Electric-Acoustic Stimulation (EAS): Subjective Findings

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Financial Disclosure

- EAS Multi-Center Clinical Trial supported by MED-EL Corporation
EAS clinical trial

- US multi-center clinical trial on the safety and efficacy of EAS
- 2006: enrollment initiated at UNC
EAS clinical trial

- **Subjective assessment**
  - Hearing Device Satisfaction Scale (HDSS)
  - Abbreviated Profile of Hearing Aid Benefit (APHAB)

- **Intervals**
  - Preoperative
  - Initial EAS activation (2 months postop)
  - Post-initial EAS activation
    - 3, 6 and 12-months

CAUTION: Investigational device. Limited by US law to investigational use.
EAS clinical trial: single-site findings

• Demographics
  » Subjects, n=32
    • Arm 1, n=20
    • Arm 2, n=12
  » Age at implantation
    • Average: 55.8 years (18.2 - 76.6 yrs)

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EAS clinical trial: HDSS

- Assessment of satisfaction with different features of the device
  - Cosmetics
  - Sound quality
  - Manipulation
  - Effectiveness in noise

<table>
<thead>
<tr>
<th>FEATURE</th>
<th>Very Satisfied</th>
<th>Satisfied</th>
<th>Neutral</th>
<th>Dissatisfied</th>
<th>Very Dissatisfied</th>
<th>Does not Apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall fit or comfort</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Visibility to others</td>
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<tr>
<td>Sound quality of my own voice</td>
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<td>Effectiveness in background noises (i.e.,</td>
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<td>performance)</td>
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</tbody>
</table>
EAS clinical trial: HDSS

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EAS clinical trial: HDSS

Stable Responses

- Overall Fit & Comfort
- Visibility to Others
- Manipulation
- Telephone Usage

Better

PreOp  Initial EAS  3 Month  6 Month  12 Month

CAUTION: Investigational device. Limited by US law to investigational use.
EAS clinical trial: HDSS

Differences

Effectiveness in Background Noise
Clearness of Sound
Improvement in Quality of Life
Radio
Television
Theatre
Movies

Better

PreOp  Initial EAS  3 Month  6 Month  12 Month

CAUTION: Investigational device. Limited by US law to investigational use.
EAS clinical trial: APHAB

- Assessment of ability/difficulty in specific situations
- Subscales
  - Ease of Communication (EC)
  - Background Noise (BN)
  - Reverberation (RV)
  - Aversiveness (AV)

A Always (99%) A
B Almost Always (87%) B
C Generally (75%) C
D Half-the-time (50%) D
E Occasionally (25%) E
F Seldom (12%) F
G Never (1%) G

1. When I am in a crowded grocery store, talking with the cashier, I can follow the conversation...........A B C D E F G...............................A B C D E F G

CAUTION: Investigational device. Limited by US law to investigational use.
EAS clinical trial: APHAB

APHAB

<table>
<thead>
<tr>
<th>Subtest</th>
<th>Difficulty Percentage</th>
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</thead>
<tbody>
<tr>
<td>Ease of Communication</td>
<td>60</td>
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<tr>
<td>Reverberation</td>
<td>80</td>
</tr>
<tr>
<td>Background Noise</td>
<td>60</td>
</tr>
<tr>
<td>Aversiveness</td>
<td>40</td>
</tr>
<tr>
<td>Global</td>
<td>60</td>
</tr>
</tbody>
</table>

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EAS clinical trial: single-site findings

• **Summary: HDSS**
  - General improvement in device satisfaction
  - Largest gains in challenging listening situations
    - Background noise
    - Improvement in quality of life
    - Movies & theater
  - No change in cosmetics, visibility to others, manipulation

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EAS clinical trial: single-site findings

• **Summary: APHAB**
  
  » Reported improvement with EAS over conventional amplification on the following subtests:
    
    • Ease of communication
    • Background noise
    • Reverberation

  » Increase on aversiveness subtest
    
    • Presumably due to access of sound
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THANK YOU