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Research Article

Description of Curve Patterns with Sensimed Triggerfish® Contact Lens through 24-Hours Intraocular Pressure Monitoring. Pilot Study

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Abstract

Purpose: To describe the curve patterns of IOP monitoring with SENSIMED Triggerfish® device in patients with Primary open-angle glaucoma (POAG).

Materials And Methods: A prospective, longitudinal, observational study was designed. This study recruited patients with POAG diagnosis, who met the inclusion criteria and who signed an informed consent form. Registration of a conventional monitoring was carried out by recording the IOP measured by a Goldman tonometer during the day and with Perkins and Shiötz tonometers during the night. The IOP registration using the continuous monitoring Triggerfish® devise was performed 3 days after the conventional monitoring. Each of the patients was taught the procedure, as well as the appropriate use and care of the continuous monitoring Triggerfish® device.

Results: Seven patients were included with a mean age of 57.28 ± 14.5 years. Analysis of the curve pattern generated with Triggerfish® software and comparing them with the curves generated by conventional IOP monitoring resulted in three different patterns identified: As increasing wave, Epsilon and Carousel.

Conclusions: Three types of curve patterns were identified in the continuous monitoring Triggerfish® recording, each with specific characteristics that clearly demonstrate different behaviors of IOP in a group.

Keywords: *Curve Patterns; Intraocular Pressure Monitoring; SENSIMED Triggerfish® Patterns*

Introduction

Glaucoma is a disease recognized as a global public health problem that affects about the 4% of the population over 40 years old; its prevalence increases exponentially as life expectancy increases. It is a progressive, chronic and irreversible asymptomatic disease that leads to blindness if not treated promptly.

Intraocular pressure (IOP) is one of the most studied risk factors in the pathogenesis of glaucoma and IOP fluctuations during the day is considered an independent risk factor for the disease's progression [1]. For some time identifying the changes and fluctuations in IOP during the day has been taken as an indication for treatment adjustments in 79.3% of patients with POAG [2].

Recognizing the need for continuous IOP monitoring in patients with glaucoma, several unsuccessful attempts have been made to develop a convenient and portable solution. Maurice [3] made the first attempt in 1957 by designing a tonometer with a tape recorder; this device was large and heavy and was adjusted to the patient's head to record the IOP measurements generated by indentation of the cornea. Collins [4] in 1966, proposed a wireless pressure sensor via magnetic fields, but the device had to be implanted in the eye, limiting its use. In 1967, Gillman and Greene [5] proposed the first non-invasive contact lens method; however the lens had to be specially made to fit each patient, making it a very expensive method so the project was abandoned. Several researchers have attempted noninvasive methods using the applanation principle, like Couvillon [6] in 1976 that with a hydrogel ring flattened a 5 mm portion of the sclera or with suction induced applanation cup by Nissen [7] in 1977. Later, Svedbergh [8] in 1992 returned to the idea of implanting an IOP transducer inside the eye that worked wirelessly by passive telemetry in an intraocular lens' haptics, this approach remains limited to the patient's need to undergo cataract surgery.

The Sensimed Triggerfish® group offers a minimally invasive method for IOP monitoring. The key element of this method is the use of a soft silicone contact lens with a pressure micro sensor which allows the measurement of curvature and diameter changes in the cornea caused by fluctuations in IOP. The first prototype of Sensimed Triggerfish® group required cables leaving the contact lens to load the sensor and record the signal [9] (Figure 1). Subsequently a contact lens with wireless sensor was developed.

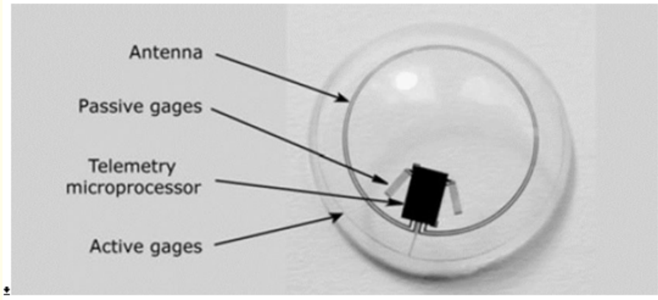

Figure 1: *Contact lens sensor for continuous intraocular pressure monitoring.*

Several studies have shown that a 1 mmHg IOP change causes a 3 µm change in the radius of curvature of the central cornea, approximately [10,11]. The correlation between the recorded signal by the ocular telemetric sensor (OTS), which generates a signal of 50 microvolts per mmHg change, and the artificially induced IOP in pork eyes pork was demonstrated [12], finding that the sensor is capable of monitoring the IOP of each eye individually with a reproducibility of + / - 0.2 mmHg with a confidence interval of 95%.

How does Triggerfish® work? (Figure 1)

1. It is loaded by radiofrequency with 27 MHz waves from the external antenna integrated into the periocular patch.
2. The sensors record changes in the cornea caused by the IOP. They have an 11.5 mm diameter (average measure of the corneoscleral junction), where the maximum corneal deformation is expected.
3. The microprocessor sends the output signal in microvolts at a frequency of 10 Hz which is transmitted to the recorder to be registered.
4. Measurements lasting 60 seconds are performed every 300 seconds (5 minutes), recording a total of 288 measurements in a 24 hours period.
5. The data is analyzed by software.

The progress and development of new technologies for the diagnosis of Primary Open Angle Glaucoma (POAG) is of paramount importance because it is a chronic, progressive disease of great social impact. These technologies will always require verification to analyze their actual implementation in our country.

Material and Methods

A prospective, longitudinal, observational and comparative study was designed. Patients with POAG diagnosis, who met the following inclusion criteria, were consecutively recruited: patients of either gender, over 18 years old, that were under maximum treatment (defined as the regular application of all 3 or 4 glaucoma drops used in the treatment of glaucoma), with positive Conventional IOP Monitoring (CM+: defined when it met one or more of the following criteria: greater than 4 mmHg fluctuation, IOP of 22 mmHg or greater at any time of CM, 30% increase from baseline IOP, or less than 50 mmHg of ocular perfusion pressure), and who signed an informed consent form.

Patients with previous ocular surgery, eye injuries, ocular inflammatory diseases, active infections, bacterial and/or viral infections or eyelid pathologies such as chronic blepharitis, entropion, ectropion or symblepharon were excluded. Patients with corneal vascularization, scarring or injury, corneal hypoesthesia, insufficient tear film (measured by tear breakup time), known allergy to silicone or intolerance to contact lenses (a contact lens trial to test tolerability was performed previous to patient selection) and those who were unable to follow instructions due to any cause (mental or physical) were also excluded.

Registration of a conventional monitoring was carried out by recording the IOP measured by a Goldman tonometer during the day (form 8:00 am until 5:00 pm) and with Perkins and Shiötz tonometers during the night (from 8:00 pm onwards). For each IOP registry a topical anesthetic drop (tetracaine 5.0 mg) and fluorescein was applied 2 minutes previous to the measurement. The IOP registration using the continuous monitoring Triggerfish® devise was performed 3 days after the conventional monitoring, starting registration at 8:00 am. Each of the patients was taught the procedure, as well as the appropriate use and care of the continuous monitoring Triggerfish® device, both verbally and with a written manual. Likewise, a tolerability questionnaire using visual analog scale was handed out to each participant.

We used descriptive statistics to report demographic data of the sample, a nonparametric test for correlation between scalar variables (Spearman's Rho) to analyze the data of the time curves and the Triggerfish® recordings, and a subjective observational analysis of the IOP pattern curve for each patient.

The study met the criteria established by the Hospital's Ethics Committee (and the Helsinki's International Convention).

Results

Seven patients were included with a mean age of 57.28 ± 14.5 years; 85.7% were females. A continuous monitoring Triggerfish® devise was eliminated from the study due to failure to establish the wireless connection.

The highest signal recorded by the Triggerfish® device was overnight in all patients as with conventional IOP monitoring and prolonged peaks (> 1 hour) were observed in 100% of patients, after hours.

No statistically significant correlation between the conventional IOP monitoring values and microvolts values recorded by Triggerfish® devise (correlation coefficient -0.28, p-value 0.52) was found (Figure 2).

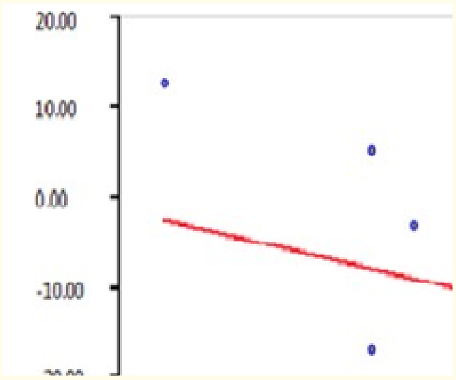

Figure 2: *Correlation between the conventional IOP monitoring values and microvolts values recorded by Triggerfish.*

However, when performing an analysis of the curve pattern generated with Triggerfish® software and comparing them with the curves generated by conventional IOP mon However, when performing an analysis of the curve pattern generated with Triggerfish® software and comparing them with the curves generated by conventional IOP monitoring 3 different patterns were identified: itoring 3 different patterns were identified:

- As increasing wave: IOP behave stably in the morning, gradually increasing with different slopes to reach maximum values above the baseline. There are nocturnal IOP peaks. There is a high variability between 46.9 - 45.2 µV (Figures 3-5).
- Epsilon (resembling the Greek letter): It begins with a clear reduction in IOP in the morning and then has a gradual increase reaching maximum values at baseline level overnight. The peaks are nocturnal and variability is moderate at 39.2 - 42.9 µV (Figures 6-8).
- Carousel: It's an irregular curve pattern with a lot of interference or noise, having a low variability between 24.7 - 24.2 µV (Figures 9-11).

Figure 3: *Increasing wave pattern.*

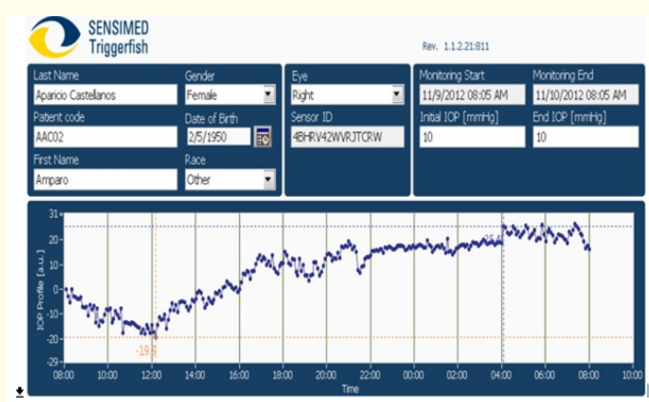

Figure 4: *Increasing wave pattern.*

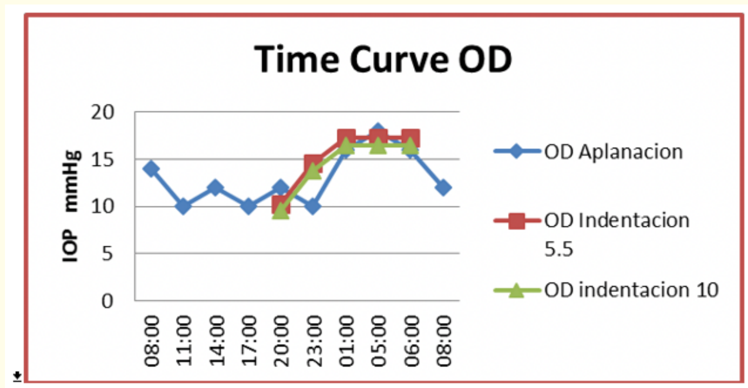

Figure 5: *Increasing wave pattern.*

Figure 6: *Epsilon pattern.*

Figure 7: *Epsilon pattern.*

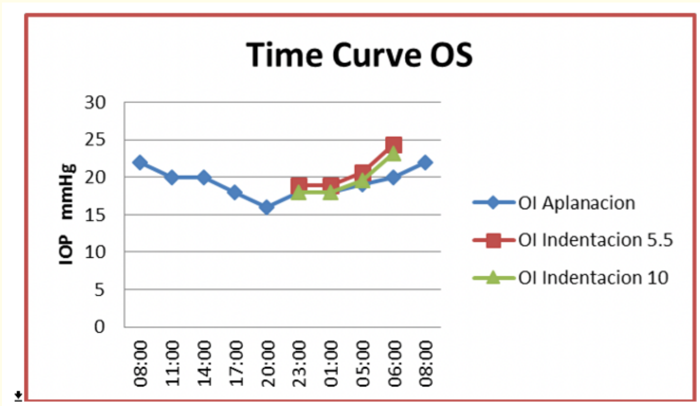

Figure 8: *Epsilon pattern.*

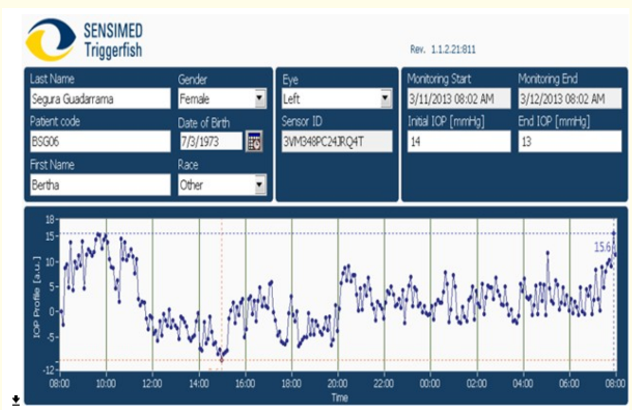

Figure 9: *Carousel pattern.*

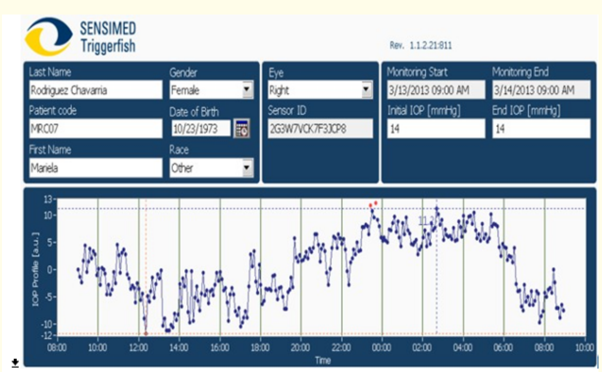

Figure 10: *Carousel pattern.*

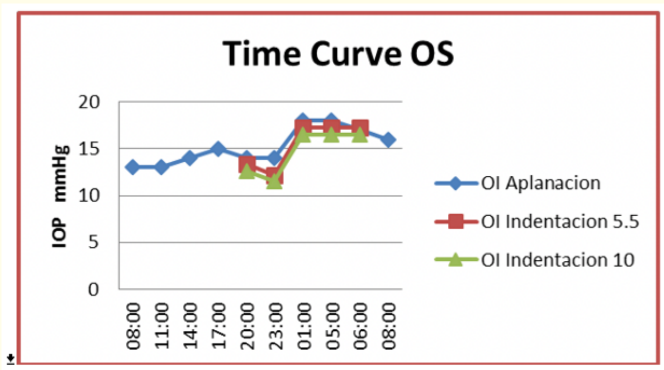

Figure 11: *Carousel pattern.*

No serious adverse effects were reported. In one case superficial punctate keratitis was identified, which was considered a minor complication and resolved in 24 hours with topical lubricant, without sequalae. On a scale of 0 to 10 (where 0 = not tolerable and 10 = completely tolerable) the average of the assessment for the tolerability of the device given by the patients was 6.5. The survey reported periocular pruritus generated by the patch antenna in 85.7% of cases, foreign body sensation in the same proportion and in 100% of cases red eye in the afternoon.

Discussion

Advances generated to detect high intraocular pressure or its fluctuations in non-working hours have an important role in the treatment and monitoring of primary open-angle glaucoma. Although continuous monitoring Triggerfish® technology does not directly measure IOP, but the change in curvature of the cornea produced by it, it registers a signal during 24 hours and a graph of the intraocular pressure's behavior is obtained.

A correlation between the values of the conventional IOP monitoring and Triggerfish were not comparable probably due to several factors. Registration in microvolts cannot be extrapolated to mmHg for each patient as the record begins with a value of 0 (zero) regardless of baseline value in mmHg; from this point on, and for 24 hours, changes in microvolts are recorded.

This pilot study was able to identify 3 types or patterns of tension curves in seven patients with primary open-angle glaucoma. There are probably more of these patterns and larger population is required to confirm this statement and to compare them with controls. Likewise, further studies are required that aim to correlate the clinical variables of each patient with curved pattern recorded by Triggerfish®.

We know that IOP behavior is a dynamic event in which many factors intervene. Some of these factors are: corneal thickness, biomechanical properties of the cornea, blinking and its correlation with other factors such as systemic hypertension and ocular perfusion pressure. It is likely that these graphic patterns recorded by Triggerfish® are generated by several of these factors interacting among themselves, so they will have to be analyzed to estimate their involvement independently and discover the role in the disease.

Conclusion

Three types of curve patterns were identified in the continuous monitoring Triggerfish® recording, each with specific characteristics that clearly demonstrate different behaviors of IOP in a group. We found no statistically significant correlation between the values recorded by Triggerfish® and mmHg obtained in conventional IOP monitoring.

Clinical Significance

The ocular telemetry Triggerfish® sensor has the potential to improve the approach and monitoring of patients with glaucoma as the isolated and static measurements of IOP both by day and during night are only a proportion of the IOP, and do not reflect the dynamic nature of the intraocular pressure during 24 hours. This study opens the door to a wide branch of research on IOP and continuous monitoring.

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