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Assessing the Benefit-Risk Profile for Pediatric Implantable Auditory Prostheses

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Abstract

Background/Aims—Children with congenital cochleovestibular abnormalities associated with profound hearing loss have few treatment options if cochlear implantation does not yield benefit. An alternative is the auditory brainstem implant (ABI). Regulatory authority device approvals currently include a structured benefit-risk assessment. Such an assessment, for regulatory purposes or to guide clinical decision-making, has not been published, to our knowledge, for the ABI and may lead to the design of a research program which incorporates regulatory authority, family, and professional input.

Methods—Much structured benefit-risk research has been conducted in the context of drug trials, here we apply this approach to device studies. A qualitative framework organized benefit (speech recognition, parent self-report measures) and risk (surgery- and device-related) information to guide the selection of candidates thought to have potential benefit from ABI.

Results—Children with cochleovestibular anatomical abnormalities are challenging for appropriate assessment of candidacy for a cochlear implant or an ABI. While the research is still preliminary, children with an ABI appear to slowly obtain benefit over time. A team of professionals, including audiological, occupational, and educational therapy, affords maximum opportunity for benefit.

Conclusions—Pediatric patients who have abnormal anatomy and are candidates for an implantable auditory prosthetic require an individualized, multi-systems review. The qualitative

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benefit-risk assessment used here to characterize the condition, the medical need, potential benefits, risks, and risk management strategies has revealed the complex factors involved. After implantation, continued team support for the family during extensive post-implant therapy is needed to develop maximum auditory skill benefit.

Keywords

Auditory brainstem implant; cochlear implant; cochleovestibular abnormality; pediatric; deaf

Introduction

Congenital profound deafness accompanied by abnormal inner ear anatomy presents difficult treatment decisions for neurotologists and audiologists. To bypass the inner ear and implant an electrode for direct brain stimulation is not approved in the United States at present. The Food and Drug Administration (FDA) device approval best practices involves a structured benefit-risk assessment.^{1,2} The purpose of the present work is to propose a structured assessment of implantable auditory prostheses for the indication of congenital bilateral profound deafness. The cochlear implant (CI) and the auditory brainstem implant (ABI) devices will be the focus.

Structured Benefit-Risk Assessment

The structured process for organizing medical condition and treatment information emerged from an appreciation that the approval of new drugs and devices involved factors beyond demonstration of safety and efficacy. Including consideration of family/patient risk tolerance, and differing levels of outcomes conditioned on disease state provides a more global assessment of the benefits and risks. The proposed benefit-risk assessment strategies include both quantitative and qualitative approaches^{1,3–5}. A qualitative or narrative framework will be adopted here and applied to decision-making for implantable auditory prostheses in young children.⁶ The narrative approach involves integrating information from research within neurosurgery, neurotology, audiology, and education, around 5 key factors: an analysis of the condition, a description of the unmet medical need, a summary of the device's benefits and risks, including managing those risks⁷. The framework facilitates communication among stakeholders, informs a research agenda for identified knowledge gaps, and sets the context for informed consent discussions.⁸ The narrative approach allows for wide-ranging discussion of factors throughout the treatment path in very young children.

Implantable Auditory Prosthesis: Cochlear Implant—The first commercially available CI consisted of a single-electrode system.⁹ Much more impressive outcomes (safety and efficacy) for 3 advanced multichannel systems (manufacturers: Advanced Bionics, Cochlear Limited, and MED-EL) led to the FDA-approved systems now in widespread use. CI indications have expanded from adults deafened after language acquisition to congenitally deaf children as young as 12 months of age. Implantation is conducted on an outpatient basis. When the required pre-surgery vaccinations are in place, the child should experience few medical or device-related side effects¹⁰. The peripheral auditory nerve is stimulated by converting sound pressure waves into electrical pulses delivered by an external speech processor to a thin, wire-like electrode array, threaded inside

the cochlea (Figure 1a). The tonotopic arrangement of the cochlea and nerve fibers affords impressive electrical programming flexibility, including targeting stimulation toward the regions transducing specific frequencies.^{11,12} This, in turn, produces electrical stimulation patterns for optimal neural synchrony, increasing the potential for “normal” auditory neural pathway development in the young child.¹³

Implantable Auditory Prosthesis: Auditory Brainstem Implant—An ABI consists of an internal device which sends electrical signals to a flat, paddle-like, electrode array placed over the cochlear nucleus in the brainstem (Figure 1b). The ABI has an external speech processor, similar to those used in CI systems. However, the cochlear nucleus is not clearly arranged in a tonotopic fashion, as is the cochlea,¹⁴ and this results in speech processor programming challenges. The Cochlear Americas ABI is FDA-approved for individuals (12 years and older) who lose hearing during resection of a vestibular schwannoma related to Neurofibromatosis 2.^{15,16} The MED-EL ABI has obtained a CE Mark Certificate for use in the European Union. Implanting an ABI in non-Neurofibromatosis 2, prelingually deafened children consists of an elective craniotomy and a multi-day hospital stay.

Methods: Bilateral congenital deafness

Congenitally deaf children face significant struggles to develop language skills (spoken or sign), with attendant educational and psychosocial delays.¹⁷ The younger the child at device implantation, the greater the benefits to the patient and the family.^{18,19} Thus, hearing in almost every baby born in the US is screened before leaving the hospital,²⁰ and those failing the screen are referred for further evaluation. If bilateral deafness is confirmed through behavioral testing, and CT and/or MR imaging show normal or near normal cochleas and cochlear nerves, the child may be given a cochlear implant as young as 12 months of age.^{21,22}

Performance Assessment of Children with an Auditory Prosthesis—Intuitively, an auditory prosthesis should provide the sensation of meaningful sound forming the basis for language acquisition. However, quantifying “auditory” benefit in a very young child is not straightforward, given the complex interaction between electrical sensory input and developing perception, attention, language, and cognition. At the most basic level, a prosthesis must provide access to sound, or the “sensory primitive”.^{23,24} The development of auditory perception can be characterized as a hierarchy with discrete levels between sound detection and speech recognition, as the sensory primitives are re-organized into neural representations.^{25–27} Pediatric assessments derived from the hierarchy start with a discrimination test between two phonemes, which can be used to gauge the ability to differentiate two sounds²⁸ (see Figure 2). Identification of words or sentences within a closed, or limited, set of distractors and recognition of words or sentences in an open, or very large, set of distractors require more complex perceptual encoding.^{23,25} Detection, discrimination, identification, and recognition tests are essential for demonstrating the effectiveness of implantable auditory prosthetic devices.²⁸

Researchers face challenges when attempting to demonstrate auditory skill performance in children without language skills during auditory prosthesis use.²⁹ Parent report measures provide information on specific behaviors, such as the number of hours in a day a child wears the device, and provide anecdotal evidence that the child has “bonded” to the device³⁰. Device bonding suggests the child is receiving some level of sensory input that more formal audiological testing is unable to demonstrate.^{31,32} The brief overview of the evaluation of auditory skill development in young children with an implantable auditory prosthesis reveals the complexity of demonstrating auditory “benefit”. Here, we will restrict our focus to the first levels of the auditory hierarchy, ranging from sound detection to open-set sentence recognition.

Auditory Prosthesis Unmet Medical Need

Cochleovestibular malformation—Most congenitally deaf children have normal inner ear anatomy upon imaging (CT/MRI). However, investigators have described a number of significant inner ear malformations which appear on routine imaging.^{33–35} The abnormalities can be broadly categorized as either a cochleovestibular deformity (e.g., complete ossification, absent modiolus, etc.), a cochlear nerve abnormality (hypoplasia, aplasia, also cochlear nerve deficiency), or a combination.^{36–38} The type of abnormality affects the surgical procedure employed, the type of CI electrode used, how the speech processor is programmed, and the ability of the child to accommodate to the device. The prevalence of abnormal inner ear anatomy ranges from 9 to 40% of congenitally deaf children.^{39,40} Thus, cochleovestibular abnormalities associated with hearing loss can be considered a rare disease, defined as affecting fewer than 200,000 persons in the United States⁴¹. Additional congenital disorders are more common in these children, reducing the pool of typically developing, congenitally deaf children who might be able to participate in prospective clinical trials.^{42,43}

As standard of care, children with abnormal inner ear anatomy, but an implantable bony structure, are given CIs. Auditory skill development of these children is variable, with some demonstrating open-set speech recognition⁴⁴. Other children show more disappointing post-implant performance, which has led some to conclude that a CI may not be the optimal treatment.^{45–48} The disappointing findings have also been used to support denial of third party payer coverage [authors’ experience] for children with abnormal anatomy. Recent findings suggest there may be some benefit, however,^{49–51} and this remains an active area of research.

For any type of cochleovestibular malformation, the implantation procedure is longer and surgical adverse events are more frequent.⁵² (see Table 1) Facial nerve anomalies are common, increasing the possibility of adverse intraoperative facial nerve events.^{39,53} Implantation of an abnormal cochlea may result in perilymph or cerebrospinal fluid leak (“gusher”^{54,55}) or meningitis.⁵⁶ Postoperatively, CI speech processor programming sessions are prolonged, due to abnormal tonotopicity and/or abnormal nerve placement. The final speech processor program thereby may result in decreased dynamic range and/or uncomfortable facial stimulation, e.g., twitching or eye tearing.^{51,55}

Cochlear nerve aplasia/hypoplasia—A CI cannot improve auditory perception if there is no nerve to transmit the signals from the cochlea to the brainstem. Correct detection of an aplastic/hypoplastic cochlear nerve is problematic, however⁴⁹. If the recommended MRI and CT protocols are followed, it can still be difficult to make a definitive finding of aplasia/hypoplasia⁵⁷. Prior to implantation, during behavioral testing, children may appear to have some pure-tone or vibrotactile response to sound. Children with behavioral responses are somewhat more likely to develop open-set speech perception with the CI relative to children with no auditory perception and an aplastic/hypoplastic nerve.^{49,58–61} In cases of ambiguous imaging and auditory test results, neurotologists have tended to recommend CI,^{35,59,62,63} with careful follow-up for at least 6 months. If there is little progression in acquiring auditory skills, then the child may be referred for an ABI.^{45,46,57,63–65}

Summary—Children with congenital inner ear abnormalities contraindicating a CI lack a clear treatment approach for access to auditory perception.^{51,52,59,66} Third-party payers deny coverage for a CI, even if cochlear implantation were possible. A clear medical need for additional treatment options is needed.

Results: Demonstration of Auditory Prosthesis Benefit

There are few studies of the audiological benefits associated with pediatric ABI use and these are primarily from a single center in Italy.^{67,68} These early papers measured outcome using the Categories of Auditory Performance, a non-specific auditory performance evaluation. An early report described improved sentence recognition in non-tumor patients relative to Neurofibromatosis 2 patients.⁶⁹ A case report of a child implanted in Italy and assessed in the US showed emerging closed-set speech recognition skills at 12 months post-activation.^{70,71} In Brazil, 4 pediatric ABI subjects showed variable speech perception ability.⁷² At least 12-months post-activation, the children's use of the ABI ranged from "bonded to device" to "able to derive some meaning from sound" on parental questionnaires³⁰. Finally, a child implanted in the US demonstrated device bonding and good speech detection at 4-months post-activation.^{73–75} These sparse efficacy data indicate that development of auditory skills is slow, but likely supportive of voice monitoring and lip-reading for those children who attempt communication via spoken language. However, even this level of benefit is likely reduced in children with additional disabilities.⁷⁶

Reviewing outcomes from children with inner ear malformations implanted with a CI allows a window into the potential benefit of an ABI. CI outcomes show significant variability, but some malformations have been shown to result in near-normal performance.

Cochleovestibular malformations coupled with an open cochlear aperture and cochlear nerve, considered a mild to moderate malformation, are associated with speech perception results similar to those without a malformation.⁵⁶ Malformations stemming from a "common cavity" for the labyrinth and cochlea also have resulted in successful development of open-set speech perception.⁶⁶ However, children with hypoplastic bony structures and lack of a nerve have limited auditory skill acquisition,^{45,55} minimal sound awareness, and delayed speech understanding.^{49,77} The limitations may not resolve over time, as suggested by a longitudinal study of electrophysiological responses to sounds, children with an absent nerve showed abnormal waveforms and poor behavioral auditory results up to 10 years

following implantation.⁴⁶ Taken together, the auditory results do not appear to exceed those achieved by children with aplastic/hypoplastic cochlear nerve after receiving an ABI.⁷⁸

Risks and risk mitigation

There are four categories of risks associated with safety of an ABI in the very young child. The categories are: limitations of imaging modalities to accurately diagnose the underlying abnormality⁴⁹, surgical/medical aspects of the implantation procedure⁷⁹, experiencing a non-auditory side effect during programming or everyday use^{80,81}, and internal device failure⁸¹. Two categories of risks associated with efficacy involve the parental perspectives on implantable auditory prostheses and the ability of the family to sustain intensive auditory therapy for an extended length of time.

We have found a team approach to evaluation and treatment helpful for risk mitigation. Members of the transdisciplinary team, including a neuroradiologist with ample cerebellopontine angle imaging experience, pediatric neurosurgeon/neurotologist, pediatric audiologist, speech-language pathologist, psychologist, and an experienced educator of the deaf, can develop an integrated strategy to evaluate and care for the child, thus, potentially avoiding circumstances that increase the risks.

A second risk mitigation strategy is comprehensive medical and psychological review of the child. The child should be free of any major medical conditions and able to undergo a craniotomy. Children at least 2 years of age should be considered, because the brain and skull size is nearly adult-like at 2 years of age^{82,83}. The child should be free of additional disabilities, as can be assessed at 2 years of age, to effectively participate in the extensive training process post-implantation. The presence of additional disabilities, such as developmental delay or autism⁴², limit the child's ability to make meaningful associations between electrical stimulation and the environment.^{43,76} Environmental factors, such as involved and efficacious caregivers play a significant role in the child's ability to develop auditory skills.^{84,85} Supportive hearing therapy, educational services, and intensive speech-language therapy all serve to increase the likelihood the child will develop speech and language (Figure 3). Collectively, these factors shape the child's circumstances and impact the ability to achieve an optimal outcome.

Limitations of Imaging—Both thin-slice MRI and HR CT of the temporal bone are employed to diagnose profound hearing loss in cases where abnormal inner ear anatomy or cochleovestibular nerve anatomy is found⁸⁶. Cochleovestibular malformations and/or cochlear nerve aplasia can be viewed using current acquisition protocols, however, patient movement artifacts, incomplete visualization of the petrous apex, or other imaging issues may compromise clarity⁶⁰. The “false positive”, judging that a nerve is present when it is not, risks delay during the critical time for language development^{21,87} by focusing on receiving a CI. A “false negative”, judging that no auditory nerve is present when a viable nerve is present risks moving forward with an ABI, when the simpler procedure of cochlear implantation would likely provide similar levels of access to sound and support for language development. Mitigating the risk of cochlear nerve false positives/negatives involves

consultation with an experienced neuroradiologist, images acquired under best-practices acquisition protocols, behavioral audiometry and/or electrophysiological testing.⁵⁹

Surgical/medical risks: The risks associated with an ABI are similar to those of cochlear implantation in children with abnormal inner ear anatomy. The risks of a cerebrospinal fluid leak, encountering abnormal facial nerve anatomy, and difficulty placing the electrode are frequently encountered in CI surgery.³⁷ In ABI surgery, these risks can be greater (see Table 2).

A cerebrospinal fluid leak during or after ABI surgery is likely due to changes and subsequent leakage of the dural seal around the exit of the device⁷⁹. In either surgery, such leaks may encourage meningitis. Management begins with ensuring the patient receives appropriate vaccinations prior to surgery¹⁰. For the ABI, intra-operative placement of a lumbar drain may be appropriate prophylactic measure (MK, EPW experience). Careful packing of the defect and closure of the dura reduces, but does not eliminate, the possibility of a leak.

Facial nerve impairment may occur if an abnormally positioned nerve is irritated inadvertently. Facial nerve monitoring gives the surgeons information about the degree to which the nerve is affected.⁸⁸ Confirmation of ABI electrode placement is guided by electrically evoked auditory brainstem response (EABR) monitoring after the electrode array is placed.⁸⁹ Each electrode on the ABI array is stimulated and the patient closely observed for change in respiration, blood pressure, or other vital signs, as well as waveforms thought to be associated with auditory pathway stimulation.⁹⁰ An additional risk carried by ABI implantation is prolonged exposure to general anesthesia, which has been associated with reduction in language skills and performance IQ in children.^{91,92}

Programming risks: The risks associated with programming the external speech processor to electrically stimulate the cochlear nucleus are higher than programming a CI. CI programming has great flexibility, such as lengthening electrical pulse width or current steering; both options are critical for beneficial speech processing⁹³. An abnormal cochlea reduces these CI programming options, lessening the ability to leverage the cochlea's tonotopic representations⁹⁴. Further, the ABI electrode is placed over the cochlear nucleus, a region with no discernable tonotopic arrangement¹⁴.

Pre-linguistic children are less able to communicate uncomfortable symptoms which might be precursors to more serious non-auditory side effects.⁴⁰ The lack of ABI programming flexibility, in turn, limits how non-auditory side effects can be addressed and still maintain usable levels of stimulation. Currently, the most appropriate post-implantation procedure is testing the internal ABI with the child under sedation one-month post-surgery⁹⁵. The electrophysiologist provides detailed electrode information to the audiologist conducting the behavioral programming. The initial programming is done with ready access to a Pediatric Advanced Life Support team, to address any life-threatening non-auditory side effects, unlike the initial programming for a CI. In addition, the programming audiologist and a test assistant carefully scrutinize the child to detect any subtle non-auditory side effects when stimulating the ABI. Each of these steps mitigates the risk of a non-auditory side effect

during the first time the child is stimulated while awake and allows for the creation of a program which can be safely used outside of the clinic⁹⁵.

Internal device failure: Internal device failure is rare for CI and ABI alike, but it is possible. For example, after a direct impact from a fall. Explanting a CI requires patience to extricate the electrode from the cochlea, but it can be accomplished with minimal disruption^{96,97}. Children who are re-implanted generally are able to continue with effective use of their CI.⁹⁸ There is little in the literature regarding ABI failures. ABI electrode removal requires careful excision of the fibrotic tissue surrounding the electrode on the brainstem, and the neurosurgeon may elect to forgo removal if he/she believes that damage may occur to the brainstem⁷⁴. Thus, risk mitigation in the ABI begins with good device placement and potentially extends to head protection, such as a helmet in children prone to falls.⁷⁵

Parent perspectives

Patient and family perspectives have become an important factor in regulatory and third-party payer decision-making.^{2,5,99–101} The extent of the family's risk tolerance² for selecting the CI or the ABI has not been well characterized. Some insight into a family's willingness to obtain an ABI for their child is evidenced in the numbers who travel outside the US for the procedure. Our center has evaluated over 50 families, each seeking an ABI for their deaf child. After discussions with study staff, a few families have decided on their own that the risk of an ABI was too great compared to the potential benefit and have not moved forward.

The capability of the family to deal with the demands of implantation and post-implantation therapy are also significant. Auditory skill and language acquisition is slow and best conducted with a holistic therapeutic approach. The family should be involved alongside speech language pathologists and educators of the deaf every day. The impetus to more fully involve families comes from clinical experience (LSE, AM) and from studies showing the impact of the primary caregiver (usually the mother) on language development⁸⁴. Generalization of auditory skills the child has demonstrated in a sound-attenuated booth to everyday situations has been slow to emerge. We have found that the ability of the family to devote the hours of language training (auditory and/or sign) varies considerably, depending on family resources and on the level of services in the community. Assessment of family perspective and ability to engage in intense post-surgical auditory skill development is an area needing investigation.

Discussion

Summary

A benefit-risk structured assessment process, commonly used in the context of drug and device studies, provides a transparent method for investigators to evaluate an appropriate treatment approach and for regulatory authorities to appraise the drug/device for marketing approval. It also serves as a communication tool with the patient and families. Congenital deafness accompanied by abnormal inner ear anatomy is a rare condition with no FDA-approved treatment option, other than a cochlear implant (see Summary Table 3). A CI has

been shown to be safe and effective treatment, however, benefits are reduced commensurate with the severity of the anatomical abnormality. Some children with cochleovestibular abnormalities are able to develop speech recognition skills. Others receive no access to sound from the CI, eventually becoming non-users.

Children with no obvious nerve leading to an intact or abnormal cochlea have poor prognosis for obtaining access to sound with a CI, as do children with additional disabilities. An auditory brainstem implant (ABI) has been suggested as an alternative. The ABI requires an elective craniotomy for electrode placement, with consequent increase in risk over the outpatient CI implant procedure. Auditory skill development after ABI surgery is variable, ranging from good access to sound to no apparent auditory perception.

At the present time, the child with abnormal anatomy represents a difficult weighing of benefits to risks when an ABI is considered. Parent perspective for the kinds of treatment they can afford or manage across many years has not been systematically explored. Families with resources for intensive auditory skill and language therapy, in conjunction with excellent services through a school district, have an optimal chance to help their child become a full-time user of the auditory prosthesis.

Conclusions

Young children with bilateral hearing loss and abnormal inner ear anatomy are faced with an unmet medical need: What is an appropriate hearing loss treatment pathway? The structured benefit-risk assessment carried out here to characterize the condition, the unmet medical need, potential benefits and risks, along with proposed strategies for risk management has revealed the complex factors involved. We have found, based on the literature and clinical experience, that individualized, thorough audiological, psychological, educational, and medical review undertaken prior the treatment decision will enhance the probability of auditory skill development with either a CI or ABI. Extensive post-implant transdisciplinary team interventions, including occupational, physical, speech language, educational, and auditory skill therapy also enhance incorporation of the device into the child's life and development of communication. Finally, undertaking the benefit-risk process in cooperation with an investigative team is critical for clarification of concerns surrounding application of new technology and for transparent communication with patients and families.

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Figure 1a.
Overview of how a cochlear implant works. (From NIDCD website).

Figure 1b.
Auditory brainstem implant. (Neurowiki 2013).

Implantable auditory prosthesis for congenital deafness: Measurement of benefit hierarchy

Figure 2.

Assessment hierarchy of auditory skill benefit from an implantable auditory prosthesis in a pediatric indication.

Figure 3.
Integration of team and family input leading to a decision to implant an auditory brainstem stimulation device.

Table 1

Cochlear Implant Adverse Events: Surgical and Speech Processor Programming.

Surgery - related	Speech Processor - related
CSF leak/gusher	Unpleasant sensations
Perilymph leak/gusher	Vibrotactile sensations
Partial electrode placement	Facial nerve stimulation
Dizziness	Dizziness/imbalance
Wound infection/flap infection	
Meningitis	
Tinnitus	
Facial nerve injury	
Taste disturbance	

Table 2

Auditory Brainstem Implantation Adverse Events: Estimated Incidence for all patient populations undergoing a retrosigmoid craniotomy for device implantation (Colletti et al., 2010).

Major Complications	Estimated Incidence
Death	<1%
Intracranial hemorrhage	<5%
Meningitis	<5%
Hydrocephalus with cerebellar swelling or hemorrhage	<5%
Brainstem injury with hemiparesis	<1%
Facial nerve palsy	<1%
Hemodynamic instability due to blood loss	<1%
Cerebral spinal fluid leakage	<10%
Cerebellar swelling not requiring intervention	<10%
Hydrocephalus without cerebellar swelling, hemorrhage, or other comorbidities	<1%
Device failure	<1%

Minor Complications	Estimated Incidence
Superficial wound infection	<10%
Blood loss requiring transfusion	<10%
Delayed extubation due to anesthetic issues	<10%
Any radiographic or laboratory abnormality without clinical symptoms that requires additional monitoring	<10%

Table 3
Benefit-Risk Suggestion for Treatment based on a Team Approach to Selecting an Auditory Prosthesis in a Pediatric Indication

Inner Ear Malformation	Likely Treatment	Likely Audiological Benefit	Ambiguous Imaging Risk	Surgery - related Risk *	Speech Processor Programming- related Risk	Device - related Risk
Cochleovestibular abnormal/Nerve present	Cochlear Implant	Access to sound, word/ sentence recognition skill	Absent nerve = delayed auditory skill development, no auditory accommodation supporting language learning	Facial nerve weakness CSF leak/meningitis Headache Wound Infection Temporary dizziness	Processor threshold requires higher current Non-auditory side effect, e.g., facial stimulation	Hard internal device failure, explant/re- implant
Cochleovestibular abnormal/Nerve absent	Possibly Auditory Brainstem Implant	Access to sound, word identification skills	Present nerve = could have had a CI, potential for greater auditory skill acquisition	Facial nerve weakness CSF leak/meningitis Headache Wound Infection Temporary dizziness	Processor threshold requires higher current Non-auditory side effect, e.g., facial stimulation	Hard internal device failure, rarely able to explant/re- implant electrode
Cochleovestibular aplasia	Auditory Brainstem Implant	Access to sound, phoneme discrimination skills	Rare for imaging to be ambiguous	Craniotomy risks Bleeding, hydrocephalus, hemiparesis, hematoma, cerebellar edema CSF leak/ meningitis Headache	Processor threshold requires higher current Non-auditory side effects: facial stimulation, body sway, gagging, choking	Hard internal device failure, rarely able to explant/re- implant electrode

* The most common risks are listed; see Table 2 for comprehensive list.