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24-h IOP and its monitoring

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Associate Executive Vice President
World Glaucoma Association
Financial disclosures

- Alcon
- Allergan
- IplanData
- Glaukos
- Fabrinal SA
- Novartis
- NWM
- Optovue
- Santen
- Sensimed
- Thea
IOP is the only treatable risk factor for glaucoma
“Goldmann Applanation Tonometry has many shortcomings”
GAT provides just a snapshot

IOP is a highly dynamic parameter
Factors that influence IOP

- Stress
- Body position
- Head Position
- Blinks
- Eye Movements
- Eye rubbing
- Liquid intake
- Caffeine
- Medications
- Circadian rhythm

- Seasons
- Hormonal cycles
- Tight neck ties
- Goggles
- Pillows
- Blood pressure
- Wind instruments
- Yoga
- Sex
- ...This talk...etc.
We miss peak IOP in > 2/3 of patients *
= 50% axonal injury at “physiological” IOP

* Liu JHK, Weinreb RN et al. – 20 years of published research
So, why are your values always higher at night/sleep?
IOP, the "Sleeping Giant"

Liu JHK, Weinreb RN et al. IOVS 2003
Addressing An Unmet Need: Continuous IOP Monitoring

1. 24-h IOP monitoring
   
   Extraocular sensors (Contact lens)

2. Continuous long term IOP monitoring
   
   Implantable sensors

* Only devices presented with 1) published clinical data and/or 2) regulatory approval
First “intelligent” contact lens: Triggerfish CLS

- Measures limbal strain, reflecting:
  1) IOP
  2) intraocular volume
  3) biomechanical properties

- Data *not* provided in mmHg
Look into my eyes

The technology has huge potential, says Babak Parviz, a researcher at the University of Washington, in Seattle, who is one of the pioneers of smart contact lenses. Such lenses could act as both sensors and displays, providing new ways for data to pass in and out of the body. By adding tiny light-emitting elements to contact lenses, they could reveal an awful lot about some health conditions.

Biotechnology: Smart contact lenses exploit the unusual characteristics of the eye to diagnose disease, deliver drugs and more besides.
Excellent comparison to manometry – in the lab
“Without data you’re just another person with an opinion”

W. Edwards Deming
Continuous 24-Hour Monitoring of Intraocular Pressure Patterns With a Contact Lens Sensor

Meeting an unmet need in glaucoma: continuous 24-h monitoring of intraocular pressure

Intraocular pressure changes during sexual activity

Effect of overnight wear of the Triggerfish® sensor on corneal thickness measured by Visante anterior segment optical coherence tomography

Analysis of Continuous 24-Hour Intraocular Pressure Patterns in Glaucoma

Kaweh Mansouri, John H. K. Lai, Robert N. Weinreb, Ali Tafreshi, and Felipe A. Medeiros

Continuous 24-hour intraocular pressure monitoring for glaucoma with a contact lens sensor – time for a paradigm change

Kaweh Mansouri, Robert N. Weinreb

Intraocular pressure changes during sexual activity

Kaweh Mansouri, Felipe A. Medeiros, and Robert N. Weinreb

Continuous 24-Hour Monitoring of Intraocular Pressure Patterns With a Contact Lens Sensor

Kaweh Mansouri, Robert N. Weinreb, and Felipe A. Medeiros

Original Investigation

Measured Changes in Limbal Strain During Simulated Sleep in Face Down Position Using an Instrumented Contact Lens in Healthy Adults and Adults With Glaucoma

Florentina J. Freiberg, Jennifer M. Lindell, Lisa A. L. Théderan, Svetlana Leirbe, Yasmine Shih, and Thomas Klink

Continued...
CLS – How to interpret?

mVeq
“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.”

\[ f(x) = a_0 + \sum_{n=1}^{\infty} \left( a_n \cos \frac{n\pi x}{L} + b_n \sin \frac{n\pi x}{L} \right) \]
Continuous IOP Monitoring

1. 24-h IOP monitoring
   Extraocular sensors (Contact lens)

2. Continuous long term IOP monitoring
   Implantable sensors
EyeMate intraocular sensor

- CE mark approved
- Placed in sulcus
- Patients undergoing CE-IOL
- K-Pro patients

ASIC
EyeMate – On-demand or continual
Adverse events

- Gonioscopic pigment dispersion in 30% (all immediately after surgery)
- No transillumination effects
EyeMate – Do patients use it?

Good “adherence” with device, beyond study duration

Choritz, Mansouri et al. Telemetric measurement of intraocular pressure via an implantable pressure sensor - twelve-month results from the ARGOS-02 trial. *Am J Ophthalmol.* 2019
EyeMate – Performance

Good concordance to GAT:

- 0.783 (95% CI: 0.743 – 0.817, Intraclass correlation coefficient)
- 0.882 (95% CI: 0.835 – 0.915, Cronbach’s alpha)

→ Which device measures real IOP?
EyeMate – Performance

Patient 1
### EyeMate – Performance

#### Patient 1

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EyeMate
Patient 1

EyeMate – Comparison to other methods

EyeMate

CLS

Sleep laboratory
EyeMate Intraocular Sensors

- CE mark approved
- Placed in sulcus
- Patients undergoing CE-IOL
- K-Pro patients

- In CE mark approval study (12 patients included)
- Placed in suprachoroidal space, trans-choroidal IOP measurement
- Applicable also for phakic glaucoma patients
EyeMate SC – Implantation

Implantation of ARGOS SC implant by Dr. Kaweh Mansouri
EyeMate-SC – first in human study

- Multicenter study
  - 24 eyes
  - 5 centers (4 Germany, 1 Switzerland)
  - Non-penetrating glaucoma surgery
EyeMate SC – Day 1
GAT and EyeMate-SC within 5 mm Hg, from 78% to 100% at various visits
EyeMate-SC – safety

- Safe after 1 year (average follow-up)
  - No SAE
  - 1 case of choroidal detachment (resolved under medical treatment)
  - Similar AEs to regular NPGS
Lesson 1 – IOP is **unstable**
Lesson 2 – IOP is **poorly repeatable**

22 eyes, 92,860 measurements, 15,811 days:

*Moderately* repeatable over **short-term** (<3 months)

ICC: 0.52-0.66
Lesson 2 – IOP is **poorly repeatable**

*Poorly* repeatable over **long-term (>12 months)**

ICC: 0.29-0.51
Lesson 3 – no week-day pattern

22 eyes
Total of 106,754 IOP readings (Ø 4850/per patient) over 15,811 measurement-days (Ø 718/per patient)

No week-day differences
(P > 0.05)
Lesson 4 – IOP has a **seasonal pattern**

22 eyes
Total of 106,754 IOP readings over 15,811 measurement-days

Weekly and seasonal changes of intraocular pressure measured with an implanted intraocular telemetry sensor

Kaweh Mansouri,1,2 Kevin Gillmann,1 Harsha Laxmana Rao,3 Robert N. Weinreb,4 On behalf of ARGOS–2 Study Group

Between mid-winter (December-January) and mid-summer: reduction in IOP of **7.1%**

(-1.16 mmHg, p < 0.05)
Lesson 5 – IOP and intra-vitreal injections
Actionable Pearls

1. Implantable Sensors (*approved in EU) or CLS
2. Diurnal Tension Curve (DTC)
08:00 – 18:00 - DTC
08:00 – 18:00

Too good to be true?
Actionable Pearls

1. Implantable Sensors (*approved in EU) or CLS
2. Diurnal Tension Curve (DTC)
3. Patient home tonometer
Actionable Pearls
Conclusions 1

• Ability to offer routine continual IOP monitoring
  o Improved management
  o Enabling sustained-release treatment
  o Improved adherence to medications
  o Improved QoL
Conclusions 2

- Tele-ophthalmology in COVID-era:
  - Data from 34 patients during lockdown
  - 8415 measurements from 370 measurement days
  - Leading to 5 treatment changes
  - 9/10 centers judged info to be "very helpful"

Ophthalmol Glaucoma. 2021 Feb 4

Intraocular Pressure Telemetry for Managing Glaucoma during the COVID-19 Pandemic

Kaweh Mansouri, MD, MPH,1,2,7 Inga Kersten-Gomez, MD,3 Esther M. Hoffmann, MD,4 Peter Szurman, MD, PhD,5 Lars Choritz, MD,6 and Robert N. Weinreb, MD7
• **Challenges**
  - Long-term safety
  - Big data interpretation (→ Machine learning and AI)
  - Need to reevaluate practice patterns
  - Reimbursement
THANK YOU!