ORIGINAL RESEARCH—OTOLOGY AND NEUROTOLOGY

Demagnetization of cochlear implants and temperature changes in 3.0T MRI environment

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OBJECTIVE: To investigate the level of demagnetization of the magnets and temperature changes in cochlear implants (Cis) in a 3.0 tesla (3.0T) MRI.

STUDY DESIGN: Experimental.

SUBJECTS AND METHODS: Demagnetization and remagnetization measurements were done on magnets for different types of CIs. Temperature of different body and electrode sides was measured in the MRI environment.

RESULTS: Demagnetization of the magnets of the CI is dependent on the angle between the magnetic field of the CI magnet and the MRI. When this angle was greater than 80 degrees, relevant demagnetization occurred and sufficient remagnetization was not possible with the 3.0T MRI magnet. Maximum temperature rise was 0.5°C.

CONCLUSIONS: Patients carrying CIs with non-removable magnets should not enter a 3.0T MRI device in a routine clinical setup. Under special conditions (angle between the two magnets less than 80 degrees) imaging in a 3.0T MRI may be possible without harming the patient or the implant.

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Three tesla (3.0T) MRI scanners are rapidly becoming a significant role in radiographic imaging. One study predicts that the lifetime prevalence of neurological disorders requiring brain MRI imaging is 6.25 percent.[1] This percentage includes the greater than 110,000 individuals who have cochlear implants (CI).[2]

CIs contain internal magnets used to transcutaneously couple the externally worn processor to the surgically implanted components. However, these magnets interact with other magnets such as those found in MRI scanners where the static and dynamic electromagnetic fields may interfere with the CI magnet. In addition, the pulsed magnetic fields and time-variant gradient fields can induce voltages and potentially harm the implant electronics, lead to unintentional stimulation, and increase temperature of implant components.

Several CI magnets are removable through an in-office, surgical procedure. These CI magnets include Cochlear Corporation's CI24M, CI24R (CS), Nucleus Freedom, and CI24ABI devices (Cochlear Corporation, Melbourne, Australia) as well as the Advanced Bionics HiRes90K (Advanced Bionics, Sylmar, CA). These devices are all designed so that the internal magnet can be removed prior to MRI scanning and replaced thereafter, preventing potentially harmful interactions between the magnet of the CI and the magnetic field of the MRI.[3-8] Other CIs, notably C40+, PULSAR, and SONATA (MED-EL Corporation, Innsbruck, Austria), are designed with a non-removable magnet and have been reported to be safe in MRI devices up to 1.5T.[9,10] To date, they have not been studied in 3.0T scanners.

Regulations governing safety requirements of MRI scanners—including interactions between CIs and MRIs—are in preparation by CENELEC (Comité Européen de Normalisation Electrotechnique, or European Committee for Electrotechnical Standardization) as well as ASTM International (American Society for Testing and Materials). This study was designed following the recommendations of these organizations (60601-2-23 norm, issued May 2006).

MATERIALS AND METHODS

All tests were performed in a 3.0T ALLEGRA Head MRI scanner (SIEMENS AG, Munich, Germany) with active shielding. Magnets used in the MED-EL C40+ and PULSAR devices (type C) as well as SONATA device (type T) were tested. Both C and T magnets are made from the rare earth compound Samarium-Cobalt. The physical size of the magnets is the only difference between the two,

with the type C magnet having a diameter of 7.9 mm and a thickness of 2.0 mm, and the type T having a diameter of 7.9 mm but a thickness of 2.3 mm.

Human or animal subjects were not utilized in this study; therefore, the approval of the institutional review board was not necessary.

Demagnetization

A practical concern regarding interaction between a CI magnet and an MRI magnetic field is demagnetization of the CI magnet. The consequence of this is failure of transcutaneous coupling of the external receiver and internal components. The purpose of this test was to determine the extent of demagnetization of CI magnets by a 3.0T MRI scanner and to determine if remagnetization is possible.

Because magnetic field interactions depend on geometric orientation of poles, testing took place with magnets in various orientations to the MRI magnet. A custom rack was constructed of Plexiglas to allow for secure attachment of the CI magnets within the scanner at various orientations. The magnetically stable orientation of the CI magnet (poles aligned with MRI scanner) was experimentally determined by holding a CI magnet within the MRI scanner. The MRI scanner used in this study—SIEMENS 3.0 Tesla ALLEGRA Head MRI scanner—was noted to have its *south* pole in the front of the scanner with the *north* pole toward the rear. The rack was designed to hold magnets at angles of 0, 80, 90, 100, 110 and 180 degrees relative to their magnetically stable orientation aligned along the MRI dipole (Fig 1). Angles were chosen to maximize pole interactions. The custom-made rack, in addition to holding the 12 type C magnets, also was designed to hold a type T magnet at an angle of zero degrees relative to the magnetically stable orientation (Fig 1).

Two experiments were undertaken to assess degree of demagnetization. First, to assess the effect of the number of MRI scans on demagnetization, we placed the test rack in the scanner for one, five, or 10 scans. Two data points for each angle and magnet type were obtained with 12 type C and type T magnets being used. On the basis of these results, we chose to further investigate demagnetization after five MRI runs. For the second experiment, a total of 36 type C and 36 type T magnets were tested. For both experiments (first experiment with a varying number of scans and second experiment for further investigation of magnets that underwent five scans), magnets were labeled at their south pole. The pre-scan magnetic field strength was measured with the Gauss meter (Bell 5070; F. W. Bell, Orlando, FL) at a distance of 1 mm from the pole surface. Each of the magnets was then fixed inside the rack; the rack was placed on the movable patient platform and inserted into the scanner. The stretcher with the rack was removed after 1 second, a period long enough to induce demagnetization, which occurs in the order of fractions of seconds. To test magnet weakening after exposures to the 3.0T field, we moved the rack in and out of the scanner the specified number of times (Fig 1). The magnetic field strength of the individual mag-
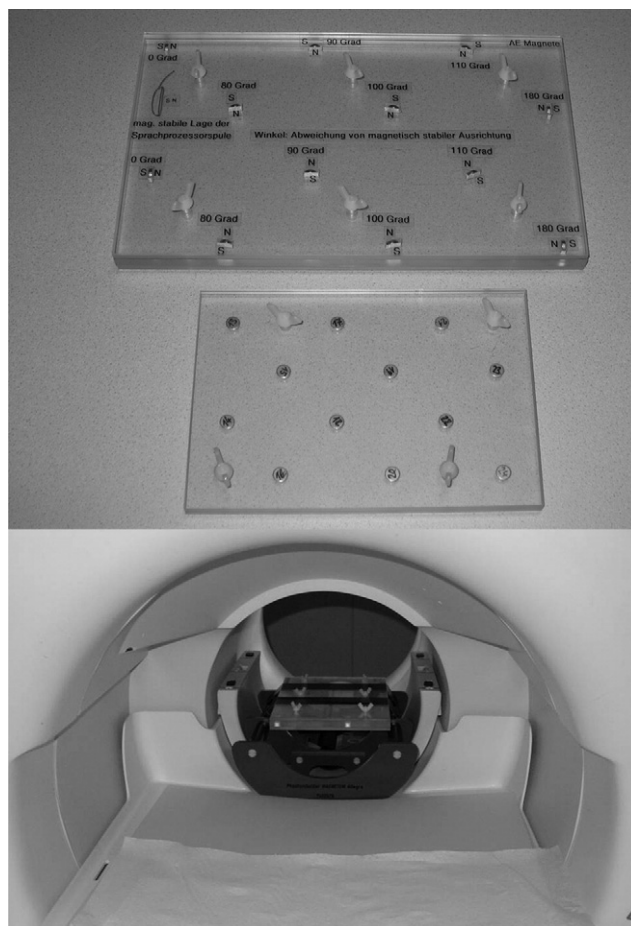

Figure 1 *Top,* Racks for magnet weakening test and remagnetization test. *Bottom,* Rack for the weakening test inside the scanner tube.

nets was measured post-scan(s) with the Gauss meter at a distance of 1 mm from the pole surface.

Although demagnetization of CI magnets by MRI magnets was the primary purpose of our study, we also chose to test the corollary hypothesis, namely that MRI magnets can be used to remagnetize CI magnets. Remagnetization from a stronger magnet to a weaker magnet is a well-characterized phenomenon and is achieved when the poles are positioned in parallel with each other, inducing alignment of the electrons such that the weaker substance magnetizes along these poles.

To test this hypothesis, a remagnetization rack was made such that the poles of the CI would be aligned with those of the MRI (Fig 1). Next, to identify the correct orientation of the patient to the MRI, we first determined the stable magnetic orientation of the externally worn coil of the CI system, noting that it contains a magnet that couples with the internal CI magnet and is thus aligned parallel with the internal CI magnet. The externally worn coil has a design where one side is flat and the other is curved, thus our arbitrary standard became to convey proper alignment according to the orientation of the curved side to the MRI magnet. The externally worn coil was hung in the entrance

of the MRI scanner to determine its magnetically stable orientation. Then, as the internal magnet has the same polarity as the externally worn coil, the remagnetization position equals the magnetically stable orientation.

After recording the data, we measured the remagnetization test and then measured the magnetic field strength of the individual magnets with the Gauss meter at a distance of 1 mm from the pole.

Temperature Changes

In addition to the static magnetic field of the MRI magnet, time-varying magnetic fields—pulsed magnetic fields, time-variant gradient fields, and radiofrequency (RF) pulses—are present during an MRI scan. These magnetic fields are capable of inducing electrical currents in the metallic components of a CI, theoretically leading to an increase in temperature. Heating occurs primarily as a result of RF exposure to electrical conductors, whereas the gradient fields are thought to have only a minor thermal effect.[11,12] The clinical concern is that excessive heating may lead to tissue damage. As such, CENLEC and ASTM International recommend limiting RF heating during MRI scanning to a 1°C increase.

A testing apparatus was constructed as shown in Figure 2. CIs were embedded into a tissue dummy gel, simulating brain tissue. The tissue dummy gel consisted of, in mass percentage, 91.48 percent H_2O, 0.12 percent NaCl, and 8.4 percent TX-151[11,13] and, in absolute values, 1500 g deionized H_2O, 2.0 g NaCl, and 137.7 g TX-151 gelling agent. To measure the temperature without touching the CI, we placed a thin layer of phosphorus material on the various positions of interest of the CI. The fluorescence signal of this phosphorus material has a temperature-dependent time decay. Signal intensity of the phosphorous was transmitted via a fiber optic cable outside the MRI room to a LUXTRON 710 fluoroptic thermometer (LumaSense Technologies, Santa Clara, CA). This thermometer has an accuracy of 0.1°C.
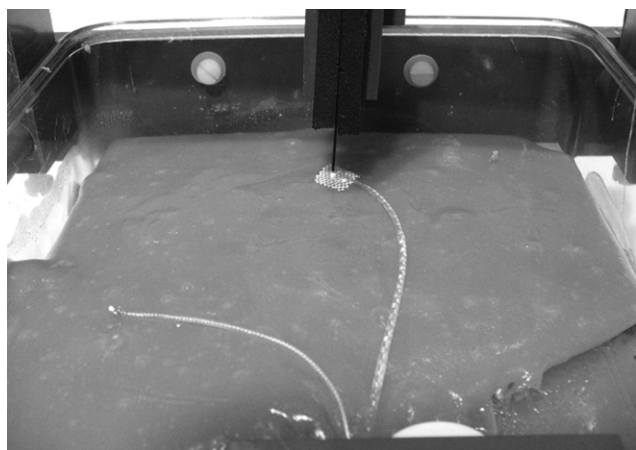

Figure 2   A C40+ implant with implant electrode placed onto the surface of the gelling material. The temperature of an ABI contact is measured through a fluoroptic probe.

The analogue output was displayed on an oscilloscope (TDS2024 oscilloscope; Tektronix Inc, Beaverton, OR), and the temperature curves were stored on a computer. This entire setup was placed in the MRI cabin 24 hours prior to testing to allow equilibration with ambient temperature. Worst case MRI sequences—sequences with the maximum possible specific absorption rate (SAR)—were identified as T2-weighted turbo spin echo sequences with repetition time of 4030 milliseconds, echo time of 75 milliseconds, flip angle of 180 degrees, field of view (FOV) read of 220 mm, FOV phase of 100 percent, and a slice thickness of 5 mm over 23 slices. This number of slices was chosen to stay just below the maximum possible head specific absorption rate (SAR) limit of 3.2 W/kg for a given body weight of 80 kg for the testing phantom.

Temperature changes were measured at 1) electrode contacts, 2) the external housing of PULSAR and SONATA CI devices (according to ASTM International standard F 2182-02a), and 3) the temperature of a water bath containing the CI compared with a similar volume water bath without the CIs (in accordance with CENELEC prEN45502-2-3, clause 22.2).

To test temperature changes at electrode contacts, two auditory brain stem implant (ABI) devices were used. ABIs and CIs use the same electrodes but are spaced differently, with the ABI configuration better suited for ease of the testing described herein. Temperature was measured at the stimulation reference electrode, the Electrically evoked Action Potentials (EAP) recording reference electrode, the housing shell, the header flange, and the magnet housing of the SONATA device. On the PULSAR implant, temperature was measured at the stimulation reference electrode, the EAP recording reference electrode, and the header flange. On the C40+ implant, the temperature of electrode contacts 1 and 11 was measured as well as the temperature at the stimulation reference electrode and the header flange (both identical to that of the PULSAR Implant).

In addition to direct measurement of temperature on the devices, in accordance with CENELEC recommendations, a water bath test was performed. The PULSAR and SONATA implants were each separately placed into a small Plexiglas container that was filled with saline solution at a volume three times that of the implant. A second test container was filled to the same level without the addition of the implant. Four nonmetallic containers were used, two for the PULSAR device and two for the SONATA device. To achieve thermal equilibrium with the environment, we placed all containers inside the MRI scanner room 24 hours prior to the start of the experiment. As in the other temperature measurements mentioned previously, MRI sequences with maximum possible SAR (see above) were applied and allowed to run for a minimum of 15 minutes. The temperature of the fluid in the container with the implant and the reference container was then measured.
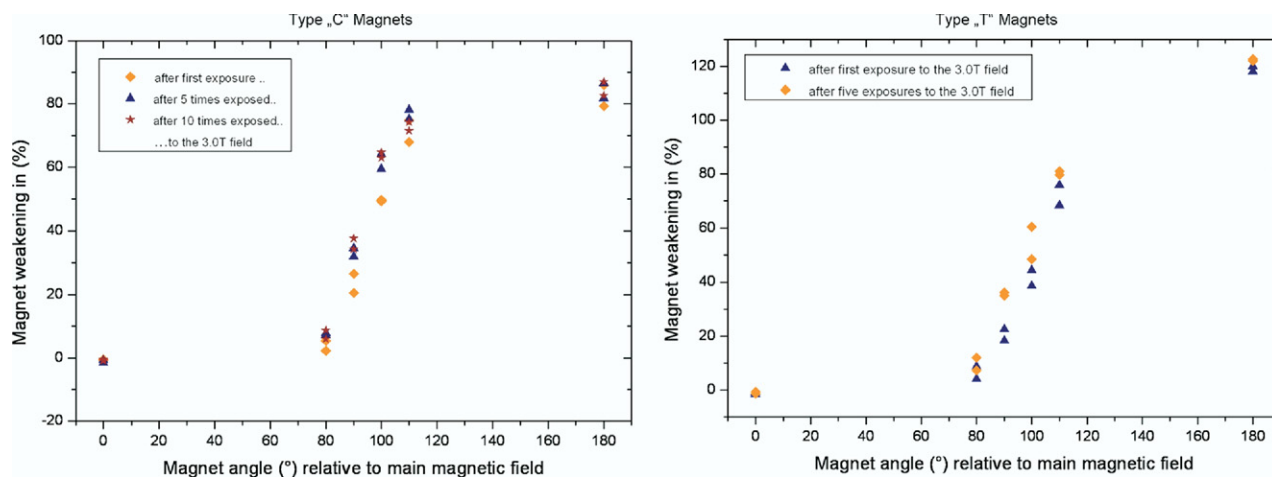
Figure 3   Weakening of 12 implant magnets, type C (implant magnets of the implants C40+ and PULSAR, *left diagram*), and 12 implant magnets, type T (implant magnet of the SONATA implant, *right diagram*), after one exposure (DIAMOND), five exposures (TRIANGLE), and 10 exposures (STAR) to a 3.0T field.

RESULTS

Demagnetization

Six data points were taken for each magnet at angles of 0, 80, 90, 100, 110, and 180 degrees (Fig 1). Each test condition was completed six times.

Figure 3 shows results for the type C and type T magnets after exposure to one, five, and 10 scans. Table 1 shows the data presented as percentage of magnetic weakness, with 100 percent representing complete demagnetization and 0 percent representing no demagnetization.

On the basis of the data from Figure 3 and Table 1, we interpreted one MRI scan as insufficient to effect maximal demagnetization, whereas the results from five versus 10 scans appeared similar. Thus, we selected five MRI scans as the number at which to further investigate both demagnetization as well as remagnetization. These data are shown in Figure 4 (results for the type C magnets in the left diagram and for the type T magnets in the right diagram) as well as Table 2. For these sets of experiments, six data points were captured for each magnet type at each angle. In addition, following the fifth MRI scan, the magnets were placed on the remagnetization test rack and underwent remagnetiza-

tion. The resultant magnet strength is also shown both as raw data and median value.

The results show that, after the first exposure to magnets with angles over 80 degrees, the magnetic force diminishes rapidly, whereas exposing the implant's magnet to the MRI field with an angle less than 80 degrees does not have much effect in terms of demagnetization of the implants (Fig 3). Weakening of a permanent magnet in a strong external magnetic field in antiparallel orientation occurs immediately during first exposure, and there is almost no additional magnet weakening with repeated exposure. With a strong external magnetic field in transverse orientation (ie, when the magnet angle is around 90 degrees), the primary amount of magnet weakening still occurs during the first exposure to the magnetic field, but repeated exposure also leads to a further magnet weakening.

Figure 4 shows results for the type C and type T magnets after five exposures to the magnetic field. Mean values of the six experimental data points are shown. Also shown is the magnetic value after remagnetization, that is after five exposures to the MRI field and subsequent remagnetization as described in Materials and Methods. A reduction in magnet strength down to 90 percent is considered accept-

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Table 1
Weakening of the implant magnets type C after one, five, and 10 exposures to the 3.0T field (mean data for two magnets being under test for each subject)

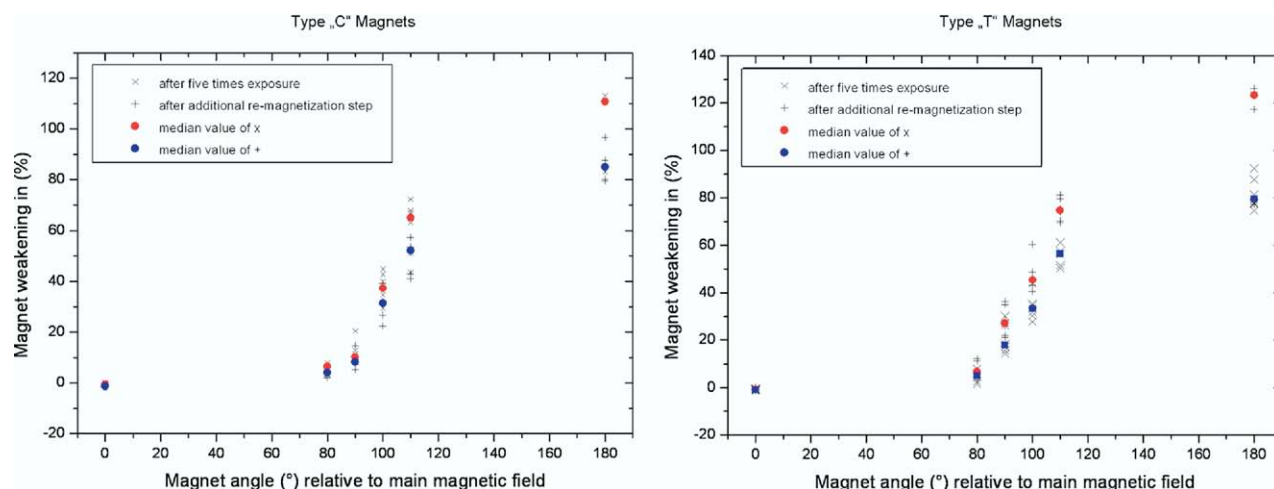| Angle between the magnetic fields of the CI magnet and MRI (degrees)	Magnet strength weakening after one time exposure of the CI magnet to the 3.0T MRI (%)	Magnet strength weakening after five exposures of the CI magnet to the 3.0T MRI (%)	Magnet strength weakening after 10 exposures of the CI magnet to the 3.0T MRI (%)
80	3.90	7.45	7.35
90	23.50	33.25	35.85
100	49.55	61.90	63.85

Figure 4   Weakening (individual and median values) of 36 implant magnets, type C (implant magnet of the implants C40+ and PULSAR, *left diagram*), and 36 implant magnets, type T (implant magnet of the SONATA implant, *right diagram*), after five weakening steps and a final remagnetization step.

able to preserve the ability of magnetic coupling. Note that the maximum acceptable angle between the actual implant magnet orientation and the static magnetic field orientation to preserve function is reached when the CI magnet and MRI magnet are at 90 percent alignment. Below this angle (eg, at 80 degrees), little to no weakening occurs.

Temperature Changes

The temperature changes at the various locations of the CIs in the 3.0T MRI device during different sequences are noted in Table 3. The temperature did not rise more than the acceptable limit of 1.0°C in any location.

In addition, according to the CENELEC standard, the temperature change in a water bath with the implants was measured relative to the temperature change in the water bath without implants. With both implant housing types (titanium housing in the SONATA or ceramic encapsulation in the PULSAR and C40+ Implants), there was no difference between the temperature in the container with the implant and the reference container filled only with saline solution.

DISCUSSION

It is inevitable that, with the increasing number of CIs and increasing popularity of MRI scans, more patients with CIs will need MRI scans. Although safety of the patient is paramount, the impact of MRI scans on the CI must also be considered. The primary concerns are the interference of the magnetic fields imposing undesirable forces on the patient,[10,14] damage to the internal device, and artefact of the imaging study,[9] This paper focuses on potential damage to the CI in terms of demagnetization of the internal magnet and temperature changes.

Unlike the CIs of Cochlear Corporation and Advanced Bionics Corporation, the magnet of MED-EL CIs is not removable. Therefore, the aim of this study was to deter-

Table 2

Weakening of the implant magnets, type C and type T, after five exposures to the 3.0T field and after the remagnetization step

Magnet type	Angle between the magnetic fields of the CI magnet and MRI (degrees)	Magnet weakening after five exposures to the 3.0T field (%)			Magnet weakening after one step of remagnetization (%)		
		Mean	Standard deviation	Maximum (worst case)	Mean	Standard deviation	Minimum (worst case)
C	80	5.71	±1.93	7.70	3.83	±1.19	2.00
T	80	7.35	±3.69	12.10	4.93	±2.65	1.60
C	90	11.68	±4.71	20.46	8.90	±3.23	5.20
T	90	28.08	±6.43	36.30	20.35	±6.32	14.40
C	100	37.10	±6.34	44.91	30.53	±5.66	22.40
T	100	47.25	±7.03	60.50	33.98	±5.61	27.70

Table 3
Maximal temperature change at various parts of the implant after exposure to magnetic fields of a 3.0T MRI for at least 15 minutes

Implant type and location	Maximum temperature increase ΔT (°C)
C40+ ABI contact 1	0.3
C40+ ABI contact 11	0.3
C40+ stimulation ref. electrode	0.5
C40+ Header flange	0.0
PULSAR stimulation reference electrode	0.0
PULSAR EAP recording reference electrode	0.2
PULSAR header flange	0.0
SONATA stimulation reference electrode	0.0
SONATA EAP recording reference electrode	0.0
SONATA housing shell	0.0
SONATA header flange	0.0
SONATA magnet housing	0.0

mine the compatibility of a 3.0T MRI on patients with MED-EL CIs containing nonremovable magnets.[5-7] These implants have CE approval for use in 0.2T, 1T, and 1.5 T devices and are FDA approved for imaging in 0.2T MRI scanners.[9]

Our results show that for the type T and type C magnets found in MED-EL CIs, unacceptable weakening occurs during 3.0T MRI scanning. Although little to no demagnetization occurred if the angle between the poles of the CI magnet and MRI magnet was up to 80 degrees, identification of magnetic poles is not uniform between patients or scanners. Extensive procedural changes would be necessary to ensure that a safe orientation was maintained before 3.0T MRI scanning with such implants could be advocated. Even for 1.5T MRI scanners, when the angle between the MRI magnet and CI magnet exceeds 80 degrees, some demagnetization occurs. This problem has prompted warnings to have patients lie supine with the head rotated slightly in an effort to align the poles of the MRI magnet and the CI magnet. Extensive head turning is to be avoided.[14,15]

Perhaps more surprising to us, remagnetization after demagnetization did not bring the magnetic field strength of CI magnets back to an acceptable level. The maximum remagnetization was 10.7 percent and it occurred after near maximal demagnetization of 42.7 percent at a 100-degree angle between the magnetic fields. After five MRI scans, mean remagnetization of 3.74 percent was quite smaller than the mean demagnetization of 18.16 percent. Although stronger static magnetic fields could be used to remagnetize these magnets (eg, 7.0T or 9.0T MRI scanners), it is unlikely that the same scanner used for imaging can also be used for remagnetization purposes. Furthermore, for bilat-

erally implanted patients, attempts to remagnetize one side would adversely demagnetize the contralateral side.

Regarding increases in temperature due to the 3.0T magnetic field, we found that only small temperature increases (maximum 0.5°C) occurred. This increase is far below the industry standard of maximal temperature increase of 2.0°C (CENELEC standard prEN45502-2-3)—a standard set to limit tissue damage and patient discomfort. Our result is in agreement with previous reports.[14,16]

CONCLUSION

Demagnetization of type C and type T magnets in MED-EL CIs in 3.0T MRI scanners reaches unacceptable levels when the angle between the MRI magnet and the CI magnet is greater than 80 degrees. Because no procedures are currently in place to identify the CI pole or the MRI pole, scanning type C and type T magnets should be performed only when 1) a 1.5T MRI is unavailable and 2) the benefits of the scan far outweighs the risk of CI demagnetization.

Minimal changes less than 0.5°C in temperature due to 3.0T MRI could be documented.

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FINANCIAL DISCLOSURE

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