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Evaluation of Magnetic Resonance Imaging Issues for a Wirelessly Powered Lead Used for Epidural Spinal Cord Stimulation

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Objective: The objective of this investigation was to evaluate magnetic resonance imaging (MRI) issues (magnetic field interactions, MRI-related heating, and artifacts) for a wirelessly powered lead used for spinal cord stimulation (SCS).

Materials and Methods: A newly developed, wirelessly powered lead (Freedom-4, Stimwave Technologies Inc., Scottsdale, AZ, USA) underwent evaluation for magnetic field interactions (translational attraction and torque) at 3 Tesla, MRI-related heating at 1.5 Tesla/64 MHz and 3 Tesla/128 MHz, and artifacts at 3 Tesla using standardized techniques. MRI-related heating tests were conducted by placing the lead in a gelled-saline-filled phantom and performing MRI procedures using relatively high levels of radiofrequency energy. Artifacts were characterized using T1-weighted, spin echo (SE), and gradient echo (GRE) pulse sequences.

Results: The lead exhibited minor magnetic field interactions (2 degree deflection angle and no torque). Heating was not substantial under 1.5 Tesla/64 MHz (highest temperature change, 2.3°C) and 3 Tesla/128 MHz (highest temperature change, 2.2°C) MRI conditions. Artifacts were moderate in size relative to the size and shape of the lead.

Conclusions: These findings demonstrated that it is acceptable for a patient with this wirelessly powered lead used for SCS to undergo MRI under the conditions utilized in this investigation and according to other necessary guidelines. Artifacts seen on magnetic resonance images may pose possible problems if the area of interest is in the same area or close to this lead.

Keywords: artifacts, implants, magnetic resonance imaging (MRI), MRI, MRI safety, spinal cord stimulation (SCS)

Conflict of Interest: The authors report no conflict of interest.

INTRODUCTION

There is an increasing incidence of patients receiving neurostimulation systems for spinal cord simulation (SCS) to manage neurologic conditions, especially chronic pain disorders (1–5). Neurostimulation systems used for SCS typically involve the surgical implantation of three basic components: a pulse generator (PG), which sends mild electrical pulses via an insulated lead to a targeted area of the spinal cord; an extension wire, which connects a lead to the PG; and a lead, which consists of insulated wires with electrodes that deliver programmable electrical signals to the desired area (2–4,6).

Recently, technologies have been developed to implement wireless, micro-size neuromodulation systems powered by external devices (7,8). Thus, for this specialized neurostimulation system, a percutaneously placed lead with electrodes that does not require extension cable or, more importantly, an implanted PG may be utilized for SCS (8). We speculate that the potential benefits associated with the development of such a neurostimulation system when used for SCS include the following: there may be a possible reduction in the risk of infection (i.e., related to having no open ports or PGs), there is no need for implanted batteries or PGs, and there is no need for extension line tunneling (7,8).

A patient with a conventional neurostimulation system used for SCS may require assessment using magnetic resonance imaging (MRI), but is currently unable to undergo the examination without adhering to substantial limitations because of risks primarily related to magnetic field interactions and MRI-related heating, as well as concerns associated with possible damage to the implanted PG (6,9,10). Notably, altered function of the neurostimulation system may result from exposure to the electromagnetic fields used in MRI, causing discomfort, pain, or serious injury to the patient (6,9). In the United States, there are relatively few neurostimulation systems with MRI labeling approved by the Food and Drug Administration (FDA). For these SCS devices, the highly specific MRI conditions that must be adhered to include using a 1.5 Tesla/64 MHz MR system only; a transmit/receive radio frequency (RF) head coil must be used (thus, MRI may only be performed on the patient's brain), and other procedures must be carefully followed to prevent patient injuries and/or damage to the neurostimulation system. Recently, SCS

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devices have been released with special modifications (i.e., "SureScan MRI" technology, Medtronic, Minneapolis, MN, USA) that permit MRI examinations to be conducted on other body parts in addition to the head, but these devices are not in widespread use, there are conditions (note, these devices are labeled "MR conditional") that still must be followed to ensure that safe MRI procedures are performed, and 3 Tesla MRI exams are still prohibited (10). Therefore, the alternative approach to providing SCS using the wirelessly powered lead described above may be desirable insofar as there may not be substantial restrictions related to the performance of an MRI procedure in a patient with this device.

To ensure patient safety and prevent problems in patients with neurostimulation systems (6,9), *in vitro* test methods are utilized to characterize magnetic field interactions, MRI-related heating, and artifacts for a given device. Therefore, the objective of this investigation was to evaluate MRI issues for a wirelessly powered lead used for SCS.

MATERIALS AND METHODS

Wirelessly Powered SCS Lead

A newly developed, wirelessly powered lead (Freedom-4, Stimwave Technologies Inc., Scottsdale, AZ, USA) intended for epidural SCS underwent evaluation for MRI issues in this investigation. This lead (length: 11.3 cm; diameter: 1.3 mm; four electrodes, electrode length: 3 mm), which is small enough to be placed through a 14-guage needle, is made from the following materials: MP35N—platinum–iridium; polyimide; copper (i.e., for flexible circuit, dipole antenna); silver-infused, electrically conductive epoxy; and polyurethane (Figs 1 and 2). The entire neurostimulation system consists of the lead that is placed in the epidural space and a portable, external device that transmits power wirelessly through the skin to a receiver embedded within the lead (8). The external power unit is programmable and generates effective stimulation parameters including the waveform pulse shape, period, and duration, which are transmitted transcutaneously, as an electromagnetic wave carrier (8). Thus, the external device utilized with this lead involves a passive, wireless, micro-size stimulator platform for neurophysiologic treatment therapies that is powered by a high-frequency, external transmitter that may be worn around the patient's waist (Fig. 3). The external device is not intended for use in a patient undergoing an MRI examination and, therefore, it did not undergo MRI testing in this study.

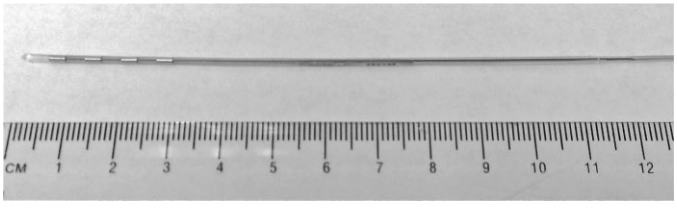

Figure 1. The wirelessly powered lead used for SCS that underwent testing for MRI issues: photograph.

Magnetic Field Interactions

Magnetic field interactions were determined for the lead using a 3 Tesla MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare Milwaukee, WI, USA).

Translational Attraction

Translational attraction was assessed using the deflection angle test, as previously described (11–13). The wireless lead was attached to a special test fixture to measure the deflection angle in the MR system. The test fixture consisted of a sturdy structure capable of holding the lead in position without movement and contained a protractor with 1-degree, graduated markings attached to the structure. The 0-degree indicator on the protractor was oriented vertically. The test fixture has a plastic bubble level to ensure proper orientation in the MR system during the test procedure.

The lead was suspended from a thin, lightweight string (weight, less than 1% of the weight of the lead) that was attached to the 0° indicator position on the protractor. The length of the string was 20 cm, which was long enough so that the lead could be suspended from the test fixture and hang freely in space (11–13). Motion of the string with the lead was not constrained by the support structure of the protractor.

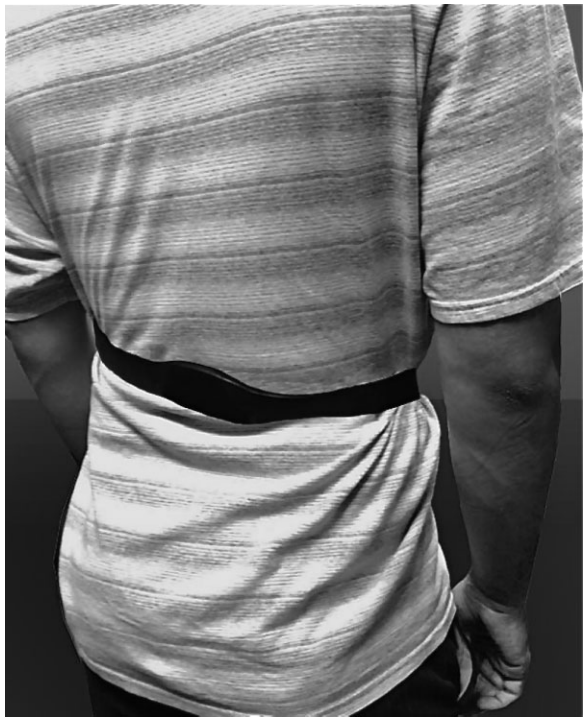

Figure 3. The external device used with the wirelessly powered lead as shown as applied on a volunteer subject. Note that this external device is not intended for use in the MR system room.

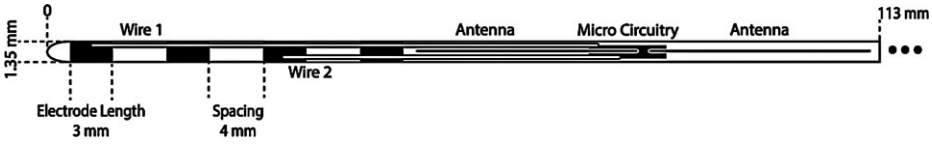

Figure 2. The wireless powered lead used for SCS that underwent testing for MRI issues: diagram.

Measurements of deflection angles for the lead were obtained at the position in the 3 Tesla MR system that produced the greatest magnetically induced deflection (11–13). This position is related to the point of the highest "patient accessible" (i.e., the place where the patient would pass through while entering the bore of the MR system), spatial gradient magnetic field (14). The highest patient accessible, spatial gradient magnetic field for the 3 Tesla MR system used in this investigation is 720 gauss/cm and occurs at an off-axis position that is 74 cm from isocenter of the scanner (11–13). This position was determined for the MR system using gauss line plots, measurements using a gauss meter (Extech 480823 Electromagnetic Field and Extremely Low Frequency Meter; Extech, Nashua, NH, USA) and visual inspection to identify the location. The lead was held vertically from the test fixture and then released. The deflection angle from the vertical position to the nearest 1° was measured three times, and the mean value was calculated (11–13).

Qualitative Assessment of Torque

Magnetic field-induced torque was assessed qualitatively for the lead, as previously described (11–13). The test apparatus was a flat plastic material with a millimeter grid on the bottom. The lead was placed on the test apparatus at a 45° orientation relative to the static magnetic field of the 3 Tesla MR system (11–13). The test apparatus with the lead was then moved into the center of the MR system, where the effect of torque from the static magnetic field is greatest based on well-known characteristics of the 3 Tesla scanner used for this assessment. The lead was observed with respect to alignment or rotation relative to the static magnetic field in 45° increments to encompass a full 360° of rotation. This procedure was conducted three times, and a mean value of torque was calculated for the lead. The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild or low torque (the lead slightly changed orientation but did not alight to the magnetic field); +2, moderate torque (the lead alignment gradually to the magnetic field); +3, strong torque (the lead showed rapid and forceful alignment to the magnetic field); +4, very strong torque (the lead showed very rapid and very forceful alignment to the magnetic field) (11–13).

MRI-Related Heating

Because of the fact that MRI-related implant heating may be different in relation to the transmit frequency of the RF energy used by a particular MR system (9), MRI-related heating was evaluated for the lead at 1.5 Tesla/64 MHz and 3 Tesla/128 MHz. This procedure simulated human tissue using a plastic American Society for Testing Materials (ASTM) phantom filled to a depth of 10 cm with a semi-solid, gelled-saline (i.e., 1.32 g/L NaCl plus 10 g/L polyacrylic acid in distilled water) (11,12,15). The lead was placed in a position in the phantom where there was a high uniform electric field tangential to the lead, ensuring extreme RF heating conditions for this experimental setup, as previously described (i.e., in consideration of an analysis of the ASTM phantom and the MRI conditions used for this assessment) (11,12,15). A relatively high level of RF energy was applied under each MRI condition during the MRI-related heating experiments (11,12,15). Because this experimental setup lacks blood flow or perfusion, it simulates an extreme condition used to assess heating scenario for this lead.

MRI Conditions

MRI was performed at 1.5 Tesla/64 MHz (Magnetom, Software Numaris/4, Version Syngo MR 2002B DHHS, Siemens Medical Solutions, Malvern, PA, USA) and 3 Tesla/128 MHz (Excite, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, USA). The body RF coil was used to transmit RF energy in each case. MRI parameters were selected to generate a relatively high level of RF energy (11,12,15). An MR system-reported, whole-body averaged specific absorption rate (SAR) of 2.9 W/kg was applied under the 1.5 Tesla/64 MHz conditions for 15 minutes. An MR system-reported, whole-body averaged SAR of 2.9 W/kg was applied under the 3 Tesla/128 MHz conditions for 15 minutes. The landmark position for both MRI conditions was center of the lead, with multiple section locations obtained through the lead.

Temperature Recording System and Placement of Thermometry Probes

Temperature recordings were obtained using a fluoroptic thermometry system (Lumasense, Model 3100, Luxtron, Santa Clara, CA, USA), previously demonstrated to be unperturbed by MRI conditions up to static magnetic field strengths of 9 Tesla. Small fiber optic probes (0.5 mm in diameter) were calibrated immediately before each heating test and attached to the lead and to record temperatures during the heating evaluations. The fluoroptic thermometry probes were placed in direct contact with the end portions of the lead, where the greatest amount of heating will occur for this device as follows: probe #1, placed in contact with the most distal electrode; probe #2, placed in contact with second from the most distal electrode.

MRI-Related Heating Protocol

The gelled-saline-filled ASTM head/torso phantom was placed in the 1.5 T and 3 Tesla MR systems, respectively, and equilibrated to the environmental conditions for more than 24 hours. The fan for each MR system was not on during the experiments, and there was sufficient thermal equilibrium in the phantom such that the temperature did not change by ± 0.2°C during the pre-MRI observation time for a period of at least 15 minutes.

Baseline (pre-MRI) temperatures were recorded at four-second intervals for five minutes. MRI was then performed for 15 minutes with temperatures recorded at four-second intervals. Post-MRI temperatures were recorded for two minutes with temperatures recorded at four-second intervals. The highest temperature changes recorded by the thermometry probes are reported, herein, for the lead tested at 1.5 Tesla/64 MHz and 3 Tesla/128 MHz.

Background temperatures (i.e., heating of the phantom without the lead present) also were recorded during the MRI-related heating evaluation. Accordingly, the temperature changes were measured at the same fluoroptic thermometry probe positions and at the same time intervals as those used when measuring the temperatures for the lead in the gelled-saline-filled ASTM International phantom (11,12,15). The highest background temperature rises obtained from these assessments at 1.5 Tesla/64 MHz and 3 Tesla/128 MHz also are reported.

Artifacts

Artifacts seen on MR images for the lead were evaluated by performing MRI with the lead attached to a plastic frame (to facilitate positioning) that was then placed inside of a gadolinium-doped, saline-filled, plastic phantom, as previously described (11,12). MRI was performed using a 3 Tesla MR system, a transmit/receive RF coil, and the following pulse sequences: T1-weighted, spin echo pulse

Table 1. Summary of MRI Artifacts at 3 Tesla for the Wireless Lead.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size Imaging Plane	616 mm^2 parallel (long axis)	104 mm^2 perpendicular (short axis)	1,226 mm^2 parallel (long axis)	314 mm^2 perpendicular (short axis)

T1-SE, T1-weighted, spin echo; GRE, gradient echo.

sequence; repetition time: 500 ms; echo time: 20 msec; matrix size: 256 × 256; section thickness: 10 mm; field of view: 26 cm; number of excitations: 2; bandwidth: 16 kHz; and gradient echo (GRE) pulse sequence; repetition time: 100 msec; echo time: 15 ms; flip angle: 30°; matrix size: 256 × 256; section thickness: 10 mm; field of view: 26 cm; number of excitations: 2; bandwidth: 16 kHz.

The imaging planes were oriented to encompass the long axis and short axis of the lead. The frequency encoding direction was parallel to the plane of imaging. Importantly, the image locations obtained through the lead were selected to represent the worst case artifact size for the lead. Planimetry software provided with the MR system was used to measure the cross-sectional areas (accuracy and resolution of ±10%) of the largest artifact size associated with the lead (11,12). This was done for each pulse sequence and for each orientation/section location. Image display parameters (i.e., window and level settings, magnification, etc.) were carefully selected and applied in a consistent manner to obtain accurate measurements of sizes for the artifacts. While we acknowledge that there are innumerable possible MRI parameters that may be utilized to characterize artifacts for metallic implants, this methodology has been used in many previous reports and, thus, allows comparison with other implants that have undergone similar evaluations for artifacts (9,11,12).

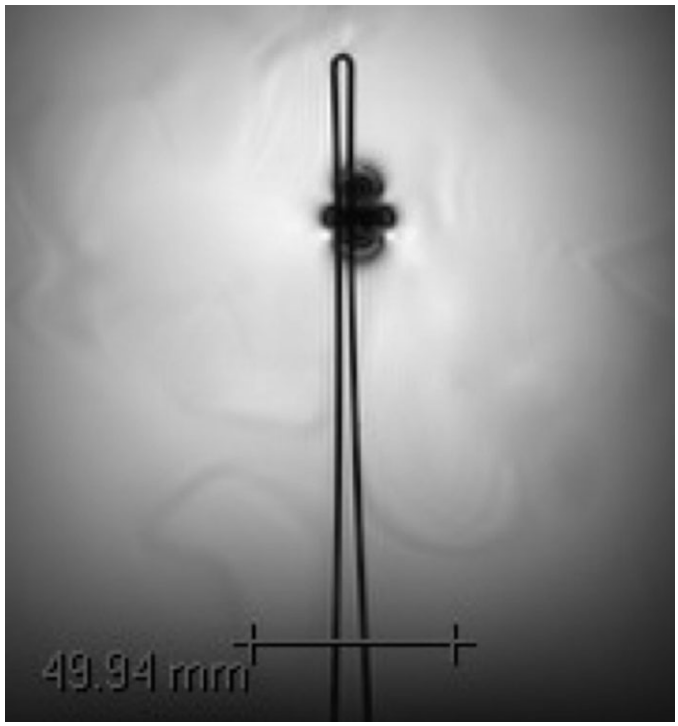

Figure 4. MRI artifacts associated with the wireless lead: short axis view (gradient echo pulse sequence; TR/TE, 100 msec/15 msec; flip angle, 30 degrees; long axis imaging plane).

RESULTS

The average deflection angle was 2° ± 0, and the qualitatively measured torque was 0 (no torque) for the lead at 3 Tesla. The MRI-related heating evaluation under the 1.5 Tesla/64 MHz conditions yielded a highest temperature change of 2.3°C, with a background temperature rise of 1.4°C. The MRI-related heating evaluation under the 3 Tesla/128 MHz conditions yielded a highest temperature change of 2.2°C, with a background temperature rise of 1.8°C.

The artifact test results for the lead are shown in Table 1. Artifacts were seen as low intensity signal losses that were relatively moderate in size in relation to the size and shape of the lead. The GRE pulse sequence (Figs. 4 and 5) produced larger artifacts than the T1-weighted, spin echo pulse sequence. The worst case artifact size observed on the GRE pulse sequence extends approximately 15 mm relative to the dimensions of the lead.

DISCUSSION

During the past 30 years, the use of electrical stimulation for treatment of chronic and other conditions has become well accepted (1–6). Compared with conventional neurostimulation platforms used for SCS that involve a PG, an extension, and a lead with electrodes, considering that a rather simple lead is implanted and based on the findings of this investigation, the MRI safety issues associated with the wirelessly powered lead used for SCS are substantially less than those related to conventional neurostimulation systems (6,9).

Magnetic Field Interactions

The lead that underwent tests for magnetic field interactions exhibited an average deflection angle of 2-degrees and no torque during exposure to a 3 Tesla static magnetic field. The criteria stated by the ASTM International (13) indicates that if the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity. For this condition, it is presumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. The relative lack of magnetic field-related issues is related to the materials used to make this lead, which either have low, magnetic susceptibility values or are nonmetallic (16). Accordingly, this wirelessly powered lead will not present an additional risk or hazard to a patient

Figure 5. MRI artifacts associated with the wireless lead: long axis view (gradient echo pulse sequence; TR/TE, 100 msec/15 msec; flip angle, 30 degrees; long axis imaging plane).

in the 3 Tesla or less MRI environment with regard to movement or displacement.

MRI-Related Heating

MRI-related heating that potentially results in substantial patient injuries is the greatest concern for devices used for neurostimulation, including those utilized for SCS (6,9). In the evaluation of MRI-related heating for neurostimulation systems, it is important to consider the length of the implanted lead in relation to the wavelength of the RF field used for MRI (e.g., 1 Tesla/42 MHz, 1.5 Tesla/64 MHz, 3 Tesla/128 MHz) which will, in turn, impact the amount of temperature rise that occurs (6,9,15,17). According to Kainz (17), for an implant to become "resonant," the length of the device must be in the range of an odd number of half wavelengths of the electromagnetic field inside the patient. Once resonant with the electromagnetic field, implant heating may become dangerously high. Kainz (17) reported that the half wavelengths of the electromagnetic field inside of a patient for 1.5 Tesla/64 MHz MR systems are approximately 25 cm and, for 3 Tesla/128 MHz systems, they are about 12 cm.

In the present study, under relatively high RF deposition conditions, the MRI-related heating at 1.5 Tesla/64 MHz and 3 Tesla/128 MHz demonstrated highest temperature rises of 2.3 and 2.2 degrees, respectively, with the highest background temperature rises being 1.4 and 1.8 degrees, respectively. Importantly, these temperature increases will not cause any physiologic consequences. Furthermore, these findings are not surprising in consideration of the relatively short length of the lead that underwent evaluation (Fig. 1).

Artifacts

The relationship between position and frequency of the local magnetic field is essential to proper image reconstruction in MRI. MRI artifacts associated with metallic implants can be attributed to a disruption in this relationship and are dependent on the magnetic susceptibility, quantity, shape, orientation, and position of the implant in the patient as well as the technique use for imaging (i.e., the specific pulse sequence parameters) and the image processing method (9,11,12,18,19). Artifacts seen on MR images related to metallic objects typically appear as localized, low-intensity, signal voids. For implants that are made from materials with high magnetic susceptibility values (9,16), severe distortion of the MR image may also occur.

MR images for the wirelessly powered lead appeared to be moderate in size in relation to the size and shape of this implant, with the GRE pulse sequence showing larger artifacts compared with T1-weighted sequence. The worst case artifact size seen on the GRE pulse sequence displayed a signal loss of 15 mm relative to the size and shape of the lead. Therefore, the artifacts for the lead may present problems if the MR imaging area of interest is in or near the area where the lead is located. However, when a metallic implant is present in a patient referred for MRI, the imaging parameters are typically optimized to minimize the extent of the associated artifacts or newly developed, metal reduction techniques may be applied to correct this possible issue (18,19).

CONCLUSIONS

MRI tests performed on the wirelessly powered lead used for SCS indicated that there are no significant safety issues regarding magnetic field interactions and MRI-related heating related to the MRI procedures used in this investigation. Artifacts seen on MR images may be problematic if the area of interest is near or at the site of the lead. Thus, these findings demonstrated that it is acceptable for a patient with this lead to undergo MRI under the conditions utilized in this investigation and according to other necessary guidelines.

Using current MRI labeling terminology (20,21), the wirelessly powered lead used for SCS is "MR conditional" (i.e., MR conditional is defined as an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use) for a patient undergoing an MRI examination at 3 Tesla or less (20,21). Importantly, in comparison with the current FDA approved MRI labeling for other neurostimulation systems used for SCS may have extensive restrictions, the MR conditions allowing patients to undergo MRI are substantially less limited and essentially allow MRI examinations to be performed on all body parts of the patient.

Authorship Statement

Dr. Frank Shellock designed and conducted the study, including data collection and analysis. Annabelle J. Audet-Griffin was involved in data preparation and presentation. Annabelle J. Audet-Griffin prepared the manuscript's first draft and shared an important intellectual input along with Dr. Frank Shellock. Both authors approved the final manuscript. Both Dr. Frank Shellock and Annabelle Audet-Griffin had complete access to the study data.

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COMMENT

This is a well-written article regarding the concern that faces all implanters with the use of MRI in patients receiving a neural prosthesis. The authors presented a convincing methodology to test the effect of MRI on an implantable electrode that is powered wirelessly with a power source outside the skin. The results of this in vitro study showed minimal deflection, torque of the wire and surrounding temperature.

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Comments not included in the Early View version of this paper.

