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A Micro-Drive Hearing Aid: A Novel Non-Invasive:

Hearing Prosthesis Actuator

Peyton Elizabeth Paulick¹, Mark W. Merlo², Hossein Mahboubi³, Hamid R. Djalilian^{1,3}, and Mark Bachman¹

¹University of California, Irvine; Department of Biomedical Engineering, Irvine CA

²Modular Bionics Inc. Santa Ana, CA

³University of California Irvine; Department of Otolaryngology - Head and Neck Surgery, Orange, CA

Abstract

The direct hearing device (DHD) is a new auditory prosthesis that combines conventional hearing aid and middle ear implant technologies into a single device. The DHD is located deep in the ear canal and recreates sounds with mechanical movements of the tympanic membrane. A critical component of the DHD is the microactuator, which must be capable of moving the tympanic membrane at frequencies and magnitudes appropriate for normal hearing, with little distortion. The DHD actuator reported here utilized a voice coil actuator design and was 3.7 mm in diameter. The device has a smoothly varying frequency response and produces a precisely controllable force. The total harmonic distortion between 425 Hz and 10 kHz is below 0.5% and acoustic noise generation is minimal. The device was tested as a tympanic membrane driver on cadaveric temporal bones where the device was coupled to the umbo of the tympanic membrane. The DHD successfully recreated ossicular chain movements across the frequencies of human hearing while demonstrating controllable magnitude. Moreover, the micro-actuator was validated in a short-term human clinical performance study where sound matching and complex audio waveforms were evaluated by a healthy subject.

Index Terms

Auditory implants; auditory prostheses; cadaveric testing; hearing aids; microactuators; temporal bone measurements

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P. E. Paulick is with the Biomedical Engineering Department, University of California, Irvine, CA 92697 USA (ppaulick@uci.edu).

M. W. Merlo is with Modular Bionics Inc, CA 94122 USA (mark@ModularBionics.com).

H. Mahboubi is with the Department of Otolaryngology, University of California, Irvine, CA 92697 USA (hmahboub@uci.edu).

H. Djalilian is with the Department of Otolaryngology and Biomedical Engineering, University of California, Irvine, CA 92697 USA (hdjalili@uci.edu).

M. Bachman is with the Electrical Engineering and Computer Science Department, University of California, Irvine, CA 92697 USA (phone: 949-824-6421; mbachman@uci.edu).

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I. INTRODUCTION

Hearing loss is one of the most prevalent chronic conditions in the U.S., affecting over 10% of the population, totaling 34.25 million in 2008 (S. Kochkin 2009). Hearing aids remain the most common method for treating hearing loss, yet fewer than 24% of people who need a hearing aid actually own one (Sergei Kochkin 2007). Reasons for this low adoption rate include cost (51%), stigma and appearance (43%), and sound quality (24%). Stigma and appearance issues are attributed to the visibility of the hearing aid and sound quality dissatisfaction is in part due to feedback and the occlusion effect (Sergei Kochkin 2007). Feedback occurs when the sound from the speaker escapes and re-enters the microphone producing a high-pitched whistling. The complete blockage of the ear canal results in the occlusion effect, where bone-conducted sound vibrations of a person's own voice are trapped between the tympanic membrane and the hearing device, creating a hollow or booming type sound when a person speaks (Goode et al. 1994).

Hearing aid designs must compromise between visibility, feedback, and the occlusion effect. Two common methods for preventing feedback are to: (1) separate the microphone from the speaker; or (2) occlude the ear canal. The former makes the hearing aid more visible and the latter increases the occlusion effect. The occlusion effect can be reduced by adding vents to allow sounds trapped in the ear canal to escape (Chung 2004). However, these vents reduce the attenuation between the microphone and the speaker and therefore feedback is more likely to occur, reducing the level of amplification that can be applied. For those with severe hearing loss, a visible behind-the-ear hearing aid is the only option.

Middle ear implants (MEI) have been developed to address the problems with conventional hearing aids (Counter 2008; Shinnars, Hilton, and Levine 2008). In general, these implants work by moving the ossicles, oval window, or round window with direct mechanical movements. This is in contrast to hearing aids, which use amplified sound pressure to move the tympanic membrane. By driving the ossicles directly, the MEI operates silently and the occlusion effect and feedback are eliminated. This translates to better sound quality compared to conventional hearing aids (Uziel et al. 2003; Hough et al. 2002). Examples of these devices include the Vibrant Soundbridge (MED-EL; Innsbruck, Austria) and the Esteem (Envoy Medical; St. Paul, MN). Despite the promise of middle ear implants, they suffer from several disadvantages, including prohibitive cost, invasive surgery, irreversible surgery, surgery for removal, and unknown performance until after implantation.

Given the shortcomings of hearing aids and MEIs, there is a need for a hearing prosthesis for moderate to severe hearing loss that is invisible, produces no occlusion, and does not require invasive surgery.

Our group is developing a direct hearing device (DHD), a novel auditory prosthesis for moderate to severe hearing loss that is invisible and can be placed without surgery. The device is placed deep in the ear canal and recreates sounds by driving the tympanic membrane or umbo directly (Fig. 1). Similar to a hearing aid, the device is placed in the ear canal and therefore no surgery is required for placement or removal. But, since it recreates sound by mechanically moving the tympanic membrane and the ossicular chain, sound

quality limitations, such as feedback and the occlusion effect, can be reduced. In addition to our work, other groups have also explored direct actuation of the tympanic membrane and ossicular chain, for example, by using an electromagnet to drive a small magnet attached to the tympanic membrane (Perkins et al. 2010).

A direct hearing device would consist of a microphone, amplifying electronics, and an actuator to drive the TM and the ossicular chain. A critical component of our direct hearing device is the direct hearing device actuator (DHDA), which must meet several criteria to be suitable as a tympanic membrane driver. This includes appropriate, smoothly varying frequency response, low-distortion movements, and silent operation. In this paper we give an overview of the DHDA and present initial characterization data demonstrating its suitability as a tympanic membrane and ossicular chain driver.

II. Direct Hearing Device Actuator Overview

A. Requirements

The DHDA must meet several performance criteria to faithfully reproduce sounds with mechanical movements. It has to satisfy several practical requirements to be feasible for prosthesis use. From a performance perspective, the DHDA must have the appropriate dynamic range in both frequency (20 Hz to 20 kHz) and displacement (10 μm to less than 1 nm) (Goode et al. 1994)(Chien et al. 2007). The distortion across this range must be minimal since the sensitivity of the ear will translate these distortions into perceived noise to the user. Additionally, actuation must produce little or no sound since audible noise from the actuator is a potential source of feedback and could be directly perceived by the user.

From a practical perspective, the DHDA must be small enough to fit within the bony portion of the ear canal. To ease placement requirements, it must accommodate relatively large variations in distance from the tympanic membrane without influencing device performance. Performance should also not be influenced by the natural static movements of the tympanic membrane (e.g., from changes in air pressure).

B. Design

A specialized voice coil actuator was designed for the driving mechanism (Fig. 2). This design had several desirable features: (1) a lightweight moving component to minimize loading effects; (2) a flat response; (3) constant performance across large displacements since there was a constant number of coils in the active region and; (4) nearly frictionless motion.

The magnetic flux circuit of the DHDA was formed by a permanent magnet, outer flux guide, and inner flux guide (Fig. 3). This flux circuit directed the magnetic flux through the small air gap between the inner and outer flux guides. The voice coil was located in this air gap and an axial force was produced when current passed through the coil. The density of voice coil turns within this air gap remained constant and therefore the force produced for a given current was constant over a large range of displacements. The spring held the voice coil in place and was used to provide a preload force between the interface tip and the tympanic membrane. This arrangement provided low friction, since the spring was the only

source of friction. Frictionless motion was critical in achieving the large dynamic range in displacement and frequency without undue distortion.

The permanent magnet was a grade N45, nickel-plated, neodymium (NdFeB) magnet. The inner and outer flux guides were made of iron and were chosen due to iron's high magnetic permeability. The inner and outer flux guides were made on a computer numerical control lathe and mill (Haas Automation Inc.; Oxnard, CA). The voice coil was a two-layer, air core coil formed with 0.031 mm diameter (48 AWG), polyurethane-coated, copper magnet wire. The DC resistance of the voice coil was 22 Ω and it had a maximum DC current threshold of ~95 mA (4.75 V) before failure.

The spring had approximately 4 active turns, was formed from 0.089 mm diameter, silver-coated, beryllium copper wire, and had a spring rate of 0.0044 N/mm (provided by the manufacturer). This spring design was a balance between achieving a low spring constant and practical fabrication methods. It was also critical to have a completely nonmagnetic spring. Since the spring had a very small spring constant and was in contact with the magnetic flux circuit, springs with even the smallest magnetic properties (e.g., stainless steel) collapsed due to magnetic forces. The assembled actuator had a static magnetic field strength of approximately 25 mT. This was well below the International Commission on Non-Ionizing Radiation Protection guidelines of 400 mT (Vecchia, Hietanen, and Ahlborn 2009) as a limit of exposure to static magnetic fields by the general public.

The DHDA displacement had an operating range of 3 mm. Pressure differences can exist between the middle ear cavity with ambient pressures reaching over 1 kPa. This static pressure change deforms the tympanic membrane and can result in tympanic membrane static displacements over 0.4 mm at 1.6 kPa (Decraemer 1992; Decraemer, Dirckx, and Funnell 1991). During natural hearing the tympanic membrane has a maximum displacement of 6 μ m (Kurokawa and Goode 1995). This gives the DHDA placement tolerance of ~2.6 mm, a range large enough to allow the device to be placed by hand.

The vibrational force required to drive the middle ear is an important piece of information in the design of middle ear implants, however few experimental studies report the necessary driving force, but instead focus on the displacements of the ossicular chain. Some groups report between 20 – 200 μ N needed to recreated 100 dB SPL sounds (Liu, Rao, and Ta 2010; Ko, Zhu, and Maniglia 1995; Hong et al. 2009). Therefore the design of the DHDA aimed to deliver forces ranging from 1 μ N to 1 mN and displacements ranging from 1 nm to 1 mm.

The average human external auditory ear canal is composed of two segments; the lateral cartilaginous portion and the medial osseous portion (Djalilian and Mahboubi). The dimensions of the external auditory canal is approximately 7 mm in diameter and 26 mm in length; (Paulsen 2004). The osseous portion of the ear canal averages approximately 8.5 mm in length (Djalilian and Mahboubi). Therefore, with a diameter of 3.7 mm and a length of 6.2 mm, the DHDA was designed to fit completely within the bony portion of the ear canal.

This actuator design enabled nearly friction-free motion, which lowered movement distortion, allowed fine movements, and reduced any sound generated by the device. It also

allowed large static displacements of the actuator without affecting its dynamic performance since the density of wire turns within the air gap was constant.

III. Methods

A. DHDA Bench Testing

The DHDA was characterized at the California Institute of Telecommunications and Information Technology (CalIT2) Microscopy Center at the University of California Irvine. The frequency response, total harmonic distortion, and sound generation were determined by driving the device with a frequency sweep while recording its displacement. Displacements were measured with a laser Doppler vibrometer (LDV) system, which consisted of an MSA-500 Micro System Analyzer, an OFV-5000 Modular Vibrometer Controller, a DD-900 displacement decoder, and a VD-09 velocity decoder (Polytec; Irvine, CA).

A small piece of retroreflective tape (Polytec) was placed on the connection plate to improve the reflectivity, increase laser signal strength, and reduce the influence of out-of-plane motions on laser signal strength. Displacements were measured with respect to a single point on the reflective tape, which was selected on the basis of maximizing laser signal strength.

SoundCheck 8.0 (Listen, Inc.; Boston, MA) was used to acquire and analyze all data collected by a CDX-01 CardDeluxe sound card (Digital Audio Labs; Chanhassen, MN). Device displacement was acquired from the LDV's displacement card voltage, which was directly proportional to the measured displacement by a software-selectable range factor (i.e., 5 $\mu\text{m/V}$). The DHDA was driven by the headphone output of a calibrated amplifier (Crown Audio, Inc.; Elkhart, IN.; D-75A) with near unity gain ($\sim 1 \text{ V/V}$).

Sound near the DHDA was monitored with a calibrated ER-7C probe microphone (Etymotic Research, Inc.; Elk Grove Village, IL). The probe inlet faced the actuating portion of the device and was positioned approximately 1 mm radially from the device's outer diameter.

The stimulus waveform was a stepped sine wave from 300 Hz to 20 kHz in 1/6 octave steps at a constant root-mean-square (RMS) voltage. Each frequency was played either 50 cycles or 100 ms, whichever was longer.

1) Frequency Response—The frequency response of the displacement waveform was calculated using the heterodyne algorithm in SoundCheck. This algorithm measured the fundamental response with good background noise rejection. The frequency response analysis discarded the first cycle of each frequency to remove any transient responses contributed to changing frequencies. Noise floor measurements were recorded in the same manner, except the actuator was disconnected from the driving signal.

2) Total Harmonic Distortion and Acoustic Noise Generation—Total harmonic distortion (THD) of the displacement was calculated using the THD analysis algorithm in SoundCheck, which utilized both the displacement and stimulus waveform. This algorithm calculated the noise contributed to the harmonics of the device. The first, second, and third harmonics were used in the THD analysis. Again, the first cycle of each driving frequency

was discarded to remove any transient responses from changing frequencies. The acoustic broadband noise generation of the DHDA was calculated from the recorded waveform of the probe microphone using the broadband RMS algorithm in SoundCheck. Background noise was measured in the same manner; except the device was disconnected from the driving signal and therefore the background noise measurements also includes electrical noise and other noise sources.

3) DHDA Force Measurement—The force generated by the DHDA was calculated by applying a current to the coils and measurement the displacement using the LDV system. The resulting force was calculated using the spring constant of the DHDA spring and the measured displacement.

B. Human Temporal Bone Testing

Ossicular chain movements of a human temporal bone were measured to demonstrate the DHDA's ability to generate adequate ossicular chain displacements for sound reproduction. Baseline displacements from acoustic stimulation of the tympanic membrane were also measured for comparison purposes.

1) Temporal Bone Preparation—A left cadaveric temporal bone of a 59-year-old male with no history of middle ear diseases was obtained from the Willed Body Program at the University of California, Irvine. During the time of testing, the temporal bone was eight years post mortem. The bone had been fixed in a 10% solution of neutral buffered formalin and was kept at a temperature of 4 °C. After securing the temporal bone in a bone holder, a simple mastoidectomy with facial recess approach was performed.

The bone was prepared using a mastoidectomy and posterior tympanotomy approach to provide a good view of the stapes footplate and posterior crus. Previous studies have shown both the umbo and the stapes footplate are effective locations for studying middle ear mechanics and ossicular chain displacement as a means of quantifying hearing (Kurokawa and Goode 1995; Chien et al. 2006; Goode et al. 1994). Since the facial nerve and stapedius tendon were preserved, drilling only provided a view of the middle ear cavity. Therefore, the stapes footplate was not fully visible and the posterior crus was selected to measure displacement.

A small piece of retroreflective tape (~0.5mm × 0.5mm) (Polytec Inc.) was placed on the posterior crus of the stapes to assure strong signal strength of the reflected laser. Additionally, the placement of the tape on the posterior crus assures that displacement measurements were taken from the exact same location during each trial.

2) Stapes Baseline Displacement Measurements—To demonstrate the DHDA as a tympanic membrane driver, a cadaveric temporal bone was used (Chien et al. 2006; Kurokawa and Goode 1995) and the corresponding posterior crus displacement was measured (Fig. 4). Baseline measurements of the middle ear response were taken to account for size, age, and other physiological variability. The pure tone sound stimuli were delivered through an ER-5A insert earphone (Entymotic Research, Inc.; Elk Grove Village, IL) placed 2 mm from the tympanic membrane. Simultaneously, the sound pressure levels at the

tympanic membrane were monitored with an ER-7C probe microphone (Etymotic Research, Inc). The stimulus waveform was a stepped sine wave from 300 Hz to 10 kHz in 1/6 octave steps at 104 and 120 dB SPL. Each frequency was played either 50 cycles or 100 ms, whichever was longer.

The movement of the stapes bone was piston-like, however due to the geometry of the cadaveric middle ear and experimental setup this movement was measured at an experimental angle. A cosine correction of the measured displacement was applied to account for the measurement angle offset using an established protocol (Chien et al. 2006; Voss et al. 2000; Hato, Stenfelt, and Goode 2003). An offset angle of 45° was determined by two independent observers (with an approximate error of 5°) and used to calculate the correct displacement.

3) Stapes Displacement from DHDA Actuation—A custom interface tip was made by taking an impression from the TM of the cadaveric temporal bone using silicone impression material (Siemens Silhouette™), and then placed on the connection plate of the DHDA facilitating a custom fit interface between the device and the TM (Fig. 5). The DHDA was coupled to the cadaveric temporal bone TM under a surgical microscope in the temporal bone lab of UCI Medical Center allowing for appropriate visualization of this coupling. The device was then secured in place using surgical bone wax, but still allowing for proper ventilation of the ear canal. The stapes displacement measurements and correction factor adjustments were performed in the same manner as the baseline measurements. The stimulus waveform was a stepped sine wave from 300 Hz to 12 kHz in 1/6 octave steps. Each frequency was played either 50 cycles or 100 ms, whichever was longer. The RMS voltage of the waveform was selected and held constant during the entire frequency sweep. Selected input voltage levels were 50mV, 200 mV, 400 mV, 600 mV, and 1V.

4) Clinical Performance Test—To evaluate the sound quality and ability of the DHDA to transmit sound information through this direct drive mechanism, a short-term clinical trial was conducted. The University of California, Irvine Institutional Review Board (UCI IRB) approved the human subject research project (UCI IRB HS #2001–8486) and the trial was carried out at the UCI Medical Center.

The trial consisted of sound matching experiments and complex audio waveform evaluations. The DHDA was placed in contact with the TM in the right ear and an audiometry earphone was placed in the left ear. A topical anesthetic was used and the device was inserted manually. Pure tones of increasing loudness at 5 dB SPL increments were played in the headphones while the matching pure tone was played through the DHDA. Each pure tone at a corresponding dB level played through the audiometry headphones and was matched to the perceived loudness of the DHDA, effectively evaluating the current required to drive a certain decibel level of each pure tone. The complete clinical protocol of the short term performance test was presented elsewhere (Mahboubi et al. 2014; Paulick et al. 2014).

IV. Results

A. Frequency Response

The frequency response magnitude of an uncoupled direct hearing device is shown in Fig. 6a. The device exhibited a smoothly varying response with no apparent distortions or resonances in the area of interest. Noise floor measurements from the LDV data acquisition system are shown in red.

B. Total Harmonic Distortion and Acoustic Noise Generation

Below 0.5% THD is considered a reasonable level for an implantable hearing aid (Leysieffer et al. 1997). The THD was well below 0.5% above 400 Hz (Fig. 6b). The increase in THD in the lower frequency region appeared to be correlated with the natural frequency of the device. This distortion could have been from the DHDA, but drift in the displacement measurements of the LDV at frequencies near resonance could also have been a contributing factor. The uncoupled DHDA did not generate any detectable noise above background levels. These measurements were not taken in a sound booth and the sound level of ~34 dB SPL was considered to be the actual acoustic noise of the room and not electrical noise in the experimental system.

C. DHDA Force Generation

The results of the force produced by the DHDA in response to current input are displayed in Fig. 7. The DHDA produced a very controlled and reproducible force that was proportional to current that can be delivered to the TM and attached ossicular chain. With a driving voltage of 800 mV (36 mA), the 3 mm DHDA contact plate delivered a pressure of approximately 58 Pa to the TM. A 1% probability of TM rupture occurs at 16.5 kPa and a 90% probability of rupture occurs at 84.5 kPa (Mannan 2012). The pressure the DHDA delivered to the TM was well below any potentially harmful values.

D. Stapes Baseline Displacement

The baseline frequency response of the stapes displacement was shown in Fig. 8. At 40 dB SPL acoustic simulation, the posterior crus of the cadaveric stapes bone had a minimum displacement of ~0.01 nm at 10 kHz and a maximum displacement of ~0.65 nm at 2.1 kHz. At 90 dB SPL acoustic simulation, the stapes bone had a minimum displacement of ~1.1 nm at 10 kHz and a maximum displacement of ~140 nm at 2.1 kHz.

Additionally, the frequency response of this cadaveric temporal bone demonstrated the resonance of the middle ear system occurring at ~2120 Hz. This value was slightly higher than the reported middle ear resonance frequency at 1200 Hz (Homma et al. 2009). This may be due to the natural ossification process of the cadaveric middle ear or the result of the preservation process.

E. Stapes Displacement from the DHDA

The amplitude of the stapes displacement from the DHDA was shown in Fig. 9. The frequency response of the tympanic membrane and DHDA coupled system displayed a resonance mode at ~ 2.1 kHz. When energizing the DHD using a 200 mV driving signal, the

posterior crus of the stapes bone had a minimum displacement of ~ 0.2 nm and a maximum displacement of ~ 5.4 nm. When energizing the DHDA using a 1 V driving signal, the posterior crus of the stapes bone had a minimum displacement of ~ 0.57 nm and a maximum displacement of ~ 34.5 nm. Actuation at 200 mV resulted in displacements comparable to a 60 dB sound and corresponded to a power consumption of approximately 2 mW.

F. Clinical Performance Test

Six pure tones at six different decibel levels were matched and a complex audio waveform (music) was played for qualitative evaluation by the subject. Pure tones of increasing loudness from 30 dB to 80 dB SPL at 5 dB increments were played into the headphones while the matching pure tone was played through the DHDA. Certain levels were not identified as 'matched' by the subject; therefore the testing proceeded to the next 5 dB increment. This results in certain dB SPL levels to not have a corresponding driving voltage measurement from the DHDA. This is a result of the subject's variation in hearing level at certain frequencies or can be a result of human error in matching recognition.

The required driving voltage to achieve each decibel level was substantially lower in the human trials compared to the cadaver trials as demonstrated in Fig. 10. For example, a 1000 Hz tone at 40 dB required a ~ 24 mV driving signal, 70 dB required ~ 34 mV, 75 dB required ~ 49 mV (Fig. 10). Whereas a ~ 1 V driving signal was needed to recreate an 80 dB sound in the cadaveric temporal bone. At 70 dB, power consumption was approximately 45 μ W. The subject reported no discomfort, no occlusion, and indicated that the sound quality of the music was equivalent to commercially available headphones. The neurotologist conducting the clinical trial reported no audible sound coming from the device. The complete clinical protocol of the short term performance test was presented elsewhere (Mahboubi et al. 2014; Paulick et al. 2014).

V. Discussion

The DHD represents a new hearing prosthesis approach with the ability to overcome the shortcomings of current hearing prosthesis technologies by addressing the need for an invisible device for moderate to severe hearing loss that does not require invasive surgery. A key technology needed for this is a microactuator small enough to fit in the bony portion of the ear canal. In bench testing, the DHDA demonstrated a linear frequency response, low THD, and small acoustic noise production. The smoothly varying frequency response is acceptable for a feed-forward actuator and reduces the computation requirements of the digital signal processor in the prosthesis. When the complex dynamics of human hearing are considered, the smooth response also simplifies the combined dynamic system between the DHDA and human hearing anatomy (e.g., tympanic membrane, ossicles) making the implementation of a clinical device more practical.

The THD was measured to be 0.45% on average, putting it below the 0.5% level that is considered to be adequate for an implantable hearing aid (Hong et al. 2009).

Research that utilizes human cadaver temporal bones, generally uses specimens obtained within 48 hours after death and frozen, and are thus considered 'fresh'. These fresh temporal

bones most closely mimic the mechanical properties of live human middle ears (Stieger et al. 2012), (Goode et al. 1994; Kurokawa and Goode 1995). The temporal bone used in this paper had been refrigerated and preserved in formalin solution for 8 years. Formalin fixation changes the mechanical properties of human tissue, generally resulting in human tissue becoming stiffer (Stieger et al. 2012). Therefore the magnitude of displacement obtained with the formalin fixed cadaver should be reduced compared to a 'fresh' cadaver due to the increase in stiffness of the ^{TM}TM and ossicular chain. The reduced power needed in the human subject test also suggests the increased stiffness of the fixed temporal bone.

The temporal bone experiments demonstrated that the DHDA when coupled to the tympanic membrane could recreate the appropriate displacements of the ossicular chain when compared to the acoustic baseline frequency responses.

The frequency response of the stapes displacement when driven by the DHDA did not match the baseline stapes response when driven by sound. Since the DHDA by itself demonstrated a non-flat response, it is likely the coupling of the two systems (DHDA and the ossicles) resulted in this complex frequency response that is different than normal hearing. Contributing factors could include point actuation forces compared to distributive forces, preload forces on the ossicular chain, and coupling dynamics between the DHDA and tympanic membrane. Further experiments are needed to determine the main factors contributing to the coupled frequency response.

Overall, the bench testing demonstrated the DHDA's ability to produce low distortion movements at the displacements and frequencies typically found during normal hearing. The cadaveric testing demonstrated that DHDA could effectively couple to tympanic membrane and drive the ossicular chain at similar displacements as those found with acoustic stimulation.

The short-term clinical performance test confirmed that the DHDA is able to successfully transmit sound information by mechanically driving the tympanic membrane. This trial also provided insight into the possible locations where a direct drive device can couple to the TM. Upon inception of the clinical trial, our group believed we would couple the DHD to the umbo of the TM. When the DHDA was placed in the subject's ear canal and the device was tested at different contact points on the tympanic membrane, the lateral process of the malleus appears to be the most promising. The subject reported the sound to be louder when coupled to the lateral process as compared to other locations. This may be due to the anatomy of the lateral process of the malleus and how it protrudes slightly from the plane of the TM allowing for easier access as well as a more secure contact point (Gulya 2010). Moreover, the subject's positive assessment of the sound quality the DHD produces compared to traditional headphones is encouraging and supportive of the direct drive mechanism. Power consumption for the live human subject was markedly lower than that for the cadaver.

Future work will focus on improving the interface between the DHDA and the tympanic membrane, securing the device in place, and optimizing the actuator design. In addition, the

long-term outcomes associated with placement of the device in the ear canal remains to be studied in the future clinical trials.

VI. Conclusion

We have presented a DHDA that enables a semi-implantable hearing prosthesis similar in principle to a middle ear implant but does not require surgery. The DHDA is located deep in the ear canal and couples directly to the bony portion of the tympanic membrane. This device recreates sounds through mechanical movements of the tympanic membrane and attached ossicular chain. It was demonstrated that the DHDA could move the ossicular chain at frequencies and magnitudes appropriate for normal hearing, with little distortion, and with minimal noise generation. The DHDA has demonstrated in preliminary cadaveric testing to be an appropriate driver capable of achieving the proper range of displacements that occur during natural hearing. A shortterm clinical performance test was conducted and concluded that the DHDA can successfully transmit high quality sound through mechanical coupling. This work lays the foundation for continued cadaveric and human testing as well as development of the DHDA as a clinical device.

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Fig. 1. Schematic drawing of a DHD in the ear canal. A microphone on the DHD detects sound entering the ear. The DHD actuator recreates the sounds with movements of the tympanic membrane (image in part from (Chittka and Brockmann 2005)).

Fig. 2.

(a) Cross section of the DHD actuator. The inner and outer flux guides, magnet, and voice coil form an actuator. The spring provides a restoring force to hold the interface tip against the tympanic membrane. (b) A direct hearing device actuator without an interface tip attached.

Fig. 3.

(a) Cross section of the DHDA in both compressed and uncompressed state demonstrating that the number of voice coil turns in the air gap remain constant at varying states of compression. (b) Cross section of the DHDA demonstrating the magnetic flux circuit of the device.

Fig. 4.

Cadaveric temporal bone secured within bone holder. A mastoidectomy was performed that provides access to the middle ear for stapes footplate displacement monitoring with the LDV. This figure depicts the temporal bone stapes baseline displacement measurement setup. Insert earphones and probe microphone (for SPL monitoring) are placed within the ear canal and a frequency sweep at a designed SPL was played through the insert earphones while the corresponding stapes footplate displacement is measured using the LDV.

Fig. 5. DHDA with a custom TM interface. The custom contact tip is made from a silicone polymer mold taken of the cadaveric TM. A 3mm cutout of the umbo impression was then mounted on the DHD connection plate to provide a custom interface between the TM and device.

Fig. 6.

(a) Frequency response magnitude of an uncoupled DHDA. DHDA voltage was held constant at 50 mV RMS throughout the entire frequency sweep and a noise floor measurement was taken by disconnecting the device and repeating the measurement in an identical fashion. The DHDA displays a linear frequency response with a primary resonance occurring around 300 Hz. (b) Total harmonic distortion of an uncoupled DHD. Driving voltage was held constant at 50 mV RMS throughout the entire frequency sweep. The LDV range was adjusted at 3 kHz. Below 0.5% THD is considered suitable for an implantable hearing aid (Leysieffer et al. 1997).

Fig. 7.

Force generation of the uncoupled DHDA using a stepped input signal. The relationship between input current and resulting force of the actuator is expected to be linear. The static displacements were measured using the LDV system and the corresponding force was calculated using the spring constant of the DHD.

Fig. 8.

Cadaveric middle ear frequency response. Each line depicts the LDV measured value of posterior crus displacement (nm) during each frequency sweep at the designed SPL. A cosine correction has been applied to the displacement values corresponding to the experimental angle, 45° , at which the measurements were taken. This experimental angle is due to the cadaveric temporal bone setup.

Fig. 1.

Frequency response when the DHDA was coupled directly to the tympanic membrane. Five different input voltage levels were tested and the increase in input voltage corresponds directly to an increase in displacement of the posterior crus. The voltage was held constant throughout the entire frequency sweep. A cosine correction has been applied to the displacement values corresponding to the experimental angle, 45° , at which the measurements were taken. This experimental angle is due to the cadaveric temporal bone setup.

Fig. 10.

Short term clinical test results for pure tone stimulation. The DHDA was driven at various input voltage levels and the sound generated by the DHDA was decibel SPL matched to sound delivered by an audiometry earphone. The voltage level of the DHDA driving signal was matched to the perceived dB SPL level and graphed in this figure. Figure 10a represents the results for 250 Hz, 500 Hz, 1000 Hz, and 2000 Hz stimulation. Figure 10b represents the results for 4000 Hz and 8000 Hz stimulation.