

# Neurostimulation Systems for Deep Brain Stimulation: In Vitro Evaluation of Magnetic Resonance Imaging–Related Heating at 1.5 Tesla

Ali R. Rezai, MD,<sup>1</sup> Daniel Finelli, MD,<sup>2</sup> John A. Nyenhuis, PhD,<sup>3</sup>  
Greg Hrdlicka, BSEE, MBA,<sup>4</sup> Jean Tkach, PhD,<sup>2</sup> Ashwini Sharan, MD,<sup>1</sup> Paul Rugieri, MD,<sup>2</sup>  
Paul H. Stypulkowski, PhD,<sup>4</sup> and Frank G. Shellock, PhD<sup>5\*</sup>

**Purpose:** To assess magnetic resonance imaging (MRI)-related heating for a neurostimulation system (Activa® Tremor Control System, Medtronic, Minneapolis, MN) used for chronic deep brain stimulation (DBS).

**Materials and Methods:** Different configurations were evaluated for bilateral neurostimulators (Soletra® Model 7426), extensions, and leads to assess worst-case and clinically relevant positioning scenarios. In vitro testing was performed using a 1.5-T/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 radio frequency (RF) coils. Various levels of RF energy were applied with the transmit/receive body (whole-body averaged specific absorption rate (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.

**Results:** Using the body RF coil, the highest temperature changes ranged from 2.5°–25.3° C. Using 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.

**Conclusion:** The temperature increases were 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. Based on this information, MR safety guidelines are provided. These observations are restricted to the tested neurostimulation system.

**Key Words:** magnetic resonance imaging, safety; magnetic resonance imaging, implants; heating; deep brain stimulation; neurostimulation

**J. Magn. Reson. Imaging** 2002;15:241–250.

© 2002 Wiley-Liss, Inc.

MAGNETIC RESONANCE IMAGING (MRI) is generally regarded as an extremely safe, noninvasive diagnostic technique (1,2). However, maintaining a safe MR environment is a daily challenge and important responsibility for MR health-care workers. The types of biomedical devices that are encountered in patients continue to grow. Experimental data must be obtained for these devices using in vitro testing techniques to establish safe MR conditions and parameters (1). This is particularly important for devices that are electronically activated because of the obvious inherent risks (1–3).

Currently, there is a heightened interest in the use of chronic deep brain stimulation (DBS) of the thalamus, globus pallidus, and subthalamic nucleus for the treatment of medically refractory movement disorders and other types of neurological conditions (4,5). Thus, the number of patients receiving implantable pulse generators (IPGs) and DBS electrodes is rapidly growing. 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 (4–7). Additionally, the nature of these neurological conditions often necessitates further examinations using 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 (8–11). 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 (1–5, 8–12).

<sup>1</sup>Section of Stereotactic and Functional Neurosurgery, Department of Neurosurgery, Cleveland Clinic Foundation, Cleveland, Ohio.

<sup>2</sup>Department of Radiology, Cleveland Clinic Foundation, Cleveland, Ohio.

<sup>3</sup>Department of Computer and Electrical Engineering, Purdue University, West Lafayette, Indiana.

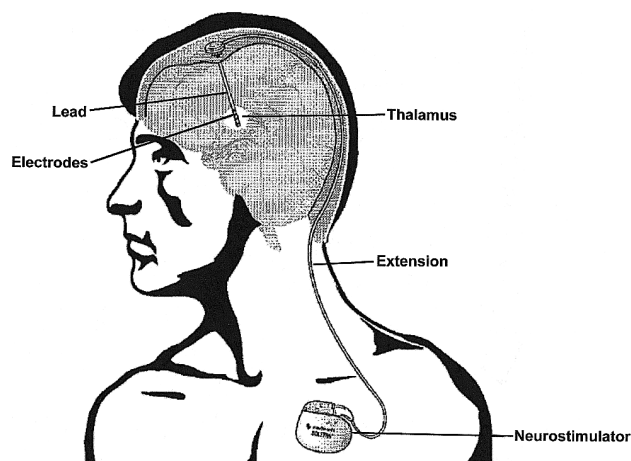
<sup>4</sup>Medtronic, Minneapolis, Minnesota.

<sup>5</sup>Keck School of Medicine, University of Southern California Los Angeles, Los Angeles, California.

Contract grant sponsor: Medtronic, Minneapolis, MN (to the Cleveland Clinic Foundation, Cleveland, OH).

\*Address reprint requests to: F.G.S., 7511 McConnell Ave., Los Angeles, CA 90045. E-mail: Frank.Shellock@gte.net

Received August 16, 2001; Accepted November 13, 2001.



**Figure 1.** 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.

One of the most crucial MR safety concerns is related to excessive heating of electronically activated implants, which can occur in association with MRI (1,2,12–17). Radio frequency (RF) and pulsed gradient magnetic fields used for MRI induce currents in the body (12–15). It is well known that implants that are electrical conductors can locally increase these currents, and under certain MR operational conditions, excessive heating of biomedical devices may occur (12–17). For example, Achenbach et al (16) reported a temperature increase at the tip of a pacing electrode of up to 63.1° C during 90 seconds of scanning. Thus, there is supportive experimental evidence that the combination of MRI with certain electrically conductive implants can rapidly produce a substantial temperature increase. The MR safety implications of this are readily apparent.

Therefore, this investigation was performed to determine MRI-related heating for the only neurostimulation system currently approved for DBS (Activa® Tremor Control System, Medtronic, Minneapolis, MN; note: it is currently approved only for unilateral use in the United States). Different configurations of bilateral neurostimulators, extensions, and leads were evaluated along with different uses of a 1.5-T MR system (i.e., transmit/receive body vs. head RF coil) to assess worst-case and clinically relevant scenarios. The primary intent of this study was to develop guidelines that would permit patients with implanted neurostimulation systems and DBS electrodes to undergo MRI safely. To our knowledge, this is the first investigation of MRI-related heating for bilateral neurostimulation systems.

## MATERIALS AND METHODS

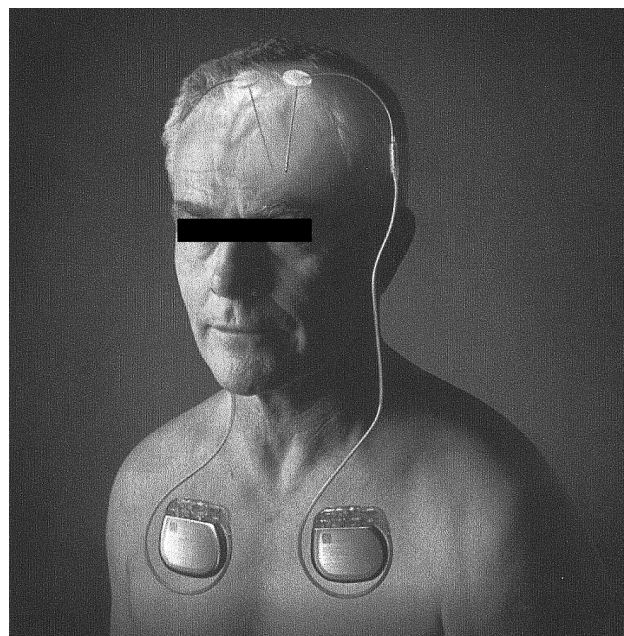
### Neurostimulation System for DBS

The Activa® Tremor Control System (Medtronic, Minneapolis, MN) is a fully implantable, multiprogrammable neurostimulation system designed to deliver electrical stimulation to the thalamus or other brain structures. The implantable system is comprised of the neuro-

stimulator (or IPG), DBS lead, and an extension that connects the lead to the IPG (Fig. 1). This system delivers electrical stimulation to a multiple contact electrode placed in the ventral intermediate nucleus of the thalamus for control of essential or Parkinsonian tremor. Investigationally, the same system components are used within other deep brain structures for other therapies. The neurostimulator is placed subcutaneously in the pectoral area and is connected to an extension, which is tunneled subcutaneously and connects to the implanted DBS lead. This particular neurostimulation system was selected for evaluation in this study because it is one of the most widely used devices for DBS. For the purpose of this investigation, two neurostimulators, extensions, and leads were used to simulate a worst-case clinical application (described later in this section) of DBS (Fig. 2).

### Neurostimulators

Two Soletra® Model 7426 quadripolar neurostimulators (Medtronic, Minneapolis, MN) designed for DBS were used in this investigation (Figs. 1 and 2). This neurostimulator contains integrated circuits and a 3.7-volt lithium ion battery that are hermetically sealed within an oval-shaped titanium case with the following dimensions: length,  $2\frac{5}{16}$  inches; height,  $2\frac{1}{8}$  inches; thickness,  $\frac{3}{8}$  inches. 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.



**Figure 2.** 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.

### Extensions

Model 7495 quadripolar extensions (diameter, 2.5 mm; length, 51 cm; Medtronic, Minneapolis, MN) (Figs. 1 and 2) were connected between the two Soletra® neurostimulators and the DBS leads. These extensions contain four individual quadra-filar coils of MP35N conductor wires within a quadra-lumen silicone rubber jacket. The resistance of the extension is approximately 25 ohms per channel.

### Leads

The extensions were connected to Models 3387 or 3389 DBS™ (Medtronic, Minneapolis, MN) leads. These quadripolar leads contain four individually insulated (fluoropolymer) platinum-iridium conductors, within a polyurethane jacket, that connect to four cylindrical 1.5-mm platinum-iridium electrode contacts separated by 0.5 mm (Figs. 1 and 2). The diameter of the lead is 1.27 mm, and the length used in this investigation was 40 cm. The resistance for this lead is approximately 40 ohms per channel.

### Phantom Design

The in vitro evaluation of MRI-related heating for the neurostimulator system required development of a special Plexiglas (bottom thickness, 1.3 cm; side thickness, 0.6 cm) phantom designed to approximate the size and shape of the head and torso of a human subject (Fig. 3). The dimensions of this phantom were as follows: head portion: width, 16.5 cm; length, 29.2 cm; height, 16.5 cm; torso portion: width, 43.2 cm; length, 61.0 cm; height, 16.5 cm. Since most heating during MRI is due to eddy currents in the head and body, it was unnecessary to include extremities in this phantom for the assessment of MRI-related heating of a metallic object (13–15).

The phantom was filled to a depth of 91 mm with a semisolid gel that was prepared to simulate the thermal convection and dielectric properties of human tissue (13–15). This was accomplished using a gelling agent (polyacrylic acid (PAA), Aldrich Chemical) in an aqueous solution. Thus, 5.85 g of PAA and 0.8 g of NaCl per liter of distilled water were used to make the semisolid gel. This produced an acceptable dielectric constant and an acceptable conductivity for evaluation of MRI-related heating of a metallic implant or device (13–15). This basic experimental setup has been used in several prior investigations published in the peer-reviewed literature (13,14,18–21). Because there was no blood flow associated with this experimental setup, it represents an extreme condition simulated for MRI-related heating of the neurostimulation system.

A plastic frame with adjustable posts was placed at the bottom of the phantom and allowed for variable positioning and support of the neurostimulators, extensions, and leads within the phantom (Fig. 3). The individual system components were secured to the posts by various means using nonmetallic fasteners (e.g., sutures, plastic clips, and putty). The use of the plastic frame and posts permitted consistent placement of the neurostimulators within the phantom and allowed the

extensions and leads to be routed to approximate common clinical practice, as described below. These experimental procedures facilitated proper and repeatable approximation of the standard in vivo positioning and orientation of the devices.

### Positioning of the Neurostimulation Systems

In consideration of the fact that positional differences can impact MRI-related heating of neurostimulators (unpublished observations from pilot data obtained by our group) and in order to simulate the intended in vivo use of the neurostimulation systems, careful attention was given to the positioning of the two neurostimulators, extensions, and leads within the phantom. (Notably, the positioning scenarios that were evaluated for the bilateral neurostimulation systems are considered to be the most common.) The manufacturer's (Medtronic, Minneapolis, MN) product insert information was followed, along with the recommendations of a neurosurgeon (A.R.R.) with extensive DBS implant experience.

Because there are several possible positioning scenarios for these devices, we selected only two that were representative of a commonly used clinical configuration (no. 1) and a worst-case (no. 2) placement, as described below.

### Configuration 1, Commonly-Used Positioning

#### Rationale

In current clinical practice, many patients undergoing DBS will have electrodes placed in the subthalamic nucleus, globus pallidus internus, or ventralis intermedius nucleus bilaterally (again noting that in the United States the Activa® Tremor Control System is currently approved only for unilateral use), while fewer patients will undergo unilateral implantation. The DBS lead length is typically 40 cm; thus, to keep the extension connector at the level of the cranium and avoid positioning it at the neck, the lead must be looped at the top of the head, usually around the burr hole. Similarly, the typical extension length is 51 cm, which may result in extra wire when the IPG is implanted infra-clavicularly. As such, implanting physicians tend to coil any excess length of extension around the perimeter of the IPG.

#### Neurostimulators

The two neurostimulators were placed in the upper left and right quadrants of the thorax portion of the phantom. They were within 2 cm of the gel surface, separated by a distance of approximately 30 cm (Fig. 4).

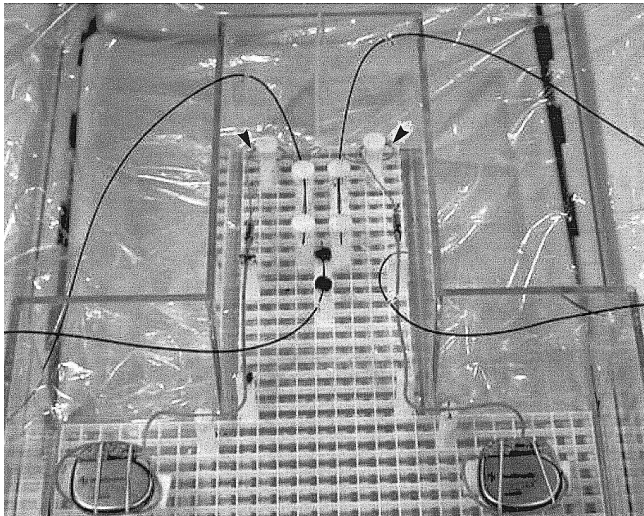
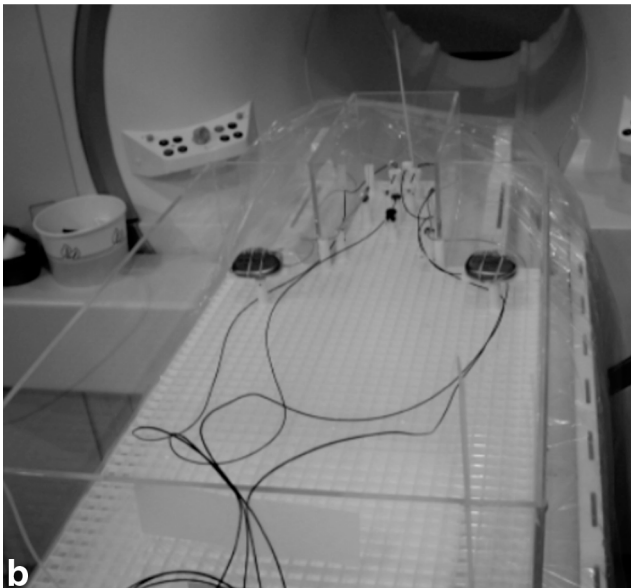
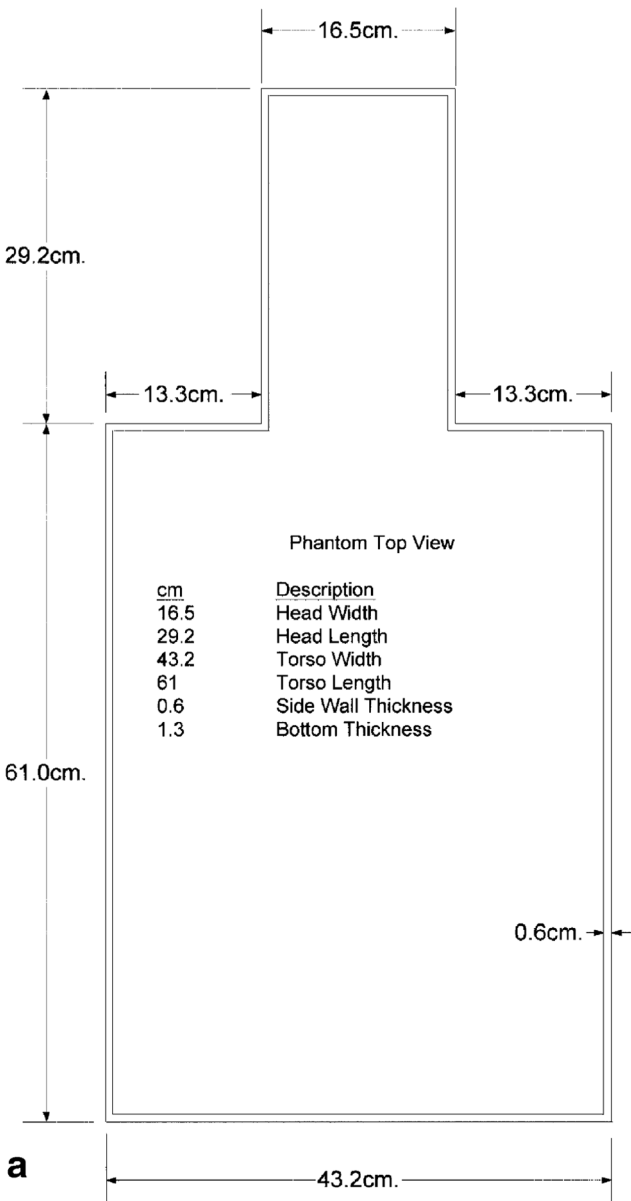
#### Extensions

The extensions were connected to the neurostimulators and the excess lengths were wrapped two times around the perimeter of the neurostimulators. Care was taken not to bend, kink, or stretch the extension wires.

#### Leads

The leads were positioned with two small loops (approximately 2.5 cm in diameter) placed in an axial orienta-





**Figure 4.** Close-up view of head portion of the phantom showing positioning of the neurostimulation systems for configuration 1, commonly used positioning. The two neurostimulators were placed in the upper left and right quadrants of the thorax portion of the phantom. The excess lengths of the extensions were wrapped two times around the perimeter of the neurostimulators. The leads were positioned with two small loops placed in an axial orientation at the top of the head portion of the phantom (arrow heads). The electrodes were positioned relative to a bilateral in vivo use to approximate the typical placement for a DBS target. Note positions of fluoroptic thermometry probes to measure temperatures on and in between the distal electrodes and a reference temperature near the edge of the phantom.

tion at the top of the head portion of the phantom (i.e., in order to simulate a loop placed near the burr hole cover). The electrodes were positioned relative to approximate a bilateral in vivo use of these devices and at a depth of 41 mm in the gel-filled phantom to approximate the typical placement for a DBS target (i.e., the thalamus).

### Configuration 2, Worst-Case Positioning

*Rationale*

Based on pilot studies by our group, a worst-case configuration was created (i.e., using two neurostimulation systems with leads and extensions positioned as described in this section), intended to simulate the situation where an implanting physician takes up the entire slack of extra lead and extension length by coiling it within the IPG pocket. This results in a significant number of extra coils around the IPG (which is proposed to impact MRI-related heating). (Note: an implanting phy-

**Figure 3.** **a:** Plexiglas phantom designed to approximate the size and shape of the head and torso of a human subject. **b:** Phantom with plastic frame placed at the bottom. This frame had adjustable posts that allowed variable positioning and support of the neurostimulators, extensions, and leads within the phantom. Note the cables for the four fluoroptic thermometry probes used to record temperatures.

sician would never leave the entire length of extra lead and extension at the level of the head given its impracticality.) Finally, situations in which the IPG were implanted at other locations on the torso (i.e., infra-axillary or abdominal) would tend to uncoil the extra wire, move the IPG further away from the RF coil, and result in more favorable MRI-related heating scenarios.

#### Neurostimulators

Same as for configuration 1.

#### Extensions

Same as for configuration 1, but with the excess lengths of the extensions wrapped four times around the perimeters of the neurostimulators.

#### Leads

Same as for configuration 1, but without the small loops at the top of the head portion of the phantom. The electrodes were positioned relative to a bilateral in vivo use of these devices, as described above.

### Thermometry System and Placement of Temperature Probes

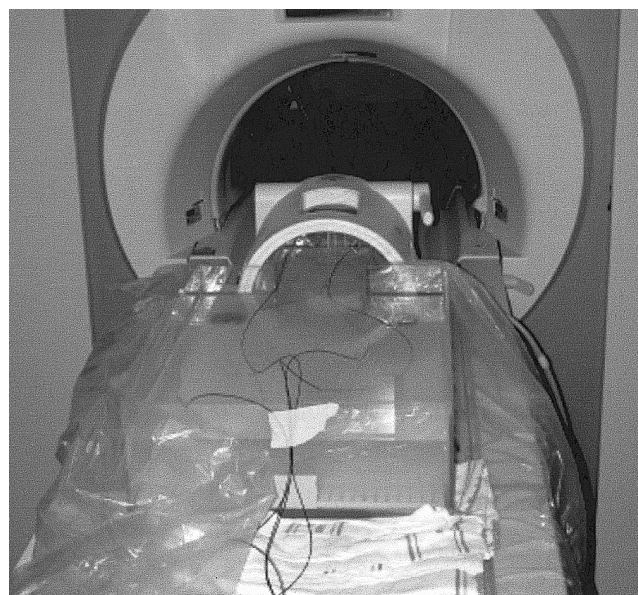
Temperature recordings were obtained using an MR-compatible Model 790 Fluoroptic Thermometry System (Luxtron, Santa Clara, CA) that has been used in many previously published studies conducted to assess MRI-related heating for implants and devices (13–15, 18–21). This thermometry system has small fiber-optic probes (0.5 mm in diameter, Model SSF) that respond rapidly (response time, 0.25 seconds).

Four fluoroptic thermometry probes were positioned to record representative sites for the neurostimulation systems that would generate the greatest heating during MRI based on previously published literature and pilot experiments conducted by our group (13, 14). For the neurostimulators, extensions, and electrodes evaluated in this study, the effects of induced currents generated during MRI will be concentrated at the electrodes of the leads. Thus, thermometry probes were positioned on or near the leads (Fig. 4), as follows:

1. R-probe, placed within 0.1 mm on the center of the distal electrode of the right lead.
2. L-probe, placed within 0.1 mm on the center of the distal electrode of the left lead.
3. M-probe, placed between the two distal electrodes of the leads. Note that the lead electrodes were spaced 3 cm apart such that the temperature probe between them was 1.5 cm from each lead.
4. Reference probe, placed at a remote position from the electrodes, within 1 cm from the edge of the head portion of the phantom (i.e., to record a reference temperature).

#### MR System

MRI was performed on the gel-filled phantom and neurostimulation systems using a 1.5-T/64-MHz MR system (Vision, software version, Numaris 3.0; Siemens



**Figure 5.** Example of experimental setup used to assess MRI-related heating for the neurostimulation systems. Note gel-filled human head and torso phantom, cables for fluoroptic thermometry probes, and the use of the transmit/receive head coil.

Medical Systems, Iselin, NJ) and either the transmit/receive body RF coil or the transmit/receive head RF coil (Fig. 5).

In order to study various RF energy exposures, pilot studies were conducted to guide selection of a range of whole-body averaged specific absorption rates (SARs) and corresponding local SARs using the transmit/receive body and head RF coils to identify safe thresholds that could be used in patients undergoing MRI procedures. Similar to other clinical MR systems, the 1.5-T MR system used in this investigation estimates the whole-body averaged and local SARs (the mass normalized rate at which RF energy is coupled to biologic tissues) for RF energy based on the pulse sequence parameters used for imaging (18–21). Thus, parameters were specifically selected to vary the whole-body and local SARs in these experiments to assess MRI-related heating for the neurostimulators under relatively high and relatively low RF power levels (22).

Using the transmit/receive body RF coil, the whole-body averaged SARs, ranged from 0.98–3.90 W/kg and the local SARs ranged from 3.05–12.20 W/kg (Table 1). Using the transmit/receive head coil, the whole-body averaged SARs ranged from 0.07–0.24 W/kg and the local SARs ranged from 2.10–7.09 W/kg (Table 1). For each experiment, MRI was conducted for a total of 15 minutes (i.e., worst-case imaging time).

### MRI Protocols for Heating Assessment of the Neurostimulators

The neurostimulators, extensions, and electrodes were positioned in the phantom and fixed in place to the positioning posts as previously described. Next, the temperature probes were placed in the above described locations and secured in place using 4.0 silk suture.

Table 1

Evaluation of MRI-related Heating for Neurostimulation Systems—Experimental Conditions and Highest Temperature Changes

Experiment	Positioning	RF Coil	Whole-body SAR (W/kg)	Local SAR (W/kg)	Time (min)	Section location	Electrode, highest temperature change	Reference probe, highest temperature change
1	Configuration #1	Body	3.90	12.20	15.00	IPGs	6.1°C	0.3°C
2	Configuration #2	Body	3.90	12.20	15.00	IPGs	25.3°C	0.5°C
3	Configuration #1	Body	0.98	3.05	15.00	IPGs	2.5°C	0.2°C
4	Configuration #1	Head	0.24	7.09	15.00	Leads/electrodes	7.1°C	0.2°C
5	Configuration #1	Head	0.13	3.87	15.00	Leads/electrodes	3.7°C	0.3°C
6	Configuration #1	Head	0.07	2.10	15.00	Leads/electrodes	2.3°C	0.4°C

Positioning: Configuration #1, Commonly-Used Positioning; Neurostimulators. The two neurostimulators were placed in the upper left and right quadrants of the “thorax” portion of the phantom. They were within 2-cm from the surface of the gel, separated by a distance of approximately 30-cm, in accordance with the product insert instructions for these devices. Extensions. The extensions were connected to the neurostimulators and the excess lengths were wrapped *two* times around the perimeter of the neurostimulators. Leads. The leads were positioned with two small loops (approximately 2.5-cm in diameter) placed in an axial orientation at the top of the “head” portion of the phantom (i.e., order to simulate a loop placed near the burr hole cover). The electrodes were positioned relative to a bilateral in vivo use of these devices at a depth of 41-mm in the gel to approximate the typical placement for a DBS target (i.e., the thalamus). Configuration #2, Worst-Case Positioning; Neurostimulators. Same as Configuration #1. Extensions. Same as Configuration #1 but with the excess lengths of the extensions wrapped *four* times around the perimeters of the neurostimulators. Leads. Same as Configuration #1 but *without* the small loops at the top of the “head” portion of the phantom. The electrodes were positioned relative to a bilateral in vivo use of these devices, as described above.

SAR, specific absorption rate; Section location, refers to centered slice for MR imaging.

Finally, the phantom was filled with gel and allowed to equilibrate to the room temperature of the MR environment for not less than 30 minutes. MRI was then performed at various SARs using the transmit/receive body and head RF coils according to the experimental conditions displayed in Table 1.

Baseline temperatures were recorded for 1 minute at 5-second intervals, after which MRI was then performed for the previously indicated times with temperatures recorded at 5-second intervals. After MRI, temperatures were recorded for 1 minute at 1-second intervals.

## RESULTS

The results of this study are summarized in Table 1. The highest temperature changes were recorded at the distal electrodes in these experiments. The highest temperature change measured by the reference probes ranged from +0.2° to +0.5° C.

For the use of the transmit/receive body RF coil (experiments 1–3), the highest temperature changes ranged from +2.5° to +25.3° C. The highest temperature change, +25.3° C, was recorded with configuration 2 and a whole-body averaged SAR of 3.90 W/kg (Fig. 6a). Of note is that the temperature increase was extremely rapid during the onset of MRI. Interestingly, the use of these same conditions with configuration 1 produced a highest temperature change that was substantially less (6.1° C). Using configuration 1 and a whole-body averaged SAR of 0.98 resulted in a highest temperature change of +2.5° C (Fig. 6b).

For the experiments involving the transmit/receive head RF coil (i.e., experiments 4 to 6), the highest temperature changes ranged from +2.3° to +7.1° C. The highest temperature change, +7.1° C, was recorded with configuration 1 and a whole-body averaged SAR of 0.24 W/kg. The smallest temperature change, +2.3° C,

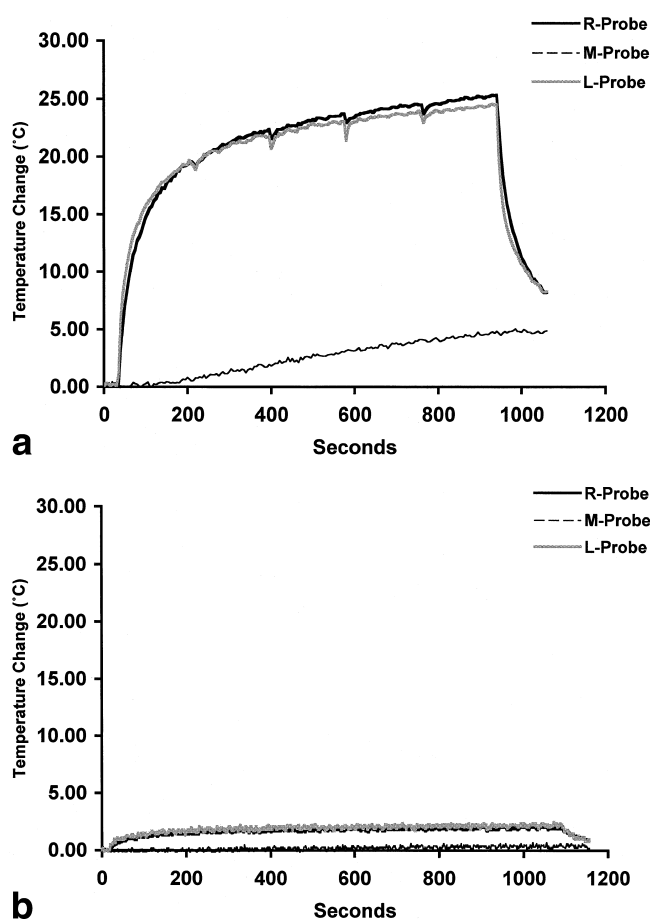
occurred with configuration 1 and a whole-body averaged SAR of 0.07 W/kg.

## DISCUSSION

MRI-related heating of implants, devices, and materials of a variety of sizes, shapes, and metallic compositions have been studied using in vitro testing techniques (8,11–16,18–21,23–27). These investigations reported that only minor temperature elevations occur during MRI for “passive” implants or materials (i.e., those that do not require activation by electronic, mechanical, or magnetic mechanisms). By comparison, substantial temperature increases may occur under certain MR operational conditions in electronically activated or electrically conductive devices (8,13,15,16,27,28). For example, excessive temperature elevations can occur under certain circumstances during MRI for cardiac pacemakers, indwelling catheters with metallic components (e.g., thermodilution catheters), guide wires, disconnected or broken surface coils, or improperly used physiologic monitors resulting in first-, second-, or third-degree burns (1,13,15,16,27–29). Thus, the potential for MRI to injure patients by excessive heating of conductive devices is well documented (1,2). Of note is that there is a tendency for excessive heating to occur in looped or coiled devices or materials because electrical currents are easily induced in these shapes (i.e., for given diameters) during MRI (1,13–15).

In general, patients with electronically activated implants are strictly prohibited from undergoing MRI (1,2,22). However, considering the importance of using MRI for the care and management of patients, research studies have been performed to determine risks associated with using MRI in the patients with certain electronically activated implants. These investigations have demonstrated that patients with pacemakers, implantable cardiac defibrillators, spinal fusion stimulators,





**Figure 6.** Examples of temperature changes recorded during assessment of MRI-related heating for the neurostimulation systems. **a:** Graph corresponds to experiment 2 (i.e., configuration 2: body RF coil, whole-body averaged SAR of 3.90 W/kg, section location through IPGs, and reference temperature change of 0.5° C). Note the rapid increase in temperatures recorded by the thermometry probes on the right and left leads. **b:** Graph corresponds to experiment 3 (i.e., configuration 1: body RF coil, whole-body averaged SAR of 0.98 W/kg, section location through IPGs, and reference temperature change of 0.2° C).

and other similar devices may undergo MRI without experiencing adverse events if specific precautions are closely followed (12,30–35). These investigations typically defined safety guidelines with respect to the conditions that must be used for the device (e.g., setting the device to the “off” mode of operation and resetting after MRI) and the parameters for the MR examinations. In fact, certain electronically activated implants have labeling claims approved by the U.S. Food and Drug Administration (FDA) that permit MRI to be performed as long as specific guidelines are followed to ensure patient safety (1,2,34).

For the neurostimulation system evaluated in this study, the product insert currently states that patients with this device should not be exposed to the electromagnetic fields produced by MRI. Nevertheless, it is known that MRI is often used in patients with this particular neurostimulation system and there have been no reported or apparent adverse events (unpub-

lished results from a recently conducted survey, A.R. Rezai, 2001). However, the operational conditions for the neurostimulation systems and exact MR parameters that were used during these examinations are not well documented.

In recognition of the fact that excessive MRI-related heating is an important concern for patients with neurostimulation systems and DBS electrodes, this study was designed to identify guidelines that would permit patients with these implants to safely undergo clinical MRI procedures. Different levels of RF energy (i.e., whole-body averaged SARs) were used because of the inherent importance of this variable on the MRI-related heating of electronically activated implants (1,13–17,22).

To put the SAR levels that were used in this study into perspective, one needs to understand the current FDA (i.e., Center for Devices and Radiological Health) guidelines for exposure to RF energy during MRI (22). In a document issued in 1998, the FDA defined the operating conditions above which patient studies would be considered “significant risk investigations” and require approval of an investigational device exemption (IDE) (22). Thus, this FDA document effectively represents the recommended limits for exposure to the electromagnetic fields used for clinical MR procedures.

For RF energy, exposures that exceed the following levels require an IDE: “specific absorption rate (SAR) greater than 4.0 W/kg whole body for 15 minutes, 3.0 W/kg averaged over the head for 10 minutes, 8.0 W/kg in any gram of tissue in the head or torso for 15 minutes, or 12.0 W/kg in any gram of tissue in the extremities for 15 minutes.” Accordingly, in the present study, a range of whole-body averaged SARs and corresponding local SARs using the transmit/receive body and head RF coils were evaluated to identify safe thresholds that could be used in patients with neurostimulation systems.

Regarding MRI procedures using a transmit/receive body RF coil, this is frequently performed in the clinical setting for assessment of the lumbar spine, abdomen, cardiovascular system, and other torso-related anatomic regions. Additionally, some MR systems use the body coil to transmit RF energy and the head coil operates in the receive-only mode, so this is effectively the same situation. Therefore, it is imperative to determine heating for neurostimulation systems under conditions that simulate these clinical uses of MRI.

According to the findings of this investigation, experiment 2 showed the highest temperature change (25.3° C) for conditions involving the use of the worst-case positioning scheme for the neurostimulation systems (i.e., excess lengths of the extensions and leads were wrapped around the IPGs) and MRI performed using the body RF coil with a whole-body averaged SAR of 3.9 W/kg. By comparison, experiment 1 used similar MRI conditions, but the positioning scheme for the neurostimulation systems was representative of a commonly used clinical practice (i.e., excess lengths of the extensions were wrapped around the IPG neurostimulators, with the leads positioned with small loops to simulate placement near the burr hole). This resulted in a highest temperature change of only 6.1° C, illustrating the

critical importance of positioning the extensions and leads of the neurostimulation systems with regard to the impact on MRI-related heating. By reducing the whole-body averaged SAR to 0.98 W/kg, the highest temperature change was 2.5° C, demonstrating that the SAR level influences the resultant MRI-related heating for the neurostimulation systems as well.

Based on this MRI-related heating information and in consideration of the threshold temperatures known to produce reversible (i.e., range, 42°–44° C) and irreversible (i.e., >45° C) thermal lesions (38), it is advisable to employ only the commonly used positioning scheme for bilateral neurostimulation systems and to restrict the whole-body averaged SAR below 0.9 W/kg whenever the body RF coil is used for MRI procedures (see additional safety guidelines below). This should ensure that any temperature changes that may occur are within physiologically acceptable levels (36–39). However, we recognize that there is considerable variability in how neurosurgeons implant neurostimulation systems, and the impact of this on MRI-related heating is currently unknown.

Because the number of patients that receive implanted neurostimulation systems is increasing, there is a greater probability that patients with these implants are going to require MR examinations for the assessment of neurological symptoms both related and unrelated to the purpose of the neurostimulator. Furthermore, the use of MRI of the brain for patients treated using DBS is desirable for a variety of reasons, including guiding placement of electrodes using stereotactic MR techniques and evaluating cases of unsatisfactory outcomes of stimulation treatment (e.g., to verify electrode position). As such, the effects of MRI-related heating of neurostimulation systems due to the use of the transmit/receive head coil require careful consideration.

Experiments conducted to assess MRI-related heating for the use of the transmit/receive head RF coil evaluation involved only the commonly used positioning technique for the neurostimulation systems because the image section location was centered on the tips of the electrodes (i.e., without the IPGs and coiled extensions and leads in the RF coil). The findings for this positioning scheme and various whole-body averaged SARs showed that the highest temperature changes ranged from 2.3°–7.1° C. In consideration of these results and to avoid potential deleterious thermogenic injuries, using the transmit/receive head RF coil for MRI, the whole-body averaged SAR should not exceed 0.1 W/kg (see additional safety guidelines below).

The mechanism responsible for MRI-related heating of the neurostimulation systems is electric current induced in the lead wires by the RF field. The lead wire essentially acts as an antenna, and the electric field accompanying the RF magnetic field induces current in the wire. A part of the induced current passes through the electrode contacts into the surrounding tissue, resulting in heating.

The temperature increase at the electrode contacts is proportional to the square of the emanating current. Since the SAR is proportional to the square of the induced electric field, the temperature rise at the elec-

trode contacts will likewise be proportional to the SAR, as was observed in this study. The temperature rise associated with using the transmit/receive head RF coil is less than that for the body coil because there is less lead wire exposed to the RF field, resulting in less induced current. Basically, if the length of lead exposed to the RF field is decreased by 50%, the temperature rise will be reduced by approximately a factor of 4.

The loops in the lead wire are expected to influence the temperature rise, though two different mechanisms. First, a voltage is induced in the loops due to coupling with the magnetic field from Faraday's Law. This voltage could either add to or subtract from the voltage generated by coupling of the straight section of lead with the electric field. However, because of the small radius of the loop and small length of wire within it, the induced voltage will be significantly less than the voltage induced along the straight section of the wire.

Second, the inductive reactance of the loops will reduce the induced current in the wire. The mechanism for the reduced temperature change seen in experiment 1 (configuration 1), compared to experiment 2 (configuration 2), is thus likely, due to this second mechanism. The loop effectively acts as an RF choke (35), reducing the current emanating from the electrode contacts, resulting in less heating during MRI. Notably, this mechanism is similar to the reduction of RF-induced temperature rise observed by Ladd and Quick (35) at the tip of a catheter when a shield was added to act as an RF choke.

Previous investigations performed to assess MRI-related heating for neurostimulator systems used for DBS have reported varying results (8,11,24). Gleason et al (8) investigated MR safety issues for various neurostimulation systems, including the unilateral ITREL II neurostimulator (Medtronic, Minneapolis, MN) in 0.35- and 1.5-T MR systems. MRI-related heating was evaluated using a fluoroptic thermometer to record the case (i.e., outer titanium casing of the IPG) temperature of a unilateral ITREL placed in air (i.e., the device was not surrounded by a conductive media to simulate human tissue) inside of a 1.5-T MR system. MRI was performed for 13 minutes using the transmit/receive body RF coil for imaging. The neurostimulation system was attached to a support 30 cm in diameter to represent the position used for implantation; however, the actual positions used for the IPG, extension, and lead were not reported. The temperature increased substantially; however, Gleason et al (8) felt that this temperature rise was a worst-case condition, since the heating effect of a device that is implanted would be reduced by the heat conduction of the surrounding tissues.

Tronnier et al (11) studied MRI-related heating for unilateral ITREL II and ITREL III neurostimulators (Medtronic, Minneapolis, MN) in 0.2-, 0.25-, and 1.5-T MR systems during MRI using standard spin-echo pulse sequences. An infrared camera was used to measure heating of the neurostimulation systems applied to the surface of a water phantom. Because an infrared camera was used, all metallic surfaces of the neurostimulation systems were covered with black paint to prevent reflection of heat radiation from other objects in the RF area. Experiments were performed using the



head and body RF coils, with the tips of the leads placed in air, in saline, or connected to a resistor (11). Tronnier et al (11) reported that “no heat induction was observed in any part of the hardware.” Unfortunately, the methods used in this study have several major limitations, including the fact that an infrared camera was used to evaluate heating (e.g., it is not possible to measure the temperature on the tip of the lead immersed in saline using an infrared camera), the neurostimulator system was not surrounded by conductive media to simulate human tissue, it is unknown whether painting the metal parts impacted the results of MRI-related heating, and the SARs that were used in the experiments were not reported.

A study conducted by Schueler et al (24) examined MRI-related heating for unilateral ITREL II and ITREL III neurostimulators using a 1.5-T MR system operating at SARs that did not exceed a whole-body averaged SAR of 0.4 W/kg (i.e., 10 times less than the highest level currently recommended by the FDA).

Experiments were performed with the neurostimulators outside (i.e., in air) and inside of a saline bath. Temperatures were recorded using a fluoroptic thermometry system. Schueler et al (24) reported that “no heating of any devices, catheters, extensions, or leads was detected in several experiments in which the location and orientation of objects within the magnet bore was varied.”

The discrepancies between the findings of the present study and those reported in previous investigations are predominantly related to important differences in methodologies, including the following: 1) the use of bilateral vs. unilateral neurostimulation systems, 2) the different RF energy levels selected for the experiments, 3) the positioning techniques used for the neurostimulation systems, 4) the method used to record temperatures (fluoroptic thermometry is considered the industry standard (12–21)), and 5) the use of a phantom filled with gel prepared to simulate the thermal convection properties of human tissue vs. saline. Notably, a gel-filled phantom is preferred over a saline-filled phantom for evaluation of MRI-related heating of devices intended for implantation in soft tissue (12–15,19–21), because the use of a saline-filled phantom will greatly underestimate MRI-related heating for electrically conductive devices (13–15 and unpublished observations from our pilot experiments on neurostimulation systems showing that thermal convection in saline is a significant source of heat transport).

Regarding possible limitations of this study, while it is acknowledged that other MR safety issues for neurostimulation systems may exist (e.g., magnetic field interactions, induced voltages, and programming changes), these were not specifically addressed in the present investigation. In general, previous MR safety investigations for neurostimulation systems have not revealed any significant hazards related to these situations (8,9,11,24). Nevertheless, further investigations are warranted to address these.

Based on the findings reported herein, 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 guidelines

pertaining to the positioning of these devices and parameters used for MRI are carefully adhered to. The recommended safety guidelines are as follows:

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 MRI 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. MRI should only be performed using an MR system with a static magnetic field of 1.5 T. 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 MRI, the whole-body averaged SAR should not exceed 0.9 W/kg.
6. If the transmit/receive head RF coil is used for MRI, the whole-body averaged SAR should not exceed 0.1 W/kg.
7. MRI should be performed using standard techniques that utilize the lowest possible SAR levels, as indicated above.
8. Patients should be instructed prior to MRI to report any unusual sensations that may occur during the examinations.
9. Patients should be continuously monitored throughout MRI using visual and/or verbal means.
10. After MRI, 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 MRI.

In conclusion, MRI-related heating was assessed for a neurostimulation system used for chronic DBS. Different configurations were evaluated for bilateral neurostimulators, extensions, and leads to assess worst-case and clinically relevant positioning scenarios. The findings indicated that excessive heating occurs under certain conditions, while others produce relatively minor, physiologically inconsequential temperature increases. Notably, the use of clinically relevant positioning techniques for the neurostimulation system and MR parameters used for imaging the brain generate little heating. These observations are restricted to the tested neurostimulation system.

## ACKNOWLEDGMENTS

We acknowledge Ralf Loeffler, PhD, for his encouragement and insights.

## REFERENCES

- Shellock FG. Magnetic resonance: health effects and safety. Boca Raton, FL: CRC Press; 2001.
- Shellock FG. Pocket guide to metallic implants and MR procedures: update 2001. New York: Lippincott-Raven Healthcare; 2001.
- Shellock FG. MR imaging and electronically-activated devices [Letter]. *Radiology* 2001;219:294–295.
- Rise MT. Instrumentation for neuromodulation. *Arch Med Res* 2000;31:237–247.
- Rezai AR, Lozano AM, Crawley AP, et al. Thalamic stimulation and functional magnetic resonance imaging: localization of cortical and subcortical activation with implanted electrodes. *J Neurosurg* 1999;90:583–590.
- Zonenshayn M, Mogilner AY, Rezai AR. Neurostimulation and functional brain stimulation. *Neuro Res* 2000;22:318–325.
- Dormont D, Cornu P, Pidoux B, et al. Chronic thalamic stimulation with three-dimensional MR stereotactic guidance. *AJNR Am J Neuroradiol* 1997;18:1093–1097.
- Gleason CA, Kaula NF, Hricak H, et al. The effect of magnetic resonance imagers on implanted neurostimulators. *Pacing Clin Electrophysiol* 1992;15:81–94.
- Liem LA, van Dongen VC. Magnetic resonance imaging and spinal cord stimulation systems. *Pain* 1997;70:95–97.
- Ouayoun M, Dupuch K, Aitbenamou C, Chouard CH. Nuclear magnetic resonance and cochlear implant. *Ann Otolaryngol Chir Cervicofac* 1997;114:65–70.
- 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.
- Chou C-K, McDougall JA, Chan KW. RF heating of implanted spinal fusion stimulator during magnetic resonance imaging. *IEEE Trans Biomed Eng* 1997;44:367–372.
- Smith CD, Kildishev AV, Nyenhuis JA, Foster KS, Bourland JD. Interactions of MRI magnetic fields with elongated medical implants. *J Applied Physics* 2000;87:6188–6190.
- Nyenhuis JA, Kildishev AV, Foster KS, Graber G, Athey W. Heating near implanted medical devices by the MRI RF-magnetic field. *IEEE Trans Magn* 1999;35:4133–4135.
- Smith CD, Nyenhuis JA, Kildishev AV. Health effects of induced electrical currents: implications for implants. In: Shellock FG, editor. *Magnetic resonance: health effects and safety*. Boca Raton, FL: CRC Press; 2001. Chapter 16, p 393–413.
- Achenbach S, Moshage W, Diem B, Biebler T, Schibgilla V, Bachmann K. Effects of magnetic resonance imaging on cardiac pacemakers and electrodes. *Am Heart J* 1997;134:467–473.
- Shellock FG. Radiofrequency-induced heating during MR procedures: a review. *J Magn Reson Imaging* 2000;12:30–36.
- 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.
- 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.
- Shellock FG, Shellock VJ. Stents: evaluation of MRI safety. *AJR Am J Roentgenol* 1999;173:543–546.
- 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.
- Zaremba L. FDA guidance for MR system safety and patient exposures: current status and future considerations. In: Shellock FG, editor. *Magnetic resonance procedures: health effects and safety*. Boca Raton, FL: CRC Press; 2001. p 183–196.
- Chou H-K, McDougall JA, Can KW. Absence of radiofrequency heating from auditory implants during magnetic resonance imaging. *Bioelectromagnetics* 1995;16:307–316.
- Schueler BA, Parrish TB, Lin JC, et al. MRI compatibility and visibility assessment of implantable medical devices. *J Magn Reson Imaging* 1999;10:596–603.
- ECRI. Health devices alert, a new MRI complication? *Health Devices Alert*, May 27, 1988, p 1.
- ECRI. Thermal injuries and patient monitoring during MRI studies. *Health Devices Alert*, June 20, 1991, p 362.
- Konings MK, Bartels LW, Smits HJ, Bakker CJ. Heating around intravascular guidewires by resonating RF waves. *J Magn Reson Imaging* 2000;12:79–85.
- Nitz WR, Oppelt A, Renz W, Manke C, Lenhart M, Link J. On the heating of linear conductive structures as guide wires and catheters in interventional MRI. *J Magn Reson Imaging* 2001;13:105–114.
- Kanal E, Shellock FG. Burns associated with clinical MR examinations [Letter]. *Radiology* 1990;175:585.
- Shellock FG, Hatfield M, Simon BJ, et al. Implantable spinal fusion stimulator: assessment of MRI safety. *J Magn Reson Imaging* 2000;12:214–223.
- Sommer T, Lauck G, Schimpf R, et al. MRI in patients with cardiac pacemakers: in vitro and in vivo evaluation at 0.5 Tesla. *Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahr* 1998;168:36–43.
- Shellock FG, Kelly D, Ivans V, O'Connor M, Toay L, Cruess JV. Pacemakers and implantable cardiac defibrillators and pacemakers are unaffected by operation of an extremity MR system. *AJR Am J Roentgenol* 1999;172:165–172.
- Gimbel JR, Johnson D, Levine PA, Wilkoff BL. Safe performance of magnetic resonance imaging on five patients with permanent cardiac pacemakers. *Pacing Clin Electrophysiol* 1996;19:913–919.
- Shellock FG. Website devoted to MR safety. <http://www.MRIsafety.com>.
- Ladd ME, Quick HH. Reduction of resonant RF heating in intravascular catheters using coaxial chokes. *Magn Reson Med* 2000;43:615–619.
- Bligh J. Temperature regulation in mammals and other vertebrates. New York: American Elsevier; 1973. p 80–84.
- Heistad DD, Abboud FM. Factors that influence blood flow in skeletal muscle and skin. *Anesthesiology* 1974;41:139–156.
- Houdas Y, Ring EFJ. Temperature distribution. In: *Human body temperature: its measurements and distribution*. New York: Plenum; 1982.
- Cosman ER. Radiofrequency lesions. In: Gildenberg PL, Tasker RR, editors. *Textbooks of stereotactic and functional neurosurgery*. New York: McGraw-Hill; 1992. Chapter 101, p 973–985.