Safety of cochlear implantation in children under 12 months of age

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Disclosures

• Kay Chang
  – Cochlear Corp: travel expenses to attend Cochlear Ossia surgical laboratory
  – MedEl: travel expenses to attend BoneBridge surgery training

• Other others
  – None
History of Pediatric Candidacy in the US

- 1985 FDA approval for adults
- 1986 Pediatric Conference
- 1990 FDA approval for age 2yrs+
- 1995 NIH consensus
- 2000 FDA approval for 12mo
History of Pediatric Candidacy in the US

- **1985**: FDA approval for adults
- **1990**: FDA approval for age 2yrs+
- **1995**: NIH consensus
- **1999**: Congress supports funding
- **2000**: FDA approval for 12mo
- **2001-2006**: 1mo Screened, 3mo Diagnosed, 6mo Intervention
- **2017**: Every state has an Early Hearing Detection and Intervention Program
- **1986**: Pediatric Conference
- **1990**: FDA approval for age 2yrs+
- **1993**: State efforts to promote newborn screening
- **1999**: Congress supports funding
- **2001-2006**: 1mo Screened, 3mo Diagnosed, 6mo Intervention
- **2017**: Every state has an Early Hearing Detection and Intervention Program

Hearing loss identified between age 2-3
What we’ve learned

• The procedure is safe  (Birman, 2009; Colletti, 2012 and others)

• Electrode array remains stable  (Hoffman, 1997; Roland, 1998 and others)

• Auditory deprivation negatively impacts development  (Hoffman, 1997; Halpin, 2010 and others)

• Treatment at 6mo results in significant gains over later identified children  (Moeller, 2000; Yoshinaga-Itano, 2003 and others)

• Earlier implantation prevents gaps in development  (Waltzman, 2005; Cuda, 2014 and others)
Dettman et al (2016) published the results of a multi-institutional prospective study of pediatric CI patients in Australia, which demonstrated a compelling advantage to implanting children under 12 months.

- Group 1 (< 12 m) 151
- Group 2 (13-18 m) 61
- Group 3 (19-24 m) 66
- Group 4 (25-42 m) 82
- Group 5 (43-72 m) 43

- Open-set speech perception scores: Groups 1,2,3 > 4,5
- Language standard scores: Group 1 > 2,3,4,5
- Speech production outcomes: Group 1 > 2,3,4,5
- Greater % Group 1 kids demonstrated language performance within normative range by school entry
Current Study

• Purpose: Gather safety information on children implanted <12m
• Method: Retrospective chart review for the years 2012-2017
• Sites: 5 investigational sites across the US and Canada
• Metrics gathered:
  • Baseline demographics
  • Duration under anesthesia
  • Estimated blood loss
  • Duration in recovery
  • Readmission to hospital within 30 days post-surgery
  • Amount of pain medication administered in hospital
  • Temperature regulation issues and/or any instances of arrhythmia
  • Facial nerve injury
  • Exposed dura during drilling
  • Skin flap breakdown or extrusion
  • Device malfunctions
  • Other significant complications
Pediatric CI Centers

• The Hospital for Sick Children (Toronto, Canada)
• NYU Langone’s Cochlear Implant Center (NY, NY)
• The Children’s Cochlear Implant Center at UNC (Durham, NC)
• Hearts for Hearing (Oklahoma City, OK)
• Children’s Hearing Center at Lucile Packard Children’s Hospital Stanford (Palo Alto, CA)
Age distribution

- n = 136 patients
- Average age = 9m 8d
- Range 3m 17d to 11m 29d
Comorbid conditions reported in 47/136 subjects

• Most common conditions reported:
  – Developmental delays (9)
  – Genetic syndromes (9)
  – Congenital malformations (12)
  – Cytomegalovirus (6)
  – Meningitis (6)
  – Seizures (7)
### Results: Surgical variables

<table>
<thead>
<tr>
<th></th>
<th>UNI (N=20)</th>
<th>BILAT (N=101)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>9.16kg</td>
<td>8.62kg</td>
</tr>
<tr>
<td>(Range)</td>
<td>6.1-11.8kg</td>
<td>6.1-11.7kg</td>
</tr>
<tr>
<td>EBL</td>
<td>11.05cc</td>
<td>14.28cc</td>
</tr>
<tr>
<td>(Range)</td>
<td>2-25cc</td>
<td>1-100cc</td>
</tr>
<tr>
<td>Anesth Duration</td>
<td>2:26</td>
<td>3:48</td>
</tr>
<tr>
<td>(Range)</td>
<td>1:22-4:48</td>
<td>2:14-6:19</td>
</tr>
<tr>
<td>Recov Duration</td>
<td>2:40</td>
<td>2:35</td>
</tr>
<tr>
<td>(Range)</td>
<td>0:26-8:25</td>
<td>0:35-10:28</td>
</tr>
</tbody>
</table>

30 unilateral CI patients

106 bilateral simultaneous CI patients
Reportable Events:
39 of 136 subjects experienced an event = 29%

There were 51 total events involving 39 individual subjects

Number of readmits to hospital within 30 days: 2
1. Surgical site infection
2. Emesis (not related to surgery)

Temperature Regulation issues: 8
1. Intra-op hypothermia (6)
2. Febrile after surgery
3. Intra-op hyperthermia

Facial Nerve injuries: 2
1. Delayed facial palsy
2. Delayed facial weakness

Skin Flap Breakdown: 1
1. Seroma resulting in re-implantation

Unintentional Exposed Dura: 0

Device Malfunction: 0
Other reported adverse events

Other AEs: 42
1. Cold Symptoms/RSV (3)
2. Otitis Media (7)
3. Mastoiditis (1)
4. Chronic ME Dysfunction
5. Scab under coil
6. Illness with fever (8)
7. Unsteady/off balance
8. ME effusion (2)
9. Seroma
10. CSF gusher (4)
11. Emesis (2)
12. Bloody otorrhea (2)
13. Influenza
14. Dx of Usher Syndrome
15. Swelling at headpiece site
16. Swelling at surgical site (2)
17. Infection at surgical site
18. Infection at magnet site
242 total implantations with 33 device/procedure related complaints resulting in an average rate of 14% for years 2012-2017

<table>
<thead>
<tr>
<th>Year</th>
<th># of Device-/Procedure-related complaints</th>
<th># of Surgeries</th>
<th>Complaint Rate</th>
<th>Surgery Type (B = Bilateral U = Unilateral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>5</td>
<td>30</td>
<td>17%</td>
<td>9B, 12U</td>
</tr>
<tr>
<td>2013</td>
<td>6</td>
<td>31</td>
<td>19%</td>
<td>13B, 5U</td>
</tr>
<tr>
<td>2014</td>
<td>3</td>
<td>23</td>
<td>13%</td>
<td>9B, 5U</td>
</tr>
<tr>
<td>2015</td>
<td>3</td>
<td>46</td>
<td>7%</td>
<td>22B, 2U</td>
</tr>
<tr>
<td>2016</td>
<td>7</td>
<td>55</td>
<td>13%</td>
<td>52B, 3U</td>
</tr>
<tr>
<td>2017</td>
<td>9</td>
<td>57</td>
<td>16%</td>
<td>54B, 3U</td>
</tr>
<tr>
<td>Average</td>
<td>5.5</td>
<td></td>
<td>14%</td>
<td></td>
</tr>
<tr>
<td>Sum</td>
<td>33</td>
<td>242</td>
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</tbody>
</table>
Only 4 of the 51 events met MDR criteria due to a specific relation to the device/procedure requiring surgical or antibiotic intervention (2% rate)

- 2015, 11m at time of implantation: Post-operative seroma drained at emergency room. Status = Resolved
- 2017, 10m at time of implantation: seroma drained, device explanted. Subject reimplanted within a few months. Status = Resolved
- 2012, 7m at time of implantation: “bump” at left CI magnet site. Site requiring treatment with oral antibiotics, resolved with Septra. Status = Resolved
- 2014, 7m at time of implantation: swelling at CI site during vacation with family, local ED visit, started on antibiotics, returned to clinic for evaluation, fluid aspirated, cultured, antibiotics given, left CI device removed. Status = Resolved

- This 2% rate compares well to a 3.1% MDR event rate seen for those implanted between 12-24m age
Conclusions

• Across the US and Canada, cochlear implantation under 12m of age is routinely performed in a variety of clinics, though the practice is currently not approved by the FDA in that age group.

• Average surgical parameters and reportable safety events associated with implantation in this population as collected by five North American CI centers were presented here.

• Substantial difference is not seen within the demographic, surgical, or post-op complication profiles of those implanted under 12m of age, while the communication outcomes demonstrated in the literature show an undeniable benefit for early cochlear implantation.
THANK YOU
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