Intraocular pressure (IOP) remains, to date, one of the most important factors to monitor disease progression in glaucoma. It is still unclear whether short-term and long-term IOP fluctuation is associated with an increased rate of glaucoma progression. \(^1\)\(^-\)\(^5\) Currently available technology only permits isolated IOP recordings during scheduled visits to the eye care provider and often fails to detect the true peak and trough of the IOP diurnal curve as well as the long-term IOP trend. \(^6\)

A device that can enable a patient to self-monitor IOP on demand or at preset intervals can conceivably capture enough data points to enable the physician to construct a true diurnal and nocturnal curve as well as long-term IOP trend. \(^6\)

A recent study\(^7\) evaluated a novel wireless IOP transducer (WIT) (Implandata Ophthalmic Products GmbH). The device exhibited favorable biocompatibility in rabbit eyes as well as concordance with IOP measured by manometry. There were no signs of intraocular toxicity or inflammation throughout the 25-month study period. The present study describes our experience with the first implantation of the WIT within the human eye and the 18-month safety and IOP data.

### Methods

**Wireless Intraocular Transducer**

The WIT integrates pressure sensors, temperature sensor, identification encoder, analog-to-digital encoder, and telemetry unit into a single microelectromechanical system application-specific integrated circuit. \(^7\) This digital ultraminiature system uses complementary metal oxide semiconductor technology for its electronic components. The electronic components are either biocompatible or inert. The application-specific integrated circuit is attached to a circular microcoil antenna made of gold, and both of these components are hermetically encapsulated in platinum-cured silicone. This biocompatible silicone material makes up the entire surface of the implant. The implant itself is designed to remain in vivo indefinitely. The outside diameter of the transponder disc is 11.3 mm, the inside diameter is 7 mm, its thickness is 0.9 mm,
An Implantable Intraocular Pressure Transducer

A woman in her 60s with history of primary open-angle glaucoma and cataract was selected to be the recipient of the WIT concurrent with cataract extraction and intraocular lens implantation. The benefits, alternatives, and risks of the procedure were discussed with the patient. The specific benefit to this particular patient was her difficulty to return for frequent visits on a long-term basis to monitor her glaucoma because she lived in a remote area. If successful, the WIT would allow the woman to obtain measurements at home and send the reader for data download with members of her family when they travel to the hospital area. Assurance was obtained that she would adhere to the follow-up visits specified in the research protocol. The protocol was approved by the institutional review board of the Lebanese American University, Beirut, Lebanon, and a written informed consent form was signed by the patient. The surgical procedure as well as the office visits were performed at the Beirut Eye Specialist Hospital, Beirut, Lebanon. The patient received no financial compensation.

The patient had a history of primary open-angle glaucoma and cataract diagnosed 5 months prior to the procedure. Her maximal IOP measured at presentation was 39 mm Hg in the eye that underwent the operation. Her visual field did not show significant visual loss. Prior to the procedure, her best-corrected visual acuity was 20/200. Examination showed a clear cornea, an open angle by gonioscopy, and a 3+ nuclear sclerotic cataract. Her other eye showed a 1+ nuclear sclerotic cataract with a best-corrected visual acuity of 20/50. The retinal examination was within normal limits. Optic nerve exami-
nation showed a cup-disc ratio of approximately 0.6 with a temporal sloped rim in both eyes. Treatment was started with topical dorzolamide hydrochloride plus timolol maleate ophthalmic solution (Cosopt; Merck) at presentation. Her IOP was measured in the mid-teens in the study eye at the last 2 visits before surgery.

Phacoemulsification was performed through a 3.0-mm incision located at the 12-o’clock position. Iris hooks were placed during the procedure because of poor dilation. The cataract extraction was uncomplicated. A plate haptic intraocular lens (Rayner Superflex 620H; Rayner) was placed in the capsular bag. The main wound was enlarged to accommodate the placement of the WIT. The WIT antenna is folded between a pair of curved forceps (A) and placed directly in the sulcus space while it is unfolding (B). It is then manipulated into place while ensuring that the sensor side of the WIT faces the cornea (C and D).

Results

Postoperative recovery was longer than expected after cataract extraction. This was most likely the result of the additional manipulation needed with iris hooks and the WIT implantation. There was initial corneal edema as well as mild iritis that resolved within the first month. Ultrasonic pachymetry was not obtained, because the level of edema noted on clinical examination was mild. The uncorrected visual acuity during the first month was 20/70. No intraocular inflammation was noted after the surgery. Best spectacle-corrected visual acuity was 20/60 at 6 weeks postoperatively and moderate posterior capsular opacification was noted. A YAG capsulotomy was performed. There was no significant improvement in vision noted. Ocular coherence tomography of the macula (3D OCT-2000; Topcon) obtained at week 23 showed the absence of edema or other abnormalities. The lessered acuity was attributed to a small capsulotomy, necessitating enlargement with additional laser treatment. This improved the patient’s vision to 20/25 with a manifest refraction of +0.25 + 0.50 × 005. Gonioscopy at 36 weeks revealed an open drainage angle with 1 clock hour of peripheral anterior synechiae at the surgical site. Subsequent visits until the last follow-up visit at 76 weeks postoperatively did not reveal new findings.

Intraocular pressure measurements were collected during office visits. A minimum of 3 IOP measurements were obtained at all visits by GAT and by the WIT. The Table shows all measurements taken with the WIT and GAT at various postoperative office visits. The IOP indicated for each visit is the mean of measurements obtained at that particular visit. The overall mean of IOP at office visits was 18.8 mm Hg for GAT and 19.4 mm Hg for the WIT. Latanoprost (Xalatan; Pfizer) was added at week 31 to treat elevated IOP (25 mm Hg by GAT). It
Table. IOP Data Collected at Various Office Visits Comparing the WIT and GAT

<table>
<thead>
<tr>
<th>Time of Visit</th>
<th>Mean IOP, mmHg</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WIT</td>
<td>GAT</td>
</tr>
<tr>
<td>Day 1</td>
<td>30.8</td>
<td>30.0</td>
</tr>
<tr>
<td>Week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>21.1</td>
<td>21.0</td>
</tr>
<tr>
<td>2</td>
<td>24.6</td>
<td>21.0</td>
</tr>
<tr>
<td>3</td>
<td>21.1</td>
<td>20.0</td>
</tr>
<tr>
<td>6</td>
<td>16.7</td>
<td>14.0</td>
</tr>
<tr>
<td>12</td>
<td>18.8</td>
<td>16.0</td>
</tr>
<tr>
<td>31</td>
<td>31.5</td>
<td>25.0</td>
</tr>
<tr>
<td>36</td>
<td>9.6</td>
<td>12.0</td>
</tr>
<tr>
<td>52</td>
<td>8.1</td>
<td>12.5</td>
</tr>
<tr>
<td>76</td>
<td>12.2</td>
<td>16.7</td>
</tr>
<tr>
<td>No. of measures</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>19.4 (8.1)</td>
<td>18.8 (5.7)</td>
</tr>
<tr>
<td>Median</td>
<td>19.9</td>
<td>18.3</td>
</tr>
</tbody>
</table>

Abbreviations: GAT, Goldmann applanation tonometry; IOP, intraocular pressure; WIT, wireless IOP transducer.

* At least 3 measurements per device were collected at each visit.

was stopped at week 36 (IOP 12 mm Hg by GAT). The reason for this transient rise in IOP was not clear.

To test preliminary concordance of the 2 sets of measurements, we performed the Brown-Forsythe test of equality of variances. For each group, we computed the median value and then subtracted this value from each IOP measurement. We then performed a one-way analysis of variance using the absolute value of this transformed response. The Brown-Forsythe test produced a P value of .32. This is well above the .05 significance level, indicating the absence of a significant difference in group variance. This demonstrates good concordance between the measurements collected using the WIT and GAT.

Discussion

Telemetric IOP assessment through an intraocular device provides several distinct advantages when compared with the standard applanation tonometry. It allows true estimation of IOP, independent of corneal biomechanics. It even makes it possible to record IOP in eyes implanted with a keratoprosthesis. It enables self-monitoring of IOP by the patient and allows for increased frequency at which such measurements can be obtained. These abilities may provide significant insight into the role of IOP fluctuation in glaucoma progression.

An intraocular device allowing telemetric IOP measurements should have as many of the following properties as possible: be safe and biocompatible, exhibit long-term stability in accuracy and reproducibility, measure IOP as frequently as possible, be independent of ocular health and/or corneal thickness and curvature, be directly correlated with currently validated IOP measurement devices, and be user-friendly to allow self-measurements by the patient. The WIT seems to have many of the above characteristics.

The WIT is designed to be placed in the sulcus space, either concurrent with or after cataract extraction. There are several risks associated with such an implantation. Anterior iris displacement with subsequent peripheral anterior synchiae 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. Our patient was monitored for all of the listed possibilities. The drainage angle did not exhibit any narrowing and there was no evidence of pigment dispersion. There was no sign of intraocular inflammation or fibrosis 1 year after implantation of the WIT. The device seems to be biocompatible in the human eye, confirming data collected during the animal studies. Although no pigment dispersion was noted in this patient, it remains to be seen whether this would occur with other types of intraocular lenses that may be thicker than the plate device used in this case. A thinner version of the WIT is currently in production to minimize this risk. Studies in a larger number of eyes are needed to confirm these preliminary findings. Other diagnostic studies would also be beneficial, such as anterior-segment ocular coherence tomography, as well as long-term endothelial cell counts. Both modalities were not available at the site of the present study.

The concordance between the WIT and GAT over the course of this study was satisfactory and statistically significant. This was seen at low and high IOP values. Nevertheless, this is a relatively small number of measurements and the degree of concordance will have to be validated by future studies encompassing a larger number of data points. Data from animal experiments have shown an unexplained downward drift in IOP measurements. This did not occur in ex vivo experiments or in our patient. It may also be interesting to see how the GAT measurements compare with other modalities of IOP measurements, such as rebound tonometry, especially when corneal thickness is taken into consideration.

De Smedt and colleagues have studied a contact lens-like telemetric IOP sensor allowing IOP measurements over a 24-hour period. Participants had a significant, but reversible, drop in visual acuity while wearing the device and a nonsignificant trend toward decreasing comfort with increased wear time. The authors postulated that offering sensors with different radii may help to alleviate these drawbacks. Limitations of the contact lens-like technology compared with the WIT include the inability to measure the IOP over several days or months. The measurements are inferred from corneal curvature rather than actual eye tension. The accuracy of the contact lens-like device may be influenced by factors such as the fit of the contact lens onto the cornea, corneal abnormalities, and edema. Changes in the pressure of the eyelids on the cornea both during the day (due to eye movements and eyelid movements) and night (change in tonus in different stages of sleep) may also affect the measurements of the contact lens-like device.
Conclusions

The present study provides an initial favorable indication concerning the safety and biocompatibility of an implantable IOP-measuring device. The study demonstrates that the WIT is able to obtain data that seem to have initial good concordance with GAT. Further development and study of this technology may allow better understanding of the role of IOP fluctuation in glaucoma progression.

ARTICLE INFORMATION

Submitted for Publication: December 9, 2013; final revision received March 1, 2014; accepted March 4, 2014.


Author Contributions: Dr Melki had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Melki, Todani.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Melki, Todani.

Critical revision of the manuscript for important intellectual content: Todani, Cherfan.

Obtained funding: Melki.

Administrative, technical, or material support: All authors.

Study supervision: Melki, Cherfan.

Conflict of Interest Disclosures: None reported.

Funding/Support: Implantdata Ophthalmic Products GmbH provided the device at no charge.

Role of the Sponsor: Implantdata Ophthalmic Products GmbH had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: Statistical analysis was conducted by Amy Driscoll, MA, who received no financial compensation for her services.

REFERENCES


