What is the next big leap for CI technology?

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Evolution for sure – Revolutions possible

Competition is good – multiple companies competing for the next best thing

Worldwide interest in the medical and scientific field – lots of publications
• Device design
  • Internal device
  • Electrode characteristics
Smaller
Thinner
Magnets?
Totally implantable

Smaller
flexible
Materials?
Foreign Body Response to Silicone in Cochlear Implant Electrodes in the Human


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Hypothesis: Silicone as part of a cochlear implant electrode may be responsible for a foreign body response in the human.

Background: Clinical evidence of a foreign body response to a cochlear implant has been reported. In a previous study, particulate material found within the fibrous sheath and within macrophages surrounding a cochlear implant has been identified as being consistent with platinum. However, to date, there has been no histologic evidence of a role for silicone in this cellular immune response.

Methods: A total of 44 temporal bone specimens from 36 patients were reviewed by light microscopy for evidence of presumed platinum and/or silicone foreign bodies in an extracellular or intracellular location. Identification of cell types involved in phagocytosis of foreign body material was accomplished using CD163 immunostaining. The identity and source of the foreign body material was confirmed using energy-dispersive X-ray spectroscopy and scanning electron microscopy.

Results: Evidence for both platinum and silicone was found in all 44 specimens. In three patients, anti-CD 163 immunostaining demonstrated phagocytized platinum and silicone foreign bodies. In five specimens, energy-dispersive X-ray spectroscopy demonstrated that the birefringent foreign bodies were consistent with silicone. Scanning electron microscopy of two electrodes removed from temporal bones demonstrated small cracks, fragmentation, and small circular defects in the silicone carrier.

Conclusion: Histologic evidence of a foreign body response to the presence of platinum and silicone in a cochlear implant has been demonstrated and may be responsible for some reported delayed failures or extrusion. Key Words: Cochlear implant—Foreign body—Human—Platinum—Silicone.
Hearing Preservation in Pediatric Cochlear Implantation


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Otology & Neurotology
• Surgical technique
  • Hearing and structure preservation
• Drug delivery to inner ear
  • Diffusion through round window
  • Drug eluting electrodes
  • Regeneration or prevention of deterioration?
Connectivity
• Expanding candidacy
• Standardization of evaluation
History of Cochlear Implant Candidacy Expansion
### Historical Expansion of FDA Guidelines

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<tbody>
<tr>
<td><strong>AGE of implantation</strong></td>
<td>Adults 18 yrs +</td>
<td>Adults &amp; Children 2 yrs +</td>
<td>Adults &amp; Children 18 mos +</td>
<td>Adults &amp; Children 12 mos +</td>
<td>Adults only for Hybrid</td>
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<tr>
<td><strong>ONSET of hearing loss</strong></td>
<td>Post linguistic</td>
<td>Post linguistic adults/ Pre &amp; Post Linguistic Children</td>
<td>Adults &amp; Children Pre &amp; Post Linguistic</td>
<td>Adults &amp; Children Pre &amp; Post Linguistic</td>
<td>Adults &amp; Children Pre- and Post- Linguistic</td>
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<tr>
<td><strong>DEGREE of hearing loss</strong></td>
<td>Profound</td>
<td>Profound</td>
<td>S/P Adults Profound</td>
<td>S/P Patients 2 yrs+ Prof Child&lt;2 yrs</td>
<td>Nucleus Hybrid: Normal to Moderate in low freq; S/P mid to high frequencies</td>
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<tr>
<td><strong>SPEECH SCORES</strong></td>
<td>0%</td>
<td>0%</td>
<td>40% or less</td>
<td>Sentences score 50% or less in ear to be implanted, ≤ 60% in best aided condition</td>
<td>CNC word score &gt;10% but less than 60% in ear to be implanted; &lt;80% CNC words in contralateral ear</td>
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Where do FDA guidelines come from?

- Role of companies – develop device
- Prove effectiveness in a group of patients
- FDA approves device for this group with this specific criteria

- What is wrong with this?
  - Overly restrictive criteria
  - Changing criteria requires new expensive study
  - Insurance criteria drive medical decision making

- What does “off-label” mean?
Candidacy

- Health equity – fairness and access
- Insurance/government guidelines
  - Interpretation?
- Testing protocols
“...the needs of the patient come first”
William W. Mayo, MD

What is best for you?
Are we sure we know when a CI is their best choice?
Can we make that work given the restrictions?
Hearing aid vs cochlear implant?

REMARKS:


See clinic note for CNC scores.

C = Hybrid condition with left ear plugged
S = HA only right, left ear plugged

Immittance/Acoustic Reflexes

Sound Right
- Reflex (HL)
- Decay (sec.)
- Reflex (HL)
- Decay (sec.)

Sound Left
- Reflex (HL)
- Decay (sec.)
- Reflex (HL)
- Decay (sec.)
HINT
AzBio Quiet
AzBio +10dB SNR
AzBio +5dB SNR
CNC words
BKB-SIN
Health equity – fairness and access

• Test protocols and criteria vary by center
• Why?
  • Criteria are complicated
  • Fear of committing fraud
  • Lack of standardization in field
  • “Gray” areas
    • Which sentence test to use? Noise?
    • Bilateral implants in Medicare patients?
Health equity – fairness and access

• The result of this lack of clarity and standardization is why many patients are denied access
• What is right for our patients?
  • hit/miss ratio

• What will be accepted by insurance upon review?

• How about Medicare/Medicaid?
Research

• Establish unequivocally the quality of life benefit
  • ACI Alliance in collaboration industry are able to fund the development of several patient outcomes tools to capture the benefits of cochlear implantation. This knowledge is important for improving outcomes, increasing awareness and promoting advocacy efforts
If the past is an indicator of our future...things will be very different in 10 years

• Technology improvements – for surgeons, audiologists and patients
• Biochemical manipulation of inner ear
• Expanding indications – single sided deafness