Surgical Survey on the Usability and Applicability of the HiFocus Mid Scala Electrode

Matthew L. Bush, M.D.
Assistant Professor
Department of Otolaryngology – Head and Neck Surgery
University of Kentucky
Disclosures

• No off-label use of medications or devices
• Unpaid consultant for Advanced Bionics to participate in this research
• Advanced Bionics was not involved in the recruitment of patients or in analysis of data in the hearing preservation portion of this presentation
• Educational grant recipient as a Surgical Advisory Board Member of Med El
HiFocus Mid Scala Electrode
Design Considerations

1. To provide optimal cochlear placement for complete electrical coverage to provide full-spectrum hearing

2. To minimize disruption of cochlear structures

3. To give surgeons the flexibility to choose among standard-of-care insertion techniques and surgical approaches, including round window insertions.
HiFocus Mid Scala Electrode Design

- Insertion techniques
  - Cochleostomy (0.8 mm)
  - Round window
- Insertion options
  - Freehand
  - With tool
- Surgical markers
HiFocus Mid Scala Electrode

Design

- Low insertion forces
  - Mid scalar positioning
  - Protects delicate structures

- Full spectrum cochlear coverage
  - Consistent 1 ¼ turn angular insertion depth
Survey Design
Three On-Line Questionnaires

1. Initial: Data on surgeon experience and preferences (completed at study onset)

2. Surgical: Data on experience with individual insertions (completed after each surgery)

3. Final: Summarizes overall surgeon experience with the HiFocus Mid Scala electrode across a number of surgical cases (completed at end of study)
Survey Results

Participants

- 22 surgeons in the United States
- 12 implanting centers
- 103 surgeries (23 children, 80 adults)
- Conventional implant candidates

![Pie chart showing age distribution:]

- Baby: 3%
- Young Child/Todder: 12%
- Child: 4%
- Teenager: 5%
- Young Adult: 32%
- Adult: 41%
Survey Results

Experience and Surgical Preferences

Years of CI Surgical Experience
- 10+ Years: 71%
- 7-9 Years: 14%
- 4-6 Years: 10%
- 1-3 Years: 5%

Preferred Electrode Design
- Mid-Scala: 71%
- Lateral Wall: 24%
- Perimodiolar: 5%
- Variable: 0%

Preferred Insertion Location
- Round Window: 48%
- Round Window (ext/mod): 19%
- Variable: 24%
- Cochleostomy: 10%

Preferred Insertion Technique
- Free-hand: 81%
- Insertion Tools: 19%
Survey Results
Reasons for Choosing HiFocus Mid Scala Electrode

- Preservation of Cochlear Structures: 30%
- Flexible Insertion Techniques: 20%
- Prefer Round Window Insertion: 30%
- Prefer Soft Surgery: 50%
- Insertion Depth Maximizes Benefit: 10%
- Newest AB Electrode Option: 40%
- Other: 5%
Survey Results

Overall

- All 103 surgeries resulted in full insertions (to blue marker)
- 7 electrode re-loadings
- In 87% of surgeries, ease of insertion was rated Easy-Very Easy
Survey Results

Surgical Preferences and Techniques

HiFocus Mid Scala electrode allowed surgeons to vary their intended insertion location based upon presenting anatomy (e.g., rotated cochlea, access to round window niche, ossification, fibrosis).

- Round window to modified/extended round window = 7
- Round window to cochleostomy = 6
- Modified/extended round window to cochleostomy = 6
- Cochleostomy to modified/extended round window = 1

Hi Focus Mid Scala electrode allowed surgeons to vary their intended insertion technique depending upon the presenting anatomy.

- Freehand to insertion tool = 4
- Insertion tool to freehand = 5
Survey Results - Overall Experience

16 surgeons completed final questionnaire

- 15 would recommend HiFocus Mid Scala electrode for all patients
- 1 stated that electrode was more difficult to insert than 1j and therefore would use primarily for patients with residual hearing

Reasons for recommending:

“Easy to use, delicate and great for soft surgery techniques.”
“Ease of use. Less traumatic compared to 1j. Potential for hearing preservation.”
“Atraumatic electrode that is easy to insert for all populations.”
“It is a good electrode, easy to insert WITHOUT THE TOOL. I feel comfortable with this electrode for anatomic preservation…”
“Excellent postop outcomes - both thresholds and speech recognition ability.”
“Ease of insertion and better able to choose to not use the inserter in difficult exposure cases. Also, theoretically more atraumatic insertion for long term improvement in ability to replace an implant if needed.”
Survey Conclusions

HiFocus Mid Scala electrode allows surgeons to choose among standard-of-care insertion techniques and surgical approaches

- Freehand insertion technique preferable to using tools
- Round window or extended round window insertions were preferred
- Insertion rated as easy /very easy

Post-surgical follow-up will demonstrate benefit from the electrode.

- Speech perception
- Acoustic thresholds
Survey Participants

Duke University
  David Kaylie
  Debara Tucci

Ear Medical Group
  Brian Perry

Indiana Ear
  Michael J. Disher

Indiana University
  Charles W. Yates

New York Eye & Ear Infirmary
  George Alexiades
  Wontaek Choe
  Ronald Hoffman
  Ana H. Kim
  Darius Kohan
  Neil Sperling

Northwestern University
  Alan G. Micco

Tampa Bay Hearing & Balance
  Kyle Allen
  Loren Bartels
  Christopher Danner

University of Arizona
  Abraham Jacob

University of Arkansas
  John Dornhoffer

University of Cincinnati
  Ravi N. Samy

University of Colorado
  Stephen Cass
  Herman Jenkins

University of Kentucky
  Matthew Bush
  Raleigh O. Jones
Hearing Preservation Outcomes

- University of Kentucky IRB approved study investigating prospective hearing preservation outcomes and speech perceptions performance.
- Simultaneously during the course of the questionnaire study, we enrolled 6 adult patients who selected Advanced Bionics.
Hearing Preservation Outcomes

• 5 males : 1 female, Mean age 62.5 (32-84)
• All extended round window insertions
• 4/6 post-op threshold below 80dB

### Mid Scala Hearing Preservation

<table>
<thead>
<tr>
<th>Decibels</th>
<th>125 Hz</th>
<th>250 Hz</th>
<th>500 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>41.67</td>
<td>56.25</td>
<td>77.5</td>
</tr>
<tr>
<td>1 month Post-op</td>
<td>62.5</td>
<td>80</td>
<td>100</td>
</tr>
</tbody>
</table>
Hearing Preservation Outcomes

- 2 patients with 3-month and 6 month data
- Initial 20 dB threshold increase stabilizes
## Speech Perception Outcomes

- **3 patients with 3-month and 6 month data**

### Speech Perception Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HINT</strong></td>
<td>23%</td>
<td>52%</td>
<td>83.67%</td>
</tr>
<tr>
<td><strong>AzBio</strong></td>
<td>22%</td>
<td>40%</td>
<td>54.33%</td>
</tr>
</tbody>
</table>

---

### Percentage Correct

<table>
<thead>
<tr>
<th>Percentage Correct</th>
<th>Pre-Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>10%</td>
<td>10%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>40%</td>
<td>40%</td>
<td>40%</td>
<td>40%</td>
</tr>
<tr>
<td>50%</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>60%</td>
<td>60%</td>
<td>60%</td>
<td>60%</td>
</tr>
<tr>
<td>70%</td>
<td>70%</td>
<td>70%</td>
<td>70%</td>
</tr>
<tr>
<td>80%</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>90%</td>
<td>90%</td>
<td>90%</td>
<td>90%</td>
</tr>
</tbody>
</table>

---

Provided by [HINT](https://www.example.com) and [AzBio](https://www.example.com)
HF 1J vs Mid Scala Electrode

- 72 yo white male enrolled in study in 2013
- High focus 1J electrode in 2013 → FN stim
- Mid Scala electrode in 2014

![Chart showing Low Frequency PTA (125, 250, 500 Hz)]

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op</th>
<th>Post-Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1J</strong></td>
<td>66.7</td>
<td>95</td>
<td>96.7</td>
<td>96.7</td>
</tr>
<tr>
<td><strong>Mid Scala</strong></td>
<td>66.7</td>
<td>71.7</td>
<td>81.7</td>
<td>70</td>
</tr>
</tbody>
</table>

Decibels
HF 1J vs Mid Scala Electrode

### Threshold at 125 Hz

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op</th>
<th>Post-Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1J</td>
<td>55</td>
<td>80</td>
<td>85</td>
<td>80</td>
</tr>
<tr>
<td>Mid Scala</td>
<td>55</td>
<td>60</td>
<td>70</td>
<td>55</td>
</tr>
</tbody>
</table>
## HF 1J vs Mid Scala Electrode

### Threshold at 250 Hz

<table>
<thead>
<tr>
<th>Time Period</th>
<th>1J</th>
<th>Mid Scala</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Post-Op</td>
<td>100</td>
<td>60</td>
</tr>
<tr>
<td>3 months</td>
<td>100</td>
<td>75</td>
</tr>
<tr>
<td>6 months</td>
<td>100</td>
<td>65</td>
</tr>
</tbody>
</table>

Decibels

---

Threshold at 250 Hz
HF 1J vs Mid Scala Electrode

Threshold at 500 Hz

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op</th>
<th>Post-Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1J</strong></td>
<td>80</td>
<td>105</td>
<td>105</td>
<td>110</td>
</tr>
<tr>
<td><strong>Mid Scala</strong></td>
<td>80</td>
<td>95</td>
<td>100</td>
<td>90</td>
</tr>
</tbody>
</table>
Thank You!

• Advanced Bionics
  – Dawn Koch, PhD
  – Smita Agrawal, PhD

• University of Kentucky Cochlear Implant Program
  – Meg Adkins, AuD
  – Raleigh Jones, MD

matthew.bush@uky.edu