Modeling of MRI-induced Heating in Pacemaker Patients during 1.5T MRI Scans

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Abstract

Some MRI scans, including many cardiac and spinal scans, exceed 2 W/kg whole body SAR. We utilized the ISO/IEC JWG 10974 Tier 3 (ED2) approach to evaluate heating of pacemaker systems under normal (2 W/kg) and 1st level controlled mode (4 W/kg). Electric fields were simulated using five virtual human models with various transvenous pathways in MRI RF body coils. Clinically relevant lead states of various levels of fluid ingress were studied, and the validated lead transfer function (TF) with the highest heating was selected. It was then integrated with the extracted electric fields along lead pathways inside human models to estimate the temperature rises without blood flow (in vitro). A validated thermal model scaled the in vitro temperature estimates to in-vivo results. Uncertainties from measurements, TF, thermal model and in vivo simulations were incorporated with the Monte Carlo (MC) method. Safety was assessed based upon the accepted 43 ºC standard for cardiac tissue interfacing with the lead helix electrode and lead MRI filter inductor.

1. Introduction

Magnetic resonance imaging (MRI) has become the fastest growing technique in diagnostic imaging, and is the modality of choice for many clinical indications. However, MRI historically has been contraindicated in patients with cardiac implantable devices because of potential adverse interactions. Growing interest in MRI compatibility has fostered advancements in design and testing to allow safe access to MRI for patients implanted with select pacemakers under carefully monitored conditions [1,2]. These advancements were designed to mitigate the risk of potential adverse interactions between the pacemaker system and MR fields. These interactions include gradient magnetic field interactions, radio frequency (RF) heating, and image artifacts [2]. Notably, 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 (eg, scanner, scan sequence, patient anatomy, patient position, and lead characteristics), a practical clinical trial that produces meaningful and valid conclusions is not readily feasible. Accordingly, MRI safety issues are generally characterized by standards, which are based on appropriate test procedures published by the International Organization for Standardization, the International Electrotechnical Commission (ISO/IEC) and the American Society for Testing and Materials (ASTM) International [3]. To address the safety concerns, an MR conditionally safe pacemaker system was developed, specifically designed to allow for whole-body MRI scan in the first level controlled mode. In this study, the ISO/IEC JWG 10974 Tier 3 (ED2) approach was utilized including extensive computer modeling/simulation and validation with measurements during radiated RF tests, in order to quantify and assess patient risks associated with MRI induced RF heating during MRI scans.

2. Methods

We evaluated the heating of the Tendril ™ MRI lead connected to an Accent™ MRI™ pacemaker (St. Jude Medical) under normal (2 W/kg) and 1st level controlled mode (4 W/kg) MRI scanning conditions. The design of the Accent MRI pacemaker is based on modifications made to the Accent pacemaker. All commercially available features of the Accent pacemaker are included in the MRI device. The Accent MRI pacemaker has new hardware and firmware to prevent unintended stimulation due to electromagnetic fields created by the MRI scanner. The new hardware and firmware include:

- Reduction in feed-through capacitance to mitigate gradient-induced stimulation
- Addition of a band-stop filter (MR filter assembly) to attenuate MRI-specific frequencies, which otherwise

could result in RF rectification and/or other interference in device.

The Tendril MRI lead is an endocardial, bipolar, active fixation lead with an IS-1 connector based on the commercial Tendril™ Model 1888TC lead. The Tendril MRI lead incorporates filters to mitigate MRI induced RF tissue heating near the lead electrodes, one near the tip electrode and another near ring electrode. These filters provide high impedance to the transmission of the 64 MHz RF frequency of a 1.5T MRI scanner, which reduces the RF-induced heating at the electrodes.

The lead's body has a co-axial design and uses MP35N coils and an Optim™ outer insulation. The lead fits through an 8F introducer.

We utilized the ISO/IEC tier 3 standard in the evaluation of RF heating of the pacemaker system. This includes electromagnetic simulations inside human body model, pacemaker lead pathway generation, tangential electrical fields extraction along lead pathways inside human models, transfer function for the lead and pacemaker system and its validation [5,6], estimation of temperature change, converting this to in-vivo temperature, and lastly determination of the probability of injury based upon this temperature change.

The process involved identifying MR hazards on implantable devices through literature review and guidance from the ISO/IEC JWG. Each identified risk was fully characterized and system requirements were added to mitigate the risks when necessary.

2.1. Solving electromagnetic fields inside human body models

Five body models were used from the Virtual Population Project: obese male (Fats), adult male (Duke), adult female (Ella), girl (Billie), and boy (Thelonius) [4]. The SEMCAD X software package was used to simulate the electric fields generated throughout the human body when exposed to electromagnetic energy generated by a 1.5T MRI RF body coil.

The simulation conditions also included circularly polarization field rotations (counter clockwise and clockwise), body positions inside RF coils, tissue properties and RF coil size. All the reported results were scaled to 4 W/kg whole body SAR and then 2 W/kg whole body SAR, unless limited by head SAR or partial body SAR.

2.2. Generating lead pathways

The set of representative transvenous pathways for the implanted pacing lead was determined systematically from three-dimensional anatomical representations inside the human body models. Clinically representative sites for the subcutaneous device pocket, venous access, and intra-cardiac lead tip location were utilized. The subcutaneous device pocket sites were limited to the pectoral and submammary regions on either the left or right sides. The venous access sites were limited to the axillary, subclavian, and jugular veins on either the left or right sides. The intra-cardiac lead tip implanted sites were limited to the right atrial and right ventricular endocardium with fixation at multiple sites.

2.3. Characterizing the leads by transfer functions and prediction of temperature

During MR scans, the lead picks up RF energy, which gives rise to a current flowing along the lead body and into the tissue around the lead electrodes resulting in increased temperature in the tissues around them. The amount of RF-induced lead heating is mainly attributed to the tangential electric field (Etan) along the lead path. This amount of heating can be predicted for each lead path by using a transfer function (TF) for each hot spot of each lead length.

The predicted temperature rise (ΔT) for each hot spot is calculated using the E_{tan} and transfer function S [5]:

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

In Equation 1, the E_{tan} magnitude and phase along each pathway were determined through extraction from the simulation or measurement.

The predicted temperature rise in human body model without effect of blood flow came from the integral of E_{tan} and S in Equation 1. Firstly the E_{tan} magnitude and phase were extracted along the lead pathways from simulations in virtual human body models. Secondly the transfer function S was obtained through an accepted published method [6] for the Tendril MRI lead attached to Accent MRI pacemaker within HEC gel phantom (minimal convection). Clinically relevant lead states of various levels of fluid ingress were studied, and the transfer function with the highest heating was selected [8]. Since all TFs were obtained in gel phantom with minimal convection, the predicted temperature rise from TFs is here called the in vitro temperature rise. A validated thermal model (section 2.5) was used to scale the in vitro temperature by TFs to those that would be experienced in vivo.

2.4. Model validation

For transfer function validation, the measured temperature rises in a gel phantom along the various pathways of lead placement (105 pathways) in a 1.5T RF

body coil were compared to TF predictions in associated cases.

2.5. Thermal modeling from in vitro to in-vivo transfer

Firstly the predicted temperature rise in human body models as described in 2.2 was based TF obtained in gel with minimal convection. The in vivo condition of the blood interface at the inductor needs to be considered. Secondly chronically implanted pacing leads are typically encapsulated with fibrous tissue over time, due to the human body's natural reaction to a foreign object. This encapsulation covers the distal end of the lead. The inductor may be coved with encapsulation that could range up to a thickness of 2.3 mm [9] and that encapsulation may have either blood, cardiac tissue or both at its interface. A validated thermal FEA model was used to study the relationship in temperature rise around distal lead between in vitro and in vivo w/o encapsulation.

The thermal FEA model was generated by using Abaqus FEA software (version 6.11) consisting of all the components in the distal end of the lead placed in a tissue bath tank. The tissue property around the lead was simulated to mimic in vitro and in vivo from acute to chronic conditions in order to determine the relationship between in vitro and in vivo conditions. For the chronic case this included a variety of encapsulation thicknesses, and a variety of encapsulation to blood, cardiac tissue, or mixture interfaces.

2.6. Uncertainty analysis

In order to validate the computer model and relate the lead electrode temperature rise associated with MRI scanning to patient safety, an extensive uncertainty budget for the temperature measurement, device under test, RF transmit coil and phantom, tissue simulating media, lead and device model, in vivo Etan simulation and conversion from in vitro to in vivo was assessed [10]. All discrepancies between the model and prediction were accounted for in the uncertainty analysis.

Some of the quantifiable sources of error in this process were the E-field uncertainty, temperature probe accuracy, probe placement sensitivity, phantom media variation, lead to lead variability, inhomogeneous media, TF, thermal model, power measurement uncertainty and numerical uncertainties. Each of these individual errors was combined (using RSS method) into an overall uncertainty. The overall uncertainty from temperature measurements, and in vivo simulations were incorporated with the Monte Carlo (MC) method. Patient safety was assessed based upon the accepted 43 ºC standard [7] for cardiac tissue interfacing with the lead helix electrode and lead MRI filter inductor.

3. Results

Over 400 different patient and MRI system permutations were done in five human body models over simulation conditions of circular polarization field rotations (counter clockwise and clockwise), body positions inside RF coils, tissue properties and RF coil size. Electrical fields from the solution were extracted along the lead pathways in each model, a total of 198 pathways for the adult female and a total of 144 pathways for each of the obese male, adult male, girl and boy models.

3.1. Model validation

The validation of model prediction is shown in Figure 1 and Figure 2. The predicted temperature rise at the tip inductor and proximal lead body region was plotted against the measured temperature for all validation 105 pathways in a gel phantom as shown in Figure 1 and Figure 2 respectively. The drawn lines of 34.4%+-1^{0}C bounded most data points with ΔT of tip inductors as shown in Figure 1, while the drawn lines of 43.4%+-1 ^{0}C for most data points of ΔT with proximal body area in Figure 2.

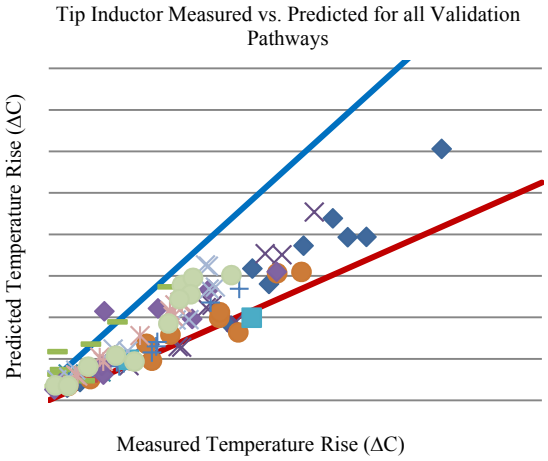

Figure 1. RF-induced tip inductor temperature rises for each worst case lead and its associated validation pathway in a gel phantom.

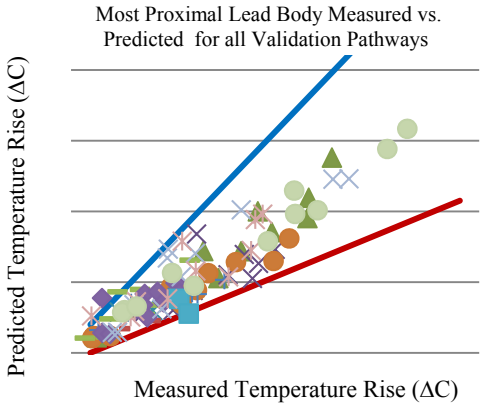

Figure 2. RF-induced proximal lead body temperature rises for each worst case lead and its associated validation pathway.

3.2. In-vivo risks of cardiac tissue damage

Over 400 different patient and MRI system permutations were simulated. When combined with exhaustive lead pathways, and MC analysis, over 14 million scans were simulated. The risk associated with MRI scans was based upon the number of these 14 million simulations exceeding the safety criterion. For 2 W/kg scans, none of the 14 million scans exceeded the safety criterion at the lead helix or the MRI filter inductor, and therefore the risk is estimated as <1 in 14 million. For 4 W/kg scans, the risk was <1 in 15,000 at the lead helix and <1 in 14 million at the MRI filter inductor.

4. Discussions

There are studies reporting successful MRI scans in a small number of patients who have undergone an MRI scan without complication. Since there are thousands of permutations in clinical settings, observational data that only tests a few conditions cannot support a claim of safety. The complete assessment of a transvenous pacemaker lead in the MRI environment through modeling is the direction of safety evaluation. With the ability to provide data for thousands of combinations of variables, lead heating modeling demonstrates safety outside a clinical study and provides a pathway to get safety confirmation to physicians and products to patients more quickly.

St. Jude Medical has used this modeling data to support regulatory submissions for approval of 1.5T MR Conditional products. In particular, the modeling data has been the primary vehicle to demonstrate system safety. In addition, the clinical trials of Accent MRI systems were supplemental to this modeling data for FDA submissions. Outside the United States, the human body modeling has also been used extensively to gain CE mark and regulatory approval in a number of other geographies (e.g., Europe, Japan, and Korea). This modeling approach is also applicable for approval of MRI 3T conditional pacemakers.

5. Conclusions

Our results indicate that the risk associated with MRI scans of patients with an Accent MRI pacemaker system due to cardiac injury at the lead helix electrode or at the lead MRI filter inductor is extremely low for 4 W/kg scans, and miniscule for 2 W/kg scans, even taking into account worst case considerations into every modeling step.

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