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Risk assessment of electromagnetic fields exposure with metallic orthopedic implants: A cadaveric study

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Orthopaedic device;
Metallic implant;
Temperature

Summary Metallic materials are well known to strongly interact with electromagnetic fields. While biological effects of such field have been extensively studied, only few works dealt with the interactions of electromagnetic waves with passive metallic device implanted in biological system. Hence only several numerical and phantom simulation studies were focusing on this aspect, whereas no in situ anatomic experiment has been previously performed. In this study the effect of electromagnetic waves on eight different orthopaedic medical devices (six plates from 55 to 318 mm length, a total knee and a total hip prosthesis) were explored on six human cadavers. To mimic a random environmental exposure resulting from the most common frequencies band used in domestic environment and medical applications (TV and radio broadcasting, cell phone communication, MRI, diathermy treatment), a multifrequency generator emitting in VHF, UHF, GSM and GCS frequency bands was used. The different medical devices were exposed to an electromagnetic field at 50 W/m\(^2\) and 100 W/m\(^2\). After 6 min exposure, the temperature was measured on three points close to each medical device, and the induced currents were estimated. No significant temperature increase (<0.2 \(^\circ\)C) was finally detected; beside, a slight induced tension (up to 1.1 V) was recorded but would appear too low to induce any biological side effect.

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Introduction

Improved electromagnetic environmental exposure appears closely related with; for instance, such ubiquitous exposure
result from all days sources such as cell phones, Wi-Fi, TV-radio diffusions, but also medical applications (e.g.: MRI, diathermy therapy); finally, population exposure continuously increases in terms of power, duration, and also frequency diversity, resulting in a random general environmental multifrequencies exposure [1—3].

For the protection of general population and workers, safety standards, recommendations and guidelines for exposure to radiofrequency (RF) and microwave energy have been developed by a number of international and national organizations [4,5]. These restrictions have been established by taking into account the previously described health effects of EMF exposure. The main observed health adverse effects have been related either to the induction of electric currents in the body able to induce nerve stimulation or to the temperature increase leading to heat stress.

Beside these safety standards, one of the safety aspects of EMF that should be assessed according to the international organization recommendation was the coupling with active and passive metallic implant in the human body [6]. Hence, a significant part of the population bears metallic devices including orthopaedic plates, rods, screws, prosthesis but also dental implants, stents, electrodes wires or electronic devices. Metallic devices are well known to strongly interact with EMF by diffraction or focusing thus, leading to a significant local enhancement of field intensity. However, while the EMF interactions with actives implants have been widely explored [7—10], only few studies have focused on passive implants and are mostly numerical simulation studies [6,11,12] or phantom experiment [13,14]. These works reported that implanted devices would induce significant local increase of EMF intensity so that the permissible exposure levels (PEL) for general population would be exceeded. In most of the case, the local EMF increase is not important enough to cause a temperature rise above 1°C [15]. However all these experiments were performed by simulating a single frequency emitting system in far field conditions [6,15,16], clearly differing from environmental global exposure. A clear discrepancy between theoretical calculations and clinical observation arises here: several case reports and mentioned serious injuries and death after MRI or diathermy exposure of patients bearing metallic medical device [17]. Nutt et al. [18] described in a 70-year-old patient implanted with a deep brain stimulation device a permanent diencéphalic and brainstem lesions resulting in a vegetative state after diathermy treatment of maxilla. For the authors, this complication probably resulted from current induction by RF and heating of the electrodes. Some complications have been also reported in patients with implanted deep brain electrodes following MRI scans of their head, such as transient dystonia and ballism of one leg [19] or lumbar spine [20]. This effect observed with a very few quantity of metal could be exacerbated by a high quantity of metal, especially if more superficially located as for the orthopedic devices.

These features led us to experimentally assess the effects of a multifrequency electromagnetic field on implanted orthopaedic device. Eight medical implants (six plates, from different size and localisation, one total hip prosthesis and one total knee prosthesis) have been implanted in human cadavers. Each implant was exposed to four concomitant RF exposures, resuming a multi sources random environmental exposure at the general power density of the workers safety limit exposure, and twice of it. The temperature variation was measured near the implant at three points (extremities and middle). Beside, the induced electrical current was simultaneously recorded and evaluated.

Materials and methods

Anatomic models

All procedures were in accordance with the guidelines of “Good Scientific Practice” edited by the Army Biomedical Research Institute (IRBA) and were approved by IRBA scientific committee for experiments (decree 87-848, 19 October 1987 edited by the French government).

The experiments were performed on six fresh human cadavers (four women, two men, mean age of death, 92 ± 6 years) donated for scientific and teaching purposes to the Anatomy Laboratory of the Grenoble University. All donors gave their written consent.

In order to limit the modification of the permittivity and conductivity parameters (respectively ε and σ) of the tissues, the cadavers were not embalmed but kept at −20°C. Twenty-four hours before the beginning of the experiment, the cadavers were placed in dissection room for thawing at room temperature (20°C).

Surgical materiel and implantation

Six orthopaedic locking plates made of stainless steel (from different dimensions and locations) and two prosthesis (total knee and total hip) have been selected to resume most of configuration and to be the most representative of implanted orthopaedic devices. Components were supplied by Laboratoires Tornier (Monbonnot, France). The components types and dimensions are shown on Table 1.

Each cadaver was implanted with the whole materials. Implantation was made according to the orthopaedic surgical protocols. Briefly after incision, dissection and fixation of the materiel, all the layers were carefully sutured before exposure to preserve the anatomic organisation. The devices were removed at the end of the experiment.

Exposure system and exposure procedure

The exposure system consisted of four RF generators and a power amplifiers (Thomson UM-440 RSK, 4 × 100 W) emitting simultaneously on the four most common frequency bands present in the environment: VHF: 27—100 MHz (TV and radio diffusion, emergency, police and aeronautic communication, many domestic wireless system, diatermy treatment . . . ), UHF 100—500 MHz (other broadcasting bands, satellite communication, medical uses as MRI applications), GSM 902—960 MHz and GCS 1805—1900 MHz (frequency band used for the cell phone communications). To mimic environmental random exposure, this system was performing 10,000 random frequency hops per second. Each channel was connected to a specific antenna. The four antennas were located in an anechoic box, open on one side, in order to limit the operator over exposure (Fig. 1). All the experiments were performed under an anechoic tent (Swiss shield,
Legrand Habitat, France) giving at least 60 dB attenuation on all the frequency range used; this system was used to limit the impact of the environmental electromagnetic pollution during experiment and to avoid any residual leak.

The four generators were emitting at the same power. The exposure power density was determined using a multifrequency anisotropic field meter (PMM OR.3, PMM Construzioni, Italy), located close to the implanted material. Each medical implant was individually exposed to two power density conditions: 50 W/m² corresponding to the ICNIRP exposure recommendation for workers, and higher condition at 100 W/m². The higher condition had not been reached for the metacarpal plate.

Temperature measurement

The temperature measurement was performed using four channels biomedical fiber optic thermometers (luxtron, Fluoroptic). This system uses the fluorescence of phosphors reporter groups at their tips to sense temperatures based on optical signals. Because of their non-metallic, and electrically non-conductive structure, they are immune to electromagnetic interference and can measure temperatures accurately in such environments with an accuracy of 0.2 °C [21].

One of the probes was used as the reference temperature located in the liver out of RF exposure. The other ones were located at the extremities of the implant (according the numerical simulation showing the maximum increase of SAR at the extremities of the implant [11]) and one at the middle. The temperatures measurement of the hip prosthesis was performed in the center of the acetabular cup, in contact with the head of the femoral component and next to the distal part of the femoral stem. The temperatures for the knee prosthesis evaluation were recorded at, the condylar part of the femoral component, the tibial tray and between the polyethylene spacer and the femoral implant.

The temperatures were recorded every 1 s for 18 min: 6 min before exposure, during exposure (7 min) and 6 min after exposure for all of the conditions and all the devices. According to the ICNIRP recommendation, the 6 min delay is the time needed to reach the maximum temperature increase.

Induced current assessment

Quantification of the induced current in the prosthesis was performed using an induction coil to detect the resulting voltage tension. This coil was made of 14 turns of copper wire rolled around the main axis of the device. Due to the technical constraints, this measurement was only made for the biggest materials (i.e.: humeral shaft plate, femoral plate, tibial plate and the femoral part of the hip prosthesis). At first, the signal was recorded during the cadaver exposure to electromagnetic field with a digital oscilloscope (Tektronic TDS 1012, USA). This signal resulted from the effect of RF on studied devices but also on the measurement coil. In a second time, the current specifically induced in the plates and prosthesis was experimentally determined by using a frequency generator (Wavetek, USA). The generator was directly connected at the extremities of the metallic device, the voltage and the frequencies were tuned to obtain the same signal on the oscilloscope than during EMF exposure (Fig. 2). The voltage generated by the generator

<table>
<thead>
<tr>
<th>Table 1 Specificity of implanted materials.</th>
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<tbody>
<tr>
<td>Reference</td>
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<tr>
<td>Clavicle plate</td>
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<tr>
<td>Radial head plate</td>
</tr>
<tr>
<td>Humeral shaft plate</td>
</tr>
<tr>
<td>Metacarpal plate</td>
</tr>
<tr>
<td>Femoral plate</td>
</tr>
<tr>
<td>Tibial plate</td>
</tr>
<tr>
<td>Total knee prosthesis</td>
</tr>
<tr>
<td>Proximal piece</td>
</tr>
<tr>
<td>Distal piece</td>
</tr>
<tr>
<td>Total hip prosthesis</td>
</tr>
<tr>
<td>Proximal piece</td>
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<tr>
<td>Distal piece</td>
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</tbody>
</table>
Electromagnetic no rage mined expressed the thesis. Middle temperature and temperature was determined as the voltage induced by EMF in the prosthesis.

Statistics

All results are presented as mean ± SEM. The experiments were repeated six times. Statistical comparisons were achieved using non-parametric tests. Significance was determined using Wilcoxon test for paired data.

Results

Temperature

All the temperature measurements were performed after equilibration of the cadaver temperature with the controlled room temperature. The monitoring of the body’s central temperature (results not shown) showed that the stability was reached within the 24 hours following the removal of the anatomic subject from the refrigerated storage area (−20 °C).

The effects on temperature of EMW with the different implanted plates are shown on the Fig. 3. The Fig. 3A shows the temperature variations at 50 W/m², while 100 W/m² exposures could be observed on Fig. 3B. The results are expressed as the variation of the mean temperature in °C recorded during the 30 s before exposure and the mean temperature recorded during the last 30 s of the exposure. For all the plates and in both conditions no significant modifications have been shown before and after RF exposure. No significant differences could be observed between plates and the reference probe in the liver (not exposed to RF), and no difference was found with the same plate between the middle of the plates and theirs extremities.

As for the implanted plates, the temperatures recorded at the three different locations of the total hip or knee prosthesis do not show any variation before and after RF exposure in both conditions (Fig. 4).

Whatever the implanted devices used, no modification of the temperature was shown.

Thus, no correlation could be made between the dimensions, the weight or the location of the implanted device with the temperature variations. The maximum temperature variation at 50W/m² reached +0.1 °C at the middle point of the femoral plate and −0.1 °C at the middle point of the radial head plate. For the 100W/m² condition the value reached +0.15 °C at the middle point of the femoral plate and at the proximal piece of the hip prosthesis. For reference temperature the elevation reached +0.19 °C. These values are below the accuracy of the sensors and could be attributed to the probe errors.

Induced currents

The frequency and the evaluated voltage in each device could be observed on the Table 2. As shown, the main frequencies able to induce a current belong to the VHF band (30–300 MHz). No frequencies above 250 MHz were recorded. Due to the dimensional resonance, the main dimension of the implanted device slightly influence the frequency recorded: from 125 to 245 MHz for the smallest plate (humeral plate) and from 40 to 168 MHz for the biggest one (femoral plate).

While the frequency recorded in the implanted device was not influenced by the power density of the RF field the tension induced appeared quite proportional; when the RF field gets from 50 W/m² to 100 W/m² the evaluated tension was doubling. These tensions never exceed 1.7 V peak-to-peak (Vpp) even during the most powerful EMW exposure. The highest tension was observed with the total hip prosthesis at 100 W/m² and was 1,667 ± 0.371 Vpp meaning an effective tension of 1.178 ± 0.219 Vrms. The EMW exposure at the power restriction level (50 W/m²) induced a very small tension in the devices with: 0.395 ± 0.078 Vrms for the humeral shaft plate, 0.395 ± 0.049 Vrms for the femoral plate, 0.436 ± 0.067 Vrms for the tibial plate, and 0.644 ± 0.098 Vrms for the total hip prosthesis. The voltage seems also to be influence by the quantity of metal of the implant and the depth of its localization. The two maxima values were observed respectively with the heaviest device (hip prosthesis) and the most superficially implanted plate (tibial plate).

Discussion

Few studies have dealt with the coupling of the EMF with the metallic devices implanted in the human body except numerical simulations [6,12,22], phantom exposures [14] or animal cadaver experiments [23].

By taking into account these previous results, the temperature measurement in this study was performed at the extremities of the implant where the SAR increase should be the highest [11]. In the worst case, some SAR simulations found a significant increase, up to a factor of 2 or 3 and an extrapolated temperature increase which did not exceed 1 °C [15]. The results of this first human cadaveric study are in agreement with the results of previous
Figure 3   Temperature variation (°C) at the extremities and at the middle point of the implanted plates. The Reference probe was located in the liver and not exposed. A. Temperature variation after 6 min electromagnetic exposure at the power density of 50 W/m². B. Temperature variation after 6 min electromagnetic exposure at the power density of 100 W/m². Data are shown as means ± SEM for n = 6.

Numerical and phantom simulation showing no deleterious effects of electromagnetic field in such conditions. However, the temperature increase appeared lower than numerical assessment and should be even lower in living tissue due to the blood circulation and the thermoregulation process. According to Vitanen et al. [15] the numerical simulations allow the highest spatial resolution of the SAR; nevertheless, the modification of the SAR values are not always realistic:

Table 2 Tension and frequency of the current induced in the implanted devices.

<table>
<thead>
<tr>
<th>Frequency range (MHz)</th>
<th>Induced voltage peak-to-peak Vpp</th>
<th>Effective induced voltage Vrms 50 W/m²</th>
<th>Effective induced voltage Vrms 100 W/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humeral shaft plate</td>
<td>125–220</td>
<td>0.560 ± 0.111</td>
<td>0.395 ± 0.078</td>
</tr>
<tr>
<td>Femoral plate</td>
<td>40–168</td>
<td>0.559 ± 0.070</td>
<td>0.395 ± 0.049</td>
</tr>
<tr>
<td>Tibial plate</td>
<td>43–245</td>
<td>0.617 ± 0.096</td>
<td>0.436 ± 0.067</td>
</tr>
<tr>
<td>Total hip prothesis distal piece</td>
<td>35–172</td>
<td>0.911 ± 0.139</td>
<td>0.644 ± 0.098</td>
</tr>
</tbody>
</table>

Vpp was the peak-to-peak tension measured. Vrms was the calculated effective induced voltage with $V_{\text{rms}} = V_{\text{pp}}/\sqrt{2}$. 
Figure 4  Temperature variation (°C) for the total hip prosthesis and for the total knee prosthesis after 6 min of electromagnetic waves exposure (50 and 100 W/m²). For each one, the temperature was recorded at proximal piece, interfacial piece and distal piece. The reference probe was not exposed and located in the liver. Data are shown as means ± SEM for n = 6.

due to the complexity in the averaging procedure. Thus a temperature distribution might give a better information about the effect of the implant. The temperature directly shows the physical corollary of the RF exposure [24], and in many studies RF induced heating has already been used as an indicator of whether the RF exposure could be harmful or not.

Moreover, human corpse keeps the whole heterogeneity of the body structure in this model, what is a major point due to the variation of the the permittivity and conductivity parameters according to the nature of the tissue (e.g.: at 64 MHz \( \varepsilon = 0.06 \) \( \varepsilon_r = 8.5 \) MHz for bone and \( \varepsilon = 0.08 \) \( \varepsilon_r = 80.00 \) for blood [25]). These parameters slightly differ between dead and living tissue, but are still closer than phantom parameters or than tissues from different species [26]. Human models perfectly fit with the surgical material, permitting the study of the effects of RF with relevant location of the implants and width of the tissues. These results confirmed the perfect matching between cadaveric model and the assessment of the complex interaction of EMF with surgical implants.

The discrepancy between the numerical results and this experimental work could also be attributed to the thermal properties of the implant. This parameter would have a significant effect on the induced temperature in tissues. Materials with high thermal conductivity as metal transfer thermal energy efficiently thus the temperature gradients near the implant quickly normalized and no thermal hot spot could be induced due to local enhanced SAR. This suggestion does not run counter the observed injuries after MRI on patient wearing deep brain electrodes [17,18,20]: in this specific case, the needle shape of the electrode highly increases the SAR at its tip, but due to its few quantity of metal and its small diameter could not significantly dissipate the heat.

The difference of the temperature elevation observed between the temperature measurement of this experiment and the temperature extrapolation of numerical SAR assessment could also be attributed to the exposure system. The sweeping of frequencies of our system, highly limit the settlements of any dimensional resonance between the size of the device and the length wave of the EMF. All the previous studies used the simulation of a single frequency perfectly tuned with the size of the implant, leading to the highest energy absorption configuration. This simulation consisted of the worst condition and is not consistent with an environmental exposure.

The other aspect of this study was the assessment of the tension induced in the metallic device by the EMF. To our knowledge no previous studies focused on this aspect before. A metallic device in an electromagnetic field could act as an antenna resulting in the induction of an electric current. The results confirmed the induction of a tension in the implant. According to the recommendation, the tension induction concerned the lowest frequency. However in this experiment the tension appeared too weak to induce any harmful effect. By comparison the maximal induced tension was 1.1Vrms at 100 W/m², while pacemaker or deep brain stimulation was using tension from 2 to 10V. Also the observation of the same effect as these simulating medical devices would be observed for a power density of the EMF 4 times higher than the restriction level. However if no deleterious effect could be observed with RF field, a special interest should be paid to High Frequencies band (HF from 3 to 30 MHz, i.e.: electric induction cooktop, long distance radio diffusion or in medical application such as diathermy knife) and especially below 10 MHz where electromagnetic field side effects mainly concern electric stimulation on nervous system [5].

As a conclusion, no deleterious effect has been observed in this experiment. Implanted device exposed to electromagnetic field could not induce harmful electric tension and would not increase enough the local SAR leading to burns. No specific restriction or recommendation has to be made.
for people wearing this kind of material. However some specific cases remain to be explore, as the exposition of small device (i.e.: deep brain electrodes, stent) able to concentrate the EMF but not to dissipate the calories, or specific frequencies able to induced higher current. The effects in relation to implants adjacent to vital organs, such as central nervous system or vascular system should also be explored. These experiments are now undertaken.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Acknowledgment

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