Original Research

Implantable Spinal Fusion Stimulator: Assessment of MR Safety and Artifacts

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The objective of this investigation was to perform magnetic resonance (MR) imaging safety and artifact testing of an implantable spinal fusion stimulator. Magnetic field interactions, artifacts, and operational aspects of an implantable spinal fusion stimulator were evaluated in association with a 1.5 T MR system. Magnetic field-related translational attraction was measured using the deflection angle test. A special test apparatus was used to determine torque at 4.7 T. Artifacts were characterized using fast multiplanar spoiled gradient-echo, T1-weighted spin-echo, and T1-weighted fast spin-echo sequences. Operational aspects of the implantable spinal fusion stimulator before and after exposure to MR imaging at 1.5 T were assessed. In addition, nine patients (six lumbar spine and three cervical spine) with implantable spinal fusion stimulators underwent MR imaging. The findings indicated that magnetic field interactions were relatively minor, artifacts were well characterized and should not create diagnostic problems, and there were no changes in the operation of the spinal fusion stimulator. The nine patients underwent MR procedures without substantial adverse events or complaints. Based on the results of this investigation and in consideration of the findings from previous studies of MR imaging safety for the implantable spinal fusion stimulator, MR imaging may be performed safely in patients using MR systems operating at 1.5 T or less following specific recommendations and precautions. J. Magn. Reson. Imaging 2000;12:214–223. © 2000 Wiley-Liss, Inc.

Index terms: magnetic resonance imaging; MR safety; bioeffects; implant; artifacts

THE IMPLANTABLE SPINAL FUSION stimulator (SpF-2T/CW; Electro-Biology, Parsippany, NJ) is designed for use as an adjunct therapy to a spinal fusion procedure (Physicians Manual; EBI Medical Systems, Parsippany, NJ). The use of this implant provides a faster consolidation of the bone grafts, leading to higher fusion rates and improved surgical outcomes, along with a reduced need for orthopedic instrumentation (1–3). To date, the implantable spinal fusion device has been utilized to increase the probability of bone fusion in more than 70,000 patients.

In general, the presence of an electronic implant is considered to be a relative contraindication for a patient referred for MR imaging (4–7). However, several investigations have demonstrated that patients with certain electronic implants including neurostimulators, cochlear implants, cardiac pacemakers, and other similar devices may undergo MR imaging safely if specific precautions are followed with respect to the conditions and imaging parameters used for the MR examinations (4,8–21). Notably, at least one neurostimulator (NeuroCybernetic Prosthesis, NCP, Pulse Generator, model 100; Cyberonics, Houston, TX) and one chochlear implant (Nucleus Mini-22 Cochlear Implant; Cochlear Corporation, Englewood, CO) have received clearance from the United States Food and Drug Administration that permits the use of MR imaging in patients with these electronic implants. The product labels for the neurostimulator and chochlear implant provide highly specific recommendations for performing safe MR imaging in patients with these devices. For example, for the NeuroCybernetic Prosthesis, NCP, Pulse Generator, MR procedures should only be performed using a head coil because an MR imaging procedure performed with the body coil could produce heat in the leads of the device.

Several potential problems exist for a patient undergoing MR imaging with an implantable spinal fusion stimulator, including (4,21–23) movement or dislodgment of the stimulator by magnetic field interactions; artifacts associated with the stimulator that can impair the diagnostic quality of the examination, damage to the circuitry of the stimulator by exposure to the electromagnetic fields [ie, static, gradient, and radiofrequency (RF) fields] during operation of the MR system; heating of the device and adjacent tissue by RF energy absorption; and production of electric fields by the low-

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frequency switched gradient magnetic fields that could excite nerves or cause a similar unwanted response.

Recent studies using extreme exposures to MRI-related electromagnetic fields under highly specific experimental conditions and modeling scenarios for the lumbar/torso area (ie, high-field-strength MR system, excessive exposures to RF fields, excessive exposures to gradient magnetic fields, etc.) demonstrated that the implantable spinal fusion stimulator will not present a hazard to a patient undergoing MR imaging with respect to heating or induced electric fields during the use of conventional MR pulse sequences and parameters (21–23). Notably, these studies addressed the use of conventional pulse sequences and parameters with an acknowledgment that echoplanar techniques or imaging parameters that require excessive RF power will have different implications and consequences for the patient with an implantable spinal fusion stimulator. Nevertheless, MR examinations have been performed in over 120 patients (conceivably, using MR imaging conditions that involved a wide variety of imaging parameters and conditions) with implantable spinal fusion stimulators, without reports of substantial adverse events (based on recent review of data obtained through the Freedom of Information Act and unpublished observations, B. J. Simon, Electro-Biology, 1998). Furthermore, the manufacturer of this implant and the Food and Drug Administration have not received claims or reports of patient injuries associated with the presence of this device in patients undergoing MR procedures. Admittedly, for a variety of reasons, there is the potential for substantial underreporting of adverse events.

Because of the relatively high incidence of recurrent or new symptoms following spine surgery and the widespread use of MR imaging for other types of clinical applications, an investigation is warranted to address each of the afore-mentioned MR-related problems that remain for the implantable spine fusion stimulator. Therefore, this study was performed to assess magnetic field interactions, artifacts, and the operational aspects of the implantable spinal fusion stimulator. Data were also obtained in patients with this electronic implant who underwent MR imaging.

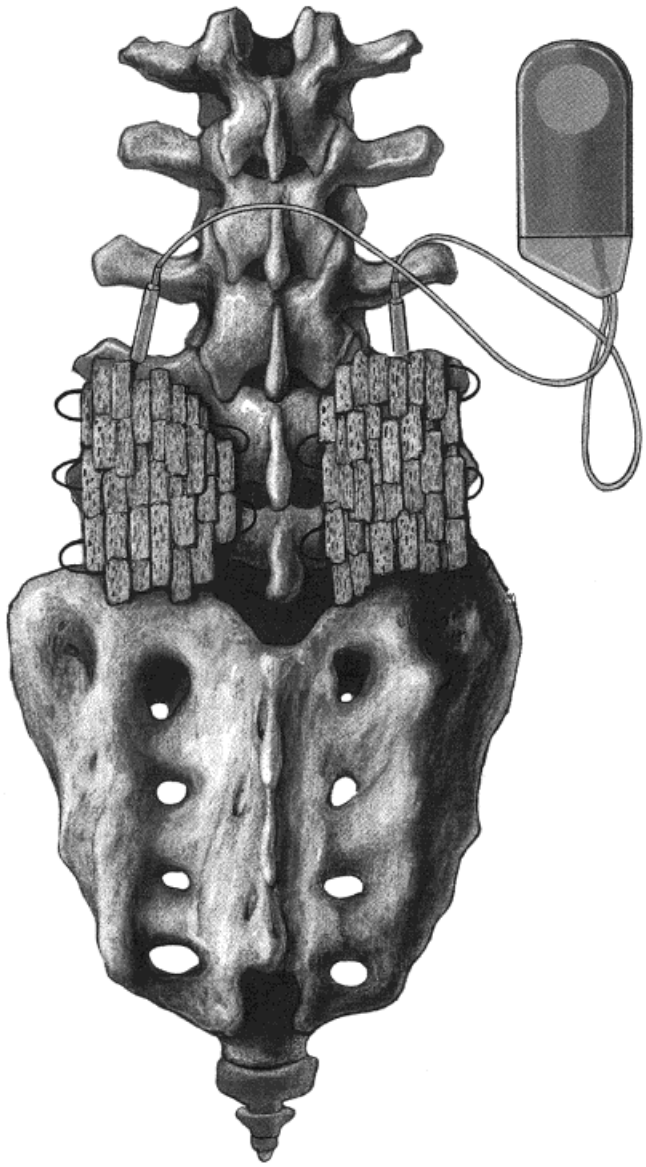

Figure 1. Drawing of spinal fusion stimulator shows electrodes implanted at L4–L5 level embedded in pieces of bone grafted onto lateral aspects of fusion sites.

MATERIALS AND METHODS

Implantable Spinal Fusion Stimulator

The implantable spinal fusion stimulator (SpF-2T/CW, Electro-Biology) consists of a direct current generator with a lithium iodine battery and solid-state electronics encased in a titanium shell, partially coated with platinum that acts as an anode (1). The generator weighs 10 g and has the following dimensions: 45 × 22 × 6 mm. Two nonmagnetic silver/stainless steel leads insulated with Silastic provide a connection to two titanium electrodes that serve as the cathodes. A continuous 20-μA current is produced by this device. The cathodes are composed of insulated wire leads that terminate as bare wire leads, which are embedded in pieces of bone grafted onto the lateral aspects of fusion sites (Fig. 1). The generator is implanted beneath the skin and muscle near the vertebral column and provides the full-rated current for approximately 24–26 weeks (1).

Assessment of Magnetic Field Interactions

Magnetic field-related translational attraction was assessed using a previously described in vitro procedure indicated as the deflection angle test (24–28). This test was conducted using a shielded 1.5-T MR system (Signa MR System; General Electric Medical Systems, Milwaukee, WI) (24–28). The test was performed on one randomly selected SpF-2T/CW Implantable Spinal Fusion Stimulator.

The implantable spinal fusion stimulator was suspended by a 30-cm-long piece of thread that was attached to the estimated center of the device. The thread was then attached to a plastic protractor so that the

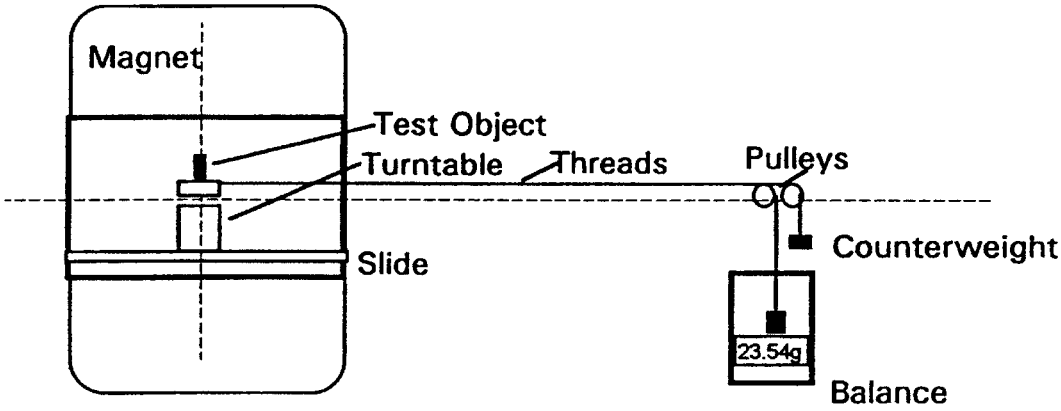

Figure 2. Schematic showing the device used for the measurement of magnetic field-related torque. The test apparatus consists of a low-friction turntable connected by means of cotton threads to two uneven weights (ie, 15.54 and 23.54 g each), with the heavier of the two resting on an analytical balance. Two pulleys mounted on a fixture above the balance were used to convert the lateral motion of the threads under tension to the up-down motion required to measure gravitational force. Rotation of the turntable is prevented by applying a circumferential counterforce whose magnitude is read from the digital display of the balance. The analytical balance was positioned several feet from the shielded magnet to avoid fringe field effects. The implantable spinal fusion stimulator was placed on the top of the turntable, which was positioned in the center on the 4.7 T magnet using the slide mechanism.

angle of deflection from the vertical could be measured. The accuracy of this measuring device is ±0.5° based on the ability to read the protractor in the MR system (24–28).

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 (35 cm inside of the bore of the MR magnet) to determine the magnetic field attraction with regard to an extreme exposure condition (24–29). The highest spatial gradient for this MR system is 450 gauss/cm. Deflection angles for the implantable spinal fusion stimulator were measured three times and averaged.

Magnetic field-related torque was assessed in three orthogonal axes for the implantable spinal fusion stimulator using a 4.7-T superconducting magnet (Oxford Instruments) and a specially designed, nonferromagnetic test apparatus (Fig. 2). Measurements were obtained at the center of the magnet to determine torque with respect to a worst-case condition (29). The test apparatus consisted of a low-friction turntable (radius, 48.54 mm) connected by means of fine cotton threads (positioned on the outer race of the turntable wheel) to two uneven weights (ie, 15.54 and 23.54 g each), with the heavier of the two resting on an analytical balance (Fig. 2). Two pulleys mounted on a fixture above the balance were used to convert the lateral motion of the threads under tension to the up-down motion required to measure gravitational force. In this manner, rotation of the turntable is prevented by applying a circumferential counterforce whose magnitude is read from the digital display of the balance. The analytical balance was positioned several feet from the shielded magnet to avoid fringe field effects, and this was verified in pilot studies designed to assess this matter (Fig. 2). The detectability limits and "noise" of the measurements under "no-load" conditions for this test apparatus were assessed and determined to be ±0.002 Newton meters.

By securely attaching the implantable spinal fusion stimulator to the turntable placed in the magnet, the magnetically induced torque is transferred to the turntable and, in turn, to the analytical balance, permitting a precise characterization of torque. Knowledge of the radius of the turntable allows for calculation of torque in units of gram centimeters, which can be converted to Newton meters. Measurements of torque for the implantable spinal fusion stimulator were obtained with it placed in incremental angles from 0° to 360° at 20° increments while on the turntable in the following orientations: horizontal (device placed flat on the turntable), upright (device placed with its long axis perpendicular to the axis of rotation and with its width parallel to the axis of rotation), and vertical (device placed with its long axis parallel to the axis of rotation and with its width perpendicular to the axis of rotation). These orientations were selected in consideration of the possible positions for which a patient with an implantable spinal fusion stimulator may be subjected under in vivo conditions in the MR imaging environment. Values for the maximum torque measured as described above were recorded.

Assessment of Artifacts

Artifacts in vitro associated with the presence of the implantable spinal fusion stimulator were assessed by performing MR imaging with device placed inside of a plastic phantom (height, 15 cm; width, 26 cm; length, 38 cm) filled with physiologic saline. Paper tape (Micropore tape, 3 M Company, Minneapolis, MN) was used to suspend the SpF-2T/CW at the approximate center of the phantom.

MRI was conducted using a transmit/receive body coil along with three different pulse sequences with the following imaging parameters (24,25,30,31): a fast multiplanar spoiled gradient-echo (FMPSPGR) pulse sequence with TR/TE 50/3.3 msec, flip angle 30°, matrix

size 256 × 128, bandwidth 16 kHz, section thickness 5 mm, field of view 26 cm, and 4 excitations; a T1-weighted spin-echo pulse sequence with TR/TE 300/20 msec, matrix size 256 × 128, bandwidth 16 kHz, section thickness 5 mm, field of view 26 cm, and 1.5 excitations; and a T1-weighted fast spin-echo pulse sequence with TR/effective TE 300/17 msec, matrix size 256 × 192, bandwidth 16 kHz, section thickness 5 mm, field of view 26 cm, and 2 excitations.

These are commonly used pulse sequences that are clinically applied for MR imaging of the spine and body. (T2-weighted spin-echo, T2-weighted fast spin-echo, and a variety of other pulse sequences are used for these applications, as well.) Notably, the FMPSPGR pulse sequence is a partial flip angle technique that tends to have a great degree of artifact associated with it when MR imaging is performed on a metallic implant, and the specific imaging parameters for these sequences have been used in several previous studies evaluating implant-related artifacts (24,25,30,31).

The intended goal of the in vitro artifact testing procedure was to obtain data that could be compared appropriately with previously published studies using similar techniques (ie, to be able to compare the relative artifacts size for one implant compared with another). The FMPSPGR pulse sequence tends to have a greater artifact associated with higher echo times (TE) than what was used in this assessment of artifacts and may be as much as two times larger using a longer TE.

The imaging planes were oriented at perpendicular and parallel positions relative to the short and long axes of the implantable spinal fusion stimulator. The frequency-encoding directions were parallel to the planes of imaging. Artifacts that result from other positions of the imaging plane relative to the implant or with regard to the particular orientation of the implants to the main magnetic field of the MR system may be slightly more or less than those observed under the experimental conditions used in the above-indicated test for artifact assessment.

Artifact size was measured using a planimetry technique (accuracy and resolution ±10%) provided by the software of the 1.5-T MR system (24,25,31). Cross-sectional area measurement of artifact size was recorded for each pulse sequence and for each imaging plane (24,25,31).

Assessment of Operational Aspects of the Implantable Spinal Fusion Stimulator

To assess the effects of MR imaging on the operational aspects of the implantable spinal fusion stimulator, MR imaging was performed in vitro on six stimulators using imaging conditions specifically selected to potentially damage the device. Six SpF-2T/CW stimulators were evaluated in this experimental protocol. The SpF-2T/CW stimulators were attached three at a time to a plastic mesh and placed at a height of 13 cm in a plastic phantom used to simulate the dimensions of a human torso (width 38 cm, length 76 cm, height 38 cm). The phantom was filled with physiologic saline (0.9% NaCl solution) and maintained at room temperature. The stimulators had their leads extended and separated by 6 cm to mimic the configuration found in an in vivo condition. Notably, the resistance in the leads is 10–100 times greater in bone than when the leads are placed in physiologic saline, allowing an extreme condition for this experimental procedure (personal communication, B. Simon, Electro-Biology, November, 1999).

MR imaging was performed using the following imaging conditions: MR system 1.5 T/64 MHz, fast spin-echo, TR/effective TE 200/12 msec, echo train length 3, field of view 48 cm, section thickness 20 mm, matrix size 256 × 256, excitations 28, whole-body averaged specific absorption rate 1.25 W/kg, and imaging time 24 minutes. The spinal fusion stimulator was placed in a parallel orientation relative to the magnetic field of the MR system. The length and position of the electrodes were utilized in consideration of the in vivo use of the device.

Measurement of current and frequency output were obtained immediately before and after MR imaging using a Fluke model 83 multimeter. To measure the frequency of the telemetry signal, a model ST-72 tester was modified so that its output could be directly connected to the multimeter, which was set to the frequency mode. In this manner, the implantable spinal fusion stimulators were thoroughly assessed to determine any malfunction or failure resulting from exposure to the above-indicated MR procedure.

MR Imaging Performed in Patients With the Implantable Spinal Fusion Stimulator

Nine patients underwent MR imaging at 1.5 T (Signa MR System, General Electric Medical Systems) involving the lumbar spine (six patients) or cervical spine (three patients). In each case, the implantable spinal fusion stimulator was located in the region examined by MR imaging. For MR imaging of the lumbar spine, the following imaging parameters were used: T1-weighted coronal localizer (TR/TE 600/16 msec), T1-weighted sagittal images (TR/TE 600/16 msec), spin density- and T2-weighted sagittal images (TR/TE/TE 2000/30/80 msec) followed by fast spin-echo axial images (TR/effective TE 3500/95 msec), and T1-weighted axial images (TR/TE, 600/17 msec) through the L2–S1 disc space levels before and after intravenous gadolinium-diethylene triamine pentaacetic acid (DTPA) (Magnevist; Berlex, Princeton, NJ) administration. Fast spin-echo T2-weighted sagittal images (TR/effective TE 3000/104 msec) were also obtained. The echo train length for the fast spin-echo sequences was 8, the field of view ranged from 20 to 30 cm, the imaging matrix was 128–256 × 256, the section thickness ranged from 2 to 4 mm, and the whole-body averaged specific absorption rates ranged from 0.1 to 0.9 W/kg.

For the cervical spine examinations, the afore-mentioned parameters were used along with an axial gradient-echo, three-dimensional T2*-weighted sequence (TR/TE 50/15 msec, flip angle 15°). The echo train length for the fast spin-echo sequences was 8, the field of view ranged from 19 to 25 cm, the imaging matrix was 256 × 256, the section thickness ranged from 1.5 mm (for the three-dimensional T2*-weighted pulse se-

TABLE 1
Testing Condition During Assessment of Artifacts Produced by the Implantable Spinal Fusion Stimulator (SpF-2T/CW) During MR Imaging*

Parameter	Condition no.					
	1	2	3	4	5	6
Position in magnetic field	Perpendicular	Parallel	Perpendicular	Parallel	Perpendicular	Parallel
Signal void size (cm^2)	140	156	118	129	95	96
Static field (T) strength	1.5	1.5	1.5	1.5	1.5	1.5
Pulse sequence	FMPSPGR	FMPSPGR	T1-SE	T1-SE	T1-FSE	T1-FSE
TR (msec)	50	50	300	300	300	300
TE (msec)	3.3	3.3	20	20	17 (effective)	17 (effective)
Flip angle	30°	30°	N/A	N/A	N/A	N/A
Bandwidth (kHz)	16	16	16	16	16	16
Field of view (cm × cm)	26 × 26	26 × 26	26 × 26	26 × 26	26 × 26	26 × 26
Matrix size (cm × cm)	256 × 128	256 × 128	256 × 128	256 × 128	256 × 192	256 × 192

* FMPSPGR = fast multiplanar spoiled gradient echo, T1-SE = T1-weighted spin-echo, T1-FSE = T1-weighted fast spin-echo, N/A = not applicable. Physiologic saline solution will fill phantom that has T1 and T2 values similar to muscle or liver tissue.

quence) to 4 mm, and the whole-body averaged specific absorption rates ranged from 0.1 to 0.7 W/kg.

The patients were monitored via visual observations and the MR system intercom during the MR procedures. After MR imaging, the patients were questioned to determine whether they experienced any unusual sensations or physical feelings during or after the examination, particularly with respect to sensations of heating or neuromuscular excitation. Extreme or worst-case conditions were not utilized for the MRI examinations conducted in the patients.

RESULTS

Assessment of Magnetic Field Interactions

The deflection angle measured for the implantable spinal fusion stimulator tested at 1.5 T was 43°. There was no significant torque interaction for the implantable spinal fusion stimulator when it was placed in the horizontal orientation (ie, torque = 0), given the shape of the device relative to the direction of the magnetic field for the 4.7-T magnet. For the upright orientation, the maximum torque was 17.5 Newton meters × 10 e-3, and for the vertical orientation the maximum torque was 18.4 Newton meters × 10 e-3. Therefore, the vertical orientation produced a greater torque effect than the upright orientation for the stimulator. The scaling of torque as a function of the magnetic field can be assumed to be linear within a large range of values, such that torque can be calculated for other magnetic field strengths. For a 1.5-T magnetic field, the maximum torque in an orientation that is also at a maximum for the implantable spinal fusion stimulator (ie, the vertical orientation) is calculated to be 5.9 Newton meters × 10 e-3, and for a 1.0-T magnetic field it is 3.9 × 10 e-3 Newton meters.

Assessment of Artifacts

A summary of the planimetry measurements of the cross-sectional artifact sizes for the various test conditions is shown in Table 1. Figure 3 shows the artifacts seen with the use of the FMPSPGR sequence for MR images obtained in planes that were perpendicular and parallel to the implantable spinal fusion stimulator. The artifacts were predominantly observed to be signal voids (ie, signal dropout) and distortions of the fluid-filled phantom. These examples were selected because they demonstrate the largest artifacts with respect to the different MR imaging pulse sequences that were used. In general, the cross-sectional areas of the artifacts (ie, the signal voids) varied according to the pulse sequence used, as follows (in descending order): FMPSPGR, T1-weighted spin-echo, T1-weighted fast spin-echo.

Assessment of Operational Aspects of the Implantable Spinal Fusion Stimulator

For the six implantable spinal fusion stimulators that were evaluated, the average current and the average frequency before the MR imaging procedures were 19.3 ± 0.27 μA and 3.31 ± 0.04 Hz, respectively. After the MR imaging procedures, the average current and the average frequency were 19.1 ± 0.26 μA ($P < 0.01$) and 3.26 ± 0.04 Hz ($P < 0.01$), respectively. These data indicate that the MR imaging procedures produced no statistically significant alterations in the operational aspects of the implantable spinal fusion stimulators.

MR Imaging Performed in Patients With the Implantable Spinal Fusion Stimulators

There were no reports of immediate or delayed (minimum of 1-month follow-up) adverse events from pa-

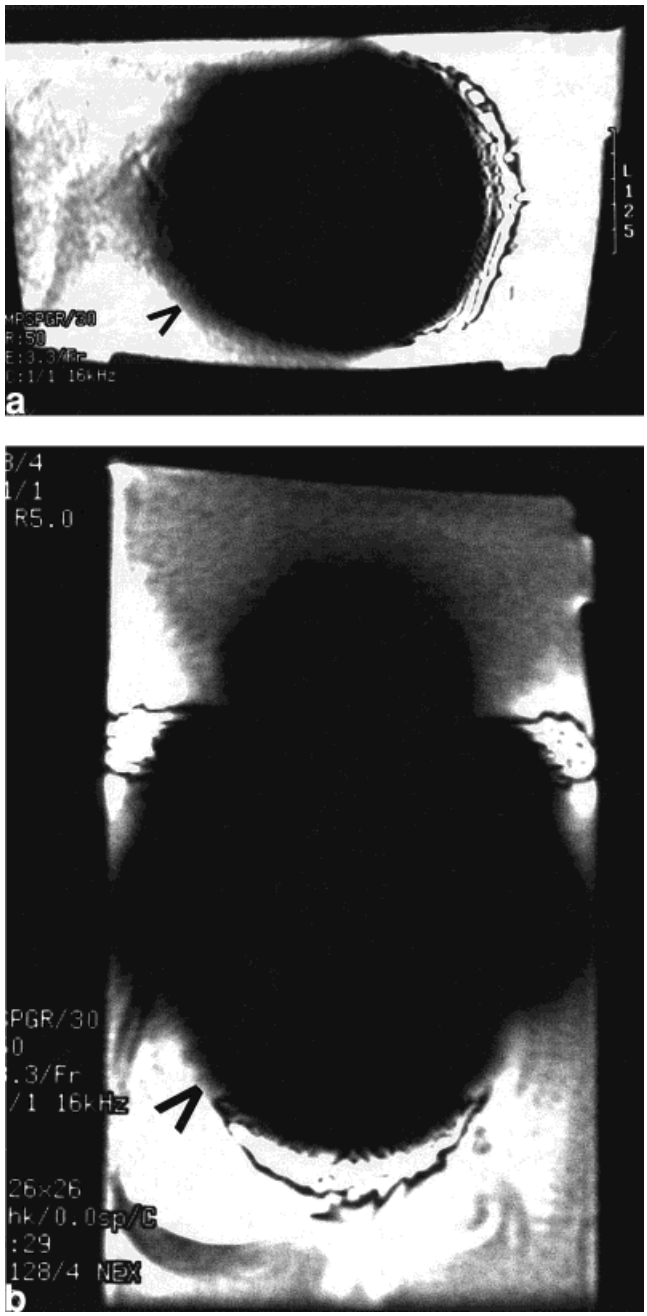

Figure 3. Examples of artifacts assessed for the implantable spinal fusion stimulator. The device was placed in a fluid-filled phantom, and MR imaging was performed using a fast spoiled multiplanar spoiled gradient-echo pulse sequence (TR/TE 50/3.3 msec, flip angle 30°). The imaging planes were oriented at perpendicular (**a**) and parallel (**b**) positions relative to the short axis and long axis of the implantable spinal fusion stimulator. Note the signal voids (arrowheads) associated with the presence of the spinal fusion stimulator. Cross-sectional area measurements of artifact sizes were 140 cm^2 (a) and 156 cm^2 (b).

tients with implantable spinal fusion stimulators who underwent MR imaging at 1.5 T. Each patient was visually inspected following the MRI study, and there was no evidence of excessive heating (ie, change in skin color or other similar response). Nevertheless, one patient indicated a sensation of "warming" felt at the site of the stimulator. However, this feeling was described as minor, and the MR examination was completed without further reports of sensations or problems. There were no reports of excessive heating or neuromuscular stimulation in association with the presence of the implantable spinal fusion stimulators in the MR imaging environment. Furthermore, there was no evidence of malfunction or failure of the implantable spinal fusion stimulators after the MR procedures were completed in the nine patients evaluated.

The diagnostic quality of the MR examinations was variable and depended on the position of the implantable spinal fusion stimulator relative to the specific area of interest, the pulse sequence used, and the presence of orthopedic fixation devices (ie, screws, wires, rods, etc.). In general, MR images were the most acceptable when obtained using T2-weighted fast spin-echo pulse sequences in patients who had stimulators implanted in positions relatively remote from the areas of interest (Figs. 4, and 5).

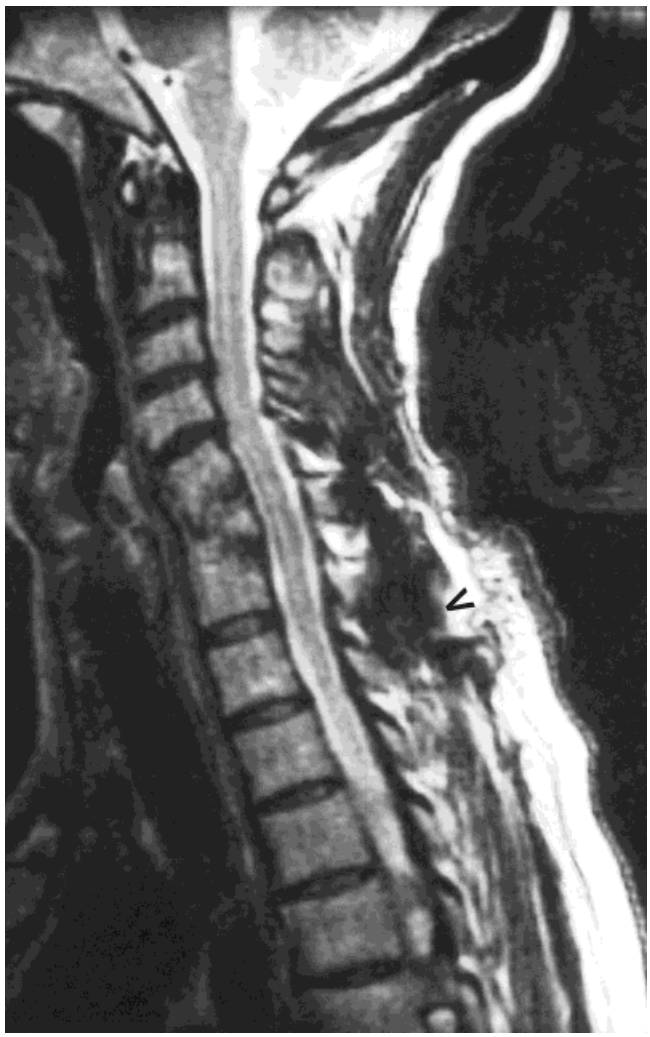

Figure 4. MR image of the cervical spine (sagittal, T2-weighted fast spin-echo; TR/effective TE, 3000/104 msec, echo train length 8) shows relative lack of effect of the associated artifact (arrowhead) on the disc space level, neural foramen, and spinal canal.

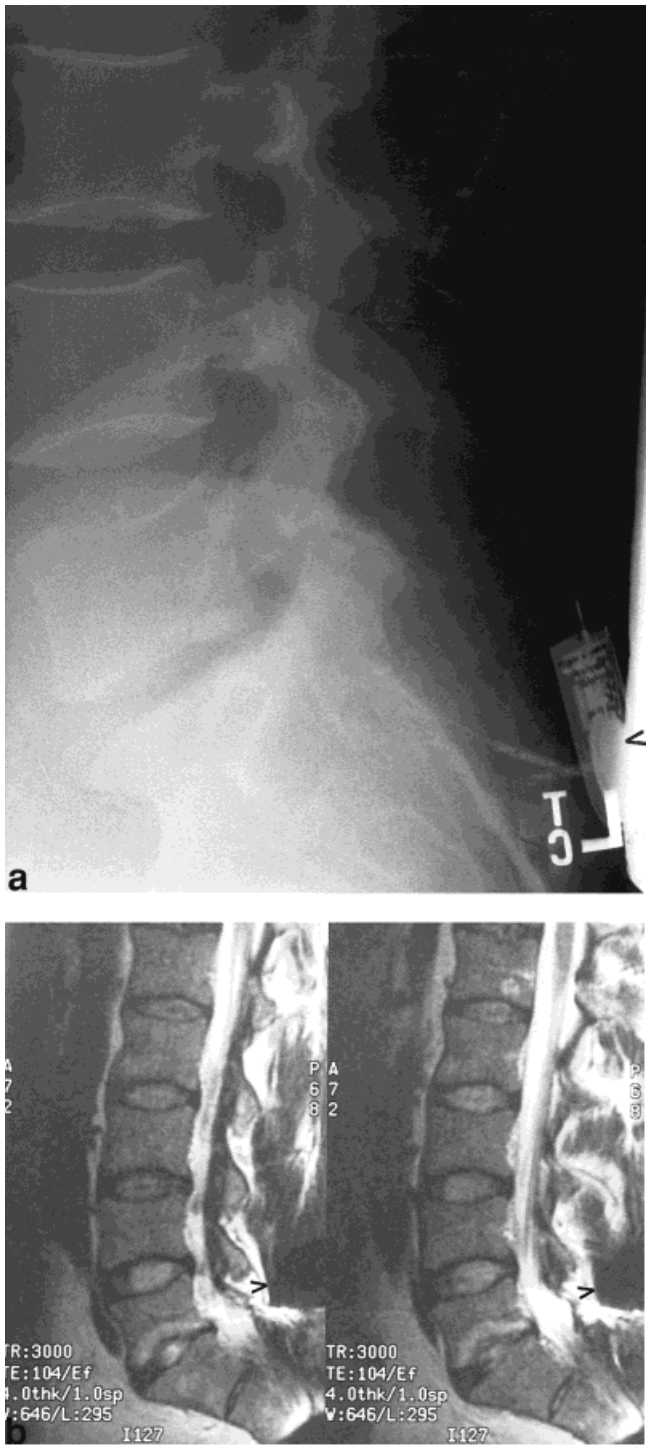

Figure 5. **a:** Lateral radiograph of the lumbar spine shows the implantable spinal fusion stimulator (arrowhead) in a position posterior and lateral to the sacral spine at approximately the level of S2–S3. **b:** MR image of the lumbar spine (sagittal, T2-weighted fast spin-echo; TR/effective TE, 3000/104 msec, echo train length 8) shows relative lack of effect of the associated artifacts for the stimulator in this position (arrowhead).

DISCUSSION

Magnetic Field Interactions

The implantable spinal fusion stimulator contains small ferromagnetic electronic components, while the leads, cathodes, and battery are each made from nonferromagnetic materials. Since the deflection angle measured for the implantable spinal fusion stimulator was 43° in association with the 1.5-T MR system, this device would be considered to be acceptable for patients undergoing MR procedures using a 1.5-T MR system or less, based on the criteria set forth by the American Society for Testing and Materials (28). According to the American Society for Testing and Materials guideline, the magnetic force acting on a device is less than the gravitational force if the deflection angle from the vertical is less than 45° (28). The translational force for the deflection angle of 43° corresponds to a force of approximately 0.1 Newton. Since the magnetic attractive or translational force acting on the stimulator was less than its gravitational weight (ie, the deflection angle was 43°), the magnetic field will neither move the implant in vivo nor will it be uncomfortable for the patient. In other words, the force acting on this implant in a lateral manner is similar to that acting on it in a downward manner from gravity with respect to testing in a shielded 1.5-T MR system. In simple terms, for the shielded conditions commonly found throughout the world for clinical 1.5-T MR systems, the implantable spinal fusion stimulators experience less force on them directly laterally into the MR system than downward from gravity. Therefore, there would be little to no risk to a patient with respect to movement or dislodgment of the implantable spinal fusion stimulator. Of further note is that implantable spinal fusion stimulators are placed in subcutaneous tissue that provides retention forces on the implant, thus reducing the translational effects of the magnetic field.

Torque acting on the implantable spinal fusion stimulator was evaluated as a function of the rotation about three orthogonal axes in a 4.7-T magnetic field. Testing was conducted using this high-field-strength magnet to ensure that all ferromagnetic components of the implantable spinal fusion stimulator would be "magnetically saturated." The torques were then scaled to correspond to a magnetic field of 1.5 T, since this is the highest static magnetic field that is most often used for MR procedures.

The implantable spinal fusion stimulator is typically placed subcutaneously in the region of the spine, which corresponds to the horizontal orientation described in the Methods section of this report. In this position for the device, the torque was zero. The maximum torque was observed when the stimulator was in a vertical orientation, perpendicular to the static magnetic field. Since the long axis of the patient's body is always parallel to the static magnetic field of a 1.5-T MR system, the generator could never be perpendicular to this magnetic field strength nor subjected to the maximum torque. However, even under a worst-case scenario, magnetically induced torque is unlikely to cause a problem for a patient in consideration of the counterforces created by the subcutaneous tissues (including tissue formed as a result of encapsulation of the implant) that surround the implantable spinal fusion stimulator. Notably, this is not the case when the patient sits on the scanner table; however, the strength of the MR system at this point is considerably lower.

In further support of the lack of substantial magnetic

field interactions (ie, with regard to translational attraction and torque), none of the nine patients studied in this investigation experienced sensations related to motion of the implantable spinal fusion stimulator. Additionally, there has never been a published report of a patient incident that involved movement or dislodgment of the implantable spinal fusion stimulator.

Artifacts

MR imaging artifacts associated with a metallic object are mostly dependent on the magnetic susceptibility of the specific material(s) used to make the object as well as the quantity, shape, orientation, and position of the object in vivo (4,20,24,25,30–32).

Since the implantable spinal fusion stimulator is mostly made from nonferromagnetic materials, the artifacts were regarded as relatively minor. According to the ex vivo characterization of artifacts for the implantable spinal fusion stimulator, the FMPSPGR pulse sequence produced the largest artifacts, while the fast spin-echo pulse sequence produced the smallest artifacts. Similar findings have been reported for other metallic implants insofar as there are advantages to using fast spin-echo pulse sequences to minimize artifacts compared with using conventional spin-echo and gradient echo sequences (24,25,30–32).

The quality of the MR images obtained in the patients in this study was variable and depended on the position of the stimulator relative to the specific area of interest, the pulse sequence used, and the presence of other orthopedic devices. Understandably, MR images obtained using the T2-weighted fast spin-echo pulse sequences showed the least amount of artifacts. Accordingly, fast spin-echo techniques should be utilized to minimize the extent of the artifacts associated with the implantable spinal fusion stimulator or whenever there are metallic implants present in the spine (4,32).

While MR imaging artifacts are not inherently a safety issue, in the best interest of the patient, an additional step may be taken to reduce the amount of artifact that may occur at a future potential imaging site. This involves implantation of the stimulator a distance of at least 5–8 cm from the imaging area of interest in order to maintain the diagnostic quality of the MR procedure.

Operational Aspects

Tests performed to determine the effect of MR imaging on the implantable spinal fusion stimulators indicated that the operational aspects of the devices were essentially unchanged. Therefore, according to the results of the ex vivo experiments, in combination with the findings for the patients that were studied (ie, there was no evidence of malfunction or failure of the device), MR imaging does not appear to alter the function of implantable spinal fusion stimulators. Additional support for the lack of MR-induced effects for these devices is provided by the fact that there have been no reports to the company (personal communication, B. J. Simon, Electro-Biology), in the peer-reviewed literature of such changes, or in data obtained through the Freedom of Information Act.

Heating Effects

Chou et al (21) conducted a thorough investigation of the effect of heating of the implantable spinal fusion stimulator associated with MR imaging. This work was performed using a full-sized human phantom during MR procedures involving a relatively high exposure to RF energy (ie, at whole-body averaged specific absorption rates of approximately 1.0 W/kg) (21). Fiberoptic thermometry probes were placed at various positions on and near the cathodes, leads, and the stimulator for each experiment to record temperature changes. The phantom used by Chou et al (21) did not include the effects of blood flow, which obviously would help dissipate heating that may occur during MR imaging; therefore, it further represents an excessive RF exposure condition.

With the implantable spinal fusion stimulator in place and the leads intact, the maximum temperature rise after 25 minutes of scanning occurred at the center of the stimulator and was less than 2.0°C (21). The temperature rise at the cathodes was less than 1.0°C. When the simulator and leads were removed, the maximum temperature rise was less than 1.5°C, recorded at the tip of the electrode with insignificant temperature changes occurring at the cathode (21). These temperature changes are within physiologically acceptable ranges for the tissues where the implantable spinal fusion stimulator is implanted, especially considering that the temperatures for muscle and subcutaneous tissues are at levels known to be several degrees below the normal core temperature of 37°C (33–36).

Chou et al (21) also investigated heating of the tips of broken leads of the implantable spinal fusion stimulator (this device was the same as that which underwent testing in the present study). Temperature changes occurred in localized regions that were within a few millimeters of the cut ends of the leads, with maximum temperature increases that ranged from 11.0 to 14.0°C (21). If these levels of temperatures occurred during MR imaging, the amount of possible tissue damage would be comparable in characteristics and clinical significance to a small electrosurgical lesion and would probably occur in the scar tissue that typically forms around the implanted leads. Additionally, the potential for tissue damage is only theoretical, and a brief temperature elevation around a broken lead, over an approximated volume of 2–3 mm radius may not be clinically worse than the scar tissue that forms over the leads during implantation. Fortunately, broken leads are rare, occurring in approximately 10 of the 70,000 devices implanted over the last 10 years (personal communication, B. J. Simon, Electro-Biology).

While one patient in the series evaluated in this investigation reported a warming sensation during MR imaging, it was determined that this feeling did not present a substantial risk to the individual and, therefore, the MR examination continued without any indication of short- or long-term clinical problems. It is possible that an MR procedure performed at a higher level of RF energy and/or in a larger patient may result in greater heating. Therefore, MR users should vigilantly monitor patients with implantable spinal fusion stimulators undergoing MR procedures to ensure that

they do not experience warming or heating sensations. Care should also be taken to select MR imaging parameters in consideration of using a relatively low level of RF energy for these cases.

As was previously stated, there has never been a report of a patient being injured as a result of excessive heat developing in an implantable spinal fusion stimulator. [Notably, patients without implants have experienced heating during MR procedures due to the pulse sequence used and/or the environmental conditions of the MR system (37,38).] While this anecdotal information does not definitively indicate that there is no possibility of a patient being injured in association with an MR procedure, it does suggest that a margin of safety probably be achieved for patients with implantable spinal fusion stimulators by following highly specific guidelines and recommendations.

Based on the above information, RF energy-induced heating during MR imaging does not appear to present a major problem for a patient with the implantable spinal fusion stimulator, as long as there is no broken lead. The integrity of the leads should be assessed using a radiograph prior to the MR procedure.

Induced Electrical Fields

Buechler et al (23) calculated the electrical fields induced near an implantable spinal fusion stimulator by MR-related switched gradient magnetic fields under worst-case conditions using a three-dimensional finite difference model. (This device is the same as that which underwent testing in the current study.) In these calculations, which were performed to assist in the assessment of possible nerve stimulation in patients, several approximations were made. These approximations included a uniform magnetic field excitation, U-shaped implant representation, and square wire shape both to simplify and to provide worst-case result (23). Additionally, induced electrical fields were calculated for several variations of the implantable spinal fusion stimulator and with respect to different orientations of the magnetic field (24).

The work of Buechler et al (23) was used by Reilly and Diamant (22) to determine possible nerve stimulation using a Spatially Extended Nonlinear Node model. The results indicated that, in a gradient magnetic field having a time derivative of 10 T/sec, nerve excitation is possible under worst-case conditions for nerve fibers that are within 0.14 mm of the bare wire tip of the cathode (23). At 20 T/sec, nerve excitation is possible for nerve fibers within 1.0 mm of the tip of the wire. In regard to the anatomical considerations of these findings, when the implantable spinal fusion stimulator is properly implanted (1), the cathode should never be closer than 1 cm from the nearest nerve root (manufacturer's recommendation). Therefore, nerve excitation should not occur during MR imaging provided the cathodes are positioned appropriately (ie, according to the product recommendations for implantation of the stimulator) and the gradient magnetic fields are less than 20 T/sec.

For the patients evaluated in this investigation, there was no evidence of induced electrical currents associated with the MR procedures. To date, there has been no published report of neuromuscular or other similar stimulation related to the presence of implantable spinal fusion stimulators in patients undergoing MR examinations.

CONCLUSION AND RECOMMENDATIONS

In conclusion, experiments conducted to assess magnetic field interactions, artifacts, and operational aspects of implantable spinal fusion stimulators combined with data and experience in patients and findings from previous MR imaging safety investigations for this device have been evaluated. The implantable spinal fusion stimulator is safe for patients undergoing MR procedures following specific guidelines. (The United States Food and Drug Administration has recently approved an "MR safe" labeling claim for this implantable spinal fusion stimulator.) Recommended guidelines for conducting an MR examination in a patient with the implantable spinal fusion stimulator are as follows:

1. The cathodes of the implantable spinal fusion stimulator should be positioned a minimum of 1 cm from nerve roots to reduce the possibility of nerve excitation during an MR procedure.
2. Plain films should be obtained prior to MR imaging to verify that there are no broken leads present for the implantable spinal fusion stimulator. If this cannot be reliably determined, then the potential risks and benefits to the patient requiring MR imaging must be carefully assessed in consideration of the potential for excessive heating to develop in the leads of the stimulator.
3. MR imaging should be performed using MR systems with static magnetic fields of 1.5 T or less, and conventional techniques including spin-echo, fast spin-echo, and gradient echo pulse sequences should be used. Pulse sequences (eg, echo planar techniques) or conditions that produce exposures to high levels of RF energy (ie, exceeding a whole-body averaged specific absorption rate of 1.0 W/kg) or exposure to gradient fields that exceed 20 T/sec, or any other unconventional MR technique should be avoided.
4. Patients should be continuously observed during MR imaging and instructed to report any unusual sensations including any feelings of warming, burning, or neuromuscular excitation or stimulation.
5. Placement of the implantable spinal fusion stimulator as far as possible from the spinal canal and bone graft is desirable since this will decrease the likelihood that artifacts will affect the area of interest on MR images. Consideration should be given to selecting an imaging strategy that minimizes artifacts if the area of interest for MR imaging is in close proximity to the implantable spinal fusion stimulator. The use of fast spin-echo pulse sequences will minimize the amount of artifact associated with the presence of the implantable spinal fusion stimulator.

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