Setting a New Benchmark in Hearing Performance with Slim Modiolar
Wade Colburn – Product Manager
Amy Popp, AuD – Sr. Manager Clinical Training Services

Introductions

Amy Popp
AuD, CCC-A, FAAA
Current Role:
Sr. Manager Clinical Training Services
Past Experience:
- Clinical Application Specialist
- Coordinator of Cochlear
- Implant Center at Manhattan Eye, Ear and Throat
- AuD: Central Michigan University

Wade Colburn
Current Role:
Product Manager – Nucleus Implants
Past Experience:
- Program Leader – Cook Biotech
- Design Engineer – Cook Biotech
- BS Biomedical Engineering: North Carolina State University

Disclosure: We both work for Cochlear Americas
Learner Outcomes

After this course, participants will be able to:

• Illustrate to their colleagues the clinical evidence supporting the use and performance of perimodiolar electrode arrays.
• List all audiology considerations with the Slim Modiolar array.
• Elaborate on the new multicenter trial and the performance and bimodal benefits of the Nucleus 7 with Slim Modiolar system.

What will we cover?

**Placement**
- Historical Look at Perimodiolar Electrodes
- Slim Modiolar: An Introduction

**Performance**
- Audiological Considerations of Slim Modiolar
- Slim Modiolar Multicenter Trial Results
### History of Perimodiolar Electrodes

<table>
<thead>
<tr>
<th>Series Name</th>
<th>Generation 1</th>
<th>Generation 2</th>
<th>Generation 3</th>
<th>Generation 4</th>
<th>Generation 5</th>
<th>Generation 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Body</td>
<td>CI22M</td>
<td>CI24M</td>
<td>CI24R</td>
<td>CI24RE / CI400</td>
<td>CI500/Profile</td>
<td>CI600</td>
</tr>
<tr>
<td>Registered Implants1</td>
<td>17,665</td>
<td>19,520</td>
<td>53,495</td>
<td>191,252</td>
<td>29,891/83,755</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Design Differences

Lateral Wall Electrodes

Perimodiolar Electrodes

Multiple Approaches (RW, ERW, Coch)
- Thin and Soft Array
- Optimal Length
- Consistent Scala Placement
- Distance from Outer Hair Cells

Does placement impact performance?

Placement ➔ Performance
Lateral vs. Perimodiolar Electrodes

**ELECTRODE POSITIONING**

- Lateral wall
- Spread of excitation
- Spiral ganglion cells
- Modiolus

**PERIMODIOLAR ELECTRODE**
Smaller spread of excitation with perimodiolar placement.

**LATERAL WALL ELECTRODE**
Larger spread of excitation with lateral wall placement.

**Predictors of Good CI Performance**

- **Blamey et al 2013**
  - Retrospective, observational design
  - 15 centers
  - $n = 2,251$

- **Lazard et al 2012**
  - Single-center
  - $n = 114$

- **Holden, et al 2013**
  - Single-center
  - $n = 114$
Primary Design Factors Associated with Performance

- Greater number of electrodes within scala tympani
- Absence of translocation from the scala tympani to the scala vestibuli
- Not excessively deep insertion
- Reduced distance to the modiolus

Does placement within scala tympani lead to better performance?

<table>
<thead>
<tr>
<th>Study (year)</th>
<th>Method for determining electrode location</th>
<th>Statistical Analysis</th>
<th>Number of Implants</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skinner et al (2002)</td>
<td>Pre- and post-operative CT</td>
<td>UV</td>
<td>15</td>
<td>Negative correlation between number of electrode contacts in the scala vestibuli and CNC score</td>
</tr>
<tr>
<td>Autschendorf et al (2007)</td>
<td>Rotational tomography</td>
<td>UV</td>
<td>43</td>
<td>In patients with short duration deafness, Fisher's numbers and Oldenburg sentence scores were higher for ST insertions than SV insertions</td>
</tr>
<tr>
<td>Finley et al (2008)</td>
<td>Pre- and post-operative CT</td>
<td>MV</td>
<td>14</td>
<td>Overall scalar position of the electrode array and number of electrode contacts in the scala vestibuli was significantly associated with hearing scores in CNC scores</td>
</tr>
<tr>
<td>Holden et al (2013)</td>
<td>Pre- and post-operative CT</td>
<td>MV</td>
<td>114</td>
<td>The percentage of electrode contacts in the SV was inversely correlated with the oldenburg sentence scores</td>
</tr>
<tr>
<td>Wanna et al (2014)</td>
<td>Pre- and post-operative CT</td>
<td>UV</td>
<td>116</td>
<td>CNC score was higher for ST insertion (50%) than SV insertion (30%)</td>
</tr>
<tr>
<td>O'Connell et al (2016)</td>
<td>Pre- and post-operative CT</td>
<td>MV</td>
<td>220</td>
<td>CNC score was higher for ST insertion (60%) than SV insertion (50%)</td>
</tr>
</tbody>
</table>

Table retrieved from O'Connell et al, 2016.
Does placement within scala tympani lead to better performance?

- Contour Advance
- 57 Patients
- Post-lingual matched group

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Scala tympani</th>
<th>Scala vestibuli</th>
<th>Translocation</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>41</td>
<td>6</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>Age (mean [SD]; years)</td>
<td>66.9 [14]</td>
<td>64.4 [20]</td>
<td>69.5 [10]</td>
<td>0.34</td>
</tr>
<tr>
<td>Deadness duration (mean [SD]; years)</td>
<td>17.8 [13]</td>
<td>15.6 [12]</td>
<td>16.1 [14]</td>
<td>0.16</td>
</tr>
<tr>
<td>Pre-op phoneme score (mean [SD]; % correct)</td>
<td>14.2 [17]</td>
<td>16.5 [8]</td>
<td>12.6 [12]</td>
<td>0.35</td>
</tr>
<tr>
<td>3-months post-op phoneme score (mean [SD]; % correct)</td>
<td>63.6 [24]</td>
<td>52.7 [20]</td>
<td>47.3 [23]</td>
<td>0.11</td>
</tr>
<tr>
<td>12-months post-op phoneme score (mean [SD]; % correct)</td>
<td>69.1 [17]</td>
<td>54.2 [25]</td>
<td>50 [21]</td>
<td>0.013*</td>
</tr>
</tbody>
</table>

*Analysis conducted using the Kruskal-Wallis test. *p < 0.05. SD = standard deviation; pre-op = pre-operative; 3m = 3 months; post-op = post-operative.

Table retrieved from Shaul et al, 2018.

Is there a benefit to placement close to the hearing nerve?

- Holden et al, 2013\(^2\)
  - Evidence supports that a smaller wrapping factor has correlation to speech performance

- Polonenko et al, 2016\(^7\)
  - Focused stimulation leads to lower current levels to elicit neural responses

- Hughes et al, 2006\(^8\)
  - Reduced channel interaction as measured with ECAP

Studies support there are programming and performance benefits with a perimodiolar array.\(^2,7,8\)
Our results confirm the significance of electrode positioning in audiological outcomes. The most significant positional predictors of outcome for pre-curved arrays were scala tympani insertion and the modiolar distance, while for the later wall arrays the depth of insertion was the most significant factor.
Slim Modiolar Design Goals

1. Thin, atraumatic electrode
2. Consistent scala tympani insertion
3. Consistent proximity to the modiolus
4. Inserted via all 3 surgical approaches

Slim Modiolar Specifications

Active electrode array: 14 mm

- Apical dimensions: 0.35 x 0.4 mm
- Basal dimensions: 0.475 x 0.5 mm
- Distance between white markers: 1 mm
- Reloading notch
- White alignment marker on electrode
- Electrode tip to first marker: 16.4 mm
- Sheath tip to sheath stopper: 5.5 mm
- Sheath stopper: 1.5 mm diameter
- Tapered sheath diameter: 0.68-0.76 mm
- White alignment marker on sheath
- Sheath handle
# Slim Modiolar Design

**APICAL SECTION**

<table>
<thead>
<tr>
<th>CI932</th>
<th>0.35 x 0.40 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>0.50 x 0.50 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BASAL SECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI932</td>
</tr>
<tr>
<td>CA</td>
</tr>
</tbody>
</table>

- **60% reduction in volume** compared to previous generation Contour Advance.
- In our largest ever temporal bone study (n=56) no intracochlear trauma was evident in 98% of specimens.
- Perimodiolar design places the electrode away from the functional structures of the lateral wall and basilar membrane.

## Slim Modiolar Design

*(n=25 reloading attempts)*

**PROTOCOL:** Same bone, insert Slim Modiolar, Insert Contour Advance, Reload & Insert Slim Modiolar

**RESULTS:** 92% of Slim Modiolar electrodes had more contacts positioned medially compared to CA^10^.

**ANGULAR INSERTION DEPTH:**
- No difference in 1st & 2nd insertions using Slim Modiolar => successful reload and insertion
- Length of Slim Modiolar and Contour Advance are identical => greater angle with Slim Modiolar due to closer- and more consistent perimodiolar positioning

Images courtesy of A/Prof. Briggs & Hearing CRC, Melbourne, Australia
Shaul et al, 2018

- Speech Performance:
  - In matched group, 12 month mean post-op phoneme scores were significantly different (p value = .017):
    - Matched group (post-lingual, non-significant difference in pre-op scores) with a full scala tympani insertion
      - CI512 (n=31): 69.4%
      - CI532 (n=18): 79.5%

With a compared dataset with scala tympani location, CI532 patients performed significantly better at 12 months.

Slim Modiolar Design Goals

1. Thin, atraumatic electrode
2. Consistent scala tympani insertion
3. Consistent proximity to the modiolus
4. Inserted via all 3 surgical approaches
Data on Slim Modiolar

Matched Cohort Comparison Indicates Superiority of Precurved Electrode Arrays

Jourdan T. Helder, Robert J. Yawn, Ashley M. Nassiri, Robert T. Duver, Alejandro Rivas, Robert F. Labadie, and Rene H. Giffio

*Department of Hearing and Speech Sciences; and †Department of Otolaryngology—Head and Neck Surgery Medical Center, Nashville, Tennessee

Surgical Experience and Early Outcomes With a Slim Perimodiolar Electrode

David R Friedmann, Emily Kamen, Baishakhi Choudhury, and

Department of Otolaryngology-Head & Neck Surgery, NYU Cochlear

Scalar localisation of peri-modiolar electrodes and speech perception outcomes


1Department of Otolaryngology, Royal Victorian Eye and Ear Hospital, East Melbourne and 2Otolaryngology, Department of Surgery, University of Melbourne, Australia

Objective, audiological and quality of life measures with the CI532 slim modiolar electrode

Matthias Hey, Thomas Wesarg, Alexander Mewes, Silke Helbig, Joachim Hornung, Thomas Lenarz, Robert Briggs, Mathieu Marx, Angel Ramos, Timo Stöver, Bernard Escudé, Chris J. James & Antje Aschendorff

Audiological Considerations with Slim Modiolar

Hear now. And always.
Considerations of Perimodiolar

1. Focused stimulation with 22 electrode contacts
   a) Reduced channel interaction

2. Lower and stable impedances
   a) Less charge and improved battery life

3. Lower T's and C's
   a) More likely to stay within compliance

How are electrode impedances measured?
How are electrode impedances measured?

Electrode impedance can increase significantly during certain medical conditions, such as:
- Implant site infection
- Middle ear infection
- Bladder infection
- Autoimmune disorder
- Hormonal change (puberty, menopause, thyroid disorders)
- Dizziness or Vertigo
- Stroke
- Meningitis
- Otosclerosis
- Shingles
- Post-operative acoustic hearing loss
Summary of Key Factors

<table>
<thead>
<tr>
<th>Factor</th>
<th>Impact on electrode impedances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment - fluid contact, proximity to bone etc</td>
<td>If there is not good fluid contact or there is fibrosis or ossification in the area there will be more resistance to the current (therefore higher impedances).</td>
</tr>
<tr>
<td>Medical, pharmaceutical (drugs), hormonal changes</td>
<td>Medications, drugs and hormonal fluctuations change the conductive nature of the fluid the current passes through (and therefore may change the resistance or impedance value).</td>
</tr>
<tr>
<td>CIS (unused channels) Disabled channels</td>
<td>Due to conditioning of the electrode with the surrounding environment, unused or disabled channels will typically have higher impedance values.</td>
</tr>
<tr>
<td>Time of day measurement taken</td>
<td>Impedance values will typically be lower after a period of stimulation due to conditioning of the electroneural interface.</td>
</tr>
</tbody>
</table>

Lateral Wall vs Perimodiolar Electrodes

- **Lateral Wall Electrodes**
  - CI422/522/622 & Hybrid L24
  - Smaller electrodes, resulting in higher impedance
  - Electrodes further from the nerve, resulting in higher stimulation levels

- **Perimodiolar Electrodes**
  - CI24RE/CI512/612/532/632
  - More fluid between the electrode and the nerve, resulting in higher impedance changes with medical conditions

*Note:* Proportions have been exaggerated to more clearly show differences
Impedance Differences

In comparing the impedance values of the Slim Modiolar electrode (CI532) to the Slim Straight electrode (CI422/522), the average impedance value for the Slim Modiolar electrode (6,787 ohms) was significantly lower than the Slim Straight electrode (8,021 ohms), p<0.001. Differences across the electrode type are shown in figures 4 and 5.

Managing Out-of-Compliance

- Increasing pulse width allows the same electrical charge and loudness percept to be achieved at lower current level
- The lower current level keeps the stimulation below the compliance limit

25 µsec/ph

37 µsec/ph
Both houses are 2700 Square Feet…

Perimodiolar Arrays have a default 25 µs pulse width

Lateral Wall Arrays have a default 37 µs pulse width
Multiple studies have shown significantly lower threshold and comfort levels with perimodiolar arrays.\textsuperscript{11,20}
US Multicenter Study

- Washington University, St. Louis, MO
- Center for Hearing and Balance, St. Louis, MO
- Dallas Ear Institute, Dallas, TX
- Ear Medical Group, San Antonio, TX
- Hearts for Hearing, Oklahoma City, OK
- Midwest Ear Institute, Kansas City, KS
- New York University, New York, NY
- Ohio State University, Columbus, OH
- Rocky Mountain Ear Center, Denver, CO
- Spokane ENT, Spokane, WA
- University of California San Francisco, CA
- University of Iowa, Iowa City, IA
- University of Michigan, Ann Arbor, MI
- 13 Sites
- 26 Surgeons
- 37 Audiologists
- 100 Subjects

US Multicenter Subject Demographics (N=96)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (S.D.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implantation</td>
<td>67.39 years (±15 yrs)</td>
</tr>
<tr>
<td>Range: 23 – 91 years</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>62 males (65%)</td>
</tr>
<tr>
<td></td>
<td>34 females (35%)</td>
</tr>
<tr>
<td>Duration of Hearing Loss</td>
<td>27.1 years (±14 yrs)</td>
</tr>
<tr>
<td></td>
<td>26.7 years (±14 yrs)</td>
</tr>
<tr>
<td>Pre CI CNC Word Score</td>
<td>15% (±12%)</td>
</tr>
<tr>
<td></td>
<td>24% (±15%)</td>
</tr>
<tr>
<td>Pre CI AzBio +10 Score</td>
<td>15% (±17%)</td>
</tr>
<tr>
<td></td>
<td>25% (±21%)</td>
</tr>
<tr>
<td>Pre CI PTA (500, 1 &amp; 2 KHz)</td>
<td>85 dB (±15 dB)</td>
</tr>
<tr>
<td></td>
<td>78 dB (±13 dB)</td>
</tr>
</tbody>
</table>
Understanding the 3D Reconstructions

Key Metrics

1. Electrode Position
   - Wrapping Factor
   - Basal electrode: insertion depth (mm) insertion angle °
   - Apical electrode: insertion depth (mm) insertion angle °

2. Electrode Location
   - Scala tympani vs. scala vestibuli

Consistent Scala Tympani Placement

89% (82/92) Scala tympani placement
   - 3% (3/92) Scala Vestibuli placement
   - 8% (7/92) translocated

89% remained within scala tympani

Multiple studies show that the translocation rate of CI512 varies between 27% and 53% 5, 13, 14
Electrode Proximity to the Modiolus

**Consistent Wrapping Factor** \(^{11}\): Mean: 59.6% (SD± 5%)

Previous studies reported lateral wall electrodes to have wrapping factor closer to 100% and well placed individual arrays that led to increased performance were found to be <60%. \(^2\)

59.6%

average
wrapping factor \(^{11}\)

---

US Multicenter Study: Speech Understanding in Quiet at 6 Months (N=96)

**CNC Scores**

![Graph showing CNC Scores]

Median 64%

46 points

61%

Pre Op (1 HA) CI Alone

***p = < 0.001

4X

speech understanding with CNC word scores in quiet compared to aided pre-operative scores\(^{11}\)
More People Hearing Better Faster\textsuperscript{11}

\begin{itemize}
  \item 2017 CI532 Clinical Trial (N=96)
  \begin{itemize}
    \item 50\% of subjects scored above 60\%
    \item \geq 60 \%
  \end{itemize}
  \item 2010 CI512 Clinical Trial (N=41)
  \begin{itemize}
    \item 35\% of subjects scored above 60\%
    \item \geq 60 \%
  \end{itemize}
  \item 2005 CI24RE Clinical Trial (N=54)
  \begin{itemize}
    \item 30\% of subjects scored above 60\%
    \item \geq 60 \%
  \end{itemize}
\end{itemize}

A New Benchmark with N7 System\textsuperscript{11}

\begin{itemize}
  \item % Scoring greater than 60\% CNC
  \item 6 mos
  \item 3 mos
\end{itemize}
US Multicenter Study: Speech Understanding in Noise at 6 Months (N=96)

AzBio Sentences, +10 dB SNR S_n N_n

<table>
<thead>
<tr>
<th>Percent correct</th>
<th>Pre Op (1 HA)</th>
<th>CI Alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>15%</td>
<td>43%</td>
</tr>
<tr>
<td>10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>70%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>80%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>90%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Median 41% vs 43% 28 points

MORE THAN DOUBLED
Secondary study endpoint met – CI more than doubled mean score than with a hearing aid

**p = < 0.001

Study Conditions and Technology

Bilateral Hearing Aids
fit to NAL-Targets
- Preop condition
- HA Experience on average 20 yrs. (1-54 yrs.)

Smart Bimodal System
- Nucleus Slim Modiolar Implant + N7 Sound Processor
- ReSound Hearing Aid

A comprehensive audiological, quality of life, and hearing satisfaction/disability test battery was designed for use in the study.
Outcomes with Bilateral Hearing Aids

1. Hearing Aid History
   - Fit to NAL-Targets
     - Hearing aid experience on average 20 years (Range 0-54 years) for the ear implanted
     - Average number of hearing aids purchased is 6 (±4)

2. Speech Perception
   - Bilateral Hearing Aids
     - 29% Word Recognition in Quiet
     - 32% Sentence Recognition in Noise
   - One Hearing Aid (Ear Implanted)
     - 15% Word Recognition in Quiet
     - 15% Sentence Recognition in Noise

3. Patient Reported Outcomes
   - 91% were very dissatisfied/dissatisfied with bilateral hearing aid performance

Speech Understanding with a CI+HA (N=94)*

- Speech perception SIGNIFICANTLY IMPROVED in both quiet and noise
  - Median 74% for Bilateral Hearing Aids
  - Median 56% for Bimodal Hearing

* Median 69% CNC Words, 40 points
  - 23% Bilateral Hearing Aids, 24 points
  - 32% Bimodal Hearing

**p < 0.001

*p two subjects not bimodal
Patient Reported Hearing Disability (N=95)

SSQ

**SIGNIFICANT BENEFIT ACROSS ALL SUBSCALES**

Secondary Endpoint: PRQoL (N=94)

**Study Endpoint met**
- Average HUI score significantly better by 0.19
  (p < 0.001)
Comparison to Results from Other Studies

<table>
<thead>
<tr>
<th>Reference</th>
<th>Device</th>
<th>Baseline</th>
<th>Post Score</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeny &amp; Eng (2004)</td>
<td>Hip Replacement</td>
<td>0.53</td>
<td>0.72</td>
<td>0.19</td>
</tr>
<tr>
<td>Groessl et al (2013)</td>
<td>Cataracts</td>
<td>0.66 1 mo &amp; 6 mo = 0.72</td>
<td>1 mo = 0.048 6 mo = 0.011</td>
<td></td>
</tr>
<tr>
<td>Arnoldner, et al (2014)</td>
<td>Cochlear Implant</td>
<td>0.46</td>
<td>0.61</td>
<td>0.146</td>
</tr>
<tr>
<td>CI532 Study</td>
<td>Cochlear Implant</td>
<td>0.45</td>
<td>0.64</td>
<td>0.19</td>
</tr>
</tbody>
</table>


Changing the Conversation

- **Bilateral Hearing Aids**
  - CNC Words: 29% correct
  - Az Bio +10: 32% correct
- **Bimodal Hearing**
  - CNC Words: 69% correct
  - Az Bio +10: 56% correct

**Satisfaction**

- Ability to understand what is said on TV: 76%
- Ability to understand conversations in a small group: 79%
- Hearing performance in background noise: 58%
- Ability to listen to and appreciate music: 68%
- Ability to understand people on the phone: 71%

**Satisfied or Very Satisfied**: 95%
References

1. Nucleus® ANSI/AAMI C66 Reliability Report, Volume 1, Date as of June 2019