MR Critical Implants, MR Critical Medical Devices and ASTM MR Safety Standards

The presentation will focus on MR critical implants, MR critical medical devices, the ASTM standards for MR testing of passive implants and the revision of ASTM Standard F2182–02a for a "Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging" [1]. In addition, an update on the latest labeling recommendations from FDA of passive implants, where computational methods are used to assess the in-vivo-heating, is discussed.

MR critical implants: MR critical implants [2] are defined as either active implantable medical devices (AIMDs), semi-active implants — i.e., implants powered from outside of the body — or as elongated metallic structures that are in the range of the "critical length". For MR heating safety, the length and dimensions of the implant (i.e., lead length, stent length, etc.) in relation to the wavelength of the MR radio frequency field inside the patient or the phantom is critical. To become resonant, the length of the implant must be in the range of an odd number of half wavelengths of the electromagnetic field inside the patient or the phantom. Once resonant with the electromagnetic field, the RF induced implant heating could become dangerously high. The half-wavelengths of the electromagnetic field inside a patient for 1.5T systems are about 25 cm, and for 3.0T MR systems they are about 12 cm. However, even for implants that do not have the exact resonant length, heating may occur and could become unacceptably high. It is currently unknown how much the implant length needs to differ from the resonant length to avoid unacceptable high heating and how much influence the insulation of a implant has on the "critical length". Thorough and sound heating evaluation of MR critical implants is, therefore, especially important [3]. Results of the ASTM SAR Intercomparison Protocol [4, 5] show that for an insulated 20-cm-long straight wire with 1-cm-long bare ends, the heating can be up to 48°C (temperature rise or ΔT) in the normal operating mode of 1.5T MR systems with calorimetric assessed whole-body averaged SAR of 2 W/kg.

MR critical devices have one or more of the following characteristics: made of conductive material, have critical masses or dimensions, partially implanted and partially outside of the patient's body, and in electrical contact with the patient. An example of such devices is a bone fixation device (Fig. 1, left) made of long conductive components assembled on the outside of the patient's leg and with fasteners going through the bone. This structure has long conductive parts partially outside and partially inside the patient and could induce sufficiently high RF currents to cause dangerous heating. Another example of an MR critical device is a stereotactic head fixation system (Fig. 1, right) made of conductive material and with conductive pins holding the head in place. This device has large conductive structures and therefore conductive loops through the patient's head are possible, leading to excessive MR induced RF heating.

In conclusion, thorough and sound heating evaluations of MR critical implants and MR critical devices are essential. For both, MR critical implants and MR critical devices unintended gradient induced stimulation is also an important safety factor to consider. More on unintended gradient induced stimulation can be found in [6].

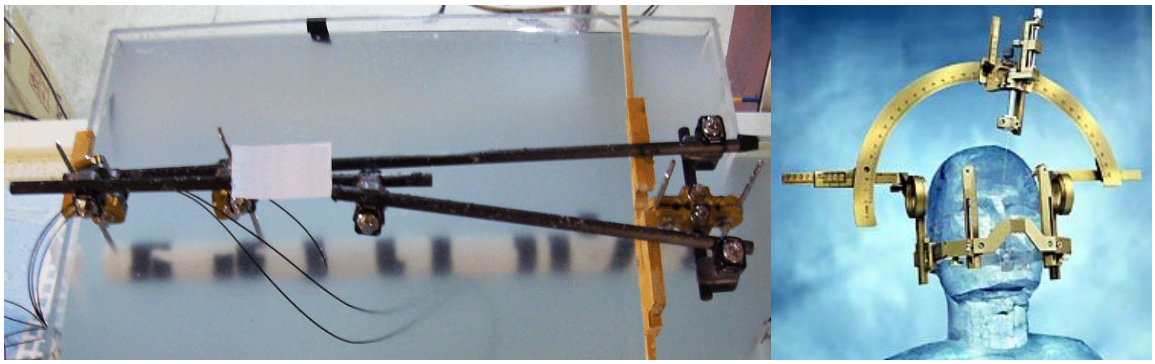

Figure 1. left: a bone fixation device, right: stereotactic head fixation system; both are made of conductive material and are in electrical contact with the patient

ASTM terminology: MR safety terminology for medical devices and other items is defined in ASTM F2503 [7] as follows: (1) MR Safe — an item that poses no known hazards in all MR environments. Such items include non-conducting, non-magnetic items, such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data; (2) MR Conditional — an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required; and (3) MR Unsafe—an item that is known to pose hazards in all MR environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors. These terms may be used for medical devices and for any other objects (e.g. furniture, tools, fire extinguishers, etc.) that may be brought into the vicinity of an MR scanner. The standard also introduces corresponding icons that are intended to be used on items that may be brought into or near the MR environment as well as in product labeling. The icons may be reproduced in color or in black and white however, the use of color is encouraged because of the improved visibility. For MR Conditional items, the item labeling must include results of testing sufficient to characterize the behavior of the item in the MR environment and a description of the conditions of use that fully describes how to scan the patient safely. In particular, testing for items that may be placed in the MR environment should address magnetically induced displacement force and torque, and RF heating. Other possible safety issues include but are not limited to, thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and the safe functioning of the item and the safe operation of the MR system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition should be described.

Revision of ASTM F2182: Several technical problems made a substantial revision of ASTM F2182 necessary. The field distribution inside a phantom strongly depends on the frequency, the shape of the phantom, and the position of the phantom inside the MR birdcage coil [8]. Additionally, the phantom field distribution cannot be related spatially to the field distribution inside a patient. Therefore, it is important to realize that for MR critical implants and MR critical medical devices, the anatomical placement of the implant inside the patient cannot be mapped to the phantom for realistic or worst-case

MR heating tests [9]. This means that placing an implant in the phantom in an anatomically equivalent position does not necessarily result in a realistic or worst-case testing for the whole patient population. For realistic heating assessment, the local electric and magnetic field distribution inside the phantom needs to mimic the exposure situation of the implant inside the patient in such a way, that the heating of the implant in the phantom is comparable or at least scalable to the heating inside the patient. Once the worst-case local field distribution inside the patient is known, the implant can be appropriately placed inside the phantom. This fact is now considered in the revision of F2182. Also, the evaluation of the local field distribution inside the patient needs to be evaluated for the whole patient population under worst-case assumptions. Computer modeling, using anatomically-correct models of the whole patient population, can be used to evaluate the local field distribution inside the patient for the specific implant location. New definitions, including a detailed rationale for the chosen parameter and a detailed description of the mixing procedure of the phantom materials are also included in the revision. Handling of medical devices including flexible components and the influence of blood perfusion in the assessment of in-vivo heating is discussed. The section about data reporting was updated and a procedure for measuring of local and phantom averaged SAR was included. The shape of the phantom was changed (as an option) to a headless phantom, without changing the original dimensions. An explanation on the critical issues of temperature probe placement is now included [10]. Finally, the proposed MR sequences are updated.

Labeling: Latest labeling recommendations from FDA of passive implants will be discussed during the presentation.

References

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