Measuring 24h intraocular pressure fluctuations with a new sensing contact lens device

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1. Background and Purpose

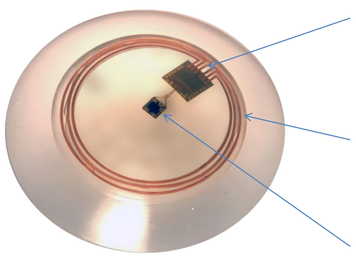
Intraocular pressure (IOP) is the sole proven modifiable risk factor for glaucoma onset and progression[1] and is characterized by significant short- and long-term variability[2]. The importance of the nycthemeral IOP pattern for successful management of glaucoma has been well documented[3], especially for patients who experience visual loss despite normal and/or controlled office hours IOP.

Since its development in the 50s, Goldmann applanation tonometry (GAT) remains the gold standard method for measuring IOP, despite its limitations. However, tonometry may be an imperfect method for measuring changes in IOP because it allows only snapshot and non-continuous measurements; it is not physiologic and disturbs the sleep architecture. These limitations may have biased previous descriptions of physiological IOP rhythm. Therefore, assessing IOP continuously over 24 hours is pivotal for the management of glaucoma.

There have been many efforts in the past decades to search for an ambulatory and frequent method to monitor IOP for 24 hours. In this context, Sensimed AG has developed a sensing contact lens (SCL)-based device intended to measure IOP over 24 hours, GF.

This feasibility study investigated the ability of GF to measure IOP continuously in healthy subjects and glaucoma patients.

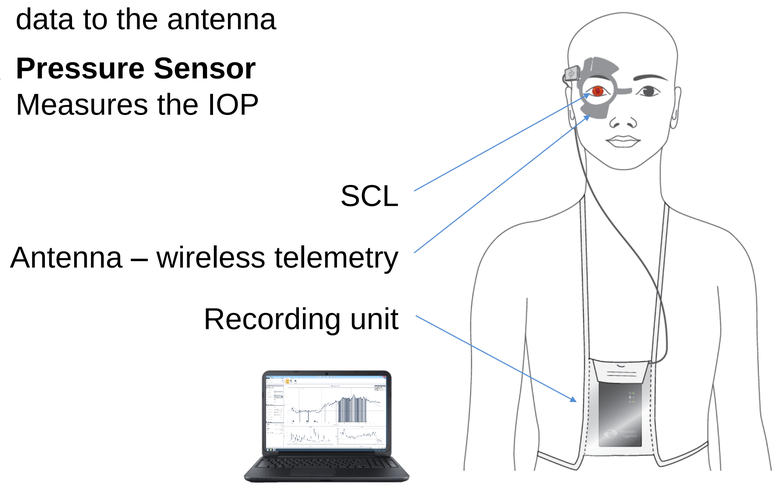
2. The device



Microprocessor (ASIC)
Digitizes IOP data and sends it to the recorder

Antenna
Receives energy and sends data to the antenna

Pressure Sensor
Measures the IOP



3. Methods

Key inclusion/exclusion criteria

- Between eyes IOP difference within 2.5 mmHg (at screening in sitting position)
- Same direction of IOP variation for the 2 eyes, when moving from sitting to supine positions at screening
- Previous glaucoma, cataract or refractive surgery
- Severe dry eye syndrome

Data acquisition

- Single base curve SCL
- Repeated 3min cycles with 10s intense and 170s less intense sampling

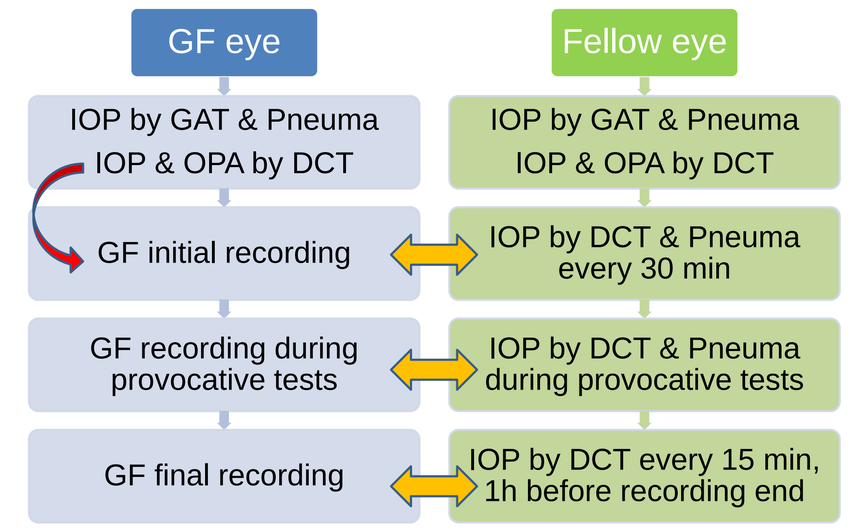
Analysis

Study eye: GF vs. **GAT / DCT / Pneumatonometer**

Fellow eye: GF vs. **DCT / Pneumatonometer**

- Comparison between median of closest GF burst (intense sampling) and IOP measured by tonometry
- Comparison between the closest OPA value for a burst and OPA measured by DCT
- Comparison between GF signal acquired with closed eye for a 15 min period and values acquired 7.5 min before and 7.5 min after that period (sleep period simulation)

Analysis using 1- or 2-sided t-tests with 95% CI

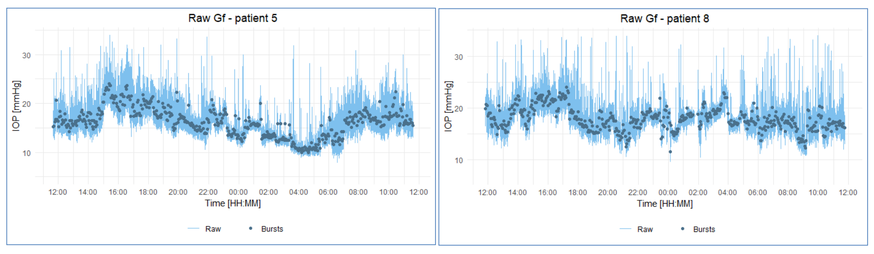


Pneuma: Pneumatonometer; Provocative tests: Postural change, WDT

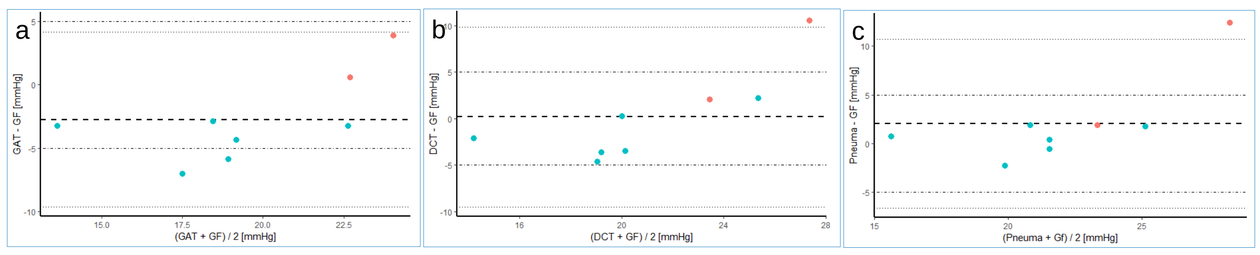
4. Results

8 subjects (4 healthy, 4 POAG); Mean age: 52.9 ± 17.2 years, 62.5% females; Transient AEs on 66.7% of the eyes (corneal erosion), all resolved after GF removal.

24h GF IOP recording in healthy subject (a) and POAG (b)



IOP: GF vs. GAT (a), GF vs. DCT (b) and GF vs. Pneuma (c), same eye



Mean diff: -2.75 ± 3.52 mmHg; 75% within ± 5 mmHg

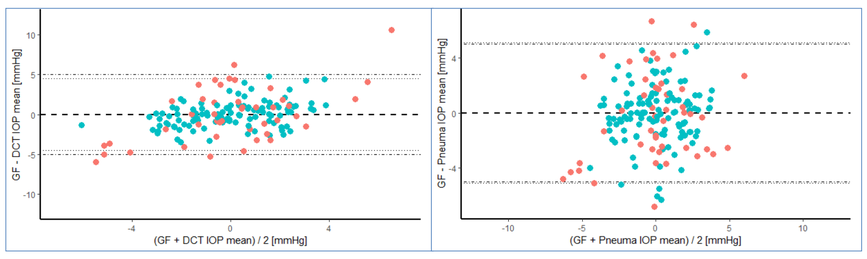
Mean diff: 0.18 ± 4.95 mmHg 87.5% within ± 5 mmHg

Mean diff: 2.03 ± 4.43 mmHg 87.5% within ± 5 mmHg

- *Subjects with borderline keratometries*

Dashed line: mean of the difference
Dotted lines: +/- 95% CI
Dotted-dashed lines:+/- 5 mmHg

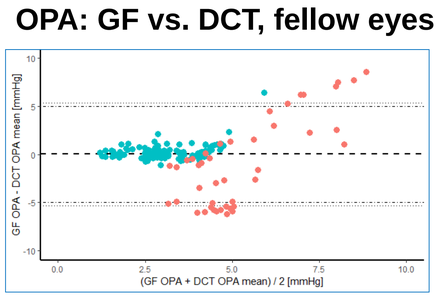
IOP: GF vs. DCT (a) and GF vs. Pneuma (b), fellow eyes



97.2% mean var. within ± 5 mm Hg; 95% CI = 92.1%, 100.0%], p = 0.00

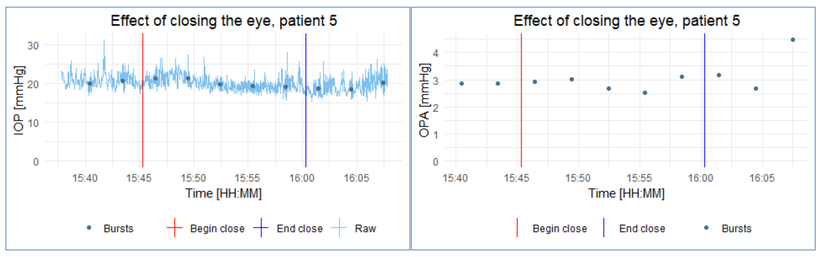
94.3% mean var. within ± 5 mm Hg; 95% CI = [88.3%, 100.0%], p = 0.00

OPA: GF vs. DCT, fellow eyes



85.5% of points within ± 5 mm Hg

IOP (a) and OPA (b) GF signal during closed eyes



IOP: Mean diff.: -0.24 mmHg, 95% CI = [-1.25, 0.76], p = 0.58
OPA: Mean diff: -0.03 mmHg, 95% CI = [-0.69, 0.64], p = 0.93
Mean SD by DCT, fellow eye: 0.85 mm Hg for IOP and 0.25 mm Hg for OPA

5. Discussion & Conclusion

- First-in-human data from a first-of-a-kind SCL capable of measuring IOP and OPA continuously during 24h, including undisturbed sleep
- Good agreement between GF and tonometry values, comparable to literature results for routinely used tonometers[4,5]
- GF signal not impaired by closed eyes

GF shows potential for ambulatory 24h continuous monitoring of IOP and OPA, collecting over 320k points in 24h. More research is needed to confirm the safety and accuracy of this device.

References: [1] Weinreb et al. Lancet 2004, [2] Realini et al. Ophthalmol. 2011 , [3] Sit J Glaucoma 2009, [4] Andreanos et al. Clin Ophthalmol. 2016 , [5] Mangouritsas et al. Clin Ophthalmol. 2011

Disclosures: K Mansouri (Consultant, Sensimed AG); T Varidel (Employee, Sensimed AG), S Simon-Zoula (Employee, Sensimed AG), M Schlund (Employee, Sensimed AG), S Cerboni (Employee, Sensimed AG), R Wasilewicz (none)