ABSTRACT

Objective: Compare high-frequency functional gain of a patient’s own air conduction hearing aid with a light-driven tympanic membrane contact hearing aid (Earlens).

Study Design: FDA-approved multi-center self-controlled prospective study in adults with mild to severe sensorineural hearing loss. Forty-one subjects (78 ears) completed the 90-day trial.

Methods: Sound-field thresholds (125Hz to 10kHz) and the APHAB questionnaire of hearing aid benefit unaided pre-treatment, added pre-treatment with own air conduction hearing aid (HA), and added with the Earlens Contact Hearing Aid (CHA): a subjective benefit questionnaire at study completion.

Results: The functional gain was significantly better at all frequencies from 250Hz to 10kHz with the Earlens CHA compared to the patients’ own conventional air conduction hearing aids (p≤0.05 to 0.001). With the Earlens CHA, the functional gain at the higher frequencies (6kHz-10kHz) ranged from 32.8dB to 34.5dB compared to a range of 1.0 to 15.4dB with the patients' own hearing aids.

The greater functional gain provided by the Earlens CHA was subjectively associated with a “Patient Satisfaction” and “APHAB” questionnaire. Study three (63.6%) rated the CHA as Superior or Fairly Superior to their own hearing aids and 78% reported being Satisfied or Very Satisfied with the CHA regarding overall benefit of hearing. In addition, there was a significant improvement in APHAB Ease of Communication score (p<0.045).

Conclusions: The Earlens contact hearing aid delivered better functional gain from 250 Hz to 10 kHz compared to conventional air conduction hearing aids and substantially more amplification (32.8 dB to 34.5 dB) in the high frequencies. This resulted in high levels of user satisfaction and evidence of superior performance when compared to subjects' own air conduction hearing aids.

RESULTS

Significant improvements in detection over unaided at baseline occurred at all frequencies other than 125Hz with the CHA (p's ≤ 0.001). The CHA provided significantly more functional gain than the subjects' own HAs at all frequencies other than 125Hz, with substantial differences at and above 4kHz (Fig. 3). Mean amount of improvement on APHAB scales over the unaided condition was greater with the CHA than with subjects' own HAs for all three subtests, and was significant for the EC subscale (p≤0.045). 78% were ‘Very Satisfied’ or ‘Satisfied’ with overall benefit to hearing of the CHA, and 78% were satisfied with its benefit specifically for speech understanding (Table 2). 63.6% of those with their own HA rated the CHA as ‘Far Superior’ or ‘Superior’ in overall benefit and sound quality, and 60% preferred the Earlens CHA. The mean gain for patients with overall speech and sound understanding benefits was greater at both 9kHz and 10kHz than for those less than satisfied (Table 1). Those who rated the CHA as superior to their own HA had significantly more gain with the CHA at 9kHz and 10kHz than those who felt their own HA was the same or superior (p≤0.02 and 0.042, respectively).

INTRODUCTION

The human ear has capacity to detect sounds from 20Hz to 20,000Hz. Optimally, a hearing aid would be able to replicate this. However, due to feedback issues, functional gain drops off significantly above 5000 Hz with conventional air conduction hearing aids.

The conventional hearing aid specification is misleading when they report amplification up to 10kHz. These figures are based on the hearing aid output in a sealed 2cc coupler, and they do not represent what the hearing aid user actually receives. Studies using KEMAR to replicate the real-ear environment confirm that traditional hearing aids have a significant roll-off in this. However, due to feedback issues, functional gain drops off significantly above 5000 Hz with traditional air conduction hearing aids.

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MATERIALS & METHODS

Subjects: 41 subjects (78 ears) at eight investigative sites completed the 90-day trial. Primary Inclusion Criteria: Adult and with sensorineural hearing loss. Standard unaided and aided air conduction thresholds were measured at Baseline and 90-days after fitting. Secondary Inclusion Criteria: 1.125 Hz to 10 kHz with a maximum output of 90-110dB SPL and an average maximum gain of 40 dB.

RESULTS

Air conduction HAs have limitations in providing adequate amplification at high frequencies (>9kHz) and in gain provided before feedback occurs. This study confirmed the ability of the Earlens Hearing Aid to overcome these problems. Functional gain was provided with the CHA across a broad frequency spectrum (125 Hz to 10kHz) gains; 2.8dB – 34.5dB at 6-10 kHz). With subjects’ own HAs, gain at high frequencies was ≤35.5 dB and was poorer at all frequencies than with the CHA (p≤0.05 to 0.001). Perceived benefit was also greater with the CHA. Mean gain for those satisfied with overall hearing and speech benefit with the CHA was greater than for those less than satisfied at 9kHz and 10kHz. Those who rated the CHA as superior had significantly more gain with the CHA at 9kHz and 10kHz than those who rated their own HA as the same or superior. i.e., more gain at high frequencies was related to subject satisfaction. As predicted by mechanical modeling of the middle ear, the tympanic Lens is known to cause a 4 dB average damping effect. This damping effect was only mildly perceived by the study patients. When the tympanic Lens was Light activated, the damping effect was offset by the significant functional gain from 250Hz to 10kHz produced by the Contact Hearing Device.

DISCUSSION

The Earlens Light-Driven Contact Hearing Aid delivered substantially more amplification in the high frequencies when compared to air conduction hearing devices, providing high levels of user satisfaction and evidence of superior performance when compared to subjects’ own air conduction hearing aids.

CONCLUSIONS

References

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Table 2. Subject questionnaire (n=41).