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Research Article

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MRI Safety with Cochlear Implants up to Three Tesla – Experiences by Performing an *In Vitro* Test

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Abstract

Objective: This study aimed to quantify the demagnetization of the magnet of a new Cochlear Implant with removable magnet in a 1.5 T and a 3.0 T MRI scanner *in vitro*.

Study design: Experimental cadaver head model.

Subjects and Methods: Ten implant magnets were examined through a routine protocol in a 1.5 T and 3.0 T MRI scanners. Magnetization prior to and after the experiment was measured.

Results: No statistically relevant change in the magnetization of the magnets was observed for in the surrounding of the MRI scanner or the isocenters of the 1.5 T and 3.0 T scanners. No protective head bandage was required to prevent implant movement. In our experience, magnet replacement is a minimally invasive surgical procedure requiring about 15 minutes.

Conclusion: Demagnetization of the CI with removable magnet did not occur at 3.0 T MRI. However, to improve the quality of diagnostic imaging in patients with ipsilateral brain disease removal of the implant magnet is recommended.

Keywords

Cochleae Implants; MRI compatibility; 1.5/3.0 Tesla MRI machines; Demagnetization; Electromagnetic interferences; Magnetic attraction force

Introduction

Magnetic Resonance Imaging (MRI) is a non-invasive medical investigation, which depicts the different structures of the human body. It is used as a diagnostic tool; in contrast to computer tomography it does not emit radiation to the body.

To date, over 400 million people have undergone MRI scans [1], and young people today are expected to have an MRI at least once in their lifetime [2]. However, for cochlear implant (CI) patients, MRI scans carry a certain risk as the static magnet field, gradient magnetic field and RF field of the MRI scanner can interact with the implant in the patient's body [3]. The interaction between the static MRI field and ferromagnetic materials in the CI can cause translation or rotation of the ferromagnetic components leading to local pain, demagnetization and/or dislocation of the ferromagnetic components resulting in implant malfunction and the need for surgical intervention [4,5].

As a result, physicians have to balance the risks associated with the interaction between the CI and the MRI fields, which can potentially cause harm to the patient and/or damage the device, and the risk of misdiagnosis or underestimation of the patient's condition as a consequence of not performing an MRI scan.

The SYNCHRONY is a new CI (MED-EL, Innsbruck, Austria) used for patients with severe to profound hearing loss who obtain no benefit from acoustic amplification in the best-aided conditions. The CI system consists of an internal part, the implant, and an external part, the SONNET audio processor. One of the features of the implant is that it is the only CI that is MRI-safe at 3.0 Tesla (T) without having to remove the magnet. The magnet is a rotatable self-aligning holding magnet (Table 1). To date, to our knowledge, no studies have been published which measure the effects of a 3.0 T MRI on such a magnet in a CI. Therefore, this preliminary study aimed to determine in a cadaver head model the effects of 3.0T MRI on the magnet of the CI. It is known that the intensity of the applied magnetic field determines the strength of the change in the magnetization of a magnet. Therefore, the present study focused on the effect of 3.0 T MRI on the demagnetization of the CI magnet. The demagnetization of the magnet in the CI with removable magnet was quantified at 1.5 T and 3 T in vitro in an MRI scanner.

Materials and Methods

Ten SYNCHRONY CI with pin were used in the present study to evaluate demagnetization of the removable magnet after exposure to a 1.5 T and a 3.0 T MRI scan. The CI consists of a stimulator, a coil with a removable magnet within its center, a stimulation reference electrode, an evoked action potential (EAP) reference electrode, and an active electrode permanently attached to the stimulator. The CI is CE certified and FDA approved.

Ethical statement

Cadaver heads were obtained from the anatomical institute,

Table 1: Investigations, which were performed for the different magnets at different positions of the head.

Magnet	Serial Number	MRI exposition	Position of the head
1	104500	3.0 T stroke examination	Standard supine position, fixed at head fixation
2	104541	3.0 T stroke examination	Standard supine position, fixed at head fixation
3	104456	Reference magnet	
4	104473	1.5 T stroke examination	Standard supine position, fixed at head fixation
5	103444	1.5 T stroke examination	Standard supine position, fixed at head fixation
6	104434	Reference magnet	
7	103434	3 T at 1 m from isocenter	Head straight
8	104471	3 T at 1 m from isocenter	Head left side
9	104487	3 T at 1 m from isocenter	Head right side
10	104486	3 T at 1 m from isocenter	Head reversed

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University Vienna, Austria. Informed consent was obtained for cadaver donation, for scientific purposes, from live donors.

Pre MRI measurements

In order to determine possible demagnetization effects as a result of the MRI exposure, the magnetic attraction force between the implant magnets and a reference magnet at an air gap of 7 mm was measured before carrying out the MRI test. A calibrated Alluris GmbH precision force meter FMI-210 A5 with a measuring range of 5 N and an accuracy of ± 0.0025 N was used. The reference magnet belonged to the same magnet type as used within the transmitter/receiver coil of the SONNET audio processor (MED-EL). It was mounted onto a customized cylindrical aluminum holder, which was connected to the force meter. Each implant magnet was aligned coaxially with the reference magnet using a second customized aluminum magnet holder. As the measurement setup was aligned vertically, the magnetic attraction force was calculated as the difference between the measured forces and the gravitational force; equivalent to the weight of the reference magnet and its holder. Each magnet measurement was performed three times.

MRI exposure

At the University Clinic St. Pölten, Austria, the magnets (n=10) were exposed to different MRI fields (see Table 1).

With the appropriate insertion tool, the first magnet was placed into the recess of the coil disk of the implant, which was subsequently implanted into a fresh cadaver head, following the standard surgical procedure. Using a minimally invasive approach, a retroauricular skin incision with 4 cm length was made. After preparation of a musculoperiosteal c-shaped flap, a mastoidectomy and posterior tympanotomy was performed. The implant was only fixed in position in a 3 mm deep implant bed by its titanium fixation pins and no additional sutures were placed. Immediately after closing the wound the cadaver head was placed in a 3.0 T MRI scanner in the standard supine position, i.e. head straight and facing upwards. The MRI examination was initiated according to routine protocols used for stroke examinations (see section MRI protocol). The examination took approximately 20 minutes. After the first MRI, the first magnet (magnet no. 1) was removed from the cadaver head using the magnet removal tool, following the removal procedure as recommended by the CI manufacturer. The second magnet (magnet no. 2) was then inserted into the recess of the implant coil and the MRI examination was started again.

The same procedure was used to investigate the demagnetization of magnets no. 4 and magnet no. 5. However, instead of a 3.0 T MRI scanner, a scanner with a static magnetic field of 1.5 T was used. Magnet no. 3 and magnet no. 6 served as reference samples and were therefore not exposed to an MRI field.

Magnet no. 7, 8, 9, and 10 were placed in the room 1 m from the 3.0 T scanner, to determine the impact of MRI on persons with a CI under exposure to the static magnetic field around the MRI scanner. A summary of the procedure (magnet use) is shown in Figure 1.

Post MRI measurements

After MRI exposure, the magnetic attraction force was measured three times again (as described in Pre MRI measurements).

Statistical analysis

For statistical analyses, Minitab Inc. Minitab Statistical Software (Stat Guide), Release 15 for Windows (2007), was used.

The paired t-confidence interval and test procedures were applied to analyze the differences between paired observations. The procedure was used to determine if the mean difference for the population was likely to be different from a reference value (usually zero). To use the paired t-procedure, the distribution of the differences should be normally distributed.

MRI protocol

MRI was performed on two MRI scanners, a 1.5 T (Philips Achieva) and a 3 T (Siemens Trio Magnetom Trio Tim) scanner, using a Sense-Head-8 coil and a Synergy Head 8 coil respectively (Table 2).

Results

The results of the measurements prior to and after the MRI experiment are summarized in Table 3. As a comparison of the mean force of different magnets showed there is no apparent change in the mean force prior to and after MRI exposure (Figure 2). The p-values received for the normality tests of the differences in magnetic force from magnets before and after the different investigations (Table 2) were above 0.05 and therefore greater than the chosen α-level. Consequently, there is enough evidence to suggest that all the data sets are normally distributed.

The results of paired t-tests to determine the differences in magnetic force measured for each magnet before and after the investigations are shown in Figure 3. The mean difference between paired observations labeled X in Figure 3, is within the limits of the 99 % confidence interval. H_0, i.e. zero difference, lies within the confidence interval (depicted in Figure 2 as a solid blue line framed by brackets). Therefore, H_0 cannot be rejected The outcome of this analysis is, that the force of the magnets does not change in a statistically significant manner after MRI. No significant demagnetization occurred in magnets exposed to the 1.5 T or 3.0 T static magnetic field of the MRI scanners.

Despite the fact that the implant was only fixed with the titanium pins in the implant bed, no change in the position of the CI, exposed to the 1.5 T or 3.0 T static magnetic field of the MRI scanners was observed. Therefore, no implant displacement occurred.

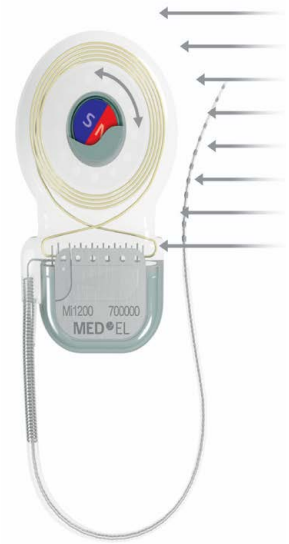

Figure 1: The implant magnet can freely rotate and self-align within its titanium housing, minimizing implant torque and the risk of demagnetization during MRI scans.

Table 2: MRI protocol, 1.5 and 3.0 Tesla.

MRI scanner	Protocol
1.5 Tesla	**Philips Achieva scanner**
	ref. scan (TR/TE 8.0/0.76 ms), transversal FLAIR with slice thickness 4 mm, TR/TE = 10925/140 ms, NSA 2, Matrix 256 x 135, FOV 230 mm; transversal 3D FFE TOF Angio with slice thickness 1 mm, TR/TE = 17 ms/6.9 ms, NSA 1, FOV 230 mm; transversal Diffusion EPI sequence with slice thickness 4 mm, TR/TE = 2749 ms/68 ms, NSA 2, FOV 180 mm, matrix 88 mm x 118 mm; transversal MS FFE with slice thickness 4 mm, TR/TE = 218 ms/2.5 ms, NSA 2, FOV 230 mm, Matrix = 388 mm x 247 mm.
3.0 Tesla	**Siemens Trio Magnetom Trio Tim scanner**
	Localizer multistack haste with slice thickness 4 mm, TR/TE = 1500 ms/83 ms), NSA 1, voxel size 1.2 mm x 1.0 mm x 4.0 mm, FOV 250 mm; transversal T2w-TSE with slice thickness 2.5 mm, TR/TE = 5280 ms/107 ms, NSA 1, voxel size 0.6 mm x 0.6 mm x 2.5 mm, FOV 245 mm; transversal T2 tirm darkfluid with slice thickness 3 mm, TR/TE = 5000 ms/458 ms, NSA 1.9, voxel size 0.9 mm x 0.9 mm x 3.0 mm, FOV 230 mm; transversal TOF Angio with slice thickness 0.8 mm, TR/TE = 22 ms/3.7 ms, NSA 1, voxel size 0.8 mm x 0.5 mm x 0.8 mm FOV 220 mm; transversal Diffusion EPI sequence with slice thickness 4 mm, TR/TE = 4000 ms/89 ms, NSA 5, voxel size 1.3 mm x 1.2 mm x 4.0 mm, FOV 130 mm; transversal T1w-GRE with slice thickness 4 mm, TR/TE = 250 ms/2.78 ms, NSA 1, voxel size 0.6 mm x 0.5 mm x 4 mm, FOV 220 mm; coronal T2w-tse with slice thickness 4 mm, TR/TE = 6000 ms/88 ms, NSA 2, voxel size 0.5 mm x 0.3 mm x 4.0 mm, FOV 220 mm.

Table 3: Arithmetic mean and standard deviation of the difference of the magnetic attraction force before and after the different investigations and results of the p-value of paired t-test and the normality test.

Investigation	MRI exposure	Mean [N]	Standard deviation [N]	p-value of paired t-test	p-value of normality test
1.5 T stroke examination	yes	-0.0012	0.0050	0.595	0.561
3 T stroke examination	yes	-0.0028	0.0055	0.262	0.737
3 T at 1 m from isocenter	yes	-0.0006	0.0059	0.737	0.142
Reference magnet	no	0.0005	0.0041	0.779	0.768

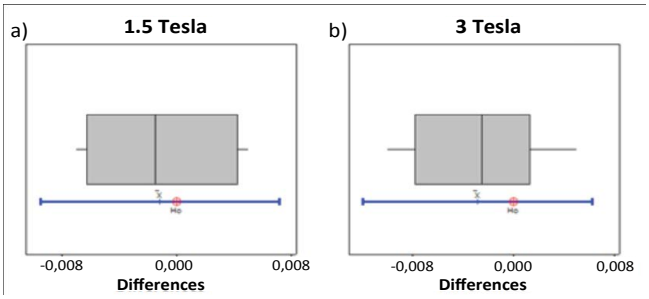

Figure 2: Comparison of the magnetization prior (black) and after (gray) different investigations.

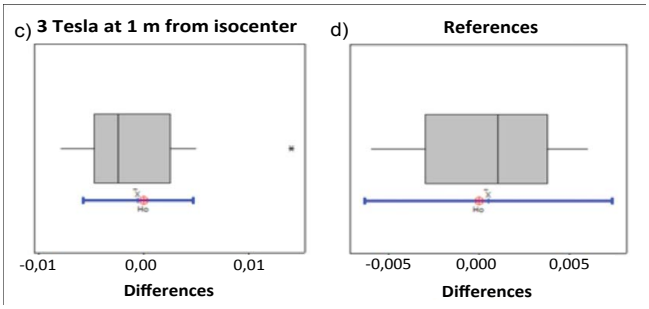

Figure 3: Results of the paired t-test of the differences with H_0 (red), and 99 % t-confidence interval for the mean of the magnetic attraction force; before and after MRI experiment.

Although, no head bandage or additional sutures were applied the implant magnet sat flush in the implant coil after MRI exposure. Consequently, it was apparent that no implant magnet dislocation had occurred.

In addition, no retraction of the electrode from the cochlea was observed after the MRI. This indicated that only negligible reversible medial and lateral displacement of the implant was caused by the static magnetic field.

During this study the CI magnet was replaced four times in the cadaver head. The average duration for one magnet replacement was approximately 15 minutes. The procedure is minimally invasive, as only local anesthesia is required for the small skin incision to insert the magnet removal and magnet insertion instruments next to the coil.

Discussion

No demagnetization occurred for the magnets exposed to the isocenter of the MRI scanners. Similarly, there was no demagnetization of the magnets placed outside of the isocenter of the scanner in the static magnetic field around the 3.0 T scanners.

Demagnetization might occur when the magnetic axis of the implant magnet and the outer magnetic field are in opposite direction towards each other. Vincent et al. [6] demonstrated the importance of the magnetic field orientation of the internal magnet relative to the static magnetic field of the MR device. Their measurements showed that the position of the patient had a direct correlation to the demagnetization of the magnet. In a side position, zero demagnetization was measured when the magnetic field was parallel to the static field. When the magnetic field of the implant was not parallel to the static field, demagnetization was high (75%). Demagnetization was 14% on average with the patient in a standard position. All investigations were performed in a 1.5 T machine.

The magnet used in the present study can rotate freely within its titanium housing and thereby align its magnetic field axis parallel to the outer magnetic field axis. Therefore, we did not stabilize the cadaver head in a special position in our study. We performed the investigation with the cadaver head located in the standard supine position (on the back, nose up). As a result, the maximum inclination angle between the internal magnet axis and the MRI scanner field axis was 90°. For the supine patient position with head kept straight, the diametrically magnetized magnet axis is parallel to the MRI scanner axis. As a result, the finding that no demagnetization occurred for the magnets exposed to the isocenter of MRI scanners at 1.5 and 3T (magnets no. 1, 2, 4 and 5), was not unexpected.

More and more radiological institutes are equipped with a 3.0 T machine, which offers the possibility of higher resolution. CI

patients are also well informed about which implants are authorized for which MRI scans; consequently we notice an increasing number of patients who choose products suitable for the highest Tesla level of MRI. MRI compatibility is therefore becoming a more important aspect when considering which cochlear implant to use. Baumgartner et al. [7] retrospectively reviewed a series of 300 cochlear implants undergoing 1.0 T MRI for various non-otologic pathologies ranging from knee degeneration to parotid tumors. No adverse effects were reported by any of the patients, and the implants retained their function. Similarly, Teissl et al. [8] tested the imposed translational force, torque, demagnetization, induced voltage, temperature change and geometric distortions caused by the internal magnet of the CI in a 1.5 T MR system. No demagnetization of the implants and the translational forces were reported, and the temperature changes and the induced voltage were minimal and within acceptable MRI safety standards. However, the aforementioned literature has only confirmed CI safety up to 1.5 T MRI.

The present study is, to our knowledge, the first cadaver study to report on the demagnetization of the magnet up to 3.0 T. Limits for RF-induced heat, displacement force, torque and implant magnet dislocation were investigated for the CE certification by the manufacturer. In line with the CE certificate, no demagnetization from 3.0 MRI imaging of cadaver heads with the CI with removable magnet was observed.

According to the MRI safety guidelines in the instructions for use of the implant, a supportive elastic head bandage is recommended to be wrapped three times around the patient's head over the implant. In addition, in the manufacturer's surgical guideline sutures are recommended to be placed around the stimulator housing. Fritsch et al. [9] and Baumgartner et al. [7] conclude that even in MRI scanners with a field strength of only 1.5 T, cochlear implant patients can only safely undergo an MRI examination after applying an external compression dressing over their implants in the superiostal pocket. The MRI in the present study was performed without supportive head bandage or sutures in order to find out whether or not any movement of the implant or implant magnet might occur. After the MRI exposures the implants were located in the initial position and there was no indication of dislocation of the implant magnet as it was still flush with the implant coil surface. However, due to the lack of objective measurements obtained, further investigations in regard to implant movement during MRI are required. Furthermore, when leaving a magnet *in situ* during MRI investigation, there are limits to the visualization of the region around the implant. Anatomical structures on the implanted side are distorted, but structures on the contralateral side are free of artifacts. If patients with ipsilateral brain disease need a follow-up MRI, it is advantageous if the magnet can easily be removed.

We removed and replaced the different magnets 4 times, in order to investigate each one, in a 15- minute minimally invasive surgical procedure. In our experience, the magnet of the implant was easy to remove and could easily be replaced using the instruments provided.

Needless to say, in addition to the data obtained in this study, clinical studies should follow to determine other parameters, which may affect a CI magnet exposed to a 3.0T MRI. For example, the temperature the implant and electrode are exposed to during an MRI. The heating of the implant and its surrounding structures, due to the RF field, may lead to tissue damage [10].

In our opinion, assessing the CI patients' subjective impressions and feelings during these MRI investigations is also very important. In future studies, it would be interesting to ascertain if patients undergoing a 3.0 T MRI describe any discomfort when approaching/entering the MRI; such as auditory sensation, pain or heat. We found no analysis of the subjective perception of MRI with a CI in our literature search. Therefore, clinical studies investigating these parameters would be contributed to the field/literature.

In conclusion, no statistical relevant change in the CI magnet's attraction force occurred for the CI with removable magnet exposed to the static magnetic field in the surrounding and isocenters of 1.5 T and 3.0 T MRI scanners. No protective head bandage is required to prevent implant movement for the implants fixed to the drilled implant bed with its titanium pins. The magnet replacement is a minimally invasive surgical procedure requiring approximately 15 minutes using the magnet removal and insertion tool provided by the manufacturer. Although image artifact, around a CI magnet, may be observed during MRI this should not preclude a patient with a CI from MRI examination when necessary. However, for patients with ipsilateral brain disease requiring MRI, we would recommend removal of the implant magnet to increase.

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