ORIGINAL ARTICLES

# Development of an adjustable suture for trabeculectomy

Yongjun Lai*[1], Husam Elkaseh[1], Robert Campbell[2]

[1] Department of Mechanical and Materials Engineering, Queen's University, Ontario, Canada
[2] Depart of Opthalmology, Hotel Dieu Hospital, Ontario, Canada

**Received:** June 19, 2017 **Accepted:** July 23, 2017 **Online Published:** July 31, 2017
**DOI:** 10.5430/jbei.v3n2p55 **URL:** https://doi.org/10.5430/jbei.v3n2p55

## ABSTRACT

This study reports a new suture design that enables simple, controlled intraocular pressure (IOP) adjustments in the postoperative period after trabeculectomy surgery, a common operation used in the treatment of glaucoma. Detailed configuration of this novel suture design and the process of fabricating the new sutures are demonstrated. Ex-vivo testing with prototyped sutures has demonstrated IOP drops of over 50% following suture adjustment. The concept of using adjustable suture to realize controllable IOP drop in the post trabeculectomy treatment is proved to be feasible.

**Key Words:** Adjustable suture, Trabeculectomy surgery, Intraocular pressure, Glaucoma

## 1. INTRODUCTION

Glaucoma affects almost 60 million people worldwide and is the most common cause of irreversible blindness in the world.[1] In the majority of cases, glaucoma is associated with elevated intraocular pressure (IOP), which occurs due to failure of the eye's natural drainage system, the trabecular meshwork.[2] Surgical treatments for glaucoma aim to create a lower resistance outflow pathway in order to lower the IOP. In particular, trabeculectomy is one of the common surgical techniques for treating glaucoma.[3,4]

In trabeculaectomy, surgeons create a fistula between the anterior chamber of the eye and the subconjunctival space, which allows for low resistance aqueous humor outflow. The fistula is fashioned beneath a trapdoor-like scleral flap, which provides a small amount of resistance in order to avoid excessive lowering of the IOP. To provide this small amount of resistance, the scleral flap is sutured in place with 10-0 nylon suture.[5] However, the final IOP achieved is highly dependent on the suturing technique. Sutures that are too tight or too loose can result in severe complications from IOP that is either too high or too low.[6,7] Consequently, in an attempt to provide more precise IOP control after trabeculectomy, a number of suturing modalities have been used to close the scleral flap such as mechanically-adjustable and releasable suturing techniques.[8] However, many of these techniques are cumbersome intra-operatively or difficult to titrate post-operatively such that the IOP adjustment achieved is unpredictable. Complete lysis of the sutures is also commonly used to lower IOP but again, the IOP drop may be precipitous, which can lead to blinding complications including severe intraocular bleeding.[9]

This study reports the development of a new suture that is adjusted with the simple cutting of a suture segment. The proposed design allows surgeons to safely and accurately control aqueous humor outflow by adding an extra measured length adjustment to the 10-0 nylon suture. This new suture

*Correspondence: Yongjun Lai; Email: lai@queensu.ca; Address: Department of Mechanical and Materials Engineering, Queen's University, Ontario, Canada.

allows IOP adjustment without additional incisional surgery, and uses laser systems already in common use in the management of patients with glaucoma.

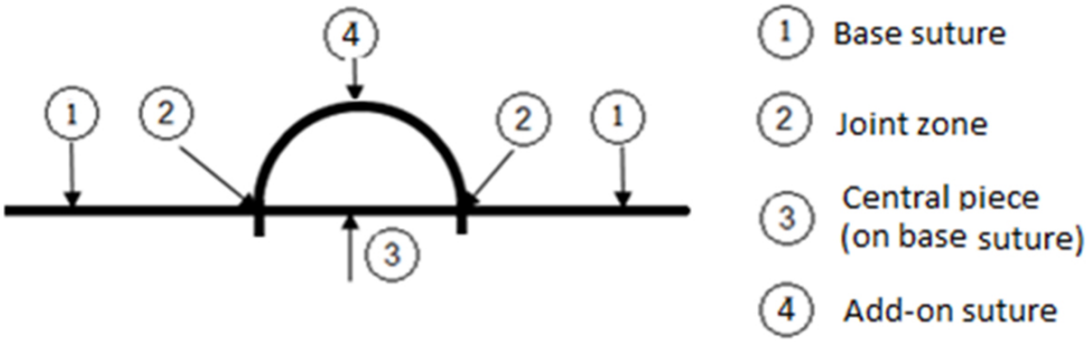



**Figure 1.** Design of adjustable suture

## 2. DESIGN

This new adjustable suture design involves a traditional 10-0 nylon suture ($\sim$ 30 $\mu$m in diameter) as the base with an add-on piece of 10-0 nylon suture forming a semicircle attached to the base suture (see Figure 1). The length of the add-on suture (element ④ in Figure 1) can be varied. The add-on suture is attached to the base suture a joint zone by a miniscule droplet of adhesive.

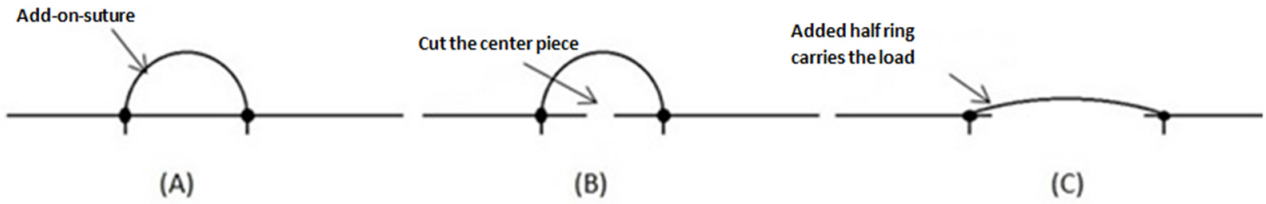



**Figure 2.** The working sequence of the new suture method

When the new suture is initially tightened, the tension load is applied to the base suture. When the central piece of the base suture is lysed (see Figure 2b), the tension load will separate the two joint zones further away from each other until the add-on suture carries the new tension load (see Figure 2c).

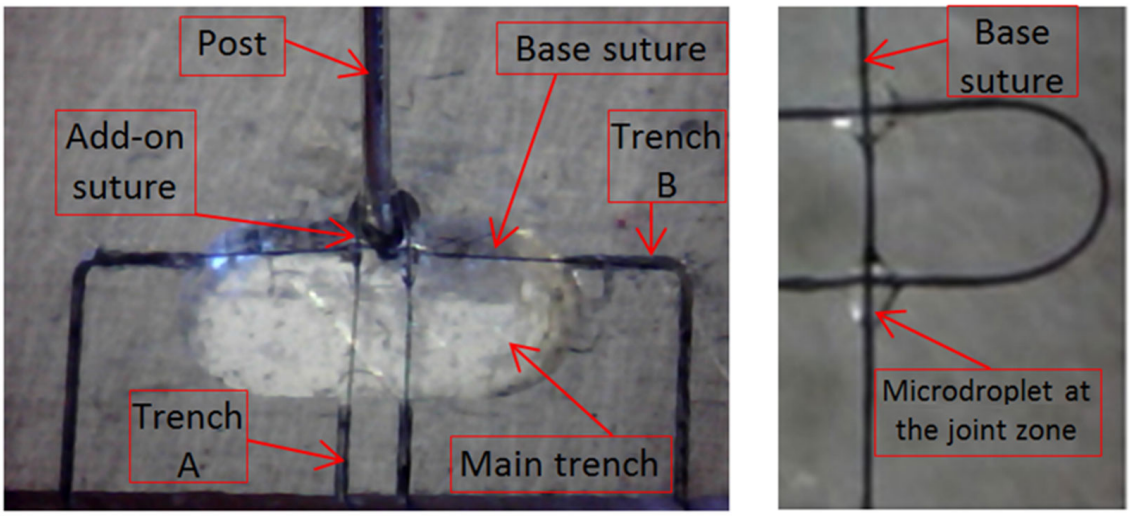



**Figure 3.** Adjustable suture sample preparation

## 3. PROTOTYPE FABRICATION

Fabrication is carried out using a micromold consisting of stations with various extension lengths (see Figure 3). Each station has a trench A where the add-on suture (extension suture) is placed, a trench B where the base suture is placed, and a main trench which provides the space for the base suture and add-on suture to intersect above a solid surface allowing an adhesive droplet to reform around the joint zone. A post is located on the side of the main trench around which the add-on suture is wrapped. The diameter of the post and the distance of the post from the edge of the main trench determine the length of the add-on piece of the new suture. The lengths of the add-on extensions ranged from 350 $\mu$m to 700 $\mu$m in the prototyped sutures.

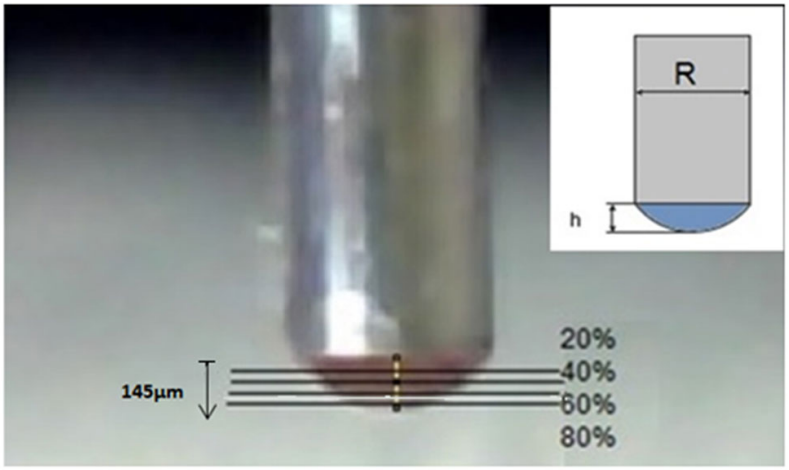



**Figure 4.** A probe with diameter of 0.6 mm

In order to bond the add-on suture to the base suture at the joint zone, a droplet of adhesive (Loctite 4311 glue) is used. To generate small droplets, a liquid separation technique is used.[10,11] A cylindrical probe with flat end is dipped into Loctite 4311 glue and then slowly pulled out of the glue. The probe surface is thus covered with glue, which flows down due to gravity. After approximately 20 seconds, excess glue drips off the tip, and a final stable drop with a diameter of R (diameter of the probe) and height of h remains (see Figure 4). Height (h) varies depending on the viscosity of the glue as well as the diameter of the probe. Both the base suture and add-on suture are the sutures that are currently used in ophthalmology surgeries, Loctite 4311 glue is also FDA approved biocompatible adhesive. Therefore, the new adjustable sutures are fully biocompatible.

Three probes with diameters of 0.3 mm, 0.6 mm and 1.6 mm were used to produce the droplets, and using Loctite 4311 at room temperature, the heights of the formed drops were 0.10 mm, 0.15 mm and 0.30 mm, respectively.

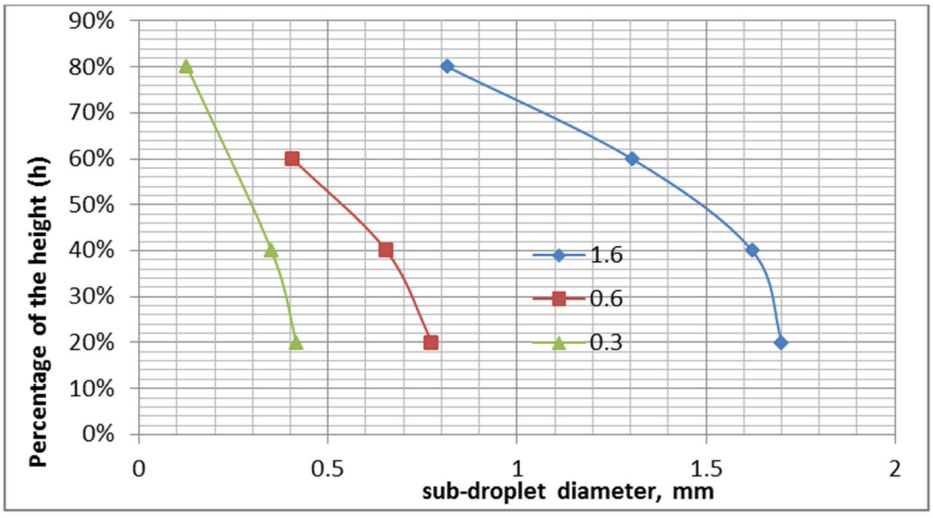



**Figure 5.** Diameter of sub-droplet *vs.* distance between the probe tip surface and joint zone surface

In order to produce different sized droplets at the joint zone, the probe and drop can be lowered to different zones (see Figure 4) to create the desired sub-droplet at the joint using a Wentworth probe station. Figure 5 shows the relationship of the diameter of the formed sub-droplet and the distance from the probe tip surface to the joint zone surface. The smallest sub-droplets are obtained when the distance between the probe tip surface and the joint zone surface is at 80% of height h. The probe with a diameter of 1.6 mm generates a droplet of 817 $\mu$m and 1,700 $\mu$m in diameter at 80% and 20% of h respectively. In general, the smaller the probe diameter, the smaller the sub-droplet produced. In addition, the larger the distance between the probe tip surface and joint zone surface, the smaller the sub-droplet formed. Based on these results, a stainless steel probe, whose diameter is 300 $\mu$m, was used to create sub-droplets range from 120 to 200 $\mu$m for suture joining.

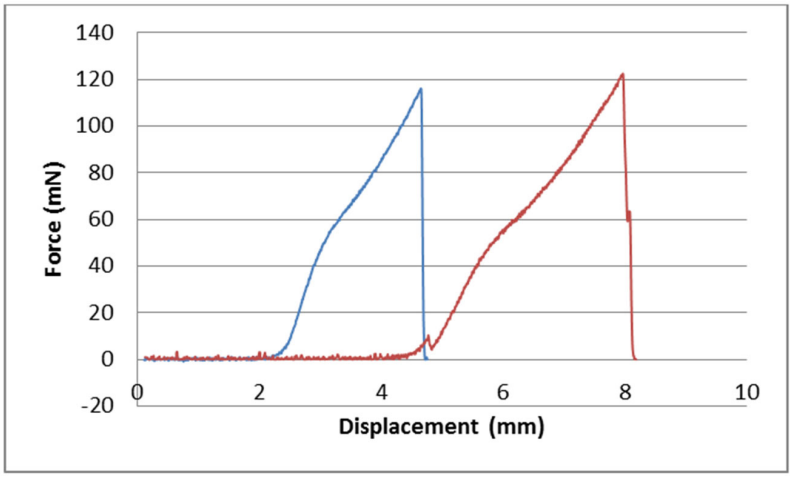



**Figure 6.** Tensile test for the joints formed by sub-droplet adhesive with diameters of 120 $\mu$m (left) and 140 $\mu$m. Force drops to zero when breakage occurs at maximum tension.

The strength of the joint is critical to the function of the new suture. A texture analyzer (TA-XT plus from Texture Technology Corp.) was used for the strength testing. Figure 6 shows the rupture strength of two joint zones with diameters of 120 $\mu$m (left) and 140 $\mu$m (right). Under this tensile strength testing, the central part of the base suture is cut. At the first part of the testing, the suture is loose, and no load applied to the joint. When the sutures are straightly tightened, the tensile load is applied to the joint. The maximum loads of 116mN and 123mN were found for the joints with diameter of 120 and 140 $\mu$m, respectively.

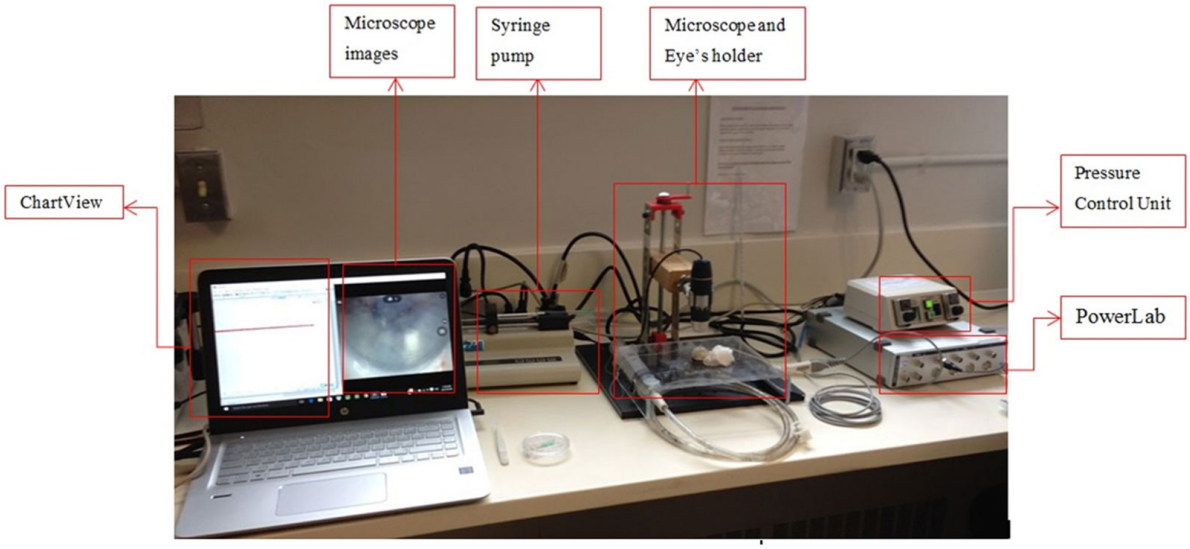
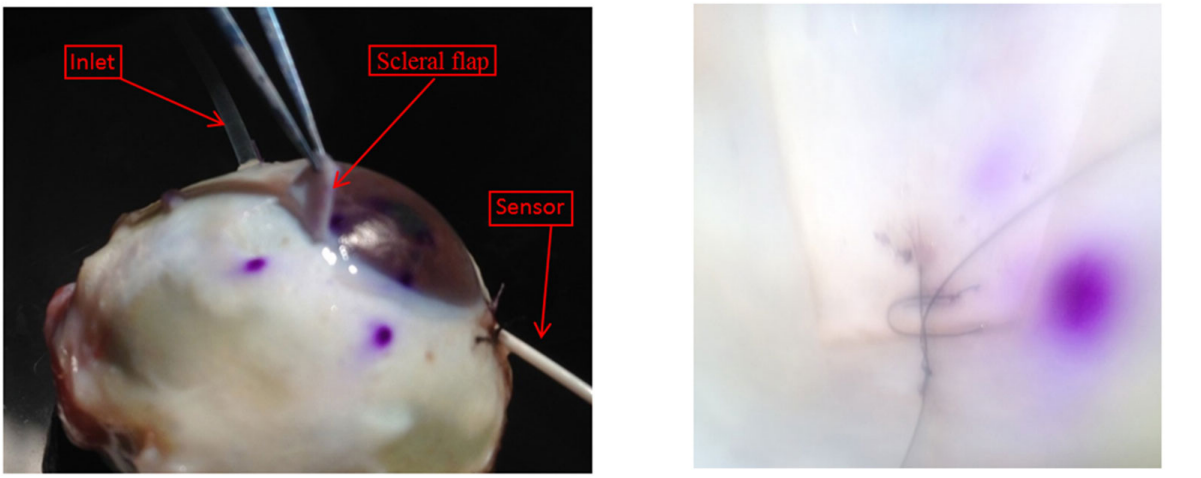



**Figure 7.** Test setup

## 4. Ex-vivo testing

Clinical use of the prototyped sutures was simulated and tested using a human cadaveric eye. The testing apparatus was set up as shown in Figure 7, and consisted of a pressure sensing unit (Milliar Inc. catheter pressure sensor A SPR-524, the Powerlab system), microscope, eye holder, syringe pump and computer.




a) Cadaveric eye setup b) Closeup of a tightened adjustable suture

**Figure 8.** Cadaveric eye evaluation model

Standard trabeculectomy surgery was carried out on the cadaveric eye. Briefly, a trapezoid incision was made and a scleral flap fashioned (see Figure 8a). The flap was then tightened with the new prototyped adjustable suture (see Figure 8b). An additional standard suture was also placed to provide some resistance to outflow once the adjustable suture was cut, as would be done clinically.

The mechanical pump was set up to inject saline into the eye to obtain a stable eye pressure in a range seen in patients with glaucoma (approximately 30 mmHg). The flow rate during the test was 3,000 $\mu$l/hr. Once the stable pressure was obtained, the central portion of the base suture was cut to loosen the flap and increase outflow rate. In this study, the suture was cut with microscissors. However, in human clinical use, the suture would be cut using a standard laser commonly used in current ophthalmology clinical practice.

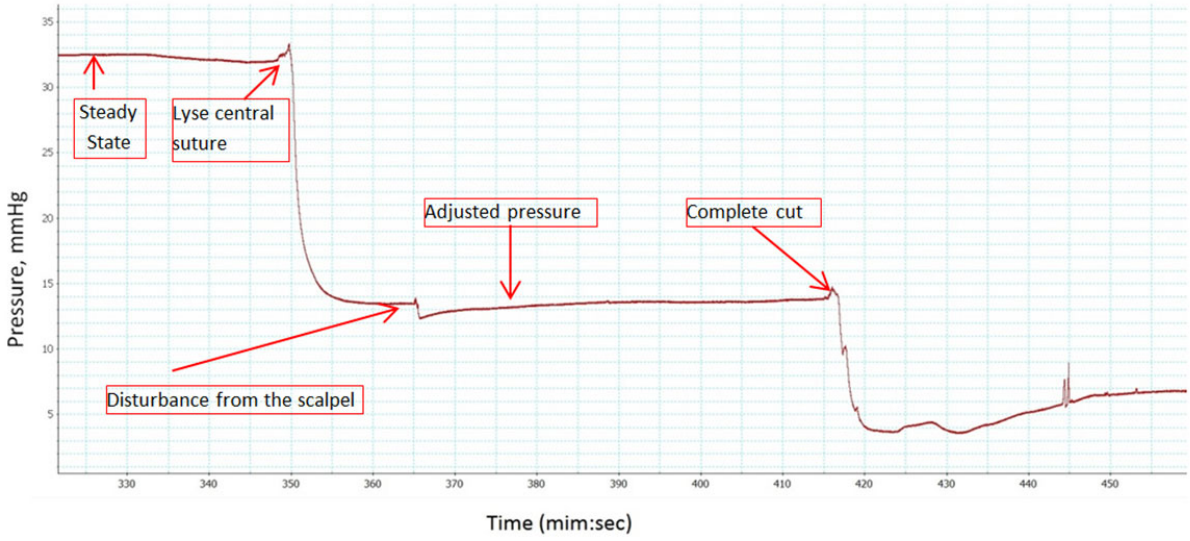



**Figure 9.** Cadaveric eye evaluation model

## 5. Evaluation Results and Discussion

Four sutures were used for the evaluation. Figure 9 is a truncation of the measured IOP in real time for one of the prototypes, and shows a typical response in the IOP of the cadaveric eye using the adjustable suture. The central portion of the base suture was lysed after a steady pressure of 32 mmHg was reached. After the central portion of the base suture was cut, an instant IOP drop to 13.5 mmHg occurred. After IOP stabilization, the added suture piece, which was now under tension, was cut completely. This led to a further pressure drop, stabilizing at 6.6 mmHg. The first cut (central base suture) introduces 57.8% pressure drop, *i.e.*, (32-13.5)/32 = 57.8% and the second cut on the add-on suture leads to additional 21.6% drop.

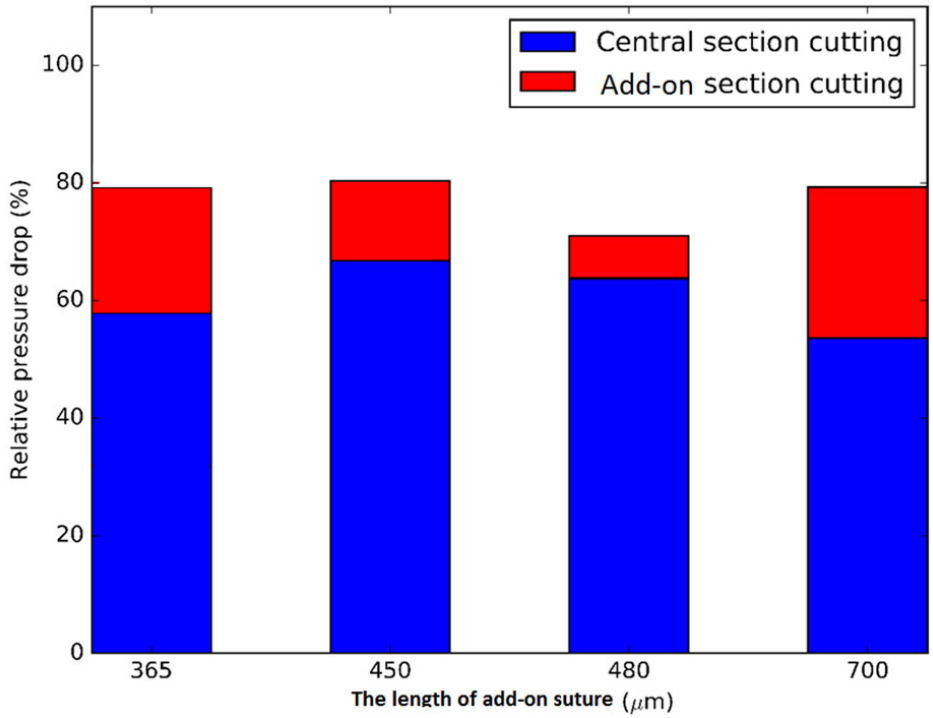



**Figure 10.** Cadaveric eye evaluation model

Three other adjustable sutures with extensions of 450 $\mu$m, 480 $\mu$m, and 700 $\mu$m were tested on the same eye. The overall IOP profiles are similar to the one shown in Figure 9. During the experiment, it was observed that the IOP in the cadaveric eye can be stabilized at flow rate of 3,000 $\mu$l/hr. However, the initial equilibrium pressure varied due to leakage rate changes. The initial pressures between tests varied between 20.7 and 34.5 mmHg. To compare the pressure drop provided by the different extensions, the pressure drop relative to the initial eye pressure was calculated for two stages of the surgery: the central section (base suture) cutting and add-on suture cutting (complete lyse). Figure 10 demonstrates the relative IOP changes using the sutures with different add-on extension. When the add-on suture increases its length from 365 $\mu$m to 450 $\mu$m, the relative pressure drops are 58% and 67% from central base suture lyses, and stabilized as 20% of its initial pressure when add-on sutures are lysed. These are aligned well with our expectations. Relative pressure drop for the sutures with 480 $\mu$m and 700 $\mu$m add-on lengths are approximately 60% from central suture cut which is slightly lower than our expectation since it was observed that eye sclera condition got worse due to multiple suturing and induced more leakage. Their final pressure reasonably stabilized at 24% and 20% of its initial pressure respectively.

## 6. Conclusions

IOP management is essential in the treatment of glaucoma. The ability to titrate IOP lowering following trabeculectomy surgery is highly desirable because excessive lowering may lead to serious adverse events. This study demonstrates the feasibility of using an add-on suture to make a conventional suture adjustable and thus enable surgeons to do better IOP control in the post trabeculectomy treatment. The fabrication of the adjustable sutures was demonstrated by using micro droplets of biocompatible adhesive to join sutures together, which is simple, reliable and economic.

## REFERENCES


[1] Quigley HA. The number of people with glaucoma worldwide in 2010 and 2020. Br J Ophthalmol. 2006; 90(3): 262-7. PMid:16488940. https://doi.org/10.1136/bjo.2005.081224

[2] Mokbel TH. End Stage Glaucoma. IN: Rumelt S, editor. Glaucoma - Basic and Clinical Concepts, InTech Open Access Publisher; 2011. p. 391-400.

[3] Arora KS, Robin AL, Corcoran KJ, et al. Use of Various Glaucoma Surgeries and Procedures in Medicare Bene fi ciaries from 1994 to 2012. Ophthalmology. 2015; 122(8): 1615-24. PMid:26092196. https://doi.org/10.1016/j.ophtha.2015.04.015

[4] Campbell RJ, Trope GE, Rachmiel R, et al. Glaucoma laser and surgical procedure rates in Canada: a long-term profile. Can J Ophthalmol. 2008; 43(4): 449-53. PMid:18711460. https://doi.org/10.3129/i08-085

[5] Rebouças-Santos V, Meira-Freitas D, Cariello AJ, et al. New adjustable suture technique for trabeculectomy. Arq. Bras. Oftalmol. 2013; 76(3): 152-4. PMid:23929074. https://doi.org/10.1590/S0004-27492013000300004

[6] Wells AP, Bunce C, Khaw PT. Flap and suture manipulation after trabeculectomy with adjustable sutures: titration of flow and intraocular pressure in guarded filtration surgery. J Glaucoma. 2004; 13(5): 400-6. https://doi.org/10.1097/01.ijg.0000133387.82126.7c

[7] Kobayashi H, Kobayashi K. A comparison of the intraocular pressure lowering effect of adjustable suture versus laser suture lysis for trabeculectomy. J Glaucoma. 2011; 20(4): 228-33. PMid:20577111. https://doi.org/10.1097/IJG.0b013e3181e3d0e4

[8] Matlach J, Hoffmann N, Freiberg FJ, et al. Comparative study of trabeculectomy using single sutures versus releasable sutures. Clin Ophthalmol. 2012; 6: 1019-27. PMid:22848142. https://doi.org/10.2147/OPTH.S32503

[9] Allingham MBSR, Damji KF, Freedman SF, et al. Shields textbook of glaucoma. 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2011.

[10] Lambert P, Letier P, Delchambre A. Capillary and surface tension forces in the manipulation of small parts. Proc. IEEE Int. Symp. onAssembly Task Planning. 2003; 54(2): 54-9. https://doi.org/10.1109/ISATP.2003.1217187

[11] Lambert P, Chau A, Rgnier S, et al. Comparison between Two Capillary Forces Models. Langmuir. 2008; 24(7): 3157-63. PMid:18315017. https://doi.org/10.1021/la7036444