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PEDIATRIC BONE ANCHORED IMPLANTS:
PROTOCOLS AND STRATEGIES

Consultant for Cochlear Americas BAS

DISCLOSURE

Osseointegrated devices have treating conductive and mixed hearing loss since 1977.
Works through direct bone conduction.
Sound is conducted through the skull bone bypassing the outer and middle ear and stimulating the cochlea.

Contains three parts:
- titanium implant
- external abutment
- detachable sound processor

BONE ANCHORED IMPLANTS

- BAHA – Entific Medical Systems
- Baha ™ Cochlear Americas
- Ponto – Oticon Medical
- Osseointegrated implants
- Bone Anchored Implants – BAI
- Aided testing – B

CANDIDACY

- Softbands
  - No age restrictions
  - Bilateral CHL
  - Bilateral MHL
  - SSD or unilateral losses
  - Unilateral or bilateral softbands available

- Implants
  - FDA – age 5 years old or older
  - FDA: Bilateral implants (can be simultaneously implanted) must be symmetric bone conduction thresholds less than 10 dB difference on average (500, 1000, 2000, and 3000 Hz) or less than 15 dB at individual frequencies
CANDIDACY

- Conductive Hearing Loss
  - TCS
  - Atresia/microtia
- MHL implants
  - Bilateral with BC PTA or 35 dB or less for children (Christensen)
  - Power devices
  - 5 years of age as other implantation guidelines
- Single sided deafness (SSD)
  - Unilateral hearing loss profound SNHL, MHL, or CHL
  - Normal (15 dB or less) in the “good ear”
  - Softband

SOFTBAND FITTING

- Placement of Baha Softband
  - Infants - not always on mastoid
  - Toddlers
  - Preschoolers
- Fitting the Softband
  - Helping parents find the perfect fit
- Functional gain/aided audiogram

SOFTBANDS: WHEN TO FIT

- Bilateral CHL/MHL will be fit ASAP
  - Just like traditional hearing aid fittings
  - Some will be implanted when they are 5 years old
  - Some will receive other surgical intervention
- Unilateral losses (SNHL/MHL/CHL)
  - fit at 9 to 12 months of age when we can get a Softband near the affected ear on a full-time basis

SOFTBAND VERIFICATION

- For bilateral CHL/MHL most common verification is Functional Gain
  - under 6 months of age – BOA
  - Testing Babies, You Can Do It! Behavioral Observation Audiometry (BOA)
  - by Jane R. Mandell
  - over 6 months – VRA, CPA, etc
- Outcome measures
- SLPs/AV Therapists
SOFTBAND VALIDATION

Any validation measure you currently use for other traditional BTE fittings with children will work well with softband validation for bilateral CHL/MHL.

Karen Anderson  - Success for Kids with Hearing Loss

When in doubt... follow the rules

- State licensure laws for verification and validation of hearing aids and implantable devices
- Clinical practice guidelines (AAA, ASHA, etc)

ARKANSAS LICENSURE LAW

Evaluation of hearing aids must be performed with the hearing aids on the patient. This shall be accomplished EITHER in sound field OR with instruments which objectively measure hearing aid performance with appropriate prescriptive techniques to account for the different means of programming the hearing aid (linear versus nonlinear, digital versus analog). The preferred verification method of fitting is to use probe microphone measures in conjunction with the patient’s ear, ear mold, and personal amplification system. A real ear to coupler difference (RECD) can be obtained and probe tube measurement performed in a coupler if a patient is unwilling to tolerate probe microphone measurement in the ear. A prescriptive measure addressing gain should be in place to address the possibility of over- or underestimating gain until the patient is five (5) years of age.

AAA CLINICAL PRACTICE GUIDELINES PEDIATRIC AMPLIFICATION JUNE 2013

3. AUDIOLOGIC CANDIDACY CRITERIA (page 12)

Recommendations for Determining Candidacy

Children with permanent conductive hearing loss should be fit with air conduction hearing aids when anatomically possible (sufficient external ear and canal anatomy to support the coupling of an earmold and retention of the device), or bone conduction hearing aids if anatomy is insufficient for coupling (atresia, chronically draining ears, or other significant anatomical malformations).
2. In cases of bone conduction hearing aids, real-ear probe microphone measures cannot be conducted (when there is no acoustic signal in an ear canal), and the aided audiogram may be the most readily available verification option. In spite of its limitations, the aided audiogram can provide information, and in the case of bone conduction and frequency transposition/compression hearing aids, may be the most valid way to quantify the aided response with currently available technologies.

SOFTBAND CASE 1

- DOB 3/30/2010
- Female
- 36 weeks gestational age
- 3 lbs.15 oz.
- Failed NBHS in rural part of Arkansas
- No family history of hearing loss
**SOFTBAND CASE 1**

- Seen at 4 months of age for follow up NBHS
- Tech notes ear pit right ear
- Type B high frequency tymps AU
- Failed OAEs AU

**SOFTBAND CASE 1**

- ENT examination – Stenosis and No TM identified in the clinic
- ABR at 7 months - During possible PET placement was consistent with a Moderate CHL AU

**SOFTBAND CASE 1**

- Loaner device fit at 8 months old
- Personal Softband fit at 9 months 22 days

**SOFTBAND CASE 2**

- Cleft palate
- Chromosome deletion 18p
- Failed NBHS and follow up screenings
  - NO atresia
  - NO stenosis
- Behavioral testing at 6 months consistent with moderate/severe CHL
SOFTBAND CASE 2

- Fit with loaner device 6 months
- Personal Baha fitting at 8 months
- Numerous repairs...

SOFTBAND CASE 2

- Fit with BP100 at 2 years of age
  - Titanium
  - Lockable battery door
  - Moisture resistant
- Importance of pediatric features
  - Softbands
  - Loaners

SOFTBAND CASE 3

- Down Syndrome
- 8 years old at the time of initial fitting
- Raised by great grandparents at the time and due to dexterity issues a Softband was the best option for the family
- Also allowed for less adjustments by the audiologist
Reimbursement for Softbands?

1. Key phrases
   - Cannot benefit from traditional BTEs
   - Malformation
   - Congenital

2. Provide data

SOFTBAND FUNDING

SOFTBAND DATA

- Hol et al 2005
  - Two subjects
  - 3 y/o and 29 months
  - Compared Baha Compact, Baha Classic, and Oticon E 300 P
  - The electro-acoustic measurements showed minor differences in gain between the three devices
  - Both children showed speech and language development that was in accordance with their cognitive development.
  - Conclusions: The Baha Softband was a valid intervention in children with congenital bilateral aural atresia who were too young for percutaneous Baha application

Arkansas Children’s Hospital
- A retrospective study of Baha charts of 20 infants and children 2002 to 2006
- 20 infants and children
- 8 months to 16 years (mean age = 5.04 years)
- Inclusion criteria was:
  (a) bilateral symmetrical conductive hearing loss
  (b) fit with Baha at ACH
  (c) consistent full-time Baha use on a Softband
  (d) followed at ACH for 6 months or longer


10/24/13
**IMPLANTATION**

Surgical procedures
- FDA recommendations - 5 years and older
- 1 stage vs. 2 stage surgeries
- Osseointegration
- Wait times
- New surgical techniques
- New technology

**PRE-SURGICAL CONSIDERATIONS**

- History
  - Progressive HL?
  - Sudden HL?
- CT
  - EVA5?
  - Other middle or inner ear anomalies?
- Family and child must be motivated
- Hygiene/ability to care for abutment by family and/or child
  - Complications happen and should be discussed

**IMPLANTATION**

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**IMPLANT CASE 1**

- 7 years old
- Wore BTEs for bilateral moderate CHL
- Normal pinnas AU
- Chronic otitis externa
- Implanted bilaterally with a two stage surgery 6 months osseointegration period between two stages

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IMPLANT CASE 1

- Family choice
- Aided thresholds were similar
- Never wore a Softband
- Chronic otitis externa was their priority
- Still uses FM as she did with the BTEs

TRADITIONAL BC AIDS VS. BAH A SYSTEM

- Why choose bone anchored implants over traditional bone conduction aids?
- Is it worth the money?
- How does a traditional bone conduction aid compare to the Softband? To an implanted Baha?


- 3 conditions:
  - Baha implanted unilaterally
  - Baha coupled to a headband
  - Baha coupled to the test band

- Results
  - Headband vs. test band were similar
  - Implantation was superior to both headband and test band
Retrospective study of 10 subjects
(a) 6 months to 18 years of age
(b) congenital bilateral conductive hearing loss
(c) initially fit with a traditional bone conduction hearing aid
(d) fit unilaterally with a Baha Compact or Divino via the Softband
(e) implanted unilaterally with the Baha system
(f) unaided and aided soundfield thresholds available for four frequencies from 500 Hz to 4000 Hz
(g) consistent full-time use of amplification

• Ear and frequency specific thresholds obtained via supra aural headphones at 500, 1000, 2000, and 4000 Hz were recorded on datasheets and transferred to an Excel sheet

• Audiometric data for frequency specific unaided and aided soundfield thresholds obtained with the speaker positioned at a 90° azimuth to the target ear were also transferred to an Excel sheet

**RESULTS**

Bone conduction transducer provides the most gain of any device tested
The implanted Baha system provided second highest amount of functional gain
Softband results provided the third amount of highest functional gain.
Traditional bone conduction hearing aids provided the least amount of functional gain.

There is some overlap among devices at 1000 Hz, but at no other frequency.
Implanted Baha has statistically as much gain as a bone conduction transducer at all frequencies tested.
Implanted Baha provides statistically more gain at 500 Hz than the Baha attached to a Softband
Traditional bone conduction hearing aid provides significantly less gain than all the other devices at all frequencies with the exception of the Baha with Softband at 2000 Hz.

PREVIOUS RESEARCH

- 'Audiometric Evaluation of Bilaterally Fitted Bone-anchored Hearing Aids'
  - 25 adults
  - Aged 12 to 69 years of age
  - Required at least 3 months experience with bilateral Baha implants
  - All had symmetrical bone conduction thresholds across 0.5, 1, 2, and 4 kHz
  - Baha Classic (no longer manufactured)

BOSMAN ET AL RESULTS

- Results:
  - Better localization skills
  - Better speech in noise
  - Better Binaural Masking Level Difference (BMLD)
    - The masked threshold of a signal can sometimes be lower when listening with two ears rather than one
    - The detection of a signal in noise is improved when either the phase or level differences of the signal at the two ears are not the same as the masker.
- Conclusions:
  - Results for localization, speech in noise and BMLD measurements indicate that bilateral Baha "do indeed result in binaural hearing" to an extent.

BILATERAL CASE 1

- 18 year old female
- TCS
- First implanted unilaterally in another state
- Received second implant approximately 2 years after the first implant
**Hearing In Noise Test (HINT)**
- 10 sentences that are scored based on the number of words repeated correctly.

- Left Baha
  - +10 dB S/N ratio = 80%

- Right Baha
  - +10 dB S/N ratio = 82%

- Bilateral Baha
  - +10 dB S/N ratio = 91%

**DI George Syndrome**
- Mixed Hearing Loss
- Malformed outer, middle, and inner ear
- Wore BTEs since shortly after birth
- Terrible balance/vestibular problems...Tons of repairs!!!
- Used Bilateral Softband prior to implantation
- Bilateral Implants

**BILATERAL CASE 1**

**BILATERAL CASE 2**

**SINGLE SIDED DEAFNESS (SSD)**
SINCE 1986...UNILATERAL HEARING LOSS...

- 35% failed at least one grade
- 13.3% were in need of some special resource assistance
- 20% were described by teachers as having behavioral problems
- 50% showed some difficulty in educational progress

(Bess & Tharpe, 1986)

UNILATERAL LOSSES

- Judith Lieu, MD
  - Washington University

- 70% of children with unilateral loss have IEP

- Unilateral loss IS associated with worse speech and language scores in children


UNILATERAL LOSSES

1. FM systems
   - Personal or soundfield
   - Works well for elementary grades
2. Preferential classroom seating
3. Counsel it away
4. Hearing aids
   - 50% parents report “never” wearing it (Davis et al 2004)
5. CROS
6. BAI

AAA CLINICAL PRACTICE GUIDELINES

PEDIATRIC AMPLIFICATION JUNE 2013

AUDILOGIC CANDIDACY CRITERIA (p 12)

Recommendations for Determining Candidacy

1. Children with aidable unilateral hearing loss should be considered candidates for amplification in the impaired ear due to evidence for potential developmental and academic delays. Children with unilateral hearing loss are at greater risk than children with normal hearing for speech and language delays and academic difficulties. For children with severe or profound unilateral hearing losses and normal hearing in the other ear, Contralateral Routing of Signal (CROS) or bone conduction devices may be considered depending on the child’s age and ability to control their environment. Currently there is a paucity of data available to inform these decisions.
Unilateral Hearing Loss

Contralateral routing of the signal (CROS) and Bilateral routing of the signal (BICROS) fittings are specially designed for patients having either unilateral hearing loss or bilateral asymmetrical hearing loss where one ear is unaidable, respectively. Currently, wired and wireless configurations are available. For the child with unilateral deafness, an FM system with the wireless remote microphone receiver portion coupled to the open, good ear may be preferable in classroom situations to the CROS arrangement to give the benefit of increased signal to noise ratio, a benefit in a noisy classroom. The transcranial CROS is an option for individuals who have no auditory response in one ear. In this configuration, a powerful hearing aid is fit to the non-responsive ear so interaural attenuation is overcome and sound is perceived by the functioning cochlea. This is not a common fitting for children and again, an appropriately fit assistive listening device may be a better communication solution in the classroom. The osseointegrated hearing device described earlier also can be used as an implanted transcranial CROS; evidence supporting benefit of this arrangement in children is limited.

### Unilateral Hearing Loss

- **CROS**
  - Shapiro 1997 Archives of Otolaryngology
    - 10 children (7 to 17 years) fit with CROS
    - Results based on teacher report and parent report (how much use? Was child forced to use it?)
    - 7 of 10 children were considered successful with CROS
  - Kenworthy 1990 Ear & Hearing
    - Speech recognition abilities of children with unilateral SNHL – goal
    - Compared unaided; CROS and personal FM
    - FM system was the only audiological recommendation that did not produce a marked reduction in speech recognition in at least one listening environment

- **BAHA & SSD**
  - Shapiro 1994 JAAA
    - 6 children amplification and CROS did not improve speech understanding in noise and had detrimental results in noisy situations.

- **SSD Guidelines**
  - CHL or SNHL – unaidable by traditional amplification options
  - Normal ear must be NORMAL and without known risk or progression
  - Testing using “power” device coupled to a metal headband
  - Ability by family and/or child to care for abutment properly
  - Counseling pre-implant to verify the family and child knows the benefits and limitations of the Baha
    - This is NOT a cure for their hearing loss.
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**SSD EVALUATION**

- Speech in noise testing
  - Testing with and without noise
  - Hearing in Noise Test (HINT) (Nilsson, Soli, and Sullivan, 1994); Words in Noise (WIN) (Wilson, 2003; Wilson and Burks, 2005); QuickSIN (Etymotic Research, 2001; Killion et al., 2004).
  - Bamford-Kowal-Bench SIN (BKB-SIN) (Etymotic Research, 2005; Bench, Kowal, and Bamford, 1979; Niquette et al., 2003).

- Outcome Measures
  - Use testing that looks at “listening skills” also not just “hearing”
  - CHILD (5 to 12 year olds)
  - SSQ (13 years and older)
  - LIFE

**WAIT...WHAT IF IT’S AN INFANT OR TODDLER?**

- Speech in noise
  - Body parts
  - WIPI
  - SRT/SAT
  - Spondee Picture Cards

- Outcome Measures
  - Must be parent measures
  - SLP evaluations

**SSD CASE 1**

- 17 Y 6M female
  - Normal hearing left ear; Profound (no response) right ear
  - Seen yearly to monitor loss
  - In office trial and testing
  - Single stage surgery

**Pre-implant Testing**

- HINT
  - +10 SNR = 100%
  - +5 SNR = 100%
  - 0 SNR = 68%
  - -5 SNR = 23%

- SSQ
  - Speech = 4.29
  - Spatial = 1.47
  - Quality = 5.61

**Post Implant Testing**

- HINT
  - +10 SNR = 100%
  - +5 SNR = 100%
  - 0 SNR = 100%
  - -5 SNR = 36%

- SSQ
  - Speech = 9.07
  - Spatial = 9.06
  - Quality = 8.89
SSD CASE 2

- 13 year old female
  - Normal hearing right ear
  - Profound left ear – absent VIIIth nerve
  - Yearly monitor of hearing loss

SSD CASE 2

- Pre-implant Testing
  - HINT
    - +10 SNR = 79%
    - +5 SNR = 60%
    - 0 SNR = 23%
  - SSQ
    - Speech = 6.86
    - Spatial = 5.06
    - Quality = 7.76

- 3 Months Post Implant
  - HINT
    - +10 SNR = 100%
    - +5 SNR = 100%
    - 0 SNR = 96%
    - -5 SNR = 96%
  - SSQ
    - Speech = 9.79
    - Spatial = 9.59
    - Quality = 9.00

SSD REIMBURSEMENT

1. Catch Phrases
   - Congenital
   - Cannot benefit from traditional amplification

2. Show HINT and CHILD/SSQ scores
   - Everyone gets percentages

3. Provide the data

SSD REIMBURSEMENT

- Average scores for all 26 subjects
  - Pre-implant
    - 0 SNR = 41%
    - +5 SNR = 76%
    - +10 SNR = 95%
  - Post-implant
    - 0 SNR = 82%
    - +5 SNR = 97%
    - +10 SNR = 99%
CHILD RESULTS

Scores 1 to 10 on 15 situations
Average scores for all 25 subjects
Parent Version Pre-Implant = 4.58
Child Version Pre-Implant = 4.50
Parent Version Post-Implant = 7.19
Child Version Post-Implant = 7.24

SSD DATA


UNPUBLISHED SSQ RESULTS

- SSQ Pre-Implant (N=9)
  Speech = 4.20
  Spatial = 2.41
  Quality = 5.40

- SSQ Post-Implant 3 months (N=9)
  Speech = 7.87
  Spatial = 6.60
  Quality = 7.70

UNILATERAL CHL
16 year old male

- Atresia right ear; Normal hearing left ear

**UNILATERAL CHL CASE**

**Pre-implant Testing**

- **HINT**
  - +10 SNR = 100%
  - +5 SNR = 92%
  - 0 SNR = 73%
  - - 5 SNR = 12%

- **SSQ**
  - Speech = 5.60
  - Spatial = 7.18
  - Quality = 7.76

**3 months**

- **HINT**
  - +10 SNR = 100%
  - +5 SNR = 98%
  - 0 SNR = 91%
  - - 5 SNR = 11%

- **SSQ**
  - Speech = 8.14
  - Spatial = 8.69
  - Quality = 8.58

**THE FUTURE: SSD AND BAI**

**WHAT ABOUT COCHLEAR IMPLANTS?**

- Prosper Meniere Society Meeting, Austria
  - Japan
  - Adults only

- Audiology Today, Jennifer Torres & Daniel Zeitier, September/October 2013
  - 10 year old with UHL

  "By all accounts, the patient was noted to be a bright student and was not having any noticeable trouble hearing in the classroom, in after school or social activities, or in the home. In fact, the patient reports that many of her friends didn’t realize she had hearing loss until she decided to tell them “so they would not think I was ignoring them.” However, her family admits they made some significant lifestyle modifications to adapt to the patient’s UHL as well as to preserve the hearing she had left (i.e., infrequent restaurant dining, no live sporting events, no firework shows)."

- Tried CROS but did not like wearing a device in her hearing ear

- Used BAI with softband, which she liked (and had slightly better test results) but insurance denied

- CI (which insurance approved)

  - At 3 months post-op testing SNR loss with the CI was increased to 3 dB SNR indicating that the patient did not perform any better with the CI than she did with the CROS or the BAI during preoperative testing conditions.

  - However subjectively the patient greatly preferred the CI
WILL WE STILL NEED BAI FOR SSD?

- Cochlear malformations
- Absent VIII nerves

COMPLICATIONS

- Retrospective study on extrusion rate
- 57 children
- 20 adults
- 3mm and 4mm implants used
- Mean age
  - 12 years 3 months for the children
  - 52 years for the adults

COMPLICATIONS

- Complication rates in Arkansas
  - 21% for children
Young age
Syndromic status
Possible failure to penetrate the inner cranium
Soft tissue infections
Local trauma

All of these factors are assumed to be the cause of the complication rate in children.