Efficient Bone Conduction Hearing Device with a Novel Piezoelectric Transducer Using Skin as an Electrode

Ichiro Furuta, Hideaki Ogita, Fukuichiro Iguchi, Takayuki Okano, Kohei Yamahara, Tatsuya Namatsu, Shuichi Kawata, Koichi Omori, and Norio Yamamoto*

***Abstract*— *Objective:* Bone conduction hearing aids are the only non-surgical devices used for conductive hearing loss. However, they are impractical for lifelong use since they require close contact of the transducer with the head skin, causing skin erosion and discomfort. Bone conduction hearing implants and active middle ear implants do not present these issues; however, they require surgery and can sometimes cause issues in the skin surrounding the devices. This study aimed to develop a new bone conduction hearing device that does not exert pressure on the skin or require surgery. *Methods:* Our device modified a piezoelectric element by using the skin of a pinna as one of the two electrodes of a conventional piezoelectric device. We compared the sound transmission of a speaker, a conventional piezoelectric device, or the new device to the guinea pig cochlea, a physiological sound transducer to the auditory nerve, in normal and air-conductive hearing loss conditions. *Results:* The novel device transmitted sound to the cochlea even after causing air-conductive hearing loss. Its bone conduction was more efficient than the speaker and the conventional piezoelectric device. *Conclusion:* We developed a novel type of bone conduction device that efficiently transmits sound to the cochlea by skipping the external auditory canal, tympanic membrane, and middle ear ossicles. This device does not exert pressure on the skin that can result in skin damage, an adverse effect of a conventional bone conduction hearing aid. *Significance:* Our novel hearing device can be used as a substitute for current bone-conduction hearing devices.**

***Index Terms*— Auditory perception, bone conduction hearing, piezoelectric transducer, skin**

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I. Introduction

HEARING loss is one of the most frequent sensory impairments in humans, affecting 466 million people, or 6% of the world population. Furthermore, a recent estimate by the World Health Organization indicates that the hearing loss population will increase to 900 million by 2050[1]. Hearing loss results in the inability to communicate with others and delayed language development in children, as well as social isolation, loneliness, and frustration in elderly people. Recently, hearing loss has been identified as a significant, but modifiable, risk factor for dementia[2]. Considering its prevalence and severe effects on quality of life, the treatment of hearing loss should be a focus of research in the next 30 years.

When humans and other mammals perceive sound, the sound waves enter the external auditory canal and vibrate the tympanic membrane (Fig. 1a). This auditory stimulus is transmitted within the middle ear through three ossicles, the malleus, incus, and stapes, which relay the sound to the cochlea (Fig. 1a). Within the cochlea, the mechanical vibration of sound is transduced into an electrical signal, which activates the cochlear nerve. After passing through several nuclei in the central auditory pathway, the signal reaches the auditory cortex in the temporal lobe of the brain, resulting in hearing perception. Hearing loss can be classified into two categories based on the affected anatomical structure. If the external auditory canal, tympanic membrane, and ossicles are involved, it is called conductive hearing loss. In contrast, sensorineural hearing loss is caused by impairment of the cochlea, cochlear nerve, and more central auditory pathways. The perception of sound through the tympanic membrane and ossicles of the ear is called air conduction hearing (yellow arrow in Fig. 1b), and perception of skull vibrations directly entering the cochlea is called bone conduction hearing (blue arrow in Fig. 1b). Bone conduction is usually measured using a bone conduction vibrator attached to the skull through the skin.

Sensorineural hearing loss is intractable, and recovery through surgical treatment is not possible. Therefore, hearing is compensated by an air-conduction hearing aid or cochlear implant. In contrast, most conductive hearing loss can be radically treated by conventional ear surgeries, including tympanoplasty and stapes surgery. However, surgical treatment is not possible for some types of conductive hearing loss, such

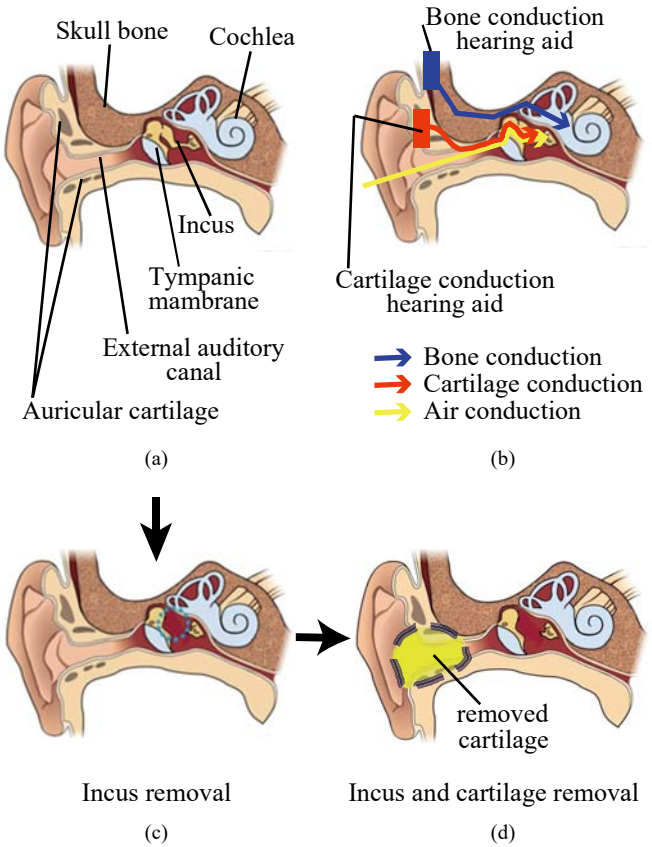

Fig. 1. Schematic representation of normal hearing and hearing loss model. The anatomical structure (a), various sound conduction modes (b), and the designs of the hearing loss model (c and d) are presented.

as severe chronic otitis media, some types of middle ear malformations, and congenital atresia of the external auditory canal (CAA), where lateral healing or severe adhesion of the tympanic membrane and facial nerve anomaly obscure eardrum and ossicular reconstruction, respectively. In cases with severe otitis media or CAA, even a conventional air-conducive hearing aid, which requires insertion into the external auditory canal, is inappropriate due to severe otorrhea within the canal or lack of the ear canal itself.

A bone conduction hearing aid (BCHA) or a bone-anchored hearing implant (BAHI) (Fig. 1b), which utilizes bone conduction, has been used to support patients with intractable conductive hearing loss who cannot use air-conduction hearing aids or cannot undergo conventional surgery. By skipping the factors of air conduction, these devices are reported to be very effective and useful prostheses for these patients. However, a BCHA causes discomfort due to the pressure exerted on the head skin since it requires close contact between the bone conduction transducer and the skull[3]. A BAHI reduces this discomfort and is associated with more efficient hearing; however, it requires implantation surgery and sometimes causes skin issues[4]. Therefore, hearing aids using cartilage conduction have been used as a less invasive option for patients with intractable conductive hearing loss[5-7] (Fig. 1b). Cartilage conduction is one of the soft tissue conductions,

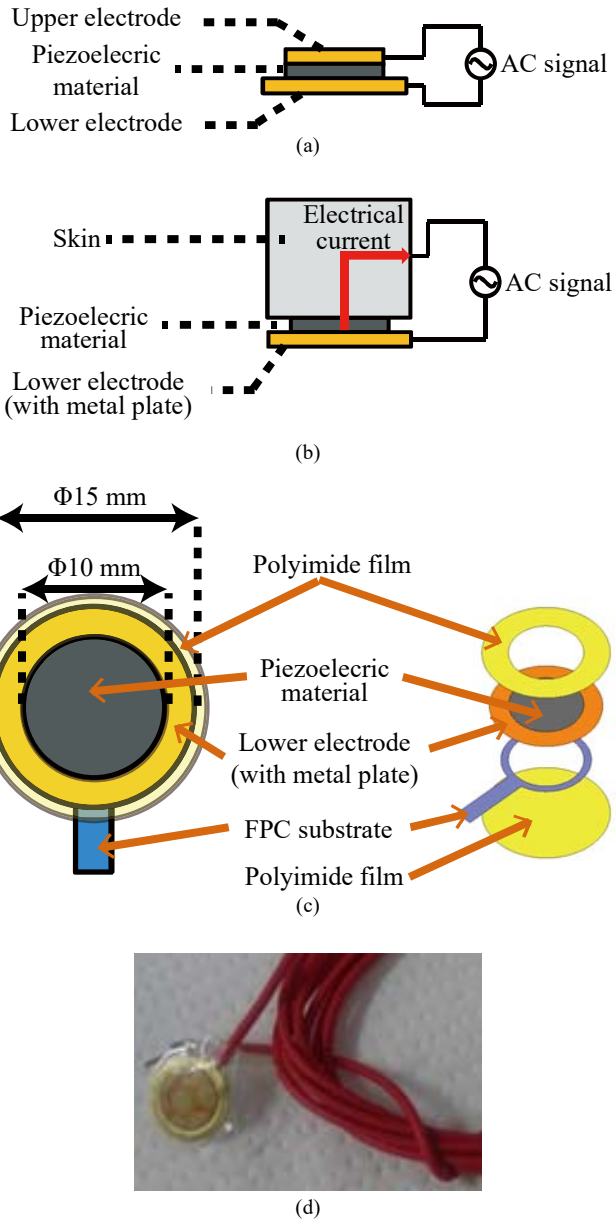

Fig. 2. Schemas of a conventional piezoelectric device and a novel piezoelectric transducer. A conventional piezoelectric device (a), a skin-mediated piezoelectric transducer (SPT) (b), and the detailed composition (c) and photograph (d) of an SPT.

which is a relatively new concept of the third sound conduction mechanism[8]. Cartilage conduction is induced by vibration of the auricular cartilage and is transmitted through an external auditory canal and tympanic membrane (red arrow in Fig. 1b). Cartilage conduction does not require close contact between a transducer and the skin and has been reported to be effective even in intractable conductive hearing loss[6].

In a previous report, a piezoelectric transducer was used to induce cartilage conduction[5]. Some materials can accumulate electric charge when they get mechanical stress and vice versa. This is called the piezoelectric effect, and it is widely used for microphones, actuators, and other transducers. In the case of a cartilage conduction device, an electrical signal that is

transduced from sound by microphones causes vibration to transmit sound wave signals to the auricular cartilage. The piezoelectric diaphragm is composed of a thin piezoelectric material, which is placed between the two electrodes (Figure 2a). The piezoelectric diaphragm causes vibration once an electrical voltage is applied between the electrodes and works as a piezoelectric transducer. In this study, we used the skin of a pinna as one of the electrodes of a piezoelectric diaphragm (Fig. 2b) and found that this novel transducer efficiently transmitted sound directly into the cochlea by skipping the tympanic membrane and middle ear ossicles.

II. Methods

A. *Fabrication of a novel piezoelectric transducer*

The production process of a commercially available conventional piezoelectric diaphragm (CPD) (7BB-15-6, Murata Manufacturing Co., Ltd.) (Fig. 2a) was modified to fabricate a novel piezoelectric transducer (skin-mediated piezoelectric transducer: SPT). Piezoelectric material with a thickness of 0.12 mm and a diameter of 10.0 mm was attached to a metal electrode plate with a thickness of 0.1 mm and a diameter of 15.0 mm as performed in the production of a CPD (Fig. 2c). In SPT, the upper electrode was not attached to the top side of the exposed piezoelectric material. The flexible printed circuit (FPC) was made of a polyimide base material and copper wiring. It was attached to a metal electrode on the lower side. The top side of the SPT is insulated with a polyimide film and insulating paint to avoid a short circuit caused by the voltage application when the lower electrode contacts the skin. The voltage was applied by connecting the leads to the electrodes attached to the FPC and by attaching a ground electrode at a distant location from the SPT application site.

B. *Physical characterization of SPT*

The impedance and vibratory characteristics of the SPT and CPD were measured using an impedance analyzer (4294A, Agilent Technologies, USA) and a laser Doppler vibrometer (PSV-400 Polytec Japan, Japan), respectively. To measure the impedance, the upper side of the piezoelectric element was attached to a copper foil with paste (ELEFIX Conductive EEG Paste, NIHON KOHDEN, Japan) by fixing the node point with the impedance analyzer. For measurement of the vibration, the upper side of the piezoelectric transducers was attached to a copper foil substrate with paste (ELEFIX Conductive EEG Paste, NIHON KOHDEN), and the acceleration of the transducer was measured throughout the entire area. For the measurement, the voltage was applied to the SPT through a copper foil substrate and FPC. To compare the physical characteristics of the SPT and CPD, the lower electrode in the CPD was attached to the FPC to apply voltage, and the upper electrode was attached to the copper foil substrate with paste.

C. *Animals*

Nine 4-week-old male Hartley guinea pigs were purchased from Japan SLC, Hamamatsu, Japan. All experimental procedures were performed in accordance with the Regulations on Animal Experimentation at Kyoto University. The Animal Research Committee of Kyoto University approved all the experimental protocols (#11179). The animals were cared for under the supervision of the Institute of Laboratory Animals, Kyoto University. We confirmed that all guinea pigs had normal hearing levels before starting the experiments using auditory brainstem response (ABR).

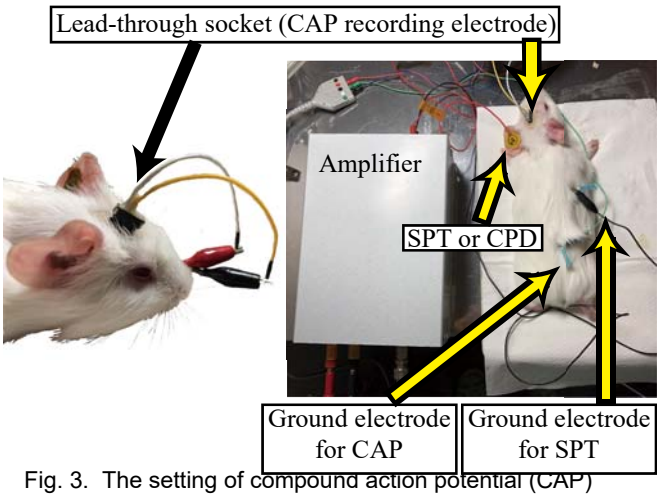

Fig. 3. The setting of compound action potential (CAP) measurement. SPT: a skin-mediated piezoelectiric transducer. CPD: a conventional piezoelectric diaphragm

D. *Anesthesia for surgical procedure*

All surgeries were performed under general anesthesia, achieved by intraperitoneal injection of midazolam (10 mg/kg, Astellas Pharma Inc. Tokyo, Japan) and xylazine (10 mg/kg, Bayer DVM, Leverkusen, Germany). The surgical procedure was performed on a heated operating table after local subcutaneous injection of 0.5% lidocaine hydrochloride.

E. *Measurement of ABR and compound action potential of the cochlear nerve (CAP)*

In order to evaluate the function of an SPT as a hearing device, we measured hearing thresholds in guinea pigs when auditory stimuli were provided by a speaker, an SPT, or a CPD. The pure tone thresholds for frequencies of 2 to 16 kHz were compared before and after treatment in the hearing organs of guinea pigs (threshold shift).

The ball electrode was surgically placed in the left ear in all animals to measure the compound action potential of the cochlear nerve (CAP). A retroauricular skin incision was made, followed by dissection of the retroauricular muscles to expose the bulla. A bone curette was used to remove the bone of the tympanic bulla and open it. A platinum wire electrode (0.005 inches bare, A-M Systems, Sequim, USA) was placed on the round window membrane (RWM), and a reference electrode was placed in the neck muscles. The lead-through socket for CAP electrodes was applied to the guinea pig head using dental cement (3M Japan, Tokyo, Japan) (Fig. 3).

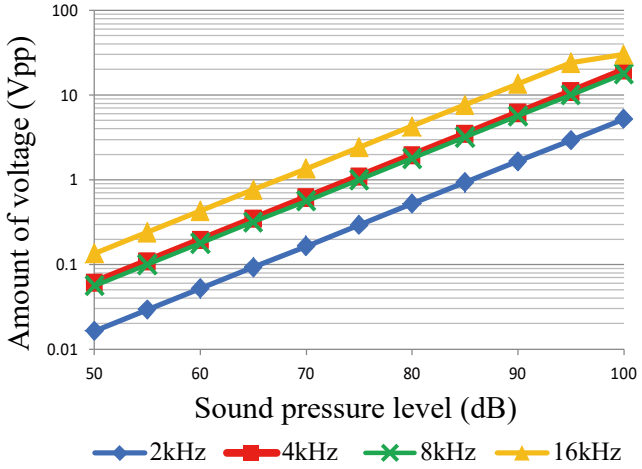

Fig. 4. The relationship between the amounts of voltage applied to the SPT or CPD and the sound pressure level

The right cochlea was mechanically destroyed to avoid cross-hearing from the contralateral side. The same surgical approach as the CAP preparation was used to approach the middle ear, and the right cochlea was drilled out. For ABR, all recording electrodes were placed under the skin using needles (Fig .3).

CAP and ABR were measured under general anesthesia achieved by injection of midazolam (10 mg/kg) and xylazine (10 mg/kg). Auditory stimuli were generated by an NI PXI-4461 signal processor (National Instruments, Austin, TX, USA) consisting of 1-ms tone bursts with a 0.2-ms rise and fall time delivered at a rate of 14/s. The polarities of the acoustic stimuli were altered to minimize stimulus artifacts. The auditory stimuli for CAP and ABR were amplified by an amplifier, SA1 Stereo Power Amp (Tucker-Davis Technologies, FL, USA), and applied through a speaker, MF1 multi-field magnetic speakers (Tucker-Davis Technologies), placed in the external auditory canal. The auditory stimuli for CAP were also applied through an SPT or a CPD (7BB-15-6). The sound stimulation from the CPD and SPT was elicited through two amplifiers, SA1 Stereo Power Amp and hand-made amplifier, by applying the voltage to the transducers. The amount of applied voltage was defined as the voltage which elicits 50–100 dB sound pressure level from the speaker used in this study. The amount of voltage applied to the SPT or CPD was measured for the sound pressure level from 50 to 100 dB using a 12-bit oscilloscope, HDO4024A (Teledyne Lecroy, NY, USA) (Fig. 4). The linearity of the logarithm of voltage and the sound pressure level was confirmed. In this study, we presented the strength of the stimulation from the CPD and SPT with the sound pressure level of the speaker. As a result, the same voltage was applied to the CPD and SPT if the presented sound pressure level was the same. The amplification factor of the hand-made amplifier was set to 25 times and the upper limit of the output was fixed at 30 V if the peak to peak voltage exceeds 30 V.

The CPD and SPT were attached behind the pinna with paste for electroencephalogram measurements (ELEFIX Conductive EEG Paste, NIHON KOHDEN). We did not apply any pressure on the skin to fix the transducer. The histological composition of the skin of the pinna is similar to that of other parts of the body. The ground electrode for SPT and CAP was placed on the back of guinea pigs with a needle. Individual responses were amplified 20,000 times (ERS 100C, BIOPACS Systems, Inc, Goleta, CA USA), digitally sampled at a rate of 20 kHz (NI PXI-4461, National Instruments), and band-pass filtered from 0.3 to 3 kHz. Each CAP waveform was saved on a computer (Mouse Computer Co. Ltd, Tokyo, Japan) as the average of 500 individual responses to stimuli of the same frequency and intensity. The waveform was displayed using the LabVIEW software (National Instruments). Intensity-amplitude functions of the CAPs were obtained at each frequency tested (2, 4, 8, and 16 kHz) by varying the intensity of the tone bursts from 0 to 100 dB SPL in 5 dB steps. An auditory threshold was defined as the lowest stimulus intensity that evoked a recognizable CAP wave pattern. In order to detect the artifact caused by the skin electrical current of the SPT, CAP measurements were performed after euthanasia of the guinea pigs. Guinea pigs were euthanized with an overdose injection of midazolam (30 mg/kg) and xylazine (30 mg/kg).

F. Preparation of conductive hearing loss and auricular cartilage removal

We surgically removed one of the ossicles, the incus, to create a stable conductive hearing loss. We used a submaxillary approach to avoid the dislocation of the implanted CAP electrode. The animal was fixed in the supine position, and a skin incision was made on the lower left jaw. The submandibular gland, sternocleidomastoid, and bicipital muscles were dissected laterally to reach the bulla without damaging the major blood vessels. A bone curette was used to remove the bone of the tympanic bulla and open it. After inspecting the ossicular connection, we cut the incudo-stapedial joint without disturbing the CAP electrode above the RWM and removed the incus (Fig. 1c). To impair cartilage conduction, the external auditory canal (EAC) cartilage was removed in a cylindrical shape following the incus removal, and the bony part of the EAC was exposed (Fig. 1d).

G. Data analysis

The threshold shifts were calculated by subtracting the threshold of the CAP wave after incus or cartilage removal from that of pre-treatment or incus removal, respectively. Threshold data with a hearing level above the detectable threshold after surgical treatment were excluded from the study.

Statistical analysis was conducted using a two-way analysis of variance, and Bonferroni's correction was used for post-hoc analysis. Statistical significance was set at $p < 0.05$.

III. Results

A. Design and fabrication of an SPT

As an auditory device, we designed a novel transducer based

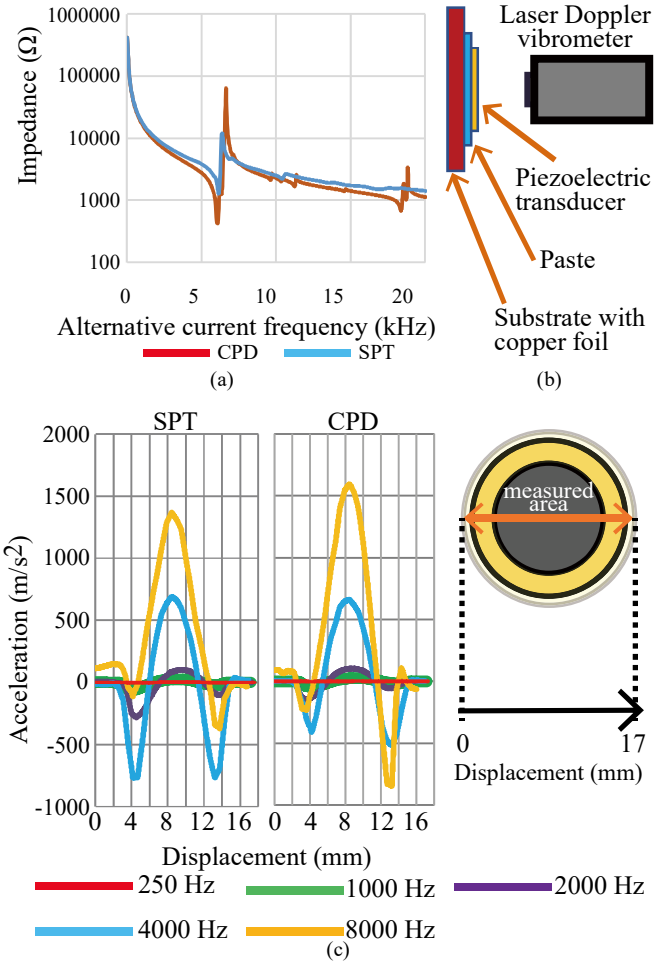

Fig. 5. The comparison of material characteristics between conventional and novel piezoelectric transducers
The electrical (a) and vibratory (b and c) characteristics of both transducers were evaluated. The electrical and vibration behaviors of both the skin-mediated piezoelectric transducer (SPT) and conventional piezoelectric diaphragm (CPD) were similar for each frequency.

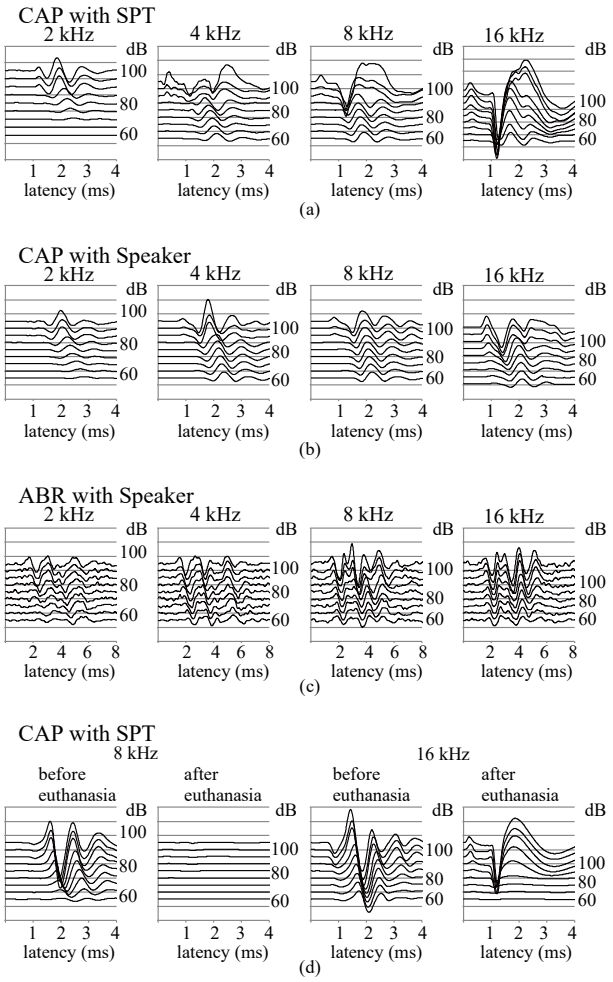

Fig. 6. Measurement of compound action potential (CAP) elicited by sound from a speaker and a novel piezoelectric transducer. Representative waveforms of CAP recorded for the sound from a skin-mediated piezoelectric device (SPT) (a) and a speaker (b) are shown. Both conditions showed similar thresholds for each frequency (2, 4, 8, and 16 kHz). Normal hearing of the guinea pig was confirmed by the auditory brainstem response (ABR) (c). In order to confirm the specificity of the CAP elicited with the SPT, CAP waveforms were recorded before (left of each panel) and after (right of each panel) euthanasia (d).

on a commercially available CPD (7BB-15-6, Murata Manufacturing Co., Ltd.). A CPD has electrodes attached to both sides of a piezoelectric material. The piezoelectric material deforms and vibrates when a voltage is applied between the upper and lower electrodes of a CPD (Fig. 2a). Our SPT has only the bottom electrode containing a metal plate attached to the piezoelectric material, and the piezoelectric material is exposed at the top (Fig. 2b). The SPT uses the skin as another electrode of the piezoelectric diaphragm by placing its top side in contact with the skin (Fig. 2b). The production process of a commercially available CPD (7BB-15-6, Murata Manufacturing Co., Ltd.) was modified to fabricate the SPT (Fig. 2c, d). The process of attaching the upper electrode was omitted, and the top side of the piezoelectric material was exposed.

B. *Physical characteristics of SPT*

In order to compare the physical characteristics of the SPT and the CPD, we quantified their frequency and vibratory characteristics (Fig. 5). A piezoelectric diaphragm usually has a unique resonant frequency depending on its structure. The impedance of the SPT and CPD was measured against the frequency (Fig. 5a). Since the upper piezoelectric element is exposed in the SPT, it may have a different resonance frequency from that of the CPD. However, the resonant frequency was about 6000 Hz in both the SPT and CPD, indicating that modification of the CPD did not affect the resonance frequency of the SPT.

To assess the vibratory characteristics, we measured the acceleration within the plane of the SPT and CPD (Fig. 5b) when 1 Voltage peak to peak (Vpp) of voltage was applied for several types of sound frequency (250, 1000, 2000, 4000, and 8000 Hz) (Fig. 5c). The acceleration was plotted along the

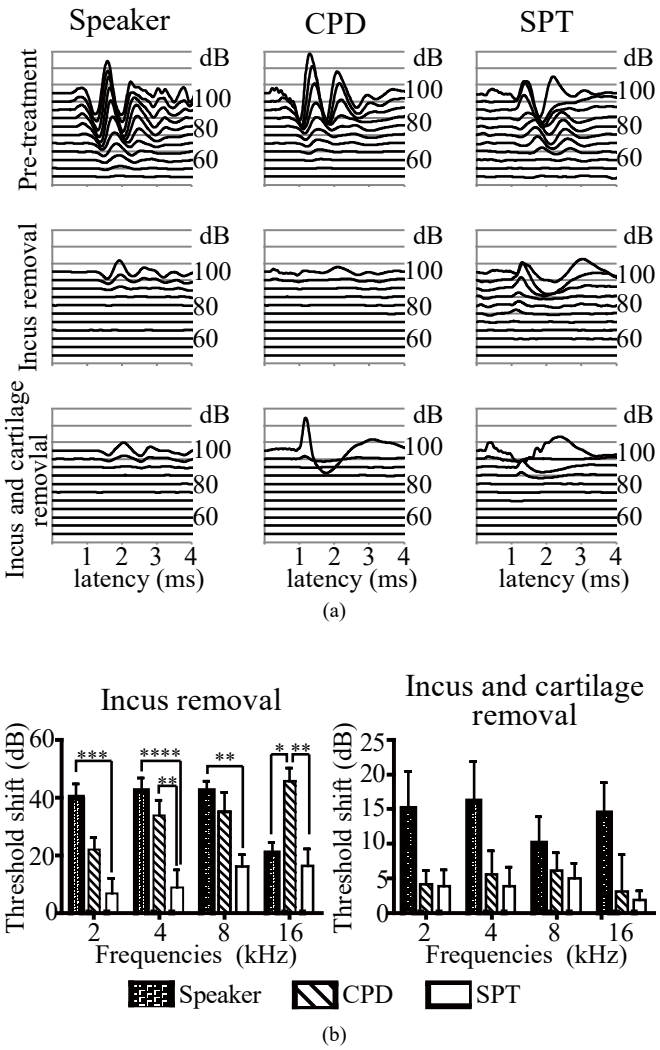

Fig. 7. Effects of conductive hearing loss on sound conduction with hearing devices. CAP measurement was performed with a speaker, a conventional piezoelectric diaphragm (CPD), or a skin-mediated piezoelectric transducer (SPT) under pre-treatment conditions and after incus or incus and cartilage removal. Representative waveforms are shown (a). The deterioration of the thresholds of sound transmission after incus removal was significantly smaller in SPT than with a speaker and a CPD (left, b). After incus and cartilage removal, the sound transmission thresholds of the speaker deteriorated severely from those of the incus removal (right, b). However, the amount of threshold deterioration from the incus removal to the incus and cartilage removal was small for the CPT and the SPT.

diameter of the membrane (displacement), and we found that the vibration behaviors of both the SPT and the CPD were similar. These results indicate that the processing of the SPT does not affect its vibration behavior.

C. *Evaluation of the SPT as a hearing device*

We could not obtain data with ABR when using an SPT since the electrical current flowing through the skin causes noise and interferes with data collection. As an alternative to ABR, we measured the CAP to evaluate the hearing function of devices. The CAP wave was successfully detected with both an SPT (Fig. 6a) and a speaker (Fig. 6b) in guinea pigs with normal ABR reactions (Fig. 6c). We confirmed that the reaction wave in CAP obtained with an SPT originated from the cochlear nerve by measuring CAP with an SPT before and after sacrificing the guinea pig (Fig. 6d). Stimulation from an SPT caused a CAP reaction wave when the guinea pig was alive (Fig. 6a and d), and the wave disappeared after it was euthanized (Fig. 6d) if the pure tone pitch was less than 8 kHz, indicating that the wave reflected the signal from the cochlear nerve and not from the noise. Even in the CAP measurement, the noise caused by the dermal electrical current was detected with a pure tone frequency higher than 16 kHz (Fig. 6d). This noise sometimes affected the waveform generated by sound stimulation at 16 kHz (Fig. 6a). As a result, we did not measure the hearing level at higher frequencies, such as 32 and 64 kHz.

D. *The hearing aid function of devices*

We investigated several hearing impairment models to determine how sound is transmitted through an SPT. Conduction hearing loss model animals were created by removing the incus (Fig. 1c). Removal of the incus causes interruption of sound transmission from the tympanic membrane to the cochlea, resulting in conductive hearing loss. After incus removal, we resected the auricular cartilage (Fig. 1d), which interfered with cartilage conduction. We collected CAP data using a speaker, a piezoelectric diaphragm, and an SPT in three different situations (pre-treatment, incus removal, and incus and cartilage removal) (Fig. 7). We calculated the threshold shift from pre-treatment to incus removal and from incus removal to cartilage removal for each device (Figure 7b). The threshold shifts caused by incus removal were 6.9 ± 4.8 dB, 8.9 ± 5.8 dB, 16.1 ± 3.9 dB, and 16.3 ± 5.6 dB for 2, 4, 8, and 16 kHz, respectively, in an SPT, which were less than those of a speaker (40.0 ± 4.3 dB, 42.2 ± 4.2 dB, 42.2 ± 3.0 dB, and 20.6 ± 3.4 dB, respectively) and a piezoelectric diaphragm (22.1 ± 3.8 dB, 33.9 ± 5.0 dB, 35.0 ± 6.4 dB, and 45.6 ± 4.3 dB, respectively). The difference was statistically significant at all measured frequencies, except 16 kHz, between an SPT and a speaker, and at 4 and 16 kHz between an SPT and a CPD. The threshold shifts in the CAP measurement using a speaker indicated that conductive hearing loss was successfully created by incus removal. The lower threshold shifts in CAP measurement using an SPT indicate that an SPT does not require the incus to transmit sound to the cochlea and has efficient bone conduction. Cartilage removal after the incus removal also caused smaller threshold shifts from the incus removal condition in the measurement using an SPT than when using a speaker, although the difference was not significant.

We did not find any damage to the skin where the SPT or its reference electrode was attached after several hours of hearing measurement, including burns due to electric currents caused by the SPT.

IV. Discussion

In this study, we developed a novel type of bone conduction device that efficiently transmits sound to the cochlea by skipping the tympanic membrane and middle ear ossicles. This novel device does not exert pressure on the skin that can result in skin damage when wearing conventional BCHAs. Hearing aids that function with soft attachment to the skin were reported by Hosoi et al.[5]. Their hearing aids, named cartilage-conduction hearing aids[7], vibrate auricular cartilage originally with a piezoelectric membrane[5]. However, clinically applied cartilage-conduction hearing aids use electromagnetic transducers to obtain stronger vibrations. As a result, cartilage-conduction hearing aids have beneficial effects on intractable conductive hearing loss, including ear canal atresia and stenosis[6, 7, 9]. In this study, we modified the piezoelectric membrane by using the skin as an electrode instead of a metal electrode.

ABR is typically used to determine the hearing thresholds of animals. ABR is an auditory evoked potential that is recorded through electrodes placed on the scalp. However, we could not obtain data with ABR when auditory stimuli were given through an SPT since the electrical current flowing through the skin, which an SPT uses as an electrode of the piezoelectric transducer, causes noise and interferes with data collection. As an alternative to ABR, we decided to measure the CAP to evaluate the hearing function of devices. The CAP captures the synchronous activation of cochlear nerve fibers, corresponds to wave 1 of ABR, and reflects the cochlear response to sound [10]. Its measurement requires an electrode placed near the cochlea, which is far from the skin and is less affected by the noise caused by dermal electrical current.

Moreover, since CAP is classified as a near-field potential, the amplitude of CAP is larger than that of ABR, which is a far-field potential [10]. Thus, CAP is suitable for the evaluation of hearing sounds delivered by the SPT. The CAP was measured from electrodes placed at the cochlear round window and in the neck muscle.

We observed more efficient sound transmission to the cochlea with the new device (SPT) compared with a conventional piezoelectric membrane. Sound transmission with SPT did not require middle ear ossicles (Fig. 1 and 6), indicating that SPT is an efficient bone conduction device. In contrast, a conventional piezoelectric membrane cannot perform bone conduction efficiently since incus removal causes a larger threshold shift than the SPT.

Bone conduction hearing is usually elicited by applying a bone conduction vibrator to the skin overlying the skull bone with a static force of 5 N. The vibrating skull is reported to transmit sound through five factors, including sound radiated into the ear canal, middle ear ossicle inertia, the inertia of the cochlear fluids, compression of the cochlear walls, and pressure transmission from the cerebrospinal fluid[11]. Vibratory auditory stimulation of soft tissue[8], such as skin on the neck[12], eyeballs[13], and brain[14], also stimulates the inner ear, causing a hearing sensation. Moreover, even if the application force of the bone conduction vibrator is weaker, vibratory stimulation of the skin over the skull bone or eyeballs can elicit skull bone vibration[15]; however, it is not efficient. The conventional piezoelectric membrane placed on the auricular skin without application force caused hearing sensation mainly through sound radiated into the ear canal in humans[16], which is consistent with the results of the CPD in the current study. These studies showed that conventional piezoelectric stimulation did not elicit sufficient skull bone vibration for bone conduction. In contrast, the SPT, which uses skin as one of the electrodes of the piezoelectric membrane, was able to transmit sound through bone conduction, as confirmed by the incus-removal model of conductive hearing loss (Fig. 7). Surprisingly, the SPT had better bone conduction ability than the CPD although the physiological property of the CPD and SPT was similar (Fig. 5). In the SPT, the vibrating membrane is directly attached to the skin, and both electrical signals and vibratory stimulation are applied to the skin. This combined stimulation may cause the changing of the physiological property of the skin and result in more efficient vibration of the skull bone and better bone conduction. It will be necessary to evaluate the physiological characteristics of the whole system, including both skin and a transducer. Considering that using skin as an electrode resulted in the better bone conduction, it may be helpful for improving the ability of piezoelectric device as a hearing aid to substitute its metal electrodes with soft material with stiffness and conductivity similar to skin.

We removed the auricular cartilage after incus removal to evaluate the function of auricular cartilage in hearing ability. Although the threshold using a speaker deteriorated from the incus removal condition to the incus and auricular cartilage removal condition, we did not observe a threshold shift when using a CPD or an SPT. Considering that hearing through a speaker was affected by the auricular cartilage in the absence of the incus, the auricular cartilage is involved in sound transmission independent of the middle ear ossicles. However, a CPD and an SPT do not use this mechanism for sound transmission.

BCHAs, BAHIs, or active middle ear implants (AMEIs) are usually applied to intractable conductive hearing loss, including CAA, middle ear anomaly, and severe otitis media, where tympanoplasty is not effective. However, these treatment methods have adverse effects despite their effectiveness. Conventional BCHAs with soft band fixation and transcutaneous BAHIs with a magnet cause pressure on the skin to achieve efficient sound conduction, resulting in skin irritation and discomfort[17]. Percutaneous BAHIs cause peri-implant skin infections, skin overgrowth, and loss of the implant and require frequent regular hygienic maintenance to avoid these issues[4]. BAHIs and AMEIs require surgery, and transcutaneous BAHIs and AMEIs have limited MRI compatibility and image artifacts due to the magnet used in implants. BCHAs do not require surgery and do not have limitations in MRI image collection. However, their effectiveness is less than that of BAHIs and AMEIs due to the dampening of sound with skin and subcutaneous tissues. The SPT reported here avoids all the disadvantages of currently available hearing devices. Moreover, the SPT works with a

small volume and can be used to create a smaller-sized hearing device.

A possible limitation of this study is the use of the skin as an electrode in a piezoelectric device. Although we did not observe any injury to the skin with the electrical current caused by the sound pressure during our experiment, significantly stronger stimulation may cause electrical injury to the skin. To avoid injury and develop a clinical device, it is necessary to evaluate the minimum electrical current that causes skin injury. The other limitation is the difference in skin impedance between humans and rodents. The human skin impedance was higher than that of rodents [18]. In developing a clinical device, evaluation in humans is necessary since the effects of SPT seen in our study may differ in the clinical setting. Especially, the difference in histology and physiological property between the human and rodent skin should be considered.

V. Conclusion

We found that an SPT, a modified piezoelectric element using the skin as one of the two electrodes of a conventional piezoelectric device, efficiently transmitted sound to the cochlea. An SPT achieved its sound transmission through bone conduction by skipping the external auditory canal, tympanic membrane, and middle ear ossicles. Moreover, it did not exert pressure on the skin, an adverse effect of a conventional bone conduction hearing aid. These findings suggest the possibility of an SPT as a material for a novel bone conduction hearing device.

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