Bone Conduction Solutions for Children with Hearing Loss

Lisa Vaughan Christensen, AuD

American Academy of Audiology, President
Cook Children's Medical Center, Audiology Program Manager

Agenda

- Conductive and Mixed Hearing Loss in Children
- Single-Sided Deafness in Children
- Advantages of Bone Conduction Solutions
- Fitting Bone Conduction Solutions for Children



Learning Outcomes

After this course learners will be able to...

- Describe the common etiologies for conductive and mixed hearing loss in children and list common treatment options.
- List the considerations for treating single-sided deafness in children.
- Explain how treatment with bone conduction is uniquely suited to conductive and mixed hearing loss in children as well as singlesided deafness.
- Describe the fitting and validation of Baha bone conduction solutions in children.

Conductive and Mixed Hearing Loss in Children

Conductive and Mixed Hearing Loss (CMHL) in Children

- Prevalence of conductive hearing loss in children may be up to 3.5% of the general population¹
- Conductive hearing loss in children may be permanent or temporary
- Causes may include otitis media, microtia/atresia, genetic causes or syndromes



1 - Feder KP, Michaud D, McNamee J, Fitzpatrick E, Ramage-Morin P, Beauregard Y. (2017) Prevalence of hearing loss among a representative sample of Canadian children and adolescents, 3 to 19 years of age

Microtia and Atresia

Microtia

- Spectrum of deformities of the outer ear
- Grades:
 - I ear is smaller than normal, minor alterations in form
 - II conchal type microtia; much of the lower 2/3 of the ear is present
 - III lobular type microtia; "peanut" shape
 - IV anotia; no ear present
- Treatments can include prosthetics or surgical reconstruction

Atresia

- Absence or closure of the external auditory canal
- Can be classified by likelihood of repair (1-10)¹
 - Based on findings of high resolution CT scan
 - 8 out of 10 equals 80% chance of hearing restoration (SRT between 15-25 dB)
 - Scores less than or equal to 5 are generally not considered candidates for surgical repair
- Surgical repair (canalplasty) usually not attempted until age 3-6

 $1 \, \text{Jahrsdoerfer, RA, Yeakley, JW, Aguilar, EA, Cole, RR, Gray, LC (1992)}. \, \text{Grading system for the selection of patients with congenital aural atresia.} \, \text{American Journal of Otology, (1) 13:6-12 and College (1) 13:6-12 and College (1) 14:6-12 and College (1)$

Chronic Otitis Media

- Persistent inflammation of the middle ear or mastoid
- Chronic suppurative otitis media can occur with tympanic membrane perforation
- 60% of those with chronic suppurative otitis media will have hearing impairment¹
- Rate of chronic otitis media is estimated at 3% in North America with 22.5% occurring in children under 5²



1 World Health Organization (2004) Chronic suppurative otitis media: Burden of illness and management options.
2 Monasta et al (2012) Burden of disease caused by Otitis Media: Systematic review and global estimates. PLoS One, 7(4), e36226

Fluctuating Hearing Loss in Childhood

- · Otitis media can cause fluctuating hearing loss in childhood
- Hearing loss due to otitis media in childhood can be more common in some indigenous populations or in developing countries¹
- 29% of children with Down Syndrome have permanent mixed or conductive hearing loss; another 32% have fluctuating losses²
- Children with cleft palate are more likely to have chronic otitis media and hearing aid use among this population is reported at around 10%³

Monasta et al (2012) Burden of disease caused by Otitis Media: Systematic review and global estimates. PLoS One, 7(4), e36226

2- Nightengale E, Yoon P, Wolter-Warmerdam K, Daniels D, Hickey F (2017) Understanding hearing and hearing loss in children with Down Syndrome. American Journal of Audio 3 - Gani B, Kinshuck AJ, Sharma R. (2012) A review of hearing loss in cleft palate patients. Int J Otolaryngol, 2012 (Online Article ID 548698)

Genetic Syndromes

Several genetic syndromes may be associated with conductive or mixed hearing loss, for example:

- CHARGE Syndrome
- Treacher-Collins Syndrome
- Branchio-oto-renal Syndrome
- Stickler Syndrome



Single Sided Deafness in Children

Single-Sided Deafness (SSD)

- Onset of universal newborn hearing screening has led to early identification of SSD, but clear recommendations for management have lagged1
- Prevalence estimates for SSD are about 1 per 1000 at birth rising to 14% of adolescents¹
- Untreated, SSD in childhood can lead to delayed speech and language development², behavioral concerns³ and academic concerns⁴
- 1 Lieu J (2018) Permanent unilateral hearing loss and childhood development. Curr Otorhinolaryngol Rep, 6(1): 74-81.

 2 Vohr et al (2012) Language outcomes and service provision of preschool children with congenital hearing loss. Early Hum Dev. Jul; 88(7):493-8.

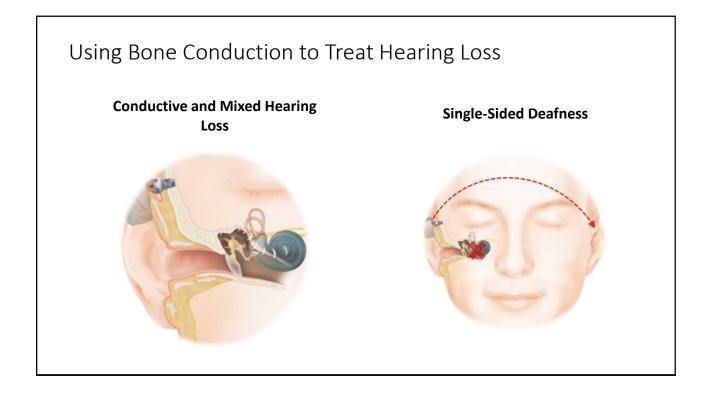
 3 Lieu J (2012) Longitudinal study of children with unilateral hearing loss. Laryngoscope, 122(9)

 4 Lieu J (2013) Unilateral hearing loss in children: Speech-language and school performance. B-ENTSuppl 21

Treatment for SSD in Children

- AAA's Pediatric Amplification Guidelines (2013):
 - "Children with aidable unilateral hearing loss should be considered candidates for amplification due to evidence for potential developmental and academic delays."
- Treatment options
 - · Monitoring with no treatment
 - · Classroom accommodations (ie, preferential seating, remote microphone technology)
 - Hearing aids (ie, traditional, CROS)
 - Bone conduction technology

Bone Conduction Solutions



Technology Foundations

- Invented and developed in the 1970's by Professor Brånemark and Dr. Tjellström
- Cleared by the FDA in 1995 for mixed and conductive hearing loss and in 2002 for single-sided deafness
- About 40,000 people in the United States now hear with a Baha solution¹



Dr Tjellström and the first Baha recipient, Mona Andersson (in 2012)

1 – Cochlear Internal Recipient Data, December 2017

Osseointegration

- The process by which living bone tissue bonds with titanium
- Makes direct bone conduction possible
- Provides the basis of long-term predictability and success of the Baha System



Why Bone Conduction?

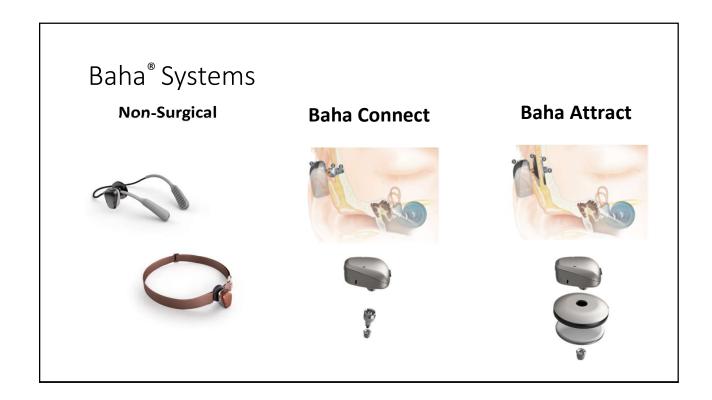
Direct Bone Conduction:

- Works independently of ear canal and middle ear
- Direct transmission gives the power needed to hear what's missing
 - Pre-operative testing is possible
 - High wearing comfort
 - Typically a routine outpatient procedure
 - Predictable outcome

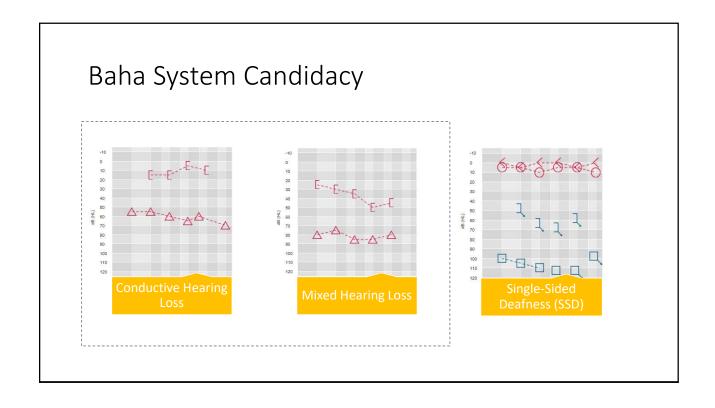








Conductive & Mixed Hearing Loss (CMHL) Candidacy is based on bone conduction thresholds Bone Conduction PTA equal to or better than 65 dB at 0.5, 1, 2 & 3 kHz Bilateral fitting requires symmetric bone conduction thresholds Less than 10 dB on average (0.5, 1, 2 & 3) or less than 15 dB at individual frequencies Single-Sided Deafness (SSD) Profound SNHL in one ear and Normal hearing in the good ear Defined as Air Conduction PTA equal to or better than 20 dB at 0.5, 1, 2 & 3 kHz Surgery can be considered for children 5 years of age or older

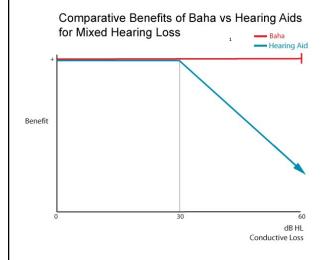


Baha System Candidacy: CMHL

- Direct bone conduction bypasses the outer and middle ear
- Baha solutions treat conductive & mixed hearing loss
 - Atresia
 - · Chronic middle ear disease
 - Cholesteatoma
 - · Congenital abnormalities
- Baha devices do not have to overcome conductive component, only amplify for any sensorineural component



Baha System vs Hearing Aids for CMHL



- The greater the air-bone gap, the more a Baha system will outperform hearing aids²
- Hearing aid prescriptions for conductive and mixed hearing loss require more gain and receive less clinical research than for sensorineural hearing loss³
- Hearing aid fitting can be difficult if there is drainage from the ear, ear pain or a mastoid cavity present after mastoidectomy⁴

-50 IA F et al. (2003) Consensus Salaments on the BAHA Systems. Where Do We Stand of Precent Familia of DRI 1.14 (125) 1951-1.12

-Falamate EMA, under Gerba, (5 shall (1998) a tributarishidadus Companisor of the bose anchored hearing ald and air condicion hearing ald and air condicion hearing ald and air condicion hearing alds. Arch Otolanyagid Head Neck Surg. (124)):712-726

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power upon upon the other companing clinical explanation. J Am Acad Audiol, 24(6):452-66.

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power. 34(6):711-84.

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power. 34(6):711-84.

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power. 34(6):452-66.

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power. 34(6):452-66.

-Inhorato EEE, (2013) Precipilor wanification recommendations for hearing losses with a conductive component and their impact on the required maximum power. 34(6):452-66.

-Inhorato EEE, (2013) Precipilor wanification recommendations of the recommendation of the rec

Baha System Advantages for CMHL

- Nothing worn on the external ear, which is helpful in cases where ear drainage is present¹ or if pinnas are misshapen
- Baha does not need to be re-adjusted if the air conduction thresholds fluctuate because gain is only required for the bone conduction thresholds
- Pre-operative testing can be used to predict postoperative benefit²
- Use of Baha is associated with high user satisfaction and good long-term benefit^{3,4}

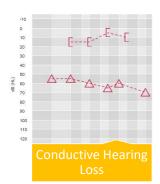


1 - Bounhabet S, Arcand P, Salba E I, (2012) Congenital aural atreas: bone-anchored hearing and vs. external auditory canal reconstruction. Int J Pediat Obominolaryingio. 16(2):272-7.

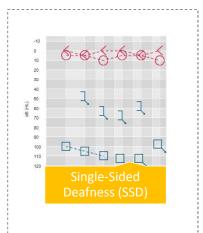
2 - Monini S, Filippi C, Alturo F, Biagini M, Lazzarino AJ, Barbara M. (2015) Individualised headband simulation test for predicting outcome after percutaneous bone conduction implantation. Acta Distributory programs of the program of the program of the programs of the program of the p

3- Gardell ISK, Andresen K, Faber CE, Wanscher JH. (2015) Bone-anchored hearing aids are effective and associated with a high degree of satisfaction. Danish Medical Journal, 62(7):A5108

Baha System Candidacy



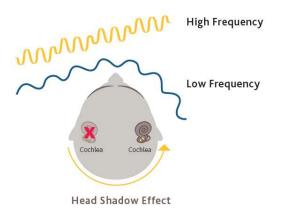




Baha System Candidacy: SSD

Two ears:

- 1. Help overcome the head shadow effect
- 2. Help understanding of speech in background noise
- 3. Help in the location of sound



Treatment Options for SSD

Treatment options: SSD

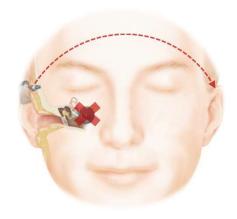
- Child remains untreated*
- CROS hearing aids
- Bone conduction devices (e.g., Baha)



*Parent or physician choice

Advantages of Bone Conduction for SSD

- Improved speech understanding in noisy environments¹
- Helps to lift the head shadow effect¹⁻⁴
- Reduces the psychosocial consequences associated with hearing impairment^{1,5-6}
- Long-term patient satisfaction and hearing benefits⁷⁻⁸



- 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 rou
 3 Pai L Kelleher C, Nunn T, Patha N, Jindal M. F, Litzerald O'Connor A, Jam B. O. Lictome of bone-anchored hearing aids for single-sided deafness: A crossocieties study. Acta Oto-Larvaneologica: Early Online 1-5.
- 4. Wazen JJ, Spitzer JB, (Indissamin SI, et al. | Iranscranial contradictal contensis stimulated to learners. Unsurengeology read netex Surg 2005;129(3):248-94.

 S. Newman CW, Sandridge DA, Wordszi LM. "Cingitudinal benefit from and satisfaction with the Baba System for patients with acquired unilateral sensorineural hearing loss. Otol Neurotol 2008; 29: 1123-113
- 6. Schroder SA, Ravn T, Bonding P. BAHA in single sided deafness: patient compliance and subjective benefit. Otol Neurotol. 2010; 31: 404-408.
- Kompis M, Wilhem W, Caversaccio. Long term benefit of bone anchored hearing systems in single sided deafness. Acta Oto-Laryngologica. 2017; 13:398-40
 Maurizio B, Riagini M, Lazzarino AL, Monini S. Hearing and quality of life in a south European BAHA population. Acta Oto-Laryngologica. 2010;130: 1040-104

Bone Conduction vs CROS

- The Baha system is a discreet solution worn on one side, while CROS hearing aids require users to wear devices on both ears
- Baha allows wireless streaming to be mixed with environmental mic from the bad side while CROS aids may require turning off the bad side in order to stream¹
- The Baha System bypasses outer and middle ear and sends clearer, more crisp sound directly to the inner ear²
- Studies show that the Baha System provides better speech understanding in noise than CROS hearing aids³⁻⁴

L – Phonak CROS II wireless compatibility, downloaded from: https://www.phonakpro.com/us/en/support/product-support/hearing-aids/cros-ii/compatibility-cros-ii.html December, 2017

⁻ Nigarko, C. ox KM, Lustig LR, Comparison of the Dense-archered hearing aid implantable hearing device with contralateral routing of foliaties (spin) amplification in the rehabilitation of unlateral deefness. Otology, 8 Neurotology, 2003 Jan;24(1):73-78.

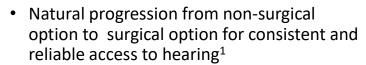
- High MS, Boron and Comparison of the Centers (Neuros) and the

Non-Surgical Bone Conduction Solutions

Baha Systems for Children: Non-surgical

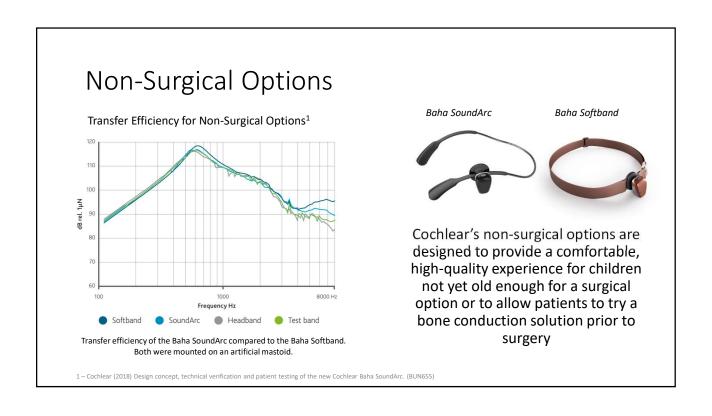


- Prior to age 5, only non-surgical alternatives are available for children
- Softband is ideal for babies and toddlers
- Baha SoundArc is an effective and stylish alternative for young children



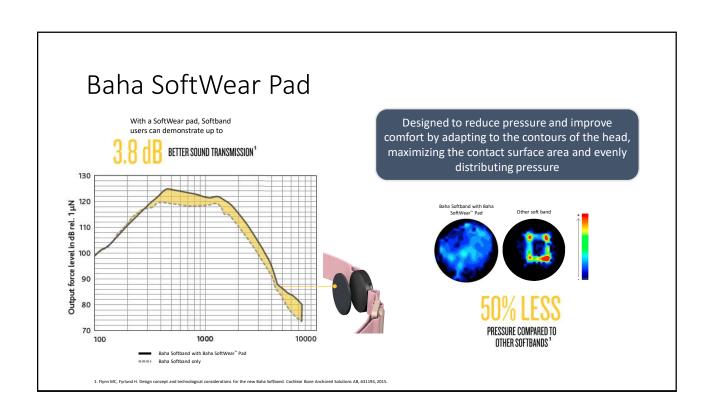


1 – Flynn MC. Design concept and technological considerations for the Cochlear Baha 4 Attract System. Cochlear Bone Anchored Solutions AB, E82744, Nov 2013.

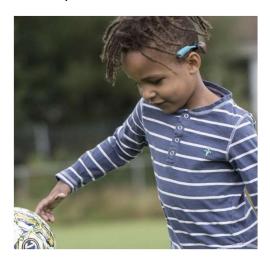








Non-Surgical Options



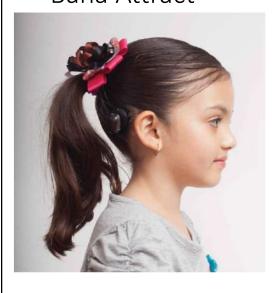
Surgical Bone Conduction Solutions

Surgical Options



- The Baha Attract provides clinically proven performance with nothing through the skin¹
- The Baha Connect's direct connection with the implant provides the maximum possible gain²
- Two systems with one strong foundation³
- Baha Attract Baha Connect
- 3 Neissen RC, Stalfors J, de Wolf MJ, Rynn MC, Wigens S, Eeg-Olofsson M, Green K, Rothera MP, Mylanus EA, & Hol MK. Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomize controlled, clinical investigation. On the Neurotol. 2013, 36(8): 1486-91.

Baha Attract







- Internal and external magnets connect to provide an invisible link between the sound processor and implant
- Comfortable, easy to use and care for
- Designed with MRI safety in mind (approved for 1.5T)

Baha Connect



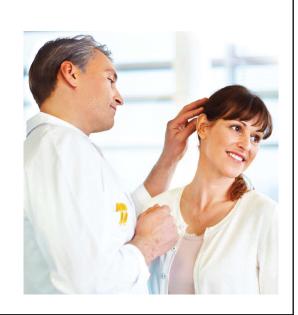




- Utilizes a small abutment to provide a direct connection between the sound processor and implant
- Requires some daily cleaning and care
- Safe for MRI (at 1.5T and 3.0T)

Surgical Details

- Surgical procedure is straight-forward, usually lasting less than an hour
- Baha Connect is designed and FDA-cleared for preservation of soft tissue
- One or two stage surgery depending on age and bone integrity
- Outpatient procedure
- Adult surgeries can be done under local anesthesia
- Sound processor is fit:
 - 12 weeks for Baha Connect
 - 4 weeks for Baha Attract



Non-surgical vs. Surgical

Why consider a surgical option?

- Significant difference in thresholds with surgical option better than non-surgical options¹
- Better sound transmission with a surgical option when compared to non-surgical option²
- Consistent access to sound
- More discretion with surgical option

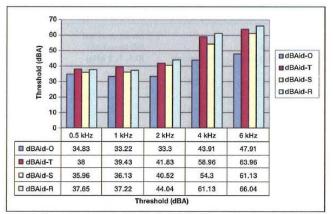


Figure 1. Chart shows the mean threshold in each listening situation at each frequency $(dBAid-O=Baha\ osseointegrated\ implant;\ dBAid-T=Baha\ Testband;\ dBAid-S=Baha\ Softband;\ dBAid-R=Baha\ test\ rod).$

Graph from Kara et al (2016)2

Heywood et al., (2011) Comparison of hearing thresholds obtained with Baha preoperative assessment tools and those obtained with the osseointegrated implant. Ear, Nose & Throat Journal, 90(5), E21-E27,
 Kara, A., Iseri, M., Durgut, M., Topdag, M., & Ozturk, M. (2016). Comparing audiological test results obtained from a sound processor attached to a Softband with direct and magnetic passive bone conduction hearing implant systems. European Archives of Oto-Rhino-Laryngology, 273(12), 4193-4198.

Baha 5 Sound Processors

Small. Smart. Powerful.

Baha® 5 Sound Processors share the same unique technology building blocks to deliver a smart and seamless hearing experience to all patients.

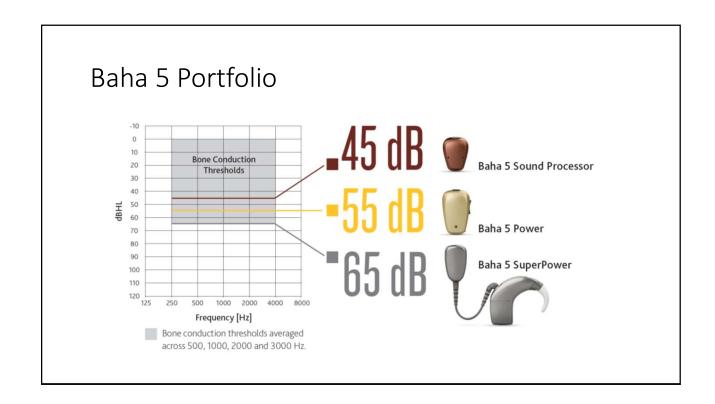


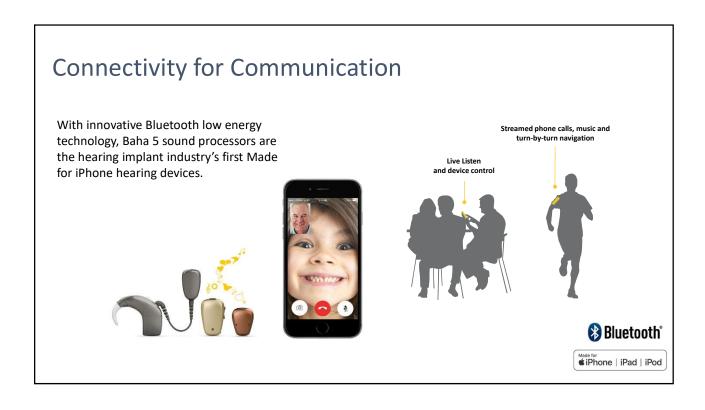
The Cochlear Nucleus 7 Sound Processor is compatible with iPhone, iPad and iPod touch. For compatibility information visit www.cochlear.com/compatibility

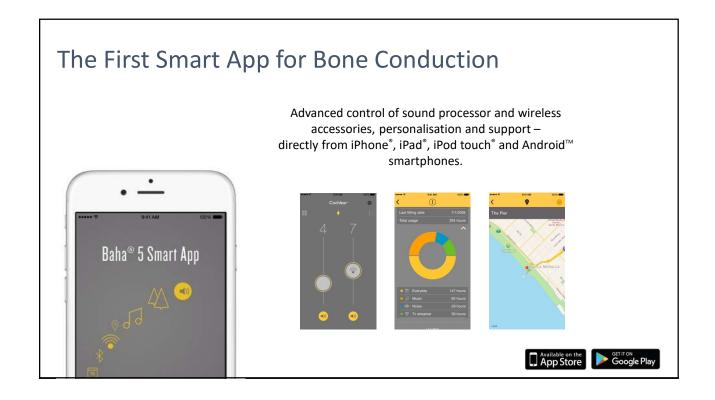
Apple, the Apple logo, Made for iPad logo, Made for iPhone logo, Made for iPhone logo, Made for iPhone logo, iPhone, iPad Pro, iPad Pro, iPad Air, iPad mini, iPad and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear is under license









True Wireless Accessories

2.4 GHz Wireless Technology

Mini Microphone 2/2+

- Range up to 82 feet[†]
- Up to 10 hours of battery life
- Drop detection mute feature
- Directional microphone
- Table mic mode*
- FM compatibility*
- Built-in telecoil*
- Line-in connector*



Phone Clip

- Hands-free connection to any Bluetooth enabled mobile phone
- Answer and end calls with one button
- Use as a basic remote control
- Up to 6 hours of talk time (80 hours of standby time)

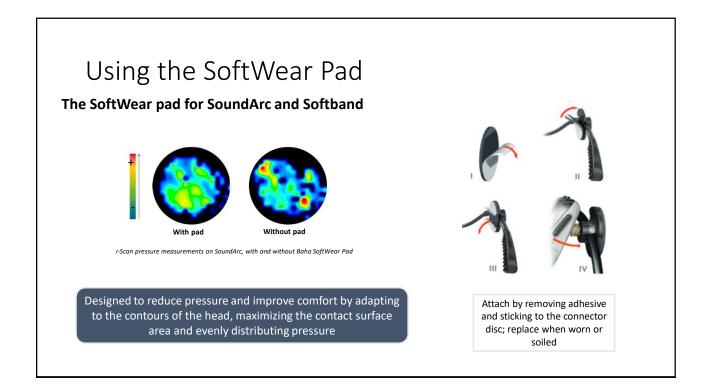
TV Streamer

- Easy to connect to virtually any analog or digital device
- Range of up to 23 feet[†]
- Install and forget just a click of a button on the processor to watch TV

*Mini Mic 2+ only †Clear line of sight

FM Capabilities with the Mini Mic 2+ Maintains dynamic FM signal across wireless connection. Mini Microphone can be placed anywhere within range and clear line of sight.

Tips for Fitting Baha in Children



Adjusting the Softband

Tighten the Softband until it is closefitting enough to be able to fit one finger between the head and connector disc. This will ensure effective sound transmission while ensuring it is loose enough so as not to cause discomfort.



It is acceptable to have variable placement of the sound processor (ie, on the forehead for infants); position compensation is disabled by default in the software for a child/softband fitting to account for this, but may be also enabled if the sound processor will be consistently placed

Adjusting the SoundArc

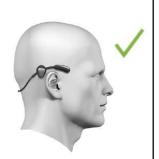
- Place just above the ears and follow the contours of the head. It should not rest on the pinna. The bow should rest against the back of the head (fig A).
- ✓ Ensure that the entire area of **the Connector disc sits flush against the skin** on the head above and behind the ear; **it should not wobble** (fig B).
- Ensure the Connector disc is in direct contact with the skin under the hair. It may be necessary to move or part the hair.
- ✓ The soft tips should rest comfortably and slightly in front of the ear (fig C).
- ✓ Interference with glasses or the pinna may cause feedback (fig D)

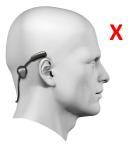












Attaching the Sound Processor

Any sound processor in the Baha Portfolio can be used with SoundArc and Softband





Attach the Baha sound processor to the connector disc

Importance of Bilateral Fitting

Audiological indications¹

- Bilateral mixed or conductive hearing loss
- <10 dB difference on average (.5, 1, 2 & 3 kHz) or
- <15 dB difference at individual frequencies

To achieve binaural hearing, bone conduction thresholds should be <u>symmetrical</u>.²



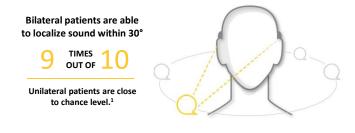
Common otological causes (pediatrics)

- Bilateral microtia/atresia
- Ear canal stenosis
- Treacher-Collins syndrome

Janssen RM, Hong P, Chadha NK. Bilateral Bone-Anchored Hearing Aids for Bilateral Permanent Conductive Hearing Loss: A Systematic review. Otolaryngol Head Neck Surg. 2012;147(3):412-22 Bosman et al; Audiometric Evaluation of Bilaterally fitted Bahas (2001). Audiology 40, 158-167

Bilateral: Improved ability to localize sounds

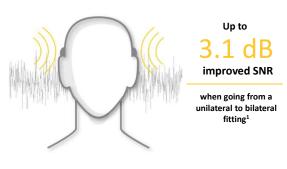
Several studies demonstrate clear localization benefits when comparing a unilateral bone conduction fitting to a bilateral fitting.¹⁻³



Localization of sound, bilateral vs unilateral¹ Within 30° 80 Score (%) 60 2000 Hz 50 500 Hz Chance 30 20 10 Bilateral

Bilateral: Improved hearing in noise

Available clinical evidence suggests that a two ear approach leads to improved hearing in noise.1-3



Difference in Speech Reception Threshold in Noise between bilateral and unilateral bone conduction implant condition

Study	N	Mean improvement in SNR with bilateral vs unilateral BCI
Bosman et al. ²	25	2.5 dB (sound and noise separated) P < .001
Priwin et al. ³	12	3.1 dB (sound and noise separated) 2.8 dB (surround sound)

Bilateral: Improved audibility

A bilateral fitting of a bone conduction solution provides a summation effect. This will improve the dynamic range and speech perception in quiet.¹



Difference in Speech Reception Threshold in Quiet between bilateral and unilateral bone conduction implant Condition

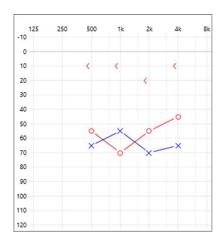
Study	N	Mean improvement in SRT with bilateral vs unilateral BCI
Bosman et al. ²	25	4.0 dB (P < .001)
Hamann et al. ³	23	4.0 dB
Priwin et al. ⁴	12	5.4 dB (P = .001)

James MR, Hong P, Chadra NR, Elabera bene anchored hearing aids for bilateral permanent conductive hearing losts: a systematic review. (Inchanged Head West-Surg. 2012;147(3):412-22 dozuma M, Silak-Y, van der Powor CF, Mighurs EA, Cremers CM, sudhorenter: coulstant on bilaterally inter

Case Studies

Manny: Introduction • Born with bilateral microtia and atresia • Diagnosed with moderate to severe hearing loss in both ears at 3 months of age • Combined microtia and atresia surgery with several follow up surgeries throughout the first 5 years of life

Manny: Audiogram (12 mos of age)



Test Method:

- Visual Reinforcement Audiometry (VRA)
- Headphones (supra-aural) for air conduction
- · Good reliability

Speech Audiometry:

Right SDT: 55Left SDT: 60

• Bone Conduction SDT: 5

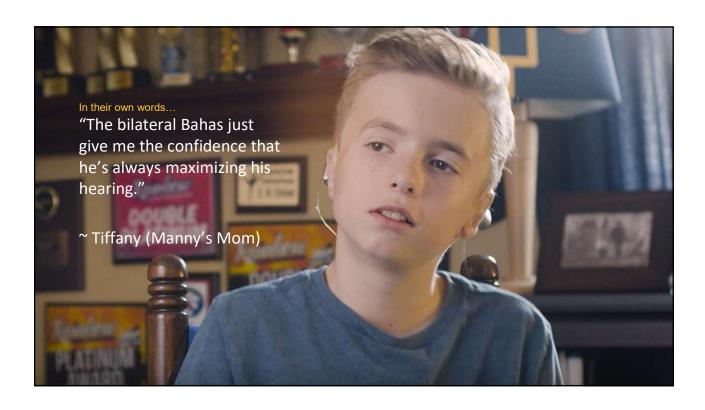
Manny: Discussion

- What would have been the best treatment option for Manny after diagnosis at 3 months of age?
- Does he have options other than Baha? If so, what are the pros and cons of a bone conduction solution?
- What options does Manny have for treatment as he grows?

Manny: Outcome

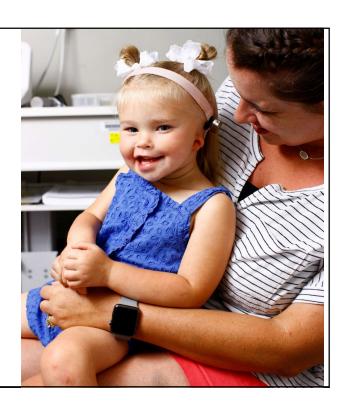


- Manny received a softband at 3 months of age; he was fit bilaterally at 12 months of age
- Thresholds were in the normal range with his Baha sound processors on the softband
- After a surgery which significantly worsened the hearing in his left ear at age 5, his family pursued a surgical Baha solution on that side and then a Baha on the other side shortly after
- Manny's family is thrilled with his progress his speech and language is age-appropriate and he attends mainstream school

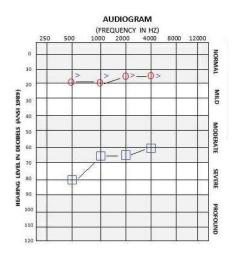


Brynlee: Introduction

- Born with unilateral microtia and atresia
- Diagnosed with moderate conductive loss in the right ear at 3 months of age
- Fit with Softband just prior to her first birthday.



Brynlee: Audiogram (18 mos of age)



Test Method:

- Visual Reinforcement Audiometry (VRA)
- Headphones (supra-aural) for air conduction
- Good reliability

Speech Audiometry:

Right SDT: 10Left SDT: 65

Brynlee: Discussion

- What would have been the best treatment option for Brynlee after diagnosis at 3 months of age?
- Does she have options other than Baha? If so, what are the pros and cons of a bone conduction solution?
- What options does Brynlee have for treatment as she grows?



Brynlee: Outcome



- Brynlee received a softband at 12 months of age
- Thresholds were in the normal range with her Baha sound processor on the softband
- Brynlee only qualifies for Deaf Education services –
 not other therapies at this time. Parents decided not
 to pursue any goals relating to that due to Brynlee
 doing well with listening/speech.
- Family is excited to meet with their surgeon to discuss implantation soon.

Conclusions

- Bone conduction is a unique treatment solution for children, especially those with conductive, mixed or unilateral hearing loss
- Cochlear offers solutions for children from Softband to SoundArc through to Baha Connect and Attract when children are ready for surgery
- Baha 5 sound processors offer wireless connectivity for FM use in the schools

