

Cochlear implantation: Audiological issues

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Purpose

- To provide information regarding audiological management and assessment of adult CI patients, including preoperative determination of candidacy and post-operative evaluation of performance.

Overview

- Historical overview of CI candidacy
 - FDA
 - Medicare
- Understanding Candidacy Criteria
 - Audiometric data
 - Speech recognition
- Post-Operative Management of CIs
- Patient Results
- Bilateral versus Unilateral Implants

FDA Candidacy for a Cochlear Implant

- The FDA oversees the selling, distribution, labeling, and marketing of cochlear implants, and determines if the specific wording used in device labeling, including indications for its use, is appropriate.
- This wording is approved by the FDA following intensive clinical trials and data collection on large numbers of patients.

FDA criteria

- The specific indications for use for a product vary depending on when FDA approval was received and the test measures employed in the clinical trial.
- Since their initial approvals by the FDA, many cochlear implants have been changed by Supplements.

Sample FDA indications for use in adults: Nucleus 5

- A moderate hearing loss in the low frequencies and a profound hearing loss in the mid to high speech frequencies bilaterally.
- Little or no benefit from hearing aids as defined as a score of $\leq 60\%$ correct in the best-aided listening condition on tape-recorded tests of open-set speech recognition when using hearing alone and a score of $\leq 50\%$ in the ear to be implanted.
- No medical or radiological contraindications.
- Motivated patient and possession of appropriate expectations.

Medicare Criteria

- Previously, Medicare required recipients to score <30% to qualify for a cochlear implant. In April, 2005, this minimum score was increased to <40% and up to 60% allowable if participating in a clinical trial.

Current Medicare Criteria

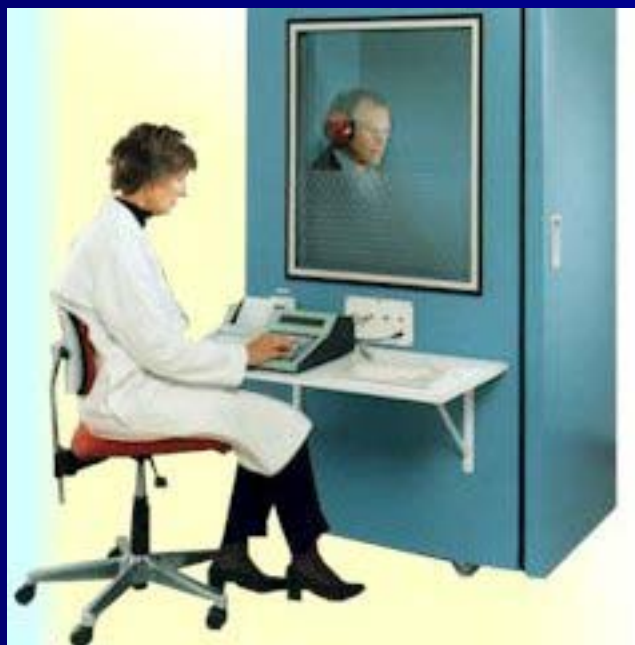
- Individuals with moderate-to-profound hearing loss with hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification.
- Individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct, where device was implanted in an acceptable clinical trial. (See Publication 100-03, chapter 1, section 50.3, for the specific coverage criteria).

Preoperative Test Procedures

- Audiological Assessment (hearing test)
- Determine appropriateness of hearing aids
- Evaluation of speech recognition with hearing aids
- Medical Evaluation
- CT Scan or MRI
- Vestibular Testing
- Counseling

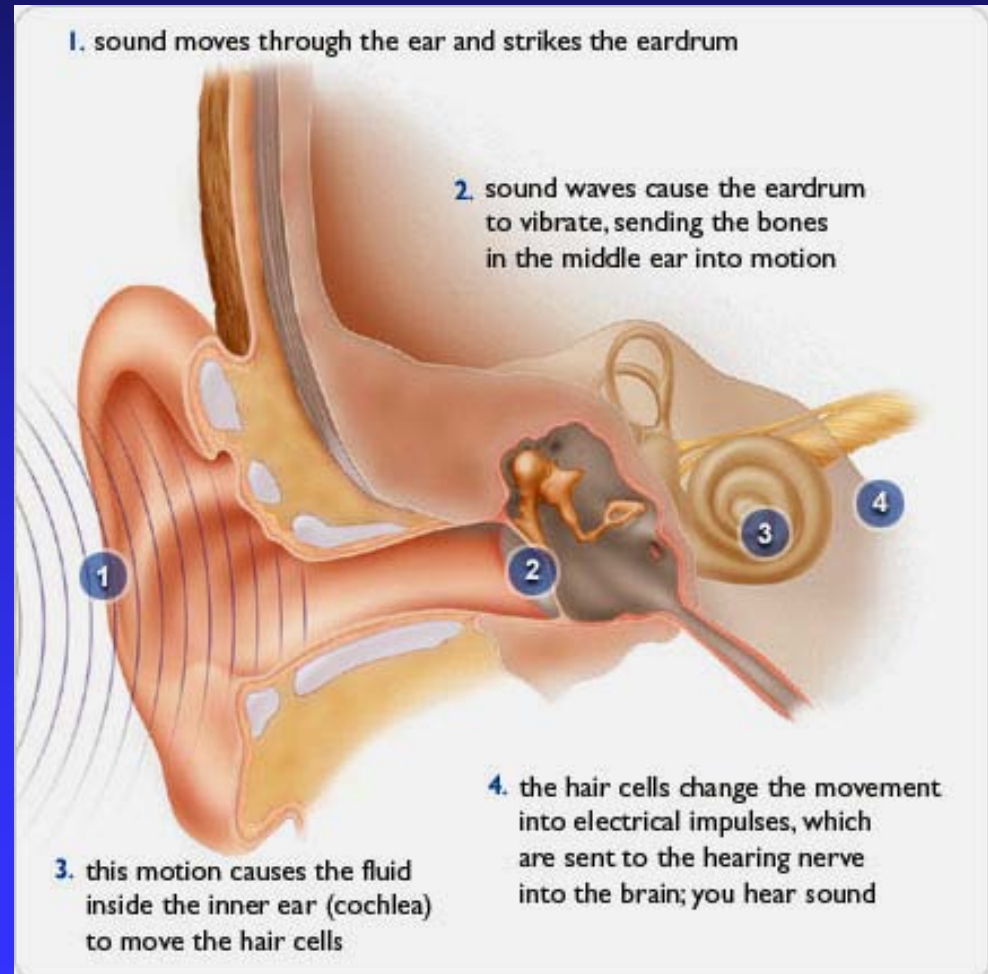


Moderate to profound hearing loss



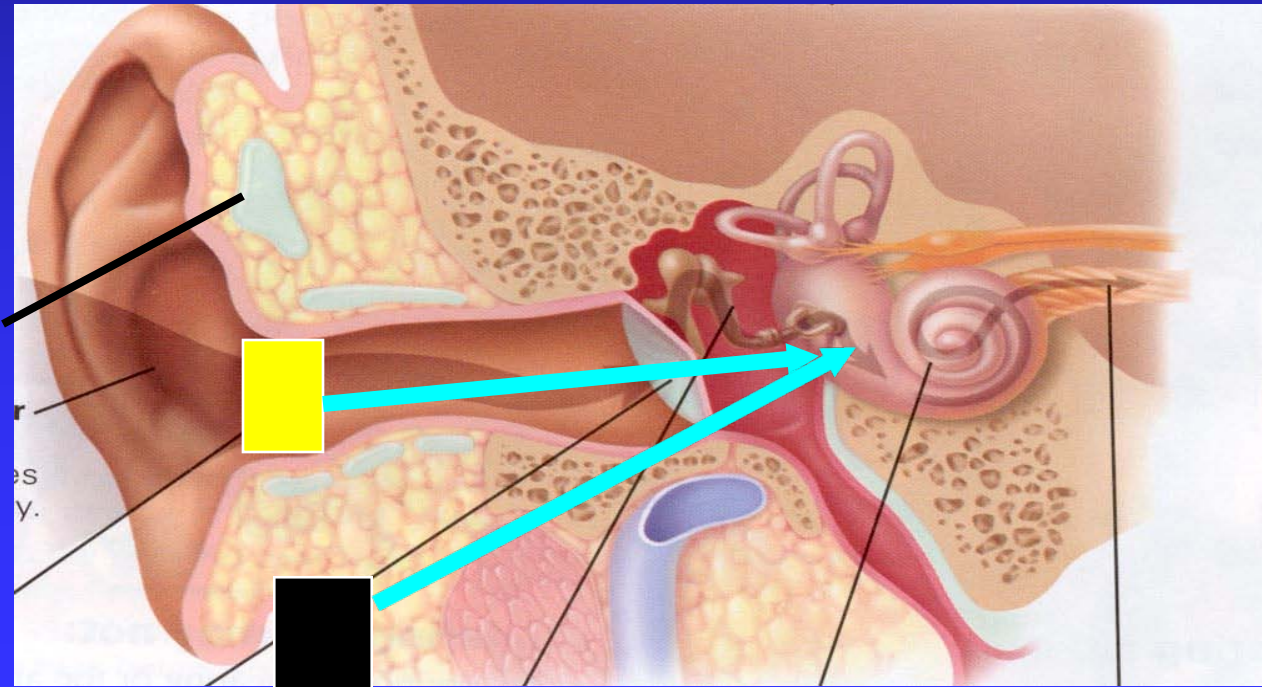
Moderate to profound hearing loss determined by Audiometric Testing

- Provides information regarding the site of lesion and the severity of the damage.
- Helps determine the optimal type of intervention.



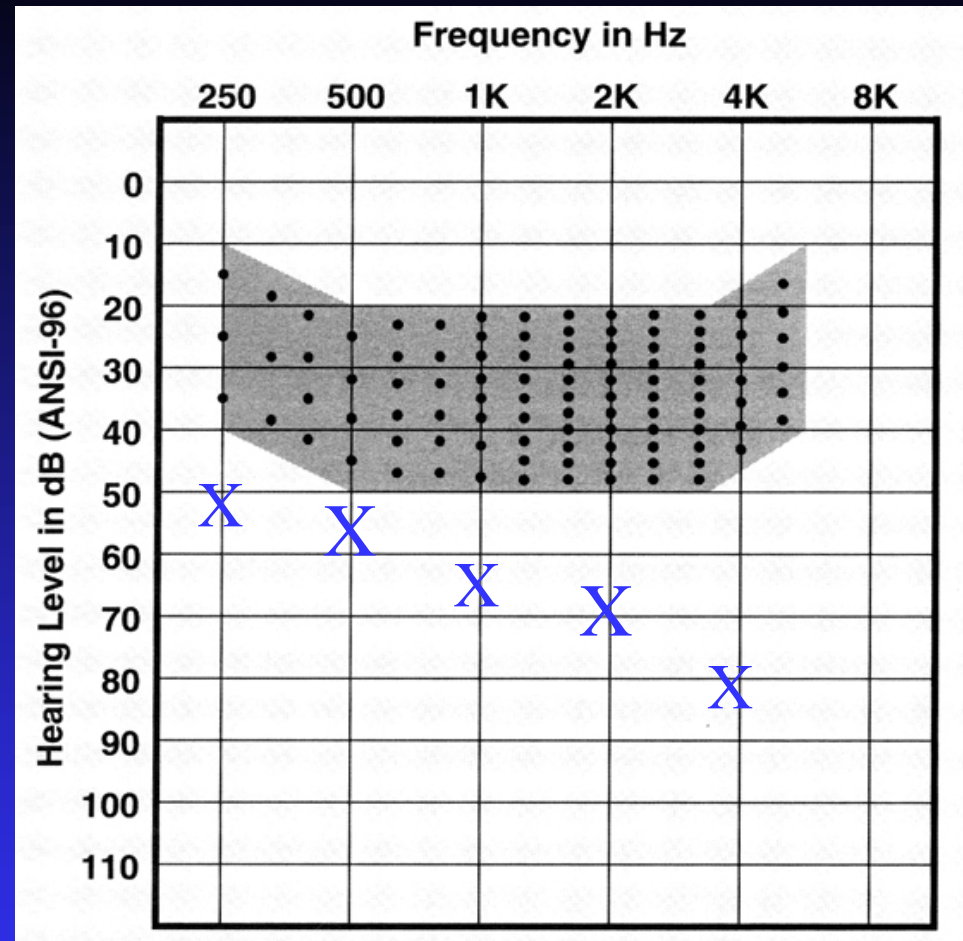
Audiometric testing

- Determines the softest sounds perceived by a listener at frequencies important for communication.
- A pure tone is presented via earphones or a bone oscillator, transmitting the signal to the inner ear.



- The softest sounds perceived by the listener (thresholds) are plotted on an Audiogram

Soft
↓
Loud



Low → High Pitch

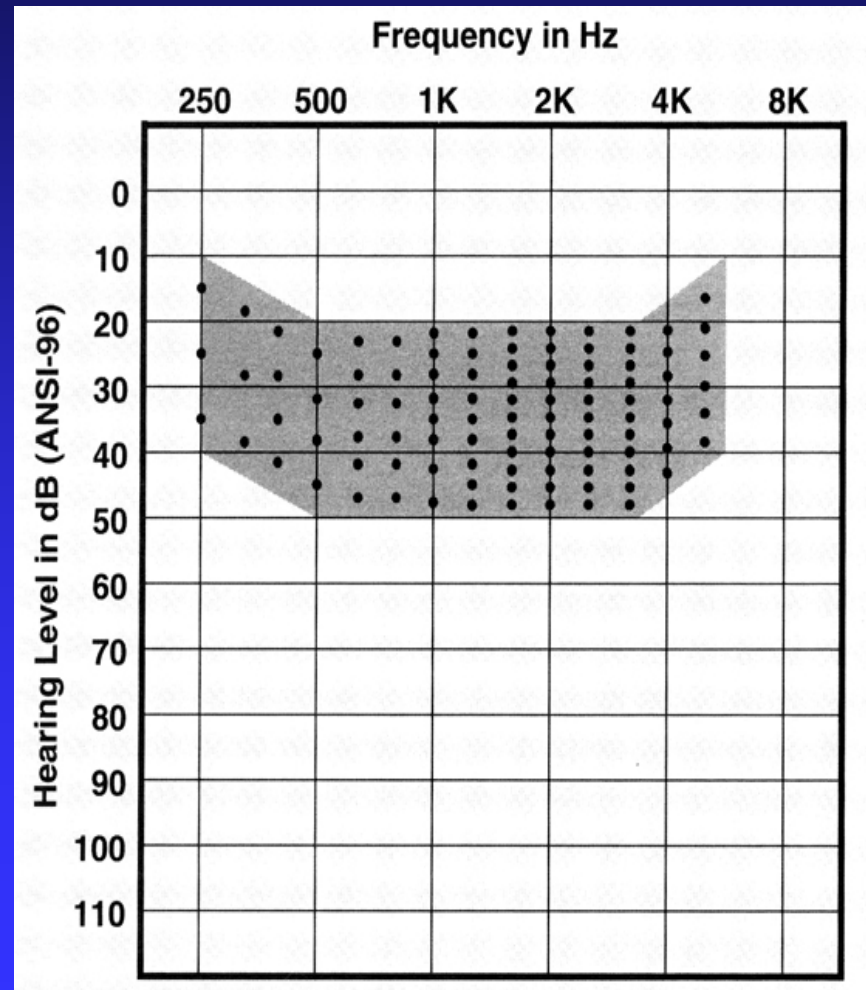
Audiometric test symbols

■ Ear	Right	Left
■ Colors	red	blue
■ Air conduction	0	X
■ Bone conduction	<	>
■ Masked Air	Δ	□
■ Masked Bone	[]

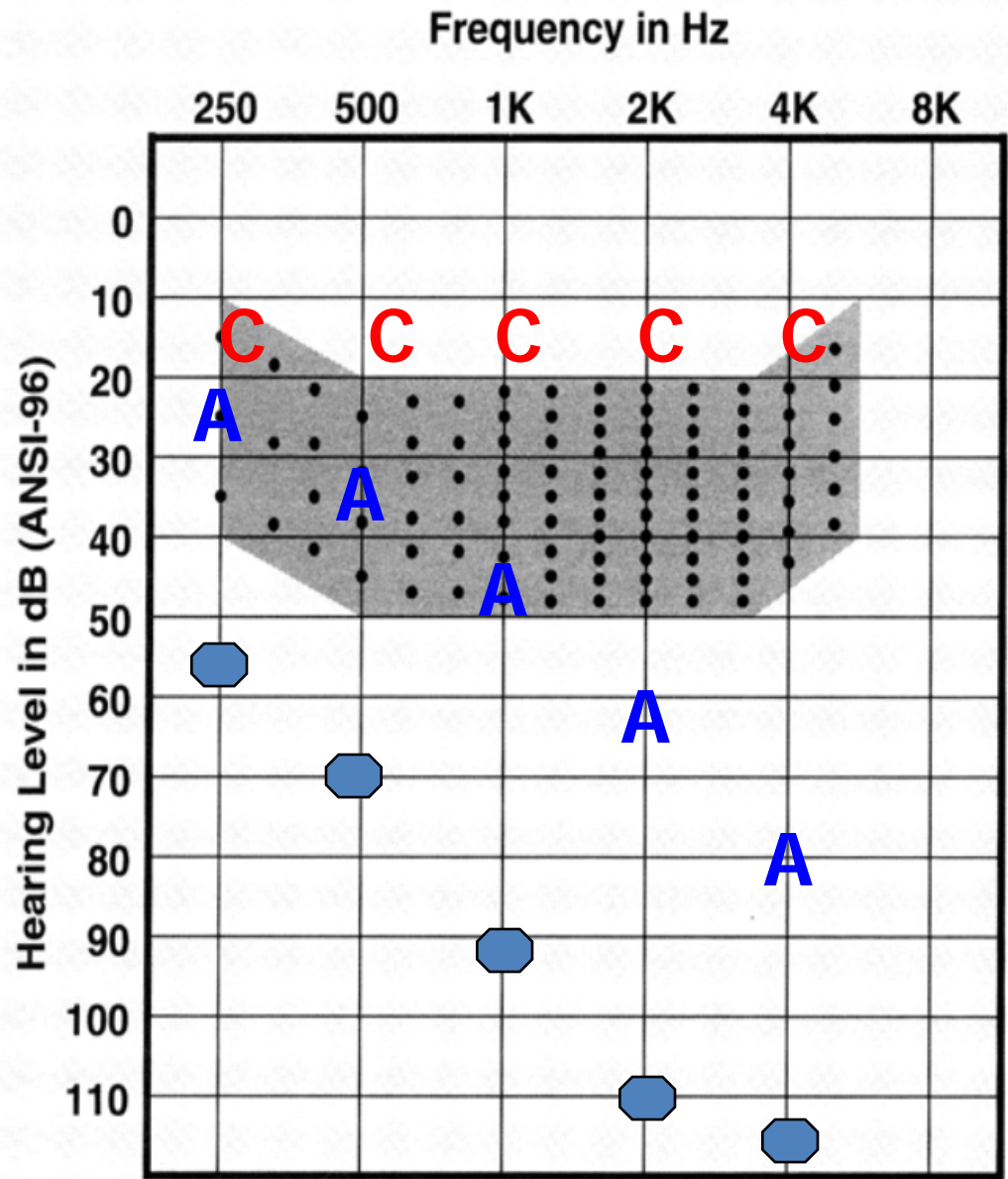
Severity of hearing loss

- The location of the threshold determines the severity of the loss:

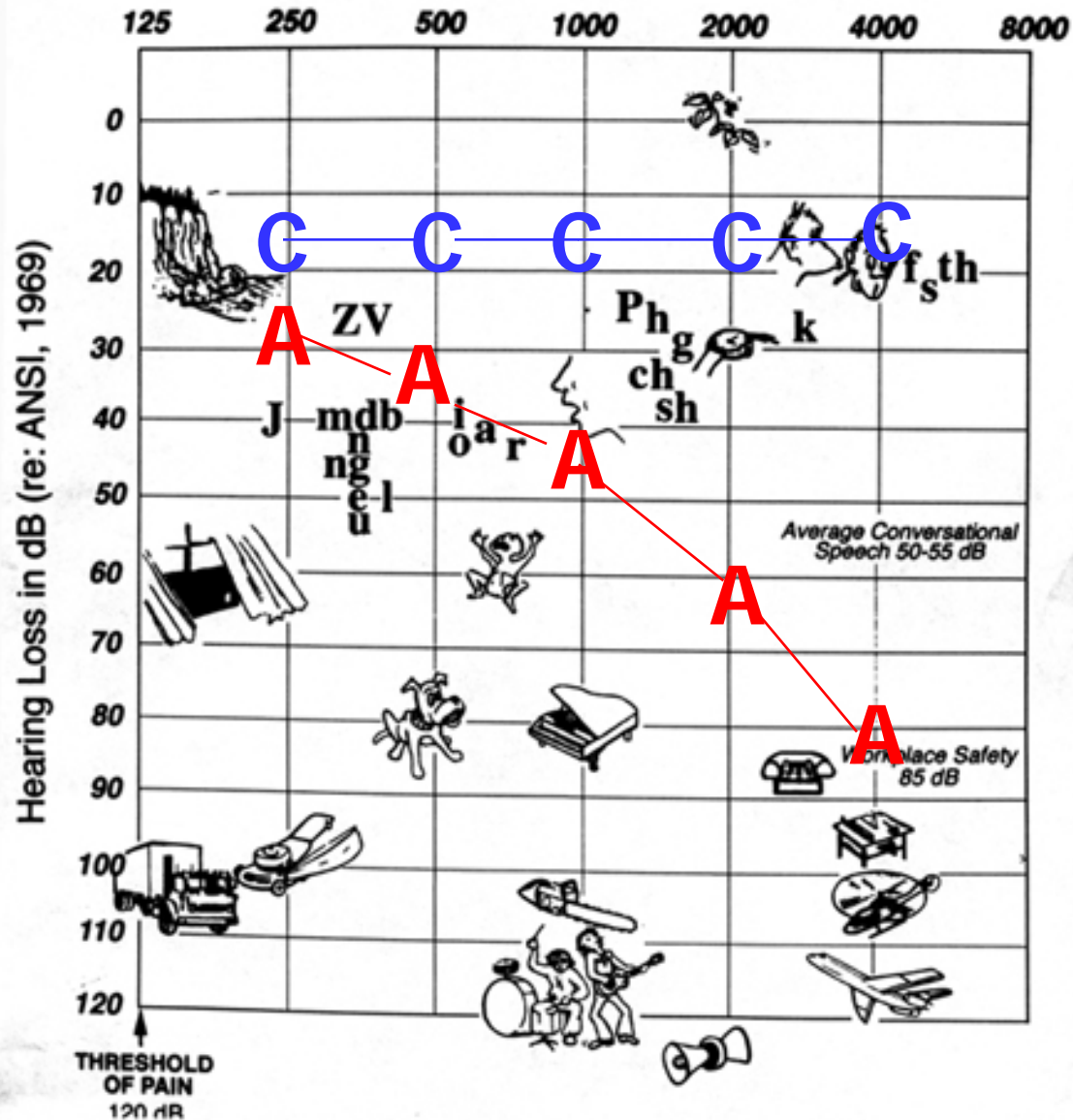
- ◆ 0-25 Normal
- ◆ 25-40 Mild
- ◆ 40-55 Moderate
- ◆ 55-70 Moderately Severe
- ◆ 70-90 Severe
- ◆ 90+ Profound



CI
Candidates
have a
moderate to
profound
SNHL



Frequency in Cycles per Second



Candidacy: Speech Recognition

- Important to evaluate how well the patient is able to recognize speech when using hearing alone (no visual cues).
- CMS states "Hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification".

“tape-recorded tests of open-set sentence recognition”

- Taped presentation: provides greater consistency and reliability for testing than live voice presentation.
- Closed set tests provide a set of choices from which the listener can select a response. If 4 choices, chance score = 25%.
- Open set tests provide the listener with an infinite set of choices, so chance score = 0%.

Sample recorded version of HINT sentences

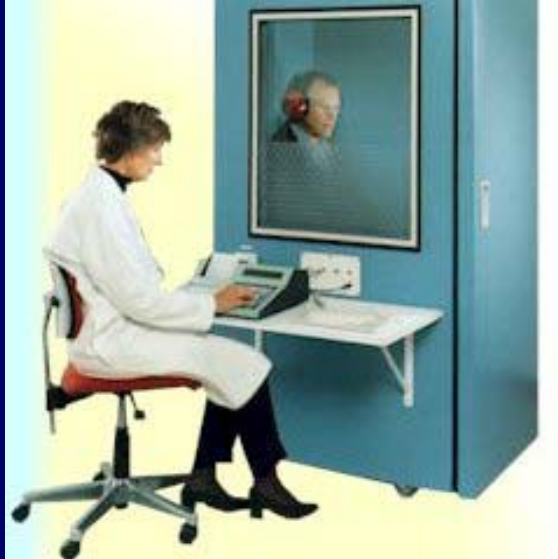
“best aided listening condition”

- Evaluate the patient's ability to understand words in sentences using an appropriate hearing aid on the right ear, the left ear, and both ears aided. Highest score = best aided condition.
- CMS states “Hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification”.

Best Aided Condition

- Left Ear Aided
- Hint = 22%

- Right Ear Aided
- Hint = 32%



- Binaural Aided
- Hint = 42%

Important to evaluate each ear separately as well as both ears together

Best Aided Condition

- Left ear Aided
- Hint = 0%

- Right ear Aided
- Hint = 24%



- Binaural Aided*
- Hint = 20%

*Binaural scores do not always represent the “best” aided condition

Typical Preoperative scores at UM in 2009*

- Binaural Aided

- Hint = 30.23

- Implant Ear Aided

- Hint = 11.9%

- Non-implant Ear Aided

- Hint = 26.5

*Based on data from 14 subjects >65 who received a CI at UM in 2009 with less than 25 years of deafness in the ear implanted.

Ear to implant

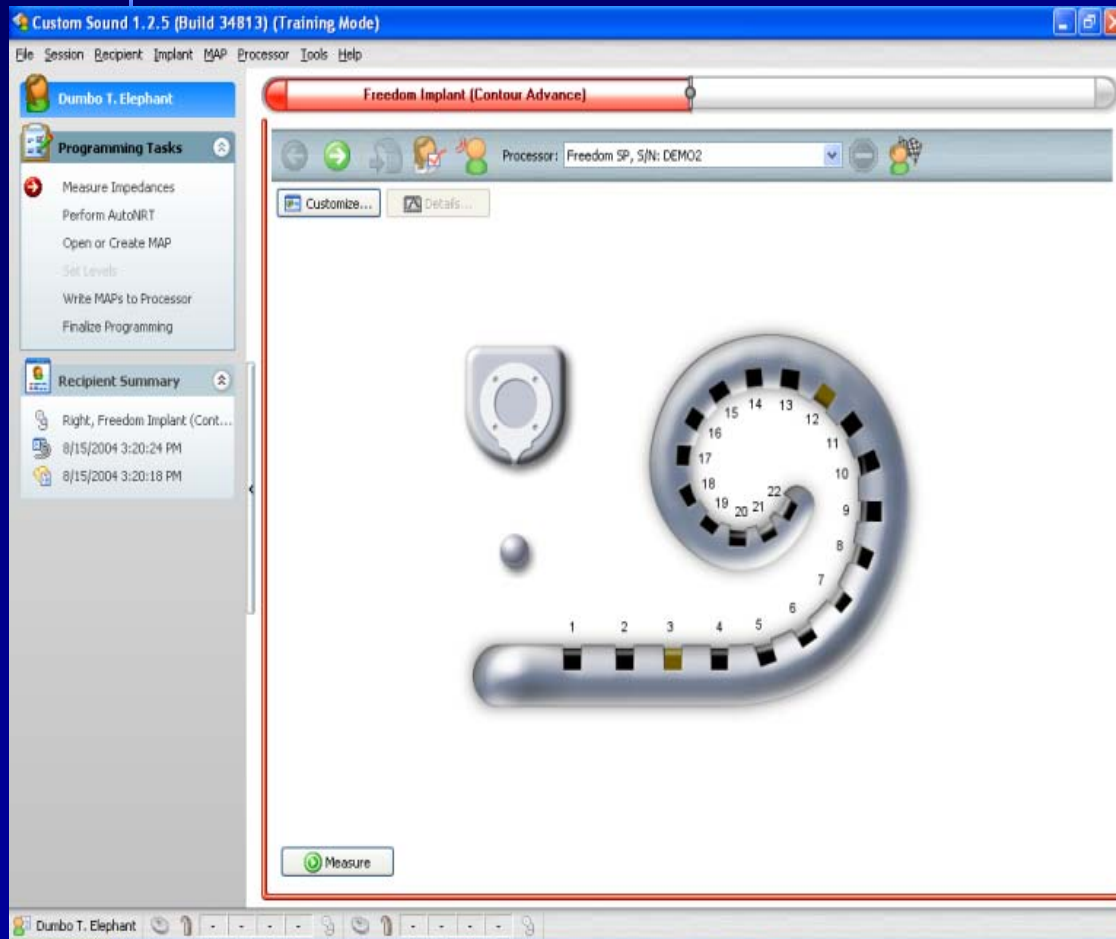
- Some centers prefer to implant the better ear while others prefer to implant the poorer ear.
- Many centers make a decision on a case by case basis.
- Best to avoid long-term deafened ears (> 25 years) as they have a poorer prognosis

Post-operative Management

- Activation 1-4 weeks following surgery
- Many clinics obtain a transorbital x-ray prior to activation to confirm placement of the device.



Telemetry provides a Quick check of the internal device



How do we set the device?



- Determine the lowest level of current required for the patient to first hear (threshold) with stimulation of each electrode.
- Determine the level of stimulation that is “loud but comfortable” (comfort level) for each electrode.
- Each electrode is assigned a frequency range for electrical stimulation, and all stimulation occurs between the threshold and C level.

Listening to speech

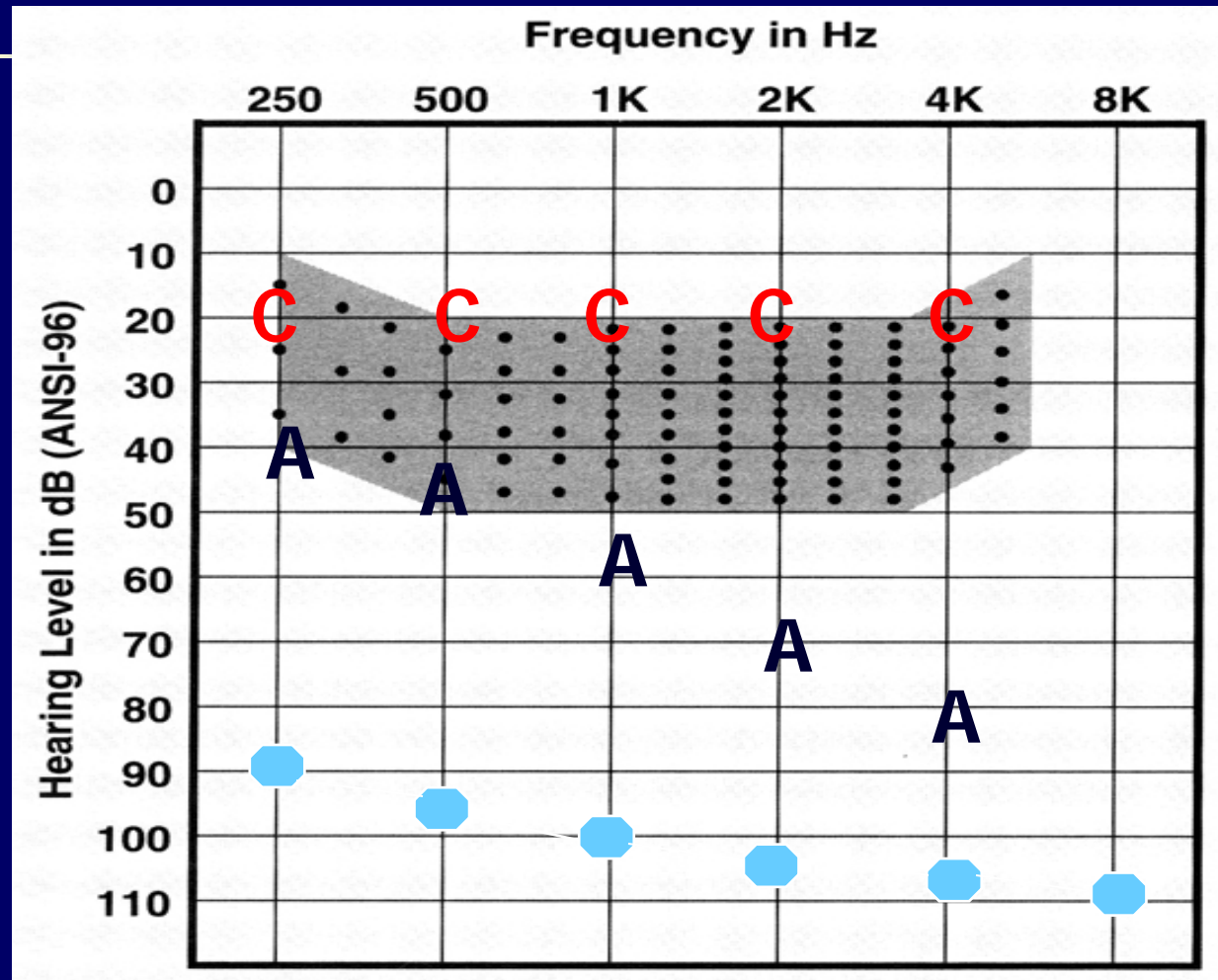


- The processor uses the threshold and comfort level information to create a map that is placed in the speech processor. The incoming signal is divided into frequency bands and the various electrodes are stimulated at levels determined by the map.
- Patients initially report that speech sounds “odd” but that it begins to sound “normal” as early as one week post-activation.

Follow up

- Adults: ~ 7 appointments first year for mapping, annually thereafter.
- Appointments include speech processor mapping and evaluation of speech recognition.

Audiometric Test Results: Improved detection of sound



Improved speech recognition: adults



- Approximately $\frac{3}{4}$ of postlingually deafened adults interactively use the telephone
- Average post-implant sentence recognition score at UM for patients $> 65 = 80.5\%$ (preoperative avg 11.9% in implant ear, 30% in best aided for 14 patients , 2009)

CI's facilitate significant improvement in speech recognition abilities of CI recipients over the age of 65

- Yeuh B, Shekelle P: Quality indicators for the care of hearing loss in vulnerable elders. J Am Geriatr Soc 2007; 55: 335–339.
- Orabi AA, Mawman D, Al-Zoubi F, Saeed SR, Ramsden RT: Cochlear implant outcomes and quality of life in the elderly: Manchester experience over 13 years. Clin Otolaryngol 2005; 31: 116–122.
- Leung J, Wang NY, Yeagle JD, Chinnici J, Bowditch S, Francis HW, Niparko JK: Predictive models for cochlear implantation in elderly candidates. Arch Otolaryngol Head Neck Surg 2005; 131: 1049–1054.
- Vermeire K, Brokx JP, Wuyts FL, Cochet E, Hofkens A, Van de Heyning PH: Quality-of-Life benefit from cochlear implantation in the elderly. Otol Neurotol 2005; 26: 188–195.
- Francis HW, Chee N, Yeagle J, Cheng A, Niparko JK: Impact of cochlear implants on the functional health status of older adults. Laryngoscope 2002; 112: 1482–1488.
- Nakajima S, Iwaki S, Fujisawa N, Yamaguchi S, Kawano M, Fujiki N, et al: Speech discrimination in elderly cochlear implant users. Adv Oto Rhino Laryngol 2000; 57: 368–369.

Speech recognition improvement cont.

- Cambron N. Speech recognition ability in cochlear implant users 65 and older. *Seminars in Hearing* 2006; 27: 345-347.
- Chatelin V, Kim EJ, Driscoll C, Larky J, Polite C, Price L, et al. Cochlear implant outcomes in the elderly. *Otology and Neurotology* 2004; 25(3):298-301.
- Haensel J, Ilgner J, Chen YS, Thuermer C, Westhofen M. Speech perception in elderly patients following cochlear implantation. *Acta Otolaryngologica (Stockholm)* 2005; 125(12):1272-1276.
- Oyanguren V, Gomes MV, Tsuji RK, Bento RF, Brito Neto R. Auditory results from cochlear implants in elderly people. *Braz J Otorhinolaryngol.* 2010 Aug;76(4):450-3.

Many report that speech recognition results of patients over the age of 65 are not significantly different from those obtained by younger patient groups

- Yeuh B, Shekelle P: Quality indicators for the care of hearing loss in vulnerable elders. *J Am Geriatr Soc* 2007; 55: 335–339.
- Orabi AA, Mawman D, Al-Zoubi F, Saeed SR, Ramsden RT: Cochlear implant outcomes and quality of life in the elderly: Manchester experience over 13 years. *Clin Otolaryngol* 2005; 31: 116–122.
- Leung J, Wang NY, Yeagle JD, Chinnici J, Bowditch S, Francis HW, Niparko JK: Predictive models for cochlear implantation in elderly candidates. *Arch Otolaryngol Head Neck Surg* 2005; 131: 1049–1054.
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- Nakajima S, Iwaki S, Fujisawa N, Yamaguchi S, Kawano M, Fujiki N, et al: Speech discrimination in elderly cochlear implant users. *Adv Oto Rhino Laryngol* 2000; 57: 368–369.

Bilateral versus Unilateral implants

- Treatment with cochlear implants has expanded in recent years to include both ears.
- Sequential bilaterals versus simultaneous
- Documented Benefits include
 - Improved speech recognition in noise
 - Improved localization (improving personal safety)
 - Ability to optimize performance (implant the “most receptive” ear)

Bilateral implants: personal experience

- Patients are less likely to be “without sound”
- Variability exists between ears, and implanting two ears optimizes hearing.
- Particularly valuable for patients with visual impairments to aid in direction of sound and maximize communication.
- Patients liken bilaterals to stereo versus mono listening, or one eyed vision versus two eyed vision.
- None of our adult patients have rejected or “not used” the second implant.

Benefits of bilateral cochlear implants are well documented

- Chang SA, Tyler RS, Dunn CC, Ji H, Witt SA, Gantz B, Hansen M. Performance over time on adults with simultaneous bilateral cochlear implants. J Am Acad Audiol. 2010 Jan;21(1):35-43.
- Laske RD, Veraguth D, Dillier N, Binkert A, Holzmann D, Huber AM. Subjective and objective results after bilateral cochlear implantation in adults. Otol Neurotol. 2009 Apr;30(3):313-8.
- Eapen RJ, Buss E, Adunka MC, Pillsbury HC 3rd, Buchman CA. Hearing-in-noise benefits after bilateral simultaneous cochlear implantation continue to improve 4 years after implantation. Otol Neurotol. 2009 Feb;30(2):153-9.

Summary

- Cochlear implants are one of the most significant technological advancements of our time.
- The safety, efficacy, and benefits of CIs are well documented, and are an important benefit for Medicare recipients.

Thank you

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