Candidacy and Counseling for Cochlear™ Bone Conduction Solutions

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Our Mission

We help people hear and be heard.

We **empower** people to connect with others and live a full life.

We **transform** the way people understand and treat hearing loss.

We **innovate** and bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes.

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Learning Outcomes

- List the candidacy criteria for the Cochlear Bone Conduction Solutions (Osia® and Baha®).
- Describe the demonstration procedure for determining candidacy for bone conduction solutions.
- List counseling considerations for treating patients with bone conduction solutions.

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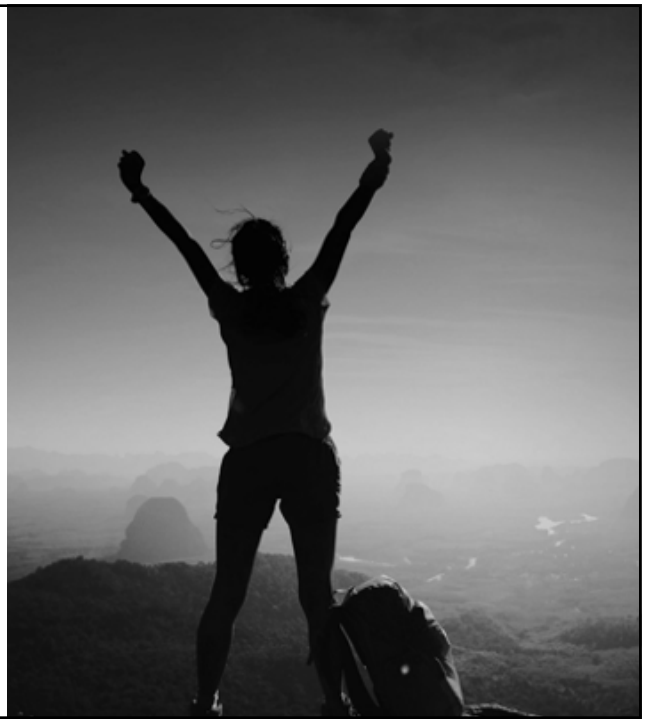
Agenda

1. Who is bone conduction for?
2. Demonstrating bone conduction
3. Counseling patients for bone conduction
4. Service for life



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Poll Question #1

Please select the description that most closely represents your daily job responsibilities:

- ❑ I see/work with patients with hearing loss in a medical setting
- ❑ I see/work with patients with hearing loss in an educational setting
- ❑ I supervise those who see/work with patients who have hearing loss
- ❑ I am an industry professional who supports those with hearing loss
- ❑ I do not regularly work with patients who have hearing loss
- ❑ Other

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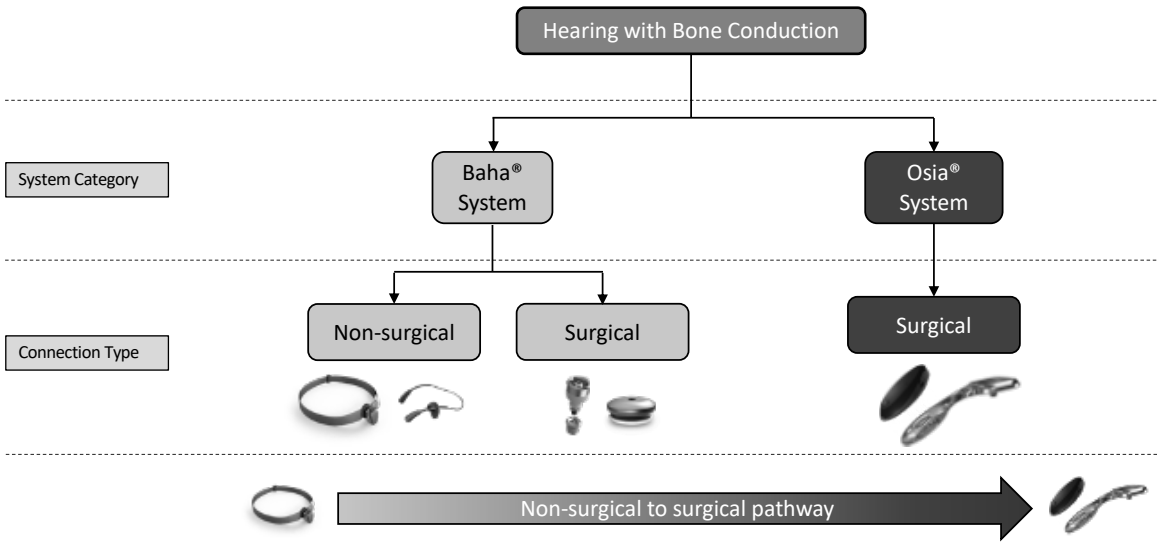
Portfolio of Bone Conduction Solutions



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Poll Question #2

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When a patient comes to your clinic with chronic middle ear problems, which of the following would you say is most true about treating their hearing loss?

- ❑ Treating hearing loss is usually considered only *after* medical intervention (eg, middle ear surgery) has failed to restore hearing
- ❑ Treating hearing loss is considered *alongside* medical interventions (eg, fitting a hearing aid or bone conduction device while treatments/surgeries are ongoing)
- ❑ Hearing loss is considered *first* before any other medical intervention takes place
- ❑ Treatment of the hearing loss is often not considered for these patients as this is seen as a medical problem only
- ❑ None of these is true

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Who is Bone Conduction For?

Krish

Mia

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Why Consider Bone Conduction

- Bypasses the middle ear and stimulates the cochlea directly
- Does not occlude the outer ear
- Improved hearing performance, even in noisy situations[1,2,3]
- Improved subjective sound quality and speech understanding over traditional air conduction (e.g., Hearing Aids)[4]

1) Flynn MC, Sadeghi A, Halvarsson G. (2009) Baha solutions for patients with severe mixed hearing loss. Cochlear Implants International, 10 Suppl 1:43-7.
2) Hol MK et al (2005) Long-term results of bone anchored hearing aid recipients who had previously used air-conduction hearing aids. Arch Otolaryngol Head Neck Surg, 131(4):321-5.
3) Data on file Windchill Document D1478473
4) Hagr A.1(2), 265-76. (2007) BAHA: Bone-Anchored Hearing Aid. International journal of health sciences. 1(2):265-276.

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Why Bone Conduction: Mixed and Conductive Hearing Loss (MCHL)

- The greater the air-bone gap, the more a Baha system will outperform hearing aids[1,2]
- Hearing aid prescriptions for conductive and mixed hearing loss require more gain than for sensorineural hearing loss[3]
- Hearing aid fitting can be difficult if there is drainage from the ear, ear pain or a mastoid cavity present after mastoidectomy[4]

1 - Snik AF et al. (2005) Consensus Statements on the BAHA System: Where Do We Stand at Present? Annals of ORL 114(12S). 195:1-12
2 – Mylanus EAM, van der Pouq K, Snik M (1998) Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. Arch Otolaryngol Head Neck Surg, 124(3):271-276
3 - Johnson EE. (2013) Prescriptive amplification recommendations for hearing losses with a conductive component and their impact on the required maximum power output: An update with accompanying clinical explanation. J Am Acad Audiol, 24(6):452-60.
4 - Gluth MB, Friedman AB, Atcherson SR, Dornhoffer JL. (2013) Hearing aid tolerance after revision and obliteration of canal wall down mastoidectomy cavities. Otology & Neurotology, 34(4):711-4.

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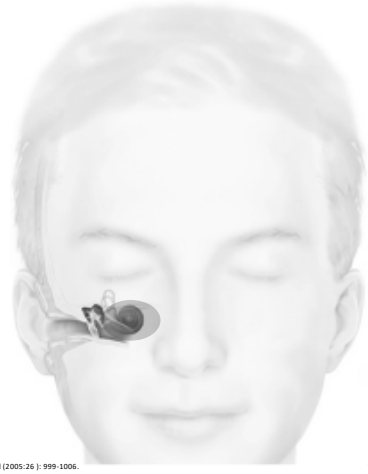
Why Bone Conduction: Single-Sided Deafness (SSD)

- The Baha System bypasses outer and middle ear and sends clearer, more crisp sound directly to the inner ear[1]
- Improved speech understanding in noisy environments[1]
- Higher patient satisfaction than CROS for Single-Sided Deafness[2]
- Helps to lift the head shadow effect[1-3]
- Reduces the psychosocial consequences associated with hearing impairment[1,5-6]
- Long-term patient satisfaction and hearing benefits[7-8]



1. Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements." Otol Neurotol (2005:26): 999-1006.
2. Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Niparko K. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otology and Neurology 2006;27(2):172-82.
3. Pai I, Kelleher C, Nunn T, Pathak N, Jindal M, Fitzgerald O'Connor A, Jiang D. Outcome of bone-anchored hearing aids for single-sided deafness: A prospective study. Acta Oto-Laryngologica, Early Online 1-5.
4. Wazen JJ, Spitzer JB, Ghossaini SN, et al. Transcranial contralateral cochlear stimulation in unilateral deafness. Otolaryngology Head Neck Surg 2003;129(3):248-54.
5. Newman CW, Sandridge DA, Wodzisz LM. "Longitudinal benefit from and satisfaction with the Baha System for patients with acquired unilateral sensorineural hearing loss. Otol Neurotol 2008; 29: 1123-1131.
6. Schroder SA, Ravn T, Bonding P. BAHA in single sided deafness: patient compliance and subjective benefit. Otol Neurotol. 2010; 31: 404-408.
7. Kompis M, Wilhem W, Caversaccio. Long term benefit of bone anchored hearing systems in single sided deafness: Acta Oto-Laryngologica. 2017; 13:398-402.
8. Maurizio B, Biagini M, Lazzarino AI, Monini S, Hearing and quality of life in a south European BAHA population. Acta Oto-Laryngologica. 2010 130: 1040-1047.

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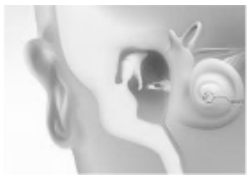
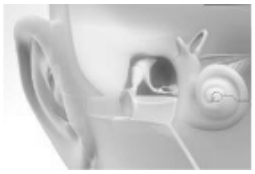
Bone Conduction for Common Etiologies



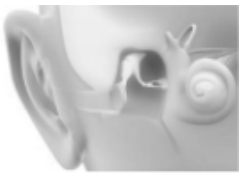
Atresia/microtia

- **Disease factors:**
  - Impossible to use hearing aid, may also be challenging after reconstruction
- **Benefit of bone conduction:**
  - Predictable and cost- effective solution[1]
  - Excellent hearing outcomes[1]



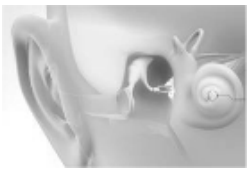
Chronic otitis media

- **Disease factors:**
  - Middle ear surgery has failed to restore hearing and/or has not resulted in a dry ear
  - Hearing aid use may contribute to recurring ear infections.[2]
- **Benefit of bone conduction:**
  - No earmold
  - Reduced need for antibiotics[2].
  - Consistent hearing



Otitis externa

- **Disease factors**
  - Hearing aid may cause irritation and allergic reactions in the ear canal
- **Benefit of bone conduction**
  - Nothing in the ear canal
  - Consistent hearing



Otosclerosis

- **Disease factors**
  - When stapedotomy has been tried and failed.
  - When other risk factors precludes middle ear surgery
- **Benefit of bone conduction**
  - Predictable hearing outcomes
  - Long term solution
  - No risk of further damage to the hearing

1. Evans AK, Kazahaya K. Canal atresia: "Surgery or implantable hearing devices? The experts question is revisited" Journal of Pediatric Otorhinolaryngology 2007; 71, 367-374
2. Watson GJ, Silva S, Lawless T, Harling JL, Sheehan PZ. Bone anchored hearing aids: a preliminary assessment of the impact on outpatients and cost when rehabilitating hearing in chronic suppurative otitis media. Clinical otolaryngology 2008

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Poll Question #3: Revisiting Krish and Mia

Without knowing their audiograms, which patient would you consider as a possible bone conduction candidate?

- ❑ Krish (mixed and conductive hearing loss)
- ❑ Mia (single-sided deafness)
- ❑ Both
- ❑ Neither

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Candidacy

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Why Demo BC?

Goals of bone conduction demos:

- Allow patient to experience bone conduction before surgery
- Assist in counseling
- Provide some objective test opportunities, if desired

Potential pitfalls:

- Expecting an exact prediction of post-surgical benefit
- Relying on it as the only way to determine candidacy

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How to Perform a Demonstration

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Fit a Baha 5 Power Sound Processor on Softband, SoundArc or Test Rod

- Option 1: Use a pre-programmed* sound processor for demos
- Option 2: Program the sound processor for the patient's hearing loss

- Allow the patient to experience the sound of bone conduction
  - Subjective benefit: "how does it sound?", questionnaires
  - Objective benefit: speech perception in noise (especially for SSD candidates), soundfield thresholds
- Demonstration is a counseling tool that can give a candidate a sense of what bone conduction might sound like for them

*See your Cochlear Representative for help in setting up a pre-programmed sound processor for demonstrations in your clinic

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Demonstration Tips

- ✓ Fit the patient early and let them listen with the demo device throughout the appointment
- ✓ Choose a demonstration method that fits your clinic's protocol
- ✓ Use subjective methods to determine benefit (eg, questionnaires, discussion), adding objective methods when needed (eg, booth testing)
- ✓ Use the demo as a counseling tool to explain what bone conduction sounds like

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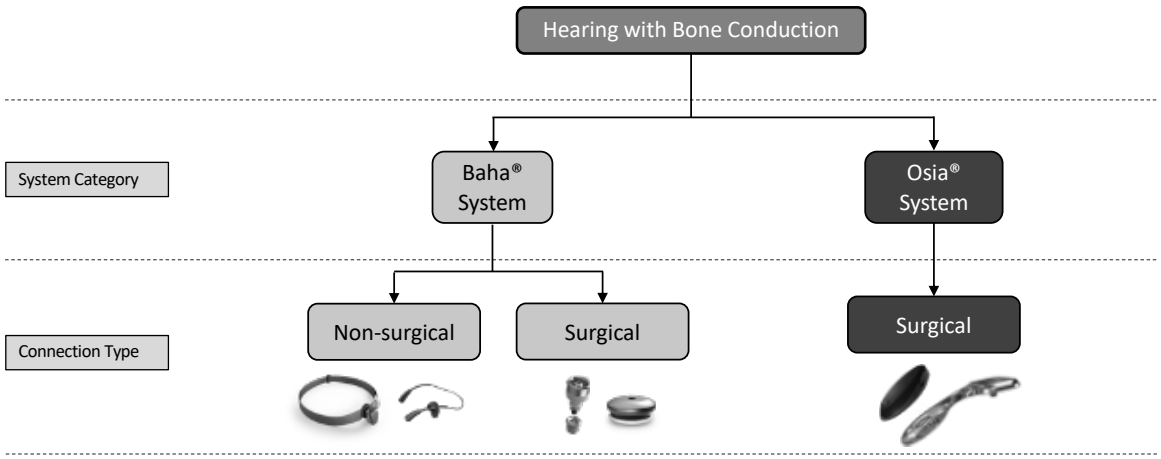
Portfolio of Bone Conduction Solutions



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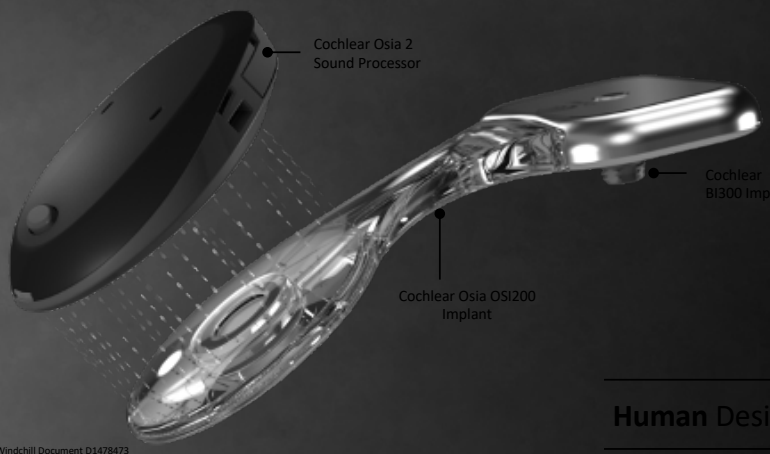
The Cochlear™ Osia® System

The Osia® System utilizes innovative technologies specifically chosen to work in and with the body, delivering excellent hearing performance in the noisy situations[1] where people tell us they struggle most.

Cochlear True Wireless™ Accessories

Osia Smart App**

Accessories and Retention Options



Human Design™

1) Data on file Windchill Document D1478473
The Osia 2 Sound Processor with Aqua+ is water resistant to level IP68 of the International Standard IEC60529 when used with LR44 alkaline or nickel metal hydride disposable batteries. Refer to the relevant User Guide for more information. The Osia 2 Aqua+ may not be available in all markets and is subject to regulatory approval and product availability.
** The Cochlear Osia Smart App is available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.

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Cochlear™ Osia® System

Osia System Candidacy

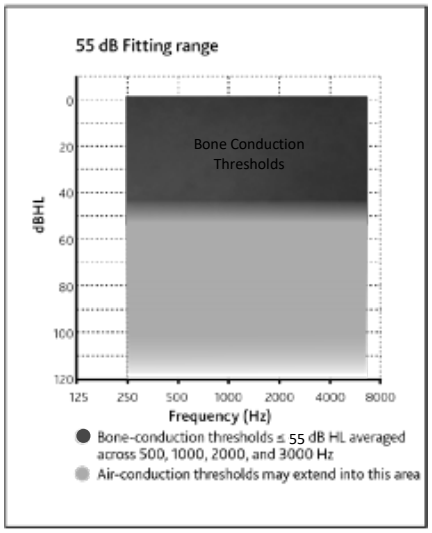
Patients 12 years or older who have:

Single-Sided Deafness

- AC PTA (0.5, 1, 2 & 3 kHz) in better hearing ear ≤ 20 dB

Conductive or Mixed Hearing Loss

- BC PTA (0.5, 1, 2 & 3 kHz) is ≤ 55 dB
- Bilateral candidates should have symmetric bone conduction thresholds (< 10 dB difference between the ears on average (0.5, 1, 2 & 3 kHz) or < 15 dB difference at individual frequencies)



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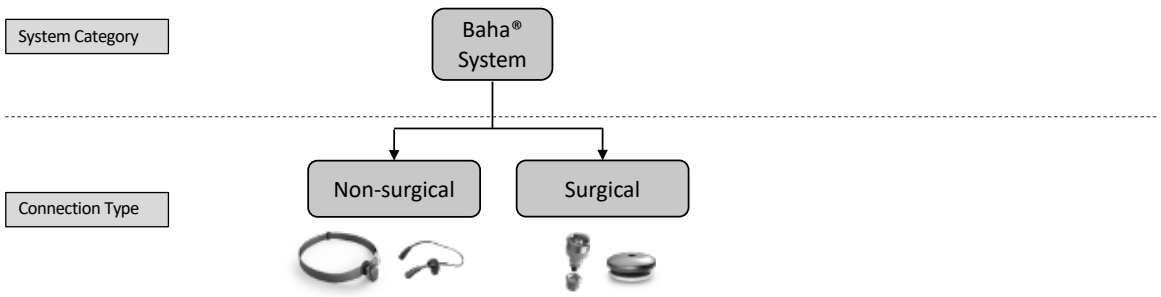
Portfolio of Bone Conduction Solutions



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Baha® 5: Proven Direct Bone Conduction Technology

Since its introduction in 2012, the Baha® Connect System with DermaLock™ technology is the most widely used direct bone conduction implant system in the world[1].

- Set the industry standard for reliability and performance, proven through the largest prospective study in bone conduction[2]
- Better performance than air conduction hearing aids as the air bone gap progresses beyond 30 dBHL[3]
- A portfolio of sound processors, including the most powerful bone conduction sound processor available[4-5], all with direct streaming to Apple® devices and wireless connectivity

1) Cochlear Annual Report, 2019 August [Internet: PDF document] Available from: www.cochlear.com
2) Den Besten CA et al (2016) Stability, survival, and tolerability of an auditory osseointegrated implant for bone conduction hearing: Long-term follow up of a randomized controlled trial. Otol Neurotol, 37(8):1077-1083.
3) Snik AF et al. (2005) Consensus Statements on the BAHA System: Where Do We Stand at Present? Annals of ORL 114(12S). 195:1-12
4) Flynn MC (2015). Smart and Small – innovative technologies behind the Cochlear Baha 5 Sound Processor. Cochlear Bone Anchored Solutions AB, 629761.
5) Norman, J. Review of Fitting Ranges. Cochlear Bone Anchored Solutions AB, D77358, 2015

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Cochlear™ Baha® System

Baha System Candidacy

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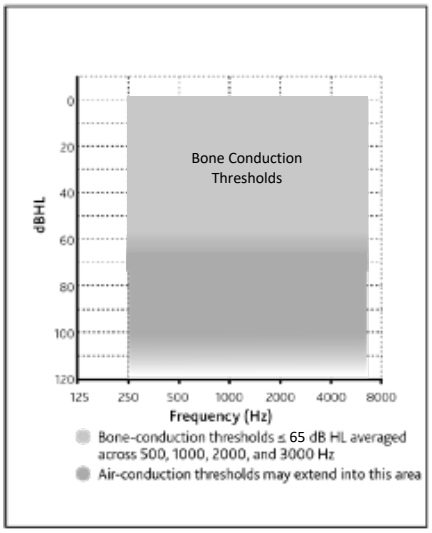
Patients 5 years or older* who have:

Single-Sided Deafness

- AC PTA (0.5, 1, 2 & 3 kHz) in better hearing ear ≤ 20 dB

Conductive or Mixed Hearing Loss

- BC PTA (0.5, 1, 2 & 3 kHz) is ≤ 45 dB for Baha 5 sound processor, ≤ 55 dB for Baha 5 Power sound processor and ≤ 65 for Baha 5 Super Power sound processor
- Bilateral candidates should have symmetric bone conduction thresholds (< 10 dB difference between the ears on average (0.5, 1, 2 & 3 kHz) or < 15 dB difference at individual frequencies)



*Children under 5 years of age may be suitable for a non-surgical bone conduction solution such as Baha Softband

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Bone Conduction Portfolio Selection Guide

Cochlear®

*SoundArc can be used if clinician prefers.

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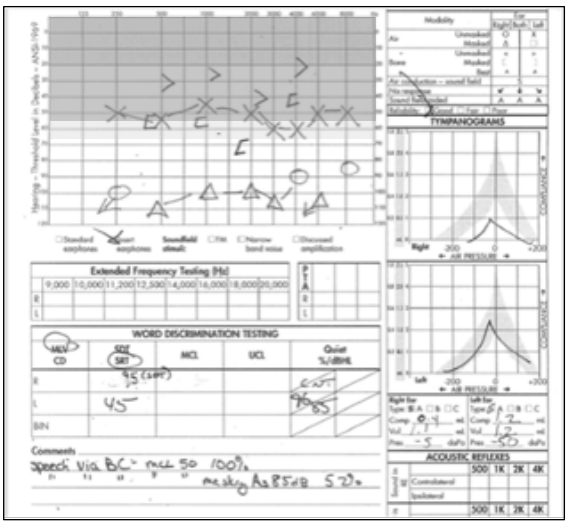
Case Example: Krish



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Case Example: Krish (cont.)

- Krish was seen at ABC ENT during a busy clinic day
- Audiologist immediately though of Bone Conduction fit him with a pre-set Baha 5 Power on Softband while she discussed options with him
- Krish told her he most wants to converse with his grandchildren on the phone and communicate better while he and his wife are travelling
- Krish loved the look of the Osia System, but the Audiologist recommended Baha based on his audio and he subjectively liked listening through the demo
- Krish remained concerned about a surgical option that “might not work”

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Case Example: Krish (cont.)

Krish saw the ENT who agreed with the Audiologist that bone conduction might be the best way to go. He was sent home with several brochures and also contact information for his local Cochlear volunteer. Krish was scheduled to return to the clinic in two weeks to make a decision.

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Poll Question #4: Krish

Which of the following would you MOST want to discuss further with Krish on his return visit?

- ❑ His concerns about surgery
- ❑ His desire for Osia
- ❑ How bone conduction might help him reach his goals
- ❑ Wireless options
- ❑ Another trial with new hearing aids

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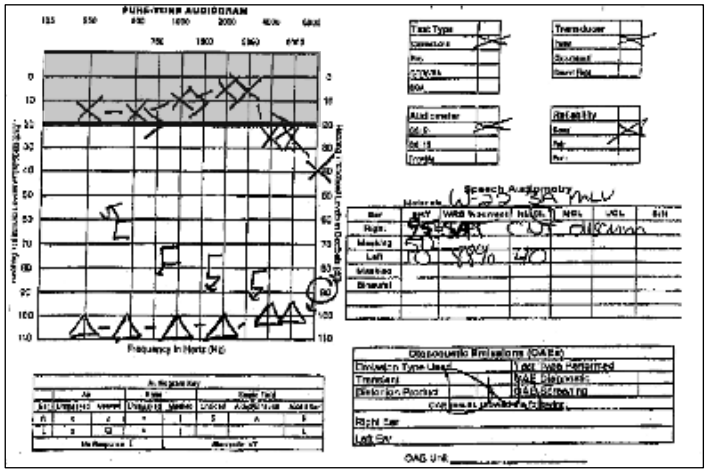
Case Example: Mia



AC PTA (.5, 1, 2 & 3 kHz) in the left ear = 8.75 dB

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Case Example: Mia (cont.)

- Mia was seen at Big U Medical Center for a "Bone Conduction Candidacy Appointment"
- Audiologist programmed a Baha 5 Super Power on SoundArc for her hearing loss she wore throughout her visit
- Mia's goals included hearing better at work when she was on the phone and hearing better in noisy situations
- Testing in the soundfield was completed with noise to the good ear and signal to the poorer ear: Unaided QuickSIN:
  - 8 dB SNR (Moderate SNR Loss)
  - QuickSIN with demo: 0 dB SNR (Normal)
- Mia liked the sound of bone conduction and loved the look of the Osia system, but she wasn't sure her insurance would cover it and was concerned about cost

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Case Example: Mia (cont.)

The clinic is submitting a request for insurance approval, but discussed both Osia and Baha with Mia. She's not sure she would proceed with Baha but is definitely interested in Osia. She received some brochures from her clinic and also decided to get on social media to learn more about bone conduction.

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Poll Question #5: Mia

Which of the following do you feel was the MOST important thing that Mia's clinic did to assist her in considering candidacy?

- ❑ A demonstration was provided by the clinic
- ❑ Audiologist programmed the Baha (instead of using pre-programmed device)
- ❑ The clinic scheduled a "candidacy" evaluation ahead of time
- ❑ Clinic discussed both Baha and Osia with her
- ❑ Clinic requested insurance approval
- ❑ Hearing in noise was tested in the soundfield

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Counseling

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- Counseling should be goal-oriented – what does the patient want to achieve?
- Should include basic information about bone conduction systems and how they are different from other treatment options
- Evaluate patient lifestyle and what options/accessories might be helpful for them

Dillon & Ginis (1997) Client Oriented Scale of Improvement (COSI) and its relationship to several other measures of benefit and satisfaction provided by hearing aids. J Am Acad Audiol, 8(1):27-43.

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Poll Question #6

Candidates describe to us a lot of different barriers to receiving treatment for their hearing loss with bone conduction. Which do you think is the most commonly reported?

- ❑ I am afraid of/don't want surgery
- ❑ It is too expensive
- ❑ No one suggested this treatment option to me
- ❑ I am worried it won't work for me
- ❑ I don't like the cosmetics
- ❑ Other

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Treating Hearing Loss with Bone Conduction (BC)

Explaining BC for Conductive or Mixed Hearing Loss

- Bypasses the outer and middle ear to stimulate the cochlea directly
- Does not require anything to be in or on the ear
- Only requires enough gain for the sensorineural component of the hearing loss (not the conductive component)

TIP: Explain what BC will do for the patient in regards to *their* goals


Chronic Otitis Media


Otitis Externa


Atresia/Microtia


Otosclerosis

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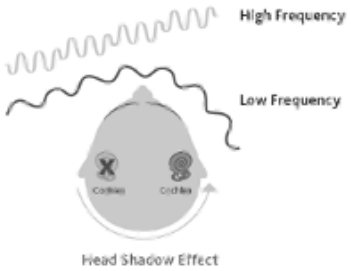
Treating Hearing Loss with Bone Conduction (BC)

Explaining BC for Single Sided Deafness (SSD)

- Does not require anything to be worn on the good ear
- Provides improved speech understanding in noisy environments for patients with SSD[1]
- Osia users show a significant improvement in their ability to understand speech in quiet and noisy conditions[2]
- Studies show that the Baha System can provide better speech understanding in noise than CROS hearing aids[3-4]



1) Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements." Otol Neurotol (2005:26): 999-1006
2) Data on file Windchill Document D1478473
3 - Niparko JK, Cox KM, Lustig LR. Comparison of the bone-anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. Otology & Neurotology, 2003 Jan;24(1):73-78
4 - Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements." Otol Neurotol (2005:26): 999-1006

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Surgical Counseling

Address any fears about surgery directly

- Bone Conduction implants are typically a same day, outpatient procedure
- The procedure generally takes about an hour, with additional time in the preparation and recovery areas
- Patient will typically go home the same day
- After a few days for recovery, most people are back to their normal routine

"The surgery was absolutely nothing. I think when I heard the word 'surgery,' I just got nervous."

Andria L. - Baha recipient

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Wireless Considerations

Both Baha and Osia systems are compatible with a wide range of wireless options

- Made for iPhone*
- Baha Smart App/Osia Smart App**
- Mini Microphone
- Phone Clip
- TV Streamer
- FM compatibility***

*The Cochlear Baha 5 and Osia Sound Processors are compatible with Apple devices, for compatibility information visit www.cochlear.com/compatibility.
**The Cochlear Baha and Osia Smart Apps are available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.
**Using Mini Microphone 2+

Bluetooth
Made for iPhone | iPad | iPod

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Ordering

Discuss lifestyle needs to assist in ordering for patient:

- Choice of one wireless accessory
- “Power up” program
- Color choice (Baha)
- Retention accessories


Cochlear Americas
Cochlear™ Osia® System Order Form

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Cochlear Concierge

Cochlear has a team of experts that are ready to answer questions and assist candidates in learning about the implant process, products, technology and company. They can connect your candidates with volunteers and let them know about events in your area.

Contact our Cochlear experts:
Tel: 877-518-3374
Email: Concierge@cochlear.com

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Why Choose Cochlear for Bone Conduction?

- Cochlear has delivered proven hearing performance and personalized service to our recipients for almost 40 years
- Cochlear offers a full portfolio of hearing solutions for bone conduction with the broadest fitting range in the industry[1-2] to help you treat more patients

1) Flynn MC (2015). Smart and Small – innovative technologies behind the Cochlear Baha 5 Sound Processor. Cochlear Bone Anchored Solutions AB, 629761.
2) Norman, J. Review of Fitting Ranges. Cochlear Bone Anchored Solutions AB, D77358, 2015.

In the United States, the Osia System is cleared for children ages 12 and older. In the United States and Canada, the placement of a bone-anchored implant is cleared for children ages 12 and older.

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Hear Now. And Always

Cochlear®

Lifetime Access

- Insurance coverage support, both before and after surgery
- Reliability and track record of quality[1]
- Access to new sound processor technology through upgrades

Fast Personal Support

- Fast, personalized service for your patients
- On-demand personalized information for your patients with myCochlear
- HearAlways expedited service for any processor repairs

Community

- Cochlear is the most chosen, most trusted hearing implant partner around the world, with more than 550,000 recipients[2]
- Recipients can connect with each other and to personalized resources with Cochlear Family

1) Cochlear Nucleus Implant Reliability Report. Volume 18 | December 2019. D1712187 V1. Cochlear Ltd; 2020
2) Cochlear Annual Report, 2019 August [Internet: PDF document] Available from: www.cochlear.com

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Case Example: Krish

- After discussions with his clinician and the Cochlear Concierge, Krish decided to move forward with a Baha Connect using a Baha 5 Power device
- He decided on the Mini Microphone to help him when travelling and eating out and he loves the iPhone features that help him connect with his grandchildren

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Case Example: Mia

- Mia's request for insurance approval of Osia was initially denied
- After working with Cochlear's Insurance Services, her clinic was able to get the denial overturned on appeal
- Mia loves using the direct to iPhone streaming at work and she can hear much better in the fast-paced office environment

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Poll Question #7

What subject would you be most interested in learning more about when it comes to bone conduction?

- ❑ Device/product information
- ❑ Research and clinical evidence
- ❑ Programming and follow-up
- ❑ More about Osia specifically
- ❑ More about Baha specifically
- ❑ Using bone conduction with pediatrics

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Conclusions

- Cochlear's bone conduction portfolio offers patients with conductive and mixed hearing loss and SSD more choices than ever before
- Bone Conduction demonstrations coupled with thoughtful counseling will ensure your patients receive the best solution possible

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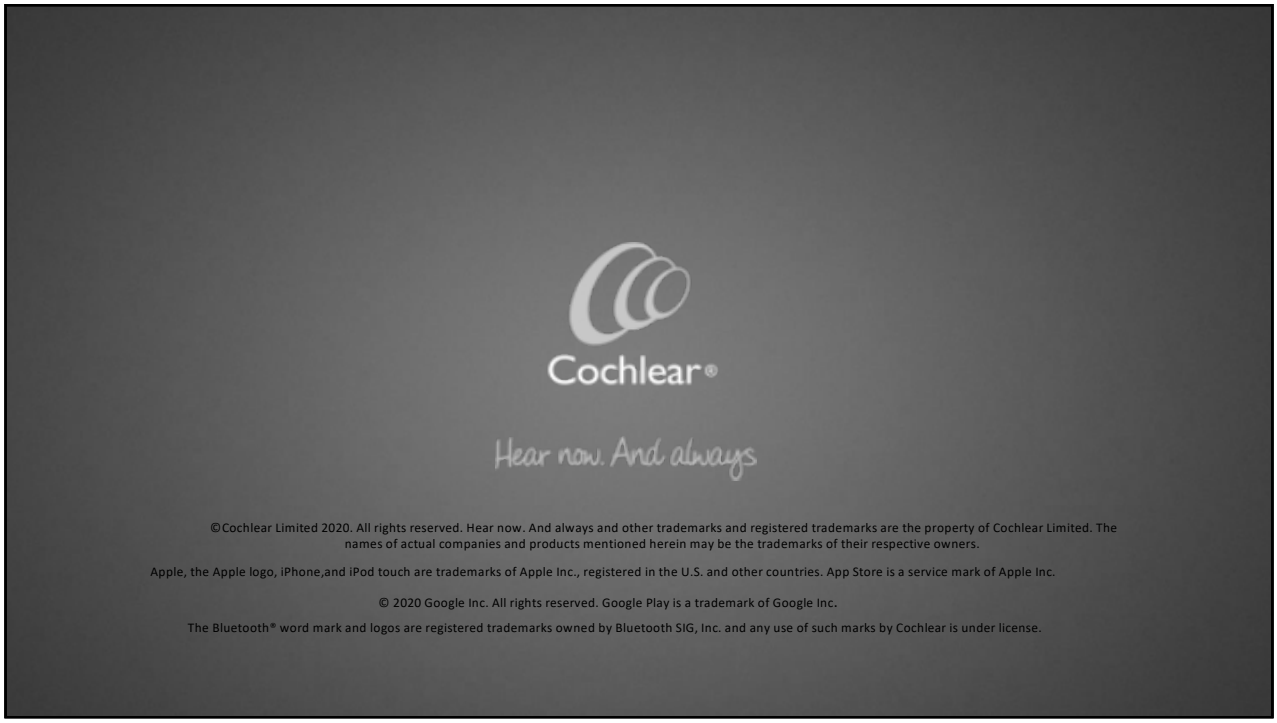
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Hear now. And always
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