Combining Residual Hearing with Electric Stimulation: Results from Pediatric & Adult CI Recipients

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• Adult Audiologists
  • English King, AuD
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  • Andrea Bucker, AuD
  • Sarah McCarthy, AuD
UNC Investigative Team

• Clinical Research Audiologists

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  • Meredith Anderson Rooth, AuD
    • Assistant Professor

  • Lisa Park, AuD
    • Assistant Professor
Topics

• Electric Acoustic Stimulation (EAS)

• Unilateral Hearing Loss (UHL) and Asymmetric Hearing Loss (AHL)
Combining Residual Hearing with Electric Stimulation: Results from Pediatric & Adult CI Recipients

Electric-Acoustic Hearing
Responding with Poll Everywhere

Web voting

Text voting
In one word, describe how you are feeling after this morning's talks...

When poll is active, respond at PollEv.com/lisapark812
Text LISAPARK812 to 22333 once to join
Could This Child Be A CI Candidate?
Could This Child Be A CI Candidate?

- **Receptive Language Score:** 95
- **Expressive Language Score:** 92
- **Aided Word Recognition Score:**
  - 30% left ear
  - 38% right ear
- **Best Aided Sentence Recognition:**
  - 0% in quiet
  - 0% in noise
Two Years Into the Future
Could This Child Be A CI Candidate?

- Of course! 81%
- No way! Look at all of that hearing! 10%
- She's doing so well. Let's watch and wait. 9%
- Is this a trick question?
Cochlear Implant: Hearing Preservation

• Potential benefits
  • Improved speech perception
    • Quiet
    • Noise
  • Improved music perception
  • Improved quality of life
Cochlear Implant: Hearing Preservation

- Two technologies, one ear
  - Cochlear Implant (amplitude)
  - Acoustic Hearing, Hearing Aid (fine structure)
Electric-Acoustic Stimulation (EAS)

• Benefits of acoustic + electric stimulation
  • Incoming speech signal includes envelope and fine structure information
  • Most CI coding strategies present envelope information
  • Acoustic component may provide fine structure information
    • Discrimination of low-frequency cues
      • Fundamental frequency
      • First formant
Electric-Acoustic Stimulation (EAS)

Benefits of combining electric and acoustic hearing

• EAS (CI + HA in one ear, HA in contralateral ear)
  • Improved speech perception in noise (Adunka et al. 2013; Gantz & Turner, 2003)
  • Improved music perception (Gfeller et al. 2006)
  • Improved localization (Dunn et al., 2010)
  • Improved quality of life (Helbig et al., 2011; Gstoettner et al. 2008)
EAS: Programming

• Two technologies, one ear
  • Cochlear Implant
    • Low-frequency cut-off of electric stimulation
    • Overlap between acoustic and electric
  • Acoustic Hearing, Hearing Aid
    • Amplification of the low-to-mid frequency region
EAS: Programming

Figure 2

Karsten et al (2013)
EAS: Programming

- Choose cross-over frequency
- Meet acoustic targets
- Crossover of acoustic signal
Adult Multi-center EAS clinical trial
UNC Experience

• 34 Participants UNC
  • Age at Implantation
    • Min: 20.2 Years
    • Max: 76.6 years
    • Avg: 55.8 years
What about kids?

• We’re studying EAS in children too!

• Can electric-acoustic stimulation provide benefits over traditional electric stimulation in pediatric patients?
# Pediatric Study: Subject Demographics

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<tr>
<th>ID</th>
<th>Etiology</th>
<th>ANSD</th>
<th>Type</th>
<th>Ear</th>
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<td>HA (now EAS)</td>
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<td>HA</td>
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<tr>
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<td>Claudin 14</td>
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<td>4y 9m</td>
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<td>HA</td>
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<tr>
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<td>left</td>
<td>7y 9m</td>
<td>Nucleus CI522</td>
<td>CI (electric)</td>
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</tbody>
</table>

9 Participants  
Age at Implantation  
**Min:** 4 Years 9 Months / **Max:** 15 Years 6 Months / **Avg:** 9 Years 9 Months
Adult EAS Clinical Trial

• Protocol
  • Assessment of residual hearing
  • Aided speech perception performance
    • Quiet (CNC words)
    • Noise (CUNY sentences)
  • Quality of life

• Intervals
  • Preoperative
  • Initial CI activation
    • Electric stimulation only
  • Initial EAS activation
    • Electric + Acoustic stimulation
  • 3, 6, and 12 months post-initial EAS activation
Pediatric Study

- **Protocol**
  - Assessment of residual hearing
  - Aided speech perception performance
    - Quiet (CNC words)
    - Noise (BabyBio sentences at +5 dB SNR)

- **Intervals**
  - Preoperative (Hearing Aid)
  - 6 months post-initial activation (CI and EAS programs)
Adult EAS Clinical Trial

• Subjects received a Med-El FlexEAS array with a shallow insertion
• Were fit with a Duet EAS Processor
• Pre-Operative hearing range:
  • Internal
    • FlexEAS
  • External
    • Duet

[Graph showing hearing levels across different frequencies]
Pediatric Study Requirements

• All children received Cochlear Slim Straight electrode arrays.
• Post-op LFPTA (125, 250, and 500 Hz) of 75 dB HL or better and a threshold of 80 dB HL or better at 500 Hz.
• Nucleus 6 processors and the hybrid hearing component.
• These children all had significant preoperative hearing, but were CI candidates because of poor single word speech perception scores.
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

Frequency (Hz)

250 500 750 1000 1500 2000 3000 4000 6000 8000

dB HL

- Preoperative
- CI Activation
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

- Preoperative
- CI Activation
- EAS Activation

Frequency (Hz)

dB HL
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

Frequency (Hz)

- Preoperative
- CI Activation
- EAS Activation
- 3 Month

dB HL
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

- Preoperative
- CI Activation
- EAS Activation
- 3 Month
- 6 Month
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

- Frequency (Hz)
- dB HL

- Preoperative
- CI Activation
- EAS Activation
- 3 Month
- 6 Month
- 12 Month
Adult EAS Clinical Trial

Residual Hearing: Surgical Ear

- Preoperative
- CI Activation
- EAS Activation
- 3 Month
- 6 Month
- 12 Month
- 2 Year
Pediatric Study: Pre-op Thresholds
Pediatric Study: Pre- and Post-Op Thresholds

Graphs showing thresholds for different patients (021, 031, 041, 061, 071, 081, 131, 191, 201).
Adult EAS Clinical Trial: Speech Perception

Figure 3

CNC Words

Adunka et al (2013)
Pediatric Study: Speech Perception

![Graph showing CNC Words vs. HA]
Pediatric Study: Speech Perception

![Graph showing speech perception results for different CNC words. The graph compares HA and CI conditions with error bars for each word and a mean value.](image-url)
Pediatric Study: Speech Perception

![Graph showing speech perception results for different CNC words with HA, CI, and EAS conditions.](graph_image)
Kids and Adults: Speech Perception

Figure 3

Mean Pediatric Scores

Adunka et al (2013)
Adult EAS Clinical Trial: Hearing in Noise

CUNY Sentences, +0 dB SNR
Pediatric Study: Hearing in Noise

Baby Bio at +5 dB SNR

Mean
Pediatric Study: Hearing in Noise

Baby Bio at +5 dB SNR

- HA
- CI

Mean
Pediatric Study: Hearing in Noise

Baby Bio at +5 dB SNR

Mean

021 031 041 061 071 081 131 191* 201**

HA CI EAS
What we know now...

• Hearing preservation can be achieved in cochlear implant recipients
• Combining acoustic and electric stimulation in an ipsilateral listening condition may improve speech perception, music perception, and quality of life as compared to conventional amplification
• Patients who receive full electrode placement and maintain aidable residual hearing can benefit from EAS.
• Are we reaching everyone?
Pediatrics: Candidacy Criteria

- Bilateral severe-to-profound sensorineural hearing loss
- Poor speech recognition with appropriately fit hearing aids
Could This Child Be A CI Candidate?
CNC Scores

Pre-Op
6 Mo
1 Year (RE), 3 Mo (LE)
1 Year 3 Mo (RE), 6 Mo (LE)

- Hearing Aid RE
- Hearing Aid LE
- EAS RE
- EAS LE
- Both ears EAS
Sentences in Noise – Right Ear
Thank You
Combining Residual Hearing with Electric Stimulation: Results from Pediatric & Adult CI Recipients

Unilateral Hearing Loss (UHL): Adults

CAUTION: Not FDA approved. Investigational Device Exemption
What we know now...

• Hearing preservation can be achieved in cochlear implant recipients.

• Combining acoustic and electric stimulation in an ipsilateral listening condition may improve speech perception as compared to conventional amplification.
What we know now...

• Hearing preservation can be achieved in cochlear implant recipients

• Combining acoustic and electric stimulation in an ipsilateral listening condition may improve speech perception and quality of life as compared to conventional amplification

• Are we reaching all of those who would benefit from cochlear implantation?
UHL: Limitations

- Unilateral Hearing Loss (UHL) as compared to normal hearers:
  - Poor speech perception in noise
    (Welsh et al, 2004; Rothpletz, Wightman & Kistler, 2012)
  - Variable ability on localization tasks
    (Slattery & Middlebrooks, 1994)
  - Increased report of hearing handicap
    (Iwasaki et al, 2013)
  - Reduced quality of life
    (Wie, Pripp, & Tvete, 2010)
UHL: Treatment Options

• Current treatment options for UHL:
  • Bone-conduction devices
  • Contralateral Routing of the Signal (CROS) hearing aid systems

• Limitations:
  • Ability to use binaural cues for speech perception in noise is variable (Kunst et al, 2007)
  • Localization abilities have been found to be at chance (Bosman et al, 2003; Hol et al, 2010)

CAUTION: Not FDA approved. Investigational Device Exemption
Cl in UHL

• Considerations for UHL:
  • Ability to integrate acoustic and electric stimulation when one ear is a normal hearing ear?
  • Distraction of the better hearing ear?
CI in Single-Sided Deafness (SSD) clinical trial

- Cochlear Implantation in Cases of SSD clinical trial
  - FDA Investigational Device Exemption (IDE)
    - n=20
  - Principal Investigator: Margaret Dillon, AuD

- Study Aim
  - Demonstrate the effectiveness of CI in subjects with SSD
    - Measures of speech perception, localization, and subjective report

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

• Inclusion Criteria
  • Affected Ear: moderate-to-profound sensorineural hearing loss (PTA ≥ 70 dB HL)
    • Aided CNC word score ≤ 60%
  • Contralateral Ear: normal-to-mild hearing (PTA ≤ 35 dB HL)
  • ≥ 18 years of age at implantation
  • Duration of moderate-to-profound hearing loss ≤ 10 years
  • Previous experience with current SSD treatment option
  • Realistic expectations
  • No reported cognitive issues

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

• Exclusion Criteria
  • Non-native English speaker
    • Speech perception materials presented in English
  • Conductive hearing loss in either ear
  • Compromised auditory nerve
  • Cochlear ossification
  • Meniere’s disease with intractable vertigo
  • Case of sudden SNHL that has not been first evaluated by a physician
  • Tinnitus as the primary purpose for seeking cochlear implantation

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD clinical trial

• Investigational devices:
  • MED-EL Concert Standard electrode array
    • Full insertion (31 mm)
    • All subjects with similar insertions depths to limit potential confounding variable (Buchman et al, 2014)
  • Opus 2 external speech processor
    • All subjects listening with an ear-level device to limit any potential microphone placement effects
    • All subjects programmed with the FS4 coding strategy
CI in SSD: Speech Perception

• Test Material:
  • AzBio sentences in noise
    • 10-talker babble
    • 0 dB SNR
  • Tested a group of normal hearers as a performance comparison
    • n=17

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Speech Perception

- Test Material:
  - AzBio sentences in noise listening conditions:
    - Speech Front, Noise Front (S0N0)
    - Speech Front, Noise to the poorer hearing ear (S0NCI)
    - Speech Front, Noise to the better hearing ear (S0NContra)
      *most challenging listening condition

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Speech Perception

Buss et al (submitted)
CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Speech Perception

AzBio

Percent correct

Position of masker

good side

front

bad side

CI pre-op
CI 1-mo
CI 3-mos
CI 6-mos
CI 9-mos
CI 12-mos

NH

Buss et al (submitted)
CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Speech Perception

AzBio

Percent correct

Position of masker

good side

front

bad side

CI pre-op
CI 1-mo
CI 3-mos
CI 6-mos
CI 9-mos
CI 12-mos
NH

Buss et al (submitted)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

- 11-speaker array
- 200 ms speech-shaped noise bursts
  - Randomize three presentation levels
  - No feedback provided
- Tested a group of normal hearers as a performance comparison
  - \( n=24 \)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Buss et al (submitted)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Better

Buss et al (submitted)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Buss et al (submitted)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

Buss et al (submitted)

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CI in SSD: Localization

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CI in SSD: Localization

Buss et al (submitted)

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Localization

CAUTION: Not FDA approved. Investigational Device Exemption

Buss et al (submitted)
CI in SSD: Summary

• Speech Perception
  • Improvement in speech perception noted as early as 1-month post-initial activation of the external speech processor
    • Even in the most challenging listening condition

• Localization
  • Improvement noted as early as 1-month post-initial activation of the external speech processor
    • Stable through the 12-month interval

• Subjective Report
  • Improvement in reported ability
    • Subtests: speech, spatial, and quality
CI in SSD: Summary

• Speech Perception
  • Improvement in speech perception noted as early as 1-month post-initial activation of the external speech processor
    • Even in the most challenging listening condition

• Localization
  • Improvement noted as early as 1-month post-initial activation of the external speech processor
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CI in SSD: Summary

• Speech Perception
  • Improvement in speech perception noted as early as 1-month post-initial activation of the external speech processor
    • Even in the most challenging listening condition

• Localization
  • Improvement noted as early as 1-month post-initial activation of the external speech processor
    • Stable through the 12-month interval

• Subjective Report
  • Improvement in reported ability
    • Subtests: speech, spatial, and quality

CAUTION: Not FDA approved. Investigational Device Exemption
CI in SSD: Current Phase

• Asymmetric hearing loss (AHL)
  • Supplemental approval: December 2015
  • n=20

CAUTION: Not FDA approved. Investigational Device Exemption
Combining Residual Hearing with Electric Stimulation: Results from Pediatric & Adult CI Recipients

UHL and AHL: Pediatrics

CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL

• Cochlear Implantation in Pediatric Cases of UHL
  • FDA Investigational Device Exemption (IDE)
    • n=20
  • Principal Investigator: Kevin Brown, MD, PhD
  • Lead Research Audiologist: Lisa Park, AuD

• Study Aims
  • Demonstrate the effectiveness of CI in children with moderate-to-profound UHL
    • Measures of speech perception, localization, and subjective report
Pediatric UHL

• Inclusion Criteria:

  • Affected Ear: moderate-to-profound sensorineural hearing loss (PTA ≥ 70 dB HL)
    • Aided CNC word score ≤ 30%
  • Contralateral Ear: normal hearing (PTA ≤ 25 dB HL)
  • Between 3.5 and 6.5 years of age at implantation
  • Willing to undergo a trial with a hearing aid verified and fit to DSL targets
  • Realistic parental expectations
  • Normal range of development and cognition within the normal range

CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL

• Exclusion Criteria:
  • English is not primary language of the home
    • Speech perception materials and parental questionnaires presented in English
  • Conductive hearing loss in either ear
  • Compromised auditory nerve
  • Cochlear ossification
  • Case of sudden SNHL that has not been first evaluated by a physician
  • History of conditions that contraindicates middle or inner ear surgery or anesthesia
Pediatric UHL

• Investigational devices:
  • MED-EL Synchrony Flex28 electrode array
    • 28 mm
  • Sonnet external speech processor
    • All subjects listening with an ear-level device to limit any potential microphone placement effects
    • All subjects programmed with the FS4 coding strategy
    • ASM 2.0 features disabled
      • Omnidirectional
      • Wind noise reduction OFF
# Pediatric UHL: Initial Review

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<tr>
<th>Enrolled</th>
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<th>Activated</th>
<th>3-Month Follow-Up</th>
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CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL: Initial Review

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CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL: Hearing Configuration

Pre-Operative Thresholds

Threshold (dB HL) vs. Frequency (Hz)

CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL: Speech Perception

CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL: Subjective Report

Pediatric QL: Only those with 3-month data points

CAUTION: Not FDA approved. Investigational Device Exemption
Pediatric UHL: Localization

- 11-speaker array
- 200 ms speech-shaped noise bursts
- Single presentation level
Pediatric UHL: Localization

- Pilot testing
  - n=3

- Clinical trial
  - n=1 (3-month interval)

- Normal-hearing (NH) children
  - n=3

CAUTION: Not FDA approved. Investigational Device Exemption
# Pediatric UHL/AHL

<table>
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<th>Subject</th>
<th>Age at Implantation</th>
<th>Duration of CI Use</th>
<th>Hearing Configuration</th>
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<tr>
<td>Pilot 1</td>
<td>9 years</td>
<td>2 years</td>
<td>AHL; contra unaided</td>
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<tr>
<td>Pilot 2</td>
<td>5 years</td>
<td>3 years</td>
<td>AHL; contra aided (BTE)</td>
</tr>
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<td>Pilot 3</td>
<td>5 years</td>
<td>2 years</td>
<td>UHL</td>
</tr>
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![Graph showing performance comparison between CI Off and CI On conditions.](image)

CAUTION: Not FDA approved. Investigational Device Exemption

**Better**

---

**Pediatric UHL/AHL**

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<td>UHL</td>
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CAUTION: Not FDA approved. Investigational Device Exemption

![Graph showing RMS error (degrees) for CI Off and CI On conditions.](chart.png)

**Better**
## Pediatric UHL/AHL

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age at Implantation</th>
<th>Duration of CI Use</th>
<th>Hearing Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot 1</td>
<td>9 years</td>
<td>2 years</td>
<td>AHL; contra unaided</td>
</tr>
<tr>
<td>Pilot 2</td>
<td>5 years</td>
<td>3 years</td>
<td>AHL; contra aided (BTE)</td>
</tr>
<tr>
<td>Pilot 3</td>
<td>5 years</td>
<td>2 years</td>
<td>UHL</td>
</tr>
<tr>
<td>PUHL 1</td>
<td>6.5 years</td>
<td>3 months</td>
<td>UHL</td>
</tr>
</tbody>
</table>

CAUTION: Not FDA approved. Investigational Device Exemption

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### NH Subject

<table>
<thead>
<tr>
<th>NH Subject</th>
<th>Age at Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8 yrs</td>
</tr>
<tr>
<td>2</td>
<td>4.5 yrs</td>
</tr>
<tr>
<td>3</td>
<td>6.5 yrs</td>
</tr>
</tbody>
</table>
Summary

Combining Residual Hearing with Electric Stimulation: Results from Pediatric & Adult CI Recipients
Summary

• Patients with substantial low-frequency hearing and severe-to-profound high-frequency hearing loss, and poor speech perception with conventional amplification may benefit from cochlear implantation
  • Variability in postoperative hearing preservation
  • Ipsilateral combination of acoustic and electric stimulation
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• Patients with substantial low-frequency hearing and severe-to-profound high-frequency hearing loss, and poor speech perception with conventional amplification may benefit from cochlear implantation
  • Variability in postoperative hearing preservation
  • Ipsilateral combination of acoustic and electric stimulation

• Patients who meet conventional CI criteria in one ear and have normal or mild hearing loss in the contralateral ear may benefit from cochlear implantation
  • Speech perception in spatially separated noise
  • Localization
  • Quality of life

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Thank you

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