

Cochlear Implantation: Medical Issues

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May 11, 2011

Prevalence of Hearing Loss: United States

- Approximately 1 in 10 have hearing difficulty
 - more than 28 million people
 - about 1 in 100 are profoundly deaf
(including prelingually deaf)
 - numbers increasing with aging population
- Hearing loss is one of the top ten chronic conditions in the U.S. population
- Hearing loss can cause severe delays in social, academic, occupational, and speech and language skills.

What is a cochlear implant?

- An electronic device that provides improved hearing and communication to adults and children with severe to profound hearing loss, via stimulation of the auditory nerve
- The device consists of a surgically implanted **internal** component and an **externally** worn headset/speech processor

How does a cochlear implant work?



1. Sound is picked up by the microphone
2. The signal travels to the speech processor
3. The signal is processed and sent to the transmitter coil located on the patient's head (held in place by external and internal magnets)
4. The signal travels across intact skin via radio frequency transmission
5. The signal is picked up by the internal receiver and is transmitted to the electrodes along the cochlear array

Cochlear Implantation

- According to the U.S. Food and Drug Administration (FDA), as of December 2010, approximately 219,000 people worldwide have received implants.
- In the United States, roughly 42,600 adults and 28,400 children are CI recipients.

<http://www.nidcd.nih.gov/health/hearing/coch.html#l#c>

History of Cochlear Implantation

- 1957: Djourno and Eyries stimulate 8th nerve with implant
- 1972: House-first single channel device
- 1978: Clark-implants 10 channel device
- 1984: FDA approval single channel device adults
- 1985: FDA approval multi-channel device adults
- 1990: FDA approval multi-channel device children
- 1991: FDA trial second multi-channel device adults

Medicare Indications for Cochlear Implantation

- Bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from optimally fit hearing (or vibrotactile) aids
- Test scores of less than or equal to 40% correct in the best-aided listening condition using tape- recorded tests of open-set sentence recognition
- 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
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.
- <https://www.cms.gov/MLNMMattersArticles/downloads/MM3796.pdf>

Criteria for Acceptable Clinical Trials and Studies

- Coverage provided for cochlear implantation of individuals with open set sentence recognition scores of $>40\%$ to $\leq 60\%$, if the patient is enrolled in an acceptable clinical trial/study, meeting the following criteria:
- Food and Drug Administration-approved category B investigational device exemption clinical trial as defined in 42 CFR 405.201;
- Trial under the CMS clinical trial policy as defined in Section 310.1 of the Medicare National Coverage Determinations Manual; or a
- Prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses and meeting specific quality standards.

FDA Candidacy Guidelines: Adults

- FDA candidacy criteria vary for each device, depending on when the device received FDA approval.
- The specific indications for use of a product (CI) will vary depending on when FDA approval was received and the test measures employed in the clinical trial.
 - since initial FDA approvals, labeling for many CI systems have been changed by Supplements
- As of April 2005, Medicare guidelines for CI candidacy have permitted implantation of those who score up to 60% speech recognition, if participating in a clinical trial.

Cochlear Implant Candidate Evaluation

- Medical Evaluation
- Audiological Evaluation – hearing tests and evaluation of speech recognition with appropriately fit hearing aids
- Radiological evaluation (CT and/or MRI)
- Counseling
- Assessment of resources and family support
- Submission for insurance pre-approval
- Contact with other implant recipients

Cochlear Implant: Medical Evaluation

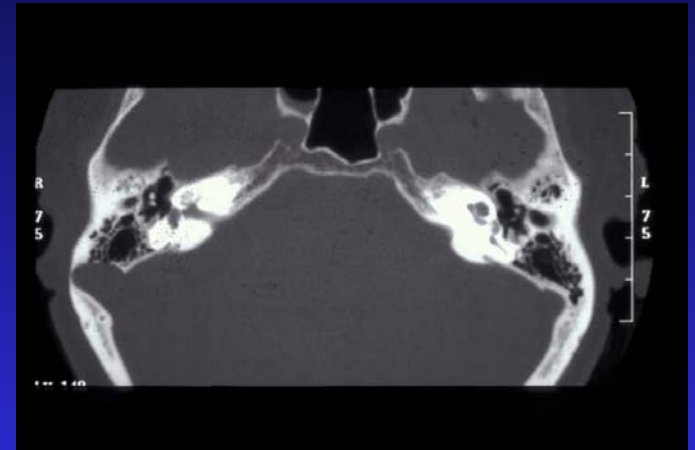
General Health Assessment

- Fitness for general anesthetic
- Ability to undergo post implant programming and rehabilitation
- Motivation and expectations
- Assess for cognitive disorders
- Assess need for psychological evaluation
 - Increased incidence of depression and loneliness in adult cochlear implant candidates
 - CI can be associated with improvement in symptoms

Cochlear Implant: Medical Evaluation

- Evaluate & treat if possible
 - review prior medical records & audiograms
 - careful history and physical exam
- If recent drop in hearing, evaluate and treat
 - autoimmune SNHL
- Other potentially treatable metabolic causes:
 - thyroid dysfunction, syphilis
- Evaluate for chronic ear disease and infection
 - cholesteatoma
- Evaluate for far-advanced otosclerosis (conductive HL)

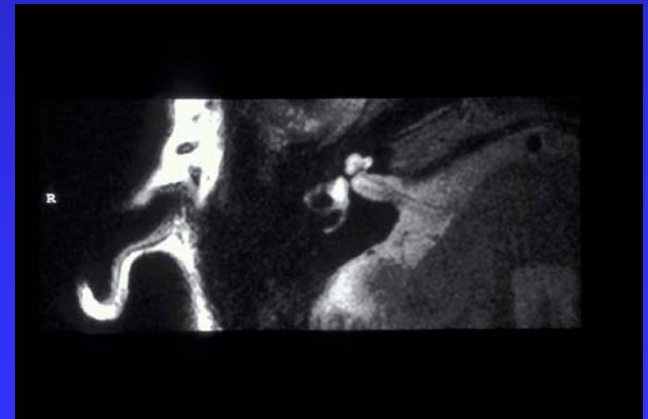
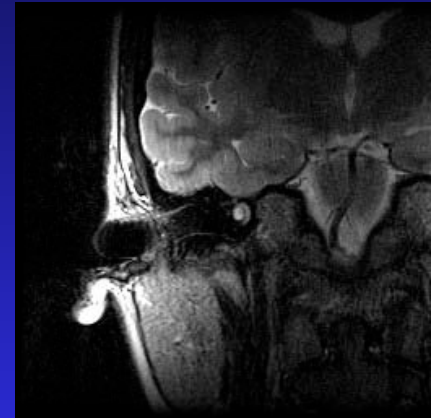
Preoperative Evaluation: Temporal Bone CT



- Cochlear anatomy
- Cochlear patency
- Mastoid anatomy

Preoperative Evaluation: MRI

- Assess cochlear patency, anatomy
- Rule out vestibular schwannoma, other CNS abnormality
- MRI generally contraindicated post CI



Device Manufacturers

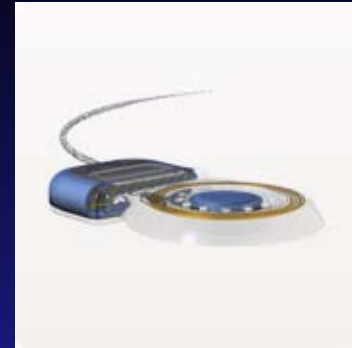
- Cochlear Americas (Nucleus 5 device)
 - Founded in 1982
 - Received FDA approval in 1984
- Advanced Bionics Corporation
 - Founded in 1993
 - Received FDA approval in 1996
- MedEl Corporation
 - Founded in 1989
 - FDA approval in the US in 2001



Internal Devices

- Med El

- SONATA_{TI100}



- Advanced Bionics

- HiRes 90K implant



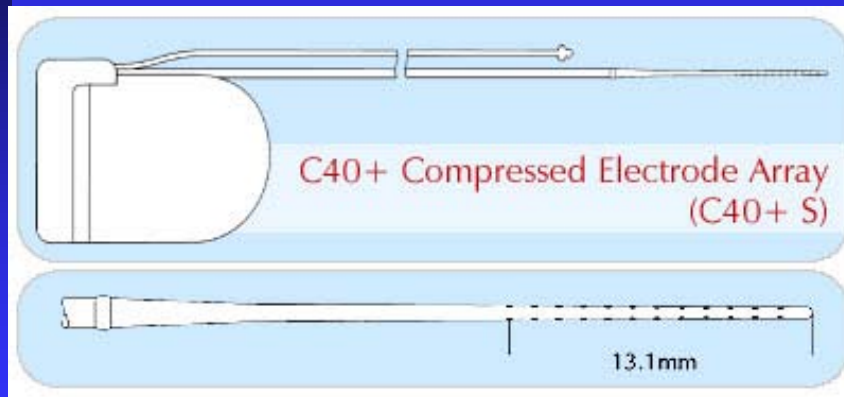
- Cochlear Corporation

- Nucleus CI 512



Special internal device considerations

- Compressed array
- Straight array
- Split array



Cochlear Implant Device: External Components

- Microphone
- Processor
 - Implements speech processing strategies
 - Able to be upgraded to future capabilities
 - Contains power supply



Speech Processing Strategy

- Determines how sounds in the environment are delivered to the listener.
- Speech processing strategies differ in:
 - number of electrodes used (not # available)
 - speed at which electrodes send information
 - number of electrodes being used at the same time
 - whether stimulation pulsatile or analog



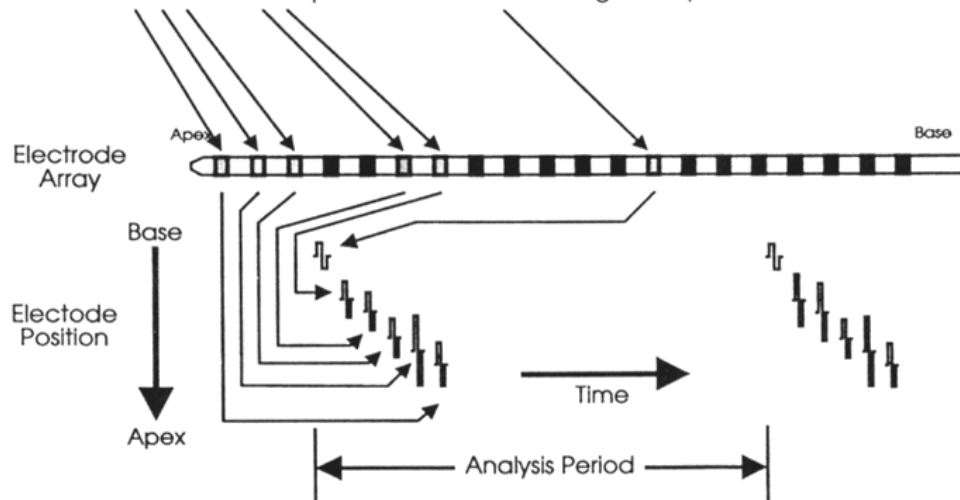
Speech Waveform



22 Channel Bandpass Filter Bank



Instantaneous Spectrum - Select 6-10 largest outputs of Filter Bank



Stimulate Electrodes (non-simultaneously)

Cochlear Implant Surgery

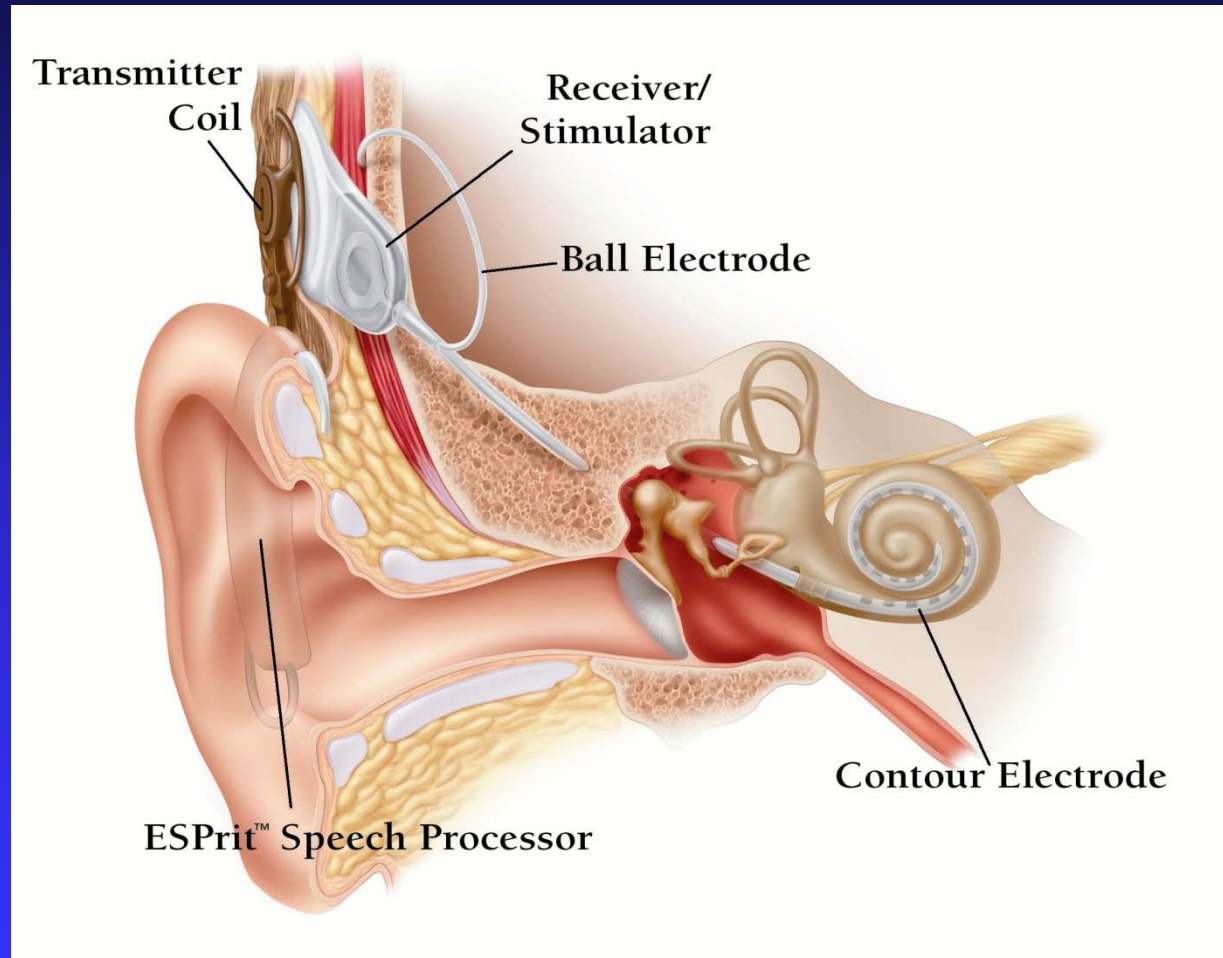


Photo courtesy of Cochlear Americas

Cochlear Implant Surgery

- Surgical time for unilateral CI
 - 2.85 hours average surgical time
 - device-dependent (30 minute)
- Surgical time for bilateral implants
 - 5 hours average surgical time
- Usually performed as an outpatient; may stay overnight if very young or old
- Patients return to work in about 7-10 days



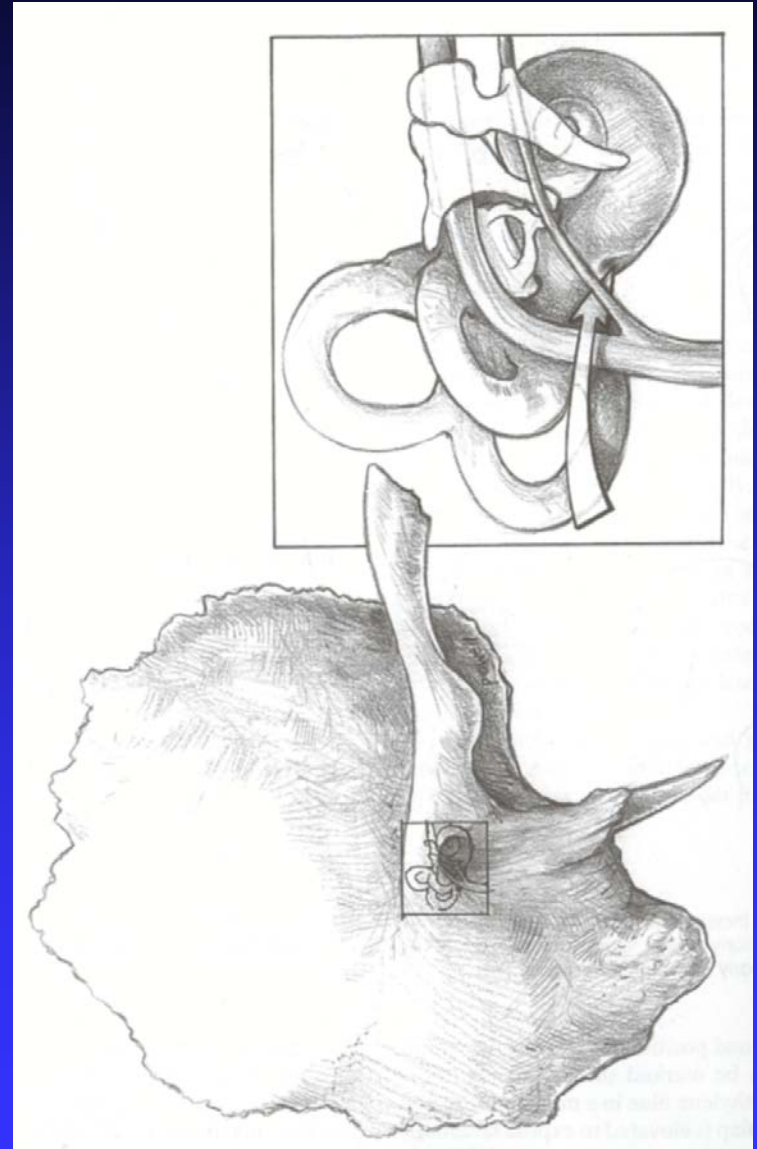
Majdani et al.: Time of cochlear implant surgery in academic settings.
Otolaryngol Head Neck Surg 142:254, 2010

Surgical Procedure

- General anesthesia
- Cochlea accessed through incision behind the ear
- Area in bone prepared for receiver stimulator
- Mastoidectomy performed
- ‘Facial recess’ approach to cochlear promontory open between facial nerve and (underneath) tympanic membrane
- Cochleostomy – opening into cochlea, near round window
- Insert electrode by gently advancing into scala tympani
- Intraoperative testing of the device confirms position in the cochlea and good function of the implant

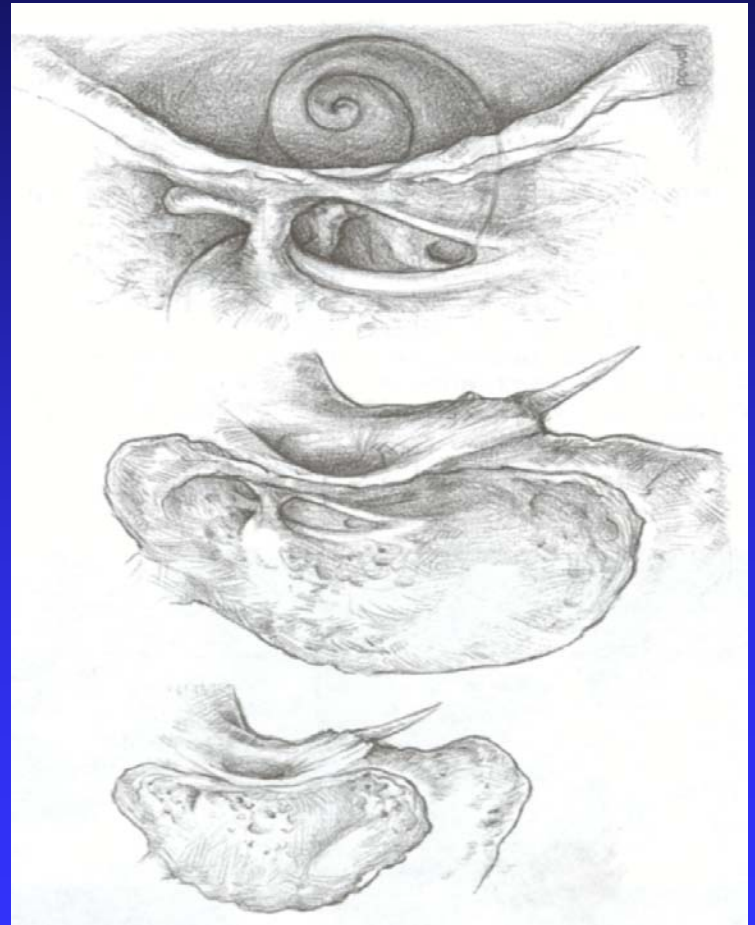
Surgical Procedure: Landmarks

- Facial nerve
- Chorda tympani nerve
- Facial recess



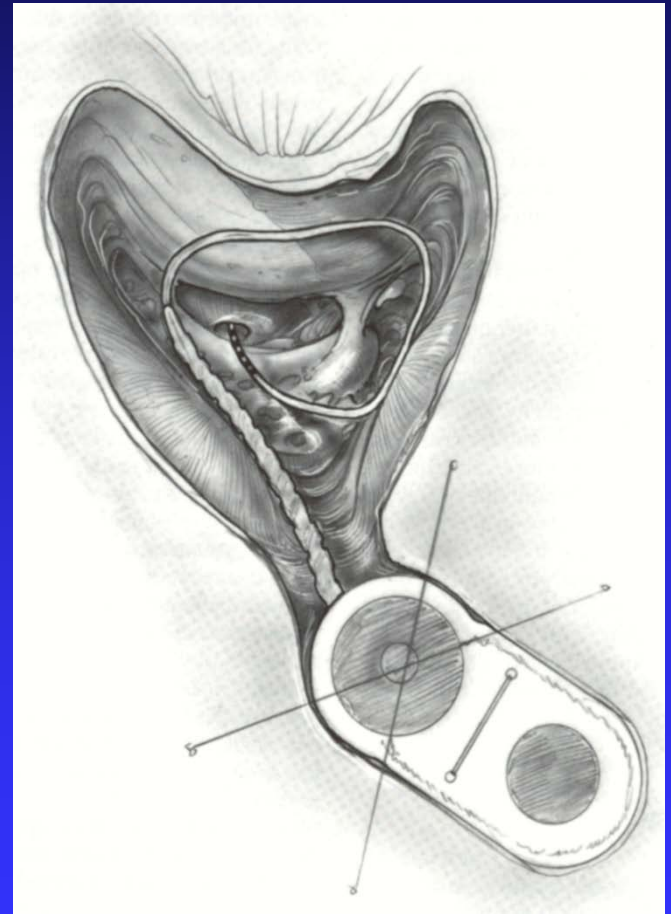
Surgical Procedure

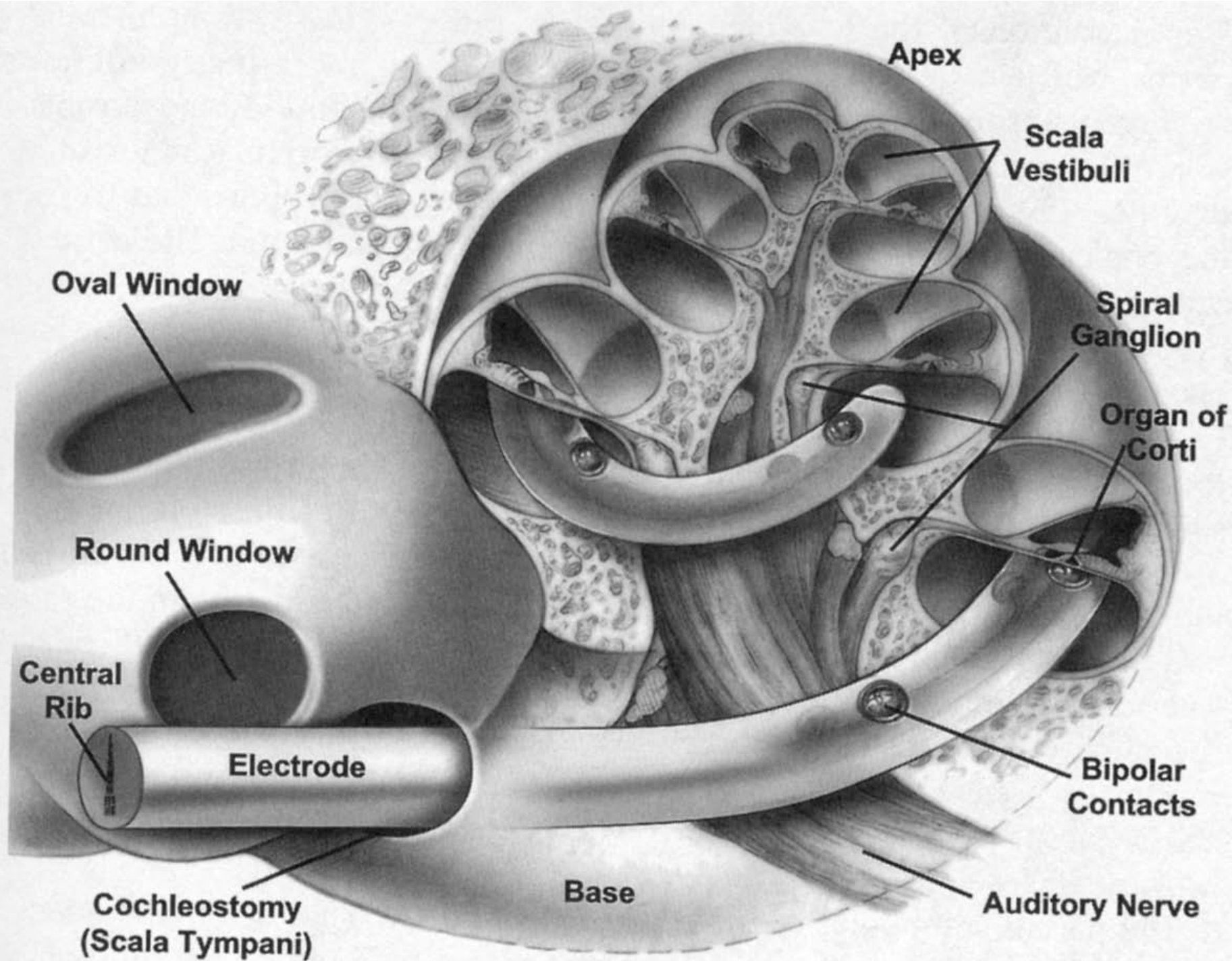
- Mastoidectomy
- Facial recess
- Cochleostomy



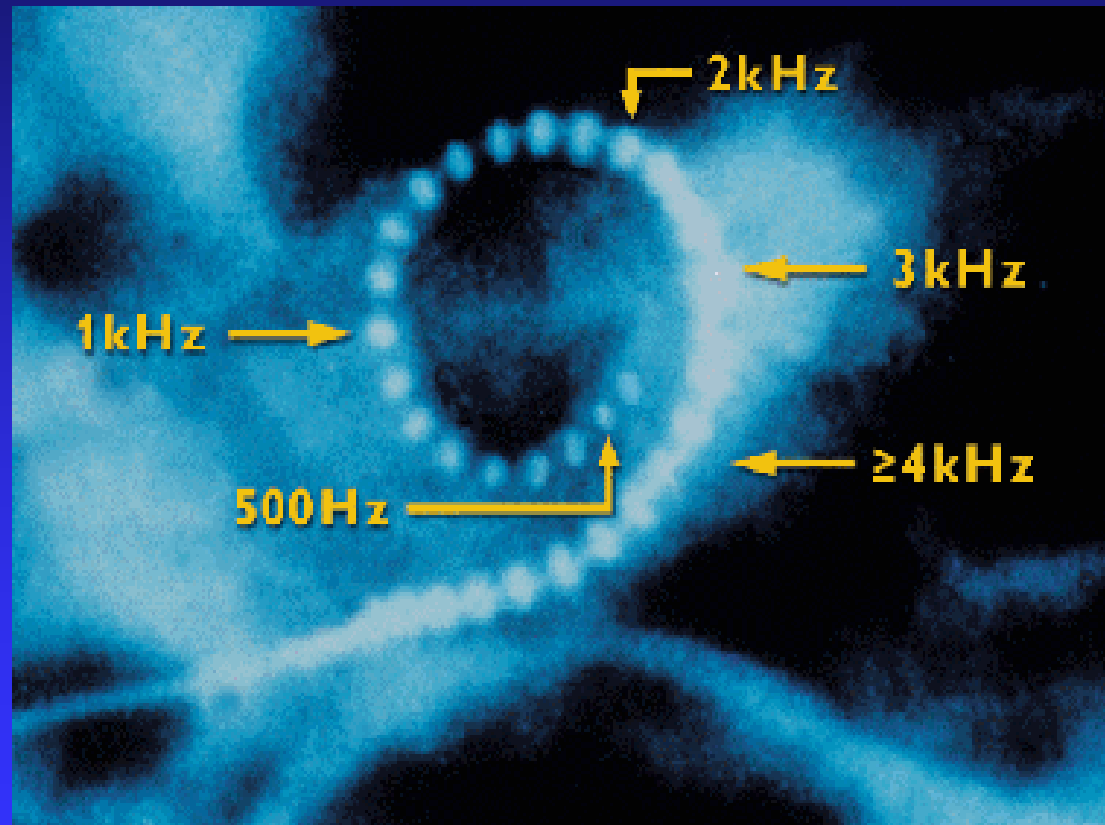
Surgical Procedure

- Mastoidectomy
- Facial recess open
- Well drilled
- Device secured
- Cochleostomy
- Electrode inserted





Tonotopic organization



Surgical Risks and Complications

- Minor – 8%;
 - requiring no or conservative treatment
- Major – 4.3%;
 - requiring revision surgery
 - involving meningitis
 - implant loss
 - facial nerve injury
- Complications may be
intraoperative, early postoperative, or delayed
- Most common complications involve problems with
wound healing - design of incision, tissue flaps
is important

Surgical Complications: Meningitis

- Children and adult implant recipients are believed to be at increased risk of pneumococcal meningitis
- Goal – vaccinate all implant patients prior to surgery
- Specific recommendations are available from the CDC; patient information available from a variety of sources including the American Academy of Otolaryngology website
- Cost covered by most health insurance plans and CI manufacturers will pay unreimbursed costs

Cochlear Implant Results: Outcome Measures

- Hearing thresholds
- Speech reception & production
- Language development (children)
- Rehabilitation issues
- Cost effectiveness:
 - education, productivity in workplace,
 - quality of life

Cochlear Implantation in Older Adults

- Is cochlear implant surgery safe in older adults?
- Is cochlear implant surgery effective in older adults?
- Is quality of life improved with a CI?
- Is cochlear implantation cost effective in this population?

Cochlear implants are safe and effective for people over the age of 60 years

- Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S: Functional use of the nucleus 22-channel cochlear implant in the elderly. *Laryngoscope* 1991; 101: 284–288.
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Intraoperative and postoperative complication rates related to CI surgeries have been found to be low in patients over the age of 65.

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- Carlson ML, Breen JT, Gifford RH, Driscoll CL, Neff BA, Beatty CW, Peterson AM, Olund AP. Cochlear implantation in the octogenarian and nonagenarian. *Otol Neurotol*. 2010 Oct;31(8):1343-9.
- Migirov L, Taitelbaum-Swead R, Drendel M, Hildesheimer M, Kronenberg J. Cochlear implantation in elderly patients: surgical and audiological outcome. *Gerontology*. 2010;56(2):123-8. Epub 2009 Aug 27.
- Eshraghi AA, Rodriguez M, Balkany TJ, Telischi FF, Angeli S, Hodges AV, Adil E. Cochlear implant surgery in patients more than seventy-nine years old. *Laryngoscope*. 2009 Jun;119(6):1180-3.
- Coelho DH, Yeh J, Kim JT, Lalwani AK. Cochlear implantation is associated with minimal anesthetic risk in the elderly. *Laryngoscope*. 2009 Feb;119(2):355-8.

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

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- 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, continued

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

- Friedland DR, Runge-Samuelson C, Baig H, Jensen J. Case-control analysis of cochlear implant performance in elderly patients. Arch Otolaryngol Head Neck Surg. 2010 May;136(5):432-8.

Performance

- Leung et al. (2005) found:
 - Age has little predictive value in determining postoperative performance with a CI
 - Patients age 65 and older may even perform better than those implanted at age < 65 for certain durations of deafness
 - Duration of profound deafness and percentage of life lived with deafness are most predictive of performance; greater duration of deafness correlates with poorer outcomes for both age groups

Leung et al., Predictive models for cochlear implantation in elderly candidates. Arch Otolaryngol Head Neck Surg 131:1049, 2005.

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, increase in social activities, and an overall improvement in Quality of Life.

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CI Cost Effectiveness in Older Adults

- Health utility scores & audiological data measured before and after CI in 47 adults age 50 – 80 years
 - highly significant gain in health utility
 - favorable cost-utility of \$9530 per QALY
 - significant improvement in hearing and emotional health
 - improvements in speech perception were predictive of gains in health related QOL and emotional well being

Francis HW et al., Impact of cochlear implants on the functional health status of older adults. Laryngoscope 112:1482, 2002.