Cochlear Implants 2016: Advances in Technology, Candidacy and Outcomes

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AMERICAN COCHLEAR IMPLANT ALLIANCE
Research. Advocacy. Awareness.

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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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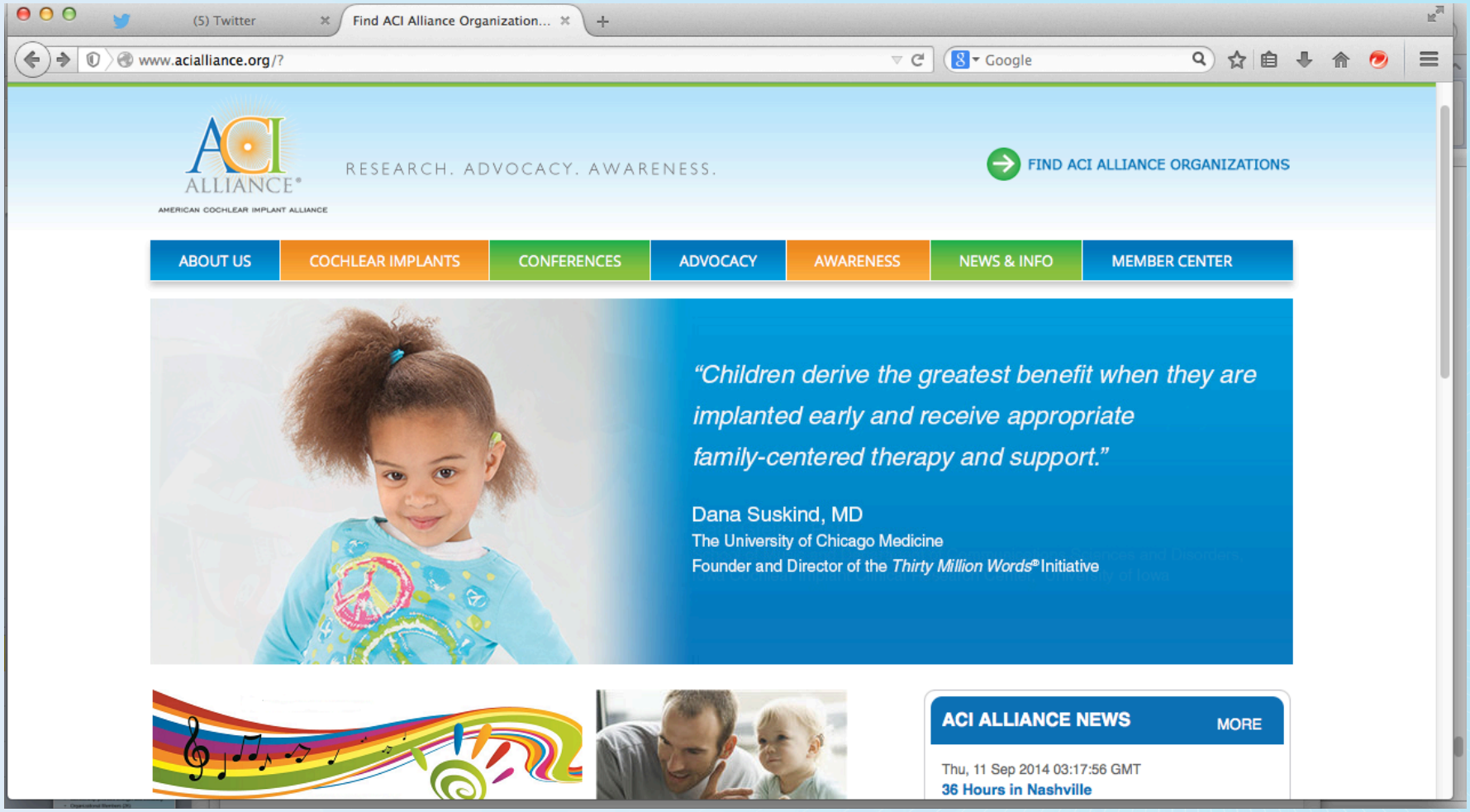
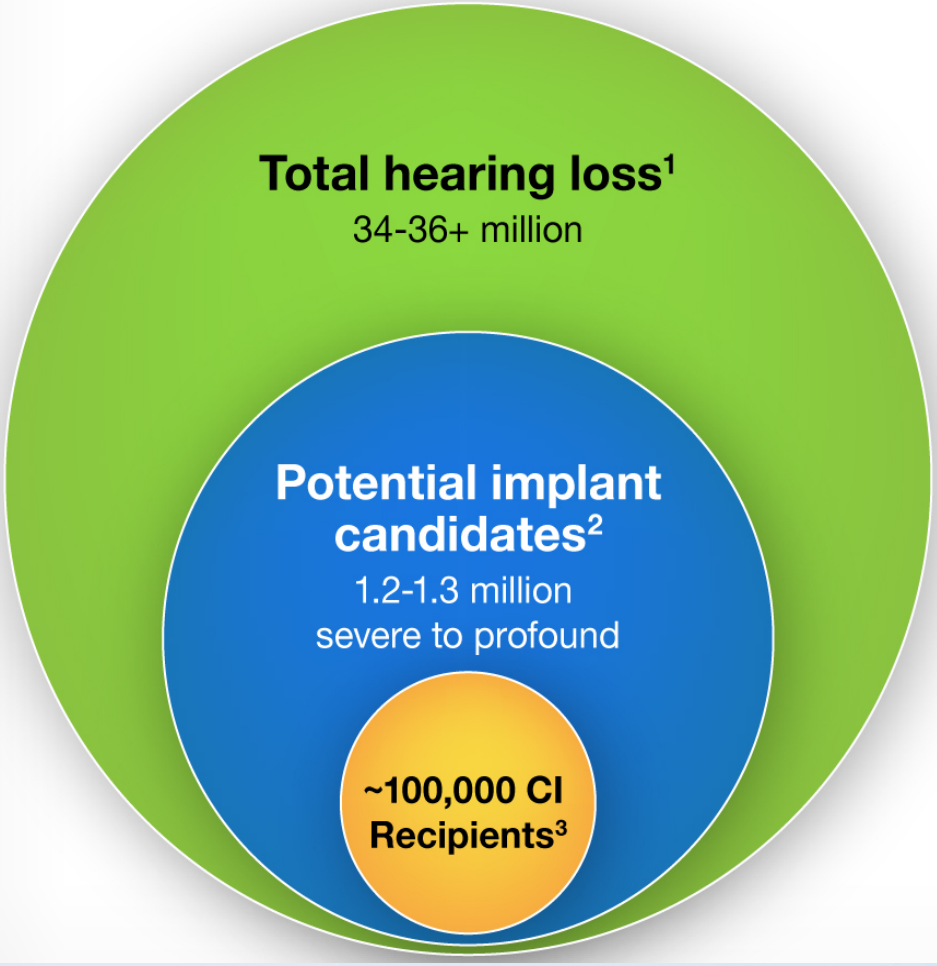


US Cochlear Implant Utilization



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

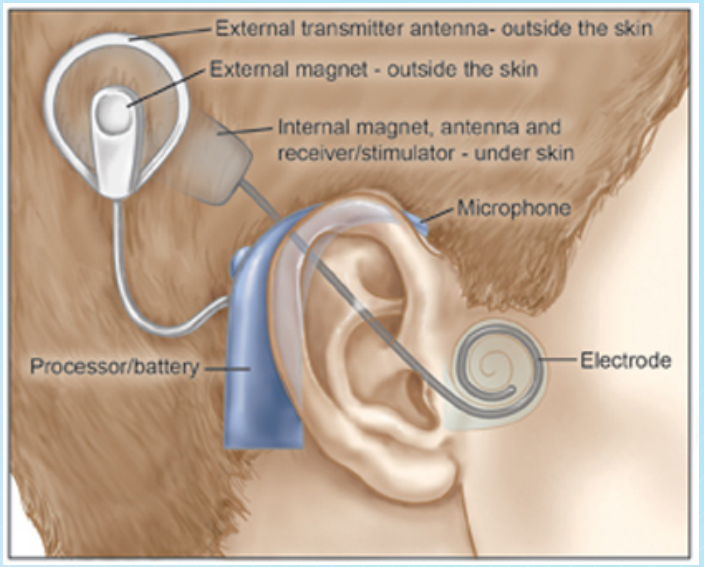
3 67k, (41.5k adults and 25.5k children) have received CIs in the U.S, NIDCD website June 2010, iData Research 2010 Report: US Market for Hearing Aids and Audiology Devices 67,241 have been treated with a cochlear implant

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 infor to adults and children with varying degrees of hearing loss.
- First approved by the FDA for use in adults in 1985 and for use in children in 1990
- 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

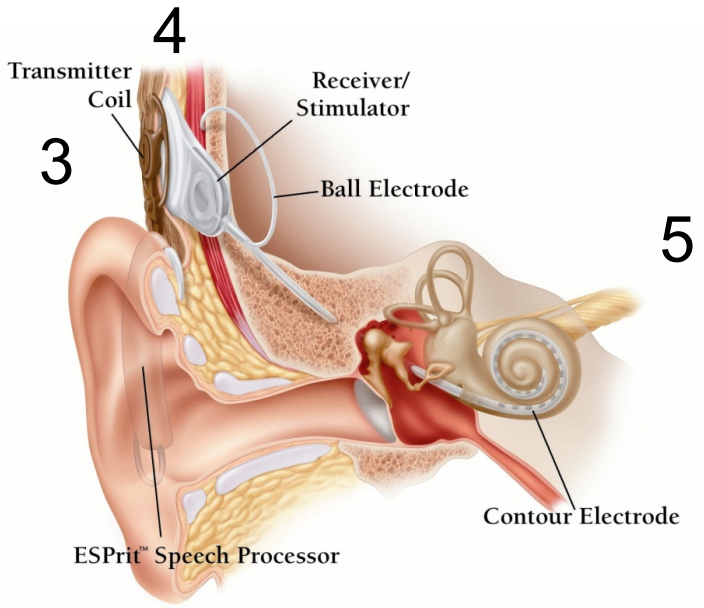
1. **Sound is picked up by the microphone.**

2. **The processor filters and codes the signal.**

3. **The signal is sent up the cable to the coil.**

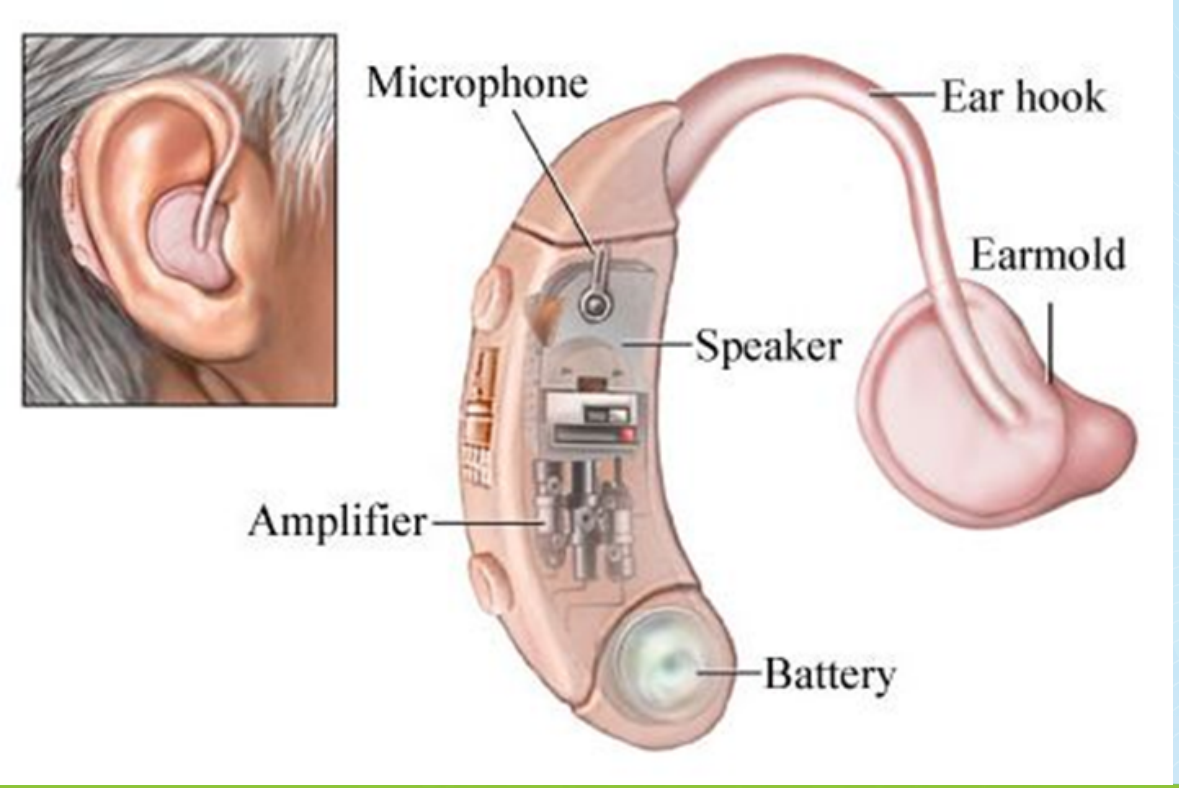
4. **The signal is then sent via radio frequencies to the internal device.**

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

Hearing Aid	Cochlear Implant
Delivers information acoustically	Delivers information electrically
For people w/mild-profound hearing loss	For people w/mlld-profound hearing loss who have minimal benefit from hearing aids
Typically do not require surgery	Requires surgery
Individuals may not be able to hear certain sounds (typically high frequency) even using powerful hearing aids	Provides sound at all frequencies
Not typically covered by health insurance	Covered by most health insurers including Medicare

History of Cochlear Implant Candidacy Expansion

Historical Expansion of FDA Guidelines

Criteria	1985	1990	1998	2000	2014
AGE of implantation	Adults 18 yrs +	Adults & Children 2 yrs +	Adults & Children 18 mos +	Adults & Children 12 mos +	Adults only for Hybrid
ONSET of hearing loss	Post linguistic	Post linguistic adults/ Pre & Post Linguistic Children	Adults & Children Pre & Post Linguistic	Adults & Children Pre & Post Linguistic	Adults & Children Pre- and Post- Linguistic
DEGREE of hearing loss	Profound	Profound	S/P Adults Profound Children	S/P Patients 2 yrs+ Prof Child<2 yrs	Nucleus Hybrid: Normal to Moderate in low freq; S/P mid to high frequencies
SPEECH SCORES	0%	0%	40% or less	Sentences score 50% or less in ear to be implanted, ≤ 60% in best aided condition	CNC word score >10% but less than 60% in ear to be implanted; <80% CNC words in contralateral ear

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

Hearing Loss and Burden of Disability with Aging - Morbidity

Genther et al, JAMA, 2013

- **Study**
  - **2005-2009 & 2009-2010 NHANES data, >70y**
  - **Outcome: hospitalization last 12 mo, burden of disability last 30 days**
  - **Normal hearing (529); mild HL (590); moderate HL (446); severe HL (97); profound HL (7)**

Hearing Loss and Burden of Disability with Aging - Morbidity

Genther et al, JAMA, 2013

	Base Model[a]			Base Model + Demographic Factors[b]			Base Model + Demographic Factors + Cardiovascular Risk Factors[c]		
	No.[d]	OR (95% CI)	*P* Value	No.[d]	OR (95% CI)	*P* Value	No.[d]	OR (95% CI)	*P* Value
Hospitalizations in past 12 mo									
Any (yes or no)	1666	1.33 (1.08-1.65)	.008	1658	1.34 (1.09-1.65)	.006	1646	1.32 (1.07-1.63)	.01
No. of hospitalizations (0, 1, >1)	1666	1.36 (1.10-1.67)[e]	.005	1661	1.36 (1.11-1.68)[e]	.005	1649	1.35 (1.09-1.68)[e]	.007
Self-reported disease burden for >10 d in past 30 d									
Poor physical health	1570	1.32 (1.06-1.64)	.02	1562	1.35 (1.06-1.73)	.02	1552	1.36 (1.06-1.74)	.02
Poor mental health	1568	1.25 (0.97-1.61)	.09	1560	1.54 (1.19-1.99)	.002	1550	1.57 (1.20-2.06)	.002
Inactivity due to health	1570	1.09 (0.72-1.67)	.66	1562	1.04 (0.68-1.58)	.87	1552	1.02 (0.67-1.56)	.93

HL per 25 dB + age **+sex, race, education, income** **+CV risk factors**

Hearing Loss and Burden of Disability with Aging - Cognition

Lin et al, JAMA Int Med, 2013

- Health ABC study: Prospective observational study starting 1997

- 1,984 adults with HL (PTA>25 dB), mean age 77.4y, HL
  - 30-40% higher rate of annual decline in cognitive measures
  - 24% increased incidence of cognitive impairment

- PTA correlated to cognitive decline and risk of cognitive impairment

Hearing Loss and Burden of Disability with Aging – Mediators

- **Depression**
- **Isolation**
- **Attention burden**

From: **Improvement of Cognitive Function After Cochlear Implantation in Elderly Patients**

JAMA Otolaryngol Head Neck Surg. 2015;141(5):442-450. doi:10.1001/jamaoto.2015.129

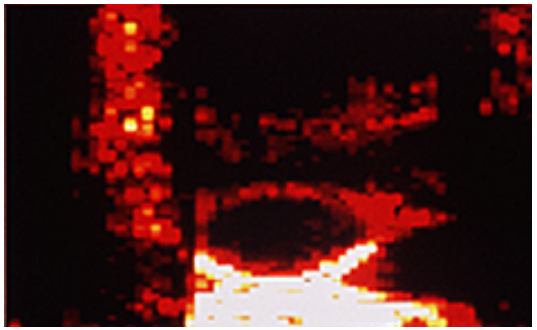
No. of abnormal test results 12 mo after implantation	No. of abnormal test results before implantation				
	0	1	2	3	**Total**
0	17	9	8	1	**35**
1	6	12	6	5	**29**
2	0	4	5	10	**19**
3	0	2	0	2	**4**
Total	**23**	**27**	**19**	**18**	**87**

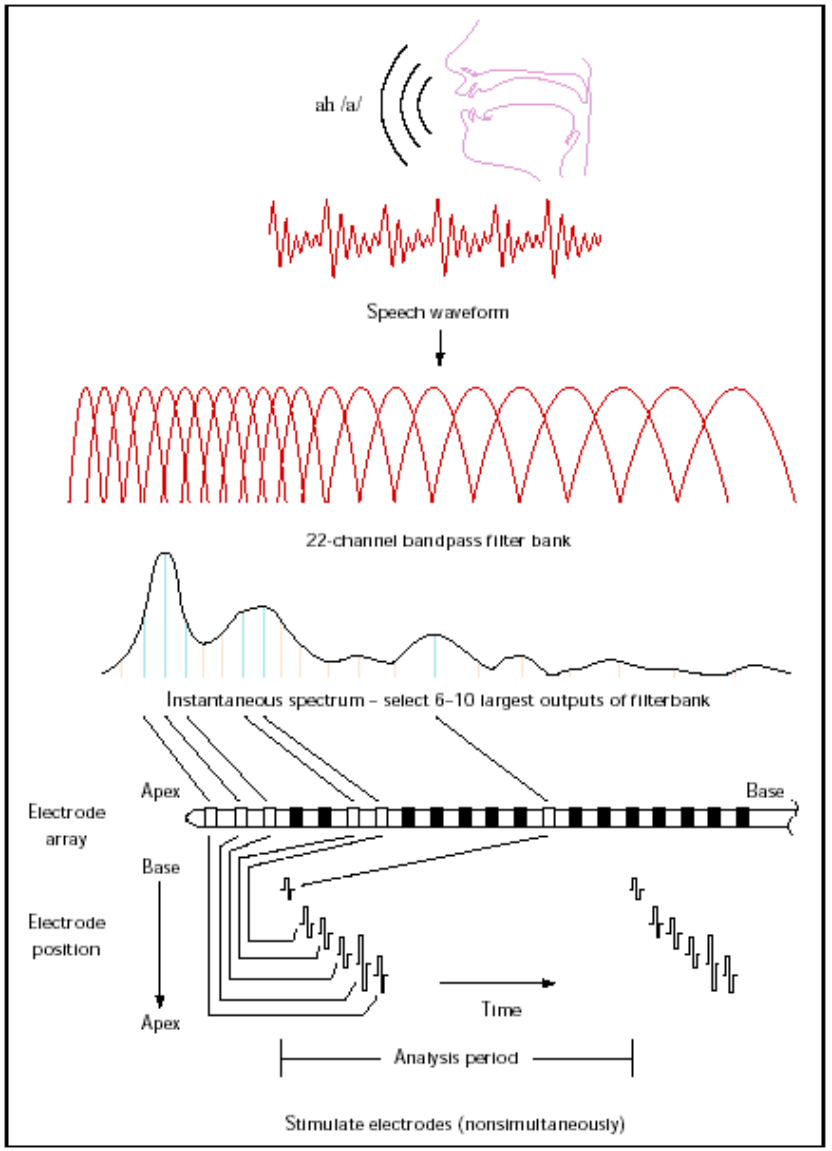
Figure Legend:

Cognitive Test Results Before and After Cochlear ImplantationIndividual cognitive outcomes at 12 months plotted in relation to the data obtained before cochlear implantation. Among the 91 patients who underwent the 6 cognitive tests before implantation, data were missing at 12 months after implantation for 4 individuals: 3 patients with 2 abnormal test scores, and 1 patient with 1 abnormal test score before implantation. Tan shading indicates better cognitive results after implantation; light blue, unchanged results; and light orange, poorer results.

Speech Processing

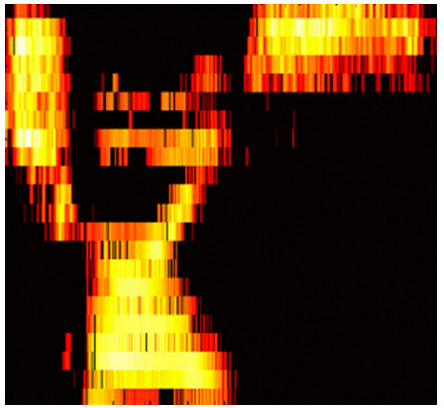
"choice"





Acoustic Features Represented:
Frequency
Timing
Intensity

"choice"



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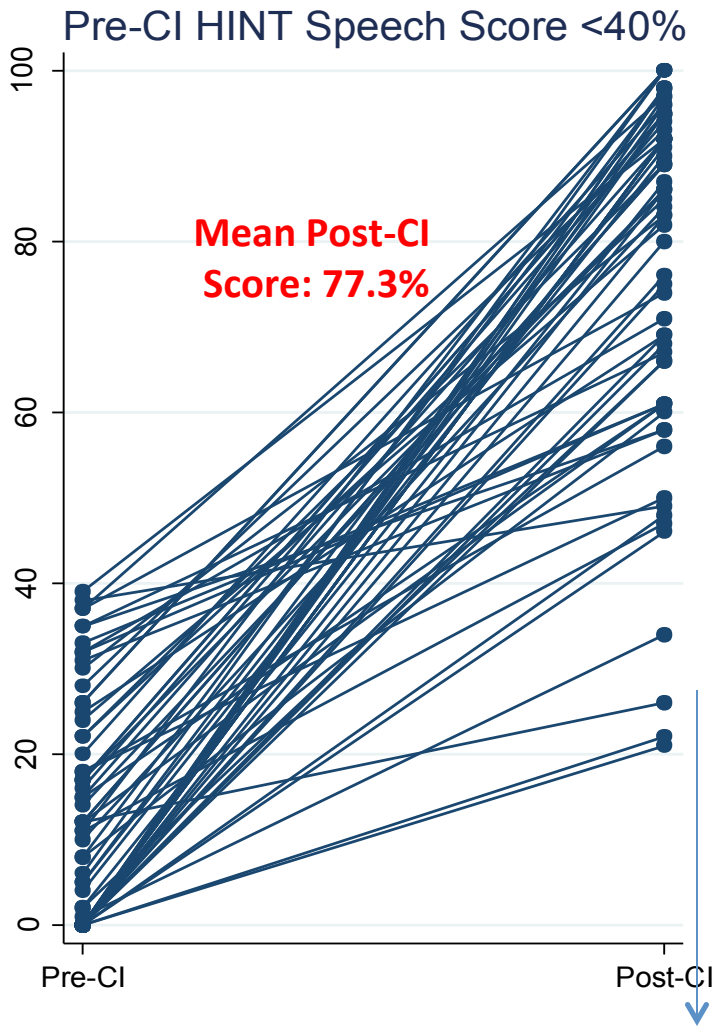
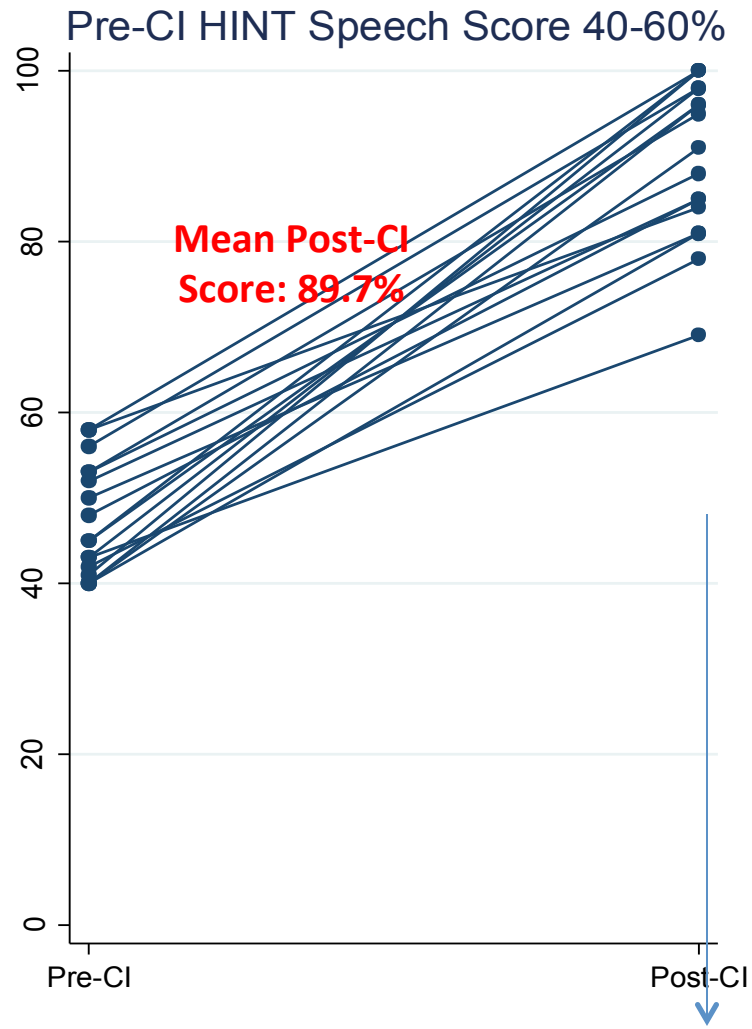
Francis and Niparko, Ped Clin NA, 2003

Relationship between Post-CI Speech Scores and Previous (<40%) vs Expanded (40-60%) Speech Criteria





Relationship between Post-CI Speech Scores and Previous (<40%) vs Expanded (40-60%) Speech Criteria

	N	Difference in Post-CI Speech Score in Individuals with Pre-CI Speech Score 40-60% vs. < 40% β (95% CI)
Unadjusted	83	12.4* (2.2 – 22.7)
Adjusted for age at CI & onset of hearing loss	79	10.0* (0.4 – 19.6)

* $p<0.05$

When adjusted for age at CI and age at onset of HL, the 40-60% group experiences a 10% larger gain on average compared to the <40% group

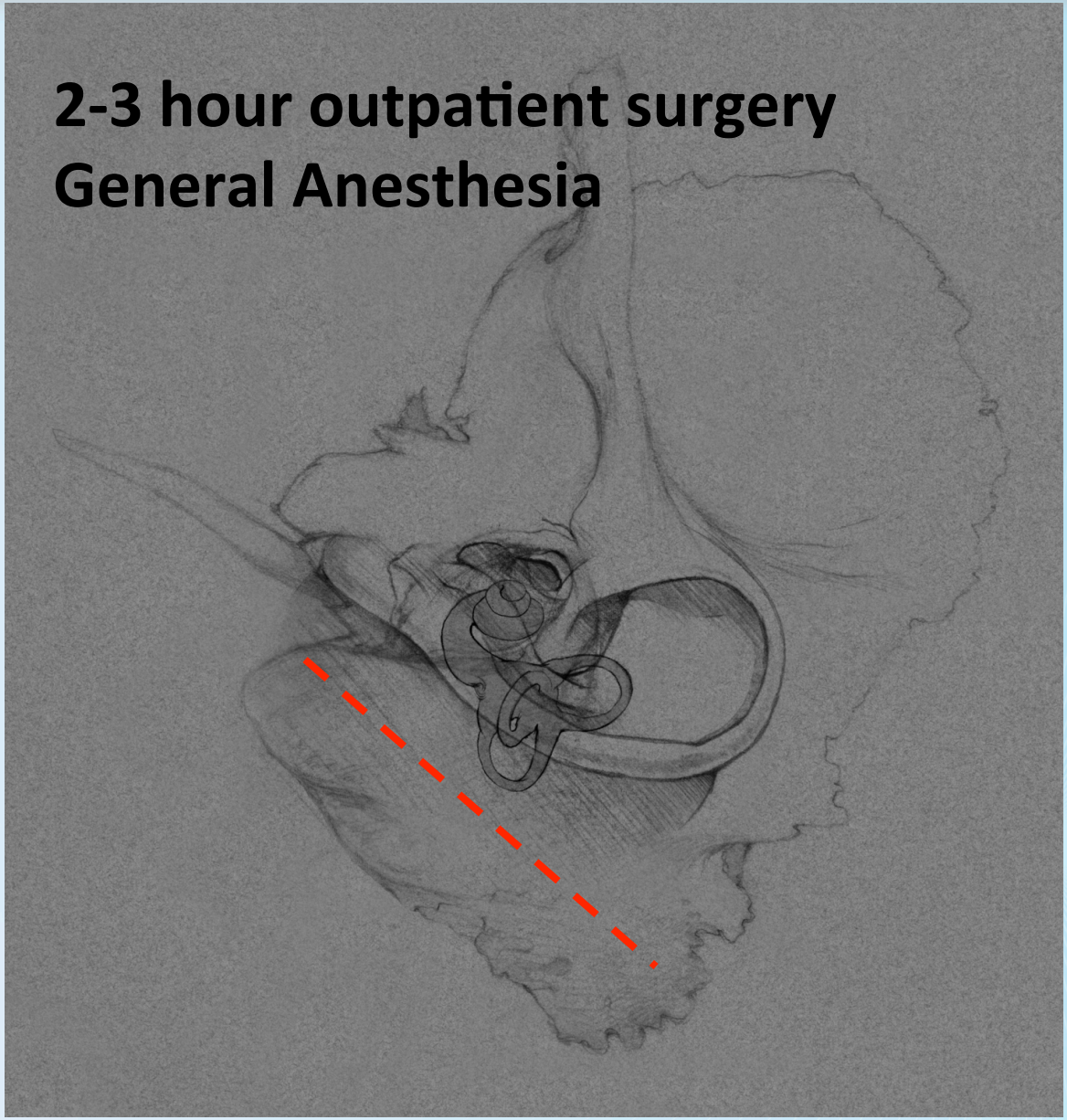
FDA Approved Devices

Advanced Bionics Corporation
www.advancedbionics.com/us/en/home.html

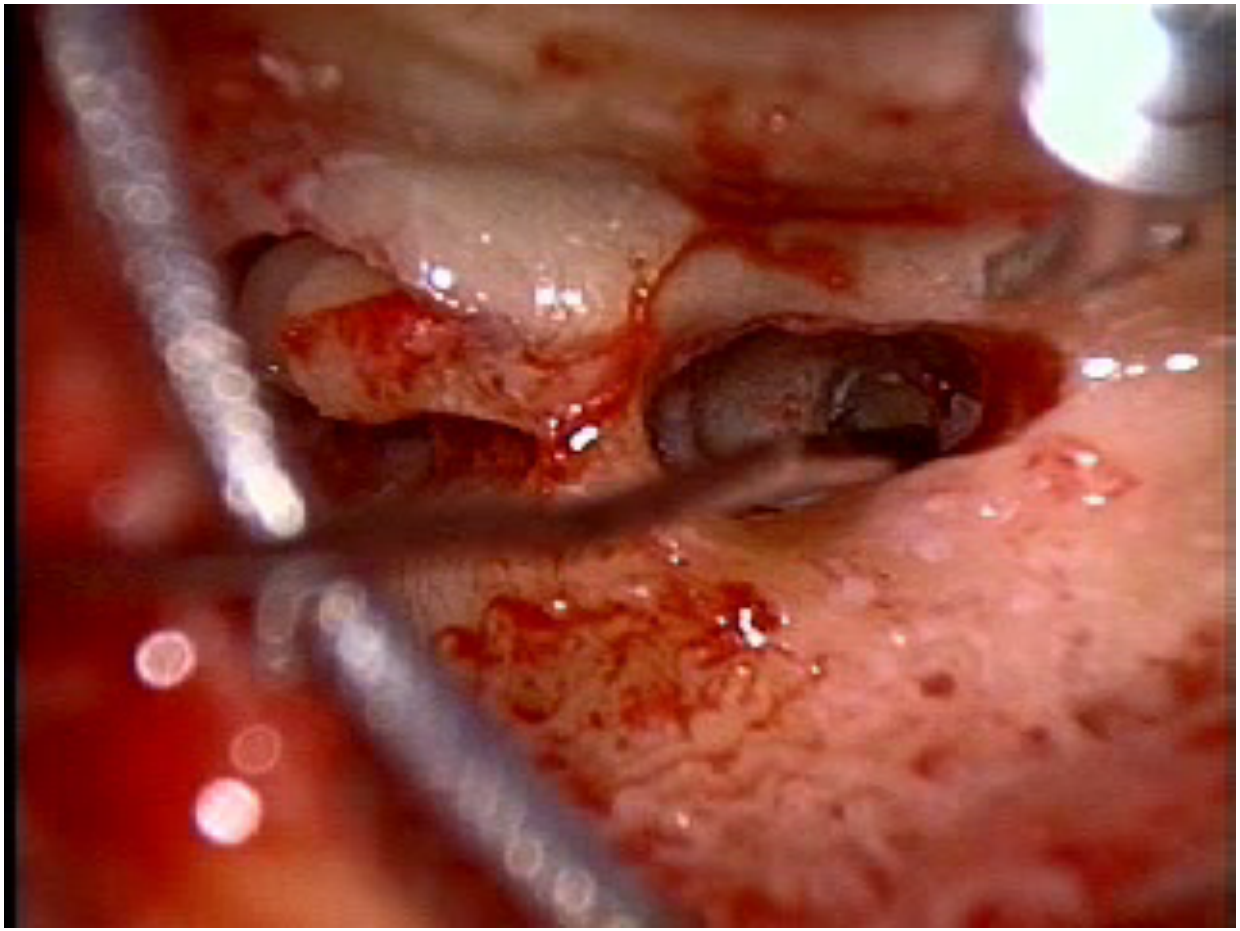
Cochlear Corporation
www.cochlear.com/wps/wcm/connect/us/home

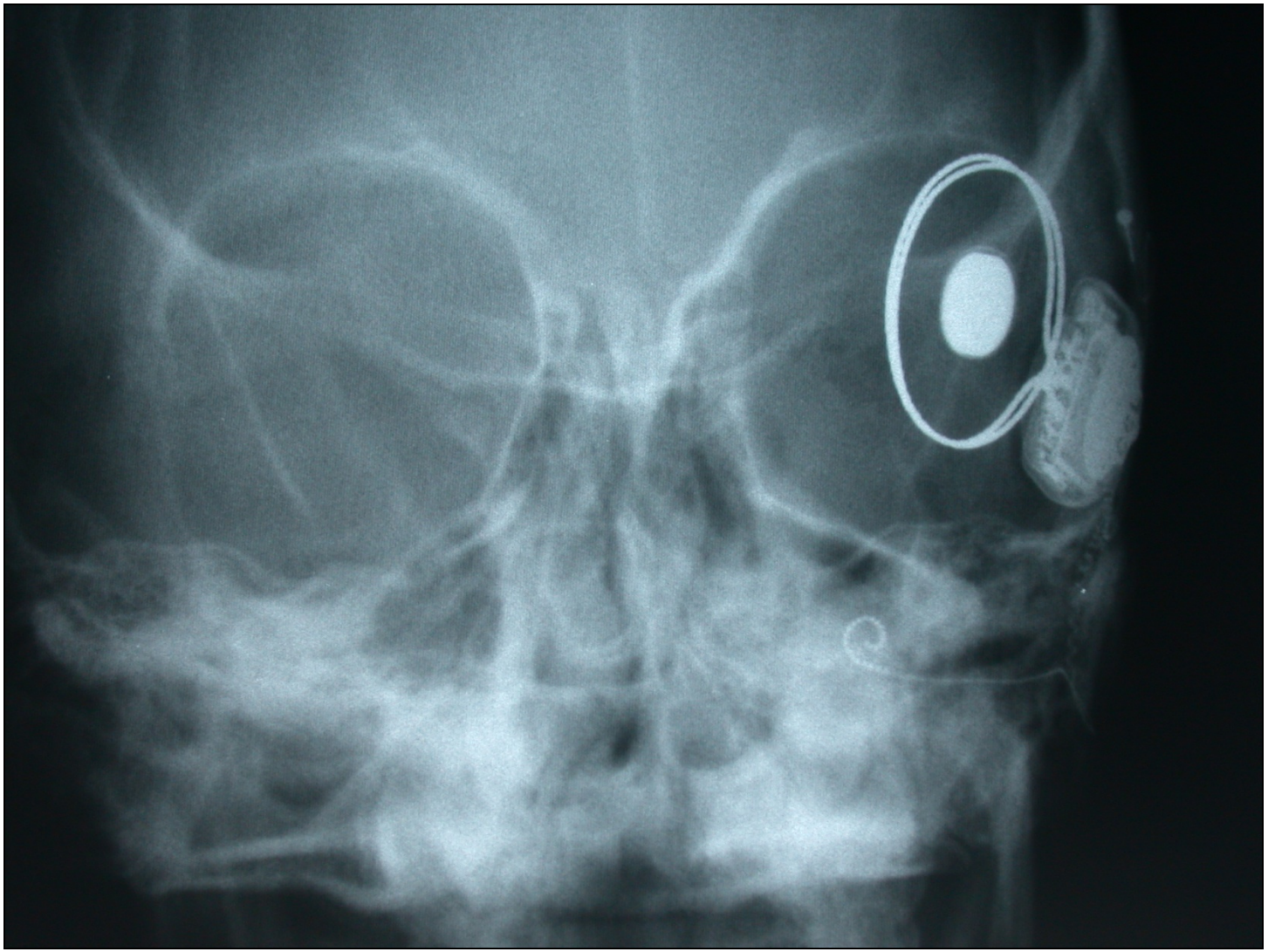
MED- EL Corporation
www.medel.com/us

2-3 hour outpatient surgery
General Anesthesia



CI Surgery





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Auditory Rehabilitation

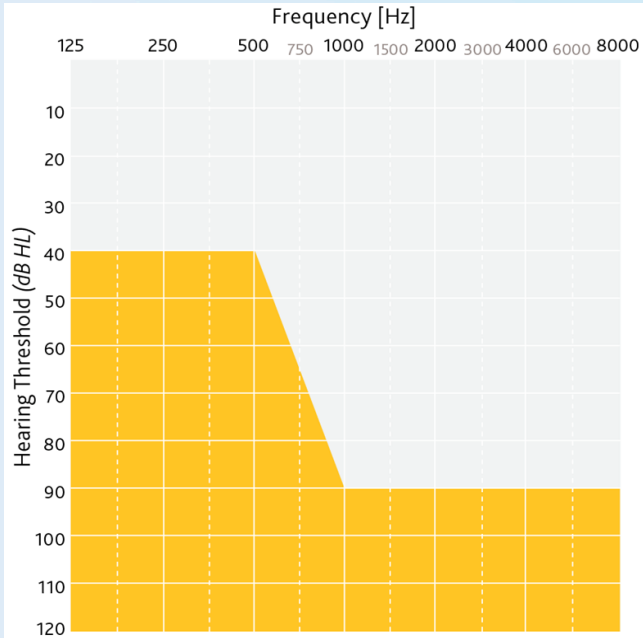
Speech Processor

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**?*

Ear mold

Traditional CI



ADULTS *(18+ Yrs)*

- *Moderate-to-profound SNHL in both ears*
- *Limited benefit from amplification defined by preoperative test scores of ≤ 50% open-set sentence recognition in the ear to be implanted and ≤ 60% in the opposite ear or binaurally*

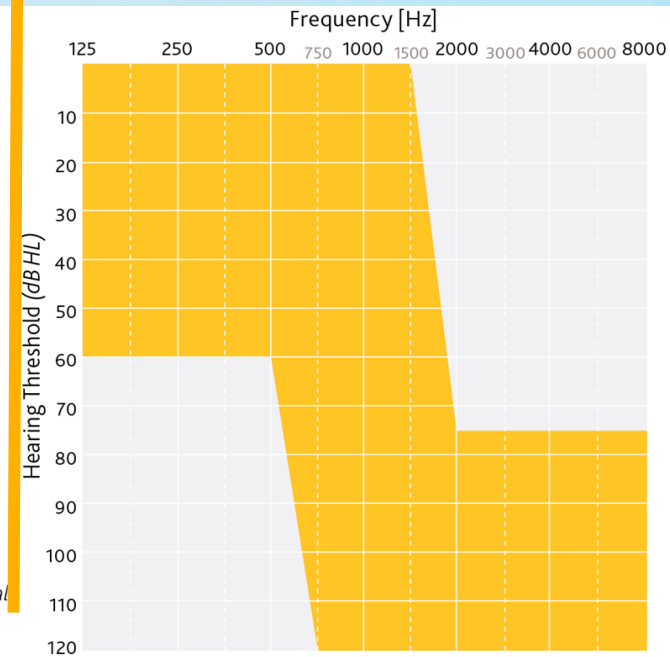
CHILDREN *(2-17 yrs)*

- *Severe-to-profound SNHL in both ears*
- *Limited benefit from binaural amplification trial with MLNT/LNT scores ≤ 30%*

CHILDREN *(12-24 mos)*

- *Profound SNHL*
- *Limited benefit from binaural amplification trial based on MAIS/IT-MAIS*

Hybrid for Adults



ADULTS *(18+ Yrs)*

- *Severe to profound high-frequency SNHL in both ears*
- *Limited benefit from appropriately fitted bilateral hearing aids*
- *Aided CNC word recognition score between 10% and 60%, inclusively, in the ear to be implanted*
- *Contralateral ear equal to or better than that of the ear to be implanted but not more than 80% correct and PTA (2,3,4 kHz) ≥ 60 dB HL*
- *Unilateral use only*

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

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 it's 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
- 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?

- Hopkins is the closest participating study center
- We can review your most recent audiogram prior to visiting Hopkins
- 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 w/ CI
- Your candidacy is unknown until you've been tested at a CI center
- Hopkins audiologists will 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)

If you think you may be a candidate for the Medicare study:

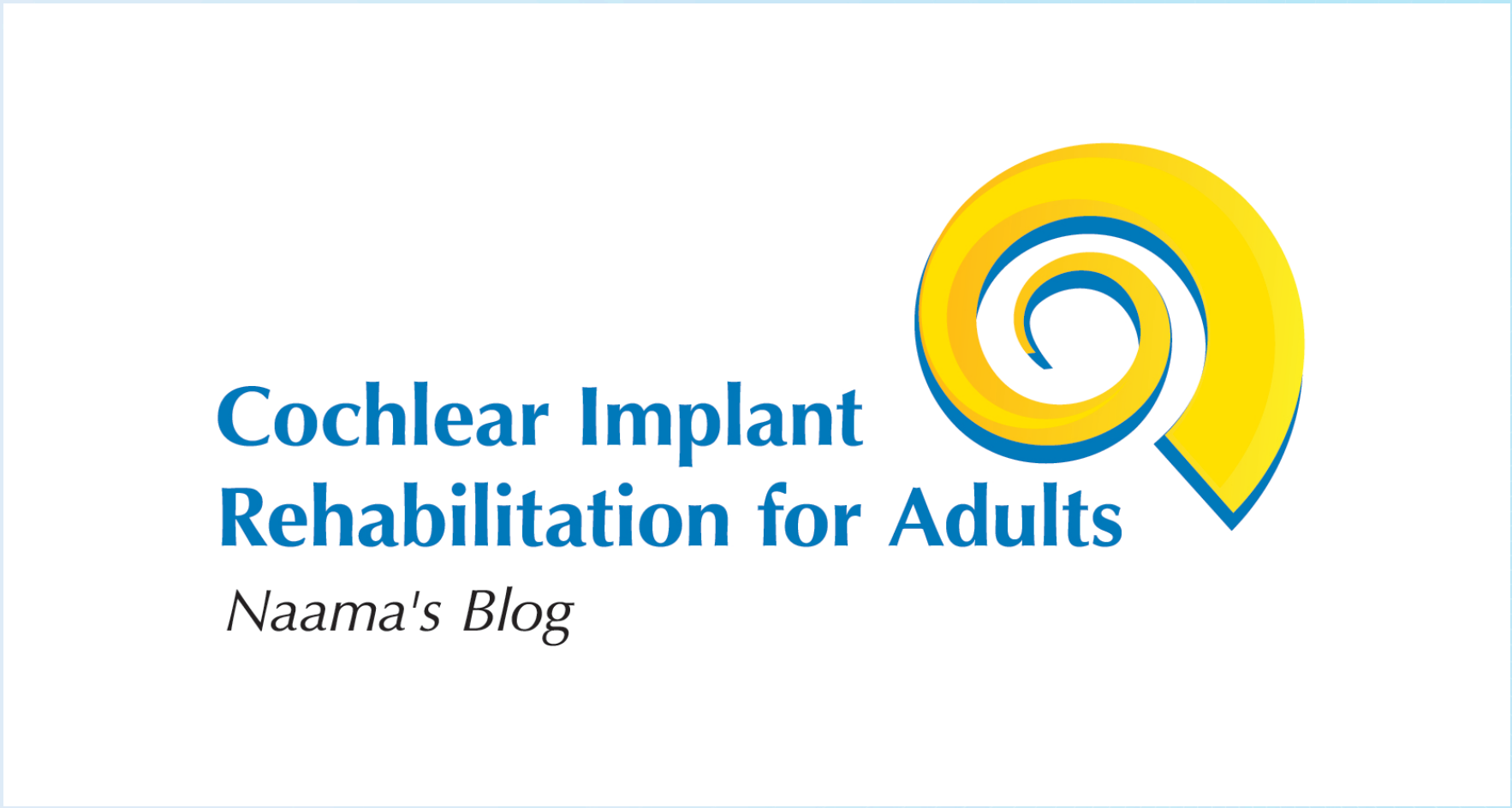
- You may send your audiogram in advance to a Johns Hopkins audiologist who can take an advanced look and indicate if a visit to the clinic is encouraged:
  - **Email** your audiogram to Jennifer Yeagle jyeagle@jhmi.edu
  - Fax audiogram to Jennifer Yeagle at: **410.614.9167**

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)



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
6. Self Learning Tips: Part I
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

Cochlear Implant Rehabilitation for Adults

Naama's Blog

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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More information on the Medicare study (and on CI) on the website under Research:

www.ACIAlliance.org

Twitter @acialliance

- Thank you!