

Safe MR scanning of patients with metallic middle ear implants

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Running title : Metallic otological implants

Abstact

Objective: To determine the MR scanning risk to patients with otologic implants.

Design: We used a repeated-measures study with an additional control measure to assess two aspects of risk; i) movement of the device in the magnetic field, and ii) absorption of energy leading to local heating. We used an *ex vivo* test method that met with international standards. We measured the effects in a Philips Intera Achieva 3 Tesla MR scanner using a Sense Head 8 channel RF coil.

Setting: University based magnetic resonance research facility

Main outcome measures: Heating or displacement of the stapedectomy pistons

Results: No evidence of displacement or heating was found.

Conclusion: Complying with the *ex vivo* standard testing protocols, the Schuknecht and McGee wire pistons, (device product numbers 140106 and 140108 respectively) were found to be safe in a 3 T MR scanner. These conclusions can be extrapolated to the *in vivo* case.

Introduction

Magnetic resonance imaging (MRI) has become a widespread clinical diagnostic tool allowing detailed illustration of the soft tissues within the body. No ionising radiation is used during the scanning process and it is usually well tolerated although some people feel claustrophobic in the scanner. However, careful consideration must be given to patients with certain biomedical implants before they are permitted to undergo an MR scan. MR scanners generate several types of electromagnetic fields to enable the acquisition of 3-D images. The main field is a large permanent static field, generated by a superconducting magnet. This field is many thousands of times greater than the earth's magnetic field and, despite some shielding, extends outside the scanner. The static magnetic field exerts strong forces on ferromagnetic materials, risking movement of metallic implants. A large number of metallic otologic implants have been assessed for their ferromagnetic qualities¹⁻³. Up to 93 different types of otologic implant have been documented (www.mrisafety.com). Each implant device must be tested individually because one cannot make any general rules about safety. For example, out of four different types of McGee piston tested three have been reported to be safe⁴, and one has been unsafe reported unsafe⁵. However, these published reports generally examine only the implant's ferromagnetic properties in MR scanners with a static magnetic field strength up to 1.5 Tesla (T). Since the relative risks are proportional to the strength of the static field⁶, further tests are required for the new generation of MR scanner that has a static magnetic field strength of 3 T.

Additional weaker transient magnetic fields inside the scanner include time-varying gradient magnetic fields and pulsed radiofrequency (RF) fields. The RF pulses can potentially induce currents on conductive objects and excessive heating; depending upon the properties of the wire (e.g. its length and diameter), of the tissue in which it is placed (e.g. its electrical and thermal conductivity) and the design of the RF coil⁶. This RF-induced heating is to be taken into consideration especially for metallic implants located in sensitive areas of the body, such as the

middle and inner ear. Middle ear implants could be at particular risk from MRI-related heating because of their elongated, closed-loop shape, yet there are no published data regarding the effect of RF-induced heating of otological implants. Given that these stapedectomy devices are made up of short wire coils, this lack of safety data is both a surprise and a concern.

This paper reports the results from *ex vivo* safety testing conducted on two middle ear implants (McGee and Schuknecht stapedectomy pistons) that are routinely used in our institution. We tested the devices for displacement in the magnetic field and for RF-induced heating by following internationally-recognised standard test methods (ASTM international, www.astm.org).

Materials and methods

Our tests were performed using a Philips Intera Achieva 3 Tesla MR scanner (Eindhoven, Netherlands). We tested McGee (stainless steel body and wire) and Schuknecht (fluoroplastic body with stainless steel wire) stapedectomy pistons. The displacement test (ASTM, Reference F-2052) examined the magnetically-induced displacement force produced by the static magnetic field gradients on each piston relative to the force of its weight. To do this, each prosthesis was vertically suspended from a cotton thread inside a transparent container and moved slowly onto the bore of the scanner on the patient table. We noted the maximal angle of the deflection. In addition, each prosthesis was placed horizontally in the centre of a grid with a millimetre scale and the measurement procedure was repeated.

The RF-induced heating test (ASTM, Reference F-2182) measured localised temperature changes around each prosthesis during MR scanning. For MRI, we used a Sense Head 8 channel RF coil to receive the RF signals transmitted by the body coil. The scanning protocol used a multiple 2D, Turbo Spin Echo RF pulse sequence to acquire sets of 14 slices using an in-plane resolution of 0.88 x 1.10 mm and a slice thickness of 6 mm. The imaging sequence was selected because it transmitted high amounts of RF energy and so it represents a 'worst-case' example. Specifically, the sequence

used 131, 110° RF pulses per TR period (1102 ms), plus one 90° excitation pulse. The 110° RF pulses had a peak amplitude of 0.9 mG and a bandwidth of 656 Hz. The 90° RF pulse had a peak amplitude of 0.6 mG and a bandwidth of 1037 Hz. The average power deposition during our experiment was estimated at 3.2 W/kg. This value markedly exceeds that for typical anatomical (e.g. 0.2 W/kg) and functional (e.g. 0.1 W/kg) scanning. The sequence was run continuously to give a total scan time of 20.03 minutes.

** Figure 1 **

For the measurements, a prosthesis (Figure 1) was suspended between three straws. Through each straw protruded a single fluoroptic temperature probe (Luxtron 3100 Thermometer (Santa Clara, CA, USA)). The thermometer had a measurement accuracy of 0.01 °C. When the straws were held vertically, the implant was no more than 5 mm from the probe tips. A plastic container was filled with a gelled solution that simulated an *in vivo* situation. The gel was made with 0.8 g/L NaCl and 5.85 g/L Polyacrylic acid dissolved in 3 L of distilled water. This formulation has a room temperature conductivity of about 0.23 S/m and a viscosity sufficient to prevent convective heat transport⁷. The straws were inserted into the liquid to a depth of 5 cm and fixed in position. An additional (control) temperature probe was inserted 13 cm away from the implant device. Each temperature measurement represents an average of 8 samples and measurements were recorded every 30 seconds before, during and after scanning. The temperature in the scanning room was also measured at 5-minute intervals using a mercury thermometer.

Results

The pistons were very light (≤ 0.01 g) and we did not observe any movement when they were positioned in the high static magnetic field. Figures 2 and 3 depict the temperature measurements for the two devices. There was no significant difference in the temperature around the prostheses compared with the control probe ($P > 0.05$). The rise in temperature was fully explained by the rise in room temperature and was unrelated to the application of RF during scanning.

**** Figures 2 and 3 ****

Discussion

In summary, our study confirms the safety of the tested McGee and Schuknecht stapedectomy pistons with respect to scanning in a 3 Tesla MR system. These results can be extrapolated to the *in vivo* case to infer minimal risk in performing head and body scans on patients with these otological implants. While the result of the displacement test is applicable to any make and model of 3 T MR system, we would like to stress that the heating result does not necessarily exclude the possibility of RF-induced heating in situations where the scanning parameters differ from those we have tested here. Patients with otological implants can undergo MR scanning safely provided the otological devices have been tested specifically for the scanner type and the scanning protocol used.

In the present study, our research questions specifically concerned issues of patient safety. Another important issue still waiting to be addressed concerns whether otological devices affect the quality of the brain image. Image distortions can occur near the interfaces between different types of tissue and/or materials and these are due to microscopic gradients or variations in the magnetic field strength. We have seen artefacts of this sort induced by non-ferromagnetic materials, such as the plastic ear cup and foam padding of ear-defenders. However, the small size of the otological pistons lowers the chance of this happening in the case of patients who have undergone stapedectomy surgery.

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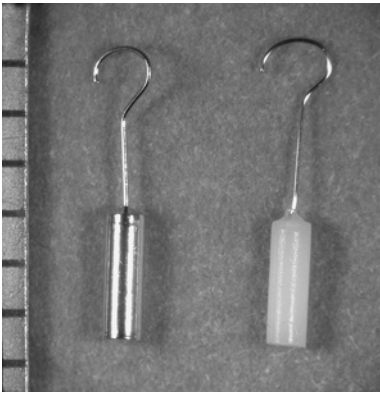


Figure 1:

Photograph of the McGee, stainless steel piston on the left and the Schuknecht, fluoroplastic and stainless steel piston on the right, with a millimetre scale to show their size.

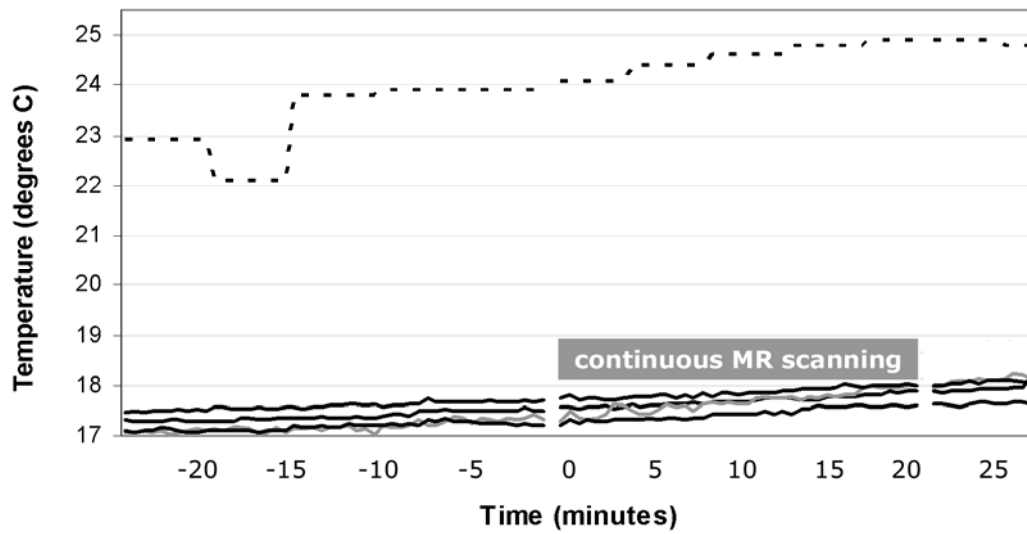


Figure 2:

Timecourse of temperature measurements for three fluoroptic probes placed near the Schuknecht piston (solid black lines) and for one probe placed in a control position within the head phantom (solid grey line). A mercury thermometer reading of the air temperature in the scanner room is shown by the dashed line.

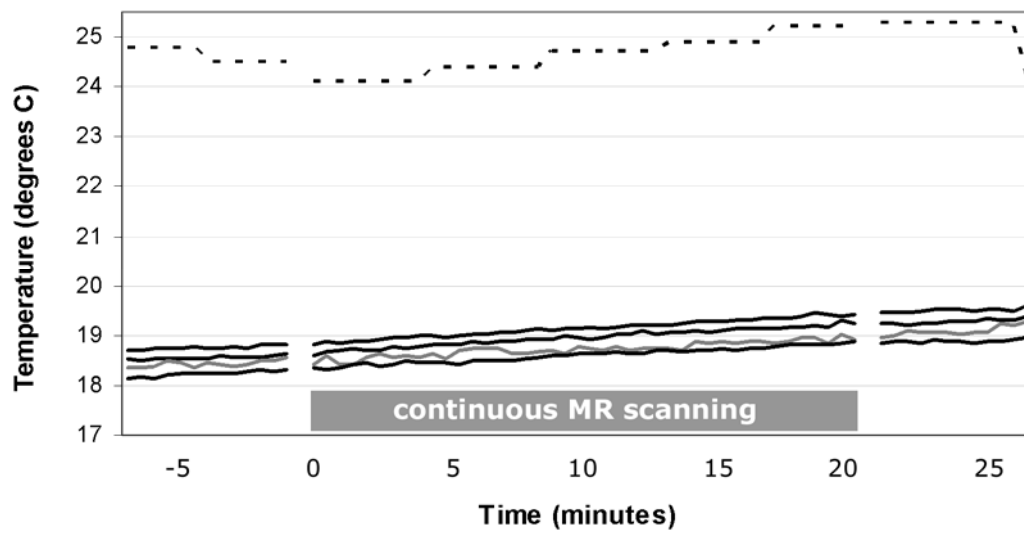


Figure 3:

Temperature measurements for the McGee piston. For explanation see legend for Figure 2.