Longitudinal Changes in Auditory Status for Cochlear Implant Users with Preserved Acoustic Hearing: Psychophysical, Physiological, and Physical Assessment

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Hearing Preservation Electrode Arrays

<table>
<thead>
<tr>
<th>Array</th>
<th>Electrodes</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>422</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>L24</td>
<td>22</td>
<td>14.5</td>
</tr>
<tr>
<td>S12</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>S8 (24RE)</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>S8 (24M)</td>
<td>6</td>
<td>10</td>
</tr>
</tbody>
</table>

Disclosures

- Cochlear Hybrid S8 and S12 arrays were implanted under Investigational Device Exemption (IDE) status and not currently approved by Food and Drug Administration (FDA) for clinical use.
- Subset of Cochlear Hybrid L24 arrays were implanted under IDE status. FDA approval for clinical use was granted March 2014.
- Cochlear 422 array is marketed to preserve cochlear structures. Subset of patients retained acoustic hearing and are presented here.
- B. Gantz holds a patent on the hybrid implant, but does not receive royalties. He is a consultant for Cochlear Corporation and Advanced Bionics.
Benefits and Risks

• Benefits
  – Improved speech understanding with combined electric and acoustic stimulation.
  
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• **Risks**
  – Initial hearing loss at CI activation (10-15 dB).
    • May be due to surgical trauma.  
Benefits and Risks

• **Benefits**
  - Improved speech understanding with combined electric and acoustic stimulation.

• **Risks**
  - Initial hearing loss at CI activation (10-15 dB).
    • May be due to surgical trauma.
  - Additional hearing loss (0-40 dB) after several months.
    • Theories: Fibrosis, synaptic damage, hydrops, hair cell loss, strial damage, excitotoxicity from excess acoustic-electric stimulation.
Retrospective Review

• Explore possible mechanisms of loss of residual hearing by characterizing changes over time.
  – Audiometric Thresholds (PTA of 125, 250, 500, & 1000 Hz)
  – Common Ground Electrode Impedances (Z)
  – Electrically Evoked Compound Action Potential (ECAP) thresholds and amplitudes

• Identify patterns in these measures for patients who retain residual hearing and for patients who lose residual hearing.
## Subject Population

<table>
<thead>
<tr>
<th>Array</th>
<th>Total</th>
<th>Included</th>
<th>Data Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>422</td>
<td>63</td>
<td>15</td>
<td>2012 to 2016</td>
</tr>
<tr>
<td>L24</td>
<td>41</td>
<td>31</td>
<td>2014 to 2016</td>
</tr>
<tr>
<td>S12</td>
<td>15</td>
<td>15</td>
<td>2008 to 2016</td>
</tr>
<tr>
<td>S8 (24RE)</td>
<td>12</td>
<td>12</td>
<td>2005 to 2016</td>
</tr>
<tr>
<td>S8 (24M)</td>
<td>12</td>
<td>12</td>
<td>2000 to 2016</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>143</strong></td>
<td><strong>85</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Common reasons for exclusion
  - Recently implanted (not enough data)
  - No contralateral ear audiometric thresholds
  - Minimal ECAP or Impedance Data
Categories of Hearing Status

1. Stable Hearing
   Implanted ear: within 10 dB.
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   Implant ear: within 10 dB.

2. Symmetrical Hearing Loss
   Implant ear: loss > 10 dB.
   Contra hearing loss within 10 dB of ipsi ear.

Graph: Patient SE6
- Pure Tone Average (dB HL)
- Implant Use (yrs)
- Ipsilateral
- Contralateral

Gradual: < 5 dB/month.
Precipitous: > 5 dB/month.
Categories of Hearing Status

Stable Hearing
- Implant ear: within 10 dB.

Symmetrical Hearing Loss
- Implant ear: loss > 10 dB.
- Contra hearing loss within 10 dB of ipsi ear.

Ipsilateral Hearing Loss
- Implant ear: > 10 dB.
- Difference between ipsi and contra hearing loss > 10 dB.
Categories of Hearing Status

Stable Hearing
  Implanted ear: within 10 dB.

Symmetrical Hearing Loss
  Implanted ear: loss > 10 dB.
  Contra hearing loss within 10 dB of ipsi ear.

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  Implanted ear: > 10 dB.
  Difference between ipsi and contra hearing loss > 10 dB.
Categories of Hearing Status

Stable Hearing
Implanted ear: within 10 dB.

Symmetrical Hearing Loss
Implanted ear: loss > 10 dB.
Contra hearing loss within 10 dB of ipsi ear.

Ipsilateral Hearing Loss
Implanted ear: > 10 dB.
Difference between ipsi and contra hearing loss > 10 dB.
2. Precipitous: > 5 dB/month.
Categories of Hearing Status

- Loss of hearing ≠ loss of functional hearing.
- Most pts still benefit from combined electric-acoustic stimulation.
- Audiograms vary between mild to profound hearing loss after loss of hearing.
- Hearing loss categories set conservatively (5 dB/month) to capture trends in impedances and ECAPs.
• Observation: Some patients demonstrate elevated electrode impedances when hearing loss occurs in implanted ear.
Stable/Symmetrical

Precipitous

Gradual

Z Change Re: Baseline (kΩ)

Time (months post CI Activation)

N=53

N=26

N=6
Average Z changes over time averaged for each patient.

- Stable/Symmetrical: N = 53
- Gradual: N = 6
- Precipitous: N = 26

- Relatively stable for stable/symmetrical group and gradual hearing loss group.
- No significant difference in average Z change between gradual hearing loss group and stable/symmetrical hearing loss group.
- Precipitous hearing loss group shows significantly greater increase in averaged Z change compared to stable/symmetrical group.
Average $Z$ change over time averaged for each patient.

At or below zero for stable / symmetrical group and gradual hearing loss group.

Precipitous hearing loss group shows significantly greater increase in averaged $Z$ change compared to stable/symmetrical group.
Z changes over time averaged for each patient.

At or below zero for stable / symmetrical group and gradual hearing loss group.

No significant difference between gradual hearing loss group and stable / symmetrical hearing loss group.

$N = 53$ Stable/Symmetrical  $N = 6$ Gradual  $N = 26$ Precipitous
Z changes over time averaged for each patient.

At or below zero for stable / symmetrical group and gradual hearing loss group.

No significant difference between gradual hearing loss group and stable / symmetrical hearing loss group.

Greater than zero for precipitous hearing loss group.
Z changes over time averaged for each patient.

At or below zero for stable / symmetrical group and gradual hearing loss group.

No significant difference between gradual hearing loss group and stable / symmetrical hearing loss group.

Greater than zero for precipitous hearing loss group.

Significantly larger average Z change compared to stable / symmetrical group.
ECAP Changes vs PTA Changes

• Change = difference between data collected at late time point and early time point.

• If changes in neural status occur with hearing loss, it may manifest as increased ECAP thresholds or decreased ECAP amplitudes.
ECAP Changes vs PTA Changes

$r^2 = 0.048$  
$p = 0.131$

$r^2 = 0.014$  
$p = 0.432$
Clinical Implications

- A percentage of hearing preservation patients lose hearing in various degrees and at different rates.
- Greater impedance fluctuations are observed in patients showing precipitous drop in hearing.
- Connection between impedance changes and hearing loss not yet known.
- Need for frequent monitoring of impedances.
- ECAP amplitudes / thresholds not correlated with PTA.
  - May reflect recordings from different sites of cochlea
  - ECAP measured from electrodes (basal regions)
  - PTA reflects acoustic hearing (apical region)
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