Patient Outcomes in Magnet-Based Implantable Auditory Assist Devices

Mallory B. O’Niel, MD; Christina L. Runge, PhD; David R. Friedland, MD, PhD; Joseph E. Kerschner, MD

IMPORTANCE Magnet-based implantable auditory assist devices (MIAADs) are a recent development in bone-anchored hearing devices. This report increases the number of children studied with specific outcome criteria and provides detailed solutions to avoid device use difficulties in other centers considering this device.

OBJECTIVE To assess hearing thresholds, use rates, and complications in children implanted with a MIAAD for conductive hearing loss.

DESIGN, SETTING, AND PARTICIPANTS Retrospective analysis of children implanted with an MIAAD at an ambulatory care quaternary referral center since the Food and Drug Administration approved the Sophono device (Sophono Inc) for use in the United States (May 2011 through January 2013). Ten pediatric patients were implanted for conductive hearing loss (14 ears; mean age at implantation, 9 years [range, 3.8-17.2 years]). Diagnoses included aural atresia (n = 7) and chronic ear disease and cholesteatoma (n = 3).

INTERVENTIONS Implantation of MIAAD and management of skin complications.

MAIN OUTCOMES AND MEASURES Demographics, hearing thresholds, use rates, and complications were assessed.

RESULTS After fitting with the magnetic baseplate and sound processor, the mean (SD) aided pure-tone average was 20.2 (6.0) dB hearing level (HL), with a mean (SD) functional gain of 39.9 (12.4) dB HL. There were no surgical complications. Negative outcomes were assessed following fitting of the sound processor. The skin complication rate was 35.7%, including skin breakdown (n = 2) and pain and erythema (n = 5), which resulted in decreased use of the device for these patients. Intervention included decreasing the magnet strength, graduated wearing schedule, antibiotic ointment, barrier protection, and reoperation for well widening with Alloderm (LifeCell Corporation) placement. Patients without skin complications are consistent users of their device, with an average daily use of 8 to 10 hours.

CONCLUSIONS AND RELEVANCE The MIAAD device has equivalent levels of hearing restoration to other previously described methods of intervention for children with conductive hearing loss. This early report indicates high rates of skin difficulties and a need for improved methods of implantation, magnetic baseplate fitting, and device use. We suggest decreased magnet strength at the initial fitting, a graduated wearing schedule, caution with patients who have a history of skin issues from a bone-anchored hearing aid or multiple surgical procedures, and parent counseling regarding potential skin irritation.

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Magnet-based implantable auditory assist devices (MIAADs) are a recent development in bone-anchored hearing devices (BAHD). The MIAAD used in this study is a transcutaneous bone conduction hearing system developed in Germany in 2006 and is a product of Sophono Inc. More than 100 patients have been implanted in Europe since its first use in Germany. The device was approved by the Food and Drug Administration for use in the United States in May 2011. In the United States, the first device implanted was in a 6-year-old child with bilateral atresia at our institution in June 2011. The device is approved for children 5 years or older, for those with conductive or mixed loss with bone conduction thresholds better than 45 dB, or for single-sided deafness with better-ear thresholds of less than 20 dB.

This device is marketed in the United States as the Sophono Alpha System. The internal device consists of a titanium implant with 2 internal magnets. The external portion consists of a sound processor and magnetic baseplate. The device is held in place by the magnets, and the vibrations are transcutaneously transmitted to the bone. The external magnet comes in different standard strengths, which Sophono Alpha System labels as #0 (weakest) to #5 (strongest).

Published data from Germany of more than 100 patients reported a 4% rate of temporary pressure marks as the only complication; this resolved after baseplate modification with force reduction. Twenty-one patients who had been implanted for congenital atresia presented for a follow-up study. The mean age of patients was 12.4 years (range, 6.0-50 years), with only 3 patients older than 18 years. This demonstrated a mean (SD) hearing gain in free field pure-tone audiogram of 31 (8) dB hearing level (HL).

To our knowledge, there have been no US studies published to date describing outcomes with this new BAHD. The objective of this study was to review our patient data to assess hearing thresholds, use rates, and complications in children implanted with a MIAAD for conductive hearing loss (CHL). In addition, this report increases the number of children studied with specific outcome criteria and, importantly, provides detailed solutions to avoid device use difficulties in other centers considering this device.

Methods

The institutional review board of the Children’s Hospital of Wisconsin approved this study. We performed a retrospective analysis of all children implanted with an MIAAD at a quaternary referral center since the Sophono device was approved by the Food and Drug Administration for use in the United States in May 2011.

Surgical procedures were performed in a standard fashion. A template was used to reliably predict the placement of the device posterior and superior to the area of the external auditory canal where this would exist in patients with auricular atresia. The measured central location of the implant wells is 6 cm posterior to the external auditory canal, at approximately a 45° angle posterior and superiorly. A curved incision was then made approximately 1 cm posterior to the measured well locations. Dissection was carried through the scalp to the pericranium. The pericranium was elevated anteriorly, and 2 wells for the implant were drilled using a high-speed otologic drill (Anschopach; Synthes Inc). A template of the device was used to judge well size, with each well measuring 1 cm in diameter and 2.5 mm thick. A bone well depth of 3 mm and diameter of 10 mm is recommended, and a minimum of 3-mm calvarial thickness is required. Computed tomographic scanning is recommended in all children because some children have a very thin calvarium and placement of the implant as well as use of the anchoring screws may be compromised in patients with a calvarium of less than 3 mm. In addition, children may have other intracranial or extracranial anatomic abnormalities that should be identified prior to surgical implantation. In younger children, in order to allow the implant to be flush with the calvarium, full-thickness removal of the 3 mm of calvarium may be necessary. In these cases the implant rests directly on the dura. A total of 5 self-tapping screws were placed to secure the implant in all but 1 case in which 4 screws were used. Care was taken to ensure that the implant was as evenly flush with the calvarium as possible. The pericranium and soft tissue were closed in layers. Operative photographs are presented in Figure 1. All patients underwent surgery as outpatients and were discharged home the day of surgery.

Demographics, indications for hearing rehabilitation, hearing thresholds before and after implantation, and negative outcomes associated with MIAAD were assessed. Patients were seen 4 to 6 weeks postoperatively for fitting of the external processor. Clinic visits were set up concurrently to assess the skin over the implant.

Complete audiometric evaluation was completed preoperatively. Children were tested with play (6 ears), visual reinforcement (1 ear), or conventional audiometry (7 ears) depending on developmental level. Air and bone conduction thresholds were recorded. Repeated audiometric testing was performed the day of the fitting if possible; otherwise, a follow-up appointment was scheduled in 1 month. Aided testing was performed with conventional sound field testing using narrowband noise, with the patient facing a central speaker with occlusion of the good ear if present. Thresholds were measured for 0.25 to 8.00 kHz if possible, always at least including 0.5, 1, 2, and 4 kHz. Yearly audiometric evaluation was scheduled after the initial encounter.

Results

Ten patients (14 ears) were implanted. The mean age at implantation was 9.0 years, median 6.3 (range, 3.8-17.2) years. Our sample consisted of 7 female and 3 male patients. Diagnoses included CHL secondary to auricular atresia in 9 ears and complications of chronic ear disease and cholesteatoma in 5 ears. Seven ears had coexisting microtia, and none had received surgical repair at the time of implantation. Prior to implantation, hearing assistance was provided with a headband bone conduction aid in 11 ears, a bone-anchored hearing aid (Baha;
All patients had a minimum of 1 comprehensive audiometric evaluation following implantation, as described in the Methods section. The mean length of follow-up with clinic visits was 11.6 months and ranged from 4.5 to 24 months. The time of audiometric follow-up reported ranged from 50 to 389 days after implantation, with a median of 68 days. Hearing thresholds were assessed measuring ear-specific air-conduction pure-tone thresholds (Figure 2). The mean (SD) unaided pure-tone average (PTA) was 60.3 (14.2) dB HL, and the mean (SD) aided PTA was 20.2 (6.0) dB HL. Mean (SD) PTA functional gain was 39.9 (12.4) dB HL.

At the initial fitting, the device was held in place with #1 magnet strength in 5 ears, #2 magnet strength in 3 ears, #3 magnet strength in 4 ears, and #5 magnet strength (strongest) in 2 ears. Difficulties following fitting, including swelling, irritation, infection, or significant decreased ability to use the device from pain or skin changes were included in the negative outcomes. There were no postoperative complications associated with surgical implantation of the device.

Negative outcomes following fitting of the external magnet and processor resulted in 5 of 14 ears (36%) having significant enough difficulties to discontinue use for a period. Negative outcomes are presented in Table 2. One patient with difficulty had both ears of a bilateral implantation affected. All 5 of these implant complications resulted in pain and erythema at the site of the implant (not the incisional site). In 2

Cochlear Ltd) in 2 ears, and a conventional aid in 1 ear. The 2 prior Baha users had significant difficulties with skin overgrowth, irritation, or infection prompting a change to the MIADD. Demographic data are included in Table 1.

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ears, this progressed to cellulitis or pressure necrosis and eventual skin breakdown. Magnet strength at fitting was #3 for 2 ears, #2 for 1 ear, and #1 for the 2 children with the skin breakdown. The patients with complications were between the ages of 3.8 and 15.2 years at the time of surgery (mean age, 7.2 years). The mean time from fitting to the first negative outcome was 61 (range, 36-98) days.

For patients with a negative outcome, the intervention consisted of a decrease in magnet strength from #3 to #1 for quiet activities, with the instruction to only use the higher strength for running activities. The sites healed within 1 week. Patient 4 experienced skin breakdown and returned to the operating room for revision after treatment with oral antibiotics and antibiotic ointment and a break from device use failed to improve the skin breakdown. Operative revision included improving the seating of the implant to ensure that it was as flush to the calvarium as possible with widening of the wells and placement of Alloderm over the implant for another layer of protection against skin breakdown. This required 6 months for revision surgery and complete healing to occur. Patient 2 experienced skin breakdown and was treated with antibiotic ointment and a break from device use. The skin in this area was already thin from previous Baha placement. After the ulceration resolved, there was continued irritation and scabbing. This was treated with moleskin placed on the baseplate (external magnet) for additional padding and protection as well as decreasing to a #0 magnet (lowest strength). This patient required about 8 months for the area to heal completely. Patient 1 (left ear), who experienced an area of redness approximately 1 month after fitting, was given a new baseplate owing to irregularities. A pinpoint ulcer developed, which was also managed with moleskin placement on the baseplate. This ulcer resolved after 2 weeks.

After recognition of these negative outcomes, new recommendations were implemented including the following: 1. Initial fitting with the lowest magnet strength possible (#0 or #1). 2. Graduated wearing schedule over 2 weeks. 3. Counsel patients and/or parents to remove the device immediately if any discomfort, redness, or irritation occurs. 4. When active, consider wearing soft-band device as opposed to higher magnet strength. 5. Be extra conservative for patients with a history of skin issues from Baha or multiple surgical procedures.

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<th>Table 2. Negative Outcomes</th>
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<td><strong>Patient No. (Ear)</strong></td>
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Abbreviations: L, left; R, right; ellipses, patients without negative outcomes.
This protocol was initiated after the first 7 ears were implanted, and the negative outcomes of the 5 ears were recognized. The decreased magnet strength at initial fitting will decrease the risk of pressure necrosis and pain. The lowest-strength magnet that allows the device to stay in place should be used. The graduated wearing schedule uses innate properties of cutaneous adaptation, including collagen, cell-cell connectivity, and vascular changes to reduce complications. Caregivers are instructed to only allow use for 2 hours per day for the first week while monitoring the skin closely and then gradually increase wearing time. When children are active, they have the option to revert to their soft-band device in place of the MIAAD to lessen the risk of skin breakdown from higher magnet strengths. Lastly, in children with a history of skin breakdown from Baha or previous surgical procedures, additional time to gradually strengthen the underlying skin through conservative use of the MIAAD is recommended. Since making these changes, the remaining 7 ears have been implanted with no negative outcomes to date. These patients have been followed up for a mean of 166 days, much longer than the mean time to first negative outcome of 63 days when the initial complications first arose in the other patients.

Use rates at last follow-up were found to be favorable in all patients. Information was available for 9 of 10 patients (12 of 14 ears [or devices]) including all who had developed prior negative outcomes. Five devices were being used during all waking hours, 6 devices were being used during school hours with some home use, and intermittent breaks were required for 1 device but otherwise was being used daily without difficulty.

**Discussion**

Bone-anchored hearing devices have been commercially available for over 30 years. These devices work on the principle of sound conduction through bone via the osseointegrated implant. BAHDs provide a method for acoustic input and have been shown to improve quality of life.

Indications for BAHD have included (1) congenital aural atresia and microtia; (2) chronic supplicative otitis media; (3) chronic otitis externa; (4) unilateral profound hearing loss; (5) unilateral mixed hearing loss; (6) failure of conventional hearing aids; and (7) trauma resulting in hearing loss.4

The Baha device has been described as prone to complications involving soft-tissue reaction due to the percutaneous abutment. Careful wound care and skin hygiene is required around the abutment to prevent adverse outcomes. Increased soft-tissue complications have been found to occur in children, including fixture loss, skin reactions, and infection.4 An article reviewing the complications of 85 pediatric ears with Baha placement identified a 46% complication rate.9 The article reports 26% of children experienced fixture loss. Fixture loss can occur from trauma or failure of osseointegration. Difficulty with skin irritation, erythema, and infection frequently occur. Skin reaction was reported in 37% of the children. Some children develop marked hypertrophy of the skin around the abutment requiring skin reduction. Revision surgery was required in 42% of cases. However, the literature is varied when it comes to reports of complications from Baha. A review article compiling data from 8 studies reported a skin complication rate between 2.4% and 44% of cases, revision surgery occurring in 7.5% to 25.9% of cases, and fixture loss in 5.3% to 40% of cases.10

The other percutaneous BAHD, the Oticon Medical Ponto (Oticon Medical), is a newer device and has a smaller volume of published literature regarding outcomes. One study following up 31 patients with Ponto implantation reported a 51.6% rate of mild skin reactions, with 19.3% of patients requiring abutment replacement and 3% requiring revision surgery.11 This demonstrates rates of notable complications similar to the other studies.9,10

There has been discussion in the literature regarding a new surgical method for Baha implantation where the skin is either not thinned at all or thinned only to a minimal degree in an effort to decrease complication rates. Three studies were identified describing a modified technique using a skin punch, minimal soft-tissue reduction, and longer abutments (8.5-12.0 mm) compared with the standard technique using dermatome for skin thinning.12-14 These reports describe advantages of shorter operative time,13-14 less numbness and pain,15 and decreased rate of infection (14% vs 43%).13 One study reports complication rates equivalent to traditional techniques (17.2% vs 18.2%).16 Another reports no skin complications requiring any intervention with follow-up for 9 to 20 months.14

The percutaneous Baha device has had the longest time with approval for use in children, and a number of reports exist on safety and efficacy. The traditional surgical procedure consists of placement of a titanium implant into the temporal bone with reduction of the subcutaneous tissue. The external processor is attached after 2 to 3 months of healing to allow for osseointegration. The devices are FDA approved for implantation in patients 5 years and older. There is no clinical consensus on the proper time for implantation.9 Necessity for implanting in a calvarium with adequate thickness has been discussed. This is believed to occur around the age of 3 years, when the device can be inserted to optimum depth of 3 to 4 mm.5 For younger children, the soft-band device can be used. The mean (SD) hearing gain with Baha use for patients with CHL has been reported as 39.8 (7.2) dB, 32 (19) dB, and 33 (6) dB in 3 separate studies.6-8
Proposed advantages of MIAAD arise from the implanted magnet in place of the percutaneous abutment. This provides the potential to decrease skin and soft-tissue complications because there is no foreign body coming through the skin. Although, as discussed, this complication has potentially decreased in the Baha with the new modified technique of decreased skin thinning, reported results are for adults. There is no daily skin maintenance required with the MIAAD, which can simplify device use and management, especially for children. Abutment or complete fixture loss or extrusion has been a significant difficulty with other BAHDs. Trauma, particularly in active children, which results in device failure or other complications, has also been a difficulty in other BAHDs. Failure due to extrusion or trauma has not been reported with the MIAAD. These design differences have been constructed in an attempt to reduce the need for revision surgical procedures. Delay in time to processor use is decreased with the MIAAD, since fitting occurs at 4 to 6 weeks after the procedure compared with 2 to 3 months with other BAHDs. An additional objective of a MIAAD is to offer cosmetic improvement, since there is no visible external post. A potential drawback to the implantable magnets would be difficulty undergoing magnetic resonance (MRI) imaging. The FDA has cleared the Sophono Alpha System for use in MRI scanners with both 1.5-T and 3-T magnetic fields; however, there will be increased distortion on MRI images from this device.

Although there is little reported literature to date regarding outcomes for MIAADs. We report outcomes for 14 pediatric ears implanted with the device. These patients all had a diagnosis of CHL. Although BAHDs have been used for sensorineural hearing loss, similar to other large series our indications included 9 ears with aural atresia and 5 ears with CHL due to chronic ear disease or cholesteatoma. One patient (2 ears) also carried a diagnosis of Proteus syndrome, having significant difficulty with bilateral external auditory canal stenosis. This patient had previously undergone Baha placement but experienced much difficulty with skin overgrowth and bone overgrowth due to Proteus syndrome, which required multiple revision surgical procedures. Another patient also had a previous Baha placement but experienced difficulty with chronic irritation and infection.

From an auditory standpoint, our series confirms appropriate gain in hearing threshold with MIAAD implants with a mean (SD) gain of 39.9 (12.4) dB HL. Compared with the results from Seigert and Kanderske (mean [SD] gain, 31 [8] dB HL) the results reported herein are slightly better. Recent data from France describes the outcomes of 6 Sophono implants for children with CHL secondary to aural atresia. Hearing outcomes reported include a mean (SD) gain of 43 [6.96] dB HL, slightly greater gain than in our series but with a smaller sample size. A study from the Netherlands compared 6 children with Sophono implantation with 6 children with Baha implantation. The mean aided PTA for the Sophono group was 36 dB HL compared with 33 dB HL for the Baha group. They noted that the difference in aided thresholds between the 2 devices were more apparent in the higher frequencies, where Baha users exhibited a 5- to 10-dB better threshold than Sophono users. In a prior study, Verstraeten et al found a 5- to 20-dB increase in threshold with the Baha implant compared with the Baha headband at the 1 to 4 kHz levels, which was thought to be due to the improved transmission of signal with direct bone oscillation without intervening skin and soft tissues. The MIAAD allows for a better fit compared with the headband because the internal magnet is implanted into the cranium. The present study demonstrates only a 5- to 7-dB downslope in the higher frequencies of 2 to
6 kHz compared with 0.25 to 1 kHz (Figure 2). With the addition of this current pediatric cohort, it appears that MIAADs are able to achieve similar hearing gain to other BAHDs, and these results can be used in discussing options with parents and families.

We have demonstrated some significant skin issues in our initial patients implanted with this device. Erythema and pain occurred in 5 ears, similar to the prior pediatric MIAAD study that described skin erythema in 2 children, which resolved with decreased baseplate magnet strength.16 The other study of 6 Sophono patients found an adverse event of pressure discomfort in 1 patient, which also resolved with decreased magnet strength.9 The mean time to first negative outcome in our study was found to be 63 days after fitting demonstrating early onset complications. Of the 5 ears, 2 were found to have a moderate magnet strength of #3 provided at the initial fitting. Decreasing this strength to #1 or #2 led to significant improvement in symptoms within a short time. Two patients developed cellulitis with skin breakdown soon after fitting, even with a magnet strength of #1. One of these patients (patient 2), who developed skin breakdown, was at high risk due to previous thinning of the skin for her Baha and her history of skin irritation and infection of this site. She responded well to treatment and decrease of magnet strength to #0, although this took an extended time to heal completely. Extra care should be taken for patients with a history of skin irritation, especially with previous Baha placement. Patient 3 (right ear) also had a prior Baha but did not experience any negative outcomes, demonstrating that prior Baha is not a contraindication to MIAAD. Revision surgery, which was performed for the other patient (patient 4), with insertion of a thick (0.74 mm) Alloderm covering over the implant to provide additional scalp thickness, may be a consideration in younger patients with relatively thin scalp tissue. Since this revision, the site has healed nicely, and the patient has consistently worn the device with magnet strength of #1 without difficulty and with good audiometric gain. Future outcome studies should emphasize age and scalp issues to determine if there is a group of younger patients who might benefit from AlloDerm placement at initial surgery.

As our initial data regarding the number of patients experiencing early skin irritation emerged, a change in fitting practice was initiated, as described in the Results section. These changes in fitting practices, starting with lower magnet strengths, and gradual increase in device use were all designed to make use of the natural protective mechanisms of the skin, which have been well documented.5-16 The skin will naturally hypertrophy over time from results of repeated trauma. If this injury is not too severe, the skin thickness and toughness can compensate rather than lead to inflammatory pathways resulting in pain, cellulitis, and potential skin breakdown.5,18 Our information on use rates indicates good tolerance of the device in all patients at last follow-up. We anticipate, based on our recent absence of complications, that our current method of early fitting will substantially lessen the complications experienced with this device.

Conclusions

The MIAAD has equivalent levels of hearing restoration as other previously described approaches for restoring CHL in children. This report indicates high rates of skin difficulties and a need for improved methods of magnetic baseplate fitting and device use. We suggest decreased magnet strength at initial fitting, a graduated wearing schedule, caution with patients who have a history of skin issues from Baha or multiple surgical procedures, and parent counseling regarding potential skin irritation. We believe these data can assist parents in making choices for their children and assist programs that are beginning to incorporate this new technology in avoiding complications. In a future study, we will compare outcomes with those in this initial analysis.

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Study concept and design: O’Niel, Runge, Kerschner.

Acquisition, analysis, or interpretation of data: O’Niel, Runge, Friedland, Kerschner.

Drafting of the manuscript: O’Niel, Runge, Kerschner.

Critical revision of the manuscript for important intellectual content: Runge, Friedland, Kerschner.

Statistical analysis: O’Niel.

Obtained funding: Kerschner.

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Study supervision: Runge, Friedland, Kerschner.

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REFERENCES


