



SENSIMED
Triggerfish®
provides an
automated
recording of
continuous
ocular
dimensional
changes
over 24 hours.

White paper

SENSIMED Triggerfish® provides reproducible 24 hour profile.

Introduction

The SENSIMED Triggerfish® developed by Sensimed AG is a contact lens-based device capable of recording qualitative circadian pressure related profiles over the full 24 hour period under physiological conditions in glaucoma patients at risk of progression.

A strain gauge embedded in a soft silicone contact lens (Sensor) captures spontaneous circumferential changes at the corneoscleral area. The data is transmitted to a portable recorder via wireless telemetry.

Method and Findings

In a recent study¹, published in Archives of Ophthalmology, Mansouri et al. at the Hamilton Glaucoma Center, University of California, San Diego report that 24 hour profiles obtained with the SENSIMED Triggerfish® have fair to good reproducibility in the short-term. As part of a FDA-trial, the investigators evaluated safety, tolerability, and pattern reproducibility of the device. Forty patients with suspected or established glaucoma underwent two ambulatory 24 hour sessions at a 1 week interval.

Safety

To assess safety, this study used a stringent definition of adverse events, defining them as any change in ocular parameters from baseline. The most common adverse events were conjunctival hyperemia (80%) and “blurred vision” (82%). These adverse events were anticipated: the former due to the fact that most patients with glaucoma suffer from some form of ocular surface disease and have never worn a contact lens before; the latter mostly due to the orthokeratologic effect of the (intended) tight fit of the Sensor. Importantly, the vast majority of adverse events were classified as mild and the mean resolution time was less than 24 hours following the Sensor removal. The authors attributed the improved safety profile of the second-generation Sensor compared to a previous report² to the availability of 3 base curves for better ocular fit.

Tolerability

Tolerability of the repeated wear was assessed using the Visual Analogue Scale³, a 100-mm horizontal line on which patients draw a mark reflecting their comfort level. With values of less than 30 mm for both sessions, tolerability of the Sensor was considered good, with a non-statistically significant tendency for better comfort at the second visit.



Patient wearing the SENSIMED Triggerfish® device either ambulatory or in-hospital use.

Reproducibility

IOP is a highly dynamic parameter influenced by intrinsic and extrinsic factors. Therefore the evaluation of measurement reproducibility is necessary to distinguish measurement variability from physiologic changes. To assess the degree of similarity of individual patient patterns between the 2 sessions (Figure 1), pairwise Pearson correlation was computed between parallel time points in both sessions. Despite the uncontrolled ambulatory nature of this study, the authors reported an overall correlation of 0.59, which indicates fair to good reproducibility. This study is the first to assess the short-term reproducibility of pressure patterns throughout the full 24 hour cycle, including undisturbed sleep. There was higher agreement between specific periods of interest, such as the transition from wakefulness to the first 2 hours of sleep, with a correlation of 0.71. In comparison, Realini et al.⁴ had previously investigated the diurnal GAT measurement repeatability in glaucoma patients. Using intraclass correlation coefficients, they found correlations ranging from 0.45 to 0.71 at different time points between the two visits. The fact that IOP measurements were assessed during 12 hours and not the entire 24 hour period may have limited the conclusions of their investigation.

Summary

This study shows that the SENSIMED Triggerfish® is a safe and well-tolerated device for 24 hour recording of ocular dimensional changes in patients with suspect and established glaucoma. It further demonstrates that 24 hour profile have fair to good reproducibility in the short term. These results suggest that 24 hour individual profile obtained in “real-life” situations have the potential to assist clinical decision-making.

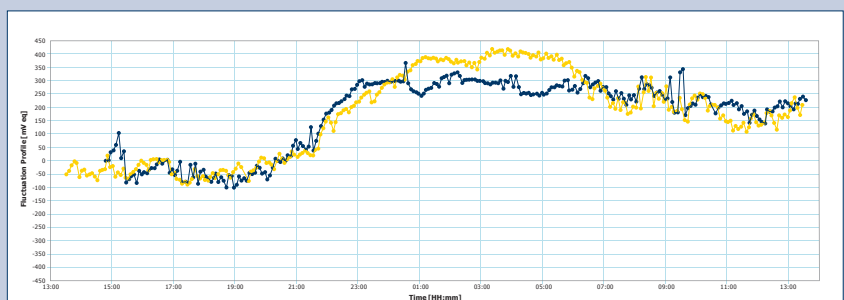


Figure 1: Example of an individual profile reproducibility with the SENSIMED Triggerfish® in a 60 year old male glaucoma suspect undergoing treatment with a once-daily prostaglandin eye drop. Two sessions at a one week interval are superimposed using the integrated software package.

Sensimed AG
Route de Chavannes 37
1007 Lausanne
Switzerland
Tel. +41 21 621 9191
info@sensimed.ch
www.sensimed.ch

© 2013 Sensimed AG. All rights reserved.

PREPARED BY

Kaweh Mansouri, MD, MPH, UC San Diego, La Jolla, CA, USA. September 2012

REFERENCES

1. Mansouri K, Medeiros FA, Tafreshi A, Weinreb RN. Continuous 24-Hour Monitoring of Intraocular Pressure Patterns With a Contact Lens Sensor: Safety, Tolerability, and Reproducibility in Patients With Glaucoma. *Arch Ophthalmol.* 2012 Aug 13;1-6.
2. Mansouri K, Shaarawy T. Continuous intraocular pressure monitoring with a wireless ocular telemetry sensor: initial clinical experience in patients with open angle glaucoma. *Br J Ophthalmol.* 2011 May;95(5):627-9.
3. Collins SL, Moore RA, McQuay HJ. The visual analogue pain intensity scale: what is moderate pain in millimetres? *Pain.* 1997 Aug;72(1-2):95-7.
4. Realini T, Weinreb RN, Wisniewski S. Short-term repeatability of diurnal intraocular pressure patterns in glaucomatous individuals. *Ophthalmology.* 2011;118(1):47-51