Chapter 49
Design and Prototyping of a Novel Head-Mounted Ophthalmic Device for Monitoring Glaucoma

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Abstract Glaucoma is an eye disease leading to progressive loss of vision. It can be detected and monitored by measuring the intraocular pressure (IOP). Conventional tonometers used for this purpose are cumbersome (require qualified ophthalmologists) and invasive (uncomfortable for the patients). In this work, a novel portable instrument for IOP measurement was developed, based on a combination of indentation and applanation principles. It employs a three-axis slider system mounted on headgear for accurate and rapid positioning of an indenter assembly over the eyelid. The assembly comprises an indenter, adjustment compartment and knob. The compartment also houses a spring, force-sensitive resistor and printed circuit board to check the IOP after applanation. The corresponding reaction force from the eye is obtained on a force-sensing resistor using Imbert-Fick's principle. This activates an LED signal for high levels of IOP that indicate a risk of glaucoma. The main components of the device were prototyped through 3D printing in ABS plastic. The device provides an efficient way to accurately position it over the eye for different face structures and varying eye positions among patients. It also allows sliding the instrument along a horizontal rail to conveniently check both eyes in the same setting. The proposed innovation can be used by healthcare workers to screen Glaucoma patients in rural medical camps. It can also be used at home for regular check-up by patients themselves and take suitable precautionary measures.

49.1 Introduction

Glaucoma is the third leading cause of irreversible blindness. It affects an estimated 65 million people worldwide; at least 3 million people become permanently blind. It is not accompanied by any pain or discomfort and is therefore not noticeable until a sudden significant worsening of vision loss (Fig. 49.1). However, with regular eye checks, early detection and treatment, it is possible to preserve the eyesight.

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Fig. 49.1 Deteriorating glaucoma vision from left to right

The major indicators of glaucoma are elevated intraocular pressure (IOP), optic disc cupping, optic nerve damage and visual field loss. The IOP depends on the amount of fluid in the eye. The aqueous humour fluid in the front part of the eye (produced by the ciliary body) flows out through the pupil and is absorbed into the bloodstream through the drainage canals around the outer edge of the iris. This helps keep eye pressure at a normal level. When the drainage system of the eye becomes clogged, the fluid builds up and causes IOP to rise. This gradually damages the sensitive optic nerve, leading to loss of vision. Elevated IOP is not a diagnostic factor and many people with high pressures have normal vision. However, IOP is the only established risk factor for glaucoma.

49.2 Previous Work

Intraocular pressure (IOP) is defined as the difference between the pressure inside the eye and the atmospheric pressure. The distribution of IOP within the general population is in a range of 11–21 mm Hg [1]. This pressure is required to maintain the proper shape. The assessment of intraocular pressure is known as tonometry; and the instrument used for this purpose is known as tonometer. They broadly use one of the two principles: applanation or indentation, as follows.

Applanation tonometry is based on the Imbert-Fick principle, which states that the pressure inside an ideal dry, thin-walled sphere equals the force necessary to flatten its surface divided by the area of flattening ($P = F/A$, where P = pressure, F = force and A = area). In this method, the cornea is flattened and the IOP is determined by varying the applanating force or the area flattened. The Goldmann applanation tonometer measures the force necessary to flatten an area of the cornea of 3.06 mm diameter. At this diameter, the resistance of the cornea to flattening is counterbalanced by the capillary attraction of the tear film meniscus for the tonometer head. The IOP (in mm of Hg) equals the flattening force (in grams) multiplied by 10. The Perkins tonometer is essentially a portable Goldmann applanation tonometer that can be used with the patient in either upright or supine position [2]. The ocular

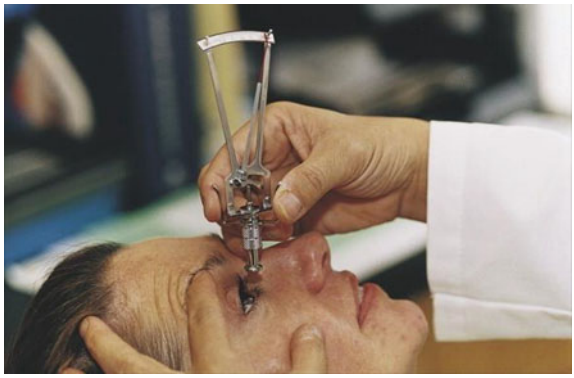

Fig. 49.2 Schiotz tonometry technique. *Source* entokey.com/intraocular-pressure

response analyser is a newer type of non-contact tonometer, which uses a column of air of increasing intensity as the applanating force.

Indentation tonometry is based on the principle that a force will indent a soft eye (lower IOP) further than into a hard eye (high IOP). The Schiotz tonometer (Fig. 49.2) that uses this principle comprises a curved footplate placed on the cornea of a supine subject. A weighted indenter is allowed to sink into the cornea (inversely proportional to the pressure in the eye). A scale at the top of the indenter gives a reading depending on how much the indenter sinks into the cornea, and a conversion table converts the scale reading into IOP measured in mm of Hg [3].

Some tonometers use both principles. The pneumotonometer is an applanation tonometer with some aspects of indentation tonometry, and its readings correlate well with Goldmann applanation tonometry within normal IOP ranges [4]. The 'Tono-Pen' involves both applanation and indentation processes [5], and its readings also correlate well with Goldmann tonometry within normal IOP ranges [6].

While the Goldmann method is considered the gold standard for measuring IOP, it has several disadvantages. For the patient, the procedure is highly invasive and uncomfortable. First, the head of the tonometer must come into direct contact with the cornea. Second, to prevent reflexes during measurement, anaesthesia must be applied to numb the eye. A fluorescein strip must also be applied to the eye to detect the applanated state. All of these steps require a skilled ophthalmologist. Since doctors only periodically check IOP, which has been known to fluctuate widely throughout the day, the measurement obtained may under or overestimate the actual pressure in the eye. As a result, patients at risk for glaucoma may not receive proper treatment (false negative) or those with normal vision may be treated unnecessarily (false positive). Ideally, patients must be able to monitor their IOP by themselves. This points to an unmet need for a simple, portable and self-use device for this purpose. Such devices will also be very useful for screening a large number of people for onset of glaucoma, even in rural medical camps by health workers.

The novel device developed in this work is based on the research work that utilized a combination of indentation and applanation principle to measure IOP [7]. It involves positioning an indenter over the eye of the patient such that it just touches the eyelid.

Then it is moved forward to gently applanate the cornea by a standard indentation to obtain the reaction pressure from the eye. The effect of varying thickness and properties of the eye in different patients is isolated using the slope of graph (reaction force versus indentation) that changes once the eyelid is fully compressed and the cornea is being flattened. The device was successfully validated by measuring the IOP in over 50 patients, which matched well with the values obtained using Goldmann tonometer.

49.3 Device Design

The overall goal is to build a portable device to allow patients with glaucoma to measure their intraocular pressure. The functional requirements were derived by discussions with expert ophthalmologists and are as follows:

- Usable by general medical practitioners
- Provide accurate indication of normal or elevated IOP
- User-friendly and not require complex instructions and training
- Should not require aesthetic drops (not permitted for home use)
- Minimize patient discomfort
- Cost effective.

The proposed design is in the form of headgear with a screening module attached to it. The patient can directly wear this headgear, increasing the feasibility and convenience for diagnosis for the clinician. This overcomes the difficulty in keeping the device stationary above the patient's eye during applanation.

The screening module houses five parts in an enclosure—screw cap, force sensitive resistor, spring and indenter. (Fig. 49.3) For assessment of IOP, the force resistive sensor (FSR) is placed on the indenter (Fig. 49.3). Using the Imbert-Fick principle, the force on the sensor can be obtained by multiplying the area of the indenter tip by the pressure of the eye. An additional spring force also acts on the sensor. The function of the spring is simply for pulling the indenter back to its original position after it is pushed for applanation. The total force on the sensor would be checked, and it should be less than the limiting force. If the IOP of the patient crosses the limiting value, then the increased load on the FSR will signal through a red LED.

The device that was developed in this project relies on the detection of limiting IOP, over which the risk of glaucoma is high. From previous literature, the pressure of the eye has been calculated to be 2253 Pa when applanated, for the limiting IOP of 21 mm Hg [1]. A standard indentation of 4 mm is given on the cornea, over the eyelid to check that pressure. An indenter in the device will move downward pressing the cornea. From Imbert-Fick's principle, the area of the tip of the indenter is used to calculate the applanation force:

Force needed to flatten cornea over eyelid

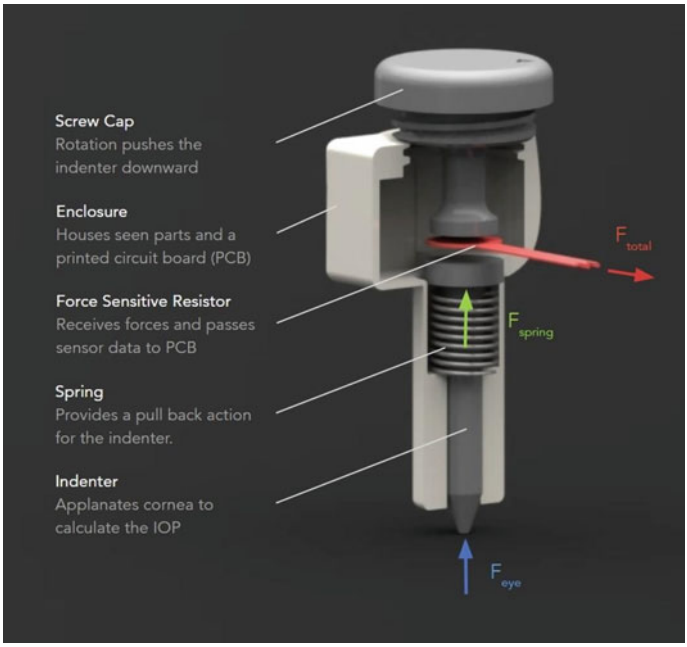

Fig. 49.3 Placement of components inside the enclosure

$$= \text{Applied Pressure} \times \text{Area of Contact}$$

To obtain a round figure of the reaction force from the eye, a force of 0.01 N was considered with which the area of contact of the indenter tip was reverse engineered. A circular cross section was used for the tip of the indenter.

$$0.01\,\text{N} = 2253\,\text{Pa} \times \pi(r)2r = 0.00118\,\text{m} \approx 1.2\,\text{mm}$$

$$F_{\text{eye}} = 2253\,\text{Pa} \times \pi \times 1.2\,\text{mm}^2 \times 10^{-6} = 0.0101923\,\text{N}$$

For the pullback of the indenter after diagnosing one eye, a spring is placed along the indenter's length which contributes to the force on the FSR. One rotation of the enclosure cap should move the indenter down by 4 mm for correct applanation. For this screw thread, the pitch is 4 mm. The spring was designed for stainless steel (304 SS) with squared and ground ends. Other design parameters include: wire diameter (d) = 0.7 mm, outer diameter (OD) = 16 mm, free length (L_{free}) = 20 mm and number of active coils (n_{a}) = 8. Using these dimensions and material properties, the spring constant can be calculated, and in turn, the compressive force $F_{\text{spring}} = kx =$ 0.072 N/mm × 4 mm = 0.288 N.

The sum of applanation force and spring force after 4 mm compression would be the total force acting on the indenter which is used to diagnose patients of their

condition.

$$F_{\text{total}} = F_{\text{eye}} + F_{\text{spring}} = 0.01\,\text{N} + 0.288\,\text{N} = 0.298\,\text{N}$$

The screening module consists of a push-button switch, force-sensing resistor, integrated circuit, two LEDs (green to show the device in ON and red for indicating elevated IOP) and potentiometer (to vary the limiting force for indication). The circuit is designed such that when the force on the FSR reaches this limiting value, a red light will flash. Figure 49.4 shows the FSR with two external connections, to the top of the indenter and the switch, respectively. In Fig. 49.4 (left), there is no force and the LED stays green. The indication works when a manual force is applied on the FSR as shown in Fig. 49.4 (right). This value at which the red LED flashes is set using the potentiometer for the load of 0.298 N.

During the prototyping phase, a pair of 3 M safety goggles with some modifications were used as the headgear (Fig. 49.5). A group of 15 participants wore these

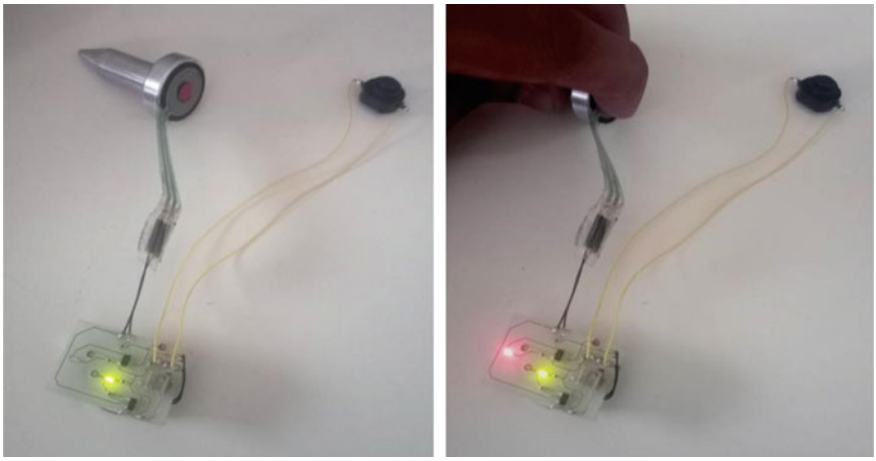

Fig. 49.4 FSR without force (left), FSR with force (right)

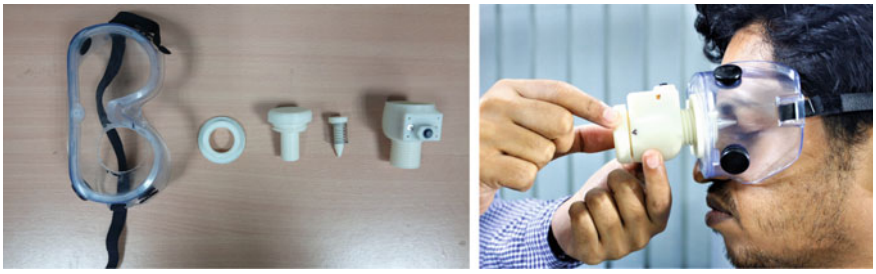

Fig. 49.5 Initial prototype of the device

goggles and were asked to look straight ahead. With a marker, dots were marked on the goggle surface vertically above the eye. The distance of these points from a reference was calculated. The concentration of points was within 1 cm^2 which was within the range where the elastic and goggle can be re-adjusted to position the indenter. A hole was cut in the goggles through which a holder was fixed. The holder with screw threads acts as an interface between the goggles and the enclosure. This way, the clinician can position the enclosure in the z-axis such that the indenter tip touches the eyelid.

There were a few limitations in the prototype. The sensor to PCB strip within the enclosure would occasionally get twisted or bent due the unavailability of space after the screw rotation. This constraint for space can be accommodated for with a slot along the cylindrical axis of indenter movement or with a hole in the device enclosure through which the connection strip can protrude from and vice-versa. However, the generalized placement of the indenter in this prototype has its drawbacks because of anatomical differences in people's faces. To solve this, an indenter positioning system was designed which is described next.

49.4 Positioning System

The headgear system must have improved functionality in terms of indenter placement and to make the device convenient and easy to use which can be operated by an individual with minimal or no training. It required a system by which the indenter can be moved through three degrees of freedom, i.e., the *x*-, *y*- and *z*-axis and be positioned such that the indenter tip is just touching the eyelid. The user should also be able to fix that position of the indenter by locking the slider movement of each axis.

With these requirements, three concept directions were explored through sketches (Fig. 49.6). The following factors were considered in the design:

- Space for the nose to prevent interference with indenter movement
- Accommodate differences in face shapes for various patients

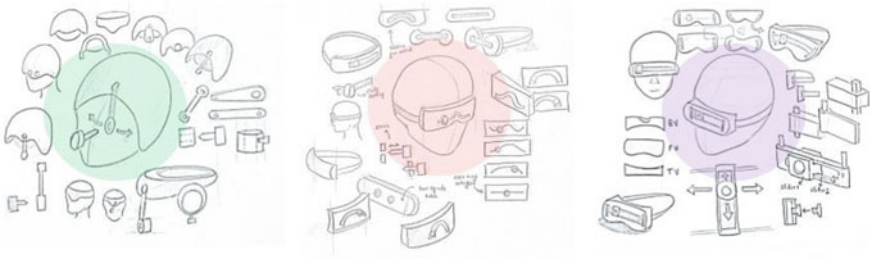

Fig. 49.6 Ideation sketches of three concepts of the headgear: **a** Rotating (left), **b** fixed rail (middle), **c** linear (right)

Table 49.1 Concept screening matrix of headgear

Criteria	Rotating (a)	Fixed rail (b)	Linear (c)
Fitting	–	+	+
Indenter positioning	0	–	+
Alignment visibility	+	0	+
Stability and comfort	+	0	0
Ease of use	0	+	0
Manufacturing cost	–	+	+
Sum '0's	2	2	2
Sum '+'	2	3	4
Sum '–'	2	1	0
Net score	0	2	4

- Contact surfaces and materials of the sliders
- Smooth and controlled movement of the indenter through all three axes.
- Ability to see whether indenter is exactly above the eye
- Locking mechanism to fix the indenter in position.

The above three concept directions were explored using a screening matrix (Table 49.1). The linear headgear system (c) with three-axis movement ranked better in most criteria and was selected. A possible concern in this design is the stability of the indenter position, which is a key requirement during glaucoma diagnosis. The helmet-mounted design (a) with a rotating indenter positioning system would be more stable than the other two that are held by an elastic, but it lacks other features.

The final design is in the form of a thin cuboidal frame, with a slider system and a screening module. (Fig. 49.7). To address this problem of stability the selected idea, a three-way elastic can be added for an additional grip around the user's head. It can be fastened around the head with the use of a modified band. It would be attached to the frame through three slots, two on either side and one on top.

Fig. 49.7 Final product rendered (left), prototyped for testing (right)

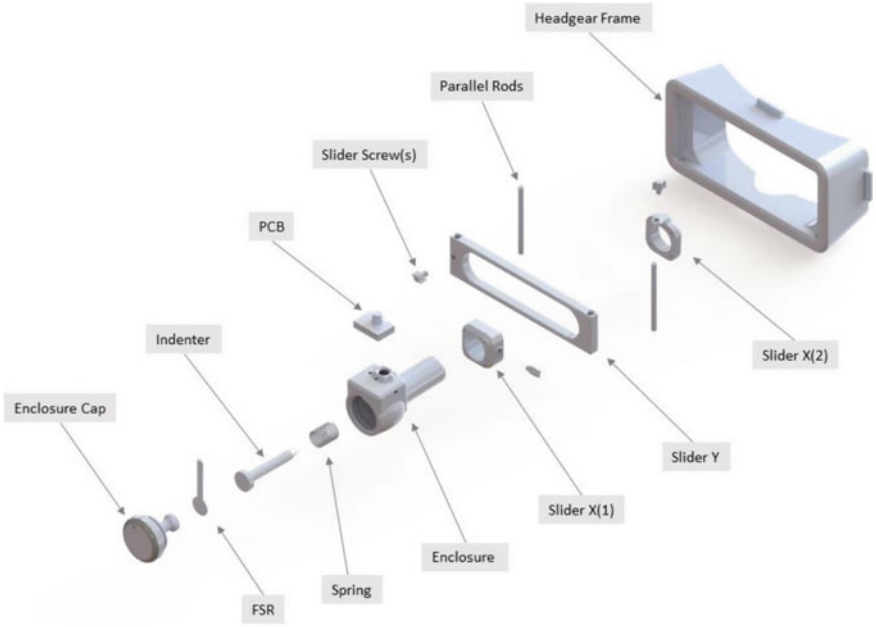

Fig. 49.8 Exploded view of the device assembly

The front of the headgear has two parallel rods on which a slider moves in the *y*-axis (Fig. 49.8). For convenience, this part is named Slider-*Y*. The rods as well as the frame have a hole such that the rods can be fixed in place with a nut and bolt. Slider-*X* is split into two parts which are fixed on either side of Slider-*Y*. This part can move in the x-axis, relative to Slider-*Y*. The Slider-*X* is cuboidal in shape with a central hole through which the enclosure's bottom extrusion will slide along the *z*-axis. There are three set-screws provided to lock the movement in each axis. One is on Slider-*Y* and two on Slider-*X*. Since the enclosure body moves through the hole in Slider-*X*, the second hole is used to lock the *z*-axis movement.

The enclosure contains the spring, indenter, PCB and FSR. The spring is placed along the length of the indenter and gets compressed by the indenter head when pushed down. The PCB is fitted in a chamber at the top of the enclosure. A screw top closes the enclosure and functions as the control for indenting the eye. It has an extrusion from the bottom which is one of the two faces between which the FSR is actuated. The other is the top of the indenter head, both the surfaces being flat.

The proposed design introduces a convenient screening method that can be performed at home and without any prior training. It is easy to operate and read the diagnosis, which switches on a red LED, indicating elevated IOP in the eye. After wearing the headgear and switching on the device, three steps are followed (Fig. 49.9):

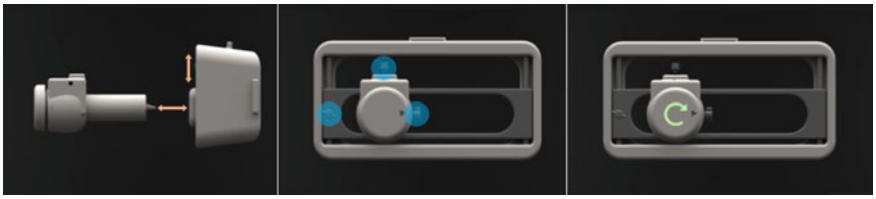

Fig. 49.9 Three steps in the diagnosis: **a** Align (left), **b** fix (middle), **c** rotate (right)

1. **Align**: Move the sliders in *X*-, *Y*-, *Z*-axes and position the screening module above the cornea.
2. **Fix**: Held in that position, fix the screws on each axis.
3. **Rotate**: From the starting point of the arrow demarcation, rotate the cap by 360° till the arrows meet again.

49.5 Conclusion

This work demonstrated the possibility of convenient self-assessment of elevated intraocular pressure to monitor glaucoma condition and ensure adequate treatment to prevent or delay the onset of blindness. The proposed design overcomes the limitations of existing devices, including the need for ophthalmologists, anaesthesia drops, invasive procedure and discomfort to patients. The major novelty is the slider system that allows the user to easily place the indenter above the eye. After that, one rotation of the screw can actuate an indicative light to warn patients of elevated IOP.

Future possibilities include advanced additive manufacturing methods to create parts using two materials joined together to further improve the functionality and manufacturability. Having rubber as the material for the elastic slot and the rest of the frame in plastic would reduce the chances of failure on the slots. Furthermore, the indication of elevated IOP is currently only through a red light. This can be improved with a digital interface which can display the IOP value of the patient using relevant data from the sensor. These improvements are planned in future versions of the product.

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