Clinical Implications and Outcomes of Active Round Window Stimulation for Conductive or Mixed Hearing Loss

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Objectives

1. To understand the physiologic mechanism of active round window stimulation

2. To better understand the indication criteria and patient selection for active middle ear implants.

3. To learn about typical outcomes, potential shortfalls, and possible complications.

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Auditory Pathway
Types of Hearing Loss

- **Sensorineural**
  - Dysfunction within the inner ear (cochlea) and/or auditory nerve

- **Conductive**
  - Dysfunction in the conduction of sound by the outer ear, TM, and/or middle ear

- **Mixed**
  - Conductive + Sensorineural hearing loss
Traditional HAs

• Amplify acoustic signals

• Signal travels from outer ear to middle ear space to cochlea
Vibrant Soundbridge

- Vibrant Soundbridge (VSB) Middle Ear Implant
  - Converts sound into controlled, amplified vibrations

- 2 Part System:
  - Vibrating Ossicular Prosthesis (VORP)
    - Internal
  - Audio Processor
    - External

MED-EL Corporation
Vibrant Soundbridge

- **Vibrating Ossicular Prosthesis (VORP)**
  - Wide frequency range up to 8 kHz
  - Preserves residual hearing
Vibrant Soundbridge

Magnet

Receiving Coil

VORP Transition

Conductor link

FMT

Demodulator

130 mm

4.6 mm deep

29 mm
Vibrant Soundbridge

- **Audio Processor**
  - Multiple programs
  - Digital processing
  - 675 battery
    - 1 week of power (12-16 hours per day)
  - 4 colors

MED-EL Corporation
Candidacy Criteria

• **Current Indications:**
  » Adults
  » Bilateral Moderate-Severe SNHL
  » Word Rec > 50%

• **Floating Mass Transducer attached to Incus**
Case Study

- Preoperative
- 78 yrs old
- History of otitis externa
Case Study

- Postoperative
- Aided: HINT(96%), HINT+10 (73%), and CNC (80%)
Clinical Trial

• Clinical Trial of the Vibrant Soundbridge as a Treatment for Conductive and Mixed Hearing Loss, Using Direct Round Window Cochlear Stimulation
  » Multi-Center clinical trial to evaluate VSB in a new population
  » Sponsored by Med-EL Corporation

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Candidacy Criteria

• Clinical Trial:
  » Conductive & Mixed HL
  » Traditional amplification unsuccessful
  » CNC Words > 30%

• FMT placed in Round Window (RW) Niche
  » Bypass conductive component to deliver vibrations directly to cochlea
  » Active RW Stimulation

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RW Stimulation

FMT on Incus
Stimulates Ossicular Chain

FMT on RW
Stimulates Cochlear Fluids

FMT on RW
Stimulates Cochlear Fluids

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Candidacy Criteria

• Potential Conditions
  » Congenital malformations (Atresia, Microtia)
  » Stenosis of external auditory canal
  » Allergies to earmold material
  » Chronic otitis externa
  » Chronic draining ears
  » Eczema/Psoriasis of the ear
  » Unresolved acoustic feedback
  » Large mastoid bowl following surgery

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Candidacy Criteria

- Exclusions:
  - SNHL
  - Active middle ear infection
  - TM perforation
  - Fluctuation in BC thresholds
  - History of post-adolescent, inner-ear disorders (vertigo, labyrinthitis)
  - Chronic vestibular/balance disorders
  - Middle ear infections not responsive to medical treatment
  - Chronic pain in or around the head
  - Current or previous use of active hearing implant (VSB, BAHA, CI)
  - Developmental Delays

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Potential Benefits

• Appropriate amplification
• Little to no acoustic feedback
• Improved ability to understand speech in quiet and in noise
• Ability to wear HA without occluding the ear canal
Methods

• **Test Intervals**
  » Preoperative
    • CNC Word Score > 30% correct
    • Conductive or Mixed Hearing Loss
    • Trial with appropriately fit HA’s for at least 28 days, unless unable to wear HA
  » Initial VSB Stimulation
    • 6-8 weeks postoperative
  » 1, 3, 6, and 10 Months Post-Stimulation

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Methods

• Unaided and Aided Thresholds

• Speech Perception Test Battery
  » CNC Words in Quiet
  » HINT Sentences in Quiet
  » HINT Sentences in Noise
    • Signal Level to achieve 50% correct

• Self-Assessment Questionnaires
  » APHAB
  » HDSS

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Single Center Results

- **Subjects (n=4)**
  - Chronic otitis externa
  - Congenital aural atresia
  - Chronic otitis media (inactive)
  - Failed ossicular surgery

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Case Study

- Congenital Atresia

- SF Results:
  - HINT in Quiet: 72 dB
  - HINT in Noise: 2.5 dB
  - CNC Words: 32%
Case Study

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Case Study

- 2 years
- Consistent user

- SF Results:
  - HINT in Quiet: 46.7 dB
  - HINT in Noise: -0.36 dB
  - CNC Words: 92%
Case Study

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Outcomes

CNC Words

Percent Correct

Pre-Op  Activation  1 Month  3 Month  6 Month

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Outcomes

HINT in Quiet

CAUTION – Investigational device. Limited by Federal law to investigational use.
Outcomes

HINT in Noise

SNR to obtain 50% Correct

Pre-Op 1 Month 3 Month 6 Month

HINT Scores
Average

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Potential Complications

• **Displacement of Device**
  » Need for Repositioning

• **Device Interference**

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