A DEVICE FOR SELF-MEASUREMENT OF INTRA-OCULAR PRESSURE AND METHOD OF USING THE SAME

TECHNICAL FIELD

The present disclosure generally relates to intra-ocular pressure (IOP) measurements, and more specifically to a self-tonometry device for monitoring and measuring intra-ocular pressure (IOP).

BACKGROUND

Glaucoma is the second most common cause of blindness in the world and is expected to affect up to 111.8 million people worldwide by 2040. Glaucoma may be characterized by irreversible optic nerve damage. Whilst studies demonstrate significant risk factors associated with glaucoma including older age, migraine, gender, ocular trauma and diabetes mellitus, the elevated intraocular pressure (IOP) remains the only modifiable risk factor. Strategies for treating glaucoma are centered at reducing the IOP. Consequently, IOP monitoring is the single most important measurement for detecting and assessing glaucoma in the eyes of a patient.

The current gold standard for measuring IOP is Goldmann Applanation Tonometry (GAT), which is a slit-lamp mounted IOP measurement device typically requiring topical anesthesia and performed by a trained ophthalmologist. Despite these limitations, probably the single most important shortcoming is that the GAT IOP measurement represents a single 2 - 3 second "snapshot" of a patient's IOP. However, there may be a normal diurnal variation of IOP, which may fluctuate even more so in eyes with glaucoma. These fluctuations may have significant inter-individual variation depending on age, activities and medical co-morbidities.

Due to these diurnal IOP variations, a measurement of the maximum IOP may easily be missed when the patient is not in the clinic. Furthermore, studies have shown that the amplitude of IOP fluctuations and maximum IOP may be associated with glaucoma progression. This may explain why the vision of one-third of glaucoma patients may continue to worsen despite seemingly adequate IOP control and reduction.

In view of the above, there is therefore a need for a self-administered, highly reproducible IOP-measuring device that permits continuous monitoring of IOP.

SUMMARY

There is thus provided, in accordance with some embodiments of the present disclosure, a self-tonometry device for measuring intra-ocular pressure (IOP) in an eye of a subject. The self-tonometry device may include a plurality of sensors, a powered force mechanism and a processor for determining the IOP in the eye. The plurality of sensors may be arranged in an array for measuring a plurality of pressures at positions on the eye of the subject corresponding to the positions of the plurality of sensors. The powered force mechanism may be configured to generate a force and transmit this force to the array when the array is contacting an eyelid of the subject. The processor may be configured to receive the plurality of pressures measured from the plurality of sensors in the array, and to determine the IOP in the eye.

The powered force mechanism may include an actuator, configured to generate the force. The powered force mechanism may further include a force-transfer assembly, configured to transmit said force to the array, when said array is in contact with the eyelid of the subject. In some embodiments, the actuator may be a mechanical actuator or an electromechanical actuator. According to some embodiments, the mechanical actuator or the electromechanical actuator may comprise a motor having a constant oscillating or rotating speed thereby generating the constant force. According to some embodiments, the device may further comprise a second force mechanism. Optionally, said second force mechanism may comprise one or more resilience means. Optionally, when the force is applied to the eyelid, the force applied on the peripheral of an eyeball may be 5 N or less. The first force mechanism comprising the actuator described above and the second force mechanism may advantageously provide synergistic effects including transmitting force and maintaining the magnitude of the force such a constant force is applied to any of the point on the outer surface of the eyelid in contact with the sensor.

According to some embodiments of the present disclosure, the processor may be configured to execute a machine learning module and is configured to receive the plurality of pressures measured from the array of the plurality of sensors as an input to the machine learning module, and to determine using the machine learning module, the IOP in the eye. The machine learning module may comprise an artificial neural network model or a random forest model. Optionally, the artificial neural network may be trained and calibrated by comparing the plurality of pressures measured by the plurality of sensors to true IOP measured using a reference device. Optionally, the device may further comprise a display

for displaying the IOP or other metrics. According to some embodiments of the present disclosure, the plurality of pressures at respective positions on the eye of the subject may be multiple pressure readings from different positions used to improve the accuracy of the intra-ocular pressure measurement.

Further, there is provided a method for measuring IOP in an eye of a subject, the method comprising generating a force, in a powered force mechanism, and transmitting the same to an array of a plurality of sensors, when said array is in contact with an eyelid of the subject, measuring a plurality of pressures at positions on the eye of the subject using the array, said positions corresponding to the plurality of sensors and in a processor, receiving the plurality of pressures measured from the array of the plurality of sensors and determining the IOP in the eye. The powered force mechanism may include an actuator, configured to generate the force. The powered force mechanism may further include a force-transfer assembly, configured to transmit said force to the array, when said array is in contact with the eyelid of the subject.

According to some embodiments of the disclosure, the processor may be configured to execute a machine learning module and to receive the plurality of pressures measured from the array of the plurality of sensors as an input to the machine learning module, and to determine using the machine learning module, the IOP in the eye. The machine learning module may comprise an artificial neural network model or a random forest model. Optionally, the method may further comprise training the artificial neural network by comparing the plurality of pressures measured by the plurality of sensors to true IOP measured using a reference device or a reference method. The method may further comprise calibrating the artificial neural network using gradient descent. According to some embodiments of the disclosure, the calibration may be undertaken per subject.

Since the size of the device disclosed herein resembles a disposable cup and ease of use of the device, such a device is suitably designed for home use and it requires minimal assistance from a healthcare professional (or a trained individual). Further advantageously, the device disclosed herein may work in any position to produce reliable and reproducible measurement readings. Still advantageously, the device and the system comprising the device disclosed herein may perform the measurements with no direct contact with the eyeball thus potentially mitigating medical complications. Since absolute IOP measurements may be performed, a more accurate result using the device disclosed herein may be achieved.

BRIEF DESCRIPTION OF THE DRAWINGS

The present disclosure will be understood and better appreciated from the following detailed description taken in conjunction with the drawings. Identical structures, elements or parts, which appear in more than one figure, are generally labelled with the same or similar number in all the figures in which they appear. Some non-limiting embodiments or features of the disclosed subject matter are illustrated in the following drawings.

In the drawings:

Fig. 1 schematically illustrates an isometric view of a hand-held self-tonometry device, in accordance with some embodiments of the present disclosure;

Figs. 2A and 2B, each illustrates a block diagram depicting the hardware structure of the self-tonometry device, in accordance with some embodiments of the present disclosure;

Figs. 2C and 2D schematically illustrate a side view of the hand-held self-tonometry device showing the internal components of the device within the housing, in accordance with some embodiments of the present disclosure;

Fig. 3A schematically illustrates a side view of an eye and a self-tonometry device before sensors contact an eyelid, in accordance with some embodiments of the present disclosure;

Fig. 3B schematically illustrates a side view of an eye and self-tonometry device while sensors contact an eyelid, in accordance with some embodiments of the present disclosure;

Fig. 4 schematically illustrates a front view of an eye with exemplary positions of sensors on an eyelid, in accordance with some embodiments of the present disclosure; and

Fig. 5 schematically illustrates a block diagram of a self-tonometry system, in accordance with some embodiments of the present disclosure.

Identical or duplicate or equivalent or similar structures, elements, or parts that appear in one or more drawings are generally labelled with the same reference numeral, optionally with an additional letter or letters to distinguish between similar entities or variants of entities, and may not be repeatedly labelled and/or described. References to previously presented elements are implied without necessarily further citing the drawing or description in which they appear.

Dimensions of components and features shown in the figures are chosen for convenience or clarity of presentation and are not necessarily shown to scale or true

perspective. For convenience or clarity, some elements or structures are not shown or shown only partially and/or with different perspective or from different point of views.

DETAILED DESCRIPTION

Some embodiments of the present disclosure provide a self-tonometry device for measurement of intra-ocular pressure (IOP) in the eye of a subject. The self-tonometry device may use a plurality of pressure sensor measurements measured by a respective plurality of sensors arranged in an array that may be guided to contact the outside surface of an eyelid of a subject. A powered force mechanism such as component 22 shown in Fig. 1 is configured to generate a force and transmit the same to the array, when the array contacts the outside surface of the eyelid, said force is applied through the eyelid onto an eye of the subject. The plurality of pressure sensors may measure a respective plurality of pressures at the respective positions along the eyeball at the inner surface of the eyelid substantially opposite to the sensor array on the outer surface of the eyelid. The self-tonometry device may compute the IOP based on the plurality of pressure sensor measurements measured through the eyelid.

Fig. 1 schematically illustrates an isometric view of a hand-held self-tonometry device 30 in accordance with some embodiments of the present disclosure. As can be seen from Fig. 1, the array of sensors 20, a second force mechanism 24, and an actuator are shown.

Fig. 2A illustrates the hardware structure of the self-tonometry device, in accordance with some embodiments of the disclosure. As can be seen from the simplified block diagram, the signal from the sensor of array may be amplified, filtered and digitalized by an analog-to-digital conversion module (ADC within circuits electronics). The converted signal that may be provided in the form of data may be sent to a device. Such a device is not limited to a smartphone or a mobile phone of the user. The data may be sent wirelessly for example via Bluetooth to a user interface (an application). In some embodiments, the data may be sent over a wire-based communication technology (see Fig. 2B) for example via SPI/I2C.

Figs. 2C and 2D depict a side view of the hand-held self-tonometry device described in Fig. 1 showing the internal components found within a housing of the device.

Fig. 3A is a side view of an eye 10 and a self-tonometry device 30 before sensors 20 contact an eyelid 15, in accordance with some embodiments of the present disclosure. As previously described, self-tonometry device 30 may include an array of a plurality of sensors 20. Eye 10 may include an eyebrow 17 and eyelashes 19 on eyelid 15.

A force mechanism such as a powered force mechanism may be used to generate a force and transmit the same to the array such that the array of the plurality of sensors 20 is being pressed into eyelid 15 using a force-transfer assembly 25 so as to allow sensors 20 to contact eyelid 15 to perform pressure measurements on an eyeball 12 of eye 10 through eyelid 15. In some embodiments, while powered force mechanism is preferred, other suitable force mechanism such as a non-powered one may also be used provided it allows generation of constant force. The IOP measurements are performed when the eyelids of the subject are closed. As shown in an enlargement 16 of Fig. 3A, pressure sensors 20 contact an outer surface 15A of eyelid 15 to perform pressure measurements on eyeball 12 opposite an inner surface 15B of eyelid 15. The gap shown in enlargement 16 between inner surface 15B and eyeball 12 is shown merely for visual clarity, and it should be clear to one skilled in the art that eyeball 12 is typically in contact with inner surface 15B. In the present disclosure, the force mechanism or the powered force mechanism may be referred as the first force mechanism or the first powered force mechanism.

In some embodiments, the force mechanism or the powered force mechanism may include one or more resilience means 36 (see Fig. 2D). One of the examples of resilience means includes spring 36 or spring release. Accordingly, the force mechanism or the powered force mechanism may include one, two, three, four, five, six or more springs. When two or more springs are employed, the two or more springs may be spaced such that the force generated and transmitted to the eye is constant.

In some embodiments, the powered force mechanism comprises an actuator 32 (see Fig. 2D). In some embodiments, the powered force mechanism may comprise two or more actuators 32. In some embodiments, the actuator is a mechanical actuator or an electromechanical actuator. In some embodiments, the actuator is configured to generate force. Advantageously, the actuator may transmit a constant force such that the variability in the pressing step or transmitting the force may be mitigated or at least minimized. According to some embodiments of the present disclosure, the powered force mechanism further comprises a force-transfer assembly 25 and said force-transfer assembly 25 is configured to transmit said force to the array of the sensors, when said array is in contact with the eyelid of the subject. In some embodiments, the force-transfer assembly 25 may be coupled to the actuator. In some embodiments, the mechanical actuator or electromechanical actuator comprises a motor having a constant oscillating or rotating speed. In some embodiments, the constant oscillating or rotating speed or depth of the motor may generate

constant force. In some embodiments, as shown in Fig. 2A or 2B, a DC motor is used to provide motion control to a stepper motor 34, enabling a controlled consistent force and speed during each measurement. Advantageously, this renders the measurement by the device 30 is highly repeatable and non-user dependent. As previously mentioned, the constant force delivered may minimize the variability in the measurement of the IOP. Such a constant force, advantageously, may result in that the variability in the measurement of the IOP is solely due to the reactive force from the cornea and/ or eyelid to the sensor. This is advantageous as the typical self-tonometry relies upon the ability of the user to manually depress the device to deliver constant force. Manually pressing the force-transfer assembly may cause the fluctuations in the force transmitted and thus errors in the IOP reading obtained. Thus, advantageously the device described in the present application may provide reproducible readings.

In some embodiments, the self-tonometry device may include a second force mechanism. In some embodiments, the self-tonometry device may include a second force mechanism and a third force mechanism. Unless specified otherwise, if the terms “second force mechanism and “third force mechanism” are not stated in conjunction with the word “powered”, it is to be understood that the force in such force mechanism is generated manually (for example the action of depressing parts or components of the device against subject’s facial features around the peripheral of the eyeball). In some embodiments, each of the second and third force mechanisms may comprise one or more resilience mechanisms. Non-limiting examples of such resilience mechanism include one or more springs. The number and size of the spring required may be varied and adjusted accordingly, for example two, three, four, five or more springs may be used. When the second or third force mechanism comprises one or more springs, the second or third force mechanism may further comprise a contacting means such as a ring that may be in contact with skin of a surface outside the perimeter of the eye. Such a contacting means may be provided in the form of a cupping feature. In some embodiments, the cupping feature may act as a guide in aligning the device to the cornea in a simple and non-obtrusive way. In some embodiments, the device described herein may include a first powered force mechanism and a second force mechanism.

In some embodiments, the force being transmitted or applied to the eyelid by the force-transfer assembly 25 such that the peripheral of an eyeball receiving a force of about 5 N or less. The force applied on the peripheral of the eyeball may be about 5 N, 4.5 N, 4 N,

3.5 N, 3 N, 2.5 N, 2 N, 1.5 N, 1 N, 0.5 N, 0.25 N or less. In some embodiments, the force applied on the peripheral of the eyeball is less than 3 N. In some embodiments, the force transmitted above may be force generated by the first force mechanism or a combination of the first force mechanism and a subsequent force mechanism.

The first force mechanism comprising the actuator described above and the second force mechanism (and subsequent force mechanism) may advantageously provide synergistic effects including transmitting force and maintaining the magnitude of the force such a constant force is applied to any of the point on the outer surface of the eyelid in contact with the sensor.

The one or more force mechanism of the device will advantageously absorb variable force applied and will not exert more than about 5 N. Hence, even when the device is fully depressed and in contact with the subject's facial features, the constant force mechanism will also ensure that the cupping feature will not exceed the force of 5 N on the peripheral of the eyeball. Further advantageously, the cupping feature of the device according to some embodiments of the present disclosure is designed to cover over an adult eyeball adequately with eyelid taken into consideration.

In some embodiments, the self-tonometry device may be provided as a portable or a hand-held device. In some embodiments, the self-tonometry device may be provided in the form of a disposable cup like. In some embodiments, the self-tonometry device may be located on a bench and a user may perform the measurements autonomously or without assistance of a healthcare worker (for example a nurse or an ophthalmologist). Stated differently, the self-tonometry device provided herein may be self-administered. Considering ease of using the hand-held self-tonometry device described in the present disclosure, advantageously, minimal or no supervision during the IOP measurement is necessary. In addition, the users may use the device without undergoing training but simply by following the instructions provided. In some embodiments, the instructions may be written, audio or audio-video instructions. Advantageously, as less or no supervision is required, the device may be used for home setting in the absence of the healthcare worker. Result or measurements may be stored in the device and sent to other devices including to healthcare worker's device (e.g. ophthalmologist's device) for review. Accordingly, if needed, the ophthalmologist may remotely recommend to the patient if further eye checks and or intervention will be necessary.

In operation, a hand-held device is schematically illustrated in Fig. 3B, where a user will cup the device over the eye where the sensor will contact user's eyelid. Upon activation, by for example pressing button 26 shown in Fig. 1, the device or the system comprising such device will measure the intra-ocular pressure (IOP) and display results to a screen integrated to the device or to another suitable device (for example a mobile phone, a computer, a tablet and so forth). A side view of eye 10 and self-tonometry device 30 are shown while sensors 20 contact eyelid 15, in accordance with some embodiments of the present disclosure. When a powered force mechanism is activated, the actuator of said powered force mechanism transmits constant force to force-transfer assembly 25, after which the force is being transferred to the array of the plurality of sensors to perform self-tonometry measurements. Advantageously, such constant force is a suitable force such that the variation in the IOP measurements is due to the reactive force of cornea and/ or eyelid to the sensor. In other self-tonometry devices, where the force-transfer assembly is manually pressed (for example by user's fingers), greater variation in the measurements is produced and thus resulting in the measurements being less reliable. The applied force may enable sensors 20 to measure the pressure at positions 40 on eyeball 12 through eyelid 15. According to some embodiments, sensors 20 may comprise six sensors, though other numbers of sensors may be implemented. Each of the six sensors 20 illustrated in Fig. 3B are substantially opposite to each of six respective positions 40 on eyeball 12 at which eye pressure is measured by the sensors in this exemplary embodiment.

Fig. 4 schematically illustrates a front view of eye 10 with exemplary positions of sensors 20 on eyelid 15, in accordance with some embodiments of the present disclosure. The side view of eye 10 shown in Figs. 3A and 3B show a planar cut through six sensors 20 arranged linearly. However, in some embodiments of the present disclosure, self-tonometry device 30 may include a miniaturized sensor array 50 with from 12 - 40 sensors 20, for example, with 12-24 respective output channels to measure the eye pressure over eyelid 15 in a consistent manner. In some embodiments, the array of 18 or 36 sensors may be used. Fig. 4 illustrates an exemplary 6 row by 4 column array of 24 sensors placed on eyelid 15. Accordingly, there are 24 pressure measurements made by the 24 sensors at 24 respective positions 40 on eyeball 15. Sensor array 50 with 6 rows and 4 columns is shown in Fig. 4 merely for conceptual clarity and not by way of limitation of the embodiments of the present disclosure. Any number of sensors 20 arranged in any suitable array 50 of rows and columns may be used.

In accordance with some embodiments of the present disclosure, self-tonometry device 30 may include a housing 56 which may have a size and/or form factor of a standard marker pen, for example. The subject or user, such as a patient, may easily perform IOP self-measurements on their own eyes using self-tonometry device 30 according to the patient's need to periodically assess if the subject measured high IOP measurements anytime during the day.

In some embodiments of the present disclosure, housing 56 may optionally include a display 56 for displaying the intra-ocular pressure (IOP) or other metrics, and/or electrical buttons such as an on/off power 26 and/or calibration button 26. As shown in Fig. 5, a substrate, such a flexible circuit board, may be housed within housing 56. Substrate may include circuitry 45. Circuitry 45 may be electrically coupled to each of sensors 20 in sensor array 50 at an end via electrical conductors.

In some embodiments of the present disclosure, sensor array 50 may include an array of capacitive pressure sensors. In some embodiments, sensor array 50 may include an array of two or more pressure sensors, where at least one of the two or more pressure sensors is capacitive pressure sensor. In some embodiments, sensor array 50 may include an array of one or more capacitive pressure sensors and one or more resistive pressure sensor. Capacitive sensors are typically more sensitive than normal resistive pressure sensors, and thus, may be able to detect the minor changes of IOP due to pathological conditions in eye 10. Array 50 of sensors 20 are used in self-tonometry device 30 instead of a single sensor, so as to provide multiple readings of the eye pressure from different positions 40, thus further improving the accuracy and reliability of the IOP measurement.

In some embodiments of the present disclosure, sensor array 50 may be integrated with 4x6 capacitive pressure elements, or sensors 20. The number of sensors typically ranges, for example from 12–40 sensors for example 12, 14, 15, 18, 20, 24, 30, 32, 36 or 40 sensors. The sensing area or array 50 may have a total area of 8 x12 mm. The sensing area may have a typical range of 8–14 mm x 12–18 mm, for example. The size of each sensor may typically be 2 x 2 mm. The thickness of the sensors array mounted on the support at end 26 may be 0.5 mm.

In some embodiments of the present disclosure, typical sensor array 50 specifications may include, for example:

Thickness: 0.5 mm

Force Ranges: 0 – 2 psi.

Linearity (Error): < ±3%

Repeatability: < ±2.5% of full scale

Hysteresis: < 4.5 % of full scale

Drift: < 5% per logarithmic time scale

Response Time: < 5 μsec

It is to be understood that sensory array having specifications other than that exemplified above may also be used.

Fig. 5 schematically illustrates a block diagram of a self-tonometry system 47, in accordance with some embodiments of the present disclosure. System 47 may include sensor array 50 with the plurality of sensors 20 coupled to circuitry 45. Circuitry 45 may be configured to relay data measured and computed by circuitry 45 in self-tonometry device 30 to a PC/Cloud Data Center 97.

Circuitry 45 may include a sensor interface 75 coupled to a microcontroller/digital signal processing (MCU/DSP) unit 65. MCU/DSP 65 may be coupled to a USB (input/output data interface) 60, a memory 77, such as SDRAM, NAND flash memory 80, LCD display 56, power management circuitry 82, a Li battery 84 for powering self-tonometry device 30, and a wireless charging module 85. Sensor interface 75 may include an amplifier 87, a filter 90, and an analog-to-digital converter 95. MCU/DSP 65 may include a processor 70 for performing the signal processing in the pressure measurements and executing a machine learning module for analyzing the pressure measurements for computing the IOP in eye 10. MCU/DSP may include a communication module and interface 72 with circuitry for relaying data between self-tonometry device 30 and any other computing and/or storage device (e.g. PC/Cloud Data Center 97) via any suitable wired and/or wireless communication protocols (e.g., Wi-Fi, Bluetooth, cellular communication).

In some embodiments of the present disclosure, signals from sensors 20 in array 50 may be relayed to sensor interface 75. Sensor interface 75 may amplify, filter, and digitize the signal using ADC 95. The digitized pressure measurement signals may then be relayed MCU/DSP 65 for signal analysis. The IOP analysis results may be displayed on integrated LCD screen 50 for the subject to observe. SD-card in a slot may be installed in self-tonometry device 30 for recording historical IOP data for later reference. Power management circuitry 82 may be used to switch off self-tonometry device 30 automatically when not in use to save power, for example after one minute not in use, the device may automatically switch-off. In some embodiments of the present disclosure, all of the components shown in Fig. 5 may be

miniaturized to fit within the size of a hand-held housing, making self-tonometry device 30 portable and easy to use.

Processor 70 (e.g., MCU/DSP unit 65) may include one or more processing units, e.g. of one or more computers. Processor 70 may be configured to operate in accordance with programmed instructions stored in SDRAM 77 and/or NAND Flash 80 or any other suitable storage device and/or memory. In operation, processor 70 may execute a method for measuring intra-ocular pressure (IOP) in an eye of a subject.

In some embodiments of the present disclosure, the plurality of pressure measurements at the respective positions may be relayed to processor 70 executing a machine learning module (MLM) 71 in self-tonometry device 30 employing machine learning regression or classification, as an input to a trained artificial neural network (ANN) model. The processor may use machine learning regression or classification through MLM 71 to calculate the IOP based on the plurality of pressure measurements at the respective positions 40. As mentioned above, since the variability of the pressure, other than the reactive force of the cornea or the eyelid to the sensor, is minimized, the reading obtained may advantageously be more reliable and accurate.

In the context of the present disclosure, the term “machine learning module” refers to an algorithm, model, function, or code that implements regression or classification. Regression is a predictive machine learning approach in which a computer program may approximate from the data input to a computing device a continues output variable. Classification is a predictive machine learning approach in which a computer program may approximate from the data input to a computing device a discrete output variable. Machine learning model or function may include, for example, an artificial neural network (ANN) model or a random forest model. Although many of the embodiments herein are with reference to the ANN model for computing IOP from the plurality of pressure measurements, self-tonometry device 30 may perform similar calculations using any suitable MLM 71, such as random forest models. Self-tonometry device 30 is not limited to calculating IOP using the ANN model.

MLM 71 such as artificial neural network (ANN) 100 may be trained to compute the intra-ocular pressure (IOP). In general, ANN 100 may mimic the architecture of the brain, for example, by passing values from one layers of artificial neurons to another. ANN 100 may be used to approximate any measurable functions.

For self-tonometry device 30, if the surface pressure on eye 10 (e.g., on eyeball 15 of the subject) has any consistent relationship with the intraocular pressure, the trained ANN may use this relationship to compute the IOP. Furthermore, the use of multiple miniaturized pressure sensors 20 in sensor array 50 may allow multiple pressure samples at predefined positions 40 on the eye (e.g., eyeball 15) for use in the IOP computation to improve the measurement accuracy. For example, noise and pressure variations in measurements from one sensor may be cancelled by measurements from the other sensors in the sensor array, assuming the noise is random.

In some embodiments of the present disclosure, ANN 100 may include different configurations of multiple neural network layers, including but not limited to fully connected layer, convolution layer, normalized layer and drop out layer, briefly explained below. The machine learning may be performed via gradient descent. In gradient descent, initially the difference between the estimated pressure and the real pressure are computed to find out the loss. Then the gradient of the loss with respect to each weight are subtracted from the weights respectively.

In some embodiments of the present disclosure, the input data to ANN 100 may include the applied force or transmitted force (e.g., generated by the powered force mechanism or force transmitted by the force-transfer assembly 25, for example) and pressure data from sensors 20 in array 50. The input data may be relayed to ANN 100 to undergo multiple linear and non-linear transformation to produce the output. The output is the estimated intra-ocular pressure (IOP).

In some embodiment of the present disclosure, the calibration of ANN 100 may be performed by measuring the pressure on top 15A of eyelid 15 using sensor array 50. The true IOP may be measured using a reference device, such as a Goldmann applanation tonometer, or a water pressure sensor inserted into an animal eye. The plurality of pressures measured by the respective plurality of sensors 20 in array 50 and the true IOP may be fed into ANN 100 as input, so as to train and to fine tune the weights in the ANN model during calibration using gradient descent. Calibrating ANN 100 for each patient produces the best IOP measurement accuracy.

In some embodiments of the present disclosure, an advanced algorithm executed by processor 70 of self-tonometry device 30 may be used to eliminate the effect of eyelid 15 on the eye pressure measurements performed by the plurality of pressure sensors 20 in sensor array 50. Since the size of sensors 20 in sensor array 50 is small (2 mm x 2 mm), the total

area of sensor array 50 may be also small, such as, for example, 10 mm x 10 mm. It may be assumed that all of pressure sensors 20 in array 50 may measure the same surface pressure of eye 10 except for minor variations introduced by the soft tissue of eyelid 15. Therefore, multiple sensors 20 in sensor array 50 may sample multiple respective pressures in eye 10 with the same underlying intraocular pressure, albeit at different respective positions 40 of eye 10 (e.g., on eyeball 15), which are determined by the position of sensors 20 in array 50 when placed onto the eye (e.g., outer surface 15A of eyelid 15) for IOP measurements.

If the measurement variation introduced by the eyelid is assumed to be random, multiple measurements made by sensors 20 in sensor array 50 may be used to cancel out the measurement variation for computing the IOP. Even if the eyelid variation is not random, as long as it has a consistent spatial relation to the sensor array (e.g., eyelid 15 may reduce the measured pressure more at the center and less on the edges of array 50), ANN 100 may automatically correct for this error by removing the pressure offset introduced by the eyelid. The ANN is a universal function approximator.

In some embodiments of the present disclosure, these dynamic properties may be used. For example, an accelerometer may be attached to self-tonometry device 30, and a force applied to the eyeball, such as a periodic compression and relaxation of the eyeball. The periodic force produced by a suitable actuator or motor may be coupled to force-transfer assembly 25 either internally and/or externally to self-tonometry device 30. In most of the existing tonometry techniques, the device performs a static measurement of the mechanical property of the eye, e.g. by measuring the pressure required to applanate the cornea. However, the IOP also affects how the eye reacts to dynamic events, for example how hard the eye resists compression and fast it returns to its original shape on relaxation. The information on this dynamic property may be obtained by affixing an accelerometer to the device described herein and the same is used to perform periodic compression and relaxation of the eyeball. Using the accelerator on the device (such as the actuator described herein), advantageously, useful information including how fast the eyeball is being compressed, and the data obtained from the pressure sensor array, thus how the eye is reacting to the applied force may be determined. It is to be understood that the periodic force mentioned here may be the same or different from the constant force generated by the first force mechanism described above. The accelerator on self-tonometry device 30 may be used to measure how fast eyeball 15 is being compressed. This information may be used with the geometry of pressure sensor array 50 to assess how eye 10 reacts to the applied force. Eyeball 15 with a

higher IOP may be more resistant to compression. Hence, the pressure values measured by sensor array 50 in self-tonometry device 30 may rise faster given the same compression velocity. The pressure values may return to the resting state faster during relaxation due to the higher IOP. Both the accelerator reading and pressure sensors reading may be input to the machine learning module such as ANN model 100 to compute the IOP.

Furthermore, one feature of the self-measurement by a subject of IOP herein is that the simultaneous intra-luminal pressure is not required to train the computational model (e.g., MLM 71). The true pressure before sensor measurements may be taken as the ground truth for training the MLM 71, and the trained MLM 71 may be stored prior to use of self-tonometry device 30. Thus, using the embodiments disclosed and described herein, the ground truth of the IOP before taking sensor measurements may be obtained from more traditional IOP measurements such as using a Goldmann applanation tonometer.

In some embodiments of the present disclosure, due to the individual difference in the eyelid thickness and mechanical property, self-tonometry device 30 may be calibrated for each patient for maximum accuracy. However, the device may estimate a reasonably accurate IOP reading without the need for individual calibration of self-tonometry device 30 for each subject.

For individually calibrating self-tonometry device 30, the subject's IOP may be measured using normal Goldmann applanation tonometry, for example, to obtain the standard IOP (e.g., real IOP). Pressure readings may be obtained by self-tonometry device 30 and ANN model 100 may then be calibrated using the standard IOP.

In some embodiments of the present disclosure, when self-tonometry device 30 may be applied in the human eyes, sensors 20 may cover the range of pressure from 5-80 mmHg. Self-tonometry device 30 may measure the IOP by assessing the dynamic property of eye 10, similar to how repeatedly pressing a finger, for example, on an object may be used to assess its hardness. The absolute pressure applied on the eye is not the relevant parameter for determining IOP using MLM 71, only the change in the measured pressures in sensors in response to the applying a cyclic force with sensor array 50 contacting eye 10, which may be used by MLM 71 for estimating IOP. Stated differently, ANN model 100 may automatically infer the IOP by observing how the pressure of each sensor element 20 may change in response to periodic compression and relaxation.

As eyeball 15 is compressed, for example, the eyeball shape may respond differently under different internal IOP pressure. For the same applied force 130, such as a compression

force for example, if the internal pressure of the eye is high, then eyeball 15 may not be easily deformed. The opposite is true for low pressure. Therefore, processor 70 is tracking the relation between applied pressure 130 and rate of deformation, for example, the internal pressure IOP of eye 10 may be determined to explain this phenomenon in simplified terms. However, in practice, the relation between the two parameters of pressure and the deformation is highly complex and non-linear. Thus, MLM 71, such as ANN 100 model or a random forest model, may be used to infer the relation between these two parameters.

It is to be understood that not necessarily all objects or advantages may be achieved in accordance with any particular embodiment of the present application. The person skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

Moreover, the person skilled in the art will recognize the interchangeability of various features from different embodiments. In other words, the features of the devices disclosed in the various embodiments can be switched between embodiments. Other combinations of the various aspects of the disclosed embodiments are also possible. In addition to the variations described herein, other known equivalents for each feature can be mixed and matched by a person skilled in the art to construct systems and techniques to ensure that a constant pressure or force is transmitted to the outer surface of the eyelid of the subject in accordance with principles of the present invention.

Furthermore, although the foregoing has been described in some detail by way of illustrations and examples for purposes of clarity and understanding, it is apparent to the person skilled in the art that certain changes and modifications may be practiced. Therefore, the description and examples should not be construed as limiting the scope of the invention to the specific embodiments and examples described herein. Rather the scope of the present invention is defined only by the claims, which follow.

CLAIMS

1. A self-tonometry device for measuring intra-ocular pressure (IOP) in an eye of a subject, the self-tonometry device comprising:

an array of a plurality of sensors configured to measure a plurality of pressures at positions on the eye of the subject corresponding to the positions of the plurality of sensors;

a powered force mechanism, configured to generate a force and transmit the same to the array, when said array is in contact with an eyelid of the subject; and

a processor configured to receive the plurality of pressures measured from the plurality of sensors in the array, and to determine the IOP in the eye.

2. The device according to claim 1, wherein said powered force mechanism comprising an actuator, configured to generate the force.

3. The device according to claim 1 or claim 2, wherein said powered force mechanism further comprising a force-transfer assembly, configured to transmit said force to the array, when said array is in contact with the eyelid of the subject.

4. The device according to claim 2, wherein said actuator is a mechanical actuator.

5. The device according to claim 4, wherein the mechanical actuator comprising a motor having a constant oscillating or rotating speed thereby generating the constant force.

6. The device according to any one of claims 1 to 5, further comprising a second force mechanism.

7. The device according to claim 6, wherein said second force mechanism comprising one or more resilience means.

8. The device according to claim 3, wherein when the force is applied to the eyelid, the force applied on the peripheral of an eyeball is 5 N or less.

9. The device according to claim 1, wherein said processor is for executing a machine learning module and is configured to receive the plurality of pressures measured from the array of the plurality of sensors as an input to the machine learning module, and to determine using the machine learning module, the IOP in the eye.

10. The device according to claim 9, wherein the machine learning module comprises an artificial neural network model or a random forest model.

11. The device according to claim 10, wherein the artificial neural network is trained and calibrated by comparing the plurality of pressures measured by the plurality of sensors to true IOP measured using a reference device.

12. The device according to any one of claims 1 to 11, further comprising a display for displaying the IOP or other metrics.

13. The device according to claim 1, wherein said plurality of pressures at respective positions on the eye of the subject are multiple pressure readings from different positions used to improve the accuracy of the intra-ocular pressure measurement.

14. A method for measuring IOP in an eye of a subject, the method comprising:

generating a force, in a powered force mechanism, and transmitting the same to an array of a plurality of sensors, when said array is in contact with an eyelid of the subject;

measuring a plurality of pressures at positions on the eye of the subject using the array, said positions corresponding to the positions of the plurality of sensors; and

in a processor, receiving the plurality of pressures measured from the array of the plurality of sensors and determining the IOP in the eye.

15. The method according to claim 14, wherein said powered force mechanism comprising an actuator, configured to generate the force.

16. The method according to claim 15, wherein said powered force mechanism further comprising a force-transfer assembly, configured to transmit said force to the array, when said array is in contact with the eyelid of the subject.

17. The method according to any one of claims 14 to 16, wherein said processor is configured to execute a machine learning module and to receive the plurality of pressures measured from the array of the plurality of sensors as an input to the machine learning module, and to determine using the machine learning module, the IOP in the eye.

18. The method according to claim 17, wherein the machine learning module comprises an artificial neural network model or a random forest model.

19. The method according to claim 18, wherein the method further comprises training the artificial neural network by comparing the plurality of pressures measured by the plurality of sensors to true IOP measured using a reference device or a reference method.

20. The method according to claim 19, wherein the method further comprises calibrating the artificial neural network using gradient descent.

21. The method according to claim 20, wherein the calibration is undertaken per subject.