

# Determinants of gradient field-induced current in a pacemaker lead system in a magnetic resonance imaging environment

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**BACKGROUND** The determinants of low-frequency-induced current by magnetic resonance imaging (MRI) gradient fields in a pacemaker lead system are largely unknown.

**OBJECTIVE** The purpose of this study was to determine the magnitude of MRI low-frequency-induced current in an implanted pacemaker lead system and to investigate in vivo determinants of low-frequency-induced current in an animal model.

**METHODS** Six mongrel dogs underwent conventional single-chamber pacemaker implantation with a current recorder connected in series. Pulse generator (PG) was programmed to V00 120 bpm with subthreshold output. MRI was performed in a 1.5-T scanner. Low-frequency-induced current was recorded during unipolar pacing, bipolar pacing, and bipolar pacing with the PG case electrically isolated from the pocket. In each mode, low-frequency-induced current was recorded with and without a large loop of additional lead connected in series.

**RESULTS** With a conventional implant, low-frequency-induced current was  $\leq 0.5$  mA in all three pacing modes. With five external

loops, the magnitude of low-frequency-induced current increased to  $>30$  mA, with consistent myocardial capture in unipolar and bipolar pacing. However, in bipolar pacing with the PG electrically isolated from the pocket, low-frequency-induced current decreased to  $<0.5$  mA with no myocardial capture even with additional looped leads.

**CONCLUSION** Under conventional implant conditions, the magnitude of low-frequency-induced current is  $<0.5$  mA and is unlikely to cause myocardial capture; however, arrhythmia induction cannot be excluded. With sufficient increase in effective loop area (additional looped leads), direct myocardial capture by the low-frequency-induced current is possible. In this study, breaking the return pathway by electrically isolating the PG case from the circuit abolished low-frequency-induced current.

**KEYWORDS** Pacemaker; Magnetic resonance imaging; Induced current; Interaction; Determinants

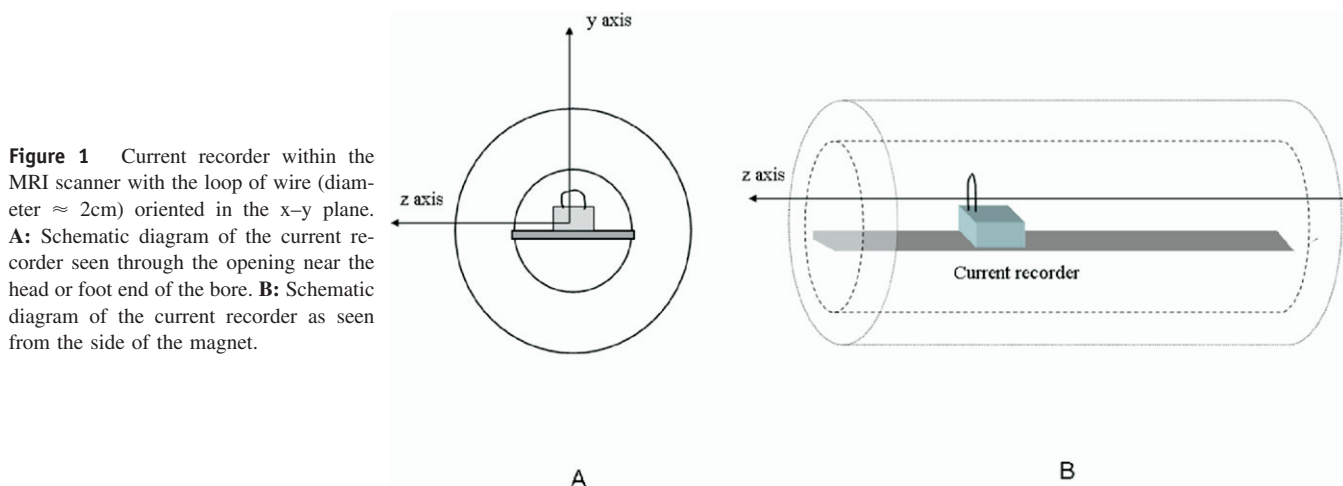
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## Introduction

Magnetic resonance imaging (MRI) has emerged as an important diagnostic tool with an increasing number of clinical applications. The majority of patients can safely undergo MRI and reap the benefits; however, MRI is contraindicated in patients with implantable devices such as pacemakers and defibrillators.<sup>1–3</sup> Studies have addressed concerns about device displacement and lead heating, and a number of patients with implanted devices have successfully undergone MRI without serious consequences.<sup>4–7</sup> Fontaine et al<sup>8</sup> reported a case of rapid cardiac pacing occurring in a patient during MRI and raised the possibility of MRI-related induction of currents in the pacemaker leads. MRI systems use three types of magnetic fields to generate images: (1) a strong static magnetic field, (2) a radiofre-

quency (RF) time-varying magnetic field, and (3) a time-varying gradient magnetic field. According to the laws of physics (i.e., Maxwell's equations), the time-varying magnetic fields can generate time-varying electric fields. For a 1.5 T-MRI system, the RF resonance frequency for hydrogen is 64 MHz. This *high-frequency* (RF) time-varying electromagnetic field potentially can transfer energy into implanted electronic devices and cause thermal injury to tissue near the tissue–electrode interface.<sup>9–12</sup> MRI gradient fields, on the other hand, have a much lower frequency (1–10 kHz) and are used to provide spatial information. The interaction between the time-varying MRI gradient field and the conductive loop formed by the pacemaker-lead system can be considered an instance of electromagnetic induction, per Faraday's law. Whether the gradient fields can induce sufficient electromotive force and current in the implanted system to result in undesired cardiac stimulation is unknown. The purpose of this study was twofold: (1) to determine the magnitude of MRI *low-frequency* (gradient field)–induced current in an implanted pacemaker-lead system and (2) to investigate the in vivo determinants of low-frequency-induced current in an animal model.

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## Methods

### In vitro experiments

Gradient fields present small transient increments or decrements in the main magnetic field. The magnitude of these transients varies as a function of location in the scanner, but the gradient fields have a vector orientation along the  $z$ -axis (main axis of the magnet cylinder). To demonstrate the  $z$ -directed component of the  $x$  gradient, we mapped the  $x$  gradient using a custom-made current recorder. The current recorder was a battery-operated MRI-compatible data acquisition unit, which digitized current waveforms and streamed them out of the MRI environment via fiberoptic cables to an external storage computer. The sampling rate was 40 kHz, with a digital bandwidth of 20 kHz and analog bandwidth of 8 kHz. The minimum measurable low-frequency-induced current waveform was approximately 0.5 mA peak to peak, with a maximum measurable limit of 30 mA. A small loop of conductive wire (diameter  $\approx 2$  cm) was attached to the current recording device and placed in the center of the MRI scanner, with the loop oriented in the  $x$ - $y$  plane, that is, perpendicular to the  $B$  field (Figure 1). The  $y$ -gradient and  $z$ -gradient coils were manually turned off by programming the magnitude to a zero value. MRI was performed with clinical scanning protocols and included fast spin echo and gradient echo imaging using the body coil. The position of the loop in the magnet was moved in 10-cm increments away from the center of the magnet, both outside toward the opening of the magnet in the  $z$  direction and from side to side in the  $x$  direction. The scan sequence was repeated in each location, and the current induced in the loop was recorded throughout the MRI scan. Following this step, the loop was oriented in the  $x$ - $z$  plane and the experiment repeated.

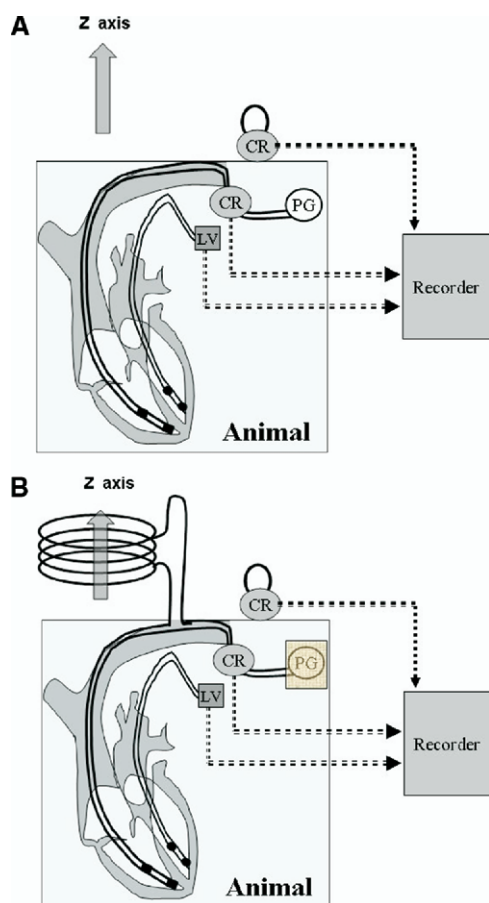
### In vivo experiments

After anesthesia was induced, a pacemaker system (Insignia Ultra, Guidant, Boston Scientific, Boston, MA) was implanted in each of six adult mongrel dogs (weight 30–35 kg). Anesthesia was induced with sodium thiopental 15–20 mg/kg IV and maintained with 1% to 1.5% isoflurane on an

anesthesia ventilator throughout the MRI scan. An arterial line was placed in the right femoral artery for hemodynamic monitoring. Under fluoroscopic guidance and sterile conditions, an active fixation ventricular lead (Fineline II, Boston Scientific, Boston, MA) was inserted through the right jugular vein to the right ventricular apex. The proximal part of the lead was tunneled subcutaneously and connected to the pacemaker, which was inserted in a pocket created in the subcutaneous tissues of the upper left thorax. A custom-made current recorder was connected in series to the pacemaker lead system (Figure 2A). In addition, intracardiac electrograms were recorded by a 6Fr bipolar electrophysiologic recording (Biosense Webster, Diamond Bar, CA, USA) catheter placed via the left external carotid artery and passively positioned in the left ventricular apex. The left ventricular recording catheter provided continuous independent recording of ventricular depolarization during the entire experiment. Following this step, the animal was advanced to the scanning position, with the heart at the center of the magnet, and MRI scanning was implemented. Recordings of lead current (low-frequency-induced current) were made after the animal was placed on the MRI table through the time it advanced to the imaging position, during the scanning period, and as the animal was removed from the scanner. The MR gradient fields were measured by a small loop of lead attached to a second current recorder that was placed in the MRI magnet close to the other current recorder perpendicular to the  $B$  field. Surface ECG was recorded continuously using a four-lead General Electric ECG monitoring system (Boston Scientific, Boston, MA).

### MRI protocol

The animals underwent MRI scanning in a 1.5-T scanner (GE Healthcare, Waukesha, WI, USA). The protocol was similar to clinical cardiac imaging protocols and included a localizing sequence followed by fast spin echo and echo planar imaging. Nongated fast spin echo (FSE) sequences were performed in the axial plane with double-inversion recovery blood suppression pulses. TR was 300 ms, and TE was 10 ms. Slice thickness was 5 mm. Matrix and field of



**Figure 2** **A:** Schematic diagram of normal implant with the current recorder (CR) connected in series to the pulse generator (PG) and the right ventricular bipolar lead. An additional bipolar left ventricular catheter (LV) is also seen. A second current recorder with a small loop of lead attached to it was placed close to the first recorder on the chest wall as shown. The output from the current recorders and the left ventricular catheter were recorded by fiberoptic cables. **B:** Schematic diagram of implant with additional looped leads (diameter  $\approx 20$  cm) connected in series to the PG lead system. The PG electrically isolated from the animal by wrapping the PG in nonconductive material also is shown.

view were  $512 \times 512$  and 24 cm, respectively. The number of excitations was increased to yield a scan time of approximately 2.5 minutes. Gradient echo sequences were performed in the axial plane using steady-state free precession imaging. Flip angle was  $40^\circ$ , and TE was set to minimum. For cine imaging, slice thickness was 8 mm. Matrix and field of view were  $256 \times 256$  and 36 cm, respectively. No images were acquired during this study, therefore no receiving coils other than the MRI body coil was used.

### Pacemaker programming

Low-frequency-induced current in the PG lead circuit during MRI scanning was recorded in three pacing configurations: (1) unipolar pacing mode, (2) bipolar pacing mode, and (3) bipolar pacing with the pulse generator electrically isolated from the animal inside the pocket by wrapping it in nonconductive material (Figure 2B). All three protocols were performed in all six animals. In each of these three configurations, low-frequency-induced current was re-

corded with and without a large loop of lead (diameter  $\approx 20$  cm) connected to the pacemaker lead system in series and the loop was oriented in the  $x$ - $y$  plane perpendicular to the B field axis during MRI scanning. Up to five additional lead loops were connected in series to simulate a worst case scenario (Figure 2B).

The pacemaker was interrogated, and the myocardial capture threshold via the right ventricular lead was determined. The pacemaker was programmed to VOO mode, the rate was set to 20 beats above the animal intrinsic heart rate, and the output was set to 0.1 V at 0.5 ms to perform subthreshold pacing (capture threshold  $\geq 0.5$  V at 0.5 ms for all animals). The reason for the subthreshold pacing is as follows. The impedance of the PG lead circuit varied during each pacing cycle; hence, low-frequency-induced current was recorded throughout the pacing cycle to investigate the effect of changing impedance on the magnitude of low-frequency-induced current. The pacer output waveform was recorded simultaneously to determine the timing of induced current to the "pacing window." The pacing window is defined as the time in which a switch in the pacemaker internal circuitry closes to deliver a pacing pulse between the cathode and anode. Further, myocardial capture (paced QRS complex) on surface ECG was an indirect assay of low-frequency-induced current. Finally, in VOO mode the pacer output amplitude was set to threshold value, and the ability of low-frequency-induced current to cause loss of myocardial capture was evaluated.

In all animals, low-frequency-induced current from the device lead system, the MR gradient field, the electrical recording from the left ventricular catheter, and the surface ECG were obtained simultaneously with careful recording of MRI pulse sequence. Surface ECG was recorded by a Magnitude MRI monitor (In Vivo Research Inc, Orlando, Florida), and then the animal was removed from the MRI scanner table. After reinterrogation of the pacemaker, the animal was euthanized.

## Results

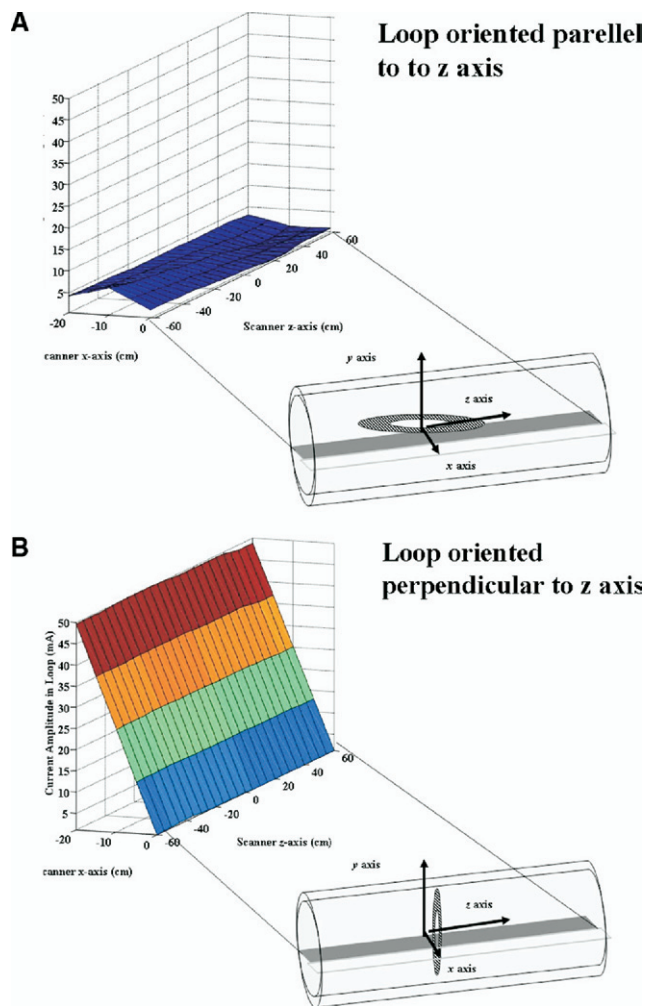
### In vitro experiments

Figure 4 shows the mapped  $x$  gradient field as a function of its position in the  $x$  and  $z$  planes. The maximum low-frequency-induced current recorded was  $<5$  mA with the loop of wire in the  $x$ - $z$  plane (Figure 3A) as the loop's cross-sectional area is minimally exposed to a  $z$ -directed  $dB/dt$ . However, low-frequency-induced current for a loop of wire in the  $x$ - $y$  plane varied with position along the  $x$ -axis (Figure 3B). In this situation, the loop's cross-sectional area was maximally oriented to a  $z$ -directed  $dB/dt$ . There was a linear increase in magnitude of low-frequency-induced current with  $>50$  mA recorded closer to the edge of the bore of the magnet in either direction from the center ( $x = 0$ ), which corresponded to the increase in magnitude of the  $x$  gradient.

### In vivo experiments

All six mongrel dogs underwent successful pacemaker implantation followed by MRI scanning without any compli-





**Figure 3** **A:** Graph showing mapped  $x$  gradient field in half of the MRI scanner with the large loop of lead oriented in the  $x$ - $z$  plane. **B:** Graph showing mapped  $x$  gradient field in half of the MRI scanner with the large loop of lead oriented in the  $x$ - $y$  plane.

cations. After device implantation, none of the dogs exhibited any ventricular or atrial premature beats prior to MRI scan. All devices could be successfully interrogated following the MRI scans. No differences in the lead parameters were noted before and after the MRI experiment.

The maximum low-frequency-induced currents recorded in the three configurations with and without additional looped leads are shown in Figure 4. Maximum low-frequency-induced current measured through the current recorder connected to the pacemaker lead system was  $\leq 0.5$  mA in all animals in both unipolar and bipolar lead configuration. When an external loop (diameter  $\approx 20$  cm) was added in series with the right ventricular lead and placed perpendicular to the  $z$ -directed  $dB/dt$  (aligned with the bore, offset from the isocenter, and near the end of the bore), a maximum low-frequency-induced current  $\leq 9.0$  mA was recorded in the unipolar configuration. With an external additional loop, compared to bipolar configuration, the maximum low-frequency-induced current was greater in unipolar configuration ( $\leq 1.5$  mA vs

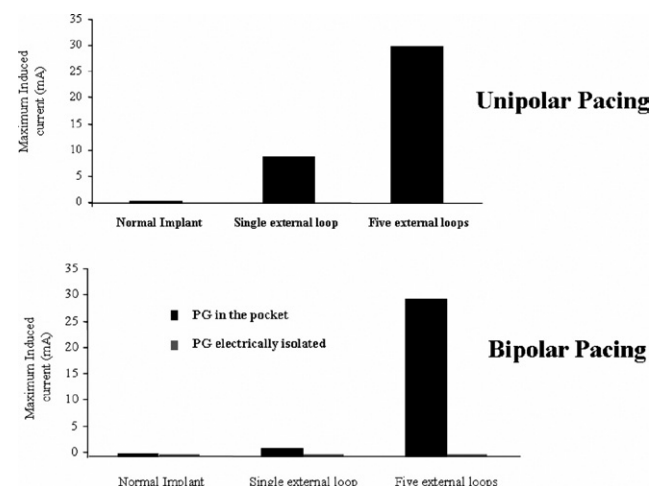
$\leq 9.0$  mA). Maximum low-frequency-induced current increased to  $>30$  mA (upper limit of current recorder) with five additional loops in both unipolar and bipolar configurations.

### Effect of pulse generator on low-frequency-induced current

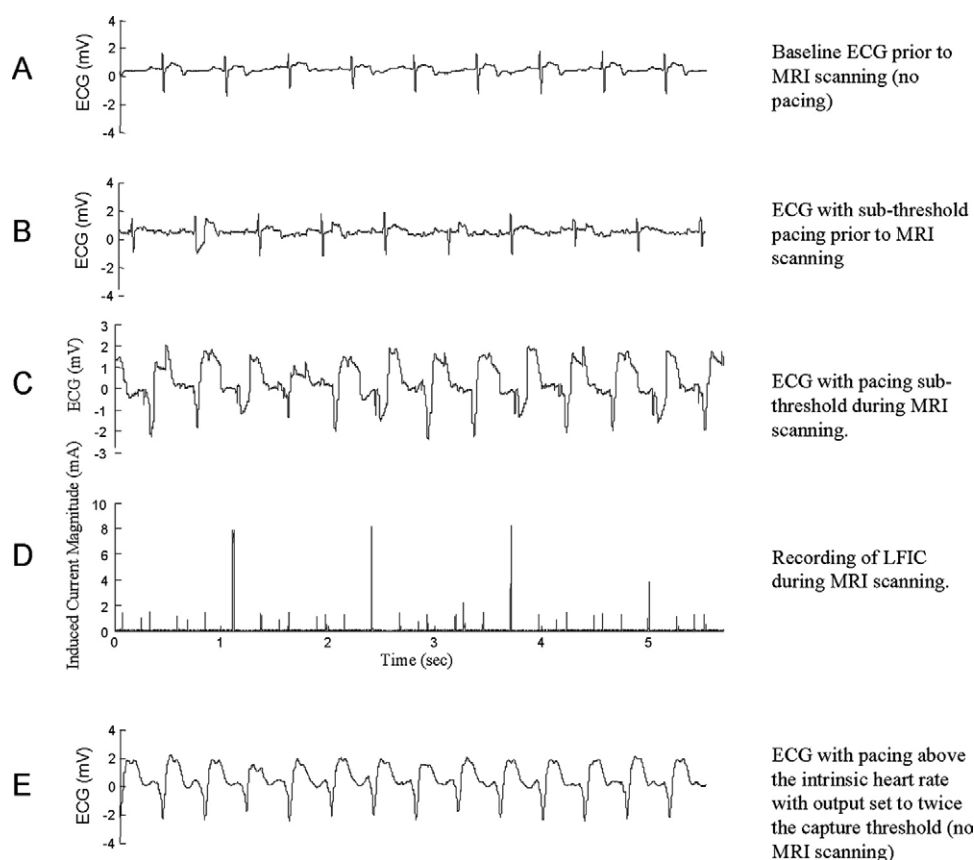
With the pacemaker programmed to VOO at 120 bpm and pacing amplitude set to a minimum value (0.1 V at 0.5 ms), recordings of the low-frequency-induced current were obtained in bipolar configuration. Low-frequency-induced current recorded by the current recorder was consistently  $<0.5$  mA with infrequent ventricular capture beats. However, with the addition of five lead loops in series, a maximum low-frequency-induced current  $>30$  mA was recorded and consistent myocardial capture beats were observed (Figure 5). When the PG was removed from the pocket and electrically isolated from tissue (infinite impedance), all low-frequency-induced current vanished, with no myocardial capture. Replacing the PG in the pocket consistently led to low-frequency-induced current induction and subsequent myocardial capture beats. Similar results were obtained in the unipolar lead configuration.

### Timing of low-frequency-induced current to the pacing cycle

Simultaneous recordings of the gradient field from the second current recorder and the low-frequency-induced current from the current recorder connected to the PG lead system in series are shown in the upper part of Figure 6. Although continuous gradient activity is observed during MRI scanning, low-frequency-induced current is recorded intermittently. Analysis of the pacing cycle and the generated low-frequency-induced current revealed that the timing of the low-frequency-induced current corresponded to the pacing window (minimal impedance), and no low-frequency-induced current was recorded outside the pacing window (maximal impedance). The low



**Figure 4** Maximum low-frequency-induced current recorded in unipolar, bipolar, and bipolar configuration with electrical isolation of the pulse generator (PG). See text for details.



**Figure 5** Low-frequency-induced current (LFIC) during MRI scanning in a pacemaker (PG) lead system with additional looped leads connected in series. **A:** Baseline ECG prior to MRI scanning shows the animal's intrinsic sinus rhythm with a narrow QRS complex. **B:** PG was programmed to pace VOO 120 bpm with a subthreshold output. No paced beats are seen during subthreshold pacing prior to MRI scanning. **C:** MRI scanning during subthreshold pacing results in low-frequency-induced current with consistent myocardial capture. **D:** Simultaneous recording of low-frequency-induced current that resulted in consistent myocardial capture. Lower impedance within the pacing window resulted in a periodic increase in the magnitude of the low-frequency-induced current. **E:** QRS morphology during VOO pacing 20 beats above the animal's intrinsic heart rate is shown for comparison. Note that the QRS morphology with myocardial capture by a low-frequency-induced current is similar to paced QRS.

impedance pacing window extends for 10 to 15 ms after delivery of the pacing pulse, accounting for the low-frequency-induced current recorded during this window period.

### Induced distortion of pacer output waveform

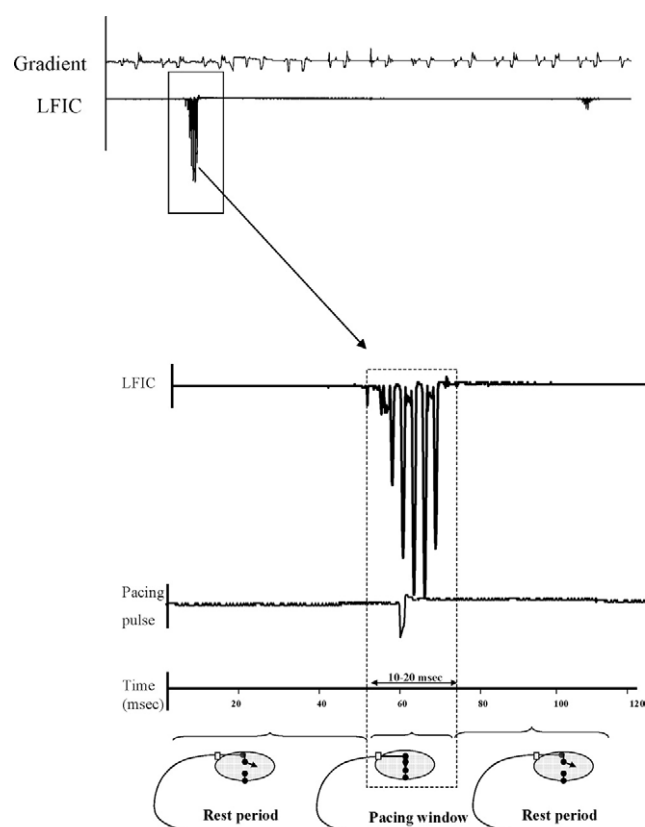
Infrequent myocardial capture beats were observed only during the MRI pulse sequence when the PG was programmed to VOO and the output set to subthreshold value (0.1 V at 0.5 ms). **Figure 7** shows recordings of the low-frequency-induced current and the surface ECG, with the pacemaker in a unipolar mode, programmed VOO to pace 20 beats above the intrinsic heart rate and the output set to subthreshold value. No myocardial capture beats are noted prior to MRI scanning. Low-frequency-induced current generated in the PG lead circuit causes distortion of the pacing pulse, which we termed *induced distortion*. Induced distortion by the low-frequency-induced current constructively added to the waveform of the pacing pulse, leading to myocardial capture when it was not intended (subthreshold pacing).

Induced distortion also led to loss of capture. The PG was programmed to pace asynchronously in VOO mode, with the pacing amplitude set to the threshold value and the rate to 20 beats above the animal's heart rate. Consistent myocardial capture was noted prior to MRI scanning. Intermittent loss of capture was noted during MRI scanning due to the destructive interference of the low-frequency-induced current on the pacer output waveform.

### Discussion

This study investigated the determinants of low-frequency-induced current in a pacemaker lead system in an MRI environment, with several interesting findings. Based on results of the in vivo experiments, it can be concluded that the return pathway for low-frequency-induced current generated in a pacemaker lead system due to MRI gradient fields under normal implant conditions is PG case-lead-tissue-PG case. The impedance path from the PG case internally to the lead is critical in controlling the magnitude of low-frequency-induced current. Under normal implant conditions, the low-frequency-induced current is maximum within the pace window and is minimum outside the pace window. The magnitude of low-frequency-induced current generated under normal implant conditions is  $<0.5$  mA and is unlikely to cause myocardial stimulation. With sufficient increase in effective loop area (additional looped leads), direct myocardial capture by the low-frequency-induced current is possible. Low-frequency-induced current can distort the pacing pulse, leading to undesired myocardial stimulation or loss of capture. Low-frequency-induced current also interferes with sensing function. Low-frequency-induced current was abolished in this study by breaking the unipolar return pathway by electrically isolating the PG case from the circuit.

Fontaine et al<sup>8</sup> reported the occurrence of rapid cardiac pacing during MR cerebral angiography in a patient with a



**Figure 6** Above two tracings are simultaneous recordings of gradient activity by the second current recorder and low-frequency-induced current (LFIC) by the current recorder connected in series to the pacemaker (PG) lead circuit. Note that even though the gradient activity is continuous, low-frequency-induced current is recorded intermittently. A higher magnification of low-frequency-induced current LFIC shows the waveform of the induced current on the right. Analysis of the pacing cycle reveals that the timing of low-frequency-induced current corresponds to the pacing window, wherein a switch in the PG internal circuitry closes to deliver a pacing pulse. The switch remains closed for 10 to 20 ms after delivery of the pacing pulse, making low-frequency-induced current possible within the window period.

dual-chamber pacemaker (Medtronic Inc., Minneapolis, MN, USA). In this case, the PG was programmed to VVI mode at a rate of 30 bpm, and the pacing amplitude and pulse width were programmed to subthreshold (0.5 V at 0.03 ms). Despite these settings, rapid pacing above the magnet rate occurred during scanning, without any change in the programmed parameters. The reason for rapid pacing in this case can be explained by the findings of our study. First, this case involved MR angiography of the brain with the head at the isocenter, so the pacemaker system was closer to the worst case location (offset in  $z$ -,  $x$ -, and  $y$ -axes). The pacemaker was programmed to VVI mode; hence, pacing would have been unpredictable during MRI scanning due to ineffective sensing. The higher dB/dt of MR angiography coupled with the worst case location of the PG lead circuit may have resulted in significant low-frequency-induced current leading to direct myocardial stimulation.

Low-frequency-induced current can be abolished by electrically isolating the PG case from the PG-lead-tis-

sue-PG circuit, thereby rendering unipolar pacing impossible. However, this is not synonymous with programming the PG to bipolar pacing, as even in a bipolar configuration unintended unipolar loop can result if sufficient electromotive force is generated. This is due to the noninfinite impedance characteristics of switches and the other internal pacemaker circuitry that result in an unintended unipolar loop formation with low-frequency-induced currents similar to unipolar lead configuration.

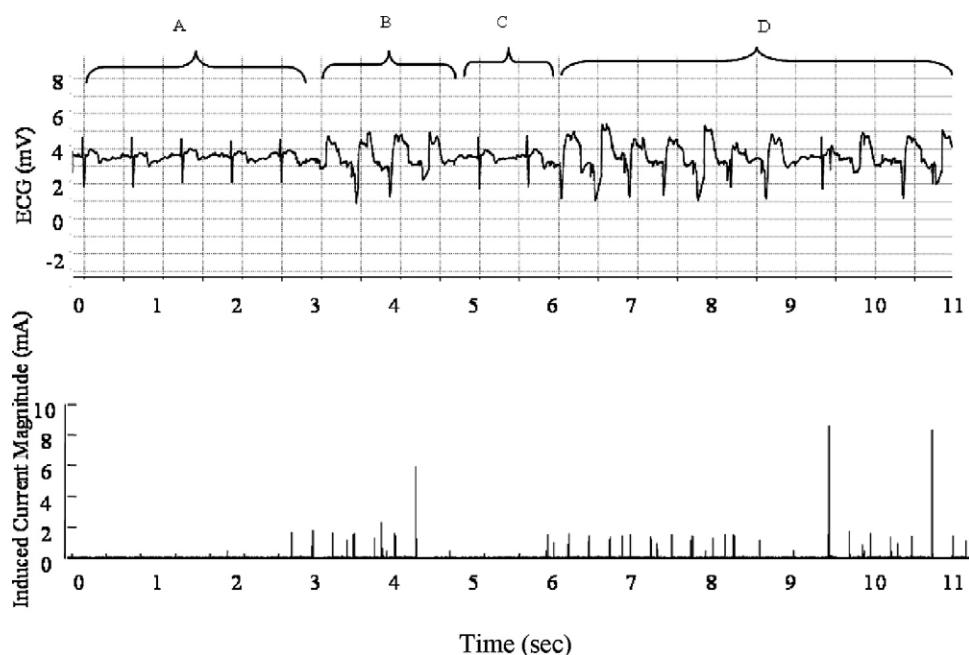
Low-frequency-induced current is more likely to occur within the pace window due to lower impedance of the circuit. Internal circuitry within the PG provides a current path between the distal lead electrode and the outer can of the device, not only during delivery of the pacing pulse but also extending up to 20 ms after the pacing pulse (termed *pace and recharge window*). This internal path is present even when the PG is programmed to bipolar pacing, resulting in generation of low-frequency-induced current during normal implant conditions.

Our study is the first to demonstrate induced distortion, the mechanism by which the pacing pulse is altered by the low-frequency-induced current. Low-frequency-induced current will add to or subtract from the voltage present between the pacemaker's anode and cathode, distorting the desired ideal pacing pulse. Induced distortion levels up to 0.5 V have been measured during in vitro tests performed in MRI. This level of induced distortion is significant and can result in loss of capture or unintended myocardial capture.

### Study limitations

No attempt was made to define the minimum loop area beyond which myocardial stimulation is possible. The magnitude of low-frequency-induced current and the chance of myocardial stimulation are a function of the loop area and the maximum dB/dt through the loop. Significant differences exist between MRI manufacturers with regard to the location of the maximum dB/dt due to variations in coil design. Furthermore, for the same loop size, the effective loop area may vary depending on the location of the loop within the scanner due to nonideal characteristics of the gradient coils as limited by coil design. This study evaluated one particular model of pacemaker. PG circuitry is similar among the different vendors, so the results of our study may be applicable to other pacemakers; however, the amplitude of low-frequency-induced current may vary depending on the impedance characteristics of the individual components. Maximum low-frequency-induced current during normal implant conditions was determined in mongrel dogs and may not reflect the values in a human implant due to the geometry of the chest wall. The small number of animals studied is a limitation; however, the results were consistent in all animals.

Finally, this study investigated pacemaker and MRI interaction in a closed MRI system where the B field is  $z$  directed. In an open MRI scanner, the B field is  $y$  directed. For a normal implant, the maximum low-frequency-induced current may be much greater in an open MRI scanner



**Figure 7** Surface ECG and low-frequency-induced current before and during MRI scanning in a pacemaker (PG) lead system with an additional looped lead connected in series. PG is programmed to unipolar mode, VOO 120 bpm (20 beats above intrinsic rate), and output is set to a subthreshold value. Myocardial capture occurs due to constructive interference of the low-frequency-induced current on the pacing pulse coinciding with onset of MRI scanning. Region A: Intrinsic beats at 100 bpm. Region B: MRI prescan, paced beats at 120 bpm due to induced distortion. Region C: MRI paused, return to intrinsic beats. Region D: MRI scanning, paced beats at 120 bpm due to induced distortion.

where most of the loop area is oriented in the  $x$ - $z$  plane. However, this was not investigated in our study.

### Clinical implications

Our study has several important clinical applications. Although rare, low-frequency-induced current has the potential to cause undesired myocardial capture due to induced distortion despite programming the PG to a low pacing rate and output level. The effective loop area for a normal pacemaker implant can vary depending on patient geometry, scan plane, and patient's position in the scanner. Programming the lead to bipolar decreases but does not eliminate the chance of low-frequency-induced current. Low-frequency-induced current can be abolished by electrically isolating the PG case. This step cannot be achieved in current-generation pacemakers due to constraints in the existing PG circuitry design, and programming the PG to bipolar pacing does not solve the problem. Pacemakers should be designed to create infinite impedance during bipolar pacing, specifically addressing this issue to prevent unintended unipolar loop. Until such time, low-frequency-induced current and subsequent induction of cardiac arrhythmias are possible.

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