

American Academy of Audiology  
Clinical Practice Guidelines

**Adult Patients with  
Severe-to-Profound Unilateral  
Sensorineural Hearing Loss**

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# American Academy of Audiology Clinical Practice Guidelines

## Adult Patients with Severe-to-Profound Unilateral Sensorineural Hearing Loss

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## Adult Patients with Severe-to-Profound Unilateral Sensorineural Hearing Loss

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## 1. INTRODUCTION

This practice guideline was prepared by the American Academy of Audiology (the Academy) task force on Adult Patients with Severe-to-Profound Unilateral Sensorineural Hearing Loss (USNHL). The specific goal of this guideline is to provide a set of statements, recommendations, and strategies for best practice in the provision of a comprehensive treatment plan for the audiological management of adults with severe-to-profound USNHL. Specific statements and recommendations were made by initially reviewing the existing scientific evidence published in peer-reviewed and non-peer-reviewed journals. When direct evidence (i.e., evidence directly relating clinical procedures to the principal health outcomes) was not available, both indirect evidence, which involves examining two or more bodies of evidence to relate the clinical procedures to the principal health outcomes,<sup>1</sup> and consensus practice were considered in making recommendations.

This guideline addresses the technical aspects of hearing device selection, fitting, verification, validation, and counseling within the context of a comprehensive treatment plan. In the process of making specific statements, recommendations, and strategies, careful consideration was given to the elements of care that optimize patient outcomes.

The primary effects of hearing loss are addressed by the World Health Organization International Classification of Functioning, Disability, and Health (WHO-ICF) Classification b230, which relates to hearing function, specifically the function of sensing the presence of sounds and discriminating the location, pitch, loudness, and quality of sounds.<sup>2</sup> Thus, the primary objective outcome measure for hearing device use is to assess the effects of the treatment in terms of improving hearing function, a process often referred to by audiologists as “verification.” Examples of verification might include real ear measures, measures of speech recognition in quiet and noise, measures of loudness discomfort or aided sound field thresholds.

The presence of a hearing loss can result in activity limitations and participation restrictions as described in the ICF classification scheme.<sup>2</sup> For example, a patient with hearing loss may have difficulties in receiving spoken messages (ICF Classification d310), engaging effectively in conversations (ICF Classification d350), learning through listening (ICF Classification d115), remunerative employment (ICF Classification d850), engaging in some forms of recreation and leisure (ICF Classification d920), attending religious services (ICF Classification d320), and so forth. Both environmental (i.e., external) factors that include the physical, social, and attitudinal environment in which patients live and patient (i.e., internal) factors, or those features of the patient that are not part of a particular health condition or state, will influence the effect of the impairment, activity limitations, and participation restrictions on the health-related quality of life (QOL) of a patient who has a hearing loss.<sup>3</sup>

If a hearing device or devices and other hearing assistive technology (HAT) are successful in reducing a hearing loss, activity limitations and participation restrictions related to communication also should be alleviated. Improvements in QOL occur when activity limitations and participation restrictions are reduced. When the audiological management of hearing loss is placed within a comprehensive rehabilitative approach, outcomes of a hearing device are also measured in terms of activity, participation, and QOL. Audiologists often refer to the outcome measured in these domains as “validation” of treatment. Measures of validation are typically in the form of questionnaires, interviews, and/or profiles. Examples might include measures of benefit and/or satisfaction, expectations, changes in activity limitations, changes in handicap, ease of use, and subjective changes in the ability to localize.

## 1.1 Need for an Evidence-Based Best Practice Guideline for Adult Patients with Severe-to-Profound USNHL

Audiologists provide a hearing device to patients with hearing loss. Occasionally, a patient will present himself/herself with severe-to-profound USNHL. Recently, the term “single-sided deafness” (SSD) has been introduced and is becoming increasingly more common. For the purposes of this guideline, these two terms are interchangeable, but the term USNHL is used throughout. A patient with USNHL has normal hearing in one ear (i.e., hearing thresholds no greater than 20 dB HL at 250-3000 Hz) and SNHL with poor word recognition score (WRS), unaidable hearing in the opposite ear, or an inability to tolerate amplified sound.

In clinical practice, some audiologists may never interact with a patient with USNHL, while others may interact with such patients infrequently, and still others may interact with such patients quite often depending upon their site of employment. Audiologists working with an otologist specializing in skull-base tumors or audiologists working in a medical school will usually interact with more patients with USNHL than those working at other sites. In either case, it is important for audiologists to be knowledgeable about current fitting and device options and the procedures for verifying, validating, and counseling patients with severe-to-profound USNHL because the fitting options, verification, validation, and counseling for these patients may be quite different from those patients whose hearing loss is appropriately addressed using past and current guidelines. This guideline provides audiologists, physicians, dentists, and other health-care providers a comprehensive overview of the diagnosis and hearing device options for adults having severe-to-profound USNHL.

### Incidence and Causes of USNHL

Hearing loss is an extremely common disorder, with approximately 32 million Americans having some degree of impairment. Sensorineural hearing loss (SNHL), which accounts for 90 percent of the cases, is caused by damage to the cochlea or the vestibule-cochlear nerve. The vast majority of patients with SNHL have bilateral hearing loss. In the United States, approximately 60,000 new cases of USNHL occur annually ([www.singlesideddeafness.com](http://www.singlesideddeafness.com)) and far more occur internationally.

Usually, it is felt that patients with severe-to-profound USNHL function normally. It is now well established, however, that USNHL is a handicap that can negatively impact QOL.

Numerous disease processes can lead to severe-to-profound USNHL. These include sudden SNHL; idiopathic SNHL; neoplasms; vestibular schwannoma (acoustic neuroma); demyelinating pathologies such as multiple sclerosis, vertebralbasilar arterial occlusion (stroke), acoustic trauma, head injury, perilymphatic fistula, ototoxic drugs, labyrinthitis, Meniere’s disease; and autoimmune disease (Cogan disease, Wegener’s granulomatosis, lupus, Takayasu arteritis, systemic sclerosis, and other rheumatological disorders).<sup>4</sup>

### Difficulties Experienced by Patients with Severe-to-Profound USNHL

Patients with severe-to-profound USNHL typically have difficulty (a) locating the sources of sound (i.e., *localization*); (b) recognizing speech when the signal arrives on the side of the poorer ear (*head shadow effect*); (c) recognizing speech in background noise, especially when the noise arrives on the side of the better ear (*scquelch effect*); and (d) loss of *binaural summation*.

### Localization

The ability to localize sound in the horizontal plane is related to the ability to take advantage of the interaural differences in time, intensity, and phase between the two ears. Patients with severe-to-profound USNHL no longer have the ability to take advantage of these interaural differences.

## Head Shadow Effect

The head shadow effect for spondee words was initially described by Tillman et al<sup>5</sup>, who reported that as a signal arrives from one side of the head (near ear or monaural direct), the intensity of the signal is attenuated across the head by an average overall level of 6.4 dB SPL before the signal reaches the opposite ear (far ear or monaural indirect). Further, the head shadow effect increases as a function of frequency. For example, at frequencies above 2000 Hz, the intensity level of the signal to the far ear can be decreased by as much as 15–20 dB than the level of the signal at the near ear.<sup>6-7</sup>

The attenuation of the higher frequencies at the far ear can impact speech recognition. For example, if speech is delivered to the side of the poorer ear and noise is directed to the side of the better ear at the same input level, the speech signal is reduced by 6.4 dB to the side of the better ear due to the head shadow effect, but the noise is unattenuated. As a result, a -6.4 dB signal-to-noise ratio (SNR) is present at the side of the better ear and a +6.4 dB SNR is present at the side of the poorer ear.

It is important to keep in mind that the primary goal of any amplification treatment option for patients with severe-to-profound USNHL is to eliminate this head shadow effect.

## Squelch Effect

Many have described the advantages of binaural hearing to squelch or reduce the deleterious effects of background noise and/or reverberation on speech recognition. Gulick et al<sup>8</sup> reported improved binaural “release from masking” when differences in time, intensity, or phase were present in the signal between the two ears. That is, the presence of interaural differences in time, intensity, and/or phase of the speech signal will result in improved performance compared with a situation in which these interaural differences are not present.

## Binaural Summation

Gulick et al<sup>8</sup> described binaural summation as an advantage in processing information (specifically, detecting threshold) with two ears over listening with one ear. They stated that, if the ears are equally sensitive, the binaural threshold is about 3 dB better than the monaural threshold and the binaural advantage expands to 6 dB during supra-threshold listening. This additional advantage may have significant effects on improved word recognition scores when listening binaurally in comparison to monaural listening. That is, if speech recognition increases at a rate of 10 percent per each additional decibel (i.e., articulation function), then the binaural advantage at supra-threshold levels could be as much as 60 percent better (6 dB X 10 percent dB) than the monaural score.

The most current national guideline in the United States designed to address issues related to management of hearing loss in the adult population was published in 2006.<sup>9</sup> Since the development of that guideline, many advances have occurred in audiology and in hearing device options, as well as in the methods used to verify and validate the outcomes of the selection and fitting process. The National Guideline Clearinghouse<sup>10</sup> of the U.S. Agency for Healthcare Research and Quality<sup>11</sup> considers for review only those guidelines developed, reviewed, or revised within five years.

Additionally, the management of hearing loss, within a comprehensive treatment plan, involves more than a simple technical matter of fitting a hearing device. It involves the provision of a systematic approach, supported by evidence, which addresses not only the hearing loss, but also the co-occurring activity limitations, participation restrictions, and consequent reductions in QOL. Statements, recommendations, and strategies made within this guideline thus address the entire treatment process. This guideline is not considered static; every five years, the American Academy of Audiology will review its recommendations and determine if they require modification as evidence, technologies, and clinical practices evolve.

This guideline is not intended to serve as a standard to dictate precisely how a hearing device should be selected, verified, or validated. Rather, this guideline is intended to provide several paths that audiologists may follow in order to decrease variability of outcomes and increase the probability of user satisfaction and benefit. The audiologist, however, has the freedom to implement segments of the guideline that are appropriate to his or her clinical environment and

patients. In addition, this guideline can help inform physicians, dentists, reimbursement agencies, government agencies, the hearing-health-care industry, and patients about what the research evidence reveals are current best practices related to a hearing device and other, non-medical treatment services for adults with severe-to-profound USNHL. Finally, although this guideline addresses the technical aspects involved in fitting a hearing device, the audiologist is reminded that the process of fitting a hearing device is an ongoing process requiring joint participation of the audiologist, patient, otologist, dentist, other health-care professionals, and family/caregivers.

## 1.2 Guideline Development Process

The process of developing this guideline was evidence-based when possible. Evidence-based practice integrates clinical expertise with the best available clinical evidence derived from systematic research. Where evidence is ambiguous or conflicting, or where scientific data are lacking, the clinical experience of the task force was used to guide the development of consensus-based recommendations. The review of the literature, evaluation of evidence, and development of the guideline proceeded in sequential steps.

The task force identified the following two guidelines as appropriate starting points for the identification of the processes involved in the audiological management of adults with severe-to-profound USNHL:

- The Guidelines for the Audiologic Management of Adult Hearing Loss<sup>9</sup>
- The Audiology Clinical Practice Algorithms and Statements<sup>12</sup>

Review of these guidelines resulted in the identification of four general process areas: (1) assessment and goal setting; (2) technical aspects of treatment; (3) orientation, counseling, and follow-up; and (4) assessing outcomes. At least two task force members were assigned to each of these general areas to search the literature to identify the best available evidence to provide support for the development of key recommendations. In searching the literature, task force members first sought to identify studies at the top of the hierarchy of study types. Once definitive clinical studies that provided valid relevant information were identified, the search stopped. The search was extended to studies/reports of lower quality (observational studies) only if there were no higher quality studies.

The task force members assigned to each area reviewed and graded the evidence using the rating scheme described below. The Quality of Evidence Ratings (**Table 1.1**) and Grades for Recommendation (Table 1.2) were adopted for use after members of the task force were oriented to the evidence-grading process.<sup>13</sup> In addition, task force members determined “effective” (EV) or “efficacious” (EF). “EV” is evidence measured in the real world while “EF” is evidence measured under laboratory or ideal conditions. All task force members reviewed the recommendations and evidence grading in each of the four general process areas and agreed on the levels of quality assigned.

**Table 1.1: Quality of Evidence (QE)**

Level	
1	Systematic reviews and meta-analysis of randomized controlled trials (RCTs) or other high-quality studies
2	Well-designed RCTs
3	Non-randomized treatment studies
4	Cohort studies, case-control studies, cross-sectional surveys, and uncontrolled experiments
5	Case reports
6	Expert opinions

**Table 1.2: Grade of Recommendation**

Grade	
A	Level 1 or 2 with consistent conclusions
B	Level 3 or 4 studies or extrapolated evidence (generalized to a situation where it is not fully relevant) from Level 1 or 2 studies
C	Level 5 studies or extrapolated evidence from Level 3 or 4 studies
D	Level 6 evidence or inconsistent or inconclusive studies of any level or any studies that have a high risk of bias

### 1.3 The Process of Audiological Management of Hearing Loss

The task force members recognize that a comprehensive treatment approach is necessary for achieving the best outcomes for adults with severe-to-profound USNHL. To achieve the greatest probability of successful treatment, the members agreed that the following components are required in the context of a comprehensive plan:

- Services must be provided by a licensed audiologist.
- The combined efforts of the audiologist, patient, otologist, dentist, other health-care professionals, and family/care-givers are essential.
- In keeping with the WHO-ICF, assessment is viewed as a multi-faceted process, including assessment of auditory function to diagnose the extent of the impairment; assessment of activity limitations and participation restrictions through self-report of communication needs and performance; assessment of environmental and patient contextual factors; and consideration of how all the levels of assessment impact QOL.
- As a result of a multi-faceted assessment, clear and realistic patient goals for treatment must be set.
- The foundation of a successful treatment plan involves the technical aspects of hearing device selection, quality control, fitting, and verification.
- The use of technology other than hearing devices, referred to as hearing assistive technology (HAT), should be part of the process.
- The success of treatment depends on provision of effective instruction and orientation to device use, counseling, and, for some patients, more intensive, on-going group and/or patient audiological services.
- The success of treatment is determined through outcome assessment (validation).

This guideline consists of descriptions of clinical processes and, where appropriate, the assessment of evidence for specific recommendations in four general areas: (1) assessment and goal setting; (2) technical aspects of treatment; (3) orientation, counseling, and follow-up; and (4) assessing outcomes.

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## 2. ASSESSMENT AND GOAL SETTING

Assessment for the purposes of developing a comprehensive treatment plan consist of evaluation in four areas: (1) auditory assessment and diagnostics; (2) self perception and communication needs and selection of treatment goals; (3) non-auditory needs assessment; and (4) candidacy.

### 2.1 Auditory Assessment and Diagnosis

#### Objective

The primary objective of auditory assessment is to diagnose the presence or absence of hearing loss, characterize the hearing loss, and determine the need for intervention. This process requires a comprehensive audiological examination including case history, otoscopy, behavioral and physiologic auditory measures, and needs assessment. The goals for the auditory assessment and diagnosis are to identify the type, degree, and configuration of the hearing loss for each ear according to recommended diagnostic guidelines (Academy, 2000), which includes, but is not limited to:

- Conduct a comprehensive case history, otoscopic examination, comprehensive audiometric examination that includes air conduction thresholds, bone conduction thresholds, speech recognition threshold (SRT) and word recognition score (WRS), otoacoustic emissions, tympanometry, and acoustic reflex thresholds and reflex decay.
- Assess the need for additional evaluation and/or medical referral.
- Assess candidacy for amplification and for hearing assistive technology (HAT).
- Determine the need for medical clearance as determined by the guidelines established by the Federal Drug Administration (FDA) for amplification or HAT.
- Characterize associated disability/handicap through needs assessment techniques (see Sections 2.2 and 2.3).
- Counsel patient, significant other, and/or caregiver on the results and recommendations of the assessment.

Additional considerations in the assessment process should include monitoring of hearing at least annually, ensuring hearing loss is stable prior to rehabilitative intervention, and utilizing a collaborative approach to the assessment and diagnosis of hearing loss including physicians and other health-care professionals as needed.

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American Academy of Audiology. (2000) Clinical practice algorithms and statements. *Audiol Today*, Special Issue:32–49.

## 2.2 Self-Perception of Communication Needs, Performance, and Selection of Treatment Goals

### Objective

The objective of this section is to examine the self-reported communication difficulties experienced by patients with severe-to-profound USNHL and how this information can be used by the audiologist and patient to select goals for remediation. Once this information is acquired, a hearing device and its features that meet these goals can be discussed, along with realistic expectations. After fitting the hearing device, the audiologist and patient can use the same or different questionnaire(s) to assess the success or failure of a hearing device in meeting the desired needs and/or goals of the patient. This initial validation is of great importance in an evidence-based practice because a baseline measure is needed to determine the success or failure of a hearing device.

### Background

Contrary to initial beliefs, a patient with severe-to-profound USNHL experiences communication difficulties in spite of having normal hearing in one ear. In 1967, Giolas and Ward<sup>1</sup> interviewed patients with USNHL and found listening situations presenting difficulty included:

1. Hearing in background noise, regardless of where the noise originated, was the greatest difficulty.
2. Localizing sound in quiet and background noise.
3. Recognizing speech originating on the side of the poorer ear in quiet and in background noise.
4. Recognizing speech from a distance.

Several studies have examined hearing handicap in patients with USNHL by using an investigator-created Visual Analog Scale<sup>2</sup> or, as reported with some other studies,<sup>3-5</sup> using the Hearing Handicap Inventory in Adults (HHIA).<sup>6</sup> Of those participants examined, two percent to 54 percent reported no hearing handicap, 15 percent to 27 percent reported a mild handicap, 15 percent to 38 percent reported a moderate handicap, and 14 percent to 45 percent reported a significant handicap.

Common environments where patients with severe-to-profound USNHL had difficulty were communicating in a crowd, restaurants, at work, in a car, and when walking on busy streets (inability to localize vehicles).<sup>4,7-8</sup> These results emphasize the importance of assessing self-perception of communication and performance, as some patients will perceive a handicap as a result of their USNHL and will be motivated toward a hearing device, while others have learned coping strategies and may not be as motivated or perceive benefit from a hearing device.

Some of these communication problems, such as poor localization and decreased speech recognition in quiet and noise due to the head shadow effect, are unique to this group of patients. Questionnaires examining communication needs and performance of a patient with severe-to-profound USNHL, therefore, should be tailored to determine the impact of these communication difficulties on the patient's daily QOL. While some questionnaires are specific to severe-to-profound USNHL for outcomes of specific hearing devices, particularly auditory osseointegrated implant systems (AOISs), there are no questionnaires designed specifically to address the needs of patients with USNHL prior to fitting the hearing device.

There are several questionnaires available examining communication needs and performance in patients with bilateral SNHL, and these could be used and tailored to examine communication needs and performance in patients with USNHL. The HHIA<sup>6</sup> and Hearing Handicap for the Elderly (HHIE)<sup>9</sup> are examples of questionnaires that could be used to assess how the hearing loss affects patients' perceived handicap in social settings and their emotional well-being.

An example of a question examining emotional effects of hearing from the HHIE is "Does a hearing problem cause you to feel depressed?" An example of a question examining effects on social situations from the HHIA is "does a hearing problem cause you difficulty hearing/understanding coworkers, clients, or customers?" The results can help the audiologist determine patients' perceptions, the impact of how hearing loss is affecting their life, and whether a patient will be motivated to obtain a hearing device.

The Communication Profile for the Hearing Impaired (CPHI)<sup>10</sup> is another questionnaire that examines handicap in communication performance, communication importance, communication environment, communication strategies, and personal adjustment. An example of a statement question from the CPHI examining maladaptive communication strategies is "one way I get people to repeat what they said is by ignoring them."

The Abbreviated Profile of Hearing Aid Benefit (APHAB)<sup>11</sup> and the Speech, Spatial and Qualities of Hearing Scale (SSQ)<sup>12</sup> are examples of questionnaires that can be used to assess handicap in typical listening situations for patients with hearing loss. The APHAB examines how patients perform in quiet, background noise, reverberation, and when around loud aversive sounds. An example of a statement question in a quiet situation is "I have to ask people to repeat themselves in one-on-one conversation in a quiet room." The SSQ examines different aspects of hearing, such as listening to speech in various environments, different spatial aspects of sound, such as localization, and different qualities of sound, such as the clarity of sound. An example statement question involving spatial hearing is "do you have the impression of sounds being exactly where you would expect them to be?" The spatial portion may be particularly relevant to patients with USNHL in determining their perceived handicap and for setting realistic expectations with hearing devices.

While these former questionnaires are useful, some of the environments may not be relevant to the patient or reflect the patient's goals for improving his or her hearing. The Glasgow Hearing Aid Benefit Profile (GHABP)<sup>13</sup> and the Client-Oriented Scale of Improvement (COSI)<sup>14</sup> are examples of open-ended questionnaires allowing the patient to state specific environments and listening situations where she or he is having difficulty. The GHABP has pre-determined environments as well as an open-ended questionnaire that inquires how a patient performs in the environment unaided and when aided with a hearing device. Questions pertaining to unaided performance are "how much difficulty do you have in this situation?" and "How much does any difficulty in this situation worry, annoy, or upset you?" The COSI allows patients to list specific hearing needs that they would like to improve, as well as rate the order of significance. This questionnaire then later assesses whether the respective hearing device improved the patient's specific needs.

Other questionnaires can assess a patient's motivation and realistic expectations of hearing devices. Some examples of these questionnaires are the Expected Consequences of Hearing Aid Ownership (ECHO)<sup>15</sup> and the Characteristic of Amplification Tool (COAT).<sup>16</sup> ECHO examines potential positive effects, services and costs, negative effects, and stigma of hearing devices. An example of a negative effect statement question is "I will be frustrated when my hearing aids pick up sounds that keep me from hearing what I want to hear." COAT examines patient needs, motivation, expectations, and other attitudes, such as cosmetics, toward hearing devices. An example of a motivation question is "how motivated are you to wear and use hearing aids?"

Results from these questionnaires provide information that can be used to determine:

1. The perceived handicap of the patient and potentially his/her motivation for pursuing a hearing device (ex. HHIA, HHIE, CPHI, ECHO, COAT, etc.).
2. Listening situations where the patient would like to improve communication (ex. APHAB, SSQ, GHABP, COSI, COAT, etc.). This information can be used to determine an appropriate hearing device and features to address these needs.

- The expectations of the patient based on his or her needs and thoughts about a hearing device (ex. GHABP, COSI, ECHO, COAT, etc.). This information can help the audiologist and patient set realistic goals and expectations for a hearing device, and also can be used as a baseline to later assess whether these expectations and goals were, or were not, met by use of the hearing device.

## Recommendations

Each patient's self-perceived communication needs and performance should be assessed via validated questionnaires to select an appropriate hearing device, features of a hearing device, and to establish realistic expectations from a hearing device.

Establishment of baseline needs and goals is necessary to determine benefit and satisfaction or lack of benefit and satisfaction from a hearing device.

Developing questionnaires specific to the communication needs and performance of patients with severe-to-profound USNHL, as well as research examining the hearing device choices of these patients, is needed.

## Evidence for Needs Assessment

Recommendations	Evidence	Source	Level	Grade	EF/EV
1,2	Patients with USNHL have varied self-perception of hearing handicap.	3-5	4	B	EV
1,2,3	Patients with USNHL experience difficulty in several different listening environments and some patients are able to use coping strategies to communicate more effectively than other patients with a similar hearing loss.	1,4,8	4	B	EV
1,2	Patients report the lowest satisfaction with their audiologist for counseling on realistic expectations of a hearing device.	17	4	B	EV
1,2	New users of a hearing device have unrealistic expectations of the benefit provided by a hearing device.	15	4	C	EV
3	There is a need for more sensitive measures of communication needs of patients with USNHL.	3,18	4	D	EV

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## 2.3 Non-Auditory Needs Assessment

### Objective

The objective of this section is to examine factors beyond those caused by the hearing loss of patients with severe-to-profound USNHL that may need to be assessed prior to the procurement of a hearing device. These non-auditory factors should be assessed to determine whether the patient needs further counseling, referral to another health-care professional, and how these factors can impact the decision for pursuing, selecting, and obtaining the optimal benefit from a hearing device.

### Background

It has been well established that patients with severe-to-profound USNHL present with communication difficulties, some of which are unique compared to patients with bilateral SNHL. It can, therefore, be hypothesized that a patient with severe-to-profound USNHL may also present with similar or unique non-auditory QOL needs that may need to be addressed prior to obtaining a hearing device. Such factors could include a patient's physical, mental, and psychosocial well-being, personality, manual dexterity, and visual abilities.

There is little research available, however, examining non-auditory needs of patients with severe-to-profound USNHL. The few studies that have examined non-auditory needs have reported variable results. Colletti et al<sup>1</sup> reported no social, psychological, educational, or employment differences between patients with congenital USNHL and those with normal hearing. Sano et al<sup>2</sup> reported that patients (in Japan) with idiopathic sudden USNHL did not differ significantly from patients with bilateral SNHL on the Short Form Health Survey (SF-36) version two.<sup>3</sup> When results were compared to the general population, patients with idiopathic USNHL had significantly poorer ratings on the mental component for ages 40 and older, while bilateral SNHL had significantly poorer ratings on the mental component for ages 70 and older only.

This indicates that, while the two groups do not differ in QOL from each other, the hearing loss impedes the QOL and functioning of these individuals compared to the general population. Other studies have reported an impact on performance at work,<sup>4-5</sup> social activities,<sup>4</sup> and that patients with USNHL have feelings of anger,<sup>5-7</sup> depression,<sup>5,7</sup> and embarrassment.<sup>7</sup>

USNHL can be congenital or acquired, and can be caused by various etiologies such as Meniere's disease, sudden USNHL, acoustic neuromas, etc. Due to the different durations and causes of USNHL, it is important to take a holistic approach and assess the non-auditory needs, as each patient will be impacted differently and some non-auditory factors may take precedence over the hearing loss. For example, Rigby et al<sup>8</sup> examined QOL outcomes in patients after surgery for an acoustic neuroma. While hearing loss was reported as the most difficult outcome of the surgery, others noted vertigo, facial paralysis, visual function, headaches, and tinnitus as well. These and other factors can play a role in whether a patient will be an ideal candidate for a hearing device. For example, a patient may determine that the tinnitus is more bothersome than the hearing loss and would like this addressed first or would need further counseling on tinnitus. Also, a patient who had surgery to remove an acoustic neuroma may not desire a treatment option that would require another surgery.

As mentioned in Valente et al,<sup>9</sup> factors can be internal (such as cognition, personality, and dexterity) and external (such as support system, work, and social environment). These non-auditory factors may be more important to certain patients and a hearing device may not be an immediate need until these other factors are resolved. On the other hand, for some patients these factors are related to the hearing loss and, by addressing the hearing loss, patients may see improvement in the non-auditory needs.

A clinical screening using assessment tools such as a modified version of the COAT, or simply having examples of devices available to show patients, can help to determine the impact of such factors of vision and dexterity. For example, if a patient has difficulty putting an AOIS on an abutment post during an in-office simulation, poor manual dexterity and range of motion for his or her arms, and does not have a good support system of help, an AOIS may not be an optimal option. If he or she is unable to clean and care for the abutment site as, although rare, minor complications could occur, such as skin overgrowth or an infection, the perceived benefit of his or her hearing device could decrease.<sup>10-12</sup>

## **Recommendations**

Due to the few research studies examining the impact of non-auditory needs in patients with USNHL and benefit from a hearing device, studies examining bilateral SNHL can be used as a starting point. Bess<sup>13</sup> notes that some health-related QOL validation measures may not be sufficiently sensitive to detect improvements after being fit with a hearing device. There are, however, several QOL factors that have not been examined and may be more sensitive to patients with hearing loss. Such non-auditory factors, such as poor vision, manual dexterity, and cognitive decline, may hinder certain hearing device choices and/or suggest the need for a strong support system for these patients. Identifying these factors should be addressed in counseling and in establishing realistic expectations with the patient. The following recommendations are made:

1. Audiologists should perform a thorough non-auditory needs assessment (see Appendix at the conclusion of this section for examples of several assessment tools) to determine which factors need additional evaluation that may impact patient motivation, realistic expectations, appropriate hearing device options, and benefit from a hearing device.
2. Audiologists with proper training should perform dexterity and screening tests, such as those for cognition and depression.
3. Audiologists should make the appropriate referral for patient management when non-auditory needs are revealed (whether by case history or screening tests).

4. Audiologists should further research the area of non-auditory needs assessment for patients with severe-to-profound USNHL compared to other types of hearing loss to determine if there are any unique needs for these patients.

The Appendix at the end of this section provides several tools that can be used to assess non-auditory needs.

### Summary of Evidence for Non-Auditory Needs Assessment

Recommendations	Evidence	Source	Level	Grade	EF/EV
1,2	Patients with severe-to-profound USNHL can experience negative consequences in the work environment.	4-5	6	D	EV
1	Some patients with severe-to-profound USNHL socially isolate themselves from difficult environments to prevent emotional stress.	2,4,7	4,6	C,D	EV
1,3	Patients with USNHL can experience emotional distress, such as feelings of depression, embarrassment, and anger.	2,5-7	4	B	EV
1	Need to evaluate each patient due to differences in non-auditory needs.	6	4	B	EV
1,3	Some patients with USNHL report a mild-to-severe tinnitus.	8,14			
1,3	Non-auditory symptoms, such as vertigo/balance, facial paralysis, visual function, headaches, and tinnitus may negatively affect a patient with USNHL's QOL.	8			
1	It is important to evaluate the patient in a holistic manner to address all needs. This can also lead to cost-benefit measures of management.	13	6	D	EV
2	Complications at the abutment site may affect satisfaction with AOISs.	10	4	D	EV
2	Some screening tests can be administered by audiologists with minor training.	15-17			
2	Vision and manual dexterity may impact the ability to use and benefit from a hearing device.	18-19	6	D	EV
3	Need to involve counseling and possibly psychotherapy for patients experiencing emotional distress.	5,19	6	D	EV
4	Need more disease-specific QOL measures for USNHL prior to hearing device intervention.	5,13,19-20	6	D	EV

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## Appendix: Examples of Tools for Non-Auditory Assessment

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### General Health Tests

Sickness Impact Profile (SIP)

Short Form—36 Health Survey (SF-36)

EuroQOL (EQ-5D)

Nottingham Health Profile (NHP)

World Health Organization Measure of QOL (WHO-QOL)

Health Utilities Index (HUI)

### Tests for Cognition

Cambridge Cognitive Examination (CAMCOG and CAMTAB)

Cognitive Status Exam (Cognistat)

Wechsler Adult Intelligence Scale (WAIS)

Kahn-Goldfarb Mental Status Questionnaire (MSQ)

Short Portable Mental Status Questionnaire (Short Portable MSQ)

MicroCog: Assessment of Cognitive Functioning Computerized Testing Instrument

Mini Mental Status Exam (MMSE)

Speech and Visual Information Processing System (SVIPS)

Beck Depression Inventory (BDI)

Patient Health Questionnaire (PHQ-9)

### Tests for Attention

Brief Test of Attention (BTA)

Continuous Performance Test (CPT)

Paced Auditory Serial Attention Test (PASAT)

Stroop Color and Word Test

Auditory Stroop Test

Trail-Making Test (TMT)

Test of Everyday Attention (TEA)

### Tests for Executive Function

Delis-Kaplan Executive Function System (D-KEFS)

Stroop Color and Word Test

Auditory Stroop Test

Tower of London Procedure (TOL)

Trail-Making Test (TMT)

### Tests for Memory

Digit Span Task

Word Span Task

Sentence Span Task

Rey Auditory Verbal Learning Test (AVLT)

Wechsler Memory Scale-III (WMS-III)

California Verbal Learning Test (CVLT)

### Personality Tests

Myers-Briggs Personality Type Test (MBTI)

NEO-Five Factor Inventory (NEO-FFI)

True Colors

Gambrill-Richey Assertion Inventory

Patient Motivation for Therapy Scale (CMOTS)

### Manual Dexterity Tests

Modified Characteristic of Amplification Tool (COAT)

### Vision Tests

Snellen Chart for Visual Acuity (Near and Far)

Peripheral Vision Test (PVT)

Visual Search and Attention Test (VSAT)

### Tinnitus Assessment

Tinnitus Functional Index (TFI)

Tinnitus Reaction Questionnaire (TRQ)

Tinnitus Handicap Index (THI)

## 2.4 Candidacy

### Objective

The primary objective of candidacy assessment is to characterize the unilateral hearing loss and determine appropriate intervention. Patients with permanent severe-to-profound USNHL have unique hearing needs. Determining candidacy for rehabilitative treatment should incorporate deficit-specific measures to quantify the degree of impairment and provide a benchmark for future outcome measures. For the purposes of this guideline, permanent severe-to-profound USNHL is defined as calculated air conduction (AC) pure-tone average (PTA) at 500, 1000, 2000, and 3000 Hz greater than or equal to 70 dB HL in the poorer ear with no measureable air-bone gap and an AC PTA500-1000-2000-3000 in the normal ear that is  $\leq 20$  dB HL.

### Background

In adults with severe-to-profound USNHL, it is important for the audiologist to determine the functional limitations of the hearing loss in addition to characterizing the peripheral sensory mechanism. Assessment of the deficit-specific impairments of USNHL will drive the clinician in determining the best treatment option(s) for the patient. Because many of these patients have normal hearing on the contralateral side, impairment is often not experienced until the listening environment becomes more difficult. Adults with USNHL most commonly report reduced sound awareness on the affected side, difficulty hearing in background noise, and poor localization.<sup>1</sup> In order to appropriately guide candidacy, the goals of the assessment should be to quantify the impairment through valid behavioral audiometric measures (see Section 2.1) and qualify the associated disability/handicap (see Sections 2.2 and 2.3) and appropriate subjective outcome measures (see Section 5). At minimum, assessment of disability/handicap and speech performance in noise should be included when determining candidacy for hearing assistive technology (HAT) (see Section 3.4).

The audiological examination should be used as an initial assessment for candidacy. Best AC responses in the better ear are used for AC devices (e.g., Contralateral Routing Of the Signal (CROS); Bilateral Contralateral Routing of the Signal (BICROS) for patients in which hearing in the normal ear should decrease), whereas best bone conduction (BC) responses in the better ear are used in BC devices (e.g., transcranial CROS, TransEar<sup>®</sup>, auditory osseointegrated implant system (AOIS), SoundBite<sup>™</sup>, etc.).

*It must be noted that, when finishing this guideline, Sonitus Medical, manufacturer of SoundBite<sup>™</sup> declared bankruptcy. It was decided by the chair of the task force to maintain reference to this technology within this guideline because of the possibility that SoundBite<sup>™</sup> could be purchased by another manufacturer.*

Federal Drug Administration (FDA) candidacy guidelines recommend a PTA of  $\leq 20$  dB HL PTA at 500, 1000, 2000, and 3000 Hz by AC in the better hearing ear for AIOS devices<sup>2</sup>. Despite the referenced criteria of an AC PTA500-1000-2000-3000 in the normal hearing ear that is  $\leq 20$  dB HL, the members of the task force acknowledge that, at times, the clinician may encounter a patient who is in need of amplification for the contralateral ear due to acquired hearing loss such as presbycusis. In the presence of contralateral hearing loss, an option providing greater additional gain (e.g., Bilateral Contralateral Routing of the Signal (BICROS)) is recommended.

Following a confirmed diagnosis of severe-to-profound UNSNHL, transcranial attenuation (TA) should be measured for any patient considering treatment with a BC device. Research has shown that TA varies significantly (as much as 35 dB per frequency) between patients and is a function of the output of the transmitting device.<sup>3-4</sup> The lower the TA, the better the efficiency for a BC transmitted signal. This is best measured clinically by calculating the difference between the BC threshold at the good mastoid and the BC threshold at the stimulation site.<sup>4</sup> Studies suggest that an average TA of  $< 10$  dB at 250 – 4000Hz is a good predictor of good post-operative performance with a device using BC transmission.<sup>3-4</sup>

For an AOIS device, the stimulator site is typically 55 mm posterior to the ear canal in line with the upper pinna.<sup>4</sup> It is important to ensure stimulation at the appropriate site, as resonances and anti-resonances will result in variations in transition by 2-3 dB.<sup>4</sup> Further, loss of BC transmission can be expected due to attenuation by transcutaneous stimulation

(i.e., use of a testband with the AOIS device coupled to a snap abutment). Verstraeten and colleagues reported a 13-17 dB difference between percutaneous (i.e., AOIS directly implanted in the mastoid) and transcutaneous (snap abutment via a testband) outcomes on an AOIS.<sup>5</sup> The use of the power AOIS device would provide additional output to overcome this difference during assessment using the testband. This is recommended so that the user might be able to experience what the “real-life” experience would be using a less powerful AOIS device post-surgery.

Speech-in-noise measurements are useful for quantifying the change in performance in listening in noise, which is one of the primary deficits of USNHL. It has been shown that pre-treatment speech-in-noise evaluation using an AOIS processor on a testband accurately predicts post-operative performance.<sup>6</sup> For reasons stated previously, it is recommended that this evaluation be completed using a power AOIS processor to overcome TA and the loss of signal strength due to the plastic snap abutment on the testband or soft-band and the thickness of the patient’s skin.

The test configuration for speech-in-noise assessment may vary. The primary benefit of any amplification option for severe-to-profound USNHL is achieved when the speech is at 45° or 90° azimuth to the side of the poorer ear and noise is at 45° or 90° azimuth to the side of the better ear.<sup>4</sup> Testing in this configuration is recommended to provide a best aided performance estimate for the purpose of demonstrating the elimination of the head shadow effect.<sup>3,5</sup> Alternatively, speech-in-noise performance may be evaluated with speech at 0° and noise at 45° or 90° azimuth to the better hearing ear. Aided performance degrades when the speech is on the good side or at 0° azimuth and noise is diffuse (i.e., surrounds the patient) or is on the side of the poorer ear. The decrease in performance observed when noise is at the aided ear is due to the failure of release from masking, which results from relying on a single auditory pathway and the aided noise being mixed with the unaided speech signal on the better ear side.<sup>3</sup> As such, this test configuration is not recommended for predicting benefit, but should be considered in counseling the patient for realistic expectations.

Not all patients with severe-to-profound UNSNHL will present with the same degree of handicap and disability. Incorporating a measure of handicap and/or disability (see Sections 2.2 and 2.3) during the assessment process is important for determining the appropriate treatment option(s) and guiding realistic expectations.<sup>7</sup> Efficacy reports have failed to adequately employ assessments of handicap and disability during the candidacy phase for treatment of severe-to-profound UNSNHL, which likely contributes to the variable outcomes observed across studies of this population.<sup>7</sup> It is recommended that clinicians utilize validated subjective measures that are specific to the deficit and needs of the patient. Further elaboration is provided in Sections 2.2 and 2.3.

Numerous studies report using a pre-treatment trial at home with either a CROS hearing device or the AOIS device worn on a testband. Investigators, however, failed to report standardized methods related to the pre-treatment trials and few studies report data investigating the validity of this method for predicting successful outcomes post-operatively. Studies of the predictive value of a testband trial report a 32 percent to 44 percent acceptance rate with AOIS devices. Rejection of the implant was largely attributed to lack of perceived benefit for listening in noise.<sup>8-9</sup> Reasons for rejection or acceptance of the AOIS device beyond lack of perceived benefit in noise varied considerably by patients and included headaches, inability to use at work, no improvement of tinnitus, poor sound quality, etc. These results suggest candidates may in fact not benefit from at-home AOIS device trials. These studies, however, did not consider the previously mentioned objective means of assessing benefit with AOIS devices prior to the testband trial, such as speech-in-noise assessment and measurement of TA. Additionally, the impact of the attenuation by the skin, device output related to TA, and the device settings were not accounted for, which may have negatively impacted patient performance in noise.

Nonetheless, pre-treatment home trials should be incorporated whenever possible. Based on the evidence, it is recommended that testband trials are reserved for those patients who have met the previously described criteria. This includes meeting initial audiometric criteria, a measured TA of less than 10 dB, and improved aided performance on speech-in-noise measures. Further, the clinician should ensure that a BC device is programmed to accommodate the patient’s TA, and a power device is used for all at-home trials, all hearing devices are electromechanically verified for optimal performance, where possible, and patients are adequately trained on device use and placement.

Additional considerations in the assessment process should include monitoring of hearing in the better ear at least annu- **19**

ally, ensuring the USNHL is stable prior to rehabilitative intervention, and utilizing a collaborative approach to the assessment and diagnosis of USNHL, including physicians and other health-care professionals as needed. Audiologists need to be cognizant that it is possible, due to the development of age-related hearing loss, that benefit from AOIS devices may diminish and alternative treatment options may become necessary (e.g., open fit hearing aid on the better ear; CROS or BICROS, etc.).

## Recommendations

1. For BC devices, the audiological candidacy guidelines recommend a PTA of  $\leq 20$  dB HL PTA at 500, 1000, 2000, and 3000 Hz by AC in the better hearing ear.<sup>2</sup>
2. TA should be measured for any patient considering treatment with a BC device by measuring the difference between the BC threshold at the good mastoid and the BC threshold at the stimulation site.<sup>4</sup> The use of the power device is recommended to provide additional output to overcome TA, as well as attenuation from the skin, during candidacy assessment using a headband.<sup>4-5</sup> It is recommended that speech-in-noise measures are used to predict post-treatment performance in noise for devices intended to eliminate the head shadow effect (i.e. CROS, AOIS, etc.).<sup>6</sup> Pre-treatment evaluation should be completed using a power processor. To provide a best aided performance estimate for the purpose of demonstrating the elimination of the head shadow effect, the recommended test configuration for speech-in-noise assessment should include speech at 45° or 90° azimuth to the side of the poorer ear and noise at 45° or 90° azimuth to the side of the better ear.<sup>3, 6</sup> Due to inherent limitations in clinical assessment of patients with hearing loss (i.e., equipment, time, etc.), additional assessment of performance in noise may not be feasible. As such, counseling regarding the impact of diffuse noise or noise directed at the aided ear is critical for establishing realistic expectations.
3. It is recommended that clinicians utilize validated subjective measures that are specific to the deficit and needs of patients with severe-to-profound UNSNHL.
4. At home testband trials should be reserved for those individuals who have met candidacy requirements including meeting initial audiometric criteria, a measured TA of less than 10 dB, and improved aided performance on speech-in-noise measures. The clinician should ensure that a BC device is programmed to accommodate the patient's TA and it is recommended to use a power device for all at-home trials, that all hearing devices are electroacoustically verified for optimal performance (where possible), and patients are adequately trained on device use and placement.

## Summary of Evidence

Recommendation	Evidence	Source	Level	Grade	EF/EV
1	Pure-tone average of $\leq 20$ dB HL at 0.5, 1, 2, and 3,000 Hz by AC in the better hearing ear.	2			
2	There is large intersubject variability in the TA of bone conducted sound. The higher the TA, the less efficient the transfer of the signal by bone conduction.	3-4	2	A	EF
2	Pre-treatment assessment resulting in a TA of $< 10$ dB is a good predictor of postoperative performance. Use of a power device is necessary to overcome both the TA and the attenuation from stimulation through the skin.	3-5	3	A,B	EF

3	Pre-treatment assessment of speech-in-noise performance using a testband is a good predictor of postoperative benefit.	5	4	B	EV
3	Test configuration should reflect best achievable performance for permanent severe-to-profound USNHL treatment devices. Care should be taken to counsel on limitations of CROS systems.	3	2	A	EF
4	Efficacy reports fail to adequately employ assessments of handicap and disability during the candidacy phase, which may contribute to the variable outcomes observed across studies.	6	4	C	EV
5	At-home testband trials should be reserved for those individuals who have met candidacy requirements by assessment of TA and speech-in-noise performance with a processor on a testband. Low acceptance rates following at-home headband trials are primarily attributed to self-reported lack of benefit with listening in noise.	5,7-9	4	B,C	EV

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## 3. TECHNICAL ASPECTS OF TREATMENT

Comprehensive management of the technical aspects of treatment consists of at least four areas: (1) device selection, (2) quality control, (3) fitting and verification of the device, and (4) hearing assistive technology (HAT).

### 3.1 Device Selection

#### Objective

The objective of this segment of the fitting process is to select, based on the patient's auditory and non-auditory needs assessments, an appropriate hearing device to adequately address the deficits caused by the presence of severe-to-profound USNHL.

#### Background

Treatment begins with the selection of an appropriate device. In the unique case of severe-to-profound USNHL, patients attempt to resolve the loss of the primary advantages of binaural hearing, including localization, release from the head shadow effect, binaural squelch, and binaural summation. Due to the presence of severe-to-profound hearing loss, very poor word recognition, and possibly hyperacusis in the poorer ear, these patients are typically unable to benefit from a conventional hearing device. Research has demonstrated that these patients may benefit from a variety of hearing devices<sup>1</sup> that may improve their auditory experience primarily by eliminating the head shadow effect. These device options utilize different modalities of hearing including AC (e.g., CROS/BICROS), transcranial BC (e.g., transcranial CROS, TransEar<sup>®</sup>, SoundBite<sup>™</sup>, AOIS), and electric stimulation (e.g., cochlear implant (CI)). Localization, partial restoration of binaural squelch and binaural summation, and reduction of tinnitus may be addressed with a CI. Typically, some of these abilities may not be restored with pseudo-binaural device options,<sup>2</sup> and the CI is currently at the clinical trial stage and is not FDA approved for the management of severe-to-profound USNHL.

Determination of candidacy for each device is a critical step in the treatment process. At this visit, it is important for the clinician to present to the patient all the available appropriate fitting options. The clinician should counsel the patient on the advantages and disadvantages of each option and then allow the patient to make the informed decision on the option(s) most appropriate for himself or herself. Although FDA labeling dictates eligibility for each device, consideration of prognostic elements that may identify a likely successful candidate are of the utmost importance.<sup>3</sup> Demographic characteristics including age, residual hearing in the poorer and better ear, gender, and etiology or duration of deafness cannot be reliably utilized for the prediction of device preference or outcomes. Several studies have investigated the correlation between demographic factors and the decision to pursue intervention for severe-to-profound USNHL.<sup>6-8</sup> Significant correlations have not been consistently identified, suggesting that demographic factors do not predict appropriate device selection or ultimate success or failure with any device.

#### Anatomic Contraindications

Most devices rely on distinct anatomic characteristics for determination of candidacy. In consultation with the team otologist/otolaryngologist and dentist (in the case of SoundBite<sup>™</sup>), anatomical issues that may preclude candidacy for a device should be considered. These exclusion criteria may include inadequate dentition for the SoundBite<sup>™</sup>,<sup>4</sup> extremely narrow ear canals (for cases where a CROS/BICROS receiver may occlude the canal of the better hearing ear, transcranial CROS, TransEar<sup>®</sup>), adequate skull thickness and stability for AOIS candidacy and (when CI may be medically necessary) etiologies related to deafferentation of the cochlea (as opposed to retrocochlear pathology such as vestibular schwannoma resection).<sup>5</sup>

## Objective Measurements

### Audiometric Thresholds

FDA labeling of devices intended for the management of severe-to-profound USNHL is based upon unaided audiometric thresholds obtained via earphones. Audiometric thresholds should be used as a starting point for inclusion/exclusion of device options. For example, FDA criteria for AOIS requires pure-tone air conduction average  $\leq 20$  dB HL from 500 Hz through 3000 Hz in the better ear, while the audiometric criteria for TransEar® is 30 dB HL or better for the test frequencies of 500 through 2000 Hz and 60 dB HL or better at 3000 Hz in the better ear. Patients, however, who fit audiometric criteria do not necessarily demonstrate improvement post-fitting. Therefore, success or failure with a device cannot be predicted based solely on pure-tone thresholds.<sup>6, 9</sup>

Pfiffner et al<sup>10</sup> reported that the pre-operative best BC threshold can be used to estimate aided sound-field thresholds with an AOIS device, however, this measurement does not necessarily correlate with outcomes.<sup>6, 9</sup> Most patients with severe-to-profound USNHL do not report problems with audibility of speech in quiet; rather, the most common report is difficulty in localization and correctly recognizing speech in noise. Aided sound-field thresholds may suggest improved audibility and eliminating the head shadow effect, but Snapp et al<sup>9</sup> reported wide variability in patient outcomes on speech-in-noise measures independent of pure-tone audiometry. Further, Snapp et al<sup>9</sup> observed variability on speech-in-noise (SIN) performance even if improved audibility was verified.

### Transcranial Attenuation

As described in Section 2.4, device selection for any BC device should include assessment of transcranial attenuation (TA) that may impact predicted outcomes. TA should be measured for each patient when the clinician is considering treatment with a BC device. Research has shown that individual TA varies significantly (as much as 35 dB per frequency) among patients and is a function of the output of the transmitting device<sup>11, 12</sup> as well as skull and tissue thickness, calibration and placement of the BC device on the mastoid, and test-retest variability. The lower the TA, the better the transmission of amplified sound from the poorer side to the better cochlea. This is best measured clinically by measuring the difference between the BC threshold at the mastoid of the better ear and the BC threshold at the mastoid of the poorer ear.<sup>12</sup>

For an AOIS, the site for placing the BC vibrator is typically 55 mm posterior to the ear canal in line with the upper pinna.<sup>12</sup> It is important to ensure stimulation at the appropriate site, as resonances and anti-resonances will result in variations in position by 2–3 dB.<sup>12</sup> Further, loss of BC transmission can be expected due to attenuation by transcutaneous stimulation (i.e., testband or soft-band). Use of a power AOIS device (i.e., Cochlear Americas Cordelle or Oticon Medical Ponto Pro Power) to provide additional output to overcome this attenuation is recommended for patients to be able to experience a better representation of what the AOIS device may sound like in-situ. Studies suggest that a mean TA of  $< 10$  dB may be a good predictor of post-operative performance,<sup>11-12</sup> although Kompis et al<sup>8</sup> reported no correlation between TA and patient acceptance or rejection of AOIS. In cases of high transcranial attenuation, use of a power device may be necessary, even when worn on a percutaneous abutment, and devices without the capacity for increased outputs (TransEar®, SoundBite™) may need to be eliminated from consideration. Further, increased transcranial attenuation may limit the clinician's ability to consider a BC device for a patient with any worse than normal hearing in the better ear.

### Pre-Treatment Trial and Demonstration

Many studies<sup>1, 3, 6-8, 14</sup> cite the importance of a pre-treatment trial, when possible, of the device(s). For example, a pre-treatment trial may not be possible with TransEar®, transcranial CROS, or SoundBite™, but may be possible with a CROS/BICROS and AOIS. Patient perception of benefit during the trial is reported to be highly predictive of the patient's decision to proceed with the device fitting, as well as ultimate satisfaction with the choice.<sup>1, 7, 14</sup> In fact, Desmet et al<sup>6</sup> cited poor speech recognition in noise as a primary reason to decline AOIS in a group of patients who completed an at-home trial with the device.

Current studies, however, fail to report standardized protocols and most discuss the implementation of an at-home trial

for the AOIS only. Additionally, current studies focus on the impact of an at-home trial for the selection of a device, but do not discuss the validity of this method for predicting post-operative outcomes. Further, minimum trial period duration has not been investigated. That is, could an in-office trial be sufficient for patients to assess preference and benefit if integrated with objective SIN testing in the sound-booth? Given the influence of experience with a device on patient acceptance of a device, minimally, an in-office trial is recommended whenever possible. Device trials should involve programming the device to the patient's hearing loss and verifying fitting, to ensure an optimal trial experience. The decision to pursue a particular device does not seem to be influenced by the order in which various devices are trialed.<sup>1</sup>

### **Speech-in-Noise Testing**

As described in Section 2.4, because insufficient improvement of speech performance in noise has been reported as a primary reason for failing to pursue intervention,<sup>6</sup> an important aspect of the device selection is to objectively predict the potential benefit with a device. Speech-in-noise testing (and specifically assessment of signal-to-noise ratio (SNR) loss) during candidacy assessment and device selection is an accurate predictor of post-intervention benefit.<sup>9</sup> SNR loss is the difference between a patient's SNR50 (SNR at which 50 percent of target words are accurately repeated) compared to normal-hearing listeners. SNR loss is a measure of how much more separation between speech and noise there must be for the device recipient to recognize speech-in-noise. This measure can be very useful when evaluating the efficacy of a device for eliminating the head shadow effect when evaluated without any device, then compared to SNR loss obtained using various demonstration devices (CROS/BICROS, AOIS on testband, and SoundBite™ demonstration device).

Depending on the test measure used, critical difference levels may be utilized to evaluate the significance of differences in performance with no device and with each available management option. A limitation of this recommendation is that some devices are custom products and/or require surgical placement for optimal benefit. Snapp et al,<sup>9</sup> however, demonstrated equivalency between pre-operative and post-operative assessment for AOIS, including persistent limited benefit post-operatively for those AOIS recipients who exhibited limited benefit pre-operatively on objective testing using the QuickSIN™<sup>15</sup> with a test device (Cochlear Cordelle). This suggests that demonstration devices may be accurately used for prediction of post-fitting outcomes. At a minimum, the CROS/BICROS and the AOIS on a testband should be demonstrated to assess the relative benefit of AC versus BC device. There is also a SoundBite™ test device that allows for objective assessment of potential benefit, however, placement is on the central incisors, where custom fitting would be on the molars.

There are many test configurations that could be used. One configuration could be the speech signal presented at 90° to the side of the poorer ear and noise presented at 270° toward the side of the better ear at 50 dB HL.

### **Subjective Measurements**

As reported in Sections 2.2 and 2.3, device selection procedures should include completion of subjective questionnaires related to experience with a trial device as well as unaided performance. Kompis et al<sup>8</sup> reported that, of all the parameters considered, a subjective questionnaire (the Bern Benefit in Single-Sided Deafness questionnaire) demonstrated the strongest correlation with the patient's subsequent device selection. Desmet et al<sup>6</sup> noted that subjective change post-intervention is often more apparent than objective improvement and is highly important for successful intervention. Because patient subjective preference is such a highly predictive measure of success, subjective questionnaires should be administered either during an at-home device trial (if administered), or at least following objective testing in the sound-booth. Other measures that have been used with this population include the Abbreviated Profile of Hearing Aid Benefit (APHAB)<sup>16</sup> and the Speech Spatial Qualities (SSQ) Questionnaire.<sup>17</sup> However, research is limited regarding a validated test measure that would be applicable in a variety of circumstances for this population.

Sections 2.2 and 2.3 address questionnaire administration for pre-device selection assessment. Questionnaire administration may also be useful post-device demonstration to assist in device selection. The following factors have been found to influence patient selection of various devices and could theoretically be important factors for consideration: listening effort, localization, reduction in perceived handicap, comfort with cosmetics/aesthetics of the device, and perceived improvement in background noise.



## Device Features

Device selection should include assessment of and consideration for the following factors: cosmetics, opposition to surgery, comfort and ease of use, opposition to occlusion of better hearing ear, battery life and manipulation, perceived benefit, ability to maintain site and device, cost and insurance coverage. Device selection should also include discussion of the benefits and limitations associated with the various device-fitting configurations, features, and technical characteristics. These include:

	<b>AOIS</b>	<b>CROS</b>	<b>SoundBite™</b>	<b>Transcranial CROS</b>	<b>TransEar®</b>
<b>Classification</b>	Durable medical equipment	Hearing aid	Durable medical equipment	Hearing aid	Hearing aid
<b>T-Coil</b>	External via DAI plug-in	Depends on manufacturer and model	No	Depends on manufacturer and model	No
<b>Wireless Connectivity</b>	Yes	Yes	No	Depends on manufacturer and model	No
<b>Microphone Placement</b>	Behind the ear by the mastoid	Depends on manufacturer and model	In-the-ear canal	Depends on manufacturer and model	On top of the pinna
<b>Automatic Adaptive Directionality</b>	Depends on manufacturer and model	Depends on manufacturer and model	No	Depends on manufacturer and model	Yes with pushing a program button
<b>Feedback Management</b>	Yes	Yes	Yes	Yes	Yes
<b>Noise Reduction</b>	Yes	Yes	No	Yes	Yes
<b>Channels/Bands</b>	12–17	4–20	16 channels 8 bands	4–20	8
<b>Programs</b>	4–5	Depends on level of technology	1	Depends on level of technology	4
<b>Warranty</b>	2 years	Depends on level of technology	2 years	Depends on level of technology	1 year
<b>Battery</b>	Size 13 or 675	Depends on manufacturer and model	Rechargeable; ITM 6–8 hours/ BTE 15–18 hours	Depends on manufacturer and model	Size 13
<b>Custom Fit</b>	No	Depends on manufacturer and model	Yes (requires dental impression)	Depends on manufacturer and model	Yes for earmold containing the BC vibrator

## Other Considerations

Device selection should include consideration of the presence and severity of tinnitus. For patients with intractable tinnitus, a CI is the only device option that may offer some relief. Faber et al<sup>7</sup> reported that 13 out of 14 patients with tinnitus and an AOIS reported no reduction in tinnitus with use of this device. Desmet et al<sup>6</sup> cited lack of relief from tinnitus as a reason for patients who completed an AOIS trial to abstain from pursuing surgical AOIS. Conversely, Van de Heyning et al<sup>5</sup> reported a significant and persistent reduction of tinnitus with electrical stimulation using a CI in 20 out of 21 recipients with USNHL and severe tinnitus. Not only the immediate, but also the long-term benefit of using a CI for tinnitus reduction has been consistently reported.<sup>2, 5, 18, 19</sup> Assessment of tinnitus severity and resulting handicap is a critical component of a device selection; subjective questionnaires such as the Tinnitus Handicap Inventory (THI)<sup>20</sup> may provide the clinician important information in the development of a device recommendation.

All of the devices available for the management of severe-to-profound USNHL are designed for use with a normal hearing better ear. Only the CROS system has the flexibility to be reprogrammed to accommodate hearing loss in the better hearing ear (BICROS). Clinicians should consider the presence/absence of any mild high frequency hearing loss and the potential for further progression, particularly when considering a more permanent solution such as AOIS.

## Recommendations

1. Consideration of anatomical exclusion criteria should be made when considering various device options (dentition, skull thickness, small ear canals, etc.)
2. Demographic characteristics cannot be utilized in establishing recommendations for device selection.
3. Audiometric thresholds, while a reasonable starting place for determining candidacy for various devices, are not adequate for ultimate device selection as many other factors may influence outcomes.
4. Device selection should include assessment of transcranial attenuation and consideration of the potential impact of transcranial attenuation on outcomes with recommended device(s).
5. Device selection should incorporate pre-treatment trial of the device(s) under consideration whenever possible. Demonstration devices available include CROS/BICROS, AOIS on testband, and SoundBite™. Research is limited regarding length of necessary trial and an in-office trial may be sufficient.
6. Device selection should include objective assessment of potential benefit from the various devices by using measures of speech-in-noise. Assessment of potential for speech-in-noise (SIN) improvement should include objective SIN testing in the sound-booth in the unaided condition as well as with various test devices.
7. Subjective questionnaires should be included to help guide the patients' assessment of their perceived benefit as an integral part of the evaluation process.
8. Device selection should include assessment of and consideration for the following factors: cosmetics, opposition to surgery, comfort and ease of use, opposition to occlusion of better hearing ear, battery life and manipulation, perceived benefit, ability to maintain site and device, cost and insurance coverage, as well as the benefits and limitations associated with the various device-fitting configurations and technical characteristics
9. Device selection should include consideration of the presence and severity of tinnitus. Assessment of tinnitus severity and resulting handicap is a critical component of device selection; subjective questionnaires such as the Tinnitus Handicap Inventory (THI)<sup>20</sup> may provide the clinician important information in the development of a device recommendation.

10. All of the devices available for the management of severe-to-profound USNHL are designed for use with a normal better-hearing ear except the CI. Only the CROS/BICROS systems have the flexibility to be reprogrammed to accommodate hearing loss in the better hearing ear. Clinicians should consider the presence/absence of any mild high frequency hearing loss and the potential for further progression, particularly when considering a more permanent solution such as AOIS.
11. Clinician should present to the patient all the possible fitting options that would be appropriate. The clinician should counsel the patient of the advantages and disadvantages of each option and allow the patient to make an informed decision on which option(s) is most desirable, bearing in mind that treatment options which are less invasive would appear to be a better starting point.

**Table 1: Level of Evidence for Recommendations for Device Selection**

Recommendations	Evidence	Source	Level	Grade	EF/EV
1	Consideration of anatomical exclusion criteria should be made when considering various device options.	4-5	6	D	EF
2	Demographic characteristics, including age, residual hearing in the poorer ear, gender, and etiology or duration of deafness, cannot be reliably utilized for prediction of device preference.	6-8	3, 4	B, C	EF
3	Pre-operative best BC threshold should be used to estimate aided sound-field thresholds with a device.	10	4	B	EF
3	Patients who fit audiometric criteria do not necessarily demonstrate improvement post-fitting; therefore success with a device should not be predicted based solely on pure-tone thresholds.	6,9	3,4	B	EF
3	There is wide variability in patient outcomes on speech-in-noise measures independent of pure-tone audiometry and resulting improvement in audibility.	9	3	B	EF
4	Device selection should include assessment of transcranial attenuation and consideration of the potential impact of transcranial attenuation on outcomes with recommended device(s).	11-12	2,3	A, B	EF
5	Device selection should incorporate pre-treatment trial of the device under consideration whenever possible.	1-2,6-8,14	2, 3, 4, 6	B, C, D	EF
5	Device trials should involve programming the device to the patient's hearing loss, including verification of fitting, to ensure an optimal trial experience.	Consensus opinion	6	D	EF
5	The decision to pursue a particular device does not seem to be influenced by the order in which various device are trialed.	1	2	B	EF

6	Device selection should include objective assessment of potential benefit from device options using speech-in-noise measures.	9	3	B	EF
6	Speech-in noise-testing (specifically assessment of SNR loss) during candidacy assessment and device selection is an accurate predictor of post-intervention benefit.	9	3	B	EF
6	Insufficient improvement of speech recognition in noise has been reported as a primary reason for patients failing to pursue intervention.	6	4	B	EF
6	Test band aided measures have been shown to be less accurate when assessing sound-field thresholds	13	4	B, C	EF
6	No significant differences using a power device on a test band compared to post-operative percutaneous BC on speech-in-noise measures.	9	3	B	EF
7	Device selection should include subjective questionnaires to help guide the patient's assessment of their perceived benefit.	1,7,14	2, 3, 4	B, C	EF
7	Device selection procedures should include completion of subjective questionnaires related to experience with trial device.	6,8	4	B, C	EF
8	Device selection should include assessment of and consideration for the following factors: cosmetics, opposition to surgery, comfort and ease of use, opposition to occlusion of better hearing ear, battery life and manipulation, perceived benefit, ability to maintain site and device, cost and insurance benefits.	Consensus opinion	6	D	EV
9	Device selection should include consideration of both the presence and severity of tinnitus.	Consensus opinion	6	D	EF
10	Lack of relief from tinnitus is a reason for patients who completed an AOIS trial to abstain from pursuing surgical AOIS.	6-7	3, 4	B	EF
11	CIs may offer immediate and long-term benefit for tinnitus reduction but are currently in the clinical trial stage.	2,5,18-19	1, 3	A, B	EF

12	All of the devices available for the management of severe-to-profound USNHL are designed for use with a normal better hearing ear. Only the CROS system has the flexibility to be reprogrammed to accommodate hearing loss in the better hearing ear (BICROS). Clinicians should consider the presence/absence of any mild high frequency hearing loss and the potential for further progression, particularly when considering a more permanent solution such as AOIS.	Consensus opinion	6	D	EF
13	Clinician should present to the patient all the possible fitting options that would be appropriate. The clinician should counsel the patient of the advantages and disadvantages of each option and then allow the patient to make an informed decision.	Consensus opinion	6	D	EF

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## 3.2 Quality Control

### Objective

The objective of this segment of the fitting process is to ensure that a hearing device meets reasonable and expected quality standards prior to scheduling patients for a hearing device fitting and subsequent verification.

### Background

An unknown percent of new hearing devices, repaired hearing devices, and earmolds may be defective on receipt. In addition, hearing devices and earmolds may arrive in good working order, but with the incorrect configuration/features. Quality control measures are therefore required to limit patient and audiologist frustration and inconvenience and to ensure the best possible care for our patients.

### Recommendations

1. Electroacoustic verification of all hearing devices (new and repaired), when possible, is recommended.<sup>1-3</sup> This verification should be completed prior to fitting to ensure the hearing device is in working order and to provide a benchmark for future quality control measures. For convenience, a hearing device's measured electroacoustic information can be scanned or otherwise inserted into the patient's electronic medical record (EMR). For TransEar® and SoundBite™ options, it is not currently possible to verify electroacoustic performance and a listening check may be the only method to verify performance. For AOISs, use of a skull simulator is available to verify performance. In the past, the cost of a skull simulator was prohibitive and very few clinics had access to it.<sup>4-6</sup> Recently (in 2013), a less expensive and commercially available (e.g., Interacoustics) skull simulator became accessible to verify electroacoustic characteristics of AOISs. For CROS and BICROS fittings, it is important to verify that the transmitter device is transmitting its output to the receiver side using either coupler or real-ear measures. It is equally important to verify that the hearing device for the receiver side (i.e., better ear) agrees with the manufacturer specifications. The performance of a transcranial device can be verified in the same manner as any conventional hearing aid using coupler measures.<sup>2</sup>

- Verification of features (e.g., directional microphone, noise reduction, feedback management) and physical parameters is also recommended prior to the hearing device fitting. <sup>3</sup>Such verification may include confirmation of earmold/shell style, ordered vent size, color, and type as well as a number of hearing device processing (memories, automatic switches, etc.) and mechanical (directional microphones, t-coil, integrated FM, etc.) features. Those features which cannot be verified through physical examination or standard electroacoustic verification methods should be verified through a listening check. These may include operation of the volume control (VC), directional microphones, FM, t-coil, and so on.

### Summary of Evidence for Quality Control

Recommendations	Evidence	Source	Level	Grade	EF/EV
1	Electroacoustic verification of a hearing device provides a benchmark against which future quality control measures can be compared. This ensures the hearing device is in working order prior to fitting.	1-6, 7	6 4	D B	EF EV
2	Verification of features and physical parameters is also recommended prior to a hearing device fitting.  Clinical experience and expert opinion reveal that errors are made in the manufacture and shipping of a hearing device and earmolds relative to inclusion of requested features.	3-6, 7  Consensus opinion	6 4	D B	EF EV

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## 3.3 Fitting and Verification of Hearing Device

### Objective

With the rapid and ongoing changes in hearing technology, this section of the guideline is not designed to mandate how a hearing device for USNHL should be fitted. Rather, it is designed to provide evidence-based recommendations to assist the clinician in optimizing device performance and improving patient outcomes and perceived benefit and/or satisfaction.

## Background

At minimum, the goal of fitting any hearing device should be to ensure aided speech is audible, clear, and comfortably loud. In USNHL, the associated auditory deficits often result in specific needs and expectations of the fitting and verification process. For example, audibility may be less important whereas elimination of the head shadow effect, localization, and listening in noise is most often considered the primary deficit<sup>1</sup>. There are standardized and well recognized fitting and verification approaches in place for conventional hearing device technology<sup>2</sup>. New and emerging technology for the treatment and rehabilitation of USNHL provides new challenges for the clinician. These include, but are not limited to, AOIS devices, BC hearing devices, CROS hearing aids, TransEar<sup>®</sup>, transcranial CROS, and SoundBite<sup>™</sup> hearing devices. The objective of this section is to provide evidence-based guidelines for fitting and verification of the existing and emerging hearing devices for the treatment of USNHL. There are well established methods of verification for conventional amplification such as CROS and transcranial CROS.<sup>3</sup> Current fitting and verification approaches for BC hearing devices and AOIS devices vary widely in the literature and in the clinical setting. There are, however, fundamental similarities that will be used to generate the following recommendations.

The fitting of any hearing device should utilize a validated prescriptive method whenever possible. There are well established prescriptive methods available for AC devices, such as the CROS hearing aid.<sup>4,5</sup> Assignment of gain/output for BC hearing devices and AOIS devices, however, is less clear. For AOIS devices, thresholds should be directly measured through the AOIS device using frequency specific stimuli whenever possible to assign appropriate gain levels during the fitting process. Clinically, audiometric BC thresholds are obtained transcutaneously by delivering the sound via a bone conductor attached to a headband through the skin at the mastoid, whereas, AOIS devices provide a direct percutaneous stimulation to the bone and cochlea of the better ear. While percutaneous stimulation is advantageous, it does not overcome the transcranial attenuation (TA) of sound that occurs in USNHL.<sup>6-7</sup> It has been suggested that fitting measures should include a direct measure of threshold responses through the AOIS device which will take into account both the benefit of percutaneous stimulation and the expected detriment of TA.<sup>8-10</sup> The resulting in-situ bone conduction thresholds can be used to more accurately assign prescriptive gain/output values.<sup>8</sup> At present, there is insufficient data to suggest that one prescriptive formula is superior to another when fitting a BC device. Regardless, as with any hearing device, it is the clinician's responsibility to ensure that the frequency and gain/output characteristics are sufficient for the specified needs of the patient. Given the unique characteristics of BC hearing devices,<sup>9-11</sup> and limitations with verification of aided output to verify device performance, it is recommended that measures of TA be used to guide the clinician in the fitting process. For example, in treatment of USNHL by AOIS devices, the signal must travel contralaterally via the temporal bone to the normal cochlea resulting in a TA of approximately 5-10 dB.<sup>6-7</sup> It has also been reported that TA can vary as much as 35 dB per frequency between patients.<sup>6-7</sup> If not appropriately managed, these factors lead to inconsistency in AOIS device fittings and are likely to result in over or underestimation of gain/output needs. By measuring BC thresholds through the implant at the time of fitting, TA is automatically accounted for and skin impact is removed, thereby allowing for a more accurate starting point for assignment of gain/output.<sup>8-10</sup>

In patients with severe-to-profound USNHL, the availability of high frequency signals  $\geq 1500$  Hz are lost due to the head shadow effect whereas low frequency signals  $\leq 1500$  Hz are not typically compromised. Employing frequency shaping that uses a low-cut at 1500 Hz does not negatively impact speech recognition in USNHL, but can decrease the negative impact of noise arriving at the processor and being delivered to the cochlea of the better ear.<sup>12</sup>

During the fitting, the device fit and manageability should be assessed in order to: 1) ensure ease of insertion/removal and attachment/detachment, 2) ensure ability to manipulate device features such as program button and volume control, 3) ensure physical fit and comfort. Specifically, one should ensure that the AOIS device processor is not in contact with and rubbing the skin, or there are any observable indications of skin overgrowth.<sup>13</sup> In the case of an oral device (e.g., SoundBite<sup>™</sup>), the clinician should ensure the mouth piece is comfortable, does not easily dislodge with talking or normal movement of the tongue and oral cavity, and does not result in intraoral, palatal or dental soreness. An efficacy study of safety using an in-the-mouth bone conductor demonstrated that the in-the-mouth (ITM) interacts with oral tissue in the same manner as all removable dental appliances and may result in minimal easily resolvable soreness in the oral cavity. The patient's teeth should be healthy and maintained when using the device. If any of these concerns arise, the patient



should be referred to his/her dentist for management.<sup>14</sup> All ear level devices should be secure to the ear, comfortable, and have appropriate earmold modifications when necessary. If a device requiring a magnet to couple to the skin is used, the clinician should ensure the device is at the lowest magnetic setting while maintaining appropriate adherence to the implant site. Note that increased magnet strength (contact force) does not result in significant improvements in hearing outcomes<sup>15</sup> and may result in tissue breakdown. Any irritation to the implant site should indicate a recommendation for discontinued use and a medical referral for management. Finally, the fitting processor should ensure feedback is appropriately managed prior to verification and validation procedures.

Verification of AC devices such as the CROS hearing aid should be verified using real ear probe microphone measures (REM) as previously described in fitting and verification guidelines.<sup>2</sup> For CROS hearing aids, the goal is to verify that the head shadow effect is lifted through appropriate transfer of the acoustic information from the poorer ear to the better ear,<sup>4-5</sup> and when available, features of the device, such as directional microphone, feedback management, and noise reduction should be made available.<sup>2</sup> In the case of transcranial CROS hearing aids, the goal is to verify that the measured real ear aided response (REAR) for 50-65-80 dB SPL exceeds the transcranial threshold.<sup>3</sup>

AOIS devices should be electromechanically verified using a skull simulator coupled to an output measurement system with reference microphone.<sup>9-11</sup> Verification is the systematic process of providing evidence that a hearing device meets specific requirements and the device is meeting the hearing needs of the patient that were identified in the assessment and selection process. The well accepted standard of verification includes verifying the frequency-specific aided output or gain of the hearing device prescribed by validated prescriptive targets generated by the hearing profile of a patient.<sup>2</sup> For AOIS devices, a version of the Desired Sensation Level (DSL) was used to provide more frequency-specific audibility for patients. This, in turn, led to beneficial outcomes.<sup>9-10</sup> This method is based on the rationale behind the accepted standard of using REM to verify AC devices.<sup>2</sup> While clinicians wait for a fully validated generic formula, they can use the prescription in the manufacturer's software as a starting point. A commercially available skull simulator has been developed and released to the market (SKS10, Interacoustics) and can be used to verify that the gain/output prescribed by the manufacturer is consistent with the measured gain/output on the skull simulator. Even without a generic prescription, the clinical goal of providing greater access to sounds > ~1500 Hz for a USNHL patient can be easily verified. At present, the members of the task force are not aware of any prescription or verification options for oral devices.

For all treatment options, aided sound-field (SF) measures can be helpful in determining the frequency-specific signals (i.e., narrow band noise, warbled pure-tones, frequency modulated pure-tones) that a patient can hear in the aided condition. In that respect, aided SF measures serve as a validation tool. Aided SF measures should not be used as the primary means of verifying response characteristics of AOIS devices, BC hearing devices, or hearing aids. It is important to note the previously described<sup>16</sup> limitations of SF measures as a verification tool. Specifically, this method only provides the clinician with information regarding low level input signals. This leads to concerns such as noise floor effects, internal noise of the device, inability to assess the output limiting characteristics, and poor frequency resolution.<sup>16-17</sup> These concerns have led to the universally recognized REM approach<sup>2</sup> for verifying the performance of hearing aids. A similar method does not currently exist for AOIS devices or other BC hearing devices. When compared with the standard SF approach, the audibility direct (AD) method suggested by Hodgetts et al<sup>9-10</sup> proved superior. Verification by SF measures resulted in an over estimation of the speech sensation level, as previously reported with AC hearing devices.<sup>9-10,16</sup> Additionally, SF measures do not account for the variability in output of these devices or that audibility is dependent of volume control settings and the frequency range of each system.<sup>15</sup>

Speech-in-noise (SIN) measures is the preferred behavioral method of verification in USNHL. The literature suggests using measures of SIN to verify device performance and demonstrate patient benefit.<sup>15-21</sup> Although no universally accepted and validated method exists for assessment of SIN performance in USNHL, there is sufficient evidence for making credible and justifiable recommendations.<sup>6,12,18-20</sup> In general, the evidence shows that patients benefit most when the signal of interest (speech) is directed at the aided ear and noise is directed at the normal hearing ear, followed by speech presented from the front of the listener and noise directed at the normal hearing ear.<sup>6,12,18-20</sup> On the contrary, a decrement in performance is seen when the noise is directed at the aided ear, regardless of the location for the speech

signal. For assessment of best performance, it is recommended for SIN measures that the speech signal be forwarded to the aided ear and/or forwarded to the front with noise directed at the better ear. Test selection should include careful review of the test signal and noise source. These factors may impact patient performance and outcomes in a variety of ways for which the clinician should be aware. For example, memory and other central auditory processing mechanisms are expected to play a role in tests where the stimuli consist of sentences rather than words. If sentences are used, one may consider using a test with lower-predictability sentences in order improve the audibility measure. Conversely, for an individual with low language levels, such as a child, words or simple sentences may be more appropriate. Specifically, adaptive tests are used most widely.<sup>18-21,24</sup> At this time, however, there are no critical reviews of which SIN measure provides a better assessment for this population.

Device performance should be verified at multiple input levels. Behavioral assessment of word recognition in noise<sup>21</sup> and loudness comfort<sup>10</sup> at multiple input levels may be used in absence of electroacoustic verification of output for soft (50 dB SPL), average (65 dB SPL), and loud (80 dB SPL) sounds. For example, the clinician could assess speech or word recognition with competing noise at 50, 65, and 80 dB SPL to ensure that speech is audible, comfortable, and clear.<sup>21</sup>

Validation should include appropriate subjective assessment tools to augment the objective measures (see Section 5). Satisfaction with AOIS devices has been reported to be highly variable.<sup>22-23</sup> When correlated to objective measures of SIN performance, Snapp et al<sup>24</sup> was also able to demonstrate an association between improved SIN performance on the QuickSIN and increased subjective satisfaction as well as a decrease in subjective disability and handicap on the Glasgow Hearing Aid Benefit Profile.

Of note, at the time of creating this guideline the application of cochlear implants (CIs) in USNHL was not approved by the FDA or is universally accepted. There is emerging evidence that CIs may have a viable role in the treatment of USNHL.<sup>25</sup> With consideration that the needs of the USNHL patient do not change and the lack of electroacoustic measures available for verification of CIs, it is recommended that the above described verification procedures be used for CI performance in USNHL. A possible advantage of CIs in this population is the ability to improve localization.<sup>25</sup> Assessment of localization, however, is limited in most clinical settings making standard application challenging.

## Recommendations

1. The fitting of any hearing device should utilize a validated prescriptive method whenever possible. It is the clinician's responsibility to ensure that the frequency and gain/output characteristics are sufficient for the specified needs of the patient. There are well established prescriptive methods available for AC devices, such as the CROS hearing aid.<sup>4-5</sup> At present, there is insufficient data to suggest that one prescriptive formula is superior to another when fitting BC devices. For AOIS devices, thresholds should be directly measured through the AOIS device using frequency specific stimuli whenever possible to assign appropriate gain levels during the fitting process.
2. Employing frequency shaping that uses a low-cut at 1500 Hz does not negatively impact speech recognition in USNHL, but can decrease the negative impact of noise arriving at the processor and being delivered to the cochlea of the better ear.<sup>12</sup>
3. Device fit and manageability should be assessed in order to: a) ensure ease of insertion/removal and attachment/detachment, b) ensure ability to manipulate device features such as program button and volume control, and c) ensure physical fit and comfort.
4. AC devices such as the CROS hearing aid should be verified using real ear probe microphone measures as previously described in fitting and verification guidelines.<sup>2</sup>
5. AOIS devices should be electromechanically verified using a skull simulator coupled to an output measurement system with reference microphone.<sup>9-11</sup>

6. As previously recommended with hearing aids,<sup>2</sup> aided SF measures should not be used as the primary means of verifying response characteristics of devices used to treat severe-to-profound USNHL. This method only provides the clinician with information regarding low-level input signals which can lead to issues such as noise floor effects, internal noise of the device, inability to assess the output limiting characteristics, and poor frequency resolution<sup>16-17</sup>.
7. Speech-in-noise (SIN) measures is the preferred behavioral method of verification in USNHL. For assessment of best performance, it is recommended for SIN measures that the speech signal be forwarded to the aided ear and/or forwarded to the front with noise directed at the better ear.<sup>6,12,18-20</sup> Care should be taken to counsel patients on device performance in diffuse noise or where noise is directed at the poorer ear in the aided condition as this will result in a decrease in audibility and listening in noise performance.
8. Behavioral assessment of word recognition in noise<sup>21</sup> and loudness comfort<sup>10</sup> at multiple input levels may be used in absence of electroacoustic verification of output for soft (50 dB SPL), average (65 dB SPL), and loud (80 dB SPL) input levels.
9. Validation should include appropriate subjective assessment tools to augment the objective measures (See Section 5).

### Summary of Evidence

Recommendations	Evidence	Source	Level	Grade	EF/EV
1	CROS and transcranial CROS devices should be fitted according to established prescriptive methods.	3-5	2	A	EF,EV
1	Hearing thresholds should be directly measured through the AOIS device using frequency specific stimuli to assign appropriate gain levels.	6-11	2	A	EF,EV
2	Using a low frequency cut-off at 1500 Hz does not negatively impact speech recognition in USNHL. This adjustment can, however, decrease the negative impact of noise arriving at the processor.	12	4	B	EV
3	Skin overgrowth can result in excessive feedback and delays in processor loading.	13	4	B	EV
3	Efficacy study of safety using an in-the-mouth bone conductor demonstrated that the in-the-mouth (ITM) interacts with oral tissue in the same manner as all removable dental appliances and may result in minimal easily resolvable soreness in the oral cavity. The patient's teeth should be healthy and maintained when using the device.	14	4	B	EV
3	Force output level increases minimally as the contact force of the device is increased.	15	2	A	EF,EV
4	The most reliable method of verification is real ear probe microphone measures to ensure AC devices are meeting prescribed targets.	2	1	A	EF, EV
5	AOIS devices should be electromechanically verified using a skull simulator coupled to an output measurement system with a reference microphone.	9-11	2	A	EF

6	SF measures cannot be used interchangeably with real ear measures (REM). SF measurements overestimate the sensation levels at which average conversational speech will be received by a listener through an amplified device. Additionally, SF measures fail to provide any information regarding output characteristics for a given input or output limiting characteristics for a given input.	10,16-17	3,6	A,B,C	EF,EV
6	The “real ear” accelerometer method for AOIS devices is superior to SF measures as a verification tool. SF measures overestimated SL levels as previously reported.	10,16-17	2,3,6	A,B,C	EF,EV
6	Output of devices can vary considerably and audibility is dependent of volume control settings and the frequency range of each system.	15	2	A	EF,EV
7	Primary deficit of individuals with USNHL is the ability to listen in noise.	1	6	C	EV
7	The lower (better) SIN test results are associated with electroacoustic fitting methods suggesting that optimal SIN test results are correlated to optimal fitting.	10	2	A	EF,EV
7	The most benefit is realized when the signal is presented to the aided side and noise is presented to the normal hearing ear followed by signal to the front and noise to the normal ear.	6,12,18-20	3	B	EF,EV
8	A measure of soft speech should be employed to ensure audibility for low level inputs.	10	2	A	EF,EV
8	Assessment of speech recognition ability in complex listening environments can provide the clinician with information about device performance at varying input levels. This can lead to indications for programming adjustments and the need for counseling on realistic expectations.	21	3	B	EV
9	Loudness perception with AOIS devices is not normalized.	10	2	A	EF,EV
10	Verification should include appropriate subjective assessment tools to augment objective measures.	22-23	3,4	B	EV
10	Improved performance on SIN tests is associated with decreased subjective disability and handicap.	24	3	B	EV

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## 3.4 Hearing Assistive Technology

### Objective

The objective of this segment of the fitting process is to use Hearing Assistive Technology (HAT), when appropriate, as part of the treatment plan in the management of hearing loss to ensure that all of the patient's communication needs are met. As one treatment option, modern AOIS hearing systems, transcranial CROS, CROS/BICROS, and TransEar® can be equipped with direct auditory input (DAI) capability (either Euro Pin or BCI standard plugs) allowing for adding a HAT device. In this capacity, the T-coil may be added via DAI. In the case of bone conduction (BC) devices, it is difficult to build a T-coil within the housing of the BC device that will be immune from the magnetic activity of the vibrating oscillator that produces the signal used to transmit sound to the skull. In these cases, the T-coil accessory separates the coil from the BC transducer that produces the interference that could impede the T-coil function. In addition, many current devices now allow for wireless communication between the hearing device and a remote microphone, remote control, cell phone, land-line phone, television, computer, or MP3 player.

### Background

Patients with hearing loss vary in their specific communication needs. The use of an AOIS device may not address all of the communication and safety needs of the patient, as is the case with acoustic hearing devices. The use of HAT, such as assistive listening, alerting, and/or signaling device, plays an important role in meeting patient needs and in the treatment of the patient with hearing loss. Various assistive technologies are available that can present auditory, visual, and/or tactile information to augment communication and/or to facilitate the patient's awareness of sounds in the environment. Some assistive systems can be used alone, while others are used in combination with personal hearing devices or an AOIS device to supplement performance in difficult listening conditions. The use of HAT addresses four basic communication needs:<sup>1</sup>

1. Live, face-to-face communication (e.g., home, restaurant, meeting, place of worship, concert, lecture, automobile, courtroom, classroom).
2. Broadcast and other electronic media (e.g., radio, television, movie theatre).
3. Telephone conversation (e.g., telephone, intercom).
4. Sensitivity to alerting signals and environmental stimuli (e.g., doorbell, smoke detector, telephone ring, appliance timer, baby's cry, child's voice, alarm clock, door knock).

HAT is selected for a particular patient based on his or her communication demands. Assistive technologies are especially useful when the speech signal is presented at a considerable distance from the patient and/or when the acoustic environment is less than ideal. Situations in which the use of these technologies might be appropriate are:<sup>1</sup>

1. In the home (e.g., one-on-one or group conversations, TV or radio, and sounds in the home environment);
2. In the community (e.g., health-care treatment, employment situations, travel, recreation, restaurant, public spaces);
3. School environments (e.g., communication with teacher and/or classmates, speech/language therapy).

HAT, such as FM systems and T-coils, can improve audibility and speech recognition in specific listening situations.<sup>1</sup> This is particularly helpful in situations where there is ambient environmental noise (noise present in a room when it is unoccupied), reverberation, background noise, or a great distance from the patient to the sound source.<sup>1</sup> The FM system picks up the sound from the source and transmits it without wires directly to a sound-generating transducer at the ear. The sound is presented to the ear at an audible level, with a favorable signal-to-noise ratio (SNR) and with minimal ambient noise, reverberation, or background noise. The expected benefits of the remote FM microphone in reducing the negative effects of distance and noise have been demonstrated in laboratory and field conditions.<sup>2</sup> Careful personal adjustment of relative gains via the FM and the hearing device microphones may be needed for optimal use.<sup>2</sup>

HAT is available as personal systems or large-area listening systems. The most common types of HATs are:<sup>1</sup>

- (a) Personal FM systems
- (b) Infrared systems
- (c) Induction loop
- (d) Hard-wired
- (e) Telephone amplifier, telecoil, TDD (telecommunication device for the deaf)
- (f) Situation specific device (e.g., television)
- (g) Alerting device
- (h) Integrated wireless radio or near field induction magnetic induction systems
- (i) Video telephone services

HAT can enable a hearing-impaired patient to participate more fully in and benefit from many social and cultural activities.<sup>3</sup> Large-area assistive listening systems supplement the use of a hearing device by providing the extra help that the hearing-impaired patient may need to supplement the use of a hearing device.<sup>3</sup> For patients with severe-to-profound SNHL, an FM hearing-aid system and an assistive device may provide a reasonable solution for hearing in a variety of demanding listening situations.<sup>4</sup> HAT can be used to assist patients with special auditory needs (e.g., patients with auditory-based deficits in dichotic listening).<sup>9</sup>

HAT has been shown to be useful for older adults living independently, for those who participate in different types of residential and day facilities, and for patients in more institutionalized settings.<sup>5</sup> With older adults, assistive technologies are an important part of the treatment process and contribute to the ability of the older adult to live comfortably and independently within his or her home.<sup>5, 8</sup> Assistive devices can also reduce the impact of hearing loss and ensure safety for older patients.<sup>5, 8</sup> HAT may be helpful and acceptable when a AOIS alone does not prove satisfactory.<sup>7, 10</sup> HAT together with environmental modification can improve communication ability and the QOL for patients in nursing homes.<sup>11</sup>

The use of a hearing device, both a personal hearing device and FM systems, has been shown to have a significant impact on the QOL of elderly patients.<sup>6</sup> If the FM equipment, however, is large and cumbersome, the older adult is usually not willing to endure the difficulties associated with its use.<sup>6</sup> Also, cost can be high in this category of HATs and this factor may impede the use of HAT. In order to ensure optimal use of FM technology for adults of any age, counseling, instruction, and coaching are needed.<sup>2</sup> Patient success with FM systems can be achieved when personalized communication goals are established and when patients are provided with systematic instruction and counseling regarding FM use over several sessions.<sup>12</sup>

## Recommendations

1. The use of HAT should be considered in the management of each patient as personal hearing devices such as AOIS, Transcranial CROS, CROS/BICROS, or TransEar<sup>®</sup> may not address all of the patient's communication and safety needs.
2. Counseling, instruction, and coaching should be included to ensure optimal use of FM systems.
3. Careful personalized adjustment of relative gains via FM and hearing device microphones is needed for successful use of the FM system.
4. The establishment of goals and the provision of systematic instruction and counseling regarding FM use over several weeks are critical to success with FM systems.

## Summary of Evidence

Recommendation	Evidence	Source	Level	Grade	EF/EV
1	When the listening condition is less than ideal, a hearing device alone may not be adequate to maximize a patient's listening potential.	1	6	D	EV
1-3	Careful, personalized adjustment of relative gain via FM and hearing aid microphones is needed to ensure optimal use of FM technology.	2	4	B-C	EF
1-3	Considerable counseling, instruction, and coaching is needed with HATs to ensure optimal use of FM technology.	2	4	B-C	EV
1	A HAT is of great potential significance for patients with hearing loss because it provides additional help to supplement the use of hearing devices.	3	4	B-C	EF
1	Successful audiologic management is accomplished for a patient with severe-to-profound hearing loss with the use of a BTE FM system for some purposes and a HAT for others.	4	5	C	EV
1	HATs constitute an important part of the rehabilitation of hearing-impaired older adults.	5	5	C	EV
1	Elderly users usually are not willing to endure the difficulties associated with the use of remote-microphone HAT systems.	6	4	B-C	EV
1	Consider the importance of trial use of HAT in elderly patients who reject conventional aids.	7	5	C	EV
1	Listeners with an auditory-based deficit in dichotic listening may function better with a HAT, such as a FM system.	9	4	B-C	EF
1	For some older patients who do not benefit adequately from a conventional hearing device, HATs may be helpful.	10	6	D	EF
1	HATs would improve communication ability and QOL of the nursing home resident.	11	4	B-C	EV
1-2, 4	When specific goals are established and patients are provided with systematic instruction and counseling regarding FM use over several sessions, success with the FM system can be achieved.	12	4	B-C	EV

The evidence base referenced in the above table is representative of peer-reviewed articles where various HATs were interfaced with an acoustic hearing device. Since AOIS, Transcranial CROS, CROS/BICROS and TransEar® have a similar signal path and utility, it is felt to be appropriate to use this evidence to support HAT in this category of device. Little reference was found to HAT usage specific to any these devices.

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## 4. ORIENTATION, COUNSELING, AND FOLLOW-UP

### 4.1 Device Orientation

#### Objectives

The objective of this segment of the fitting process is to ensure the patient is able to receive the maximum benefit from his or her hearing device. Effective counseling on the hearing device can decrease unrealistic expectations and increase satisfaction.

#### Background

Initial fitting of a hearing device begins the orientation process. Follow-up fine-tuning and counseling may continue over several visits. Because using a hearing device may be a new experience for the patient, a written information packet should be provided on orientation to the hearing device as well as how to achieve maximum benefit using the hearing device. The patient then can refer to this written information packet as he or she becomes more comfortable with using the hearing device. In addition, it is usually more beneficial if at least one family member or caregiver is also involved in the process of counseling and orientation to the hearing device.

Hearing device orientation is finalized only when all information has been conveyed and the patient (or family member/caregiver) demonstrates that he or she is able to handle the hearing device and use the hearing device to its full potential.

Hearing device orientation may be related to the use and care of the hearing device or may be related to counseling. Information concerning the use and care of the hearing device relates to the appropriate manner for utilizing and maintaining the hearing device. Counseling may include such topics as understanding hearing loss, impact of his or her hearing loss on communication in quiet, noise, reverberation, gender and age, adjustment to the hearing device, communications strategies, appropriate realistic expectations, and use of hearing protection, when appropriate, in the better ear to preserve hearing.

## Recommendations

The following hearing device related information should be conveyed to the patient, and also to family members or care-givers, as part of the hearing device fitting process:

### 1. Use/Care

- Device features (multiple programs/program button, on/off switch, directional microphone settings, direct audio input, remote control, wireless devices, volume control, low battery warning, telecoil, and other special features).
- Insertion/removal of device, battery and earmold.
- Battery use (size, voltage, insertion and removal, disposal, purchasing options, and dangers).
- Care and cleaning of earmold and hearing device.
- Comfort of earmold or dome.
- Feedback.
- Repair and Loss and Damage warranty protection, warranty extension.
- Moisture control (dehumidifier).
- User manual.

### 2. Counseling

- Wearing schedule.
- Comfort of earmolds or domes.
- Goals and realistic expectations in quiet, noise, reverberation.
- Function of the hearing device with the telephone, use of telecoil, M/T rating and labeling.
- Hearing Assistive Technology (HATs).
- Adjusting to the hearing device: family, social, school, and work settings.
- Listening environment difficulties in restaurants, groups, movies, and television.
- Improved communication strategies.
- Speechreading.
- Use of group and individual aural rehabilitation classes.
- Post-fitting care provided by the clinician and clinic where the hearing device was dispensed.
- Troubleshooting.
- Return for credit policy.
- Importance of wearing hearing protection, when appropriate, in the better hearing ear.

Recommendation	Evidence	Source	Level	Grade	EF/EV
1,2	Patients may wear hearing devices for more hours and be more satisfied if orientation, education, and follow-up fine-tuning is included.	2-3	3	B,D	EV
1,2	Patients should be counseled on how speech recognition in noise may be improved, but also on realistic expectations. Patients should be counseled on how to use the hearing devices or access special programs in the hearing device to improve speech recognition in noise.	4-12	1,3,4	B,C	EF/EV
2	It should be emphasized that hearing devices will not restore localization, but rather sound awareness. Discuss safety in the patient's environment.	5,7,11-14	1,3,6	B,C,D	EF/EV
2	Patients should be recommended to follow-up two to four weeks post-fitting to determine comfort of fit, need for fine-tuning, re-counseling on care and maintenance, and to address any questions.	14-15	6	D	N/A
2	Patients should be recommended to schedule three, four, or six month visits and annual follow-up.	15	6	D	N/A
2	Discuss communication strategies and how to effectively use the hearing device and other strategies in difficult listening environments.	15	6	D	N/A
2	Patients should be counseled on realistic expectations.	16	3	B	EF/EV
2	Counseling regarding hearing loss is beneficial in the rehabilitation of hearing loss.	17	2	A	EF/EV
2	Adult aural rehabilitation programs assist in the improvement of self-perception of hearing loss and lead to better communication strategies.	18	1	B	EF/EV
2	Patients should expect improvement in overcoming the head shadow effect.	12	3	C	EF

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## 4.2 Counseling and Follow-Up

### Objective

Effective use of strategies to reduce the effects of hearing loss relating to the patient, his or her family member, and caregivers is the primary goal of this segment of the guideline. Through the use of this information, patients, family members, and caregivers can successfully and effectively utilize the hearing device.

### Background

The fitting of hearing devices for USNHL is an important step in successful audiological management of these patients. Thorough counseling should be provided to help the patient adjust to his or her hearing device and this should be performed in the patient's and the primary communication partner's preferred language. Through this process, he or she can develop appropriate strategies to maximize and augment the assistance that is received from the hearing device. The fitting of the hearing device does not necessarily guarantee complete or even partial relief of the communication deficit caused by the hearing loss. Counseling is a necessary step to help the patient learn the purpose and limitations of the hearing device he or she is using. Emotional factors concerning hearing loss must be addressed in a comprehensive program as they may impact the outcome/benefit received from the hearing device.

### Recommendations

Evidence suggests that there are many factors that contribute to the successful use of a hearing device in overcoming the effects of USNHL. The following should be offered or included in a comprehensive counseling and follow-up protocol:

1. Post-fitting counseling and follow-up should be provided while the patient is learning the effectiveness of the chosen hearing device.
2. Primary communication partner(s)/caregivers should be included.
3. Counseling and follow-up care can be provided in a group or individual format.
4. A counseling-based program may include discussion of the following topic areas:
  - (a) Basic anatomy and physiology of the auditory system
  - (b) Understanding the audiogram and its impact upon communication
  - (c) Understanding the head shadow effect
  - (d) Problems associated with understanding speech-in-noise
  - (e) Appropriate and inappropriate hearing and listening behaviors
  - (f) Understanding how to follow conversations
  - (g) How to repair conversations when not all of the information is understood
  - (h) Controlling the environment
  - (i) Assertiveness
  - (j) Realistic expectations
  - (k) Stress management
  - (l) Basic speechreading
  - (m) Hearing assistive technology (HAT)—to provide additional help, if needed, for various situations, such as listening in the car, in background noise, or watching TV. The way this can be accomplished depends on the hearing device, but the telecoil and wireless modes of communication can be used.
  - (n) Helpful hints for communicating with spouse
  - (o) Helpful hints for spouse communicating with patient
  - (p) Device use and care
  - (q) Community resources
5. Patients should be informed that it will take time to adjust to the hearing device before the full benefit from the device is apparent.

Recommendation	Evidence	Source	Level	Grade	EF/EV
1,4	Patients should be counseled on how to use the hearing device or access special programs in the hearing device to improve speech recognition in noise.	2-5	1,3,6	B,D	EF/EV
1,5	Patients should follow-up at 2-4 weeks post-fitting to determine comfort of fit, need for fine-tuning, re-counseling on care and maintenance, and address any questions.	2-6	1,3,6	B,D	EF/EV
1,5	Patients should have regular three month, four month, six month hearing device checks and annual audiological evaluations.	4,6	6	D	N/A
1,5	Discuss communication strategies and how to effectively use the hearing device and other strategies in difficult listening environments.	4,6	6	D	N/A
1,3	Follow-up counseling can increase hearing device use and be cost effective.	7	4	B	EV
1,3	Group training in effective communication strategies and how to educate their communication partners can provide emotional and cognitive benefits.	8	4	B	EV
1,3,4	An aural rehabilitation course provides patients with improved self-perception of handicap compared to a control group receiving the hearing device alone.	9	2	A	EF
1	Adult aural rehabilitation programs assist in the improvement of self- perception of hearing loss and can lead to better communication strategies.	10	1	B	EF/EV
1	Patients should be counseled of benefits in speech-in-noise when speech is spatially separated from the noise.	11-12	3,3	B,D	EF/EV
1	Quality of life can be improved through counseling and can be cost effective through group counseling.	13	6	D	EF
2	Participation of significant others in aural rehabilitation programs can be beneficial to the patient and significant others.	14-15	2	B	EF
4	HATs can be used to help further improve difficult listening environments, such as in background noise, hearing speech from a distance, watching the TV, listening in a car, etc.	16	6	D	EV

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## 5. ASSESSING OUTCOMES

Although verification of appropriate hearing device function and gain/output are critical in any hearing device fitting, it is equally important to assess outcomes and validate that the chosen treatment is effective and beneficial to the patient. From hearing device selection to programming, there are countless decisions made by the patient, caregiver, otolaryngologist, dentist, and audiologist to try to best assist the patient and then ultimately reduce the negative impact of the hearing loss. It is important to validate the effectiveness of these decisions through outcome measures to ensure that treatment goals of the patient have been met.

Validation through the use of outcome measures is completed subjectively by the patient. Subjective outcomes typically involve questionnaires and/or interviews to evaluate the patient’s opinions, emotions, and perceptions. One goal of this guideline is to stress the importance of incorporating at least one standardized subjective validation measure into every hearing device fitting. Additionally, the goal is not to promote one outcome measure over another, but rather to document the options available and emphasize that measures should be chosen based on the treatment goals selected for the patient.<sup>2</sup>

Due to the loss of binaural auditory cues, patients with USNHL often report increased difficulties with sound and speech awareness, especially when the signal is at a soft input level and is on the side of the poorer ear. Additionally, these patients often report difficulty recognizing speech in group and background noise listening situations and the inability to identify from where sounds arrive.<sup>3-4</sup>

Subjective outcome measures have been developed to evaluate the patient's perceptions regarding his or her hearing abilities and the related treatment. Improving QOL, decreasing hearing handicap, increasing speech recognition, and achieving patient satisfaction are common goals within the hearing device fitting process. Hearing handicap questionnaires typically focus on overall communication abilities, psychosocial effects of hearing loss, and activity limitations and restrictions. Examples of such subjective questionnaires include the Client Oriented Scale of Improvement (COSI),<sup>5</sup> the Hearing Handicap for the Elderly (HHIE),<sup>6</sup> and the Abbreviated Profile of Hearing Aid Benefit (APHAB).<sup>7</sup>

Questionnaires, such as the World Health Organization's Disability Assessment Schedule (WHO-DAS II),<sup>8</sup> may be used to evaluate the treatment impact on the patient's perceived QOL by questioning overall independence, mental health, and the impact of treatment. Finally, satisfaction surveys may be conducted to evaluate the patient's views on overall treatment cost and value, comfort, expectations, benefit, and service. Examples of such questionnaires include the Satisfaction with A Hearing Aid in Daily Life (SADL),<sup>9</sup> the Hearing Aid Performance Inventory (HAPI),<sup>10</sup> and the Glasgow Hearing Aid Benefit Profile (GHABP)<sup>11</sup>. Several of the above-mentioned subjective outcome assessments, as well as many others not listed here, may also be completed by the patient's family members to provide a more well-rounded analysis of the patient's hearing handicap and outcome of the treatment approaches. It is recommended that responses and scores be reviewed with the patient, family members, and/or caretakers to identify subjective difficulties, benefits, and future treatment goals.

It is the recommendation of the task force that the clinician always evaluate outcomes following treatment. Although all of the above mentioned questionnaires are appropriate for assessing outcomes in patients with hearing loss, the following tools are felt to be specifically useful for evaluating impairments related to UNSHL.

- (a) The Speech, Spatial, and Qualities of Hearing Scale (SSQ), may be utilized to assess the movement, distance, and directional components of spatial hearing and to document difficulties associated with recognizing speech-in-noise.<sup>12</sup>
- (b) The Bern Benefit in Single Sided Deafness Questionnaire (BBSS) was developed specifically to evaluate the subjective benefit of a hearing device fitting using a CROS; however, is it appropriate for other UNSHL device options. The questionnaire specifically focuses on difficulties with multi-talkers, speech-in-noise, speech at a distance, and localization difficulties.<sup>13</sup>
- (c) The Glasgow Hearing Aid Benefit Profile (GPHAB) is useful for assessing auditory disability and handicap, hearing device satisfaction and benefit, and residual disability.<sup>11</sup>
- (d) The Hearing Handicap Inventory for Adults (HHIA) focuses on emotional, social, and situational issues. It is useful in determining if the patient's hearing loss has altered their behavior in everyday situations and for identifying rehabilitation needs and treatment goals.<sup>14</sup>

If an AOIS is chosen as the method of treatment, surgical outcome measures should also be utilized. Implant techniques have and continue to vary from institution to institution, but some essential outcome models are obtainable. First, implant loss is an important outcome variable. Implant loss ranges between 5-10 percent general.<sup>15-16</sup> There are multiple reasons for implant loss including chronic pain, failure to osseointegrate, trauma, and failure of the device. These percentages also vary, but are typically between one to two percent.<sup>17</sup> Soft tissue complications are much more common and most often involve irritation of the skin surrounding the implant. Other soft tissue problems include skin flap necrosis and wound dehiscence. These soft tissue complications can be managed in the office with topical therapy and wound care, although revision surgery may be required in extensive skin overgrowth cases. Typical rates for adverse skin reactions are six to ten percent.<sup>18</sup> Typically, re-operative rates vary but are higher in children than adults.<sup>16</sup>

As there are currently many device options available for treatment of UNSHL (CROS/BICROS, Transcranial CROS/BICROS, AOIS, SoundBite™, TransEar®, and CI), the use of published outcomes and overall patient satisfaction will help treatment providers make the most appropriate and effective recommendations for patients.



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