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RESEARCH. ADVOCACY. AWARENESS.

Cochlear Implantation in Older Adults

Teresa Zwolan PhD, Director, University of Michigan CI Program
and Vice Chair, ACI Alliance
Donna L. Sorkin, Executive Director, ACI Alliance

American Cochlear Implant Alliance
Unique Organization in Field

- Membership organization concerned with cochlear implantation and access to care
- Research, Awareness, Advocacy
- Membership comprised of physicians, audiologists, speech pathologists, educators and others on CI teams plus consumer/parent advocates

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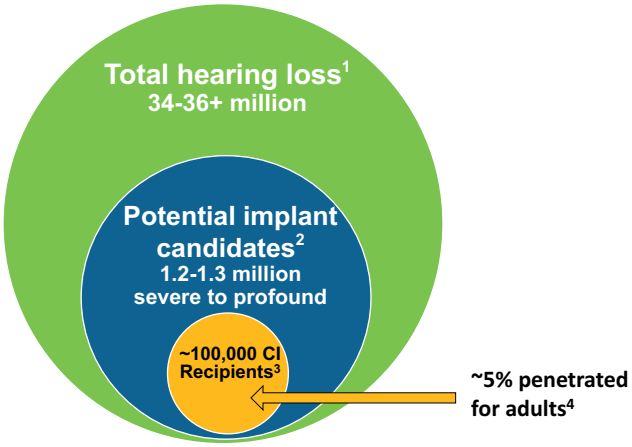
Hearing Loss in the U.S. (2012)



Data Sources:

[1] *34.52M MarkeTrak VIII:25 Year Trends in the Hearing Health Market, 2009, ~ 36 M American adults report some degree of hearing loss, NIDCD website June 16, 2010*

[2] *iData Research 2010 Report US Market for Hearing Aids and Audiology Devices in 2009 there were approximately 1.2M patients who could benefit from a CI*

[3] *96k, (58k adults and 38k children) have received Cis in the U.S., NIDCD website December 2012.*

[4] *iData Research 2010 Report: US Market for Hearing Aids and Audiology Devices; 5.6% US CI market penetration in 2009*

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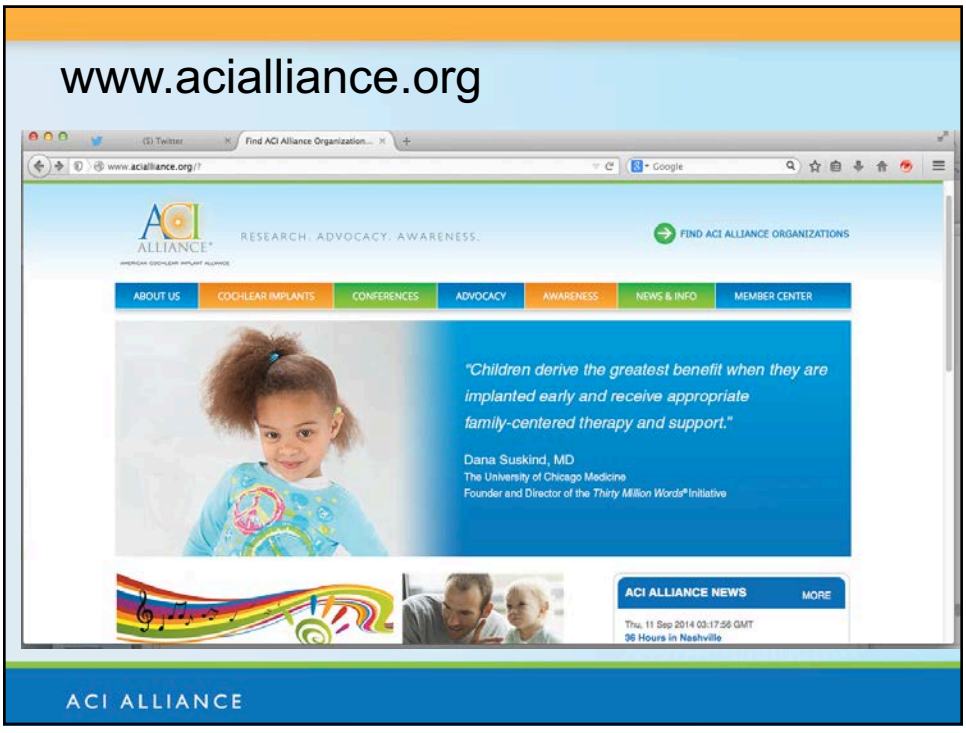

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ACI Alliance Approach

- Work across the continuum of care
- Operate as an ***Alliance*** collaborating with larger organizations in the hearing loss field
- *We don't*: Replicate what others are doing
- *We do*: Provide resources to share and use, and facilitate clinician involvement
- Focus on activities that expand access to CI
- Address very low utilization rates

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Public Policy Agenda

- Access and Visibility of CI among elected/appointed officials
- State Champions Program + Broader Member Engagement
- Ensure ACA Marketplace Plans cover CI
- Informed choice about Early Intervention options, State Medicaid policies that impact access, older adult access
- Medicare Coverage of Osseointegrated Implants
- Medicare Criteria to match FDA (focus of presentation today)
- Developing Multi-Disciplinary Clinical Guidelines

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ACI Alliance on the Hill (Oct 2013)

Messages: Familiarity with CI, access concerns, early intervention/options information for families

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CI 2015 SYMPOSIUM
October 15–17 • Omni Shoreham Hotel
WASHINGTON, DC

CI 2015 EMERGING ISSUES SYMPOSIUM

October 15-17th, 2015

Washington DC

www.acialliance.org

CONTINUED™

Emerging Topics:

- Auditory Brainstem Implants in Children
- Objective Measures
- Expanded Indications
- Quality of Life and Cost Effectiveness
- Literacy and Cochlear Implants
- Cochlear Implant Connectivity to Other Technologies

- Podium/poster presentations on a range of CI topics
- ***ACI Alliance on the Hill*** day prior: **Wednesday, Oct 14**

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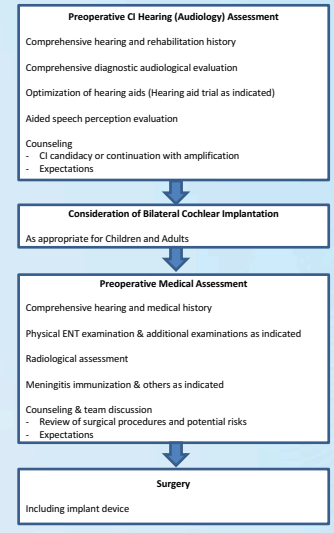
Continuum of Cochlear Implant Care (1)



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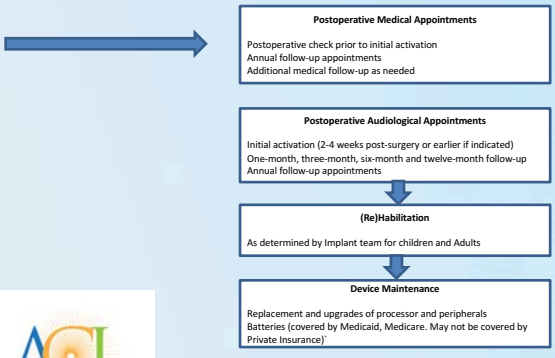
Continuum of Cochlear Implant Care (2)



Continuum of Care Chart available at www.ACIAlliance.org in Cochlear Implant info section

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Today's Agenda
Cochlear Implantation in Older Adults

- History of Medicare Coverage / Study Objectives
- Results of Recent Candidacy Expansion Studies for older adults
- Factors that contribute to successful CI use
- Guidelines for referring older adults for CI evaluation
- Summary / Q&A

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History of Cochlear Implant Candidacy Expansion/Study Objectives

Background on CI Coverage

- Three CI Manufacturers approved to provide devices in the US
- All are essentially the same in practice and appropriateness for use in adults and children
- FDA Candidacy Criteria differ somewhat because 3 companies have not all undergone the same FDA review process
- For purposes of our discussion/study, we are treating them all the same
- We are using the device with the broadest indications in our discussions (Nucleus/Cochlear Americas)

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Historical Expansion of FDA Guidelines

Criteria	1985	1990	1998	2000
AGE of implantation	Adults 18 yrs +	Adults & Children 2 yrs +	Adults & Children 18 mos +	Adults & Children 12 mos +
ONSET of hearing loss	Post linguistic	Post linguistic adults/ Pre & Post Linguistic Children	Adults & Children Pre & Post Linguistic	Adults & Children Pre & Post Linguistic
DEGREE of hearing loss	Profound	Profound	S/P Adults Profound Children	S/P Patients 2 yrs+ Prof Child<2 yrs
SPEECH SCORES	0%	0%	40% or less	50% or less in ear to be implanted, ≤ 60% in best aided condition

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Why has the FDA Guideline expanded?

- If S/P, adults and children may have better outcomes with CI than with hearing aids
- Testing previously used words in sentences; now increasingly using single word test scores acknowledging limitations of former tests
- CI technology has improved dramatically
- Research demonstrates candidates do better with more residual hearing and shorter periods of deafness (more detail on this later)

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Pre-Operative Evaluation

- Audiological Evaluation
- Medical Evaluation
  - Ensure candidate is healthy enough to undergo surgery
  - Assessment to determine cause of hearing loss though this is generally not a factor but must be sensorineural
  - Verify anatomy of cochlea will support CI
  - **Age is NOT a factor**

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Do insurers all use the same criteria?

- Private insurers typically follow FDA Guidelines
- Most cover bilateral CI
- Medicaid varies by state but tends to follow FDA
- Medicare has traditionally been more restrictive
- In April 2005, CMS expanded Medicare candidacy from 30% or less to 40% or less on sentence test
- FDA criteria varies for devices depending on when FDA approval was received. Most recent
  - $\leq$ 60% in best aided condition (typically bilateral)
  - $\leq$ 50% in ear to be implanted

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CMS MEDCAC meeting

- In 2011, CMS convened a meeting for a panel (of primarily non-CI medical professionals) to review evidence on outcomes attributable to unilateral and bilateral cochlear implantation for its beneficiaries
- They were considering expanding CI candidacy without a formalized trial
- A detailed review of the literature concluded there was insufficient evidence to support expansion without a formal study

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Research: Medicare CED

- ACI Alliance sponsored development of a CED - Coverage with Evidence Development study approved by Medicare
- Study is registered on clinicaltrials.gov
- https://clinicaltrials.gov/ct2/show/NCT02075229
- Purpose: to evaluate the safety and efficacy of CIs for older adults using expanded CMS criteria
- At present, candidacy for ≥65 year old candidates is more stringent than FDA guidelines. If approved, CMS and FDA guidelines will be more equivalent
- Innovative element is creation of new patient registry

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Centers Involved in the Medicare CED Study

- University of Michigan
- University of Iowa
- Johns Hopkins University
- University of Miami
- New York University School of Medicine
- University of North Carolina
- University of Southern California
- Vanderbilt University
- University of Washington
- Washington University School of Medicine

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Patient Eligibility CMS CED

- 65 years of age or older
- Bilateral moderate-to-profound sensorineural hearing loss in the low frequencies (up to 1000 Hz) and profound sensorineural hearing loss in the high frequencies (3000 Hz and above)
- Best aided sentence score in quiet between 40 - 60% correct on recorded HINT sentences
- Scores exceed current Medicare guideline but meet FDA criteria
- Spoken English as primary language
- Cognitive ability to use auditory clues and willingness to undergo rehabilitation
- Freedom from middle ear infection and acoustic areas of the central nervous system
- No medical contraindications for surgery

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Test Measures (Pre-op, 6, and 12 mos post)

- HINT Sentences, AZBio Sentences, CNC Monosyllabic Words, Telephone test (CUNY sentences administered live voice)
- Questionnaires
  - Health Utility Index (HUI3) to measure health status and quality of life
  - Short Form Health Survey (SF-36) measures functional health and wellbeing
  - Abbreviated Profile of Hearing Aid Benefit (APHAB) to evaluate ease of communication, Reverberation, Background Noise, and Aversiveness to Sounds

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How are subjects enrolled?

- Contact Donna Sorkin at ACI Alliance and she will put you in touch with the closest participating center
- Centers will perform preoperative testing and will follow the patient for device activation and 6 and 12 month testing. They can return to their home center for management following completion of the study
- Otherwise, many of these patients will need to wait to receive a CI….

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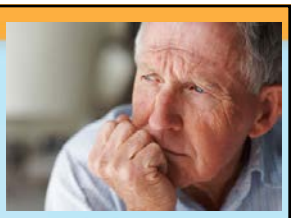
Why is it wrong to wait?



- Too many people are waiting…the average delay between onset of severe/profound hearing loss and receipt of a CI is 10 years
- Duration of deafness is consistently cited as one of the most significant predictors of post-operative hearing outcomes with a CI: longer duration of deafness results in poorer outcomes

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Catch it early

- Adults who do well with CIs typically maintain good speech recognition skills for a very long time
- Waiting to receive a CI could result in poorer speech recognition initially and it may never improve

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Why is this study needed?

- It is well known that CIs provide great benefit to aging adults who receive minimal benefit from hearing aids
- There is a need for additional studies to demonstrate these benefits so insurers, like Medicare, will support earlier and more lenient implantation of aging adults
- Clark et. al (2015) performed a literature review and concluded that a lack of attention has been paid to communication in the real world, quality of life outcomes, and information regarding the role that CI rehabilitation plays in outcomes
- The CMS CED will fill some of these needs

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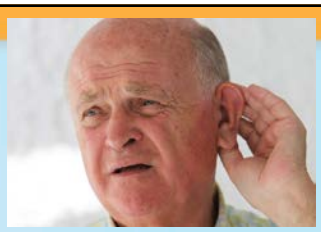
Statistics



- Only 5-10% of adult cochlear implant candidates in the US have received an implant
- The most rapidly growing segment receiving CIs are patients over the age of 65 (Miller et. al, 2015)
- Some estimate the prevalence of S/P hearing loss in this age group will grow by more than two-fold in the next 40 years

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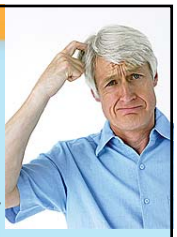
Additional reasons to support CIs in the elderly



- Lin and colleagues report that the severity hearing loss in older adults is independently linked to accelerated cognitive decline
- They found a significant correlation between hearing loss and poorer cognitive function: adults with HL demonstrated a 30% to 40% accelerated rate of cognitive decline and a 24% increased risk for cognitive impairment than adults with normal hearing (Lin et. al, 2013)

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Additional reasons…

- Mosnier et al. (2015) examined post-operative outcomes of 94 adults ages 65 – 85 years
- They found significant ***improvements in speech perception*** in quiet and in noise, ***improved quality of life***, and improved scores on the Geriatric Depression Scale – 4 (59% of patients reporting ***no depression*** preoperatively versus 76% 12 months post-implant)
- 81% of subjects showed ***improved global cognitive function***

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Hearing better makes a difference

- The impact of CIs on quality of life in the elderly is well documented and shows an increase in confidence at work and at home, increases in social activities, and an overall improvement in quality of life (Orabi et al, 2006; Vermiere et al., 2005; Poissant et al., 2008).

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CI surgery is safe in older adults

- Several investigators have found that cochlear implants are safe and effective for people over the age of 65; elderly patients do not experience more complications from surgery and do not experience more device failures than younger patients
- Chen et al suggest that concerns for increased postoperative complications in patients of advanced age do not need to be a primary consideration when determining CI candidacy

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Recent Adult Studies

- Medicare will provide approval for beneficiaries to enroll in clinical trials if the provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial, a trial under the CMS Clinical Trial Policy, or a prospective, controlled comparative trial approved by CMS…even if their scores exceed current Medicare criteria.

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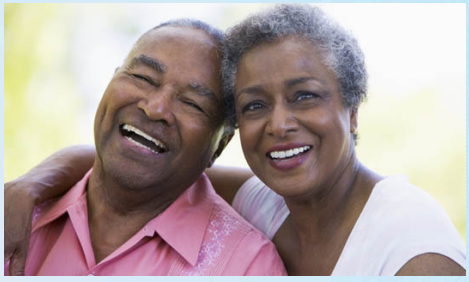
Elderly patients make excellent study subjects….

- And their inclusion in studies may help with future expansion of devices and of candidacy criteria for Medicare beneficiaries…



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Elderly patients help devices obtain FDA approval…

- The Hybrid L24 received FDA approval for use in adults in 2014 following completion of a lengthy clinical trial. This device is intended for use by patients aged 18 years or older who meet the following criteria:
  - Normal to moderate hearing loss in the low frequencies, with severe to profound loss in the mid to high frequencies.
  - (CNC) word recognition score between 10% - 60% in the ear to be implanted and not more than 80% correct in the contralateral ear
  - Almost ½ of the patients enrolled in this clinical trial were > 65

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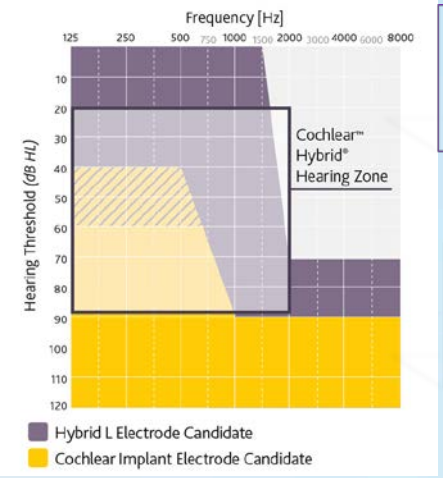
Recent Approval of Nucleus Hybrid



HYBRID

Word *(CNC)* score ≥10% and ≤60% in the ear to be implanted
Word *(CNC)* score ≤ 80% in the opposite ear

TRADITIONAL CI

Sentence *(Az-Bio)* Score ≤ 50% in the ear to be implanted
Sentence *(Az-Bio)* Score ≤ 60% in the best aided condition

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Other clinical trials…

- Zwolan, Henion, Segel, and Runge (2014) summarized the results of a multicenter clinical trial that evaluated the post-operative performance of 38 adult CI users.
- 20 subjects were < 65 years of age (n=20) and 18 subjects were > 65 years (n=18).
- Pre versus post-implant speech recognition scores were compared for each group.
- Performance of older subjects who scored >40% on HINT sentences was also evaluated.

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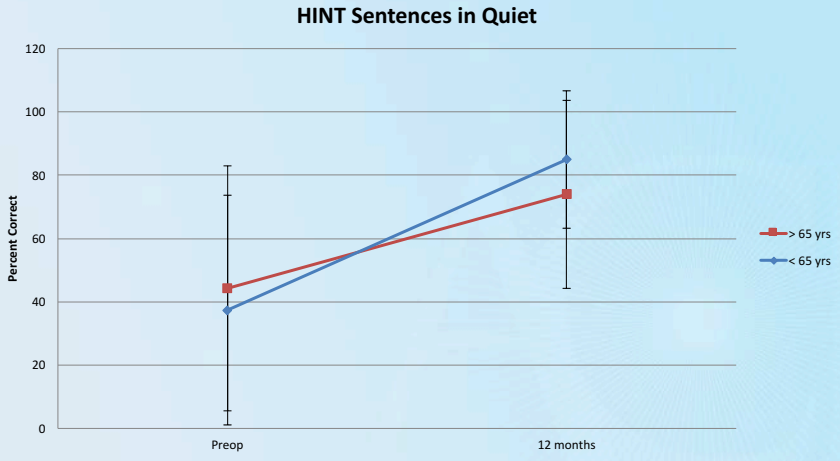
Each group demonstrated significant improvement when mean pre-implant and mean 12 month post-implant scores were compared. Differences between groups were not statistically significant at either time interval.



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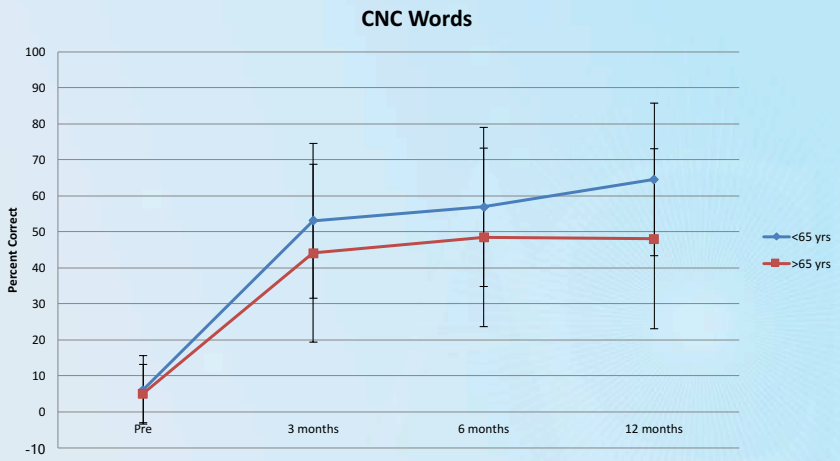
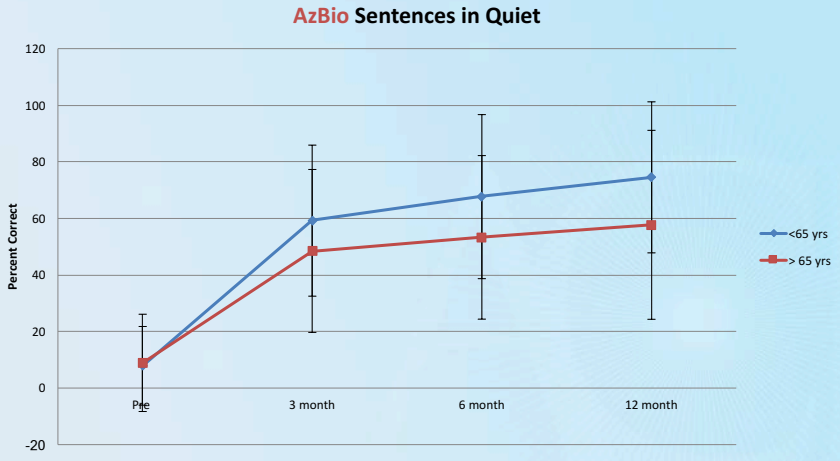
Each group demonstrated significant improvement when mean pre-implant scores were compared to scores obtained at each post-implant time interval. Differences between groups were not statistically significant at any time interval.



ACI ALLIANCE

Each group demonstrated significant improvement when mean pre-implant scores were compared to scores obtained at each post-implant interval. Differences between groups were not statistically significant at any time interval.



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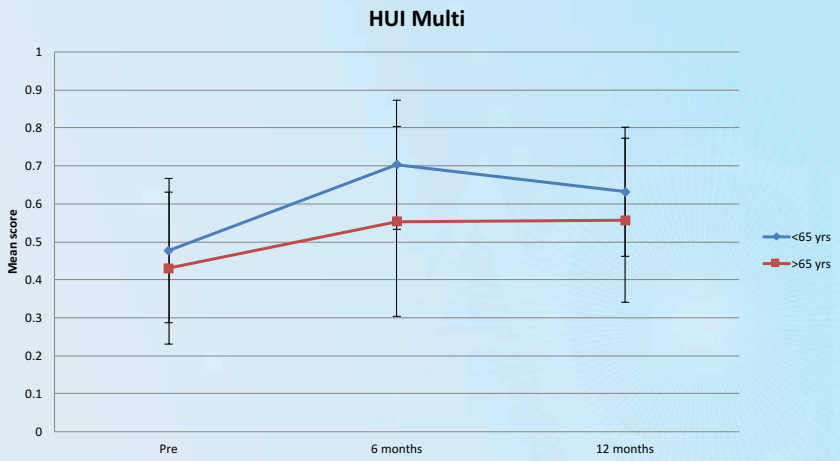
Subjects who were less than 65 years of age demonstrated significant improvement when mean pre-implant and 6 and 12 month post-implant scores were compared. Mean scores for subjects over the age of 65 years were not significantly different when pre-implant and 6 and 12 month post-implant scores were compared. Differences between groups were not statistically significant at any time interval.



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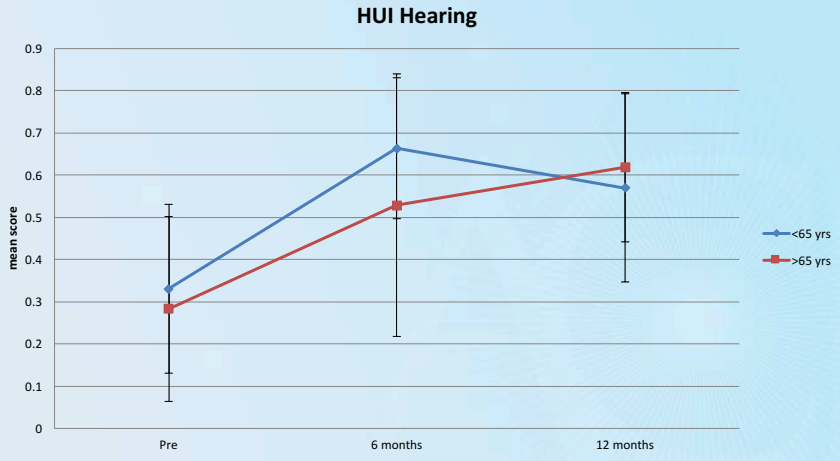
Each group demonstrated significant improvement when mean pre-implant and mean 12 month post-implant scores were compared. Subjects who were less than 65 years at time of implant additionally demonstrated significant improvement on HUI Hearing 6 months post-implant. Differences between groups were not statistically significant at any time interval.



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Additional goal

- To determine if elderly patients who scored > 40% on HINT sentences preoperatively received benefit from their devices and if they demonstrated significant improvement in Health Utility scores after receiving a CI
- CMS frequently performs literature reviews to help determine if candidacy criteria should be expanded and if doing so is safe and effective. Thus, it is important for literature to include specific analyses of data for aging adults

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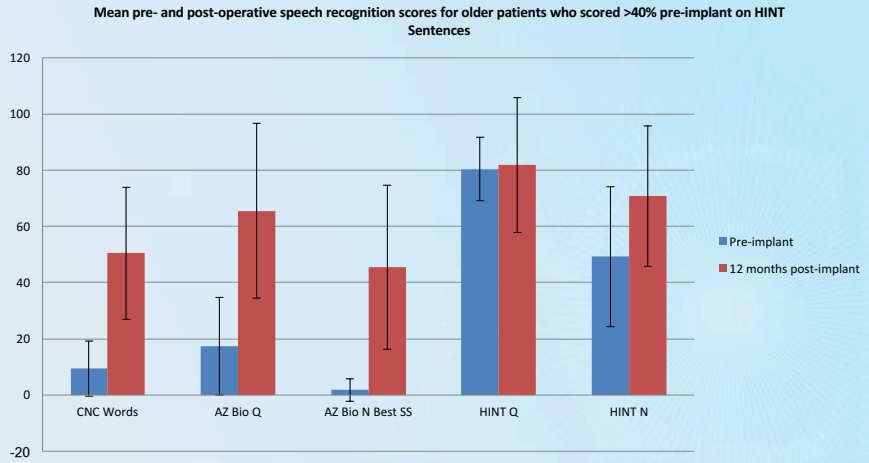
Mean speech recognition scores obtained by patients over the age of 65 years who obtained scores >40% correct on HINT sentences pre-implant. This group demonstrated significant improvement on all measures except HINT sentences in quiet and HINT sentences in Noise.



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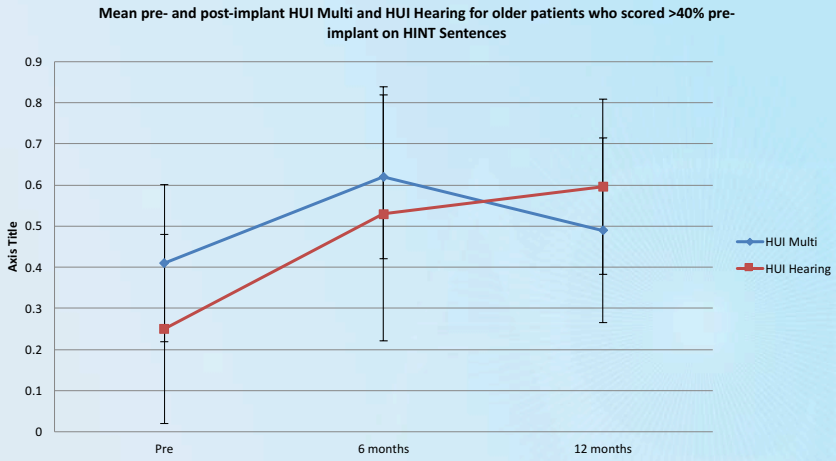
Mean scores obtained by patients over the age of 65 years who obtained scores >40% correct on HINT sentences pre-implant on the MULTI and HEARING subtests of the Health Utility Index. This group demonstrated significant improvement on each measure when pre-implant and 12 month post-implant scores were compared.



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Additional studies…

- In general, most studies indicate that aging adults over the age of 65 tend to perform similar to or slightly poorer than younger subjects.
- All studies support CIs in this age group when their pre- versus post-implant factors are compared.
- It is possible that such differences will decrease if aging adults receive CIs sooner

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Factors that contribute to successful CI use among older adults

- Implantation soon after the patient meets CI candidacy
- Understand the risks and benefits of CIs
- Realistic expectations of patient and family members
- Manufacturers are working to make devices that are increasingly “elderly-friendly”
- Manufacturers and centers are hosting outreach events to increase awareness of candidacy, foster friendships, and improve device utilization
- This population does have additional rehabilitative needs that need to be addressed by clinicians

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Guidelines for referring older adults for a CI evaluation

- Candidacy is determined on a case by case basis
- Candidacy depends on audiometric test results and speech recognition scores and also depends on availability of existing clinical trials
- Including hybrid, candidacy ranges from normal hearing in the lows to profound in the highs
- Including hybrid, speech recognition can be as high as 80% in the better ear to be considered a candidate
- Even though the hybrid is FDA approved, medicare recipients cannot receive a hybrid based on current medicare criteria
- Check to see if there are any clinical trials that your patient may qualify for

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Referral information

- Clinics vary in regards to the test measures used to determine candidacy for a CI.
- Some centers utilize HINT sentences while others use AZBio sentences
- Because AZBio sentences are more difficult, a patient may meet criteria with AZBios but not with HINT.
- Many HA audiologists do not performance sentence recognition testing, and it is difficult to determine if a patient should be referred for a CI evaluation
- Gifford et al found that AZBio scores were correlated with CNC scores, so a good estimate is to refer if the patient scores <60% on a word test

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But also consider…

- CI centers typically use taped materials to determine candidacy while many HA clinics use live voice in their daily work with patients
- Patients typically score lower if taped materials are used.
- Consider referring for a CI evaluation if the patient scores less than 70% on a word list that is presented live voice and if they have a moderate to profound SNHL

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Check with your local center…

- Many clinicians are concerned about referring patients who are **not** candidates
- Discuss this possibility with your patient ahead of time so they are aware that their candidacy is unknown until they have been tested
- Centers are often willing to review the patient's audiogram before the referral to determine if an evaluation is recommended
- Typically, patients are happy they went for the evaluation, even if they are not a candidate
- No referral is a bad referral if the patient receives appropriate information and education

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Summary

- Cochlear implants are under-utilized in the adult population, and even more so in aging adults
- Studies are underway to expand criteria and efforts are taking place to increase awareness of this life changing technology
- It is important to remain aware of changes in technology and changes in candidacy so the needs of our patients can be well served

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Questions?

- dsorkin@acialliance.org
- zwolan@umich.edu

- Thank you!

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References and additional resources

CMS MEDCAC Meeting:

- http://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=58&fromdb=true

Clinicaltrials.gov Medicare CED:

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