Overcoming High-Frequency Limitations of Air Conduction Hearing Devices Using a LIGHT-DRIVEN Contact Hearing Aid

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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, 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's≤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 15.4dB with the patients' own hearing aids.

The greater functional gain provided by the Earlens CHA was subjectively demonstrated with a "Patient Satisfaction" and "APHAB" questionnaire. Sixty-three (63.6)% 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 APHAB Ease of Communication score (p≤.045).

Conclusions: The Earlens contact hearing aid delivered better functional gain from 250 Hz to 10 kHz 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 5000 Hz 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.[1]

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 5 kHz. These high frequencies have been shown to improve speech understanding in complex sound environments.[2-6] Attempts to amplify above 5 kHz 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 125 Hz to 10 kHz with a maximum output of 90-110dB SPL and an average maximum gain of 40 dB.[7]

MATERIALS & METHODS

Subjects: 41 subjects (78 ears) at eight investigative 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 (PBmax). Exclusion Criteria: Retro-cochlear lesion; significant conductive hearing impairment (>10dB gap at 500Hz to 4kHz); or an active medical issue precluding a hearing device. The 33 males and 8 females had a mean age of 68.3 years. 73.2% were using hearing aid(s) or 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.

Figure 1. Components of the Earlens Contact Hearing Aid

Device: The Earlens CHA consists of:

- External processor in a behind-the-ear unit
- Ear tip which directs the light ("Light Tip")
- Tympanic Membrane (TM) "Lens" **(Fig. 1)**

Mechanism of Action:

- Sound is picked up by the microphone
- Signal is processed and converted to an ultraviolet light signal
- UV light wirelessly transmits signal and power from the Light Tip to the photodetector of the Lens
- Lens converts UV light into mechanical energy that is transferred to the umbo, driving the ossicular chain **(Fig. 2)**

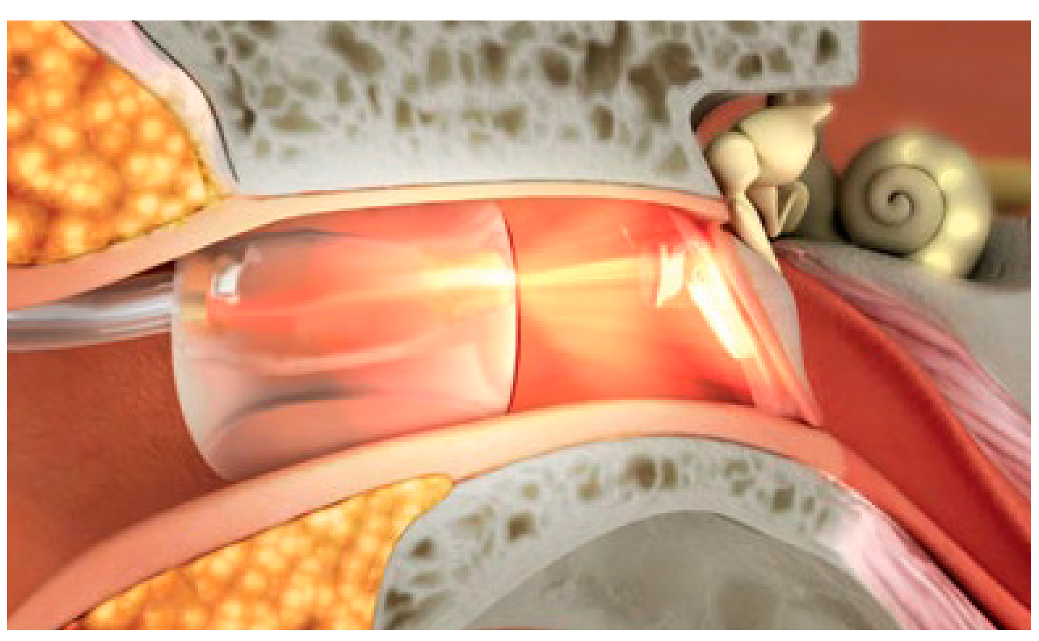

Figure 2. Schematic of the Earlens Light-Driven Contact Hearing Aid in situ.

Measurements: Standard unaided and aided air conduction thresholds were measured at Baseline and 90-days after placement of the Earlens CHA. Change in self-perceived ability to communicate with the CHA was measured using the Abbreviated Profile of Hearing Aid Benefit (APHAB) subscales Background Noise (BN), Reverberant Environments (RV) and Ease of Communication (EC). Subjects completed a patient satisfaction questionnaire to assess benefit, and, for those with previous HA experience, to compare the CHA to their own HA.

RESULTS

Significant improvements in detection over unaided at baseline occurred at all frequencies other than 125Hz with the CHA (p's all ≤0.001), and 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 1)**. 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≤.045). 78% were 'Very Satisfied' or 'Satisfied' with overall benefit to hearing of the CHA, and 78.1% 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 device. Mean gain for those satisfied with overall hearing and speech 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's≤0.02 and 0.042, respectively).

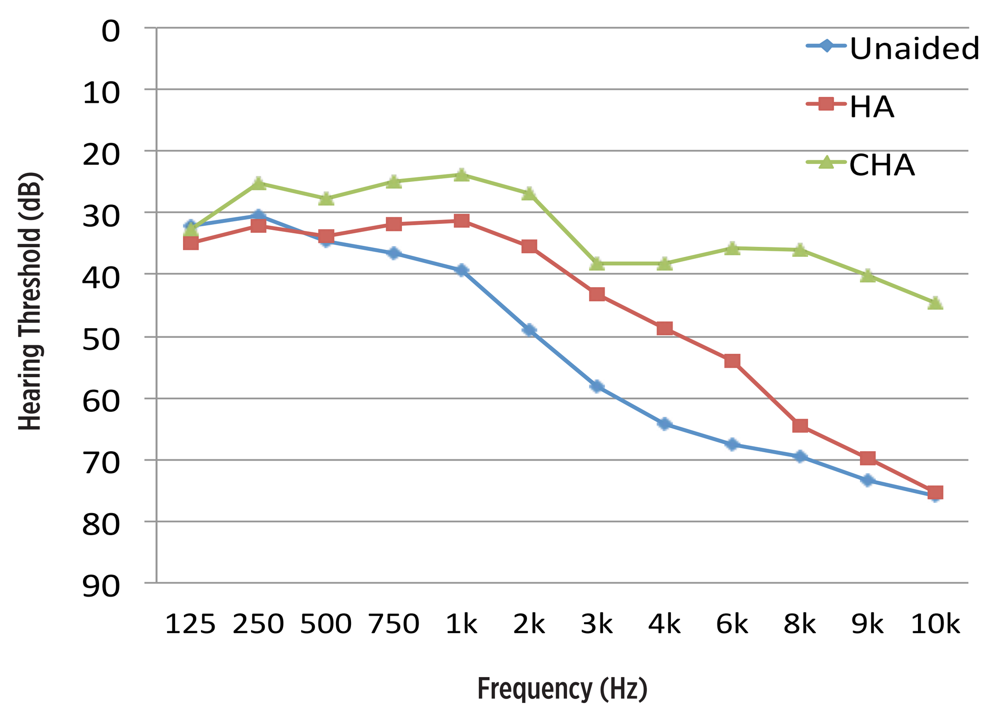

Figure 3: Mean thresholds unaided, with own HA at baseline, and with the CHA at 90 days post-fitting.

	Frequency (Hz)			
	6kHz	**8kHz**	**9kHz**	**10kHz**
All Ears				
n	76	76	52	54
CHA	32.8 (12.0)	34.5 (12.5)	34.3 (16.0)	33.0 (16.0)
Ears with own hearing aid				
n	50	50	34	36
HA	15.4 (13.7)	6.3 (13.9)	4.9 (11.6)	1.0 (10.7)
CHA	32.4 (13.1)	35.6 (11.8)	36.2 (15.7)	36.0 (15.8)
Stat. Sig.	p≤.001	p≤.001	p≤.001	p≤.001

Table 1. Mean (SD) functional gain (dB) at high frequencies with the CHA and paired-comparison of own HA to CHA.

How satisfied were you with your Earlens devices regarding:	Very Satisfied	Satisfied	Neutral	Dissatisfied	Very Dissatisfied
Overall benefit of hearing	31.7%	46.3%	12.2%	9.8%	0.0%
Benefit for speech understanding	24.4%	53.7%	7.3%	12.2%	2.4%
How would you rate the Earlens compared to your own hearing aids?	CHA Far Superior	CHA Superior	About the Same	Own HA Superior	Own HA Far Superior
Overall benefit and sound quality	33.3%	30.3%	16.7%	16.7%	3.3%
Compared to your own hearing aids, do you prefer having the Earlens overall?	Very Much Prefer CHA	Prefer CHA	About the same	Prefer Own HA	Very Much Prefer Own HA
Preference	33.3%	26.7%	16.7%	20.0%	3.3%

Table 2. Subject questionnaire (n=41).

DISCUSSION

Air conduction HAs have limitations in providing adequate amplification at high frequencies (>5kHz) 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 32.8dB - 34.5dB at 6-10 kHz). With subjects' own HAs, gain at high frequencies was ≤15.4dB and was poorer at all frequencies than with the CHA (p's≤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 9 and 10kHz than those who rated their own HA as 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 250 Hz to 10,000 Hz produced by the Contact Hearing Device."

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

1. Struck CJ, Prusick L. Real-world bandwidth of contemporary hearing instruments. Hearing Review (2017, in press).
2. Turner CW, Henry BA. Benefits of amplification for speech recognition in background noise. J. Acoust Soc Am 2002; 112:1675–1680.
3. Hornsby BW, Ricketts TA. The effects of hearing loss on the contribution of high- and low-frequency speech information to speech understanding. J Acoust Soc Am 2003; 113:1706–1717.
4. Carlile S, Schonstein D. Frequency bandwidth and multi-talker environments. Presented at the 120th Convention of the Audio Engineering Society. 2006;118:353-363.
5. Plyler PN, Fleck EL. The effects of high-frequency amplification on the objective and subjective performance of hearing instrument users with varying degrees of high-frequency hearing loss. J Speech Lang Hear Res 2006; 49:616–627.
6. Levy, SC; Freed DJ; Nilsson M, Moore BC; Puria S. Extended high-frequency bandwidth improves speech reception in the presence of spatially separated masking speech. Ear Hear 2015; 36: e214–e224.
7. Fay JP, Perkins R, Levy SC, Nilsson M, Puria S. Preliminary evaluation of a light-based contact hearing device for the hearing impaired. Otol Neurotol 2013; 34:912-921.

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