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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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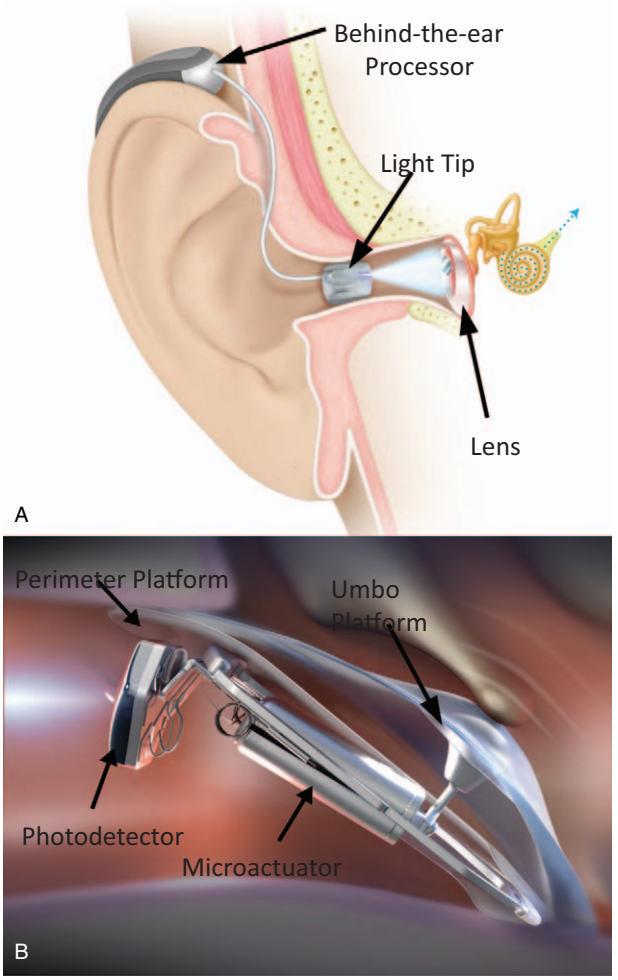

FIG. 1. *A,* The light-driven contact hearing aid (CHA), with its behind-the-ear sound processor (Processor); Light Tip, which aims a beam of encoded infrared light toward the tympanic membrane (TM); and Tympanic Lens (Lens) at the base of the ear canal, which receives the light signal and converts it 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

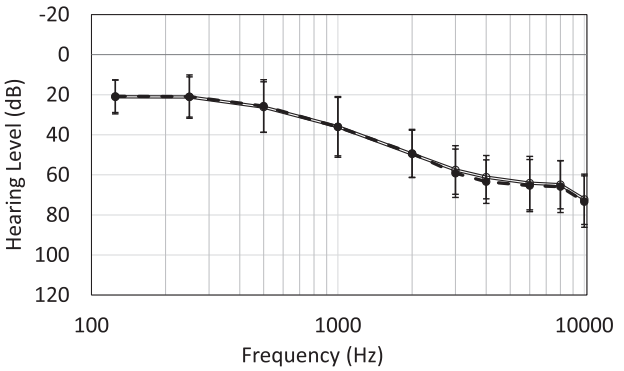

FIG. 2. Mean and standard deviation of the unaided hearing thresholds of the 43 evaluable participants, each averaged across right and left ears (86 evaluable ears), as calculated for the baseline measurements before CHA placement (*open line*) and for the measurements after CHA removal at the end of 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

TABLE 2. *All device- or procedure-related adverse events reported in the pivotal study, as categorized and rated by the study physicians and reviewed for accuracy by the Data and Safety Monitoring Board and the independent medical otologist*

Adverse Event Category	Number Occurring	UADE?	Serious AE?	Severity	Status
Abrasion/blood blister in ear canal	17	No	No	Mild	Resolved
Ear discomfort/pain	5	No	No	Mild/moderate	Resolved
Inflammation/granulation tissue on tympanic membrane	3	No	No	Mild	Resolved
Abrasion/blood blister on tympanic membrane	2	No	No	Mild	Resolved
Light Tip-related: ear canal swelling, itching, etc.	2	No	No	Mild/moderate	Resolved
Pain upon eructation and the Valsalva maneuver	1	No	No	Mild	Resolved
Sensation of fullness	1	No	No	Mild	Unresolved

None of the adverse events (AEs) were deemed to be unanticipated device effects (UADEs), none were serious, all were mild to moderate in severity, and all but one were resolved. The ongoing adverse event of the sensation of fullness is reported as unresolved because the subject was still continuing to wear the device at the conclusion of the study.

experiencing minimal improvement in word recognition due to the ceiling effect, the analysis shows that aided performance is still significantly improved over unaided performance across the study population of 39 evaluable subjects (78 evaluable ears), as expected, with a mean improvement in aided over unaided word-recognition scores of 34.9 rationalized arcsine units, or 33.4%, as shown in Figure 3, which was met with statistical significance ($p < 0.0001$).

Secondary Efficacy Endpoints

Functional Gain

While this secondary endpoint emphasizes higher frequencies due to the extended amplification range (through 10,000 Hz) of the CHA, subjects received gain at each frequency depending on the magnitude of their hearing impairment, as prescribed by the fitting algorithm. As shown in Figure 4, low-frequency gain with the CHA was not evident on average, due to the mean unaided low-to-mid-frequency hearing levels of ~20 dB. The observed dip at 500 Hz reflects a narrow Lens-related notch in the frequency response due to the resonance of the springs. As with AC hearing aids, individuals treated with the CHA were prescriptively provided gain at the frequencies where it was needed.

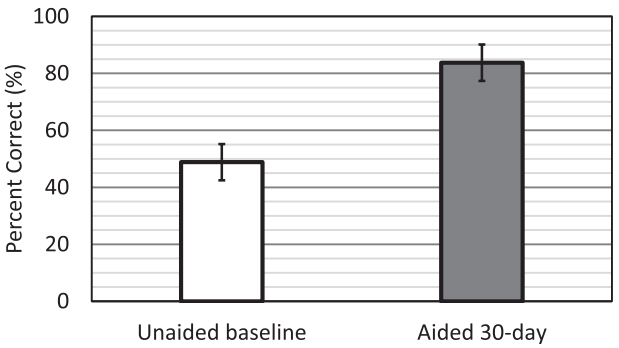

FIG. 3. Mean and standard deviation of word-recognition scores for the 39 evaluable subjects, each averaged across right and left ears (78 evaluable ears) and measured using NU-6 50-word lists, for the baseline unaided case (*open bar*) and the aided condition at the 30-day efficacy measurement interval (*shaded bar*).

Evidence of the ability of the CHA to provide adequate gain across a broad spectrum of frequencies (measured from 125 to 10,000 Hz) for the 39 evaluable subjects (78 ears) is shown in Figure 5. The secondary effectiveness endpoint, consisting of the average functional gain in the 2 to 10 kHz range, was 30.5 dB ($p < 0.0001$). Functional gain was also measured at the final (120-day) study interval, confirming its stability over time (not shown). The maximum gain provided by the CHA, for all subjects and at all frequencies, is plotted along with the mean and standard deviation of the functional gain in Figure 5. The difference between the maximum and mean gain from 125 to 2000 Hz varies between 16 and 27 dB. The mean functional gain experienced by users above 6 kHz was 30 to 40 dB, and the overall maximum functional gain was 68 dB, at 9 to 10 kHz.

Speech Understanding in Noise with an Omnidirectional Microphone

For the 39 evaluable subjects, the mean improvement in aided over unaided HINT SRTs at 30 days was 0.75 dB (Fig. 6). Note that for HINT scores, a lower, more negative score reflects better performance. This secondary effectiveness endpoint missed statistical significance, with a p value of 0.028 (the endpoint was $p < 0.01$).

Speech Understanding in Noise with a Directional Microphone

Although statistical significance was not reached for this secondary endpoint at 30 days, the protocol included another HINT measurement to be made at the 120-day interval. At that interval, the sites were instructed to activate the directional-microphone feature in the Processor programs. The data for the 37 evaluable subjects is also provided in Figure 6. The improvement in the aided 120-day scores relative to the baseline unaided scores was on average 3.03 dB, which was statistically significant using a repeated-measures analysis of variance, with a p value of <0.0001.

Additional Efficacy Assessments—APHAB Scores and Patient Satisfaction

The self-reported APHAB global benefit score for 38 evaluable subjects with the CHA was on average 28.0,

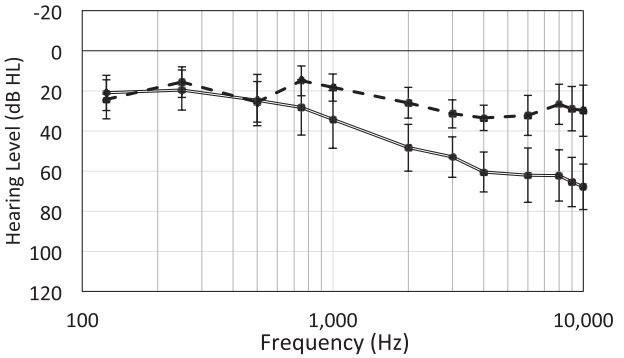

FIG. 4. Mean and standard deviations of soundfield hearing thresholds for the 39 evaluable subjects, each averaged across right and left ears (78 evaluable ears), measured at the baseline unaided interval (*open line*) and aided at the 30-day efficacy measurement interval (*dashed line*).

indicating significant reduction in self-perceived communication difficulties from wearing the CHA relative to unaided listening. The mean unaided preplacement scores for the APHAB subscales were: 46.9, 65.7, and 60.5, for the respective EC, RV, and BN subscales. The aided scores from the 30-day measurement interval were: 20.4, 31.1, and 36.0 for the same respective subscales.

All 43 subjects completed the Patient Satisfaction Study Exit Questionnaire upon exiting the study at 120 days. The majority of subjects reported that they were satisfied with their ability to understand speech in noisy environments with the CHA, as compared with unaided listening (88.4% responded Satisfied or Very Satisfied when presented with the following six-choice scale: Very Satisfied, Satisfied, Slightly Satisfied, Slightly Unsatisfied, Unsatisfied, and Very Unsatisfied). Overall, most subjects were also satisfied with the quality of sound delivered by the CHA, as compared with unaided

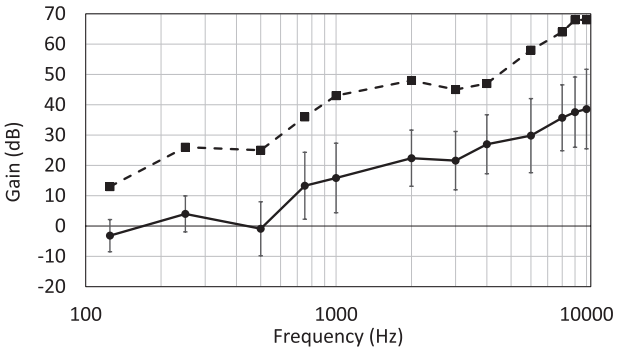

FIG. 5. Mean and standard deviation of the functional gain of the CHA for the 39 evaluable subjects (*solid line*), each averaged across right and left ears (78 evaluable ears) and computed by subtracting the aided soundfield hearing thresholds measured at the 30-day interval from the baseline unaided soundfield hearing thresholds measured before CHA placement. Also shown is the maximum measured functional gain for all subjects and at all frequencies (*dashed line*), corresponding to the same measurement intervals. Note that the measured functional gain for each subject is related to his/her prescribed gain, which is based on their hearing loss.

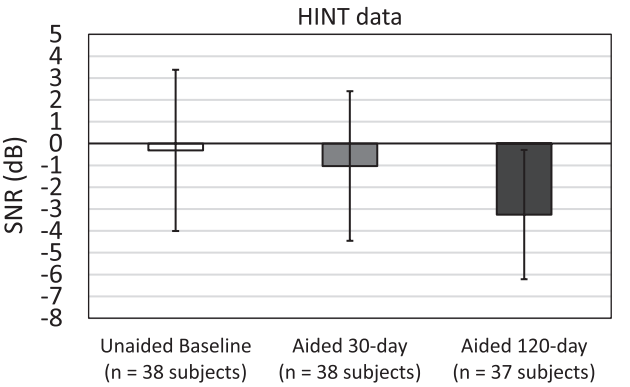

FIG. 6. Mean and standard error of the mean of the Hearing in Noise Test (HINT) scores, for the evaluable subjects, expressed as dB signal-to-noise ratio (SNR) thresholds for understanding 50% of sentences correctly. Three measurement intervals are shown: the baseline unaided condition (*open bar*), aided 30-day interval with the Processor in omnidirectional microphone mode (*light-shaded bar*), and aided 120-day interval with the Processor in directional microphone mode (*dark-shaded bar*).

listening (88.4% responded Satisfied or Very Satisfied on the six-choice satisfaction scale), and found that their devices improved their overall quality of life, compared with unaided listening (76.7% responded Improved or Very Much Improved on a similar six-choice scale).

DISCUSSION

Safety—No Change in Unaided Hearing

The safety endpoint confirmed that use of the CHA resulted in no change in residual hearing over the measured interval of wear. The mean change was well within standard test-retest error. There were no serious or unanticipated procedure/device-related adverse events, and the related adverse events were generally mild and temporary in nature. The clinical audiograms and observational safety data from the study indicate that the CHA provides a reasonable assurance of safety for its intended use.

Efficacy—Improvement in Word Recognition

Efficacy of the CHA system was assessed using standardized audiologic test metrics (word recognition, functional gain, and HINT scores). The mean improvement in word recognition over the unaided case was statistically significant, demonstrating the CHA's effectiveness at providing sufficient amplification to improve speech understanding over unaided listening. In meeting the primary effectiveness endpoint of word recognition in quiet, the CHA system has provided a reasonable assurance of effectiveness of the device.

The secondary endpoint of improved speech understanding in noise (Fig. 6) did not achieve statistical significance at the 30-day measurement interval, but came very close. When the directional microphones were enabled at the 120-day visit, however, the aided-over-unaided improvement was significant, providing an

expected 3 dB of improvement with the use of the directional microphones.

Efficacy—Functional Gain

Functional gain was significantly increased over the unaided baseline, demonstrating the device's capability of providing broad-spectrum amplification from 125 to 10,000 Hz. Functional gain in itself is not a direct measure of benefit, but provides verification that substantial amplification is being delivered to the user. The functional gain of the CHA is especially notable at high frequencies, where it is intended to provide increased audibility relative to conventional AC hearing aids, although direct functional-gain comparisons between the CHA and AC hearing aids were not measured as a part of this study. The greatest amount of gain that was measured by the device, 39 dB on average, and up to 68 dB maximum, occurred from 9 to 10 kHz (Fig. 5), which is unachievable using current AC hearing-aid technologies (1–4).

The present Gen 0.1 results can be compared to surgically implanted devices (5). The average functional gain (FG) for the MedEl FMT at the round window decreased from a peak of about 43 dB at 2 kHz to 27 dB at 6 kHz (16), and for the MET system the FG decreased from 36 dB at 2 kHz to about 28 dB at 6 kHz (17). The average FG with the Esteem system decreased from a peak of 36 dB at 2 kHz to 6 dB at 8 kHz (18). While these implantable devices provide large gains in the mid-frequency region, the CHA provides significantly higher FG as the frequency increases to 10 kHz, which is an important capability, as these large gain values are called for by fitting algorithms at the higher frequencies (7), and may contribute to improved speech understanding in the presence of spatially separated maskers (19).

The ability and willingness of subjects to accept and appreciate such large prescribed gains beyond those available in AC hearing aids has been a point of debate. However, aided soundfield measures and word-recognition scores at the final (120-day) test interval confirm functional stability of the system in spite of continued use of the gain prescriptions, including adjustments made for comfort. The self-reported substantial improvement in the APHAB scores and the reported satisfaction provide additional support for the perceived efficacy.

In the previous study using the Alpha version of the CHA (9), the average functional gain from 6 to 10 kHz was approximately 22 dB, with a maximum across all subjects of 46 dB, which is less than that of the present Gen 0.1 system. This is partly because the prescribed gain in the Alpha study was limited to 40 dB and compression was enabled, which limits the gain at the higher input levels, whereas in the current study the amount of insertion gain prescribed was dependent only on the individual gain prescription and feedback, and not artificially limited in the software.

Perception of One's Own Voice

There are two mechanisms that lead to a perception that could be described as occlusion, or autophony, which is the increased perception of one's own voice. The first is the classic occlusion effect due to acoustic plugging of the ear canal, for example with a closed-ear-canal hearing aid. The second is due to loading of the middle-ear structures including the eardrum. In the Earlens System, classic occlusion is reduced due to the widely vented Light Tip (Fig. 1A). However, the eardrum is loaded by the mass and bias-spring stiffness of the Lens. The loading of the eardrum by the Lens causes unaided hearing to be damped when the device is turned off, but the damping effect is not noticeable when the device is active. Mass loading of the eardrum is known to change the sensitivity of the bone-conduction pathway, which can lead to autophony (20). This perceptual effect varies from subject to subject, and occurs to different degrees ranging from never noticeable to noticeable even with active amplification. Some subjects adapt to the autophony, while others do not. Most subjects do not find this experience to be unpleasant and rarely discontinue use of the device for this reason.

Future Development

The Gen 0.1 version of the CHA demonstrated improved performance over the Alpha version tested in the feasibility study (9). However, there is room for additional improvements to the CHA on the path to commercialization. These include reduction of cost, manufacturing improvements for scalability, demonstration that the device can stay on the ear for a significantly longer period of time than what was investigated in this study (120 days), obtaining labeling approval for having the Lens in place continuously for more than 1 year, and further improving the Processor's features and software. Additionally, the Lens-related notch at 500 Hz should be corrected.

CONCLUSIONS

The study results support a reasonable assurance of safety and effectiveness for the CHA system in treating the intended target population of hearing-impaired individuals, based on 48 subjects and three clinical sites. The improved Gen 0.1 CHA design can be worn outside of the clinic, unlike the previous Alpha version, therefore allowing information related to normal daily use of the device to be collected. The functional gain demonstrated by the CHA up through 10 kHz exceeds what has been reported for conventional AC hearing aids and implantable hearing aids. Future studies should perform careful comparisons between other devices and the CHA, to establish whether the broad-spectrum amplification of the CHA provides additional benefits over those devices in terms of sound quality and speech understanding.

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