Frequently asked questions

Candidacy, evaluation and fitting for Cochlear™ bone conduction solutions

1. I've identified a potential bone conduction patient. How can I best determine if a Cochlear™ bone conduction solution is right for my patient?

Demonstration and evaluation with bone conduction is recommended, allowing the patient to experience bone conduction as part of the counseling process, while also gathering valuable outcome data to help determine the treatment pathway.

2. What is the difference between a demonstration and evaluation of a bone conduction solution?

In short, a demonstration is allows a patient learn how bone conduction amplification works, and an evaluation is a more formal process that will capture unaided vs aided hearing outcomes to better counsel and predict future outcomes with treatment. Using both can lead to a better educated patient and provide the confidence to know your recommendation will result in a positive outcome.

Demonstration using a Baha® sound processor on a test rod, Softband or SoundArc™ can be a counseling tool that can allow the patient to hear through bone conduction, and begin to understand the possible benefits. Since bone conduction hearing is largely not understood by the average patient, this demonstration can be novel and quite compelling. In addition, family and friends may also listen and experience bone conduction. For this group, plugging one ear to simulate a conductive hearing loss and then applying the Baha sound processor on a test rod to their skull will demonstrate how this technology sounds and works. The Baha sound processor can be used with out-of-the-box settings, programmed for conductive, mixed, or SSD hearing loss types, or programmed individually per patient for the listening experience.

A bone conduction evaluation on the other hand, sets up the device with customized programing as in a clinical fitting. Hearing and speech outcome measures are then collected to predict performance with the Cochlear Bone Conduction Solution and help you make a determination for treatment.

3. Should I just demo a device out of the box, or should I program it specifically for my patients?

Programming the device with patient's actual measured audiometric profile and completing BC Direct provides the closest approximation of sound quality and performance post-fitting since it is individualized to the patient. The patient will experience a more accurate estimation of sound quality and the evaluation will better predict individual outcomes.

Alternatively, preset programs for hearing loss types (conductive, mixed, and SSD) can be created and saved to the clinic demo processor.

With these three programs, you can select the most appropriate program for the hearing loss present with the patient for a closer approximation of sound quality.

But, if all you are looking for is a quick and simple first impression of sound quality and function for the patient, you can demonstrate the Baha sound processor using the out of box setting.

4. Why is it beneficial to complete an evaluation for a bone conduction solution?

Just like best practice in traditional hearing aid evaluation, using customized settings in the bone conduction sound processor, measures of unaided vs. aided functional gain speech awareness thresholds, and/or speech discrimination testing can be carried out to determine benefit. A clinical study showed that a non-surgical bone conduction solution, like Baha Start, is an effective method for predicting outcomes before bone conduction implantation.[2, 13]

Evaluation is crucial when evaluating mixed-conductive losses where the bone conduction pure tone average is approaching the limits of published fitting range and when working with SSD hearing loss patients to assess improvement to localization and speech understanding in noise. If the patient is doing well in the aided condition and outcomes measures reflect adequate aided benefit, counseling patient expectations and accurate outcomes for treatment can be predicted.

5. How should I set up my booth for the bone conduction 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 (Figure 1).

For conductive or mixed hearing loss, the basic set up for an evaluation is appropriate with the patient facing one speaker where frequency-specific and speech materials will be presented, and a second speaker is to the patient's the side or back where noise can be routed.

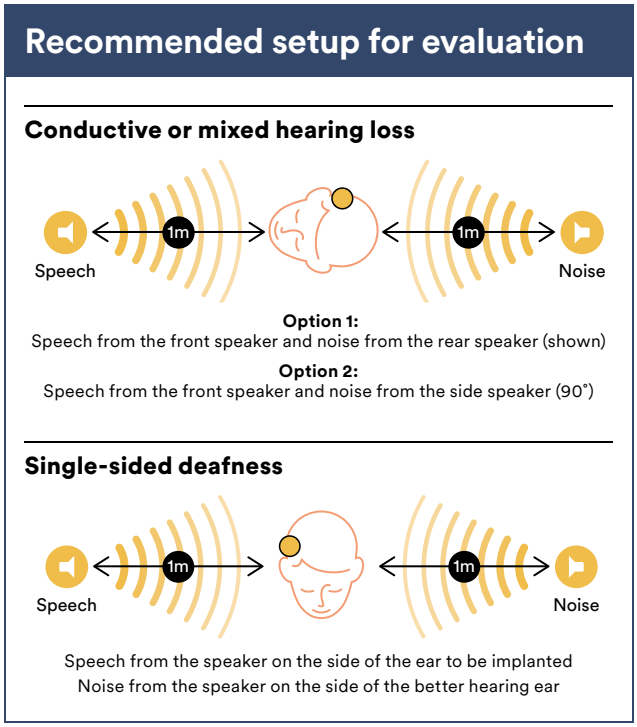

Figure 1

For SSD patients, set up the speaker arrangement to create a demonstration of the head shadow effect. Position the patient in the booth so that frequency-specific and speech materials will come from the speaker facing the affected ear and noise will come from the speaker facing the better hearing ear.

6. How do I assess frequency-specific thresholds with a bone conduction solution?

To evaluate aided performance using a traditional audiogram, some type of frequency-specific stimuli will be necessary. In sound field testing, avoid standing waves that create artifacts in the measurements at threshold by using warble tones or narrow band noise.

Also, 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 frequency-specific stimuli is to use a speech-based test. The Ling-6(HL) test developed at Western University[7] 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.

7. What should I consider when assessing outcomes with speech-based measures?

Word and/or sentence recognition testing is much more representative of the kinds of signals patients want to hear in their everyday lives. Consider presenting the speech tests in noise as well as in quiet since hearing in noise is often a main complaint of patients. Recorded materials are recommended since these provide the consistency necessary when comparing unaided to aided performance. Some speech 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.

8. Can I evaluate or demonstrate the Osia® system to a patient?

Since a direct demonstration and evaluation with the Osia® system can't be done, a Baha sound processor coupled to a Softband or SoundArc will provide an estimation of how a patient will perform with an Osia system.[2, 13]

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, 6] An implant can provide a higher quality signal as compared to a softband configuration, which should be considered and counseled when clinicians are demonstrating bone conduction solutions with their patients.[11]

9. What else should I think about when counseling a patient who is a patient for a bone conduction solution?

Setting appropriate expectations is crucial. While your patient will be introduced to bone conduction in the demonstration and evaluation, they need to be prepared for daily wear and what to expect in everyday listening situations. Take into consideration your patient's lifestyle and hearing goals when counseling. They should expect a period of adjustment as they get used to hearing with their device and all the sounds they may have been missing – even background sounds. And while they are expected to hear well in quiet one-to-one situations and most small group settings, listening may still be difficult for noisy places and with sounds at a distance.

Setting appropriate expectations is not only important in the candidacy process, but on an ongoing basis in order to help patients see their successes, identify their challenges, set hearing goals, and continue to make progress.

10. How does amplification with bone conduction impact the fitting prescription?

When prescribing amplification, a fitting formula is the basis for programming hearing devices. All device fitting software utilize either a proprietary 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 bone conduction amplification, the cochlea is generally intact, loudness growth is faster than in air conduction,[14] and the transmission of sound is via the skull bones rather than the air conduction pathway. Bone conduction fitting formulae also need to consider transcranial attenuation where there is a decrease in the stimulus when it is transmitted to the opposite ear. The fitting formula determines the degree of force required to transfer sound through the skull. The conductive component is ignored as bone conduction 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.

11. How is amplification with bone conduction different than air conduction hearing aids for mixed and conductive 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 air conduction pathway of the ear drum and middle ear. In air conduction hearing aids, 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.

Bone conduction amplification is able to bypass the air-bone gap created by the presence of a conductive block to create appropriate stimulation of the inner ear structures. Audibility is then either partially or fully restored without need for occluding the outer ear. 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 air conduction hearing aid.[4, 12]

12. How is amplification with bone conduction different than air conduction hearing aids for SSD?

With patients who present with single-sided-deafness, both air conduction hearing aids and Cochlear Bone Conduction Solutions re-route the signals presented to the non-functional side and send them to the hearing ear to lift the head shadow effect and improve localization and speech understanding in noise.[9, 10]

In the case of a hearing aid based CROS system, a device must be worn on both ears. A device with a microphone on the non-functional side transfers the signal to the device on the hearing ear which presents sound through a receiver in the ear canal. The presence of the device in the hearing ear may create some occlusion and inference in the native hearing. With a Bone Conduction Solution which transmits the signal from the non-functional side to the hearing side via the bone conduction pathway, the sound processor is discreet, light and comfortable, only worn on the non-functional side, and does not occlude the ear canal.

13. I like to use real ear measures with my air conduction hearing aid patients, but I can't do that with bone conduction devices. How do I take individual characteristics into account with a bone conduction solution?

For air conduction hearing aids, individual characteristics are considered by using real ear measurements (REM) to measure the sound pressure level in the patient's ear canal. Since bone conduction devices do not use the ear canal to transmit sound but uses the skull, direct bone conduction in-situ audiometry (BC Direct within the Cochlear Baha Fitting Software) is needed to apply individual characteristics to the fitting prescription. BC Direct is compared to audiometric bone conduction 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 waves 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.

14. I see that the AudioScan® Verifit includes a Skull Simulator. What is a skull simulator and how does it work?

The Audioscan Verifit Skull Simulator (VSS) is an artificial mastoid that simulates an adult skull. It uses an accelerometer to convert vibration from the attached Baha sound processor to a calibrated measurement system in order to view force output, gain and other acoustic attributes. This set up allows you to input the hearing loss threshold profile obtained in BC Direct into the Verifit to form a simulated "real head" response, run test measures using the programmed Baha sound processor, and predict performance for an actual implanted fitting for the patient.

15. Can I use the Audioscan Verifit Skull Simulator with an Osia?

No, the Osia sound processor does not produce a vibrational output that the Skull Simulator can measure. The Osia sound processer transfers the sound signal via a digital link through the skin to the Osia implant with the Piezo Power™ transducer which generates vibrations.

16. Is it possible to quality check a Baha® 6 Max sound processor where output and gain at reference test levels can be used to determine the function of the device?

The Technical Measurement workflow in Baha Fitting Software 6.1 will set up the Baha 6 Max sound processor to allow you to measure and compare the device to the published specification using Audioscan Verifit and Skull Simulator. Automatic features must be deactivated in the sound processor when measuring to match the published datasheet output displaying full on gain. When Technical Measurement is selected, all parameters are set up for this testing in the sound processor.

You can then conduct ANSI testing to compare the measured average Output Sound Pressure Level (OSPL) and average gain to the sound processor datasheet curves. For more information regarding the limitations of ANSI testing, please see the manual for Audioscan Verifit. For any support regarding the use of the Audioscan Verifit and the skull simulator, refer to Audioscan.

Technical Measurement settings are not for patient use and will only be temporarily available in the sound processor during verification testing. When the Technical Measurement is complete, open and close the battery door to reset the sound processor and it will go back to its previous state as it was prior to connection with the Technical Measurement workflow.

17. Can I use the AudioScan Verifit and Skull Simulator to verify the fitting of a Baha 6 Max sound processor?

The Verifit and Skull Simulator can be used to view and document the gain levels for conversational speech input and the Speech Intelligibility Index (SII) that can model or predict speech recognition outcomes for a Baha 6 Max sound processor. These measurements may be used as a baseline at the first fitting and then compared over time.

The Verifit uses Desired Sensation Level for Bone Conduction (DSL BC) to display targets for its Speechmap® feature. DSL BC is designed and validated for adults using a percutaneous connection.[8] If you are using this method to model and predict transcutaneous fittings, please consider that research is still under way to create correction factors that would permit modeling accuracy with pediatric patients and those with non-surgical, transcutaneous Bone Conduction Solutions.[1]

The Baha sound processor is programmed using Cochlear Fitting Prescription (CFP), which has different targets than DSL BC, however, CFP targets won't be displayed on the Verifit. Consider these differences in prescription targets for the fitting formulae and the population that DSL BC targets are validated for when viewing the results of Speechmap testing in the Verifit.

18. How do I validate the fitting of a bone conduction solution?

The same outcomes measures used for candidacy can be used post-fitting to validate the fitting and 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 counselling.

Speech-in-Noise testing has good face validity as a method to validate how a fitting will impact the recipients use of bone conduction amplification. Test materials such as the BKB SIN test, Quick SIN test, and AZ Bio sentence test provide a method to assess how an aided recipient of a Bone Conduction Solution can perform in a more real-world situation. The BKB SIN and Quick SIN tests are adaptive tests that will measure the signal-to-noise (SNR) ratio at an increasing level of noise interference. The AZ Bio is a fixed SNR presentation method that will yield a percent correct score.

In addition, use of questionnaires such as the Abbreviated Profile of Hearing Aid Benefit (APHAB), the 12-item Speech, Spatial and Qualities of Hearing (SSQ-12), and Client Oriented Scale of Improvement (COSI) instruments can be considered. The questionnaires can be used pre-treatment to gain a baseline and then administered at various post-treatment intervals. Well fitted devices will usually demonstrate a positive treatment effect pre- to post-treatment, providing additional data to validate performance.

19. How often should I see my patients for fitting?

For an adult patient, check in with them about 2 weeks after the first fitting. A 6 month visit is optional, depending on your clinical model and how the patient is doing. We recommend a visit at 12 months and then annually from there.

For a pediatric patient, visits are more regularly scheduled with a 1 month visit after the first fitting and then every 3 months in the first 2 years followed by annual visits from that point.[1] Please take age and developmental needs of the child into account when planning post-activation follow-up. For example, a young infant or child may need more extensive follow-up, while an older child or teenager may follow a more adult-type follow-up schedule.

At every visit, complete a check of the site as appropriate for the Bone Conduction Solution (check fit and placement of Softband or SoundArc, check magnet strength, check skin around abutment). Counsel the patient to perform regular site checks and report any issues immediately. In cases of patients with magnets, check the site at least once in the immediate post-first fitting period from 2 weeks–3 months to assess the magnet strength for appropriate retention and modification if found to be too tight or too loose.

20. Are there options for remote care for bone conduction solutions?

Yes, for your patients who have or who are upgrading to a Baha 6 Max sound processor, you can offer Remote Assist* which allows patients to meet with you remotely via a video appointment through their Baha Smart App, where you connect to their sound processor through the Baha Fitting Software to complete a full fitting, make adjustments to a program, or just check in with your patient. You can also complete upgrade fittings and set up replacement devices with Remote Assist. Because there is full access to the features and tools in Baha Fitting Software, Remote Assist is flexible to fit anywhere in your clinical model to supplement in-clinic care and provide quality hearing care without the need for your patient to visit the clinic. Please talk you your Cochlear Representative for more information.

References

1. Bagatto M, Gordey D, Brewster L, Brown C, Comeau M, Douglas C, El-Naji R, Fortier S, Gascon A, Godovin J, Ittner C, Magathan Haluschak M, Mauro L, Morgenstein K, Peterson J, Scollie S, Scott M, Wollet A. Clinical consensus document for fitting non-surgical transcutaneous bone conduction hearing devices to children. Int J Audiol. 2022 Jul;61(7):531-538. doi: 10.1080/14992027.2021.1939449.
2. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US); 2017 November 7. Identifier NCT03333577. Evaluation of the Baha SoundArc in Pediatric Patients; 2019 April 30 [cited 2021 April 27]; Available from: https://clinicaltrials.gov/ct2/show/NCT03333577
3. Data on file. Windchill Document D1478473.
4. de Wolf MJ, Hendrix S, Cremers CW, Snik AF. Better performance with bone-anchored hearing aid than acoustic devices in patients with severe air-bone gap. Laryngoscope. 2011 Mar;121(3):613-6. doi: 10.1002/lary.21167. Epub 2010 Dec 16. PMID: 21344443.
5. Dotevall M. Technical Report: Available Gain in Osia vs Baha 5 Power. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1664198.
6. Fyrlund, H. (2019). Osia performance [Powerpoint Slide 4]. Data on file.
7. Glista D, Scollie S, Moodie S, Easwar V; Network of Pediatric Audiologists of Canada. The Ling 6(HL) test: typical pediatric performance data and clinical use evaluation. J Am Acad Audiol. 2014 Nov-Dec;25(10):1008-21. doi: 10.3766/jaaa.25.10.9. PMID: 25514453.
8. Hodgetts, W. E., and S. D. Scollie. 2017. "DSL Prescriptive Targets for Bone Conduction Devices: Adaptation and Comparison to Clinical Fittings." International Journal of Audiology 57 (7): 521–530.
9. Hol MK, Bosman AJ, Snik AF, Mylanus EA, Cremers CW. Bone-anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements. Otol Neurotol. 2005 Sep;26(5):999-1006. doi: 10.1097/01.mao.0000185065.04834.95. Erratum in: Otol Neurotol. 2006 Jan;27(1):130. PMID: 16151349.
10. Newman CW, Sandridge SA, Wodzisz LM. Longitudinal benefit from and satisfaction with the Baha system for patients with acquired unilateral sensorineural hearing loss. Otol Neurotol. 2008 Dec;29(8):1123-31. doi: 10.1097/MAO.0b013e31817dad20. PMID: 19034196.
11. Pittman AL. Bone Conduction Amplification in Children: Stimulation via a Percutaneous Abutment versus a Transcutaneous Softband. Ear Hear. 2019 Nov/Dec;40(6):1307-1315. doi: 10.1097/AUD.0000000000000710. PMID: 30870242; PMCID: PMC7664715.
12. Snik AF, Mylanus EA, Proops DW, Wolfaardt JF, Hodgetts WE, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellström A. Consensus statements on the BAHA system: where do we stand at present? Ann Otol Rhinol Laryngol Suppl. 2005 Dec;195:2-12. doi: 10.1177/00034894051141s1201. PMID: 16619473.
13. Spielmann PM, Roplekar R, Rae C, Ahmed F, Jones SEM. Is the use of a bone conduction hearing device on a softband a useful tool in the pre-operative assessment of suitability for other hearing implants? J Laryngol Otol. 2018 Jun;132(6):505-508. doi: 10.1017/S0022215118000816. PMID: 30019669.
14. Stenfelt S, Håkansson B. Air versus bone conduction: an equal loudness investigation. Hear Res. 2002 May;167(1-2):1-12. doi: 10.1016/s0378-5955(01)00407-5. PMID: 12117525.

*Remote Assist for Baha is intended for a follow-up adjustment or setup of a replacement or upgrade sound processor for suitable qualified patients based on clinical judgment. Clinic must be enrolled in Remote Care to participate. For sound processor and app compatibility information visit www.cochlear.com/compatibility

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.

Cochlear Americas
10350 Park Meadows Drive
Lone Tree, CO 80124 USA
Telephone: 303 790 9010
Support: 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West
Toronto, ON M5H 1T1 Canada
Support: 800 483 3123

www.cochlear.com/us

OSI142 ISS1 FEB23

Follow us on