



Comparing the Effect of Penetrating Canaloplasty and Trabeculectomy in Pseudophakic Chronic Primary Angle Closure Glaucoma Patients

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Abstract

Background: To compare the efficacy and safety of penetrating canaloplasty with partial Schlemm's canal excision and retention suture to traditional trabeculectomy in the treatment of chronic primary angle closure glaucoma (PACG) in patients who are pseudophakic.

Methods : This is a single center prospective comparative cohort study. Eleven consecutive pseudophakic patients (14 eyes) with the diagnosis of chronic primary angle closure glaucoma who were examined at the Henan Eye Institute at Henan Provincial People's Hospital, between March 2018 and June 2019, were enrolled in the penetrating canaloplasty group. We also retrospectively reviewed the charts of 11 age and gender matched pseudophakic chronic PACG patients (14 eyes) who underwent traditional trabeculectomy the year prior at the same institution. We compared the efficacy and safety between the two surgical intervention groups.

The main outcome measure is surgical success defined as IOP ≤ 21 mmHg without topical IOP lowering medications at 6 months post-operatively. Conditional success defined as IOP ≤ 21 mmHg with topical IOP lowering medications at 6 months post-operatively.

Results: Six months after the respective surgeries, patients who underwent PC achieved a complete success rate of 85.7%, versus 42.9% in the trabeculectomy group, which is significantly higher ($p=0.018$).

Conclusion: Compared to traditional trabeculectomy, penetrating canaloplasty with partial SC resection and retention suture might be able to achieve comparable IOP reduction in pseudophakic chronic PACG patients.

Keywords: Penetrating Canaloplasty; Chronic Primary Angle Closure Glaucoma; Schlemm's Canal Glaucoma Procedures; Pseudophakic

Introduction

Primary Angle Closure Glaucoma (PACG) is a leading cause of blindness in patients with Chinese ethnicity [1]. In recent years, cataract removal with intraocular lens implantation has been shown to effectively lower intraocular pressure (IOP) in chronic PACG patients [2]. However, post-operative topical IOP lowering medications are still necessary in a significant number of these patients to maintain their IOP. Eventually some patients may continue to develop persistently elevated IOP despite maximum tolerated

medical treatment (MTMT). For those who require IOP optimization, including those who have intolerance to topical agents, additional surgical interventions are usually required to further reduce IOP [3]. Often, these patients have very short axial length (AL) and extensive posterior anterior synechia (PAS) in their anterior chamber angle, contributing to the refractory nature of their disease.

Traditional surgical options to treat these refractory pseudophakic chronic PACG patients include trabeculectomy with anti-

metabolites and/or adjustable sutures, and glaucoma drainage implants. Both of these interventions require intense post-operative care mainly for the management of the filtering bleb [4,5]. Severe complications including choroidal effusion, aqueous misdirection, blebitis/endophthalmitis, and chronic scarring and bleb failure can be sight threatening [4,5].

Penetrating canaloplasty (PC) is a relatively recent surgical development that does not depend on bleb formation. This surgical intervention has been shown to be efficacious in treating chronic PACG [6]. This surgical technique involves sectorial removal of the Schlemm's canal (SC) and circumferential retention suture which are thought to re-open the collapsed SC which in turn facilitate the aqueous outflow [6]. In this study, by comparing to traditional trabeculectomy, we aim to study the effectiveness and safety of PC in treating pseudophakic chronic PACG patients.

Materials and Methods

This is a prospective comparative cohort study. We selected 11 consecutive pseudophakic patients (14 eyes) who were examined at the Henan Eye Institute at Henan Provincial People's Hospital, with the diagnosis of chronic PACG, between March 2018 and June 2019. For those patients who received bilateral surgeries, the two eyes were operated on at least one month apart. All cases were done under general anesthesia. The study protocol was approved by the ethics committee of the Henan Provincial People's Hospital (KYK [2018]#47). All investigations followed the tenets of the Declaration of Helsinki. All patients signed written consent.

Inclusion criteria: 1) age between 45 years old and 75 years old; 2) confirmed diagnosis of primary angle closure glaucoma with PAS in more than 180 degrees of the anterior chamber angle; 3) at least six (6) months after routine phacoemulsification and intraocular lens implantation surgery with possible goniosynechiolysis in suitable cases; 4) IOP not adequately controlled despite MTMT, or with multiple medication intolerance, or with significant compliance issues.

Exclusion criteria: 1) patients with history of intraocular surgeries other than cataract removal; 2) patients with significant systemic illness who could not tolerate general anesthesia; 3) patients who are unwilling to sign the informed consent.

For comparison, we matched 11 patients (14 eyes) who fulfill the same inclusion criteria stated above but underwent Trabeculectomy with MMC instead at the same institution between January 2017 and March 2018 by age and gender.

Preoperatively, all patients underwent comprehensive ocular evaluations including best corrected visual acuity (BCVA), intraocular pressure measured by applanation (IOP, Goldmann tonometer), Slit lamp examinations, Gonioscopy, Visual field (24-2) evaluation (Humphrey visual field 750i, Zeiss, Germany), Optic coherence tomography (OCT, SFRATUS OCT 4000, Zeiss, Germany) measuring retinal nerve fiber layer (RNFL), fundus photography (FF450 Plus IR, Zeiss, Germany), Ultrasound biomicroscopy (UBM, MD-300, Tianjin Maida, China), and A/B ultrasound scan (MD-2400S, Tianjin Maida, China).

All surgeries were performed by a single surgeon. Local anesthesia with subconjunctival injection of 2% lidocaine hydrochloride (Rongsheng Pharmaceuticals Co, China) was utilized [7]. Surgical techniques for the microcatheter assisted Penetrating Canaloplasty (PC) was previously reported [6]. Briefly, primary incision for the PC is preferably at the 12:00 superior position. The superior nasal or superior temporal quadrant are also acceptable. A traction suture with 8-0 vicryl suture was placed and peritomy was then performed along the superior limbus to expose the underlying sclera (approximately a 5mm x 5mm area), followed by hemostasis. A 4mm x 4mm scleral flap of one-half scleral thickness was created with the crescent blade. The Schlemm's Canal (SC) was identified and entered. A microcatheter with blinking signal at the leading tip was inserted into the SC following the curvature of the SC, until the leading tip re-emerge from the initial incision. At this point, a segment of a 10-0 nylon suture was secured onto the leading end of the microcatheter which was then retracted through the SC lumen. After retrieval of the microcatheter, the 10-0 nylon suture was left in the lumen and the 2 ends of the suture were tied together. Dewecker scissors were employed to excise a portion (~1mm x 2mm) of the SC internal lumen wall. A peripheral iridectomy (PI) was also performed around the area of the SC excision. The scleral flap was then sutured back in place to achieve water seal. No anti-metabolites were used. The conjunctiva was also sutured tightly achieve water seal. Post operatively, patients received Fluorometholone 1.0% ophthalmic solution (Sanen, Japan) 4 times a day for 1 week; 0.5% Levofloxacin Hydrochloride eye drops (Santen, Japan) 3 times a day for 2 weeks per standard post operative care.

The group of patients who received traditional trabeculectomy had the procedures done in the standard manner. Mitomycin 0.2mg/ml (Hanhui Pharmaceuticals CO, China) soaked WeckCell sponge was placed under the scleral flap for 3-5 minutes followed by thorough irrigation with Balanced Salt Solution (BSS). Adjustable sutures (2-4) were used to close the flap. Post operatively, if

IOP was above 15mmHg, adjustable suture was adjusted immediately per standard practice. If IOP was 15mm Hg or less, adjustable sutures were removed after 2-3 weeks. Patients also received Fluorometholone 1.0% ophthalmic solution (Sanen, Japan) 4 times a day for 1 week. 0.5% Levofloxacin Hydrochloride eye drops (Santen, Japan) 3 times a day for 2 weeks per standard post operative care.

BCVA, IOP, number of IOP lowering medications were recorded at all post-operative visits starting post-operative week 1 (POW1). Slit lamp photos, gonioscopy and UBM were also performed at post-operative month (POM) 1, POM3 and POM6 visits. Any post-operative complications, and the functionality of the filtering bleb were also assessed and recorded. Presence of the filtering bleb was defined by a combination of slit lam photo and UBM images.

Surgical success was defined as IOP less than 21 mmHg at POM6. Secondly, complete success was defined as IOP less than 21mmHg without any IOP lowering medication throughout the 6 months post-operative period. Conditional success was defined as IOP less than 21 mmHg with IOP lowering medications at any point of the 6 months post-operative period. Severe surgical complications such as loss of light perception (LP vision), hypotony (IOP less than 5 mm Hg), need for additional glaucoma surgery were also recorded.

Statistical analysis: SPSS21.0 (IBM, USA) was utilized for statistical analysis. Categorical variables were described in proportions. Continuous variables following normal distribution were displaced using Mean (Standard deviation). Continuous variable with non-normal distribution were displaced as median number (range). Inter-group comparison was conducted using the student-t test. Changes in medications between pre-operative and POM6 were compared using wilcoxon rank sum test. $P < 0.05$ was defied as statistically significant.

Results

Twenty-two pseudophakic PACG patients (28 eyes) were included in our study. 11 patients (15 eyes) underwent penetrating canaloplasty (PC group). One of the 15 eyes (7.1%) did not achieve 360 SC canalization and hence was converted to trabeculectomy. Therefore, total of 10 patients from the PC group were included

in the statistical analysis. 11 patients (14 eyes) underwent trabeculectomy with MMC (T group). The two groups had comparable mean age and gender composition due to matched selection criteria (Table 1).

	Eye		Mean Age ± SD (yrs)	Gender	
	OD	OS		M	F
PC Group	8	6	69.500 ± 2.546	6	8
T Group	7	7	70.071 ± 4.379	4	10
	$X^2 = 0.144$		$t = -0.473$	$X^2 = 0.622$	
P	0.705		0.640	0.430	

Table 1: Comparison of age and gender between the penetrating canaloplasty group and trabeculectomy group.

PC: Penetrating Canaloplasty; T: Trabeculectomy; OD: Right Eye; OS: Left Eye; M: Male; F: Female; SD: Standard Deviation; $P < 0.05$ is Statistically Significant.

Pre-operative IOP, BCVA, extend of angle closure measured by PAS, number of IOP lowering medications, the mean deviation from humphery visual field, time elapsed since phacoemulsification were compared between the 2 groups and no statistical significance was found (Table 2).

Post-operative IOP also showed no significant difference between the 2 groups at POW1, POM1, POM3, and POM6 visits (Table 3). BCVA (logMAR) at POM1, POM3, and POM6 also showed no significant difference (Table 4).

At the POM6 visits, complete success rate for the PC group was (12/14) 85.7%, which was significantly higher than that of the T group (6/14,42.9%, $p=0.018$, Table 5). Conditional success was achieved in (13/14) 92.8% and (10/14) 71.4% patients of the PC and T groups, respectively; though this was not statistically significant (Table 5). The median number of IOP lowering medications post-operatively (0 in PC group vs. 1 in T group) was also significantly lower in the PC group compared to the T group ($p < 0.001$, Table 5).

In the PC group, 2 eyes had a small amount of hyphaema, which resolved one week later. Six eyes had IOP elevation to above 21mmHg approximately 2 weeks after the surgery. Brinzolamide

	Pre-op IOP (Mean ± SD)	Preop Meds (#)	Pre-op BCVA (logMar)	PAS(Degree of angle)	Pre-op UCVA (logMar)	MD	Time since Phaco (Months)
PC Group	27.93 ± 3.85	2.93 ± 0.48	0.25 ± 0.09	301.43 ± 32.31	0.47 ± 0.15	20.406 ± 3.160	17.00 ± 6.59
T Group	27.71 ± 2.59	2.86 ± 0.54	0.207 ± 0.14	297.14 ± 29.98	0.39 ± 0.14	21.05 ± 3.73	18.14 ± 5.59
T value	0.15	0.32	0.95	0.39	1.50	-0.64	-0.69
P value	0.89	0.75	0.36	0.70	0.16	0.54	0.50

Table 2: Comparison of pre-operative measurements between the penetrating canaloplasty group and trabeculectomy group.

PC: Penetrating Canaloplasty; T: Trabeculectomy; Pre-op: Pre-operatively; IOP: Intraocular Pressure in mmHg; BCVA: Best Corrected Visual Acuity, in LogMar; UCVA: Uncorrected Visual Acuity, in LogMar; PAS: Posterior Anterior Synechia, measured via gonioscopy examination, in degree of angles; MD: Mean deviation of Humphery visual field (24-2); Time since Phaco: Time elapsed since phacoemulsification and IOL implantation surgery; SD: Standard Deviation; P < 0.05 is Statistically Significant; #: Number; P < 0.05 is Statistically Significant.

	Preop IOP mmHg (Mean ± SD)	POW1 IOP mmHg (Mean ± SD)	POM1 IOP mmHg (Mean ± SD)	POM3 IOP mmHg (Mean ± SD)	POM6 IOP mmHg (Mean ± SD)
PC Group	27.93 ± 3.85	11.86 ± 1.66	16.79 ± 3.14	16.21 ± 1.85	17.43 ± 2.41
T Group	27.71 ± 2.59	11.64 ± 2.02	14.36 ± 2.65	18.07 ± 3.93	18.93 ± 3.69
T Value	0.15	0.31	1.71	-1.72	-1.29
P Value	0.89	0.76	0.11	0.11	0.22

Table 3: Comparison of Pre-operative IOP and Post-operative IOP of the penetrating canaloplasty group and Trabeculectomy group.

Preop: Pre-operative; Postop: Post-operative; PC: Penetrating Canaloplasty; T: Trabeculectomy; IOP: Intraocular Pressure (mmHg); POW 1: Post Operative Week 1; POM 1: Post Operative Month 1; POM 3: Post Operative Month 3; POM 6: Post Operative Month 6; P < 0.05 is Statistically Significant.

	PreopBCVA (LogMar)	POM 1 BCVA (LogMar)	POM3 BCVA (LogMar)	POM 6 BCVA (LogMar)
PC Group	0.25 ± 0.09	0.47 ± 0.17	0.30 ± 0.09	0.28 ± 0.09
T Group	0.21 ± 0.14	0.54 ± 0.25	0.36 ± 0.18	0.29 ± 0.12
T Value	0.95	-0.95	-0.98	-0.16
P Value	0.36	0.36	0.34	0.87

Table 4: Comparison of Pre-operative best corrected visual acuity and Post-operative best corrected visual acuity of the penetrating canaloplasty group and trabeculectomy group.

Preop: Pre-operative; Postop: Post-operative; PC: Penetrating Canaloplasty; T: Trabeculectomy; BCVA: Best Corrected Visual Acuity; POM 1: Post Operative Month 1; POM 3: Post Operative Month 3; POM 6: Post Operative Month 6; P < 0.05 is Statistically Significant.

	Conditional Success Ratio	Complete Success Ratio	Postop Medication (Median)
PC Group	13/14	12/14	0
T Group	10/14	6/14	1
X ²	X ² = 2.191	X ² = 5.600	
P Value	0.139	0.018	<0.0001

Table 5: Comparison of success rate (complete and conditional) and number of intraocular pressure lowering medications post-operatively between the penetrating canaloplasty and trabeculectomy groups at post operative month 6.

Postop: Post-operative; PC: Penetrating Canaloplasty; T: Trabeculectomy; P < 0.05 is Statistically Significant.

eye drops were added for IOP control. 2 weeks later, all IOPs were within normal limits. 4 out of the 6 eyes gradually stopped IOP lowering medications. 2 out of the 4 eyes once again had IOP elevation after the attempt to stop the medication, and were continued on Brinzolamide eye drops 2 times a day indefinitely. 3 eyes experienced shallow anterior chamber for approximately 2-3 weeks after surgery. All of the 3 patients were treated with topical Atropine 1% with resolution of the shallow AC.

In the T group, 6 eyes experienced shallow AC accompanied by gradual increase of IOP to above 21mmHg, about 2 weeks post-operatively. Atropine and Brinzolamide eye drops were started. One month later shallow AC resolved and IOP also reduced to below 21mmHg. Brinzolamide was stopped 1 week after restoration of normal IOP and atropine was stopped 8 weeks after. 4 out of the 6 eyes had IOP elevation after cessation of Brinzolamide, which was then restarted and continued indefinitely. Another four eyes had scarring of the bleb, and Alphagan and Tafluprost were started in addition to Brinzolamide eye drops. IOP for these 4 patients were maintained between 15 -21mmHg, and no additional surgical intervention was performed.

Discussion

As the age of patients with chronic PACG increases, more and more patients develop visually significant cataract. Compared to CEIOL alone, whether combined CEIOL- glaucoma surgery could lower IOP more effectively is still under investigation. However, complications rate is significantly higher in combined procedures [9].

In these patients the anterior chamber can often be deepened after cataract surgery alone, accompanied by lowered IOP and improved vision [2,10]. However, many pseudophakic chronic PACG patients continue to require topical medications. In these patients, posterior anterior synechia (PAS) formation may continue to worsen, resulting in even higher IOP [9,11]. Toxicity from the eye drops may also lead to intolerance and incompliance. Additional glaucoma surgeries may become inevitable [12,13]. Traditional filtering procedures (including trabeculectomy and glaucoma drainage device implantation) in this group of patients are more likely to lead to early post-operative shallow chambers, aqueous misdirection, and other complications [14]. Long term bleb fibrosis and scarring is almost inevitable [15]. Traditional Schlemm's canal procedures

including canaloplasty and ab internal trabeculectomy, may not be suitable in a near completely closed angle due to severe PAS formation [16,17].

Liang et. al. published an innovative surgical procedure known as "ab external penetrating canaloplasty", which is highly effective at treating chronic angle closure glaucoma [6] [Figure 1]. This novel procedure is based on canaloplasty, a procedure that has been widely used in treating open angle glaucoma [18]. This new technique utilizes a retention suture within the lumen, and partial excision of the SC [6] through an ab external approach. A microcatheter is used to first dilate the SC, and at the same time to thread the suture through the lumen, which then was left in place to stent the lumen and prevent reattachment of the cut ends of the SC [Figure 2]. This procedure is non-bleb forming, avoiding associated complications such as leakage and bleb- related infections.

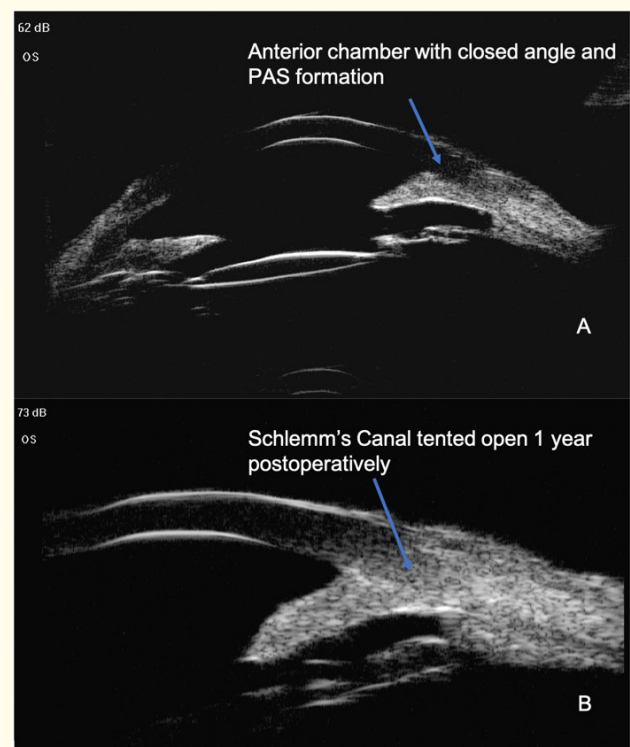


Figure 1: Ultrasound biomicroscopy (UBM) imaging of the anterior segment. A: Anterior chamber with closed angles and PAS formation prior to surgery. B: Schlemm's canal tented open 1 year after penetrating canaloplasty surgery.

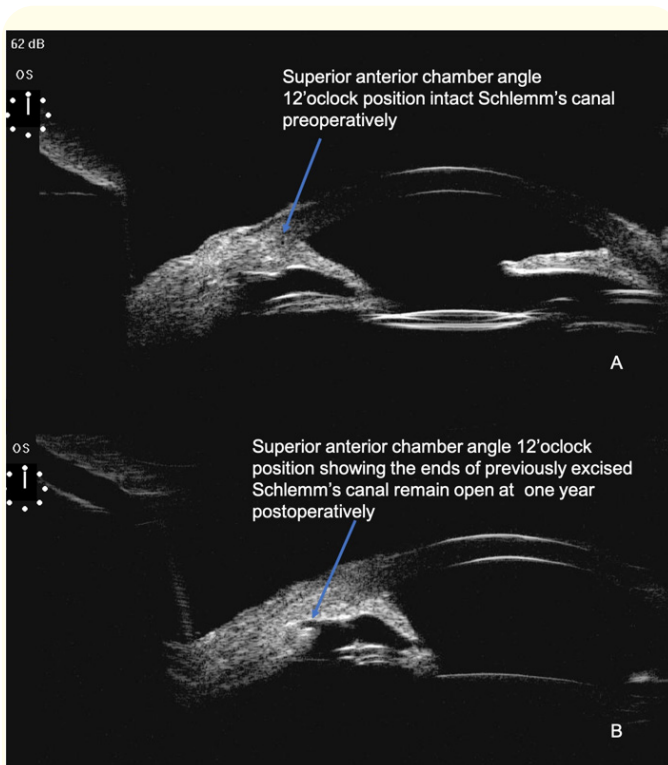


Figure 2: Ultrasound biomicroscopy (UBM) imaging of the anterior segment. A: Superior anterior chamber angle at 12 o'clock position with intact Schlemm's canal preoperatively. B: Superior anterior chamber angle at 12 o'clock position showing the ends of previously excised Schlemm's canal remained open at 1 year post operatively.

In our study, PC effectively lowered IOP in this group of pseudophakic chronic PACG patients. On average, IOP was reduced from 27.9 mmHg to 14.7mmHg at POM6, nearly 50% reduction. Both the rate of complete success and conditional success were shown to be better than the traditional trabeculectomy counterparts at POM6. Previous studies have shown that, in patients with chronic PACG, compared to combined CEIOL-Trabeculectomy procedures, trabeculectomy alone had similar levels of long term IOP and/or medication reduction. Rates of surgical complications were also similar between the two procedures, though trabeculectomies are more likely to worsen existing cataracts leading to subsequent CEIOL [8,19]. Studies worldwide have shown that the rate of IOP reduction from trabeculectomy with antimetabolites and/or releasable sutures is between 44-70% [9,14]. Song., *et al.* reported that the

conditional success rate of trabeculectomy is between 72-91% at around 6 months after the surgery; however, this was significantly reduced to 54-56% at post op year 3 presumably due to bleb scarring [5,17,20].

PC is a non-bleb forming procedure, relying on expansion of the Schlemm's canal with the retention suture and the removed portion to allow outflow which subsequently lower IOP. It therefore avoids the complication of bleb scarring and may have better long-term efficacy. In our study, 13 eyes in the PC group did not have any obvious filtering bleb on slit lamp exam or UBM. One eye showed localized low rising bleb, which is consistent with previous reporting [8,21,22]. Patient in the PC group did not receive antimetabolites intraoperatively, the deeper layer of the sclera remained intact, and both layers of the sclera flap were sutured to watertight. Additionally, no goniosynechiolysis was performed with no significant difference in angle closure before or after the surgery. Therefore, we hypothesize that the main mechanism for IOP lowering in our study is through the open segment of the Schlemm's canal allowing increased outflow with minimal resistance, while the rest of the anterior chamber angle remains closed. We did notice that during the early post-operative period, there were 6 eyes in the PC group that showed signs of filtering blebs, which subsequently disappeared after 2 weeks [Figure 3]. Only 1 eye had persistent localized elevated bleb at the POM3 visit [Figure 3]. We could not exclude the possibility that there is active filtering through the sclera and conjunctiva, without having obvious blebs. Future aqueous humor flow angiography might help in investigating this possibility.

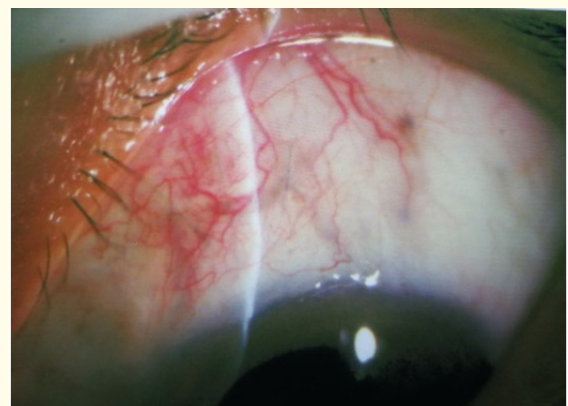


Figure 3: External photo of the operated eye, illustrating superior shallow diffuse filtering bleb, 2 weeks after penetrating canaloplasty procedure. The bleb does not appear to be localized or significantly elevated.

The most common complication in our study is early hyphaema (15%) which all resolved within 1 week after the surgery with no residual long term side effects. Previous reports have suggested that hyphaema might indicate patency of distal channels, which is a positive sign for surgical success [23]. The hyphaema is most likely due to episcleral vein reflux and/or peripheral iridectomy. Gonioscopy at approximately POM1 failed to detect any changes to the cut ends of the SC. Future studies with a larger sample size is necessary to further elucidate the relationship between hyphaema and long-term success of PC in this patient population. In order to prevent anterior movement of the peripheral iris which may subsequently block the open SC, the peripheral iridectomy performed in our study were relatively large, wider than the length of the open portion of the SC. We observed no iris plugging post operatively, even in patients who developed shallow anterior chamber.

Six eyes in the PC group developed transient high IOP at around 10-20 days post operatively, without any evidence of shallow anterior chamber or aqueous misdirection. Brinzolamide eye drops were used in these patients with normalization of their IOPs within 2 weeks. No recurrence of IOP elevation was observed after cessation of the topical eye drops. The underlying causes of transient IOP elevations are unclear. It may be related to chronic collapsing of the collector channels in patients with chronic angle closure glaucoma due to lack of aqueous flow through SC and collector channels. After the procedure, despite flow of aqueous through SC, the reconstitution of aqueous flow through these once collapsed distal channels may take even longer time. Future studies are necessary to further characterize the risks factors related to IOP elevation after PC procedure. Close monitoring and initiation of treatments are recommended in these patients.

In our study, 3 eyes (21.4%) in the PC group had shallow anterior chamber as compared to 6 eyes in the T group (42.3%), both higher than that previously published associated with PC procedures (5.9%) [6,23], though similar to what was reported in traditional trabeculectomy surgeries (22%) [24]. We suspect this higher frequency of shallow chamber in our PC group is intrinsic to our study population, where patients all have chronic angle closure glaucoma with a higher tendency to develop shallow anterior chambers [25].

One eye in the PC group had 180-degree trabeculectomy secondary to high tension of the SC retention suture. As a result, the suture

was removed from the Schlemm's canal, and the patient underwent Trabeculectomy instead.

Our study has limitations. First the sample size is small with limited enrollment in both study arms, which may inevitably introduce statistical bias. Secondly, although we prospectively enrolled patient into the PC group, the comparison group constitute patients enrolled retrospectively. A true prospective randomized clinical trial is necessary in order to compare the safety and efficacy of penetrating canaloplasty with traditional trabeculectomy. Thirdly, the follow up period is relatively short. Studies with longer follow up time is necessary to determine the long-term effectiveness of this new surgical technique. Lastly, despite the innovativeness of the procedure, the mechanism behind IOP reduction and increased aqueous outflow need to be further elucidated.

In summary, our study showed that penetrating canaloplasty with retention suture and sectorial SC excision may help to reform the physiological aqueous outflow pathway in PACG patients. This type of procedure can be safely used in treating refractory disease in pseudophakic chronic PACG patients with potentially better efficacy than traditional trabeculectomy.

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Conflict of Interest

No conflicting relationship exists for any authors.

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