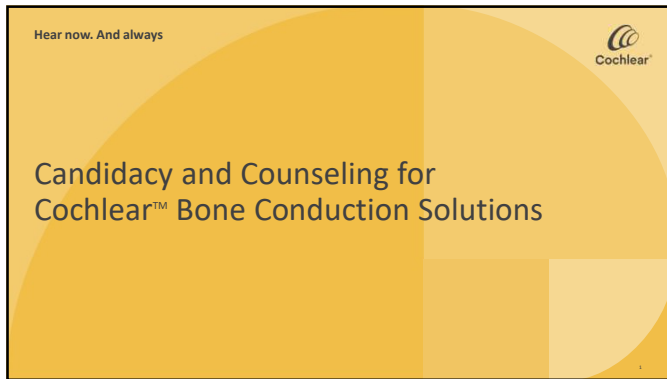




1

Learning Objectives

- After this course, participants will be able to list the candidacy criteria for bone conduction solutions for both Single-Sided Deafness (SSD) and Mixed and Conductive Hearing Loss.
- After this course, participants will be able to outline considerations for selecting a treatment within the Bone Conduction Portfolio.
- After this course, participants will be able to identify important points for counseling a candidate and list resources that are available to support bone conduction candidates.



2

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.



3

Agenda

Why bone conduction

Who might benefit

How to demonstrate

What else should be considered?



4

Hear now. And always



Why Bone Conduction

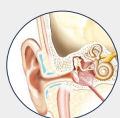
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Common etiologies of conductive or mixed hearing loss



Chronic Otitis Media

21% of patients will still need amplification*, even after middle ear surgery to restore conductive hearing loss.



Otosclerosis

A systemic literature review of 25 publications showed that **29.12%** of ossicular chain reconstruction and/or tympanoplasty surgical patients still experienced a postoperative ABG of > 20 dB.



Microtia / Atresia

The earlier bilateral and unilateral atresia patients receive a hearing solution, preferably before the age of 1 year, the better their speech and language development.



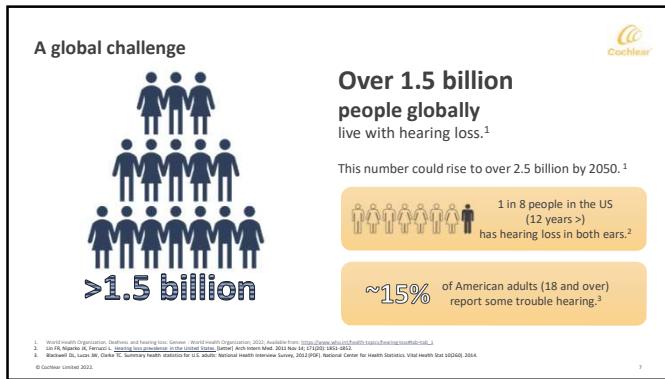
Otitis Externa

Irritation and allergic reactions in the ear canal may make it challenging to wear hearing aids – bone conduction solutions leave the canal open.

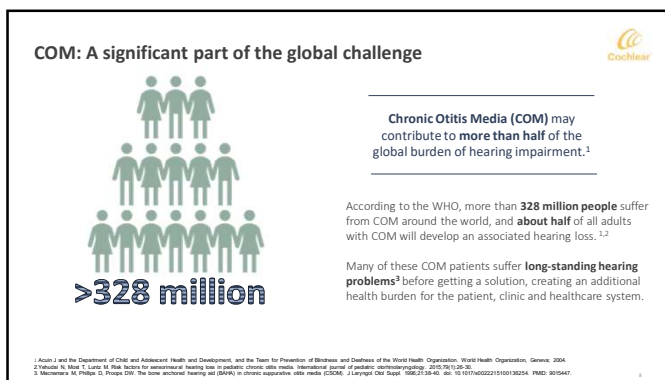
Offering a bone conduction solution may be the ideal next step in hearing treatment.

1. Cohen M, Cohen M, Bragan M, Haddad M, & Datta P. Pattern and degree of hearing loss in chronic suppurative otitis media. *Ameghin* 2010;102:106-107.
2. Cohen M, Cohen M, Bragan M, Haddad M, & Datta P. Bone conduction hearing aids: a preliminary comparison of the degree of improvement and patient satisfaction. *Ameghin* 2010;102:108-109.
3. Cohen M, Haddad M, Bragan M, Haddad M, & Datta P. Bone conduction hearing aids: a preliminary comparison of the degree of improvement and patient satisfaction. *Ameghin* 2010;102:110-111.
4. Cohen M, Haddad M, Bragan M, Haddad M, & Datta P. Bone conduction hearing aids: a preliminary comparison of the degree of improvement and patient satisfaction. *Ameghin* 2010;102:112-113.

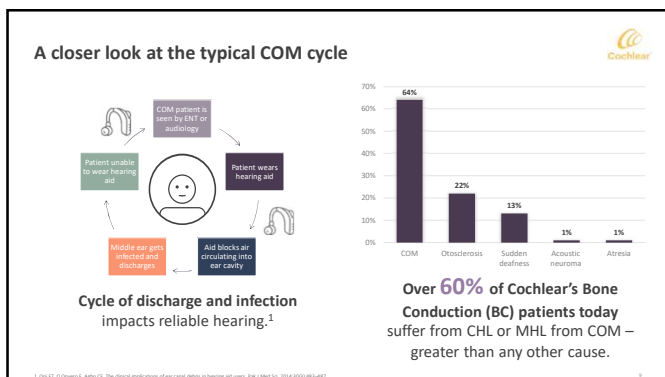
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8



9

Treat the Disease, Treat the Hearing

Standard of care for COM-related hearing loss does not exist

Many patients suffer for years before they are introduced to bone conduction.¹ Why?



LACK OF RESEARCH FOCUS

Clinical evidence gaps:

- Comparisons between available treatments
- Clinical outcomes on defined patient groups



LACK OF STANDARDIZATION

Standards needed regarding:

- How to define severity
- Treatment categorization
- Reporting clinical outcomes



LACK OF AWARENESS

Healthcare professionals often unaware that bone conduction may be an appropriate and effective treatment.

1. Barlow, D, Choi BY, Jarvella R, et al. Current State of Knowledge: Hearing Rehabilitation in Patients with Chronic Otitis Media: A Discussion of Current Status and Research Priorities. Ear Hearing. 2020; Submitted manuscript.

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Clinical benefits of bone conduction

Consistent hearing^{1,2,3}

Improved hearing performance, even in noisy situations^{4,5,6}

Ear canal remains open

Improved subjective sound quality and speech understanding over traditional air conduction (e.g., over Hearing Aids)⁷

Predictable hearing outcomes⁸

Long term solution

1. Gilbert, F, Fink, M, Choudhury, T, Bass, A, Gosselin, J. Bone anchored hearing aids: results of the first eight years of a programme in a district general hospital, assessed by the Glasgow benefit inventory. J Laryngol Otol. 2002;116(11):147-162.
2. Barlow, D, Choi, Y, Jarvella, R, et al. Bone anchored hearing aids: a preliminary assessment of the impact on independence and quality of life in children with severe to profound hearing loss. Cochlear Implant. 2003;16(1):104-110.
3. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.
4. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.
5. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.
6. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.
7. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.
8. Jarvella, R, Choi, Y, Jarvella, R, et al. Bone anchored hearing aid: comparison of benefit by patient category. The Laryngoscope. 2004;114(10):1842-1848.

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When you look at your busy schedule for today, who is on it?



The gentleman you and the ENT also saw two weeks ago with a draining ear?

Your patient with a large air-bone gap whose power hearing aid isn't strong enough?



Your patient with microtia?



The woman with otosclerosis?



The patient with SSD?



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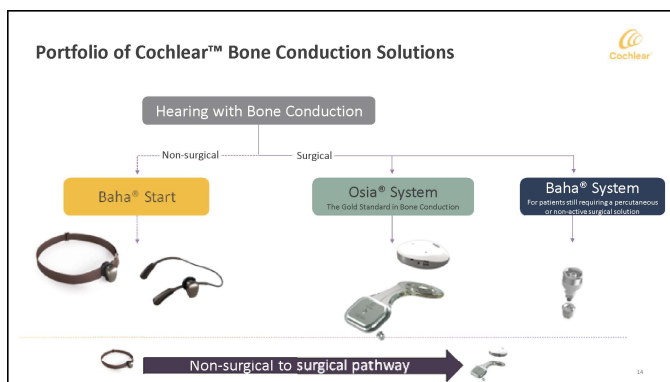
Hear now. And always

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Device Selection

Cochlear™ Bone Conduction Solutions Portfolio

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For More Details

Foundations of Bone Conduction Curriculum

- **Candidacy and Counseling (60 min)**
- **Technology**
 - Baha (30 min)
 - Osia (30 min)
- **Prescription and Fitting**
 - Baha (30 min)
 - Osia (30 min)

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Candidacy and Indications

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What's the Difference?

Indication
Guideline based primarily on
*audiometric and speech
perception data*

Candidacy
Considers the
whole patient

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Cochlear Bone Conduction Solutions indications

Mixed and conductive
PTA BC threshold ≤ 55 dB SNHL**
(0.5, 1, 2, 3 kHz)

Single-sided deafness
Poor ear Non-functional hearing
(i.e. profound hearing loss)
Good ear PTA AC threshold ≤ 20 dB SNHL
(0.5, 1, 2, 3 kHz)

Fitting range (bone conduction thresholds)

Osia 2 **Baha 6 Max**

65 dB **65 dB**

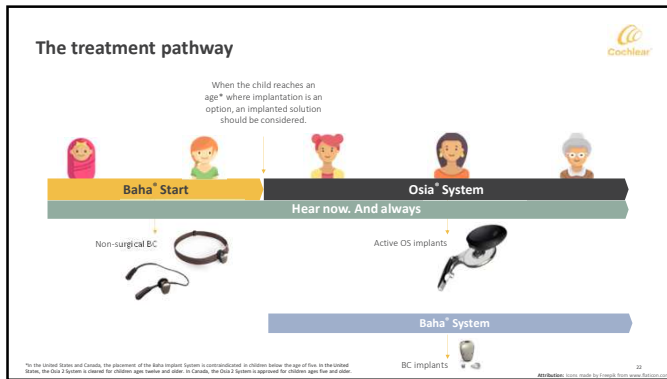
* The Baha 6 Max Sound Processor and the Osia 2 and 2(i) System have a fitting range of up to 55 dB SNHL.

** Additional powerful Baha device available with up to a 65 dB fitting range. Contact your Cochlear representative for more information.

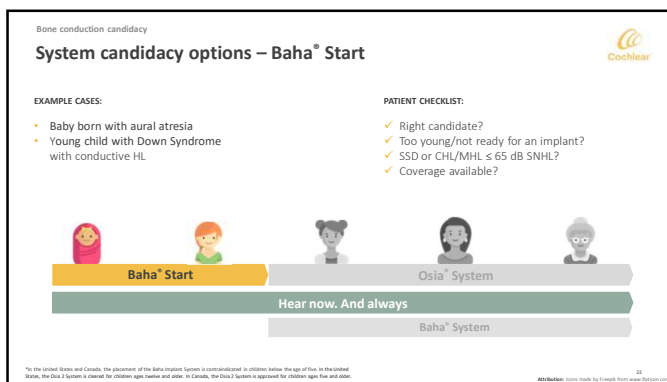
In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

In the United States, the Osia System is cleared for children ages twelve and older. In Canada, the Osia System is approved for children ages 5 and older.

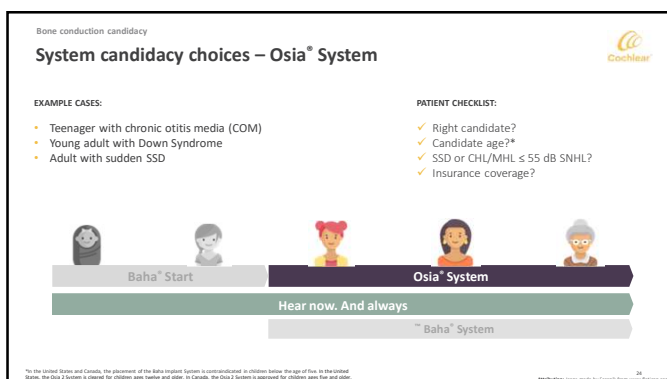
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Bone conduction candidacy

System candidacy choices – Baha® System

EXAMPLE CASES:

- Adult with COM resulting MHL requiring a 65 dB fitting range
- Adult with SSD with limited insurance coverage requiring a percutaneous surgical solution.

PATIENT CHECKLIST:

- ✓ BC candidate?
- ✓ Candidate age?*
- ✓ SSD or CHL/MHL ≤ 65 dB SNHL?
- ✓ Insurance coverage?

*In the United States and Canada, the placement of the Baha implant system is contraindicated in children below the age of five. In the United States, the Osia System is cleared for children ages twelve and older. In Canada, the Osia System is approved for children ages five and older.

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Bone conduction candidacy

The right solution for the right patient

- A three-year-old girl - Born with aural atresia	- A 55-year-old woman - COM-related hearing loss	- A 65-year-old man - Unilateral Profound hearing loss
✓ Right candidate ✓ Too young/not ready for implant ✓ Conductive hearing loss ✓ 60 dB air-bone gap ✓ Coverage available	✓ Right candidate ✓ Conductive Hearing Loss ✓ Prefers low profile processor ✓ Coverage available ✓ Doesn't want daily maintenance and hygiene tasks	✓ Right candidate ✓ Requires an abutment solution due to insurance coverage ✓ Lost hearing 12 years ago ✓ Normal hearing in the good ear ✓ Funding available
Baha® Start - Baha 6 Max Sound Processor - Baha Softband - Cochlear Wireless Mini Mic - Baha Smart App*	Osia® System - Osia 2 Sound Processor - Cochlear Wireless Mini Mic - Osia Smart App†	Baha® System - Baha 6 Max Sound Processor - Baha Connect - Cochlear Wireless TV Streamer - Baha Smart App

*In the United States and Canada, the placement of the Baha implant system is contraindicated in children below the age of five. In the United States, the Osia System is cleared for children ages twelve and older. In Canada, the Osia System is approved for children ages five and older.

*The Cochlear Baha 6 Max Sound Processor is compatible with Apple and Android devices. The Cochlear Baha Smart App is available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.

†The Cochlear Osia Sound Processor is compatible with Apple Devices. The Cochlear Osia Smart App is available on the App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.

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What are you hearing from your patients?

Do they experience ANY of the following?

- ☐ Unhappy with hearing aids
- ☐ Favors one ear
- ☐ Struggles localizing sounds
- ☐ Withdraws from social events
- ☐ Often needs others to repeat themselves

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Demonstrating and Evaluating Bone Conduction

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Bone conduction demonstration and evaluation

Demonstrating and evaluating bone conduction

Goals

- Demonstrate a bone conduction solution
- Complete a bone conduction evaluation
- Provide recommendations based on evaluation results and other considerations
- Create audiological treatment plan in conjunction with medical treatment plan to address hearing needs of patients

Potential pitfalls

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



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Demonstration and Evaluation Options

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Test rod demonstration	Baha® Softband or SoundArc™ demonstration and evaluation options	
		
Simple Demo: A quick and simple first impression of sound quality and function for the candidate using the out of box settings on a test rod.	Demo with Preset Programs: A demonstration by category of hearing loss type to get a closer approximation of the candidate's performance with a bone conduction solution and allow the patient to wear the device for a longer period.	Demo + Evaluation with Custom Program: A full demonstration and evaluation of the candidate's performance with custom program to capture unaided vs aided hearing outcomes and predict outcomes.
Predictability of post surgical experience ● LOW ● ● MODERATE ● ● ● ● HIGHEST		

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Bone conduction demonstration and evaluation

Demonstration and evaluation 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 the demo as a counseling tool to explain what bone conduction sounds like
- ✓ Use subjective methods to determine benefit (e.g., questionnaires, discussion)
- ✓ Evaluate using objective methods (e.g., booth testing)



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Hear now. And always

Counseling and Treatment Determination

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Bone Conduction Solution Recommendations

Patient qualification	Recommendation	Recommendation	Recommendation
• CHL/MHL, with bone conduction threshold PTA < 55dB • Meets age requirement • Motivated to proceed with a surgical hearing implant solution	 Cochlear Osia System*	 Cochlear Osia System*	 Cochlear Baha Start with Baha 6 Max Sound Processor worn with a SoundArc or Softband
• SSD • Meets age requirement • Motivated to proceed with a surgical hearing implant solution	OR  Conduct a cochlear implant evaluation for a Cochlear Nucleus® System*, more info at www.cochlear.us/cicandidacy		

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Talk about...

- ☐ Goals for hearing
- ☐ Daily wear and lifestyle
- ☐ Temporary vs. permanent solution
- ☐ Listening environment
- ☐ Imaging and diagnostic needs
- ☐ Localization vs. lateralization
- ☐ Potential improved clarity, loudness and high frequency access with surgical system vs demonstration device



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Bone conduction counseling: key points

- 1 Demonstrate bone conduction early and throughout the counseling session
- 2 Consider and counsel on the optimal wearing option best suited for the patient (surgical or non-surgical)
- 3 Clarify the advantages a surgical option will have compared to the demo experience
- 4 Establish the importance of treating the hearing loss, regardless of the treatment chosen

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Hearing with a demo vs hearing after surgery

Discuss the differences between hearing with a demo and hearing after surgery

Baha®:

Baha Start can be used to predict outcomes with Bone Conduction devices after surgery^{1,2}

**Osia®:**

An exact demonstration of Osia does not exist. Differences exist in the output of Baha on a Softband or SoundArc vs an Osia system, especially in the high frequencies, where Osia is better¹



1. Groppecke M, Ribault G, Teyssie F et al. Clinical performance of the Osia system, a new active osseointegrated implant system. Results from a prospective clinical investigation (2018, 14033). 2.12.2.15.
2. Stepp HA, Fahry DA, Tellez PP, Arheart R, Angell S. (2020). A clinical protocol for predicting outcomes with an implantable prosthesis device (Baha) in patients with single-sided deafness. J Am Acad Audiol 2020;35:442.

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Surgical counseling

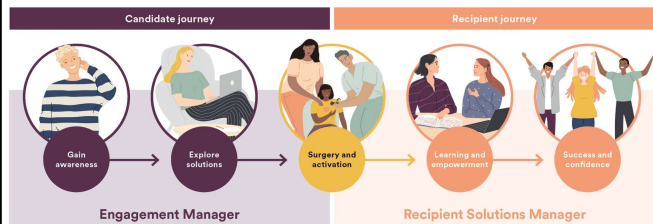
Address any fears about surgery directly

- 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



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Candidate engagement



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Hear now. And always



Case Studies

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Let me introduce you...

Mia



Layla

Krish

*Not actual patients

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Case Example: Mia



- History of SSD (profound loss) in Right ear
- Air conduction threshold PTA of 13.75 dBHL in the good (Left) ear (Measured at 500, 1000, 2000, 3000 Hz)
- Sudden SNHL five years ago
 - Tried steroids but no improvement in hearing.
 - Has been counseled about CROS aids but is uninterested in trying them.
- 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 Baha 6 Max demo: 0 dB SNR (Normal)



Mia's goals include:

- Hearing better at work when she is on the phone
- Hearing better in noisy situations

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Case Example: Mia

- Mia received her Osia® system and chose the Aqua+ accessory since she loves 5k races – rain or shine.*
- Mia loves using the direct to iPhone streaming at work and she can hear much better in the fast-paced office environment

* The Cochlear Osio 2 SoundProcessor is protected against water to level IP62 of the international standard IEC60529 and IP67 with the battery compartment removed. The Cochlear Osio 2 SoundProcessor with Aquo+ is dust and water resistant to the level of IP68 of the international standard IEC60529 when used with LiMnO₄ alkaline or nickel metal hydride disposable batteries. This water protection rating means that the sound processor with the Aquo+ can be continuously submerged under water to a depth of up to 2 meters (9 feet and 4 inches) for up to 2 hours. Aquo+

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Case Example: Layla

• 2 years old
 • History of bilateral atresia with conductive loss bilaterally
 • Bone conduction threshold PTA (500, 1000, 2000, 3000 Hz) of 8.75 dBHL in Right ear and 11.25 dBHL in Left ear

Layla's family's goals include:

- Meeting speech and language development targets
- Developing her social skills and comfort in social situations with peers

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Case Example: Layla

- Layla's family would like her to be fit with a Baha® Start Solution using bilateral Baha 6 Max Sound Processors
- Layla is covered under her state's Medicaid program and her family has some concerns about how long the approval process will take.

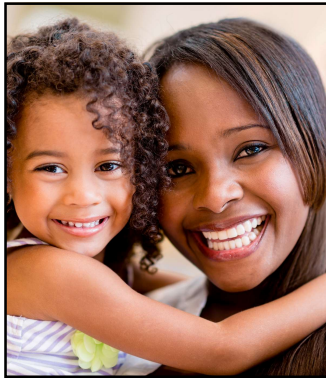
*The Cochlear Baha 6 Max Sound Processor is compatible with Apple and Android devices. The Cochlear Baha Smart App is available on the App Store and Google Play. For compatibility information, visit www.cochlear.com/compatibility.

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Cochlear™ Lend an Ear Program

- Fast access to sound with Baha® Start
- Loan-to-Own concept
- Available for pediatric candidates 12 & under

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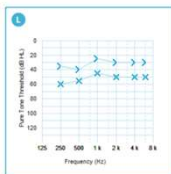
Case Example: Layla

- Layla is fit with a Baha® Start Solution using bilateral Baha 6 Max Sound Processors on a Softband under the Lend an Ear program – the processor will be hers once insurance approval is obtained
- Her parents really like having access to the Baha Smart App* to control and monitor her devices
- Her family uses the Mini Microphone 2+ when at the park, in the car, etc and anticipate Layla will love the direct streaming feature as she gets a bit older
- She is enrolled in preschool and will start in the next few months when she turns 3!

* The Cochlear Baha 6 Max Sound Processor is compatible with Apple and Android devices. The Cochlear Baha Smart App is available on the App Store and Google Play. For compatibility information, visit www.cochlear.com/compatibility

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Case Example: Krish



- History of Mixed Hearing Loss in Left Ear
- Bone conduction threshold PTA of 31 dBHL (Measured at 500, 1000, 2000, 3000 Hz)
- Long history of chronic otitis media with several attempts at surgical reconstruction



Krish's goals include:

- Converse with his grandchildren on the phone
- Communicate better while he and his wife are travelling

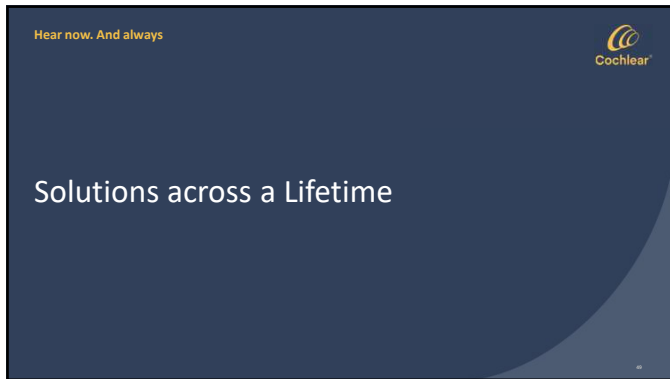
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Case Example: Krish

- After discussions with his clinician and the Cochlear Concierge, Krish decided to move forward with an Osia® system
- He chose a Mini Microphone 2+ 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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Why Choose Cochlear for Bone Conduction?

- Cochlear has delivered proven hearing performance and personalized service to our recipients for over 40 years
- Cochlear offers a full portfolio of bone conduction hearing solutions with a broad fitting range (up to 65 dB) to help you treat more patients



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Additional Resources

Bone conduction demonstration and evaluation

Goals

- Identify the goals of the demonstration and evaluation process
- Identify the goals of the demonstration and evaluation process
- Identify the goals of the demonstration and evaluation process

Recommended setup for evaluation

Equipment

Suggested tasks

Unaided over-the-ear testing of ear to be implanted

Aided over-the-ear testing of ear to be implanted

Candidacy, evaluation and fitting protocol

Cochlear® bone conduction hearing systems



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