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What is This?
Completely-in-the-Canal Magnet-Drive Hearing Device: A Temporal Bone Study

Hossein Mahboubi, MD, MPH1*, Melinda J. D. Malley2*, Peyton Paulick, MS3*, Mark W. Merlo, PhD3, Mark Bachman, PhD3,4, and Hamid R. Djalilian, MD1,3

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Abstract
The magnet-drive hearing device (MHD) is a small completely-in-the-canal hearing aid prototype that drives the tympanic membrane (TM) through a magnetic interface. A cadaveric temporal bone was prepared. The MHD was coupled to a nickel-epoxy pellet glued to the umbo. Frequency sweeps between 0.3 and 10 kHz were performed, and the MHD was driven with various levels of current. Displacements of the posterior crus of the stapes were measured using a laser Doppler vibrometer and compared with sound-induced displacements. The MHD had a linear frequency response and low total harmonic distortion. The pellet placement altered the stapes movements; however, the changes were statistically insignificant. Inputs of 100 and 300 mV produced displacements equivalent to those of the natural sound at 70- and 80-dB sound pressure level, respectively. The coupling of this novel device using a magnetic interface to the umbo had a frequency output wider than air conduction devices, and its actuator was effective in driving the TM.

Keywords
hearing aids, temporal bone, laser Doppler vibrometer, prosthesis

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Hearing aids are worn by only about 20% of those who could benefit from hearing amplification. The barriers to adoption of conventional hearing aids include sound distortion, occlusion effect, feedback, and stigma.1 Modern completely-in-the-canal (CIC) designs, which have overcome some of the aforementioned drawbacks, are not effective for moderately severe to severe hearing loss. In addition, implantable hearing aids require surgery and are expensive. We have developed a magnet-drive hearing device (MHD) prototype that combines the invisibility of CIC with the potential sound quality of implantable devices. The MHD fits entirely into the osseous external auditory canal (OEAC) and mechanically drives the tympanic membrane (TM) through a ferromagnetic interface. In this study, we aimed to test the MHD on a cadaveric temporal bone to determine whether it was effective in creating displacements of the stapes equivalent to those of sound.

Materials and Methods
The dimensions of the device were 6.2 × 3.7 mm. It consisted of a permanent magnet, 2 flux components to guide the permanent magnet, a voice coil actuator, and a contact tip. No battery or digital signal processing was incorporated at this level. Technical details of the device are published elsewhere.2 Frequency response and noise generation of the MHD were validated prior to cadaver testing. This study was exempt from review by the Institutional Review Board at the University of California, Irvine. A simple mastoidectomy with facial recess approach was performed on a cadaveric temporal bone to access the middle ear space and place a small piece of reflective tape on the posterior crus of the stapes. A 3-mg ferromagnetic pellet was made with nickel powder and epoxy glue. Then, the pellet was glued to the umbo (Figure 1A). Baseline measurements were performed prior to and after attaching the pellet to record the displacements of the stapes in response to natural sound of 70 and 80 dB sound pressure level (SPL) from 300 Hz to 10 kHz. The measurements were obtained using a laser Doppler vibrometer (LDV) through the reflections from the umbo.
reflective tape. Then, a 5-mg magnet was glued on an 8-mg angled silicone mold attached to tip of the magnet-drive hearing device. The angled silicone compensated the angle between the tympanic membrane and the external auditory canal axis.

Figure 1. (A) A 3-mg nickel powder and epoxy pellet (small box) glued to the umbo with cyanoacrylate. (B) The pellet was driven by a 5-mg magnet placed on an angled silicone mold attached to tip of the magnet-drive hearing device. The angled silicone compensated the angle between the tympanic membrane and the external auditory canal axis.

Figure 2. Mass loading effect of the pellet on the stapes displacements prior to coupling the device (no actuation from the device). Although the shape of the displacements was altered, the difference was statistically insignificant.

Figure 3. Frequency response of the magnet-drive hearing device at different voltage inputs when the device was coupled to the attached pellet on the tympanic membrane, compared with the baseline measurements at 70 dB sound pressure level prior to attachment of the pellet.

The MHD was found to have a linear frequency response. The generated noise did not exceed that of the background. The pellet attachment altered the displacements of the stapes; however, the differences in mean displacements were statistically insignificant (Figure 2). At 70 dB SPL, the mean displacements were 0.65 ± 0.25 nm (range, 0.12-1.09 nm) and 0.86 ± 0.89 nm (range, 0.28-4.56 nm) before and after the pellet attachment, respectively (P = .3). At 80 dB SPL, the mean displacements were 2.08 ± 0.79 nm (range, 0.36-3.51 nm) and 3.02 ± 3.07 nm (range, 1.05-15.83 nm) before and after the pellet attachment, respectively (P = .8). A 100-mV input produced a range of displacements equivalent to those of the sound prior to attachment of the pellet at 70 dB SPL (mean, 0.32 ± 0.30; range, 0.01-1.45). A 300-mV input produced a range of displacements equivalent to those of the sound at 80 dB SPL (mean, 0.76 ± 0.71; range, 0.01-3.34; Figure 3). The THD of the displacements was low (less than 1% in more than 85% of all tested frequencies). The harmonic distortion was highest below 400 Hz.

Discussion

The MHD prototype had a frequency output wider than air conduction devices. The MHD could be a potential candidate for moderately severe to severe hearing loss because the mechanical actuator of the device was effective in producing displacements of the stapes equivalent to 70 to 80 dB SPL with low voltage. The practicability of umbo vibration has been reported in a clinical study on a malleus vibration audiometer as a diagnostic tool for assessing ossicle function and integrity. Mass loading of the ossicles as little as 25 mg can cause a reduction in stapes displacement. The pellet that we placed on the umbo weighed 3 mg, and its effect as shown in Figure 2 was minimal. One of the early attempts to drive the TM was done by Goode and Glattke. In their study, a 2.4-cm-wide current-carrying coil produced a magnetic field that induced movements of a 55-mg magnet glued to the umbo. EarLens later followed a similar approach but used a 9-mg cobalt magnet that floated on the TM by means of mineral oil. The MHD, in contrast, is a completely enclosed voice coil actuator that comes into direct contact with a 3-mg ferromagnetic pellet placed on the umbo. This design would lead to smaller size, lower power consumption (about 20 mA for 70-dB gain), and minimal mass loading effect. At the current stage, the device prototype does not include battery or digital signal processing. Adding these...
parts, in the future, will probably double the length of the device. Future efforts will focus on improving the device-TM interface. Long-term consequences of attaching a mass to the TM remain to be studied in animal models.

Author Contributions

Hossein Mahboubi, designing, acquisition of data, analysis and interpretation of data, drafting the article, final approval of the version to be published; Melinda J. D. Malley, designing, acquisition of data, analysis and interpretation of data, drafting the article, final approval of the version to be published; Peyton Paulick, designing, drafting the article, final approval of the version to be published; Mark W. Merlo, designing, drafting the article, final approval of the version to be published; Mark Bachman, designing, drafting the article, and final approval of the version to be published; Hamid R. Djalilian, designing and interpretation of data, drafting the article and final approval of the version to be published.

Disclosures

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