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Impact of Cochlear Implant With Diametric Magnet on Imaging Access, Safety, and Clinical Care

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Objectives/Hypothesis: Review safety and effectiveness of magnetic resonance imaging (MRI) of patients implanted with a cochlear implant (CI) containing a diametric magnet housed within the undersurface of the device.

Study Design: Retrospective chart review with additional review of MRI at a tertiary-care children's hospital.

Methods: Seven patients with mean age of 8.4 years (range = 1.3–19 years) with a diametric magnet in situ during MRI. The intervention comprised one or more sessions of 1.5 T or 3.0 T MRI without a head wrap. The main outcome measures were the occurrence of magnet-related complications including discomfort and magnet displacement, use of anesthesia or sedation, and clinical usefulness of MRI studies.

Results: Seven CI recipients underwent 17 episodes of 1.5 or 3.0 T MRI with an in situ diametric magnet. Thirteen of 17 (76%) MRI sessions were completed in awake patients. No patients had device-related discomfort. No magnet-related complications occurred. Thirteen of 14 (93%) brain studies were clinically useful despite artifacts.

Conclusions: The diametric magnet enabled MRI with magnet in situ without the discomfort or magnet displacement associated with removable axial magnets. The reduction in MRI magnet-related complications occurred because torque is not directed perpendicular and outward from the plane of the magnet, and the magnet is securely contained within its housing. The design of this device increased access and reduced the need for sedation or anesthesia.

Key Words: Cochlear implant, diametric magnet, safety.

Level of Evidence: 4

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INTRODUCTION

In 2015, the first cochlear implant (CI) with a diametric magnet (Synchrony; MED-EL, Innsbruck, Austria), received Food and Drug Administration (FDA) approval for commercial use, including conditional approval for 1.5 and 3 T magnetic resonance imaging (MRI) with a magnet in situ. Axial magnets previously were used in all CI devices. Axial magnets are magnetized such that one magnetic pole is toward the skin flap resulting in outward torque perpendicular to the skull during MRI. In contrast, the magnetic field forces on the diametric magnet during MRI cause the magnet to rotate within its housing to a neutral position (Fig. 1), analogous to the needle of a compass rotating in response to an external magnetic field. The magnet within the Synchrony device may be removed and replaced when artifact reduction is needed to improve image quality, an important option for recipients requiring brain imaging. The housing of the diametric magnet is different from other devices in that the opening is on the undersurface of the device, enclosing the magnet between the intact surface of the device and the skull. Placement of a head wrap over the receiver stimulator, done to counteract the outward force on an axial magnet, is not required.

Access to MRI for CI recipients is of growing importance due to its increasing use to diagnose a wide variety of conditions. Initially, no CI device had conditional FDA approval for use in MRI. One approach to enable access was to make the magnet removable and replaceable. However, this approach has the drawback of requiring additional surgical procedures. For this reason, placement of a head wrap to counter the outward force was recommended by several manufacturers. CI models with FDA conditional approval for up to 1.5 T MRI with a magnet in situ with a head wrap are in widespread use worldwide. However, there are a growing number of reports that MRI of CI recipients with axial magnets may cause pain and anxiety, as well as magnet displacement, especially when the magnet is removable.[1–11]

Our CI program has a longstanding protocol to obtain MRI without magnet removal for all recipients for whom MRI is medically necessary. In 2016 we reported our CI recipient MRI experience.[1] All magnets were axial.

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Fig. 1. Diametric magnet poles rotate within the device to align with the static magnetic field of the magnetic resonance scanner. MRI = magnetic resonance imaging.

Despite a head wrap, four of 13 (33%) of 1.5 T scan sessions with magnet(s) were associated with complications. All complications occurred during sessions that included a body or spine study. Three magnets rotated 180° while remaining within the housing. One magnet became displaced and required surgical replacement. In addition, one partial demagnetization of a nonremovable magnet within a ceramic case occurred. Some forces on an in situ axial magnet may be stronger when body or spine images are acquired, depending upon multiple variables including patient height and head position in the MRI bore.[1,12,13]

The housing for removable axial magnets is a Silastic sleeve with a central opening on the lateral aspect of the device. Although this design facilitates magnet removal and replacement, it permits rotation perpendicular to the plane of the device in response to the outward torque (Fig. 2). Despite head wrap placement, the magnet may tilt or fully rotate, and rarely extrude from the sleeve.[1–11] The movement allowed by a lateral Silastic sleeve may contribute to patient discomfort and anxiety, which is commonly reported and may lead to premature study termination.[3,5,6–10] Our policy is that CI recipients with an axial magnet in situ receive sedation or general anesthesia, regardless of age, and that a head wrap be placed after the child is sedated.

Scheduling and completing MRI for CI recipients at our hospital is time consuming because of multiple considerations including: 1) informed consent if the device does not have conditional FDA approval for MRI; 2) medical necessity determination, which may require discussion with the ordering physician; 3) determination for brain studies if magnet removal to reduce artifact is necessary; and 4) scheduling of general anesthesia or sedation if an axial magnet is present. In addition, scheduling is further complicated by our policy of having a CI audiologist, rather than medical imaging personnel, place the head wrap. The complexity of scheduling of recipients with axial magnet(s) does not lend itself to urgent MRI evaluation.

The primary purpose of this study was to review our MRI experience in children implanted with the

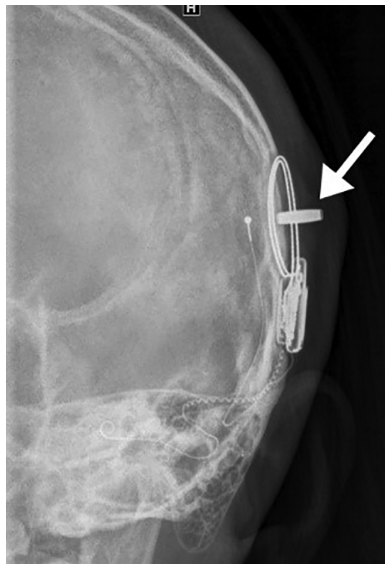

Fig. 2. Anterior–posterior skull radiograph demonstrating 90° rotation of axial magnet (arrow) due to outward torque during magnetic resonance imaging. Patient complained of pain and swelling over the magnet site. The magnet exited its Silastic sleeve on the surface of the device but remained beneath the scar tissue capsule. Surgical magnet replacement was required.

Synchrony CI (MED-EL) containing a diametric removable magnet. The primary outcome measures were magnet-related complications, need for anesthesia or sedation, and whether a diagnostic study was obtained. The secondary outcome of interest was the impact on our process of obtaining MRI. The authors' clinical experience that inspired this retrospective study is that the diametric magnet 1) reduces magnet-related complications, 2) reduces the need for sedation and anesthesia, and 3) improves the efficiency of obtaining MRI.

MATERIALS AND METHODS

Subsequent to institutional review board approval, charts of children who underwent MRI with a MED-EL Synchrony device(s) were retrospectively reviewed. The following data were abstracted: date of CI(s), date of MRI(s), presence of magnet, head wrap use, MRI tesla strength, number and types of studies during each episode of scanning, clinical reason for MRI, complications related to magnet (discomfort during and after scanning, magnet displacement, demagnetization, magnet alignment, and external transmitter coil retention problems after MRI), use of sedation or general anesthesia, and whether the diagnostic goal of the study was met. Members of the implant team and Department of Medical Imaging involved in scheduling and study monitoring were retrospectively asked whether there was any difference in scheduling these patients in comparison to CI recipients with devices containing axial magnets.

SUBJECT CHARACTERISTICS

Seven (four males, three females) CI recipients who met inclusion criteria were identified (Table I). Mean age at first implantation was 8.4 years (range = 1.3–19 years).

Six children were implanted unilaterally and one bilaterally when imaged. No child had a device other than the Synchrony. All had a magnet(s) in situ when scanned. None had a head wrap. The mean age at MRI was 10.6 years (range = 16 months to 19 years). Relevant medical history for each recipient is noted in Table I. Prior to implantation, five children (patient 1, 3, 4, 5, 7) were known to require future MRI. Their diagnoses included brain tumor history, hydrocephalus, Chiari 1 malformation, and recent lumbar laminectomy for abscess drainage.

TABLE I.
Cochlear Implant Recipient Characteristics.

Subject No.	Age at CI, yr	Unilateral/ Bilateral CI	Medical History
1	2.9	Unilateral	Chiari 1
2	6.7	Unilateral	Down syndrome, seizure disorder, SIADH
3	9.3	Unilateral	Neuroblastoma
4	15.5	Unilateral	Craniopharyngioma
5	4.0	Bilateral	Pneumococcal meningitis with epidural thoracic abscess
6	19.0	Unilateral	Cerebral palsy
7	1.3	Unilateral	VP shunt for hydrocephalus s/p bacterial meningitis

CI = cochlear implant; SIADH = syndrome of inappropriate antidiuretic hormone; s/p = status post; VP = ventriculoperitoneal.

RESULTS

Seven children underwent 17 MRI sessions, during which 18 studies (14 brain and four body or spine) were obtained (Table II). One recipient (patient 4) underwent two 3 T brain scans (Siemens Skyra magnet; Siemens Medical Solutions USA, Malvern, PA). The remaining MRI studies were 1.5 T (Siemens Aera magnet; Siemens Medical Solutions USA). Three children underwent more than one MRI session, including one (patient 4) who underwent six brain studies. Of the 13 brain studies, five were limited fast brain scans done to evaluate ventricular size.

Thirteen of 17 (76%) MRI sessions were done without sedation or anesthesia. All five fast brain studies were done awake, including a 21-month-old (patient 7). Another child (patient 4) underwent a fast brain in the emergency department to rule out hydrocephalus. The remaining seven awake sessions were standard brain and/or body or spine MRI of three recipients between age 9 and 19 years. These awake studies included one child (patient 5) with bilateral CIs and one child (patient 4) who underwent two 3 T brain MRIs. Four studies were done under general anesthesia because of patient age and inability to cooperate, not presence of a CI.

TABLE II.
MRI Study Results.

Subject No.	Studies	Tesla	Age, yr	Sedation/ GA	Indication	Diagnostic Goals Met	Complication
1	Fast brain	1.5	3.7	No	Ventricle size	Yes	No
2	Brain	1.5	9.1	GA	Epileptogenic focus localization	No	No
	Brain and pituitary	1.5	9.7	GA	SIADH etiology	Yes	No
3	Brain and pituitary and heart/ liver†	1.5	9.3	No	Tumor FU	Yes	No
	Heart/liver	1.5	11.3	No	Tumor FU	Yes	No
4	Brain	1.5	15.8	No	Tumor FU	Yes	No
	Brain	1.5	17.1	No	Tumor FU	Yes	No
	Fast brain	1.5	17.8	No	Headache evaluation (ventricle size)	Yes	No
	Brain and pituitary	1.5	17.8	No	Headache evaluation (tumor status)	Yes	No
	Brain	3.0	18.1	No	Tumor FU	Yes	No
	Brain	3.0	18.5	No	Tumor FU	Yes	No
5	Total spine*,†	1.5	4.1	GA	Laminectomy/abscess FU	Yes	No
6	Lumbar spine	1.5	19.5	No	Back pain and compression fracture	Yes	No
7	Fast brain	1.5	1.7	No	VP shunt FU (ventricle size)	Yes	No
	Fast brain	1.5	1.8	No	VP shunt FU (ventricle size)	Yes	No
	Brain	1.5	2.4	GA	Abnormal head circumference	Yes	No
	Fast brain	1.5	3.4	No	VP shunt FU (ventricle size)	Yes	No

*CI surgery–MRI interval 27 days.
†Bilateral CIs.
FU = follow-up; GA = general anesthesia; MRI = magnetic resonance imaging; SIADH = syndrome of inappropriate antidiuretic hormone secretion; VP = ventriculoperitoneal.

The mean interval between most recent CI surgery and MRI session was 42 months (range = 0.9–37 months). Two children (patients 3 and 5) underwent MRI 28 days after surgery without complication.

No magnet-related complications, including discomfort during scanning of awake patients, were reported during or after MRI. No studies were terminated prematurely. There were no reports of problems with external transmitter coil realignment or retention after MRI. No artifact interfered with the body imaging quality. Despite the presence of magnet and device-related artifact, 13 of 14 (93%) brain studies were clinically useful. One patient with brain tumor history (patient 4) underwent imaging 2 days in a row to evaluate new onset of headache. A fast brain was done to urgently rule out hydrocephalus, followed by a standard brain to evaluate tumor progression. Both studies achieved diagnostic goals. One brain scan (patient 2) done to localize seizure focus was very limited and therefore nondiagnostic for this indication.

Improved efficiency was reported due to 1) elimination of the head wrap and involvement of audiologist, 2) elimination of informed consent for off label use, 3) reduction in scheduling of sedation/anesthesia, and 4) elimination of consultations to evaluate complaints of pain and poor transmitter coil retention. No reduction in time occurred for some aspects of scheduling including confirmation of device model and the need to determine if brain scans could proceed without magnet removal.

DISCUSSION

The ability to safely obtain an MRI is of growing importance for patients who receive cochlear implants. When the first CI system received FDA approval in 1991, MRI was primarily used for brain imaging and was not widely available. Since that time, MRI has become readily available in the United States, and advanced imaging techniques and increased imaging speed have increased clinical use. MRI of body, spine, and brain are commonly used by specialists, and primary care and emergency department physicians to diagnose many conditions. Contributing to increased use is increased physician reliance on imaging,[14] and a national movement away from ionizing radiation associated with other imaging modalities, particularly for younger patients.[15,16]

Our prior experience and published literature support use of anesthesia or sedation for CI recipients, including some adults, with an axial magnet in situ to address discomfort and anxiety.[3,5,6] In this series, there were no reports of any child experiencing discomfort, and no awake studies were prematurely terminated. It is notable that this was true for two children scanned 28 days after implantation, and one child scanned twice with a 3 T magnet. The elimination of discomfort enabling awake imaging is advantageous, especially for children with brain tumors, shunted hydrocephalus, and other conditions for whom repeated imaging is needed.

After exposure to strong magnet fields during MRI is over, the diametric magnet must rotate freely within its housing to achieve proper realignment. Realignment is necessary for proper retention of the transmitter coil. Realignment is also necessary for proper orientation of the microphone within button-style speech processors. In contrast, microphone orientation of behind-the-ear processors is not affected by magnet alignment. No problems with coil retention or microphone position occurred after MRI in this series.

In addition to permitting scanning of older children without sedation or general anesthesia, several young children underwent awake fast brain studies. In published literature, these limited studies are also referred to as rapid or quick brain MRI, fast or ultrafast magnetic resonance (MR), and MR ventricle exams and were developed as an alternative to computer tomography. They can be performed without sedation, even in very young children.[17,18] One of the most common indications for this study is evaluation of ventricular size in children with suspected or shunted hydrocephalus. Because of the need for sedation, no CI recipient with an axial magnet has undergone a fast brain study at our medical center. The ability to obtain an awake fast brain study enabled timely hydrocephalus evaluation of a recipient seen in the emergency department. Thus, availability of the diametric magnet increased MRI access, as well as significantly reduced the need for general anesthesia or sedation for recipients of all ages.

The presence of a diametric magnet did not negate clinical usefulness of the majority of MRI studies. To minimize the occurrence of nondiagnostic MRI evaluations, we believe it important to evaluate the goal of the study. The diagnostic yield of MRI with in situ magnet(s) depends heavily on the area imaged and the precise clinical question. Body studies, with the possible exception of the upper cervical spine, are not affected by CI artifact. However, all brain scans will have significant artifact, especially of patients with bilateral implants containing magnets. Regions closest to the magnet are most affected, so brain abnormalities in the posterior hemispheres may be obscured. Additionally, the type of MRI sequences governs the degree of artifact, and certain sequences are more limited than others. Diffusion-weighted sequences, helpful for acute stroke evaluation, and gradient or hemesensitive sequences, used to detect blood products, are particularly degraded by magnet artifact.[19]

Our center has long had a policy in place to enable medically necessary MRI so that important diagnostic information may be obtained without added cost and risk of additional surgery. However, carrying out the policy is time consuming. MRI of CI recipients with a diametric magnet is more streamlined due to elimination of the head wrap and consent for off-label use and reduced need for sedation or anesthesia. In addition, absence of magnet-related complications has eliminated urgent calls to CI team members.

CONCLUSION

The presence of a diametric magnet housed within the undersurface of the device positively impacts patient care. In our series, magnet-related complications were eliminated, most notably discomfort and magnet displacement. Elimination of outward magnet torque enabled the majority of our patients to undergo MRI studies without

sedation or general anesthesia, including children as young as 21 months. Reduced need for anesthesia was a major benefit that is especially important for children requiring repeated MRI to manage comorbidities. In addition, the elimination of the head wrap, increased number of awake studies, and lack of magnet complications improved MRI access and overall efficiency.

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