Navigating Change: Parental Perspectives on Children's Transition to Surgical Bone Conduction Devices

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DISCLOSURES

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- No relevant non-financial relationships exist

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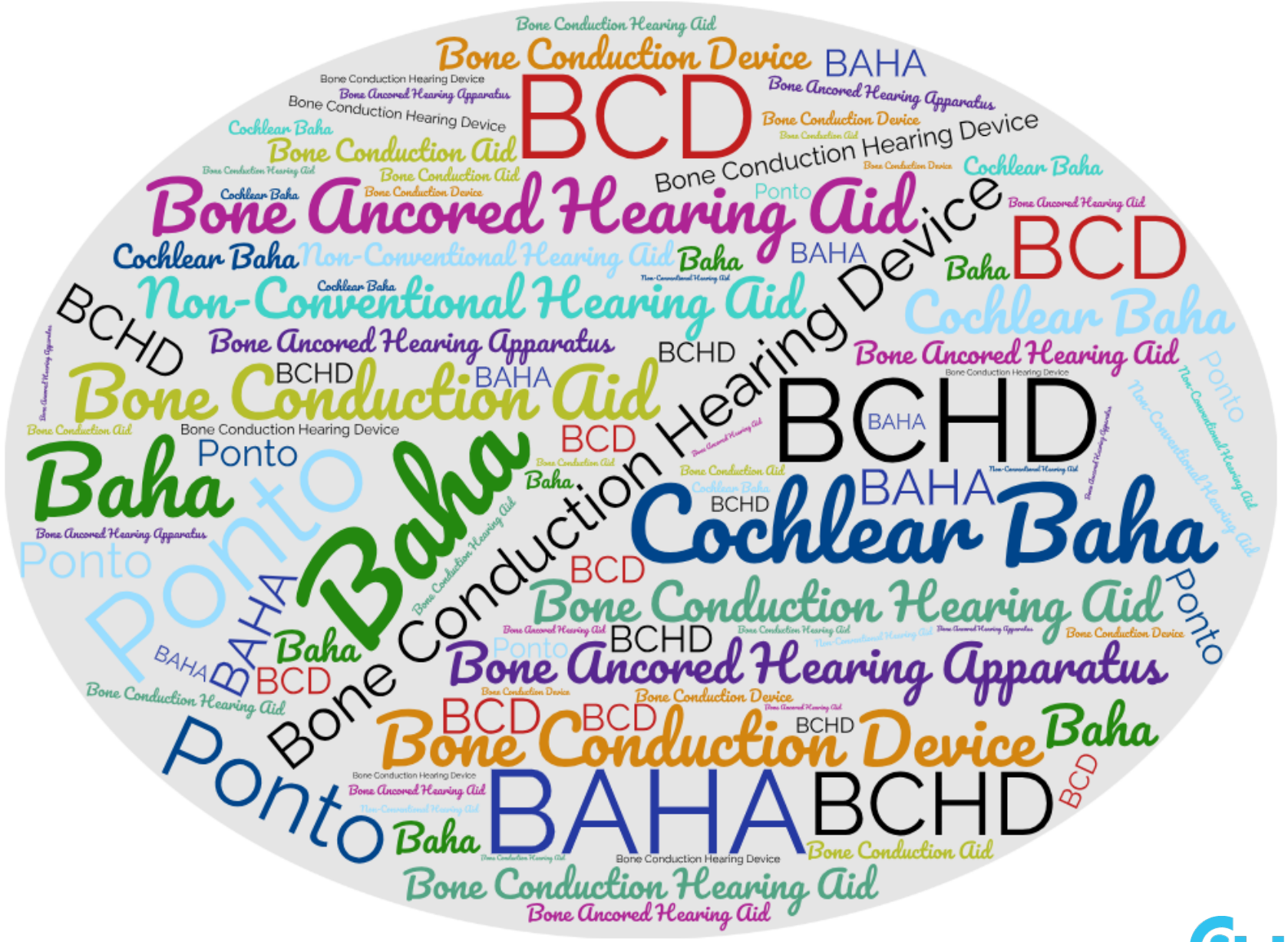

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BONE CONDUCTION DEVICE (BCD)

A non-conventional form of amplification used to treat hearing loss through direct bone conduction.

Hearing loss may be unilateral or bilateral conductive, mixed, or single-sided deafness.

A BCD can be non-surgical or surgically implanted.

A BCD should be recommended to individuals who are unable to use conventional air conduction amplification.

Bone Conduction Devices

Direct Drive Surgical

Percutaneous (>5 years)

- Baha Connect
- Ponto

Active Transcutaneous Surgical

- BONEBRIDGE (≥ 12 years)
- Osia (*≥5 years)
- Sentio (⁂≥12 years)

Skin Drive

Transcutaneous Non-Surgical

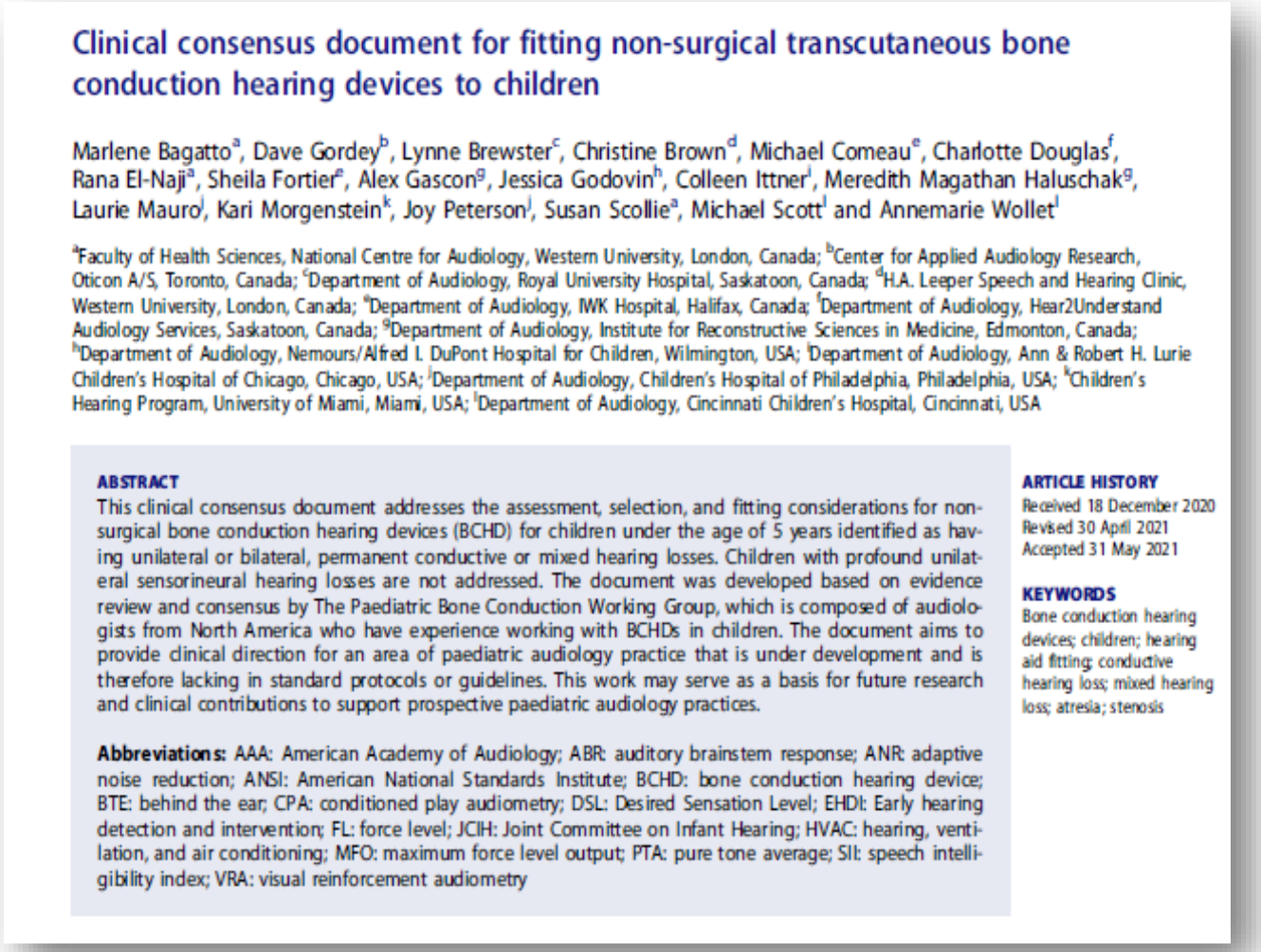
- Headband SoundArc
- Soft Band

Passive Transcutaneous Surgical

- ADHEAR
- ✢ Baha Attract

*FDA approved ≥5 years old 4/2024
⁂FDA approved≥12 years old 7/2024
✢ Baha Attract is no longer available for new systems as of 2/2025

CLINICAL OUTCOMES IN PEDIATRIC AUDIOLOGY (COPA) WORKING GROUP



Clinical consensus document for fitting non-surgical transcutaneous bone conduction hearing devices to children

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ABSTRACT

This clinical consensus document addresses the assessment, selection, and fitting considerations for non-surgical bone conduction hearing devices (BCHD) for children under the age of 5 years identified as having unilateral or bilateral, permanent conductive or mixed hearing losses. Children with profound unilateral sensorineural hearing losses are not addressed. The document was developed based on evidence review and consensus by The Paediatric Bone Conduction Working Group, which is composed of audiologists from North America who have experience working with BCHDs in children. The document aims to provide clinical direction for an area of paediatric audiology practice that is under development and is therefore lacking in standard protocols or guidelines. This work may serve as a basis for future research and clinical contributions to support prospective paediatric audiology practices.

Abbreviations: AAA: American Academy of Audiology; ABR: auditory brainstem response; ANR: adaptive noise reduction; ANSI: American National Standards Institute; BCHD: bone conduction hearing device; BTE: behind the ear; CPA: conditioned play audiometry; DSL: Desired Sensation Level; EHDI: Early hearing detection and intervention; FL: force level; JCIH: Joint Committee on Infant Hearing; HVAC: hearing, ventilation, and air conditioning; MFO: maximum force level output; PTA: pure tone average; SII: speech intelligibility index; VRA: visual reinforcement audiometry

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Bone conduction hearing devices; children; hearing aid fitting; conductive hearing loss; mixed hearing loss; atresia; stenosis

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TRANSITION: FROM SOFTBAND TO SURGICAL BCD

Softband BCDs are commonly used for young children under 5 years of age who are not candidates for surgical BCD solutions.

Early access to hearing solutions is crucial for language, cognitive, and social development.

Challenges as children grow:

- Increased exposure to complex listening environments (i.e., classrooms, playgrounds) and need for high-frequency speech access.
- Limited high-frequency access with softband use due to skin transmission loss and wear time challenges.

Bagatto et al., 2022
Fabian et al., 2024
Yoshinaga-Itano et al., 2017
Yoshinaga-Itano et al., 2013

COUNSELING FOR SURGICAL BCD

- An exact demonstration of surgical BCD does not exist
- Differences exist in the output of a non-surgical device compared to a surgically implantable system
- Benefit with a non-surgical BCD can give some indication of expected performance

Bagatto et al., 2022

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BENEFITS OF SURGICAL BCD

- Improvement in aided thresholds and speech perception testing
- Better sound quality and performance
- Increase in learning speed
- Enhanced working memory
- More high frequency emphasis

Kara et al., 2016
Pittman, 2019

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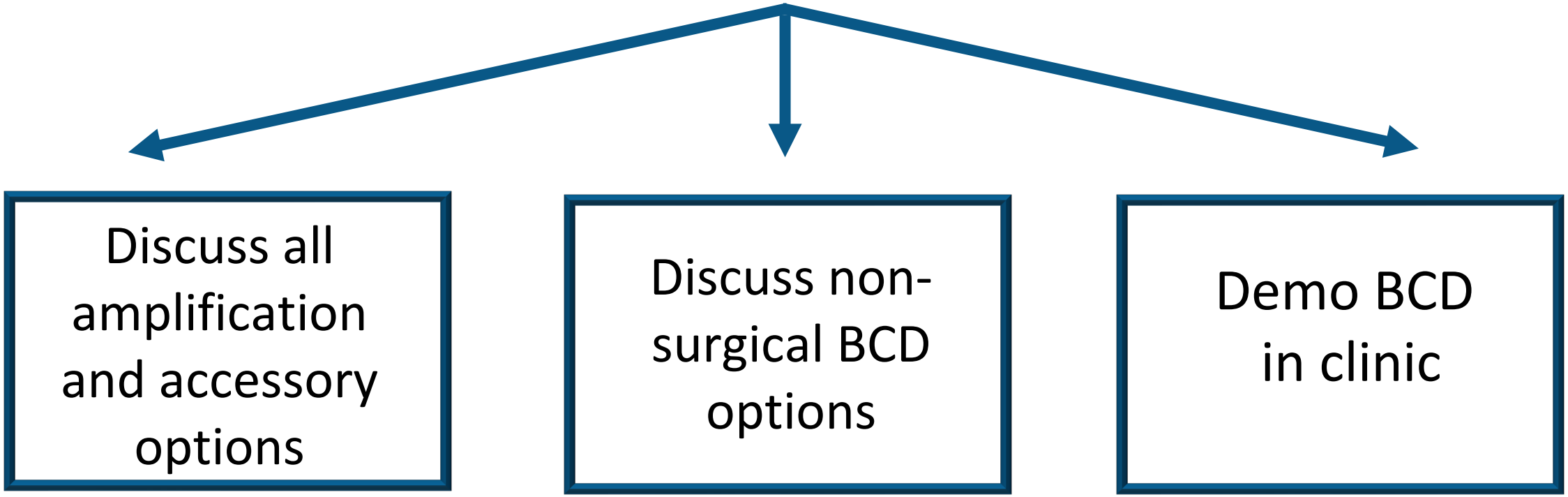
PARENT PERSPECTIVES

- Uncertainty regarding the audiological benefits of the surgical system
- Challenges in determining the optimal timing for transition
- Anxiety about potential outcomes and complications
- Hesitation about surgery– concerns regarding the procedure, recovery time and risks
- Emotional impact – concerns about the child's comfort, appearance and adjustment to a more permanent and different solution

CASE STUDY: GRACE

- Born in China, adopted and moved to the United States at age four
- Initial Audiology visit to CHOP in conjunction with an ENT visit
- Hemifacial microsomia
- Atresia/microtia of left ear
- Normal-appearing right ear
- Diagnosed with a unilateral moderate conductive hearing loss in the left ear
- BCD evaluation completed one month later

GRACE'S BCD EVALUATION



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Bone Conduction Devices

- **Direct Drive Surgical**
  - **Percutaneous (>5 years)**
    - Baha Connect
    - Ponto
  - **Active Transcutaneous Surgical**
    - BONEBRIDGE (≥ 12 years)
    - Osia (*≥5 years)
    - Sentio (⁂≥12 years)
- **Skin Drive**
  - **Transcutaneous Non-Surgical**
    - Headband SoundArc
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GRACE 4-YEARS OLD:
BCD NON-SURGICAL OPTIONS

Cochlear Baha 5 Power Softband

Oticon Medical Ponto 4 Softband

MED-EL ADHEAR

TECHNOLOGY NEEDS MAY CHANGE

- As child gets older, different features may be warranted
- New processors are released
- Manufacturer and device choice for non-surgical should meet current needs
- Choice for non-surgical BCD does not commit the patient to single manufacturer for lifetime

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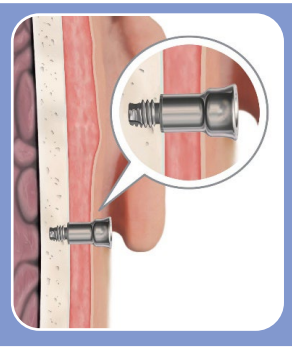
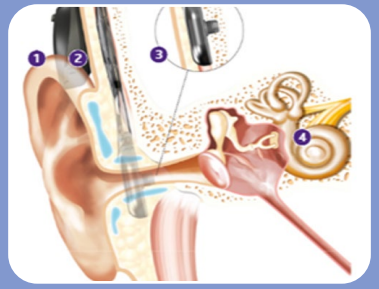
GRACE 6-YEARS OLD: NEXT STEPS

Continue with softband



Percutaneous Implant



Active Transcutaneous Implant

Bone Conduction Devices

Direct Drive Surgical

Percutaneous (>5 years)

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Active Transcutaneous Surgical

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BCD SURGICAL OPTIONS

PERCUTANEOUS

≥ 5 years of age

Through the skin (abutment)

Cochlear Connect

Oticon Medical Ponto

ACTIVE TRANSCUTANEOUS

≥ 12 years of age

Across the skin (magnetic connection)

Cochlear Osia 2

MED-EL BONEBRIDGE

Oticon Medical Sentio

Candidacy criteria for surgical BCD options is determined according to the Food and Drug Administration (FDA) regulations for specific device indications

COCHLEAR OSIA® PEDIATRIC CLINICAL TRIAL STUDY DESIGN AND OBJECTIVES

Multi-center, prospective, open-label, FDA Investigational Device Exemption (IDE) G200325

7 participating clinical sites distributed by geographical location, practice size, and type

50 children aged 5 to 11 years with mixed, conductive & SSD

1 Objective: Evaluate audiological improvements in pediatric patients transitioning from non-surgical BCDs to surgical systems

2 Objective: Assess parental satisfaction with surgical BCDs

ClinicalTrials.Gov ID NCT 05000931

Safety and Efficacy of the Cochear™ Osia® 2 System in a Pediatric Population: Multi-Center Trial Results

STUDY DEMOGRAPHICS

Characteristic	SSD (N=13)	M/CHL (N=37)
Gender		
Male	7 (54%)	16 (43%)
Female	6 (46%)	21 (57%)
Race		
White	8 (61%)	25 (67%)
Other	4 (31%)	2 (5%)
Asian	0 (0%)	4 (11%)
Non-Disclosed	1 (7%)	2 (5%)
Black	0 (0%)	2 (5%)
Native American	0 (0%)	2 (5%)
Ethnicity		
Non-Hispanic	8 (61%)	22 (59%)
Hispanic	5 (38%)	14 (38%)
Prefer Not to Disclose	0 (0%)	1 (3%)

Characteristic	SSD (N=13)	M/CHL (N=37)
Age at Surgery		
5 years	3 (23%)	9 (24%)
6 years	1 (7%)	8 (22%)
7 years	3 (23%)	2 (5%)
8 years	1 (7%)	7 (19%)
9 years	3 (23%)	5 (13%)
10 years	0 (0%)	3 (8%)
11 years	3 (23%)	2 (5%)

- 10 bilateral participants with mixed/conductive hearing loss
- 27 participants with unilateral mixed/conductive hearing loss

ClinicalTrials.Gov ID NCT 05000931

GRACE: 8 YEARS OLD

- Grace had difficulty ensuring the softband stayed securely in place without slipping
- Percutaneous implant was not considered, due to known concerns regarding skin overgrowth as well as infection that is often associated with abutments
- Grace and her mother were interested pursuing surgical active transcutaneous BCD
- Grace enrolled in the Cochlear Osia Pediatric Expansion Clinical Trial

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AIDED LEFT SOUNDFIELD TESTING

Test Materials	Baha 5P Softband (Pre-operative)	Osia 2 (Post-operative, 6-month visit)
CNC (60 dBA)	78%	94%
BKB-SIN (65 dBA)	+6 dB SNR Loss	+2 dB SNR Loss
Narrowband Noise (dBHL)	500 Hz: 20 1000 Hz: 20 2000 Hz: 25 4000 Hz: 40	500 Hz: 20 1000 Hz: 20 2000 Hz: 20 4000 Hz: 20

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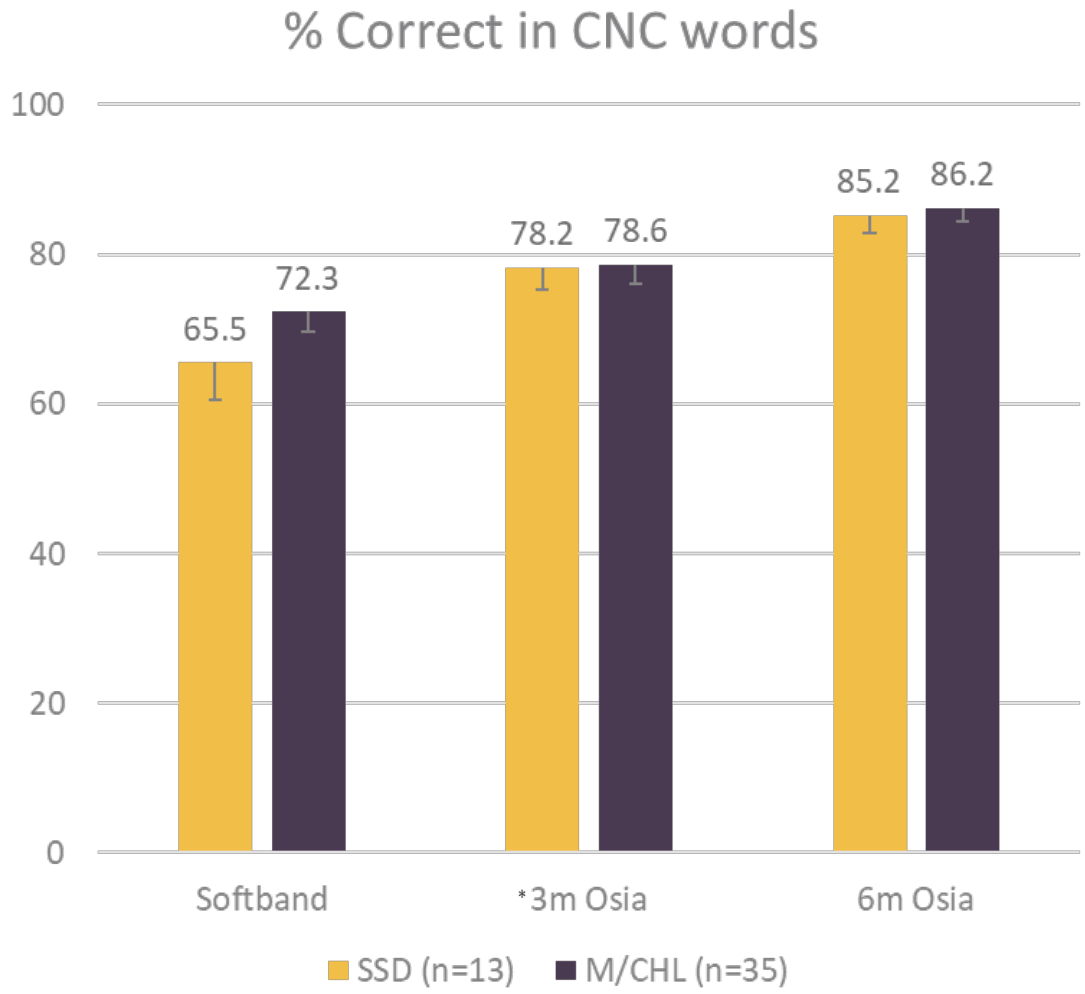
SOFTBAND VS. 6-MONTH OSIA VISIT: CNC WORDS

CNC word scores significantly improved from the pre-operative aided condition with the **softband to 6 months post-surgery** ($p < 0.001$) for both the SSD and M/CHL populations (n = 48) in their treated ear.



* Additionally, CNC word scores significantly improved from preoperative baseline to 3 months post surgery

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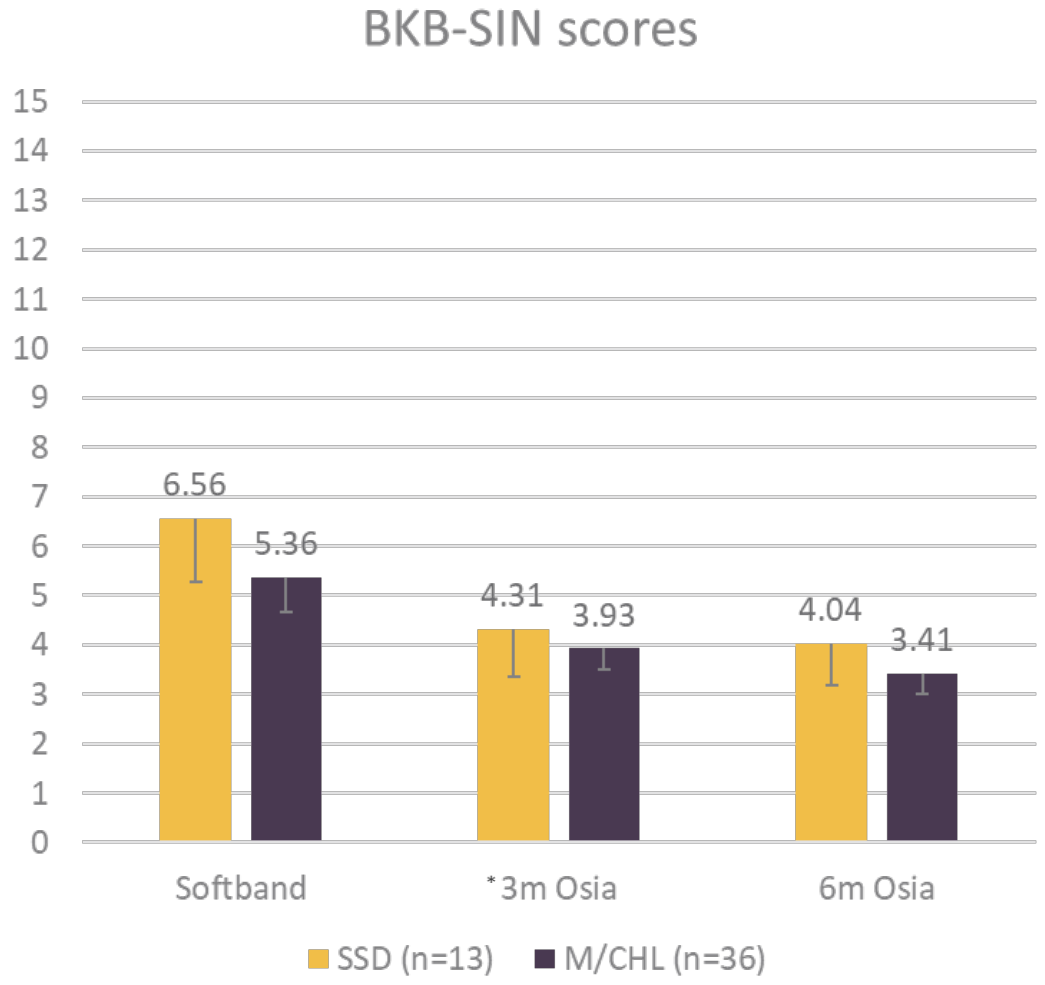
SOFTBAND VS. 6-MONTH OSIA VISIT: BKB-SIN

Children with an Osia implant can achieve scores in noise similar to those of their normal hearing peers, with age effects observed in a similar manner[1]

A significant improvement in SNR-50 was observed from pre-operative aided condition with the **softband to 6 months post-surgery** for combined SSD and M/CHL populations ($p = 0.044$) in their treated ear (n=49).



* Additionally, BKB-SIN scores significantly improved from preoperative baseline to 3 months post surgery

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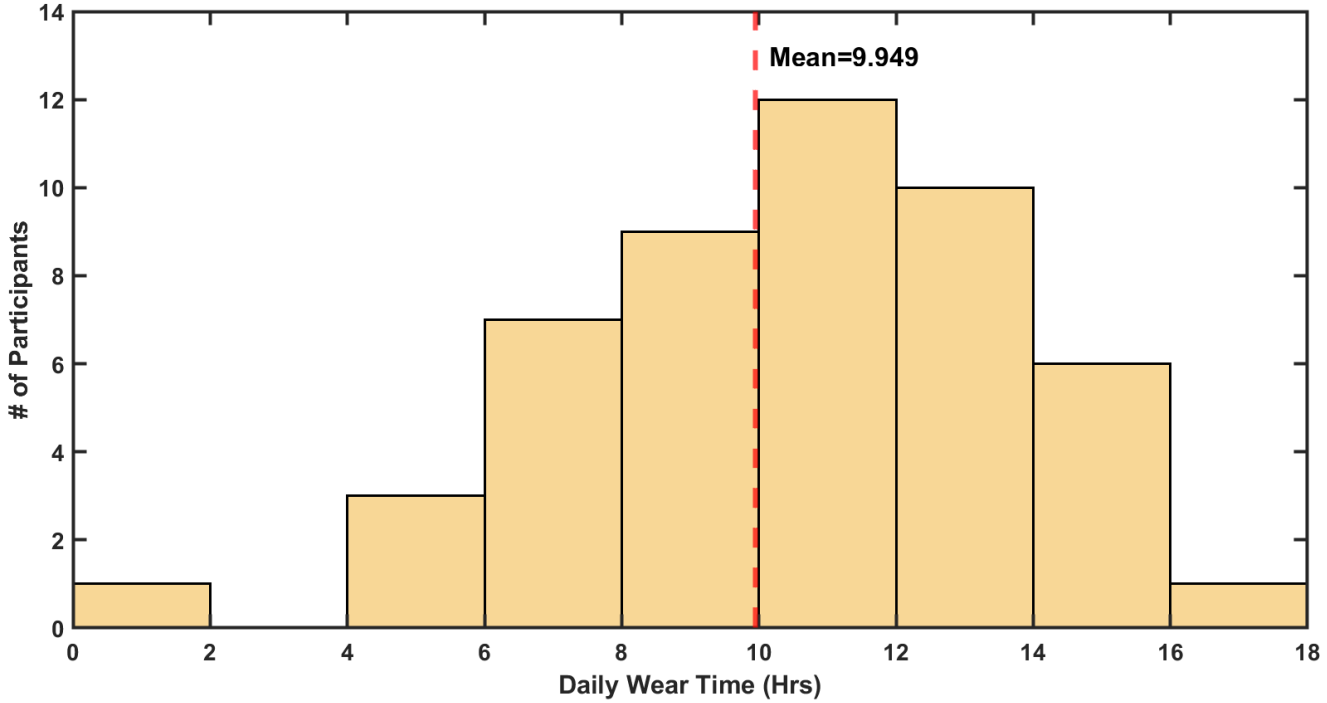
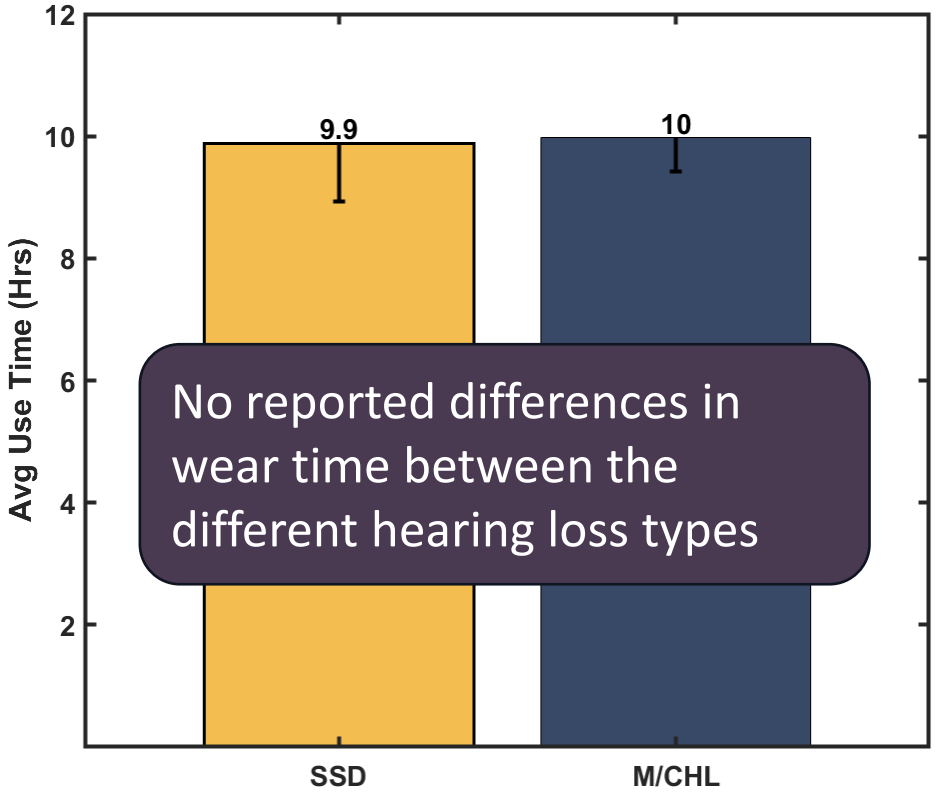
Holder et al., 2016

DEVICE USE QUESTIONNAIRE: SELF REPORTED WEAR TIME





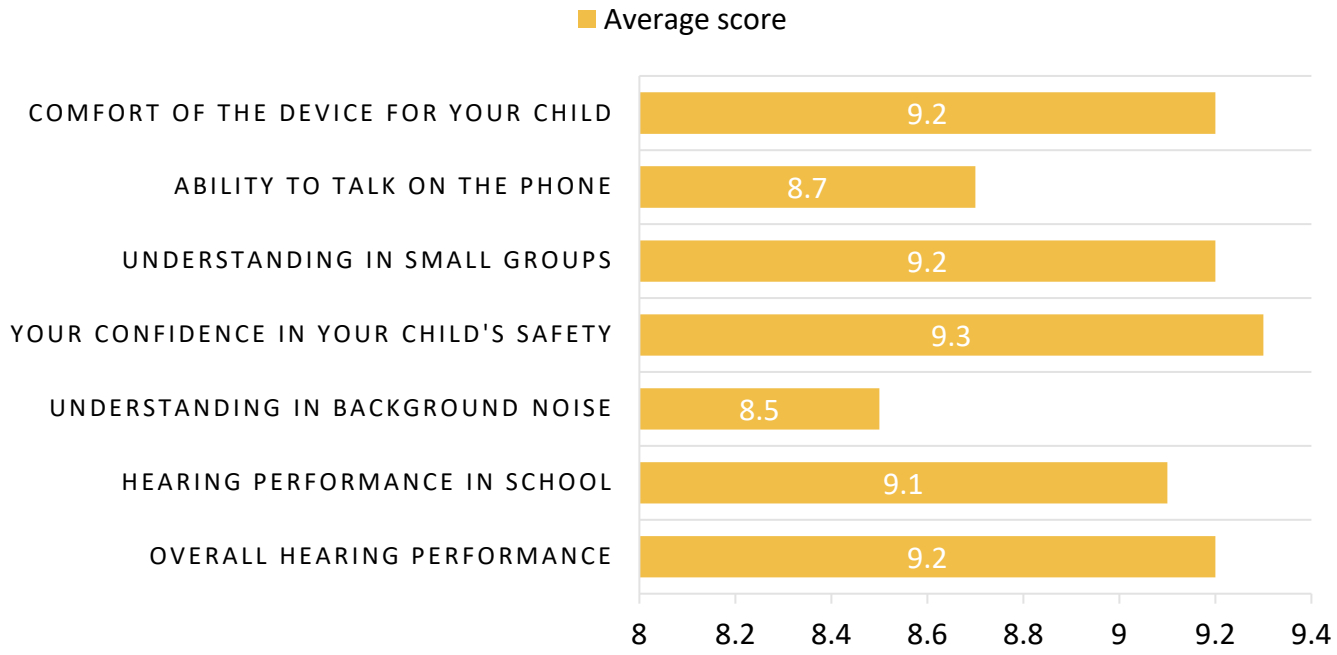
Safety and Efficacy of the Cochear™ Osia® 2 System in a Pediatric Population: Multi-Center Trial Results

ClinicalTrials.Gov ID NCT 05000931

DEVICE USE QUESTIONNAIRE: PARENTAL SATISFACTION

100% of parents would recommend the Osia device to other parents and families based on their experience (n=49)

Parents report high satisfaction with their child's experience using the Osia System compared to pre-surgery



0 = VERY DISSATISFIED AND 10 = VERY SATISFIED

Safety and Efficacy of the Cochear™ Osia® 2 System in a Pediatric Population: Multi-Center Trial Results

ClinicalTrials.Gov ID NCT 05000931

GRACE'S PERSPECTIVE

- "It doesn't make a sound with my hair anymore."
- "The clip keeps it from falling off."
- "It's not squeaky."
- "It is great in school because I can hear the teacher with the mini mic."
- "I can change the volume at lunchtime when it's crazy loud."
- "I can even watch TV better with the TV adapter."
- "I also like that I can play music to it from my phone that no one can hear."
- "It only hurt for a couple of days after surgery."
- "I would say do it because it really helps your hearing get better. And I can turn it off when Mom is annoying me (giggle giggle)."

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PARENT PERSPECTIVE

- “The Osia has been a game changer for Grace in how she hears, understands, and is progressing in school.”
- “We are now learning where her hearing gaps were that we never knew before and working hard with her school team ensure she is reaching her full academic potential.”
- “She loves the independence of controlling the Osia herself, although getting an iPhone for a 9-year-old has been a challenge. However, allowing her to do that has been critical for her independence and self-advocacy at school and in community settings.”
- “The process from surgery to activation and beyond was smooth and not nearly as challenging as we thought.”
- “The softband did not fit securely due to an uneven head shape due to hemifacial microsomia.”

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COCHLEAR PEDIATRIC BONE CONDUCTION PROTOCOL

COCHLEAR PEDIATRIC BONE CONDUCTION PROTOCOL

Bone conduction counseling considerations

- ☐ Counsel on the optimal option for the patient
- ☐ Discuss wireless accessories, apps and connectivity options and how these may be an effective complement to a bone conduction solution
- ☐ Discuss retention options
- ☐ Discuss appropriate expectations
- ☐ Discuss MRI considerations
- ☐ Discuss cost, reimbursement and funding
- ☐ **Osia patients:** Counsel on the expected improvement in sound quality with Osia, compared to a demonstration with non-surgical solution[9]
- ☐ **SSD patients:** Counsel that hearing in the profound ear will not be restored but the bone conduction sound processor will send sound from the profound side to the better hearing ear
- ☐ **Baha 6 Max Sound Processor patients:** Discuss Remote Care via Remote Assist* to supplement in-clinic care

Surgical counseling considerations

- ☐ Bone conduction implants are typically a same day, outpatient procedure
- ☐ The procedure generally takes about an hour, with additional time in the preparation and recovery areas
- ☐ Patients typically go home the same day
- ☐ Most patients are back to their normal routine after a few days for recovery

Next steps

- ☐ Review Cochlear Bone Conduction Solutions: Your guide to preparing for surgery (BUN535)
- ☐ Provide Engagement Manager contact information to the family
- ☐ Complete order form

Tip

Demonstration vs. implantable bone conduction solution

Counsel patients about the expected improvement in sound quality a patient can receive with a surgical bone conduction solution like an Osia System, compared to a demonstration with non-surgical solution using the Baha 6 Max Sound Processor.[9] A surgical solution has direct access to the bone conduction path with no skin attenuation to overcome. Additionally, Osia technology is uniquely suited to transmitting high frequency sounds to help patients hear better, especially in challenging situations like noisy environments.[2,10]

COCHLEAR OSIA PEDIATRIC CLINICAL TRIAL SUMMARY

- Improvement in word recognition from the softband to the Osia System:
  - Highlights the real-life advantages of a surgical solution
  - Supports better communication in everyday environments
  - Significant implications for academic and social performance
- High levels of parent satisfaction suggest:
  - Increased confidence in their child's hearing abilities
  - Assurance that they made the right decision for their child's needs

ClinicalTrials.Gov ID NCT 05000931

Safety and Efficacy of the Cochear™ Osia® 2 System in a Pediatric Population: Multi-Center Trial Results

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In the United States and Canada, the Osia System is indicated for children 5 years and older.

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

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THANK YOU

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