IN VIVO CHARACTERIZATION OF IMPLANTABLE UNPOWERED PARYLENE MEMS INTRAOCULAR PRESSURE SENSORS

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Abstract

This work presents a complete suite of *in vitro* and *in vivo* characterizations of an unpowered, biocompatible, parylene-based micro-electro-mechanical-systems (MEMS) pressure sensor for intraocular pressure (IOP) sensing. *In situ* mechanical responses of the sensors facilitate real-time pressure readouts without power consumption/ transduction. Two types of IOP sensors (high-sensitivity and needle-implantable) have been fabricated and characterized. *In vitro* and *in vivo* testing results have successfully demonstrated that the high-sensitivity IOP sensors can achieve mmHg-sensitivity pressure responses both on-bench and inside an enucleated porcine eye, while the needle-implantable IOP sensors can be implanted into a porcine eye through a needle and secured inside the eye. Using this new IOP sensor paradigm we can realize unpowered, real-time, faithful, and convenient IOP monitoring in glaucoma patients.

Keywords: In Vivo, Intraocular Pressure, Parylene, Pressure Sensor, Unpowered

1. Introduction

Unpowered parylene MEMS IOP sensors were described previously [1][2] and are essentially all-mechanical compliant structures inspired by a Bourdon tube (free-standing curved thin-walled tube). They are systematically deformed by a pressure difference applied between the pressure encapsulated in the tube/channel and the ambient pressure, realizing direct pressure measurement through observation of tube deformation. Therefore, after the IOP sensors are implanted on the iris of the eye, their visible IOP readouts can be observed with a microscope/stereoscope from outside the eye through the transparent cornea. Design, fabrication, and *in vitro* characterization of the novel IOP sensors were presented [2]. In this work, continuing the progress of this research, we have more extensively developed the IOP sensors and demonstrated practical *in vivo* pressure sensing in the mmHg range inside a real eye.

2. Experimental

By implementing state-of-the-art micromachining technology, two types of IOP sensors were microfabricated for characterization. Fig. 1 shows a spiral-tube sensor and a long-armed-tube sensor for high-sensitivity pressure responses, and Fig. 2 shows the needle-implantable IOP sensor. For the needle-implantable sensors, integrated packaging has been designed to facilitate secure anchoring and functionality of the

device after implantation on the iris of the eye [2]. All of these IOP sensors were monolithically micromachined so assembly processes were not required.

Figure 1. Microfabricated high-sensitivity parylene IOP sensors with 1.1-mm-diameter spirals.

Figure 2. Microfabricated needle-implantable IOP sensors: (left) Concept of integrated device packaging; (right) A fabricated device situated inside a 19-gauge needle.

3. Results and discussion

The micromachined IOP sensors were first tested on-bench to characterize their *in vitro* behaviors. Testing results of the needle-implantable sensors were previously reported [2]. For the high-sensitivity sensors their pressure sensitivity was 0.46 degree/mmHg in rotational trajectory with the spiral-tube design and 11.24 µm/mmHg in lateral trajectory with the long-armed-tube design as shown in Fig. 3.

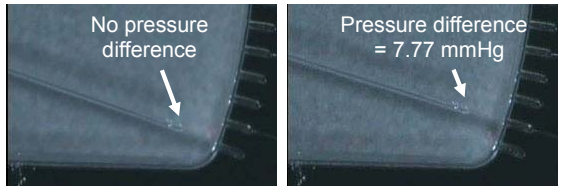

Figure 3. *In vitro* pressure response of the long-armed-tube sensor with a lateral sensing trajectory. Pressure difference is applied between inside and outside of the parylene tube.

Implantation has been conducted in several enucleated porcine eyes to characterize the *in vivo* performance of the IOP sensors. For the high-sensitivity sensors, a flat incision and suturing were performed to implant the devices. Testing results show that both the spiral-tube and long-armed-tube designs successfully registered IOP variations under observation with a surgical microscope. A real-time 8.72 µm/mmHg IOP sensitivity was achieved with the long-armed-tube sensor as shown in Fig. 4. In addition, repeatable pressure responses of the sensors were confirmed by applying cyclic pressure variations. For the needle-implantable sensors, in spite of their minimally observable pressure

responses due to low optical magnification of the scope as shown in Fig. 5, preliminary testing of the tissue anchors has shown promise that the devices can be securely anchored on the iris even when vigorously pushing them using a blunt tube or shaking the eye. Further anchoring studies are underway to more precisely determine the reliability of the devices in the intraocular environment.

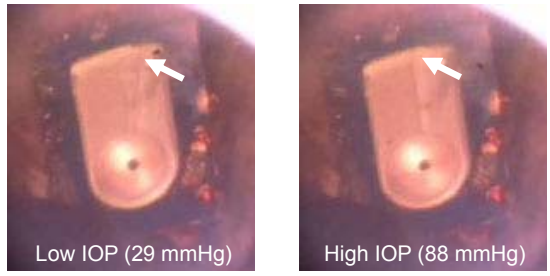

Figure 4. *In vivo* pressure response of the long-armed-tube IOP sensor.

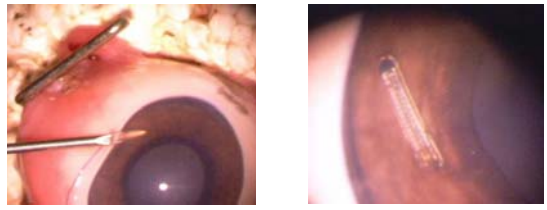

Figure 5. *In vivo* characterization of the needle-implantable IOP sensor: (left) Image of device implantation through a needle incision; (right) Device implanted inside the eye. The tissue anchors mechanically secure the device on the iris in the intraocular environment.

4. Conclusion

In this work both *in vitro* and *in vivo* characterizations of the developed pressure sensors have been successfully performed to prove the concept of unpowered IOP sensing. Testing data have yielded positive results toward realization of real-time IOP readout.

Acknowledgments

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References

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