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Original Research Article

Glaucoma: a new approach for detection in rural eye care

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ABSTRACT

Background: There is a dare need of a device for the measurement of intraocular pressure by making the contact of plunger with closed eyelid eliminating the need of anesthesia and expert ophthalmologist. The main purpose of this study is to develop a device for the indicative measurement of intraocular pressure (IOP) of eyeball, a key cause for glaucoma.
Methods: TRIZ 'The theory of solving inventor's problem' is an era of technical development and innovation. Developing a device for detecting glaucoma by using TRIZ and top ten innovative principles recommended by expanded TRIZ matrix can exceed the disadvantages that classic tonometer has. The field of Ophthalmology will be experiencing a paradigm shift towards the use of collaborative approach of classical and expanded TRIZ.
Results: In early diagnosis and treatment of glaucoma accurate measurement of IOP is important. The methods and devices which are available for the measurement of IOP have their own limitations which cause discomfort to the patients during measurement and needs anesthesia. This approach shows a good result in development of a device for detecting glaucoma in patient's eye through eyelid instead of cornea.
Conclusions: There is a substantial need for early detection and diagnosis of glaucoma in rural and remote areas (worldwide). This study has demonstrated the development of new device for detection of glaucoma using TRIZ, will help the medical practitioners in rural and remote areas for detection of glaucoma.

Keywords: Glaucoma, Intraocular pressure, Eyelid, Contradiction matrix, Expanded matrix, Innovative principle

INTRODUCTION

Glaucoma is a progressive optic nerve neuropathy which may damage the optic nerve.[1] It results into irreversible vision loss and considered as one of the leading cause of blindness worldwide.[2] It has been estimated that glaucoma affects 70 million people worldwide; however the fundamental causes remain unknown for many types of glaucoma.[3] The anterior segment of the eye is filled with a clear fluid called aqueous humor (AH). It is produced in the posterior chamber in the ciliary body at the rate of 2-3 ul/min. Glaucoma causes due to the resistance of the aqueous humor out flow, which in turn leads to an increase of the intraocular pressure (IOP).[4,5] In the assessment of glaucoma the only risk factor is the elevated IOP. The measurement of IOP is essential in early detection and diagnosis of glaucoma.

In detection of glaucoma the main parameter is the elevated intraocular pressure (IOP). Therefore for early diagnosis and treatment of glaucoma accurate measurement of IOP is important.[6] According to the survey conducted by World Health Organization, the number of glaucomatous patients will increase to 80 million people worldwide in 2020.[7]

Meena et al described the evolution of tonometry used in IOP measurement and the different tonometry principles used in various tonometers since last two centuries.[8] Paper has been organize as selecting parameters and comparing them by focusing the frequency of occurrence of innovative principles finding out mostly used innovative principles in mechanical engineering applications. Further a case study has been discussed to develop a biomedical device for the measurement of IOP through eyelid.

TRIZ, the theory of inventive problem solving offers a realistic and systematic way to solve the problem which otherwise was unknown.[9,10] GenerichAltshuller is considered the founder of TRIZ; he started developing TRIZ in 1946. One of the major contributions of Generich Altshuller in solving the innovative problem is the development of contradiction matrix, which is popular as ‘Classical TRIZ’ matrix.[10,11]

Latter development in the field of science and technology has made a trade off for use of classical TRIZ. Darell Mann and his fellow mates worked out on the patent research carried out between 1985 to 2006. They analyzed the US patents issued between 1985 to 2006; sampling study of some randomly selected patent was carried out.[12,13] Also the inventors have introduced the new parameters other than 39 parameters used in “Classical TRIZ”. Based on this new trend a new matrix was developed known as “2010 expanded TRIZ matrix”.[13-15] It introduced 50 parameters and proved its high accuracy to match with the solutions of current invention by analyzing the US patents randomly.[16-19] In 2010 expanded TRIZ matrix, 50 parameters were introduced that were not addressed in the original matrix (specifically those were not consider to be important that time). In reordering the parameters of the original matrix (for which the matrix contain blank entries) the growth of matrix is made base on the facts of world new inventions, in which new parameters become important in the design process. This paper reports the findings of top ten innovative principles recommendation by classical and expanded TRIZ matrix. The study aimed to develop a tonometer for detection of glaucoma in patient’s eye, using top ten innovative principles recommended by expanded TRIZ matrix.

Sequencing of inventive principles

There are many different ways of using the inventive principles. The two possibilities that users like to use all 40 principles and the tool like contradiction matrix. In order to focus on a smaller number “most likely” principle recommendations, the flexibility of use is one of the great strengths of the principles.[13]

An attempt is made to offer flexibility to the users working on mostly used Mechanical Engineering parameters by focusing on prioritization of “Most likely” innovative principle used in Mechanical Engineering applications. It was decided that the list of innovative principles can be used based on their frequency of occurrence. In the present study only 11 parameters (most used in Mechanical Engineering) from classical TRIZ matrix were selected. Then the classical TRIZ matrix has been reduced to 11 × 11 matrix and the recommended innovative principles are selected. Further these principles are arranged based on their frequency of occurrence in classical TRIZ and expanded TRIZ matrix.

After finding the frequency of occurrence of 40 inventive principles, the top ten innovative principles recommended by classical and expanded TRIZ matrix are shown in Table 1. Furthermore the top ten principles recommended by expanded TRIZ matrix were used for the development of a device which can measure IOP in patient’s eye through eyelid. The device will help the rural physicians to detect the glaucoma in patient’s eye for its early diagnosis and treatment.

Table 1: Top 10 principles.

Top 10 rank	Classical TRIZ matrix		Expanded TRIZ matrix	
	Principle no.	Principle	Principle no.	Principle
1	35	Parameter change	35	Parameter change
2	10	Preliminary action	10	Preliminary action
3	28	Mechanical substitution	26	Copying
4	1	Segmentation	1	Segmentation
5	2	Separation	2	Separation
6	18	Mechanical vibration	19	Periodic action
7	3	Local quality	13	Inversion
8	37	Thermal expansion	28	Mechanical substitution
9	40	Composite material	15	Dynamicity
10	14	Curvature increase	24	Mediator

Description of the portable device

The device was developed which is simple, cost effective and user–friendly. The Engineering Parameters used from expanded TRIZ matrix were 1. Force for the measurement of IOP (applanation) 2. Harmful effects to eliminate the need of anesthesia. This has evolved a concept to develop a device for IOP measurement wherein the IOP can be measured through eyelid instead of cornea. Also it has recommended making a use of applanation and indentation principles for IOP measurement. The top ten innovative principles recommended by expandable TRIZ matrix were used to solve the Problem. The principles used are preliminary action (10), inversion (13), dynamicity (15), copying (26), mechanical substitution (28) and parameter change (35). By using the above innovative principles the device was developed.

The present device can be placed on closed eyelid by applying a pressure (applanation force) on the eyelid through plunger with its tip (No. 3123|MUM|2015 IP). The calibrated scale present on the cylinder will indicate the IOP in patient’s eye. The scale is provided with zones of green, yellow and red colors which will identify whether the patient’s eye is glaucomatous or non-glaucomatous. Further it can be used externally through eyelid does not required an aesthetic drops to be added in patient’s eye. The device is simple and convenient for use. Measurement is taken from the eyelid; hence the chance of transmission of diseases can be eliminated. The device is used for screening patient’s eye. It helps the Doctors or medical practitioners to find out the IOP in patient’s eye in rural and remote areas. This serves the patient to avoid the further damage to his/her eyesight. The main body of the device comprises a main cylinder enclosing small plunger and compression spring inside. The pointer attached to the spring is moveable on the upper surface of the main cylinder inside a slot comprising a scale with IOPs. The main cylinder carries a piston and plunger inside which allows the movement of the plunger. At the end of the cylinder fine adjustable knob is provided with another plunger. Compression spring is being compressed between contact plunger and by rotating the knob of end plunger. The tip of the plunger is provided with a flat circular cross section with a diameter of 3.06 mm required to applanate the cornea. The knob provided at the end of the cylinder records the indentation of the plunger into the eye. In normal working the tip of the plunger is placed normal to the eyelid on patient’s eye with a closed eyelid. The plunger exerts a pressure on eyelid to applanate the cornea. The pressure exerted by the plunger on eyelid will transfer through contact plunger on compression spring the spring will transfer this applanated force on the glaucoma scale. The recorded values will be directly indicated on the scale (Figure 1). A suitable device is being designed. Then the full prototype was fabricated.

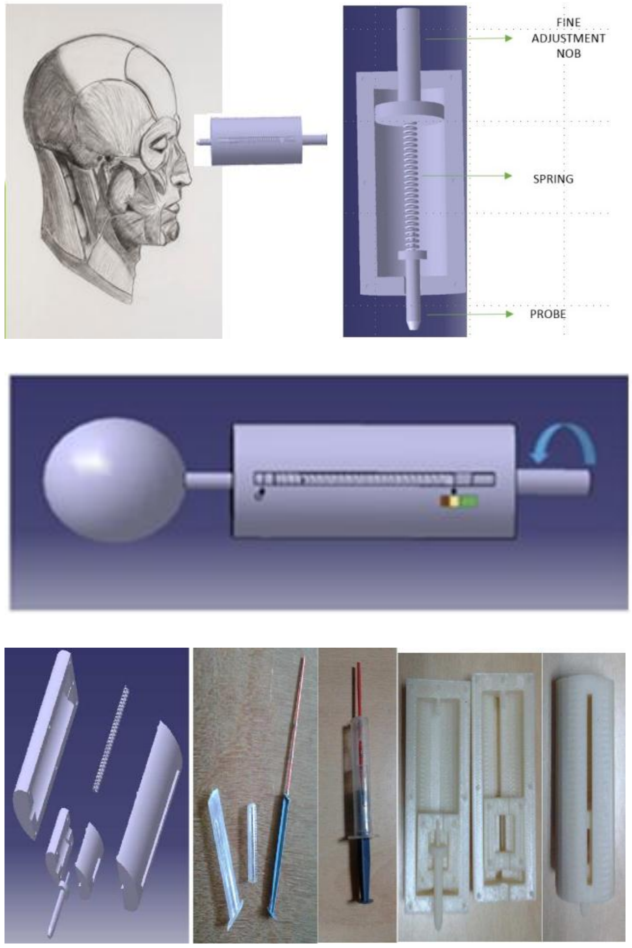

Figure1: Prototype and CAD Model of proposed device.

Objective

The methods and devices which are available for the measurement of IOP have their own limitations. These causes discomfort to the patients during measurement. Also these methods used to measure IOP over cornea needs anesthesia. There is a dare need of a device for the measurement of intraocular pressure by making the contact of plunger with closed eyelid. This will completely eliminates the need of anesthesia and expertise ophthalmologist to record the IOP. The goal is to build a device which should measure the IOP easily. The requirements are as follows:

1. The person should be able to use the device by himself/herself without the assistance of another person
2. The device should be user-friendly and not require complex instructions and additional training.
3. The device should be accurate and operate within the range of 0-100 mm Hg. While the normal IOP ranges from 10-21 mm Hg, it may be as high as 100 mm Hg for patients with late stage glaucoma.
4. The device should not require anesthetic drops.
5. The device should minimize patient discomfort.

METHODS

The fabricated device was calibrated on human eye by conducting experimental trial in laboratory. The readings are cross verified by Schiotz's tonometer Figure 2. Further these values of potentiometer readings are used to set the upper limit of IOP for the device.

Figure 2: Calibration of a device on human eye.

After calibration of actual device the further study is carried out at Government Hospital Bhandara, Maharashtra, India. The fabricated device was presented to ophthalmic surgeon at Government Hospital, Bhandara and permission was granted to test it on patient's eye. The examination was done by an ophthalmic practitioner who received extra training, especially in judging the optic disc and working with Schiotz tonometer. Initially the study included 25 patients. For the measurement we decided to exclude patients who had undergone filter operations in the past. 5 patients with 5 operated eyes as they might distort the value of the parameters for the detection of increased eye pressure. This resulted in 20 participants. These patients came to special eye clinic or to a general clinic due to ocular complaints. Age and gender were recorded and eyes were examined with medical doctor. The testing of the device was carried out in the month of June 2016 with the aids of ophthalmologist. A simple procedure was adopted to test the device on patient's eye with closed eyelid (Figure 3). For the comfort of the patients it was decided to test the device on patient's eye in sleeping posture. Each patient was asked to sleep on bed and eyelid was closed. Then contact of plunger tip was made with closed eyelid and pressure was exerted to check the ocular hypertension in the indicative form by the device. Afterward anesthetic drops were added in the patient's eye to numb it and eye pressure was measured with calibrated Schiotz tonometer by expert Ophthalmologist. The results are verified with Schiotz's tonometer by the ophthalmologists in ophthalmic section at Bhandara.

Figure 3: Testing of device on patient's eye.

RESULTS

Of the 20 patients were selected from the age group 50-70 years shown in figure 4. 9 (45%) patients were found to have a pressure above 21 mm Hg. 3 (15%) patients were found to have a pressure above 25 mm Hg those were indicated by our device with red indicator with a high risk of higher ocular tension. The variation of the age and the intraocular pressure across the number of patients and age is shown in Figure 4 and 5. The parameters gender and age for all the patients were recorded 12 (60%) were female and 8 (40%) were male. The testing of fabricated model of the device was carried out at Govt. Hospital, Bhandara Maharashtra, India. Further the team of ophthalmic surgeons at Govt. Hospital Bhandara tested it on patient's eye. The device was tested on patient's eye for detecting glaucoma and cross verified by ophthalmologist with Schiotz's tonometer and digital palpation technique. The comparison of results with Schiotz's tonometer is presented in Figure 6.

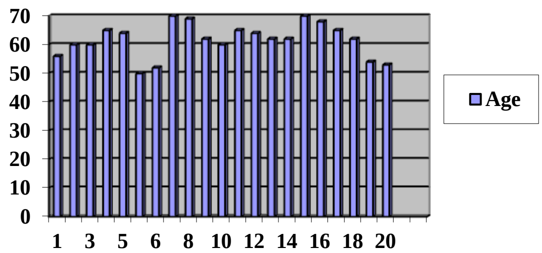

Figure 4: Variation of age across no. of patients.

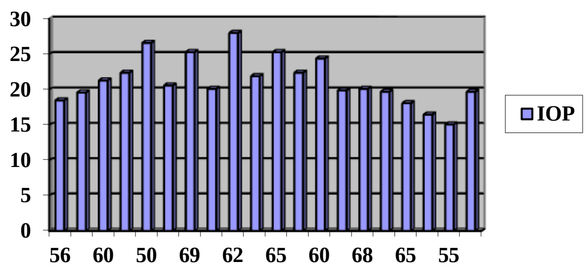

Figure 5: Variation of IOP across the age of patients.

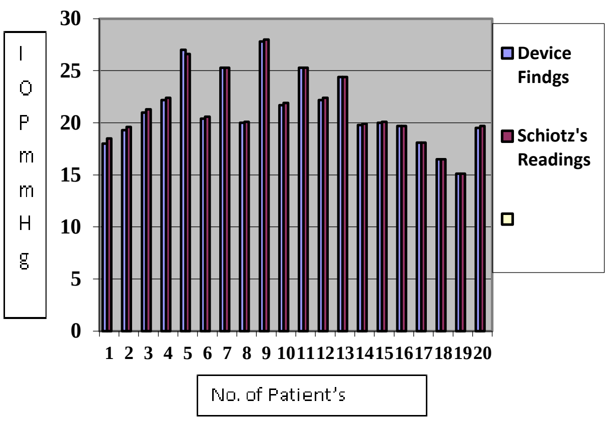

Figure 6: Comparison of results with Schiotz's tonometer.

DISCUSSION

Normal IOP ranges between 10-21 mm Hg. After 23 mm Hg, the risk of glaucoma increases by 10% for every additional 1 mm Hg pressure. Higher pressure damages the neuronal tissue in the optic nerve head (lamina cribrsa). Current treatment involves reducing the pressure to slow the progression of the disease. This requires accurate methods to measure IOP.[4,23] Tonometry is an eye pressure measurement that is most commonly performed on the cornea. Its objective is to determine the intraocular pressure of the eye and diagnose diseases such as glaucoma, which if left untreated, could lead to optic nerve damage.[24] The gold standard of tonometry is the Goldman applanation technique (GAT), where the cornea is flattened to a pre-determined area.[25] While it can measure IOP at a given time during a visit to an ophthalmologist, applanation tonometry cannot monitor variations over time at different periods of the day, which is its main limitation.[26] The Goldmann tonometer applies pressure to the cornea, which occasionally frightens patients, and although eye drops are used to numb the eye, pain has been reported by some patients. Although the non-contact tonometer has not been reported to cause pain, patients are sometimes startled by the sudden blast of air.[27] More recent studies have indicated that the accuracy of GAT depends on the position and orientation of the probe.[28] Therefore, researchers and clinicians in the field recognize the urgent need for an improved diagnostic tool.[26]

Not surprisingly, a large number of alternative techniques and devices have been reported These include portable versions of the GAT tonometers such as the Perkins and Draeger tonometers, the MacKay-Marg tonometer (Tonopen), a non-contact air-puff tonometer, and a rebound tonometer (I-Care).[29-33] When these tonometers used on patients with contact lenses, many of these corneal tonometers report statistically significant errors due to the presence of a soft contact lens.[34] More recently, two trans-scleral tonometers have also been reported – a rebound tonometer (Diaton), which uses a plunger rebounding from the sclera, and a trans-scleral indentation tonometer (Pro-view), which is based on measuring the force resulting in a pressure phosphene reaction.[35-36] Yet another group of instruments is based on optical methods such as optical coherence tomography (OCT), however at present time these are not suitable for measuring pressure.[37] A common disadvantage of these tonometer is that the detector is immediate in contact with the cornea. Therefore, sterilization of the detector and anesthetization are required. The procedure causes an unpleasant sensation in the eye; measurement of IOP in the children is rather difficult. Also the procedure does not exclude contamination.[38]

The present device used applanation and indentation principles to measure the IOP through eyelid.

Ideally, the measurement instrument should neither cause pain nor startle the patient. The abovementioned problems indicate that a lightweight noninvasive tonometer, or possibly even an instrument that would enable at-home testing, is required. The tonometer currently under development by the authors measures ocular pressure through the eyelid of the closed eye. Although development of this type of tonometer was attempted more than 40 years ago, this previous attempt was not successful.[39] The presented device is used for measuring IOP through the eyelid without anesthetization. The measuring procedure is painless so IOP can be measured even in children of any age. Contamination is excluded because there is no immediate contact between the device and the eye. The device is easy to use and absolutely harmless for the patient. In rural and remote areas hardly there is a chance of availability of expertise. Therefore the device is most suitable to the doctors working in remote and rural areas. There is a little empirical evidence of tonometers working through eyelid in literature. The results are compare with Schiotz"s tonometer and found almost similar.

CONCLUSION

An innovative device has been developed for the measurement of intraocular pressure (IOP) by the use of mostly used mechanical Engineering parameters and top ten innovative principles recommended by expanded TRIZ matrix. A new method of measuring ocular pressure over a closed eyelid was developed and has been shown to successfully discriminate differences in the internal pressure of an object. In addition, the eyelid, which had previously been an obstacle to measurement, has now been shown to have little effect on measurement. The development of the new tonometer will allow patients who were unaware of their glaucoma to recognize their condition earlier. The developed device requires a better method of placement on the eyelid and an improved method of correcting IOP values. We hope that the proposed device will contribute to the field of ophthalmology for internal pressure measurement.

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