Cochlear Implant Adult Outcomes: "How do I Know I Will Gain More Than I Lose?",

in partnership with American Cochlear Implant Alliance

Jan Larky, AuD
Donna L. Sorkin, MA

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Helping Your Patients Understand Benefits (and Addressing their Fears)

American Cochlear Implant Alliance
www.acialliance.org

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Speakers

- Jan Larky AuD, FAAA
- Donna Sorkin MA, Executive Director, American Cochlear Implant Alliance

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Why another organization in hearing health?

- Membership organization focused on cochlear implantation and access to care
- Members are audiologists, physicians, speech pathologists, educators and others on CI teams + consumers/parents, advocates
- Website designed for those in and out of CI
- Highly collaborative with other organizations
- Welcome your involvement!

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https://www.facebook.com/ACIALLIANCE.ORG/

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American Cochlear Implant Alliance

- Mission: Advance access to the gift of hearing provided by cochlear implantation through research, advocacy and awareness
- Address factors contributing to underutilization of cochlear implants
- Improve awareness regarding candidacy and outcomes
- Objective today: Share information to help patients who may benefit from CI move forward

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Four Part Series on Adult Concerns

- In 2019, CI utilization by US adult candidates was 5-7%
- Surveys by ACI Alliance found that adult perceptions of cochlear implants contribute to long wait periods and reluctance by some to ever to move forward
- This set of 4 courses designed to address commonly cited reasons for not moving forward
- This first course will discuss common fears and the perception: **I'm doing ok**

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Forthcoming Courses in this Series

- Insurance and Cochlear Implants
- Understanding Cochlear Implant Surgery
- Cochlear Implant Rehabilitation for Adults

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Cochlear Implant Adult Outcomes: "How do I know I will gain more than I lose?"

Jan Larky, AuD

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Learning Outcomes

As a result of this course, participants will be able to:

1. State expected improvement on word and sentence recognition tests for adults post-implant compared to pre-implant.
2. Describe the association between hearing loss and cognitive decline and how cochlear implantation might mitigate the effects.
3. List 5 general areas where CI recipients experience improvement.

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What do candidates want to know? Part 1

- Medical
  - Am I too old?
  - What is surgery like? How long is it?
  - What is the recovery?
  - Side effects e.g. Dizziness and imbalance? Taste?
  - Hearing loss or hearing preservation?
- Device reliability (internal and external)
- Device cosmetics
- Can I….???
  - Scuba dive? Swim?
  - Box? Wrestle?
  - Ride a horse? Ride a bike?

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What do candidates want to know? Part 2

- Improvement in hearing
  - Will it work?
  - What will it sound like?
  - Better hearing in restaurants/groups/on the phone/concerts?
  - Is there a guaranteed outcome?
  - How long will it take to hear better?
  - What kind of commitment is required to optimize success?
- Technology Compatibility
  - Bluetooth streaming
  - app control
  - Accessories

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What do I want candidates to think about?

1. Getting by isn't enough
2. How much effort do they expend in trying to "hear" and communicate?
3. How frustrated are their family members?
4. How frustrated are they?
5. Have they withdrawn socially? (consider a questionnaire APHAB/COSI)
6. What are their hearing goals?
7. Where do they experience the most difficulty hearing and communicating?
8. Can they come for follow-up visits?
9. Can they manage the device? Batteries?

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What I want the candidate to know

- If they are a candidate I **know** they will "hear" better
  - Better access to sound
  - Exact outcomes are not guaranteed
- The relationship between hearing loss and cognitive decline
- Bimodal benefit
- If their expectations are realistic
  - Will I get a job? Vs. Will I hear my spouse better? Will music sound natural?
- The more effort they put in, the better the outcomes
- The Implant Center provides ongoing support
- The implant companies provide ongoing support
  - Tech help, insurance help, replacement products, listening therapy activities, support meetings

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Why Implant?

- ✓ Better hearing
- ✓ Easier communication
- ✓ Increased social benefits
- ✓ General health benefits
- ✓ Cognitive benefits

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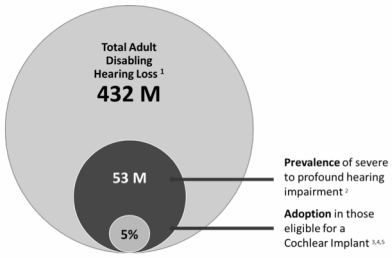
What we know

- 40 years of data with CI
- Outcomes well documented
- Improvement compared with hearing aid only or no treatment, in terms of:
  - speech perception[6,7]
  - educational[8] and employment[9] opportunities
  - quality of life[6,10]
- CIs have been shown to be cost effective[11]



Global adult hearing loss (2018)

6. Lenarz T *et al. Audiol Neurootol* 2017;22:61–73; **7.** Bassim MK *et al. Laryngoscope* 2005;115:1568–73; **8.** Shield B. Evaluation of the social and economic costs of hearing impairment. A report for Hear-it. 2006. Available from: https://www.hear-it.org/sites/default/files/multimedia/documents/Hear_It_Report_October_2006.pdf (Accessed June 2019); **9**. Woodcock K, Pole JD. *Int J Rehabil Res* 2008;31:297–304; **10.** Sanchez-Cuadrado I *et al. Ann Otol Rhinol Laryngol* 2013;122:222–8; **11**. Bond M *et al. Health Technol Assess* 2009;13:1–330

CI, cochlear implant; M, millions

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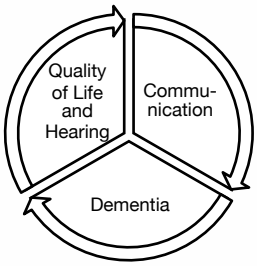
Hearing Loss Is A Health Concern



Should be screened e.g. high blood pressure, cholesterol

1 Hearing loss → withdrawal from social interaction → negative impact on psychological well- being & physical health[1,2]

2 Significant impact on communication and reduced well-being[4]

3 Hearing loss is the single largest modifiable risk factor for dementia[3]

1 Nachtegaal J, Festen J, Kramer S. Hearing ability in working life and its relationship with sick leave and self-reported work productivity. Ear And Hearing [serial on the Internet]. (2012, Jan), [cited July 3, 2018]; 33(1): 94-103. **2** Nachtegaal J, Kuik D, Anema J, Goverts S, Festen J, Kramer S. Hearing status, need for recovery after work, and psychosocial work characteristics: Results from an internet-based national survey on hearing. International Journal Of Audiology [serial on the Internet]. (2009, Oct), [cited July 3, 2018]; 48(10): 684-691. **3** Livingston G *et al. Lancet* 2017;390(10113):2673–734. **4** World Health Organization. Deafness and hearing loss. Available from: https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss (Accessed June 2019)

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Hearing Loss and Cognition

- "Researchers at Johns Hopkins found that untreated hearing loss increased the risk of developing dementia by 50 percent and depression by 40 percent in just five years when compared to those without hearing loss."[1]
- The greater the degree of the hearing loss the more rapid the cognitive decline, the poorer quality of life and the greater the social, emotional and communication difficulties.[2]

"Hearing Loss Threatens Mind, Life and Limb" - The New York Times Online[1]*

1. Brody, J. E. (2018, December 31). Hearing Loss Threatens Mind, Life and Limb. Retrieved from https://www.nytimes.com/2018/12/31/well/live/hearing-loss-threatens-mind-life-and-limb.html **2.** Lin FR *et al. Arch Neurol* 2011;68(2):214–20

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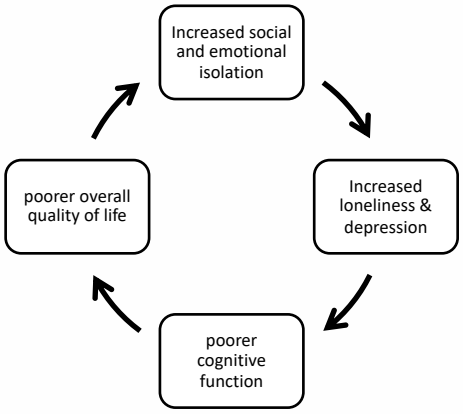
Impact Of Hearing Loss On Mental Health

- Compared with people with normal hearing[1]
  - 30–40% accelerated rate of cognitive decline
  - 24% increased risk for incident cognitive impairment over a 6-year period
- Greater hearing loss was associated with poorer executive function.[1]
- Greater anxiety was positively correlated with poorer executive function.[1]
- Increased deterioration in cognitive performance for every 10 dB increase in hearing loss (PTA) in the better ear, controlling for age, sex, and education.[1]
- A hearing device is better than none, but is it good enough?



1. Sarant J, Harris D, Busby P, Maruff P, Schembri A, Dowell R, Briggs R (2019). The Effect of Cochlear Implants on Cognitive Function in Older Adults: Initial Baseline and 18-Month Follow Up Results for a Prospective International Longitudinal Study. *Front Neurosci*. 2019; 13: 789. Published online 2019 Aug 2

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Cognitive Improvement following CI

- Study participants reported a threefold ***decrease*** **in listening disability** in their everyday lives (APHAB)[1]
- Statistically **significant improvement** in ability to conduct conversations
- Recent Cochlear America's Study – 38% improved into the normal range on MoCA.[2]

Take home message: Better hearing → better quality of life

1. Sarant J, Harris D, Busby P, Maruff P, Schembri A, Dowell R, Briggs, R. The Effect of Cochlear Implants on Cognitive Function in Older Adults: Initial Baseline and 18-Month Follow Up Results for a Prospective International Longitudinal Study. *Front. Neurosci*., 02 August 2019 https://doi.org/10.3389/fnins.2019.00789. **2.** Cochlear 532 investigator's meeting. 4/6/19.

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Most Successful Neural Prosthesis In Use

I. Introduction Go to:

The cochlear implant (CI) has transformed the field of otology. Just 50 years ago, there were no effective treatments for deafness and severe losses in hearing. The development of the CI changed that completely and today most recipients of CIs can converse with ease using their cell phones. The development has been both rapid and remarkable.[1]

- Early technology benefits - the "Bilger Report" 1976
  - better quality of life for each subject
  - Improved lip-reading
  - Improved speech comprehension

1. Eshraghi AA, Nazarian R, Telischi FF, Rajguru SM, Truy E, Gupta C. The cochlear implant: historical aspects and future prospects. *Anat Rec (Hoboken)*. 2012;295(11):1967–1980. doi:10.1002/ar.22580 **2.** Henkel G. Milestones in Development of Cochlear Implant Technology. *ENT TODAY* 2015, Sept 8. https://www.enttoday.org/article/milestones-in-development-of-cochlear-implant-technology/

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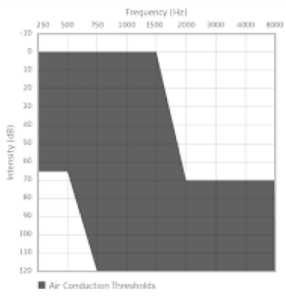
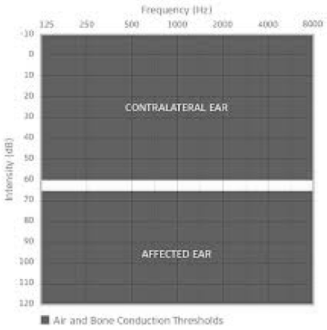
Expanding Candidacy

- Moderate-profound bilateral SNHL
- LF hearing is not a contra-indication
- ≤60% on CNC Word lists (Private Insurance)
- ≤40% on sentence material in best aided condition (Medicare)



Single Sided Deafness (Med-El)



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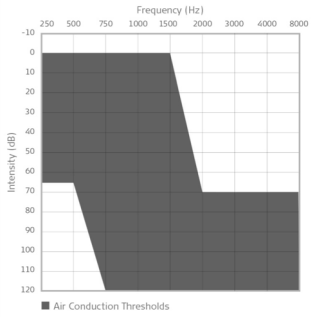
Choice of cochlear implant types

EAS - Electric Acoustic Stimulation

- The combination:
  1. a cochlear implant for high frequencies
  2. acoustic amplification for low frequencies.
- Provides auditory access across entire frequency spectrum
- Pre-op Criteria: ≤60% on CNC words in quiet in each ear with a hearing aid



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Think CI referral when….

- Difficulty using the phone
- Cannot hear /s/
- ≥70 dB PTA (500, 1000, 2000 Hz)
- Bimodal hearing solution

Cannot identify all Ling Six Sounds

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Am I too old?

- Age is not a barrier (100 years of age is not too old)
- major complication rates similar to younger patients
- dizziness or vertigo were not as frequent as might be expected
- *"Discussion:* Cochlear implantation is a safe procedure even among elderly patients who can significantly benefit from hearing threshold ($p < 0.001$) and speech perception ($p < 0.01$) improvements."
- Benefit not age dependent: better thresholds & better speech perception ***is*** realistic

Castiglione A, Benatti A, Girasoli L, Caserta E, Montino S, Pagliaro M, Bovo R, Martini A. Cochlear implantation outcomes in older adults. *Hearing, Balance and Communication* 2015; 13(2):86-88.

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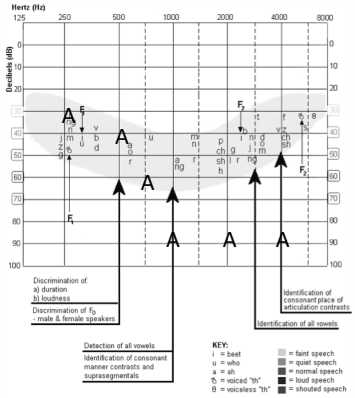
Speech Acoustics

- Hear speech but can't understand
- ~5% of candidates score near or higher than the candidacy criteria[1]
- Mean pre-op CNC scores = 8.7%
- 6 mos Post-implant expect 60% correct[1]



[1] Holder JT, Reynolds SM, Sunderhaus LW, and Gifford RH. Current Profile of Adults Presenting for Preoperative Cochlear Implant Evaluation. *Trends in Hearing*, 2018; Volume 22: 1–16.

https://www.pinterest.com/pin/427419820855677133/?lp=true

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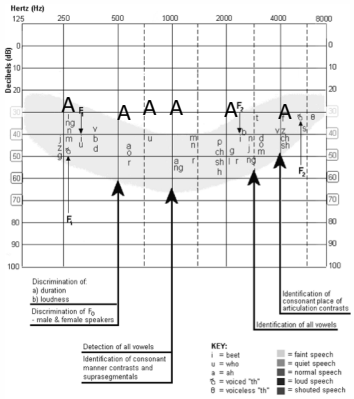
Immediate benefits Post-Implantation

- Within the mild-hearing loss region
- SRT 20-30 dB
- Access to all phonemes
- Identification of all Ling Six Sounds
- Easier access to speech
- Less tired at the end of the day
  - Watch body posture
- Volume Self-monitoring



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Duration of Deafness

- Earlier implantation is always better
  - Keep the brain ”fed” with sound
  - Shorter duration of deafness
- Significant improvement in speech understanding even if duration of profound hearing loss is >15 years

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Streamers, bimodal, directional, phone apps

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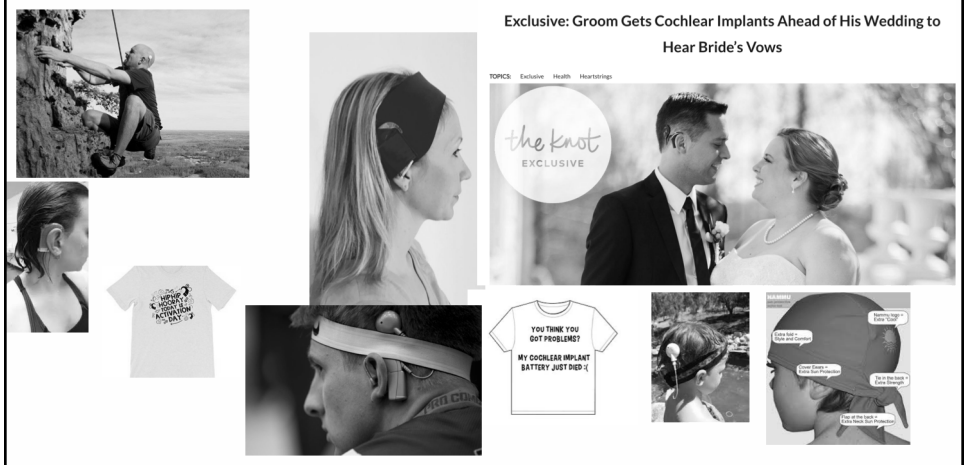

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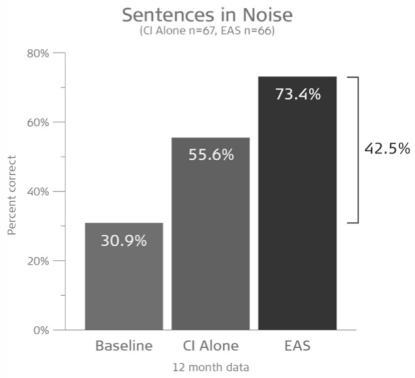
Med-El EAS Study

- Sentences in noise 42% better compared to Pre-op.
- 90% preferred EAS to their hearing aids.
- 92% reported improved hearing in noisy environments.
- 90% reported communication was less difficult overall.
- 97% performed similarly or better on CNC words in quiet, with 84% demonstrating improvement.



Pillsbury, HC 3rd, Dillon, MT, Buchman, CA, Staecker H, Prentiss SM, Ruckenstein MJ, Bigelow DC, Telischi FF, Martinez DM, Runge CL, Friedland DR, Blevins, NH, Larky JB, Alexiades G, Kaylie DM, Roland PS, Miyamoto, RT, Backous DD, Warren FM, El-Kashlan HK, Slager HK, Reyes C, Racey AI, Adunka OF. Multicenter US Clinical Trial With an Electric-Acoustic Stimulation (EAS) System in Adults: Final Outcomes. *Otol Neurotol.* 2018 Mar;39(3):299-305.

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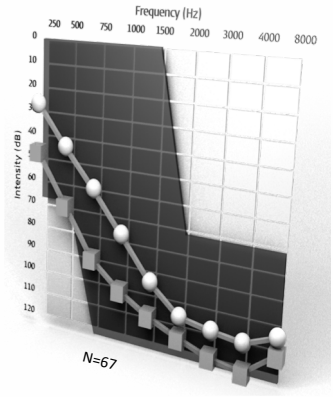
Med-El EAS Hearing Sensitivity

Average pre- and post-op hearing thresholds for all study participants



- 97% of study participants were able to be fit with the acoustic unit
- 97% of study participants demonstrated benefit from the EAS device
  - Measured by speech perception improvement, subjective improvement, or both
- 70% of patients had residual hearing within 30 dB of pre-

Source for Hybrid data: S Source for Hybrid data: Summary of Safety and Effectiveness Data (SSED) http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130016B.pdf

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Cochlear Multicenter Study on CI532

- Washington University, St. Louis, MO
- Center for Hearing and Balance, St. Louis, MO
- Dallas Ear Institute, Dallas, TX
- Ear Medical Group, San Antonio, TX
- Hearts for Hearing, Oklahoma City, OK
- Midwest Ear Institute, Kansas City, KS
- New York University, New York, NY
- Ohio State University, Columbia, OH
- Rocky Mountain Ear Center, Denver, CO
- Spokane ENT, Spokane, WA
- University of California San Francisco, CA
- University of Iowa, Iowa City, IA
- University of Michigan, Ann Arbor, MI

Clinical Evaluation of the Cochlear Nucleus CI532 Cochlear Implants in Adults Investigator Meeting. 2019 Apr.

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Comprehensive Audiology and Health Assessment Battery for Cochlear 532

Audiological	Audiometric (AC, BC, SF)	X		X	X	X	X	X
	CNC Words	X				X	X	X
	AzBio +10 dB SNR	X				X	X	X
	AzBio +5 dB SNR	X					X	X
Questionnaires	HA Exp./N7 Questionnaire	X					X	
	Mini Tinnitus Questionnaire	X					X	X
	SSQ	X					X	
	HUI3	X					X	
	PBRE	X					X	
	MoCA	X					X	
Surgical Data	Imaging	X	X	X				
	Surgical Questionnaire		X					
CDX Files	Map Parameters			X	X	X	X	X
	Datalogging			X	X	X	X	X

Clinical Evaluation of the Cochlear Nucleus CI532 Cochlear Implants in Adults Investigator Meeting. 2019 Apr.

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Outcomes with Bilateral Hearing Aids

Cochlear 532 Study

1 Hearing Aid History

Fit to NAL-Targets

- Hearing aid experience on average 20 years (Range 0 -54 years) for the ear implanted
- Average number of hearing aids purchased is 6 (±4)

2 **Speech Perception**

Bilateral Hearing Aids

- **29%** Word Recognition in Quiet
- **32%** Sentence Recognition in Noise

One Hearing Aid
(Ear Implanted)

- **15%** Word Recognition in Quiet
- **15%** Sentence Recognition in Noise

3 **Patient Reported Outcomes**

- **91%** were **very dissatisfied/ dissatisfied** with bilateral hearing aid performance

Clinical Evaluation of the Cochlear Nucleus CI532 Cochlear Implants in Adults Investigator Meeting. 2019 Apr.

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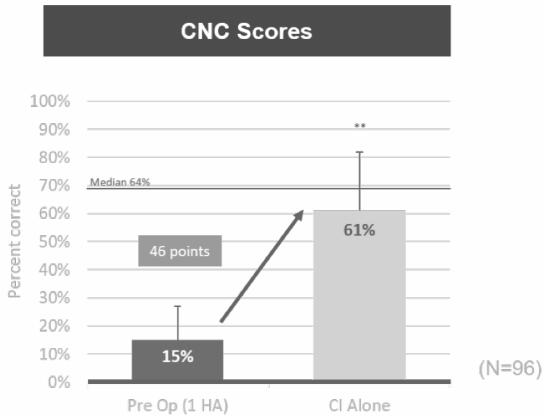
Speech Understanding in Quiet 6 Mos



(N=96)

4X BETTER
4x better with a CI than a hearing aid

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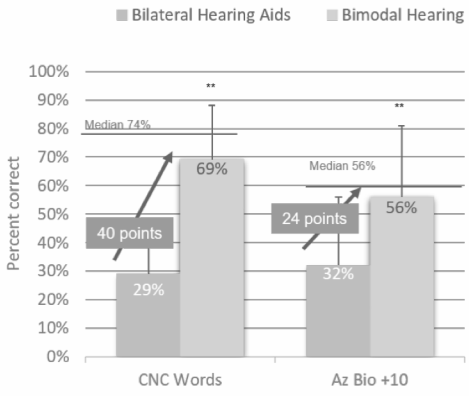
Speech Understanding with a CI+HA (N=94)*
Cochlear 532 Study



- 9 out 10 patients hear significantly better in quiet
- 7 out of 10 patients do significantly better in noise

Speech perception **SIGNIFICANTLY IMPROVED** in both quiet and noise

* two subjects not bimodal

Clinical Evaluation of the Cochlear Nucleus CI532 Cochlear Implants in Adults Investigator Meeting. 2019 Apr.

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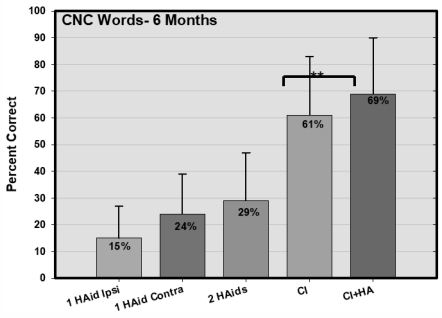
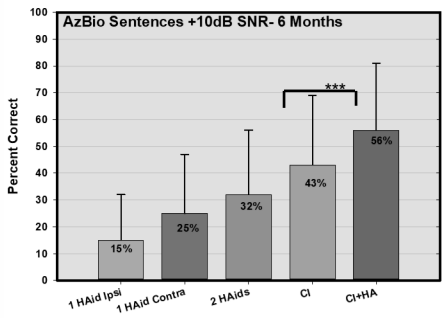
Speech Understanding with Two Ears

(N=94) Cochlear 532 Study



**p=0.002



***p<0.001

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Post-implant improvement

- 18 mo post implant scores[1]
  - Mean CVC words increased from 9.4 to 66.3% correct[1]
  - Mean CVC phoneme score increased from 27.4 to 82.4% correct[1]
  - SRT score decreased from 16.0 to 6.2 dB[1]
  - All APHAB scores except for Aversiveness significantly improved[1]
  - All changes highly statistically significant ($p < 0.0001$)[1]
- Expect soundfield thresholds within the speech range, e.g. 20-35 dB HL from 250-6000 Hz

1 Sarant J, Harris D, Busby P, Maruff P, Schembri A, Dowell R, Briggs, R. The Effect of Cochlear Implants on Cognitive Function in Older Adults: Initial Baseline and 18-Month Follow Up Results for a Prospective International Longitudinal Study. *Front. Neurosci.*, 02 August 2019 https://doi.org/10.3389/fnins.2019.00789

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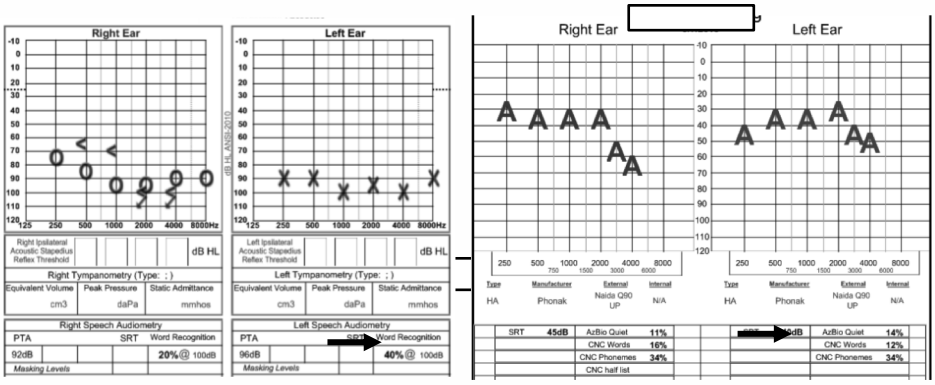
Case 1
CI Evaluation



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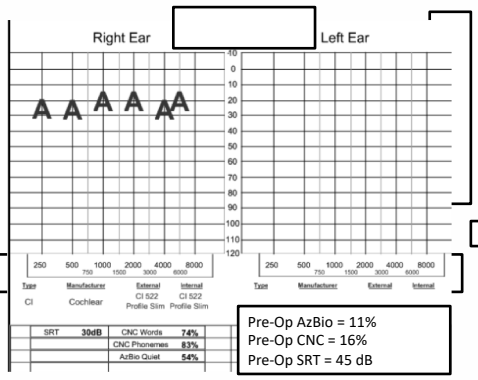
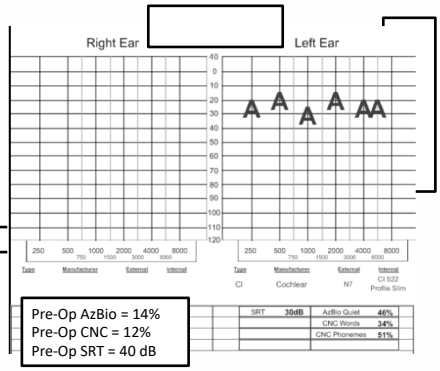
Case 1
7 Mo follow-up right ear



Pre-Op AzBio = 11%
Pre-Op CNC = 16%
Pre-Op SRT = 45 dB

Right Ear first, Left Ear 13 months later
1 Mo follow-up left ear



Pre-Op AzBio = 14%
Pre-Op CNC = 12%
Pre-Op SRT = 40 dB

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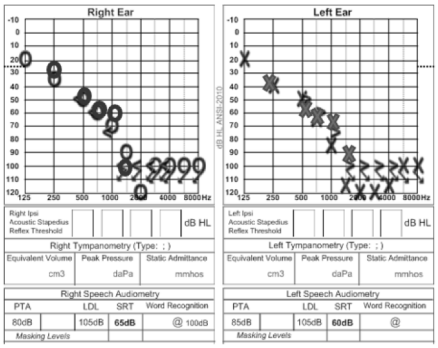
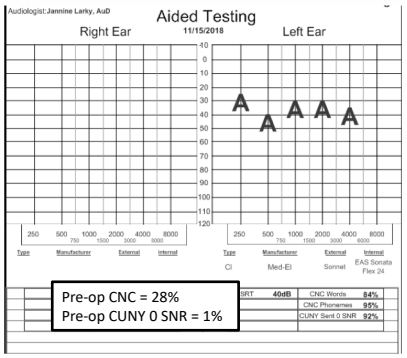
Case 2

2013 CI Evaluation
2018 Follow-up Evaluation Med-El
EAS left ear



2018
MED-EL EAS DEVICE



Pre-op CNC = 28%
Pre-op CUNY 0 SNR = 1%

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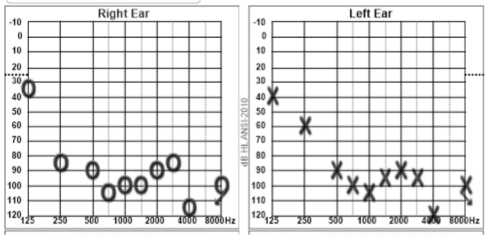
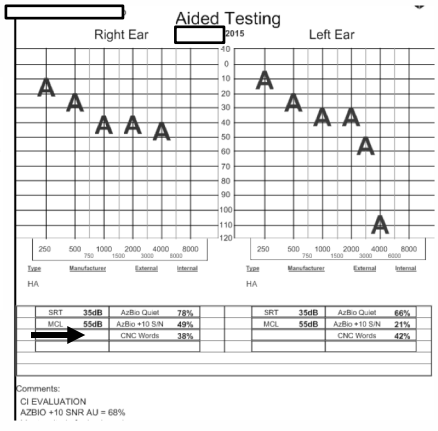
Case 3

CI Evaluation





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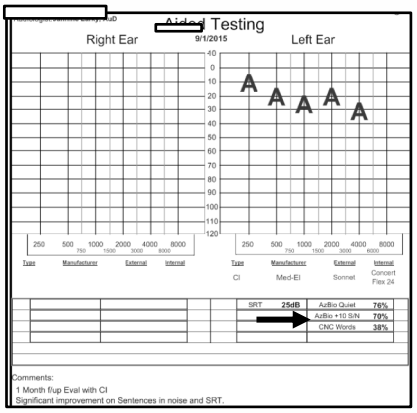
Case 3

1 Month follow-up



Left Ear

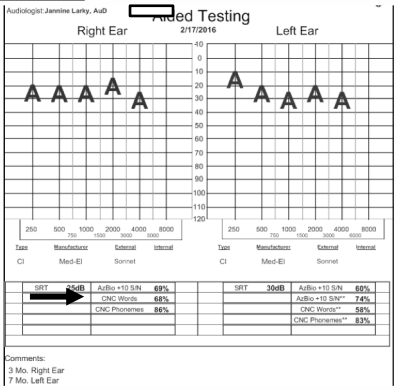
Pre CNC = 42% AzBio +10 = 21%

1 Mo CNC = 38% AzBio +10 = 70%

7 Mo CNC = 58% AzBio +10 = 74%

3 Month right ear

7 Month left ear follow-up



Right Ear

Pre CNC = 38% AzBio +10 = 49%

1 Mo CNC = n/a AzBio +10 = n/a

3 Mo CNC = 68% AzBio +10 = 69%

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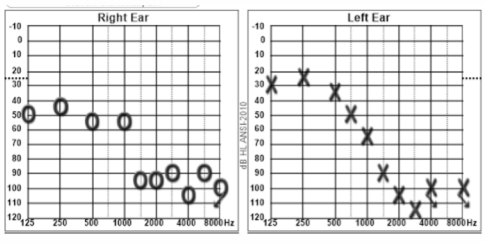
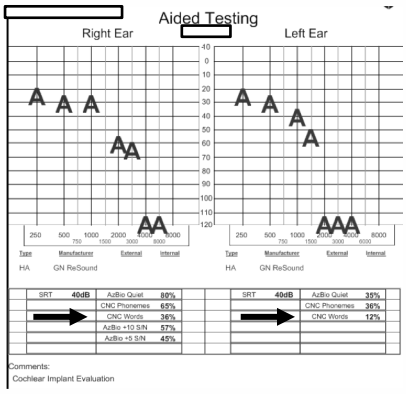
Case 4

CI Evaluation





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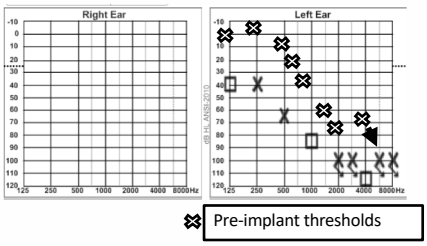
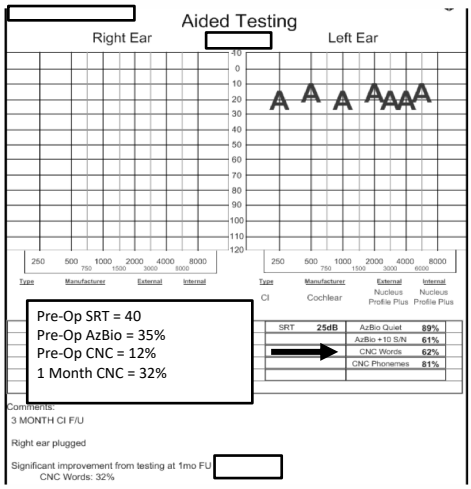
Case 4

3 Month CI follow-up





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Overview Of The Cochlear Implant Delphi Process

1. **Recruit steering committee** and panel and design the process
2. Conduct **literature searches** and draft report
3. Draft up to **25 consensus statements**, reflecting the available evidence
4. **Obtain input** via three rounds of Delphi voting and steering committee
5. **Create peer-reviewed publication** of consensus statements and submit

The process has been facilitated by Oxford PharmaGenesis (https://www.pharmagenesis.com), an independent HealthScience communications consultancy providing services to the healthcare industry, professional societies and patient groups through specialist practices

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Delphi Panel Members

- **Chair** - Craig Buchman, MD, Washington University School of Medicine, St. Louis
- **30 Delphi panel members**
  - ENT/Otologists
  - Audiologists
  - Consumer and Professional Advocates (HLAA, German Association of the HoH, etc)
- **13 countries represented**

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Best Practice Clinical Pathway For Diagnosis

Statement 4: Age alone should not be a limiting factor to cochlear implant candidacy, as positive speech recognition and quality of life outcomes are experienced by older adults as well as younger adults.

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Clinical effectiveness of CIs

- Statement 7: Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss; these gains in speech recognition are likely to remain stable over time.[1]
- Statement 9: Cochlear implants significantly improve overall and hearing-specific quality of life in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss. [1]
- Statement 10: Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize post-implantation speech recognition.[1]

[1]Delphi Consensus Group on Cochlear Implantation in Adults

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Factors Associated With Post-implantation Outcome

- Statement 11: Where appropriate, individuals should use hearing aids with their cochlear implant in order to achieve bilateral benefits and the best possible speech recognition and quality of life outcomes.
- Statement 13: Long durations of unaided hearing loss do not rule out potential benefit of cochlear implants: individuals who receive an implant in an ear that was previously unaided for more than 15 years have been shown to experience improvements in speech recognition.[1]

[1]Delphi Consensus Group on Cochlear Implantation in Adults

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The Relationship Between Hearing Loss And Depression, Cognition, And Dementia

- Statement 15: Adults with hearing loss can be substantially affected by social isolation, loneliness, and depression; evidence suggests that treatment with cochlear implants can lead to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area.[1]
- Statement 18: The use of cochlear implants may improve cognition in older adults with bilateral severe to profound sensorineural hearing loss.[1]
- Statement 19: Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia.[1]

[1]Delphi Consensus Group on Cochlear Implantation in Adults

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Cost implications of CIs

- Statement 20: Unilateral cochlear implantation in adults is cost effective when compared with no implant or no intervention at all and is associated with increased employment and income.[1]

[1]Delphi Consensus Group on Cochlear Implantation in Adults

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CONTINUED

ACI ALLIANCE
AMERICAN COCHLEAR IMPLANT ALLIANCE
Research, Advocacy, Awareness

Conclusion

- Most candidates "don't have much to lose" given their degree of hearing loss and poor speech recognition results pre-CI.
- Recipients can expect about 60% word understanding by 6 mos., >40% improvement from their pre-CI comprehension.
- Bimodal solutions are an option for 60-80% of adult CI candidates (Holder, et al 2018). Bimodal can improve the overall sound quality without detracting from the speech perception benefit provided by the CI.
- We need to work more on referrals

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