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CI2020 Online - Session 1

May 4, 2020

Presenters:
Allison Biever, AuD; Stephanie Bourn, AuD; Craig Buchman, MD;
Sarah Coulthurst, MS; Margaret Dillon, AuD, CCC-A; Camille Dunn, PhD;
Jourdan Holder, AuD; Artur Lorens, PhD; Megan Mears, AuD;
Brendan O'Connell, MD

AudiologyOnline Course #35060

This handout accompanies Session 1 which covers the following topics:

- Candidacy Evaluation for Expanding Indications for Cochlear Implantation
- Implications and Techniques for Individualized Mapping
- Challenging Mapping Cases
- Maximizing the Possibilities for Every Patient.

Candidacy Evaluation for Expanding Indications for Cochlear Implantation

Presenters:

Terry Zwolan, PhD

Craig Buchman, MD

Camille Dunn, PhD

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An Evaluation of Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population

Teresa A. Zwolan, Ph.D.
Professor and Director of the Cochlear Implant Program, Department of Otolaryngology- Head and Neck Surgery, Michigan Medicine

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We gratefully acknowledge Dorina Kallogjeri, MD, MPH for her statistical expertise and also acknowledge Jill Firszt,Ph.D. and the late John Niparko, M.D., for contributions to the development and initiation of this study. This study was supported in part by the American Cochlear Implant Alliance and the Centers for Medicaid and Medicare Services. Finally, we would like to thank the participating centers for their devotion of time and energy to this study.

Study Rationale

- CMS indications for a cochlear implant have been in existence since 4/4/2005 and require beneficiaries to demonstrate a bilateral moderate to profound SNHL and to score less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition to qualify for a cochlear implant
- These indications are more stringent than FDA-approved indications, meaning some Medicare beneficiaries are less likely to receive a CI because of their insurance

Current Medicare NCD (CAG-00107N)

- The evidence is sufficient to conclude that a cochlear implant is reasonable and necessary for individuals with hearing test scores of > 40 % and ≤ 60 % only when the provider is participating in and patients are enrolled in either an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

Outcomes are improving and indications are expanding

- Great change has taken place in FDA approval since this study was initiated.
- The FDA has now approved:
  - Cochlear and MedEL devices for EAS/Hybrid
  - MedEl device for single-sided deafness (SSD) and asymmetric hearing loss (AHL) for individuals 5 years of age and older.
- The time is right for Medicare indications to change

Study Timeline

- May 11, 2011
  - Medcac Meeting to review the clinical evidence for cochlear implant (CI) procedures to examine, in part, clinical outcomes associated with unilateral CIs with sentence test scores in two ranges: 40-50% and 51-60%
- July 2013
  - ACIA submits proposal to CMS to investigate expansion of the NCD
  - July 30, 2013: The CED study was approved NCT02075229
- September 10, 2015
  - Protocol change was approved to use AzBio sentences instead of outdated HINT sentences for candidacy determination and outcome measurement
- September 27, 2018
  - Interim review of the data by CMS
- August 27, 2019
  - Final review of the data by CMS
- March, 2020
  - Submission of manuscript summarizing study findings

Participating Centers

Johns Hopkins University
NYU Langone Health
University of Iowa
University of Miami
University of Michigan
University of North Carolina
University of Southern California
University of Washington
Vanderbilt University
Washington University St Louis

Univ of Texas Southwestern
Loyola University Chicago
Medical College of Wisconsin
Univ of Pennsylvania
St. Luke’s Midwest Ear Institute
Rocky Mountain Ear Center
Massachusetts Eye & Ear
Medical Univ of South Carolina
Ohio State University

Study Purpose

- The proposed Coverage with Evidence Development (CED) study evaluates the use of cochlear implants in Medicare beneficiaries with preoperative open-set sentence recognition scores in quiet that fall between 40-60% correct in the best-aided listening condition.
- We examined the hypothesis that intervention with a CI would improve the AzBio Sentence score in the best-aided condition by 25% or more and in the implanted ear alone condition by 30% or more

Test Measures and Data collection visits

- Preoperative, 6, and 12 Months Post-Activation
- Testing included
  - AzBio Sentences in Quiet 60 dB (A)
    - RE aided, LE aided, RE+LE aided
  - CNC Words at 60 dB(A)
    - RE aided, LE aided, RE+LE aided
  - Telephone Testing
    - CUNY Sentences administered Monitored live voice to the ear to be implanted
  - Self Assessment Questionnaires
    - Health Utility Index (HUI3)
    - SF-36 with utility transforms
    - APHAB Form A

Self Assessment Questionnaires

- Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995)
  - Helps quantify the disability associated with a hearing loss
- Short Form-36 (SF-36) (Ware, 1993)
  - Can be used to derive a preference-based health utility index through the use of utility transforms. Has been used to differentiate the health benefits produced by a variety of treatments
- Health Utility Index (HUI) (Furlong, W., Feeny, D., Torrance, G.W., Barr, R.D., 2001)
  - Provides a comprehensive description of the health status of subjects in clinical studies

Hearing Aid Use

- Stimuli were presented at 60 dB A in quiet
- All measures were administered in a CI alone condition
- If patients reported they used a contralateral hearing aid more than 4 hours each day, measures were also administered in the bimodal condition of CI+HA (Telephone test only administered CI alone)
- The “best” score from CI alone or CI+HA was used in the calculation of “Best Aided”

A total of 32 adult patients who received Cochlear Implants between 09/17/2014 and 07/10/2018 were enrolled at 8 participating centers

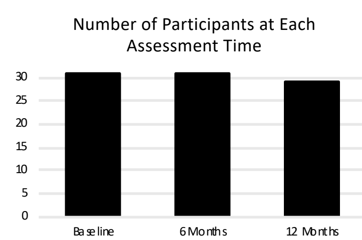
Site	N (%)
John Hopkins University	2 (6)
University of Michigan	9 (29)
New York University	1 (3)
University of Southern California	1 (3)
University of Washington	6 (19)
Washington University	8 (26)
University of Texas Southwestern	3 (10)
Rocky Mountain Ear Center	1 (3)

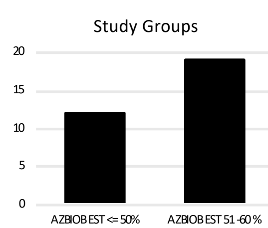
1 subject was excluded from analysis due to not using CI

Subjects

- Total Sample
  - Included in analysis 31
  - 6 months: 31
  - 12 months (complete): 29
    - 1 subject lost to follow-up
    - 1 subject deceased

- Study Groups:
  - Baseline AZBIO score <=50%: 12
  - Baseline AZBIO score 51-60%: 19





There were no significant differences in distribution of baseline characteristics between the 2 study groups

Baseline Characteristics

Demographics	N (%)
Sex	
Male	23 (74)
Female	8 (26)
CI ear	
Left	13 (42)
Right	18 (58)
	Median (Min-Max)
Age at CI activation	73.5 (66-85.2)
Age obtained hearing aid CI ear	56.0 (4.5-77.2)
Age obtained hearing aid in non-CI ear	56.0 (4.5-77.2)
Age Onset General in CI ear	49.0 (4.0-67.0)
Age Onset General in non-CI ear	52.0 (4.0-67.0)
Age Onset Severe in CI ear	61.0 (4.0-82.0)
Age Onset Severe in non-CI ear	62.0 (4.0-80.0)
Length of deafness in CI ear	10.7 (0.2-62.4)
Length of deafness in non-CI ear	9.0 (0.2-62.4)

Analyses

- Primary outcome measure = change in AzBio score from baseline to 12 months post-implant. $\Delta AzBio = AzBio_{12\ months\text{-}}\ \Delta AzBio_{\ Baseline}$
  - One-sided Hypothesis:

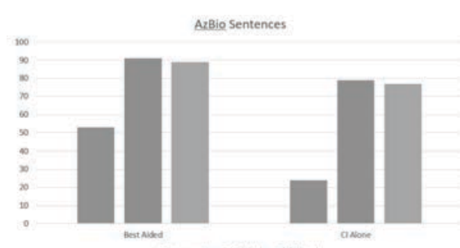
    $\Delta AzBio_{\ Best\text{-}aided} \geq 25\%$

    $\Delta AzBio_{\ CI\ ear} \geq 30\%$
- Shapiro-Wilk's test indicated data were not normally distributed, so median and range are used to describe the variables
- Median differences and 95% confidence intervals were used as measures of effect size, and a mixed effects model was used to examine differences between groups (< 50% and > 50%) through study visits
- Spearman's correlations were used to explore the relationship between speech perception and self-assessment questionnaires

Results

AzBio Sentence Scores

Measure	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
AZ BIO SCORE BEST AIDED	53 (26 to 60)	91 (25 to 100)	89 (36 to 100)
AZ BIO SCORE CI ONLY	24 (0 to 53)	79 (0 to 99)	77 (13 to 100)



Testing the null hypothesis

Group Data

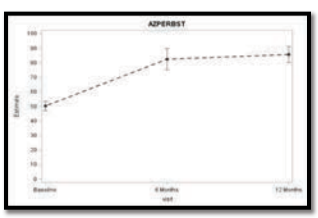
- As a group, the median change in Best Aided AzBio sentence score was 39% and is significantly greater than the hypothesized improvement of 25%
- The median change in CI Alone AzBio score was 52% and is significantly larger than the hypothesized improvement of 30%

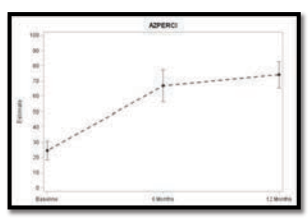
Individual Scores

- 21/31 subjects (72%) demonstrated > 25% improvement in AzBio score when preoperative and 12 month postoperative scores were compared
  - 12/12 (100%) Group 1
  - 9/17 (53%) Group 2

AzBio Estimated Marginal Means

Best-Aided





CI Alone

Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	32.3	23.7	40.9
12Months - Baseline	35.4	28.2	42.5
12Months-6Months	3.1	-2.0	8.1

Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	42.4	30.6	54.2
12Months - Baseline	49.6	39.2	60.1
12Months-6Months	7.2	0.7	13.8

Mixed Model analysis indicates a significant change in AzBio scores through time. The largest increase is seen between baseline and 6-Month and 12-Month assessments, with a much smaller difference observed between 6-Month and 12-Month assessments.

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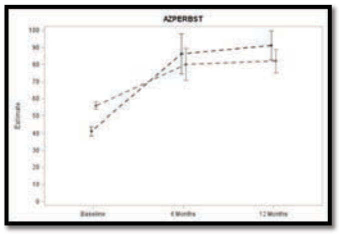
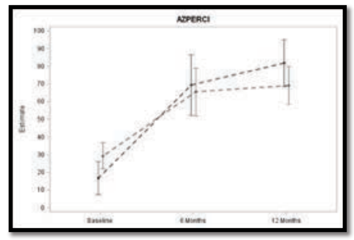
AzBio Sentences: Comparison by Study Group

Best-Aided



Comparison	AzBioBST 40%-50% Estimated Mean difference (95% CI)	AzBioBST 51%-60% Estimated Mean difference (95% CI)
6Months- Baseline	45.1 (32.4-57.8)	24.2 (14.2-34.3)
12Months - Baseline	50.1 (40.9-59.2)	26.1 (18.6-33.5)
12Months-6Months	5.0 (-3.1-13.1)	1.9 (-4.7-8.5)

CI Alone



Comparison	AzBioBST 40%-50% Estimated Mean difference (95% CI)	AzBioBST 51%-60% Estimated Mean difference (95% CI)
6Months- Baseline	52.5 (33.8-71.1)	36.1 (21.2-50.9)
12Months - Baseline	64.9 (49.7-80.2)	39.6 (27.3-51.9)
12Months-6Months	12.4 (2.3-22.6)	3.6 (-4.8-11.9)

The change in AzBio scores through study assessments was significantly different between the study groups.

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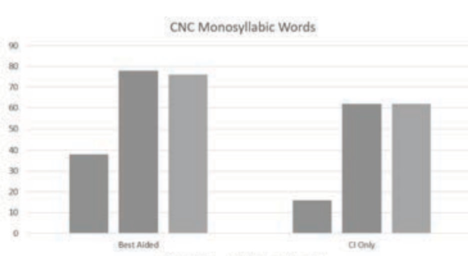
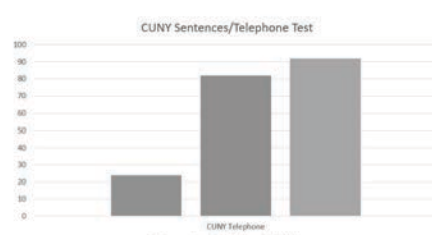
CNC Words and CUNY Telephone Scores

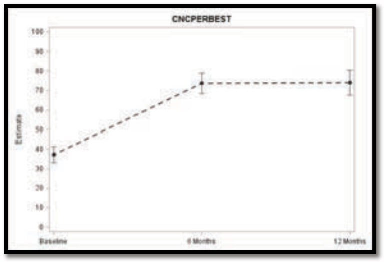
Measure	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
CNC WORDS BEST AIDED	38 (16 to 60)	78 (40 to 96)	76 (34 to 96)
CNC WORDS CI ONLY	16 (0-42)	62 (4 to 92)	62 (18 to 93)
CUNY SENTENCES TELEPHONE CI ONLY	24 (0 to 97)	82 (1 to 100)	92 (0 to 100)



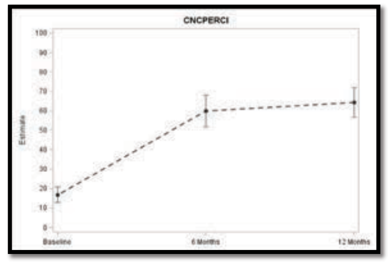


CNC Estimated Marginal Means

Best-Aided



CI Alone



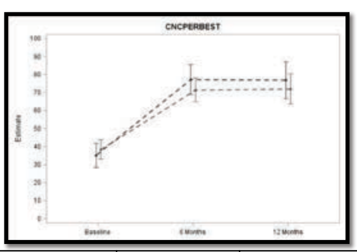
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	36.5	29.3	43.8
12Months - Baseline	36.7	28.5	44.9
12Months-6Months	0.1	-3.7	4.0

Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	43.0	34.2	51.8
12Months - Baseline	47.4	38.9	55.9
12Months-6Months	4.4	-0.1	8.9

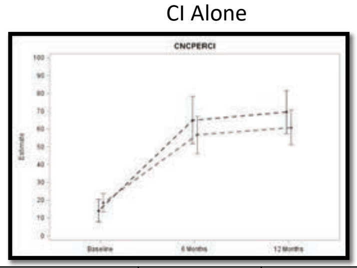
Estimated marginal means graphs show there is significant change in CNC word scores through time. The largest increase is seen between baseline and 6-Month and 12-Month visits, with a much smaller difference observed between 6-Month and 12-Month assessments.

CNC Comparison by Study Groups

Best-Aided



CI Alone



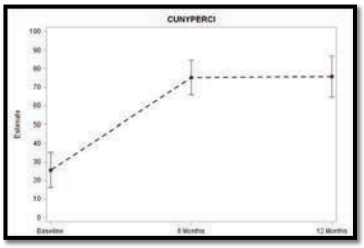
Comparison	AzBioBST 40%-50% Estimated Mean difference (95% CI)	AzBioBST 51%-60% Estimated Mean difference (95% CI)
6Months- Baseline	42.2 (30.6-53.8)	33.0 (23.8-42.2)
12Months - Baseline	41.8 (28.7-54.8)	33.5 (23.0-44.1)
12Months-6Months	-0.4 (-6.5-5.7)	0.5 (-4.6-5.7)

Comparison	AzBioBST 40%-50% Estimated Mean difference (95% CI)	AzBioBST 51%-60% Estimated Mean difference (95% CI)
6Months- Baseline	50.8 (36.9-64.7)	38.1 (27.0-49.2)
12Months - Baseline	55.3 (42.1-68.6)	42.4 (31.7-53.1)
12Months-6Months	4.5 (-2.7-11.7)	4.3 (-1.8-10.3)

There was a significant change in CNC words scores through study assessment visits. This change was not significantly different between the study groups.

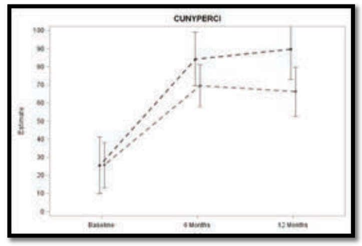
CUNY Telephone

Estimated Marginal Means



Comparison	Estimated Mean difference	95% CI	
6Months - Baseline	49.6	36.1	63.2
12Months - Baseline	50.1	35.7	64.6
12Months-6Months	0.5	-5.6	6.7

Study Groups

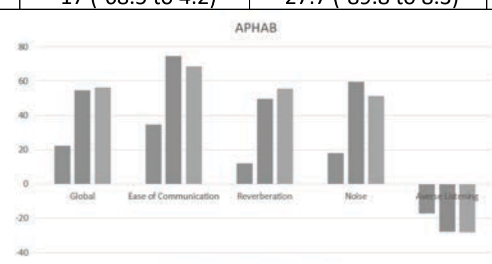


Comparison	AzBioBST 40%-50% Estimated Mean difference (95% CI)	AzBioBST 51%-60% Estimated Mean difference (95% CI)
6Months- Baseline	58.7 (36.9-80.4)	43.9 (26.6-61.2)
12Months - Baseline	64.3 (41.7-86.8)	40.7 (22.5-58.8)
12Months-6Months	5.6 (-3.7-14.9)	-3.2 (-11.1-4.7)

Significant change in CUNY sentence scores through time. No significant difference between study groups.

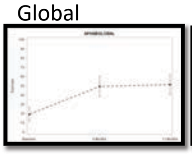
APHAB Test Scores

APHAB Domain	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
GLOBAL	22.4 (-21.4 to 67.2)	54.8 (-32.1 to 89.5)	56.2 (0.6 to 94.3)
EASE	34.7 (-27.2 to 84.8)	74.5 (-63.3 to 99.0)	68.5 (-2.0 to 92.5)
REVERB	12.2 (-22.5 to 54.2)	49.8 (-2.0 to 99.0)	55.5 (2.0 to 97.0)
NOISE	18 (-20.5 to 72.0)	59.5 (-30.8 to 97.0)	51.5 (4.0 to 99.0)
AVERSE	-17 (-68.5 to 4.2)	-27.7 (-89.8 to 8.3)	-28.2 (-79.8 to 2.8)

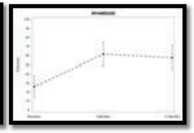


APHAB Estimated Marginal Means

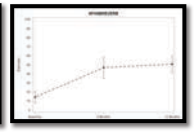
Global



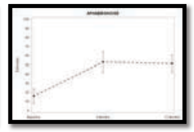
Ease



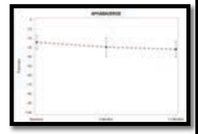
Reverb



Noise



Averse



Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	30.3	19.3	41.2
12Months - Baseline	32.1	21.5	42.7
12Months-6Months	1.8	-6.8	10.4

Comparison	Estimated Mean difference	95% CI	
6Months - Baseline	35.7	22.4	49.0
12Months - Baseline	31.6	18.9	44.2
12Months-6Months	-4.1	-14.7	6.4

Comparison	Estimated Mean difference	95% CI	
6Months - Baseline	32.7	19.8	45.6
12Months - Baseline	36.5	26.0	46.9
12Months-6Months	3.8	-8.5	16.1

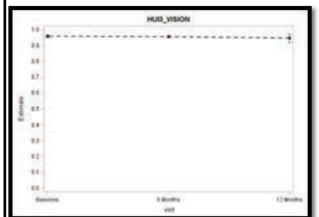
Comparison	Estimated Mean difference	95% CI	
6Months - Baseline	37.1	26.7	47.6
12Months - Baseline	35.4	26.6	44.3
12Months-6Months	-1.7	-11.4	7.9

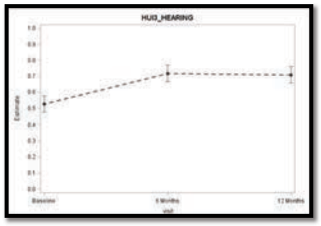
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-5.4	-13.6	2.8
12Months - Baseline	-7.7	-16.6	1.3
12Months-6Months	-2.2	-12.5	8.0

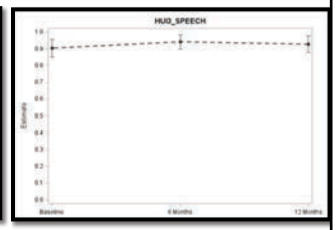
The estimated marginal means graphs indicate significant change in APHAB test scores through time with the exception of APHAB Averse which displays a much smaller change that is not significant.

HUI3 Domain	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
VISION	0.958 (0.951-0.965)	0.959 (0.952-0.966)	0.948 (0.931-0.966)
HEARING	0.526 (0.476-0.576)	0.712 (0.667-0.768)	0.709 (0.657-0.761)
SPEECH	0.903 (0.849-0.957)	0.941 (0.899-0.984)	0.927 (0.877-0.977)
AMBULATION	0.924 (0.881-0.969)	0.898 (0.841-0.956)	0.903 (0.852-0.953)
DEXTERITY	0.996 (0.967-1.025)	0.947 (0.918-0.977)	0.985 (0.955-1.015)
EMOTION	0.929 (0.876-0.982)	0.923 (0.871-0.976)	0.950 (0.918-0.982)
COGNITION	0.971 (0.938-1.004)	0.938 (0.875-1.002)	0.960 (0.909-1.011)
PAIN	0.895 (0.853-0.937)	0.866 (0.789-0.943)	0.928 (0.897-0.958)
Multi	0.558 (0.502-0.614)	0.610 (0.526-0.694)	0.653 (0.589-0.717)

HUI3 Estimated Marginal Means







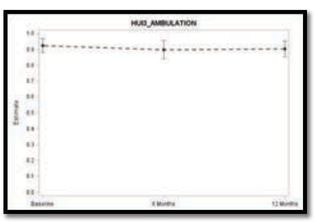
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	0.00081	-0.00708	0.00869
12Months - Baseline	0.00982	-0.02630	0.00666
12Months-6Months	-0.01063	-0.02807	0.00681

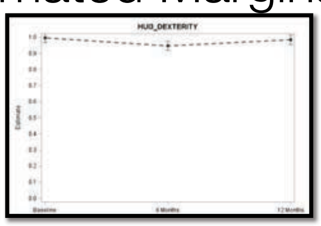
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	0.1916	0.1294	0.2538
12Months - Baseline	0.1828	0.1193	0.2462
12Months-6Months	-0.0088	-0.0723	0.0546

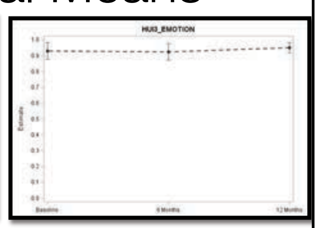
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	0.0381	-0.0211	0.0972
12Months - Baseline	0.0236	-0.0399	0.0872
12Months-6Months	-0.0145	-0.0573	0.0284

No significant change in HUI3_vision or HUI3 _speech through different assessments, but there is significant change in HUI3_Hearing scores through time. The largest increase is seen between baseline and 6-Month and 12-Month visits in HUI3_Hearing.

HUI3 Estimated Marginal Means







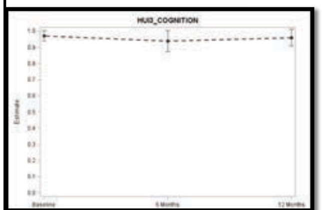
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-0.0261	-0.0731	0.0208
12Months - Baseline	-0.0217	-0.0676	0.0242
12Months-6Months	0.0044	-0.0399	0.0486

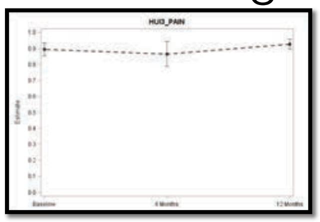
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-0.0487	-0.0869	-0.0105
12Months - Baseline	-0.0111	-0.0501	0.0278
12Months-6Months	0.0376	-0.0014	0.0765

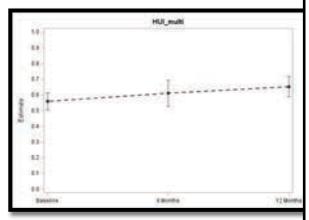
Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-0.0058	-0.0515	0.0399
12Months - Baseline	0.0211	-0.0186	0.0609
12Months-6Months	0.0269	-0.0182	0.0721

No significant change in HUI_3 ambulation and HUI3_emotion through different assessments, but there is significant change in HUI3_Dexterity scores through time.

HUI3 Estimated Marginal Means







Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-0.0326	-0.0944	0.0293
12Months - Baseline	-0.0109	-0.0574	0.0357
12Months-6Months	0.0217	-0.0316	0.0750

Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	-0.0290	-0.0823	0.0242
12Months - Baseline	0.0327	0.0014	0.0640
12Months-6Months	0.0617	-0.0014	0.1249

Comparison	Estimated Mean difference	95% CI	
6Months-Baseline	0.0521	-0.0163	0.1206
12Months - Baseline	0.0954	0.0425	0.1482
12Months-6Months	0.0432	-0.0155	0.1020

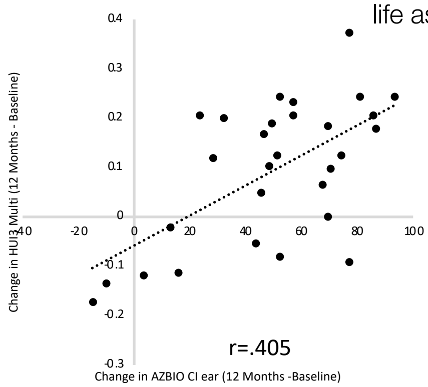
No significant change in HUI3_cognition and HUI3_Pain but there is significant change in HUI3_Multi through different visit assessments.

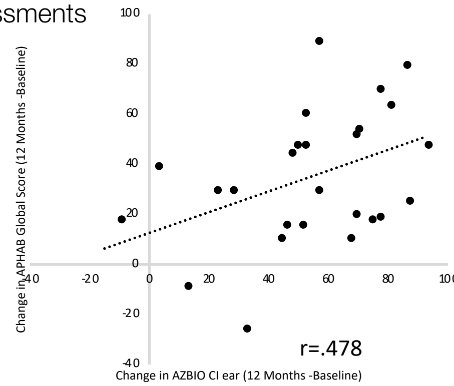
SF-36 Domain Scores

SF36-Domain	Baseline Median (Min-Max)	6-month Assessment Median (Min-Max)	12-month Assessment Median (Min-Max)
Physical Functioning	80 (20 to 100)	75 (20 to 100)	80 (5 to 100)
Role limitations due to physical Health	100 (0 to 100)	75 (0 to 100)	75 (0 to 100)
Role limitations due to emotional problems	100 (0 to 100)	100 (0 to 100)	100 (0 to 100)
Energy/Fatigue	70 (35 to 90)	75 (10 to 85)	70 (25 to 85)
Emotional Well-Being	84 (40 to 100)	84 (40 to 100)	88 (48 to 100)
Social Functioning	100 (37.5 to 100)	87.5 (25 to 100)	100 (37.5 to 100)
Pain	75 (37.5 to 100)	75 (0 to 100)	75 (25 to 100)
General Health	75 (15 to 95)	75 (20 to 95)	75 (35 to 95)

There is no significant change in SF-36 domain scores through different study visits.

Selected correlations between changes in Hearing tests and Quality of life assessments





There were moderate to strong correlations noted between the Change in AZBIO scores (%) in CI ear (12 months – baseline) with the change in HUI3_Multi score and APHAB Global score

Summary of findings

- Currently available CI systems are an effective treatment for HL in Medicare beneficiaries with preoperative sentence recognition scores that fall between 41 and 60%.
  - Adults in this study demonstrated significant improvements in sentence, word, and telephone recognition scores after receiving a CI
  - Improvements on AzBio sentences in both the Best Aided and CI Alone conditions were significantly larger than the pre-defined clinically important changes of 25% and 30%.
- Improvements in speech recognition appear to be related to positive changes on self-reported assessments, such as those noted on HUI Hearing, HUI Multi, and various domains of the APHAB

The results of this CED support the following proposed change to the CMS NCD for cochlear implants

- Cochlear implantation may be covered for treatment of bilateral pre- or- post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on tape-recorded tests of open-set sentence recognition.
- This requested change, if approved by CMS, will increase access to CIs for Medicare beneficiaries, and will facilitate treatment of hearing loss in a more timely fashion – a factor that could help reduce the impact that hearing loss has on patients' overall health and quality of live.

Next Steps

- Manuscript recently submitted for publication
- Upon publication, a formal request for a National Coverage Determination for Cochlear Implants will be submitted. This will include opportunities for public comment, so we'll be reaching out for many of you to be involved.
- This has been a very long process, but it will be worthwhile if we can improve access to CIs for Medicare beneficiaries

Thank you

- Terry Zwolan (zwolan@med.umich.edu)
- Craig Buchman (buchmanc@wustl.edu)

Development of a 60/60 Guideline for referring adults for a Traditional CI Evaluation

Terry Zwolan, Ph.D. Kara Schvartz-Leyzac, AuD, Ph.D., and Terrance Pleasant, M.D.

Department of Otolaryngology, Head & Neck Surgery

Michigan Medicine

COCHLEAR IMPLANT PROGRAM

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

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Access to cochlear implants is poor

- It is estimated that less than 10% of adults who qualify for a CI actually receive one
- Proposed reasons for this are many, and include:
  - Lack of hearing screening for adults
  - Lack of candidacy awareness amongst PCPs, audiologists, and the general population (Sorkin and Buchman, 2015)
  - Lack of referral guidelines for audiologists who dispense hearing aids
  - Weak to moderate positive correlations between unaided WRS and aided WRS (McCracken et al., 2018)
  - Poor communication between HA and CI clinics
    - Referral sources are worried that patients will be upset if they travel to a CI clinic and find out they are NOT a candidate
  - Differences in test procedures used by referral sources and CI clinics

Evidence-based criteria is lacking regarding when to refer

- A few investigators have published evidence-based criteria for when to recommend a CI
- Very few criteria exist for when to *refer* for a CI Candidacy Evaluation
  - Gubbels (2016) examined the medical records of 139 patients over a 5 year period and found that 86% of patients with monosyllabic word scores at or below 32% met criteria for a CI and concluded that PTA of $\geq$ 75 dB and/or a word recognition score of $\leq$40% have a high likelihood of being a CI candidate.
  - Candidacy was based on HINT sentences, Az Bio Sentences in quiet, and AzBio Sentences in +5 SNR.
- Different CI clinics utilize different materials to determine candidacy adds to the confusion
  - AzBio Sentences in quiet, +10 SNR, +5 SNR

The CI scenery has changed recently

- Recent approval of SSD and AHL (MedEl, 2019)
- CI clinics are more likely to ask insurers to preauthorize implantation "off-label" than in the past
- Yet, we continue to "miss" the "traditional candidates" – those who meet traditional criteria for a CI; clinics continue to see patients who have likely been candidates for a long time
- The purpose of this study was to develop referral guidelines for "traditional candidates"

Traditional FDA Candidacy Guidelines vary for available devices

- For this study, criteria was based on the most lenient FDA indications for a contemporary device:
  - Bilateral moderate to profound sensorineural hearing loss
  - Score $\leq$ **60%** correct on recorded sentences when tested in the **best aided** condition
- We additionally examined the applicability of the guideline to the Medicare population:
  - Bilateral moderate to profound hearing loss
  - score $\leq$ **40%** correct on recorded sentences in the **best aided condition**

We wanted a guideline that would be clinically useful for referring clinicians

- Focused on measures typically performed by referring audiologists that relate to measures used in CI candidacy determination:
  - Unaided Pure Tone Average (PTA) of the better hearing ear
  - The highest preoperative unaided monosyllabic word recognition score when the right and left ears were compared

Methods

- We reviewed the medical records of 661 adults who participated in a CICE at the University of Michigan between January 1, 2016 and September 30, 2019
  - Timeline selected based on consistent use of protocol: AzBio Sentences in quiet or in +10 SNR in order to be considered a traditional CI candidate
  - Examined test results to determine if patient met traditional criteria defined as:
    - Bilateral moderate to profound SNHL in the low frequencies and a profound HL in the mid to high speech frequencies.
    - Best aided sentence recognition score of less than or equal to 60% in quiet or +10 SNR

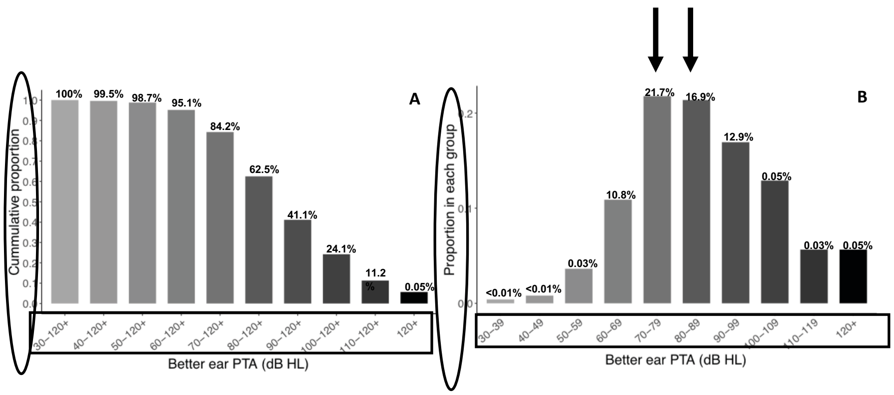
661 records examined

- 250 adults met traditional indications for a CI
- 279 did not meet traditional indications for a CI
- 132 removed from the analysis (Non-English-speaking, presence of cognitive impairment, inappropriate referrals, known “non-traditional referrals, such as SSD).
- Wanted to develop a guideline and also to examine both “hit” and “miss” rates when using the guideline so we looked at both candidates and non-candidates
- Result = 529 subjects

Next: Examined preoperative data for candidates and non-candidates

- Unaided thresholds for each ear.
    - Determined PTA (500, 1K, 2K) of better hearing ear
    - Data was available for all 529 subjects
- Best Unaided Monosyllabic Word recognition score when scores for the right and left ears were compared
    - If available, used score obtained at referring clinic. If unavailable, used score obtained as part of the CICE.
        - Accepted “all-comers” (NU6, CNC, CID-W22, Taped, live voice, variety of presentation levels)

RESULTS: Pre-operative Unaided Better Ear PTA Traditional Candidates

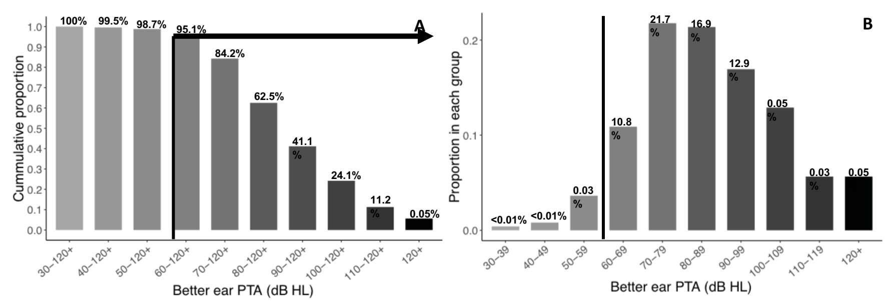


Cumulative percentage data

Proportion of patients with various PTAs

As the PTA goes up, the cumulative %age goes down

RESULTS: Pre-operative Unaided Better Ear PTA Traditional Candidates

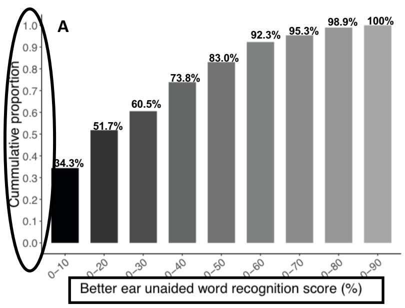


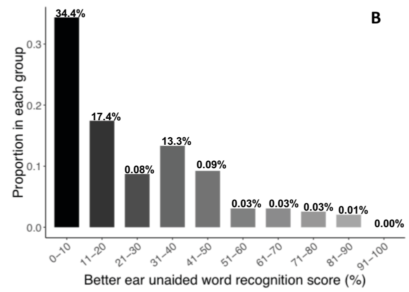
Cumulative percentage data

Proportion of patients with various PTAs

95% of patients presented with a Better Ear PTA > 60 dB and a vast majority of patients had a PTA much > 60 dB

BEST UNAIDED WORD RECOGNITION SCORE of Traditional Candidates



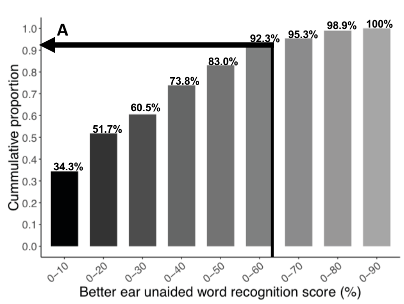


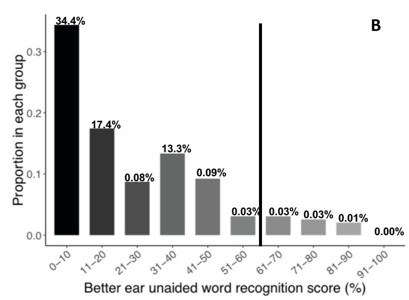
Cumulative percentage data

Proportion of patients with various WRSs

As the WS goes down, the cumulative %age goes down

BEST UNAIDED WORD RECOGNITION SCORE of Traditional Candidates





Cumulative percentage data

Proportion of patients with various WRSs

Patients with an unaided word recognition score in their better ear that is less than 60%
Will likely be a candidate for a CI

60/60 Referral Guideline

- More than 90% of patients who qualified for a CI demonstrated a better ear PTA greater than or equal to 60 dB.
- More than 90% of patients for whom a better ear unaided monosyllabic word score was available (n=198), 92% demonstrated an unaided better ear word score less than 60%.
- Hit Rate: Based on 415 patients with both data points, the 60/60 referral guideline was accurate for 340/415 (82%) of the patients.
- Miss Rate: 18% of patients who met the 60/60 guideline did qualify for a cochlear implant
- Based on these findings, we believe patients should be referred for a CICE if they meet the 60/60 guideline

How effective is 60/60 as a screening tool?

	Candidate	**Non-Candidate**	**Total**	
Meets 60/60	212	67	279	PPV = 76%
Does not meet 60/60	8	128	136	NPV=94%
Total	220	195		
	Sensitivity = 212/220 (96%)	Specificity = 67/195 (66%) False positive rate of 34%		

Positive predictive Value (PPV) OF 76% means a patient has a 76% probability of MEETING traditional indications if they meet the 60/60 guideline

Negative Predictive Value (NPV) of 94% means there is a 94% probability that a patient WILL NOT meet traditional indications if they have a PTA less than 60 dB and a WRS greater than 60%.

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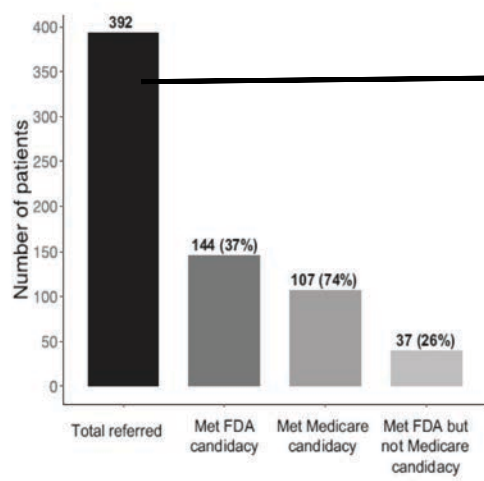
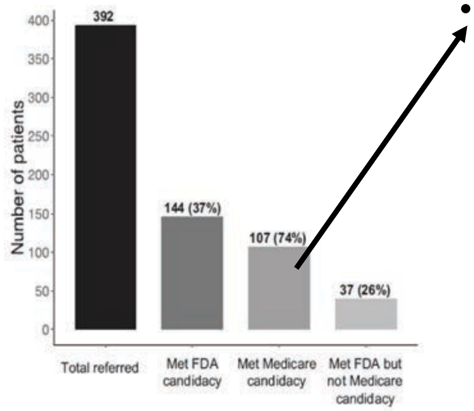
Does this apply to Medicare Beneficiaries?



392 (59%) of 661 patients seen were 65 years or older

Does this apply to Medicare Beneficiaries?

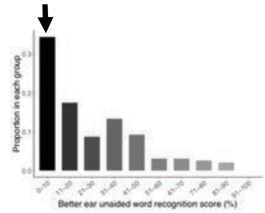


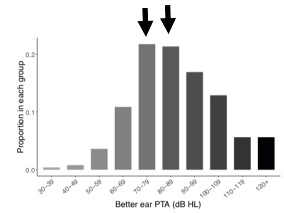
- 66 patients > 65 years had word and PTA information available
  - 62/66 (94%)of these patients met the 60/60 guideline
  - Based on these findings, we feel the 60/60 guideline is appropriate for use with Medicare beneficiaries

DISCUSSION

- One possible reason for under-referral may be the difference in test procedures used by referring professionals and audiologists who perform CICEs
  - Of the 661 records reviewed, we did not observe a single record where sentence testing had been performed by the referring audiologist
- Professionals often indicate they prefer to recommend a patient for a CICE when they are fairly certain they will be a candidate. The 60/60 guideline, based on this data set, provides professionals with justification for such referrals

DISCUSSION





- 34% of the patients seen in our clinic for a CICE demonstrated an unaided word score in their better ear that was less than 10%, and many demonstrated a PTA between 70 and 89 dB HL.
  - Richard Dowell (2016) reported that recipients' chances of a good outcome are significantly better if implantation occurs soon after onset of severe hearing loss and before the loss of all functional auditory skills. Thus, timing is important.
  - An outcome of a CICE that indicates a patient is a non-candidate is not a bad thing: many of our patients returned annually and eventually became candidates, allowing us to provide the CI in a timely manner

SUMMARY AND DISCUSSION

- Based on these findings, we recommend that patients be considered for a CICE if they obtain a score less than or equal to 60% correct on an unaided monosyllabic word test in the better ear and if they demonstrate a PTA greater than or equal to 60dB HL.
- It should be noted that many patients who fall outside traditional indications are receiving CIs, and that this guideline only refers to traditional candidates: it does not apply to patients who may be considered excellent candidates for a CI even though they do not meet traditional indications.
- We are hopeful that this simple guideline will result in an increase in the number of patients who are referred for a traditional cochlear implant candidacy evaluation.

Thank you

- zwolan@umich.edu

Benefits of a Cochlear Implant Registry:

Candidacy in Quiet vs Noise

Camille Dunn, PhD., CCC-A
University of Iowa

How many of us think of a question and can’t come up with an answer?

Road Blocks

- Not enough time to collect research
- No funding
- Takes a lot of data to answer questions
- Personnel is limited
- Statistics are hard
- Where do I store data for easy access?

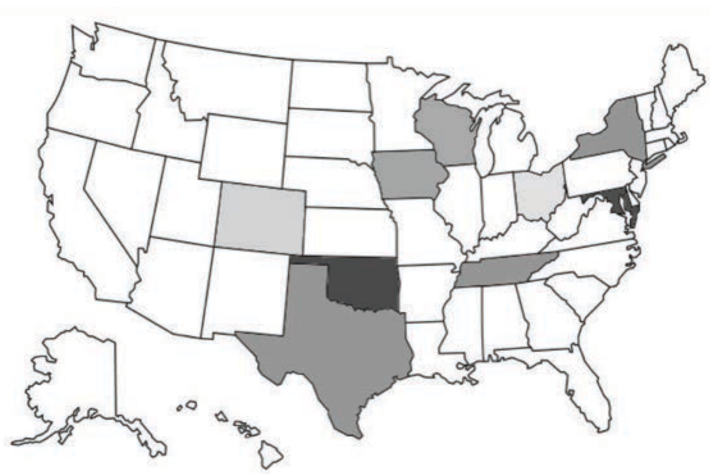
Purpose of the Project

- To establish database of CI outcomes to answer big questions
  - Address analysis related to:
    - CI Candidacy
    - Pre and Post-Operative CI Assessment
    - Patient management
    - Counseling
- Goal:
  - Generate meaningful information using evidence based data to guide current clinical practice.

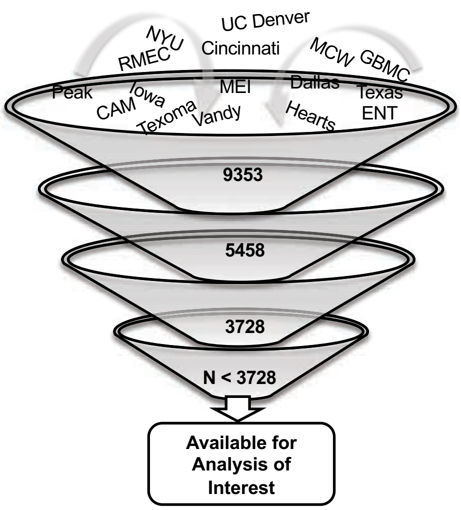
Data Sources

1. HERMES – Web-based application for centers to enter outcomes
   - 32 Centers
2. Static Databases
   - Funding sponsored by Cochlear

Data Sources - Static



Cochlear Combined Database + HERMES



Minimum Criteria for Inclusion:
1. 18 years or older at CI (or activation).
2. Implanted in at least one ear.

Minimum Requirement for Analysis:
1. Present and valid age at implant.
2. Valid age at onset of hearing loss.
3. Valid duration of hearing loss.

Analysis Specific Filter
1. Determined based on question of interest.
2. Will vary based on specific analysis required.

Data Table Descriptions

Data Table	Description	# of Entries
Patient	Demographics	9353
Manufacturer	Cochlear, AB, Med-El, Unknown	4
Device	Type of Device	55
Patient Device	Uniquely defines implant	8382
Audiogram	All Audiogram Data	48735
CNC	Scores	37039
AzBio (Q and Noise)	Scores	39007
HINT (Q and Noise)	Scores	9923
APHAB	Scores	1151
SSQ	Ratings	2899
HUI3	Scores	783

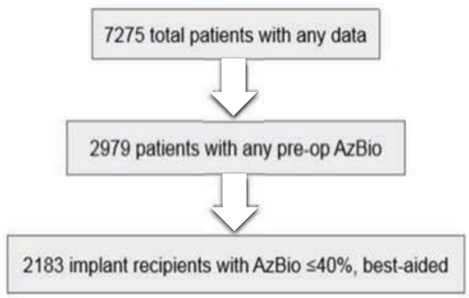
Data Table Descriptions

Variable	Preoperative	Pre & Postoperative
Demographics (Age, Duration, HA Use)	9353	9353
AC Audiogram Implant Ear	4439	2977
AC Audiogram Both Ears	4515	3045
CNC (Implant Ear)	3081	2518
AzBio Quiet (Implant Ear)	2619	2041
AzBio Noise (Implant Ear)	1767	1078
HINT Quiet (Implant Ear)	804	549
HINT Noise (Implant Ear)	134	68
APHAB	406	226
SSQ	673	422
HUI3	334	162

Study Questions

- (1) explore the proportion of candidates who qualified for a CI in quiet and/or noise
- (2) define the demographic characteristics of the cohorts
- (3) examine post-operative relationships between outcomes and test condition (i.e., quiet or noise) used to determine candidacy

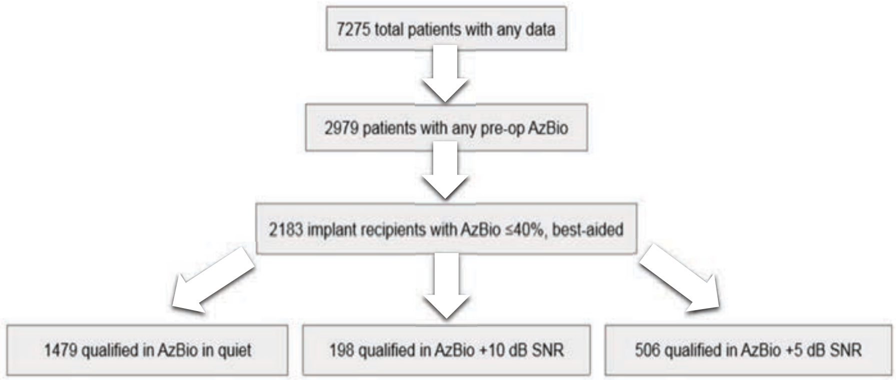
Dataset Filter for Qualifying Groups



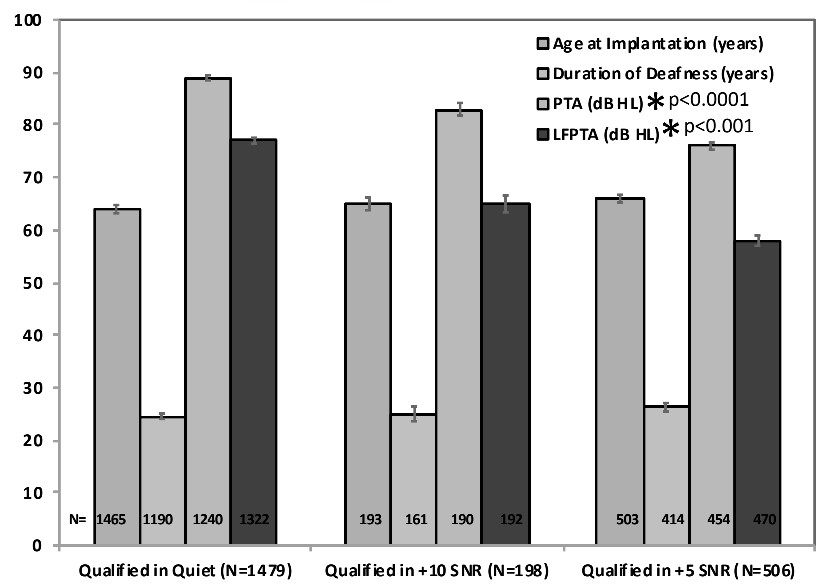
Qualifying Group Stratification

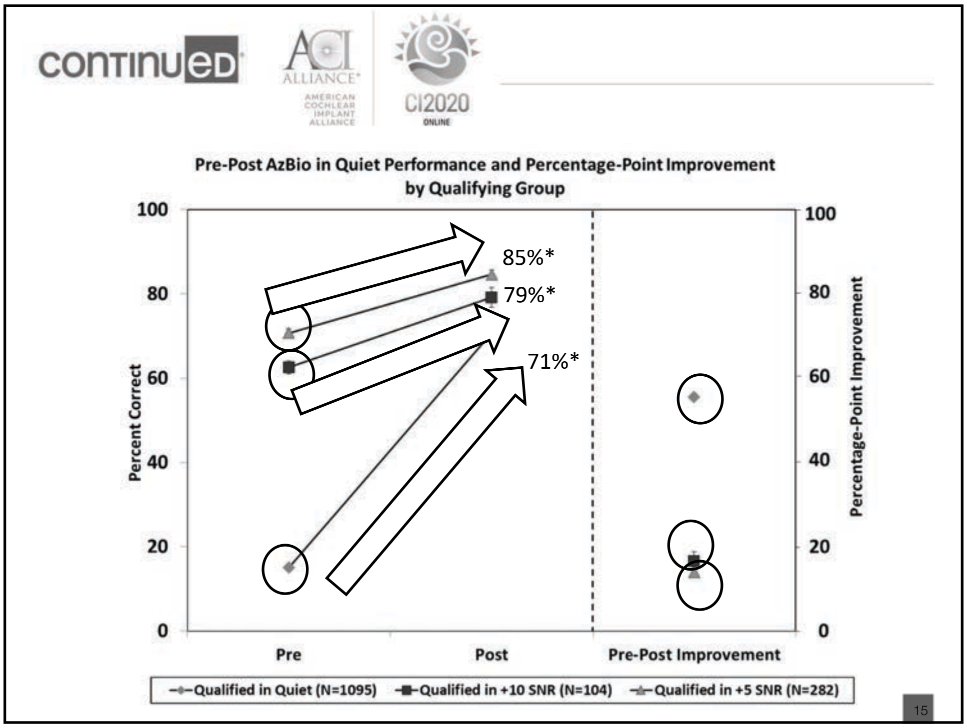
- 2183 patients were stratified into three groups
  - Patients might have had outcomes for noise and in quiet
  - Patients were assigned to group representing the least adverse listening condition that they scored ≤ 40%
    - i.e., if a patient scored 29% in quiet and 15% in +10 dB SNR, s/he was included in the AzBio-quiet group

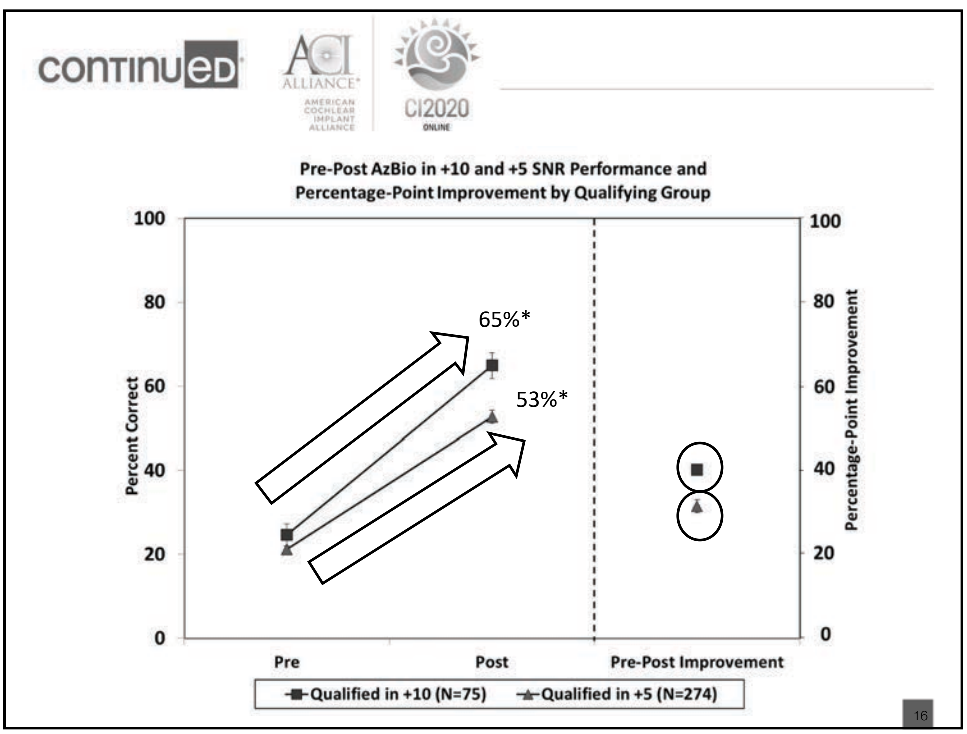
Dataset Filter for Qualifying Groups



dB = decibels, SNR = signal-to-noise ratio




Pre-Post AzBio in Quiet Performance and Percentage-Point Improvement by Qualifying Group
Percent Correct
Percentage-Point Improvement
85%*
79%*
71%*
Pre
Post
Pre-Post Improvement
Qualified in Quiet (N=1095)
Qualified in +10 SNR (N=104)
Qualified in +5 SNR (N=282)
15


Pre-Post AzBio in +10 and +5 SNR Performance and Percentage-Point Improvement by Qualifying Group
Percent Correct
Percentage-Point Improvement
65%*
53%*
Pre
Post
Pre-Post Improvement
Qualified in +10 (N=75)
Qualified in +5 (N=274)
16

Conclusion

1. Most patients derive significant benefit in speech perception
   - especially if performance is measured using the listening condition under which the patient was qualified
2. Expectations and room for postoperative improvement differ for patients qualified in quiet than those qualified in noise

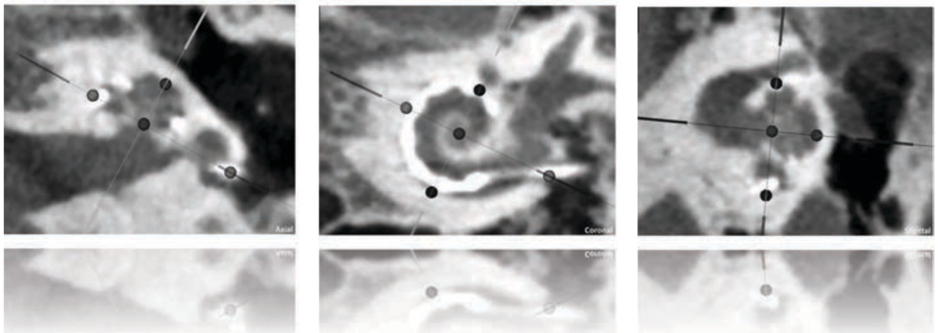
Acknowledgement

- Some data in this study was supported by NIDCD/NIH grant 2P50DC000242
- Cochlear for funding this idea to formulate big data to help answer “big” questions
- Colleagues who are co-authors on this study
  - Sharon Miller, Ph.D.
  - Erin C. Schafer, Ph.D.
  - Christopher Silva, B.S.
  - René H. Gifford, Ph.D.
  - Jedidiah J. Grisel, M.D.

Implications and Techniques for Individualized Mapping

Presenters:
Brendan O'Connell, MD;
Margaret Dillon, AuD, CCC-A;
Mario Svirsky, PhD

continuED



Frequency-to-Place Mismatch in Adult Cochlear Implant Recipients

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UNC Team

Physicians
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- Brendan O'Connell, MD
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Background

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continuED

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Background

- Default mapping capitalizes on tonotopic organization of the cochlea

Image courtesy of MED-EL

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continued | ACI ALLIANCE AMERICAN COCHLEAR IMPLANT ALLIANCE | CI2020 ONLINE

Background

- Default mapping capitalizes on tonotopic organization of the cochlea
- **Frequency-to-place mismatch results when there is a discrepancy between distribution of frequency information and natural tonotopy of the cochlea**

Image courtesy of MED-EL

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continued | ACI ALLIANCE AMERICAN COCHLEAR IMPLANT ALLIANCE | CI2020 ONLINE

Background

- **For CI-alone users, variability in electrode position results in varying degrees of mismatch and impacts spectral cues delivered to patient**

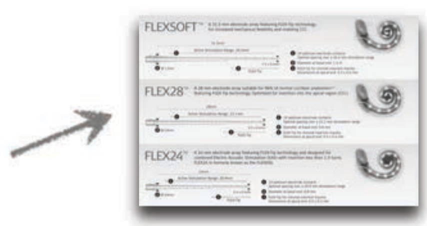

Image courtesy of MED-EL

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- **For CI-alone users, variability in electrode position results in varying degrees of mismatch and impacts spectral cues delivered to patient**

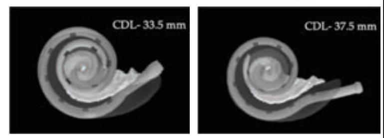

Image courtesy of Vanderbilt

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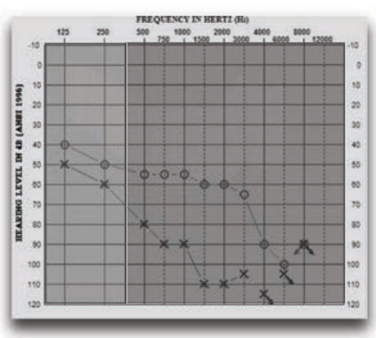
Background

- For CI-alone users, variability in electrode position results in varying degrees of mismatch and impacts spectral cues delivered to patient

- **For EAS users, frequency filters also vary as function of residual acoustic hearing**



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Outline

1) Investigate variability in AID in large cohort of lateral wall arrays

2) Determine the associated frequency-to-place mismatch for CI-alone and EAS users mapped with default frequency filter assignments

3) Investigate the impact of frequency-to-place mismatch on speech recognition in CI-alone condition

4) Assess whether speech benefit conferred by decreased mismatch is mediated by improved spectral resolution

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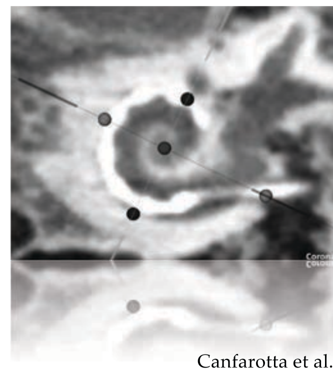
Angular Insertion Depth

Angular Insertion Depth

Methods

- 111 adult CI recipients
- All patients underwent post-operative CT
- AID for each electrode contact was calculated
- Subsequent AID was used to approximate the cochlear place frequency based on the average spiral ganglion map



Canfarotta et al. 2020

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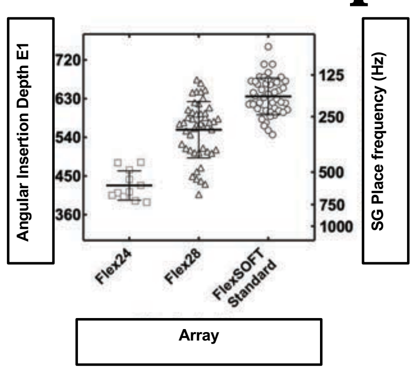
Angular Insertion Depth



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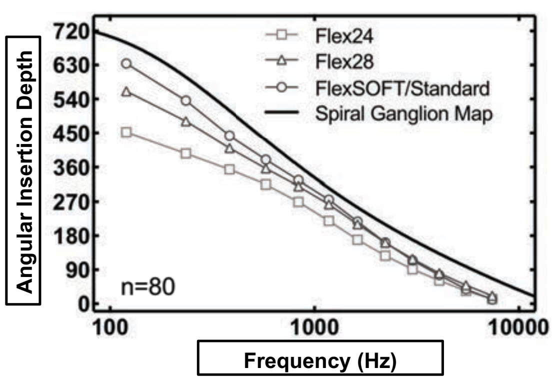
Frequency-to-Place Mismatch CI-Alone

Frequency-to-Place Mismatch



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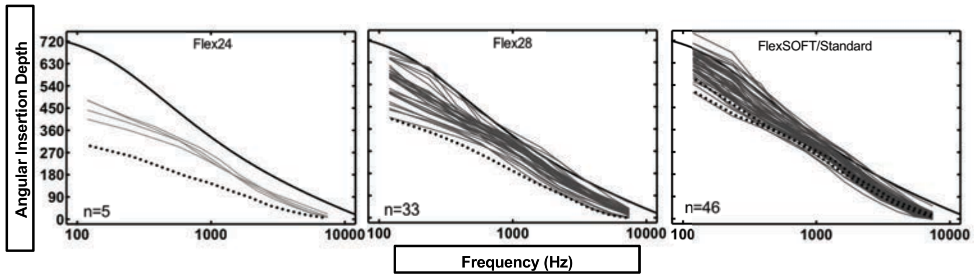
Frequency-to-Place Mismatch



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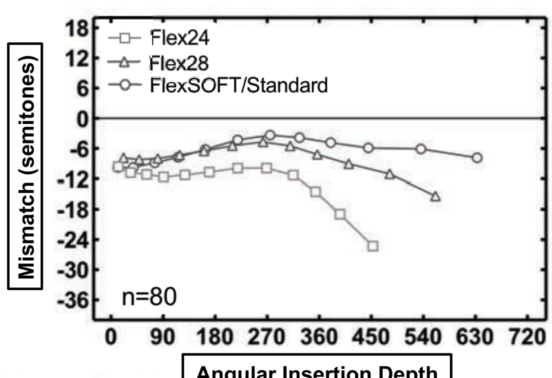
Frequency-to-Place Mismatch



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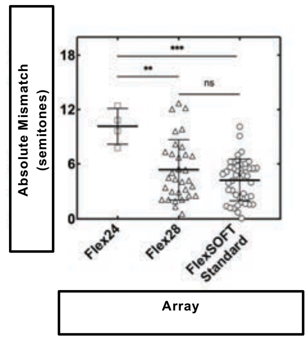
Frequency-to-Place Mismatch

Absolute Mismatch

- Semitone deviation at 270 degree AID (corresponds to ~1500 Hz region)
- Important region for frequency alignment in vocoder simulation
- Corresponds to approximate spectral center of speech information required for recognition



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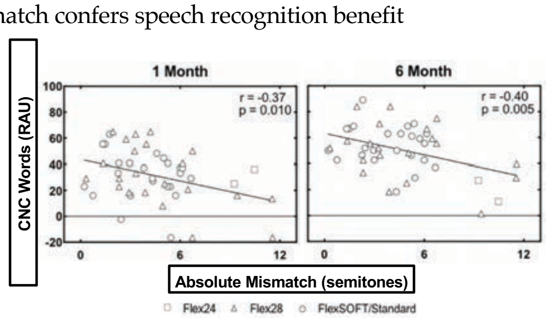
Frequency-to-Place Mismatch

Impact of Mismatch on Performance

- Less mismatch confers speech recognition benefit



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Spectral Resolution

Spectral Shift vs Resolution

- Mismatch data support idea that shift in spectral cues impacts performance
- But with default filters/fixed frequency range, changes in length of electrode impacts spacing between contacts
- As longer electrodes generally decrease mismatch AND have larger contact spacing, the latter could confound outcomes

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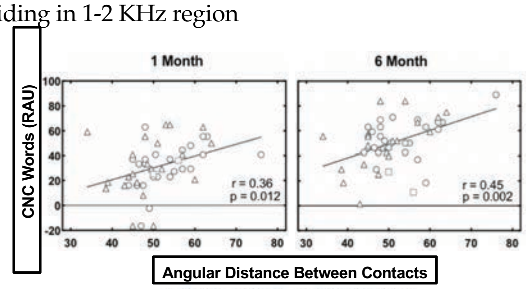
Spectral Resolution

Impact Angular Distance between Contacts on Performance

- As proxy for spectral resolution, angular distance between contacts measured for contact residing in 1-2 KHz region



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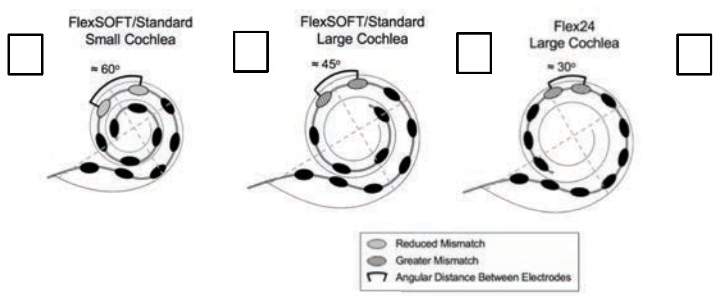
Spectral Resolution

- Hypothesized that electrode spacing would be highly correlated with mismatch



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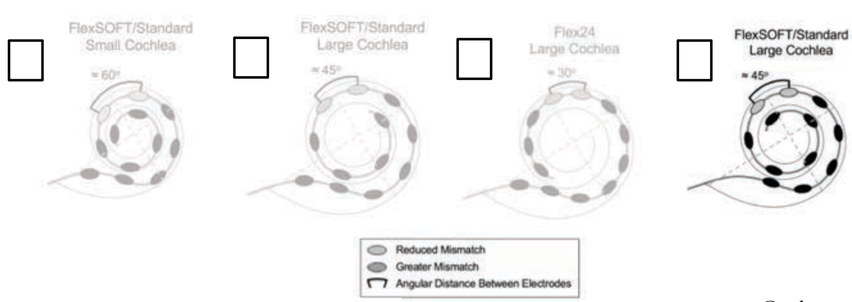
Spectral Resolution

- Hypothesized that electrode spacing would be highly correlated with mismatch
- This wasn't the case…spectral resolution independently impacts performance



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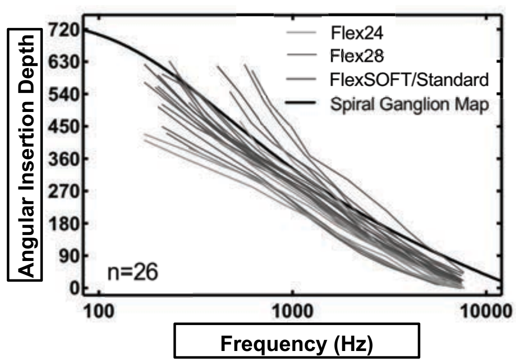
Frequency-to-Place Mismatch in EAS

Frequency-to-Place Mismatch



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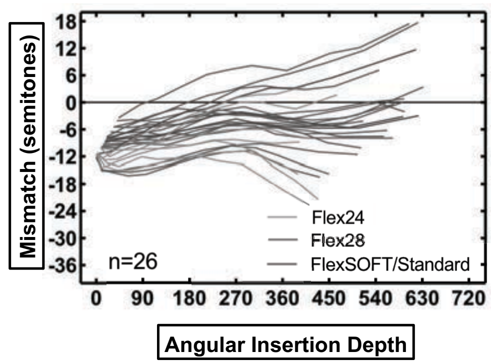
Frequency-to-Place Mismatch



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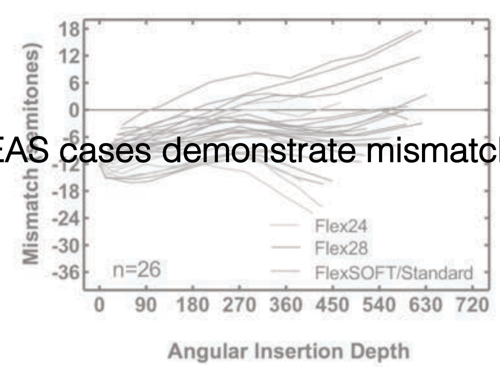
Frequency-to-Place Mismatch



55% of EAS cases demonstrate mismatch > 1/2 octave

Canfarotta et al. 2020

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Summary

1) Significant variability in AID is observed across recipients with same electrode array

2) This contributes to frequency-to-place mismatch among CI-alone and EAS-device users listening with default frequency filters

3) Both reduced mismatch and greater angular distance between electrodes were independently associated with better speech recognition in CI-alone condition

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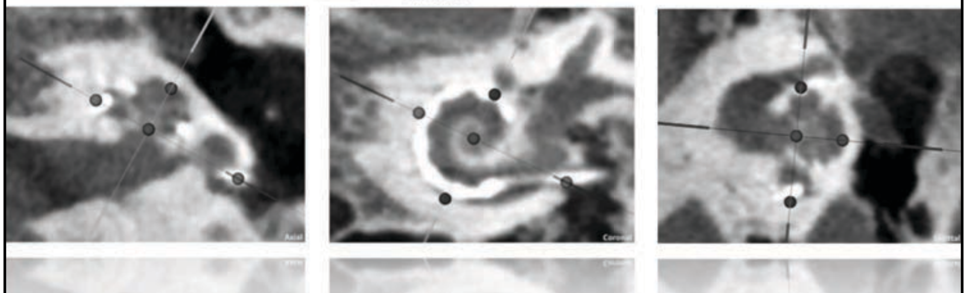

Individualizing Electric Frequency Filters for Cochlear Implant and Electric-Acoustic Stimulation Devices

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Director, Cochlear Implant Clinical Research
Otolaryngology/Head & Neck Surgery
UNC School of Medicine

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Collaborators

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  Assistant Professor
- Emily Buss, PhD
  Professor
- Michael Canfarotta, MD
  PGY-3 Resident, NIH T-32 Research Fellow
- Joseph Hopfinger, PhD
  Professor, Department of Psychology & Neuroscience

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Outline

- Variability in angular insertion depth
- Default mapping procedure
  - CI-alone
  - Electric-Acoustic Stimulation (EAS)
- Place-based mapping procedure
- Pilot data
  - CI-alone & EAS simulations

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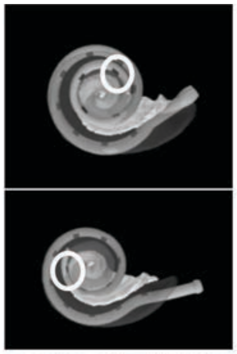
Background

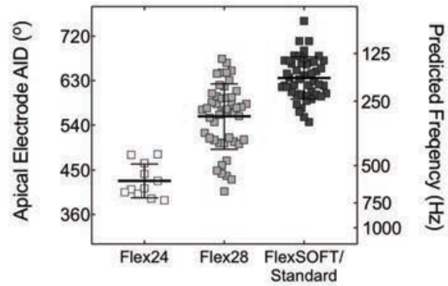
Insertion depth

- Evidence of better speech recognition for recipients of longer lateral wall electrode arrays as compared to shorter arrays (Buchman et al., 2014; O'Connell et al., 2016)
- Closer alignment between the electric frequency filters and the cochlear place frequency may support better monaural & binaural hearing (Fu & Shannon, 1999; Başkent & Shannon, 2003; Goupell et al, 2013; Aronoff et al., 2015; Dillon et al., 2017; Buss et al., 2018)

Angular insertion depth



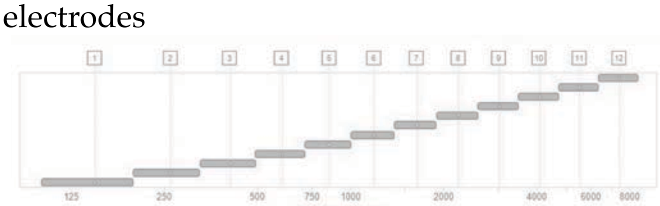
Images courtesy of Vanderbilt University



Canfarotta et al. (2020)

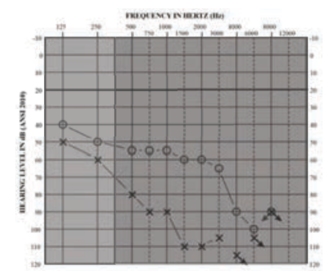
Default mapping procedure

- **CI-alone devices**
  - Provide the speech frequency range electrically
    - e.g., 100-8500 Hz
  - Logarithmically distributed across the active electrodes



Default mapping procedure

- **EAS devices**
  - Provide the speech frequency range
    - e.g., 100-8500 Hz
  - Divide between acoustic versus electric output
    1. Identify the region of aidable hearing
    2. Logarithmically distribute remaining frequency information across active electrodes



Place of stimulation

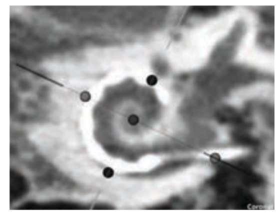
- Assigning electric filters to match cochlear place frequency (Fu & Shannon, 1999; Başkent & Shannon, 2003)

- Post-operative CT imaging and algorithms calculating cochlear place frequency associated with individual electrode contacts (Shuman et al., 2010; Noble et al., 2012; Canfarotta et al., 2020)

Place of stimulation

Place-Based Mapping Procedure:

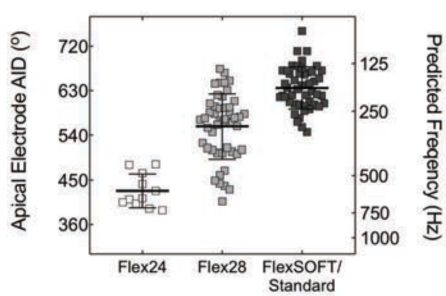
1. Post-operative CT to calculate cochlear place frequency
2. Assign the electric frequency filters for individual electrodes to match the cochlear place frequency



Place-based mapping

Considerations

- CI-alone devices: **limit** the low-frequency information



Canfarotta et al. (2020)

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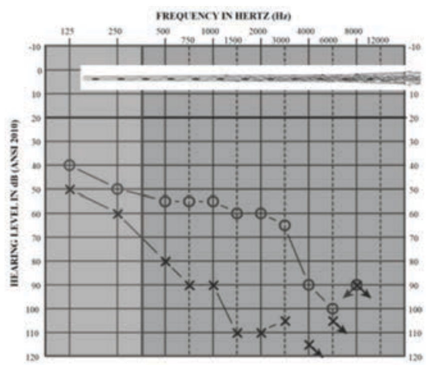
Place-based mapping

Considerations

- CI-alone devices: limit the low-frequency information
- EAS devices: can create an **overlap** in acoustic & electric information
  - Decrease stimulation levels below detection on channels in region of acoustic hearing



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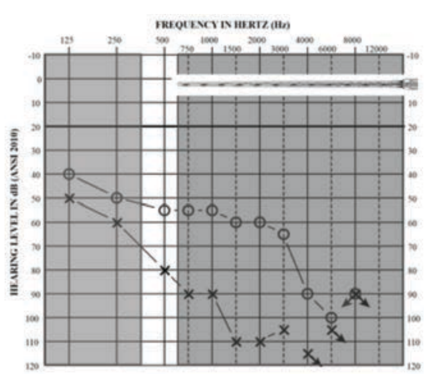
Place-based mapping

Considerations

- CI-alone devices: limit the low-frequency information
- EAS devices: can create an overlap in acoustic & electric information
- EAS devices: can create a **gap** in frequency information



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Place-based mapping

Is there a difference in acute speech recognition when listening with a place-based map as compared to listening with a default map for CI-alone and EAS devices?

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Simulation Data

Methods

Simulation

- Flex24 electrode array recipient
- Calculated the cochlear place frequency with the SG frequency-to-place function (Stakhovskaya et al., 2007)

Subjects

- 22 normal-hearing, young adults

Randomization

- CI-alone or EAS simulation with default or place-based map

Methods

CI-alone simulation

- Default: 70-8500 Hz
- Place-Based: 550-8500 Hz

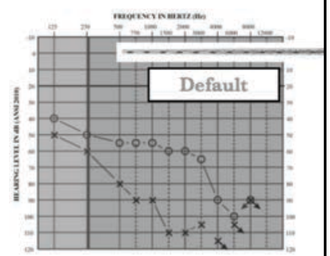
Methods

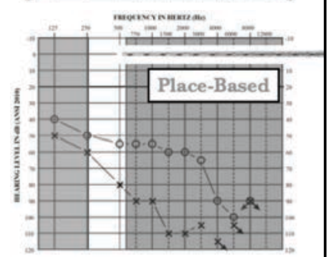
CI-alone simulation

- Default: 70-8500 Hz
- Place-Based: 550-8500 Hz

EAS simulation

- Default: 250-8500 Hz
- Place-Based: 550-8500 Hz





Methods

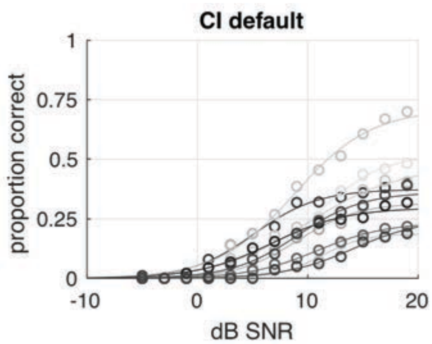
Test Battery

- AzBio sentences in a 10-talker masker

Procedure

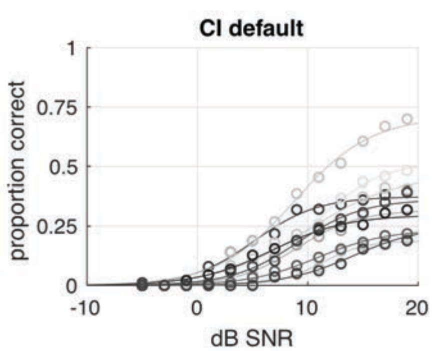
- Repeated-stimulus, ascending signal-to-noise ratio (Buss, Calandruccio, & Hall, 2015)
- Masker: 60 dB SPL
- Target sentence intensity increased until the subject response was 100% correct or reached the maximum signal-to-noise ratio (19 dB SNR)

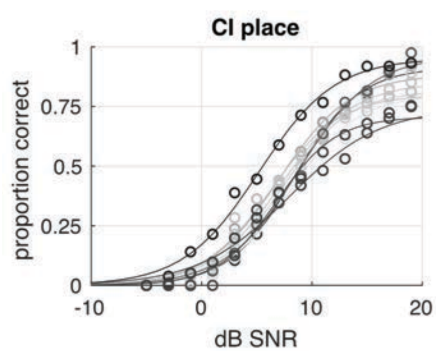
Results: CI-alone



Dillon et al. (in preparation)

Results: CI-alone





Dillon et al. (in preparation)

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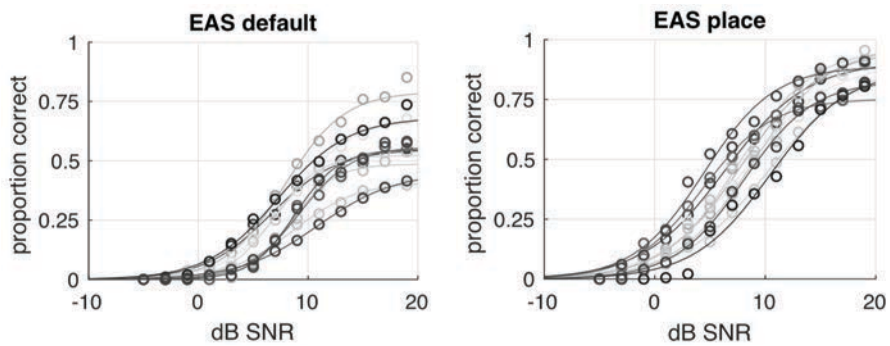
Results: EAS



Dillon et al. (in preparation)

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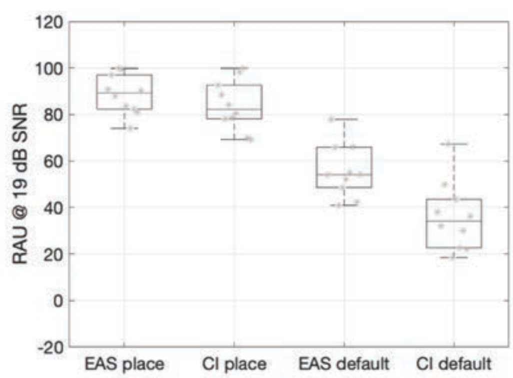
Results



Dillon et al. (in preparation)

Summary

- CI & EAS simulation with normal-hearing listeners
  - Better masked sentence recognition with the place-based map as compared to the default map
  - Better performance with the place-based map observed in the EAS condition even in the presence of a gap in frequency information

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Prospective investigation

- Prospective, randomized investigation of performance between CI-alone and EAS subjects listening with a default versus a place-based map during the first year of device use

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The Influence of Electrode Insertion Depth and Auditory Plasticity on Tonotopic Mismatch in SSD Patients

Mario A. Svirsky
Noel L. Cohen Professor of Hearing Science
Vice-Chairman for Research

(…and a long list of crucial collaborators, see next slide)

Department of Otolaryngology
New York University School of Medicine
New York, NY, USA

Crucial collaborators in the work described today:

NYU: Nicole Capach, Jonathan Neukam, Nai Ding, Keena Seward, Katelyn Glassman, Maggie Miller, Annette Zeman, Elad Sagi, Mahan Azadpour.

Vanderbilt University: Robert Dwyer, René Gifford.

World Hearing Center (Poland): Marika Kruszyńska, Artur Lorens.

Acknowledgments

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We also acknowledge the invaluable assistance of NYU's Cochlear Implant Center, its Co-Directors J. Thomas Roland, MD and Susan B. Waltzman, PhD, its chief audiologist, William Shapiro, AuD, and the staff.

Three questions

1) What does a cochlear implant sound like*?
2) Acoustic models of cochlear implants: are they valid?
3) How plastic is the human brain?

*to postlingually deaf adults

Question 1: What does a cochlear implant sound like? (*)

- Before, we had to rely on informal comments.
- Now we can explore this question more systematically with the help of SSD CI users.

Actual comments from social media:

(*) And does this change with experience?

Question 2- Acoustic models of cochlear implants: are they valid?


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[redacted]

Mice Fall Short as Test Subjects for Humans' Deadly Ills

By GINA KOLATA

Published: February 11, 2013 | 295 Comments

For decades, mice have been the species of choice in the study of human diseases. But now, researchers report evidence that the mouse model has been totally misleading for at least three major killers — sepsis, burns and trauma. As a result, years and billions of dollars have been wasted following false leads, they say.

FACEBOOK | TWITTER | GOOGLE+ | SAVE

BASIC PRINCIPLE: ALL MODELS MUST BE VALIDATED

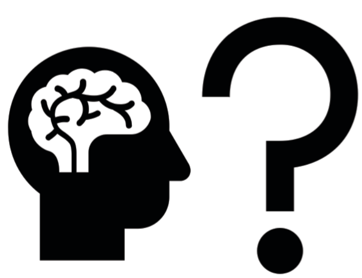
"…researchers report evidence that the mouse model has been totally misleading for at least three major killers — sepsis, burns and trauma."

Standard acoustic models of CIs use signal processing that is similar to CIs and the resulting speech perception scores are in a similar ballpark.

THIS IS NICE BUT IT IS NOT ENOUGH.

- **For over thirty years, acoustic models have been used in numerous studies to simulate the percepts elicited by auditory neural prostheses.**
- **However, speech perception by normal hearing listeners using the standard acoustic model, even without any training, is much better than speech perception by average CI users with months or even years of experience (c.f. Dorman et al, Friesen et al.).**
- **Pitch perception results using CIs or acoustic models are sometimes very different (Laneau et al, 2006).**

Question 3: How plastic is the human brain?



- Some postlingually deaf CI users must adapt to **tonotopic mismatch**.
- **How well** they adapt and the **time course** of that adaptation tells us about the extent and the limitations of human auditory plasticity.

Hypotheses

1) What a cochlear implant sounds like depends on electrode location and CI experience.
2) Standard acoustic models without tonotopic mismatch are generally not valid.
3) Human listeners can adapt to frequency-shifted auditory input- but some listeners may not adapt completely.

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OUTLINE

1. Signal processing in cochlear implants and in acoustic models.
2. What is tonotopic mismatch?
3. Methods:
    1. Acoustic model selection
    2. Speech perception and questionnaires
    3. Electrode location along the cochlea
4. Results:
    1. Selected acoustic models as a function of
        1. Electrode location
        2. Time after initial stimulation
    2. Acoustic model validation
5. Discussion: Initial answers to the three big questions

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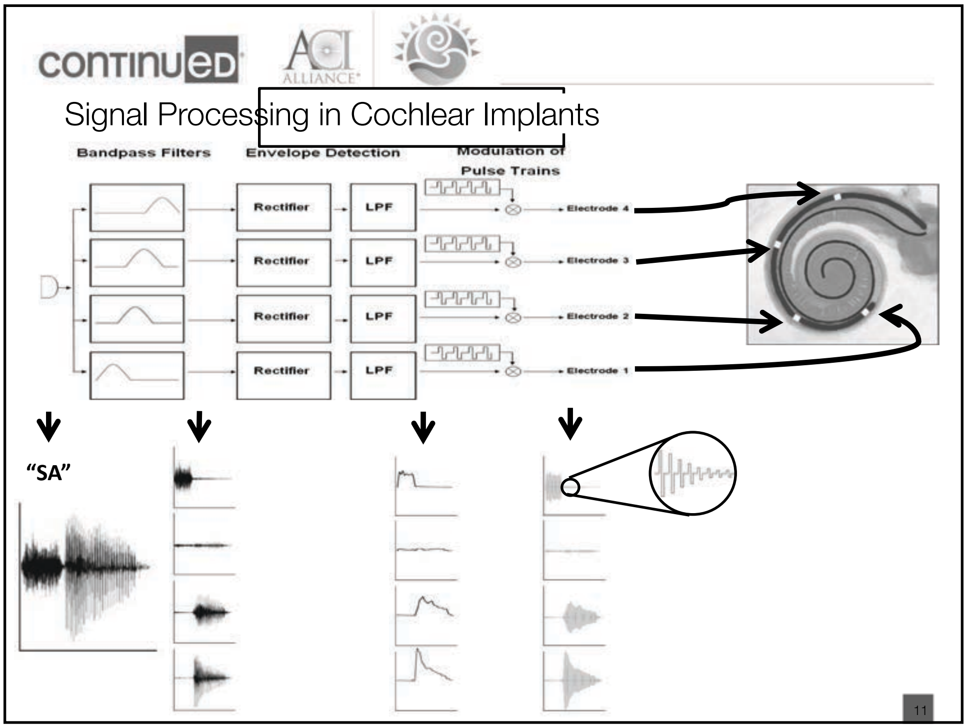
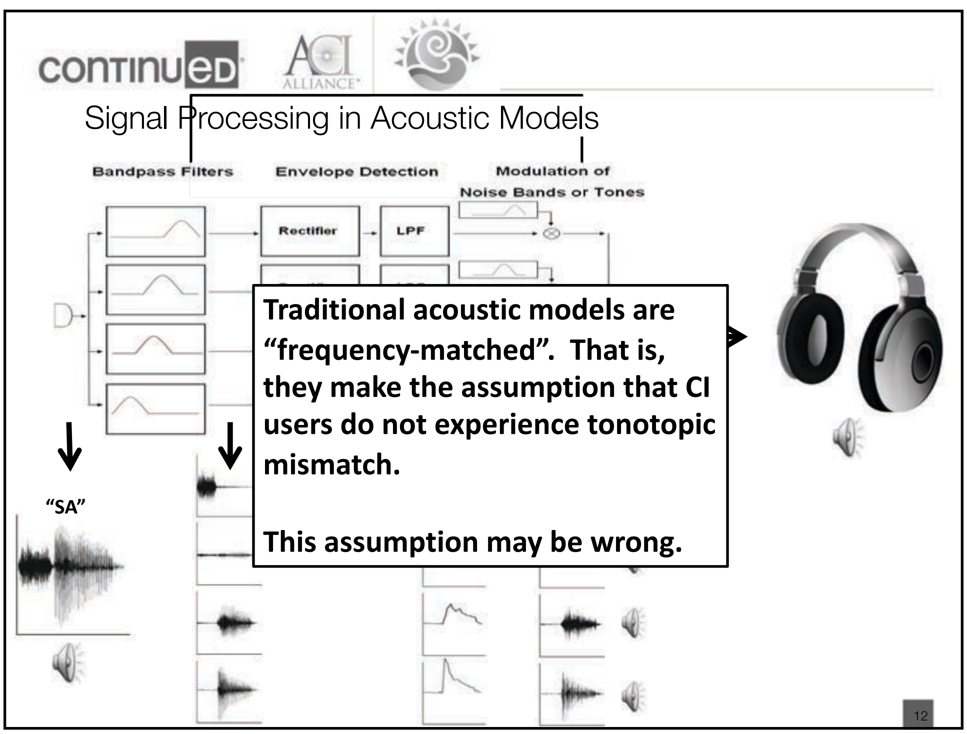
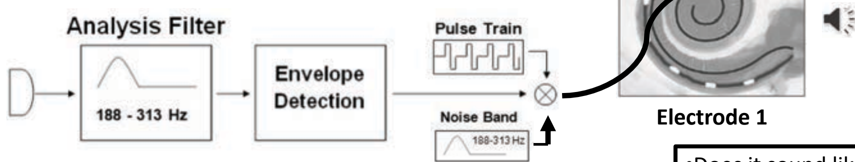

continuED
Signal Processing in Cochlear Implants
Bandpass Filters
Envelope Detection
Modulation of
Pulse Trains
Rectifier
LPF
Electrode 4
Electrode 3
Electrode 2
Electrode 1
"SA"
11

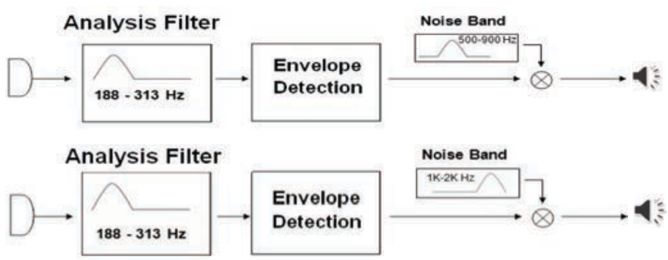

continuED
Signal Processing in Acoustic Models
Bandpass Filters
Envelope Detection
Modulation of
Noise Bands or Tones
Rectifier
LPF
Traditional acoustic models are "frequency-matched". That is, they make the assumption that CI users do not experience tonotopic mismatch.
This assumption may be wrong.
"SA"
12

What does the most apical electrode sound like?

Classic/Standard Cochlear Implant Model



Other Possible Acoustic Models

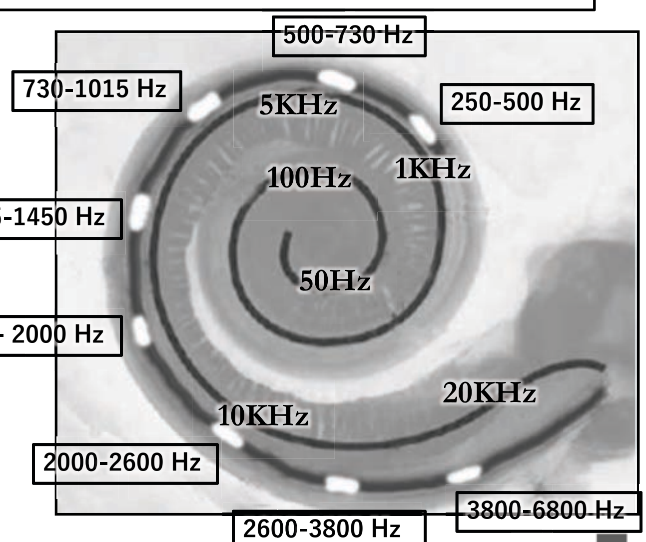


- Does it sound like a 188-313 Hz noise band? Or a 250 Hz pure tone? This is what standard acoustic models of CIs assume.
- Studies of electroacoustic pitch matching suggest that this is not the case

Tonotopic Mismatch in CI Users*

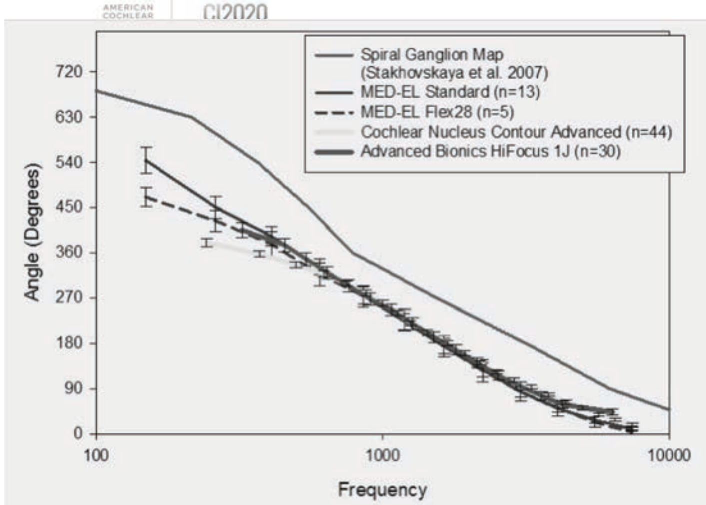
Blue numbers: **characteristic frequency of the stimulated neurons** (obtained using Greenwood's equation).

Red numbers: **analysis filters of the cochlear implant's speech processor.**



*Postlingually deaf

Another way to illustrate tonotopic mismatch



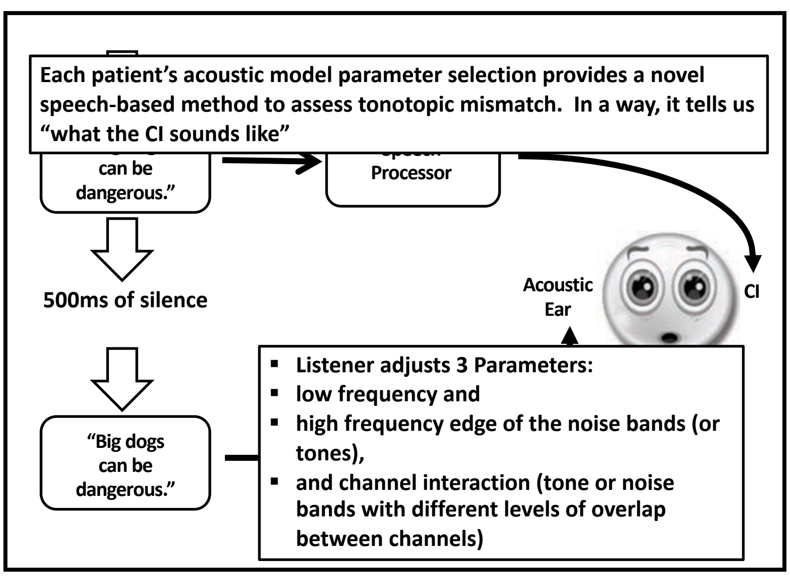
Average insertion angle for each electrode array type plotted as a function of the corresponding default frequency allocated for that electrode. The estimate of spiral ganglion place pitch is plotted in green. Colors of bars are coded by electrode array type.

Landsberger et al., 2015

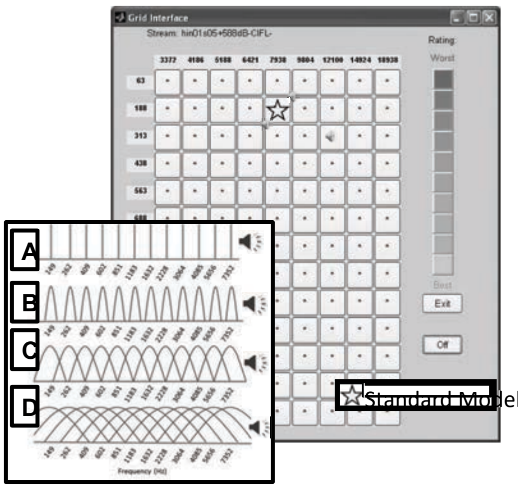
METHODS

Subjects

- 53 SSD CI subjects were tested over a total of 96 testing sessions.
  - Average age is 52, with a range of 26 to 71 years.
- CI experience at the time of each testing session:
  - < 0.3 year: n = 45
  - 0.3 to 1 year: n = 27
  - > 1 year: n = 24
- Manufacturer and Electrodes:
  - 27 Cochlear users: 10 CI532, 6 CI512, 5 CI24RE, 4 CI632, 1 CI522, 1 CI612
  - 22 MED-EL users: 16 Flex28, 5 standard, 1 Flex24
  - 4 AB users: 2 HiFocus 1J, 2 HiFocus Mid-Scala

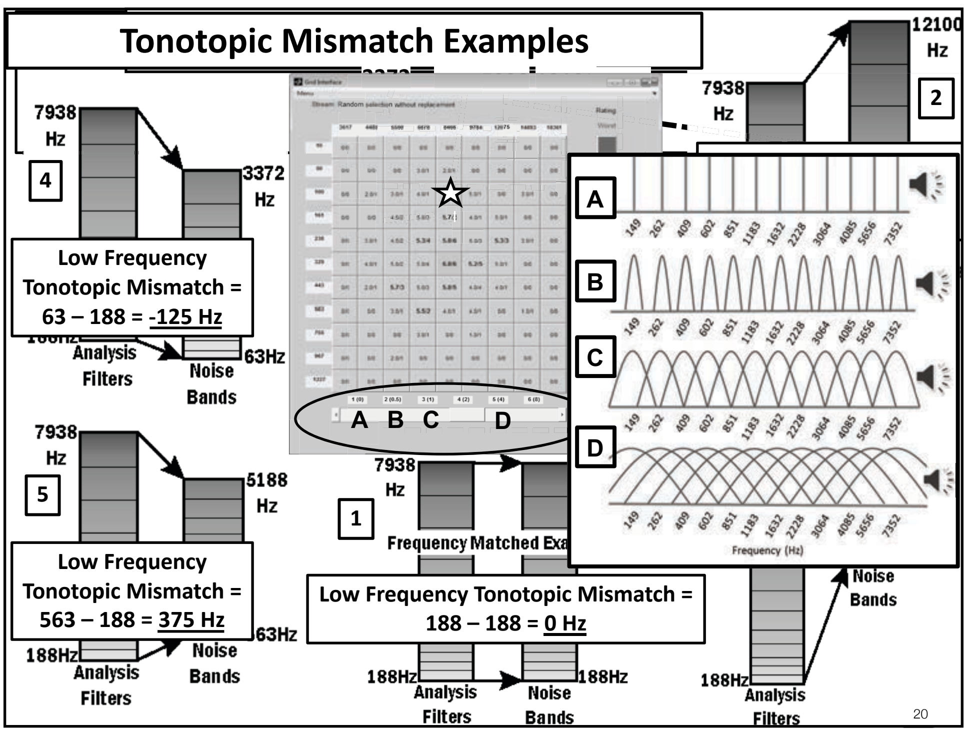


Acoustic model selection: Subjects explore the grid to find the location that sounds as similar as possible to their CI



- Each square represents a different acoustic model.
- The input filter bank (analysis filters) remained constant, with the same fixed frequency range and number of channels as the subject's speech processor.
- The changes are made to the noise bands or tones.
- UP-DOWN movement: change low frequency edge of noise bands.
- LEFT-RIGHT movement: change high frequency edge of noise bands.
- Slider control (not shown) for channel interaction (A-D)

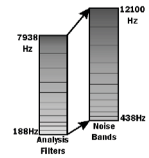
Tonotopic Mismatch Examples



Five types of Acoustic Models were evaluated

1 Self-Selected Model (Subject Specific):

- Same fixed frequency range and number of channels as the subject's speech processor.
- Noise bands (or tones) are listener-selected



4 Traditional Frequency-matched Acoustic Models:

	ALL CHANNEL MODELS	SIX CHANNEL MODELS
TONE MODELS	ALL CH. TONE	6 CH. TONE
NOISE MODELS	ALL CH. NOISE	6 CH. NOISE

continued ACI ALLIANCE

Validation Measurements

Similarity Ratings:

- Overall perception (see Table A)
- Intelligibility (example B)
- Pleasantness
- Harshness
- Loudness

Speech Testing:

Speech testing of all 5 acoustic models, to be compared to a CI only (direct audio input) condition

- CNC30 Word Testing
- AzBio Sentences or HSM Polish Sentences

B

-2	-1	0	1	2
The sound through the CI is A LOT more intelligible	The sound through the CI is A BIT more intelligible	The sounds are EQUALLY intelligible	The sound through my unimplanted ear is A BIT more intelligible	The sound through my unimplanted ear is A LOT more intelligible

A

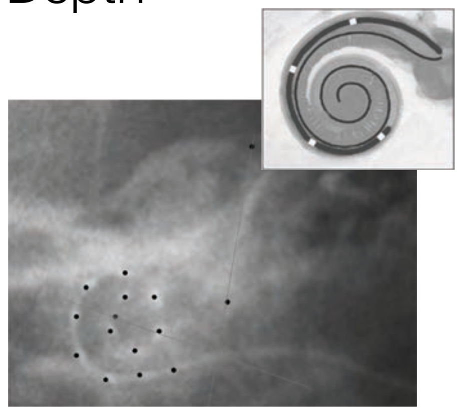
The sound I hear through my unimplanted ear is...

- ☐ (1) Not at all similar (completely different)
- ☐ (2)
- ☐ (3) Not very similar
- ☐ (4)
- ☐ (5) Somewhat similar
- ☐ (6)
- ☐ (7) Very similar
- ☐ (8)
- ☐ (9) Identical

...to the sound I hear through my implant

Electrode Insertion Depth Measurement

- Insertion depths were measured for the most apical and the most basal electrodes.
- CT scans or x-rays were used.



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RESULTS

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Hypotheses

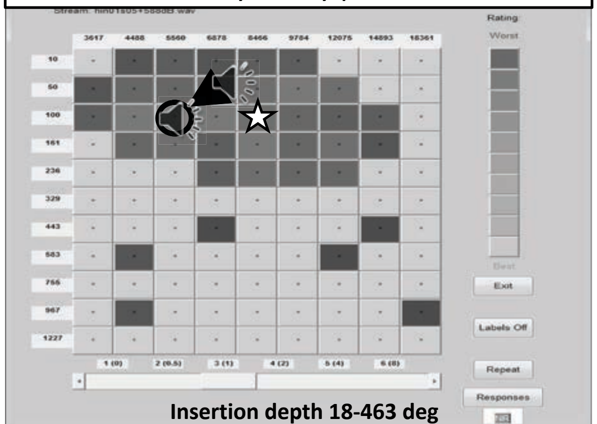
1) What a cochlear implant sounds like depends on electrode location and CI experience.
2) Standard acoustic models without tonotopic mismatch are generally not valid.
3) Human listeners can adapt to frequency-shifted auditory input- but some listeners may not adapt completely.

Plasticity Questions

- How much tonotopic mismatch is there shortly after implantation?
- Is it a function of electrode insertion depth?
- Does tonotopic mismatch decrease with more CI experience? Does it go away completely?

Example 1: Little tonotopic mismatch, no change

CI214	0.03 yr to 1.42 yr post

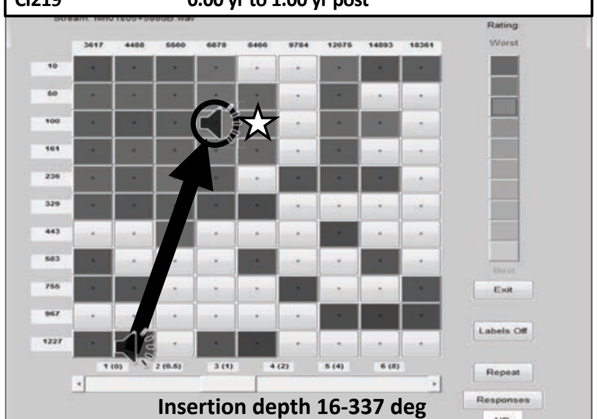


Insertion depth 18-463 deg

Little Mismatch	No Change

Example 2:
Initial tonotopic mismatch, almost full adaptation

CI219	0.00 yr to 1.00 yr post

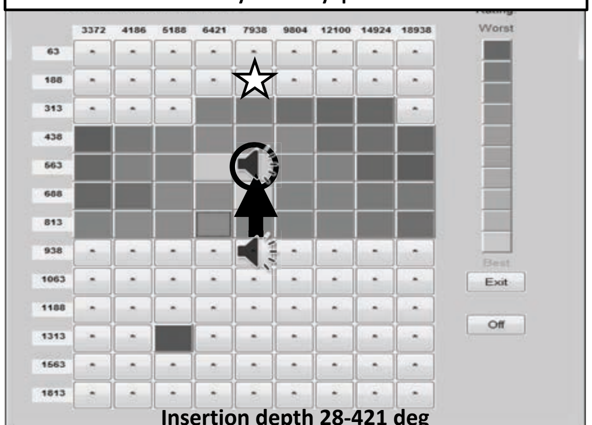


Insertion depth 16-337 deg

Initial Mismatch	Almost Full Adaptation

Example 3:
Initial tonotopic mismatch, partial adaptation

CI216 0.00 yr to 0.17 yr post

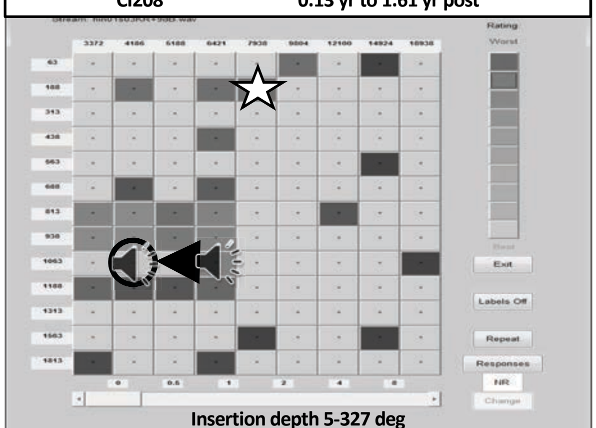


Insertion depth 28-421 deg

Initial Mismatch Partial Adaptation

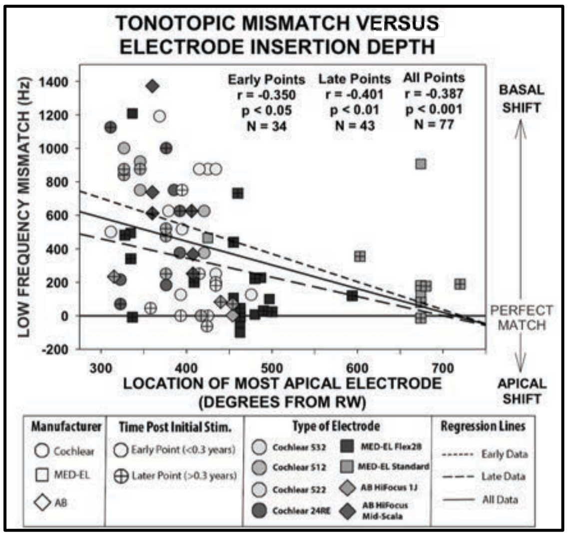
Example 4:
Initial tonotopic mismatch, no adaptation

CI208 0.13 yr to 1.61 yr post



Insertion depth 5-327 deg

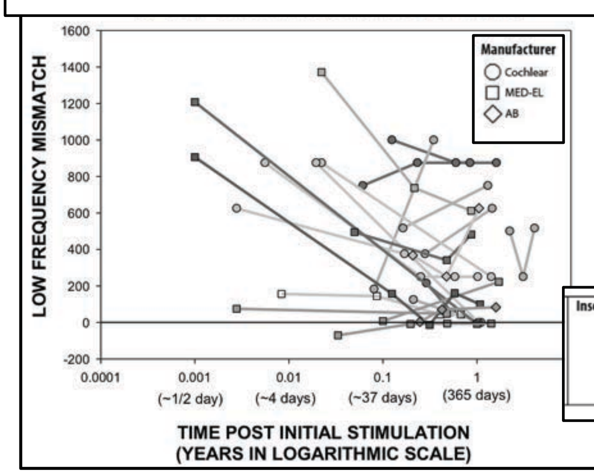
Initial Mismatch No Adaptation



- **Shallower electrode insertions – more tonotopic mismatch**
  <u>(in the low frequencies).</u>

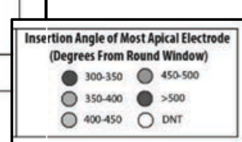
TONOTOPIC MISMATCH DECREASES AS A FUNCTION OF LISTENING EXPERIENCE…

…BUT IT DOES NOT GO AWAY COMPLETELY FOR ALL CI USERS, EVEN AFTER ONE YEAR OF CI EXPERIENCE

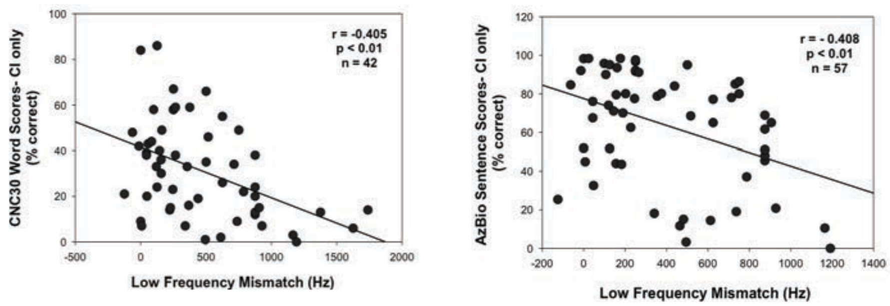


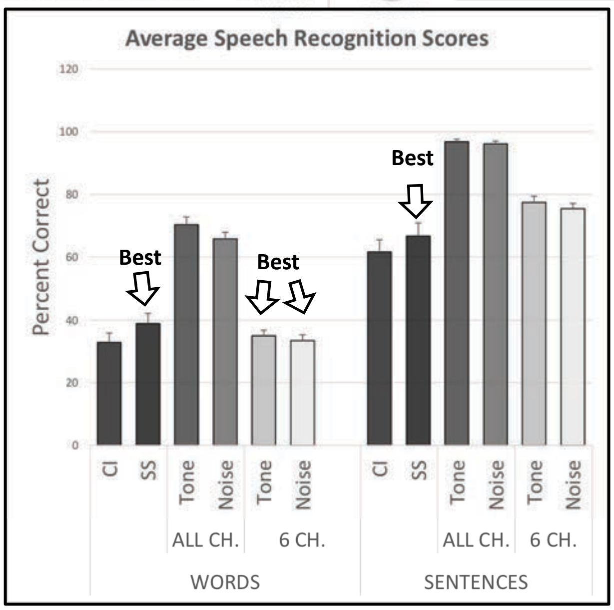
plastic, but only so much.

- **Note: it may be possible to hack the brain to make it more plastic (Glennon et al., Brain Research, 2018).**

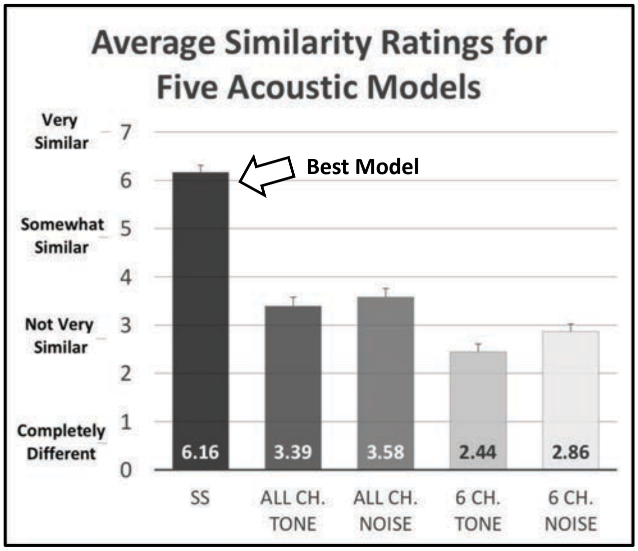


Degree of tonotopic mismatch is associated with poorer speech scores



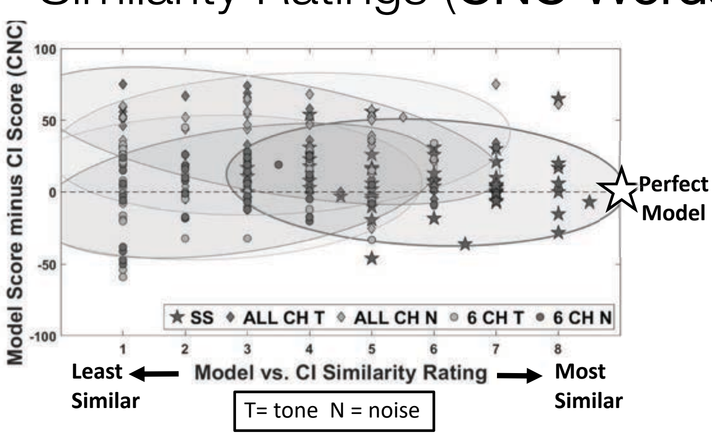


- SS models best represented CI performance across BOTH word and sentence speech recognition testing



Average rating for SS models was ~ 6, which falls between 5 ("somewhat similar") and 7 ("very similar"). In contrast, traditional acoustic models were rated around 3 on average ("not very similar").

Speech Recognition Versus Similarity Ratings (**CNC Words**)



Conclusions- Question 1

1) What does a cochlear implant sound like?
   A. It may sound like Darth Vader, like Minnie Mouse, or like a traditional noise or tone vocoder.
   B. Minnie Mouse is more likely early on after initial stimulation.
   C. It is also more likely when electrode insertion is shallower.
   D. The Minnie Mouse quality becomes less pronounced over time, but not for all CI users.

Conclusions- Question 2

2. Acoustic models of cochlear implants: are they valid?
   A. Traditional models with zero tonotopic mismatch generally are not. Even when speech scores are close (which happens for words but not for sentences), they sound very different from a CI.
   B. Listener-adjusted models with tonotopic mismatch provide a much better fit, both in terms of speech perception and perceived similarity.

Conclusions- Question 3

3. How plastic is the human brain?
   A. Good news: the human auditory brain is plastic and can overcome tonotopic mismatch.
      A. Some patients show complete adaptation after a few months.
      B. Patients with deeper electrode insertions may have little tonotopic mismatch to begin with, making this type or plasticity less necessary.
   B. Bad news: some listeners do not.

What can be done to avoid or minimize tonotopic mismatch?

1) Use longer electrodes*.
2) Modify frequency allocation tables**.
3) Provide additional behavioral rehabilitation
4) Use neuromodulation.

* As long as it doesn't affect hearing preservation or BM integrity.

** As long as it doesn't eliminate too much low-frequency information.

NOTE: Deep electrode insertion at the expense of basal cochlear coverage is probably a bad idea. Don't do it.

THANK YOU

NYU Langone Health

Challenging Mapping Cases

Presenters:
Allison Biever, AuD;
Sarah Coulthurst, MS;
Artur Lorens, PhD;
Kara Schvartz-Leyzac, AuD, PhD

CASE STUDY

Allison Biever, Au.D.
Rocky Mountain Ear Center

Case History:

- 90-year-old male
- Hearing loss identified 35 to 40 years ago; loss has been progressive
- Dx: moderate-to-profound sensorineural hearing loss AD, severe to-profound sensorineural hearing loss AS
- Etiology: otosclerosis; stapes surgery AS 40 years ago
- Aided 18 years ago; consistent user of Oticon BTEs, which Real Ear measures confirm are fit appropriately

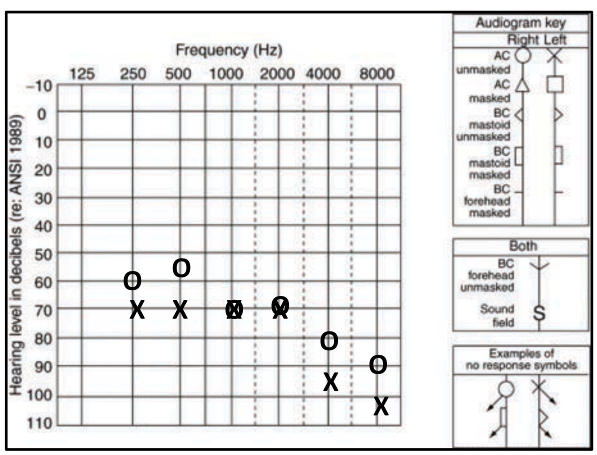
Additional Background

- Sister has a cochlear implant
- Pt has CLL (chronic lymphocytic leukemia)
- No history of noise exposure
- No tinnitus or dizziness reported
- CT and MRI reveal normal patent cochlea

Pre-operative Audiogram

Word Recognition:
36% AD
28% AS

Aided HINT Quiet:
38% AD
30% AS
Aided CNC words:
40% AD
20% AS



Case History: (continued)

- Implanted AS at 90 years of age
  - Cochlear CI532
- Full Insertion of device
- Obtain Auto NRT thresholds on 8 of 9 electrodes tested in OR (no threshold obtained on e1)
- Patient had difficult activation: problems adapting to high frequency input; reported that speech is “unintelligible and screechy”
- PW need to be set at 37 due to compliance issues

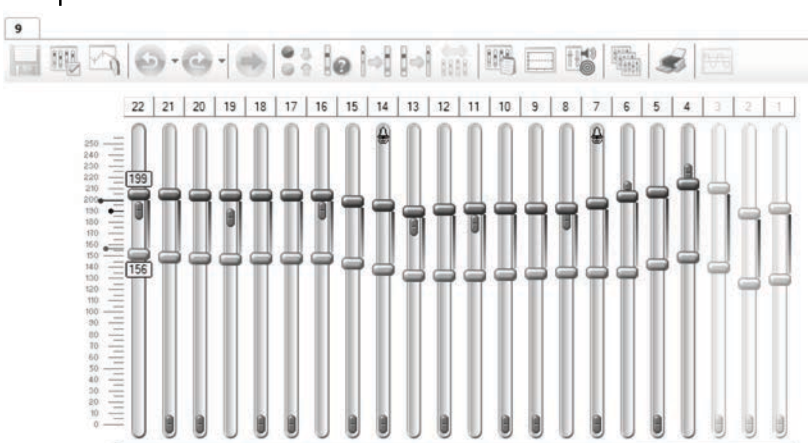
Challenge:

- At 2 weeks post-activation, patient is reporting he can’t understand with CI, speech is unintelligible
- Auto NRT thresholds are obtained for 8 of 9 electrodes (no response obtained on e1). The thresholds are lower than those obtained in the OR, but C levels well below Auto NRT thresholds, so C levels are increased significantly
- T levels are re-measured and also increase significantly compared to MAPs created at activation
- Rx pt isolate left ear as much as possible and continue with intensive rehab (self-guided)

Challenge: (continued)

- At 1 month post-activation, patient is still reporting he can't understand with CI unless people talk slowly, speech is still unintelligible and screechy
- HINT administered – pt scored 20% recorded HINT AS
- MOCA ministered, which indicated essentially normal cognitive function
- ESRTs attempted but cannot be obtained (seal issues; hx of otosclerosis)
- Electrodes 3-1 turned off, patient reports improved sound quality; C levels increased in apical end but remain the same in basal end. T-levels unchanged

Map at 1 Month Post-Activation

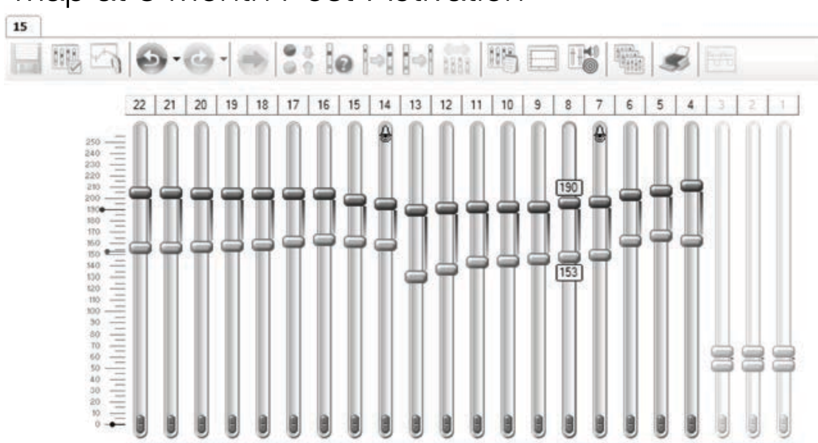


	22	21	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
C	199	199	198	198	198	198	198	193	189	184	185	186	186	186	186	191	197	201	208	204	182	186
T	156	154	153	152	153	153	153	148	143	137	137	137	138	139	140	140	140	147	154	145	130	134
PW	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37
DR	43	45	45	46	45	45	45	45	46	47	48	49	48	47	46	51	57	54	54	59	52	52

Challenge: (continued)

- At 3 month post-activation, patient is still reporting poor understanding of speech when using CI alone
- Pt is switched to a 500 Hz MAP with 12 maxima; pt immediately reports improved sound quality (used predict levels)
- Thresholds and Comfort levels are reassessed; biggest difference noted between 900 Hz MAP and 500 Hz MAP – T levels were significantly higher across all frequencies in 500 Hz MAP, C levels were essentially unchanged
- HINT score: 65%; CNC score 56% (CI only)

Map at 3 Month Post-Activation



	22	21	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
C	199	199	198	198	198	198	198	193	189	184	185	186	186	186	190	191	197	201	205	59	59	59
T	161	161	162	163	164	166	168	166	164	136	142	148	149	151	153	155	167	172	167	57	57	57
PW	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37	37
DR	38	38	36	35	34	32	30	27	25	48	43	38	37	35	37	36	30	29	38	2	2	2

UCSF Benioff Children's Hospitals

UCSF BCHO Pediatric Audiology Department and Cochlear Implant Team

Cochlear Implants in Children with Hypoplastic Nerves: A Case Study

Sarah Coulthurst, M.S., Cochlear Implant Clinical Director

Erik: Transfer Unilateral Cochlear Implant Patient

- Received LEFT Med-EL concert electrode at 1.5 year of age
- Utilizing Rondo and Opus 2 processors
- Parents opposed to signing as they wanted LSL
- Beginning exposure to ASL
- Right ear difficult to test and no longer wearing hearing aid

Erik: Transfer Unilateral Cochlear Implant Patient History:

Full term birth without complication

Referral on his newborn infant hearing screen

Diagnosed with Auditory Neuropathy Spectrum Disorder at 6 months of age

Fit with hearing aids at 9 months of age

MRI then revealed bilateral hypoplastic nerves

Left Cochlear Implant placed at 1.5 year of age after family was told this was the more viable nerve

Communication Mode

- Parents interpretation of counseling was that they should not sign with their son if they wanted him to develop listening and spoken language.
- Attending an ORAL program until 3 ½ years of age – was then counseled to move to a total communication preschool.
- At this point, family wanted a second opinion as they would like to move ahead with a sequential implant - with the continued hope of acquiring spoken language.

First Visit: 4 years of age; 2.5 years out

Informal Behavioral Observations: Auditory awareness and communicative intent were the main focus.

Erik did not respond to auditory stimuli: Lings, noisemakers, etc. Inconsistent response to loud drum.

Attempted a task with teaching signs for 5 familiar objects which he easily carried out in a closed set. Very eager to learn and communicate!

Equipment Check, Tymps and Brief Map Review

Evaluated Impedance measurements, equipment and carried out listening checks. All WNL

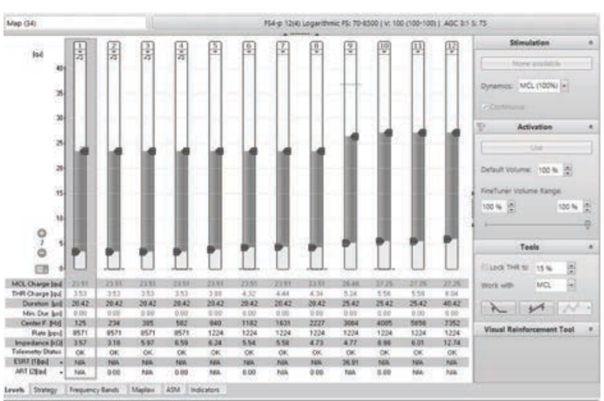
Spent the bulk of the visit discussing language acquisition, sequential cochlear implant candidacy, expectations and projected outcomes.**discussed issues with CCS authorization of sequential ear without the first ear providing language acquisition.

Normal Tympanometry.

Attempted First Audiogram

- Brought into the booth in order to condition via bone – vibrotactile responses were reliable; paired with auditory stimuli continued to be reliable; auditory only = no responses

Primary Transfer Map



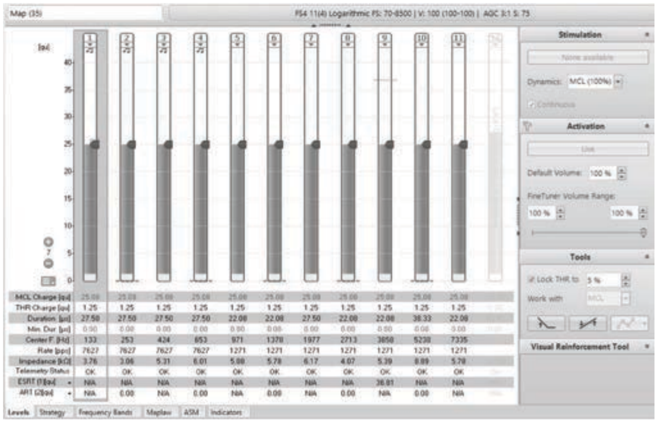
- Came to us with FS4-p
- Faster stim rate
- Maplaw 1000
- Thresholds locked at 15%

Not just double, but triple dipping. Giving the greatest emphasis on soft and medium sounds

No datalogging with opus 2 or rondo – normal tymps

eSRT attempted, but CNE

First map we created



Starting with small changes with limited information:

FS4 - Slowed rate down a bit

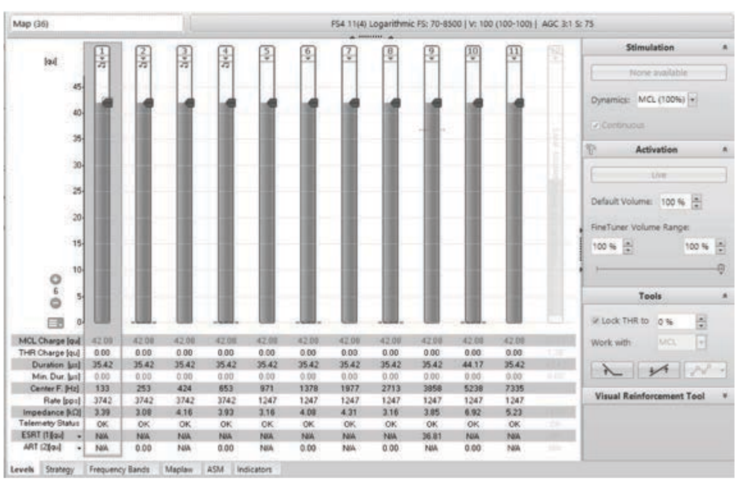
Disabled e12 due to non auditory percept

Lowered threshold lock

Kept maplaw at 1000 for now bringing soft and medium sounds higher into their dynamic range

Slightly increased charge units

3rd Mapping



Staying with FS4

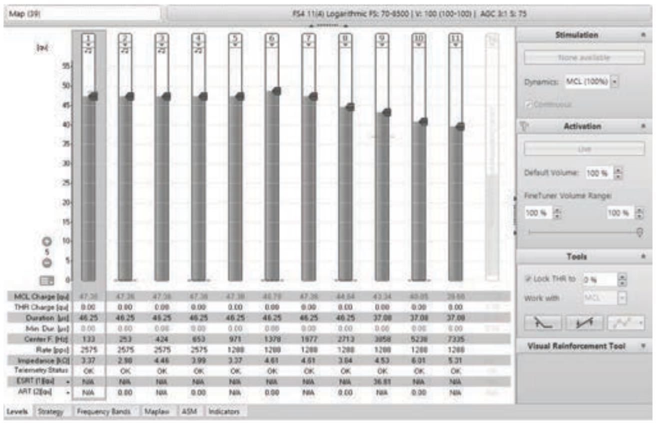
Duration is higher as charge levels were taken up again as he could provide loudness level feedback and eSRT

Thresholds moved back to the default at the time (0)

**eSRT only on e9 at 36.81qu

Slightly increase m levels – but clearly still below audibility so gave them progressive maps to work toward eSRT level

4th map 10/25/18

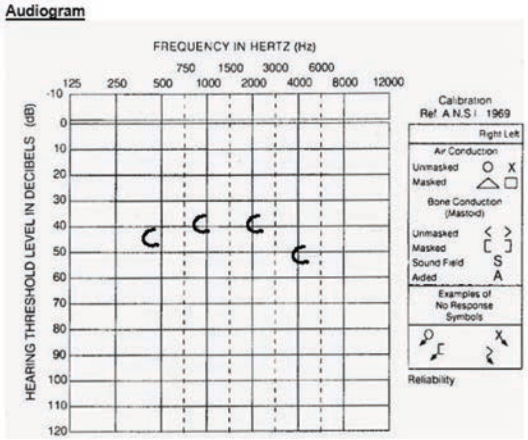


Staying with FS4

Duration is higher as charge levels were taken up again as he could provide loudness level feedback as well as balancing of M levels* (40-48qu)

Thresholds moved back to the default at the time (0) in order to simplify and head towards parameter defaults

First aided audio 10/25/18



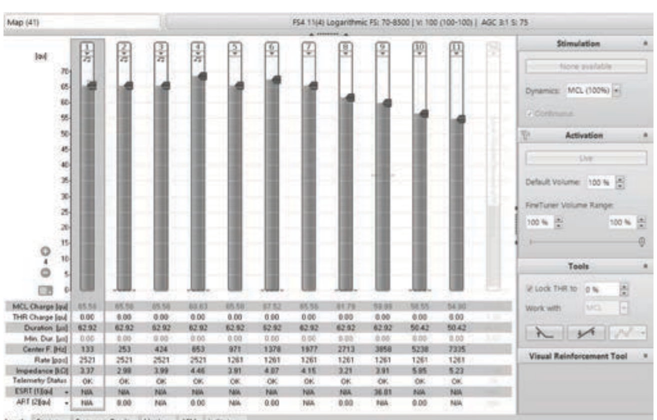
Left Ear Speech
Detection: 35-40
Reception:

Doesn't look like much, but…he conditioned to auditory stimuli with good reliability!

Ongoing Team Communication

- Focus continues to be on Language acquisition.
- Parent counseling.
- Fluctuation in hearing for the right “hearing aid” ear, as well as current levels in the left implanted ear.
- Communication with educational setting as family continues to want LSL and will not sign.

Mapping 1/17/19



Staying with FS4

Duration is higher as charge levels were taken up again as he could provide reliable loudness level feedback (now 54-65qu)

Rate is basically the same

T’s kept the same

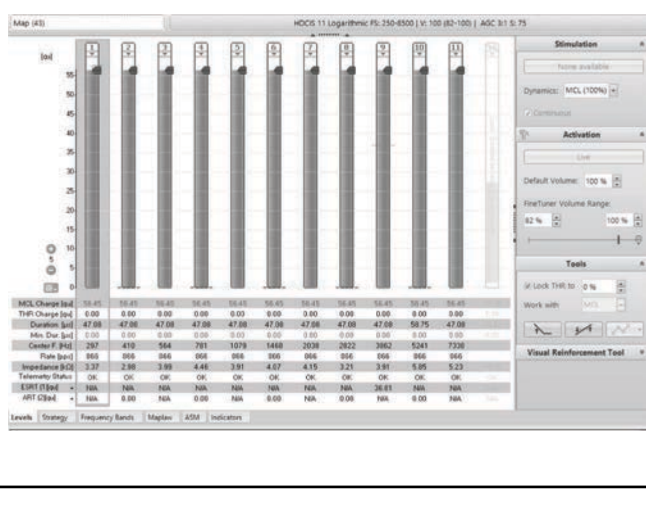
***now developing strong suprasegmental auditory skills, using 3 consistent word approximations, and family has accepted and modeled ASL throughout appt!!!**

First speech appointment 1/17/19

goals

- Increase ability to discriminate /identify Ling sounds in a closed set of 2-3.
- Increase ability to discriminate between familiar words/phrases that differ by suprasegmental cues (i..e, length, rhythm, and/or intonation).
- Increase intentional use of voice on/off.
- Increase imitation/spontaneous production of suprasegmentals.
- Increase ability to produce /ah, oh, ee, ow, oo, b, m, p, d,n,w/ in vocal play including babble and jargon.
- Increase imitation and spontaneous production of verbal word approximations to communicate.
- Increase imitation/spontaneous production of sound sequences: CV, CV reduplicated/babble, CVCV different V, CVCV different V and C.

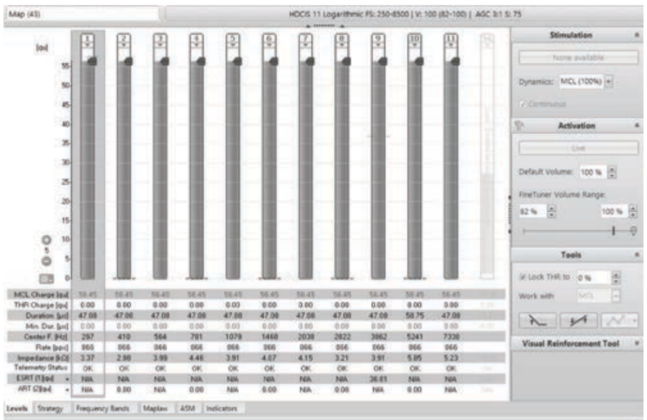
Mapping 3/23/19



MEDEL attended today's appointment with our clinical specialist as well as their Spanish speaking consumer specialist! Also here for repeat SLP session as family is requesting AVT

Thought was that because he was prelingual, let's slow the rate, reduce the maplaw, and change strategy to HDCIS

Mapping 3/23/19 cont.



HDCIS – without that variable rate – you will have asteady rate across all channels

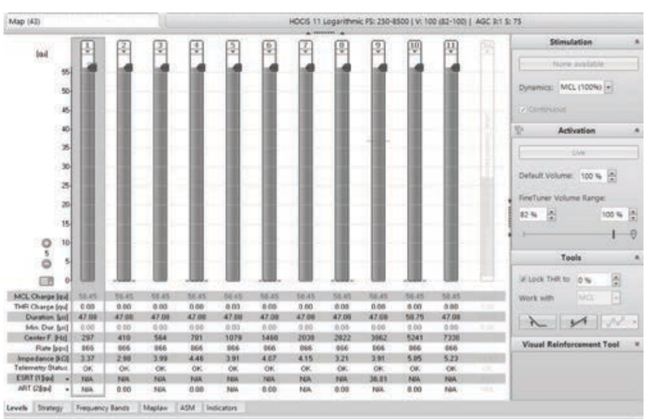
Automatically changes the lower limit of the frequency band to 250Hz (now it is 250-8000)

Lowered all m levels with a flat map of 56 charge units

Duration is backed down a bit with the lower m's

T's stayed at 0 – going back to the philosophy of let's not change everything – but let's talk about t's…

Mapping 6/20/19

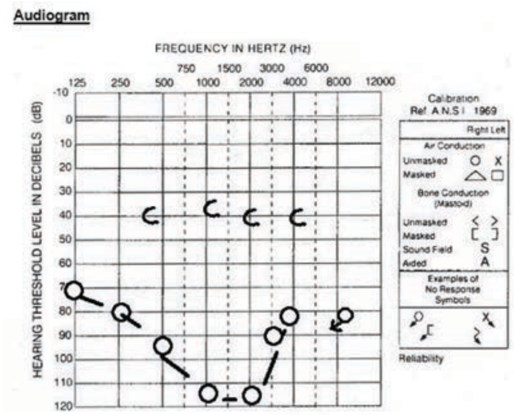


After having 3 months with the new map – started in the booth and came in between 35-40

Kept all parameters, discussed observations, gave progressive maps with increased charge levels to work through

Rec: to move it to FS4 to inch back into fine structure, play around with eSRT with pulse burst at 700 instead of 500 (making that duration longer to capture more neural activity – but then you risk losing some specificity.

Aided Audio 6/20/19



SDT AIDED CI – 35-40

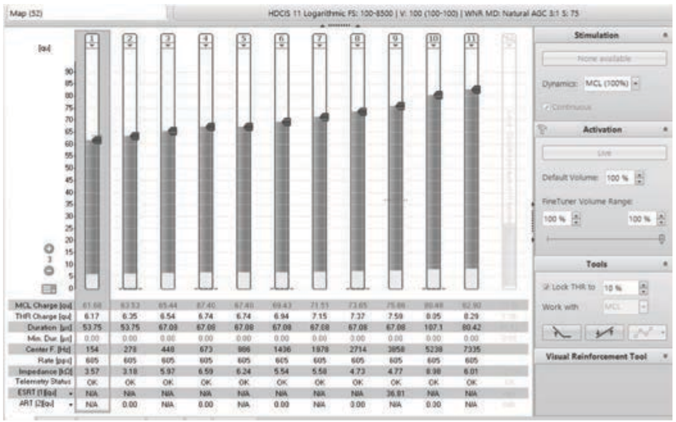
SDT AIDED HA – 55

First reliable unaided (right) – recommended new hearing aid

Neurotology Consult

- Obtained CT in order to evaluate placement of the electrode: WNL.
- Pre Op MRI was reviewed and thought that the opposite (right) ear was a more viable nerve.
- Reviewed projected outcomes vs parent expectations for sequential CI.
- Provided medical clearance for right hearing aid.

Mapping 8/20/19



Seen here for the Sonnet fitting and hearing aid fitting for right ear *datalogging is in our future!

Family had been going to AVT 2 x a week in addition to TC program

Family consistently signing with him

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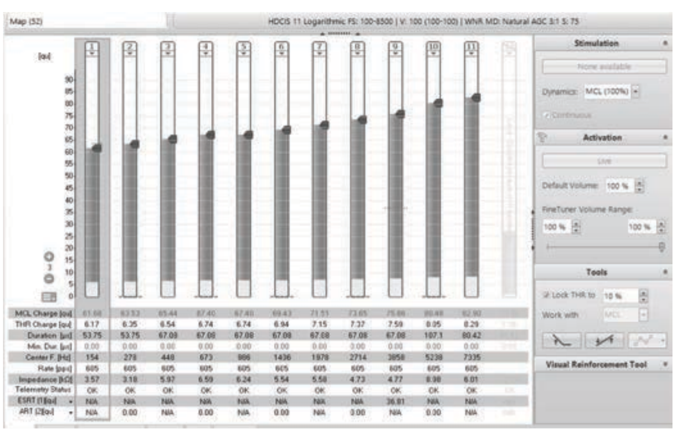
Mapping 8/20/19 cont



As gains are being made auditorily:

Moved to FS4; however, with the charge units being so high, fine structure falls out

With strategy change, low frequency went from 250 to 100Hz

Took T's up to 10%

Measured / balanced M levels

Focused on aided and speech session today

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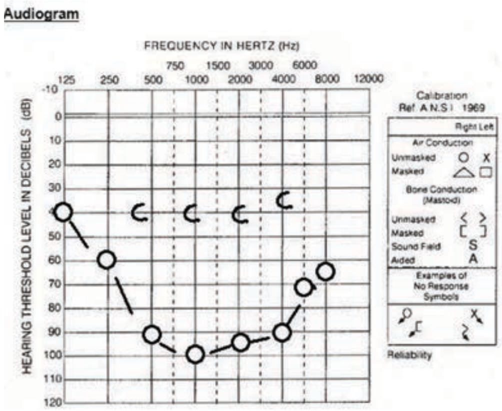
Aided Audio 8/20/19



Continue to see fluctuation in right ear, but very consistent responses and reliability today for both ears

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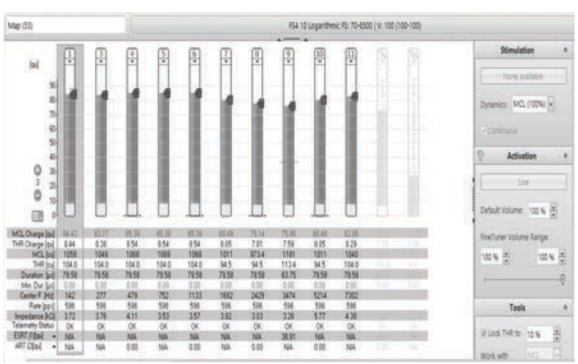
Mapping 2/28/20



- First time datalogging: Aug 20 – 2/28 (192 days) shows 6.9 hours a day for Sonnet – he did also wear his Rondo
- Turned off e2 as no auditory percept up to 70 qu's (making it irrelevant to have FSP because of the affect on fine structure?)
- Balanced M's

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continuED

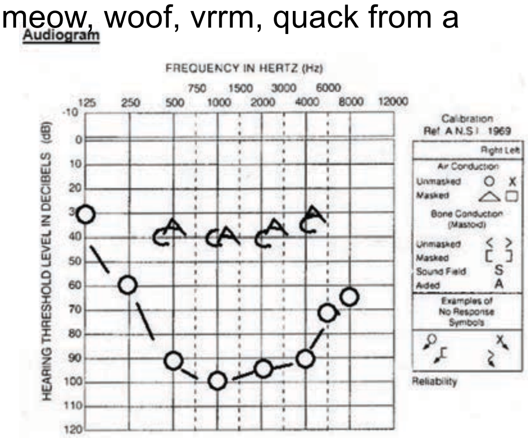
Aided Audio 2/28/20

With his implant, Erik detected all 6 Ling sounds. He imitated "ah" "sh" "s". He imitated "oo" "mm" and "ee" as "uh".

He can identify items by suprasegmentals: ex: meow, woof, vrrm, quack from a field of two when there is contrast in length.

Continues to use up to 30 consistent

word approximations



Speech Appointment 2/28/20

Sign skills have improved greatly and auditory skills have made slow but steady gains:

Auditory Discrimination Skills	Able to identify?
1- Different by suprasegmantal (duration, intensity, pitch)	Yes
2- Different by syllable number	Yes in most cases. Erik was able to discriminate 1 vs. 2 syllables and 1 vs 3 syllables Ex: fish/butterfly, ball/cookie He was not able to discriminate 2 vs 3 syllables (zebra/butterfly or apple/birthday cake)
3- Different Consonant and Vowel Content	He is able to in some cases: cup/house, dog/cat but not baseball/popcorn
4- Same Initial consonant, Different by vowel	Not yet discriminating at this level.

Carried out during each visit:

- ART – no resonses.
- eSRT – consistently carried out with only response seen for e9 *so taken with a grain of salt.
- Continued focus on auditory training and conditioning – loudness scaling was emerging as more wear time was observed and language obtained.
- Speech evaluations or routine sessions.
- Counseling regarding outcomes.

Goals

Matched auditory input

- With our anatomical and physiological differences as well as fluctuations secondary to ANSD – we are going to miss each time.
- Move ahead with sequential CI with appropriate expectations? The hearing aid ear is seemingly the more viable ear.

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Lessons Learned and Thoughts for the Future:

- Try again to open up burst parameters for eSRT – focus on one basil and one apical.
- Feedback from SLP / AVT.
- Lower M levels and double the PW manually and then move Maplaw back to 1000 if progress is shown.

ANSD and Hypoplastic Nerves

- Simultaneous implantation if appropriate family expectation and services.
- We all need a second set of eyes – reaching out to colleagues and clinical specialists is a must!
- TC approach until we understand access to auditory stimuli and emerging spoken language.

Thank You

- The entire pediatric cochlear Implant Team at UCSF Benioff Children's Hospital Oakland and our wonderful families
- The tireless effort exhibited by ACIA, AudiologyOnline, Speechpathology.org, and the Scientific Chairs for ACIA 2020!
- Can't wait to see everyone in one room again!

continued

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CI2020 ONLINE

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Lorens A., Skarżyński H.

The challenging Partial Deafness Case

How to optimize fitting after delayed HL in the implanted ear?

1

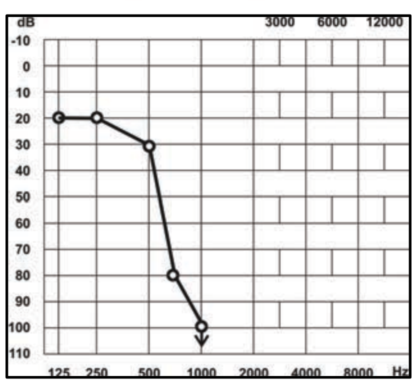
Signature: Med Sci Monit, 2003; 9(4): CS20-24
PMID: 12709676

WWW.MEDSCIMONIT.COM
Case Study

Received: 2002.12.05
Accepted: 2003.02.10
Published: 2003.04.23

A new method of partial deafness treatment

Henryk Skarżyński, Artur Lorens, Anna Piotrowska



The Laryngoscope
Lippincott Williams & Wilkins

Outcomes of Treatment of Partial Deafness With Cochlear Implantation: A DUET Study

Artur Lorens, PhD; Marek Polak, PhD; Anna Piotrowska, MD; Henryk Skarzynski, MD

OPTIMIZING THE FITTING

- prescriptive fitting strategy to determine the gain and maximum power output of the hearing aid portion of the device
- cut-off frequency for acoustic amplification
- the frequency range over which electrical stimulation will be allocated

Wolfe, Schafer Programming Cochlear Implants

OPTIMIZING THE FITTING

- fitting strategy to determine the gain and maximum power output of the hearing aid portion of the device
- cutoff frequency for acoustic amplification
- the frequency range over which electrical stimulation will be allocated

Wolfe, Schafer Programming Cochlear Implants

THE FREQUENCY RANGE OVER WHICH ELECTRICAL STIMULATION WILL BE ALLOCATED

Three situations can arise when selecting the lower limit of the electric frequency range (crossover frequency): it can be: below, at, or above the frequency up to which acoustic hearing is maintained.

1) Below – Stimulus overlap
2) At – Minimum overlap (also called the “meet condition”)
3) Above – No overlap, with a gap between electric and acoustic stimulation

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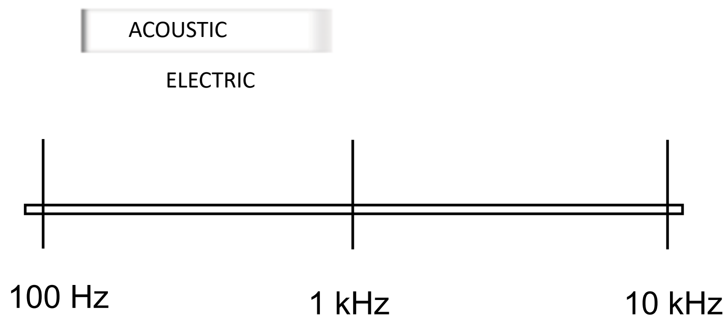
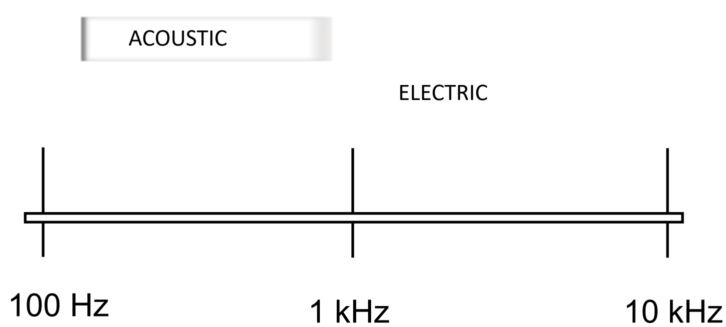
STIMULUS OVERLAP

Stimulus overlap is a condition where frequencies
in a particular band (70–750 Hz)
are represented both acoustically and electrically



MINIMUM OVERLAP
THE “MEET CONDITION”

The “meet condition” is achieved when the cross-over frequency for electric stimulation is matched by the upper edge of acoustic amplification



THE "MEET CONDITION"

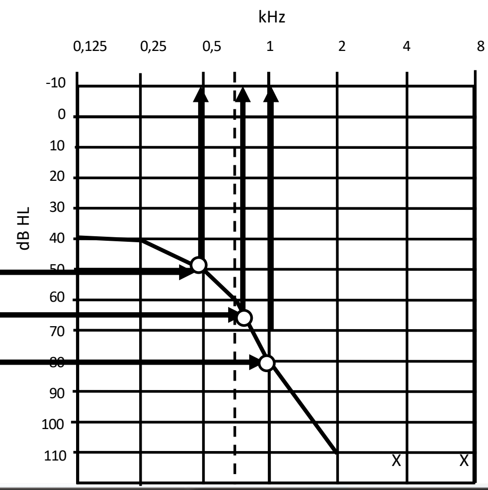
Frequency where

the audiogram crosses

50 dB,

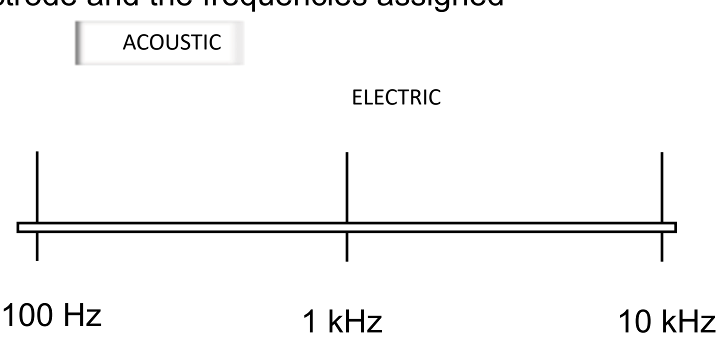
65 dB,

80 dB



NO OVERLAP WITH A GAP BETWEEN ELECTRIC AND ACOUSTIC STIMULATION

The non-overlap condition, with a gap between electric and acoustic hearing, usually results from an attempt to minimize the mismatch between the position of the most apical electrode and the frequencies assigned



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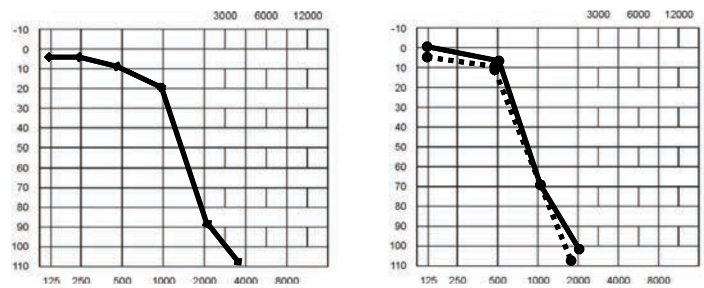
PDT CASE - 1 month postop

21 years old women at the moment of implantation
SHL diagnosed at the age of 12



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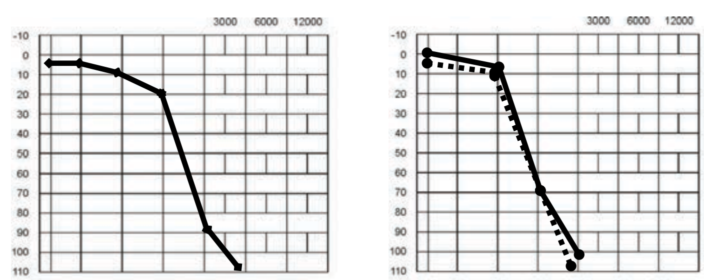
THE CROSS-OVER FREQUENCY

?



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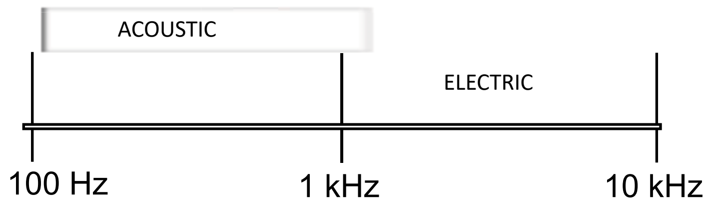
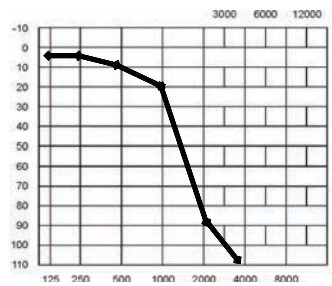
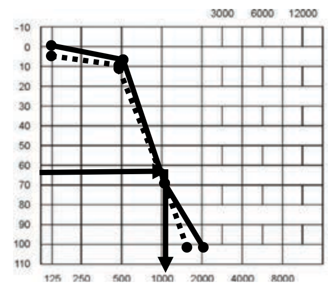
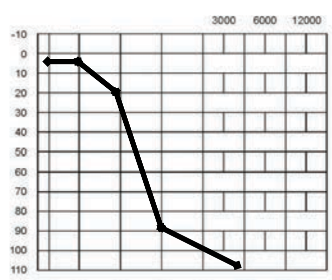
PDT CASE - 1 month postop

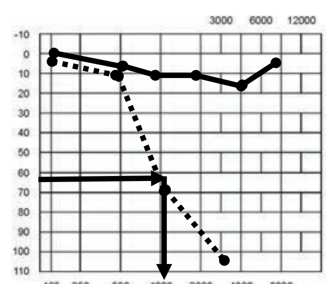






PDT CASE - 1 month postop



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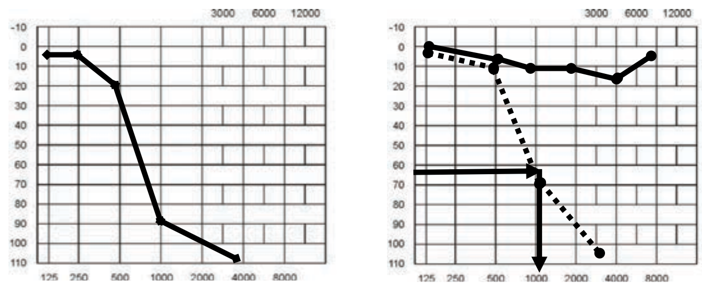
THE CROSS-OVER FREQUENCY

1100 Hz



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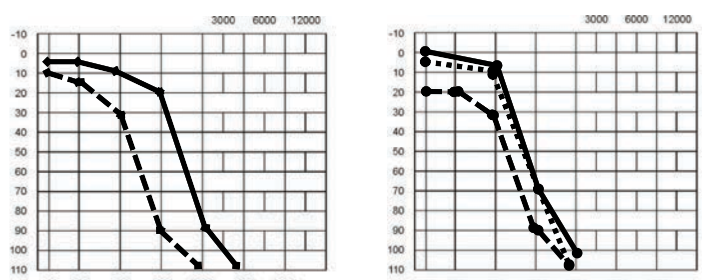
PDT CASE – 3 years postop



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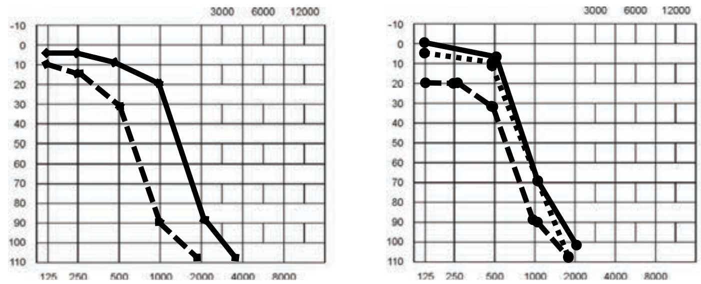
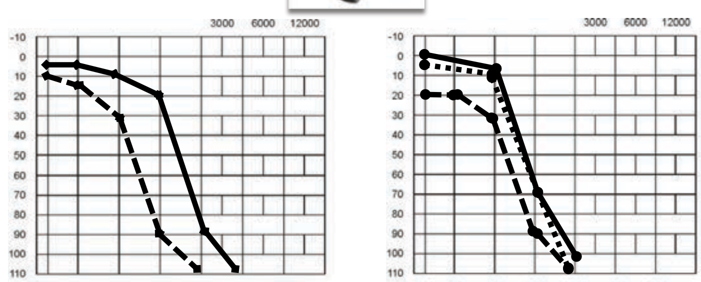
PDT CASE – 3 years postop

?

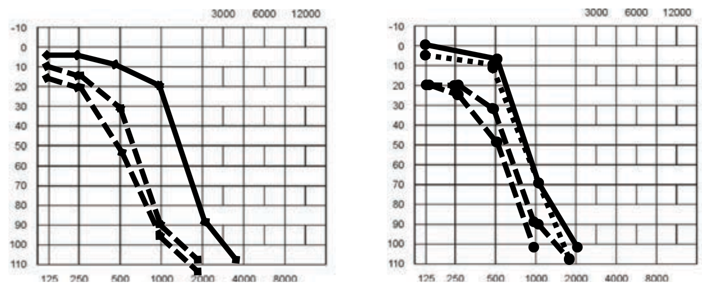


PDT CASE – 3 years postop



PDT CASE – 5 years postop

?



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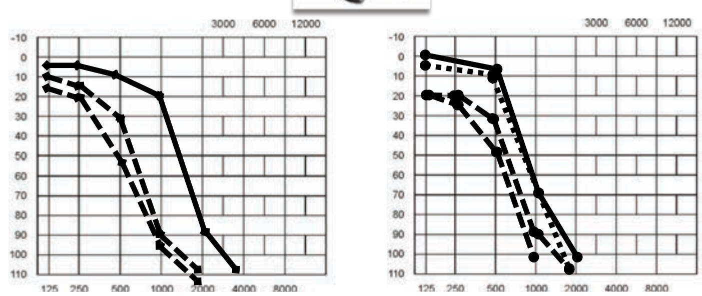
PDT CASE – 5 years postop



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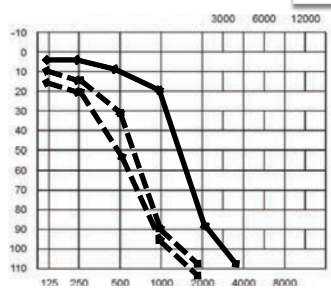
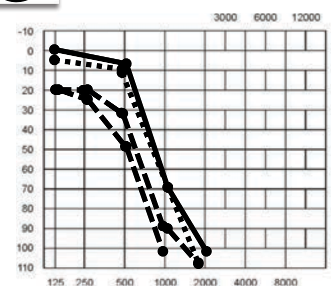
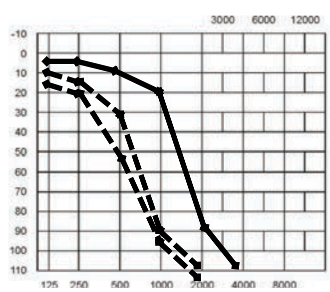
PDT CASE – 5 years postop

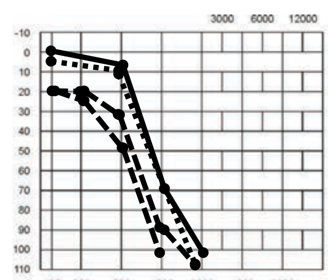




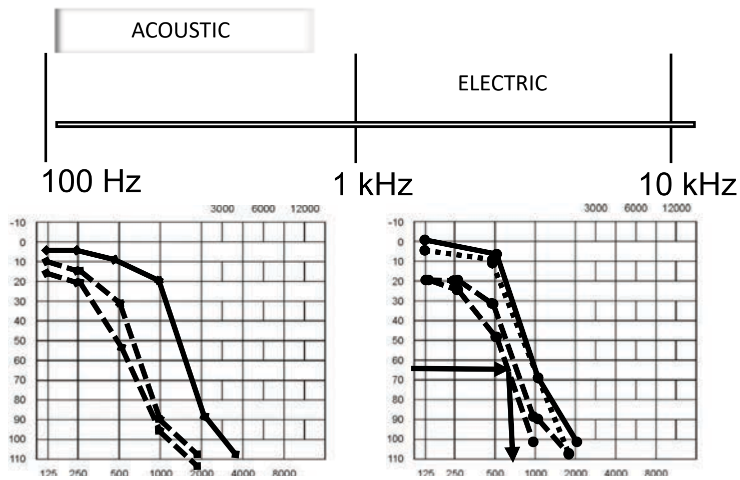
THE CROSS-OVER FREQUENCY

?



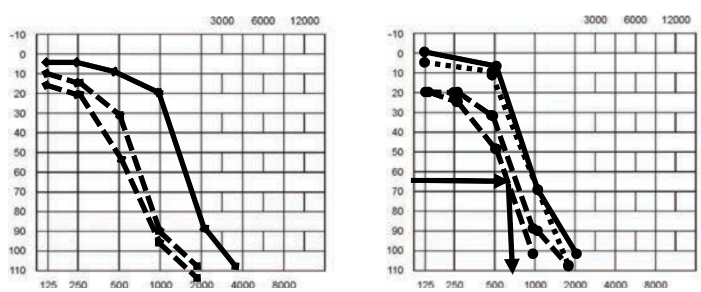


THE CROSS-OVER FREQUENCY

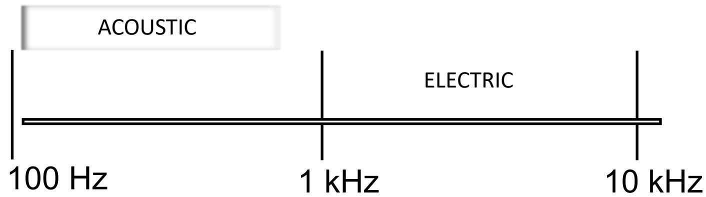


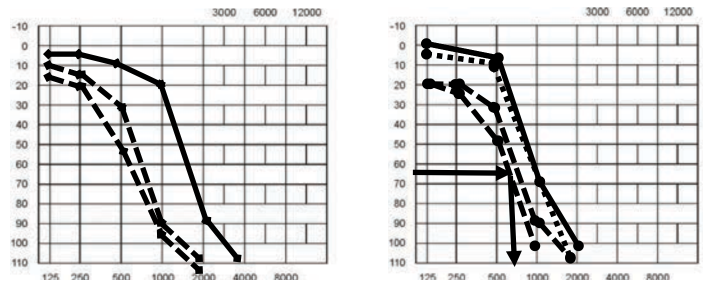
THE CROSS-OVER FREQUENCY

800 Hz



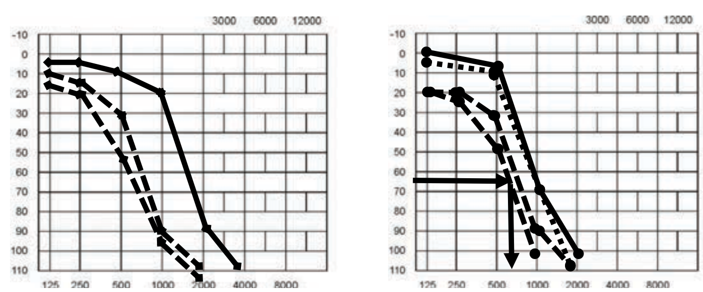
THE CROSS-OVER FREQUENCY





THE CROSS-OVER FREQUENCY

1100 Hz ⇨ 800 Hz



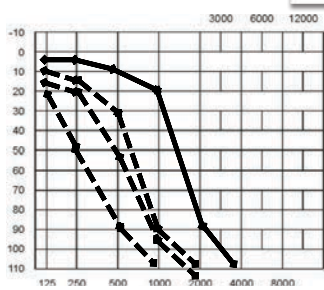
ENCOUNTERED PROBLEMS

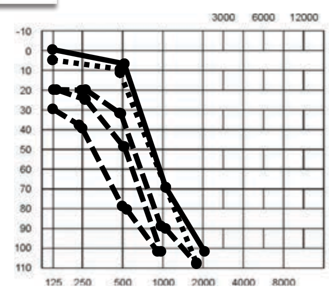
- Lack of acceptance
- To high pitch of sounds
- Difficulty with controlling own voice
- Listening effort
- Speaking effort

SOLUTIONS

- To use brain plasticity
- Tolerable frequency shift around 50 Hz
- Desired frequency shift: 300 Hz / 50 Hz = 6 steps
- 2 months for accommodation

PDT CASE – 7 years postop





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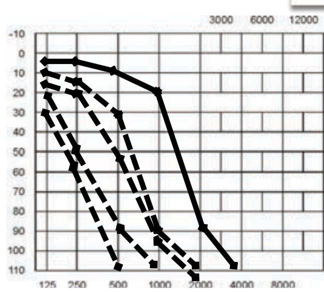
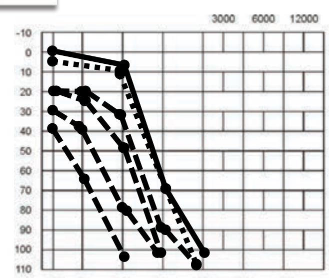
PDT CASE – 9 years postop





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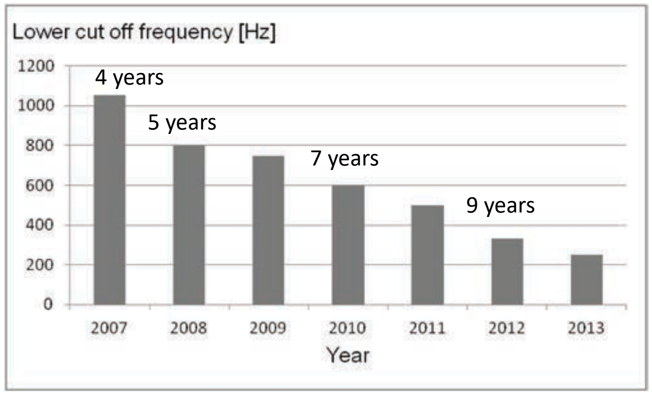
FITTING SOLUTION



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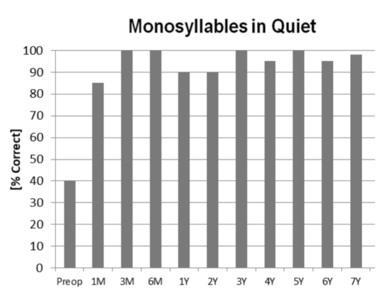
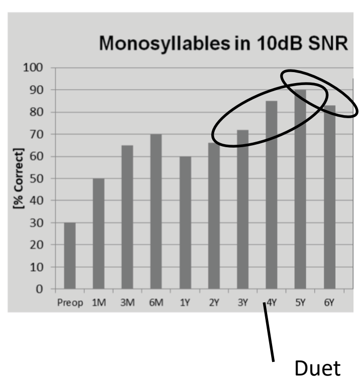
SUMMARY: SPEECH OUTCOME





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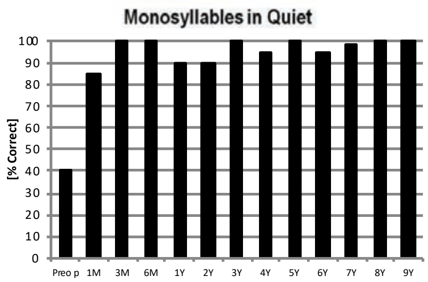
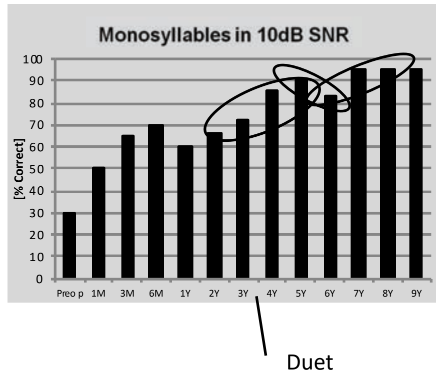
SUMMARY: SPEECH OUTCOME



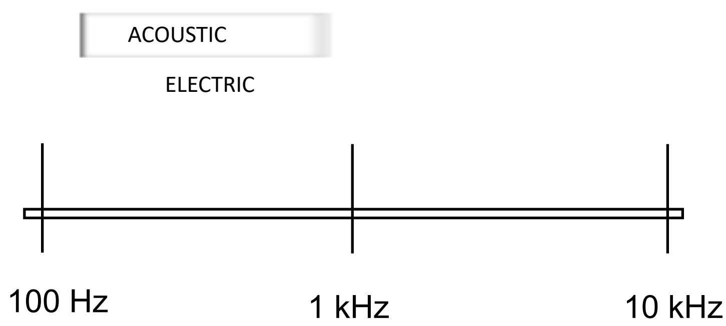


THINGS TO CONSIDER

- AT thr follow up
- Increase the gain of the hearing aid part of the device
- Reduce cross-over frequency
- Apply small steps strategy (50 Hz per 2 months)

THINGS TO CONSIDER

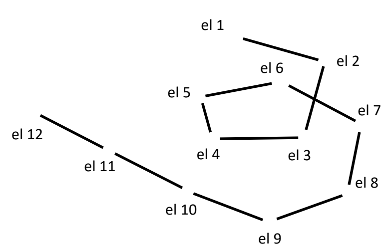
- Stimulus overlap at the activation.



-

THINGS TO CONSIDER

- Stimulus overlap at the activation.



Polak M, Lorens A, Furmanek M, Skarzyński H. Electrode estimation in the acoustic region of the human Cochlea. Acta Otolaryngol. 2020 Mar 30:1-10.

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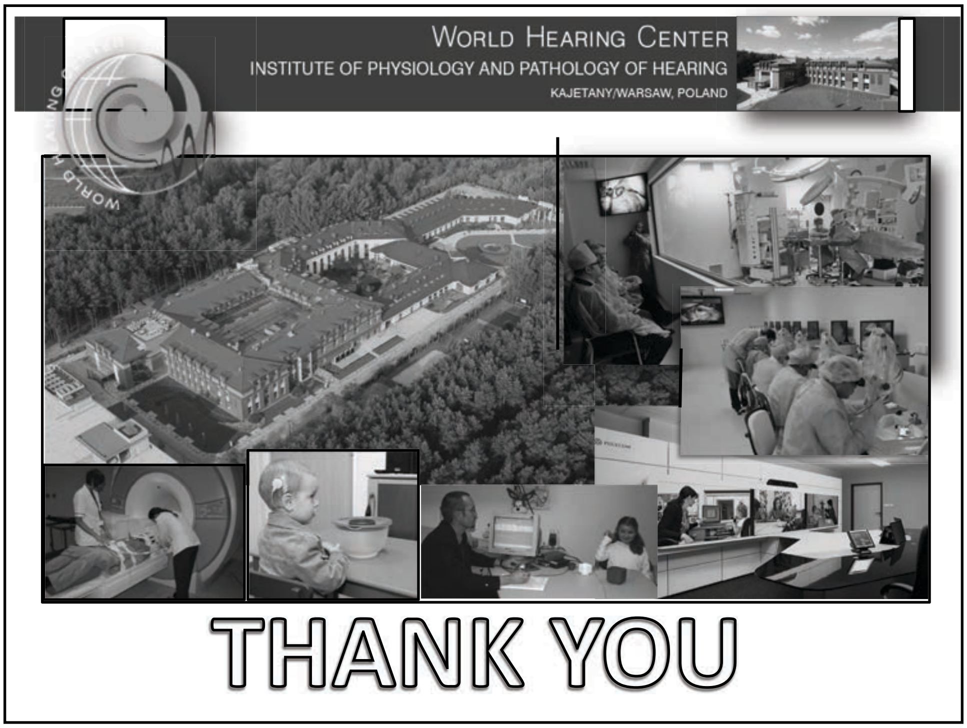

WORLD HEARING CENTER
INSTITUTE OF PHYSIOLOGY AND PATHOLOGY OF HEARING
KAJETANY/WARSAW, POLAND
THANK YOU

A couple of difficult (or just plain interesting) CI mapping cases

Kara Schvartz-Leyzac, AuD, PhD & Elizabeth Camposeo, AuD

MUSC CI Team

Director: Kara Leyzac, AuD, PhD
Asst. Director: Elizabeth Camposeo, AuD
Medical Director: Teddy McRackan, MD
Claire Hauschildt, AuD
Paul Lambert, MD
Ted Meyer, MD, PhD
Kimberly Orr, AuD
Nevitte Morris, MS, CCC-SLP
Habib Rizk, MD
Christine Strange, AuD

JO

- 49 year old male
- Progressive hearing loss, Meniere's Disease
- Left ear: Med-El Combi 40+ in 2003
- Not great about following up regularly
- 2014: Reported visual disturbances, nystagmus and severe vertigo exacerbated with CI turned on
- Vestibular evaluation:
    - Bilateral hypofunction, but not complete loss
    - CT scan identified bilateral EVA as well
    - DHI: 84 (severe impairment)

JO

4/9/2015:

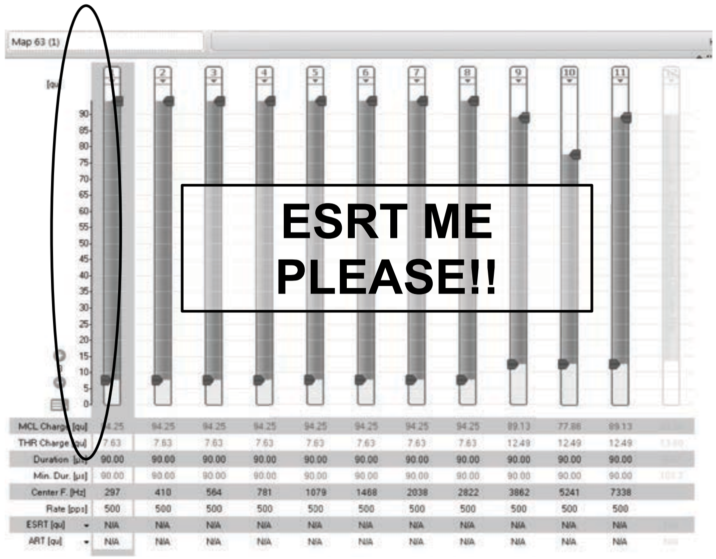
- HDCIS, 500 pps, Maplaw = 1000

Implanted Ear	Map #	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	SRT
Left	63 (1)	30	30	30	30	40	40	35	25

Speech Perception Testing: The following tests of auditory speech perception were administered in the sound field at 60 dB SPL using recorded materials:

Test	List #	Score
CNC- Words	5	40%
CNC- Phonemes	5	53%
AzBio Sentences- Quiet	2	70%
AzBio Sentences- +10 SNR	3	34%
HINT Sentences- Quiet	4&5	80%

JO



ESRT ME PLEASE!!

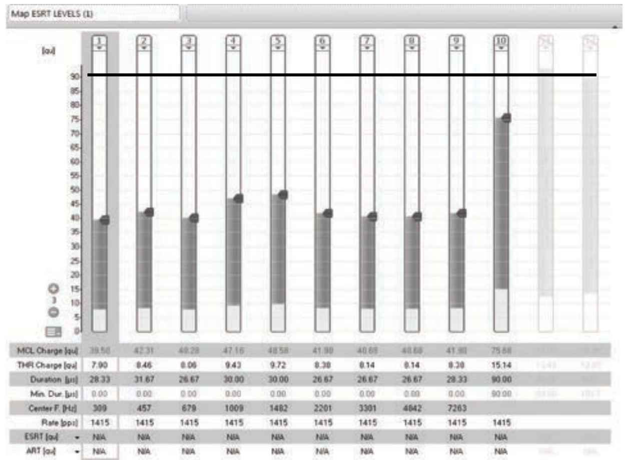
Electrically-Evoked Stapedial Acoustic Reflex (ESRT)

- Consistent response observable at levels that are highly correlated with recipients C/M levels (Hodges et al., 1997; Brickley et al., 2005)
- Pitt et al (2019) reported the following recommended offset values:

Advanced Bionics	Cochlear	Med-El
M = ESRT – 10%	C = ESRT – 19 CU	M = ESRT – 3%

BO

- 11/25/15: ESRT could be measured on electrodes 1-10
- Facial nerve stimulation noted on E11 and E12 extracochlear



JO

Immediately after programming showed stable thresholds, decreased speech understanding, and patient not too happy with his prescribed 'sound diet':

TEST RESULTS:

Behavioral Audiometry: Ear specific cochlear implant testing was completed in a calibrated sound field using warble tone stimuli and conventional audiometry. The following results were obtained in dB HL with good reliability:

Implanted Ear	Map #	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	SRT
Left	63 (8)	45	40	40	40	40	40	35	40

Speech Perception Testing: The following tests of auditory speech perception were administered in the sound field at 60 dB SPL using recorded materials:

Test	List #	Score
CNC- Words	3	24%
CNC- Phonemes	3	28%
AzBio Sentences- Quiet	4	21%

Pre-ESRT scores:

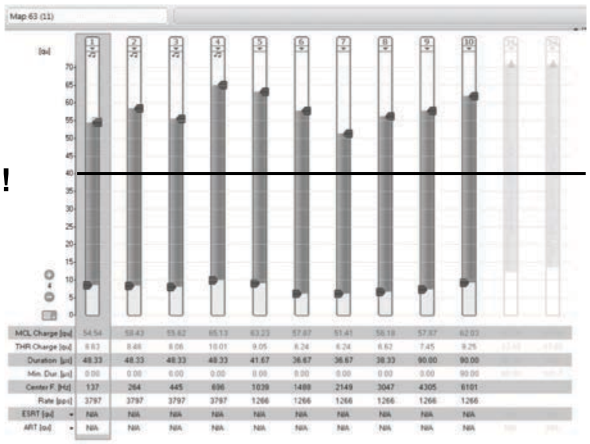
CNC Words: 40%
CNC Phonemes: 53%
AzBio Quiet: 70%

JO

7/20/2016:

- Speech much too quiet, still not adjusted; M levels adjusted globally then loudness balanced

Lost to follow-up!



	1	2	3	4	5	6	7	8	9	10
MCL Charge [qu]	54.54	58.43	55.62	65.13	63.23	57.67	51.41	56.18	57.87	62.03
THR Charge [qu]	8.83	8.46	8.06	10.01	9.05	6.24	6.24	6.62	7.45	9.25
Duration [µs]	48.33	48.33	48.33	48.33	41.67	36.67	36.67	38.33	90.00	90.00
Min. Dur. [µs]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	90.00
Center F. [Hz]	137	264	445	696	1039	1489	2149	3047	4305	6101
Rate [pps]	3797	3797	3797	3797	1266	1266	1266	1266	1266	1266
ESRT [qu]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ART [qu]	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Sometimes, these things really sneak up on you…

LC

- 41 year old female
- Progressive hearing loss, since early childhood
- Hearing aid use since age 4
- Right ear: Cochlear CI24RE(CA) in 2012
- Consistently followed up, good user of her device and subjectively very pleased

LC

4/30/2018:

TEST RESULTS:
Behavioral Audiometry: Ear specific cochlear implant testing was completed in a calibrated sound field using warble tone stimuli and conventional audiometry. The following results were obtained in dB HL with good reliability:

Implanted Ear	Map #	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	SRT
Right	47	20	25	20	25	30	25	25	25

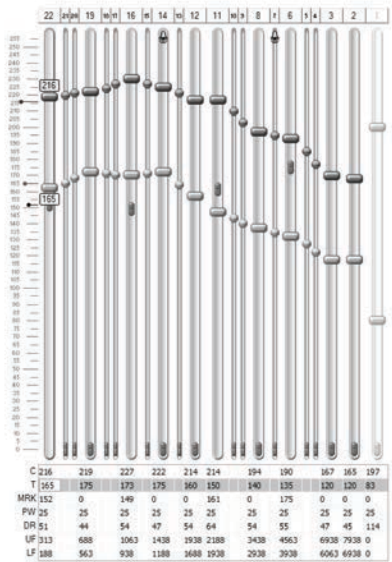
Speech Perception Testing: The following tests of auditory speech perception were administered in the sound field at 60 dB SPL using recorded materials:

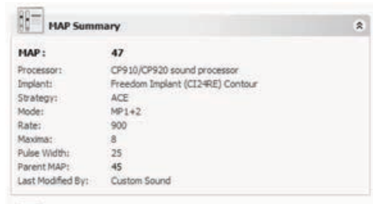
Test	List #	CI R	List #	CI + HA
CNC- Words	3	76%		
CNC- Phonemes	3	87%		
AzBio Sentences- Quiet	2	77%		
AzBio Sentences- +10 SNR	5	59%		
AzBio Sentences- +5 SNR	7	11%	4	26%

Pre-op scores:

CNC Words: 8%
CNC Phonemes: 13%
AzBio Quiet: 16%

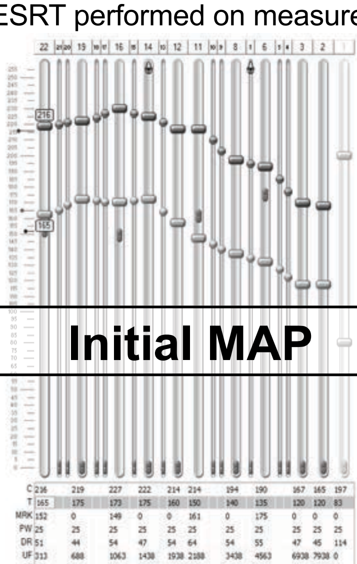
LC

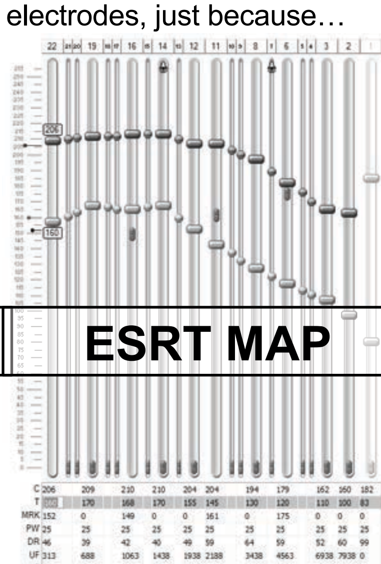




LC

ESRT performed on measured electrodes, just because…





LC

ESRT performed on measured electrodes, just because…

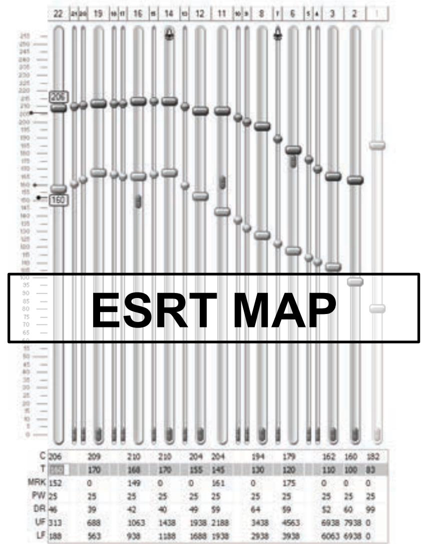
TEST RESULTS:

Functional Gain Audiometry: Ear specific cochlear implant testing was completed in a calibrated sound field using warble tone stimuli and conventional audiometry. The following results were obtained in dB HL with good reliability:

Implanted Ear	Map #	250 Hz	500 Hz	1000 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz	SRT
Right	52	25	35	30	20	30	30	30	20

Speech Perception Testing: The following tests of auditory speech perception were administered in the sound field at 60 dB SPL using recorded materials. Testing was abbreviated today since we worked her in to today's schedule.

Test	List #	CI Score
CNC- Words	9	96%
CNC- Phonemes	9	97%
AzBio Sentences- Quiet	8	88%



Previous scores:

CNC Words: 76%
CNC Phonemes: 87%
AzBio Quiet: 77%

Conclusions

- ESRT can be a powerful tool
- Should be used to assess patients when clinician feels that behavioral reporting is inaccurate
- Can provide as objective data for patient when levels are inappropriate
- BUT, also consider measuring routinely even in patients who seem to be performing appropriately

THANK YOU!

Cochlear: Maximizing the Possibilities for Every Patient

Presenters:

Stephanie Bourn, AuD

Jourdan Holder, AuD

Megan Mears, AuD

Shawn Stevens, MD

Terry Zwolan, PhD

Patricia Trautwein, AuD

continuED

Maximizing the Possibilities for Every Patient

CI2020 International Online
Spring 2020

Hear now. And always
Cochlear

Speaker disclosures

Patti Trautwein, AuD
Financial: Employee, Cochlear Americas
Non-Financial: None

Terry Zwolan, PhD
Financial: Consultant and research funding, Cochlear Americas; Envoy Medical Advisory Board Member; Course Director & Instructor, Institute for Cochlear Implant Training
Non-financial: None

Jourdan Holder, AuD
Financial: Consultant, Cochlear Americas; Consultant, Advanced Bionics
Non-financial: None

Stephanie Bourn, AuD
Financial: Consultant, Cochlear Americas
Non-financial: None

Shawn Stevens, MD
Financial: Consultant, Cochlear Americas
Non-financial: None

Megan Mears, AuD
Financial: Employee, Cochlear Americas
Non-financial: None

Maximizing the Possibilities for Every Patient

CI2020 International Online

Patricia Trautwein, MA, AuD

Hear now. And always

Cochlear

The story that started it all…

Professor Clark grew up seeing the hardship of living in silence from his father being deaf - including the frustration, anguish and resulting isolation.

He also witnessed his father's desire for a greater connection to others, and was determined to make it possible.

Cochlear was founded in 1978 when the first multi-channel cochlear implant was implanted. Since then there has been a commitment to:

Innovation
Quality
Patients

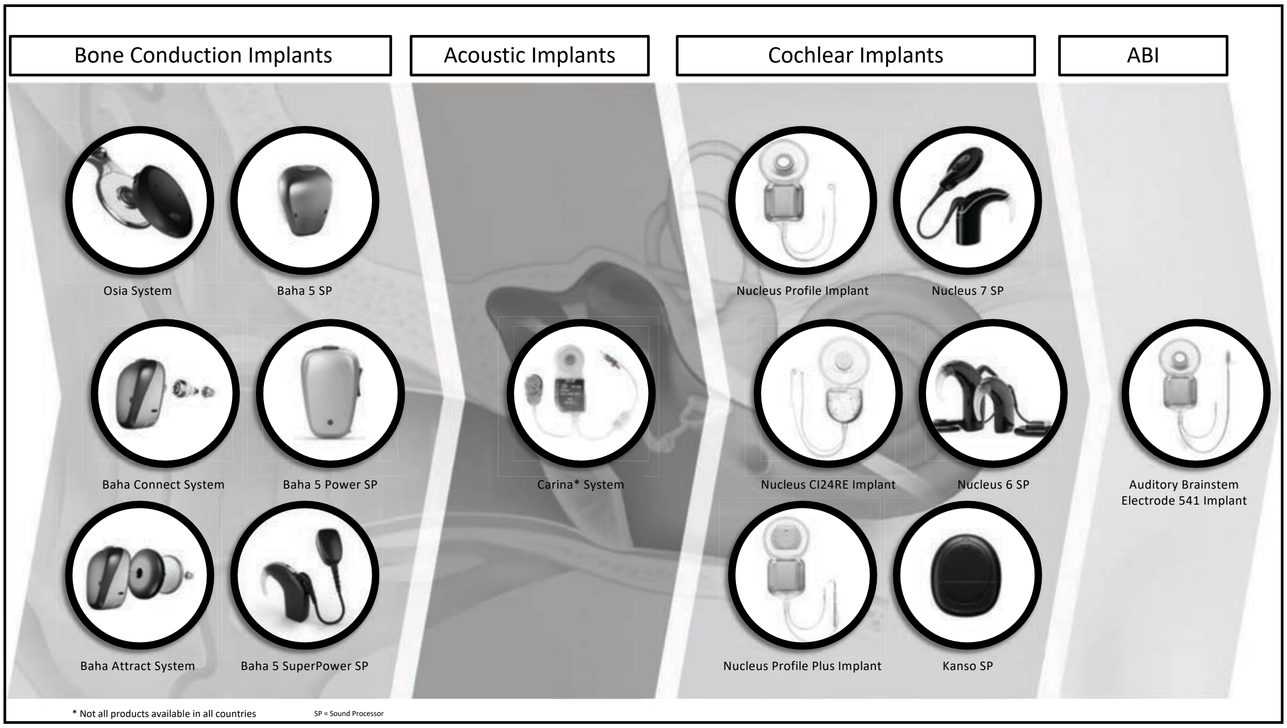
Our Mission

We help people hear and be heard.

We **empower** people to connect with others and live a full life.

We **transform** the way people understand and treat hearing loss.

We **innovate** and bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes.



Innovation focus areas

Cochlear

Hearing Outcomes

Lifestyle

Hearing Indications

Connected Care

Expanding access via Connected Care

Cochlear

In-clinic care

High quality personal care delivered cost effectively

Remote care

Convenient access to care at home

Self care

Empower patients to achieve the results with self help resources

Cochlear's Connected Care innovations are designed to:

1) Open access for clinics to provide care for more patients
2) Optimize outcomes through powerful fitting tools applied consistently, and
3) Transform care delivery through evidence based data driven insights.

myCochlear™ – Clinic and Recipient online resource hubs

Cochlear

myCochlear Clinic

- Product info and technical guides
- Patient management resources
- Professional learning tools
- Reimbursement services

myCochlear for Recipients

- Personalized
  - Device information
  - Troubleshooting
  - Warranty details
- Part of Cochlear Family membership

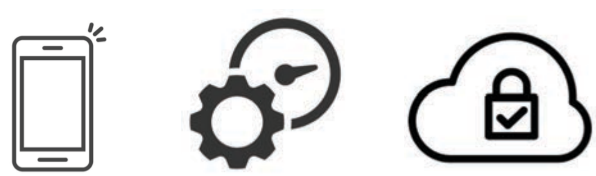
Cochlear™ Link – enabling faster service and less time ‘off-air’ for patients requiring a replacement processor

Cochlear Link:
- secure, cloud-based service
- connects clinics to the Hear Always Program
- allows replacement processors to be programmed and shipped to patients without additional clinic involvement

* Cochlear Americas. [data on file] 2016 October. Valid MAP required and some warranty restrictions may apply for next business day service.

SignHEAR, powered by DocuSign® – simple, fast and secure

Streamline the management of documentation requests with Cochlear’s mobile-friendly **SignHEAR** eSignature solution



EASY **EFFICIENT** **SECURE**

Clinics utilizing **SignHEAR** reduce turnaround time on Letters of Medical Necessity by 64% (7 days sooner)[1]

1. Internal data on file, 2019

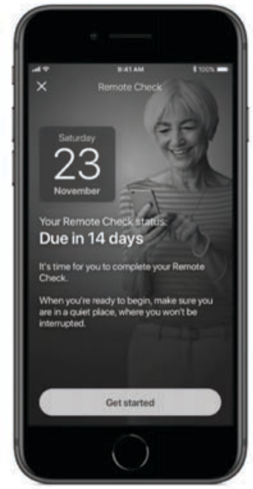
NEW: Remote Check receives expedited FDA approval

About Remote Check*

- Convenient, at-home, clinician-enabled testing tool
- Results sent remotely to the patient's clinic for review
- Results may be used to determine need for an in-person visit

With Remote Check, hearing health professionals can:

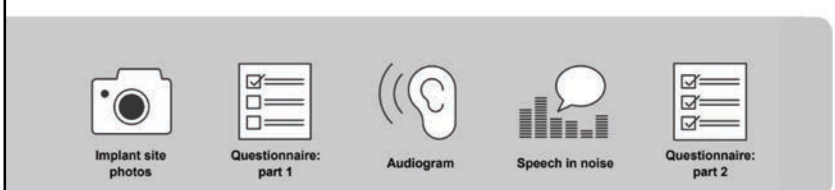
- Reduce unnecessary visits for patients who are on track
- Spend more quality time with patients who have complex needs
- See more patients who are waiting for an initial candidacy assessment
- Reduce the burden on patients by offering a convenient, time-saving option of care



* Remote Check does *not* replace clinical care and does *not* involve remote programming of the sound processor

Remote Check – the patient experience

Remote Check patient activities



Remote Check activities are designed to take as little as 15 minutes for patients to complete, and about 10 minutes for a health care professional to assess.*

*Based on internal Cochlear data. Some users may take longer than 15 minutes and 10 minutes, respectively. Data on file.

Remote programming – allowing clinicians to provide clinical care to home-bound patients

Remote programming through Custom Sound®

- FDA approved in 2017
- Allows follow-up programming sessions for the Nucleus® Cochlear Implant System through a telemedicine platform
- Proven equivalence between in-office and remote programming appointments[1]
- Addendum to the User Guide for Custom Sound provides comprehensive guidance to initiate use
    - Available through through myCochlearClinic

1. Slager H, Jensen J, Kozlowski K, Teagle H, Park L, Biever A, Mears M. Remote Programming of Cochlear Implants. Otol Neurotol (2019) 40(3) e260-e266.

Innovation focus areas

Hearing Outcomes

Lifestyle

Hearing Indications

Connected Care

Session agenda

ANSI/AAMI CI86 Standard and Reliability Reporting
Terry Zwolan, PhD
University of Michigan

Slim Modiolar: A Center's Perspective
Jourdan Holder, AuD
Vanderbilt University

The Osia System: A Surgeon's Perspective
Shawn Stevens, MD
AOC Physicians

The Osia System: An Audiologist's Perspective
Stephanie Bourn, AuD
Center for Neurosciences

Expanding Pediatric Indications
Megan Mears, AuD
Cochlear Americas

AAMI/ANSI CI 86 Standard and Reliability Reporting

Terry Zwolan, PhD
University of Michigan

The representations and views expressed in this presentation are those of the presenter and do not directly reflect the views of Cochlear.

Hear now. And always

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AAMI CI86 Cochlear Implant Systems – Requirements for Safety, Functional Verification, Labeling, and Reliability Reporting

AAMI CI-86 Standards Committee

Terry Zwolan, Ph.D.
Professor and Director
University of Michigan Cochlear Implant Program

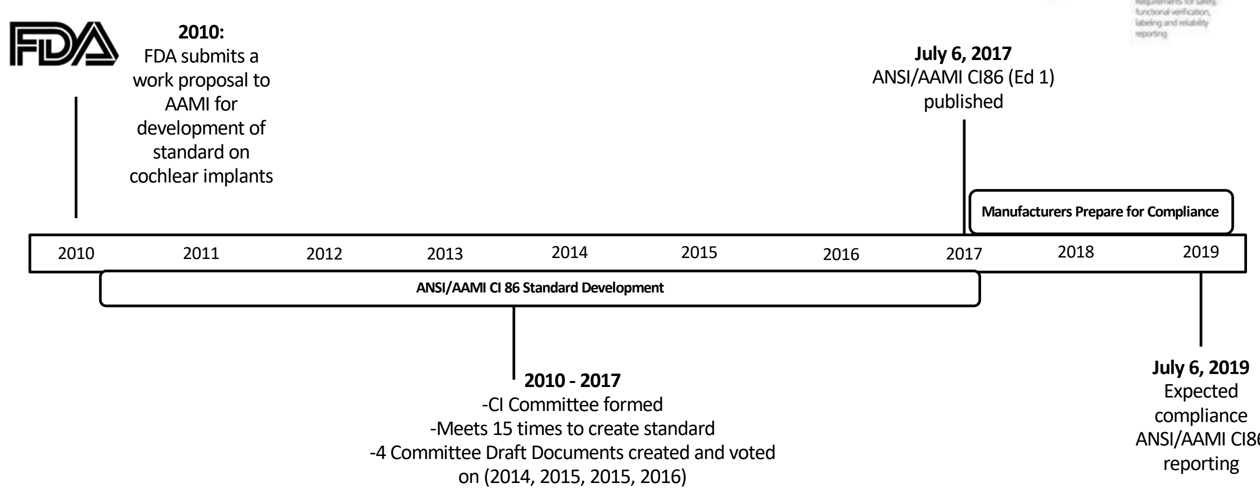
Disclosures

- Cochlear Americas Advisory Board Member
- Envoy Medical Advisory Board Member
- Institute for Cochlear implant Training
  - Course Director, Instructor

Why a new standard? Because reliability matters

- To establish uniform guidelines for reliability reporting
- Reporting per previous Standards was inconsistent
  - Did not include devices removed for medical reasons
  - Did not adequately differentiate between children and adults
  - Did not provide information regarding sound processor reliability
  - Did not provide minimum testing standards (which are needed!)
- Reports provided to the public by CI manufacturers varied
  - Mfrs. cited various references with little consistency
  - Confusing for even the most seasoned clinicians, patients, and their families
    - Reliability reports were not always reliable sources of information
- A new standard was needed so clinicians and consumers can have the information they need to include reliability information in their device selection process

AAMI CI86: Development Timeline



So what does a “standard” mean?

- **Standard:** Set of guidelines that manufacturers can *voluntarily* comply to - this will help <u>provide consistency</u>
- ANSI Essential Requirements for standard development state “The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.”
  - For AAMI/CI-86 those interest categories included
    - Regulatory and general interest/organizations
    - CI manufacturers
    - Clinicians

AAMI CI Committee Member Affiliations/diverse interest categories

- Four cochlear implant manufacturers
  - Advanced Bionics
  - Cochlear
  - MED-EL
  - Oticon/Neurelec
- FDA
- Clinicians/Academicians from a variety of settings
  - American Neurotology Society
  - Chattering Children
  - Gallaudet U.
  - Swedish Medical Center
  - U. California-Irvine
  - U. Iowa Hospital and Clinics
  - U. Maryland
  - U. Michigan
  - Arizona Ear Center

How AAMI-CI Impacts Manufacturers

- Specifications regarding
  - Device labeling
  - Reliability reports to the public
  - Regulatory Submissions
  - Design and Verification Requirements
  - Reliability reporting to regulatory bodies

How AAMI CI86 impacts clinicians

- AAMI CI86 provides clinicians and recipients with improved information regarding device reliability
  - Detailed, proprietary reports for regulatory authorities, leading to better monitoring and enhanced safety
  - Simplified reports for the public and clinical community: manufacturers report their public data on their company website using a format and explanatory language that is <u>common across all manufacturers</u>, aiding patients and clinicians in interpreting reliability data.
  - Let’s take a look at such reporting…

COCHLEAR IMPLANT PROGRAM

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

What are the key differences amongst reliability reporting?

	European Consensus Statement	ANSI/AAMI CI86 Standard
IMPLANT RELIABILITY METRIC	The reliability metric used is Cumulative Survival Percentage (CSP). CSP measures the percentage of functioning implants, at given time intervals, after implantation.	The reliability metric used is Cumulative Removal Percentage (CRP). CRP measures the percentage of implanted devices that have been removed, at given time intervals, after implantation.
DEFINITION OF ADULT AND CHILD POPULATION	A child is defined as a recipient who was aged less than 18 at the time of implantation.	A child is defined as a recipient who was aged less than 10 at the time of implantation.
INCLUSION OF SOUND PROCESSOR RELIABILITY	Sound processor reliability data is not included.	The standard specifies principles for the reporting of sound processor reliability. Data is reported for all sound processors which are currently marketed in the US.

Fundamental Differences in Implant Reporting

Both reliability reports provide data in accordance with the standards they are based on, however the standards have different requirements for reporting

European Consensus Statement	ANSI/AAMI CI86 Standard
Considers **device failures** when reporting implant reliability.	Considers **device removals**, including those for medical reasons which may be unrelated to the device or its operations (e.g. infection).

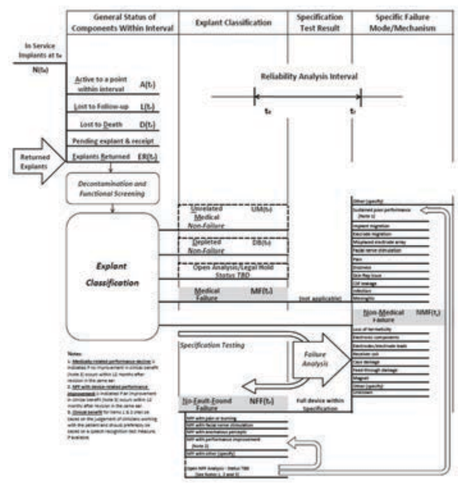
99.81% **Within 6 years**

Cochlear Nucleus Profile Series[6,7]

98.83% **Within 6 years**

According to the standard, such reports should include the following

- Percentage of implanted devices that have been removed following implantation. This = CUMULATIVE REMOVAL PERCENTAGE (CRP)
  - Total number of devices compared to the total number of implanted devices of the same make, model and similar duration of use
- There are detailed procedures manufacturers must follow to determine the CRP



Reasons for removal should be tracked

- CRP classifies removed devices into three different categories:
  - o Medical
    - Infection, rejection of the device due to allergy, improper positioning or placement
  - o Non-Medical
    - Mechanical or electronic issues, moisture damage
  - o Inconclusive

Cochlear also reports a combined total in the company's summary report.

COCHLEAR IMPLANT PROGRAM
MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

Data are reported separately for each type of device

MORE PEOPLE CHOOSE COCHLEAR THAN ANY OTHER IMPLANT BRAND

OVER 410,000 REGISTERED COCHLEAR NUCLEUS IMPLANTS WORLDWIDE

Number of registered implants - 31 December 2019

DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	4,920	2,385	7,305
Profile™	50,287	40,116	90,403
CI24RE	79,297	116,635	195,932
CI500	15,385	14,507	29,892
CI24R	18,679	34,831	53,510
CI24M (All)	7,772	11,750	19,522
CI22M	9,670	7,995	17,665

Reliability should be tracked based on age at implant

- Data are provided for
  - 1) patients younger than 10 years
  - 2) patients older than 10 years
- It is assumed that children younger than 10 years will have a higher chance of activity-related damage to the device.

NUCLEUS® PROFILE™ PLUS SERIES IMPLANT

Number of registered Profile™ Plus Series Implants - 31 December 2019

ADULTS	CHILDREN	COMBINED
5,303	2,002	7,305

Profile Plus Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down
1	0.08%	0.00%	0.00%	0.08%	0.18%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.05%	0.00%	0.00%	0.05%	0.13%	0.00%

NUCLEUS PROFILE SERIES IMPLANT

Number of registered Profile Series Implants - 31 December 2019

ADULTS	CHILDREN	COMBINED
55,314	35,089	90,403

Profile Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down
1	0.56%	0.04%	0.00%	0.60%	0.67%	0.54%	0.31%	0.07%	0.00%	0.38%	0.41%	0.31%	0.47%	0.05%	0.00%	0.52%	0.57%	0.47%
2	0.84%	0.08%	0.00%	0.91%	1.00%	0.83%	0.41%	0.15%	0.00%	0.56%	0.64%	0.47%	0.68%	0.10%	0.00%	0.78%	0.84%	0.72%
3	1.04%	0.10%	0.00%	1.13%	1.24%	1.03%	0.48%	0.18%	0.00%	0.66%	0.75%	0.56%	0.82%	0.13%	0.00%	0.95%	1.03%	0.89%
4	1.16%	0.12%	0.00%	1.27%	1.39%	1.15%	0.49%	0.25%	0.00%	0.74%	0.86%	0.63%	0.91%	0.17%	0.00%	1.07%	1.16%	0.98%
5	1.20%	0.14%	0.00%	1.34%	1.48%	1.20%	0.60%	0.29%	0.00%	0.89%	1.07%	0.70%	0.98%	0.20%	0.00%	1.17%	1.29%	1.06%
6	1.20%	0.14%	0.00%	1.34%	1.48%	1.20%	0.60%	0.29%	0.00%	0.89%	1.07%	0.70%	0.98%	0.20%	0.00%	1.17%	1.29%	1.06%

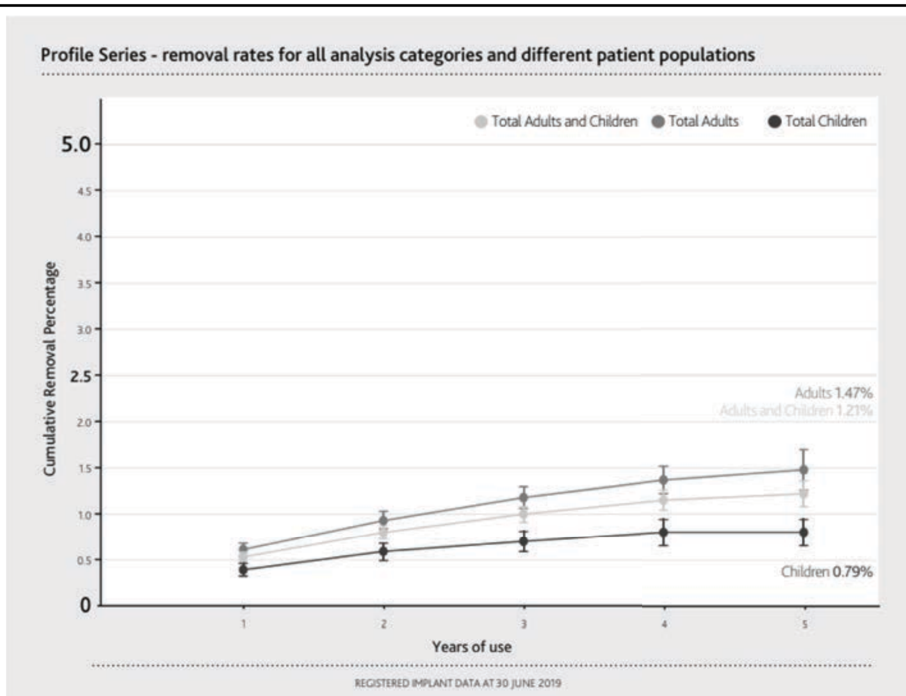
Cumulative Removal rate

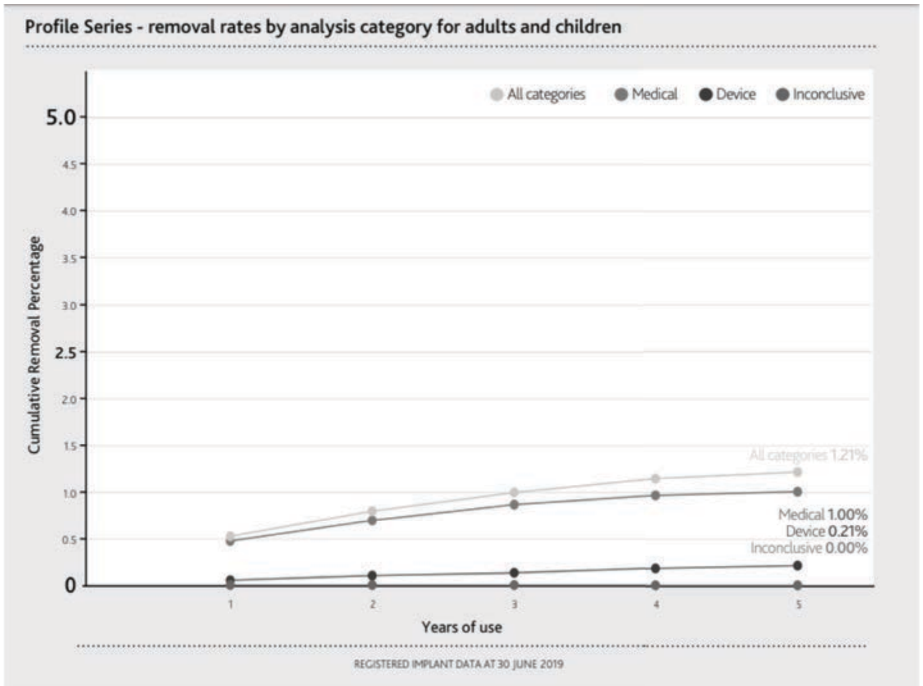
Reason for removal (Medical, Device, Inconclusive, Total

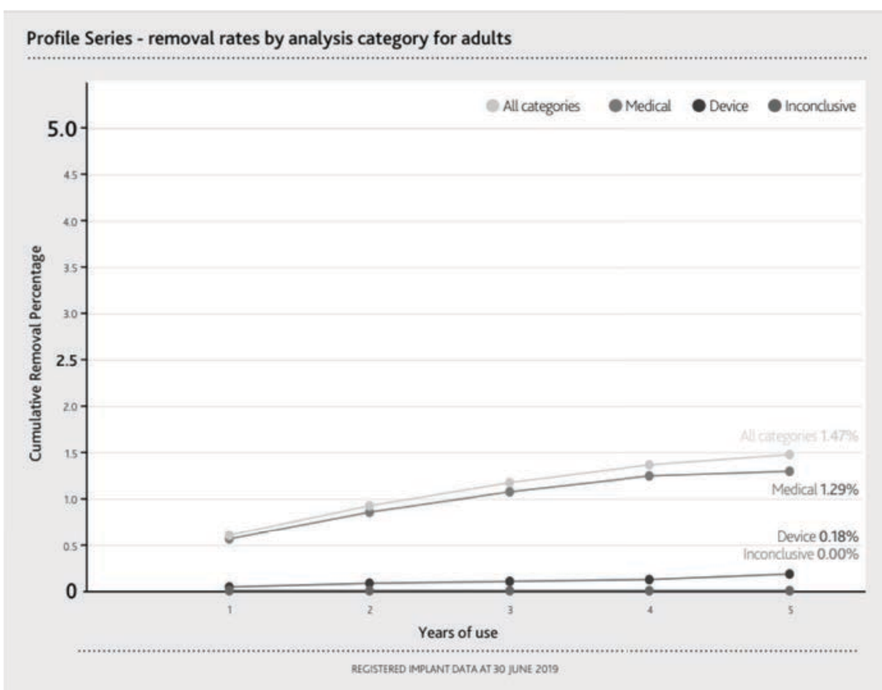
For adults, children, and combined

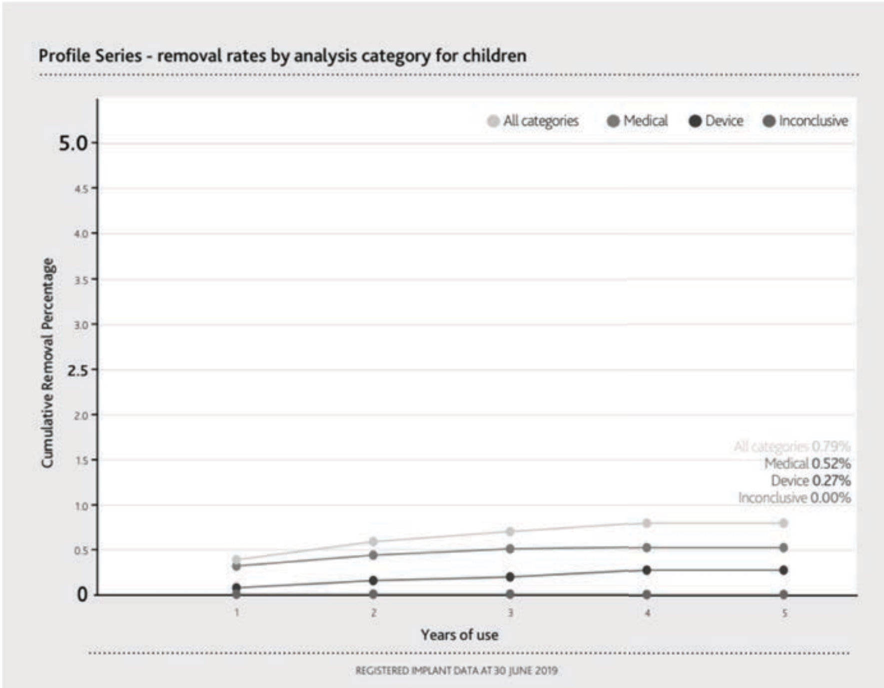
Profile Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total		Medical Related	Device Failure	Incon-clusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down	CRP	CRP	CRP	CRP	CI_up	CI_down
1	0.56%	0.04%	0.00%	0.60%	0.67%	0.54%	0.31%	0.07%	0.00%	0.38%	0.45%	0.31%	0.47%	0.05%	0.00%	0.52%	0.57%	0.47%
2	0.84%	0.08%	0.00%	0.91%	1.00%	0.83%	0.41%	0.15%	0.00%	0.56%	0.64%	0.47%	0.68%	0.10%	0.00%	0.78%	0.84%	0.72%
3	1.04%	0.10%	0.00%	1.13%	1.24%	1.03%	0.48%	0.18%	0.00%	0.66%	0.76%	0.56%	0.82%	0.13%	0.00%	0.95%	1.03%	0.88%
4	1.16%	0.12%	0.00%	1.27%	1.39%	1.15%	0.49%	0.25%	0.00%	0.74%	0.86%	0.63%	0.91%	0.17%	0.00%	1.07%	1.16%	0.98%
5	1.20%	0.14%	0.00%	1.34%	1.48%	1.20%	0.60%	0.29%	0.00%	0.89%	1.07%	0.70%	0.98%	0.20%	0.00%	1.17%	1.28%	1.06%
6	1.20%	0.14%	0.00%	1.34%	1.48%	1.20%	0.60%	0.29%	0.00%	0.89%	1.07%	0.70%	0.98%	0.20%	0.00%	1.17%	1.28%	1.06%




Profile Series - removal rates by analysis category for adults and children
All categories
Medical
Device
Inconclusive
Cumulative Removal Percentage
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0
All categories 1.21%
Medical 1.00%
Device 0.21%
Inconclusive 0.00%
1
2
3
4
5
Years of use
REGISTERED IMPLANT DATA AT 30 JUNE 2019

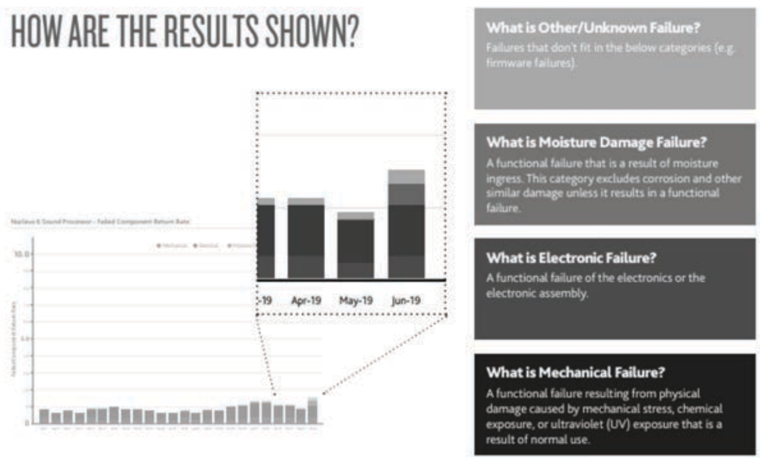

Profile Series - removal rates by analysis category for adults
All categories
Medical
Device
Inconclusive
Cumulative Removal Percentage
5.0
4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0
All categories 1.47%
Medical 1.29%
Device 0.18%
Inconclusive 0.00%
1
2
3
4
5
Years of use
REGISTERED IMPLANT DATA AT 30 JUNE 2019



SOUND PROCESSOR RELIABILITY

Failed Component Return Rate (FCRR)

- Displayed in monthly color-coded bar graphs that describe the reasons for failure, which include:
  - Other/unknown
  - Moisture Damage
  - Electronic Failure
  - Mechanical Failure



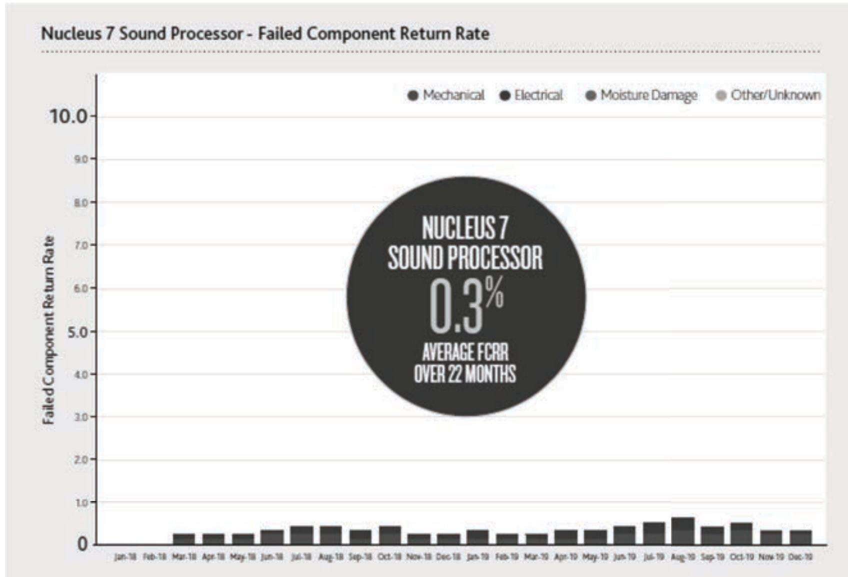
The standard includes **Failed Component Return Rate (FCRR)**, which describes <u>sound processor</u> reliability. FCRR = the percentage of the total number of failed processors received within the last month compared to the total number of the same processor sold in the US by the end of that month.

Nucleus 7 Sound Processor Component Return Rate

Fail mode	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18
Mechanical	-	-	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%
Electrical	-	-	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.1%	0.2%	0.1%	0.1%
Moisture	-	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	-	-	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	-	-	0.3%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%

Fail mode	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19
Mechanical	0.2%	0.1%	0.1%	0.2%	0.2%	0.2%	0.3%	0.3%	0.2%	0.2%	0.1%	0.1%
Electrical	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.3%	0.2%	0.3%	0.2%	0.2%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.3%	0.4%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.2%

- Failed Component Return Rate = percentage of total number of original non-implantable components sold that are returned as failed devices each month



The Standard Includes Tools for Clinicians and the public

Several informative annexes have been included in the AAMI CI86 standard that provide clinicians with tools to understand device analysis, reporting, and aid patients in interpreting reliability data:

<u>Annex A: Clinical identification & management of device failures</u>

- Provides suggestions for pre-, peri-, and post-operative considerations when discussing and/or evaluating device failures

<u>Annex B: Clinical checklist</u>

- For completion by clinicians to ensure consideration of steps that should be taken to evaluate device function and also to note signs and symptoms that may be related to malfunction of a cochlear implant. This information is to be shared with the device manufacturer prior to device explant and an explant kit must be obtained from the manufacturer prior to explantation.

<u>Annex C: Returned implant analysis report template</u>

- Provides an example of how device manufacturers will report the results of the full device analysis

<u>Annex D: Indications of performance decline</u>

- Provides a list of symptoms clinicians can watch for that may indicate a device failure

<u>Annex H: Reliability reporting template for the public and clinical community (previously described)</u>

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Conclusion

- ANSI/AAMI CI86 has been published and is available in the AAMI store: http://my.aami.org/store/SearchResults.aspx?searchterm=CI86&searchoption=ALL
- This is an important new CI standard that represents the collaborative effort of clinicians, device manufacturers, and regulatory personnel to improve reporting of device reliability
- We encourage clinicians and patients and their families to take advantage of this new standard by looking at the reliability reports provided by the device manufacturers, when making the important decision regarding which device is most reliable

References

1. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
2. Battmer RD, Backous DD, Balkany TJ, Briggs RJ, Gantz BJ, van Hasselt A, et al. International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators. Otol Neurotol. 2010 Oct;31(8):1190-3.
3. International Standard ISO 5841-2. Implants for Surgery — Cardiac Pacemakers — Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads. Geneva (Switzerland): International Organization for Standardization. 2000.
4. International Standard ISO 5841-2. Implants for Surgery — Cardiac Pacemakers — Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads. Geneva (Switzerland): International Organization for Standardization. 2014.
5. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification,. (2017). Arlington, VA: American National Standards Institute.
6. Cochlear Limited. D1712187 ISS1 MAR20. Cochlear™ Nucleus® Implant Reliability Report Volume 18, December 2019.
7. Cochlear Limited. D1712146. ISS1 MAR20. Cochlear™ Nucleus® Implant Reliability Report Volume 2, December 2019.

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Innovation focus: Hearing outcomes with Nucleus

Hearing Outcomes

Lifestyle

Connected Care

Hearing Indications

Maximize hearing outcomes with Slim Modiolar

Minimize cochlear trauma

- Consistent Scala Tympani Placement[1]
- Avoiding lateral wall/Basilar Membrane[2]

Closest to the hearing nerve[1,3,4]

- Reduced spread of excitation
- Reduced stimulation levels[5,6]

High number of independent channels[7]

- Improved electrode discrimination[8,9]

1. Clinical Evaluation of the Cochlear Nucleus CI532 Cochlear Implants in Adults Investigator Meeting. 2019 Apr.
2. Risi F. Considerations and Rationale for Cochlear Implant Electrode Design – Past, Present and Future. J Int Adv Otol. 2018 Dec; 14(3): 382-391.
3. Holden LK, Finley CC, Firszt JB, Holden TA, Brenner C, Potts LG, et al. Factors affecting open-set word recognition in adults with cochlear implants. Ear Hear 2013; 34: 342-60.
4. Shaul C, Dragovic AS, Stringer AK, O'Leary SJ, Briggs RJ. Scalar localisation of peri-modiolar electrodes and speech perception outcomes. J Laryngol Otol. 2018;132:1000–6.
5. Hughes ML, Abbas PJ. Electrophysiologic channel interaction, electrode pitch ranking, and behavioral threshold in straight versus perimodiolar cochlear implant electrode arrays. J Acoust Soc Am 2006; 119: 1538-47.
6. Polonenko et al. Stimulation parameters differ between current anti-modiolar and peri-modiolar electrode arrays implanted within the same child. The Journal of Laryngology & Otology. 2016; 130(11):1007-1021.
7. FUN1142: Cochlear Implant Electrode Comparison Chart
8. Chakravorti, et al. Further evidence of the relationship between cochlear implant electrode positioning and hearing outcomes. Otology and Neurotology. 2019. doi: 10.1097/MAO.0000000000002204.
9. Berg K, Noble J, Dawant B, Dwyer R, Labadie R, Gifford R. Speech recognition as a function of the number of channels in perimodiolar electrode recipients. J Acoust Soc Am. 2019; 145(3):1556-1564.

Slim Modiolar: A Center's Perspective

Jourdan Holder, AuD
Vanderbilt University

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Maximizing the Possibilities for Patients with Severe to Profound or High Frequency Hearing Loss
Precurved Electrode Arrays

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Cochlear Implant Audiologist

PhD Candidate

Vanderbilt Cochlear Implant Research Laboratory

Nashville, Tennessee

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Disclosures

- Speaking honoraria from Cochlear
- Consultant for Advanced Bionics

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VANDERBILT UNIVERSITY MEDICAL CENTER

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NIH R01DC008408, R21DC012620, and R01DC010184: imaging studies

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Robert Labadie, MD, PhD
Matthew O'Malley, MD
Alejandro Rivas, MD
Christopher Wootten, MD
Frank Virgin, MD

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Jack Noble, PhD
Robert Labadie, MD, PhD

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Straight Arrays

Precurved Arrays

Historical perspectives on straight arrays

- Less likely to translocate
  - ➢Better rates of hearing preservation

(e.g., Wanna et al., 2015; Boyer et al., 2015)

- Greater electrode to modiolus distance
  - ➢Higher upper stimulation levels and reduced stimulation specificity

(e.g., Sauders et al., 2002; Davis et al., 2016; Shepherd et al., 1993; Cohen et al., 2006)

Historical perspectives on precurved arrays

- More prone to translocation
  - ➢Intracochlear trauma and poorer hearing preservation

(e.g., Wanna et al., 2015; O'Connell et al., 2016)

- Shorter electrode to modiolus distance
  - ➢Reduced charge required for upper stimulation levels and improved stimulation specificity

(e.g., Sauders et al., 2002; Davis et al., 2016; Shepherd et al., 1993; Cohen et al., 2006)

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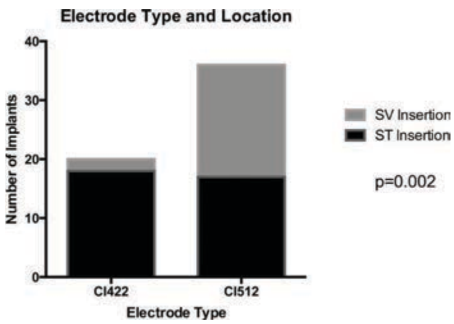
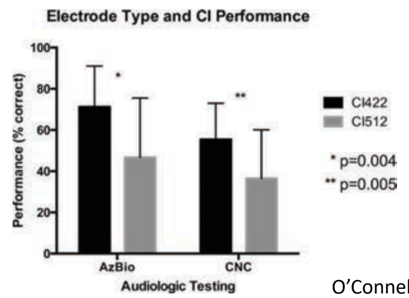
Previous reports of straight vs. precurved

- Several previous studies have compared precurved vs. straight electrodes (i.e., 512 vs. 522)
  - ➢ Previous precurved electrodes were especially prone to translocation
  - ➢ Or translocation was unknown





O'Connell et al., 2016

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Cochlear's Slim Modiolar electrode array

- Non-stylet, precurved electrode array
- Vanderbilt experience to date:
  - Low rates of translocation (6.3%, 8/126)
  - Rates of tip fold over (2.4%, 3/126)
    - o Detected and resolved using intraoperative CT

Vanderbilt Data; Nassiri et al., 2020; Holder et al., in prep

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Research Question:

In light of more similar rates of translocation, how does the Slim Modiolar compare to the Slim Straight in terms of speech recognition, hearing preservation outcomes, and programming parameters?

Slim Modiolar (5/632)
Translocation Rate = 6.3%

vs.

Slim Straight (4/5/622)
Translocation Rate = 16.3%

Vanderbilt Data; Nassiri et al., 2020; Holder et al., in prep

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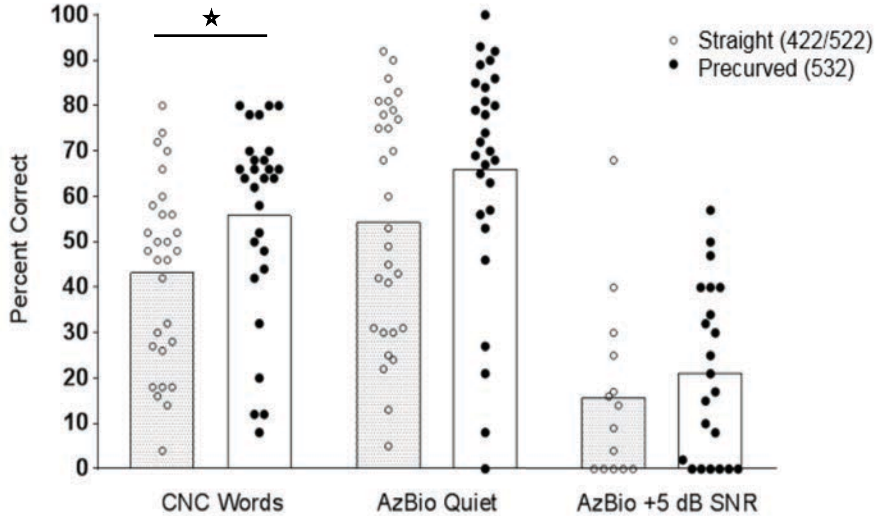
Study Design

- N = 58
- Each 532 was *individually* matched to a 522 recipient in terms of age, preoperative hearing, and daily CI use to control for other factors known to affect outcomes

	522 (n=29)	**532 (n=29)**
Age	66.9 years	67.0 years
Preoperative LFPTA	84.5 dB HL	83.6 dB HL
Preoperative CNC	5.5%	7.3%
Daily CI Use	12.2 hrs	12.3 hrs

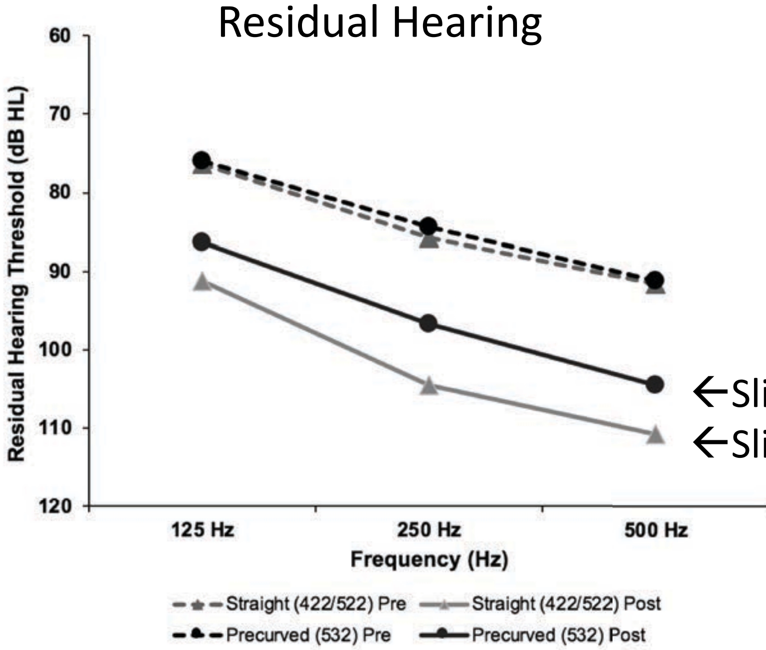
Holder et al., 2019

Speech Recognition



Holder et al., 2019

Residual Hearing



←Slim Modiolar
←Slim Straight

Holder et al., 2019

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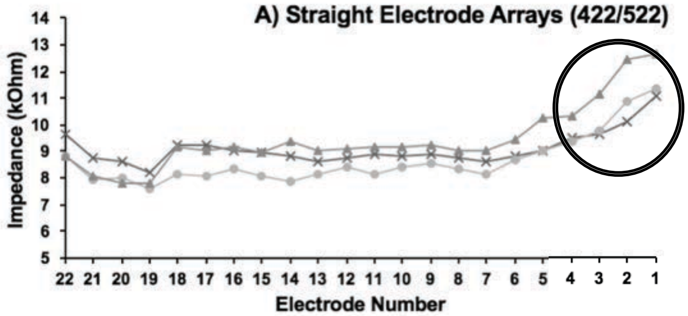
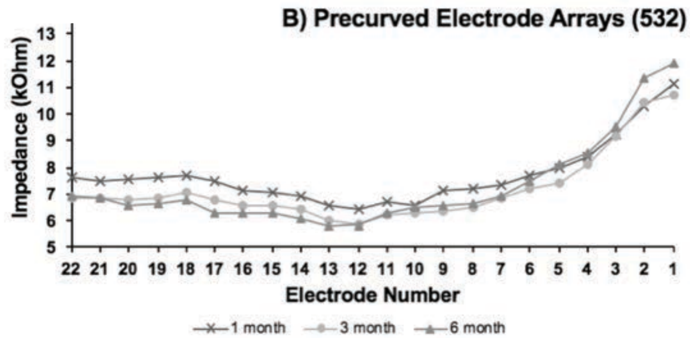
Impedances





- Precurved: Significantly lower impedances overall
- Straight: Significantly higher impedances at 6 months than at 3 months

Holder et al., 2019

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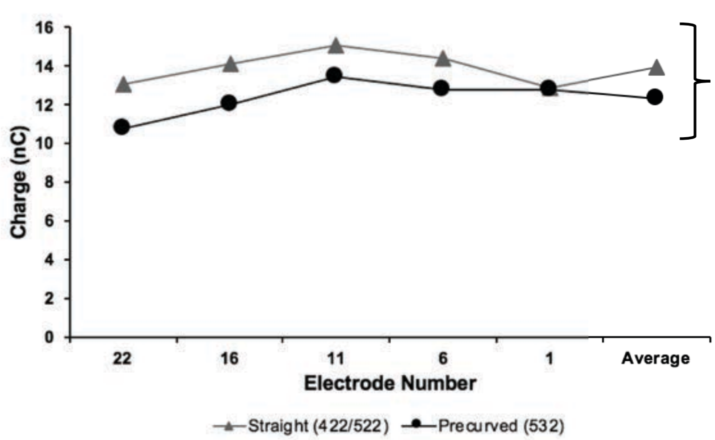
Charge - Upper Stimulation Levels

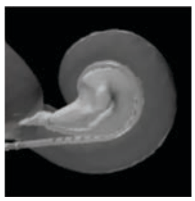


Slim Straight required higher charge, but the difference was not significant.

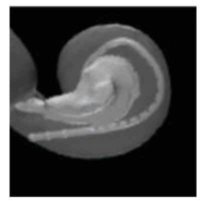
Holder et al., 2019

Precurved array placement matters

- Electrode-to-modiolus distance correlated with charge for upper stim levels (e.g., Litvak et al., 2007; Kang et al., 2015; Davis et al., 2016)
- Higher charge → greater channel interaction (e.g., Chatterjee & Shannon, 1998; Chatterjee et al., 2006)
- Greater channel interaction → poorer spectral resolution



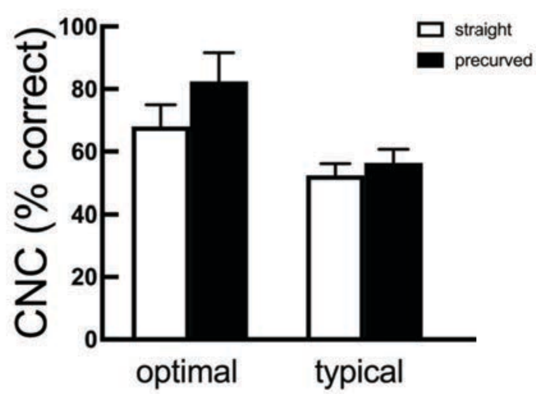
CI532
AVG electrode-to-modiolus distance: **0.13 mm**



CI532
AVG electrode-to-modiolus distance: **0.60 mm**

Chakravorti et al. (2019)

- n = 220
- Variables found to be significant:
  - Precurved:
    - Mean electrode-to-modiolus distance (mm)
    - Age at implantation
    - Full ST insertion
    - Prelingual onset of deafness
  - Straight:
    - Base insertion depth
    - Prelingual onset of deafness



Chakravorti et al., 2019

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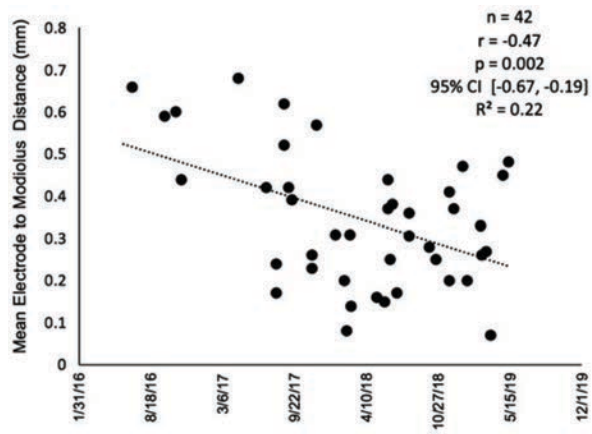
Achieving optimal placement

- Improved precurved placement with the slim modiolar electrode array over time with intraoperative feedback via CT scan immediately following implantation
- Mean Distance to modiolus
  - Slim Modiolar: 0.37
  - Contour Advance: 0.5



Labadie et al., 2020

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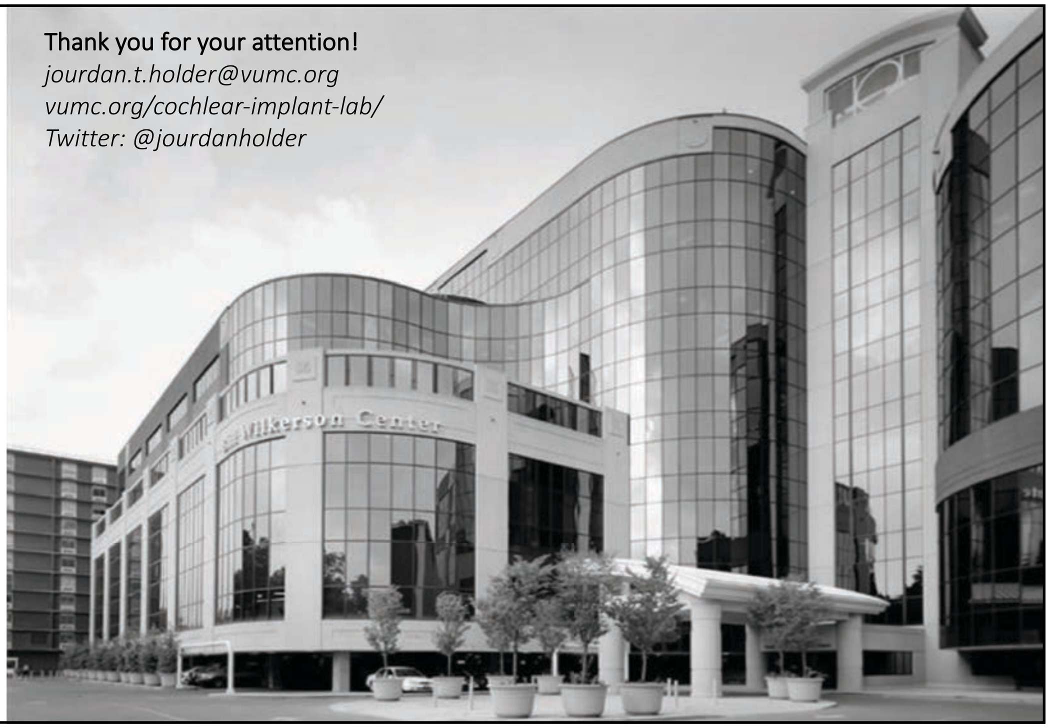
Key Takeaways

- Well-placed precurved arrays outperform straight arrays
- Placement of precurved devices (distance to modiolus and scalar location) matters, and experience and feedback may be required to optimize placement in order to maximize patient outcomes
  - Slim Modiolar array → less likely to translocate & shorter electrode to modiolus distance than previous precurved devices

COCHLEAR IMPLANT
Research Laboratory



Thank you for your attention!
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Twitter: @jourdanholder

Innovation focus: Hearing outcomes with Nucleus

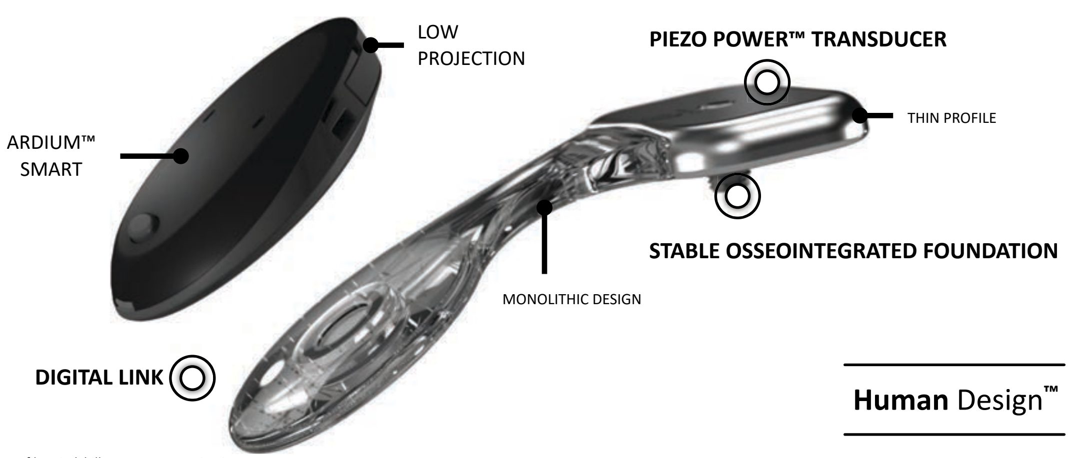
Cochlear

Hearing Outcomes	Lifestyle	Connected Care	Hearing Indications

The Osia System: A hearing implant reimagined

Cochlear

The Osia® System utilizes innovative technologies specifically chosen to work in and with the body, delivering excellent hearing performance in the noisy situations where people tell us they struggle most[1].



Human Design™

D1602035-V1

1. Data on file Windchill Document D1478473

The Osia System: Surgical experience

Shawn Stevens, MD
AOC Physicians
Barrow Neurological Institute

The representations and views expressed in this presentation are those of the presenter and do not directly reflect the views of Cochlear.

Hear now. And always

Cochlear®

The Cochlear™ Osia® System: The surgical experience

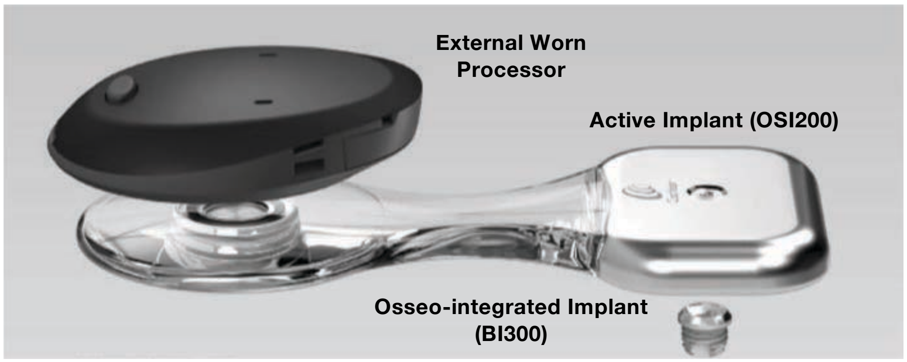
Shawn M. Stevens, MD

Neurotology, Otology, and Skull Base Surgery
The Arizona Ear Institute (Dv. AOC)
Assistant Professor; Barrow Neurological Institute
President Elect; The Arizona Society of Otolaryngology

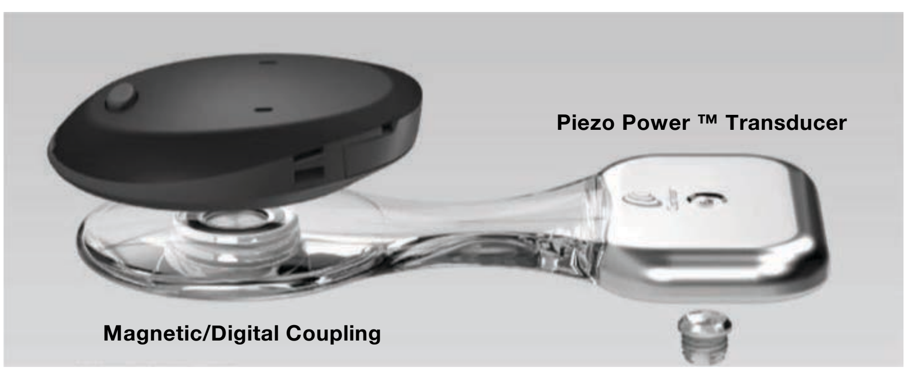
Disclosure

Paid Consultant. Cochlear Americas

The Osia System



The Osia System

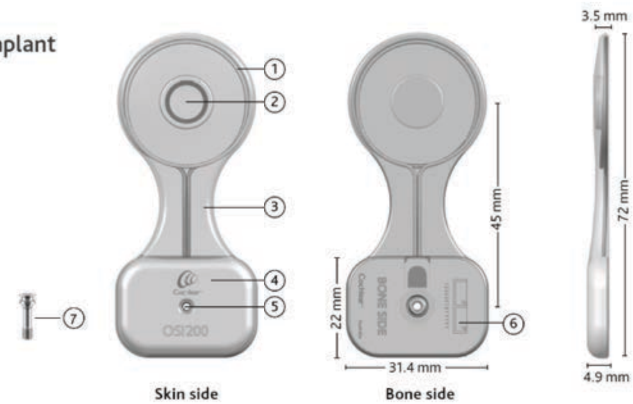


TECHNICAL SPECIFICATIONS

Cochlear™ Osia® 2 System

Cochlear™ Osia® OSI200 Implant (P1170466)

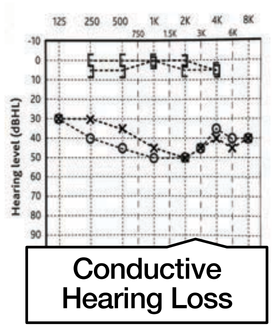
1. Coil
2. Removable magnet
3. Waist
4. Actuator
5. Fixation interface
6. Serial number and QR-code
7. Fixation screw

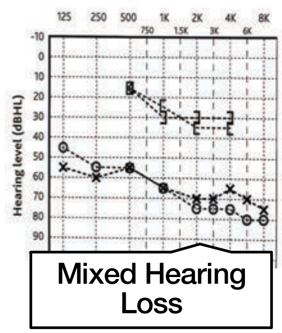


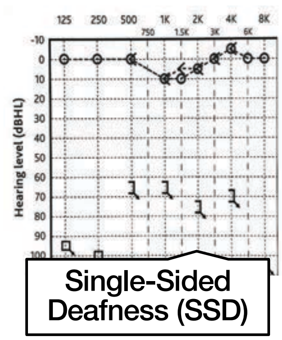
Key Facts – The Osia System

- Uses Digital Link technology
- Piezo Power™ Transducer produces sound transfer
- Prior surgery not a contra-indication
- Fitting range – 55 dB bone line
- Power equivalent to Baha® 5 Power device
- MRI Conditional (magnet removed) at 1.5 and 3.0T

Indications

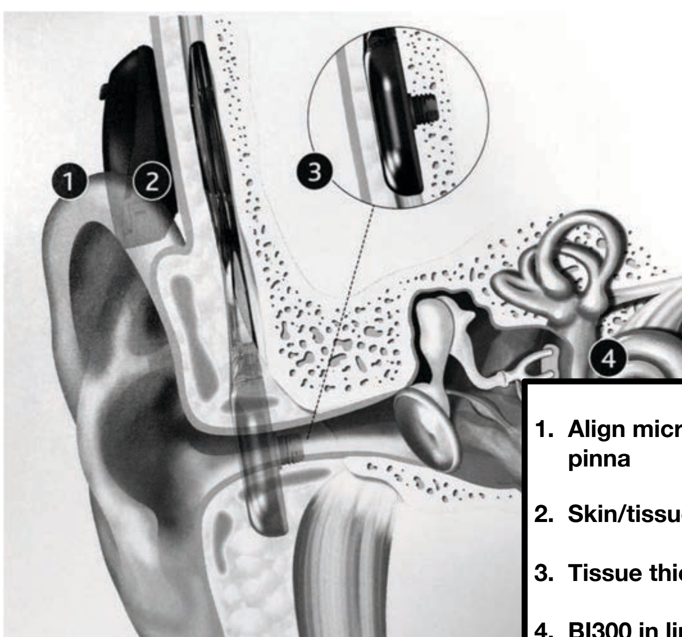




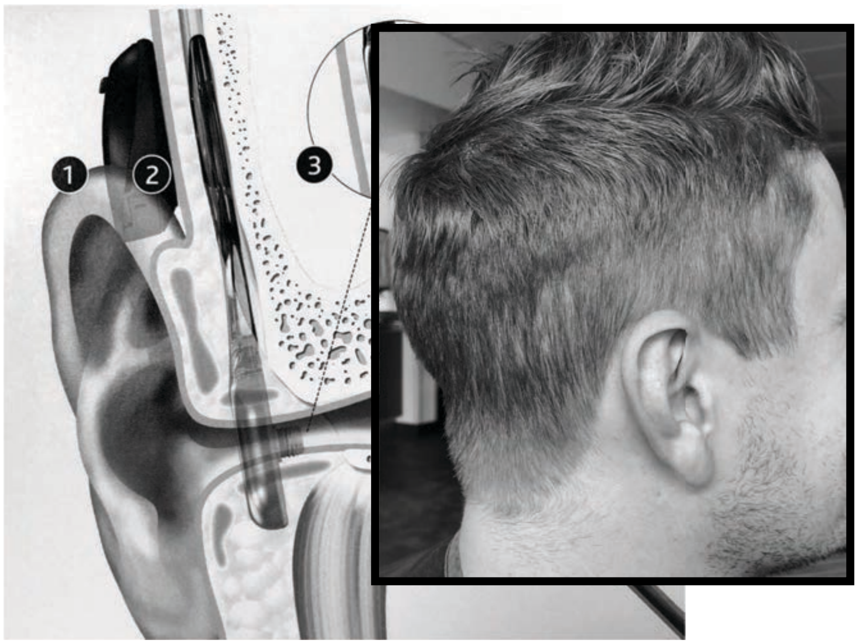


CMR Patient Profile

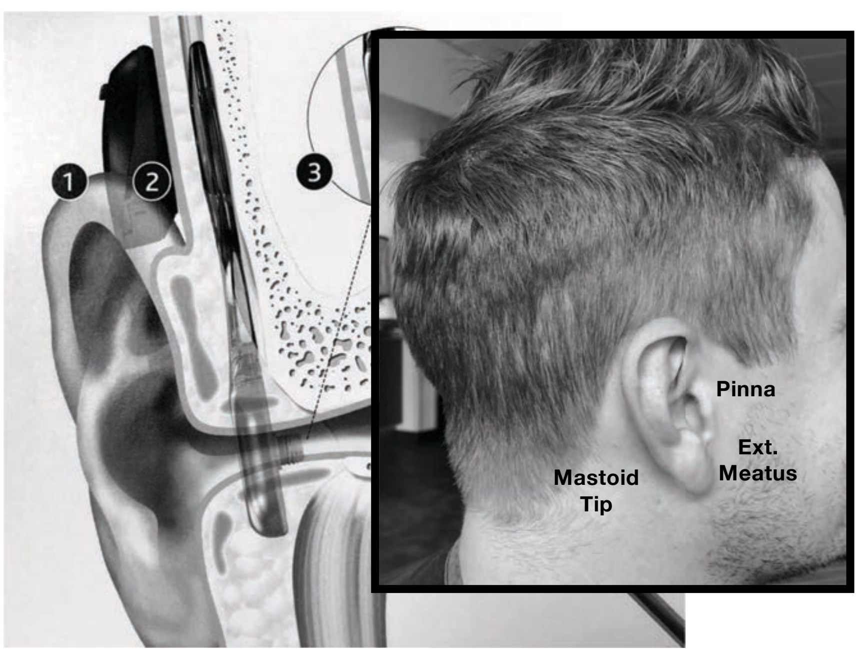
- 52yo M, prior tymp/OCR x2.
  Left moderate MHL
- 63yo F, Otosclerosis, stapedectomy x 2.
  Left Mod-Severe MHL; **Mild Right SNHL**
- 22yo F, Turners Syndrome.
  Right Profound SNHL (SSD)
- 75yo F, Progressive Hearing Loss.
  Left Severe MHL, **Right Moderate SNHL**



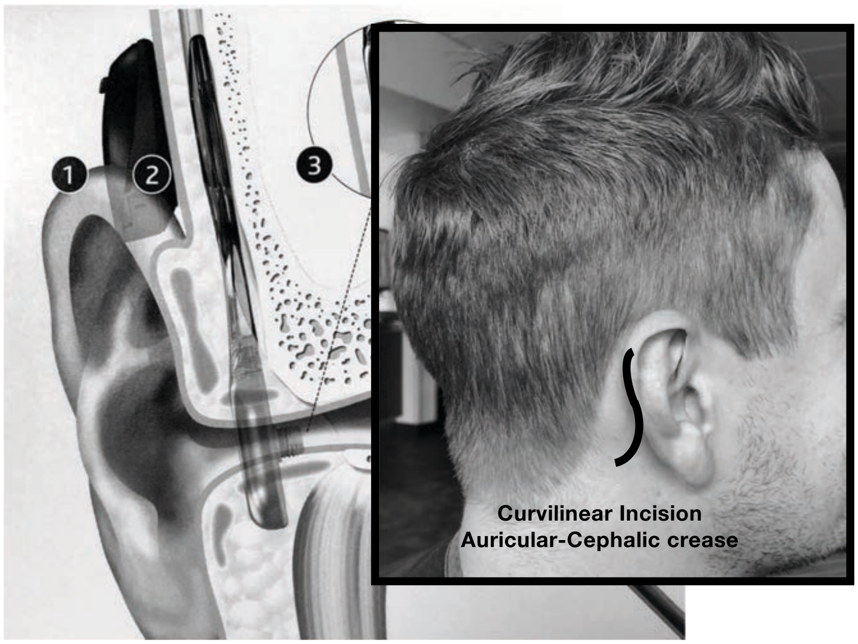
1. Align microphones with top of pinna
2. Skin/tissue thickness <10mm
3. Tissue thickness/Bone Bed
4. BI300 in line with ear canal

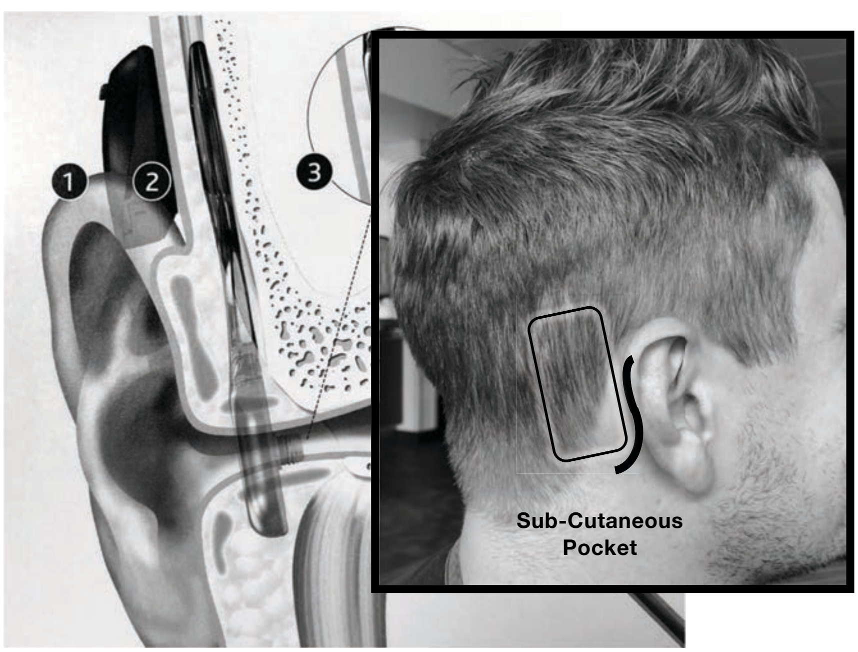


1
2
3

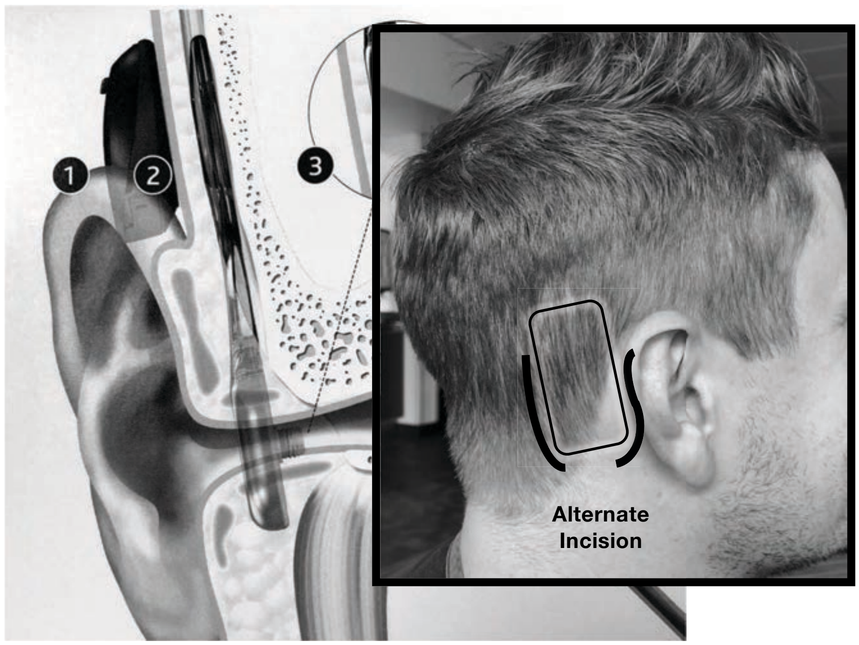


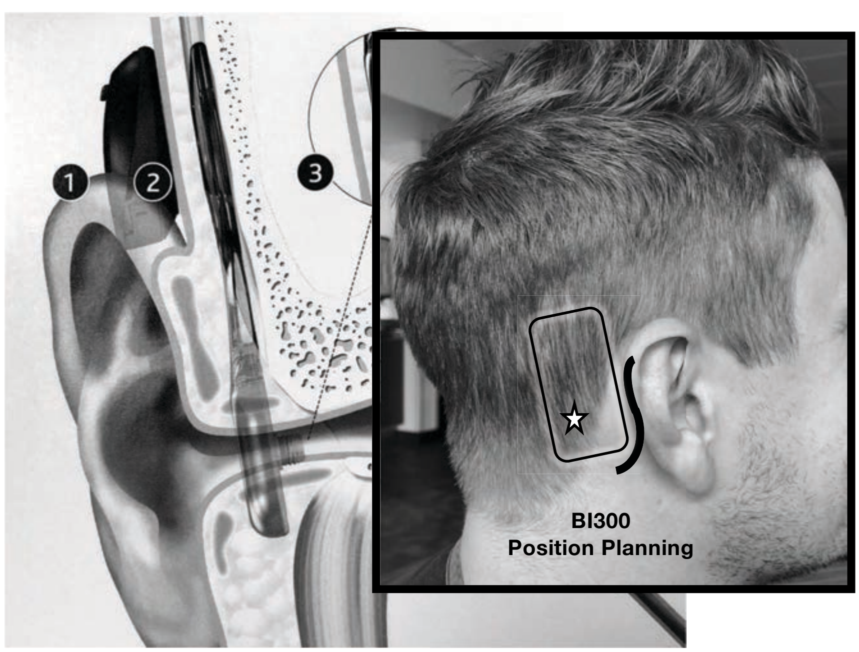
1
2
3
Pinna
Ext.
Meatus
Mastoid
Tip

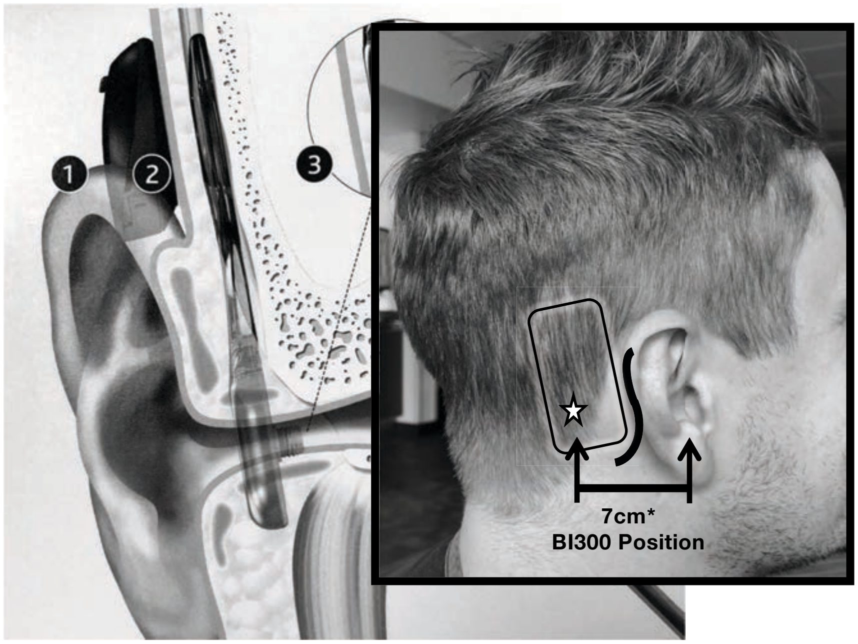

1
2
3
Curvilinear Incision
Auricular-Cephalic crease


1
2
3
Sub-Cutaneous
Pocket

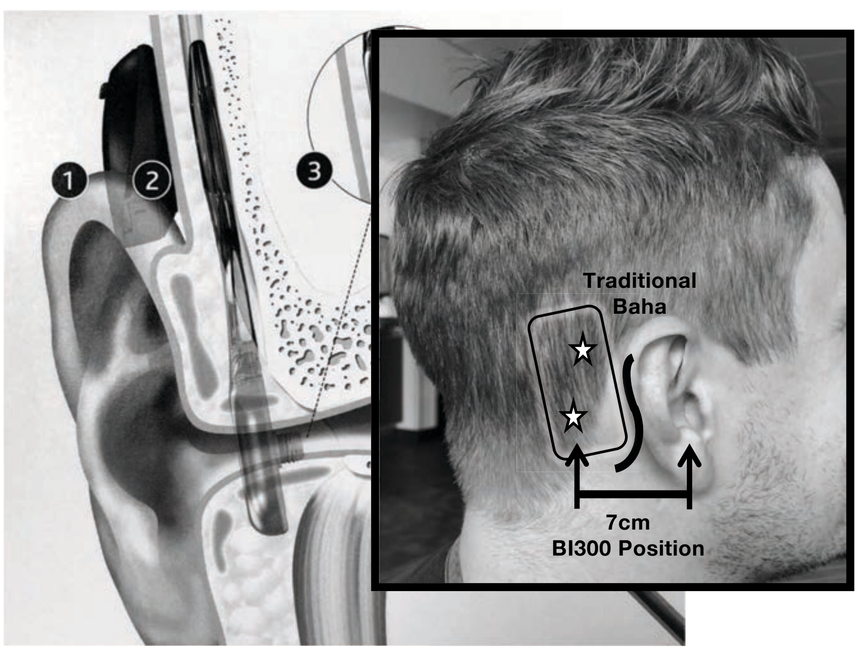
continuED

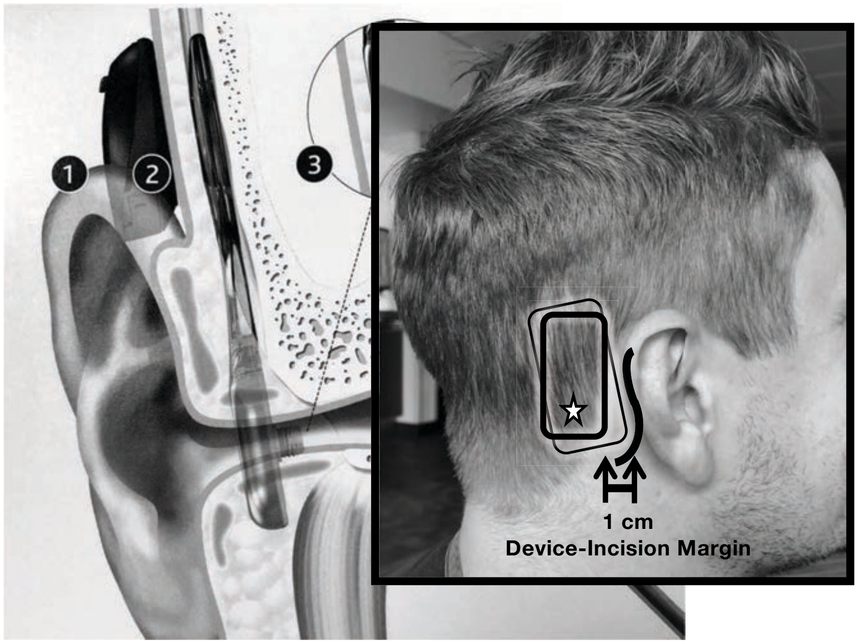

1
2
3
Alternate
Incision


1
2
3
BI300
Position Planning



*not a manufacturer recommendation

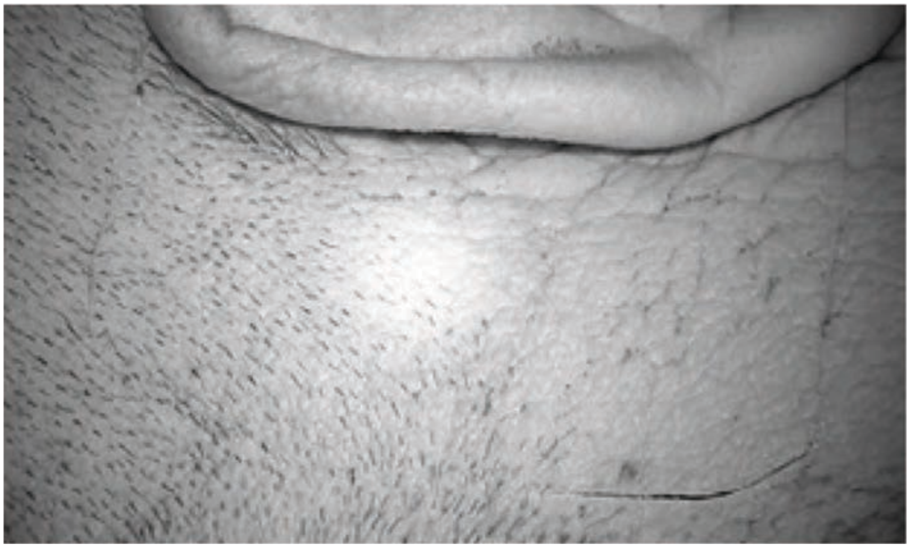




Optimal position

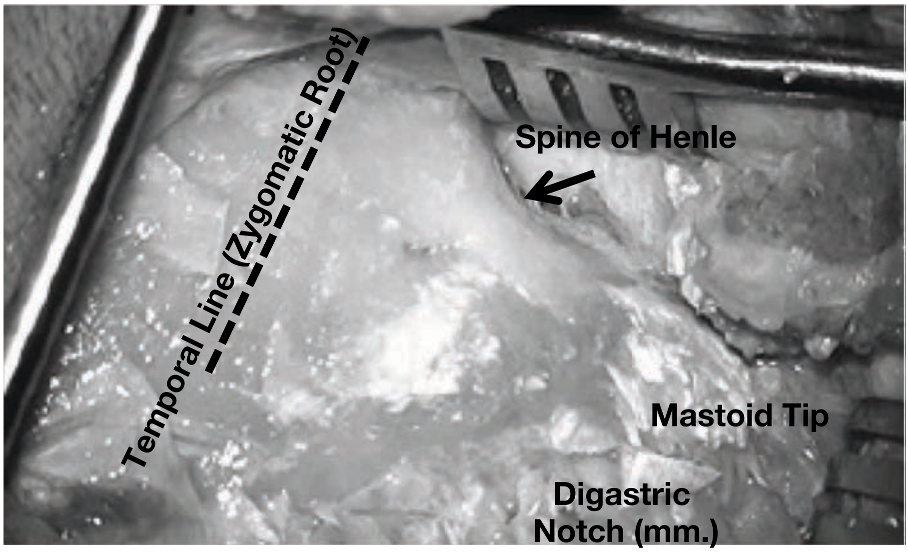
External processor

Microphones aligned with top of pinna

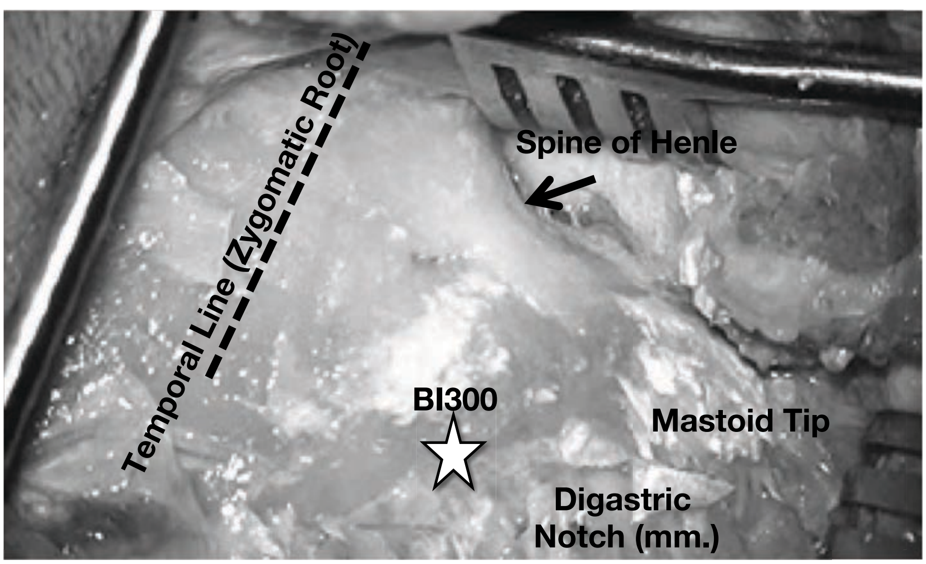


Cadaveric Specimen – Demonstrating Tissue Planes and Internal Anatomy
**NOT a representation of Osia Incision Planning*

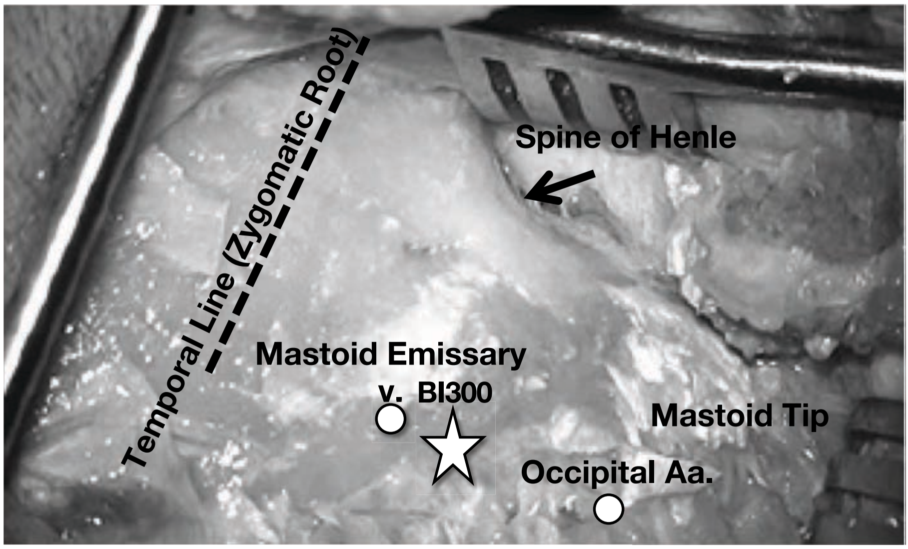
Cadaveric Specimen – Demonstrating Tissue Planes and Internal Anatomy
**NOT a representation of Osia Incision Planning*



Cadaveric Specimen – Demonstrating Tissue Planes and Internal Anatomy
****NOT a representation of Osia Incision Planning***

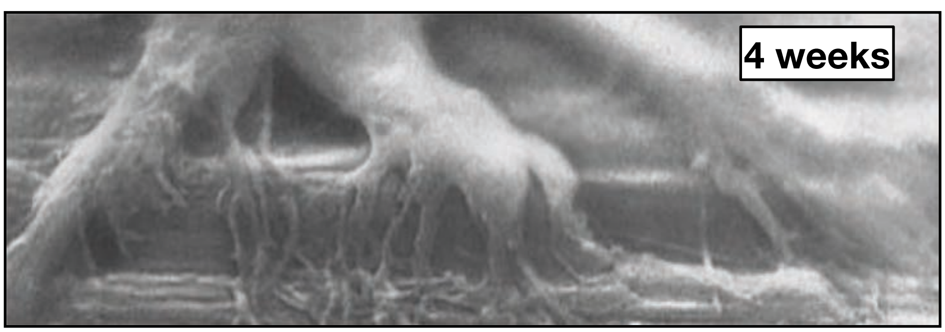


Cadaveric Specimen – Demonstrating Tissue Planes and Internal Anatomy
****NOT a representation of Osia Incision Planning***



Cadaveric Specimen – Demonstrating Tissue Planes and Internal Anatomy
**NOT a representation of Osia Incision Planning*

Osseo-Integration



Outcomes

Thank You!

www.azearinstitute.com

The Osia System: You've never heard anything like it

Cochlear

High power, high gain & advanced signal processing.[1]
For hearing performance in noise & quiet

Slim, connected & off-the-ear.
To help patients hear without getting in their way

Designed to implant. Made to last.
For minimally invasive surgery and reliability over time[2]

1. Osia 2 System Datasheet. D1618102. Cochlear Bone Anchored Solutions AB, Sweden 2019
2. Goh J. OSI200 Implant Accelerated Life Test Report. D1439967. Cochlear Bone Anchored Solutions AB, Sweden 2019

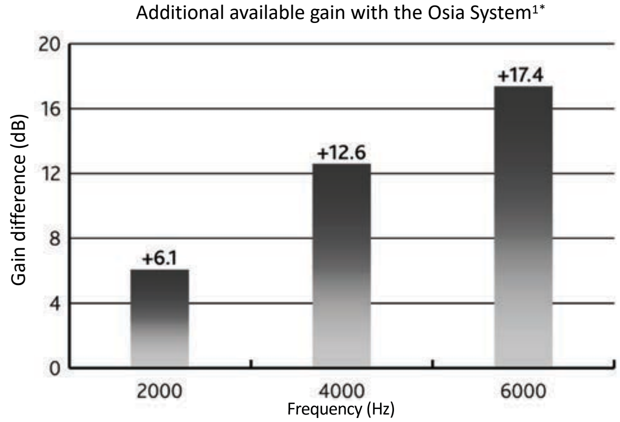
More available gain than BC systems

Cochlear

The Osia® System has more available gain in the high frequencies compared with 55 dB percutaneous BC implant systems. [1*]

Average of **12 dB more** available gain in high frequencies[1*]

Additional available gain with the Osia System[1*]



The additional available gain with the Osia System, when compared with Baha 5 Power on the Baha Connect System.

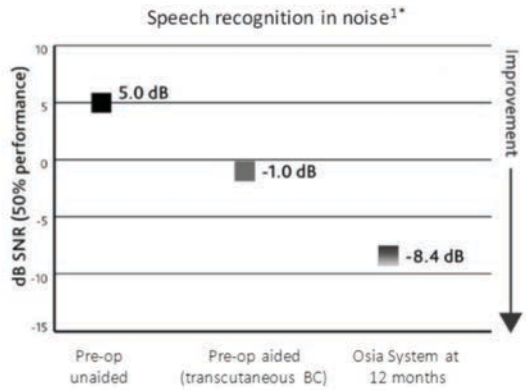
1. Fyrlund, H. (2019). Osia performance PowerPoint. Data on file.
* Data collected using an investigational system.

D1602035-V1

Better hearing in noise

In a global multi-center study the Osia® System has proven to deliver excellent speech recognition in noise.

More than **7 dB** in noise[1*]
improvement



Adaptive speech recognition in noise, 50% performance, Speech from front, noise from behind. Mean values and standard deviation shown.

!035-V1

1. Data on file Windchill Document D1478473
* Data collected using an investigational system

The Osia System: Audiological experience

Stephanie Bourn, AuD
Center for Neurosciences

The representations and views expressed in this presentation are those of the presenter and do not directly reflect the views of Cochlear.

Hear now. And always

Early Osia Experience

Controlled Market Release

Stephanie S. Bourn, Au.D., CCC-A, FAAA
Audiologist
Ear & Hearing at The Center for Neurosciences

EAR & HEARING CLINIC

- The most experienced otologist/neurotologist in Southern Arizona
- 2 full-time audiologists
- 2 audiology externs
- Personalized clinical coordination
- Comprehensive hearing and vestibular (balance) testing
- State-of-the-art implantable hearing devices program
- Active clinical research program

Ear & Hearing at the Center for Neurosciences provides unmatched care in Southern Arizona for all disorders of the ear & lateral skull base.

EAR & HEARING CLINIC

Vision

To provide personalized, compassionate, and state-of-the art care that generates outstanding clinical outcomes and high patient satisfaction.

PRE-OP COUNSELING

- Bone conduction that you cannot demonstrate
- No one had experience on counseling patients with this new approach
- Quickly learned to discuss traditional bone conduction technology to provide a long history of use and discuss the updates and potential benefits to Osia technology
- Learned to discuss Osia System similar to cochlear implants
- Battery life and MRI
- FDA trial results were very helpful in offering patients a reason why to try something new
- Demonstrated bone conduction devices on a listening post in clinic; it never once came up that patients could not demo the Osia device

PATIENT PROFILES

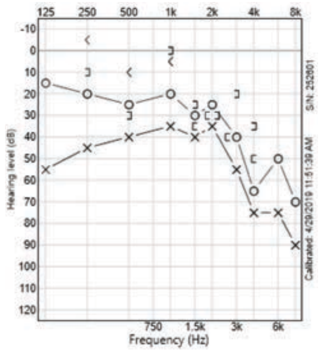
- 60+ patients fit with Cochlear Americas bone anchored devices since April 2017-November 2019
- 6 patients in the CMR
- 3 Mixed/CHL
  - 2 right ears
  - 1 left ear
- 3 Single-Sided Deafness
  - 2 right ears
  - 1 left ear

PROGRAMMING EXPERIENCE

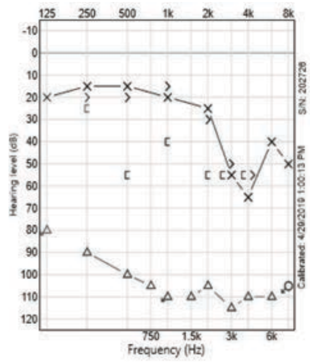
- Simple, very similar to Connect/Attract programming
- Very quick ~10 minutes of active programming
- Differences:
  - Cable in 1st time then wireless; programming faceplate attached
  - Digital link to determine magnet strength

PATIENT PROFILES: Mixed/CHL

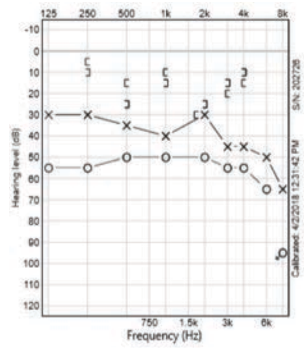
Pre-Op Audios n=3



74-year old male with history of left chronic mastoiditis, TM perforation, cholesteatoma. S/p tympanoplasty with CWD mastoidectomy and OCR.



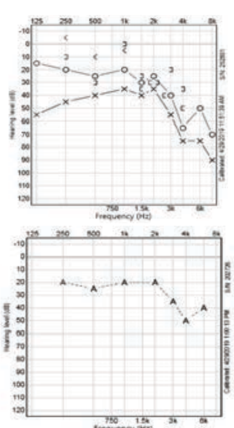
71-year old male with history of right chronic mastoiditis following injury. S/p 3 mastoidectomies with OCR.



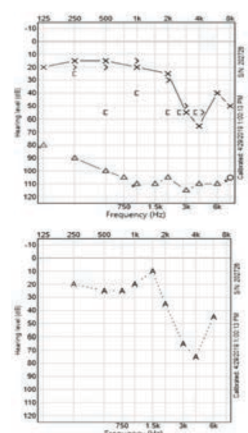
62-year old male with history of ETD, right cholesteatoma, chronic mastoiditis. S/p right revision tympanoplasty with CWD mastoidectomy and OCR.

PATIENT PROFILES: Mixed/CHL

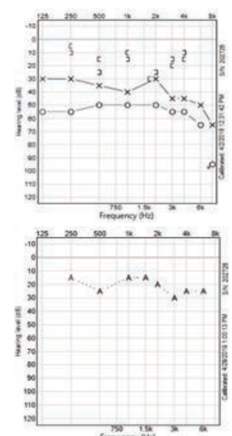
Pre vs Post Audios (n=3)



74-year old male



71-year old male



62-year old male

All 3 patients cannot wear a conventional hearing aid either due to anatomy or increased risk of infection.

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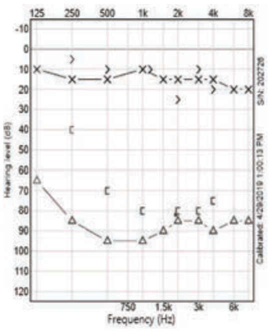
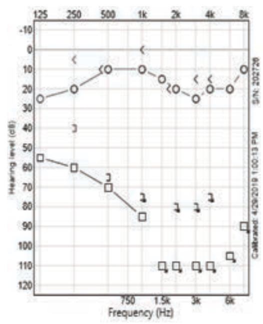
PATIENT PROFILES: SSD

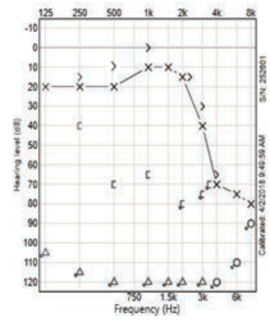
Pre-Op Audios (n=3)



66-year old female with sudden SNHL in right ear. Treatment with oral and intratympanic steroids was unsuccessful in recovering hearing.



72-year old female with history of left vestibular schwannoma radiated 12 yrs ago.



48-year old male with history of right vestibular schwannoma. S/p right transtemporal craniotomy with subsequent cranioplasty for CSF leak repair

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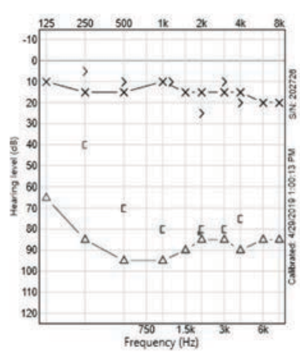
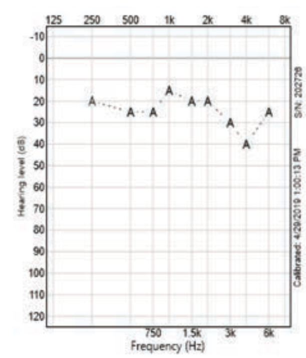
PATIENT PROFILES: SSD

Pre vs Post Audios

66-year old female with sudden SNHL in right ear. Treatment with oral and intratympanic steroids was unsuccessful in recovering hearing.

Medicare; therefore cochlear implant not an option





<u>Head Shadow Effect</u>, +5 SNR with speech presented to the poor ear and noise presented to better ear.
Aided: 64%
Unaided: 49%

<u>Word Recognition</u>
Aided: 96%
Unaided: 0%

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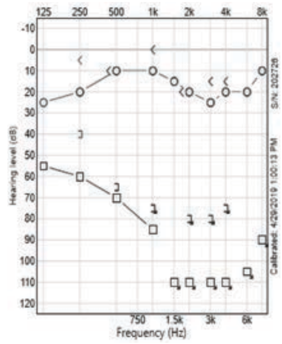
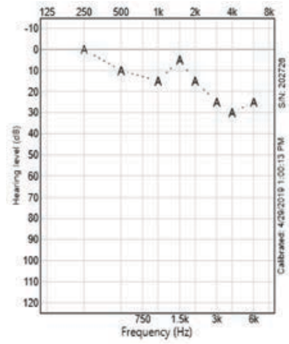
PATIENT PROFILES: SSD

Pre vs Post Audios

72-year old female with history of left vestibular schwannoma radiated 12 yrs ago.

Long-duration of deafness and Medicare; therefore cochlear implant not an option





Head Shadow Effect, +5 SNR with speech presented to the poor ear and noise presented to better ear.
Aided: 67%
Unaided: 14%

Word Recognition
Aided: 88%
Unaided: 4%

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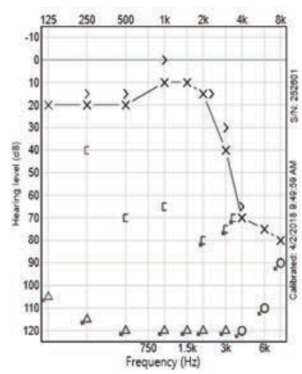
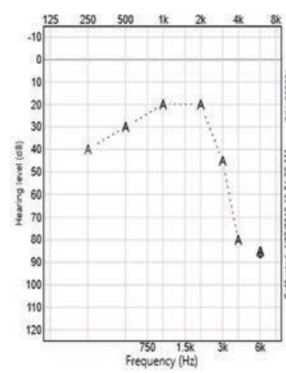
PATIENT PROFILES: SSD

Pre vs Post Audios

48-year old male with history of right vestibular schwannoma. S/p right transtemporal craniotomy with subsequent cranioplasty for CSF leak repair

CI not an option due to surgical approach.





Equipment error prevented speech testing results from being saved. However; speech results were consistent with other SSD patients.

LESSONS LEARNED/BEST PRACTICE

- Improved gain in the high-frequencies
- Battery life not an issue
- Looks nice; appealing to patients
- Retention improved
- Magnet has been a non-issue so far
- Aided testing proves benefit of SSD (head shadow) and is billable

PATIENT FEEDBACK*

- Immediate subjective benefit
- Battery life not an issue
- Retention has not been an issue
- No difference in quiet situations or diffuse noise (SSD)
- Improvement in noise with speaker on Osia side
- Seems “loud” at initial activation
- Feel safer crossing the street
- More socially active
- Minimizes the interruptions to daily life

*collected anecdotally

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CLINICAL USE

MCHL:

- Excellent option for patients that have a large conductive component
- Excellent option for patients that cannot anatomically or safely wear a HA

SSD:

- Osia is a strong treatment option for many patients, depending on their circumstances

*Counseling for SSD is very critical to provide patients with realistic expectations

Center for NEUROSCIENCES | EAR & HEARING

Thank you for your time and consideration

Experience Matters!

Ear & Hearing |Center for Neurosciences
2450 East River Road
Tucson, AZ 85718
Work Phone: 520-795-7750
Cell Phone: 520-820-1654

Innovation focus: Hearing indications

Hearing Outcomes	Lifestyle	Connected Care	Hearing Indications

Expanding Pediatric Indications

Megan Mears, AuD
Cochlear Americas

Hear now. And always

Expanding Pediatric Indications

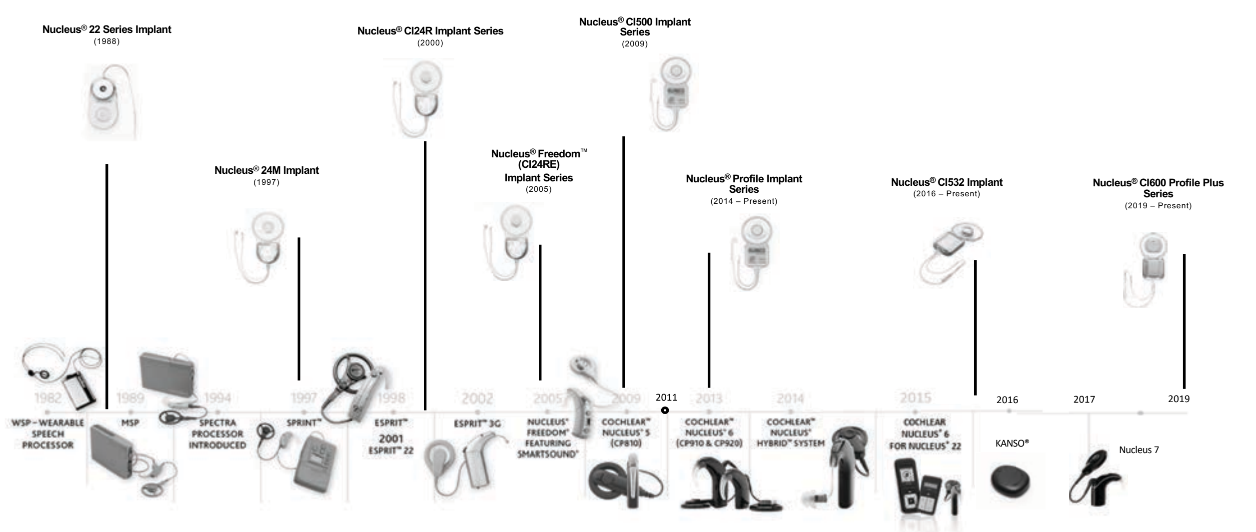
Megan Mears, AuD
Cochlear Americas

Hear now. And always

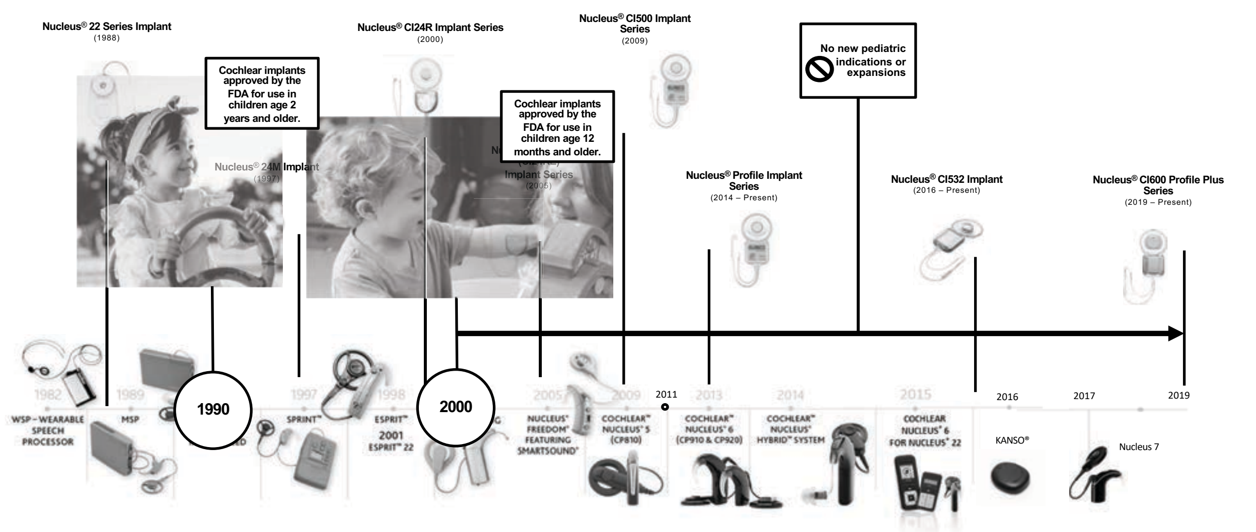
Cochlear®

Cochlear Product Innovation: 30 Years and Counting

Cochlear®



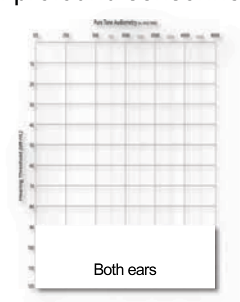
Cochlear Product Innovation: 30 Years and Counting



Pediatric Indications, 2000 - 2020

Age 12-24 months

- Bilateral profound sensorineural deafness



Age 2-17 years

- Bilateral severe to profound hearing loss

- Demonstrate limited benefit from appropriate binaural hearing aids
- 3 to 6 month hearing aid trial is recommended

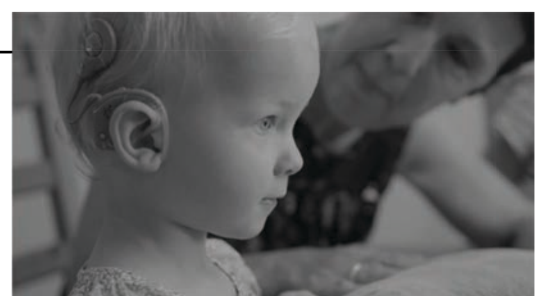
Why Lower the Age?

Research demonstrates that children implanted under 12 months of age can achieve age-appropriate language skills faster and at a higher rate than children implanted after 12 months

1) Ching, D. D. (2009). Early language outcomes of children with cochlear implants: interim findings of the NAL study on the longitudinal outcomes of children with hearing impairment. *Cochlear Implants Int, 10*(Suppl 1), 28-32.
2) Colletti, M. Z. (2011). Infants versus older children fitted with cochlear implants: Performance over 10 years. *Int J Pediatr Otorhinolaryngol, 75*(4), 504-509.
3) Wie. (2010). Language development in children after receiving bilateral cochlear implants between 5 and 18 months. *Int J Pediatr Otorhinolaryngol, 74*(11), 1258-66.
4) Leigh, D. D. (2013). Communication development in children who receive a cochlear implant by 12 months of age. *Otol Neurotol, 34*(3), 443-50.
5) Ching, D. (2013, Dec). Major findings of the LOCHI study on children at 3 years of age and implications for audiological management. *Int J Audiol, 52*(Suppl 2), 65-8.

Early Access to Sound

- For children receiving their implant prior to 18 months of age – 73% scored within the average range for spoken language skills at age 10.5[1]
- Up to 80% of children who received implants younger than 12 months demonstrated receptive vocabulary **within the normal range** by school entry[2]
- A clear predictor of spoken language competency at 10.5 years of age was a child's language skills at pre-school[1]



1) Geers AE and Nicholas JG. Enduring advantages of earlier cochlear implantation for spoken language development. J Speech Lang Hear Res. (2013 Apr); 56(2):643-55.
2) Dettman, e. a. (2016, Feb). Long-term communication outcomes for children receiving cochlear implants younger than 12 months: A multicenter study. *Otol Neurotol, 37*(2), e82-e95.

Early Access to Sound

460 Australian children receiving hearing aids or cochlear implants prior to 3 years of age who will be followed over time

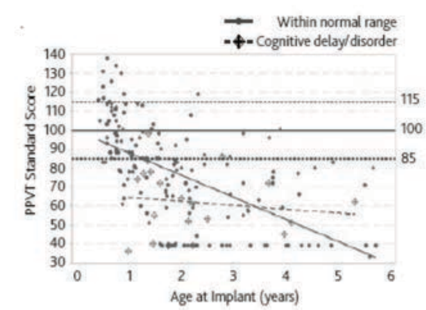
Key Findings:

- Early age at intervention (with a HA or CI) leads to better spoken language outcomes
- The greater the hearing loss, the greater this effect
- Early fitting of devices is key to achieving better speech, spoken language and functional performance outcomes by five years of age

1) Ching TYC, Dillon H, Leigh G, Cupples L. Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study: summary of 5-year findings and implications. Int J Audiol. (2018 May); 57(sup2):S105-S111.

Early Access to Sound

- Children in the LOCHI study were divided into groups by age at implant
- A larger proportion of children in group 1 (those implanted under 12 months of age) demonstrated language abilities that were within the normal range by primary school



Graph showing PPVT standard scores for n = 207 at school entry; children with cognitive skill within the normal range (circles) and children with additional diagnos of cognitive delay/impairment (diamonds).

1) Ching TYC, Dillon H, Leigh G, Cupples L. Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study: summary of 5-year findings and implications. Int J Audiol. (2018 May); 57(sup2):S105-S111.

Why Lower the Age?

Cochlear

Studies of children implanted under the age of 12 months demonstrate that the procedure is safe in young children

1) Holman, C. D. (2013). Cochlear implantation in children 12 months of age and younger. *Otol Neurotol, 40*(4), 251-258.
2) O'Connell, H. M. (2016). Safety of cochlear implantation before 12 months of age: Medical University of South Carolina and Pediatric American College of Surgeons-National Surgical Quality improvement program outcomes. *Laryngoscope, 126*(3), 707-12.
3)Birman C. Cochlear implant surgical issues in the very young child. Cochlear Implants Int. 2009; 10 (Suppl 1):19-22.
4) Colletti L, Mandalà M, Colletti V. Cochlear implants in children younger than 6 months. Otolaryngol Head Neck Surg. 2012; 147(1):139-146.
5) Hoffman RA (1997) Cochlear implant in the child under two years of age: skull growth, otitis media, and selection. Otolaryngol Head Neck Surg 117:217–219.
6) Waltzman SB, Roland JT Jr. Cochlear implantation in children younger than 12 months. Pediatrics. 2005; 116 (4):487-493.

Cochlear Pediatric Study

Cochlear

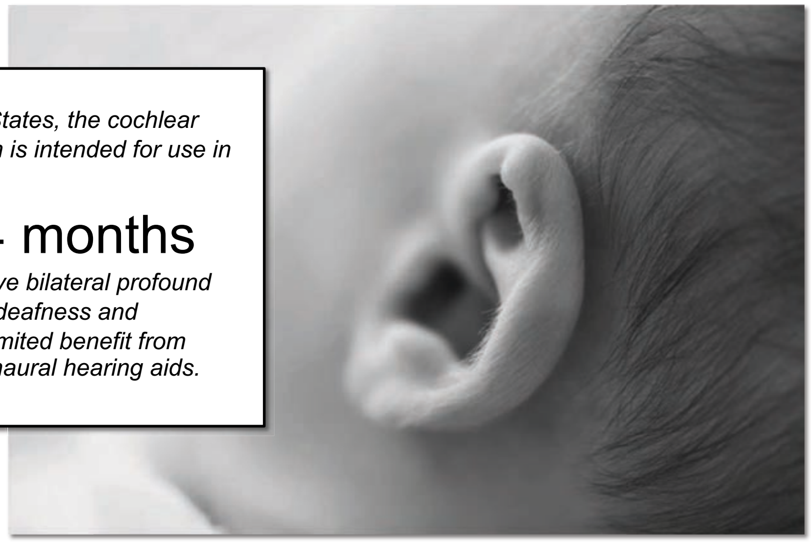
- Demographics
- Surgical variables
- Anesthesia variables
- Post-operative complications

136 subjects

5 sites

March 17, 2020 - FDA clears new pediatric indication

Cochlear®



In the United States, the cochlear implant system is intended for use in children

9 to 24 months

of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.

Cochlear®

Hear now. And always

Remote Check does not replace clinical care and does not involve remote programming of the sound processor.

In the United States, the cochlear implant system is intended for use in children 9 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.

In Canada, the cochlear implant system is intended for use in children 12 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids. Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.

Hear now. And always

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