish Institute of Occupational Health was the coordinator of the project.

WIRECOM - National research programme into the health effects of mobile phones

Final report

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Thermal effects of RF fields (TERFI)

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CONTENTS

1 INTRODUCTION

The electromagnetic fields produced by the cellular phone have evoked concern about possible adverse health effects of the exposure. Results of the neurophysiological studies are inconsistent (Kwon and Hämäläinen, 2011). It has been suggested that heat production of mobile phones might play the most important role in the development physiological responses. In a previous study, 35 min exposure to the radiofrequency (RF) field of cellular phones increased the temperature of the exposed ear canal by up to 1.5 °C in adults (Tahvanainen et al., 2007). The human brain is well protected against the external heat load and the rise of the actual brain temperature quickly activates thermoregulatory reflexes. The assessment of the peripheral circulatory autonomic responses and the local cerebral blood flow reveals indirect evidence from physiological changes during the RF exposure (Barker et al., 2007, Aalto et al., 2006). The superficial cerebral blood can be estimated by near- infrared spectroscopy (NIRS) and there is a correlation between NIRS and more accurate methods, e.g. positron emission tomography (PET) (Cui et al., 2011). In some studies, biomarkers of the central nervous system (CNS) disorders have been used to study biological responses during the EMF exposure by mobile phones (Söderqvist et al, 2009).

The aim of this study was to examine thermal and local blood flow responses in the head area and peripheral sites of the body among preadolescent and adult populations during exposure to radiofrequency (RF) electromagnetic fields produced by a GSM mobile phone. The study design was a double-blinded sham-controlled study. The SAR distribution was calculated and modelled in detail.

The specific aims were to determine local temperature changes in head area, superficial cerebral blood flow and peripheral circulatory reactions, and changes in some biomarkers of adult brain CNS dysfunction during exposure to RF fields.

2 MATERIALS AND METHODS

2.2 Ethical considerations

The study protocols were approved by the Ethics Committees of the Hospital District of Helsinki and Uusimaa (299/13/03/00/09). The volunteers were paid a small compensation based on the ethical guidelines of Hospital District of Helsinki and Uusimaa.

2.2 Test environment

The measurements were carried out in a climatic chamber in controlled thermoneutral conditions. The chamber space is large enough to accommodate the experimental procedures and the control system minimizes the effects of the environmental temperature changes. The room temperature was 26 °C and the relative humidity was 30%. The subjects were positioned semi-sitting on a bed with the head up angle of 45° (Fig 1).

Figure 1. Test subject positioning during the test.

2.3 Exposure setup and dosimetric calculations

Two modified GSM phones were placed with 4 mm distance to the ear canal on both sides of the head. Only the phone on the right side was transmitting. Before the human studies dosimetric calculations were performed especially to model the SAR values of a preadolescent head. The phone transmitter was deactivated, the battery removed, and the antenna input replaced by an external coaxial cable. The signal was taken from an identical phone

controlled by the service software. The power was adjusted with an amplifier to produce maximum specific absorption rate (SAR) of 2 W/kg for preadolescents and 4 W/kg for adults averaged over a 10 g tissue (SAR10g). The corresponding maximum SAR10g in brain tissue was 0.66 W/kg for preadolescents and 1.32 W/kg for adults. SAR distribution was computed with a FDTD software (SEMCAD X). In the calculations, the European adult male Duke (Virtual family) was used. The head sizes of preadolescent subjects were close to the model head size. In addition to the head, the numerical model included the exposing and dummy phones, and temperature probes. Results were validated with measurements (SAM head model) and the achieved SAR values agreed well. The system is presented in detail in the RFDOS-report by STUK**.**
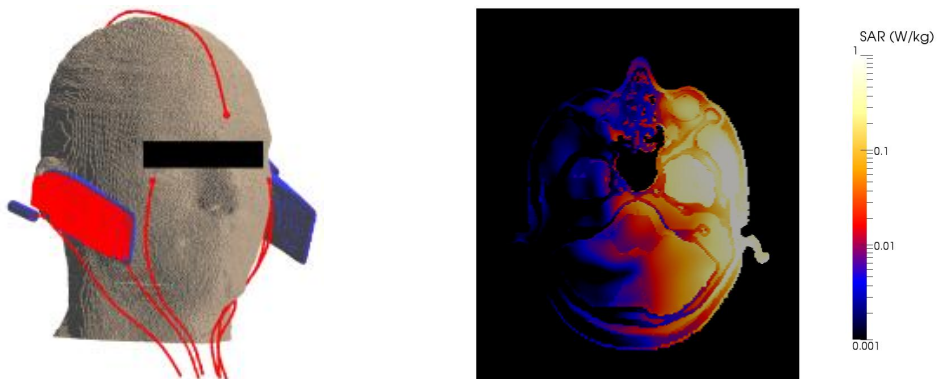

Figure 2. Used voxel model and calculated SAR-distribution.

2.4 Physiological measurements

2.4.1 Temperature measurements

The local temperatures of the head were measured bilaterally from thermally insulated ear canal in the depths of 7 and 17 mm (YSI 555, YSI Inc, USA). The facial skin temperatures (YSI 427, YSI Inc, USA) were recorded on several sites of the face. The changes in the skin temperatures of the trunk and extremities were recorded continuously with nine thermistors (Veriteq Instruments Type 1400, Canada). The gradients of facial skin temperatures were also monitored by infrared camera (ThermaCAM PM695 PAL, FLIR Systems AB Sweden), which enables detection of superficial temperature gradients of 0.03° C.
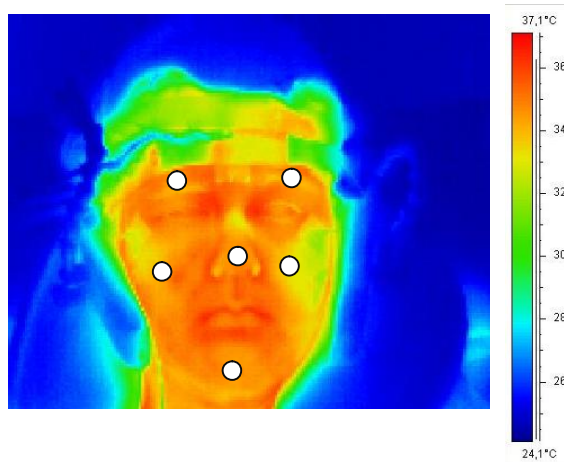
Figure 3. Thermal camera measurement points.

2.4.2 Near-infrared spectroscopy

The cerebral total blood flow (TBF) was measured non-invasively by near infrared spectroscopy (NIRS). The NIRS device emits light beams with wavelengths of about 760 nm and 860 nm (Oxymon MkIII, Artinis BV, the Netherlands). The penetration depth is about 2,2 cm, and the light beam thus reaches the superficial brain circulation. The oxy- and deoxyhemoglobin have distinct absorption spectra, and it is therefore possible to quantify the changes of the blood hemoglobin contents which are closely related to the TBF of the monitored area. The optodes were placed on the right side of the skull at frontal and parietal areas. The parietal placement of NIRS detector was as near as technically possible to the temporal area of the brain above the right ear. The changes of NIRS variables were calculated during the sham, exposure and recovery period separately.

2.4.3 The peripheral blood circulation and autonomic nervous system function testing

The peripheral blood circulation was continuously monitored by the electrocardiogram (ECG, WinAcq, Absolute Aliens, Finland) and digital blood pressure (Portapres, Finapres Medical Systems, the Netherlands) recordings. The circulatory parameters were calculated with special software of neurocardiological analyses (WinCPRS, Absolute Aliens, Finland).

2.4.4 Biochemical analyses

The blood samples were taken only in the adult group before and after the session. The protein S100 B is mainly produced in the brain by astrocytes. There are also other peripheral sources of this protein. S100B has however been suggested to serve as a screening tool of CNS injury (Sen and Belli, 2007). Also neuronspecific enolase, the marker of vascular cerebral injury, was analysed. Both biochemical analyses based on chemiluminescence technique were performed in the laboratory of Helsinki University Hospital.

2.4.5 Medical examination

A general medical examination was performed before the study session to exclude diseases, medications and other potential medical factors affecting the measurements (Fig. 4).
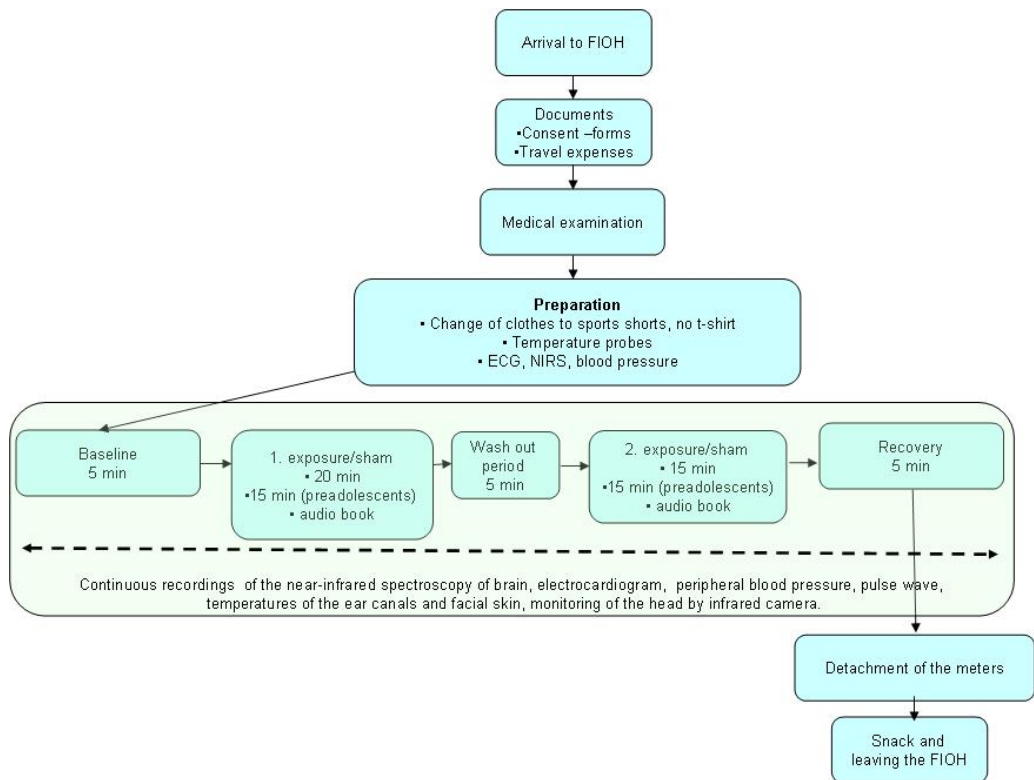

Figure 4. The flow chart of the study protocol.

2.5 Study cohorts

2.5.1 Cohort 1: Preadolescent boys, age 14-15

The study population was recruited from two primary schools in Helsinki. Detailed information package was sent to the volunteered pupils and to their parents. A written consent of the volunteers and their parents was required before the study session. The study population was restricted to 14 -15 years old, healthy boys to avoid age- and gender related differences in adolescents' physiology. A total of 26 boys were studied. The mean age of the study group was 14.7 years (SD 0.5), and the mean body mass index (BMI) ($kg \cdot m^{-2}$) was 20.7 (SD 2.4).

The duration of the sham periods and exposures with GSM 900 phone was 15 min each. The maximal antenna energy was 2 W.

2.5.2 Cohort 2: Adults

The 33 male subjects were recruited among the students of a local university and other contacts of FIOH. The recruited university students and other subjects, including firemen and police officers, were given detailed information packages prior to the study dates. A written consent of each volunteer was required before the study session. The mean age of the study population was 27.6 years (21- 38 years). Their health condition was assessed in the physical medical examination by a senior physician. Only healthy subjects with no continuous medication were chosen. The health examination included also the measurement of vascular stiffness (VasEra, Fukuda Inc, Japan). The mean BMI was 24.6 (SD 2.6).

3 RESULTS

3.1 The adult group

3.1.1 Ear canal temperatures of the adult group

The ear canal temperature increased about 0.5 °C both in the thermistor near the tympanic membrane and in the thermistor 1 cm apart from the deeper thermistor (Figure 5) during the 20 min exposure with SAR value of 4 W/kg.
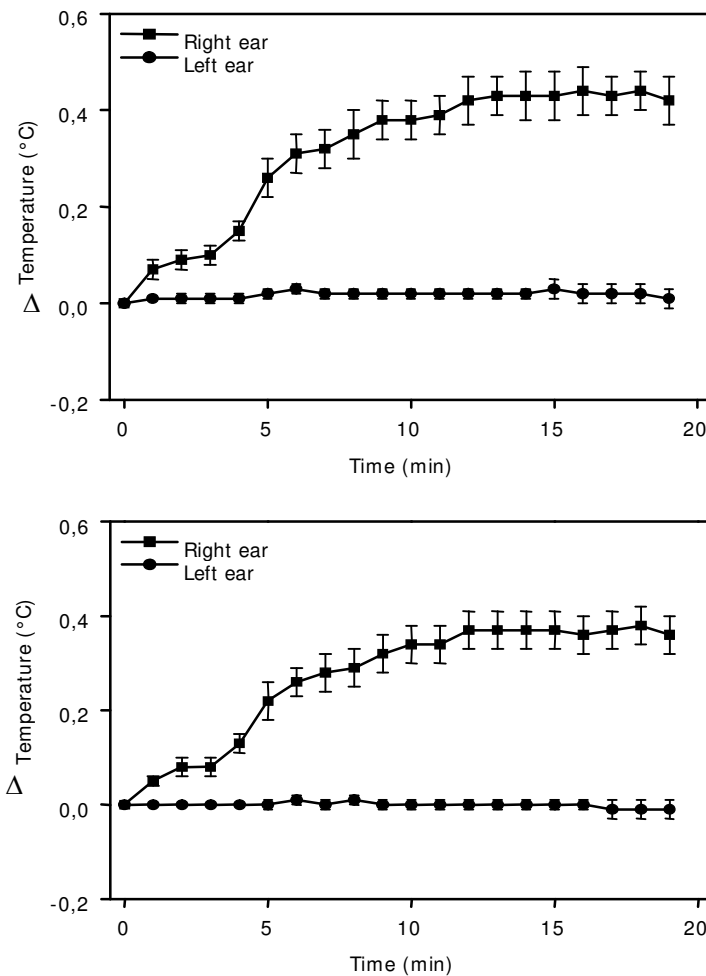

Figure 5. The ear canal temperature near the tympanic membrane (above) and at the level 1 cm from the deep thermistor (below) during the RF field exposure in the adult group

3.1.2 The autonomic nervous system in the adult group

The square root of the mean of sum of the squares of differences between adjacent RR intervals (RMSSD) reflects mainly the parasympathetic (relaxing) component of cardio-vascular autonomic control in the time domain analyses of heart rate variability (HRV). RMSSD of the adult group was normal before the exposure and no signficant changes were found during the exposure (Fig 6). The interplay between blood pressure and heart rate was also normal indicated by baroreflex sensitivity in cardiac autonomic analyses.
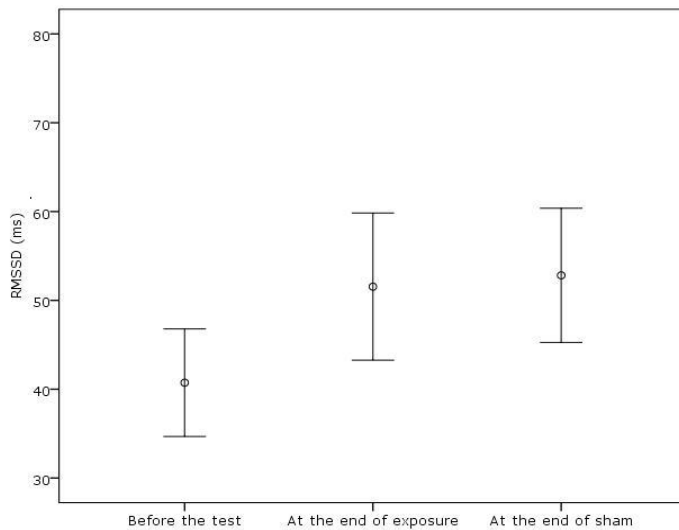

Figure 6. The square root of the mean of sum of the squares of differences between adjacent RR intervals (RMSSD) before the session and after sham and exposure periods.

3.2.3 NIRS in adult group

A decreasing trend was found in the calculation of total Hb content in the frontal area (Fig 7). The difference, however, was not significant due to the great individual variation. No significant changes were found in the parietal/temporal areas.

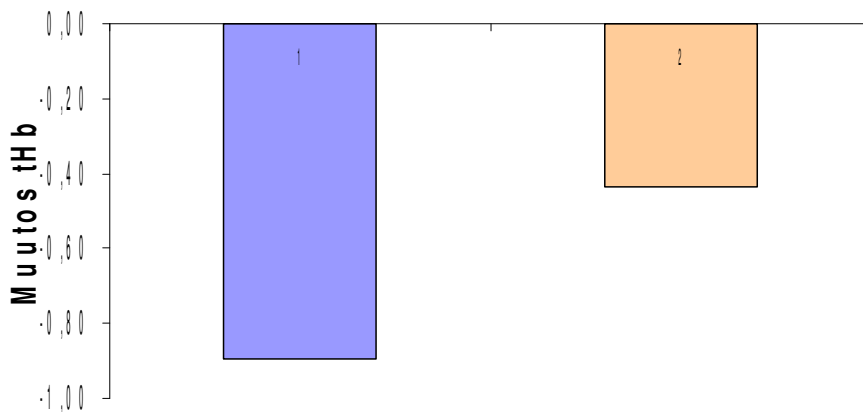Figure 7. The change in the total Hb in NIRS of the frontal area in the adult population (1= before and after exposure, 2= before and after the sham).

3.2.4 Biochemical analyses

S100B concentration decreased significantly during the exposure (p<0,01). The levels, however, were within biological normal range both before and after the exposure. Any significant changes were neither found in other biochemical markers.
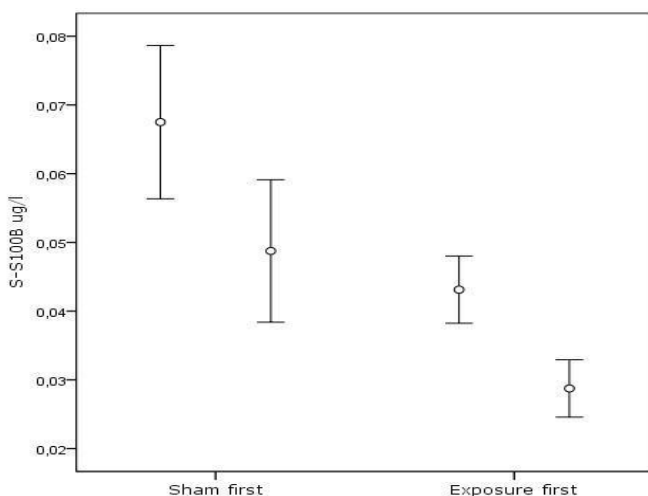
Figure 8. The brain specific protein (S100B) during the exposure to RF field among adult subjects. Normal value is below 0.11 ug/l.

3.3 The preadolescent group

3.3.1 The autonomic nervous system in the preadolescent group

An increase was found in the sympathetic indices of the cardiac autonomic control in the group of preadolescents boys. It was not correlated to the RF field. The main explanation was the enhanced discomfort due to the the prolonged immobilization.

3.3.2 The ear canal and facial temperatures in the preadolescents

The ear canal temperatures of preadolescent group did not change significantly during the test sessions (Fig. 9). The facial superficial temperatures slightly decreased during the test sessions.
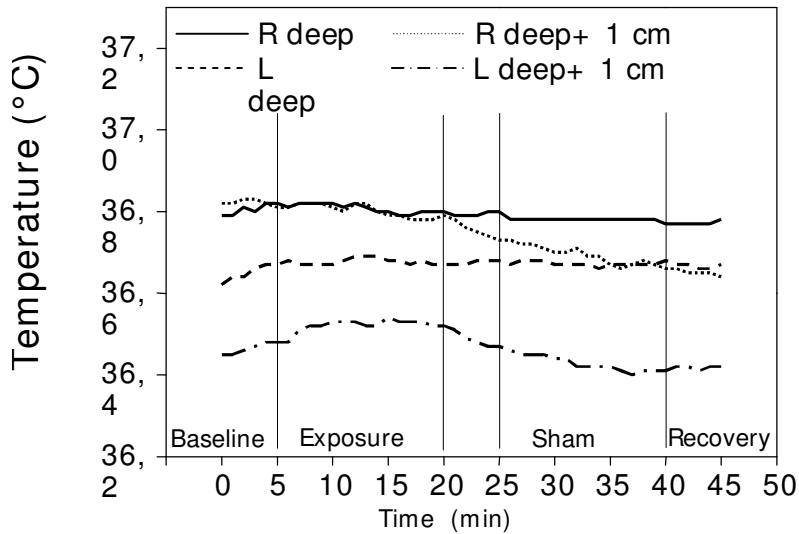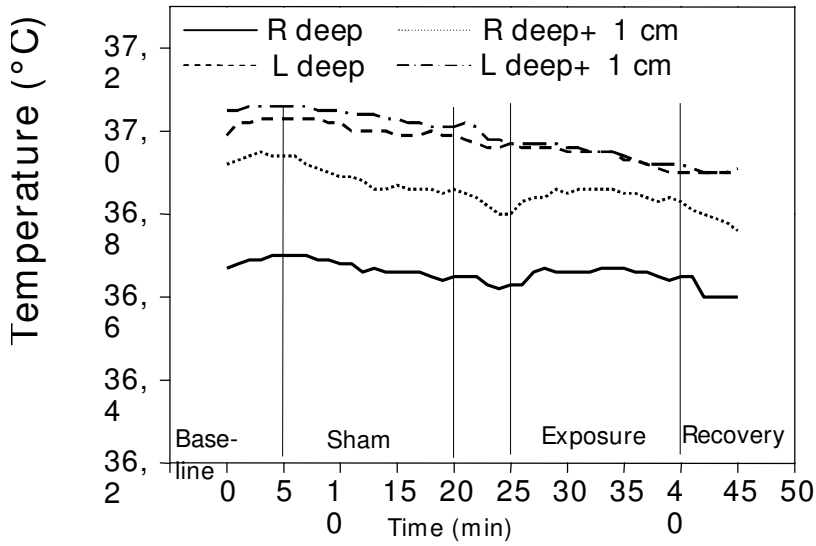
Figure 9. The ear canal temperatures in the depth of 7 mm and 7 mm+ 10 mm (R= right, L= left) during the 15 min sham period (above= sham first, below= exposure first) and 15 min RF exposure produced by the GSM mobile phone.

3.3.3 NIRS in preadolescent group

The changes in the oxyhemoglobin and deoxyhemoglobin contents during the sham and exposure periods did not differ significantly in the frontal area (p = 0.488) and in the parietal area (p= 0.629).

4 DISCUSSION AND CONCLUSIONS

Among the preadolescent boys local cerebral blood flow did not change, the ear canal temperature did not increase and autonomic nervous system was not interfered during the short-term RF exposure. These unique results have been reported recently by the study group (Lindholm et al, 2011).

In the adult group, the SAR value of 4 W/kg was used in the experiments. It is higher than the normal maximum allowed GSM SAR value of 2 W/kg, but clearly below the safety limits for RF exposures. During the exposure time of 20 min, a slight decrease in the blood flow indicators of the frontal area was found. This finding is in accordance with the recent finding reported by Kwon (Kwon et al, 2011 b).

The strengths of this study were the young subpopulation, multifactorial physiological monitoring and strictly controlled thermal environment. The limitations of the study were large inter-individual variation in the physiological responses, and short duration of the exposure. Longer provocation protocols, however, might cause in children distress related confounding physiological responses.

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WIRECOM - National research programme into the health effects of mobile phones

Final report

Dnro 2216/31/08

Effects of mobile phone electromagnetic field on human brain: PET-study

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Effects of mobile phone electromagnetic field on human brain: PET-study

We have conducted two positron emission tomography (PET) studies to investigate the effects of mobile phone radiation on brain glucose metabolism and cerebral blood flow (CBF) using fluorodeoxyglucose ([^{18}F]FDG) and radioactive water ([^{15}O]H$_2$O), respectively. Sixteen healthy right-handed males aged 18-30 years participated in each study.

The studies were conducted at Turku PET Centre involving many physicians (blood sampling, tracer injection), radiographers (scanner operation), medical laboratory technologists (tracer production), and other scientists (data processing). In addition, Säteilyturvakeskus (STUK) supported us with the exposure setup and dosimetry (SAR measurement, numerical simulations), and Työterveyslaitos (TTL) provided us with the equipment for temperature measurement in the head region during exposure.

FDG-PET study

The experiment was scheduled for September-December 2009, but it could not be completed in 2009 because the PET center reserved our scanning times for only four subjects starting from October. Then, the equipment for exposure and temperature measurement was handed over to TTL for two months and then we continued the experiment in February 2010 until May 2010.

We had two responsible physicians in 2009 but they suddenly left the PET center for their own clinical work and study in 2010, and we had trouble in finding new physicians while catching up with the schedule. Eight physicians were (temporarily) involved in the FDG study and we have completed data collection in May 2010.

We processed and analyzed the data in June 2010 and found promising results: Brain glucose metabolism was significantly reduced in the temporoparietal junction and anterior temporal lobe of the exposed (right) hemisphere. The results were published in *Journal of Cerebral Blood Flow and Metabolism* in September 2011. These results were also presented at the 33rd Annual Meeting of the Bioelectromagnetics Society held in Halifax, Canada in June 2011. These results were also reported in national news-media.

There is a need for replicability of the present results and to determine possible dose-response relations using different radiation intensities. It is one important way to evaluate the causality of the events.

There is only one previous FDG-PET study (Volkow et al, 2011), which reported increased brain glucose metabolism after a 50-min mobile phone exposure. However, the methodology of the study and the reporting of the results have evoked considerable criticism (Kosowsky et al, 2011; Davis and Balzano, 2011; Nordström, 2011). Our study has several methodological advantages, especially accurate SAR assessment, well-controlled exposure setup, measurement of temperature in the head region, and objective monitoring of the subject's alertness state. Proper dosimetry (Kuster et al, 2004) is crucial in this kind of bioelectromagnetic studies.
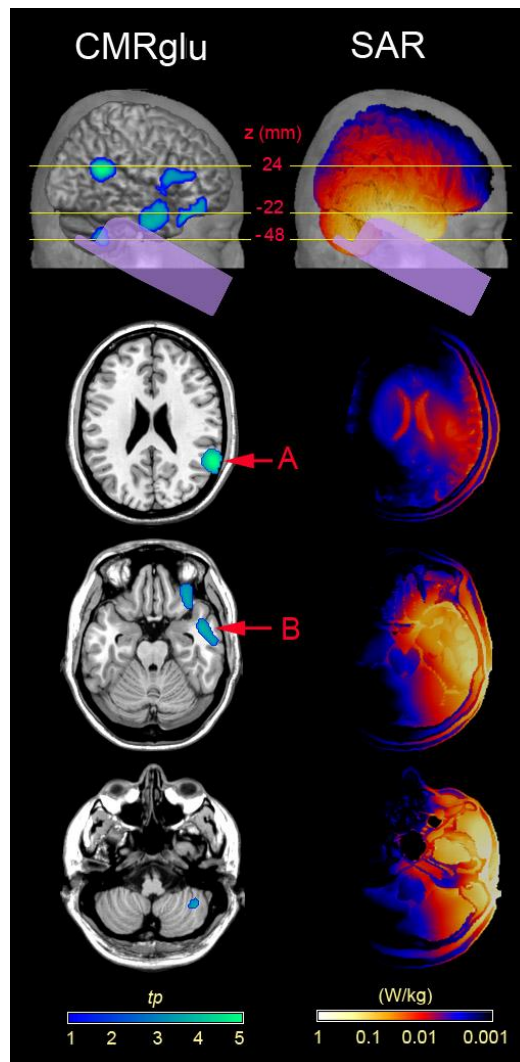
Fig. 1. Decreased brain glucose metabolism (left column) and SAR distribution (right column) in the presence of mobile phone exposure. The top row shows the lateral view of the projections of decreased brain glucose metabolism and superficial SAR distribution in relation to the phone position on the right hemisphere. Horizontal lines indicate the coordinates for the three brain slices below. Arrows A and B depict peaks of significant decreases of brain glucose metabolism ($P < 0.05$, $n = 13$).

CBF-PET study

The experiment was scheduled for January-June 2010, but it actually started in April 2010 because the FDG study was delayed due to the aforementioned reasons. We could find two reliable physicians for this study and reserve enough scanning times to complete data collection in time, in June 2010.

We processed and analyzed the data in August 2010, but found no significant changes in CBF. The results of no effects could be due to the short, intermittent exposure. This study employed three different phone locations at the expense of exposure duration, allowing three repetitions of 5 min exposures for each of the four conditions. Indeed, the previous studies that revealed effects of phone radiation on CBF (Huber et al., 2002, 2005; Haarala et al., 2003; Aalto et al., 2006) or glucose metabolism (Volkow et al., 2011), as well as our FDG study used longer exposure periods. These results were published in *Bioelectromagnetics* in September 2011.

The results of the two studies were also presented at the WIRECOM seminar, which was open to the public and held at the University of Turku in March 2012. In addition, we shared our participants of both studies with TTL for a near-infrared spectroscopy (NIRS) study. The NIRS data were analyzed in January-April 2012, and a joint publication is currently in preparation. Finally, we published a review article on human behavioral and neurophysiological studies on the effects of mobile phone electromagnetic fields in *Bioelectromagnetics* in December 2010.

List of publications

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WIRECOM - National research programme into the health effects of mobile phones

Final report

Dnro 2255/31/08

RF dosimetry for biological studies (RFDOS)

Sami Kännälä, Tommi Toivonen and Lauri Puranen

Contents

1 INTRODUCTION

The RFDOS project belonged to WIRECOM (Wireless Communication Devices and Human Health) which is a national research programme into the health effects of mobile phones. The main tasks of the project were to provide exposure set-ups and radiofrequency (RF) dosimetry for human studies and to participate in designing of the epidemiological cohort study to improve the exposure assessment of different groups. The main objective was to provide reliable and accurate exposure assessment in human and epidemiological studies. The work supporting the epidemiological study was carried out in the designing phase where the most important factors affecting the exposure were analyzed. This helped in selecting the information which is needed from the mobile phone network operators. However, the main focus of the RFDOS project was on the RF dosimetry for human exposure studies and therefore, it is addressed in this final report.

The utilization of the results of an exposure study is possible only if the distribution and intensity of the exposure is reliably known. In case an effect is found, the question will be the threshold of it. In case of no effect is found, the question will be what effects do the results exclude or what intensity should be used in the next experiment. These questions can only be answered based on a thorough dosimetric analysis of the setup. Moreover, the significance of any study alone is very limited. The risk assessment as a whole is based on reviews of all studies. In these reviews, the classification of the studies is often based on exposure parameters. If the parameters are insufficiently assessed or reported, the study might be discarded or misclassified.

A good dosimetric analysis includes the assessment of detailed exposure distribution and intensity, validation of the assessment methods and comprehensive analysis of the limitations and uncertainties related on the given data. A well established method exists for detailed dosimetry, i.e. FDTD-based numerical simulations. Also suitable numerical models of humans are presently available. The exposure source is, however, often difficult to model and the simulation results are very sensitive to flaws in this part of the model. Hence, for adequate reliability, the models have to be validated by comparing the simulation results to measurements. A specific experimental setup is often necessary due to the fact that the exposure in human head is impossible to measure directly.

The uncertainty assessment of dosimetry is very challenging. The conventional error sources, for example positioning and measurement accuracies are naturally present in the actual experiment. Moreover, the accuracy of dosimetry is limited by the fact that numerical human models are based on single individuals who anatomically differ from the exposed volunteers, as well as the volunteers differ from each other. The effect of these differences on the exposure has to be studied by modifying the numerical model manually to cover the anatomies of all volunteers.

Three experiments were conducted in WIRECOM project in order to study the effect of mobile phone use on the metabolism of brain. All experiments were based on exposure setup which irradiated the heads of the volunteers with GSM-type microwaves while they were under medical observation. The biological hypotheses and observation methods varied, yet the exposure setup was similar in all three experiments, excluding some minor

modifications. Therefore, the dosimetric analyses, related to these experiments, are described together in this report.

2 MATERIALS AND METHODS

Three different dosimetric assessments were carried out for Finnish Institute of Occupational Health (FIOH) and University of Turku. Identical exposure instrumentation was used in all of the studies but the exposing mobile phones were in slightly different positions.

In the FIOH study the subjects were exposed to GSM phone radiation and the temperature and blood circulation were monitored during the exposures. The study was carried out for adult and adolescent subjects.

University of Turku made two separate exposure studies for adult subjects. In the first study ^{18}F-deoxyglucose (FDG) tracer was injected into subjects' blood circulation and they were exposed to GSM phone radiation. During the exposure the subjects' carried out cognitive tasks. After the exposure the distribution of FDG was imaged with a Positron Emission Tomography (PET) scanner. The long half-life of the tracer allowed separation of the exposure and imaging. In the second study the exposure and PET imaging were carried out simultaneously. Cerebral blood flow (CBF) in the brain was examined with the PET scanner during the exposures.

2.1 Exposure instrumentation

The exposing mobile phones were Nokia 6110 GSM phones in all of the studies. The phones were modified so that their transmitters were deactivated and antenna inputs replaced by external coaxial cables. GSM signal was taken from an identical phone which was controlled by a service software (WinTesla v. 6.03., Nokia Group, Espoo, Finland) to continuously transmit a typical GSM voice-call signal. The signal consisted of 0.577 ms bursts of 902.4 MHz carrier frequency (GSM channel # 62) repeated every 4.615 ms. The power level was adjusted with an amplifier (RF Power Labs R720F) and signal was fed to the antenna of the exposing phone with a coaxial cable. The transmitted and reflected power levels were monitored during the exposures with an RF power meter (NAS Z7, Rohde & Schwarz, Munich, Germany). The block diagram of the exposure setup is presented in Fig. X. The temperature changes were monitored by placing temperature probes inside ear canals and on facial skin.
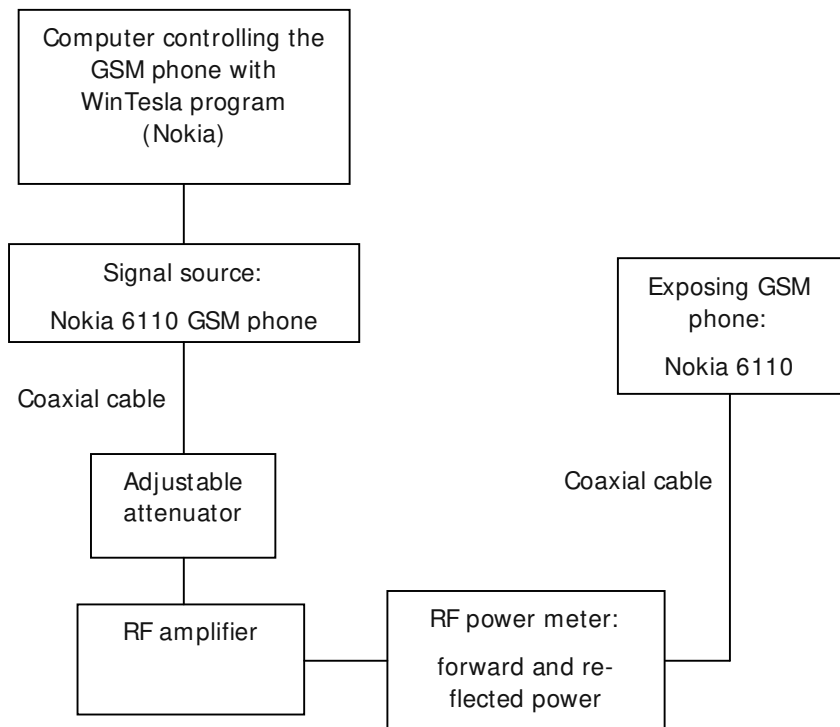
Figure 1. Block diagram of the exposure setup for all of the studies.

The return loss for each exposing phone was measured with a network analyzer (HP 8752C, Hewlett-Packard, Santa Clara, CA) prior to the exposures to ensure that the external antenna feeding was properly attached. The phones were measured at both sides of a homogeneous phantom (Specific Anthropomorphic Mannequin; SAM) and the return loss varied from 15.9 to 24.7 dB at 902.4 MHz frequency (Fig. X). Hence, the feeding was operating as intended and the antenna matching was adequate. The phone with the best matching was used as an exposing phone in the FIOH and FDG studies. In the CBF study all three phones were used as exposure sources.

2.2 Numerical simulations

Numerical simulations were carried out to evaluate the specific absorption rate (SAR) distributions in subjects' heads. The radio frequency (RF) exposure of the subjects was assessed at 902.4 MHz frequency by calculating the SAR distribution with commercial Finite-Difference Time-Domain (FDTD) software (SEMCAD X v. 14.2. Schmid and Partner Engineering AG, Zurich, Switzerland). The results were visualized with open-source soft-

ware (ParaView v. 3.8.). The calculations were carried out in a Dell Precision 490 workstation with Intel Xeon 5160 processor, 32 GB RAM and Windows XP 64 bit operating system.

The numerical head model used in the calculations was an MRI-based model Duke (34 year old European male) from the Virtual Family [Christ et al. 2010]. The model was cut at the shoulder level. The phones were modeled from CAD (computer-aided design) data provided by the manufacturer. The numerical source model was validated with experimental methods (chapter 2.5).

The basic resolution of the head model was 1 mm for the FIOH and FDG studies and 2 mm for the CBF study. The graded rectilinear grid was reduced to 0.2 mm for the antenna of the transmitting mobile phone in all of the studies. The phones that were not transmitting were modeled with a coarser grid. The dielectric properties for the head tissues were taken from the data in [Gabriel 1996]. The dielectric properties of the phone parts were same as in [Boutry et al. 2008].

The temperature probes were modelled as 2 mm thick metallic wires in all of the studies. The probes inside the ear canals were coated with an insulator. All the metallic parts in the numerical model were treated as perfect electric conductors (PEC).

a)   b)   c)
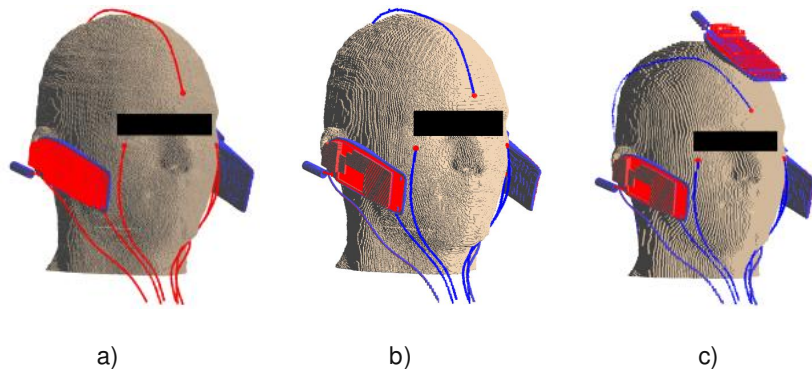
Figure 2. The voxel models used in the dosimetric computation for a) the FIOH, b) FDG and c) CBF studies. The PET device is excluded from the CBF figure. The phone on the right ear is transmitting in all of the figures and therefore the grid is finest near it.

2.3 Validation of computational model

The numerical source model was validated by comparing the measured and simulated SAR values in a homogeneous SAM phantom. The SAR distribution was measured with Dosimetric Assessment System 4 (DASY4, Schmid and Partner Engineering AG, Zurich, Switzerland) for right and left cheek positions. Measurements were conducted according to the standard IEC 62209-1 [IEC 2005] and the SAM phantom was filled with head tissue simulating liquid (σ = 1.023 S/m, ε_r = 42.01, ρ = 1000 kg/m^3). The validations were car-

ried out with the power level used in the FDG and CBF studies. Similar setups and dielectric parameters were used in the simulations.

The simulated SAR_{1g} and SAR_{10g} values varied less than 7.7 % from the measured values (Table 1). Moreover, the simulated return loss and center frequencies agreed well with the measured values (Fig. 3). The quality of the source model was therefore considered adequate.

Table 1. Results from the validation measurements and simulations.

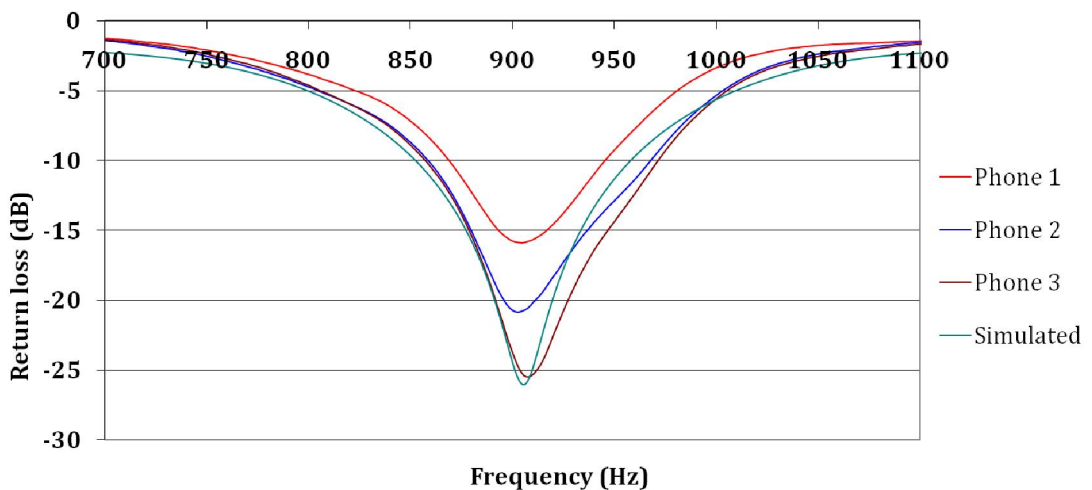| | SAR_{1g} (W/kg) | | Difference | SAR_{10g} (W/kg) | | Difference |
	Measured	Simulated	(%)	Measured	Simulated	(%)
Right	1.51	1.52	0.7	1.07	1.04	-2.9
Left	1.58	1.70	7.6	1.12	1.17	4.5

Figure 3. Measured and simulated return loss for the mobile phones when the phones are placed against the right side of the SAM phantom.

2.4 FIOH study

Two modified GSM phones were placed within a small distance from each ear in the FIOH study (Figure X). The distance from the phone surface to the mouth of the ear canal was 4 mm. Only the phone on the right side was transmitting. The simulation model consisted of two phones, head and temperature probes.

The power level for the adult subjects was adjusted to be equal to the level which produces the maximum numerically simulated 10 g averaged SAR value (SAR_{10g}) of 4 W/kg. The SAR level for the adolescent subjects was 2 W/kg. The head size of adolescent subjects was assessed to be equal to adult head size. Therefore, separate dosimetry was unnecessary and the power level for adolescent subjects was half of the power for adult subjects.

The maximum SAR_{10g} value was 1.32 W/kg in the brain for the adult subjects and 0.66 W/kg for the adolescent subjects. Tissue specific SAR values are presented in Appendix 1 and selected SAR slices in Appendix 2.

2.5 University of Turku studies

2.5.1 FDG study

Two modified GSM phones were placed against each ear in the FDG study (Figure X). Only the phone on the right ear was transmitting. The simulation model consisted of two phones, head and temperature probes.

The SAR_{10g} value used in the experiments was adjusted to the level which corresponds to the SAR of the used phone model, measured as specified in Chapter 2.3. The measured SAR_{10g} was 1.07 W/kg. The maximum SAR_{10g} value simulated with a heterogeneous head model was 0.74 W/kg while SAR_{10g} in the brain was 0.22 W/kg. Tissue specific SAR values are presented in Appendix 1 and selected SAR slices in Appendix 2.

2.5.2 CBF study

Three modified GSM phones were placed against right and left ear and forehead in the CBF study (Figure X). One phone was transmitting at a time. During the exposures the subjects' brain activation was scanned with a PET device. The power level used in the CBF study was same as in the FDG study. The simulation model consisted of two phones, head, temperature probes and PET scanner.

A simplified model of the PET scanner was generated by connecting two concentric hollow metallic cylinders consecutively with a flange. The diameter of the cylinder surrounding the head was 345 mm and it was 315 mm long whereas the corresponding dimensions for the cylinder above it were 265 and 500 mm.

The SAR values varied slightly in different exposure scenarios which is due to the non-symmetric structure of the phone and head anatomy. Although the maximum SAR values in the head varied considerably the variation in brain tissues was less. The simulated SAR_{10g} values were 0.72 W/kg (right), 1.00 W/kg (left) and 0.67 W/kg (front). The corresponding SAR_{10g} values in the brain were 0.24, 0.21 and 0.23 W/kg. Tissue specific SAR values are presented in Appendix 1 and selected SAR slices in Appendix 2.

2.6 Uncertainty analysis

The main factors influencing the uncertainty of the dosimetric calculations are (Kuster et al. 2004):

- postural changes during exposure
- difference in head anatomy
- uncertainty in incident field power
- numerical uncertainties (e.g. dielectric parameters, resolution)

In the FIOH study the distance between the surface of the exposing phone and the mouth of the ear canal was 4 mm. This produces a higher uncertainty than in the FDG and CBF study where the phones were positioned against the ear and facial skin. The uncertainty in the FIOH study was assessed by calculating the SAR_{10g} with the phone at distances of 2, 3, 4, 5, 6 and 8 mm from the ear canal. The phone was also moved 4 mm from the center point to other Cartesian coordinate directions and simulations with 5° rotations of the exposing phone were also carried out. Based on the simulations the postural changes create an uncertainty of ± 9 % in the FIOH study. The uncertainty from phone positioning was assessed to be ± 6 % in the FDG and CBF studies.

The subjects in the FDG and CBF studies were adults. In the FIOH study also adolescent subjects were used. The head dimensions of an adolescent subject were assessed to be equal to an adult subject's dimensions. The variation in SAR because of different head sizes was assessed by scaling the head model ± 10 %. The uncertainty from variation in head anatomy was ± 9 % based on the simulations.

The power fed to the antenna of the exposing phone was continuously monitored during the exposures. The uncertainty in incident power was estimated to be ± 10 %.

The numerical uncertainties result from e.g. uncertainty in dielectric properties and stair casing error. The order of magnitude of these errors was estimated to be ± 10 %.

The PET scanner in the CBF study creates an estimated uncertainty of 10 %.

The expanded uncertainties (95 % confidence level) for SAR_{10g} were:

- FIOH study ± 19 %
- FDG study ± 18 %
- CBF study ± 20 %

3 DISCUSSION AND CONCLUSIONS

Reliable dosimetric assessments were successfully made for three different studies. The quality of the numerical source model used was found adequate by comparing the measured and simulated SAR values in a homogeneous liquid phantom. Also the simulated return loss and center frequencies agreed well with the measured values.

The effect of local SAR on brain glucose metabolism could be studied in the future with a setup delivering smaller and better defined and targeted exposed volume. With a dipole or planar antenna the exposure could be targeted to a certain brain lobe. Higher SAR values could be used to study the dose-dependence of the changes in metabolism.

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APPENDIX 1. TISSUE SPECIFIC SAR VALUES

Table A1-1. Tissue specific SAR values for the FIOH study for adult and adolescent subjects.

	Adults			Adolescents		
	SAR_{1g} (mW/kg)	SAR_{10g} (mW/kg)	SAR_{avg} (mW/kg)	SAR_{1g} (mW/kg)	SAR_{10g} (mW/kg)	SAR_{avg} (mW/kg)
Grey matter	1736.8	1476.3	104.3	868.4	738.1	52.1
White matter	1667.3	1226.9	44.4	833.6	613.4	22.2
Cerebellum	373.9	440.1	51.7	186.9	220.1	25.8
Midbrain	122.4	68.9	55.8	61.2	34.5	27.9
Thalamus	104.6	*	47.8	52.3	*	23.9
Brain avg.**	1981.7	1317.5	73.2	990.9	658.7	36.6
Total head	8580.8	4000.0	134.3	4290.4	2000.0	67.1

* Mass of thalamus is less than 10g.

** Brain avg. includes grey matter, white matter, cerebellum, midbrain and thalamus.

Table A1-2. Tissue specific SAR values for the FDG study of University of Turku.

	SAR_{1g} (mW/kg)	SAR_{10g} (mW/kg)	SAR_{avg} (mW/kg)
Grey matter	375.1	250.99	18.9
White matter	173.5	98.0	8.3
Cerebellum	98.3	61.5	12.2
Midbrain	18.4	10.6	8.9
Thalamus	9.9	*	8.7
Brain avg.**	352.8	220.9	13.7
Total head	1954.8	744.8	22.3

* Mass of thalamus is less than 10g.

** Brain avg. includes grey matter, white matter, cerebellum, midbrain and thalamus.

Table A1-3. Tissue specific SAR values for the CBF study of University of Turku.

	SAR_{1g} (mW/kg)			SAR_{10g} (mW/kg)			SAR_{avg} (mW/kg)		
	Right	Left	Front	Right	Left	Front	Right	Left	Front
Grey matter	400.3	337.5	359.4	270.2	222.1	263.3	24.4	17.7	34.8
White matter	183.8	157.5	182.3	107.3	74.6	128.2	11.4	6.8	22.5
Cerebellum	77.1	153.2	63.1	51.6	87.6	33.8	10.9	14.3	13.2
Midbrain	23.9	21.4	17.6	16.5	12.2	10.7	13.9	10.4	9.6
Thalamus	14.9	9.5	13.5	*	*	*	13.1	8.2	12.1
Brain avg.**	392.6	334.4	340.4	244.9	212.0	234.2	17.4	12.8	27.0
Total head	1884.9	2786.7	1046.8	715.5	1007.8	666.7	29.1	27.7	24.5

* Mass of thalamus is less than 10g.

** Brain avg. includes grey matter, white matter, cerebellum, midbrain and thalamus.

APPENDIX 2. SELECTED SAR FIGURES

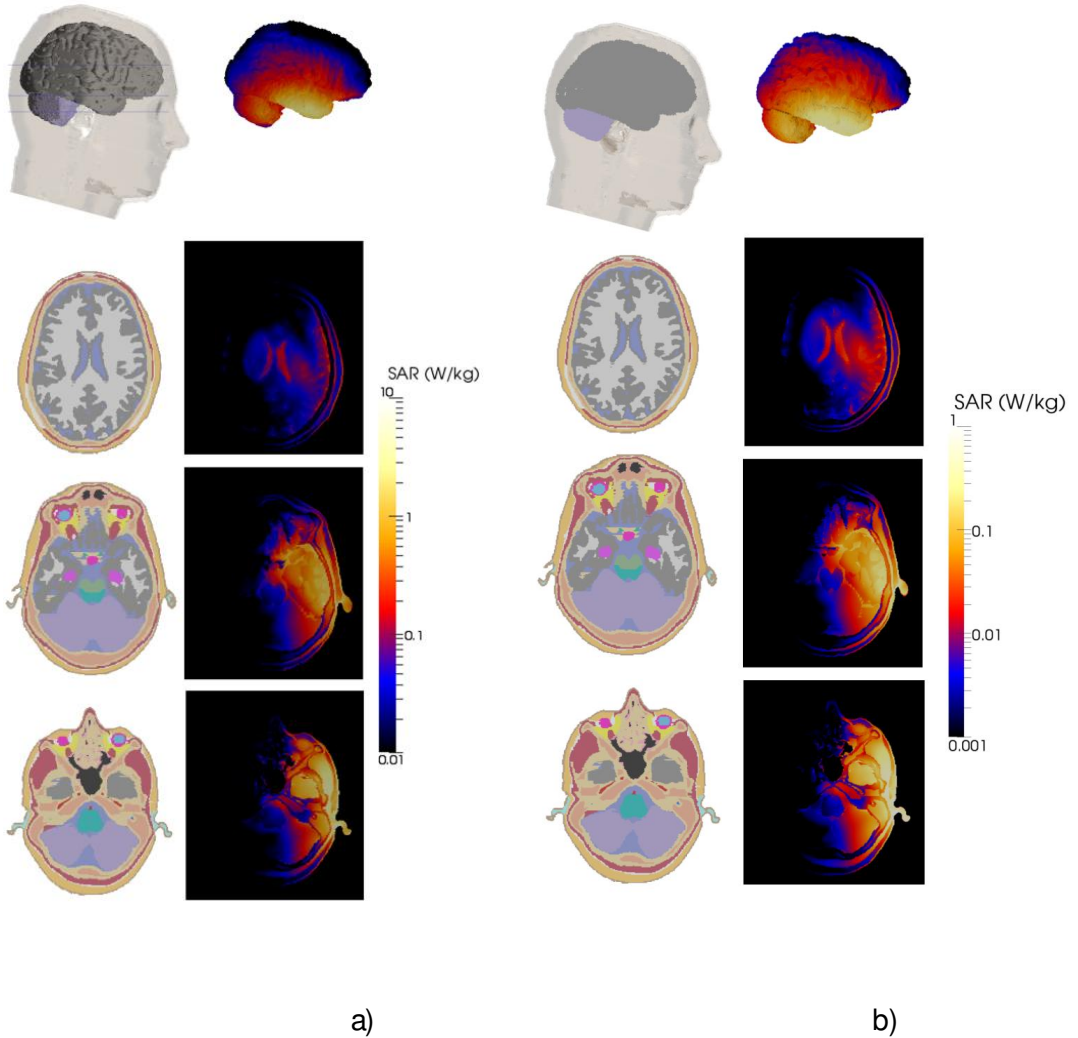a)　　　　　　　　　　　　　　b)

Figure A2-1. Selected SAR slices and the corresponding voxel slices for the a) FIOH (adults) and b) FDG study. The uppermost figure presents the superficial SAR distribution in brain.
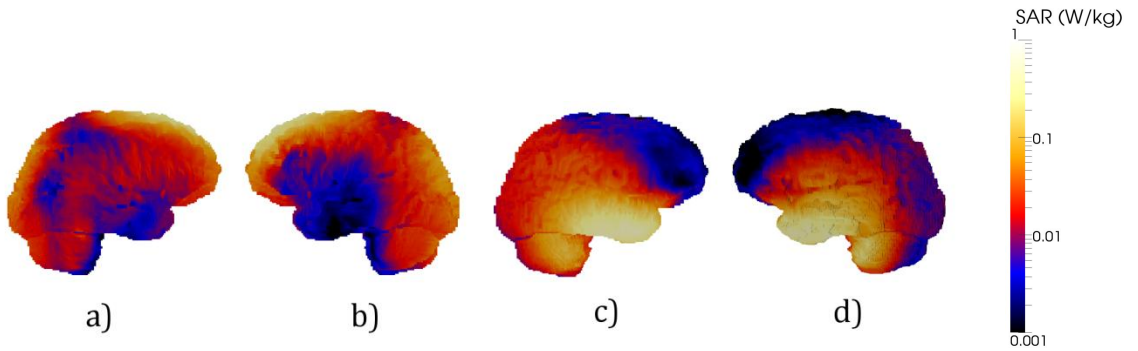
Figure A2-2. The superficial SAR distributions in brain for the CBF study. a) and b) present the distribution for the front exposure and c) for the right exposure and d) for the left exposure.
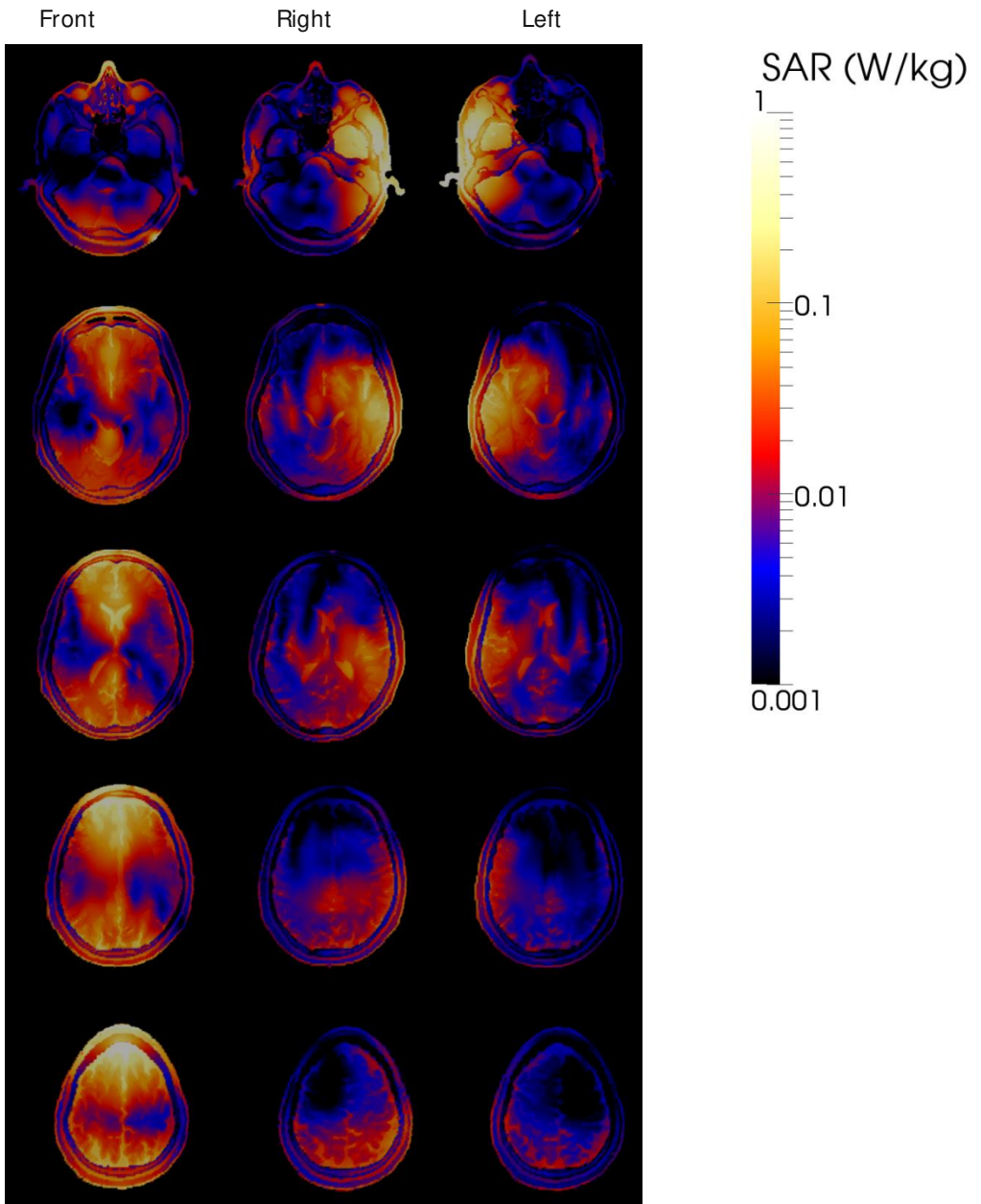
STUK

Front   Right   Left

Figure A2-3. Selected SAR slices from the CBF study for front, right and left exposure.

APPENDIX 3. DIELECTRIC PROPERTIES OF TIS-SUES

	Relative permittivity ε_r	Conductivity σ (S/m)	Density ρ (kg/m^3)
Artery	61.35	1.54	1060
Blood vessel	61.35	1.54	1060
Bone	12.45	0.14	1990
Brain grey matter	52.71	0.94	1039
Brain white matter	38.88	0.59	1043
Cartilage	42.64	0.78	1100
Cerebellum	49.43	1.26	1040
CSF	68.63	2.41	1007
Commissura anterior	38.88	0.59	1043
Commissura posterior	38.88	0.59	1043
Connective tissue	28.58	0.41	1000
Cornea	55.23	1.40	1032
Ear cartilage	42.64	0.78	1100
Ear skin	41.39	0.87	1100
Esophagus	65.06	1.19	1040
Eye sclera	55.26	1.17	1032
Eye lens	46.57	0.79	1090
Eye vitreous humor	68.90	1.64	1009
Fat	11.33	0.11	916
Hippocampus	52.71	0.94	1039
Hypophysis	59.68	1.04	1000
Hypothalamus	59.68	1.04	1000
Intervertebral disc	42.64	0.78	1100
Larynx	42.64	0.78	1100
Mandible	12.45	0.14	1990
Marrow red	11.27	0.23	1027
Medulla oblongata	45.80	0.77	1039
Midbrain	45.80	0.77	1039
Mucosa	46.07	0.85	1050
Muscle	55.03	0.94	1041
Nerve	32.52	0.57	1038
Pineal body	59.68	1.04	1000
Pons	45.80,	0.77	1039
SAT**	11.33	0.11	916
Skin	41.39	0.87	1100
Skull	12.45	0.14	1990
Spinal cord	32.52	0.57	1038
Teeth	12.45	0.14	2160
Tendon ligament	45.82	0.72	1110
Thalamus	52.71	0.94	1039
Tongue	55.26	0.94	1040
Trachea	42.00	0.77	1100
Vein	61.35	1.54	1060
Vertebrae	12.45	0.14	1990

* CSF = cerebrospinal fluid

** SAT = subcutaneous adipose tissue

WIRECOM - National research programme into the health effects of mobile phones

Final report

Dnro 2205/31/08

COHORT STUDY ON MOBILE PHONE USERS AND HEALTH (COSMOS)

Sirpa Heinävaara and Anssi Auvinen

COHORT STUDY ON MOBILE PHONE USERS AND HEALTH (COSMOS)

A prospective cohort study was launched to investigate the potential health effects of radiofrequency electromagnetic fields from mobile phone use. The approach was chosen to avoid the sources of error inherent for the previous studies including selection bias and information bias, which make it difficult to interpret the findings of the earlier case-control studies. Conducting a prospective cohort study was recommended in several expert reports and endorsed by the WHO as the next step forward in advancing the understanding of the possible health effects related to mobile phone use. The health outcomes covered include head and neck area cancers, neurological disease (multiple sclerosis, Parkinson's and Alzheimer's disease, neurodegenerative disease) and cerebrovascular disease. In addition changes in symptoms will be analysed. The rationale is to use within cohort comparisons by contrasting subjects with different amount of use.

Study cohort for the prospective cohort study on mobile phone users and health was established in Finland during the funding period 2009–2012. Private customers of network operators Elisa and TeliaSonera were recruited by mailed information leaflets and informed consent forms. Those who agreed to participate in the study gave written permissions to researchers to obtain a) mobile phone use data from network operators and b) health-related data from health care registries and medical records. Study participants filled in a questionnaire either in the internet or on paper.

The study started with an EU-level competitive biding for a study management contract in the spring 2009. The study management included mailing of study invitations, questionnaires and reminders; making and maintenance of internet questionnaire; data entry of informed consent forms and paper questionnaires; as well the establishment and maintaining of a registry of study procedures (dates of sending and receiving mailings for each person etc.). A contract for the overall study management was made with MC-Info Oy in autumn 2009.

Study invitations were sent to altogether to 164,000 mobile phone users (stratified by the amount of usage into three categories) aged 18-69 years annually at the end of the years 2009–2011. Press releases about the study were made at the same time.

A total of 15,800 persons have agreed to participate in the study (9.6 % of those invited) and about 13,000 have also filled in the study questionnaire (8.0 % of those invited). About 56 % of the study participants were women and the mean age of the participants was 48 years. The participation proportion was low and it decreased during the recruitment period. It is unclear if this reflects e.g. low perceived importance of the topic or long-term commitment to allow access of the researchers to phone use data and health records. However, the low participation does not threaten the validity of the study (which depends on comparability of the participants across levels of mobile phone use), even if it increases the costs of setting up the study. The feasibility and the chosen recruitment method used in the Finnish study were reported based on a pilot study (Heinävaara et al., 2011).

The study questionnaire has been designed in collaboration with the COSMOS researchers. It covers details of mobile phone use (past amount of usage and current modes of use), risk factors for the diseases chosen as end-points for the study (potential confounders), previous diagnoses of the diseases of interest, as well as occurrence of certain specific symptoms (headache, well-being and sleep disorders) based on validated questionnaires (HIT-6 for headache, SF-12 v2 for health-related quality of life and MOS sleep scale).

In the study questionnaire participants reported most often having started their use of mobile use in the mid-1990s. About 1 % never had used a mobile phone at least once a week and yet another 1 % had not used a mobile phone this much during the preceding three months. Of those who did, study participants usually reported having called their mobile phone 1-3 hours per week (38 %); 6 % belonged to the highest category of call time (> 6 h per week) and < 1 % belonged to the lowest category (< 5 min per week). About 60 % had used one mobile phone and about 5 % had used at least three mobile phones during the preceding three months.

Headache had at least sometimes limited usual daily activities for 12 % of the study participants and about 24 % had been bothered by light when having a headache. On average 15 % considered their health being fair or poor. Almost 13 % had been feeling sleepy at least a good bit of the time during the day time.

In addition, participants reported any symptoms occurring in relation to mobile phone use. Almost 10% of the respondent reported headache, 15% tinnitus and 10% partial hearing

loss in conjunction with mobile phone use (always, often or sometimes vs. never). Nausea was the least common (3%) and burning sensation in the ear was the most common symptom (49%).

All three major Finnish operators (DNA, Elisa and TeliaSonera) agreed to deliver operator data for the participants upon researchers' request. Operator data have been received from all the operators at least for a three month period each year.

Study participants are being kept up to date about the progress of the study through a newsletter (sent by email) and through the study web page (www.cosmostutkimus.fi).

The Finnish COSMOS study is a part of international collaborative COSMOS study with a common study protocol. Besides Finland, national COSMOS study components have been launched in Sweden, Denmark, and the UK (30,000-66,000 participants in each country), and are being prepared in the Netherlands and France. The international COSMOS has meetings at least twice a year with additional working group meetings and telephone conferences. The target size of the international COSMOS cohort is 200,000–250,000 mobile phone users. The implementation and objectives of the study have been described in detail in a joint paper (Schüz el al., 2011). International collaboration increases the statistical power of the study considerably, which is essential particularly for rare diseases such as brain tumours (glioma, meningioma) and Parkinson and Alzheimer disease.

After the recruitment period, the Finnish COSMOS is now entering the follow-up phase. We aim to send the first follow-up questionnaires in 2013 to those recruited in 2009. An option to extend the recruitment by one more round of study invitations in 2012 is being considered. A major threat for the future of the Finnish study is the lack of continued funding, but an application to an EU call for research is planned in late 2012. Collection of end-point data from the hospital discharge registry (National Institute for Health and Welfare), cancer registry (Cancer Society), medication purchases and reimbursement entitlements (Social Insurance Institution) will start in 2014. A joint analysis of disease incidence within the international COSMOS consortium is anticipated around 2015-16 and the study is expected to continue until at least 2020 or beyond.

Publications:

Heinävaara S, Tokola K, Kurttio P, Auvinen A. Validation of exposure assessment and assessment of recruitment methods for a prospective cohort study of mobile phone users (COSMOS) in Finland: a pilot study. *Environmental Health* 2011, 10:14.

Schüz J, Elliott P, Auvinen A, Kromhaut H, Harbo Poulsen A, Johansen C, Olsen JH, Hillert L, Toledano M, Heinävaara S, Slottje P, Vermeulen R CH, Ahlbom A. An international prospective cohort study of mobile phone users (Cosmos): design considerations and enrolment of cohort members. *Cancer Epidemiology* 2011 Feb; 35(1):37-43.

The rapid spread of mobile phones and other wireless communication devices has increased the population's exposure to electromagnetic fields at radio frequencies (RF). Even though the electromagnetic fields emitted by mobile phones and base stations are weak compared to safety limits, public discussion and some research findings have raised concern about possible health effects.

The joint project WIRECOM (Wireless Communication Devices and Human Health) was a national research project into the health effects of mobile phones' RF fields. It was made up of four different projects, containing a large-scale international cooperation that includes epidemiological monitoring research as well as provocative projects focussing on possible effects on the head area. This is the final report of the WIRECOM-project.

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