Self-Reported Benefits after Implantation in a Group of Hybrid Implant Recipients

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Disclosures:
Member of Cochlear Americas Medical Advisory Board
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- **Background**
  - In recent years, increased demand for PRO’s in addition to objective measures of CI performance.
  - The Health Utilities Index–Mark 3 (HUI3) is a well studied, validated 15–item population based tool used to measure overall health and health related quality of life.
  - Results include information on 8 separate health domains in addition to a multi–attribute score.
  - The purpose of this investigation is to examine pre–and post–intervention health utility scores in a group of Hybrid L24 subjects participating in a long term, multicenter investigation of safety and effectiveness.
Methods

- Subjects enrolled in a post approval study investigating the long-term safety and effectiveness of the Nucleus Hybrid L24 cochlear implant are included from 18 study sites in the U.S.
- All subjects are adults with “ski-slope” sensorineural hearing loss who met standard FDA criteria for cochlear implantation.
- The Health Utilities Index Mark 3 was administered preoperatively and at 6 month and 12 months postactivation.
- To date, 27 adults subjects have completed the 12 month interval and data are presented here.
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Key Demographics N=27
- Gender: Male 16 (59.3%) Female 11 (40.7%)
- Age at implant: Mean (SD) 59.1 yrs (14.9)
- Ear Implanted: Right 17 (63%) Left 10 (37%)
- Duration of hearing loss: Mean (SD) 23.1 yrs (10.3)
- Duration of S/P hearing loss: Mean (SD) 11.5 yrs (5.7)
- Etiology of hearing loss
  - Noise exposure 11 (40.7%)
  - Familial 3 (11.1%)
  - Unknown 9 (33.3%)
  - Others 4 (14.8%)
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Results
- The Health Utility Index Mark 3 is scored from 0–1, and a 0.03 change is considered significant.
- Significant improvement was seen in the hearing domain and also the multi-attribute score at 6 months postactivation with stable results after 12 months.
- Minor changes were seen in two additional domains:
  - Improvement in Emotion attribute at 12 months.
  - Negative score on Pain scale at 6 months but recovered by 12 months.
<table>
<thead>
<tr>
<th>HUI Domain</th>
<th>Preop</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision</td>
<td>0.955 (0.0096)</td>
<td>0.957 (0.0035)</td>
<td>0.961 (0.0041)</td>
</tr>
<tr>
<td>Hearing</td>
<td>0.4361 (0.0527)</td>
<td>0.611 (0.0378)*</td>
<td>0.651 (0.0368)**</td>
</tr>
<tr>
<td>Speech</td>
<td>0.938 (0.0237)</td>
<td>0.937 (0.0223)</td>
<td>0.913 (0.0271)</td>
</tr>
<tr>
<td>Ambulation</td>
<td>0.981 (0.0105)</td>
<td>0.975 (0.0146)</td>
<td>0.969 (0.0155)</td>
</tr>
<tr>
<td>Dexterity</td>
<td>0.996 (0.0044)</td>
<td>0.987 (0.0074)</td>
<td>1.00 (0.0000)</td>
</tr>
<tr>
<td>Emotion</td>
<td>0.953 (0.0147)</td>
<td>0.932 (0.0274)</td>
<td>0.963 (0.0120)*</td>
</tr>
<tr>
<td>Cognition</td>
<td>0.977 (0.0079)</td>
<td>0.956 (0.0188)</td>
<td>0.961 (0.0162)</td>
</tr>
<tr>
<td>Pain</td>
<td>0.944 (0.0123)</td>
<td>0.909 (0.0241)*</td>
<td>0.915 (0.0280)</td>
</tr>
<tr>
<td>Multi</td>
<td>0.586 (0.0326)</td>
<td>0.634 (0.0395)*</td>
<td>0.668 (0.0353)**</td>
</tr>
</tbody>
</table>

* significant change when compared to previous interval
** significant change when compared to two previous intervals
Conclusions:
- The Health Utility Index Mark 3 scale is sensitive to changes in patient reported health-related outcomes following implantation with the Hybrid L24 cochlear implant.
- The interim data in this report supports the use of this implantable technology for those who meet the expanded indications.
- These results, along with the SSQ and objective measures of speech perception ability and audiometric results will be presented at study completion.

See poster #97 for additional details.
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References:


See poster #97 for additional details