

Continuous Intraocular Pressure Monitoring by Means of the Sensimed Triggerfish® System

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Abstract

Intraocular pressure (IOP), like other biological parameters, has a 24-hour rhythm with physiological oscillations around 5mmHg. Recently, it has been demonstrated that IOP fluctuations represent an independent parameter for progression of glaucoma. The most common clinical methods able to detect the diurnal state of IOP are the tonometric curve (with IOP measurements taken from 9:00 am to 20:00 pm) or two provocative tests, such as the water drinking test (WDT) and the ibopamine test. Recently introduced in clinical practice, the Sensimed Triggerfish® is a system enabling continuous IOP monitoring based on a disposable contact lens with a sensor linked to a telemetric microprocessor. The purpose of this project was to investigate the clinical applicability of the system as an additional tool, providing useful information for the management of glaucoma patients. Of eight evaluated patients, two cases are presented in detail in this report. The monitoring system that provides 24-hour continuous data appears to be very promising, as it captures clinically useful, real-life IOP fluctuations day and night while patients maintain normal activities, including undisturbed sleep.

Keywords

Glaucoma, continuous intraocular pressure (IOP) monitoring, water drinking test, IOP fluctuation, 24-hour IOP

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Glaucoma is a progressive, chronic and irreversible neuropathy with typical structural changes at the optic nerve head and with functional defects in the visual field, leading to blindness at the end stage. It is estimated that over 60 million people worldwide are now affected by this disease and this number will dramatically increase to about 80 million by 2020. Glaucoma is the second leading cause of blindness in the world: it is estimated that 10% of people affected by glaucoma progress to blindness.¹

Glaucoma is a multifactorial disease, but the only proven way to reduce its progression is by lowering intraocular pressure (IOP), by means of pharmacological, laser or surgical therapy.

Intraocular Pressure Management

IOP is a biological parameter that has a 24-hour biorhythm: in the majority of people it shows little variation – without clinically significant differences during the 24-hour period – while in some cases, IOP may be higher during the morning, or in the afternoon, or during the night.² IOP oscillations of up to 5mmHg are observed in healthy subjects, while they may reach up to 11mmHg in glaucoma patients. IOP fluctuations have been recognised as a significant risk factor for the development and progression of glaucoma.³ Therefore, a single IOP measurement taken during office hours, may not provide information regarding the effective IOP behaviour during the entire 24-hour period. In clinical practice, glaucoma patients frequently

present with progressive visual field loss despite IOP values in the range of normality at follow-up visits. In these cases, a tonometric daily curve (IOP measurements taken every four hours from 9:00 am to 20:00 pm) may point out IOP peaks during the day. In other cases, a water drinking test (WDT) or an ibopamine test can be performed with the same purpose. Glaucoma patients with controlled IOP after surgery still show significant increase of IOP when subjected to the WDT.⁴ Both the ibopamine test and WDT were shown to correlate with daytime peak IOP.^{5,6} A relationship between WDT and 24-hour peak IOP has been suggested.⁷ Finally a 24-hour tonometric curve with IOP measurements taken also during the night may be established. Twenty-four-hour IOP curves are more frequently performed in a clinical trial setting than as standard clinical practice, as it requires patient hospitalisation.^{8,9}

Sensimed Triggerfish® 24-hour Continuous Intraocular Pressure Monitoring

Recently developed by Matteo Leonardi, the Sensimed Triggerfish® (Sensimed AG; hereafter the monitoring system) provides an interesting and long sought after possibility to continuously monitor IOP fluctuations for up to 24 hours.¹⁰ A strain gauge embedded in a soft silicone contact lens detects circumferential fluctuations in the area of the corneoscleral junction, correlating directly with fluctuations in IOP, which are transmitted to a portable recorder using wireless connection. The device relies on the finest precision

Figure 1: Placement of the Sensimed Triggerfish® and Antenna



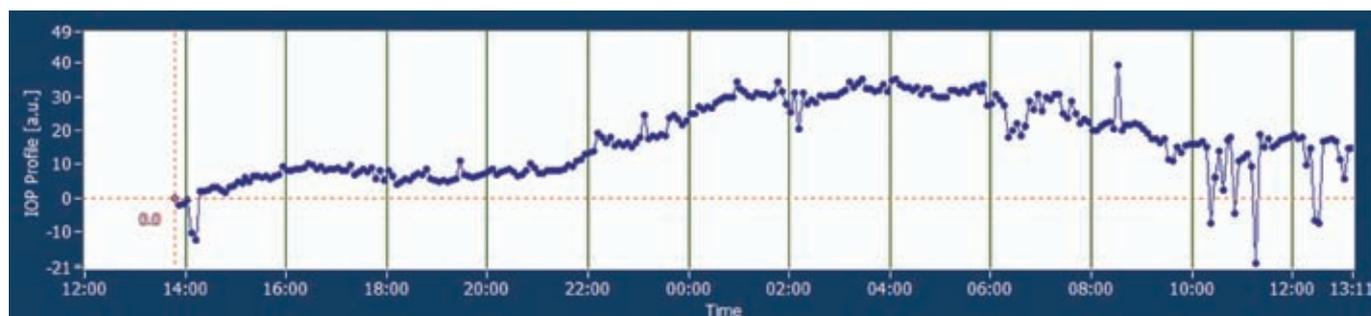
A: Well-positioned contact lens; B: Lateral view; C: Frontal view.

Figure 2: 24-hour Intraocular Pressure Profile Case One



IOP = intraocular pressure.

Figure 3: 24-hour Intraocular Pressure Profile Case Two



IOP = intraocular pressure.

manufacturing and cutting-edge technology. The lens is made of silicone, which is highly permeable to oxygen (125 x 10⁻⁹Dk/t units). Since silicone is hydrophobic, the lens surface is treated with oxygen plasma, making it hydrophilic for patient safety.

Contact lenses are available in three base curves to better adhere to the corneo-scleral junction in eyes of varying biometry. For this reason, a keratometry is needed before its application.

Before lens application, a reference Goldmann applanation tonometry (GAT) reading is carried out. The system starts registration of IOP fluctuation every five minutes for 24 hours. During this period, the patient reports on a chart any daily events that may lead to abnormal IOP fluctuation, such as eye drop instillation times, or sneezing, coughing, eye rubbing and nightly waking, but otherwise carries on with normal activities, including undisturbed sleep. After 24 hours, the recording stops automatically and the contact lens is removed. IOP

is measured again by GAT, so that the relationship between IOP fluctuation recorded by the monitoring system and the initial and final tonometric measurements can be assessed. The graphic we obtain shows the IOP fluctuation – with a normalised starting point set to zero – during the registration period and reports the fluctuation in arbitrary units on the vertical axis. These units are different from millimetres of mercury (mmHg).

Comparison of Daily Intraocular Pressure Curve, Water Drinking Test and Sensimed Triggerfish

An open-label, prospective clinical study was performed at the Glaucoma Research Center, Department of Ophthalmology and Otolaryngology, on a group of glaucomatous patients who presented progressive visual field loss despite follow-up visit IOP values in the normal range. The purpose of the study was to investigate the clinical applicability of the monitoring system. Eight patients (five male and three female), aged between 52 to 67 years and under topical

IOP-lowering therapy for a minimum of one year were recruited. All patients initially underwent a daily tonometric curve (that did not show any clinically significant variation) and a WDT (that demonstrated abnormal IOP peaks). WDT was carried out after a GAT baseline measurement by ingestion of one litre of water in 10 minutes, followed by GAT every 15 minutes for 1.5 hours. The monitoring system recorded elevated values during night-time (from 23:00 pm to 7:00 am) in all patients. Moreover, IOP fluctuation, as continuously registered by the system during daytime, overlapped the GAT IOP curve. The diurnal IOP curve, WDT and 24-hour IOP fluctuation monitoring were performed on separate occasions. Here we present two cases:

Case One

Male, 52 years of age, diagnosed with primary open-angle glaucoma since five years of age, treated with a fixed combination of timolol and dorzolamide twice daily, presenting IOP values ranging from 17 to 21mmHg during office-hour follow-up, but a visual field loss of 1.9dB per year over the last two years. The tonometric daily curve was (OD/OS): 16/17 (9:00 am), 17/17 (12:00 pm), 16/18 (16:00 pm) and 18/19 (20:00 pm). WDT showed an IOP peak of 8mmHg 30 minutes after water ingestion. The monitoring system was applied on the right eye and showed one maximum around 2:00 am and another around 6:00 am (see *Figure 2*). Reference GAT IOP before and after IOP fluctuation monitoring were 12 and 14mmHg, respectively.

Case Two

Male, 59 years of age, diagnosed with primary open-angle glaucoma since eight years of age, treated with a prostaglandin analogue, presenting IOP values around 16mmHg at follow-up visits, but a visual field loss of 1.5dB per year over the last year. The tonometric daily curve was (OD/OS): 14/17 (9:00 am), 17/18 (20:00 pm), 15/18 (16:00 pm) and 17/18 (20:00 pm). WDT showed an IOP peak of 7mmHg 30 minutes after water ingestion. The monitoring system was applied on the right eye and showed increased IOP at night (from 23:00 pm to 7:00 am

(see *Figure 3*). Reference GAT IOP before and after IOP fluctuation monitoring were 21 and 24mmHg, respectively.

Conclusion

This study demonstrated that the monitoring system is able to show the IOP fluctuation at times when it is not possible to acquire data with classical methods for practical reasons, especially during the nocturnal and sleep periods. The stable daily profiles emerging from monitoring system data correspond to the absence of clinically significant IOP fluctuation measured with GAT during daytime. Mansouri and Shaarawy have previously shown the clinical relevance of 24-hour continuous IOP monitoring, which lead to an immediate treatment change in two-thirds of their patients.¹¹

Correlation between peak IOP measured after WDT and 24-hour peak IOP has been reported.⁶ In our patients, abnormal IOP peaks were detected after provocative testing using water ingestion during daytime. Since the daytime IOP curves showed no significant fluctuation, the elevated IOP predicted by the WDT results could be expected to occur outside office hours. The night-time monitoring system data concur with this hypothesis and with the findings of a relationship between WDT IOP peak and elevated IOP during the 24-hour period cited above. Both IOP peaks in association with WDT and intrinsic IOP fluctuation have been linked to visual field progression, including in glaucoma patients with apparently controlled IOP.^{3,4,12-14}

In summary, these findings allow us to confirm the validity and usefulness of the monitoring system in ophthalmological practice. Compared to IOP curves established through repeated tonometric assessments, the monitoring system offers several advantages that warrants the exploration of new opportunities in the area of IOP fluctuation monitoring as part of the management of patients with glaucoma. ■

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