Magnetic Properties of Middle Ear and Stapes Implants in a 9.4-T Magnetic Resonance Field

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Hypothesis: A 9.4-T magnetic resonance (MR) field may cause motion displacement of the middle ear and stapes implants not previously observed with 1.5- and 3.0-T magnets.

Background: Publications have described the safety limitations of some otologic implants in 4.7-T field and resulted in several companywide patient safety-related recalls. To date, no studies have been reported for otologic implants in a 9.4-T MR field nor have comparisons been made with 4.7-T field strengths.

Methods: Twenty-three commonly used middle ear and stapes prostheses were selected and exposed to 9.4-T MR fields in vitro within petri dishes, and eight of the 23 implants were further studied ex corpus in human temporal bones (TBs) in a 9.4-T MR field. This study has been approved by the institutional review board.

Results: Eight prostheses in petri dishes grossly displaced at 9.4 T, three of which had not previously moved in either the 1.5- or 3.0-T magnets. The eight TB preparations showed no avulsions or motion indicators after exposure at 9.4 T.

Conclusion: Middle ear and stapes implants can move dramatically in petri dishes at 9.4-T MR field, more so than at 1.5 and 3.0 T. The absence of avulsions in the TB group strongly suggests that the surgical means used to fixate the middle ear implants to the middle ear structures successfully overcomes the magnetic moment produced at MR field strengths up to 9.4 T. The use of MR imaging is not contraindicated by this study’s findings.

Key Words: Ferromagnetic—Magnetic resonance—Metal prostheses—Middle ear—MRI—Implants—Stapes implant.


Magnetic resonance imaging (MRI) is a powerful diagnostic tool; however, its use and safety for patients with implants has been debated since it was first introduced. Fortunately, tragic accidents are rare (1,2). Evolving MR technology with stronger static and gradient magnetic fields and more powerful radiofrequency transmission coils allows for increasing resolution of the images. The practice safety guidelines for accident prevention need continuous revisions and updates as MR imaging technology advances and matures.

The American College of Radiology published a “white paper on MR safety” (3) that contains excellent recommendations for an MRI department and includes:

“Decisions based on published MR compatibility or safety claims should recognize that all such claims apply to specifically tested static field and static gradient field strengths. For example, ‘MR compatible up to 3.0 T at gradient strengths of 400 G/cm’ or ‘MR safe tested up to 1.5 T up to maximum static gradient fields experienced in an unshielded 1.5 T [manufacturer name] whole-body MR scanner tested 1.5 feet within the bore’.”

There are no specific MRI guidelines published for implanted middle ear prostheses. Otologists are confronted with MRI-related questions daily. As MRI is increasingly used, calls and discussions among colleagues and patients will also proportionally increase. If movement, displacement, vibration, rotation, or heating of a middle ear prosthesis occurs, it could be a source of serious patient injury. Several studies evaluating the ferromagnetic properties of middle ear implants and prostheses to determine their compatibility with MRI have been conducted (4–9).

Early in vitro studies showed significant ferromagnetic properties of middle ear prostheses with gross rotational forces demonstrated in commonly used 1.5-T MR scanners (4,5). Using in vitro and in vivo models, one study evaluated magnetic deflections of multiple prostheses made from stainless steel and one from platinum suspended from a string in a 1.5 T-MR (6). A deflection of all suspended stainless steel prostheses, with the exception of the platinum one, was observed. Prostheses made from titanium metal, which had been found safe at 1.5 T in earlier studies, also did not move in the presence of higher magnetic fields at 3 T (7). In another
study, not only the increase in magnetic fields but also
the cold-working of nonferromagnetic (austenitic) stain-
less steel was thought to induce conversion, making the
object ferromagnetic (10).

Recently, we reported on the movements of middle ear
implants and stapes prostheses in petri dishes and ex
corpus temporal bones (TBs) in a 3-T MR field and
concluded that when comparing the results for prostheses
exposed to 1.5 T and 3 T, the 1.5-T fields results should
not be used directly for safety recommendations in
stronger fields (9). Additionally, no prostheses subjected
to a 3-T field were displaced from the TB-implanted sites.
The studies, all put together, provide a picture of move-
ment, with potential for in situ displacement, with stain-
less steel-based prostheses but not with titanium,
platinum, or other nonmetallic materials.

MATERIALS AND METHODS

The Indiana School of Medicine institutional review board
approval for testing was obtained. All prostheses were studied
under the same conditions by the same investigators. This
study was comparable in methodology with our previously pub-
lished report (9) and was conducted on all middle ear implants
using the Varian 9.4-T/31 cm actively shielded horizontal bore
MR scanner (Fig. 1).

Part 1. In Vitro Experiment

A paper with a 2.5-mm grid width was marked with a 0.5-cm
long red arrow, with the arrow base at the center of the grid
(Fig. 2A). The grid paper was secured on the undersurface of
the 5-cm-diameter plastic petri dishes. The dishes were placed on
the transport platform of the scanner with each of the individual
prostheses placed on the red arrow, with the stapedial prosthesis
end at the base of the arrow. The red arrow was used to define
the position and the orientation of the prosthesis within the mag-
netic field. The petri dish containing the prosthesis was then
placed onto the conveyer for smooth transport into the magnet’s
isocenter. The prosthesis was exposed to the 9.7-T magnetic

FIG. 1. A photograph of the Varian 9.4-T MR scanner showing
the 31-cm bore diameter.

FIG. 2. Images showing Prosthesis 20 before and after expo-
sure. A, Prosthesis 20 is in position within the petri dish before
exposure to the 9.4-T MR field. B, Maximum displacement after
exposure, with the prosthesis confined by the petri dish wall.

field for 15 seconds and then smoothly withdrawn. Two obse-
vers carefully noted any movement or displacement that oc-
curred. After the initial passage, the petri dish was serially
twice rotated 90° clockwise and, at each time, was reexposed
to the scanner to include all three axes of space. The rotational
(around the central axis) and the translational (off the central
axis, causing sliding along the grid) movements were recorded

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for each prosthesis (Fig. 2B). Twenty-three commonly used middle ear implants and stapes prostheses were examined. Detailed information regarding each implant, including materials, manufacturer, reference, and lot numbers are listed in Table 1. The whole testing process was consistent with our previous description of the 3-T MR study so that comparisons could be drawn (9).

Part 2. In Vivo Simulation

In the second experiment, all prostheses that showed any movement in Part 1 in vitro experiment were studied. Each prosthesis was implanted in prepared human cadaver TB specimens through a posterior stapedectomy and an areolar temporalis fascia graft at the oval window was used. The prosthesis used was placed in its intended location, and then was positioned and attached. The implantation was performed through a facial recess approach for better observation and through simulation of an intact tympanic membrane in a postoperative patient. The grommet tube that moved in Part 1 was implanted in the tympanic membrane as prescribed. The exact position of the prosthesis and its various parts was then recorded. The TB with the implanted prosthesis was placed in a transparent cubic acrylic safety container. It was then serially exposed to the 9.4-T MR field for 1 minute in each of the three axes of space.

### Table 1. Summary of the prostheses used in the in vitro experiment

<table>
<thead>
<tr>
<th>Prosthesis no.</th>
<th>Prosthesis description</th>
<th>Manufacturer</th>
<th>Material of fabrication</th>
<th>Reference/Lot no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modified cupped stapedes piston (diameter, 0.4 mm; well diameter, 0.88 mm; length, 4.25 mm)</td>
<td>Xomed</td>
<td>Stainless steel piston</td>
<td>Ref. No. 11-33372</td>
</tr>
<tr>
<td>2</td>
<td>Fisch-type piston (diameter, 0.4 mm; functional length, 6.0 mm)</td>
<td>Smith &amp; Nephew</td>
<td>Fluoroplastic and stainless steel</td>
<td>Ref. No. 140444</td>
</tr>
<tr>
<td></td>
<td>Winkel-Partial-Plester; titanium (0.2 x 3.25 x 0.5 mm)</td>
<td>Richards</td>
<td>Titanium</td>
<td>Ref. No. 2022329</td>
</tr>
<tr>
<td>4</td>
<td>Clip-Piston a Wegen; titanium (0.6 x 4.5 mm)</td>
<td>Kurz</td>
<td>Titanium</td>
<td>Ref. No. 1006857</td>
</tr>
<tr>
<td>5</td>
<td>Slim Shaft Schuknecht; wire piston (diameter, 0.6 mm; length, 4.5 mm)</td>
<td>Smith &amp; Nephew</td>
<td>Fluoroplastic and stainless steel</td>
<td>Ref. No. 140126</td>
</tr>
<tr>
<td>6</td>
<td>Activent; antimicrobial vent tube; Armstrong-beveled; grommet style; silicone/silicon oxide (inside diameter, 1.14 mm)</td>
<td>Xomed</td>
<td>Silicone and silver oxide</td>
<td>Ref. No. 10-26055</td>
</tr>
<tr>
<td>7</td>
<td>Reuter Bobbin w/ flange holes (PET); (inside diameter, 1.1 mm)</td>
<td>Xomed-Treace</td>
<td>Stainless steel</td>
<td>Ref. No. 10-27015</td>
</tr>
<tr>
<td>8</td>
<td>Scheer stapes; piston and wire (shank diameter, 0.6 mm; length, 4.75 mm)</td>
<td>Xomed-Treace</td>
<td>Teflon and stainless steel</td>
<td>Lot No. 8102300</td>
</tr>
<tr>
<td>9</td>
<td>Cause Total w/ Shoe HA cam head (length, 10.0 mm)</td>
<td>Xomed-Treace</td>
<td>Teflon and stainless steel</td>
<td>Ref. No. 11-12195</td>
</tr>
<tr>
<td>10</td>
<td>Robinson; stapes prosthesis (overall length, 4.5 mm; stem, narrow; well, large)</td>
<td>Storz</td>
<td>Stainless steel</td>
<td>Lot No. 6217300</td>
</tr>
<tr>
<td>11</td>
<td>Wehrs Incus stapes prosthesis; double notch (shaft diameter, 0.9 mm; overall length, 7.3 mm)</td>
<td>Richards</td>
<td>Dense hydroxylapitate</td>
<td>Ref. No. 140244</td>
</tr>
<tr>
<td>12</td>
<td>Plasti-pore; drum-to-stapes prosthesis; (length, 9.474 mm)</td>
<td>Richards</td>
<td>Plastic-pore polyethylene</td>
<td>Ref. No. 14-09045</td>
</tr>
<tr>
<td>13</td>
<td>House type; preformed wire loops (wire diameter, 0.005; wire length, 4.50 mm)</td>
<td>Richards</td>
<td>Stainless steel</td>
<td>Ref. No. 14-0186</td>
</tr>
<tr>
<td>14</td>
<td>Fisch Teflon platinum piston (0.4 x 6.00 mm)</td>
<td>Xomed-Treace</td>
<td>Teflon (PTFE) and platinum</td>
<td>Ref. No. 11-5623</td>
</tr>
<tr>
<td>15</td>
<td>Richards; platinum ribbon loop (length, 4.5 mm)</td>
<td>Richards</td>
<td>Platinum</td>
<td>Lot No. 44932-00</td>
</tr>
<tr>
<td>16</td>
<td>McGee; stainless steel; narrow piston (diameter, 0.6 mm; length, 4.75 mm)</td>
<td>Xomed</td>
<td>Stainless steel</td>
<td>Ref. No. 14-0167</td>
</tr>
<tr>
<td>17</td>
<td>Ceravital; total ossicular replacement prosthesis</td>
<td>Xomed</td>
<td>Bioactive glass ceramic</td>
<td>Ref. No. 60-12020</td>
</tr>
<tr>
<td>18</td>
<td>Ceravital; partial ossicular replacement prosthesis; (length, 4.00 mm; shank diameter, 1.4 mm)</td>
<td>Xomed</td>
<td>Bioactive glass ceramic</td>
<td>Lot No. 2905725711</td>
</tr>
<tr>
<td>19</td>
<td>Smart stapes prosthesis (0.5 x 4.75 mm)</td>
<td>Gyrus</td>
<td>Nitinol and fluoroclastic</td>
<td>Ref. No. 70145924</td>
</tr>
<tr>
<td>20</td>
<td>Classic stapes prosthesis (well, large; internal diameter, 1.00 mm; shank, 0.4 mm [narrow]; length, 4.5 mm)</td>
<td>Smith &amp; Nephew</td>
<td>Stainless steel</td>
<td>Lot No. 142102</td>
</tr>
<tr>
<td>21</td>
<td>Brackmann; Polycyl Total, with malleable shaft (shaft diameter, 0.6 mm; head diameter, 3 mm; length, 8 mm)</td>
<td>Xomed</td>
<td>Polycyl and stainless steel</td>
<td>Lot No. 8085623950</td>
</tr>
<tr>
<td>22</td>
<td>Fisch; titanium; stapes prosthesis (diameter, 0.4 mm; length, 7 mm)</td>
<td>Storz</td>
<td>Titanium</td>
<td>Ref. No. 19359000</td>
</tr>
<tr>
<td>23</td>
<td>Fisch; titanium; total prosthesis (diameter, 0.6 mm; length, 10 mm)</td>
<td>Storz</td>
<td>Titanium</td>
<td>Ref. No. 227520</td>
</tr>
</tbody>
</table>

**QA, quality assurance.**

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TABLE 2. Comparison of the in vitro results of our previous study in the 1.5-T, 3-T, and the 9.4-T MR field (9)

<table>
<thead>
<tr>
<th>Prosthesis no.</th>
<th>Prosthesis</th>
<th>1.5-T MR field</th>
<th>3-T MR field</th>
<th>9.4-T MR field</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Modified cupped stapes piston</td>
<td>No movement</td>
<td>Gross displacement</td>
<td>Gross displacement</td>
</tr>
<tr>
<td>7</td>
<td>Reuter Bobbin with flange holes (PET)</td>
<td>No movement</td>
<td>No movement</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Scheer stapes piston and wire</td>
<td>No movement</td>
<td>No movement</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Cause Total with Shoe HA cam head</td>
<td>No movement</td>
<td>Gross displacement</td>
<td>Gross displacement</td>
</tr>
<tr>
<td>10</td>
<td>Robinson stapes prosthesis</td>
<td>No movement</td>
<td>No movement</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>McGee stainless steel piston, narrow</td>
<td>No movement</td>
<td>Not tested</td>
<td>Not tested</td>
</tr>
<tr>
<td>20</td>
<td>Classic stapes prosthesis</td>
<td>Not tested</td>
<td>Not tested</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Brackmann, Polycel Total</td>
<td>Not tested</td>
<td>Not tested</td>
<td></td>
</tr>
</tbody>
</table>

Note that none of the prostheses moved in the 1.5-T, but all moved in the 9.4 T-MRI scanner.

The limitations on our use of metal equipment within the MRI room prevented the direct measurement or visualization of the magnetic dipole moment, temperature, voltage induction, or vibration of the prostheses while in the MR scanner core.

RESULTS

The prostheses used in this study were categorized into the following groups:

1. Pure materials
   1. Stainless steel only
   2. Platinum or titanium only
   3. nonmetallic (fluoroplastic, glass ceramic, hydroxylapatite, plastipore)

2. Mixed composite materials
   1. Metallic with stainless steel (fluoroplastic/stainless steel, Teflon/stainless steel, Polycel/stainless steel)
   2. Metallic without steel (Teflon/platinum, silicone/silver oxide)
   3. Nonmetallic (nitinol/fluoroplastic)

In the first part of the study, eight of the twenty-three prostheses (Prostheses 1, 7, 8, 9, 10, 16, 20, and 21) showed gross translational displacement motion that was confined by the limiting wall of the petri dish. All prostheses that moved were either made only of stainless steel or made with steel components (Group 1a or 2a). Only three prostheses made of stainless steel or containing stainless steel components (Prostheses 2, 5, and 13) did not move.

The results in the 9.4-T MRI are shown next to the previously published results in the 1.5-T and 3-T MR scanner in Table 2 (9). Three implants that moved because of the 9.4-T MR field had not moved in the 3-T MRI. None of the prostheses tested had moved in the 1.5-T MR field (9).

In Part 2 of the study, each of the eight prostheses which showed movements in the petri dish were implanted into a TB. While in their intended-use positions in the cadaver TBs and after exposure to the 9.4-T MR field, no gross displacement or signs of movement were found. The lack of movement included the otherwise freely mobile parts of some prostheses such as "bucket handles." In addition, there was no sign of a shift of the stapes end of the implants within the oval window niche.

DISCUSSION

MR images are based on the combination of a strong static magnetic field, a weaker rapidly varying gradient magnetic field, and a radiofrequency pulse. The magnetic forces found in an MRI field act on ferromagnetic objects and can indeed lead to movement, torque, heat, and voltage production. The complications of exposing metallic middle ear implants to MR fields have been increasingly raising concerns as advances in MR technology make scanners with higher field strengths available.

We present the data and the conclusions on the ferromagnetic movements of individual middle ear implants of different types in a 9.4-T field. As a background, one criticism regarding testing individual prostheses arose during the studies on aneurism clips (11). Of 1765 clips studied, the alleged nonferromagnetic clips actually showed 63 clips being ferromagnetic. It was concluded that the testing of a single copy of a prosthesis from a manufacturer would not completely assess the safety of performing MR imaging in all patients implanted with that type of prosthesis. In addition to prosthesis variability, we observed that the changes in MR field strengths will change individual middle ear prosthesis test results. In Part 1 in vitro model of our study, a gross displacement that did occur in stainless steel prostheses at 9.4 T had not occurred at lesser MR field strengths. A prosthetic may be considered nonferromagnetic by the manufacturer on the basis solely of the overall class of stainless steel (i.e., austenitic versus martensitic). However, because of the multiple variables, the prostheses type should not be considered nonferromagnetic from the limited testing. If the materials used to make the middle ear prosthesis contain a ferromagnetic base metal, it seems incumbent upon the manufacturer to consider every individual prosthesis before it is sold as nonferromagnetic.

In a study presented by Williams et al. (6), an in vivo cadaver TB model demonstrated no displacement of prostheses made from nonferromagnetic stainless steel. In a recent animal study presented by Symns (8), where the
stapedectomies with prosthetic reconstruction were performed on guinea pigs, no displacement or inflammatory reaction was found 10 days after exposure to a 4.7-T MRI. Because no gross displacement was found, the authors revised their concern for MR compatibility in the in vitro experiment (5) and concluded that it seemed very unlikely that MR imaging is unsafe. Symns concludes that the lack of damage in the animal model is strong evidence that using 4.7-T and lesser-strength MRIs in patients with implants is safe (8).

Comparing our titanium prostheses results with the previously published data on in vivo and animal models, similar findings were noted (6). Williams et al. (6) observed no deflections on their suspended string models when titanium was tested. No induced force on titanium prostheses was found by Martin et al. (7) in a 3-T MR field; in addition, it was shown, using a new commercially available Fluoroptic thermometer (Luxtron, Santa Clara, CA), that no heating occurred in the titanium prostheses. Applebaum and Valvassori (4) observed no movement of their tested titanium prosthesis in a 1.5-T scanner. In our study, none of the titanium prostheses moved in the petri dishes nor in the TBs when exposed to the 9.4-T MR field.

Symns and Peterman referenced the threshold for titanium and platinum prostheses as relating to the magnetic moment when exposed to a given MR field (5). This threshold is the magnetic force required to overcome friction and gravity between an object and its substrate and to cause gross rotation or translational movement. Their study used a vibrating sample magnetometer to quantify the dipole forces of an applied MR field on various middle ear prostheses. The samples tested included titanium and platinum, which demonstrated small magnetic moments and led to the conclusion that “none of the implants are nonmagnetic.” However, a small dipole finding cannot be translated into “reaching threshold.” In our study, despite the strong 9.4-T MR field, none of the TB-implanted prostheses of any material were found displaced when surgically secured as intended in a cadaver TB. Even the stainless steel grommet was not displaced from the tympanic membrane. The induced magnetic threshold for the motion of the prostheses was not reached when properly implanted. The attachment of the prosthesis to the incus is critical not only for the restoration of hearing but also for the assurance of safety during exposure to MR fields.

Other forces, such as vibration and electric current induction, may also act on the implant without causing displacement. However, because of the present inability to introduce commonly available testing equipment into the MRI suite, these other two forces cannot be measured. It is uncertain whether these forces can lead to the significant vibration of the in situ prostheses or to the generation of electric current through the oval window into the vestibule. In addition, the variables arising from the physical background of the MRI, such as the static magnetic field strength, the static magnetic field spatial gradients, and the rate of motion through the spatial static field gradient, are difficult to control in patients. Whether the forces generated by more powerful MR fields, along with the other variables, are significant enough to raise a clinical risk is still not completely known.

To date, only one published article discusses MR-related injuries from the movements of stapes prostheses in patients. In a survey of 259 neurologists who had performed an estimate of 185,204 stapes surgeries in the United States, only three questionable cases of hearing loss associated with MRI and stapes implants were identified (8).

Whether the MR imaging was actually the inciting factor in these cases remains unclear in two cases. Approximately 10% of the respondents of Symns’ survey would not postoperatively allow the patients who had undergone stapedectomy to undergo an MRI at all, despite its invaluable addition as a diagnostic tool (8).

The fact that none of the prostheses in the TBs in our study of the 9.4-T MR field moved or was displaced is a strong indicator that the MRI fields used on patients today and, probably, for some time to come, will not cause displacement of their stapes prostheses no matter what type it is. Indeed, not even the metal grommet was displaced from the eardrum. If the manufacturers convert to completely nonferromagnetic materials, such as titanium and platinum, then an even greater reassurance can be given to patients and physicians alike. The physical clinicians should consider using the presently available otologic implants made of titanium or nonmetallic materials. Further evaluation would be needed to assess all the clinical implications of all the magnetic properties of metallic—especially steel-containing—otologic implants. However, without gross displacement of the TB-implanted prostheses in our study and in previous studies, along with the lack of heat production and the absence of injury cases, strong reassurance is given to conscientious clinicians and their patients receiving, or having received, stapes and other middle ear implants.

CONCLUSION

Certain middle ear and stapes implants used today can show dramatic movements when placed in petri dishes and exposed to a 9.4-T MR field. Several of those implants were previously described as safe in 1.5-T or 4.7-T MR fields. In this study, the proper mechanical fixation of the middle ear implant in the TB model prevents displacement by completely resisting the magnetic threshold of motion of those implants. The threshold of motion was also resisted by a stainless steel grommet tube placed into the tympanic membrane. This study found no avulsion or displacements of any of the prostheses in the implanted TB group exposed to a 9.4-T field. In striving for better patient treatment courses, it is suggested that prostheses be manufactured with nonferromagnetic materials to further ensure safety beyond the findings in this study. This study supports the previous studies but extends the MRI field strength exponentially higher than all the previous studies on 9.4-T MR field. This study does not contradict the use of MR imaging in patients with middle ear and stapes implants.
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REFERENCES


