

MRI Scanners and the Stapes Prosthesis

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Objective: Physicians and patients alike have concerns regarding exposing in vivo implanted metal stapes prostheses to magnetic resonance imaging (MRI) scanners. As MRI scanners become more powerful, the possibility for stapes prosthesis displacement due to ferromagnetic forces increases. It is hypothesized that some metal stapes prostheses may be exposed to powerful MRI scanners without leading to potential adversities for patients.

Study Design: Literature review, retrospective case review, and physician survey.

Settings: Tertiary care, University Medical Center.

Materials and Methods: A review of the medical literature, a retrospective case review, and a clinical survey were performed.

Results: In the history of stapes prostheses, 1 adverse patient outcome was causally substantiated when a defective stapes prosthesis was exposed to an MRI field. Otherwise, a review of

the literature on experiments investigating stapes prostheses and MRI fields revealed a lack of any adverse clinical reports. In addition, 2 physician's surveys revealed no other cases of symptoms or damage to the ears of patients with stapes prostheses that had been exposed to an MRI scanner.

Conclusion: All patients with a metallic stapes prosthesis may be sent to the MRI scanner, with the exception of 1 specific defective prosthesis type. The exception is a 1987 accidental mismanufacture of several lots of McGee pistons with a magnetic alloy. Patients with these specifically identified lots of McGee pistons should go to a computed tomographic scanner or be reimplanted with another prosthesis if MRI scans are mandatory. It would be advisable for manufacturers to use nonferromagnetic metals such as titanium for production of future stapes prostheses. **Key Words:** Magnetic—MRI scan—Otosclerosis—Prosthesis—Stapes.

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Magnetic resonance imaging (MRI) scans have been used since the 1980s for imaging the human body. Multiple metals and alloys have been used for stapes prosthesis manufacturing, including stainless steel (SS). Pertinent to clinical MRI scanning, implanted prostheses made totally or partially of ferrous alloys and subjected to MR fields can result in the prosthesis becoming magnetically active. There is a question of whether metal prostheses become active in an MR field, leading to prosthesis movement or heating. The otologic surgeon, the radiologist, and the patient may ponder the safety of administering an MRI scan to someone with a metal otologic prosthesis.

Stainless steel is a ferrous alloy of greater than 10% chromium content (1). Two series of SS are used in medicine. They are known as the "300 series" (Austenitic) and the "400 series" (Martensitic). The 300 series alloy contains chromium, carbon, nickel, and manga-

nese, whereas the 400 series is made with only chromium and carbon added. A major difference between these 2 SS series is that of magnetic dipole variation. The 300 series has magnetic microdipoles vectored in random directions and minimizes any magnetism. The 400 series has virtually all magnetic microdipoles vectored in the same direction that results in strong magnetism.

The US Food and Drug Administration (FDA) has required 300 series SS for all types of medical implants (2). Thus, all stapes prostheses that have ever been manufactured fall under this requirement and are made of 300 series SS. The 400 series SS is used for making general medical instruments. There was 1 accidental exception to the FDA manufacturing guidelines that happened in 1987. A total of 28 lots of the McGee piston (Richards Company, Memphis, TN, USA) were made with ingots of 400 series Martensitic SS (Table 1) (3). These 400 series prostheses were highly magnetic, even interacting with household magnets, and posed a distinct risk to patients. A research study originally revealed the atypical magnetic behavior of these prostheses and resulted in a worldwide recall in August 1987 (4). Nevertheless, between August 25, 1987 and June 30, 1989,

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TABLE 1. *Recalled implant: 1987 McGee Piston item and lot numbers*

Item number	Lot number
14-0330	1W91100, 4U09690
14-0331	4U09700
14-0332	1W91110, 4U58540, 4U86300
14-0333	4U09710, 1W34390, 2WR4073
14-0334	4U09720, 1W34390, 2WR4073
14-0335	1W34400, 4U09730
14-0336	3U18350, 3U50470, 4UR2889
14-0337	3U18370, 4UR2889
14-0338	3U18390, 4U02900, 4UR1453
14-0339	3U18400, 3U50500
14-0340	3U18410, 3U50500
14-0341	3U41200, 4UR2889

1,333 of the prostheses were sold. One thousand thirty-four prostheses were sold to 76 US accounts, and 299 prostheses were sold internationally. After the recall, in which the company contacted all hospitals and physicians, there were still 366 prostheses that were no longer in the medical system or "unaccounted for." These prostheses had either been implanted or discarded. It is thought that most were immediately discarded upon the recall notification, but that the discards were not specifically documented. After the recall, there were no further prostheses "on the shelves" that could have been implanted at a later date. Between the manufacturing date and the recall date, 64 patients are known to have been implanted; those identified received warning cards instructing them not to undergo MRI exposure (K Pawlowski, personal communication, 2006–2007).

LITERATURE REVIEW

Experiments

Experiments used by investigators to study ferromagnetism in relation to stapes prostheses fall into 5 general methodology groups. These include the petri dish experiments, suspended-string experiments, vibratory-magnetometer (VM) experiments, heat production experiments, and temporal bone (TB) implantation experiments. Surveys have also been used.

In the petri dish experiments, various otologic implants were placed into calibrated petri dishes and then placed into MRI scanners at 1.5, 3.0, 4.7, and 9.4 T (4.5–10). Measurements of implant locations within the dishes were taken before and after MRI magnet exposure. The conclusions of these series of experiments showed that various 300 series SS prostheses moved within their petri dishes when exposed to the MRI scanner, but that none of the nonferrous implants moved (Table 2). Specifically, the most mobile were the McGee piston (Richards Company, Elmwood Park, NJ, USA), Robinson prosthesis (Storz, Bausch & Lomb, San Dimas, CA, USA), and Modified cup-piston (Xomed, Jacksonville, FL, USA). In addition, 1 study revealed a highly magnetic prosthesis, the McGee pis-

ton (Richards), which was the result of a 1987 mis-manufacture substitution of a 400 series SS ingot for a 300 series SS ingot (4). Titanium, platinum, and tantalum showed no movement.

In the suspended-string experiments, the studied prosthesis was attached to the end of a string with a measuring device placed alongside the string to quantify string movement or deflection (6,10–12). Upon exposure to the MRI field, the strength of the interaction between the prosthesis and the magnetic field is inferred from the amount of string deflection from the original position. As a group, these experiments showed that the 300 series SS prostheses all moved to various degrees within an MRI scanner (Table 3). In addition, there were no titanium prostheses that showed any movement. 400 series SS prostheses moved the most and by a wide margin.

In the VM experiments, a prosthesis was placed into a magnetic field with electric field sensors surrounding the object (13). If the prosthesis was magnetic, an electric induction field occurred. Moving or "vibrating" the object caused the electric field to proportionately fluctuate. The field fluctuations were measurable by the sensors and directly reflected the strength of the magnetic dipole for that object. Measurements were in electromagnetic units. The 300 series SS prostheses all showed various low magnetic dipoles (Table 4).

TABLE 2. *Petri dish experiments*

Reference	Summary
Appelbaum and Valvassori (5)	1.5-T, 7-stapes prosthesis types, no movement of any prosthesis, including McGee SS
Appelbaum and Valvassori (4)	1.5-T, 21-stapes prostheses and 2 CI: a McGee piston manufactured in 1987 "impelled rapidly against petri dish edge"; all other prostheses "showed no displacement," "no induced magnetism after 90-h MR exposure"; Nucleus 22 CI with magnet "strongly attracted to magnetic field"
Syms and Peterman (6)	1.5-T, 19-stapes prosthesis types, 95 total prostheses: all Xomed SS wires/pistons/cups "demonstrated rotational and translational movement" with MR and handheld magnet; no movement with titanium, platinum, and tantalum
Williams et al. (10)	4.7-T, 9-stapes prosthesis types, 6 made of 300 SS and 2 of 400 SS: "all SS prostheses moved to front edge of petri dish"; no displacement or torque with titanium
Kwok et al. (7)	1.5-T, 4 titanium stapes prosthesis types and 2 ventilation-tube types of titanium, platinum, 300 SS, gold: "none of the implants moved"
Fritsch and Gutt (8)	1.5-/3-T, 18-stapes prostheses types, all 3 made of 300 SS–stapes prosthesis types variably moved: McGee, Robinson, and Modified-cup piston
Fritsch et al. (9)	9.4-T, 23 prosthesis types: 8 made of 300 SS moved, with "gross displacement"

CI indicates cochlear implant.

TABLE 3. *Suspended-string experiments*

Reference	Summary
Matucci et al. (11)	0.6-T, 8-stapes prosthesis types, with 6 made of 300 SS and 2 CI: no stapes prosthesis "torque or motion", both CIs (3m/House and Vienna) "exhibited tremendous torque and deflection"
Williams et al. (10)	4.7-T, 9-stapes prosthesis types: all 6 made of 300 SS prostheses deflected 7-49 degrees, both made of 400 SS (deflected 90 degrees; maximum) titanium with "no deflection or torque"
Kwok et al. (7)	1.5-T, 4 titanium stapes-prosthesis types and 2 ventilation-tube types made of titanium, platinum, 300 SS, gold: "none of the implants moved"
Martin et al. (12)	3-T, 7 titanium stapes-prosthesis types with 24 prostheses tested, 1 control made of 400 SS prosthesis: 400 SS "obvious movement"; "90-degree deflection"; "titanium force essentially zero"

However, the 400 series SS prosthesis had a very high magnetic dipole. As a comparison, the VM showed that a prosthesis made of titanium was 3,400 times less magnetic than 400 series SS and 280 times less magnetic than 300 series SS. The 400 series SS was 12.14 times more magnetic than the 300 series.

In the heat production experiments, various thermometers and thermocouples were used to directly or indirectly measure heat gain in various prostheses after exposure to MRI fields (6,12,14-18). Studies on prostheses and devices much larger than stapes prostheses have been conducted (Table 5). Heat production is directly related to mass and magnetism. Stapes prostheses are very small and weigh approximately 10 mg. Results from experiments using massive-sized hip prostheses and other implants can provide indications for heat production from stapes prostheses. The hip prostheses, cochlear and auditory brainstem implants (without magnets), and other large-sized prostheses experiments showed no physiologically, anatomically, or clinically significant heating issues. In addition, there was no heating observed with direct measurements on titanium stapes prostheses.

In the cadaver TB implantation experiments, stapes and middle ear prostheses were implanted and exposed to 1.5-, 3.0-, 4.7-, and 9.4-T MR fields (8-10,19). Of the 5 study types, the TB implantation experiments most closely simulate an actual patient exposure to the

TABLE 4. *Vibratory-magnetometer experiments*

Reference	Summary
Syms and Peterman (13)	15 prosthesis types made of 300 SS, 1 control of 400 SS, 1 of titanium, 1 of platinum: 300 SS prostheses = 0.08-0.55 emu/g dipoles, 400 SS = 156 emu/g, titanium = 0.046 emu/g, platinum = 0.023 emu/g

TABLE 5. *Heat production experiments*

Reference	Summary
Davis et al. (14)	Harris-type hip prosthesis (210 g), aircore magnet: "no significant heating," <1°C
Shellock and Morisoli (18)	1.5 T, 13 different heart valves made of pyrolytic carbon and titanium (Carbo-Medics, Austin, TX, U.S.A.); "worst-case MR imaging sequence" scenario: 0.3°C temperature increase, "inconsequential from a safety and biological effects standpoint"
Chou et al. (16)	1.5 T, auditory brainstem implant- and Nucleus 22-type CI (without magnets; Cochlear Corp.), implanted in modeled, artificial head: "no detectable heating"
Kainz et al. (17)	1.5/3.0 T, neurologic electric pulse generator (ITREL III; Medtronic, Inc., Minneapolis, MN), implanted in modeled, artificial head with trunk. Electric lead tip in 1.5 T increased 2.1°C, lead tip in 3 T increased 8°C. "Cannot be considered as harmful to the patient," "blood flow in head would decrease temperature increase"
Kwok et al. (7)	1.5 T, 4 different titanium stapes prostheses and 2 ventilation-tube types made of titanium, platinum, 300 SS, gold. "No rise in temperature was recorded"
Martin et al. (12)	3 T, 7 stapes titanium prosthesis types, 24 prostheses total, "heating did not occur"
Drescher et al. (15)	1.5 T, 2 hip stems made of titanium-aluminum-vanadium alloy (Waldemar GmbH, Hamburg, Germany), sized 325 × 20 mm, implanted ex vivo in cattle tibia: <1°C temperature rise, "thermal side effects not expected with scanning of patients"

MRI scanner. Overall, these experiments showed that the 300 series SS prostheses did not have any movement, displacement, or avulsion up to 9.4 T (Table 6). Specifically, even prostheses with bucket handles showed no movement of the handles, nor was an SS tympanostomy tube displaced from the tympanic membrane at 9.4 T. The 400 series Robinson prostheses were displaced 5 of 6 times at 4.7 T, whereas they showed no

TABLE 6. *Cadaver TB experiments*

First author	Summary
Williams et al. (10)	1.5/4.7 T, 9 prosthesis types. All 6 made of 300 SS "remained in position," "no loosening"; both 400 SS prostheses "displaced at 4.7 T," but at 1.5 T, "all remained in place"
Syms (19)	4.7 T, 15 Guinea pig-sized prostheses implanted, 4 made of 300 SS and 3 of 400 SS. All TBs had "no histologic evidence of injury or reactive cells" and "no prostheses displaced from oval window"
Fritsch and Gutt (8)	1.5 and 3.0 T, 18 prosthesis types. No prosthesis showed evidence of movement, including 3 that moved in petri dish experiment
Fritsch et al. (9)	9.4 T, 23 prosthesis types. No prosthesis showed evidence of movement, including SS grommet in tympanic membrane, bucket handles, and the 8 prostheses that moved in petri dish

avulsion at 1.5 T. Guinea pig experiments using miniature stapes prosthesis replicas showed neither avulsions nor any histologic damage from 400 SS prostheses at 4.7 T (19).

Surveys

A mail survey of otologic surgeons showed knowledge of only 3 possible adverse cases (19). Of these 3 cases, only 1 case was thought to have been causally substantiated. The case involved a particular prosthesis that was a 400 series SS McGee piston from recalled 1987 mis-manufactured lots. Further investigation of the case revealed that the patient denied having an otologic prosthesis, misunderstanding "prosthesis" to mean "hearing aid" on the pre-MRI scanning questionnaire, but suffered sudden right conductive hearing loss and dizziness upon entering into the 1.5-T scanner room. Eventually, the patient was observed by a second surgeon (referenced), who reimplanted a nonmagnetic prosthesis, and hearing was regained (D. McCleve, personal communication, 2006–2007). At the time of explantation of the defective prosthesis, a handheld kitchen magnet caused movement of the prosthesis over a countertop. Other anecdotal cases reported to the author have had histories where the time interval between the MRI scan and the "incident" was as long as a week, but it never occurred while in the scanner room. Indeed, at the time of the MRI exposure, when the full magnetic field force was actually applied to the prosthesis, these other cases showed no types of ear symptoms. The prosthesis problems occurred separately and unrelated to the actual MRI scan. Magnetic resonance imaging scanner-related problems, as demonstrated by the defective McGee prosthesis case, have a turbulent course starting immediately with MR magnetic field exposure.

A large body of otologic surgeons' personal experience, spanning both time and numbers of cases, was surveyed through telephone conferences (E. L. Appelbaum, D. E. Brackmann, J. H. Fritsch, J. V. Hough, W. F. House, C. G. Jackson, W. H. Lippy, C. M. Luetje, D. E. McCleve, R. C. Perkins, M. Robinson, J. J. Shea, C. Shelton, H. Silverstein, M. Smith, R. E. Wehrs, personal communication, September 2006 through March 2007). The 16 otologists and stapedectomists in the survey were chosen based on their individual experiences of each having performed a lifetime total of between 3,000 and 25,000+ stapedectomies, their wide knowledge of other otologists' experiences with stapedectomy, and/or their professional expertise as a "quaternary" referral destination. No otologist contacted refused to contribute to the survey. The survey queried regarding the particular otologist's personal lifelong medical experiences, including known experiences of medical colleagues and relatives, regarding stapes prostheses and MRI scanners. Specifically, the questions addressed were each otologic surgeon's own experience with patients having adverse outcomes or untoward effects; if the practitioner knew of any other adverse cases; if there were any known "dangerous" prostheses currently in circulation; if MRI

scanning of their own patients was allowed; and if there were objections to not using prostheses containing SS. The collective unanimous responses to the telephone survey indicated that there was only 1 known case of adverse outcome resulting from MRI exposure to the patient implanted with an anomalous McGee piston. Otherwise, there were no known adverse cases of any implanted stapes patient initiated by an MRI procedure. Currently, there were no known overtly "dangerous" prostheses on the market. All the otologists allowed MRI scanning of their patients, although several cited a 1.5-T limit due to the manufacturer's package insert instructions. No otologist objected to switching from SS to any other nonmagnetic metal such as stapes prostheses made of titanium. One surgeon (W.H.L.) showed a preference for titanium bucket-handle prostheses because of the lack of light reflection compared with SS.

A previous and present online search of the FDA Medical Device Reporting database showed no reports of stapes prosthesis-MRI scanner injuries during the available search years 1992 to 2006 (19,20).

DISCUSSION

Physicians and patients alike rightly question the possibility of a stapes prosthesis interacting with an MR field and the effects on an implanted patient. Of major consideration is the possibility of stapes prosthesis movement and heating within the patient causing a disruption of hearing or harm to the ear.

That there is the potential for some SS prostheses to move is abundantly clear in multiple types of referenced experiments. In contrast, prostheses made of nonmagnetic metals and alloys, including titanium, platinum, and tantalum showed no potential for movement.

The petri dish and suspended-string experiments showed some 300 SS series prostheses to move to the limits of the petri dish and to deflect the string to large degrees. Nonmagnetic metal prostheses made of titanium and gold remained without motion. Vibratory-magnetometer experiments showed dipoles corresponding to "low," "high," and "no" potential for movement in 300 series SS, 400 series SS, and titanium, respectively. Reassurance for patients already implanted with 300 series SS prostheses and having "low" potential for movement, but not "no potential," is gained from the ex vivo human and in vivo guinea pig TB implantation experiments. No prosthesis ever implanted in a human cadaver TB, and including those made using 300 series SS, when exposed to a 9.4-T field showed movement or was avulsed. Not even the handle of a bucket-handle piston prosthesis or a 300 series SS tympanostomy tube held by the thin tympanic membrane was moved or displaced. Furthermore, guinea pigs with implanted stapes prostheses that were exposed to a 4.7-T field showed no signs of histologic damage or reparative tissue formation. Review of the literature and 2 surveys of otologic surgeons revealed that of all the patients with

stapes prostheses ever implanted since the 1960s, there has been only 1 known patient who had a mismanufactured 400 series SS McGee prosthesis to have an adverse outcome related to MRI scanners. Regarding stapes prostheses, with the exception of the defective McGee piston, there has been no indication that adverse prosthesis movement will occur in patients when previously or currently available commercial stapes prostheses are placed into MRI scanners.

The consideration of heat production is important as a parameter unrelated to movement. Heat production occurs largely due to head coil radiofrequency energy that acts on the prosthesis during all phases of MRI scanning. Heat production is amplified when an object is made with magnetic materials and when it has mass. Studies of relatively massive hip prostheses have shown no physiologically or clinically significant heating to occur. Heart valves have also shown no significant heating. Cochlear and auditory brainstem implants without magnets and neurologic stimulation implants showed no significant heating to occur. Considering that the weight of a hip prosthesis is greater than 200 g, compared with a stapes prosthesis of approximately 10 mg, and that multiple types of nonotologic human implants all showed no significant heating, it would follow that no significant heating occurs when patients implanted with a commercial stapes prosthesis are exposed to an MRI scanner. Lastly, direct measurements of titanium stapes prostheses showed no heating.

The only patients at present known to be in any danger of an adverse reaction are those that were implanted with the 400 series SS mismanufactured McGee piston in the 3 years starting in 1987. With a lifetime stapes revision rate of approximately 20% and with a natural mortality rate, significantly lesser numbers of patients exist today compared with when the problem was identified 20 years ago (K. Pawlowski, personal communication, 2006–2007). Any patients still having defective implants would be expected to have significant problems immediately upon entering the scanner room. These patients should undergo computed tomographic scanning. Alternately, if a patient is known to be implanted with an anomalous 400 series SS prosthesis, and definitely needs 1 or more MRI scans, reoperating the ear to remove or exchange the prosthesis should be considered.

The stapes prosthesis manufacturing process can be changed so that only nonferrous metals and alloys are used. Not only would any question of magnetism be mute, but there would also be a lesser chance of mismanufacture by the accidental switching of SS ingots such as of the 400 series SS instrument ingots with the recommended 300 series SS implant ingots. Titanium has been successfully used in multiple prosthesis types and is ideally suited for stapes prostheses. It may even be superior in its nonreflective sheen, which can aid with visualization of implant positioning during the surgery. Titanium has been studied and shown to be equivalent in hearing outcomes compared with SS prostheses

(21). Alternately, various other metals and plastics are available.

Manufacturer's labels are not included except with Medtronic Corporation (Minneapolis, MN, USA) prostheses. Medtronic specifically states that their Austenitic SS prostheses may be scanned up to 1.5 T. The package insert has been reprinted since the year 2000, which is long before the most recent significant studies into this topic were performed, and is not up-to-date.

CONCLUSION

All commercially available stapes prostheses made of implant grade 300 series SS seem to be safe from movement and dislodgement up to 9.4 T. In 1987, a mismanufactured McGee piston prosthesis accidentally using 400 series Martensitic SS was made by the Richards Company. This prosthesis is highly magnetic and would give rise to immediate problems upon approaching the MRI scanner. Thus, patients that were implanted in the 3 years 1987, 1988, and 1989 with a McGee piston should avoid the MRI scanner and should be sent to the computed tomographic scanner. The same practice should be followed if the patient's prosthesis was implanted during those 3 years, and it is not known with certainty to not be a McGee piston. No middle ear prostheses have been shown to cause significant heating during MRI. In view of the ever-increasing power of the magnetic coils used in MRI scans, it would probably be advisable that future metal prostheses be made of nonferrous, nonmagnetic metals such as titanium.

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