Verification-Based Approaches to Bone-Conduction Amplification: Using Objective Measurements to Shape Clinical Practices

October 7, 2024
25th Canadian Academy of Audiology Conference, Delta Grand Okanagan Resort, Kelowna, BC

Alex Gascon, B.Sc., MPA., R.Aud, PhD Candidate
PhD Supervisor: Dr. Bill Hodgetts, R.Aud, PhD

Institute for Reconstructive Sciences in Medicine - Misericordia Community Hospital, Edmonton, AB
Department of Communication Sciences and Disorders - Faculty of Rehabilitation Medicine, University of Alberta

iRSM Institute for Reconstructive Sciences in Medicine | Alberta Health Services | University of Alberta | Covenant Health

No conflict of interest to declare

Learning objectives

- Review bone-conduction hearing implant candidacy considerations for various types of hearing losses
- Review current and upcoming verification tools in bone-conduction amplification
- Explore how verification tools can support clinical practices in bone-conduction amplification
- Understand the differences between bone-conduction hearing thresholds in diagnostic assessments and for device fitting purposes

Université de Montréal

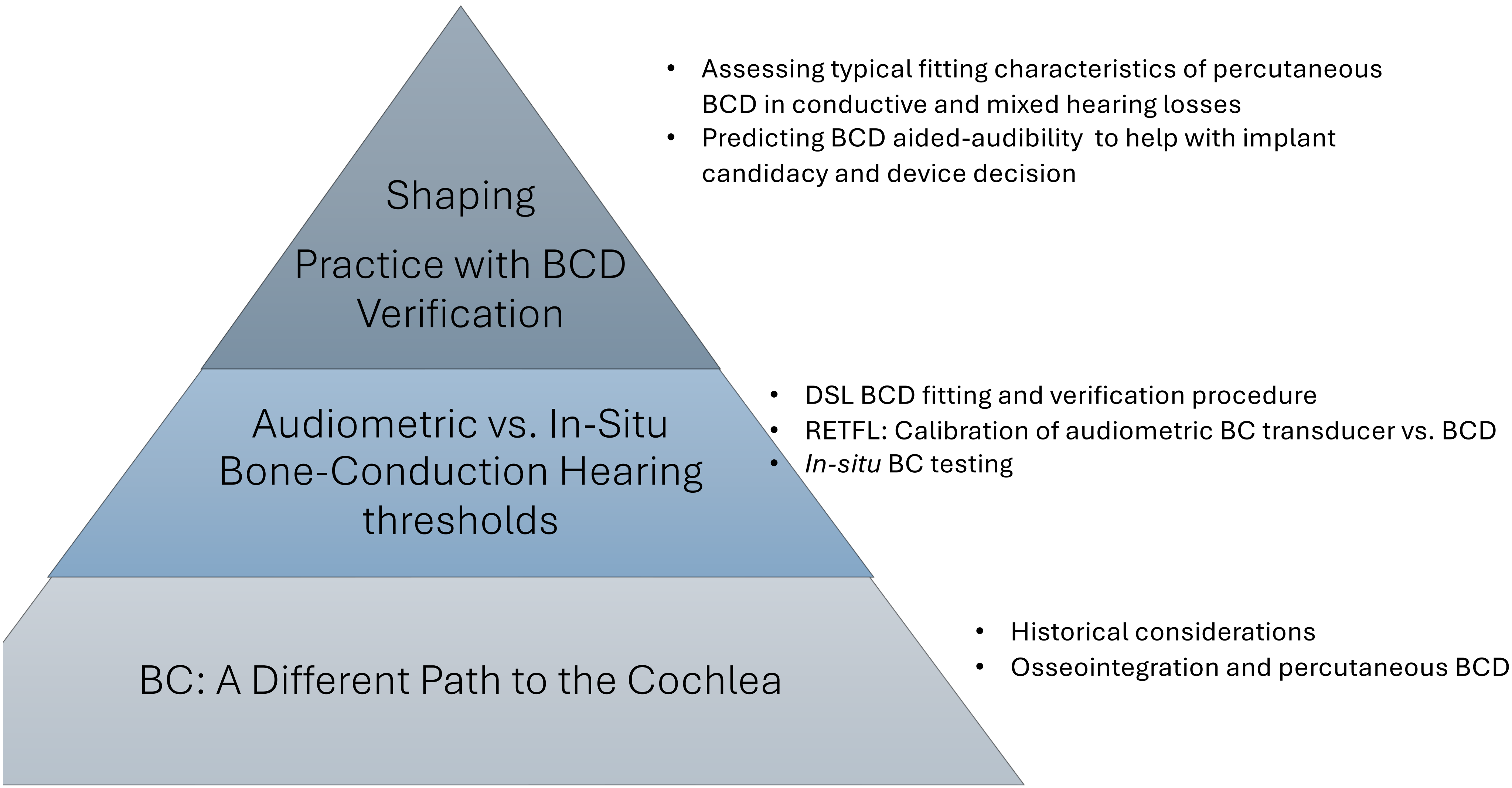
Faculté de médecine

École d'orthophonie et d'audiologie

Covenant Health

IRSM Institute for Reconstructive Sciences in Medicine

UNIVERSITY OF ALBERTA


Shaping
Practice with BCD Verification
Audiometric vs. In-Situ Bone-Conduction Hearing thresholds
BC: A Different Path to the Cochlea
• Assessing typical fitting characteristics of percutaneous BCD in conductive and mixed hearing losses
• Predicting BCD aided-audibility to help with implant candidacy and device decision
• DSL BCD fitting and verification procedure
• RETFL: Calibration of audiometric BC transducer vs. BCD
• *In-situ* BC testing
• Historical considerations
• Osseointegration and percutaneous BCD

Bone-Conduction : An Alternative Path for Sounds to Reach the Inner Ear

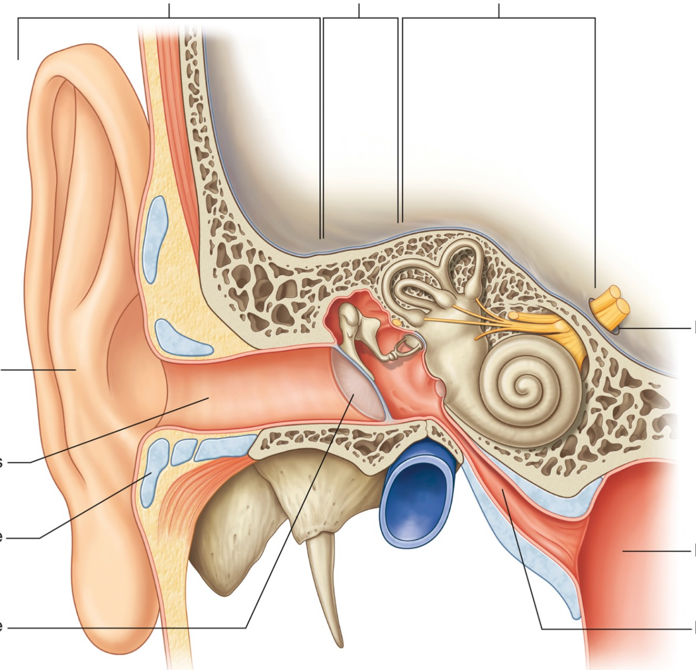
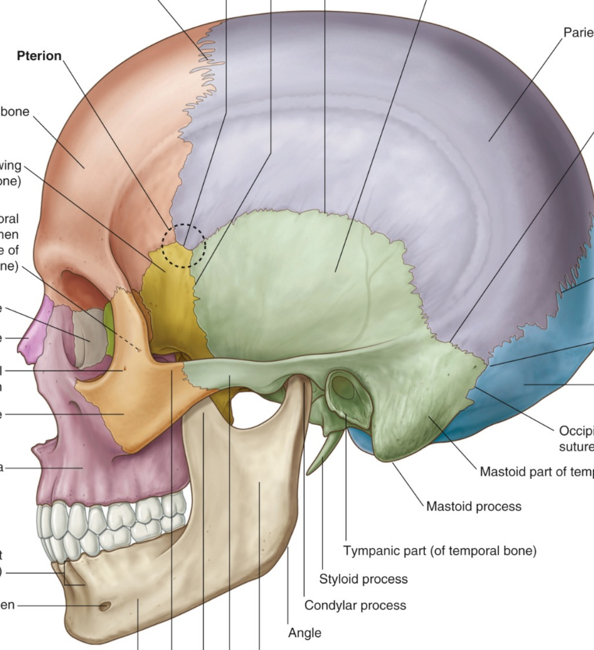


Fig. 8.116
Right Ear.



Images retrieved from Drake, R. L. (2015)

- Bone-conduction hearing in human has been a known phenomenon since at least Antiquity
- Using bone-conduction hearing devices (BCD) for rehabilitation in individuals with hearing loss have been documented as early as the 1800s
- The physiological mechanisms of bone-conduction hearing were described by Georg Von Békésy in the early 1930s

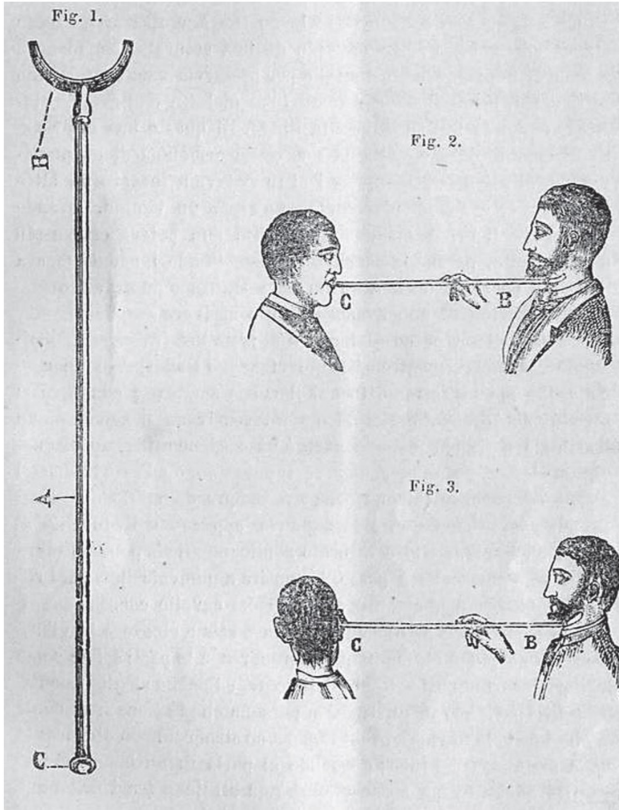
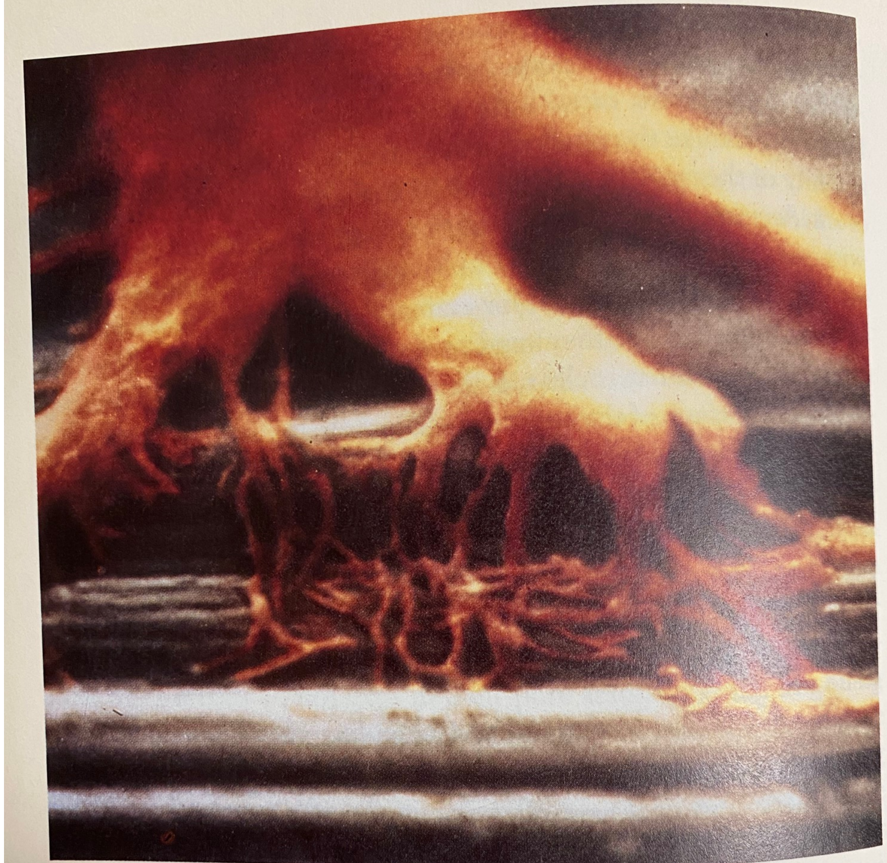


Fig. 2. Fonifero, 1876.

Mudry and Tjellström, 2011



Bone tissue growing onto a titanium screw. Microscopy. Photo supplied by P.-I. Brånemark.

Professor Brånemark and his first patient, Gösta Larsson, photographed in 1990. Gösta Larsson had just undergone surgery for a bone-anchored hearing aid. Photo supplied by Nobelpharma.

Pictures retrieved from A Matter of Balance, 1992, Elaine Williams

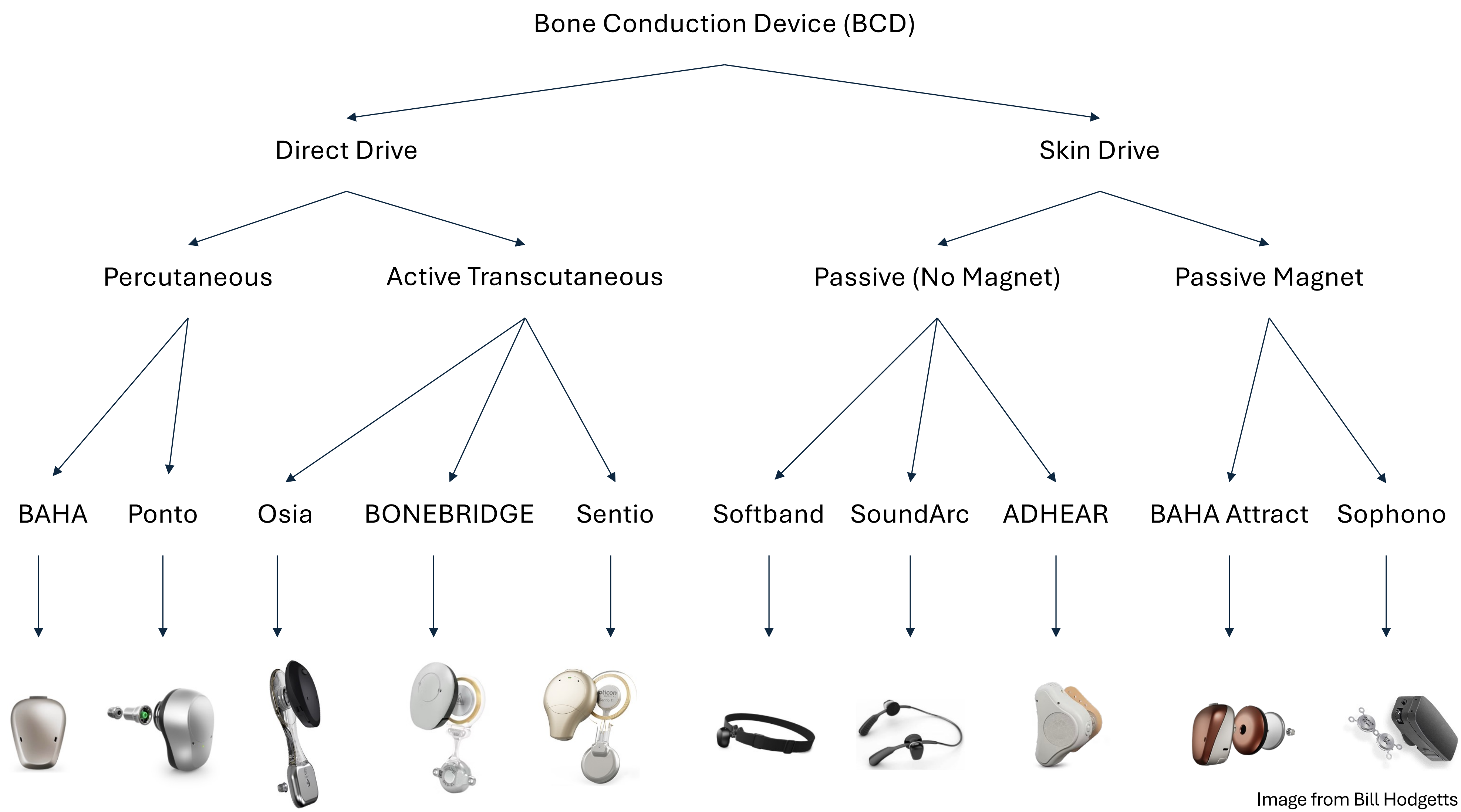
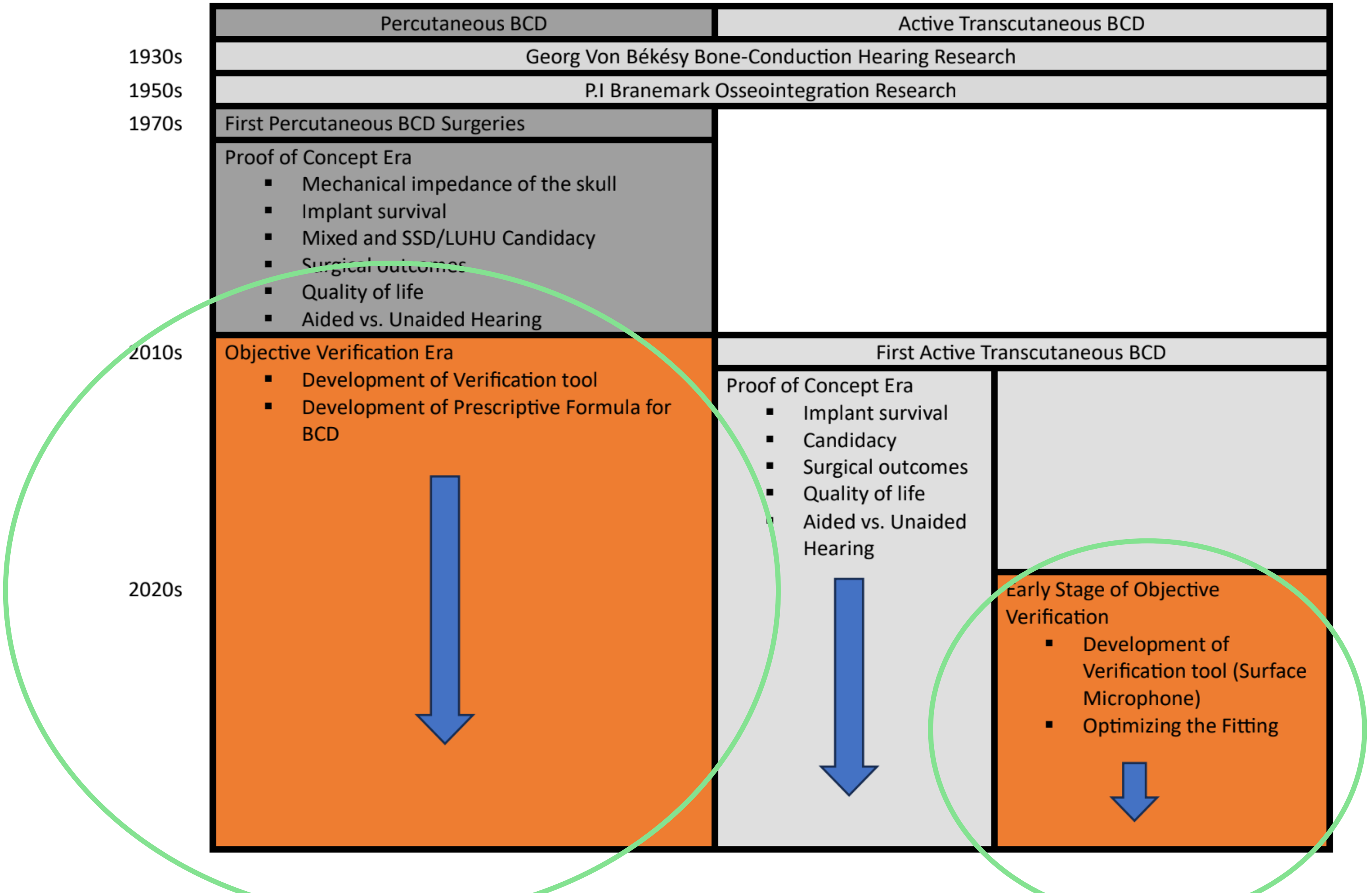


Image from Bill Hodgetts


Percutaneous BCD
Active Transcutaneous BCD
1930s
Georg Von Békésy Bone-Conduction Hearing Research
1950s
P.I Branemark Osseointegration Research
1970s
First Percutaneous BCD Surgeries
Proof of Concept Era
Mechanical impedance of the skull
Implant survival
Mixed and SSD/LUHU Candidacy
Surgical outcomes
Quality of life
Aided vs. Unaided Hearing
2010s
Objective Verification Era
Development of Verification tool
Development of Prescriptive Formula for BCD
First Active Transcutaneous BCD
Proof of Concept Era
Implant survival
Candidacy
Surgical outcomes
Quality of life
Aided vs. Unaided Hearing
2020s
Early Stage of Objective Verification
Development of Verification tool (Surface Microphone)
Optimizing the Fitting

Skull-simulator measurement and Force-level-o-gram

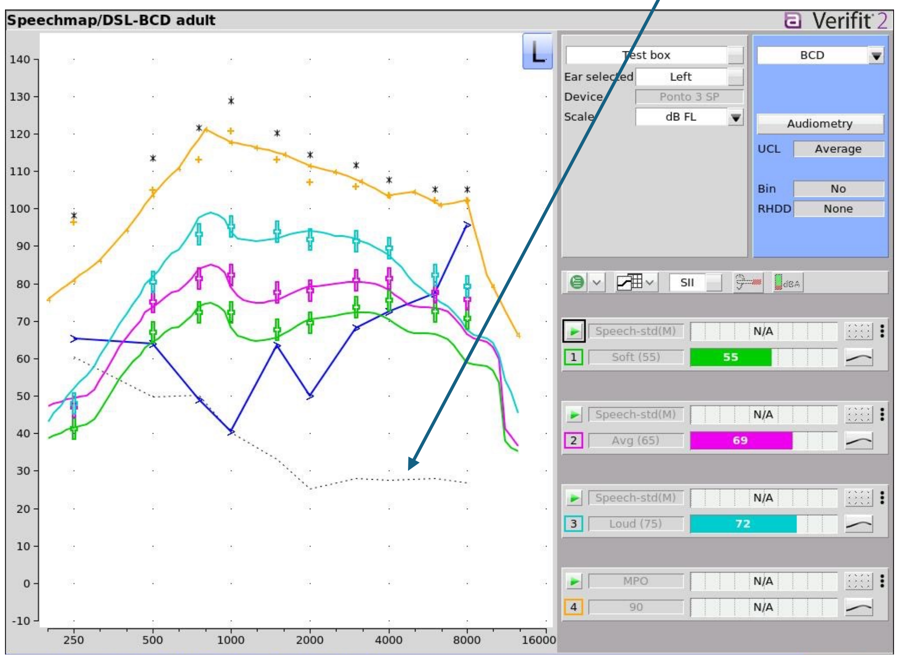
Dotted line = 0 dB DL from 250 to 8000 Hz

Output (Y axis)

dB FL on skull simulator + microphone location effects + RHCD = dB FL on abutment

DSL-BCD v1.1 Targets

- In-situ thresholds (RETFLdbc)
- Device characteristics:
  - MFO
  - RHCD
- Pediatric DSL BCD targets
- Monaural/Binaural fitting



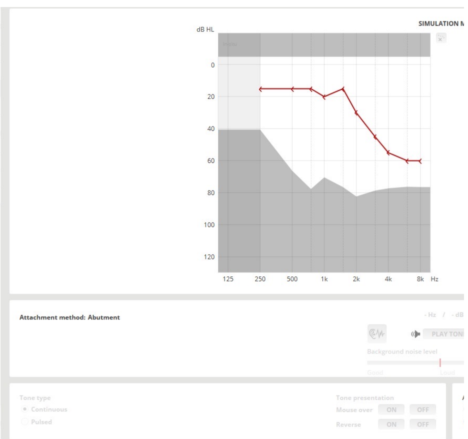
Frequency (Hz)

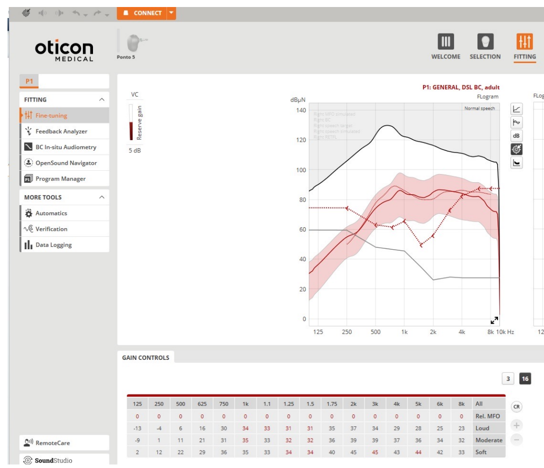
Input

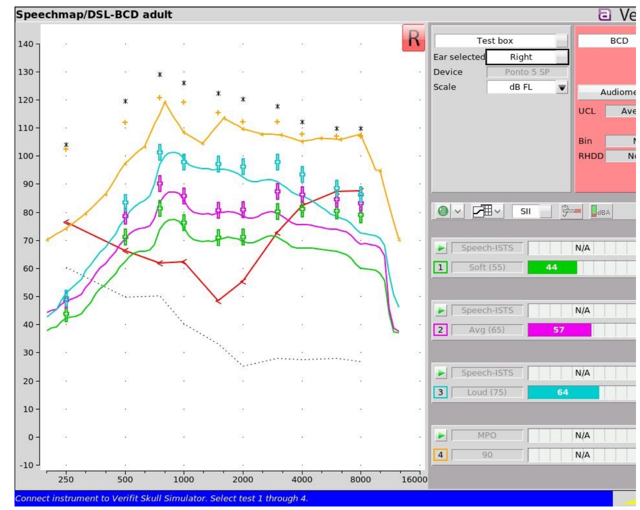
ex. International Speech Test Signal

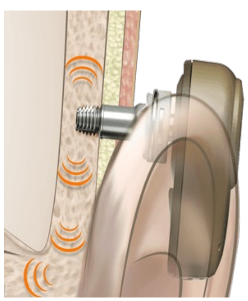
- levels: 55, 65 and 75 dB
- MFO (90 dB Tone Sweep)
- Etc.

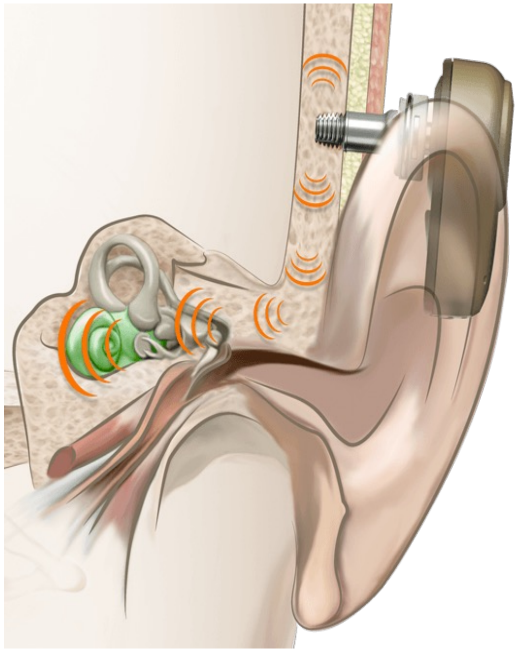
DSL BCD fitting procedure

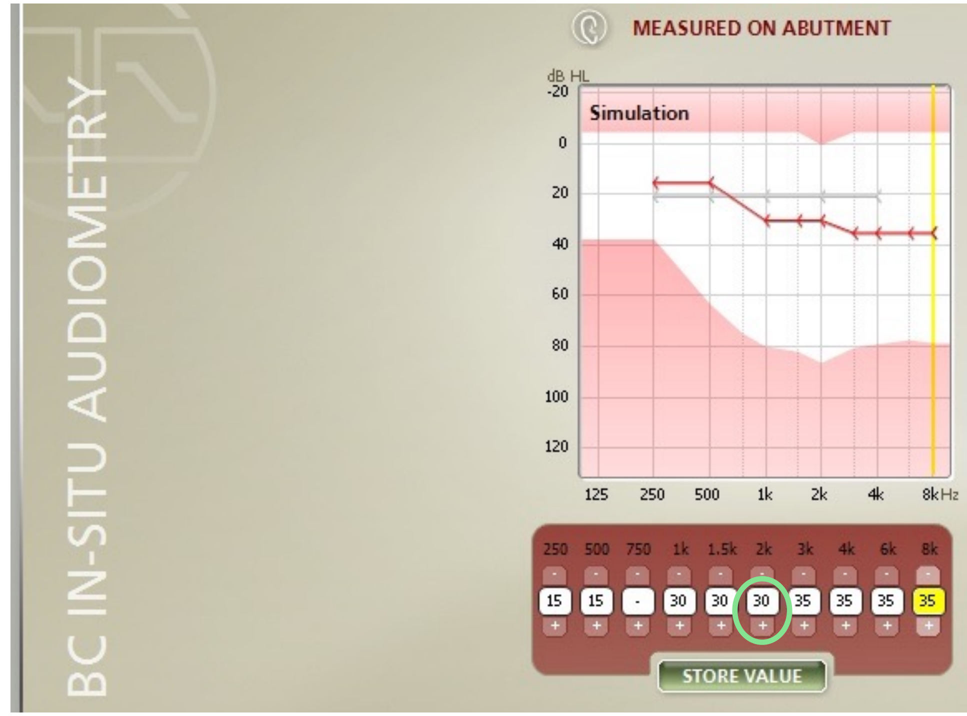












Reference Equivalent Threshold Force Level $_{dbc}$

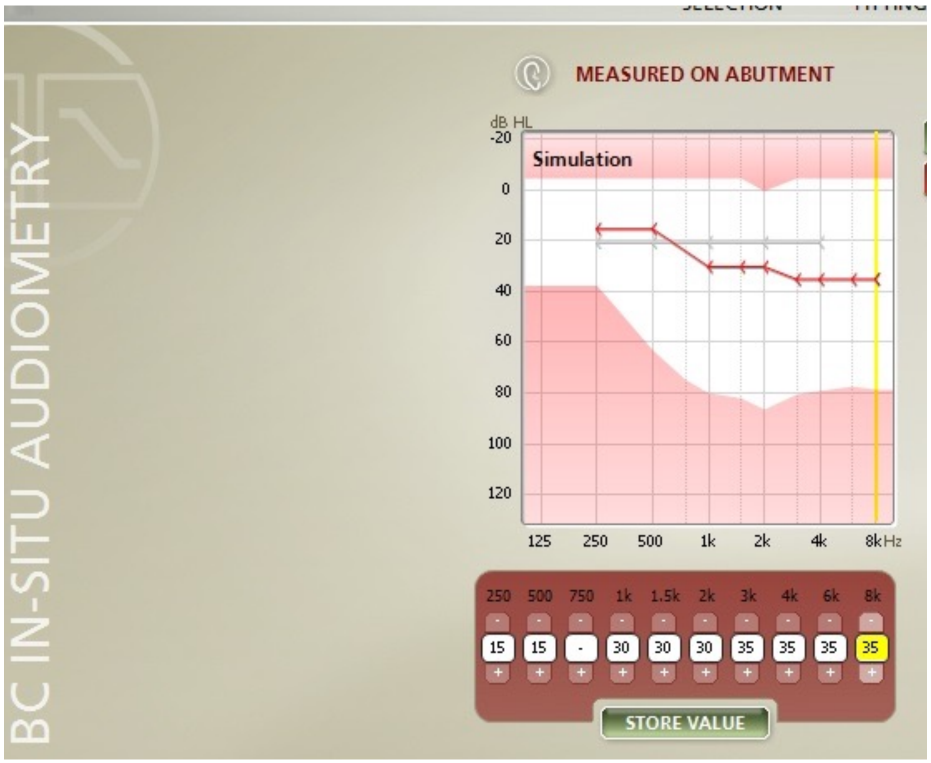
Frequency (Hz)	250	500	750	1000	1500	2000	3000	4000	6000	8000
RETFLdbc (dB FL)	59.5	48.0		45.5	34.5	26.0	28.0	27.5	27.5*	27.5*
RETFL ANSI S3.6 2010 (dB FL)	67.0	58.0	48.5	42.5	36.5	31.0	30.0	35.5	40.0	40.0

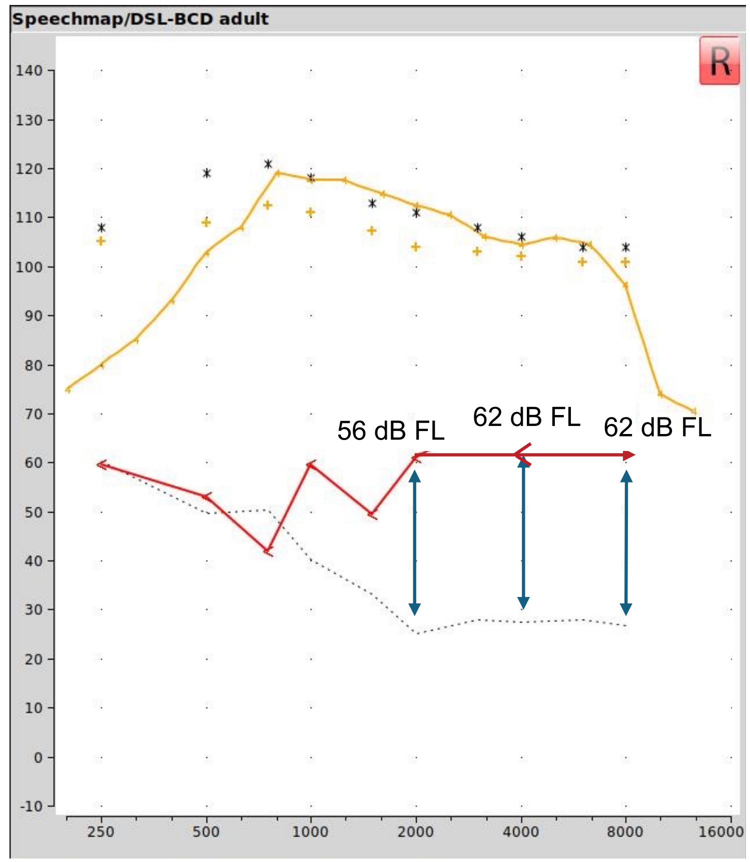
In-situ BC threshold in dB Force Level = $RETFL_{dbc}$ + In-situ thresholds + RHCD

Real-Head to Coupler Difference
(Frequency and device specific, ~ less than 3 dB)

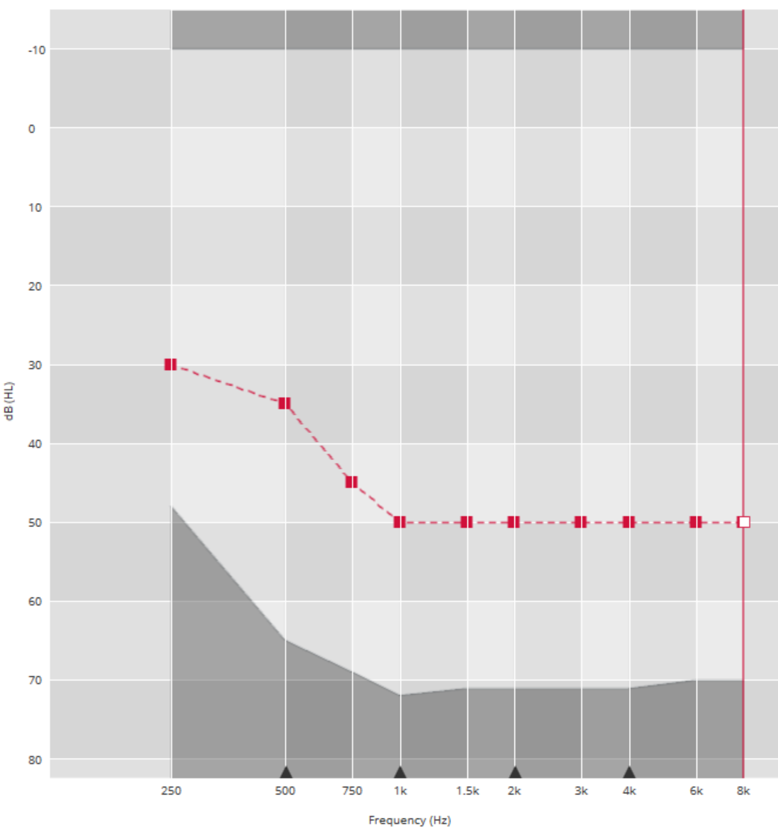
Ex. At 2 kHz, for an in-situ threshold of 30 dB DL, for this BCD model, the dB FL on abutment is 56 dB FL

Normal sloping moderate mixed : *in-situ* dB DL to dB FL

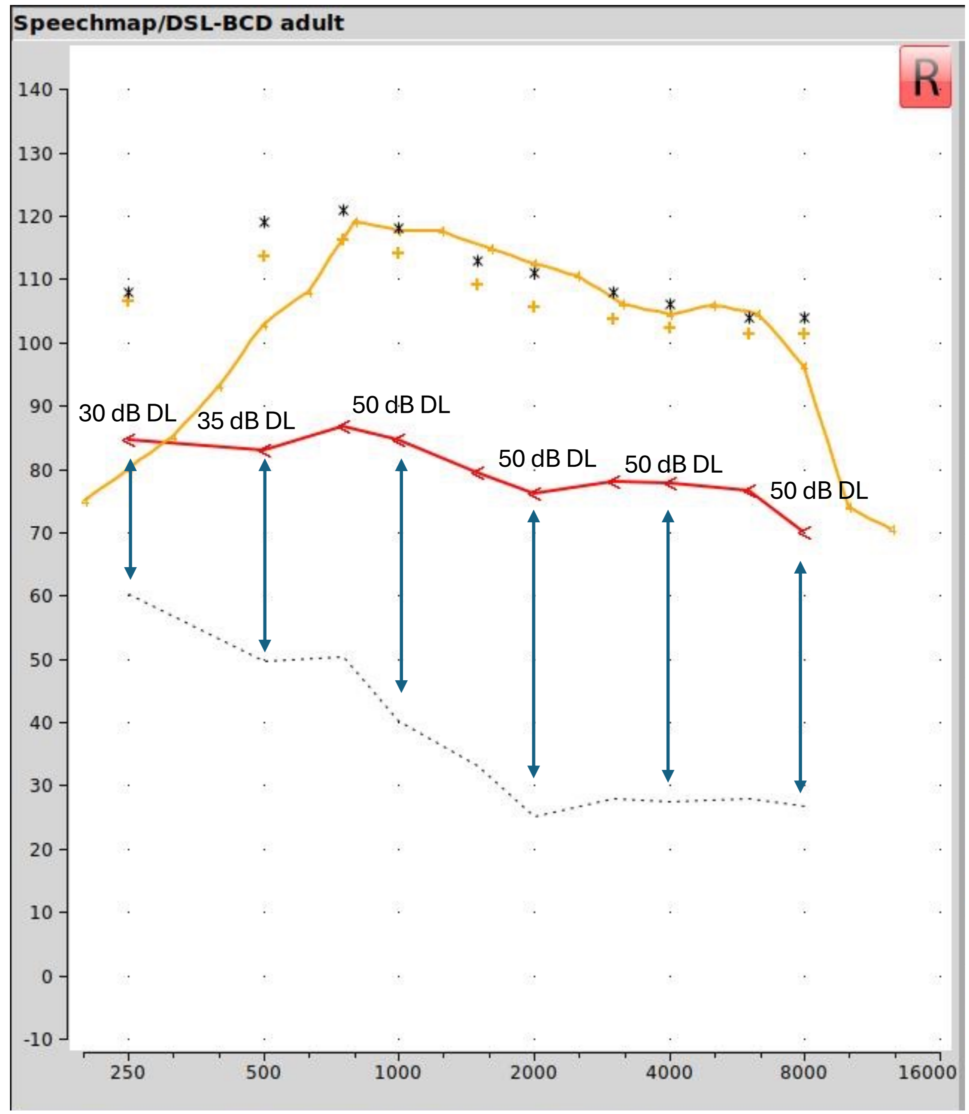




+ RHCD…



250	500	750	1k	1.5k	2k	3k	4k	6k	8k
30	35	45	50	50	50	50	50	50	50



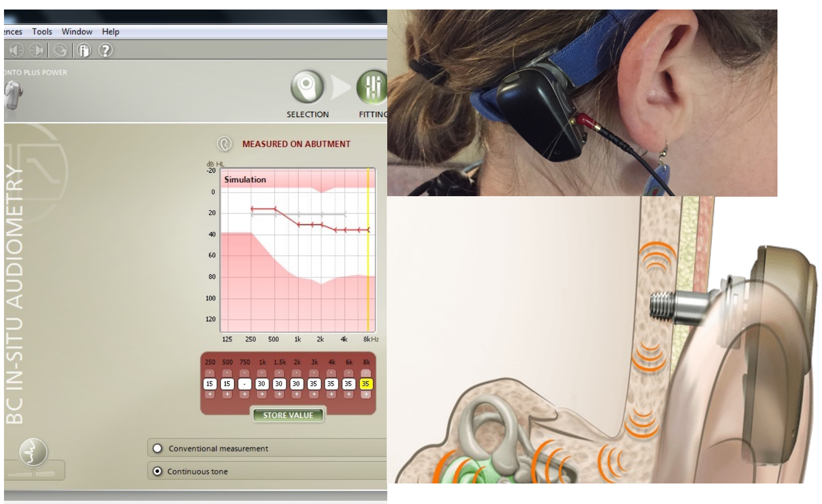
In-situ BC Thresholds vs. Audiometric BC Thresholds

RETFL$_{dbc}$ (percutaneous, direct drive)

dB Dial Level (dB DL)

A mixture of ipsi-lateral and contro-lateral responses from one, or both cochlea

Purpose: BCD verification and fitting

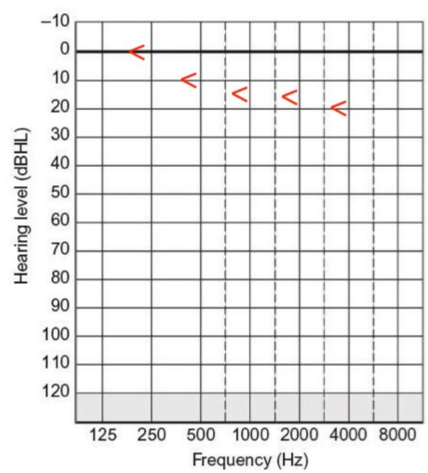


RETFL ANSI S3.6 (transcutaneous, transducer on steelband)

dB Hearing Level (dB HL)

Response from one cochlea (ANSI norm obtained with contro-lateral masking)

Purpose: diagnostic, assess for conductive/mixed/sensorineural



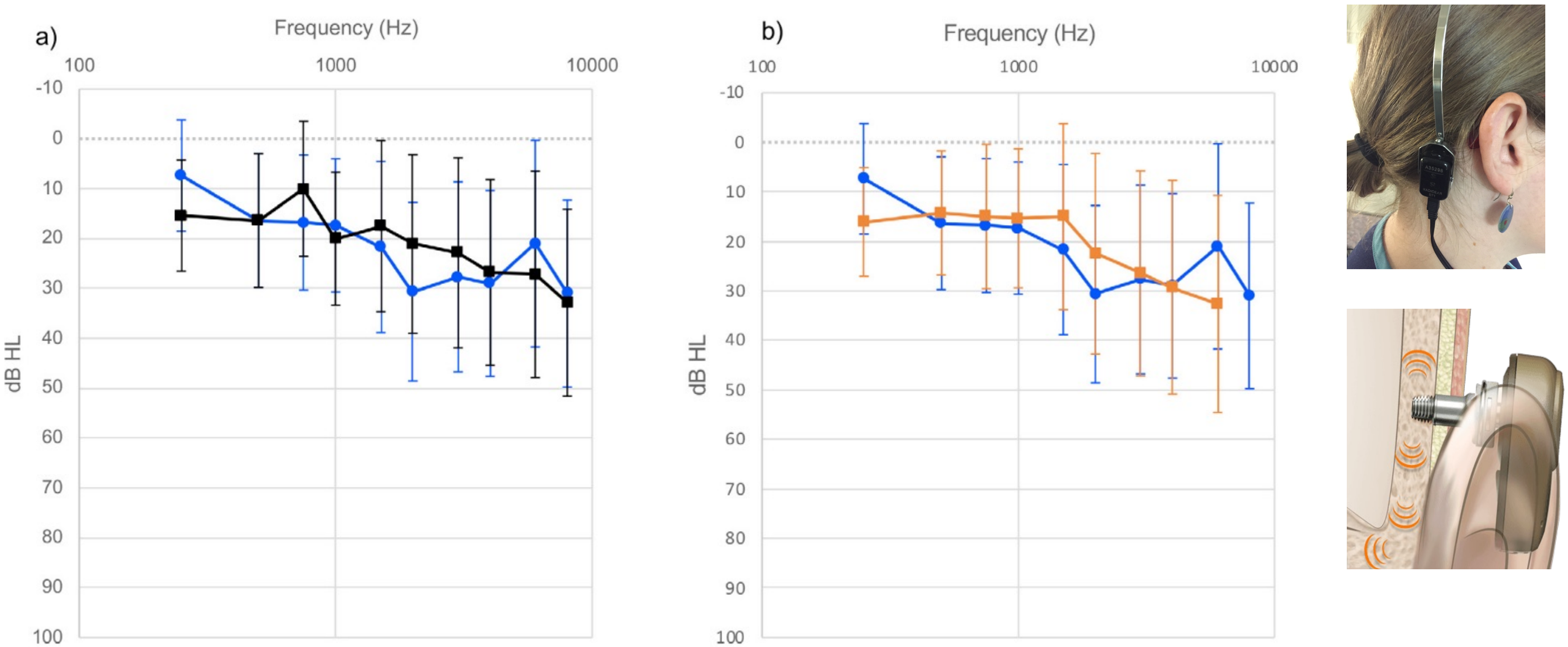


Fig. 3. On each figure, the blue line represents the average B71 bone conduction hearing thresholds in dB HL for the BCD user participants. Whiskers indicate +/- 1 standard deviation. In a) and b), squares represent the average bone-conduction hearing thresholds in dB "HL" obtained in-situ percutaneously. Average in-situ percutaneous bone-conduction hearing thresholds for the Ponto 3 SP are shown in a), and for the BAHA 5 P in b).

Frequency (Hz)	250	500	750	1000	1500	2000	3000	4000	6000	8000
RETFLdbc (dB FL)	59.5	48.0		45.5	34.5	26.0	28.0	27.5	27.5*	27.5*
RETFL ANSI S3.6 2010 (dB FL)	67.0	58.0	48.5	42.5	36.5	31.0	30.0	35.5	40.0	40.0

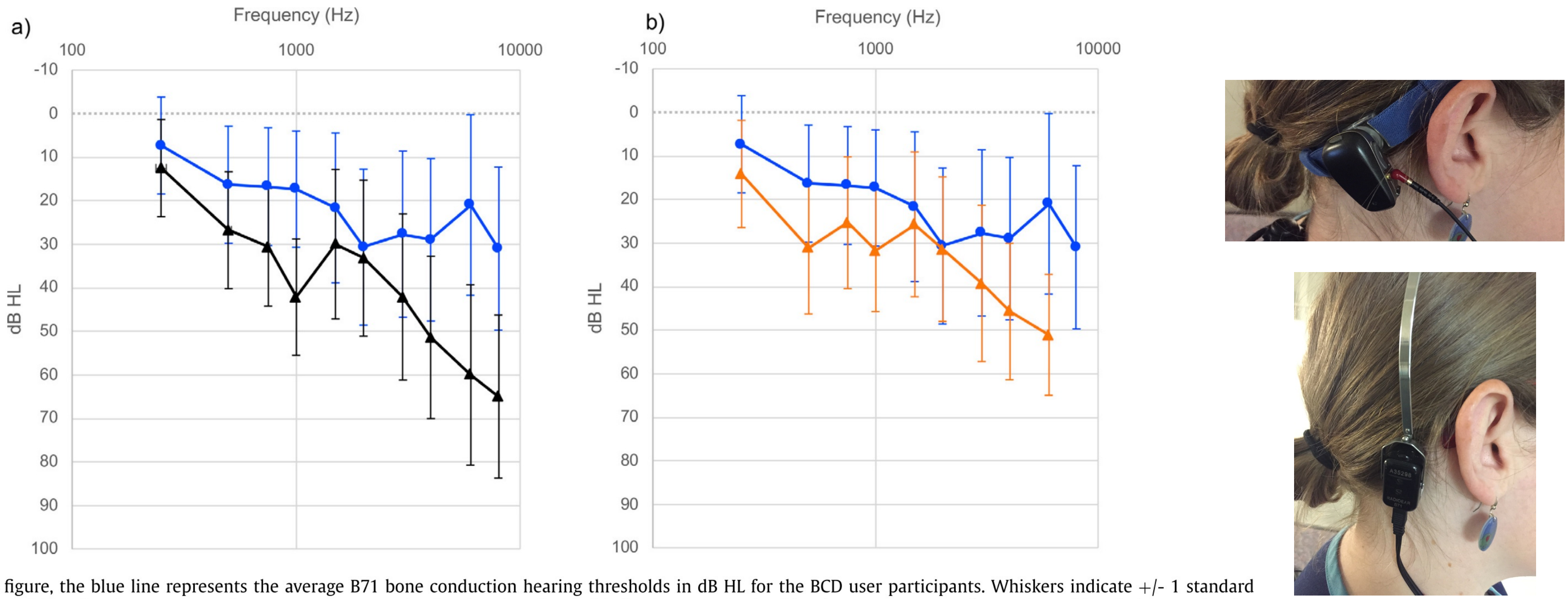
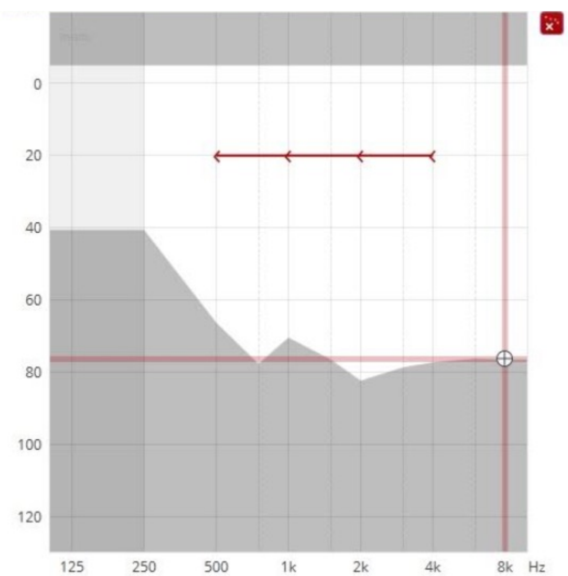
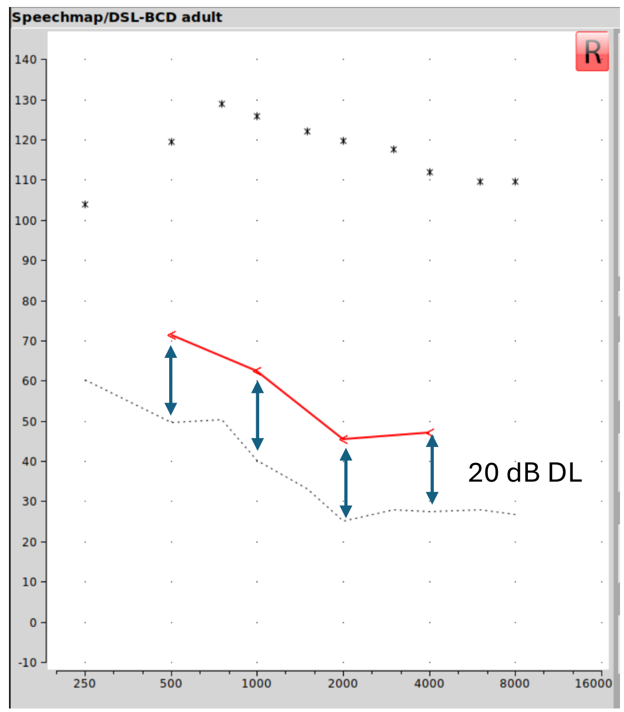


Fig. 4. On each figure, the blue line represents the average B71 bone conduction hearing thresholds in dB HL for the BCD user participants. Whiskers indicate +/- 1 standard deviation. In a) and b), triangles represent the average bone-conduction hearing thresholds in dB "HL" obtained in-situ transcutaneously on the softband. Average in-situ transcutaneous bone-conduction hearing thresholds for the Ponto Super Power are shown in a), and for the BAHA 5 P in b).

BCD with non-surgical attachment





In this example, 20 dB DL with the device on the elastic head band was required to generate a response (i.e., hearing threshold).

This level was sufficient to overcome:

- Cochlear loss (if any)
- Skin attenuation loss
- Other loss of signal (ex. headband coupling mechanism, hair)

Key points – BC thresholds

- *In-situ* BC fitting thresholds are unmasked bone-conduction hearing thresholds obtained with the patient's personal BCD connected to their head
    - Used for BCD fitting and verification purposes (see DSL-BCD fitting procedure and UWO PedAmp 2023→ Hodgetts and Scollie, 2017, Bagatto et al., 2023)
    - Expected to be different than audiometric BC thresholds due to skin attenuation, calibration, contact force and contact size differences between the transducers/coupling methods
    - *In-situ* BC thresholds should be measured with all types of BCD coupling (i.e., soft elastic headband, abutment, etc.) whenever possible, although some BCD do not have *in-situ* testing capabilities

DSL-BCD v1.1 (Hodgetts and Scollie, 2017)

- Adapted from DSL v5.0 prescriptive algorithm (air-conduction hearing aids)
- Developed with a sample of adult BCD users (skin-penetrating abutment), monaurally aided (N=39)

Image retrieved from https://www.audioscan.com/en/verifit2/

Research Questions

What does typical percutaneous skull-simulator measurements look like for percutaneous BCDs?

- Investigate a wide range of hearing loss

What are typical output-to-target deviations and aided SII for adult percutaneous BCD wearers?

Goal

- Provide a better understanding of typical BCD fitting characteristics for various types of hearing losses

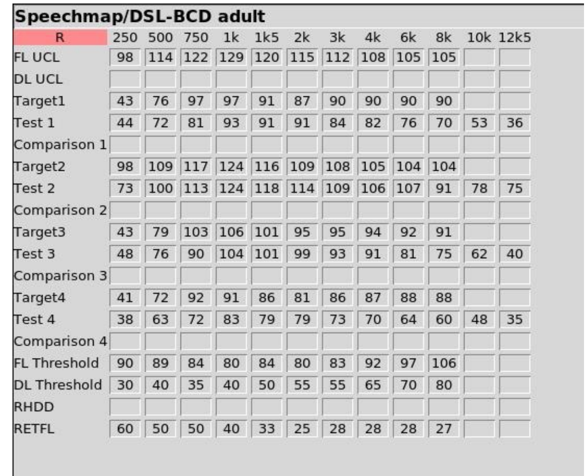
Unpublished data, data analysis ongoing
Alex Gascon, Marlene Bagatto, Susan D. Scollie, Cassandra Cowan and William E. Hodgetts

Methodology

- Health Research Ethics Board #Pro00125725 (University of Alberta)

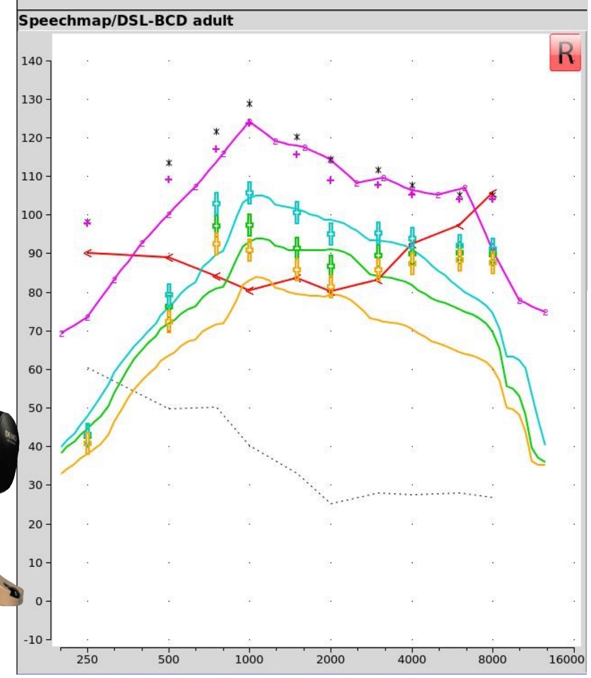
- Retrospective chart review
  - 100 percutaneous BCD users (e.g., skin-penetrating abutment) → Cochlear BAHA, Oticon Medical Ponto
    - Demographic information
    - BCD model
    - Fitting characteristics, output in dB FL of the device set at daily use setting
    - Aided Speech Intelligibility Index (SII, calculated by the Verifit 2)
    - In-situ BC thresholds

- Descriptive statistics, regression analysis
  - SPSS 28, IBM
  - GraphPad Prism 10.0.02 (171) for macOS



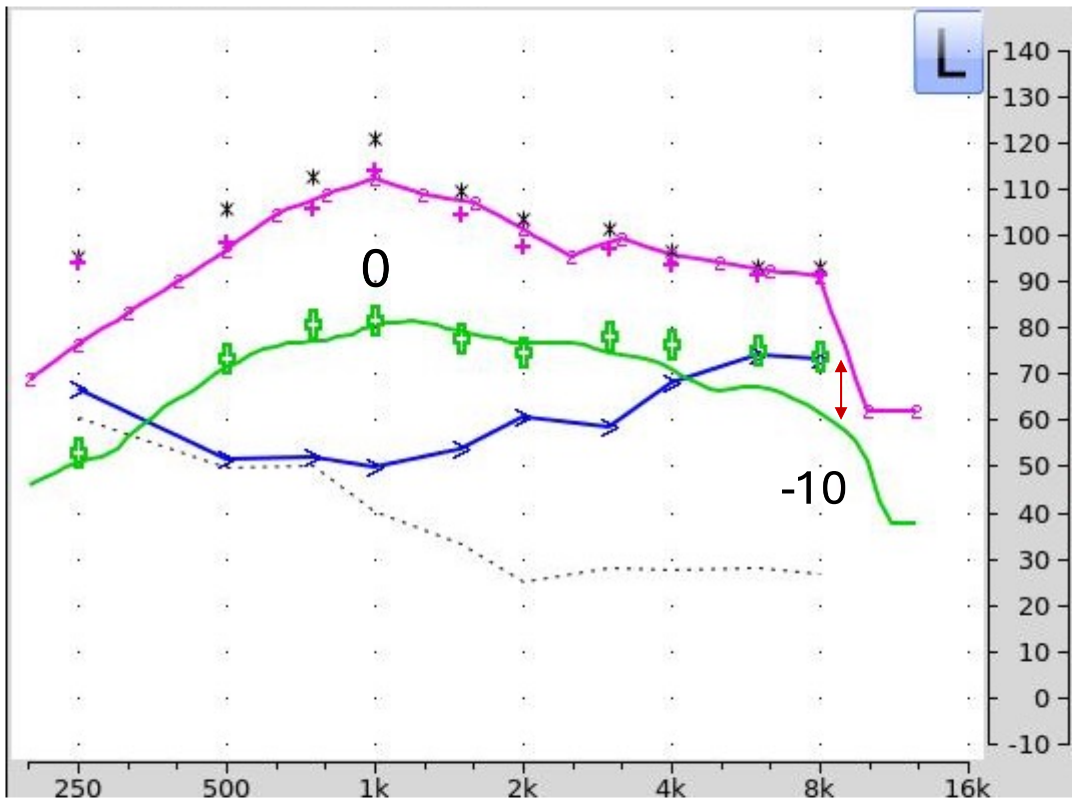
Speechmap/DSL-BCD adult

R	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10k	12k5
FL UCL	98	114	122	129	120	115	112	108	105	105		
DL UCL												
Target1	43	76	97	97	91	87	90	90	90	90		
Test 1	44	72	81	93	91	91	84	82	76	70	53	36
Comparison 1												
Target2	98	109	117	124	116	109	108	105	104	104		
Test 2	73	100	113	124	118	114	109	106	107	91	78	75
Comparison 2												
Target3	43	79	103	106	101	95	95	94	92	91		
Test 3	48	76	90	104	101	99	93	91	81	75	62	40
Comparison 3												
Target4	41	72	92	91	86	81	86	87	88	88		
Test 4	38	63	72	83	79	79	73	70	64	60	48	35
Comparison 4												
FL Threshold	90	89	84	80	84	80	83	92	97	106		
DL Threshold	30	40	35	40	50	55	55	65	70	80		
RHDD												
RETFL	60	50	50	40	33	25	28	28	28	27		

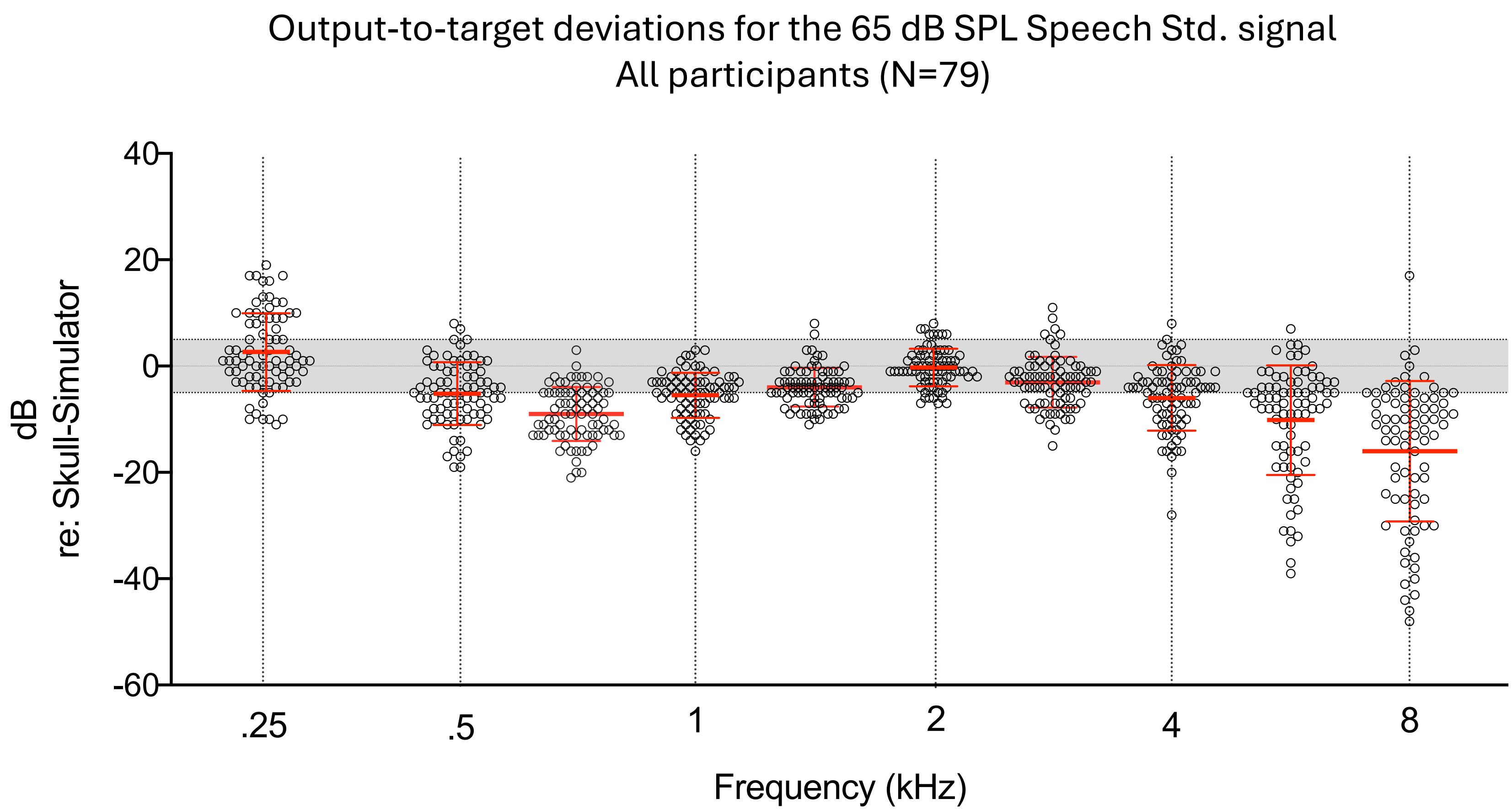


Target-to-output difference

BCD Output (dB FL) – DSL-BCD target (dB FL)

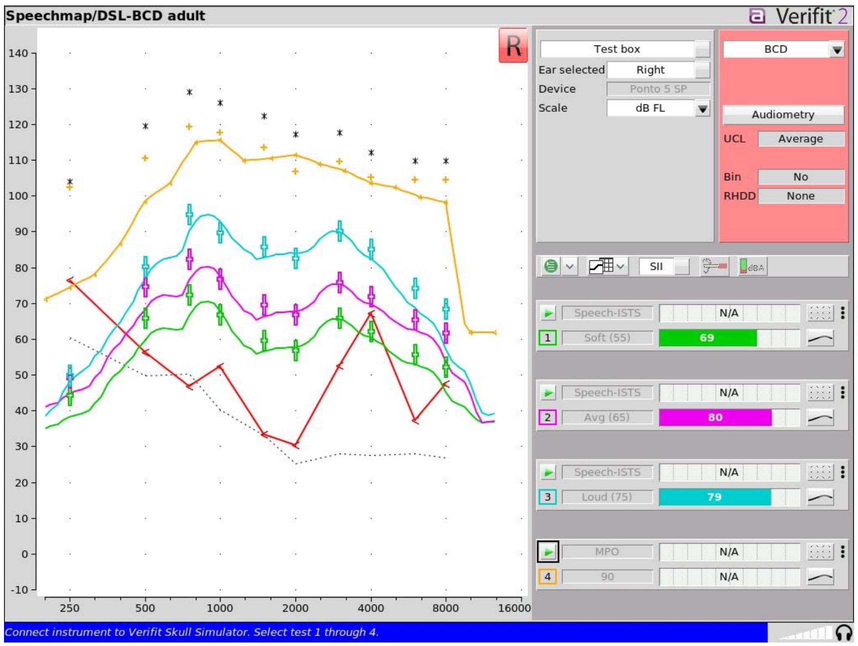


Results

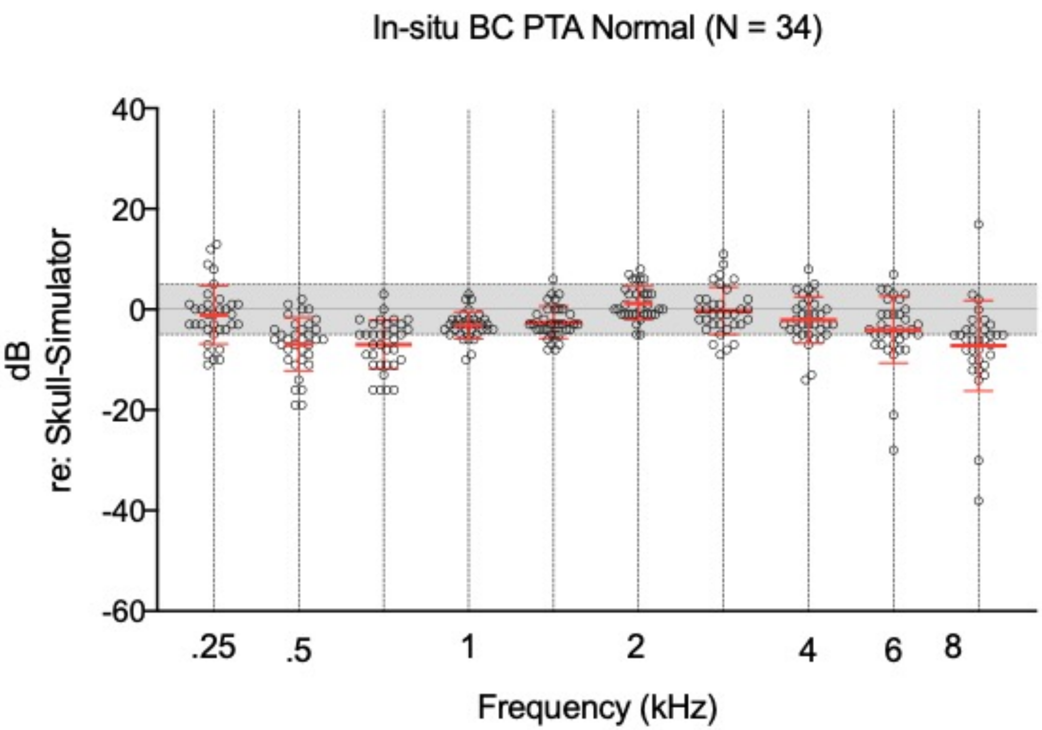


Unpublished data, preliminary results, data analysis ongoing

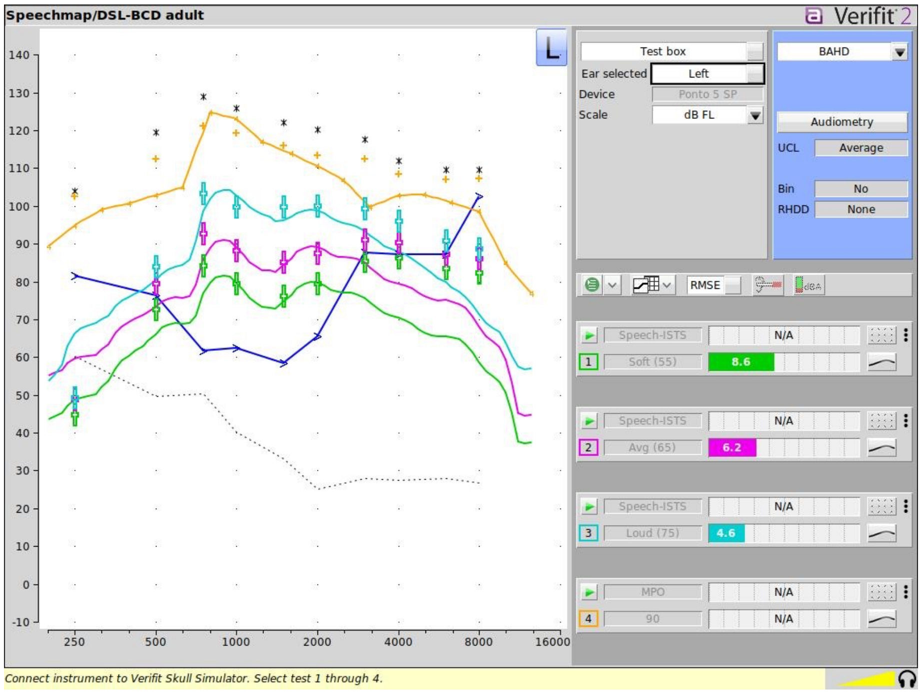
Output-to-target deviations for the 65 dB SPL Speech Std. signal



In-situ 4PTA = 15 dB

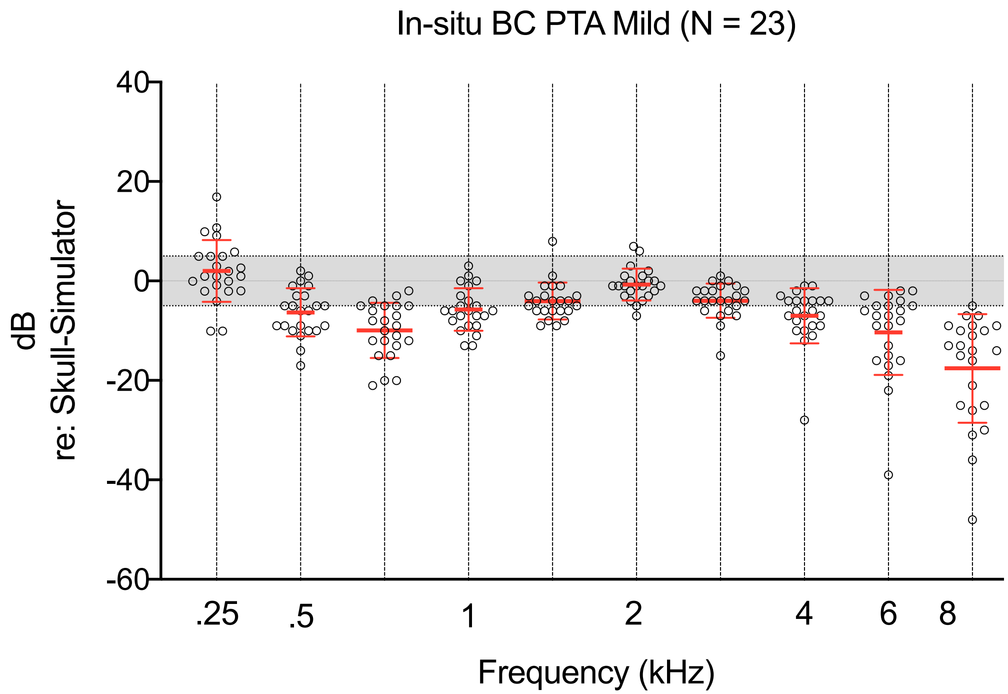


Unpublished data, preliminary results, data analysis ongoing



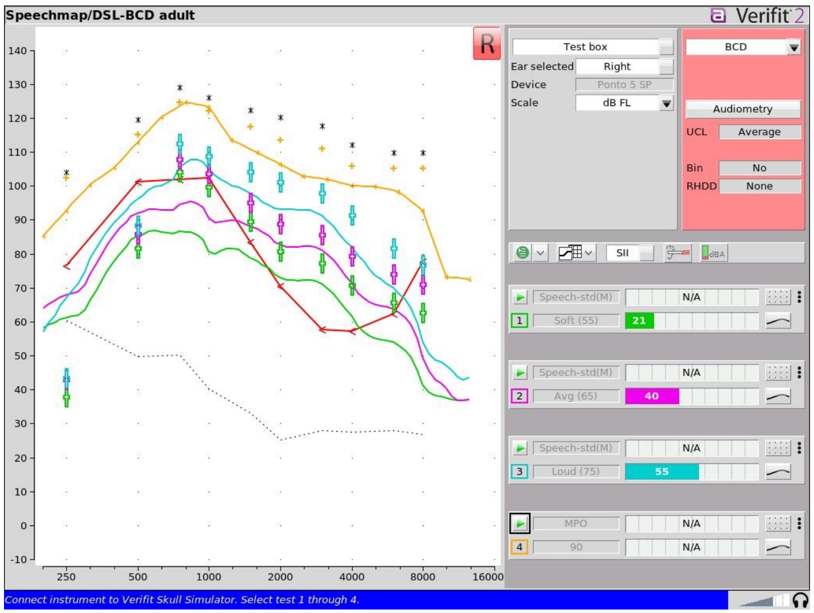
In-situ 4PTA = 36 dB

Output-to-target deviations for the 65 dB SPL Speech Std. signal



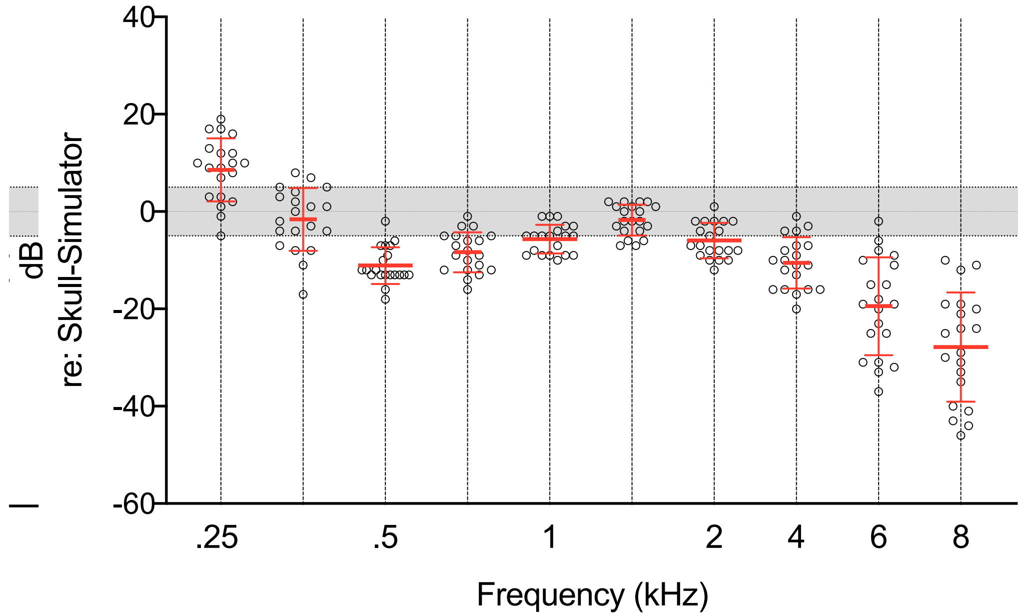
Unpublished data, preliminary results, data analysis ongoing

Output-to-target deviations for the 65 dB SPL Speech Std. signal



In-situ 4PTA = 46 dB

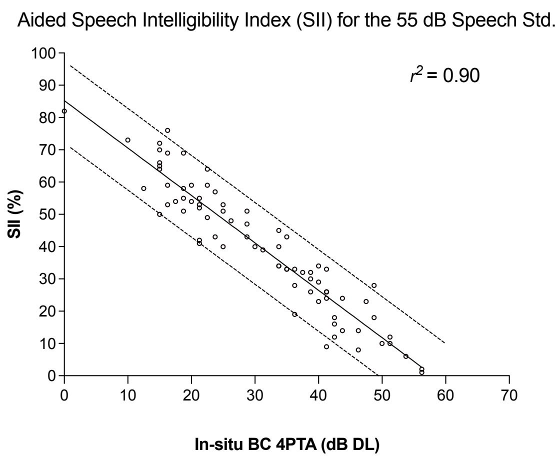
In-situ BC PTA Moderate (N = 20)

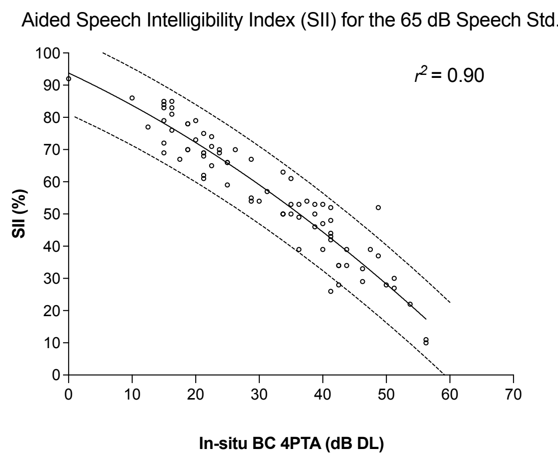


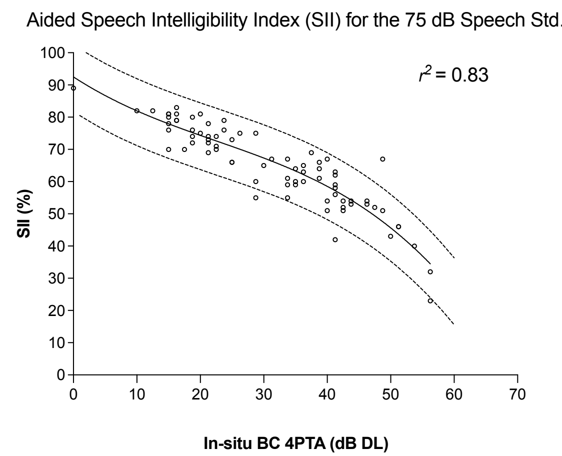
Unpublished data, preliminary results, data analysis ongoing

Aided Speech Intelligibility Index (SII) with Percutaneous BCD

BCD

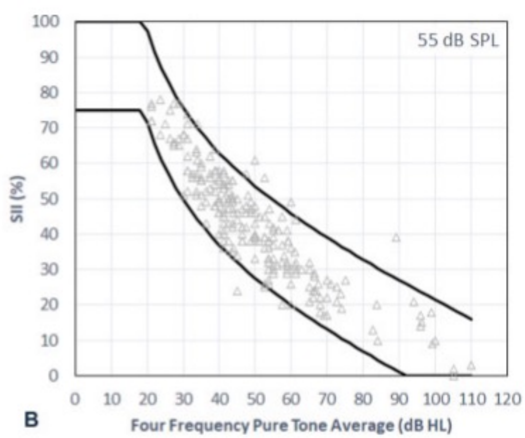


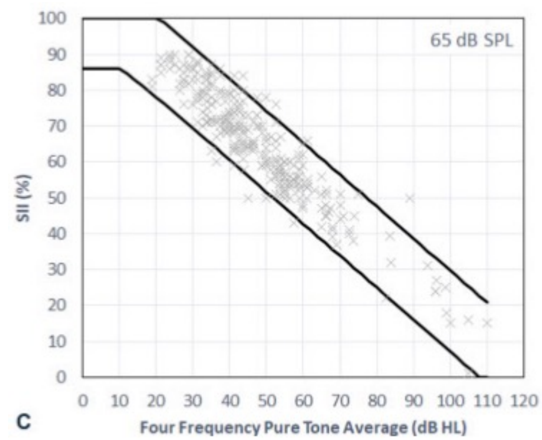


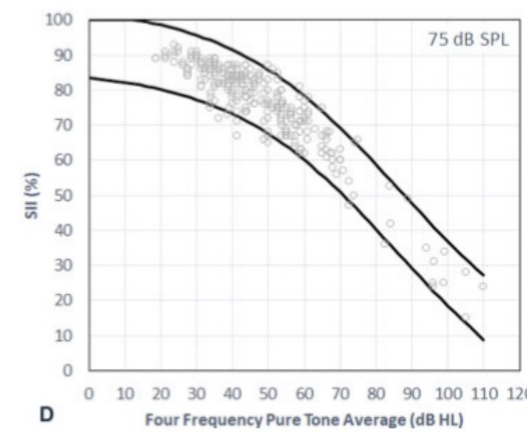


Unpublished data, data analysis ongoing

Air-conduction hearing aids







Dao et al., (2021)

Key points – typical fitting characteristics of percutaneous BCD fittings in adults

- DSL BCD targets are typically met with in-situ 4PTA better than ~40 dB
- As cochlear loss worsens, deviation to targets increases (output under targets), which is particularly noticeable at 4 kHz and above
  - Likely due to unstable gain and BCD Maximum Force Output limitations
- Data analysis ongoing

Limitations

- Retrospective chart review, BCD set at *daily setting*
- Whether fine tuning could have improved match to targets is not addressed by this study
- Aided SII → not a BC hearing measure, it was developed for air-conduction hearing

Potential BCA Candidate

Inbox ×

Carmen Sandiego

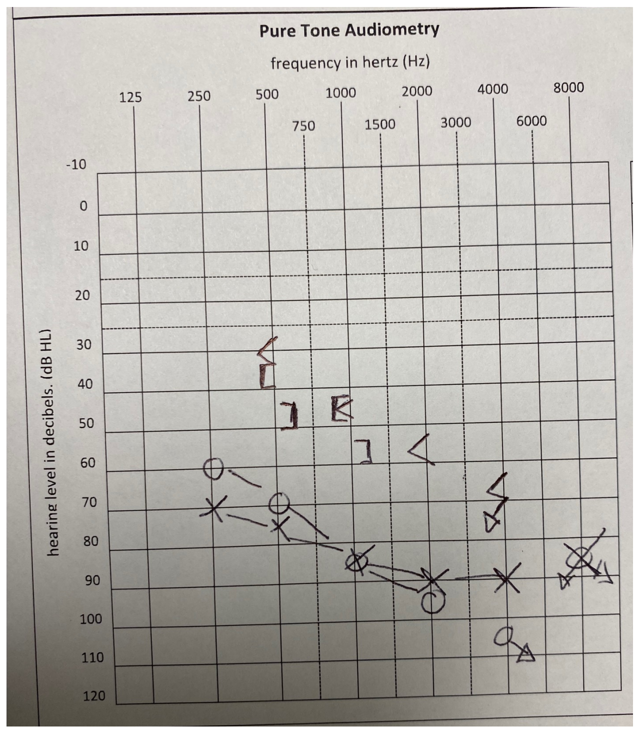
to me

3:30 PM (2 minutes ago)

Hi Alex,

Could you look at the audiogram attached? I am wondering if I should refer for a bone-conduction implant candidacy assessment. The bone line is not great, but the patient is not doing well with their hearing aids. See audio attached.

Let me know what you think, merci

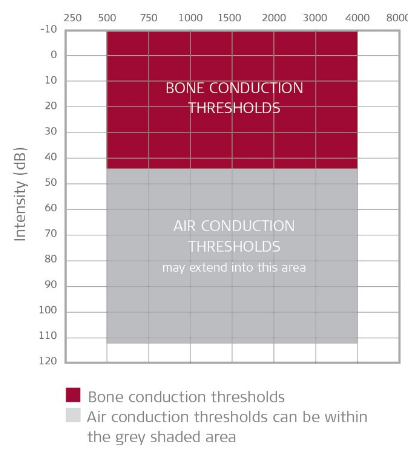


Introducing the Baha® 6 Max Sound Processor: Small never sounded this powerful

- Premium-power sound processor in a small size with a 55dB SNHL fitting range[1]

Ponto 5 Mini

Up to 45 dB HL

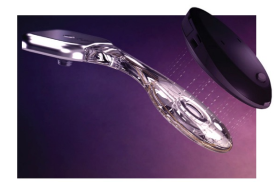


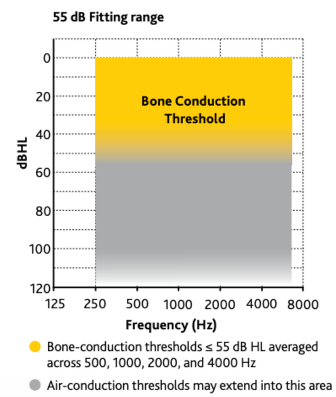
Ponto 5 SuperPower

65 dB HL BC

Fitting range
55 dB

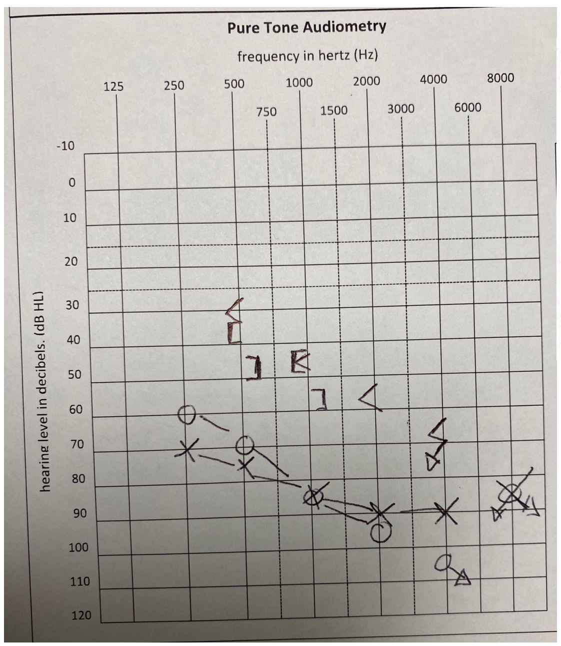
The Osia 2 System is indicated for individuals with bone conduction thresholds within the yellow area indicated in the fitting range. For further details, see the candidate selection guide.[1]

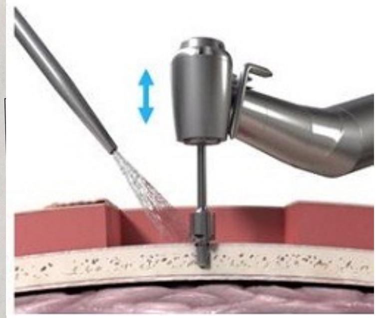


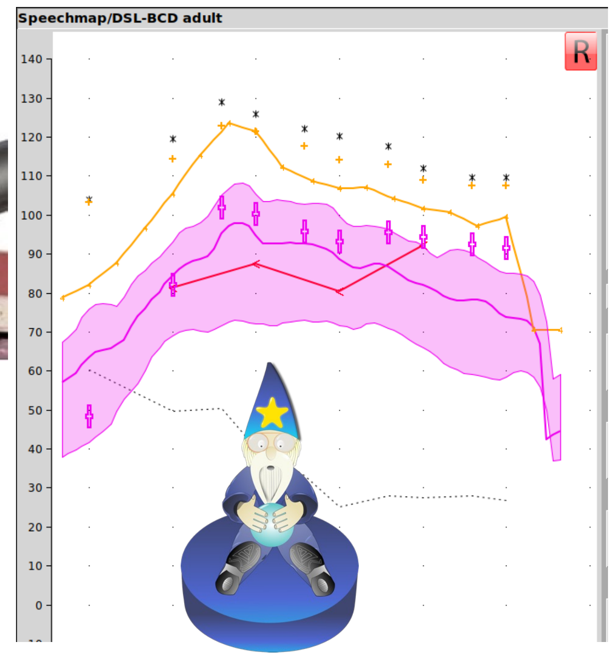


Images retrieved from:
Cochlear.com
https://www.audiologyonline.com/interviews/med-el-celebrating-10-years-bonebridge-27886Oticonmedical
Oticonmedical.com

?


Pure Tone Audiometry
frequency in hertz (Hz)
125 250 500 1000 2000 4000 8000
750 1500 3000 6000
-10 0 10 20 30 40 50 60 70 80 90 100 110 120
hearing level in decibels. (dB HL)




Speechmap/DSL-BCD adult
R
140 130 120 110 100 90 80 70 60 50 40 30 20 10 0

Canadian Academy of Audiology
Academie Canadienne d'audiologie

CAA Clinical Research Grant 2023

Objective

A better understanding of the relationship between pre-surgical hearing thresholds (diagnostic BC thresholds) and percutaneous BCD verification characteristics (aided audibility measured with skull-simulator)

Research Questions

1. Can audiometric bone-conduction hearing thresholds predict in-situ bone-conduction hearing thresholds obtained on a skin-penetrating bone-conduction hearing implant?

2. Can audiometric bone-conduction hearing thresholds predict the output of the BCD once connected to a bone-conduction hearing implant?

Canadian Academy of Audiology
Academie Canadienne d'audiologie

CAA Clinical Research Grant 2023

Methodology and Proposed Analysis

Design: quasi-experimental prospective study, repeated measure

Sample size: 100 (currently at 86 participants)

Inclusion criteria:

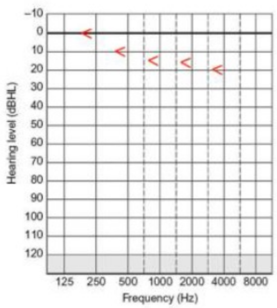
- Adults (≥ 18 years old)
- Using a BCD connected to an osseointegrated implant with skin-penetrating abutment

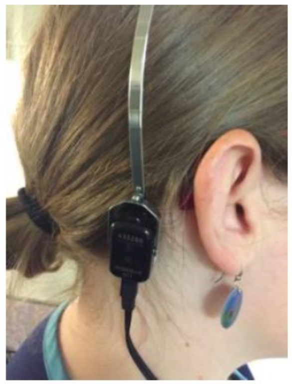
Procedure

- Measure In-situ BC thresholds
- Measure audiometric BC threshold
- Store skull-simulator measurement with device set at "daily use" , reflecting how the device is used in day-to-day situations (feedback management activated, accounts for device limitations related to MFO and unstable gain)

Proposed analysis:

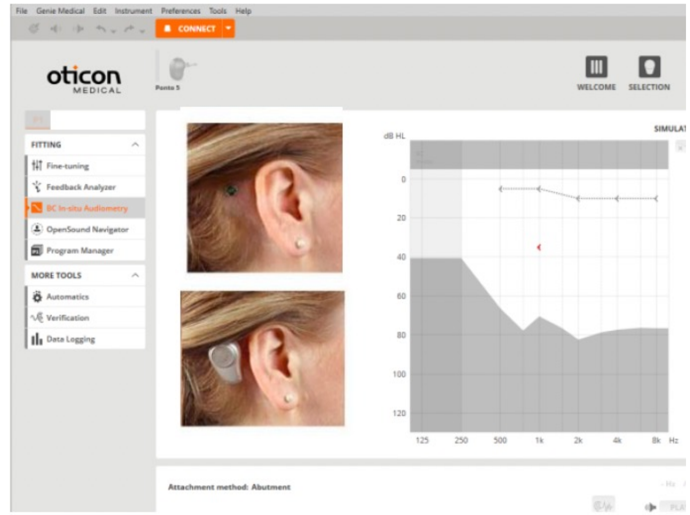
- Regression analysis





Pure-tone audiometry with the RadioEar B71 diagnostic transducer.

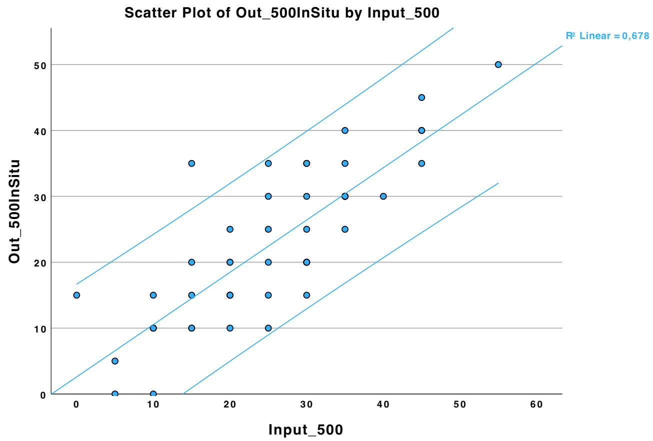
Regression

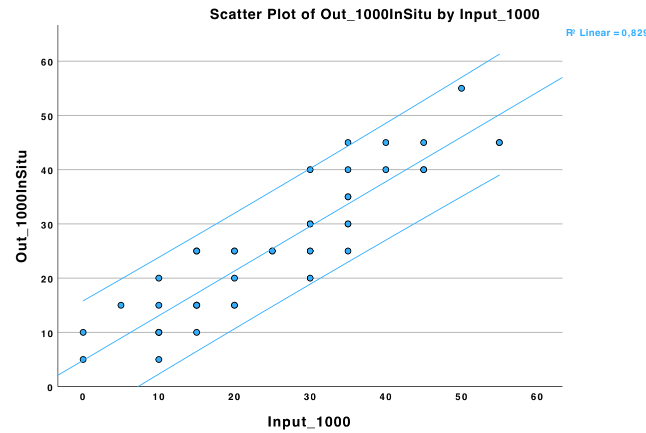


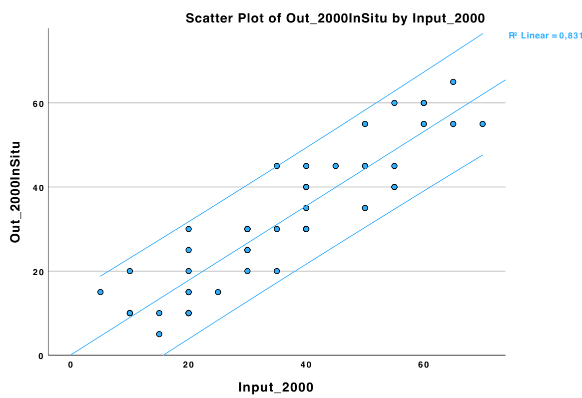
- *In-Situ* pure-tone audiometry. *B*one-conduction hearing thresholds measured using the BCD as the transducer. Hearing thresholds are measured with the device connected to the abutment. Tones are presented with the hearing device software

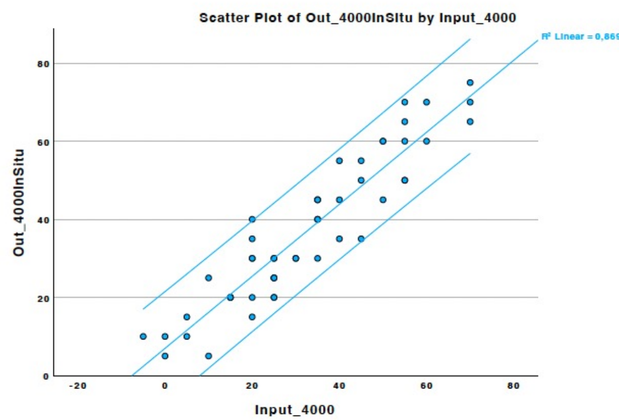
Predictor: BCthresholds

Outcome Variable: InSituBC







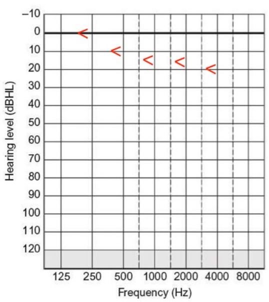


$p < 0.001$ and large effect size for each model

Unpublished data, preliminary results, data analysis ongoing

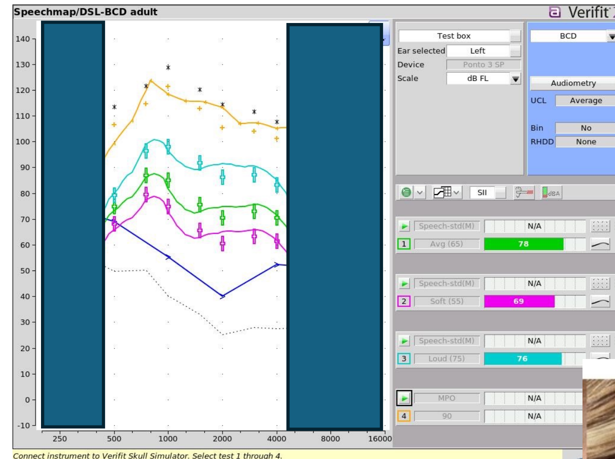
Predicting output of the BCD

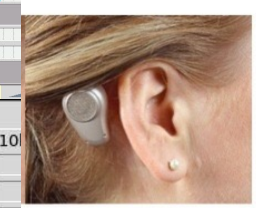
- Predictor: Diagnostic BC thresholds



Outcome variable:

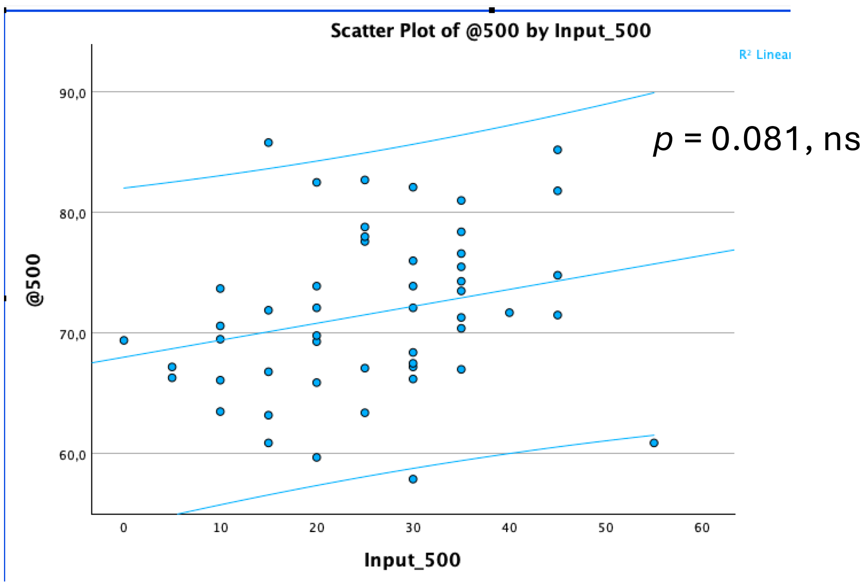
- Predicted Output in dB FL, for a 65 dB speech signal, at 500, 1000, 2000 and 4000 Hz
- <u>**Device set a patient at patient daily use settings**</u>

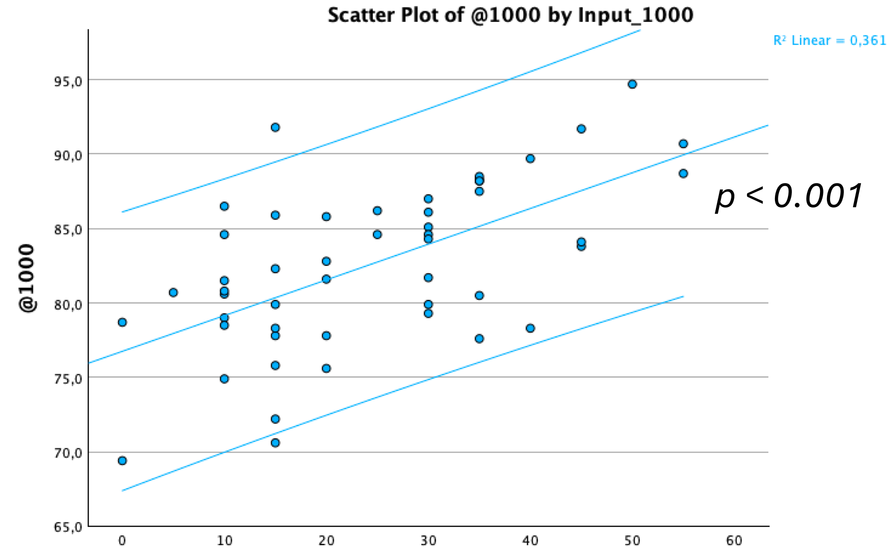


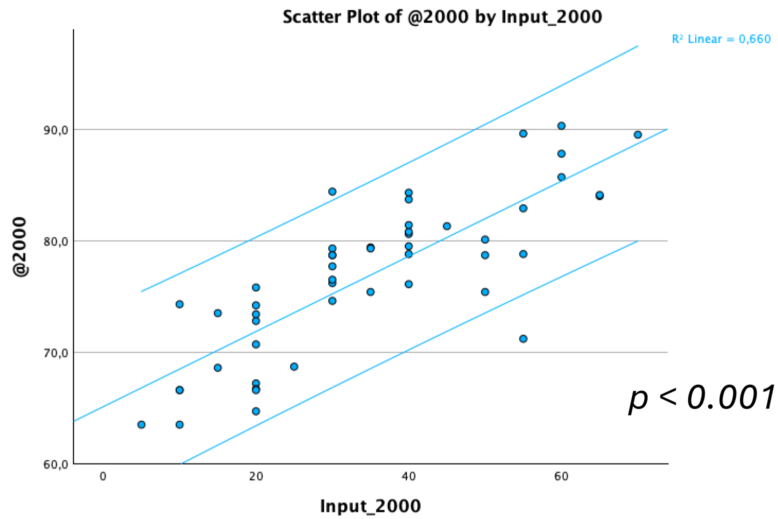


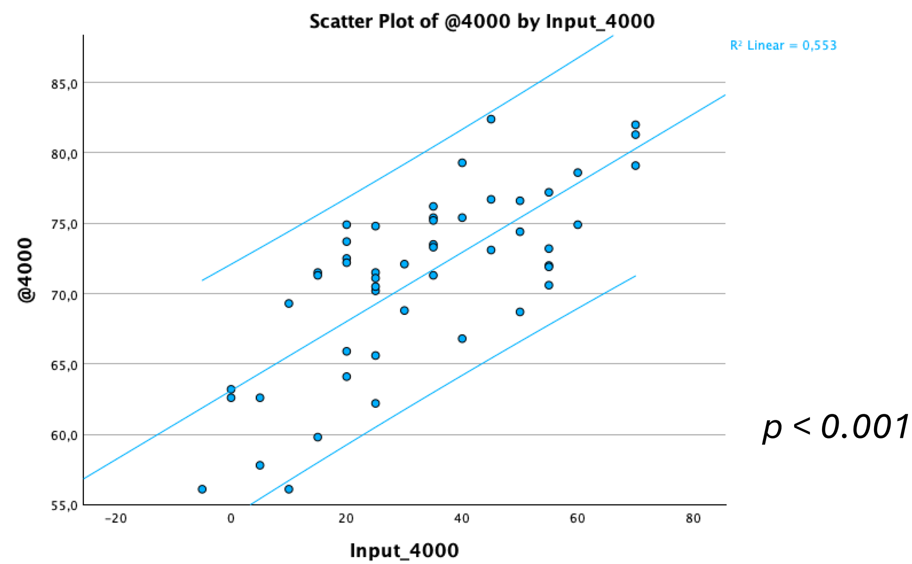
Speechmap/DSL-BCD adult

L	250	500	750	1k	1k5	2k	3k	4k	6k	8k	10[illegible]	
FL UCL	98	114	122	129	120	115	112	108	105	105		
DL UCL												
Target1	45	[illegible]	87	[illegible]	76	[illegible]	73	[illegible]	65	62		
Test 1	50	73	86	82	73	75	76	72	62	59	46	35
Comparison 1												
Target2	41	68	79	75	66	61	63	61	56	[illegible]	[illegible]	[illegible]
Test 2	44	66	77	73	63	65	66	62	[illegible]	[illegible]	[illegible]	[illegible]
Comparison 2									[illegible]	[illegible]	[illegible]	[illegible]
Target3	45	79	96	98	92	86	87	83	[illegible]	[illegible]	[illegible]	[illegible]
Test 3	51	80	99	96	89	92	90	85	[illegible]	[illegible]	[illegible]	[illegible]
Comparison 3									[illegible]	[illegible]	[illegible]	[illegible]
Target4	97	107	115	121	113	105	104	101	[illegible]	[illegible]	[illegible]	[illegible]
Test 4	80	99	119	118	115	113	107	105	[illegible]	[illegible]	[illegible]	[illegible]
Comparison 4								[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
FL Threshold	75	69		55		40		[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
DL Threshold	15	20		15		15		25	[illegible]	[illegible]	[illegible]	[illegible]

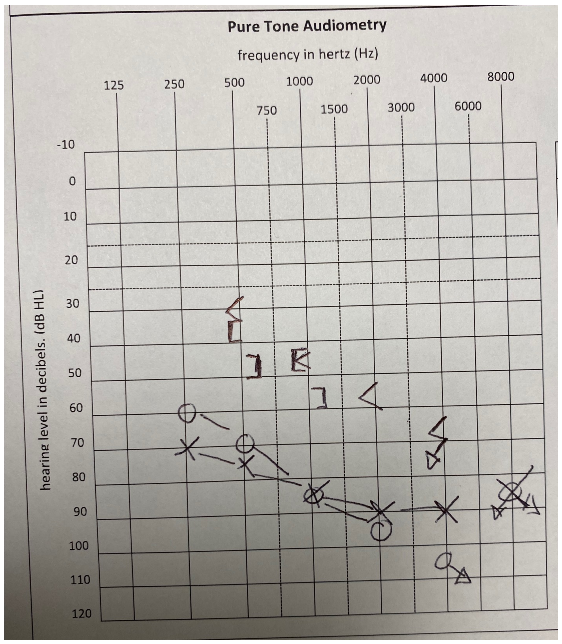


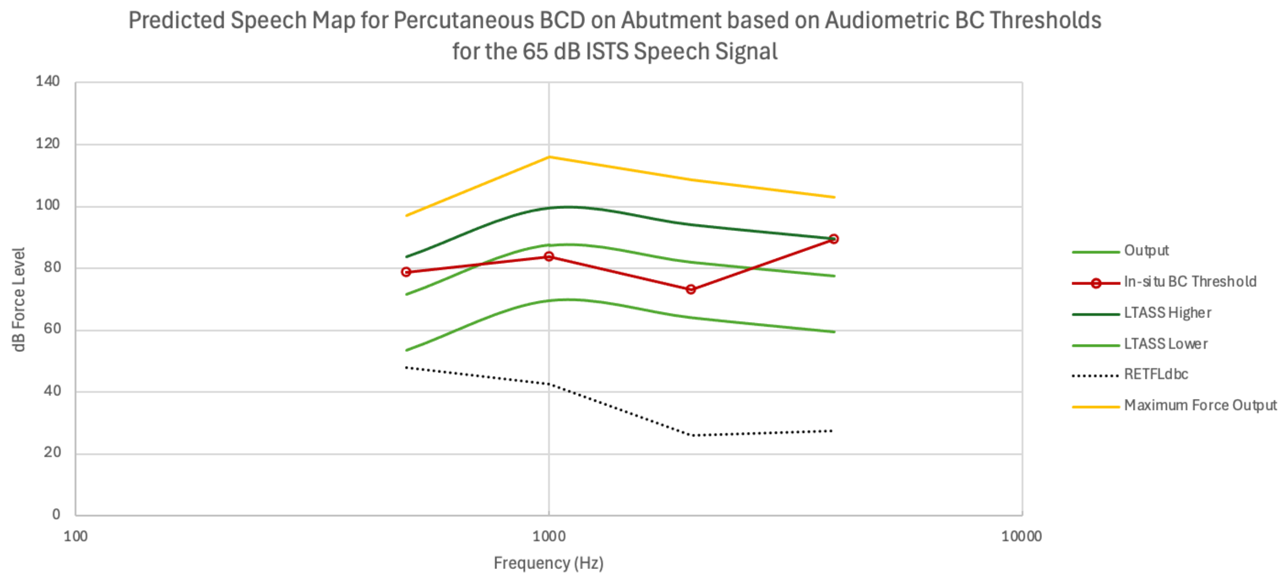




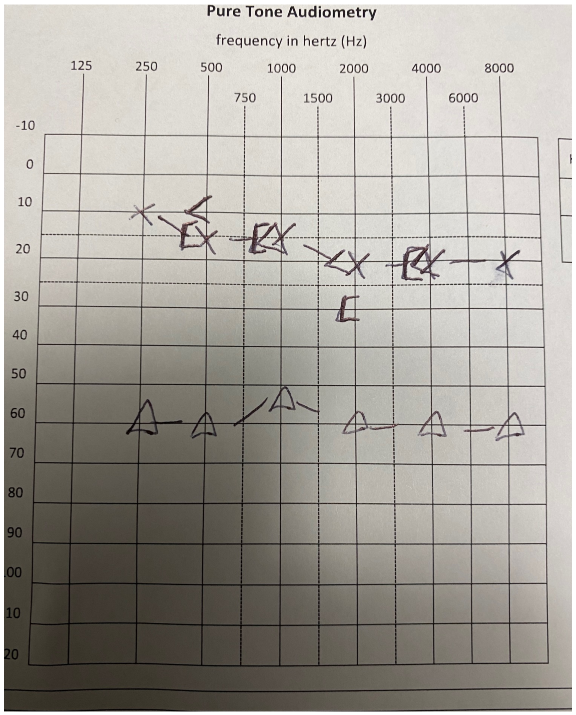


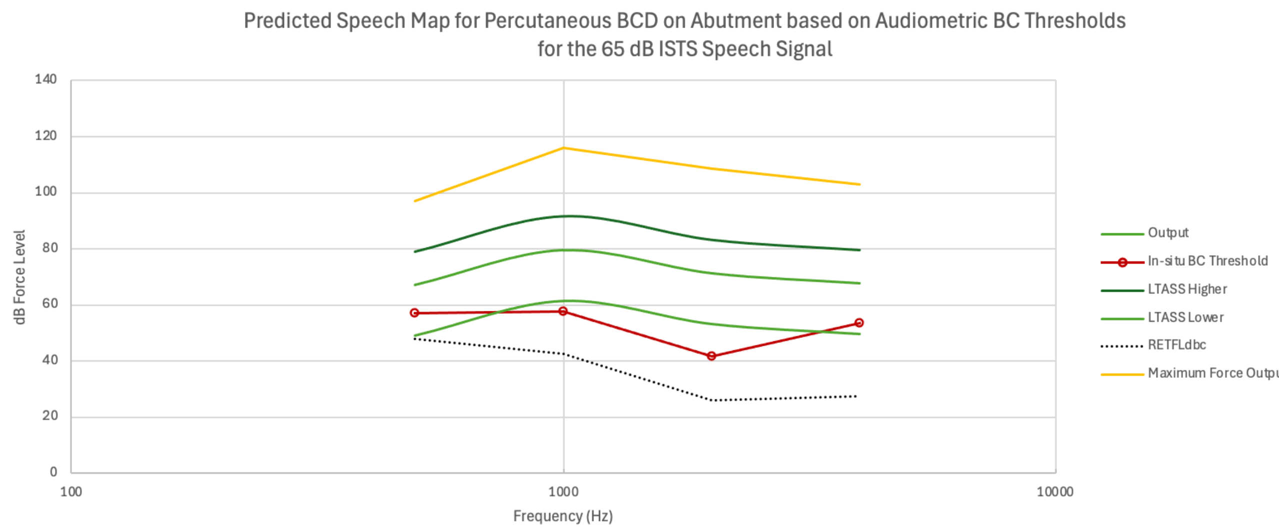
Unpublished data, preliminary results, data analysis ongoing





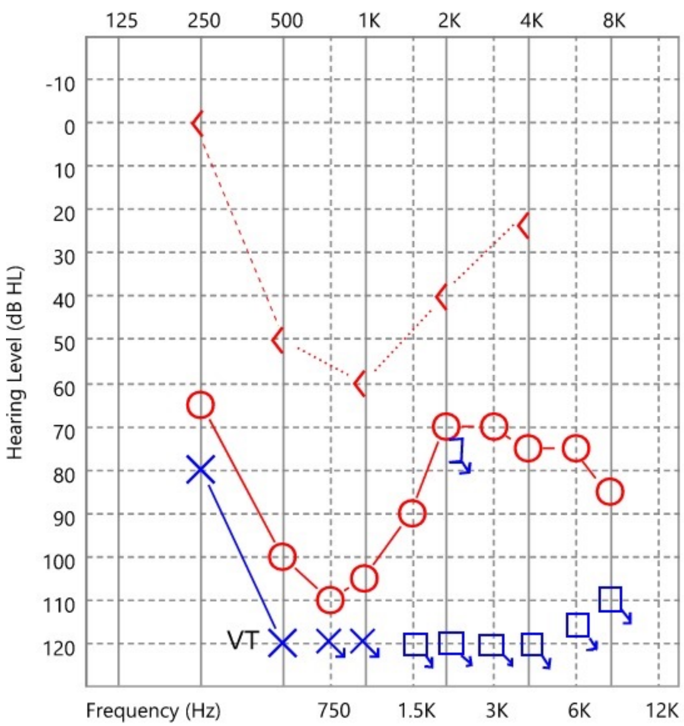
Frequency (Hz)	500	1000	2000	4000
Unmasked Audiometric BC thresholds (dB HL)	30	45	55	65
Predicted in-situ BC thresholds (dB DL)	25	45	50	60

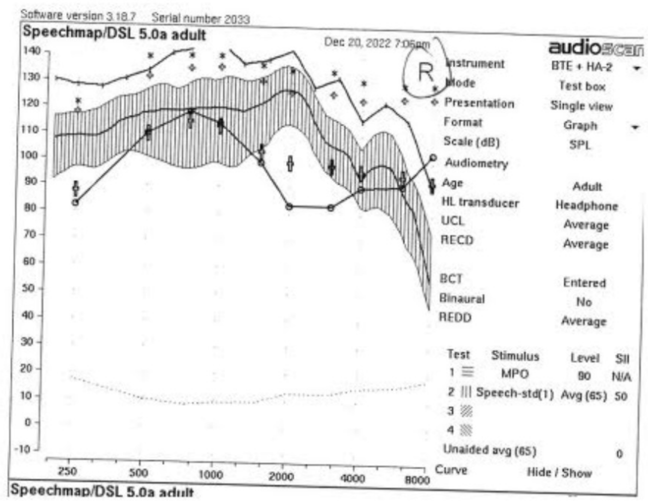




Frequency (HZ)	500	1000	2000	4000
Unmasked Audiometric BC thresholds (dB HL)	10	15	20	25
Predicted in-situ BC thresholds (dB DL)	10	15	15	30

Mixed Hearing Loss - Clinical case 1

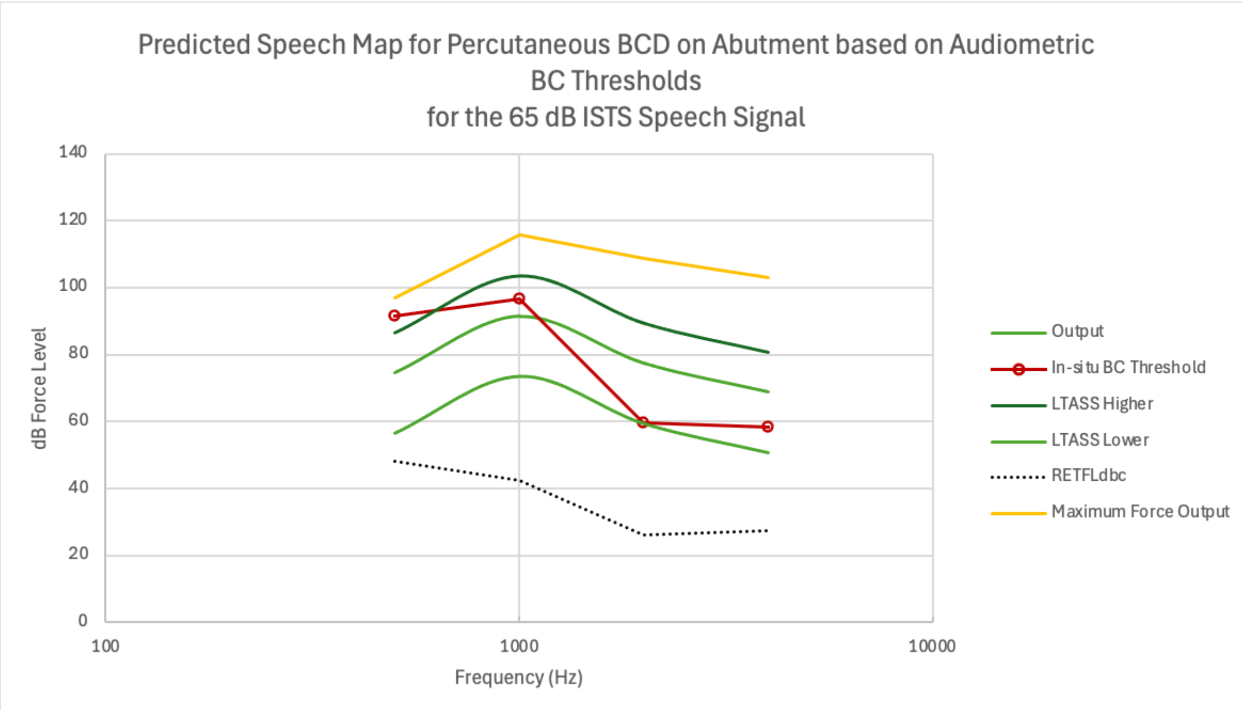




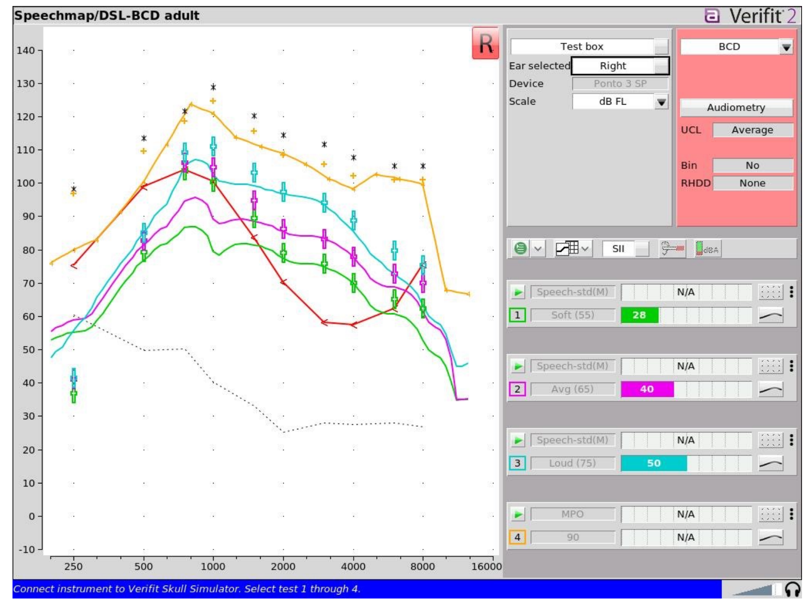
- Word Recognition Score (NU6) on right: 100% at 100 dB HL

At 60 dB SPL aided with BICROS system

- CNC word : 62%
- CNC phoneme: 83%
- AZ Bio: 97%

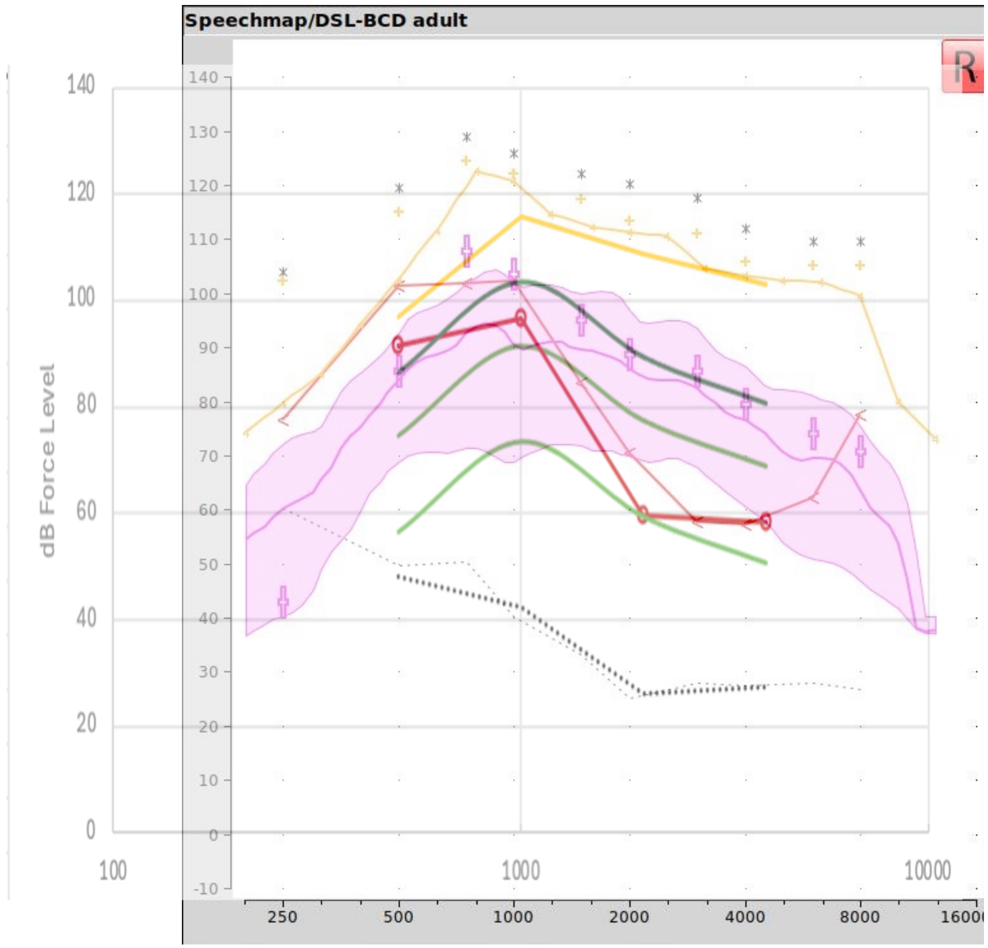


Skull-simulator measurement at patient preferred settings



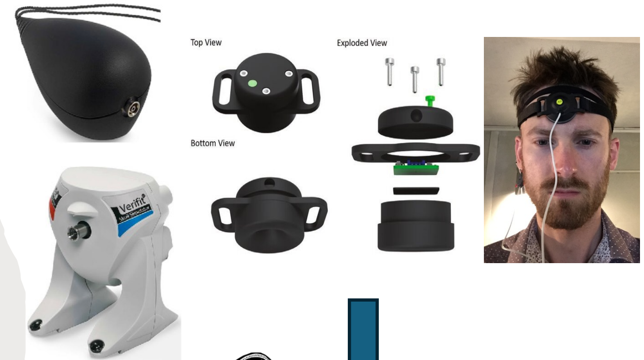
Prescription in software: DSL BCD Pediatric

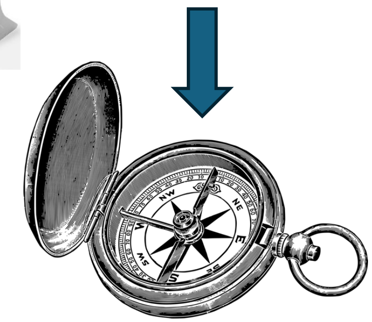
Frequency (Hz)	500	1000	2000	4000
Unmasked Audiometric BC thresholds (dB HL)	50	60	40	25
Predicted in-situ BC thresholds (dB DL)	45	55	35	30


Speechmap/DSL-BCD adult
R
dB Force Level
140
120
100
80
60
40
20
0
100
1000
10000
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
250
500
1000
2000
4000
8000
1600

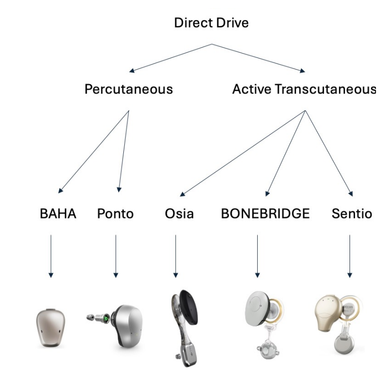
- Provide another tool to support clinicians in their decision about:
  - Bone-conduction hearing implant candidacy
  - Device type (ex. regular vs. power device)
  - Bone-conduction implant type (current study is percutaneous with skin-penetrating abutment only)

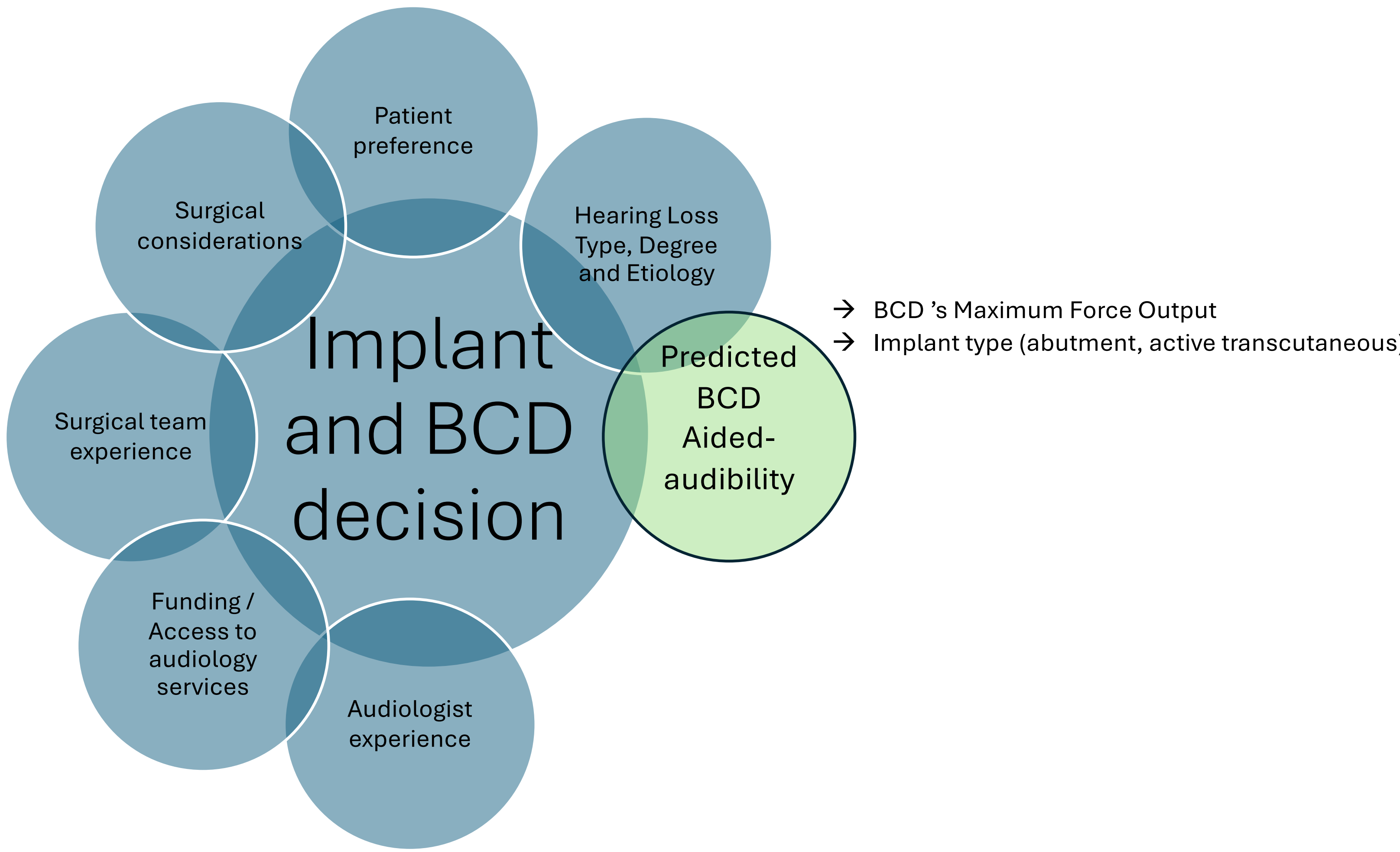
- Current work:
  - Data collection ongoing
  - Eventually, develop a web-based tool to be used by clinicians (i.e., clinician enter unmasked audiometric threshold to generate a predicted Speech Map post-implant)
  - Extend data collection to active transcutaneous BCD measured using objective verification tool (Surface/skin microphone currently in prototype stage, under development)





Prediction Tool





Patient preference
Surgical considerations
Hearing Loss Type, Degree and Etiology
Implant and BCD decision
Surgical team experience
Predicted BCD Aided-audibility
Funding / Access to audiology services
Audiologist experience
→ BCD 's Maximum Force Output
→ Implant type (abutment, active transcutaneous)

Key points - Predicting BCD aided-audibility to help with implant candidacy and device decision

- The unmasked audiometric BC threshold at .5, 1, 2 and 4 kHz can predict the *in-situ* BC thresholds, BCD output and the aided SII in percutaneous fittings
    - *In-situ* BC threshold are more precisely predicted than the aided audibility (likely due to variability in user preferred settings)
    - This prediction can be used to generate an estimated predicted SpeechMap of the aided audibility fitting post-surgery
    - Further analysis needed to understand the size of the error of the predictions, and how to use this prediction as a clinical tool to help guide decisions surrounding the BCD

Final thoughts

- Audiologists have the training and knowledge to be an integral part of the decisions surrounding bone-conduction implant candidacy and device decisions
  - Aided audibility with the BCD should be a key factor in these decisions
- The bone-conduction amplification framework and verification tools are analogous to air-conduction amplification
  - Objective verification tools can be used to optimize fitting individually, and larger data set of BCD objective measurements in clinic are being gathered to help inform practice

Merci!

PhD Committee: Dr. Bill Hodgetts, Dr. Jacqueline Cummine, Dr. Marlene Bagatto, Dr. Daniel Aalto

iRSM team, iRSM BCD users, Rhys Kooistra, Dr. Marshall Chasin, Dr. Kathleen Jones, Dr. Susan Scollie, Cassandra Cowan, Hope Valeriote, Canadian Academy of Audiology, Mitchell Holmes, all the Albertan audiologists for their questions and collaboration

Alex Gascon, R.Aud

Registered Audiologist, PhD Candidate

Bone-Conduction Amplification Laboratory – iRSM

Department of Communication Sciences and Disorders - Faculty of Rehabilitation Medicine, University of Alberta

agascon@ualberta.ca

iRSM Institute for Reconstructive Sciences in Medicine | Alberta Health Services | University of Alberta | Covenant Health