ABSTRACT

Objective: Compose high-frequency 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 APhAHR questionnaire of hearing aid benefit unaided pre-treatment, aided pre-treatment with own air conduction hearing aids (HA), and aided 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 when 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 (6-10kHz) ranged from 32.8dB to 34.5dB compared to a range of 1.0 to 5.6dB with the patients’ own hearing aids.

The greater functional gain provided by the EarLens CHA was subjectively demonstrated with a “Patient Satisfaction” and “APHAHR” questionnaire. Fifty-three (63.5%) rated the CHA as Superior or Far 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 APHAHR Ease of Communication score (p ≤ 0.05).

Conclusions: The EarLens contact hearing aid delivered better functional gain from 250Hz to 10kHz when compared to conventional air conduction hearing aids and substantially more amplification (32.8 dB-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.

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 5000Hz with traditional air conduction hearing aids.

The conventional hearing aid specification sheets are 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 the high frequencies, particularly above 5kHz. These high frequencies have been shown to improve speech understanding in complex sound environments. Attempts to amplify above 5kHz with conventional air conduction hearing aids results in the output of the speaker being picked by the microphone producing unacceptable feedback. The EarLens CHA circumvents this feedback issue because the device does not contain an acoustic speaker but instead uses a light-driven mechanism to directly vibrate the umbo. Based on previous studies, the EarLens CHA is able to provide “real ear” frequency response from 125Hz to 10kHz with a maximum output of 90-110dB SPL and an average maximum gain of 40dB.

MATERIALS & METHODS

Subjects: 41 subjects (78 ears) at eight investigational sites completed the 90-day trial. Primary Inclusion Criteria: Adult speakers of American English; mild to severe hearing impairment (min. threshold 30dB, max. 80dB at 4kHz and above); normal Type A tympanometry; ≥50% speech discrimination (PBMx); Exclusion Criteria: Retro-custator lesion; significant conductive hearing impairment (>20dB gap at 500Hz to 4kHz); or an active medical issue precluding a hearing device.

The 15 males and 23 females had a mean age of 68.5 years; 73.2% were using hearing aids; and had in the past, Mean 4-frequency unaided PTA, based on individual ears, and aided PTA (for those wearing hearing aids) were 47.6dB and 37.9dB, respectively.

RESULTS

Significant improvements in detection over unaided at baseline occurred at all frequencies other than 125Hz with the CHA (p ≤ 0.05 to 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 Table). Mean amount of improvement in APhAHR scales over the unaided condition was greater with the CHA than with subjects’ own HAs for all three subtests and was significant for the CHA frequency sub-scale (p ≤ 0.05). 78% were ‘Very Satisfied’ or ‘Satisfied’ with overall benefit to hearing of the CHA, and 78% 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 66% preferred the Earlens device. Mean gain for those satisfied with overall hearing and speech understanding benefits was greater at both 9kHz and 10kHz than for those less 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 0.04, respectively).

CONCLUSIONS

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.

REFERENCES