CANDIDACY CONSIDERATIONS FOR BONE CONDUCTION HEARING DEVICES (BCHD) IN PEDIATRICS

Oticon Medical Webinar Series
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Learning Objectives

01	Participants will be able to explain the non-surgical and surgical audiologic candidacy criteria for BCHDs in infants and children.
02	Participants will be able to identify three specific challenges that impact children with unilateral hearing loss.
03	Participants will be able to list specific features that are desired when fitting BCHDs on children.
04	Participants will be able to identify the benefits of fitting BCHDs on children.

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Agenda

- Introduction
- BCHD Candidacy Criteria
- BCHD Evaluation and Fitting
- Non-Surgical vs. Surgical Devices
- Case Studies
- Conclusions/Q&A

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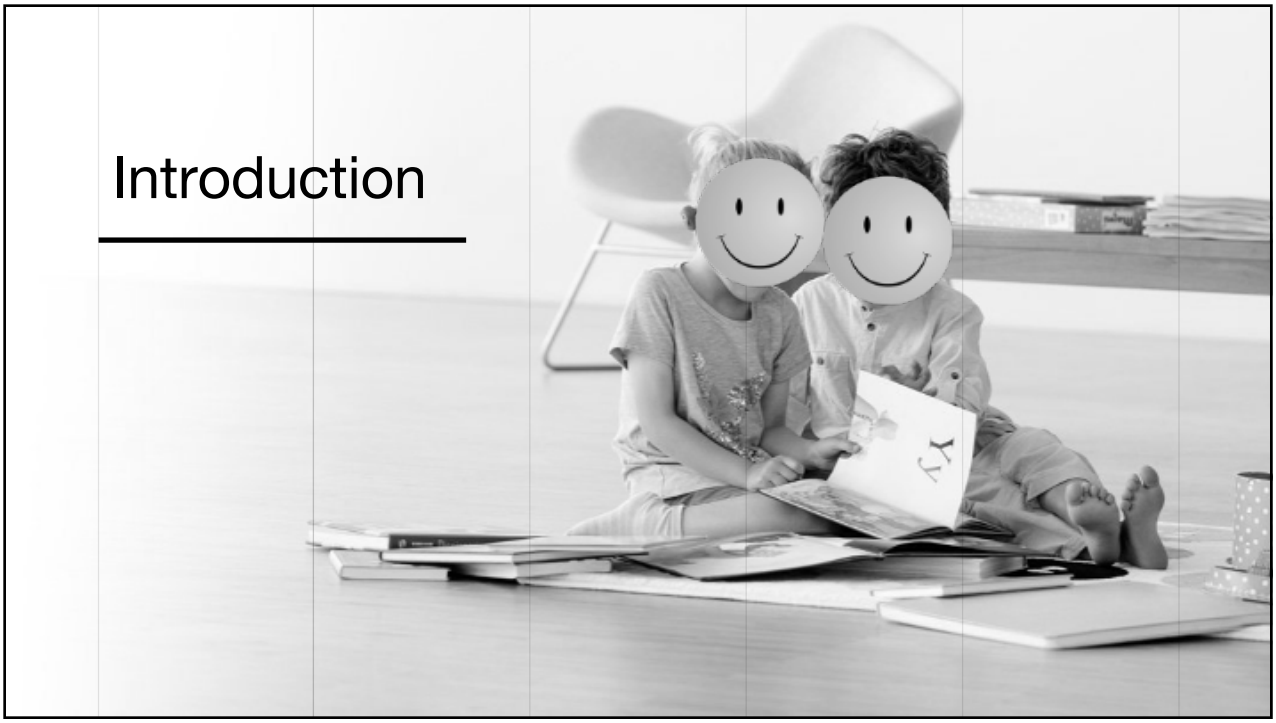
Introduction



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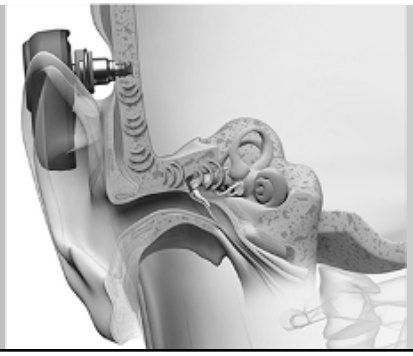
Bone Conduction Hearing Device (BCHD)

A non-conventional form of amplification used to treat hearing loss through direct bone conduction. A BCHD can be **non-surgical or surgically implanted.** A BCHD should be recommended to individuals who are unable to use conventional air conduction amplification.



www.oticonmedical.com

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Background

- To date, **fitting protocols for BCHD are not standardized**, leaving gaps in clinical practice.
- Children's Hospital of Philadelphia (CHOP), like many other institutions, used **existing evidence** and **clinical experience** to develop practice guidelines.
- Information discussed today will include **manufacturer recommendations**, **practice guidelines** used by CHOP audiologists, **clinical experience**, and **data** from the Pediatric Bone Conduction Working Group (PBCWG).

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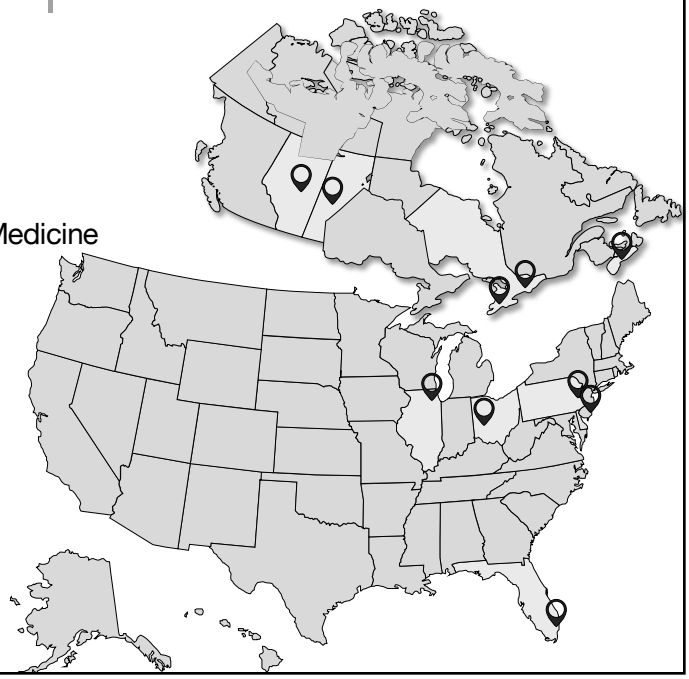
Pediatric Bone Conduction Working Group (PBCWG)

- Children's Hospital of Philadelphia
- Cincinnati Children's Hospital
- Institute for Reconstructive Sciences in Medicine
- IWK Health Centre
- Lurie Children's Hospital of Chicago
- Nemours Alfred I. DuPont Hospital
- Oticon A/S
- Saskatoon Health Region
- University of Miami
- Western University



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PBCWG Projects

- In 2015, **144 pediatric audiologists** were surveyed across North America on their BCHD selection and fitting practices. 68.47% of respondents reported that they **did not feel confident in their BCHD fitting procedures**.
- In 2016, a retrospective chart review was completed to obtain additional information. From the 65 files reviewed from six sites, **no consistent protocols were identified** as being used for verification or validation of BCHDs for children.
- In 2018/2019, two surveys were administered to pediatric audiologists and parents on **bone conduction technology, candidacy, counseling, recommendations and decision making** for unilateral CHL/MHL.
- Presently **developing fitting guidelines** for non-surgical BCHD in children with CHL/MHL.

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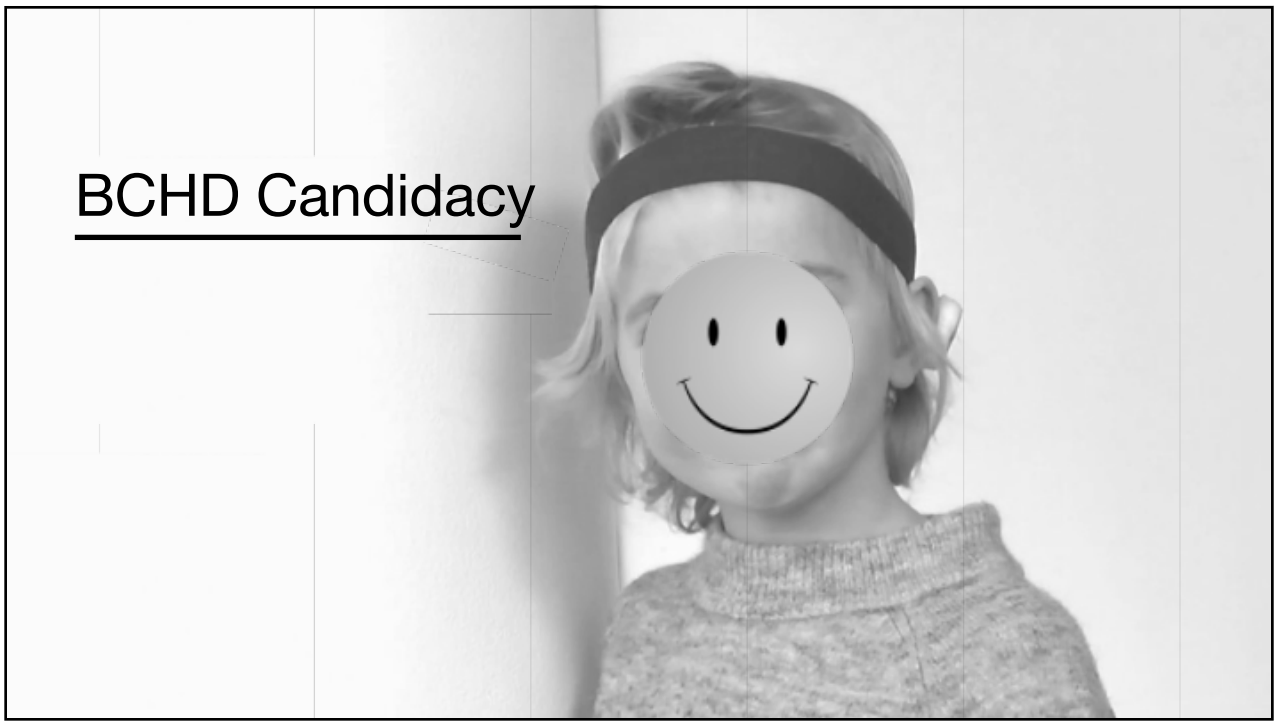
BCHD Candidacy



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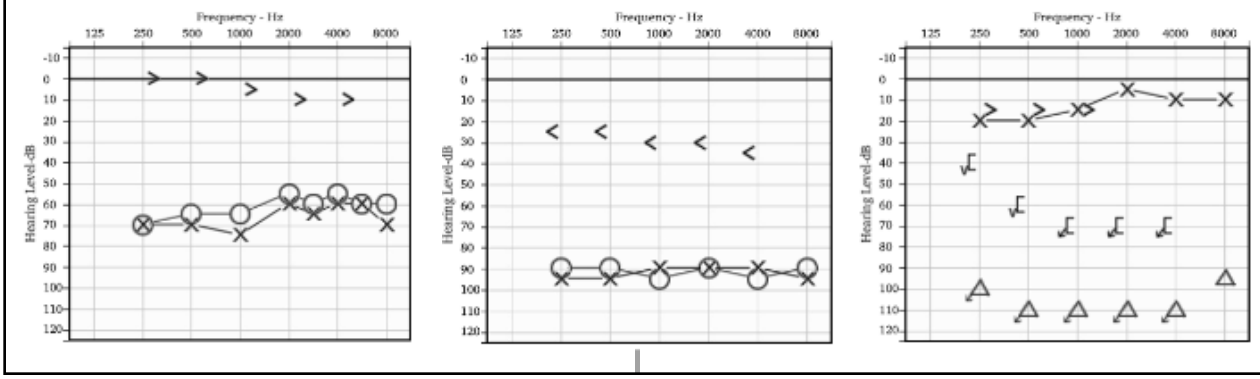
Candidacy Overview

Bilateral or Unilateral Conductive Hearing Loss (CHL)	Bilateral or Unilateral Mixed Hearing Loss (MHL)	Single-Sided Deafness (SSD)



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Candidacy for Bilateral CHL and/or MHL

Manufacturer Criteria

BC PTA (.05, 1, 2 & 3 kHz)
- < 45 dB HL (most devices)
- ≤ 65 dB HL (SP devices)

Additional Considerations

- Limited evidence/outcome data for hearing loss >45 dB HL
- 4kHz adds more clinical value for children than 3k Hz
- PTA air-bone gap >30 dB

Agterberg et al., 2018
Colquitt et al., 2011
De Wolff et al., 2011
Roman et al., 2011
Zeitooni et al., 2016

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Bilateral BCHD Fitting

- Bilateral fittings should have symmetric BC thresholds:
  - < 10 dB difference PTA between ears
  - < 15 dB difference at individual frequencies between the two ears

Agterberg et al., 2018
Roman et al., 2011

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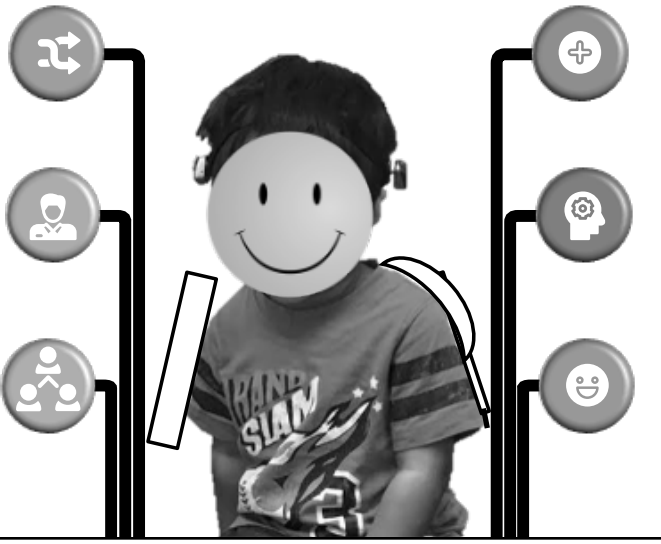
Benefits of Binaural Fitting

Improved sound localization

Better speech recognition in quiet

Better speech recognition in noise



Binaural Summation

Improved spatial awareness

Higher patient satisfaction

Agterberg et al., 2018
Jansen et al., 2012
Zeitooni et al., 2016

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Candidacy for Unilateral CHL and/or MHL

Manufacturer Criteria

BC PTA (.05, 1, 2 & 3 kHz)
- < 45 dB HL (most devices)
- ≤ 65 dB HL (SP devices)

Audiologic Criteria

Same as bilateral hearing loss, in addition to:

- AC PTA in indicated ear: > 40 dB HL
- AC PTA in "normal" ear: < 20 dB HL
- PTA air-bone gap: > 30 dB, most benefit perceived ≥ 50 dB

Cooper et al., 1996
Danhauer et al., 2010
Roman et al., 2011

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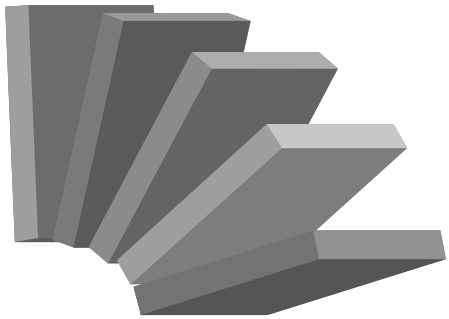
Importance of Fitting Unilateral Hearing Loss

Children with unilateral hearing loss have reduced audibility, difficulty localizing sounds, and difficulty understanding in noise and from a distance.

Putting them at risk for:

- Speech and language delays
- Educational challenges
- Fatigue
- Social-emotional struggles



Hornsby et al., 2017
Lieu, 2013
Tharpe, 2008

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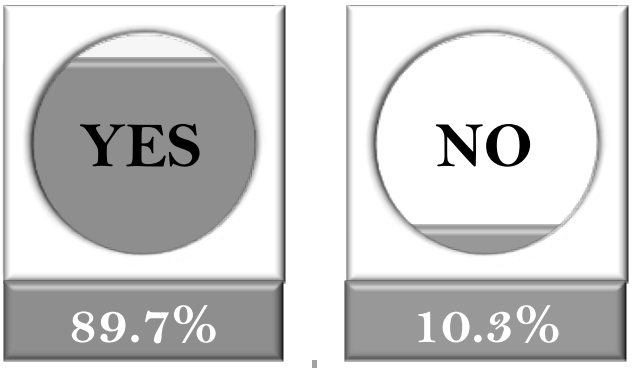
PBCWG Audiologist Survey

For unilateral conductive or mixed hearing loss (e.g., atresia and microtia) in children, do you recommend bone conduction hearing devices at the time of hearing loss diagnosis?



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Benefits of Fitting BCHD in Unilateral Conductive Hearing Loss

- Provides binaural hearing
- Avoids auditory deprivation
- Improved localization
- Better speech recognition in noise
- Objective and subjective benefit

Poloneko et al., 2016
Agterberg et al., 2013
Vogt et al., 2018
Vyskocil et al., 2017
Sharma et al., 2002

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Candidacy for SSD

Audiologic Criteria

- Severe to profound sensorineural hearing loss in the indicated ear
- Normal hearing: AC PTA $\leq$ 20 dB HL, in the contralateral ear

Additional CHOP Criteria

- School aged, deemed developmentally appropriate by both managing audiologist and parent
- Out-of-office trial

Desmet et al., 2011
Roman et al., 2011

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Additional Considerations for SSD

Collaboration

Managing Audiologist and Otolaryngologist agree that BCHD use may provide benefit

Expectations

Appropriate expectations and awareness of the limited outcome data that is available on BCHD use for children with SSD

Age

Child must demonstrate the ability to manipulate the device when listening environment changes

Amplification Trial

An out-of-office trial with a BCHD is recommended to determine benefit

Kenworthy et al., 1994

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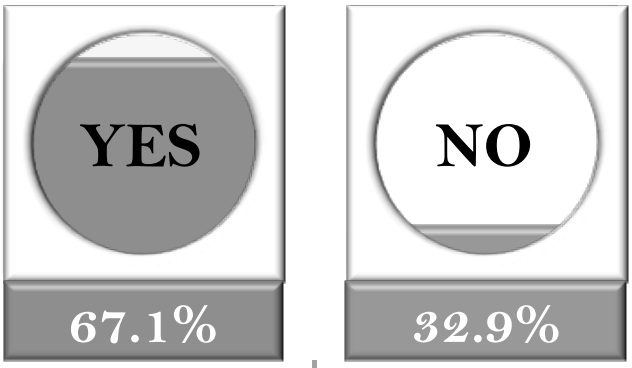
PBCWG Audiologist Survey

Do you offer an out-of-office bone conduction hearing device trial?



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At-Risk Populations

Common Syndromes	Temporary/ Acute	Long-Term/ Chronic
• Goldenhar • Hemifacial Microsomia • Aural Atresia • Microtia • Treacher-Collins • Branchio-oto-renal (BOR) • Stickler • CHARGE • Trisomy 21	• Serious otitis media • Chronic drainage • TM perforation • Middle ear surgery • Otitis externa • Ventilator dependent • Inpatients • Cleft plate	• Chronic otitis media • Chronic drainage • Cholesteatoma • Severe allergies • Fluctuating conductive hearing loss

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Candidacy for Children with Temporary/Chronic CHL

- **Candidacy:**
  - Patients who have fluctuating air conduction thresholds due to middle ear pathology
  - Patients who have an underlying medical condition causing CHL and are awaiting therapeutic/surgical procedure
  - Patients who have an underlying medical condition which is chronic, but could resolve (e.g. drainage)
- **Benefit:**
  - Provision of consistent benefit without concern for over/under amplifying
  - Non-surgical connection options

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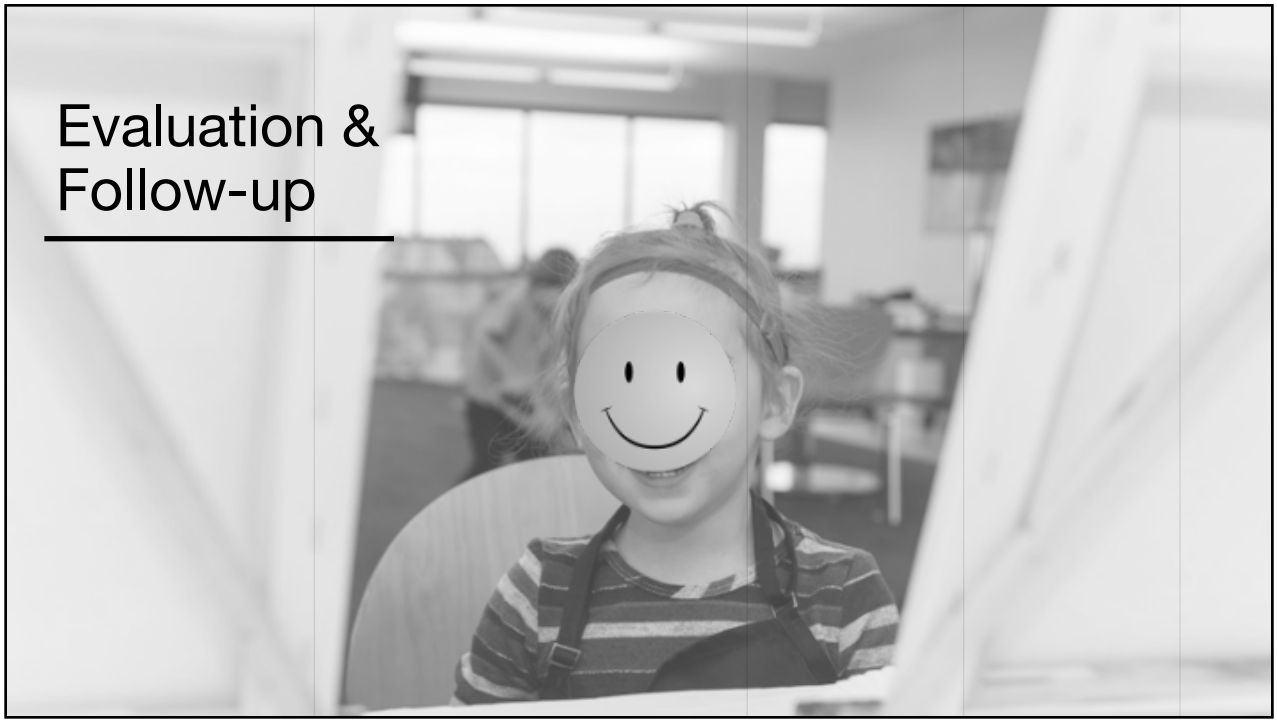
Evaluation & Follow-up



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Initital Audiologic Assessment: Obtaining Threhsolds for BCHD Candidacy

Auditory Brainstem Response (ABR)

- ≤ 6 months of age or those unable to complete behavioral testing
- Air and bone conduction testing (if indicated)

Behavioral Testing

- When developmentally appropriate
- Air and bone conduction testing (if indicated)

NOTE: Minimally, it is recommended to obtain one low and one high frequency bone conduction threshold in the indicated ear to fit a device

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Recommended Referrals

1 **Otolaryngologist** to investigate etiology and provide medical clearance

2 **Early Intervention/ Hearing Support** for evaluation & service provision

3 **Speech Language Pathologist** for evaluation & monitoring

4 **Geneticist** for evaluation

5 **Ophthalmologist** for evaluation

Joint Committee on Infant Hearing (JCIH), 2019

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CHOP Family Wellness Services

- All children diagnosed with hearing loss are referred to one of our child and family wellness therapists
- Adjusting to hearing loss following diagnosis
- Monitor to promote healthy social, emotional and behavioral development

https://www.chop.edu/centers-programs/family-wellness-services

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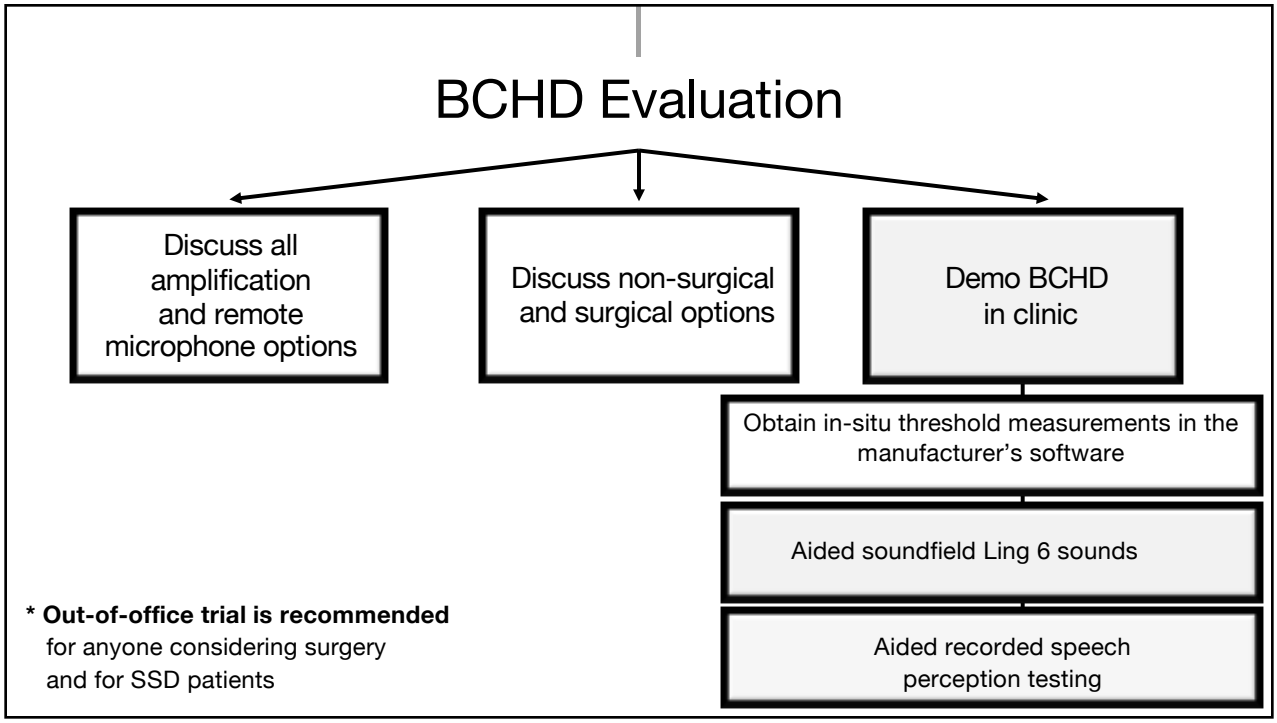
BCHD Evaluation
Discuss all amplification and remote microphone options
Discuss non-surgical and surgical options
Demo BCHD in clinic
Obtain in-situ threshold measurements in the manufacturer's software
Aided soundfield Ling 6 sounds
Aided recorded speech perception testing
* Out-of-office trial is recommended for anyone considering surgery and for SSD patients

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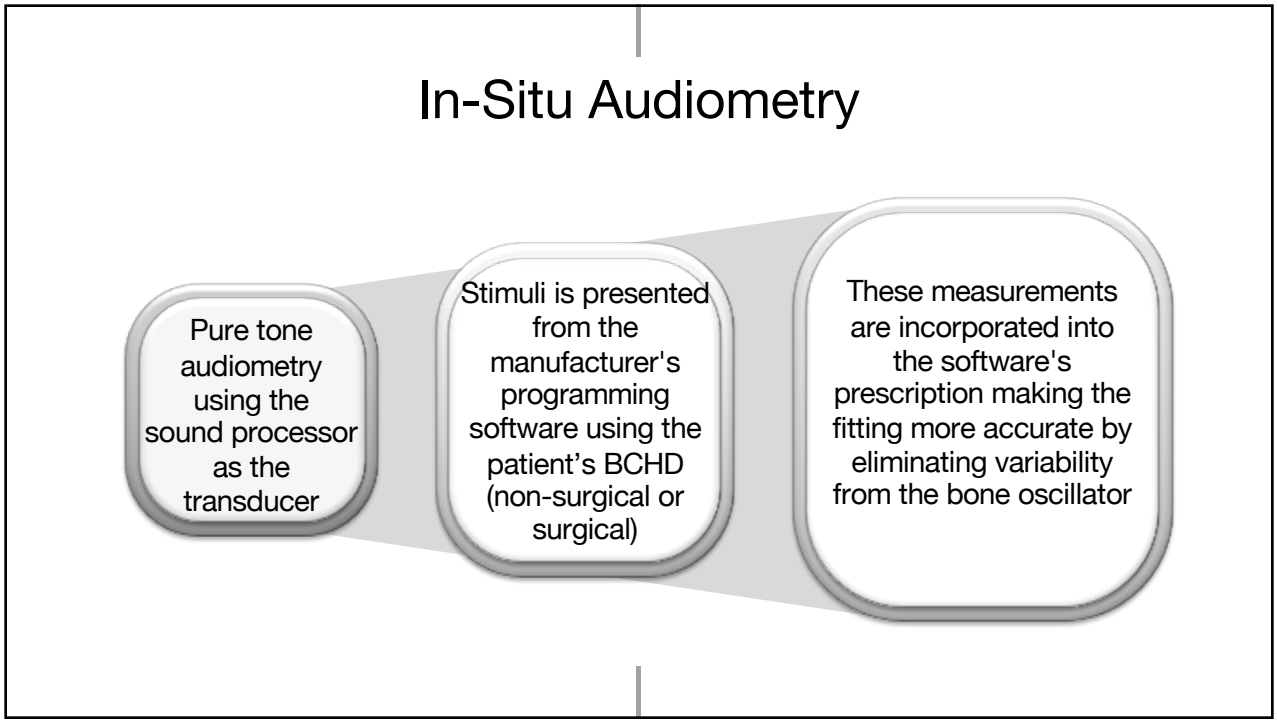
In-Situ Audiometry
Pure tone audiometry using the sound processor as the transducer
Stimuli is presented from the manufacturer's programming software using the patient's BCHD (non-surgical or surgical)
These measurements are incorporated into the software's prescription making the fitting more accurate by eliminating variability from the bone oscillator

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Performing In-Situ Audiometry

Completed in programming room or soundbooth using Noahlink Wireless or HiPro patched through the wall panel

Allows for VRA, CPA, and voluntary to be completed in a quiet environment

Install Noah or manufacturer stand alone software

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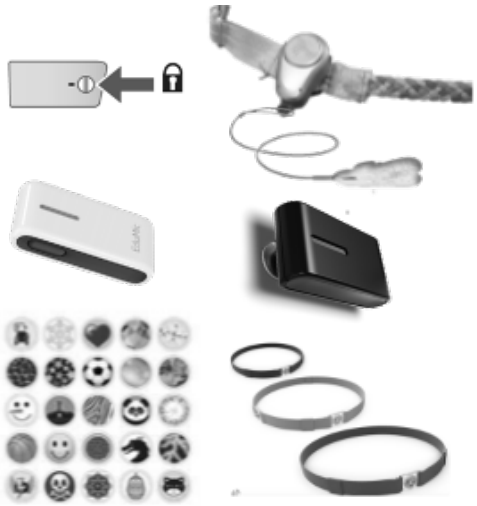
Important Pediatric Features for BCHDs

- Tamper resistant battery door to industry standards
- Durability
- Safety clip
- Disable volume control and programming button
- Indicator light
- Remote Microphone accessibility
- Soft headband (unilateral and bilateral)
- Fun colors (bonus)



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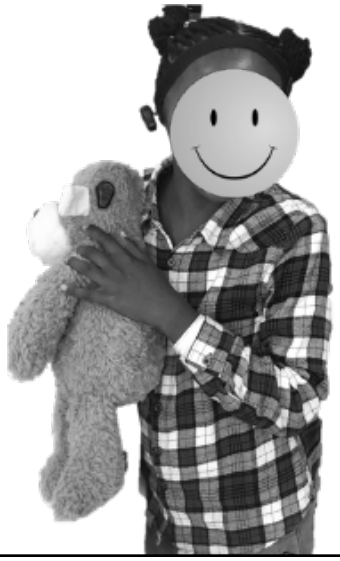
Non-Surgical/Soft Headband Candidacy

- Can be fit at any age
- Only option for children <5 years
- Option for “at risk” populations
- Unilateral and bilateral soft headband options
- For infants and young children, manufacturer recommended soft headband is preferred due to adjustability and comfort



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Soft Headband Fitting Considerations

1. Position BCHD on the mastoid or high temporal bone as studies show improved hearing compared to forehead placement
2. Maintain sufficient and consistent tightness of the BCHD soft headband to ensure consistent output
3. Soft headband should have a snug fit, but still be comfortable
4. Consider head control capabilities for fitting unilateral hearing loss and bilateral fittings

Agterberg et al., 2018
Mackey et al., 2016
Hodgetts et al., 2006; 2012

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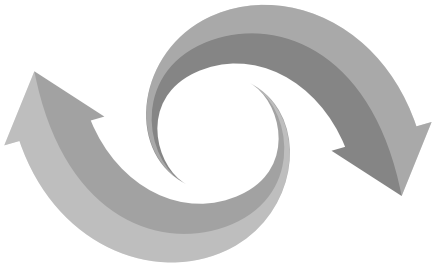
Percutaneous vs. Transcutaneous Surgical Options

THROUGH
the skin



ACROSS
the skin

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Surgical Candidacy

- ≥ 5 years of age
- No medical contraindications
- Sufficient skull thickness (>2.5 mm) and bone quality
- Ability to maintain/clean abutment site
- Note: significant developmental delays or behavior problems that may jeopardize surgical site need to be considered on a case by case basis

Davids et al., 2007
Papsin et al., 1997
Roman et al., 2011
Tjellstrom et al., 2001

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Surgical Fitting Considerations

Benefits of surgical direct transmission

- Improvement in aided thresholds and speech perception testing
- Better sound quality and performance
- Increase in learning speed
- Enhanced working memory
- More high frequency emphasis with surgical transmission than with a soft headband since they are weakened by the passing through skin

Kara et al., 2016
Pittman, 2019

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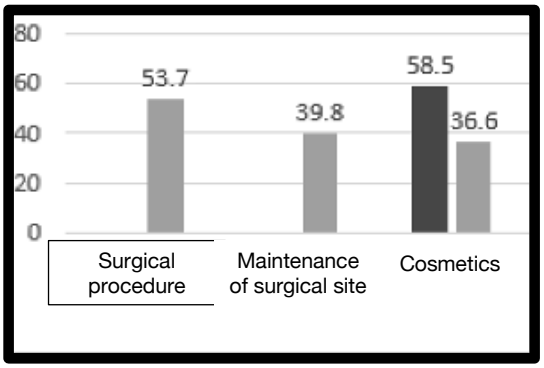
PBCWG Audiologist Survey

In your experience, what potential concerns led the patient/family not to proceed with the recommended BCHD? (check all that apply)



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Surgical Fitting Timeline

All Patients

- Must be medically cleared for processor fitting
- Soft tissue should be healed to avoid discomfort
- In some cases, it may be beneficial to wait until the implant is fully osseointegration

One-stage vs. two-stage surgery

- Determined by surgeon based on bone thickness, chronological and developmental age

One-stage

- Processor fitting on the abutment is typically 2-6 months following surgery

Two-stage

- Second stage to place the abutment is typically 3-6 months later
- Fitting on abutment is typically 2-8 weeks following the second stage

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Audiologic Follow-Up Recommendations

BCHD Monitoring

- 1 month post fitting
- Every 3 months for first year
- Every 3-6 months for second year
- Every 6-12 months thereafter
- Sooner if concerns arise

Validation Tools

- Access to information (data logging)
- Aided speech perception testing
- Outcome measurements

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Aided Speech Perception Testing

- Recorded, full list (50 words), age-appropriate speech perception tests should be administered to each ear whenever possible
- Speech at conversational levels in quiet: 60 dBA
- Speech at soft levels in quiet: 50 dBA
- Conversational speech in noise: 65 dBA (higher intensity to approximate louder speech levels observed in background noise- Lombard effect)
  - + 5 dB signal-to-noise ratio (SNR) should be used, as it is typical of a classroom setting
- Additional speech-in-noise testing paradigm for unilateral hearing loss
  - Complete unaided during evaluation
  - Complete aided during evaluation and/or follow-up

Gelfand, 1997
Thibodeau, 2007

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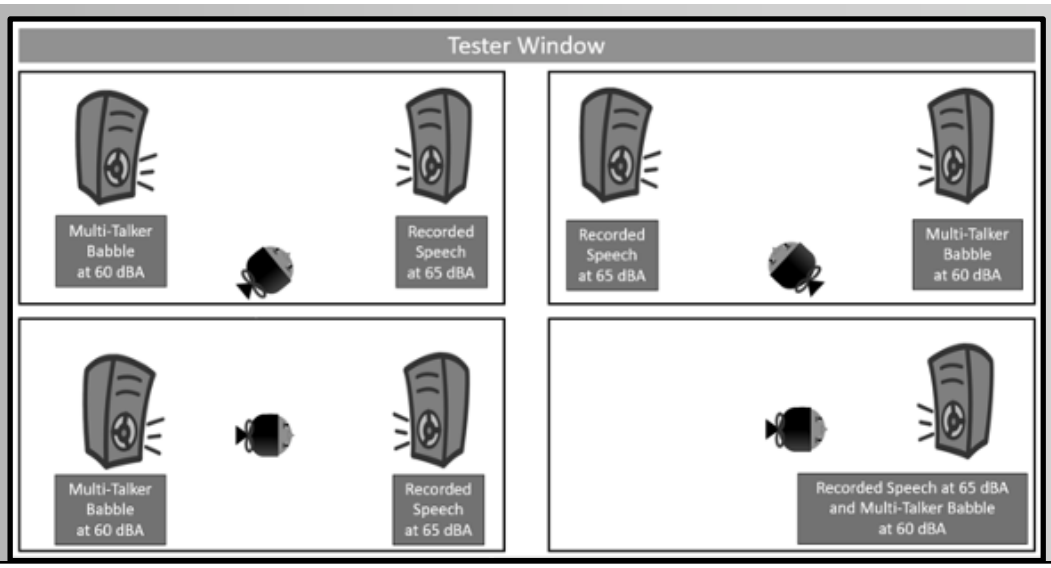
Testing Paradigm for Unilateral Hearing Loss



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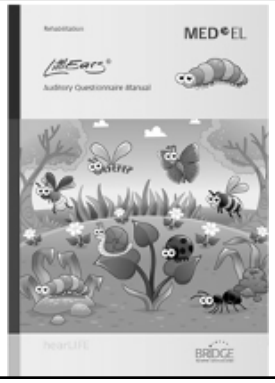
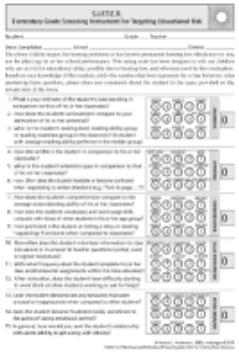
Outcome Measures

LittlEars
Birth to 2 years of age



PEACH
3 years of age through school-age

SIFTER
School-age



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CHOP Unilateral Amplification Questionnaire

- Post-amplification questionnaire comparing current amplification to no amplification
  - Listening situations which would be most difficult for a child with UHL, including localization of a sound source
  - Confidence, frustration level, attention
  - Subjective feelings about the device
- Option for parent and child to complete
- Information obtained can be used to guide counseling

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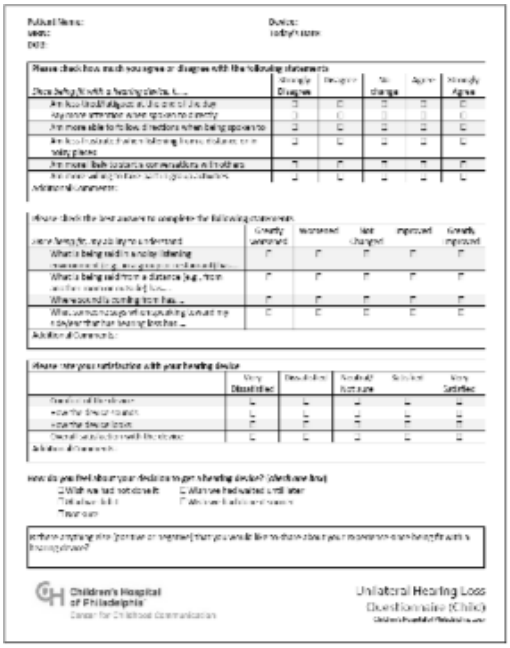

Children's Hospital of Philadelphia
Center for Childhood Communication

Unilateral Hearing Loss Questionnaire (Child)

Children's Hospital of Philadelphia
Center for Childhood Communication

Unilateral Hearing Loss Questionnaire (Caregiver)

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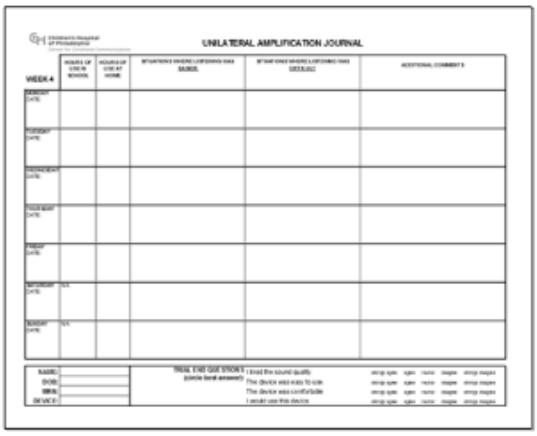
CHOP Unilateral Amplification Journal

- Four week daily journal
  - Hours worn at school
  - Hours worn at home
  - Easy listening situation
  - Difficult listening situation
  - Additional comments
- Final week
  - Comfort
  - Sound quality
  - Ease of use
  - "Would you use this device?"


UNILATERAL AMPLIFICATION JOURNAL

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Case Study #1: Bianca

- Treacher Collins Syndrome
- Bilateral Microtia
- Bilateral Conductive Hearing Loss
- Otitis Media

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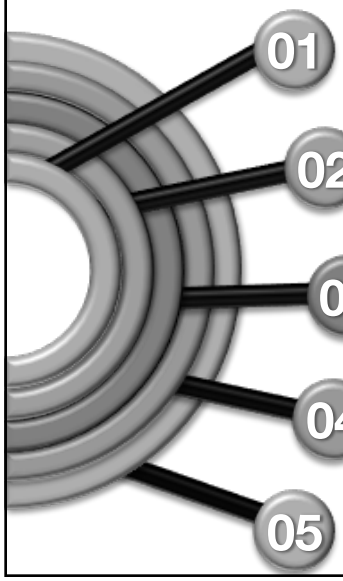
Treacher Collins Syndrome



01 Underdevelopment of the facial bones and tissues

02 Downward slanting eyes

03 Notched lower eyelid

04 Underdeveloped/malformed ears

05 Hearing loss

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Treatment Timeline

3 weeks	2-6 months	6-12 months	1-2 years	3-5 years
• ABR • Atypical facial features • Malformed ears • Bilateral CHL • Otologic consult	• Two follow-up ABRs • Recommended BCHD • Parents chose to attempt trial with AC aid • Confirmed Treacher Collins	• Right ear too stenotic for earmold • Left ear fit with AC aid • Retention/ earmold issues • Again revisited BCHD	• Hearing and speech concerns • Discussed binaural amplification • Revisited BCHD and fit one on the right ear	• Continued to use BCHD on a soft headband in right ear and AC aid in the left ear

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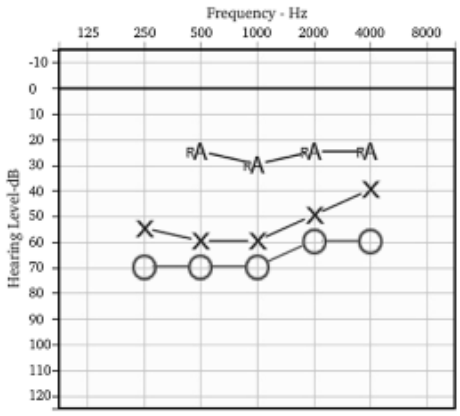
Audiology Visit: 3 years of age

- Right ear BCHD on a soft headband
- Left ear air conduction hearing aid
- Preferred binaural amplification

Ling 6	Left ear AC aid	Right ear BCHD
ah	20	25
ee	25	25
oo	25	30
s	25	40
sh	25	30
m	20	25



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Bianca's Outcome

- Continued to use binaural amplification during all waking hours
- Constant retention issue with right air conduction hearing aid
- Continued to recommend BCHD
- At age 5, surgical options were discussed
- Bianca and her parents chose not to pursue a surgical option

Test Condition	PB-K 50	dB HL	SNR
Aided Right (BCHD)	92%	50	
Aided Left (AC)	92%	50	
Aided Both	100%	50	
Aided Both	64%	50	+5

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Case Study #2: Teddy

- Goldenhar Syndrome
- Unilateral Atresia/Microtia
- Bilateral Conductive Hearing Loss
- Chronic Otitis Media
- Respiratory Failure

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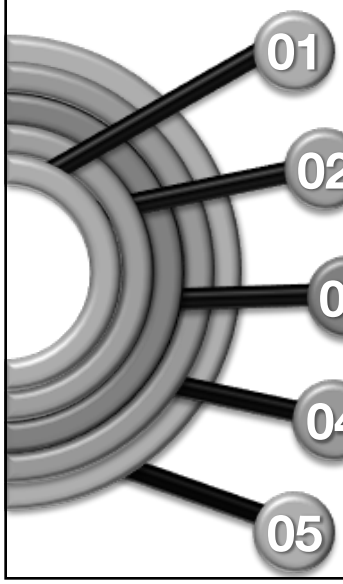
Goldenhar Syndrome



01 Cranial facial syndrome

02 Hemifacial microsomia

03 Mainly affects development of the eye, ear and spine

04 Ear abnormalities most commonly atresia/microtia

05 Hearing loss

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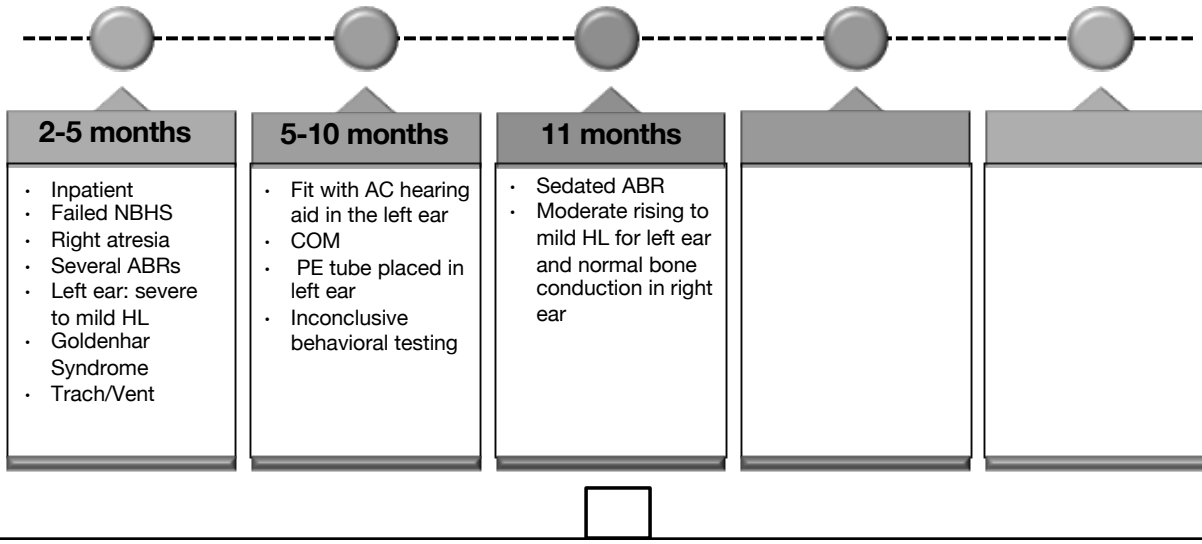
Treatment Timeline



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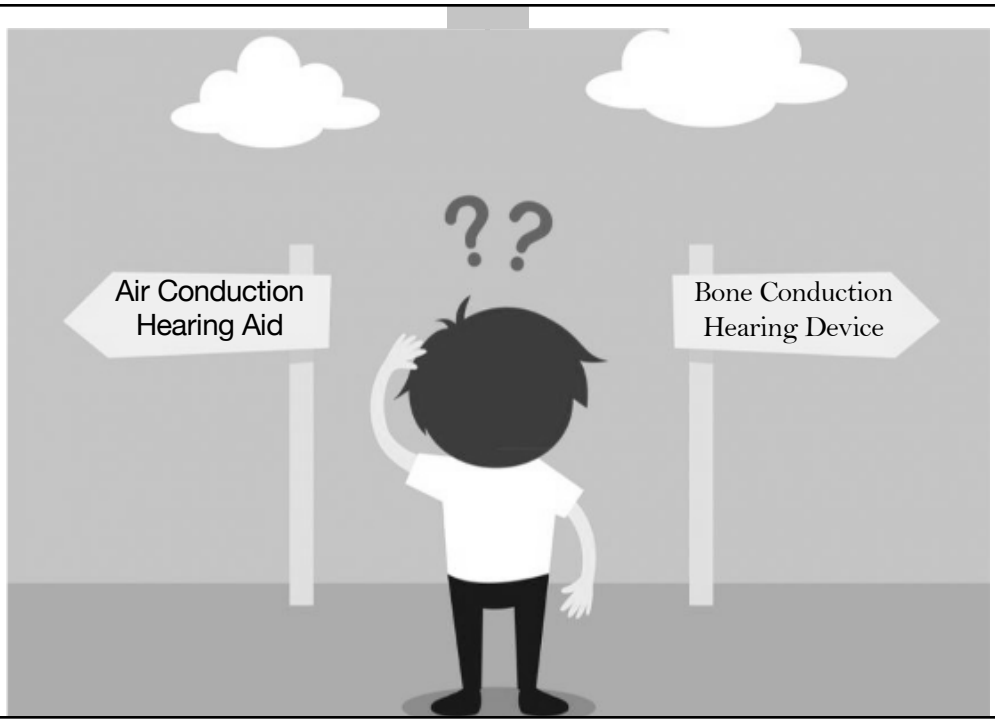

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Treatment Timeline

2-5 months	5-10 months	11 months	1-2 years	3-5 years
• Inpatient • Failed NBHS • Right atresia • Several ABRs • Left ear: severe to mild HL • Goldenhar Syndrome • Trach/Vent	• Fit with AC hearing aid in the left ear • COM • PE tube placed in left ear • Inconclusive behavioral testing	• Sedated ABR • Moderate rising to mild HL for left ear and normal bone conduction in right ear • Continue with left hearing aid	• Left ear AC hearing aid • COM • PE tube replaced • Recommended BCHD	• Finally able to obtain behavioral results • Continued to use BCHD in right ear

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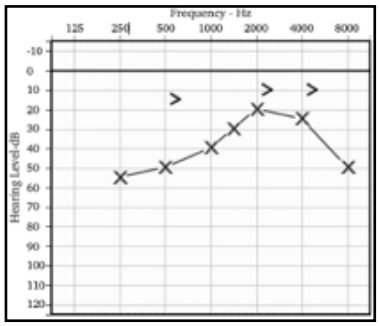
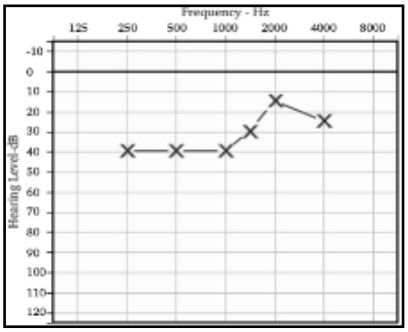
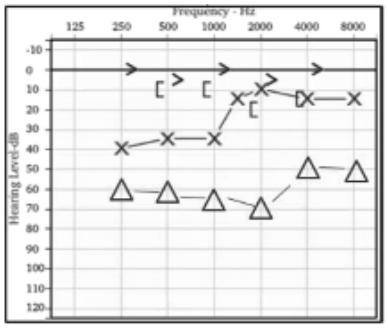
Next Few Years







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Teddy's Outcome

- Good benefit from BCHD on soft headband
- Discontinued air conduction hearing aid
- Wanted best hearing outcome being that he is fit unilaterally
- Percutaneous BCHD surgery completed at 5 years of age

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Case Study #3: Ben

- Trisomy 21
- Fluctuating Bilateral CHL
- Chronic Otitis Media

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Trisomy 21 and Hearing Loss

- Between 35-80% of children with T21 have hearing loss
- Hearing loss can be conductive, mixed, or sensorineural
- Risk factors for progressive hearing loss are often present
- Between 50-80% of children with T21 will have otitis media

AAP, 2011
Austeng, 2013
Manickam, 2016

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Treatment Timeline

6 weeks

- Failed newborn hearing screening in one ear
- ABR revealed bilateral CHL
- Otologic consult

3-6 months

- Two additional ABRs
- Canals too stenotic for tubes
- Amplification recommended
- Fit with one BCHD on soft headband

1-2 years

- Fit with second BCHD with bilateral soft headband
- Enrolled in EI
- PT, OT, speech and TOD
- Family wellness

3 years

- PE tubes placed
- Sedated ABR revealed normal hearing
- Discontinued BCHD
- Hearing test every 3-6 months

4-8 years

- Multiple sets of PE tubes (blocked /drainage)
- Already at risk for delays
- BCHD would provide consistent auditory access

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Ben's Outcome

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Lessons Learned: Bianca

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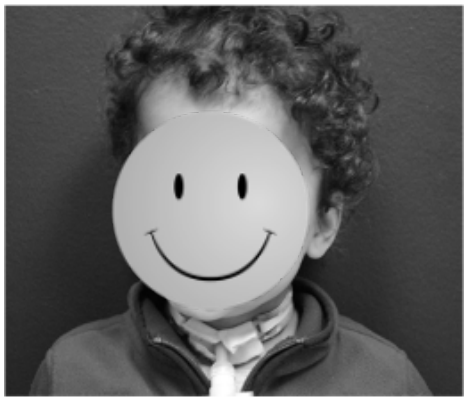
Lessons Learned: Teddy



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Lessons Learned: Ben

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ANY QUESTIONS?

Thank You

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