Otology & Neurotology
27:1064–1069 © 2006, Otology & Neurotology, Inc.

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

*Michael H. Fritsch, †Jason J. Gutt, and *Ilka C. Naumann

**Indiana University Medical Center, and †Private Practice in Otolaryngology-Head and Neck Surgery, Indianapolis, Indiana, U.S.A.*

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 prosthesis—Middle ear—MRI—Implants—Stapes implant.
Otol Neurotol **27**:1064–1069, 2006.

Magnetic resonance imaging (MRI) is a powerful diagnostic tool; however, its use and safety for patients with implants has been debated on 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

Address correspondence and reprint requests to Michael H. Fritsch, M.D., F.A.C.S., Department of Otolaryngology—Head and Neck Surgery, Indiana University Medical Center, 702 Barnhill Drive, Suite 0860, Indianapolis, IN 46202; E-mail: mfritsch@iupui.edu

study, not only the increase in magnetic fields but also the cold-working of nonferromagnetic (austenitic) stainless 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 movement, with potential for in situ displacement, with stainless 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 methology with our previously published 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 magnetic 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 field for 15 seconds and then smoothly withdrawn. Two observers carefully noted any movement or displacement that occurred. 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

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

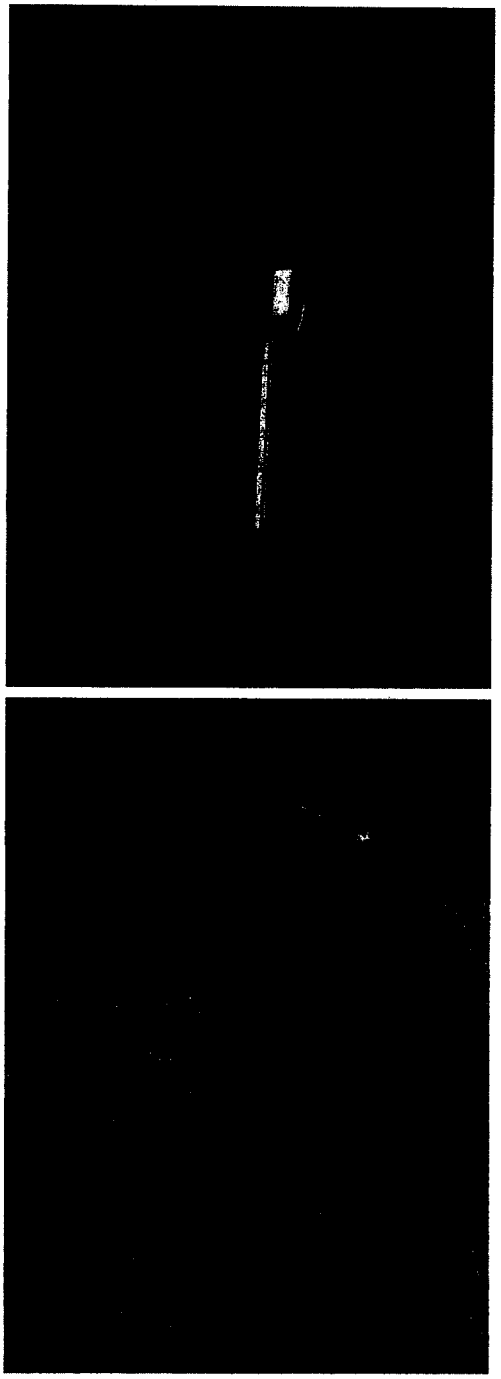

FIG. 2. Images showing Prosthesis 20 before and after exposure. *A*, Prosthesis 20 is in position within the petri dish before exposure to the 9.4-T MR field. *B*, Maximum displacement after exposure, with the prosthesis confined by the petri dish wall.

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 grommette 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*

Prosthesis no.	Prosthesis description	Manufacturer	Material of fabrication	Reference/Lot no.
1	Modified cupped stapes piston (diameter, 0.4 mm; well diameter, 0.88 mm; length, 4.25 mm)	Xomed	Stainless steel piston	Ref. No. 11-33372 Lot No. 20713800
2	Fisch-type piston (diameter, 0.4 mm; functional length, 6.0 mm)	Smith & Nephew Richards	Fluoroplastic and stainless steel	Ref. No. 140444 Lot No. 0211106158
3	Winkel-Partial-Plester; titanium (0.2 × 3.25 × 0.5 mm)	Kurz	Titanium	Ref. No. 1002612 Lot No. 2022329
4	CliP-Piston a Wengen; titanium (0.6 × 4.5 mm)	Kurz	Titanium	Ref. No. 1006857 Lot No. 2022834
5	Slim Shaft Schuknecht; wire piston (diameter, 0.6 mm; length, 4.5 mm)	Smith & Nephew Richards	Fluoroplastic and stainless steel	Ref. No. 140126 Lot No. 9105739514
6	Activent; antimicrobial vent tube; Armstrong-beveled; grommet style; silicone/silver oxide (inside diameter, 1.14 mm)	Xomed	Silicone and silver oxide	Ref. No. 10-26055 Lot No. 8347900
7	Reuter Bobbin; w/ flange holes (PET) (inside diameter, 1.1 mm)	Xomed-Treace	Stainless steel	Ref. No. 10-27015 Lot No. 49763-00
8	Scheer stapes; piston and wire (shank diameter, 0.6 mm; length, 4.75 mm)	Xomed-Treace	Teflon and stainless steel	Ref. No. 11-28185 Lot No. 8102300
9	Causse Total w/ Shoe HA cam head (length, 10.0 mm)	Xomed-Treace	Teflon and stainless steel	Ref. No. 11-12195 Lot No. 6217300
10	Robinson; stapes prosthesis (overall length, 4.5 mm; stem, narrow; well, large)	Storz	Stainless steel	Cat. No. N0008 Lot No. 0189
11	Wehrs Incus stapes prosthesis; double notch (shaft diameter, 0.9 mm; overall length, 7.3 mm)	Richards	Dense hydroxylapatite	Ref. No. 140844 Lot No. 3X35640
12	Plasti-pore; drum-to-stapes prosthesis; (length, 9.474 mm)	Richards	Plasti-pore polyethylene	Ref. No. 14-0059 QA No. 3NS5161
13	House type; preformed wire loops (wire diameter, 0.005; wire length, 4.50 mm)	Richards	Stainless steel	Ref. No. 14-0186 QA No. 1PS3244
14	Fisch Teflon; platinum piston (0.4 × 6.00 mm)	Xomed-Treace	Teflon (PTFE) and platinum	Ref. No. 11-56234 Lot No. 44922-00
15	Richards; platinum ribbon loop (length, 4.5 mm)	Richards	Platinum	Ref. No. 14-0705 QA No. 3NS4276
16	McGee; stainless steel; narrow piston (diameter, 0.6 mm; length, 4.75 mm)	Richards	Stainless steel	Ref. No. 14-0167 Packaging. Date: 11/29/77A
17	Ceravital; total ossicular replacement prosthesis	Xomed	Bioactive glass ceramic	Ref. No. 60-12020 Lot No. 290565259111
18	Ceravital; partial ossicular replacement prosthesis (length, 4.00 mm; shank diameter, 1.4 mm)	Xomed	Bioactive glass ceramic	Ref. No. 60-12005 Lot No. 29057525711
19	Smart stapes prosthesis (0.5 mm × 4.75 mm)	Gyrus	Nitinol and fluoroplastic	Ref. No. 70145924 Lot No. 0416842799
20	Classic stapes prosthesis (well, large; internal diameter, 1.00 mm; shart, 0.4 mm [narrow]; length, 4.5 mm)	Smith & Nephew Richards	Stainless steel	Ref. No. 142102 Lot No. 8085623950
21	Brackmann; Polycel Total, with malleable shaft (shaft diameter, 0.6 mm; head diameter, 3 mm; length, 8 mm)	Xomed	Polycel and stainless steel	Ref. No. 11-56303 Lot No. 19359500
22	Fisch; titanium; stapes prosthesis (diameter, 0.4 mm; length, 7 mm)	Storz	Titanium	Ref. No. 227510
23	Fisch; titanium; total prosthesis (diameter, 0.6 mm; length, 10 mm)	Storz	Titanium	Ref. No. 227520

QA, quality assurance.

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)*

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

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 transitional 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 rapid time-varying gradient magnetic field, and a radiofrequency pulse. The magnetic forces found in an MRI field act on ferromagnetic objects and can 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 prosthesis may be considered nonferromagnetic by the manufacturer on the basis solely of the overall class of stainless steel (i.e., austentic versus martensitic). However, because of the multiple variables, the prostheses type should not to 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 Syms (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. Syms 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.

Syms 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 metal grommette 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 neurotologists 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 Syms' 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 grommette 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 physicalclinicians 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 grommette 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.

Acknowledgments: The authors thank Navin Bansal, Ph.D., for generous teaching regarding the 9.4-T scanner, and Becky Colson, secretary, for great help in preparing the manuscript.

REFERENCES

1. Boutin RD, Briggs JE, Williamson MR. Injuries associated with MR imaging: Survey of safety records and methods used to screen patients for metallic foreign bodies before imaging. *AJR Am J Roentgenol* 1994;162:189–94.
2. Ta CN, Bowman RW. Hyphema caused by a metallic intraocular foreign body during magnetic resonance imaging. *Am J Ophthalmol* 2000;129:533–4.
3. Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology white paper on MR safety: 2004 update and revisions. *AJR Am J Roentgenol* 2004;182:1111–4.
4. Applebaum EL, Valvassori GE. Further studies on the effects of magnetic resonance imaging fields on middle ear implants. *Ann Otol Rhinol Laryngol* 1990;99:801–4.
5. Syms MJ, Peterman DW. Vibratory sample magnetometry of middle ear prostheses and manufacturing materials. *Otol Neurotol* 2001;22: 487–91.
6. Williams MD, Antonelli PJ, Williams LS, et al. Middle ear prosthesis displacement in high-strength magnetic fields. *Otol Neurotol* 2001; 22:158–61.
7. Martin AD, Driscoll CL, Wood CP, et al. Safety evaluation of titanium middle ear prostheses at 3.0 tesla. *Otolaryngol Head Neck Surg* 2005;132:537–42.
8. Syms MJ. Safety of magnetic resonance imaging of stapes prostheses. *Laryngoscope* 2005;115:381–90.
9. Fritsch MH, Gutt JJ. Ferromagnetic movements of middle ear implants and stapes prostheses in a 3-T magnetic resonance field. *Otol Neurotol* 2005;26:225–30.
10. Teitelbaum GP, Bradley WG Jr, Klein BD. MR imaging artifacts, ferromagnetism, and magnetic torque of intravascular filters, stents, and coils. *Radiology* 1988;166:657–64.
11. Kanal E, Shellock FG, Lewin JS. Aneurysm clip testing for ferromagnetic properties: Clip variability issues. *Radiology* 1996; 200:576–8.