Clinically Standard Verification and Validation of OTC Self-Fitting Hearing Aids

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INTRODUCTION

In 2022, the US Food and Drug Administration issued final regulations to establish a category of over-the-counter (OTC) hearing aids. As these regulations are new and technology is rapidly changing, users' objective and subjective outcomes with these devices are not yet well understood.

The main goal of this study was to assess the objective fitting and subjective effectiveness of then in-development (Eargo SE) self-fitting hearing aids using standard clinical measures.

METHODS

- 24 subjects with self-perceived hearing loss were recruited for this study.
- Subjects followed the manufacturer's in-app instructions for self-fitting (Sound Match), including a self-administered hearing assessment in which the hearing aid acts as the transducer.
- A traditional audiogram was completed in a sound-treated booth by an experienced audiologist, who was blinded to the results of the subject's self-fitting assessment results.
- The clinical audiograms were compared to the self-administered hearing assessment results.
- Objective fit was assessed by using Audioscan Verifit2® to compare measured real ear aided responses (REAR) to NAL-NL2 targets. Target generation was based on subject's booth thresholds.
- Real-world sound quality and overall hearing-aid satisfaction were validated with APHAB and COSI questionnaires after 4-5 weeks of device wear in-field.

PARTICIPANTS

Table 1 – Participant Demographics

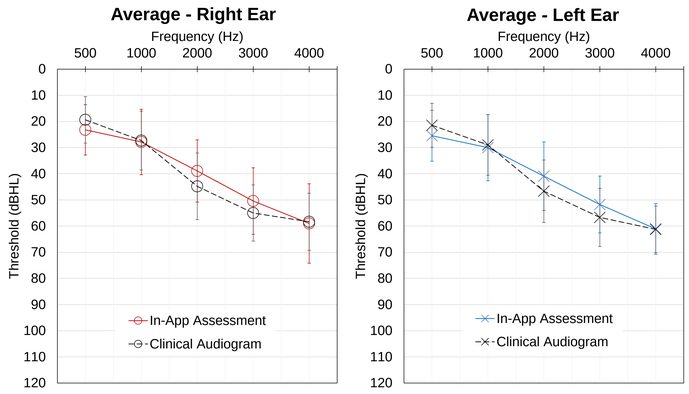
Characteristic	*Value*
Age (years)	
Mean (SD)	74.4 (7.2)
Median	75
Range	60-87
Gender, n (%)	
Female	8 (33.3%)
Male	16 (66.7%)
In-study days per week use	
0-2 days	0 (0%)
3-4 days	2 (8.3%)
5-7 days	22 (91.7%)
In-study hours per day use	
1-4 hours	1 (4.2%)
4-8 hours	9 (37.5%)
8+ hours	14 (58.3%)
High-Frequency Pure Tone Average (1, 2, 3, 4 kHz), (dB)	
Mean (SD)	47.4 (9.0)
Median	47.5
Range	31.3-66.3

RESULTS

Sound Match Process

User instructed to insert left and right devices → App performs ambient noise check to ensure a quiet environment → App guides users through threshold measurement → In-situ thresholds obtained using modified Hughson-Westlake procedure → App calculates custom gain settings based on hearing assessment results → Custom settings programmed to devices

Clinical Audiogram vs. In-App Assessment



Real-Ear Aided Response compared to NAL-NL2

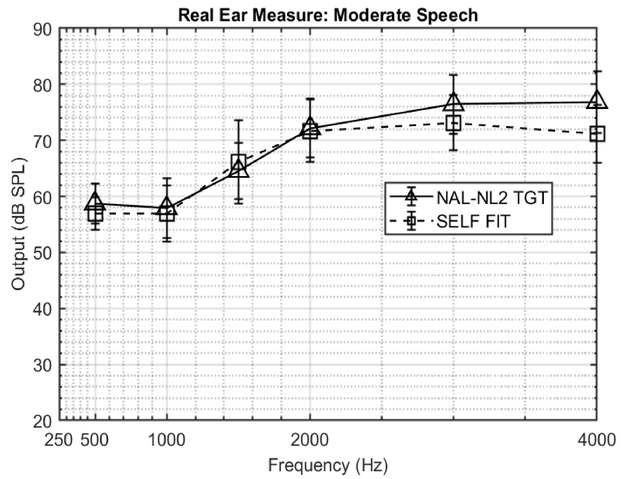
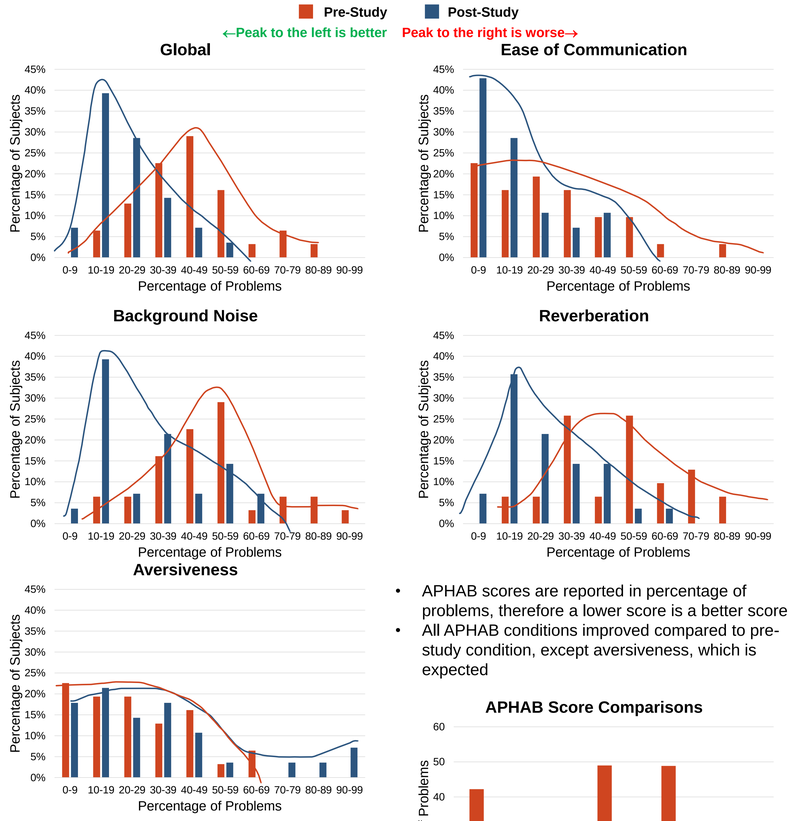


Figure above – REAR in response to moderate ISTS speech and NAL-NL2 moderate targets. Average device response shown after the Sound Match process, without adjustments, and compared to targets generated from the gold standard booth audiogram. Average target error from 500-4000 Hz. ranges from 0.7-5.7 dB for moderate ISTS input signal.

APHAB Results

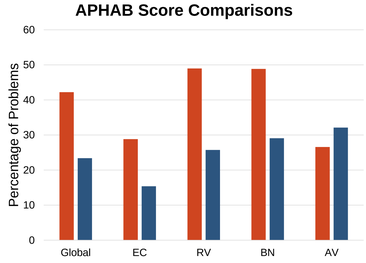


- APHAB scores are reported in percentage of problems, therefore a lower score is a better score
- All APHAB conditions improved compared to pre-study condition, except aversiveness, which is expected

Using APHAB normative data, on average Eargo SE users are performing better than…

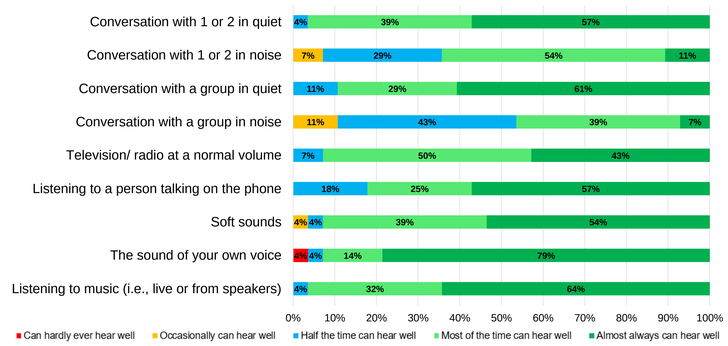
- 71.2% of hearing aid users with ease of communication
- 70.5% of hearing aid users with reverberation
- 68.4% of hearing aid users with background noise
- 59.45% of hearing aid users with aversiveness

APHAB Score Comparisons

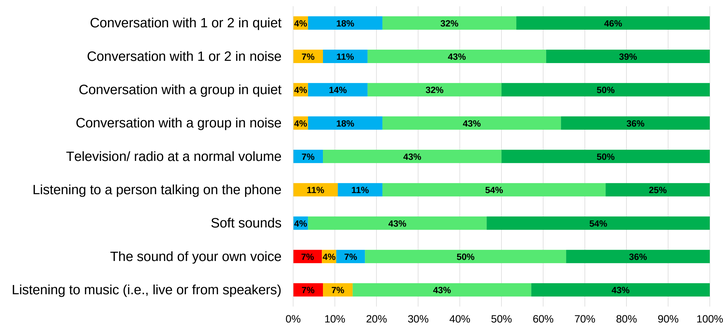


COSI Results

COSI: Rate your ability to hear well in the following situations while using these hearing aids



COSI: When using these hearing aids, how much better are you hearing in the following situations compared to without hearing aids?



DISCUSSION

Study results show effective objective and subjective verification and validation of a new OTC device using standard clinical measures.

This is evidenced by:

- Minimal average deviation (<6dB) of in-app threshold to clinical audiogram threshold
- Minimal average deviation of REAR values from NAL-NL2 moderate targets (<6dB)
- Notable improvement across all APHAB domains post-study (except for aversiveness, as expected)
- Great comparative subjective performance to regular users of WDRC hearing aids across all domains as measured by APHAB
- Great subjective effectiveness of hearing aid fit across varied listening situations as measured by COSI
- Improved subjective effectiveness of hearing aid fit across varied listening situations when comparing the unaided and aided conditions as measured by COSI

Taken together, this data reconfirms objectively and subjectively that new-to-market self-fitting OTC hearing aids are able to appropriately compensate for mild-to-moderate hearing loss.

FUTURE DIRECTIONS

- These results may aid in future research and development of self-fitting hearing aid strategies as they continue to be developed from principles of clinical audiology and hearing science.
- Efforts should be made to evaluate future products using varied clinical verification and validation methods to continue to ensure similar clinical efficacy to traditional hearing aids.

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