Magnetic Resonance Safety Testing of a Newly-Developed Fiber-Optic Cardiac Pacing Lead

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Purpose: To assess magnetic resonance (MR) safety for a newly developed, fiber-optic cardiac pacing lead.

Materials and Methods: MR safety was assessed for the fiber-optic cardiac pacing lead by evaluating magnetic field interactions and heating. Translational attraction and torque were evaluated using a 1.5-Tesla MR system and previously described, standardized techniques. MR imaging-related heating was assessed using a 1.5-Tesla MR system and a transmit/receive, body radiofrequency (RF) coil with the fiber-optic lead positioned to simulate an in vivo condition in a saline-filled phantom. The phantom had dimensions similar to a human subject's torso and head. A fluoroptic thermometry system was used to record temperatures on and near the electrodes of the fiber-optic pacing lead at five-second intervals immediately before and during 20 minutes of MR imaging performed at a whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg. Temperatures were also recorded from a reference site during this experiment.

Results: Magnetic field interactions for the fiber-optic lead were minimal (deflection angle, 23°; torque, +2). The highest temperature change recorded for the fiber-optic cardiac pacing lead and reference site was +0.8°C.

Conclusion: The minor magnetic field interactions and relative lack of heating for the fiber-optic pacing lead indicate that it should be safe for patients with this device to undergo MR imaging procedures using MR systems operating at 1.5-T or less and at a whole-body-averaged SARs up to 1.5 W/kg.

Key Words: magnetic resonance imaging, safety; magnetic resonance imaging, implants; heating; cardiac pacemakers; implants


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Rochester, NY). This innovation could eliminate possible dangers associated with having a conductive pacing wire in a patient undergoing an MRI examination.

For implanted devices, the main objectives of MRI safety testing are to determine the presence of magnetic field interactions and heating (1–8,15,20,23–30). Therefore, the purpose of this investigation was to use in vitro testing techniques to determine MR safety at 1.5-Tesla/64 MHz for this fiber-optic cardiac pacing lead.

**MATERIALS AND METHODS**

**Fiber-Optic Cardiac Pacing Lead**

The fiber-optic cardiac pacing lead (Biophan Technologies, Inc., Rochester, NY) is intended for use via connection to the Temporary Photonic Pulse Generator (Model X-801, Biophan Technologies, Inc., Rochester, NY). This cardiac pacing lead is made from 200-μm fiber-optic cable. The distal end of the lead has two electrodes (silver-plated, thin-wall copper; “tip” electrode and “ring” electrode) designed to stimulate the heart (Fig. 1). Within the ring and tip portions of the lead are a power converter, resistor, and capacitor. Inside the ring electrode is a power converter that changes light energy into electrical energy for heart stimulation. The pulse generator (Temporary Photonic Pulse Generator, Model X-801) produces a 1-millisecond pulse (variable from 0.1 to 30 msec), which drives a 150-milliwatt gallium-arsenide laser. The light pulse is connected to the distal end of the fiber-optic lead where it illuminates a band of six gallium-arsenide photo diodes. The diodes are electrically connected in series to produce a voltage pulse of four volts, which drives the tip and ring electrodes to stimulate the heart. Accordingly, this device is capable of generating sufficient current to pace the heart. The overall dimensions for the fiber-optic cardiac pacing lead are as follows: lead length (tip to connector) = 145 cm, diameter = 0.5 cm, ring length = 1.8 cm, tip length = 0.6 cm, and distance between the ring and tip = 1.0 cm (Fig. 1).

**MR System**

MR safety tests for magnetic field interactions (translational attraction and torque) were conducted using a 1.5-Tesla/64 MHz MR System (Signa, General Electric Medical Systems, Milwaukee, WI). For the evaluation of MRI-related heating, this MR system was used with a circularly polarized, quadrature-drive, transmit/receive body RF coil.

**Assessment of Magnetic Field Interactions**

Tests for magnetic field interactions were performed on the fiber-optic cardiac pacing lead using a previously described, standardized procedure known as the deflection angle test (23–29). This test was conducted using a shielded, 1.5-Tesla MR system (General Electric Medical Systems, Milwaukee, WI). A 15-cm length of thin thread (weighing less than 1% of the weight of the device) was attached to the fiber-optic pacing lead. The thread with the device was then attached to a plastic protractor so that the angle of deflection from the vertical could be measured. The test fixture consisted of a sturdy structure capable of holding the fiber-optic pacing lead in the proper position without deflection of the test fixture, and contained a protractor with 1° graduated markings, rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically. The test fixture also had a plastic bubble level device permanently affixed to the top to ensure proper orientation in the MR system during the test procedure. Sources of forced air movement within the MR system bore were shut off during the measurements. The accuracy of this measuring device is ± 0.5° based on the ability to read the protractor in the MR system (24–29).

The deflection angle test was conducted at the position in the shielded 1.5-T MR system where the spatial gradient of the magnetic field was previously determined to be at a maximum to determine the magnetic field attraction with regard to an extreme (24–29). This was done to assess translational attraction with regard to an extreme magnetic field exposure condition (23–29). The highest spatial gradient for the MR system that was used in this investigation was 450 gauss/cm and
occurred at a radially off-axis position, 35 cm from the entrance of the bore of the magnet.

To facilitate measurement of the deflection angle for the 147-cm long pacing lead, this device was formed into a coil with an approximate diameter of 10 cm. In addition, deflection angle measurements were performed on the distal (electrodes) and proximal (connector) ends of the fiber-optic pacing lead. Deflection angles were measured three times for the device and averaged.

The next assessment of magnetic field interactions for the fiber-optic cardiac pacing lead was conducted to qualitatively determine the presence of magnetic field-related torque. This procedure involved the use of a flat plastic material with a millimeter grid on the bottom, as previously described (24–29). The metallic components of the fiber-optic pacing lead (i.e., the distal and proximal ends of the lead) were situated on the test device in an orientation that was 45 degrees relative to the 1.5-Tesla static magnetic field of the MR system. The observation process was facilitated by having the investigator inside of the bore of the magnet during the test procedure. The device was moved 45 degrees relative to its previous position and again observed for alignment or rotation. This process was repeated to encompass a full 360 degrees rotation of positions for the device (24–29).

The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild torque, the device slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the device aligned gradually to the magnetic field; +3, strong torque, the device showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the device showed very rapid and very forceful alignment to the magnetic field (4–8). Several peer-reviewed, scientific publications support the use of this methodology to qualitatively assess magnetic field-related torque for a metallic implant or device in association with a MR system (24–29).

Assessment of MRI-Related Heating

MRI-related heating was determined for the fiber-optic cardiac pacing lead by monitoring temperatures during MR imaging performed at a relatively high level of RF power deposition with the device placed inside of a specially constructed, saline-filled phantom.

Phantom

The in vitro evaluation of MRI-related heating for the fiber-optic cardiac pacing lead required the use of a special plastic (bottom thickness, 1.3 cm; side thickness, 0.6 cm) phantom designed to approximate the size and shape of the head and torso of a human subject (30) (Fig. 2). The dimensions of this phantom were as follows: “head” portion, 16.5 cm wide, 29.2 cm long, 16.5 cm high; “torso” portion 43.2 cm wide, 61.0 cm long, 16.5 cm high. Because most heating during MRI is due to eddy currents in the head and body, it was unnecessary to include extremities in this phantom for the assessment of MRI-related heating of a metallic object (30–33).

To achieve geometric and electrophysiologic conditions similar to in vivo conditions, the phantom was filled with a 0.9% sodium chloride solution to permit conductive fluid to surround the lead, as described by Sommer, et al (20) and Shellow, et al (21). We have described the saline-filled phantom was 90 kg. Note that because this phantom and experimental set-up lacks “blood flow”, it further simulates a worst case or extreme condition used to assess MRI-related heating of the lead for the fiber-optic cardiac pacing lead (20,21,30–33).

Positioning of the Fiber-Optic Cardiac Pacing Lead

The fiber-optic pacing lead was fixed to a plastic frame using plastic pegs and positioned to simulate a worst case in vivo orientation while in the MR system (i.e., located close to the inside of the bore of the MR system) (Fig. 2) (20,31,32). The use of the plastic frame and pegs permitted placement of the lead within the phantom to approximate common clinical practice. The normal anatomic distribution for a patient in the supine position with an implanted lead entering from the femoral vein (i.e., for the greatest length of the lead present in the MRI environment) was simulated (20). A semicircular configuration of lead in the coronal plane was chosen to achieve a maximal magnetic induction area for the lead as it was placed in the center (i.e., anterior to posterior position) of the phantom (20,31,33).

MR Imaging

A T1-weighted spin-echo pulse sequence was used for imaging as follows: total imaging time, 20 minutes; axial plane; repetition time, 135 msec; echo time, 20 msec; field of view (FOV), 48 cm; imaging matrix, 256 × 128; section thickness, 20.0 mm; number of section locations, four; number of excitations, 27; number of echoes, four; phasing direction, anterior to posterior; transmitter gain, 200. This pulse sequence produced a whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg and a spatial peak SAR of 3.0 W/kg. This level of exposure to RF energy exceeds that typically used for most types of clinical MRI procedures (however, we acknowledge that the current recommendations from the Food and Drug Administration permit exposure to RF energy during MRI up to a whole-body-averaged SAR of 4.0 W/kg for subjects with normal thermoregulatory function). Also, note that this exposure to RF energy was similar to that indicated for assessment of other implanted devices (20,24–31,33). The center section location for MR imaging (landmark) was directly through the tip of the lead, again to create a worst-case MRI-related heating scenario (30,31).
Temperature Recordings

Temperature recordings were obtained using a Luxtron Model 3000 Fluoroptic Thermometry System (Luxtron, Santa Clara, CA) previously demonstrated to be MR-compatible and unperturbed at static magnetic field strengths up to 9.0-Tesla (i.e., nuclear magnetic resonance [NMR] spectrometer). This thermometry system has small fiber-optic probes (0.5 mm diameter) that respond rapidly (response time, 0.25 seconds), with an accuracy and resolution of ± 0.1°C.

Because the greatest heating during MRI is known to occur at the electrodes for leads (15,20,30,31,33), fluoroptic thermometry probes were attached to record representative temperatures during the MRI-related heating experiment, as follows: probe 1, placed on middle of distal electrode; probe 2, placed on middle of second electrode; and probe 3, placed 1.0 mm from the “tip” of the distal electrode. In addition, a thermometry probe was placed in the saline-filled phantom at a position removed (approximately 40 cm away from the tip) from the fiber-optic pacing lead to record a reference temperature during the heating experiment. It should be noted that the positions of the fluoroptic thermometry probes were inspected and verified immediately before and after the in vitro experiment.

Experimental Protocol

The saline-filled phantom was allowed to equilibrate to the environmental temperature for two hours before the assessment of MRI-related heating for the fiber-optic pacing lead. The lead and thermometry probes were attached to the plastic frame and then placed inside of the saline-filled phantom. The room temperature and temperature of the bore of the MR system were 20.1°C, with relative humidity of 45%. The MR system fan was not on during this experiment. Baseline temperatures were recorded at 10-second intervals for two minutes. MRI was then performed for 20 minutes with temperatures recorded at 10-second intervals. This basic protocol has been previously used for assessment of lead-based, implantable devices (30). The highest temperature changes are reported herein.

RESULTS

Magnetic Field Interactions

The fiber-optic cardiac pacing lead exhibited a deflection angle of 23°. The deflection angle measured for the distal end (electrodes) was 3° and the deflection angle measured for the proximal end (connector) was 68°. The qualitative assessment of torque showed a value of +2 (moderate torque, the device aligned gradually to the magnetic field) for the distal end and +4 (very strong

Figure 2. Materials and methods used for MRI-related heating of the fiber-optic pacing lead. a: This figure shows the fiber-optic pacing lead placed on plastic pegs on a plastic frame to permit simulation of a worst case positioning scenario (i.e., the pacing lead was primarily located close to the bore of the MR system). Fluoroptic thermometry probes were attached to the fiber-optic pacing lead to record temperatures. b: The plastic frame with the fiber-optic pacing lead and fluoroptic thermometry probes were placed into a saline-filled phantom. The phantom then underwent MR imaging at 1.5-Tesla using the transmit/receive body RF coil.
torque, the device showed very rapid and very forceful alignment to the magnetic field for the proximal end of the lead.

**MRI-Related Heating**

The highest temperature change measured for the fiber-optic cardiac pacing lead was +0.8°C. This temperature change was measured on the middle of the ring electrode (fluoroptic thermometry probe 2) and at the 1.0-mm position from the tip of the distal end of the lead (fluoroptic thermometry probe 3). The highest temperature change recorded for the reference temperature was +0.8°C.

**DISCUSSION**

Currently, the basic design of a cardiac pacemaker includes an electrically-conductive, metallic lead that connects a temporary (wearable) or implantable pulse generator to the heart. In recognition of the inherent problems with this design (magnetic field interactions, heating, EMI, etc.), a fiber-optic cable and a semiconductor laser that operates under very low power to regulate the heart beat (fiber-optic lead with a photonic-based pulse generator) has been developed to replace the standard pacemaker components known to be problematic. This is the first study of MRI safety for the fiber-optic cardiac pacing lead, the most critical component of what eventually will become the MRI-compatible temporary cardiac pacemaker. The use of a temporary pacemaker may be applied for unstable patients or patients with cardiac arrhythmias who require MRI procedures. Additionally, an MRI-compatible temporary pacemaker may be used as means of performing non-exercise-induced stress in combination with cardiac MRI techniques to evaluate patients with suspected cardiovascular disease.

Magnetic field interactions create problems for patients with certain metallic implants in the MRI environment (1–8,23–29). Therefore, it is imperative to use in vitro testing techniques to carefully characterize magnetic field interactions for a device in order to prevent injuries or other hazards related to movement or dislodgment of the object (2–8,21,24–29). Thus, this study evaluated magnetic field interactions for the fiber-optic cardiac pacing lead.

Radiofrequency (RF) and pulsed gradient magnetic fields used for MRI induce currents in the body (1,2,6,7,15,19,20,22,30–33,34–37). It is well known that implants that have electronically-activated or electrically-conductive components can locally increase these currents and, under certain operational conditions, excessive heating of biomedical devices may occur in association with MRI procedures (1–8,15,19,20,30–37). For example, exorbitant temperature elevations from MRI-related heating have been reported for cardiac pacemakers, indwelling catheters with metallic components (e.g., thermoliation catheters), guide wires, disconnected or broken surface RF coils, or improperly used physiologic monitors, resulting in first, second, or third-degree burns (2–8,15,19,20,22,31–37). Thus, thermal injury must be considered as a possible adverse outcome if RF power is transmitted in the direct vicinity of the implanted device or its attached components. Of note is that there is a tendency for excessive heating to occur in looped or coiled devices because electrical currents are easily induced in these shapes during MRI (6,7,19,20,30–37). Therefore, in consideration of the above, MRI-related heating was assessed for the fiber-optic cardiac pacing lead.

Tests for magnetic field interactions were conducted on the entire lead, the “tip” of the lead, and the “connector” of the fiber-optic cardiac pacing lead. According to this information, the entire lead exhibited a deflection angle of 23°, the tip showed a deflection angle of 3°, and the connector showed a deflection angle of 68° when tested using the 1.5-Tesla MR system. The qualitative torque value was +2 for the tip of the lead and +4 for the connector of the lead during exposure to the 1.5-Tesla MR system (it was not possible to determine torque for the entire pacing lead nor was it deemed necessary in consideration of its intended use).

According to the American Society for Testing and Materials (ASTM) document (23), if a device deflects less than 45 degrees, then the magnetically-induced deflection force is less than the force on the device due to gravity (i.e., its weight). Therefore, the entire lead (deflection angle, 23°) passes the ASTM acceptance criteria, demonstrating an acceptable level of magnetic field interaction that will not pose an additional risk to a patient undergoing a MRI procedure. Additionally, the deflection angle of 3° measured for the tip of the lead passes the ASTM safety criteria for magnetic field interactions. While the deflection angle for the connector portion of the fiber-optic pacing lead exceeds the ASTM criteria for a device to be considered MR safe (i.e., 68°), it should be noted that this portion of the lead is not implanted in the patient, as it will be connected to the Temporary Photonic Pulse Generator (Model X-801, Biophan Technologies, Inc., Rochester, NY). With regard to the torque value of +2 measured for the tip of the lead, this is considered to be a relatively low value and should not present a problem to a patient in the 1.5-Tesla MRI environment. Regarding the +4 torque value for the connector, this is again considered to be a non-issue in consideration of the intended use of the fiber-optic cardiac pacing lead. Therefore, based on the findings for magnetic field interactions and in consideration of the intended use of the lead, there should be no additional risk to a patient with this device undergoing a procedure using an MR system operating at 1.5-Tesla or less.

According to the findings for MRI-related heating, the highest temperature change measured for the fiber-optic cardiac pacing wire was +0.8°C in association with MRI performed at a whole-body-averaged SAR of 1.5 W/kg. The highest temperature change recorded for the reference probe used to monitor the results of the RF power absorption for the saline-filled phantom was also +0.8°C. Thus, the only MRI-related temperature increase for the fiber-optic cardiac pacing wire was due to the heating of the saline bath of the phantom.

By comparison, in an in vitro evaluation of 44 commercially-available pacemaker leads, Sommer, et al (20) reported the maximum temperature change measured...
at the lead tip was 23.5°C in association with MRI performed at 0.5-Tesla and a whole-body-averaged SAR of 1.3 W/kg for 10 minutes. Additionally, Achenbach, et al (15) reported a peak temperature change of 63.1°C measured for a temporary pacing electrode that occurred within 90 seconds of MRI (the SAR was not reported). Furthermore, MRI at 1.5-T and an SAR of 3.0 W/kg has been shown to cause severe necrosis in the mucous membranes of dogs with transesophageal cardiac pacing leads in situ (39).

Previous attempts to develop a MRI-safe cardiac pacing lead have been reported by Jerzewski, et al (38) and Hofman, et al (39). Jerzewski, et al (38) modified a commercially available pacing catheter by leaving out the stainless steel catheter shaft braiding and using 90% platinum/10% iridium electrodes at the tip. The electrical wiring was made of nearly pure copper of reduced conductance (38). Thus, this pacing device still involved the use of conductive metallic materials. MRI was performed on rabbits with this temporary pacing lead at 1.5-Tesla. These laboratory animals were primarily monitored for extrasystolic cardiac contractions (38). Notably, Jerzewski, et al (38) did not assess magnetic field interactions or heating for the cardiac pacing lead but rather evaluated imaging artifacts, which is not a MR safety issue (1.4–6.23). In fact, in a letter to the editor, Hofman (40) pointed out that “...before it can be claimed that cardiac pacing during MRI is safe, the issue of heating of tissue around the pacing catheter should be addressed.”

In an investigation performed in laboratory dogs, Hofman, et al (39) studied the feasibility of transesophageal cardiac pacing during MRI at 1.5-Tesla and concluded that tissue around the catheter tip may become heated. As previously stated, severe necrosis in the mucous membranes of dogs with transesophageal pacing leads in situ has been found during MRI in combination with high levels of RF energy. Therefore, while it may be possible to perform transesophageal atrial pacing during MRI, it requires relatively low levels of RF energy, which is likely to be impractical for most anticipated clinical uses of this technology.

In view of the previously published reports on cardiac pacemakers and, more specifically, pacing leads, the information from the present study on the fiber-optic cardiac pacing lead is particularly compelling from a MRI safety viewpoint. Notably, this unique technology may be applied to other devices that require leads but are known to present potential hazards to patients undergoing MRI procedures (e.g., neurostimulation systems) (30).

One final consideration for the fiber-optic cardiac pacing lead is the issue of electromagnetic interference (e.g., inappropriate or rapid pacing due to pulsed gradient magnetic fields and/or pulsed RF from the operating MR system, with the pacing lead acting as an antenna). From a theoretical consideration, because of the “fiber-optic nature” of this specially-designed pacing lead, there should be no problems related to this device acting like an antenna during MRI procedures because it should be immune from such problems. Other devices (pulse oximeters, cutaneous blood flow monitors, electrocardiographic systems, thermometry systems, etc.) have likewise incorporated fiber-optic interfaces to the patients to successfully prevent EMI-related problems from occurring in the MRI environment (2–8). However, additional investigation directed at addressing the EMI aspects of the fiber-optic cardiac pacing lead in the MRI setting is warranted.

In conclusion, the results of the MRI safety tests for the fiber-optic cardiac pacing lead indicated there were minor magnetic field interactions associated with exposure to the 1.5-Tesla MR system. In addition, there was essentially no MRI-related heating for the fiber-optic lead in association with MRI conducted at a whole-body-averaged SAR of 1.5 W/kg. Based on this information, it appears this newly developed device will not present an additional hazard or risk to patients undergoing MRI procedures under the conditions used for this evaluation. Obviously, the findings of this study have important implications for patients who require cardiac pacing during MR imaging.

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REFERENCES