Clinical White Paper

Discussion on Candidacy, Evaluation and Fitting for Cochlear™ Bone Conduction Solutions

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Introduction

Amplification via Bone Conduction is a safe, effective, and reliable treatment for conductive and mixed hearing loss,[8, 11] as well as single-sided-deafness (SSD),[10] and has been shown to provide appropriately identified patients with good hearing perception outcomes[1, 6, 12] and a significant improvement in their reported quality of life.[13, 14, 16]

Cochlear™ Bone Conduction Solution configurations consist of the surgically implantable, active Osia® system, the non-surgical Baha® Start solution, and the surgically implantable percutaneous Baha Connect system. The Osia System has a fitting range of up to 55 dB HL. This fitting range is achieved through an active transcutaneous implant with a piezoelectric transducer connected to an osseointegrated BI300 titanium implant, which transmits sounds from the Osia 2 sound processor. The non-surgical Baha Start solution is well suited for younger patients or those who cannot undergo surgery. The Baha 6 Max sound processor is coupled to a Softband or SoundArc on the head and provides up to a 55 dB HL fitting range. The Baha Connect System consists of the osseointegrated BI300 titanium implant with a percutaneous abutment connection. The Baha 6 Max sound processor couples to the percutaneous abutment and provides up to a 55 dB HL fitting range.

Bone conduction amplification is a variation on components and signal paths that are implemented in fitting traditional air conduction hearing aids. However, with bone conduction systems, the mechanism of transmission of amplified sound and the fitting prescription are significantly different than traditional hearing aids and should be considered when determining candidacy and in fitting bone conduction devices.

This paper provides a description and rationale for patient demonstration and evaluation with bone conduction amplification, a discussion on the key differences between bone conduction and air conduction amplification including background as to why the fitting prescription is crucially different, best practices to ensure an effective fitting with a Cochlear Bone Conduction Solution, and considerations for outcomes measures at any point in the patient's journey.

Demonstration and Evaluation of Bone Conduction Solutions

A unique advantage of bone conduction is the ability to demonstrate and evaluate the technology prior to surgical intervention. This supports a clinician's ability to counsel their patients more effectively about treatment options, and allows patients to experience sound through a bone conduction solution. Methods for clinicians to demonstrate bone conduction and evaluate outcomes will be described below.

Demonstration

The simplest demonstration of how bone conduction works is to use a Baha sound processor attached to a test rod, which is a small piece of Lucite plastic with a position for snapping the Baha sound processor into the top (see Figure 1). The opposite flat end can be held in position at the mastoid prominence with slight

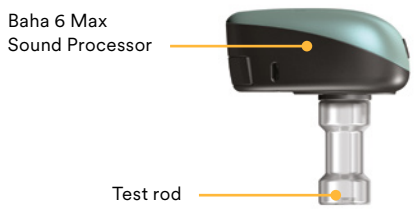

Figure 1: Baha 6 Max Sound Processor on a Test Rod

pressure. With the Baha sound processor turned on, the patient will hear the amplified signal as it is transmitted through the bone conduction pathway. Keep in mind this quick demonstration may be used with the patient as well as a significant other, to provide a sense of hearing through bone conduction. However, it is not useful for longer trials or in booth testing since it needs to be manually held in place.

To demonstrate a bone conduction solution for a more extended wearing period and offer a real-world experience, a Baha sound processor may be coupled to a Softband or SoundArc (see Figure 2) and fitted on the patient's head. This approach allows the patient to listen with the Baha sound processor in different sound environments, for example by taking a walk around the facility, using it with a connected device such as their phone, or during a home trial. This configuration is also useful to evaluate the patient's performance with the Baha sound processor in the booth.

Baha Softband Baha SoundArc

Figure 2: Baha 6 Max Sound Processor on a Softband and Baha 6 Max Sound Processor on a SoundArc

The Baha sound processor may be demonstrated by using it with out of box setting, which is designed for a simple non-customized demonstration of function. This configuration provides a first impression of sound quality and function for the patient.

Alternatively, preset programs can be created with the Baha Fitting Software representing a pure conductive hearing loss bone conduction pure tone average (BC PTA of 10 dB placed in program slot 1), a mixed-conductive hearing loss (BC PTA of 35 dB for program slot 2), and finally an SSD program (identical to program 1 for conductive loss but with the low frequency gain reduced by 10 to 12 dB in the frequencies below 750 Hz for program slot 3). With these three programs saved in the clinic demonstration processor, a clinician can select the most appropriate program for the hearing loss type present with the patient for a closer approximation of sound quality.

Finally, a customized fitting in Baha Fitting Software can be created for the patient's actual measured audiometric profile to provide the closest approximation of sound quality individualized to hearing loss of the patient. In this case, in-situ audiometry (BC Direct) testing is completed for a custom fitting. The patient may utilize the programmed Baha sound processor for a longer trial period and/or complete unaided vs. aided testing to produce measured outcomes values.

Evaluation

The goal of a bone conduction evaluation is to set up the Baha sound processor in Baha Fitting Software with customized programing to emulate the actual clinical fitting. Hearing and speech outcomes measures are then collected to predict performance with the Cochlear Bone Conduction Solution. A non-surgical bone conduction solution, like Baha Start, is an effective method for predicting outcomes before bone conduction implantation.[2, 18] *See section "Best Practices for Outcomes Measures with Bone Conduction Solutions" for more details on the set up and test procedures.*

With customized settings in the device, unaided vs. aided functional gain measures, speech awareness thresholds, and/or speech discrimination testing can be carried out, which is consistent with techniques used in a traditional hearing aid evaluation. The evaluation process is crucially important when evaluating mixed-conductive losses where the bone conduction pure tone average is approaching the limits of the published fitting range. If the patient is doing well in the aided condition and outcomes measures reflect adequate aided benefit, additional confidence in the treatment option will be apparent to both the patient and the evaluating clinician.

This same concept can be true when evaluating SSD hearing loss patients. In this process, lifting of the head shadow and aided function in background noise situations can be assessed to gain insight and confidence in the recommended treatment proposal. The patient can begin to understand the possible benefits of hearing with a bone conduction solution and understand how this treatment will impact the hearing problems they are trying to manage.

Demonstration vs. Implantable Bone Conduction Solution

The Baha sound processor coupled to a Softband or SoundArc provides the means to demonstrate function and allow for the capture of aided outcomes data. The outcomes from the demonstration and evaluation assists both the clinical team and the patient and family members in the counseling and decision making process. It is important to counsel patients about the expected improvement in sound quality and hearing performance they can receive with a surgical bone conduction solution like the Osia system, compared to a demonstration with non-surgical solution using the Baha sound processor on a Softband or SoundArc.[3] A surgical solution has direct access to the bone conduction path with no skin attenuation to overcome. Additionally, Osia technology is uniquely suited to transmitting high frequency sounds to help patients hear better, especially in challenging situations like noisy environments.[5, 7] An implant can provide a higher quality signal as compared to a softband configuration, which should be considered and counseled to when clinicians are demonstrating bone conduction solutions with their patients.[15]

Since there is no way to actively demonstrate a surgical solution ahead of implantation and activation, the use of a Baha sound processor on a Softband, Sound Arc, or Test Rod is our best tool for demonstration, evaluation, and counseling of patients.[2, 18]

Amplification with Bone Conduction vs. Air Conduction

In our everyday hearing and listening experience, the predominant method of conducting sound through the auditory pathway is via air conduction (AC). Although bone conduction (BC) propagation of sound is at work in tandem with AC, a normal auditory system relies on the air conducted sound wave as its primary means of transduction. In BC hearing, when vibration is applied to the skull, the bones in the skull transmit sound vibration directly to the cochlea. When there is an interruption to the AC pathway, the BC pathway can be leveraged to create access to transduction of an acoustic sound to the inner ear for processing.

Conductive and Mixed Hearing Loss

The goal of amplification in the case of conductive or mixed hearing loss is to overcome the loss of the ear's ability to route sound through the AC pathway of the ear drum and middle ear. A significant amount of sound pressure must be provided to drive the acoustic signal through this conductive block in order to stimulate the hair cells in the cochlea. Additionally, in cases of active disease in the middle ear space, the occlusion of the ear with an earmold coupled to an air conduction hearing aid creates potential for ongoing infection. In these cases, bone conduction amplification is able to bypass the air-bone gap created by the presence of a conductive block to provide appropriate stimulation of the inner ear structures. Audibility is then either partially or fully restored without occluding the outer ear. The audiometric air-bone gap is a strong indicator of candidacy for a bone conduction solution. The greater the air-bone gap, the greater the benefit of a bone conduction solution compared to an air conduction hearing aid. Clinical data indicates that patients with an air-bone gap of more than 30 dB pure-tone average will experience significant advantages from a bone conduction system as compared to using an AC hearing aid.[4, 17]

Single Sided Deafness

With patients who present with single-sided-deafness, or complete unilateral sensorineural hearing loss in one ear and normal hearing in the contralateral ear, clinicians are challenged by the inability to provide acoustic amplification to the impaired ear to facilitate binaural auditory function. A solution is to re-route the signals presented to the non-functional side and send them to the good ear to lift the head shadow effect. This contralateral routing of signal can be accomplished via the bone conduction pathway. The goal of this approach is to improve spatial awareness of sound and to improve audibility of sounds that are incident to the nonfunctional ear. In this subset of patients, lifting of the head shadow effect situationally improves localization and speech understanding in noise.[10, 14]

Fitting Prescription Differences between Bone Conduction and Air Conduction

When prescribing amplification, a fitting formula is the basis for programming hearing devices. All device fitting software utilize either a proprietary formula and/or an open-source formula (such as National Acoustics Laboratories (NAL) and Desired Sensation Level (DSL)). These formulae are designed to take the range of sound inputs and place them within the remaining dynamic range of the listener. Acoustic hearing aid fitting formulae assume a damaged cochlea (sensorineural loss), provide compensation for ear canal resonance, and focus on residual auditory capacity. However, fitting formulae for bone conduction devices cannot follow these same assumptions.

For BC amplification, the cochlea is generally intact, loudness growth is faster than AC,[19] and the transmission of sound is via the skull bones rather than the air conduction pathway. BC fitting formulae also need to consider transcranial attenuation, where there is a decrease in stimulus when the BC stimulation at one ear is transmitted to the opposite ear. The BC fitting formula determines the degree of force required to transfer sound through the skull. The conductive component is ignored as BC amplification bypasses the outer and middle ear.

Cochlear Fitting Prescription (CFP) is designed specifically for bone conduction. It applies appropriate loudness compensation for direct bone conduction stimulation and a correction factor for the head transfer function and interaural attenuation while capturing the patient's unique factors through in-situ audiometry. Developed for the BP100 Sound Processor, CFP was released in 2009 with the first digitally programmable bone conduction sound processor and has evolved through generations of Cochlear Bone Conduction Solutions.

Best Practices for Fitting a Bone Conduction Solution

The goal of the fitting is to provide improved sound quality and speech intelligibility with comfortable wear for the recipient to use their device to their maximum potential. An additional goal for SSD patients is to reduce the head shadow effect.

Cochlear Fitting Software allows for customization of the fitting prescription and configuration of the sound processor to match the patient's thresholds, profile, and individualized listening needs.

Cochlear Fitting Prescription is calculated using parameters set in the fitting software. Completing BC Select provides basic patient information to determine the hearing loss type (conductive or mixed hearing loss or SSD), the connection type (surgical or non-surgical), and age to set a baseline prescription. Measuring feedback provides a personalized feedback curve based on the user's anatomy to reduce the feedback risk. For the Osia system, measuring the Digital Link Calibration calculates an optimal individual reference gain baseline and reduces the need for fine-tuning.

Further individualization is completed by entering the patient's audiometric data. When selecting a candidate ear for the Bone Conduction Solution, masked bone-conduction thresholds are needed. However, unmasked bone-conduction thresholds of the treated ear are used to create the prescription since the cochlea with the best bone conduction thresholds is stimulated by the device, either the ipsilateral or contralateral cochlea.

A customized fitting prescription is completed when BC Direct is measured. BC Direct (in-situ audiometry) uses the bone conduction processor coupled to the surgical or non-surgical solution to measure hearing thresholds in order to apply unique patient factors to the fitting prescription. For air conduction devices, individual characteristics are considered by using real ear measurements (REM) to measure the sound pressure level in the patient's ear. Since bone conduction devices do not use the ear canal to transmit sound but rather use the skull to transmit sound, direct bone conduction in-situ audiometry is needed to apply individual characteristics to the fitting prescription. BC Direct is compared to audiometric BC thresholds obtained using the audiometer to make individualized correction factors. Variability arises from skull vibration characteristics of the individual. Differences in the size and mass of the head, tissue and bone density, and the dimensions of the oral and sinus cavities all manipulate the incoming sound by boosting some frequencies and attenuating others. In addition, differences

related to skin thickness, implant placement, sound processor placement (non-surgical), and bone quality contribute to this variability. Therefore, at any given frequency, the degree of force required to ensure audibility is determined by conversion of the patient's audiometric BC threshold into a direct BC value. These changes in the frequency profile help create a unique perception of the sound for the listener and an individualized fitting prescription.

Best Practices for Outcomes Measures with Bone Conduction Solutions

Outcomes measures including functional gain measures, speech awareness thresholds, and/or speech discrimination testing completed at candidacy help to determine the best treatment pathway and create an audiological baseline, while outcomes measures completed post-fitting at various intervals allow comparison to the pre-treatment baseline as well as previous post-fitting intervals to monitor performance and serve as a point of discussion in post-treatment counseling.

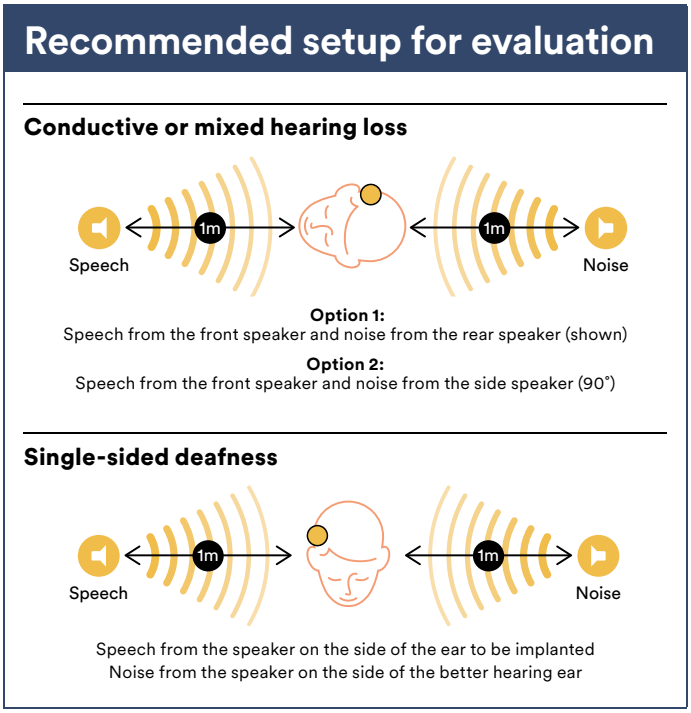

Figure 3: Recommended speaker set up for bone conduction evaluation

Considerations for Booth Speaker Setup for Evaluation

When completing a bone conduction evaluation, set up the testing with consideration of the type of hearing loss presented to best evaluate the patient (see Figure 3).

Booth set up includes two speakers connected to a two-channel audiometer. Present frequency-specific signals, speech materials, and noise at calibrated levels to assess both unaided performance and aided outcomes with a programed bone conduction sound processor.

For conductive or mixed hearing loss, position the patient in the booth approximately 1 meter away from each speaker with the patient facing the first speaker and the second speaker is either to the side or the back of the patient. Present frequency-specific and speech materials from the front-facing speaker and route noise from the side- or back-facing speaker.

For SSD patients, attention should be given to setting up the speaker arrangement to best create a demonstration of the head shadow effect. Position the patient in the booth approximately 1 meter away from each speaker with frequency-specific and speech materials from the speaker facing the affected ear and noise from the speaker facing the better hearing ear.

Considerations for Test Materials and Procedures for Evaluation

To evaluate aided performance using a traditional audiogram, some type of frequency-specific stimuli is needed. In sound field testing for this purpose, a pure tone sinusoidal wave is undesirable due to the potential for standing waves to create artifacts in the measurements at threshold. An alternative to pure tones is to use either a frequency modulated sinusoidal signal (i.e., wable tone) or narrow band noise stimulus. Both types of stimuli avoid measurement artifact in the sound booth.

Clinicians should keep in mind that when a bone conduction sound processor is programed with fitting software, automatic processing features such as feedback reduction, noise reduction, and directionally are enabled. These automatic features can impact the perception and measurement of the frequency-specific stimuli by the patient, which may result in elevated threshold measures in the aided condition. If using frequency-specific stimuli, an ascending presentation method is recommended, where initial stimuli are presented at the softest levels first, to mitigate potential artifacts in threshold measurement due to interactions with the automatic functions enabled in the sound processor.

An alternative to tonal- or noise-based frequency-specific stimuli is to use a speech-based test. The Ling-6(HL) test developed at Western University[9] contains calibrated recordings of the Ling 6 sounds. This material is presented through the auxiliary input of the audiometer and each of the Ling sounds is presented to measure detection and plotted on an audiogram. Since the stimuli are phonemes of speech, they may be more clinically relevant and would be less likely to interact with automatic features of the signal processing enabled in the sound processor.

Speech-based suprathreshold measures such as aided word or sentence recognition are much more representative of the kinds of signals patients want and need to hear in their everyday lives. In addition to in-quiet presentation of these stimuli, noise can be co-presented to measure speech-in-noise performance which is often a main complaint of patients.

When considering speech materials for use in aided bone conduction evaluations, the most important factor is consistent presentation of these materials. Monitored live voice presentation has been documented to be highly variable even if output is measured with a volume unit metering system. Recorded materials are recommended since these materials provide the consistency necessary when comparing unaided to aided performance.

Some materials are more appropriate for use with pediatric patients. Consideration should be given to the age-appropriate use of materials as well as the child's speech and language development.

Conclusion

The Cochlear portfolio of bone conduction solutions offers non-surgical and implantable options that are designed to meet individual patient needs and provide unparalleled hearing performance. Bone conduction is a scientifically proven treatment for conductive and mixed hearing loss and single-sided-deafness. Bone conduction systems such as Baha and Osia are unique in that pre-treatment demonstration and outcomes measurement can be carried out with patients which can lead to a better educated patient and provide the clinician confidence to know that their recommendation will result in a positive outcome. Amplification with bone conduction is based on the transmission of sound via bones of the skull rather than the air conduction pathway. Factors to determine the degree of force required to transfer sound through the skull are reflected in the fitting formula. Customization in fitting to capture individual patient characteristics further allows improved sound quality, speech intelligibility, and quality of life for bone conduction patients.

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*In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

In the United States, the Osia 2 System is cleared for children ages twelve and older. In Canada, the Osia 2 System is approved for children ages five and older.

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