Single-Sided Deafness & Asymmetric Hearing Loss

New MED-EL Indication

Allison Racey, AuD

Single-Sided Deafness & Asymmetric Hearing Loss

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.

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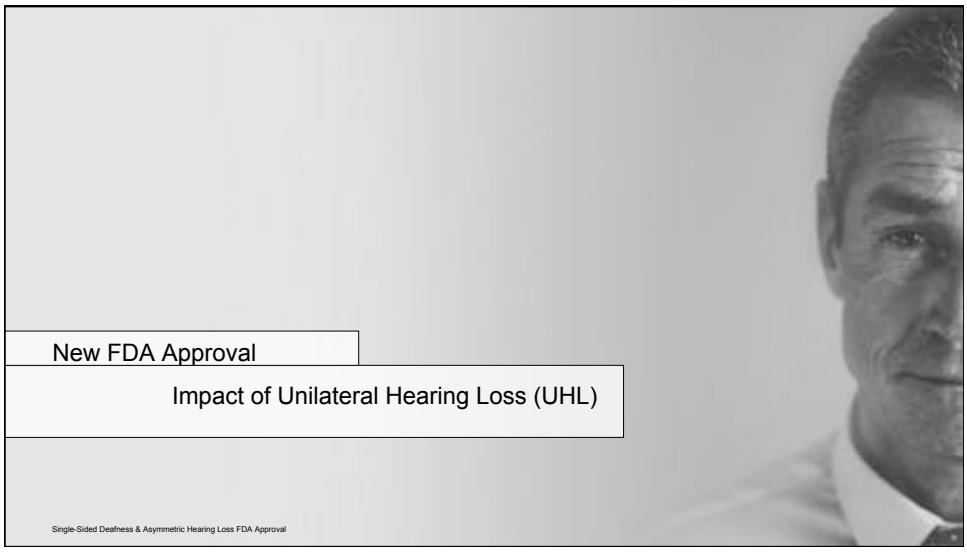
FDA approves MED-EL cochlear implants for SSD and AHL

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



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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

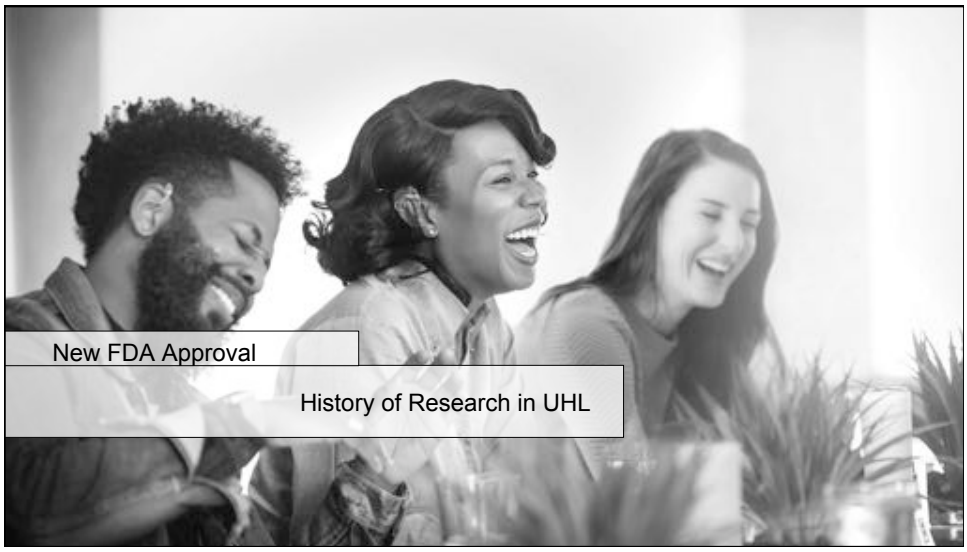
Golub et al. (2018), Dillon (2017)

SSD & AHL

Impact of Unilateral Hearing Loss

- 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)



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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
  - Van de Heyning et al. (2008) Incapacitating unilateral tinnitus in single-sided deafness treated by cochlear implantation. Ann Otol Rhinol Laryngol.
- Soon realized CI provided binaural hearing benefit
  - Significant speech perception and subjective benefit
  - Vermeire et al. (2009) Binaural hearing after cochlear implantation in subjects with unilateral sensorineural deafness and tinnitus. Audiol Neurotol.

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

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

FDA Approval Letter

SSD & AHL
Indication

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

FDA Approval Letter

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

Summary of Safety and Effectiveness Data

Single-Sided Deafness & Asymmetric Hearing Loss FDA Approval

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

Summary of Safety and Effectiveness Data

Single-Sided Deafness & Asymmetric Hearing Loss FDA Approval

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Cochlear Implantation in Cases of Single-Sided Deafness & Asymmetric Hearing Loss

Margaret Dillon, AuD
Research Associate Professor
Director, UNC Cochlear Implant Clinical Research
Department of Otolaryngology/Head & Neck Surgery
University of North Carolina at Chapel Hill

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Disclosures

- Research grant from MED-EL Corporation.

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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

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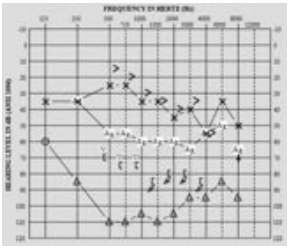
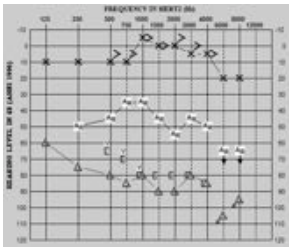
AHL & SSD

Asymmetric Hearing Loss (AHL)



Single-Sided Deafness (SSD)



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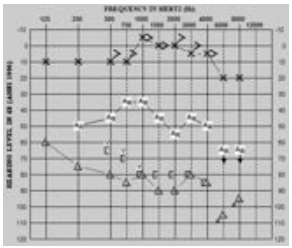
AHL & SSD: Challenges

- Challenges for UHL
- Challenges for normal hearers:
  - Poor speech perception in noise (Welsh 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)



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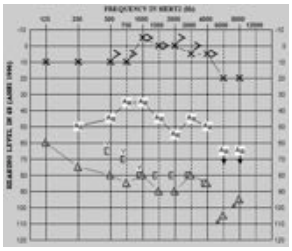
AHL & SSD: Treatment Options

- *Initial* treatment options
  - Conventional HA
  - Bone-conduction devices
  - CROS/BiCROS HA



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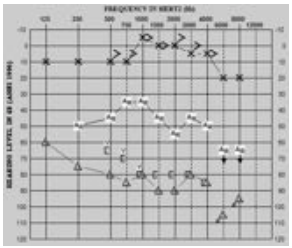
AHL & SSD: Treatment Options

- *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 (Bosman et al., 2003; Hol et al., 2010)



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Cochlear Implant (CI)

MED-EL Corporation

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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?

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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.

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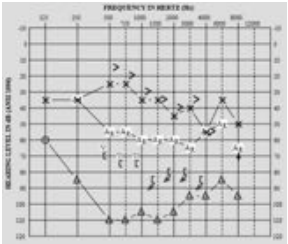
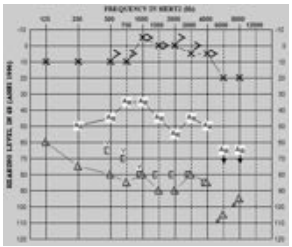
Cohorts: AHL & SSD

Asymmetric Hearing Loss (AHL)



Single-Sided Deafness (SSD)



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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

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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

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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

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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

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Spatial Hearing

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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

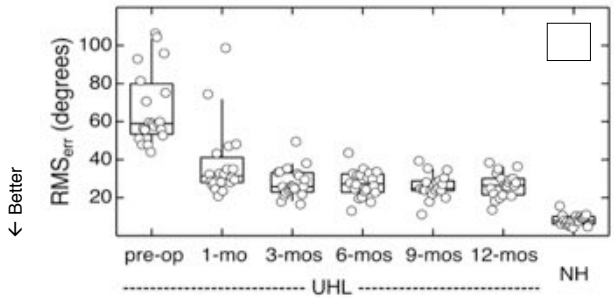
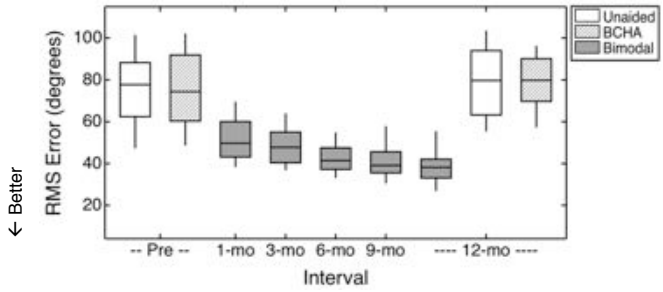


Figure 4.a, Buss et al. (2018)

Localization: AHL



Dillon et al. (submitted)

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Quality of Life

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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)

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APHAB: SSD

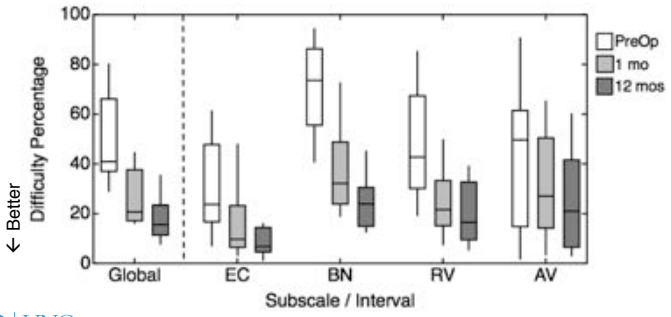

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Figure 2, Dillon et al. (2017)

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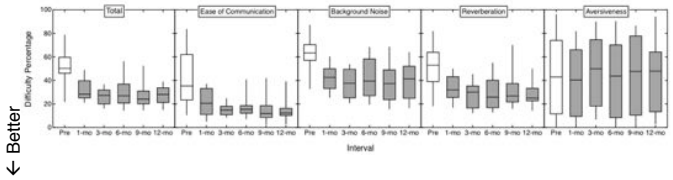
APHAB: AHL



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SSQ: SSD

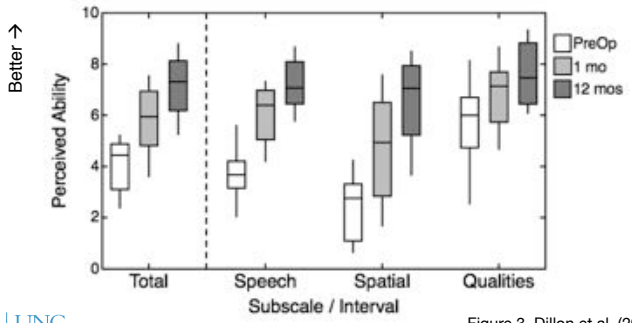

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Figure 3, Dillon et al. (2017)

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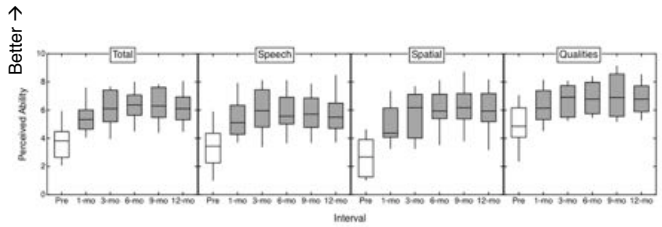
SSQ: AHL



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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]

Speech, Spatial, and Qualities of Hearing Scale		
Speech hearing	Spatial hearing	Qualities of hearing
1. Speech in quiet	1. Localization	1. Sound quality and naturalness
2. Speech in noise	2. Distance and movement	2. Identification of sound and objects
3. Speech in speech contexts		3. Segregation of sounds
4. Multiple speech stream processing and switching		4. Listening effort

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Table 1, Dillon et al. (2017)

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Pragmatic Subscales: SSD

Speech

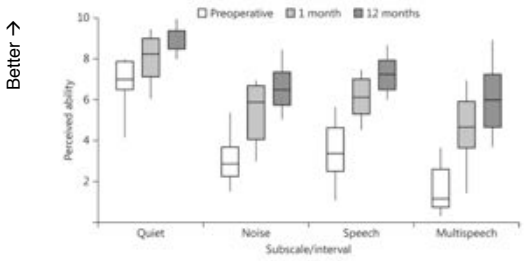

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Figure 4, Dillon et al. (2017)

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Pragmatic Subscales: SSD

Spatial

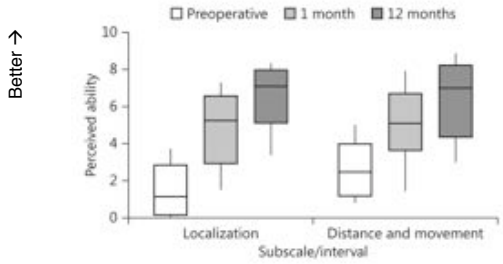

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Figure 5, Dillon et al. (2017)

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Pragmatic Subscales: SSD

Qualities

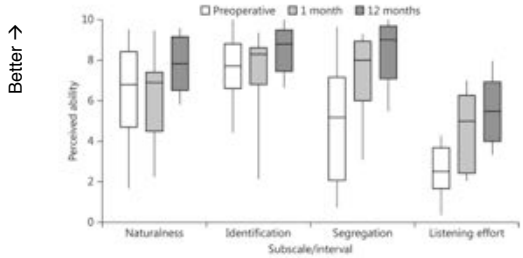

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Figure 6, Dillon et al. (2017)

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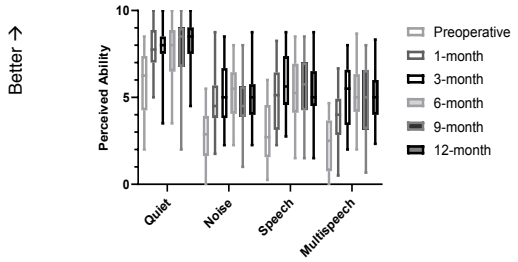
Pragmatic Subscales: AHL

Speech



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Thompson et al. (submitted)

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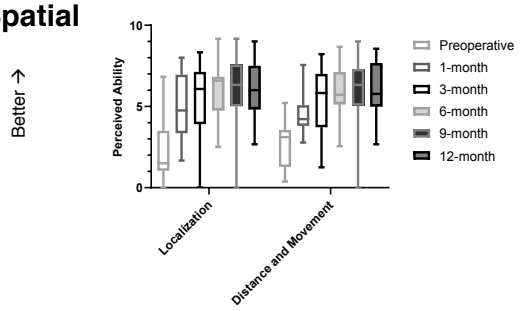
Pragmatic Subscales

Spatial



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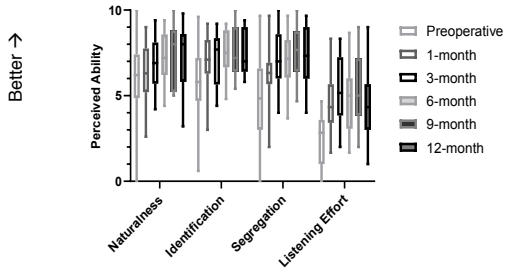
Pragmatic Subscales

Qualities



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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

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SSD & AHL
Further Discussion

- Key Learnings
- Future Directions
- MED-EL Philosophies

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