MRI scanning considerations with cochlear implants and other hearing implants

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Aims and objectives

- To understand the distinctive features of cochlear implants and resulting potential hazards when with a cochlear implant is scanned in an MRI.
- To understand which risk factors can be effectively avoided.
- To learn about measures and possibilities to allow safe MRI of hearing implant users.
- To get an overview about literature on clinical experience with MRI of patient with hearing implants.
- To know where safety information for MRI scanning of hearing implant users can be found.
Methods and materials

However, this risk has been overcome by improved implant magnet design, allowing safe scans with certain types of cochlear implants. Patients with secure implants should not be turned away from MRI.

Cochlear implants (CI) are electronic implants which electrically stimulate neural structures in the inner ear. These systems are available from several manufacturers, but all share a similar general concept.

The hearing implant system consists of an implant, and an external audio processor which is held in place magnetically over the implant. In every case, the external processor needs to be taken off before an MRI scan.

Interactions between a cochlear implant and the magnetic fields in an MRI scanner can lead to following hazards:

- Implant magnet weakening
- Magnet dislocation due to forces and torque
- Unintentional stimulation
- Vibrations
- Damage of the implant
- Heating

Additionally, and mainly due to the implant magnet, MRI susceptibility artifacts are present. Such imaging artifacts extend a few centimeters from the implant and are not a risk per se but may affect or preclude diagnosis. Metal artifact suppression sequences may help to reduce the artifact. Certain models have a magnet which can be surgically removed, leading to a reduced image artifact in MRI brain scans.

Generally, issues such as heating of the electronic components can be safely minimized by following the SAR limits defined in the instructions for use for each specific implant.

The most challenging interaction between a hearing implant and the powerful magnetic fields in an MRI is existence of the implant magnet.
Most hearing implants have the magnetization of their implant magnet perpendicular to the long body axis and thus the axis of the main magnetic field $B_0$. When the magnetic axis of the implant magnet is not parallel to the static magnetic field of the MRI scanner a torque is exerted to the magnet, trying to align the magnet with the static magnetic field $B_0$.

In addition, at locations of an inhomogeneous static magnetic field (e.g. at the entrance of the scanner) also a linear force is acting on the implant magnet, aiming to pull the implant magnet into the direction of the gradient (i.e. into the inner side of the scanner bore).

There are two main types of implant magnet designs:

1. A surgically explantable axial magnet held in a soft silicone pocket. This open-pocket design is intended to allow surgical magnet removal prior to an MRI scan. The thin silicone provides minimal resistance to the torque forces of the MRI scan on the implant magnet. For MRI scans with the magnet in place, a rigid splint and tight head bandage is usually required.

2. A secure implant magnet. This design is intended to provide access to MRI without the need for surgical magnet removal or risk of magnet dislocation. With rotatable, self-aligning magnets in certain newer models, torque forces are minimal and a head bandage is not needed. Certain models also allow for surgical removal to minimize image artifacts in ipsilateral brain scans.

**Magnet Dislocation**

In nearly every case of adverse events during MRI with a cochlear implant in published literature, the implant had an axial magnet in a soft silicone pocket.

Due to the powerful magnetic torque acting on the implant magnet in an MRI scanner, an axial magnet in an open silicone pocket can tilt or even fully dislocated out of the silicone pocket towards the skin flap (figure 2). This often results in significant pain, and if the magnet is dislocated it usually needs to be surgically re-positioned.

Such magnet-related problems are not limited to head MRI scans, but may also occur if the head of the implant user is located near the entrance of the scanner bore. This would be the case as the patient enters the scanner or with scans of the lower extremities.
To reduce these issues, manufacturers utilizing axial magnets in a soft silicone pocket require a rigid splint over the implant and a tight head bandage. Although this may reduce risk in certain cases, adverse events are common even while following these conditions.

Another strategy to avoid magnet dislocation in MRI is to surgically remove the implant magnet before an MRI. However, this can damage the silicone pocket, which could necessitate replacing the entire implant.

In contrast, implant magnets with secure magnets are essentially impossible to dislocate during an MRI scan. Designed specifically for MRI access, newer generations with secure self-aligning magnets are highly effective at reducing magnetic torque, allowing safe 3T scans without a head bandage.

As the primary risk of adverse event can be reliably avoided, patients with a hearing implant with a secure magnet should not be turned away from MRI scans.

The following issues are less likely but still underline the importance of following implant-specific MRI scanning conditions as detailed by the manufacturer.

**Demagnetization**

Most hearing implants have the magnetization of their implant magnet perpendicular to the long body axis and thus the axis of the main magnetic field $B_0$. With high field scanners and especially with 3 Tesla scanners there is the risk of implant magnet weakening (figure 1). Thus, following correct conditions and maintaining the correct head orientation is essential.

**Vibration and unintentional (electrical) stimulation**

Electrode leads of an electronic implant may act as antenna and pick up the powerful electromagnetic signals, and ferromagnetic and magnetic parts of an implant may vibrate due to switching gradient fields. Even if an implant does not actively stimulate, there may be an electrical or vibratory output present. This is generally not harmful but may cause patient concern. Slower gradient slew rates may reduce the intensity of such unintended output.

**Damage of the implant**
Voltages induced in the implant circuitry due arising from the switching of the gradients or from RF pulses may not only cause vibrations or unintended stimulation, it may potentially also damage the implant if conditions are not correctly followed.

**Heating of electrode contacts**

Compared to other active implants (pace makers, ICDs, spinal cord and deep brain stimulators) hearing implants have a relatively short electrode lead length. Thus, electrode heating with thermal damage of the surrounding tissue is usually not a problem with hearing implants. Still with some implants and for certain MRI field strengths the maximum head and whole-body SAR values may be less than 3.2 W/kg and 2.0 W/kg, respectively. Therefore, it is crucial to confirm the exact SAR conditions for each specific cochlear implant before scanning.

All these risks are evaluated by pre-clinical testing according to MRI safety standards including ISO 10974 and ASTM standards.

The results of these tests define safety measures like limitation of the SAR value or the gradient slew rate or exclude certain MRI hardware (to limit electrode heating), or there may be implant-specific measures like the need to apply a head bandage over the implant. All these MRI safety measures are part of the implant product labeling which is shipped with each implant and with each audio processor. Implant manufacturers typically publish these MRI safety guidelines also on their webpage.
**Fig. 1:** Illustration showing a cochlear implant where the implant magnet has a component of its magnetization anti-parallel to the main magnetic field in an MRI.

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Magnet Dislocation
Non-secure axial magnet in soft silicone pocket

Fig. 2: Non-secure implant magnet in soft silicone pocket.

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**Fig. 5:** Illustration of a cochlear implant system with the external audio processor, which is removed for scans. The implant is placed under the skin and rests on top of the mastoid.

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Fig. 6: Overview over interactions between a cochlear implant and the magnetic fields in an MRI. Primary issue is the magnet shown with the green arrow.

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Results

The primary cause of adverse events during MRI with a cochlear implant is magnet dislocation. Extensive literature shows this is due insufficient retention of axial magnets in a soft silicone pocket. Implants with this design show adverse event rates of up to 100% in 1.5 T MRI.

In contrast, cochlear implants using secure magnet designs offer safe, reliable MRI access up to 3T. There have been no reported cases of magnet dislocation with this design.

In a prospective study, Todt et al. 2017 found that cochlear implant users with a secure, rotatable magnet do not feel any pain during MRI. Five patients with the SYNCHRONY cochlear implant (MR conditional at 1.5 & 3 Tesla) received head scans in a 3.0 Tesla MRI. After initial MRI scans with head bandage scanning was repeated without any head bandage. All patients reported no sensations of pain; 0/10 on the visual analog scale (figure 3). [2,3]

Furthermore, Shew et al. 2018 found in a retrospective case series that in 4/4 cases where patients with non-secure axial implant magnets in a silicone pocket were scanned at 1.5 Tesla, each scan resulted in pain, with magnet dislocation in 3/4 cases. In contrast, 19/19 MRI scans at 1.5 Tesla could be successfully performed with an implant model with a secure, self-aligning implant magnet [4].

Kim et al. 2015 reported that 7 of the 13 patients (7 of 19 MRI scans) experienced discomfort or pain during the MRI scans. In 5 out of 15 cases MRI scanning could not be completed due to pain and discomfort. [1] These were all cases where patients had an implant with the magnet embedded in an open silicone pocket.

In contrast, 8 out of 8 MRI scans on patients with implants using a securely embedded implant magnet were performed successfully (figure 4).

None of the studies showed any case of magnet dislocation with implants with secure, self-aligning implant magnet.

Magnet removal prior to MRI to minimize the imaging artifact is only needed in very rare cases. With the SYNCHRONY implant, which has been on the market over more than four years, there have been less than 10 cases of magnet removal worldwide so far.
(MED-EL internal data.) Magnet removal requires coordination with the ENT department, but can be performed safely even in young children [5].

Information about safe MRI scanning of patients with a hearing implant is part of the labeling shipped with each implant. For some hearing implants this information is also available for download from the manufacturer's webpage.

For MED-EL hearing implants this information can be found at www.medel.com/isi containing the MRI safety information.

As MRI safety information is specific for the different models it is important to know the brand and model of the implant before an MRI is performed. This information can be found on the implant pass or user ID card which each implant user has.
**Successful 3.0 T MRI**

Without surgical magnet removal or head bandage

![Graph showing 100% success rate for MRI scans with self-aligning magnet implant and 0% pain index](image)

Reference: Todt et al. 2017

**Fig. 3:** Five patients with CI with self-aligning magnet received 3.0 T head MRI scans (one with and one without head bandage). All scans could be performed, with no pain experienced in any case (level 0 on a visual analog scale from 0 to 10).

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Fig. 4: Seven patients with CI with secure, self-aligning magnets had in total nineteen scans in a 1.5 T MRI. All scans could be successfully performed without any pain. In 4 out of 4 cases where patients had an implant with the axial magnet embedded in an open silicone pocket there were magnet-related adverse events: In three cases patients experienced pain and magnet dislocation, in a fourth case the implant magnet stayed in place, but the MRI could not be finished because of pain.

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Fig. 7: MED-EL SYNCHRONY implant with secure, self-aligning diametrically magnetized magnet.

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Conclusion

When it comes to MRI, there are two completely different types of cochlear implant. Soft-silicone pocket designs represent significant risk. MRI scanning of patients with these cochlear implants can often lead to magnet-related pain or magnet dislocation, and even a tight head bandage cannot prevent this.

However, improved implant designs with secure magnets can offer true MRI safety, and these patients can be reliably scanned without significant risk of pain, discomfort, or magnet dislocation.
Personal information

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