Implanted detection of audio signals for cochlear implants: a literature revision.

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Abstract— Traditional cochlear implants comprise internal and external components, but external parts present a series of limitations such as fragility, cosmetic concerns, and interruptions during sport-related activities. This article reviews two acoustic sensor implementations designed to replace the external microphone of current cochlear implants, aiming for a totally implantable solution to the previously mentioned issues. Both sensors use piezoelectric materials to generate voltage from intracochlear pressure or middle ear vibrations. The PVDF sensor [1] measures intracochlear pressure and has advanced development and testing, although factors such as the signal-to-noise ratio need to be refined. The PZT sensor [2] measures membrane vibrations and proposes mechanical filtering of the sound signal through a multi-channel prototype that covers the range of daily sound frequencies, but is less developed than the PVDF sensor. While both designs show promise, each is at a different stage of development and faces technical challenges that need to be overcome for successful clinical application.

***Keywords*— totally implantable cochlear implant, piezoelectric sensors, implanted sensors.**

INTRODUCTION

Cochlear implants are implantable medical devices that help restore hearing to people with severe to profound deafness. Conventional cochlear implants consist of two main parts: one internal and one external. The external part includes a battery, a microphone, a processor and a transmitter that sends the processed signal picked up by the microphone to the internal part of the implant. The internal part contains an array of electrodes that work on different frequencies and a receiver that directs the signal to the corresponding electrode, which stimulates the auditory neurons through current pulses [3].

However, having an external component entails several limitations for the user. This component is fragile and can prevent the user from taking part in sport activities. Hearing may also be interrupted during activities involving water or sleep, and many patients express a sense of annoyance due to cosmetic concerns [4]. From a more technical perspective, it is also important to note that the use of an external microphone completely bypasses the natural hearing mechanism (middle ear vibrations and intracochlear pressure) that may still function in cochlear implant candidates.

These limitations would be addressed by the development of a totally implantable cochlear implant (TICI). Currently, there are a few devices undergoing testing. The Envoy Medical Acclaim is a TICI that has been implanted in three patients, all of whom were able to hear after the device was activated [5].

In this article, we review two different implementations of acoustic sensors designed to replace the external microphone of current cochlear implants. Both implementations use piezoelectric materials to generate voltage through vibration or pressure resulting from sound in the middle or inner ear, utilizing the natural hearing mechanism.

I. Materials and methods

To explore the existing literature on acoustic sensors for totally implantable cochlear implants, a focused review of two main articles [2] [1] was conducted. The research was primarily conducted using Google Scholar, as a result of a "cochlear implant sensor" search. Complementary bibliographical references were identified through Google Scholar searches using key terms such as "Envoy Acclaim" [5], "piezoelectric", "totally implantable cochlear implant" [6].

The selection criteria for these articles were based on their proposal of prototypes that use the piezoelectric effect in two distinct ways. At the same time, both implementations address various technical and design challenges through different approaches.

II. Results

A. PVDF-Based piezoelectric microphone [1].

The article "PVDF-based piezoelectric microphone for sound detection inside the cochlea: toward totally implantable cochlear implants" (2018) proposes a prototype for a PVDF sensor and explores its feasibility. The sensor is designed to be implanted in the cochlea to sense sound signals by measuring intracochlear pressure. The proposed design consists of a β-phase PVDF thin film (50 μm thick) with two Au or Ag electrodes on the top and bottom surfaces of the piezoelectric material. The electrodes form a capacitor where they overlap, referred to as the active area, which is used to measure the voltage generated by the piezoelectric material as a result of intracochlear pressure changes. This design uses the piezoelectric properties of the materials to transduce pressure changes into electrical signals.

Through the study of the piezoelectric properties of the material and the proposed configuration, the dependence of the device's output voltage on the active area is established. It is observed that the capacitance and the output voltage decrease as the active area decreases, implying design limitations that need to be explored due to the dimensions of the inner ear.

To study the different properties of this configuration, such as the device's sensitivity, it is connected to an amplifier as shown in Fig. 1, where the amplifier's impedance is modeled as a resistor and a capacitor in parallel. The relation between the input voltage for the amplifier, the voltage produced by the PVDF device, its impedance, and the amplifier's impedance is shown in Eq. 1, indicating that the input voltage to the amplifier decreases at lower frequencies as the PVDF device's impedance increases.

$$V_{IN} = V_{PVDF} \frac{Z_{I.AMP}}{Z_{I.AMP} + Z_{O.PVDF}}$$
$$V_{IN} = V_{PVDF} \frac{(j\omega C_I + 1/R_I)^{-1}}{(j\omega C_I + 1/R_I)^{-1} + (j\omega C_{PVDF})^{-1}} \quad (1)$$

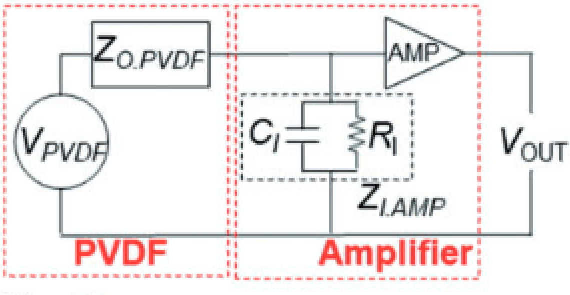

Fig. 1: circuit diagram of the device connected to an amplifier, taken from Park [1].

The dependence of signal-to-noise ratio (SNR) and output voltage on the active area was experimentally tested. Different sounds, with varying sound pressure and frequency, were applied to PVDF devices with active areas of 40, 20, 10 and 1 mm^2. The results show that the sensitivity of the devices are 45, 43, 21 and 6 mV/Pa respectively, and that SNR decreases with the active area.

For the experimental tests, a device with the area of 7.5 mm^2 was used. In this case, the electrodes were designed to cover the entire piezoelectric material, maximizing the active area, and, based on the previously mentioned results, achieving the maximum output voltage and signal-to-noise ratio. Additionally, since the device needs to operate in the intracochlear fluid, it was encapsulated in a PDMS cylinder.

An initial feasibility test was conducted in vivo on a gerbil. It was not possible to implant the device throughout the cochlea due to the dimensions of the gerbil's round window; therefore, the portion of the cochlea closest to the round window was sensed. Apart from the PVDF sensor, a fiber optic sensor was also implanted to measure intracochlear pressure. Although the area sensed by the PVDF sensor was limited, this test was significant and provided valuable information.

Firstly, the results obtained pre- and post-mortem were compared, revealing no significant differences. This is crucial as it indicates that the device did not pick up electrical activity from hair cells, which ceases shortly after death. Secondly, the sensor's response drastically decreased when the middle ear was disarticulated, as expected.

Following this initial experiment, the sensor was tested in fresh human cadaveric temporal bones. The PVDF sensor was inserted into the cochlea, sound was delivered to the ear canal, and a hearing aid microphone was used to measure the sound, as shown in Fig. 2. Results of speaking directly into the ear canal can be seen in Fig. 3. Although time domain signals are not expected to be exactly alike since they are measured in different parts of the ear, the two signals are similar. Noise is more noticeable in the PVDF sensor signal than it is in the one picked up by the microphone, and this is quantified by taking the Fast Fourier Transform of the two signals. The SNR is higher for the hearing aid microphone by 10 to 20 dB between 100 and 10000 Hz.

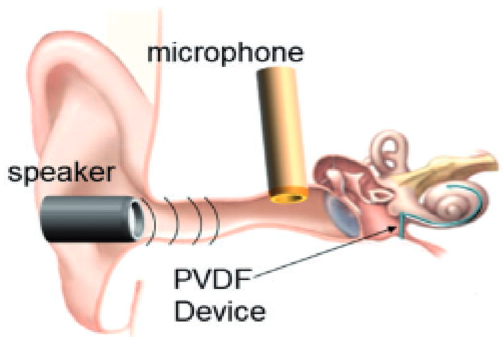

Fig. 2: Schematic depiction of the experimental configuration in human cadaveric temporal bones. Taken from Park [1].

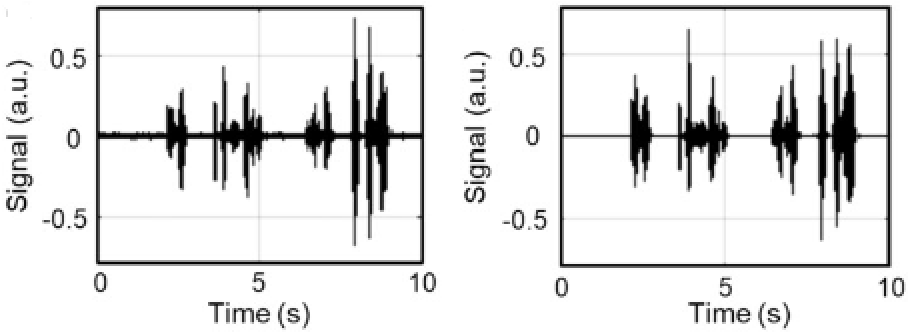

Fig. 3: Time domain signals from the PVDF sensor (left) and the hearing aid microphone (right) as a result of speaking directly into the ear canal. Taken from Park [1]. a.u.: arbitrary units.

B. Thin film piezoelectric acoustic sensor [2].

The article "Thin film piezoelectric acoustic sensor for fully implantable cochlear implants" (2017) proposes a multi-channel piezoelectric acoustic sensor that consists of eight cantilever beams, each one of those beams resonating at a specific frequency. Using thin film piezoelectric materials with MEMS, these cantilevers function as bandpass filters covering the range of daily sound frequencies. The development of one cantilever beam is reported, with the device intended for implantation on the eardrum or ossicles in the context of a totally implantable cochlear implant.

Due to the limitation of volume, mass and dimensions in the middle ear, this work aims to design a multichannel device that meets these constraints and achieves an adequate voltage output. The proposed solution is the joint implementation of piezoelectric materials with MEMS, allowing mechanical filtering of the input signal through an 8-channel device. The piezoelectric material used is Pulsed Laser Deposited Lead Zirconite Titanate (PLD-PZT). Each transducer consists of a fixed end, a tip mass, and a thin film PZT piezoelectric, as shown in Fig. 4.

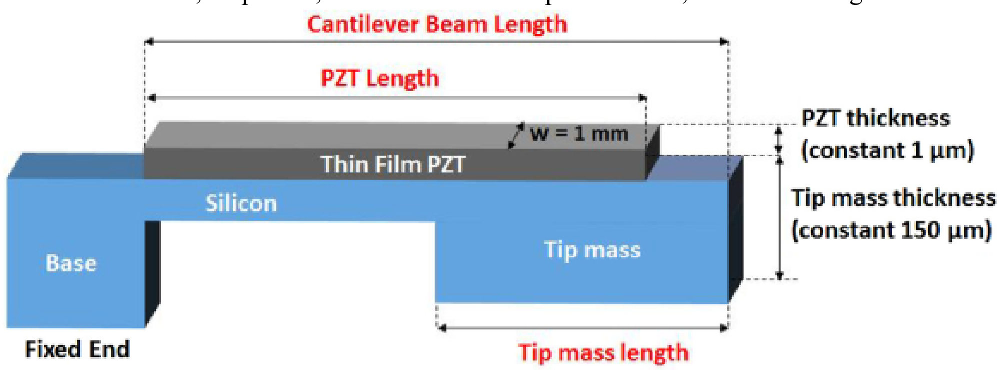

Fig. 4: schematic depiction of the transducer, taken from Ilik [2].

Using COMSOL Multiphysics software, a design was generated that considers the geometric constraints of the device, such as the mass and volume that the middle ear can support. Subsequently, using the same tool and a finite element analysis, various simulations were carried out to determine the electrical and mechanical properties of the prototype. Table I shows the results obtained through these simulations for each frequency.

TABLE I

RESULTS OBTAINED THROUGH FINITE ELEMENT SIMULATIONS, TAKEN FROM ILIK [2].

Frequency (Hz)	Beam length (mm)	Output voltage (mV)	Sensitivity (mV/Pa)	Quality factor
300	3.4	22.98	363.34	984
600	2.4	16.87	265.4	1012
900	1.9	64.79	391.9	1285
1200	1.7	15.88	251.2	1196
1600	1.4	22.71	358.94	976
220	1.2	13.12	204.6	1043
3200	1	7.21	114.1	996
4800	0.8	3.75	59.3	1121

An initial experimental approach to test the basic functionality of the device involved fabricating a single cantilever and assembling it onto a PCB. To study the sensor's response, the PCB was mounted on a shaker table with controlled acceleration, and the device's output voltage was monitored with an oscilloscope. Each acceleration applied represents a different level of sound. The results obtained were as expected, showing that the sensor resonance frequency decreases with higher acceleration due to the ferroelectric properties of the material and their effects on the material's internal structure. Fig. 5 shows the output voltage obtained experimentally and through simulations at two different sound pressure levels (SPL).

A second experimental setup was conducted to observe the device's performance in an environment that mimics the eardrum's behavior, using a Parylene membrane that vibrates in response to sound. The results obtained from this configuration show a bandpass behavior of the output signal, with a bandwidth of approximately 150Hz.

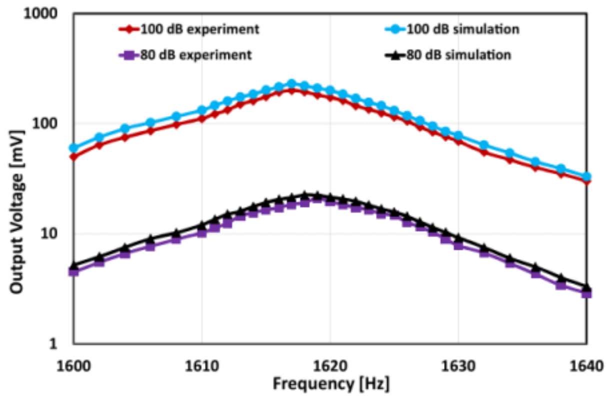

Fig. 5: output voltage obtained experimentally and through simulations at 100dB and 80dB. Taken from Ilik [2].

III. DISCUSSION AND CONCLUSION

Both reviewed articles present different alternatives for the creation of an implanted acoustic sensor. The main similarities between the two designs are the use of piezoelectric materials and the utilization of the natural hearing mechanism.

There is a more advanced development and testing in the PVDF sensor, with a finalized prototype. While the results show promise, there are factors that need to be refined such as the signal-to-noise ratio, which is important in order to get a clear signal. Although it was not the focus of the work revised, it would be important to analyze the sensor's integration into a complete cochlear implant system, with emphasis on its interaction with the electrodes of the CI. The electrical shielding necessary for the sensor to work in a CI is mentioned as the subject of future study [1].

In the case of the PZT sensor, there is a proposed model that is less developed compared to the PVDF sensor. Although the finished prototype was not fabricated, the basic principle behind it was tested showing promising results. One of the highlights of the proposed prototype is the concept of mechanical filtering, which clearly differentiates this sensor from the previously mentioned one. This characteristic could imply a change in the processing hardware used in cochlear implants.

It is noteworthy that both sensors are designed to be implanted in different parts of the ear, each facing distinct design challenges and limitations. Additionally, different piezoelectric materials are used in each case. Given that the voltage generated by the PVDF sensor is significantly lower than that of the PZT sensor [1], [2], it would be highly interesting to investigate how the material used and the location of the implanted device impact the output signals obtained.

Both implementations show promising results as well as a set of technical difficulties that need to be overcome.

References

[1] S. Park *et al.*, «PVDF-Based Piezoelectric Microphone for Sound Detection Inside the Cochlea: Toward Totally Implantable Cochlear Implants», *Trends Hear.*, vol. 22, p. 233121651877445, may 2018, doi: 10.1177/2331216518774450.

[2] B. İlik *et al.*, «Thin Film PZT Acoustic Sensor for Fully Implantable Cochlear Implants», *Proceedings*, vol. 1, n.º 4, Art. n.º 4, 2017, doi: 10.3390/proceedings1040366.

[3] M. Svirsky, «Cochlear implants and electronic hearing», *Phys. Today*, vol. 70, n.º 8, pp. 52-58, ago. 2017, doi: 10.1063/PT.3.3661.

[4] C. Y. Lo, R. Clay-Williams, B. Elks, C. Warren, y F. Rapport, «The (in)visibility of deafness: Identity, stigma, quality of life and the potential role of totally implantable cochlear implants», *Health Expect.*, vol. 27, abr. 2024, doi: 10.1111/hex.14060.

[5] J. R. Dornhoffer, S. K. Lawlor, A. A. Saoji, y C. L. W. Driscoll, «Initial Experiences with the Envoy Acclaim® Fully Implanted Cochlear Implant», *J. Clin. Med.*, vol. 12, n.º 18, p. 5875, sep. 2023, doi: 10.3390/jcm12185875.

[6] N. Cohen, «The Totally Implantable Cochlear Implant : Ear and Hearing». Accedido: 5 de junio de 2024. [En línea]. Disponible en: https://journals.lww.com/ear-hearing/fulltext/2007/04001/the_totally_implantable_cochlear_implant.24.aspx