



**Vanderbilt Bill Wilkerson Center for Otolaryngology  
and Communication Disorders**

# **Bone Conduction Implants**

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# Outline

- Overview of Bone Conduction Implants
  - History
  - Surgery
  - Candidacy
- New Devices
- Selection/Verification/Validation

● Disclosure: *I do not have any financial or other relationship with any vendor or manufacturer represented in the following discussion(s).*



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# History

- First application of titanium implants in the temporal bone was in 1977
- Pioneered in Gothenburg Sweden
- Has become a well-established and successful method of auditory rehabilitation
- Initially for conductive and mixed hearing losses, but now used for single sided deafness



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# PATHWAYS for bone conduction

- Ear canal: cartilaginous portion of ear canal resonates, creates sound waves in canal to strike TM
  - Most sound leaks out the open EAC
- Middle ear: as skull moves with sound vibrations, the bony chain swings/sways and causes vibrations to the inner ear (similar to air conduction hearing aid)
- Inner ear: bones of the skull are compressed; this movement causes changes in size and shape of cochlea which creates fluid movement and triggers response



# Composite BC Stimulation

**OUTER, MIDDLE, & INNER  
ear stimulation**

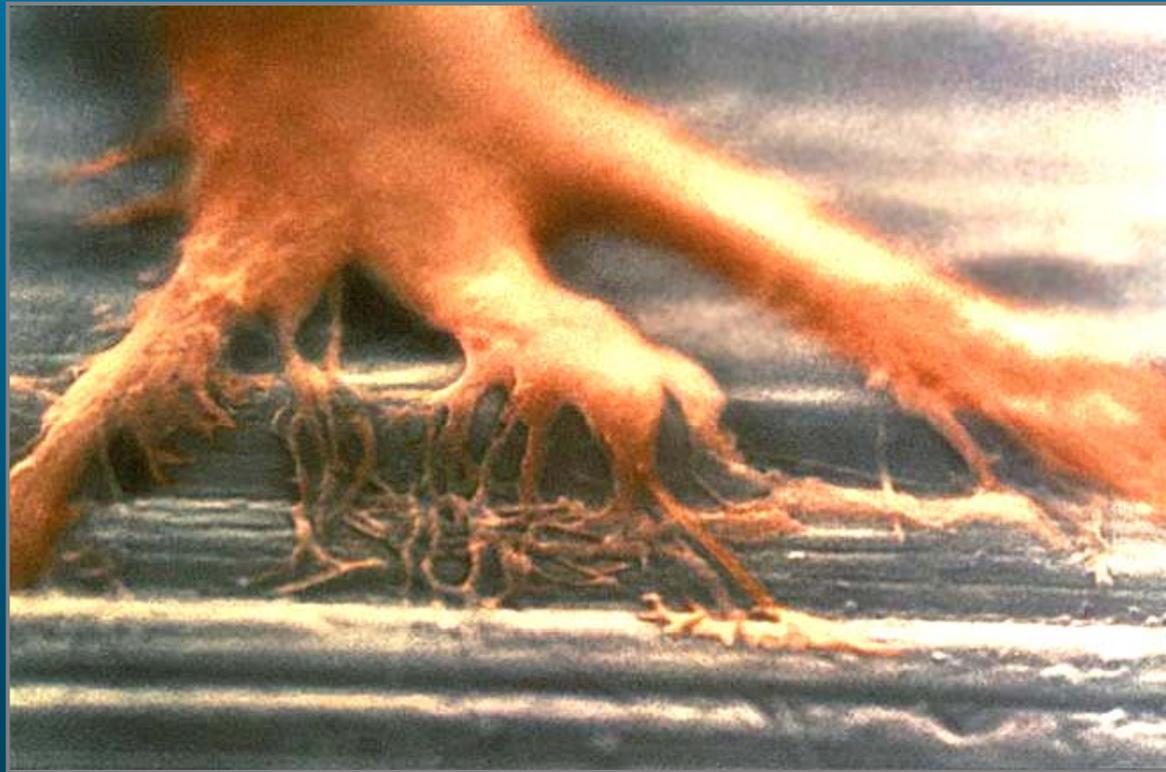
**Hearing response of the inner ear  
is a direct result of all three  
stimulation pathways**



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**Term “osseointegration”:** os meaning “bone” and integro meaning “renew”; the process by which living bone tissue bonds with titanium



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# Surgical and Healing Process

- Outpatient surgery, relatively non-invasive
- Surgically placed implant is connected to an abutment that will protrude through the skin
- Small, hair-free, possibly numb area will remain around the abutment
- Dressing and pressure bandage for one to two weeks following surgery
- 3 months for osseointegration before external sound processor is fit for adults
- Procedure for Very Young Children - Two Stage Operation: The first stage involves drilling holes for the fixture and placing a sleeper receptor under the skin and allowing the skull to continue to thicken. After osseointegration (can be 6-8 months) the "post" is attached during a second surgery



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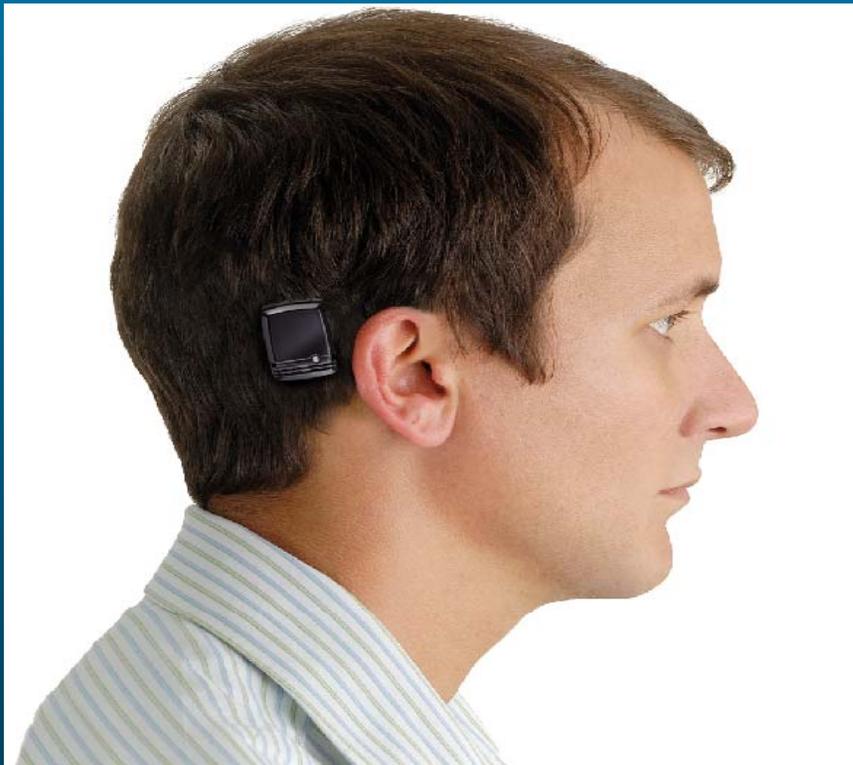
# Abutment



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# Processor



- External sound processor which connects to the implant via an abutment



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# Softband



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# New Devices

1) BP 100-Cochlear Corp

2) Ponto-Oticon Medical



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# Introducing...Oticon Ponto

- **Why Oticon Medical?**
  - The most up to date product...
    - Oticon RISE platform, Superb design
    - Intuitive and flexible fitting, Innovative improvements
- **From a solid company...**
  - 100 years of experience in traditional hearing aids
  - Based on and committed to a scientific approach to R&D
  - Great people and service organization
- **Developed and supported by a dedicated and experienced team of experts...**



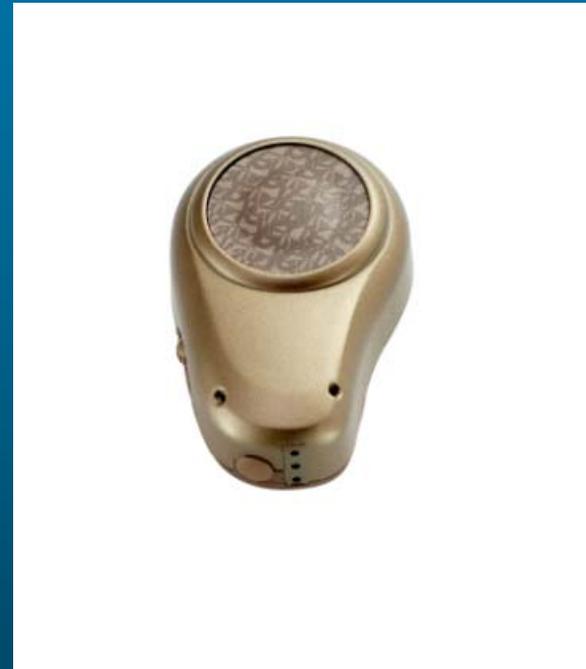
Courtesy of Oticon Medical

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# Design is not just how it looks – it is how it works

- Advanced processing
- Easy to use
- Easy to configure



Courtesy of Oticon Medical



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# Design is not just how it looks – it is how it works

- **Advanced features for new technology**
  - Big and easy to find/use program button
  - Automatic selection of best user features
  - Self learning volume control
  - Battery warning system

•



Courtesy of Oticon Medical

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# Design is not just how it looks – it is how it works

- **Easy to configure**
  - Can be adapted to any user need
  - **Special programs for special needs**
    - **Can turn off...**
      - Volume control
      - **Directionality**
      - Noise reduction

Courtesy of Oticon Medical



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# Design is not just how it looks – it is how it works



Features	Ponto Pro	Ponto
10 channel frequency response shaping	✓	✓
Multiband Adaptive Directionality	Automatic	Manual
Tri-state Noise Reduction	✓	
Data Logging	✓	
Learning Volume Control	✓	
Wind Noise Reduction	✓	✓
Output AGC	✓	✓
Up to 4 programs	✓	✓
Volume Control	✓	✓
Start-up delay	✓	✓
Mute function	✓	✓
Low battery warning	✓	✓
Telecoil/DAI/FM input	✓	✓
Fitting software, Genie Medical	✓	✓
Styles available	Left and right	Left and right
Color palette	Chroma Beige Mocca Brown Diamond Black	Chroma Beige Mocca Brown Diamond Black

Courtesy of Oticon Medical



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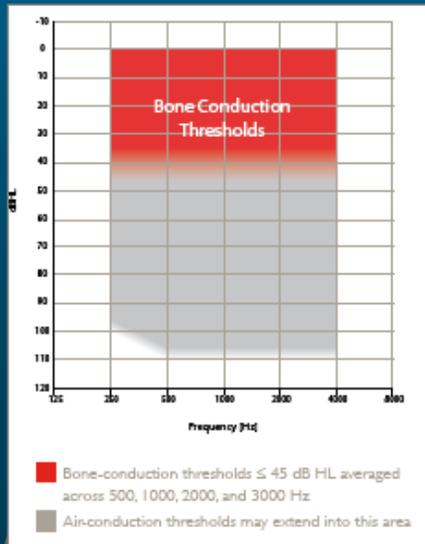


# 2009 Baha portfolio



•Cochlear Baha® BP100

- Client need:
- Top performance, fully automatic, head-worn,
  - All-round device

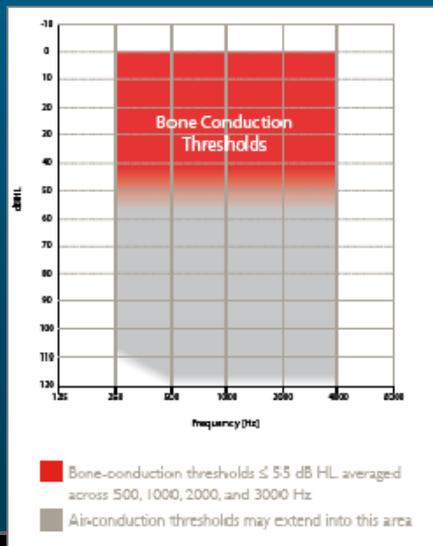


•CAM MKTP-170



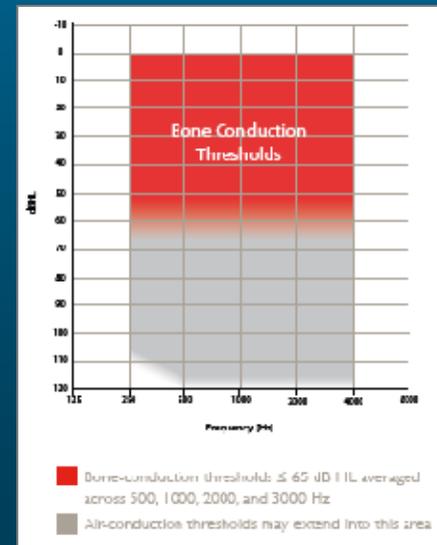
•Baha Intenso™

- Client need:
- Head-worn power,
  - Discreet device



•Baha® Cordelle II

- Client need:
- Super power, body-worn



## •Brilliance in design



•CAM MKTP-170

- Modern design for greater cosmetic appeal
- Easy FM/phone integration with Europin
- Use of skin-friendly titanium platform

Symmetrical device – use BP100 on left or right side, inventories are reduced

- Status indication with beeps and LEDs
- Tactile button user interface for ergonomic operation reducing the risk for accidental program changes

•courtesy of Cochlear Corp

# Simplicity in use - flexibility in fitting



1

•Ready to wear



2

•Button programming



3

•Cochlear Baha Fitting Software

Time

Individulization



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- **Designed for kids**



Visual and audible indicators provide sound processor status and low battery warning



Keylock secures the ergonomic buttons from accidental changes



The optional tamper-proof door keeps the battery from being removed



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• **courtesy of Cochlear Corp**



- **Designed for kids**



Safety line secures BP100 to the child's clothing to prevent it from being lost



The standard Europin connector allows easy integration with classroom FM systems



Baha Softband compatibility for infants and toddlers

• **courtesy of Cochlear Corp**



• CAM MKTP-170

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# FDA Clearance

- 1996 - The Baha System was cleared to treat mixed and conductive hearing loss.
- 1999 - The Baha System was cleared for pediatric use in children age five and older.
- 2001 - The Baha System was cleared for bilateral fittings. In 2002, the Baha® Softband was introduced for children under the age of five.
- 2002 - The Baha System was cleared for use in patients with unilateral sensorineural hearing loss also known as single sided deafness™ (SSD).
- 2009 - Oticon Ponto and Cochlear BP100 cleared as programmable devices



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# Candidacy

- Conductive/ mixed hearing loss
  - 5 years of age and older
  - BC PTA for **BP100** 45 dBHL (at .5, 1, 2, 3 kHz)
  - BC PTA for **Intenso** 55-60 dBHL
  - 60% or better monosyllabic word score
- Single Sided Deafness (SSD)
  - Transcranial routing from the deaf side to the WNL ear
  - 5 years of age or older
  - profound SNHL and normal hearing in the opposite ear
    - 20 dBHL AC PTA (.5k, 1k, 2k, 3kHz)
- **Asymmetrical hearing losses? (profound one ear, SNHL in contralateral ear)**



# Audiologic Assessment Pre-operative

## PEDIATRICS

- Puretone & speech audiometry
- Speech in noise testing
  - Soundfield NuCHIPS, PBK, WIPI



# Audiologic Assessment Pre-operative

- Use a Baha with a higher force output during testing (for example: patient is a candidate for BP 100, use the Intenso for the workup)
- Significant difference in headband vs. implant of 5-20 dB in the frequency range of 1000-4000Hz.
- Improvement in SRT of 4-7dB which can translate to 20-40% difference in speech understanding

(Versraeten et al. 2008)



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# Audiologic Assessment Pre- and post-operative

## PEDIATRIC

- Outcome inventory measurements
  - Children's Home Inventory for Listening Difficulties (CHILD)
  - Children's Outcome Worksheets (COW)
  - Screening Instrument for Targeting Educational Needs (SIFTER)
  - Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)



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# Verification

- Aided testing in the soundfield



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# Validation

- Outcome measures
- Speech pathologist
- Teachers
- Parents
- Aided Thresholds



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# Evidence-based practice:

- Baha > BCHA
  - Snik et al (1995), Tjellstron (1995), Skik et al (2004)
- Baha < = > ACHA
  - Mylanus et al (1994), Snik et al (1994), Mylanus (1995), Snik et al (2004)
- Limited studies with random discourse in reverberant, multi-source noise conditions (i.e. real world situations)
- Limited studies using pediatric patients



**Newman CW, Sandridge SA, Wodzisz LM. (2008). Longitudinal Benefit From and Satisfaction With the Baha System for Patients With Acquired Unilateral Sensorineural Hearing Loss. *Otology & Neurotology*; 29:1123-1131.**

- **Objective:** To analyze the short-, medium-, and long-term benefits from and satisfaction with the Baha for patients with profound unilateral SNHL.
- **Outcome measures used:** Speech Perception in Noise, HINT, localization testing, APHAB, HHIA, and SSD questionnaire.
- **Conclusion:** The Baha is effective at reducing psychosocial consequences of unilateral profound SNHL for the long-term.
- **Improvement in speech understanding occurred when the primary signal was spatially separated from BGN.**
- **Localization performance did not improve with Baha use.**
- **Overall, patients were satisfied with their Baha and would still elect to have this procedure if given a second chance.**



**Christensen L, Dornhoffer, JL. (2008). Bone-Anchored Hearing Aids for Unilateral Hearing Loss in Teenagers. *Otology & Neurotology*; 29: 1120-1122**

- **Objective:** to report on follow-up of a case series of teenage patients who received Bahas to compensate for SSD.
- **Results:** There were higher CHILD scores post-implant, indicating improved child and parent satisfaction. Better results on HINT post-implant indicated an improved ability to understand speech in noise.
- **Conclusion:** The Baha appeared to be of benefit to these teenage patients with unilateral hearing loss.



**Christensen L, Richter, G., Dornhoffer, JL. (2010). Update on Bone-Anchored Hearing Aids in Pediatric Patients With Profound Unilateral Sensorineural Hearing Loss. Arch Otolaryngol Head Neck Surg. 2010;136(2):175-177.**

- **Objective:** To evaluate the use of bone-anchored hearing aids (Bahas) in children with single-sided deafness.
- **Results:** Preimplant mean HINT scores at speech-noise ratios of 0, +5, and +10 dB were 42%, 76%, and 95%, respectively. Postimplant mean HINT scores improved to mean speech-noise ratios of 82%, 97%, and 99% at 0, 5, and 10 dB, respectively. The CHILD scores also improved from mean preimplant ratings of 4.49 and 4.60 for patients and parents, respectively, to postimplant ratings of 6.90 and 7.10. Both teenagers (n = 15) and children younger than 13 years (n = 7) demonstrated improved HINT and CHILD scores. The complication rate was 17%.
- **Conclusions:** Bone-anchored hearing aids are a durable treatment option that can achieve noticeable improvements in hearing in noise and in listening difficulties in children with profound unilateral sensorineural hearing loss.



Hol MK, Cremers CW, Coppens-Schellenkens W, Snik AF. The BAHA Softband: A new treatment for young children with bilateral congenital aural atresia. *Int J of Ped Otorhinolaryng*. 2005;69:973-980.

- Objectives: To evaluate the validity of a bone-anchored hearing aid (BAHA) Softband (fitted unilaterally and bilaterally) in young children with bilateral congenital aural atresia.
- Results: The electro-acoustic measurements showed minor differences in gain between the three devices. At a reduced volume setting, the mean input level at which the output levelled off was largely comparable between the BAHA Classic and the conventional device, but somewhat poorer with the BAHA Compact. 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
  - N = 2



## Christensen, et al (2007) “Aided Verification of Baha Softbands for Children” Poster Submission American Academy of Audiology.

- Objective: The purpose of this study was to (a) determine benefit of Baha coupled to the Softband for infants and children with bilateral conductive hearing loss; and (b) verify audibility of the speech spectrum for octave frequencies 500 through 4000 Hz.
- Results: Results revealed an improvement in soundfield thresholds with Baha amplification for the four octave frequencies.
- Conclusions: Benefit of the Baha in providing audibility of the speech spectrum for infants and children with bilateral congenital conductive hearing loss has been demonstrated.
  - N = 20
  - **Nicholson N, Christensen L, Dornhoffer J, Martin P, Smith-Olinde L. (2010). Verification of Speech Spectrum Audibility for Pediatric Baha Softband Users with Craniofacial Anomalies. The Cleft Palate-Craniofacial Journal In-Press.**



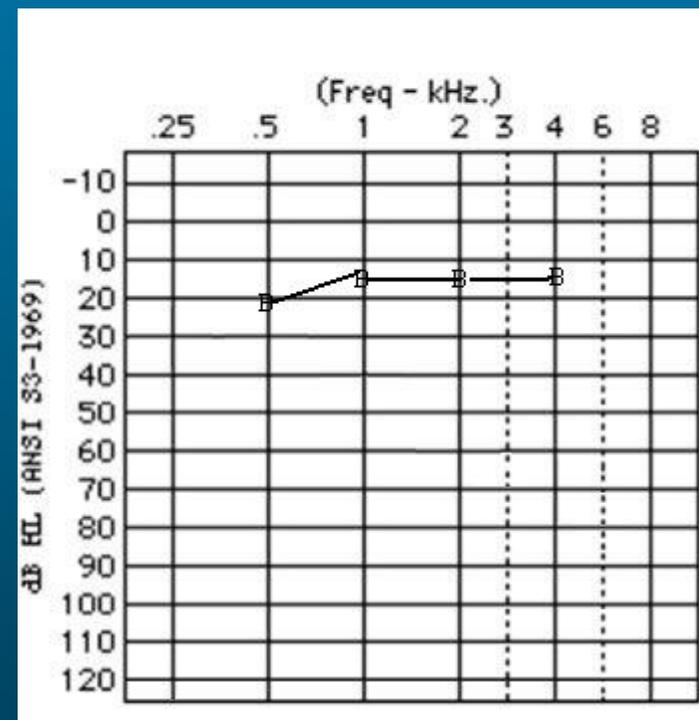
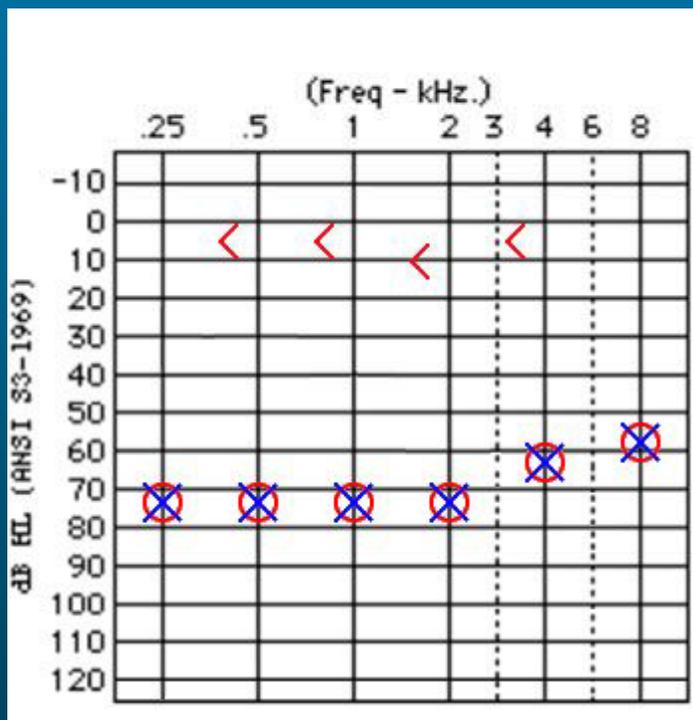
# Softband Case



- Failed NBHS
- Pierre Robin Sequence
- ABR at 3 months 8 days of age confirmed moderate CHL AU
- Fit with loaner Baha at 3 months 20 days of age



# Softband Case



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# Implant Case

- Previously worn BTEs for bilateral moderate CHL
- Normal pinnae AU
- Chronic otitis externa
- Recommended Baha trial 3-14-2005
- First Stage Baha surgery 8-24-2005
- Second Stage Baha surgery 2-27-2006
- Implanted bilaterally





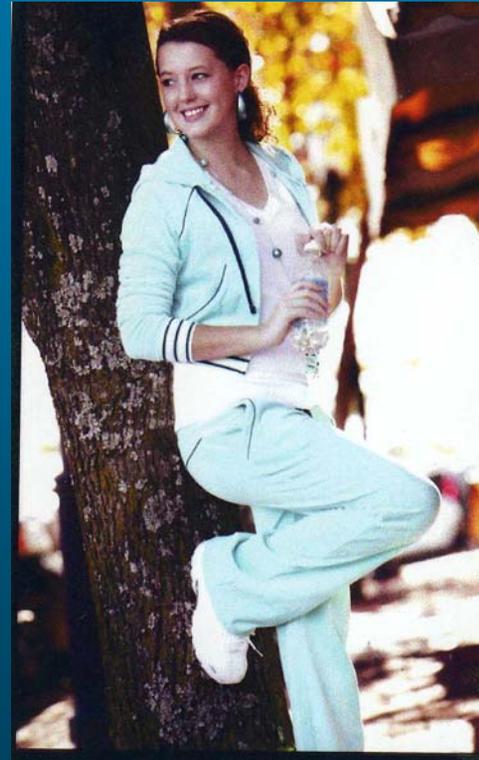
# Implant Case

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



# SSD Case

- 14 y/o female
- Normal hearing right ear
- Profound loss left ear
- Receives tutoring at school



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# SSD Case

	Pre-Implant	Post-Implant 3 months
HINT 0 SNR	11%	94%
HINT +5 SNR	50%	100%
HINT +10 SNR	91%	100%
CHILD – Alivia	3.73	7.87
CHILD- grandmother	2.80	7.00
SSQ – speech	5.50	7.56
SSQ – Spatial	1.50	7.64
SSQ - Quality	6.25	8.00



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