Impact of Mixed Media on Transfer Functions with a Pacemaker System for Estimation of RF Heating during MRI Scans

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Abstract

Patients with active implantable medical devices (AIMD) may be at risk of harm from RF-induced heating during an MRI scan. The amount of RF-induced lead heating is mainly attributed to the electric field tangential (Etan) to the lead path, which can be predicted by using an electrical field transfer function (TF) associated in different media. The objective of this study is to investigate the difference in estimating RF heating through TFs of a pacemaker system in high conductivity media (HCM), low conductivity media (LCM) and mixed media simulating in-vivo.

The ANSYS HFSS was used to calculate the electromagnetic fields in a tank model built from the TF measurement set-up, with a pacer and a cardiac lead model (length=52 cm) placed inside. The tank is filled with homogenous media such as Blood (σ=1.2 S/m, ε_r = 78) denoted as high conductivity media HCM or low conductivity media LCM (σ=0.47 S/m, ε_r = 78). For mixed media, blood vessels (HCM) are around a lead with the cardiac dimension. Outside vessels, the space was filled with myocardium (σ =0.678 S/m, ε=106.5). Reciprocal method was used with current excitation at the tip. Currents along lead conductors are obtained by loop integrals of H fields. The TFs are the currents along the lead divided by the excitation, denoted as $S(\tau)$. The heating was accessed by integrals of tangential electrical fields (Etan) over 133 clinical pathways inside virtual human family models giving by normalized power $PE \sim \sigma {*} Etip^2 = \sigma\,|\int Etan(\tau) * S(\tau)\, d\tau|^2$.

Three curves of TF magnitude $S(\tau)$ run closely to each other and TF for the mixed media was in the middle, LCM on the top and HCM in the bottom. Predicted normalized PEs at 99 percentile are 0.974 for HCM, 0.536 for mixed and 0.519 for LCM. For the scenarios evaluated, using TFs with LCM provides a closer in-vivo heating evaluation with a 3% underestimation while HCM overestimates by 80%.

1. Introduction

MRI-RF induced heating may cause damage of bodily tissue adjacent to the pacemaker system, especially around elongated metallic components. Given the number of variables that impact the safety of MRI scanning in pacemaker patients (e.g. scanner, scan sequence, patient anatomy, patient position, lead location and lead construction), a practical clinical trial that produces meaningful and valid conclusions is not readily feasible. Accordingly, MRI safety issues are generally characterized by technical specifications and standards , which are based on appropriate test procedures published by the International Organization for Standardization, the International Electrotechnical Commission (ISO/IEC) [1]and the American Society for Testing and Materials (ASTM) International [2].

The ISO/TS 10974 Clause 8, Tier 3 based evaluation of RF heating of the pacemaker system has been commonly used for pacemaker manufactures through regulatory bodies world-wide. The implementation of Tier 3 includes electromagnetic simulations inside human body models, pacemaker lead pathway generation, tangential electrical fields extraction along lead pathways inside human models, transfer function (TF) for the lead and pacemaker system and its validation, estimation of temperature change, converting this to deposited power which is proportional to the temperature rise, and lastly determination of the probability of injury. Generating TFs for the lead and pacemaker system is therefore an essential component.

Currently TFs of an implant are determined in a homogeneous tank filled with recommended media. Two types of media are recommended. One of them is based on the conductivity of blood (ε_r = 78, σ = 1.2 S/m, referred to as HCM) recommended by ISO/TS 10974 [1] because it is predominantly surrounding the lead body for pacemaker implants. Another is proposed in ASTM F2182 [2] (ε_r = 78, σ = 0.47 S/m, referred to as LCM) that is based on the tissue-averaged conductivity. In-vivo conditions surrounding the pacemaker implants are not homogeneous, but with blood, myocardium, lung, connective tissues, fat, muscle etc. nearby or on the pathways. It has been desired to understand the impact of mixed media on TFs and the resulting estimated power deposition.

The objective of this study is to investigate the impact from the selective use of the TFs derived in HCM, LCM

 ISSN: 2325-887X DOI:10.22489/CinC.2017.272-135

and the mixed media, on the power dissipated near the tip electrode.

2. Methods

This study used a computational model of a St. Jude Medical pacemaker system to calculate transfer functions by using reciprocal theory in electromagnetics with RF frequency 64 MHz of 1.5 T MRI.

The tank model with the pacemaker system placed inside was built using ANSYS HFSS, a finite element method (FEM) modeling software package, to simulate high frequency electromagnetic fields at 64 MHz.

Figure 1: distal portion of a pacing lead and a pacemaker modeled.

Detailed structures of a pacemaker and a lead are modeled as shown in Figure 1. The inner and outer coils of the pacemaker lead are approximated by solid metallic tubes. As shown in Figure 2, a tank is enclosed by a larger air box with a dimension of 100 cm x 40 cm x 30 cm. The radiation boundary condition is applied to the outbound of the air box. The tank size is 84 cm in length, 20 cm in width and 10 cm in height. A pacemaker lead with 52 cm length and 2.2 mm diameter was placed symmetrically inside the tank, connected with a pacemaker. The tank was filled with homogeneous media of either low conductivity (LCM, σ = σ=0.47 S/m, ε =78) or high conductivity (HCM σ =1.2 S/m, ε=78). For simulating mixed media in human, cardiac anatomy was approximated. Right ventricular blood chamber was simplified to a cylinder of diameter of 3 cm around the distal lead. Superior Vena Cava and left innominate veins were represented by a cylinder of diameter 1.3 cm. The property of blood was used inside cylinders and myocardium (σ =0.678 S/m, ε=106.5) was used for the tissues outside the cylinders. The tip electrode of the pacing lead is embedded into myocardium. Based on reciprocal theory, the excitation was near the tip of the pacemaker lead. Electrical current along the lead conductors were obtained by loop integrals of magnetic field H at 1 cm increments starting 1.84 cm from the tip of the lead. The transfer function is the current along the lead divided by the current of excitation, denoted as $S(\tau)$.

The pacemaker lead was also simulated with dry and wet conditions by either having both lead lumens filled with air or inner lumen filled with blood, respectively. With each lead state (either dry or wet), a set of transfer functions were obtained through simulations for LCM, HCM and mixed media.

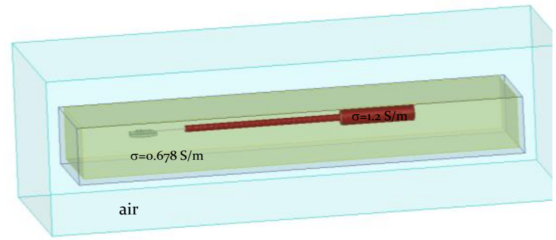

Figure 2: The tank model for mixed media with a pacer and a lead enclosed.

Park et. al [3] developed and demonstrated a method by using a transfer function approach to predict the temperature rise that is induced by the MRI RF field. Using this approach, the temperature rise at the electrode of the lead is then

$$\Delta T = A\left|\int_0^L E_{\tan}(\tau)S(\tau)d\tau\right|^2 \qquad (1)$$

where E_{tan} is the incident tangential electric field, τ is parametric distance along the lead, and A is a scaling constant which can be determined by measurement of the temperature rise in a phantom using a procedure similar to the one described in ASTM F2182-11a[2]. Using the method described [4], firstly electromagnetic fields at 64MHz were solved inside the adult male model Duke from the virtual family by using SEMCAD-X. All the fields were scaled to 4 or 2 W/kg whole body SAR, unless limited by head SAR or partial body SAR. The adult male model Duke was placed inside a high pass RF body coil such that the thoracic region was at the isocenter (Figure 3). Secondly clinical lead pathways were generated inside them and E_{tan} along clinical lead pathways was extracted. Finally the estimated ΔT can be calculated from the equation (1). Theoretically coefficient A is approximation from bio-heat equation that is $\sigma/(c*\rho)$ at the site ΔT is measured, where c is specific heat and ρ is mass density. Since we are interested in relative changes in ΔT, the coefficient A is eliminated and instead power PE is used in equation (2).

$$PE = \sigma\left|\int_0^L E_{\tan}(\tau)S(\tau)d\tau\right|^2 \qquad (2)$$

In this study, both amplitude and phase of transfer functions were also presented along the lead in three media, respectively. We used electric fields along the 133 clinical pathways solved inside adult male model of the virtual family. Transfer functions with LCM, HCM and mixed media were used for the integrals in equation (2) to create three sets of the power distributions in each media respectively.

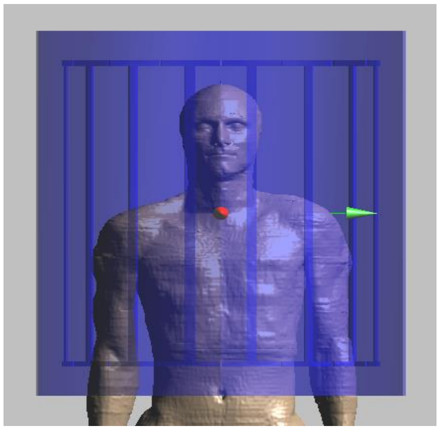

Figure 3: The position of Adult Male Model Duke inside a high pass RF birdcage body coil.

3. Results

The transfer functions at 64 MHz in HCM, LCM and mixed media were shown Figure 4 in magnitudes and Figure 5 in phases. Shown in Figure 4, the magnitudes of TFs are higher with lower conductivity (σ =0.47 S/m vs. σ =1.2 S/m), while the TF of mixed media falls in between. Phases of TFs show in Figure 5 that curves for HCM and LCM follow each other with the maximum difference of 40 degree near the device header and those with LCM were higher. The phases for mixed media are lower than both HCM and LCM but have a region with a jump near the interface of HCM and LCM which is reasonable.

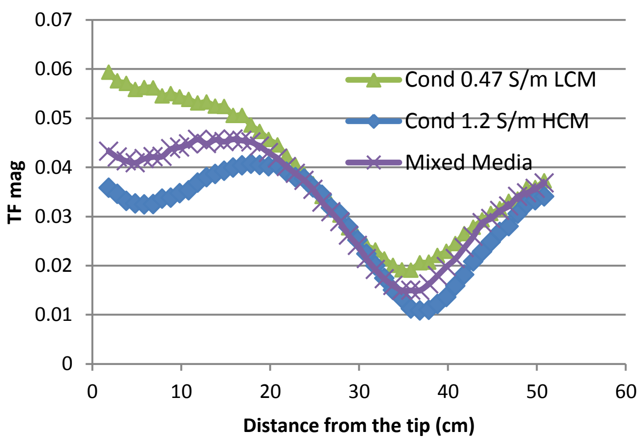

Figure 4. Amplitudes of Transfer Functions in HCM, LCM and mixed media with dry leads.

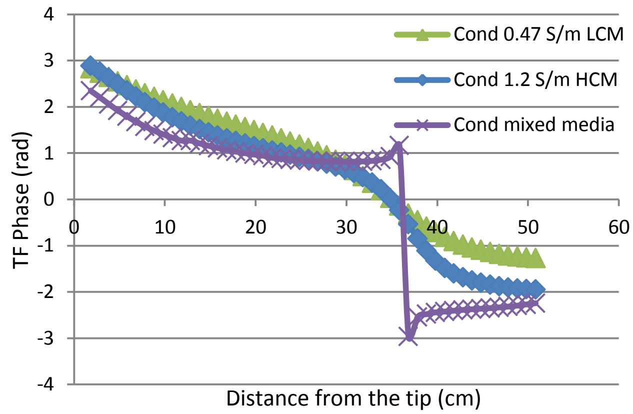

Figure 5. Phases of TFs in HCM, LCM and mixed media with dry leads.

Little difference in TFs was seen between dry and wet leads for this specific structure of leads, due to solid tubes for the inner and outer conductors.

Figure 6 shows normalized power near the tip electrode of the pacing lead derived through the integral of equation (2) using Etan along 133 pathways and TFs for HCM, LCM and mixed media. As shown in Table 1 in group 1 associated with the left implants (pathways #1-#64), more power density at the tip is seen compared to those from group2 of the right implants (pathways #65-#133). In the group 1, HCM trends to have higher averaged normalized power (0.54±0.18) than LCM (0.39±0.07) and mixed media (0.21±0.12). In the group 2, normalized power deposited is much lower than those in group 1, i.e. HCM (0.11±0.12 vs. 0.54±0.18), LCM (0.06±0.09 vs. (0.39±0.07) and mixed media (0.13±0.08 vs. 0.21±0.12). Overall all 133 lead pathways, the averaged normalized power are (0.31±0.26) for HCM, (0.21±0.18) for LCM and (0.17±0.11) for mixed media. Predicted normalized Power at 99 percentile are 0.974 for HCM, 0.536 for mixed and 0.519 for LCM. Using TFs with LCM provides a better in-vivo heating evaluation with a 3% underestimation while HCM overestimates by 80%.

Table 1: Normalized Power PE in Group 1 (the left implants) and Group 2 (the right implants)

	LCM	HCM	Mixed Media
Group 1 PE	0.39±0.07	0.54±0.18	0.21±0.12
Group 2 PE	0.06±0.09	0.11±0.12	0.13±0.08

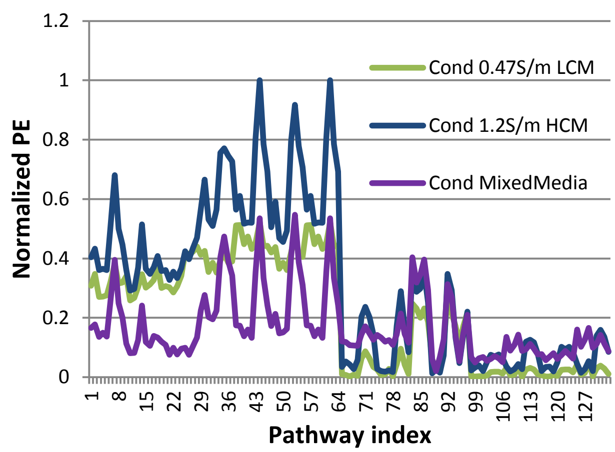

Figure 6. Normalized power PE dissipated near the tip of the electrode of 133 lead pathways in the adult male model.

4. Discussion

Interactions between pacemaker implants and MRI RF are complicated and power dissipated is a function of the characteristics of the implant and the surrounding media. Simulations in this study demonstrate that the transfer function for a lead will depend on the surrounding media and discontinuity of the media. Figures 4 and 5 show properties of media have impacts on both magnitudes and phases of TFs. Media with lower conductivity causes less attenuation of the fields than those with higher conductivity so that TF with LCM has higher magnitudes than those with HCM. In the model for mixed media with majority of lead body in blood, and the tip in myocardium, it is reasonable that magnitudes of TF with mixed media falls in-between, with LCM on the top and HCM in the bottom . However for power dissipation as in equation (2) product of conductivity and the integral, the trend is reversed as shown in Figure 6, that power dissipated with LCM is lower than that with HCM.

Because the inner and outer coils are simplified as solid metallic tubes limited by the technology of today's computer and software, the TFs could have difference from those with realistic leads with coil conductors. With coil conductors in the realistic leads, conduction velocity or wave length along the lead could be different from the tube conductors. This can also impact comparisons between dry and wet leads. Majority of leads in chronic conditions are with inner lumen filled with blood. In this simulation study, no difference was observed in TFs between dry and wet. The approach of using computer simulation is expected to be more accurate due to the capability of simulating the leads with wire or cable conductors such as those for spinal cord stimulation (SCS) and deep brain stimulation (DBS) devices etc.

Surrounding tissues for other implants such as SCS and DBS have different tissue properties. Appropriate selection of media for deriving TFs will be investigated for SCS and DBS implants in future work.

5. Conclusions

Under specific simulation conditions with simplified lead conductors in this study, predicted normalized PEs at 99 percentile are 0.974 for HCM, 0.536 for mixed and 0.519 for LCM. Using TFs with LCM provides a closer in-vivo heating evaluation with a 3% underestimation while HCM overestimates by 80%. This study indicates appropriate section of media for deriving TFs could lead to more clinically relevant RF heating predictions during MRI scans. This media selection is dependent on in vivo tissues around the implants.

References

[1] 2. ISO/TS. 10974:2016, Requirements for the safety of magnetic resonance imaging for patients with an active implantable medical device. ISO/TS 10974 2016.ISO/TS 10974.

[2] ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging, ASTM International., 2011.

[3] Park SM, Kamondetdacha R, Nyenhuis JA. Calculation of MRI-induced heating of an implanted medical lead wire with an electric field transfer function. J MagRes Imag 2007; 26:1278 –1285.

[4] G Mouchawar, S Sison , S Chen, X Min , J Chen, J Nyenhuis, D Gutfinger, R Williamson. Modeling of MRI-induced Heating in Pacemaker Patients during 1.5T MRI Scans, Computing in Cardiology 2015; 42:769-772.

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