Outcomes with Vibrant Soundbridge (VSB) Middle Ear Device

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Objectives

• Discuss the differences in candidacy criteria for Vibrant Soundbridge (VSB), including the currently approved indications and criteria for enrollment in the clinical trial

• Describe the potential benefits of middle ear implantation for varying types of hearing loss (SNHL, CHL & Mixed HL)

• Analyze the benefits and limitations of VSB versus other interventions for SNHL, CHL and Mixed HL

Caution: Investigational device. Limited by Federal law to investigational use.
Anatomy: 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, tympanic membrane, and/or middle ear

- **Mixed**
  - Conductive + Sensorineural
Interventions

• **Traditional hearing aids (HA)**
  » Amplify acoustic signals

• **Bone-anchored hearing aids (BAHA)**
  » Bone-conduction

• **Cochlear implantation**
  » Electrical stimulation

• **Middle ear implantation**
  » Vibratory stimulation
Vibrant Soundbridge (VSB)

- **VSB Middle Ear Implant**
  - Converts sound into controlled, amplified vibrations
  - Direct drive stimulation of the middle ear structures
Vibrant Soundbridge (VSB)

- **Two Part System:**
  - Internal
    - Vibrating Ossicular Prosthesis (VORP)
Vibrant Soundbridge (VSB)

- Vibrating Ossicular Prosthesis (VORP) with Floating Mass Transducer (FMT)
  » Wide frequency range up to 8 kHz
  » Preservation of residual hearing
Vibrant Soundbridge (VSB)
Vibrant Soundbridge (VSB)

- Two Part System:
  - External
    - Audio Processor
Vibrant Soundbridge (VSB)

• Magnetic connection between internal and external components
Vibrant Soundbridge (VSB)

- **Audio Processor**
  - Amadé Features
    - Multiple programs
    - Digital processing
    - 675 battery
      - ~ 1 week of power (12-16 hrs/day)
    - 4 color options
Vibrant Soundbridge (VSB)

• **Approved Indications**
  » Adults
  » Bilateral moderate-to-severe sensorineural hearing loss
  » Word Rec > 50%
Vibrant Soundbridge (VSB)
Vibrant Soundbridge (VSB)

- Placement of the FMT on the incus
VSB Case Study

- Case Study will be added prior to meeting
VSB 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 MED-EL Corporation

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VSB Clinical Trial

• **Candidacy Criteria**
  » Conductive & mixed hearing loss
  » Traditional amplification unsuccessful
  » Word Rec > 30%
    • CNC Words

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VSB Clinical Trial

• 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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VSB Clinical Trial

• Exclusions
  » Sensorineural hearing loss
  » 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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VSB Clinical Trial

- FMT placed in Round Window (RW) Niche
  - Bypass conductive component to deliver vibrations directly to the cochlea
  - Active RW stimulation

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Vibrant Soundbridge (VSB)

Placement on Ossicular Chain

Placement on Round Window

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- **Potential Benefits**
  - Appropriate amplification
  - Little to no acoustic feedback
  - Improved ability to understand speech in quiet and noise
  - Ability to wear HA without occluding the ear canal

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VSB Clinical Trial

• Feasibility & pivotal portions

• Test Intervals
  » Preoperative evaluation
  » Initial VSB activation
    • 6-8 weeks postoperatively
  » 1, 3, 6, and 10 months post-activation

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VSB Clinical Trial

• **Methods**
  » Unaided and aided thresholds
  » Speech perception test battery
    • CNC words in quiet
    • HINT sentences in quiet
    • HINT sentences in noise
      » SNR to achieve 50% correct
  » Self-assessment questionnaires
    • APHAB
    • HDSS

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Single-Site Results

• Results will be added prior to meeting
Vibrant Soundbridge (VSB)

- Potential complications
  - Displacement of device
    - Need for repositioning
  - Device interference

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Summary

- Summary of single-site results will be added prior to meeting
Future Directions

• Comparison between BAHA and VSB
  » Localization

• Impact of directional microphones with new external processor
UNC VSB Research Team

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