New CI Delivery Model using Artificial Intelligence: A Case Study

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Disclosures

• The case study being presented is part of a larger multicenter study being sponsored by Cochlear Americas
• The FOX and Audiqueen software is not FDA approved
Purpose and Rationale for Change

- Consistent approach to programming
- MAP changes based on data
- Efficiency without sacrificing quality
Study: New CI delivery Model

*FOX/Audiqueen software not approved by the FDA
Clinical Study goals:

Goal 1: Usability & Training

Goal 2: Existing Patients

Goal 3: Newly Implanted
Study Overview

Study Design
- Nonrandomized
- Multi-site
- Within subject (repeated measures)
- Two arm study:
  - Group 1 (Newly implanted)
  - Group 2 (Existing recipients)

Study Hypothesis
- Existing Recipients: Performance on a FOX psychoacoustic tests will be the same or better with FOX MAP at Visit 2 compared to expert clinician (EC) MAP at Visit 1 in the unilateral condition

Study Sites
- Hearts for Hearing
- NYU Langone Health
- Rocky Mountain Ear Center
- St. Luke’s Midwest Ear
- University of Michigan
- PEAK ENT
- Cochlear Hearing Center
- Vanderbilt University Medical Center
- Greater Baltimore Medical Center
Subject Selection

Inclusion criteria

- Age 12 years and older
- Fluent spoken English
- For Existing recipients only: 3 months or greater combined experience with Nucleus® 5, 6, Kanso, or 7 series sound processor

Exclusion criteria

- Use of an acoustic component in the implanted ear
- Less than 18 active electrodes
- Hybrid L24 cochlear implant
- Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations
- Additional cognitive, medical or social handicaps that would prevent completion of all study requirements
- Unwillingness or inability of the subject to comply with all investigational requirements
Fitting Scheme: Group 2
(Existing Recipients)

Visit A
- Expert Clinician MAP
- Sound Booth Testing with EC MAP
  - CNC & AzBio +10 SNR S0N0
- Audiqueen Test with EC MAP
  - Audiology
  - Phoneme Discrimination
  - Loudness Scaling
  - Speech Discrimination
- Create AutoMAP
- Audiqueen tests with FOX MAP
  - Audiology
  - Phoneme Discrimination
- Get FOX Advice

Visit B
- 4 week Take Home AI (FOX) MAP
- Sound Booth Testing with FOX MAP
  - CNC & AzBio +10 SNR S0N0
- Audiqueen Test with FOX MAP
  - Loudness Scaling
  - Speech Discrimination
- Get FOX Advice
- Sound Booth Testing with FOX MAP
  - CNC & AzBio +10 SNR S0N0
- Subject Questionnaire
Case Study

- 14yr, Male
- Congenital CMV and Mild Cerebral Palsy
- Diagnosed with HL at 12 months of age.
- Implanted Left CI @ 27 months; Right CI @ 4 years
- Preferred Left CI to Right CI
  - Right CI wear time is poorer 5-6 hours
Testing

Visit A: 1) Audiometry with EC MAP (burgundy) 2)Initial FOX autoMAP (yellow)

Visit A: Phoneme Discrimination w/ EC MAP (right); FOX autoMAP(left)
Visit A-Loudness scaling with EC MAP

Visit A- Speech Audiometry (CNC words) with EC MAP
Comparing Visit A (EC MAP) to Visit B (FOX MAP)

<table>
<thead>
<tr>
<th>Date</th>
<th>Stimulus</th>
<th>Device R</th>
<th>Device L % EaSI R</th>
<th>% EaSI Bi</th>
<th>% EaSI L</th>
<th>Tester</th>
<th>Notes</th>
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<td>5/8/2018</td>
<td>CNC Mono Word Test K</td>
<td>CI Cochlear Freedom CI24RE(CA) + CP910</td>
<td>75</td>
<td></td>
<td></td>
<td>Sara NeumannR124</td>
<td>---</td>
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<tr>
<td>4/5/2018</td>
<td>Short</td>
<td>CI Cochlear Freedom CI24RE(CA) + CP910</td>
<td>85</td>
<td></td>
<td></td>
<td>Sara NeumannR112</td>
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</tbody>
</table>
Loudness scaling improved

![Graphs showing loudness scaling at 250 Hz, 1000 Hz, and 4000 Hz.](image)

<table>
<thead>
<tr>
<th>Date</th>
<th>Stimulus</th>
<th>Device R</th>
<th>Device L</th>
<th>RMS R</th>
<th>RMS Bi</th>
<th>Tester</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/3/2019</td>
<td>250Hz, 1000Hz, 4000Hz CI Cochlear Freedom CI24RE(CA) + CP910</td>
<td>-1.0</td>
<td>-0.8</td>
<td>+0.5</td>
<td>Sara Neumann R127 -</td>
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<tr>
<td>4/5/2018</td>
<td>250Hz, 1000Hz, 4000Hz CI Cochlear Freedom CI24RE(CA) + CP910</td>
<td>-1.4</td>
<td>-0.4</td>
<td>-0.7</td>
<td>Sara Neumann R112 -</td>
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</table>
Expert clinician MAP
• AZ Bio (65 dB A + 10 dB SNR) S0N0
  – 63%
• CNC words at 60 dB A: 72% words; 91% phonemes/ 78% words; 91% phonemes

AI MAP (Visit B- one month post-visit A)
Initial testing Visit B:
• AZ Bio (65 dB A + 10 dB SNR) S0N0
  – 54%
• CNC words at 60 dB A: 64% words; 82% phonemes; 70% words; 88% phonemes

Acute testing Visit B (after AI MAP)
• AZ Bio (65 dB A + 10 dB SNR) S0N0
  – 48%
• CNC words at 60 dB A: 62% words; 83% phonemes; 76% words; 89% phonemes
Participant’s perspective

• How satisfied or dissatisfied were you with the direct connect testing (testing completed in the programming room with your audiologist)?

<table>
<thead>
<tr>
<th>Very Dissatisfied</th>
<th>Somewhat dissatisfied</th>
<th>Neutral</th>
<th>Somewhat satisfied</th>
<th>Very Satisfied</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

• Please rate the sound quality delivered through the system:

<table>
<thead>
<tr>
<th>Poor</th>
<th>Fair</th>
<th>Average</th>
<th>Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

• Were you more or less comfortable completing the evaluation outside of the soundbooth today?

<table>
<thead>
<tr>
<th>Very comfortable</th>
<th>Somewhat more comfortable</th>
<th>No difference</th>
<th>Less comfortable</th>
<th>Very uncomfortable</th>
</tr>
</thead>
</table>
Review of EC MAP to optimized AI MAP

Visit B- Acute
- AZ Bio (65 dB A + 10 dB SNR) S0N0
  - 48%
- CNC words at 60 dB A: 62% words; 83% phonemes

1 year later
- AZ Bio (65 dB A + 10 dB SNR) S0N0
  - 69%
- CNC words at 60 dB A: 78% words; 89% phonemes

Compared to Visit A- Expert Clinician MAP:
- AZ Bio (65 dB A + 10 dB SNR) S0N0
  - 63%
- CNC words at 60 dB A: 72% words; 91% phonemes/ 78% words; 91% phonemes

**TAKE AWAY:** On existing users, the changes may be drastic at first.
Speech perception may go down initially, but with repeat visit for optimization and time to acclimate to changes, performance should improve back to expected levels or possibly higher.
Participant Summary

• This teenage participant had a good experience with FOX
• Wear time improved to 8-9 hours, motivated to try something new
• With additional visits to further optimize FOX MAP, his performance was equivalent to his performance with EC MAP, but with preferred sound quality resulting in better wear time.
Conclusion

• This tool provides a standardized approach to programming cochlear implants
• Direct connect testing frees up booth time and makes it more convenient to collect performance testing
• Artificial intelligence (AI) is gaining traction in healthcare as an acceptable clinical tool
  – Not a substitute for trained clinician
• Participating in AI programming was more interactive and different from the typical appointment.
• Additional development is needed to improve software usability