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Light-Driven Contact Hearing Aid for Broad-Spectrum Amplification: Safety and Effectiveness Pivotal Study

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Objective: Demonstrate safety and effectiveness of the light-driven contact hearing aid to support FDA clearance.
Study Design: A single-arm, open-label investigational-device clinical trial.
Setting: Two private-practice and one hospital-based ENT clinics.
Patients: Forty-three subjects (86 ears) with mild-to-severe bilateral sensorineural hearing impairment.
Intervention: Bilateral amplification delivered via a light-driven contact hearing aid comprising a Tympanic Lens (Lens) with a customized platform to directly drive the umbo and a behind-the-ear sound processor (Processor) that encodes sound into light pulses to wirelessly deliver signal and power to the Lens.
Main Outcome Measures: The primary safety endpoint was a determination of ''no change'' (PTA4 < 10 dB) in residual unaided hearing at the 120-day measurement interval. The primary efficacy endpoint was improvement in word recognition using NU-6 at the 30-day measurement interval over the baseline unaided case. Secondary efficacy endpoints included functional gain from 2 to 10 kHz and speech-in-noise improvement over the baseline unaided case using both omnidirectional and directional microphones.
Results: The results for the 86 ears in the study determined a mean change of −0.40 dB in PTA4, indicating no change in residual hearing ($p < 0.0001$). There were no serious device- or procedure-related adverse events, or unanticipated adverse events. Word recognition aided with the Earlens improved significantly ($p < 0.0001$) over the unaided performance, by 35% rationalized arcsine units on average. Mean functional gain was 31 dB across 2 to 10 kHz. The average speech-recognition threshold improvement over the unaided case for the Hearing in Noise Test was 0.75 dB ($p = 0.028$) and 3.14 dB ($p < 0.0001$) for the omnidirectional and directional microphone modes, respectively.
Conclusion: The safety and effectiveness data supported a de novo 510(k) submission that received clearance from the FDA. **Key Words:** Contact hearing aid—Contact hearing device—Hearing aid—Hearing in noise—Light-driven—Sensorineural hearing loss—Speech in quiet.

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The mechanism of directly driving the tympanic membrane (TM) or middle-ear ossicles to deliver sound to a user has been shown to be capable of providing gain to higher frequencies than what is currently possible with air-conduction (AC) hearing aids (1–5). These types of large gains are required by high-frequency fitting algorithms intended to treat sensorineural hearing impairment (6,7). Direct vibration of the umbo from the lateral side of the TM has been used to demonstrate the ability to provide amplification in a magnetic (8) as well as a photonic (9) implementation, both without requiring surgery. Most recently, the photonic implementation was shown to be a feasible method of providing broad- spectrum amplification to a small population of subjects with mild-to-severe bilateral sensorineural hearing impairment (9).

Results from the single-site IDE-approved feasibility study on 13 subjects, using an earlier ''Alpha'' version of the light-driven contact hearing aid (CHA), indicate that a CHA that directly vibrates the umbo can deliver broad-spectrum output levels up to 110 dB SPL for frequencies from 125 Hz up to 10 kHz, while maintaining high maximum gain margins with the ear canal left widely vented (9). A shortcoming of the Alpha version of the CHA was that the battery life of the behind-the-ear sound processor (Processor) lasted only 4 hours, and the Processor was not designed to be worn outside the laboratory. Since then,

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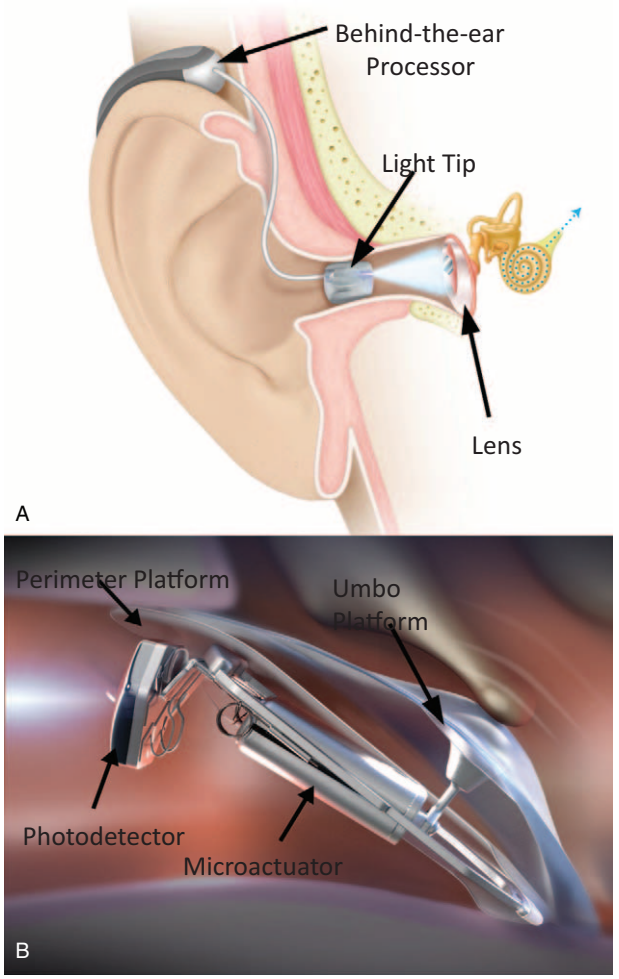

FIG. 1. *A,* The light-driven contact hearing aid (CHA), with its behind-the-ear sound processor (Processor); Light Tip, which aims a beam of encoded infrared light toward the tympanic membrane (TM); and Tympanic Lens (Lens) at the base of the ear canal, which receives the light signal and converts it into vibration of the umbo. The Processor sits behind the ear (BTE) and is similar in size to the current BTE-style acoustic hearing aids on the market. The Light Tip is customized to the individual ear-canal anatomy and is vented as widely as possible, with the vent having a minimum diameter of 2 mm. *B,* The Lens component of the CHA, showing the photodetector that converts the light signal into energy to power the microactuator. The microactuator is connected to the chassis via springs, and is suspended over the TM to vibrate the umbo platform on the umbo. The Lens is stabilized in position by the peritympanic platform and is removed using a grasping tab.

the system has been redesigned for compactness and energy efficiency in the present ''Gen 0.1'' version, with the Processor reduced to about a third of the previous size and an extended battery life to allow subjects to wear the CHA similarly to how they would wear an acoustic hearing aid. Figure 1A shows the Gen 0.1 CHA, with the removable Processor connected to the customized Light Tip, aiming the emitted laser light down the ear canal to activate the Tympanic Lens (Lens).

The Lens of the CHA is a tiny microactuator mounted to a customized ring-shaped perimeter platform that rests on the skin of the anterior sulcus and the peritympanic canal epithelium (Fig. 1B). The photodetector receives the emitted light signal, converting it into an electrical current that activates the microactuator, which in turn drives the TM directly at the umbo. The direct coupling of the Lens to the TM allows the system to produce effective pressure output and gain levels up to 10 kHz, as required by the high-frequency-capable fitting algorithm (7). When driven at the umbo, the sound radiation due to vibration of the TM surface decreases with frequency due to the presence of multiple modes, thus producing less acoustic feedback (10) than for an acoustic sound source in the ear canal generating the same effective drive pressure.

To demonstrate the safety and effectiveness of the Gen 0.1 version of the CHA on listeners with sensorineural hearing impairment, a single-arm open-label pivotal study using the unaided hearing of each subject as his/her own control, was run at three sites. The main purpose of the study was to show CHA performance relative to the unaided condition; the study was not designed to collect data comparing to AC hearing aids. Functional-gain comparisons to middle-ear implants will be discussed.

METHODS

Ethics, IRB, and Consent

This study was conducted under Good Clinical Practices in accordance with US FDA, 21 CFR requirements for medical devices under IDE, and EU MDD and ISO 14155 requirements for investigations of medical devices; in accordance with the Declaration of Helsinki; and in compliance with applicable Local and Federal Regulations. The procedures followed in the study were in accordance with the ethical standards of the Western Institutional Review Board (WIRB protocol ID 20131270) and were overseen by each medical principal investigator (B.G., M.M., and R.P.). All subjects signed informed-consent documents before participating in study activities.

Participants

Inclusion/Exclusion Criteria

All inclusion/exclusion criteria are summarized in Table 1. Audiometric thresholds (125–10,000 Hz) were measured using an audiometer with extended high-frequency capabilities (either a GSI 61 [Grason-Stadler, Eden Prairie, MN, U.S.A.], or a Madsen Astera 1066 or Astera2 [Otometrics, Schaumburg, IL, U.S.A.]), and high-frequency earphone testing (8000–10,000 Hz) was performed with Sennheiser HDA 200 circumaural headphones (Sennheiser, Wedemark, Germany). Earphone thresholds at other frequencies (125–8000 Hz) were made with either insert earphones or circumaural headphones.

Enrollment and Demographics

A total of 48 participants with mild-to-severe sensorineural hearing impairment were enrolled, consisting of 20 males (60%) and 19 females (40%). The mean age was 69 years, with a range of 34 to 83 years. The mean and standard deviation of the preplacement unaided baseline audiograms are plotted in Figure 2. The participants comprised two subject cohorts: 5 roll-in subjects evaluable only for safety, and 43 primary-cohort subjects evaluable for both safety and efficacy. All safety data was included regardless of cohort or withdrawal status. Five primary-cohort participants exited the study before completion,

TABLE 1. *Inclusion and exclusion criteria for the safety and effectiveness pivotal study of the light-driven contact hearing aid*

Inclusion Criteria

- Subjects of either sex (male or female) must be 18 years of age, or older.
- The subject must be able and willing to commit to the travel and time demands of the study (for 6 months or longer) and able to comprehend and comply with the study materials and instructions.
- The subject must be a native speaker of American English, due to the use of English Language test materials.
- The subject's thresholds for both ears in decibels (dB) hearing level (HL) must fall within the target fitting range shown below (inclusion criteria allow one test frequency to fall outside the range):

Frequency (Hz)	125	250	500	1000	2000	4000	6000	8000	10,000
HL min (dB)	0	0	0	0	15	30	30	30	30
HL max (dB)	50	60	60	70	75	80	80	80	80

- The subject must have not more than 10 dB HL of air-bone gap (no conductive hearing impairment) at three of four tested frequencies (500, 1000, 2000, and 4000 Hz).
- The subject's thresholds for the right and left ears must be within 15 dB HL of each other (symmetric hearing impairment), at five of eight tested frequencies (125, 500, 1000, 2000, 4000, 6000, 8000, and 10,000 Hz).
- The subject's performance must be $\geq$60% on diagnostic word-recognition scores presented at PBmax.
- The subject's diagnostic word-recognition scores must not differ by more than 25% between the two ears, to reduce the possibility that the subject may have an acoustic neuroma.
- The subject must exhibit normal Type A tympanometry (indicating normal mobility of the tympanic membrane and middle-ear bones).
- The subject must have been a current user of one or two of their own air-conduction hearing aids for at least 6 weeks prior to enrollment in the study.

Exclusion Criteria

- The subject cannot have known or active medical issues that would preclude having a device placed in the ear canal, including:
  - an abnormal TM (deemed perforated, inflamed, sclerotic, or having a dimeric or monomeric area, or in any other way abnormal)
  - an abnormal middle ear or a history of previous middle-ear surgery other than tympanostomy tubes
  - an ear-canal anatomy that prevents the physician from seeing an adequate amount of the TM, or an anatomical configuration of the external auditory canal that prevents satisfactory placement of the TM transducer (examples include a large anterior canal bulge and exostoses of the ear canal)
- The subject cannot have other known medical issues, including:
  - a history of chronic and recurrent ear infections in the past 24 months
  - a history of dizziness and/or vertigo in the past 24 months
  - taking medications/treatments with known ototoxic effects
  - a rapidly progressive or fluctuating hearing impairment
  - having been diagnosed with having a compromised immune system that may impact the tissue of the auricle or ear canal, keratosis obturans, ichthyosis, or eczema of the auricle or ear canal; or having ever received radiation to the head, or chemotherapy for cancer within the last 6 months
  - a rapidly progressive or fluctuating hearing impairment (e.g., Ménière's disease)
- The subject cannot fit the definition of a vulnerable subject, as per FDA regulations 21 CFR Parts 50 and 56.
- The subject cannot have an ear-canal anatomy that precludes manufacture of the Lens transducer, as determined by the manufacturer's analysis of the impression.

four due to unrelated adverse events, and one due to inability to meet the time requirements necessary to complete the study. The unrelated adverse events that led to withdrawal of four of the subjects were 1) fluctuating hearing loss caused by cochlear hydrops, 2) hospitalization due to a bike accident, 3) hospitalization for cardiac and dizziness issues, and 4) hospitalization for an intentional overdose leading to death.

Evaluable subjects include 39 of 43 primary-cohort participants through the 30-day efficacy measurement interval and 38 of 43 primary-cohort and 5 of 5 roll-in-cohort subjects through the 120-day safety measurement interval.

Intervention

The intervention was treatment of the hearing impairment using amplification provided by the Earlens CHA (Menlo Park, CA, U.S.A.) for a duration of 120 days. Baseline measures and assessments were made before device placement. A deep ear-canal impression collected by the physician was used to manufacture the customized Lens and Light Tip for each ear. The Lens was inserted by the physician. Subjects were instructed to insert one to two drops of mineral oil in each ear canal every week to keep the interface between the slowly migrating epithelium (11,12) and the Lens platforms well lubricated. A more detailed description of the Lens placement is provided in Fay et al. (9).

The Processor and Light Tip was fit, calibrated, and programmed by the audiologist with up to four configurable programs. A detailed description of the system calibration is provided in Fay et al. (9). The Processor battery life was dependent on a combination of factors, and was primarily driven by the hearing level and the optical coupling between the Light Tip and the Photodetector. Subject-reported Processor battery life on a single charge ranged from 6 to 15+ hours. If a subject reported Processor battery life that did not meet desired usage per day, the subject was provided with a second set of Processors.

Study Outcome Measures and Methods

Primary Safety Endpoint

Unaided AC thresholds were measured twice before device placement for each treated ear during the first visit, and averaged to obtain the baseline unaided AC hearing thresholds. The unaided AC hearing thresholds were again measured after

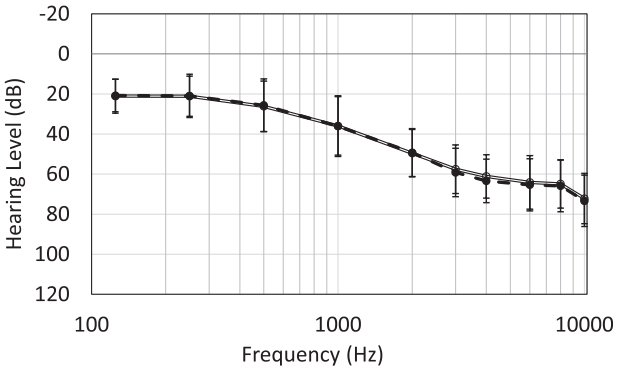

FIG. 2. Mean and standard deviation of the unaided hearing thresholds of the 43 evaluable participants, each averaged across right and left ears (86 evaluable ears), as calculated for the baseline measurements before CHA placement (*open line*) and for the measurements after CHA removal at the end of the study (*dashed line*), which shows no substantial hearing change across any measured frequency.

device removal during the last visit (120 days later). A PTA4 (pure-tone threshold at 500, 1000, 2000, and 4000 Hz) was computed on both occasions. Hearing change in terms of PTA4 in individual ears was computed as the difference between the final unaided AC hearing thresholds and the baseline unaided AC hearing thresholds. Audiometric threshold testing was done with a 2-dB step size (ANSI S3.21). The primary safety endpoint was a determination of ''No Hearing Change,'' which was defined as a calculated Hearing Change of the PTA4 of less than 10 dB for the population.

Additional Safety Measure

Anticipated and unanticipated adverse events related to the device and procedures were characterized in terms of severity and seriousness.

Primary Efficacy Endpoint

The primary efficacy endpoint was a statistically significant improvement in aided word-recognition scores over baseline unaided word-recognition scores for the population, using the NU-6 word list (13) presented at 45 dB HL in the soundfield at a 0-degree azimuthal angle. Each treated ear was isolated and tested separately in the subject's most commonly used program.

Secondary Efficacy Endpoint—Functional Gain

A secondary efficacy endpoint was a statistically significant improvement of at least 10 dB for the study population in aided soundfield hearing thresholds at the 30-day interval, compared with the unaided baseline threshold, averaged from 2 to 10 kHz (i.e., the functional gain). Each test ear was isolated and tested separately in a ''functional gain mode'' on the Processor, which was programmed to provide linear insertion gain (expansion and compression disabled) with noise reduction and directional microphones disabled but feedback cancellation enabled.

Additional Secondary Efficacy Endpoint—Speech in Noise

Another secondary efficacy endpoint was statistically significant improvement in aided Hearing in Noise Test (HINT) scores (14) for the study population at the 30-day interval, compared with the unaided baseline case. This was a bilateral per-subject measure with both ears tested at the same time, and was assessed by comparing the aided HINT 90 speech reception thresholds (SRTs) to the baseline unaided condition. SRTs were measured using HINT materials with the signal (speech presented at 0 degrees) adapted relative to the noise (presented at 90 degrees and held fixed at 60 dB SPL). HINT 90 was measured twice, once with the noise 90 degrees to the right and once with the noise 90 degrees to the left, and the two SRTs were averaged to obtain the per-subject HINT SRT.

Additional Efficacy Assessments

Self-perceived hearing difficulty was measured for all participants using the Abbreviated Profile of Hearing Aid Benefit (APHAB (15)) at the beginning of the study relative to unaided hearing, and again at the 120-day measurement interval. The global benefit scores (average of the three subscales for ease of communication [EC], background noise [BN], and reverberation [RV]) were calculated as the difference between the unaided and aided global score for each subject. Scores for each subscale are also reported. Additionally, an internally developed Patient Satisfaction Study Exit Questionnaire was administered at the 120-day measurement interval for all participants, and a subset of the results is reported.

Statistical Analysis Methods

This single-arm open-label study uses each subject's unaided hearing as his/her own control.

RESULTS

Primary Safety Endpoint—Audiometric Safety (Baseline and 120-Day PTA4 Measurements)

For the 43 evaluable subjects (86 ears), the mean PTA4 hearing level decreased by only 0.4 dB after wearing the CHA for 120 days (Fig. 2), which is a statistically significant endpoint ($p < 0.0001$).

Safety Assessment—Adverse Events

All events that were determined to be possibly, probably, or definitely related to the device or associated procedures, such as the deep ear-canal impressions performed before device manufacture, are presented in Table 2. There were no serious device- or procedure-related adverse events and no reports of unanticipated device effects. Of the 48 subjects (96 ears), a total of 31 related adverse events were experienced by 20 subjects in 22 ears. All but one of the reported events were temporary and resolved. The study was conducted under the oversight of an NIH-appointed Data and Safety Monitoring Board (DSMB), and an independent medical otologist. The DSMB reviews confirmed that the description, management, and relatedness of all reported adverse events were appropriate. The independent medical otologist also reviewed all adverse events for relatedness and severity.

Primary Efficacy Endpoint—Word Recognition

The unaided word-recognition scores reflect the baseline scores of the study population, which contained some subjects with only mild impairment in the low to mid frequencies who consequently received high unaided baseline scores. Even with those mildly impaired subjects