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Biocompatibility and implant of a less invasive intraocular pressure sensor

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ABSTRACT

We discussed the design and fabrication consideration for an Intraocular Pressure (IOP) systems according to surgical and biocompatibility implant limitations. A new less invasive IOP system is implanted successfully in the eye of a rabbit by a minimum invasive surgical procedure. The MEMS array is over a flexible, biocompatible polyimide substrate in a maximum 8 × 8 mm area. The substrate flexibility allows it to fit a small surface of the eye. The implanted coil is under the conjunctiva, out of the interior chamber. However, the pressure sensor is deposed inside the interior chamber through a minimum invasive procedure. The capacitive sensor is fabricated considering a maximum area of 0.5 × 0.5 mm^2. Increasing sensor capacitance is achieved by a set of windows cavities getting a sensible reduction of the separation of its capacitor plates at the base of the windows anchored. The coil and pressure sensor consist of alternating layers of polyimide–metal–polyimide, patterned using reactive ion etching over a thin silicon wafer that is used only as a sacrificial layer. We pointed out the way micron-scale metal layers can be incorporated in a thin flexible plastic substrate to integrate into the same process both: the coil and the intraocular pressure sensor. The whole structure encapsulated in a biocompatible polymer fits into the shape of the ocular globe.

1. Introduction

Glaucoma is the second leading cause of blindness worldwide. Glaucoma is a group of eye disorders associated with a high intraocular pressure (IOP). Researchers and clinicians in the field recognize the need for a continuous monitoring of patients [1,2,3], particularly in cases of abnormal ranges of IOP. An implanted IOP sensor is a new alternative to study Glaucoma aetiology.

Most authors agree that an intraocular device allowing telemetric IOP measurements should have as many of the following implant properties as possible: 1). — The artefact must be biocompatible, 2). — Be safe and less invasive, 3). — Be implanted with a friendly surgical procedure, 4). — Exhibit long-term stability in accuracy and reproducibility, 5). — Measure IOP as frequently as possible, 6). — Be independent of corneal thickness. 6). — The implant should be easily retrievable There have been several attempts to construct an implantable intraocular pressure sensor looking to fit above properties, [4–8]. However, there is not yet a whole solution to satisfy those requirements. We find the following approaches as the most persuasive:

Resonant L-C IOP based sensors. Most implantable IOP sensors look to measure pressure variation throughout capacitance changes caused by pressure acting on a capacitive sensing chamber. Wireless IOP sensors include simple resonant L-C devices to sense and transmit IOP date. Wireless IOP sensors in this way can enable the development of lowest complexity platforms inside ocular globe where one very sophisticated readout unit could interface with several cheap, passive sensors [5,6,7.8,9,10]. Among others, The Semismed's triggerfish IOP contact lens, the implanted capillary tube sensor and The WIT ring-shaped intraocular device seem to be the most promising IOP artefacts.

A). — IOP contact lens. The Semismed's triggerfish is an IOP measurement system that appears in 2009 to measure and register intraocular pressure across the cornea by embedding a pressure sensor into contact lens [4]. It is a silicone contact lens with a diameter of 14.4 mm and contains two active strain gauges made out of platinum–titanium with wire loops of 7-μm diameter. We find too a diameter of 11.5 mm, two passive strain gauges for temperature compensation, one antenna (gold, 30 μm) and one microprocessor (50 μm thick) (Fig. 1-A) [4]. Power and data transfer work telemetrically and are wireless from and to an antenna, worn as a ring around the orbit. It is less invasive and has the better wireless performance. However, there are still unsolved issues. IOP measurement is not accurate enough due to its reliance on a good long-term physical contact between the sensor and the cornea. Also, the contact lens method depends on the mechanical properties of the cornea, which is different for each. In summary IOP sensing contact lenses are not yet technically mature tools in managing glaucoma [13,14] Fig. 1-A.

B). — Authors in [6,7] report an Implanted capillary tube sensor. This sensor consists of a MEMS planar coil surrounding a circular capacitive

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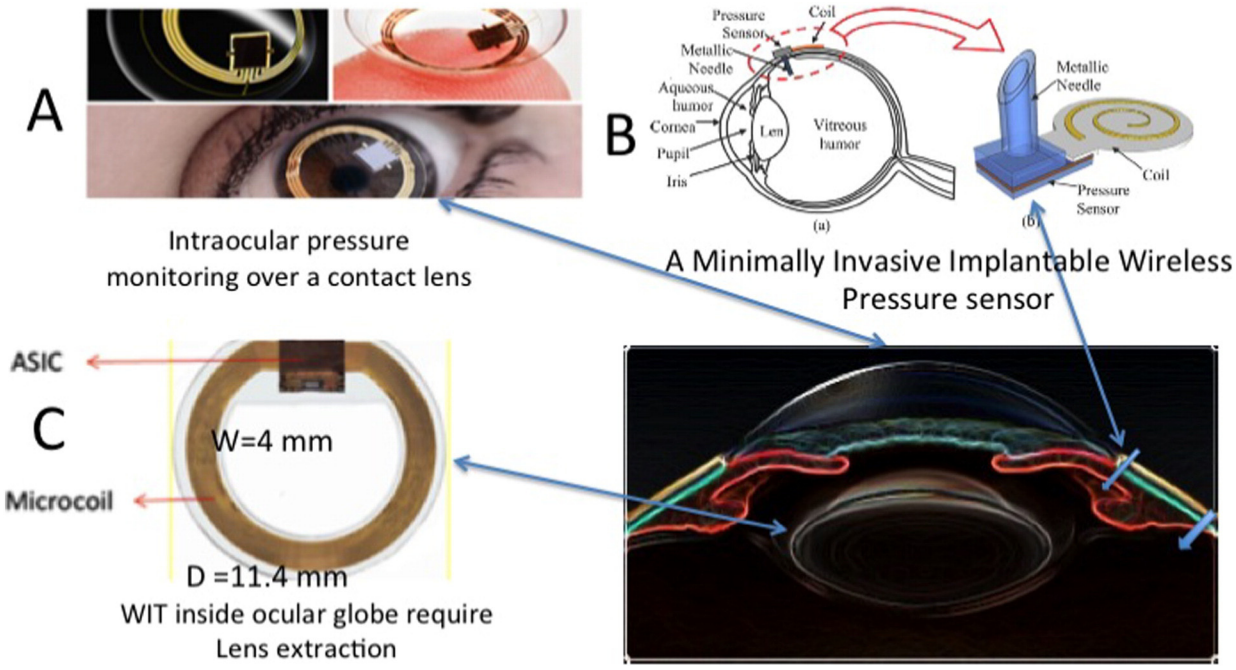

Fig. 1. Most implantable IOP sensors look to measure pressure variation throughout capacitance changes caused by pressure acting on a capacitive sensing chamber, A-over the cornea, B-Through a capillary tube, C-inside ocular globe.

sensing chamber. The capillary tube fixes to one side of the device with access to the sensing chamber. The device is over the sclera outside the ocular globe with only the capillary tube penetrating into the vitreous body. Vitreous Pressure acts on the capillary tube causing movement over a flexible diaphragm at the top of the tube outside the ocular globe. Furthermore, implantation here allows a striking sensing distance and a smaller coil size because the inductive coupling on which telemetry for this device depends on, is not as hampered by the loosely material of the eye [7]. However intraocular fibrosis around the capillary tube may occur. Further study is needed to determine the validity of this approach. Since the sensor lies on the surface of the eye, the force of the tear film and eyelid acting directly on the device must be evaluated. While this sensor provides excellent sensitivity and telemetry distance, these effects may affect readings in practical applications. Also, of concern is the comfort level associated with this device. Furthermore, if users find it irritating, they may try to remove it. Fig. 1-B.

C). — WIT ring-shaped intraocular device. The WIT is a ring-shaped intraocular device that allows wireless IOP measurements through radiofrequency [9]. This device uses sophisticated RFID technology to provide telemetry at distances up to 2 cm. The system uses a hand-held reader coil Fig. 1-C where IOP measures with 0.1-mmHg resolution. However, the device is intended for human implantation during cataract surgery. It is in the posterior chamber of the eye and requires removal of the lens. The sensor is 900 μm thick and is 11.3 mm in diameter. A biocompatible silicone encapsulates it. The reader can follow the WIT surgery procedure. It is available at http://youtu.be/NKW8VSQ99ko. As reported by WIT Authors they founded several risks associated with such an implantation [9,10]. Anterior iris displacement with subsequent peripheral anterior synechia as well as angle narrowing may occur. Iris chafing leading to pigmentary glaucoma is another risk. Intraocular fibrosis around the transducer may occur, leading to impingement on the surrounding ocular structures as well as device malfunction [9,10]. We believe that even WIT shows promising results for human implantation it suffers from several shortcomings, which have so far prevented their widespread application. The WIT implanted inside the eye is naturally too invasive for an extensive use of a majority of glaucoma and non-glaucoma population.

2. Materials and method

Our proposal looks for desirable implant properties defined in the introduction. Then the coil, the largest artefact in the IOP sensor, must be out the ocular globe looking for the fewest surgical procedure. However, the MEMS capacitor will be in the interior chamber, between the cornea and the pupil. Both, the coil and the sensor require the minimum area of a thin flexible polyimide substrate to fit the curvature of the human eye. The location of the capacitive sensor must be inside the interior chamber. However, the MEMS capacitor requires the highest capacitance in the smallest possible area. The implant must not touch the cornea or even the pupil. The capacitive plate will be in contact with the intraocular pressure. Then the applied pressure deforms the bending plate. By those above we decided to fabricate both the coil and pressure sensor over the same polyimide substrate. We show in Fig. 2 the coil and the capacitive sensor over a minimum area of a thin flexible polyimide substrate to fit the curvature of the human eye. The coil and the capacitor interconnected through a pair of wires on the same substrate. In there, the tip of the neck has the capacitive sensor that goes into the interior chamber through a 1 mm scoring assuring a minimum invasive surgical procedure, Fig. 2-c.

The ultimate goal of this study is to design and fabricate an IOP sensor system capable of measuring pressure directly into the aqueous humour to avoid possible measurement errors caused by the hardness of the sclera, which usually varies from patient to patient. The IOP sensor must be into the eyeball so it can be in direct contact with the aqueous humour. However, the implant coil must remain over the sclera and away from the interior chamber, allowing it both; to have a better magnetic coupling with the reader coil [11] and assuring less invasive surgical procedures.

The coil and IOP sensor fit inside a small bag between the sclera and the conjunctiva. Then the artefact will remain fixed to prevent coming out of the eyeball as well as isolation from outside world preventing bacteria's contact. The thin neck of the polyimide is the supporting unit of the sensor inside the ocular globe. The polyimide substrate is biocompatible; then it works as a mechanical support for the capacitor plates avoiding sensor come out of its position once inserted into the interior chamber of an eye. Once the MEMS sensor attached to the