Clinical Recommendations for the Treatment of Unilateral Hearing Loss/ Single Sided Deafness with Cochlear Implantation

In collaboration with Kevin Brown, MD, PhD, University of North Carolina, and participants of the Cochlear Sponsored UHL/SSD Thought Leadership Conference

Introduction

In 1985 the first FDA approval of a multichannel cochlear implant was approved for adults with profound bilateral sensorineural hearing loss and little to no speech discrimination abilities. Cochlear implants (CI) have since become a well-established, safe and efficacious treatment for adults and children with moderate to profound bilateral sensorineural hearing loss and poor speech discrimination abilities with hearing aids. To date over 170,000 individuals have undergone either unilateral or bilateral cochlear implantation (Nassiri et. al., 2022). Since 1985, technological advances such as improved sound coding strategies, smaller sound processors and perimodiolar electrode arrays have significantly improved performance and satisfaction. This supports continued expansion of indications for use, and in 2013, the FDA approved the Nucleus® Hybrid CI system for individuals with substantial low frequency hearing. Recently the FDA approved the use of the Nucleus CI System to treat Unilateral Hearing Loss (UHL), aka Single Sided Deafness (SSD), further expanding the number of individuals who could benefit from treatment. SSD is defined by a patient experiencing a hearing loss in one ear that is severe to profound in nature with poor speech discrimination with normal hearing or near normal in the other ear. As of 2021, there are an estimated 345,000 individuals in the United States with SSD who could benefit from cochlear implantation (Kay-Rivest et al., 2021).

The CI technology used to treat a patient with SSD is identical to that used to treat patients with bilateral sensorineural hearing loss. Patient selection, counseling, and cochlear implant programming with an SSD patient may be very different. It is important that hearing healthcare providers treating SSD with CI consider the unique needs of this population to counsel and program the technology for optimal outcomes. This paper provides the pertinent information to better identify, treat and/or refer those with SSD as well as recommendations for programming and management of the technology. Cochlear partnered with 24 surgeons, audiologists, and hearing scientists with expertise in treating SSD (See table 1) to develop recommendations for evaluation (both pre and post op), programming, and follow up protocols when treating SSD patients with CI.

Table 1 : Thought Leader Meeting Participants

Surgeons	Affiliation	Audiologists	Affiliation
Kevin Brown*	University of North Carolina School of Medicine Chapel Hill, NC	Allison Beiver	Rocky Mountain Ear Center Denver, CO
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* Moderator ^ virtual attendee

Why treat?

Individuals with SSD have historically been undertreated due to lack of understanding around the importance of binaural hearing. It was often assumed that one normal hearing ear was sufficient, and treatment of the impaired ear was often not considered. Binaural hearing presents several important advantages including improved localization of sound, increased loudness perception due to binaural summation, overall improved hearing in both quiet and noisy environments, and improved ease of listening (Vila & Lieu, 2015). These benefits of binaural hearing can only be achieved with auditory inputs from two functional sides, such as by providing input to the impaired ear with a CI.

For adults with SSD, the inability to hear in one ear results in difficulties localizing sound and understanding speech in an environment with background noise (Kumpik & King, 2019). Noise is a constant attendant in many human interactions both socially and at work. This can cause individuals with SSD to have reduced

confidence in social interactions and may cause difficulty in complex work environments. In these complex social and work environments, they may experience listening fatigue from straining to hear with their better ear (Lucas et al., 2018). This can contribute to individuals with SSD experiencing social isolation and decreased quality of life (Vannson et al., 2015). In addition, individuals with SSD may experience psychological distress from worrying about possible loss of hearing in their good ear.

The auditory, speech and language ramifications for children may be significant. Lack of binaural hearing (similar to adults), makes it difficult for children to process timing and amplitude cues which are critical for sound localization and speech perception in noisy environments. (Gordon, et al., 2015). Speech and language issues, behavioral issues, academic concerns, and decreased quality of life may result when compared to their normal hearing peers. (Jin et al. 2014, Fitzpatrick et al., 2019). Research has shown that SSD also promotes an abnormal aural preference. If implantation is delayed, this may preclude benefits of subsequent implantation. (Gordon et al., 2015; Jiwani et al., 2016; Propst et al., 2010; Schmithorst et al., 2014).

Treatment options

There are a range of treatment options available for those with SSD and those options include: no treatment/ observation, CROS hearing aids, Baha™/Osia™ devices and now, cochlear implants. The outcomes for each type of treatment have been evaluated and have been summarized in Table 2. When discussing treatment options with SSD candidates it is important to identify the patient's goals of treatment as part of the decision-making regarding devices. CROS hearing aids, Baha and Osia systems all transfer signals from the impaired ear to the better hearing ear and due to the single cochlea being stimulated, limit the more complex binaural benefits. Patients using Baha and Osia systems report numerous benefits, including improved speech in noise perception and quality of life benefits (Almugathwi et al., 2020). However, for maximal binaural benefits, input from both ears is necessary. A cochlear implant provides the ability to stimulate the deaf ear whereas the other options do not.

Table 2 : Auditory Benefit of Treatment Options

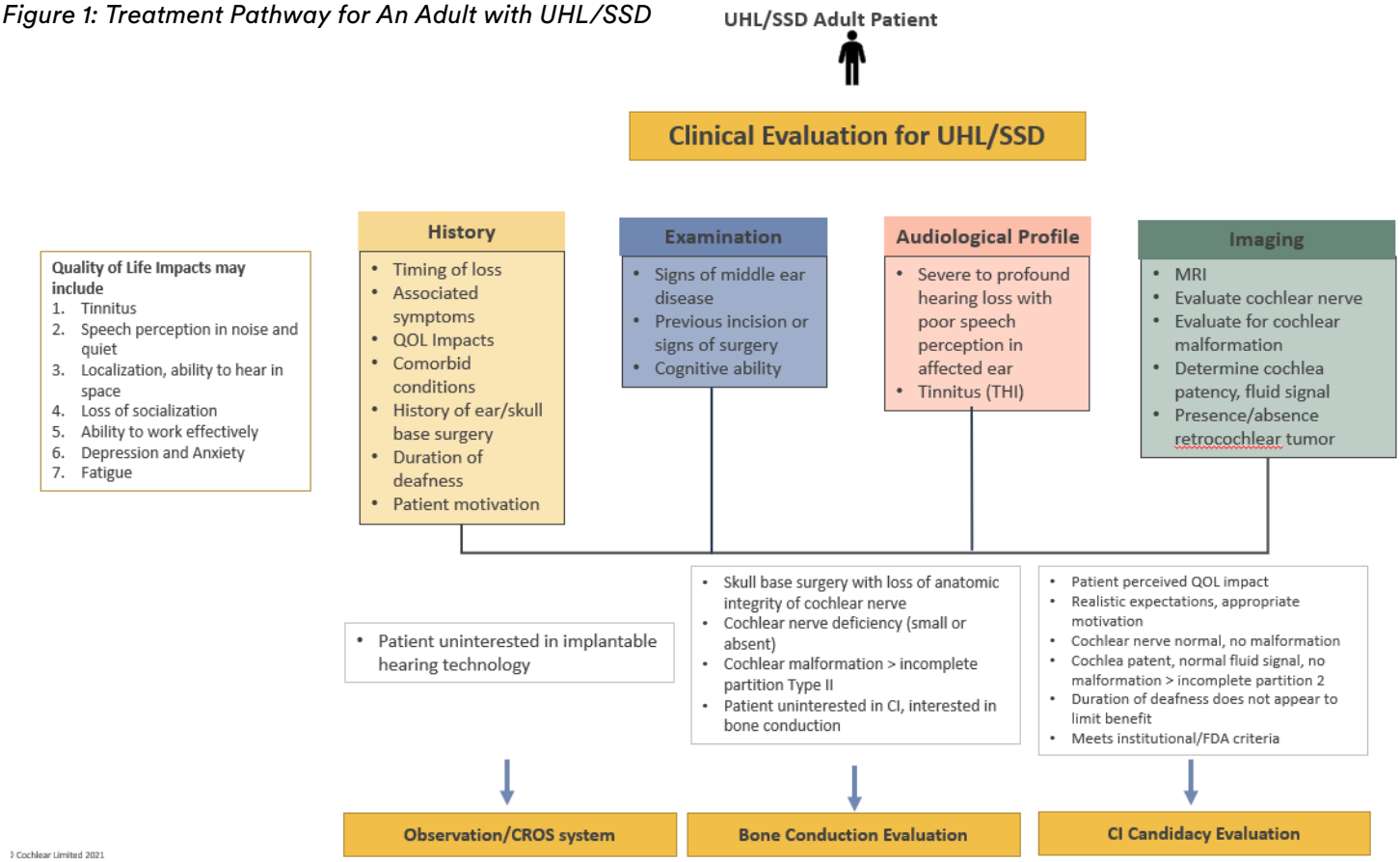
		TREATMENT OPTION			
		No Treatment/ Observation	**CROS/BiCROS**	**Baha™/Osia™ System**	**Nucleus® Cochlear Implant**
AUDITORY BENEFIT	Overcome Head Shadow	✗	✓	✓	✓
	Sound Lateralization	✗	✓	✓	✓
	Improved Localization	✗	✗	✗	✓
	Binaural Summation	✗	✗	✗	✓
	Squelch	✗	✗	✗	✓

For those seeking treatment for UHL/SSD, multiple factors should be considered to determine the best course of treatment. These factors include a comprehensive medical/hearing history and audiologic evaluation, imaging of inner ear/auditory nerve, quality of life impact, and identification of the patient's specific concerns regarding their hearing.

The Treatment Decision Pathway (Figure 1) was developed by the Thought Leadership Group and is an excellent tool for professionals treating this population. Many patients may be candidates for more than one treatment option and in those instances, it is especially important to consider lifestyle and desired outcomes.

As previously mentioned, it is also important to recognize that individuals with anatomical malformations such as cochlear nerve deficiencies, cochlear aplasia and those who have lost cochlear nerve function following acoustic neuroma removal surgery are not candidates for a cochlear implant but remain candidates for an Osia, Baha or CROS hearing device. For all other etiologies where a functional cochlea and cochlear nerve are present, a cochlear implant is a consideration and should be discussed with the patient.

Figure 1: Treatment Pathway for An Adult with UHL/SSD



The Nucleus Cochlear Implant and bone conduction system (Baha and Osia) indications are listed in the table below. There is overlap in the indications which provides the clinician a range of treatment options to best tailor the individual patient needs with an implantable solution.

Table 3. Patient Demographics, N =113 patients, 116 ears

	Cochlear Implant	Bone Conduction Solution
Age	5 years & Older	5 yrs + Baha • 12 yrs + Osia*
Ear to be implanted	• Severe to profound SNHL defined as PTA at .5, 1, 2, 4 kHz >80 dBHL • Aided CNC words or developmentally appropriate word test <5%	Patients who have profound SNHL in one ear and normal hearing in the opposite ear
Contralateral Ear	• Normal or near normal hearing defined as PTA at .5, 1, 2, 4 kHz <30 dB	The PTA air conduction hearing thresholds of the haring ear should be < 20 dB HL (measured at 5., 1, 2, & 3 kHz)

*Pediatric IDE Study underway to lower age to 5 years for Osia
^ See Appendix B for full labeling & contraindications

CI for SSD evaluation protocol

This section provides the professional with a suggested protocol to evaluate and assess hearing performance in the SSD patient.

Medical Evaluation

For individuals with SSD, a typical medical evaluation includes an extensive history and physical examination with careful attention paid to chronic ear disease, meningitis, bacterial labyrinthitis and autoimmune inner ear disease. Imaging is recommended due to the asymmetry of the hearing loss and, for children or adults with a congenital loss, to confirm cochlear nerve integrity. An MRI will document the patency of the cochlea as well as visualization of the internal auditory canal to diagnose cochlear nerve deficiencies. In addition, genetic testing is also recommended for children presenting with SSD.

Candidacy Evaluation

For pre-operative evaluations, the goal is to establish baseline measurements for both objective and subjective measures. The need to document the hearing levels and speech understanding abilities of the ear to be treated and confirmation of normal hearing levels in the contralateral ear are a necessary part of the evaluation process, especially for reimbursement purposes. Evaluations should include both audiometric and patient reported outcomes to demonstrate the need for intervention. See Appendix A for additional information on assessments.

Device Programming

To support the SSD indication Cochlear analyzed retrospective data to demonstrate with reasonable assurance the safety and effectiveness of cochlear implantation in individuals with SSD (https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S205B.pdf). Analysis of the data for the 42 participants, who received a cochlear implant for the treatment of SSD, demonstrated that the cochlear implant restored some level of functional hearing to an otherwise severely compromised/non-functional hearing ear, with 83% of the participants demonstrating at least a 30% improvement on CNC word recognition. Furthermore, when comparing speech understanding in noise, preoperatively in the best listening condition (HA + Normal Hearing (NH) or NH alone) to post-activation in the binaural listening condition (CI + NH), 78% of the participants demonstrated a clinically meaningful head shadow benefit (>1 dB). Additionally, 67% of the participants demonstrated an improvement in sound source localization, of at least 15°. The significant improvements in speech understanding in noise and localization ability were further substantiated by improved subjective hearing ability on the Speech, Spatial and Qualities questionnaire (SSQ).

These improved hearing outcomes were achieved through the use of standard default programming techniques. However, as with any new indication there may be other programming options that could render enhanced sound quality and improved outcomes. This section will present the goals of programming and may require differences in thinking as compared to standard CI programming. Due to the presence of a normal hearing ear, when programming, the following recommendations should be standard for all SSD sessions-

- Sound from the computer should be disabled/muted during the programming session
- Consider the use of an earplug to minimize any cues of stimulation via the normal hearing ear
- Minimize background noise in the test environment
- Limit conversation during programming

For individuals with SSD, the programming recommendations for activation of the CI are slightly different from historically traditional cochlear implant recipients. The SSD individuals have limited familiarity with amplification and could report the presence of tinnitus, therefore the use of population mean settings is suggested as a starting point for measurement of psychophysics. The use of population mean enables the audiologist to easily create a map that is audible and comfortable without needing to make many threshold (T) and comfort (C) level measurements in an initial activation. This method creates a starting MAP using mean T and C level profiles derived from an analysis of a large global patient data set to generate a starting MAP (Cochlear LTD 2020) and is electrode specific. A population mean map starts with a dynamic range of 40 clinical levels (CLs) and typically has thresholds of 70-80 CLs and comfort levels of 110-120 CLs. This programming mode avoids the need to count or detect threshold levels during activation.

Since the CI for the SSD population will have a built-in comparison between normal hearing and hearing with a CI, there may be some sound quality aspects that need to be addressed following a period of device use and acclimatization. Similar to a traditional CI patient, some patients may acclimate quickly, while others may have difficulty due to the normal hearing on the other side. This may include addressing the place pitch mismatch that occurs with cochlear implantation. Our recommendation is to create MAPs with both the default and alternate frequency allocation table assignments. MAPs should be created with low frequency cut-off of 188 Hz (default), 438 Hz and 563 Hz. Patients should be encouraged to try each of the MAPs to assess sound quality prior to returning for their first follow up visit.

These frequency allocation table recommendations are based upon the research by Landsberger and colleagues (2015), who report that a mismatch was observed between the predicted frequency and default frequency provided by all electrode arrays. In situations where that adaptation does not occur, the mismatch may be resolved by making changes to the frequency allocation table (FAT) within Custom Sound Pro™.

At follow up programming sessions further refinement of the MAP and confirmation of audibility should occur. With experience, recipients should be able to provide consistent measurement of threshold levels. Confirmation of these levels should be conducted via soundfield audiograms in the booth, or, if needed, via direct streaming in Remote Check. Comfort-level (C-Level) programming can also be adjusted based upon Electrically Evoked Stapedial Reflex Thresholds (ESRT).

For all test intervals, both primary measurements and interim, the use of Remote Check should be considered either to augment the in-person assessment or in lieu of the implant recipient coming into the clinic. Remote Check allows for complete isolation of the implant ear for detection thresholds, hearing performance in noise and monitoring of datalogging. For more information on this option, please visit **https://www.cochlear.com/us/en/campaign/remote-check-pro**

Post implant evaluations

Based upon the discussions with the Thought Leadership Group, the following evaluation recommendations have been made:

1-Month Post Implant

- Datalogging monitoring of at least 10 hours wear time per day
- OPTIONAL TESTING
  - Aided Soundfield Thresholds & CNC Words (CI ear alone)
  - BKB SIN Speech Front/Noise normal hearing ear 1 list pair CI ON/1 list pair CI OFF

3-, 6-, 12-months Post Implant

- Datalogging Monitoring of at least 10 hours wear time per day
- Aided Soundfield Thresholds & CNC Words (CI ear alone)
- BKB SIN Speech Front/Noise normal hearing ear 1 list pair CI ON/1 list pair CI OFF
- Optional Test Conditions
  - BKB SIN Speech Front/Noise CI ear CI ON/CI OFF
  - BKB SIN Speech Front/Noise Front CI ON/CI OFF
  - AZBio Sentences in Noise CI ON/CI OFF
- Questionnaires (SSQ, THI, CIQoL35)

These post implant evaluation measures are used to determine the level of improved binaural hearing including speech understanding and localization. Test protocols have been established for adults as well as children (Park et. al., 2022) for the CI for SSD population. The most difficult listening situation for individuals with unilateral hearing loss are noisy environments requiring the implementation of binaural squelch. Testing in noise with the cochlear implant on and again with it off will document the improvement provided by the CI. In assessing this benefit, an adaptive noise test is suggested to avoid floor or ceiling effects. See Appendix C for additional information on assessments.

Conclusion

The treatment of SSD with a cochlear implant has been proven to be safe and effective for adults and children. Individuals who have received a CI for SSD demonstrate improved speech understanding in quiet and noise. Additionally, data has shown that using a CI for treatment of SSD enables central processing of complex auditory signals via binaural squelch and summation. The evaluation protocols and programming suggestions provide surgeons and audiologists with the information necessary to document improved patient performance.

Additional opportunities exist in ongoing research including a post approval study as well as ways in which to enhance and improve outcomes as more individuals with SSD receive a CI as routine clinical practice.

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Appendix A: Evaluation protocols

Adult Candidacy Evaluation

- Confirm appropriate amplification with hearing aid fit to DSL/NAL, if patient cannot be fit with amplification, assume 0% score on word recognition
- Testing of treated/implant ear (aided):
  - CNC words in quiet at 60 dBA while masking the contralateral ear with insert earphone at 60/65 dBHL using speech shaped noise
  - *Optional*: AZBio sentences in noise
- Testing in bimodal condition (ear to be implanted fit with HA or CROS)
  - BKB SIN: Speech Front/Nosie to normal hearing ear
- Questionnaires: SSQ, CIQoL35, THI

Adult Post Implant Evaluations (1-, 3-, 6-, 12-month, annually)

- CI Ear Alone
  - Aided Soundfield Thresholds CI ear along (normal hearing ear: adults-masking)

    Optional: Use of Remote Check
  - CNC Words at 60 dBA, Mask normal ear with 60/65 dB HL speech shaped noise
- Binaural Testing
  - BKB SIN Speech Front/Noise normal hearing ear 1 list pair CI ON/1 list pair CI OFF
  - Optional Test Conditions
    - BKB SIN Speech Front/Noise CI ear CI ON/CI OFF
    - BKB SIN Speech Front/Noise Front CI ON/CI OFF
    - AZBio Sentences in Noise CI ON/CI OFF
- Questionnaires
  - SSQ, THI, CIQoL35

Pediatric Candidacy Evaluation

- Confirm appropriate amplification with hearing aid fit to DSL/NAL, if patient cannot be fit with amplification, assume 0% score on word recognition
- Testing of treated/implant ear (aided):
  - CNC words in quiet at 60 dBA (or developmentally appropriate test) while using plug/muff technique on normal hearing ear
  - *Optional*: BabyBio/AZBio sentences in noise
- Testing in bimodal condition (ear to be implanted fit with HA or CROS)
  - BKB SIN: Speech Front/Nosie to normal hearing ear
- Questionnaires: SSQ for Parents, HEAR-QL, Peds QL™4.0

Pediatric Post Implant Evaluations (1-, 3-, 6-, 12-month, annually)

- CI Ear Alone
  - Aided Soundfield Thresholds CI ear along (normal hearing ear: pediatrics-plug & muff)
    - *Optional*: Use of Remote Check
  - CNC Words or developmentally appropriate word test at 60 dBA, plug & muff normal ear
- Binaural Testing
  - BKB SIN Speech Front/Noise normal hearing ear 1 list pair CI ON/1 list pair CI OFF
  - Optional Test Conditions
    - BKB SIN Speech Front/Noise CI ear CI ON/CI OFF
    - BKB SIN Speech Front/Noise Front CI ON/CI OFF
    - AZBio Sentences in Noise CI ON/CI OFF
- Questionnaires: SSQ for Parents, HEAR-QL, Peds QL™4.0

Appendix B: Labeling and Indications

Cochlear Implants for UHL/SSD:
5 years of age and older

Ear to be implanted

- Severe to profound sensorineural hearing loss defined as: Pure-tone average at .5, 1, 2, 4 KHz >80 dB HL
- Aided CNC word score or developmentally appropriate word test <5%

Contralateral Ear

- Normal or near normal hearing defined as: Pure-tone average at .5, 1, 2, 4 kHz <30 dB HL

It is recommended prior to CI surgery that individuals with SSD have at least 2 weeks to 1 month experience wearing appropriately fit CROS hearing aid or other suitable hearing device.

Contraindications

- A Nucleus cochlear implant is not suitable for individuals with the following conditions:
  - Absence of cochlea development
  - Absence of a cochlear nerve
  - Active middle ear infections
  - Tympanic membrane perforation in the presence of active middle ear disease
- For individuals with single sided deafness the following contraindication is also applicable:
  - Duration of profound sensorineural hearing loss greater than 10 years

This approval comes with the removal of the following contraindication:

- Deafness due to lesions of the cochlear nerve or central auditory pathway

Bone Conduction for UHL/SSD: Baha 5 years of age & older, Osia 12 years & older

- Poorer Hearing Ear
  - Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear
- Hearing Ear
  - The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at .5, 1, 2, and 3 kHz)
- Contraindications
  - Insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI200 Implant
  - Chronic or non-revisable vestibular or balance disorders that could prevent benefit from the device, as determined by good clinical judgment
  - Abnormally progressive hearing loss
  - Evidence that hearing loss is bilateral retrocochlear or bilateral central origin
  - Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment
  - Skin or scalp conditions that may preclude attachment of the Sound Processor or that may interfere with the use of the Sound Processor

Appendix C: Isolation of ear to be treated

Assessment of the ear to be treated will require a method to allow for maximum attenuation of hearing from the normal hearing ear via masking or a “plug and muff”. As there is no equation available that can predict the attenuation of an earplug and earmuff combination, some crossover auditory input may remain. Research has found that at and above 2000 Hz, all dual-protection combinations provide attenuation of approximately 40 to 50 dB, depending upon frequency . Below 2000 Hz, variability is controlled by the effective attenuation level of the earplug (AudiologyOnline Extra Protection: Wearing Earmuffs and Earplugs in Combination, Elliott H. Berger, MS, INCE Bd. Cert., August 6, 2001). Masking using speech shaped noise via an insert earphone can also be used to isolate the normal hearing ear. Care should be taken regarding the level of masking provided to avoid any central masking issues that can occur during testing. For pediatrics, research suggests that the level of central auditory processing required for masking speech perception does not reach adult-like levels until 6-11 years of age (Moore, 2011). While some children may be able to perform these tasks there is wide variability, therefore the recommendation of using a “plug and muff” technique for children and masking for adults is suggested.

An adaptive procedure for varying the speech or noise levels is commonly used to track the signal-to-noise ratio (SNR) that produces a target of 50% correctly recognized items (e.g. Levitt & Rabiner, 1967). For children, this also accommodates for issues related to auditory development as “There is evidence that children require higher SNRs than young adults to achieve similar performance on a wide range of speech-in-noise measures (e.g., Corbin, Bonino, Buss, & Leibold, 2016; Elliott, Connors, Kille, Levin, Ball, & Katz, 1979). In many studies, mature performance has been observed by about 9–10 years of age (e.g., Corbin et al., 2016; Nishi, Lewis, Hoover, Choi, & Stelmachowicz, 2010), providing evidence that the ability to perceptually segregate target speech from a noise masker may be immature early during the school-age years but is adult like by adolescence.” (Speech Perception in Complex Acoustic Environments: Developmental Effects, Lori J. Leibold, Journal of Speech, Language, and Hearing Research, 17 Oct 2017). Additional testing can also be completed using AZ Bio sentences, if these were used as part of the pre-operative evaluation. Questionnaires should also be utilized to quantify changes in the patient’s perception of their hearing performance and listening abilities. See Appendix C for adult and pediatric post-operative evaluation recommendations.

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

Views expressed are those of the individual. Consult your health professional to determine if you are a candidate for Cochlear technology.

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