

Cochlear Implants in 2020: Candidacy, Technology, Outcomes

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University of Miami Cochlear Implant Team

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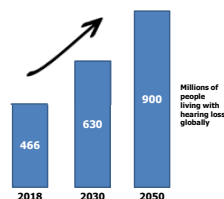
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ACI Alliance Annual Conference <http://ci2021.org/>

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Global Burden of Hearing Loss

- Hearing loss is one of the leading causes of overall disability worldwide.
- Globally, approximately **466 million** adults have a disabling hearing loss.
- This is projected to rise to:
 - 630 million by 2030
 - over 900 million by 2050.
- Hearing loss has a substantial impact on people's lives (e.g. communication difficulties and reduced well-being!).



1. World Health Organization, Addressing the consequences of hearing loss, 2018. Available from: <https://www.who.int/news-room/fact-sheets/detail/world-hearing-loss> (Accessed June 2019)

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Hearing Loss & Other Health Concerns



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Hearing Loss and Dementia

- The risk of dementia and Alzheimer's disease increases with hearing loss severity¹
- Hearing loss is the single largest modifiable risk factor for dementia²
- Dementia incidence could be reduced with the treatment of hearing loss³

Memory Loss & Hearing Loss

Adults with hearing loss develop a significant impairment in their cognitive abilities, 3.2 years sooner than those with normal hearing.

Those with hearing loss experience a 30% to 40% greater decline in thinking abilities compared to their counterparts without hearing loss.

Dementia & Hearing Loss

Mild hearing loss: 2 times more likely to develop dementia

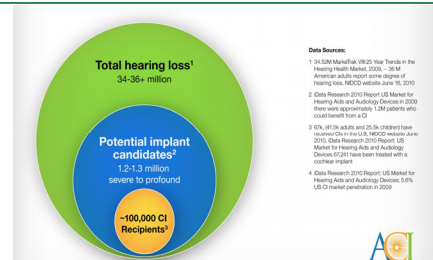
Moderate hearing loss: 3 times more likely to develop dementia

Severe hearing loss: 5 times more likely to develop dementia

1. Liu H et al. Arch Neurol. 2011;68(2):A. 2. Livingston J et al. Lancet. 2017;390(10132):2673-274

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US Cochlear Implant Utilization



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Cochlear Implant Utilization

- CI has now been available for >30 years in many countries.
- CI is the **standard of care** for **newborns** with severe to profound sensorineural hearing loss (SNHL) in many developed countries. In children, penetration of CIs is high.
- In **adults**, CI is often only considered when there is no benefit from hearing aids.
- Many adults who could benefit from CIs do not receive them.
- CI use in adults has potential to become the **standard of care**.



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Why is CI utilization so low?

- Limited awareness in general population
- Limited number of CI referrals
 - Confusion with candidacy criteria
 - Will patient really benefit from CI?
 - Few HA practices test HA patients in aided condition
- Deaf culture controversy
- Insurance coverage issues

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Clinical Review & Education

JAMA Otolaryngology-Head & Neck Surgery | Review

Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss: A Systematic Review and Consensus Statements

Craig A. Buchman, MD, René H. Gifford, PhD, David S. Haynes, MD, Thomas Lenarz, MD, Gerard O'Donoghue, Oliver Adunka, MD, Allison Biever, AuD, Robert J. Briggs, Matthew L. Carlson, MD, Pu Dai, MD, Colin L. Driscoll, MD, Howard W. Francis, MD, Bruce J. Gantz, MD, Richard K. Gurgel, MD, Martin R. Hansen, MD, Meredith Yokumbe, AuD, Eva Kartong, MD, Michael Krieger, MD, ENT, Jennifer Laffey, AuD, Emmanuel A. M. Mylonis, MD, J. Thomas Roland Jr, MD, Shikael R. Saad, MD, Henry Skarzynski, MD, Piotr H. Skarzynski, MD, Mark Syme, MD, Holly Teagle, AuD, Paul H. Van de Heyning, MD, Christophe Vincent, MD, Hao Wu, MD, Tatsuya Yamasoba, MD, Terry Zwolan, PhD

IMPORTANCE Cochlear implants are a treatment option for individuals with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss (SNHL) who receive little or no benefit from hearing aids; however, cochlear implantation in adults is still not routine.

OBJECTIVE To develop consensus statements regarding the use of unilateral cochlear implants in adults with severe, profound, or moderate sloping to profound bilateral SNHL.

Viewpoint page 985 and
Invited Commentary
page 994

Author Audio Interview

Related articles pages 916,
925, and 933

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Consensus Statement Categories

1. Level of awareness of CIs
2. Best practice clinical pathway for diagnosis
3. Best practice guidelines for surgery
4. Clinical effectiveness of CIs
5. Factors associated with post-implantation outcomes
6. The relationship between hearing loss and depression, cognition, and dementia
7. Cost implications of CIs



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Geographic spread of panel members

- The Delphi panel and steering committee bring together clinical experts, ear nose and throat specialists and audiologists from around the globe

- Chair
- 30 Delphi panel members
- 13 countries represented

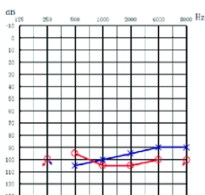


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CI Candidacy & Technology

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In the Beginning...



PATIENT HISTORY (CHARACTERISTICS)				
PATIENT		HEARING LOSS		
NAME	AGE	DATE	TYPE	DEGREE
1. NAME	10	10/10/10	SNHL	Profound
2. NAME	10	10/10/10	SNHL	Profound
3. NAME	10	10/10/10	SNHL	Profound
4. NAME	10	10/10/10	SNHL	Profound
5. NAME	10	10/10/10	SNHL	Profound
6. NAME	10	10/10/10	SNHL	Profound
7. NAME	10	10/10/10	SNHL	Profound
8. NAME	10	10/10/10	SNHL	Profound
9. NAME	10	10/10/10	SNHL	Profound
10. NAME	10	10/10/10	SNHL	Profound
11. NAME	10	10/10/10	SNHL	Profound
12. NAME	10	10/10/10	SNHL	Profound
13. NAME	10	10/10/10	SNHL	Profound
14. NAME	10	10/10/10	SNHL	Profound
15. NAME	10	10/10/10	SNHL	Profound
16. NAME	10	10/10/10	SNHL	Profound
17. NAME	10	10/10/10	SNHL	Profound
18. NAME	10	10/10/10	SNHL	Profound
19. NAME	10	10/10/10	SNHL	Profound
20. NAME	10	10/10/10	SNHL	Profound



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Evolution of External Devices



CLARION 1.0 CLARION 1.2

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Criteria	1985	1990	1998	2000	2014	2019	2020
AGE of Implantation	18 yrs +	3 yrs +	18 mos +	12 mos +	12 mos +	Adults & Children Synt (SSD, AHL) - Mild to	Preschool - Cochlear
ONSET of hearing loss	Post-lingual	Adults: Pre- & Post-lingual	Pre- & Post-lingual	Pre- & Post-lingual	Pre- & Post-lingual	Pre- & Post-lingual	Pre- & Post-lingual
DEGREE of hearing loss	Profound	Profound	Adults: Severe to profound SNHL in both ears	Adults: Moderate to profound SNHL in both ears	Adults - EAS & Hybrid: Normal to moderate SNHL in low to mid frequencies; severe to profound HL in high frequencies	SSD: Profound SNHL, one ear Normal or mild SNHL, other ear	Adults: Moderate to profound SNHL in both ears
Speech SCORES	0%	0%	Adults: ≤40%	Adults: Sentence score ≥50% in ear to be implanted, ≥20% in best aided condition	EAS/Hybrid: CNC word score > 50% but < 60% in ear to be implanted, < 60% CNC words in contralateral ear	Asymmetrical HL: Profound SNHL, one ear Mild to mod severe SNHL, other ear	Adults: Sev to prof 2 yrs + Prof < 2 yrs

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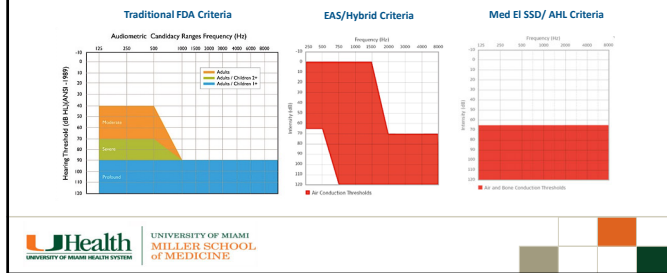
Indications Vary: Insurance, CI Company Labeling

- Degree of hearing loss
- Onset of hearing loss
- Auditory skill assessment
- Length / need for HA trial
- Test materials used
- Presentation level (70,65,60,50 dB)
- Mode of presentation (quiet vs noise)
- Speech recognition score
- Approval of bilateral CI
- "Willingness to participate in an aural rehab program"



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Current Adult CI Candidacy (FDA)



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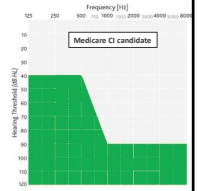
Adult Candidacy: Medicare (Older Adults)

Unchanged since 2005

Nationally Covered Indications

Medicare coverage is provided only for those patients who meet all of the following selection guidelines.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit (test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition) from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.



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Expanded CI Criteria

Bimodal hearing: acoustic and electrical hearing in *opposite* ears

HA CI
Bimodal



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Expanded CI Criteria

Acoustic and Electric (A+E): acoustic and electrical hearing in *same* ear

- Typically uses a contralateral hearing aid
- Accomplished using:
 - Hearing preservation electrode
 - Standard length electrode

HA CI + HA
A+E

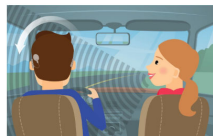


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CROS Option – Unilateral CI



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Waterproof Options



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Streaming, Accessibility



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Considerations for CI Candidacy



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CI Evaluation

Past

Medical Exam

Imaging

Audiology Exam

Present

Medical Exam
Imaging
Audiology Exam
Genetics
Speech / Language Evaluation
Cognitive Testing
Psychology Exam
Quality of Life
Realistic Expectations
Others

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Adult CI Evaluation: Aided Testing

Adult Sentence Test
List 1
WSTB CD - Track 61
(Left Channel - Speech, Right Channel - Noise)

Score: _____

Practice items: 1. DUCK 2. DUCK 3. DUCK

Test items: 1. DUCK 2. DUCK 3. DUCK

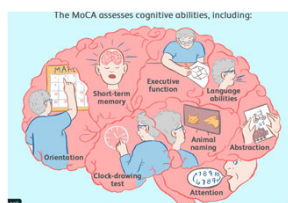
Score: _____

Sum of scores checked for: _____

Grand Total: _____

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Adult CI Evaluation: Cognitive Screener



Nonverbal Cognitive Assessment (NCA)

Score: _____

Practice items: 1. DUCK 2. DUCK 3. DUCK

Test items: 1. DUCK 2. DUCK 3. DUCK

Score: _____

Sum of scores checked for: _____

Grand Total: _____

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Adult CI Evaluation: Realistic Expectations

COSI

CLIENT ORIENTED SCALE OF IMPROVEMENT

Score: _____

Practice items: 1. DUCK 2. DUCK 3. DUCK

Test items: 1. DUCK 2. DUCK 3. DUCK

Score: _____

Sum of scores checked for: _____

Grand Total: _____

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Adult CI Evaluation: Quality of Life

Cochlear Implant Quality of Life-35 Profile

INSTRUCTIONS: Think about your daily life with your cochlear implant (and/or hearing aid). If you also wear glasses, please note how often you use them. Please indicate how often you use each statement below even if you don't use cochlear implants or hearing aids.

	Never	Seldom	Often	Always
1. I can talk to people in a quiet place without using the other person to repeat themselves.				
2. Other people's voices sound clear and natural to me.				
3. I can talk to people in a noisy place without using the other person to repeat themselves.				
4. I can hear and understand without needing to be near the speaker.				
5. I have to ask a lot of questions about what is being said in a conversation.				
6. I can understand a conversation in a crowded noisy place (e.g., a restaurant, a party, etc.).				
7. I can understand a conversation in a noisy place without needing to be near the speaker.				
8. I can understand enough without needing to be near the speaker.				
9. I can follow the conversation in a group of five people in a noisy place without needing to be near the speaker.				
10. I feel comfortable being myself.				
11. My hearing loss makes me feel inadequate.				
12. My hearing loss makes me feel sad.				
13. I have to ask a lot of questions to understand what is being said.				
14. I have to ask a lot of questions to understand what is being said.				

McRackan et al, MUSC



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When to Refer for a CI Eval



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Speech Perception Gap & Cochlear Potential

Cochlear Potential:

- Unaided WRS (PB max) using 50 word list recorded

Speech Perception Gap:

- Discrepancy between patient max cochlear potential for unaided WRS (PB max) and actual aided WR (WR aided)

- Part 1: https://journals.lww.com/thehearingjournal/Fulltext/2020/04000/Using_speech_perception_gap_to_validate_hearing_8.aspx
- Part 2: https://journals.lww.com/thehearingjournal/Fulltext/2020/06000/Causes_of_Speech_Perception_Gaps_Part_10.aspx
- Part 3: https://journals.lww.com/thehearingjournal/Fulltext/2020/08000/Measuring_Speech_Perception_Gap_Part_Three_5.aspx
- **Hospe U, Hocke T, Miller A, Haal A. Speech Perception and information-carrying capacity for hearing aid users of different ages. *Audiol Neurotol*. 2016;21(suppl 1):16-20. doi:10.1159/000448349.



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Speech Perception Gap & Cochlear Potential

Table 1. Example of SP Gap Calculation

	R	L
Unaided PB max (UCL-5)	68%	80%
Aided WRS (50 dB HL)	44%	48%
Speech Perception gap	24%	32%
SP gap = PB max – Aided WRS		

Avg SP Gap = 20%**

- Part 1: https://journals.lww.com/thehearingjournal/Fulltext/2020/04000/Using_speech_perception_gap_to_validate_hearing_8.aspx
- Part 2: https://journals.lww.com/thehearingjournal/Fulltext/2020/06000/Causes_of_Speech_Perception_Gaps_Part_10.aspx
- Part 3: https://journals.lww.com/thehearingjournal/Fulltext/2020/08000/Measuring_Speech_Perception_Gap_Part_Three_5.aspx
- **Hospe U, Hocke T, Miller A, Haal A. Speech Perception and information-carrying capacity for hearing aid users of different ages. *Audiol Neurotol*. 2016;21(suppl 1):16-20. doi:10.1159/000448349.



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Earphone and Aided Word Recognition Differences in CI Candidates

McRackan TR, Fabie JE, Burton JA, Munawar S, Holcomb MA, Dubno JR. *Otology & Neurology*. June 15 2018.

OBJECTIVE:

- Compare word recognition scores for adults undergoing cochlear implant evaluations (CIE) measured using earphones and hearing aids.

STUDY DESIGN:

- Retrospective review of data obtained during adult CIEs at MUSC CI Program.

PATIENTS:

- 208 ears in 183 subjects with >10% word recognition scores

INTERVENTIONS/MAIN OUTCOMES MEASURED:

- Pre-op pure-tone thresholds and word recognition scores unaided vs aided conditions



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Earphone and Aided Word Recognition Differences in CI Candidates

McRackan TR, Fabie JE, Burton JA, Munawar S, Holcomb MA, Dubno JR. Otolaryngology & Neurotology. June 15 2018.

EAD: earphone to aided difference

- unaided earphone condition minus the score in aided condition

+EAD:

- earphone scores better than aided

-EAD:

- earphone scores equal or worse than aided

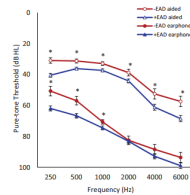


FIG. 2. Mean earphone and aided pure-tone thresholds for +EAD and -EAD groups with error bars indicating ± 1 standard error at each frequency. Statistically significant differences in earphone pure-tone thresholds were found at 250, 500, and 1000 Hz. Aided thresholds significantly differed at all frequencies measured (asterisks, all $p < 0.05$).

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Earphone and Aided Word Recognition Differences in CI Candidates

McRackan TR, Fabie JE, Burton JA, Munawar S, Holcomb MA, Dubno JR. Otolaryngology & Neurotology. June 15 2018.

Unaided WRS compared to Aided WRS (quiet)

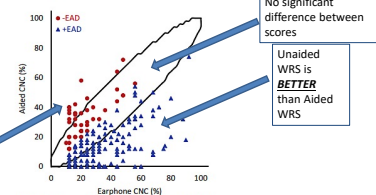


FIG. 3. Earphone word recognition scores plotted against aided scores. Black lines indicate 95% confidence interval. The correlation between earphone and aided word recognition scores was statistically significant ($r = 0.83$; 95% CI 0.172–0.995; $p < 0.001$; $n = 208$).

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Earphone and Aided Word Recognition Differences in CI Candidates

McRackan TR, Fabie JE, Burton JA, Munawar S, Holcomb MA, Dubno JR. Otolaryngology & Neurotology. June 15 2018.

Unaided WRS compared to Aided AzBio +10 SNR (noise)

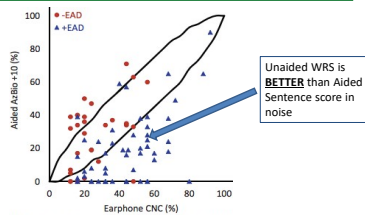


FIG. 5. Earphone word recognition scores plotted against aided AzBio sentence scores in noise. Lines indicate 95% confidence interval. The correlation between earphone word recognition and aided sentence scores in noise was statistically significant ($r = 0.948$; 95% CI 0.150–0.995; $p < 0.001$; $n = 80$).

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Earphone and Aided Word Recognition Differences in CI Candidates

McRackan TR, Fabie JE, Burton JA, Munawar S, Holcomb MA, Dubno JR. Otolaryngology & Neurotology. June 15 2018.

Results:

1. Weak correlation with unaided and aided word recognition.
2. Of the patients with $\geq 50\%$ unaided word scores, 82.6% were CI candidates based on aided sentence testing in noise.

Conclusion:

1. HA patients should undergo aided testing to assess true functional benefit from HAs.
2. Aided speech testing is necessary for appropriate clinical decision making about the use of HAs and potential CI candidacy.
3. Results do not support the widespread assumption that unaided speech recognition scores of $>50\%$ accurately predict good benefit with hearing aids.

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NEW: 60/60 CI Referral Guideline

	Candidates	Non-candidates	Total	
Meets 60/60	212	67	279	PPV = 76%
Does not meet 60/60	8	128	136	NPV = 94%
Total	220	195	415	
	Sensitivity: 212/220 = 96.3%	Specificity: 67/195 = 65.6%		

Otolaryngology, Vol. 41, No. 7, 2020

60/60 Referral Guideline

The data in this study showed that patients are very likely to qualify for a CI if they demonstrate a PTA in the better ear ≤ 60 dB HL and a better ear monosyllabic word score of $\geq 60\%$. When examined as a screening tool for cochlear implant candidacy, the 60/60 guideline demonstrated a sensitivity (detection rate) of 96.3%, and a specificity rate of 65.6% (false-positive rate of 34%). Based on these findings, the authors believe that patients should be referred for a CICE if they meet the 60/60 guideline.

Z. Zwolan, Teresa A. Schwartz-Lycas, Kara C. Mossant, Terence Development of a 60/60 Guideline for Referring Adults for a Traditional Cochlear Implant Candidacy Evaluation. Otolaryngology-April 20, 2020 - Volume Publish Ahead of Print - Issue - doi: 10.1097/HAO.0000000000000264

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Consider Referral for Adult CI Eval:

- Unaided PTA of ≥ 60 dB HL
- Unaided word rec score $\leq 60\%$
- Patient has difficulty communicating with appropriate fit HAs

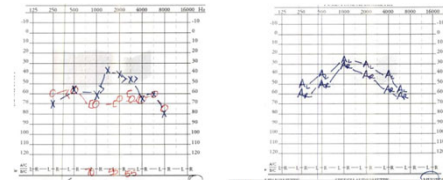
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Bimodal Case

- 62 y.o. male, physician
- Referred by managing audiologist due to aided score on Az Bio +10 SNR screen
- History of SNHL first identified in his 40s
- Unknown etiology
- Wears bilateral HAs
- Reports difficulty understanding patients when not looking at them
- Stated he struggles on telephone and in noisy office conditions

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Cochlear Implant Evaluation



Unaided WRS:

Right = 56%

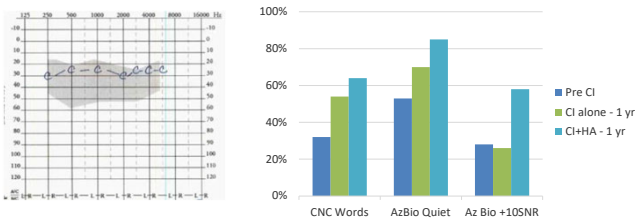
Left = 64%

Test	List #	Left Aided	List #	Right Aided
CNC Words	4	34%	2	32%
CNC Phonemes	4	58%	2	49%
AZ Bio - Quiet	6	68%	4	53%
AZ Bio - +10 SNR	7	34%	8	28%

Speech Gap: Right = 22%
Left = 32%

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1 Year Post-Op – Speech Recognition



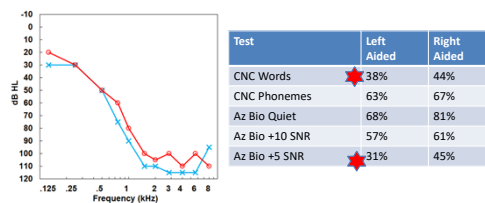
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Adult CI Case

- Patient History
 - 58 yo male, long term SNHL
 - Bilateral HAs since 2000
 - Owns his company
 - HA audiologist said he hears too well for CI
 - Met at a social event, came for CIE 2x and scored too well
 - Now severely struggling at work, on the phone, in meetings

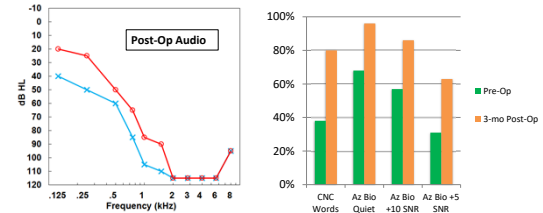
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Adult CI Case




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Adult CI Case – 3 months post activation



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How to **Counsel** Hearing Aid Users About Their Prospective Candidacy for a **Cochlear Implant**



By Terry Zwolan, Ph.D.

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Referral Recommendations

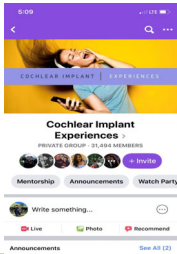
- Show an audiogram with FDA indications overlaid with patient's audiogram
- Perform functional gain testing in combination with a "speech banana"
- Provide patient with literature and brief counseling
 - Impact of duration of deafness, age, etc.
- Provide patients with websites for CI manufacturers

Zwolan, T.

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Resources for Patients



Cochlear™

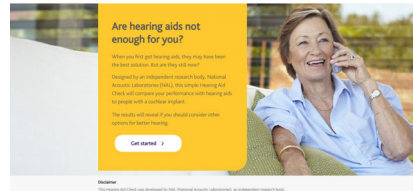
AB Advanced Bionics

MED-EL

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Resources for Patients: www.hearingaidcheck.com



- Online aided speech in noise test
- Can take test on smartphone or tablet
- Free!
- Quick!

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What NOT To Do

- Tell patients to try hearing aids "to see if they work"
- Refer to the CI as a "last resort" treatment option
- Wait until a patient is a clear-cut candidate to refer
 - Ask your CI team if unsure!
- Assume the patient is too medically involved for CI
- Assume the patient is too old for CI

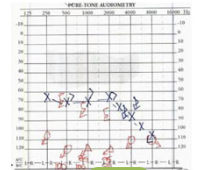
Zwolan, T.

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Older Adult Case

- 91 y.o. female
- 20 years of SNHL
- HA use in L ear for 20 years
- No HA use in R ear for 15 years
- No hearing in R ear for 15 years
- Lives alone, isolated, avoids social activities due to HL
- Family pushing for CI
- PCP told patient she is "too old" for CI



Test	List #	Left Aided	List #	Right Aided
CNC- Words	1	44%	2	0%
CNC- Phonemes	1	64%	2	0%
AzBio Sentences- Quiet	5	44%	2	0%
AzBio Sentences- +10 SNR	6	17%	DNT	DNT

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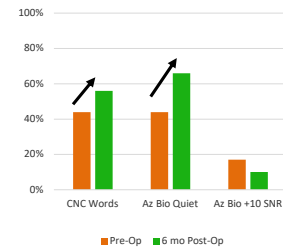
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Initial Activation Day



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6 months Post-Op



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CI Expectations

- Good sound awareness and detection (20-30dB HL)
- Improved speech understanding in quiet and often in noise.
- Less stress/less fatigue.
- Background noise still difficult.
- Multiple talkers/large groups still difficult.
- Telephone and TV often improved but not perfect.
- Music appreciation takes time.

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Patients often appreciate the recommendation, even if they are not a candidate!

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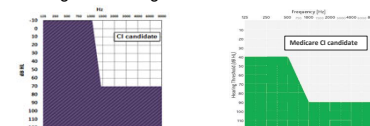
Summary

- CI candidacy is more than an audiogram.
- Bilateral CI, bimodal, acoustic + electric, and CI for SSD are proven to be highly beneficial for many patients struggling with their hearing aids.
- CIs are an excellent treatment option for adults with hearing loss that negatively impacts their communication abilities and quality of life.
- Hearing loss that is not treated properly may lead to:
 - Decreased quality of life
 - Decreased speech understanding
 - Decreased social interaction
 - Increased risk for depression
 - Increased risk for dementia/cognitive decline

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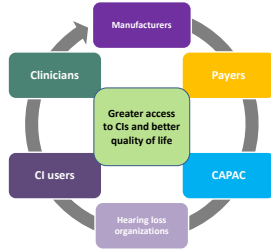
Summary

- 60/60 rule: Consider referral for CI eval for patients with:
 - Unaided PTA of ≥ 60 dB HL
 - Unaided word rec score $\leq 60\%$
- Consider referral for cochlear implant evaluation for patients struggling with speech understanding when using HAs & remember these audiograms:



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Working together towards the same goal!



CAPAC, Consumer and Professional Advocacy Committee. CI, cochlear implant.

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THANK



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