Cochlear Implantation in Adults with Single-Sided Deafnesss: Update from a North American Clinical Trial

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Disclosures

- Daniel Lee is a paid consultant for:
  - Auregen Biotherapeutics
  - Storz
  - Frequency Therapeutics
- Ruth Litovsky has consulted for Cochlear Corp.
- This trial is financially supported by Med-El
Single-Sided Deafness (SSD)

- 36,000 – 72,000 new cases per year in US\(^1\)
- Functional deficits\(^2\)
  - Sound localization
  - Speech-in-noise
  - Tinnitus
  - Reduced QOL
  - Fear of losing remaining hearing

Treatments for SSD

- Listening strategies
- CROS
- Bone Conduction Implant
- Cochlear Implant
  - Not FDA-approved for SSD
Previous Trials of CI for SSD

• Mostly done outside of US
• Improvements in:
  – Tinnitus
  – Speech-in-noise
  – Sound localization
  – Quality of life
Cochlear Implantation for the Treatment of Single-Sided Deafness (NCT02532972)

- Prospective, single-arm, investigational device exemption
- Med-El MAESTRO CI with Flex 28 electrode array
- Key inclusion criteria:
  - ≥ 18-years-old
  - ≥70 dB at 500, 1000, 2000 Hz in one ear and ≤35 dB in contralateral ear
  - Subjective reports of tinnitus
  - No retro-cochlear pathology on CT/MRI
- Currently recruiting subjects
CI for the Treatment of SSD: Outcome Measures

Pre-op and 3, 6, and 12 months post-activation:

- Sound field thresholds
- Word recognition
- Subjective measures
  - Tinnitus suppression
  - Quality of life
    - SF-36
    - HHI/THI
    - APHAB
    - Speech and Spatial Qualities of Hearing

Pre-op and 12 months post-activation:

- Sound localization
- Speech-in-noise
What’s Notable about this Trial?

• Performed in US
• Plan to enroll 20 subjects
• Thorough audiological and survey assessments
• Sophisticated sound localization and speech-in-noise testing
  – Tracking moving sound source
Sound Localization Testing

- Stationary sound location
- Stationary vs. moving sound
- Moving sound direction and excursion
Study Progress

- 9 subjects enrolled and implanted (Nov 2016 – Dec 2017)
  - Age range: 26 – 67 years
  - Duration of deafness: 2.7 [1 – 7] years
  - Etiologies
    - 7 idiopathic sudden SNHL
    - 1 Ménière’s disease
    - 1 post-traumatic
- 1 subject withdrew after 3 months ($)
- 1 subject with TM perforation between 3-6 months post-op
Insurance Paid for Trial CIs

• 8 / 9 subjects had CI paid for by insurance
  – Average co-pay $2,333
  – United Health, Blue Cross, Aetna, Cigna
Preliminary Results
Preliminary Data from UW-Madison
Preliminary Data from UW-Madison
Thank You