Magnetic Resonance Imaging in Patients with Cochlear Implants without Magnet Removal: A Radiology-Administered Protocol to Enhance Operational Efficiency and Improve Workflow

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Objective: To describe the development, implementation, and validation of a radiology-administered protocol to obtain magnetic resonance imaging (MRI) in patients with cochlear implants and auditory brainstem implants without magnet removal.

Study Design: Retrospective review and description of novel care pathway.

Methods: A radiology-administered protocol was designed based on careful input from the radiology safety committee and neurotology. Radiology technologist training modules, consent instructions, patient educational material, clinical audits, and other safeguards were implemented, with samples provided in this report. The primary outcomes measured included instances of magnet displacement during MRI and premature termination of MRI studies secondary to pain.

Results: Between June 19, 2018, and October 12, 2021, 301 implanted ears underwent MRI without magnet removal, including 153 devices housing diametric MRI-conditional magnets, and 148 implants with conventional axial (i.e., nondiametric) magnets. Among cases with diametric MRI-conditional magnets, all studies were completed without magnet dislodgement or need to terminate imaging early due to pain. Among cases with conventional axial (nondiametric) magnets, 29 (19.6%) MRI studies were stopped prematurely secondary to pain or discomfort; the overall

rate of this event was 9.6% (29 of 301) among the entire study cohort. In addition, 6.1% (9 of 148) experienced confirmed magnet displacement despite headwrap placement; the overall rate among all cases was 3.0% (9 of 301). Eight of these patients received successful external magnet reseating through manual pressure on the external scalp without surgery, and one required surgical replacement of the magnet in the operating room. There were no documented instances of hematoma, infection, device or magnet extrusion, internal device movement (i.e., gross receiver-stimulator migration), or device malfunction in this cohort related to MRI. Conclusions: We present the successful implementation of a radiology-administered protocol designed to streamline care for cochlear implant and auditory brainstem implant recipients who require MRI and ease clinical demands for otolaryngology providers. Examples of resources developed, including a process map, radiology training modules, consent instructions, patient educational materials, clinical audit, and other procedural safety measures are provided so interested groups may consider adapting and implementing related measures according to need. Key Words: Cochlear implantation-Magnet removal-Magnetic resonance imaging.

Otol Neurotol 00:00-00, 2023.

INTRODUCTION

Cochlear implantation is an well-established safe and effective rehabilitative option for adults with moderate to profound sensorineural hearing loss (SNHL) who no longer sufficiently benefit from hearing aids (1). As of December 2019, over 736,900 people have received a cochlear implant worldwide and it is estimated that at least 1.2 million adults in the United States and 50 million adults globally have at least severe hearing loss and may benefit from this technology (1,2). There has also been an increase in magnetic resonance imaging (MRI) use observed, with an average of 82 MRIs being performed per 1,000 people in high-income countries, increasing to 118 MRIs per 1,000 people in the United States within the last decade (3). Correspondingly,

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Sources of support and disclosure of funding: Internal departmental funding was used without commercial sponsorship or support.

Conflict of interest: The authors disclose no conflicts of interest. Institutional Review Board Approval: Mayo Clinic Institutional Review Board Protocol 6-006130.

Statement of Originality: This material has not been previously published in part or whole and is not currently under consideration for publication elsewhere.

Supplemental digital content is available in the text. DOI: 10.1097/MAO.00000000003898

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the number of cochlear implant recipients who have undergone MRI and who will have a diagnostic MRI recommended in the future continues to rise.

Early cochlear implant models were considered MRI unsafe, and imaging was only performed after the internal magnet was removed under strict imaging specifications (4). Although considered "off-label", several centers began performing MRI studies in patients with retained internal magnets after applying a tight headwrap, through specialized scanning protocols (5-7). These protocols typically required coordination of a radiologist, a MR safety physicist, and an otolaryngologist, to enhance safety and imaging results. Between 2014 and 2019, all three FDA-approved cochlear implant device manufacturers have released MRI conditional devices, for field strengths between 1.5 and 3.0 T, that incorporate internal magnets that dynamically align (e.g., roll, rotate) with the MR static magnetic field to reduce untoward translational forces. Despite these developments, many centers do not routinely scan patients with retained internal magnets, given attendant concerns of patient safety and escalated resources required for such protocols.

The authors' center has performed MRI on cochlear implant and auditory brainstem implant recipients without magnet removal since January 2012 (5,8). With initial protocols, an otolaryngology provider was required to meet patients in the MRI suite to assist with pre-scan head wrapping and post-scan evaluation to examine for cochlear implant magnet dislodgement or other adverse events. Although this protocol was successful in producing quality MR imaging with a relatively low rate of adverse safety events, routine participation of an otolaryngology provider often resulted in delays in radiology workflow. Similarly, increasing demand for this service resulted in increasingly strains on the otolaryngology service. Thus, a revised radiology-administered protocol, without routine otolaryngology provider involvement, was jointly conceived and refined by the otolaryngology and radiology departments to enhance operational efficiency and improve workflow. The present study seeks to describe this recently implemented radiology-administered protocol and provide sample resources so interested centers may consider adapting and implementing related measures according to need.

METHODS

Institutional review board authorization was obtained before initiation of this study (16-006130). All cochlear implant and auditory brainstem implant recipients who underwent MRI with an internal magnet in place were included, encompassing a range of device models from all three FDA-approved cochlear implant manufacturers: Cochlear Corporation (Sydney, Australia), MED-EL GmbH (Innsbruck, Austria), and Advanced Bionics Corporation (Valencia, CA). Specifically, this scanning protocol was inclusive of all cochlear implant models, irrespective of MR conditional status.

Beginning June 19, 2018, a revised radiology-administered protocol was implemented to streamline workflow and reduce clinical disruption; a process map is presented in Figure 1 and further detailed here. When a provider places an order for MRI, whether head imaging or otherwise, a series of order prompts investigate whether the patient has a cochlear implant or other implantable devices. If an order is placed for an MRI study on a patient with a cochlear implant, the MRI scheduling team emails the institutional MRI Safety Officer (MRSO). If the order request is reviewed and approved by the MRSO, the make and model of the cochlear implant is determined, manufacturer MR guidelines are reviewed, and the patient is scheduled under the protocol as indicated. Patients with self-aligning magnets [i.e., Advanced Bionics Hi Res Ultra 3D, MED-EL SYNCHRONY, and Nucleus Profile Plus Implant (Cochlear CI 600)] do not require head wrapping for MRI and thus are not scheduled in "device slots." In this protocol, all patients without self-aligning internal magnets undergo headwrap placement and are scheduled in a "device slot" where the patient is matched to an MRI technologist trained in obtaining imaging with a cochlear implant magnet in place and with an overseeing MR safety physicist present.

On the day of the MRI, the MRSO delivers a printout of the device make and model and a cochlear implant device checklist (Appendix I, http://links.lww.com/MAO/B628) to the scanner where the patient is scheduled. Upon arrival, informed consent is obtained, which includes a discussion surrounding the estimated risks of performing the MR study with the magnet in place, and alternative options, including magnet removal (Sample Informed Consent Form, Appendix I, http://links.lww.com/MAO/B629). The protocol trained MRI technologist then screens the patient for MRI safety and completes the device checklist through the exam process. After safety screening, the patient is brought to American College of Radiology (ACR) MRI Zone III⁹ (i.e., the locked controlled access zone which includes the MRI control panels and other support components, but is outside Zone IV, the magnet room itself) where they are provided basic instructions about optimal positioning, what to expect during the exam, and how to report discomfort.

The external processor of the cochlear implant is then removed, a headwrap is placed if indicated (Fig. 2) (5,8), and the patient is positioned supine on the MRI table. Currently, headwraps are used for every device without an MRI conditional self-aligning magnet; those with a self-aligning magnet do not receive a headwrap. Briefly, headwrap placement consists of centering a 2-by-2-inch square of flat thermoplastic splinting material over the cochlear implant magnet, followed by limited gauze sponges or gauze wrap, and then a Coban self-adherent wrap (3 M Health Care; Saint Paul, MN) with the goal of obtaining a snug wrap (5,8). Ideally, the patient should report a uniformly snug feeling, without focal tenderness or true "pain;" because a typical MR examination often requires more than 40 minutes, any pain experienced early on will only magnify with time.

Patients are then slowly wheeled into the scanning room (ACR Zone IV (9)), where the MRI is performed with the physicist assisting in planning for specific absorption rate (SAR) and metal suppression techniques, as previously described (5). Typically 1.5 T MRI is used, however, if a

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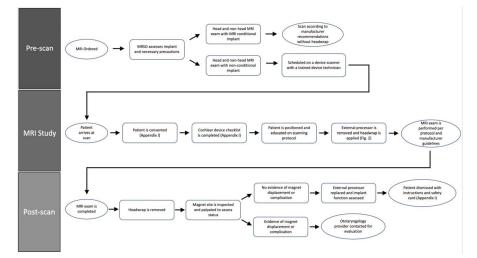


FIG. 1. Process map detailing protocol for obtaining MRI in patients with cochlear implant or auditory brainstem implant magnets in place, from ordering of the MRI through dismissal of the patient.

specific MR sequence is performed using a 3T scanner and the patient has a 3 T conditional device, then the MRI study is conducted on a 3T scanner. To limit force and torque on the cochlear implant or auditory brainstem implant magnet, "dockable" examination tables are used for patient positioning outside the examination room, and patients are then brought slowly straight into the bore (without angulation) of the MR scanner to reduce translational forces on the internal device and potential discomfort (5,8,10). During MR examination, the SAR is limited to maximal value of 1.0 W/kg, and a certified medical physicist ensures this limit is not exceeded (5,8). A previous publication details strategies used to reduce imaging artifact (8).

After completion of the MR scan, the patient is slowly wheeled out of ACR Zone IV (9) in the same manner to minimize translational and torque forces. In ACR Zone III (9), the patient is returned to the upright position, the headwrap is removed if used, and the receiver-stimulator site is inspected visually and by palpation. If any concern for magnet tilt or rotation is detected, an otolaryngology provider is contacted for evaluation. In people with thin scalp tissue, identifying displacement is often straightforward. However, for people with thick scalps, or in cases of suspected mild displacement, an oblique plain film x-ray, or use of ultrasound may be used

to clarify magnet seating (Fig. 3) (8,11). It is worth noting that some devices with removeable magnets are subject to silicone magnet housing fatigue and small tears that may occur during past magnet removal, which heightens risk of future magnet displacement. If no sign of dislodgement, the external processor is replaced, and baseline device functionality is subjectively confirmed by the patient. The patient is then given a small safety card outlining postimaging symptoms that may indicate magnet rotation or displacement (Appendix I, http:// links.lww.com/MAO/B630), which includes the phone number to the otolaryngology appointment scheduling desk. If no concerning signs or symptoms are present, the patient is then accompanied back to the Zone II (9), examined by nursing staff as indicated (e.g., IV removed if contrast given), escorted back the MRI lobby, and dismissed. Any adverse events noted are carefully documented and investigated with the goal of achieving maximum patient safety and process improvement.

The MRI safety group maintains a detailed record of all MRI studies performed on patients with cochlear implants, with or without magnet removal. This record includes device make and model, anatomic site/subsites imaged, magnet rotation or displacement, premature examination termination secondary to discomfort, free text entry to archive

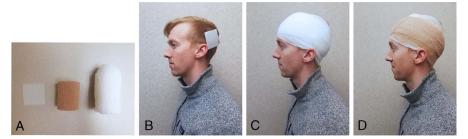


FIG. 2. Headwrap materials and stepwise protocol. Panel A demonstrates key supplies, including thermoplastic splint, gauze wrap, and Coban wrap. Panel B shows the approximate positioning of the thermoplastic splint, followed by placement of the gauze wrap (panel C) and Coban (panel D) (used with permission; Fussell WL, Patel NS, Carlson ML et al. Cochlear implants and magnetic resonance imaging: Experience with over 100 studies performed with magnets in place. Otol Neurotol 2021; 42:51–58).

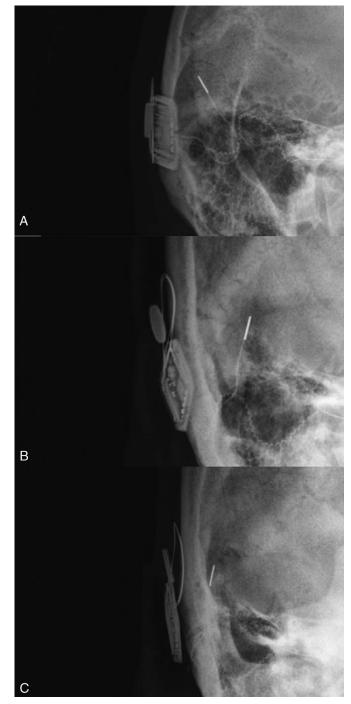


FIG. 3. Panel A demonstrates an oblique plain radiograph of a right cochlear implant demonstrating the magnet coplanar with the radiofrequency coil of the internal device. Panels B and C demonstrate oblique views of a left cochlear implant showing a tilted magnet out of plane with the coil (used with permission; Fussell WL, Patel NS, Carlson ML et al. Cochlear implants and magnetic resonance imaging: Experience with over 100 studies performed with magnets in place. *Otol Neurotol* 2021; 42:51–58).

general information about patient experience, and other rare but potential adverse events. For the purposes of this study, a magnet was considered dislodged if magnet dislodgement was confirmed via palpation, or less commonly from imaging, by an otolaryngology provider. These records are regularly audited by the MRI safety team in conjunction with a designated cochlear implant surgeon and compared with historic data to ensure patient safety, operational efficiency, and to inform the need for protocol revision. In addition, educational updates and refresher material are provided to trained technologists based on protocol performance and updates to device models that may

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impact the protocol. Training consists of both online educational modules, and in-person traineeship under the direction of an experienced MRI technologist. Online educational modules were created through collaboration between the MR safety group and the senior author (M.L.C.), a cochlear implant surgeon. In brief, the modules review internal and external cochlear implant components, possible complications (e.g., canting/tilting, reversal of polarity), artifact created by the cochlear implant magnet, and an overview of patient educational materials including consent, a safety card, and contact information (Fig. 4). In addition, a video example of placing a headwrap over the cochlear implant is included in the online modules.

RESULTS

Study Population

Between June 19, 2018, and October 12, 2021, 162 unique implant recipients with retained internal device magnets underwent MRI studies using the radiology administered protocol. The median age at time of MRI study was 66 years (IQR, 52.1-79.9 yr), 112 (69.1%) were male, and 31 (19.1%) had bilateral cochlear implants. Considering that some subjects received more than one MRI study under this protocol and many had bilateral cochlear implants, the total number of times a cochlear implant underwent MRI in this study was 301, including 153 implants housing

diametric MRI-conditional magnets, and 148 implants with conventional axial (i.e., nondiametric) magnets. Table 1 presents device data for the study cohort.

Outcomes for Patients With MRI-Conditional Cochlear Implant Magnets

During the study period, there were 153 device-ears housing diametric MRI-conditional magnets (up to 1.5 T) that underwent MRI that did not require headwrap placement (Table 1). All studies were completed without magnet dislodgement or need to terminate imaging early due to pain. No other patient- or device-related complications associated with MRI were documented in this cohort.

Outcomes for Patients With Conventional Axial (Not MRI-Conditional) Cochlear Implant Magnets

During the study period, there were 148 device-ears housing conventional axial (i.e., not MRI-conditional) internal magnets that underwent MRI that received a headwrap. Within this subpopulation of subjects, 29 (19.6%) MRI studies were stopped prematurely secondary to pain or discomfort; the overall rate of this event was 9.6% (29 of 301) among the entire study cohort (Table 2). The rate of this event by manufacturer was 18.8% (26 of 138) for non-MRI-conditional Cochlear Corporation devices and 30.0% (3 of 10) for non-MRI-conditional Advanced Bionics Corporation devices (p = 0.41).

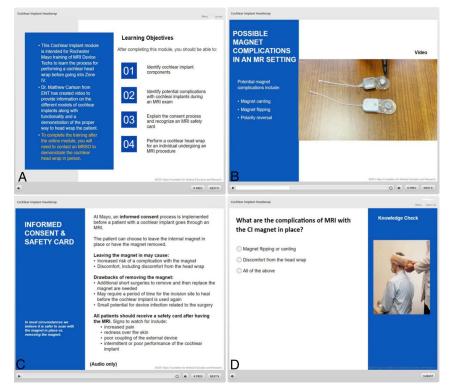


FIG. 4. MRI technologist online training module excerpts. Introduction to the module and course objectives (panel A). Slide demonstrating components of a cochlear implant and an example of a canted/tilted magnet (panel B). Instructions regarding informed consent process (panel C). Example of headwrap and questions about symptoms of complications of MRI with cochlear implant or auditory brainstem implant magnets in place (panel D).

TABLE 1.	Device data for 301 implanted ears that underwent
an	MRI study with the internal magnet in place

MRI Conditional Make and Model	n	%	Total (153)
Advanced Bionics Corporation			
Hi Res Ultra	2	1.3	24
Hi Res Ultra 3D	22	0.1	
Cochlear Corporation			
CI612	3	2.0	32
CI622	22	14.4	
CI632	7	4.6	
MED-EL GmbH			
Concert	16	10.5	97
Sonata	1	0.7	
Synchrony	80	52.3	
Nonconditional Make and Model	n	%	Total (148)
Advanced Bionics Corporation			10
HiRes 90K	7	4.7	
HiRes 90 K Advantage	3	2.0	
Cochlear Corporation			
CI24	2	1.4	
CI24M	1	0.7	
CI24RCA	1	0.7	
CI24RE	37	25.0	
CI422	15	10.1%	
CI512	13	8.8	
CI522	49	33.1	
CI532	4	2.7	
ABI 24M	13	8.8	
Nucleus ABI541 (ABI)	3	2.0	

Among cases with non–MRI-conditional internal magnets, 6.1% (9 of 148) experienced otolaryngology provider confirmed magnet displacement despite headwrap placement; the overall rate among all cases was 3.0% (9 of 301). Eight of these patients received successful external magnet reseating through manual pressure on the external scalp without surgery, and one required surgical replacement of the magnet in the operating room. The rate of this event by manufacturer was 6.5% (9 of 138) for non–MRI-conditional Cochlear Corporation devices and 0% (0 of 10) for non–MRI-conditional Advanced Bionics Corporation devices (p = 1.0). There were no documented instances of hematoma, infection, device or magnet extrusion, internal device movement (i.e., gross receiver-stimulator migration), or device malfunction in this cohort related to MRI.

DISCUSSION

Indications for MR imaging and the number of patients with cochlear implants are increasing worldwide, and thus the number of implant recipients who will need MRI continues to rise (2,3). Between January 2012 and June 2018, the authors' center used a protocol that required regular in-person participation of an otolaryngology provider before and after each MR study. In earlier years, workload under this model was tenable given a relatively low demand. However, with time, increasing demand resulted in escalating MR workflow inefficiencies (e.g., waiting for ENT provider availability) and clinical strains on the part of the otolaryngology service. These changes motivated the development and refinement of the described radiology-administrated protocol, that was developed through close collaboration between the Departments of Radiology and Otolaryngology. The protocol described herein has enhanced workflow in the Radiology Department, decreased burden for otolaryngology providers, and enhanced patient safety when compared with a reference cohort. Most importantly, like past protocols, it allows most patients to undergo MR imaging without needing two procedures for magnet explantationreimplantation and attendant risks (12). This study also reported no cases of magnet complications or need to prematurely terminate imaging acquisition for pain in patients with MRI-conditional internal magnets, underscoring the benefit of new diametric magnet designs. Notwithstanding, given the large number of patients previously implanted with conventional axial magnets, before availability of MRI conditional devices, centers should anticipate continued need to accommodate imaging needs among patients implanted with earlier generation devices for many years to come.

Published rates of adverse events among cochlear implant recipients undergoing MRI without magnet removal vary from 3.5% to 33% according to study definitions and experience (8,13–15). In this cohort, there was a relatively low rate of magnet-related complications. Specifically, 6.1% who had nonconditional devices and were scanned with magnet in-situ experienced magnet displacement, of which only one required surgical magnet reseating; the overall rate among the entire cohort was 3.0%. Notably, these rates are lower than a historic cohort studied at the same institution, spanning January 2012

Make and Model	Ν	% Nonconditional Cases	% all Cases
Advanced Bionics Corporation			
Hi Res 90K	3	2.0%	1.0%
Cochlear Corporation			
CI24M	1	0.7%	0.3%
CI24RCA	1	0.7%	0.3%
CI24RE	11	7.4%	3.7%
CI 422	1	0.7%	0.3%
CI 512	1	0.7%	0.3%
CI 522	10	6.8%	3.3%
ABI 541	1	0.7%	0.3%
Total	29	19.6%	9.6%

TABLE 2. Data regarding MR examinations that were stopped prematurely secondary to pain

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through June 2014 (5), comprised exclusively of non-MRI conditional devices performed before implementation of the current protocol. In this previous study, 15% cases experienced a magnet-related complication. Furthermore, 19.6% of subjects with non–MRI-conditional magnets required premature MR study termination due to pain at the implant magnet site; 9.6% of all cases. This is comparable to a 13% discontinuation rate of a the previously studied cohort at the same institution (5). Although an in-depth statistical comparison of magnet-related complications is outside the scope of this study, the lower prevalence of magnet complications in recent years can be reasonably attributed to the benefits of MRI conditional magnets, and improvements in our protocol over time.

This report provides granular description detailing the implementation of a radiology-administered protocol to obtain MRI in patients with cochlear implant magnet in place. Within the last decade, we have received regular inquiries from other centers regarding the details of our CI-MRI scanning protocols and are often informed that other radiology practices are reluctant to scan patients with retained internal magnets given attendant safety concerns and also constraints surrounding program infrastructure necessary to support this work. Specifically, each scan requires substantially more time and resources. However, these concerns must be weighed against the inconvenience and potential risks of two surgical procedures for removal and reimplantation of the cochlear implant magnet. General surgical risks include a 1.9% risk of infection (1), 1.1% risk of hematoma (1), as well as the risk of weakening the silicone housing in which the magnet sits, putting the patient at risk for dislodgement of the magnet with routine use. In addition, patients incur the general risks and cost of undergoing local or general anesthesia, potentially halting antiplatelet or anticoagulant medications, and the inconvenience of waiting at least several days after the procedure before resuming processor use again while the incision heals.

It has also come to our attention that other large centers with well-established scanning protocols have experienced similar workflow strains when using a traditional model requiring regular onsite participation of otolaryngology providers. Thus, the primary impetus for this report is to present a detailed blueprint of our most recently implemented protocol to benefit other centers that are interested in incorporating a similar model, either on the whole or individual aspects of the protocol based on specific need. In addition to providing a process map and description of various technical aspects of our scanning protocol, we have included sample educational material used for MRI technologist training, and samples of safety forms and consent that may be reviewed and adapted based on individual practice need. We acknowledge that every center has unique procedures in place for process implementation, protocol approval, and safety oversight. Thus, the protocol described herein, along with example materials, must be thoughtfully adapted to specific practice needs and regulations.

This study has several strengths and limitations that warrant discussion. Although obviating the need to wait for an otolaryngology provider to leave clinic or the OR to assist with headwrap and examination before and after each MRI case incontrovertibly improves workflow, we do not have granular data surrounding improvements in time and cost-savings with the new protocol compared with past iterations. We also do not have prospective patient-reported outcome data comparing patient experience or discomfort. With the overarching goal of improving patient safety and workflow efficiencies, this publication highlights the benefit of providing more in-depth process descriptions in future publications on the topic—details which are commonly not sufficiently described and sometimes omitted in past reports.

CONCLUSION

As indications for both MRI and cochlear implantation expand, so will the number of MR studies recommended in patients with cochlear implants. Motivated by MR workflow inefficiencies and escalating clinical strains, the Departments of Radiology and Otolaryngology jointly developed a radiology-administered protocol to streamline care, reduce clinical strains, and improve patients' safety and care experience. Resources, including a process map, radiology technologist training modules, consent examples, patient educational sample materials, clinical safety audit log, and other procedural safety measures are included so that this protocol may be reviewed and potentially adapted by other centers according to specific needs.

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