A Comparative Analysis of Technical Performance and Effectiveness of Multiple Over-the-Counter Hearing Aids

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Problem Background

The FDA’s October 2022 rules for over-the-counter (OTC) hearing aids (HA) offer adults with mild to moderate hearing loss (MMHL), defined as only hearing in or above the 26-40 dB and 41-55 dB ranges respectively (ASHA, 2024), an easier way to acquire them without prescriptions. (FDA, 2022) Despite increased accessibility, consumers face challenges in choosing from the vast array of available models due to limited pre-purchase information. Details are often only accessible through aftercare or apps after purchasing, which can lead to unmet expectations. Additionally, the absence of professional audiologist guidance in the OTC process means consumers miss out on personalized tuning and hearing assessments, which could affect the hearing aid’s performance.

Verification and Testing: Materials and Methods

Audioscan Verifit 2 was used to evaluate several OTC hearing aid models, focusing on FDA-required descriptors and user usability for adults with MMHL. ANSI tests were conducted simultaneously, assessing OSPL-90dB, full-on gain, and harmonic distortion using a blue 2cc coupler inside a test box. Additionally, speech mapping tests simulated mild to moderate hearing loss at various speech levels to check the OTC device outputs, using a silver 0.4cc coupler for setup.

OSPL90dB, Binaural Full-on Gain Testing

Figure 5: Binaural OSPL90dB Measurement. This figure displays the maximum output sound pressure level achieved by a model of OTC HA when the input signal is at 80 dB SPL, highlighting the device's peak loudness capabilities. The columns represent the peak SPL recorded for the device, emphasizing their performance in potentially loud environments. Left shows output given full volume input, while right shows output given a medium volume input. Full on volume control is when the HA's volume is turned to max; same follows for medium-volume.

Conclusion

Our preliminary analysis has pinpointed distinct functional capabilities among OTC hearing aids, enabling us to discern performance variations. We are expanding our testing to refine these findings and examining patient profiles more closely to optimize our hearing aid matching process.

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References