MAGNETIC RESONANCE (MR) SAFETY TESTING OF IMPLANTS USING NUMERICAL SIMULATION FOR WORST-CASE DETERMINATION

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Abstract

MR safety and compatibility are important issues for all devices used within an MR environment. MR testing of medical devices is required for device approval by the regulatory agencies worldwide. Besides basic testing also computer modeling of electromagnetic fields and SAR distribution of passive devices has been established. Further methods for numerical analysis and testing are currently under development for active implantable medical devices. The methods will be published soon as an ISO Technical Specification listing such as RF- and gradient-induced voltages, heating, vibration and device malfunction by exposure to the static magnetic, switched gradient magnetic and electromagnetic field.

1. Introduction

Until today MR scanning of electrically conductive implants is contraindicated unless MR labeling information is provided by the implant manufacturer stating that a device is “MR safe” or “MR conditional”. Before an implant is exposed to an MR environment it has to be tested with standardized methods. Results must be coded into a comprehensive device labeling covering global “worst-cases” considering readability and adaptability to the MR user interface.

2. MR interactions

The following interactions of a medical device can be identified for the MR environment:

1. Magnetic induced displacement force (static, dynamic)
2. Magnetic induced torque (static, dynamic)
3. Radio frequency (RF) and switched gradient-induced heating
4. RF and switched gradient-induced voltages (stimulation, activation)
5. Switched gradient-induced vibration
6. Malfunction of the device within the MR environment (dependent on individual device demands)
7. Malfunction of the MR system = image quality issues; MR compatibility (SNR, B_0-homogeneity, artifacts, etc.)

MR standard test procedures

Most MR labeling today are based on standardized testing of above mentioned interactions. Categorized in “MR safety”, ASTM standard test methods cover basic interactions of displacement force (ASTM F2052), torque (ASTM F2213), RF heating (ASTM F2182). Other listed interactions are necessary to be tested based on the existing physical MR interactions for active medical devices, but also relevant for some passive implants (e.g. gradient-induced heating and vibration for orthopedic implants because of greater electrically conductive cross sections). Currently these additional testing necessities are coded into standardized test procedures in ISO/TS 10974 [9] for active implantable medical devices (AIMDs) regarding RF and gradient interactions as well as covering the electromagnetic interference/compatibility (EMI/EMC) related to the safe operation of the medical device.
Interferences to be tested and categorized in category "MR compatibility" are such as image artifacts of medical devices (ASTM F2119) or MR image degradation by decrease in signal-to-noise (SNR), B_0-homogeneity, eddy currents, RF noise, signals from remaining protons in plastics, therefore these interactions need to be covered by individual procedures, whereas some can be derived from IEC 62464-1 for essential image characteristics.

ASTM standard F2503 [3] and the new DIN draft standard 6877-1 [4] provide comprehensive marking requirements for items (incl. medical devices) used in the MR environment. “MR Safe”, “MR Conditional” and “MR Unsafe”

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terms and definitions are used to classify items according to device properties and MR interactions, which have to be clarified in standardized MR testing summarized as follows:

Magnetically induced displacement forces exist for devices consisting of ferro- or paramagnetic materials. Forces can be measured indirectly via a deflection angle generated by the magnetically induced force and the gravity force of the device. The forces are dependent on the static magnetic field, the gradient in the static fringe field and the magnetic saturation of the device material. Magnetically induced torque aligns the device relative to the orientation of the main magnetic field.
The torque depends on the device dimensions and the magnetic saturation and is measured at the magnet isocenter. ASTM F2052 [5] and F2213 [6] provide testing methods of force and torque.
Radio frequency induced heating is a complex and multi-parameter dependent MR safety issue. RF pulses are in the area of MHz and apply the main amount of heating energy. Not only device properties like electric conductivity, dimension, etc. have to be considered, but also the geometric arrangement relative to the specific MR environment.
ASTM standard F2182 [7] provides a basic test method, but requires additional specific knowledge about calorimetry testing, temperature probe placement, phantom characteristics and specific absorption rate (SAR) adjustment and monitoring as well as knowledge about the specific MR system. Numerical analysis of electromagnetic fields, SAR and temperature distribution is requested to assist in heating testing.
This multi-parameter dependent interaction is upgraded for testing on AIMDs in ISO/TS 10974 proposing certain discrete tier evaluation on RF heating in relation to the local E-field in amplitude, orientation and phase. Knowledge about E-fields as incident source for RF heating is therefore necessary as well as applying numerical simulation methods for calculating phantom cases and transferring results to human models representing a global worst-case.
A time varying gradient magnetic field is used in MRI for coding spatially MR signal information. These gradients induce an electric field in conductive tissues of the body. The primary biological effect of switching gradient magnetic fields (frequencies between 100 and 5000 Hz) is peripheral nerve stimulation [8]. As well as RF pulses, switched gradients can generate induced voltages in conductive wires, loops and structures and can increase the risk of unintended tissue stimulation or can lead to burns or even fire by spark discharges, especially for devices being in contact with the patient or percutaneously implanted. ISO/TS 974 establishes appropriate standardized test methods for gradient-induced voltages, heating and vibration.
Further safety concerns for active and non-active devices are the safe operation. A device must undergo an individual malfunction testing procedure to prove it is working correctly inside the MR system during different levels of magnetic and electromagnetic field exposure. In case of non-active devices the static field could inhibit mechanical parts like springs and levers. In addition to its function, active devices have to prove not to disturb the proper imaging function of the MR system e.g. by emission of RF.
MR imaging artifacts do not affect the patient safety primarily, but distort or misplace image information. In case of instruments like needles this can become a safety concern. Susceptibility and RF (coupling) artifacts can lead to diagnostic misinterpretation by significant lack of information and may obstruct follow-up examination. Notification about artifacts should be included in the device marking. As an appropriate standard test method ASTM F2119 [10] can be used. To acquire comprehensive information up to 3 object orientations relative to B_0, up to 3 slice directions (sag, tra, cor), standard spin echo and gradient echo sequences with phase swap are necessary. Measurement of image distortions based on B-field inhomogeneities beyond susceptibility artifacts is of importance in some cases.

3. RF heating: How to find the “worst-cases”

Heating of tissue during magnetic resonance imaging (MRI) in the vicinity of a multi-component implant system (e.g. orthopedic devices, product matrices of e.g. different sizes of stents) is mainly caused by the coupling of such implant systems with the emitted electromagnetic field of the MR system. Radio frequency induced heating is complex and multi-parameter dependent. Because multi-component implant systems consist commonly of several parts there are a great number of possible combinations regarding the influences. For example Total Hip Endoprostheses consists of different designs, sizes, and materials for the stem, the ball head, the inlay and the cup. Here, the number of possible combinations exceeds easily the 10000. Evaluating the status of every combination regarding MR safety (and image compatibility) is far beyond most economical capabilities. Therefore it is necessary to define “worst-cases” covering the product portfolio of a medical device manufacturer. These “worst-cases” define upper limits for the risk applying MRI on patients with such implants. The progress in numerical simulation of RF-induced heating has led to a capable instrument for comparing different cases of the implant system. A protocol for determining “worst cases” with the help of numerical simulation is presented below.

The implant manufacturer supplies all relevant parameters regarding the implant system for which an investigation on RF-induced heating shall be performed.

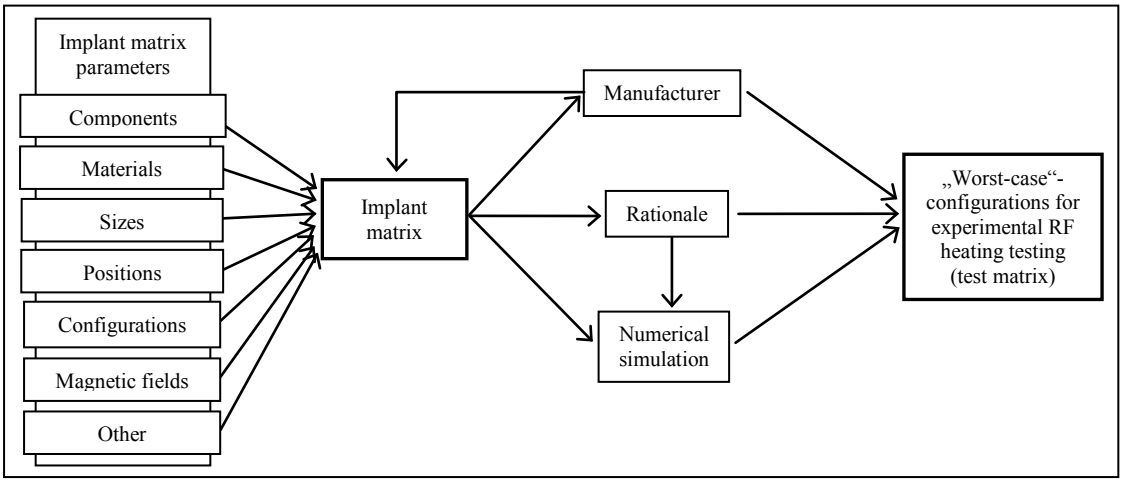

FIG. 1: Flowchart of "worst-case" sample selection protocol

The implant matrix in FIG. 1 represents all clinically allowed configurations of a given implant system. The basic concept of the presented protocol is finding a path through this matrix by eliminating the irrelevant cases step by step. Steps are possible by

- the manufacturer, categorically excluding matrix areas (e.g. not clinically used cases),
- using a analytical or scientific rationale and/or
- by numerical simulation; used very effectively for comparing the cases on every step and for finding that combination, which leads to the greatest temperature increase in a given in-vitro RF environment.

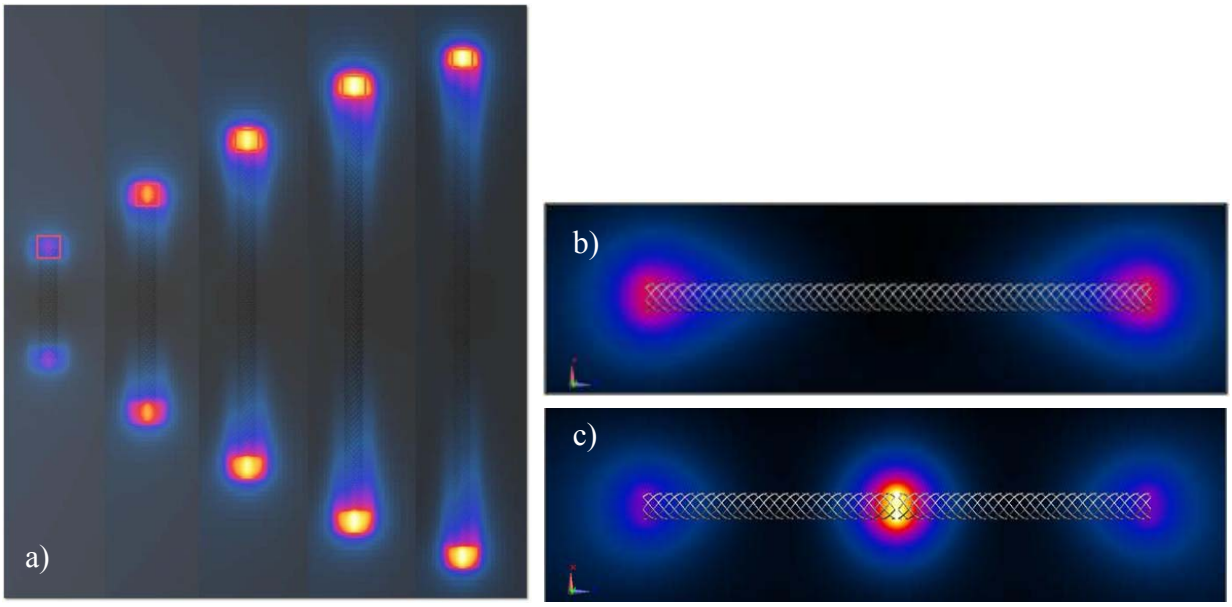

FIG. 2: Finding the "worst-case" of an implant matrix (exemplary results on generic stent models using numerical simulation software SEMCAD X (SPEAG, Switzerland) and virtual generic birdcage resonator at 64 MHz): a) 1g-avg. SAR distribution of 5 simulated stent lengths (50 to 250 mm), linear scaling; b) temperature distribution on 160 mm stent and c) two 80 mm fragments ("160 mm fractured") at 1 mm distance after 900 seconds of heating, same scaling (black = low values, white = high values).

The method illustrated here, is limited and showing an example of a reduced hip implant system in terms of number of sizes, designs, materials and components: For this example the assumption is made that the implant system

consists of two different stem designs, with 10 sizes and 2 different materials each, 2 different sizes and materials for the ball head and 3 different cup designs with 3 sizes and 2 materials for each of them. This results into 2880 cases. In the first step, determining the influence of the design of the different stems is important. 1440 cases remain. Secondly, the material of it has to be covered. 720 cases remain. The next steps take into account the size and material of the ball head (180) followed by the design (60), material (30) and size of the cup (10) (numbers in brackets are the cases left after the respective step). The last step is to determine the length of the whole implant regarding its coupling with the applied electro-magnetic field.
In this ideal case 1 potential "worst-case" would remain for the experimental RF-heating testing. In reality more configurations can remain because of the system's complexity. The configurations left are those one can expect exhibiting the greatest temperature increases in the implant surrounding tissue and which can be regarded as an upper limit for the implant system covered by the test matrix. As an additional result, a rationale is given for positioning of temperature probes for the experimental testing.

5. Conclusion

Comprehensive investigation of all interactions and worst-case scenarios is deemed to be necessary for MR safety and compatibility. ASTM International has developed useful standardized MR test methods for magnetic force, torque, RF heating and MR artifacts. Continuous redefining and adaptation of international standard test methods is required for covering multi-dimensional MR interactions such as induced voltages, heating and vibration based on RF and switched gradient field interactions. MR testing has basically implemented computer based numerical simulation. Further research and validation is necessary for implementing MR-related simulation tools as standardized process into the device testing chain.
Due to the great number of possible configurations of multi-component implant systems and product matrices, a worst case sample selection is necessary to reduce the number of samples being tested in RF heating measurements according to ASTM F2182 and ISO/TS 10974. Numerical simulation helps with great potential to determine representative cases by eliminating the irrelevant ones. This leads to advantages of easier implementation of for example new designs or changes of material properties during the research and development process.
Standardized MR testing of medical devices and items used in the MR environment is compulsory for providing the MR user with a comprehensive and reliable MR safety labeling. Standardized tests minimize patient risk and are guiding device manufacturers in development of MR suitable devices as well as supporting the MR operator with meaningful experimental results.

7. References

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