

## Development of Fully-Implantable Middle Ear Hearing Device with Differential Floating Mass Transducer : Current Status

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**Abstract:** It is expected that fully-implantable middle-ear hearing devices (FIMEHDs) will soon be available with the advantages of complete concealment, easy surgical implantation, and low power operation to resolve the problems of semi-implantable middle-ear hearing devices (SIMEHDs) such as discomfort of wearing an external device and replacement of battery. Over the last 3 years, a Korean research team at Kyungpook National University has developed an FIMEHD called ACRHS-1 based on a differential floating mass transducer (DFMT). The main research focus was functional improvement, the establishment of easy surgical procedures for implantation, miniaturization, and a low-power operation. Accordingly, this paper reviews the overall system architecture, functions, and experimental results for ACRHS-1 and its related accessories, including a wireless battery charger and remote controller.

**Key words:** Fully-implantable middle-ear hearing device, Differential floating mass transducer, Wireless charger, Remote controller

### INTRODUCTION

In the case of conventional acoustic hearing aids used to cover severe sensorineural hearing loss, there are still unavoidable problems, such as sound distortion, howling, and unwanted acoustic feedback when the sound signals are delivered with a high gain amplification. Plus, the discomfort associated with wearing conventional hearing aids still needs to be resolved.

As the implantable middle-ear hearing devices (IMEHDs) directly drive the ossicular chain by changing the acoustic sound into a mechanical vibration, there is no feedback of the acoustic sound output from the hearing aid. Therefore, according to several reports, IMEHDs are able to produce a high quality of sound, especially for hearing-impaired people who are dissatisfied with conventional acoustic hearing aids[1-7].

Semi-implantable middle-ear hearing devices (SIMEHDs) have already been developed in several countries, for example, the Vibrant Medel's sound bridge[8-12] and the Rion device[13] developed by Ehime University. Yet, the common limitations of these two SIMEHDs are the discomfort associated with wearing the external module and poor cosmetic appearance. In addition, SIMEHDs cannot be used in a swimming pool or bath. Thus, to overcome these limitations, fully-implantable middle-ear hearing devices (FIMEHDs) have now been developed, for example, the Envoy system from St. Croix Medical[14], which is currently undergoing clinical tests for FDA approval. However, since the malleus in the ossicular chain must be disconnected to prevent feedback from the incus vibration to the tympanic membrane, any air conduction residual hearing of the hearing-impaired person is lost, plus the ossicle chain is permanently destroyed. In contrast, ACRHS-1, an FIMEHD developed at Kyungpook National University, is based on a differential floating mass transducer (DFMT) that does not involve destroying the ossicular chain, and a small skin incision is sufficient to replace the battery. Furthermore, the DFMT of ACRHS-1 is less influenced by environmental electromagnetic fields[15-18].

Accordingly, this paper introduces the main design and implementation characteristics of

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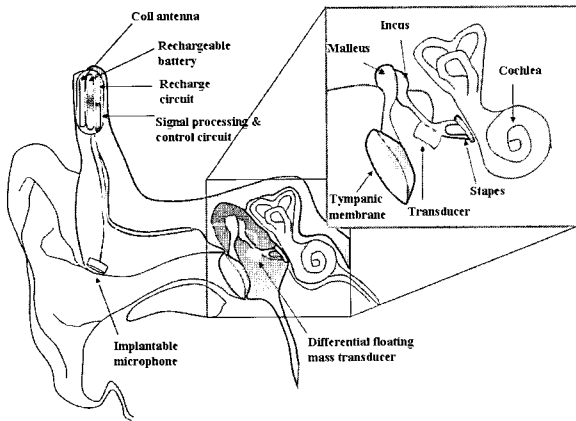
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ACRHS-1, including the frequency characteristics of the vibrating transducer and implantable microphone, functional improvement of the audio processing module, and size miniaturization and low-power operation of the implanted device. The DFMT and implantable microphone are designed to have high efficiency and sensitivity using a finite element analysis (FEA). Experimental results using the ossicular chain of a cadaver and guinea pig are presented to verify that the ACRHS-1 can provide a suitable performance for individuals with a moderate to severe sensorineural hearing loss.

### CONSTRUCTION OF ACRHS-1

As shown Fig. 1, ACRHS-1 is composed of five main parts: the vibration transducer, implantable microphone, audio signal processor with adjustable filter characteristics, control signal transmitting and receiving module for communication with a remote controller and battery charger, and recharging circuit for the internal battery of ACRHS-1.



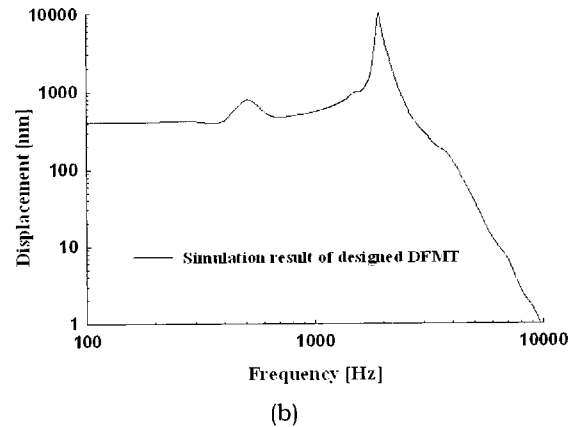
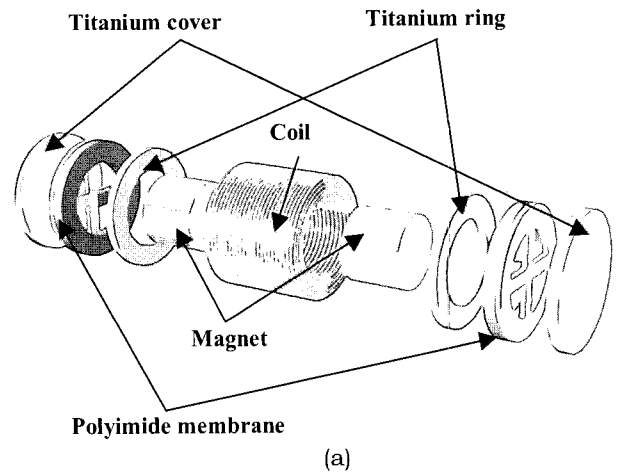
**Fig. 1.** Concept of ACRHS-1, fully-implantable middle-ear hearing device (FIMEHD), developed by Kyungpook National University.

### DIFFERENTIAL FLOATING MASS TRANSDUCER (DFMT)

#### Design and Analysis of DFMT

A DFMT with similar frequency characteristics to those of a normal middle ear was designed and implemented. In consideration of the cavity space in

the middle ear, the DFMT was minimized to the appropriate size for implantation. To optimize the DFMT characteristics, which are practically determined by the electromagnetically forced vibration, an FEA simulation was carried out. The simulation results were evaluated as regards their suitability for the transducer in the ACRHS-1 system and used as the specifications for the optimal design. The most distinct advantage of a DFMT is its structural design that is unaffected by environmental magnetic fields, unlike a conventional FMT. Fig. 2 (a) shows the components of the designed DFMT, including two polyimide membranes, titanium covers, a driving coil, and two magnets. The two magnets are glued with the same pole facing each other inside the coil. Thus, since the magnets face each other with the same polarity, forces induced by environmental magnetic fields are completely canceled. Also, the efficiency of generating the force by supplying a signal current to the solenoid coil is higher than that of an FMT.



**Fig. 2.** (a) Components of DFMT and (b) simulation results for vibration characteristics of designed DFMT.

The actuating force of the DFMT driving parts can be defined using Lorentz's force theory. To design the DFMT with the maximum actuating force and appropriate size for implantation, the size of the electromagnetic actuating part was optimized by an FEA simulation. As a result, the air gap between the magnet and the coil, the optimal magnet length considering the thickness of the polyimide membrane and titanium cover, the coil lengths, and coil thickness were all determined to produce the maximal force[19].

The momentum equation for the free-body diagram of the DFMT was obtained using Newton's second law.

The vibration displacements of the DFMT, in the force vibration mode, were defined using the following equation, and the amplitudes of the displacements computed using a theoretical formula[19].

$$x_1 = \frac{F_0(k_2 - m_2\omega^2)}{[(k_2 - m_2\omega^2)(k_1 + k_2 - m_1\omega^2) - k_2^2]} \sin \omega t \quad (1)$$

where  $m_1$  is the outer case mass of the DFMT, with the exception of the magnet mass,  $m_2$  is the magnet mass,  $k_1$  is the stiffness of the lead wire connected to the DFMT,  $k_2$  is the stiffness of the polyimide membrane,  $x_1$  is the vibration displacement of the DFMT,  $F_0$  is the constant electromagnetic force, and  $\omega$  is the circular frequency. In order for the DFMT to have similar frequency characteristics to a normal middle ear, an optimized FEA model of the DFMT was designed and simulated. The frequency characteristics of the stapes were flat in a frequency range lower than 1.5 kHz. However, at more than 1.5 kHz, the responses gradually attenuated. Therefore, the resonant frequency of the DFMT was designed to be close to the primary pole, which rapidly changes the characteristics of the stapes. As shown in Fig. 2 (b), the designed DFMT exhibited similar vibration characteristics to those of a normal middle ear.

### Experimental Results for DFMT

The designed membrane was fabricated using micro electro mechanical system (MEMS) processing. The developed DFMT had a diameter of 1.8 mm and length of 2 mm, as shown in Figs. 3 (a) and (b). In Fig. 3 (c), the measurement results show that the vibration displacement of the DFMT was about 200 nm between 0.1 and 1.5 kHz when a current of 1 mA was applied to the coil, confirming that the DFMT had similar frequency characteristics to stape vibrations in a normal ear.

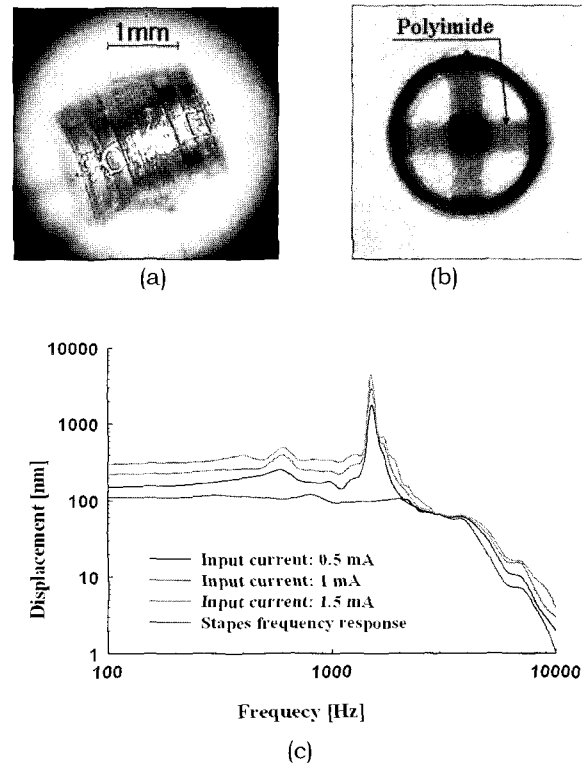


Fig. 3. (a) Developed DFMT, (b) fabricated membrane, and (c) measured vibrating characteristics.

### IMPLANTABLE MICROPHONE

The microphone in ACRHS-1 consists of a small electret condenser microphone (ECM), titanium case, and vibrating membrane made of very thin stainless steel. A high sensitivity is the most important factor for an implantable microphone, while reliability is essential for a steady long-term operation *in-vivo*[20]. Therefore, a 10  $\mu\text{m}$ -thick flexible vibrating membrane with a wider area than the ECM was used to collect more sound energy and increase the sensitivity of the microphone. Sound vibrations from a speaker are transmitted to the vibrating membrane of the microphone through the skin, where they change the fluid pressure of the air layer, then the changed air pressure is transmitted to the vibrating membrane of the ECM. Figs. 4 (a) and (b) show the microphone structure and a cross-sectional diagram of the microphone, respectively.

When a sound pressure of 70 dB was transmitted to the vibrating membrane of the microphone, a loading pressure ranging from 0.1 kHz to 9 kHz was simulated on the electric microphone membrane.

The sensitivity of the microphone was then calculated by an algebraic formula using the simulated sound pressure, and Fig. 4 (c) shows the calculated results[21].

The implantable microphone case was made of titanium with a polymer coating and hermetic sealing process for safety purposes, and the vibrating membrane was fabricated using 10  $\mu\text{m}$  SUS316L stainless steel. After assembling the fabricated components and miniaturized ECM, the resulting microphone was 6.2 mm in diameter and 3 mm high, as shown in Fig 5 (a). The frequency characteristics of the fabricated microphone were measured using an experimental method that excluded any effects due to environmental noise, the characteristics of the speaker, and the shielding chamber. Fig. 5 (b) shows the measurement system used to determine the microphone characteristics, while Fig. 5 (c) presents the experiment results for the fabricated microphone when using pig skins with different thicknesses. When using 6 mm-thick pig skin, the implantable microphone had a bandwidth of 5 kHz, which is adequate for hearing aids.

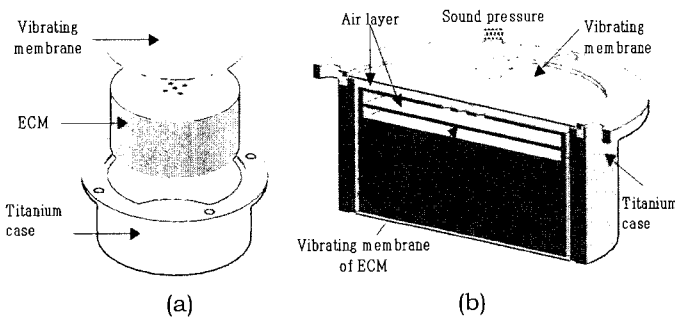
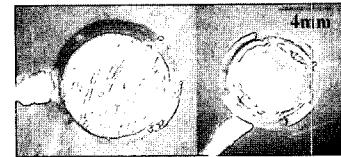
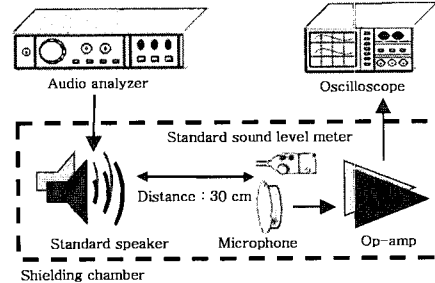


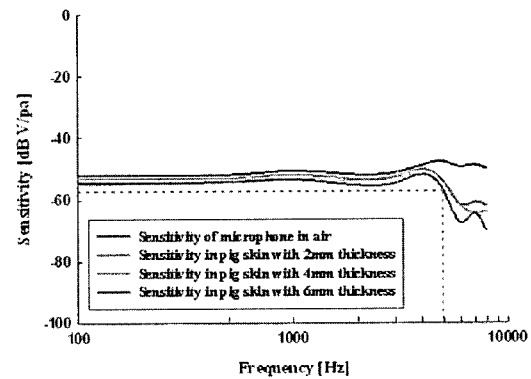
Fig. 4. (a) Microphone components, (b) cross-sectional diagram, and (c) simulation results as regards its sensitivity.



(a)



(b)



(c)

Fig. 5. (a) Top and bottom view of fabricated implantable microphone, (b) measurement system used for tests, and (b) experimental results in air and with pig skin.

### SIGNAL PROCESSING AND CONTROL MODULE

The audio signal processing module needs to be designed to compensate for the hearing loss of a hearing impaired person. As such, the signal processing module amplifies the electrical input signal produced by the implantable microphone based on a calculated gain-frequency curve using the prescriptive method, one-half gain rule, or Byrne method etc.[22]. The output stage of the signal processing module then needs to be designed as an efficient current amplifier. The audio signal processing module of ACRHS-1 was designed as an analog type. The low-power microprocessor within the implanted device controls the activation of the device power, volume up and down, and the adjustment of the frequency characteristics. To transmit the control signal from outside the body to

the implanted device, the RF communication method is used.

The audio signal processing module was designed using an analog hearing aid hybrid IC (Gennum, 3000 series) for use in ACRHS-1. The hybrid IC offers optimal performance with a class-D amplifier and the advantage of low power consumption. As the features of IC can be controlled by variable resistors, a 32-tap digitally programmable potentiometer was adopted to facilitate the volume control, low frequency gain control (LFC), and high frequency gain control (HFC). The audio signal of the output stage is transmitted to the transducer implanted in the ossicular chain. Thus, for low power consumption in the output stage, a class-D amplifier and efficient transformer are used. The range of the volume control, LFC, and HFC are shown in Fig. 6.

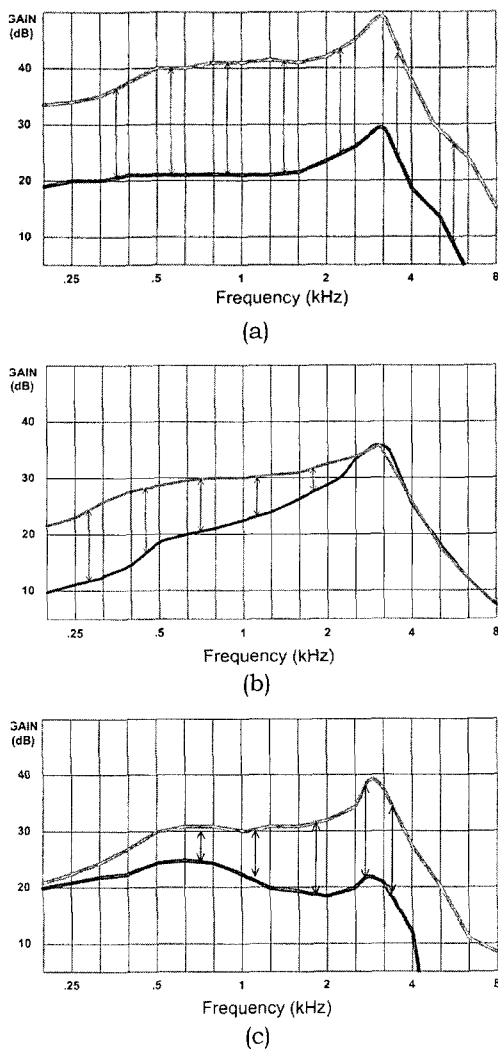


Fig. 6. Range of (a) volume control, (b) low frequency control, and (c) high frequency control.

The power control, volume control, LFC, and HFC of the audio signal processing module are controlled by a wireless communication method, IR communication, or RF communication, from outside the body. The control signal is transmitted to the IR or RF receiving module and decoded by the microprocessor in the implanted device. Through the bidirectional communication between the remote controller and the implanted device, the implanted device can accept the control signal and correctly operate the specified functions, as well as transmitting outward internal information on the status of the battery or filter setting. A block diagram of the analog signal processing module and control module is shown in Fig. 7 (a). The implemented ACRHS-1 consists of an implantable microphone, audio signal processing and control module, and transducer as in Fig. 7 (b). The size of the implanted device is 30 (L) mm, 25 (W) mm, and 6 (H) mm. The case and cover are made of titanium and ceramic material, respectively, for biocompatibility. The surface of the implanted device is also coated with a biocompatible material before being implanted in the body. The specifications of the overall device are shown in Table 1.

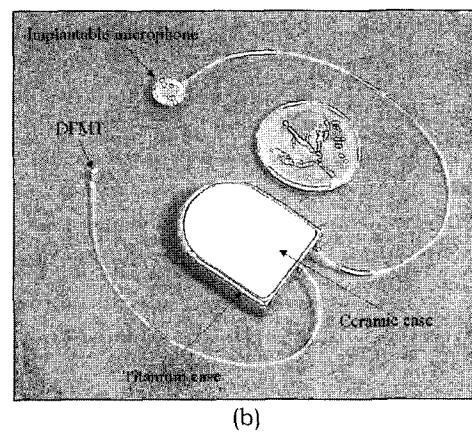
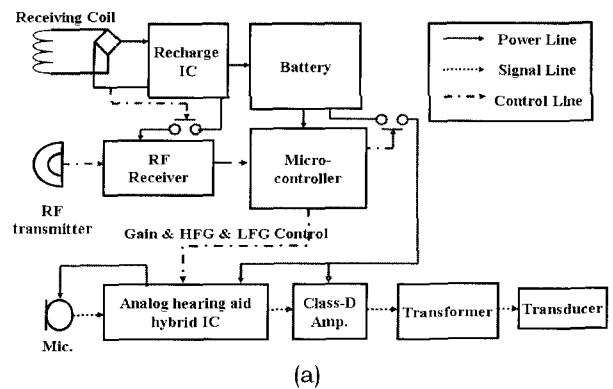
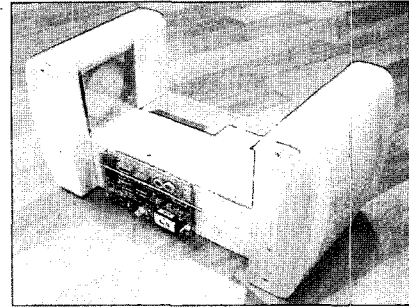


Fig. 7. (a) Block diagram of analog signal processing module and control module, and (b) implemented ACRHS-1 based on DFMT.

**Table 1.** Specifications of ACRHS-1.

Current consumption	in active	0.8 mA <sub>rms</sub> ~ 1.2 mA <sub>rms</sub>
	stand-by	70 μA <sub>rms</sub>
Rechargeable battery capacity		75 mAh
Overall size (mm)		30 (L) × 25 (W) × 6 (H)
Recharging cycle (15 hours / day)		5 days
Case material		Titanium
Cover material		Zirconia ceramic



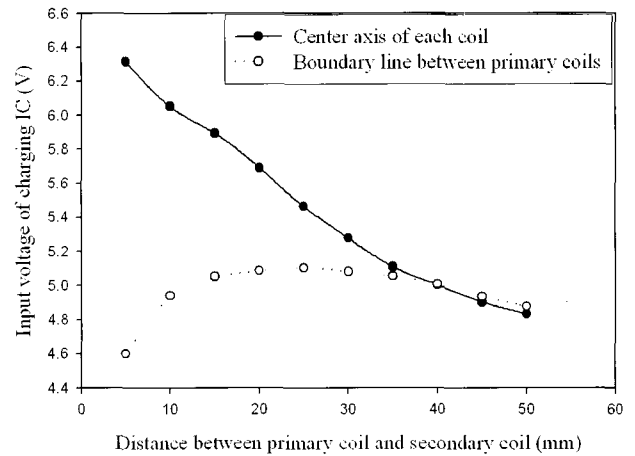
(b)

**Fig. 8.** (a) Schematic of pillow-type charger and (b) implemented charger.

### WIRELESS CHARGER

ACRHS-1 uses a lithium-ion rechargeable battery. However, the general charge method using contact with a metal plate cannot be utilized owing to the skin barrier. Thus, to solve this problem, a wireless charger was developed for ACRHS-1 based on electromagnetic induction. In each coil, the LC resonance is used to enhance the efficiency[23-25]. Two kinds of chargers are designed in the form of a pillow to allow charging while sleeping.

The pillow-type charger was designed using electromagnetic induction. To produce an AC to drive the two primary coils, a 60 V DC is switched using a power MOSFET. Therefore, the charging voltage during the charging process is unaffected by any head movement, and two primary coils are used. A schematic of the pillow-type charger using two primary coils is given in Fig. 8 (a), and the developed wireless chargers are implemented as in Fig. 8 (b). Using these devices, charging experiments were carried out while varying the distance between the primary and secondary coils. The results of the charging experiment are shown in Fig. 9, where the pillow-type charger was able to sufficiently charge the battery within a distance of 40 mm.



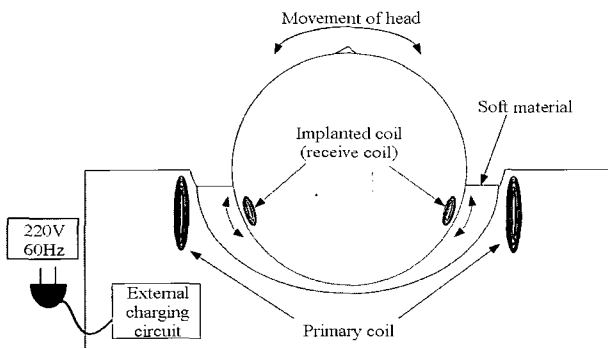
**Fig. 9.** Input voltage for charging IC when varying distance between two coils in pillow-type charger.

### REMOTE CONTROLLER

An RF-type remote control unit was developed for the FIMEHD to eliminate the disadvantages of an IR-type control unit, such as position matching with the IR receiver and the power consumption by the receiver.

Plus, the implemented remote controller can recharge the battery, transmit a control signal to ACRHS-1, and communicate bidirectionally based on the design of the coupled coils, external and internal control parts, and data protocol using an on-off keying modulation[26-28].

Through inductive coupling between the external and implanted coil, the control signal and power can both be transferred to ACRHS-1. Also, the two coils are used to transfer the confirming data back from ACRHS-1 to the remote controller as a two-way communication. Fig. 10 (a) illustrates how the inductively coupled controller operates. The



(a)

remote controller for ACRHS-1 has a LCD to display the mode of the control signal and low-power microprocessor. The controller includes an on/off function, controls 32 levels of volume and frequency, and can recharge the internal battery in ACRHS-1. A 9V alkaline battery is used for the power source. The developed remote controller is shown in Fig. 10 (b).

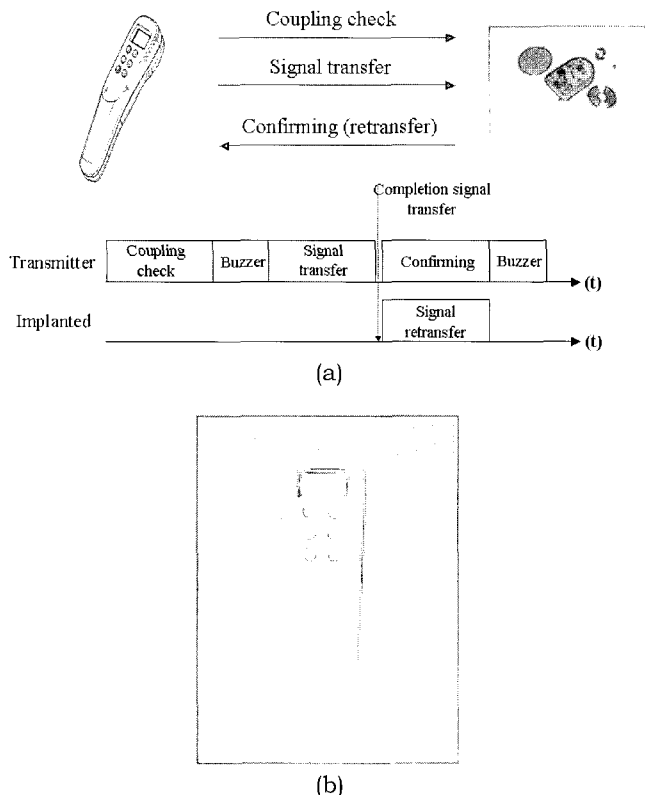


Fig 10. (a) Data communication process and (b) implemented remote controller.

## EXPERIMENTAL RESULTS

### Experiment Using Cadaver

The performance of the transducer was measured based on testing the vibrating DFMT attached to the ossicle of a cadaver. Fig. 11 (a) shows the attachment of the proposed DFMT to the long process of the incus using a mechanical clip made of  $80\mu\text{m}$  SUS316L. In Fig. 11 (b), the vibrating displacements of the incus head and stapes head are displayed when a sinusoidal current of  $1\text{ mA}_{\text{rms}}$  was applied to the DFMT. As shown by the results, the proposed DFMT was able to apply an adequate vibrating force to the ossicular chain of the cadaver

for sound delivery to the cochlea on an equivalent level of 100 dB SPL.

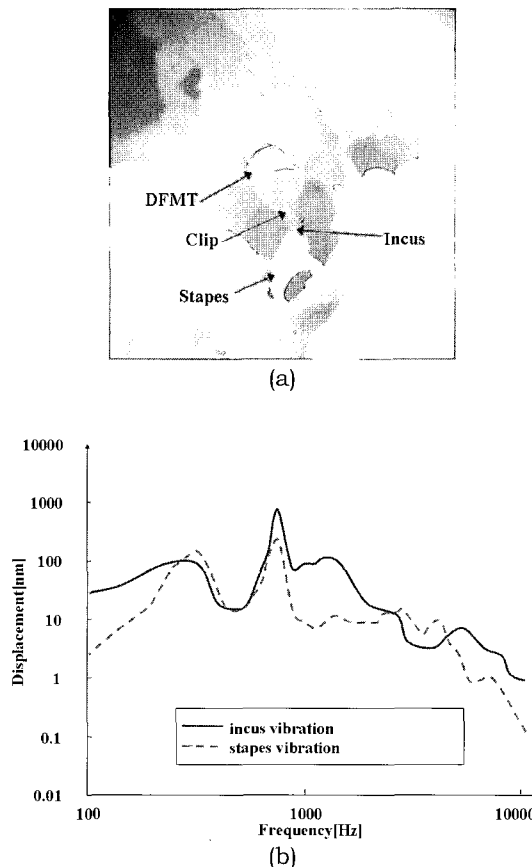


Fig 11. (a) DFMT attached to long process of incus and (b) results of vibrating displacement when supplying 1 mArms.

### Experiment Using Guinea Pig

The sound delivery produced by ACRHS-1 was also tested in an animal experiment. Fig. 12 (a) shows the DFMT attached to the umbo of a guinea pig, and Fig. 12 (b) displays the results of the auditory brainstem response (ABR) when inputting different levels of sound pressure to the ACRHS-1 implantable microphone. As demonstrated by the results, the ACRHS-1 DFMT was able to produce the enough vibration on the ossicular chain to deliver an audio signal to the cochlea. Plus, all the functions, including the volume control, filter programming, recharging, and implantable microphone worked properly. Therefore, it is expected that the ACRHS-1 will soon progress to animal and clinical tests after safety approval from the Korea Food and Drug Administration (KFDA).

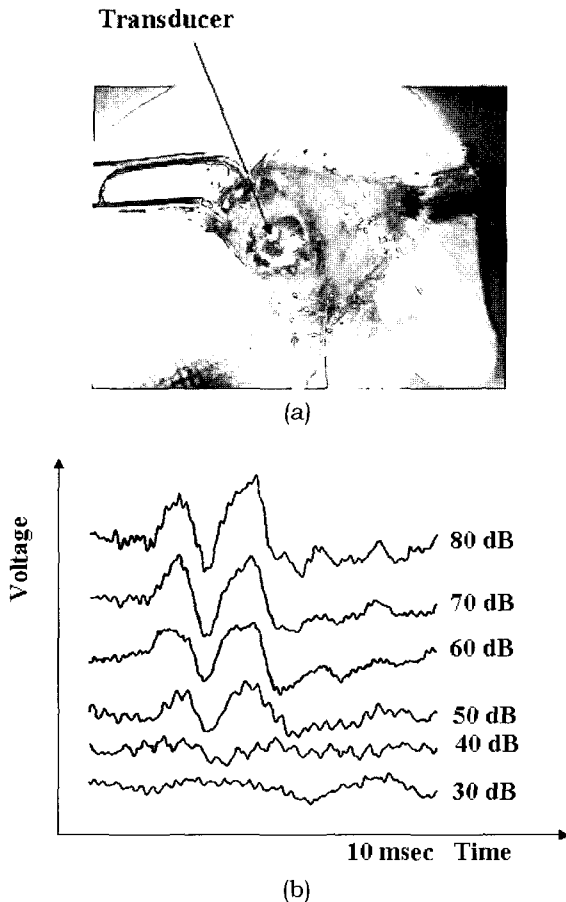


Fig 12. (a) Experiment attaching transducer to umbo of guinea pig and (b) results of ABR test.

## CONCLUSION

Fully implantable middle-ear hearing devices (FIMEHDs) that can directly drive the ossicular chain using a vibrating transducer have been developed to overcome the problems of conventional hearing aids, such as sound distortion, howling effects, and discomfort during wearing. One such example is ACRHS-1 based on a differential floating mass transducer (DFMT) that has been developed by Kyungpook National University. Therefore, this paper provided a review of the overall system architecture, functions, and experimental results for ACRHS-1 and its related accessories, such as a wireless battery charger and remote controller.

The experimental results using the ossicular chain of a cadaver and guinea pig demonstrated that ACRHS-1 using a DFMT can provide a suitable performance for individuals with a moderate to severe sensorineural hearing loss. Therefore, it is expected that ACRHS-1 will soon progress to animal and clinical tests based on safety approval from the Korea Food and Drug Administration (KFDA).

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