Vibrant Soundbridge: Round Window Placement for Treatment of Conductive and Mixed Hearing Loss

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Pittsburgh, Pa.
Vibrant Soundbridge for SNHL
FDA August 2000

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Vibrant SoundBridge to Round Window
Colletti 2006

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Vibrant Soundbridge
Audio processor + VORP
Vibrant Soundbridge for Conductive and Mixed Hearing Loss

Pittsburgh Ear Associates

- U.S. FDA Investigational Device Exemption
- Multi-institutional study
- Single subject, repeated measures design in which each subject serves as their own control
Vibrant Soundbridge for Conductive and Mixed Hearing Loss

Pittsburgh Ear Associates

- Unaided preoperative and postoperative aided air and bone conduction audiometry
- Word recognition in quiet
- HINT sentences in quiet and noise
- Abbreviated Profile of Hearing Aid Benefit (APHAB)
- Hearing Device Satisfaction Scale (HDSS)
Inclusion/Exclusion Criteria

- Ear anatomy allows positioning of FMT at round window
- Absence of active middle ear infection and/or chronic fluid in the ear
- No skin conditions preventing placement of audio processor
- Absence of retrocochlear disease
- 18 years of age
- 1 month hearing aid trial within the past year
Audiometric Criteria

- **Conductive Criteria**
  - BC $< 25$ dB at 0.5, 1, 1.5, 2, 3, 4 kHz
  - 15 db A-B gap, 3 freq

- **Mixed Criteria**
  - BC within the shaded area
  - 15 db A-B gap, 3 freq

- **Monosyllabic word score**
  - $> 30\%$ CNC at 40 dB SL under headphones or at MCL

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Surgery

**Vibroplasty** - treatment of hearing loss via vibratory stimulation in the middle ear

- Outpatient
- 2 to 2.5 hours
- Use of facial nerve monitoring
- Standard mastoid surgical approach behind ear
- Pocket drilled for Audio Processor (AP) similar to CI
- Activation of AP eight weeks after surgery and healing
- Will have ID card indicating NO MRI
Results

- 6 patients enrolled

- 5 patients with COM
  *(4 patients with facial recess approach, 1 patient with CWD approach)

- 1 patient failed stapes
  *(facial recess approach)
Subject 3902-001 (completed study)

Word Recognition Ability
Pre-Op Unaided 78% @ 51 dB HL (70 dB SPL) 35 dB HL
Most Recent Aided 96% @ 51 dB HL (70 dB SPL) 25 dB HL

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Subject 3902-002 (completed study)

**Word Recognition Ability**

- **Pre-Op Unaided**: 28% @ 51 dB HL
- **Most Recent Aided**: 96% @ 51 dB HL

**SRT**

- **Pre-Op BC**: 55 dB HL
- **Most Recent BC**: 25 dB HL
- **Pre-Op AC**:
- **Most Recent AC**:
- **Most Recent Aided**:

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Subject 3902-003 (6 Months)

Word Recognition Ability

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<tr>
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<th>Pre-Op Unaided</th>
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<td>45 dB HL</td>
<td>30 dB HL</td>
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Subject 3902-004 (3 Months)

Word Recognition Ability

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<td>Pre-Op Unaided</td>
<td>92% @ 51 dB HL</td>
<td>100% @ 51 dB HL</td>
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Subject 3902-005 (3 months)

Word Recognition Ability

Pre-Op Unaided: 88% @ 51 dB HL (70 dB SPL)
Most Recent Aided: 100% @ 51 dB HL (70 dB SPL)

SRT
Pre-Op AC: 55 dB HL
Most Recent Aided: 25 dB HL

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Subject 3902-006 (Initial Stimulation)

Word Recognition Ability

Pre-Op Unaided 100% @ 51 dB HL (70dB SPL) 40 dB HL
Most Recent Aided 100% @ 51 dB HL (70dB SPL) 15 dB HL

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Mean Average of All Subjects Combined

Word Recognition Ability

Pre-Op Unaided 81% @ 51 dB HL
Most Recent Aided 98.6% @ 51 dB HL

SRT
Pre Op 45.8 dB HL
Most Recent 24.2 dB HL

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Average Improvement Across All Subjects

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Average Improvement:

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Abbreviated Profile for Hearing Aid Benefit (APHAB)

Percentage of Difficulty

- EC
- RV
- BN
- AV

Unaided
Hearing Aid
VSB

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Hearing Device Satisfaction Scale (HDSS)

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General Comments

Negative

- 2 subjects reported significant problems with electrical interference (ie: microwave, security detectors) – even prior to activation
- Subjects report the desire to have a VC or 2nd program
- Minor software and programming glitches
General Comments
Positive

- All subjects are very pleased with their outcomes
- All demonstrated objective improvement in overall hearing measurements (unaided vs. aided)
- All subjects find the device easy to use
- All subjects prefer VSB device over conventional hearing aid (no occlusion)
- None report negative feelings about the cosmetics of the device
Thank you

For your kind attention and interest in this ongoing research