Invited Review _____

Magnetic Resonance Safety Update 2002: Implants and Devices

Frank G. Shellock, PhD*

The preservation of a safe magnetic resonance (MR) environment requires constant vigilance by MR healthcare professionals, particularly with regard to the management of patients with metallic biomedical implants or devices. The variety and complexity of implants and devices constantly changes, requiring continuous attention and diligence with regard to obtaining the most current and accurate information about these objects relative to the MR environment. This review article discusses MR safety and MR compatibility issues and presents important information for a variety of implants and devices, with an emphasis on those objects that have recently undergone evaluation or that require additional consideration because of existing controversy or confusion.

Key Words: magnetic resonance imaging (MRI); MRI, safety; MRI, implants; MRI, heating; MRI, artifacts
J. Magn. Reson. Imaging 2002;16:485–496.
© 2002 Wiley-Liss, Inc.

THE PRESERVATION OF A SAFE MAGNETIC resonance (MR) environment requires constant vigilance by MR healthcare professionals, particularly with regard to the management of patients with metallic biomedical implants or devices (1–6). The variety and complexity of implants and devices constantly changes, requiring continuous attention and diligence with regard to obtaining the most current and accurate information about these objects relative to the MR environment.

Since the introduction of MR imaging (MRI) as a clinical modality in the early 1980s, more than 100,000,000 diagnostic procedures (estimated) have been completed with relatively few major incidents (review of the Medical Device Report database, Center for Devices and Radiological Health, U.S. Food and Drug Administration, April 20, 2002, and references 1–9). Notably, most reported cases of MR-related injuries have been the direct result of mis-

information related to the MR safety aspects of metallic objects or due to deficiencies in pre-MR procedure screening methods (6).

The MR environment may be unsafe for patients or individuals with certain biomedical implants or devices, primarily due to movement or dislodgment of objects made from ferromagnetic materials (1–6,10–75). While excessive heating and the induction of electrical currents may also present risks to patients with implants or devices, these MR safety problems are typically associated with implants that have elongated configurations and/or that are electronically activated (e.g., neurostimulation systems, cardiac pacemakers, etc.) (1–5,28,53,61,62,68,75).

To date, more than 1,100 implants and objects have been tested for MR safety or MR compatibility (1–5,10–74). This information is readily available to MR healthcare professionals as individual published reports and compiled lists and in an online format (3,5,8,75). Unfortunately, a comprehensive presentation and discussion of MR procedures and metallic objects is not within the scope of this review article due to space limitations. However, this topic has been covered in great detail elsewhere (3,5,8,75).

The intent of this review article is to discuss MR safety and MR compatibility issues and to present important information for a variety of implants and devices, with an emphasis on those objects that have recently undergone evaluation or that require additional consideration because of existing controversy or confusion.

MR SAFETY AND MR COMPATIBILITY

The terms *MR safe* and *MR compatible* are typically used to designate specific aspects of metallic implants and devices (9,76). Therefore, it is important to appreciate the differences between these terms, as they should *not* be used interchangeably. For those in the MR community unfamiliar with these terms, they are defined as follows (76):

MR safe: The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individual, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the term

MR safe since a device that is safe under one set of conditions may not be found to be so under more extreme MR conditions.

MR compatible: A device is considered MR compatible if it is MR safe and if it, when used in the MR environment, has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the term MR compatible since a device that is safe under one set of conditions may not be found to be so under more extreme MR conditions.

It should be noted that MR safety testing of an implant or object involves assessment of magnetic field interactions, heating, and induced electrical currents, while MR compatibility testing requires all of these as well as characterization of artifacts (9,76). In addition, the functional or operation aspects of the implant or device should be evaluated.

MAGNETIC FIELD-RELATED ISSUES

In the MR environment, magnetic field-related translational attraction and torque may cause hazards to patients and individuals with ferromagnetic implants or devices (1–8). The relative risks are proportional to the strength of the static magnetic field, the strength of the spatial gradient, the mass of the object, the shape of the object, and the magnetic susceptibility of the object (1–8). Furthermore, the intended in vivo use of the implant or device must be taken into consideration because existing counteracting forces may be present that effectively prevent movement or dislodgment of a ferromagnetic object.

Obviously, an important aspect of MR safety testing for metallic implants and devices involves the determination of translational attraction and torque (1–8,10–27,29–44,60,71–74). Translational attraction is typically assessed using the deflection angle test originally described by New et al (1), modified and used by others (10,22–26), and recommended by the American Society for Testing and Materials (ASTM) (76). According to this procedure, the deflection angle for an implant or device is typically measured at the point of the highest spatial gradient for the specific MR system used for testing (76). If the deflection angle from the vertical is less than 45°, the object passes the translational attraction test insofar as the magnetic force acting on the implant is less than the gravitational force (76).

Torque rotates or aligns the object parallel to the magnetic field and is dependent on the strength of the magnetic field, the dimensions of the object (primarily the length), and the initial angulation of the object relative to the static magnetic field (1,7). A variety of techniques have been used to qualitatively or quantitatively determine magnetic field-related torque for implants and devices (1,20,22,25,31,39). To date, a test procedure and acceptable measurement value for torque imposed on implants or devices has not been defined. However, according to the ASTM (76), a torque value for an implant "that is less than that produced by normal daily activities (which might include rapidly accelerating vehicles or amusement park rides) is assumed to be safe." Notably, the amount of torque necessary to displace an implant or device is unknown, and depends on a variety of factors.

MR System Field Strength

Currently, MR systems operating in clinical and research settings have static magnetic fields that range from 0.064–8.0 Tesla. Presently, the clinical use of 3.0-Tesla MR systems is increasing in the United States and abroad. Obviously, important MR safety issues exist relative to the use of these powerful MR systems, especially with regard to the management of patients and individuals with metallic implants and devices.

Most previous ex vivo tests performed to determine MR safety or MR compatibility for implants and devices used MR systems with static magnetic fields of 1.5 Tesla or lower (1–5,10–25,29–44,64,71–74). This could be problematic for a patient or individual with a metallic implant or device exposed to an environment associated with a higher static magnetic field strength. For example, it is possible that a metallic object that displayed "weakly" ferromagnetic qualities in association with a 1.5-Tesla MR system may exhibit substantial magnetic field interactions in association with exposure to an MR system operating at a higher static magnetic field strength. Therefore, investigations must be conducted to acquire MR safety information for implants and devices relative to exposure to MR systems operating above 1.5 Tesla before allowing individuals with these objects to enter these very high magnetic field MR environments.

Long-Bore vs. Short-Bore MR Systems

Various types of magnet configurations exist for commercially available 1.5- and 3.0-Tesla MR systems. These include conventional long-bore and short-bore scanners used for whole-body (1.5- and 3.0-Tesla MR systems) and head-only (3.0-Tesla MR systems) clinical applications. Because of physical differences in the position and magnitude of the highest spatial gradient for different magnets, measurements of deflection angles for implants or devices performed according to the ASTM document (76) using long-bore vs. short-bore MR systems may produce substantially different results (Tkach et al, unpublished observations, March 2002). Therefore, this important point must be taken into careful consideration whenever translational attraction is assessed for a metallic implant or device.

MR PROCEDURES AND POSTOPERATIVE PATIENTS WITH IMPLANTS AND DEVICES

Surprisingly, there is a lot of confusion regarding the issue of performing an MR procedure during the postoperative period in a patient with a metallic implant or device. In general, if the metallic object is a "passive" implant (i.e., there is no power associated with the operation of the object) and made from a nonferromagnetic material (e.g., Elgiloy, Phynox, MP35N, titanium, titanium alloy, Nitinol, tantalum, etc.), the patient may

Table 1
Guidelines Recommended for Consideration Prior to Exposing Patients and Individuals With Aneurysm Clips to the MR Environment

1. Specific information (i.e., manufacturer, type or model, material, lot and serial numbers) about the aneurysm clip must be known, especially with respect to the material used to make the aneurysm clip, so that only patients or individuals with nonferromagnetic or weakly ferromagnetic clips are allowed into the MR environment. This information is provided by the manufacturer in the product label for the clip. The implanting surgeon is responsible for properly communicating this information in the patient's or individual's records.
2. An aneurysm clip that is in its original package and made from Phynox, Elgiloy, MP35N, titanium alloy, commercially pure titanium or other material known to be nonferromagnetic or weakly ferromagnetic at 1.5 Tesla or less does not need to be evaluated for ferromagnetism. Aneurysm clips made from nonferrromagnetic or weakly ferromagnetic materials in original packages do not require testing of ferromagnetism because the manufacturers ensure the pertinent MR safety aspects of these clips and, therefore, are held responsible for the accuracy of the labeling.
3. If the aneurysm clip is not in its original package and properly labeled, it should undergo testing for magnetic field interactions.
4. The radiologist and implanting surgeon should be responsible for evaluating the available information pertaining to the aneurysm clip, verifying its accuracy, obtaining written documentation and deciding to perform the MR procedure after considering the risk vs. benefit aspects for a given patient.

undergo an MR procedure immediately after placement of the object using an MR system operating at 1.5 Tesla or less.

For an object that is weakly magnetic, it is typically necessary to wait a period of 6–8 weeks prior to performing an MR procedure. In this case, retentive or counter forces provided by tissue in growth, scarring, or granulation serve to prevent the object from presenting a risk or hazard to the patient in the MR environment. For example, certain types of coils, filters, stents, and cardiac occluders that are weakly ferromagnetic typically become firmly incorporated into the tissue 6–8 weeks following placement (3,5,11,39–41). Therefore, it is unlikely that these objects will be moved or dislodged magnetic field interactions associated with MR systems operating at 1.5 Tesla or less. Obviously, if there is any concern regarding the integrity of the tissue with respect to its ability to retain the object in place during an MR procedure or during exposure to the MR environment, the patient or individual should not be exposed to the MR environment.

IMPLANTS AND DEVICES

Aneurysm Clips

Neurosurgical management of an intracranial aneurysm or arteriovenous malformation by application of a temporary or permanent aneurysm clip is a well-established procedure. Aneurysm clips come in a wide variety of shapes and blade lengths and are made from different materials with varying magnetic susceptibilities. These factors can greatly influence the MR safety aspects of these implants. While certain aneurysm clips are a contraindication for the MR environment, others classified as nonferromagnetic or weakly ferromagnetic are deemed safe for patients or individuals exposed to MR systems operating at 1.5 Tesla or less (1–5,8, 11–24).

Most MR healthcare professionals are familiar with the potential dangers of exposing patients or individuals with ferromagnetic aneurysm clips to the MR environment. The presence of a ferromagnetic aneurysm clip requires the utmost consideration due to magnetic field interactions that can dislodge the implant, potentially resulting in serious injury or death (1–6,8,77–79). There has been one documented incident of a patient

mortality due to the displacement of the clip that occurred during an MR procedure (77). The aneurysm clip was originally thought to be a nonferromagnetic or weakly ferromagnetic type, but it was later confirmed that the information originally obtained about the clip was incorrect (77).

There has been much controversy and confusion regarding the amount of ferromagnetism that needs to be present in an aneurysm clip to constitute a hazard for a patient in the MR environment. Presently, the specific guidelines indicated in Table 1 are recommended for consideration prior to exposing patients or individuals with aneurysm clips to the MR environment (3,5,8,20,21,75). There has also been concern that long-term exposures to strong magnetic fields may grossly magnetize aneurysm clips made from nonferromagnetic material (21). Therefore, different aneurysm clips made from Elgiloy, Phynox, titanium alloy, pure titanium, and austenitic stainless steel were tested in association with long-term and multiple exposures to the static magnetic fields of a 1.5-Tesla MR system (21). The results of this study demonstrated a lack of clinically significant changes in the magnetic properties of these implants (21).

Previous reports investigating magnetic qualities of aneurysm clips indicated that aneurysm clips made from stainless steel alloy, Phynox, Elgiloy, commercially pure titanium, and titanium alloy were safe at 1.5 Tesla (1–3,5,8,11–23). However, as previously discussed, few studies have been performed to evaluate magnetic field interactions for implants in association with MR systems operating above 1.5 Tesla. A study conducted at 8.0 Tesla by Kangarlu and Shellock (26) reported that all aneurysm clips, even those made from titanium or titanium alloy, displayed positive translational attractions (deflection angles ranged from 5–53°). Importantly, several aneurysm clips reported to be safe at 1.5 Tesla were found to be potentially unsafe at 8.0 Tesla because they showed excessive deflection angles and relatively high qualitative torque values (26). Again, this emphasizes the need to evaluate implants and devices in association with MR systems operating above 1.5 Tesla.

Heart Valve Prostheses and Annuloplasty Rings

Many heart valve prostheses and annuloplasty rings have been evaluated as MR safe. Of these, the majority

of the implants displayed measurable yet relatively minor translational attraction and/or torque in association with exposure to the MR systems used for testing (1,2,30–35). Heating and induced currents do not appear to be problematic for these implants (30–35). Because the actual attractive forces exerted on heart valves and annuloplasty rings were minimal compared to the force exerted by the beating heart (33,34), an MR procedure is not considered to be hazardous for a patient that has any of the heart valve prostheses or annuloplasty rings that have undergone testing (1,2,30–35). This recommendation includes the Starr-Edwards Model Pre-6000 heart valve prosthesis, which was previously suggested to be a potential risk for a patient undergoing an MR procedure. With respect to clinical MR procedures, there has never been a report of a patient incident or injury related to the presence of a heart valve prosthesis.

Recently, Condon and Hadley (80) reported the theoretical possibility of a previously unconsidered electromagnetic interaction with heart valves that contain metal in the disk or leaflet component. Basically, any metal (not just ferromagnetic metals) moving through a magnetic field will develop a magnetic field that opposes the original magnetic field. This phenomenon is referred to as the *Lenz effect*. In essence, a resistive pressure may develop with the potential to inhibit both the opening and closing of the mechanical heart valve prosthesis (80). The Lenz effect is proportional to the strength of the static magnetic field (80). Accordingly, there may be problems for patients with heart valves that have metal leaflets undergoing MR procedures on MR systems greater than 1.5 Tesla, although this has never been demonstrated or reported.

Coils, Stents, and Filters

A wide variety of stents, filters, and coils have been evaluated for MR safety (25,27,38–43). Notably, heating and induced currents have been evaluated for a wide variety of shapes and sizes of these implants and there do not appear to be any safety issues for these devices (25,27,38–43). Coils, stents, and filters that are made from nonferromagnetic materials (e.g., titanium, titanium alloy, Phynox, Elgiloy, MP35N, 316L stainless steel, or Nitinol) are considered safe for patients undergoing MR procedures using MR systems operating at 1.5 Tesla or less immediately after implantation. If the coil, stent, or filter is made from weakly ferromagnetic material (e.g., certain types of stainless steel), a waiting period of 6–8 weeks is recommended for tissue ingrowth or other mechanisms to help retain it in position during the MR procedure (39).

Unfortunately, some implant manufacturers, in their product documentation, may not differentiate between their nonferromagnetic devices and those that are weakly ferromagnetic (i.e., indicating a waiting period of 6–8 weeks for all implants regardless of the material used to make the device), which results in confusion for the MR safety aspects of these implants. Under all circumstances when dealing with coils, stents, and filters, obtaining documentation that clearly identifies the device and the manufacturer is always recommended. An MR procedure should never be performed if there is any possibility that the device is not firmly in place or positioned properly within the vessel.

Importantly, it must be acknowledged that new types of coils, stents, and filters continue to be developed that have not undergone MR safety testing. In addition, one must consider the presence of implants that were placed several years ago and/or are no longer on the market. Notably, at least two prototype stents have been identified that display excessive magnetic field interactions at 1.5 Tesla, indicating that not all coils, stents, and filters are safe for individuals in the MR environment (Shellock, unpublished observations, February 2000).

ESSURE Device for Permanent Contraception

The ESSURE device (Conceptus, San Carlos, CA) is a new metallic implant developed for permanent female contraception (Fig. 1) (10). This implant is a dynamically expanding microcoil that is placed in the proximal section of the fallopian tube using a nonincisional technique. Subsequently, the device elicits an intended benign tissue response, resulting in tissue ingrowth into the device, anchoring it firmly into the fallopian tube (10). This benign tissue response is local, fibrotic, and occlusive in nature. Accordingly, the presence of this implant is intended to alter the function and architecture of the fallopian tube, resulting in permanent contraception.

The ESSURE device is composed of the following materials: 316L stainless steel, platinum, iridium, nickle-titanium alloy, silver solder, and polyethylene terephthalate fibers. It has the following dimensions: inner coil length, 2.9–3.1 cm; outer coil diameter after deployment, 1.5–2.0 mm (10). Currently, this device is undergoing clinical trials as an investigational device in the United States, but it is used clinically in other countries.

The MR safety assessment of this ESSURE device involved testing for magnetic field interactions (1.5 Tesla), heating, induced electrical currents, and artifacts using previously described techniques (10). There were no magnetic field interactions, the highest temperature changes were $\leq +0.6°C$, and the induced electrical currents were minimal. Furthermore, artifacts should not create a substantial problem for diagnostic MRI unless the area of interest is in the exact same position as where the implant is located. Thus, the findings of this investigation indicated that it should be safe for patients with this metallic implant used for permanent contraception to undergo MR procedures using MR systems operating with static magnetic fields of 1.5 Tesla or less (10).

Implantable Spinal (Bone) Fusion Stimulator

The implantable spinal (bone) fusion stimulator (Electro-Biology, Inc., Parsippany, NJ) consists of a generator (which includes a battery and electronics in a titanium shell) and electrodes implanted near the area of treatment of the spine (63,64). Two wire leads are connected from the generator to the fusion sites, where
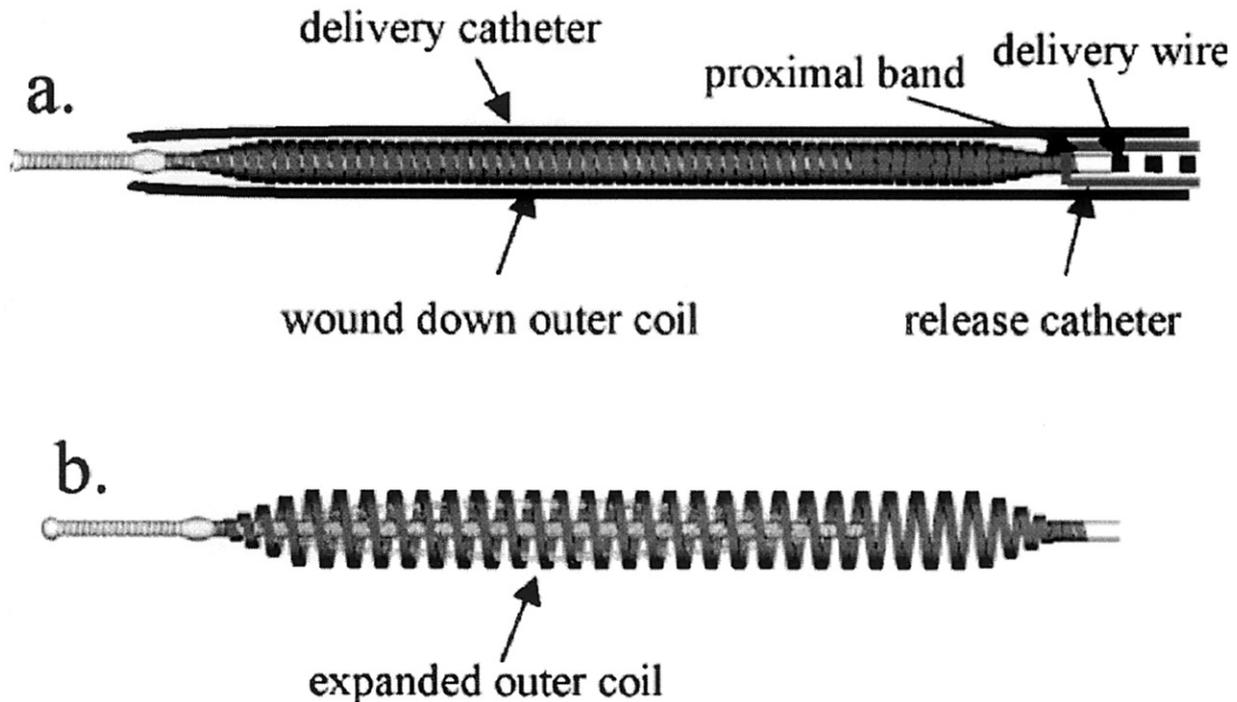
Figure 1. Schematic of metal implant (ESSURE device) used for permanent female contraception. **a:** Diagram shows device attached to delivery system in a low-profile wound-down configuration. **b:** Diagram shows expanded configuration with the expanded outer coils. (Reproduced with permission from Shellock FG, AJR Am J Roentgenol 2002;178:1513–1615.)

they are embedded in pieces of bone grafts. The device remains in place for approximately 24–26 weeks. The implantable spinal fusion stimulator is used to enhance and facilitate the rate of bone healing. This device received approval from the FDA, which designated it as MR safe based on comprehensive investigations, as long as specific guidelines are followed, as provided by the manufacturer in the product insert labeling (63,64). These guidelines are indicated in Table 2 (64).

MR Safe Fiber-Optic Cardiac Pacing Lead

Cardiac pacemakers present potential problems to patients undergoing MR procedures from several mechanisms, including: 1) movement of the pacemaker (implantable pulse generator and/or leads) due to the strong static magnetic field of the MR system; 2) MRI-related heating of the pacemaker lead by the time-varying fields; 3) inhibition or modification of the function of the pacemaker by the electromagnetic fields used for MRI; and 4) inappropriate or rapid pacing due to pulsed gradient magnetic fields and/or pulsed radio frequency (RF) fields (i.e., electromagnetic interference) from the operating MR system (i.e., with the pacing lead acting as an antenna) (4,5,8,45–60). These problems may result in serious injuries or lethal consequences for patients.

With specific regard to the cardiac pacing lead, there are concerns related to magnetic field-induced movement and substantial heating that may occur (4,5,8,53). In addition, the electrically conductive lead may pick up electromagnetic interference (EMI) from the MR system,

Table 2
Guidelines Recommended for Conducting an MR Procedure in a Patient With the Implantable Spinal (Bone) Fusion Stimulator*

1. During implantation, the implantable spinal fusion stimulator should be placed as far as possible from the spinal canal and bone graft since this will decrease the likelihood that artifacts will affect the area of interest on MR images.
2. The cathodes of the implantable spinal (bone) fusion stimulator should be positioned a minimum of 1 cm from nerve roots to reduce the possibility of nerve excitation.
3. Plain film radiographs should be obtained prior to the MR procedure 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 the MR procedure must be carefully assessed in consideration of the possibility for excessive heating to develop in the leads.
4. MR examinations must only be performed using MR systems operation at 1.5 Tesla or less, and only with conventional imaging techniques such as spin echo, turbo or fast spin echo, or gradient echo pulse sequences. Pulse sequences or conditions that produce exposures to high levels of RF energy (i.e., exceeding a whole body averaged specific absorption rate of 1.0 W/kg) or exposure to gradient fields that exceed 20 Tesla per second (e.g., echo planar imaging) or any other unconventional MR technique should be avoided.
5. The patient should be continuously observed during the MR procedure and instructed to report any unusual sensations including any feelings of warming, burning, or neuromuscular excitation or stimulation.

*Electro-Biology, Inc., Parsippany, NJ. Reference 64.

which can impair the pacemaker's performance or produce a life-threatening situation for the patient (4,5,8,47–52,57). In consideration of the above, it is obviously desirable to have a cardiac pacing lead that could function safely in the MR environment.

Recently, new technology has been developed that involves the stimulation of the heart by means of a fiber-optic lead that replaces the standard metallic lead of a cardiac pacemaker (60). The fiber-optic cardiac pacing lead incorporates specially designed components that include a low-power semiconductor laser to regulate the patient's heartbeat (60). This innovation essentially eliminates possible dangers associated with having a conductive pacing wire in a patient undergoing an MR procedure.

The fiber-optic cardiac pacing lead (Biophan Technologies, Inc., Rochester, NY) is intended for use via connection to the Temporary Photonic Pulse Generator (Model X-801, Biophan Technologies, Inc., Rochester, NY) (60). This cardiac pacing lead is made from a 200-μm fiber-optic cable. The distal end of the lead has two electrodes (silver-plated, thin-wall copper; tip electrode and ring electrode) designed to stimulate the heart (Fig. 2). Within the ring and tip portions of the lead are a power converter, resistor, and capacitor. Inside the ring electrode is a power converter that changes light energy into electrical energy for heart stimulation. The pulse generator (Temporary Photonic Pulse Generator, Model X-801) produces a 1-msec pulse (variable from 0.1–30 msec), which drives a 150-mW gallium-arsenide laser. The light pulse is connected to the distal end of the fiber-optic lead, where it illuminates a band of six gallium-arsenide photo diodes. The diodes are electrically connected in series to produce a voltage pulse of 4 V, which drive the tip and ring electrodes to stimulate the heart. Accordingly, this device is capable of generating sufficient current to pace the heart (60).

RF and pulsed gradient magnetic fields used for MRI induce currents in the body (4,5,8,53,61–63,68,69). It is well known that implants that have electronically activated or electrically conductive components can locally increase these currents, and under certain operational conditions, excessive heating of biomedical devices may occur in association with MR procedures (4,5,8,53,61–63,68,69). For example, exorbitant temperature elevations from MRI-related heating have been reported for cardiac pacemakers, neurostimulation systems indwelling catheters with metallic components (e.g., thermodilution catheters), guide wires, disconnected or broken-surface RF coils, and improperly used physiologic monitors resulting in first-, second-, or third-degree burns (3–5,8,59,68,75). Thus, thermal injury must be considered as a possible adverse outcome if RF power is transmitted in the direct vicinity of the implanted device or its attached components. Of note, there is a tendency for excessive heating to occur in looped or coiled devices because electrical currents are easily induced in these shapes during MRI (4,5,8,52,53,59,61–63,68,69).

Therefore, in consideration of the above, MRI-related heating was assessed for the fiber-optic cardiac pacing lead positioned in a saline-filled phantom. According to the findings, the highest temperature change measured

for the fiber-optic cardiac pacing wire was +0.8°C in association with MRI at 1.5 Tesla/64 MHz using a whole-body-averaged RF specific absorption rate of 1.5 W/kg. The highest temperature change recorded for the reference probe used to monitor the results of the RF power absorption for the saline-filled phantom was also +0.8°C. Thus, the only MRI-related temperature increase for the fiber-optic cardiac pacing lead was due to the heating of the saline bath of the phantom.

By comparison, in an in vitro evaluation of 44 commercially available pacemaker leads, Sommer et al (52) reported that the maximum temperature change measured at the lead tip was 23.5°C in association with MRI performed at 0.5 Tesla and a whole-body-averaged specific absorption rate (SAR) of 1.3 W/kg for 10 minutes. Additionally, Achenbach et al (53) reported a peak temperature change of 63.1°C measured for a temporary pacing electrode that occurred within 90 seconds of MRI (the SAR was not reported). Furthermore, MRI at 1.5 T and a SAR of 3.0 W/kg have been shown to cause severe necrosis in the mucous membranes of dogs with transesophageal cardiac pacing leads in situ (59).

Tests for magnetic field interactions were conducted on the fiber-optic cardiac pacing lead to assess 1) the entire lead, 2) the tip of the lead, and 3) the connector. Based on the findings for magnetic field interactions and in consideration of the intended use of the pacing lead, there should be no additional risk to a patient with this device undergoing an MR procedure using an MR system operating at 1.5 Tesla or less. Obviously, the findings of this study have important implications for patients that require cardiac pacing during MRI. Furthermore, this unique technology may be applied to other devices that require leads but are known to present potential hazards to patients undergoing MRI procedures (e.g., neurostimulation systems) (68, 69).

Reveal Insertable Loop Recorder System

The Reveal® Insertable Loop Recorder (ILR) System (Medtronic, Minneapolis, MN) is a new, state-of-the-art technology that represents a breakthrough in the diagnosis of fainting (81). The Reveal ILR can determine if fainting is related to a heart rhythm problem in up to 88% of cases. The Reveal ILR is inserted subcutaneously in the upper chest area and continuously monitors the rate and rhythm of the heart for up to 14 months.

According to the product insert information for the Reveal ILR, magnetic and RF fields produced by MRI may adversely affect the data being stored by this device (81). Also, since the Reveal ILR contains ferromagnetic components, the strong magnetic field of the MR system may apply a mechanical force on the device that may be felt by the patient. While this is not believed to pose a serious safety hazard, a patient or individual with this device must be made aware of this possibility to avoid undue concern if exposed to the MR environment (81).

Neurostimulation System for Deep Brain Stimulation

Currently, there is heightened interest in the use of chronic deep brain stimulation (DBS) of the thalamus,
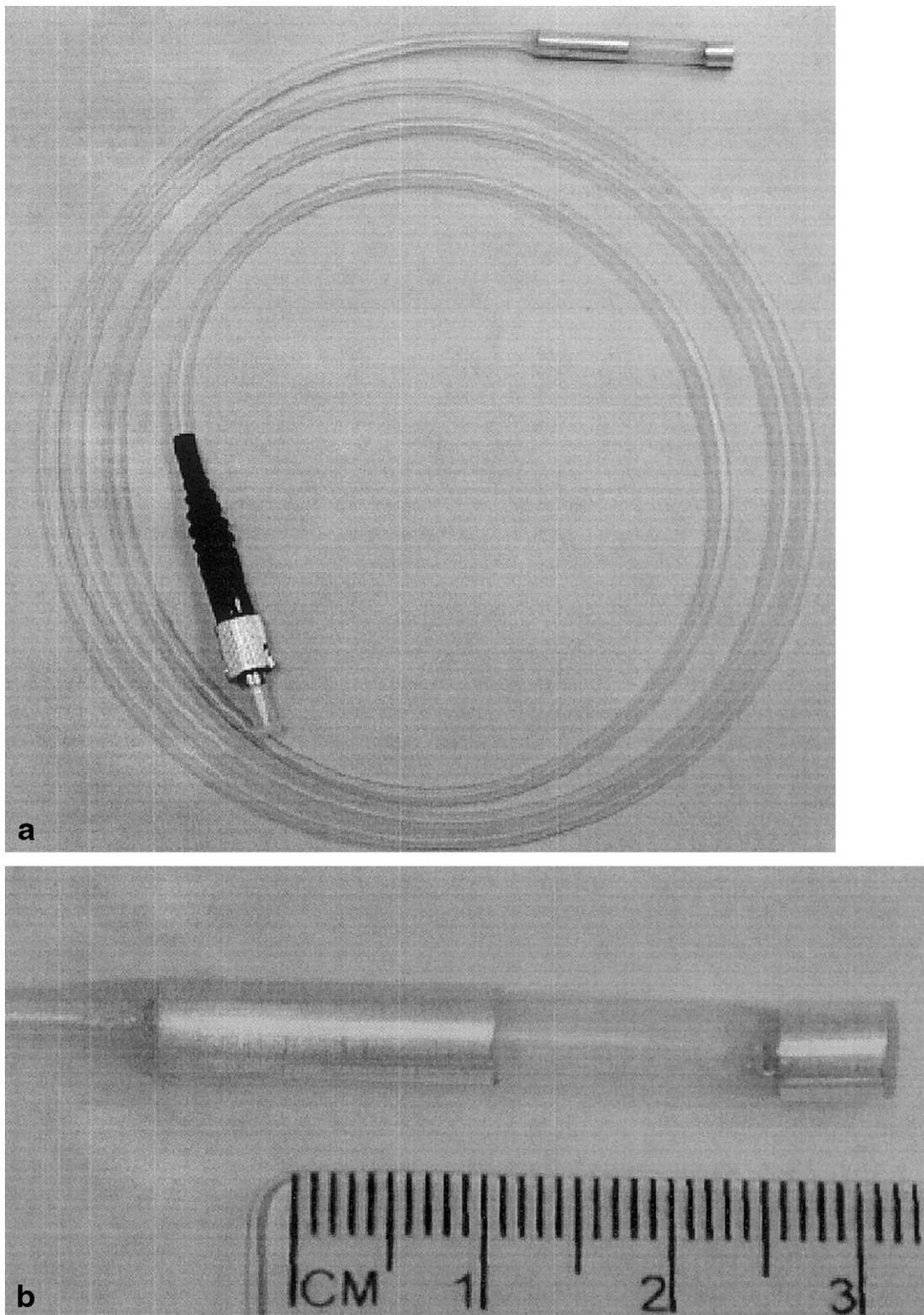
Figure 2. **a:** The fiber-optic cardiac pacing lead. **b:** Close-up showing the tip and ring electrodes for the fiber-optic cardiac pacing lead (Reproduced with permission from Greatbatch et al., JMRI 2002;16:97-103).

globus pallidus, and the subthalamic nucleus for the treatment of medically refractory movement disorders and other types of neurological conditions (67–70). Thus, the number of patients receiving implantable pulse generators (IPGs) and DBS electrodes is rapidly growing. Obviously, it is desirable to be able to use MRI in patients with neurostimulators as well as to use MR guidance techniques to optimally place DBS electrodes (67–70). Additionally, the nature of these neurological conditions often necessitates further examinations us-
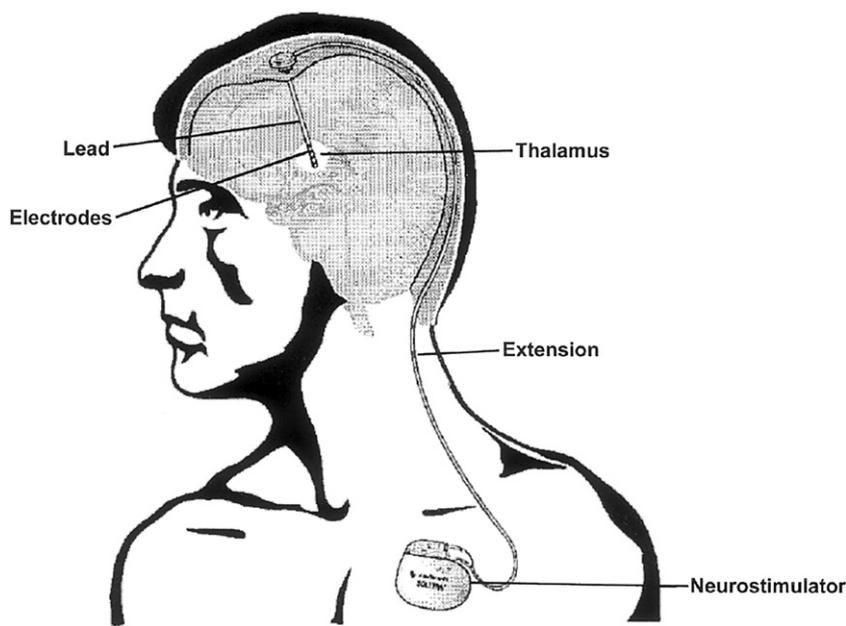
Figure 3. The Activa® Tremor Control System showing the Soletra® Model 7426 neurostimulator, Model 7495 quadripolar extension, and Model 3389 DBS™ lead. The quadripolar lead is positioned in the thalamus. (Reproduced with permission from Rezai et al., JMRI 2002;15:241-250).

ing MR procedures after the electrodes are implanted. However, only a limited number of studies have addressed MR safety issues for implantable IPGs and DBS electrodes (67–70). The possible MR safety issues that exist for neurostimulation systems include magnetic field interactions, heating, induced electrical currents, and functional disruption of the operational aspects of these devices (67–70).

Therefore, a recent study was conducted to evaluate MRI-related heating for a neurostimulation system (Activa® Tremor Control System, Medtronic, Minneapolis, MN) used for chronic DBS (Fig. 3) (68). This neurostimulation system is a fully implantable, multiprogrammable device designed to deliver electrical stimulation to the thalamus or other brain structures. The basic implantable system is comprised of the neurostimulator (or IPG), DBS lead, and an extension that connects the lead to the IPG (Fig. 3). This neurostimulation system delivers high-frequency electrical stimulation to a multiple contact electrode placed in the ventral intermediate nucleus of the thalamus for control of the essential or Parkinsonian tremor. The particular neurostimulation system evaluated in the study by Rezai et al (68) was selected because it is one of the most widely used devices for DBS.

Notably, in order to simulate a worst-case clinical application of DBS, two neurostimulators, extensions, and leads were assessed in this investigation (Fig. 4). Thus, two Soletra® Model 7426 quadripolar neurostimulators (Medtronic, Minneapolis, MN) designed for DBS were used in the investigation. The Soletra® has programmable electronics that allow the physician to select various configurations of active electrode contacts and to adjust the amplitude, pulse width, and frequency. During this investigation, the neurostimulators were programmed to the off mode (i.e., no stimulation was delivered) and set to 0 voltage, as is the common clinical practice during MRI (68). Two Model 7495 quadripolar extensions (Medtronic, Minneapolis, MN)

were connected between the two Soletra® neurostimulators and the DBS leads. These extensions were connected to Models 3387 and 3389 DBS™ quadripolar leads (Medtronic, Minneapolis, MN) (68).
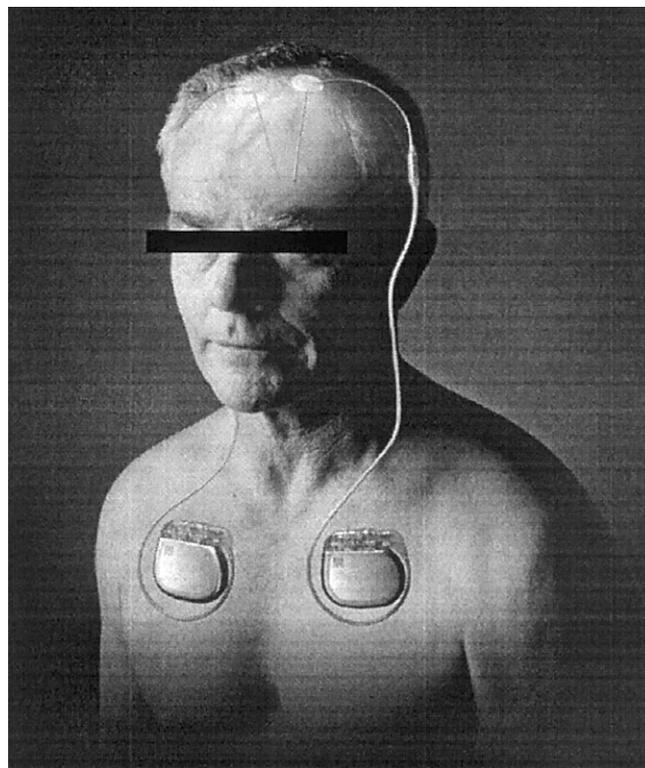

Figure 4. Schematic showing bilateral neurostimulators, extensions, and leads to simulate the common clinical application of DBS and to assess a worst-case clinical situation for neurostimulation systems in this investigation (Reproduced with permission from Rezai et al., JMRI 2002;15:241-250).

Table 3
Guidelines Recommended for Conducting an MR Procedure in a Patient With Bilateral Neurostimulation Systems Used for DBS*

1. The two neurostimulators should be placed in left and right subclavian, subcutaneous pockets, separated by a distance of approximately 30 cm. Excess length of extensions should be wrapped around the perimeter of the neurostimulators. Care should be taken not to bend, kink, or stretch the extension wires. The leads should be placed with two small loops (approximately 2.5 cm in diameter) in an axial orientation near the burr hole.
2. The neurostimulation systems should be interrogated prior to MR imaging to ensure proper operation of all components and that there are no broken electrodes, leads, and extensions.
3. The amplitude for each neurostimulation system should be set to 0 volts and the neurostimulation system's output should be turned to "off".
4. MR imaging should only be performed using an MR system with a static magnetic field of 1.5 Tesla. The safety of using other MR systems operating at other static magnetic field strengths to scan a patient with bilateral neurostimulation systems is unknown.
5. If the transmit/receive body RF coil is used for MR imaging, the whole body averaged SAR should not exceed 0.9 W/kg.
6. If the transmit/receive head RF coil is used for MR imaging, the whole body averaged SAR should not exceed 0.1 W/kg.
7. MR imaging should be performed using standard techniques that utilize the lowest possible SAR levels, as indicated above.
8. Patients should be instructed prior to MR imaging to report any unusual sensations that may occur during the examinations.
9. Patients should be continuously monitored throughout MR imaging using visual and/or verbal means.
10. After MR imaging, the neurostimulation systems should be evaluated to verify that they are functional.
11. The neurostimulation systems should be reprogrammed to stimulation parameters used prior to MR imaging.

*Activa® Tremor Control System; Soletra® Model 7426, quadripolar neurostimulators; Model 7495, quadripolar extensions; and Models 3387 and 3389 DBS™ quadripolar leads; Medtronic, Minneapolis, MN. Reference 68.

Importantly, different configurations were evaluated for bilateral neurostimulators (Soletra® Model 7426, Medtronic, Minneapolis, MN), extensions, and leads to assess worst-case and clinically relevant positioning scenarios (68). In vitro testing was performed using a 1.5 Tesla/64 MHz MR system and a gel-filled phantom designed to approximate the head and upper torso of a human subject. MRI was conducted using the transmit/receive body and transmit/receive head RF coils. Various levels of RF energy were applied with the transmit/receive body (whole-body-averaged SAR; range, 0.98–3.90 W/kg) and transmit/receive head (whole-body-averaged SAR; range, 0.07–0.24 W/kg) coils. A fluoroptic thermometry system was used to record temperatures at multiple locations before (1 minute) and during (15 minutes) MRI (68).

During the use of the body RF coil, the highest temperature changes ranged from 2.5–25.3°C. By comparison, during the use of the head RF coil, the highest temperature changes ranged from 2.3–7.1°C. Thus, these findings indicated that substantial heating occurs under certain conditions, while others produce relatively minor, physiologically inconsequential temperature increases. The temperature increases were highly dependent on the type of RF coil, level of SAR used, and how the lead wires were positioned. Notably, the use of clinically relevant positioning techniques for the neurostimulation system and low SARs commonly used for imaging the brain generated little heating (68,69).

Based on the findings of the study by Rezai et al (68), MRI-related heating does not appear to present a major safety concern for patients with the bilateral neurostimulation systems that underwent testing, as long as highly specific guidelines pertaining to the positioning of these neurostimulation devices and parameters used for MRI are carefully adhered to. These guidelines are indicated in Table 3.

FREEHAND System Implantable Functional Neurostimulator

The FREEHAND System Implantable Functional Neurostimulator (FNS) (NeuroControl, Cleveland, OH) is an RF-powered motor control neuroprosthesis that consists of both implanted and external components (82). This highly specialized neurostimulation system utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand providing functional hand grasp patterns. The FREEHAND System is intended to improve a patient's ability to grasp, hold, and release objects. This device is indicated for use in patients who are tetraplegic due to C5- or C6-level spinal cord injury, have adequate functional range of motion of the upper extremity, have intact lower motor neuron innervation of the forearm and hand musculature, and are skeletally mature (82).

During testing of the FREEHAND System in a 1.5-Tesla MR system with a maximum spatial gradient of 450 gauss/cm, the device exhibited a translational force less than that of a 3-g mass and a torque of 0.063 N-cm (i.e., significantly less than that produced by the weight of the device) (82). Furthermore, findings from of an MRI-induced heating experiment during which the FREEHAND System was exposed to a whole-body-averaged SAR of 1.1 W/kg for 30 minutes showed that localized temperature increases were no greater than 2.7°C with the device in a gel-filled phantom (i.e., without blood flow) (82).

Based on this information, a patient with a FREEHAND System may undergo an MR procedure using a shielded or unshielded MR system with a static magnetic field of 1.5 Tesla only (since RF fields associated with other MR systems operating at other field strengths may adversely affect the operation of this device) and a maximum spatial gradient of 450 gauss/cm or less (82). The external components of the FREEHAND System must be removed prior to the MR procedure (82). Also, the use of transmit RF coils other than the MR system's body or head coil is

prohibited. Testing of the function of each electrode for the FREEHAND System should be conducted prior to MRI to ensure that there are no broken leads (82). Patients must be continuously observed during the MR procedure and instructed to report any unusual sensations (e.g., warming, burning, or neuromuscular stimulation). Scanning must be discontinued immediately if any unusual sensation occurs (82).

VOCARE Bladder System Implantable Functional Neuromuscular Stimulator

The VOCARE Bladder System Implantable Functional Neuromuscular Stimulator (FNS) (NeuroControl, Cleveland, OH) is an RF-powered motor control neuroprosthesis that consists of both implanted and external components (83). The VOCARE Bladder System delivers low levels of electrical stimulation to a spinal cord-injured patient's intact sacral spinal nerve roots to elicit functional contraction of the muscles innervated by them (83).

The VOCARE Bladder System is indicated for the treatment of patients who have clinically complete spinal cord lesions with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce postvoid residual volumes of urine (83). A secondary intended use is to aid in bowel evacuation.

During testing of the VOCARE Bladder System in a 1.5-Tesla MR system with a maximum spatial gradient of 450 gauss/cm, the device exhibited a translational force less than that of a 12-g mass and a torque of 0.47 N-cm (i.e., significantly less than that produced by the weight of the device) (83). Furthermore, findings from an MRI-induced heating experiment during which the VOCARE System was exposed to a whole-body-averaged SAR of 1.1 W/kg for 30 minutes showed that localized temperature increases were no greater than 5.5°C with the device in a gel-filled phantom (i.e., without blood flow) (83).

Based on this information, a patient with a VOCARE Bladder System may undergo an MR procedure using a shielded or unshielded MR system with a static magnetic field of 1.5 Tesla only (since RF fields associated with other MR systems operating at other field strengths may adversely affect the operation of this device) and a maximum spatial gradient of 450 gauss/cm or less (83). The external components of the VOCARE Bladder System must be removed prior to the MR procedure. Patients should be advised to empty their bladder or bowel prior to the MR examination as a precaution (83). Also, the use of transmit RF coils other than the MR system's body or head coil is prohibited (83). Testing of the function of each electrode for the VOCARE Bladder System should be conducted prior to MRI to ensure that there are no broken leads (83). Patients must be continuously observed during the MR procedure and instructed to report any unusual sensations (e.g., warming, burning, or neuromuscular stimulation). Scanning must be discontinued immediately if any unusual sensation occurs (83).

CONCLUSIONS

With the continued evolution of MR technology, the clinical and investigative uses of MR systems that use higher static magnetic fields, higher and faster gradient fields, and stronger RF fields are becoming increasingly common. Concomitant with the rapid advances in MR technology is the increased potential for hazardous situations related to performing MR procedures in patients with implants and devices. This requires heightened awareness by the MR community to continually review and update their policies and procedures pertaining to MR safety based on the information in the relevant medical literature (9).

REFERENCES

1. New PFJ, Rosen BR, Brady TJ, et al. Potential hazards and artifacts of ferromagnetic and nonferromagnetic surgical and dental materials and devices in nuclear magnetic resonance imaging. Radiology 1983;147:139–148.
2. Shellock FG, Crues JV. High-field MR imaging of metallic implants: an ex vivo evaluation of deflection forces. AJR Am J Roentgenol 1988;151:389–392.
3. Shellock FG. Pocket guide to metallic implants and MR procedures: update 2000, 7th edition, New York: Lippincott-Raven Healthcare; 2001. p 1–159.
4. Shellock FG, Kanal E. Magnetic resonance: bioeffects, safety, and patient management, 2nd edition, New York: Lippincott-Raven Press; 1996.
5. Shellock FG. Reference manual for magnetic resonance safety: 2003 edition. Salt Lake City: Amirsys, Inc.; 2003.
6. Sawyer-Glover A, Shellock FG. Pre-MRI procedure screening: recommendations and safety considerations for biomedical implants and devices. J Magn Reson Imaging 2000;12:92–106.
7. Schenck JF. Health effects and safety of static magnetic fields. In: Magnetic resonance procedures: health effects and safety. Boca Raton, FL: CRC Press; 2001. p 1–31.
8. Shellock FG. Magnetic resonance procedures: health effects and safety. Boca Raton, FL: CRC Press; 2001.
9. Shellock FG, Crues JV. MR safety and the American College of Radiology white paper [Commentary]. AJR Am J Roentgenol 2002; 178:1349–1352.
10. Shellock FG. New metallic implant used for permanent female contraception: evaluation of MR safety. AJR Am J Roentgenol 2002; 178:1513–1516.
11. Becker R, Norfray J, Teitelbaum G, et al. MR imaging in patients with intracranial aneurysm clips. AJNR Am J Neuroradiol 1988;9: 885–889.
12. Dujovny M, Kossovsky N, Kossowsky R, et al. Aneurysm clip motion during magnetic resonance imaging: In vivo experimental study with metallurgical factor analysis. Neurosurgery 1985;17:543–548.
13. Dujovny, Alp MS, Slavin KV, et al. Magnetic characteristics of Yasargil aneurysm clips. Surg Neurol 1997;47:547–550.
14. Dujovny M, Gundamjaj NR, Misra M, Alp MS. Aneurysm clips. Crit Rev Neurosurg 1997;7:169–175.
15. Romner B, Olsson M, Ljunggren B, et al. Magnetic resonance imaging and aneurysm clips. J Neurosurg 1989;70:426–431.
16. Kato Y, Sano H, Katada K, Ogura Y, Ninomiya T, Okuma I, Kanno T. Effects of new titanium cerebral aneurysm clips on MRI and CT images. Minim Invasive Neurosurg 1996;39:82–85.
17. Lawton MT, Heiserman JE, Prendergast VC, Zabramski JM, Spetzler RF. Titanium aneurysm clips: Part III. Clinical application in 16 patients with subarachnoid hemorrhage. Neurosurgery 1996;38: 1170–1175.
18. Piepgras A, Guckel F, Weik T, Schmiedek P. Titanium aneurysm clips and their advantages in diagnostic imaging. Radiologe 1995; 35:830–833.
19. Wichmann W, Von Ammon K, Fink U, Weik T, Yasargil GM. Aneurysm clips made of titanium: characteristics and artifacts in MR. AJNR Am J Neuroradiol 1997;18:939–944.
20. Shellock FG, Kanal E. Yasargil aneurysm clips: evaluation of interactions with a 1.5 Tesla MR system. Radiology 1998;207:587–591.

21. Kanal E, Shellock FG. Aneurysm clips: effects of long-term and multiple exposures to a 1.5 Tesla MR system. Radiology 1999;210: 563–565.

22. Shellock FG, Shellock VJ. MR-compatibility evaluation of the Spetzler titanium aneurysm clip. Radiology 1998;206:838–841.

23. Shellock FG, Crues JV. Aneurysm clips: assessment of magnetic field interaction associated with a 0.2-T extremity MR system. Radiology 1998;208:407–409.

24. Shellock FG, Kanal E. Aneurysm clips: evaluation of MR imaging artifacts at 1.5 Tesla. Radiology 1998;209:563–566.

25. Shellock FG, Detrick MS, Brant-Zawadski M. MR-compatibility of Guglielmi detachable coils. Radiology 1997;203:568–570.

26. Kangarlu A, Shellock FG. Aneurysm clips: evaluation of magnetic field interactions with an 8.0 T MR system. J Magn Reson Imaging 2000;12:107–111.

27. Hennemeyer CT, Wicklow K, Feinberg DA, Derdeyn CP. In vitro evaluation of platinum Guglielmi detachable coils at 3 T with a porcine model: safety issues and artifacts. Radiology 2001;219: 732–737.

28. Davis PL, Crooks L, Arakawa M, et al. Potential hazards in NMR imaging: heating effects of changing magnetic fields and RF fields on small metallic implants. AJR Am J Roentgenol 1981;137:857–860.

29. Shellock FG, Shellock VJ. Metallic marking clips used after stereotactic breast biopsy: ex vivo testing of ferromagnetism, heating, and artifacts associated with MRI. AJR Am J Roentgenol 1999;172: 1417–1419.

30. Hassler M, Le Bas JF, Wolf JE, et al. Effects of magnetic fields used in MRI on 15 prosthetic heart valves. J Radiol 1986;67:661–666.

31. Soulen RL, Budinger TF, Higgins CB. Magnetic resonance imaging of prosthetic heart valves. Radiology 1985;154:705–707.

32. Shellock FG, Morisoli SM. Ex vivo evaluation of ferromagnetism, heating, and artifacts for heart valve prostheses exposed to a 1.5-Tesla MR system. J Magn Reson Imaging 1994;4:756–758.

33. Soulen RL. Magnetic resonance imaging of prosthetic heart valves [letter]. Radiology 1986;158:279.

34. Shellock FG. Prosthetic heart valves and annuloplasty rings: assessment of magnetic field interactions, heating, and artifacts at 1.5-Tesla. J Cardiovasc Magn Reson 2001;3:159–169.

35. Edwards, M-B, Taylor KM, Shellock FG. Prosthetic heart valves: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. J Magn Reson Imaging 2000;12:363–369.

36. Shellock FG, Shellock VJ. Cardiovascular catheters and accessories: ex vivo testing of ferromagnetism, heating, and artifacts associated with MRI. J Magn Reson Imaging 1998;8:1338–1342.

37. Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. Radiology 1998;207:822–825.

38. Shellock FG, Shellock VJ. Metallic stents: evaluation of MRI safety. AJR Am J Roentgenol 1999;173:543–546.

39. Teitelbaum GP, Bradley WG, Klein BD. MR imaging artifacts, ferromagnetism, and magnetic torque of intravascular filters, stents, and coils. Radiology 1988;166:657–664.

40. Matsumoto AH, Teitelbaum GP, Barth KH, Carvlin MJ, Savin MA, Strecker EP. Tantalum vascular stents: in vivo evaluation with MR imaging. Radiology 1989;170:753–755.

41. Teitelbaum GP, Raney M, Carvlin MJ, Matsumoto AH, Barth KH. Evaluation of ferromagnetism and magnetic resonance imaging artifacts of the Strecker tantalum vascular stent. Cardiovasc Intervent Radiol 1989;12:125–127.

42. Scott NA, Pettigrew RI. Absence of movement of coronary stents after placement in a magnetic resonance imaging field. Am J Cardiol 1994;73:900–901.

43. Taal BG, Muller SH, Boot H, Koops W. Potential risks and artifacts of magnetic resonance imaging of self-expandable esophageal stents. Gastrointest Endosc 1997;46:424–429.

44. Shellock FG. Metallic neurosurgical implants: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. J Magn Reson Imaging 2001;14:295–299.

45. Shellock FG. MR imaging and electronically-activated devices [letter]. Radiology 2001;219:294–295.

46. Shellock FG, O'Neil M, Ivans V, et al. Cardiac pacemakers and implantable cardiac defibrillators are unaffected by operation of an extremity MR system. AJR Am J Roentgenol 1999;72:165–172.

47. Erlebacher JA, Cahill PT, Pannizzo F, et al. Effect of magnetic resonance imaging on DDD pacemakers. Am J Cardiol 1986;57: 437–440.

48. Fetter J, Aram G, Holmes DR, et al. The effects of nuclear magnetic resonance imagers on external and implantable pulse generators. Pacing Clin Electrophysiol 1984;7:720–727.

49. Hayes DL, Holmes DR, Gray JE. Effect of a 1.5 Tesla magnetic resonance imaging scanner on implanted permanent pacemakers. J Am Coll Cardiol 1987;10:782–786.

50. Holmes DR, Hayes DL, Gray JE, et al. The effects of magnetic resonance imaging on implantable pulse generators. Pacing Clin Electrophysiol 1986;9:360–370.

51. Pavlicek W, Geisinger M, Castle L, et al. The effects of nuclear magnetic resonance on patients with cardiac pacemakers. Radiology 1983;147:149–153.

52. Sommer T, Hahlhaus C, Lauck G, et al. MR imaging and cardiac pacemakers: in vitro evaluation and in vivo studies in 51 patients at 0.5 T. Radiology 2000;215:869–879.

53. Achenbach S, Moshage W, Diem B, Bieberle T, Schibgilla V, Bachmann K. Effects of magnetic resonance imaging on cardiac pacemakers and electrodes. Am Heart J 1997;134:467–473.

54. Lauck G, Von Smekal A, Wolke S, et al. Effects of nuclear magnetic resonance imaging on cardiac pacemakers. Pacing Clin Electrophysiol 1995;18:1549–1555.

55. Duru F, Luechinger R, Candinas R. MR imaging in patients with cardiac pacemakers. Radiology 2001;219:856–858.

56. Vahlhaus C, Sommer T, Lewalter T, et al. Interference with cardiac pacemakers by magnetic resonance imaging: are there irreversible changes at 0.5 Tesla? Pacing Clin Electrophysiol 2001;24(4 Pt 1):489–495.

57. Gimbel JR. Implantable pacemaker and defibrillator safety in the MR environment: new thoughts for the new millennium. In: 2001 Syllabus, Special Cross-Specialty Categorical Course in Diagnostic Radiology: Practical MR Safety Considerations for Physicians, Physicists, and Technologists. Radiological Society of North America, 2001; p 69–76.

58. Jerewski A, Patynama PMT, Stendijk P, Doornbos J, de Roos A, Baan J. Development of an MRI-compatible catheter for pacing the heart: initial in vitro and in vivo results. J Magn Reson Imaging 1996;6:948–949.

59. Hofman MB, de Cock CC, van der Linden JC, et al. Transesophageal cardiac pacing during magnetic resonance imaging: feasibility and safety considerations. Magn Reson Med 1996;35:413–422.

60. Greatbatch W, Miller V, Shellock FG. Magnetic resonance safety testing of a newly-developed, fiber-optic cardiac pacing lead. J Magn Reson Imaging 2002;16:97–103.

61. Nyehnuis JA, Kildishev AV, Foster KS, Graber G, Athey W. Heating near implanted medical devices by the MRI RF-magnetic field. IEEE Trans 1999;35:4133–4135.

62. Smith CD, Kildishev AV, Nyenhuis JA, Foster KS, Bourland JD. Interactions of MRI magnetic fields with elongated medical implants. J Appl Phys 2000;87:6188–6190.

63. Chou C-K, McDougall JA, Chan KW. RF heating of implanted spinal fusion stimulator during magnetic resonance imaging. IEEE Trans Biomed Eng 1997;44:357–373.

64. Shellock FG, Hatfield M, Simon BJ, et al. Implantable spinal fusion stimulator: assessment of MRI safety. J Magn Reson Imaging 2000; 2:214–223.

65. Liem LA, van Dongen VC. Magnetic resonance imaging and spinal cord stimulation systems. Pain 1997;70:95–97.

66. Ouayoun M, Dupuch K, Aitbenamou C, Chouard CH. Nuclear magnetic resonance and cochlear implant. Ann Otolaryngol Chir Cervicofac 1997;114:65–70.

67. Tronnier VM, Stauber A, Hahnel S, Sarem-Aslani A. Magnetic resonance imaging with implanted neurostimulators: an in vitro and in vivo study. Neurosurgery 1999;44:118–125.

68. Rezai AR, Finelli D, Nyenhuis JA, et al. Neurostimulator for deep brain stimulation: ex vivo evaluation of MRI-related heating at 1.5-Tesla. J Magn Reson Imaging 2002:15:241–250.

69. Ruggieri P, Finelli DA, Rezai AR, et al. Neurostimulation systems used for deep brain stimulation: *in vitro* evaluation of MRI-related heating at 1.5-Tesla. In: Proceedings of the International Society for Magnetic Resonance in Medicine, Book of Abstracts, Berkeley, CA, 2002. 10:843.

70. Gleason CA, Kaula NF, Hricak H, et al. The effect of magnetic resonance imagers on neurostimulators. Pacing Clin Electrophysiol 1992:15;81–94.

71. Shellock FG. MR-compatibility of an endoscope designed for use in interventional MRI procedures. AJR Am J Roentgenol 1998;171: 1297–1300.

72. Moscatel M, Shellock FG, Morisoli S. Biopsy needles and devices: assessment of ferromagnetism and artifacts during exposure to a 1.5 Tesla MR system. J Magn Reson Imaging 1995;5:369–372.

73. Shellock FG, Shellock VJ. Ceramic surgical instruments: evaluation of MR-compatibility at 1.5 Tesla. J Magn Reson Imaging 1996; 6:954–956.

74. Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. J Magn Reson Imaging 2001;3: 152–157.

75. http://www.MRIsafety.com. Website devoted to MR safety. Created and maintained by Frank G. Shellock, Institute for Magnetic Resonance Safety, Education, and Research.

76. American Society for Testing and Materials (ASTM) Designation: F 2052. Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. In: Annual book of ASTM standards, Section 13, Medical devices and services, Volume 13.01, Medical devices; emergency medical services. West Conshohocken, PA: ASTM; 2002. p 1576–1580.

77. Klucznik RP, Carrier DA, Pyka R, Haid RW. Placement of a ferromagnetic intracerebral aneurysm clip in a magnetic field with a fatal outcome. Radiology 1993;187:855–856.

78. Johnson G. Need for caution during MR imaging of patients with aneurysm clips. Radiology 1993;188:287–288.

79. Pride GL, Kowal J, Mendelsohn DB, Chason DP, Fleckenstein JL. Safety of MR scanning in patients with nonferromagnetic aneurysm clips. J Magn Reson Imaging 2000;12:198–200.

80. Condon B, Hadley DM. Potential MR hazard to patients with metallic heart valves: the Lenz effect. J Magn Reson Imaging 2000;12: 171–176.

81. Reveal Plus Insertable Loop Recorder System. Product information manual. Medtronic, Minneapolis, MN.

82. FREEHAND System. Package insert. NeuroControl Corporation, Cleveland, OH.

83. VOCARE™ Bladder System Implantable Functional Neuromuscular Stimulator. Package insert. NeuroControl Corporation, Valley View, OH.