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Effect of Incus Removal on Middle Ear Acoustic Sensor for a Fully Implantable Cochlear Prosthesis

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Abstract— **System miniaturization and steady progress towards a totally implantable prosthetic system is the current trend in cochlear implant technology. To achieve this objective, the external microphone of present implants needs to be implantable. This goal can be accomplished by placing a miniature accelerometer on the ossicular chain in the middle ear to detect and convert bone vibrations into an electrical signal for further processing and stimulating cochlear electrodes. This paper describes the characterization of the umbo of a human temporal bone before and after the removal of the incus to determine the impact of the resulting change in umbo mechanics and attached accelerometer performance. With the removal of the incus, the umbo vibration acceleration frequency response in the direction perpendicular to the tympanic membrane increases by 5 dB below 2 kHz. Above 2 kHz the response diverges due to the change of ossicular chain resonant frequency caused by the removal of the incus. However, at each frequency the umbo vibration acceleration exhibits a linear function of the input sound pressure level (SPL) with a slope of 20 dB per decade before and after removal of the incus. A commercial accelerometer attached to the umbo shows similar characteristics. From the measurement results of umbo characterization, a miniaturized implantable accelerometer with a packaged mass below 20 milligrams, a sensing resolution of $35\,\mu g_{rms}/\sqrt{Hz}$, and a bandwidth of 10 kHz would be required to detect normal conversation.**

I. Introduction

Over 20 million people in the United States are affected by sensorineural hearing loss. Contemporary acoustic hearing aids can achieve moderate rehabilitation in a large number of sensorineural hearing loss cases. However, inherent technological limitations and perceived social stigma associated with these devices has resulted in many patients being deprived of basic hearing abilities. Although partially implantable middle ear and cochlear prosthetic systems have gained acceptance, reliability, practicality, and social stigma concerns are presented by the use of external accessories such as microphones and electronics. Therefore, the development of fully implantable high-performance prosthetic systems is essential.

Several research groups have made progress [1] - [3] in developing systems that rely on electromagnetics or piezoelectric effect for compensating conductive hearing loss. To date, however, no fully implantable prosthetic system is commercially available. External radio frequency coils, microphone, and speech processor are used for modern semi-implantable cochlear implants. Current speech processors can be potentially integrated as a part of the existing implant unit to achieve complete implantability, however, a significant challenge is presented in realizing a high-performance implantable microphone. In this research, a MEMS-based accelerometer is proposed as an implantable microphone for a future fully implantable cochlear prosthesis. Fig. 1 shows the conceptual prosthetic system architecture.

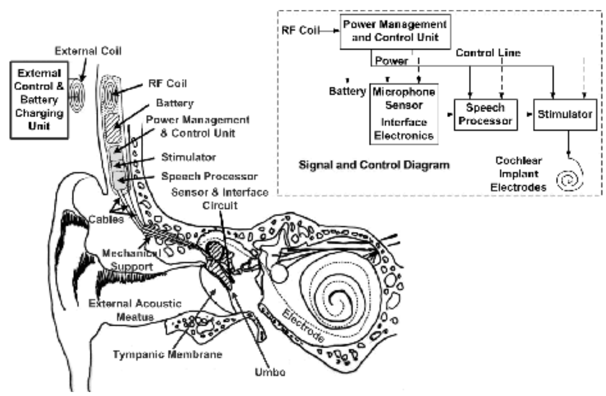

Fig. 1. Proposed fully implantable cochlear prosthetic system architecture.

Based on accelerometer operating principle, the proposed middle ear sound sensor can be attached to the umbo to convert the bone vibration to an electrical signal representing the input acoustic information. Further processing of the electrical signal can be performed by the cochlear implant speech processor, which is followed by a stimulator to drive cochlear electrodes. The speech processor, stimulator, power management and control unit, rechargeable battery and radio-frequency (RF) coil can be housed in a biocompatible package located under the skin to form a wireless communication link with the external adaptive control and battery charging system.

The most efficient sensing performance can be achieved by attaching the accelerometer at an ossicular location exhibiting the greatest vibration amplitude responding to an external acoustic stimulus. Published data indicates that the

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umbo vibrates with the largest vibration amplitude in response to auditory inputs [4] - [5]. Our previous work [6] shows that attachment of an accelerometer to the umbo can produce an adequate electrical signal corresponding to an input acoustic stimulation, which can be processed by the cochlear implant speech processor for further stimulating auditory nerves. Since the incus and stapes are not used to couple acoustic energy into the cochlea in our proposed system, the incus may be removed to reduce the mechanical impedance seen by the umbo as a means to further enhance its vibration amplitude in response to an acoustic stimulation. Therefore, it is important to investigate the effect of removing the incus on umbo vibration characteristics. Section II focuses on human temporal bone vibration characterization before and after incus removal. Section III reports the measurement results of an accelerometer attached on the umbo before and after incus removal with conclusion and future work presented in Section IV.

II. Human Temporal Bone Characterization

A. Temporal Bone Preparation

A cadaveric temporal bone was used to investigate the umbo vibration characteristics before and after incus removal. After thawing, the bone was kept stored in 1:10,000 merthiolate in 0.9% saline solution to maintain soft tissue compliance and hydration. The temporal bone was inspected under a microscope before and after the mastoidectomy to verify an intact tympanic membrane, ear canal, and ossicular bone structure.

The temporal bone was then sequentially opened in two stages. First, a simple mastoidectomy with a facial recess approach was performed. The temporal bone was further opened in a second stage of drilling after the initial opening of the middle ear cavity. In this stage, the facial recess was widened such that a full access was gained into the middle ear, and drilling proceeded until the tympanic membrane could be visualized. After thoroughly rinsing the bone in saline, a piece of 1 mm^2 reflective material, weighing approximately 50 micrograms, was placed as an optical target for umbo characterization. After optical vibration characterization of the umbo with a fully intact ossicular chain was completed as will be described in the following, the incus was removed. A new piece of reflective material was then attached to the umbo for further characterization.

B. Characterization Setup and Procedure

Fig. 2 depicts a schematic drawing of the temporal bone characterization setup. An insert earphone driven by a waveform generator presented pure tones within the audible spectrum to the tympanic membrane. A probe microphone was positioned approximately 4 mm from the tympanic membrane to monitor the input sound pressure level. A laser Doppler vibrometer (LDV) was then used to measure the ossicles' vibration characteristics by focusing the laser beam

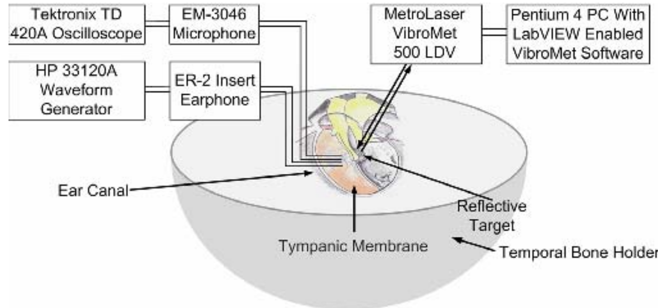

Fig. 2. Temporal bone setup schematic.

onto the reflective target attached to the umbo. The LDV exhibits a velocity resolution of 5μm/s over the frequency range from DC to 50 kHz.

The experimental setup with a magnified view of the middle ear is shown in Fig. 3. Fig. 3(a) presents the equipment and setup used in these measurements with the temporal bone secured in a temporal bone holder. Fig. 3(b) shows the temporal bone after removing the medial wall of the middle ear. The arrow points to a reflective target placed on the umbo for vibration characterization along the axis that moves in and out of the viewing plane. Vibration acceleration amplitude of the umbo was measured before and after incus removal in the frequency range from 250 Hz to 10 kHz with input tones between 70 dB and 100 dB SPL in increments of 5 dB.

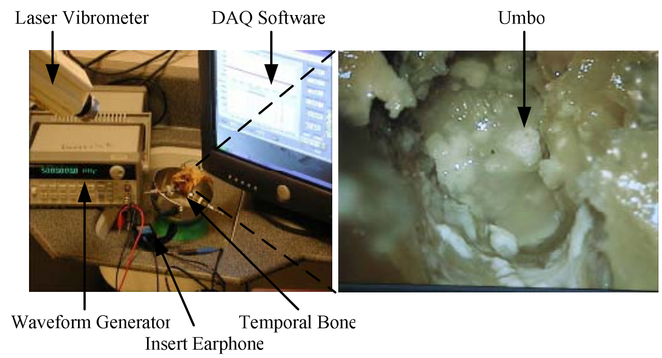

Fig. 3. (a) Photograph of equipment used in characterizing temporal bone vibrational response. (b) Magnified view of tympanic membrane and umbo after medial wall removal.

C. Measurement Results and Discussion

Fig. 4 presents the acceleration of the umbo before and after incus removal, stimulated by input tones of 80 dB and 100 dB SPL within the audible spectrum. The acceleration amplitude measured along the direction perpendicular to the tympanic membrane before incus detachment increases with a slope of 40 dB per decade from 250 Hz to 1 kHz and with a slope of 20 dB per decade from 1 kHz to 6 kHz. Above 6 kHz, the acceleration amplitude is approximately flat.

After removal of the incus, Fig 4 shows the vibration acceleration frequency response increases by a constant 5 dB below 2 kHz. The frequency associated with maximum acceleration amplitude shifts from 6 kHz to 3 kHz after incus

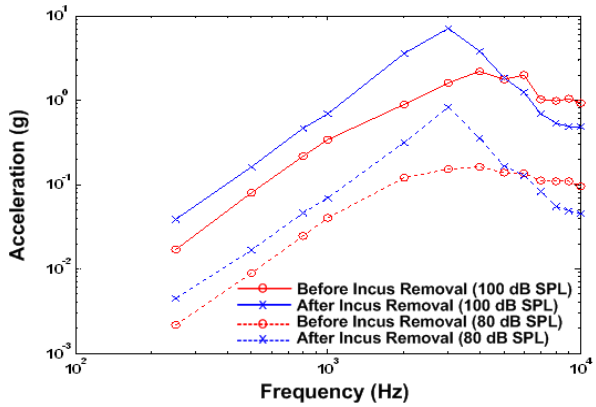

Fig. 4. Laser Doppler vibrometer measurements of umbo acceleration vs. frequency before and after incus detachment at 80 SPL and 100 SPL.

detachment. The frequency response after incus removal decreases with a slope of approximately -40 dB per decade above the frequency of maximum acceleration.

Fig. 5 presents the corresponding umbo acceleration as a function of input sound level at 500 Hz and 5 kHz before and after detachment of the incus, indicating a linear relationship of 20 dB per decade for both cases.

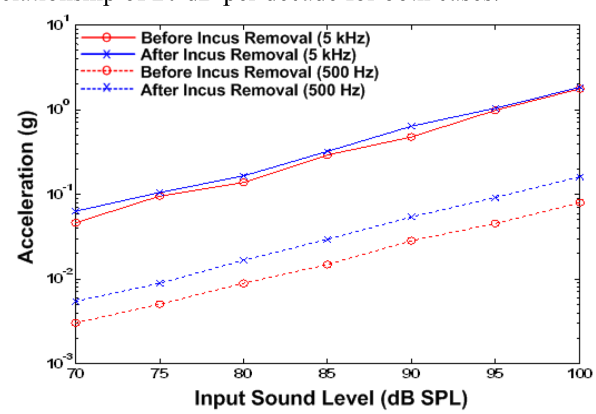

Fig. 5. Laser Doppler vibrometer measurements of umbo acceleration vs. input sound level before and after incus detachment at 5 kHz and 500 Hz.

The measurement results demonstrate that removing the incus can be a useful means to enhance the implant accelerometer performance. Audiologists report that audible speech is primarily focused between 500 Hz and 8 kHz, and that the loudness of normal conversation is approximately 60 dB SPL. From Fig. 4 it can be seen that within the audible speech spectrum, 500 Hz has the lowest acceleration response, and thus it is the most difficult to detect. By removing the incus, acceleration at 500 Hz is increased by 5 dB. Therefore, the implanted accelerometer needs to exhibit a sensing resolution of 35 $\mu g_{rms}/\sqrt{Hz}$ to detect a 60 dB SPL tone at 500 Hz for a cochlear implant electrode bandwidth of 200 Hz.

III. UMBO MEASUREMENT WITH ACCELEROMETER

An Analog Devices ADXL 320, was selected to investigate the effect of incus removal on umbo vibration with mass loading. The sensor was chosen because it has the smallest package size commercially available, with dimensions of 4 mm x 4 mm x 1.45 mm and a mass of 85 milligrams. It has been shown [7], [8] that adding a mass greater than 20 milligrams can potentially result in a significant damping effect on the frequency response of the middle ear ossicular chain, particularly at frequencies above 1 kHz. The sensor exhibits a sensitivity of 123 mV_{rms}/g with a noise floor of 250 $\mu g_{rms}/\sqrt{Hz}$ from a 3 volt supply. The device can measure a peak acceleration of 5 g with a variable bandwidth up to 2.5 kHz. Although the mass of the ADXL is greater than desired and its bandwidth less than required to measure the entire audible spectrum, it can provide useful insights for an optimized acoustic sensor performance.

A piece of double-sided adhesive was first applied on the back side of the ADXL. After orienting the sensor along the desired axis a few millimeters above the umbo, gentle pressure was applied for 30 seconds to attach the accelerometer to the temporal bone as shown in Fig. 6. The black arrow represents the direction of motion of the umbo being measured. Input tones from 300 Hz to 2.4 kHz were presented to the tympanic membrane in decreasing intervals of 5 dB SPL starting at 100 dB SPL. Acceleration electrically measured by the accelerometer was recorded. The ADXL was also used as a target for the LDV to simultaneously record acceleration optically to confirm measurement accuracy, and to measure umbo acceleration above the sensor bandwidth. The accelerometer was then detached from the bone to allow for incus removal as described in Section II A. After the optical characterization of the umbo with incus removed was completed, the sensor was attached to the umbo again for electrical measurement.

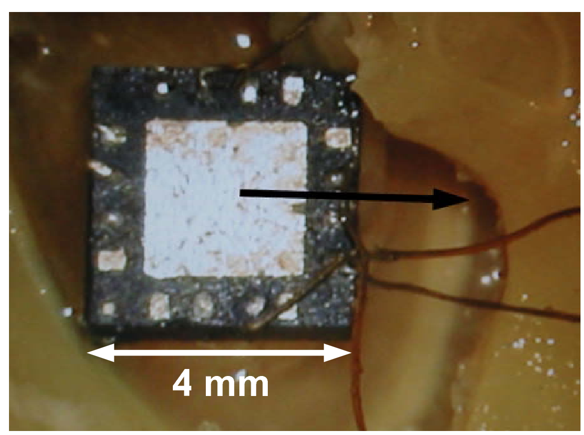

Fig. 6. Photograph of ADXL 320 attached to the temporal bone umbo. Direction of measured motion is indicated by the black arrow.

Fig. 7 presents the acceleration frequency response of the umbo at 95 dB SPL before and after incus removal measured electrically as well as optically with the accelerometer attached on the umbo as a target, and compares the data to the optical measurement performed without the sensor attached. The electrically measured acceleration frequency

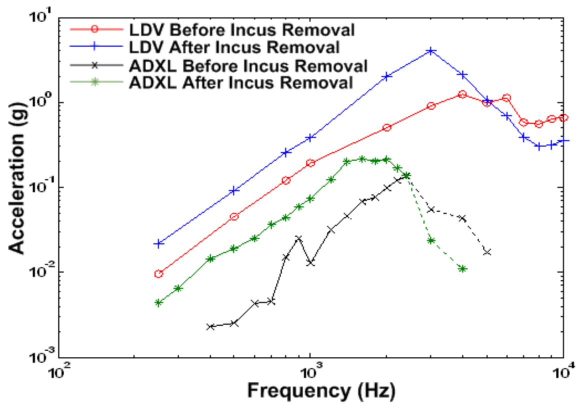

Fig. 7. LDV and ADXL measurements of umbo acceleration vs. frequency before and after incus detachment at 95 dB SPL. Dashed lines above 2.4 kHz represent acceleration measured by LDV using the ADXL as a target.

responses with the accelerometer attached on the umbo are identical to the simultaneous optical measurement taken with the LDV, thus confirming the measurement accuracy.

After incus removal, the ADXL-measured acceleration shows a 10 dB increase in amplitude at low frequencies. This is an important improvement for the proposed middle ear acoustic sensor because low frequency sounds are the most difficult to detect. However, there is a 10 to 15 dB suppression of acceleration at low frequencies before and after the incus detachment compared to the LDV measurements without sensor attachment onto the umbo due to the relative heavy mass of the accelerometer. The ADXL mass loading also causes the frequency of the maximum acceleration to decrease from 2.4 kHz to 2 kHz, and introduces high frequency distortions. The undesirable effects can be suppressed by employing an accelerometer with a reduced packaged mass below 20 milligrams.

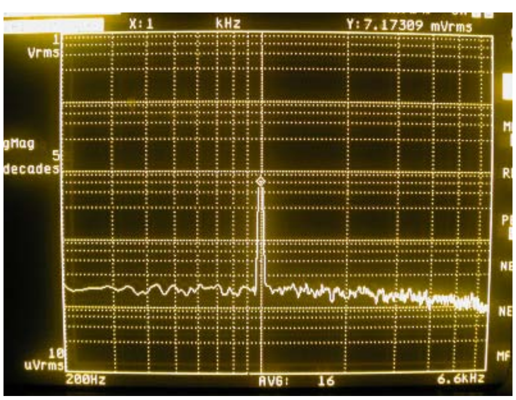

Fig. 8. 1 kHz tone measured by ADXL 320 at 90 dB SPL with a 30 Hz bandwidth.

Fig. 8 displays the acceleration output spectrum measurement with an input stimulus of 90 dB SPL at 1 kHz after incus detachment. The resulting signal to noise ratio is approximately 30 dB for the resolution bandwidth of 30 Hz. Fig. 9 shows the minimum detectable sound level by the ADXL over its bandwidth with and without the incus removed. The plot shows a 10 dB improvement in sensitivity below 2 kHz with the incus removed. An improved MEMS accelerometer with reduced packaged mass below 20 milligrams, a sensing resolution of $35\,\mu g_{rms}/\sqrt{Hz}$, and an increased bandwidth of 10 kHz would be required to detect normal conversation.

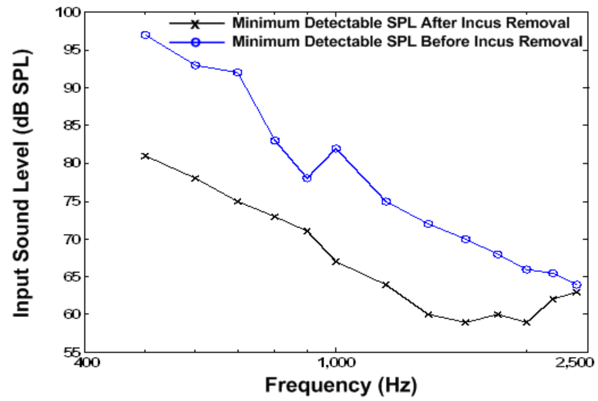

Fig. 9. ADXL 320 minimum detectable SPL vs. frequency before and after incus removal.

IV. Conclusion

Characterization of a temporal bone to determine the effect of incus removal on umbo mechanics and an implantable MEMS sound sensor has been reported. The removal of the incus to increase umbo acceleration amplitude and enhance the ability of an implanted acoustic sensor to detect an auditory stimulus has been demonstrated. An improved, fully integrated MEMS accelerometer with reduced packaged mass below 20 milligrams, sensing resolution of $35\,\mu g_{rms}/\sqrt{Hz}$, and an increased bandwidth is currently under development.

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