

Bone Conduction Hearing Devices

Practice and Pitfalls from a Canadian Implant Centre



30-OCT-2019

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University
of
Manitoba



Shared health
Soins communs
Manitoba



Health Sciences Centre
Winnipeg

Disclosures

Research grant through Advanced Bionics

Learning Objectives

1. Provide an overview of implantable and non-implantable bone conduction technologies
2. Detail candidacy criteria and common surgical procedures for implantable technology
3. Describe challenges to care from an ethical, geographical and limited resource perspective

Overview

1. Role of Audiology in Public Health
2. Evolution of Bone Conduction Technology
3. Fitting Considerations
4. Outcome Measures
5. Future Outlook

PUBLIC HEALTH AUDIOLOGY





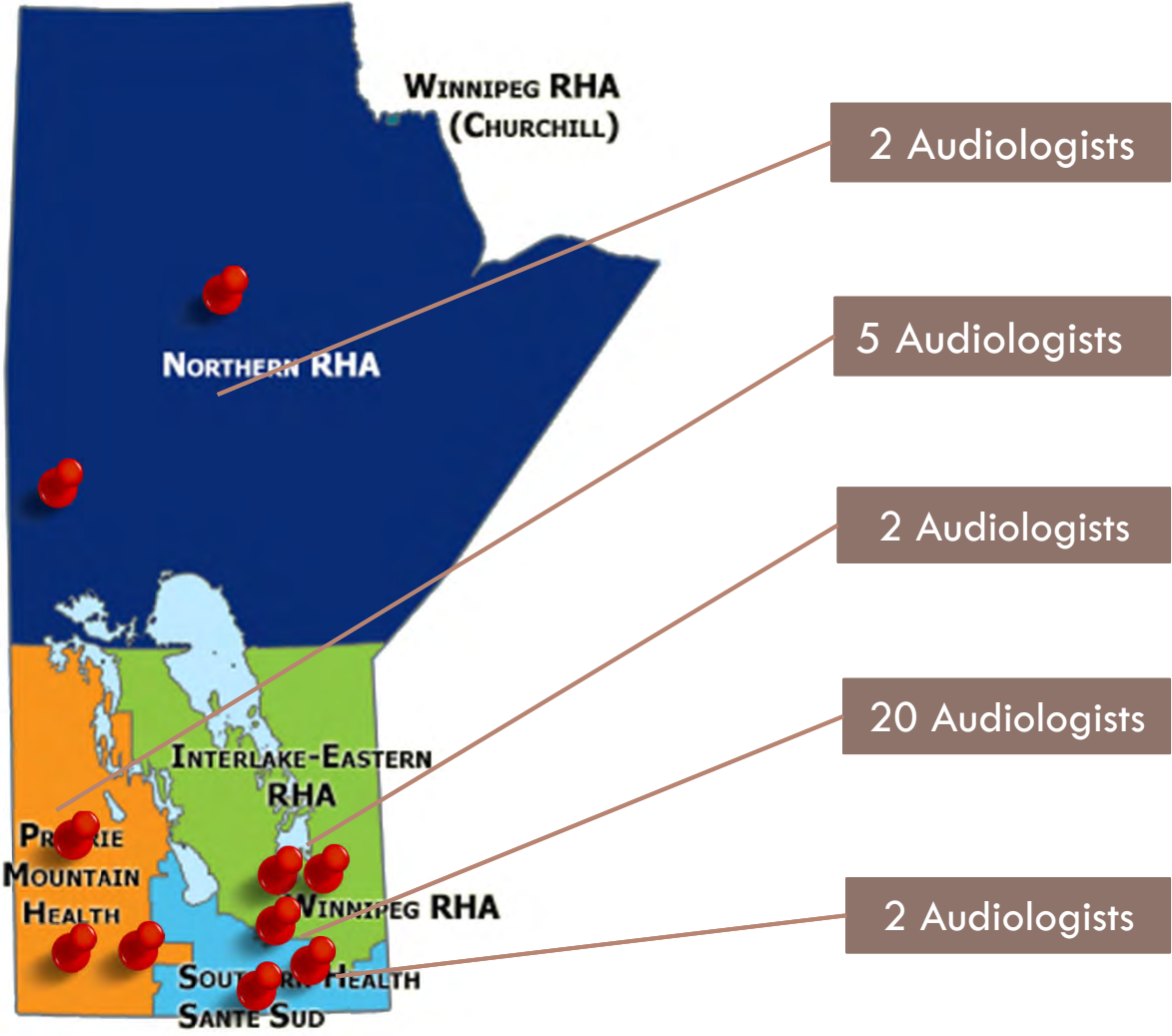
649,947 square km



Population: 1.282 million



31 Public Health Audiologists



Surgical Hearing Implant Program

HSC – Surgical



Central Speech & Hearing - Clinical



Universal Newborn Hearing Screening

12,115 babies born (Winnipeg)

11,746 babies screened for hearing loss (99%)

455 babies referred for full audiologic assessment (3.8%)

274 (60%) – Normal Hearing

97 (21%) – Confirmed Hearing Loss

84 (19%) – Not Yet Diagnosed/ Lost to Follow-Up

97 babies with confirmed hearing loss:

64 (66%) – Temporary Conductive Hearing Loss

3 (3%) – Permanent Conductive Hearing Loss

20 (21%) – Sensorineural Hearing Loss (SNHL)

Role of Audiologist in Public Health

Clinician

System analyst

Patient advocate

Lobbyist

Accountant

Educator

Marketer

Quality control

Researcher

Event organizer

HR Specialist

Tech support



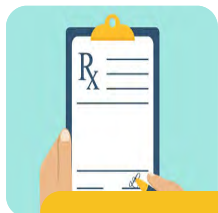
Government Investment (Manitoba)



2011
Surgical
Hearing
Implant
Program



2013
Sound
Processor
Replacement
Program



2014
Direct
Referral to
ENT



2016
Universal
Newborn
Hearing
Screening

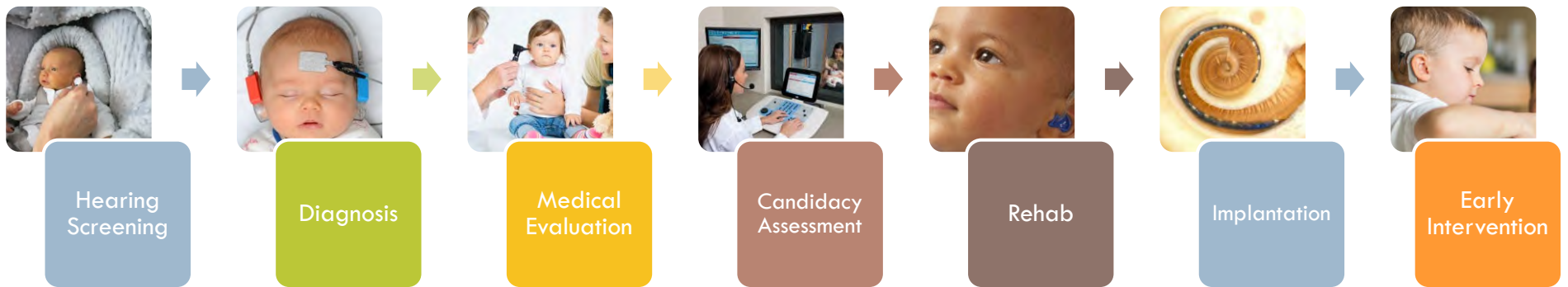


2016
Specialized
Services for
Children &
Youth (SSCY)



2017
Jordan's
Principle /
NIHB
Investment

Public Health Audiology (Manitoba)



BONE CONDUCTION TECHNOLOGY



Bone Conduction Hearing Devices

Amplification device that conducts sound directly to the cochlea via mechanical vibrations through the skull



Bone Conduction Devices

Direct Drive

Passive Drive

Percutaneous
BAHD

Active
Transcutaneous

Non-Magnetic

Passive
Transcutaneous

Cochlear
BAHA

Oticon
Ponto

Med-El
Bonebridge

Cochlear
"BCI"

Oticon
"BCI"

Softband

Cochlear
SoundArc

Med-El
AdHear

Medtronic
Sophono

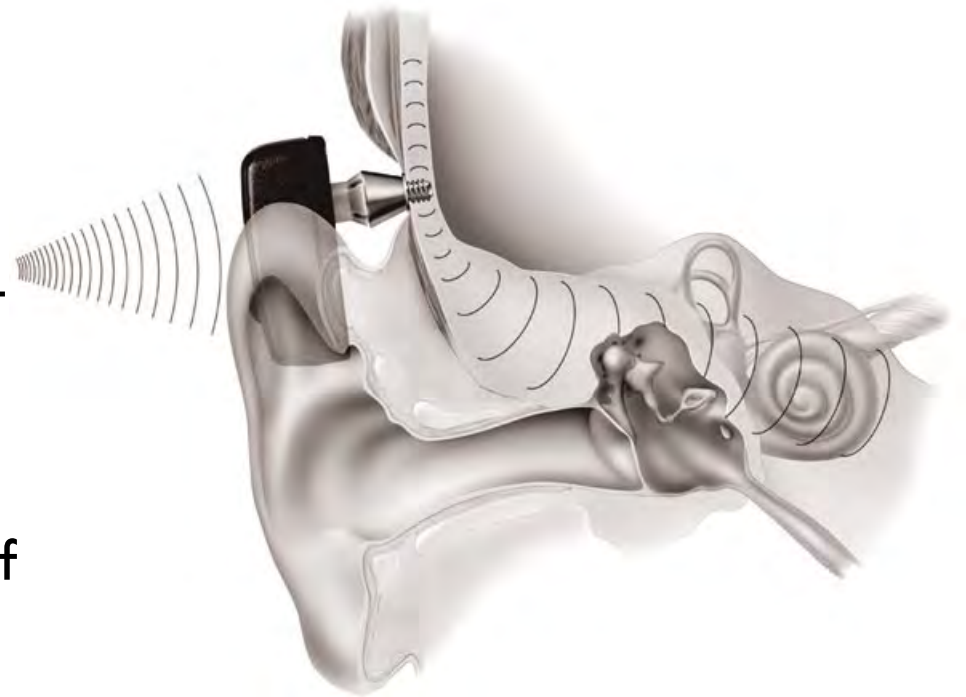
Cochlear
Attract



Percutaneous Implants

Anchoring the hearing aid to the skull involves osseointegration, or the functional merging of living bone with a load bearing implant

Osseointegration allows for an efficient and consistent delivery of amplified sound to the cochlea



BAHD Components

External processor – contains the 3 essential hearing aid components: microphone, amplifier and receiver

Abutment – the coupling between the external processor and internal implant (6mm to 14mm)

Titanium implant – a 4mm screw drilled directly into the skull



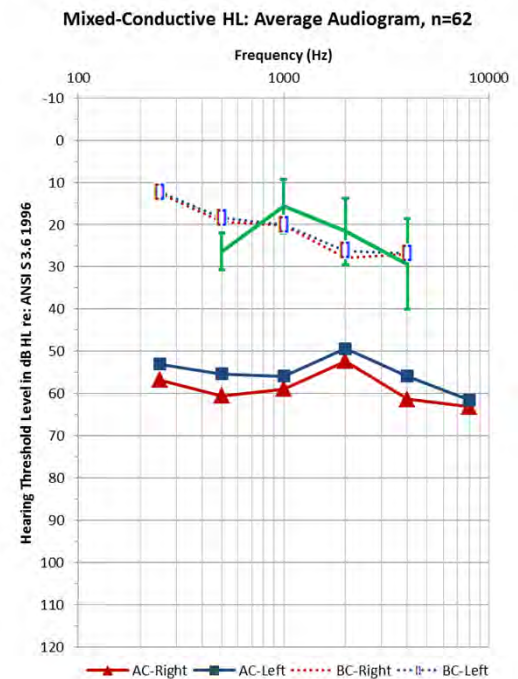
Mixed/Conductive Hearing Loss

Comprises approximately **83%** of our patient population

Hearing sensitivity at the cochlea is normal or near-normal

BCHD bypasses problematic middle ear space to send sound directly to inner ear

Goal: to restore hearing audibility for soft and average sounds



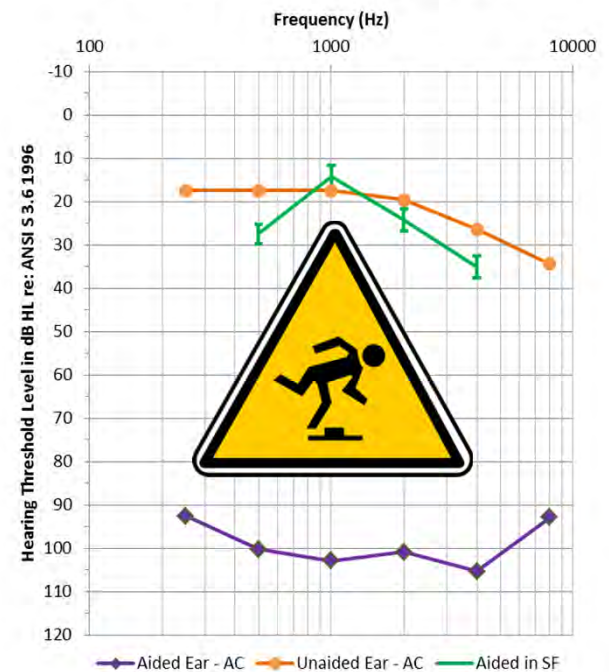
Single Sided Deafness

Comprises approximately **17%** of our patient population

Better the bone conduction thresholds of contra ear = increased benefit

Reluctance to upgrade processors when needed due to reduced benefit

Unilateral HL: Average Audiogram, n=18



Surgical Procedure



Biopsy punch or incision makes a hole through the skin and soft tissue

Specialized drill counter-sinks the 4mm titanium implant into the skull

Abutment protrudes through skin by 3-4mm for device coupling



Abutments

1st Generation



Sharp Edges
Skinny/Smooth
Single Length

2nd Generation



Rounded
Wider Implant
Single Length

3rd Generation



Hydroxyapatite Coating
Further Smoothing
Variable Lengths



Recurrent post-operative skin issues have decreased from approximately 12% to 4-5% (but those that remain seem to be chronic and harder to resolve)

Case Study #1

40 year old female with bilateral mixed hearing loss

Chronic OM, previous mastoidectomy (right ear)

Fit on softband for 2-week trial with significant benefit

Allergy testing indicated negative to nickel/titanium

Immediately reported pain and significant swelling around implant site



Case Study #2

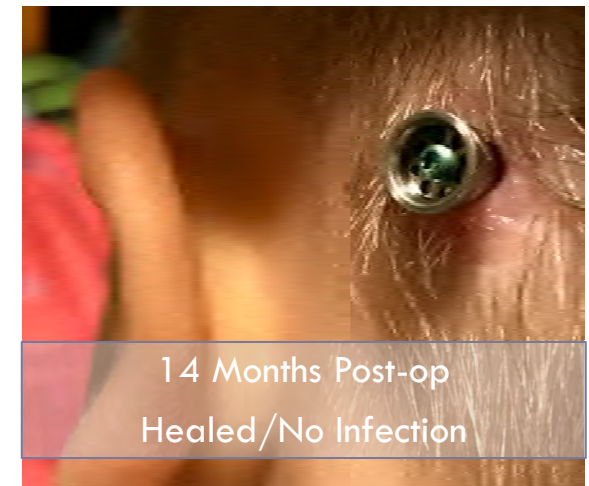
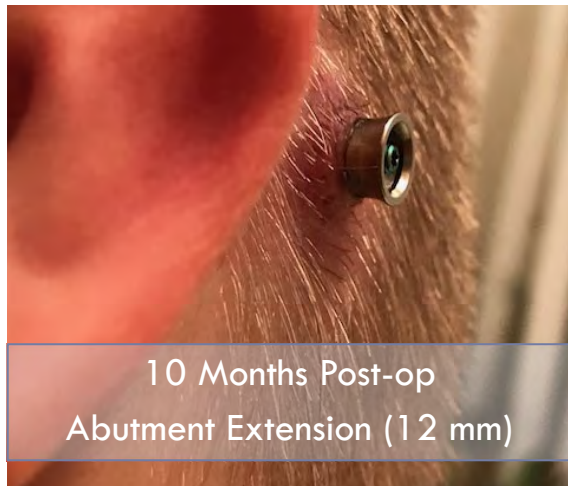
7 year old male with bilateral microtia (Grade 2) and associated conductive hearing loss

Duane Syndrome, asthma, ADHD

Fit on softband at age 2

Responded positively with change in behaviour

First implant at age 5 (R) and second at age 6 (L)



FITTING CONSIDERATIONS



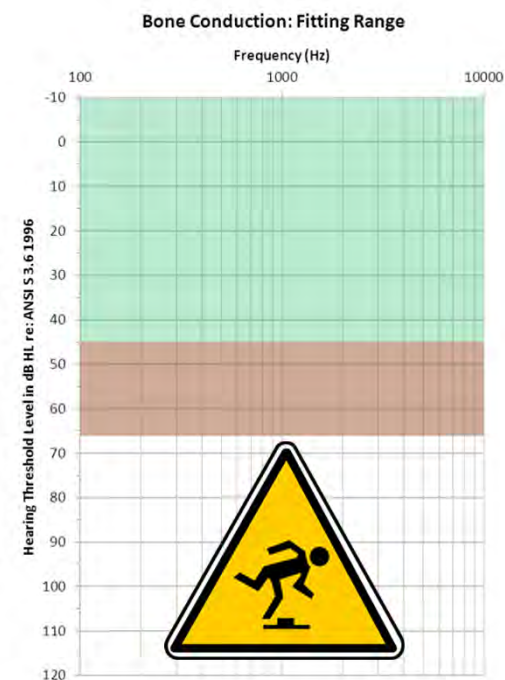
Candidacy Criteria

BC Thresholds < 65 dBHL

Air-Bone Gap of > 30 dB @ .5, 1 & 2KHz

Minimum of 5 years of age

Subjective benefit from amplification



Clinical Protocol

Protocol includes

- Pre-op assessment & audiogram
- 2-week trial on soft head band
- (Un)aided sub/obj outcome measures
- Implant/device selection
- Initial fitting and fine-tuning
- Aided thresholds in SF
- Aided SIN testing
- Coupler verification of user settings
- Aided subjective outcome measures

	Appointment Type	Description	Time (hrs)
1	Candidacy Assessment	<ul style="list-style-type: none"> • Patients receive complete audiometric exam, including air/bone thresholds, speech audiometry, unaided pure tones in soundfield, unaided SIN testing. 	1.0
2	Initial Consultation	<ul style="list-style-type: none"> • Patients are provided with information on Baha technology, bone anchored implant technology, surgical procedure and risks. • Trial devices are programmed for use in the field with device orientation conducted. • Patients are provided with manufacturer literature and a trial questionnaire for benefit assessment (custom) 	1.0
3	Post-Consult	<ul style="list-style-type: none"> • Patients return the trial device. • Completed questionnaire and subjective information are reviewed. • Patient and provider decide on appropriate clinical course. • Device selection performed at this time provided patient wants to proceed. 	0.5
4	Device Activation	<ul style="list-style-type: none"> • Wound and implant placement evaluated. • Processor is activated according to software fitting prescription and fine-tuned per subjective comments. • Device orientation conducted and practiced with patient. • Patients provided with fine-tuning questionnaire (custom). 	1.0
5	Post-Fit (1)	<ul style="list-style-type: none"> • Device is cleaned and checked. • Further fine-tuning as necessary. • Completed questionnaire is reviewed. • Questions/concerns addressed. 	0.5
6	Post-Fit (2)	<ul style="list-style-type: none"> • Device is cleaned and checked. • Further fine-tuning as necessary. • Questions/concerns addressed. 	0.5
7	Post-Fit (3) - optional	<ul style="list-style-type: none"> • Device is cleaned and checked. • Further fine-tuning as necessary. • Questions/concerns addressed. • Patients provided with QOL/Satisfaction questionnaires. 	0.5
8	Outcome Measures	<ul style="list-style-type: none"> • Device is cleaned and checked. • QOL/Satisfaction questionnaires are reviewed. • Further fine-tuning as necessary. • Electroacoustic measurements to document user settings. • Sound field testing in booth. • Aided thresholds, speech understanding in quiet/noise. • Localization & QuickSin Testing. 	1.0
9	Troubleshooting (multiple)	<ul style="list-style-type: none"> • Issues are assessed per patient. • May require return visit. 	0.5
10	Annual Review	<ul style="list-style-type: none"> • Device is cleaned and checked. • Further fine-tuning as necessary. • Questions/concerns addressed. • Repeat audiogram for monitoring purposes. 	0.5

Candidacy Assessment

Interview

- History
- Motivations
- Expectations

Audiometry

- AC/BC pure tones
- Speech audiometry
- Speech in Noise Testing
- Unaided questionnaires

Hearing Loss Questionnaire

Dr. Jordan Hickman
Department of Otolaryngology
Health Science Centre

Patient ID: _____

Patient Name: _____

Patient to complete

What approximate date did you first notice your hearing loss? _____ (DD/MM/YYYY)

What age were you when you first noticed your hearing loss? _____

Was the onset of your hearing loss (check one): Sudden Gradual

Your hearing loss has been... (check one): Progressive Stable Fluctuating

Do any members of your immediate family suffer from hearing loss (check one)? Yes No

For the following questions please **check the best answer**:

You suffer hearing loss in... (check one): Left Ear Right Ear Both Ears

Do you suffer from any ringing in the ear (check one)? Left Ear Right Ear Both Ears None

If YES, check the noise that most closely applies: Roaring Whistling Crickets Pulsing

Have you ever had ear surgery before (check one)? Yes No

Do you have a history of ear infections (check one)? Left Ear Right Ear Both Ears None

Do you have a history of ear drainage (check one)? Left Ear Right Ear Both Ears None

Do you or have you previously suffered from any of the following... (check all that apply):

Difficulty Swallowing Double/Blurred Vision Syphilis

Previous Chemotherapy Meningitis/Brain Infection Major Head Trauma

Recurrent Eye Infections Weakness when moving your face Infections requiring IV treatment

Any autoimmune disease (Rheumatoid arthritis, Lupus, IBD)

Do you participate in employment or non-work activities that involve high levels of noise (check all that apply):


Loud music Auto repair Woodworking

Metal working Motorcycling Flying in an aircraft

Hunting/Target practice

Please list all current medications:

Physician to complete

	Normal	Left side	Right side	History
Cranial Nerve Exam (II-VII, IX-XI)	<input type="checkbox"/>			
Fistula Test	<input type="checkbox"/>			PMH Meds
Nystagmus				Allergies Sx
Spontaneous Oaze Evoked Post Head Shake Halmagy Impulse Test	<input type="checkbox"/>			
Dix-Hallpike Test	<input type="checkbox"/>			
Tympanic Membrane				Audiogram
				ENG
				CT Scan

Normal 512 Hz Tuning Fork Gait Romberg Test Modified Romberg Test Tandem Gait Cerebellar Exam Dynamic Visual Acuity Voluntary Hyperventilation

Abnormal Description

Impression and Plan:

Softband Trial



Cursory fitting

Generally 1 program (unless experienced user)
Compensate for softband
Conduct general orientation
Assess subjective benefit (trial questionnaire)

Common issues

Limited loaner bank, may be outdated technology
Loaner devices are often lost/damaged
Added gain can lead to excessive feedback
Device placement not optimized



Subjective Questionnaire – Softband Trial



Name: _____ Date: _____

Bone Anchored Hearing Aid - Trial Questionnaire

1. How often were you able to detect sound from your impaired ear? *(Circle one)*

Never	Rarely	Sometimes	Often	Always
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Please describe:

2. How often were you able to locate a sound source while wearing the BAHA? *(Circle one)*

Never	Rarely	Sometimes	Often	Always
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Please describe:

3. How often were you able to understand speech while wearing the BAHA? *(Circle one)*

Never	Rarely	Sometimes	Often	Always
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Please describe:

4. Were SOFT sounds ever too soft? *(Circle one)* Y or N

Please describe:

5. Were LOUD sounds ever too loud? *(Circle one)* Y or N

Please describe:

6. How would you rate the overall sound quality of the BAHA? *(Circle one)*

Very Poor	Poor	Okay	Good	Very Good
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Please describe:



Name: _____ Date: _____

7. How would you rate the sound quality/performance of the BAHA in these environments? *(circle one)*

Quiet room with one other person	Very Poor	Poor	Okay	Good	Very Good
Noisy restaurant/party	Very Poor	Poor	Okay	Good	Very Good
Family or large group gathering	Very Poor	Poor	Okay	Good	Very Good
In the car	Very Poor	Poor	Okay	Good	Very Good
Large meeting with many people	Very Poor	Poor	Okay	Good	Very Good
Auditorium or large hall	Very Poor	Poor	Okay	Good	Very Good
Outside	Very Poor	Poor	Okay	Good	Very Good
Watching TV	Very Poor	Poor	Okay	Good	Very Good
Listening to Music	Very Poor	Poor	Okay	Good	Very Good
Other:	Very Poor	Poor	Okay	Good	Very Good
Other:	Very Poor	Poor	Okay	Good	Very Good

Physical Fit



Implant Placement: Angle, Length

Feedback: Hats, Glasses, Helmets

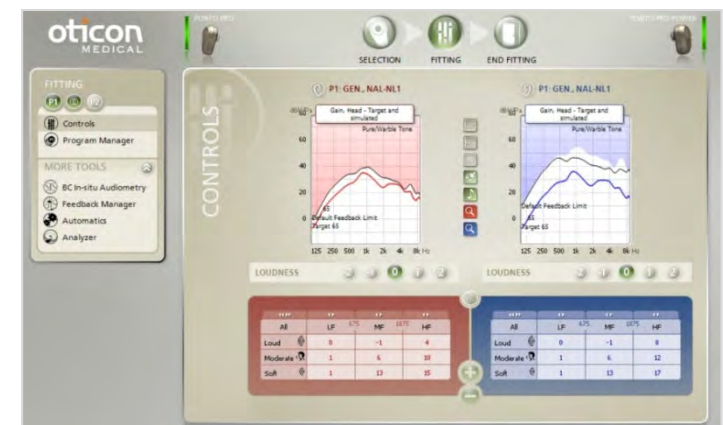
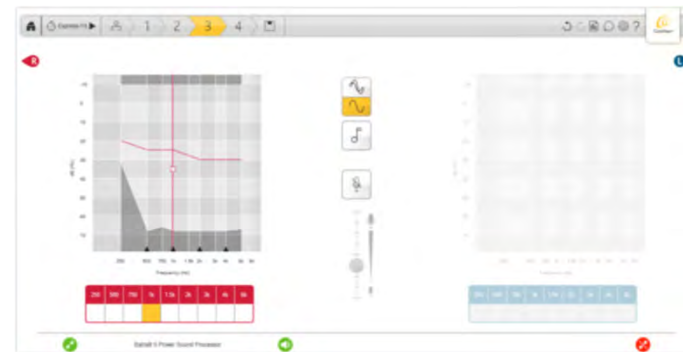
Performance: Height, Proximity



Device Activation

Coupler target match
In-situ audiometry
Feedback Manager
Gain adjustments
Subjective impressions
Soundfield validation

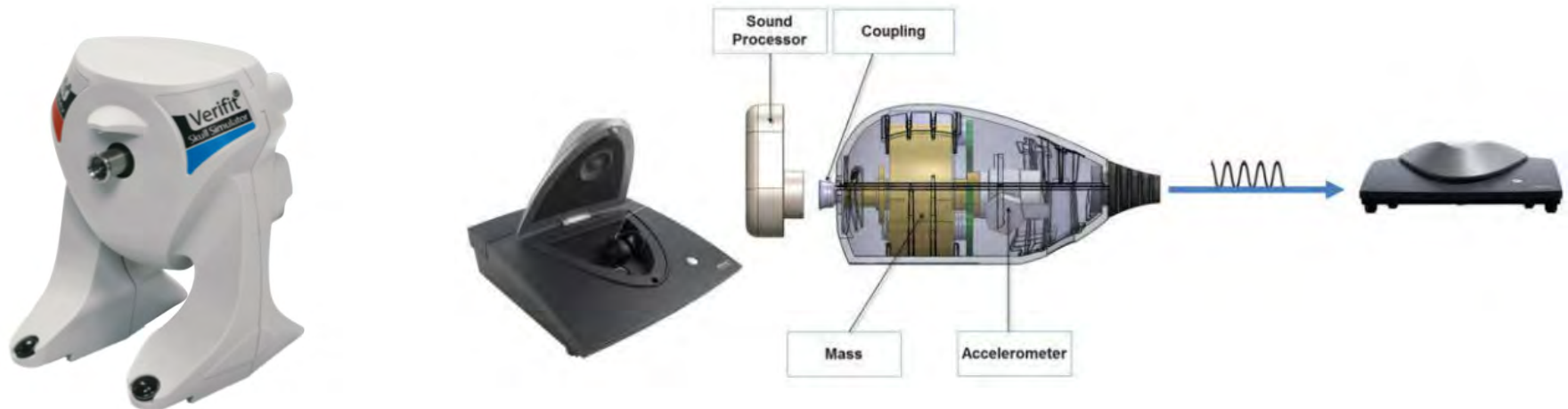
Repeat as necessary



Verification

Skull Simulator available from Audioscan and Interacoustics

Converts force output from BAHD to an electrical signal



Verification



International Journal of Audiology 2017; 56: 515-524

*International
Journal of
Audiology*

Technical Report

DSL prescriptive targets for bone conduction devices: adaptation and comparison to clinical fittings

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¹Communication Sciences and Disorders, Faculty of Rehabilitation Medicine, University of Alberta, Alberta, Canada and ²National Centre for Audiology, Faculty of Health Sciences, University of Western Ontario, Ontario, Canada

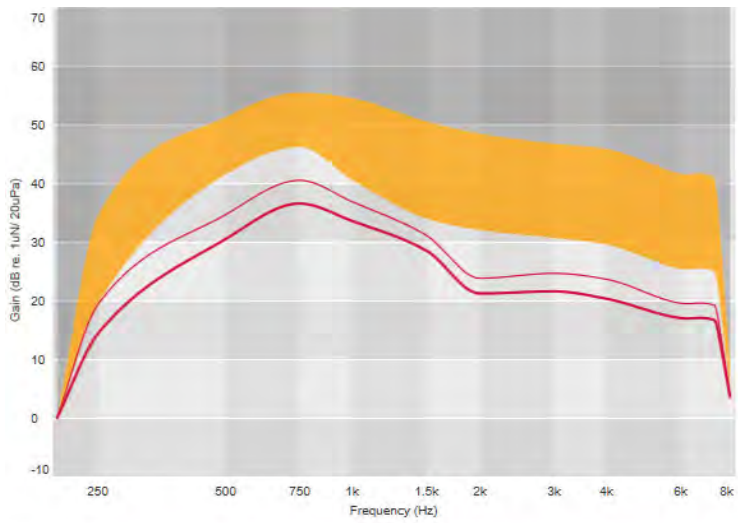


Abstract

Objective: To develop an algorithm that prescribes targets for bone conduction frequency response shape, compression, and output limiting, along with a clinical method that ensures accurate transforms between assessment and verification stages of the clinical workflow. **Design:** Technical report of target generation and validation. **Study sample:** We recruited 39 adult users of unilateral percutaneous bone conduction hearing aids with a range of unilateral, bilateral, mixed and conductive hearing losses across the sample. **Results:** The initial algorithm over-prescribed output compared to the user's own settings in the low frequencies, but provided a good match to user settings in the high frequencies. Corrections to the targets were derived and implemented as a low-frequency cut aimed at improving acceptance of the wearer's own voice during device use. **Conclusions:** The DSL-BCD prescriptive algorithm is compatible with verification of devices and fine-tuning to target for percutaneous bone conduction hearing devices that can be coupled to a skull simulator. Further study is needed to investigate the appropriateness of this prescriptive algorithm for other input levels, and for other clinical populations including those with single-sided deafness, bilateral devices, children and users of transcutaneous bone conduction hearing aids.

Key Words: Hearing aids; bone-anchored hearing aids; prescription; verification; force; levels; validation

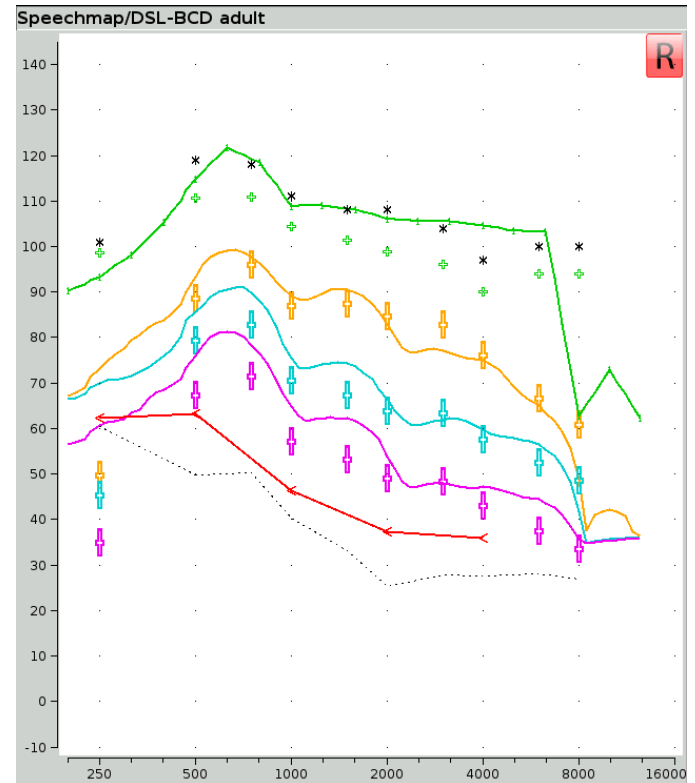
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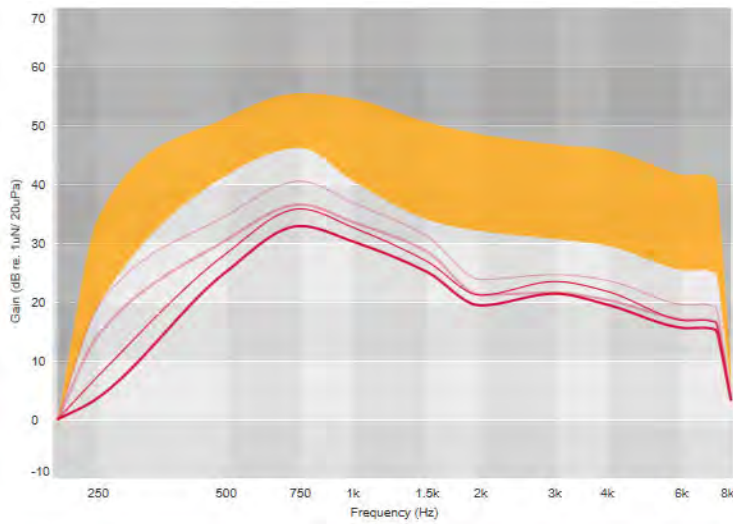
Grid scaling: Offset Gain

▶ Collapse

	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
G40	0	0	0	0	0	0	0	0	0	0
G60	0	0	0	0	0	0	0	0	0	0
CR	2.0	2.0	1.4	1.4	1.4	1.4	1.4	1.7	1.2	1.0
MPO	0	0	0	0	0	0	0	0	0	0



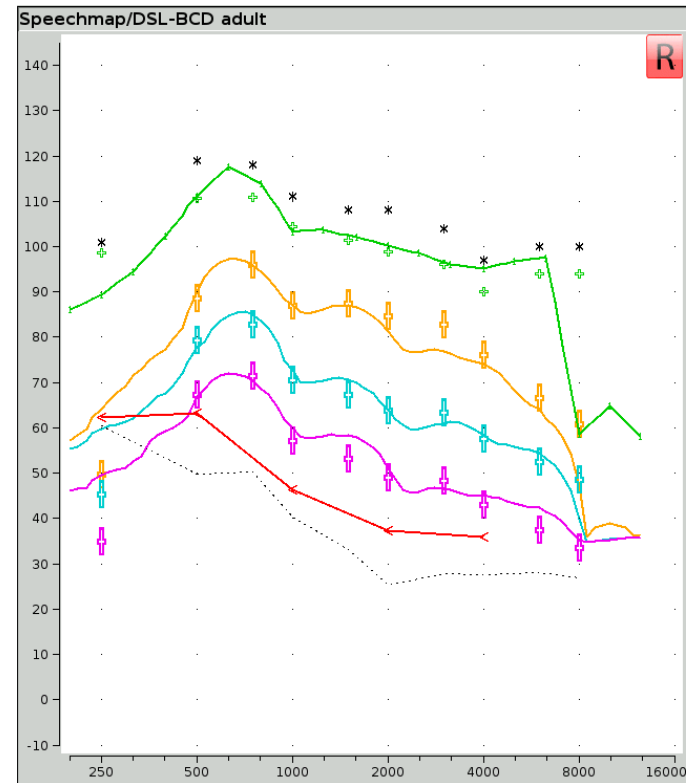
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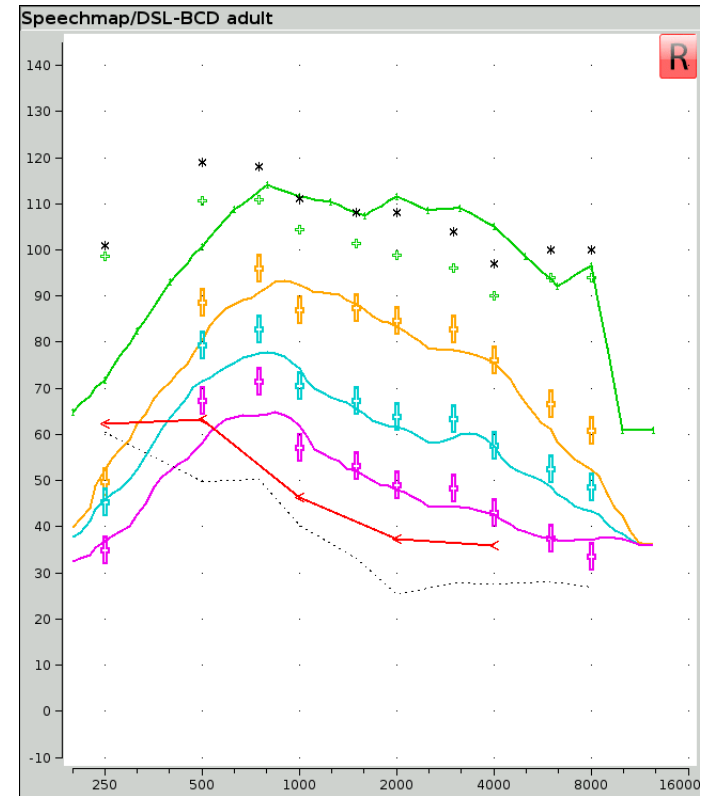
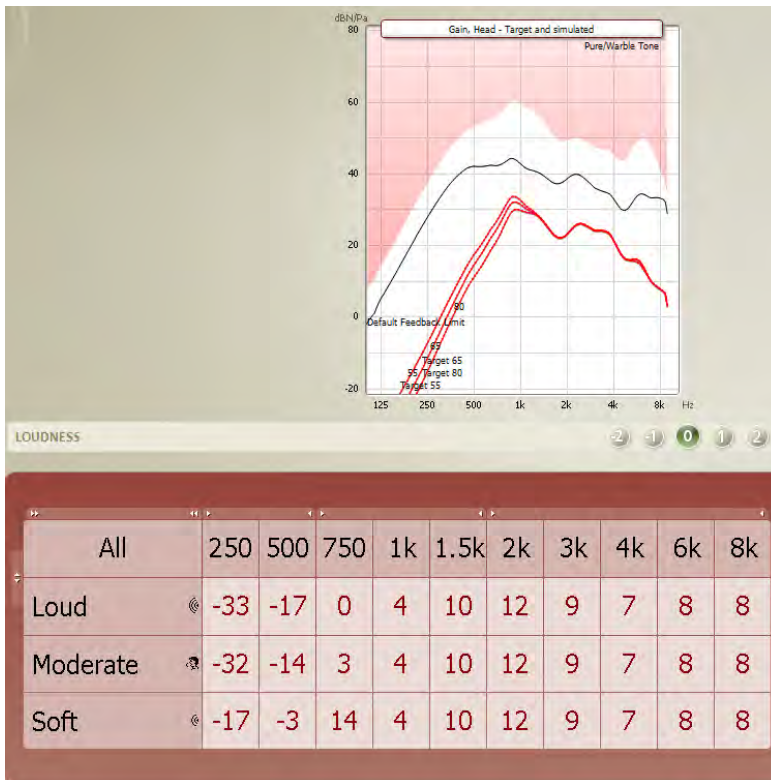
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▶ Collapse

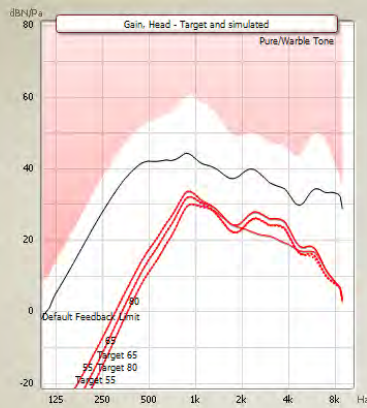
	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
G40	-12	-7	-4	-4	-4	-3	-2	-2	-2	0
G60	-10	-5	-4	-4	-3	-2	-1	-1	-1	0
CR	1.4	1.4	1.4	1.4	1.2	1.2	1.2	1.4	1.1	1.0
MPO	-7	-6	-7	-8	-9	-10	-13	-13	-8	0



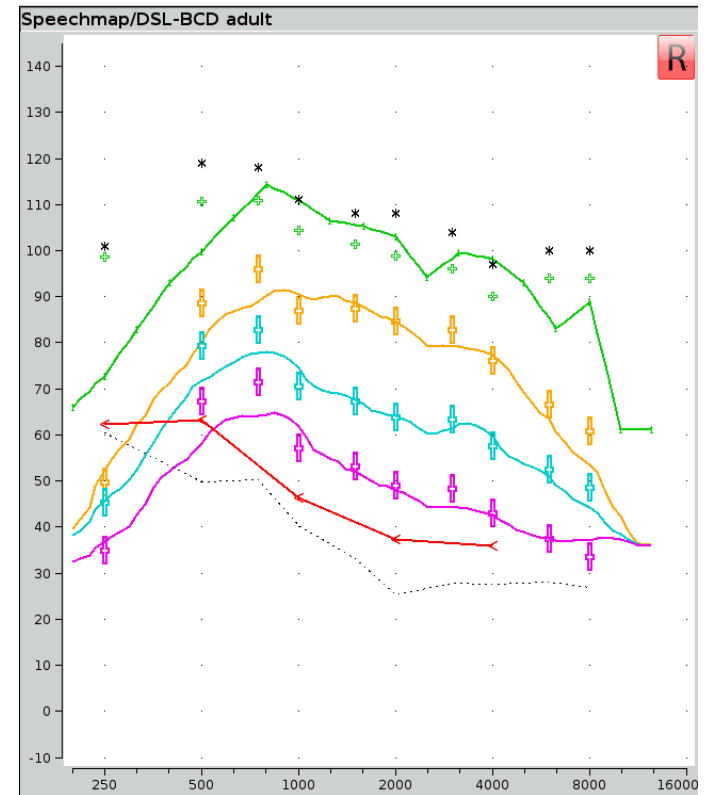
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Verification



All	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
Rel.maxMFO	-4	-4	-9	-12	-12	-10	-10	-8	-5	-5
Loud	-33	-17	0	4	12	14	11	9	10	8
Moderate	-32	-14	3	4	12	14	11	9	10	8
Soft	-17	-3	14	4	12	14	11	9	10	8

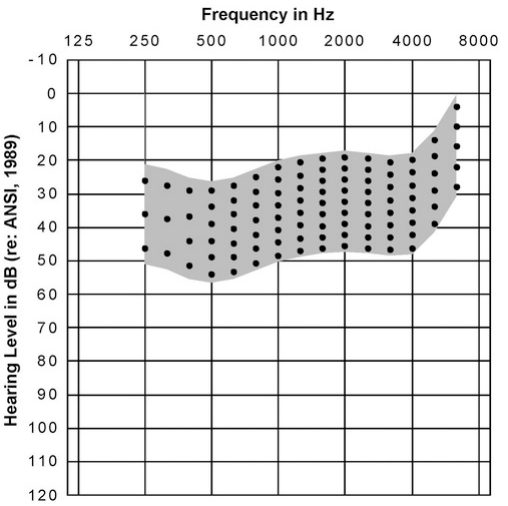
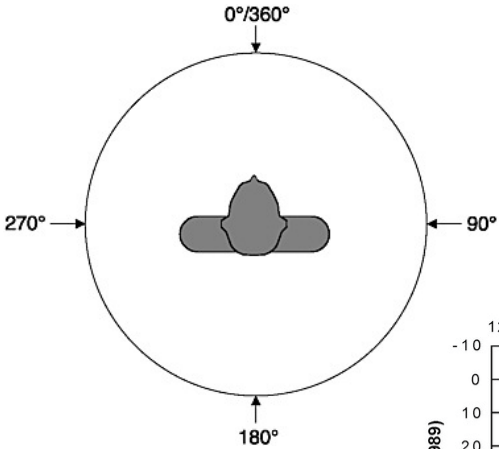


OUTCOME MEASURES



Validation

- Aided thresholds in SF
- Count the Dots Audiogram
- SRT in SF
- WRS in SF
- SIN testing
- Ling sounds
- Frequency specific LDL's



Subjective Questionnaire – Unaided vs. Aided

DOSO - Form C

Name: _____ Date of Birth: _____ Today's Date: _____

This questionnaire measures how well your hearing aids work. Please read each question and circle one letter to show the answer that is closest to your opinion.

The guide shown on the right describes the meaning of each letter.

How good are the hearing aids at...

- A Not at all
- B A little
- C Somewhat
- D Medium
- E Considerably
- F Greatly
- G Tremendously

1	Making loud speech clear?	A	B	C	D	E	F	G
2	Eliminating the need to have someone else explain what was said?	A	B	C	D	E	F	G
3	Making other people's voices sound clear in a moving car?	A	B	C	D	E	F	G
4	Making children's voices understandable?	A	B	C	D	E	F	G
5	Catching the beginning of sentences?	A	B	C	D	E	F	G
6	Picking up overhead announcements in stores?	A	B	C	D	E	F	G
7	Catching your name being called in a waiting room?	A	B	C	D	E	F	G
8	Picking up speech when the talker's lips are not visible?	A	B	C	D	E	F	G
9	Catching what waiters say in a busy restaurant?	A	B	C	D	E	F	G
10	Catching what someone says on the first try?	A	B	C	D	E	F	G
11	Picking up soft sounds that follow loud ones?	A	B	C	D	E	F	G
12	Making speech clear in a face-to-face conversation?	A	B	C	D	E	F	G
13	Picking up what strangers say the first time?	A	B	C	D	E	F	G
14	Improving enjoyment of everyday activities?	A	B	C	D	E	F	G
15	Catching the words when someone speaks from another room?	A	B	C	D	E	F	G
16	Picking up what someone says across a large room?	A	B	C	D	E	F	G
17	Picking up sounds that are missed without them?	A	B	C	D	E	F	G
18	Catching a person's name when they are introduced?	A	B	C	D	E	F	G

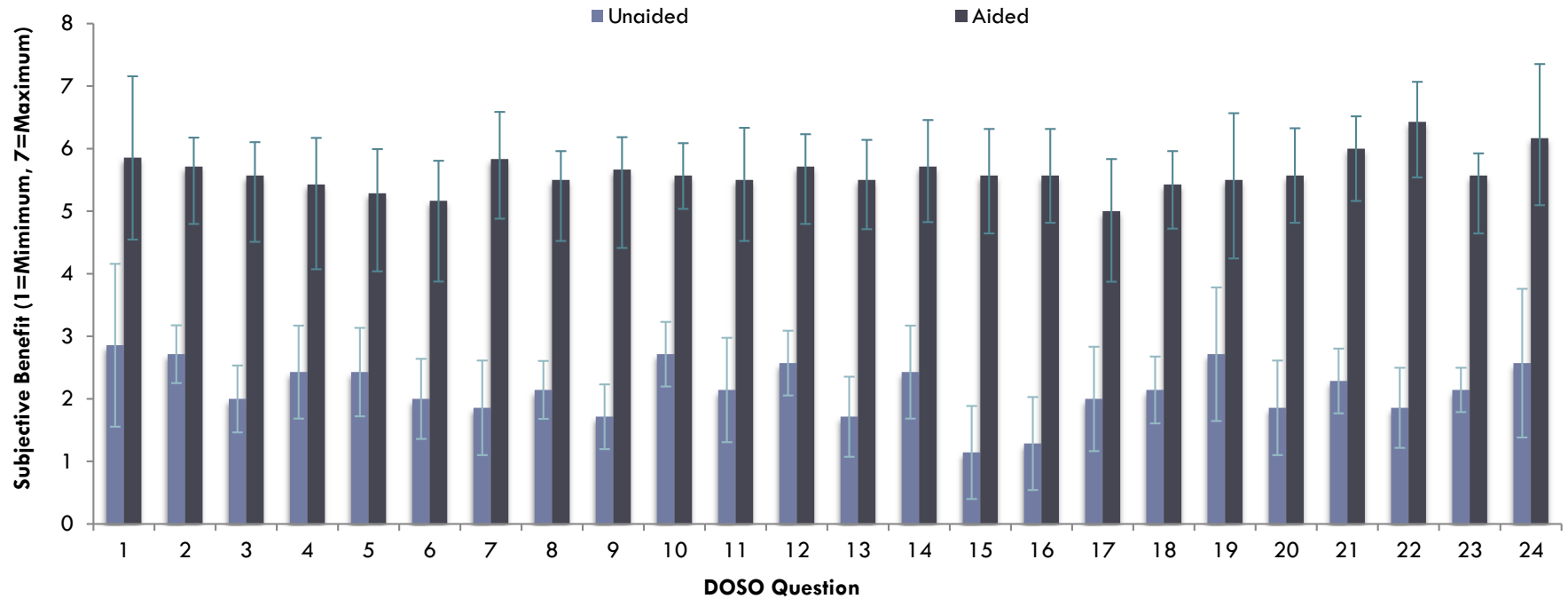
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19	Recognizing different voices?	A	B	C	D	E	F	G
20	Reducing misunderstandings during conversations?	A	B	C	D	E	F	G
21	Making the television sound clear?	A	B	C	D	E	F	G
22	Making conversation easier?	A	B	C	D	E	F	G
23	Keeping the volume at a pleasing level?	A	B	C	D	E	F	G
24	Distinguishing between male and female voices?	A	B	C	D	E	F	G

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Results

BAHD Subjective Benefit: Mixed/CHL (12 months), n=40



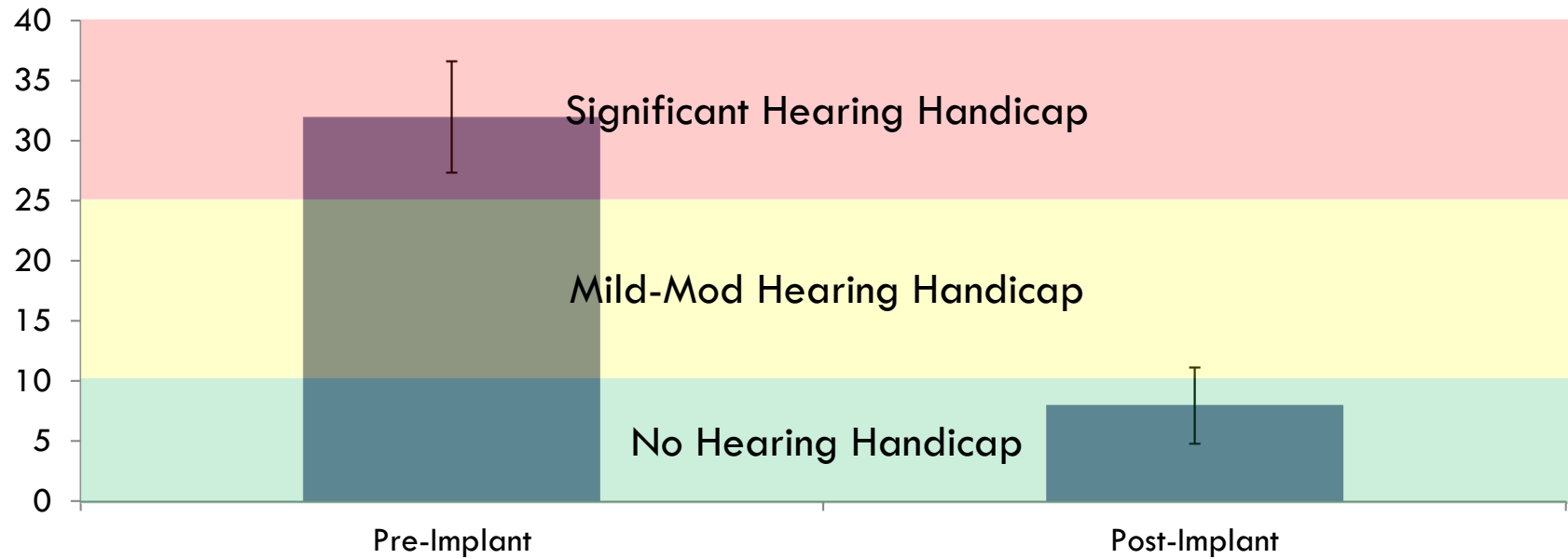
Subjective Questionnaire (HHIE) – Unaided vs. Aided

	Item	Yes (4 pts)	Sometimes (2 pts)	No (0 pts)
E	Does a hearing problem cause you to feel embarrassed when meeting new people?	_____	_____	_____
E	Does a hearing problem cause you to feel frustrated when talking to members of your family?	_____	_____	_____
S	Do you have difficulty hearing when someone speaks in a whisper?	_____	_____	_____
E	Do you feel handicapped by a hearing problem?	_____	_____	_____
S	Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?	_____	_____	_____
S	Does a hearing problem cause you to attend religious services less often than you would like?	_____	_____	_____
E	Does a hearing problem cause you to have arguments with family members?	_____	_____	_____
S	Does a hearing problem cause you difficulty when listening to TV or radio?	_____	_____	_____
E	Do you feel that any difficulty with your hearing limits or hampers your personal or social life?	_____	_____	_____
S	Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?	_____	_____	_____
TOTAL SCORE = _____ (sum of the points assigned to each of the items)				

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Results

BAHD Subjective Benefit: Mixed/CHL (12 months), n=40



FUTURE OUTLOOK

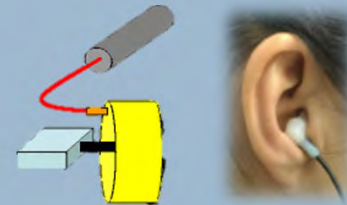


Future Outlook

Active transcutaneous implants



On-ear verification



Future Outlook

Clinician

System analyst

Patient advocate

Lobbyist

Accountant

Educator



Marketer

Quality control

Researcher

Event organizer

HR Specialist

Tech support

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