Self-Inflating, Sound-Activated Balloon-Style Hearing Aid Coupling Device

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Disclosures

- **Funding:**
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- **Small Business Involved:**
  - ✓ Asius Technologies, LLC
- **Participants:**
  - ✓ Staab/Ambrose: Co-PI; Staab: Limited consulting with SeboTek
  - ✓ Vanderbilt University - Contract via grant
- **Test location:**
  - ✓ Dan Maddox Hearing Aid Research Laboratory, Vanderbilt University, Nashville, TN
    - Todd Ricketts, Ph.D.
    - Telani Leuder
    - Kristen D’Onofrio
Background

- Hearing aid coupling to the ear has improved substantially over the years.
- Still, designs continue to seek solutions for:
  - Comfort
  - One size fits most
  - Occlusion effect management
  - Increase REAR before acoustic feedback
  - Ear impression elimination
    - In-office, same session fit
  - Ear coupling for surgically-altered ear canals
  - Seal to manage the dynamic ear canal
  - Security of fit
  - Cerumen avoidance
  - Etc.
New Coupler Development

- **ADEL™ (Ambrose Diaphonic Ear Lens)**
  - Innovative approach to harvesting energy from a hearing aid speaker to perform work
  - In this case, to inflate a folded balloon (like automobile air bag) in ear canal.

- **Mechanism:**
  - Small diaphonic pump is attached to (integrated with) a balanced armature HA speaker

- **Goal:**
  - Provide a universal alternative for many current hearing aid ear coupling methods
Study

Preliminary Report on some aspects of the study (partial)

1. Proof of concept (confirm - what has been already designed)
   - Will Bubble inflate to sounds produced by the hearing aid?
   - Will bubble remain inflated?

2. How does performance compare with existing coupling methods (must be equal or better to be acceptable)
   - Occlusion Effect
   - Sound Isolation Properties
     - Acoustic Feedback - REAR Measurement
     - Sealing Property - REOR Measurement
   - Subjective Properties
     - Comfort
     - Own voice quality
     - Retention
     - Insertion/removal ease
Proof of Concept

✓ Will bubble inflate to HA produced sounds?
  ✓ Yes. Evaluated previously with known results
    • Reconfirmed in this study with design used
    • Time to inflate
      – Amplified voice: 5 to 30 sec. (can be varied)
      – To speed up inflation, use short-term HA-generated sound
    • Bubble size and inflation - Faster inflation with smaller bubble

✓ Pressure to Inflate and Maintain Inflation
  ✓ Inflation Goals: Good seal, minimal FB, comfortable, secure in ear
  ✓ Inflation (syringe coupled to manometer) for controlled measurements
    • Optimal pressure range: 500 - 1200 Pa (0.5 to 1.2 kPa) = 0.07 - 0.17 psi
    • Optimum pressure: 1000 Pa (1 kPa) = 0.15 psi
    • Maintenance pressure: 100 - 300 Pa (0.1 to 0.3 kPa) = 0.01 - 0.04 psi
Coupling Performance Comparisons

- Test hearing aid - SeboTek HD 16 Easy CLICK RIC
  - Selected for ease of use and ADEL construction
    - RIC - Open fit
    - RIC - Closed fit
    - RIC - Sealed with earmold impression material
    - RIC - ADEL™ syringe inflated (for control: spkr maintained)
      - Shallow fitting balloon (n = 13)
      - Deep fitting balloon (n = 7)
Subjects

- n = 20
- Mean age: 65.9
- 60% Male; 40% Female
- Sensorineural
- Hearing aid wearers
Hearing Aid Programming

☞ SeboTek HD 16

✓ OSPL90 = 117 dB SPL  HFA OSPL90 = 112 dB SPL
✓ Max Gain = 51 dB  HFA-FOG = 45 dB

☞ Programmed:

✓ Audiogram at 50 dB HL from .25 to 1k, and 60 dB HL from 2 to 4 kHz
✓ Programmed linear
  • Compression: 1:1
  • Thresholds: Maximum
  • Advanced Features:
    – Feedback canceler  Off
    – Ambient noise reduction  Off
    – Voice priority  Low
Performance Comparison Results
Occlusion Effect Results

- **Question:** Might bubble inserted shallow into the ear canal “absorb” vibrations and reduce OE?
  - ✓ **Measurements:** Did not support

(Control: “0” is Occlusion Effect reference control to live voice, no coupling)

✓ Redesigned with bubble deep
Max REAR Output Before Feedback

Procedure:

✓ Tester used headphones in Audioscan Verifit to establish FB threshold as HA gain was increased in high band (2-4 kHz) on subject
  • Input: 65 dB SPL speech input
✓ Then reduced gain 1 click; jaw movement, etc., to confirm level
✓ From resultant graph, pulled date for 2k, 3k, and 4k, and plotted

But, didn’t reach FB, except for open tip
Higher Output Aid to Test FB

- **Widex Super RIC**
  - ✓ Programmed linear
  - ✓ Three comparison conditions
    - • Comply™ tip
    - • Instamold™ earmold
    - • ADEL deep fitting bubble
Max REAR Output Before Feedback
High Gain HA

Result: When compared to next best solution, the ADEL deep fit enabled 10 dB of additional output at 2000 Hz, 5 dB at 3000 Hz, and 6 dB at 4000 Hz.
Sound Isolation (REOR)

ADEL (Shallow and Deep) to Other Coupling Methods (Moderate Gain HA)

RESULT: ADEL deep showed substantially greater sound isolation in the low frequencies.
ADEL to Other Couplers (Cont.)

✓ Sealing Property (REOR) Re: Sealed
  - **Shallow Seal** (negative number is poorer)

<table>
<thead>
<tr>
<th></th>
<th>250 Hz</th>
<th>500 Hz</th>
<th>1000 Hz</th>
<th>2000 Hz</th>
<th>3000 Hz</th>
<th>4000 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shallow</td>
<td>-1.3 dB</td>
<td>-1.6 dB</td>
<td>0.4 dB</td>
<td>-0.5 dB</td>
<td>-2.5 dB</td>
<td>-1.4 dB</td>
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</table>

<Result: Comparable to a good ear plug>

- **Deep Seal**

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<th>4000 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep</td>
<td>13.6 dB</td>
<td>12.5 dB</td>
<td>5.6 dB</td>
<td>4.0 dB</td>
<td>-1.7 dB</td>
<td>-1.0 dB</td>
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</tbody>
</table>

<Result: Substantially better seal resulting in LF isolation>
✓ RESULT: ADEL comparable with other coupling methods
✓ Comfort
  • Additional 4 subjects wore RIC closed and RIC ADEL deep (one to each ear) throughout everyday activities, including lunch (up to 1 hr.). Split (50/50%) as to which was more comfortable.
Conclusions

- Balloon inflates to amplified sound from HA speaker
- Balloon pressure - maintained even in periods of silence
- Balloon appears to “mold” into nooks and crannys
- REAR output before feedback - balloon was best
- Seal - manages ear canal dynamics (chewing, speaking, etc.)
- Security in ear - retention is excellent, with comfort
- Cosmetics - comparable to current RIC hearing aids
- OE - comparable when deep
- Comfort - good as or better than other coupling methods
- No cerumen blockage of sound
- OVERALL: Good substitute for existing HA coupling
Thank you for listening...