Bone Conduction Solutions for Children with Hearing Loss

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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 single-sided 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 population\(^1\)
• Conductive hearing loss in children may be permanent or temporary
• Causes may include otitis media, microtia/atrophia, genetic causes or syndromes

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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

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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 impairment\(^1\)
- Rate of chronic otitis media is estimated at 3% in North America with 22.5% occurring in children under 5\(^2\)


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 countries\(^1\)
- 29% of children with Down Syndrome have permanent mixed or conductive hearing loss; another 32% have fluctuating losses\(^2\)
- Children with cleft palate are more likely to have chronic otitis media and hearing aid use among this population is reported at around 10%\(^3\)


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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 lagged\(^1\)
- Prevalence estimates for SSD are about 1 per 1000 at birth rising to 14% of adolescents\(^1\)
- Untreated, SSD in childhood can lead to delayed speech and language development\(^2\), behavioral concerns\(^3\) and academic concerns\(^4\)


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

Using Bone Conduction to Treat Hearing Loss

Conductive and Mixed Hearing Loss

Single-Sided Deafness
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 solution\(^1\)

\(^1\) 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

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Baha® Systems

- Non-Surgical
- Baha Connect
- Baha Attract
Baha System Candidacy

**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

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

Surgery can be considered for children 5 years of age or older

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Baha System Candidacy

- **Conductive Hearing Loss**
- **Mixed Hearing Loss**
- **Single-Sided Deafness (SSD)**

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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 aids
- Hearing aid prescriptions for conductive and mixed hearing loss require more gain and receive less clinical research than for sensorineural hearing loss
- Hearing aid fitting can be difficult if there is drainage from the ear, ear pain or a mastoid cavity present after mastoidectomy

Baha System Advantages for CMHL

- Nothing worn on the external ear, which is helpful in cases where ear drainage is present 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 post-operative benefit
- Use of Baha is associated with high user satisfaction and good long-term benefit

Baha System Candidacy

Conductive Hearing Loss

Mixed Hearing Loss

Single-Sided Deafness (SSD)
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

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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 environments
• Helps to lift the head shadow effect
• Reduces the psychosocial consequences associated with hearing impairment
• Long-term patient satisfaction and hearing benefits

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 stream
• The Baha System bypasses outer and middle ear and sends clearer, more crisp sound directly to the inner ear
• Studies show that the Baha System provides better speech understanding in noise than CROS hearing aids

References:

The Baha system is a discreet solution worn on one side, while CROS hearing aids require users to wear devices on both ears.
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
- Natural progression from non-surgical option to surgical option for consistent and reliable access to hearing

Non-Surgical Options

Transfer Efficiency for Non-Surgical Options

Cochlear’s non-surgical options are designed to provide a comfortable, high-quality experience for children not yet old enough for a surgical option or to allow patients to try a bone conduction solution prior to surgery.

1 – Cochlear (2018) Design concept, technical verification and patient testing of the new Cochlear Baha SoundArc. (BUN655)

Baha SoundArc

Soft silicone tips create a snug and comfortable fit

Silicone grips for greater retention

Secure coupling, minimizes risk of feedback

Connector disc design allows easy attachment to Baha sound processors.

Custom fit spring steel band fits neatly around the head

Variety of soft colored tips to match hair, mood and clothes

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The Baha Softband

- Comfortable, non-latex material to make wearing easy
- Adjustable strap to maximize fit
- Safety release for peace of mind
- Connector disc(s)* for a secure connection to any Baha 5 sound processor
- Available in a variety of fun colors and patterns

*Bilateral option available

Baha SoftWear Pad

- Designed to reduce pressure and improve comfort by adapting to the contours of the head, maximizing the contact surface area and evenly distributing pressure

With a SoftWear pad, Softband users can demonstrate up to 3.8 dB better sound transmission.


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Non-Surgical Options

Surgical Bone Conduction Solutions
Surgical Options

- The Baha Attract provides clinically proven performance with nothing through the skin\(^1\)
- The Baha Connect’s direct connection with the implant provides the maximum possible gain\(^2\)
- Two systems with one strong foundation\(^3\)

\(^2\) Clinicaltrials.gov ID NCT01796236. Clinical and Health Economic Evaluation With a New Baha® Abutment Combined With a Minimally Invasive Surgical Technique

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 options

• Better sound transmission with a surgical option when compared to non-surgical option

• Consistent access to sound

• More discretion with surgical option


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

Graph from Kara et al (2016)

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.

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Baha 5 Portfolio

Bone conduction thresholds averaged across 500, 1000, 2000 and 3000 Hz.
Connectivity for Communication

With innovative Bluetooth low energy technology, Baha 5 sound processors are the hearing implant industry’s first Made for iPhone hearing devices.

The First Smart App for Bone Conduction

Advanced control of sound processor and wireless accessories, personalisation and support – directly from iPhone®, iPad®, iPod touch® and Android™ smartphones.
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

Using the SoftWear Pad

The SoftWear pad for SoundArc and Softband

- Designed to reduce pressure and improve comfort by adapting to the contours of the head, maximizing the contact surface area and evenly distributing pressure.

- Attach by removing adhesive and sticking to the connector disc; replace when worn or soiled.

[i-Scan pressure measurements on SoundArc, with and without Baha SoftWear Pad]
Adjusting the Softband

Tighten the Softband until it is close-fitting 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 indications

- 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 symmetrical.

Common otological causes (pediatrics)

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


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

Bilateral patients are able to localize sound within 30°

Unilateral patients are close to chance level.


Bilateral: Improved hearing in noise

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

Up to 3.1 dB improved SNR when going from a unilateral to bilateral fitting


<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Mean improvement in SNR with bilateral vs unilateral BC</th>
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<tbody>
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<td>Bosman et al.¹</td>
<td>25</td>
<td>2.5 dB (sound and noise separated) P &lt; .001</td>
</tr>
<tr>
<td>Priwin et al.¹</td>
<td>12</td>
<td>3.1 dB (sound and noise separated) 2.8 dB (surround sound)</td>
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</tbody>
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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

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</tr>
</thead>
<tbody>
<tr>
<td>Bosman et al.</td>
<td>25</td>
<td>4.0 dB (P &lt; .001)</td>
</tr>
<tr>
<td>Hamann et al.</td>
<td>23</td>
<td>4.0 dB</td>
</tr>
<tr>
<td>Priwin et al.</td>
<td>12</td>
<td>5.4 dB (P = .001)</td>
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</tbody>
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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: 55
- Left 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.
In their own words...

“The bilateral Bahas just give me the confidence that he’s always maximizing his hearing.”

~ Tiffany (Manny’s Mom)

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: 10
- Left 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