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Development of a Device in Detection of Glaucoma for Rural Eye Care Using Additive Manufacturing and TRIZ

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Abstract: 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. 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. 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. Additive manufacturing (AM) is an era of technical development and innovation. Developing a device for detecting glaucoma by using AM and TRIZ 'The theory of inventive problem solving' (A Collaborative approach) can overcome the disadvantages that classic tonometer have. The field of Ophthalmology will be experiencing a paradigm shift towards the use of collaborative approach of TRIZ with AM. The developed new device was tested on 40 patient's eye at Government Hospital Bhandara, (M. S.), India. The results of new device were cross verified by expert clinicians using calibrated Schiotz's tonometer and digital palpation technique. The developed new device was tested on patient's eye through eyelid and results were compared with calibrated Schiotz's tonometer. The results from the new device were found in good agreement with results from Schiotz'stonometer with the average error of 0.033 ± 0.18 (mean $\pm$ SD) mm of Hg and mean relative error was -0.0018 ± 0.0096 (mean $\pm$ SD). To conclude, there is a substantial need for early detection and diagnosis of glaucoma in rural and remote areas (worldwide). A new device for detection of glaucoma using AM and TRIZ was introduced in this paper and measurements by the new device were validated by currently well accepted Schiotz's tonometer. The new device will help the medical practitioners in rural and remote areas for early detection of glaucoma.

Keywords: Glaucoma, intraocular pressure, tonometry, additive manufacturing, triz.

1 Introduction

Glaucoma is a progressive optic nerve neuropathy which may damages the optic nerve [Hitchings, 2009]. It results into irreversible vision loss and considered as one of the leading cause of blindness worldwide [Ferreira et al.(2013)]. It has been estimated that

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glaucoma affects 70 million people worldwide; however the fundamental causes remain unknown for many types of glaucoma [ManikGoel et al.(2013)]. 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) [Adan et al.(2005); Ying, et al.(2012)]. 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.

Glaucoma is considered as a one of the main cause of the legal blindness in the world and the most prevalent retinal neurodegenerative disease [S. Pinar-Sueiro et al.(2011)]. According to the survey conducted by World Health Organization, the number of glaucomatous patients will increase to 80 million people worldwide in 2020[Auvray, et al.(2012)]. At present the only way out for the treatment of glaucoma is the accurate recording of IOP. Meena et al [Meena, et al. (2009)] described the evolution of tonometry used in IOP measurement and the different tonometry principles used in various tonometers since last two centuries. In the present study an innovative product is developed for detecting glaucoma. A novel approach to develop a device for detecting glaucoma is presented and discussed. Further a case study has been discussed to develop a biomedical device for the measurement of IOP through eyelid.

2 Definition of problem

Glaucoma stems from optic nerve damage due to a buildup of intraocular pressure (IOP) in the eyeball. Normal IOP ranges between 10-21 mm of Hg. After 23 mm of Hg, the risk of glaucoma increases by 10% for every additional 1 mm of Hg pressure. Higher pressure damages the neuronal tissue in the optic nerve head (lamina cribrosa). Current treatment involves reducing the pressure to slow the progression of the disease. This requires accurate methods to measure the IOP.

The present devices used to measure the IOP are Applanation and indentation tonometer. Although the applanation tonometry is considered the standard procedure for measuring IOP; it has a number of 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, anesthesia must be applied to numb the eye. All of these steps require a skilled technician or expertise of the ophthalmologist. In rural and remote areas hardly there is a chance of availability of expertise.

3 Methods

3.1 Working of device

The device was developed which is simple, cost effective and user–friendly. 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 the eyelid, does not required an aesthetic drops to be added in the 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 the 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 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 IOP scale. The recorded values will be directly indicated on the scale. A suitable device was designed and checked for its functionality (Figure 1).

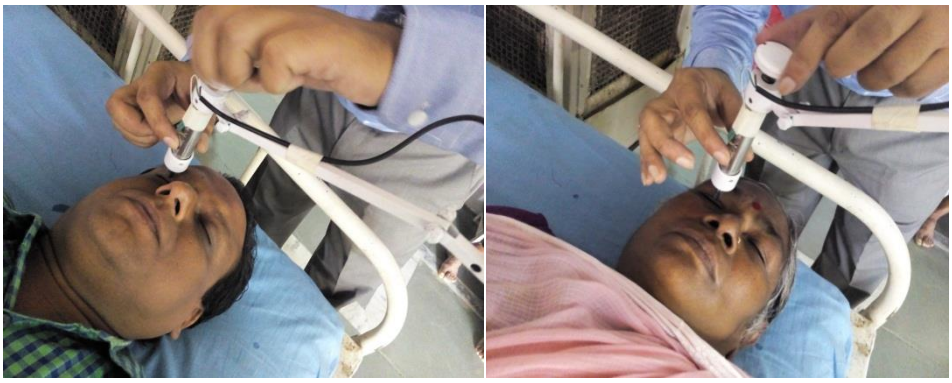

Figure 1: Testing of proposed device on eye.

3.2 Development of device

In the modern society more and more attentions are paid on the medical equipment or devices that have greater impact to improve quality of people's life. TRIZ offered a powerful technique for inventive idea generation. This technique can be used successfully in designing mechanical product. Subsequently the applications of TRIZ in medical equipment design process grasp the researcher's attention. The AM technology based on TRIZ can help the conceptual design for the new product [Gao et al.(2015)]. Medical organizations explicitly need both creativity and innovations together. Mawale et al [Mawale et al.(2016)] represented the use of collaborative approach of TRIZ with AM.

This approach provides realistic and systematic way to solve the innovative problems (Figure 2).

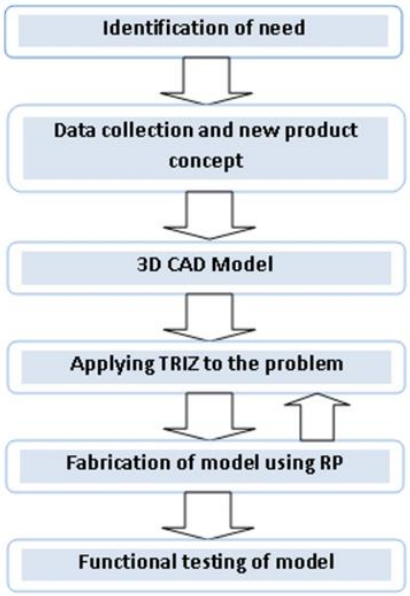

Figure 2: Approach for design and development of (RP+TRIZ) assisted device for glaucoma detection.

The work had been carried out for innovative design of a device for detecting glaucoma. In the presented work the patient's (having glaucoma) and doctor's (Ophthalmologists) requirement of new product was realized. Afterwards the Engineering parameters from 2010 expanded TRIZ matrix concerned to those requirements were explored. The Engineering parameters were including 1. Force for the measurement of IOP (applanation) 2. Harmful effects for eliminate the need of anesthesia. Using top ten innovative principles and examining the above parameters six inventive principles, preliminary action, inversion, dynamicity, copying, mechanical substitution and parameter change were selected. Using collaborative approach the inventive principles parameter change and copying were chosen as close relationship with the problem. The final prototype was developed using rapid prototyping (RP). For constructing the conceptual model of device Solid works 15 was used (Figure 3). After modelling the device in Solid works v15 the models are converted into STL format. The RP is the technique used to produce the physical models based on radiography image. Medical models were developed especially using the Stereo lithography (STL) and the fused deposition modeling (FDM) techniques of RP over last few years [Raghtate et al.(2014)]. Dahake et al[Dahake et al.(2016)] developed a workflow for design and fabrication of surgical guides (CSG) using Rapid prototyping (RP).The STL file of device was imported to the Catalyst Ex, pre-processing software to link with RP machine. This STL file was then sent to RP machine (uPrint SE, Stratasys Inc., Ontario, CA, USA) to get the acrylonitrile butadiene styrene (ABS) model of the new device using fused deposition modelling (FDM) method (Figure 4).FDM technique

was used for fabrication because of its minimum post processing requirements and superior mechanical properties like strength of the build material [Deshmukh et al.(2011)]. Using the prototype of the new device the final model of the device was fabricated (Figure 1). Furthermore the fabricated model of the new device was presented to the team of ophthalmic surgeons at Government Hospital, Bhandara and the study was approved by the Institutional Ethical Committee constituted at Government Hospital Bhandara, (M.S.) India in June 2016. Each subject provided informed consent prior to participation in the study, in line with the declaration of Helsinki. The 40 participants were selected from age group 18-80 years. The parameters gender and age for all the patients were recorded 24 (60%) were female and 16 (40%) were male shown inTable 1.

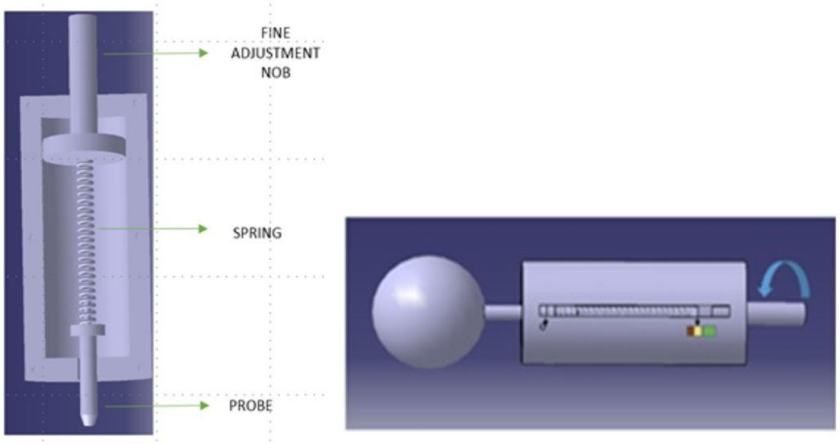

Figure 3: CAD model of a device.

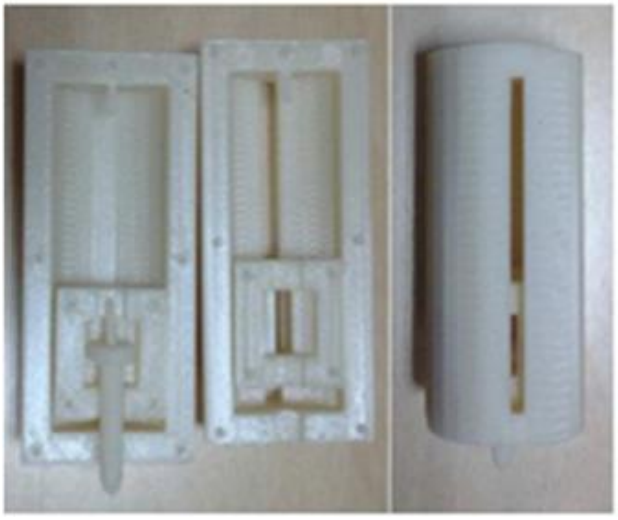

Figure 4: Fabricated prototype of a device using RP

4 Validiation

The testing of fabricated model of the new device was carried out at Govt. Hospital, Bhandara (M.S.), 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 validiated by ophthalmologist with calibrated schiotz's tonometer and digital palpation technique. The results were shown almost linear relationship with calibrated Schiotz's tonometer, represented in Table 1. For representing the cases of high risk ocular hypertension the reference IOP has considered 25 mm of Hg. The *t*-tests on the 40 eyes were performed to determine whether the new device offered any benefit in the IOP measurement by comparing the measurements obtained with the two devices. The significance level was set to 0.05. The t-test showed no statistically significant IOP result between new device and Schiotz tonometer in terms of mean ± SD was 18.99 ± 2.36 mm of Hg in the new device and 19.02 ± 2.35 mm of Hg in Schiotz tonometer ($p > 0.05$).

Table 1: Findings of device for detecting glaucoma

Subject	Age	Sex	Eye	Device Findings	IOP (Schiotz)
1	18	M	L	17.0	17.3
2	51	M	L	17.2	17.3
3	53	F	R	17.3	17.3
4	50	F	L	18.7	18.9
5	52	F	R	17.0	17.3
6	65	M	L	20.3	20.6
7	61	F	R	17.3	17.3
8	67	F	L	19.0	18.9
9	58	F	R	17.2	17.3
10	36	M	L	20.0	20.1
11	39	M	R	22.0	21.9
12	55	F	L	18.0	18.1
13	51	F	R	19.6	19.7
14	60	F	L	21.5	21.4
15	61	M	R	20.0	19.7
16	35	M	L	17.3	17.3
17	33	F	R	16.0	15.9
18	55	F	L	21.0	20.6

19	50	F	R	18.5	18.9
20	50	F	L	18.9	18.9
21	48	M	R	18.1	18.1
22	80	M	L	17.3	17.3
23	75	F	R	15.7	15.9
24	25	M	L	17.2	17.3
25	24	F	R	17.0	17.0
26	50	F	L	20.5	20.6
27	52	F	R	22.4	22.4
28	80	M	L	15.6	15.6
29	78	F	R	17.2	17
30	48	F	L	21.0	20.6
31	47	M	R	26.5	26.6
32	59	M	L	18.6	18.5
33	58	F	R	20.0	20.1
34	45	M	L	20.0	19.7
35	44	M	R	18.0	18.1
36	43	M	L	18.0	18.0
37	42	F	R	19.3	19.6
38	58	F	L	21.2	21.4
39	57	F	R	25.1	25.3
40	56	F	L	17.0	17.0

5 Result

Out of the 40 patients, those were selected from the age group 18-80 years 6 (15%) patients were found to have a pressure above 21 mm Hg. 2 (5%) patients were found to have a pressure above 25 mm Hg those were indicated by our device with a high risk of higher ocular tension. The recorded values of IOP by Schiotz's tonometer and findings of our device are represented in Table 1. Table 1 showed that the new device readings had good agreement with Scsiotz's tonometer results. The error is defined as the differences between the IOP readings obtained by new device and Schiot z's tonometer. The average error was -0.033 ± 0.18 (mean ± SD) mm Hg and average relative error was -0.0018 ± 0.0096 (mean ± SD).The error in new device shows that new device almost gives similar results as the Schiotz tonometer. It means that new device gives almost similar results as compared to results obtained by expert clinicians using calibrated Schiotz's tonometer and digital palpation technique.

Also from Figure 5 the variation in IOP across the age was observed. The variation was found random, indicating that glaucoma may cause to any patient irrespective of their age. This fact emphasis on the measurement of IOP to find the proneness to glaucoma so that, early treatment can be done. The new device can measure the IOP through eyelid eliminating the need of anesthesia and can be used by any medical practitioner those are working in rural and remote areas whereas Schiotz's tonometer needs anesthesia and expert clinician to measure the IOP.

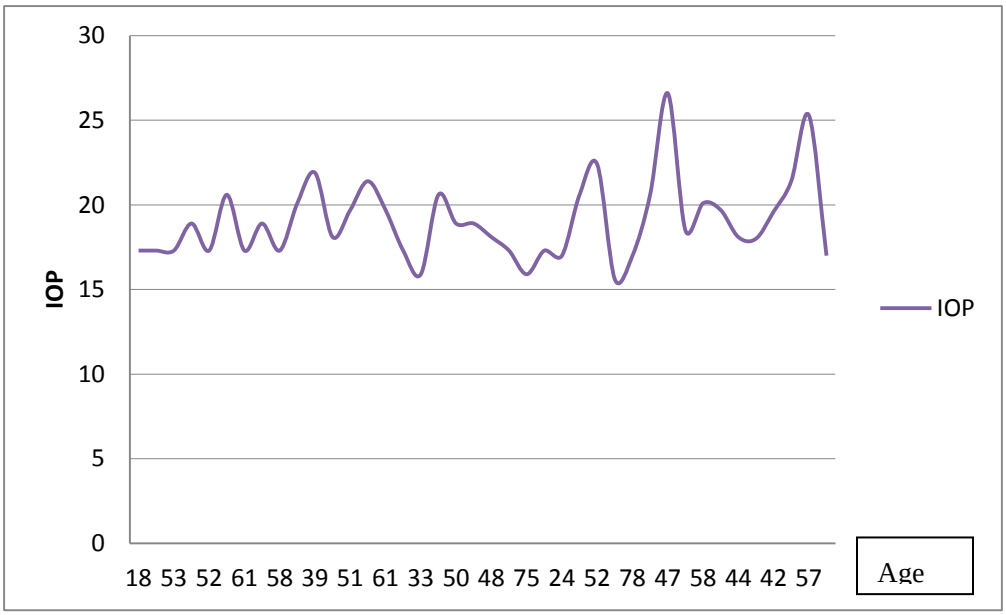

Figure 5: variation of IOP across age.

6 Discussion

The common disadvantages, of the various tonometers are 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;therefore measurement of IOP in the children is rather difficult. Also the procedure does not exclude contamination.The present device used applanation and indentation principles to measure the IOP through eyelid. Ideally, the measuring instrument should neither cause pain nor startle the patient. 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. 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 same.

7 Conclusion

The innovative principles used in development of a device to detect a glaucoma are parameter change, preliminary action, segmentation, separation and mechanical substitution.The developed device can be used by any medical practioner those are working in rural and remote areas. The patient will be more comfortable during the measurement of IOP. The device will totally eliminate the need of anesthesia and aid of expert ophthalmologist. This will help in screening the patient's eye. In future the functional prototype is required to be tested for IOP measurement and results can be compared with Goldman Tonometer.

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Conflict of interest: The authors have no conflict of interest to declare.

References

Auvray, P.; Rousseau, L.; Lissorgues, G.; Soulier, F.; Potin, O.; Bernard, S.; Dieulevuelt, F.; Scorsone, E.; Bergonzo, P.; Chicaud,L.; Picaud, Sahil, J. A. (2012): A passive pressure sensor for continuously measuring the intraocular pressure in glaucomatous patients. *IRBM,* vol. 33**,**pp. 117-122.

Chakrabarti, M.; John, S. R.; Chakrabarti, **A.**(2009): 180 years of evolution in Tonometry. *Kerala Journal of Ophthalmology***,**vol. 21, pp. 23-31

Dahake, S. W.; Kuthe, A. K.; Chawla, J.; Mawale,**M. B.** (2017): Rapid prototyping assisted fabrication of customized surgical guides in mandibular distraction Osteogenesis.*Rapid prototyping Journal*, vol. 23, DOI: 10.1108/RPJ-09-2015-0129.

Deshmukh, T.; Kuthe, A.; Chaware, S.; Vaibhav, B.; Ingole, D. (2011): Rapid prototyping assisted fabrication of the customized temporomandibular joint implant. *Rapid Prototyping Journal***,**vol. 17, pp. 362-368.

Ferreira, J. A.; Deoliveira, P.; DasilvaP. M.; Murta, **J. N.** (2013): Numerical simulation of aqueous humor flow from healthy to pathologic situations. *Applied Mathematics &Computation,* vol. 226, pp. 777-792.

Gao, C.; Guo, L. M.; Gao F. L.; Yang, **B.** (2015): Innovative design of medical equipment based on TRIZ.*Technology and Health care*,vol. 23,pp. s269-s276.

Goel, M.; Picciani, R. G.; Lee, R. K.; Bhattacharya, S. K. (2010): Aqueous humor dynamics: A review. *The open Ophthalmology Journal*,vol. 4: pp. 52-59.

Hitchings, **R. A.**(2009): Glaucoma: an area of darkness. *Eye***,** vol. 23.pp.1764-1774.

Ju, Y.; Wang, B. L.;Xie, J. Z.; Huang, L. W.;Huang, S. H.; Huang, X. Y. (2005): Dynamic model of the aqueous humor circulation with application to simulation of the treatment for primary open angle glaucoma. *Proceedings of the IEEE Engineering in Medicine and Biology 27th Annual Conference Shanghai*, vol. 1, pp. 15-18.

Mawale, M. B.; Kuthe, A. K.; Dahake,**S. W.**(2016): Additive layered manufacturing: state –of-the-art applications in product innovations. *Concurrent Engineering Research and Applications*,vol. 24, pp. 94-102.

Pinar-Sueiro, S.; Rodriguez-Puertas, R.; Vecino, E.(2011): Cannabinoid applications in glaucoma. *Archivos de la SociedadEspañola de Oftalmología*, vol.1,pp. 16-23.

Sameer, R.; Kuthe, A. M.; Deshmukh, T. R.; Sandeep W. Dahake, S. W.(2014): Rapid prototyuping assisted fabrication of customized metatarso phalangeal joint implant (Samku).*Rapid Prototyping Journal***,**vol. 20,pp. 270-279.

Villamarin, A.; Roy, S.; Hasballa, R.;Vardoulis, O.;Reymond, P.;(2012): 3D simulation of aqueous flow in the human eye. *Medical Engineering and Physics*, vol. 34, pp. 1462-1470.