Single-Sided Deafness & Asymmetric Hearing Loss
New MED-EL Indication

Allison Racey, AuD

Learning Outcomes

- After this course, participants will be able to differentiate Single-sided deafness and Asymmetric Hearing Loss candidacy for cochlear implantation with the MED-EL cochlear implant system.
- After this course, participants will be able to list at least two questionnaires used in the UNC study to assess Quality of Life.
- After this course, participants will be able to define spatial hearing and fine structure.
FDA approves MED-EL cochlear implants for SSD and AHL

MED-EL is the first and only cochlear implant manufacturer to be granted an indication for this traditionally underserved population.

New FDA Approval

Impact of Unilateral Hearing Loss (UHL)
SSD & AHL
Impact of Unilateral Hearing Loss

• Millions of Americans face the impact of single-sided deafness or asymmetric hearing loss
• What are the impacts of SSD/AHL?
  • Hearing in noise
  • Locating where sounds originate
  • Quality of life

Golub et al. (2018), Dillon (2017)

Previous treatment options:
• Hearing aids
• CROS/Bi-CROS
• Bone conduction

• These options do not restore binaural hearing
  • Route signal from poorer hearing side to better hearing side
  • Do not improve localization
  • Only improve spatial hearing in certain configurations

Niparko (2003)
A lot of the things I did in my life changed. I loved going to movies.
SSD & AHL
History of Research in Unilateral Hearing Loss

- Over a decade of MED-EL supported research in this population

- First implanted CI for tinnitus & unilateral hearing loss
  - Significant reduction in tinnitus

- Soon realized CI provided binaural hearing benefit
  - Significant speech perception and subjective benefit

SSD & AHL

Data submitted to FDA included:

1. University of North Carolina at Chapel Hill Clinical Trial
2. Confirmatory evidence from House Clinic, Antwerp University Hospital, and University of Western Australia
3. Published literature

Summary of Safety and Effectiveness Data

Presented in partnership with
SSD & AHL

Indication

Single-Sided Deafness (SSD) & Asymmetric Hearing Loss (AHL)

• 5 years of age and older

• Profound sensorineural hearing loss in the ear to be implanted
  • PTA ≥90 dB at 500, 1000, 2000, and 4000 Hz

• Word score in quiet worse than 5% in the ear to be implanted
  • CNC words for adults
  • Developmentally appropriate list for children

FDA Approval Letter

Single-Sided Deafness & Asymmetric Hearing Loss FDA Approval

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SSD & AHL

Indication

Single-Sided Deafness (SSD)
• Normal hearing to mild sensorineural hearing loss in the contralateral ear
  • PTA ≤30 dB at 500, 1000, 2000 and 4000 Hz

Asymmetric Hearing Loss (AHL)
• Mild to moderately-severe sensorineural hearing loss in the contralateral ear
  • PTA 31 – 55 dB at 500, 1000, 2000, and 4000 Hz

Candidates should have prior experience with a CROS (or Bi-CROS) hearing aid or other relevant device.

Examples of other relevant devices:
• Bone conduction hearing aid
• Bone conduction implant
• Soundbite
• ADHEAR
SSD & AHL

Indication

Contraindications for SSD/AHL

• Profound hearing loss for more than 10 years
• Acoustic neuroma
• Non-functionality of auditory nerve
• Other contraindications of CI

SSD & AHL

CI for Unilateral Hearing Loss Outcomes

1. Improved speech perception in noise
2. Increased sense of spatial awareness or "hearing in stereo"
3. Better localization of speech and other environmental sounds
4. Reduction in fatigue from listening effort
5. Greater participation in social and work activities
Cochlear Implantation in Cases of Single-Sided Deafness & Asymmetric Hearing Loss

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Department of Otolaryngology/Head & Neck Surgery
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Disclosures

- Research grant from MED-EL Corporation.
Outline

- Cochlear implantation in cases of single-sided deafness (SSD) and asymmetric hearing loss (AHL) clinical trial
  - Cohorts
  - Protocol
- Study results
  - Spatial hearing
  - Quality of life

AHL & SSD

Asymmetric Hearing Loss (AHL)  Single-Sided Deafness (SSD)
AHL & SSD: Challenges

- Challenges to functional hearers:
  - Poor speech perception in noise (Walsh et al., 2004)
  - 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)

AHL & SSD: Treatment Options

- Initial treatment options
  - Conventional HA
  - Bone-conduction devices
  - CROS/BiCROS HA
AHL & SSD: Treatment Options

- Initial treatment options: 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 (Bozman et al., 2003; Hol et al., 2010)

Cochlear Implant (CI)

MED-EL Corporation
CI in Cases of AHL & SSD

- Cochlear implantation considerations:
  - Ability to integrate acoustic and electric stimulation when one ear has normal hearing?
  - Distraction of the better-hearing ear?

Clinical Trial

- Cochlear Implantation in Cases of Single-Sided Deafness
  - Obtained an Investigational Device Exemption from the FDA

- Primary Aim: determine whether subjects with AHL & SSD experience an improvement in speech perception, localization, and quality of life with a cochlear implant as compared to an unaided listening condition.
Cohorts: AHL & SSD

Asymmetric Hearing Loss (AHL)  Single-Sided Deafness (SSD)

Cohorts: SSD

- 20 adults with moderate-to-profound SNHL in the affected ear
  - Mean duration of hearing loss: 3 years
  - Mean aided CNC word score: 22%

- Normal to near-normal hearing in the contralateral ear
  - ≤ 35 dB HL, 125-8000 Hz

- Mean age at implantation: 50 years
Cohorts: AHL

- 20 adults with moderate-to-profound SNHL in the affected ear
  - Mean duration of hearing loss: 3 years
  - Mean aided CNC word score: 8%

- Contralateral ear
  - Unaided PTA (.5, 1, 2 kHz): 35-55 dB HL
  - Mean aided CNC word score: 87%

- Mean age at implantation: 70 years

Protocol

- Timeline
  - Preoperative evaluation
  - Cochlear implantation
  - Initial activation
    - 2-4 weeks postoperatively
  - Follow-up intervals
    - 1, 3, 6, 9, and 12 months

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Protocol

- Test Measures
  - Spatial Hearing
    - Masked sentence recognition
    - Localization
  - Quality of life

Protocol

- MED-EL Standard electrode array
- Ear-level device
- FS4 coding strategy
- Mapping procedures
  - Threshold and comfort levels
  - Loudness balancing across all channels
  - Overall loudness balancing
Spatial Hearing

- Localization
  - 200-ms speech-shaped noise bursts
  - Randomized speaker and signal level
  - RMS error

- Contralateral Ear:
  - SSD: Open
  - AHL: HA

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Localization: SSD

Figure 4.a, Buss et al. (2018)

Localization: AHL

Dillon et al. (submitted)
Quality of Life

1. Abbreviated Profile of Hearing Aid Benefit (APHAB) (Cox & Alexander, 1995)
2. Speech, Spatial, & Qualities of Hearing Scale (SSQ) (Gatehouse & Noble, 2004)
APHAB: SSD

Figure 2, Dillon et al. (2017)

APHAB: AHL

Dillon et al. (submitted)
SSQ: SSD

Better →

Perceived Ability

Total  Speech  Spatial  Qualities

Figure 3, Dillon et al. (2017)

SSQ: AHL

Better →

Perceived Ability

Total  Speech  Spatial  Qualities

Dillon et al. (submitted)
Pragmatic Subscales

- Speech, Spatial, & Qualities of Hearing Scale (SSQ) 
  (Gatehouse & Noble, 2004)
- Pragmatic Subscales (Gatehouse & Akeroyd, 2006)

Table 1, Organization of the SSQ pragmatic subscales as defined by Gatehouse and Akeroyd (2006)

<table>
<thead>
<tr>
<th>Speech hearing</th>
<th>Spatial hearing</th>
<th>Qualities of hearing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Speech in quiet</td>
<td></td>
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<tr>
<td>2. Speech in noise</td>
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<td>3. Speech in speech contexts</td>
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<td>4. Multiple speech streams processing and switching</td>
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<tr>
<td>1. Localization</td>
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<tr>
<td>2. Distance and movement</td>
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<tr>
<td>1. Spatial quality and intrinsic</td>
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<tr>
<td>2. Identification of sound sources</td>
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<tr>
<td>3. Segregation of sounds</td>
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<td>4. Encoding effort</td>
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</tbody>
</table>

Table 1, Dillon et al. (2017)

Pragmatic Subscales: SSD

Speech

Figure 4, Dillon et al. (2017)
Pragmatic Subscales: SSD

Spatial

Figure 5, Dillon et al. (2017)

Pragmatic Subscales: SSD

Qualities

Figure 6, Dillon et al. (2017)
Pragmatic Subscales: AHL

Speech

Spatial

Thompson et al. (submitted)
Pragmatic Subscales

**Qualities**

<table>
<thead>
<tr>
<th>Time</th>
<th>Preoperative</th>
<th>1-month</th>
<th>3-month</th>
<th>6-month</th>
<th>9-month</th>
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<tbody>
<tr>
<td>Microphone</td>
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<tr>
<td>Identification</td>
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<tr>
<td>Segregation</td>
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<tr>
<td>Listening Effort</td>
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</table>

Thompson et al. (submitted)

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**Summary**

- Subjects with SSD and AHL demonstrate significant improvements in spatial hearing and quality of life with CI use as compared to preoperative abilities.

- Differences in spatial hearing abilities and reported subjective benefit were observed between the SSD and AHL cohorts.

- Future Directions: identify the variables (e.g., age at implantation, severity of HL in contralateral ear) that contribute to performance differences.
SSD & AHL
Further Discussion

• Key Learnings
• Future Directions
• MED-EL Philosophies