Optimized methodology for worst-case determination of orthopedic implants for magnetic resonance safety testing

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INTRODUCTION

With an increasing number of magnetic resonance imaging (MRI) scans being performed every year, especially since the advent of interventional MRI, implantable medical devices may impose a potential risk to patient safety and comfort. Under certain conditions, the radiofrequency (RF) electromagnetic (EM) fields present in the bore of a scanner during an MRI exam may induce currents on the implant, thus producing deposition of power in the surrounding tissue. This power is then dissipated through a thermal process which yields a temperature rise in the tissue. This effect is usually measured by a specific absorption rate (SAR), defined as the amount of power absorbed per unit weight. The amount of RF-induced heating depends on several parameters such as implant geometry, material electrical properties, device orientation, location in the bore, as well as other scanner-dependent parameters (coil design, input power, pulse sequences used, frequency of operation, etc.). Current standards on RF-heating safety (ASTM 2182-11a [1] , ISO/TS 10974 [2]) establish a methodology for testing temperature rise of implants and provide guidelines for experimental setups. For a wide range of products, parameters, sizes, etc., as is the case for orthopedic multi-component implants, a reduction of the test matrix becomes necessary as testing all products would otherwise take an enormous amount of time and effort. In this work, an optimized process for achieving a considerable reduction of the test matrix through computer simulation is shown for a specific type of orthopedic implants.

MATERIALS AND METHODS

Since high local SAR values are correlated with high temperature increases [3], the results obtained from the simulation are used to determine a worst-case setup and location of temperature probes to design subsequent metrological experimental RF heating measurements. Two knee prosthetic systems, each composed of several parts each with several lengths and/or diameters available, are considered in this study. In order to theoretically predict the SAR distribution in the surroundings of the implant, as well as to determine its worst-case location and orientation, the experimental setup defined by the ASTM 2182-09 [1] standard was implemented into a numerical solver based on the finite-difference time-domain (FDTD) method (SEMCAD X, v14.4.3, Schmid & Partner Engineering AG, Zürich, Switzerland). A CAD model of the original phantom was designed and placed in shielded generic 64 and 128 MHz RF birdcage coils (resembling the center frequency of 1.5 and 3 T MRI systems, respectively). A gel-filled phantom, according to the standard, was placed at the isocenter of the birdcage. An empty-phantom simulation was first performed at each frequency for reference. Detailed CAD models of the test objects, provided by the device manufacturer (Smith & Nephew Orthopaedics AG, Switzerland) were then included in the model to obtain local SAR values for each configuration. A total of 25 configurations were simulated for each frequency, and local peak SAR values were compared to those obtained from reference simulations to determine the locations where RF-heating effects are the highest. The location of such hot-spots was then used to place temperature probes in experimental measurements using Philips Intera and Siemens Magnetron Trio MRI scanners operating, respectively, at 1.5T and 3T. The longitudinal axis of the test objects was placed, in each case, along the axis of the bore to have it oriented parallel to the electric field at this location. The results for both numerically calculated SAR value and temperature increase are presented for a single worst-case at each frequency of operation.

RESULTS

The results obtained from the numerical simulations for all 50 configurations were used to determine a single worst-case configuration for each B_0 field strength (1.5 and 3 T), where B_0 corresponds to the static magnetic field of the MRI coil. Table I shows the simulated SAR values obtained for each worst case. Reference local SAR values, i.e. computed at the same hot-spots without the presence of the implant, are also included to calculate SAR gain at these locations. At 64 MHz, configuration #1 produced a maximum local SAR (0.1g-averaged, normalized to 1 W/kg WBA) of 267.64 W/Kg/W, found at the tip of one of the stems; this corresponds to a local SAR gain of 67.8 (257.89/3.8). At 128MHz, a different configuration was established as the worst case, with a local SAR of 156.67 (SAR gain of 70.8). The measured temperature increase values for these configurations are also given in the table, where higher RF heating was found for the worst-case configuration selected at 1.5T.

CONLCUSION

Due to a large number of available configurations for orthopedic implant systems, a worst-case selection is necessary to reduce the number of samples to be tested during measurement of RF heating. A methodology, combined with numerical simulation to determine a representative worst-case by eliminating irrelevant cases has been shown. With the use of such a protocol it becomes easier to implement new designs or changes in several parameters. Although a full validation of our simulation and experimental setups would be required in order to provide quantitative results, the method described can be used to provide qualitative results as shown by the results.

Configuration	B_0 (T) strength	Simulation results			Experimental results
		0,1g-averaged Local SAR [W/kg]	0,1g-averaged local SAR (normalized to 1W/Kg WBA SAR) to 1 W/Kg WBA SAR [W/kg/W]	0,1g-averaged reference local SAR [W/Kg]	ΔT (°C)
# 1	1.5	257.89	267.64	3.8	15.9
# 2	3	425.18	156.67	6	12.6

Table I. Simulated SAR and measured temperature increase for two worst-case configurations as determined through numerical simulation.

REFERENCES

[1] ASTM F2182-09, "Standard Test Method for Measurement of Radio Frequency Induced Heating On and Near Passive Implants During Magnetic Resonance Imaging"; 2002, www.astm.org.

[2] ISO/TS 10974, International Standards Organization Technical Specification "Requirements for the safety of magnetic resonance imaging for patients with an active implantable medical device"; to be published 2011, www.iso.org.

[3] W. R. Nitz, G. Brinker, *et al.*, "Specific Absorption Rate as a Poor Indicator of Magnetic Resonance-Related Implant Heating", Investigative Radiology, Vol. 40, Number 12: pp.773-776, December 2005.