厚生労働科学研究研究費補助金
感覚器障害研究事業

軽量コイルにより耳小骨を直接加振する新駆動方式Hi-Fi補聴システムの開発に関する研究

平成14年度　総括研究報告書
主任研究者　小池　卓二
平成15（2003）年　4月

目　次

厚生労働科学研究研究費補助金　（感覚器障害研究事業）

I. 総括研究報告書

軽量コイルにより耳小骨を直接加振する新駆動方式Hi-Fi補聴システムの開発に関する研究

主任研究者　小池　卓二　電気通信大学電気通信学部・助教授

Abstract

As the number of people affected by deafness due to aging increases year by year, high-quality hearing aids are needed for improving the quality of life. Generally, the hearing level of the aged becomes lower particularly at high frequencies. The majority of these hearing-impaired individuals can benefit from conventional hearing aids that transmit the sound by an earphone. However, there are still many individuals who have not experienced satisfactory results. The dissatisfaction with using conventional hearing aids is due to many inherent problems such as sound distortion, feedback, cosmetic factors, and so on.

Recently, in order to resolve these problems, implantable hearing devices have been developed. These devices, rather than using amplified sound, directly vibrate the ossicular chain with an implanted magnet or piezoelectric bimorph. However, they have not been widely used because their vibrators are too heavy to obtain a good performance at high frequencies and invasive surgery has to be performed to implant them.

In this study, in order to develop an effective and non-invasive electromagnetic hearing aid which directly vibrates the ossicular chain via the tympanic membrane, some simple prototypes of transducers were made on the basis of results of FEM analysis, and their fundamental properties were evaluated by experiments using an artificial middle-ear model and by experiments using guinea pigs.

1. Introduction

Impairment of hearing is one of the most common physical disabilities. In the United States, more than 24 million individuals over the age of 65 are afflicted, most of them suffering from sensorineural hearing loss (Spindel et al., 1995).

The majority of these hearing-impaired individuals can benefit from conventional hearing aids that transmit the sound by an earphone. However, there are still many individuals who have not experienced satisfactory results. The dissatisfaction with using conventional hearing aids is due to many inherent problems such as sound distortion, feedback, cosmetic factors, and so on.

Research and development over the past two decades have identified implantable hearing aids as a means of circumventing some of the problems found in conventional hearing aids. Implantable vibrators in use today utilize either a piezoelectric bimorph or a magnet.

Piezoelectric transducers have been investigated both in animal models and humans by Suzuki et al. (1995) and Zenner et al. (2000). Typically, the approaches used with these transducers have required disarticulation of the ossicular chain and implantation of a piezoelectric vibrator.

Electromagnetic transducers consist of a small magnet placed on component of the ossicular chain and can eliminate the required disruption of the normal acoustic input pathway (Maniglia et al., 1995 and Symphonix Devices, Inc., San Jose, CA). Clinical studies in humans have clearly shown the benefits of this type of aid; the degree of hearing enhancement achieved, however, has been less than that required for the rehabilitation of severe sensorineural hearing loss, and disarticulation of the ossicular chain remains an inherent problem. Furthermore, there is a problem that vibrators are too heavy to obtain a good performance at high frequencies.

In this study, in order to develop an effective and non-invasive electromagnetic hearing aid which directly vibrates the ossicular chain via the tympanic membrane, some simple prototypes of transducers were made on the basis of results of FEM analysis, and their fundamental properties were evaluated by experiments using an artificial middle-ear model and by experiments using guinea pigs.

2. Structure and function of the middle ear

Figure 2.1 shows the human auditory system. The auditory system is divided into the external ear, the middle ear and the inner ear. The middle ear consists of the 'funnel-shaped' tympanic membrane connected to three ossicles, namely, the malleus, incus, and stapes. These ossicles are called the 'ossicular chain' (Ferris, 2000). Vibration of the tympanic membrane leads to motion of the stapes which, in turn, generates waves in the cochlea. As a result, action potential is produced in the auditory nerve fiber. Owing to this mechanism, we can finally hear sounds (Lighthill, 1991).

Figure 2.2 shows the schematic of a guinea pig ear. The auditory system of the guinea pig is also divided into three parts, the same as in humans. The middle and the inner ear of the guinea pig are wrapped in a bone structure called the bulla. The ossicular chain of the guinea pig also consists of the malleus, incus, and stapes. However, the malleoincudal joint is not as clear as that in humans.

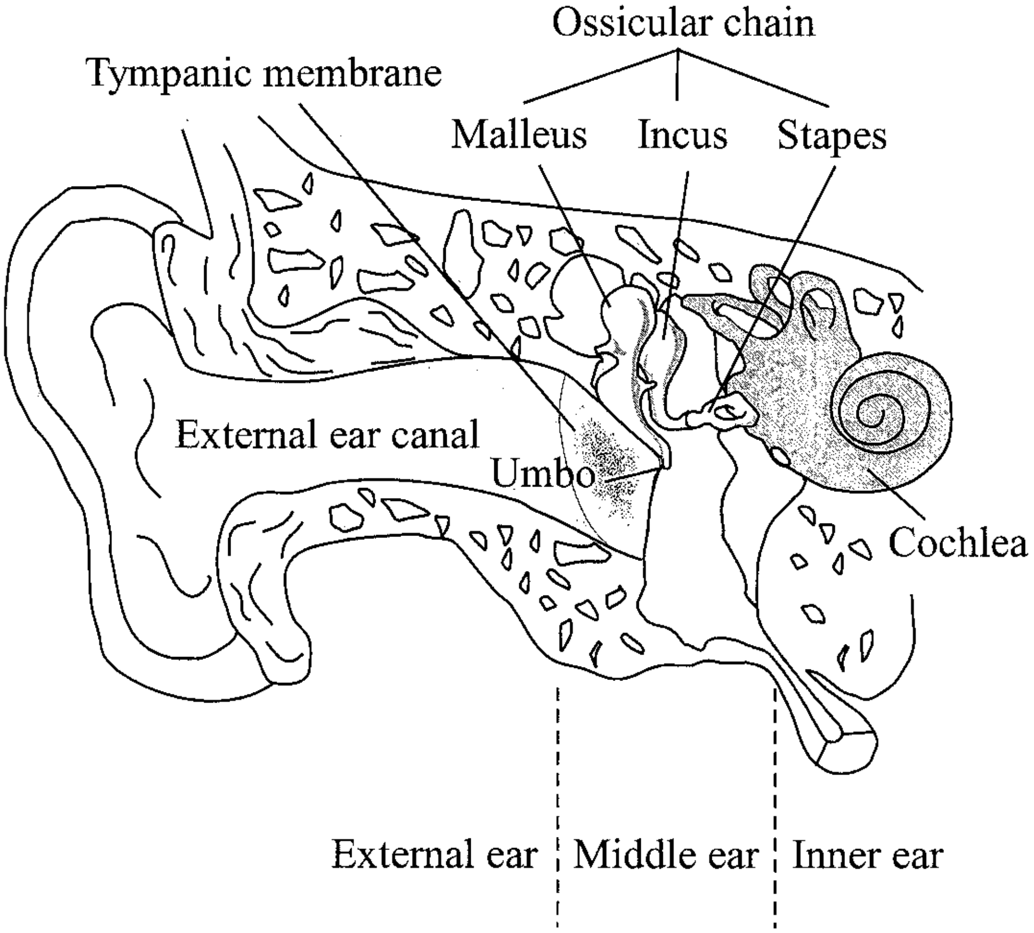

Figure 2.1. The human auditory system. The auditory system is divided into the external ear, the middle ear, and the inner ear. Vibration of the tympanic membrane leads to motion of the stapes which, in turn, generates waves in the cochlea. The long process of the malleus connected to the tympanic membrane is called the manubrium, and the apex of the tympanic membrane is called the umbo.

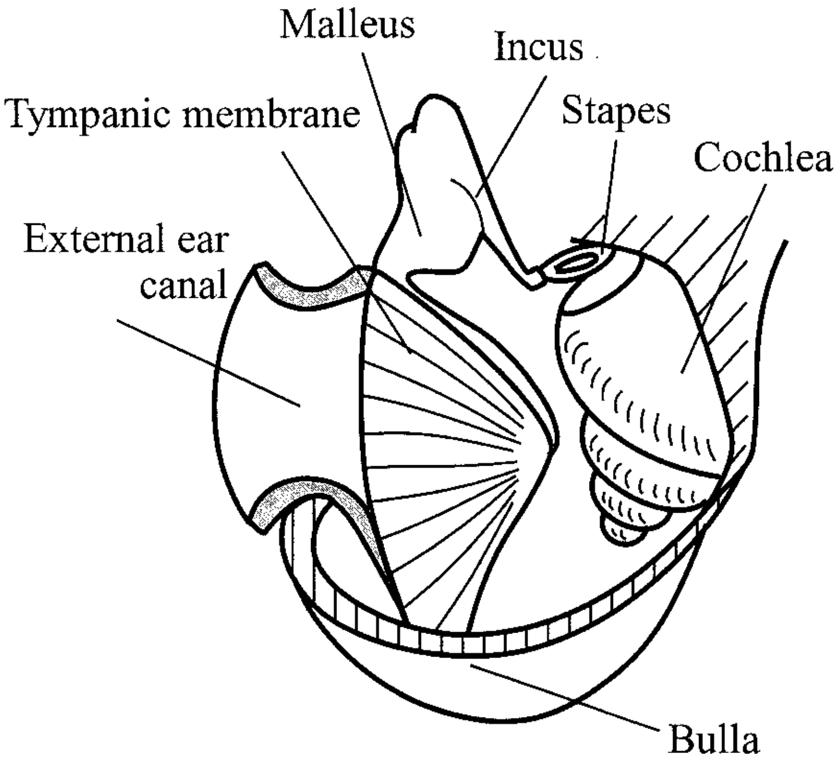

Figure 2.2. Schematic of the auditory system of the guinea pig. The middle and inner ear of the guinea pig are wrapped in a bone structure called the bulla. The malleoincudal joint is not as clear as that in humans.

3. Hearing aids

3.1. Sensorineural hearing loss

Recently, sensorineural hearing loss is observed in a steadily increasing number of younger patients as well as in aged patients (Plinkert et al., 2000). The main cause is an increase in environmental noise. Sensorineural disorders may result from the loss of function of the cochlear amplifier, the outer hair cells in particular, or from a major loss of hair cells. There are several methods for treating sensorineural hearing loss at present, including acoustic hearing aids and implantable hearing aids.

3.2. Acoustic hearing aids

Figure 3.1 shows a schematic of the acoustic hearing aid generally used. Acoustic sound is picked up by the microphone, transformed into an electrical signal and amplified. By means of the transducer, the electrical signal is transformed into sound, which vibrates the tympanic membrane and ossicular chain.

Miniaturization of electronics has made it possible to develop hearing aids which are smaller and more functional. Thus, hearing aids can now be positioned in rather than at the opening of the external auditory canal and are not visible when worn. As for functionality and signal processing, the aids shifted from being purely analogue to being digitally programmable in the late 1980s and totally digital by the middle of the 1990s (Stenfelt, 1999).

However, achievement of high-fidelity responses with low distortion by conventional acoustic hearing aids is limited, despite advances in miniaturization and programming technology. The transducer of the hearing aid is the most important factor in the realization of high-fidelity responses. The proximity of the microphone to the transducer increases the electroacoustic and mechanical feedback. In addition, sound distortion, ringing, and the need for a tightly fitted ear-mold, which plugs the auditory canal, discourages many people who need amplification from wearing these devices (Maniglia et al., 1997).

3.3. Implantable hearing aids

The concept of an implantable hearing aid is very appealing and has been discussed for the past three decades. The most prominent feature of the implantable hearing aid is that the transducer is directly coupled to the one of the middle ear ossicles. It has the advantage of leaving the ear canal open, and problems with feedback can be eliminated. There are two major methods for achieving excitation, namely, by way of piezoelectric transducers and electromagnetic transducers.

3.3.1. Piezoelectric transducers

Several investigators have devised different approaches for driving the ossicular chain by way of a piezoelectric transducer. The Japanese researchers Suzuki, Yanagihara and co-workers developed an implantable transducer with government support during the late 1970s and the beginning of the 1980s. As shown in Fig. 3.2, the transducer is a piezoelectric ceramic bimorph attached to the stapes. The microphone, battery, and electronics are housed in a behind-the-ear unit, and the signal is transmitted to the transducer transcutaneously by way of an external induction coil and an internal one.

These types of transducers require disarticulation of the ossicular chain, which means that the surgery is nonreversible (Spindel et al., 1995). Furthermore, the incus must often be removed to accommodate the transducer within the middle ear cavity. In addition, with implantation, the middle ear is sensitive to infections.

3.3.2. Electromagnetic transducers

Middle-ear implants designed with electromagnetic technology consist mostly of a permanent magnet placed on the ossicular chain and an inductive coil to drive the magnet. The magnet can achieve a static magnetic flux. As shown in Fig. 3.3, Maniglia et al. (1995) reported an electromagnetic device with the magnet attached to the body of the incus, in which signals with a radio frequency of 8 - 10 MHz signals are used for the transcutaneous transmission.

A system which is commercially available in Europe is the Vibrant Soundbridge® (Symphonix Devices, Inc., San Jose, CA), which is shown in Fig. 3.4. The Vibrant Soundbridge® uses a transducer named the Floating Mass Transducer™, which is a magnet surrounded by two induction coils in a titanium container. The Vibrant Soundbridge® is attached to the long process of the incus by a clip, and vibrations of the magnet are transmitted to the ossicular chain by the inertia of the magnet. The microphone, battery, controls, electronics, and an external coil for transcutaneous energy transmission are housed in a single unit placed at the mastoid behind the ear and aligned with the subcutaneous implanted coil. However, this transducer is too heavy to obtain a good performance at high frequencies because it adds to the mass of the ossicular chain.

As previously mentioned, different types of implantable hearing transducers have been developed. However, because patients are often reluctant to undergo the surgery necessary to implant these vibrators and because such surgery is relatively expensive, they are not as yet widely used.

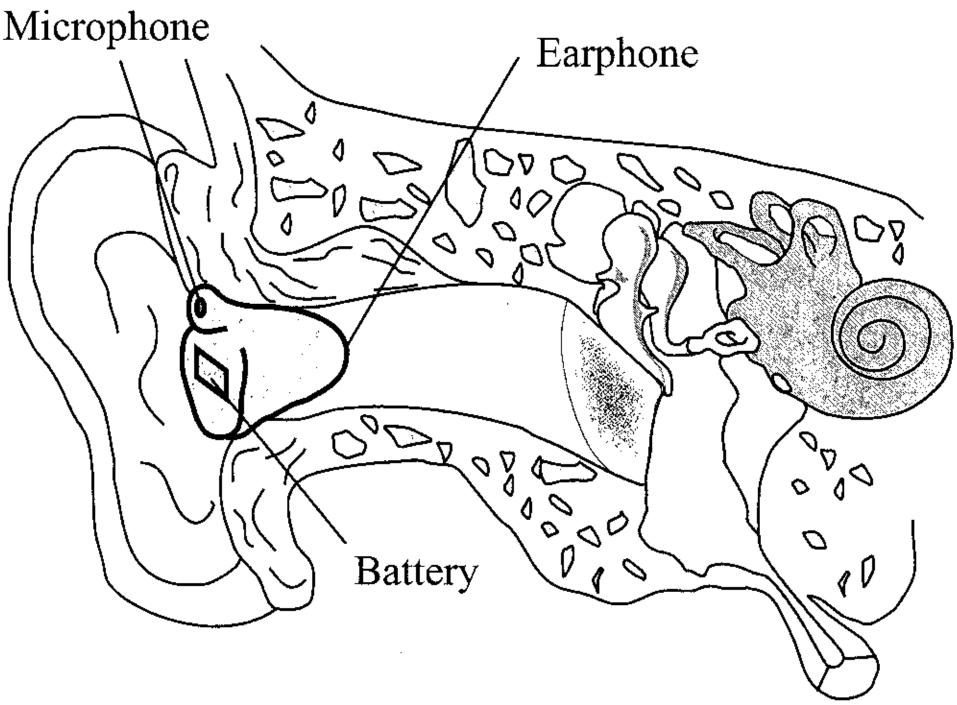

Figure 3.1. Schematic of the acoustic hearing aid generally used. Acoustic sound is picked up by the microphone, transformed into electrical signals, and amplified. By means of the transducer, the electrical signal is transformed into sound, which vibrates the tympanic membrane and ossicular chain.

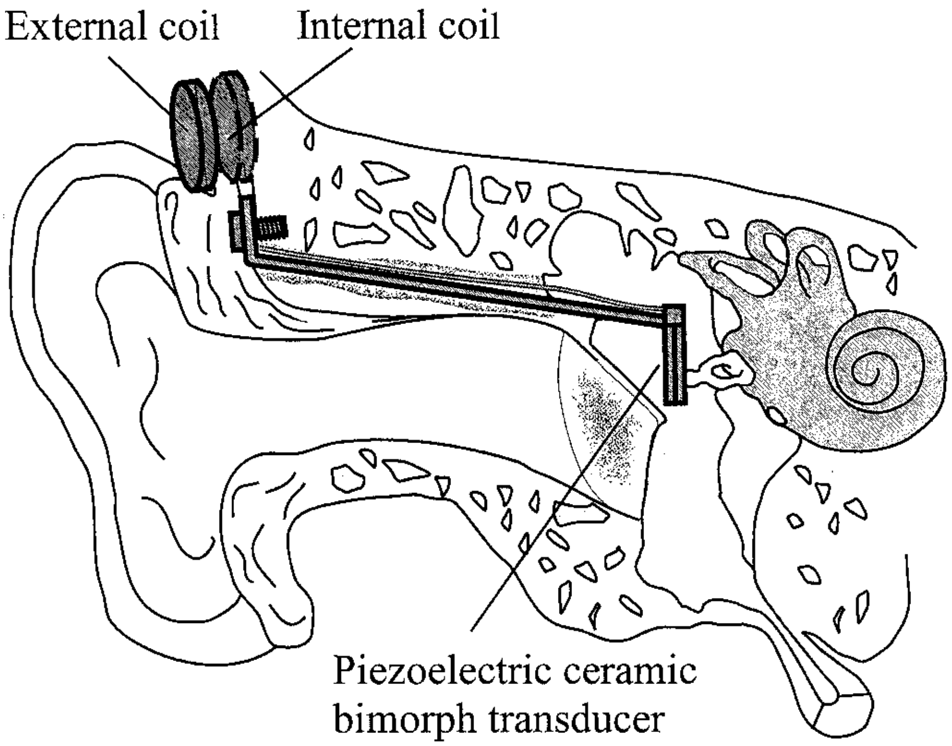

Figure 3.2. Schematic of a piezoelectric transducer (Suzuki et al., 1995). The transducer shown is a piezoelectric ceramic bimorph, attached to the stapes.

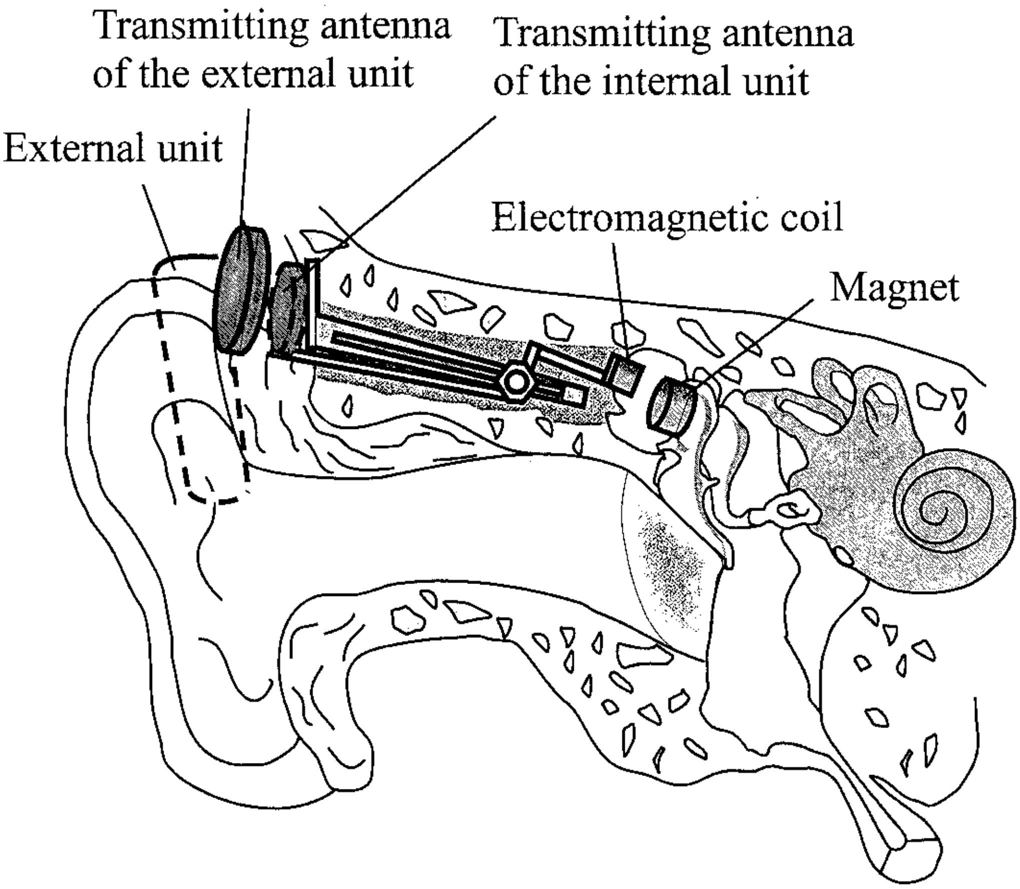

Figure 3.3. Schematic of an electromagnetic hearing device with the magnet attached to the body of the incus. Signals with a radio frequency (RF) of 8 - 10 MHz are used for the transcutaneous transmission (Maniglia et al., 1997).

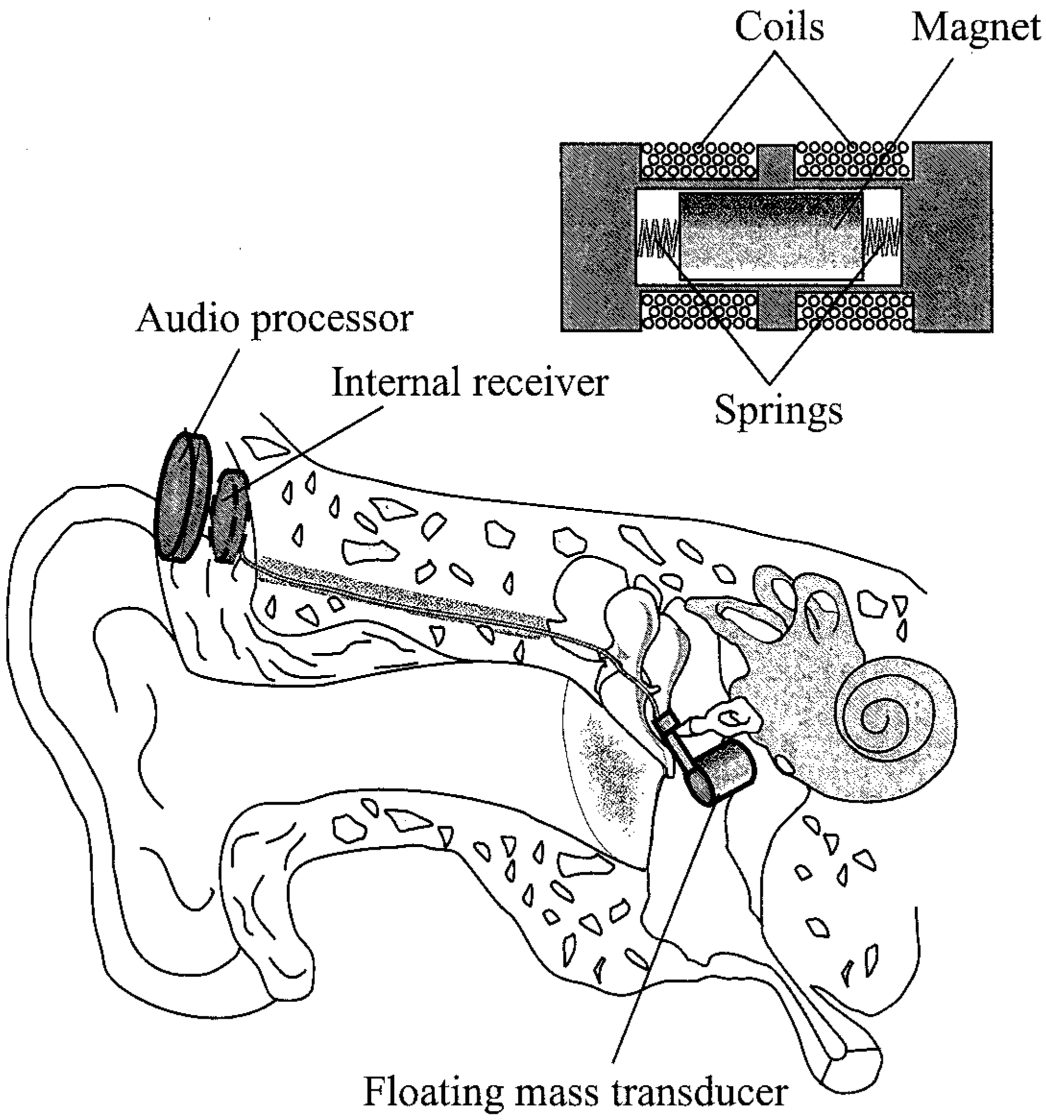

Figure 3.4. Schematic of the Vibrant Soundbridge®(Symphonix Devices, Inc., San Jose, CA). The Vibrant Soundbridge®uses a transducer named the Floating Mass Transducer, which is a magnet surrounded by two induction coils in a titanium container, and is attached to the long process of the incus by a clip.

4. Principles of the non-implantable electromagnetic hearing aid

4.1. Goal of this study

In this study, in order to overcome the inherent problems mentioned in Section 3.3, an “effective”, “non-implantable” electromagnetic hearing aid was investigated. This non-implantable electromagnetic hearing aid was designed so as to have the following advantages.

(a) High fidelity (flat frequency characteristics and lower distortion).

(b) Efficient sound transmission mechanism driving the ossicular chain in a contactless manner and elimination of acoustic feedback.

(c) Adequate acoustic gain and improvement of speech discrimination.

(d) Applicable to adults and children with conductive and sensorineural hearing losses.

(e) Ease of wearing and removal.

4.2. Principles

A schematic of the non-implantable hearing aid proved in this study is shown as Fig. 4.1. It is composed of three coils (driving, induction and vibrator coils) and a magnet. When the input current, I, is supplied to the driving coil, an induced electromotive force is generated at the induction coil. Then, the induced current, I_v, that flows into the vibrator coil causes magnetic interaction between the magnetic field generated by the vibrator coil and the static magnetic flux of magnet. As a result, the vibrator coil is vibrated by repulsive force which acts between the magnet and the vibrator coil.

In the present study, we focused on only the transducer composed of three coils and a magnet as the first stage in the development of a non-implantable electromagnetic hearing aid.

A theoretical model of the transducer is shown in Fig. 4.2. When the input current, $I = I_0 \sin \omega t$, is supplied to the driving coil, magnetic flux through the driving coil, Φ, can be represented as follows:

$$\Phi = \mu_0 \mu_c \pi r^2 lnNI, \qquad (4.1)$$

where l [m] is the length of the driving coil, n is the turns per unit length of the driving coil, and N is the turns of the induction coil. r [m] is the radius of the driving coil, μ_0 and μ_c [N/A^2] are the magnetic permeability of the vacuity (= 4p × 10^{-7}) and the core material, respectively. The induced electromotive force, V_{em}, generated in the induction coil can be represented as follows:

$$V_{em} = -\frac{d\Phi}{dt} = -\mu_0 \mu_c \pi r^2 lnNI_0 \omega \cos \omega t. \qquad (4.2)$$

The induced current, I_v, which flows to the vibrator coil, is given by

$$I_v = \frac{1}{L} \mu_0 \mu_I \pi r^2 lnNI_0 \sin \omega t, \qquad (4.3)$$

where L [H] is self inductance and L depends on the shape of the coils.

When I_v flows to the vibrator coil, repulsive force, F, acts between the magnet and the vibrator coil. F can be represented by another electromagnetic formula as follows:

$$F = \frac{n_v I_v S M t \mu_0 b^2}{2(b^2 + d^2)^{3/2}}, \qquad (4.4)$$

where b and t [m] are the radius and thickness of the magnet, respectively, and d [m] is the distance between the magnet and the vibrator coil. S [m^2] and n_v are the area and turns per unit length of the vibrator coil, respectively, and M [A/m] is the magnetic vector.

The calculated force, F, acts on the tympanic membrane as a result of magnetic interaction between the magnetic field of the magnet and that of the vibrator coil, and this force mainly depends on the radius of the magnet and the distance between the magnet and the vibrator coil.

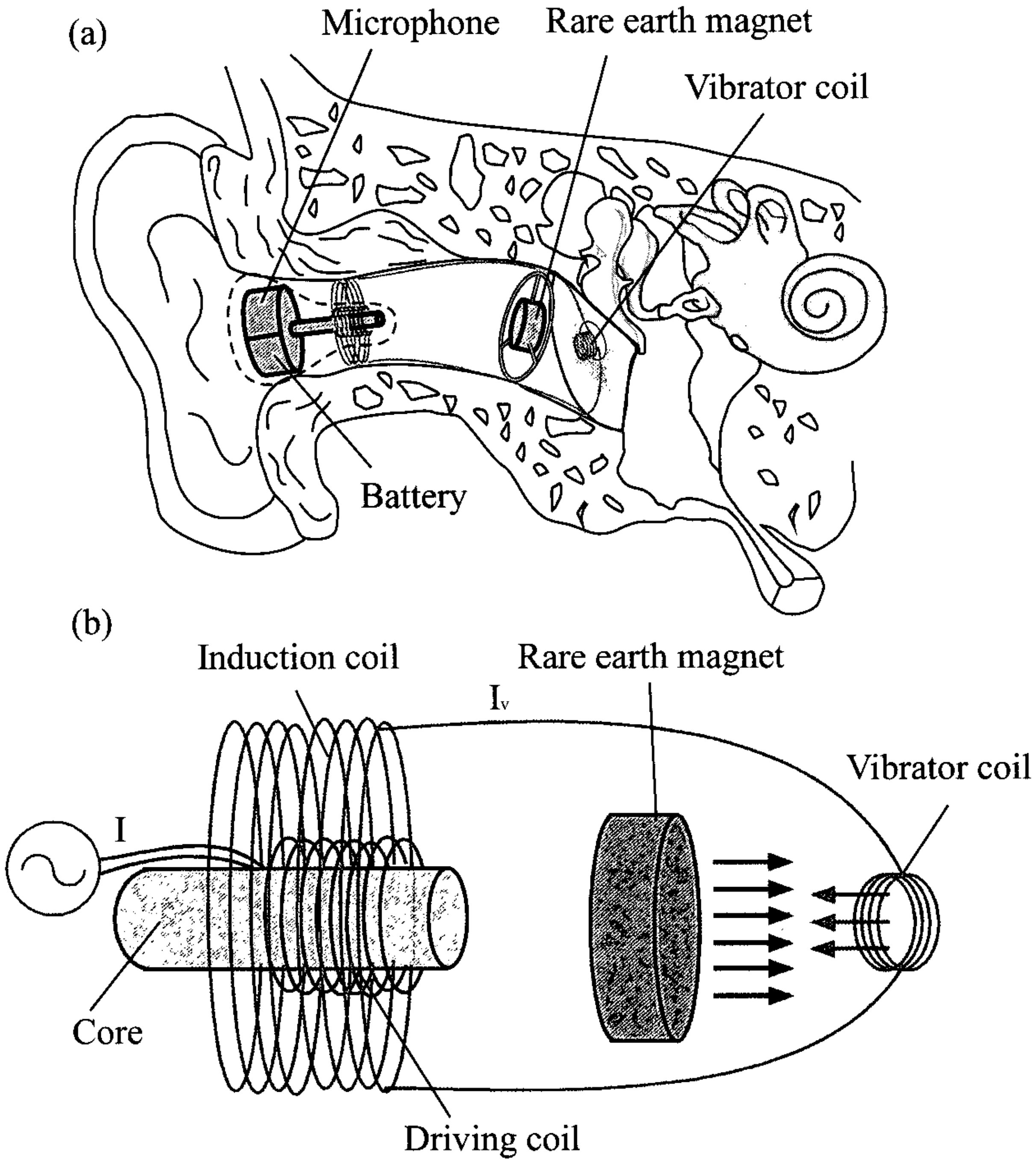

Figure 4.1. Schematic and principle of the non-implantable hearing aid proposed in this study. (a) Schematic of the electromagnetic hearing aid. This hearing aid is composed of three coils (driving, induction and vibrator coils) and a magnet. (b) The principle of the transducer. When the input current, I, is supplied to the driving coil, an induced electromotive force is generated at the induction coil. Then, the induced current, Iv, that flows into the vibrator coil causes magnetic interaction between the magnetic field generated by the vibrator coil and the static magnetic flux of the magnet. As a result, the vibrator coil is vibrated by repulsive force which acts on the magnet and the vibrator coil.