VALIDATION OF A FITTING METHOD FOR OVER-THE-COUNTER HEARING AIDS: A CLINICAL TRIAL

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INTRODUCTION

- Financial barriers to conventional amplification experienced by older adults with hearing loss has driven them towards cheaper Over-the-counter (OTC) hearing devices.
- Many of the existing OTC hearing devices are inappropriate for age-related sloping hearing loss due to their low-frequency emphasis[1,2]. This could lead to poorer outcomes and reduced satisfaction with OTC devices.
- Our **long-term goal** is to aid in the development of affordable, evidence-based, pre-configured hearing aids for older adults with hearing loss.
- To achieve this goal, in earlier studies[3,4], our lab developed an evidence-based set of four gain-frequency responses (presets) for pre-configured devices. These gain frequency responses were chosen such that they could provide adequate amplification for 67.9% of older adults with bilateral mild-moderate hearing loss from the National Health and Nutrition Examination Survey database.

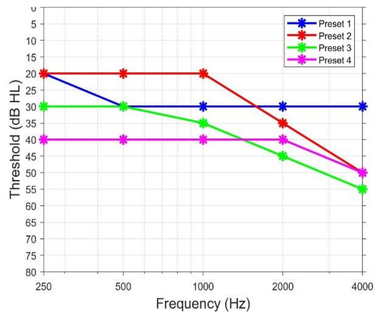


Figure 1. Audiograms associated with the four presets

- The **aim of the present study** was to compare patient outcomes using the four previously developed presets (denoted as **HAAR**) to patient outcomes of an existing OTC hearing aid (**OTC**) and to patient outcomes of traditional fittings completed by an audiologist (**AUD**).
- We **hypothesized** that the outcomes of the presets or HAAR condition will be better than the outcomes of the existing OTC hearing aid while being similar to the audiologist-based fitting.

METHODS

- Participants: 37 older adults, aged 55 to 88 (Mean =70.5) with bilateral mild-moderate sensorineural hearing loss. 17 participants were experienced hearing aid users and the rest were new users.
- Hearing Aids: Entry-level Behind-the-ear power hearing aids with slim tubes.
- Outcome measures:
- Laboratory: The Office of Research in Clinical Amplification Nonsense Syllable Test (NST[5]): In quiet and in +3 dB SNR (65/ 62 dB SPL).
- Real-world: Abbreviated profile of Hearing Aid Benefit (APHAB[6])
- Subjective preference: In last visit, asked participants which condition they preferred.
- Conditions: A pre-trial condition (duration: one week to familiarize participants with the hearing aids) was followed by the following conditions (duration: 4 weeks) in a single-blinded randomized cross-over design:
- **AUD**: Hearing aids fit using Audiology best-practices and NAL-NL2 prescriptive formula
- **HAAR**: Participants chose one of the four presets developed by our lab by listening to sentences in quiet and in noise with each of the four presets.
- **OTC**: The gain frequency response of the hearing aids was programmed to match the frequency response of a commercially available personal sound amplification product FocusEar RS2 available in the market (low and mid-frequency emphasis[7]).

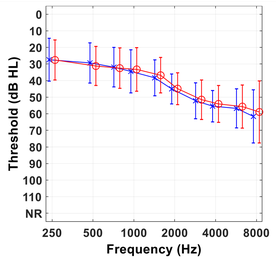


Figure 2. Mean Audiograms of all participants

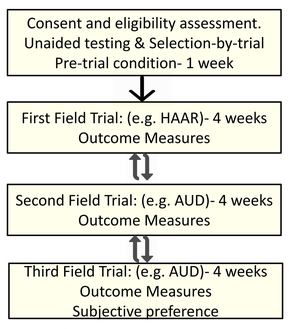
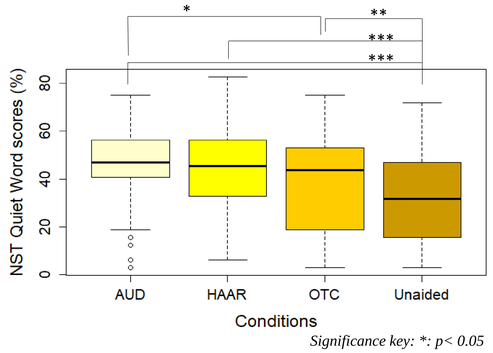


Figure 3. Study design. Field trial conditions were randomized.

RESULTS

- Linear Mixed effects model was used to analyze the differences between the unaided and the three aided conditions for the laboratory measure as well as the questionnaire. The different conditions (unaided, HAAR, OTC and AUD) were the independent variables and the outcome measures (NST word scores and APHAB) were the dependent variables. In the mixed model, the different conditions were the fixed effect and a random effect was added for participants. We conducted post-hoc testing using Tukey test with correction for multiple comparisons.



*Significance key: *: p< 0.05 **: p<0.01 ***: p< 0.001*

Figure 4. Mean Scores for Nonsense Syllable Test (NST) in quiet for unaided and different aided conditions

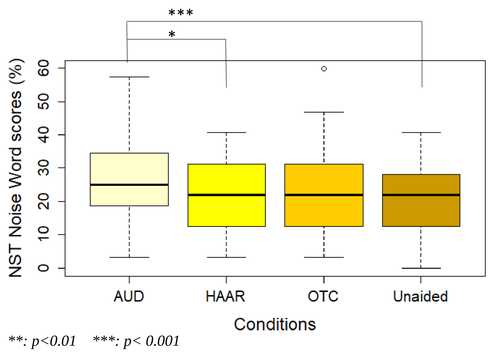
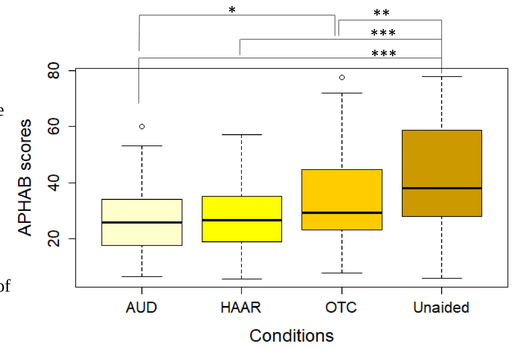


Figure 5. Mean Scores for Nonsense Syllable Test (NST) in noise for unaided and different aided conditions

- For NST word scores in quiet(Figure 4), we saw significant main effect of condition ($F_{(3,107)}$= 18.20, $p < 0.001$). Pairwise post-hoc comparisons revealed that the NST scores for AUD ($p < 0.001$), HAAR ($p < 0.001$) and OTC ($p = 0.001$) were significantly better than the unaided condition. Additionally, the scores for AUD condition were also significantly better than OTC condition ($p = 0.030$).
- For NST scores in noise (Figure 5), we saw a significant main effect of condition ($F_{(3,108)}$= 6.06, $p < 0.001$). Pairwise post-hoc comparisons revealed that the scores for AUD condition were better than unaided ($p < 0.001$) and HAAR conditions ($p = 0.026$).
- APHAB scores (Figure 6): We saw significant main effect of condition ($F_{(3,106)}$= 18.20, $p < 0.001$). Pairwise post-hoc comparisons revealed that the APHAB global scores for unaided condition were significantly higher than AUD ($p < 0.001$), HAAR ($p < 0.001$) and OTC ($p = 0.0019$) conditions. Additionally, the scores for AUD condition were also significantly lower than OTC condition ($p = 0.029$).



*Significance key: *: p< 0.05 **: p<0.01 ***: p< 0.001*

Figure 6. Global Scores for Abbreviated Profile for Hearing Aid Benefit (APHAB) for unaided and different aided conditions: These scores indicate how frequently participants experienced performance problems. Thus, high score indicates more performance problems

- Subjective preferences (Figure 7): Out of 37 participants, 20 preferred the HAAR, 23 the AUD and 5 the OTC configuration. Using Cochran's Q test, there was a statistically significant difference between the preferences (Q = 9.94, $p = 0.007$). We conducted follow-up pairwise testing using Dunn test with Bonferroni correction for multiple comparisons. Results showed that the HAAR configuration was significantly preferable to OTC ($p < 0.001$), while there was no significant difference between preferences for AUD and HAAR ($p = 0.134$).

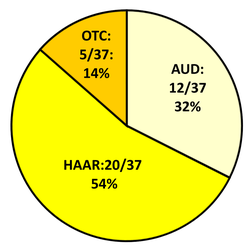


Figure 7. Participants' subjective preferences of hearing aids

DISCUSSION

- We hypothesized that our pre-configured model, HAAR would perform as well as traditional audiologist fitting and it will perform better than an existing OTC hearing aid.
- Although there was no significant difference between the AUD and the HAAR conditions in the laboratory and real-world questionnaire, we found that majority of the participants (54.05%) indicated a subjective preference for hearing aids in the HAAR condition, followed by the AUD condition (32.43%).

CONCLUSIONS AND IMPLICATIONS

- Our study provides indication that though audiologist-fit hearing aids showed significantly better performance than OTC hearing aids, and there was no significant difference between our pre-configured hearing aids and the AUD or the OTC hearing aid performance, our pre-configured settings are still subjectively preferred over both the AUD and OTC hearing aids.
- These finding support the use of gain-frequency responses developed in our lab (HAAR) in pre-configured hearing aids. Further analysis is needed to determine the reason for these preferences.
- Further exploring these evidence-based gain-frequency responses and then implementing them in OTC hearing aids will make these devices more affordable while maintaining the quality of pre-configured hearing devices.

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CONTACT

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