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RF induced energy for partially implanted catheters: a computational study

Elena Lucano [Student Member, IEEE],

Sapienza University of Rome (Rome, 00184 Italy) and was with the U.S. FDA, CDRH, Office of Science and Engineering Laboratories, Division of Biomedical Physics, Silver Spring, MD 20993 USA

Micaela Liberti [Member, IEEE],

Sapienza University of Rome (Rome, 00184 Italy)

Tom Lloyd,

Imricor Medical Systems (Burnsville, MN 55337, US)

Francesca Apollonio [Member, IEEE],

Sapienza University of Rome (Rome, 00184 Italy)

Steve Wedan, Imricor Medical Systems (Burnsville, MN 55337, US)

Wolfgang Kainz [Member, IEEE], and

U.S. FDA, CDRH, Office of Science and Engineering Laboratories, Division of Biomedical Physics, Silver Spring, MD 20993 USA

Leonardo M. Angelone [Member, IEEE]

U.S. FDA, CDRH, Office of Science and Engineering Laboratories, Division of Biomedical Physics, Silver Spring, MD 20993 USA

Abstract

Magnetic Resonance Imaging (MRI) is a radiological imaging technique widely used in clinical practice. MRI has been proposed to guide the catheters for interventional procedures, such as cardiac ablation. However, there are risks associated with this procedure, such as RF-induced heating of tissue near the catheters. The aim of this study is to develop a quantitative RF-safety method for patients with partially implanted leads at 64 MHz. RF-induced heating is related to the electric field incident along the catheter, which in turns depends on several variables, including the position of the RF feeding sources and the orientation of the polarization, which are however often unknown. This study evaluates the electric field profile along the lead trajectory using simulations with an anatomical human model landmarked at the heart. The energy absorbed in the volume near the tip of ageneric partially implanted lead was computed for all source positions and field orientation. The results showed that varying source positions and field orientation may result in

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changes of up to 18% for the E-field magnitude and up to 60% for the 10g-averaged specific absorption rate (SAR) in the volume surrounding the tip of the lead.

I. Introduction

Magnetic Resonance Imaging (MRI) is a radiological imaging technique widely used in clinical practice thank to its clinical versatility, the absence of ionizing radiation, and the high soft-tissue contrast. One of the clinical hazards related to the MRI is the patient tissue heating that can occur due to the absorption of radiofrequency (RF) energy. RF-induced heating may be of particular significance for patients with partially or fully implanted metallic medical device, because of the antenna effect of the implant [1]. Partially implanted devices may be used in interventional procedures such as cardiac ablation or catheters for diagnostic catheterization (e.g., cardiac and cancer biopsies). These procedures may require guiding or tracking the device within the patient using MRI.

Traditionally, RF-induced heating has been evaluated using experimental methods, such as temperature measurements in gel-filled phantoms [2]. In recent years, computational modeling has been increasingly used to complement experimental results. In the safety assessment process, computational modeling is used to calculate the electromagnetic field generated by the RF coil used during MRI. The technical specification (TS) ISO 10974 [3] describes a methodology for numerical assessment of in-vivo exposure of the fully implanted devices. The methodology described in [3] for the evaluation of the RF safety follows a four-tier approach. With increasing tier level, the level of complexity for the evaluation of the RF-induced heating increases. For the evaluation of a system including an object in the µm range (i.e., dimensions of the internal sections of a catheter) inside a structure in the meters range (i.e., RF coil), the computational cost of the simulations can be high, especially when using simulations based on the Finite Difference time Domain (FDTD) method. One of the proposed solutions to this problem is the transfer function approach proposed by Park and colleagues [4], and included in the Tier 3 approach of the ISO TS10974 [3]. The method aims to decouple the problem of the coupling of lead to the electric field from the effective exposure level; the deposited power in the tissue surrounding the implant is then computed by multiplying the transfer function of the specific lead with the complex component electric field tangential to the lead.

The scope of the TS10974 is limited to fully implanted devices. Currently, there is no methodology to assess RF-induced heating in patients with partially implanted devices during MRI. Safety evaluation of the procedure is further complicated because a portion of the catheter is outside of the body, where the electric fields are high in magnitude and strongly affected by the coil design [5]. In addition, in commercial 1.5 T MRI scanners used in clinical applications, the position of feed excitation and orientation of the polarization with respect to the patient are often unknown. In this study we extend the application of a Tier 3 approach suggested by [3] to a generic lead partially implanted in a body model. The tangential component of the electric field (E_{tan}) in absence of the lead and the specific absorption rate (SAR) at the tip of the lead were assessed for several exposure conditions

accounting for complexity of the numerical coil model, field orientation, and position of feed excitation.

II. Methods

A. Birdcage coil model

EM simulations were implemented with the commercially available FDTD-based platform Sim4Life (Zurich Med Tech, Zurich, Switzerland). The computational model of the birdcage coil was based on the commercially available high-pass 64 MHz birdcage body coil MITS1.5 (Zurich Med Tech). The MITS1.5 system is composed of 16 rectangular strips (rungs) 570 mm long, which are laid out in cylindrical symmetry (diameter = 746 mm). The coil is shielded by a 16-sided regular polygonal enclosure. The system is driven at two ports (*I* and *Q*, located 90° apart) in quadrature mode (i.e., equal amplitude with a 90° phase shift between each port excitation). The numerical model used for the simulations matched the geometry of the MITS1.5 system.

Two implementations of the birdcage coil were used, following the "specific" *S2*, and "generic" *G32* schemes described in [5]. Excitation characteristics of the used models were as follows: i) the *S2* model was comprised of two sources set in two gaps of one of the two rings, 90° spatially apart, as in the physical coil (Fig. 1a), and ii) the *G32* model included a source in each gap of the two coil rings for a total of 32 sources (Fig. 1c). In both cases the ports were modeled as a voltage source with a resistor $R_S = 50 \Omega$ in series. For each simulation both the coil and the shield were modeled as perfect electric conductor (PEC), as was the internal conductor of the lead.

B. Numerical models of human body and generic lead

The study was performed with the coil loaded with an adult human female model ("Ella", Fig. 2a) [6], which is part of the Virtual Family 3.0, and is subdivided in 305 anatomical structures. The electrical properties were automatically assigned to the anatomical structures by the software platform with respect to the working frequency (i.e., 64 MHz). The model was landmarked at the heart inside the RF coil.

A generic lead (black line in Fig. 2a), consisting of a 1.3 m long insulated wire (1.4 mm diameter with a 3 mm insulation), was partially inserted for 10 mm inside the groin region of the model (Fig. 2c).

Simulations were performed with the human body model with and without the lead. The insulation of the wire was modeled as Teflon ($\sigma = 0.462 \text{ mS/m}$, $\epsilon_r = 2.08$). An isotropic resolution of $3 \times 3 \times 3 \text{ mm}^3$ was imposed to the coil and the human model, whereas a minimum geometry resolution of $0.5 \times 0.5 \times 0.5 \text{ mm}^3$ was imposed to the lead when present.

C. Numerical simulations

The two sources in the *S2* model were rotated in pairs inside the ring with 90° angle (Fig. 2b), for a total of 4 pairs (i.e., 2–6, 6–10, 10–14, 14–2, in Fig. 2c). In addition, for each source pair the feeding phase was chosen to produce two opposite quadrature driven coils, namely orientations Clockwise (CW) (i.e., feeding phases equal to 0° and 90° , respectively)

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and Counter Clockwise (CCW) (i.e., feeding phases equal to 90° and 0°, respectively). In the G32 model the effect of field orientation was considered by forcing currents flowing inside the coil in CW and CCW orientations. The numerical results of E_{tan} and 10g-averaged SAR were collected to evaluate the effect of different positions of feed excitation with respect to the human model. The E_{tan} was extracted with the IMSAFE tool embedded in the Sim4Life.

Because the RF-induced heating of tissue near metallic wires depends on the tangential component of the electric field along the wire [4], the first step of the analysis included an evaluation across different exposure conditions of the baseline (i.e., anatomical model without lead) and extracting the E_{tan} along the lead path (Fig. 2a). Additionally, the 10gaveraged SAR in the tissue region surrounding the catheter tip was calculated (Fig. 2c). All the simulations were normalized to obtain a whole body average SAR (WbSAR) of 2 W/kg without the lead present. For the simulations with the lead present, the power factor obtained by the one without the lead was used for the specific port position and filed polarization.

III. Results and Discussion

Results showed that amplitude and phase of E_{tan} was affected by the source position and the field polarization. Fig. 3 reports the profiles of the magnitude and phase of the E_{tan} in CW vs. CCW polarization. Peaks of electric field magnitude were present at the catheter insertion point (distance along lead = 0.04 m, in Fig. 3a and 3b) and at the location of the feet (distance along lead = 0.9 m).

The opposite field orientation affected both the magnitude and phase of the E_{tan} . The pairs 2–6, and its opposite 10–14, were more affected by the field orientation, showing differences up to 18%. For all source positions, change in the field orientation was reflected in a mirroring of the phase profile at the level of the thigh (Fig. 3).

The G32 model allowed to generate similar profiles for the magnitude of E_{tan} (Fig. 3c and d), but with overall smaller absolute values. Additionally, the G32 model did not allow for the estimation of the same dynamic range found for the S2 model with respect to the different port positions. This may represent a significant limitation of such model, particularly when safety of a partially implanted wire is assessed, because it does not assure that the worst case scenario is evaluated.

For all source positions the 10g-averaged SAR was under 25 W/kg. When comparing the results obtained by switching CW and CCW polarization, there were significant differences up to 54 % for the pair 2–6 (Table 1), whereas results for pairs 6–10 and 14-2 were less affected by field polarization with differences less than 5 %. This trend is in accordance with the results for the E_{tan} profile. The change in source position generated up to 50 % differences in local SAR at the tip of the catheter. The G32 model showed values of local SAR 50 % and 30 % smaller with respect to the S2 model in CW and CCW field orientation, respectively (Table 1). Additionally the CCW polarization showed overall higher SAR for both S2 and G32 model.

Our data indicates that exposure conditions affect E_{tan} profile and the 10g SAR at the tip of a partially implant lead. The data suggest that the evaluated variables need to be taken into account when assessing the safety of partially implanted catheters. Ongoing work is in progress to develop a systematic RF-induced heating test method for partially implanted leads in phantoms that will take into account the effect of these variables.

IV. Conclusion

The data analysis shows that source position, field orientation, and complexity of the numerical coil model may significantly affect 10g-average SAR at the tip of a partially implant catheter, suggesting that such information should be taken into account when evaluating the safety of patients with partially implanted leads undergoing 1.5T MRI. Ongoing work is in progress to develop a systematic RF-induced heating test method for partially implanted leads in phantoms that will take into account the effect of these variables.

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References

- 1. Guy AW. Biophysics-energy absorption and distribution. AGARD. 1974
- Atalar E. Radiofrequency safety for interventional MRI procedures. Academic radiology. 2005; 12:1149–57. [PubMed: 16112515]
- ISO/TS 10974, ISO/TS 10974, First Edition. Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device, Reference number ISO/TS 10974:2012(E)
- Park SM, Kamondetdacha R, Nyenhuis JA. Calculation of MRI-induced heating of an implanted medical lead wire with an electric field transfer function. Journal of Magnetic Resonance Imaging. 2007; 26(5):1278–1285. [PubMed: 17969143]
- Lucano E, Liberti M, Mendoza G, Lloyd T, Iacono MI, Apollonio F, Wedan S, Kainz W, Angelone LM. Assessing the electromagnetic field generated by a radiofrequency body coil at 64 MHz: defeaturing vs. accuracy. IEEE Trans Biomed Eng. In press.
- Gosselin MC, Neufeld E, Moser H, Huber E, Farcito S, Gerber L, Jedensjö M, Hilber I, Di Gennaro F, Lloyd B, Cherubini E, Szczerba D, Kainz W, Kuster N. Development of a new generation of high-resolution anatomical models for medical device evaluation: the Virtual Population 3.0. Phys Med Biol. 2014 Sep 21; 59(18):5287–303. [PubMed: 25144615]

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Figure 1.

Two electrical models of MRI RF coil implemented: (a) S2 model with two sources excitation, and (b) G32 model 32 sources excitation placed in the two rings.

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Figure 2.

a) Coil loaded with the human model "Ella" landmarked at the heart. The trajectory of the partially implanted lead is drawn in black. b) Scheme of source position for the S2 model. The results for the pairs in the green dots are shown in Fig. 3; c) Black area indicate the volume selected to calculate 1g averaged SAR around the catheter tip.

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Figure 3.

 E_{tan} profile along the catheter path for Ella (in Fig 1a) using the S2 (cases a) and b)) and G32 model (cases c) and d)). Results are reported for the clockwise (cases a) and c) and counterclockwise (cases b) and d)) orientation of the field with respect to the human model. Profiles are reported for the magnitude (V/m) and phase (rad) of the E_{tan} .

TABLE I

SAR IN 10g VOLUME AROUND LEAD TIP

	10g-average SAR (W/kg)	
S2	CW	CCW
Pair 2–6	15.3	21.8
Pair 6–10	19.9	18.9
Pair 10-14	13.1	20.1
Pair 14-2	17.5	18.3
G32	14.54	21.32

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