Cochlear Implants 2016: Advances in Technology, Candidacy and Outcomes

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Today’s Agenda

- What is ACI Alliance and why another organization
- How and Why Has CI Candidacy Changed
- Device Changes and Impact on Outcomes
- Candidacy Expansion Study for Adults 65+
- Factors that contribute to successful CI use
- Summary / Q&A
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 + consumer/parent advocates

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“Children derive the greatest benefit when they are implanted early and receive appropriate family-centered therapy and support.”

Dana Suskind, MD
The University of Chicago Medicine
Founder and Director of the Thirty Million Words® Initiative
US Cochlear Implant Utilization

Total hearing loss\(^1\)
34-36+ million

Potential implant candidates\(^2\)
1.2-1.3 million severe to profound

~100,000 CI Recipients\(^3\)

Data Sources:
1. 34,52M MarkTrak VIII:25 Year Trends in the Hearing Health Market, 2009, ~ 38 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. 67k, (41.5k adults and 25.5k children) have received CIs in the U.S, NIDCD website June 2010, iData Research 2010 Report: US Market for Hearing Aids and Audiology Devices 67,241 have been treated with a cochlear implant
4. iData Research 2010 Report: US Market for Hearing Aids and Audiology Devices; 5.6% US CI market penetration in 2009
Why is utilization so low?

- Low awareness in general population
- Referrals not typically made by primary care physicians nor even by hearing aid audiologists
  - Don’t know candidacy criteria
  - Don’t understand how much benefit people derive
- Deaf culture perspectives insert controversy and misunderstanding
- Insurance coverage issues though this is no longer a major concern for traditional CI
Cochlear Implants

- Small, complex electronic device providing auditory information to adults and children with varying degrees of hearing loss.
- Consists of an external portion that sits behind the ear and a second portion that is surgically placed under the skin. The implanted portion electrically stimulates the inner ear to deliver sound.
How a CI Works

1. Sound is picked up by the microphone.
2. The processor filters and codes the signal.
3. The signal is sent up the cable to the coil.
4. The signal is then sent via radio frequencies to the internal device.
5. The electrodes are activated, and the coded electric signal is sent via the hearing nerve to the brain for interpretation.
How a Hearing Aid Works

1. Sound is picked up by the microphone
2. amplified
3. Then sent to the ear via the earmold
### Differences Between a Cochlear Implant and a Hearing Aid

<table>
<thead>
<tr>
<th>Hearing Aid</th>
<th>Cochlear Implant</th>
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<tbody>
<tr>
<td>Delivers information acoustically</td>
<td>Delivers information electrically</td>
</tr>
<tr>
<td>For people w/mild-profound hearing loss</td>
<td>For people w/mlld-profound hearing loss who have minimal benefit from hearing aids</td>
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<tr>
<td>Typically do not require surgery</td>
<td>Requires surgery</td>
</tr>
<tr>
<td>Individuals may not be able to hear certain sounds (typically high frequency) even using powerful hearing aids</td>
<td>Provides sound at all frequencies</td>
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<tr>
<td>Not typically covered by health insurance</td>
<td>Covered by most health insurers including Medicare</td>
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History of Cochlear Implant
Candidacy Expansion
# Historical Expansion of FDA Guidelines

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<tbody>
<tr>
<td><strong>AGE</strong> of implantation</td>
<td>Adults 18 yrs +</td>
<td>Adults &amp; Children 2 yrs +</td>
<td>Adults &amp; Children 18 mos +</td>
<td>Adults &amp; Children 18 mos +</td>
<td>Adults only for Hybrid</td>
</tr>
<tr>
<td><strong>ONSET</strong> of hearing loss</td>
<td>Post linguistic</td>
<td>Post linguistic adults/ Pre &amp;</td>
<td>Adults &amp; Children Pre &amp; Post</td>
<td>Adults &amp; Children Pre &amp; Post</td>
<td>Adults &amp; Children Pre- and Post- Linguistic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Post Linguistic Children</td>
<td>Linguistic</td>
<td>Linguistic</td>
<td></td>
</tr>
<tr>
<td><strong>DEGREE</strong> of hearing loss</td>
<td>Profound</td>
<td>Profound</td>
<td>S/P Adults Profound Children</td>
<td>S/P Patients 2 yrs+ Prof Child&lt;2 yrs</td>
<td>Nucleus Hybrid: Normal to Moderate in low freq; S/P mid to high frequencies</td>
</tr>
<tr>
<td><strong>SPEECH SCORES</strong></td>
<td>0%</td>
<td>0%</td>
<td>40% or less</td>
<td>Sentences score 50% or less in ear to be implanted, ≤ 60% in best aided condition</td>
<td>CNC word score &gt;10% but less than 60% in ear to be implanted; &lt;80% CNC words in contralateral ear</td>
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Why have FDA Guidelines expanded?

- CI technology improved
- Early guidelines stated no open set (i.e., 0% on words in sentences)
- Adults and children with S/P hearing loss have better outcomes with CIs than with hearing aids
- Testing previously only used sentence scores; now increasingly using single word test scores and hearing in noise (more people are candidates)
- Research demonstrates candidates do better with more residual hearing and shorter periods of deafness
FDA Changes Tied to Changes in Outcomes

- Age at implantation decreased for children
- Greater numbers of younger children who receive CIs are using Oral communication w/out sign
- FDA approved devices enable provision of CIs to adults with better auditory skills and more residual hearing
  - Rationale: studies show adults do better w/ CI than w/ hearing aids if they have more residual hearing
  - Also brought about re-examination pediatric candidacy
Electric-Acoustic Devices aka “Hybrid”

What if you could combine a hearing aid with a cochlear implant to **amplify sounds at low frequencies and provide electrical hearing at high frequencies**?
Audiometric requirements have changed greatly for adults
Why was this expansion appropriate?

- FDA approval of a hybrid device signifies recognition that:
  - CI Hybrid electrode more likely to result in more preserved residual hearing than traditional CI electrode
  - Opened door for patients with greater pre-operative hearing to receive Hybrid CI
  - Studies show hybrid hearing provides improved speech recognition in noise compared to traditional CIs, leading to greater attention being paid to testing in noise
Auditory Brainstem Implants (ABI)

• Surgically implanted electronic device providing sound for someone with non-functioning auditory nerve
  – Unable to use cochlear implant which requires a working auditory nerve
  – Originally approved only for adults with neurofibromatosis type II (NF2)

• Similar to CI but electrical stimulation of brainstem (rather than the cochlea)

• Outcomes are typically not as good as CI
Auditory Brainstem Implant
ABI Wider Adoption

- First developed in 1979, FDA approved Cochlear device in 2000 for individuals 12 years+ w/ NF2
- Other devices being studied
- Around 1500 ABIs in use around the world
- FDA approved *clinical trial* for children in 2013
- Longer history of pediatric use in Europe
- Children typically use sign or Cued Speech in conjunction with ABI but there are a range of outcomes in children and adults
  - Typically not open set as in CI
What about health insurance coverage?

- 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 before recent change
  - ≤ 60% in best aided condition (typically bilateral)
  - ≤ 50% in ear to be implanted
- 2014 FDA change (for Hybrid) allows 80% in contralateral ear
Medicare and Cochlear Implants
Medicare and Cochlear Implantation

• Federally funded health insurance program for people 65+
• Medicare has its own criteria for CI Coverage
  – Limited benefit from hearing aids with 40% or less words in sentences in best aided in ear to be implanted
• Clinical trial allows up to 50% in ear to be implanted and 60% bilaterally
Research Project: Medicare CED

- ACIA sponsored development of Coverage with Evidence Development study approved by Medicare
- Study is registered on clinicaltrials.gov
- [https://clinicaltrials.gov/ct2/show/NCT02075229](https://clinicaltrials.gov/ct2/show/NCT02075229)
- Purpose: To evaluate safety and efficacy of CIs for older adults using expanded CMS criteria
- If approved, CMS and FDA guidelines will be more equivalent
CI surgery is safe in older adults

• Studies document that cochlear implants are safe and effective for people over age 65
• No significant differences in outcomes
• Older adults do not experience more complications from surgery than younger people
• Lots of benefits including cognitive health, maintaining social contact, supporting activities of daily living
Hearing better makes a difference

- Older adults who receive CIs show an increase in confidence at work and at home, increases in social activities, and overall improvement in quality of life.
Centers Involved in the Medicare 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
Patient Eligibility Medicare Expansion Study

- 65 years of age or older
- Bilateral moderate-to-profound sensorineural hearing loss in low frequencies (up to 1000 Hz) and profound sensorineural hearing loss in 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
- Spoken English as primary language
- Cognitive ability to use auditory clues and willingness to undergo rehabilitation
- No medical contraindications for surgery
Have you been told you’re “not deaf enough” even though you have difficulty hearing?

- Contact dsorkin@acialliance.org or sthomas@acialliance.org
- We will put you in touch with the closest participating study center
- We may ask you to send your most recent audiogram prior to traveling to a distant center
- After initial testing (6-12 months), you may return to your home center for management
- Insurance coverage is the same as under Medicare
Why is it wrong to wait?

- Too many people are waiting...the average delay between onset of severe/profound hearing loss and CI is 10 years

- Duration of deafness is one of the most significant predictors of outcomes with a CI: shorter duration of deafness results in better outcomes
How to go forward if you think you may be a candidate for the Medicare Clinical Trial

- Many audiologists are hesitant to refer based on early candidacy criteria and unfamiliarity with CI
- Your candidacy is unknown until you’ve been tested at a CI center
- CI Centers may be willing to review your audiogram before the apt to determine if an evaluation is recommended
- Typically people are happy they went for an evaluation, even if they are not a candidate, as they receive information
- Unlike a hearing evaluation, testing for CI candidacy is typically covered by health insurance (including Medicare)
What contributes to successful outcomes?
Factors that contribute to successful CI use among older adults

- Implantation soon after meeting candidacy
- Realistic (but optimistic) expectations by patient and family members
- Family support
- An appropriate rehabilitation program
www.ACIalliance.org
(on home page or Member Center)

Cochlear Implant Rehabilitation for Adults

Naama's Blog
Topics Covered To Date

1. Welcome/Naama's Background
2. Why Adult Rehabilitation is Important
3. The Hearing Assessment
4. Constructive Communication
5. Listening to the Sounds Around You
7. Self Learning Tips: Part II
8. Unilateral Hearing
9. Adult CI Support Groups: Part I
10. Adult CI Support Groups: Part II
11. Emotional Impact of Cochlear Implantation
Using Recorded or Other Materials in Self-Learning Rehabilitation

There are a number of recorded and written auditory rehabilitation programs that were developed specifically for rehabilitation post cochlear implantation. You may also use other general materials such as books on tape (in different lengths and linguistic levels but preferably with minimal background music or noise) or English as a Second Language teaching materials such as Rosetta Stone®.

- Using **written materials** will be more effective if you are able to be creative and adaptive in their use. In addition to repetition, be aware of the appropriate speech rate of the stimuli presentation. You can use the same stimuli in a more normal (higher) speech rate with time, as your speech perception skills improve. Similarly, you can use more speech-reading (lip-reading) cues during the first period of training, moving towards auditory-only perception with time. Another way to adjust the existing
Summary

- Cochlear implants are under-utilized in the adult population and even more so in aging adults.
- Studies are underway to expand criteria, improve devices, and increase awareness of this life changing technology.
- Remain aware of changes in technology and candidacy so that you can follow up appropriately.
Questions?

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• Thank you!