2024 Clinical Recommendations for the Treatment of Unilateral Hearing Loss/Single-Sided Deafness with Cochlear Implantation

In collaboration with participants of the Cochlear sponsored UHL/SSD Thought Leadership Conferences

Introduction

Single-sided deafness (SSD) impacts over 345,000 adults in the United States, with an estimated 5.2% experiencing some degree of unilateral hearing loss (Kay-Rivest et al, 2021). SSD significantly impacts spatial hearing, speech understanding in noise, and quality of life, affecting various auditory and non-auditory functions (Dillon et al., 2017b; Kumpik & King, 2019). Historically, treatment options for SSD have been limited. Many patients have gone untreated or relied on treatment options which stimulate the contralateral ear, such as contralateral routing of signal (CROS) hearing aids or bone conduction solutions. Today, expanding criteria in conjunction with advancements in hearing technologies, such as cochlear implants (CIs) and bone conduction devices, have significantly changed the treatment landscape for individuals with SSD. Since approval in early 2022, SSD accounts for between 13-16% of CI registrations. This number continues to grow, as cochlear implantation is the only solution which allows for binaural input from two ears, providing potential benefits and improved outcomes over other treatment options.

Early experiences with SSD have sparked new investigations into individual patient factors, candidacy criteria, and incidence of non-use. These insights have shifted the focus during implant candidate selection with increased emphasis on quality of life, expectations, and motivation.

This paper will provide comprehensive information on the treatment of SSD with a CI, based on recommendations from industry experts and Cochlear North America, two years post-FDA approval. Key areas of focus include:

- Adult treatment pathway and candidacy considerations
- Patient selection criteria, quality of life assessment, patient motivation, and establishing realistic expectations for performance and rehabilitation
- Essential aspects of programming a cochlear implant for patients with SSD
- Follow-up protocols to ensure optimal outcomes for adults

A list of professionals supporting this consensus can be found in Appendix A.

SSD thought leadership workshops

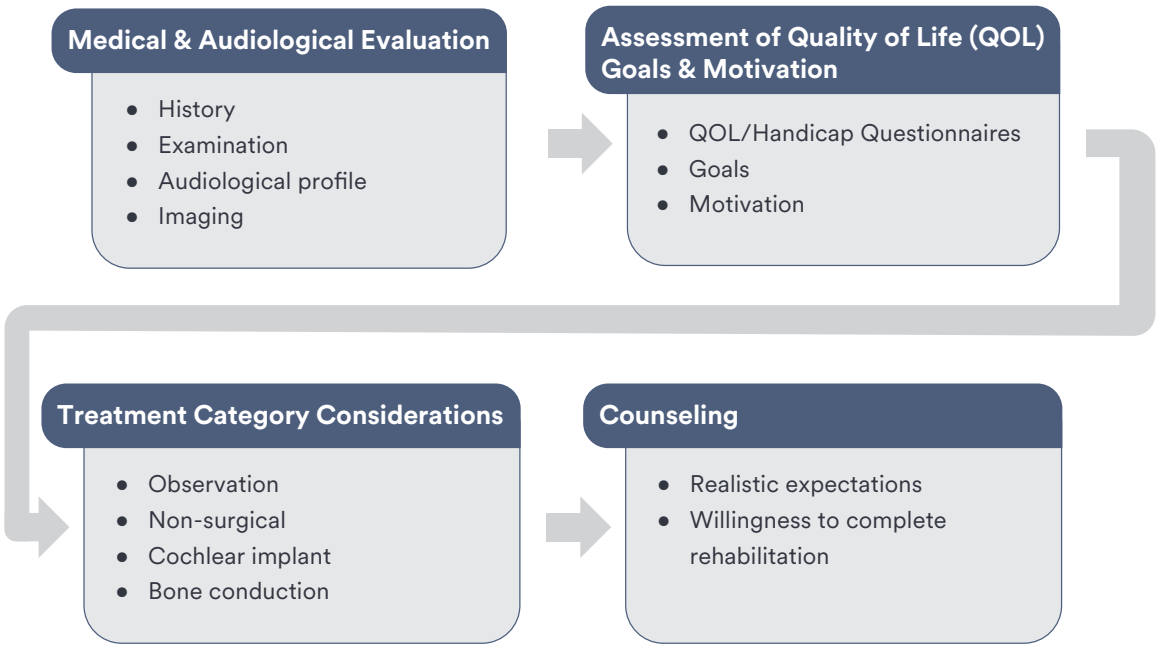
In preparation for FDA approval of CI for SSD, an inaugural Thought Leadership Workshop was held in December 2021. This collaborative effort led to the development of a comprehensive SSD treatment pathway and development of a white paper focused on quality-of-life impacts, medical history, audiological profile, imaging, device programming, and post-implant assessments for adults. A follow-up Thought Leadership Workshop was conducted in May 2024. Moderated by Doctors Kevin Brown and Daniel Zeitler, the agenda included a mix of scientific presentations and panel discussions, aimed at refining and enhancing candidacy and treatment protocols based on the latest clinical experiences and outcomes. The critical updates to the previous guidance for adults include the following:

- Counseling during the candidacy evaluation phase is critical and assessment of patient expectations, motivation, and hearing deficits should be standard practice. Additionally, it is crucial to establish the expectation that outcomes are contingent upon device usage and aural rehabilitation.
- The SSD pre- and post-implant evaluation protocol was updated to align with the Minimum Speech Test Battery, Version 3 (MSTB-3), utilizing AzBio Sentences with a fixed signal-to-noise ratio (SNR) as the primary metric for evaluating speech understanding in noise, as an alternative to the Bamford-Kowal-Bench Speech-in-Noise (BKB-SIN).
- The post-implant activation and follow-up schedule should align with current care model practices and be updated to include intervals at Initial Activation, 1 month, 3 months, and 12 months. This eliminates the 6-month visit from the previous treatment pathway.

Navigating single-sided deafness: Adult treatment pathway

The Adult Treatment Pathway (Figure 1.) summarizes the steps in the evaluation process including important considerations and assessments which help the implant team determine the most appropriate intervention and guides counseling. Refer to Appendices B and C for additional references, resources, and supporting discussion.

Figure 1: Adult Treatment Pathway for Single-Sided Deafness



Indications

The Cochlear™ Nucleus® Implant system indication was expanded in January 2022 to include patients with SSD aged 5 years or older. However, depending on patient history, etiology of hearing loss, and other factors, bone conduction solutions, non-surgical options, or no treatment/observation may be considered in some cases. The current Nucleus® Cochlear Implant and bone conduction Baha® and Osia® systems indications are listed below in Figures 2 and 3. There is overlap in the indications for these implantable solutions which provides the clinician with a range of treatment options available to meet individual patient needs.

Figure 2.

Cochlear Implants for UHL/SSD

5 years of age or older

Ear to be Implanted	Contralateral Ear
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%	Normal or near normal hearing defined as: Pure-tone average at .5, 1, 2, 4 kHz <30 dB HL Recommended 2 weeks to 1 month experience wearing appropriately fit CROS hearing aid or other suitable hearing device

Contraindications for cochlear implantation include: 1) absence of cochlea development, 2) absence of cochlear nerve, 3) active middle ear infections, 4) tympanic membrane perforation in the presence of active middle ear disease, or 5) duration of profound sensorineural hearing loss greater than ten years.

Figure 3.

Bone Conduction for UHL/SSD

5 years of age or older

Poorer Hearing Ear	Contralateral Ear
Profound sensorineural hearing loss	Normal or near normal hearing defined as: Pure-tone average at .5, 1, 2, 3 kHz </= 20 dB HL

Contraindications for bone conduction implantation include the following: 1) insufficient bone quality or quantity to support implantation of both the BI300 Implant and the OSI300 Implant, 2) chronic or non-revisable vestibular or balance disorders that could prevent benefit from the device, as determined by good clinical judgment, 3) abnormally progressive hearing loss or evidence that hearing loss is bilateral, retrocochlear or bilateral central origin, 4) evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment, or 5) skin or scalp conditions that may preclude attachment of the Sound Processor or that may interfere with the use of the Sound Processor.

Candidacy evaluation

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 otologic history with careful attention to details regarding chronic ear disease, history of vestibular dysfunction, previous ear or skull-based surgery, meningitis, bacterial labyrinthitis, autoimmune inner ear disease other comorbidities. A thorough physical examination including a cranial nerve exam and microscopic otoscopy should also be performed. Etiology of the hearing loss with consideration for risk of progression in the affected ear or contralateral ear is also important to consider. In addition to this, tinnitus is prevalent in this population and can significantly impact quality of life, making it crucial to incorporate tinnitus into the overall treatment plan and evaluation process. Imaging is recommended due to the asymmetry of the hearing loss and to confirm cochlear structural integrity in cases of congenital hearing loss. An MRI will document the anatomy and patency of the cochlea as well as allow visualization of the internal auditory canal to provide insight into possible cochlear nerve deficiencies or retrocochlear pathology which could impact potential outcomes. Duration and progression of the hearing loss should also be considered. Shorter duration of deafness (severe-to-profound hearing loss < 10 years) may result in improved outcomes as suggested by Rahne & Plontke (2016). However, other studies suggest duration of deafness for SSD has less impact on outcomes compared to duration in cases of bilateral sensorineural hearing loss (Nassiri et al. 2021a). Thus duration alone should not preclude consideration and should be considered along with other patient variables.

Audiological Evaluation

The pre-operative candidacy evaluation should establish baseline measurements for both objective and subjective measures to confirm hearing loss meets FDA or institutional audiometric criteria, demonstrate the need for intervention and provide a basis for pre- and post-implant comparison. This includes routine audiometric testing and evaluation of the speech understanding abilities with the better ear either plugged and/or masked depending on patient age or risk of central inhibition.

Specifically, evaluation of aided and unaided CNC words, as well as AzBio Sentences in noise in the ear to be implanted (65 dBA with 60-65 dB of masking to the normal hearing ear) is recommended to align with MSTB-3 recommendations. Aided binaural testing is not required for SSD candidates; however, confirmation of normal hearing levels in the contralateral ear is necessary for reimbursement purposes.

For additional information regarding MSTB-3 materials and set-up refer to https://www.cochlearimplanttraining.com/minimum-speech-test-battery.

Assessment of Quality of Life, Goals, Motivation and Expectaions

Emphasis should be placed on using one or more validated objective assessments to better understand individual impact on quality of life, tinnitus handicap, listening fatigue, and other reported challenges. Several tools are available to evaluate and understand an individual's unique needs. The Cochlear Implant Quality of Life Profile (CIQOL), developed by McRacken and Hand (2019), offers insights into a patient's functional hearing ability. The Speech, Spatial, and Qualities of Hearing Scale (SSQ-12), created by Noble et al. (2019), provides valuable information about spatial hearing in real-world scenarios, particularly beneficial for the SSD population. The Tinnitus Handicap Inventory (THI) by Newman et al. (1996) should be considered when tinnitus is reported. All these measures can be administered both pre- and post-implantation to monitor progress. These tools can also be used during the counseling process to evaluate and discuss patient and family expectations and establish goals. This is critical, as alignment with realistic outcome expectations is often tied to patient satisfaction. Appendix C provides additional description of these assessments, the information they offer, and how they can be administered.

Additionally, thought leaders agree evaluating patient and family motivation to pursue treatment is essential, along with their understanding and willingness to complete aural rehabilitation. Expectations for device wear time of 10+ hours daily and regular direct streaming should also be established.

Treatment options

When discussing treatment options with SSD candidates, the importance of understanding quality of life impacts, as well as establishing expectations and goals has become evident. Understanding patient motivation for treatment and other co-existing complaints, such as tinnitus, is also critical and may help guide discussion. Observation might be considered for patients who are not interested in treatment or do not perceive a quality-of-life impact as a result of their hearing loss. Non-surgical options such as CROS or Baha SoundArc™ have historically been considered in cases where the patient is seeking treatment but medical comorbidities or other factors preclude surgical intervention. Bone conduction implants such as Osia systems offer viable solutions in cases where structural or neural integrity is a concern or when the hearing history does not support CI candidacy. Patients using Baha and Osia systems report numerous benefits, including improved speech in noise perception and improvements in quality of life (Almugathwi et al., 2020). However, both non-surgical and bone conduction solutions rely on transcranial re-routing of sound, which limits more complex binaural sound processing capability which can only be achieved with a cochlear implant. Presence of tinnitus may also influence treatment options since cochlear implants have been shown to significantly reduce tinnitus in a substantial 50-90% of cases with only a small percentage experiencing no change or worsening of their tinnitus (Idriss et al, 2022, Assouly et al, 2021, Borges et al, 2021, and Levy et al, 2019). Treatment options and potential auditory benefits have been summarized below (Figure 4).

Table 4 : Potential Auditory Benefit of Treatment Options

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

Post-Implant programming & assessment

Device Programming for SSD/UHL

Due to the presence of a normal hearing ear, the following recommendations are for all SSD/UHL programming sessions:

- Sound from the computer should be disabled/ muted during the programming session
- 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

Population mean is the standard starting point at initial activation and 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 numerous threshold (T) and comfort (C) level measurements during the initial activation. This method creates a starting MAP using mean T- and C-level profiles derived from a large global patient data set to generate a starting MAP (Cochlear Limited 2020) which is electrode specific. A population mean MAP starts with a dynamic range of 46 clinical levels (CLs) and typically has thresholds of 70-80 CLs and comfort levels of 110-120 CLs. The T- and C-level profile is gradually increased while maintaining the dynamic range until the patient perceives the sound to be "loud." Sweeping using banded C-levels can then be performed to account for any profile differences.

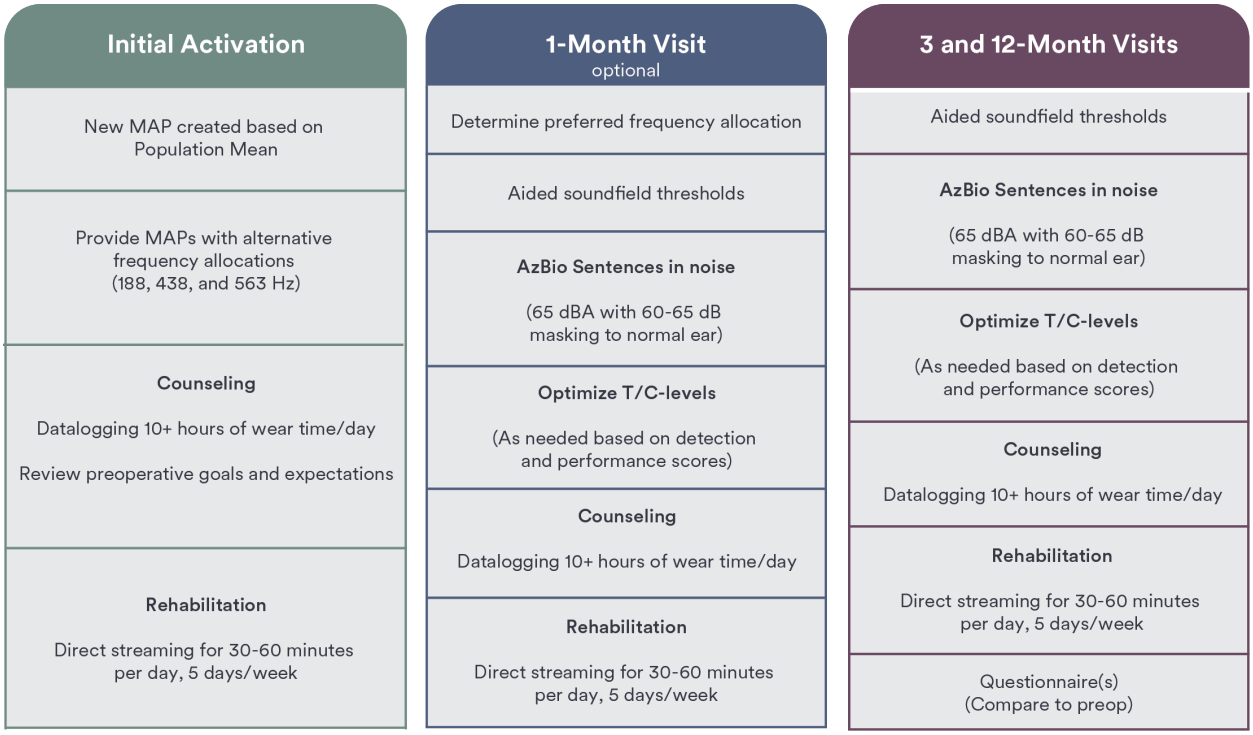
Since the SSD population has a natural comparison between normal hearing and hearing with a CI, there may be some sound quality adjustments that need to be addressed. Mismatch between ears may be resolved by making changes to the frequency allocation table (FAT) within Custom Sound® Pro. To optimize sound quality in these cases, MAPs with the default and alternative frequency allocation table assignments are recommended (Landsberger et al, 2015, Sagi et al, 2021, and Tóth et al, 2023). MAPs should be created with a low frequency cut-off of 188 Hz (default), 438 Hz and 563 Hz and trialed at initial activation. Patients should be encouraged to try each of the MAPs to assess sound quality prior to returning for their first follow-up visit.

Clinical experience collected following FDA approval supports this approach as a simple and effective way to overcome subjective mismatch between ears and does not require additional imaging.

At follow-up programming sessions, further optimization of the MAP and confirmation of audibility should occur. T-levels should be measured at least one time. With experience, recipients should be able to provide consistent measurement of sound field detection levels to confirm T-levels are set appropriately and to confirm good audibility of sound (detection between 20-30 dB HL) with consideration to the frequency allocation utilized in the MAP. The low frequency boundary would be expected to impact detection at 250 and/ or 500 Hz, depending on the settings. Confirmation of these levels should be conducted via sound-field audiograms in the booth with the better ear plugged, or via direct streaming using Remote Check. T-levels would only be remeasured if indicated by sound-field testing or remote check audiograms. C-levels can also be optimized and adjusted based upon Electrically Evoked Stapedial Reflex Thresholds (ESRT). Neural Response Telemetry (NRT) is another tool which may be utilized to help confirm mapping.

The following evaluation protocol, based on Thought Leadership collaboration, outlines recommended assessments and intervals (Figure 5).

Figure 5.



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

Conclusion

In conclusion, two years post-FDA approval this paper provides updated guidance based on early experiences to support surgeons and audiologists in the identification, evaluation, counseling, and ongoing management of patients with single-sided deafness or unilateral hearing loss. Through collaboration with leading industry experts, we have identified critical candidacy considerations and emphasized the importance of comprehensive assessments to better understand the quality of life and other impacts on this unique patient population, both pre- and post-implantation.

Understanding patient motivation and establishing realistic expectations are crucial components of this process. These elements ensure that patients are well-prepared for the journey ahead and can achieve the best possible outcomes. Efforts have been made to align evaluation protocols with current MSTB-3 guidelines, and detailed programming guidance has been provided to optimize and streamline the cochlear implant experience.

As we continue to learn and refine these guidelines, there is also an opportunity for Cochlear to develop similar guidance for pediatric patients. This ongoing collaboration aims to ensure optimal outcomes and enhance the overall patient experience, ultimately contributing to the advancement of care for individuals with SSD/UHL.

Appendix A: Thought leadership meeting participants

Table 1: 2024 Thought Leader Meeting Participants

Surgeons	Affiliation
Kevin Brown*	University of North Carolina School of Medicine Chapel Hill, NC
Daniel Zeitler*	Virginia Mason Franciscan Health Seattle, WA
Samantha Anne	Cleveland Clinic Cleveland, OH
Richard Gurgel	University of Utah Salt Lake City, UT
David Kelsall	Rocky Mountain Ear Center Englewood, CO
Shawn Stevens	Barrow Neurological Institute Phoenix, AZ
Emily Stucken	University of Michigan Ann Arbor, MI

Psychologist	Affiliation
Ivette Cejas	University of Miami Miller School of Medicine Miami, FL

* Moderator

Audiologists	Affiliation
Allison Beiver	Rocky Mountain Ear Center Denver, CO
Olivia Boothby	Virginia Mason Franciscan Health Seattle, WA
Camille Dunn-Johnson	University of Iowa Iowa City, IA
Jill Firszt	Washington University School of Medicine St. Louis, MO
Melissa Hurtado	Mount Sinai New York, NY
Kristen Lewis	Midwest Ear Institute Kansas City, MO
Laurie Mauro	Children's Hospital of Philadelphia Philadelphia, PA
Jessica Novak	Children's Minnesota Minneapolis, MN
Andrewa Overton	University of North Carolina School of Medicine Chapel Hill, NC
William Shapiro	NYU Langone Health New York, NY
Molly Smeal	Cleveland Clinic Cleveland, OH
Hillary Snapp	University of Miami Health System Miami, FL
Sarah Sydlowski	Cleveland Clinic Cleveland, OH
Viral Tejani	University Hospitals Cleveland, OH
Gabrielle Watson	University of of Iowa Iowa City, IA

Table 2: 2021 Thought Leader Meeting Participants

Surgeons	Affiliation
Kevin Brown*	University of North Carolina School of Medicine Chapel Hill, NC
Syed Ahsan	Kaiser ENT Health Anaheim, CA
Samantha Anne	Cleveland Clinic Cleveland, OH
Renee Banakis Hartl^	University of Utah Health Salt Lake City, UT
Maura Cosetti	Mount Sinai New York, NY
Richard Gurgel	University of Utah Salt Lake City, UT
Michael Hoffer^	University of Miami Health System Miami, FL
Jacob Hunter	UT Southwestern Medical Center Dallas, TX
David Kelsall	Rocky Mountain Ear Center Denver, CO
Eric Lupo	Rocky Mountain Ear Center Denver, CO
Brendan O'Connell	Charlotte Eye, Ear, Nose & Throat Assoc Charlottee, NC
Alex Sweeney	Baylor College of Medicine Otolaryngology Houston, TX
Christopher Welch^	University of Michigan Ann Arbor, MI
Daniel Zeitler	Virginia Mason Franciscan Health Seattle, WA

Audiologists	Affiliation
Allison Beiver	Rocky Mountain Ear Center Denver, CO
Andrea Bucker	UNC Health Chapel Hill, NC
Camille Dunn-Johnson	University of Iowa Iowa City, IA
Jill Firszt	Washington University School of Medicine St. Louis, MO
Meredith Holcomb	University of Miami Health System Miami, FL
Jourdan Holder	Vanderbilt University Nashville, TN
Laura Schadt	Baylor College of Medicine Houston, TX
Molly Smeal	Cleveland Clinic Cleveland, OH
Johanna Whitson	UT Southwestern Medical Center Dallas, TX

Hearing Scientist	Affiliation
Mario Svirsky	NYU Langone New York, NY

* Moderator ^ Virtual Attendee

Appendix B: Evidence supporting CI for SSD

Individuals with SSD struggle to process timing and amplitude cues, which are critical for sound localization and speech perception in noisy environments (Gordon et al., 2015). These challenges can lead to listening fatigue, social isolation, and decreased quality of life (Lucas et al, 2018). This may be especially true in complex listening environments such as work, school, or other social situations. In some cases, psychological distress related to fear of losing hearing in the better ear may also impact quality of life (Vannson et al, 2015).

Binaural hearing offers numerous benefits, including improved sound localization, increased loudness perception due to binaural summation, and overall enhanced hearing in both quiet and noisy environments, which can only be achieved with auditory inputs from both ears (Vila & Lieu, 2015). Cochlear implants can help restore some degree of binaural hearing, thereby improving spatial awareness and reducing the cognitive load associated with listening. Early intervention for both adults and children is crucial, as it can prevent the brain from adapting to the loss of input from the deaf ear, thereby preserving binaural auditory processing capabilities. This early intervention ensures that individuals can fully benefit from the advantages of binaural hearing, leading to better auditory outcomes and an improved quality of life.

Tinnitus is also prevalent in this population with some studies reporting up to 86% of individuals with SSD or UHL presenting with some degree of tinnitus (Quaranta et al, 2004). The exact cause of tinnitus is not fully understood, but it is believed that reduced or absent auditory input contributes to changes in neural activity along the auditory pathway (Eggermont & Roberts, 2004). The resulting co-occurrence of hearing loss and tinnitus can significantly impact quality-of-life, making it essential to consider tinnitus in the overall treatment plan and evaluation process. Cochlear implantation has been shown to effectively reduce tinnitus severity while wearing the cochlear implant in a high percentage of cases (50-90%) as reported by Idriss et al, 2022; Assouly et al, 2021; Borges et al, 2021; Levy et al, 2019; while only a small number of cochlear implant cases result in exacerbation or no change in tinnitus perception. This provides strong evidence to support consideration of a CI during the evaluation process.

Although this paper focuses on adults, it is crucial to recognize that children with SSD or UHL also face unique challenges. SSD in children has been correlated to speech and language delays, which can lead to decreased academic performance, behavioral problems, and a reduced quality of life (Jin et al., 2014; Fitzpatrick et al., 2019). Research indicates that SSD can promote an abnormal aural preference, and delayed implantation may hinder the benefits of subsequent implantation (Gordon et al., 2015; Jiwani et al., 2016; Propst et al., 2010; Schmithorst et al., 2014). Addressing these issues early is essential to mitigate their impact and improve outcomes for children with SSD/UHL.

In addition to this, a review of retrospective data was completed by Cochlear and further demonstrates with reasonable assurance the safety and effectiveness of cochlear implantation in individuals with SSD. Full details can be found at https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S205B.pdf.

Appendix C: Assessments for QoL, Tinnitus, and Spatial Hearing

In our efforts to match the right candidate with the optimal solution, quality-of-life and handicap profiles offer clinicians valuable insights for evaluating these factors both before and after implantation. The following tools should be considered and implemented when appropriate.

The Cochlear Implant Quality of Life (CIQOL)- 10 and -35 Profile were derived from the full CIQOL and provides a comprehensive assessment of functional abilities in adults with cochlear implants. Either shortened version may be considered; although the CIQOL-10 does not provide domain specific information but rather a general overview of quality-of-life. Developed at the Medical University of South Carolina, the CIQOL-35 measures outcomes for 6 domains (communication, emotional, entertainment, environment, listening effort, and social). Responses are scored and converted for each domain to an outcome measure score (McRacken & Hand, 2019). These scores can then be compared to normative data to help guide pre- and post-implant counseling. For additional information regarding development and use of the CIQOL-35, please refer to the "Publications" section of MUSC CIQOL website: https://education.musc.edu/CIQOL.

The Tinnitus Handicap Inventory (THI), from Newman et al. (1996), was developed as a quick and simple way to evaluate the impact of tinnitus to a patient. It consists of 25 questions and should be considered for use during candidacy evaluation if tinnitus is reported. This assessment can then be compared to post-implant THI scores to measure treatment outcome.

The SSQ-12 is a shortened version of the Speech, Spatial, and Qualities of Hearing Scale (SSQ) consisting of 12 items designed to assess hearing abilities in everyday situations to evaluate hearing abilities that are not reflected on the audiogram. It focuses on three main areas: speech perception, spatial hearing, and qualities of hearing (Noble et al., 2013). For patients with SSD, this tool assists clinicians in evaluating their ability to localize sounds, judge distances, and distinguish between simultaneous sounds.

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