Our Experience with AB HiFocus MSE Cochlear Implant from Laboratory to OR: 
Electrode and Access Variables

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DISCLOSURES

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OBJECTIVE

Evaluate a new cochlear implant electrode array in laboratory setting

Define initial histological results, insertion depth of each trial implantation and documentation of damage observed in each specimen, if present.

Each insertion in lab done under fluoro

Reviewing clinical data from our initial experience with MSE at our center
SURGICAL APPROACHES

- Cochleostomy
- Peri-Round Window
- Round Window
Total length of the array is 18.5mm; 16 platinum contacts are enclosed in a silicone carrier

Full electrode array
METHODS

• 10 fresh-frozen temporal bones
  • 5 right, 5 left
  • 4 Peri-Round Window
  • 3 Cochleostomy
  • 3 Round Window
• Performed by single experienced surgeon who in clinical practice uses AOS technique
• Insertion tool was used in all insertions
METHODS

Combination of insertion tool and free-hand insertion utilized

Fluoroscopy used during each insertion; insertion video captured

- Fluoroscopy
  - Angular depth of insertion
  - Insertion trajectory
- Histologic sectioning
  - Intracochlear trauma
  - Insertion position
METHODOLOGY

Presence of Fluoro essentially created a situation where optimal insertion vector was not possible due to physical constraints.

Forced an inferior to superior vector of insertion.

Insertions were done under fluoro and on normal cochlea’s.
## INSERTIONS

<table>
<thead>
<tr>
<th>Specimen Number</th>
<th>Side</th>
<th>Tool Used</th>
<th>Opening to Scala Tympani</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R</td>
<td>Tool</td>
<td>RW</td>
<td>Full Insertion,</td>
</tr>
<tr>
<td>2</td>
<td>R</td>
<td>T+ FH</td>
<td>Extended RW</td>
<td>Array deviated ST to SV @ 160°</td>
</tr>
<tr>
<td>3</td>
<td>L</td>
<td>Tool</td>
<td>Cochleostomy</td>
<td>Full Insertion</td>
</tr>
<tr>
<td>4*</td>
<td>L</td>
<td>T+ FH</td>
<td>Cochleostomy</td>
<td>Tip foldover, 2nd full</td>
</tr>
<tr>
<td>5</td>
<td>R</td>
<td>Tool</td>
<td>RW</td>
<td>Full Insertion,</td>
</tr>
<tr>
<td>6</td>
<td>L</td>
<td>Tool</td>
<td>Cochleostomy</td>
<td>Insertion, Full</td>
</tr>
<tr>
<td>7</td>
<td>R</td>
<td>Tool</td>
<td>Extended RW</td>
<td>Full Insertion,</td>
</tr>
<tr>
<td>8*</td>
<td>L</td>
<td>Tool</td>
<td>RW</td>
<td>Tip foldover, 2nd Insertion Full</td>
</tr>
<tr>
<td>9</td>
<td>R</td>
<td>Tool</td>
<td>Extended RW</td>
<td>Felt resistance, Reload, 2nd Ins.</td>
</tr>
<tr>
<td>10</td>
<td>L</td>
<td>Tool</td>
<td>Extended RW</td>
<td>Full insertion</td>
</tr>
</tbody>
</table>
## INSERTION DEPTH AND HISTOLOGY

<table>
<thead>
<tr>
<th>Specimen Number</th>
<th>Insertion Depth</th>
<th>ST or SV</th>
<th>Trauma Observed</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>423.4°</td>
<td>ST</td>
<td>None</td>
<td>Array rotated CW at Base</td>
</tr>
<tr>
<td>2</td>
<td>360.0°</td>
<td>ST/SV</td>
<td>1mm @ 160°</td>
<td>Array rotated CCW 60° at Base</td>
</tr>
<tr>
<td>3</td>
<td>424.7°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>4*</td>
<td>457.5°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>5</td>
<td>445.1°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>6</td>
<td>440.3°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>7</td>
<td>474.4°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>8*</td>
<td>439.9°</td>
<td>ST</td>
<td>BM/RM Tear</td>
<td>BM and RM torn, limited dist.</td>
</tr>
<tr>
<td>9</td>
<td>426.2°</td>
<td>ST</td>
<td>None</td>
<td>Contact with BM, no damage</td>
</tr>
<tr>
<td>10</td>
<td>399.8°</td>
<td>ST</td>
<td>None</td>
<td>Appeared to be small cochlea</td>
</tr>
</tbody>
</table>
2 foldovers

One specimen with limited trauma as result of foldover on histology

Foldovers were not identified with increased resistance

Vector of insertion was sub optimal due to physical constrains introduced by presence of fluoro
SV INSERTION

Poor trajectory led to outer wall forces directing electrode into SV
COMPARISON OF INSERTION DEPTH

![Graph showing comparison of insertion depth across different temporal bone specimen numbers. The graph illustrates data points for HiFocus MS (prev., n=21), HiFocus MS (NYU, n=10), and HiFocus 1j (n=20).]
IMPORTANCE OF VECTOR OF INSERTION

Superior to inferior is desired
Adequate facial recess
Removal of superior lip of round window
FACIAL RECESS

Most common issue seen in lab sessions and surgeries

Maximize size of FR

• Funnel not a Tunnel
• Skeletonize post EAC
• Skeletonize facial nerve
• Chorda tympani, identify and preserve
• Drill bone in front of the facial nerve!!!
• Posterior and Inferior exposure
VECTOR OF INSERTION

Insertion Forces

Axial Cross-section

Radial Cross-section
Rollover

No Rollover
FLUOROSCOPY

Superior Semicircular Canal (SSC)

Vestibule (V)

Modiolus

Superior Semicircular Canal (SSC)
VIDEO OF TIP ROLLOVER
INITIAL NYU CASES (N=63):
SURGICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Electrode</th>
<th>MSE (N=63)</th>
<th>1j (N=63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other otologic disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vestibulocochlear dysplasia</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Cochlear ossification</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Chronic otitis media</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>X-ray abnormality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rollover</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Incomplete insertion</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Impedances &amp; NRT (N)</td>
<td>61</td>
<td>61</td>
</tr>
<tr>
<td>Open electrodes/high impedances</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Abnormal NRT responses*</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td>Postoperative complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound infection</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Failed device</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
ADOI: 1J VS MSE ELECTRODE

all surgeons: angular depth of insertion (aDOI)

adoi (degrees)

660
600
540
500
480
420
400
360
300

1j
MSE

type of electrode
MSE aDOI change with insertion method

aDOI (degrees)

insert tool  advance off stylette
insertion method
TIP ROLLOVERS ARE IDENTIFIED ON INTRAOPERATIVE X-RAY

Abnormal NRT

39

Abnormal EI

16

1

0

0

Abnormal XR

0

4

SUMMARY

Successful insertion of the HiRes 90K™ Advantage implant with HiFocus™ Mid-Scala electrode achieved in temporal bone specimens using the insertion tool or free-hand approach with forceps

- 2/10 tip fold-over observed during insertions – Insertion Angle Observation- important to direct electrode away from modiolus- superior to inferior direction
- 1 scala vestibuli insertion directly related to vector
- Reloading stylet capacity is an advantage

The Mid-Scala electrode can be successfully inserted using a round window, traditional cochleostomy or extended round window technique with minimal intracochlear trauma

- Preferred Approach may be based on access to round window
- Insertion Depth is very consistent
- Intra cochlear trauma minimal to none even with tip rollover and re-insertion
Tip rollovers were not appreciated clinically in either lab or in the operating room 1/61 cases.
Tip rollover is not detected with traditional electrical testing
Spread of excitation may detect tip foldover
Currently X-ray is utilized to detect any abnormal insertion along with electrical testing to ensure the patient leaves the operating room with the best situation possible.
Either insertion tool or free hand AOS technique is viable. Do what you are comfortable with.
Delicate electrode array, even in face of tip rollover in 2 cases with re-insertion minimal intra-cochlear damage was noted
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THANK YOU
THANK YOU
<table>
<thead>
<tr>
<th>No.</th>
<th>Right/Left Bone</th>
<th>Approach*</th>
<th>Insertion Method</th>
<th>Observation During Electrode Insertion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R</td>
<td>RW</td>
<td>Tool</td>
<td>Full insertion, smooth</td>
</tr>
<tr>
<td>2</td>
<td>R</td>
<td>RW</td>
<td>Tool</td>
<td>Full insertion, smooth. Fluoroscopy view – modiolar contact seen</td>
</tr>
</tbody>
</table>
| 3   | L              | RW        | Tool            | 1. Tip fold-over encountered on first insertion; no resistance no twist  
2. Reloaded on insertion tool and 2nd insertion increased superior-inferior angle. Full insertion achieved with some modiolar contact observed |
| 4   | R              | XRW       | Tool            | Full insertion, smooth                 |
| 5   | L              | XRW       | Tool/Freehand   | 1. Partial insertion, resistance encountered; Reloaded on insertion tool  
2. Tip fold-over encountered  
3. Reloaded and inserted freehand using two jewelers forceps. Full insertion achieved with no tip fold-over; some modiolar contact observed |
| 6   | R              | XRW       | Tool            | 1. Resistance encountered; Reloaded on insertion tool  
2. Changed insertion angle ; achieved full, smooth insertion |
| 7   | L              | Cochl     | Tool/Freehand   | 1. Stylet issue encountered during first insertion attempt  
2. Reloaded on to a new insertion tool due. 2nd insertion, tip fold-over observed – possibly insertion angle related  
3. Reloaded onto stylet only for a freehand insertion; full insertion achieved |

* Approach: RW = Round Window, XRW = Extended Round Window, Cochl = Cochlea