In Vitro Magnetic Resonance Imaging Evaluation of Ossicular Implants at 3 T

*Frank G. Shellock, †Lauren N. Meepos, ‡Matthew R. Stapleton, and §Sam Valencerina

*Keck School of Medicine, University of Southern California and Institute for Magnetic Resonance Safety, Education, and Research, Los Angeles, California; †University of Pennsylvania, Philadelphia, Pennsylvania; ‡Creighton University, School of Medicine, Omaha, Nebraska; and §University of Southern California, University Hospital, Los Angeles, California, U.S.A.

Hypothesis: Ossicular implants made from metallic materials may be acceptable or pose hazards for patients referred for magnetic resonance imaging (MRI) examinations, depending on the outcome of proper MRI testing procedures.

Background: Using a 3-T MR system, 2 ossicular implants were tested for magnetic field interactions, heating, and artifacts.

Materials and Methods: Two different ossicular implants (Stainless Steel/Fluoroplastic Sanna-Type Piston [6 mm in length] and the Offset ALTO Total Prosthesis [15 mm in length, titanium/silicone]; Grace Medical, Memphis, TN, USA) were selected for testing, which represented the largest metallic mass and materials with the highest magnetic susceptibilities, with the intent of applying the MRI findings to other ossicular implants. The implants were evaluated at 3-T for magnetic field interactions, heating, and artifacts using standard previously described techniques.

Results: Each ossicular implant showed relatively minor magnetic field interactions that will not be associated with movement in situ. Heating was not excessive (highest temperature change, 1.6°C; background temperature change, 1.5°C). Artifacts, although relatively small, may create issues for diagnostic imaging if the area of interest is in the same area or close to these ossicular implants.

Conclusion: The results of this investigation demonstrated that it would be acceptable (i.e., “MR conditional” using current terminology) for patients with these ossicular implants to undergo MRI examinations at 3 T or less. In consideration of the materials and dimensions of the implants that underwent testing, these findings pertain to many other similar ossicular implants from the same manufacturer.

Key Words: Artifacts—Implants—Magnetic resonance imaging—Safety—Specific absorption rate.


A variety of prostheses may be used in ossicular reconstruction procedures with the goal of improving or restoring hearing. Ossicular or middle ear implants are made from either nonmetallic or metallic materials. Notably, the presence of a metallic ossicular implant in an individual referred for a magnetic resonance imaging (MRI) procedure must be given careful consideration owing to the possible issues that exist, including those related to magnetic field interactions, MRI-related heating, and artifacts (1,2). This is even more important given the increased use of 3-T MR systems, which is the highest-field-strength magnet type used in the clinical setting. Accordingly, there have been many reports directed toward addressing these issues for ossicular implants (3–23). To date, several “MR-unsafe” ossicular implants exist, necessitating the careful pre-MRI screening of patients to identify these contraindicated devices (2,21,22,24).

With the continued development of ossicular implants and because many have yet to undergo proper MRI testing, it is necessary to conduct in vitro testing, particularly at 3 T (i.e., worst-case conditions for clinical MRI) to characterize MRI issues for these devices. Importantly, in consideration of the close anatomic relationship for these metallic implants in the temporal bone, it is necessary to know whether it is hazardous to patients with metallic middle ear implants regarding displacement and a rise in temperature. The presence of artifacts may also be problematic and compromise the diagnostic use of MRI.

Therefore, this investigation evaluated the MRI issues (i.e., magnetic field interactions, MRI-related heating,
and artifacts) at 3 T for 2 different metallic ossicular implants. In consideration of the materials and dimensions of the implants that underwent testing, these findings pertain to many other similar ossicular implants from the same manufacturer that have smaller sizes and are made from materials with lower magnetic susceptibilities (25), thus expanding the MRI information for many other devices. This same strategy of MRI testing for implants has been successfully applied to aneurysm clips and hemostatic clips (26,27).

METHODS

Ossicular Implants

Two different ossicular implants (Stainless Steel/Fluoroplastic Sanna-Type Piston [6 mm in length] and Offset ALTO Total Prosthesis [15 mm in length, titanium/silicone]; Grace Medical, Memphis, TN, USA) (Figs. 1 and 2) were selected for testing because they represented the largest metallic masses and sizes and they had the highest magnetic susceptibility values (i.e., based on material information for all items) (25) among many other similar ossicular implants from the same manufacturer listed in the Appendix. Accordingly, for the other ossicular implants from the same manufacturer, these items were made from materials with lower magnetic susceptibilities than stainless steel or titanium and/or had smaller dimensions.

Magnetic Field Interactions

Each ossicular implant was evaluated for translational attraction and torque in association with a 3-T MR system (Excite, Software G3.0-052B; General Electric Healthcare, Milwaukee, WI, USA; active-shielded, horizontal field scanner).

Translational Attraction

To evaluate translational attraction for the ossicular implants, the deflection angle technique was used according to previously described methods (26–28). Each ossicular implant was connected to a test fixture to determine the deflection angle in the 3-T MR system. The test fixture incorporated a protractor with 1-degree graduated markings (26–28). The test sample was suspended on the apparatus by a lightweight string (20 cm in length; weight, <1% of the weight of each implant) that was fixed at the 0-degree indicator of the protractor. Deflection angles for each ossicular implant were assessed at the point of the highest spatial magnetic gradient for the 3-T MR system (26–28). The highest “patient accessible” spatial gradient magnetic field for the 3-T MR scanner used in this investigation is 720 G/cm and occurs at an off-axis position that is 74 cm from isocenter of the MR system (26,27,29). The maximum deflection angle from the vertical direction to the nearest 1 degree was measured 3 times for each ossicular implant, and an average value was calculated (26–28).
**OSSEOUS IMPLANTS AND 3-T MRI**

Torque

Torque for each ossicular implant in association with exposure to the 3-T MR system was determined using a previously described, qualitative assessment technique (26,27). This involved the use of a flat plastic device with a millimeter grid (26,27). Each ossicular implant was placed on the test apparatus in an orientation that was 45 degrees relative to the static magnetic field of the 3-T MR system. The test apparatus was then positioned in the center of the scanner, where the effect of torque is the greatest (26,27). Each implant was carefully observed for possible alignment or rotation relative to the 3-T static magnetic field. The ossicular implant was then moved 45 degrees relative to its previous position and observed for alignment or rotation. This process was repeated to encompass a full 360-degree rotation of positions for each ossicular implant. The following previously described, qualitative scale was applied to the results (26,27): 0, no torque; +1, mild or low torque, the ossicular implant slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the ossicular implant aligned gradually to the magnetic field; +3, strong torque, the ossicular implant showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the ossicular implant showed very rapid and very forceful alignment to the magnetic field.

**MRI-Related Heating**

Magnetic resonance imaging-related heating at 3 T/128 MHz was assessed for each ossicular implant. This procedure used a plastic, ASTM phantom (i.e., which has dimensions that simulate the human head and torso) filled to a depth of 10 cm with gelled saline (i.e., 1.32 g/L NaCl plus 10 g/L polyacrylic acid in distilled water), with each implant placed in a position in the phantom where there was a highly uniform electric field tangential to the implant, ensuring extreme radiofrequency (RF) heating conditions for this experimental setup (i.e., based on an analysis of the ASTM phantom and the MRI conditions used for this assessment) (26,27,30). A relatively high level of RF energy was applied during the MRI-related heating experiment, as previously described (26,27). Because this experimental setup lacks “blood flow,” it simulates an extreme condition for this assessment) (26,27,30). Therefore, each ossicular implant was placed on the left side of the ASTM head/torso phantom to yield the worst-case temperature rise for the described measurement conditions, based on previous analyses of device heating for this particular MR system (i.e., due to asymmetry in heating patterns for this phantom and MR system) (26,27).

Each ossicular implant was positioned in the ASTM head/torso phantom at a position mid line on the left side, slightly (5 mm) below the mid depth (vertical orientation) of the gelled saline. For this particular 3-T/128-MHz MR system and experimental setup, the left side of the ASTM head/torso phantom was found to be associated with a greater temperature rise than the right side of the head/torso phantom for a given implant or device (i.e., based on pilot experiments). Therefore, each ossicular implant was placed on the left side of the ASTM head/torso phantom to yield the worst-case temperature rise for the described measurement conditions, based on previous analyses of device heating for this particular MR system (i.e., due to asymmetry in heating patterns for this phantom and MR system) (26,27).

Each ossicular implant was positioned in the plastic phantom using a grid and small plastic after set up as previously described (26,27). The fluoroptic thermometry system was calibrated, and the fluoroptic thermometry probes were applied. The phantom was filled with the gelled saline and allowed to equilibrate to the environmental temperature for more than 24 hours. The MR system fan was not on during the MRI-related heating investigations. The room and MR system bore temperatures were at constant levels throughout each experimental session. After recording baseline temperatures (5 min), MRI was performed for 15 minutes with temperatures recorded at 5-second intervals. This procedure was repeated for the next ossicular implant after the gelled saline returned to thermoequilibrium facilitated by manual mixing and verified by recording temperatures at multiple positions in the phantom. The highest temperature changes recorded by the fluoroptic thermometry probes are reported for each ossicular implant.

The “background” temperature was also recorded in the gelled saline-filled ASTM phantom. Accordingly, the temperature change was recorded at the same position, middle temperature probe position (i.e., corresponding to the position for Probe no. 3 for the MRI-related heating test with the implant present) in the phantom in association with MRI-related heating of the gelled saline-filled phantom without the implant present (26,27,30). To record the background temperature, a fluoroptic thermometry probe was placed in the ASTM head/torso phantom at a position mid line on the left side, slightly (5 mm) below the mid depth (vertical orientation) of the gelled saline, and recordings were obtained as described previously.

**Artifacts**

Magnetic resonance imaging artifacts were assessed at 3 T for each ossicular implant. This test was conducted with each ossicular implant attached to a plastic frame and then placed in a gadolinium-doped, saline-filled plastic phantom (26,27). Magnetic resonance imaging was conducted using a 3-T MR system (Excite, Software G3.0-052B; General Electric Healthcare), a transmit/receive RF head coil, and the following pulse sequences (26,27):

1. T1-weighted, spin echo pulse sequence: repetition time, 500 milliseconds; echo time, 20 milliseconds; matrix size, 256 × 256; section thickness, 10 mm; field of view, 24 cm; number of excitations, 2; bandwidth, 16 kHz.

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RESULTS

The average deflection angle was 1 degree in each case for the each different ossicular implant and the qualitatively measured torque was 0, no torque. Findings for the MRI-related heating assessments for the ossicular implants indicated that the highest temperature changes were equal to 1.6°C or less (range, 1.5–1.6°C). The background temperature change was 1.5°C in each case. Artifact test results are presented in Table 1. In general, the artifacts associated with the 2 different ossicular implants were observed as signal losses or “voids” that were small in relation to the size and shape of each implant, with the gradient echo pulse sequence producing larger artifacts than the T1-weighted, spin echo sequence. Figure 3 shows examples of artifacts for the ossicular implants, as observed on the gradient pulse sequence in the view oriented to the long axis of the respective implant.

DISCUSSION

Magnetic Field Interactions

The average deflection angle was 1 degree, in each case, for the selected ossicular implants that underwent testing at 3 T. These translational attraction findings are considered with regard to the document from the American Society for Testing and Materials International (30), which states “If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth’s gravitational field.” Therefore, the 2 different ossicular implants passed this acceptance criterion relative to the 3-T MR system that was used in this investigation. The qualitatively measured torque was 0, no torque, in each case. Accordingly, these ossicular implants displayed very low magnetic field interactions and, thus, will not present a hazard to a patient in a 3-T or less MRI environment.

For a metallic implant or device, the associated magnetic field interactions are dependent on the strength of the static magnetic field, the maximum spatial gradient magnetic field, the mass of the object, the shape of the object, and the magnetic susceptibility of the material(s) (1,2,22,25–29). The 2 different ossicular implants were specifically selected in this study for MRI testing because they represented the largest metallic masses and sizes with the highest magnetic susceptibility values compared with many other similar ossicular implants from the same manufacturer (Appendix). Therefore, because these additional ossicular implants have lower masses and dimensions, along with being made from materials with lower

| TABLE 1. Summary of artifact sizes for the ossicular implants evaluated at 3 T |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Pulse sequence                | T1-SE                         | T1-SE                         | GRE                          | GRE                          |
| Stainless Steel/Fluoroplastic Sanna-Type Piston | 20 | 12 | 88 | 41 |
| Imaging plane                 | Parallel (long axis)          | Perpendicular (short axis)    | Parallel (long axis)         | Perpendicular (short axis)   |
| Offset ALTO Total Prosthesis  | 70 | 15 | 168 | 49 |
| Imaging plane                 | Parallel (long axis)          | Perpendicular (short axis)    | Parallel (long axis)         | Perpendicular (short axis)   |

Imaging plane is relative to each ossicular implant. GRE indicates gradient echo; T1-SE, T1-weighted, spin echo.
magnetic susceptibilities, the magnetic qualities will be inherently less relative to the 3-T MRI environment.

Interestingly, some reports and documents have presented information for magnetic field interactions relative to ossicular implants using MR systems operating at 7 T and even 9.4 T (19,24,31). However, this information may not be helpful insofar as the MRI evaluations were not conducted using an MRI-relating heating assessment, or the heating test was improperly performed (i.e., not in adherence with the ASTM International guidance information) (30), which is a critical part of the proper characterization of MRI issues for implants and devices according the U.S. Food and Drug Administration (32). Furthermore, rarely is a patient with a metal implant scanned using these experimental, very-high-field-strength scanners. At the present time, 3 T is the highest-field-strength MR system currently used worldwide in the clinical setting.

MRI-Related Heating

With regard to MRI-related heating, extreme conditions were applied to determine the temperature rises for the 2 different ossicular implants. Thus, using a relatively high level of RF energy at 3 T (i.e., the MR system reported, whole-body-averaged SAR, 2.9 W/kg) with each ossicular implant placed in a “worst-case” position in the gelled saline–filled phantom, the highest temperature changes ranged from 1.5 to 1.6°C. Under the same MRI experimental conditions, the background temperature change was 1.5°C. Importantly, the recorded temperature elevations for the ossicular implants are not considered to be physiologically consequential for a human subject.

Potentially injurious, MRI-related heating may be generated in an implant or device depending on the dimensions of the object with regard to its length and/or if it is in the shape of a closed loop with a relatively large diameter (2,33–35). For an ossicular implant, the length and closed-loop aspects for these various devices, when considered relative to MRI-related heating, do not involve dimensional aspects that will be associated with substantial temperature rises insofar as they are relatively short and have very small, closed loops (Fig. 2). Thus, it is not surprising that the measured temperature increases (i.e., 1.5 and 1.6°C, respectively), even during extreme experimental conditions at 3 T, were not substantial compared with the background temperature rise of 1.5°C. These temperature rises will not impose thermophysiological stress to a human subject. Because the 2 ossicular implants tested had the largest dimensions (albeit relatively short) compared with those listed in the Appendix, the findings of the MRI-related heating tests can be applied to these other implants from the same manufacturer, with a similarly presumed lack of excessive temperature rises. Comparable findings have been reported in the evaluation of intracranial aneurysm clips (26) and hemostatic clips (27) from investigations that followed a similar MRI testing strategy as that applied to this assessment of ossicular implants.

Artifacts

The presence of a metallic implant during an MRI examination can cause substantial image artifacts, including signal loss, failure of fat suppression, geometric distortion, and other issues (36). Although many factors are known to affect the size of an artifact observed with a metallic implant, it is well known that, for ossicular implants, the extent of the size is predominantly dependent on the magnetic susceptibility of the material (3,25–27,36). The associated artifacts may affect the diagnostic use of the MRI examination if the area of interest is the same as or close to the site of the ossicular implant. Careful parameter and pulse sequence selections can significantly reduce artifacts from metallic devices (36).

Overall, the artifact areas (i.e., in relation to the size of the implant) observed on MRI using T1-weighted, spin echo and gradient echo pulse sequences for the Stainless Steel/Fluoroplastic Sanna-Type Piston were smaller than those associated with the Offset ALTO Total Prosthesis, although stainless steel has a higher magnetic susceptibility than titanium. Obviously, the larger artifact for the titanium implant was because it was larger (15 mm) than the stainless steel one (6 mm). Fortunately, because of the small dimensions and the materials used for the ossicular implants that underwent testing, the artifacts were correspondingly small and should not present substantial problems. However, even a small artifact could limit MRI evaluation of the middle ear. The artifact findings are vital for interpreting radiologists to know to avoid diagnostic dilemmas, including misconstruing an artifact as an abnormality on MRI.

MRI Recommendations

The current standard of care when managing patients in the MRI setting is for health care professionals to conduct a pre-MRI screening procedure that involves identifying implants in the patients and determining whether these objects are “MR safe,” “MR conditional,” or “MR unsafe” (1,2,37,38). On the basis of the methodology used for testing in this study, MRI-specific labeling for each ossicular implant includes the following information (37,38):

Nonclinical testing demonstrated that patients with these specific ossicular implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 3 T or less.
- Maximum spatial gradient magnetic field of 720 G/cm or less.
- MR system reported whole-body-averaged SAR of 2.9 W/kg for 15 minutes of scanning (i.e., per pulse sequence).
Implications for Other Metallic and Nonmetallic Ossicular Implants

The “MR-conditional” findings for the 2 metallic ossicular implants can be applied to many other ossicular implants from the same company that have the same or smaller dimensions and made from materials with lower magnetic susceptibilities (Appendix).

In addition, many ossicular implants are made from nonmetallic, nonconducting materials, including hydroxyapatite, fluoroplastic, and silicone, which are also included in the Appendix. Magnetic resonance imaging health care professionals may not know that these particular ossicular implants exist and, more importantly, may not be aware that these are, in fact, “MR safe.” The term MR safe according to the current criteria and labeling terminology is any item that poses no known hazards in all MRI environments because it is made from nonconducting, nonmetallic material(s) (37,38).

CONCLUSION

In consideration of the minor magnetic field interactions, relative little heating (i.e., above the background temperature when using extreme experimental conditions), and the characterization of artifacts, the results of this investigation demonstrated that it would be acceptable, or “MR conditional” (i.e., using current MR labeling terminology) (37,38), for patients with the Stainless Steel/Fluoroplastic Sanna-Type Piston and Offset ALTO Total Prosthesis to undergo MRI procedures at 3 T or less. In consideration of the materials and dimensions of the implants that underwent testing, these findings pertain to many other similar ossicular implants from the same manufacturer (Appendix).

REFERENCES

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APPENDIX

In consideration of the materials and dimensions of the implants that underwent testing (Stainless Steel/Fluoroplastic Sanna-Type Piston [6 mm in length] and the Offset ALTO Total Prosthesis [15 mm in length, titanium/silicone]), these findings pertain to many other similar ossicular implants from the same manufacturer that have smaller sizes and are made from materials with lower magnetic susceptibilities, thus expanding the MRI information for many other devices (all ossicular implants are from Grace Medical, Memphis, TN, USA; www.gracemedical.com).

<table>
<thead>
<tr>
<th>Device family</th>
<th>Family product number(s)</th>
<th>Device material(s)</th>
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<tr>
<td>MR-conditional ossicular implants</td>
<td></td>
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<tr>
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<td>Titanium, HA, silicone</td>
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<tr>
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<td>2XX, 193</td>
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HA indicates hydroxyapatite.