



A multicenter study shows that a single 24-hour recording of ocular dimensional changes with TF provides a “signature” that is significantly associated with the rates of prior VF progression.

A single 24-hour recording of SENSIMED Triggerfish® provides a signature that is significantly associated with the rates of prior visual field progression: a multicenter study

Introduction

The SENSIMED Triggerfish® (TF) developed by Sensimed AG (Lausanne, Switzerland) is a contact lens-based device capable of recording qualitative circadian ocular dimensional changes over the full 24-hour period under physiological conditions.¹ The inbuilt sensor captures spontaneous circumferential changes at the corneo-scleral junction that occur due to ocular pressure and volume changes. Output signals from the CLS are in electronic units of millivolt equivalents (mVeq) whose mean 24-hour pattern have been correlated with the mean 24-hour tonometric curve.²

TF is a CE marked product also approved by FDA with the following indication for use statement: “*The SENSIMED Triggerfish® is a prescription device indicated to detect the peak patterns of variation in intraocular pressure over a maximum period of 24 hours to identify the window of time to measure intraocular pressure by conventional clinical methods. The SENSIMED Triggerfish® is indicated for patients 22 years of age and older.*”

In a recent study, published in *Ophthalmology*, De Moraes et al demonstrated that certain parameters derived from TF provide a “signature” that can differentiate glaucoma patients experiencing fast versus slow visual field (VF) progression.³ They also demonstrated in their cohort of 40 treated glaucoma patients that this signature obtained during a single 24-hour session was a better predictor of rates of visual field progression than Goldmann applanation tonometry (GAT) measurements taken multiple times over years.³ However, this study had limitations that prevented the generalizability of the results, such as a relatively small sample size, stringent inclusion/exclusion criteria, and patients coming from a single referral glaucoma practice.

To overcome these limitations and test the generalizability of the previous findings, data from a large, multi-center consortium of treated open-angle glaucoma (OAG) patients who underwent 24-hour TF recording and had a series of VF tests available to evaluate the relationship between TF parameters and rates of glaucoma progression was recently analysed (**FishUP** study, manuscript under review).

Methods

FishUP was based on a multi-center collaboration consisting of 50 centers from 13 countries. FishUP compiled the data of 1231 subjects who had undergone TF recording as part of different prospective studies or registries. The present analysis included subjects who had an established diagnosis of OAG and had at least 3 reliable Humphrey VF tests (SITA-Standard or SITA-Fast algorithm; 24-2 or 30-2 strategy) performed within 5y before the date of recording with the TF. The algorithm and strategy had to be consistent within each patient during their follow-up period. Subjects with unreliable VF tests (false-positive responses <15%) and incomplete CLS recordings were excluded.

Analysis

Fifty-five parameters extracted from the TF output were used as explanatory (independent) variables in the analysis. As these parameters are intrinsically correlated with one another, they cannot be used as such for the analyses. Therefore, principal component analysis (PCA), a statistical method to reduce the large number of parameters to a few, interpretable variables, called principal components (PC), was used for the analysis. PCs are linear combinations of the original parameters which retain as much of the variability in the data as possible, and are not correlated to one another.

The outcome (dependent) variable, rate of VF progression, was the rate (slope) of mean deviation (MD) change calculated from the VF tests using linear mixed effects models. Rate of VF progression, a continuous variable, was converted to a binary variable; MD slopes of < -1.0 dB/year were classified as fast progression and MD slopes of \geq -1.0 dB/year as slow progression.

The association between the PCs and the likelihood of having been a fast progressor was analysed using univariate logistic regression analysis. Similarly, other potential confounders that are likely to be associated with VF progression were also analysed: age, VF MD value closest to the date of TF recording (herewith called “baseline MD”), number of IOP-lowering medications at the time of TF recording, and number of surgeries (laser and incisional) during the VF testing period.

Findings

Four hundred and forty-five eyes of 445 subjects were eligible for the analysis. Mean age of the subjects was 68.9 years, mean number of VF tests per subject was 7.5 over a mean period of 4.7 years, mean baseline MD was -7.0 dB and the mean slope of MD was -0.52 dB/year. Fifty-two eyes (11.6%) showed fast progression.

PCA reduced the 55 parameters into multiple PCs and 14 PCs which accounted for 84% of the variance in the data were chosen for the analysis.

Univariate analysis showed that fast progression was significantly associated with worse baseline MD (odds ratio (OR): 0.85, $P < 0.01$), greater number of IOP-lowering medications (OR: 1.17, $P = 0.01$), laser (OR: 1.74, $P = 0.03$), and incisional procedures (OR: 2.46, $P < 0.01$). Among the 14 PCs, fast progression was associated with 4 PCs: one describing nocturnal TF signal (OR: 1.21, $P = 0.02$), one related to ocular pulse frequency (OR: 1.14, $P = 0.19$), one related to ocular pulse amplitude (OR: 1.32, $P = 0.01$) and the last one to the overall fluctuations (OR: 1.25, $P = 0.13$).

Summary

A multicentre study showed that a single 24-hour recording of ocular dimensional changes with TF provides a signature that is significantly associated with the rates of prior VF progression. Prospective studies are warranted to show the ability of the TF to predict future VF progression.

Academic groups worldwide are using the findings of this study for further research purposes such as using a TF recording to indicate the likelihood of VF progression. Indeed the rate of future VF progression has been shown to be strongly associated with the rate of initial VF progression.⁴

Prepared by

Kaweh Mansouri, MD, MPH, Clinique Montchoisi, Lausanne, Switzerland, February 2018

References

1. 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;95:627-9.
2. Mansouri K, Weinreb RN, Liu JH. *Efficacy of a contact lens sensor for monitoring 24-h intraocular pressure related patterns*. PLoS One 2015;10:e0125530.
3. De Moraes CG, Jasien JV, Simon-Zoula S, et al. *Visual Field Change and 24-Hour IOP-Related Profile with a Contact Lens Sensor in Treated Glaucoma Patients*. Ophthalmology 2016;123:744-53.
4. Bengtsson B, Patella VM, Heijl A. *Prediction of glaucomatous visual field loss by extrapolation of linear trends*. Arch Ophthalmol 2009;127:1610-1615.

Sensimed SA

Route en Rambuz 17
1037 Etagnières
Switzerland

+41 21 621 9191
info@sensimed.ch
www.sensimed.ch
Subsidiary of SEED Co., Ltd