Magnet Dislocation: An Increasing and Serious Complication Following MRI in Patients with Cochlear Implants

Magnetdislokation – eine zunehmende und folgenreiche Komplikation nach MRT bei Patienten mit Cochlea Implantat

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Key words
- head/neck
- MR imaging
- conventional radiography
- instrumentation
- safety

Abstract

Purpose: Cochlear implantation (CI) represents the gold standard in the treatment of children born deaf and postlingually deafened adults. Initial magnetic resonance imaging (MRI) was contraindicated in CI users. Meanwhile, there are specific recommendations concerning MRI compatibility depending on the type of CI system and the device manufacturer. Some CI systems are even approved for MRI with the internal magnet left in place. The aim of this study was to analyze all magnet revision surgeries in CI patients at one CI center and the relationship to MRI scans over time.

Materials and Methods: Between 2000 and 2013, a total of 2027 CIs were implanted. The number of magnet dislocation (MD) surgeries and their causes was assessed retrospectively.

Results: In total 12 cases of MD resulting from an MRI scan (0.59 %) were observed, accounting for 52.2 % of all magnetic revision surgeries. As per the labeling, it was considered safe to leave the internal magnet in place during MRI while following specific manufacturer recommendations: MRI intensity of 1.5 Tesla (T) and compression head bandage during examination.

Conclusion: A compression head bandage in a 1.5 T MRI unit does not safely prevent MD and the related serious complications in CI recipients. We recommend a Stenvers view radiograph after MRI with the internal magnet in place for early identification of MD, at least in the case of pain during or after MRI examination. MRI in CI patients should be indicated with restraint and patients should be explicitly informed about the possible risks. Recommendations regarding MRI compatibility and the handling of CI patients issued with MRI for the most common CI systems are summarized.

Key Points:
- MRI in CI patients: manufacturer recommendations must be followed.
- Magnet dislocation due to MRI is a serious complication.
- In case of suspected magnet dislocation: Use Stenvers view radiograph for diagnosis.
- Instant presentation to a CI center is mandatory for proper management of dislocation.
- Immediate CI revision surgery must be performed in the case of magnet dislocation.

Citation Format:

Zusammenfassung

Ziel: Das Cochlea-Implantat (CI) repräsentiert den Goldstandard in der Therapie von gehörlos geborenen Kindern und postlingual ertaubten Erwachsenen. Initial war die Magnetresonanztomografie (MRT) bei CI-Trägern kontraindiziert. Inzwischen gibt es je nach Implantattyp unterschiedliche Richtlinien zur MRT-Tauglichkeit, sodass bei manchen Systemen sogar mit in situ belassenen internen Magneten eine MRT möglich ist. Ziel dieser Arbeit war die Analyse aller Magnetrevisionsoperationen eines CI-Zentrums bei CI-Patienten und deren Zusammenhang zu MRT-Untersuchungen im zeitlichen Verlauf.

Material und Methoden: Zwischen 2000–2013 wurden insgesamt 2027 CIs implantiert. Die Anzahl Magnetrevisionsoperationen und deren Ur-
Einleitung

Fördert die beginnende Geräteentwicklung bei Cochlea Deutschland GmbH (Cochlear Nucleus 
24, Cochlear Ltd, Lone Cove, Australia) [4]. Alle Dislokationen waren durch Kopfverletzungen verursacht. Innerhalb der Magnetdislokation repräsentiert eine dringende Indikation zur Operation mit Reimplantation der Magnetvorrichtung.

Als Ergebnis der erweiterten Indikationen für CI-Treatment, hinzuweisen, dass viele Patienten einen CI erhalten haben. In der Folge, der CI-Benutzer ist zunehmend äußert bei der Verwendung von CI-Systemen, die ein magnetisches Moment enthalten. Äußerst wichtig ist dabei die Kenntnis der möglichen Interaktionen zwischen magnetischen Feldern und dem CI-System.

Material und Methoden


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Hasspass F et al. Magnet Dislocation: An...
Hassepass F et al. Magnet Dislocation: An explanation with the corresponding specific precautions. Formed starting in 2009 in our clinic without prior magnet implants were approved for 1.5 T MRI, MRI scans were performed starting in 2004 after explantation of the internal magnet and subsequent reimplantation. The surgery (explanation and reimplantation) was performed under local anesthesia on the same day as the MRI examination to reduce the risk of infection of the implant site. After various implants were approved for 1.5 T MRI, MRI scans were performed starting in 2009 in our clinic without prior magnet explanation with the corresponding specific precautions.

Results

2027 CIs were implanted from January 2000 to May 2013. In total, magnet revision surgery was indicated in 23 cases (22 CI patients). Direct head trauma was the reason for three of these revision surgeries (13.0%). All other magnet revision surgeries are related to MRI examinations. MRI after explantation of the internal magnet and subsequent reimplantation affected 8 patients in the above collective (34.8% of all magnet revision surgeries) who were all operated between 2004 and 2009. In total, 12 magnet dislocations (0.59%) occurred between 2009 and 2013 as a result of interference between the internal magnet and the 1.5 T MRI unit as a consequence or complication during MRI examination with consecutive magnet revision surgery. With 52.2%, this is the main cause of all magnet revision surgeries. The dislocated CI systems were as follows: 6 magnet dislocations for the Cochlear CI512, 5 for the Cochlear Nucleus Freedom and 1 for the Cochlear CI422. The affected CIs were labeled by the manufacturer as being MRI-compatible with the magnets left in place. Therefore, surgical intervention was not performed prior to MRI. In 10 of the indicated magnet dislocations (2009–2011), the examination was performed in the hospital’s own radiology clinic. The specific recommendations of the CI system manufacturer were strictly followed in these cases. The speech processor was removed during the examination in each case. 2 patients were examined at an outpatient radiology center in 2013. The distribution of the magnet revision surgeries between 2000 and 2013 is summarized in Fig. 3. According to the patient history, a compression bandage was also used in these cases. A Stenvers view radiograph was performed after MRI in the case of clinical suspicion of magnet dislocation for confirmation purposes (Fig. 4). All MRI examinations were reviewed strictly with respect to indication after other imaging modalities had been considered.

In the case of magnet dislocation due to MRI, magnet revision surgery was performed (Fig. 2). After a small incision was made in the skin occipital to the silicone body of the CI, the original magnet was reimplemented with the administration of antibiotics (10/12 cases). The CI was explanted while leaving the intracochlear electrode array in place in one CI patient due to magnet extrusion with skin infection in order to reduce the risk of transfer of the infection. In addition, systemic antibiotic therapy was administered. A new CI was able to be implanted 6 weeks after treatment.

Table 1 Summary of leading CI systems and their MRI compatibility. No liability assumed.

<table>
<thead>
<tr>
<th>Manufacturer/CI system</th>
<th>MRI field strength</th>
<th>Manufacturer recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochlear®</td>
<td>more than 1.5 T up to and including 3 T</td>
<td>The magnet must be surgically removed for MRI. Not necessary to contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td></td>
<td>more than 0.2 T up to and including 1.5 T</td>
<td>The magnet may be left in place. Bandage according to Fig. 5 required. Not necessary to contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td></td>
<td>0.2 T or less</td>
<td>The magnet may be left in place. Bandage not required. Not necessary to contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td>Nucleus® 22 with removable magnet (middle radiopaque character: L or J)</td>
<td>up to and including 1.5 T</td>
<td>The magnet must be surgically removed for MRI. Not necessary to contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td>Nucleus® 22 without removable magnet</td>
<td>all field strengths</td>
<td>MRI is contraindicated.</td>
</tr>
<tr>
<td>Med-EL®</td>
<td>up to and including 1.5 T</td>
<td>Bandage according to Fig. 5 required. Not necessary to contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td>Advanced Bionics®</td>
<td>0.2, 1.0 and 1.5 T</td>
<td>OP &gt;= 6 months earlier. Not necessary to contact manufacturer prior to MRI examination. The thickness of the bone layer beneath the implant must be at least 4.0 mm. Bandage necessary at 1.0 T and 1.5 T. The longitudinal axis of the head must be parallel to the main magnet field (patient on back looking straight ahead).</td>
</tr>
<tr>
<td>C 2SC6</td>
<td>all field strengths</td>
<td>Contact manufacturer prior to MRI examination.</td>
</tr>
<tr>
<td>Hilites90k Advantage (Titanium, 2003 to today)</td>
<td>up to and including 1.5 T</td>
<td>Contact Advanced Bionics® at least 48 hours prior to MRI examination. The magnet must be surgically removed for MRI.</td>
</tr>
<tr>
<td>C1.2 and C2 implants (ceramic until 2003)</td>
<td>all field strengths</td>
<td>MRI is contraindicated.</td>
</tr>
</tbody>
</table>
In a further case, the implant was moved and antibiotic therapy was performed due to the start of an infection in the region of the dislocated magnet. No equipment failure or demagnetization due to MRI examination was seen.

**Discussion**

Dislocation of the internal magnet is a rare but serious complication in CT users and requires revision surgery. This entails opening of the implant site thus providing potential germs indirect access to the meninges via the intracochlear electrode array. The consequences of an untreated magnet dislocation can be serious and can result in complete magnet extrusion through the scalp [1–3]. Head trauma was considered one of the main causes of magnet migration in the past. Small children in particular are affected more frequently due to the higher probability of minor head injuries compared to adults [3, 11, 12]. In the present retrospective study, head trauma was the reason for magnet revision surgery in only 13.0% of the cases.

The majority of magnet revision surgeries and magnet dislocations were due to MRI examination. MRI is contraindicated in earlier implant generations. Extensive studies were able to show MRI safety for more sophisticated implant designs so that limited MRI application in CT patients (depending on the type of implant) is now permitted [7, 13, 14]. Starting in 2004, magnet revision surgery with explantation of the internal magnet prior to MRI examination and subsequent reimplantation was performed at our hospital in CI patients (when possible and permitted for the corresponding implant). This method is also selected if it is necessary to visualize the entire skull without artifacts. The operation can be performed with a small incision in the skin under local anesthesia. Explantation of the internal magnet and reimplantation after MRI were to be performed on the same day to keep the risk of infection as low as pos-
sible [15, 16]. In the present collective, this method was performed in 8 cases among 2027 CI operations in the period between 2004 and 2009 and resulted in 34.8 % of all magnet revision surgeries. However, every operation on an implanted CI has a risk of infection at the operation site. Moreover, explantation of the magnet results in weakening of the silicone pocket and thus increases the risk for a recurrence of dislocation [11, 17]. These factors initially seem to support the attractiveness of MRI examinations without removal of the magnet. In relation to special implant types, multiple in vitro and in vivo studies were able to show that MRI examinations can be performed safely if the magnet remains in the silicone pocket. However, special implant-dependent precautions must be taken: For example, no field strengths above 1.5T; use of a compression head bandage; prior comprehensive patient counseling [7, 15, 16, 18]. In the case of an indicated MRI examination, this bandage technique was used without prior explantation of the internal magnet starting in 2009 at our clinic, provided that the particular CI system was approved. This is the main indication for magnet revision surgery in the present retrospective analysis. In total, 12 of the 23 magnet revision surgeries (52.2 %) were performed to correct magnet dislocation caused by a 1.5T MRI scan. To date, there are only two individual case reports in this regard in the literature [10, 11]. Overheating of the implant, implant defects and demagnetization, which are specified in the literature in the case of higher field strengths, were not observed in the present collective [5, 6]. At first glance, the magnet dislocation rate after MRI of 0.59 % in the present study does not seem particularly high (12 cases among 2029 implanted CIs). However, all CIs were classified as MRI-compatible and the specific recommendations of the manufacturer were strictly followed in at least 10 of the 12 cases. There is a clear increase in the occurrence of magnet dislocation following MRI with a jump in the year 2011 (83.3 % of the magnet dislocations after MRI occurred between 2011 and 2013 (Fig. 3). The various reasons for this increase need to be discussed. The bandage technique was first introduced at our clinic in 2009 and was initially only indicated on a limited basis so that corresponding complications could only be seen starting in 2009. Moreover, there is an increase in MRI examinations in general due to the expanded indications for MRI scans. A British study predicts that the lifetime prevalence of neurological diseases requiring MRI of the skull is 6.25 % [19]. All dislocations during MRI occurred in Cochlear® implants. This can be partly attributed to the fact that the majority of our patients chose Cochlear® implants preoperatively (87.1 % of all CI users between 2000 and 2013). In addition, CIs from this manufacturer are MRI-compatible to 1.5T (if the CI system was implanted after 1996) in contrast to CIs from Advanced Bionics, for example, which are not approved for MRI examinations with the magnet left in place. As a result of the frequency of magnet dislocations despite the use of the bandage technique during 1.5T MRI particularly in the year 2011, Cochlear® modified the original guidelines since the recommended bandage technique could no longer be considered sufficient [20]. The recommendations for performing MRI in CI patients with a newer Cochlear® CI system (CI512, CI513, CI551, CI422 and the Freedom™, Hybrid™ und Nucleus® 24 series; refer to Table 1) now include application of a splint directly on the scalp over the internal magnet in addition to the compression bandage [21]. This is made of a folded piece of paper, a plastic card, or a self-hardening adhesive (refer to Fig. 5 for details). The modification of the compression bandage seems to minimize the dislocation risk since it prevents possible rotation and shear movements of the internal magnet. At least, no additional MRI-based magnet dislocations have occurred at the University Freiburg during MRI examination of patients with a Cochlear® CI system since the introduction of the splint technique at the beginning of 2013 (n = 3 patients). The two described cases of MRI-based magnet dislocation in 2013 did not occur at our hospital. Both patients indicated that they wore a circular head bandage without application of a special splint over the magnet. To verify the diagnosis in the case of clinical suspicion of magnet dislocation after MRI, a Stenvers view radiograph, which showed a dislocated magnet as diagnosis confirmation in every case, was acquired in the present collective. The limitation of the present retrospective study is the lack of opportunity to specify the incidence of magnet dislocation in CI patients due to MRI. The total number of MRI examinations performed among our 2027 CI patients, including the complication-free MRI scans, could not be retrospectively determined. If this data had been available for analysis, the frequency and the individual risk of magnet dislocation in the case of MRI could have been specified. The assessment would also simplify indication determination and the counseling of CI patients prior to an MRI examination. The ideal situation in the clinical routine would include standardized documentation of MRI examinations in CI patients including the protocol used, the indication, and the use of the bandage technique according to the guidelines in order to provide an exact representation of the incidence of magnet dislocation and other complications such as heating of the implant. It is questionable whether clinical implementation of such follow-up is possible, primarily if CI patients undergo MRI examination at another radiology clinic or outpatient practice. In our experience, radiologists working outside of CI centers or on an outpatient basis are very conservative with MRI examinations in CI patients and recommend having examinations performed at the CI clinic’s radiology department. Moreover, CI clinics and CI manufacturers are often contacted by radiologists for advice in the case of questions regarding MRI guidelines in CI patients. Even without specification of the incidence, the present data show the necessity for precise and careful handling before and during MRI examination. Examining radiologists should always consider possible magnet dislocation in CI patients with magnets left in place during MRI examination. In the case of pain during or after MRI examination or problems connecting to the external speech processor, we recommend immediately performing a Stenvers view radiograph in order to ensure prompt diagnosis. Moreover, treatment ideally at the responsible CI clinic should be initiated immediately in the case of patients with magnet dislocation in order to avoid serious complications. It remains to be seen whether the above modification can reliably prevent magnet dislocation caused by MRI examination. Further research in the field of magnet and silicone pocket design and optimized guidelines for MRI ex-

Table 1: now include application of a splint directly on the scalp over the internal magnet in addition to the compression bandage [21]. This is made of a folded piece of paper, a plastic card, or a self-hardening adhesive (refer to Fig. 5 for details). The modification of the compression bandage seems to minimize the dislocation risk since it prevents possible rotation and shear movements of the internal magnet. At least, no additional MRI-based magnet dislocations have occurred at the University Freiburg during MRI examination of patients with a Cochlear® CI system since the introduction of the splint technique at the beginning of 2013 (n = 3 patients). The two described cases of MRI-based magnet dislocation in 2013 did not occur at our hospital. Both patients indicated that they wore a circular head bandage without application of a special splint over the magnet. To verify the diagnosis in the case of clinical suspicion of magnet dislocation after MRI, a Stenvers view radiograph, which showed a dislocated magnet as diagnosis confirmation in every case, was acquired in the present collective. The limitation of the present retrospective study is the lack of opportunity to specify the incidence of magnet dislocation in CI patients due to MRI. The total number of MRI examinations performed among our 2027 CI patients, including the complication-free MRI scans, could not be retrospectively determined. If this data had been available for analysis, the frequency and the individual risk of magnet dislocation in the case of MRI could have been specified. The assessment would also simplify indication determination and the counseling of CI patients prior to an MRI examination. The ideal situation in the clinical routine would include standardized documentation of MRI examinations in CI patients including the protocol used, the indication, and the use of the bandage technique according to the guidelines in order to provide an exact representation of the incidence of magnet dislocation and other complications such as heating of the implant. It is questionable whether clinical implementation of such follow-up is possible, primarily if CI patients undergo MRI examination at another radiology clinic or outpatient practice. In our experience, radiologists working outside of CI centers or on an outpatient basis are very conservative with MRI examinations in CI patients and recommend having examinations performed at the CI clinic’s radiology department. Moreover, CI clinics and CI manufacturers are often contacted by radiologists for advice in the case of questions regarding MRI guidelines in CI patients. Even without specification of the incidence, the present data show the necessity for precise and careful handling before and during MRI examination. Examining radiologists should always consider possible magnet dislocation in CI patients with magnets left in place during MRI examination. In the case of pain during or after MRI examination or problems connecting to the external speech processor, we recommend immediately performing a Stenvers view radiograph in order to ensure prompt diagnosis. Moreover, treatment ideally at the responsible CI clinic should be initiated immediately in the case of patients with magnet dislocation in order to avoid serious complications. It remains to be seen whether the above modification can reliably prevent magnet dislocation caused by MRI examination. Further research in the field of magnet and silicone pocket design and optimized guidelines for MRI ex-
amination in CI users are necessary before additional recommendations can be made.

Summary

Magnet dislocation is a serious complication in CI users that can occur with greater frequency during MRI examination. The examining radiologist should be aware of this risk even if the patient has an MRI-compatible CI. The particular recommendations of the manufacturer must be strictly followed. The user manual of the CI system or the manufacturer must be strictly followed even if the patient has an MRI-compatible CI. The particular recommendations of the manufacturer must be strictly followed.

Relevance of the study

- There is an increasing number of MRI examinations in cochlear implant patients
- There is a risk of subcutaneous magnet dislocation during MRI examination and if left untreated the dislocation can result in serious complications
- Precautions and recommendation of the manufacturer must be strictly followed

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