Changing the Landscape for Auditory Bone Conduction Device Recipients

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Disclosures

• I am an employee of Cincinnati Children’s Hospital. Some of the background for the case studies are derived from clinical experience.

• I am receiving an honorarium for this presentation.

• No other disclosures
Goals and Objectives

• Discuss the principles behind auditory bone conduction devices
• Describe currently available options
• Identify technological and clinical advancements in BCDs
• Provide a glimpse into the clinical utility of BCDs
How the devices work

- Sound is picked up by the bone conduction device mic
- Sound is converted into mechanical vibration
- Transferred through the bone in the skull to the **good** cochlea
- Note: better ear must have normal hearing (PTA no worse than 20dB)
Newer, but still history
Devices available today...
...at a website near you!

LF-18 Bone Conduction Bluetooth V4.1 Headset with Mic - Gray
Sports Headset / Volume Control / Multi-point Connection / Foldable Headset

Dispatch: Ships within 3-5 business days  FREE SHIPPING

$48.19

QTY: 1

Color: BLACK  WHITE  GRAY  GOLDEN

Shipping Cost to: United States

Add to Cart

www.Gearbest.com
Audio Bone 1.0

SKU: N/A.

The Audio Bone 1.0 headphone provides the best quality sound, a stylish design, and is our most popular product. It carries an IPx7 waterproof rating and is available in several stunning colors. (Be sure to increase the volume on your device as bone conduction requires higher audio input)

Pick Your Color:
To Hear More

Release the ears to listen the world, liberated the ear, far away from dangerous, response to the surrounding situation quickly, suitable for walking, running, climbing, skating, riding, sport, etc.
Osseointegrated BCD History

• Brånemark discovered osseointegration coincidentally while studying healing in damaged bone
• mid-1960’s began to be applied to dental implants in humans
• Tjellström developed applications outside of oral cavity and BAHA was born in the late 1970’s
Candidacy

- Conductive
- Mixed
- SSD
- Bilateral
- Unilateral
Statistics on Infants/Children with UHL/SSD

- **Newborns** – 1-3 per 1000 are identified through newborn hearing screenings
  - **Accuracy**: many are missed due to lack of follow-up, variations in test methods and definitions of hearing loss (Ear Hear 2000, Int’l Journal Pediatric Otorhinolarygnology 1994)

- **School-Age** – 30-56 per 1000
  - **Increase**: additional gained through progressive or late onset hearing loss (Ear Hear 1998, JAMA 1998)

- One of the most common congenital conditions affecting live births
- Under reported – reports vary from 1-3 % in 1000 births
- Limited research studies – past and present
- Conflicting findings in studies – problems vs no problems, Left ear vs Right ear, etc.
- Uncertainty about factors that need to be studied
Congenital Unilateral Aural Atresia

- Occurs in about 1/10,000-20,000 births
- Causes a “maximum conductive hearing loss”
- Often presents reconstructive challenges resulting in many of these patients being poor candidates for surgical consideration

- Treatment options:
  - Surgery
  - Amplification
  - No intervention
## Etiology for SSD

<table>
<thead>
<tr>
<th>Cause</th>
<th>Frequency of Occurrence</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMV – Congenital Cytomegalovirus</td>
<td>Leading cause of UHL; 2-2.5 % of all live births</td>
<td>Leung et al., 2003; Nance, 2007</td>
</tr>
<tr>
<td>Bacterial Meningitis</td>
<td>~30% result in at least UHL</td>
<td>Kutz et al., 2006</td>
</tr>
<tr>
<td>Viral/Bacterial Mumps</td>
<td>~80-95% of hearing loss result</td>
<td>Unal et al., 1998</td>
</tr>
<tr>
<td>EVAS – Enlarged Vestibular Aqueduct Syndrome</td>
<td>~20% of cases are UHL</td>
<td>Covaerts, et al., 1999</td>
</tr>
<tr>
<td>Chiari Malformation</td>
<td>~ 65 % UHL</td>
<td>Simons et al., 2008</td>
</tr>
<tr>
<td>ANSD – Auditory Neuropathy Spectrum Disorder</td>
<td>Most cases are bilateral but some are UHL</td>
<td>Podwall et al., 2002</td>
</tr>
<tr>
<td>Sudden Sensorineural Hearing Loss</td>
<td>~85% in children are UHL</td>
<td>Roman et al., 2001</td>
</tr>
<tr>
<td>Atresia</td>
<td>Occurs 1 in 10,000; 70% are UHL</td>
<td>Schuknecht, 1989</td>
</tr>
<tr>
<td>Gap Junction Beta 2 (Connexin 26)</td>
<td>Over 80 mutations are known; most are profound</td>
<td>Kenna et al., 2001/Wilcox et al., 2000</td>
</tr>
<tr>
<td>Prematurity</td>
<td>~5% of premature babies have HL</td>
<td>Herrgard, et al., 1995</td>
</tr>
</tbody>
</table>
The Effects of SSD

- Difficulty *localizing* the sound source
- Difficulty *hearing in noisy situations*
- Difficulty *hearing from a distance*
- *Turns head* to hear better
- Often *misunderstands* what people say
- Frequently *asks people to repeat* or asks, "What?"
The Effects of Unilateral Conductive Hearing Loss

- Difficulty *localizing* the sound source
- Difficulty *hearing in noisy situations*
- Difficulty *hearing from a distance*
- *Turns head* to hear better
- Often *misunderstands* what people say
- Frequently *asks people to repeat* or asks, "What?"
Candidacy

- Unilateral or bilateral conductive or mixed hearing loss (up to 55 dB SN component) who are unable to wear conventional (air conduction) hearing aids due to:
  - Chronic OM
  - Congenital malformations of middle/external ears
  - Acquired malfunctions of middle/external ears
- Patients who have a chronic conductive/mixed hearing loss who are doing poorly with traditional amplification
- Single-sided deafness or unilateral hearing loss with poor discrimination ability.
Candidacy

Conductive Hearing Loss
• PTA BC threshold ≥ 20dB HL at .5, 1, 2, 3 kHz
• Speech discrimination score 60% or better
• AC threshold can be equal to or poorer than BC
• Air-bone gap >30 dB is best

Examples:
• Chronic Otitis Media
• Abnormal EAC patency
• Otosclerosis
• External Otitis
• Congenital Malformations
• Cholesteatoma
Candidacy

Mixed Hearing Loss

- PTA BC threshold $\geq 45$ dB HL at $0.5, 1, 2, 3$ kHz
- Speech discrimination score 60% or better
- AC threshold can be equal to or poorer than BC
- Mild-moderate SNL

Examples:
- Chronic Otitis Media
- Abnormal EAC patency
- Otosclerosis
- External Otitis
- Congenital Malformations
- Cholesteatoma
Candidacy

Unilateral Sensorineural Hearing Loss

• One ear profound SNHL
• One ear PTA AC threshold $\leq 20$ dB HL at .5, 1, 2, 3 kHz

**Examples:**

• Trauma
• Viral Infection
• Measles
• Chicken Pox
• Sudden SNHL
• Meniere’s Disease
• Acoustic Neuroma (translab approach)
Candidacy

• Single sided deafness
  ▪ Sound is picked up by the bone conduction device and transferred through the bone in the skull to the good cochlea
  ▪ Better ear must have normal hearing
    ▪ (PTA no worse than 20dB at 500, 1000, 2000 & 3000 Hz)
Candidacy- summary

• Conductive hearing loss
  – When traditional hearing aids are contraindicated

• Single-Sided Deafness

• Mixed hearing loss
  – bone conduction thresholds worse than 35 dB will require power device
  – When traditional hearing aids are contraindicated
Indications for Considering Implantable Device

• Skin Allergies caused by ear mold
• Congenital malformations
• Draining ears
• Ear canal stenosis
• Previous ear surgery
• Radical cavity
• Syndromic hearing losses
• Reasonably good cochlear reserve
• Must be able to manage after-care
Candidacy- contraindications

• No surgery for patients under 5 years old. Softband option available on all surgical BCDs.

• Contraindications

  • Speech discrimination scores poorer than 60% for patients with conductive/mixed hearing losses
  
  • Patients incapable of maintaining abutment hygiene

    *new advancements to be discussed later in presentation

• Patients who have SSD and the contralateral ear AC PTA is worse than 20dBHL for the frequencies of .5, 1, 2, and 3KHz
Fitting

• Softband
• Post and abutment
• Magnetic
• In-the-ear
• Others?!?
Current Devices

- Cochlear Baha
- Oticon Medical Ponto
- Sophono
- TransEar by EarTechnologies
Oticon Medical

• **Bone anchored hearing system (Ponto)** by Oticon Medical
  • Ponto/Ponto Pro – digitally programmable processor
  • Ponto Pro Power – digitally programmable power processor (up to 55 dB HL bone threshold)
  • Programmed on Oticon’s software which incorporates many of the features of Oticon hearing aids
  • Ability to complete in-situ bone conduction measurements
Oticon Medical Ponto
(surgically implanted post)

• An abutment is surgically implanted into the bone and the hearing aid device is separately attached – only for children 5 years and older
• Osseointegration requires 3-6 months to complete (device may be worn on softband during that time)
• Ponto Plus fit on abutment once surgeon has given clearance
• Uses Ponto Streamer for wireless connection (optional accessories available
• FM input with MLxi universal receiver via streamer
Ponto Streamer
Cochlear Baha

- Digitally programmable power processor - can fit up to 55 dB bone threshold
- Ability to complete in-situ bone conduction measurements (BC Direct)
- Softband (unilateral and bilateral)
The Cochlear™ Baha® 5 SuperPower
Recently Approved By the FDA
Cochlear Baha Connect
(surgically implanted post)

• An abutment is surgically implanted into the bone and the hearing aid device is separately attached – only for children 5 years and older
• Osseointegration requires 3-6 months to complete (device may be worn on softband during that time)
• Baha can be fit on abutment once surgeon has given clearance
• Wireless accessories available for Baha 4 and 5
Possible Complications from Transcutaneous approach

- Bone too thin or soft
- Post-operative infection
- Implant extrusion
- Loose abutment
- Soft-tissue overgrowth
Cochlear Baha Attract

• Magnet is surgically implanted under the skin and the device attaches to the magnets
• FDA approved for children 5 years and older but Cochlear suggests waiting until 8 years.
• Device may be fit approximately 4-6 weeks post-surgery (time may vary due to healing time of the skin).
Connect vs. Attract

Baha 5 Connect System
Measured on skull simulator TU1000.

Baha 5 Attract System
Measured on Artificial Mastoid IEC 60318-6.

Graphs showing:
- Maximum output force level
- Full-on gain

Frequency [Hz]
Output force level [μl/μl]
Wireless!!

Cochlear™ Wireless Mini Microphone 2+

Ultimate performance with full connectivity

- FM compatibility
- Built-in Telecoil
- Line-in connector
- Range up to 82 feet (25 meters)*
- Up to 11 hours battery life
- Directional microphones
- Table Mic Mode
- Drop detection mute feature
- Volume lock and volume indicators
- Battery status indicator
- Swivel clip

3 x the range¹

FM & Loop connectivity

50% longer battery life¹

Cochlear Wireless Phone
Clip

Cochlear Wireless TV Streamer

Cochlear App Portfolio
Apps

• Baha 5 Smart App
  Compatible with iPhone, iPad
• Baha Control App
  Compatible with iPhone, iPad and iPod touch
  and Android smartphones. Requires Cochlear Wireless Phone Clip.
• Baha Support App
  Compatible with iPhone, iPad and iPod touch
  and Android smartphones.
BAHA/PONTO Pros and Cons

**Pros:**
- Osseointegration provides excellent sound conduction
- Good ear is unoccluded
- Easy to maintain and use
- Can be used on a softband until surgery is an options (≥ age 5)
- FM compatible

**Cons:**
- Requires surgery and recovery time
- Requires consistent cleaning to maintain site of abutment
- Occasional problems with abutment and surgical site
Sophono

- Conductive hearing loss and SSD
- Subcutaneous magnetic plate is secured to the mastoid bone by maxillo-facial screws.
- Processor attaches externally when coupled to an acrylic plate (used to disperse pressure equally and decrease soft tissue breakdown from pressure between magnets).

Sophono

- Digitally programmable processor
- Decreases concerns for infection and skin breakdown by eliminating percutaneous post.
  - Good for patients where there is concern for hygiene and cleanliness of surgical site.
- Poor choice for patients who receive serial MRIs due to magnets.
Sophono
(surgically implanted magnet)

- Alpha 2 MPO by Sophono
- Magnet is surgically implanted under the skin and the device attaches to the magnets
- FDA approved for children 5 years and older
- Device may be fit approximately 4-6 weeks post-surgery (time may vary due to healing time of the skin).
- May also be worn on a softband
- Direct FM input available (MLxi universal)
Sophono Alpha Pros and Cons

Pros:
- No post/abutment protruding through the skin
- Easy to maintain and use
- Good ear is unoccluded
- Can be used on softband until surgery is an option (age ≤ 5)
- FM compatible

Cons:
- Requires surgery and recovery time
- Not many outcomes studies performed in the US
- Possible challenges with magnet strength and pressure sores
Trans-cranial Bone Conduction

- **TransEar by Ear Technology**
  - Only used for patients with SSD
  - Sound is picked up by a speech processor *behind the ear*
  - Sound is then sent to the *transfer unit in the ear* to vibrate the bony portion of the ear canal
  - Sound is perceived by the good cochlea
TransEar Pros and Cons

**Pros:**
- Does not require surgery
- Good ear is not occluded
- Easy to use
- Single device

**Cons:**
- Behavioral test results may not show as much benefit as other device options
- May need to re-case transfer unit in younger children
- Pieces may disconnect (transfer unit, connector wire and speech processor)
- Not FM compatible
What we already know:

• Treatment options for single-sided deafness and unilateral max conductive hearing loss are often overlooked as the patient typically has one good hearing ear.

• Despite evidence reported in past literature regarding the difficulties experienced by patients with SSD and unilateral max conductive hearing loss, they often do not receive intervention.
What we already know:

- Difficulties reported in the literature and anecdotally by patients, parents, and educators include:
  - poor speech perception in background noise
  - decreased localization ability
  - and academic challenges

- While one intervention may not provide sufficient benefit for one patient, another could perceive a more favorable outcome
Snapp H, et al. (2010)
- there is no established protocol for determining candidacy, fitting methods, or expected outcome

Danhauer J. (2010)
- Lack of evidence supporting a strong recommendation for use of Baha in patients with CUAA
- Clinicians, patients and parents should not be discouraged from considering the Baha ... especially considering that noninvasive Softband trials can be conducted...
Currently, there is no established protocol specific to these patient populations.

We probably could not apply a single protocol to all patients...
Evidence Based Practice

Knowledge of possible outcomes, and the collection of data as we evaluate and treat patients, can only contribute further to improved patient care.
Thinking Outside of the “Box”
Gratitude

• Patients

• Colleagues:
  – Lori Garland
  – Annemarie Wollet
  – Tim Nejman
  – Jill Stephens
  – Jeanie Hamilton
  – John Greinwald
  – Dan Choo
ANY QUESTIONS?

Thank You

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