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

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A B S T R A C T

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.

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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.

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).
Concordance between the telemetric IOP measurements and the intracameral manometry was assessed 1, 4, 8, 12 and 30 weeks after implantation. Five telemetric IOP measurements were taken at each intracameral IOP level from 10 mmHg to 45 mmHg. Therefore the anterior chamber was cannulated with a blunt hollow needle (Lewicky Anterior Chamber Maintainer, Rumex International Co., USA) after performing a 20-gauge clear-cornea incision (MVR knife 20 gauge, Mani Inc., Japan). The cannula was connected to a portable manometer (Delta-Cal, Utah medical products Inc., US) and to a height adjustable water column (Balanced Salt Solution (BSS), Bausch & Lomb GmbH, Germany). The manometer was then equalised to the intracameral incision by manual height adjustment of the manometer’s lifting platform (Digimatic Height Gage, Mitutoyo Corp., Japan). Different IOP levels in ascending and descending order (10 mmHg, 15 mmHg, 20 mmHg, 25 mmHg, 35 mmHg, 45 mmHg, 40 mmHg, 30 mmHg, 20 mmHg and 10 mmHg) were generated using a height adjustable water column (BSS infusion bag). The intracameral manometry values were noted simultaneously to every telemetric IOP measurement. An adjustment time of at least 2 min was used prior to every telemetric IOP measurement after changing the intracameral pressure level to avoid any measurement error.

The investigation of our microsensor focused on the measurement functionality and the reproducibility of data, so the comparability of the IOP values across all sensors was necessary. Therefore each sensor was calibrated to its own individual intracameral 20 mmHg level by correcting the data for the measurement difference between the mean telemetrically assessed IOP during intracameral simulation of 20 mmHg and the real intracameral IOP of 20 mmHg. This correction was performed for each pressure transducer at the beginning of each series of measurements.

Prior and after the implantation as well as at the beginning of each comparative intracameral measurement (1, 4, 8, 12 and 30 weeks after implantation) clinical examinations of the implantation site with additional assessment of the eyelids, conjunctiva, cornea, anterior chamber and lens were performed with a portable slit lamp hand-held unit (Keeler PSL, Keeler Ltd., UK). The posterior segment was assessed by indirect binocular ophthalmoscopy (Heine Omega 500 binocular ophthalmoscope, Heine Optotechnik, Germany) in addition with a 20 Diopter Lens (20D Lens, Volk Optical Inc., USA). At the end of the 30 weeks follow-up the rabbits were sacrificed and the eyes were fixated in phosphate buffered formaldehyde solution (Rothi-Histofix 4%, Carl Roth GmbH + Co KG, Germany). The implantation sites were then sectioned and stained with hematoxylin and eosin for histological assessment.

This study was carried out in strict accordance with the EU Directive 2010/63/EU for animal experiments and complied with the ARRIVE guidelines. The protocol was approved by the governmental authority and the Committee on the Ethics of Animal Experiments of the University of Tuebingen. Surgery and invasive IOP measurements were conducted under intramuscular ketamine hydrochloride (Ketamin 10%, Wirtschaftsgenossenschaft deutscher Tierarzte eG, Germany) and xylazine hydrochloride (Xylazin 2%, Albrecht GmbH, Germany) anaesthesia. A combined ketamine and xylazine anaesthesia was used in a concentration of 45 mg/kg body weight and 3.75 mg/kg body weight, respectively for both, induction and at the beginning of each follow-up measurement. Topical treatment was administered three times a day for two weeks. Carprofen (Paracarp, IDT Biologica GmbH, Germany) 5 mg/kg body weight was administered subcutaneously for postoperative analgesia after each invasive procedure.

Further deepening of anaesthesia was enforced after the last intracameral IOP measurements 30 weeks after implantation (total concentration of ketamine and xylazine 62.5 mg/kg and 5 mg/kg, respectively). Once a stable and very deep anaesthesia had been achieved the euthanasia solution (T61 Injection Solution, Intervet GmbH, Austria) containing tetracaine hydrochloride (5 mg/ml), mebezonium iodide (50 mg/ml) and embutramide (200 mg/ml) was administrated intravenously (0.3 mg/kg body weight). All efforts were made to minimize suffering.

Statistical analyses were performed using SPSS 22.0 (IBM Inc., USA) and figures were generated using Microsoft Excel 2010 (Microsoft Corp., USA). Accordance between telemetric and intracameral IOP measurements was assessed using scatter plots and Bland-Altman analysis. Mean bias between telemetrically assessed IOP values and intracameral pressure values was calculated as mean difference between intracameral and telemetric IOP values with corresponding limits of agreement (95% CI).

### 3. Results

Bland-Altman plots were used for analysing agreement between intracameral simulated pressure levels and corresponding telemetric pressure values (Figs. 3 and 4). Overall mean bias between telemetric IOP and intracameral IOP was higher 12 and 30 weeks after implantation compared to measurements 1 week, 4 weeks and 8 weeks after implantation. Furthermore, higher intracameral pressure tended to result in a positive shift of overall mean bias. Table 1 and Fig. 3 represent the total mean bias, standard deviations (SD) and limits of agreement 1 week, 4 weeks, 8 weeks, 12 weeks and 30 weeks after implantation.

Fig. 4 illustrates the concordance between overall telemetric IOP values and intracameral IOP levels using a scatter plot and a Bland-Altman plot. Overall mean measurement difference for all pressure sensors and for all follow-up measurements was +0.31 mmHg (lower limit of agreement –2.55 mmHg; upper limit of agreement 3.18 mmHg).

Telemetric IOP values were analysed for each IOP level between 10 mmHg and 45 mmHg. Mean bias between the telemetrically assessed IOP and the intracameral IOP levels increased continuously from −0.73 and −0.69 mmHg for the intracameral 10 mmHg and 15 mmHg level, respectively to 1.89 mmHg for the intracameral simulated 45 mmHg level. Hence, the mean overall bias showed increasing values with increasing intracameral pressure (Table 2).

Telemetric data was corrected for the mean difference between telemetric and intracameral pressure at the 20 mmHg level to enable a reliable comparison of measurement variations between the different follow-up measurements and the different pressure sensors. Corresponding correction factors are displayed in Table 3. One suprachoroidal IOP sensor required higher adjustment values (up to −69.77 mmHg) than the other sensors (Table 3). Another suprachoroidal IOP sensor measured suitable IOP values 1 week after implantation but showed deficient IOP values during the following measurements and was therefore excluded from the pressure comparison after the first week.

Ophthalmological examinations of the entire eyeballs and the implantation sites in particular were performed prior and after the implantation and at the beginning of each follow-up measurement. In some cases the implants tended to move towards the scleral incision (Fig. 5). During animal care no defensive attitude or foreign body sensation was noted. None of the investigated eyes showed retinal detachment, perforation of the sclera or the choroid, clinical signs of inflammation (except post interventional irritation as expected) or chronic irritation (Fig. 5). One rabbit suffered from obesity and died of cardiac insufficiency 18 weeks after implantation.
Histological examinations did not show any signs of irritation or inflammation of the suprachoroidal implantation site. Nevertheless a small band of fibrosis could be seen in the suprachoroidal space around the microsensors. Fig. 6 shows a cross-section of an eyeball 30 weeks after implantation.

4. Discussion

This is the first study to investigate a novel suprachoroidal pressure sensor and the concordance between telemetrically assessed IOP and intracameral manometry under in-vivo conditions. The suprachoroidal pressure sensors were easy to implant and remained in the suprachoroidal space during the entire follow-up. Telemetrically assessed data reflected the effective IOP with good reproducibility, accuracy and concordance in comparison to the directly measured intracameral pressure.

Suprachoroidal IOP sensors are able to detect circadian fluctuations and also long-term IOP variability within days, weeks or
even months in any kind of position (body orientation) and 24 h a day. Even IOP self-measurements can be performed in an easy and pain-free manner. These findings are supported by other studies using a similar technical principle (Koutsonas et al., 2015; Todani et al., 2011).

Telemetric suprachoroidal IOP measurements showed a slight combined scale and location shift. Overall mean differences between telemetric IOP measurements and intracameral manometry

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### Table 1

Mean difference (mean bias) between telemetric suprachoroidal pressure and intracameral pressure 1, 4, 8, 12 and 30 weeks after implantation with standard deviation (SD) and limits of agreement (loA). Mean bias was adjusted for each implant and for each follow-up measurement to the intracameral 20 mmHg level.

<table>
<thead>
<tr>
<th>Time after implantation</th>
<th>Mean bias [mmHg]</th>
<th>SD [mmHg]</th>
<th>Upper loA [mmHg]</th>
<th>Lower loA [mmHg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Week</td>
<td>0.14</td>
<td>1.11</td>
<td>2.31</td>
<td>−2.04</td>
</tr>
<tr>
<td>4 Weeks</td>
<td>0.01</td>
<td>1.45</td>
<td>2.86</td>
<td>−2.83</td>
</tr>
<tr>
<td>8 Weeks</td>
<td>0.62</td>
<td>1.38</td>
<td>3.32</td>
<td>−2.08</td>
</tr>
<tr>
<td>12 Weeks</td>
<td>0.47</td>
<td>1.79</td>
<td>3.98</td>
<td>−3.04</td>
</tr>
<tr>
<td>30 Weeks</td>
<td>0.33</td>
<td>1.57</td>
<td>3.42</td>
<td>−2.75</td>
</tr>
<tr>
<td>Total</td>
<td>0.31</td>
<td>1.46</td>
<td>3.18</td>
<td>−2.55</td>
</tr>
</tbody>
</table>

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### Table 2

Comparison of intracameral IOP levels and mean differences (mean bias) between telemetric IOP and intracameral IOP, analysed for each intracameral IOP level with standard deviation (SD) and limits of agreement (loA).

<table>
<thead>
<tr>
<th>Intracameral pressure</th>
<th>Mean bias [mmHg]</th>
<th>SD [mmHg]</th>
<th>Upper loA [mmHg]</th>
<th>Lower loA [mmHg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mmHg</td>
<td>−0.73</td>
<td>1.24</td>
<td>1.71</td>
<td>−3.17</td>
</tr>
<tr>
<td>15 mmHg</td>
<td>−0.69</td>
<td>1.27</td>
<td>1.80</td>
<td>−3.18</td>
</tr>
<tr>
<td>20 mmHg</td>
<td>0.00</td>
<td>0.72</td>
<td>1.42</td>
<td>−1.42</td>
</tr>
<tr>
<td>25 mmHg</td>
<td>0.27</td>
<td>1.03</td>
<td>2.29</td>
<td>−1.76</td>
</tr>
<tr>
<td>30 mmHg</td>
<td>0.91</td>
<td>1.35</td>
<td>3.57</td>
<td>−1.74</td>
</tr>
<tr>
<td>35 mmHg</td>
<td>0.83</td>
<td>1.28</td>
<td>3.33</td>
<td>−1.68</td>
</tr>
<tr>
<td>40 mmHg</td>
<td>1.23</td>
<td>1.65</td>
<td>4.45</td>
<td>−2.00</td>
</tr>
<tr>
<td>45 mmHg</td>
<td>1.89</td>
<td>1.72</td>
<td>5.27</td>
<td>−1.48</td>
</tr>
</tbody>
</table>

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### Table 3

Correction factor for each suprachoroidal implant (Implant Nr. 1 to 6) and each follow-up measurement (1, 4, 8, 12 and 30 weeks). Values represent mean IOP differences between telemetric and intracameral pressure for the intracameral 20 mmHg level.

<table>
<thead>
<tr>
<th>Time after implantation</th>
<th>Sensor 1 [mmHg]</th>
<th>Sensor 2 [mmHg]</th>
<th>Sensor 3 [mmHg]</th>
<th>Sensor 4 [mmHg]</th>
<th>Sensor 5 [mmHg]</th>
<th>Sensor 6 [mmHg]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Week</td>
<td>0.21</td>
<td>2.82</td>
<td>4.06</td>
<td>0.13</td>
<td>−1.55</td>
<td>−5.72</td>
</tr>
<tr>
<td>4 Weeks</td>
<td>−0.71</td>
<td>4.41</td>
<td>−2.26</td>
<td>−1.95</td>
<td>−25.76</td>
<td>−</td>
</tr>
<tr>
<td>8 Weeks</td>
<td>0.16</td>
<td>8.59</td>
<td>−6.88</td>
<td>3.04</td>
<td>−65.14</td>
<td>−</td>
</tr>
<tr>
<td>12 Weeks</td>
<td>1.74</td>
<td>6.26</td>
<td>3.04</td>
<td>1.68</td>
<td>−69.77</td>
<td>−</td>
</tr>
<tr>
<td>30 Weeks</td>
<td>1.36</td>
<td>2.33</td>
<td>—</td>
<td>6.58</td>
<td>−25.06</td>
<td>−</td>
</tr>
</tbody>
</table>
increased with ascending intracameral IOP levels (Figs. 3 and 4). One possible explanation for these shifts and also for the systemic implant offsets observed in some cases could be an interaction between the implant’s rectangular cuboid form and the changes of the scleral or choroidal tension caused by ascending IOP levels. These mechanical forces could have affected especially the edges of the implants and these altered proportions could result in mechanical stress on the area of pressure sensing. Furthermore, in some cases the implants showed a slight tendency to move towards the scleral incision. This could lead to an incarceration and could also influence the telemetric IOP measurement. However, rabbit and human eyes differ in their portions. In rabbit eyes the anterior segment is proportionally larger and the posterior segment is smaller than in human eyes (Davis, 1929), so mechanical stress and dislocation of the implant due to altered conditions is more likely in rabbit eyes.

The histological analysis revealed a small band of fibrosis at the implantation site which could be a determining factor influencing the accuracy of the suprachoroidal IOP measurement. This kind of fibrosis had been described earlier for suprachoroidal implants (Agnifili et al., 2012) and was attributed to scleral and choroidal fibroblasts (Harrison et al., 1990; Loebler et al., 2013).

In this study telemetrically assessed IOP values were compared to intraocular pressure measurements following direct cannulation of the anterior chamber. Other studies compared telemetric measurements with GAT (Koutsonas et al., 2015) as an indirect measurement method of IOP. Accuracy of GAT can be reduced in patients with irregular cornea (Meyenberg et al., 2008; Rosa et al., 1998) or significantly increased or decreased central corneal thickness and therefore should be interpreted carefully regarding its reliability in those patients (Ceruti et al., 2009). Our experimental set-up was independent of the corneal physiology and for that reason more reliable than other indirect IOP measurements.

The portable manometer displayed only integral numbers without decimal places, so the intracameral IOP levels were affected by a measurement error of up to ±0.5 mmHg. For each rabbit at each follow-up measurement the height of the manometer’s pressure sensing unit was manually equalised to the cannula inside the anterior chamber. This kind of equalisation induced an additional systemic measuring error, which could bias the comparison between different pressure transducers and different follow-up measurements. To ensure that the readings from one suprachoroidal implant were consistent with those measurements from the other suprachoroidal microsensors, each microsensor was calibrated at each follow-up measurement to the 20 mmHg IOP level. One advantage of this system is the simple calibration. This
could be used to calibrate the microsensor to GAT readings taken during a routine visit in an ophthalmology office. As additional advantages, the suprachoroidal implantation is minimally invasive, it requires only a few minutes to perform and it can potentially reduce the rate of anterior segment complications observed with other intraocular telemetric sensors (Koutsonas et al., 2015; Melki et al., 2014). Furthermore, the suprachoroidal implantation can be performed regardless of the lens status (phaco-, pseudophaco-) and of possible anterior chamber findings or pathologies. Hence, younger glaucoma patients without cataract and patients with secondary glaucoma due to anterior chamber pathologies could benefit from the novel suprachoroidal pressure sensor. The suprachoroidal implantation procedure avoids most of the complications associated with opening the anterior chamber. However, the implantation is associated with surgical manipulation of the conjunctiva and the sclera next to the implantation site (approximately 2–3 clock hours). This can potentially make further glaucoma surgeries involving those structures more difficult.

One sensor (sensor 5) required higher adjustment values than the other sensors. The IOP sensing parts of the sensors are located at the bottom of the sensor, which is facing the vitreous body. Even though fibrosis was observed at the edges of all implantation sites, fibrosis could have caused direct and permanent mechanical pressure due the development of additional fibrotic material between the choroid and the sensing part of the sensor (lateral third of the implant). This thesis is supported by the appearance of the intraocular pressure sensor in patients with glaucoma (ARGOS study). 1-Year results. Investig. Ophthalmol. Vis. Sci. 56, 1081–1089.


