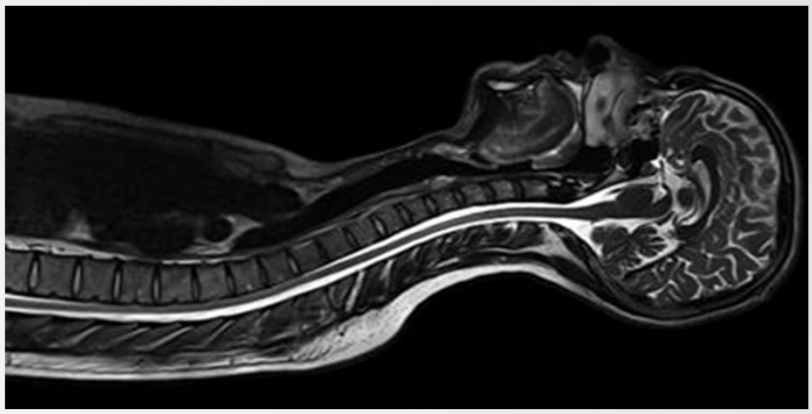

Hearing Implants and MRI: Issues and Safety

Darla Franz, VP Education
MED-EL North America

Martin Zimmerling, Head of Implant R&D
MED-EL Headquarters

Why Should This Topic Matter to Audiologists?

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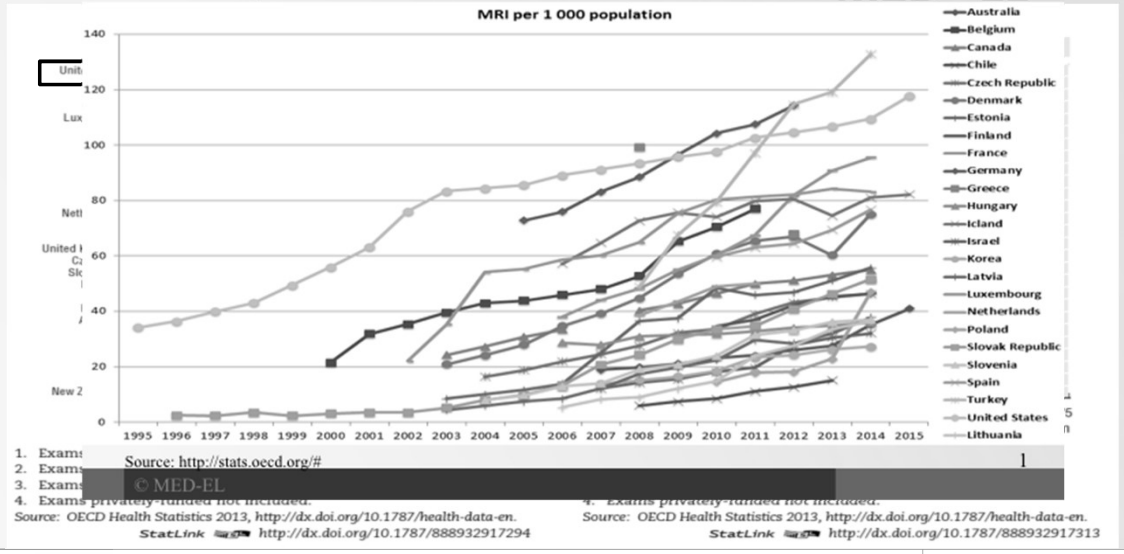
Numb

2015 MRI Usage Statistics from OECD



Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en.
StatLink http://dx.doi.org/10.1787/888932917294

Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en.
StatLink http://dx.doi.org/10.1787/888932917313

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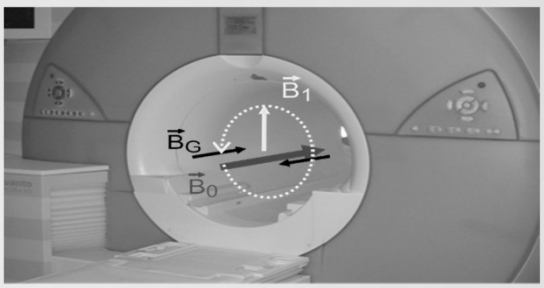
Possible Interactions with Implants



- **Static Magnetic Field:**
  - Linear force and torque
  - Magnet dislocation
  - Demagnetization
- **Radio Frequency Field:**
  - Voltage induction
  - Unintended stimulations
  - Heating (electrode contacts)
- **Magnetic Gradient Fields:**
  - Vibrations of the implant
  - Implant damage
  - Unintended stimulations
  - Heating (housing)
- **Influence on the MRI System:**
  - Image artifacts

MRI with MED-EL Implants

- 2001 First FDA approval of MRI at 0.2 T with axial magnet in place for the COMBI 40+ implant
  - Required company pre-authorization
  - International approval for 0.2T, 1.0T, 1.5T with magnet in place
- 2005 PULSAR implant FDA approved for 0.2T with axial magnet in place
- 2007 SONATA implant FDA approved for 0.2T with axial magnet in place
- 2013 MED-EL CONCERT, SONATA and PULSAR implants approved for MRI with the axial magnet in place 1.5 T
  - Prior authorization requirement was lifted
- At that point, literally hundreds of scans had been completed around the world on MED-EL implants with no major reported adverse events

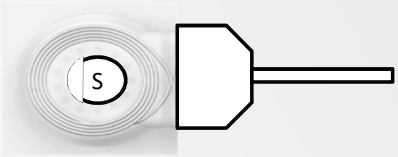
Recent News

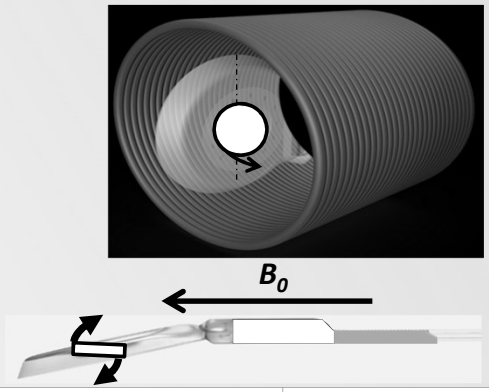
- 2015: SYNCHRONY implant with revolutionary diametric magnet approved for
  - 1.5T and 3.0T MRI with magnet in place
  - 1.5T and 3.0T MRI with magnet optionally removed
  - No pre-authorization requirement in the USA
  - Bandaging/splinting is *optional*
- 2016: Early COMBI 40+ implant received FDA approval for 1.5T MRI with axial magnet in place
  - Implanted 1998-2005 in the USA

Do All "MR Conditional" Approved Hearing Implants Behave the Same in MRI?

- Implant magnet design and fixation is the key to MRI safety

Some CIs with axial magnets placed in a silicone pocket:

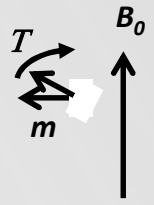




Magnet Design for SONATA and CONCERT

Torque = in standard position the magnet is nearly perpendicular to Bo. Torque is exerted, trying to align the magnet

Demagnetization = If the magnet cannot align, there is a risk of the magnet weakening

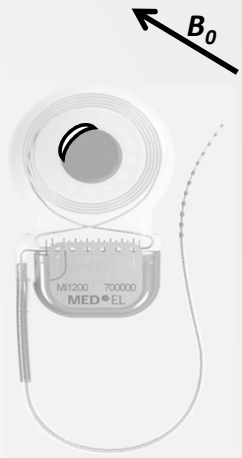


Design Feature to Reduce Pressure Footprint

Magnet fixation disc distributes lever arm force when torque is exerted

- Large pressure footprint with **very little pressure**
- Feature of all MED-EL titanium housing Implants

Pressure Footprint During MRI



For comparison:

What would happen without a magnet fixation disc:

There would be a pronounced, punctual pressure footprint.

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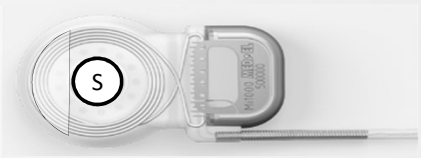
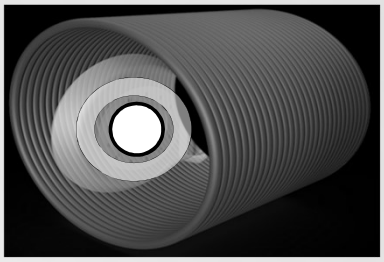
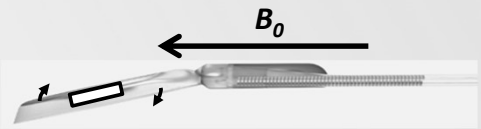
Do All "MR Conditional" Approved Hearing Implants Behave the Same in MRI?

- Implant magnet design and fixation is a key to MRI safety

SONATA, CONCERT: with axial magnet and magnet fixation disc







11

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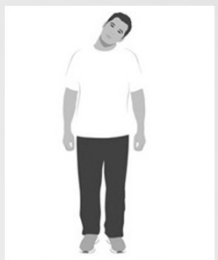
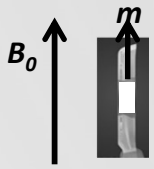
SYNCHRONY Implant Optimized for MRI

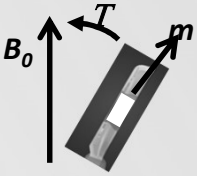
NEW! Diametrical Magnetization

Torque = in standard position the magnet can almost perfectly align with Bo, even if patient turns head to the side. Only if the patient tilts head to the side (not a typical MRI orientation) would torque be present.

Demagnetization = zero







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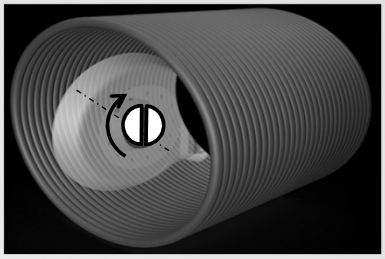
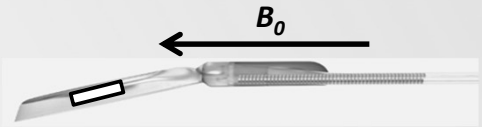
Do All "MR Conditional" Approved Hearing Implants Behave the Same in MRI?

- Implant magnet design and fixation is a key to MRI safety

SYNCHRONY with diametrical magnet and fixation disk:





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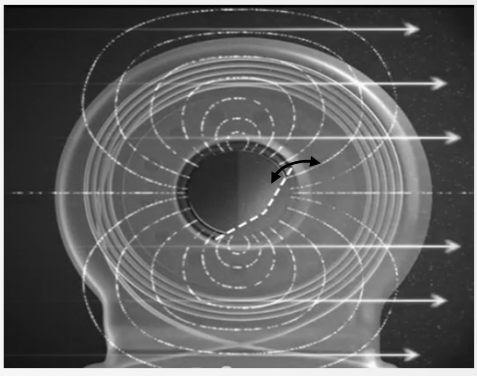
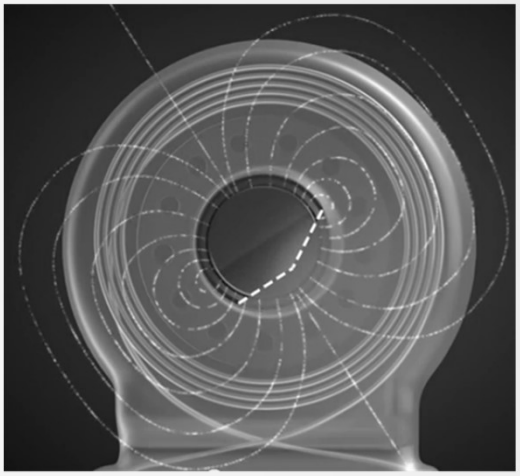
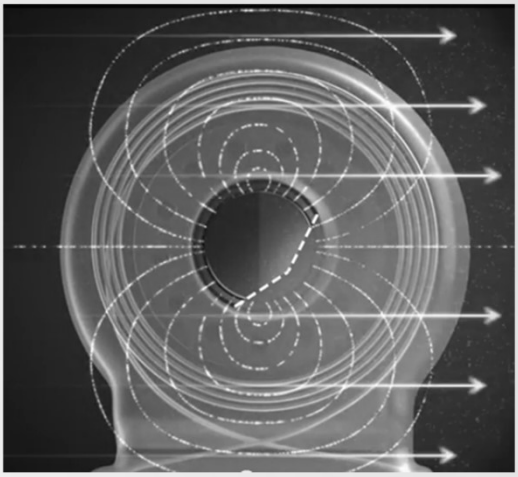
Self-Adjusting Magnet Optimized for MRI



- Diametrically magnetized internal magnet
- Placed to freely rotate in hermetic housing
- Aligns parallel to magnetic field
  - Implant magnet never weakens
  - Torque is close to zero
- Addresses increasing popularity of 3.0T scanners
- Patented design

Why Does It Matter?





Spontaneous Magnet Displacement

- BC Mickelson et al 2008: Child with minor head trauma resulting in magnet dislocation, then suffered a repeat dislocation after being hit with a snowball. AB device.
- Reported that 50 dislocations had been experienced (cited industry) and one other repeat dislocation

International Journal of Pediatric Otorhinolaryngology (2008) 72, 1071–1076

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International Journal of Pediatric Otorhinolaryngology

www.elsevier.com/locate/ijporl

Magnet dislodgement in cochlear implantation: Correction utilizing a lasso technique

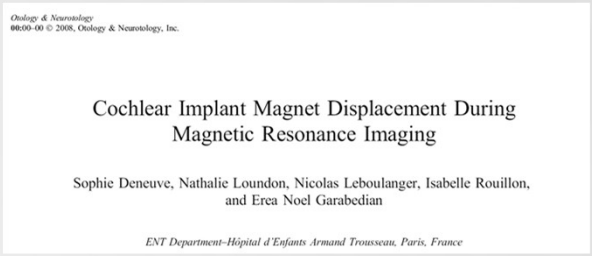
Jon-Ivar Mickelson, Frederick K. Kozak*

Division of Pediatric Otolaryngology, BC Children's Hospital, Division of Otolaryngology, University of British Columbia, 4480 Oak Street, Vancouver, BC, Canada

Received 10 January 2008; received in revised form 20 March 2008; accepted 22 March 2008

Magnet Dislodged During MRI

- 2008 Paris Deneuve et al
- Child with Cochlear device underwent successful MRI. 2nd MRI a year later resulted in pain, burning. Both MRIs followed manufacturer's instructions re compression dressing
- Two weeks later the patient developed pain and edema, magnet was found to be out of the pocket.



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Cochlear Implant Magnet Displacement During Magnetic Resonance Imaging

Sophie Deneuve, Nathalie Loundon, Nicolas Leboulanger, Isabelle Rouillon, and Erea Noel Garabedian

ENT Department–Hôpital d'Enfants Armand Trousseau, Paris, France

Spontaneous Magnet Displacement

- 2009 Swiss case report of 3 Cochlear patients who had spontaneous magnet dislocation
  - Magnetic toys that were placed near the implant
  - Impact resulting in dislocation of the magnet
- Authors suggest no longer implanting children with removable magnets!

Eur Arch Otorhinolaryngol
DOI 10.1007/s00405-009-1017-5

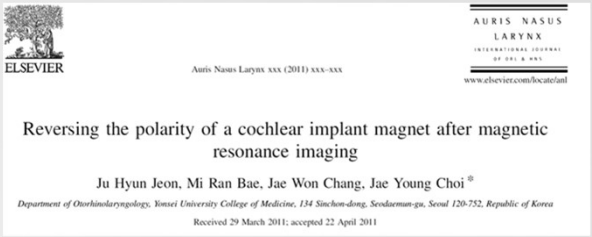
OTOLOGY

Magnet displacement: a rare complication following cochlear implantation

Corina Wild · John Allum · Rudolf Probst · Daniel Abels · Claude Fischer · Daniel Bodmer

Magnet Reversal

- 2011 Korea
- AB patient presented with opposite magnet polarity after 2nd 1.5T MRI with magnet in place (head bandage was used)
- Patient reported temporary sensation of magnet on end



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Auris Nasus Larynx xxx (2011) xxx–xxx

AURIS NASUS LARYNX

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Reversing the polarity of a cochlear implant magnet after magnetic resonance imaging

Ju Hyun Jeon, Mi Ran Bae, Jae Won Chang, Jae Young Choi *

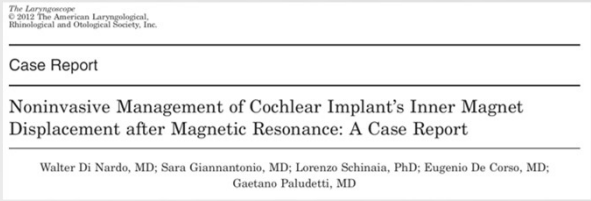
Department of Otorhinolaryngology, Yonsei University College of Medicine, 134 Sinchon-dong, Seodaemun-gu, Seoul 120-752, Republic of Korea

Received 29 March 2011; accepted 22 April 2011

- Authors surmise the magnet flipped in its pocket during the scan

Magnet Dislodged During MRI

- 2012 Rome
- Patient underwent MRI without contacting clinic, and without dressing
- Magnet flipped on end, and stayed that way
- Surgeon successfully manipulated magnet back into pocket through the skin



The Laryngoscope

Case Report

Noninvasive Management of Cochlear Implant's Inner Magnet Displacement after Magnetic Resonance: A Case Report

Walter Di Nardo, MD; Sara Giannantonio, MD; Lorenzo Schinaia, PhD; Eugenio De Corso, MD; Gaetano Paludetti, MD

Magnet Dislodged After MRI

- 2013 CI International Journal, Manchester UK
- Patient with bilateral Cochlear devices
- Pain bilaterally during scan, but images were obtained. 10 days later patient presented with bilateral skin reactions and left magnet displacement. Both magnets were eventually permanently removed for serial scanning.

Case report

Cochlear implants and magnetic resonance scans: A case report and review

Stephen J Broomfield[1], Melville Da Cruz[2], William P R Gibson[2]

[1]Manchester Cochlear Implant Centre, Manchester, UK, [2]Sydney Cochlear Implant Centre, Sydney, Australia

Retrospective Review: Adverse Events

- 2014 Kim et al Korea
- 18 patients in MRI at various locations / one or multiple scans (30 scans)
- 3 MED-EL patients (one had 4x brain scans + 2 lumbar spine scans). Remaining 15 patients all with "pocket" removable magnet designs (2 CC patients had 3.0T scans)
  - 8 / 15 had pain or discomfort during MRI
  - 5 / 15 MRI couldn't be completed due to pain and discomfort
  - 1 case each of magnet dislocation and magnet reversal
- All scans were uneventful for patients with MED-EL CI

Adverse Events and Discomfort During Magnetic Resonance Imaging in Cochlear Implant Recipients

Bo Gyung Kim, MD, PhD; Jin Won Kim, MD; Jeong Jin Park, MD; Sung Huhn Kim, MD, PhD; Hee Nam Kim, MD, PhD; Jae Young Choi, MD, PhD

JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2014.2926
Published online November 20, 2014.

Table 1. Characteristics of the CI Recipients

Patient No./ Sex/Age at CI, y	CI Device[a]	MRI Site	Reason for MRI	MRI Machine[b]	MRI Field Strength
1/M/24	Nucleus CI 24RE(CA)	Knee	Degenerative osteoarthritis	Philips Achieva	1.5 T
2/F/25	Nucleus CI 24RE(CA)	Lumbar spine (×2)	Malignant ependymoma, spinal cord	Philips Achieva	1.5 T
3/M/17	Nucleus CI 24RE(CA)	Knee (×3)	Ruptured anterior cruciate ligament	Philips Achieva	1.5 T
4/M/1	Nucleus CI 24RE(CA)[c]	Brain	Bacterial meningitis	Philips Achieva	1.5 T
5/F/17	Nucleus CI22M	Knee	Tear of discoid lateral meniscus	Discovery MR750	3.0 T
6/F/66	Nucleus CI 24RE(CA)	Brain	Traffic crash	Philips Achieva	1.5 T
7/F/54	Nucleus CI 24RE(CA)	Cervical spine	Traffic crash	Philips Achieva	1.5 T
8/F/66	Nucleus CI 24RE(CA)	Brain	Optic neuritis	Philips Achieva	1.5 T
9/F/38	Nucleus CI22M	Shoulder	Chronic pain	Philips Achieva	3.0 T
10/F/11	Nucleus CI512	Whole spine	Thoracic scoliosis	Philips Achieva	1.5 T
11/F/25	Clarion CII	Thigh	Degenerative osteoarthritis	Philips Achieva	1.5 T
12/M/2	Clarion CII	Brain	Preoperative evaluation before ABI	Philips Achieva	1.5 T
13/F/65	Clarion HiRes 90K	Right knee Left knee Lumbar spine	Degenerative osteoarthritis	Magnetom Essenza	1.5 T
14/M/4	Clarion HiRes 90K[c]	Brain	Preoperative evaluation before ABI	Philips Achieva	1.5 T
15/M/2 (R) 15/M/9 (L) 15/M/12 (R)	Clarion CII Clarion HiRes 90K Nucleus CI422	Brain (×3)	Diabetes insipidus Langerhans cell histiocytosis	Philips Achieva	1.5 T
16/F/6	MED-EL Combi 40+	Brain (×4) Lumbar spine (×2)	Medulloblastoma	Philips Achieva	1.5 T
17/F/60	MED-EL FLEXsoft	Thoracolumbar spine	Lumbar pain	Philips Achieva	1.5 T
18/M/35	MED-EL Pulsar	Wrist	Chronic pain	SIGNA HDxt	1.5 T

Review of Adverse Events

- 2015 Carlson et al, Mayo Clinic
- Retrospective case review of all CIs undergoing MRI between 2012-2014
- 19 ears, 34 MRI scans with bandaging and lidocaine (18 Cochlear and 1 AB)
  - 2 pts couldn't tolerate and required magnet removal
  - 1 pt experienced 2 episodes of magnet reversal, requiring surgical repositioning
  - 3 pts had canting of the magnet that was physically repositioned without surgery
  - 1 pt had 3 MRI studies with magnet removal, at 3rd surgery a tear was found in the silicone

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Magnetic Resonance Imaging with Cochlear Implant Magnet in Place: Safety and Imaging Quality

*†Matthew L. Carlson, *†Brian A. Neff, *†Michael J. Link, ‡John I. Lane, ‡Robert E. Watson, ‡Kiaran P. McGee, ‡Matt A. Bernstein, and *†Colin L. W. Driscoll

*Departments of Otolaryngology–Head and Neck Surgery, †Neurologic Surgery, and ‡Radiology, Mayo Clinic School of Medicine, Rochester, Minnesota, U.S.A.

No difficulty seeing necessary brain structures in 94% of pts receiving head MRI

Magnet Dislocation Not Visualized on Xray

- 2016 COSM Poster
- 5 year old child sustained a minor head trauma
- Magnet's silicone pocket torn both laterally and medially, with magnet displaced *medially* and not visible on Xray due to being under the R/S
- Search of manufacturer database revealed 49 cases in a one year period (2014-2015) of dislodged magnet due to trauma

Medial Displacement of Cochlear Implant Magnet Following Trauma

Mary Lauren Worthen, MD[1]; Arun Gadre, MD, FACS[1];
[1]Department of Otolaryngology-HNS and Communicative Disorders, University of Louisville School of Medicine

MED EL

680 Head/Neck

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

Authors F. Hassepass[1], V. Stabenau[1], S. Arndt[1], R. Beck[1], S. Bulla[2], T. Grauvogel[1], A. Aschendorff[1]

Affiliations [1] Department of Otorhinolaryngology-Head and Neck Surgery, University Medical Center Freiburg
[2] Department of Diagnostic Radiology, University Medical Center Freiburg

York - (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

Bandage ***does not*** prevent issues with pain and discomfort

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The MRI Landscape Continues to Change

- Rapidly increasing prevalence of 3.0T scanners
- Diagnostic need for increased scanner resolution
- Rapidly increasing rate of MRI usage as diagnostic tool of choice
- Clear desire from the field of medicine to make high resolution scanning more feasible
- Clear desire from recipients with significant medical issues to make MRI easier/more comfortable

Tests to Demonstrate MRI Safety

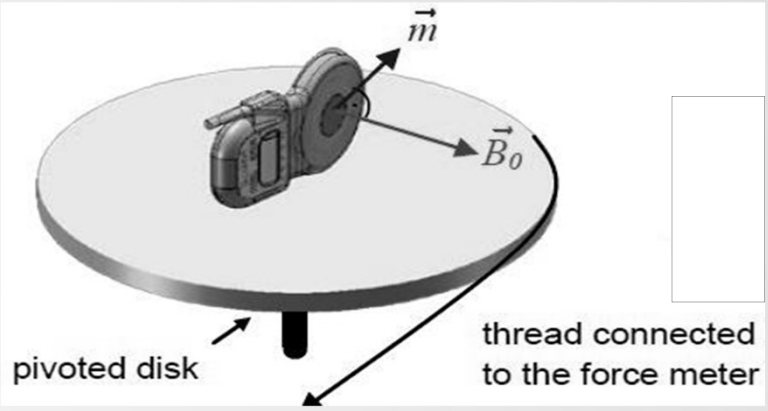
- All testing done to ASTM standards
- Some testing done by MED-EL using a clinical scanner
- Some testing done at external test houses

MRI Testing with MED-EL Cochlear Implants

- Force at entrance of scanner vs gravitational force
- If the angle of the attractive force is less than 45 degrees, the implant isn‘t subjected to a force greater than gravity at the scanner entrance

MRI Testing with MED-EL Cochlear Implants

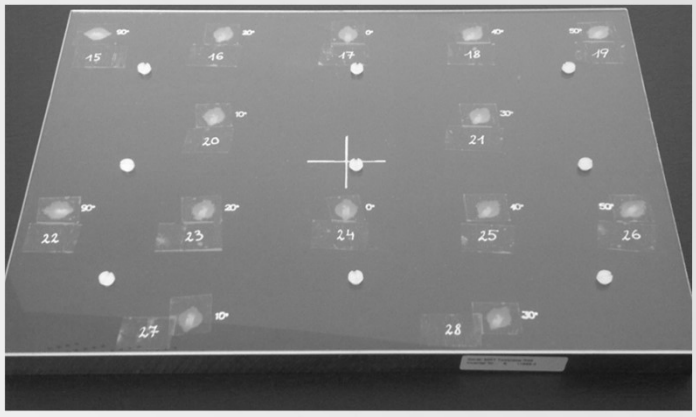
- Torque:
  - Pain
  - Magnet dislocation



MRI Testing with MED-EL Cochlear Implants

Demagnetization

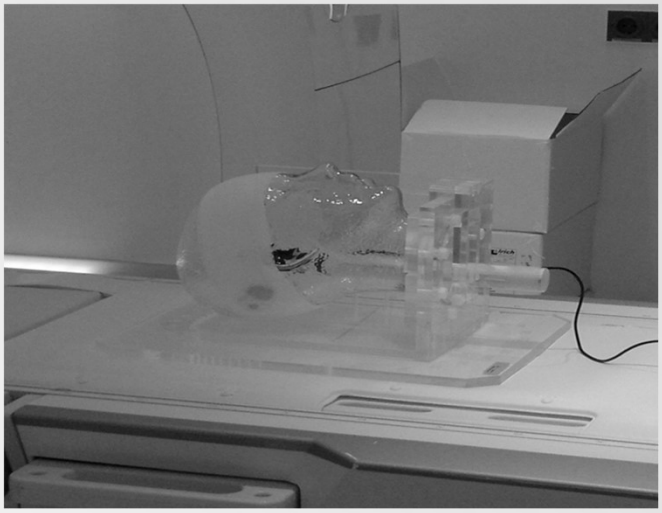
- Magnet weakening occurs within a fraction of a second
- Test before and after
- Repeat x 10
  - Demagnetization isn‘t linear
  - If orientation angle is unchanged, subsequent scans don‘t increase the exposure



MRI Testing with MED-EL Cochlear Implants

Magnet dislocation

- Glass model of the head
- Implant affixed with bandage (optional when scanning clinically)
- Tiny CCD camera monitors movement to ensure the magnet does not dislocate during the scan

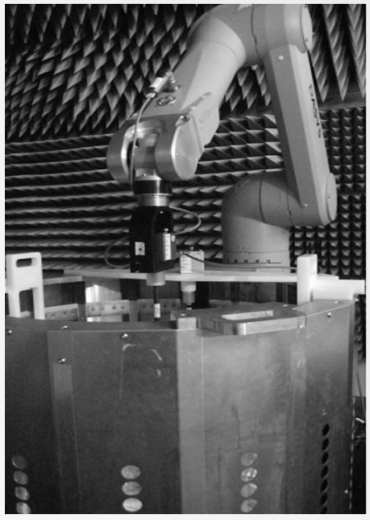


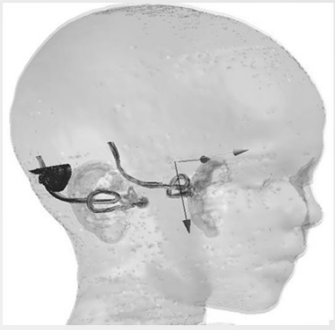
MRI Testing with MED-EL Cochlear Implants

Testing done at external test houses:

- Heating (gradient fields)
- Heating (RF field)
- Unintended stimulation (gradient fields)
- Unintended stimulation (RF field)
- Robustness against MRI sequences
- Image artifacts

External Testing: Heating

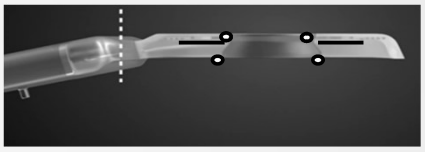




Not just the magnetic field but a combination of measurement and stimulation together

- Properties of the skull and brain
- Thermal conductivity
- Thermal capacity
- Electrical capacity
- Electrical conductivity
- Variety of electrode trajectories
- Electrode in liquid vs air

Magnet Fixation and Removal



Goal: Remove the magnet only when necessary

- Magnet housing has double-conical shape in cross-section
- Magnet fixation disc supports snap-in locking mechanism and force distribution
- Thin, smooth polymer coating of titanium housing to prevent cell adhesion
- Magnet removal only in medial direction

Magnet Extraction Force

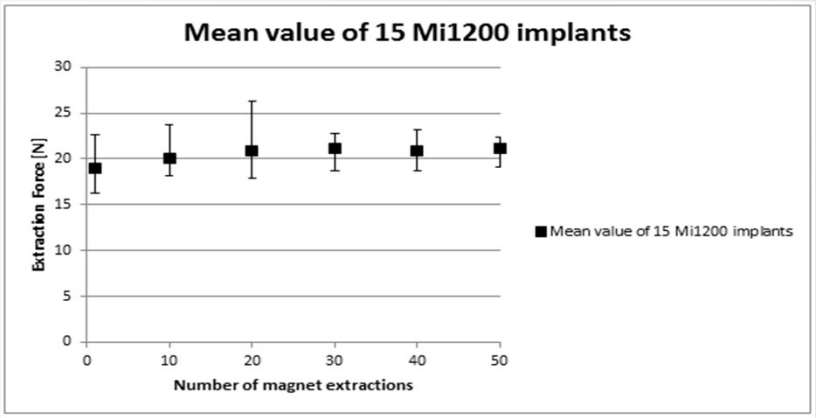
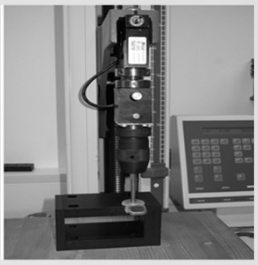
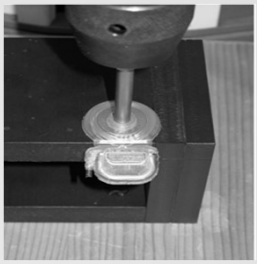


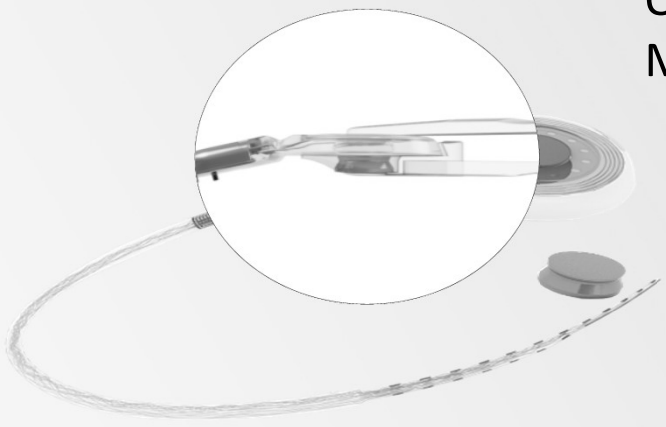
Figure 3: *Mean values of magnet extraction forces measured for 15 Mi1200 implants vs number of magnet extractions.*





No fatigue even after 50 removals and reinsertions

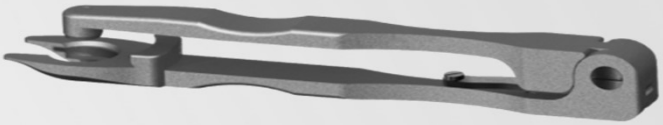
SYNCHRONY Cochlear Implant



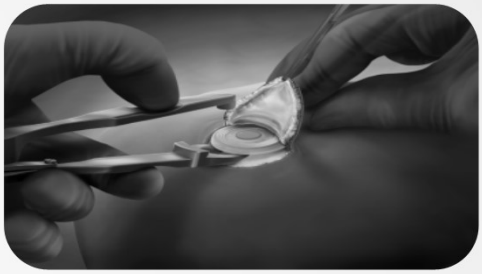
Optionally Removable Magnet

- Minimized image distortion on MRI head scans
- Non-Magnetic Spacer available for repeated head scans
- Simple procedure with dedicated instruments

Magnet Removal Tool



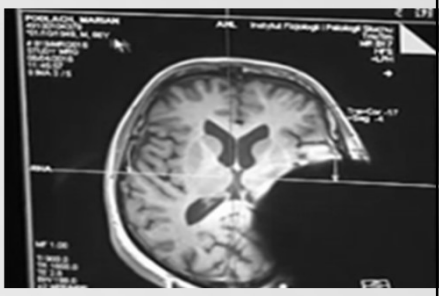
The magnet is pushed out to the bottom



Magnet Insertion Tool

To reinsert the magnet into the implant

Magnet Replacement Kit



Courtesy Prof Skarzynski, Poland

Non-Magnetic Spacer

Replacement Magnet

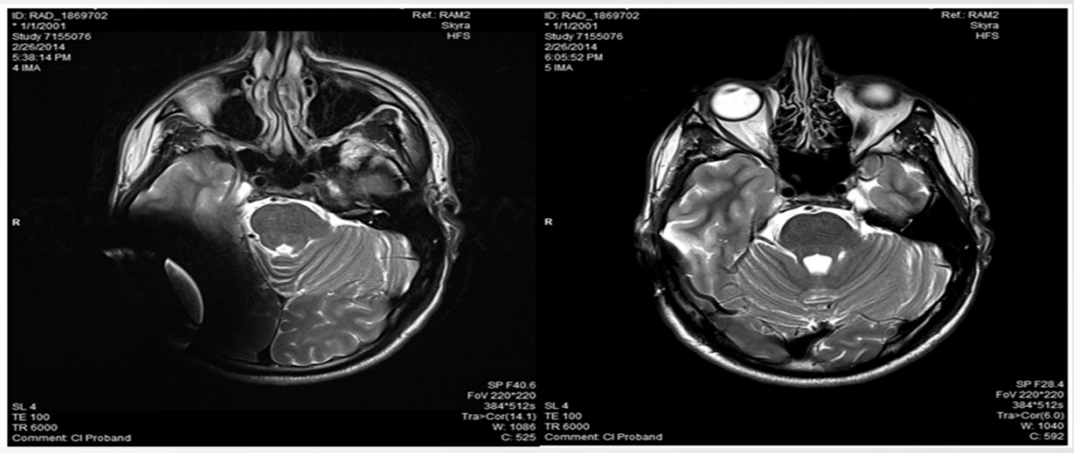
Sterile & Single-use

MR Image Artifact at 1.5 Tesla

With implant magnet

With non-magnetic spacer

MR Image Artifact at 3.0 Tesla



With implant magnet

With non-magnetic spacer

MRI Safety Classification of Implants

~~MR~~ **MR Safe**

~~MR~~ **MR Unsafe**

MR Conditional

The SYNCHRONY Implant

- **Patented** magnet design
- **FDA approved** and labelled as
  MR conditional at 1.5 and 3.0 Tesla
  (with magnet in place)
- Magnet is optionally removable
- Safe and comfortable for the patient
- Increased image resolution for the physician

How Often Does the Magnet Really Need to be Removed?

MED-EL

What is the Real Need for Magnet Removal?

- MED-EL "*rough estimate*": 4-5% of patients may need magnet removal
  - Field experience from earlier days (number of devices implanted vs. number of cases where the implant had to be removed to reduce artifact)
    - A factor of 2-3 added to accommodate for some patients who had CT rather than MRI/removal
  - Global MED-EL ABI experience with NF2 patients who need MRI every 6-12 mos: not one single ABI removed for MRI
  - MRI artifact reduction sequences now available which can reduce artifact by 25-30% may improve efficacy

ABI not FDA approved in the USA

MED-EL

Overview: Brain MRI

in US hospitals (in 2007 and 2010)

Anatomical region	2007	2010	Portion
Brain and Neck	32%	29%	30%
Spine	27%	25%	70%
Extremity	20%	24%	
Vascular (MRA)	9%	8%	
Pelvic & Abdominal	7%	7%	
Breast	2%	4%	
Chest, other cardiac	3%	4%	
Other (Inc. interventional)	1%	1%	

(GIA; Report linker, US, 2010)

MED EL

What is the Real Need for Magnet Removal?

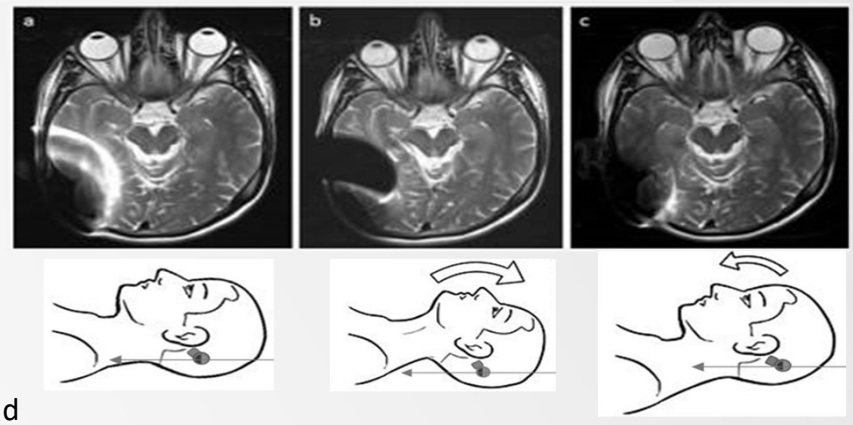
- Lifetime prevalence of neurological disorders requiring MRI in patients with CI = 6.25%
  - MacDonald et al “The incidence and lifetime prevalence of neuro disorders in a prospective community’ Brain, 2000.
  - Could we assume that only some of these cases would require imaging the region of the brain immediately around the implant that overlaps with artifact?

COVERSTORY I

MRT bei Patienten mit Cochlea-Implantat – Sicherheit und Optimierung der Bildgebung

v. B. Henninger und Ch. Kremser

ERG
Österreichische Röntgengesellschaft
Gesellschaft für Medizinische Radiologie
und Nuklearmedizin



T2w TSE sequence

MRI artifact can be shifted out of slice by head orientation.

This is only possible with SYNCHRONY!

head orientation: normal neck stretched neck bent

THIEME OPEN ACCESS

Magnetic Resonance Imaging in a Neurofibromatosis Type 2 Patient with a Novel MRI-Compatible Auditory Brainstem Implant

Matthew Shew[1] Judson Bertsch[2] Paul Camarata[3] Hinrich Staecker[1]

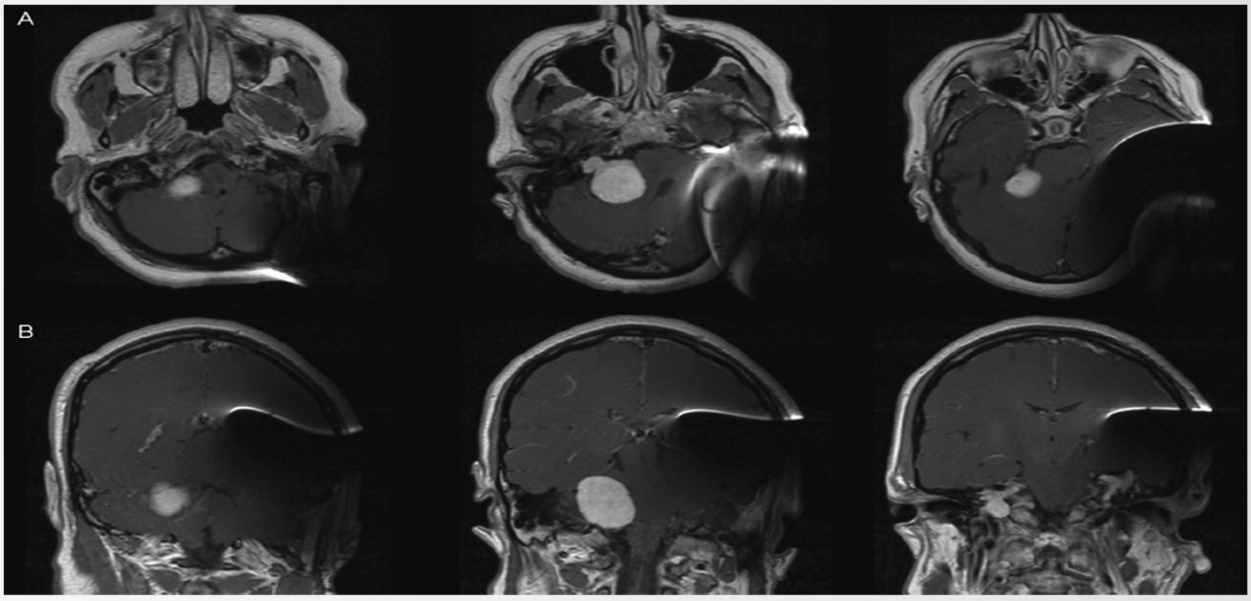
J Neurol Surg Rep 2017;78:e12–e14.

- Case report on 1.5 Tesla MRI in a NF2 Patient with SYNCHRONY ABI in the US
- Synchrony was chosen (FDA exemption) because of MRI need and the high level of MRI safety of SYNCHRONY
- All together 7 MRI scans successfully performed
- Good visibility of tumor in cerebellopontine angle

Matthew Shew[1] Judson Bertsch[2] Paul Camarata[3] Hinrich Staecker[1]

J Neurol Surg Rep 2017;78:e12–e14.

MED EL



© MED-EL

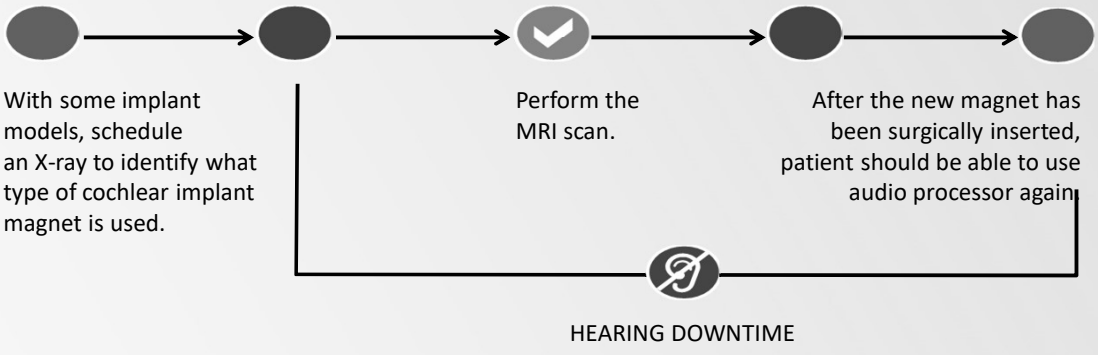
What Are the Ramifications for the Patient?

Magnet removal and replacement

- Two surgeries
- Insurance preauthorization for both
- Need to order/purchase a replacement magnet
- Necessary each time a repeat MRI is ordered
- Scar tissue development around multiple incisions

MRI Scans

With Competitors' Implants



MRI Scans

With MED-EL SYNCHRONY

Plan MRI.

Perform the MRI scan.

The MRI is a routine procedure, and MED-EL patients can go back to using their audio processor right away.

MRI Scans

With MED-EL SYNCHRONY

No Surgery
No Discomfort
No Hearing Downtime

MRI Scans

With MED-EL SYNCHRONY

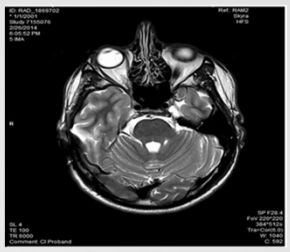
No other cochlear implant brand is FDA-approved for MRI at 3.0 Tesla without requiring additional surgery to remove the magnet.

SYNCHRONY Implant

Feedback & field experience June 2017:

- 38 months since market introduction, 27 months on US market
- Very positive clinical experience
- Not a single magnet has been weakened in MRI
- Not a single magnet dislocated in the course of an MRI or due to a mechanical impact over the implant
- So far only four cases of SYNCHRONY magnet removal for MRI, one completed here in the US

@3.0 Tesla

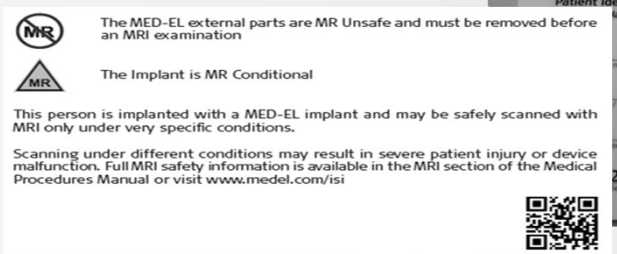


Where to Easily Find Scanning Instructions

- *Important Safety Information* link, found at the bottom of all MED-EL web pages

Where Can MRI Safety Info Be Found?

- Product labeling
  - Medical Procedures Manual
  - Patient ID Card
  - User Manual



YouTube Instructional videos

Go to the MED-EL YouTube Channel, or

Search for “MRI MED-EL”

MED EL

- How likely are you to stress the importance of MRI compatibility with cochlear implant candidates?
  - Very likely
  - Somewhat likely
  - Not likely

  Do you feel more confident discussing MRI issues with recipients and candidates?
  - Yes
  - No