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Application of piezoelectric multi-layered actuator to floating mass transducer for implantable middle ear hearing devices

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Abstract Implantable middle ear hearing devices (IMEHDs), which have been developed since the 1970s, directly stimulate the middle ear and can realize a high efficiency of sound transmission with better sound fidelity. For such kinds of IMEHDs, this paper presents the design and application of a piezoelectric floating mass transducer (PFMT) using a PMN-PT multi-layered actuator as a new type of vibrating transducer. The proposed PFMT consists of only three components of a multi-layered piezoelectric actuator, a metal case, and a clamping clip. The actuator's one side is connected with the metal case and the other side is linked to the clamp for the attachment to an incus long process of middle ear ossicles. The vibration displacement of the PFMT attached to the incus is studied theoretically by simplified kinetic model between the PFMT and the incus. Through an *in-vitro* experiment using a human temporal bone, it has been verified that the proposed PFMT can generate the vibration force equivalent to the sound pressure of about 100 dB SPL. Therefore, the proposed PFMT is expected to be used as an IMEHD transducer with the advantages such as simple surgical implantation, no interference from external electromagnetic fields, and improved productivity.

Keywords Piezoelectric multi-layered actuator · Piezoelectric floating mass transducer · Implantable middle ear hearing devices

1 Introduction

As one of the advanced hearing aid systems, an IMEHD that can directly stimulate the ossicular chain in the middle ear by the use of a miniaturized vibration transducer attached to an ossicle with bypassing an external ear canal and a tympanic membrane. Generally, air-conductional hearing aids have several kinds of disadvantages such as occlusion effect, sound distortion, and howling effect due to acoustic feedback. Thus, for hearing impaired individuals with a mild-to-severe sensorineural hearing loss, IMEHDs have been studied and developed as a new hearing aid to solve the problems of conventional hearing aids [1–4].

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The vibration transducers, which directly stimulate the ossicular chain and play the most important role in the components of an IMEHD, can be divided into two types: piezoelectric and electromagnetic. Piezoelectric vibrators have been extensively studied by Yanagihara and Suzuki *et al*. [5–6], and their vibrators shown to exhibit better frequency characteristics and a higher sound fidelity than electromagnetic vibrators. Currently developed devices using a piezoelectric vibrator are Otoloics' MET, St. Croix Medical's Envoy, Implex AG's TICA, and Rion's implantable hearing device. However, since one end of a piezoelectric vibrator should be contacted precisely with a certain point of middle ear ossicles and the other end has to be fixed somewhere in the temporal bone, they lead a complex and difficult surgery procedure, including a mastoidectomy and some form of manipulation of the ossicular chain. So, it has been demanded that the surgery procedure time should be below 2 h and the multiple steps needed to properly install a piezoelectric vibrator should be reduced and simplified [4].

Among the electromagnetic vibrators that have been developed for IMEHDs [7–11], the Vibrant Soundbridge (MED-EL Corporation) is the only device obtained the US Food and Drug Administration (FDA) approval. The floating mass transducer (FMT) of their IMEHDs is an electromagnetic transducer attached with a titanium clamp to the incus long process through a facial recess approach. However, despite such an easy surgical process, the FMT suffers from the interference due to the environmental electromagnetic fields, unlike piezoelectric transducers. This electromagnetic interference was recently significantly resolved by Cho *et al.* through the use of a differential floating mass transducer (DFMT) [12]. Yet, since their electromagnetic transducer consists of about ten components within a very small cylinder of 2.1 mm (diameter)× 1.8 mm (length), the complex assembling process results in a low productivity and irregular vibration characteristics.

Therefore, a solution to the problems of surgical procedures and interference from environmental electromagnetic fields may be the realization of a new floating mass transducer using a piezoelectric actuator rather than an electromagnetic one. However, since piezoelectric materials only show expansion-and-contraction in the direction of the applied voltage, a floating mass type transducer that can produce an alternating vibration has not been developed yet.

Accordingly, this paper proposes the piezoelectric floating mass transducer (PFMT) with a simple structure, consisting of a PMN-PT multi-layered piezoelectric vibrator and a metal case. Similar to the FMT, the PFMT can be attached to the incus long process with a clamp and vibrates the ossicular chain according to the force originating from the piezoelectric actuator's expansion-and-contraction. To design the vibrating characteristics of the PFMT, the vibration displacement has been investigated. The *in-vitro* experimental results using a human cadevar and the implemented PFMT demonstrates that the proposed PFMT can provide enough sound pressure to the cochlea for utilization in an IMEHD for individuals who have the mild-to-severe sensorineural hearing loss.

2 Proposed PFMT

The transducer is the most important component of an IMEHD and its vibration characteristics should be designed to facilitate a clear sound signal transmission to the cochlea. Also, a simple surgical operation should be considered without affecting the auditory ossicles. Figure 1(a) shows the proposed PFMT which is attached to the incus long process.

2.1 Structure of PFMT

The PFMT consisting of a metal case and a multi-layered piezoelectric actuator, as shown in Fig. 1(b), is attached to the incus long process with an attachment clamp. One side of the piezoelectric actuator is fixed to the metal case, while the other side is stuck to the clamp. Then, the ossicle is vibrated by the repetition of the piezoelectric actuator's expansion and contraction according to the applied voltage. When the PFMT is attached to the ossicle, the relationship between the metal case and the ossicular chain can be regarded as the movement of two objects ruled by the pair of action-reaction forces in both sides of the piezoelectric actuator.

The multi-layered PMN-PT piezoelectric actuator has the high vibration efficiency required for a middle ear implant. It has also been reported that the PMN-PT piezoelectric material has better vibration efficiency than PZT materials [13, 14]. In a multi-layered actuator, the displacement, ΔT,

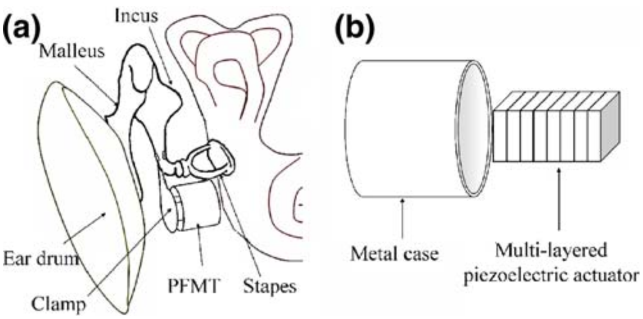

Fig. 1 Schematic of the proposed PFMT; (**a**) the PFMT is attached to the incus long process via a clamp and (**b**) structure of the PFMT

and driving force, F_P, produced from an actuator with n layers excited by the applied voltage, V, are given by

$$\Delta T = nd_{33}V \tag{1}$$

$$F_P = k_T \Delta T \tag{2}$$

where d_{33} is the strain coefficient [m/V] and k_T is the stiffness [N/m] of the piezoelectric material [15]. The PMN-PT multi-layered actuator used in this study has the cross section area of 1×1 mm^2. Each layer is 0.2 mm thick and our implemented actuator with nine layers has the thickness of 1.8 mm. Total mass of PFMT is 10 mg [13].

2.2 Displacement of PFMT vibration

Figure 2 shows the displacement of the vibration driven by the piezoelectric actuator force, F_P, when the PFMT attached on the incus. If the damping and spring of the incus are disregarded, M_1, M_P, and M_2 move in the same straight line and the actuator expands the displacement, Δd, by the same amount toward the both sides. The displacement, Δd, can then be expressed by the following equation.

$$\begin{aligned}\Delta d &= s_1 + s_1' \\ &= s_2 + s_2'\end{aligned} \tag{3}$$

where,

- s_1 the displacement toward M_1 by the action force of the actuator,
- s_1' the displacement toward M_2 by the reaction force of the actuator,
- s_2 the displacement toward M_1 by the reaction force of the actuator,
- s_2' the displacement toward M_2 by the action force of the actuator

When the actuator expands the displacement by Δd toward M_1, the movement toward M_1 is only s_1 due to the action and reaction, and the movement toward the other side is s_1'. Meanwhile, when the actuator expands the displacement by Δd toward M_2, s_2 and s_2' occur in the same way. Thus, the displacement toward M_1 is s_1+s_2. The relationship between the weight and the displacement is given by Newton's 3rd law of motion.

$$\frac{s_1}{s_1'} = \frac{s_1}{\Delta d - s_1} = \frac{M_P + M_2}{M_1} \tag{4}$$

$$\frac{s_2}{s_2'} = \frac{s_2}{\Delta d - s_2} = \frac{M_2}{M_P + M_1} \tag{5}$$

by combining Eqs. 4 and 5, the displacement toward M_1 can be established as

$$s_1 + s_2 = \frac{M_P + 2M_2}{M_1 + M_P + M_2}\Delta d \tag{6}$$

2.3 Design considerations

In a normal ear, the initial sound pressure that enters the external auditory canal is amplified by an auditory transmission process through the tympanic membrane and ossicular chain. Therefore, the vibrator that is implanted in an incus in the middle ear cavity is designed to consider the amplified displacement of the sound pressure. The stapes displacement of 100 nm is enough for the transducer to be used in current IMEHDs [7] and the frequency response characteristics of the incus are similar to that of the stapes [3]. From the Eq. 6, if the mass of incus is 27 mg [16], then the vibration displacement of the incus is about 100 nm when the mass of metal case is about 20 to 30 mg.

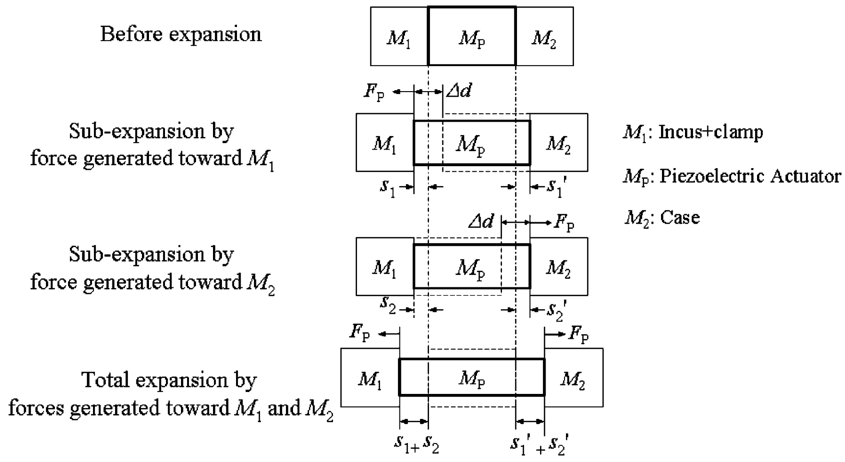

Fig. 2 Schematic representation of vibration displacement originating from action and reaction of actuator's expansion

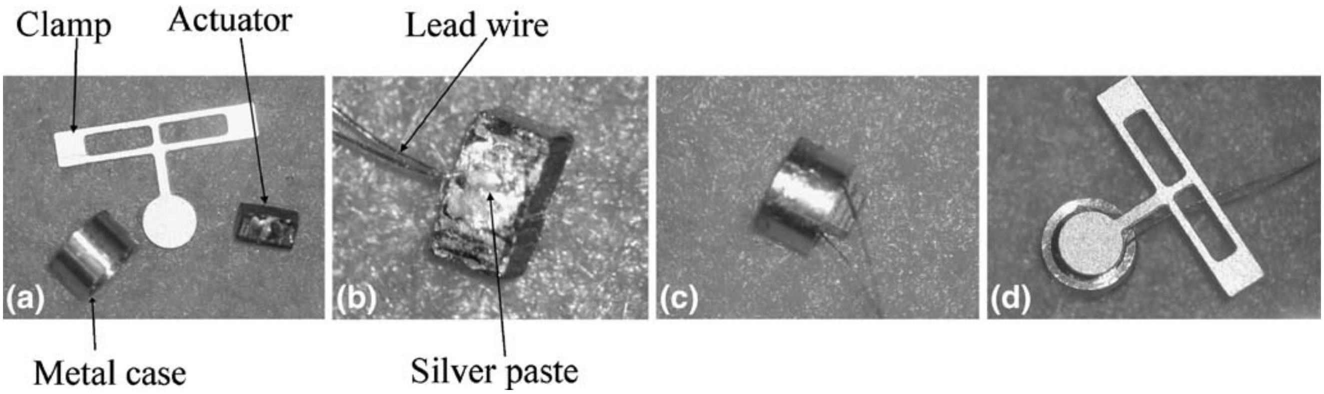

Fig. 3 Photograph of implementation; (**a**) components of the PFMT, (**b**) lead wire bonding, (**c**) case and actuator bonding, and (**d**) the implemented PFMT

The PFMT is surgically implanted and attached to the incus long process via a metal clamp. However, due to the confined space between the tympanic membrane and the incus, the dimensions and the mass of the transducer are limited. The size of the transducer which can be attached to the incus long process in the middle ear cavity has a diameter of 3–4 mm and height of 2.4 mm. In case of the FMT, the maximum size is height of 2.4 mm [17]. The actuator used in this study is 1× 1 mm cross-section and 1.8 mm thick. So, the metal case which is 20 mg can be determined by a size of 2.5 mm in diameter and 1.5 mm in height. The resulted PFMT has a diameter of 2.5 mm and the height of 2 mm or more.

Biocompatibility is an essential condition for any implantable system. To enhance the durability and biocompatibility of the PFMT, a 3 μm-thick Parylene film will be uniformly deposited on the entire surface of the implemented PFMT.

2.4 Implementation

The components of the implemented PFMT are a piezoelectric actuator, a metal case, two lead wires, and a metal clamp. Figure 3 shows the implemented PFMT. The piezoelectric material was 1 mm×1 mm×1.8 mm in size and weighed 10 mg. The lead wire is an insulated copper wire with 0.05 mm diameter and it is stuck to the actuator using a silver paste. The titanium clamp is fabricated using a process including photolithography and dry etching and its thickness is 0.08 mm and the weight is 1 mg. The gold case, an elaborately wrought carving using a process of micromachining, shows the mass of 20 mg, the diameter of 2.5 mm, and the height of 1.5 mm. One side of the actuator is attached to the metal case and the other side is stuck to the clamp by an adhesive. The components are precisely assembled and a 3 μm-thick parylene coating is uniformly deposited on the entire surface of the implemented PFMT. The resulted PFMT which shows the diameter of 2.5 mm and the height of 2.1 mm was shown in Fig. 4. The total mass of the PFMT, including the clamp and the adhesive, is 35 mg.

3 Results and discussions

To certificate the proposed transducer for IMEHDs, after measuring the displacement of the actuator itself, in-vitro test to measure the stapes displacement using the PFMT and a human temporal bone has been performed to analyze the vibration displacement.

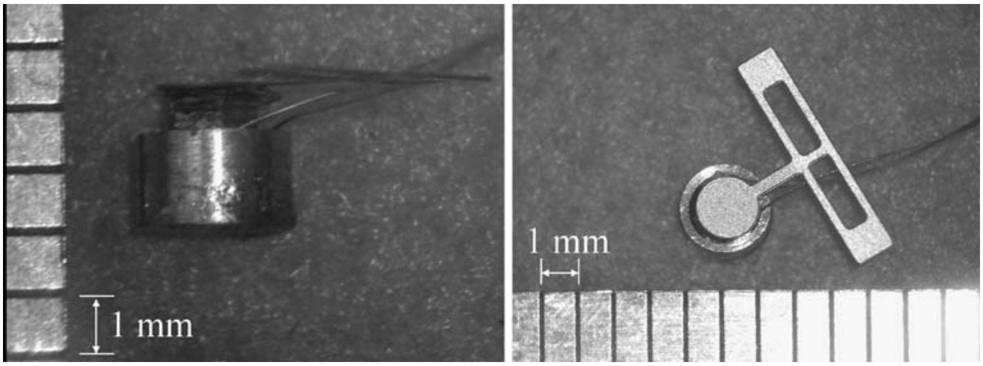

Fig. 4 Size of the implemented PFMT

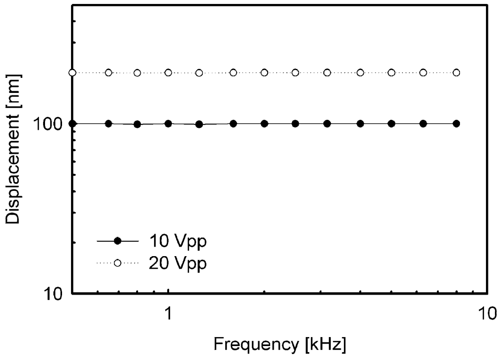

Fig. 5 Vibration displacements of the PMN-PT multi-layered actuator

3.1 Measurement of piezoelectric actuator displacement

To measure the displacement of the piezoelectric actuator, the lead wires are bonded to the actuator. One end of the actuator is bonded to an anti-vibration table and the displacement of the other side of the actuator can be measured by applying a sine wave voltage with a frequency range from 500 Hz to 8 kHz. As shown in Fig. 5, the measurement results shows that the frequency characteristic of the actuator is flat within 8 kHz, while the vibration displacement is about 200 nm at 20 V_{P-P}.

Generally, the force generated from the piezoelectric actuator is enough for driving the ossicular chain, but the transmission of this force from the actuator to the ossicle is inefficient when the actuator is not fixing in the middle ear. The proposed PFMT can deliver the force from the actuator to the ossicle using the metal case as a floating inertial mass.

The hearing impaired individuals suffer from hearing loss in a high frequency range from about 1 to 4 kHz [18]. Thus, the transducers used in IMEHDs are designed to provide significant high frequency compensation. As shown in Fig. 5, the measurement results show that the frequency characteristic of the PFMT is flat in the frequency range lower than 8 kHz. Therefore, the proposed PFMT can provide significant high output from 1 to 4 kHz.

The vibration displacement is proportional to driving voltage of the piezoelectric actuator. In this experiment, the driving voltage is 20 V_{P-P}. Practically, increasing the driving voltage is limited by the characteristics of the piezoelectric material. The piezoelectric actuators used in this experiment operate up to 40 V_{P-P} in normal operation and the vibration displacement of the actuator itself can be magnified twice of this experiment, about 400 nm according to the voltage-displacement linearity [15].

3.2 *In-vitro* test

To investigate the usefulness of the proposed PFMT as a transducer for IMEHDs, an *in-vitro* experiment has been carried out using an ossicular chain of the cadaver sampled three years ago. To examine the vibration characteristic of the middle ear ossicles, the stapes vibration in response to the acoustic stimulation in front of the tympanic membrane should be measured prior to the PFMT attachment. The stapes vibration data from acoustic stimulation act as a reference to the stapes vibration data from actuator stimulation. A 100 dB SPL acoustic stimulation was chosen as a reference which is commonly used in other studies. Using an audio amplifier and a loudspeaker, sounds with an audible frequency of 100 dB SPL can be generated and applied to the eardrum of the temporal bone through a tube and the vibration displacements of the stapes are measured.

After measuring the ossicle vibration, the PFMT is attached to the incus long process. The PFMT implanting position should be as close as possible to the incudostapedial joint to minimize the decrease of displacement [11]. The designed PFMT is small enough to be attached to the incus long process using a clamp in the middle ear cavity, as shown in Fig. 6(a). Then, the vibration displacements of the stapes are measured by a laser vibrometer when sine wave signals are applied to the PFMT.

Figure 6(b) shows the measured stapes displacements driven by the PFMT and the acoustic stimulations. From the

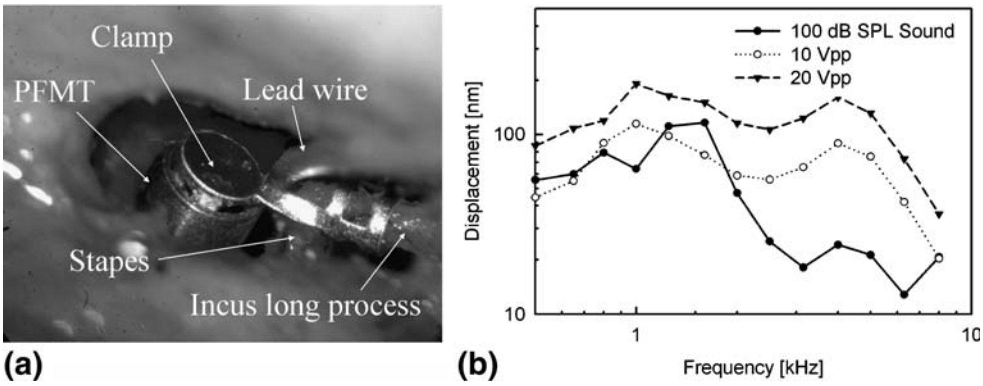

Fig. 6 *In-vitro* test; (**a**) photograph of implanted PFMT and (**b**) stapes displacements driven by the PFMT and the acoustic stimulations at the tympanic membrane

stapes displacement of a physical stimulation using the PFMT, the primary resonant frequency appears at approximately 1 kHz and the displacement is 191 nm and the stapes displacement is more than 100 nm from 600 Hz to 6 kHz. Also, the PFMT can generate a vibration force equivalent to a sound pressure of about 100 dB SPL up to 8 kHz. From 3 to 7 kHz, the stapes vibration from the PFMT was considerably greater than that from acoustic stimulation. These stapes vibrations are sufficient for an implantable transducer and show the PFMT to have a useful frequency characteristic.

4 Conclusion

This paper presented the application of a piezoelectric multilayered actuator to the piezoelectric floating mass transducer that combines the advantages of a piezoelectric vibration transducer and electromagnetic transducer for use in an IMEHD. The proposed PFMT simply consists of a multilayered piezoelectric actuator and metal case. The PFMT vibrates the ossicle based on the action-and-reaction force between the ossicle and the piezoelectric actuator. An *in-vitro* experiment using a cadaver confirmed that the proposed PFMT with a weight of 35 mg could generate a vibration force equivalent to a sound pressure of about 100 dB SPL up to 8 kHz. Accordingly, the proposed PFMT is expected to be a useful transducer for current IMEHDs.

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