Updates in Cochlear Implantation

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Disclosures

- I have no disclosures to report.

Impact of CIs

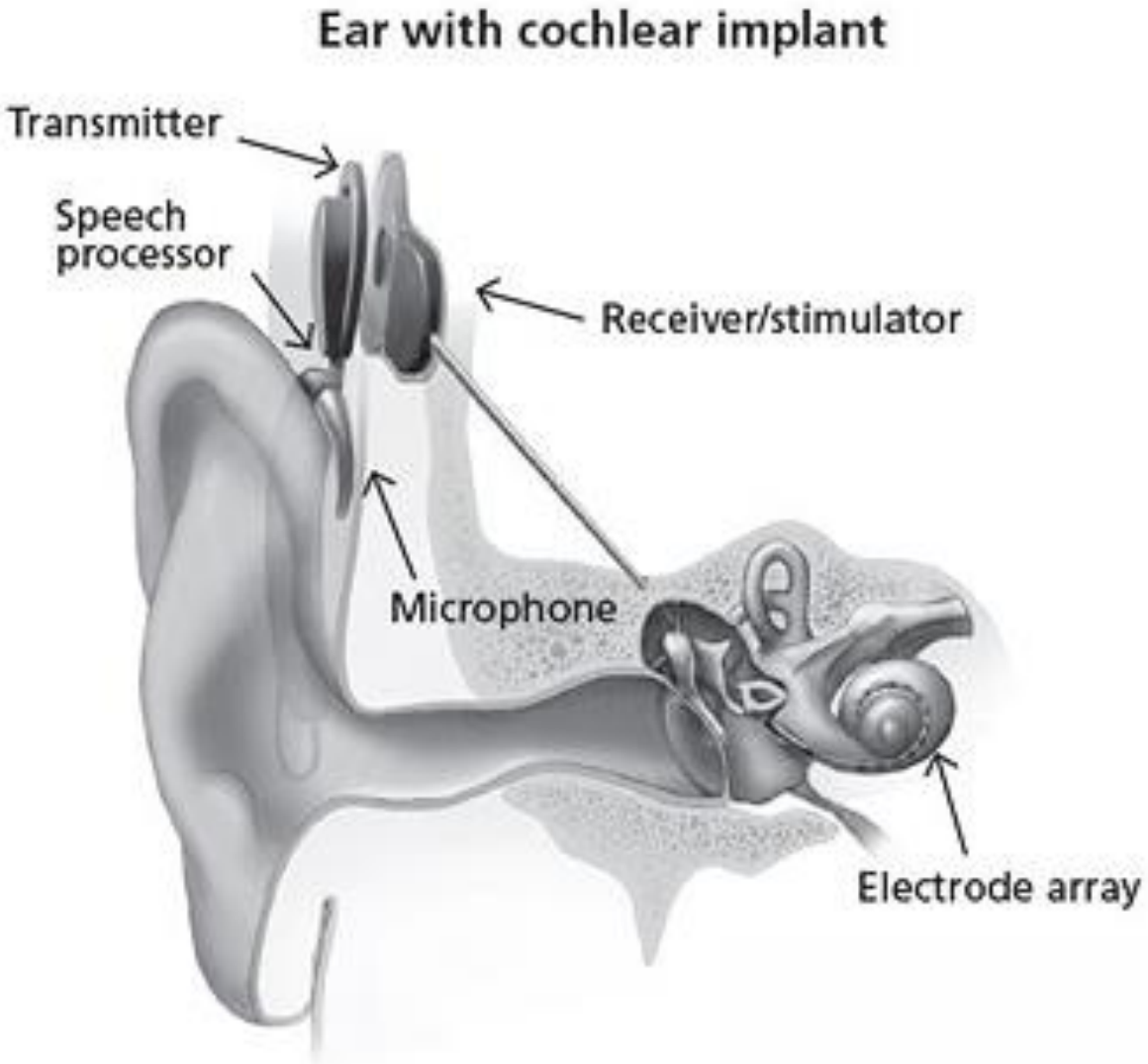
- 700,000+ CIs worldwide (2019)
- 118,000 CIs in the US (2019)
- Most common, most successful cranial nerve stimulator
- 40+ years of commercial experience and research
- Proven benefit for recipients

Underutilization of CIs

- >400 million worldwide have debilitating hearing loss
- Over 1.3 million in US would qualify for CI
- ~12% utilization rate in the US

The Modern Implant

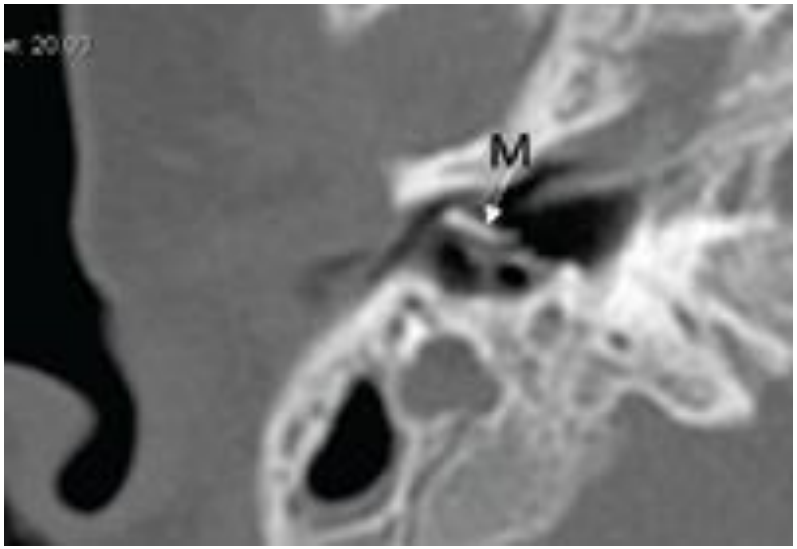
RUSH

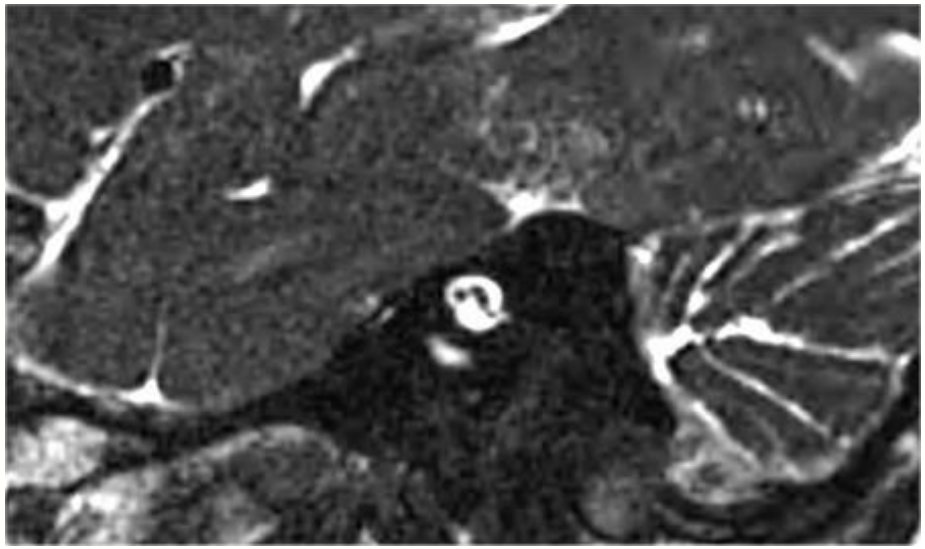


Candidacy Evaluation

CI Contraindications

- Most severe inner ear malformations
  - Complete labyrinthine aplasia
  - Complete cochlear aplasia
- Cochlear nerve agenesis





CI Considerations

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- Higher level auditory pathway dysfunction
- Less severe inner ear malformations
  - Common cavity
  - Cochlear hypoplasia
  - Incomplete partition
- Cochlear fibrosis/ossification
- Active otitis media
- Medical comorbidity
- Psychiatric comorbidity
- Psychosocial environment
- Pre-lingually deafened adult
- Unrealistic expectations

Candidacy Evaluation

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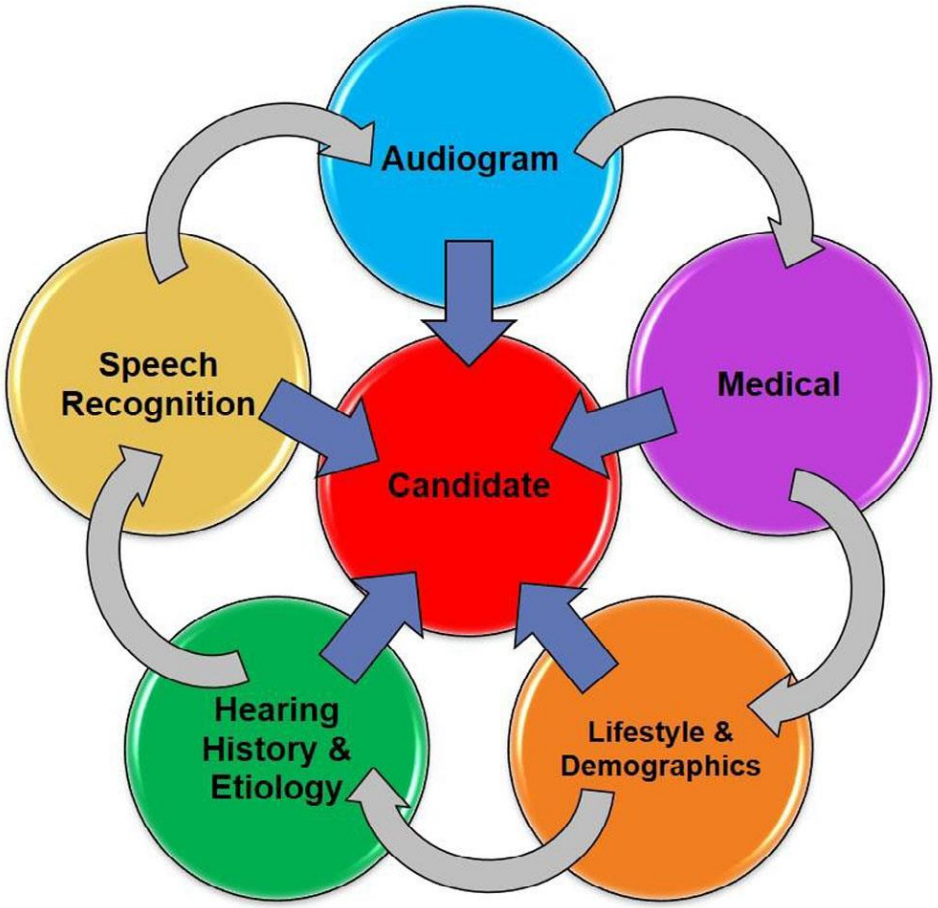
- Pure tone audiometry
- Speech recognition testing
- Counseling



Speech Testing

- Goal of CI is to facilitate hearing
  - Not simply noise perception
- AAO-HNS and AAA developed a Minimum Speech Test Battery
  - 1996, revised 2011
  - Guideline for candidacy evaluation and post-implant testing
- MSTB recommends testing in 3 conditions
  - Monosyllabic words (CNC)
  - Sentences in quiet (HINT in 1996, AzBio in 2011)
  - Sentences in noise, +5 or +10 signal-to-noise ratio

Speech Testing

- Test in “best aided condition”
  - Binaural, with hearing aids that are well-fitted
- Individual ear testing should be done
  - Provides baseline to compare post-implant test results
  - Increasing movement toward individual ear assessment
- Test materials are open-set, recorded
- Presented at 60 dB SPA
  - Approximates conversational speech

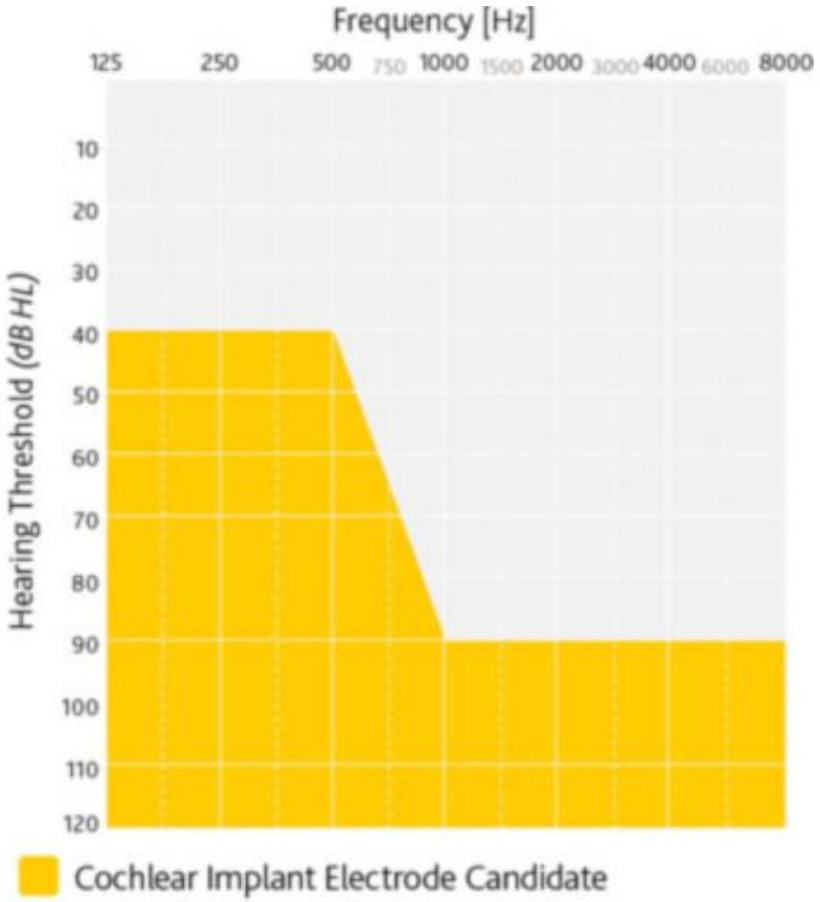
Traditional Criteria

Criteria

- By payor
  - CMS (Medicare)
  - VA
  - Insurance companies
- By governing body
  - FDA criteria—different for each device
  - Off-label use
    - At the discretion of providers

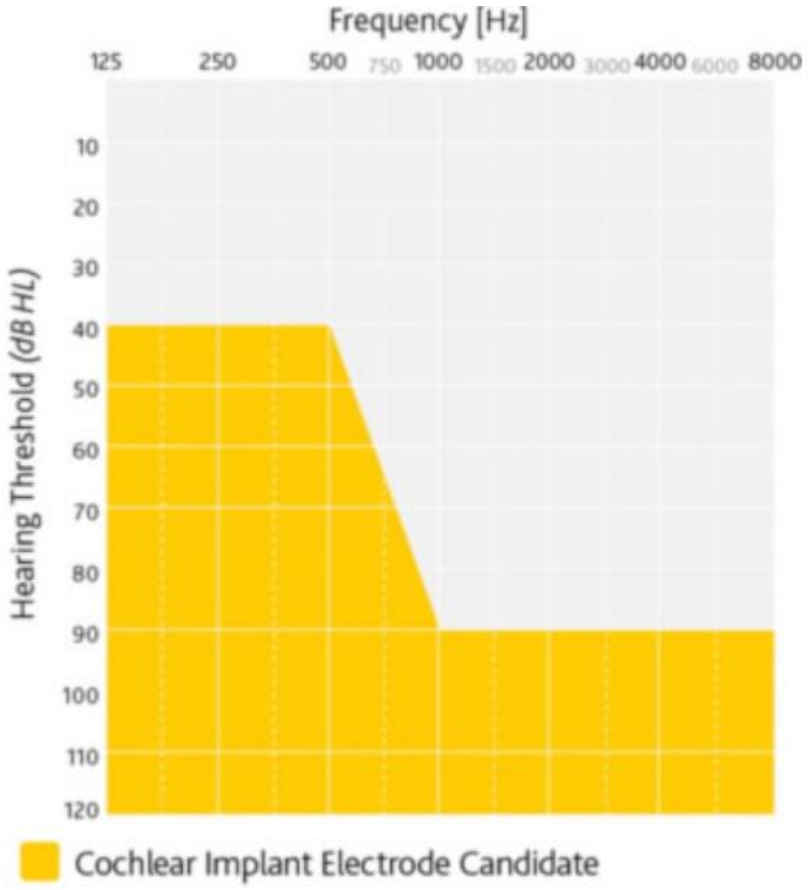
CMS Criteria 2005-2022

1. Bilateral moderate-to-profound SNHL
2. ≤40% best-aided condition on recorded open-set sentences
3. No infection
4. No cochlear fibrosis
5. No retrocochlear lesion



CMS Criteria 2022-present

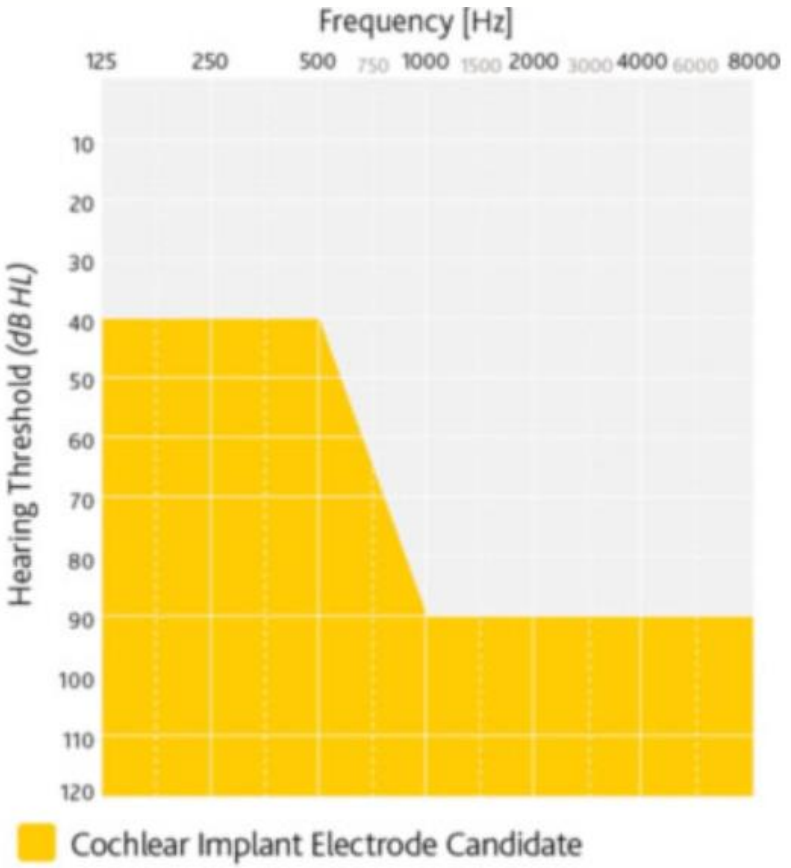
1. Bilateral moderate-to-profound SNHL
2. **≤60%** best-aided condition on recorded open-set sentences*
3. No infection
4. No cochlear fibrosis
5. No retrocochlear lesion



*no comment on testing in noise

FDA Criteria

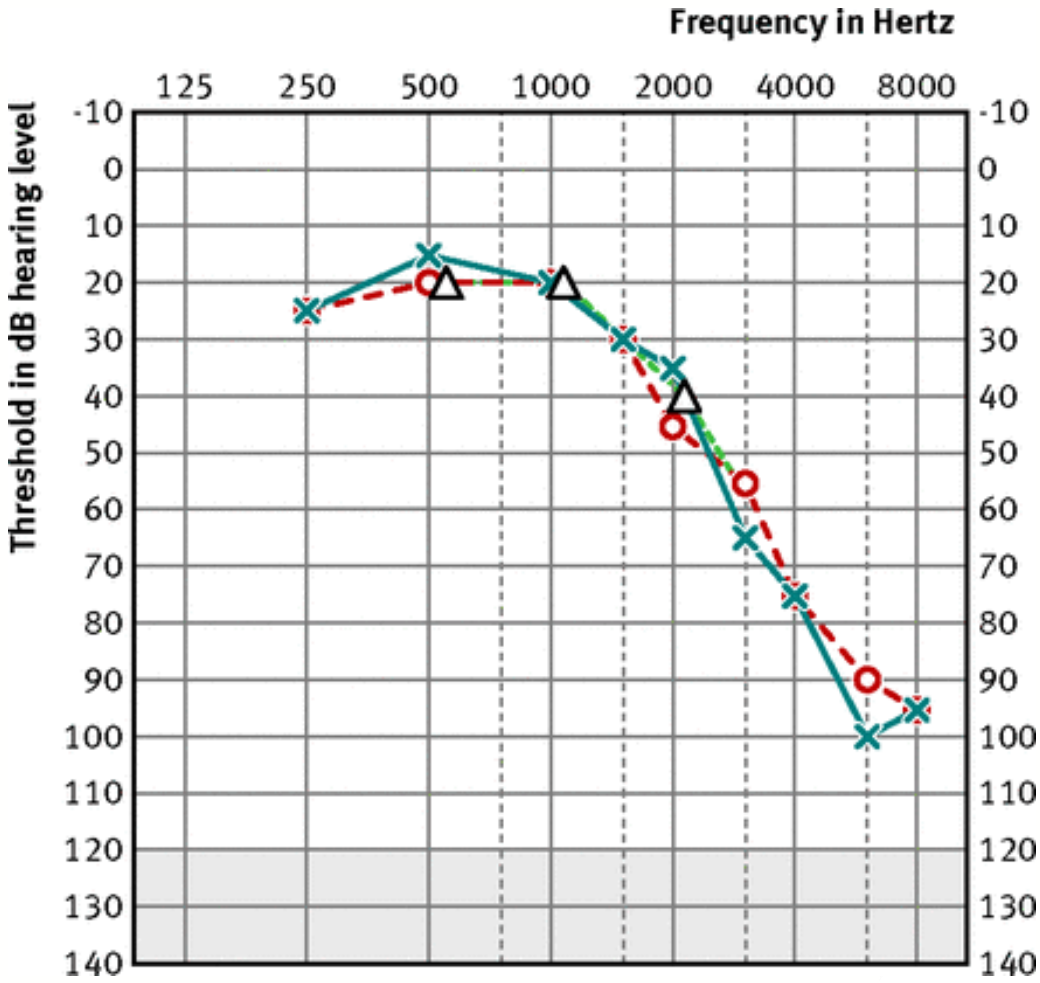
- Varies by device
- Least restrictive for “traditional” candidate:
  - Moderate-to-profound bilateral SNHL
  - ≤50% sentence test ipsilateral ear
  - ≤60% sentence test contralateral or binaural



Hearing Preservation

Hearing Preservation

- What about patients with normal low frequency hearing?
- Commonly seen
  - presbycusis
- “ski slope” audiogram



Hearing Preservation

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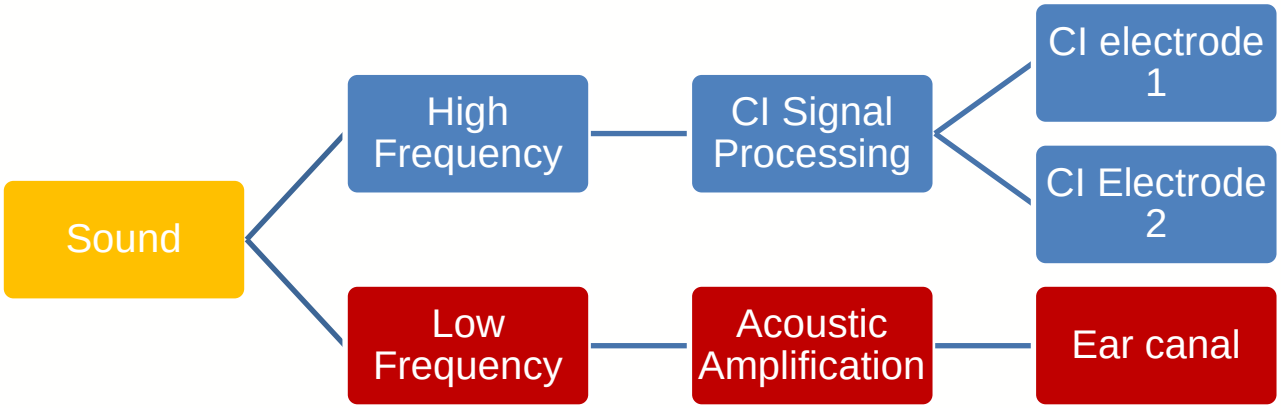
- Electric-acoustic stimulation (EAS)



Hearing Preservation

- Benefits of EAS:
  - Speech understanding in noise
  - Sound localization
  - Music appreciation

Hearing Preservation

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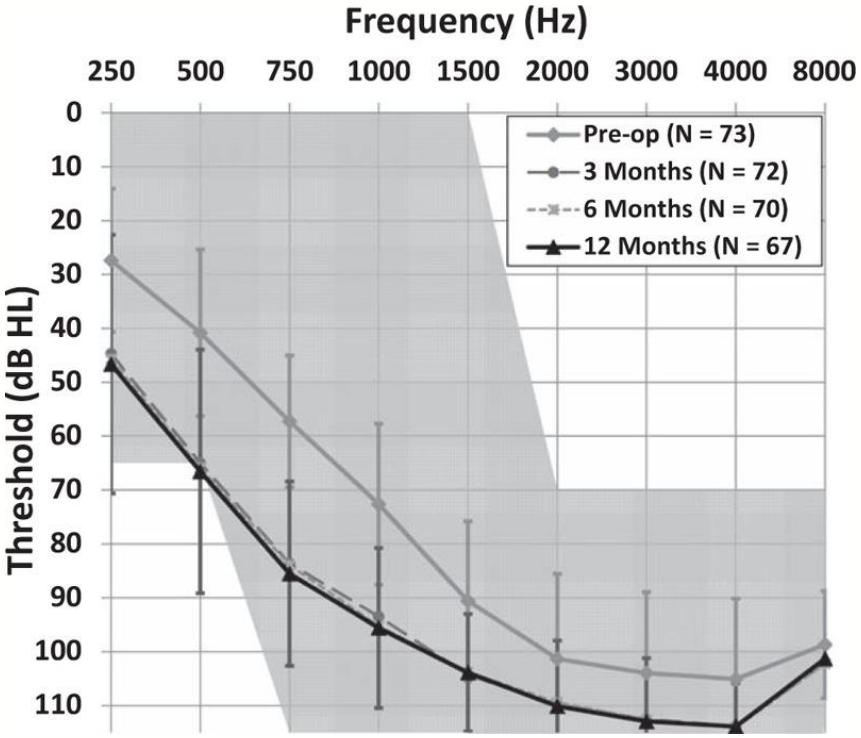
- Techniques to minimize trauma
  - Electrode array
    - lateral wall vs perimodiolar
    - Shorter array to minimize trauma at apex
    - Slimmer electrode array to minimize trauma
  - Cochleostomy approach vs round window
  - Slow insertion, constant force
  - Steroid use
    - Systemic
    - Topical in middle ear
  - Lubricant use
- Rates of hearing preservation highly variable
  - Can be up to 90% on early on with at least partial
  - Typically declines over time at 12 months

Hearing Preservation

- EAS Trial results:

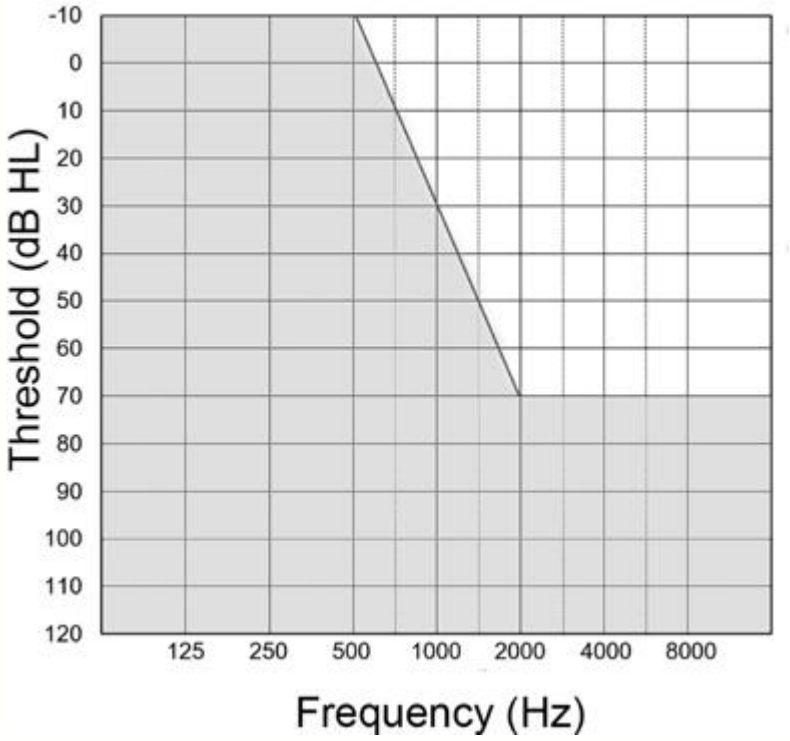


- 91% patients reported improved hearing in noise subjectively compared to HA use alone

	Pre-op Acoustic	12 mos EAS	12 mos Electric
Sentences in noise	31%	+42%	+25%
CNC Words	30%	+37%	+18%

Hearing Preservation

- Least restrictive EAS FDA criteria:
  - Normal to severe SNHL
    - >70dB HL 2kHz and higher
  - <60% CNC in ear to be implanted
  - <80% CNC contralateral ear



Unilateral Hearing Loss

Unilateral/Asymmetric Loss

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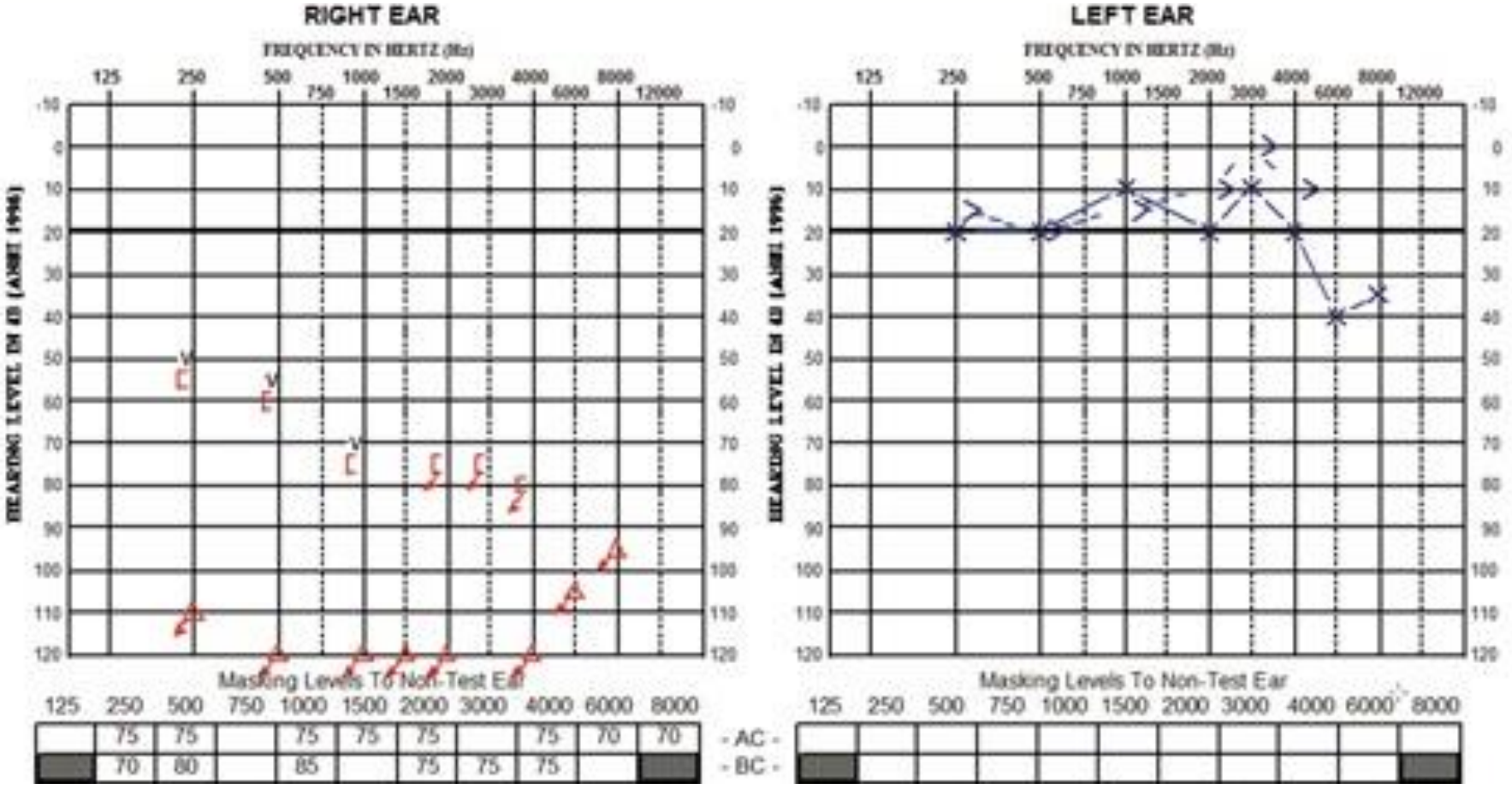
- Single-sided deafness (SSD)



Unilateral/Asymmetric Loss

- Some causes of SSD/UHL/AHL:
  - Sudden SNHL
  - Meniere's disease
  - Vestibular schwannoma
  - Trauma
  - Advanced otosclerosis
  - Advanced chronic ear disease
  - Inner ear malformation

Unilateral/Asymmetric Loss

- Benefits of binaural hearing in complex environments
  - Localization
  - Head shadow—when noise is on one side, other side has less noise due to head shadow
  - Binaural summation—when speech and noise are in front, signal is summed
  - Binaural squelch—central auditory pathways use bilateral signals for improved spatial hearing in noise

Unilateral/Asymmetric Loss

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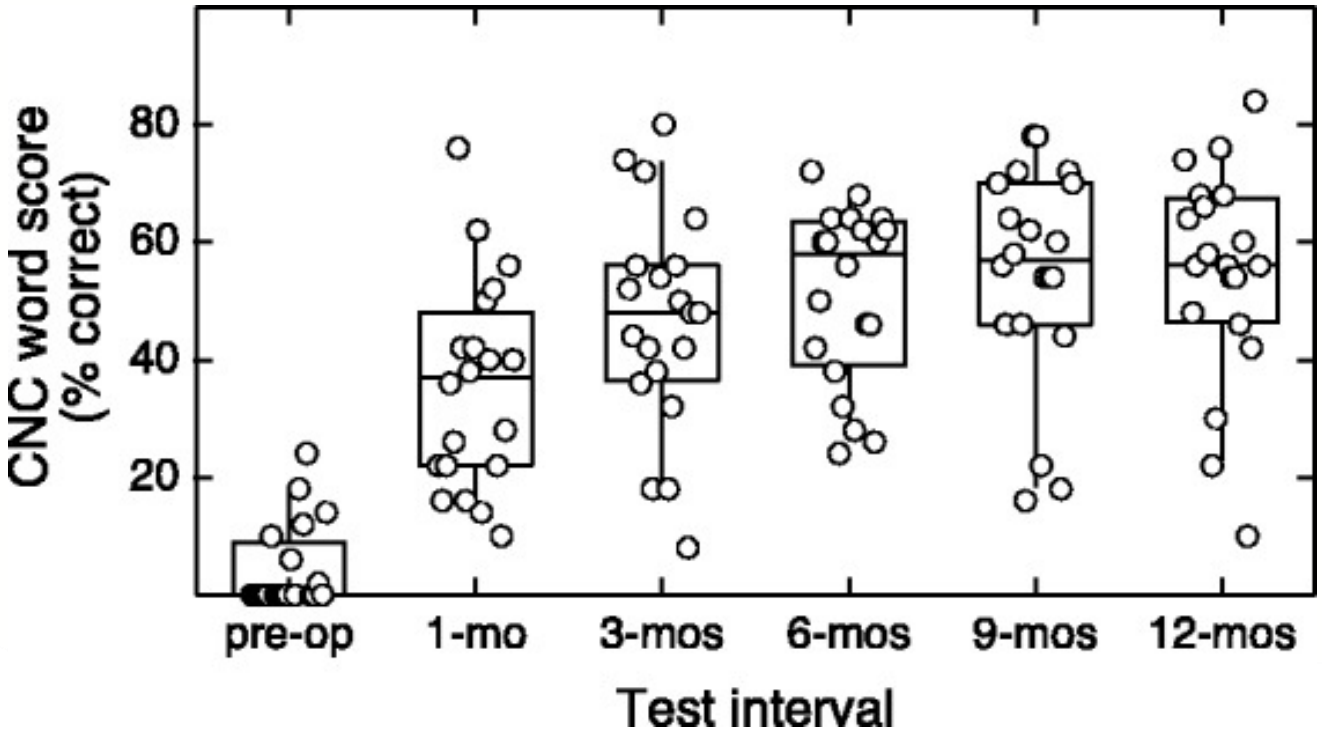
- Patients qualified for CI criteria in 1 ear
- Contralateral ear was normal or mild hearing loss
- CNC results in CI ear:



Unilateral/Asymmetric Loss

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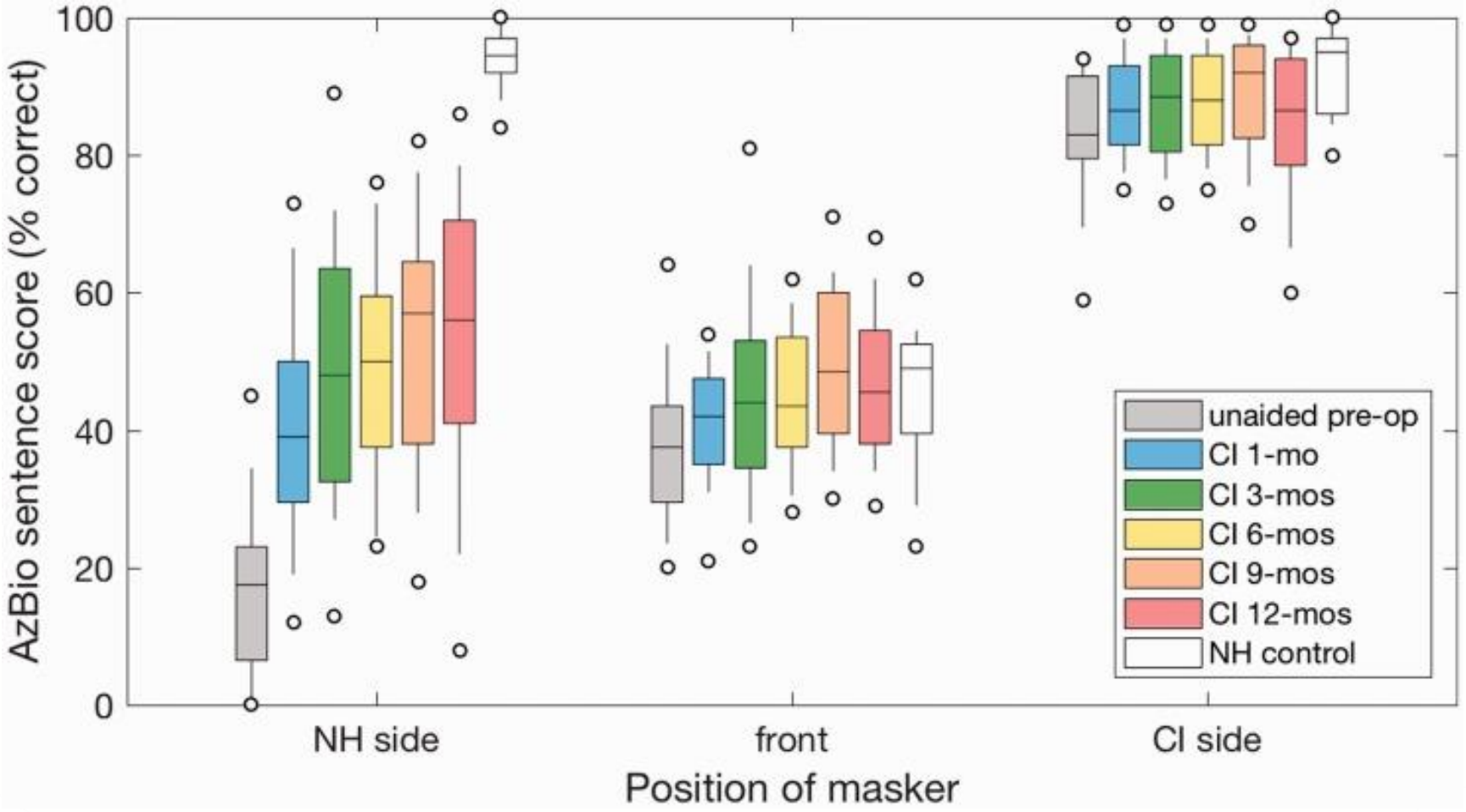
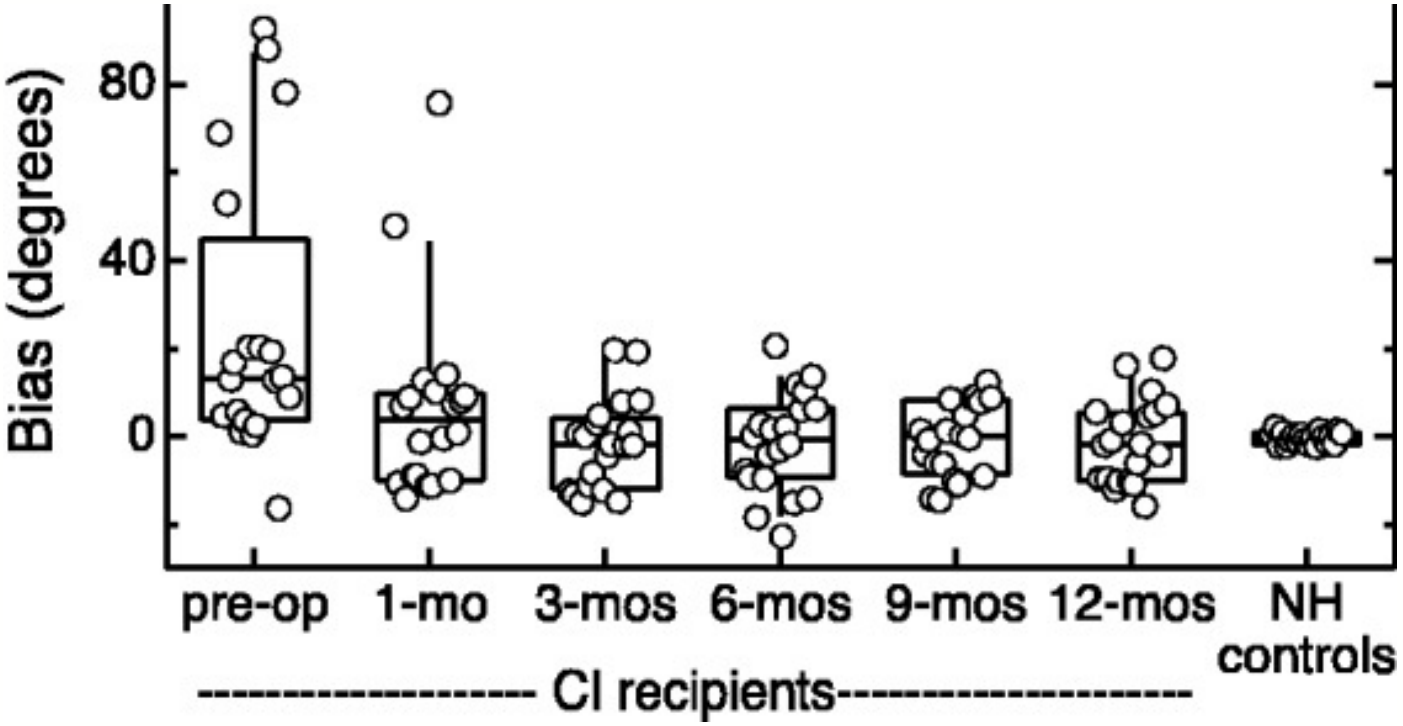
- Sentences in noise



Unilateral/Asymmetric Loss

- Localization results
  - Likelihood of assuming random sound is coming from the better side



Unilateral/Asymmetric Loss

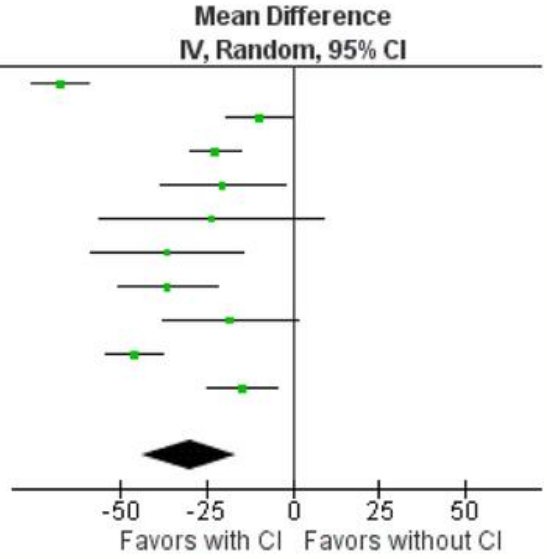
- Tinnitus improvement

Patient-reported Tinnitus Handicap Index

Study or Subgroup	With cochlear implant Mean	SD	Total	Without cochlear implant Mean	SD	Total	Mean Difference IV, Random, 95% CI
Ahmed et al, 2007	12	13.5	13	79.6	7	13	-67.60 [-75.87, -59.33]
Arndt et al, 2017	35	14.52	10	44.9	5.3	10	-9.90 [-19.48, -0.32]
Dillon et al, 2018	2.92	4.94	20	25.4	16.5	20	-22.48 [-30.03, -14.93]
Dorbeau et al, 2018	41.7	20.1	9	62	19.5	9	-20.30 [-38.60, -2.00]
Galvin et al, 2018	25.2	30.6	10	48.7	42.6	10	-23.50 [-56.01, 9.01]
Holder et al, 2017	24.6	28.2	12	61.2	27.5	12	-36.60 [-58.89, -14.31]
Macías et al, 2018	34.7	25.9	13	71.02	7.64	13	-36.32 [-51.00, -21.64]
Peter et al, 2019	23	17.5	10	41.2	26.5	10	-18.20 [-37.88, 1.48]
Poncet-Wallet et al, 2020	26	20	26	72	9	26	-46.00 [-54.43, -37.57]
Sullivan et al, 2019	37.01	26.45	60	51.72	28.98	60	-14.71 [-24.64, -4.78]
Total (95% CI)			**183**			**183**	**-29.97 [-43.88, -16.06]**

Heterogeneity: $Tau^2 = 438.38$; $Chi^2 = 123.92$, df = 9 ($P < 0.00001$); $I^2 = 93\%$

Test for overall effect: $Z = 4.22$ ($P < 0.0001$)



Unilateral/Asymmetric Loss

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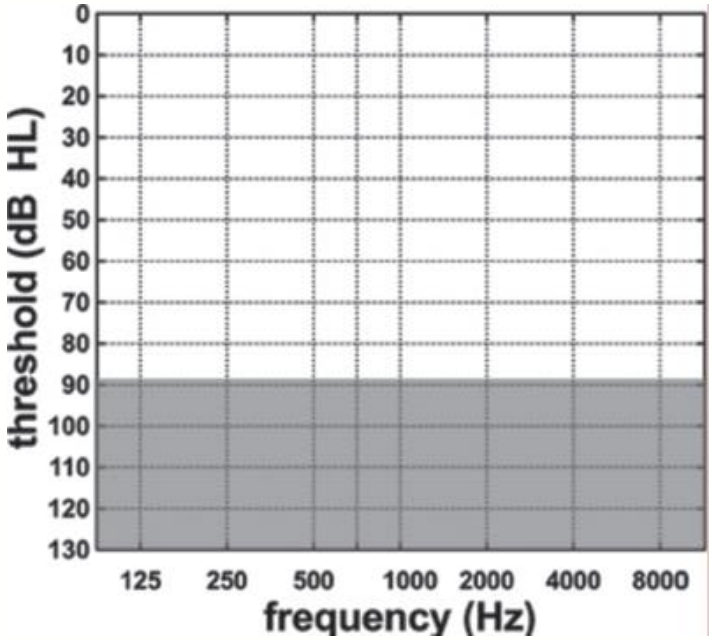
- SSD FDA approval
- In the ear to be implanted:
  - Thresholds > 90dB HL
  - CNC < 5%
  - <10 year duration of deafness



Summary

Summary

- There are FDA criteria, but often lagging
- New expanded criteria for:
  - Normal to moderate low frequency hearing loss
  - Single sided deafness
- CI may help with tinnitus suppression
- Candidacy expected to continue to expand!

Key Reference

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