



UNC
SCHOOL OF MEDICINE

Implantable Treatments for Different Types of Hearing Loss

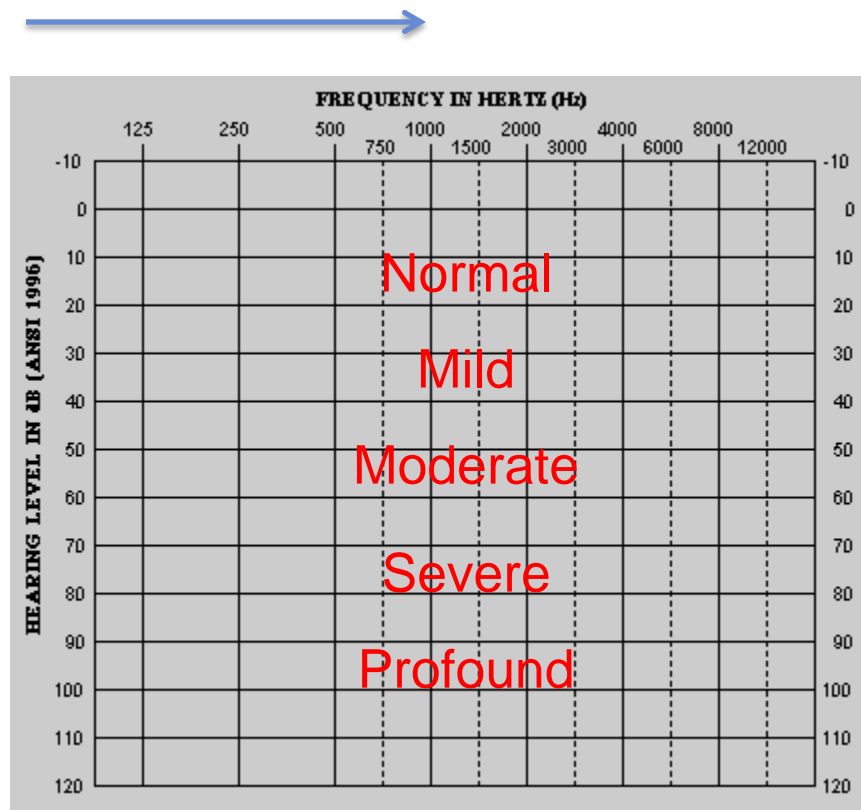
Margaret Dillon, AuD

Marcia Adunka, AuD

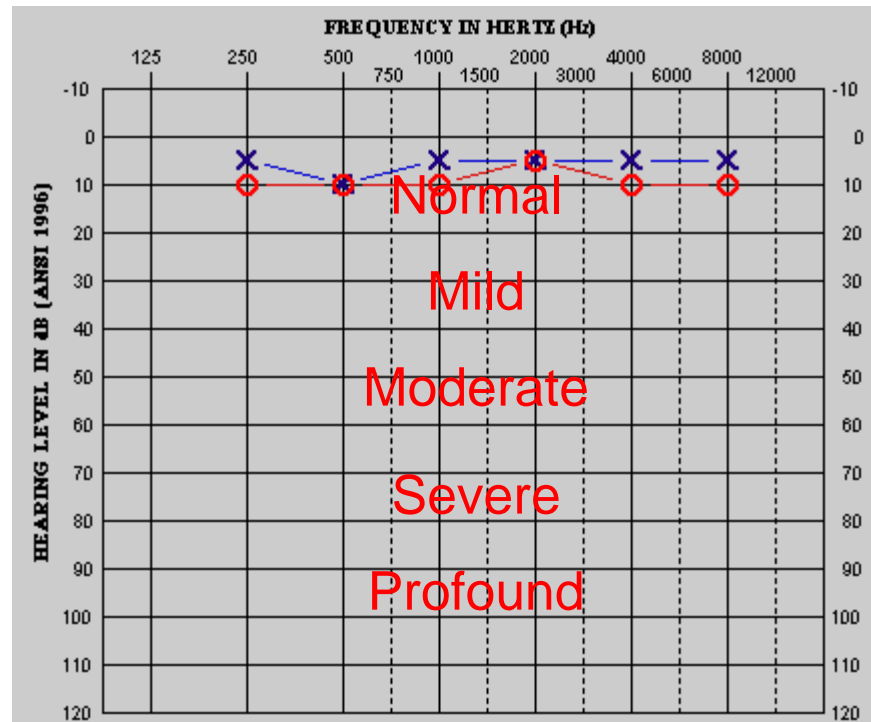
Implantable Technologies

- Types of hearing loss
- Bone-anchored devices
- Middle ear implantation
- Cochlear implantation

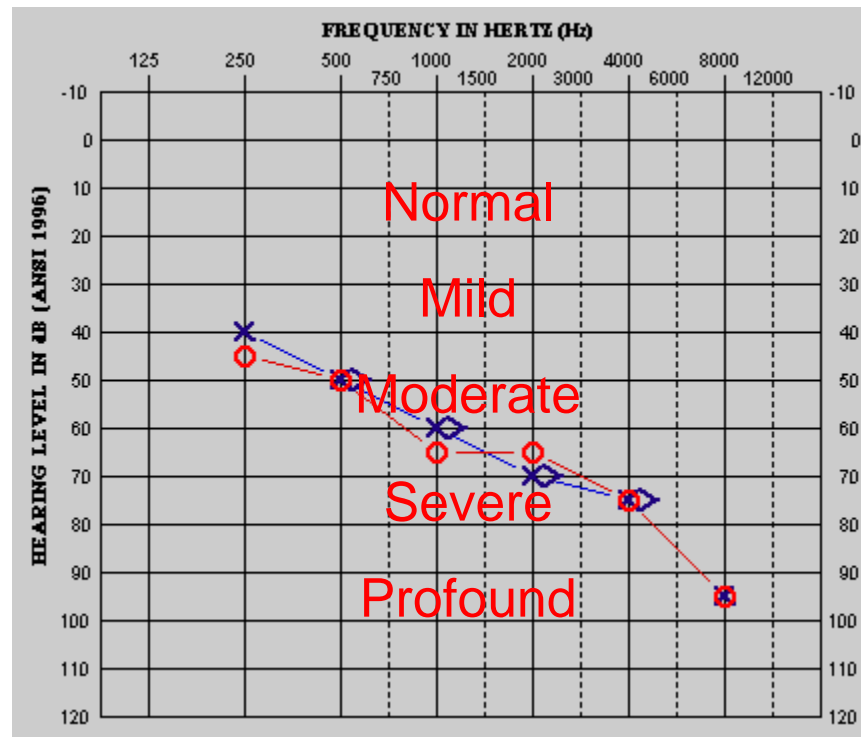
Audiogram



Audiogram



Audiogram

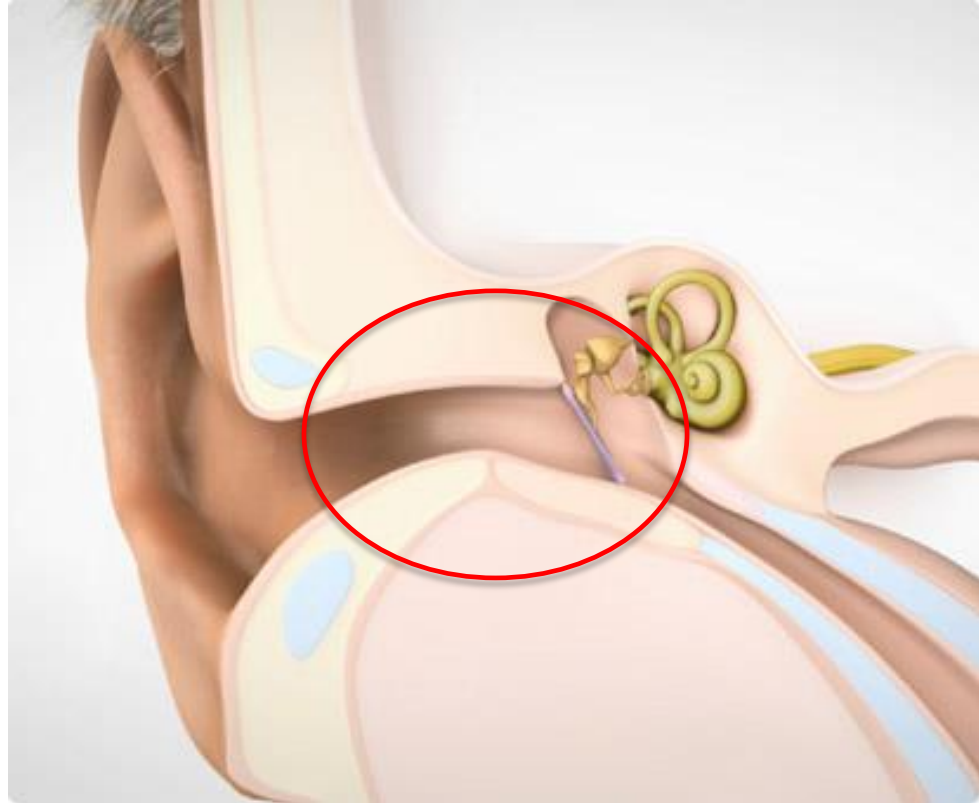


Types of Hearing Loss

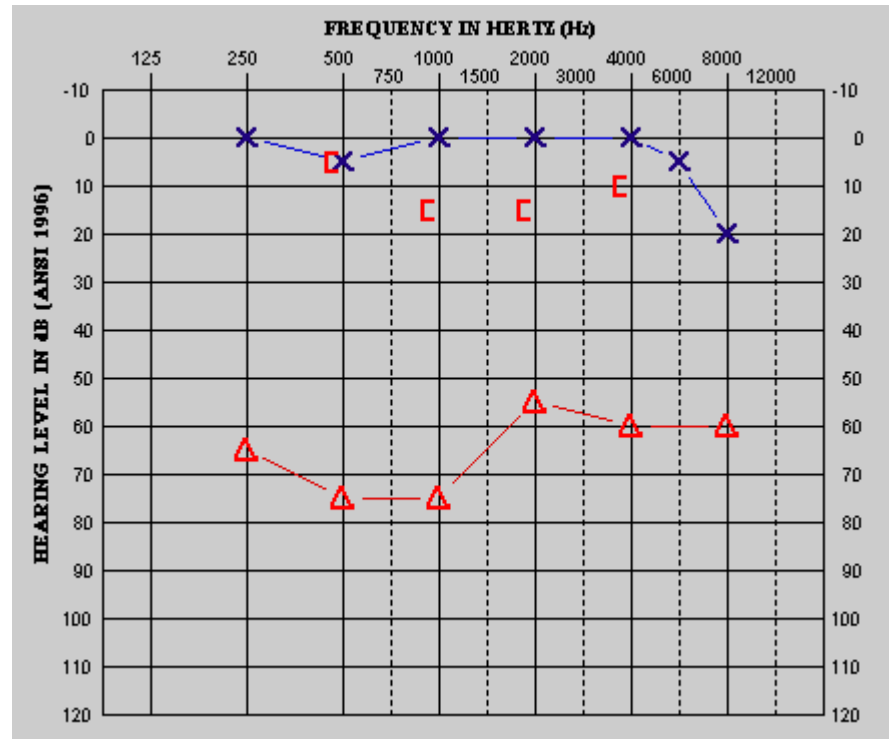
- **Conductive**
 - » Dysfunction in the conduction of sound by the outer ear, tympanic membrane, and/or middle ear
- **Sensorineural**
 - » Dysfunction within the inner ear (cochlea) and/or auditory nerve
- **Mixed**
 - » Conductive + Sensorineural

Types of Hearing Loss

- Conductive
 - » Dysfunction in the conduction of sound by the outer ear, tympanic membrane, and/or middle ear

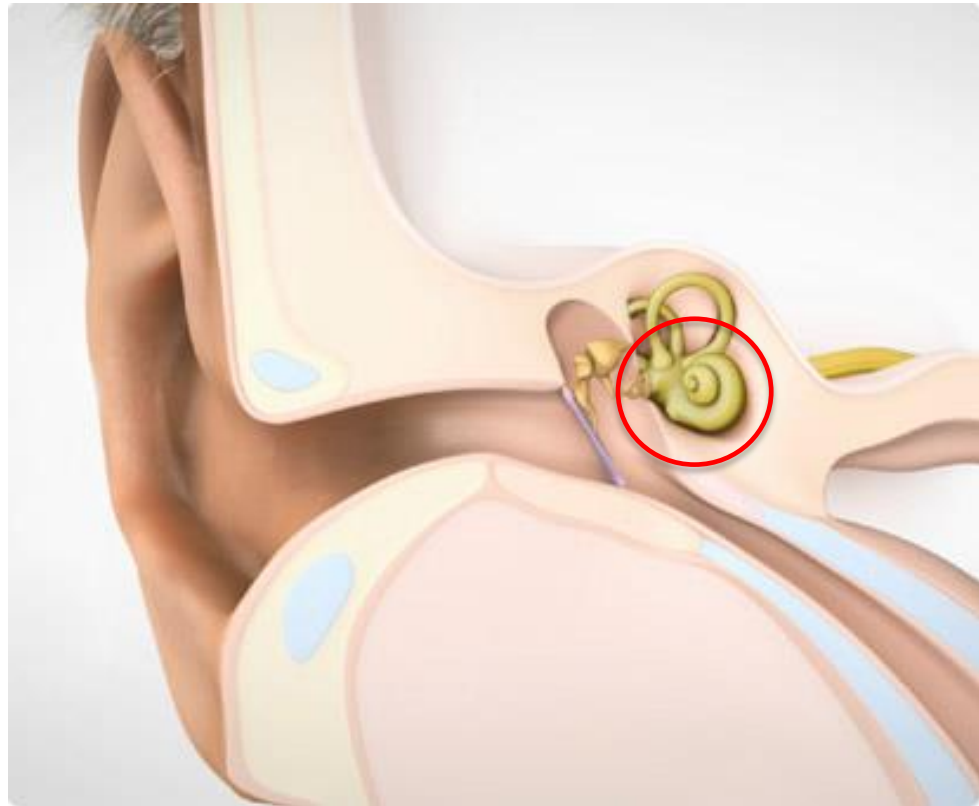


Types of Hearing Loss: Conductive

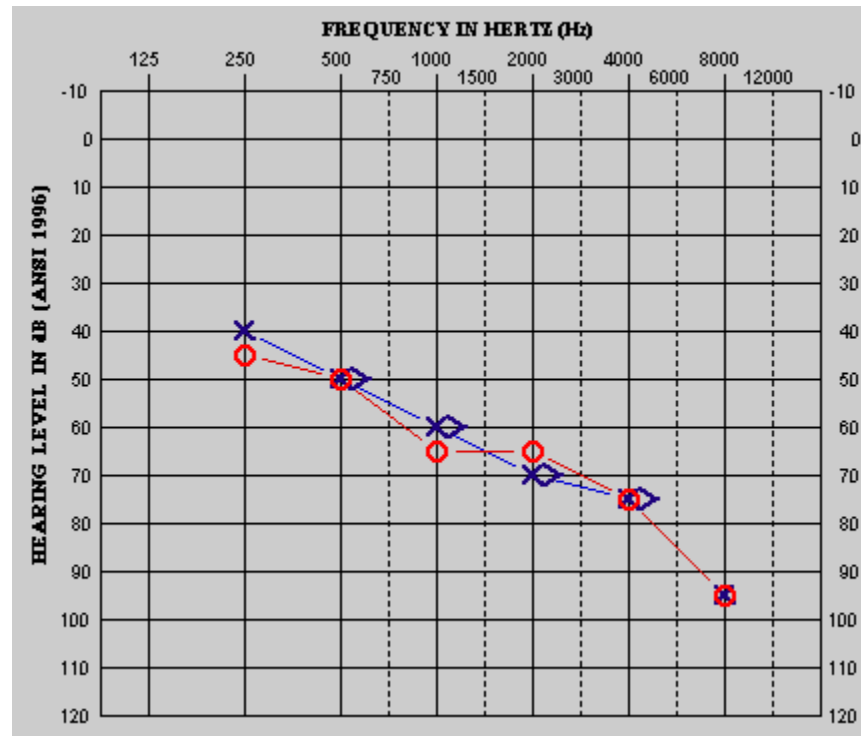


Types of Hearing Loss

- Sensorineural
 - » Dysfunction within the inner ear (cochlea) and/or auditory nerve

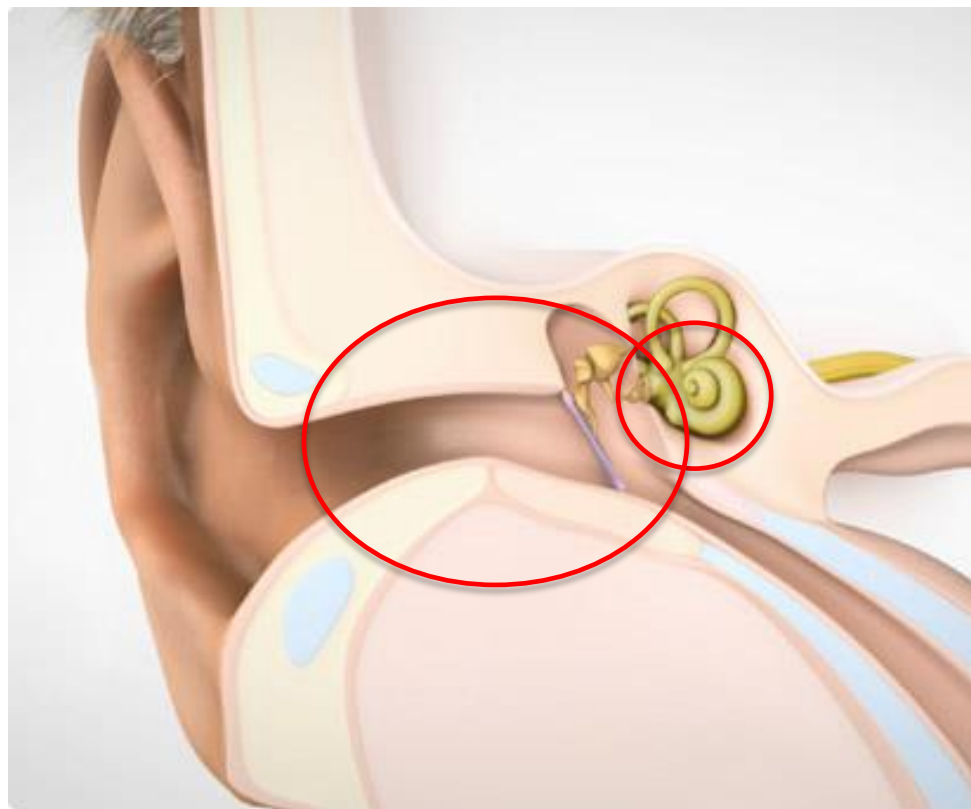


Types of Hearing Loss: Sensorineural

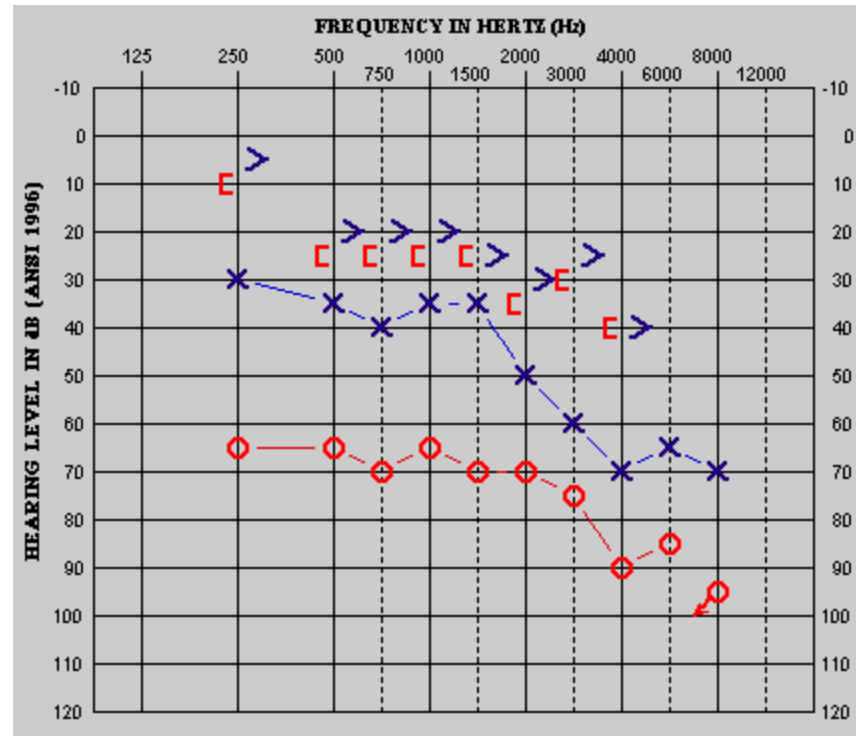


Types of Hearing Loss

- Mixed
 - » Conductive + Sensorineural



Types of Hearing Loss: Mixed



Hearing Aids

- Amplify the acoustic signal



Implantable Treatments

- Bone-anchored devices
 - » Transmission of sound via bone conduction
- Middle ear implants
 - » Transmission of sound via vibratory stimulation
- Cochlear implants
 - » Transmission of sound via electric stimulation of the auditory nerve



Bone-Anchored Devices

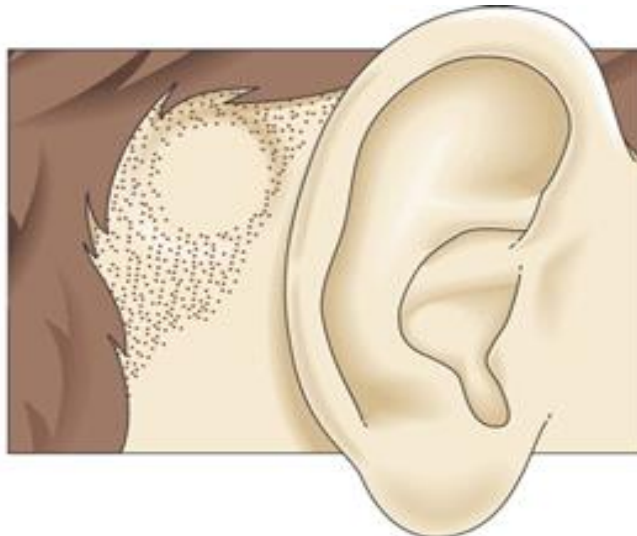
- Stimulation of the acoustic signal via bone conduction





Bone-Anchored Devices

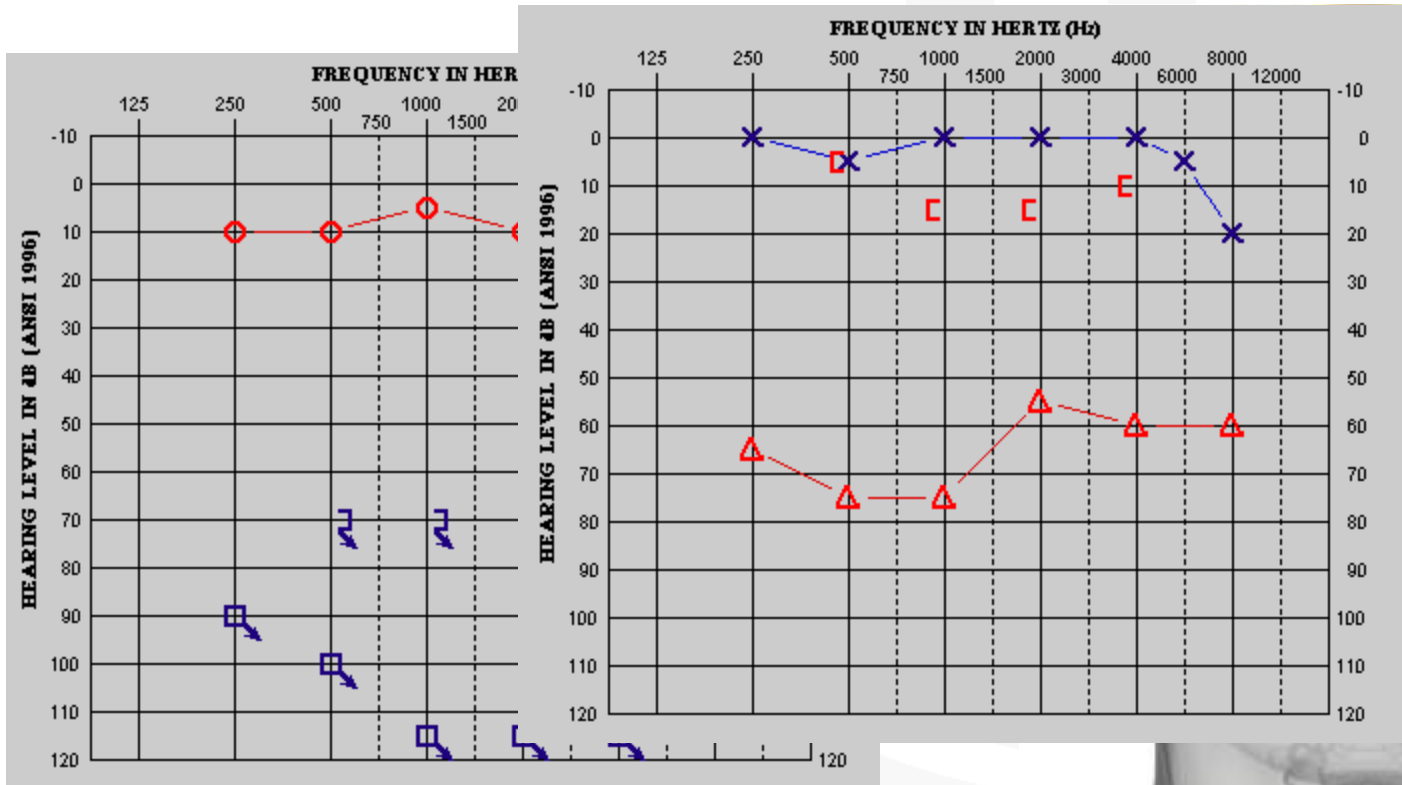
- **Three Part System:**
 - » **Titanium Screw** surgically implanted into mastoid
 - Approximately 2 month osseointegration
 - » **External Abutment** transfers the sound vibrations
 - » **Sound Processor**





Bone-Anchored Devices

- Indications (FDA approvals)
 - » CHL and Mixed HL (1996)
 - » Single-Sided Deafness (SSD; 2002)



Middle Ear Implants

- Esteem
 - » Envoy Medical
- Maxum
 - » Ototronix
- Vibrant Soundbridge (VSB)
 - » MED-EL Corporation

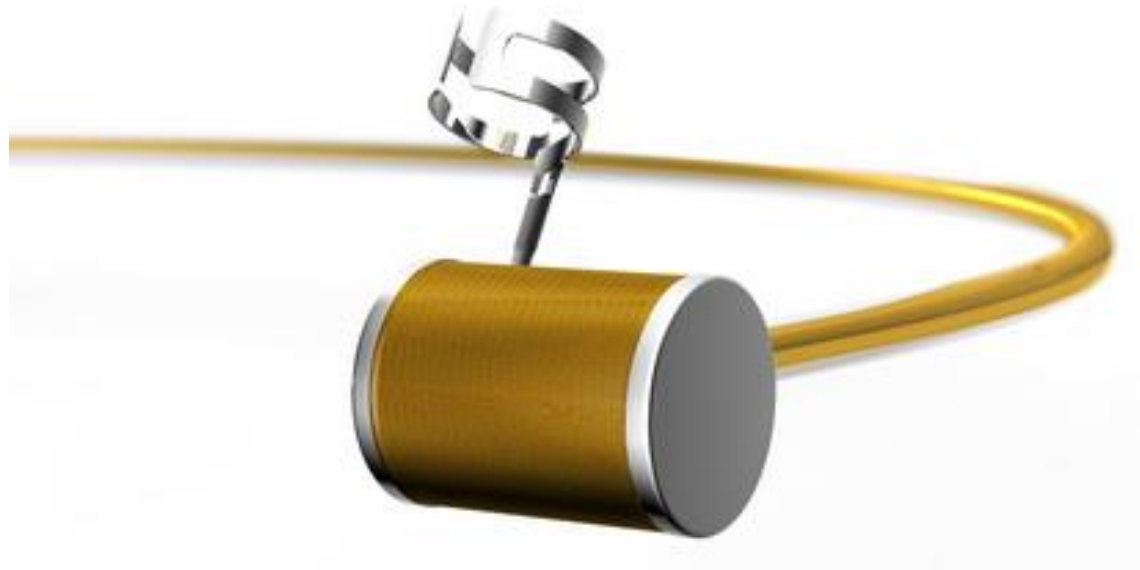
Vibrant Soundbridge (VSB)

- Converts sound into controlled, amplified vibrations
- Direct drive stimulation of the middle ear structures



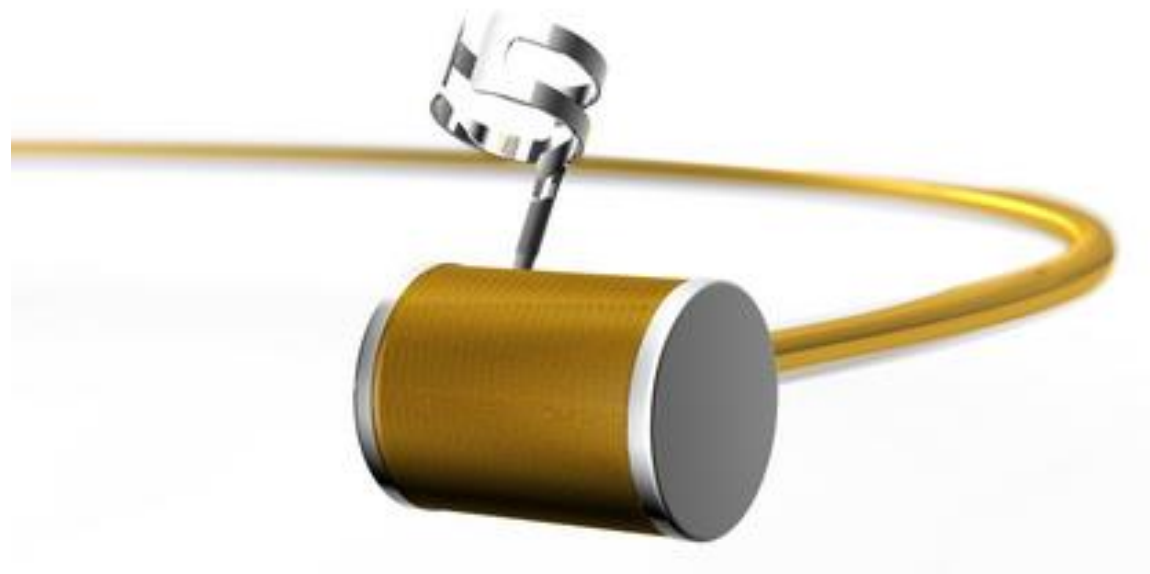
Vibrant Soundbridge (VSB)

- Two Part System:
 - » Internal
 - Vibrating Ossicular Prosthesis (VORP)

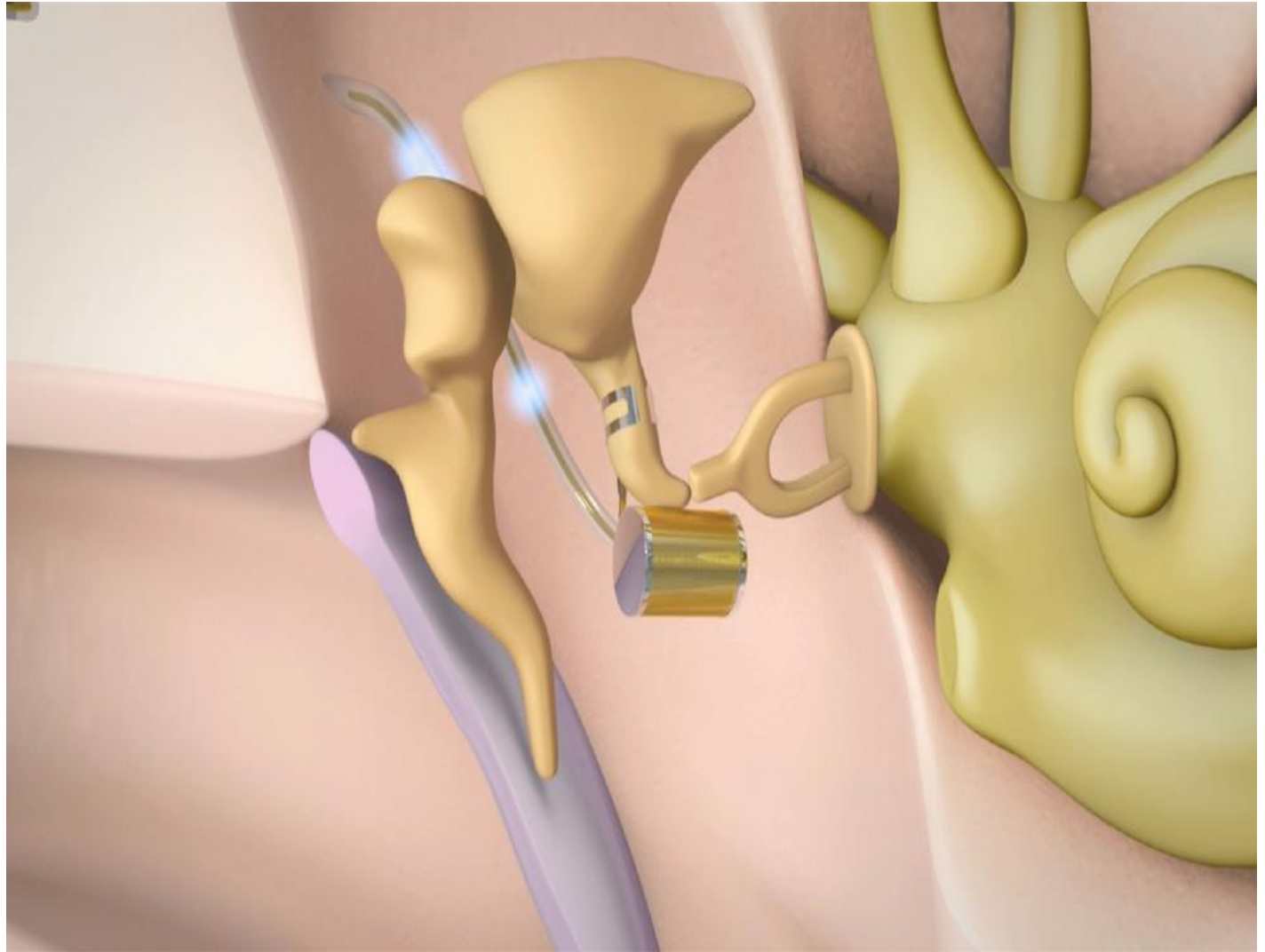


Vibrant Soundbridge (VSB)

- Vibrating Ossicular Prosthesis (VORP) with Floating Mass Transducer (FMT)
 - » Wide frequency range up to 8 kHz
 - » Preservation of residual hearing



Vibrant Soundbridge (VSB)



Vibrant Soundbridge (VSB)

- Two Part System:
 - » External
 - Audio Processor



Vibrant Soundbridge (VSB)

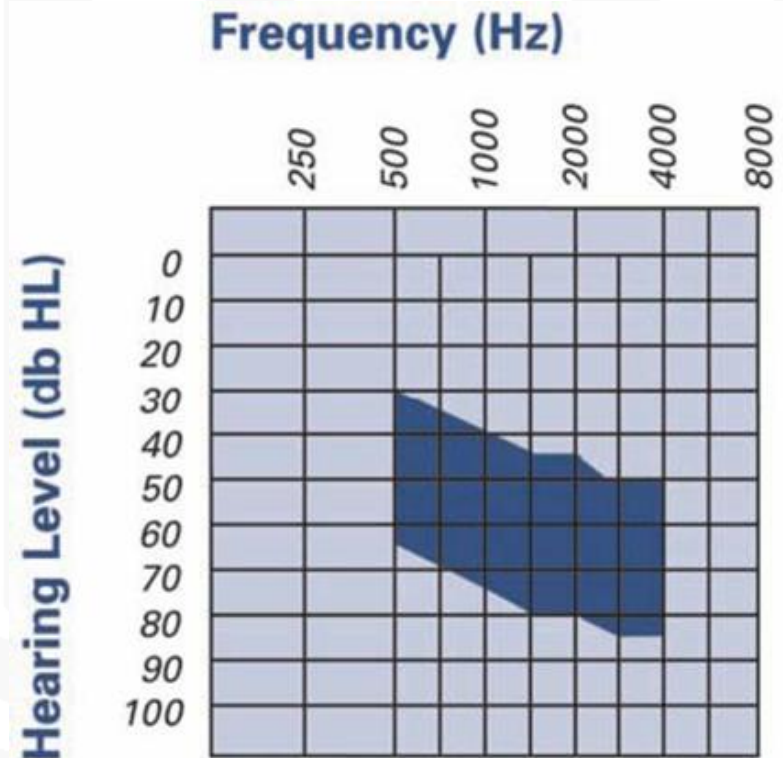
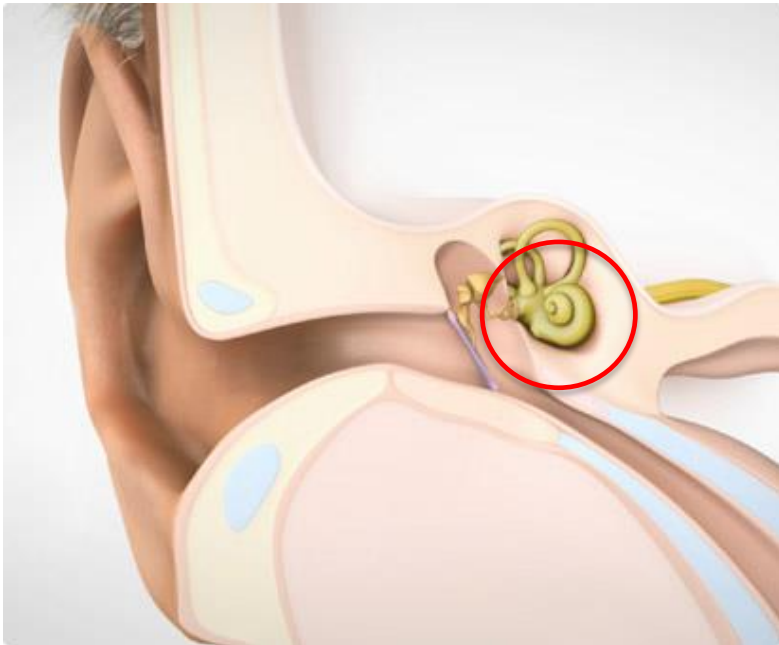
- Magnetic connection between internal and external components





Vibrant Soundbridge (VSB)

- Approved Indications
 - » Adults
 - » Bilateral moderate-to-severe sensorineural hearing loss
 - » Word Rec > 50%



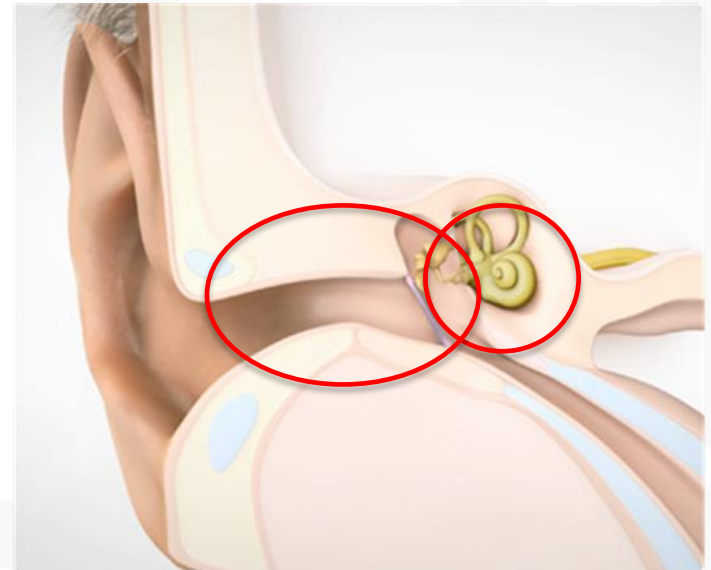
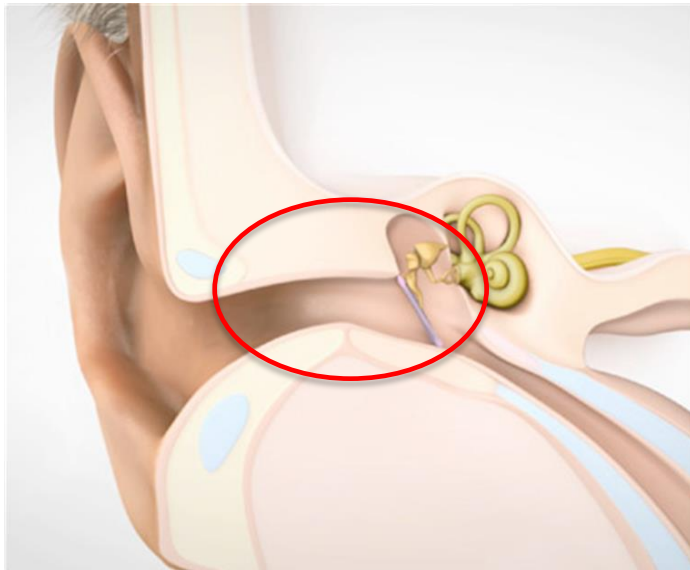
VSB Clinical Trial

- Clinical Trial of the Vibrant Soundbridge as a Treatment for Conductive and Mixed Hearing Loss, Using Direct Round Window Cochlear Stimulation
 - » Multi-center clinical trial to evaluate VSB in a new population
 - » Sponsored MED-EL Corporation



VSB Clinical Trial

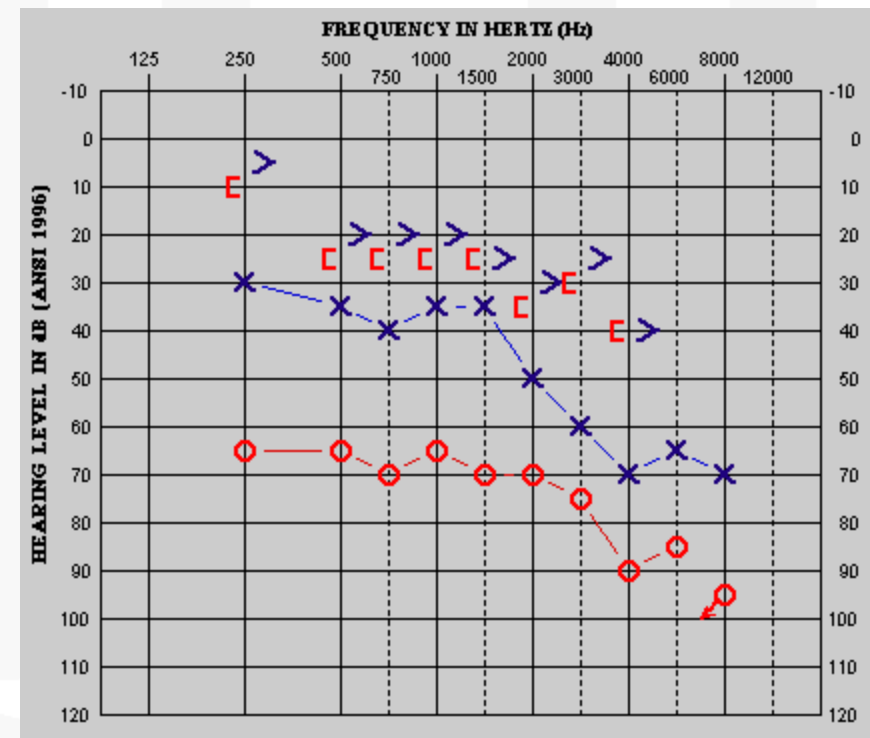
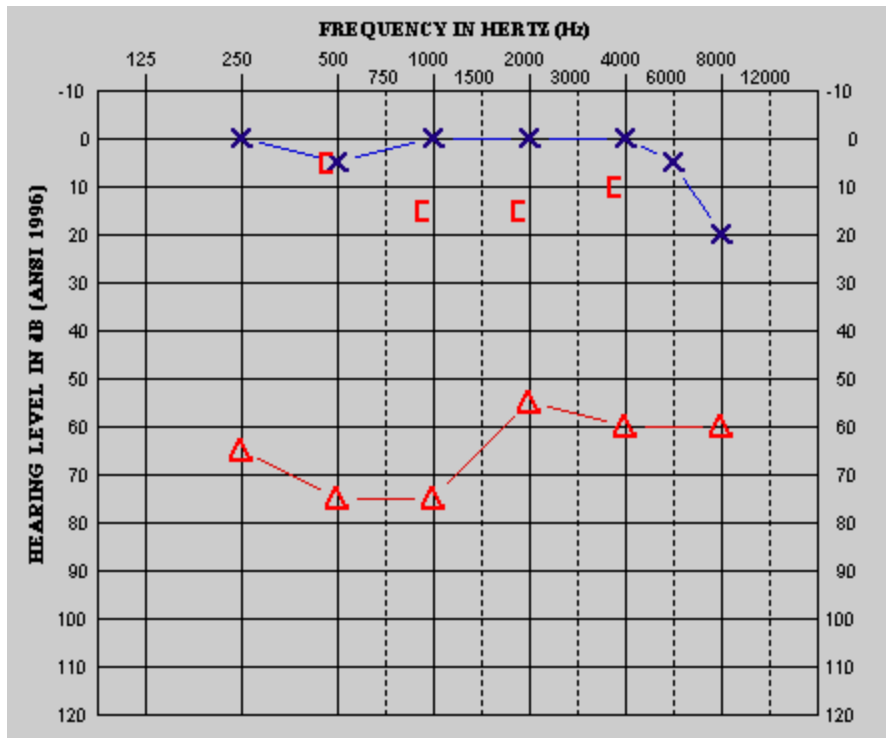
- **Candidacy Criteria**
 - » Conductive & mixed hearing loss
 - » Traditional amplification unsuccessful
 - » Word Rec > 30%
 - CNC Words



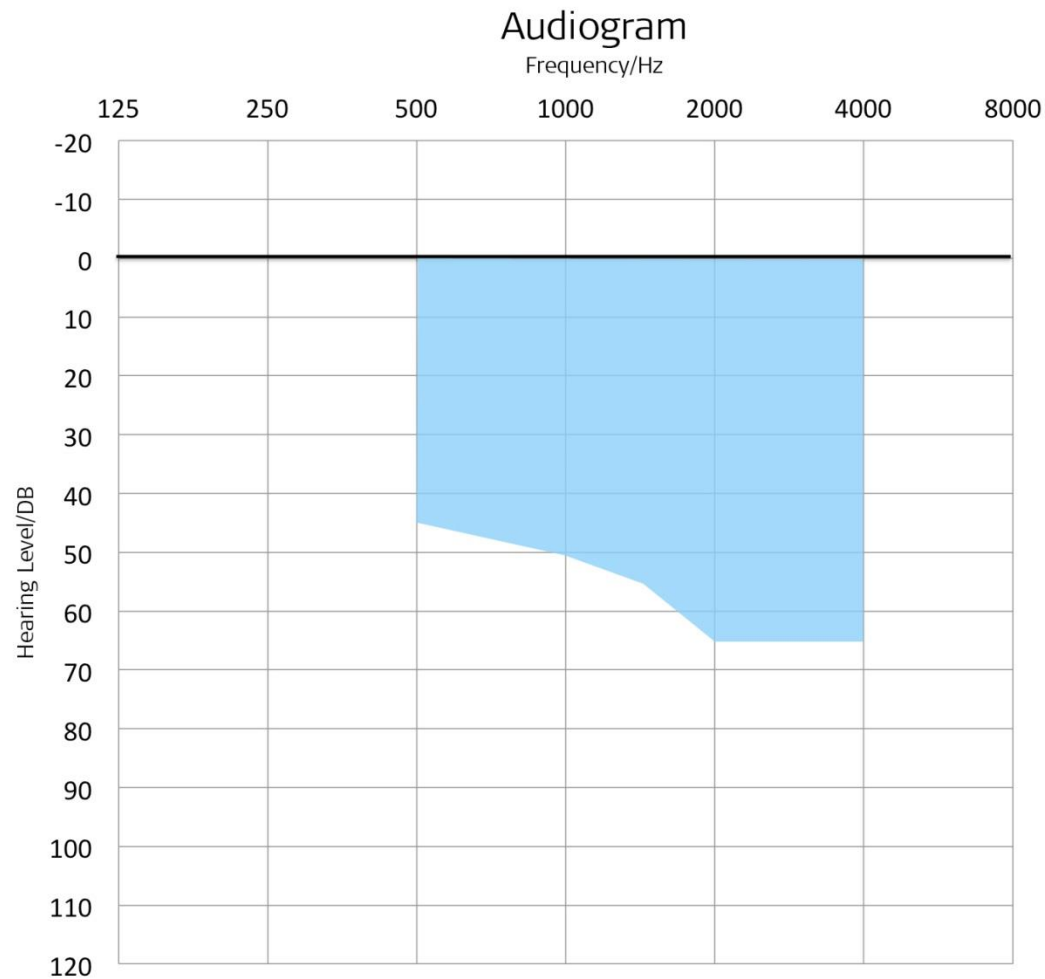


VSB Clinical Trial

- Candidacy Criteria
 - » Conductive & mixed hearing loss



VSB Clinical Trial



MED-EL Corporation

CAUTION: Investigational device. Limited by US law to investigational use.

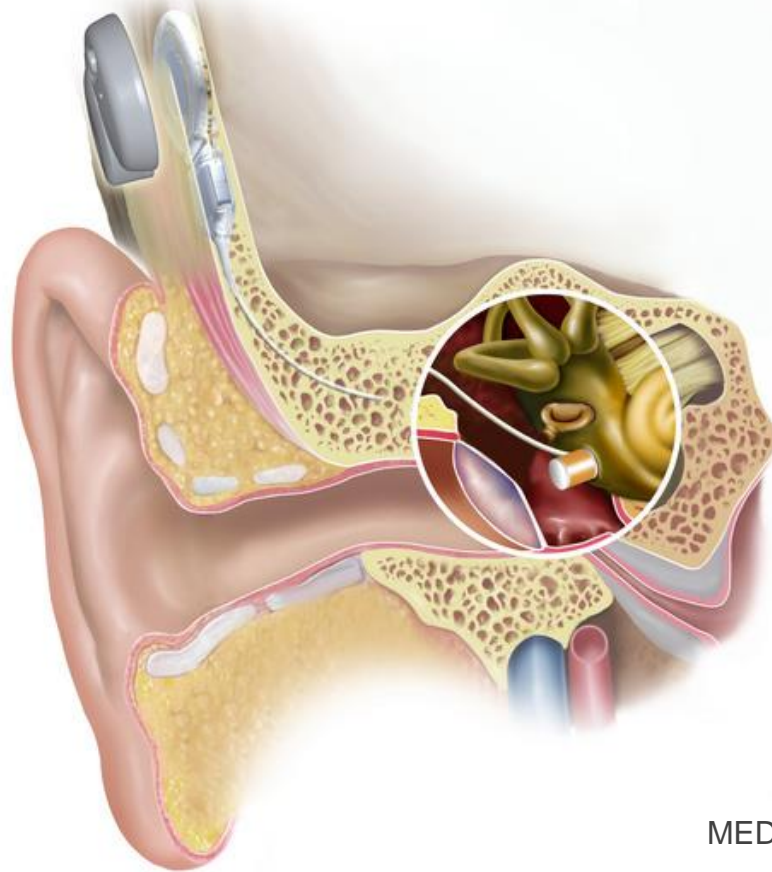
VSB Clinical Trial

- Potential Conditions
 - » Congenital malformations (Atresia, Microtia)
 - » Stenosis of external auditory canal
 - » Allergies to earmold material
 - » Chronic otitis externa
 - » Chronic draining ears
 - » Eczema/Psoriasis of the ear
 - » Unresolved acoustic feedback
 - » Large mastoid bowl following surgery



VSB Clinical Trial

- FMT placed in Round Window (RW) Niche
 - » Bypass conductive component to deliver vibrations directly to the cochlea
 - » Active RW stimulation



MED-EL Corporation

CAUTION: Investigational device. Limited by US law to investigational use.

VSB Clinical Trial

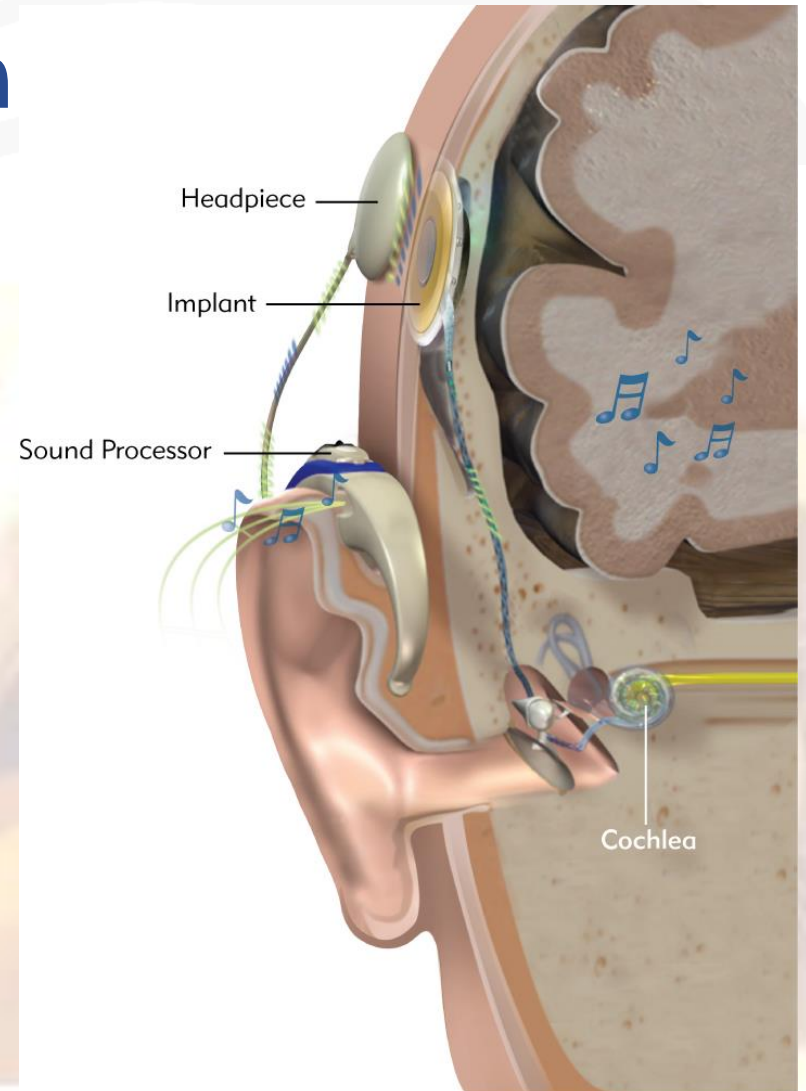
- Potential Benefits
 - » Appropriate amplification
 - » Little to no acoustic feedback
 - » Improved ability to understand speech in quiet and noise
 - » Ability to wear technology without occluding the ear canal

VSB Clinical Trial

- Results

Cochlear Implantation

- Electrical representation of an acoustic signal
 - » Insertion into scala tympani of the cochlea
 - » Bypass damaged sensory cells



Components of the Cochlear Implant System



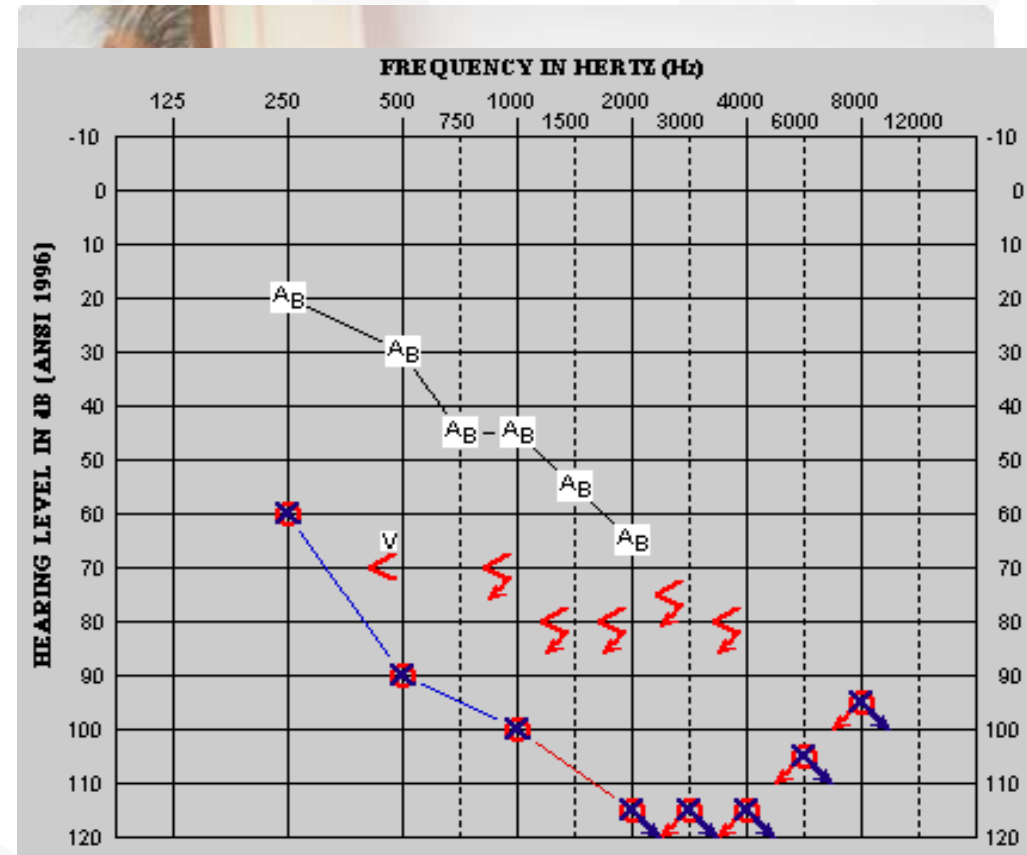
Cochlear Implantation



Cochlear Implantation

- Indications
 - » Moderate-to-profound sensorineural hearing loss
 - » Limited speech perception abilities with conventional amplification.

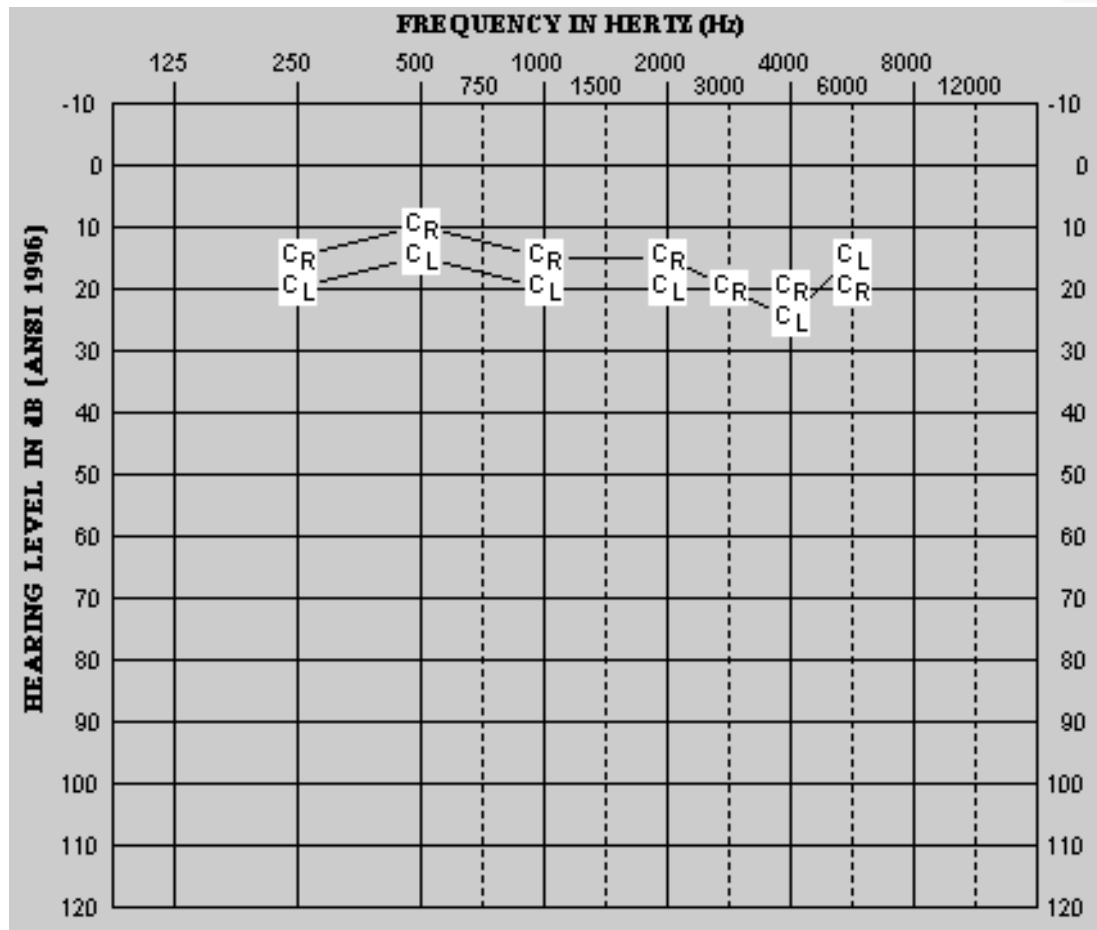
Pre-Operative
Aided Speech Testing
<u>Word Test</u>
Hearing Aid: 16%
A_B = Hearing Aid Both Ears





Cochlear Implantation

Post-operative



Post-Operative
Aided Speech Testing
Word Test

CI Right **80%**

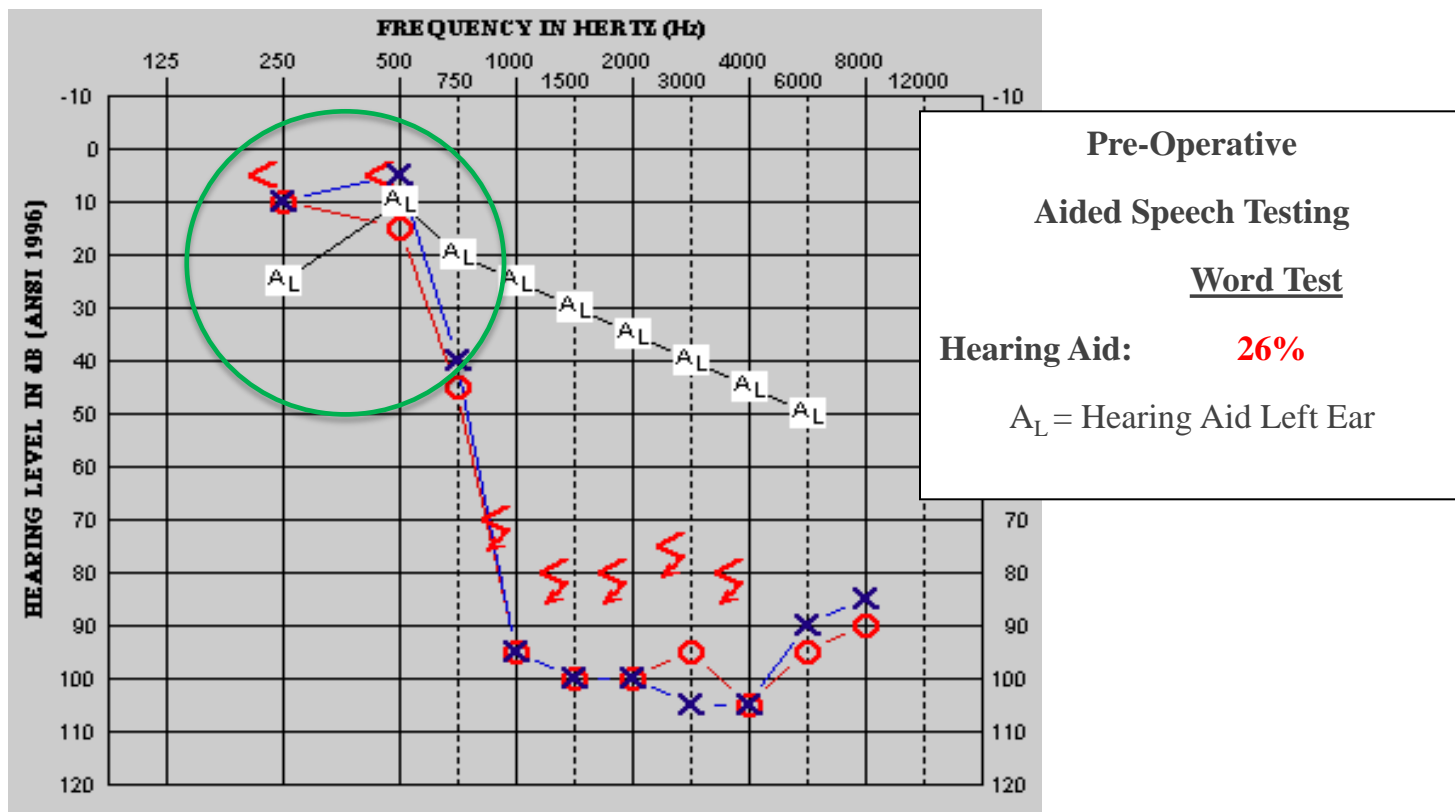
CI Left **84%**

C_R = Cochlear Implant Right Ear

C_L = Cochlear Implant Left Ear

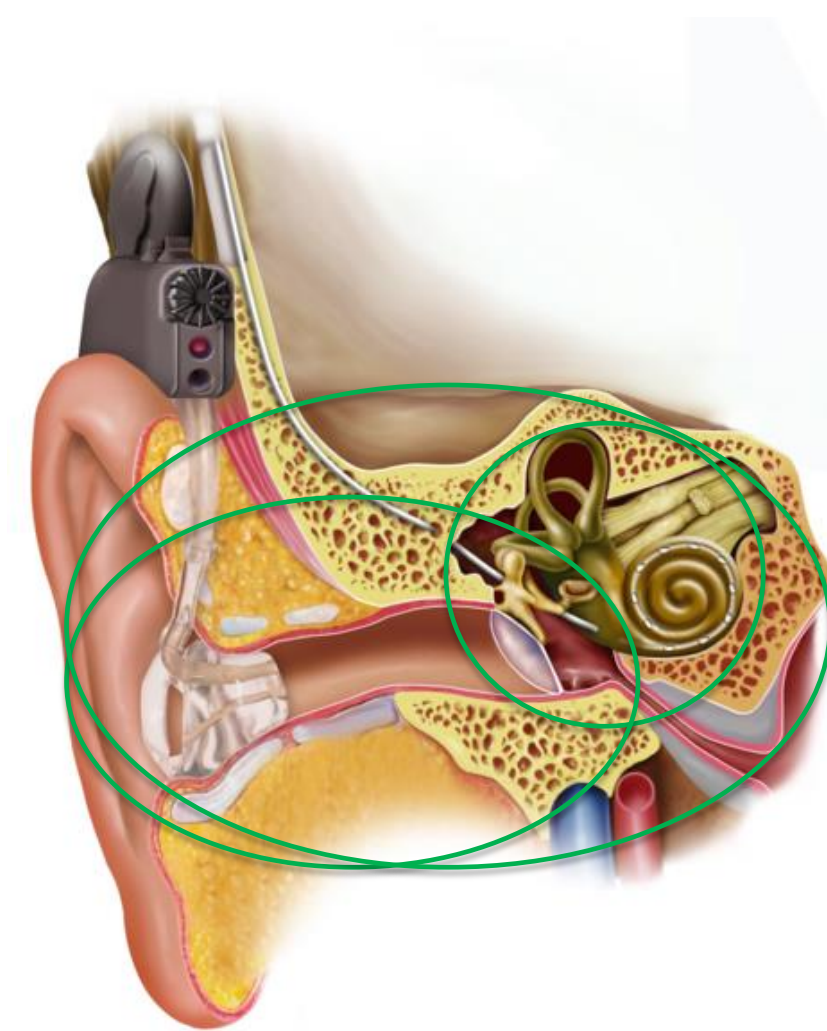
Cochlear Implantation

- Cochlear Implant Candidate?
 - » Greater residual low-frequency hearing, yet poor speech perception



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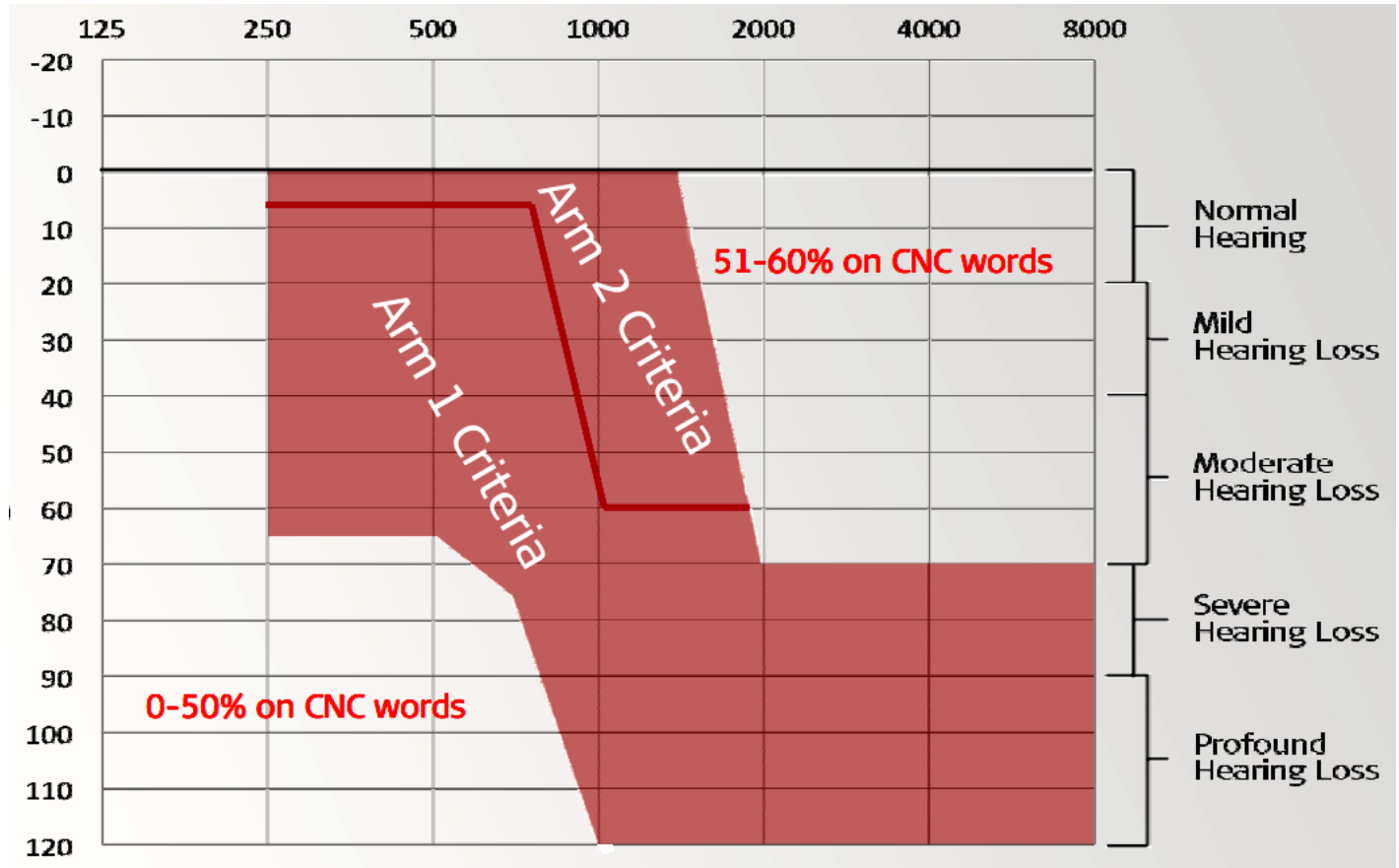
Electric-Acoustic Stimulation



CAUTION: Investigational device. Limited by US law to investigational use.

Electric-Acoustic Stimulation

- Candidacy criteria



CAUTION: Investigational device. Limited by US law to investigational use.

Electric-Acoustic Stimulation

- Candidacy Criteria
 - » Adults (>18 years)
 - » Stable hearing thresholds
 - » Poor speech perception with appropriately fit hearing aids



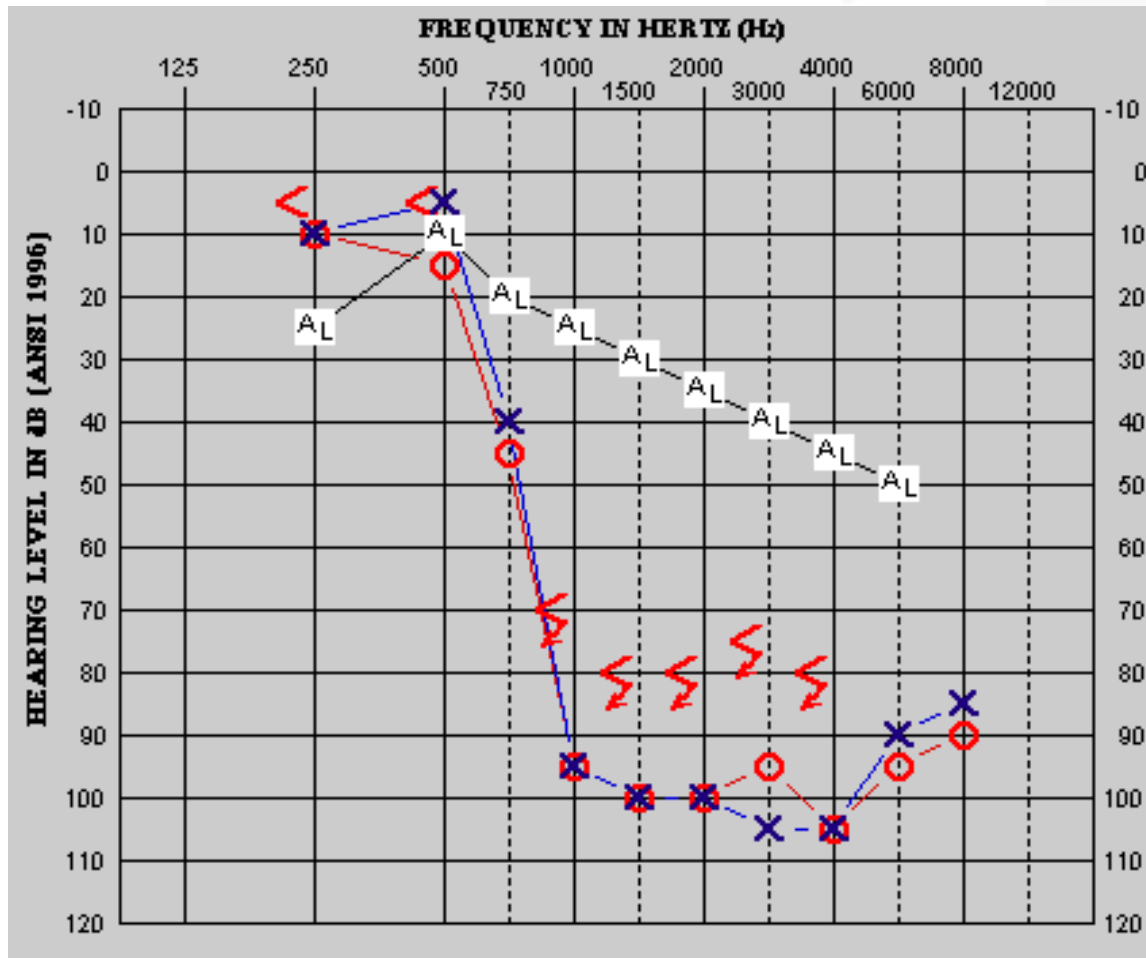
Electric-Acoustic Stimulation

- Results



Electric-Acoustic Stimulation

- Preoperative

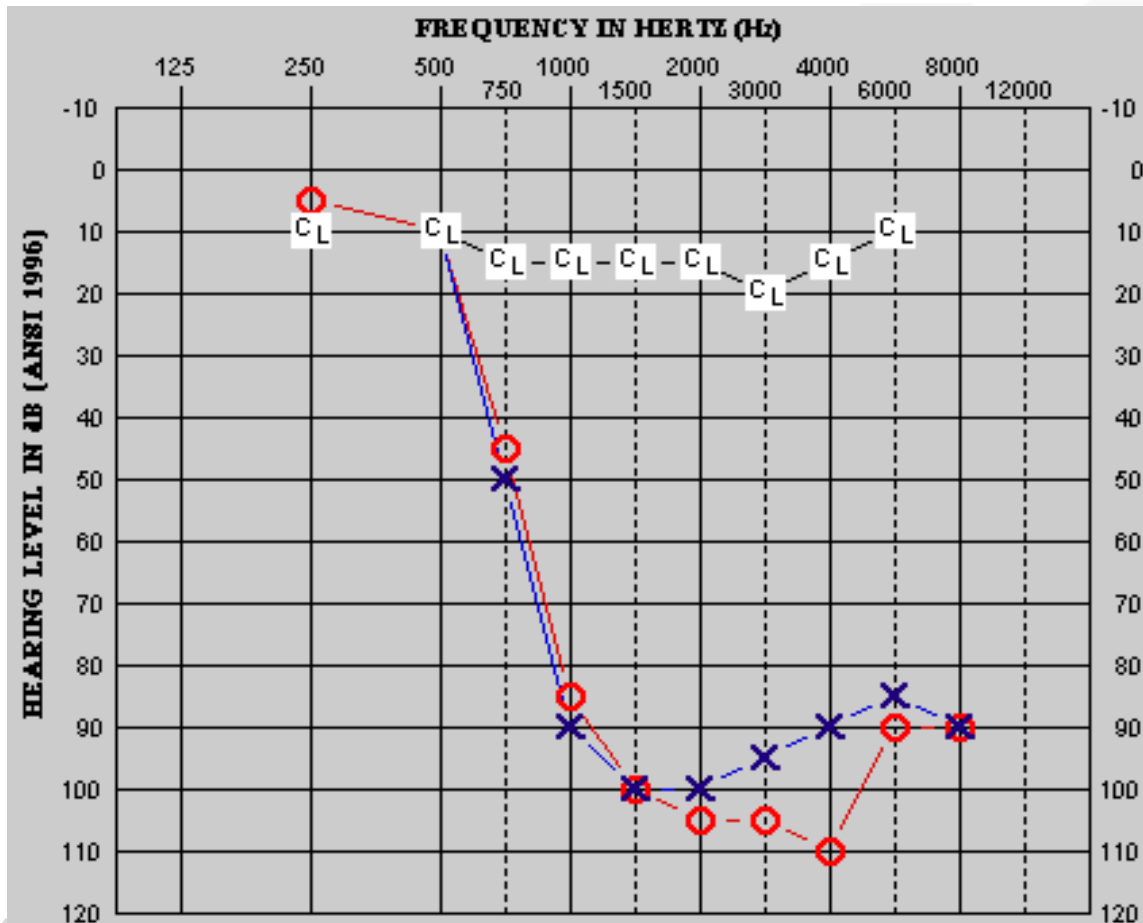


Pre-Operative
Aided Speech Testing
Word Test
Hearing Aid: 26%
A_L = Hearing Aid Left Ear



Electric-Acoustic Stimulation

- Post-operative



Post-Operative

Aided Speech Testing

Word Test

EAS

90%

C_L = Cochlear Implant Left Ear



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