

1 **Effects of the numbers and the shapes of venting slits on intraocular**  
2 **pressure after Baerveldt glaucoma drainage implant**

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1 **Abstract**

2 **Purpose:** Venting slits are widely used as an effective method to avoid the high  
3 intraocular pressure (IOP) phase immediately after the implantation of non-  
4 valved glaucoma drainage devices. However, there have been no detailed  
5 reports comparing the types of needles used and the numbers of slits made. In  
6 this study we investigated the effects of different needle types and the number  
7 of venting slits. **Methods:** IOP was measured using a Keyence NR-600  
8 transducer connected to the limbus of a pig eye with a 27G needle. A  
9 microsyringe pump was also connected to the corneal limbus using a 27 G  
10 needle to make a continuous perfusion system at the rate of 200 µl/hr. The  
11 silicone tube of a Baerveldt glaucoma drainage implant (BG101-350) was  
12 ligated near the plate and then implanted in the anterior chamber of the pig eye.  
13 The tube was covered with scleral tissue of another pig eye after 1 or 3 venting  
14 slits were created in the middle of the outer diameter using different types of  
15 needles (7-0 Vicryl<sup>®</sup>, 7-0 PDS II<sup>®</sup>, 5-0 PDS II<sup>®</sup>, 3-0 PDS Plus<sup>®</sup>). IOP  
16 measurement was started from 50 mmHg and then we monitored the  
17 chronological changes of IOP for 15 minutes. **Results:** The IOPs at 15 minutes  
18 after continuous perfusion with the venting slits made using 7-0 Vicryl needles  
19 were 29.0±2.5 mmHg (1 slit) and 23.1±8.3 mmHg (3 slits). The IOPs were  
20 23.1±3.1 mmHg and 23.5±4.7 mmHg with 7-0 PDS needles (1 slit and 3 slits,  
21 respectively), 21.8±2.2 mmHg and 20.8±4.3 mmHg with 5-0 PDS needles (1 slit  
22 and 3 slits, respectively), and with 3-0 PDS needles they were 12.2±3.0 mmHg

1 for one slit and  $13.2 \pm 3.5$  mmHg for 3 slits. **Conclusions:** Usage of a round  
2 (PDS) needles produces more predictable IOP than a spatulated (Vicryl)  
3 needle.

4 **Key words:** Baerveldt glaucoma drainage implant, ligated suture, venting slits

5

## 1 **Introduction**

2 Glaucoma drainage implants (GDIs) have become increasingly popular in the  
3 surgical treatment of glaucoma in recent years.<sup>1)</sup> There are two types of GDIs in  
4 common use at the present time, the Ahmed glaucoma valve (AGV, New World  
5 Medical, Los Ranchos, CA, USA) as a valved implant, and the Baerveldt  
6 glaucoma drainage device (BGDI, Johnson and Johnson, New Brunswick, New  
7 Jersey) or Molteno glaucoma drainage device (Molteno Ophthalmic Limited,  
8 Dunedin, New Zealand) as non-valved implants.<sup>2)</sup> The Ahmed Baerveldt  
9 Comparison Study (ABC study) showed that the Baerveldt group had a lower  
10 mean IOP at all postoperative visits at 6 months and continuing through 5 years.<sup>3)</sup>  
11 To prevent serious complications related to hypotony, including suprachoroidal  
12 hemorrhage, non-valved tube shunts such as the BGDI require temporal flow  
13 restrictions.<sup>4)</sup> Among the various surgical techniques, tube occlusion with an  
14 absorbable ligation suture followed by tube fenestration is one of the widely  
15 accepted methods.<sup>5)</sup> This method has been used as an effective way to restrict  
16 flow and also avoid the early hypertensive phase of intraocular pressure (IOP)  
17 after implantation of the BGDI. Gilbert et al. (2007) reported that a 1.2mm  
18 longitudinal venting slit anterior to a ligated tube produced acceptable pressures  
19 with the BGDI in cadaver eyes.<sup>6)</sup> Lim et al. (2002) showed that tube ligation  
20 followed by tube piercing with a 27-gauge syringe needle could reduce immediate  
21 postoperative high IOP after non-valve Molteno tube implantation in *ex vivo*  
22 experimental conditions. They showed that IOPs after piercing with a 27G needle

1 were between 8 mmHg and 30 mmHg. The report also showed that the probability  
2 of a pressure of less than 15 mmHg was under 20% after piercing with a 27G  
3 needle.<sup>7)</sup> Sherwood et al. reported the results of a clinical trial (32 eyes) using  
4 Molteno implant occluding with a 3-0 Supramid stent and 8-0 Vicryl<sup>®</sup> ligation. They  
5 made two venting slits with a spatulated needle and found that the postoperative  
6 IOP ranged from 2-26 mmHg until the day of stent removal.<sup>8)</sup> In this study, we  
7 evaluated the effects of the sizes and the types of needles for making venting  
8 slits in pig eyes.

### 9 **Materials and methods**

10 An experimental apparatus (Figure 1) was constructed to examine the IOP of the  
11 pig eye with constant perfusion of tap water. IOP was measured using a Keyence  
12 NR-600<sup>®</sup> electronic transducer (Keyence, Osaka, Japan), connected to a 27G  
13 needle inserted into the anterior chamber of the eye through the limbus. This  
14 analog-digital converter contains a digital calibrator and digital recorder, the Wave  
15 logger pro<sup>®</sup> (Keyence, Osaka, Japan). A syringe pump S-1235<sup>®R</sup> (Atom Medical,  
16 Tokyo, Japan) was also connected to a 27 G needle inserted into the anterior  
17 chamber and water was perfused into the chamber at 200µl/hr. The tube of the  
18 BGD (BG101-350) was first completely occluded at its root adjacent to the plate  
19 with 7-0 PDS II<sup>®</sup> (Ethicon Inc, Somerville, New Jersey). The occlusion was  
20 confirmed by attempting to flush fluid through the tube with a 27-gauge cannula.  
21 Then slits were made perpendicular to the tube, piercing from the front side of  
22 the tube wall to the far side. One or three venting slits were created at the center

1 of the tube region using a spatulated suture needle (7-0 Vicryl, Ethicon Inc,  
2 Sommerville, New Jersey) or a round needle (7-0 PDS, 5-0 PDS or 3-0 PDS,  
3 Ethicon Inc). It should be noted that one tube-piercing maneuver (one slit) makes  
4 two tube openings, and three slits make six tube openings. The flows from the slit  
5 valves were verified by flushing fluid through the tube. The BGDI plate was  
6 secured to the sclera of the pig eye at 10 mm from the limbus with 7-0 PDS. 23G  
7 injection needle was inserted from the limbus into the anterior chamber to make  
8 long tunnel within cornea in order to avoid the water leakage. Then the tube of  
9 BGDI was inserted into the anterior chamber along this tunnel. The venting slits  
10 of the tubes were completely covered with a 4.0×6.0 rectangular squared scleral  
11 patch of another pig eye and secured to the sclera using 10-0 nylon sutures (Mani,  
12 Utsunomiya, Japan) at the 4 angles. IOP was measured from 50 mmHg at 10 Hz  
13 and we monitored it for 15 minutes. In this experiment, 8 conditions were tested;  
14 1 slit 7-0 Vicryl, 3 slits 7-0 Vicryl, 1 slit 7-0 PDS, 3 slits 7-0 PDS, 1 slit 5-0 PDS, 3  
15 slits 5-0 PDS, 1 slit 3-0 PDS and 3 slits 3-0 PDS. One pig eye was used with one  
16 BGDI. One eye was used 3 times for 15-minute test runs and three BGDIs were  
17 tested for each condition (9 test runs for each condition). We also tested the BGDI  
18 setting without slits as a control. Since IOP did not reach to the plateau phase in  
19 the conditions using 7-0 Vicryl and 5-0 PDS at 15 minutes, we extended  
20 monitoring periods to 60 minutes in 4 conditions; one slit 7-0 Vicryl and 3 slits 7-  
21 0 Vicryl, one slit 5-0 PDS and 5-0 PDS 3 slits. Data were recorded using  
22 Keyence's data logger software, and statistical analysis was carried out with the

1 unpaired Student's t-test. *P* values of less than 0.05 were considered significant.  
2 We examined the shapes of the slits used in this experiment with an upright  
3 microscope (Eclipse 50i<sup>®</sup>, Nikon, Tokyo, Japan) equipped with a digital  
4 microscopic camera (DS-Fi1<sup>®</sup>, Nikon, Tokyo, Japan).

## 5 **Results**

6 We examined the effects of the shape and size of the slit valve on IOP of the pig  
7 eye. Table 1 shows the averages, standard deviations (SD), and ranges of the  
8 final IOPs in 15-minute test runs (Table 1). For 7-0 Vicryl spatulated needle  
9 conditions, IOP decreased to 29.0 mmHg (25.0 mmHg-33.6 mmHg) at 15 minutes  
10 with one slit. Intraocular pressure decreased to 23.1 mmHg (15.5 mmHg-39.9  
11 mmHg) with 3 slits (Table 1). The IOP at 15min in the 3-slit condition was  
12 significantly lower than for one slit when using the 7-0 Vicryl needle (*P*<0.05,  
13 unpaired Student's t-test). For the 7-0 PDS round needle, IOP decreased to 23.1  
14 mmHg (18.4 mmHg-28.3 mmHg) at 15 minutes with one slit and decreased to  
15 23.5 mmHg (17.0 mmHg-31.4 mmHg) with 3 slits (Table 1). For the 5-0 PDS  
16 round needle, IOP decreased to 21.8 mmHg (18.7 mmHg-25.6 mmHg) at 15  
17 minutes with one slit and decreased to 20.8 mmHg (13.9 mmHg-25.4 mmHg) with  
18 3 slits (Table 1). For the 3-0PDS round needle, IOP decreased to 12.2 mmHg (7.3  
19 mmHg-17.5 mmHg) at 15 minutes with one slit and to 13.2 mmHg (7.9 mmHg-  
20 16.4 mmHg) with 3 slits (Table 1). There were no significant differences in IOP at  
21 15 min between the 1 slit and 3 slit conditions with PDS needles (*P*>0.05,

1 *unpaired Student's t-test*). IOP remained high at 41.7 mmHg (9 mmHg-44.5  
2 mmHg) with no slit at 15 min. Comparing the IOPs of the same one slit and three  
3 slit conditions, the average IOPs decreased with increasing slit size for the round  
4 needles ( $P<0.01$ , unpaired Student's t-test). When the number of the slits  
5 increased, the SD of IOP tended to increase. The venting slits of the 7-0 Vicryl  
6 needle had the widest IOP range. Figure 2 shows the chronological changes of  
7 average IOPs for each condition. The curves of 3-0 PDS conditions reached the  
8 plateau phase at 15 min (Figure 4). The IOP recording curves for the 7-0 Vicryl  
9 and 5-0 PDS needles did not reach to the plateau phase at 15 min (Figures 3 and  
10 4), however, they reached to the plateau phase at 60 min (Supplementary figure  
11 1 and 2). The final IOP with 7-0 Vicryl one slit and 3 slits were 17.3 mmHg (14.0  
12 mmHg-21.7 mmHg) and 17.3 mmHg (14.9 mmHg-20.5 mmHg), respectively. The  
13 final IOP with 5-0 PDS one slit and 3 slits were 13.5mmHg (12.0 mmHg-14.6  
14 mmHg) and 14.0 (12.9 mmHg-16.0 mmHg), respectively. The final IOP without  
15 any slit was 30 mmHg (Supplementary Figure 3). The shape of the venting slit  
16 made with the 3-0 round needle (Figure 5A) was relatively regular and arc-like,  
17 whereas the shape of the slit with the spatulated needle was more uneven (Figure  
18 5B).

## 19 **Discussion**

20 According to Brooks et al., the length of the slit valve and its opening pressure  
21 are inversely related.<sup>2)</sup> Our results were consistent with their results because



1 significantly lower IOP was observed with slits made using the 3-0 PDS needle  
2 compared to the 7-0 PDS, 5-0 PDS or 7-0 Vicryl needles. Since postoperative  
3 aqueous humor contains various proteins and sometimes blood-derived factors,  
4 it is possible that slit valves can be partially or totally occluded. In such situations,  
5 multiple slits may prevent total occlusion. Therefore, we consider that multiple  
6 slits are desirable to avoid total occlusion rather than to reduce IOP further.

7 Three venting slits tended to have wider ranges of final IOP after the 15-minute  
8 perfusion trials compared to one venting slit especially in case of the three slits  
9 condition made with a 7-0 Vicryl needle (Figure 2). Therefore, we considered a  
10 PDS needle can made more predictable IOP than a spatulated needle. We further  
11 extended perfusion time to 60 minutes for selected conditions (using either a 7-0  
12 Vicryl needle or a 5-0 PDS needle) and found that IOP fluctuations among the  
13 trials were smaller in the trials using 5-0 PDS needles (Supplementary Figure 1  
14 and 2). Furthermore, we evaluated the shapes of slits made by the different  
15 needles. The slits made with the round needles had more regular shapes (Figure  
16 5A) than those made with the 7-0 Vicryl (Figure 5B). This result is consistent with  
17 our results showing that the venting slits made with round needles resulted in  
18 more consistent final IOP than those made with spatulated needles (Figure 2).  
19 Considering the final IOP range (13.9-25.4 mmHg) at 15 min and (12.9-16.0  
20 mmHg) at 60 min in our study, we think that three slits made with 5-0 PDS needles  
21 will be a good option for venting slits. The final IOP range (7.3-15.5 mmHg) by  
22 the slits made with 3-0 PDS may cause hypotonic complications in some cases,

1 so we considered the slits made with 5-0 PDS are safer choice.

2 It is considered that a scleral patch also produces some resistance pressure. In  
3 our pilot study, the data without a scleral patch had more variability and were not  
4 stable (data not shown). It has been reported that the opening pressure of the  
5 venting slit under air is higher than that in water and has wide variability.<sup>3)</sup> The  
6 space under a scleral patch contains water from the tube, so we consider such a  
7 patch to be an essential component of venting slit procedures. Limitations of our  
8 study are that (1) we used pig eyes instead of human eyes due to the availability  
9 of eyeballs, (2) we used tap water for ocular perfusion for accurate measurement  
10 of IOP, which may be different from the IOP produced with aqueous humor.  
11 According to Brooks, the alterations of aqueous humor significantly influence slit  
12 valve performance, and the net effect of these changes cannot be predicted with  
13 certainly.<sup>5)</sup>

14 The strength of our study is comparison of the IOP-lowering effects between one  
15 slit and multiple slits in occluded BGDs. Our results suggested that usage of  
16 round needles produces more predictable IOP than when using a spatulated  
17 needle. Clinical trials are underway to compare the efficacies of spatulated  
18 needles and round needles for venting slit procedures.

### 19 **Declaration of Interest**

20 This study was partially supported in experimental instruments by Johnson and  
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12

1 **Table 1. IOP after 15 minutes with various types of slits**

Needle type	IOP (at 15 min)	Minimum IOP (at 15 min)	Maximum IOP (at 15 min)
7-0 Vicryl 1 slit	29.0±2.5 mmHg	25.0	33.6
7-0 Vicryl 3 slits	23.1±8.3 mmHg	15.5	39.9
7-0 PDS 1 slit	23.1±3.1 mmHg	19.4	29.3
7-0 PDS 3 slits	23.5±4.7 mmHg	18.0	32.4
5-0 PDS 1 slit	21.8±2.2 mmHg	18.7	25.6
5-0 PDS 3 slits	20.8±4.3 mmHg	13.9	25.4
3-0 PDS 1 slit	12.2±3.0 mmHg	7.3	17.5
3-0 PDS 3 slits	13.2±3.5 mmHg	7.9	16.4

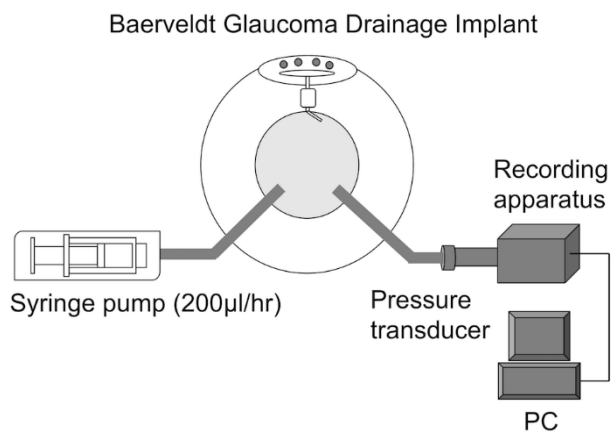
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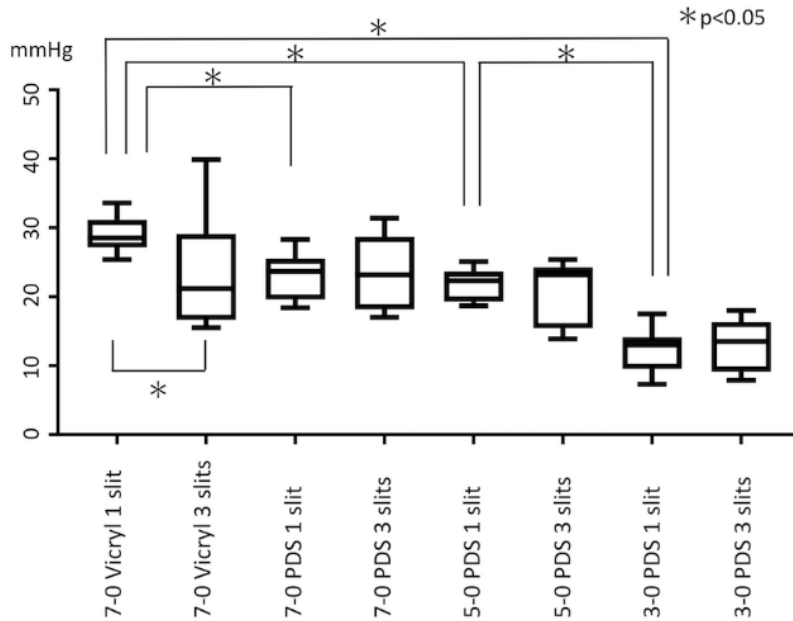
- 1 Table 1. IOP after 15 minutes with various types of slits
- 2 Figure 1. Experimental setup
- 3 Figure 2. Comparison of IOPs among various conditions at 15 min after perfusion
- 4 Figure 3. IOP curves of 1 slit and 3 slits made with 7-0 Vicryl needle
- 5 Figure 4. IOP curves of 1 slit and 3 slits made with PDS needles
- 6 Figure 5. Microscopic view of the slits made with two types of needles
- 7 Supplementary Figure 1. IOP curves of 1 slit and 3 slits made with 7-0 Vicryl
- 8 needle (recorded for 60 minutes)
- 9 Supplementary Figure 2. IOP curves of 1 slit and 3 slits made with 5-0 PDS
- 10 needle (recorded for 60 minutes)
- 11 Supplementary Figure 3. IOP curves of no slits (recorded for 60 minutes)
- 12
- 13



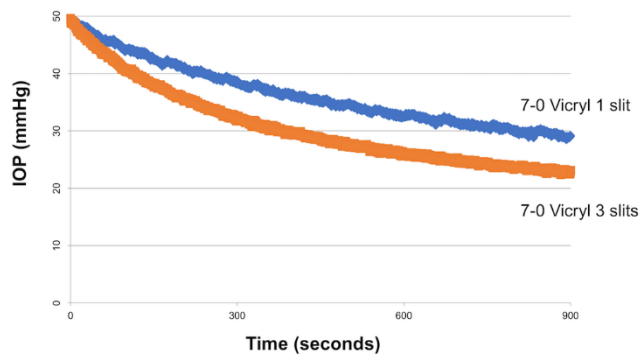
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Figure 1.

- 1 The syringe pump supplies a constant flow of water to the pig eye. IOP is
- 2 monitored with a pressure transducer connected to a tube inserted into the
- 3 anterior chamber of the pig eye.



- 4
- 5 Figure 2.
- 6 IOP with 1 slit decreased significantly in the order of 7-0 Vicryl, 7-0 PDS, 5-0 PDS
- 7 and 3-0 PDS needles ( $*P<0.05$ , unpaired Student's t-test). There is a significant
- 8 difference of IOP between 1 slit and 3 slits made with the 7-0 Vicryl ( $*P<0.05$ ) but
- 9 not with the PDS (7-0, 5-0 and 3-0) needles.

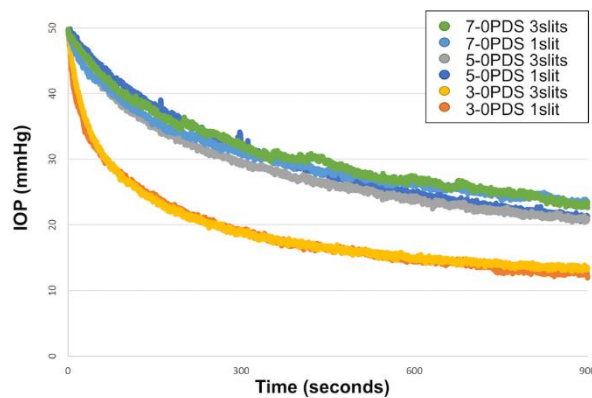


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2 Figure 3. IOP curves of 1 slit and 3 slits made with 7-0 Vicryl needle

3 At 15 minutes after perfusion, there is a significant difference of IOPs between 1  
 4 slit and 3 slits made with the 7-0 Vicryl (\*P<0.05). The chronological changes of  
 5 IOPs showed that IOP did not reach the plateau phase under these conditions.  
 6 Mean IOP curves of the 9 experiments were shown in this figure.

7

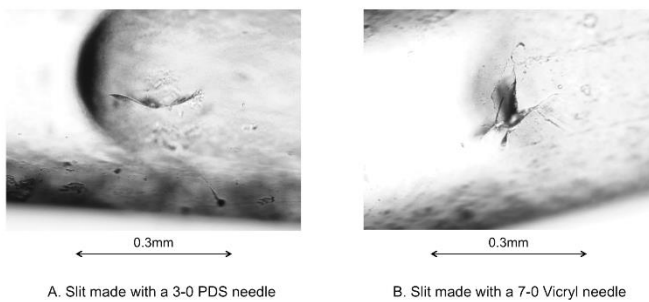


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9 Figure 4.

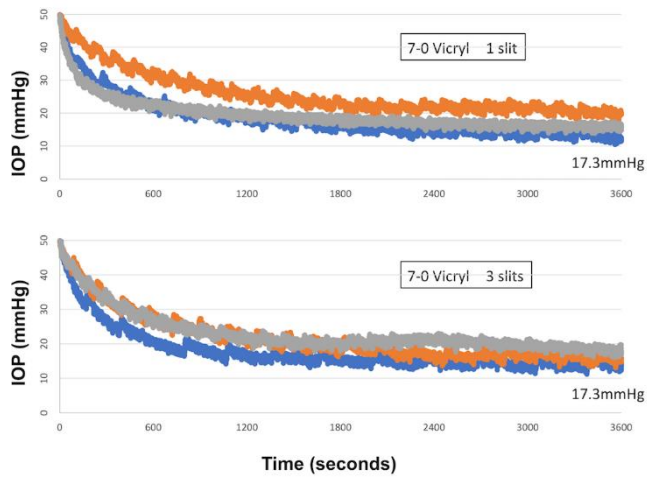


1 Figure 4. IOP curves of 1 slit and 3 slits made with PDS needles  
2 There was no significant difference of IOPs between 1 slit and 3 slits made with  
3 PDS (7-0, 5-0 and 3-0) needles. The chronological changes of IOPs showed that  
4 IOP reached the plateau phase with the slits made with 3-0 PDS needles. Mean  
5 IOP curves of the 9 experiments were shown in this figure.



6  
7 **Figure 5.**  
8 A: A venting slit made with a spatulated needle. It has an opening with an irregular shape.  
9 B: A venting slit made with a round needle. It has a more regular arc-like shape (original  
10 magnification 200x).

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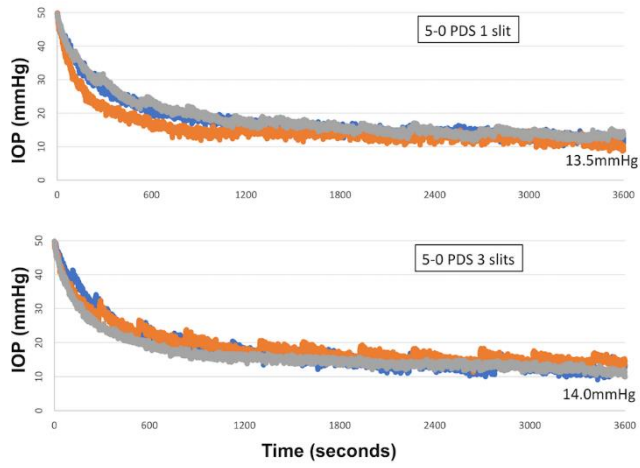
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2 Supplemental Figure1. IOP curves of 1 slit and 3 slits made with 7-0 Vicryl needle  
3 (recorded for 60 minutes)

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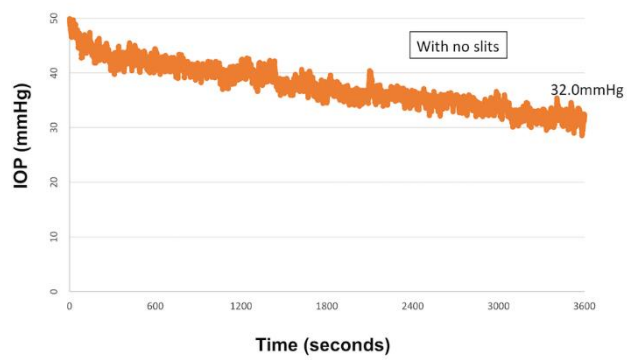
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2 Supplementary Figure 2. IOP curves of 1 slit and 3 slits made with 5-0 PDS

3 needle (recorded for 60 minutes)

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1

2 Supplementary Figure 3. IOP curves of no slits (recorded for 60 minutes)

3