Learning Outcomes

- After this course learners will be able to define the candidacy considerations for bone conduction hearing devices in infants and young children.
- After this course learners will be able to list the types of bone conduction hearing devices available.
- After this course learners will be able to identify the key elements of a hearing aid fitting protocol.

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Acknowledgements

- Marlene Bagatto, Associate Professor, Western University
- Pediatric Bone Conduction Working Group

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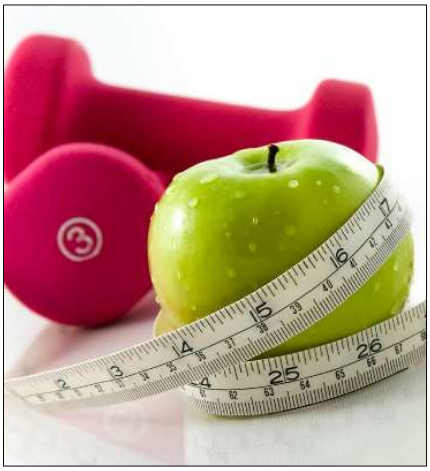
Guideline versus Protocol



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Guideline

- **Systematically developed statements** to assist clinicians (in fitting hearing aids to the pediatric population)
- **Summary and appraisal** of the best available research evidence or expert consensus
- Does not provide information about the **exact clinical processes** that would fulfill the guideline

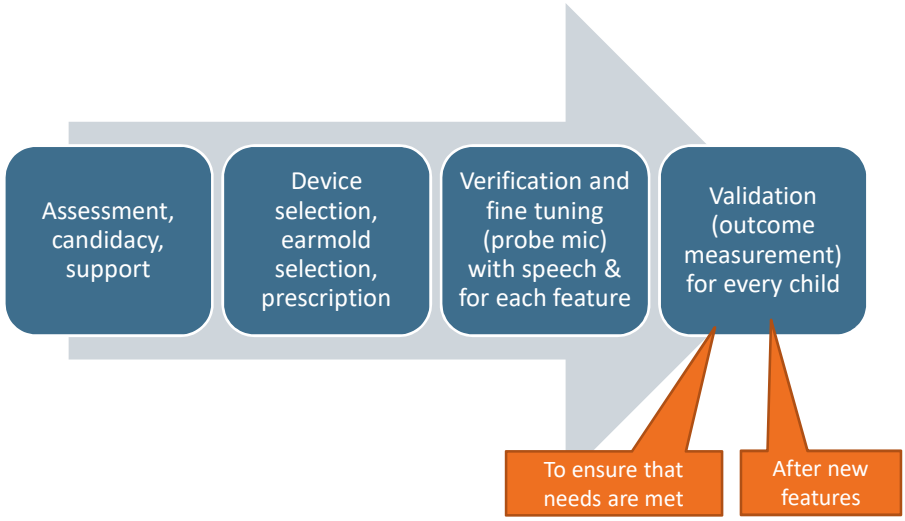
Protocol

- **Specifics** about how to execute a guideline
- **Tailored** for use with specific equipment or test signals
- **Details** that allow a step-by-step operationalization to fulfill a guideline
  - Morris, 2003

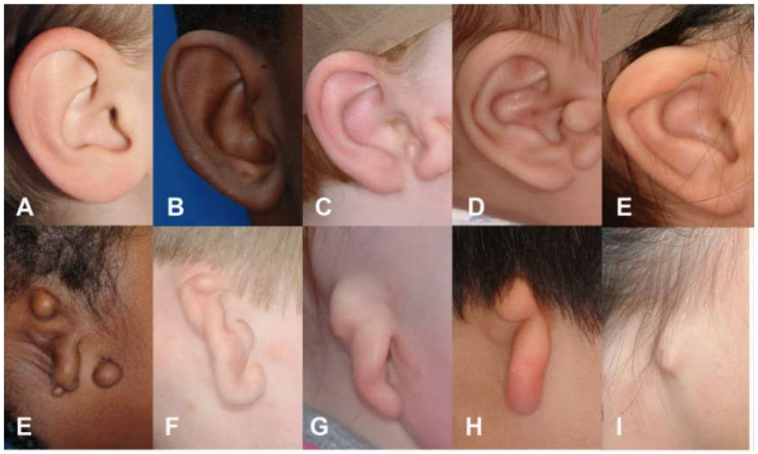
Provision of Hearing Aids

- Suitable technology and evidence-based hearing aid fitting guidelines and protocols support accurate and safe hearing aid fittings for the pediatric population
  - American Academy of Audiology, 2013
  - Australian Protocol; King, 2010
  - British Columbia Early Hearing Program, 2006
  - Modernizing Children's Hearing Aid Services, 2005
  - Ontario Protocol; Bagatto, Scollie, Hyde & Seewald, 2010; **Updated in 2014: www.dslio.com**

AAA Pediatric Amplification Guideline (2013)



Fitting Protocols for Bone Conduction Hearing Devices (BCD) are not Well-Defined



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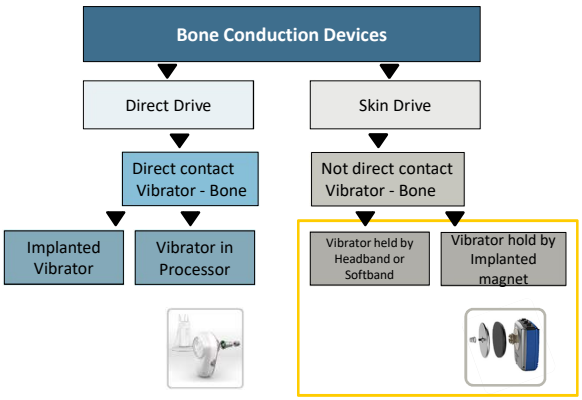
Options for Delivering Bone Conducted Sound

Direct Drive vs Skin Drive systems

- There are two types of bone conduction devices:
  - **Direct Drive** devices send vibrations via direct route to bone
  - **Skin Drive** devices send vibrations through the skin to bone
- Softband and magnet solutions provide similar performance[1]

1) Briggs (2015) Clinical Performance of a New Magnetic Bone Conduction Hearing Implant System: Results from a Prospective, Multicenter, Clinical Investigation. Otol Neurotol. 2015 Jan 28. [Epub ahead of print]



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Surgical Eligibility

- Children must have sufficient skull thickness and bone quality before implantation of a magnet, abutment or active bone stimulator can be considered
  - At least 2.5 mm thick (Davids et al, 2007; Papsin et al, 1997; Tjellstrom et al, 2001)
  - Currently the smallest implant available is 3 mm thick
- Currently, the placement of a bone anchored implant is recommended around age 5 years
  - Hakansson et al, 1990; Wade et al, 2002
  - Surgical criteria varies from country to country

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Non-Surgical Option
Headband or Softband

- Delivers sound via vibrations across the skin to the skull. Device is snapped onto a soft headband for use; *no surgery is required*.
- Recommended for children with conductive or mixed hearing losses who do not have properly formed outer ear or ear canal to accommodate a BTE hearing aid.

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Infants with unilateral & bilateral aural atresia….

- Will be identified at birth through EHDI programs
- Are candidates for bone conduction hearing devices on a softband
- Are not eligible for surgical device for several years

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Output of BC Devices (BCD)

Input		Output
dB SPL	→  →	Acoustic Sound pressure level [dB SPL]
dB SPL	→  →	Vibrations Force [dB µN]

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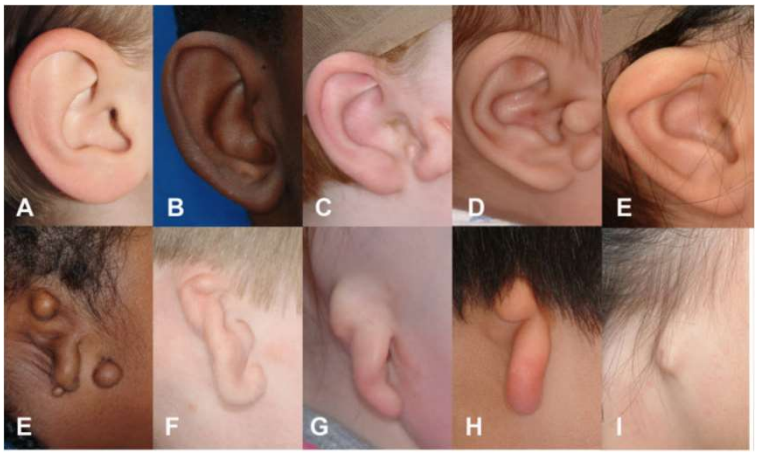
How do I fit/verify bone conduction hearing devices (BCD) to infants/children?



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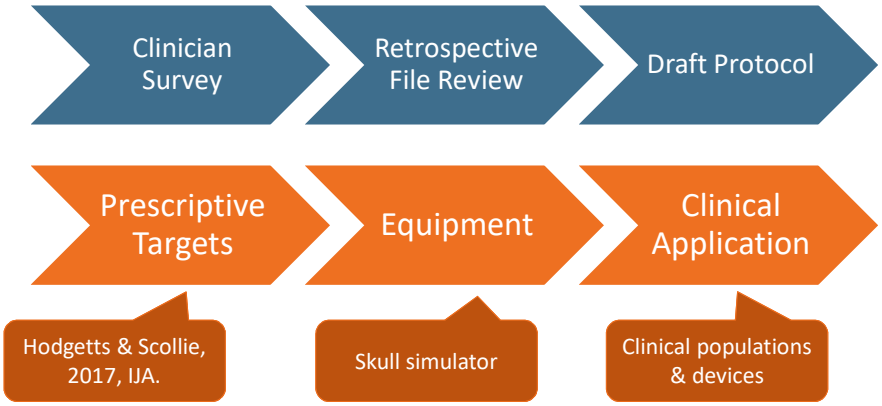
Improving Clinical Practice: Current Research



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Dave Gordey, Ph.D.
Marlene Bagatto, Au.D., Ph.D.

Clinician Survey of Bone Conduction Hearing Device Fitting Practices in Children

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Introduction

- There are no well-established fitting protocols for children using bone conduction devices (BCD).
- Anecdotal evidence suggests that clinicians feel the fitting process for BCD to infants and young children is “uncertain”.
- We developed a survey to understand current pediatric bone conduction fitting practices and challenges clinicians may face.

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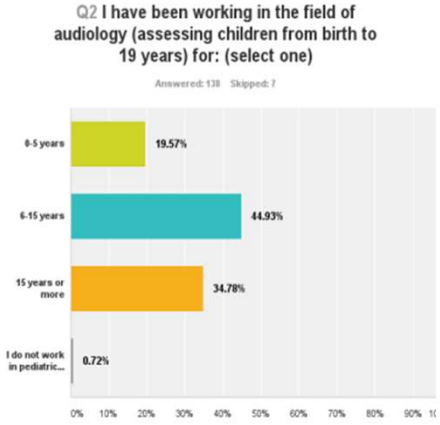
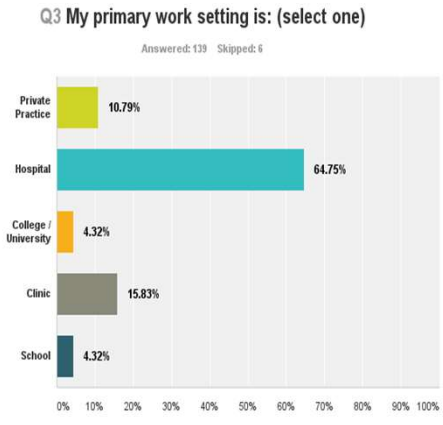
Survey of North American Pediatric Audiologists (2015) N = 144 (408)





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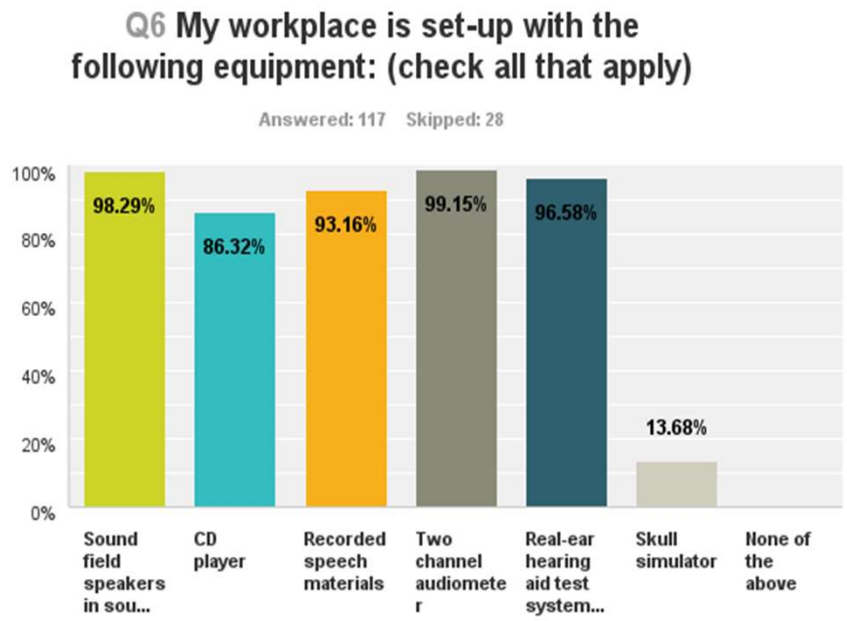

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What is a Skull Simulator?

Device used to measure the output of BCDs; similar to how a 2cc coupler is used to verify air conduction hearing aids.

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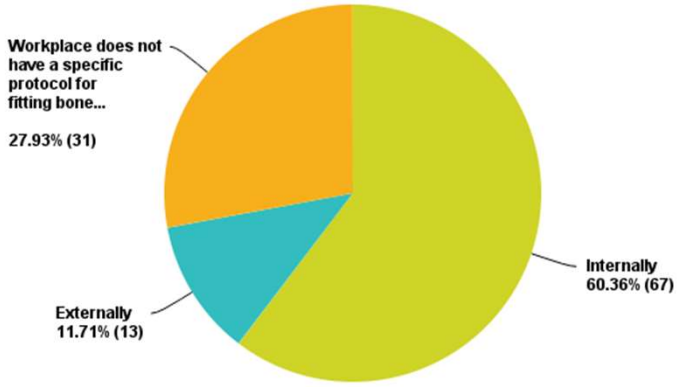
Understanding Current Pediatric Fitting Protocols for BCD

Q10 I follow a protocol for fitting children with bone conduction devices that was developed: (select one)

Answered: 111 Skipped: 34



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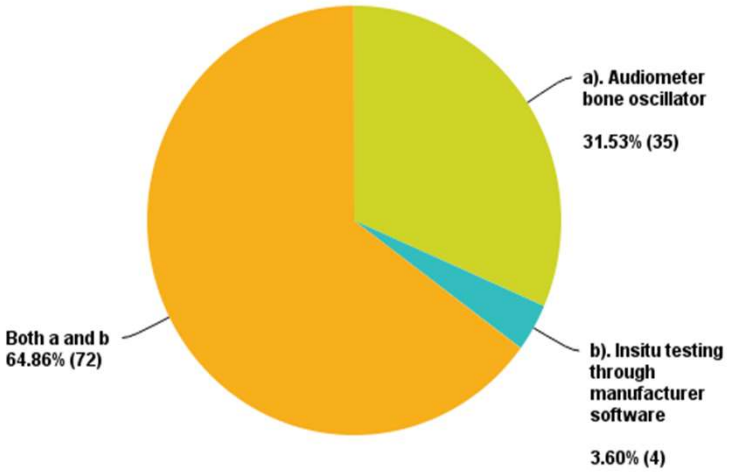
Q12 I routinely measure the child's bone conduction thresholds using: (select one)

Answered: 111 Skipped: 34



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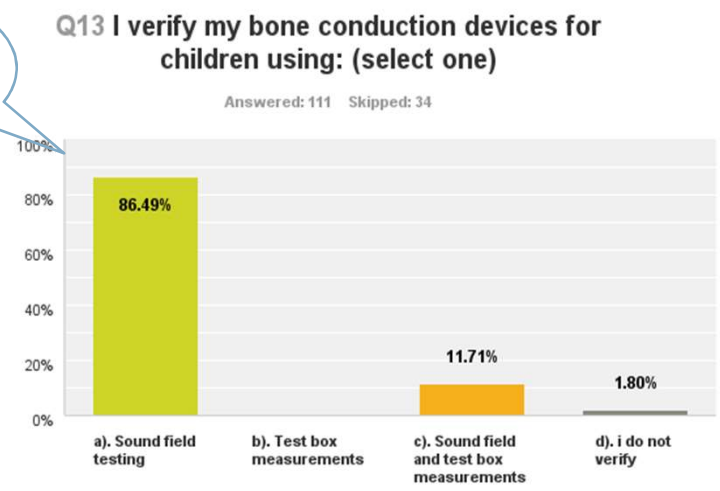
Understanding the use of (Verification?) Tools

Validation tool in AC HA Fittings



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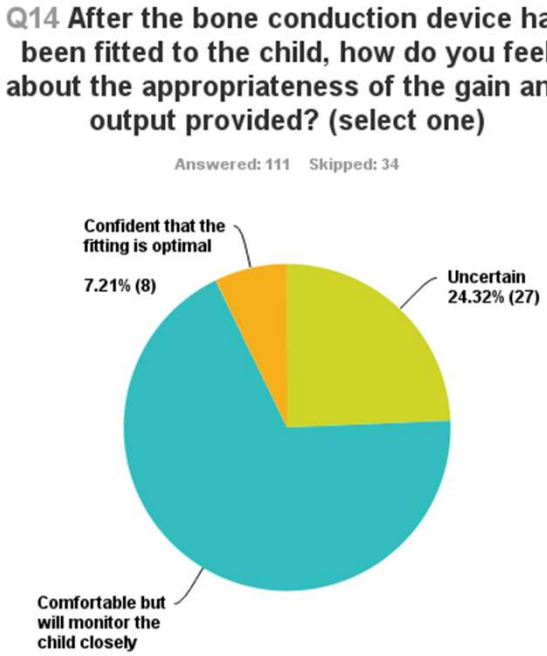

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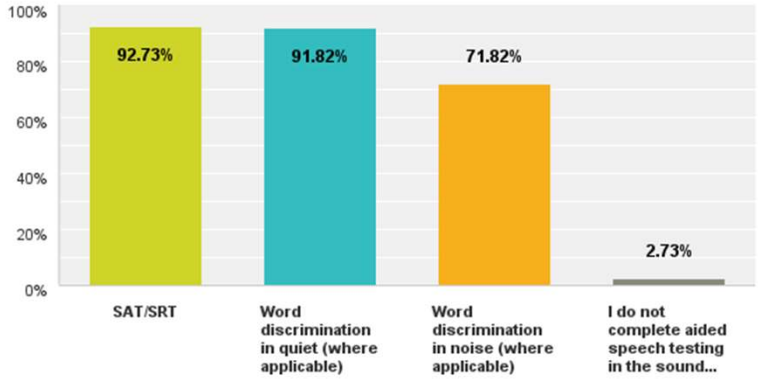
Majority of Clinicians Test Speech in Noise!

Q16 For most of my bone conduction fittings, i use the following aided speech measurements in the sound field: (check all that apply)

Answered: 110 Skipped: 35



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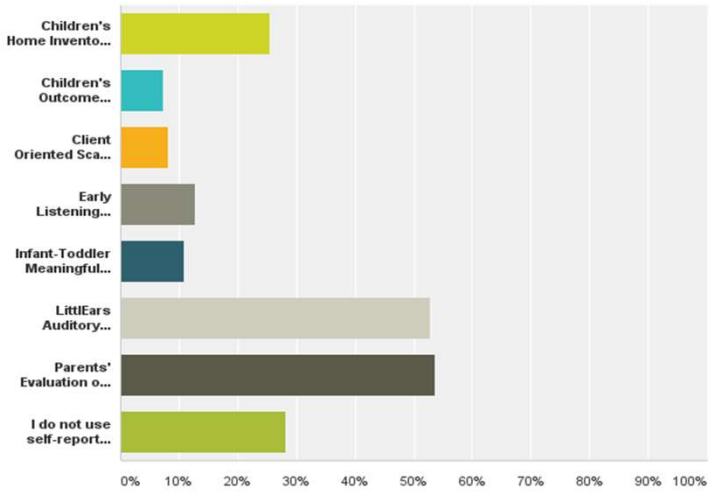
Q17 I use the following self-report questionnaires as part of my bone conduction fitting process: (check all that apply)

Answered: 110 Skipped: 35



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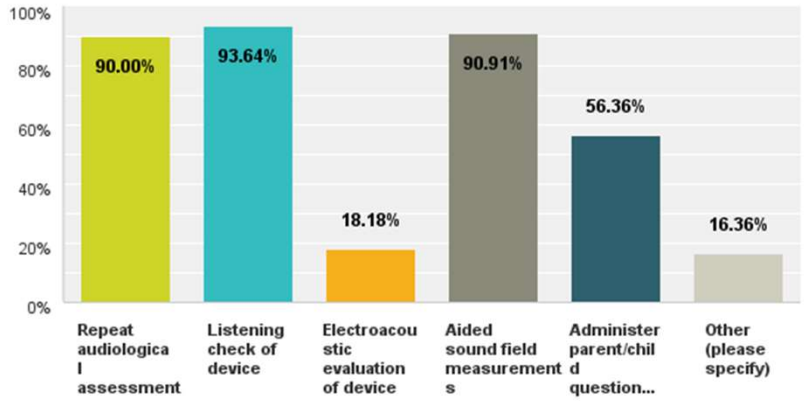
Q19 What activities are completed during your follow up appointments with children who wear bone conduction devices? (check all that apply)

Answered: 110 Skipped: 35



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How Do We Define a Successful BCD fitting in Children? Survey Comments

Themes

- Consistent use
- Audibility of speech
- No feedback
- Comfortable
- Improved communication

Similar to Air Conduction Fittings

- **Aided audiogram within the normal range of hearing**

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How Do We Define a Successful BCD fitting in Children?
Aided Audiogram - Challenges and Considerations

- How do we determine a good aided sound field audiogram? What is acceptable? What is exceptional? How does this vary with degree of hearing loss?
- What are appropriate age outcomes for aided audiograms? How do we expect them to change as they get older?
- What is the preferred method (i.e., azimuth) for assessing functional gain in the sound field?

Survey Summary

- We have confirmed that due to the lack of evidence-based fitting protocols for BCD, the majority of clinicians are using their own fitting methods.
- The use of insitu measurements with children suggests there is a desire by clinicians to address individualization of fittings using objective measurements.
- Verification methods being used in BCD fittings reflect subjective strategies rather than objective (electroacoustic) measurements that are used in AC fittings.
- Only a small percentage of clinicians reported feeling confident about their fitting of the BCD device; those that felt comfortable, wanted to monitor the fitting closely.

Current Work: Retrospective File Review

Purpose: To gain further knowledge about the clinical fitting and management of infants and young children who wear BC devices

Collaborators: *The Pediatric Bone Conduction Working Group*

- Nemours (Baltimore)
  - Jessica Godovin
- Children's Hospital of Philadelphia
  - Joy Peterson, Laurie Mauro
- Cincinnati Children's Hospital
  - Annemarie Wollet, Michael Scott
- Institute for Reconstructive Sciences in Medicine, Alberta, Canada
  - Meredith Haluschak
- Saskatoon Health Region, Canada
  - Charlotte Douglas, Lynne Brewster
- University of Miami Children's Hearing Program
  - Kari Morgenstein
- Western University
  - Christine Brown, Marlene Bagatto
  - Lurie Children's Hospital (Chicago)
    - Katie Collela
    - Dalhousie University
      - Sheila Fortier and Michel Comeau

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Research Questions

1. What selection practices are pediatric audiologists demonstrating when providing bone conduction hearing systems (BCD) to their patients?
2. What fitting/verification practices are pediatric audiologists demonstrating when providing BCD to their patients?
3. What outcome evaluation practices are pediatric audiologists demonstrating when providing BCD to their patients?
4. What are the aided soundfield performance ranges for children fitted with BCD?

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Method

- Review of patient files from large pediatric centers experienced in managing infants and young children who wear BCD
- Date range of file review: January 1, 2000 to January 31, 2016
- Inclusion criteria:
  - Birth to 6 years; 11 months
  - Unilateral conductive or mixed hearing loss with < 45 dB HL bone conduction pure tone average in affected ear
  - Bilateral conductive or mixed hearing loss with < 45 dB HL bone conduction pure tone average
  - Fitted with BCD (surgical or non-surgical)

Method (continued)

- Exclusion criteria:
  - Children older than 6 years; 11 months
  - Single sided deafness (profound sensorineural hearing loss in one ear, normal hearing in the other)
  - Does not currently wear a bone anchored hearing system (BCD)
  - Children with sensorineural hearing loss
  - Children with mixed hearing loss with > 45 dB HL bone conduction pure tone average

Data Collection

- Each site reviewed clinical files of up to 15 children who currently wear BCD
- Provided the following anonymized information from each file for every visit within the study dates:
  - Gender, description of hearing loss, complex factor(s)
  - Age at time of test/fitting/procedure
  - Type of BCD
  - Outcome Measures
  - Device usage (e.g., hours per day either reported or datalogged)
  - Aided testing (description of test and thresholds)

Results: Demographic

- 65 files were reviewed
  - Average age = 41 months; Range = 2 to 83 months
  - 34 Female; 31 Male
  - 78% Atresia
    - 60% unilateral (38% right)
    - 28% bilateral
  - 50% Syndrome
  - 47% Complex Factors
- Average age at first fitting: 17 months
- Fitted using BC ABR thresholds: 75%
- BC device on soft headband: 94%

- Variety of makes & models
- Mostly on softband
- 1 modified BTE device

Results: Usage

- Reported from 38% of the files
  - Parental report & datalogging
- Ranged from 1 to 9.4 hours per day
  - Usage increased with age
- Low usage not necessarily due to complex factor

Aided Soundfield Testing

- Survey data indicated that the most prevalent clinical tool for measuring the performance of BCD was aided soundfield testing
- Was being used for both Verification and Validation

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Verification and BCD

- *Verification* involves ensuring the electroacoustic characteristics of the hearing aid support the auditory habilitation needs of the child
- For BCD, clinically feasible tools (e.g., targets, equipment, protocols) are in development
- Clinicians are using aided soundfield testing as a method of verification for BCD
  - Age-related performance ranges (norms) are not available

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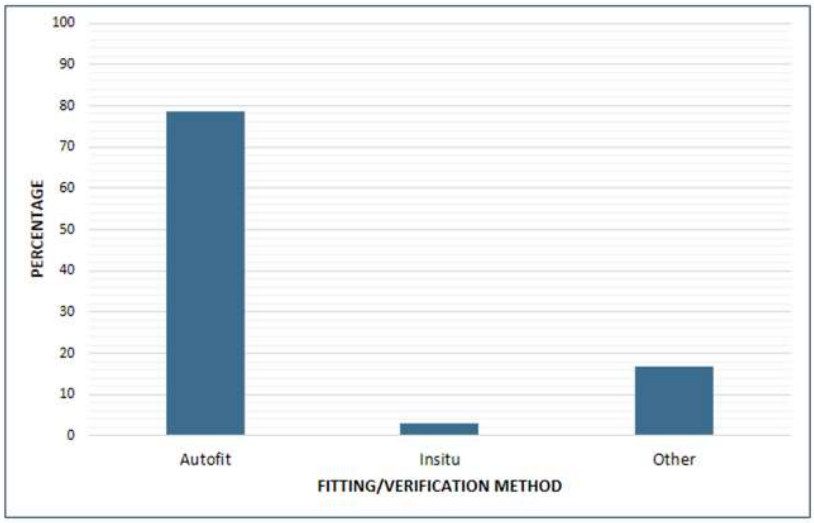
Results: Fitting/Verification Method



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Results: Aided Testing

- Warble tones
- Ling 6
  - Monitored live voice or calibrated procedure (Glista et al, 2014)
- Speech in Quiet
- Speech in Noise
- Speaker azimuth varied
  - 0 or 90 degrees

Results: Aided Testing

- Strategies used were clinic-dependent and/or clinician-dependent
- Collaborators indicated that aided testing was used for verification, validation, or both
- Not enough data to describe performance ranges (norms) yet
  - Goal for future work

Validation and BCD

- *Validation* is the process of assessing the impact of the hearing aid fitting to determine whether it is delivering the intended outcome
- *Outcome measures* are used in the validation stage to determine progress and treatment efficacy
- Current outcome measurement tools could be applied
  - UWO PedAMP (Bagatto et al, 2011)
  - Ling 6 HL (Glista et al, 2014)

Results: Validation

- Clinics are using a combination of subjective and objective outcome measurement tools
- Tools used were clinic as well as age dependent

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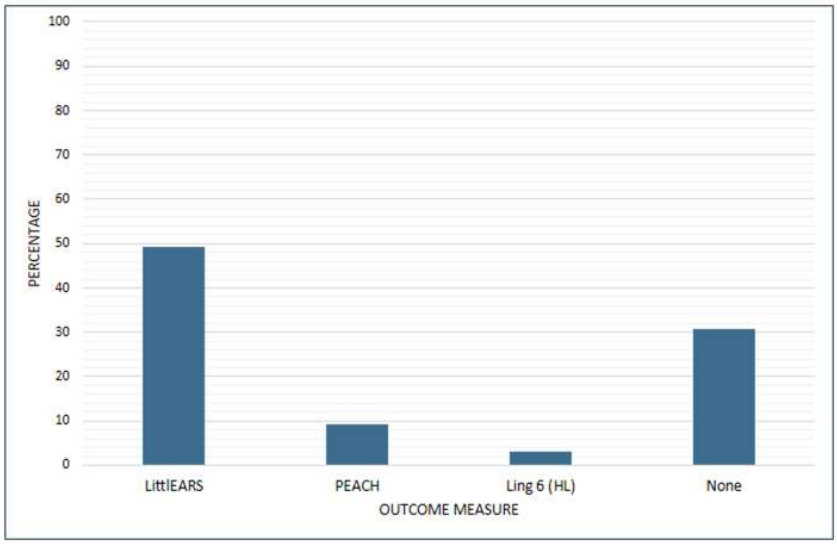
Results: Outcome Measures



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Conclusions

- BCD on softbands are fitted to infants and young children
  - Unilateral atresia/microtia
- Due to the lack of necessary elements for verifying BCD, clinicians are applying their own strategies
  - Variability across clinics and clinicians
- Some consistency in outcome measurement tools used for validation
  - LittlEARS, PEACH, Ling 6 (HL)

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Conclusions

- Variability in aided soundfield testing protocols
  - Verification vs Validation
  - Speaker azimuth
  - Stimuli
- Need to conduct targeted data collection to gather relevant performance ranges

Important Updates

- DSL targets for Oticon Ponto BCD unilateral percutaneous fittings for adults (Hodgetts & Scollie, 2017)
- Skull simulators for clinical hearing aid test systems

Interacoustics Affinity

Audioscan Verifit

Future Directions

- Develop a draft protocol for providing BCD to infants and children
- Assess clinical feasibility and effectiveness of Pediatric BCD fitting protocol
- Align protocol with current and emerging BCD technological developments

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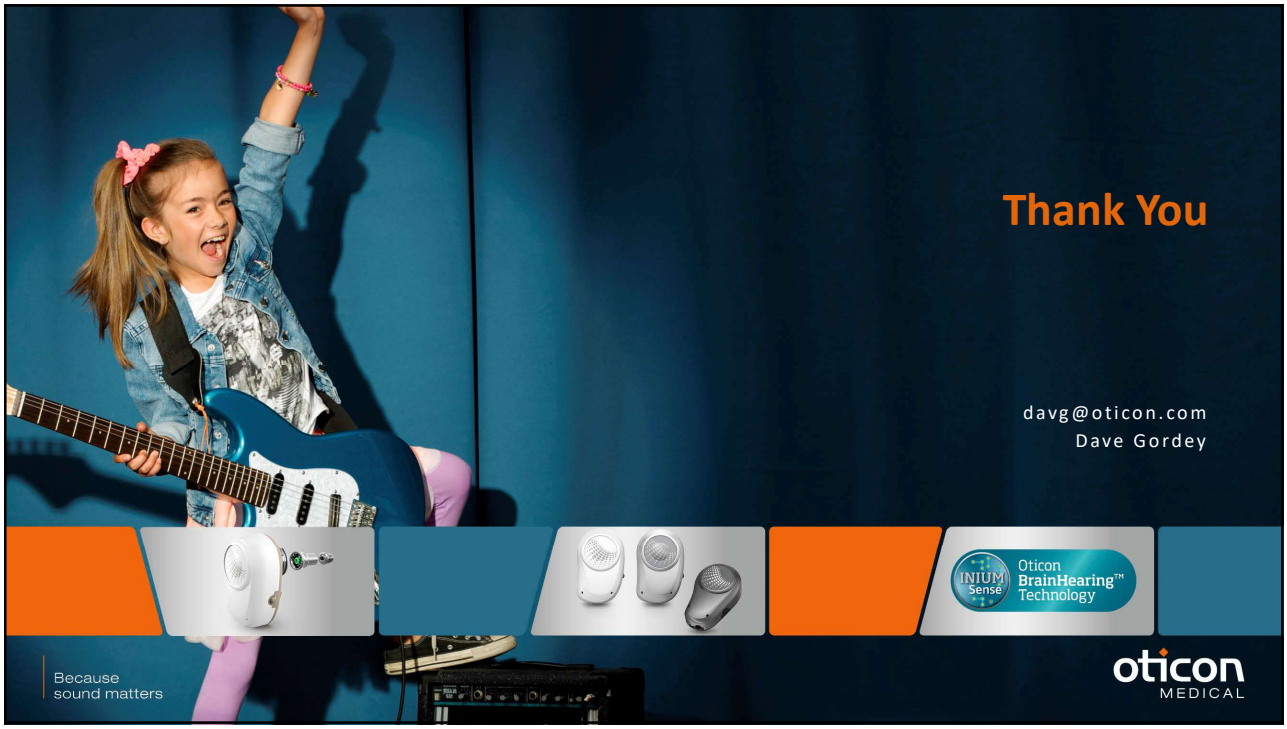

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