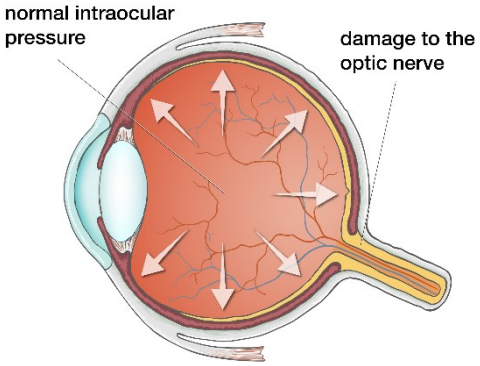
SENSIMED Triggerfish® could help identify POAG patients potentially misclassified as NTG

Normal Tension Glaucoma



Also known as low tension or normal pressure glaucoma, normal tension glaucoma (NTG) is a form of open angle glaucoma (OAG) in which damage occurs to the optic nerve without intraocular pressure (IOP) to exceed the normal range of 12 to 22 mm Hg, hypothesizing the involvement of additional causative risk factors, beyond IOP.[1] NTG is the predominant form of OAG in Asian population (up to 92%), especially in Japan.[2, 3] The incidence in Caucasian populations is between 30% and 39%, and is about 57% in populations of African descent.[3]

With the glaucomatous damages, NTG diagnosis is usually confirmed based on IOP measurements taken during office hours, and since IOP is known to be a dynamic parameter a diurnal or 24-hour IOP curves is sometimes performed with repeated tonometry measurements every single hour at best. Such procedures, however, are cumbersome (consumes scarce resources), expensive (usually requires hospitalization), inconvenient (disturbed sleep cycle as patient is awoken for nocturnal measurements) and may not adequately reflect the IOP profile occurring in real-life, i.e. indicate when the IOP peak can be expected. Nevertheless, alike primary OAG (POAG), current NTG treatment usually consists in a further reduction of IOP, that is not always efficient.

A state-of-the-art device for a better assessment of misclasified POAG

The SENSIMED Triggerfish® (TF) developed by Sensimed SA (Lausanne, Switzerland) is a contact lens-based device capable of recording ocular dimensional changes over the full 24-hour period in ambulatory setting, under physiological conditions.[4] With a strain gauge embedded in a soft contact lens (Sensor) TF captures spontaneous circumferential changes at the corneo-scleral junction, that occur due to ocular pressure and volume changes. TF output signals are in electronic units of millivolt equivalents (mVeq) whose mean 24-hour pattern have been correlated with the mean 24-hour tonometric curve.[5]

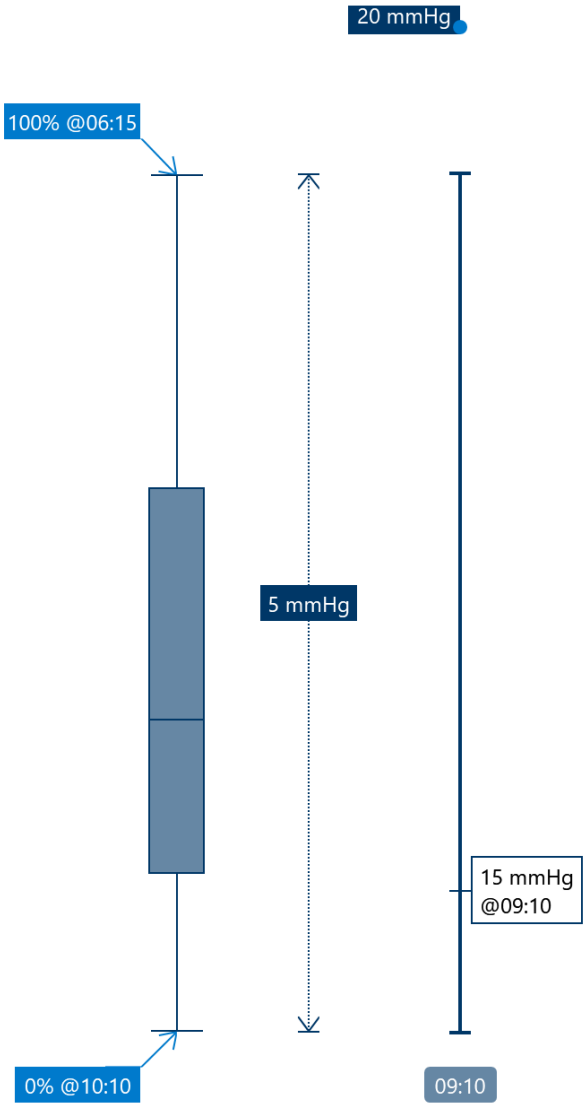
Using the TF software, the combination of the 24-hour TF data represented as a box-plot with a single tonometry IOP reading acquired on the same eye can indicate if the IOP is susceptible to exceed a specified threshold within the course of 24 hours.

TF is a **CE** marked product also approved by **FDA** (USA) and **PMDA** (Japan).

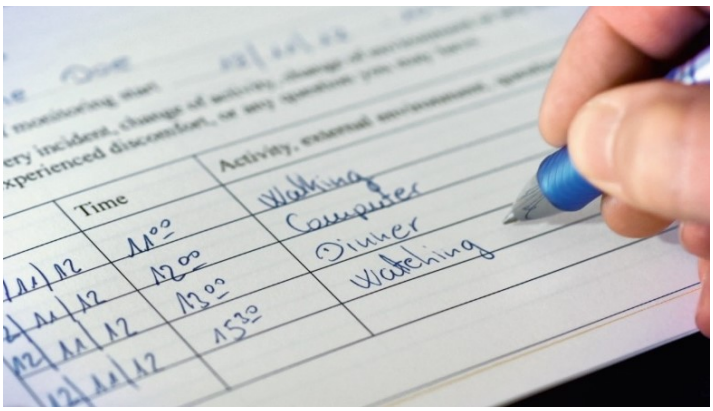
Findings

A study conducted at Kanazawa University, in Japan evaluated the use of a 24-hour ocular dimensional profile recorded with TF combined with a single tonometric IOP reading to indicate the potential for exceeding the diagnostic threshold for NTG anytime within a 24-hour period, in untreated Japanese patients.[6] Using a box-plot presentation, the IOP peak time, the potential for exceeding the threshold value of 20 mm Hg and the duration of time during which each patient had a measurement above or below this specific IOP value was assessed.

On the 65 initially diagnosed NTG, TF together with tonometric IOP preferably measured at 15h or 18h provided the best classifier that allowed identification of the 5 misclassified POAG with a high sensitivity and a negative predictive value. Below is an example of the boxplot.



The combination of a 24-hour SENSIMED Triggerfish® profile with a single tonometry IOP reading of the same eye can indicate if the IOP is susceptible to exceed a specified threshold within the course of 24 hours



Conclusion

SENSIMED Triggerfish® is a non-implantable device capable of identifying the peak pattern related to IOP changes outside office hours. The device information can be used in conjunction with a single tonometric reading to determine patients' potential of having IOP levels exceeding a specific threshold within a 24-hour period, without the need to perform a 24-hour tonometric curve. Twenty-four-hour monitoring with TF could thus reduce the number of POAG patients who may otherwise be eventually misclassified as NTG, for a more accurate diagnosis and appropriate, effective, and why not IOP-independent, treatment.

References

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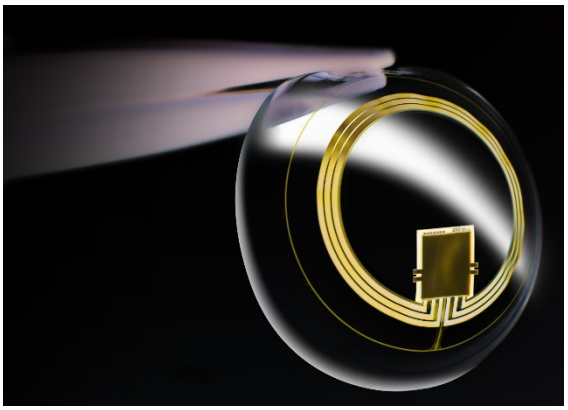
About Us



Sensimed SA, a Swiss company, has developed a unique technology platform on non-invasive soft contact lens-based solution. The first application, the SENSIMED Triggerfish®, provides an automated recording of continuous ocular dimensional change over 24 hours with the aim of revolutionizing glaucoma management enhancing personalization of patient care.

The SENSIMED Triggerfish® received the CE mark in 2010 and was approved by the U.S. Food and Drug Administration (FDA) in 2016. Since 2018 the device is registered in Japan at the Pharmaceuticals and Medical Devices Agency (PMDA).

Other non-invasive on-eye sensing applications are in development to provide clinically pertinent data with the same continuous monitoring approach. The Company is furthermore focused on expanding the knowledge of how this individual data can best be used in the clinical setting to deliver customized treatment. The data, analysed and modelled on an ongoing basis, is processed in an attempt to identify pathological patterns that can be used to differentiate indication, personalize treatment and assess efficacy of treatment.

The Company is directly positioned at the convergence between devices, treatment and information. Sensimed believes that with this global knowledge-based approach it will be possible to provide valuable insights that allow ophthalmologists to better understand and treat glaucoma.

Sensimed became a subsidiary of SEED Co., Ltd after the acquisition of a majority participation end of 2019.

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