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Comparisons of electromagnetic and piezoelectric floating-mass transducers in human cadaveric temporal bones[☆]

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Abstract

Electromagnetic floating-mass transducers for implantable middle-ear hearing devices (IMEHDs) afford the advantages of a simple surgical implantation procedure and easy attachment to the ossicles. However, their shortcomings include susceptibility to interference from environmental electromagnetic fields, relatively high current consumption, and a limited ability to output high-frequency vibrations. To address these limitations, a piezoelectric floating-mass transducer (PFMT) has recently been developed. This paper presents the results of a comparative study of these two types of vibration transducer developed for IMEHDs. The differential electromagnetic floating-mass transducer (DFMT) and the PFMT were implanted in two different sets of three cadaveric human temporal bones. The resulting stapes displacements were measured and compared on the basis of the ASTM standard for describing the output characteristics of IMEHDs. The experimental results show that the PFMT can produce significantly higher equivalent sound pressure levels above 3 kHz, due to the flat response of the PFMT, than can the DFMT. Thus, it is expected that the PFMT can be utilized to compensate for high-frequency sensorineural hearing loss.

[☆]Research background: This paper presents comparative study results, using human cadaver temporal bones, for two types of vibration transducer developed by our team for IMEHDs. The data were collected with the cooperation of Kyungpook National University, Korea, and Stanford University, USA.

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1. Introduction

Implantable middle-ear hearing devices (IMEHD) have been developed to overcome some of the disadvantages of conventional air-conduction hearing aids [Ko et al., 1987; Goode, 1995; Backous and Duke, 2006]. One of the most important components of IMEHDs is the miniaturization of the vibration transducer, which is attached to the ossicular chain in the middle ear, and directly stimulates it to deliver mechanical vibration to the cochlea. Since the vibration transducer plays an important role in defining the degree of hearing-loss compensation and the overall efficiency of the IMEHD system, its structure and vibration mechanism have been studied. Additional design goals include easy attachment to the ossicles, better high-frequency characteristics, and low power consumption [Yanagihara et al., 1995; Hough et al., 2002; Jenkins et al., 2007].

The vibration transducers developed to date are commonly grouped by attachment method and actuator type. The vibration transducer attachment is either a floating mass or a fixed driver, and the vibration mechanism is either electromagnetic or piezoelectric.

One of the most successful floating-mass transducers is the MED-EL Vibrant Soundbridge®. This device uses an electromagnetic floating-mass transducer that was proposed by Ball in 1996 and consists of a permanent magnet and two coils [Ball, 1996; Dietz et al., 1997]. Since this transducer can be easily attached by a titanium clip to the incus long process in the middle ear, the surgical procedure for implantation is simple and the device has been implanted in over 5000 ears worldwide according to the MED-EL website. However, the electromagnetic floating-mass transducer can be susceptible to interference from environmental electromagnetic fields, and its use in strong magnetic fields such as MRI environments is a contraindication according to FDA guidelines [FDA, 2000]. To solve the MRI interference problem, our team proposed a differential electromagnetic floating-mass transducer (DFMT) [Cho, 2004; Song et al., 2002; Kim et al., 2006]. However, both of these transducers have vibration characteristics limited to frequencies below 8 kHz, and require relatively high currents of several milli-amperes.

Piezoelectric transducers such as those in the Implex TICA and the RION implantable hearing aid (IHA) have been considered for IMEHDs because they are not susceptible to interference from electromagnetic fields, and have the potential for good vibration characteristics up to 10 kHz and possibly higher [Zenner and Leysieffer, 2001; Yanagihara et al., 2006; Wang et al., 2002]. However, the surgical procedure for implanting piezoelectric transducers is complicated because it requires two connection points. One side of the actuator must precisely contact one of the middle-ear bones, and the other side must be affixed to the bony wall of the middle ear. To solve these problems, our team proposed a piezoelectric floating-mass transducer (PFMT) [Hong et al., 2007]. The PFMT can be attached to the ossicular chain in a manner similar to that used for the Vibrant Soundbridge® FMT, and there are no magnetic components within the transducer. It thus has the advantages of a simple surgical procedure and no interference from environmental electromagnetic fields. However, comparative experimental results for the PFMT and the electromagnetic floating-mass transducer implanted in cadaveric temporal bones have not been reported until now.

This paper describes the results of a comparative study of implantations in cadaveric temporal bones using these two types of vibration transducer. Our DFMT and PFMT were implanted in two separate sets of three fresh human temporal bones (*i.e.* a total of six bones) at the Palo Alto VA Hospital (Palo Alto California). Under the same measurement conditions, the stapes vibration characteristics of the transducers attached to the long process of the incus were measured and compared on the basis of the ASTM F2504-05 standard for describing the output characteristics of IMEHDs [Rosowski et al., 2007]. The experimental results show that both the DFMT and the PFMT can produce equivalent sound pressures of 94 dB SPL or better above 1 kHz, with electric drive signals of 1 mA_{peak} and 3.3 V_{peak} respectively. However, when stimulated with identical electrical power levels, the equivalent sound pressures produced by the PFMT in this frequency range are larger and can better compensate for the high-frequency hearing loss commonly seen for sensorineural pathology.

2. Materials and methods

2.1. Structure of the DFMT and PFMT

The differential electromagnetic floating-mass transducer (DFMT) can significantly reduce interference from environmental magnetic fields. Since the two DFMT magnets are arranged with matching magnetic poles facing one another, as shown in Fig. 1(a), the forces from the homogeneous background electromagnetic fields theoretically cancel out [Song et al., 2002]. This is the main functional difference from the Vibrant Soundbridge® FMT. The characteristics of the frequency response and the vibration mechanism are otherwise similar to those of an electromagnetic floating-mass transducer.

Fig. 1(b) shows the structure of the PFMT: it is composed of a piezoelectric multilayered actuator (MLA), a metal case, a clamp, and a feedthrough. A PFMT attached to the incus long process can stimulate the ossicular chain because of the interconnections between the ossicle, the piezoelectric actuator, and the metal case. The expansion and contraction of the piezoelectric actuator from an applied voltage signal causes vibration to be transferred to the ossicular chain by the law of action-and-reaction [Hong et al., 2007]. We use a lead zirconate titanate (PZT) MLA as the piezoelectric actuator, which is placed within a hermetically sealed metal case as shown in Fig. 1(b). The PZT MLA was fabricated by Morgan Electroceramics Co., USA, and has dimensions of 1 mm × 1 mm × 1.8 mm. The layer thickness is 0.02 mm and the total number of layers is 90.

2.2. Attachment of the DFMT and PFMT to the incus long process

Each vibration transducer was attached to the incus long process by a clamp, as shown in Fig. 2. To affix each transducer more firmly, we applied a tiny amount of instant glue (Instant Krazy® glue) or bone cement (3M ESPE Durelon®, carbonxylate cement) after using forceps to clamp the transducer to the incus long process. Two separate sets of three fresh human temporal bones were used for our study. The process of preparing and drilling the temporal bones and verifying the intactness of the ossicular chain was carried out by an otolaryngologist.

2.3. Transducer stimulation and measurement of displacement

To determine the equivalent output pressure level of the implanted transducers, we had to first obtain as a reference, prior to implantation, the stapes displacement due to acoustic stimulation of the tympanic membrane. The transducer's output level can be expressed as an equivalent sound pressure level, SP_{equiv} , using the following equation:

$$SP_{\text{equiv}} [\text{dB SPL}] = SP_{\text{ref}} [\text{dB SPL}] + 20 \log (SD_{\text{trans}} / SD_{\text{ref}}), \quad (1)$$

where SP_{ref} is the reference input sound pressure applied to the temporal bone at the tympanic membrane, prior to implantation, and SD_{ref} is the resulting measured stapes displacement. SD_{trans} is the stapes displacement produced by the implanted transducer.

Fig. 3 summarizes the overall measurement process. All the vibration displacements were measured using a laser Doppler vibrometer (LDV), based on the ASTM standard for describing the output characteristics of IMEHDs. The LDV used in our experiments is the Polytec HLV-1000. An ER-2 earphone and an ER-7C probe microphone (Etymotic Research, USA) were used to generate sound pressures at the tympanic membrane and to measure the pressure level. Before each transducer was clamped to the incus long process, the vibration characteristics of the unloaded transducer were measured. A sinusoidal current input of 1 mA_{peak} was applied to the DFMT transducer, and a sinusoidal voltage input of 3.3 V_{peak} was applied to the PFMT transducer, at frequencies varying from 100 Hz to 10 kHz, and the displacements were then measured with the LDV to check that the transducers worked properly and to obtain the frequency responses. To find the baseline characteristics of each temporal bone, the vibrating displacements of the stapes footplate were measured, prior to implantation, with the 94 dB SPL stimulus calibrated in the ear. To find the loading effect of the transducer attachment, the vibrating displacements of the footplate were also measured after attaching the DFMT to the incus, with a 94 dB SPL stimulus at the tympanic membrane. Finally, the vibrating displacements of the footplate were measured with the attached transducer driven by a sinusoidal electrical signal ranging from 100 Hz to 25 kHz. As reference values for driving the DFMT and PFMT, 1 mA_{peak} and 3.3 V_{peak} were chosen because of considerations related to the capacity and voltage level of batteries for implantable hearing aids. These values were also chosen because it is known that the vibration displacement and electrical signal input of our DFMT and PFMT behave linearly at these signal levels [Hong et al., 2007; Kim et al., 2006].

All measurements were made using SYSid version 6.5 (Richmond, CA) and the accompanying Ariel DSP-16 + board, with the board output connected to the input of a Crown amplifier, and the microphone and LDV outputs connected to the inputs of the board as described previously [O'Connor et al., 2008].

The experiments were carried out using two sets of three cadaveric adult human temporal bones, and were conducted according to the guidelines of the Veterans Administration and Stanford University.

3. Results

3.1. Vibration characteristics of the transducers

The measured displacements of the DFMT and PFMT, prior to implantation, are shown in Fig. 4. Since the DFMT is vibrated by an electromagnetic force between the magnets and a current-conducting coil, such that the two sides exhibit equal and opposite motions with respect to the coil, we can measure the displacement of the DFMT while it is suspended in air [Kim et al., 2006]. However, since only one side of the PFMT can move with respect to the metal case, the vibration of the PFMT was measured with one side fixed to a rigid wall so as to not interfere with the measured motion due to opposite movement of the assembly [Hong et al., 2007]. The DFMT has a resonance frequency of about 1 kHz and a roll-off above 1 kHz, similar to the vibration displacement of a normal middle ear. The vibration displacement below 1 kHz is more than 200 nm with a current source of 1 mA_{peak}. Meanwhile, because of the wide vibration bandwidth of the piezoelectric actuator, the PFMT shows a vibration of about 100 nm from 200 Hz to beyond 10 kHz when a sinusoidal voltage signal of 3.3 V_{peak} is applied.

3.2. In-vitro DFMT experiment

In Fig. 5, the stapes displacement as driven by the DFMT is compared with the displacement produced by acoustic stimulation before implantation of the DFMT. In addition to the mean curves, maximum and minimum displacement curves are also shown for these two conditions. The DFMT-driven results in Fig. 5 were converted into equivalent sound pressure levels, i.e. sound pressures at the tympanic membrane that would lead to the same observed displacements at the stapes, and these are shown in Fig. 7. The results indicate that the DFMT can produce an equivalent sound pressure level of about 94 dB SPL above 1 kHz when a current of 1 mA_{peak} is applied. The mean equivalent dB SPLs at 1 kHz, 4 kHz, and 8 kHz are 98 dB, 98 dB, and 96 dB SPL respectively. The lower DFMT-driven displacements relative to the sound-driven displacements in the frequency range below 1 kHz are similar to those seen for other floating-mass transducers. Irregular changes in the sound-driven displacements were observed after attaching the transducer to the incus long process, but there was no significant variation in the frequency response trend. The discrepancies between the loaded and unloaded states are discussed below in the Discussion section.

3.3. In-vitro PFMT experiment

As for the DFMT, the PFMT implantation was performed for three different human temporal bones. There were again differences in the sound-driven stapes displacements before and after attaching the transducer to the incus, but the frequency-response trends for the two conditions remained similar. Fig. 6 compares the PFMT-driven stapes displacement with the sound-driven stapes displacement before PFMT implantation (94 dB SPL at the tympanic membrane). Maximum and minimum displacement curves are shown in addition to the mean curves. As for the DFMT, there was a decrease in the low-frequency response below 1 kHz relative to the sound-driven case. However, the most distinctive difference between the DFMT and PFMT curves can be found in the high-frequency region above 3 kHz. Fig. 7 provides a conversion of the results from Fig. 6 into equivalent sound pressure levels. As seen in Fig. 7, when applying 3.3 V_{peak} to the PFMT, the equivalent sound

pressure level is more than 100 dB SPL above 3 kHz. The mean equivalent dB SPLs at 2 kHz, 4 kHz, 8 kHz, and 16 kHz are 102 dB, 122 dB, 120 dB, and 140 dB respectively.

Fig. 7 shows that the DFMT has a roughly constant equivalent sound pressure level above 1 kHz, whereas for the PFMT an increasing tendency is evident above 2 kHz. This means that the PFMT is better at compensating for high-frequency hearing loss. However, the current consumption of the PFMT in the high-frequency region also increases because of the capacitance effect in the multilayered piezoelectric actuator. According to the datasheet from the actuator manufacturer, the capacitance of our PZT actuators is less than 30 nF and the resistance is about 30 M Ω . We assume that the capacitance is independent of frequency and supply voltage, and use these values to estimate the equivalent sound pressure level of the PFMT for the same power consumption as the DFMT. Since the impedance of the DFMT is about 50 Ohms below 25 kHz, the calculated power consumption in the case of applying 1 mA_{peak} to the DFMT is about 25 μ W. In Fig. 7, we compare the equivalent sound pressure levels of the DFMT and PFMT for the same power consumption of 25 μ W. This figure shows that the PFMT output level is higher in the high-frequency range than that of the DFMT for the same power consumption. However, the calculated output level in the low-frequency range for the PFMT is not practical under realistic conditions because the PFMT would require supply voltages above the allowable maximum input range of 6.6 V_{peak} in order to consume the same power due to its high impedance in the low-frequency range.

4. Discussion

We have obtained comparative experimental results for an electromagnetic floating-mass transducer and a piezoelectric floating-mass transducer implanted in fresh temporal bones. O'Connor et al. (2008) reported stapes velocity to tympanic membrane pressure difference ratios for frequencies up to 20 kHz, which is higher in frequency than other previous studies (Aibara et al., 2001; Gan et al., 2004; Chien et al., 2006). When these previous velocity measurements are converted to displacements and compared to our baseline displacements shown in Figs. 5 and 6, the means agree in magnitude to within 7 dB below 1 kHz, 5 dB in the 1–10 kHz range, and 5 dB in the 10–16 kHz range.

Since the DFMT has vibration characteristics tuned to have a resonance frequency of 1–1.5 kHz like the human middle ear, the vibration characteristics of the DFMT above the resonance frequency decrease, as seen in Fig. 4. To increase the vibration efficiency of the DFMT, the number of coil wire turns should be as high as possible, but this number is limited by the small size requirement of the transducer. The output of the DFMT at 1 mA_{peak}, measured by following the ASTM F2504–05 standard, yields the equivalent of about 94 dB SPL above 1 kHz. The mean equivalent dB SPLs at 1 kHz, 4 kHz, and 8 kHz were 98 dB, 98 dB, and 96 dB SPL respectively. If we consider a current supply of up to 10 mA_{peak}, such output levels are enough to cover moderate to severe sensorineural hearing loss [Gelfand, 2004; Moore et al., 2008]. However, the current consumption for fully implantable middle-ear hearing devices needs to be lower because the rechargeable implantable batteries normally have a limited capacity of about 4 mAh (milliampere-hours).

The PFMT has been developed to address the limitations of electromagnetic floating-mass transducers, such as their relatively high current consumption and limited high-frequency responses. The PFMT also has the advantage of being a floating-mass transducer, in that it can be attached easily to the incus long process with no need to deform the ossicular chain. The PFMT vibration results from the volume variation of the PZT piezoelectric actuator due to the applied voltage signal. Since the PZT actuator's resonance frequency is above 20 kHz, the vibration response of the PFMT is flat within the audible frequency range. To increase the vibration efficiency of the PFMT, the PZT actuator has a 90-layer stacked structure so that the total displacement is about 90 times that of a single layer. Therefore, the PFMT has an improved high-frequency response compared to the DFMT under conditions of identical power consumption.

As shown in Fig. 7, the PFMT with 3.3 V_{peak} applied has an equivalent sound pressure level greater than 100 dB SPL above 3 kHz. The mean equivalent dB SPLs above 4 kHz are more than about 120 dB. The most distinctive differences between the PFMT and DFMT can be found by comparing the results of Fig. 7. The DFMT has a roughly constant equivalent sound pressure level above 1 kHz, whereas for the PFMT there is an increasing tendency above 2 kHz. This is because the PZT MLA within the PFMT has a flat vibration bandwidth and high vibration displacement up to 10 kHz and above, as shown in Fig. 4. However, since the PZT MLA within the PFMT has a capacitive electrical impedance, the current consumption of the PFMT with constant voltage increases as frequency increases. As shown in Fig. 7, the equivalent sound pressure level of the PFMT, with a power consumption equal to that of the DFMT as driven by a 1 mA_{peak} current, was estimated with the assumption that the capacitance of the PFMT is independent of the frequency and voltage of the applied signal. Using this assumption, we computed a PFMT output level that is higher in the high-frequency range than that of the DFMT for the same power consumption.

During stapes displacement measurements for the sound-driven condition, the differences in the frequency response before and after transducer implantation, *i.e.* the loading effect of the transducer, were also determined (not shown). The loading effect of the transducer attachment has been previously reported to be a decrease of about 3 dB in the stapes vibration [Needham et al., 2005]. After the transducer was attached to the incus, dips and peaks were sometimes observed in the frequency response of the transducer-driven stapes displacement that might have been caused by imperfect clamping of the transducer onto the incus long process. When we were trying to attach our transducers to the incus long process of four of the temporal bones (TB#1, TB#2, TB#4, and TB#5), we used instant glue (cyanoacrylate) to correct the imperfect clamping achieved by the forceps. However, the bone cement (carbonxylate cement), used for TB#3 and TB#6, was more effective at strengthening the connection between our transducers and the ossicle. The precise location of the tip of the probe-tube microphone within the ear canal can affect the determination of the sound pressure used for estimating the sound-driven stapes-velocity transfer function.

5. Conclusions

This paper gives the results of a comparative study of implantations in cadaveric temporal bones using two different types of vibration transducers for IMEHDs. Our DFMT and

PFMT were each implanted in a different set of three fresh human temporal bones. Under the same measurement conditions for all six temporal bones, stapes displacements were measured and compared on the basis of the ASTM standard for describing the output characteristics of IMEHDs. The experimental results show that the PFMT can produce a better high-frequency response and higher equivalent sound pressure due to the flat response of the PFMT. These results show that the PFMT can be utilized to compensate for the high-frequency hearing loss that commonly results from sensorineural pathology.

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Fig. 1. Structure of the (a) differential electromagnetic floating-mass transducer (DFMT), and (b) piezoelectric floating-mass transducer (PFMT).

Fig. 2.
Schematic of an implanted vibration transducer attached by a clamp to the incus long process.

Fig. 3. Overall experimental procedure for measuring the vibration characteristics of the DFMT and PFMT.

Fig. 4. Displacement magnitude as a function of frequency of the DFMT floating in air and the PFMT with one side fixed to a rigid wall.

Fig. 5. Comparison of stapes footplate displacement measurements with sound drive (before DFMT implantation) and with DFMT drive after implantation.

Fig. 6. Comparison of stapes footplate displacement measurements with sound drive (before PFMT implantation) and with PFMT drive after implantation.

Fig. 7.
Comparison of equivalent ear-canal sound pressure levels for the measured DFMT and PFMT displacements.