

Managing Chronic Otitis Media in Children with Bone Conduction Hearing Devices

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Disclosures

- Employed by Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio
- Honorarium and travel provided by CAA
- Devices for research study provided by Oticon Medical



Cincinnati, Ohio
USA



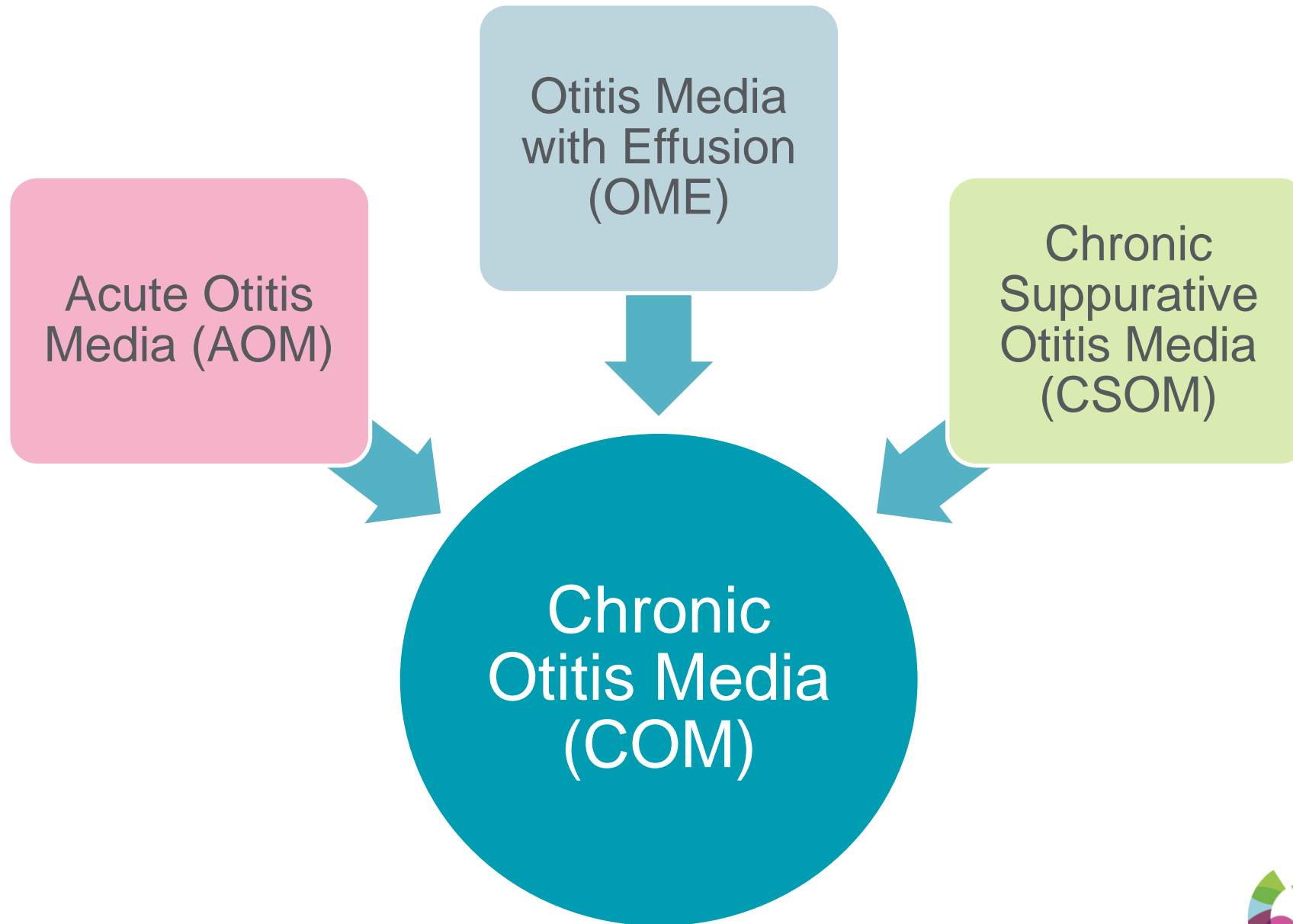
11 Locations



37 AuDs



14 ENTs



COM Facts



Affects an estimated 65-330 million individuals¹
60% have significant hearing loss



One of the most common diseases in young children²



Leading cause for medical consultation, antibiotic prescription and surgery in high-income countries²



80% of children are diagnosed with at least one ear infection by 3 yrs and over 50% by the age of 1 yr³



Middle ear disease and CHL may persist or fluctuate, despite treatment with pressure equalization tubes (PET)⁴

¹ World Health Organization. (2004). Chronic suppurative otitis media: burden of illness and management options.

² Schilder AG, Chonmaitree T, Cripps AW, Rosenfeld RM, Casselbrant ML, Haggard MP, Venekamp RP. Otitis media. Nat Rev Dis Primers. 2016 Sep 8;2(1):16063. doi: 10.1038/nrdp.2016.63. PMID: 27604644; PMCID: PMC7097351.

³ Vakharia, K. T., Shapiro, N. L., & Bhattacharyya, N. (2010). Demographic disparities among children with frequent ear infections in the United States. *The Laryngoscope*, 120(8), 1667-1670.

⁴ Sidell D, Hunter L, Lin L, Arjmand E. Risk factors for preoperative and postoperative hearing loss in children undergoing pressure equalization tube placement. *Otolaryngol Head Neck Surg*. 2014; 150(6):1048-1055.

COM Facts



Most common cause of childhood hearing loss¹



Recurrent OM in childhood is associated with hearing loss as an adult²



Early CHL is linked to listening and auditory processing deficits that persist after hearing has returned to normal^{3,4}



Fluctuating hearing loss associated with OM impacts speech and language development⁴



Academic performance can be impacted by fluctuating hearing loss and OM⁴

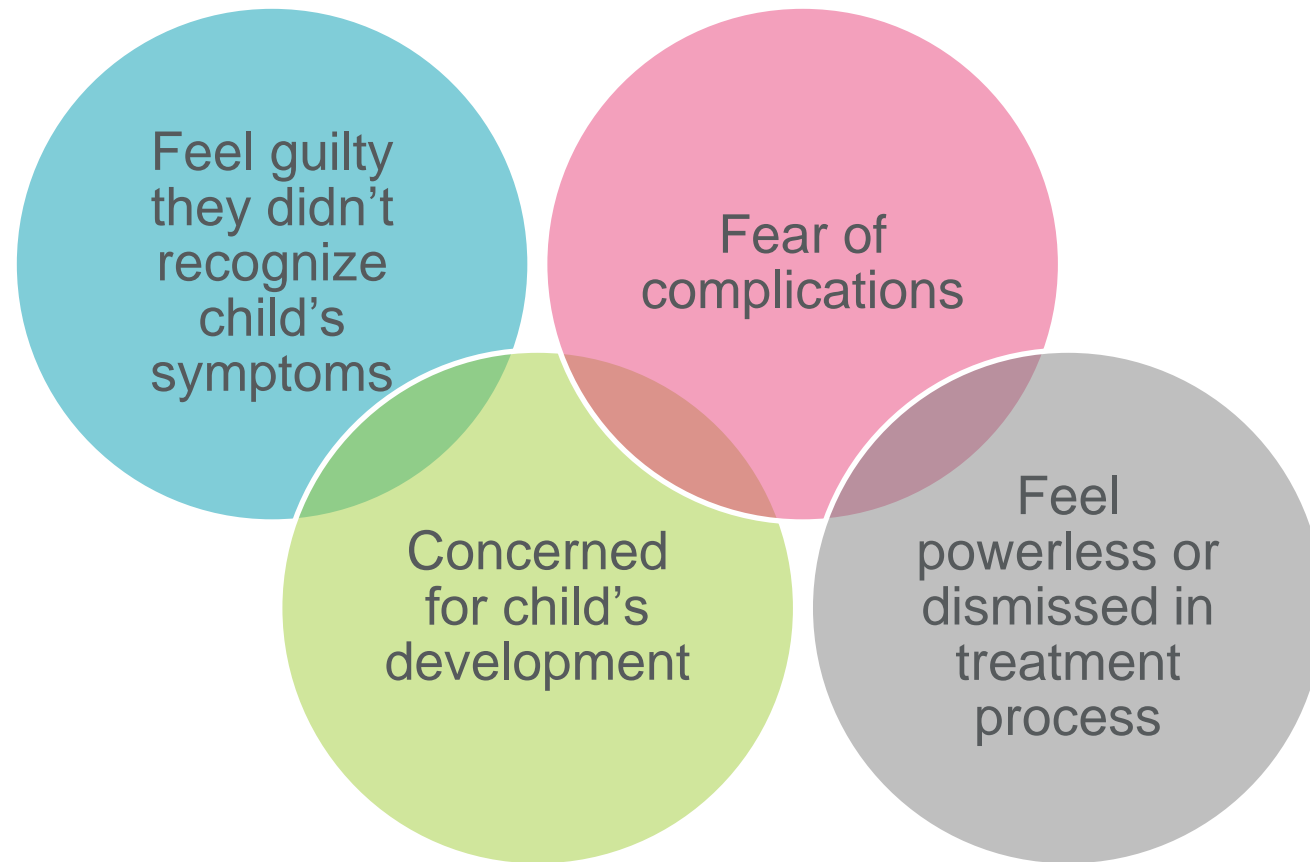
¹ Gravel, JS, Wallace, IF. Effects of otitis media with effusion on hearing in the first 3 years of life. *J Speech Lang Hear Res* 2000;43:631-44

² Aarhus, L., Tambs, K., Kvestad, E., & Engdahl, B. (2015). Childhood otitis media: a cohort study with 30-year follow-up of hearing (the HUNT study). *Ear and hearing*, 36(3), 302.

³ Graydon, K., Rance, G., Dowell, R., & Van Dun, B. (2017). Consequences of early conductive hearing loss on long-term binaural processing. *Ear and hearing*, 38(5), 621-627.

⁴ Homøe, P., Heidemann, C. H., Damoiseaux, R. A., Lailach, S., Lieu, J. E., Phillips, J. S., & Venekamp, R. P. (2020). Panel 5: Impact of otitis media on quality of life and development. *International journal of pediatric otorhinolaryngology*, 130, 109837.

Parental Perspectives of COM

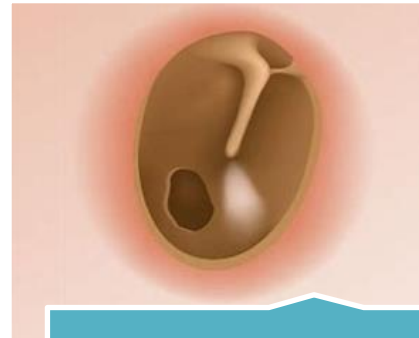




Antibiotics



PE tubes



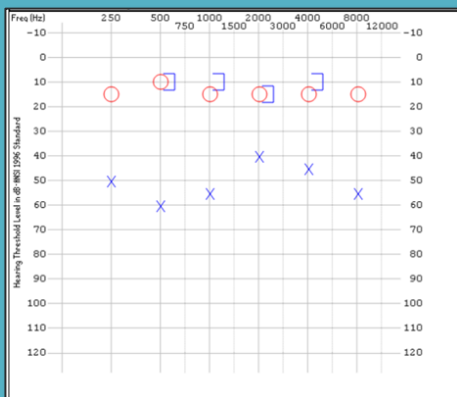
TM perforations



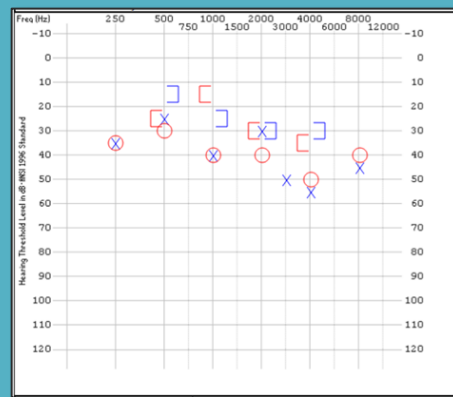
Cholesteatoma



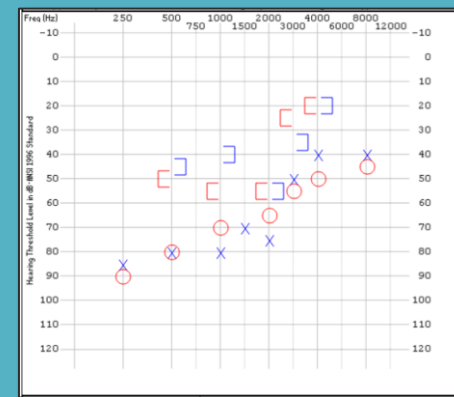
Middle ear surgery/reconstruction



COM associated hearing loss is primarily conductive



Persistent COM is linked to the development of significant SNHL¹

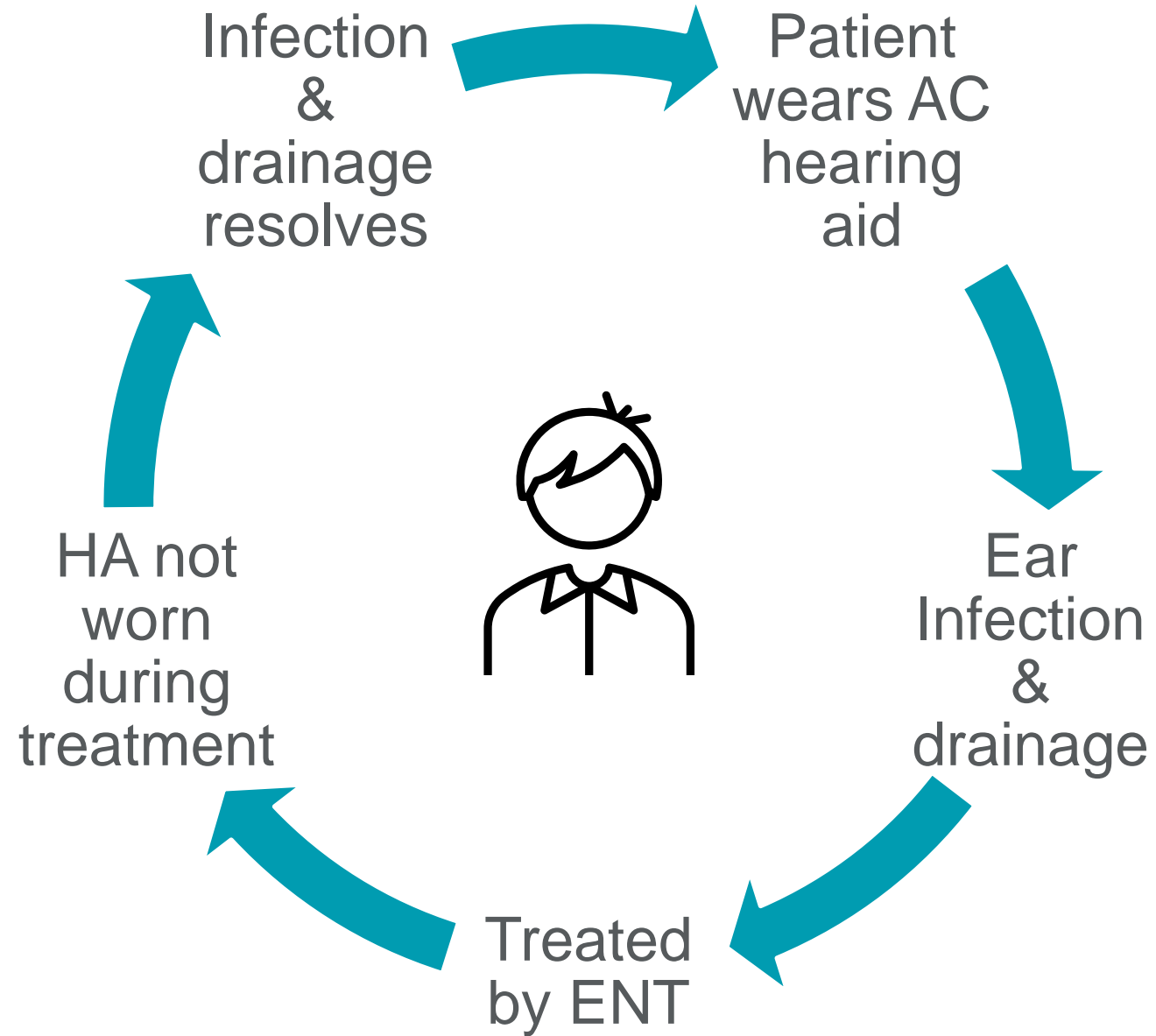


Not every patient with COM associated hearing loss has normal baseline hearing

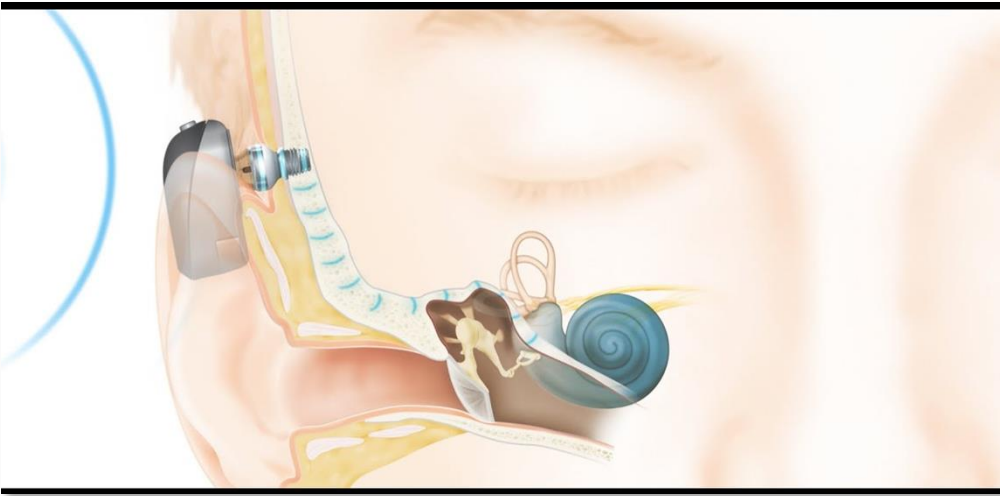
Air Conduction Hearing Devices



- ✓ Minimally Invasive
- ✓ Non-Surgical
- ✓ Common form of treatment for hearing loss
- ✗ Earmold blocks air circulation to ear canal
- ✗ Risk of bacteria
- ✗ Consistent use impacted by ongoing COM



Bone Conduction Hearing Devices



Sound processor converts sound into vibrations and transfers directly to cochlea, via bone conduction.

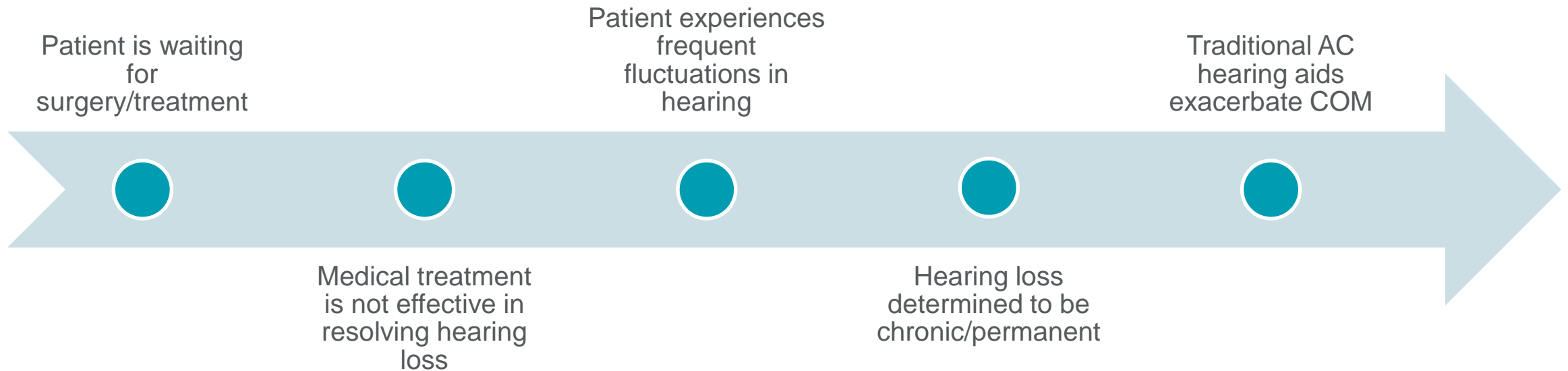
Completely bypasses outer and middle ear

Benefits of BCHD



- ✓ Ear canal remains open
- ✓ Consistent hearing despite fluctuations associated with middle ear disease
- ✓ Clinical flexibility
- ✓ Surgical and non-surgical options
- ✓ Good option when AC hearing aids fall short
- ✓ Current technology can fit BC losses up to 65 dB*

When to introduce BCHD



Bone Conduction Hearing Devices

Direct Drive

Skin Drive

Percutaneous

Active Transcutaneous Implant

Passive Non-Surgical

Passive Transcutaneous Implanted Magnet

Baha Connect

Ponto

Bonebridge

Osia

Headband

Softband

Adhear

Baha Attract

Sophonon



Skin Drive



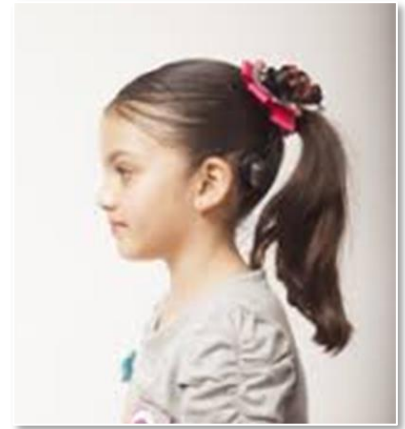
Sound transmitted through skin/tissue
before reaching bone

Concern for high frequency attenuation

Non-surgical options appropriate for infants

Non-surgical option good for temporary or
intermittent hearing loss

Surgical option – 5+ yrs



Direct Drive



Sound transmitted directly to bone

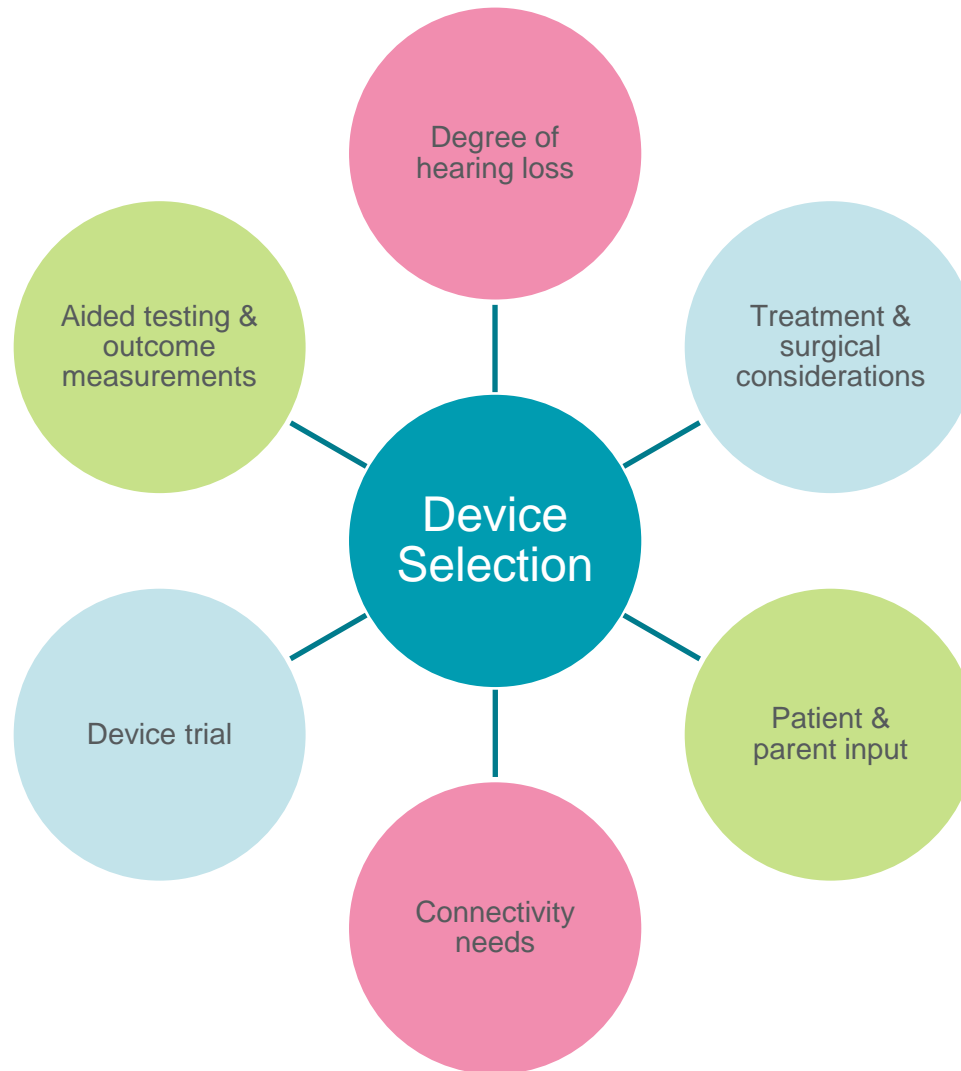
Most direct access point to sound

Better access to high frequency sounds

Better option for greater BC hearing loss

Surgical options – 5+ yrs
(12+ yrs for active transcutaneous in US)





Follow Best Practice



Evaluation/Selection



Fitting

- In-Situ measures



Verification



Validation

- Aided speech perception testing
- Outcome Questionnaires

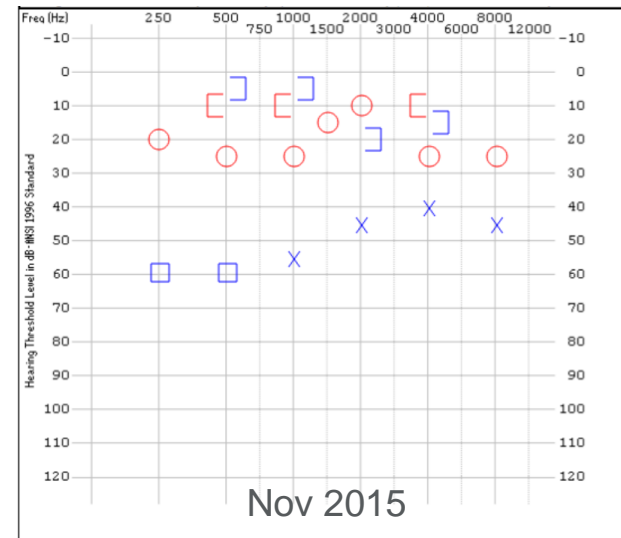
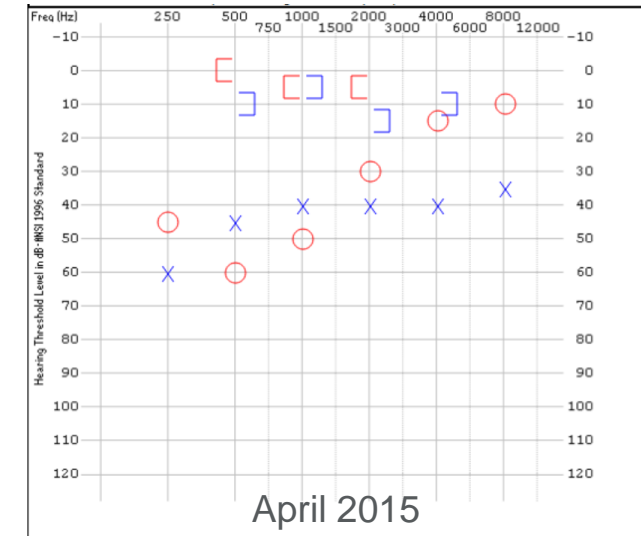
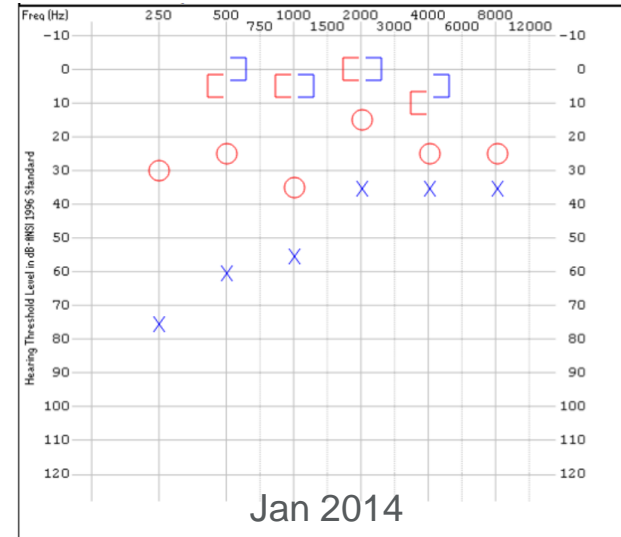


Bagatto, M., Gordey, D., Brewster, L., Brown, C., Comeau, M., Douglas, C., ... & Wollet, A. (2022). Clinical consensus document for fitting non-surgical transcutaneous bone conduction hearing devices to children. *International journal of audiology*, 61(7), 531-538.

Case Examples

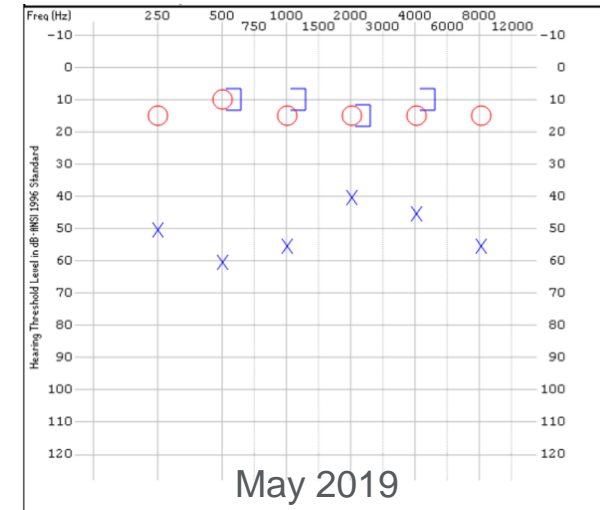
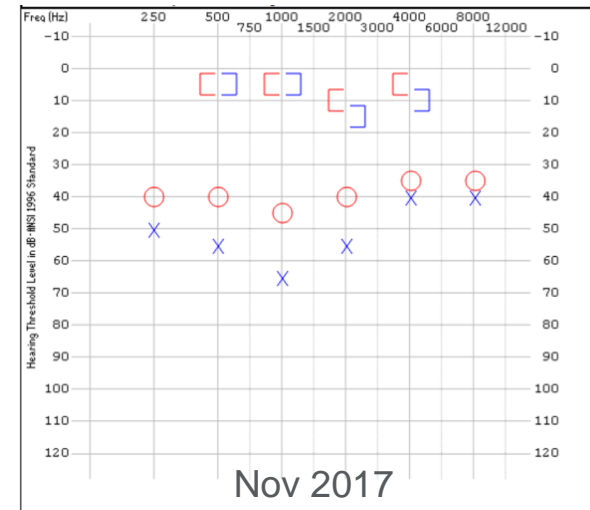
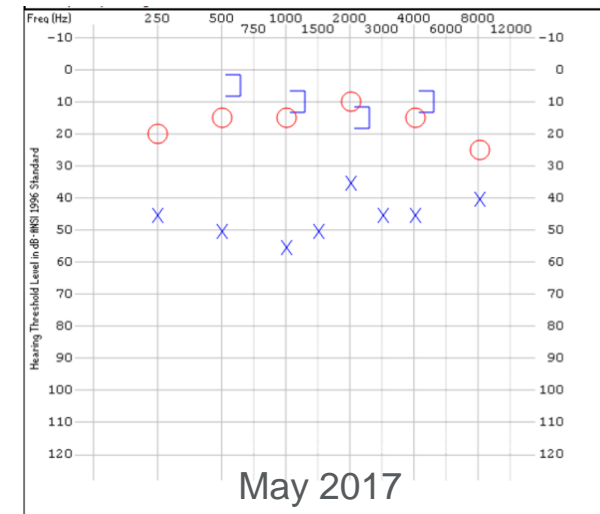
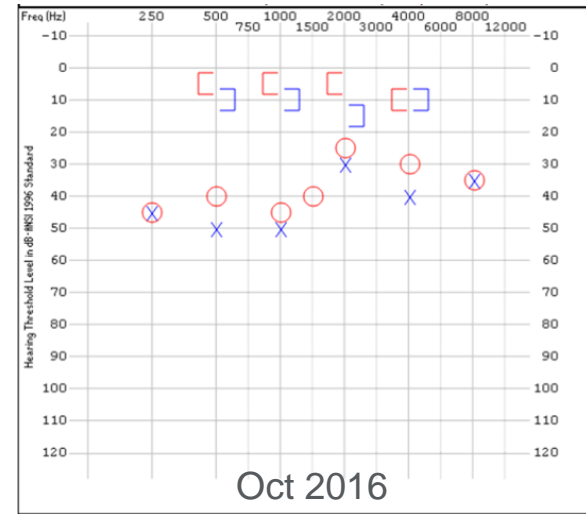
Case #1 – “H”

- 15 months
 - Bilateral PE tubes
- 6 yrs (2014)
 - Bilateral EUA – Jan
 - Confirmed left cholesteatoma
 - Left tympanomastoidectomy – Feb
 - Left tympanoplasty and Right EUA – Dec
 - Confirmed right cholesteatoma
- 7 yrs (2015)
 - *HA Evaluation Discussed*
 - Currently using desktop FM system
- 8 yrs (2016)
 - Bilateral EUA – Jan
 - Left tympanoplasty and ossicular reconstruction – April
 - *HA evaluation completed*



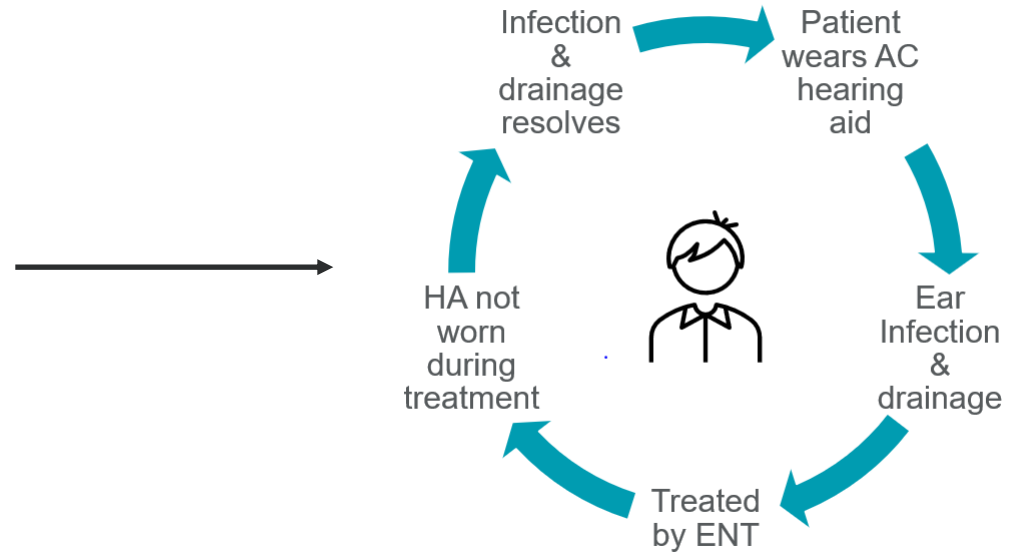
Case #1 – “H”

- 8 yrs (2016) cont...
 - Hearing Aid Evaluation (Oct) and Fitting (Nov)
 - Left AC hearing aid fit – ENT denied concerns for persistent drainage
 - Surgery scheduled for Right cholesteatoma – HA not recommended at that time
 - Right tympanoplasty – Dec
- 9 yrs (2017)
 - HA check w/ Audio (May)
 - Right WNL post- op
 - HA check w/ Audio (Nov)
 - Change in right ear hearing
- 10 yrs (2018)
 - Bilateral PE tubes (Jan)
- 11 yrs (2019)
 - HA check w/ Audio (May)
 - Right ear hearing WNL



Case #1 – “H”

- 12 yrs (2020)
 - Bilateral PE tubes (Feb)
- 2020-2022
 - Experiences multiple episodes of drainage which prevents consistent HA use
 - ENT/Audiology make joint decision to discuss alternate amplification options
- 15 yrs (2022)
 - BCHD evaluation (Sept)
- 16 yrs (2023)
 - Bilateral PE tubes and Cochlear Osia surgery (Jan)
 - Osia activation (Feb)
 - Initial follow-up (March)
 - Reports he hears better with Osia than with previous amplification. Aided speech testing confirms good benefit





Nov 23 2016

FB post:

Big changes for Hayden today. When they put in on he was smiling from ear to ear. Wish I would have gotten a video. It made me tear up. So excited for this new adventure for him.

Jan 11 2023

FB Post:

Lucky #13 complete. He did great & now has an OSIA2 in his head. Here's to better hearing in the future.



Feb 10 2023

FB Post:

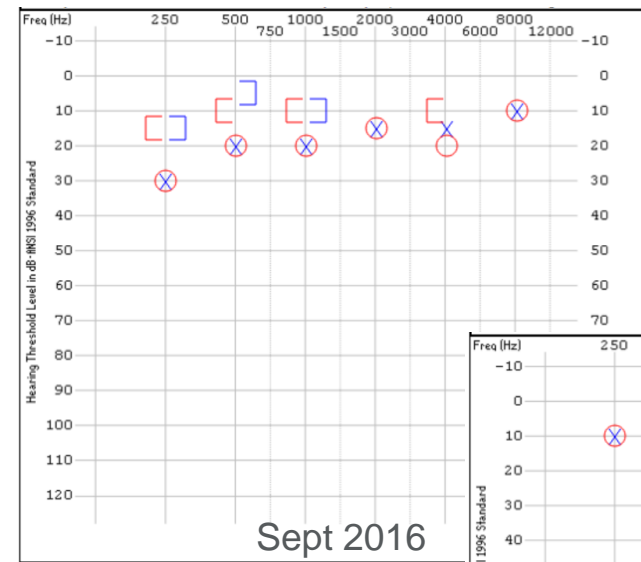
All turned on & working now. You can hardly see it with his long hair (the guide wire is just so he doesn't lose it while he is getting used to it).



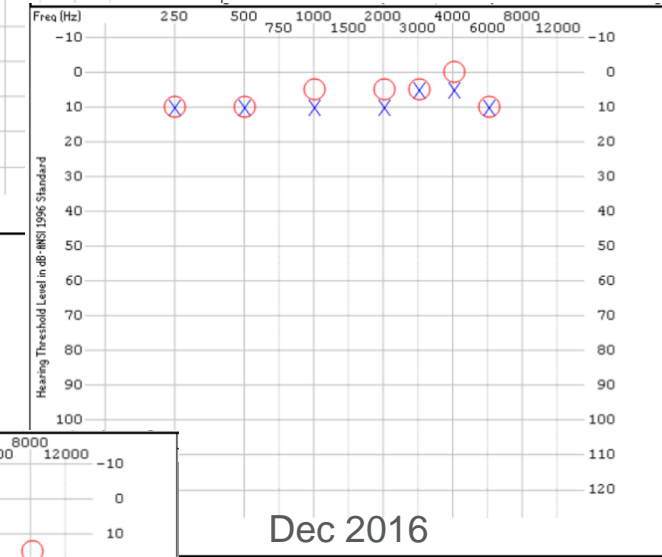


Case #2 – “E”

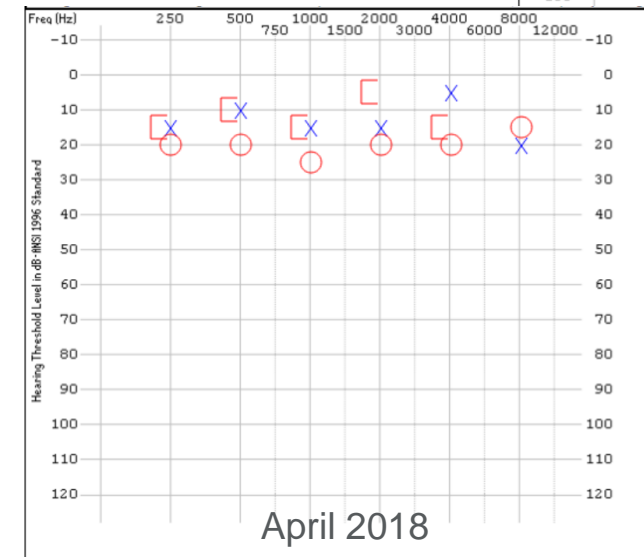
- Hx of PE tubes x 2, tonsils and adenoids removed
- 11 yrs (2016)
 - Audio = Low frequency CHL, Type B tympanograms (Sep)
 - PE tubes (Nov)
 - Audio = hearing WNL (Dec)
- 13 yrs (2018)
 - T-tubes (Feb)
 - Audio = Left WNL and Right slight CHL



Sept 2016



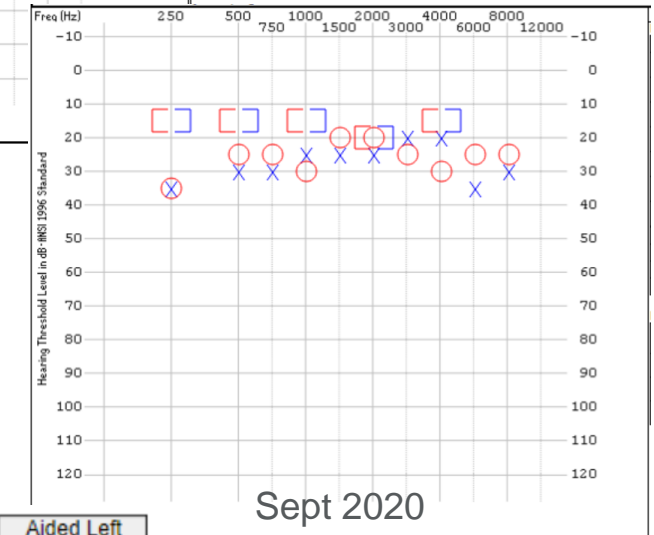
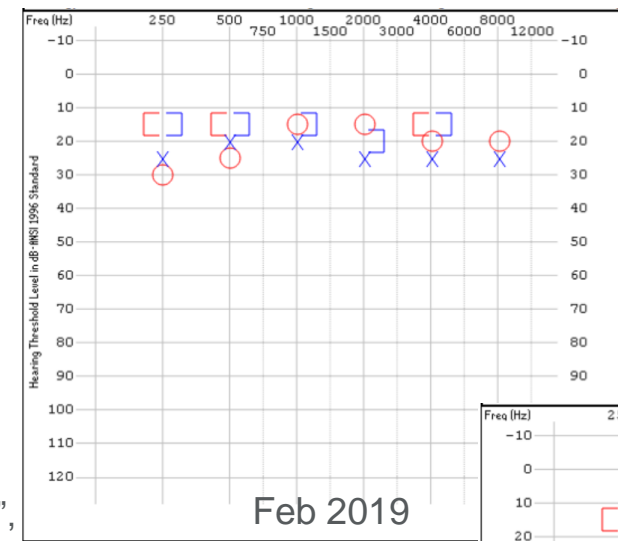
Dec 2016



April 2018

Case #2 – “E”

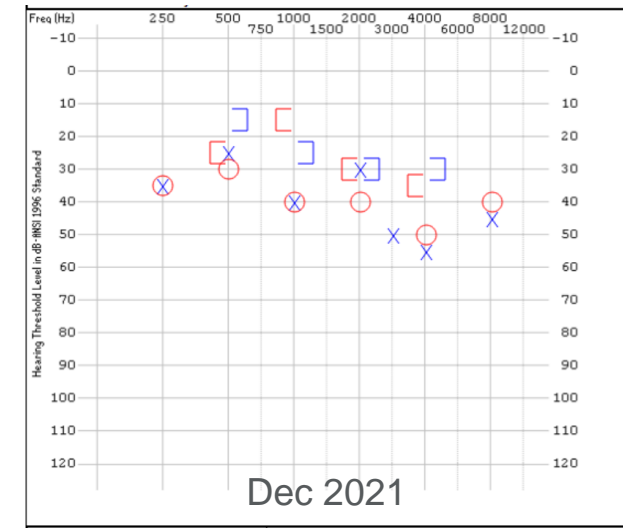
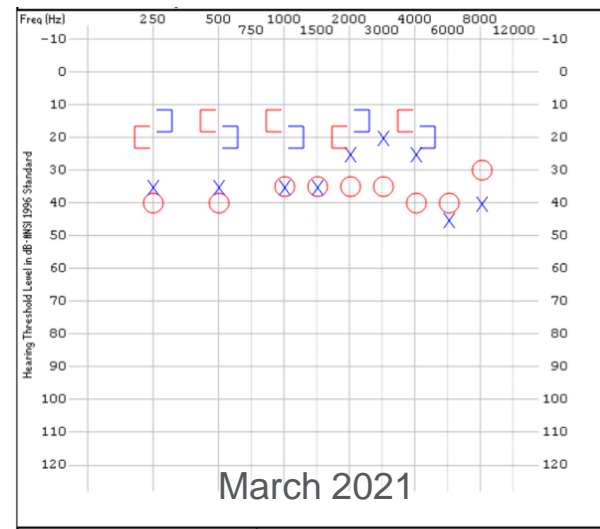
- 14 yrs (2019)
 - Audio = bilateral slight HL (Feb)
 - Patient reports difficulty hearing, primarily in situations with competing noise
 - ENT visit notes indicate “very mild auditory processing symptoms”, mom not interested in APD eval
 - HA evaluation (April)
 - Discussed AC and BC options, fit with demo RITE aids
 - HA follow-up (May)
 - “E” reported struggling with too much low freq noise and background noise. Asked to try Adhear. Fit with loaner
 - BCHD follow-up (June)
 - “E” reported Adhear was more comfortable and preferred the sound quality over the RITE aids.
 - Fit with personal Left Adhear device (July)
- 15 yrs (2020)
 - BCHD follow-up w/ Audio – shows change in hearing (Sep)
 - Aided speech in noise testing shows benefit with Adhear
 - Covid – attends in-person school, teachers wearing masks and/or shields
 - Wears device at school and for cheer
 - Reports chronic infections and drainage in right ear
 - Fit with second loaner Adhere – “E” reports feeling more balanced



Speech Perception Testing Results in NOISE	Unaided Both	Aided Left
Discrimination of Speech in Noise: % of Words Correct 50 dBHL (+5 SNR)	64%	84%
Discrimination of Speech in Noise: Sentences and/or Phrases/Signal to Noise Ratio (SNR) or Threshold Score	2.5 (Raw Score) 5 (SNR Loss)	-0.5 (Raw Score) 2 (SNR Loss)
Summary:	Mild SNR loss (3-7 dB)	Normal to near normal SNR (0-3 dB)

Case #2 – “E”

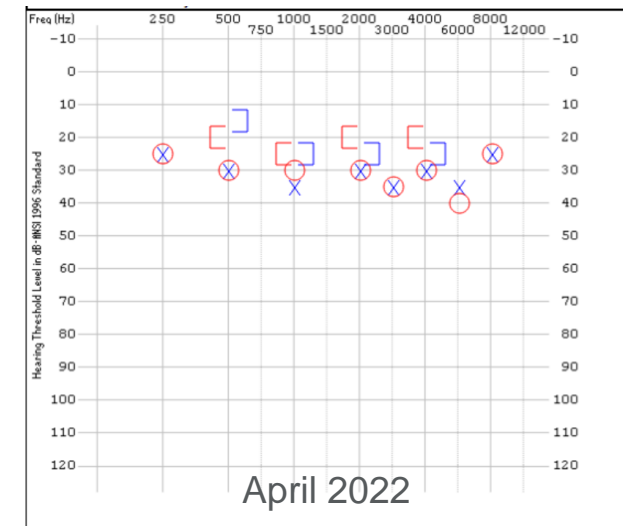
- 15 yrs (2020) cont...
 - Right tympanoplasty (Nov)
- 16 yrs (2021)
 - BCHD check w/ Audio (March)
 - Hearing worse bilaterally
 - “E” reports she feels “the end of people’s words ‘drop off’”. Continued difficulties in school
 - ENT visit (March)
 - Offered tympanoplasty and reconstruction to hopefully improve hearing or can consider surgical BCHD
 - BCHD evaluation (Dec)
 - Discussed multiple device options: AC vs BC, monaural vs binaural
- 17 yrs (2022)
 - Right sided Cochlear Osia surgery (March)
 - Osia activation (April)
 - BCHD check (May)
 - “E” is very happy with device. Aided speech testing shows good benefit



Speech Perception Testing Results in QUIET	Aided Right
Identification of Speech:	10
Speech Reception Threshold (SRT)	
Discrimination of Average Speech: % of Words Correct 50 dBHL in Quiet	100%
Discrimination of Soft Speech: % of Words Correct 35 dBHL in Quiet	84%

Speech Perception Testing Results in NOISE	Aided Right
Discrimination of Speech in Noise: Sentences and/or Phrases/ \Signal to Noise Ratio (SNR) or Threshold Score	2.5
Summary:	Normal to near normal SNR (0-3 dB)

LING-6 Sound Assessment	Threshold Aided
/a/ "ah"	15 dB HL
/u/ "oo"	20 dB HL
/i/ "ee"	15 dB HL
/S/ "sh"	15 dB HL
/s/ "ss"	15 dB HL
/m/ "mm"	15 dB HL



Case #2 – “E”

Lessons Learned

- No “managing” audiologist to push for amplification as she was seen by numerous audiologists though ENT clinic
- Hearing challenges were greater than expected for degree of hearing loss
- Parent advocating is what triggered intervention
- Post-covid school challenges increased academic difficulties
- Adhear was a good gateway to other BC technology
- Amplification made such an impact on her quality of life that she wrote a poem about her device and her college essay about her hearing journey



Case #3 – “M”

- CHARGE association
- Initial ABR (date unknown) indicated bilateral mild CHL
- 18 mo (2012)
 - Behavioral test
 - Hx semicircular canal abnormalities, developmental delay and persistent fluid in ears
 - Limited results obtained
 - Type B tympanograms bilaterally
 - Recommendation: ABR in OR following PE tubes

Case #3 – “M”

- 18 mo (2012) cont...
 - PE tubes and ABR
 - bilateral moderately-severe mixed hearing loss
 - Recommended HA evaluation
 - BTE hearing aids fit
- 2013 – 2016
 - HA check visits every 6-12 months
 - Behavioral testing limited
 - PE tubes 2 yrs, 3 yrs and 4 yrs
 - ABRs completed with procedures
 - PE tubes fall out very quickly
 - HA fluctuations expected with COM

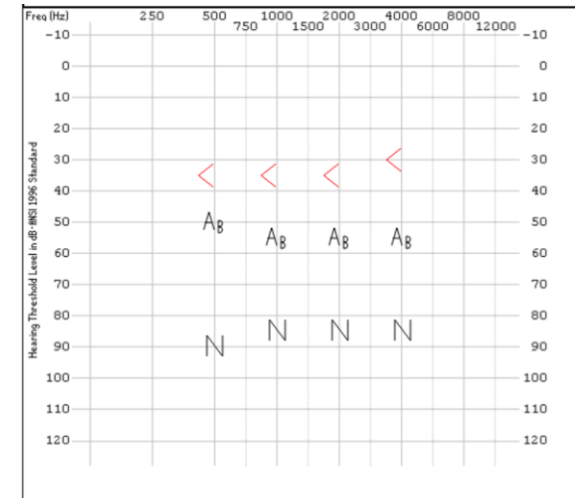


Predicted Hearing Thresholds (dB eHL)

	500 Hz	1000 Hz	Clicks	2000 Hz	4000 Hz
Right AIR	50 dB	60 dB	50 dB	55 dB	45 dB
Right BONE	25 dB	40 dB			40 dB
Left AIR	50 dB	70 dB	70	65 dB	65 dB
Left BONE	25 dB	30 dB		40 dB	55 dB

Case #3 – “M”

- 6 yrs (2017)
 - HA check
 - Behavioral testing = severe MHL
 - Parent reports consistent use and limited progress with speech
 - Concerns for continued ME fluid
 - BCHD loaner softband fitting
 - BCD follow-up
 - “M” accepted device well and parents noticed increased responses compared to AC HAs
 - PE tubes and ABR
 - Fit with bilateral Ponto 3 SP softband

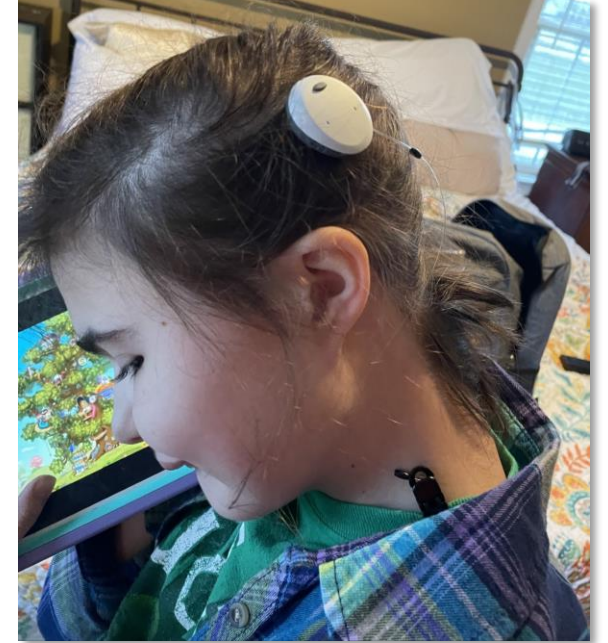


Predicted Hearing Thresholds (dB eHL)

	500 Hz	1000 Hz	Clicks	2000 Hz	4000 Hz
Right AIR	50	65		65	55
Right BONE	20	20		30	30
Left AIR	50	60		50	80
Left BONE	20	20		30	30

Case #3 – “M”

- 2017 – 2022
 - Continued with regular BCHD checks
 - Surgical BCHD options discussed, parents chose to wait until “M” was old enough for the Cochlear Osia
- Feb 2023 (12 yrs)
 - Left Osia surgery
 - Left side chosen due to patient behaviors (laying on right side, pressing iPad to right side, etc)
 - Goal is for right sided surgery in future



Case #3 – “M”

Parent perspective:

“Our transition over the years from unaided, to behind the ear, through softband to now implanted BAHA has been such a tremendous experience. To see the benefits presented with each device and my daughter’s advancements made with each technological advance has been astounding. Most definitely notable the bone conductive devices versus behind the ear but even more significantly from soft band to implantation was incredible. I feel her independence has grown so much in the last several months and I am so excited to give her this opportunity each day when I put her device on. ”



Special Populations

Down Syndrome



Hearing loss is common among individuals with Down Syndrome, with an estimated prevalence of 40-80% throughout childhood and early adulthood.¹

CHL is the most common type of loss, comprising ~80% cases

40-60% of cases of CHL are attributed to COM²

Middle ear disease and CHL may persist or fluctuate, despite treatment with PE tubes³

¹ Park AH, Wilson MA, Stevens PT, Harward R, Hohler N. Identification of hearing loss in pediatric patients with Down syndrome. *Otolaryngol Head Neck Surg.* 2012; 146(1):135-140.

² Shott SR, Joseph A, Heithaus D. Hearing loss in children with Down syndrome. *Internat J Pediatr Otolaryngol.* 2001; 61:199-205.

³ Sidell D, Hunter L, Lin L, Arjmand E. Risk factors for preoperative and postoperative hearing loss in children undergoing pressure equalization tube placement. *Otolaryngol Head Neck Surg.* 2014; 150(6):1048-1055.

Case #4 – “W”

- Born at 31 weeks
 - Trisomy 21
 - Assisted ventilation
 - 10 weeks in NICU
 - g-tube at 2 months
- ABR at 2 months = normal hearing bilaterally
 - Recommended follow-up ABR at 4 months to monitor
- Behavioral test at 8 months
 - Cerumen occlusion
 - Flat tympanogram bilaterally
 - Limited behavioral results obtained
 - Recommended ENT visit and retest hearing following treatment

Case #4 – “W”

- ENT visit w/ DS specialist at 9 months
 - Cerumen removal
 - TM partially visualized, unable to confirm fluid
 - Behavioral test
 - No parental concerns for hearing loss
 - Flat tympanogram bilaterally
 - Elevated soundfield SAT – no other results able to be obtained
 - Recommended EUA with PE tubes and ABR
- EUA at 12 months
 - Fluid in left, clear right
 - Ear canals stenotic, PE tubes could not be placed
 - ABR = mild bilateral CHL
 - Recommended BCHD evaluation and continued medical management

Minimal Response Levels (dB eHL)

ABR minimal response levels are an estimate of peripheral hearing sensitivity and can be expected to be within 10dB of behavioral thresholds.

	1000 Hz	2000 Hz	4000 Hz
Right AIR	35	40	30
Right BONE	15	15	15
Left AIR	35	30	25
Left BONE	15	15	15

ABR Summary:

Right Ear: Mild conductive hearing loss

Left Ear: Mild to slight conductive hearing loss

Case #4 – “W”

- BCHD evaluation at 13 months
 - Softband recommended for use until PE tubes could be placed
 - Fit with loaner Baha 5
- Follow-up at 15 months
 - ENT: Ears cleaned, canals stenotic, f/u in 3 months
 - Audiology
 - wearing device primarily when actively engaged and during therapy
 - LittleEARS = not meeting auditory milestones for adjusted age
 - Aided speech testing indicated benefit with softband device
 - Parents report noticing benefit and request personal devices
 - Fit with personal binaural Ponto 5 mini devices on softband

Speech Perception Testing Results in QUIET	Unaided Both	Aided Right
Detection of Speech: Speech Awareness Threshold (SAT)	45	20/25



Case #4 – “W”



- Follow-up device check appointments with behavioral testing every 3-6 months over next 15 months
 - Parents report observing benefit and improvement in auditory awareness when wearing softband but she “becomes very vocal and upset when she isn’t in the mood to wear them”
 - Continued flat tympanograms
 - Limited behavioral results obtained = abnormal

Case #4 – “W”

- EUA and ABR at 32 months
 - PE tubes able to be placed
 - Normal hearing in both ears
 - Recommended discontinue BCHD use, follow-up in 6 months for continued monitoring



Down Syndrome Study

- Examine clinical outcomes of infants and young children with Down Syndrome diagnosed with conductive or mixed hearing loss who are initially managed with a bone conduction hearing device.
 - Audiologic outcomes
 - Speech and language outcomes
 - Developmental outcomes
 - Parent reported outcomes
- Currently in the enrollment process: patients 3-12 months old will be enrolled and followed through course of standard clinical care until 36 months



NICU Population



Cleft Lip and Palate

- More than 200 syndromic conditions are associated with cleft lip and palate¹
- Significantly higher prevalence of COM and associated hearing loss²

Tracheostomy-dependent

- Associated with increased risk of requiring PE tubes³
- Patients requiring mechanical ventilation have significantly higher likelihood of developing middle ear effusion⁴

¹ Stuppia, L., Capogreco, M., Marzo, G., La Rovere, D., Antonucci, I., Gatta, V., ... & Tete, S. (2011). Genetics of syndromic and nonsyndromic cleft lip and palate. *Journal of Craniofacial Surgery*, 22(5), 1722-1726.

² Flynn, T., Möller, C., Jönsson, R., & Lohmander, A. (2009). The high prevalence of otitis media with effusion in children with cleft lip and palate as compared to children without clefts. *International journal of pediatric otorhinolaryngology*, 73(10), 1441-1446.

³ McAfee, J. S., Demarcantonio, M., Fine, B. R., Beydoun, H., & Derkay, C. S. (2013). Prevalence of ventilation tubes in children with a tracheostomy tube. *International Journal of Pediatric Otorhinolaryngology*, 77(1), 65-68.

⁴ Wynings, E. M., Jaffal, H., John, R. S., Johnson, R. F., & Chorney, S. R. (2022). Mechanical ventilation and middle ear effusions among tracheostomy-dependent children. *International Journal of Pediatric Otorhinolaryngology*, 155, 111062.

Case #5 – “J”

- Born at 33 weeks
- Multiple congenital anomalies: micrognathia, bilateral clubbed feet, cleft palate, cerebellar hypoplasia, tracheobronchomalacia
- Respiratory failure, chronic lung disease
- 8 months in NICU
- Tracheostomy at 3 months
- Middle ear effusion was noted on two MRI evaluations (1 month and 3 months)

Case #5 – “J”

- ABR @ 3 mo = Mild CHL bilaterally w/ abnormal tymps
- ABR @ 5 mo = Moderate CHL bilaterally
 - Bedside nurse and mom agreed his secretions are consistently thick since his trach placement

Minimum Response Levels (dB eHL)

	1000 Hz	Clicks	4000 Hz
Right AIR	50		50
Right BONE	15		
Left AIR	50		40
Left BONE	20		

Delayed absolute latency responses in both ears, consistent with a conductive hearing loss.

Tympanometry: 1000 Hz Probe tone:
Right Ear: flat
Left Ear: flat

Case #5 – “J”

- A BCD loaner fitting was offered as a temporary solution due to long term middle ear fluid and moderate conductive hearing loss until ears are clear and normal hearing is established.
- Discussed with mom that the purpose of this treatment is to provide improved access to sound until ears are clear.

RECOMMENDATIONS: The following were discussed at length with mom:

- 1) It is recommended that [REDACTED] use the BCD while being held by mom while she is interacting with him (talking, singing, etc) in a quiet environment. Mom was counseled to monitor [REDACTED] cues throughout this time.
- 2) Follow up ABR in 8 weeks or sooner with any change in middle ear status/ treatment
- 3) If the family no longer wants to use the device, it should be returned to Audiology.

Case #5 – “J”

- “The BCD was used while mom engaged with “J” on his play mat or while holding him. She felt that he responded very well to her voice and was more engaged during interactions with herself and the staff. Mom reported that he was more interested in her while she was talking rather than wanting to go to sleep.”
- PE tubes placed and ABR at 7 months
 - Mother felt that he was now responding to sounds and voices the same as what he did with the BCD.

ASSESSMENT

ABR Evaluation:

The auditory brainstem response was observed at levels that rule out a significant hearing loss:

Minimum Response Levels (dB eHL):

	1000 Hz	2000 Hz	4000 Hz
Right AIR	20	20	20
Left AIR	20	20	20

Waveform Morphology: Normal-appearing for infant’s adjusted age.

SUMMARY

These results rule out any significant peripheral hearing loss at this time.

RECOMMENDATIONS

1. Discontinue use of bone conduction device due to resolution of temporary hearing loss. Mom felt that the BCD was beneficial and was very appreciative for being able to use it. The BCD was returned to Audiology.
2. Behavioral hearing test in 9-12 months or sooner if concerns arise.

Hearing Intervention in NICU

- Infants who require immediate medical care in the Neonatal Intensive Care Unit (NICU) are not only at a higher risk for hearing loss, but intervention is often delayed until after they are discharged from the hospital.
- There are many reasons why hearing intervention should be considered:
 - Support parent bonding*
 - Awareness of environmental cues
 - Anticipation of medical care
 - Benefit from interventions to support calming and development
 - Supports sensory needs



Hearing Intervention in NICU

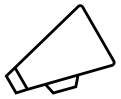
- BCHD good option for this population
 - Appropriate treatment for the type of hearing loss
 - Ease of placement and use
 - Flexibility of device position for reduced feedback
 - Adjustable softband for child growth
 - Consistent auditory access with frequent or fluctuating middle ear fluid
- Inpatient Audiology program
 - Sensory care plan
 - Specialized inpatient audiologists
 - Close monitoring of patient and device
 - Collaboration with medical staff



Grosnik, A., & Baroch, K. (2020). Earlier Intervention for Medically Fragile Pediatric Inpatient Population. *The Hearing Journal*, 73(10), 22-23.

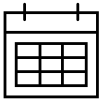
Takeaways

It's ok to push for amplification! If you don't, who will?



- Your role as the audiologist is to manage hearing needs while collaborating with ENT's medical management

Consider loaner or short-term amplification

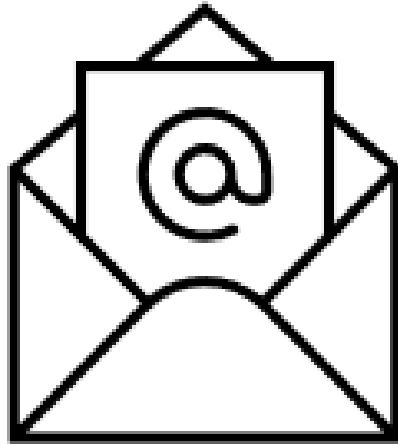


- Loaner devices are important to have available in your clinic

Think outside the box



- Current BCHD technology can meet hearing needs of a wide variety of patients



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