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# Metallic Otologic Implants: In Vitro Assessment of Ferromagnetism at 1.5 T

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MR imaging is contraindicated for patients with certain ferromagnetic implants because of potential risks related to movement or dislodgement. This is especially true for metallic implants located in sensitive areas of the body, such as those placed in and around the ear. Therefore, the ferromagnetic qualities of 35 different metallic otologic implants were assessed by placing them individually on a millimeter scale in a plastic petri dish that was slowly moved into the center of a 1.5-T MR imaging system. None of the metallic otologic implants moved during this procedure. The results demonstrate that each of these implants are made from nonferromagnetic materials and do not pose a risk to patients undergoing high-field-strength MR imaging. These data effectively expand the list of metallic implants that appear to be safe for MR imaging.

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MR imaging is contraindicated for patients with certain ferromagnetic biomedical implants, materials, and devices primarily because of the possibility of injury if the object is moved or dislodged [1-9]. Despite this concern, previous studies have indicated that many metallic implants, materials, or devices are safe for MR imaging if the objects are nonferromagnetic or display insignificant ferromagnetism and, therefore, have no possibility of becoming displaced [1-9].

Metallic implants, materials, or devices must be subjected to an ex vivo assessment of their interaction with the MR imaging system to ascertain the presence of ferromagnetism and determine the relative risk of imaging patients with these objects [1-9]. This is especially true for metallic implants located in sensitive areas of the body, such as those placed in and around the ear [4-7]. Therefore, we designed a study to determine whether 35 different metallic otologic implants displayed any ferromagnetism in association with a 1.5-T MR imaging system. The results are reported here.

## Materials and Methods

Thirty-five different metallic otologic implants were evaluated (Table 1). For 12 of these, two or more were tested. Since the present manufacturing process and adherence to strict metallurgical guidelines are so rigid for otologic implants, it is unlikely that some of the implants would be magnetic while others would not (Marc Wheatley, Richards Medical Company, personal communication). These particular 35 implants were selected for testing because they are commonly used in the United States and are typically encountered in the MR imaging setting.

Because of the minute size of the metallic middle ear prostheses tested, the conventional assessment of deflection force or torque was not attempted [2, 3, 8, 9]; therefore, we used the technique developed by Applebaum and Valvassori [4]. The otologic implant was placed in a specific position inside a plastic petri dish that had a millimeter scale on the underside. The petri dish was then placed on the MR imaging scanner table a distance of 2 m from the bore and slowly introduced into the center of a 1.5-T MR imaging scanner (Signa, GE) while

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**TABLE 1: Metallic Otologic Implants**

1. Austin tytan piston <sup>a</sup> (titanium)
2. Berger "V" bobbin ventilation tube <sup>b</sup> (titanium)
3. Ehmke hook stapes prosthesis <sup>b</sup> (platinum)
4. House single loop <sup>c</sup> (ss)
5. House single loop <sup>c</sup> (tantalum)
6. House double loop <sup>c</sup> (tantalum)
7. House double loop <sup>c</sup> (ss)
8. House-type wire loop stapes prosthesis <sup>b</sup> (316L ss)
9. House-type ss piston and wire <sup>d</sup> (ss)
10. McGee piston stapes prosthesis <sup>b</sup> (316L ss)
11. McGee piston stapes prosthesis <sup>b</sup> (platinum/316L ss)
12. McGee Shepherd's Crook stapes prosthesis <sup>b</sup> (316L ss)
13. Plasti-pore piston <sup>b</sup> (316L ss/plasti-pore material)
14. Platinum ribbon loop stapes prosthesis <sup>b</sup> (platinum)
15. Reuter bobbin ventilation tube <sup>b</sup> (316L ss)
16. Richards piston stapes prosthesis <sup>b</sup> (platinum/fluoroplastic)
17. Richards bucket handle stapes prosthesis <sup>b</sup> (316L ss)
18. Robinson stapes prosthesis <sup>c</sup> (ss)
19. Robinson-Moon offset stapes prosthesis <sup>c</sup> (ss)
20. Robinson-Moon-Lippy offset stapes prosthesis <sup>c</sup> (ss)
21. Robinson incus replacement prosthesis <sup>c</sup> (ss)
22. Ronis piston stapes prosthesis <sup>b</sup> (316L ss/fluoroplastic)
23. Schea cup piston stapes prosthesis <sup>b</sup> (platinum/fluoroplastic)
24. Scheer piston stapes prosthesis <sup>b</sup> (316L ss/fluoroplastic)
25. Schuknecht tef-wire incus attachment <sup>c</sup> (ss)
26. Schuknecht tef-wire malleus attachment <sup>c</sup> (ss)
27. Schuknecht piston stapes prosthesis <sup>b</sup> (316L ss/fluoroplastic)
28. Sheehy incus replacement <sup>c</sup> (ss)
29. Sheehy-type incus replacement strut <sup>b</sup> (316L ss)
30. Spoon bobbin ventilation tube <sup>b</sup> (316L ss)
31. Tantalum wire loop stapes prosthesis <sup>b</sup> (tantalum)
32. Tef-platinum piston <sup>d</sup> (platinum)
33. Trapeze ribbon loop stapes prosthesis <sup>b</sup> (platinum)
34. Williams microclip <sup>b</sup> (316L ss)
35. Xomed stapes <sup>d</sup> (ss)

Note.—ss = ASTM-318-76 grade-2 stainless steel.

<sup>a</sup> Manufactured by Treace Medical, Nashville, TN.

<sup>b</sup> Manufactured by Richards Medical Company, Memphis, TN.

<sup>c</sup> Manufactured by Storz, St. Louis, MO.

<sup>d</sup> Manufactured by Xomed-Treace, Inc., a Bristol-Myers Squibb company, Jacksonville, FL.

close observations were made to determine any visible displacement along the scale [4]. The otologic implant was then turned 90° and this procedure was repeated three times. The entire testing process was repeated three times for each otologic implant.

## Results

None of the 35 metallic otologic implants moved during any portion of the evaluation, indicating that all these implants were made from nonferromagnetic materials and were therefore safe for MR imaging at 1.5 T.

## Discussion

Several factors determine the absolute risk of imaging a patient with an implanted ferromagnetic object, including the strength of the static and gradient magnetic fields, the degree of ferromagnetism of the object, the geometry of the object, the orientation and location of the object in situ, the length of time the object has been implanted (i.e., the presence of fibrosis or granulation, which serves to stabilize the object), and the means by which the object is held or maintained in place [1–9]. Each of these factors must be carefully considered and assessed before subjecting a patient with an implanted metallic object to examination by MR imaging.

Prior knowledge of whether a metallic implant exhibits ferromagnetism is essential for proper screening of patients before MR imaging [1–9]. Manufacturers of otologic and other metallic biomedical implants do not routinely test their devices, nor do they guarantee that the implants are nonferromagnetic. In fact, certain biomedical implants are ferromagnetic and display sufficient deflection and torque in association with MR imaging systems to be regarded as potentially hazardous for patients [1–3, 8, 9]. Therefore, we tested metallic otologic implants typically encountered in the clinical setting in order to obtain information necessary for determining the relative safety of subjecting patients with these implants to MR imaging.

Each of the otologic implants tested for ferromagnetism was made from known nonferromagnetic metals (i.e., tantalum, titanium, platinum, etc.). However, it cannot be assumed that just because an implant is made from nonferromagnetic materials it is totally safe for MR imaging. Austenitic forms of stainless steel that are nonmagnetic in bulk form may take on ferromagnetic qualities as a result of cold working, which is often used to create the shape of the implant [8, 9]. An example of this phenomenon was reported by Teitelbaum et al. [8], who described a stainless steel version of the Greenfield filter made from an austenitic form of stainless steel (316L stainless steel) that was found to be ferromagnetic.

Our results demonstrate that none of the 35 otologic metallic implants tested pose a hazard to patients, since the implants did not move when they were exposed to a 1.5-T MR imaging system. Several otologic metallic implants have been previously assessed for ferromagnetism at 0.5 and 1.5 T [4–7]. Results of these studies demonstrated that none of the middle ear implants evaluated were ferromagnetic [4–7].



Despite the results of the present study as well as the findings of previous investigations, the possibility exists that a patient may have an older otologic implant that may have been made from a ferromagnetic material or has a metallic otologic implant that has not been previously evaluated for ferromagnetic qualities. Therefore, the general safety of performing MR imaging in patients with metallic otologic implants cannot be assumed.

Cochlear implants are the only reported type of otologic implants contraindicated for patients undergoing MR imaging [1, 6]. Some types of cochlear implants are electronically activated and employ a cobalt samarium magnet used in conjunction with an external magnet to align and retain a radiofrequency transmitter coil on the patient's head [10]. In addition, cochlear implants have been reported to be ferromagnetic and the electronic and/or magnetic components may be disrupted by the electromagnetic fields used for MR imaging [6, 10]. Consequently, patients with these implants should not be examined by MR imaging because of the possibility of injuring the patient as well as damaging or altering the operation of the cochlear implant [1].

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