A PIEZOELECTRIC MIDDLE-EAR MICROPHONE FOR COCHLEAR IMPLANTS

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ABSTRACT

We present the development and evaluation of an implantable middle-ear microphone, named UmboMic, for fully implanted cochlear implants. We describe the fabrication of the UmboMic sensor using the piezoelectric thin film, PVDF, and titanium electrodes. Furthermore, we test the UmboMic on the bench and in human cadaveric ears. Results demonstrate consistent microphone performance across sensors and ears, regardless of fabrication differences or anatomical ear variations. The sensitivity and linearity of the UmboMic is high and its equivalent input noise is comparable to commercially available hearing aid microphones.

KEYWORDS

Implanted Microphone, Umbo, Middle-Ear, PVDF Sensor

INTRODUCTION

Cochlear implants are devices that can restore hearing to people with sensorineural deafness. Despite their name, cochlear implants rely on an external unit which contains components such as a microphone. Due to this external unit, cochlear implants cannot be used during sleep and vigorous activity, are susceptible to noise from wind, and function poorly in loud environments. Implanting the entire device would mitigate these problems and provide users with the discretion of an invisible device. An implanted microphone would also enable benefits from the filtering and pressure boost of the outer ear. We present the design, fabrication, and testing of an implantable middle-ear microphone called the "UmboMic."

The UmboMic is a piezoelectric displacement sensor that is implanted in the middle-ear cavity and contacts the umbo. The umbo is the point where the malleus attaches to the center of the tympanic membrane. We target the umbo because its unidirectional motion produces a well-represented sound signal at most auditory frequencies. As the umbo moves, it displaces the UmboMic, resulting in a charge that is amplified with a custom amplifier. Our design contrasts the MED-EL subdermal Mi2000 microphone [1], which suffers from sound attention through skin and does not take advantage of the outer ear structure. It also differs from the Envoy Acclaim piezoelectric microphone [2]. This sensor targets the incus, which has smaller and more complex modes of motion than the umbo, making the incus a less ideal sensing target.

We fabricate the UmboMic from two thin layers of piezoelectric polyvinylidene fluoride (PVDF). The biomorphic design reduces common mode noise and aids in rejecting electromagnetic interference. Furthermore, we use titanium as our conductive material so as to step towards biocompatibility. After fabrication, we test sensors on the bench with an "artificial umbo" and in human cadaveric specimens. We present the fabrication and testing of seven sensors in three cadaveric ears to demonstrate fabrication consistency and microphone reliability in different anatomy. This expands upon our previous work in [3], which only showed one sensor in one ear. Furthermore, we confirm that progress towards biocompatibility by using safe materials does not degrade microphone performance.

FABRICATION METHODS

A custom flex printed circuit board (PCB) functions as the core

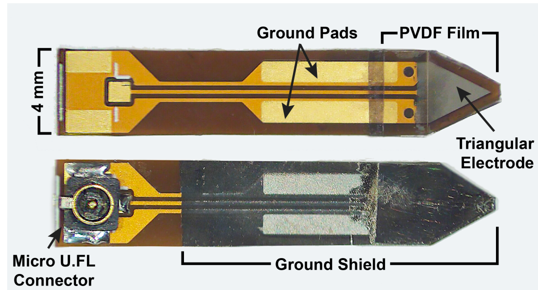

Figure 1: A picture of two UmboMic sensors. The top sensor is partially fabricated; the triangular electrodes have been patterned, the flex PCB trimmed, and the PVDF layer adhered. It is missing the ground shield and U.FL connector which can be seen in the finished bottom sensor.

substrate for the sensor. The flex PCB simplifies connecting the sensor to the amplifier and is a temporary solution to ease prototyping. The main difference between this version of the UmboMic and the earlier UmboMic presented in [3] is the use of titanium as the conductive material, and a final layer of Parylene C for waterproofing. The switch from aluminum to titanium is an important step in making the UmboMic biocompatible.

Electrode Patterning

We pattern a triangular electrode at one end of the flex PCB using photolithography. First, O2 plasma cleans the flex PCB substrate. A spinner spins a 3-µm thick layer of negative photoresist on each side of the substrate and a hotplate bakes the substrate for one minute at 110 C. A mask aligner flood exposes one side of the sample through a contact mask for 40 seconds, then a hotplate bakes the sample for one minute at 110 C. We repeat this step on the other side of the substrate. AZ 726 MIF develops the baked photoresist for 90 seconds and O2 plasma removes any excess photoresist. Next, electron beam evaporation deposits a 100-nm layer of titanium on each side of the sample. Finally, acetone dissolves the remaining photoresist. This process results in a triangular electrode on either side of the PCB substrate, as shown in the top sensor of Figure 1.

PVDF Adhesion

After electrode patterning, a Silhouette Cameo dices the sensors and cuts around the triangular electrode tip, leaving a 1-mm border as seen in Figure 1. The border prevents moisture in the middle-ear environment from reaching the electrode layer and shorting the sensor. We then use a thin layer of epoxy to adhere a 50 µm piece of PolyK PVDF film to each side of the sensor on top of the patterned electrodes. The two PVDF films are orientated such that they have opposing polarization. After the epoxy cures overnight, we trim the overhanging PVDF to match the shape of the sensor beneath. The PVDF layer on either side of the sensor capacitively couples to the electrodes through the epoxy.

Ground Layer and Finishing Steps

Acetone and O2 plasma clean the surface of the sensor before

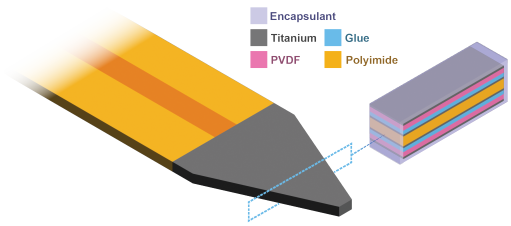

Figure 2: A diagram of the UmboMic sensor stack up after fabrication.

depositing the ground layer. Electron beam evaporation deposits a 75-µm layer of titanium on either side of the sensor. To prevent the sensor from heating above 80 C, the evaporator deposits the titanium in three layers of 25-µm, allowing the sample to cool between each deposition step. A thermal evaporator deposits a 15-µm layer of Parylene C onto the sensor surface to act as a liquid barrier. Finally, we solder micro U.FL connectors to either side of the sensor's tail. Figures 1 and 2 depict a finished UmboMic sensor.

EXPERIMENTAL SET UP

We conduct bench and cadaveric experiments in a sound-proofed and electrically-isolated chamber located in Mass Eye and Ear. All measurements occur on an air table to minimize vibrational noise.

Bench Testing

We characterize a finished sensor by stimulating it with an "artificial umbo" actuator rod and measuring its differential charge output as a function of tip displacement. A custom clamp attached to a manipulator holds the sensor in contact with the actuator rod. The sensor is connected to our custom differential charge amplifier to amplify its output [3]. We drive the actuator with a sinusoidal sweep from 100 Hz to 20 kHz and use laser Doppler vibrometry (LDV) to measure the displacement of the sensor's tip. The displacement of the artificial umbo is on the order of tens of nm for a standard input voltage of 100 mV. We designed the clamp to not introduce resonance into our signal over the frequency range of hearing. LDV measurements at different points on the clamp showed stability.

Cadaveric Testing

All sensors were tested in fresh cadaveric human ears sourced from Massachusetts General Hospital. We conducted our experiments in a total of three different human ears. Surgical preparation of the specimens allows access to the middle-ear cavity, similar to cochlear implant surgery.

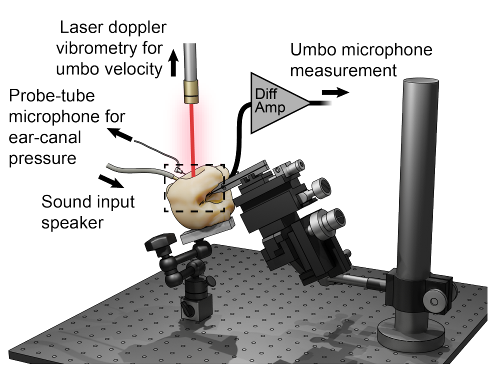

Figure 3: An illustration of the experimental setup for testing the UmboMic in human cadaveric ears.

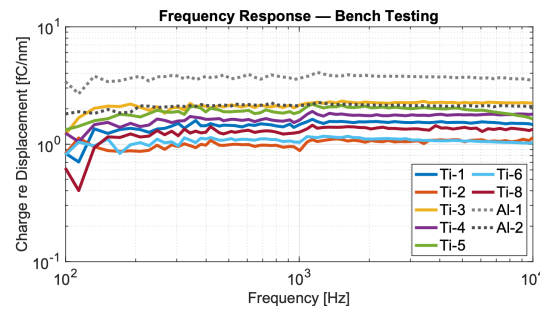

Figure 4: Frequency response of UmboMics when displaced by an "artificial umbo." Ti-# sensors are fabricated with a Titanium electrode and ground layer, while Al-# sensors are fabricated with an Aluminum electrode and ground layer.

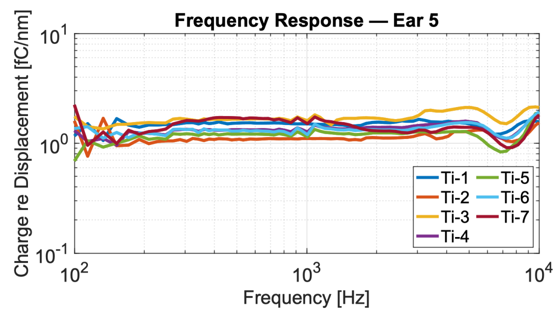

Figure 5: Frequency response with respect to umbo displacement of UmboMic in ear 1.

Figure 3 illustrates the experimental setup when working with human specimens. A sinusoidal tone sweep from 0.1-20 kHz is introduced to the ear canal. This sound is measured at the ear canal using a probe tube microphone (Knowles EK3103) with the tip 1-2 mm from the tympanic membrane. The velocity of the umbo is measured with LDV through the ear canal. From the middle-ear cavity, the UmboMic sensor and amplifier detect umbo motion resulting in charge.

RESULTS AND DISCUSSION

Bench Testing

Figure 4 plots the bench testing results with the UmboMics vibrated by an "artificial umbo." Unlike a real umbo, the displacement of the artificial umbo is constant across all frequencies of hearing and is not mechanically loaded by the UmboMic sensor. Consequently, the charge output of the UmboMic is constant with respect to frequency, as shown in Figure 4. The small fluctuations in the response are likely due to unavoidable vibrations in the test setup. The resonant frequency of the UmboMic is around 20-25 kHz, and thus outside the bandwidth of hearing.

Figure 4 also compares the sensitivity of the aluminum based UmboMic to those made with titanium, as well as the spread between titanium sensors. When compared to aluminum-based sensors, the titanium-based sensors are from 0 to 10 dB less sensitive. This could be due to slight depoling of the PVDF during titanium deposition which occurs at a higher temperature than aluminum deposition. Meanwhile, the spread between titanium sensors is minimal with only a 2 dB difference between the best and worst performing sensors. This data demonstrates repeatability in sensor fabrication.

Cadaveric Testing

After characterizing the sensors on the bench, we test them in

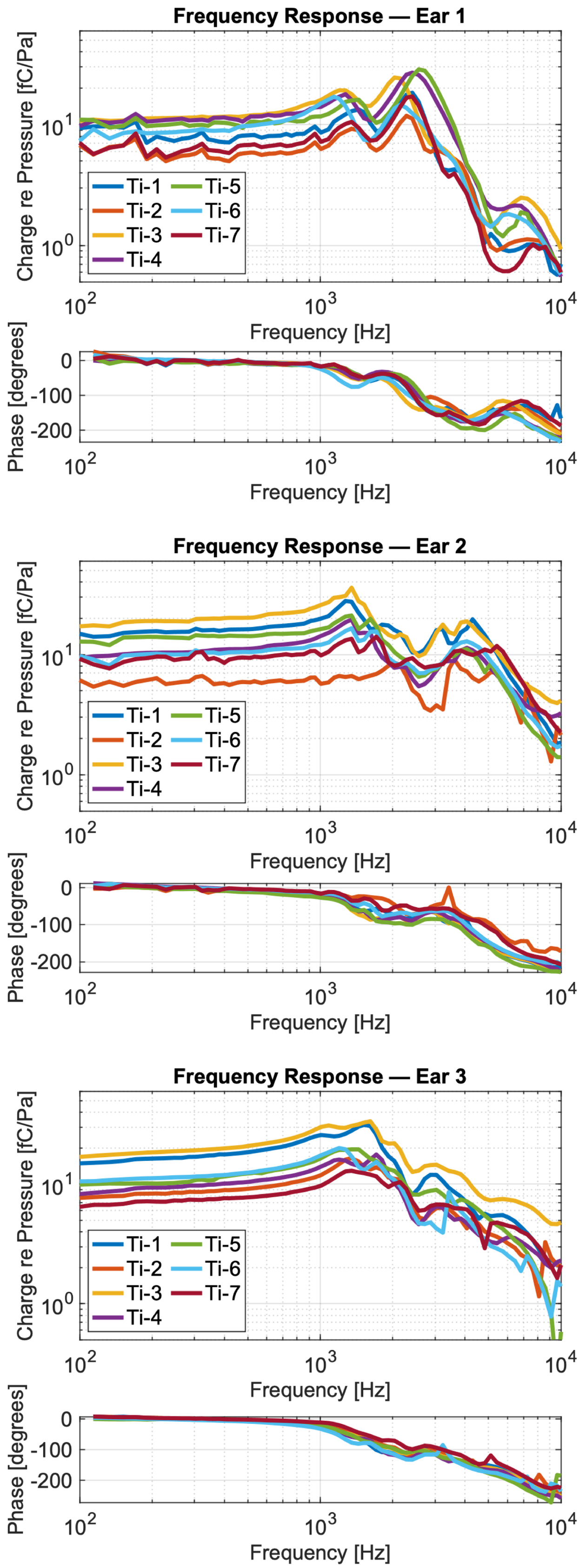

Figure 6: The frequency response of seven sensors across experiments in three human cadaveric ears.

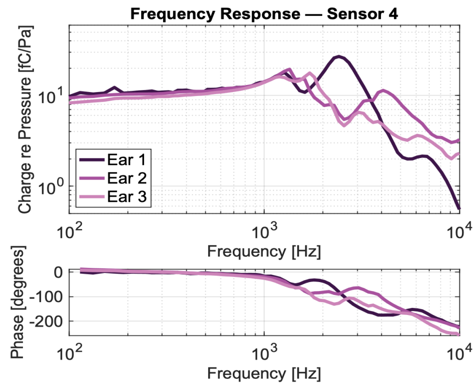

Figure 7: The frequency response of sensor Ti-4 in three ears.

human cadaveric ears. Figure 5 shows the charge output of the UmboMic with respect to umbo displacement in Ear 1. As expected, this data looks similar to the bench testing data with an artificial umbo. In bench testing the LDV directly measures displacement of the sensor tip, but in cadaveric ear experiments, the LDV measures displacement of the tympanic membrane directly above the umbo. This discrepancy might be the cause of fluctuation in the response above 3 kHz, as the measured displacement does not exactly capture the deflection of the sensor tip.

Figure 6 shows the frequency response of all seven sensors in three ears, where each plot corresponds to a different ear. The y-axis shows the charge output of the sensor normalized by the measured stimulus ear canal sound pressure. The frequency response of the sensors across specimens is very comparable, which demonstrates that the UmboMic can work well on a variety of patients. The sensitivity is high up to the target of 8 kHz, and the frequency response is very flat up to and above 1 kHz. Around 1 kHz to 2 kHz, the magnitude peaks, and the phase decreases. The resonance of the umbo at these frequencies is well established in [5] [6] [7]. Around 2-4 kHz, there is a 20-40 dB/dec roll off in sensor sensitivity due to the change in umbo motion. At higher frequencies, the umbo starts to rock, and less kinetic energy is transferred directly to the sensor. In all of the ears, the sensitivity above 8 kHz is still within 15 dB of the flat lower frequency sensitivity below 1 kHz. The anatomical differences between ears can account for much of the variability between experiments with the same sensors.

Figure 7 overlays the frequency response of sensor Ti-4 in all three ears. This plot highlights the consistency of a single sensor across different ears. The sensor amplitude below 1 kHz is almost identical across experiments. Above this frequency, the unique motion of the umbo means that the response is different between experiments.

When positioning the sensor under the umbo, the pressure of the sensor loads the ossicular chain. Loading causes the ossicular chain to stiffen, and thus reduces motion at lower frequencies. Figure 8 demonstrates the difference in umbo motion when it is loaded and unloaded, and how this loading impacts the sensor's output. We used the manipulator to position the UmboMic sensor tip under the umbo and lifted the sensor's position such that it pressed hard against the umbo. With each subsequent measurement, we gradually dropped the sensor's position by about 0.5 mm using the manipulator to reduce loading pressure on the umbo. We observed that, in order for the sensor to be properly coupled to the umbo, it must press hard enough to reduce umbo motion. From there, increasing the pressure of the sensor against the umbo does not significantly impact the umbo's motion. There are two takeaways from this observation. First, the surgeon does not need to be exact regarding the pressure of the sensor against the umbo when

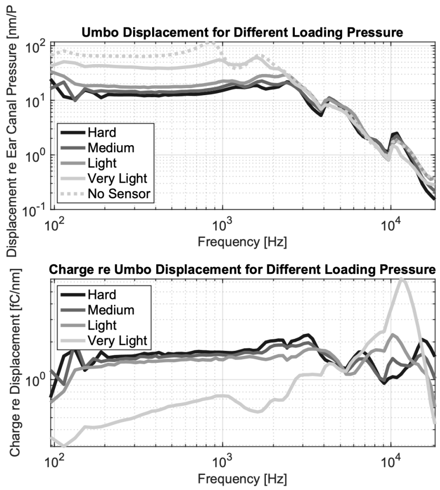

Figure 8: Impact of the UmboMic's pressure against the umbo on umbo displacement and sensor output. "Hard" pressure refers to significant loading of the umbo, while "very light" pressure is when the sensor is barely touching the umbo.

implanting. Second, a less stiff sensor would reduce loading of the umbo at low frequencies and perhaps increase sensitivity but decrease bandwidth. In the future, we plan to experiment with less stiff sensors to test this hypothesis.

Equivalent Input Noise and Linearity

The equivalent input noise (EIN) of the microphone and amplifier is an important metric for determining the minimum sound it can sense. Figure 9 plots the EIN of our system against that of the commercially-available Knowles EK3103 hearing aid microphone (shown in black). The dark blue line corresponds to EIN data from our microphone in Ear 2 without the outer ear. The blue line shows the decreased EIN after considering the increase in pressure gain due to the outer ear [8] [9]. The A-weighted EIN of the Knowles microphone, our microphone, and our microphone with the outer ear is 33.8 dB SPL, 43.3 dB SPL, and 32.4 dB SPL respectively. Thus, the UmboMic performs comparably to a commercially available microphone, and even better from 0.9 to 6 kHz. This result is very similar to what is presented in our previous paper [3], therefore proving that the use of titanium instead of aluminum does not increase the noise floor of our device. The most significant source of noise in our system is from the amplifier, thus the EIN of our system is resilient to different sensors.

Figure 10 shows the linearity of sensor output with respect to ear canal pressure for sensor Ti-3 in Ear 3 at five different frequencies. The UmboMic sensors show almost no nonlinearities across 70 dB of dynamic range. This is consistent with our findings in [3], demonstrating that the switch to titanium from aluminum does not impact the UmboMic sensor's linearity.

CONCLUSION

Developing an implantable microphone is the largest barrier to achieving a fully internal cochlear implant. We present the fabrication and testing of the UmboMic, a piezoelectric microphone that senses motion of the umbo in the middle-ear. By using titanium and PVDF, we ensure that all active materials in our sensor are biocompatible. Through testing our microphone in three human cadaveric ears, we show that seven individually fabricated sensors behave similarly despite anatomical differences. All UmboMics have a flat frequency response up to 1 kHz, good linearity and robust

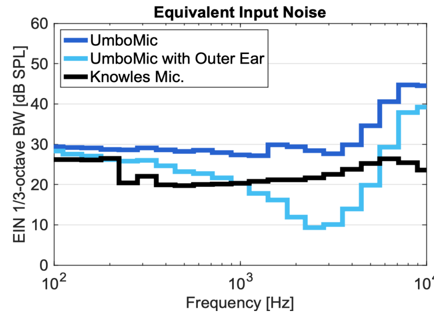

Figure 9: Equivalent input noise (EIN) normalized to 1/3-octave bandwidth for the UmboMic with and without the outer ear, and the Knowles hearing aid microphone.

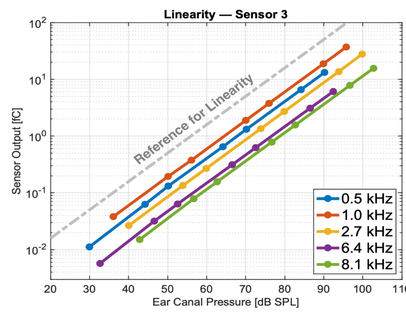

Figure 10: Linearity of UmboMic sensor Ti-3's charge response to ear canal pressure across 70 dB of dynamic range.

sensitivity above 8 kHz. These results indicate that the UmboMic can function well in a variety of patients. Furthermore, we show that the UmboMic has an EIN comparable to commercially available hearing aid microphones. This work demonstrates important progress towards achieving a fully implanted cochlear implant.

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