HEARING PRESERVATION, HYBRID STIMULATION, AND SPEECH UNDERSTANDING IN AN EXPANDED INDICATION STUDY: PRELIMINARY RESULTS

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CI422 Study Group

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- Denver Ear Associates
- Greater Baltimore Medical Center
- Mayo Rochester
- Medical College of Wisconsin
- Midwest Ear
- Northwestern
- Ohio State University
- Silverstein Institute
- University of Michigan
- Weill Cornell

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Why Expand Adult Cochlear Implant Indications?

• Speech perception outcomes continue to improve:
  » Cochlear implant technology,
  » Speech coding strategies,
  » Surgical techniques
  » Hearing preservation with combined stimulation

• HA users struggle despite borderline candidacy
• Auditory thresholds under-represent handicap
Why Expand Adult Cochlear Implant Indications?

• Recent literature reports *implanted ear-specific scores* of:
  » >80% on *open-set sentence scores*
  » >60% on *monosyllabic word scores* \(^1\)-\(^4\)

• Contralateral ear adds significant benefit (Gifford et al 2010)

• Individuals implanted outside guidelines demonstrate success with cochlear implantation\(^5\)-\(^7\)

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Study Objectives

- Expand indications
- Collection of **hearing preservation data** using a lateral wall implant array
- Gather data to support **treatment of each ear individually** to provide the best binaural hearing for recipients (no contralateral ear audiometric requirement)
- Avoid ceiling effects by using **appropriate test metrics** (CNC words instead of sentences) to determine CI candidacy and track performance over time
Materials and Methods

• Multicenter IDE trial – Total Number of Sites: 20
• Total number of Subjects: 55 (>18 yrs)
• Study Duration: 12 months Postactivation

**Current Nucleus Indications**

- **Bilateral Moderate to profound hearing loss**
- Aided **sentence** scores 50% or less *ear to be implanted*; Best aided 60%

**CI422 Study Indications**

- **Ear to be implanted** Moderate hearing loss through 1000 Hz sloping to severe above 3000 Hz
- **5 freq LF PTA 125-1000 Hz ≥ 40 dB**
- **3 freq HF PTA 4000-8000 Hz ≥ 70dB**
- Aided **word** score 10 - 50% *ear to be implanted*; Up to 70% contralaterally

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Protocol Test Measures

- Pure-tone audiometry & tympanometry
- CNC Word Test – Quiet (60 dBA)
- AzBio Sentence Test – Noise (65 dBA + 5 dB & +10 dB SNR)
- University of Washington Clinical Assessment of Music Perception (UW-CAMP) – Pitch Perception Subtest (65 dBA)
- Questionnaires
  - Device Use Inventory (DUQ)
  - Glasgow Benefit Inventory (GBI)
  - Speech Spatial and Qualities of Hearing - Benefit (SSQ-B) Scale
Study Device

- Cochlear Nucleus CI422 cochlear implant
- Cochlear Nucleus 6 (CP900 series) sound processor
  - Acoustic Component for Subjects with Aidable Hearing

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Subject Accountability

- 46 of 55 subjects are approved for Candidacy
  - 34 have been implanted
    - 31 completed Initial Activation
    - 22 completed 3 months evaluation
    - 11 completed 6 months evaluation
## Demographics

<table>
<thead>
<tr>
<th>N = 22</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td>Female = 11; Male = 23</td>
</tr>
<tr>
<td>Implanted Ear</td>
<td>Left = 18; Right = 16</td>
</tr>
<tr>
<td>Age at Implant</td>
<td>70.0 years (11.7)</td>
</tr>
<tr>
<td>Duration of Hearing Loss</td>
<td>28.0 years (14.8)</td>
</tr>
<tr>
<td>Preoperative CNC Score</td>
<td>26.5% (13.5)</td>
</tr>
<tr>
<td>Preoperative LF PTA</td>
<td>58.3 dB (12.6)</td>
</tr>
</tbody>
</table>

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Preoperative Thresholds

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Low Frequency PTA Overtime

<table>
<thead>
<tr>
<th>Interval</th>
<th>LF PTA (dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>58.3</td>
</tr>
<tr>
<td>Initial Activation</td>
<td>81.8</td>
</tr>
<tr>
<td>3 Months Postactivation</td>
<td>97.2</td>
</tr>
</tbody>
</table>

**Preop to Initial Activation Change in LF Thresholds**
(Mean 125 through 1k Hz)

**Preop to 3 Months Postoperative Change in LF Thresholds**
(Mean 125 through 1k Hz)
3 Months Postactivation

CNC Words
60 dBA

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3 Months Postactivation

AzBio Sentences
+5 dB SNR

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Speech Perception Overtime

CNC Words

60 dBA
N = 11

CAUTION: Investigational device. Limited by Federal (US) law to investigational use
Speech Perception Overtime

AzBio Sentences

+5 dB SNR

N = 11

% Correct

Best Unilateral
Best Bilateral

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Summary

- **Hearing preservation** is possible with CI422 electrode
  - At 3 months postactivation, 36% of the subjects demonstrated a LFPTA (125 – 1000Hz) within 30 dB of their preoperative status
- **Significant speech perception improvements** for the treated ear in both quiet and noise
  - By 3 months postactivation, significant improvement on monosyllabic word understanding pre- to post-operatively
  - By 6 months postactivation, significant improvement on sentences in noise at +5 dB SNR pre- to post-operatively
- **More to come for:**
  - Hybrid hearing, Music perception, and QOL
References


