Localization Abilities after Cochlear Implantation in Cases of Single-Sided Deafness

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Single-Sided Deafness

- Challenges of Single-Sided Deafness (SSD) as compared to normal hearers
  - Poor speech perception in noise
  - Variable ability on localization tasks
  - Increased report of hearing handicap
  - Reduced quality of life
Single-Sided Deafness

• Current treatment options for SSD
  » Bone-conduction devices
  » Contralateral Routing of the Signal (CROS) hearing aids

• Limitations
  » Ability to use binaural cues for speech perception in noise is variable
  » Localization abilities have been found to be at chance

CAUTION: Not FDA approved. Investigational Device Exemption
Single-Sided Deafness

- Potential benefits of cochlear implantation
  - May improve speech perception in the affected ear
  - Stimulates the auditory pathway of the affected side
    - Bilateral stimulation of the auditory system has been shown to improve speech perception in spatially-separated noise and localization abilities

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

- Cochlear Implantation in Cases of Single-Sided Deafness clinical trial

- FDA Investigational Device Exemption
  - Conditional approval in June 2014
  - Approved in October 2014
  - Maximum enrollment fulfilled in June 2015
    - \( n=20 \)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

- **Inclusion Criteria**
  - Affected Ear: moderate-to-profound sensorineural hearing loss
    - Aided CNC word score ≤ 60%
  - Contralateral Ear: normal-to-mild hearing
  - ≥ 18 years of age at implantation
  - Duration of moderate-to-profound hearing loss ≤ 10 years
  - Previous experience with current SSD treatment option
  - Realistic expectations
  - No reported cognitive issues

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

- Exclusion Criteria
  - Non-native English speaker
  - Conductive hearing loss in either ear
  - Compromised auditory nerve
  - Cochlear ossification
  - Meniere’s disease with intractable vertigo
  - Case of sudden sensorineural hearing loss that has not been first evaluated by a physician
  - Tinnitus as the primary purpose for seeking cochlear implantation

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

• Device
  » MED-EL Concert Standard electrode array
    • Full insertion (31 mm)
    • All subjects with similar insertions depths to limit potential confounding variable (Buchman et al, 2014)
      » Brown, Presentation #84
CI in SSD clinical trial

• **Device**
  - Opus 2 external speech processor
    - All subjects listening with an ear-level device to limit any potential microphone placement effects
    - All subjects programmed with the FS4 coding strategy

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

• Protocol
  » Speech perception
    • Dillon, Presentation #24
  » Localization
  » Quality of Life
    • Anderson, Poster #54
    • Burton, Poster #85
  » Aural Rehabilitation
    • Evans, Poster #84

• Intervals
  » Preoperative
  » 1, 3, 6, 9 and 12 months post-initial activation

CAUTION: Not FDA approved. Investigational Device Exemption
## CI in SSD: Initial Review

<table>
<thead>
<tr>
<th>Enrolled</th>
<th>Implanted</th>
<th>Activated</th>
<th>3-month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>20</td>
<td>20</td>
<td>15</td>
</tr>
</tbody>
</table>

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## CI in SSD: Initial Review

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Max</th>
<th>Min</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of Hearing Loss</td>
<td>6.6</td>
<td>0.3</td>
<td>2.6</td>
</tr>
<tr>
<td>Age at Implantation</td>
<td>66.0</td>
<td>22.6</td>
<td>48.6</td>
</tr>
</tbody>
</table>

### Subjects who completed the 3-month interval

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CI in SSD: Localization

- 11-speaker array
- 200 ms speech noise bursts
  » No feedback provided

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CI in SSD: Localization

• Listening Conditions
  » Preoperative
    • Unaided (better ear only)
    • Bone-Conduction HA
  
  » Postoperative
    • CI + Better Ear

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

• Tested a group of normal hearers as a performance comparison
  » n=4
CI in SSD: Localization

Timeline

Localization

PreOp

PreOp Unaided

Better

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Localization

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Localization

Timeline

PreOp
1 mo
3 mo

PreOp Unaided
PreOp BCH
CI + Better Ear

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Localization

Timeline

PreOp Unaided
PreOp BCH
CI + Better Ear
Average

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Localization

Timeline

PreOp

1 mo

3 mo

NH

PreOp Unaided

PreOp BCHA

CI + Better Ear

Average

Normal Hearers

CAUTION: Not FDA approved. Investigational Device Exemption
Initial Findings

• Localization
  » Subjects experiencing an improvement in localization abilities, measured as early as 1 month post-initial activation
  » Subjects may experience additional improvement with continued device use
  » Subject with poorer performance at 1-month was counseled on consistent device use, and experienced an improvement at the 3-month interval

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THANK YOU