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Preliminary Evaluation of a Light-Based Contact Hearing Device for the Hearing Impaired

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Objective: To assess the safety, stability, and performance of the broad-spectrum, light-based contact hearing device (CHD) on listeners with hearing impairment.
Study Design: Feasibility study.
Setting: Single-site research and development facility.
Participants: Thirteen participants with symmetric mild-to-severe sensorineural hearing impairment had the CHD placed bilaterally.
Intervention: A custom-molded light-activated tympanic contact actuator (TCA) was placed into each ear by a physician, where it stayed in contact with the umbo and a portion of the medial wall of the ear canal for 4 months. Each CHD was calibrated and programmed to provide appropriate broad-spectrum amplification.
Main Outcome Measures: Safety was determined through routine otologic examinations. Aided and pre-TCA-insertion unaided audiometric thresholds (functional gain), maximum gain before feedback, tympanic membrane damping, Reception Threshold for Sentences (RTS), and Abbreviated Profile of Hearing Aid Benefit (APHAB) measurements were made to characterize system performance as well as the benefits of amplification via the CHD.
Results: The TCAs remained on participants' ears for an average total of 122 days, without causing signs of inflammation or infection, and there were no serious device-related adverse events. Measured average maximum output of 90 to 110 dB SPL in the range of 0.25 to 10 kHz, average maximum gain before feedback of 40 dB, and functional gain through 10 kHz show extended-bandwidth broad-spectrum output and gain. RTS results showed significant aided improvements of up to 2.8 dB, and APHAB results showed clinically significant aided benefits in 92% of participants (11/12).
Conclusion: The safety, stability, and performance demonstrated in this initial 4-month study suggest that the CHD may offer a feasible way of providing broad-spectrum amplification appropriate to treat listeners with mild-to-severe hearing impairment.
Key Words: Contact hearing device—Hearing in noise test—Hearing in speech test—Microactuator—Photonic hearing system—Sensorineural hearing impairment.

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Two of the most frequently reported problems by the users of air-conduction hearing aids are difficulty understanding speech in noisy environments, especially in the presence of competing speech, and unsatisfactory sound quality, particularly when listening to music (1,2). Although hearing above 5,000 Hz has been shown to improve speech understanding in complex listening environments (3) and improve perceived sound quality (4), the inability of hearing aids to amplify these frequencies effectively (5,6) has prompted a search for alternate designs that can, without compromising comfort or safety, provide the broad spectrum necessary for a richer and more pleasurable listening experience. This article presents the results of an initial feasibility study for one such alternate design: the light-based contact hearing device (CHD).

THE CONTACT HEARING DEVICE

The CHD is an open-canal hearing device designed to have a frequency range of 0.1 to 10 kHz, which is intended for patients with mild-to-severe hearing impairment. In contrast to the operation of a hearing aid, in which amplified acoustic energy is input into the ear canal via a small loudspeaker, the CHD involves the mechanical vibration of the tympanic membrane (TM) via a custom-tailored light-activated wireless actuator placed in the medial end of the ear canal by a physician such that it can maintain comfortable physical contact with the umbo over an extended period. Mechanical vibration of the TM is believed to offer the advantages of an open-canal hearing aid design, while at the same time being less susceptible to acoustic feedback (7) and potentially broadening the

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frequency range significantly at both low and high frequencies (reviewed in (8)).

Components of the Contact Hearing Device

The CHD has 2 primary components: 1) the light-generating behind-the-ear unit (BTE) and 2) the light-activated tympanic contact actuator (TCA). Figure 1 shows the entire CHD, including the TCA and the BTE. The TCA, composed of 6 subcomponents, is held in place by a custom-molded peritympanic platform shaped to fit an individual's medial ear-canal anatomy and by surface tension because of a layer of mineral oil between the contact lens–like umbo platforms and the TM surface. The applied layer of mineral oil allows the device to float above the skin of the anterior sulcus, the peritympanic surface, and the umbo. This makes it possible for the epithelial tissue (9,10) underneath the device to migrate without causing irritation or unwanted dislodging of the TCA. The small forces from the biasing mechanism further enable the umbo platform and attached microactuator (Fig. 2) to maintain contact with the TM, in spite of TM flexion due to naturally occurring events such as swallowing, eructation, coughing, or postural changes.

OBJECTIVE AND STUDY DESIGN

This initial feasibility study was intended to test the safety, stability, and performance of the CHD when placed bilaterally on participants with sensorineural hearing impairment. The study populations were not randomized, in that a participant's unaided results served as the control for that participant's CHD-aided results. This was also not designed to be a comparative study to air-conduction hearing aids. The study protocol was approved by the Food and Drug Administration (FDA) and the Western Institutional Review Board (Olympia, WA, USA). The prototype BTE had a short battery life of approximately 4 hours, and IDE approval from the FDA was for limited use. Consequently, participants were not permitted to wear the BTE component without the supervision of the investigators, and they typically had use of the fully activated CHD in the clinic only.

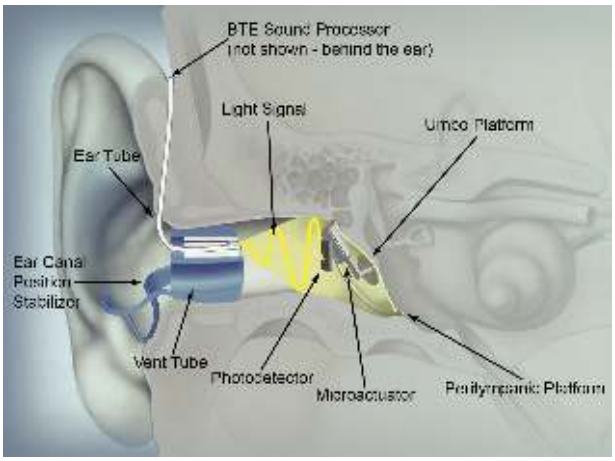

FIG. 1. The light-based contact hearing device (CHD), shown *in situ*. A prototype of the light-generating behind-the-ear unit (BTE) is shown, which consists of a sound processor (not shown) that contains microphones, a digital signal processor, a battery, and a low-power laser diode that emits encoded infrared light (with a wavelength of 1,480 nm); an ear tube for transmitting the light to the ear canal; and an ear canal position stabilizer for holding the ear tube in place while keeping the ear canal open and well vented. The encoded light shines onto the tympanic membrane (TM) to provide both power and signal to activate the tympanic contact actuator (TCA).

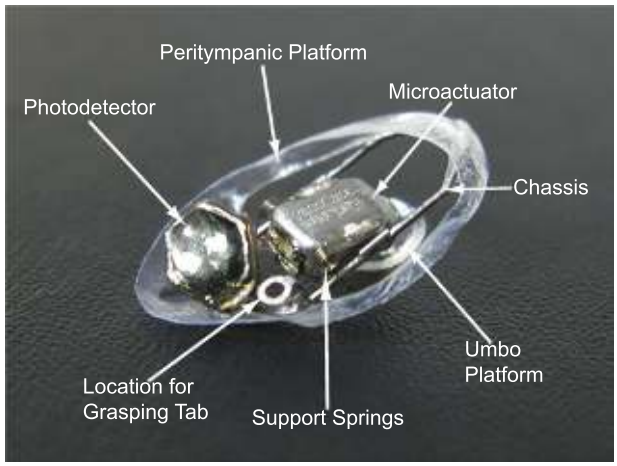

FIG. 2. A close-up photograph of a TCA and its subcomponents, composed of the following: 1) a peritympanic platform with a chassis, to provide structure to the device and hold it in place by fitting above the rim of the TM and along the medial wall of the ear canal; 2) a photodetector to receive the light and convert it into electrical energy; 3) a microactuator to convert the electrical energy from the photodetector into mechanical motion (an electrokinetic actuator), which is similar to the receivers used in hearing aids, although it is smaller and has an impedance optimized to drive the TM rather than a speaker diaphragm; 4) an umbo platform to contact and directly vibrate the TM; 5) a biasing mechanism consisting of a pair of support springs, to allow flexibility in the structure between the chassis and microactuator; and 6) a physician's grasping tab for placement and removal of the device. For scale, the chassis is typically 9 mm long, and the microactuator is 3.5 × 2.5 × 1.5 mm.

METHODS

Participants

Inclusion and Exclusion Criteria

Inclusion/exclusion audiometric criteria are summarized in Table 1. Audiometric thresholds (125–11,200 Hz) were measured using a GSI 61 (Eden Prairie, MN, USA) audiometer with extended frequency range, and testing was performed with circumaural headphones.

Enrollment and Demographics

Eighteen participants, consisting of 10 males and 8 females were initially enrolled in the study. One participant exited because his anatomy determined by manufacturing to be was too restricted to accommodate a TCA, and 4 participants withdrew because of personal changes and their inability to meet the time requirements necessary to complete the study. The mean age of the

TABLE 1. *Inclusion and exclusion criteria for the light-based contact hearing device study*

Inclusion criteria

- Participants of either sex (male or female) must be 18 years of age or older.
- The participant must be able and willing to commit to the travel and time demands of the study (for 4 months or longer).
- The participant must be a native speaker of American English, because of the use of English language test materials.
- The participant's audiometric thresholds for both ears in decibels (dB) hearing level (HL) must fall within the target fitting range shown below (inclusion criteria allow 1 test frequency to fall outside the range):

Frequency (Hz)	125	250	500	750	1,000	1,500	2,000	3,000	4,000	6,000	8,000	10,000
HL min (dB)	0	0	0	0	0	7.5	15	22.5	30	30	30	30
HL max (dB)	60	60	60	63	66	70	73	76	80	80	80	80

- The participant must have no more than 10 dB HL of air-bone gap between 250 and 4,000 Hz (no conductive hearing impairment), with an allowable exception at one frequency.
- The participant's thresholds for the right and left ears must be within 15 dB HL of each other between 250 Hz and 8 kHz (symmetric hearing impairment), with an allowable exception at 1 frequency.
- The participant's performance must be 70% or greater on clinical speech discrimination.
- The participant must exhibit normal Type A tympanometry (indicating normal mobility of the tympanic membrane and middle-ear bones).
- The participant must be tolerant to tones presented at 10 dB above threshold to ensure a minimum 10-dB dynamic range between 250 Hz and 10 kHz.

Exclusion criteria

- The participant cannot have a tympanic membrane that is perforated or inflamed, has a dimeric or monomeric area, or is in any other way deemed abnormal as determined by visual inspection by the study physician.
- The participant cannot have a rapidly progressive or fluctuating hearing impairment (e.g., Ménière's disease), or a history of recent dizziness or vertigo.
- The participant cannot have a history of previous middle-ear surgery other than tympanostomy tubes.
- The participant cannot have a history of chronic and recurrent middle-ear or external-ear infections or have had an ear infection within the past 12 months.
- The participant cannot have ear anatomy that prevents the study physician from easy visual inspection of the umbo and manubrium in the ear canal.
- The participant cannot be planning on taking or currently taking medications/treatments with known ototoxic effects or properties.
- The participant cannot have been diagnosed as having a compromised immune system (including insulin-dependent diabetes mellitus), keratosis obturans, ichthyosis, eczema of the auricle or ear canal, nor can the participant have received radiation therapy to the head or chemotherapy for cancer within the last 6 months.
- The participant cannot have unrepeatable audiograms (audiometric thresholds between 250 and 10,000 Hz greater than 10 dB apart on repeated testing).
- The participant cannot fit the definition of a vulnerable participant, as per FDA regulations 21 CFR Parts 50 and 56.
- The participant must be able to follow simple instructions during clinical tasks, based on the discretion of the investigators.

remaining 13 participants (8 males and 5 females) included in the full analysis set was 71 years, with a range of 50 to 87 years. The results and analyses presented here are based solely on the 13 participants (26 ears with placements) from whom complete data sets were obtained (unless otherwise stated).

The right and left preinsertion unaided audiograms for each participant are plotted in Figure 3, with the mean audiograms for each ear and the inclusion criteria overlaid for reference.

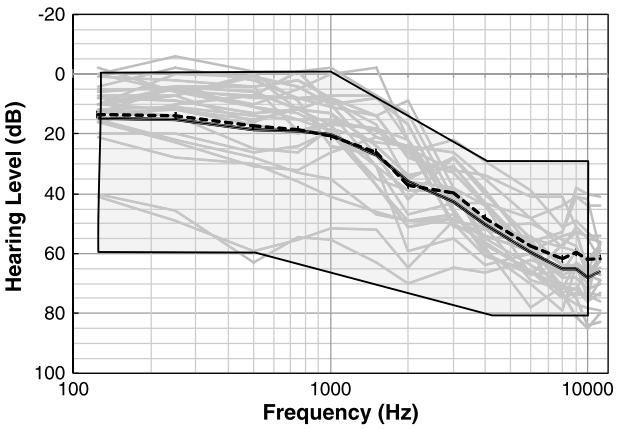

FIG. 3. Audiograms for all right and left ears (*light gray lines*), the mean of all right ears (*thick line*) and left ears (*dashed line*), along with the inclusion criteria (*shaded and outlined area*) from Table 1.

Intervention

TCA Placement

The shape of the peritympanic platform that surrounds the TM and provides positional stability was customized for each ear using a deep impression of the ear canal and TM obtained at the start of the study. After all of a participant's baseline unaided preinsertion tests were completed, the physician inserted and placed an appropriately customized TCA in each ear through a speculum. Approximately every week, the physician placed a drop of mineral oil in each ear canal, to keep the interface between the slowly migrating epithelium and the umbo and peritympanic platforms well lubricated.

CHD Calibration and Programming

After placement of the TCA, the BTE was used to activate the system to obtain light-driven hearing thresholds for the CHD of each ear. These thresholds were then compared with the participant's preinsertion unaided air-conduction audiometric thresholds to obtain calibration curves characterizing the transfer function from the light output of the ear tube to the air-conduction-driven perception of sound at the TM. The preinsertion unaided air-conduction audiometric thresholds were also used as inputs to a fitting algorithm based on the high-frequency CAM2 algorithm (11), which produced prescriptions for gain and compression ratios at audiometric frequencies from 125 to 10,000 Hz that were then programmed into the BTE devices along with the calibration curve. With those settings in place for both ears, the CHD devices were activated using their omnidirectional

microphone mode to obtain the aided sound-field thresholds and speech-testing thresholds (described later).

Main Outcome Measures

Safety and Stability

Safety and positional stability of the TCA over the course of the study was determined from initially weekly then monthly medical otologic examinations throughout the total wear time, supplemented by endoscopic videos.

Maximum Equivalent Pressure Output

The calibration curves were used along with known system specifications to calculate the maximum output and effective bandwidth of the system (12), which is represented in terms of the maximum equivalent pressure output (MEPO) on the ear. Because of the way MEPO values are calculated, they are representative of the system's behavior independent of the hearing level of the ear.

Maximum Gain Before Feedback

With the BTE placed on a participant's ear, a feedback measurement was made by driving the TCA with a swept-tone light input from the BTE and recording the resulting pressure at the BTE-microphone location (the movements of the TM produce sound waves that travel back into and out of the ear canal [7]) using a probe-tube microphone (Etymotic, ER-7C). This measurement was then used to calculate (see 12) the maximum gain that could be applied to an input signal before generating positive acoustic feedback, i.e., the gain before feedback, which is a function of the individual's anatomy but does not depend on their hearing level.

Functional Gain

Functional gain is calculated as the difference between the soundfield audiometric thresholds measured unaided before TCA placement and measured aided after the CHD is activated. It is a perceptual reflection of the prescribed gain at each frequency, which is dependent on the hearing level of the participant.

TM Damping

Because the TCA is placed in contact with the TM, it is likely that unaided air-conduction thresholds with the passive TCA in place will differ from unaided air-conduction thresholds without it in place. These effects are represented by the TM damping, which was determined (from 125 to 11,200 Hz) by obtaining the unaided air-conduction thresholds after TCA placement (without it being activated) and subtracting the unaided air-conduction thresholds obtained before placement.

Speech Recognition Testing

The hearing in noise test (HINT) is a standard metric that quantifies a participant's ability to understand speech in the presence of steady-state noise (13,14). Two HINT conditions were tested: a ''colocated'' condition with masking noise and target speech presented from directly ahead of the listener (0 degrees), and a ''separated'' condition with the target speech presented from 0 degrees, whereas the masking noise is presented from 90 degrees to the right of the listener. All speech tests were performed for the unaided case before TCA insertion, as well as for the CHD-aided

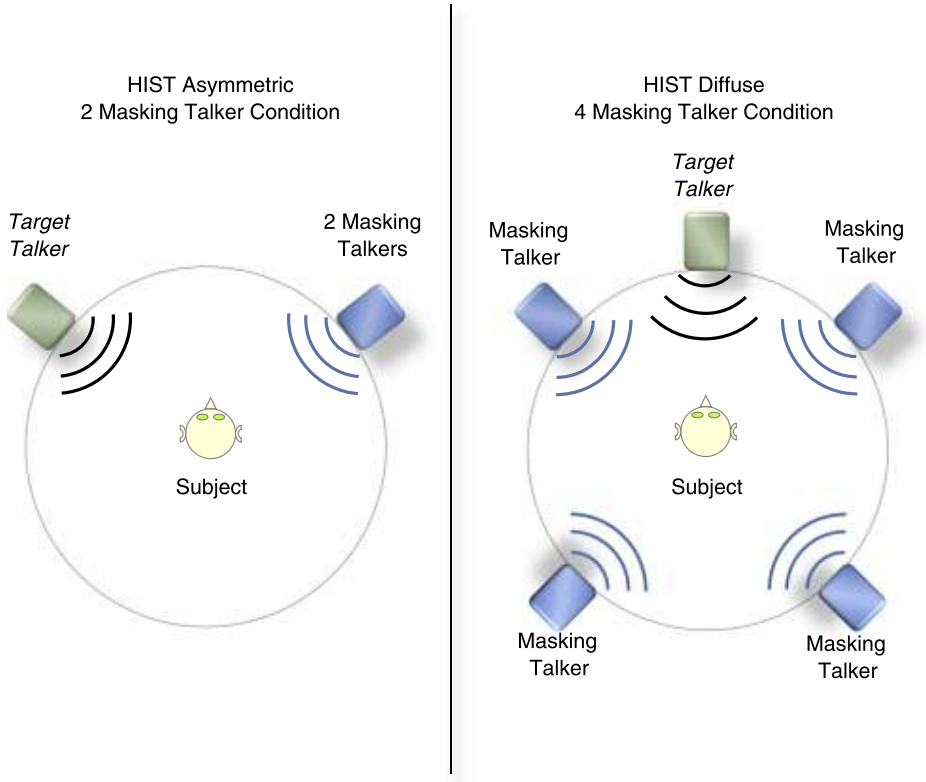

FIG. 4. Hearing in speech test (HIST): (left) asymmetric (target at −45 degrees and 2 masking talkers at +45 degrees) and (right) diffuse (target at 0 degree, 4 masking talkers at +/−45 degrees and +/−135 degrees) conditions.

case. The stimuli were presented in a sound booth through speakers 1 m away from the listener, and the metric of interest was the Reception Threshold for Sentences (RTS), or the speech level at which the participant correctly repeated 50% of the target sentences in the presence of a 65 dB masker.

The Hearing in Speech Test (HIST) is a similar test to the standard HINT, except the masking signals are other talkers instead of steady-state noise, as described in Puria et al. (15). The HIST speech materials include sound energy covering the full 20 kHz bandwidth range of human hearing, whereas the HINT noise is limited to frequencies below 8 kHz. Two HIST conditions were evaluated: an ''asymmetric'' condition with the target speech presented from 45 degrees to the left of the listener and speech from 2 masking talkers presented from 45 degrees to the right and a ''diffuse'' condition with the target speech presented from straight ahead (0 degrees) and speech from 4 masking talkers presented from ± 45 and ± 135 degrees. Figure 4 illustrates these 2 HIST conditions.

APHAB Questionnaire

Participants were asked to fill out an Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire (16,17) to assess the self-perceived benefit from amplification, measured as their unaided score using the activated CHD minus their aided score before the TCA was placed.

Data Analysis

For measures of performance, mean and standard deviation (SD) or standard error (SE) were computed. For speech testing, the mean and SE were computed, and a repeated measures analysis of variance (ANOVA) was used, with $p < 0.05$ considered statistically significant.

RESULTS

Otologic Results

See Table 2 for a summary of otologic results, and see Figure 5 for representative photos from one participant of both ears before and after initial placement of the TCA device, as well as before and after removal of the device after wearing it for 4 months. See Table 3 for a summary of all adverse device effects and adverse events.

TABLE 2. *Summary of otologic results for 13 participants with complete data sets*

1. Deep canal impression procedure	
Description	To make a custom mold for the TCA, a deep canal impression was taken at the beginning of the study for each ear.
Known Complications	The procedure is known to cause discomfort, abrasions of the canal, and small hematomas (or blisters) on some people.
Results	• On 22/26 ears, the removal was reported by the physician to be smooth and uncomplicated. • On the remaining 4 ears (2 participants), the physician reported mild to moderate resistance to removal and blisters formed.
Blisters	When blisters occurred, they were bilateral, suggesting a relationship to anatomic factors, fragility of the skin, or a combination of both. All participants who developed a blister on one side opted to proceed with the second side.
2. TCA placement procedure	
Description	The physician inserted a TCA into both ears of each participant using a speculum.
Manipulation	• On 8/13 participants, placement of the customized TCA required minimal manipulation by the physician. • On the remaining 5 participants, moderate manipulation was required.
Pain or discomfort	• 10/13 participants reported no pain or discomfort from the procedure. • 3/13 participants reported mild transient pain or moderate transient discomfort during the procedure, which subsided shortly afterward.
3. TCA positional stability	
Description	Positional stability was analyzed by summarizing the physician's observations made during each otologic exam. Exams occurred every week at the start of the study, and continued on a monthly basis through the end of the 122 ± 14 day protocol.
Wear time	The average total on-ear wear time was 122 days. The devices remained in place without interruption for an average of 117 straight days.
Displacements	There were a total of 4 displacements on 3 participants because of 3 determined causes: insufficient oiling of the TCA in both ears of the first participant, epithelial material under the peritympanic platform in 1 ear of the second participant, and improper fit of the peritympanic platform of the TCA in 1 ear of the third participant.
Analysis of displacements	The displacements all consisted of <1 mm of lift of the platform from the canal wall, and none of the devices migrated completely out of position. The participants reported no awareness or sensation associated with the displacements. No devices were observed to have been dislodged because of activities such as flying in a plane or swimming, activities in which several participants took part.
4. TCA device removal procedure	
Description	The physician removed the TCA from each ear at the end of the study with the aid of the grasping tab on the TCA (Fig. 2).
Manipulation	On 13/13 participants, minimal manipulation was required to remove the device.
Pain or discomfort	13/13 participants reported no pain or discomfort during the removal procedure.
5. Summary of safety of TCA and adverse events	
No serious device-related adverse events were seen over the course of the study. Of the 26 ears for which the long-term wear of the TCA was completed, no evidence of inflammation, perforation, infection, or injury to the ear canal, TM, or middle ear related to the study was observed by the physician over the total wear time (see Fig. 5 for example photos). This was the case for all placements, removals, and periodic examinations of the TCA. See Table 3 for all Adverse Device Effects and Adverse Events.	

FIG. 5. Endoscopic photos of a representative participant's right and left ear canals at the beginning of the study immediately before TCA placement (first column), immediately after TCA placement (second column), as well as at the end of the study, after 4 months (118 days) of wear, immediately before TCA removal (third column), and immediately after TCA removal (fourth column).

Measured Results

Maximum Equivalent Pressure Output

The maximum equivalent pressure output (MEPO) of the CHD system, at approximately 1% distortion, is shown in Figure 6 in terms of the mean ± SD of the values acquired for the 26 ears (independent of hearing level) from 125 to 11,200 kHz. The highest value is 110 ± 10 dB SPL at 6 kHz, and the mean stays above 105 dB SPL from 1 to 10 kHz. The minimum and maximum measured MEPO values lie about 13 dB away from the average across all frequencies. Bench tests show that this variability comes from differences in the efficiency of the optical coupling between the end of the ear tube and the TCA (because of anatomic differences, ±8 dB) and from transducer variability (±3 dB). Perhaps the most important variability comes from the middle-ear input impedance at the umbo, which is expected to be on the order of ±10 dB (18). Because the TCA operates by vibrating the umbo, this middle-ear impedance variability is included in the calibration curves and thus the MEPO. This source of participant variability occurs with the use of air-conduction hearing aids as well but is not apparent from fixed acoustic-coupler measurements that do not relate measured pressure to perceptual thresholds (19).

The sound pressure levels corresponding to the maximum hearing impairment still satisfying the inclusion criteria of the study (Table 1), to the mean hearing impairment of the participants in the study, and to a person with ''normal'' hearing (20) are plotted underneath the MEPO for comparison in Figure 6. Comparing the sound pressure level curve for the maximum hearing impairment criteria with the mean MEPO minus 1 SD, it can be seen that the system is likely to provide adequate audible output for the maximum allowable hearing impairment for every frequency up to 10 kHz, with the exception of 125 Hz.

Maximum Gain

The maximum available gain before feedback (GBF) at the BTE is shown in Figure 7 for 26 ears, along with the mean and SD. Below 670 Hz, the measurement is limited by the noise floor, but the maximum GBF is still expected to be higher than the hatched lines (>55 dB) because at those frequencies, the delays in the system are too short to produce instability. The mean GBF stays above 50 dB

TABLE 3. *Summary table of adverse device effects and adverse events for all 18 enrolled participants*

ADE/AE category		Total no. of events	No. of each event	Description	Severity	Outcome
ADEs	Serious ADEs	0	—	—	—	—
	Nonserious ADEs	2	1	Water in ears[a]	Mild	Resolved
			1	Sensation of mild pain during eructation[a]	Mild	Resolved
AEs	Serious, nonrelated AEs	2	1	Artificial hip replacement surgery	Serious	Ongoing
			1	Worsening back pain, elective back surgery	Serious	Ongoing
	Nonserious, nonrelated AEs	12	3	Hematoma on ear canals[b]	Mild	Resolved[c]
			2	Back pain	Moderate	Ongoing
			1	Bloody nose off-site	Mild	Resolved
			1	Dizziness—BPPV	Mild	Resolved[d]
			1	Tendonitis in foot	Mild	Ongoing
			1	Worsening cataracts, cataract surgery	Mild	Resolved
			1	Flu	Moderate	Resolved
			1	Head cold	Mild	Resolved
			1	Blocked parotid duct	Mild	Resolved

ADE indicates adverse device effect; AE, adverse event; BPPV, benign paroxysmal positional vertigo.
[a]These effects were related to the TCA and were not accompanied by any adverse event or sign of inflammation or irritation.
[b]Related to deep canal impression procedure.
[c]Resolved before TCA placement.
[d]BPPV diagnosed and resolved with Epley maneuver performed by own physician before TCA placement.

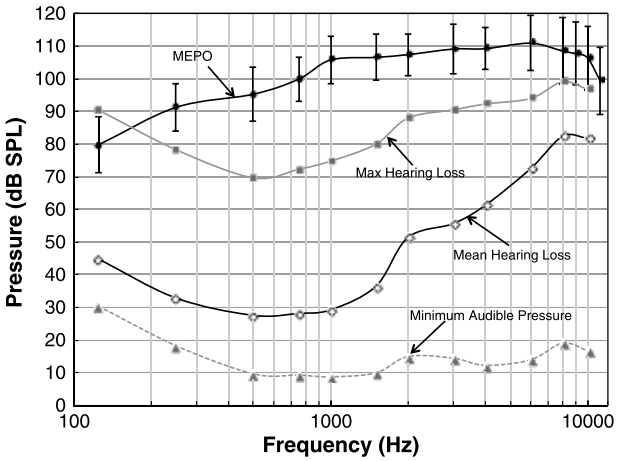

FIG. 6. The mean of the MEPO for the CHD, based on the threshold measurements for the 26 ears (*black circles*). Error bars represent 1 SD above and below the mean. Three minimum audible pressure curves are included for comparison, corresponding to the following: 1) the maximum hearing impairment allowed in this study (*gray squares*), based on the inclusion criteria; 2) the mean hearing impairment of the 13 participants in this study (*hollow diamonds*); and 3) the minimum audible pressure (20) corresponding to normal hearing (gray triangles). For all curves, measurements were made only at the frequencies indicated by the symbols, with spline-smoothed lines used to connect the symbols.

for frequencies below 2 kHz and above 5 to 10 kHz, and above 40 dB for frequencies from 2 to 5 kHz. These GBF results far exceed the maximum gain requirements of 40 dB for a user with the highest HL used in this study.

Functional Gain

Figure 8 shows the mean (solid line) and SE of the functional gain. Also plotted is the maximum of the measured gain across all participants (dashed line). Mean functional gain increases with mean impairment, as expected (refer to audiograms in Fig. 3). In the range of 6 to 10 kHz, the peak mean gain is approximately 22 dB. The highly repeatable dip at 8 kHz is due to the use of a fixed KEMAR transfer function in the calibration procedure, which will be corrected in the future. At 0.5 kHz and below, no gain is measured on average, although the maximum gain shows that gain can be prescribed and measured in that region. The maximum of the measured gains across all participants reaches up to about 46 dB.

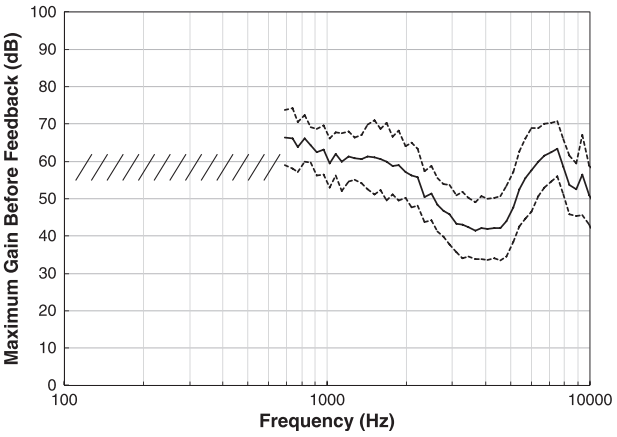

FIG. 7. The maximum available acoustic gain before feedback (GBF), determined for a BTE-compatible microphone position at the top of the pinna. The *solid line* represents the mean, and 1 standard deviation above and below the mean is represented by the *dotted lines*. Below 670 Hz, the maximum GBF could not be accurately determined because of insufficient signal to noise ratios for the required feedback measurements, but they are expected to lie somewhere above the hatched lines.

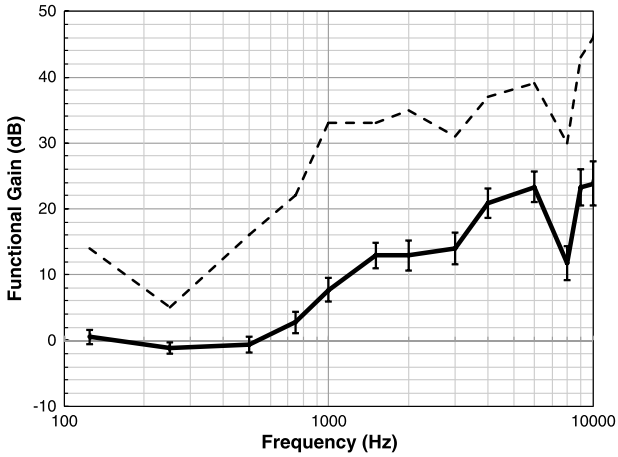

FIG. 8. Functional gain is the difference between the sound-field unaided audiometric threshold measured before placement of the TCA and the aided threshold after placement of the TCA with the CHD activated. The solid line and error bars show the mean and SE respectively (N = 26 ears), whereas the dashed line shows the maximum gain across all ears. The measured gain depends on the amount of gain prescribed, which was limited to 40 dB.

TM Damping

Figure 9 shows the mean and SD of the TM damping for all 26 ears. A TM-damping value of 0 dB would indicate no threshold change due to having the TCA in place. The mean overall TM damping across all frequencies was 4.1 dB, peaking to 7 dB at 1 kHz. The largest peaks were both measured on 1 participant, who had a maximum damping of 20 dB at 500 Hz in the left ear and 14 dB at 1,000 Hz in the right ear. Individuals showed peaks at specific frequencies, but no participants maintained a large amount of damping across all frequencies. The maximum TM-damping peaks of 20 dB are mild enough to not be a safety concern, although when they occur at lower frequencies (500 Hz), they can be more noticeable to the participant. Eight of the 13 participants reported noticing damping when listening to soft speech sounds without amplification.

Speech Recognition Data

Figure 10 presents the measured RTS for the noise maskers (HINT) and the speech maskers (HIST). The unaided (gray bars) and CHD-aided (white bars) cases are shown. In this representation, better performance results

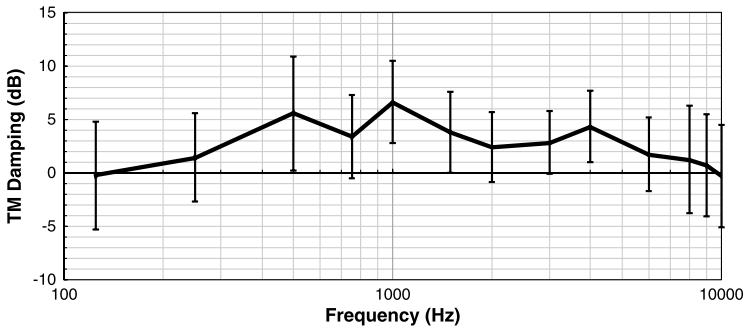

FIG. 9. Mean TM damping for 26 ears, with error bars representing 1 SD. Positive TM damping indicates that hearing was diminished by the presence of the passive TCA on the eardrum.

in a more negative number. Significance was evaluated using statistical software (SYSTAT 13). An analysis of variance (ANOVA) for repeated measures was performed to determine if the CHD amplification (CHD-aided versus unaided) and/or the test condition (HINT 0 degrees versus HINT 90 degrees versus HIST asymmetric versus HIST diffuse) had significant effects on RTS results. Analysis of the whole data set revealed significant main effects of CHD amplification ($p < 0.001$) and test condition ($p < 0.001$), as well as a significant interaction ($p < 0.001$).

An ANOVA was also performed on the HINT and HIST test conditions separately. Analysis of the HINT data showed a significant main effect of CHD amplification ($p < 0.008$), a main effect of noise at 0 degrees versus noise at 90 degrees ($p < 0.001$), and no significant interaction between the 2 variables ($p = 0.13$). There was significant benefit from the CHD under both HINT conditions relative to the unaided conditions, averaging 1.2 dB.

Analysis of the HIST data showed a significant main effect of CHD amplification ($p < 0.002$), a main effect of asymmetric versus diffuse noise ($p < 0.001$), and a significant interaction between these conditions ($p < 0.001$). There was significant benefit from the CHD of 2.8 dB for the asymmetric condition but no significant benefit for the diffuse condition.

Abbreviated Profile of Hearing Aid Benefit

Figure 11 shows the APHAB benefit scores for 12 participants. (The 13th participant declined to fill out the CHD-aided portion of the questionnaire and, therefore, could not be included in the benefit analysis.) A benefit increase of greater than 5% for all 3 subscales or greater than 22% in 1 subscale is considered statistically significant for an individual participant (17), and 11 of 12 participants (92%) had clinically significant benefits. The large global benefit of 32% indicates a potential for significant reduction in problems with amplification from the CHD.

DISCUSSION

Safety and Stability

The TCA stayed on 13 participants (26 ears) in a safe manner for the duration of the study (average of 117 days uninterrupted) without causing any signs of infection, inflammation, perforation, or damage to the ear. There were 2 device-related mild adverse events related to the TCA

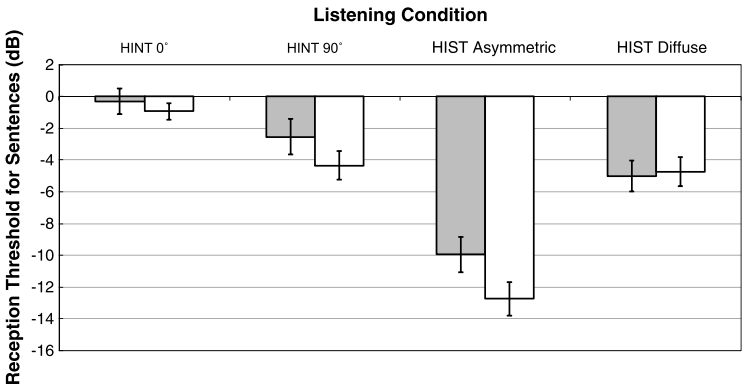

FIG. 10. The RTS results for 13 participants in unaided (before TCA placement; *gray bars*) and aided (*white bars*) listening through the CHD with an omnidirectional microphone. Error bars represent 1 SE above and below the mean. Test conditions included the HINT with noise maskers originating from 0 degrees (straight ahead) or 90 degrees (off to the right) and the HIST with asymmetric or diffuse speech maskers (Fig. 4). Better performance results in a more negative number.

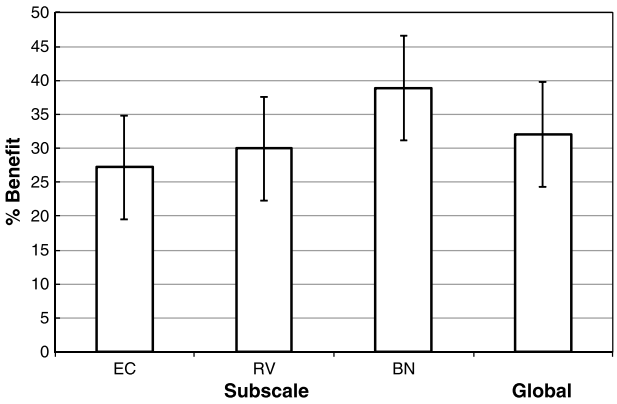

FIG. 11. Mean APHAB results, representing the percent reduction of problems reported for CHD-aided versus unaided (before TCA insertion) listening conditions and SE (n = 12). The APHAB questionnaire was modified by removing the "aversiveness" questions that involve rating the loudness of warning signals such as sirens or alarms because the participants were not expected to have experience with those sounds during their limited time listening through the whole system at the clinic. Thus, only the ease of communication (EC), reverberant environments (RV), and background noise (BN) subscales are reported in addition to the Global Benefit. The participants filled out the APHAB questionnaire unaided at the beginning of the study and aided at the end of the study to provide their results based on CHD-aided listening. The benefit scores represent the self-perceived benefit from the amplification provided by the CHD.

device awareness, which resolved, and 3 procedure-related mild adverse events related to the impression procedure, which also resolved (Table 2). There were 4 instances of a slight displacement of the TCA platform that could affect performance, although none of the devices became completely dislodged from their positions.

The TCA should be oiled regularly and with sufficient volume to wet the peritympanic platform and the umbo platform, a task which was performed during this study on a weekly basis by a physician. A dispenser is currently being developed for participants to control the mineral oil application themselves.

Maximum Output and Gain

The system performance results indicate that, for the 26 ears in this study, the CHD is capable of producing an average of 90 to 110 dB SPL of MEPO all the way through 10 kHz, with the exception of 80 dB SPL at 125 Hz (Fig. 6). For the average hearing impairment in this study, and even for participants with a hearing impairment matching the worst-case inclusion criterion, the mean MEPO has sufficient headroom to provide amplification to 10 kHz (excluding 125 Hz).

The maximum gain before feedback averages above 40 dB for frequencies up to 10 kHz (Fig. 7). These gain curves were measured in an open configuration and without using any sort of feedback-cancellation algorithm, so real-world values should be 7 to 10 dB higher, or in excess of 50 dB of maximum gain on average between 3 to 4 kHz, and more than 60 dB at other frequencies. The measured in situ functional gain is based on the gain prescriptions for the individuals, and demonstrates perceptual improvement in audibility across a broad spectrum to 10 kHz.

To provide useful audible output up through high frequencies, a hearing system must be capable of producing both high output and high functional gain. The measured results on these 13 participants shown in Figures 6 to 8 indicate that the CHD can meet these criteria and suggest that it can feasibly deliver broad-spectrum amplification to an individual with up to 80 dB of hearing impairment out to 10 kHz.

TM Damping and Autophony

The peak average TM damping of 7 dB at 1 kHz shown in Figure 9 was only noticeable by participants when the CHD was turned off and the passive TCA was left unpowered on the eardrum.

Autophony, or the perceived amplification of internally generated sounds (e.g., one's own voice), is an issue known to occur with mass-loading of the TM and is well described in the literature (21–23). As expected, participants did report autophony with the TCA on the eardrum. Subjective device awareness as it relates to both damping and autophony will likely be reduced by wearing the fully activated CHD at home in addition to just in the clinic. In this study, many participants adapted to the awareness issues (i.e., started reporting no device awareness) within a couple of weeks.

Speech Testing and Self-Perceived Benefit

The CHD provided statistically significant performance improvements in speech intelligibility tasks. Significant improvements were seen in both HINT conditions and in the HIST asymmetric condition but not in the HIST diffuse condition, as shown in Figure 10. As shown in Figure 11, participants perceived significant benefit with the use of the CHD as measured with the APHAB relative to unaided listening, which is predictive of noticeable reductions in problems as well as success with amplification. Acclimatization to the broad spectrum of the CHD over a longer period of time may improve performance on both speech tests and APHAB scores.

Study Limitations

Limitations of this study include the small participant population as well as the participants' limited experience of just being able to wear the prototype BTE inside the clinic. The positive safety and efficacy feasibility results demonstrate that the CHD is ready to move forward with further engineering and development efforts toward increased power efficiency, leading to a reduction in BTE size and increased battery life so that patients will be able to wear the system as intended for a full day of use. Wearing the amplification for extended periods outside the clinic will allow participants more access to the realistic listening situations needed to adequately determine the subjective measures.

CONCLUSION

This study demonstrated the safety of the TCA for 13 participants, who each wore it bilaterally for an average total of 122 days and had it in place and in contact with their eardrums continuously for an average of 117 days. This study also demonstrated a potential for benefit of the CHD in terms of speech intelligibility and subjective measures. The system had sufficient output and gain to restore audibility to participants with large amounts of high-frequency hearing impairment (up to 80 dB in this study). There was some awareness of the passive TCA on the eardrum related to damping and autophony. Because this study was limited in scope in terms of the participants not being able to wear the BTE for normal daily use, a future study will determine the full benefit of the CHD.

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