Safe magnetic resonance imaging scanning of patients with cardiac rhythm devices: A role for computer modeling

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BACKGROUND Although there are several hazards for patients with implanted pacemakers and defibrillators in the magnetic resonance imaging (MRI) environment, evaluation of lead electrode heating is the most complex because of the many influencing variables: patient size, anatomy, body composition, patient position in the bore, scan sequence (radiofrequency power level), lead routing, and lead design. Although clinical studies are an important step in demonstrating efficacy, demonstrating safety through clinical trials alone is not practical because of this complexity.

OBJECTIVE The purpose of this study was to develop a comprehensive modeling framework to predict the probability of pacing capture threshold (PCT) change due to lead electrode heating in the MRI environment and thus provide a robust safety evaluation.

METHODS The lead heating risk was assessed via PCT change because this parameter is the most clinically relevant measure of lead heating. The probability for PCT change was obtained by combining the prediction for power at the electrode–tissue interface obtained via simulations with a prediction for PCT change as a function of radiofrequency power obtained via an in vivo canine study.

RESULTS The human modeling framework predicted that the probability of a 0.5-V PCT change due to an MRI scan for the Medtronic CapSureFix MRI SureScan model 5086 MRI leads is <1/70,000 for chest scans and <1/10,000,000 for either head scans or lower torso scans.

CONCLUSION The framework efficiently models millions of combinations, delivering a robust evaluation of the lead electrode heating hazard. This modeling approach provides a comprehensive safety evaluation that is impossible to achieve using phantom testing, animal studies, or clinical trials alone.

KEYWORDS 5086 MRI lead; Computer modeling; Hazards; Lead electrode heating; MR conditional; Magnetic resonance imaging; SureScan

ABBREVIATIONS AAMI = Association for the Advancement of Medical Instrumentation; ISO = International Organization for Standardization; MRI = magnetic resonance imaging; PCT = pacing capture threshold; RF = radiofrequency

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Introduction

Regarded by many as the gold standard for soft tissue imaging, magnetic resonance imaging (MRI) has become the imaging modality of choice for neurologic, soft tissue, tumors, and musculoskeletal disorders.1 The prevalence of common comorbidities increases rapidly for individuals older than 65 years, resulting in an increasing likelihood of benefiting from MRI.2–4 For example, pacemaker patients, who on average are 75 years of age,3,6 have a 70% chance of developing an indication for an MRI scan over the expected life of the implanted device.1 MRI scans have been considered contraindicated for pacemaker patients since the development of MRI more than 30 years ago. MR Conditional pacing and defibrillator systems represent a technological breakthrough in the medical device industry, addressing a compelling market need with significant patient benefit.

MRI system: Source of hazards

MRI scanners deliver pulsed radiofrequency (RF) and switched gradient magnetic fields in the presence of a powerful static magnetic field to create an image of the body. Together, the three powerful fields (static, RF, and switched gradient) create a hostile environment for an implantable pacing or defibrillation system.8 However, with proper design and evaluation methods, it is possible to mitigate the hazards and produce a system that will allow patients to be safely scanned.
Hazards for patients with implanted pacemakers and defibrillators undergoing MRI scans fit into several categories: (1) arrhythmias initiated by MRI-induced cardiac stimulation, (2) RF-induced tissue heating near the lead electrodes causing tissue damage, (3) temporary or permanent device malfunction that results in inappropriate therapy, and (4) device and/or lead dislodgement, caused by interaction between the static and fast switching gradient magnetic field and ferrous materials.

Rationale for computer modeling
The lead electrode heating complexity is due to a combination of multiple clinical variables, including patient size, anatomy, body composition, patient position in the bore, scan sequence (RF power level), lead routing, and lead design. This leads to a significant variation in lead electrode heating. Figure 1 shows lead electrode heating variation due to patient size (three different human body models), patient position in the bore (shown along the x-axis), and lead routing in the body (four different lead routings are shown using different color lines). Figure 1 illustrates the extreme variation in lead electrode heating due to these variables: (1) there is at least a 10× difference between the highest- and lowest-heating lead routings within a specific human body model; (2) the highest- and lowest-heating lead routings are different for different human body models (e.g., compare the lead routing marked with a black line); and (3) the peak heating is different for different size human body models.

Computer-aided modeling is a practical and efficient method for exploring millions of variable combinations in a holistic manner. Computer modeling also allows for analysis of parameter extremes, outside the bounds of normal clinical practice, which allows further assessment of safety margin and the sensitivity of influencing variables. The accuracy of modeling results is dependent on the ability to simulate and predict real use scenarios. The objective of this study was to develop a robust modeling framework to predict risk of lead electrode heating in the MRI environment and thus provide a robust safety evaluation for new and existing products.

MRI lead electrode model overview
The modeling framework consists of two major parts: (1) the RF power at the electrode–tissue interface is simulated using models of human bodies, RF coils, leads, and lead routings; and (2) the effect of RF power on pacing capture threshold (PCT) is evaluated in vivo via a canine study. PCT is the minimum voltage required to pace, or capture, the heart. The results of these two steps are combined to develop a statistical prediction of PCT change during an MRI scan. A block diagram of the strategy is shown in Figure 2. Note that this approach does not rely on in vivo temperature rise measurements because the relationship between the change in PCT and RF power is directly obtained.

PCT was chosen as the basis of the lead electrode heating evaluation strategy because the change in PCT is directly caused by tissue heating near the lead electrode. In addition, it is the most sensitive parameter for monitoring changes in the electrode–tissue interface and is the parameter of most significance with respect to pacing therapy delivery.

Models of human bodies, RF coils, leads, and lead routings are simulated in order to calculate the coupled RF power. In addition, an in vivo canine study is performed to measure PCT change as a function of RF power delivered directly to the cardiac lead. These two components are combined in order to calculate the probability of MRI-induced PCT change.

Methods
As discussed in the Introduction, the modeling framework consists of two parts: (1) the simulations that predict lead
electrode heating (RF power), and (2) the in vivo canine study that measures PCT change as a function of RF power. These two parts are discussed in more detail below.

**Part 1: Lead Electrode Heating Simulations**

**RF coil models**

Medtronic Cardiac Rhythm Disease Management has assembled a library of seven RF coil models from four major manufacturers. These models were simulated using the SEMCAD X (version 14.8.1) electromagnetic simulation software (Speag, Zurich, Switzerland). The SEMCAD X software uses the finite difference time domain (FDTD) method, which is a widely accepted numerical analysis technique for electrodynamics.9

**Human body models**

Because the amount of lead electrode heating depends on patient size and anatomy, a library of human body models was developed. These bodies are anatomically correct and span the 2nd to 97th percentile of the adult human population in height and weight (height range 154–187 cm, weight range 42–114 kg).10 All tissues in each human body model were assigned with appropriate electromagnetic properties. In the simulations, each of the human body models is placed inside the RF coil in various locations in order to mimic a patient undergoing an MRI scan. The result is a three-dimensional electromagnetic field induced in the human body.

**Cardiac lead modeling**

An electromagnetic model of the cardiac lead at the 1.5-T magnetic resonance frequency (64 MHz) was developed in order to predict the power dissipated in tissue near the lead electrode due to the electric field distribution along the lead body. The cardiac lead modeling must accurately describe two phenomena: (1) the RF energy coupling to the lead body and (2) the RF energy propagation through the lead body to the lead electrode–tissue interface. The lead model is empirically derived by measuring the voltage drop at the lead electrode due to a unit voltage applied along the lead body.11 Because of differences in lead body and electrode constructions between different lead types (e.g., pacing leads, defibrillation leads, active fixation, passive fixation), a different electromagnetic model must be derived for every lead type. Lead models for several different Medtronic pacing and defibrillation leads were experimentally evaluated using this methodology (see further discussion in “Comparative lead electrode heating assessment” in the Results section and “Interpretation of the modeling” in the Discussion).

**Lead routings**

The RF energy that couples to the lead is a function of the electric field along the lead. The electric field in the human body is highly heterogeneous due to anatomic complexity. One thousand clinically relevant and anatomically correct lead routings were developed, created from pacemaker patient chest X-ray images (Figure 3). Using this methodology, it is possible to simulate approximately 2.4 million unique cases (= 19 body models * 9 positions in RF coil * 7 RF coils * 2 electric field polarizations * 1000 lead routes).

**Model validation**

In order to ensure accuracy of the model, model validation was performed in vitro in a body phantom filled with a homogeneous saline solution. The variables included as part of in vitro model validation are shown in Table 1. Simulation results were compared to empirical measurements for well-defined cases. In order to ensure that the model retained validity for a large number of scenarios, values for a number of parameters were varied among extreme cases.

**Part 2: PCT as a function of RF power**

The physiologic effect of lead electrode heating was evaluated via an in vivo canine study, which measured the change in PCT as a function of RF power. Four modified 5086 MRI leads were implanted in eight canines (two leads in the right atrium, two leads in the right ventricle), for a total of 32 leads. The modified leads consist of a micro-coaxial cable connected to the 5086 MRI lead distal end (tip and ring electrodes) and enable accurate quantification of the amount of RF power that reaches the electrode–tissue interface. After implantation, the leads were allowed to mature for 6 weeks, followed by application of RF power to the leads for 15 minutes. PCT was measured before RF application and 5 minutes after RF application. The change in PCT was defined as PCT 5 minutes after RF application minus PCT prior to RF application.

**Results**

**Model validation results**

Figure 4 shows the results of model validation for the different lengths of the CapSureFix MRI SureScan model 5086 MRI lead. Excellent agreement was found between the
simulated and measured powers, showing very good accuracy for the model.

**Comparative lead electrode heating assessment**

In order to further demonstrate the power of the modeling framework presented here, Figure 5 shows the normalized simulated lead electrode dissipated power for several different Medtronic cardiac pacing and defibrillation leads. The dissipated power is normalized to the 5086 MRI 52-cm power. The shaded bars (leads “A”–“E”) correspond to leads that have secured MR Conditional labeling in at least one geography; leads “F”–“I” have not yet been evaluated for MR Conditional labeling.

**5086 MRI lead**

The modeling framework combines simulated RF power dissipated at the lead electrode with the RF-induced PCT change empirically measured in the animal studies. The results of the 5086 MRI animal study are shown in Figure 6. The solid curve shows the mean change in PCT as a function of dissipated power at the lead electrode. The dashed curves show the 95% confidence bounds. These data show a gradual onset of PCT change as dissipated power increases. Also, the change in PCT is linear with dissipated power. Note that for the 5086 MRI lead, clinically relevant dissipated power levels are below approximately 110 mW, where PCT change is extremely unlikely. Clinically relevant dissipated power levels differ by lead.

The final result of the analysis generates a probability that a patient with an implanted cardiac system undergoing an MRI scan will experience a change in PCT. Table 2 lists PCT change probabilities from simulations for the 5086 MRI lead for different scan types (head only, chest only, lower torso/legs only). The probability of PCT change is highest for the chest-only scan, which is to be expected because in this orientation the implanted system is in the middle of the bore, where the electric field, and therefore heating, is highest. The model is powerful and flexible because it allows one to alter different inputs, such as lead route or patient position in the bore, to see the effect on the probability of PCT change.

**Discussion**

Evaluating the impact of MR exposure to patients with cardiovascular implantable electronic devices is largely dependent on the potential for heating induced at the tip of the leads and the changes in capture threshold induced by that heating. Because thousands of permutations of variables and conditions must be accounted for in this evaluation, only a modeling framework can practically provide a full assessment. We required both a simulation model that predicts lead electrode heating (RF power) and an *in vivo* canine study that measured PCT change as a function of RF power. Together this provides a robust assessment.

**Interpretation of the modeling**

When there is a translation of the induced RF power into capture threshold changes, it places the model in specific context of a particular lead. However, it is inappropriate to draw conclusions about the relative safety of the leads in Figure 5 without the *in vivo* data because there are no established requirements for RF-induced lead heating. Industry and regulators are working with traditional standards organizations (International Organization for Standardization [ISO] and Association for the Advancement of Medical Instrumentation [AAMI]) to establish test methods and requirements for each MRI-induced patient hazard. When this work is complete, it is possible that leads F–I will also secure MR Conditional labeling. In the mean time,
regulators will make approval decisions based on their comfort level with the evidence presented.

The power of the modeling approach is the ability to quickly analyze several million combinations of patient attributes, implanted system attributes, and scan sequence permutations to derive the comparative analysis shown in Figure 5. This modeling approach has been adopted by the ISO and AAMI efforts and likely will become the expected method for evaluating MRI-induced lead heating.12

Clinical implications

PCT is the most basic clinical measurement of lead function made by heart rhythm professionals. Variation in PCT occurs within a single encounter, often 0.5 V. Normal variation in PCT, up to 1.0 V, is often observed, without concern for lead system integrity.13 Small MRI-induced elevations of temperature produce small elevations in PCT. These perturbations of capture efficiency are for relatively brief durations because the temperature changes are small. The ability to predict the magnitude of the heating also strongly correlates to patient safety. The data presented here for the 5086 MRI lead show that the probability of an acute 1.0-V change in PCT as a result of an MRI scan is extremely low and likely would not be observed in a clinical setting. The EnRhythm MRI clinical study randomized patients to receive an MRI scan (MRI group) or to not receive an MRI (control group).14 The number of patients experiencing a 0.5-V increase in PCT following MRI (or no MRI) was slightly higher in the control group than in the MRI group; only one subject had a 1.0-V increase in ventricular PCT, and this patient was in the control group. This study concluded that, regarding the significant changes in PCT (atrial and ventricular), the MRI group was statistically equivalent (defined as within 10%) to the control group. It can be observed from these study data that changes of this magnitude may be attributed to normal variation in cardiac electrophysiology. Similarly, the modeling results presented in Table 2 predicted that a change in PCT due to MRI for the 5086 MRI lead is remote.

In the canine study, acute PCT measurements were made 5 minutes after RF application to accelerate the execution of the study. However, the majority of the healing response of cardiac tissue to thermal injury is complete approximately 2 to 4 weeks after RF application. Data gathered in parallel canine studies indicate that acute PCT changes measured 5 minutes postinjection are larger than chronic PCT changes (measured at the 2-week end-point).

This human body modeling framework was used to predict the probability of change in PCT for a population of pacemaker or defibrillator patients with a particular

![Figure 5](image-url) Normalized simulated lead electrode dissipated power for several different Medtronic pacing and defibrillation leads. All dissipated powers are normalized to the dissipated power of lead “A” (5086 MRI 52 cm). Lead models are labeled “A” through “I” on the horizontal axis. Leads “A” through “E” are coaxial pacing leads, whereas leads “F” through “I” are multilumen defibrillation leads. From the figure, one can see there is a 2.5× difference in heating among pacing leads alone and a greater difference (8×) compared to the defibrillation leads. Bars with diagonal lines (“A”–“E”) represent lead models that have secured MR Conditional labeling in at least one geography. Leads “F”–“I” have not yet been evaluated for MR Conditional labeling. It is impossible to evaluate safety from these data alone because an animal study would need to be conducted for each lead model to evaluate the physiologic effect of the dissipated power.

![Figure 6](image-url) Change in pacing capture threshold (PCT) as a function of radiofrequency (RF) power dissipated at the lead tip–tissue interface collected in chronic canine study. ΔPCT was calculated by subtracting the pre-RF PCT measurement from the PCT measurement after each exposure. Solid line shows the mean change in PCT. Dashed lines indicate the 95% confidence bounds. Note that clinically relevant power levels for the model 5086 MRI lead are below approximately 110 mW, where no PCT change is expected.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Probability for MRI-induced pacing capture threshold change (0.5 and 1.0 V) for 5086 MRI leads for different scan types</th>
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<td></td>
<td>0.5 V</td>
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<td>Chest scan only</td>
<td>&lt;1/70,000</td>
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<tr>
<td>Head scan only</td>
<td>&lt;1/10,000,000</td>
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<td>Lower torso only</td>
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MRI = magnetic resonance imaging.
implanted lead undergoing an MRI scan in a 1.5-T scanner. The electromagnetic model depends on the frequency of the RF field, which is directly proportional to the static magnet strength. Therefore, it is important to note that the results for probability of PCT change presented here are not directly applicable to other static magnet strengths (e.g., 0.1 or 3 T). However, similar methodology can be used to analyze lead electrode heating at other static magnet strengths.

**Regulatory implications**

Medtronic Cardiac Rhythm Disease Management has used this modeling data to support regulatory submissions for approval of MR Conditional products. In particular, the modeling data have been the primary vehicle to demonstrate system safety. In addition, two confirmatory clinical trials of SureScan systems, the EnRhythm MRI study and the Advisa MRI study, were supplemental to this modeling data to support regulatory submissions for Food and Drug Administration submissions. Both trials confirmed the SureScan system was safe in the MRI environment when labeling was followed, adding confidence to the modeling approach. 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., Canada, Europe, Japan, and Korea).

**Evaluating products for safety**

Although several cardiac devices are currently market released as MR Conditional, the development of new products as well as the safety evaluation of currently released products for the MRI environment is becoming a focus of many device manufacturers. The development of a lead electrode heating model provides a comprehensive safety evaluation of thousands of scenarios not reachable in a clinical trial and allows evaluation of safety margin by simulation of key variable values beyond the range of standard clinical practice.

Publications reporting case studies of successful MRI scans in patients with implanted cardiac devices are common in journals today. Many describe a small number of patients who have undergone an MRI scan without complications. Because there are thousands of permutations, observational data that only test a few conditions cannot support a claim of safety. The complete assessment of a lead in the MRI environment through modeling is the future 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 provide safety confirmation to physicians and products to patients more quickly.

**Conclusion**

The analysis of MRI risk for patients with implanted pacemakers or defibrillators is extremely complex because of the many variables that influence lead heating: patient size, anatomy, body composition, patient position in the bore, scan sequence (RF power level), lead routing, and lead design. Although clinical studies play an important confirmatory role, demonstration of safety through clinical trials is not practical. Likewise, phantom and animal testing play an important role in deriving the modeling results but at this time are not sufficient by themselves to assess safety.

The modeling framework presented herein provides for the evaluation of millions of combinations of variables in order to predict the probability of PCT change as a result of an MRI scan. The results presented here are specific to the 5086 MRI lead and 1.5-T MRI scanners. Although these results are not directly applicable to leads or scanners other than 1.5 T, a similar methodology can be used to analyze other leads (e.g., pacing, defibrillation, and cardiac resynchronization) and static magnetic strengths. The robustness of the modeling framework provides assurance of safety to physicians, patients, and regulators.

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