Candidacy Considerations for Modern Implantable Hearing Technologies: An Otologist's Perspective

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Disclosure

- I have no financial interest in any of the devices or companies discussed
- Consultant for Advanced Bionics, Cochlear, and MedEL Corporation as a Surgical Advisory Board Member
- Ongoing clinical trials with all 3 manufacturers

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Overview

- Available Implantable Auditory Devices
  - » Neural stimulation (poor speech perception)
    - Cochlear Implants
      - » Conventional Cochlear Implant*
      - » Electroacoustic stimulation
    - Brainstem implants (no cochlear nerve)
  - » Hair Cell Stimulation (preserved speech perception)
    - Bone Anchored Hearing Devices (BAHA)*
    - Active Middle Ear Implants
      - » Electromagnetic
      - » Piezoelectric

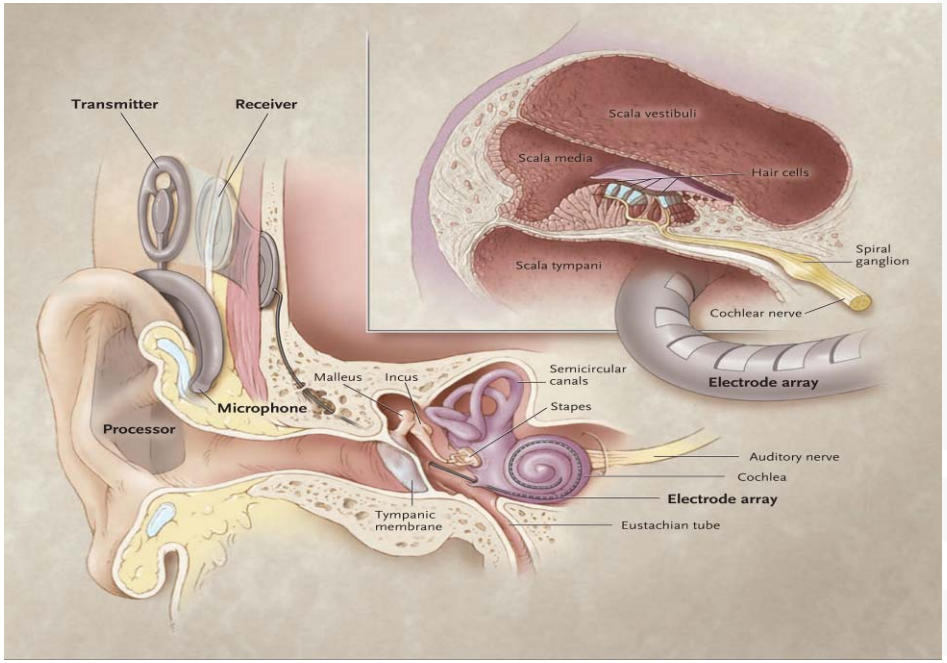
*Approved for use in children

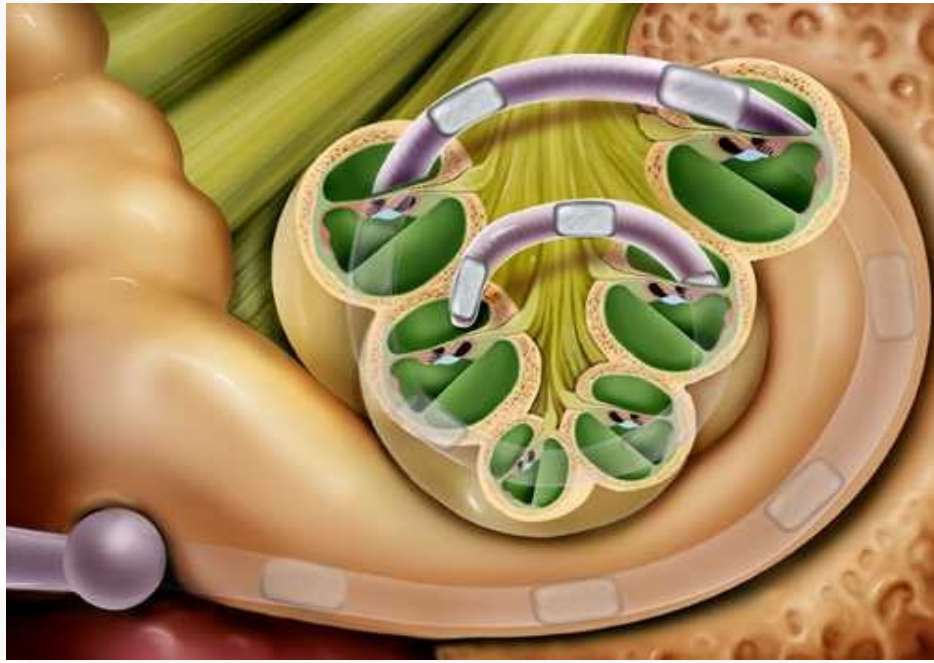
Cochlear Implantation

- Candidacy Considerations in Children
- Current *clinical* research topics:
  - » Expanding criteria
  - » EAS/Hybrid & Hearing preservation
  - » Tinnitus suppression
  - » Unilateral hearing loss
- New Vaccination Indications
  - » PCV-13

Criteria for Implantation in Children

- Severe to profound SNHL
- Limited benefit from hearing aids
- No active middle ear pathology
- Normal eighth nerve and present cochlea





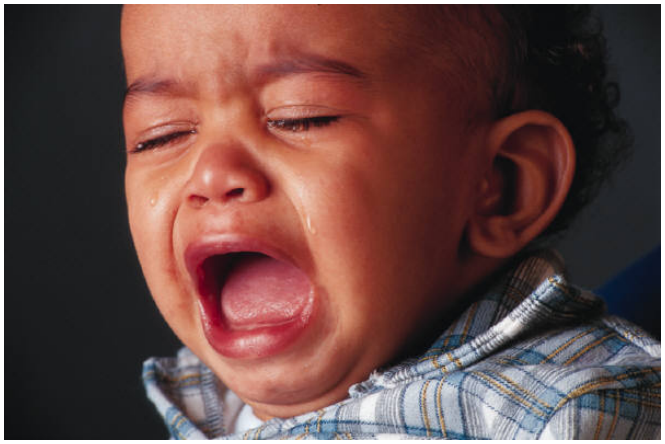
So what's the big deal?

Criteria for Implantation in Children

- Severe to profound SNHL → Pediatric audiologist
- Limited benefit from hearing aids → Speech pathologist
- No middle ear pathology → Otologist
- Present cochlear nerve and cochlea

- This requires complex interdisciplinary teamwork.
- Must become conversant in others discipline

Essence of the Problem in Pediatric CI

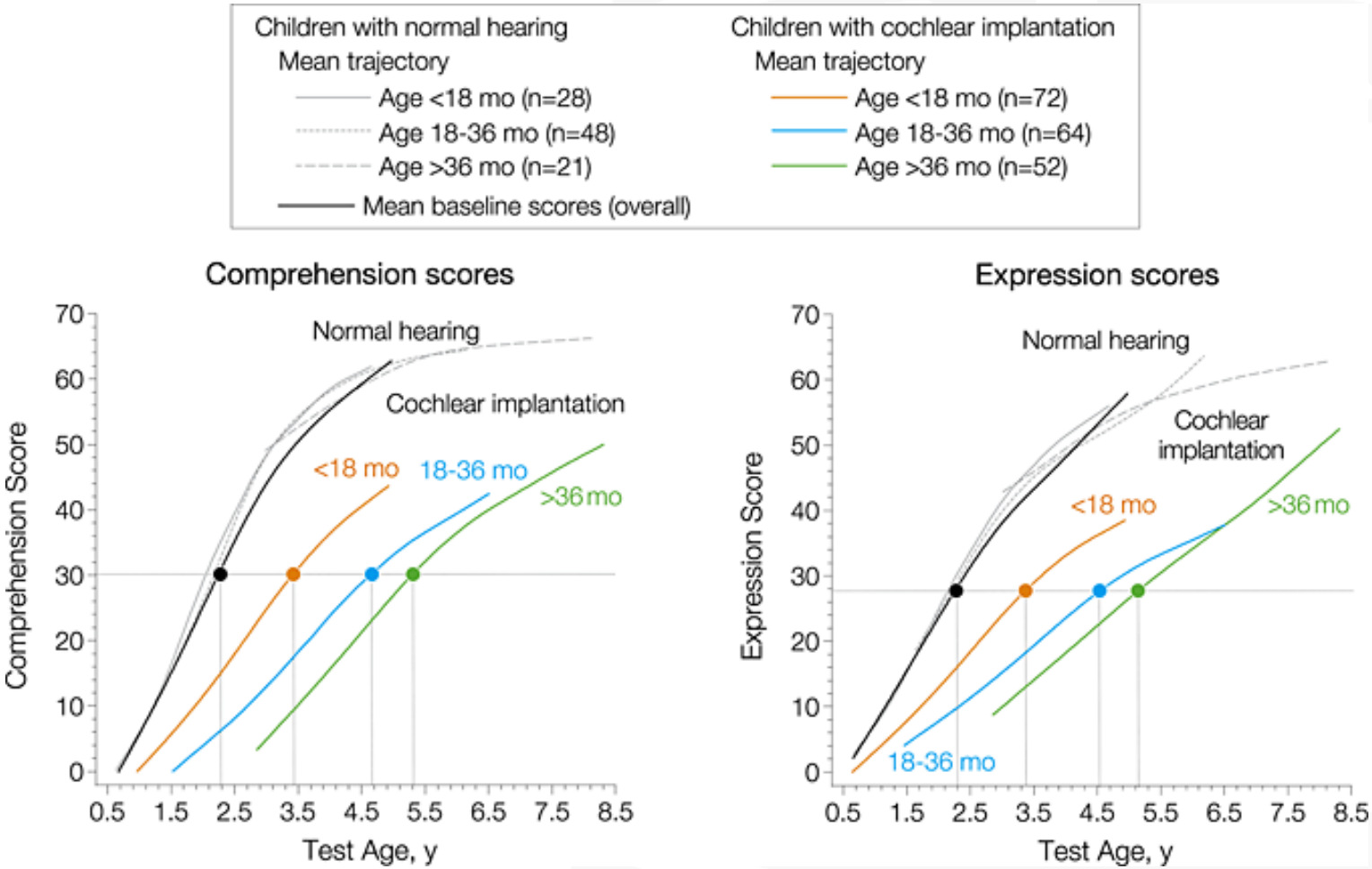


Destroy Residual Hearing

Earlier Is Better

Earlier is Definitely Better

Reynell Developmental Language Scores



Niparko, J. K. et al. JAMA 2010;303:1498-1506.

Pediatric Audiology Issues

- How sure are about the degree of hearing loss?
  - » Are electrophysiological results sufficient?
  - » Are the behavioral thresholds accurate?
- Amplification adequate?
- Auditory Neuropathy Spectrum Disorder
  - » Auditory and biological uncertainty

- Comprehensive evaluation rather than relying on one test result!
- Lots of team discussion!

Mixed Hearing Loss

5 yo excellent BAHA user

1.5 yo→speech delay

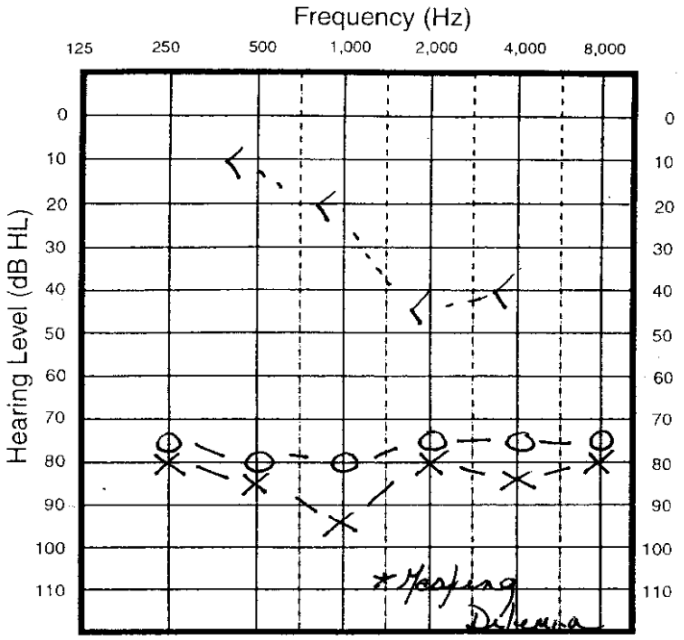
ABR
- Clicks-NR

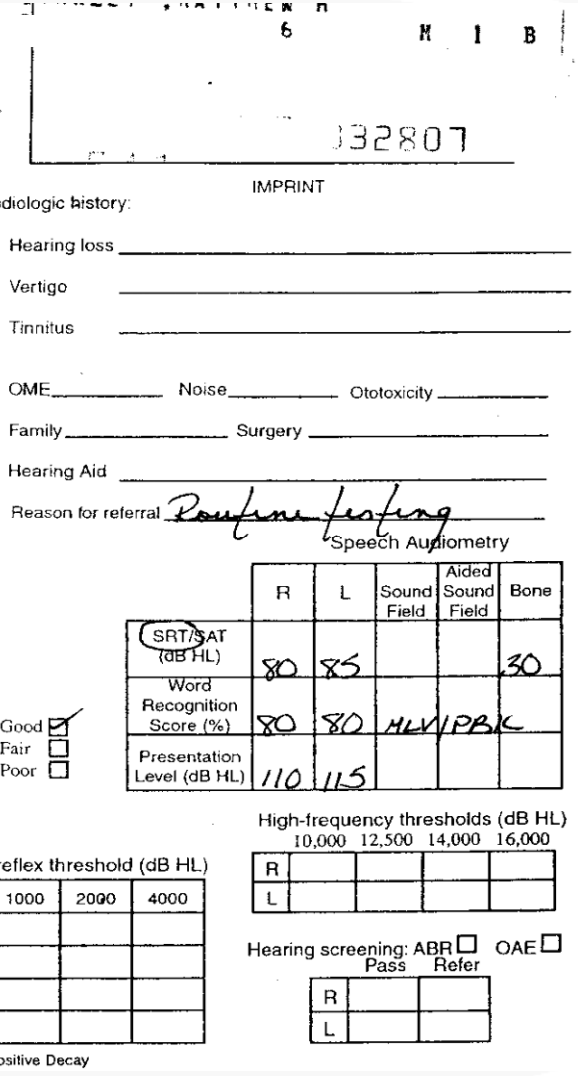
Tone Bursts
- 250 Hz-NR
- 1K Hz-NR

Bone-NR

ASSR-NR

CT-X-linked Gusher





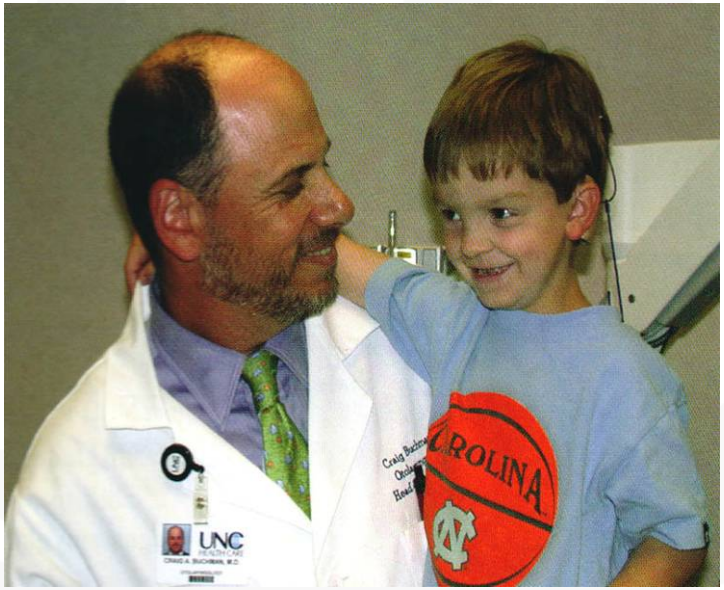
Speech Pathology Issues

- What is an adequate hearing aid trial?
- Is the child making progress?
- How much progress with hearing aids is enough?

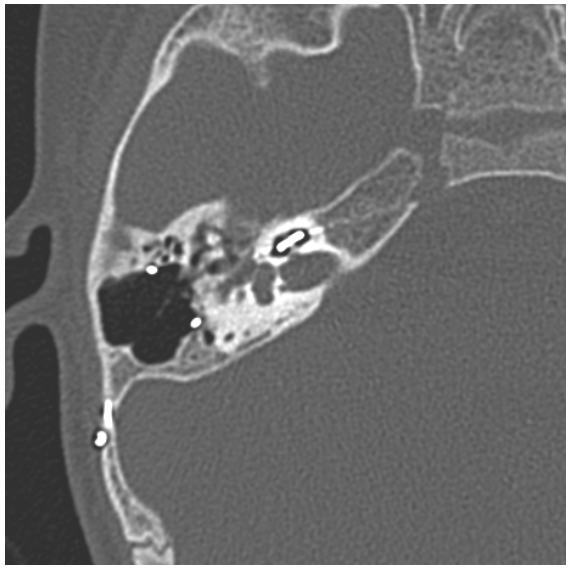
- Repeated diagnostic and therapeutic sessions from the beginning.
- Lots of team discussion!

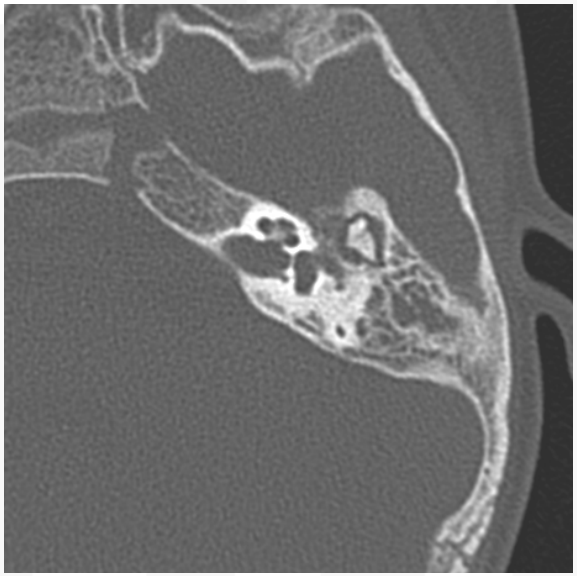
MRI versus CT Imaging?

- 3 yr old with sudden, bilateral SNHL
  - Mild pre-hearing loss speech delay
  - Could talk on phone prior to loss
  - Passed newborn hearing screen (OAEs)
  - Normal pregnancy, full-term, no hyperbilirubinemia, hypoxia, antibiotics, etc.
  - No family history
  - Normal exam
  - No response to steroids X 21 days
  - MRI→"Normal" (2003)
  - ABR
    - →Responses right
    - →No Response left



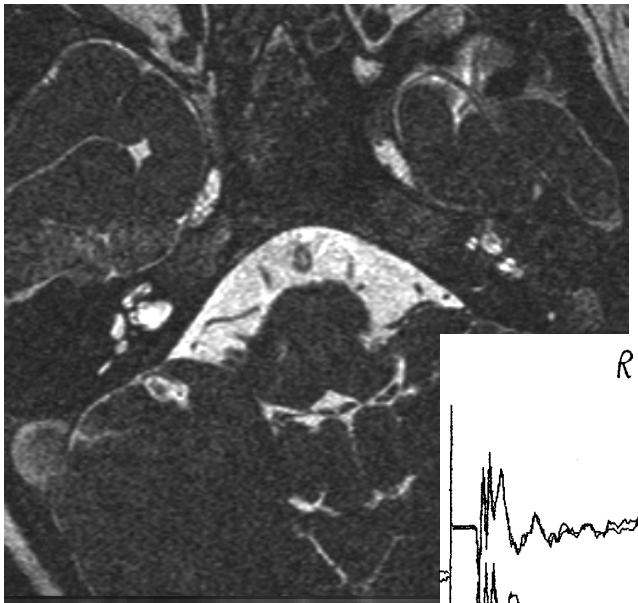
CT versus MRI in Cochlear Implants

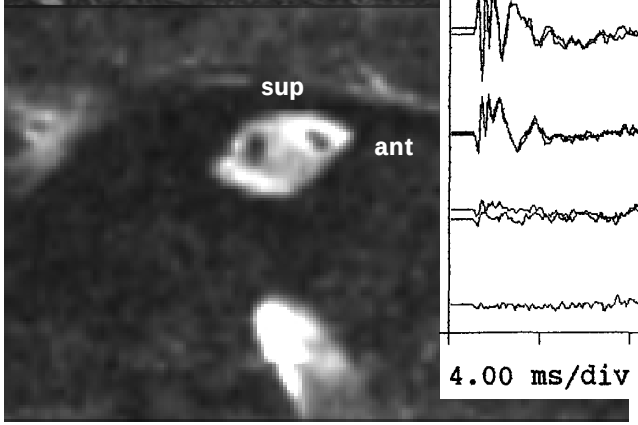


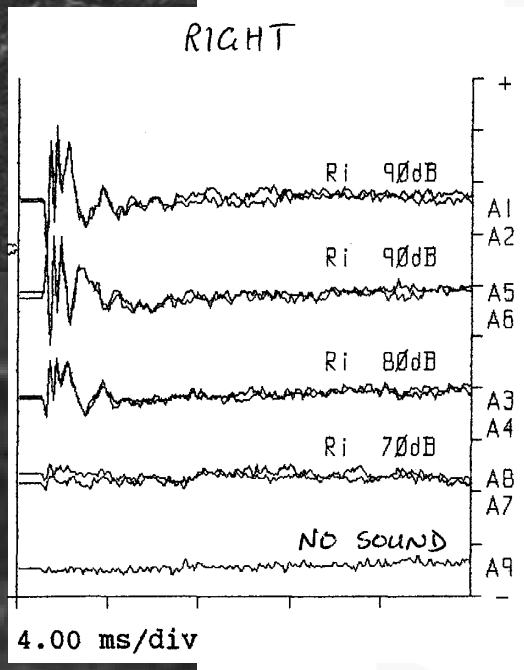


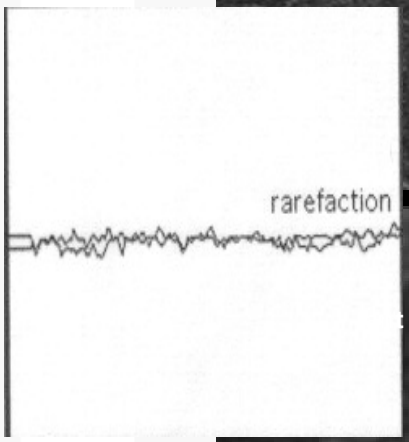
16 months of implant experience
Chance responses on closed set test
No eABR or eCAP
Asked to see patient for “Auditory Neuropathy”

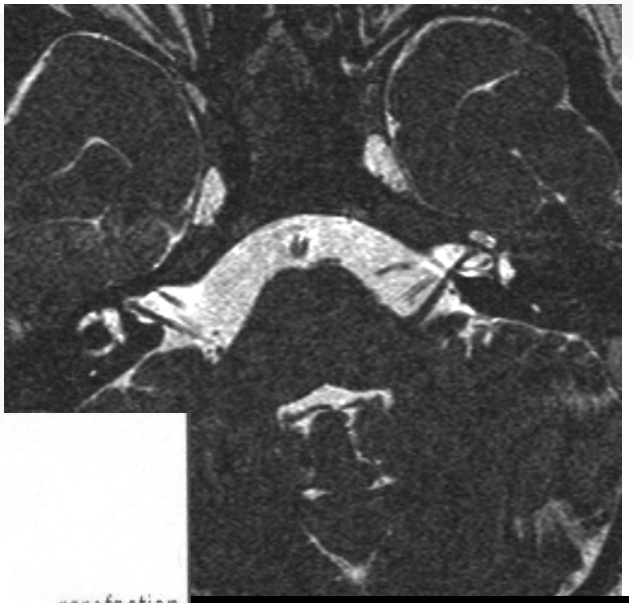
MRI and ABR From Prior to Implant

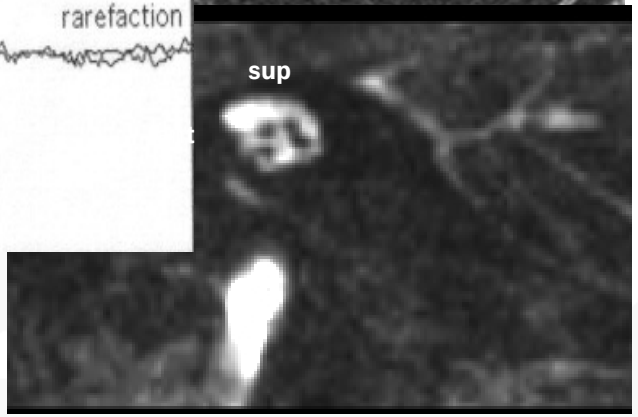












Left Cochlear Implantation

- Left Nucleus Freedom→uncomplicated
- Normal NRT in OR and thereafter
- At 9 weeks
  - » ESP Standard Monosyllables→75%
- At 6 months
  - » ESP Standard Monosyllables→100%
  - » MLNT Hard→73%
- 3 yrs
  - » PBK words->100%
- Talks on the phone!!

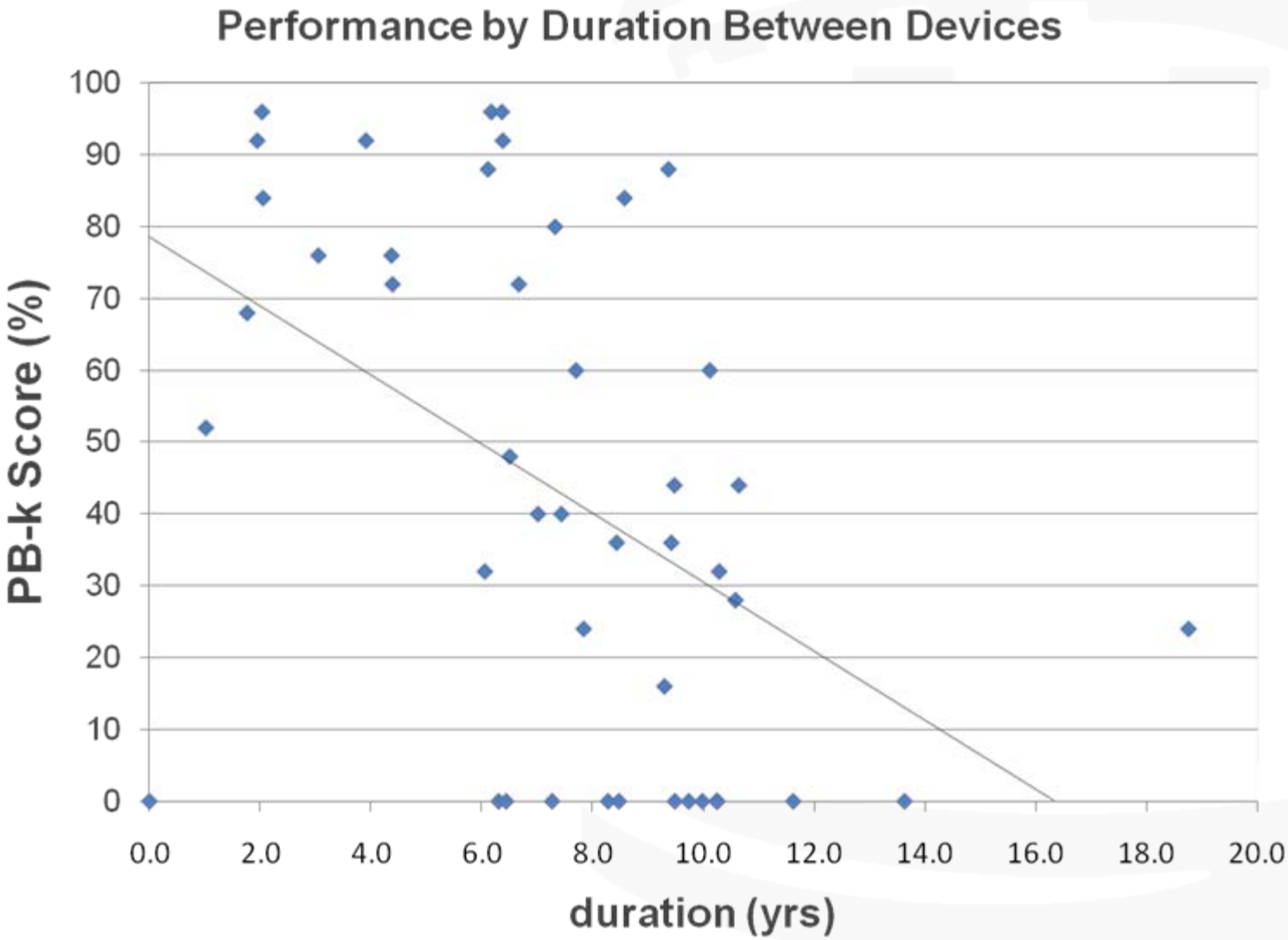
MRI is better than CT in choosing CI candidates!

Bilateral Cochlear Implantation

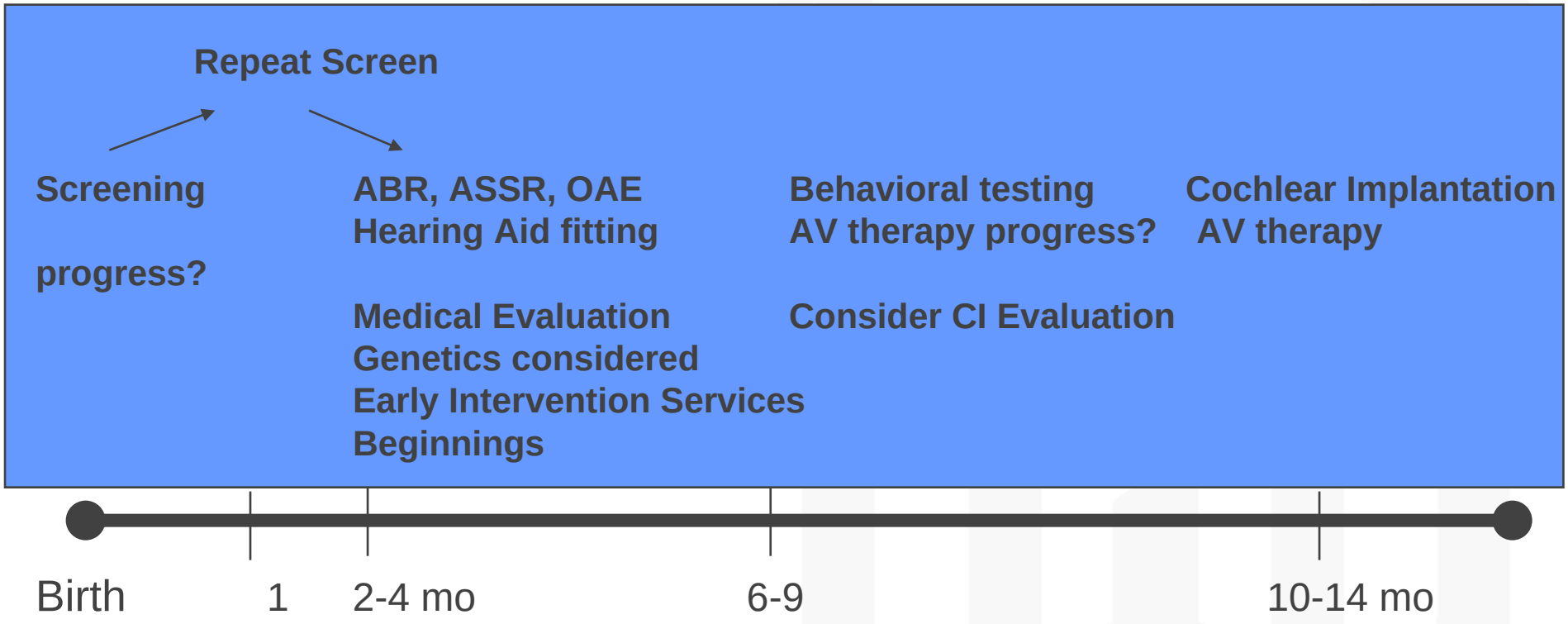
Bilateral Cochlear Implants

- Advantages
  - Always implant better ear
  - Hearing in quiet
  - Hearing in noise
  - Never off the air
- Disadvantages
  - Two surgeries
    - 1 or 2 anesthesias
  - Loss of acoustic hearing
    - Bath tub hearing
    - CI limited frequency spectrum
  - Future therapies
  - Vestibular effects
  - Double programming
  - Economics

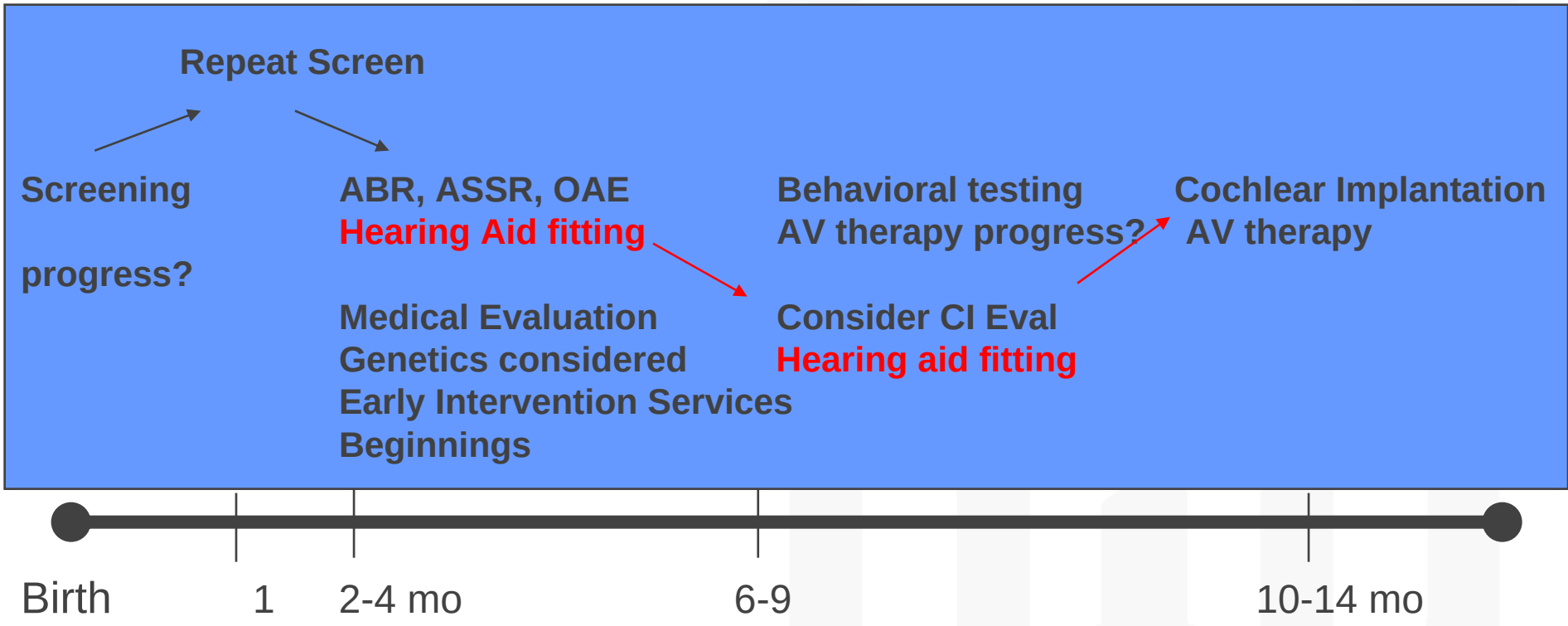
Are all children second side candidates?



What do we try to do



What about ANSD?

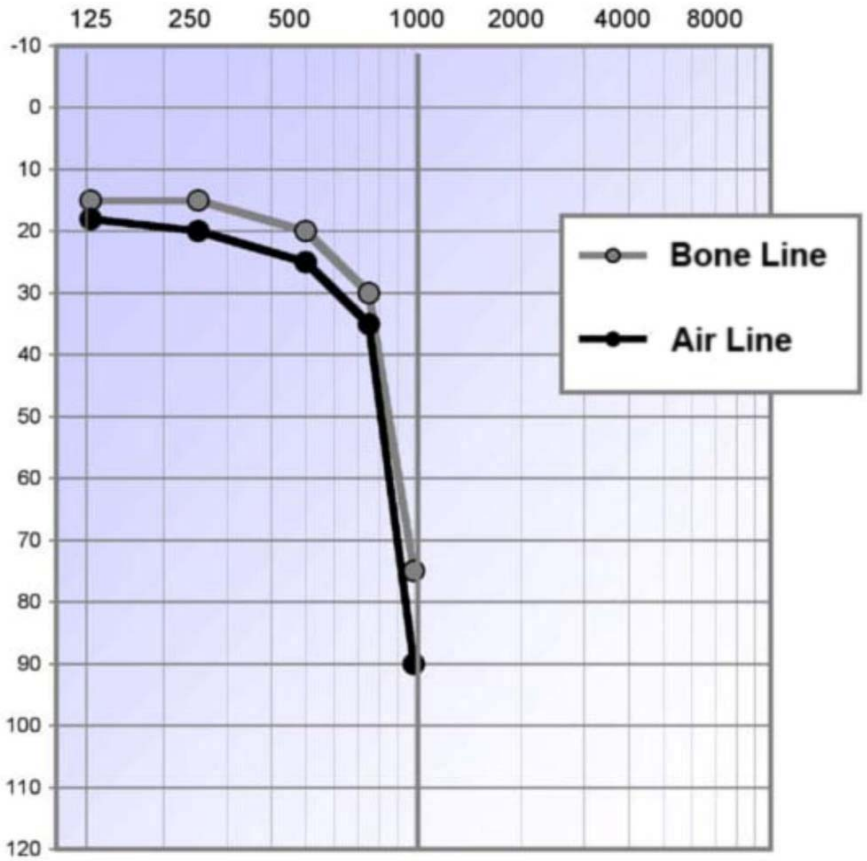


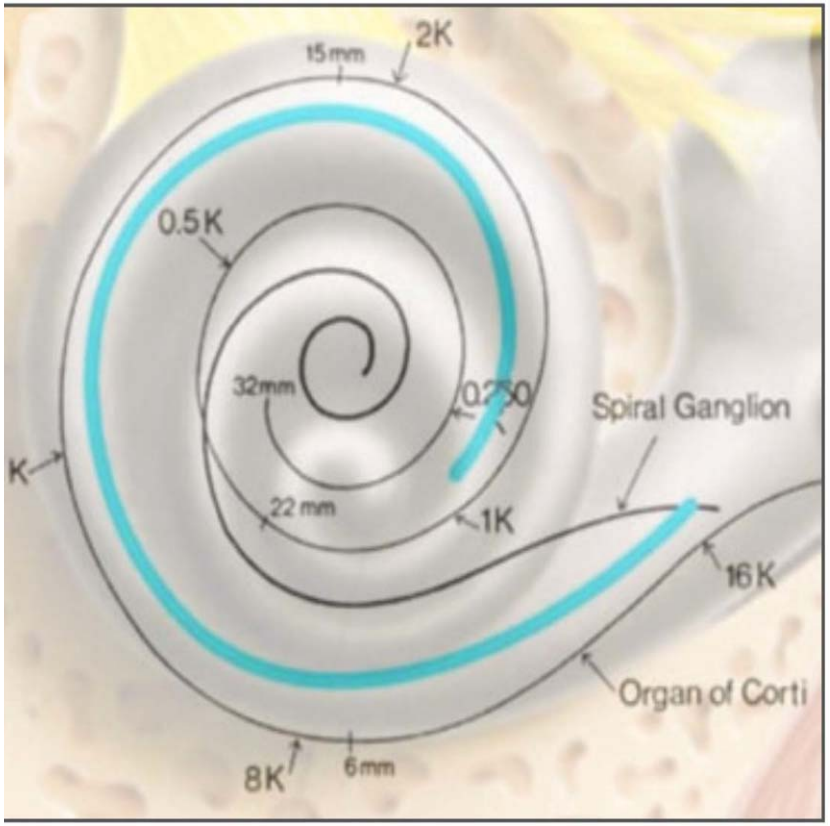
Factors that Delay implantation

- Auditory
  - Delay in diagnosis
  - Significant residual hearing
  - Fluctuating hearing
  - Unreliable or conflicting test results
  - ANSD
  - Underfit amplification
- Speech development
  - Good progress despite profound HL
- Parental issues
  - Missed appointments
  - Don’t wear devices
  - No educational buy-in
  - Socioeconomic
- Medical
  - Anatomic uncertainty
    - CN deficiency
    - Severe inner ear malformation
  - Multiple Challenges
    - Cerebral palsy
    - Autism
    - Other

ELECTROACOUSTIC STIMULATION

ELECTROACOUSTIC STIMULATION (EAS)

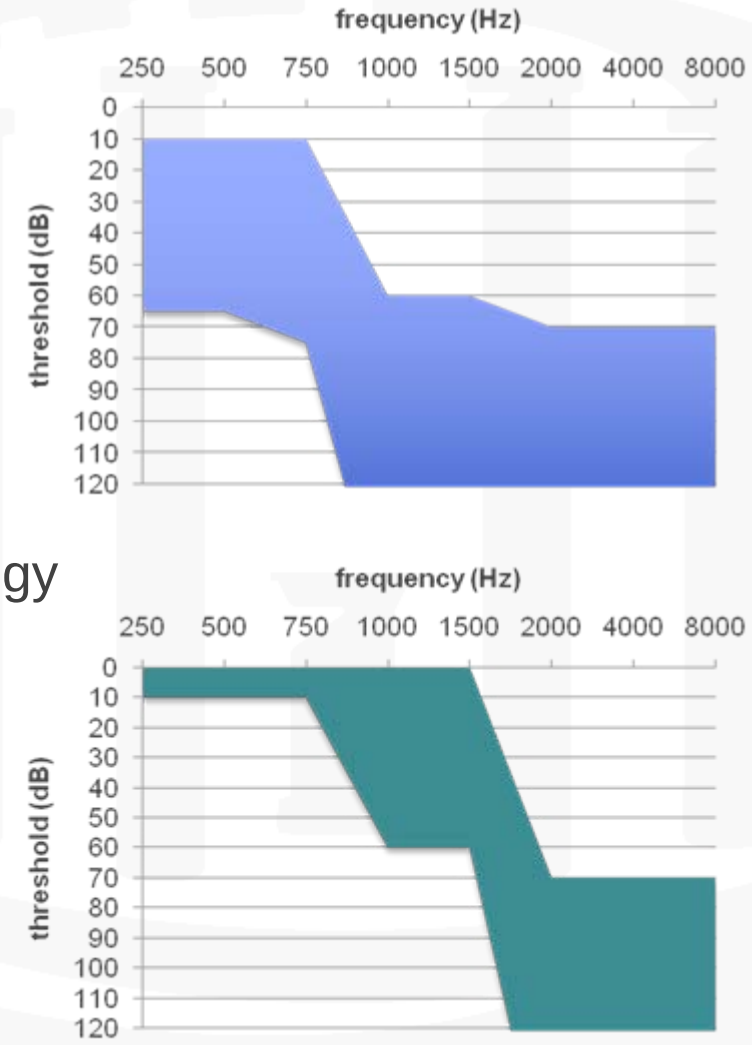




CAUTION: Investigational device. Limited by US law to investigational use.

US EAS Clinical Trial

- Arm 1
  - Adults 18-70 yrs
  - Pure tones within criteria
  - <20 dB asymmetry
  - ABG<10 dB
  - Best-aided CNC word<50%
  - Normal ME function
  - No vestibular or retrocochlear pathology
  - Hearing aids >3 mo
- Arm 2
  - Same except new pure tone criteria
  - CNC 51-60%



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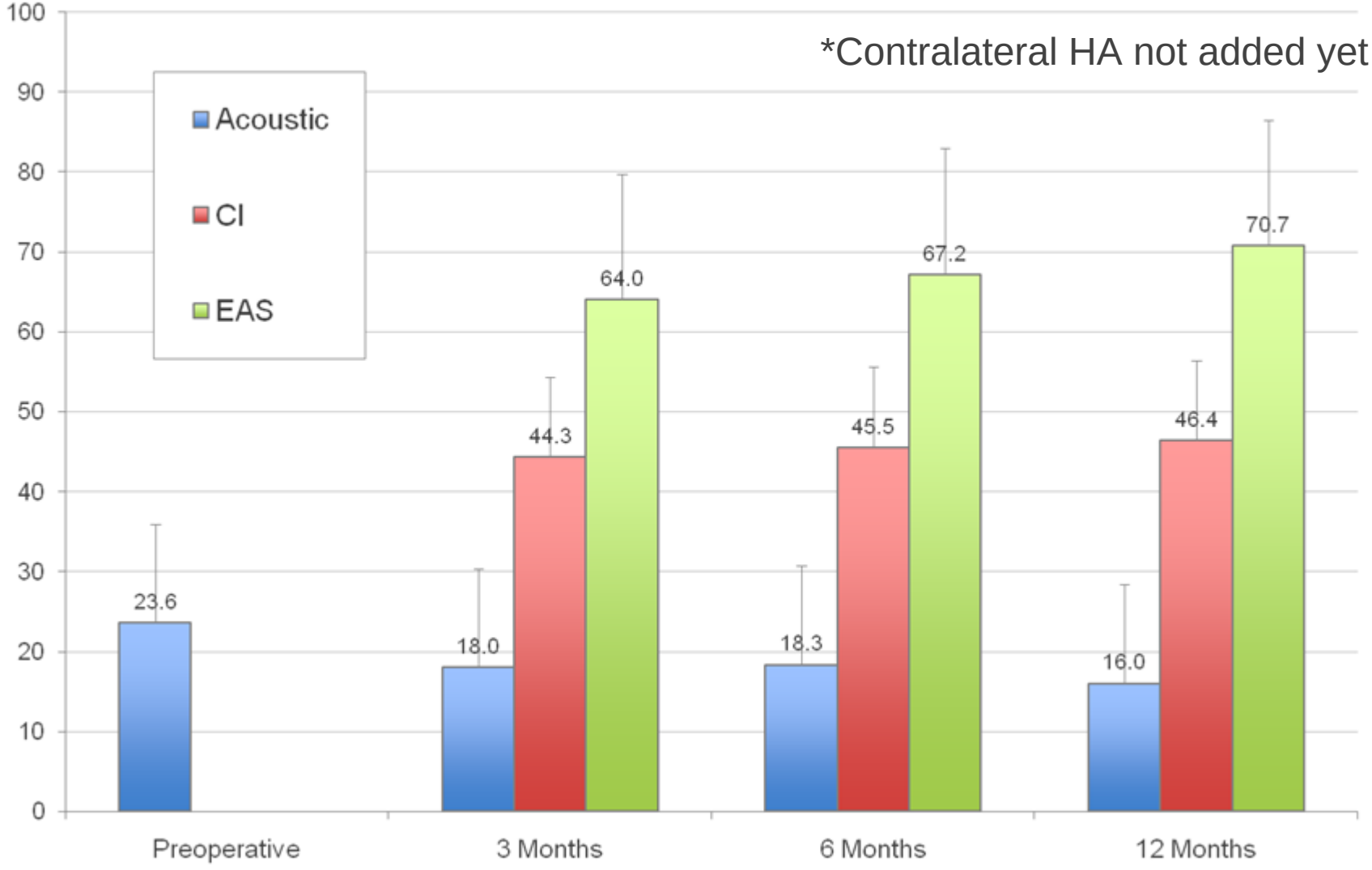
CNC Word Scores for 11 EAS Subjects*

*Contralateral HA not added yet



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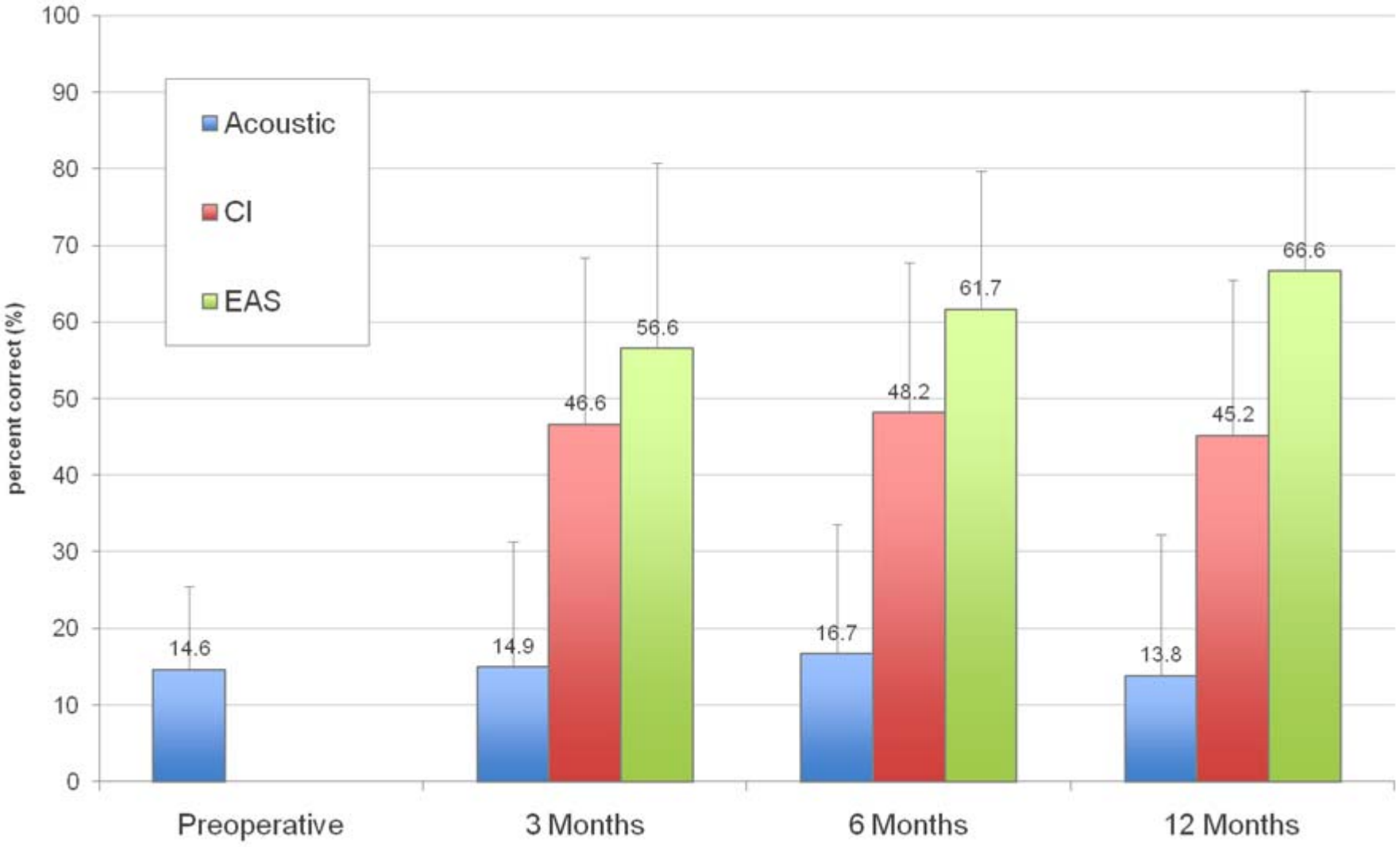
CUNY in Noise (SNR+0) for 11 EAS Subjects*



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

Electroacoustic Stimulation

- Hearing Preservation
  - » Possible in adults
  - » Requires special devices and special surgery
  - » Children maybe different than adults

- When reliable, this ***may*** change the paradigm for all children with hearing loss.

Cochlear Implants and Meningitis

- Pneumococcal Vaccinations recommended for all patients
  - » PCV 7 (Prevnar-7)
  - » Polysaccharide vaccine (PCV-23)
  - » PCV-13 (Prevnar-13)

Pediatrics 2010;126:381-91

- Visit the CDC Website for details
- AAO-HNS Implantable Hearing Devices Subcommittee

Hair Cell Stimulation

- Preserved speech perception ability
- Problems with hearing aids
  - Requires an ear canal
  - Occlusion effects
  - Distortion
  - Feedback
  - Discomfort
  - Stigma of wearing a hearing aid

Osseointegrated Implant

- Bone Conduction
  - » Ipsilateral stimulation
    - Conductive HL
    - Mixed HL
  - » Contralateral stimulation
    - CROS
- Surgically simple
  - » Requires 3-4 mm bone
  - » ~2-3 months of healing
- Percutaneous connection
  - » Site tolerance issues
  - » Aesthetic issues
- Not ear specific

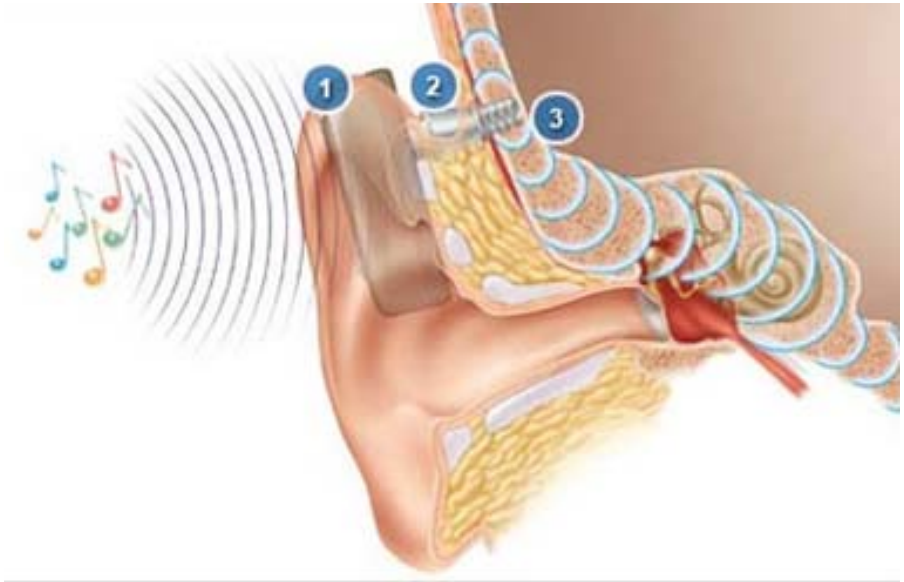
Two Manufacturers

Cochlear Corp→BAHA®

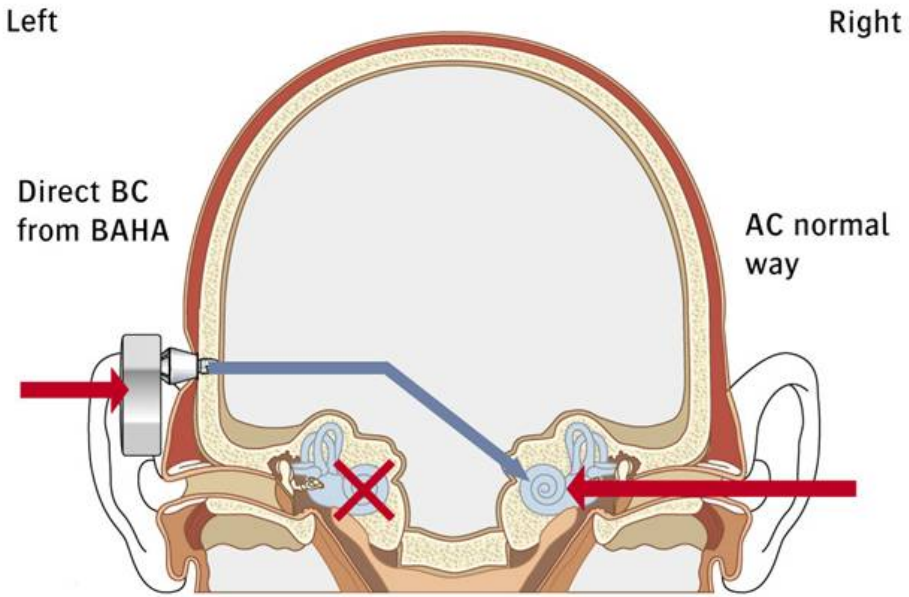
Oticon Corp→Ponto®

Osseointegrated Implant

Conductive or Mixed Loss



Single-Sided Deafness

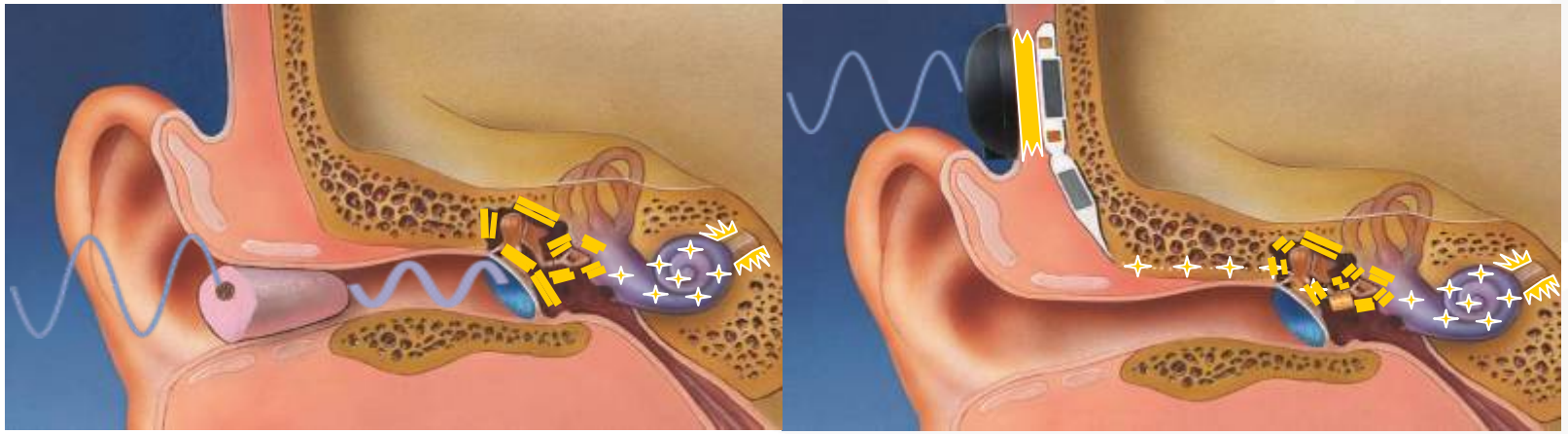


BAHA® Osseointegrated Implant in Children

- Requires 3-4 mm of bone (>5 yrs)
- Permanent Conductive or Mixed hearing loss
  - » Ossicular disorders
  - » X-linked stapes gusher syndrome
  - » Atresia
- Headband Option
  - » Transition to Implant
- Pediatric Research
  - » Single-sided deafness (SSD)
    - Don’t control environment
    - No compelling data
  - » Bilateral BAHA
    - No compelling data

Active Middle Ear Implants

- Direct Ossicular Chain or Cochlear Fluid Drivers
  - » Occlusion effects
  - » Distortion
  - » Feedback
  - » Discomfort
  - » Stigma of wearing a hearing aid



Active Middle Ear Implants*

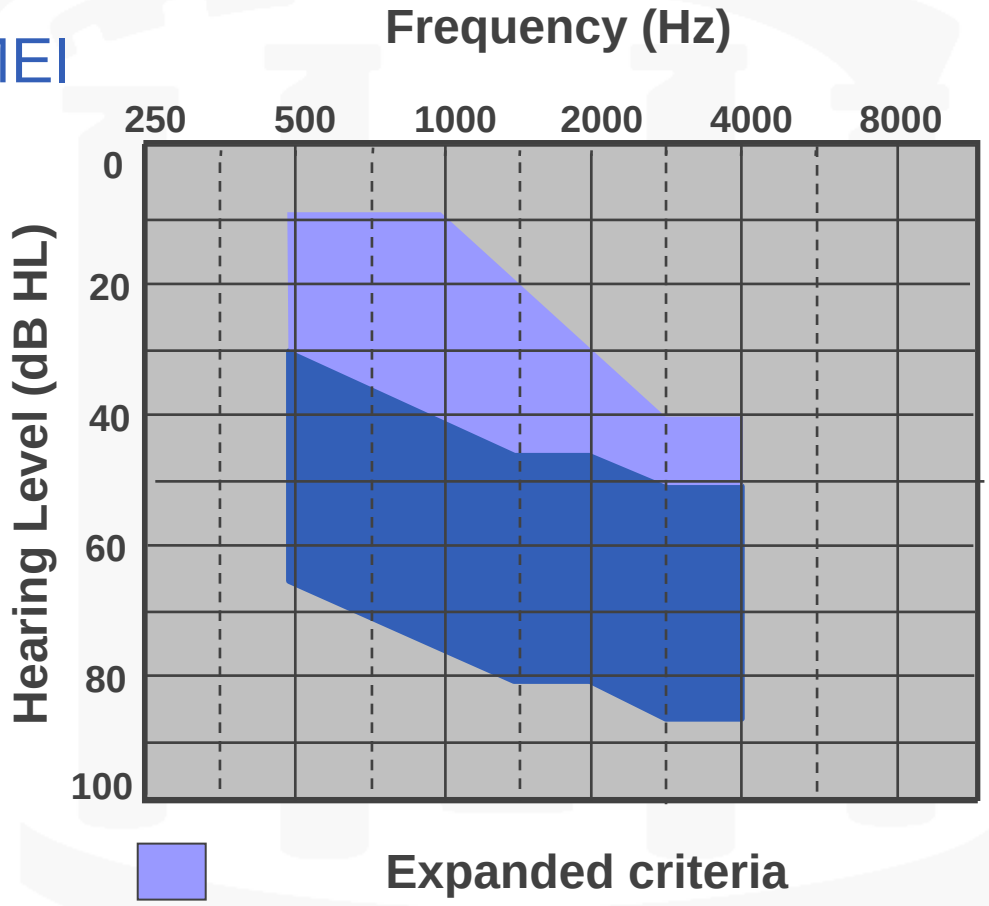
	Transducer type
• Partially implantable	
» Vibrant® Med-EL	Electromagnetic*
» Otologics MET®	Electromagnetic
» Ototronix Maxum®	Electromagnetic
• Totally implantable	
» Envoy Esteem®	Piezoelectric*
» Otologics MET®	Electromagnetic

*FDA Approved for SNHL only

*Not approved for children

Vibrant® MED EL

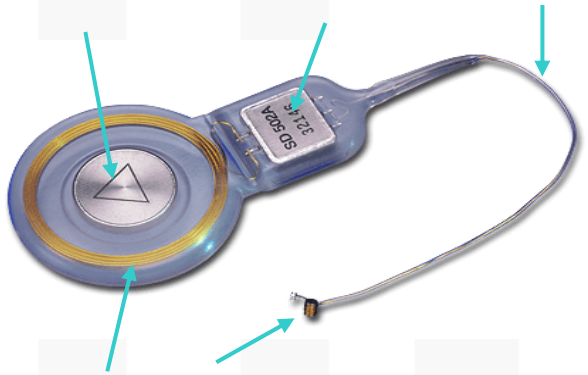
- First FDA-approved Active MEI
  - Semi-Implantable
  - SNHL indication
  - Symphonix® device
- Adults 18+ yrs
  - Word recognition >50%
  - Normal ME function
  - Realistic expectations



Vibrant® MED EL

- Components
  - » External audio processor
    - Held in place with a permanent magnet
    - battery

  - » Implanted receiver

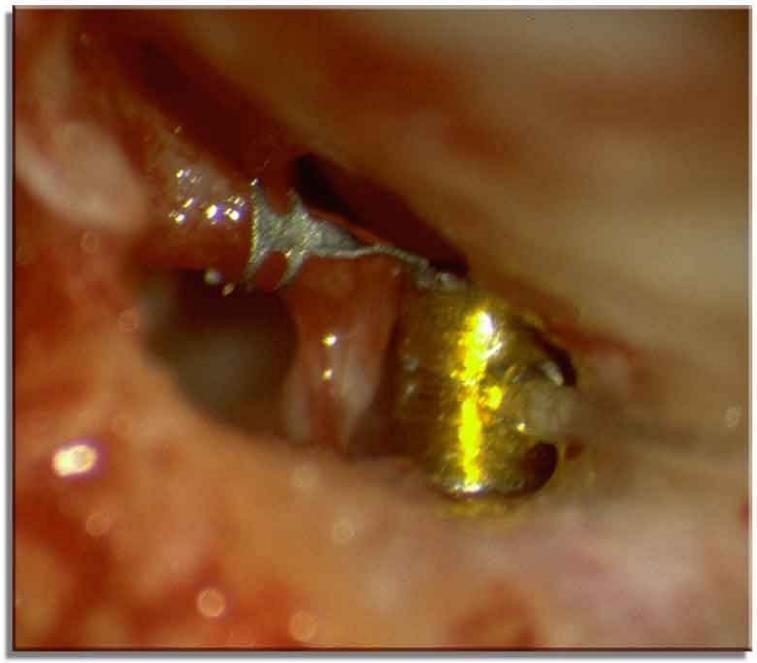


  - » FMT “floating mass transducer”
    - (permanent magnet suspended in a titanium can wrapped with gold wire)

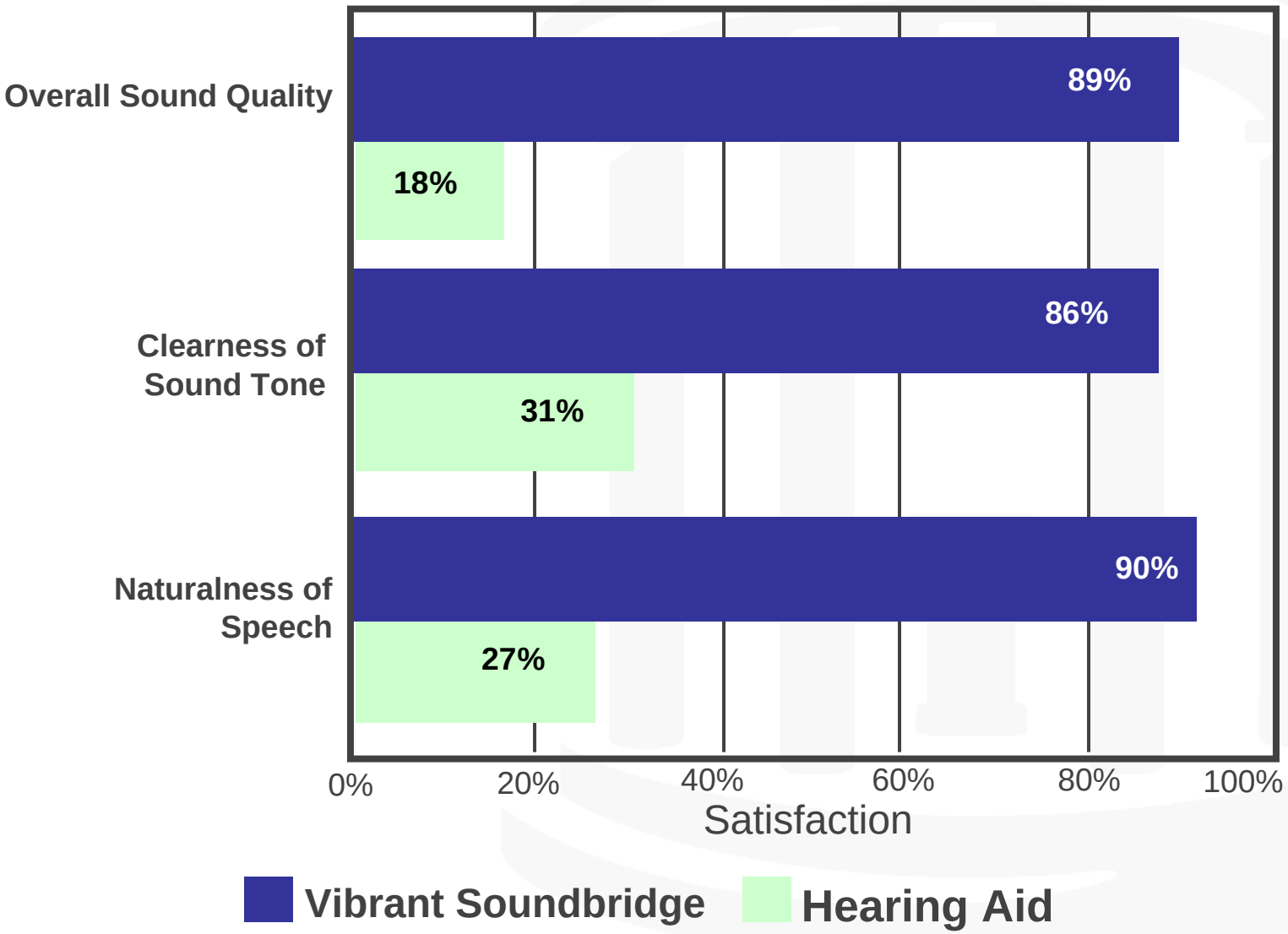
Vibrant® MED EL Surgery

Mastoidectomy and facial recess approach

Magnet placed against the incudo stapedial joint for the SNHL application



Better Subjective Sound Quality

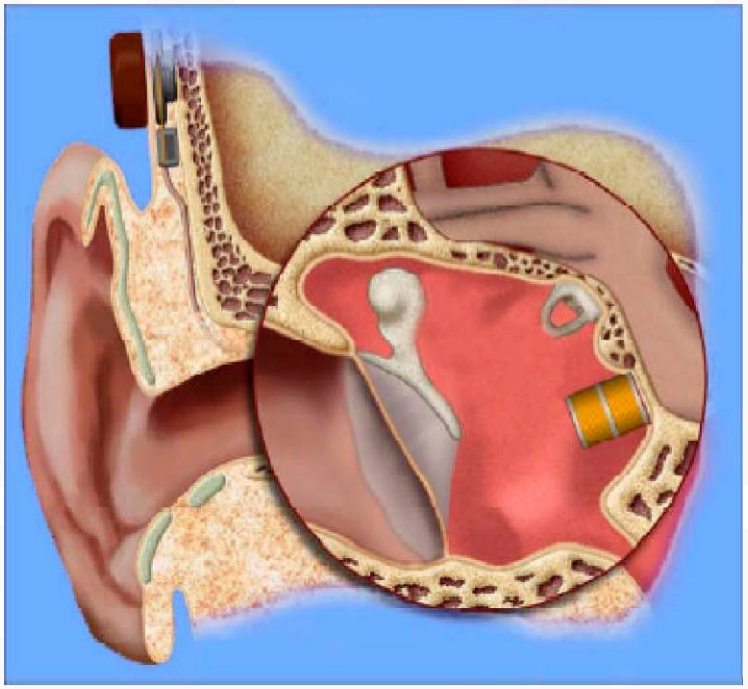


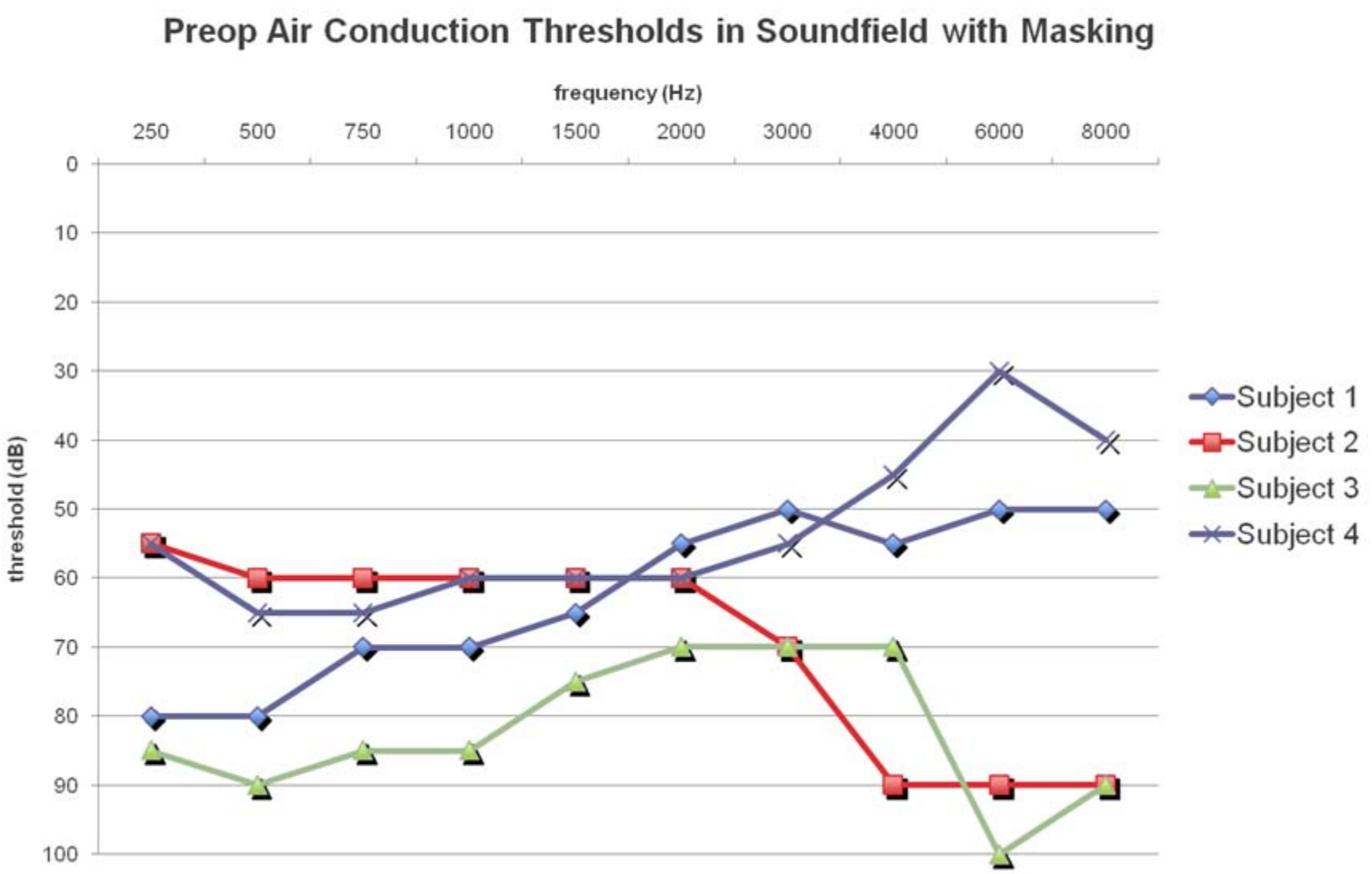
Active Middle Ear Implants

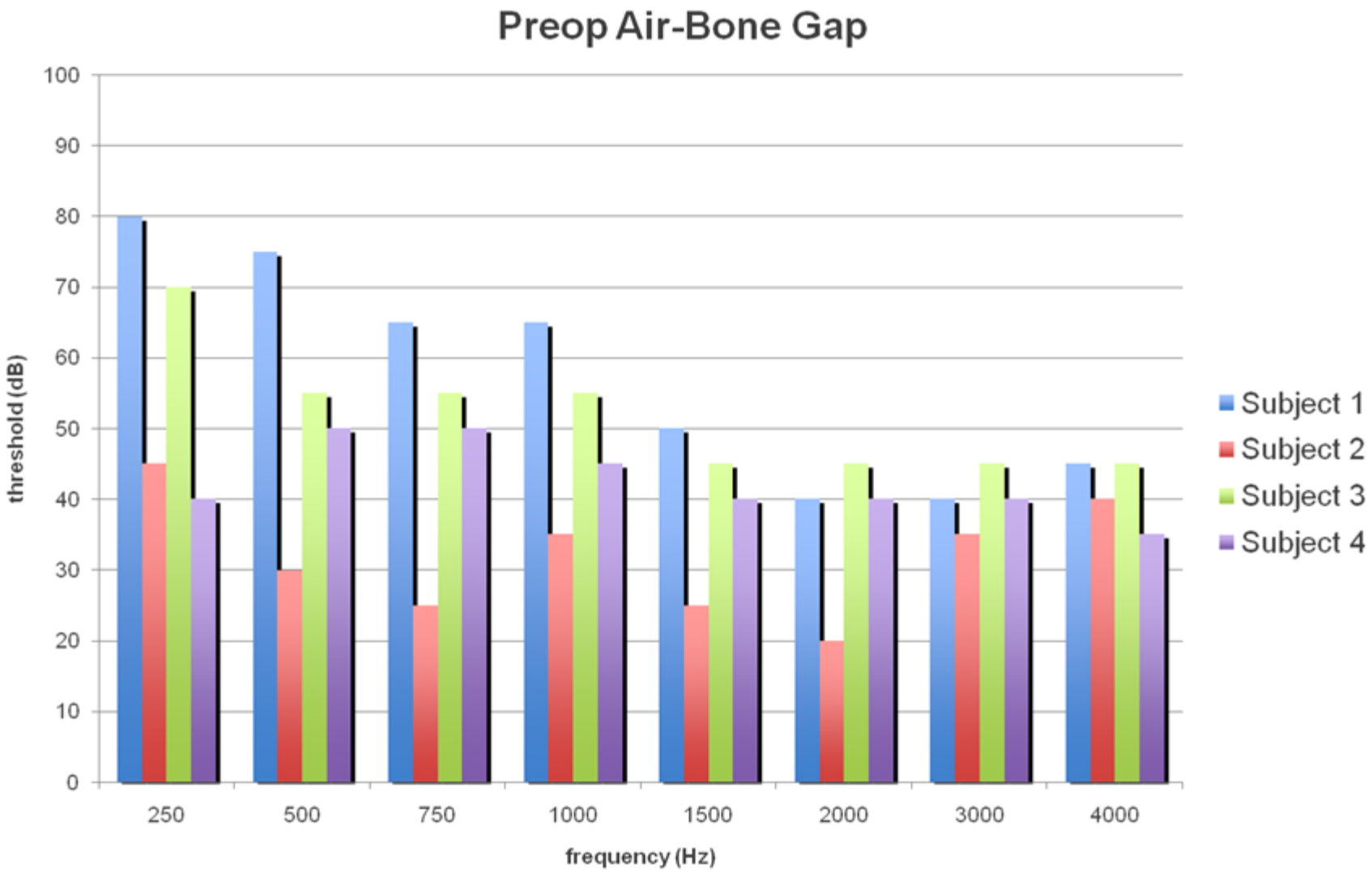
- VERY compelling for patients with:
  - Atresia
  - Cholesteatoma
  - Severe tympanic membrane problems
  - Mastoid cavity
  - Feedback issues
- Anatomic issues frequently include:
  - Absent ossicles
  - Fixed stapes
  - Facial nerve dehiscence
  - Mastoid cavity
  - Collapsed middle ear space

Concept of Round Window Stimulation

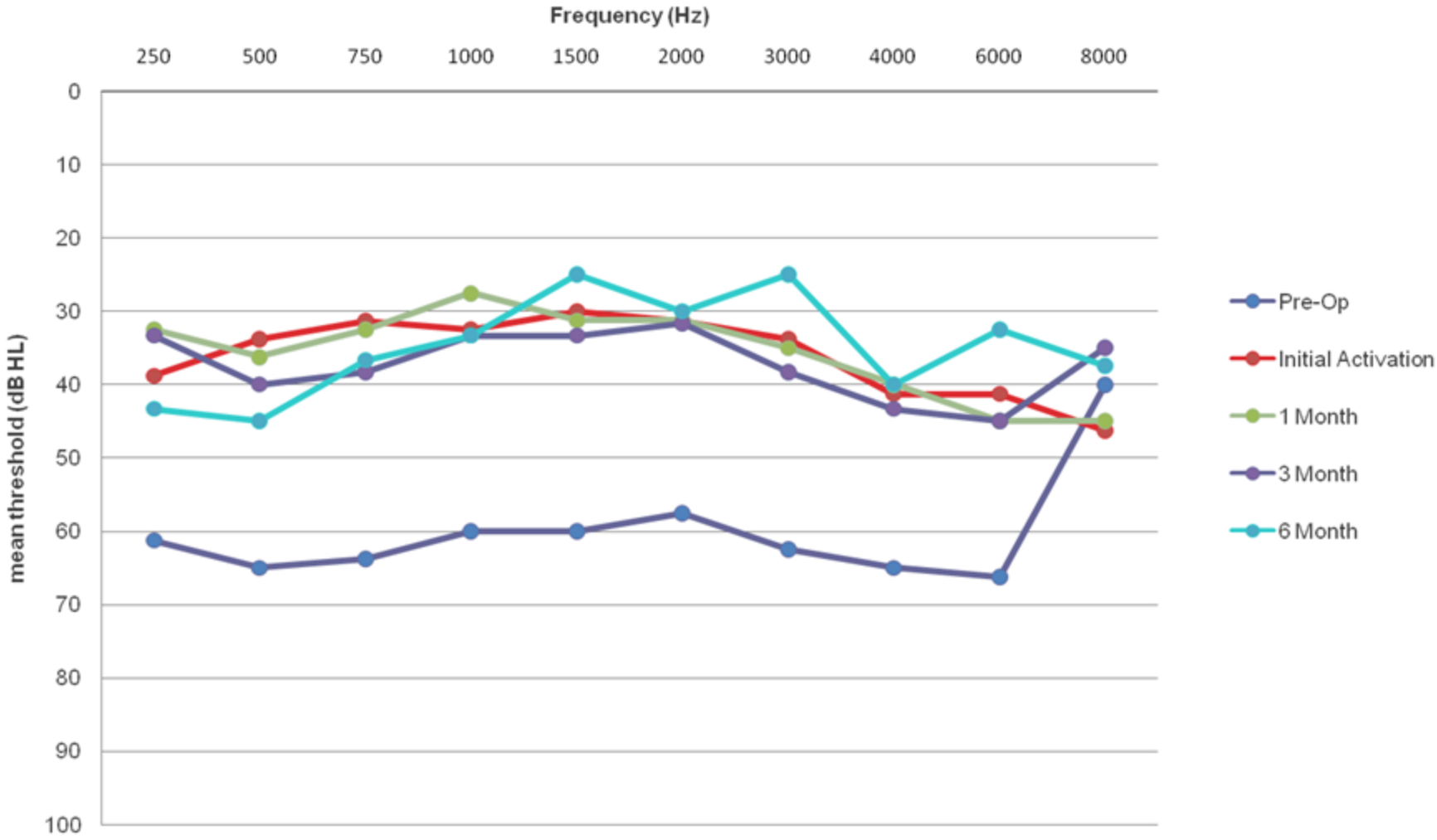
- Rationale
  - » Retrograde vibration of inner ear fluids
  - » Oval window not available
    - Previous stapes or ossicular surgery
    - Overhanging facial nerve
    - Obliteration

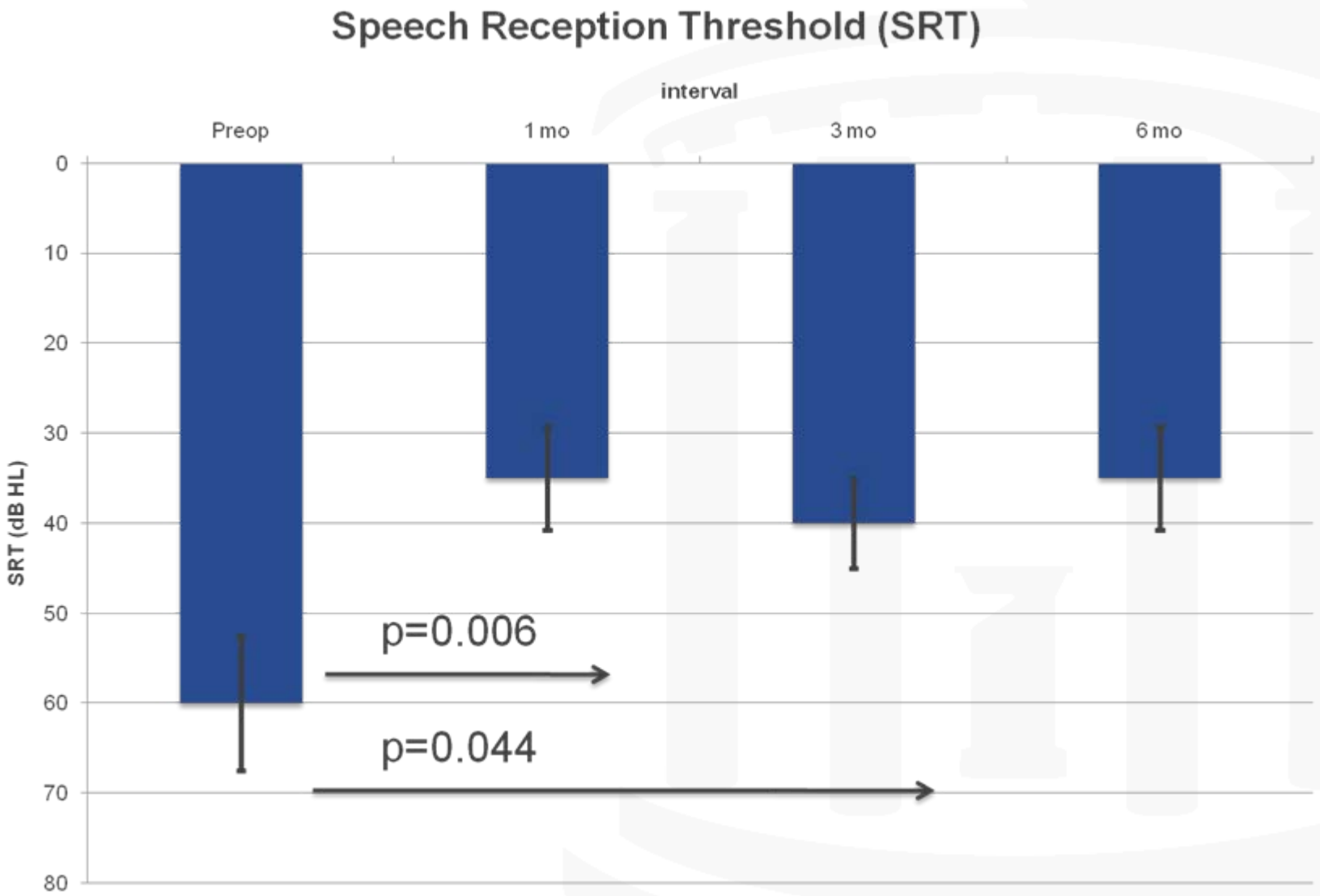


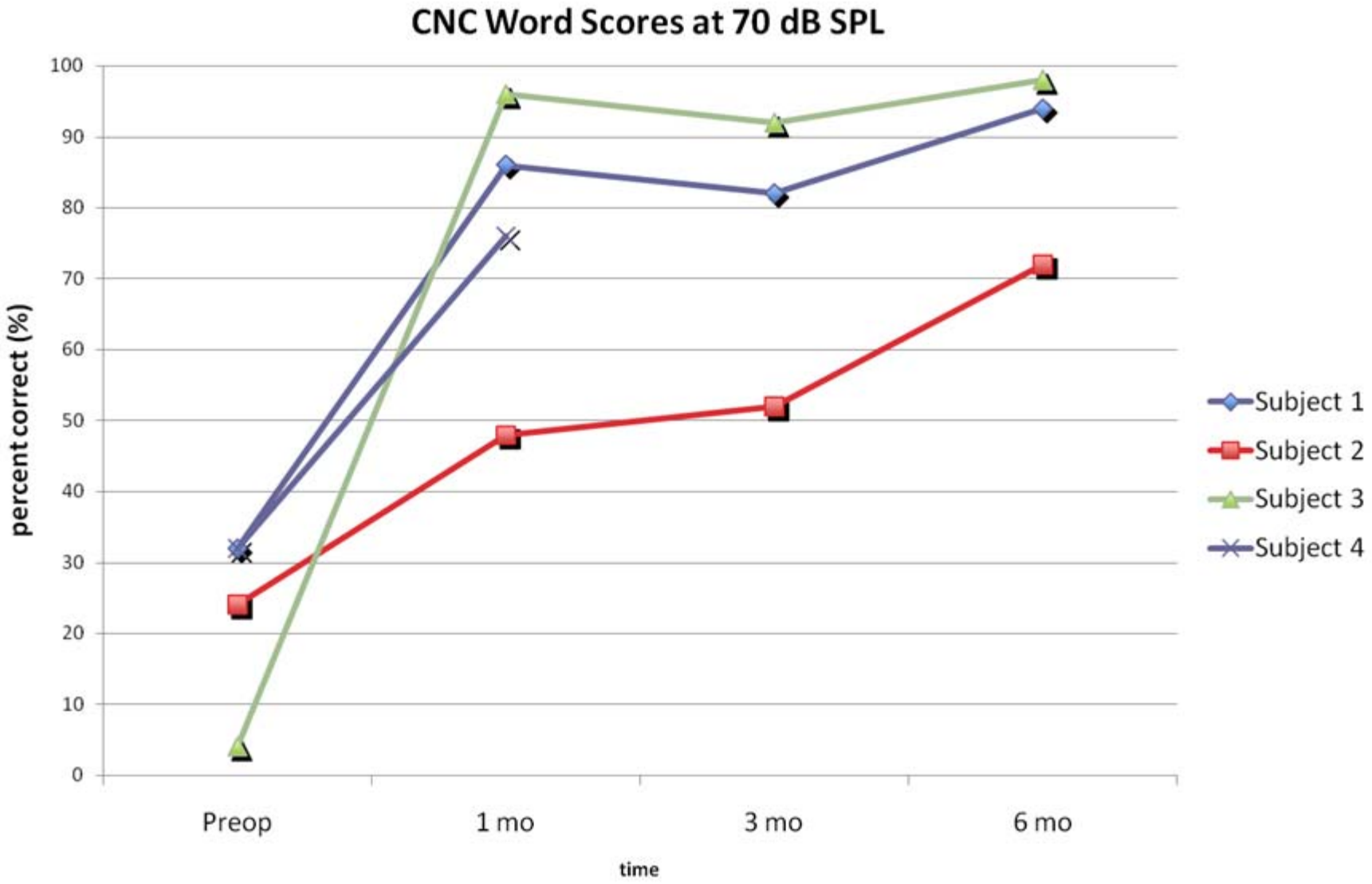

Preop Air Conduction Thresholds in Soundfield with Masking
frequency (Hz)
250
500
750
1000
1500
2000
3000
4000
6000
8000
threshold (dB)
0
10
20
30
40
50
60
70
80
90
100
Subject 1
Subject 2
Subject 3
Subject 4


Preop Air-Bone Gap
threshold (dB)
100
90
80
70
60
50
40
30
20
10
0
250
500
750
1000
1500
2000
3000
4000
frequency (Hz)
Subject 1
Subject 2
Subject 3
Subject 4

Mean Aided Thresholds in Soundfield




Speech Reception Threshold (SRT)
interval
Preop
1 mo
3 mo
6 mo
SRT (dB HL)
0
10
20
30
40
50
60
70
80
p=0.006
p=0.044


CNC Word Scores at 70 dB SPL
percent correct (%)
100
90
80
70
60
50
40
30
20
10
0
Preop
1 mo
3 mo
6 mo
time
Subject 1
Subject 2
Subject 3
Subject 4

Implantable Devices

- Cochlear Implants
  - Currently Sacrifices Residual Hearing
  - Earlier is Better
  - Complex Multidisciplinary Evaluation
  - Reliable hearing preservation will change things dramatically
    - Better hearing outcomes
    - More candidates
- Middle ear stimulation
  - Osseointegrated implants
    - Effective and simple
    - Requires percutaneous connection and thick bone
  - Active middle ear implants
    - Might change paradigm for CHL and MHL