Cochlear Hybrid System: Factors Involved in Outcomes

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ACIA Nashville 12/19/14
FDA Presentation

• Panel in November- led to approval
• Multicenter Data on 50 patients
• Discuss Outcomes of Study
• Discuss factors that might influence outcomes
Outcomes by Hearing Loss

CNC Word Recognition N=48

AzBio +5dB SNR N=48

Percent Correct

0 10 20 30 40 50 60 70 80 90 100

Acoustic Alone Pre
Hybrid Mode 6m

Change in LF Hearing

N=12
N=12
N=3
N=21

N=12
N=12
N=3
N=21
Clinical Significance of Groups 1 and 2

CNC Word Recognition
6 Months Postactivation N=48

<table>
<thead>
<tr>
<th>Degree of LF Hearing Loss</th>
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<tbody>
<tr>
<td>Moderate</td>
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<td>Mod-Sev</td>
<td>9</td>
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AzBio +5dB SNR
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Clinical Significance of Groups 1 and 2

CNC Word Recognition
6 Months Postactivation N=48

- Acoustic Alone Pre
- Hybrid Mode 6m

AzBio +5dB SNR
6 Months Postactivation N=48

- Acoustic Alone Pre
- Hybrid Mode 6m

Percent Correct

Severe or Better
Group 1 N=33

Profound/Total
Group 2 N=15

p<0.0001
p<0.05

Severe or Better
Group 1 N=33

Profound/Total
Group 2 N=15

p<0.0001
### Potential Predictive Factors – Hearing Sensitivity

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Gender P-value*</th>
<th>Age P-value*</th>
<th>Duration of Loss P-value*</th>
<th>Duration of Severe to Profound Loss P-value*</th>
<th>Etiology P-value*</th>
<th>Baseline CNC Score P-value*</th>
<th>Baseline AzBio Score P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change LFHL</td>
<td>0.010</td>
<td>0.160</td>
<td>0.722</td>
<td>0.275</td>
<td>0.970</td>
<td>0.450</td>
<td>0.900</td>
</tr>
<tr>
<td>Degree LFHL</td>
<td>0.016</td>
<td>0.088</td>
<td>0.536</td>
<td>0.581</td>
<td>0.949</td>
<td>0.910</td>
<td>0.264</td>
</tr>
</tbody>
</table>

*ANOVA p-value.

Age >70, long duration of HF PSNHL, Male Gender
Hearing Status Dichotomized by Median Age

Degree LFHL 6m by Median Age N=50

Pre- to postoperative change:
27.5 dB for < 68 years
38.9 dB for > 68 years

10/17 profound losses were > 68 years
4/5 complete losses were > 68 years
(5\textsuperscript{th} subjects was 67.9 years)
Outcomes Dichotomized by Median Age

**CNC Words Dichotomized by Median Age N=50**

- Improvement significantly greater for < 68 years (p = 0.027) but pre- to postoperative improvement significant for both groups.

**AzBio +5 dB SNR Dichotomized by Median Age N=50**

- Improvement significantly greater for < 68 years (p = 0.038) but pre- to postoperative improvement significant for both groups.
Age Conclusions

• Younger subjects (< 68 years) as a group experienced greater pre- to postoperative improvement and higher absolute levels of performance for CNCs and AzBio in noise
  – BUT older subjects still showed significant improvement over their preoperative status

• May have been related to shorter duration of overall hearing loss based on multivariate analyses
**Group 2a/2b Analyses**

**CNC Word Recognition**

- **Group 1 (N=33)**
  - Listening Condition: Acoustic, Acoust, Elect, Hybrid, Comb
  - Percent Correct: 0, 20, 40, 60, 80, 100

- **Group 2a (N=9)**
  - Listening Condition: Acoustic, Bilat, Elect, Bimodal
  - Percent Correct: 0, 20, 40, 60, 80, 100

- **Group 2b (N=8)**
  - Listening Condition: Acoustic, Bilat, Elect, Bimodal
  - Percent Correct: 0, 20, 40, 60, 80, 100

Moderate to Severe hearing levels (or better) by 6 months and benefit on one or both CNC/AzBio

Profound Loss by 6 months and NOT benefit on either CNC/AzBio
### Group 1 & 2 Baseline Characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Degree LFHL Mean dB HL (SD)</th>
<th>CNC Score Mean % (SD)</th>
<th>AzBio Score Mean % (SD)</th>
<th>Age Mean yrs. (SD)</th>
<th>Duration Mean yrs. (SD)</th>
<th>Duration SP Mean yrs. (SD)</th>
<th>Gender Males</th>
<th>Gender Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>42.0 (9.5)</td>
<td>29.1 (14.9)</td>
<td>17.2 (14.4)</td>
<td>61.8 (15.2)</td>
<td>25.5 (13.1)</td>
<td>12.5 (SD)</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>N=33</td>
<td>19-59</td>
<td>10-64</td>
<td>0-64.1</td>
<td>37.5-86.2</td>
<td>3.4-52.4</td>
<td>1.6-30.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2a</td>
<td>53.4 (9.7)</td>
<td>25.0 (14.1)</td>
<td>19.7 (17.9)</td>
<td>64.1 (15.7)</td>
<td>22.3 (5.2)</td>
<td>12.2 (6.9)</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>N=9</td>
<td>33-63</td>
<td>9-49</td>
<td>4.9-26.7</td>
<td>23-75.1</td>
<td>13.1-29.4</td>
<td>1.8-25.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2b</td>
<td>49.6 (6.3)</td>
<td>29.4 (16.1)</td>
<td>8.6 (6.6)</td>
<td>73.4 (7.7)</td>
<td>44.9 (18.4)</td>
<td>14.5 (7.6)</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>N=8</td>
<td>42-60</td>
<td>12-59</td>
<td>0-19.1</td>
<td>63.8-85.7</td>
<td>15.4-74</td>
<td>3.8-27.5</td>
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- Five of 6 reimplantation cases come from Group 2b cases
- Group 2b cases were 9 years older on average but most notably had 45 years of hearing loss compared with Group 1 and 2a subjects who had 26 and 22 years of hearing loss, on average
- Degree of change in LF hearing was no different between Group 2a and 2b (~50 dB on average)
Group 2b Status

- 5 of the 8 Group 2b subjects elected reimplantation to address performance concerns
- 1 of the 8 Group 2b subjects was very satisfied with their performance and showed improved speech scores for both CNC and AzBio when using both ears
- 1 of the 8 Group 2b subjects passed away for reasons unrelated to the device
Overall Conclusions

• Older subjects with very long durations of overall HF hearing loss should be considered with caution
  – *Trend* towards higher risk of significant loss
  – Most significant loss occurs, with long duration of preoperative hearing loss, don’t appear to benefit from electrical stimulation
HA fittings for “dead regions”

Audiogram
“Fitting curve”

Air-Conduction Threshold dBHL

Pure-tone Frequency Hz

125 250 500 1000 2000 4000 8000

120 110 100 90 80 70 60 50 40 30 20 10 0

80
Considerations

• Look at low frequency start point - start at 50 and lose 30dB......
• Also look at high frequencies, detection vs dead
• Duration of S/P HF hearing loss, “are there ganglion cells to stimulate?”
• Patient age
• Male Gender