Development of methods for safe MR-scanning of patients with implantable medical devices. Metal structures heating

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Abstract. The paper presents the experience of experimental determination of implanted medical devices heating value during an MR-study. This work is a part of the development of a comprehensive methodology for ensuring the safety of patients with metal structures. Objects of various shapes and materials were placed in a gel phantom, scanning was performed on an MR scanner with a static magnetic field of 1.5 T. It is shown that the temperature change in close proximity to the surface of a metal object can be within the permissible normative documentation limits or be negligible. The existing in Russia indications for magnetic resonance imaging (MRI) for patients with various metal objects should be reviewed.

1. Introduction

MRI is one of the most common methods of medical imaging today. However, this procedure assumes the presence of some risk factors during the study: objects are acted upon by a constant magnetic field, a low-frequency gradient magnetic field, and a radio frequency (RF) magnetic field is used to excite the spin system. Studies have shown that a constant magnetic field of up to 7 T and gradient fields do not have a significant effect on humans [1]. Exposure to an RF field can cause a local increase in temperature, pulse, blood pressure within acceptable limits [2] - the so-called direct effects [3].

In addition to the direct effects of the RF field, an MRI study may result indirect effects caused by the presence of foreign objects in the MRI field, which have an indirect effect on the patient. For example, implantable medical devices (implants) and other metal structures can heat up if the manufacturer’s requirements are not followed and lead to burns of 1–3 degrees [1].

It should be also considered that technical documentation of the implant or other foreign objects (a result of injury or trauma) in patient’s body could be unavailable. Moreover, the patient could be unconscious.

In all the listed above situations, the patient is refused an MRI scanning according to the established practice. However, experimental studies show that when an MR-unsafe implant or other metal object is located, both inside and outside field of view, temperature fluctuations may remain within the acceptable limits of regulatory documentation or be absent.

Thus, ballistic objects — bullets, shrapnel, and other striking elements — are often small (several millimeters) ferromagnetic elements. Their presence in the patient's body, as a rule, is the reason for refusing MRI due to such risk factors as displacement, rotation and heat. In the case when the movement of an object is limited, for example, by bone or other dense tissues, it is possible to perform an MR scan without consequences for the patient from the factors of displacement and rotation.
This paper considers studying the process of heating metal structures during an MR imaging in order to increase the safety of scanning such patients and reduce the number of refusals of the procedure.

2. Materials and methods

The heating of tissues in MRI occurs as a result of surface currents generated by a radio frequency magnetic field [1]. The value used to determine the amount of energy $W$ absorbed per unit of time $dt$ is the mass unit of the object under study, is the specific absorption rate (SAR):

$$\text{SAR} = \frac{d}{dt} \times \left( \frac{dW}{dV} \right) = \sigma |E|^2 \rho,$$

(1)

where $W$ is the absorbed energy, $W$; $V$ is the volume of the object, $m^3$; $\rho$ - density, $kg/m^3$; $\sigma$ is the specific conductivity of the substance, $S/m$; $E$ - electric field strength, $V/m$.

On the other hand, the SAR describes the rate of the temperature changes in tissue:

$$\frac{dT}{dt} = \frac{\text{SAR} + P_m - P_c - P_b}{c},$$

(2)

where $P_m$ is the heat released by metabolism ($W/kg$); $P_c$ and $P_b$ are heat losses due to heat conduction and blood flow, respectively ($W/kg$); $c$ - specific heat capacity ($J/(kg \cdot ^\circ C)$); $T$ is the temperature ($^\circ C$).

We have conducted a series of experiments to determine the maximum amount of heating of a metal object during the MR-study. Scanning was performed on an MR scanner with a magnetic induction of 1.5 T. The Fast Spin Echo pulse sequence was chosen with parameters that reach the maximum SAR value not exceeding the maximum permissible level of 2 $W/kg$ during scanning for 6 minutes in normal operation mode [4].

At the first stage, small metal objects of different shapes and materials were placed on a flat non-magnetic substrate or on the surface of a uniform cylindrical phantom with an MR-contrast liquid and were thermally insulated with cloth. The sizes of objects ranged from 5 to 100 mm, differed in shape (from parallelepiped to a round rod) and were made of steel, titanium, aluminum, copper, brass, etc.

In addition, a series of experiments was carried out with an elongated orthopedic stainless steel implant according to a method similar to ASTM recommendations [5]: a rectangular container filled with hydroxyethylcellulose gel with the addition of sodium chloride, simulating the electrical parameters of human tissues. Moreover, containers of 5 and 30 liters were used. For the last one, the position of the phantom and the implant in it was changed in order to determine the conditions that ensure maximum heating.

Due to the peculiarities of the experimental conditions, the choice of temperature measurement tools was a separate task. Thus, at the first stage, a thermal camera with the following characteristics was used: resolution $640 \times 480$ pixels, temperature sensitivity less than 0.04 $^\circ C$, field of view $6.6^\circ \times 5.0^\circ$, which allows recording thermograms of objects located at a great distance. However, due to the insignificant, compared with the measurement range (from $-30$ to $+100 \ ^\circ C$) change in the temperature of the samples, as well as the indicated measurement error of $\pm 2 \ ^\circ C$, this method was decided to be abandoned.

To measure the temperature, a multichannel system for measuring deformation and temperature was used. It has fiber-optic sensors recording the change in temperature by 0.01 $^\circ C$. The temperature measurement error does not exceed 0.1 %, the range of measured temperatures is from $-30$ to $+80 \ ^\circ C$. Sensors of this type are non-sensitive to electromagnetic fields. The measuring unit of the system was located in the technical room. The fiber optic cable was stretched into a room with an MRI scanner through the technological opening of the Faraday cage.

3. Results

Heating of small (up to 1 cm) metal objects on a non-magnetic substrate was 2.5–4.0 $^\circ C$ for 90 min (Fig. 1). At the same time, the readings of the control sensor, which measured the air temperature near the
surface of the phantom, indicate the absence of additional heat sources.

Figure 1. Heating of small objects on a non-magnetic substrate.

Heating of metal rods 50 and 100 mm long and 10 mm in diameter, mounted on the surface of a cylindrical homogeneous phantom, under the same conditions was no more than 1.5 °C for 90 min.

The use of the phantom with the gel recommended by ASTM led to an increase in the heating rate of the metal object. Thus, in the center of a 5-liter container, the implant warmed to 2.3 °C in 15 min. The use of a 30-liter container gave a result of 2.5 °C in 15 min at the peripheral location of the implant and phantom, and 0.1 °C at the central one (Fig. 2).

Figure 2. Implant heating registered in different positions of phantom and implant in MR scanner (gentry is indicated by a circle, phantom – by rectangle, implant – by point).

4. Conclusion
The presented results confirm the possibility of MR-study conducting for patients with metal structures and the need to revise the current practice of refusing to conduct such studies in cases where this medical imaging method is the only non-invasive way to diagnose and plan surgery. To solve this problem, it is necessary to develop a domestic integrated patient safety system.
The proposed experimental technique can be used in the development of implantable medical devices, when planning a study, for demonstration purposes, and also for heat transfer models identifying.

References

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