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Journal

The Laryngoscope, 127(4)

ISSN

0023-852X

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Publication Date

2017-04-01

DOI

10.1002/lary.26221

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Development of a Novel Completely-in-the-Canal Direct-Drive Hearing Device

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Objectives/Hypothesis: To develop a novel completely-in-the-canal device capable of directly driving the tympanic membrane (TM) and ossicular chain from the ear canal.

Study Design: Development and feasibility study.

Methods: A voice coil actuator design was developed to drive the TM. Bench testing of the device using laser Doppler vibrometry (LDV) and sound recording was performed. Temporal bone studies using LDV were performed using different designs of the contact tip-TM interface to find the most efficient method of sound transmission. Two short-term clinical performance studies were performed using the latest 3-mm-wide device. Comparison was made to natural sound and to the Vibrant SoundBridge floating mass transducer simulator.

Results: On bench testing, the device was found to have a low (<0.5%) total harmonic distortion in all frequencies above 400 Hz. Temporal bone studies revealed the device was capable of producing vibrations equivalent to 104 to 120 dB sound across most frequencies. The most efficient method of stimulation was when the device was coupled to the malleus. Short-term clinical performance studies indicated that pure tones and complex sound can be presented with the device. The sound quality of the experimental device was rated as better than the SoundBridge simulator device.

Conclusions: The direct-drive hearing device is capable of producing a wide range of sound frequencies and amplitudes. The device can transmit complex sound with low power requirements. Further work on the development of the device is needed for long-term and wider clinical use.

Key Words: Hearing aid, device, hearing loss, direct drive, actuator.

Level of Evidence: NA

Laryngoscope, 127:932-938, 2017

INTRODUCTION

Hearing loss is one of the most prevalent chronic conditions in the United States, affecting over 16% of US adults or approximately 30 million Americans.^{1,2} The decision to provide hearing-impaired patients with acoustic amplification depends on the age, the degree of hearing loss, and the individuals' self-perceived communication difficulty.³ Although hearing aids (HAs) are available to assist sufferers of hearing loss, fewer than 20% of people who need them actually own an HA.⁴ Despite technological improvements in conventional HAs and the recent introduction of middle ear implants,

patient satisfaction with air-conduction HAs has remained low due to lifestyle restrictions, sound distortion, occlusion effect, and feedback issues.^{5,6}

Conventional HAs rely on amplification of sound to improve hearing. An alternative to conventional HAs is the semi-implantable, implantable, or fully implantable middle ear transducer. Implantable hearing prostheses have provided a higher quality sound, but suffer from prohibitive cost and risks of surgery. In addition, almost all have been designed for patients with moderate to severe sensorineural hearing loss, with discrimination scores of more than 40% to 60%.^{7,8}

In an attempt to address the drawbacks of commercially available HAs, a hearing device was conceptualized that combines the advantages of various types of HAs into a single device. Previous work has shown the feasibility of using a device to drive the tympanic membrane (TM) for production of sound.⁹⁻¹¹ The authors have been designing and developing the direct-drive hearing device (DHD) prototype, a novel device that fits entirely into the bony external auditory canal (EAC), touches the TM, and directly drives the TM. The DHD would operate similar to a middle ear implant but would sit on the TM, eliminating the need for surgery. The purpose of the current investigation was to perform bench, temporal bone, and in vivo testing to prepare it for clinical use.

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Editor's Note: This Manuscript was accepted for publication July 5, 2016.

This work was funded by the Center for Hearing Research, University of California, Irvine, Irvine, California, U.S.A. Intellectual property related to the device is owned by the University of California-Irvine. The authors H.R.D., P.P., M.W.M., and M.B. are named on the patent.

The authors have no other funding, financial relationships, or conflicts of interest to disclose.

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DOI: 10.1002/lary.26221



Fig. 1. (Top) The direct-drive hearing device (DHD) actuator composed of a permanent magnet, two flux components to guide the magnetic field, a voice coil, a spring, and a contact tip. (Bottom) Encased DHD actuator used in the studies. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

MATERIALS AND METHODS

Manufacturing and Bench Testing

The DHD has four major components: 1) TM/malleus driver, 2) microphone, 3) signal processor, and 4) power system (Fig. 1). The malleus driver, which is a voice coil actuator, is composed of a permanent magnet, two flux components to guide the magnetic field, a voice coil, a spring, and a contact tip. This design creates a motive force that drives the TM through the contact tip.

The bench tests included measuring the prototype devices' operating range, noise generation, frequency response, total harmonic distortion (THD), static magnetic field strength, and actuator force generation while performing frequency sweeps from 300 Hz to 20 kHz in 1/6 octave steps. A laser Doppler vibrometer (LDV) system was used and enabled quantification of the displacements of the contact tip of the device through the laser reflection. The device was then placed and stabilized under the laser beam.

Cadaveric Temporal Bone Studies

A facial recess approach was performed on all specimens. The posterior crus of the stapes was used to measure the displacement of the stapes using the LDV (Fig. 2). Baseline measurements of stapes displacement to sound were taken. An ER-5A insert earphone was placed, and sound stimuli at various frequencies from 300 Hz to 10 kHz in 1/6 octave steps at

various dB sound pressure level (SPL) levels were introduced. The simultaneous SPL changes at the TM level were monitored with an ER-7C probe microphone.

Once the baseline measurements were taken, the device was carefully inserted inside the osseous EAC to come into contact with the TM under the microscope. The device was secured with bone wax in the EAC. Similar parameters using the LDV were obtained as outlined above and compared to those induced by sound in the baseline measurements.

Different scenarios for the device-TM interface were tested to determine the optimal design and positioning. Comparisons were made based on the magnitude of the posterior crus displacement induced by the device versus sound across all frequencies and at different input voltage levels to the device. A custom-fit interface was achieved by taking an impression from the TM of the cadaveric temporal bone using silicone impression material. The part of the impression representing the umbo was then cut to the size of the contact tip and placed on the contact tip of the device (Fig. 3).

Human Subject Trials

The institutional review board at our institution was obtained. A longer, custom fit tip was used to allow better visualization of the tip while placing the device in the EAC. A



Fig. 2. Cadaver temporal bone fixed under the laser Doppler vibrometer. The reflective taped on the posterior crus of the stapes is seen in the monitor. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

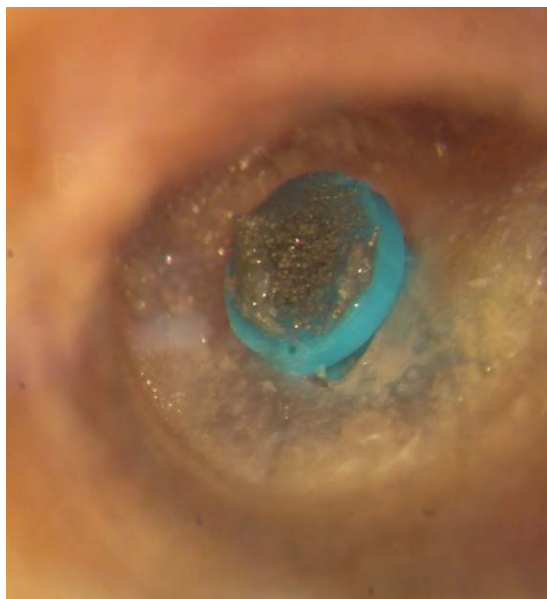


Fig. 3. Tympanostomy tube with ferromagnetic cap sealed inside the tympanic membrane. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

calibrated MP3 player was connected to the device to deliver the desired sounds through actuation of the TM. The current and real-time voltage drop of the device was monitored with a resistor and oscilloscope, respectively.

Two short-term clinical performance trials were performed. The right ear of a 46-year-old male was selected for device placement, and the left ear was selected for presenting sounds using a headphone. The EAC and TM were anesthetized with topical benzocaine 20% for 15 minutes. The device was held with an alligator forceps and gently placed in contact with the TM (Fig. 4).

For the sound loudness matching, the headphone in the left ear was connected to an audiometer. Pure-tone sounds of 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz were preloaded on the MP3 player and played through the device in the right ear at various voltage levels. Pure tones with the same frequencies were played through the audiometer and headphone in the left ear, and the loudness was increased incrementally at 5-dB steps. The subject was instructed to respond when the sounds were perceived as equal. The power requirements of the device was determined from the oscilloscope. The ability to transmit complex audio waveforms was determined by playing music directly through the device and asking the subject whether he was able to understand the lyrics.

A few changes were made before the second trial. The device diameter was reduced from 3.6 mm to 3 mm, and an extension was added to the tip to provide the additional length needed to reach different locations of the TM. Thirteen different tips were made of varying lengths to be tested to determine the most feasible one. Finally, the plastic embodiment of the device was made out of softer material.

The second trial was conducted on the same subject on a different day. Sound loudness matching experiments were repeated as described in the first trial. The NU-6 was used for speech discrimination testing. This test was composed of four lists of 50 consonant-nucleus-consonant monosyllabic words. Two lists of this test were used, 2A and 3A. A 2-second pause was given between each word. The 2A list was delivered at approximately 20 dB above the pure-tone average. The 3A list was delivered at the subject's hearing threshold.

Another test performed during the second trial was to compare the sound quality of the DHD with that of the MED-EL (Innsbruck, Austria) Vibrant SoundBridge simulator. The testing kit of the Vibrant SoundBridge is generally used to test the sound quality of the device prior to implantation. The small floating mass transducer that is normally implanted onto the incus is packaged in a small, polymer housing and has a flat silicone disc at the end to couple directly to the malleus/TM of the subject. This kit was connected to the MP3 player, and music was played. The same procedure was repeated with the experimental device, and the subjects was asked to rate the sound based on the visual analog scale (from 0 to 10) and qualitatively.

RESULTS

Bench Testing

The operating range of the contact tip of the device was 3 mm. This allows for the TM to move by 3 mm laterally. The acoustic noise generation of the uncoupled device was undetectable in a quiet room, making it less than the background sound level of ~34 dB SPL across all frequencies (Fig. 5). The frequency response magnitude of an uncoupled device had a negative linear relationship with the frequencies from 300 Hz to 20 kHz (range, 0.9–9,000 nm). The THD was below 0.5% across frequencies above 400 Hz, with a maximum of 2.3% at 300 Hz. The static magnetic field strength of the actuator was approximately 250 G. The force generated by the actuator in response to current input was very controlled and reproducible, and was proportional to the current. A driving voltage of 800 mV (36 mA) produced a pressure of approximately 58 Pa from the 3-mm-wide tip.



Fig. 4. Placement of the direct-drive hearing device in the ear canal using alligator forceps. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

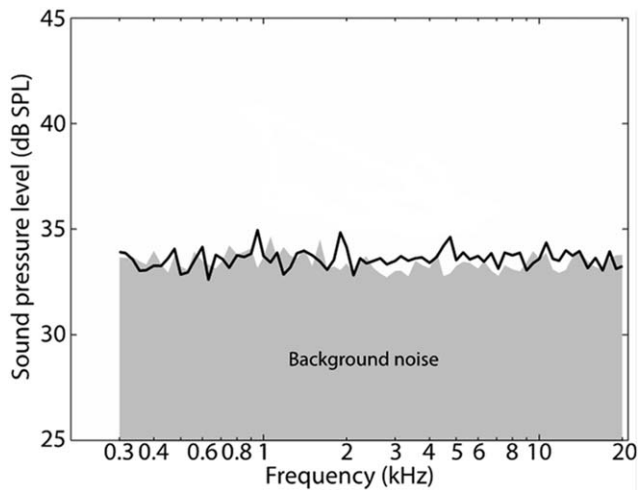


Fig. 5. Acoustic sound generation of an uncoupled direct-drive hearing device actuator during a frequency sweep. The background noise was measured by performing the same experiment with the device disconnected.

Cadaveric Temporal Bone Studies

In the first temporal bone experiment, the straight hearing contact tip was placed on the posterior-superior quadrant of the TM and on the umbo. Baseline measurements for this scenario were performed at 104 and 120 dB and resulted in posterior crus displacements ranging 0.34 to 10.02 nm and 2.56 to 63.48 nm, respectively. Displacements at 400 mV input to the device when it was coupled to the posterior-superior quadrant (0.11–24.11 nm) and at 200 mV input when it was coupled to the umbo (0.38–26.62 nm) resembled the displacements of the TM, with 104 dB SPL of air-conduction sound. Similarly, displacements at 800 mV input when coupled to the TM (0.33–54.45 nm) and at 400 mV input when coupled to the umbo (0.64–55.22 nm) were equivalent to displacements created by 120 dB SPL sound (Fig. 6).

The second temporal bone experiment scenario used the custom fit design. When the device was energized with a 200 mV driving signal, the range of displacements of the posterior crus of the stapes was 0.2 to 5.4

nm. This was comparable to 60 dB SPL sound and corresponded to a power consumption of approximately 2 mW. When energized at 1 V, the range of displacements was 0.57 to 34.5 nm (Fig. 7).

Human Subject Trials

The first short-term clinical performance test lasted approximately 3 hours. Various sites on the TM were tested during the location test. The lateral process of the malleus appeared to yield the best results. The sound-matching test revealed the frequency of the pure tones produced by the device in the right ear and that of air-conduction sound in the left ear were subjectively equivalent. The driving voltages required to achieve certain loudness levels in the *in vivo* experiment was substantially less than that of the cadaveric tests. This is likely due to the stiffness of the cadaver ossicular chain and TM from formalin fixation.

The quality of complex audio waveform transmission (music) was described as “pure,” with no muffled sounds by the subject. The TM tolerated the device for 3 hours without any major adverse events. During the second trial, the decrease in the diameter of the device from 3.7 mm to 3 mm provided increased visibility and ease of manipulation as reported by the surgeon. The longer and narrower extension tip (5 mm) made placement on different locations of the TM easier.

The second trial also involved speech discrimination testing. The 2A list that was delivered at an approximately 20 dB above the pure-tone average yielded a score of 47/50 (94%) word discrimination (WD). The 3A list that was delivered at the subject’s hearing threshold yielded a score of 44/50, resulting in 88% WD. As for the comparison between the DHD and the MED-EL Vibrant SoundBridge simulator, the subject rated them 7/10 and 6/10 for sound quality, respectively. The subject described his music experience through the DHD as being able to hear it perfectly without any distortion or occlusion. The subject described his music experience through the Vibrant SoundBridge similar to that of the DHD, with the exception of not hearing the high

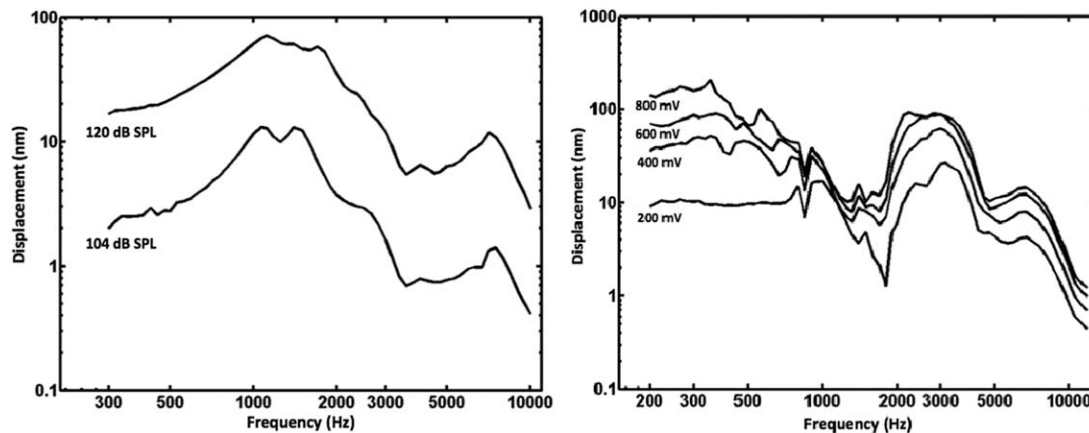


Fig. 6. (Left) Speaker baseline measurements at 104 and 120 dB SPL. (Right) Frequency response of the coupled direct-drive hearing device (to the umbo) at different voltage levels.

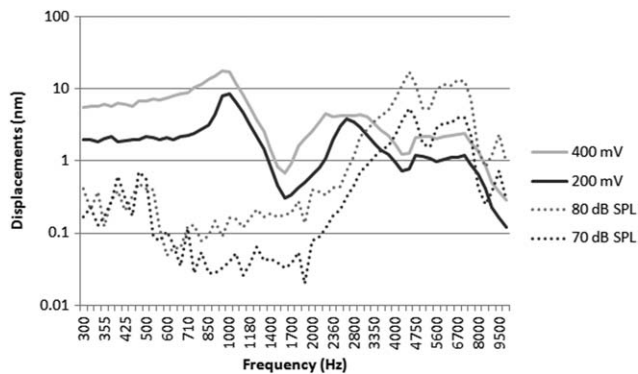


Fig. 7. Displacements of the posterior crus of the stapes in response to various frequencies.

frequencies as well. The subject also reported increased occlusion with the SoundBridge device, which was most likely due to the larger diameter of its contact plate (Fig. 8).

DISCUSSION

The DHD is a novel hearing device prototype that aims to address the drawbacks of current HAs. This device is placed deep inside the bony part of the EAC and in contact with the TM. Unlike conventional HAs, this device works by mechanically moving the TM and the ossicular chain. The device has shown the ability to produce sound in cadaveric and limited short-term clinical testing, with no significant distortion and a wide frequency range. The subject reported the sound to be louder when the device was coupled to the lateral process of the malleus compared to other locations.

The dimensions of the actuator in the current prototype are 6.2 mm × 3 mm, which allows it to fit deeply into the EAC. The EAC is 20 to 30 mm long, with the bony portion averaging 8.5 mm in length and 7 mm in height.^{12,13} Therefore, the device with the added battery, microphone, and digital sound processor would be able to fit into the normal EAC without difficulty.

Placing a device in contact can create several potential problems, including movement of the TM with sneezing and eructation, and the concern for TM perforation. The pressure difference between the middle ear and the atmosphere could reach over 1 kPa, which would deform the TM. This deformity has been calculated in the past and was estimated at over 0.4 mm at 1.6 kPa.^{14,15} During natural hearing, the TM has a maximum displacement of 6 μm.¹⁶ Bench testing of the DHD showed that the contact tip of the device had an operating range of 3 mm. This leaves the device approximately 2.6 mm of tolerance, which is large enough to allow the device to be placed manually under microscopy with some room for error in cases of significant pressure changes. The force generated by the device, 58 Pa at 800 mV input, was reasonable and safe. Given previous research has shown a 1% probability of TM rupture at 16.5 kPa and a 90% probability of rupture at 84.5 kPa¹⁷; it is unlikely that TM rupture would occur with the forces generated by the device.

Potential issue with devices used for hearing include the noise created by the device, electromagnetic energy, and limited frequency range of the device. The actuator design that was tested was able to provide friction-free fine movements without noise and allowed large static displacements of the actuator without affecting its dynamic performance. The static magnetic field

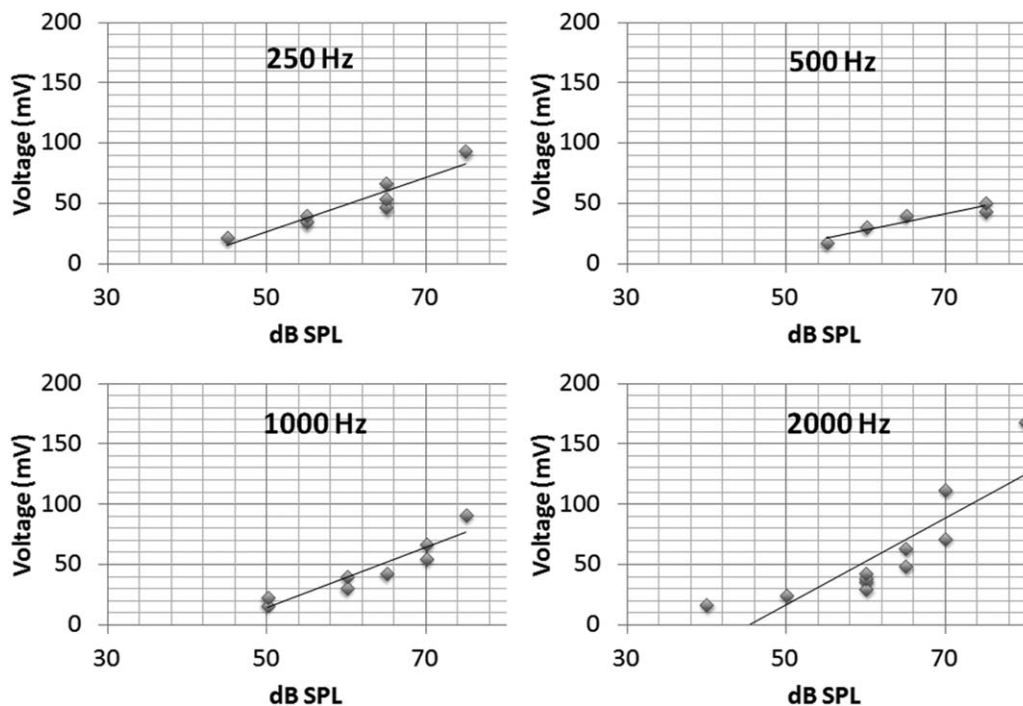


Fig. 8. Results for the direct-drive hearing device sound-matching experiments in the second human clinical performance test.

strength of the actuator was well below the International Commission on Non-Ionizing Radiation Protection guidelines of 400 mT (4,000 G).¹⁸ The total harmonic distortion of the device was mostly below 0.5%, which was in compliance with recommendations for implantable HAs.¹⁷ The increase in THD in the lower frequency region (less than 400 Hz) might be due to the natural resonance frequency of the device or a drift in the displacement measurements of the LDV at frequencies near resonance. Although this presents some limitations in amplification in frequencies below 400 Hz, the smaller requirement for amplification in those frequencies would likely not present problems when tested on patients with hearing loss. Overall, the DHD is capable of producing enough vibration to assist patients with moderately severe to severe hearing loss with a wide frequency range.

The temporal bone studies overall demonstrated the device was capable of driving the ossicles in temporal bones and induce displacements of the stapes similar to sound. The placement of the device on the malleus showed higher amplitudes and lower power requirements than when the device was placed on the TM. A 200 mV input was able to produce displacements of the stapes equivalent to 104 dB SPL and 400 mV input simulated 120 dB SPL. The stapes displacement in the DHD ranged between 1 and 200 nm and was comparable to those of the previous reports. Javel et al.¹⁹ tested two piezoelectric transducers with an input of 1 V on an anesthetized cat, and the displacements recorded at the malleus level ranged between 1 and 100 nm. In another study by Huber et al.,²⁰ a middle ear prosthesis was assembled using the Vibrant Soundbridge and a Bell Tubingen titanium prosthesis (Heinz Kurz GmbH, Dusslingen, Germany). Their prosthesis was energized with 100 mV and was able to induce 1- to 200-nm displacements of the stapes footplate in a fresh cadaver bone. The experiments with the DHD showed smaller displacements primarily due to the stiffer nature of the formalin-fixed temporal bone.

The safety and feasibility of umbo vibration has been established before. The malleus vibration audiometer (MVA) is a diagnostic tool for assessing ossicle function and integrity,²¹ which presents mechanical vibrations to the umbo via a rod about the length of the EAC, with a specially shaped tip that couples with the TM. The study found no pure-tone threshold shifts after 25 minutes of measurement procedures performed on 2 days. Based on the experience with the MVA, vibration of the malleus is unlikely to cause significant issues.

The second short-term clinical performance test included a number of changes including device diameter reduction, housing modifications, and interface tip modifications. These changes resulted in a smaller contact point, which proved to be as functional, and resulted in marked improvement in comfort for the subjects' EAC. During this experiment, the subject reported as not feeling an occlusion effect perceived with the Vibrant SoundBridge simulator. The sound-loudness matching results were similar to the first trial, and the speech discrimination results were promising.

Much work needs to be done in device development before it enters the market. The next step is to use a fixture that stabilizes the device in the EAC. Future work is directed toward adding a battery, digital signal processing unit, and microphone to the device embodiment. This would allow the authors to conduct a long-term clinical trial and study the outcomes of the device in a larger subject population. Other issues to surmount include keratin accumulation at the tip-TM interface. Great work by the Perkins research team²² has shown that intermittent use of oil at the TM eliminates the keratin accumulation at the TM. We believe that most issues hindering the clinical use of the device can be overcome with time, research, innovation, and collaboration.

CONCLUSION

The DHD is a novel semi-implantable hearing prosthesis similar in principle to a middle ear implant, with the advantages of a completely-in-the-canal HA. The bench testing and cadaver studies showed that the device prototypes could move the ossicular chain at frequencies and magnitudes appropriate for normal hearing, with little distortion and minimal noise generation. The DHD could successfully transmit high-quality sound through mechanical actuation of the TM. Short-term clinical performance tests revealed a few issues that need to be addressed before testing the device in human subjects on a larger scale.

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