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Research article

Investigation of a novel implantable suprachoroidal pressure transducer for telemetric intraocular pressure monitoring☆

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ABSTRACT

Intraocular Pressure (IOP) is an important and modifiable risk factor for glaucoma progression. IOP fluctuations and spikes often remain undetected despite clinical routine examinations. Therefore telemetric IOP measurement systems with continuous IOP monitoring can provide major advantages in glaucoma surveillance. To the best of our knowledge, this is the first study to investigate implantable telemetric suprachoroidal IOP sensors. Six novel telemetric pressure transducers were implanted in the suprachoroidal space of 6 eyes from 6 New Zealand White rabbits. Functionality of each microsensor was verified 1, 4, 8, 12 and 30 weeks after implantation. After cannulation of the anterior chamber different intracameral pressure levels were generated using a height adjustable water column. Telemetric assessed IOP and intracameral pressure were analysed using scatter plots and Bland-Altman analysis (95% CI). Mean bias (limits of agreement) 1, 4, 8, 12 and 30 weeks after implantation was 0.14 mmHg (−2.04 to 2.31 mmHg), 0.01 mmHg (−2.83 to 2.86 mmHg), 0.62 mmHg (−2.08 to 3.32 mmHg), 0.47 mmHg (−3.04 to 3.98 mmHg) and 0.33 mmHg (−2.75 to 3.42 mmHg) respectively. Ophthalmological examinations showed no signs of conjunctival, scleral, choroidal or retinal lesions. Histological analyses revealed a small band of fibrosis next to the implantation site but showed no signs of inflammation, necrosis or other pathologies. Implantable telemetric suprachoroidal pressure sensors provided promising concordance between telemetric and intracameral IOP values. Clinical and histological examinations revealed good biocompatibility 30 weeks after implantation. A major advantage of the suprachoroidal approach is that the anterior chamber stays unaffected during implantation. Therefore the procedure can be performed regardless of the lens status and any anterior chamber pathologies.

1. Introduction

IOP is one of the most important risk factors for progression of glaucomatous optic neuropathy (Bengtsson et al., 2007; De Moraes et al., 2011). Reduction in IOP can slow progression of glaucoma and therefore progression of visual field defects associated with glaucoma (VanVeldhuisen et al., 2000). Despite planned single IOP measurements within the desired range during clinical routine examinations many patients experience worsening in their glaucoma conditions. Furthermore, fluctuations in IOP are potentially associated with progression in glaucoma (Asrani et al., 2000; Nouri-Mahdavi et al., 2004). These fluctuations and variations can be subdivided into IOP changes within minutes (Boland and Quigley, 2007), hours and days (Asrani et al., 2000; Song et al., 2014) or even weeks and months (Musch et al., 2011). For that reason, continuous IOP monitoring may be a desirable tool in glaucoma surveillance. Goldmann applanation tonometry (GAT) as the diagnostic gold standard cannot meet these requirements, therefore new technologies have been investigated in the recent past: Contact lens sensors were developed for a 24-h application (Mansouri et al., 2012) and implantable IOP sensors were developed for implantation in the ciliary sulcus for long-term IOP measurements (Koutsonas et al., 2015). The sulcus based IOP sensors and the suprachoroidal pressure sensors are based on a similar measuring principle. The approach showed promising results

Abbreviations: CI, Confidence interval; GAT, Goldmann applanation tonometry; IOP, Intraocular pressure; SD, Standard deviation.

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(Koutsonas et al., 2015; Mansouri et al., 2012).

The indication for cataract surgery is a prerequisite for implanting the sulcus placed microsensor (Koutsonas et al., 2015), because the ring-shaped pressure device is placed in the ciliary sulcus at the end of cataract surgery after removal of the natural lens and implantation of an artificial intraocular lens. Ciliary sulcus implantation can reveal several disadvantages resulting from the direct contact between the implant and the overlaying iris. Iris chafing, iris atrophy, pupillary distortion and pigment dispersion (Chang et al., 2009; Ferguson and Malik, 2003; Koutsonas et al., 2015; Paschalis et al., 2014) were reported. As a result obstruction of the iridocorneal angle and therefore IOP exacerbation can occur (Chang and Lim, 2004; LeBoyer et al., 2005). Regarding these problems, a novel suprachoroidal approach was developed and investigated to address complications resulting from the implantation procedure and complications in relation to the implant's position in the eye. Furthermore, suprachoroidal implantation of the IOP sensing microchip enables continuous IOP monitoring even in patients without the necessity of cataract surgery.

In consequence, an implantable pressure transducer was developed based on a microchip with an integrated pressure sensor, an analog-to-digital converter, a coil antenna and an identification encoder for telemetric pressure sensing (Implandata Ophthalmic Products GmbH, Germany). The sensor was embedded in a biocompatible silicone rubber encasement to increase durability. Power supply for the implant was provided via induction. Therefore no battery was required inside or in contact with the implant.

It was the aim of this study to evaluate the potential and the limitations of this novel suprachoroidal pressure microsensor for telemetric IOP measurement.

2. Material and methods

We investigated a novel telemetric pressure transducer for minimally invasive suprachoroidal implantation. Six pressure sensors were implanted in 6 eyes of 6 New Zealand White rabbits (Charles River GmbH, Germany) under general anaesthesia. One of them was a male and the other 5 were females. All rabbits were at least 11 months old (mean age 13.33 ± 3.67 months and maximum age 19 months) to ensure a full-grown eyeball. Mean body weight was 6.03 ± 0.37 kg, with a minimum of 5.58 kg and a maximum of 6.50 kg prior to implantation.

The microsensor itself was surrounded by a wire loop in the shape of a coil and embedded in a biocompatible silicone rubber encasement. The outside of the silicone rubber encasement surrounding the electronic components (Implandata Ophthalmic Products GmbH, Germany) measured 7.8 mm long by 3.8 mm wide and the thickness was 1 mm (Fig. 1).

The IOP was telemetrically sensed with an array of surface micro-machined plate capacitors. Therefore the capacitance changed proportional to the applied pressure depending on the distance between the capacitive plates.

Telemetric IOP measurements were performed using an external hand-held wireless reading device (Fig. 2). The external reading device was placed in front of the eye and the measuring process was started by pressing the round button located in the middle of the device. The ring shaped upper part contained the coil for wireless communication and power transmission. The reading device achieved sufficient data transfer and power supply within the range of 4 cm from the sender coil inside the hand-held device to the receiver coil inside the implant. Information between the reading device and the implant was exchanged wirelessly using a 13.56 MHz radio frequency band.

The external reading device detected the ambient pressure and received uncorrected pressure values from the implant during every single telemetric measurement and translated the uncorrected pressure data from the implant into IOP values in accordance with an internal algorithm including the ambient pressure. For each displayed IOP value 10 single measurements were sampled within 1 s and subsequently averaged.

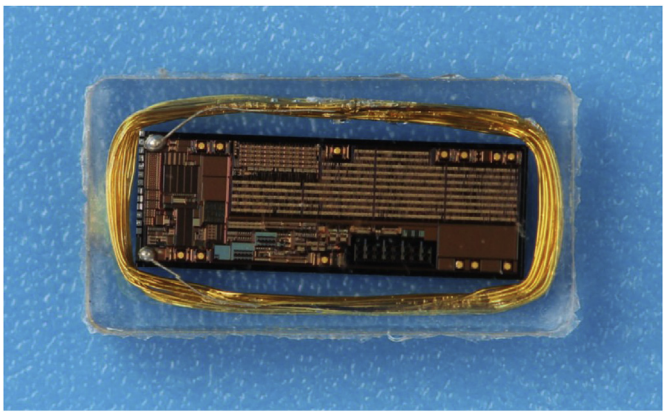

Fig. 1. Implantable suprachoroidal pressure transducer. The ASIC (application-specific integrated circuit) is surrounded by a coil and embedded in a silicon rubber encasement.

Fig. 2. Portable reading device for telemetric pressure transmission via a radio-frequency band.

In preparation for implantation the conjunctiva was excised over 3 clock hours at the temporal limbus under direct visual control with a standardized surgical microscope (OpmiCS, Carl Zeiss GmbH, Germany). A limbus-parallel scleral incision (5–6 mm) was created above the pars plana prior preparation of the suprachoroidal pocket. Ophthalmic viscosurgical devices (Healon OVD, Abbott Medical Optics Inc., USA and Z-Celcoat, Carl Zeiss Meditec AG, Germany) were used to separate the sclera from the choroid and served as safeguards protecting the implantation site from injuries during the implantation procedure. A silicone rubber-coated forceps (prototype from Implandata Ophthalmic Products GmbH, Germany) was used to protect the microsensors from mechanical irritations caused by common used unprotected surgical instruments. All implants were imbedded in the suprachoroidal pocket by sealing the scleral incision with one suture (Vicryl 8.0, Ethicon, Germany). At the end of the implantation the conjunctiva was repositioned and fixated with 1–2 absorbable sutures (Vicryl 8-0, Ethicon Inc., Johnson & Johnson, USA).