Metallic Neurosurgical Implants: Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 1.5-Tesla

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The purpose of this study was to use ex vivo testing to determine the magnetic resonance imaging (MRI) safety aspects for seven different metallic neurosurgical implants in association with the 1.5-T MR environment. Ex vivo testing was performed using previously-described techniques for the evaluation of magnetic field interactions (deflection angle and torque), heating (gel-filled phantom and fluoroptic thermometry; 15 minutes of MRI at a specific absorption rate [SAR] of 1.4 W/kg), and artifacts (using T1-weighted, spin-echo and gradient-echo pulse sequences). None of the metallic implants displayed interactions with the magnetic field. The highest temperature change was 0.6°C for the representative implant that was evaluated. Artifacts were relatively minor. The lack of magnetic field interactions and negligible heating indicate that MR procedures may be conducted safely in patients with these neurosurgical implants using MR systems with static magnetic fields of 1.5-T or less. Furthermore, these implants may be considered for use in interventional MR procedures insofar as the MR safe qualities and relatively small artifacts would likely be desirable for such procedures. J. Magn. Reson. Imaging 2001;14:295–299. © 2001 Wiley-Liss, Inc.

Index terms: magnetic resonance imaging, safety; magnetic resonance imaging, implants; heating; artifacts

CERTAIN METALLIC IMPLANTS may be unacceptable for patients that require evaluation using magnetic resonance (MR) procedures because of safety issues related to movement or heating, as well as artifacts that may present problems (1–17). Neurosurgical implants are made from a variety of materials that are either inherently safe or unsafe for patients in the MR environment (1,2,7,9,16). Notably, some of these implants, while producing no unwanted risks to patients, may inhibit the diagnostic capabilities of MR techniques because of the presence of relatively large artifacts (2,15–17).

Because evaluation of the brain or cerebral vasculature using MR imaging (MRI), spectroscopy, and angiography is often required for patients following neurosurgical procedures, it is obviously important to use metallic implants that are not only safe, but produce minimal artifacts. Additionally, interventional MR procedures that involve neurosurgical applications require instruments and implants that are safe for patients and have low magnetic susceptibility to allow visualization for intra-operative assessment (2,7,15,16).

For metallic implants and devices, MR safety testing is typically conducted to determine the presence of magnetic field interactions and heating in association with the use of an MR system. In addition, it is frequently useful or necessary to characterize the artifacts associated with the presence of a metallic object. Therefore, this investigation used an ex vivo testing technique to determine magnetic field interactions, heating, and artifacts for seven different metallic neurosurgical implants used for cranial fixation and reconstruction procedures.

**MATERIALS AND METHODS**

**Neurosurgical Implants**

Seven different metallic implants used for cranial fixation and reconstruction procedures (Bioplate, Los Angeles, CA) were assessed for MR safety (Fig. 1). These implants were primarily selected for evaluation because of the lack of safety information relative to the 1.5-T MR environment. Details for the implants evaluated in the study are shown in Table 1.

**BioMesh** is an implant designed for anatomic contouring of the cranial skeleton. This metallic mesh can be configured into three-dimensional shapes that can be molded, stretched, or bent to fit any osseous area, as needed. This implant comes in a variety of sizes. The version that represents the largest type was selected for MR safety testing. The large flexible burr hole cover, large rigid burr hole cover, and large burr hole cover are low-profile metallic plates specifically designed for cranial fixations procedures. These implants come in a variety of sizes. The versions that represent the largest types were selected for MR safety testing. The cranial screw, 1.5 × 4.5 mm and cranial screw, 1.9 × 4.5 mm are low profile screws designed for use with the above-mentioned burr hole covers. These screws are specially designed for the dense bone structure of the cranium.
The BioClip is a cranial fixation implant designed for craniotomy to reattach the bone flap to the cranium without the need for screws or drill holes. This device comes in a variety of sizes. The version that represents the largest type was selected for MR safety testing.

**Evaluation of Magnetic Field Interactions**

Translational attraction and torque were assessed for each implant in association with a shielded 1.5-T MR system (Signa MR System, General Electric Medical Systems, Milwaukee, WI). For the evaluation of translational attraction, the deflection angle was measured (3–9,17). Each implant was suspended by a 30 cm length of thin thread and attached to a plastic protractor so that the angle of deflection from the vertical could be measured. The accuracy of the measuring device was ± 0.5 degrees based on the ability to read the protractor in the MR system.

The deflection angle test was conducted at the position in the 1.5-T MR system where the spatial gradient of the magnetic field was determined to be at a maximum, as previously-described (3–9,11,17). The highest spatial gradient for the shielded 1.5-T MR system used for this evaluation was 450 gauss/cm and occurred at an off-axis position 35 cm inside of the bore of the MR system, according to the survey conducted on the magnetic field using a gauss meter (3–9). Deflection angles were determined three times for each implant and averaged.

The next evaluation of magnetic field interactions was conducted to qualitatively determine the presence of magnetic field-induced torque for the implants (5–8) This procedure involved the use of a flat plastic material with a millimeter grid on the bottom. Each implant was placed on the test apparatus in an orientation that was 45 degrees relative to the static magnetic field of the MR system.

**Figure 1.** Neurosurgical implants that underwent MR safety testing. a: BioMesh. b: Examples of burr hole covers (top row) and cranial screws (bottom row). c: BioClip. d: BioClips in place.
system (5–8). The test apparatus with the implant was then positioned in the center of the MR system, where the effect of torque from the 1.5-T static magnetic field was determined to be the greatest (i.e., based on a previous magnetic field survey for this particular MR system) (5–8).

The implant was directly observed for any possible movement with respect to alignment or rotation relative to the 1.5-T static magnetic field of the MR system. The implant was then moved 45 degrees relative to its previous position, re-inserted into the center of the magnet, and again observed for alignment or rotation. This process was repeated to encompass a full 360 degrees rotation of positions for each implant (5–8, 19).

The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild torque, the implant slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the implant aligned gradually to the magnetic field; +3, strong torque, the implant showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the implant showed very rapid and very forceful alignment to the magnetic field.

### Evaluation of Heating

Heating associated with MRI was determined for the BioMesh implant. This metallic implant was selected for evaluation because it represented the largest metallic mass and shape with regard to the various implants that underwent testing for MR safety (5,6,13,14). The heating assessment was accomplished using an extreme radiofrequency (RF) power exposure experiment with the BioMesh placed inside of a specially-constructed, gel-filled phantom (5,8,13).

A plastic phantom was filled with a semi-solid gel that was prepared to simulate the conductive qualities of human tissue. This was accomplished using a gelling agent (hydroxyethyl-cellulose, HEC) in an aqueous solution (91% water) along with 0.12% NaCl to create a dielectric constant of approximately 80 and a conductivity of 0.8 S/m at 64 MHz. This is an acceptable dielectric constant and an acceptable conductivity for evaluation of MRI-related heating of a metallic implant (5,8,13). The shape of the gel phantom was rectangular with rounded edges that approximated the mass of a human subject’s head.

The BioMesh was fixed to a plastic frame, placed parallel to the static magnetic field, and then positioned inside of the gel phantom close to the outer edge to simulate an in vivo position. Notably, the greatest RF heating that occurs during MRI is with regard to the periphery of a human subject (5,8,14).

A 1.5-T/64 MHz MR system (Signa MR System, General Electric Medical Systems, Milwaukee, WI) was used for the heating experiment. The body coil was used to send and receive RF energy in order to achieve a high exposure to RF energy. A T1-weighted, spin-echo pulse sequence was used for a total imaging time of 15 minutes. MRI was conducted in the axial plane using the following parameters: repetition time, 135 msec; echo time, 20 msec; field of view (FOV), 48 cm; imaging matrix, 256 × 128; section thickness, 20.0 mm; number of section locations, 4; number of excitations (NEX), 27; number of echoes, 4; phasing direction, anterior to posterior; transmitter gain, 200 (5,8,12,19). This pulse sequence produced a calculated whole-body-averaged specific absorption rate (SAR) of 1.4 W/kg and a spatial peak SAR of 2.5 W/kg (5,8,12,19). This level of exposure to RF energy exceeds that typically used for MRI procedures in patients.

Temperature recordings were obtained in this experiment using a Luxtron 3100 Fluoroptic Thermometry system previously demonstrated to be MRI-compatible and unperturbed at static magnetic field strengths up to 9.0-T (5,8). In consideration of the size and shape of the BioMesh implant, one fluoroptic thermometry probe was positioned on the center of the implant and one probe was placed on the opposite side of the gel phantom to record a reference temperature (5,8,14).

The gel phantom with the BioMesh and thermometry probes was placed inside of the MR system and allowed to equilibrate to the environmental temperature for a period of one hour. The room temperature and temperature of the bore of the MR system were 21.0°C, with a relative humidity of 42%. The MR system fan was not on during this experiment. Baseline temperatures were recorded at 20 second intervals for 5 minutes. MRI was then performed for 15 minutes with temperatures recorded at 20 second intervals. The highest temperature changes recorded by the probes are reported.

### Evaluation of Artifacts

Artifacts associated with the implants were assessed by performing MRI with the devices placed inside of a fluid-filled phantom (4–8). The phantom was made from plastic and was cylinder-shaped with a diameter of 9.5 inches. The implants were attached to a plastic frame to facilitate positioning and MRI within the phantom (5,8). MRI was conducted using the 1.5-T MR system, a send-receive body coil, and the following pulse sequences: 1) T1-weighted, spin-echo pulse sequence; repetition time, 500 msec; echo time, 20 msec; matrix size, 256 × 256; section thickness, 5 mm; FOV, 26 cm; NEX, 2; bandwidth, 16 kHz; and 2) gradient-echo (GRE) pulse sequence; repetition time, 100 msec; echo time, 15...
msec; flip angle, 30 degrees; matrix size, 256 × 256; section thickness, 5 mm; FOV, 26 cm; NEX, 2; bandwidth, 16 kHz.

These are commonly used pulse sequences that are clinically applied for MRI. In addition, the GRE pulse sequence is a gradient-echo or partial flip angle technique that tends to have a great degree of artifact associated with it when MRI is performed on a metallic implant and, thus, represents a type of extreme condition (5,8,15). The imaging planes were oriented to encompass the long axis and short axis of each implant. The frequency encoding direction was parallel to the plane of imaging (5,8). Artifacts that result from other positions of the imaging plane relative to the implant or with regard to the particular orientation of the implant to the main magnetic field of the MR system may be slightly more or less than that observed under these experimental conditions (5–8,17).

Artifact size was graded according to the following scheme (4–7): neg, no artifact; +1, artifact less than the size of the implant; +2, artifact same as the size of the implant; +3, artifact slightly larger than the size of the implant; +4, artifact more than twice the size of the implant.

Table 2: Summary of MRI Artifact Information: Scores for Artifact Size Based on Pulse Sequence and Plane Orientation

<table>
<thead>
<tr>
<th>Implant</th>
<th>Parallel T1-SE</th>
<th>Perpendicular T1-SE</th>
<th>Parallel GRE</th>
<th>Perpendicular GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioMesh</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Large flexible burr hole cover</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Large rigid burr hole cover</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Large burr hole cover</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Cranial screw 1.5 × 4.5 mm</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>Cranial screw 1.9 × 4.5 mm</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
<tr>
<td>BioClip</td>
<td>+2</td>
<td>+2</td>
<td>+3</td>
<td>+3</td>
</tr>
</tbody>
</table>

T1-SE, T1-weighted, spin echo; GRE, gradient echo. Grading scheme for artifacts: 0, no artifact; +1, artifact less than size of the implant; +2, artifact same as size of the implant; +3, artifact slightly larger than the size of the implant; +4, artifact more than twice the size of the implant.

DISCUSSION

Diagnostic MR techniques are relatively safe for patients (2,16). The predominant hazard for patients with metallic implants is related to movement of ferromagnetic objects by magnetic field interactions with MR systems (1–14,16). In fact, most serious injuries and deaths that have occurred in association with the use of MR procedures were related to patients with ferromagnetic implants that should not have been exposed to the MR environment (2,16,18). While MR-induced heating may be a problem for certain metallic objects (2,16), this has not been shown to be a safety issue for relatively small, “passive” implants (i.e., those that function without mechanical, electrical, or magnetic components). Nevertheless, ex vivo MR safety testing typically includes evaluation of magnetic field interactions and heating to determine potential hazards for metallic implants prior to permitting patients with these objects into the MR environment (1–14,16). Obviously, metallic neurosurgical implants are of particular concern for patients that may need MR procedures because of the close proximity of these objects to the brain or cerebral vasculature (2,7,16).

With regard to the results of the MRI safety tests conducted in the present study, there were no magnetic field interactions or substantial heating found for the seven different neurosurgical implants that were evaluated. This is not surprising considering the use of the materials used to make these implants (i.e., commercially pure [CP] titanium and titanium alloy). Previous investigations have reported that implants made from these materials did not show magnetic field interactions during exposures to MR systems operating up to 1.5-T (1–4,7,8,16).

The single neurosurgical implant (BioMesh) deemed to be representative of the others (i.e., because of its size and shape) showed the highest temperature change of +0.6°C during MRI using a high level of RF energy. Temperature changes associated with MR procedures have been determined using ex vivo experimental methods for a variety of implants and devices (2–8,10,12–14). Data from these studies indicated that relatively small, metallic implants...
will not heat excessively or produce harm to patients undergoing MR procedures, even when exposed to high levels of RF energy. Furthermore, there has never been a report of a significant patient injury related to heating of a small passive implant.

In consideration of the findings for the MRI safety tests, these neurosurgical implants should be designated “MR-safe” in association with the 1.5-T environment. The term MR-safe, as defined by the American Society for Testing and Materials (ASTM), refers to a passive implant or device that, when used in the MR environment, has been demonstrated to present no additional risk to the patient or individual, but may affect the quality of the diagnostic information (11).

Even though MRI-related artifacts are not a safety issue for metallic implants, the presence of an artifact may disrupt the diagnostic capabilities of MR examinations (1,2,4–8,10,15,16). Therefore, artifacts were characterized for the neurosurgical implants using a previously published grading scheme (4,6,7,10). While more elaborate techniques exist to assess artifacts for implants (8,17), this was not a primary objective for the present study nor do these other techniques provide clinically relevant data. The artifact findings obtained in this investigation are considered useful insofar as the results may be readily compared to other previously tested devices and the relative artifact size can be readily appreciated (4,6,7,10).

Overall, the artifacts associated with the neurosurgical implants were relatively minor and, thus, are unlikely to substantially affect the diagnostic aspects of an MR procedure, unless the imaging area of interest is where one of these implants is located. This is unlikely because these implants are used for cranial fixation and reconstruction procedures. The anatomic sites where these implants are applied are seldom areas that require imaging.

The relatively small artifacts are the direct result of the magnetic susceptibilities for the materials used to make the neurosurgical implants. Previous reports have shown that CP titanium and titanium alloy have very low magnetic susceptibilities compared to other metals (4,15,17). In fact, these materials are generally believed to be beneficial for instruments and implants designed for use in interventional MR procedures because of the MR safety and artifact qualities of CP titanium and titanium alloy (2,7,16,19,20). Because interventional MR is frequently used to perform neurosurgical procedures (20–22), it may be desirable to use the neurosurgical implants evaluated in this study.

Artifacts related to the use of the T1-weighted, spin-echo pulse sequence were smaller than those seen with the GRE pulse sequence. This is a well-known phenomenon that is related to this pulse sequence (2,15). Fortunately, there are pulse sequences (e.g., fast spin-echo) and other techniques (swapping phase and frequency) that can be used to minimize artifacts associated with the presence of metallic implants (16,17).

The results of the tests conducted to assess magnetic field interactions and heating indicated that seven neurosurgical implants that underwent evaluation will not present an additional risk for patients in an MR environment of 1.5-T or less. Accordingly, these devices should be considered MR-safe. Furthermore, because of the very low magnetic susceptibility of the materials used to make these devices, MRI artifacts are relatively small. Thus, these implants will not impair the diagnostic use of MR procedures. Furthermore, it may be advantageous to use these neurosurgical implants in interventional MR procedures that require the MR safety and artifact qualities shown by these implants.

REFERENCES