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CI2020 Online - Session 3

May 4, 2020

Presenters:

Kevin Brown, MD, PhD;
Lisa Park, AuD, CCC-A; Jill B. Firszt, PhD;
David Haynes, MD; Nancy Young, MD; Fred Telischi, MD;
Rene Gifford, PhD; Bruce J. Gantz, MD;
Paul van de Heyning, MD, PhD; Aaron Moberly, MD;
Aniket Saoji, PhD; Oliver Adunka, MD; Sarah Coulthurst,
MS

AudiologyOnline Course #35062

This handout accompanies Session 3 which covers the following topics:

- Cochlear Implantation in Pediatric and Adult Cases of Single-Sided Deafness and Asymmetric Hearing Loss
- Challenging Surgical Cases
- Cognition and Cochlear Implantation
- Bimodal, Bilateral, and Electric-Acoustic Stimulation
- Clinical Applications of the AIM System from Advanced Bionics

Cochlear Implantation in Pediatric and Adult Cases of Single-Sided Deafness and Asymmetric Hearing Loss

Presenters:

Kevin Brown, MD, PhD;

Lisa Park, AuD, CCC-A

Jill B. Firszt, PhD;

Cochlear Implantation in Adults and Children with Single-Sided Deafness

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UNC Cochlear Implant Team

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- Lauren Kilpatrick, MD
- Brendan O'Connell, MD
- Harold Pillsbury, MD
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- Madeleine Barclay, BA

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- Joshua Light, BS
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Single-Sided Deafness

- Many causes including congenital loss, congenital malformation, idiopathic (viral), meniere's disease, meningitis, labyrinthitis, barotrauma, acoustic trauma, iatrogenic
- Why is losing hearing from one ear a problem?

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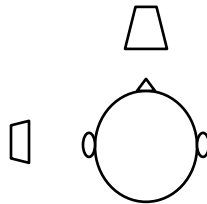
Consequences of Single Sided Deafness

1. Decreased speech understanding in noise
2. Decrease in sound localization
3. Decreased quality of hearing
4. Tinnitus

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Binaural Hearing – Head Shadow

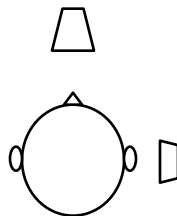
- Head Shadow – speech and noise are spatially separated, better SNR to protected ear
- High frequency attenuated more



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Binaural Hearing – Squelch

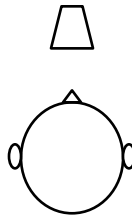
- Squelch – competing noise separated, different signals to both ears



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Binaural Hearing – Summation

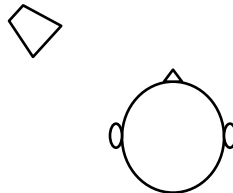
- Binaural Summation – benefit of signal presentation to both ears



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Binaural Hearing – Localization

- Sound hits ears at different times and at different intensities, difference can be used by brain to accurately compute direction sound originates



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Tinnitus

- Lack of electrical input from affected ear creates vacuum of information
- Tinnitus has been likened to a “phantom limb” syndrome in which sensation occurs in absence of functional organ
- No good treatment options for these patients

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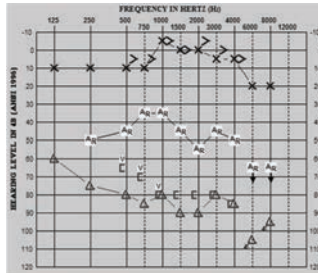
Quality of Hearing

- Inability to orient sound in an environment
- Frustration with understanding speech with any noise in the environment
- Volume of sounds seem reduced
- Loss of socialization
- Work concerns

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Cochlear Implantation

Candidacy Criteria



Condition	Words	Sentences (10 dB SNR)
Right	4%	6%
Left	100%	98%
Bilateral	98%	96%

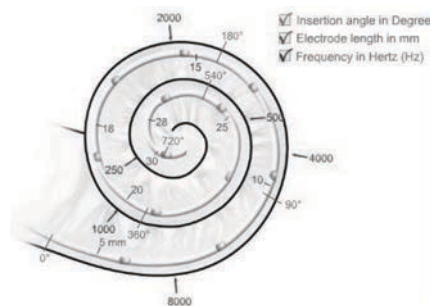
Would they wear the CI?



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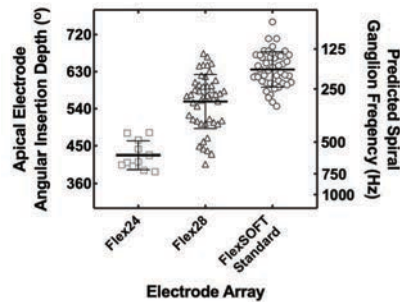
Place-Pitch Mismatch – Affects on CI Outcomes in SSD

- Want to present most accurate representation of acoustic picture by device to cochlea
- Need a long electrode
- If frequency-place mismatch were significant, could impact ability to gain benefit from device, especially at outset



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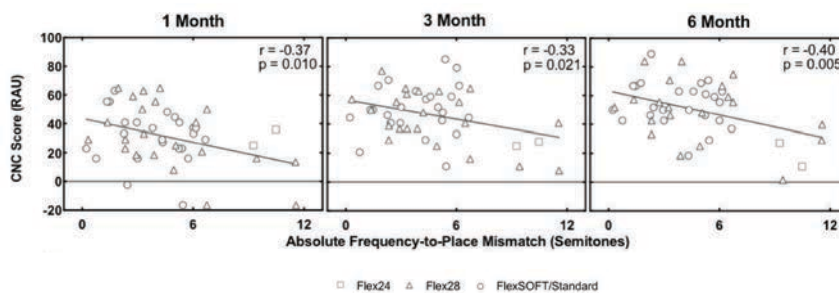
Affect of Frequency Place Mismatch



Canfarotta et al. (in press)

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Affect of Frequency Place Mismatch



Canfarotta et al. (in press)

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CI in UHL Clinical Trial

Cohort

- 20 adults with moderate-to-profound SNHL in the affected ear
 - Mean duration of hearing loss: 3 years
 - Max aided CNC word score: 22%
- Normal to near-normal hearing in the contralateral ear
 - ≤ 35 dB HL, 125-8000 Hz
- Mean age at implantation: 50 years

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CI in UHL Clinical Trial

Timeline

- Preoperative evaluation
- Cochlear implantation
- Initial activation (2-4 weeks post-op)
- Follow-up intervals
 - 1, 3, 6, 9, and 12 months

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CI in UHL Clinical Trial

Electrode Array

- MED-EL Concert
Standard electrode array



MED-EL Corporation

Processor

- Ear-level (Opus2)
 - Microphone placement effects
- FS4 coding strategy
- Mapping
 - Plugged the contralateral ear
 - Behavioral T & C measures
 - Loudness balancing

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Speech Recognition

Conditions

1. CI-Alone
 - Masking to contralateral ear
 - CNC words in quiet (60 dB SPL)
2. CI plus contralateral ear (CI+NH)
 - AzBio sentences in spatially-separated noise (0 dB SNR)

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Speech Recognition: CI-Alone

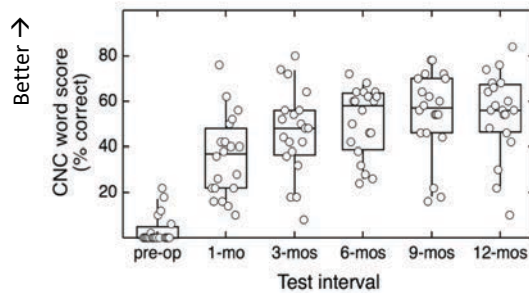


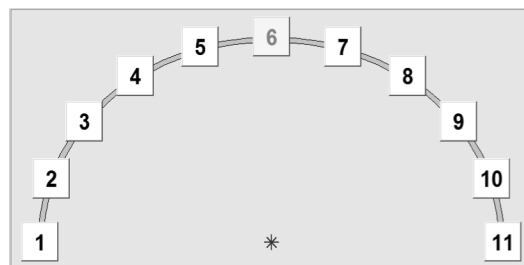
Figure 2

Buss et al. (2018)

- Significant improvement with the CI-alone on CNC words in quiet
- Performance growth similar to that observed by conventional CI recipients

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Speech Recognition: CI+NH



Conditions

- Speech Front, Noise Front
- Speech Front, Noise CI
- Speech Front, Noise NH

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Speech Recognition: CI+NH

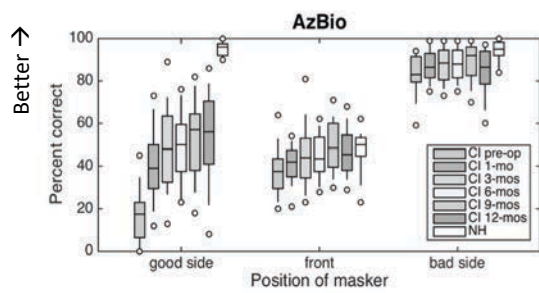


Figure 3

Buss et al. (2018)

Noise to the Good Side:

- Significant improvement observed at the 1-month interval as compared to the preoperative (unaided) condition

21

Speech Recognition: CI+NH

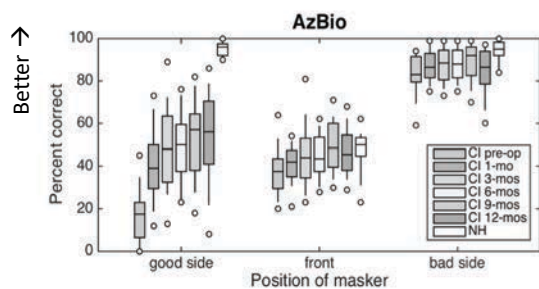


Figure 3

Buss et al. (2018)

Noise from the Front:

- Similar performance to the normal hearing comparison cohort

22

Speech Recognition: CI+NH

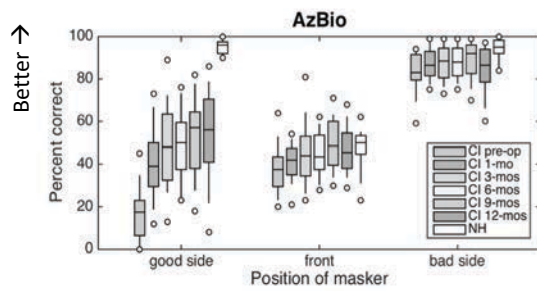


Figure 3

Buss et al. (2018)

Noise to the Bad Side:

- Ceiling effects
- No decrement in performance with the CI as compared to the unaided condition
 - CI does not reduce performance

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Localization

Procedure

- 200-ms speech-shaped noise bursts
- Randomized speaker and stimulus level
- Subject indicated the speaker number of the perceived sound source
- No feedback was provided



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Localization

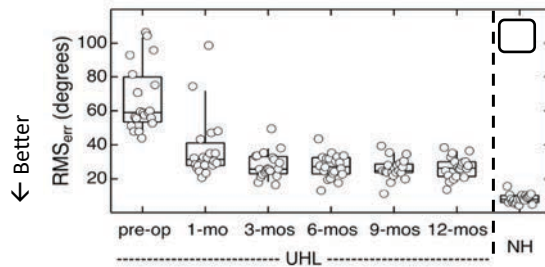


Figure 4.A

Buss et al. (2018)

- Significant improvement between the preoperative (unaided) interval and 1-month (CI+NH) interval
- Continued improvement through the 6-month interval

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Localization

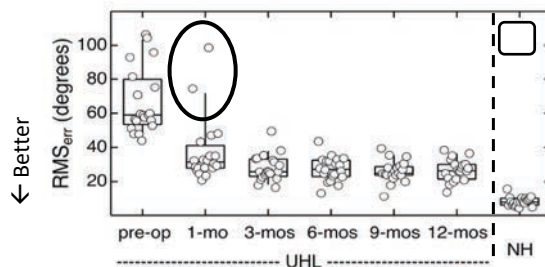


Figure 4.A

Buss et al. (2018)

Duration of Device Use:

- Two subjects listened to the device for approximately 3 hours a day at the 1-month interval
- Performance improved when daily use increased to 10 hours per day

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Subjective Report

Questionnaires administered at each interval

1. Abbreviated Profile of Hearing Aid Benefit (APHAB)
2. Speech, Spatial, and Qualities of Hearing Scale (SSQ)
3. Tinnitus Handicap Inventory (THI)

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Subjective Report: APHAB

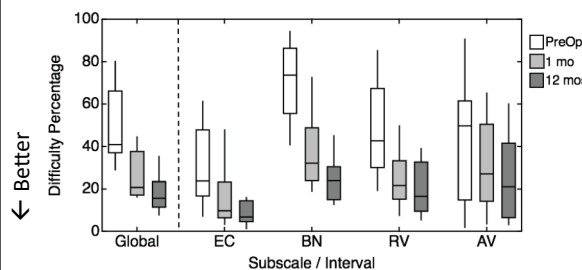


Figure 2

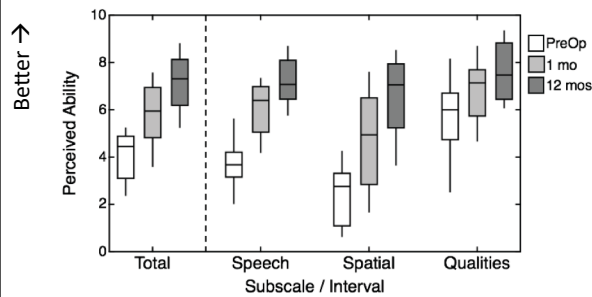
Dillon et al. (2018)

Significant improvement between the preoperative (unaided) interval and 1-month (CI+NH) interval for each subscale

- Ease of Communication (EC)
- Effectiveness in Background Noise (BN)
- Reverberation (RV)
- Aversiveness (AV)

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Subjective Report: SSQ



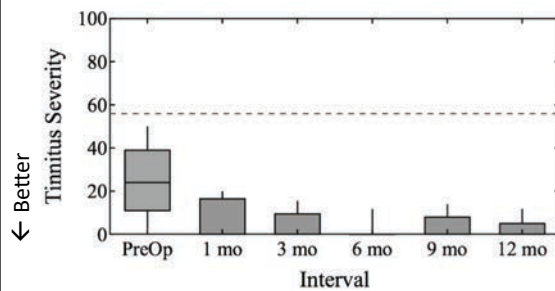
- Significant improvement between the preoperative (unaided) interval and 1-month (CI+NH) interval on the **Speech, Spatial** and **Qualities** of hearing subscales

Figure 3

Dillon et al. (2018)

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Subjective Report: THI



- Perceived tinnitus severity significantly reduced when listening with the CI as compared to preoperative report in the unaided condition.

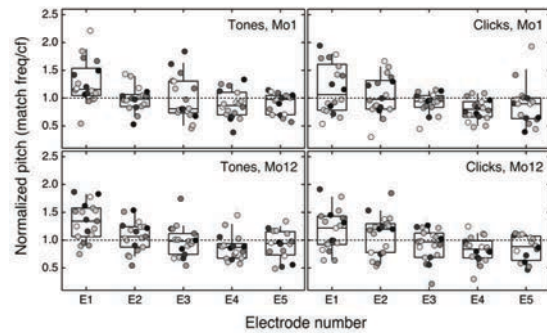
Figure 1

Dillon et al. (2018)

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Potential Device Variables

- Subjects mapped with the FS4 coding strategy



Dillon et al (in press)

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Summary

CI in UHL subjects experienced a significant improvement on:

- Speech recognition in the affected ear with the CI-alone
- Spatial hearing tasks (speech recognition in noise, localization) with the CI plus the normal hearing ear
- Subjective report
- Tinnitus reduced or eliminated
- Long electrode provides excellent pitch-place representation

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Conclusions

- Many real benefits to cochlear implantation in patients with unilateral sensory hearing loss
- FDA approved cochlear implantation in cases of unilateral SNHL as of 8/19
- Insurance carriers progressively adding as indication for implantation

Cochlear Implantation in Children with Single-Sided Deafness

Lisa Park, AuD, CCC-A

*Assistant Professor
Department of Otolaryngology/Head and Neck Surgery
Division of Auditory Research
University of North Carolina at Chapel Hill*

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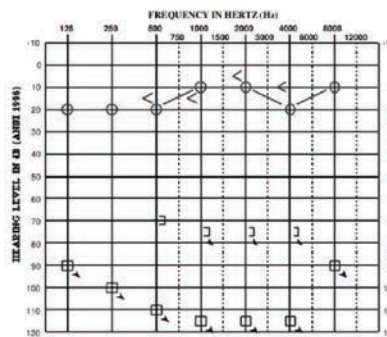
- Nofrat Schwartz, MD
- Morgan Selleck, MD

2

Single-Sided Deafness (SSD) in Children

Communication challenges as compared to peers with normal hearing:

- Poorer language outcomes (Lieu, 2013; Lieu et al, 2010; Sengen, 2017)
- Difficulty understanding speech in noise (Griffin, Poissant, & Freyman, 2018)
- Difficulty with localization (Reeder, Cadieux, & Firszt, 2015)
- Quality of Life Challenges
 - Greater difficulties reported on QoL measures (Griffin, Poissant, & Freyman, 2018; Reeder et al 2015)
 - Higher levels of fatigue (Hornsby et al, 2013).



Cochlear Implantation In Pediatric Cases of Unilateral Hearing Loss

PUHL Clinical Trial

Aim: To investigate the effectiveness of cochlear implantation in children with moderate-to-profound unilateral hearing loss.

Inclusion Criteria

- Children age 3.5-6.5 years
- Typically developing
- PTA of ≥ 70 dB HL in one ear and normal hearing in the contralateral ear
- Aided CNC word score of $\leq 30\%$ in the ear to be implanted
- No evidence of cochlear nerve deficiency (CND)
- No evidence of ossification
- No significant malformations
- English is the primary language

Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption. 5

Device

- MED-EL SYNCHRONY Flex28 or Flex24
 - Array choice at surgeon's discretion
- SONNET Speech Processor
 - All programmed in FS4
 - Omni-directional mode with wind noise reduction disabled
 - No use of RONDO processors

Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption. 6

Participant Characteristics

ID	Age at IS	Years Profound	Etiology	ID	Age at IS	Years Profound	Etiology
01	6.50	1.87	Infection	11	6.17	3.55	Unknown
02	6.42	1.37	Unknown	12	3.97	1.79	CMV
03	4.59	1.41	Trauma	13	4.90	1.26	Unknown
04	6.13	6.18	Mondini	14	5.46	4.99	Unknown
05	4.74	4.79	Waardenburg	15	5.58	0.79	Unknown
06	12.85*	2.78	Unknown	16	3.79	3.83	Unknown
07	4.00	4.04	Mondini	17	5.45	5.49	Unknown
08	6.50	4.62	Unknown	18	3.58	3.63	Unknown
09	6.50	6.62	Unknown	19	3.93	3.96	Unknown
10	7.09*	2.38	CMV	20	3.61	3.66	CMV

Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption.

7

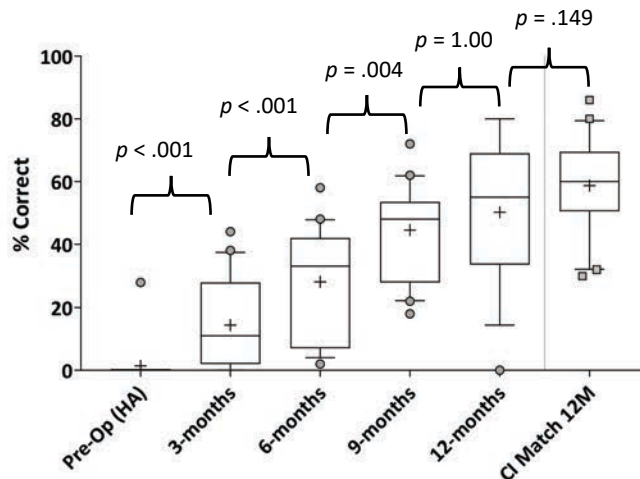
Test Battery

- Word Recognition
 - CNC
- Hearing in Noise
 - BKB-SIN, spatially separated
- Localization
- Questionnaires

Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption.

8

CNC Word Scores



Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption.

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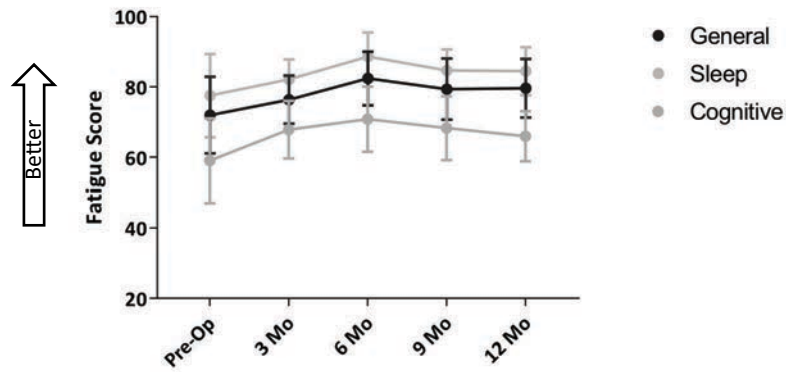
QoL and Inventory Outcomes

- Just 12-month data
- Peds-QL Fatigue Scales
 - Parent and Child ratings
- Pediatric SSQ
 - Listening Effort Subscale

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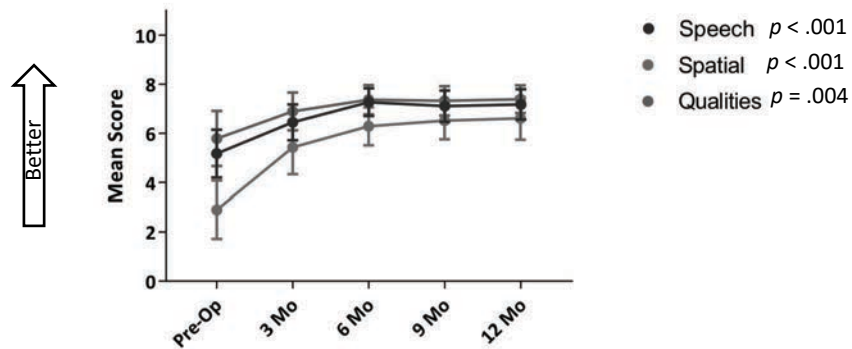
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Peds-QL: Parent Rating



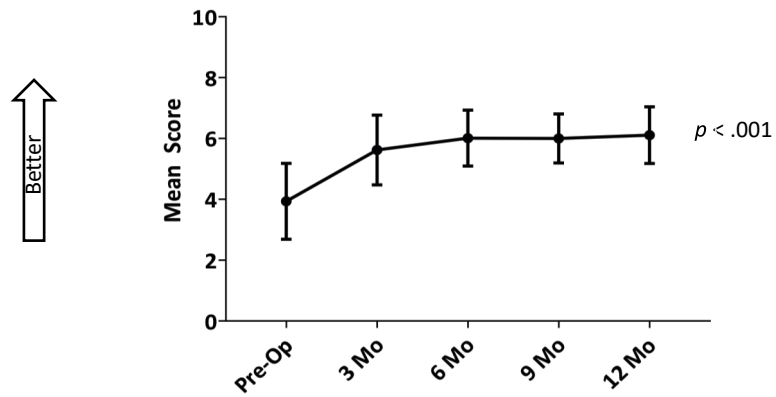
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Speech, Spatial Qualities (SSQ)



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Listening Effort SSQ Subtest



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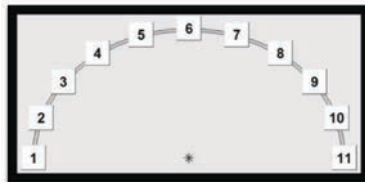
Localization



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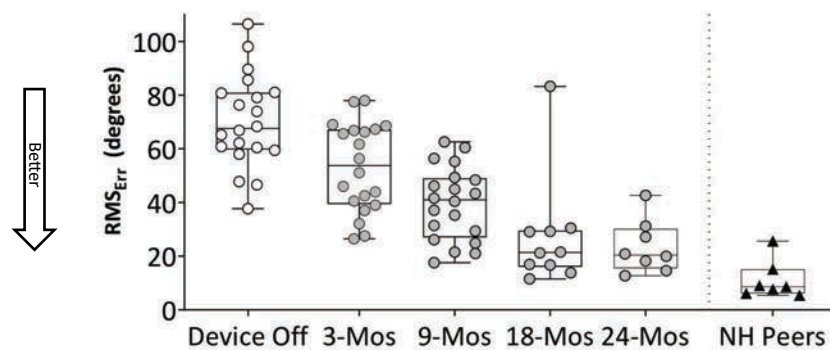
14

Localization



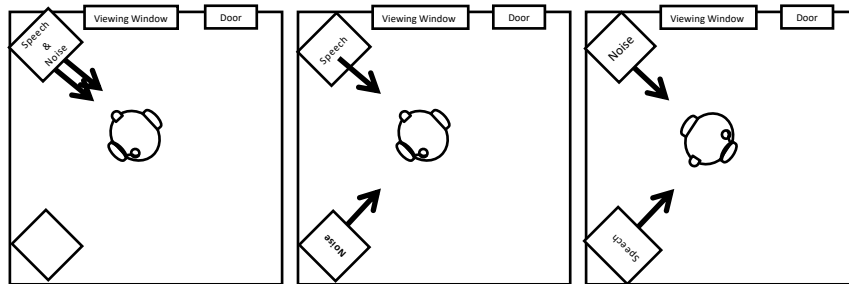
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Localization



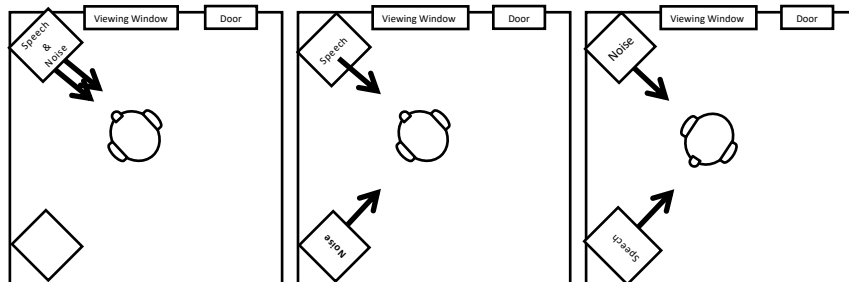
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Speech Perception in Spatially Separated Noise



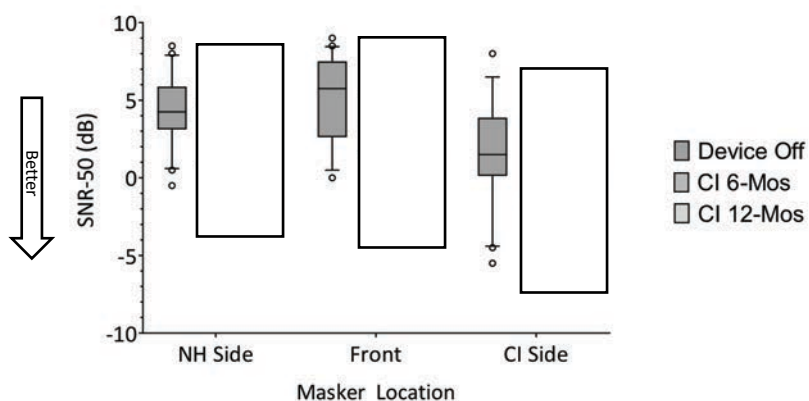
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Speech Perception in Spatially Separated Noise



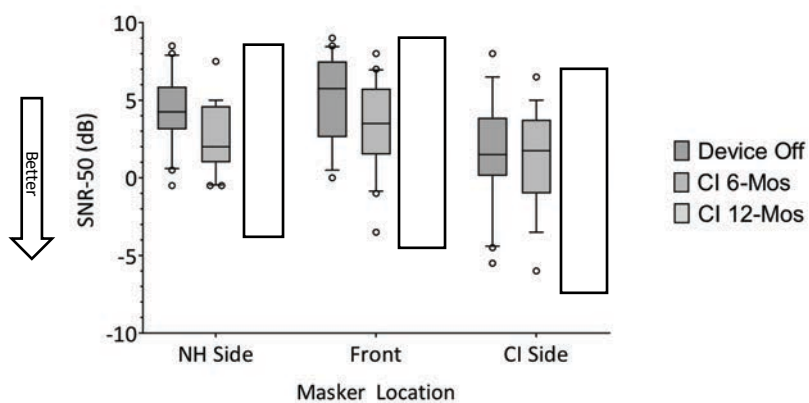
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Speech Perception in Spatially Separated Noise



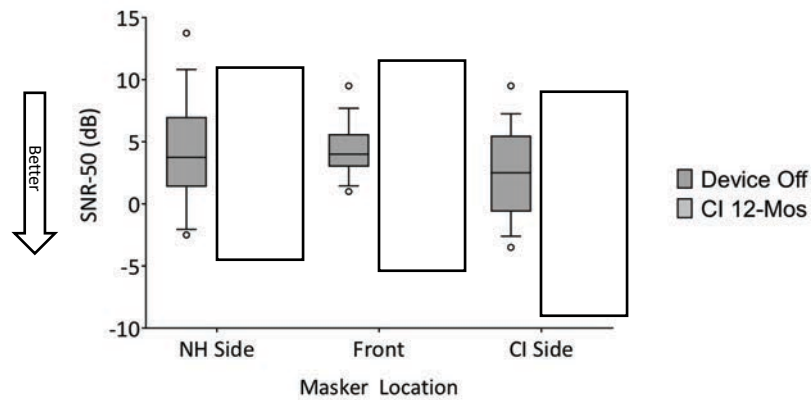
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Speech Perception in Spatially Separated Noise



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Speech Perception in Spatially Separated Noise



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Patient and Device Variables

- Contralateral hearing
 - Inner Ear Status
 - Age at implantation
 - Motivation/Expectations
 - Electrode array
 - Aural rehabilitation
 - Mapping protocol
-
- ✓ Normal hearing contralaterally
 - ✓ No Evidence of:
 - Cochlear nerve deficiency (CND)
 - Ossification
 - Significant malformations
 - ✓ Pre-School and Kindergarten age
 - Some were known congenital, but others have an estimated length of deafness
 - ✓ Clinical Trial subjects

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Patient and Device Variables

- Contralateral hearing
- Inner Ear Status
- Age at implantation
- Motivation/Expectations
- Electrode array
- Aural rehabilitation
- Mapping protocol



✓ Flex28 (28 mm) array

- More coverage in the apex
- More variability in insertion angle (Canfarotta et al., 2020)



MED-EL

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Patient and Device Variables

- Contralateral hearing
- Inner Ear Status
- Age at implantation
- Motivation/Expectations
- Electrode array
- Aural rehabilitation
- Mapping protocol



✓ Aural rehab completed bimonthly for 6-months, and monthly for 6 more months

- Direct audio input (DAI)
- Assessment and Aural Rehabilitation Tool (AART) (Evans & Dillon, 2019)

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Patient and Device Variables

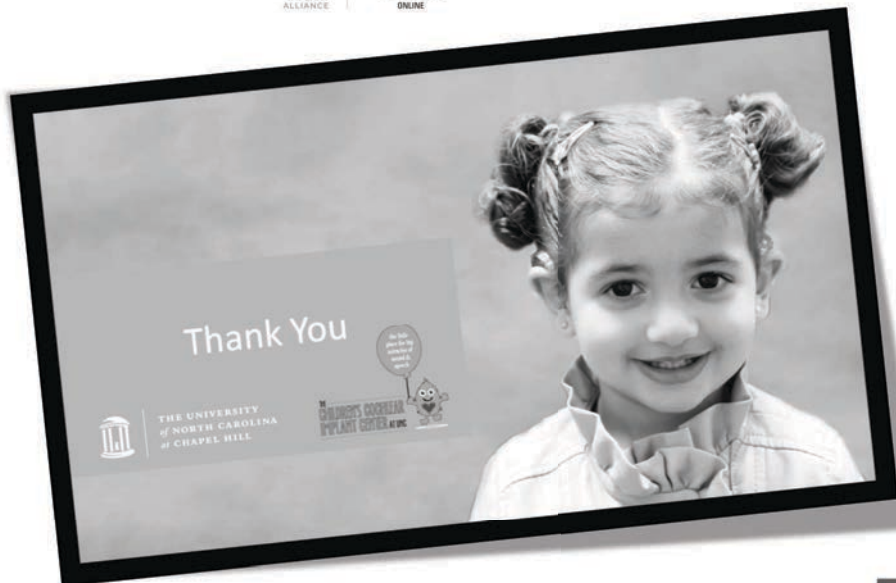
- Contralateral hearing
- Inner Ear Status
- Age at implantation
- Motivation/Expectations
- Electrode array
- Aural rehabilitation
- Mapping protocol



✓ Aim: appropriate loudness
at device activation

Caution: Not an FDA approved indication. This clinical trial has an Investigational Device Exemption.

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Outcomes for Participants with Asymmetric Hearing Loss: Initial Results of a Clinical Trial

Jill B. Firszt, Ruth M. Reeder, Laura K. Holden, Noël Y. Dwyer, Tim A. Holden
And the Asymmetric Hearing Study Team



*ACIA
CI2020 Online*



Disclosures for Jill B. Firszt

- Financial:
 - Employed by WUSM—salary
 - NIH (research funds)
 - Cochlear Americas, Advanced Bionics (audiology advisory board member, research funds)



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- Joseph Ursick, MD



Study Background

- Until recently, asymmetric hearing loss (AHL) was not an FDA approved indication for cochlear implantation
- New criteria approved July 2019 for the MED-EL device expanded candidacy
 - For AHL and single sided deafness (SSD)
 - Poor ear: profound hearing loss (PTA $\geq$ 90 dB HL, CNC word score $\leq$ 5%)
 - Allows for more hearing in non-implanted contralateral ear
 - Significant movement away from requiring bilateral hearing loss when considering CIs
- Today's study at WUSM will supplement this movement and provide new evidence to expand candidacy criteria further
 - FDA approved (IDE G140244)
 - NIH funded (NIDCD U01 14938)



Study Objectives

Primary Objective

- Obtain preliminary efficacy data in adults with AHL who receive a CI in the poor ear and maintain a hearing aid (HA) in the better ear
 - Efficacy: Post-implant improvement in the poor ear with a CI compared to pre-implant with HA

Secondary Objectives

- Obtain efficacy data related to bimodal hearing
 - Efficacy: Post-implant improvement (CI + HA) compared to the pre-implant best-aided condition
- Evaluate safety of CI in individuals with AHL
 - Number, type and degree of all adverse events
- Collect preliminary information related to test measures and methodology that could be used in a clinical setting



Study Design

- Multicenter, prospective, single-arm clinical trial
 - Repeated-measures analysis; patients act as own controls
 - Up to 40 participants will be implanted at four sites
 - WUSM, Midwest Ear (KC), NYU, and House Clinic (CA)
- Pre-implant Evaluation
 - Candidacy Evaluation & Pre-implant Study Testing
- Post-implant Evaluations
 - 3, 6, 9, & 12 months
- Participants will be in the study for approximately 18 months
- All 3 CI manufacturers are included



Inclusion Criteria

- 18 years of age or older
- Proficient in English
- Desire for functional binaural hearing
- Previously tried HA treatment for asymmetric hearing loss (either HA in the poor ear or a BiCROS) or willing to complete a trial
- Willingness to comply with all study requirements
- Ability to provide informed consent



Audiometric Inclusion Criteria

- **Poor ear (ear to be implanted):**
 - PTA at .5, 1 & 2 kHz > 70 dB HL
 - Aided word recognition score (CNC words) at 60 dB SPL $\leq$ 30%
 - Duration of SPHL $\geq$ 6 months
 - Onset of hearing loss $\geq$ 6 years of age
- **Better ear:**
 - PTA at .5, 1, 2 & 4 kHz of 40 to 70 dB HL
 - Currently using a HA
 - Aided word recognition score (CNC words) at 60 dB SPL $\geq$ 40%
 - Stable hearing for the previous 1-year period
 - ✓ “Stable” = thresholds have not changed by >10 dB or more at 2 or more frequencies



Exclusion Criteria

- Medical condition that contraindicates surgery
- Actively using an implantable device in poor ear
- Known cochlear malformation or obstruction that would preclude full insertion
- Hearing loss of neural or central origin
- Unrealistic expectations related to the benefits and limitations of CI
- Unwillingness or inability to comply with all investigational requirements



Test Measures/Conditions

- Air and bone conduction
- FM tone sound field threshold levels
- CNC words
- AzBio Sentences
 - Quiet (50 and 60 dB SPL)
 - Noise (60 dB SPL +8 SNR)
- BKB-SIN – Speech Front
 - Noise to Better Ear (SONBE)
 - Noise to Poor Ear (SONPE)
- Localization (quiet & noise):
- Test Conditions: Better ear alone, Bilateral, Poor ear alone (limited)



Questionnaires

- **CI Participant**
 - Patient Interview Form
 - Hearing Handicap Inventory (HHIE)
 - Health Utilities Index (HUI3)
 - Speech, Spatial and Qualities (SSQ) Questionnaire
 - Glasgow Benefit Inventory (GBI)
 - Satisfaction with Amplification in Daily Life (SADL)
- **Spouse/Significant Other will be asked to participate**
 - Communication Profile for the Hearing Impaired (CPHI)
 - The Hearing Impaired Impact – Significant Other Profile (HII-SOP)



Summary of Participants

- 40 participants enrolled
- 40 implanted
 - WUSM = 13, MEI = 9, House = 7 , NYU = 11
- Today we will review data from 29 participants who have completed the 6 month interval

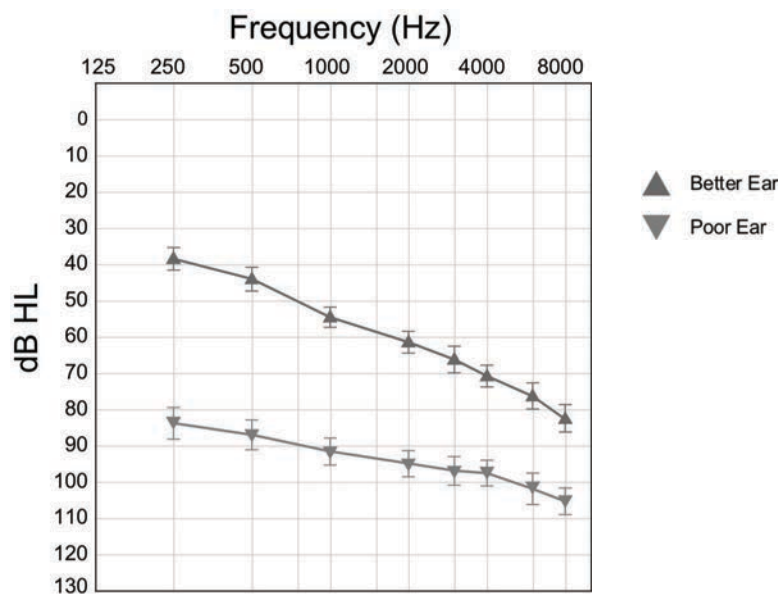


Demographics

- Age at CI surgery: Mean 69 yrs (45 - 84 yrs)
- Age at Better Ear HL onset: Mean 52 yrs (10 – 70 yrs)
- Age at Poor Ear HL onset: Mean 49 yrs (10 – 70 yrs)
- Age at Poor Ear SPHL onset: Mean 60 yrs (28 – 82 yrs)
- Length of SPHL: Mean 9 yrs (<1 – 45 yrs)

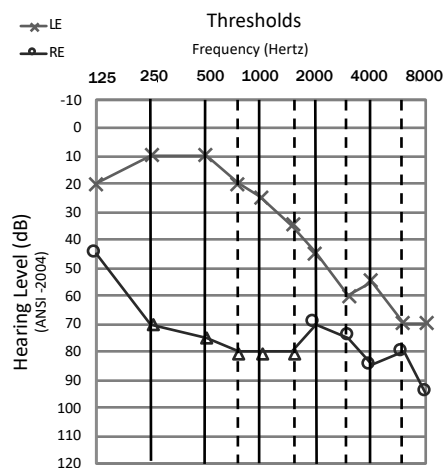
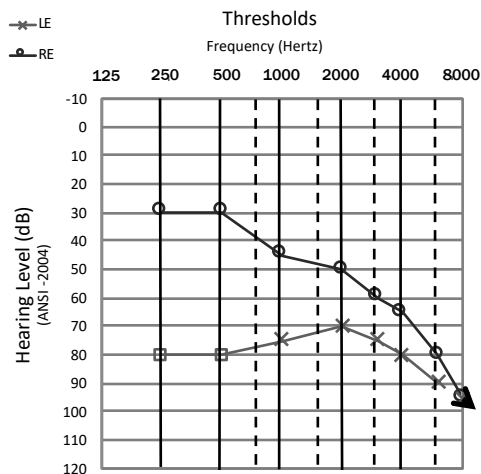


Group: Pre-Implant Unaided Thresholds

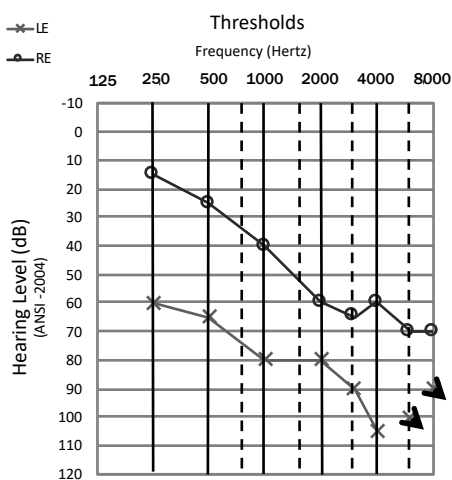
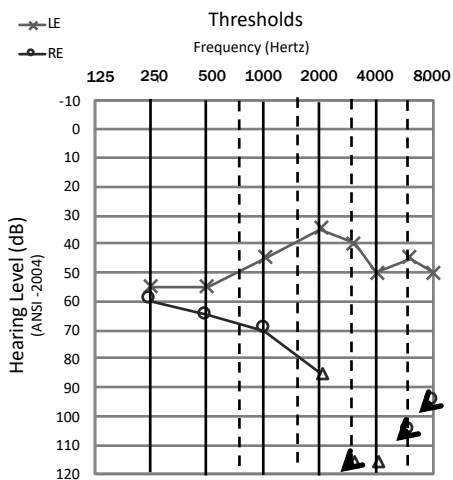




Individual: Pre-Implant Unaided Thresholds

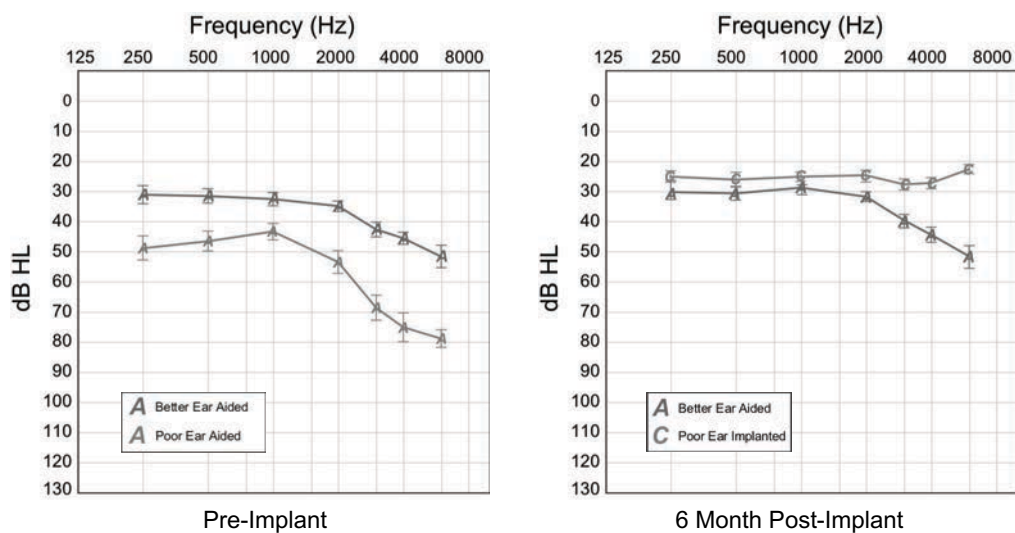


Individual: Pre-Implant Unaided Thresholds

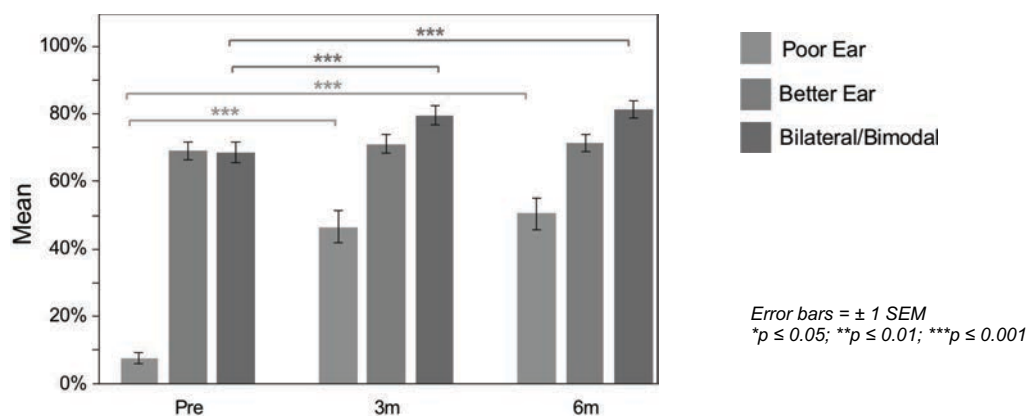




Group: Aided/Implanted Hearing Thresholds

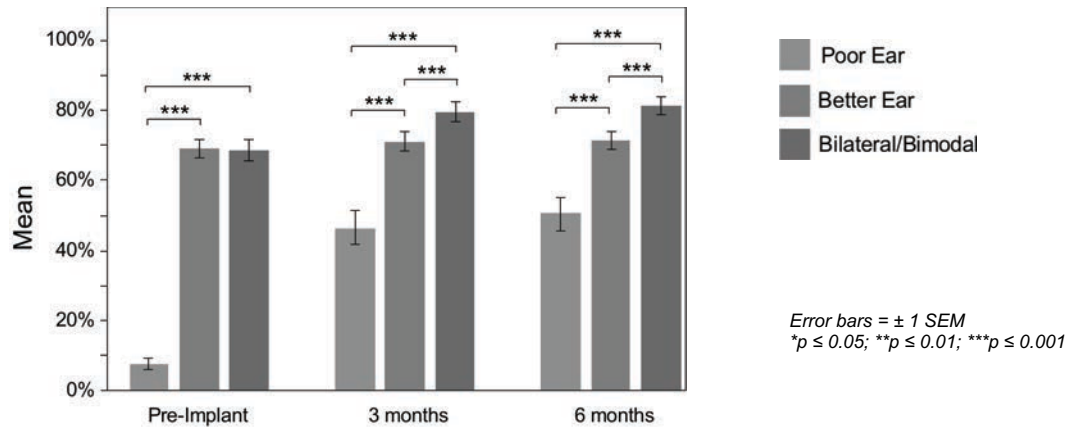


CNC Words 60 dB SPL Quiet

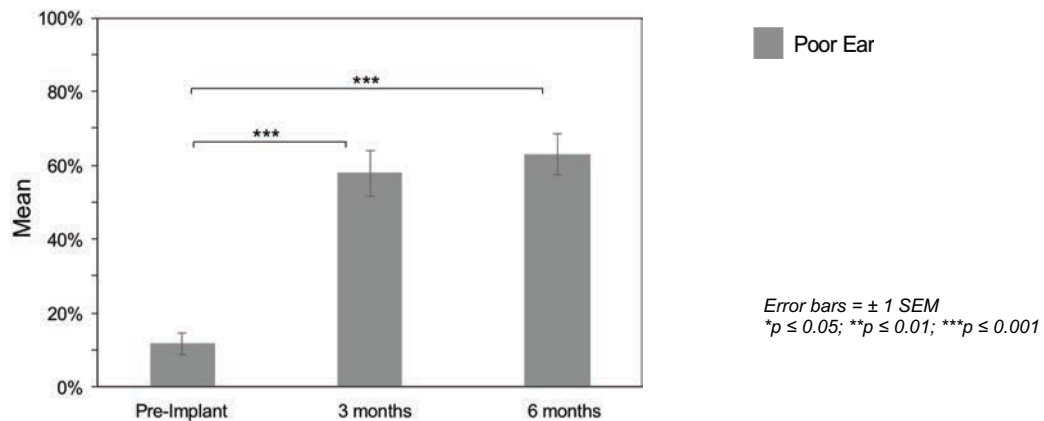




CNC Words 60 dB SPL Quiet

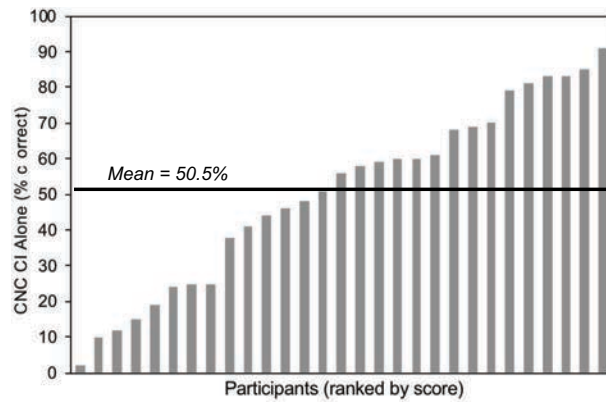


AzBio Sentences Quiet 60 dB SPL

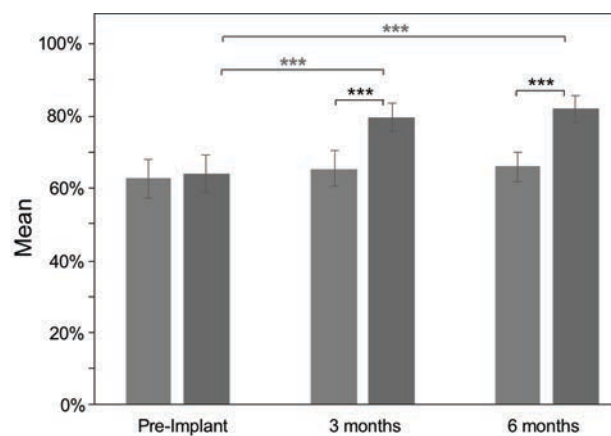
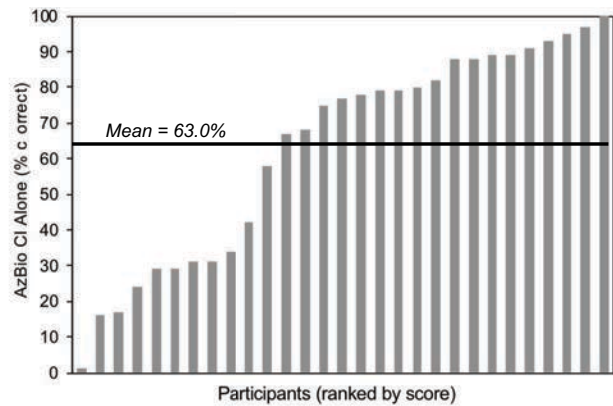




CNC Words 60 dB SPL



AzBio Sentences 60 dB SPL



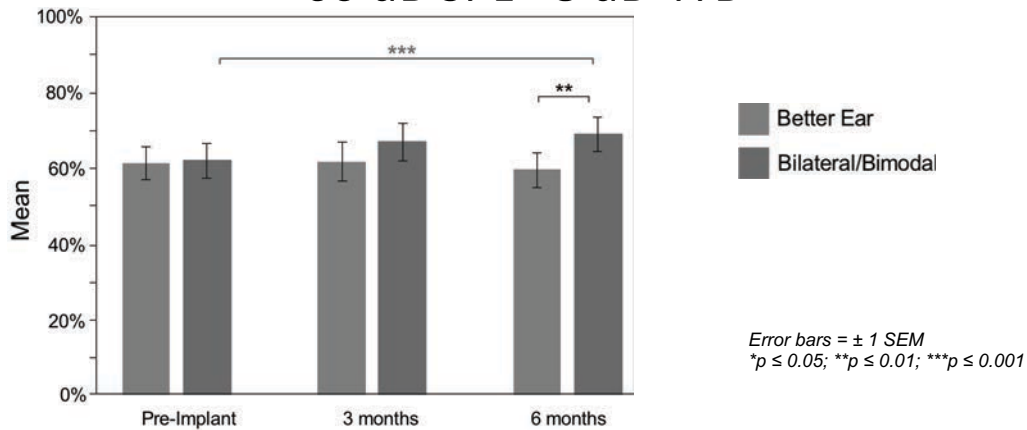
■ Better Ear

■ Bilateral/Bimodal

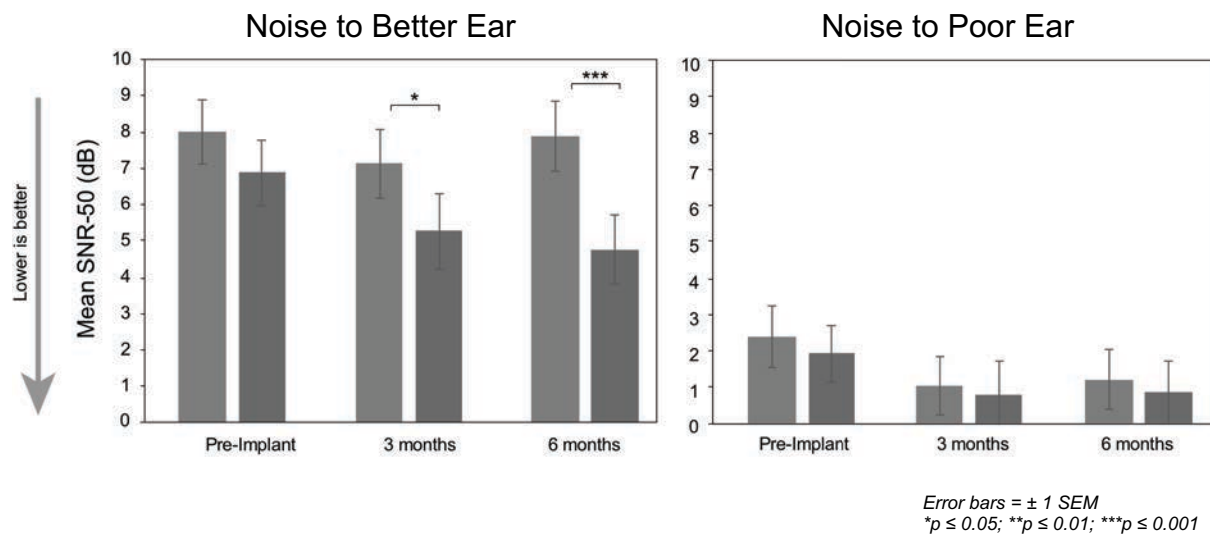
Error bars = ± 1 SEM
* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$



AzBio Sentences in Noise 60 dB SPL +8 dB 4TB

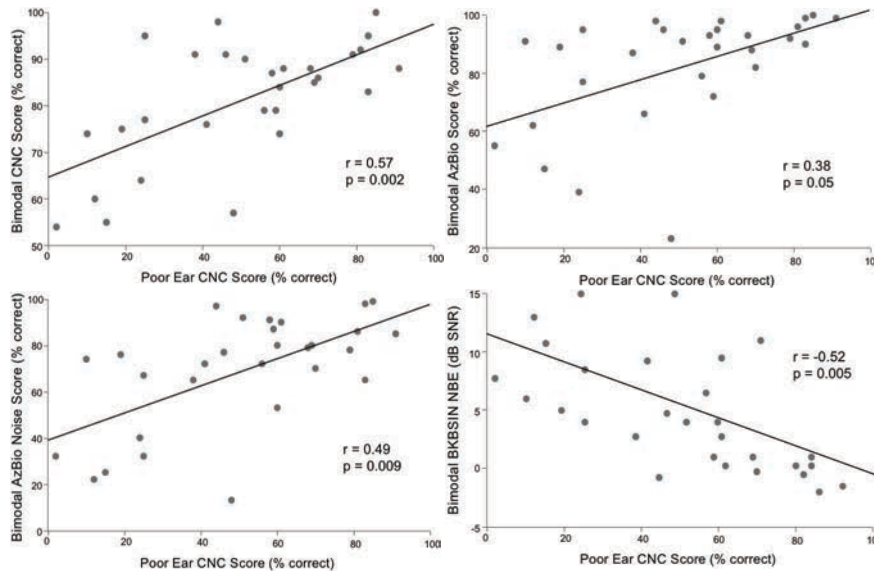


BKB-SIN Sentences





Contribution of CI to Bimodal Speech Recognition



At 6 months post-implant, word recognition with CI alone is correlated to bimodal speech recognition in quiet and in noise (after controlling for the better ear alone 6-month CNC score)



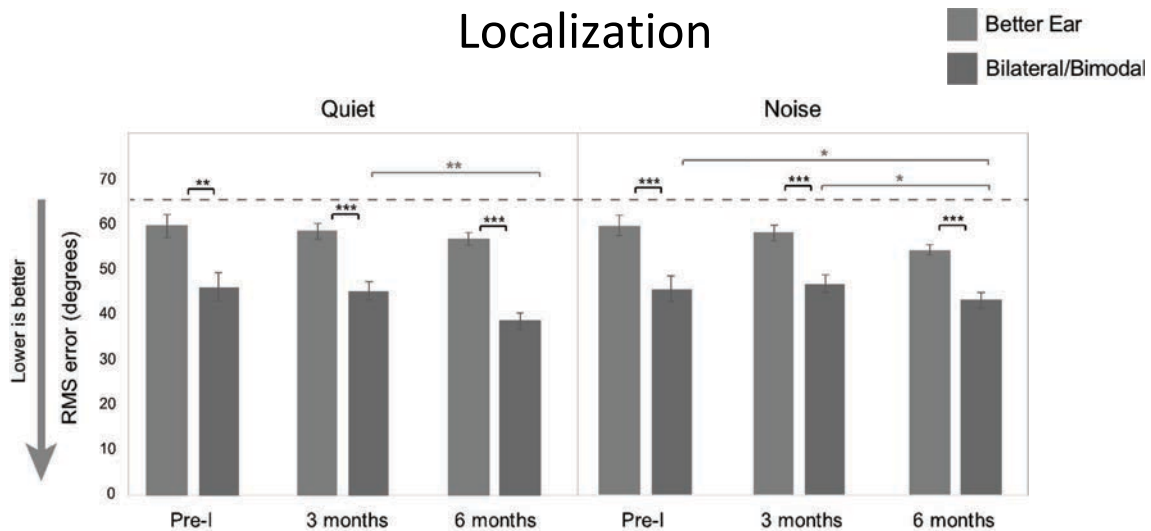
Localization Array



- Localization in Quiet
 - CNC words (64) presented randomly via loudspeaker array
 - 8 loudspeakers
 - 140° arc, loudspeakers 15° apart
 - Roved at 65 dB SPL (± 6 dB)
 - Asked to identify loudspeaker location
- Localization in Noise
 - Addition of 60 dB SPL restaurant noise from all loudspeakers



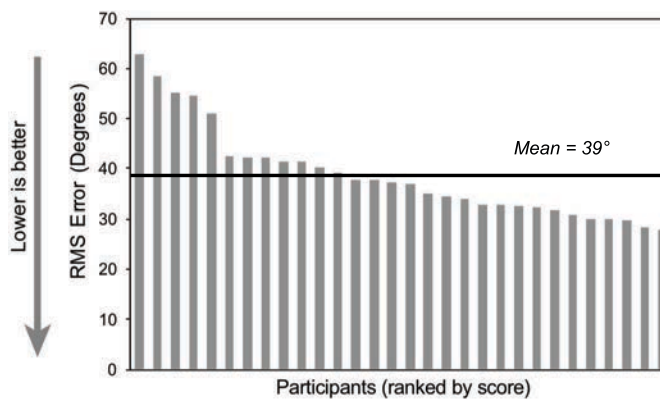
Localization



Error bars = ± 1 SEM
*p ≤ 0.05; **p ≤ 0.01; ***p ≤ 0.001



Range of Bimodal Localization Performance (6 mos Post-Implant)





Health Utilities Index (HUI3)

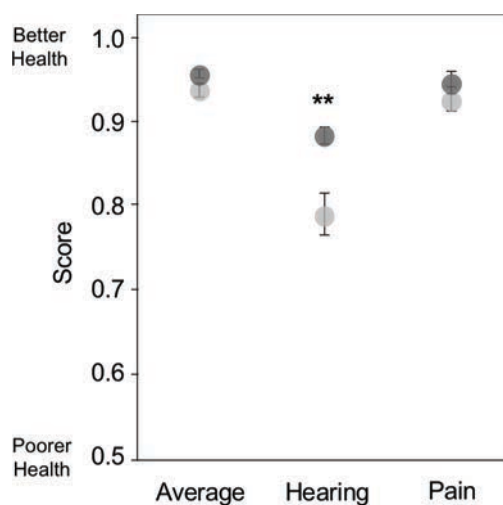
- Administered pre-implant and 6 months post-implant
- Multiple dimensions of health status
- Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition and Pain
- 1-2 questions per dimension, e.g., Hearing

Which best describes ability to hear what is said in a group conversation?

- Able to hear without HA or CI
 - Able to hear with HA or CI
 - Unable to hear, but do not wear HA or CI
 - Unable to hear at all
- Useful to ensure that overall health has not declined



Health Utility Index – HUI3



- Pre-Implant
- 6 Mos Post-Implant

- No change in the average of the 8 dimensions (Vision, Hearing, Speech, Ambulation, Dexterity, Emotion, Cognition and Pain)
- Reports on the Hearing dimension improved significantly
- No decline in any individual dimension (example Pain in figure)

Error bars = ± 1 SEM
* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

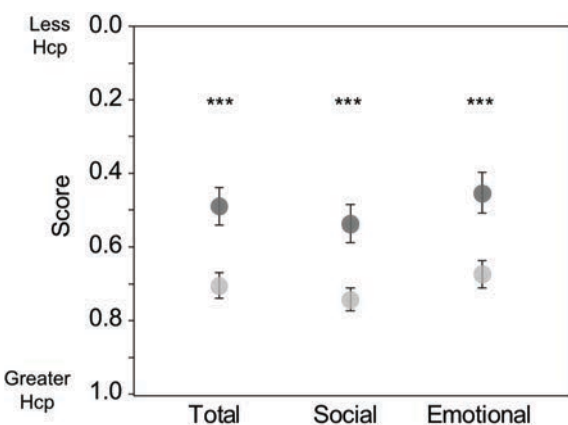


Hearing Health Inventory for the Elderly (HHIE)

- Administered pre-implant and 6 months post-implant
- Perceived Emotional and Social consequences of Hearing Loss
- 25 items – Yes, Sometimes, No
 - 13 items – Emotional; 12 items – Social
- Examples
 - Does a hearing problem make you irritable? (Emotional)*
 - Does a hearing problem cause you to avoid groups of people? (Social)*
- Useful to identify changes following treatment for hearing loss



Hearing Handicap Inventory (HHIE)



- Pre-Implant
- 6 Mos Post-Implant

- Significant reduction in perceived negative consequences of hearing loss for both Social and Emotional subscales, and overall.

Error bars = ± 1 SEM
* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

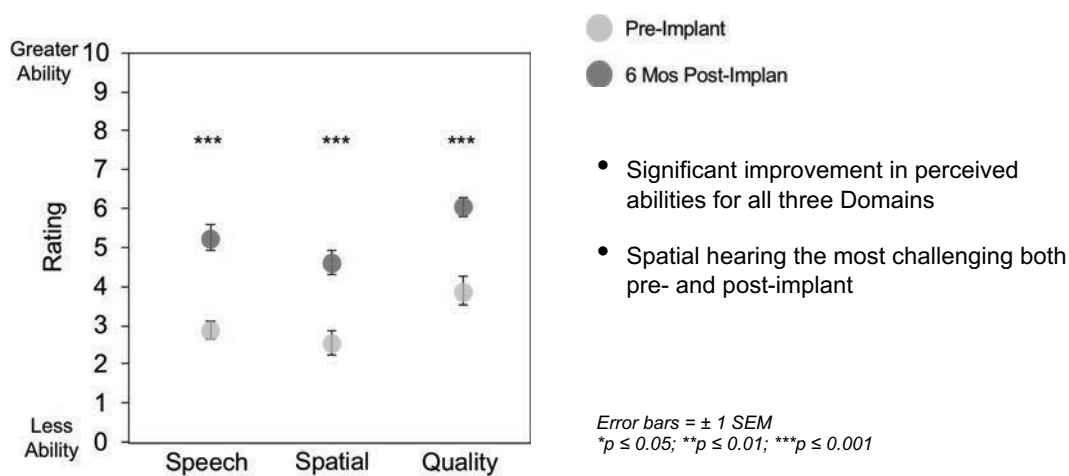


Speech, Spatial and Qualities of Hearing (SSQ)

- Administered pre-implant; 6 and 12 months post-implant
- Perceived abilities for various listening situations across 3 domains
- 50 items rated on a scale 0-10, with 10 greatest ability
- Examples
 - *You are talking with one other person in a quiet room. Can you follow what the other person says? (Speech Hearing)*
 - *You are outside. A dog barks. Can you tell where it is without having to look? (Spatial Hearing)*
 - *Do other people's voices sound clear and natural? (Sound Qualities)*
- Useful to identify specific areas of difficulty and changes following treatment for hearing loss



Speech, Spatial and Qualities of Hearing (SSQ)



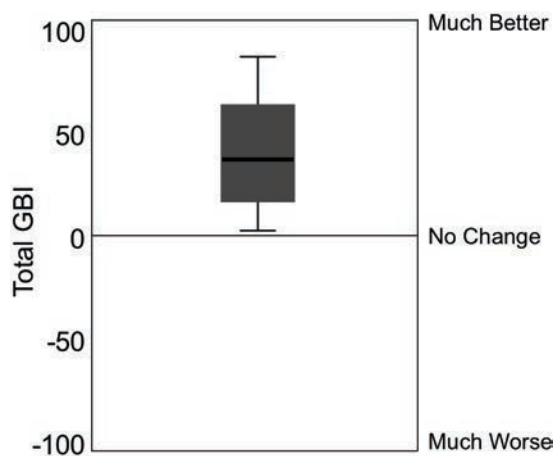


Glasgow Benefit Inventory (GBI)

- The participant's perception of the benefit from an intervention
- 18 questions answered along a 5-point scale
 - E.g., Much worse, Worse, No Change, Better, Much better
- Examples
 - *Have the results of the CI made your overall life better?*
 - *Since your CI, do you have more or less self-confidence?*
 - *Since your CI, have you been able to participate in more or fewer social activities?*
- Useful to identify the participant's perception of benefit from the CI



Glasgow Benefit Inventory (GBI)



- Administered after 6-months of CI use
- For all participants, the total GBI score indicated benefit
- For the individual question "*Have the results of the CI made your overall life better?*" All responses were either 4 (better) or 5 (much better) along the scale of 1-5.

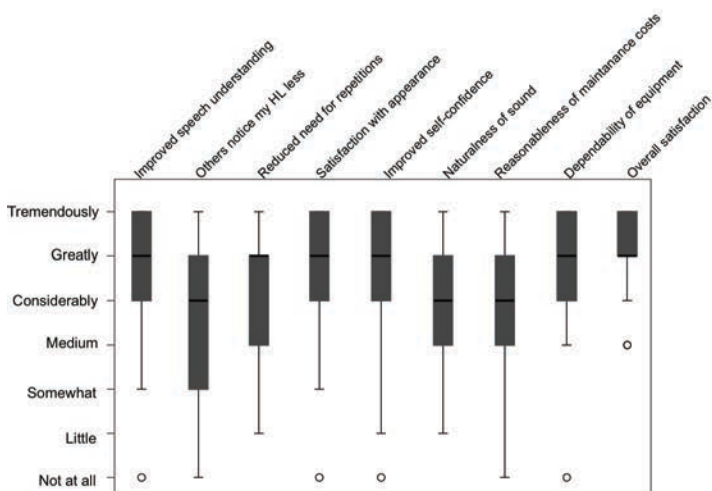


Satisfaction with Amplification in Daily Life (SADL) *modified for satisfaction with addition of CI*

- The participant's satisfaction with using the device
- 13 questions; 7-point scale from "Not at all" to "Tremendously"
- Examples
 - *Compared to using your HA alone, does wearing your HA and your CI help you understand the people you speak with most frequently?*
 - *Are you convinced that obtaining a CI was in your best interests?*
 - *Do you think people notice your hearing loss less since getting a CI?*
- Useful to identify the participant's satisfaction with using a CI for the poor ear in conjunction with a HA at the better ear



Satisfaction with Amplification in Daily Life (SADL)



- Administered after 6-months of CI use
- Variability in responses for most questions
- Overall Satisfaction – much less variability – median response was greatly satisfied



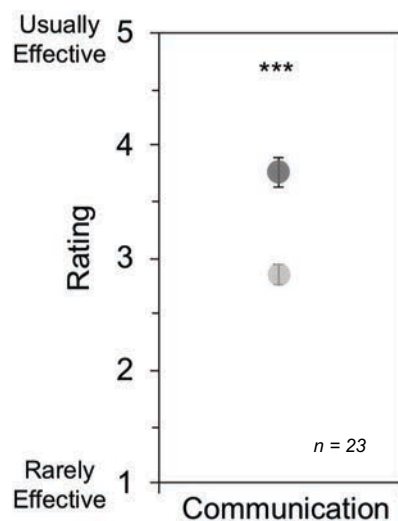
Spouse/Significant Other Questionnaire Communication Profile for the Hearing Impaired (CPHI)

- How often can your spouse/SO communicate effectively in each situation?
- 18 questions; 5-point scale from Rarely to Usually
- Examples
 - *S/he is at the dinner table with the family.*
 - *S/he is at a restaurant ordering food or drinks.*
- Useful to identify specific areas of difficulty and changes following treatment for hearing loss from the perspective of the spouse or significant other



Communication Profile for the Hearing Impaired (CPHI)

SO's perspective of participant's communication abilities



- Pre-Implant
- 6 Mos Post-Implant

- 23 participants had spouses or SOs who completed the questionnaire
- Spouses and SOs reported significant improvements in the participant's communication effectiveness

Error bars = ± 1 SEM
* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$



Spouse/Significant Other Questionnaire

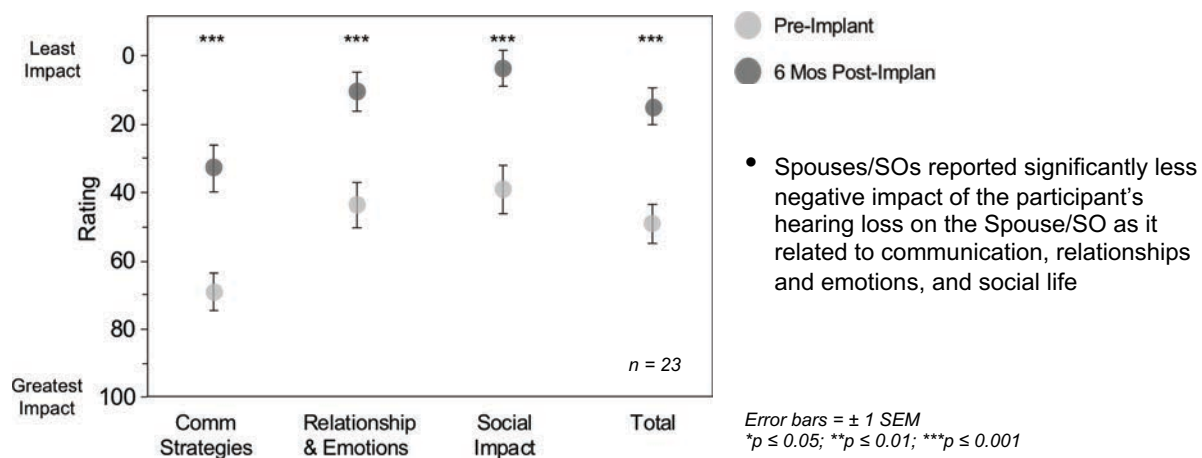
The Hearing Impairment Impact – Significant Other Profile (HII-SOP)

- The SO's perspective regarding the impact of the HL on SO
- 20 questions answered as Yes, Sometimes, No
- Three sub-area scores and a total score
- Examples
 - *Do you feel like you are shouting all the time because of your SO's hearing loss?* (Communication Strategies)
 - *Does your SO's hearing loss make you feel frustrated?* (Relationship & Emotions)
 - *Do you feel like your SO's hearing loss hampers your social life?* (Social Impact)
- Useful to identify the impact and changes in the SO's quality of life following treatment for the participant's hearing loss



The Hearing Impairment Impact – Significant Other Profile (HII-SOP)

Impact of participant's hearing loss on SO





Summary

- Poor ear alone performance improved significantly with a CI
- Pre-implant, performance with bilateral HAs was similar to the better ear alone with a HA for speech recognition in quiet and noise
- Post-implant, scores in the bimodal condition were higher than the better ear alone with a HA for speech recognition in quiet and noise
- Pre-implant, bilateral HAs improved localization compared to the better ear alone
- Post-implant, localization scores were the best after 6 mos of CI use, and may continue to improve



Summary

- Participants' self-reported ratings of communication function were better post-implant compared to pre-implant
- Participants reported both benefit and satisfaction with Bimodal hearing
- Quality of life measures indicated both participants and the participants' spouses/significant others observed improvements in the:
 - Emotional impact of hearing loss
 - Social consequences of hearing loss
 - Impact of the participant's hearing loss on the spouse
- There was no significant change in health status



Conclusion

- Fitting each ear with an optimal device is necessary to achieve the greatest level of performance for an individual
- Candidacy criteria for AHL should be broadened to include severe to profound hearing loss, and greater word recognition, in the poor ear to be implanted
- Analysis of the full data set through 12 months post-implant is forthcoming along with more detailed analyses



Acknowledgements

- NIH/National Institute on Deafness and Other Communication Disorders
 - U01 DC014938
- We thank our participants for their time and commitment to our studies
- We thank our colleagues and collaborators



WUSM: AHL Clinical Trial Research Study Team

WUSM Research Team

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Challenging Surgical Cases

Presenters:

David Haynes, MD

Nancy Young, MD

Fred Telischi, MD

Haynes Presentation

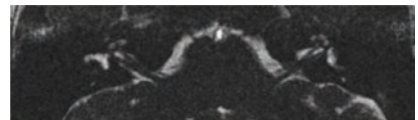
Challenging Case: CI of Teenager with Cryopyrin-associated Periodic Fever Syndrome (CAPS)

Nancy M Young, MD
Lillian S Wells Professor of Otolaryngology
Northwestern University Feinberg School of Medicine
Ann & Robert H Lurie Children's Hospital of Chicago



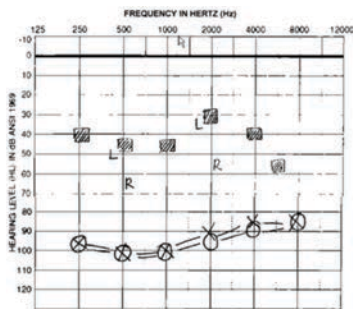
13 Year Old CI Candidate With Progressive SNHL

- PMH:
 - Age 11: new-onset bilateral mild to moderate SNHL
 - MRI revealed decreased T2 signal in cochleae
 - Fitted with hearing aids with excellent benefit
 - Subsequent onset of periodic fever, headache, nausea and vomiting
 - Age 12: inpatient evaluation of fever: lymphadenopathy, splenomegaly, anemia, *chronic aseptic meningitis*, & immunodeficiency of uncertain cause
 - Hearing loss progresses to bilateral moderately severe to severe SNHL with no measurable speech perception
 - Age 13: NIH Clinical Center evaluation & subsequent diagnosis of cryopyrin-associated periodic fever syndrome (CAPS) based on clinical presentation

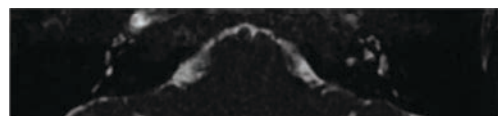


- Aseptic meningitis
 - More common than bacterial meningitis
 - Usually self limited disease with good clinical outcome
 - CSF culture & gram stain **negative** with increased white blood cells
 - Viral cause is most common
 - Less common causes
 - Fungi, TB, Lyme disease, inflammatory disease
- Cryopyrin-associated periodic fever syndrome (CAPS)
 - Rare disease
 - Autoimmune inflammatory disorder associated with NLRP3 gene
 - Multisystem disease with multiple neurological manifestations including SNHL

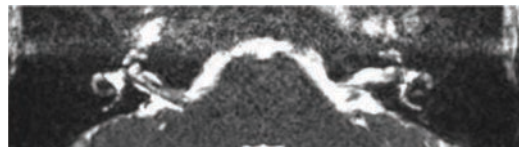
Pre-CI Audiogram & Repeat MRI



-PBK (bilat): 0%
-AZ Bio (child): 0%



Cochleae with diminished T2 signal



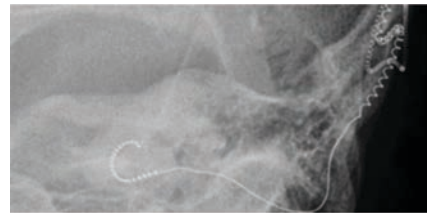
Abnormal post-contrast enhancement of cochleae, VII & VIII nerves

Behringer, Ryan et al. Neuroradiol 2019

Left Cochlear Implantation

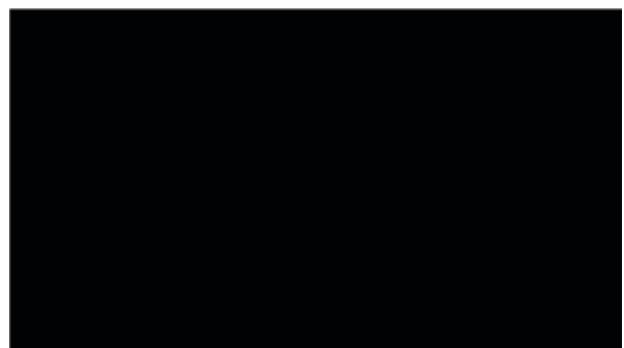
- Ossified round window & inferior basal turn
 - Drill open till depth of 8 mm
 - Narrow open distally
- Electrode: Contour array
 - Inserted with wire stylet in place
 - Full insertion
- Activation: immediate improvement

Intra-operative Xray

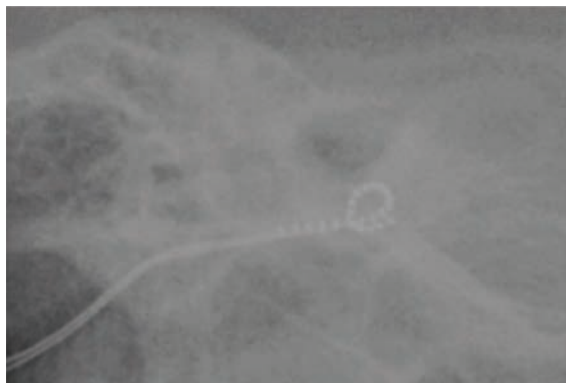


Right Cochlear Implantation

- Ossified round window & inferior basal turn
 - Drill open till depth of 6 mm
 - Open distally with thickened tissue lining
- Electrode: Contour array
 - Inserted with wire stylet in place
 - Full insertion



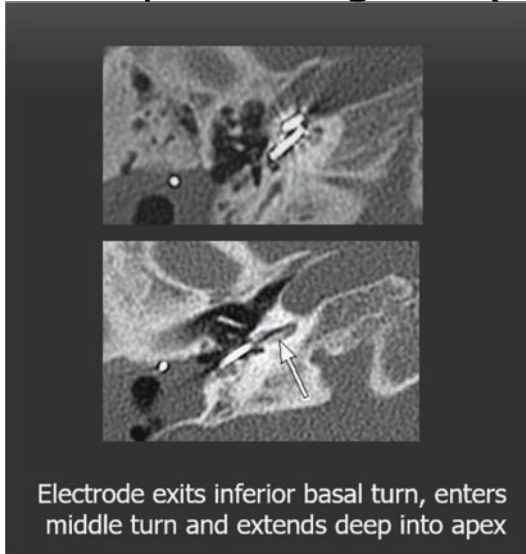
Intra-operative Xray of Right CI



Post Implant Progress

- Left ear
 - Activation: able to discriminate Ling 6 and spondee words (auditory only)
 - 3 month: AZ bio (child, recorded) 68%; PBK 48%
- Right ear
 - Activation: reported sound was “blurry”
 - Normal electrode impedances
 - eCAP present: 2,7,11,16,22

Post Implant Progress (Right CI)



- 3 week check
 - Child reports unclear sound & resistance to use
 - Apical electrodes deactivated (19-22) with immediate improvement in sound quality
- 7 week check (telephone)
 - Slow improvement in sound quality and length of device use

Cochlear Ossification

- Bacterial meningitis – well known association
 - Ossification onset may be rapid and prevent successful CI
 - Early obstruction identified by high resolution 3D MRI of cochleae
 - Shorten or eliminate hearing aid trial
 - Very common in deafness due to **Pneumococcal** meningitis
 - Dramatic decline in incidence of meningitic SNHL after introduction of Prevnar to routine infant vaccination schedule
- Continues to occur due to bacterial meningitis of all types
- CAP: example of acquired SNHL with ossification due to chronic aseptic meningitis

CI 2020

Cochlear Implant Complex Cases

Cholesteatoma and CI

TWO APPROACHES

Fred F. Telischi, MEE, MD, FACS
James R. Chandler Chair in Otolaryngology
Chairman of Otolaryngology and Professor,
Neurological Surgery and Biomedical Engineering
University of Miami Miller School of Medicine/UHealth

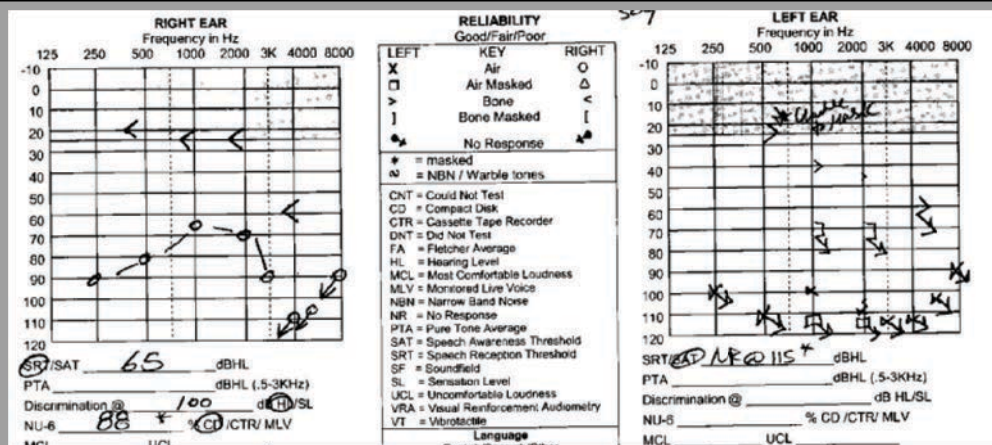
Patient History – E.A.

- Embryonal rhabdomyosarcoma (Stage 3-C Group 3) of nasopharynx
- Underwent chemoradiation at 5 years old
 - Vincristine, Actinomycin D, Cyclophosphamide, Ifosfamide
- Significant craniofacial developmental abnormalities
 - Midface & Mandible hypoplasia
 - OMFS procedures
 - Bicoronal incision
 - Lefort osteotomies
 - Bilateral rib grafts, iliac crest graft
 - **Significantly affected the skin and muscle of H&N

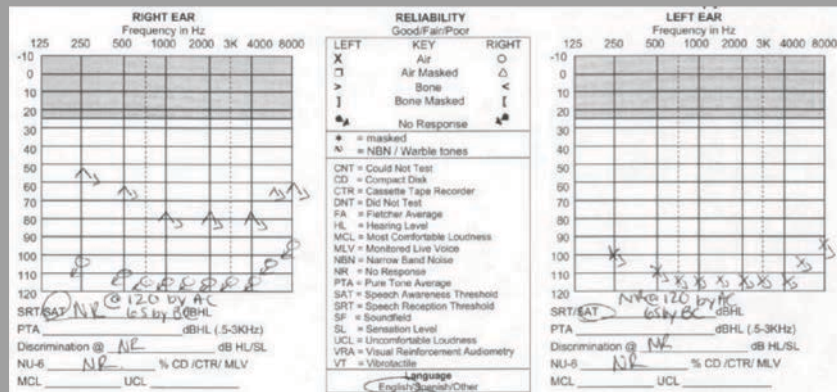
Otologic History

- Bilateral radiation-induced cholesteatoma
 - Aggressive nature
 - Multiple surgeries
 - Bilateral CHL/MHL
- Eventually leads to bilateral radical mastoidectomies
 - Chronically infected
 - Difficulty wearing conventional hearing aids
 - Eventually developed left sudden, profound hearing loss. No improvement with oral steroids and HBO. Likely due to labyrinthitis secondary to chronic, invasive cholesteatoma.
- Leads to percutaneous bone-anchored auditory implants (right side first for CHL and then left for SSD indication after favorable preop testing/trial)

Audiogram – March 2012 (prior to L BAHA)



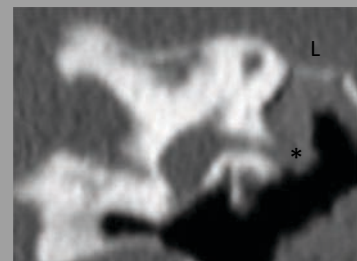
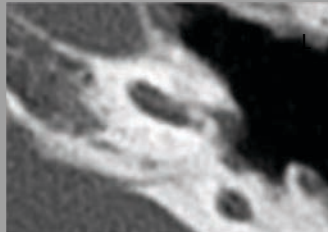
Sudden R Hearing Loss – July 2013 (age 24)



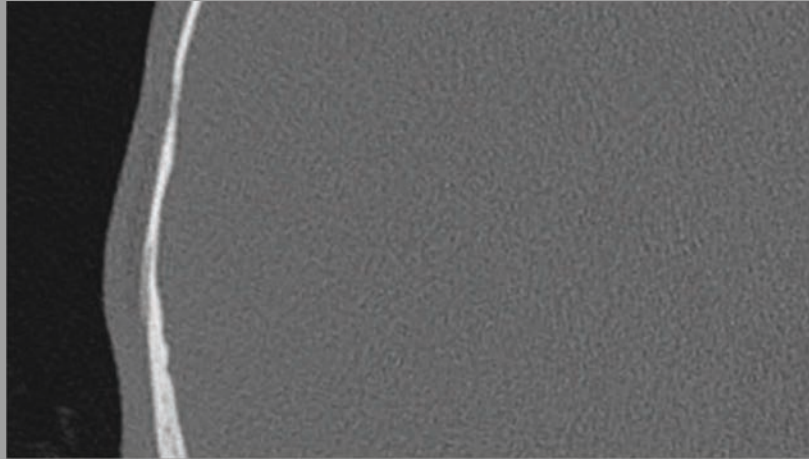
- Evaluated for CI candidacy with 2-stage procedure planned for R ear

Otologic History

- Sudden hearing loss of right ear in July 2013 (Patient age 24)
- Evaluated for CI candidacy with 2-stage procedure planned for R ear
 - Left obvious labyrinthine fistula/labyrinthitis with possible early cochlear ossification
 - Right more recently deafened and more patent



CT Temporal Bone w/o Contrast, R, axial



7/3/2013 video

Right Obliteration Procedure

- BAHA Removal
- Extensive cholesteatoma eroding descending fallopian canal segment, dura of the tegmen tympani, scala vestibuli of the basal turn of the cochlea
- Thin bone overlying sigmoid sinus, jugular bulb, carotid
- Obliteration of the Eustachian tube
- Measurement electrode placed into the cochlea as a spacer
- Abdominal fat graft and canal closure
- Temporalis muscle and Palva not utilized due to the meager nature of the scalp soft tissues

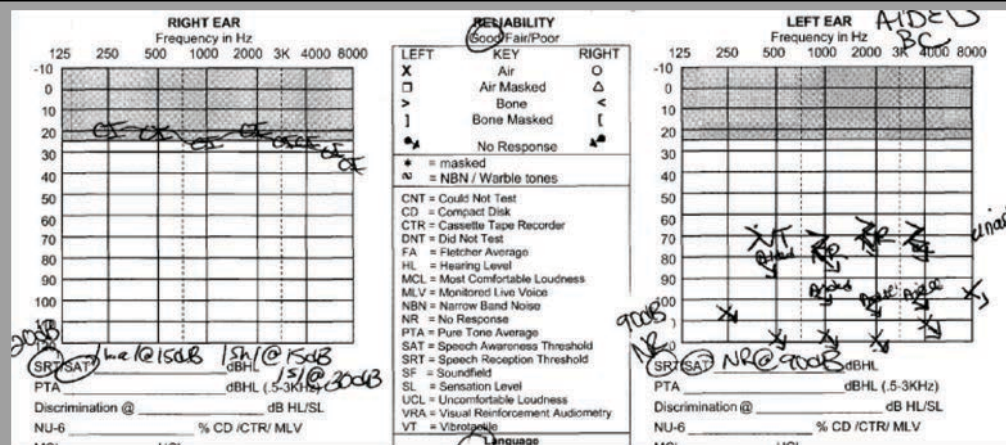
11/5/2013

Second-stage Cochlear Implant (5 months)

- Preoperative consult with H&N team for possible free flap coverage
 - Poor local/rotational flap candidate
- Dehiscent sigmoid sinus, tympanic facial nerve, and tegmen tympani
- Residual cholesteatoma on *medial* descending facial nerve
 - Similar to second look for cholesteatoma
- Full insertion of Contour Advance electrode
- No flap/graft required

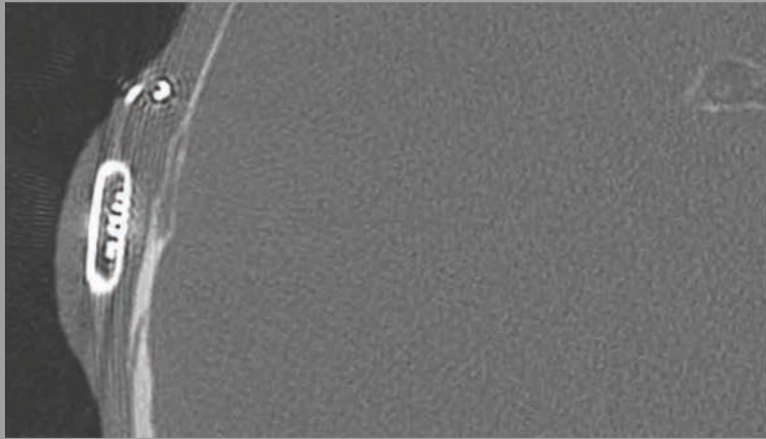
4/24/2014

Post-activation Audiogram



7/1/2015

CT Temporal Bone w/o contrast, R, axial



9/17/2019



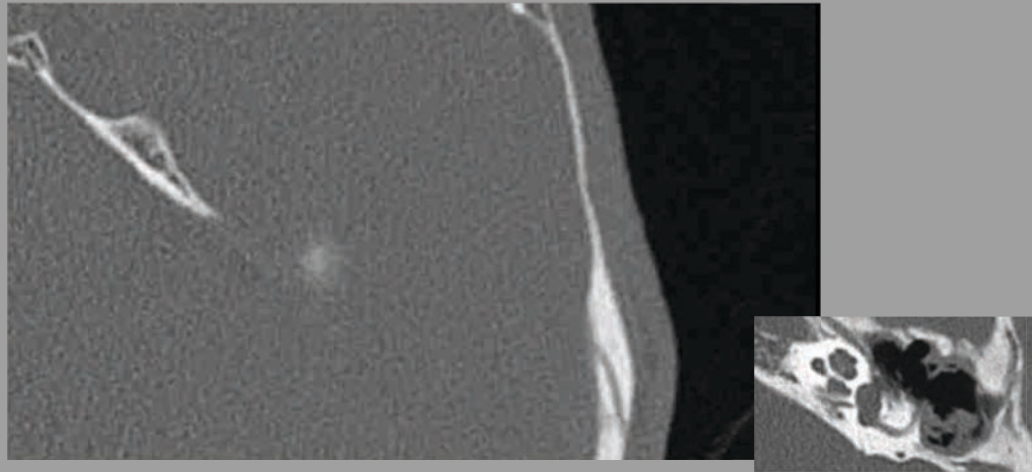
Scalp skin challenges



- Atrophic skin
- Multiple surgical incisions
- Alopecia
- Thin skull bone = prominence of CI package
- Low magnet strength



CT Temporal Bone w/o contrast, L, axial



7/3/2013 video

Left Obliteration Procedure

- BAHA removal and canal closure
- Extensive cholesteatoma throughout temporal bone
- Lateral semicircular canal fistula
- Cochlear fistula exposing the entire basal turn and basilar membrane
- Dehiscent carotid artery inferior to Eustachian tube
- Measurement electrode as a stent
- Obliteration with abdominal fat

2/5/2015

****After 3 months, patient was lost to follow up for 4 years****

Scalp Skin Challenges

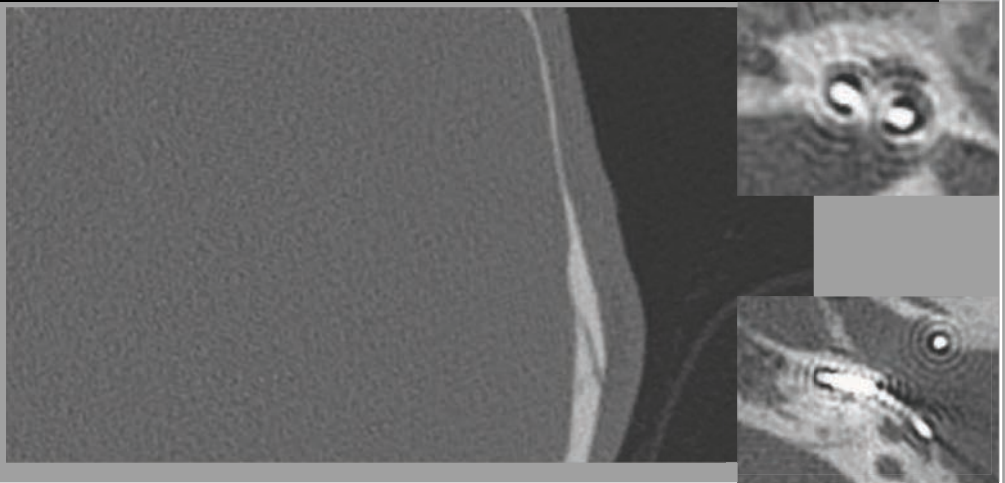


- thin, atrophic skin
- Alopecia
- Old surgical scars
- Thin skull bone



CT Temporal Bone w/o contrast, L, axial

Planning for second stage CI after COVID restrictions lifted



9/17/2019 video

Considerations

- Wound healing
 - S/p radiation = blood supply issues, prone to infections, poor/delayed healing
 - S/p multiple craniofacial and otologic procedures
 - Consultation with reconstructive team = consideration of introducing vascularized tissue
- Labyrinthitis/cochlear ossification
- Cochlear duct stenting
- Two-stage procedure:
 - Radiated field
 - Extremely aggressive cholesteatoma
- Surveillance
 - CT
 - DWI series – limited by CI

Considerations for CI with cholesteatoma

Petrosectomy and EAC closure

- Single vs two stage approach
 - Second stage allows second look for residual cholesteatoma
 - No difference in complications 1 vs 2 stage (Hunter/Wanna, 2016)
- Allowing the mastoid cavity/temporal bone to sterilize
 - 3-6 months between stages based on degree of infections
- Obliteration techniques
 - Closure of the EAC meatus
 - Palva type flap
 - Fat graft (not vascularized so not indicated for active suppuration/contamination)
 - Temporal parietal flap
 - Other local flaps
 - Free flaps = particularly useful when osteoradionecrosis is present
 - No difference among fat alone vs TP flap vs allograft fascia (Lyutenski/Lenarz, 2016)
- Open cavity techniques (electrode wire under skin) are prone to wire extrusion
 - Closure of EAC = fewer complications (Hunter/Wanna, 2016)

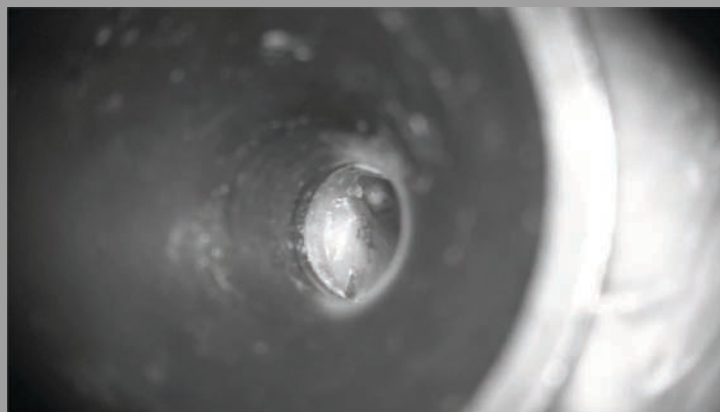
Considerations for CI with cholesteatoma

Petrosectomy and EAC closure

- Numerous small series and case reports confirm the utility of petrosectomy and CI for chronic ear disease: cholesteatoma, chronic otomastoiditis, inflammatory mastoiditis (e.g., histiocytosis/eosinophilic granuloma), severe tympanic retraction, unusual anatomy precluding standard CI surgical approach
- Results consistent with typical CI auditory/speech perception outcomes
- Complications include: recurrent cholesteatoma, infection, electrode wire extrusion, chronic infection requiring explantation/reimplantation
- Routine chronic otitis media with effusion or recurrent acute otitis media not an indication for petrosectomy/CI (managed with standard approaches, including antibiotics, tubes, commonly resolve after the mastoidectomy of CI)

Vashishth/Sanna, 2018

Cholesteatoma and CI – Case L.C.



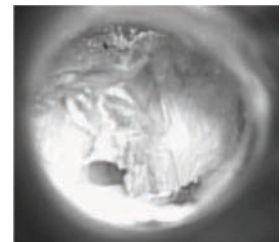
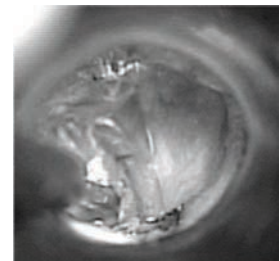
Cholesteatoma around cochlear implant electrode

9 Year old Male,
Bilateral congenital profound hearing loss
Status post bilateral sequential Cochlear Implants (age 11 and 16 months by a colleague surgeon), via cochleostomy
Right Contour CI24 RE
Left Contour Advance
Right electrode extrusion through the bony canal wall near the scutum into the external auditory canal with subsequent cholesteatoma requires tympanoplasty and mastoidectomy with explant and reimplant

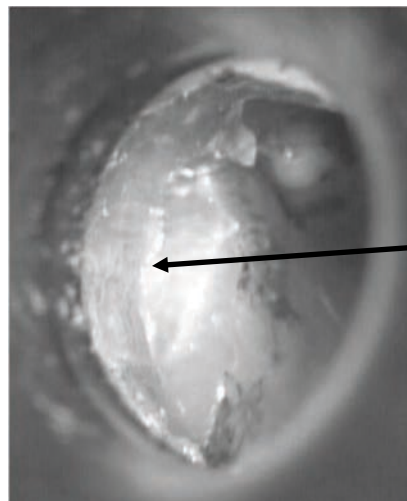


Surgeries timeline

2009 Right CI (CI24RE)
2010 Left CI (512 Contour Advance)
2011 Right Tympanoplasty (fascia), mastoidectomy, explantation with re-implant (CA)
“A previously placed right cochlear implant electrode array had eroded and extruded through the bony canal wall near the scutum into the external auditory canal and then reentered the middle ear through a tympanic membrane perforation. A stray portion of the electrode was sitting inside the external auditory canal and the tympanic membrane perforation was noted”
2012 Right tympanoplasty (perforation)
2013 Right transcanal cholesteatoma removal – TM retracted onto middle ear electrode wire
2014 Right examination and cleaning under anesthesia
“On the right ear, there was a crusting on the tympanic membrane that was retracted onto the cochlear implant wire. There was no exposure of the wire. The crusting on the retraction pocket was carefully removed. The wire was inspected and was seen to be going into the cochlea.”
2015 Right cartilage tympanoplasty
3-2018 Right examination and cleaning under anesthesia
7-2018 Right tympanoplasty and cholesteatoma excision



Pre Operative image

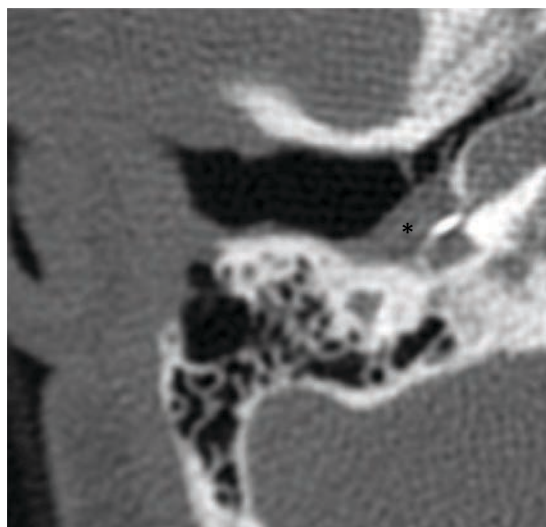


small sliver retraction

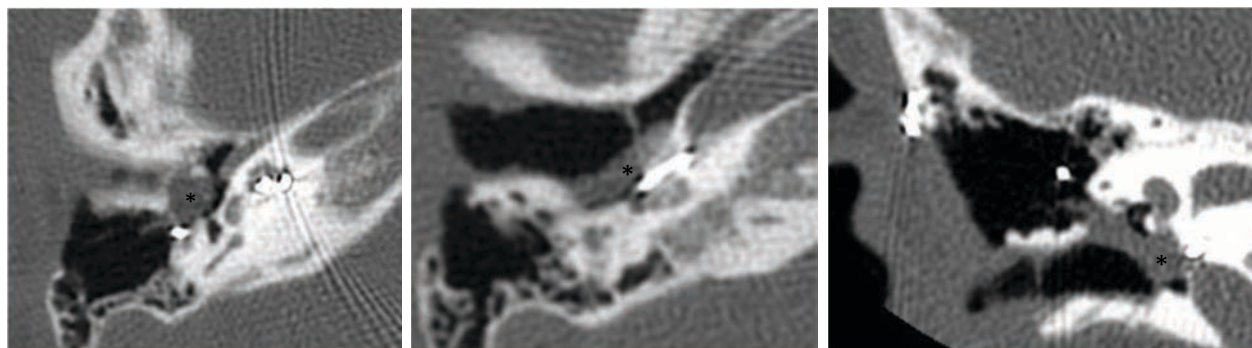
Pre Operative CT scan



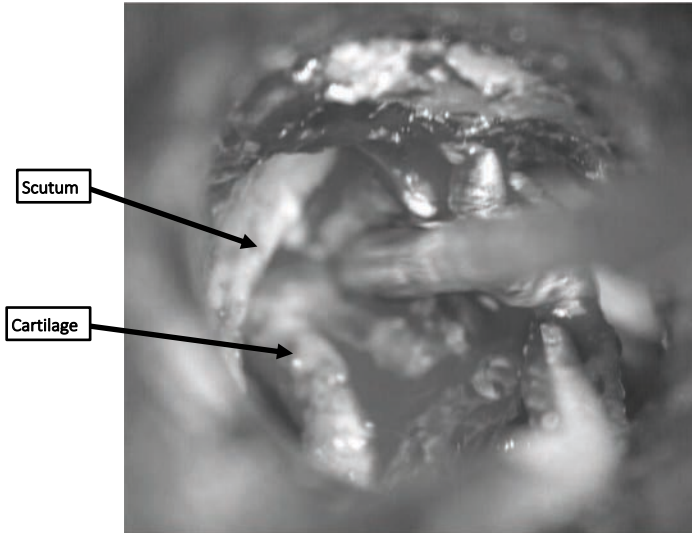
Pre Operative CT scan



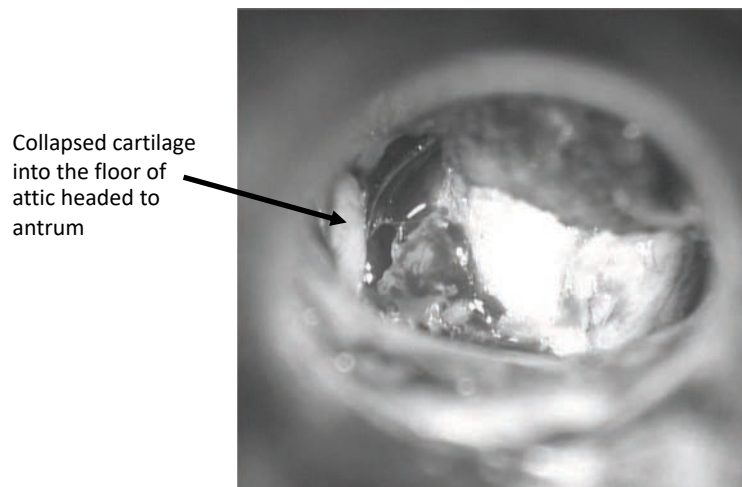
Pre Operative CT scan



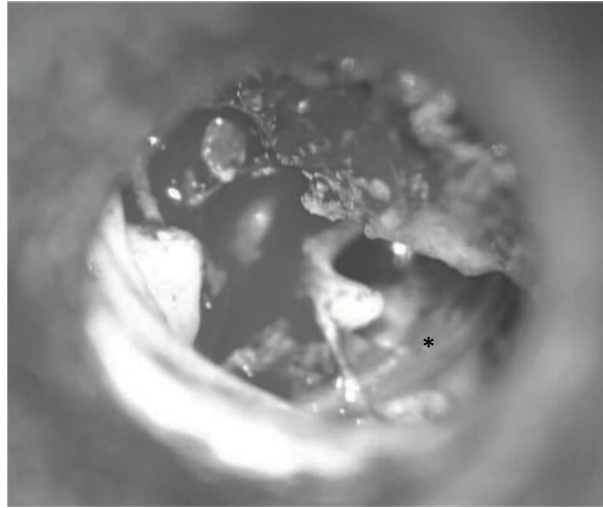
Intra Operative image show posterior superior cartilage and middle ear cholesteatoma around the electrode



Intra Operative image show posterior superior cartilage and middle ear cholesteatoma around the electrode



Intra Operative image show posterior superior cartilage and middle ear cholesteatoma around the electrode

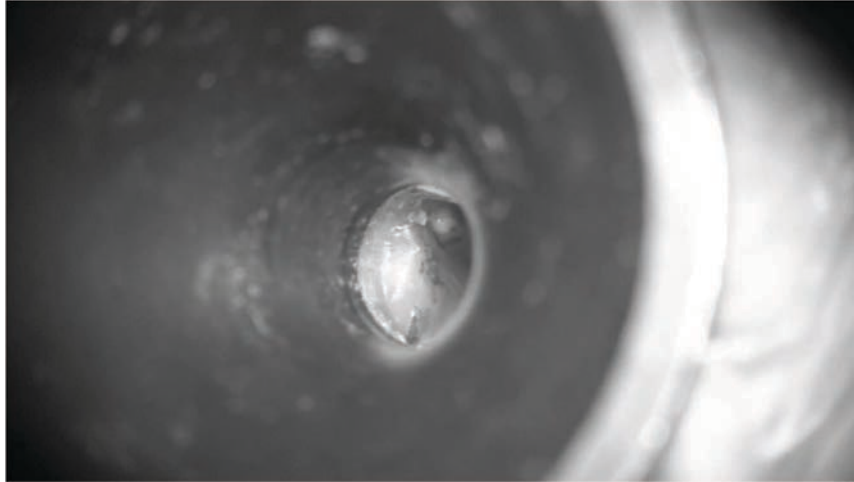


CT can underestimate extent of residual/recurrent cholesteatoma

Operation Clip

- The small sliver retraction of the tympanic membrane was excised to allow fresh tissue for healing and the cartilage graft of the tympanic membrane was mobilized.
- Extensive recurrent and residual cholesteatoma
- The allograft was placed medial to the tympanic membrane remnant and the tympanomeatal flap was then replaced

Operation Clip



Post Operative cochlear implant evaluation

Aided Thresholds:

	250Hz	500Hz	1000	2000	3000	4000	6000	8000	SAT	SRT
	z	z	HZ	Hz	Hz	Hz	Hz	Hz		
Right	20	20	20	15	20	20	20	20	/ba/ 0 /sh/ 5 /s/ 20	25

Post Operative cochlear implant evaluation

Speech discrimination testing::

Test	Condition	Ear\	Today's Results 9/10/18	Previous Results 10/02/17	Previous Results from 1/30/17	Previous Results from 7/6/16	Previous Results from 11/11/15
PBK words	Quiet 50dB HL/60dB SPL	Right	List 1 (1-25 words) 92% words 96% phone mes <i>Similar results</i>	List 1 (25-50 words) 80% words 93% phone mes <i>Similar results</i>	List 2 (25-50 words) 88% words 96% phone mes <i>Similar results</i>	List 3A 88% words 94% phone mes <i>Similar results</i>	List 1 92% words 97% phone mes

Post Operative cochlear implant evaluation

Speech discrimination testing::

Implanted Ear	250 Hz	500 Hz	1000 Hz	1500 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	SAT	SRT
Right	20	25	25	20	20	25	25	20	5 /ba/ 5 /sh/ 10 /s/	30
Left	20	20	25	25	25	25	25	25	5 /ba/ 10 /sh/ 15 /s/	25

Speech Perception Testing: The following tests of auditory speech perception were administered in the sound field (muffled or masked when necessary):

Condition/ 1/13/2020	Pedi AzBio (Quiet)	Pedi AzBio (+5 dB SNR)	CNC Words
Right Cochlear Implant	99% List 11	94% List 12	92% Words List 2 (words 1-25)
Left Cochlear Implant	99% List 10	96% List 13	88% Words List 2 (words 26-50)
Bilateral CI	99% List 15 Soft speech level 35 dB HL	97% List 14	100% Words List 4 (words 1-25)

Considerations: **General (specific to this case)** of tympanic retraction and chronic ear disease/cholesteatoma (distinct from uncomplicated CSOM with effusion)

- patient/parental concerns and desires (in this case do not want explantation or CWD approach)
- Functioning of the CI (consistent/performing well)
- Presence of active infection (none)
- Reliability of patient/family (excellent)
- Options: observation with cleaning, tympanoplasty (materials – fascia, allograft, **cartilage**), petrosectomy with closure of meatus/EAC + graft/flap (parents want the least invasive)
- Risk of recurrent/residual cholesteatoma (both in this case)
- Disease progression despite mastoidectomy
- Imaging: limitation of CT scan
- Multiple procedures/anesthetics
- Avoid dehiscence of scutum/posterior EAC wall during CI surgery
 - predispose to TM retraction
- Limited literature supports safety and efficacy of CI in chronic ear disease
 - Yoon, 2020
 - Rak et al, 2018
 - Vashishth/Sanna, 2018

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THANK



Cognition and Cochlear Implantation

Presenters:

Paul van de Heyning, MD, PhD

Aaron Moberly, MD

Cognition and Cochlear Implantation in Postlingual Older Adults with Profound Sensorineural Hearing Loss

Paul Van de Heyning

Griet Mertens, Vincent Van Rompaey, Annick Gilles,
Vedat Topsakal and Annes Claes

Univ. Dept Otolaryngology and Head and Neck Surgery
Antwerp University Hospital – University of Antwerp - Belgium



Disclosure:

Research, educational and travel grants from MED-EL and Cochlear and consultancy MED-EL



1

Hearing Loss and Cognition

HL, Cognition and CI

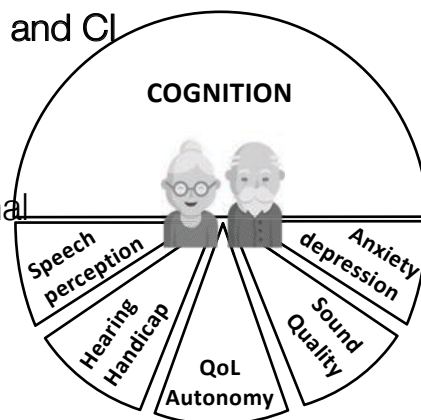
Assessment

Cross-sectional

Longitudinal

Multicenter

Conclusion



How old is old?

50 Y
55 Y
65 Y
70 Y
75 Y
80 Y
85 Y
90 Y

2

Hearing Loss and Cognition

HL, Cognition and CI

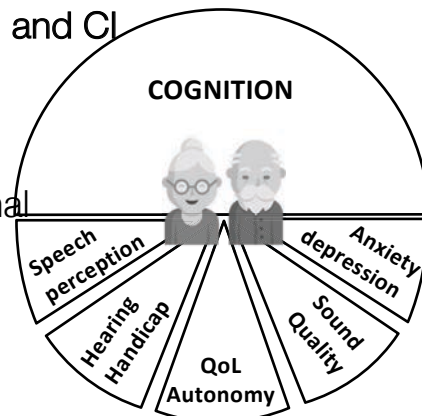
Assessment

Cross-sectional

Longitudinal

Multicenter

Conclusion



How old is old?

50 Y

55 Y

65 Y

70 Y

75 Y

80 Y

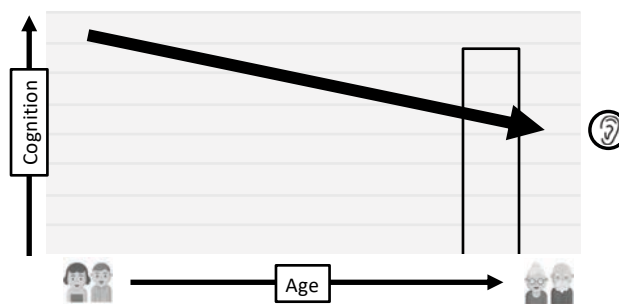
85 Y

90 Y

*Gallacher J et al Auditory threshold, phonologic demand, incident dementia. Neurology. 2012;79(15):1583-90.

3

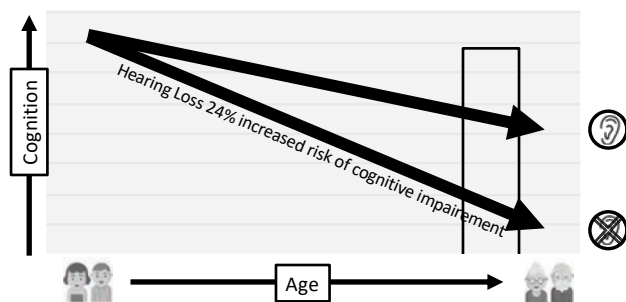
Hearing Loss and Cognition



Lin FR et al. Hearing loss and cognitive decline in older adults. JAMA Intern Med. 2013;173(4):293-9

4

Hearing Loss and Cognition



The hazard ratio for dementia was 4.94 (1.09-22.40) for severe hearing loss
The annual rates of decline in MME scores were 41% greater.

Lin FR et al. Hearing loss and incident dementia. Arch Neurol. 2011;68(2):214-20.

Lin FR et al. Hearing loss and cognitive decline in older adults. JAMA Intern Med. 2013;173(4):293-9

5

Hearing Loss and Cognition

The Lancet Commission on Dementia Prevention, Intervention, and Care

HL is a 9% potentially modifiable risk factor for dementia

(PAF: population attributable fraction)

Be ambitious about prevention of HL

Neurophysiopathology: association or causality?

- cognitive load of a vulnerable brain
- slower information processing*
- accelerated brain atrophy
- social disengagement and depression

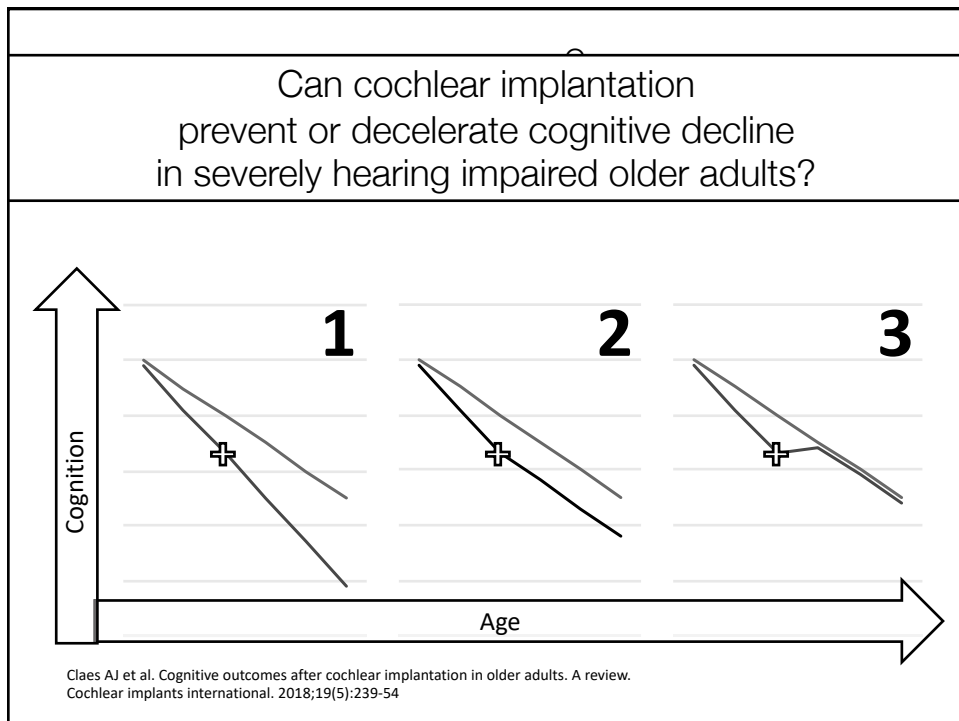
Livingston G et al. Dementia prevention, intervention, and care. Lancet. 2017;390(10113):2673-734

*Moberly A et al (2019). How Does Nonverbal Reasoning Affect Sentence Recognition in Adults with Cochlear Implants and Normal-Hearing Peers? Audiol Neurotol, 24, 127-138. doi:10.1159/000500699

6

Can cochlear implantation prevent or decelerate cognitive decline in severely hearing impaired older adults?

7



Can cochlear implantation prevent or decelerate cognitive decline in severely hearing impaired older adults?

Six cohort studies on cognitive effects of CI in older adults

1. Mosnier I et al. (2015): +
2. Cosetti M et al. (2016) +
3. Castiglione et al. (2016) +
4. Jayakody DM et al. (2017) +
5. Ambert-Dahan et al. (2017) +
6. Sonnet M. et al. (2017) = (but + executive function)

Level 4 EBM of improved cognitive function 12 mths- 5 Y after CI

Claes AJ et al. Cognitive outcomes after cochlear implantation in older adults. A review. Cochlear implants international. 2018;19(5):239-54

continued

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ONLINE

Hearing Loss and Cognition

Studies difficult to compare: many study designs

Many different tests with varying scope:

MME, MOCA, CODEX, CANTAB, RBANS, d2, Trailmaking,...

Original cognitive tests not for hearing impaired individuals

better test due to better understanding?

hence adaptation for hearing impaired persons e.g. HI-MOCA*

Control for practice effects, bias and ceiling effects

limited sensitivity to change of some tests

*Lin VY et al. Development of cognitive screening test for the severely hearing impaired: Hearing-impaired MoCA. The Laryngoscope. 2017;127 Suppl 1:S4-S11.

10

continued

Hearing Loss and Cognition

HL, Cognition and CI

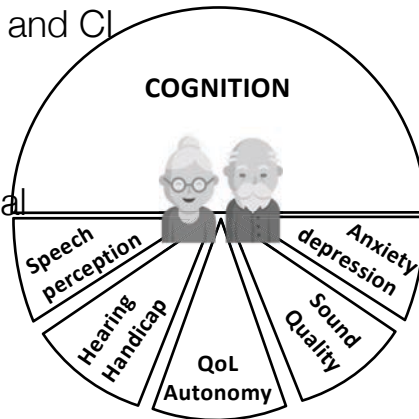
Assessment

Cross-sectional

Longitudinal

Multicenter

Conclusion



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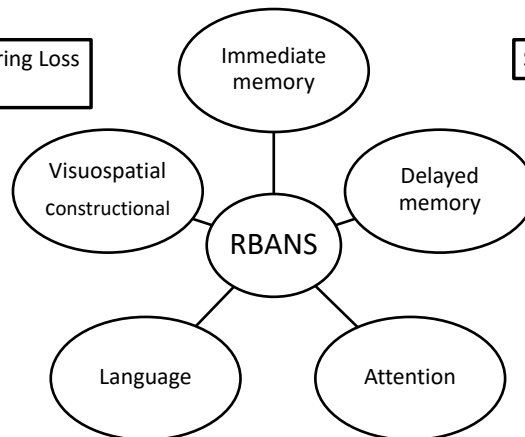
COGNITIVE TEST BATTERY

RBANS and RBANS-H

Repeatable Battery for the Assessment of Neuropsychological Status

Adapted for Hearing Loss
RBANS-H

Score 100

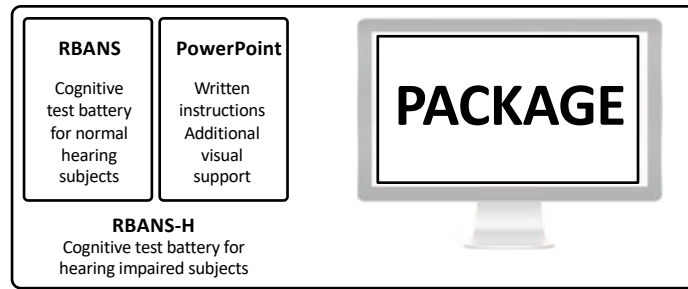


Randolph, C. (2012). *RBANS Update: Repeatable Battery for the Assessment of Neuropsychological Status*. NCS Pearson
Claes A et al., RBANS-H before and after Cochlear Implantation: A Protocol for a Prospective, Longitudinal Cohort Study. 2016,
doi:10.3389/fnins.2016.00512

4

RBANS-H

Repeatable Battery for the Assessment of Neuropsychological Status
For Hearing Impaired People



Claes A et al., RBANS-H before and after Cochlear Implantation:
A Protocol for a Prospective, Longitudinal Cohort Study. 2016, doi:10.3389/fnins.2016.00512

13

RBANS-H

Repeatable Battery for the Assessment of Neuropsychological Status
For Hearing Impaired People

One total score of cognitive function ($m = 100$, $SD = 15$)

Normative data (50-59; 60-69; 70-79; 80-89)

Extended differentiation in level of cognition: normal to moderately severe dementia; no ceiling effect

Index scores per cognitive domain ($m = 100$, $SD = 15$)

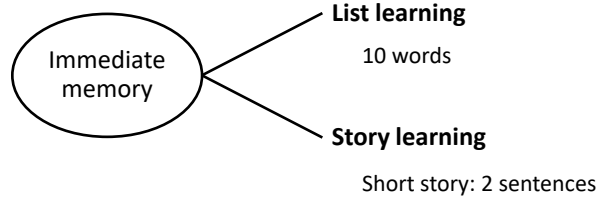
Sensitivity to change (confidence intervals)

Suitable for clinical setting: takes 30 min.

Claes A et al., RBANS-H before and after Cochlear Implantation:
A Protocol for a Prospective, Longitudinal Cohort Study. 2016, doi:10.3389/fnins.2016.00512

14

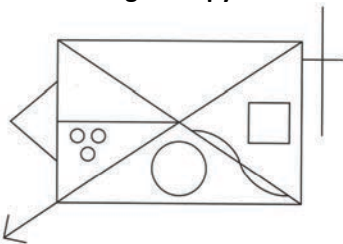
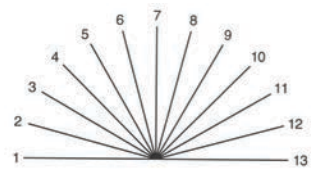
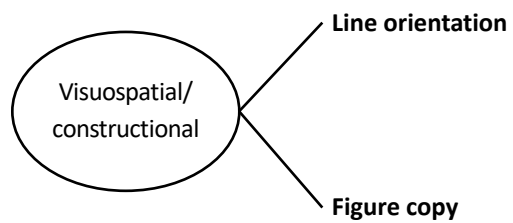
COGNITIVE TEST BATTERY



Knowledge / Experience / Care

Universiteit Antwerpen / UZA

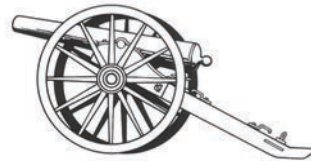
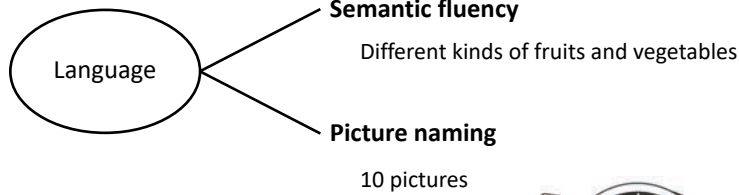
COGNITIVE TEST BATTERY



Knowledge / Experience / Care

Universiteit Antwerpen / UZA

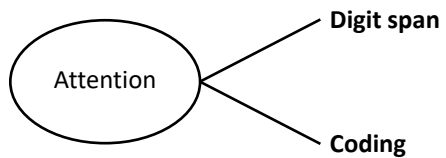
COGNITIVE TEST BATTERY



Knowledge / Experience / Care

Universiteit Antwerpen / UZA

COGNITIVE TEST BATTERY



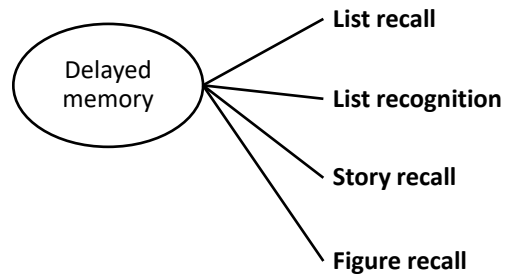
C	^	=	J	V	>	+	L	T
1	2	3	4	5	6	7	8	9

=	T	C	^	+	J	L	>	V	=	T	^	>	+
T	>	V	T	=	^	C	+	J	^	L	C	+	J

Knowledge / Experience / Care

Universiteit Antwerpen / UZA

COGNITIVE TEST BATTERY



Knowledge / Experience / Care

Universiteit Antwerpen / UZA

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Hearing Loss and Cognition

HL, Cognition and CI

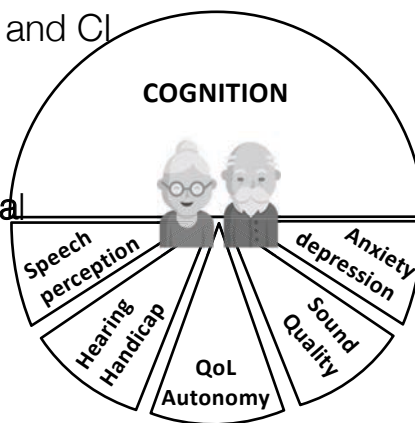
Assessment

Cross-sectional

Longitudinal

Multicenter

Conclusion

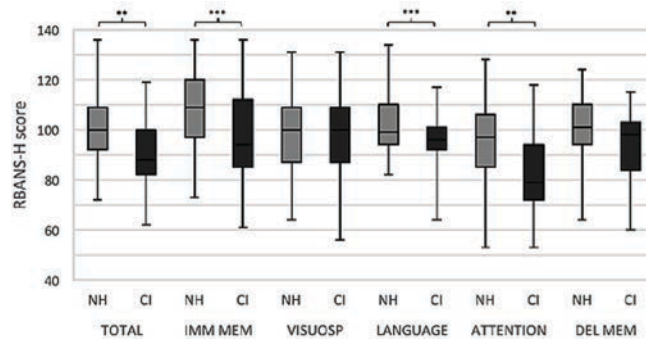


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continued

RBANS-H performance in older CI recipients: Cross-sectional data

- 61 postlingual Bil profound HL Pt >55 year (mean age: 72.0 ($\pm$ 8.3) year) and more that 1 Y CI use (mean: 9.8 ($\pm$ 5.7) year)
- 81 control participants (mean age: 69.4 ($\pm$ 10.7) with normal hearing for age and sex)
- Correction for age, gender and education



Claes AJ, et al.. Impaired Cognitive Functioning in Cochlear Implant Recipients Over the Age of 55 Years: A Cross-Sectional Study Using the RBANS-H. *Front Neurosci.* 2018;12:580

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RBANS-H performance in older CI recipients: Cross-sectional data

- Total score: CI 0.5 SD poorer (after correction age, gender and education)
 - Domains: ($p = 0.001$) Immediate memory, Language and Attention
 - Positive correlation between Cognition and SRT also for controls
- Mosnier I (2018): MCI is highly prevalent in older adults with profound hearing loss with and without CI.
- Huber M (2020): Patients with severe to profound HL suffer widespread effects on cognition

Claes AJ, et al.. Impaired Cognitive Functioning in Cochlear Implant Recipients Over the Age of 55 Years: A Cross-Sectional Study Using the RBANS-H. *Front Neurosci.* 2018;12:580
 Mosnier, I et al. (2018). Long-Term Cognitive Prognosis of Profoundly Deaf Older Adults After Hearing Rehabilitation Using Cochlear Implants. *J Am Geriatr Soc*, 66(8), 1553-1561. doi:10.1111/jgs.15445
 Huber, M. (2020). Cognition in older adults with severe to profound sensorineural hearing loss compared to peers with normal hearing for age. *Int J Audiol*, 59(4), 254-262. doi:10.1080/14992027.2019.1687947

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Hearing Loss and Cognition

HL, Cognition and CI

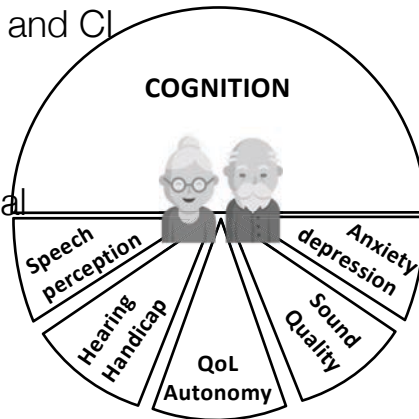
Assessment

Cross-sectional

Longitudinal

Multicenter

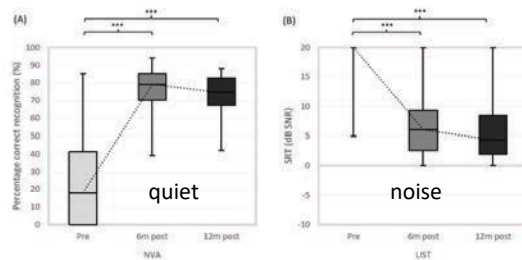
Conclusion



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RBANS-H performance before and after cochlear implantation: Longitudinal data

- n= 20 (11 ♂ - 9 ♀) Age: ≥ 55 (median: 71 [55 – 85 year])
- Post-lingually and bilaterally hearing impaired (PTA: ≥ 85 dB HL); Assessment 6 months and 12 months

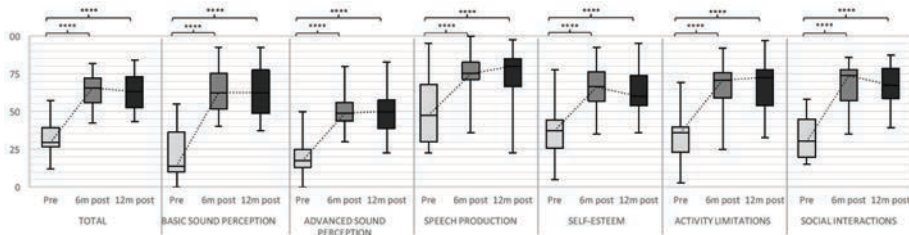


Claes AJ et al. Cognitive Performance of Severely Hearing-impaired Older Adults Before and after Cochlear Implantation: Longitudinal Cohort Study Using the RBANS-H. *Otology & neurotology*. 2018;39(9):e765-e73

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RBANS-H performance before and after cochlear implantation: Longitudinal data

NCIQ before and after cochlear implantation

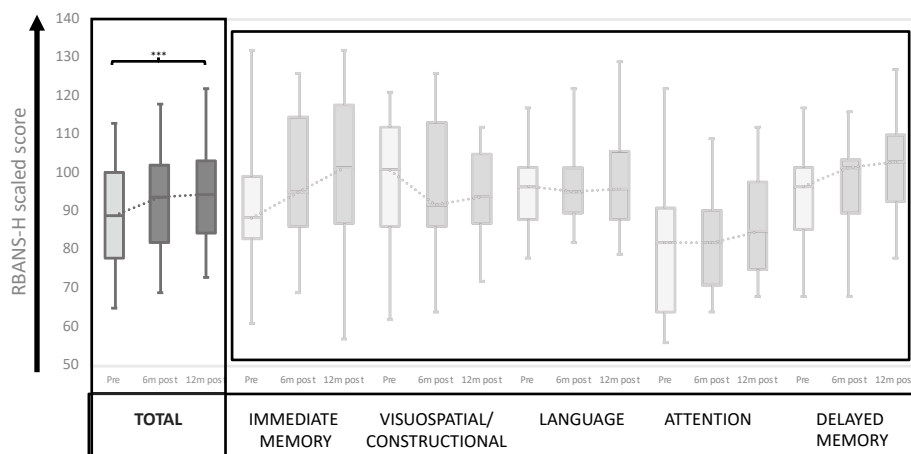


Claes AJ et al. Cognitive Performance of Severely Hearing-impaired Older Adults Before and after Cochlear Implantation: Longitudinal Cohort Study Using the RBANS-H. *Otology & neurotology*. 2018;39(9):e765-e73

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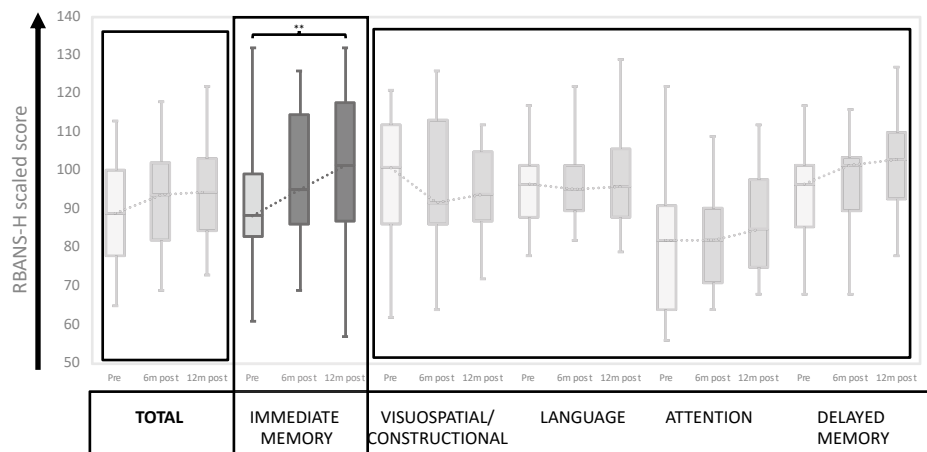
RBANS-H performance before and after cochlear implantation: Longitudinal data

Assessments: pre-op, 6M post-op, 12M post-op.



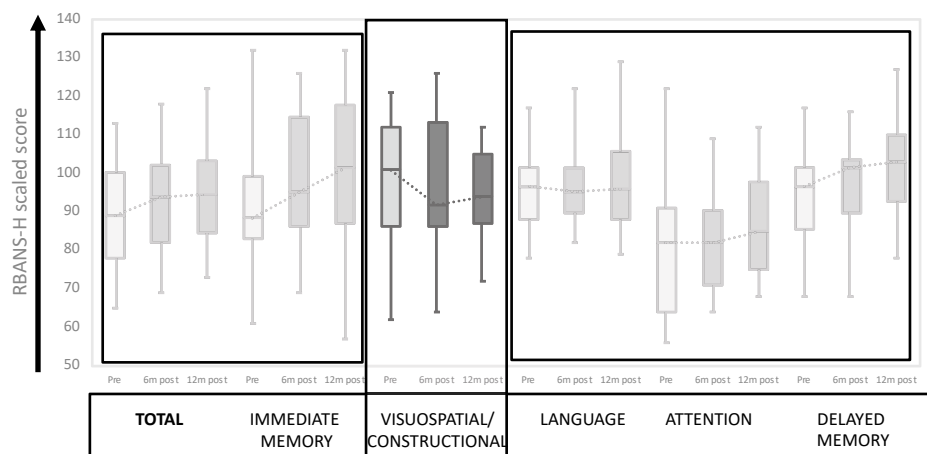
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Assessments: pre-op, 6M post-op, 12M post-op.



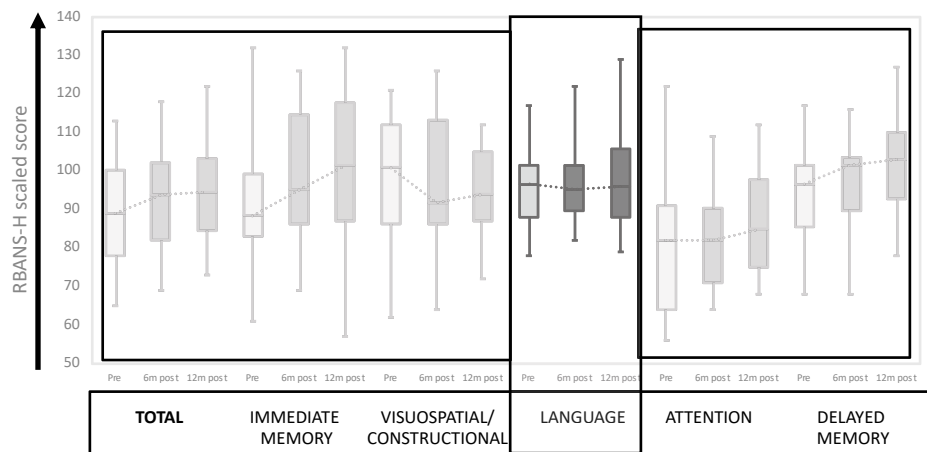
RBANS-H performance before and after cochlear implantation: Longitudinal data

Assessments: pre-op, 6M post-op, 12M post-op.



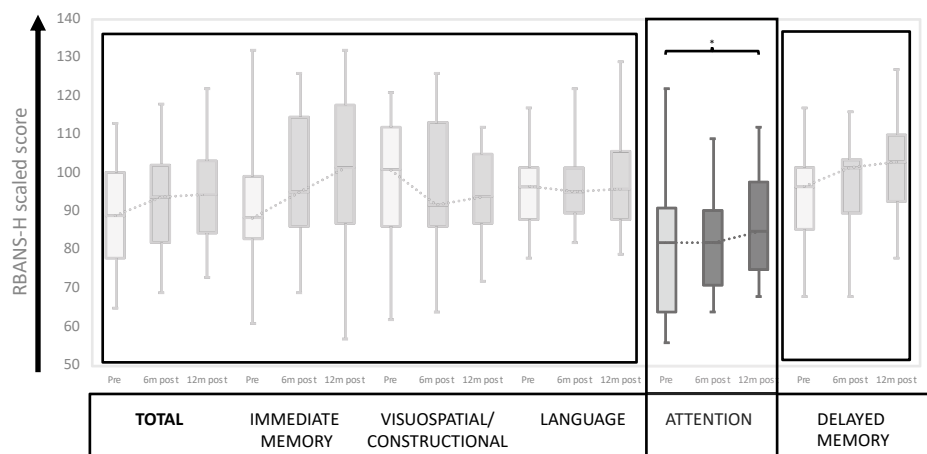
RBANS-H performance before and after cochlear implantation: Longitudinal data

Assessments: pre-op, 6M post-op, 12M post-op.



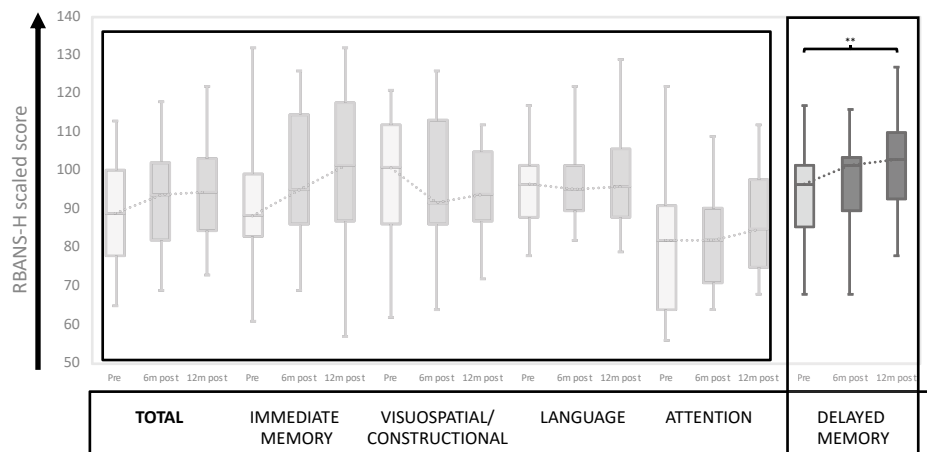
RBANS-H performance before and after cochlear implantation: Longitudinal data

Assessments: pre-op, 6M post-op, 12M post-op.



RBANS-H performance before and after cochlear implantation: Longitudinal data

Assessments: pre-op, 6M post-op, 12M post-op.



continued

ACI
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COCHLEAR
IMPLANT
ALLIANCE

CI2020
ONLINE

RBANS-H performance before and after cochlear implantation: Longitudinal data

Speech perception in quiet and in noise improved significantly after 6 months.
Significant improvement in overall cognition after 12 months of CI usage.

Domain level: significant improvements
immediate and delayed memory
attention domain

Mosnier I (2018): prospective cohort 70 pt follow-up 5.5-8.5 y):
observed a low rate of progression to dementia, and cognitive function improved
in some individuals with MCI at baseline.

Claes AJ et al. Cognitive Performance of Severely Hearing-impaired Older Adults Before and after Cochlear Implantation: Otology & neurology. 2018;39(9):e765-e73
Mosnier, I et al. (2018). Long-Term Cognitive Prognosis of Profoundly Deaf Older Adults After Hearing Rehabilitation Using Cochlear Implants. *J Am Geriatr Soc*, 66(8), 1553-1561. doi:10.1111/jgs.15445

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Hearing Loss and Cognition

HL, Cognition and CI

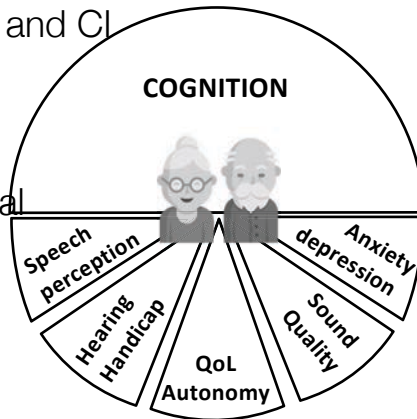
Assessment

Cross-sectional

Longitudinal

Multicenter

Conclusion

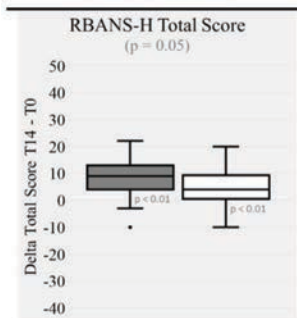


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COGNITIVE IMPROVEMENT AFTER COCHLEAR IMPLANTATION IN OLDER ADULTS: A PROSPECTIVE, LONGITUDINAL, CONTROLLED, MULTICENTER STUDY

■ Intervention group (Grey)

□ Control group (White)



24 pt with CI (grey)

vs

24 pt no CI (white)

Matched for

HL, age, gender, education

! Cognitive improvement in some domains also in control patients

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COGNITIVE IMPROVEMENT AFTER COCHLEAR IMPLANTATION IN OLDER ADULTS: LITERATURE

- Increased neurocognitive abilities at 6 months and 12 months (Volter C 2018; prospective cohort 60 pt)
- Patients with lower baseline cognitive abilities improved the most (Zahn K 2020; prospective cohort; 19 pt)
- Vestibular loss, on the other hand, was linked to worse performance on the attention subscale (Dobbels B 2019; case-control 64pt vs 83 normal control)

Volter C, et al. Can cochlear implantation improve neurocognition in the aging population? Clin Interv Aging. 2018;13:701-12

Zahn K, et al. Cognitive Functions in Adults Receiving Cochlear Implants: Predictors of Speech Recognition and Changes After Implantation. Otol Neurotol. 2020;41(3), e322-e329

Dobbels B, et al. Cognitive Function in Acquired Bilateral Vestibulopathy: A Cross-Sectional Study on Cognition, Hearing, and Vestibular Loss. Front Neurosci. 2019; 13, 340. doi:10.3389/fnins.2019.00340

35

Hearing Loss and Cognition

HL, Cognition and CI

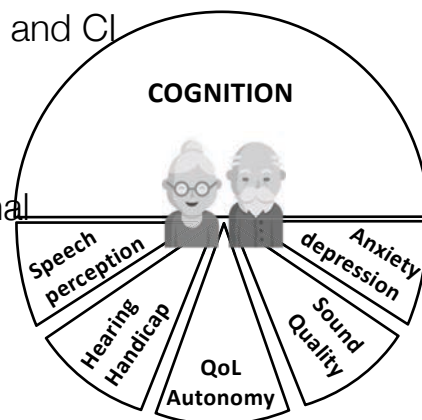
Assessment

Cross-sectional

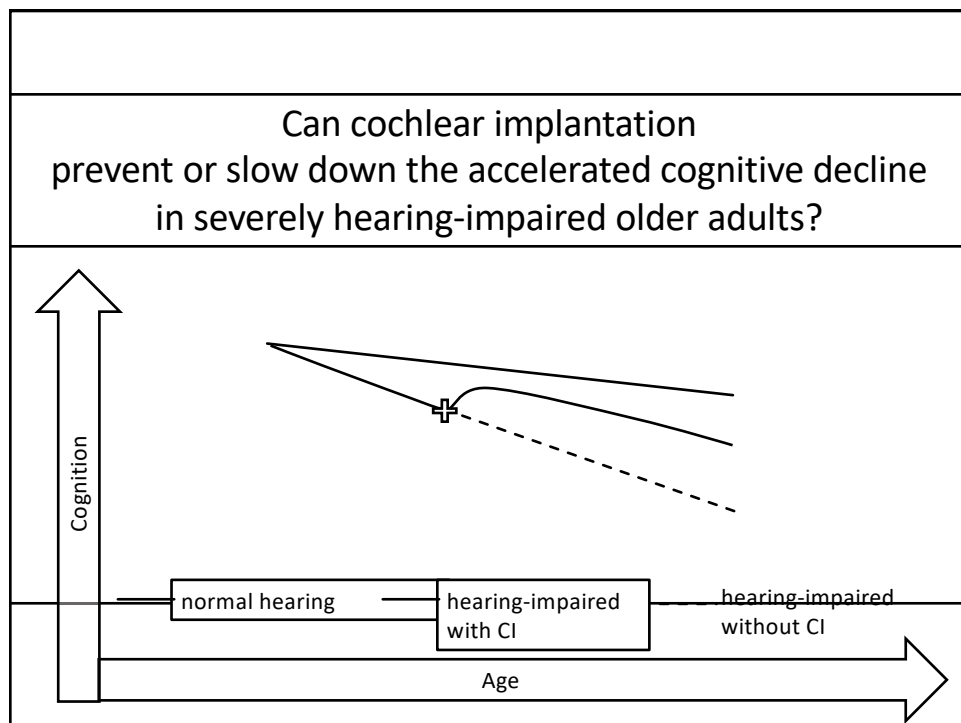
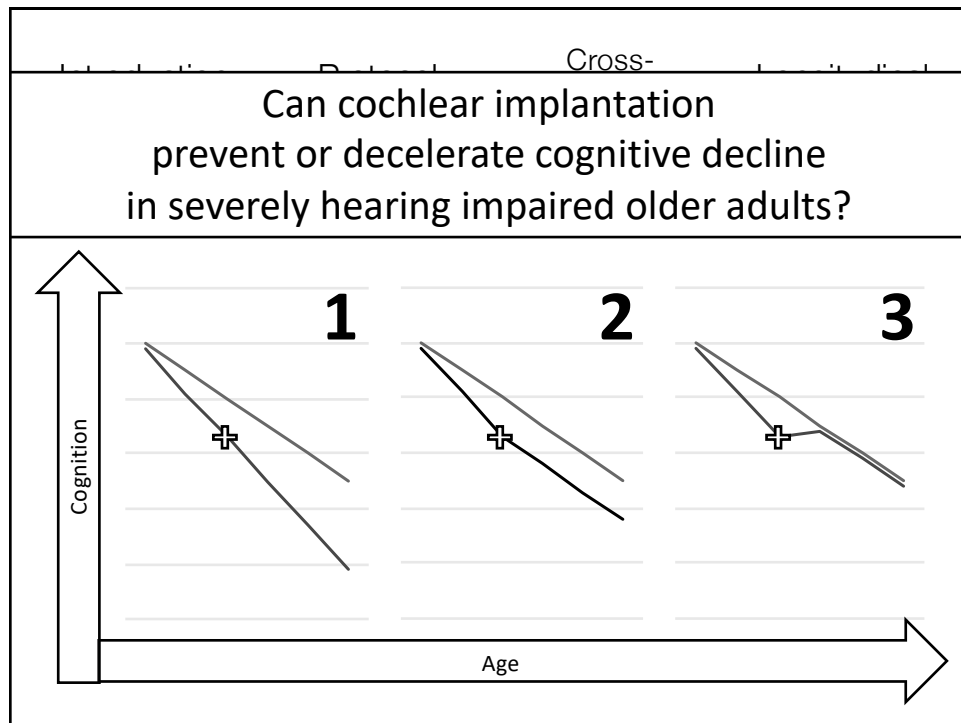
Longitudinal

Multicenter

Conclusion



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Cognition and Cochlear Implantation in postlingual older adults with profound sensorineural hearing loss

1. Intervention with a CI improves cognitive functioning (domain 'Attention' in particular): increasing evidence. But more evidence needed.
 - Be aware of insensitive or inappropriate tests !
2. CI recipients performed significantly poorer than the NH older adults
3. The cognitive functioning of a CI candidate and CI recipient has to be taken into account to optimize postoperative rehabilitation with cognitive rehab.
4. It takes 12 months after implantation before evidence arises for an improvement in subdomains of cognitive functioning
5. Lancet commission on dementia: be ambitious in preventing hearing loss.

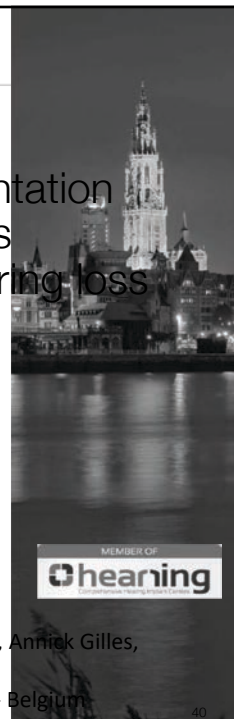
Deal et al. Hearing treatment for reducing cognitive decline: Design and methods of the Aging and Cognitive Health Evaluation in Elders randomized controlled trial. *Alzheimers Dement* (N Y)2018; 4:499-507

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Cognition and Cochlear Implantation in postlingual older adults with profound sensorineural hearing loss

Thank You for Your Attention

Warm Wishes from Antwerp



40

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Signal Quality Impacts the Role of Cognition during Speech Recognition by Adults with Cochlear Implants

Aaron C. Moberly, M.D.; Kara J. Vasil, Au.D.; Jessica Lewis, B.A.; Christin Ray, Ph.D.,
CCC-SLP; Terrin N. Tamati, Ph.D.

The Ohio State University Wexner Medical Center

1

Variability in Adult CI Outcomes

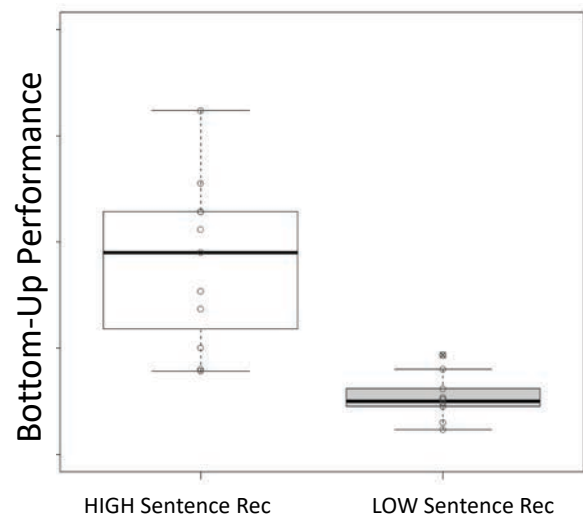
- Continues to be a dilemma for clinicians and researchers
- Most previous clinical research has focused on demographic factors (age, duration of hearing loss, severity of hearing loss, use of hearing aid...)
- More direct impact:
 - “Bottom-up” signal quality
 - “Top-down” cognitive-linguistic functions
- But how do these work together to explain outcomes?

2

Hypothesis 1

- Tapping into top-down processes requires sufficient bottom-up processing
- The better the bottom-up processing, the more top-down processing can contribute to speech recognition

3



4

Hypothesis 2

- Top-down processes contribute the most to speech recognition at intermediate degrees of bottom-up processing
- With very poor bottom-up: signal is too degraded to work with and top-down processes cannot contribute
- With very good bottom-up: signal is sufficiently clear that top-down processes are not needed

5

Bottom-up

- Spectro-temporal “resolution” or processing
 - Spectral-Temporally Modulated Ripple Test (SMRT) (Aronoff & Landsberger, 2013)
 - 3 alternative forced-choice task
 - Ripple-resolution threshold

6

SMRT considerations

- Several groups have reported on limitations of interpreting SMRT scores > 2.1 RPO (O'Brien & Winn, 2017; DiNino & Arenberg, 2018; Resnick et al., 2020)
 - CI (Cochlear) cannot encode > 2.1 RPO
 - Spectral Aliasing
 - Spectral warping
 - Modulation depth saturation
- One solution is to analyze participants with SMRT scores > 2.1 RPO all as 2.1 RPO.

7

Top-down

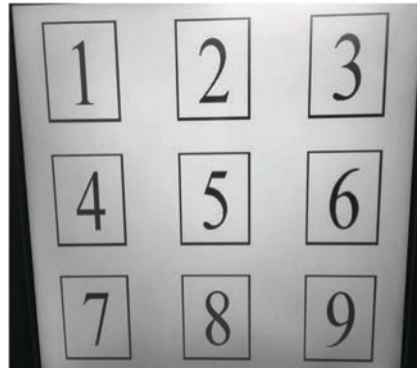
- Neurocognitive tests (visual)
 - Working memory capacity
 - Information-processing speed
 - Inhibitory control
 - Nonverbal reasoning

8

Working Memory



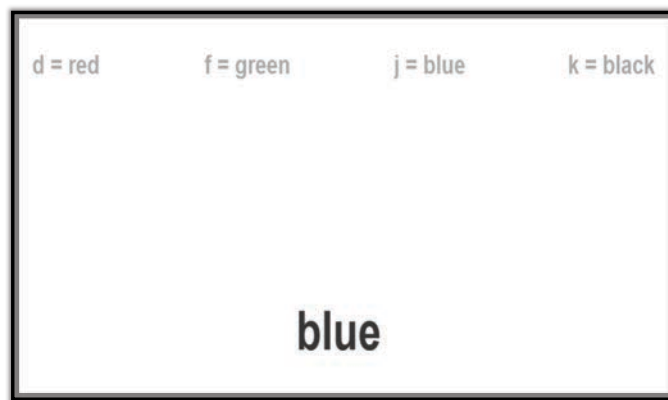
Visual Digit Span



9

Speed and Inhibitory Control

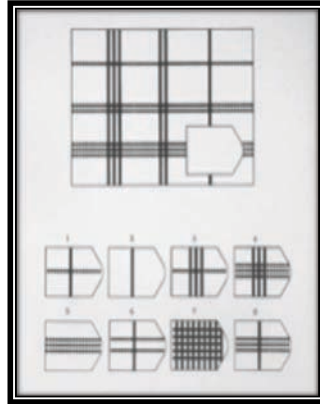
Computerized Stroop



10

Nonverbal Reasoning

Raven's Progressive Matrices



11

Research Question:

- How do bottom-up and top-down functions interact during speech recognition for CI users?

12

Study hypothesis:

- Top-down processes contribute differentially to speech recognition outcomes depending on the quality of bottom-up input

13

Participants

51 CI patients

- Mean age 66.8 years (SD 9.8, range 45-87)
- Mean hearing loss duration 38.4 years (SD 19.0, range 4-76)
- Mean better-ear PTA was 94.5 dB (SD 23.7 dB)
- All postlingually deaf

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Methods

Measures

- Demographic/Audiologic data
- SMRT (Bottom-up)
- Digit Span, Stroop, Raven's (Top-down)
- Speech Recognition
 - CID W22 Words
 - Harvard Standard Sentences
 - PRESTO Sentences

15

Analyses

Group of 51 CI users was divided into three groups based on SMRT score:

“low”: < 1.3 RPO

“intermediate”: > 1.3 but < 2.1 RPO

“high”: > 2.1 RPO

Separate Pearson correlation analyses for each group between speech recognition and top-down scores

16

Results – Group Means Demographic/Audiologic Data

Measure	Group			ANOVA p-value
	Low-SMRT (N = 16)	Intermediate-SMRT (N = 17)	High-SMRT (N = 18)	
	Mean (SD)	Mean (SD)	Mean (SD)	
SMRT (RPO)	.92 (.23)	1.6 (.22)	3.7 (1.1)	<.001
Age (years)	66.9 (9.4)	68.5 (10.1)	65.2 (10.2)	.62
SES	27.3 (18.6)	22.7 (14.4)	27.6 (11.1)	.58
Reading (standard score)	92.4 (9.4)	95.3 (11.5)	103.6 (12.4)	.014
MMSE (raw score)	28.4 (1.4)	28.9 (1.1)	28.8 (1.3)	.50
Residual PTA (dB HL)	98.5 (18.9)	95.8 (24.3)	89.4 (27.7)	.56
Duration Hearing Loss (years)	51.0 (17.5)	29.6 (17.1)	35.1 (16.6)	.002
Duration CI Use (years)	8.9 (8.7)	5.3 (3.9)	5.9 (4.4)	.20

17

Results – Group Means Neurocognitive Measures

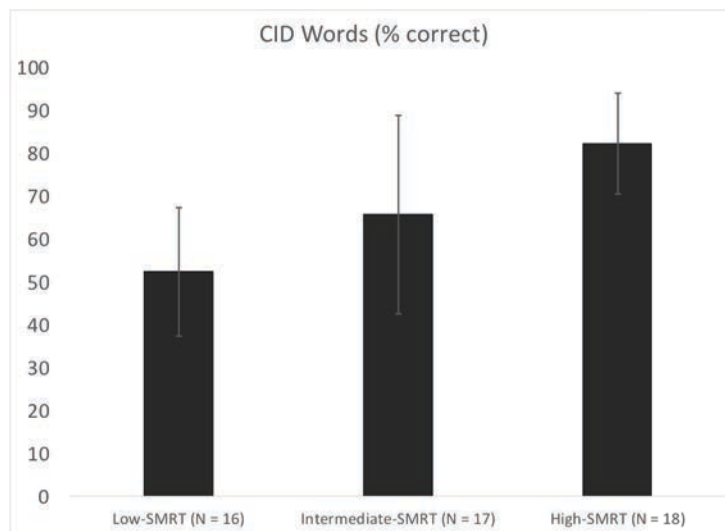
Measure	Group			ANOVA p-value
	Low-SMRT (N = 16)	Intermediate-SMRT (N = 17)	High-SMRT (N = 18)	
	Mean (SD)	Mean (SD)	Mean (SD)	
Working Memory (score)	40.5 (19.8)	36.9 (11.0)	47.1 (18.2)	.20
Speed (msec)	1279 (424)	1315 (317)	1215 (545)	.79
Inhibition (msec)	1801 (1276)	1728 (573)	1548 (626)	.68
Concentration (msec)	1338 (513)	1391 (355)	1275 (474)	.75
Nonverbal Reasoning (score)	9.6 (4.1)	9.2 (3.8)	11.8 (6.1)	.22

18

Results – Group Means Speech Recognition Measures

Measure	Group			ANOVA p-value
	Low-SMRT (N = 16)	Intermediate-SMRT (N = 17)	High-SMRT (N = 18)	
	Mean (SD)	Mean (SD)	Mean (SD)	
CID Words (% correct)	52.5 (15.0)	65.9 (23.1)	82.5 (11.8)	< .001
Harvard Sentences (% words)	63.0 (18.7)	77.5 (16.5)	82.7 (11.1)	.002
PRESTO Sentences (% key words)	41.9 (16.7)	57.7 (16.6)	73.1 (18.7)	<.001

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Results – Correlations Low SMRT Group

Speech Measure	Working Memory (score)	Top-down Measure			Nonverbal Reasoning (score)
		Speed (msec)	Inhibition (msec)	Concentration (msec)	
CID Words (% correct)	-.27	-.08	-.26	-.04	.53
Harvard Sentences (% words)	-.01	-.02	-.10	.12	.25
PRESTO Sentences (% key words)	-.21	.17	.11	.27	.16

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Results – Correlations Intermediate SMRT Group

Speech Measure	Working Memory (score)	Top-down Measure			Nonverbal Reasoning (score)
		Speed (msec)	Inhibition (msec)	Concentration (msec)	
CID Words (% correct)	.25	.08	.06	-.01	.23
Harvard Sentences (% words)	.57	-.16	-.30	-.22	.24
PRESTO Sentences (% key words)	.46	-.11	-.22	-.34	.24

22

Results – Correlations High SMRT Group

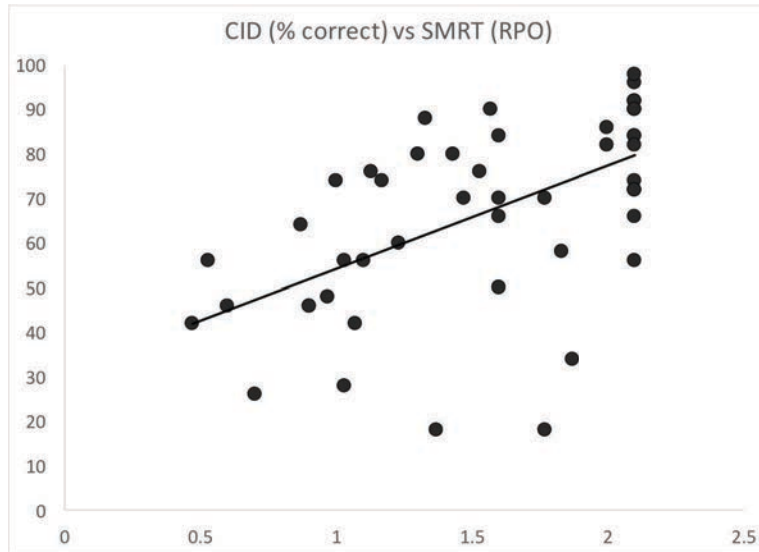
Speech Measure	Working Memory (score)	Top-down Measure			Nonverbal Reasoning (score)
		Speed (msec)	Inhibition (msec)	Concentration (msec)	
CID Words (% correct)	-.09	-.61	-.66	-.58	.44
Harvard Sentences (% words)	-.09	-.87	-.84	-.80	.57
PRESTO Sentences (% key words)	-.11	-.75	-.72	-.67	.53

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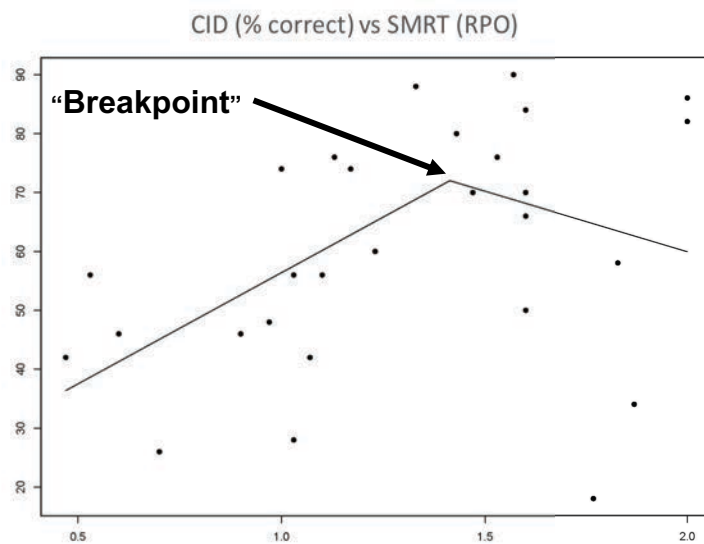
Results – Correlations with corrected SMRT scores

Speech Measure	SMRT (RPO) <i>r</i> value
CID Words (% correct)	.57
Harvard Sentences (% words)	.51
PRESTO Sentences (% key words)	.62

24



25



26

Discussion and Conclusions

Neurocognitive functions do appear to contribute differentially to speech recognition based on degree of bottom-up degradation

Low SMRT – Nonverbal Reasoning

Intermediate SMRT – Working Memory Capacity

High SMRT – Multiple functions

27

Discussion and Conclusions

Neurocognitive functions do appear to contribute differentially to speech recognition based on degree of bottom-up degradation

Low SMRT – Nonverbal Reasoning

Intermediate SMRT – Working Memory Capacity

High SMRT – Multiple functions

How do we interpret high SMRT scores >2.1 RPO?

28

Discussion and Conclusions

Neurocognitive functions do appear to contribute differentially to speech recognition based on degree of bottom-up degradation

Low SMRT – Nonverbal Reasoning

Intermediate SMRT – Working Memory Capacity

High SMRT – Multiple functions

How do we interpret high SMRT scores >2.1 RPO?

SMRT correlates strongly with all speech recognition measures in CI users

29

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Arthur Broadstock
Natalie Safdar
Jamie Kuess
Taylor Wucinich

30

Questions?

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Bimodal, Bilateral, and Electric-Acoustic Stimulation

Presenters:

Rene Gifford, PhD

Bruce J. Gantz, MD

Clinical determination of bimodal vs. bilateral cochlear implant candidacy

René Gifford, Ph.D.

Department of Hearing and Speech Science
Vanderbilt University Medical Center

VANDERBILT UNIVERSITY
MEDICAL CENTER



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Alejandro Rivas, MD
Matt O'Malley, MD
Christopher Wootten, MD
Frank Virgin, MD



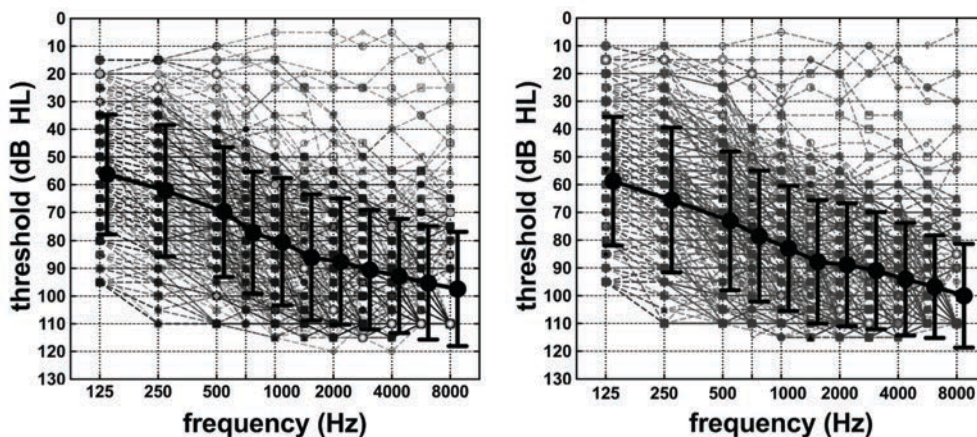
NIDCD
National Institute on Deafness and Other Communication Disorders

Holder et al. (2018). Trends Hear, 22: 1-16.

- **Purpose:** characterize auditory profile of adults presenting for preop CI eval
- n = 287 adults
 - 2-year period
 - 2013-2015

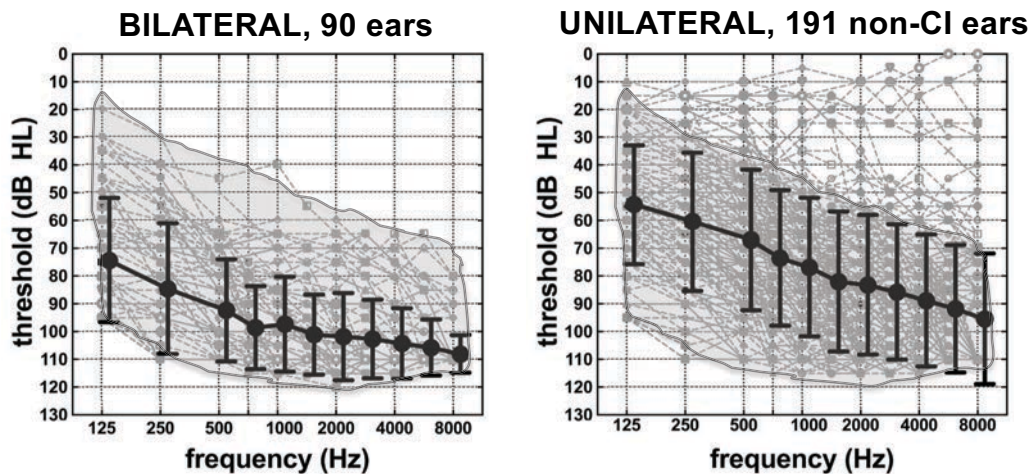
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Holder et al. (2018). Trends Hear, 22: 1-16.



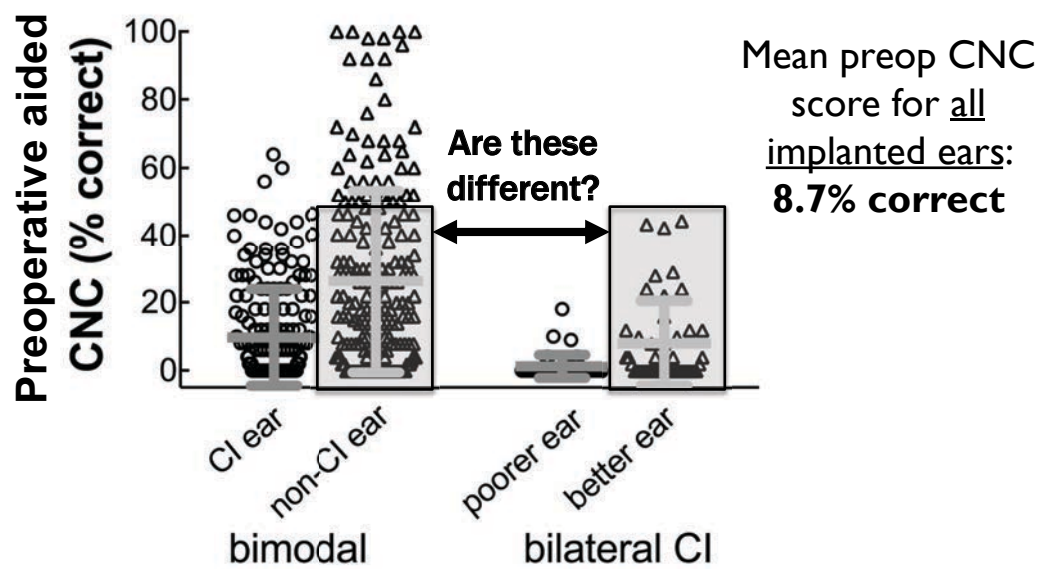
273 of 287 (95%) met CI candidacy, 236 pursued CI
191 unilateral, 45 bilateral

Holder et al. (2018). Trends Hear, 22: 1-16.



Aside from SSD or highly asymmetric audiograms for unilateral recipients, there is considerable overlap across these groups.

Holder et al. (2018). Trends Hear, 22: 1-16.



Bimodal Benefit

LF acoustic hearing (F_0 & fine structure) → source segregation and/or glimpsing of target speech

- **Clinical implication:** we should always attempt to aid the non-CI ear, but...
 - **When should a patient pursue a 2nd CI?**
 - Decision is largely patient driven

There are many variables that can affect bimodal benefit.

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How much bimodal benefit can our patients obtain?

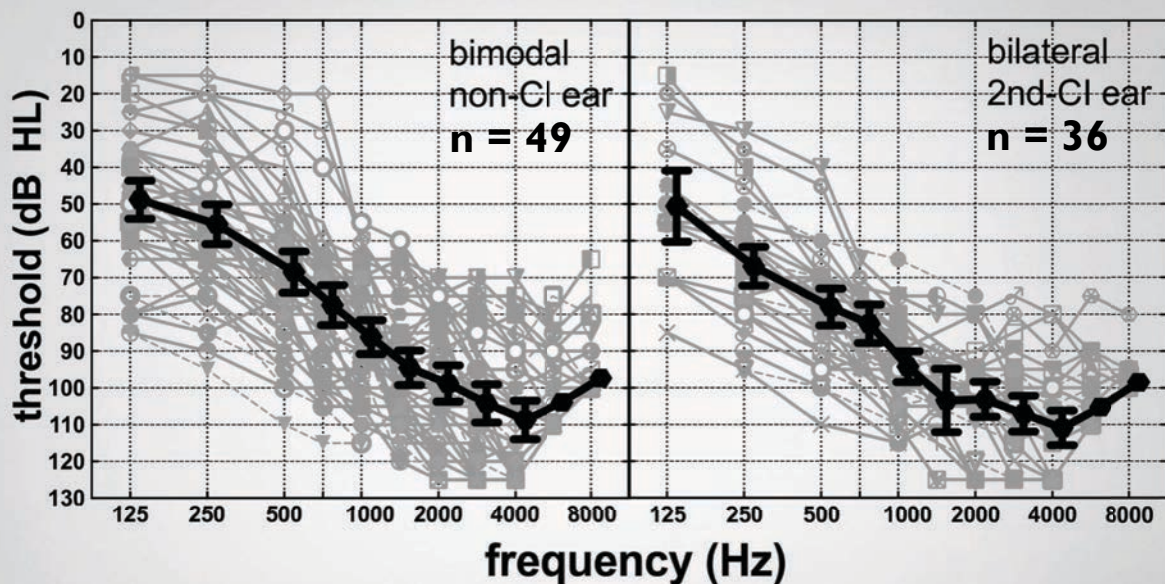
- **CI only score**
 - Dorman et al. (2015). *Hear Res.*
- **Residual hearing in non-CI ear—but not necessarily “clinically useful”**
 - Zhang et al. (2013). *Ear Hear*
 - Illg et al. (2014). *Otol Neurotol* AND Blamey et al. (2015). *Ear Hear*—weak correlation
 - Choi et al. (2016). *Laryngoscope*—**only for thresholds < 70 dB HL**
- **Spectral resolution in non-CI ear**
 - Zhang et al. (2013). *Ear Hear*; Kessler et al. (2020). *Trends Hear*—**not statistically significant**
- **Cochlear integrity (presence of dead regions)**
 - Zhang et al. (2014). *Ear Hear*.
- **CI/HA programming**
 - Fowler et al. (2015). *JSLHR*; Messersmith et al. (2015). *Am J Audiol*; English et al. (2016). *Int J Audiol*; Gifford et al. (2017). *Ear Hear*; Vroegop et al. (2018). *Ear Hear*; Neuman et al. (2018). *Ear Hear*

Clinical quandary

- Evidence-based audiology
- Maximize benefit
- Minimize loss

**Clinical recommendation:
bimodal vs. bilateral CI candidacy?**

Ask your patient!



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Gifford & Dorman (2019). Ear Hear. 40(3):501-516.

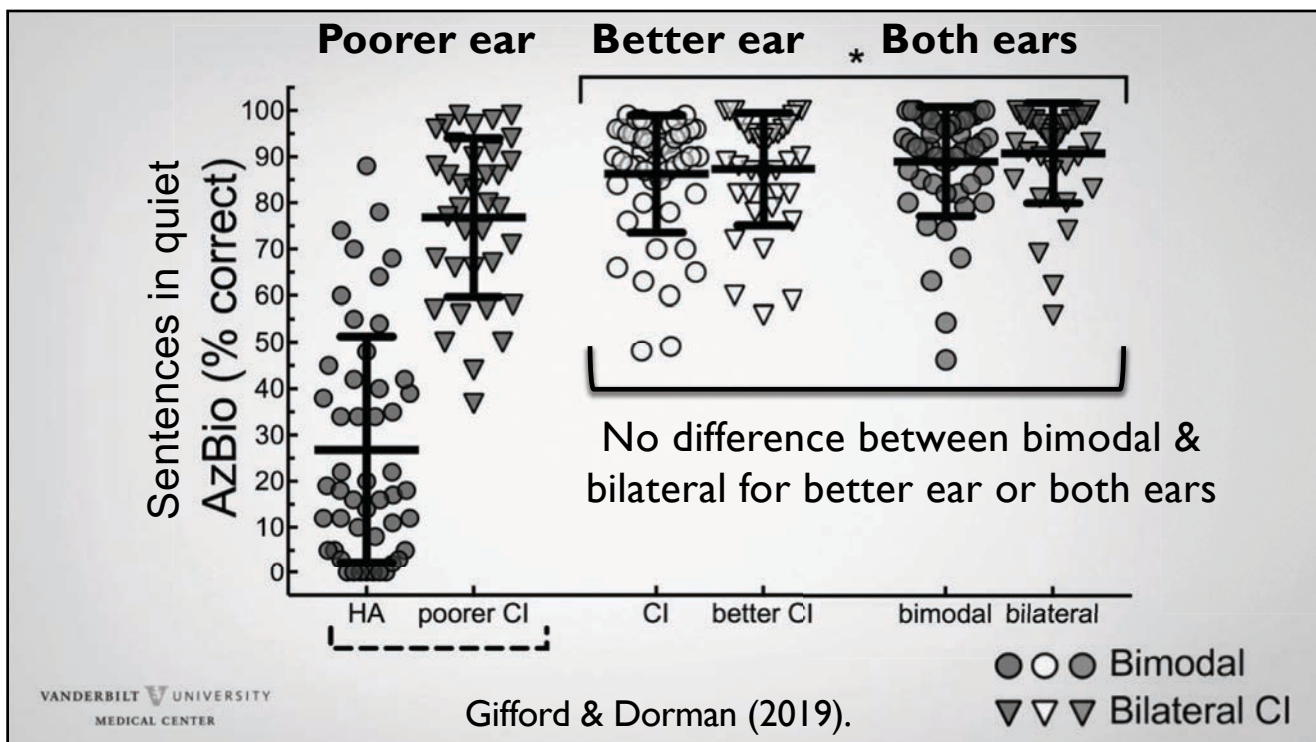
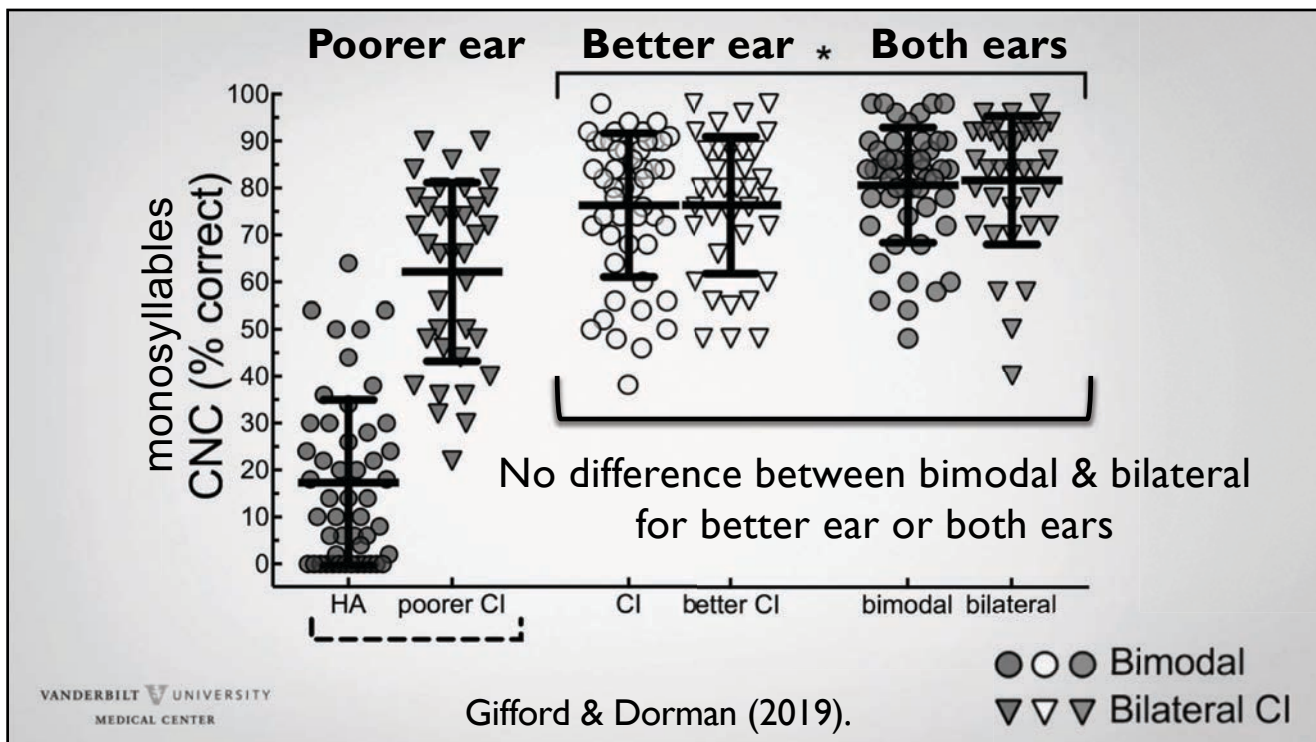
Patient demographics

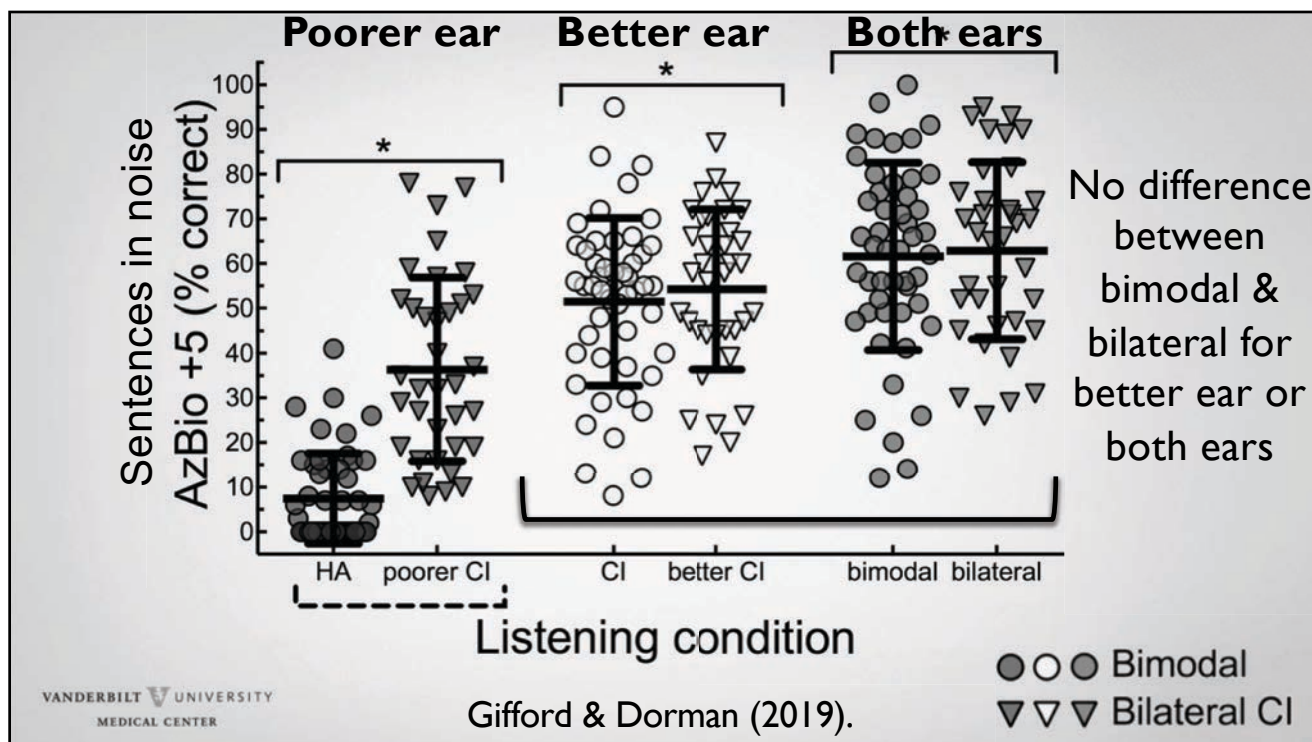
- 49 bimodal adults
 - Mean age = 65.8 years (range: 34 to 90)
 - 20 female
 - 12 AB, 30 Cochlear, 7 MED-EL
-
- 36 bilateral adults
 - Mean age = 53.8 years (range: 19 to 81)
 - 19 female
 - 8 AB, 21 Cochlear, 7 MED-EL

Speech rec:
CI > HA
in all cases

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Gifford & Dorman (2019). Ear Hear. 40(3):501-516.



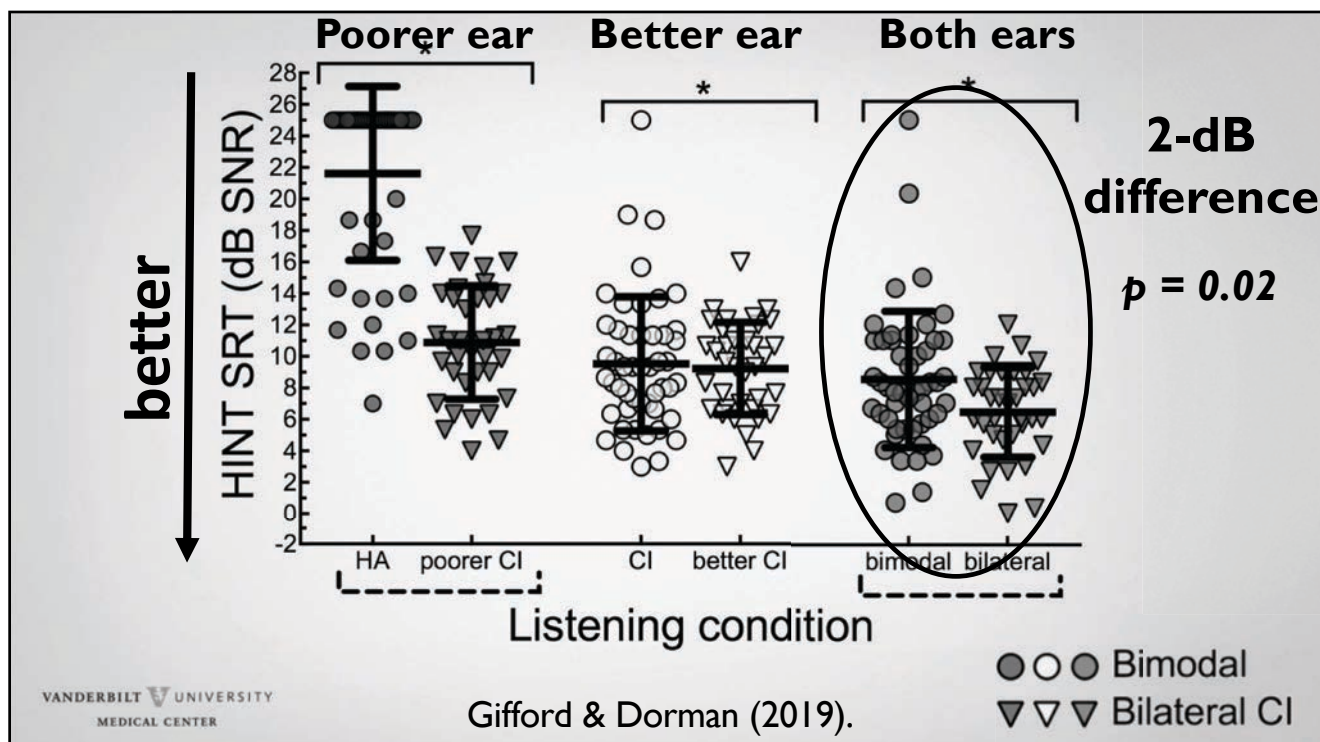


Preliminary summary

Clinical measures:

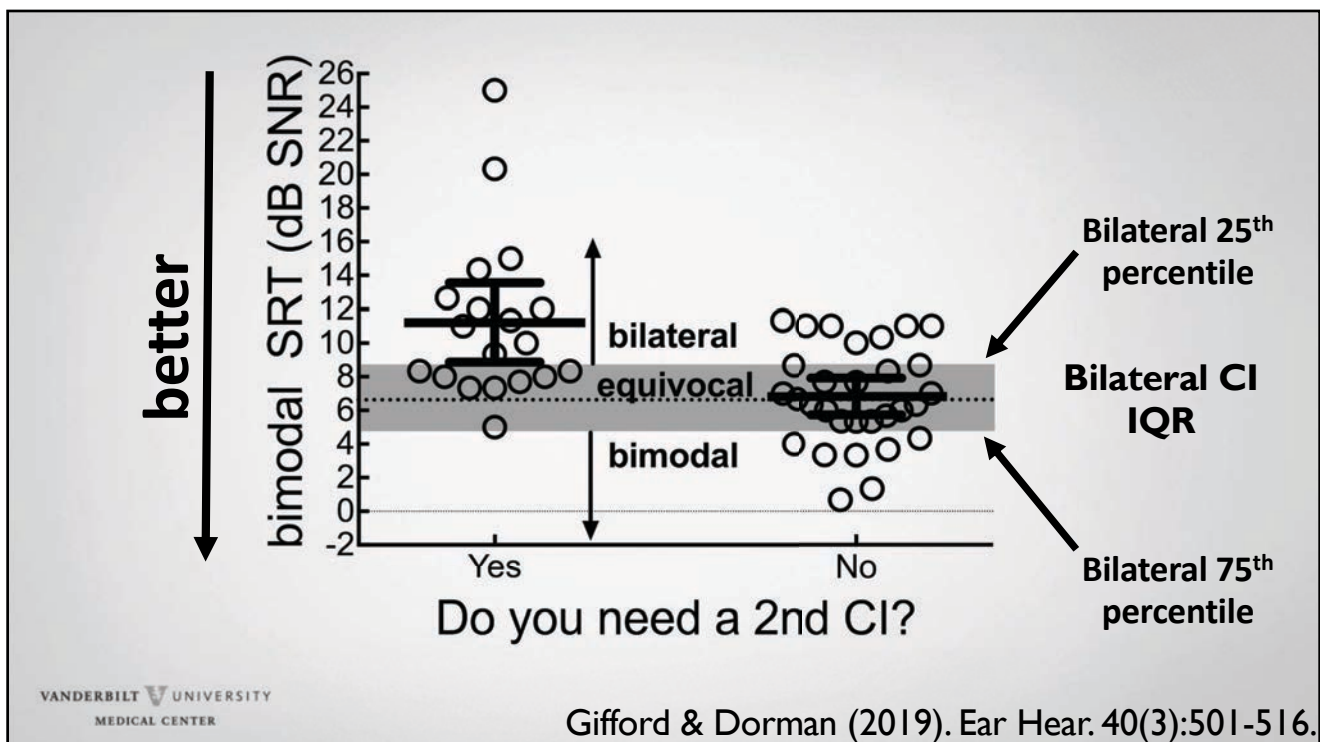
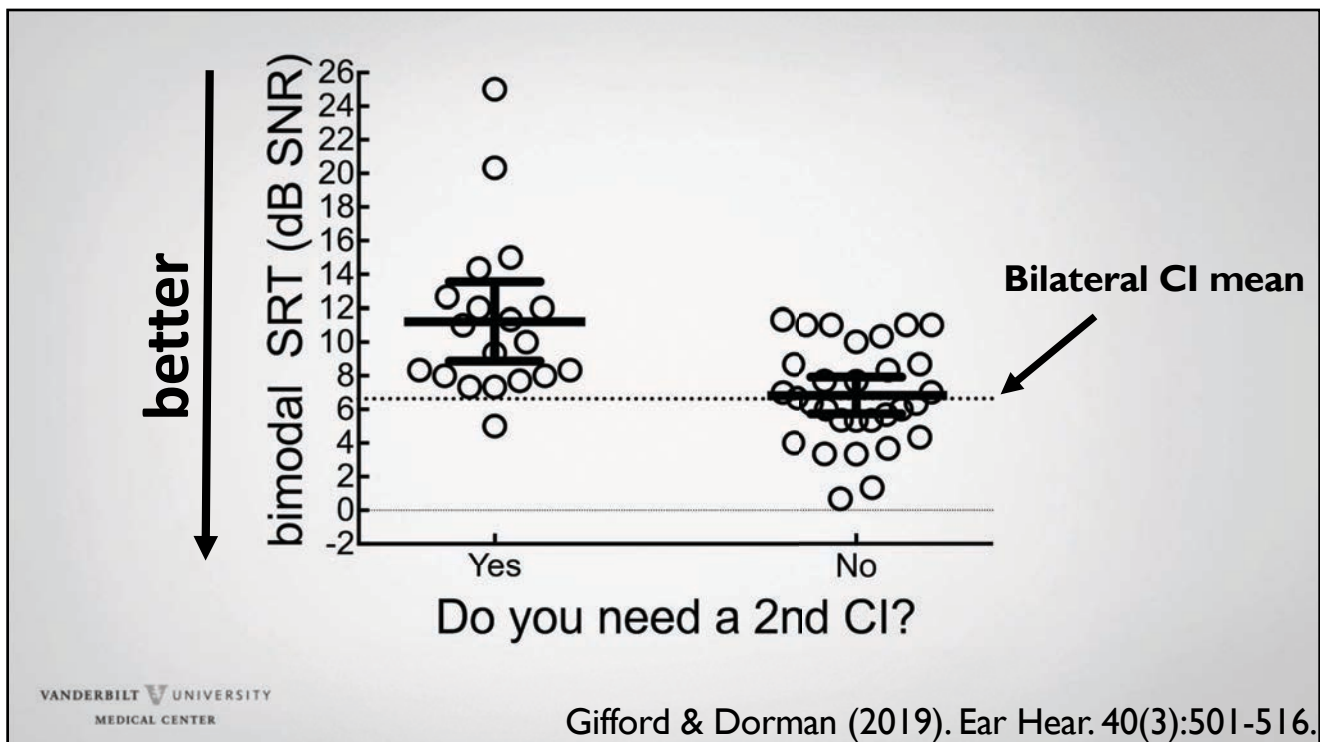
- Similar preoperative audiograms
- Similar preoperative speech understanding (Holder et al., 2018)
- Similar postoperative speech understanding

Laboratory measures?



Before testing, we asked each bimodal patient one simple question:

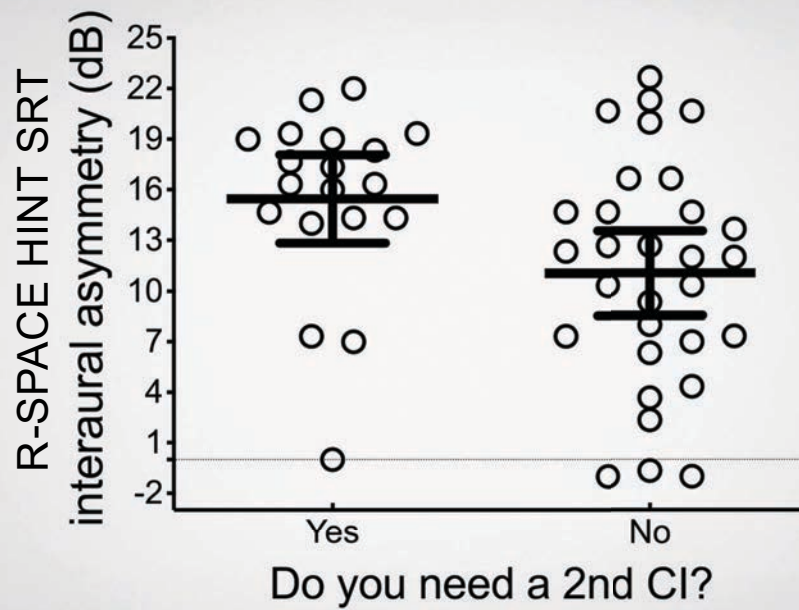
Do you think you need a 2nd CI?



Do you think you need a 2 nd CI?		“Yes”	“No”
25 th percentile	Bilateral CI candidate: SRT > 8.8 dB SNR	Hit 100% n = 19	Miss 23% n = 7
	Not bilateral CI candidate: SRT < 8.8 dB SNR	False positive 0% n = 0	Correct reject 77% n = 23
25 th percentile Conservative, accounting for “equivocal” range			

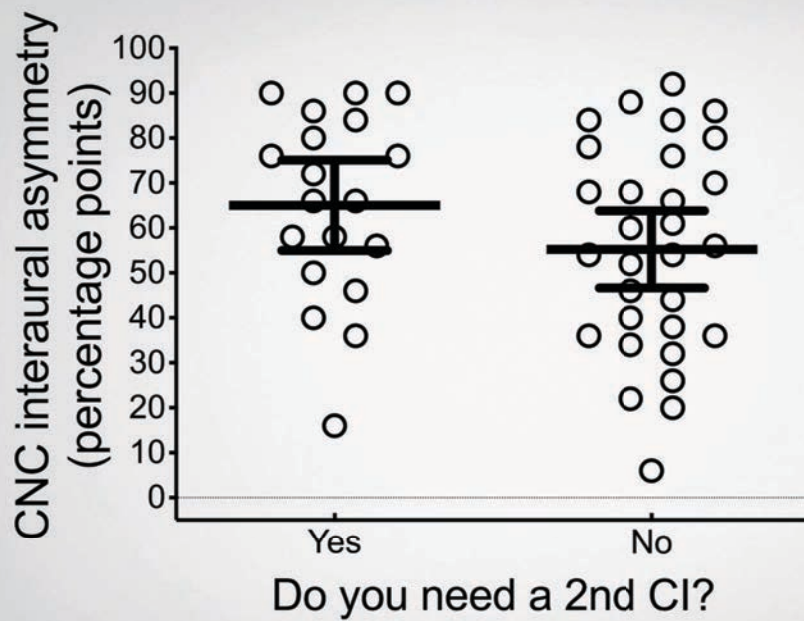
**Clinical recommendation:
bimodal vs. bilateral CI candidacy?**

- 1) Ask the patient!
- 2) CI & HA asymmetry



$t = 2.52$
 $p = 0.016$

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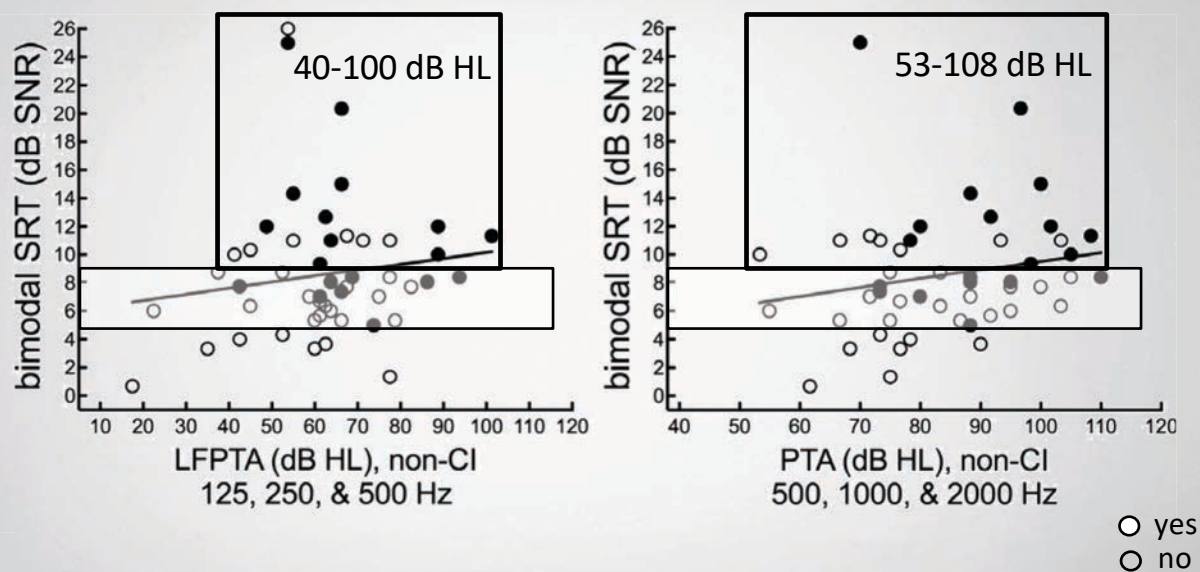


$t = 1.54$
 $p = 0.13$

Similar trends for
 AzBio in quiet
 and +5 dB SNR

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Audiogram: limited clinical guidance (at individual level)



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Gifford & Dorman (2019). Ear Hear. 40(3):501-516.

Summary

- **Audiogram & clinical speech rec:** not sensitive to distinguish bimodal & bilateral performance
 - But, laboratory conditions can distinguish b/tw groups
- **“Do you think you need a 2nd CI?”**
 - high sensitivity (hit rate): identifying bilateral CI candidates
 - moderately high specificity (correct rejection)
- **NEED:** prospective study with *sequential*, bilateral CI
 - In the meantime, patient driven selection of bilateral CI = high sensitivity & specificity

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Gifford & Dorman (2019). Ear Hear. 40(3):501-516.

Summary

- Many current bimodal listeners are bilateral CI candidates
 - **Best case scenario: bilateral CI + bilateral hearing preservation**
- ***asymmetric hearing losses*** → best bimodal candidacy
 - Especially if listener has HF audibility in non-CI ear
 - Greater access to HF ILDs & more equivalent head shadow across the ears
- Prospective research is ongoing!

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Gifford & Dorman (2019). Ear Hear. 40(3):501-516.

Thank you for your attention
rene.gifford@Vanderbilt.edu



Why is it Important to Preserve Low Frequency Acoustic Hearing: Central Auditory Processing)

Bruce J Gantz*, Inyong Choi, Bob McMurray,
Marlan Hansen, Camille Dunn

The Iowa Cochlear Implant Clinical
Research Center
Department of Otolaryngology
—Head and Neck Surgery
The University of Iowa,
Iowa City, Iowa

Supported by grants from the
NIH-NIDCD,
Iowa Lions Hearing Foundation

*Consultant for: Cochlear Corporation



Acoustic + Electric Speech Processing

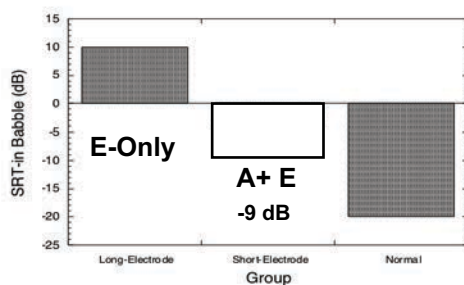
- The ability to discriminate speech in a noisy environment is one of the most difficult problems confronting those with significant hearing loss.
- Cochlear Implants improve discrimination in quiet, but fail in most to provide separation of speech in noise and appreciation of music
 - similar to standard acoustic amplification.
- One of the major advantages of preserving low frequency acoustic hearing and combining acoustic and electric speech processing is the ability to improve hearing speech in noise
 - Provides Temporal Fine Structure not available in current CI speech coding algorithms

Advantages of Acoustic Hearing + Electric Hearing

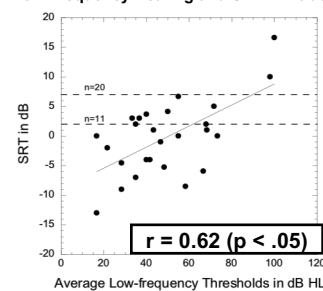
- Preservation of Low Frequency (3 Freq)

Acoustic Hearing Enhances

- Word Understanding in Quiet
 - Average: 20% >CI only
- Sentence Understanding in Noise



Relationship between Preservation of Low Frequency Hearing and SRT in Babble



Turner CW, Gantz BJ, Vidal C, Behrens A, Henry BA. Speech Recognition in Noise for Cochlear Implant Listeners: Benefits of Residual Acoustic Hearing. J Acoust Soc Am 115(4):1729-1735, 2004

Hearing Preservation: Important Concepts

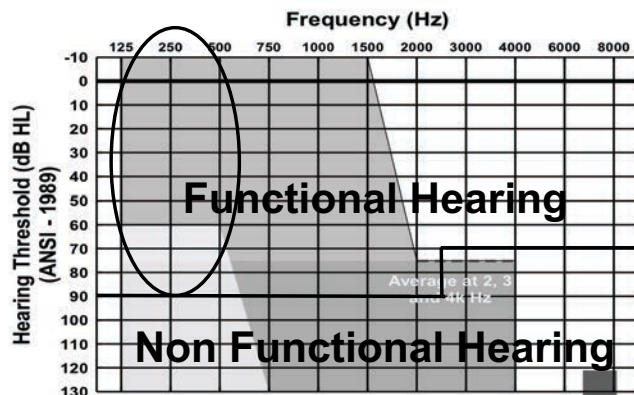
- Useful Hearing: "Functional Acoustic Hearing"
 - Must maintain better than 85-90dB in low frequencies*
 - If can not amplify with hearing aid: not useful
 - Not worthwhile to discuss the change or delta pre to post op if do not maintain function hearing

*Hornsby BWY, Ricketts TA.

The Journal of the Acoustical Society of America. 2006;119(3):1752-1763.

*Adunka, Gantz, Dunn, Gurgel, and Buchman
Minimum Reporting Standards for Adult Cochlear Implantation

Otolaryngol Head Neck Surg. 2018 August;159(2):215-219.



Hearing Preservation Electrodes

Hybrid S8,S12,SRW

10-12mm
180-200 degrees



Hybrid L24

16mm
250 degrees

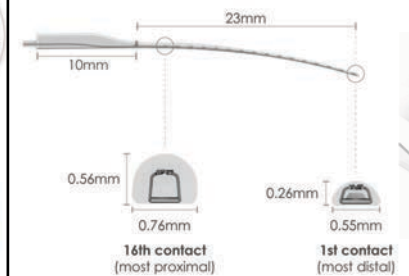


422, 522, (624)

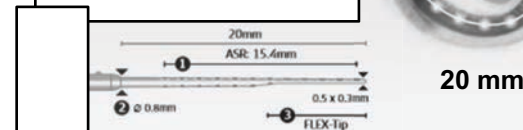
20mm
320-360 degrees



AB Slim J



Flex 20

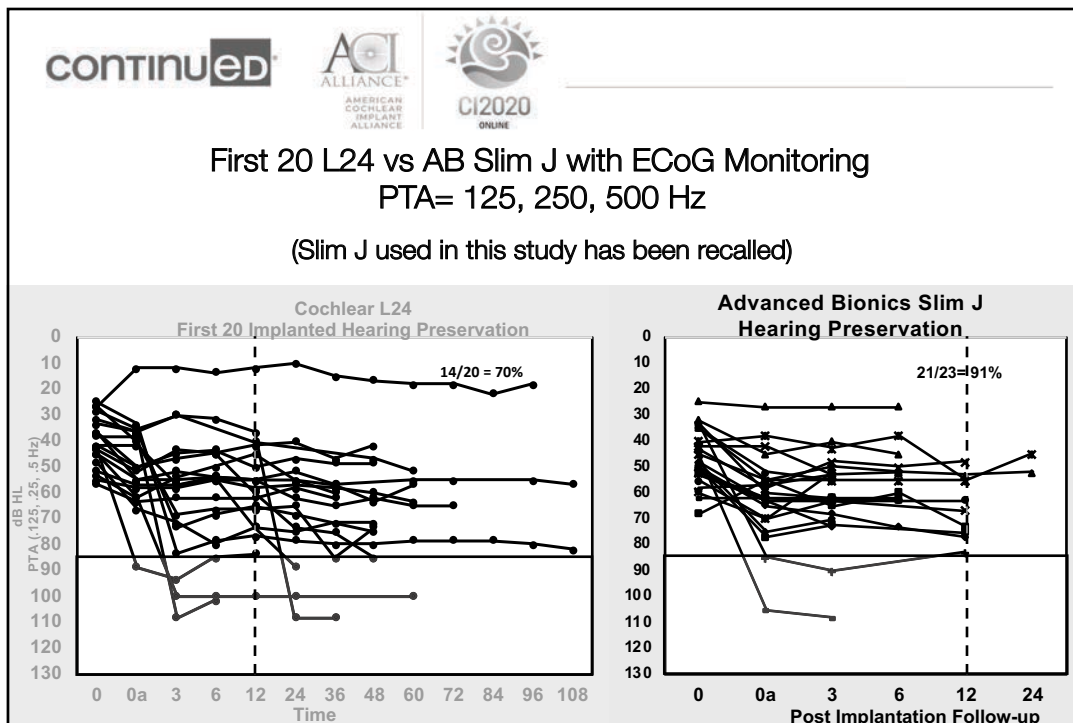
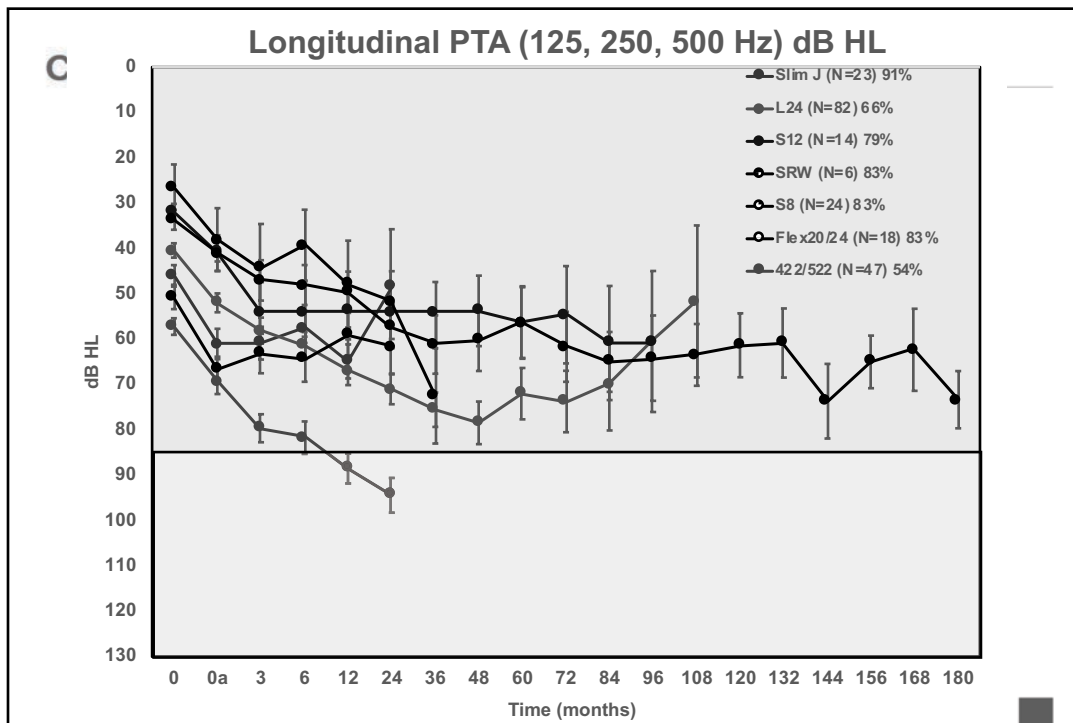


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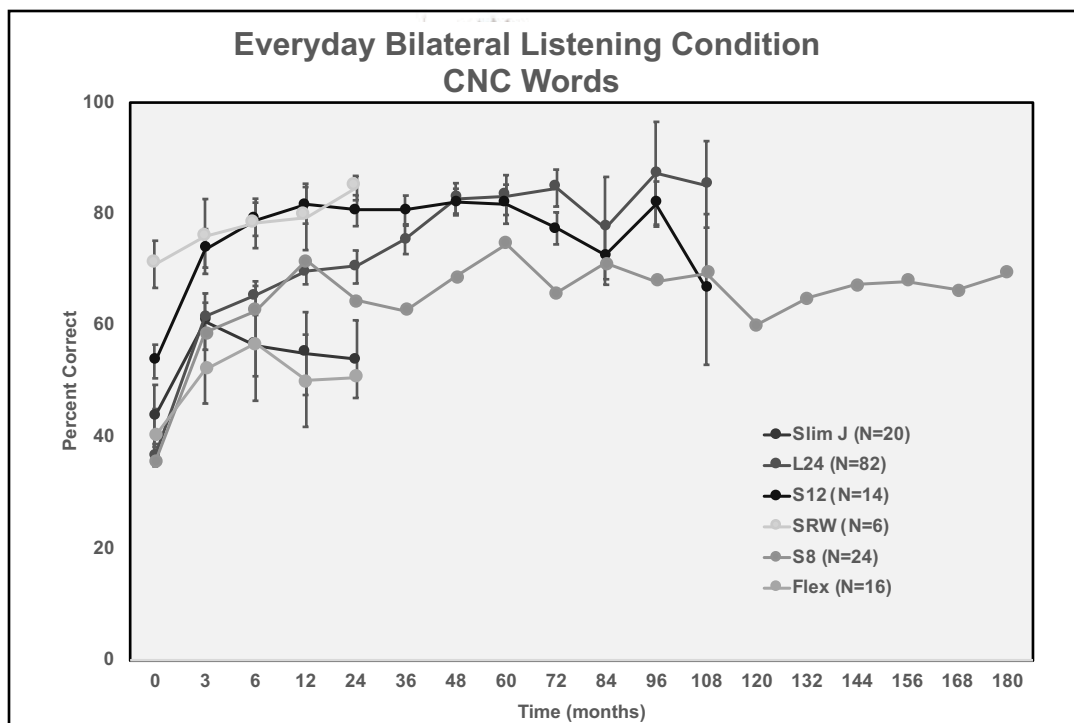
Important Issues

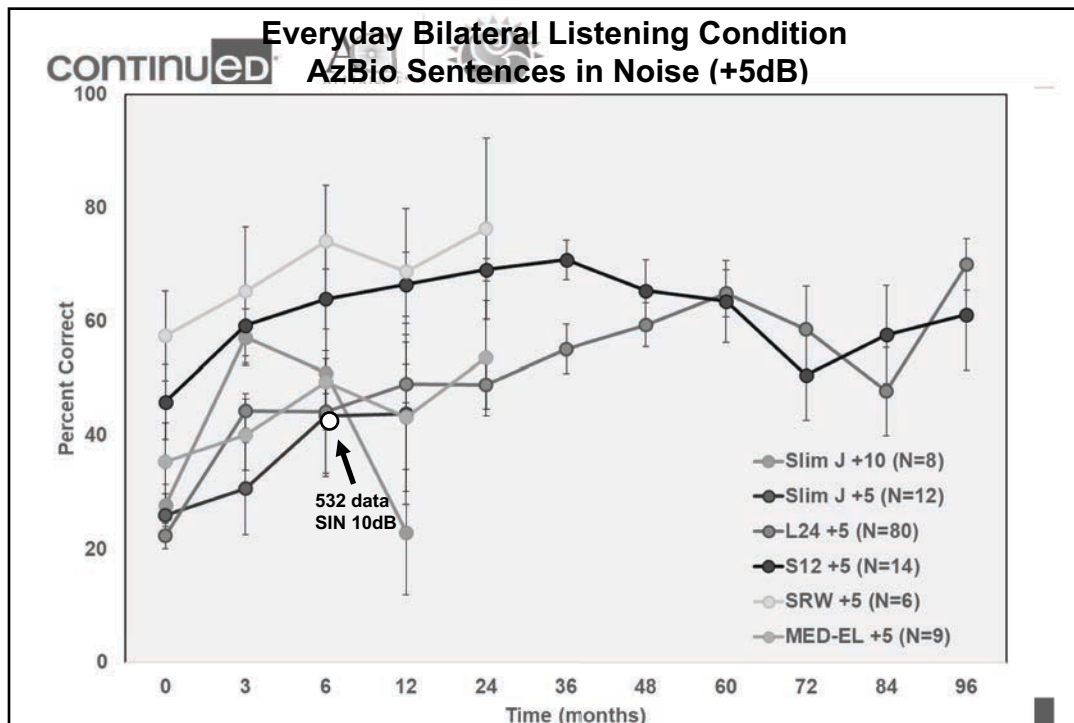


Acoustic Hearing Preservation



Results Over Time





New Auditory Neuroscience Research

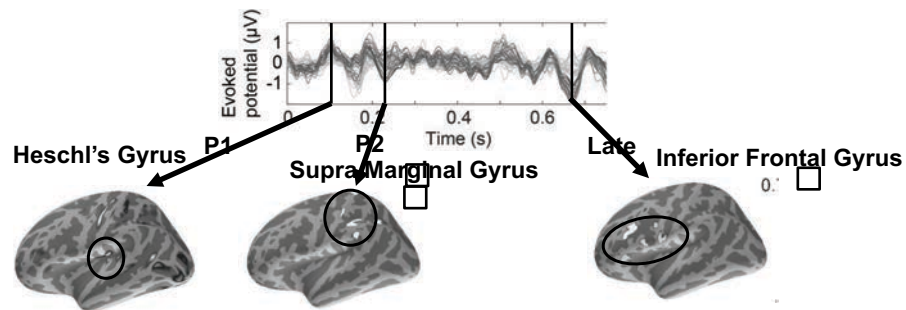
- Central Temporal Processing
 - High Density(EEG)
- Temporal Lexical Integration
 - Eye Tracking

Neuroimaging on CI Listeners (EEG)

Pre- & post-op high-density EEG



Event-related potentials on cortical surface (normal hearing)



CONTINUED A

Normal Hearing Subjects

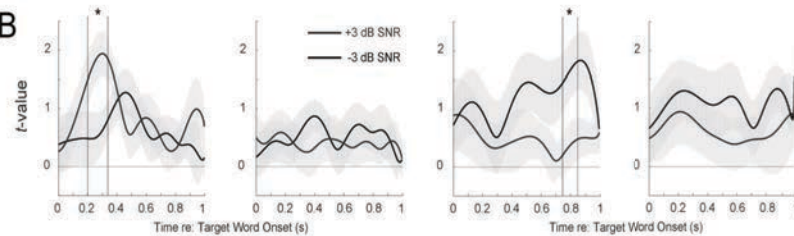
ROI: Supramarginal gyrus (SMG)

ROI: Inferior frontal gyrus (IFG)

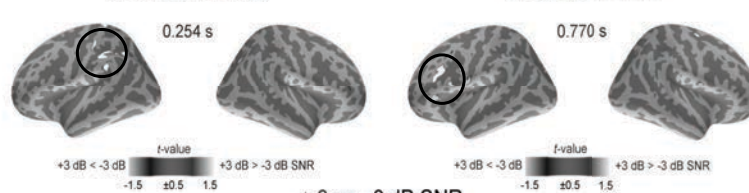
+ 3 SNR

- 3 SNR

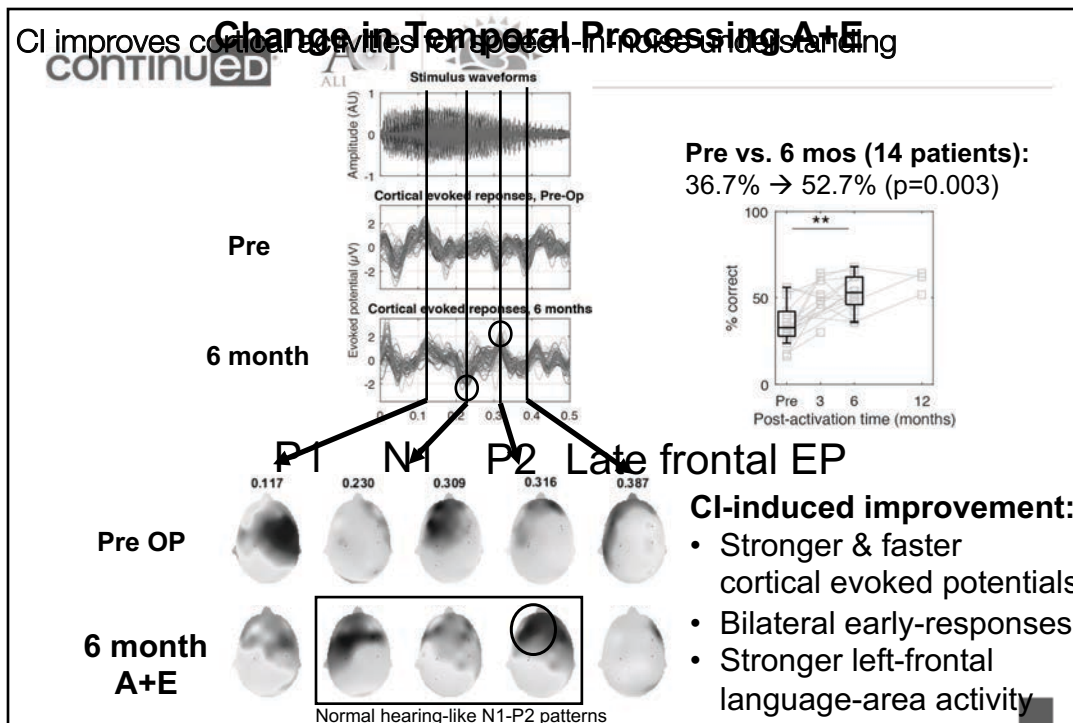
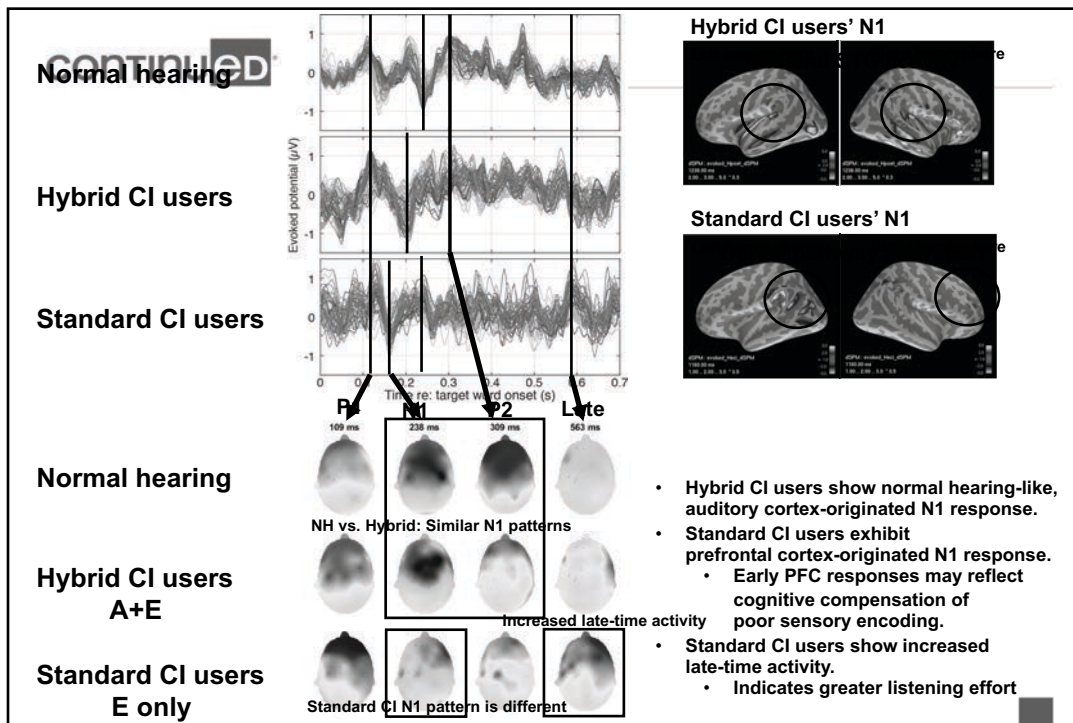
B

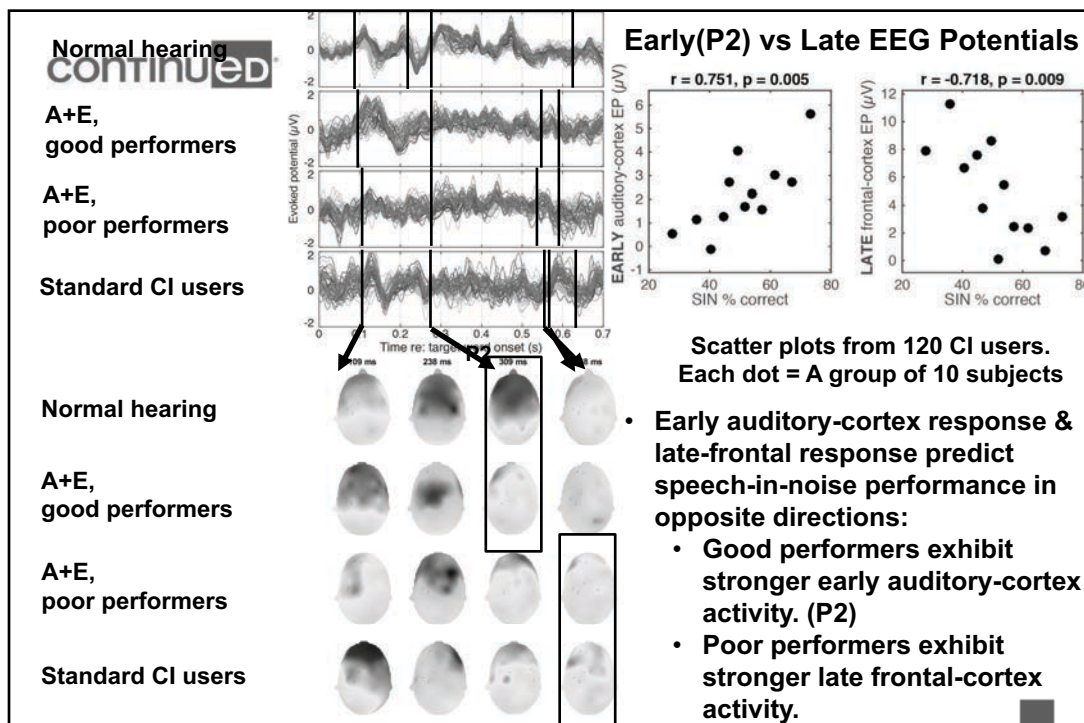


C



+ 3 vs. -3 dB SNR
(paired t-test)





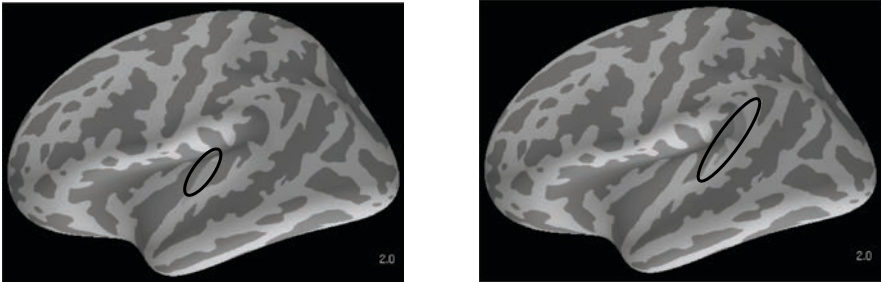
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Where to look?

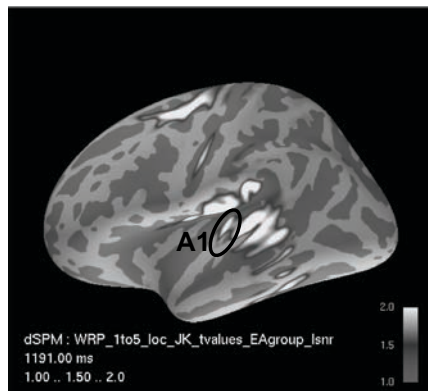
- A1 (Primary Auditory Cortex : Heschl's gyrus: HG)
- A2 (Secondary Auditory Cortex = Planum Temporale: PT)



Early (~200ms) evoked potentials

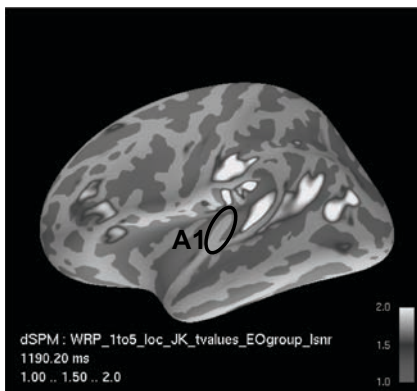
▪ EAS (n=17)

**Strong evoked activity
in both A1 and 2**



▪ E-only (n=17)

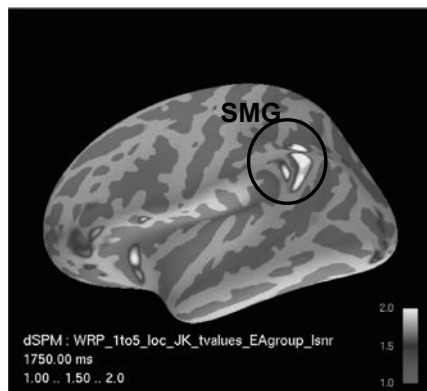
Absence of A1 activity



Late (~750ms) evoked potentials

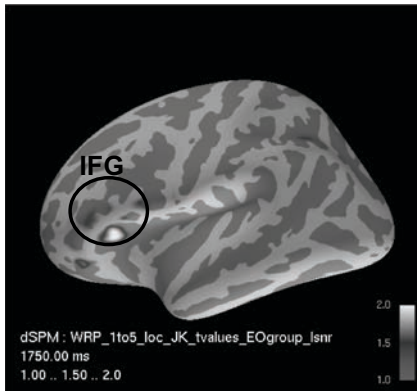
▪ EAS (n=17)

**Dominant activity in supra
marginal gyrus (SMG)
(Lexical Processing)**



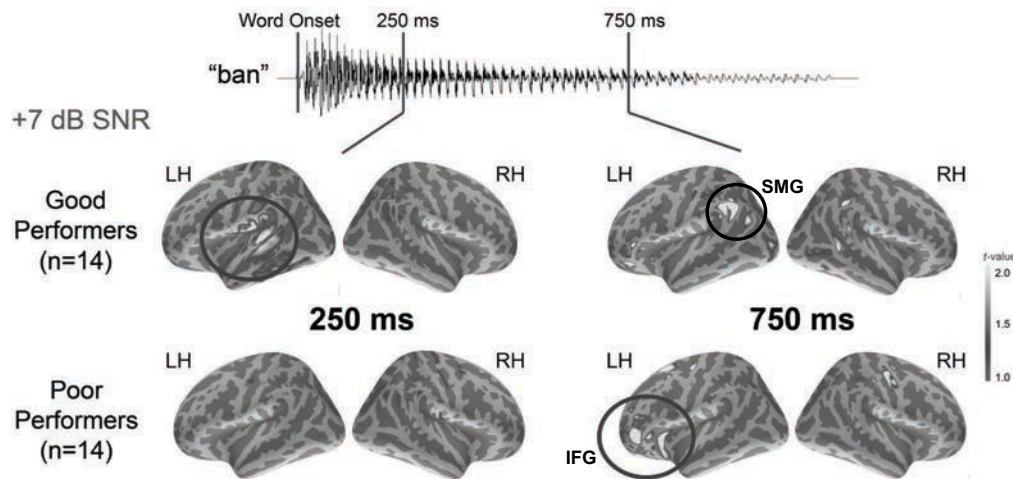
▪ E-only (n=17)

**Dominant activity in inferior
frontal gyrus (IFG)
(Greater Listening Effort)**



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Mixed EAS and E-only listeners, based on SiN performance (Good vs. Poor performers)



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Temporal Integration

Even for NH listeners recognizing a word requires people to cope with ambiguity.

- Words unfold over time.
- At early points in the signal is ambiguous – could turn out to be any number of words.
- When the rest of the word arrives listeners can commit.

What do people do while they wait?

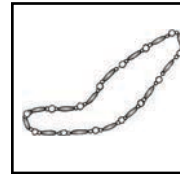
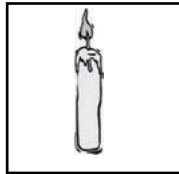
Sat~~X~~urday → sa~~X~~rk
 sandwich

continued Measuring Temporal Dynamics

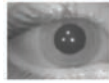
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Sandal



What's so great about this?



You have to look before you can click.

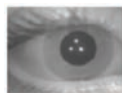
Fixations reveal people's early decisions... *at the lexical/semantic level...* before they can tell us.

Visual World Paradigm: for Eye Tracker

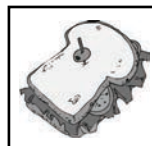
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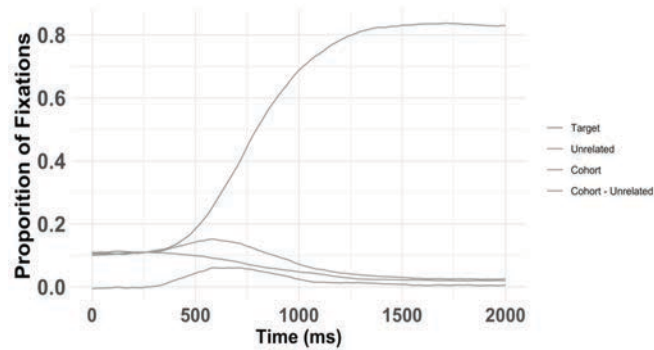


Using an eye tracker, measure a moment to view the items



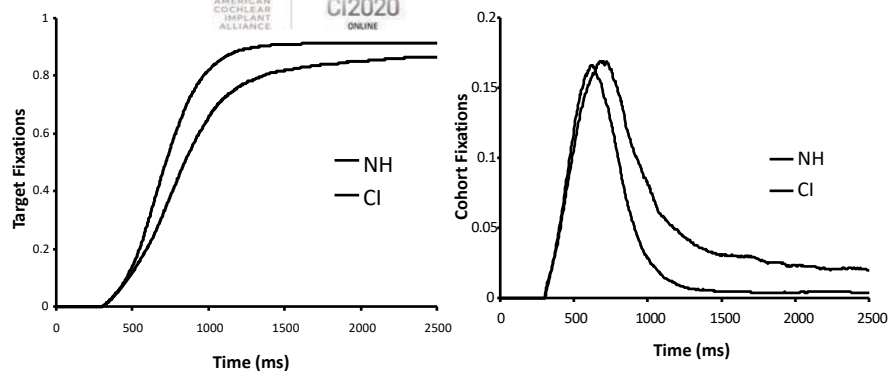
Tanenhaus, Spivey-Knowlton, Eberhart & Sedivy, 1995
Allopenna, Magnuson & Tanenhaus, 1998

Visual World Paradigm



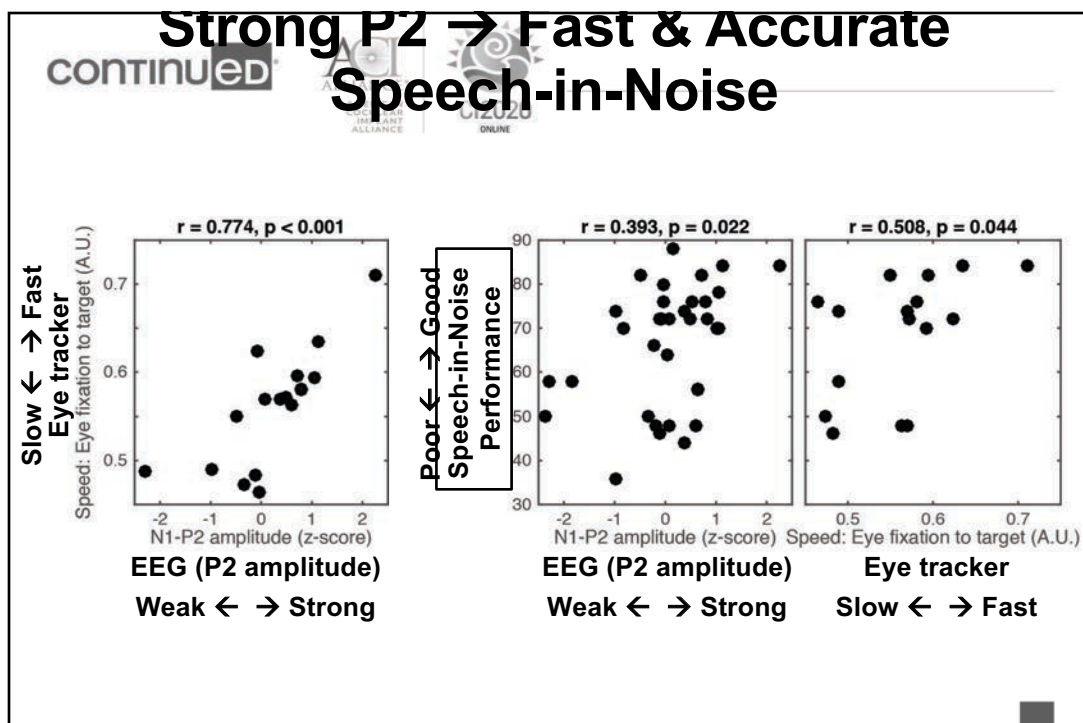
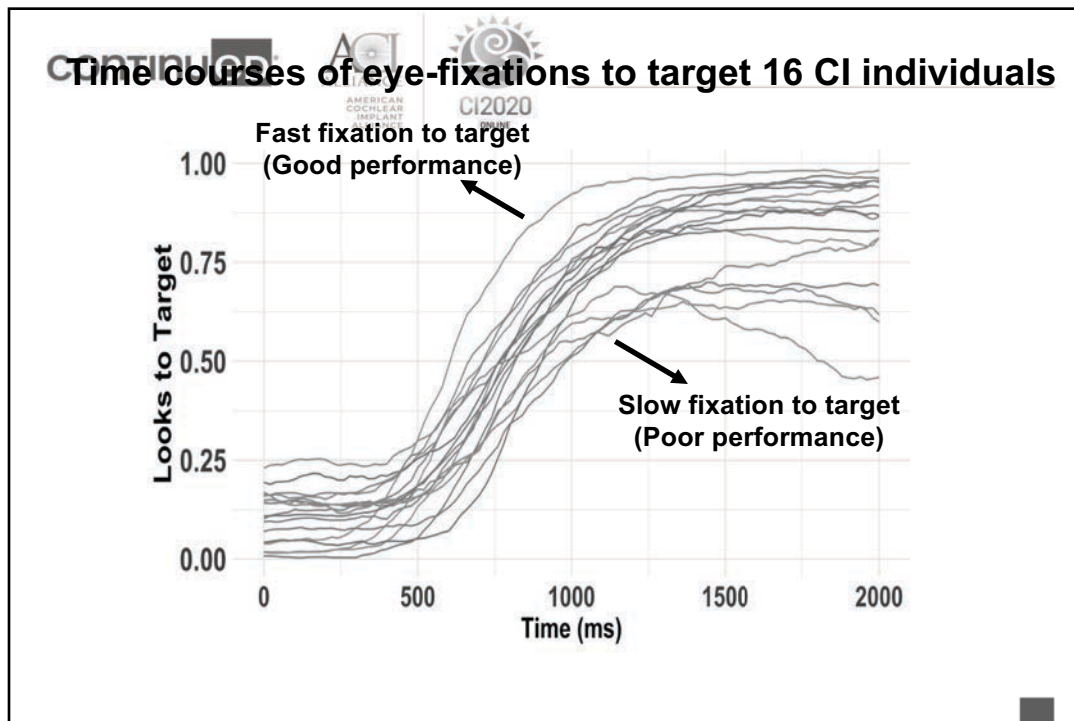
(Tanenhaus et al. 1995; Allopenna, Magnuson, and Tanenhaus 1998; Farris-Trimble and McMurray 2013)

Lexical Dynamics in Adult CI users



Post-lingually deaf adults:

- Similar processing to NH (looks to onset competitor that are later ruled out).
- BUT: they take longer to get there (~75 - 100 msec)
- AND: they never fully suppress competitors



- **“Functional” acoustic hearing can be maintained in most subjects with hearing preservation electrodes at initial activation (93%)**
 - 8-15% lose “Functional” hearing over time, loss hearing occurs between 1-6 months post implantation
- **ECoG Monitoring During Insertion Appears to Improve Preservation**
- **Performance with CI quite variable for all lengths of electrodes**
 - Longer not always better
- **“Functional” acoustic hearing and improved speech perception scores can be preserved for over 16 years using A + E**

- **Compelling Finding: A+E demonstrates near normal central temporal processing compared to electric stimulation only**
 - Correlates with improved hearing in noise
 - A+E can re-establish temporal cortical activity with almost normal P₁, N₁, P₂
 - Those with early potentials exhibit less listening effort and do better in noise
 - New metric to explore new speech coding algorithms
- **Eye Tracking: Speed of Lexical Processing improved with preserved acoustic hearing (P2 amplitude and SMG activity)**
 - Reduced Listening Effort (less IFG activity)
- **Consider implanting earlier (younger age) to preserve residual neural substrate with CI neural activation**
- **Should always try to preserve FUNCTIONAL low frequency hearing**



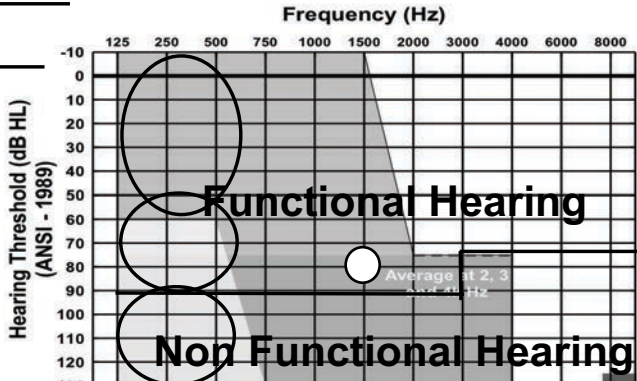


Hearing Preservation: Important Concepts

- **Hearing Preservation Should Always Considered**
- **Possibly Consider Three Different Patient Populations.**
- Must Consider Age of Patient, Duration of Profound Loss, Etiology
- **Risk Benefit Considerations**
 - Shorter array or limited insertion
 - Full lateral wall
 - Full Lateral Wall/ Perimodiolar

Must consider A+E patients
different from E only

Don't give patient choice to
be E only at activation







Thank You

32

Clinical Applications of the AIM System from Advanced Bionics

Presenters:

Aniket Saoji, PhD

Oliver Adunka, MD;

Sarah Coulthurst, MS



Future directions for AIM: Multi-frequency electrocochleography

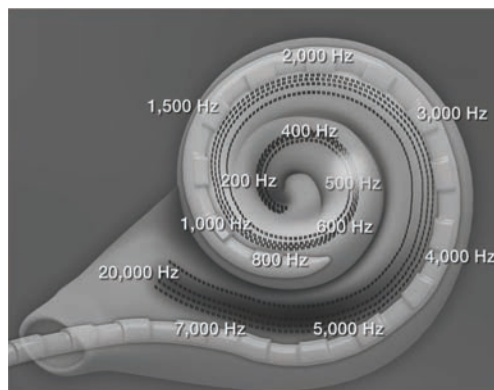
Aniket Saoji, PhD, CCC-A
Director, Cochlear Implants
Mayo Clinic, Rochester MN

Date: 04/17/2020

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Cochlear Implants

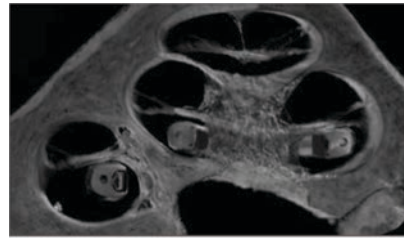
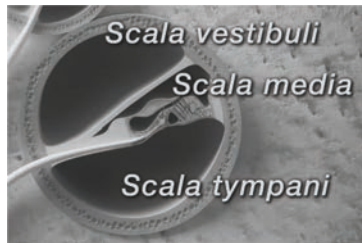
In cochlear implants an electrode array is surgically implanted in the cochlea and used to deliver electrical stimulation to the auditory nerve.



©2017 MFMER | slide-2

Cochlear Implants

Ideally the entire array should be placed into the scala tympani for (1) better cochlear implant outcome and (2) possibly better hearing preservation

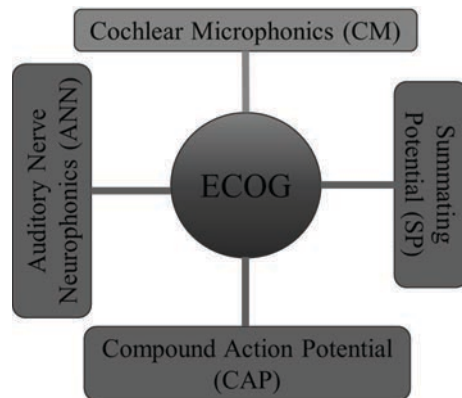


Downing (2018)

We are unable to visualize the electrode location during the placement of the electrode array.

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Electrocochleography (ECOG)

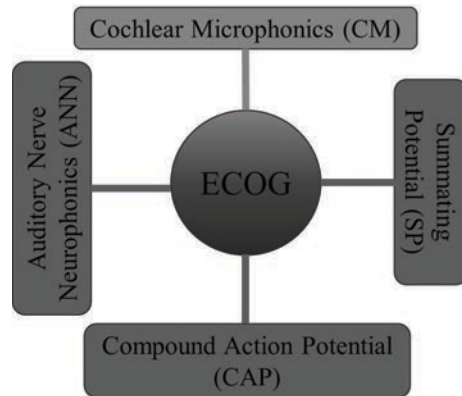


CM – Outer hair cells
ANN – Auditory nerve
SP – Hair cells
CAP – Auditory nerve

Wever and Bray (1930)

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Electrocochleography (ECOG)



Advanced Insertion Monitoring (AIM, 2019)

Wever and Bray (1930)

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ECOG



Waveform Monitor

Audio On ☒

Event Threshold (dB)

Minimum Response Amplitude (μ V)

Maximum Response Amplitude (μ V)

ECochG Insertion

Frequency (Hz) (Default)

Stimulation Level (dB HL) (Default)

ECochG Threshold

Stimulation Level (dB HL) at 500 Hz (Default)

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ECOG

Video 1 (ECOG animation)

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ECOG

Video 2 (One tone surgical video)

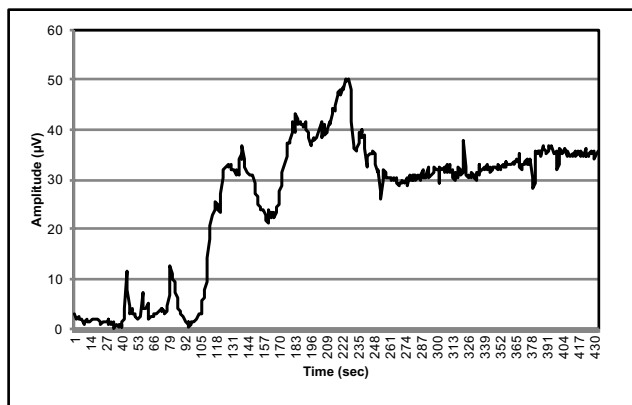
©2017 MFMER | slide-8

ECOG

Video 3 (ECOG animation, Impact to BM)

©2017 MFMR | slide-9

ECOG



How to differentiate between cochlear trauma and random variations in cochlear microphonic amplitude?

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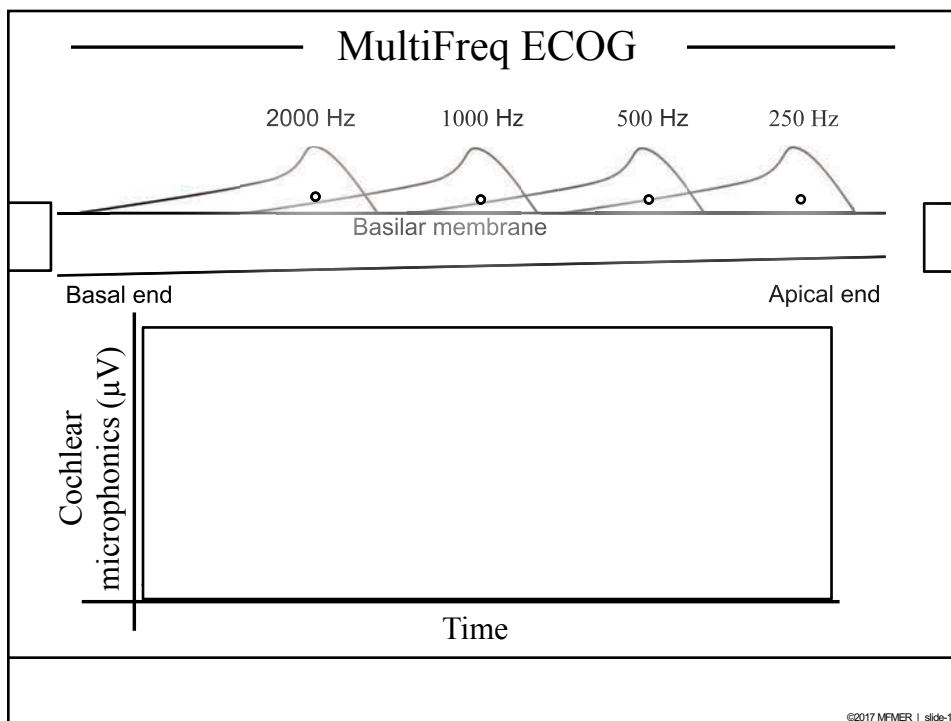
MultiFreq ECOG



Research implementation – not commercially available

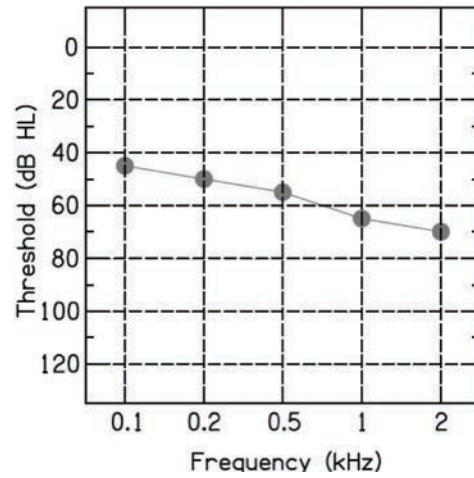
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MultiFreq ECOG



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MultiFreq ECOG



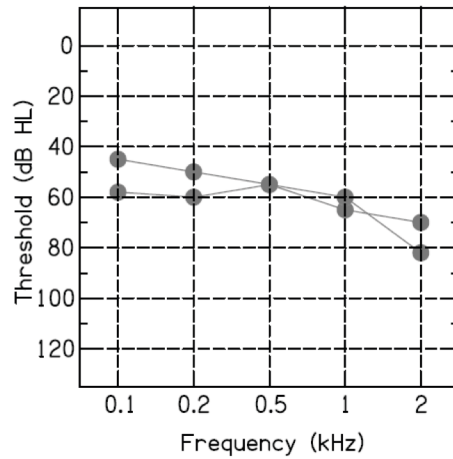
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MultiFreq ECOG

Video 4 (Four tone surgical video)

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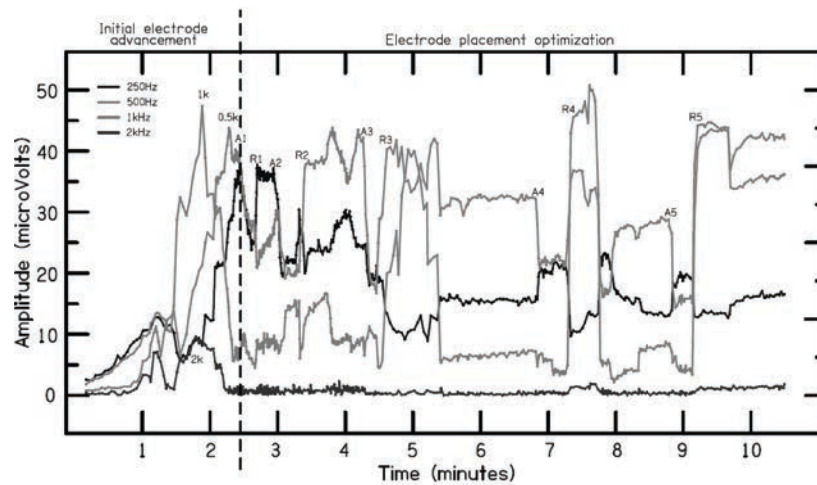
MultiFreq ECOG



- Intra-op CM thresholds
- Pre-op pure tone thresholds

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MultiFreq ECOG

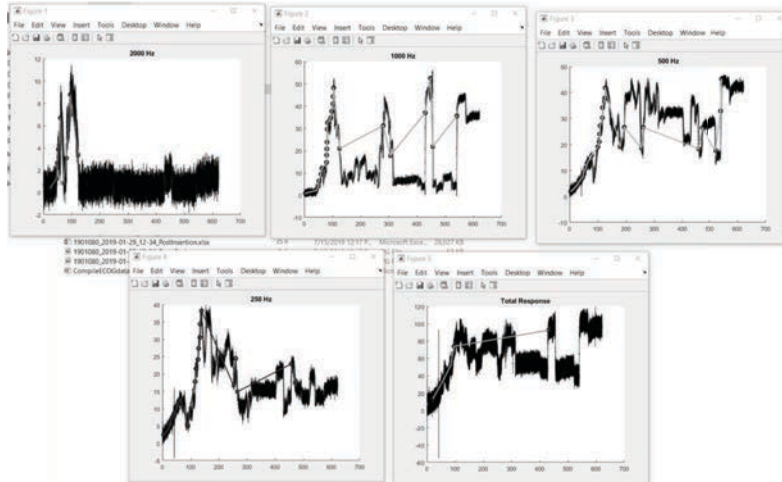


Saoji et al. (2019). Otol Neurotol

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MultiFreq ECOG

How do we provide auditory feedback?



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MultiFreq ECOG

Applications

- 1) Differentiate between apical electrode passing the characteristic place on the basilar membrane and the cochlear trauma
- 2) Estimate frequency-to-electrode map for individual cochlear implant patients.
- 3) Measure intra-operative cochlear microphonic audiogram

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—— MultiFreq ECOG collaborators ——

Mayo Clinic Cochlear Implant Team

Advanced Bionics

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University of North Carolina

Douglas Fitzpatrick, PhD

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—— Mayo Clinic Cochlear Implant Team ——



THANK YOU !!!

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Why ECochG Matters

Oliver F. Adunka, MD, FACS



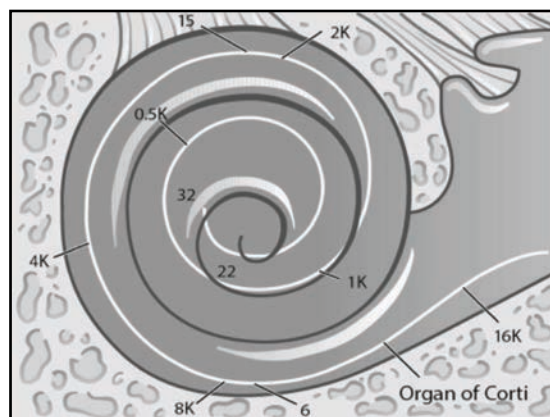
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Current Clinical Practice

- **Full insertions w/o attempted HP**
...electrode disappears into cochlea
- **Limited insertions w/ HP**
 - 6 - 28 mm
- Does **not** account for
 - **Functional** parameters
 - Cochlear **size variations**
- **Do not get feedback** during insertion



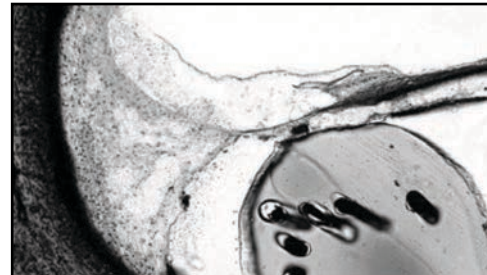
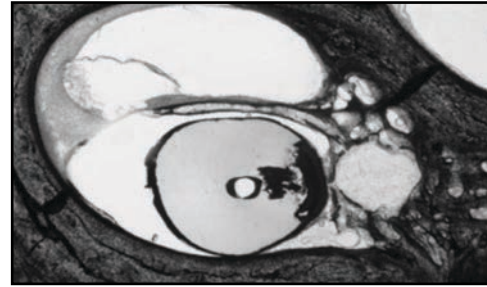
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Recent & Current Efforts

- Surgical **access**
- Non-traumatic **electrodes**
- Insertion **methods**
limited insertion **depths**



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Potential Future Philosophy

- **Customized** electrode insertions
- **Fit the insertion to the specific cochlea**
account for size, hearing, trauma, etc...
 - Long-enough electrode
enough electrode contacts
 - Record **functional** parameters **DURING** insertion
 - **Customize insertions** based on **physiology**
 - Several clinical **scenarios** possible
potential to modify clinical decision making



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Goal

- Generate a **smart insertion process**
- Real-time **feedback**
 - Electrode positioning
in relation to still **functional** regions
 - Functional status
trauma, individual contact positioning
- During electrode **insertion**

Can we use the **Implant?**



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Patient in 2005

The Laryngoscope
Lippincott Williams & Wilkins, Inc.
© 2006 The American Laryngological,
Rhinological and Otological Society, Inc.

Monitoring of Cochlear Function During Cochlear Implantation

Oliver Adunka, MD; Patricia Roush, AuD; John Grose, PhD; Corinne Macpherson, MS;
Craig A. Buchman, MD



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Electrocochleography

- The measurement of stimulus-evoked **cochlear potentials**, with isolation of the potentials to the cochlea achieved by proximity through **electrode placement**
 - in the ear canal
 - promontory or
 - **round window**

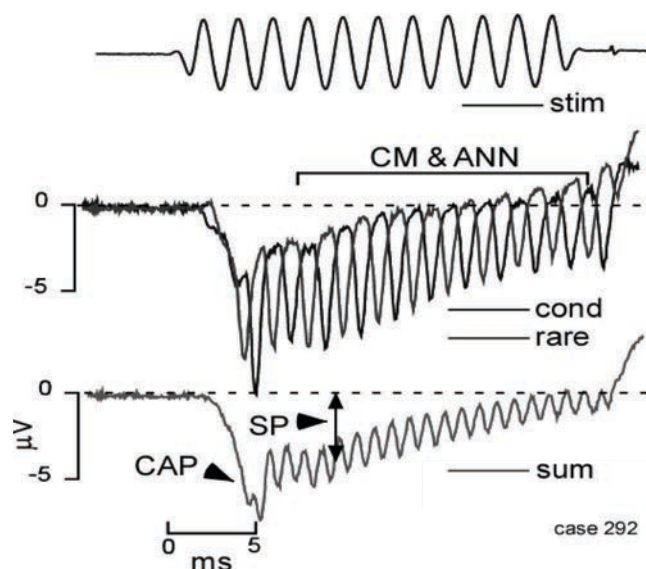


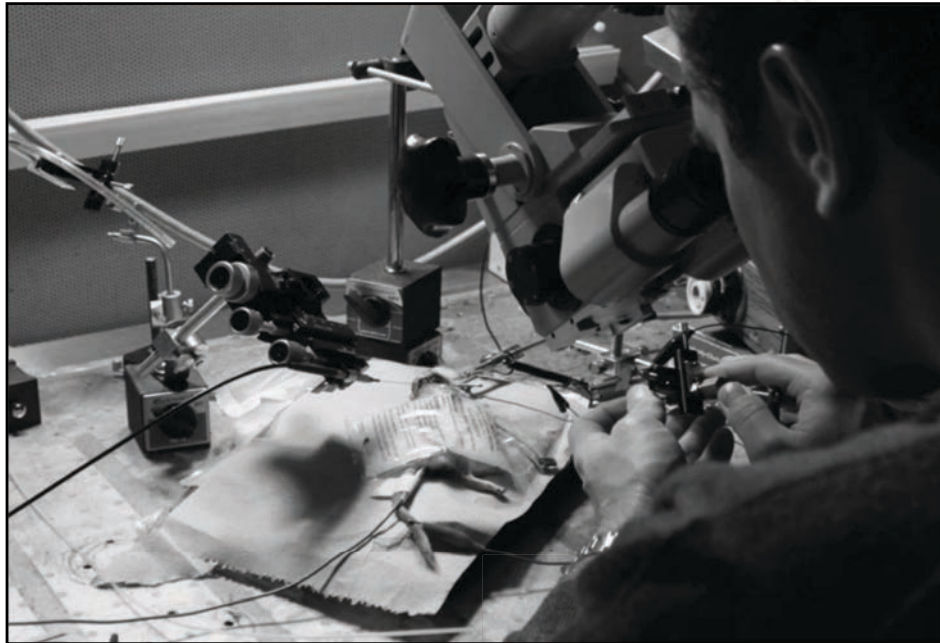
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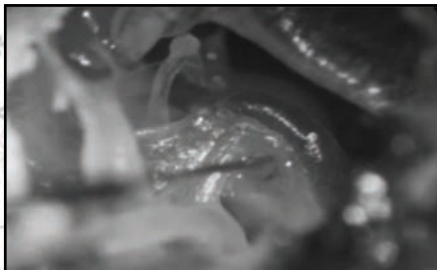
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ECoG Response





Surgery



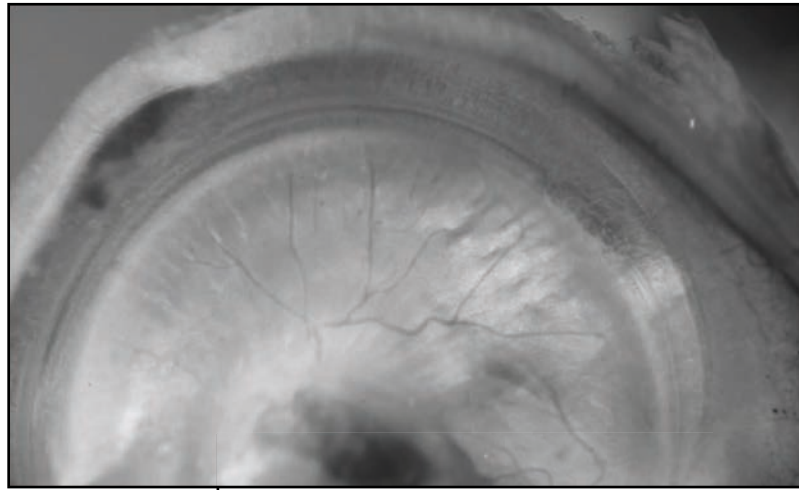
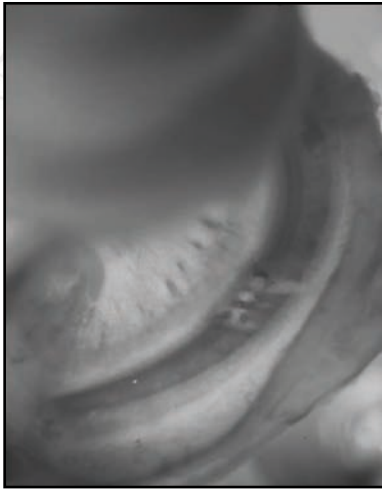
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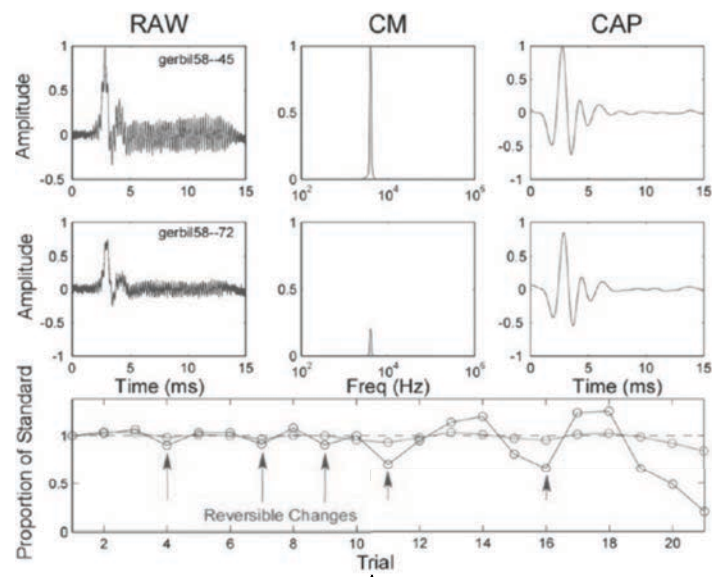
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continued®

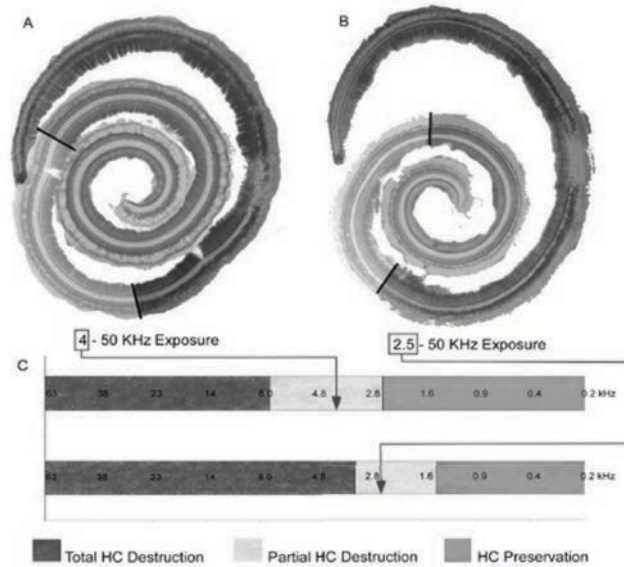
Histology



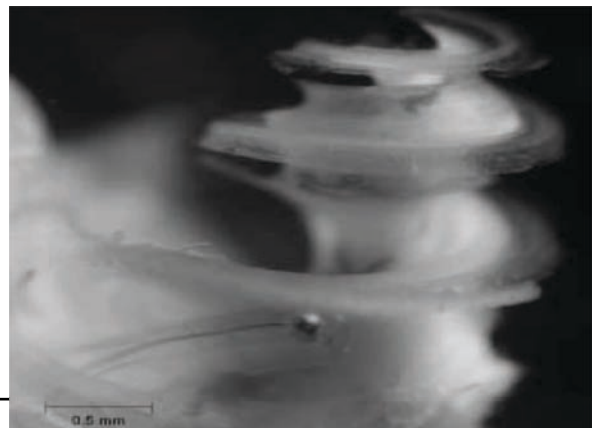
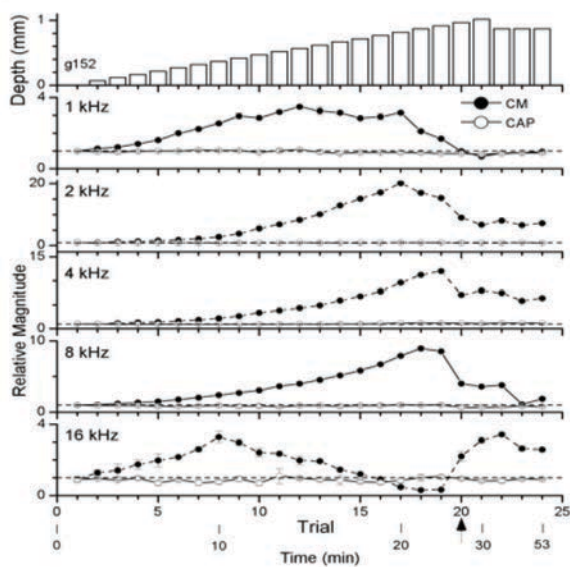
Recording Abbreviation



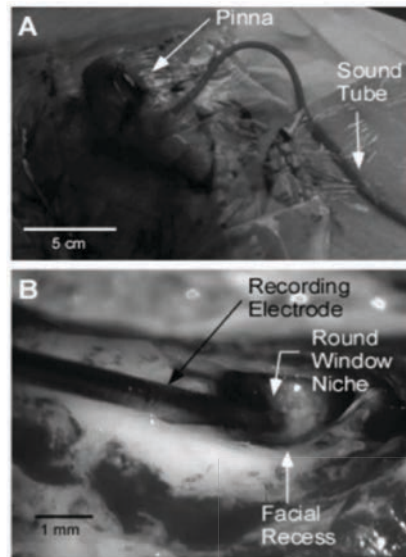
Different Configurations



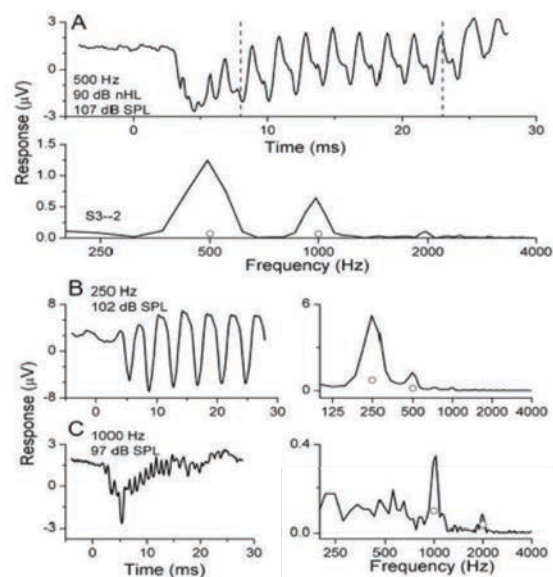
Longitudinal Penetrations



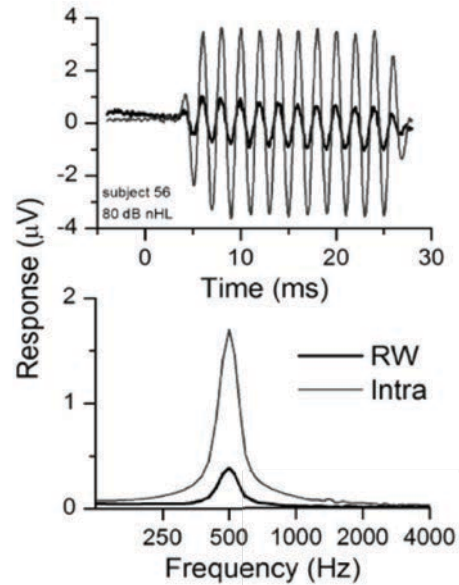
OR Recording Setup



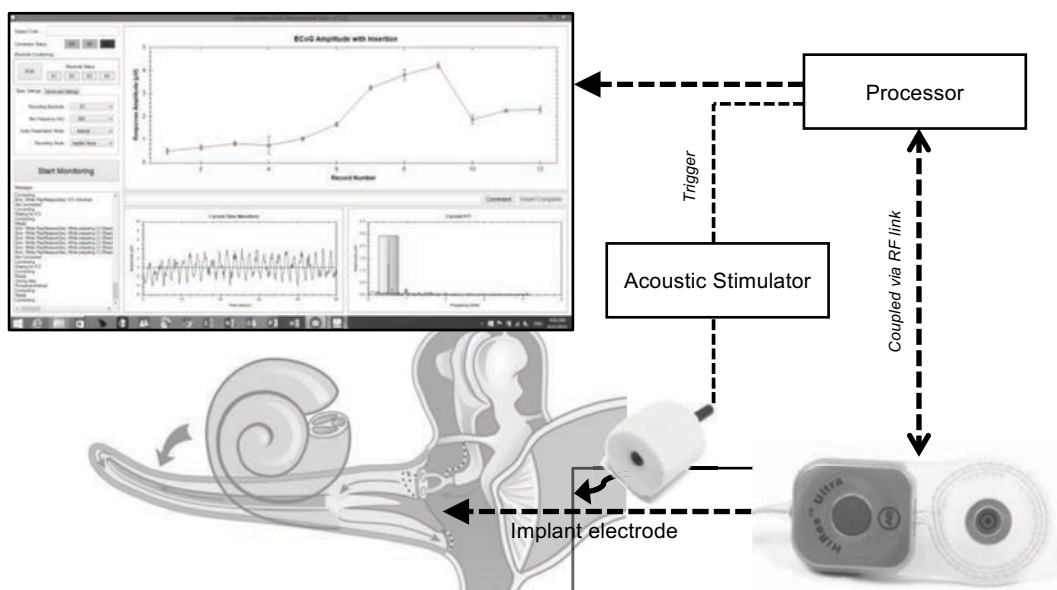
RW ECoG



Intracochlear Recordings

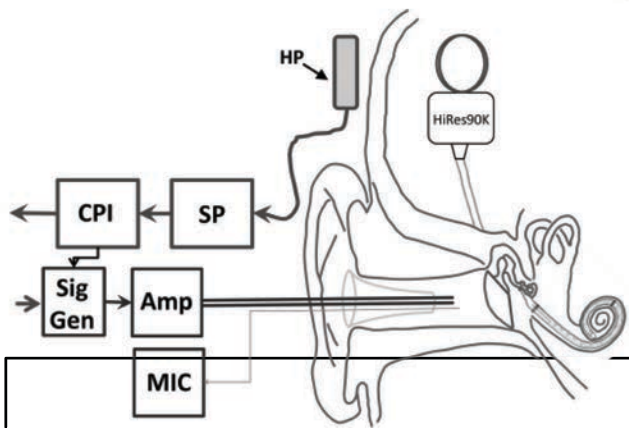


Setup via Implant



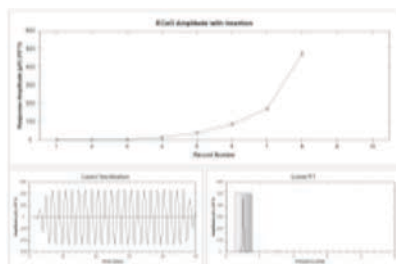
ECochG with the Device

- Long **recording buffers**
~50 ms @ 10k sample rate
- Sufficient recording **resolution**
especially with low frequency stimulation

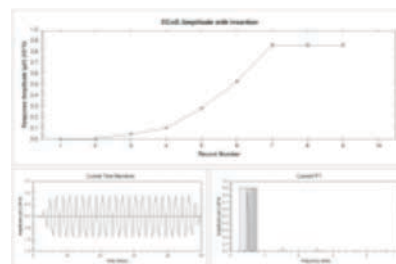


Real-Time HP Feedback

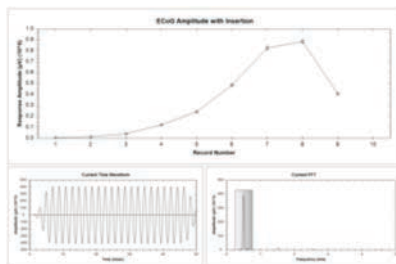
Good



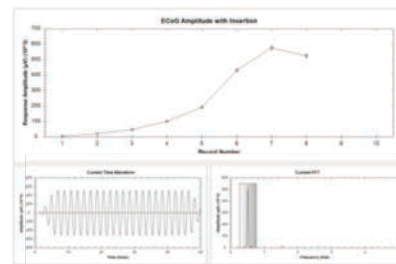
Good



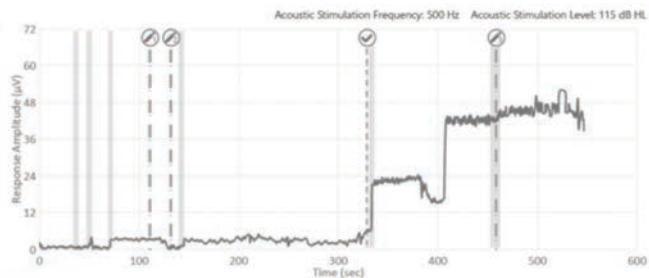
Poor



OK



No Drop w/ Continuous Increase

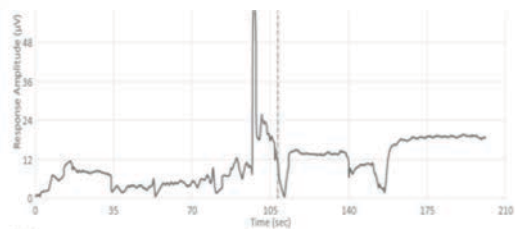


Note 1
Note 2
Note 3

Electrode Sweep

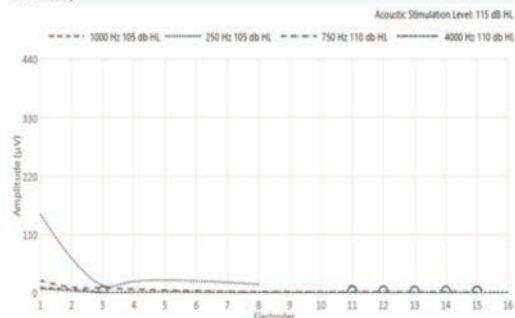


Drop w/o Recovery

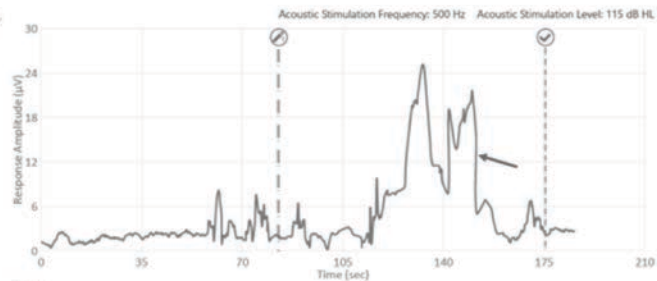


Note 1

Electrode Sweep

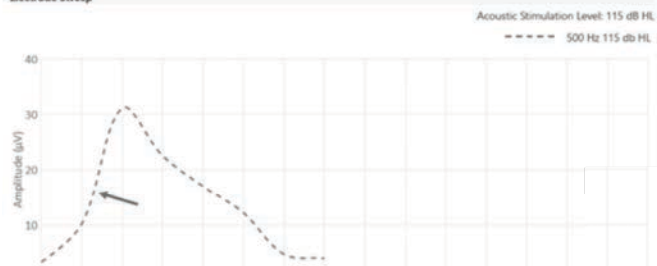


Late Drop; Passing CF

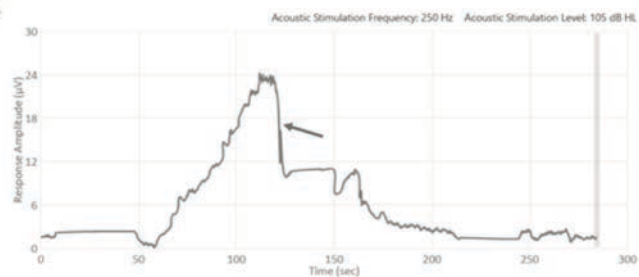


Note 1

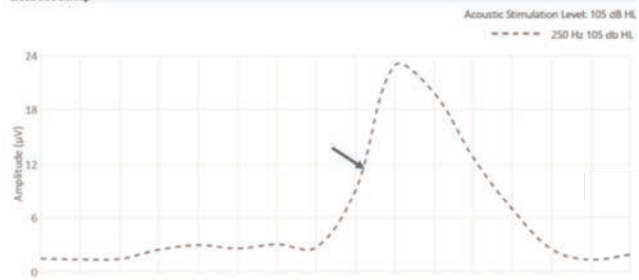
Electrode Sweep



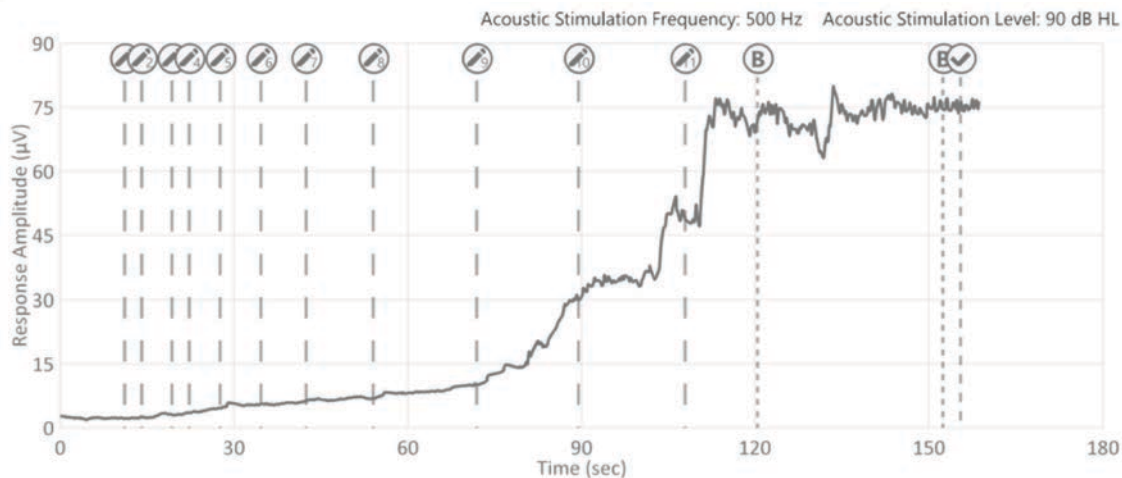
Early Drop – Hair Cell Patch



Electrode Sweep



Report Card – Insertion Graph

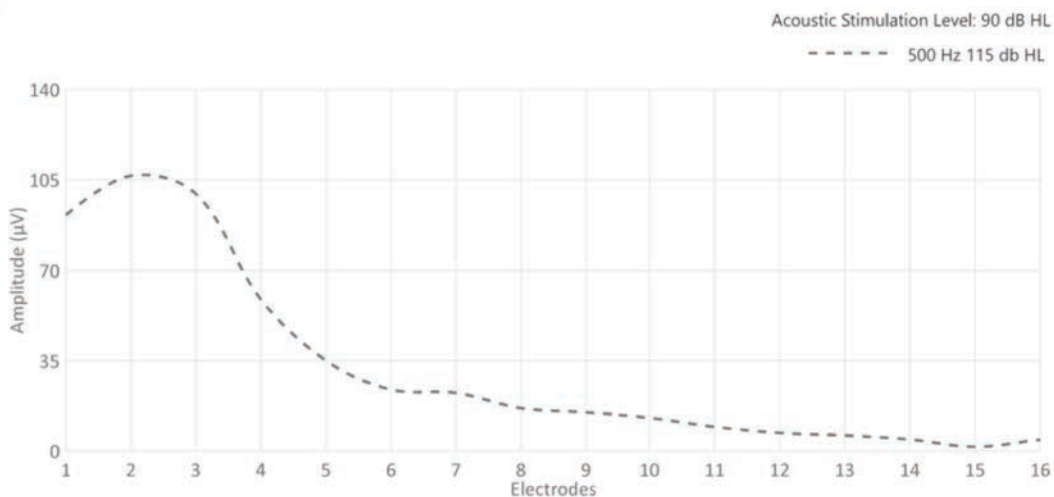


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Report Card – Electrode Sweep

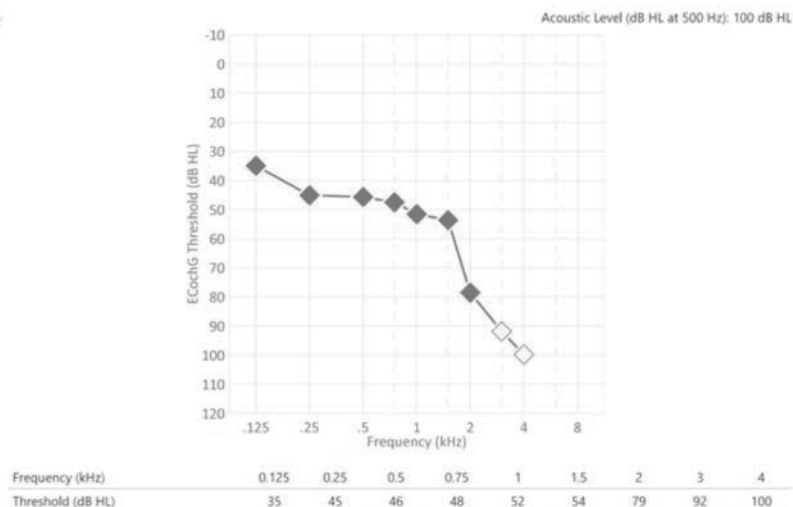


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Report Card – ECochG Thresholds



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Summary - General

- **Feasible** to use acoustically evoked potentials in the OR
Physiology remains strong
- **Intracochlear** recording **location** advantageous
- **Good** correlation w/ adult **performance**
- **NOT just** a hearing preservation monitor
...but rather an insertion **quality control monitor**



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Summary – Clinical Correlations

- **Location** within cochlea
as it relates to **tonotopicity**
- **Scalar** translocation
combination of **amplitude** over the insertion and **phase**
- Intra-/postoperative **audiogram**
HP monitor
- **Tip fold-over**
- Predict **performance**
Intraoperative metrics
 - Need more data



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UCSF Benioff Children's Hospital Oakland



Additional clinical value of AIM system with focus on
ESRT/objective measures

About Children's Hospital Oakland

Services Provided: CI programming, hearing aid fitting, comprehensive audiological services, large number of ABRs and CAEPs, growing auditory neuropathy clinic, aural rehab, speech therapy services, home visits, school site education, DHH IEP/IFSP support.

Size: Approximately 60 implants annually, current caseload is approximately 2000 CI patients

Pediatric CI Team Approach

Multi-disciplinary Team Approach evaluates the “whole” child and provides projected outcomes.

Surgeons

Pediatric Audiologists

Speech Language Pathologists

Psychologist

Educational Liaison / DHH

Social Worker



Expanded Criteria and Acoustic Access

Children with high frequency and moderate to severe hearing loss are at risk for educational and social impacts.

Even when aided appropriately, fatigue and inconsistent access to high frequency speech phonemes can affect language learning and speech production.

Routine Speech Language evaluations should be carried out in order to ensure language acquisition commensurate with their normal hearing peers in order to support success in and out of the classroom.

Expanded Criteria and Acoustic Access

With greatly expanded criteria, new electrode design and soft surgical technique – we continue to see patients with preserved residual hearing.

Couple this with shorter appointment times, limited testing space and we are faced with impacted schedules and an inability to monitor all aspects of the patient's hearing in a timely manner.

Hard to test populations pose their own set of challenges: Pediatrics, Deaf + population and the knowledge that the psychoacoustics involved with self reporting often leads to inaccurate levels and perceptions of CI benefits.

- What does the AIM System offer?

1

Real-time ECochG
Measurement

Monitoring the function of the patient's
cochlea during electrode insertion

2

Objective Audiometry

Fast and automated objective measurement of
thresholds

3

Objective Measures Suite

Designed for intra-operative and post-operative
clinical use

Obtaining the Post Op Audiogram

- Apical electrode as recording electrode
- Recordings through device telemetry
- No additional electrode contacts required
- Low frequency acoustic stimulation through ear inserts



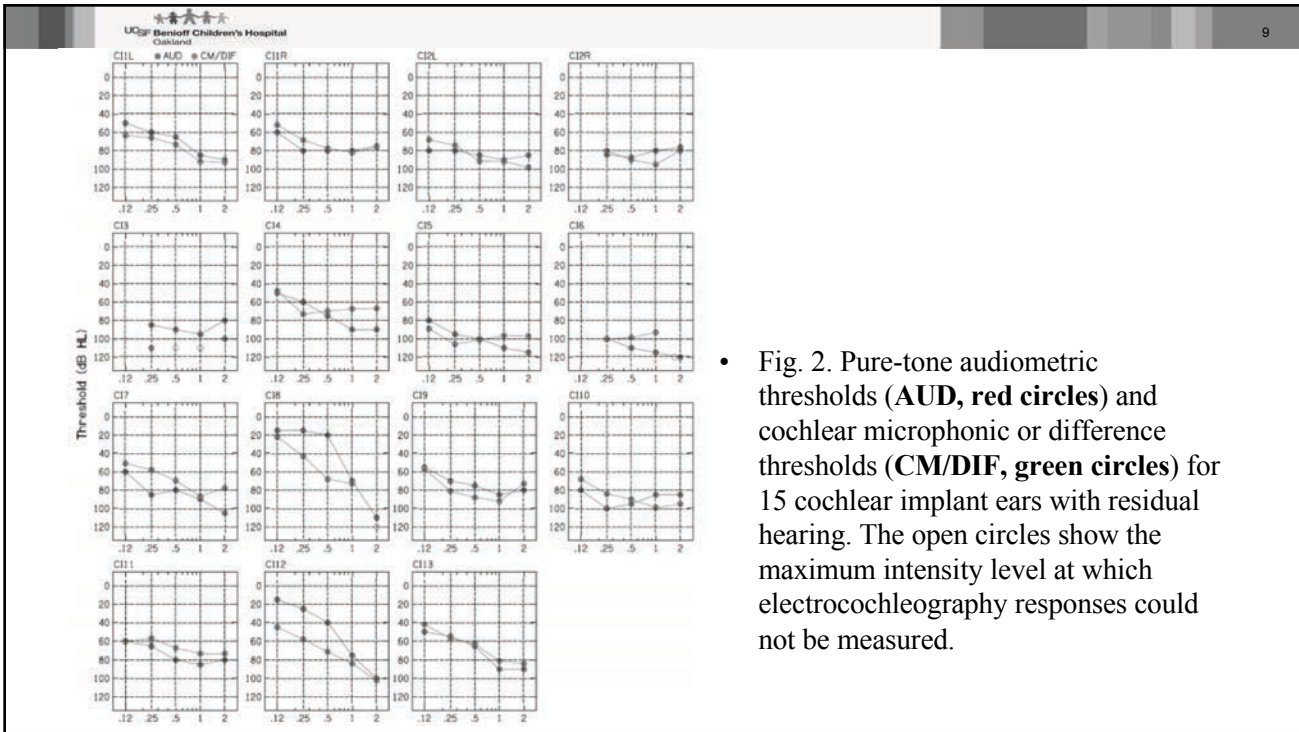
7

- Subjects Audiometric and CM/DIF thresholds were measured from 15 ears of 13 (11 unilateral and 2 bilateral) Advanced Bionics

TABLE 1. Subject demographics for pediatric cochlear implant patients that participated in this study

Subjects	Age (yrs)/Gender	Duration of Implant Use	Etiology of Hearing Loss	Audiometric Method Used to Measure Behavioral Thresholds
CI1L	7/M	2 yrs	Connexin 26	Standard
CI1R	7/M	1.5 yrs	Connexin 26	Standard
CI2L	7/M	1.3 yrs	Unknown	Standard
CI2R	7/M	2.5 yrs	Unknown	Standard
CI3	14/M	1 yr	EVA, progressive	Standard
CI4	2/F	1 yr	Unknown	BOA
CI5	14/M	1 yr	EVA, progressive	Standard
CI6	1/M	6 mos	Waardenburg syndrome	BOA
CI7	7/F	1 yr	TMPRSS3	Conditioned play
CI8	8/F	1 yr	Unknown	Standard
CI9	17/F	3 mos	Unknown	Standard
CI10	4/F	3 mos	Unknown	Conditioned play
CI11	12/F	4.5 yrs	Unknown	Standard
CI12	13/M	3 yrs	Unknown	Standard
CI13	14/M	3.5 yrs	Unknown	Standard

BOA, behavioral observation audiometry; EVA, enlarged vestibular aqueduct.



• Fig. 2. Pure-tone audiometric thresholds (AUD, red circles) and cochlear microphonic or difference thresholds (CM/DIF, green circles) for 15 cochlear implant ears with residual hearing. The open circles show the maximum intensity level at which electrocochleography responses could not be measured.

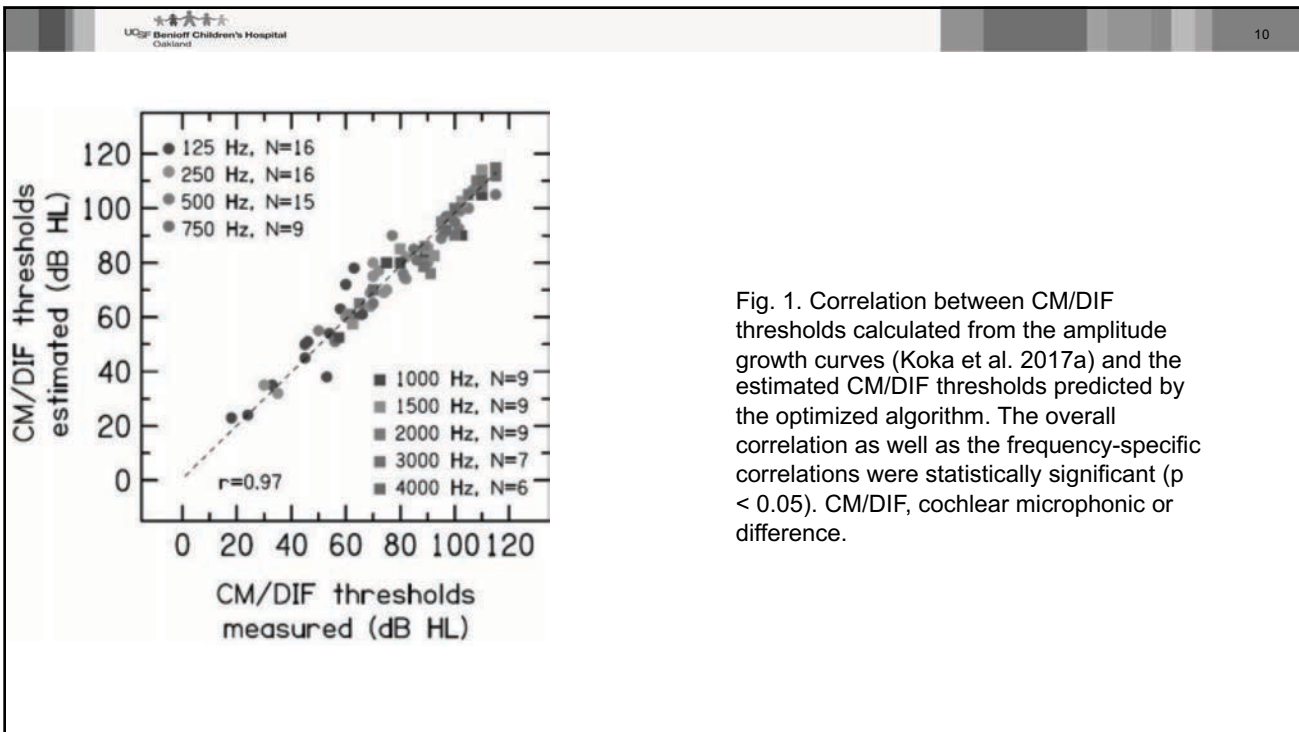


Fig. 1. Correlation between CM/DIF thresholds calculated from the amplitude growth curves (Koka et al. 2017a) and the estimated CM/DIF thresholds predicted by the optimized algorithm. The overall correlation as well as the frequency-specific correlations were statistically significant ($p < 0.05$). CM/DIF, cochlear microphonic or difference.

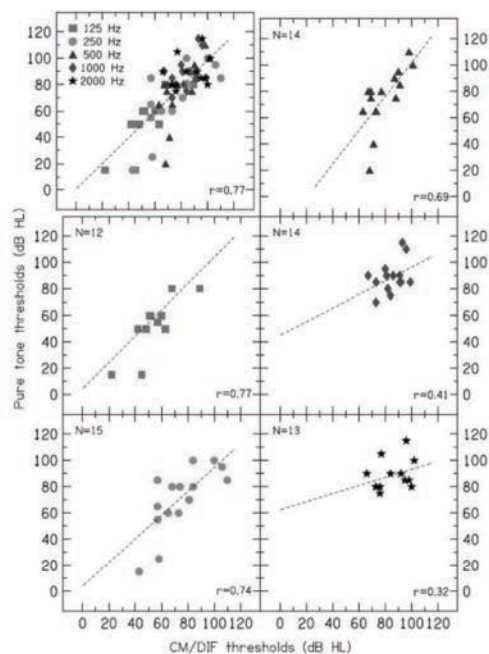


Fig. 3. The top left panel shows correlation between audiometric thresholds (HL) and CM/DIF thresholds (HL) measured at 125, 250, 500, 1000, and 2000 Hz for the 15 cochlear implant ears (11 unilateral and 2 bilateral patients). The remaining panels show frequency-specific correlation between audiometric and CM/DIF thresholds. All the correlations were statistically significant ($p < 0.05$) except the frequency-specific correlations reported for 1000 and 2000 Hz. CM/ DIF indicates cochlear microphonic or difference.

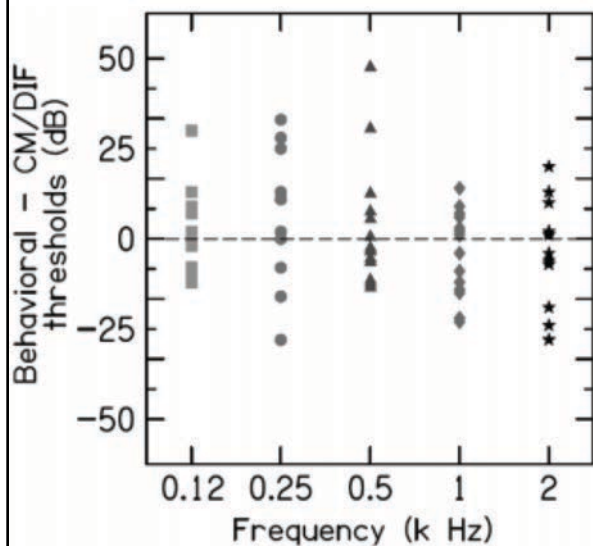


Fig. 4. Differences between CM/DIF and behavioral thresholds as a function of frequency in 15 cochlear implant ears. CM/DIF indicates cochlear microphonic or difference.

Conclusion

- The use of CM/DIF to monitor residual hearing in pediatric cochlear implant patients can be challenging and may be influenced by factors that are unique to pediatric patients.
- The present study provides evidence for the use of ECOG in determining CM/DIF thresholds that are similar to the audiometric thresholds at lower test frequencies.
- Future studies with larger pediatric patient population are needed to establish the relationship between CM/DIF and audiometric thresholds especially at higher test frequencies.

The Most Important Results

Eliminates Barriers: Lack of booth space, time, and reliability or attention of difficult to test patients.

More reliable measurements = Educational and social success by giving kids the best access to sound.

Improving access to sound while preserving hearing will provide children (ok adults matter too!) with the tools they need to support complex language development.

With soft surgical technique, we are seeing stable results expanding out to five years post implant.

- What Other Objective Measurements May be Obtained?

Impedance Measurements
Electrode Conditioning
NRI
eSRT

3

Objective
Measures Suite

Designed for intra-operative and
post-operative clinical use

eSRT

- A beautiful thing when your patient complies –
Not the end all, but an important piece of the
puzzle for verification with a complex population
as well as all CI recipients.
- Patient compliance, middle ear involvement and
multiple machines requiring more than 2 hands!

Relationship between Electrical Stapedial Reflex Thresholds and HiRes™ Program Settings: Potential Tool for Pediatric Cochlear-Implant Fitting

Relationships among objective measures and speech perception in adult users of the HiResolution Bionic Ear

Keywords: cochlear implant; electrically evoked compound action potential (eCAP); electrically evoked stapodial reflex threshold (eSRT); objective measures; speech recognition

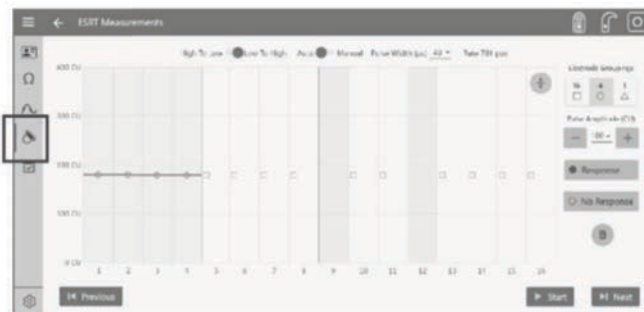
18

How to Perform ESRT Measurements

The reflex bridge needs to be set in Reflexive Decay mode and to be running. Then start ESRT stimulation on the AIM™ system and then monitor for responses on middle ear bridge. Click stop when you see a response. Repeat for each group. Depending on middle ear analyzer, it may time out after 60 seconds (GSI) and you will need to start that again (may need to stop AIM™ system stimulation).

How to Perform ESRT Measurements

- Select "ESRT Measurements"
- Can run as Automatic or Manual measure
- Select low to high (default in the Post Op mode).
- Pulse width is adjustable on the ESRT page and the corresponding rate is displayed adjacent to this.
- ESRT can be measured with Electrode Groupings of 16, 4, or 1 contact.
- Click "Start"



Always observe the recipient for any signs of discomfort

ESRT setup

- First confirm normal Middle Ear function. If normal, then proceed with measurement. If abnormal, postpone ESRT testing until the ME problem is resolved.
- Connect the AIM System, Naida Q90 processor and programming equipment, then place headpiece on patient's head.
- Require Tympanometer/Impedance bridge with Reflex Decay test. Place measurement probe of impedance bridge in patient's contralateral (non-implanted) ear.
- The patient will need to remain relatively still during testing. Ensure patients are seated comfortably. Consider testing very young children during nap time or placing them on a caregivers lap while distracting them with a video.



4. ESRT is a valuable tool to assist with CI programming and setting M levels

- Electrically evoked Stapedius Reflex Threshold testing is a useful objective measure to assist clinicians with fitting CI recipients
- It can assist with fitting recipients who are unable to provide reliable subjective feedback about loudness levels
- Although eSRT's are sometimes more difficult to obtain than NRI, they generally show a stronger correlation with behaviorally set M levels



Quick and Streamlined Way to Obtain eSRT

Our preferred set up:
GSI Bridge

If already mapped / modify PW in stimuli within AIM before running eSRT

678 Hz tone

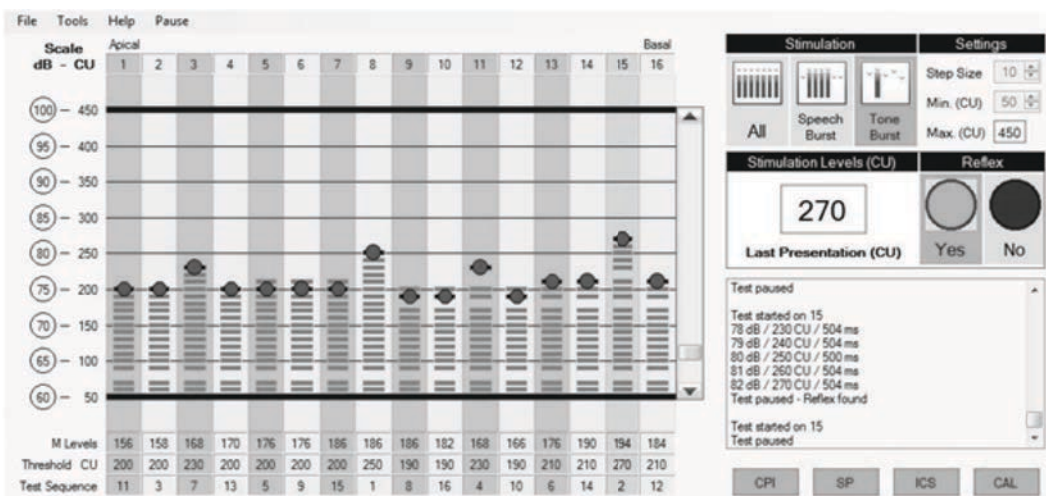
One run for eSRT for all electrodes

eSRT thresholds for each speech burst

Within each speech burst / one single electrode to shape

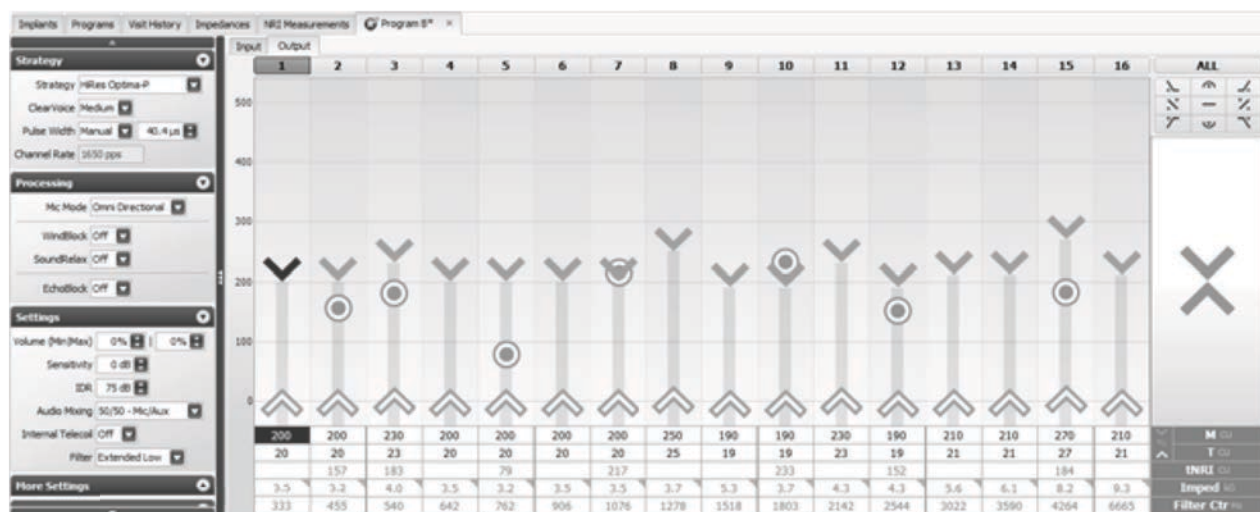


Speech Burst vs. Tone Burst



- *research based software platform

Suggested eSRT Map



How to Generate Reports and Export Data to SoundWave 3.2

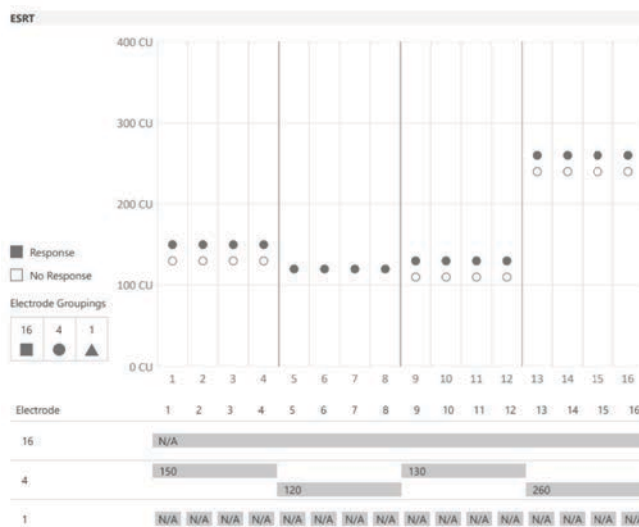
- Data can be exported and a Full PDF Report is generated automatically showing an overview of the Test Results.
- Click "Export" – this will export 3 files to the specified directory.
- Click "Export Folder" – this will open the folder where the export is saved.
- Ability to import data into SoundWave 3.2 fitting software: Demographics, Impedances, NRI for a better CI programming experience, ECoG Threshold estimation for monitoring of residual acoustic hearing.



Impedance Measurement and tNRI

Frequency (kHz)	0.125	0.25	0.5	0.75	1	1.5	2	3	4							
Threshold (dB HL)																
Impedances																
Electrode	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Impedance (kΩ)	5.5	5.9	5.7	6.3	7.2	8.2	7.7	8.1	10	6.5	5.3	5.6	9.4	12.3	13.9	11.9
Valid																
NRI Measurement																
Electrode	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
tNRI (CU)																

eSRT AIM PATIENT REPORT



Preliminary Findings for AB recipients and M level targets:

- eSRT is attempted with all patients. Data pull from all AB recipients with healthy middle ear and the ability to maintain seal and attention * we were able to correlate updated findings with existing maps
- High correlation between NRI and speech burst eSRT is found across all ears tested with responses.

In an ever-changing service model:

- During COVID 19 we have all had to stop and think:
 - What are urgent patients? Do prelingually deafened pediatric CIs fit in this category?
 - If so, how do we minimize in person visits?
 - Maximize first fit at initial stim in order to buy time and limit trips back and forth to the clinic for map/program changes?
 - How do we limit the number of rooms in which we see a patient?

Our new normal – Streamlined and proven technology is needed to safely serve our patients

Dr. Seuss Audiology?

I have seen patients in the parking lot
I have seen them under a tree
I have made earmolds outside of their car
And screened in the hall using OAEs

This is the time for portable, reliable and objective measures. Portable Impedance Measurements, eSRT, NRI and Post Op Audiometry will aide in validating and fitting our patients in one room and with minimal contact.



Maximizing First Fit

- If using AIM: Run tymps and then run ECOG post op audiogram
 - If working with patients presenting with significant residual hearing, this will help you evaluate and fit the acoustic component accurately and while remaining in one room – mitigating the contact with others and extra equipment.

One and done first fit: You may use AIM to obtain eSRT for speech burst, then once you create a first, comfortable map shaped with eSRT targets, you may then make four more progressive maps with P5 hopefully reaching your goal eSRT map. This will allow for you to follow up with tele visits in order to discuss auditory progress, goals and troubleshoot. We all know that most families need help (or need to commiserate) regarding just how hard it is to keep the devices on for the first few months.

Thank You

- Advanced Bionics (in particular Kanth Koka, Erin Castioni, Krysta Gasser and Smita Agrawal)
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- The tireless effort exhibited by ACIA, AudiologyOnline, SpeechPathology.com, and the Scientific Chairs for ACIA 2020!