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A first-in-human pilot study of a novel electrically-passive metamaterial-inspired resonator-based ocular sensor embedded contact lens monitoring intraocular pressure fluctuations

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ABSTRACT

Glaucoma is a leading cause of blindness with no cure, but early treatment and effective monitoring can often slow the progression of the disease. Monitoring of glaucoma is based on the measurement of intra-ocular pressure (IOP) that is a physiological parameter related to the mechanical state and parameters of the eye. Conventionally, diagnosing and assessing the progression of glaucoma is based on the method of measuring IOP discretely at clinics. Recent studies have demonstrated the importance of continuously monitoring IOP for 24 h to elucidate the effect of circadian rhythm. In this work, a metamaterial-inspired electrically-passive sensor-embedded contact lens is presented to monitor the IOP fluctuations based on a first-in-human pilot study. The sensor inside the contact lens is an electrically passive, metamaterial-based resonator that can be measured using a wearable antenna patch. The system has been tested with six healthy volunteers during an experiment to induce deliberate IOP changes via water-loading and placing the individuals in supine position using a recliner seat. The initial data compared with tonometer measurements suggest that the system can be used to assess the variation of IOP continuously.

1. Introduction

Glaucoma affects over 70 million people with that number estimated to increase over 110 million by 2040 [1]. It is a chronic condition with no cure and is the second leading cause of blindness [2]. As the ageing population is rising especially in developed countries, the prevalence of glaucoma is also on the rise [2]. The current medical practice for the management of glaucoma is to monitor IOP (Intraocular Pressure) that is a critical physiological parameter that reflects the balance between the production and outflow of aqueous humour in the eye. Elevated IOP is a major risk factor for glaucoma that needs to be quantified and assessed. Currently, Goldmann applanation tonometry (GAT) is the most widely used method for measuring IOP in clinical practice. However, GAT has limitations, such as its dependence on corneal properties and its inability to capture short-term fluctuations in IOP [3]. In addition, the conventional approach is to measure IOP during an eye examination and lower it via the use of drugs and/or surgery to prevent further visual loss. However, this approach has apparent medical, societal, and economic limitations. Measuring IOP levels only during doctor visits and assessing the progression of the disease based on single measurements within time periods of several months impedes eye care providers from making timely and effective actions [4].

An emerging paradigm for IOP measurement strategy is to observe the circadian cycles of IOP variation in a period of 24 h spanning a single day and repeating this measurement strategy periodically over an extended period of time [5,6]. IOP varies significantly throughout the circadian period, and these fluctuations and associated peak levels have been identified as risk factors for the progression of glaucoma. Studies support the hypothesis that IOP fluctuation should be viewed as an independent risk factor for glaucoma progression [7]. Obtaining datasets

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capturing full circadian cycles may lead to better understanding of several environmental and physiological parameters causing IOP fluctuation [8]. Treatment strategies for glaucoma are based on setting a target IOP range at which the development of further glaucomatous damage is assumed to be substantially reduced. Recent clinical recommendation includes considering the fluctuation of IOP in addition to reduction [9].

One approach to implement this strategy is to invite patients to clinics for a 24-hour period and periodically measure IOP using tonometry methods. Increasing the frequency of the doctor visits that would allow monitoring of circadian cycles is not economically feasible. In addition, this will impose certain limitations on the wellbeing of the patients. More importantly, measuring IOP using conventional tonometry methods during night time can yield systematic measurement errors. It has been reported that waking up patients at night for tonometry measurements can affect the results [10]. Nevertheless, there are significant attempts to develop a tonometer suitable for home use. iCare is a good example of this technology employing rebound tonometry [11]. The probe is in contact with the eye and single measurements are performed by the patients who are usually assumed to be medically non-trained individuals. Taking multiple measurements at night may produce inaccurate data, as IOP often rises immediately after awakening patients. [12].

Recently, several continuous IOP monitoring platforms have been introduced. Among these, Triggerfish by Sensimed is the most widely studied product based on a strain sensor embedded into a contact lens [13]. The product was granted FDA approval in 2014, and currently is the only continuous monitoring contact lens-based device in the market. Triggerfish tracks the changes in the corneal shape in response to changes in IOP. Triggerfish technology utilises a strain gage sensor and an electrically active silicon chip embedded into a disposable silicone-based contact lens. Several studies have demonstrated that this approach can be used to track IOP for extended time periods using a portable and noninvasive solution [13]. However, this technology is not without shortcomings. Weak correlation between the data from the system and external IOP measurements have been reported [14]. Embedding an electrically active silicon chip sets a limit for the lens thickness, and poses comfort, safety, and power restrictions. Also, the presence of the chip affects the flexibility of the contact lens negatively, limiting its ability to conform to the patient's eye perfectly, thus leading to inaccuracies in the measurement. In addition, the presence of an opaque and rigid silicon chip at the centre of the contact lens may restrict the field of view (FOV) of the patient causing emotional stress and restricting daily activities.

Another technology for the continuous monitoring of IOP is based on implantable sensors inside the eye. An example of this technology is from a product by Implandata Ophthalmic Products [15]. The system includes an electronic chip as a sensor that is implanted inside the eye and a wireless read out unit electrically coupled to the sensor. The safety and reliability of this method have been demonstrated in a recent multicentre clinical investigation study in a longitudinal study with 22 patients over 12 months [16]. Despite the potential for obtaining accurate measurements directly inside the eye, the sensor is invasive and requires medically complex procedures.

In this work, a new contact lens-based non-invasive continuous monitoring system has been developed. The sensing technology is based on an electrically passive sensor embedded in a disposable soft contact lens, and a wearable electronic readout system to collect, store and process the data. In a typical use scenario, a trained medical staff fits the disposable contact lens and the wearable electronic system in the clinic. The patient wears the products for 24 h and returns them to the clinic the next day, when the medical staff downloads the data from the device for further processing using a calibration algorithm based on tonometer measurements taken before and after the contact lens use. The processed data is then delivered as the result to an ophthalmologist for evaluation. As compared to electrically active silicon-based sensors, our sensor is thin, flexible and does not require power transmission. In this paper, the concept and the results of a clinical pilot are presented where the system has been tested with healthy volunteers.

2. Subjects and methods

2.1. Contact lens-based measurement system

The sensor is based on the principle of resonant frequency shift of a metallic resonator with *meta*-material properties under mechanical stress. This is a novel approach to accurately monitor fluctuations in IOP by measuring changes in the geometry of a sensor placed on the cornea. The sensors are embedded into contact lenses made of polydimethylsiloxane (PDMS). These are disposable contact lenses. The data is collected wirelessly by transmitting a very low power radio frequency signal generated by a light-weight Holter-monitor-like device comprising an electronic circuit and a custom design wearable antenna. The sensor-embedded contact lenses (Type-D and Type-B, referring to internal sensor naming conventions) that were used during the experiments are shown in Fig. 1.

2.2. Study participants

Six healthy individuals (age/sex/BMI: 27/F/20.7, 42/M/26.6, 45/F/22.2, 46/F/22, 47/F/24.7, 47/M/25.9, all white) were recruited who had no history of ocular diseases or surgeries. The female participants

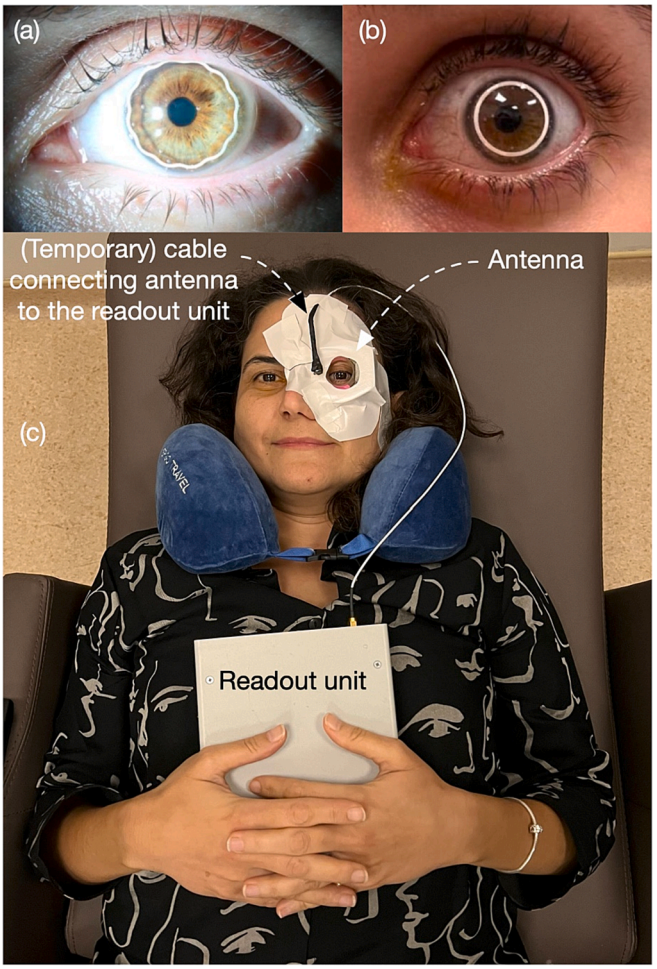

Fig. 1. Photographs of subjects (a) wearing a Type-B contact lens, (b) wearing a Type-D contact lens, (c) wearing a contact lens, an antenna and carrying a readout unit.

are professional healthcare workers who volunteered for this study. They have no professional relationship with the institutions running this study. The male participants are engineers who contributed to the development of this technology. None of the participants are habitual contact lens wearers. The body mass indices (BMI) of the participants are mostly within the healthy weight range to account for any possible effects of water loading. Participants provided written informed consent before participating in the study. The study protocol was approved by the Local Ethics Committee and was conducted in accordance with the principles of the Declaration of Helsinki.

2.3. Experimental design

Participants were instructed to refrain from drinking caffeine or alcohol, smoking, or performing strenuous activities for at least 2 h before the experiment. On the day of the experiment, participants were seated in a quiet, dimly lit room and rested for 15 min before the start of the experiment. The experiments were performed between 3:30 pm and 7 pm for consistency considering the effects of circadian rhythm. All the experimental activities explained below were performed during this time duration.

2.4. Measurement of baseline IOP

Goldmann applanation tonometry (GAT) measurements were performed on both eyes to establish a baseline IOP level. The average of three consecutive measurements was recorded as the baseline IOP. After the baseline IOP measurement, a soft contact lens with an embedded resonator-based sensor was placed on the left eye of each participant. The antenna was connected to the readout unit. Calibration steps for the readout electronics have been conducted and reference data were acquired using a Vector Network Analyser. The contact lens has always been placed on the left eye due to practical limitations in the experiment area. The antenna used in this study is better suited for left eyes because of the placement of its port as shown in Fig. 1c. The IOP was monitored for 30 min to establish a baseline in the sitting position. Then, a GAT reading of the right eye was conducted as another reference point before starting the water loading procedure.

2.5. Water loading and supine positioning

After obtaining the baseline IOP, participants were instructed to drink 1.5 L of water within 5–10 min to induce an acute increase in IOP. Influence of water loading upon IOP has been investigated in the literature with reported IOP increase by 2.24 mmHg increase among healthy young adults [17]. Immediately after water loading, participants were placed in supine position using a recliner seat. 4.1 mmHg increase in IOP was reported by changing body positions in the literature [18]. Hence, water loading and supine positioning were used as a way of intentionally increasing IOP in this work where IOP was monitored continuously for 30 min using the contact lens sensor and readout unit.

2.6. Measurement of post-intervention IOP

After the 30-minute monitoring period, the contact lens was removed, and GAT measurements were performed first on the left eye and then on the right eye within a couple of minutes after the removal of the contact lens to determine the post-intervention IOP level. All the participants wore their contact lenses consistently for a duration of 60–90 min that includes 30 min of baseline establishment and 30 min of measurements in supine position.

2.7. Limitations

Placing the contact lenses only on the left eye due to practical limitations may lead to a potential bias in the data. In addition, the sample size was relatively small and involved only healthy individuals. Therefore, the generalizability of the findings to other populations with ocular diseases or surgeries may be limited.

Continuous measurement of IOP inherently brings some challenges especially on fluctuation of measured parameters due to several factors including blinking, ocular pulse [8]. The effects of environmental and physiological parameters should be controlled or at least measured for control. These will be investigated in further studies.

Use of contact lenses may alter IOP measurements. Despite the effect being minimal, Pascal dynamic contour tonometry measurements has been shown to be affected when the subjects wear contact lenses [19].

The antenna in this study is currently connected to the readout unit through cables. While this setup posed no problems during the experiments in a controlled environment, it may cause discomfort for patients as they need to carry the readout unit connected to the antenna by cables. In the next generation, the need for the cable between the antenna and the readout unit will be eliminated. Instead, the size of the readout unit will be reduced to make it compact enough to be accommodated alongside the antenna within a wearable enclosure, similar to a head band.

3. Results

The experiments were conducted with a group of six healthy volunteers. The radii of curvature of the subjects were measured before each session as shown in Table 1. Three of the subjects wore sensor type-B and three others wore sensor type-D as shown in Fig. 1. Both sensors were manufactured using the same process and have the same thickness. The main difference is the geometry as shown in Fig. 1. All the subjects wore the contact lenses on their left eyes with a patch antenna placed around their eyes as shown in Fig. 1c. The antenna was connected to a readout unit that includes the electronic circuit measuring the resonant frequency of sensors.

The IOP levels measured by GAT before and after each experiment are presented in Table 1. Initial IOP measurements were taken within 30-minute time durations on both eyes before the participants wore the contact lens. The final IOP measurement was taken within a couple of minutes after the contact lens was removed at the end of the experiment. In addition to these measurements, IOP of the right eye was measured during the experiments before water loading as presented in Table 1.

The time traces of the sensor readings are presented in Fig. 2. In each plot, time instances for water loading and supine positioning are labelled in the figure.

The sensor readings are based on the frequency shift observed using the sensors and measured in the unit of MHz. These readings can be converted into mmHg using a calibration routine. Our proposed calibration routine is based on three measurements of IOP, an initial measurement before the contact lenses are fitted, a final measurement after the removal of the contact lens and an additional measurements while the participant is wearing the contact lens. The initial and final IOP measurements are taken from the eye where the contact lens is placed. The additional measurement after the contact lens is fitted can only be made on the free eye without the contact lens. Specifically in these experiments, this refers to the measurements on right eyes.

Based on this measurement and the initial measurements, the possibility of mapping the measured fluctuation into IOP levels in the units of mmHg was investigated. The time traces of the estimated IOP levels are shown in Fig. 3. The estimated IOP increase due to water loading and supine positioning was 3–4 mmHg for the experiments presented in Fig. 3.

4. Discussion

To our knowledge, only a few studies have investigated the use of resonator-based ocular sensors for monitoring IOP in humans. For example, De Smedt et al., reported a proof-of-concept study using a

Table 1
Details of the experimental parameters and the measurements during the experiments.

	Sensor Type	RoC, right (mm)	RoC, left (mm)	Initial IOP measurement, R-L (mmHg)	Final IOP measurement, R-L (mmHg)	IOP measurement before water loading, R (mmHg)
Subject 1 (47-year-old female, BMI: 24.7)	D-Type	7.97	7.92	16–16	24–22	14
Subject 2 (27-year-old female, BMI: 20.7)	D-Type	8.41	8.35	14–13	16–16	15
Subject 3 (45-year-old female, BMI: 22.2)	B-Type	8.14	8.11	14–14	16–15	14
Subject 4 (46-year-old female, BMI: 22)	B-Type	7.69	7.72	20–20	20–20	22
Subject 5 (47-year-old male, BMI: 25.9)	D-Type	8.14	8.15	12–13	23–23	12
Subject 6 (42-year-old male, BMI: 26.6)	B-Type	8.23	8.23	11–11	11–12	10

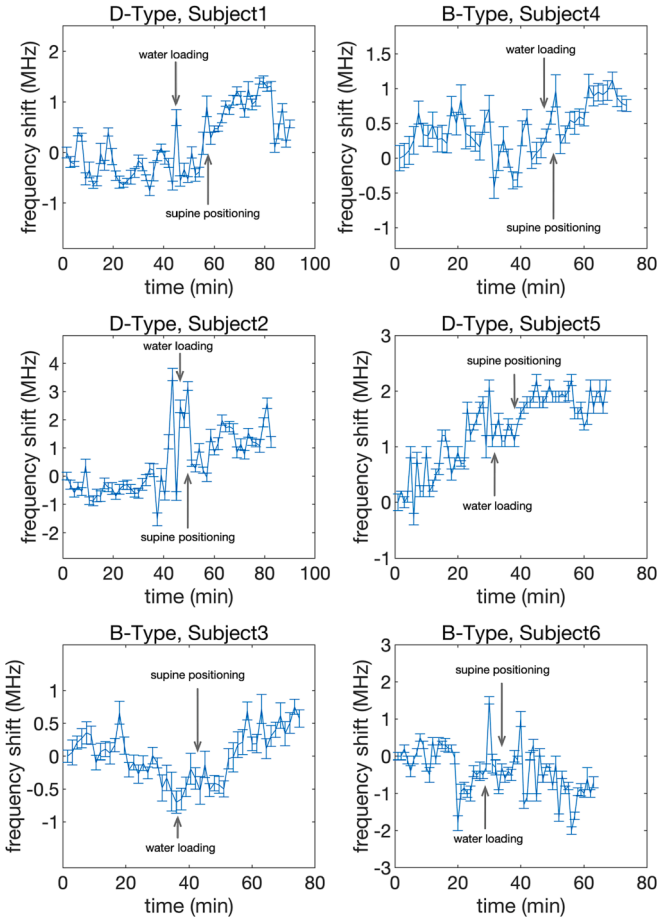

Fig. 2. Time traces of the readout data obtained during the experiments.

resonator-based sensor embedded in a soft contact lens for IOP monitoring in rabbits [20]. Pajic et al., demonstrated the feasibility of using a piezoelectric MEMS resonator for IOP monitoring in vitro [21]. However, to date, no study has investigated the use of a resonator-based ocular sensor embedded in a contact lens for monitoring IOP fluctuations induced by water loading and supine positioning in human subjects. Therefore, the present study aims to fill this gap in the literature and provide preliminary data on the performance of a resonator-based ocular sensor for IOP monitoring in human subjects. The results of this study could have important implications for the development of novel technologies for glaucoma diagnosis and management.

The initial experiments demonstrated that the contact lens and the antenna can be fitted easily. The collected results using two different sensor types show that the contact lenses respond to the effects of water loading. This is promising towards the use of the system for IOP monitoring. The original data are in the units of Hertz, reflecting the shift in the resonant frequency of the sensors. This can be converted into pressure units (mmHg) using a calibration routine. In a typical scenario, the clinician can measure the IOP using a tonometer right before fitting the contact lens and the initial measurement can be logged with the reading of the sensors. After the end of the session, another tonometer measurement can be made right after the contact lens is removed. The logged measurements can be used to map the contact lens measurements to estimated pressure values as shown in Fig. 3. In this initial study, the initial and final tonometer-based IOP measurements were complemented with an additional measurement from the eye without a contact lens during the experiments. The additional IOP measurements were in agreement with the estimated IOP values for the healthy participants in this study. The initial measurements are promising towards generating long-term continuous IOP profiles that can lead to better informed clinical decisions. Further experiments with larger cohorts of healthy individuals and patients are planned to investigate the accuracy and reliability of the sensor. The possibility of mapping will be investigated thoroughly and potential mapping methods will be evaluated for calibration of the sensors.

The key advantage of the introduced system as compared to the existing systems is based on the innovative sensor technology. The electrically passive sensor does not require external electrical energy for its operation. The sensor is interrogated using external antennas and the total current induced along the sensor is negligible during this period. This configuration is practically very advantageous as the need for electrical sources is eliminated. More importantly, the sensor is safe to wear as a contact lens.

Based on a metallised polymeric substrate, the contact lens-based sensor is simple to manufacture and cost effective to implement. The sensor comprises a single metallic layer that can be patterned using conventional methods. The manufacturing process is suitable for mass production methods such as roll-to-roll processing and printing. In addition, standard materials and curing processes are used for contact lens manufacturing where embedding the metallic sensors inside the contact lenses are easy to achieve.

The selection of standard and biocompatible materials and processes not only guarantee a cost-effective solution, but they also prove to be comfortable for the patients. The elasticity, water content and oxygen permeability of the contact lenses will be further optimised to guarantee both non-invasive and comfortable operation.

Several studies have investigated the diagnostic performance of contact lens sensors in detecting glaucoma progression by monitoring IOP fluctuations. Gaboriau et al., reported that contact lens sensors showed high diagnostic performance in detecting glaucoma progression compared to standard methods of IOP measurement [22]. Similarly, Tan et al., revealed that ultra-short-term IOP fluctuations detected by contact lens sensors were associated with disease progression in primary

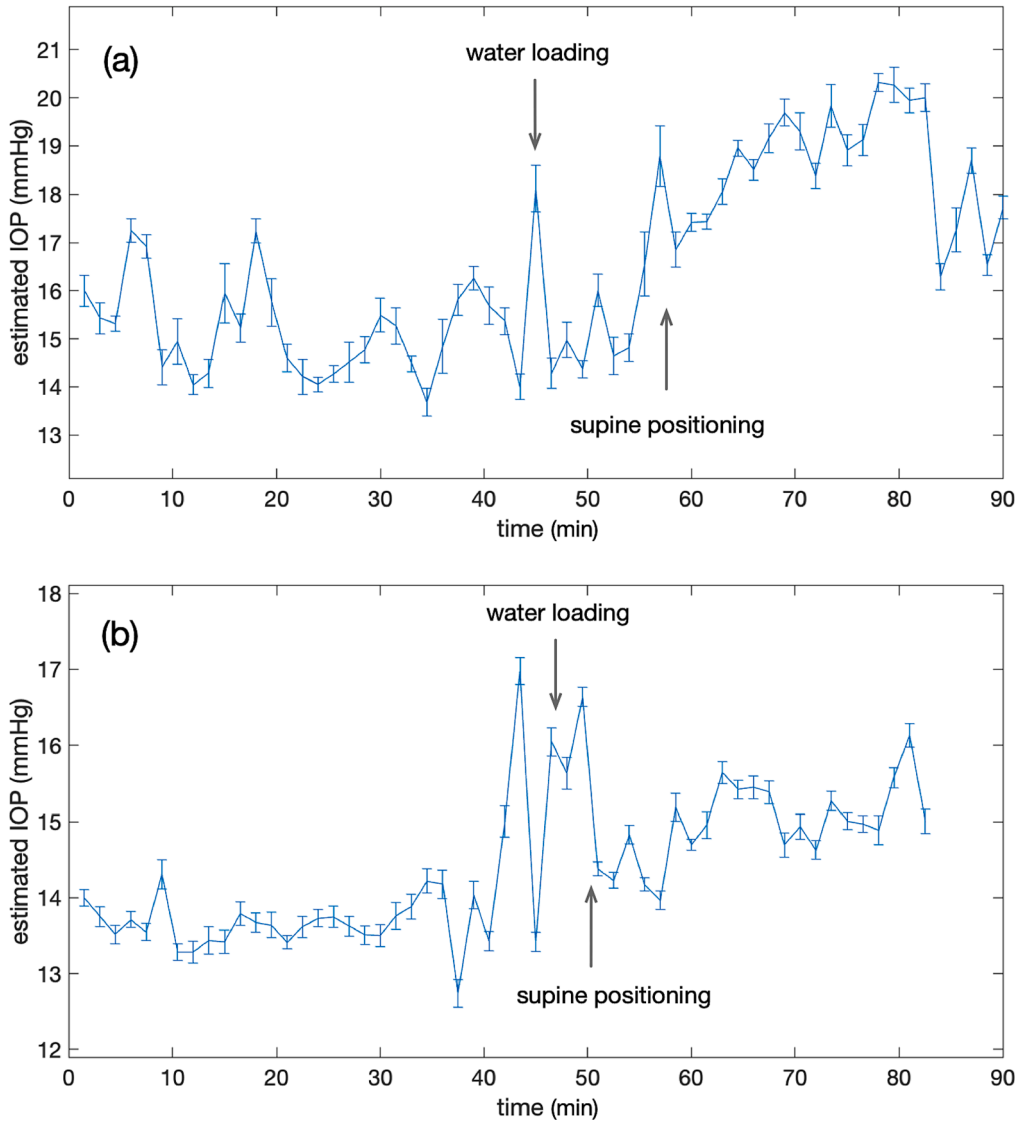

Fig. 3. Variation of the estimated IOP for the data collected using the D-Type sensors during the experiments for a) Subject-1 b) Subject-2.

angle-closure glaucoma patients [23].

Other studies have investigated the effect of daily activities on IOP-related variations in open-angle glaucoma patients [24] and diurnal spikes of IOP in uveitic glaucoma [25]. In addition, Mansouri and Gillmann studied the intereye symmetry of 24-hour IOP-related patterns in untreated glaucoma patients using contact lens sensors [26]. These studies highlight the potential utility of contact lens sensors in understanding the complex nature of IOP fluctuations in glaucoma.

Furthermore, contact lens sensors have been used to explore the nyctohemeral IOP-related pattern in normal-tension glaucoma and healthy eyes [27], as well as to identify primary open-angle glaucoma patients with IOP constantly below the diagnostic threshold [28]. These studies suggest that contact lens sensors may have a role in identifying patients who are at high risk of developing glaucoma or who require closer monitoring.

Interestingly, Tojo and Hayashi investigated the influence of ocular dimensional change on 24-hour IOP measurement with contact lens sensors and the potential use of contact lens sensors in predicting the success of trabeculectomy surgery [29,30]. Also, Karadag et al., evaluated the 24-hour IOP and systemic blood pressure at the same time [31]. These studies suggest that contact lens sensors may have a wider application beyond glaucoma management.

Finally, Rabensteiner et al., investigated the influence of electromagnetic radiation on the measurement behaviour of the Triggerfish contact lens sensor, highlighting the importance of ensuring the safety of contact lens sensors before they can be widely used in clinical practice [32].

5. Disclosure

H.T., G.D. and A.D.Y are shareholders in Glakolens A.S.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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