RF Safety Assessment of a Generic Deep Brain Stimulator during 1.5T MRI Exposure

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Introduction

The radio frequency (RF) electromagnetic field of magnetic resonance (MR) scanners can result in significant tissue heating due to RF coupling with the conducting parts of medical implants. In this study we evaluate a methodology for implant safety evaluation that is based on a four tier approach [1]. Each consecutive tier yields a less conservative result than the preceding, but requires greater effort to demonstrate safety. The evaluation is performed for 1.5T MR scanners using a generic model of a deep brain stimulator (DBS). SAR and temperature increase are numerically evaluated in an anatomical high-resolution head model. The results show that the approach proposed is technically feasible. Nevertheless, the lower tiers yield a rather high overestimation and are only suitable for short implants. Tier 4 turned out to be too computationally demanding for a complete analysis and therefore an enhanced Tier 3 approach may be the most effective way to demonstrate compliance of general elongated implants.

Objectives

The main objective of this study was to demonstrate the applicability of the methodology for implant safety evaluation as proposed in [1]. The evaluation of the temperature increase expected at the tip of an implant was demonstrated for a generic DBS which reproduced the typical RF characteristics of such a device. A combination of numerical (FDTD simulations) and experimental techniques was used.

Methods

A generic DBS consisting of a stainless steel can, a dielectric header and a generic insulated helical lead was built (Figure 1). The device was positioned inside a specially designed oval phantom which permits the exposure of long implant leads to a constant incident E-field. The phantom was filled with a tissue simulant (ε_r=78, σ=0.47S/m at 64MHz) and placed for exposure inside a 1.5T RF coil, where SAR measurements were performed. FDTD simulations with the numerical model reproducing exactly the measurement setup were run. Implants with different lead lengths were measured and simulated to account for resonance effects. The measured SAR distribution at the tip of the generic DBS was used for the validation of its numerical model. The validated model of the device was then positioned in a human head model (Duke (Figure 2), from the Virtual Family [2]) following a realistic medical implantation path. The SAR and temperature increase in the human model due to the exposure of the patient to the fields produced by the RF coil were assessed with FDTD simulations. The evaluations were done following the tiers marked in [1].

Results

The energy deposition and the temperature increase at the implant tip following the tiers in [1] were assessed and are summarized in Table 1. Lower tiers (1, 2, 3) presented less computational complexity as the energy deposition at the tip ($psSAR_{10mg}$) was obtained from simulations in the homogeneous phantom, but they yielded higher overestimation in the results. The normalization values (E-fields in Table 1) were computed following the specifications in [1]. Tier 4, in contrast, used highly realistic models and routing paths, but the demonstration of full compliance of complex leads with a large number of trajectories (Figures 2 and 3) turned out to be very demanding computationally (a single case simulation ran for 2 days on an GPU accelerated cluster providing a computational speed of 2 billion cells per second). The SAR to ΔT transformation of 3.6mK/W/kg (uncertainty: 0.95dB) was determined with worst-case perfusion models for the brain tissue (Figure 4).

Tier	Incident E-field [V/m]	$psSAR_{10mg}$ [kW/kg]	Temp. increase [K]	Ratio Tier i-1 /Tier i [dB]
1	420	84	300	
2	23	12	44	8
3	16	6	21	3
4		0.23	0.84	14

Table 1. >95th estimation of peak spatial SAR and ΔT at the tip determined according to the different tiers [1].

Conclusions

This study has demonstrated that the approach proposed in [1] is technically feasible using standard computational and experimental methods. The lower Tiers 1 & 2 are only suited for short implants and Tier 3 for RF-optimized implants. The example case of the Tier 4 analysis has shown that it is far too demanding regarding the computational resources required for a complete analysis. Therefore, an enhanced Tier 3 is suggested. This analysis could be based on the extraction of the incident field along a large number of trajectories in the anatomical models according to Tier 3, and application of these fields to the device positioned in a straight trajectory, which can be efficiently simulated using FDTD or the Method of Moments.

References

[1] 6/JWG2 I S & 62B/JWG1 I S 2009 *Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device* International Organization for Standardization. Draft International Technical Specification for ISO/TS 10974.
[2] Andreas Christ *et al* 2010 *Phys. Med. Biol.* **55** N23

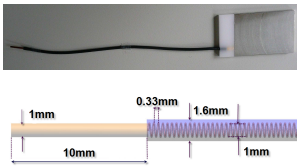

Figure 1. (Top) Generic DBS model consisting of a stainless steel can, a dielectric header and a generic insulated helicoidal lead. (Bottom) Detail and dimensions.

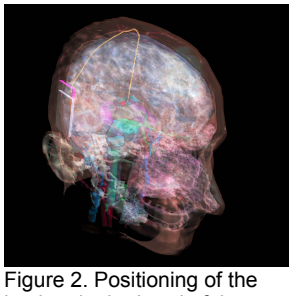

Figure 2. Positioning of the implant in the head of the anatomical model Duke.

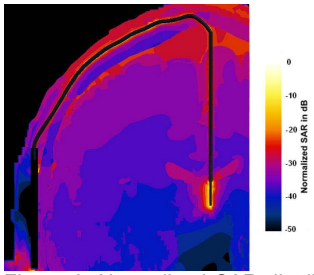

Figure 3. Normalized SAR distribution in a coronal slice of the implanted human model.

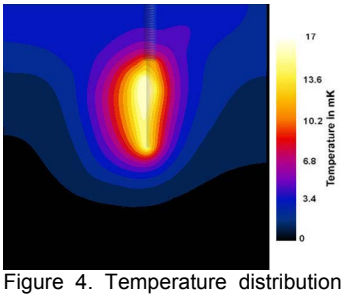

Figure 4. Temperature distribution surrounding the lead tip for SAR head limit of 3.2W/kg.