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Non-Invasive IntraOcular Pressure Monitoring with Contact Lens

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Synopsis

A novel, inexpensive, non-invasive intraocular pressure monitoring system was created to track the intraocular pressure. Utilizing micro-fluidics embedded into a contact lens that the patient can wear throughout the day to track the intraocular pressure.

Key words: Glaucoma, Intraocular Pressure, Micro-fluidics

Abstract

Background: Glaucoma is the second leading cause of blindness in the world and the first leading cause of irreversible vision loss. Currently the primary methodology of testing for the intraocular pressure (IOP) is during clinical office hours, which only provide a limited amount of information on the trends and fluctuations of the IOP. Therefore, a continuous monitoring system is required to properly determine the peaks of pressure and to negate any false results obtained by sparse, clinic hour testing. The objective of this study is to determine the ability of a newly designed contact lens with an embedded microchannel, to accurately measure the fluctuations in the IOP.

Methods: Experimentation was completed on fresh enucleated porcine eyes. The contact lens was placed on the porcine eye and utilizing a camera the fluid movement, within the microchannel in the contact lens, was recorded. A micro pressure catheter threaded into the center of the vitreous chamber, recorded the true intraocular pressure and was compared to the displacement of the indicator fluid within the microchannel.

Results: The contact lenses showed a consistent linear responsiveness to changes in IOP and robust to the effects of anatomic differences among eyes. The indicator fluid had an average fluid movement of 28 $\mu\text{m}/\text{mmHg}$ between all the trials. Additionally, the devices showed the ability to measure both increases and decreases in IOP during cyclical fluctuations.

Conclusion: The described inexpensive and non-invasive sensor is able to reliably monitor the IOP changes based on porcine eye model.

Introduction

Glaucoma is an optic neuropathy in which retinal ganglion cell death occurs leading to progressive vision loss [1] [2]. This disease is the second leading cause of vision blindness in the world with an estimation of 76 million people with the disease by 2020 [3]. The most important modifiable risk factor for glaucoma is intraocular pressure (IOP); careful monitoring of IOP is a major factor in monitoring the progression of the disease and disease management [4] [5]. IOP levels are a result from a complex interplay of factors influencing the flow of the eye's internal fluid, known as aqueous humor. The aqueous humor brings nutrients to the eye and is central to maintaining eye shape for proper light refraction [6]. In healthy eyes, the aqueous humor drains out of the eye via the trabecular meshwork; however, in individuals with glaucoma there is often increased resistance to outflow and consequently raised IOP. The IOP has been determined to fluctuate throughout the day based on diet, exercise, water intake and more; with higher levels found when patients are in the supine position and the peak IOP measurements in the early mornings [7].

To achieve precise IOP tracking, a continuous monitoring system is required to determine the IOP profile over time for individual patients. Importantly, the shape of the eye changes in response to changes in IOP. This response was exploited to develop a novel, non-invasive contact lens-based device that responds to changes in corneal curvature and directly relates the device deformation to IOP. The device consists of a contact lens with an embedded microchannel, which contains an indicator fluid that moves along the microchannel in response to changes in IOP. Utilizing the pure mechanics of the eye and capturing this phenomenon with a microfluidic channel allows for the price of manufacturing the device to be comparable to that of an average contact lens on the market [8]. A series of experiments using porcine eyes were conducted to evaluate the performance of the new device. Overall, the devices showed linear responsiveness to changes in IOP that was consistent across separate devices and robust to the effects of anatomic differences among eyes. Additionally, the devices showed the ability to measure both increases and decreases in IOP during cyclical fluctuations. The described novel, non-invasive, inexpensive device holds promise for improving the monitoring of IOP and preventing glaucoma-associated vision loss.

Goldmann applanation tonometry (GAT) is the current standard for monitoring the IOP [9]. This office-based procedure uses a device that measures the force required to flatten a specified area of the cornea. GAT requires local anesthesia and a trained eye care professional to perform the test. As a result, patients with glaucoma generally have their IOP measured in a clinic setting, in an upright position, every few months and only within typical office hours. However, IOP levels have been found to vary as much as 10 mmHg or more in a single day [7]. Invasive IOP measuring systems have also been described; however, their clinical applicability is limited [10] [11]. Recently, a continuous monitoring contact system, the Sensimed Triggerfish contact lens, has been approved for marketing. This device is designed to detect changes in eye shape induced by changes in intraocular pressure, but appears to provide data on relative changes in intraocular pressure rather than absolute intraocular pressure [12].

. The novel device described in this paper allows for accurate, non-invasive IOP monitoring using cell phone, rather than a specialized device, which makes it more affordable and easier to

access to both patients and physicians. Also the device is tracked optically decreasing any recorded errors that can occur during the patient’s daily lifestyle from such things like blinking.

Method

Previous work has shown that the radius of curvature of the cornea changes as IOP changes [12] [13]. Based on this information, a 250um thick polydimethylsiloxane (PDMS) soft contact lens was manufactured with an embedded 100 um wide by 100 um thick microfluidic channel (Figure 1). Different reference markers were embedded directly into the mold to test the ease of use during post-processing analysis. The inlet an outlet of the microchannel was tapered to allow for an ease of manufacturing when injecting the fluid into the microchannel.

Insert Figure 1 here

Figure 1: A detailed illustration of the contact lens manufactured to monitor the IOP utilizing micro-fluidics. Changes in IOP induce changes in the corneal curvature which deforms an embedded microchannel and displaces the indicator fluid. Reference markers of known length is used to calibrate displacement measurements. Image capture and analysis allows for the calculation of changes in IOP.

The flexible material properties of the PDMS along with the channel design allow for the device to capture the fluctuating corneal curvature by a correlating fluctuation in the internal volume of the channel. An incompressible fluid is partially filled within the microchannel providing visual indication of the microchannel’s changing volume as the fluid will displace in reaction to any volume change [14] (Please see detailed analytical reasoning in the supplementary document). Figure 2 illustrates the movement of the indicator (the end of the fluid in the channel, highlighted in light yellow) at four different IOP levels (please see the induced movement of flow in the supplementary video). Importantly, in the planned final product, patients will wear the contact lens throughout the day and use a cell-phone camera to take images of the contact lens at various times throughout the day. The whole system is very compact with no components affected by body position thus making it simple to read the information from the contact lens at any time of day in either an upright position or supine position. A cell-phone app will be used for post-processing of the image to determine the location of the fluid compared to a reference frame built into the contact lens and output IOP readings quickly and accurately.

Insert Figure 2 here

Figure 2: Example of fluid indicator moving to different locations at different IOP levels.

Fabrication Process

The contact lens was manufactured using a casting process; with the mold components manufactured using a Model 363-S Micro-Milling Machine, with a feed rate of 8000 rpm. PDMS was used as the main material for the contact lens device for its flexibility, gas permeability and is a known FDA approved biocompatible material, already used to manufacture soft contact lenses [15]. The elasticity of the PDMS can be modified base on the amount of pre-polymer base and curing agent used. The ratio of PDMS used was optimized to have as low an elastic modulus possible without the presence of the adhesive properties that can occur [16]. First, PDMS pre-polymer base and curing agent were mixed at a ratio of 15:1 and poured into a mold [17]. The mold was placed in a vacuum chamber for 40 min for degassing, until all the air bubbles disappeared. The mold was placed into the oven at 65°C for 40 minutes and was

cooled to room temperature and then released from the mold. A thin, 100 μm , top layer was created using a similar casting process, with a smooth mold [8]. The two pieces of PDMS were surface treated using a Corona Treater, from Electro-Technic Products Inc., then bonded together for a total lens thickness of 250 μm [18]. Dyed biocompatible avocado oil, the indicator fluid, was then injected into the 100 μm diameter microchannel and one side of the channel was sealed with PDMS while the other was left open to the atmosphere. Avocado oil was the preferred indicator fluid utilized due to its heavy molecule structure making it unable to evaporate out of the PDMS contact lens while still having enough colour to visually track its movement throughout the channel. Future work will be completed on optimizing the indication fluid used within the contact lens. The indicator fluid was positioned far enough away from the opening so that there was no risk of the indicator fluid leaking out of the microchannel.

Enucleated Porcine Eye Experimentation

The contact lens-based IOP monitoring device was evaluated in a series of experiments to test: the repeatability of the manufacturing each contact lens, the repeatability of contact lenses between porcine eyes and the accuracy of the contact lenses to capture the increase and decreases in the IOP. All studies used fresh enucleated porcine eyes, chosen for their similar shape and mechanical properties to that of human eyes [13]. The stress-strain patterns between human eyes and porcine eyes are very similar, however there are variations in the stress-relaxation patterns. To improve the accuracy of the experimentation, the testing was performed with a slow and constant stress applied with the contact lenses directly measuring the strain [19]. To mitigate any unwanted affects from the eye drying out and to add a tear layer into the system design, water was dripped onto the porcine eye throughout the experiments.

The porcine eye was prepared and placed on an eye holder with a loose fit as to allow for the eye to expand without any unwanted force applied, in turn affecting the IOP. Tubing directly connected to a syringe pump was inserted in the sclera of the eye. The syringe pump, filled with water, was used to manually simulate the increase of the IOP at a controlled rate between 10 to 34 mmHg. The real time IOP was monitored with a Miller Micro-Tip Pressure Catheter Transducer treaded into the other side of the porcine eye's sclera. The contact lens was placed onto the centre of the cornea and the top view and side view of the eye were recorded throughout the experiment. The side view of the eye was used to ensure the contact lens had proper connection and placement to the eye and that the deformation of the eye's curvature does occur; while the top view recorded the indicator fluid movement.

Results

First, to evaluate reliability, responsiveness and inter-device agreement, three separate contact lens devices were tested 2 times on a single eye. At baseline and at every 2 mmHg step increase in IOP, an image of the contact lens IOP monitoring device was captured. The absolute displacement of the indicator fluid was calculated by comparing to the reference markers included as part of the contact lens device (Figure 1). For all devices and trials, the indicator fluid showed a similar linear relationship between fluid displacement and IOP (Figure 3). The average fluid displacement between the trials was 28.5 $\mu\text{m}/\text{mmHg}$ with a standard deviation of 2.4. The small differences between devices in indicator fluid movement may have resulted from inconsistencies introduced in fabrication, the effects of positioning of the lens on

the eye or small errors introduced by the micro-catheter pressure transducer used to determine the gold standard IOP measure.

Insert Figure 3 Here

Figure 3: Indicator displacement with changes in intraocular pressure (IOP) - Agreement among individual devices. The indicator fluid positions of three devices were recorded as IOP was increased from 10 mmHg to 34 mmHg. The testing was conducted 2 times and the average of the tests was recorded.

To evaluate the ability of the contact lens device to reliably capture the IOP of different eyes, a single device was tested on three eyes. The three tested eyes had different corneal size, shape and thickness, as well as the biomechanical properties from each other, which represented the typical variations from eye to eye. Similar to the previous experiment the indicator fluid was analysed at baseline and at every 2mmHg increase in IOP. For all eyes the indicator fluid movement showed a linear relationship with increasing IOP at the slopes of 26.4, 29.3, and 28 $\mu\text{m}/\text{mmHg}$ for the eye 1, 2 and 3. The response was similar between the three eyes (See Figure 4) and gave an average fluid movement between the trials of 27.9 $\mu\text{m}/\text{mmHg}$ with a standard deviation of 1.5. The consistent results demonstrated the robustness of the proposed IOP sensor to physiological variations, i.e., the sensor could provide reliable IOP measurement to different eyes. Based on the experimental results, it may be concluded that the flexibility of the contact lens was able to overcome the variations in the physiology between the porcine eyes.

Insert Figure 4 here

Figure 4: Indicator displacement with changes in intraocular pressure (IOP) - Agreement across different eyes. The indicator fluid of a single contact lens was recorded on three different enucleated eyes, as the IOP was increased from 10 mmHg to 34 mmHg. The testing was conducted 2 times and the average of the tests were recorded.

To accurately track the fluctuations in the IOP throughout the day, the device must allow indicator fluid travel in an anterograde direction with increases in IOP and a retrograde direction with decreases in IOP, over multiple cycles. Therefore, to evaluate this capability, IOP was sequentially cycled between 10 mmHg and 40 mmHg for a total of 4 cycles and the indicator fluid position monitored (Figure 5). There were noticeable differences in results depending on the tracking point of the indicator fluid used. The outer tracking point yielded more consistent results (Figure 5 left graph) compared to the inner tracking point (Figure 5 right graph) due to micro fluid retention which affected the effective volume of the indicator fluid. As the fluid retention within the channels increase - with multiple trials- the decrease in the initial volume of the indicator fluid. This affects the accuracy of the fluid based on which point in the indicator channel is being tracked.

Insert Figure 5 here

Figure 5: Ability of devices to measure fluctuating IOP. IOP was sequentially cycled between 10 mmHg and 40 mmHg four times. The ability of the indicator fluid to return to the same positions when the pressure was decreased and increased was recorded. There was a maximum variance in the indicator position between the different trials of 56.7 μm when the pressure was 10 mmHg and 67.6 μm when the pressure was 40 mmHg. The indicator fluid was able to return over 92% of the way back to the original position after each cycle.

There was a decrease in indicator travel distance after the first cycle, but during subsequent cycles, the indicator fluid was able to maintain consistent travel distances. The indicator fluid was able to return 92% of the way back to the original position for the outer tracking point and 85% for the inner tracking point.

Discussion and Conclusion

Overall, the need for an improved methodology in tracking the IOP fluctuations throughout the day is required for a higher quality approach to monitor the progression of glaucoma. Capturing the changing corneal curvature, as a direct result in the fluctuating IOP, with an altered soft contact lens provides an inexpensive, quick and easy way to track the IOP. The contact lens-based IOP monitoring device evaluated in this report appears able to provide robust measures of changes in IOP. The indicator position is linearly responsive, highly sensitive and provides consistent measures across multiple porcine eyes and individual fabricated devices. Although the ability of the device to provide reproducible measurements in a variety of eyes with different shapes and sizes is encouraging, future research will be important in addressing the full impact of variations in corneal biomechanics across the population.

An important limitation of the current design is the need for calibration in order to establish absolute as well as relative IOP measures. It is hoped that design refinements and large scale testing to develop multivariable nomograms will address this issue. Other limitations include the inability to measure IOP during sleep and the need to refine the polymers used in order to improve tolerability in the human eye.

Promising planned refinements include the use of a mobile phone camera to take images of the contact lens to determine indicator position and a mobile phone application capable of providing real time IOP information. Innovations that will allow consistent and frequent IOP monitoring are a key goal in glaucoma care that would allow physicians to better treat patients with this disease. The novel non-invasive contact lens-based device evaluated here can be manufactured at low cost and holds promise in the prevention of glaucoma-related vision loss and blindness.

Article Information

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Author Contributions

Angelica Campigotto contributed to the redesign of the work, preformed the experimentation, analysis and contributed to the interpretation of the data. As well as contributed to the writing of the manuscript. Dr. Stephane Leahy contributed to the redesign of the concept and the experimentation working with the planar model of the design. Dr. Guowei Zhao contributed to the analysis and framework of the planar analytical model used to interpret the deformation of the system. Dr. Robert J. Campbell (MD) contributed substantial revisions to the manuscript of the lab and provided necessary training for experimentation to be properly conducted. Dr. Yongjun Lai supervised the entire project, contributed to the initial concept design, the design of the experimental testing and interpretation of the data, and the revisions of the manuscript.

Conflict of Interest Disclosures:

There are patents on the contact lens concept, PN 20170280997, which Yongjun Lai, Kongying Xie and Robert J Campbell are co-inventors.

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Figure 1: A detailed illustration of the contact lens manufactured to monitor the IOP utilizing micro-fluidics. Changes in IOP induce changes in the corneal curvature which deforms an embedded microchannel and displaces the indicator fluid. Reference markers of known length is used to calibrate displacement measurements. Image capture and analysis allows for the calculation of changes in IOP.

110x80mm (300 x 300 DPI)

Figure 2: Example images showing the fluid indicator moved to different locations at different IOP levels.

88x65mm (300 x 300 DPI)

Figure 3: Indicator displacement with changes in intraocular pressure (IOP) - Agreement among individual devices. The indicator fluid positions of three devices were recorded as IOP was increased from 10 mmHg to 34 mmHg. The testing was conducted 2 times and the average of the tests was recorded.

84x88mm (300 x 300 DPI)

Figure 4: Indicator displacement with changes in intraocular pressure (IOP) - Agreement across different eyes. The indicator fluid of a single contact lens was recorded on three different enucleated eyes, as the IOP was increased from 10 mmHg to 34 mmHg. The testing was conducted 2 times and the average of the tests were recorded.

87x80mm (300 x 300 DPI)

Figure 5: Ability of devices to measure fluctuating IOP. IOP was sequentially cycled between 10 mmHg and 40 mmHg four times. The ability of the indicator fluid to return to the same positions when the pressure was decreased and increased was recorded. There was a maximum variance in the indicator position between the different trials of 56.7 um when the pressure was 10 mmHg and 67.6 um when the pressure was 40 mmHg. The indicator fluid was able to return over 92% of the way back to the original position after each cycle.

203x78mm (300 x 300 DPI)

Supplementary Information

Volume Change Calculations

A simple volume change analytical model was conducted to determine the affect of the embedded micro-channel when deformation occurs in a planar model. From the analysis it was determine that the micro-channel increases in volume as a uniaxial force is applied. Figure S1 illustrates the simplified planar model with labeled dimensioned used for the preliminary calculations.

Figure S 1: Illustration of the model used to create the analytical calculation of the volumetric deformation of the embedded micro-channel.

Equation 1 and 2 are used to determine the volumetric strain of the system.

Equation 1:

$$\alpha = \frac{HL - hl}{HL}$$

Equation 2:

$$\frac{\Delta V}{V_0} = \frac{\epsilon_0}{\alpha} (1 - 2\nu) + \frac{\epsilon_0^2}{\alpha^2} (\nu^2 - 2\nu) + \frac{\nu^2 \epsilon^3}{\alpha^3}$$

The change in volume plotted against the strain was calculated and displayed in Figure S2. Similar dimensions to the contact lens and assigning the same Polydimethylsiloxane (PDMS) material, with an assumed poisson's ratio of 0.49 was used to complete the calculations [1].

Figure S 2: The planar model strain plotted against the change in volume. A positive parabolic trend can be shown for strains below a strain of 0.15. As the strain is below 0.15 the change in volume is increased however when the strain applied is greater than 0.15 the change in volume begins to decrease. This analysis was used to give insight to the deformation of the contact lens therefore the strain rate is assumed to be very low and thus it can be assumed that the volume of the contact lens will increase.

It can be illustrated that under small strains of 0.15 and under the change in volume follows a parabolic trend where the change in volume increases. While after the strain reaches around 0.15 the volume decreases. Since the contact lens will only be under a small amount of strain from the deformation of the eye, the volume is assumed to increase, based on the planar model. Therefore, we expected the 3D prototyped microchannel embedded in the contact lens would also increase volume when IOP increased, i.e., when IOP increases, the indicator fluid moves away from the outlets/inlets, which was proved to be true from our experimental testing (see the Supplementary Video showing the movement of the indicator fluid along the IOP changes).