

Two-Year Outcomes of the Paul Glaucoma Implant for Treatment of Glaucoma

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Purpose: To determine 2-year efficacy of the PAUL Glaucoma Implant (PGI), a novel glaucoma tube shunt in patients with advanced glaucoma.

Participants: Patients with glaucoma refractory to maximum medical therapy or previous failed glaucoma surgery.

Methods: Retrospective review of all patients who had underwent PGI implantation in a single tertiary institution between May 1, 2017 and March 30, 2021.

Main Outcome Measures: Primary outcome measure was failure defined as intraocular pressure (IOP) > 18 mm Hg or < 6 mm Hg on 2 consecutive visits after 3 months, reoperation for IOP-related indication, explantation of implant or loss of light perception vision. Complete success was defined as unmedicated IOP ≤ 18 mm Hg or ≥ 6 mm Hg in the absence of failure.

Results: Forty-five eyes in 45 patients were identified, with mean follow-up duration of 24.9 ± 2.0 months. Thirty patients (66.7%) had primary glaucoma and 11 (24.4%) with previous glaucoma surgery. At 2 years following surgery, 8 eyes (17.8%) fulfilled the failure criteria with 32 eyes (71.1%) achieving complete success. Compared with mean medicated preoperative IOP (19.8 ± 6.3 mm Hg), postoperative IOP at 24 months was 13.9 ± 3.7 ($P < 0.01$). Mean number of medications decreased from 3.2 ± 0.8 preoperatively to 0.29 ± 0.65 at 24 months ($P < 0.01$). Significant complications included self-limiting shallow anterior chamber ($n = 10$; 22.2%), hypotony requiring intervention ($n = 4$; 8.9%) and tube occlusion ($n = 4$; 8.9%).

Conclusions: The PGI was able to achieve sustained IOP reduction with reduction of medications at 2 years postsurgery in patients with advanced glaucoma.

Key Words: glaucoma, tube shunt surgery, tube drainage surgery

(*J Glaucoma* 2022;31:449–455)

Glaucoma is one of the leading causes of irreversible blindness worldwide, and control of intraocular pressure (IOP) is a mainstay of treatment. Aqueous tube shunts are gaining popularity in the treatment of advanced or medically uncontrollable glaucoma.¹ These devices comprise of a silicon tube which attaches to an endplate that is fixed to the sclera closer to the equator of the globe. Aqueous humor is shunted from the anterior chamber via the tube to the endplate and within the surrounding capsule, and subsequently absorbed by periorcular draining vessels.² The 2 most commonly used tube shunts are the Ahmed glaucoma valve (New World Medical, Rancho Cucamonga, CA) and the Baerveldt glaucoma implant (Johnson & Johnson, Santa Ana, CA).

The results of the Ahmed Baerveldt Comparison (ABC) Study and Ahmed Versus Baerveldt (AVB) Study showed that the Baerveldt Glaucoma Implant (BGI) was able to attain higher success rates, and lower IOP when compared with the Ahmed Glaucoma Valve (AGV).³ Although visual outcomes were similar, the BGI had a significantly higher rate of serious complications, particularly persistent hypotony. Both the AGV and BGI had a 5-year cumulative failure rate of 49% and 37%, respectively ($P = 0.007$). Better understanding of fluidics in the early postoperative period, postoperative wound healing of tube shunt surgeries and mechanisms of complications have led to the development of newer tube shunts that could potentially result in better outcomes.

This study aims to describe the 2-year efficacy and safety of a novel glaucoma tube shunt in reducing IOP for eyes with refractory glaucoma.

METHODS

Retrospective review of all patients who had undergone surgery with the Paul Glaucoma Implant (Advanced Ophthalmic Innovations, Singapore) in a single tertiary institution between May 1, 2017 and March 30, 2021. This study was reviewed and approved by the Domain Specific Review Board of the National Healthcare Group for ethics approval. Patients between age 21 and 80 years with glaucoma and uncontrolled IOP even with maximal tolerated medical therapy were offered surgical intervention. Primary glaucoma with or without previous failed trabeculectomy, glaucoma tube shunt or other intraocular surgery were included. Patients with secondary glaucoma such as

Received for publication May 27, 2021; accepted January 31, 2022.

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Disclosure: P.C.T.K. and C.C.A.S. are co-inventors of the PAUL Glaucoma Implant (PGI) (Advanced Ophthalmic Innovations Pte Ltd, Singapore) and hold related patents. The remaining authors declare no conflict of interest.

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DOI: 10.1097/IJG.0000000000001998

neovascular, uveitic, traumatic, aphakic or glaucoma associated with iridocorneal endothelial syndrome were also included. Patients from a prospective interventional study conducted from December 1, 2017 to December 1, 2018 in the same institution (ClinicalTrials.gov ID, identifier, NCT04297930) were included in this retrospective review.

The following information was retrieved from patient records: demographics, preoperative and postoperative best-corrected visual acuity, IOP, vertical cup-disc ratio, type of glaucoma, previous glaucoma surgeries, number of glaucoma medications, and tube placement. IOP measurements were measured using 2 readings of the Goldman applanation tonometer; a third measurement was done if the initial 2 readings differed by more than 2 mm Hg. The average for both readings was taken as the final IOP at each visit.

Primary Outcomes

The primary outcome measure was failure, which was defined as IOP more than 18 mm Hg or less than 6 mm Hg on 2 consecutive visits after 3 months, reoperation for IOP-related indication, explantation of implant or loss of light perception vision.⁴ We defined reoperation as surgery for IOP-related events that requires a return to the operating theater: procedures that can be performed at the slit-lamp were not considered reoperations—these include laser suture lysis, laser iridoplasty, intraluminal stent removal, subconjunctival needling, and anterior chamber viscoelastic gel injection.

Secondary Outcomes

Complete success was defined as unmedicated IOP \leq 18 mm Hg and $>$ 5 mm Hg at either 12 or 24 month visits. Qualified success is similarly defined but with the use of IOP-lowering agents. We also proposed alternative success criteria at 15 mm Hg. IOP outcomes, number of IOP-lowering medications and the rate of surgical complications were the other secondary outcome measures in this study. A serious complication was defined as one associated with 2 or more line decrease in Snellen acuity and/or significant surgery (reoperation in the operating theater) required to manage the complication.¹ Clinically significant hypotony referred to IOP of \leq 5 mm Hg IOP associated with 2 or more line decrease in Snellen acuity and required surgical intervention such as viscoelastic gel injection into the anterior chamber or reoperation separate from self-limiting shallow anterior chamber. The Snellen visual acuity decrease was assessed at the 1 year visit or 6-month visit (if the 1-year visit was missed). Patients without a 6 or 12-month visit would not be able to have complications that were characterized as serious by loss of vision criteria, but could still have significant surgery that would qualify as a serious complication.

Study Device

The PAUL Glaucoma Implant (PGI) (Advanced Ophthalmic Innovations Pte Ltd, Singapore) is a novel nonvalved glaucoma aqueous tube shunt that is constructed from medical implantable grade silicone (Fig. 1). The plate of the PGI has a length of 44.9 mm, width of 23 mm and an extraocular plate surface area of 342.1 mm². The PGI has a shorter wingspan compared with the BGI but extends further posteriorly due to a wider width. The plate surface area is smaller than the BGI, but larger than the AGV. The internal diameter of the PGI is the smallest amongst the 3 tube shunts at 0.127 m, about one third the diameter of both the AGV and BGI. The smaller internal tube calibre increased aqueous flow resistance which theoretically reduces the risk of postoperative hypotony. The overall

slimmer tube caliber allows for a lower tube profile protruding above the sclera and theoretically reduces risk of conjunctival erosion while also reducing the risk of tube-endothelium contact and damage.

Surgical Procedure

All surgeries were performed by a team of surgeons (V.K. T.C., M.C.A., C.C.A.S., and P.C.T.K.) in a single tertiary center. The PGI endplate was placed superotemporally or superonasally and tucked under the superior and lateral or medial recti and sutured to the sclera at 9 mm posterior to the limbus. Entry to the anterior chamber was made with a 25 or 27-G needle at the limbus, parallel to the iris plane. The tube was trimmed bevel up and positioned through the needle track flush to the iris plane, away from the corneal endothelium. A modified flow modulating method called “stability system” using a pericardial patch graft inserted between the subconjunctival space and PGI plate with cross-linked viscoelastics injected beneath the patch graft filling the plate’s reservoir was performed. The limbal portion of the tube was covered with a patch of sterilized pericardium and conjunctiva sutured closed. Viscoelastic gel was left inside the anterior chamber and cross-linked viscoelastic gel was injected in the subconjunctival space above the endplate at the conclusion of the surgery.

All eyes were given a standardized regimen of postoperative antibiotics and topical steroids over a few months depending on the clinical findings and wound healing course.

Statistical Analysis

All statistical analysis was performed using Python v3.7 with the Pandas and lifelines statistical modules. Continuous variables were reported as mean \pm SD and compared using the paired *t* test. Categorical data were compared using the χ^2 test. Snellen visual acuity measurements were converted to the logarithm of the minimum angle of resolution equivalents. For Kaplan-Meier survival analysis, the time to failure was defined as the time from implantation to reoperation for glaucoma, loss of light perception vision, or the first of 2 consecutive study visits after 3 months in which the patient showed persistent hypotony (IOP $<$ 6 mm Hg) or inadequately reduced IOP (ie, IOP $>$ 18 mm Hg). A *P*-value of 0.05 or less was considered statistically significant.

RESULTS

Baseline Characteristics

Forty-five eyes from 45 patients were identified. No patients who had undergone PGI implantation within the study period were excluded. Mean follow-up duration was 24.9 ± 2.0 months and no patients were lost to follow-up. Table 1 shows the demographics and ocular characteristics of the patients. In our study, 30 patients (66.7%) had primary glaucoma and 15 (33.3%) had secondary. Of these, 22 patients (48.9%) had previous intraocular surgery, 11 patients (24.4%) had previous trabeculectomy or previous tube shunt surgery.

Intraoperative Procedures

Of the 45 eyes operated, 28 (62.2%) underwent clear cornea phacoemulsification and PGI implantation, while 6 (13.3%) underwent a different procedure at the same sitting: 1 intracapsular cataract extraction with scleral fixed intraocular lens implantation, 1 BGI explantation, 1 AGV tube flushing, 1 IOL explantation, 1 canthotomy, and 1 bleb excision.

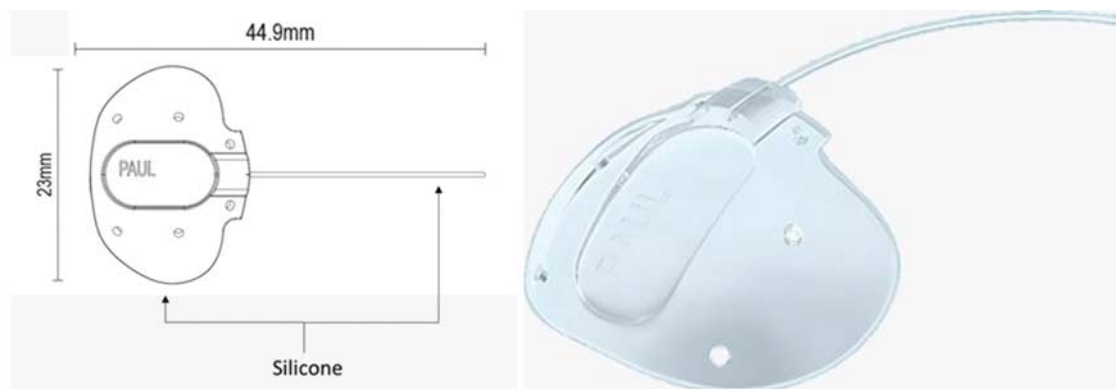


FIGURE 1. Picture of the Paul Glaucoma Implant (Advanced Ophthalmic Innovations, Singapore) with relevant dimensions.

No intraoperative mitomycin C, ligating sutures, intraluminal stents or other flow restriction techniques were used in any of the operated eyes.

Primary Treatment Outcomes

At 2 years, 8 patients (17.8%) fulfilled the failure criteria. Reasons for failure were: vitreous occluding tube requiring anterior vitrectomy and tube flushing (n=2), IOP <6 mm Hg for 2 consecutive visits (n=1) and IOP >18 mm Hg for 2 consecutive visits (n=5).

Figure 2 shows the Kaplan-Meier survival analysis over 2 years. 32 (71.1%) and 17 eyes (37.8%) were classified as complete successes at IOP cut offs of 18 and 15, respectively. Five (11.1%) and 0 (0.0%) eyes fulfilled the criteria for qualified success at IOP cut off of 18 and 15 mm Hg, respectively.

Additional analysis was done to compare between patients who had undergone previous glaucoma surgery (n=11) and patients who had not (n=34). Rates of failure in eyes with previous glaucoma surgery and without previous glaucoma surgery was 18.2% and 17.6%, respectively (P=0.97). We also compared failure rates between patients with primary glaucoma who had never undergone any previous glaucoma surgery (n=27) and patients with secondary glaucoma or had previous failed glaucoma surgeries (n=18). Rates of failure in the group with primary glaucoma was 18.5% and in the group with secondary glaucoma or previous failed surgery was 11.1% (P=0.50).

IOP Reduction

Baseline and follow-up IOPs are shown in Figure 3. None of the patients required any additional glaucoma surgery or PGI explantation and thus no patients were censored from analysis.

The mean highest preoperative IOP was 33.0 ± 11.7 mm Hg and the mean medicated preop IOP was 19.8 ± 6.3 mm Hg. All patients were on medications and mean number of class of medications was 3.2 ± 0.8.

Postoperative IOP at months 1, 6, 12, and 24 were significantly lower (P < 0.001, paired t test) when compared with both highest preoperative and premedicated preoperative IOP: 13.0 ± 5.4, 14.0 ± 3.8, 14.2 ± 3.5, and 13.9 ± 3.7, respectively (P < 0.01, paired t test). Comparing mean medicated preoperative IOP with postoperative IOP, there was a 28.2% reduction at 1 year and 29.8% reduction at 2 years. Comparing highest preoperative IOP with postoperative IOP, there was a 57.0% reduction at 1 year and

57.9% reduction at 2 years. Table 2 summarizes the postoperative outcomes of the patients.

Comparing mean number of medications from the preoperative level at 3.2 ± 0.8, the number of medications at 12, 24 months, and at last follow-up (24.9 ± 2.1 mo) after surgery were 0.07 ± 0.25, 0.29 ± 0.65, and 0.36 ± 0.88, respectively (P < 0.01, paired t test). Figure 4 shows the mean number of IOP lowering medications.

More than half the patients in this study (n=29) had a preoperative medicated IOP of ≤21 mm Hg. In this subgroup of patients the IOP was 16.2 ± 3.1, 14.7 ± 3.7,

TABLE 1. Baseline Demographic and Ocular Characteristics of Enrolled Participants (n=45)

Age (y), mean ± SD	64.3 ± 12.2
Sex, n (%)	
Male	36 (80)
Female	9 (20)
Ethnicity, n (%)	
Chinese	34 (75.5)
Malay	7 (15.6)
Indian	2 (4.4)
Others	2 (4.4)
Mean visual acuity (logMAR), mean ± SD	0.82 ± 1.0
Mean medicated intraocular pressure (mm Hg), mean ± SD	19.8 ± 6.3
Mean vertical cup to disc ratio, mean ± SD	0.72 ± 0.21
Lens status, n (%)	
Phakic	31 (68.9)
Pseudophakic	14 (31.1)
No. classes of intraocular pressure-lowering medications, n (%)	
1	1 (2.2)
2	8 (17.8)
3	15 (33.3)
4	21 (46.7)
Mean ± SD	3.2 ± 0.8
Diagnosis, n (%)	
Primary open-angle glaucoma	19 (42.2)
Primary angle-closure glaucoma	11 (24.4)
Neovascular glaucoma	4 (8.9)
Others*	11 (24.4)
Previous glaucoma procedures, n (%)	
Trabeculectomy	9 (20.0)
Glaucoma tube shunt	7 (15.5)

*Others = silicone oil related (n=1), hyphema related (n=1), anterior cleavage syndrome (n=1), uveitis related (n=1), inflammatory iris chafing (n=1), Ice syndrome (n=2), angle recession (n=1), juvenile open angle glaucoma (n=2), subluxed morcher (n=1).

logMAR indicates logarithm of the minimum angle of resolution.

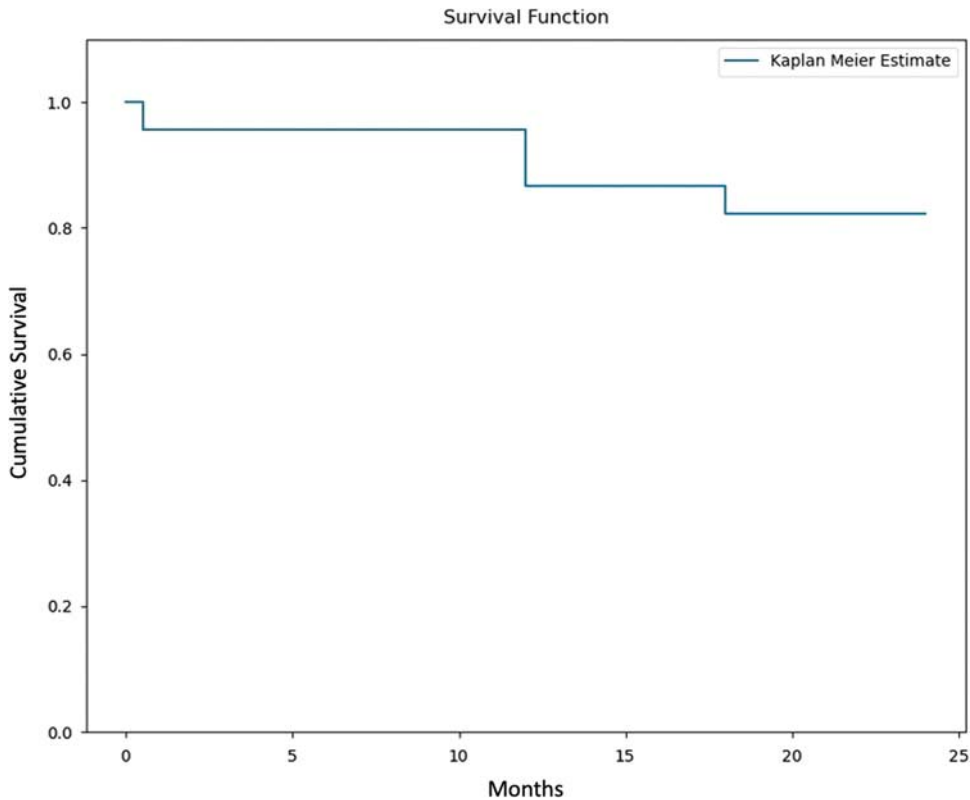


FIGURE 2. Kaplan-Meier survival curve for eyes implanted with the PAUL Glaucoma Implant (Advanced Ophthalmic Innovations, Singapore) over 2 years. Time to failure was defined as time from implantation to the first of 2 consecutive study visits after 3 months in which IOP <5 mm Hg, or > 18 mm Hg, loss of light perception or to reoperation for glaucoma or implant related complications.

14.3 ± 3.7, and 13.8 ± 3.5 for preoperative, postoperative month 6, 12, and 24, respectively. The IOP was significantly lower at 2 years (*P* < 0.01) compared with preoperative IOP.

The number of medications for this subgroup of patients was reduced from 3.2 ± 0.9 preoperatively to 0.1 ± 0.4 at 1 year and 0.2 ± 0.6 at 2 years (*P* < 0.01).

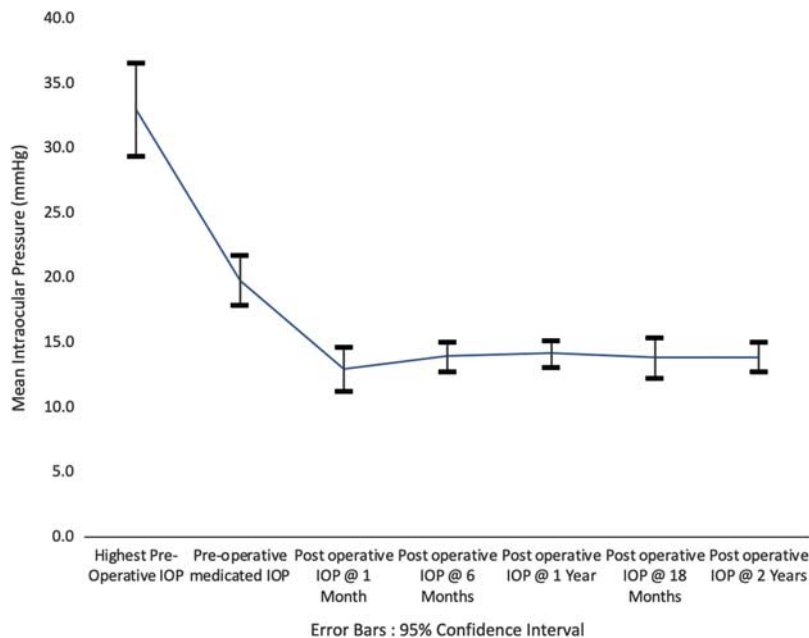


FIGURE 3. Line graph showing intraocular (IOP) trend before and after surgery up to 2 years, compared to both the highest preoperative IOP and preoperative medicated IOPs. The error bars indicate 95% confidence limits.

TABLE 2. Postoperative Outcomes of Patients (n = 45)

Outcome	Data (Mean ± SD)
Mean visual acuity (logMAR)	
Preoperative	0.82 ± 0.94
12 mo	0.80 ± 0.97
24 mo	0.96 ± 1.17
Mean intraocular pressure (mm Hg)	
Preoperative	19.8 ± 6.3
1 mo	13.0 ± 5.4*
6 mo	14.0 ± 3.8*
12 mo	14.2 ± 3.5*
18 mo	13.9 ± 4.3*
24 mo	13.9 ± 3.7*
Mean number of classes of intraocular pressure lowering medications	
Preoperative	3.2 ± 0.8
12 mo	0.07 ± 0.25*
18 mo	0.07 ± 0.25*
24 mo	0.29 ± 0.65*

*P < 0.01.

Complications

Postoperative complications included shallow anterior chamber which was self-limiting (n = 10 [22.2%]), hypotony requiring intervention (n = 4 [8.9%]) and tube occlusion (n = 4 [8.9%]). One eye developed an inferior retinal detachment requiring vitrectomy a month after implantation but this was not directly related to the PGI surgery. Of the 4 eyes with tube occlusion, 2 were occluded by iris which was treated with argon laser iridoplasty, 1 was blocked by fibrin and required an anterior chamber washout with tube flushing, and 1 which was blocked by vitreous required an anterior vitrectomy with tube flushing twice. All cases of self-limiting shallow anterior chamber resolved within a month of the surgery. For the 4 eyes with hypotony that required anterior chamber injection of viscoelastic, 2 required more than 1 injection of viscoelastic and 1 had subsequent intervention in the form of anterior vitrectomy and tube flushing for tube occlusion from vitreous. One eye had persistent hypotony at 2 years, which was complicated by blunt trauma to the eye about 1.5 years post-surgery. One eye underwent tube repositioning as the tube was felt to be too anterior, with endothelial cell count showing a

downward trend from 2100 to 1400 cells/mm². There were no serious complications and no eyes required explantation of the PGI.

DISCUSSION

In this retrospective case series of 45 eyes over a 2-year follow-up period, 8 eyes (17.8%) fulfilled the failure criteria, 32 eyes (71.1%) fulfilled the criteria for complete success, and 5 eyes (11.1%) fulfilled the criteria for qualified success. Mean IOP at 2 years was 13.9 ± 3.7 mm Hg, a significant reduction from mean medicated preoperative IOP of 19.8 ± 6.3 mm Hg (P < 0.05). Similarly, mean class of medications used was reduced from 3.2 ± 0.8 to 0.3 ± 0.7 (P < 0.05) at 2 years. Significant complications that occurred in this case series included hypotony and tube occlusion. Pooled analysis reporting the 5-year outcomes of the ABC and AVB studies show a high cumulative failure rate—49% for the AGV and 37% for the BGI at 5 years, with the most common cause of failure being inadequate IOP reduction.³ Comparatively, this study demonstrates a lower failure rate of 17.8% for the PGI at 2 years—although differences in study methodology should be noted. Table 3 shows a comparison between the PGI, AGV, and BGI based on the ABC⁵ and AVB⁶ studies.

Compared with the BGI and AGV, the PGI has an external caliber that is > 30% smaller, and an internal caliber that is > 50% smaller than both the BGI and AGV. Extrapolating from experimental flow studies, with a 10 mm length and an internal diameter of 127 mm, the PGI should have a simulated IOP between 6 and 12 mm Hg, due to flow restriction from the small internal caliber.⁷

With regards to plate dimensions—studies have attributed the higher success rates of the BGI to its larger plate surface area and flatter plate profile, with lower risk of encapsulation.⁸ The PGI addresses this by having a shorter wingspan but a longer posterior plate extension which increases the effective surface area.

These theoretical benefits in the design of the PGI have been used to explain its performance relative to the AGV and BGI, but only over a relatively short period of a year.⁷

This study aims to evaluate the performance of the PGI over a 24 month duration. Our results in this study show that

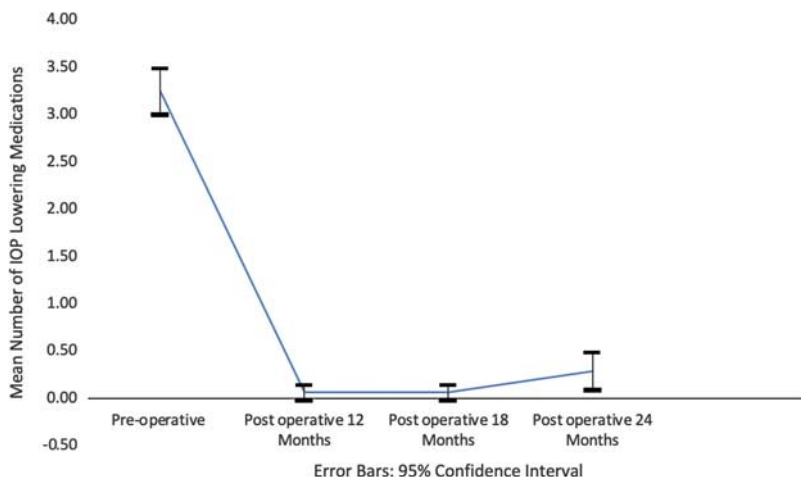


FIGURE 4. Line graph showing the number of intraocular pressure (IOP) lowering medications used before and after surgery. Error bars indicate 95% confidence limits.

TABLE 3. Comparison Between the PGI, AGV, and BGI

	PGI 2 y		ABC 5 y		AVB 5 y		AVB 2 y	
	PGI (n = 45)	AGV (n = 143)	BGI (n = 133)	AGV (n = 124)	BGI (n = 114)	AGV (n = 129)	BGI (n = 121)	
Failure	8 (17.8%)	64 (44.7%)	52 (39.4%)	53%	40%	62 (48.4%)	54 (44.2%)	
Mean IOP	13.9 ± 3.7	14.7 ± 4.4	12.7 ± 4.5	16.6 ± 5.9	13.6 ± 5.0	14.4 ± 6.7	13.7 ± 4.9	
No. med	0.29 ± 0.65	2.2 ± 1.4	1.8 ± 1.5	1.8 ± 1.5	1.2 ± 1.3	1.43 ± 1.49	0.77 ± 1.06	
Complications requiring intervention	4 (8.9%)	11 (7.7%)	22 (16.5%)	63 (51%)	58 (51%)	22 (17.1%)	31 (25.6%)	

ABC indicates Ahmed Baerveldt Comparison; AGV, Ahmed Glaucoma Valve; AVB, Ahmed Versus Baerveldt; BGI, Baerveldt Glaucoma Implant; IOP, intraocular pressure; PGI, PAUL Glaucoma Implant.

there was a sustained IOP reduction over 24 months with a corresponding reduction in IOP lowering medications. The mean IOP at 2-year follow-up after PGI surgery was 13.9 ± 3.7 mm Hg and this was higher than the BGI group of 13.2 ± 6.8 mm Hg but lower than the AGV group of 15.4 ± 5.5 mm Hg in the ABC study. This was slightly higher than the 1 year result of 13.2 ± 3.3 reported by Koh et al.⁹ The mean number of medications at 2 years postoperatively (0.3 ± 0.7) was comparable with Koh and colleagues' study (0.3 ± 0.6). These results which place the IOP lowering performance of the PGI between the AGV and BGI, but with markedly lower mean number of medications (PGI: 0.3 ± 0.7 , AGV 1.8 ± 1.3 , BGI 1.5 ± 1.4 medications), show that the PGI is capable of a sustained IOP lowering effect over a longer period and are encouraging.

A significant number ($n = 29$) of patients in this study had preoperative IOP that was < 21 mm Hg, with a mean preoperative medicated IOP of 16.2 ± 3.1 mm Hg. The indication for surgery in these patients was glaucoma progression, or visually significant cataract with intent to reduce medication burden. At 2 years, the mean IOP was 13.8 ± 3.5 mm Hg ($P < 0.01$), and the mean number of medications was reduced from 3.2 ± 0.8 to 0.24 ± 0.58 ($P < 0.01$). Five eyes achieved qualified success and 32 eyes achieved complete success. This shows that the PGI is able to effectively lower both IOP and medication burden in this particular subgroup of patients with relatively low preoperative IOP. There may be concern that for such patients with a relatively low IOP, the risk of hypotony may be higher. In our study, 2 eyes (6.9%) in this subgroup suffered from clinically significant hypotony requiring intervention, compared with 2 (12.5%) in the other group, but this was not statistically significant ($P = 0.53$).

In the ABC study the rate of failure in the neovascular glaucoma subgroup (71%) was twice that in the primary glaucoma with previous intraocular surgery subgroup (35%), although the study was not powered to compare this difference.¹⁰ We performed subgroup analysis of eyes with only primary glaucoma and those with secondary glaucoma or previous failed glaucoma surgeries, and also between eyes with and without prior glaucoma surgery. We did not find any significant differences in failure rates between groups, but this may be due to small sample size.

In this series, the most common complication was self-resolving anterior chamber shallowing ($n = 10$ [22.2%]), followed by clinically significant hypotony requiring intervention ($n = 4$ [8.9%]). Only 1 eye (2.2%) had hypotony resulting in failure which was likely compounded by blunt trauma about 1.5 years postimplantation. In the ABC study, the AGV and BGI had a 1% and 5% incidence of hypotony

requiring surgery, respectively, while in the AVB study, the BGI group had a 4% incidence of hypotony resulting in failure, with none in the AGV group,¹¹ a lower rate than seen in this case series (8.9%).¹¹ However, we defined clinical hypotony requiring intervention in this study to include anterior chamber reformation – thus it may be more relevant to compare the incidence of anterior chamber reformation for the AGV and BGI at 11% and 13%, respectively, to our rate of 8.9%.

This has been attributed to several factors including variability of the internal tube diameter from manufacturing, patient factors such as ocular biomechanics, patient behavior such as squeezing or rubbing, lens status, and type of glaucoma.

There was a lower incidence of hypotony requiring intervention in this study (8.9%) compared with Koh and colleagues (9.5%). However, there was a higher incidence of self-limiting shallow anterior chamber (22.2%) compared with both Koh and colleagues (14.9%) and the BGI (17%) in the ABC study. This may reflect the fact that no ligating sutures or intraluminal stents were used in any of the operated eyes in this study, while 27.1% of patients in Koh and colleagues and all BGI eyes in the ABC study underwent tube ligation and/or intraluminal stenting. To address this issue, a modified ripcord technique unique to the PGI has been described: following conventional technique where the tube is occluded with a 6-0 prolene suture, the surgeon then utilizes the well at the posterior end of the PGI end plate after inserting the stent to visualize the rate of aqueous outflow directly.⁷ By adjusting the length of the ripcord within the tube, the surgeon can modulate the rate of outflow to some extent. This could potentially blunt postoperative IOP volatility, but other factors such as variability of suture diameter due to manufacturing tolerance, individual ocular biomechanics, and patient behavior still remain. Risks include IOP spikes due to inadvertent total occlusion of the tube or migration of the suture, or late persistent postoperative hypotony poststent removal.¹² Stent removal may also necessitate a return to the operating theatre in some practices, and incur a small risk of infection. In this series, the self-limiting nature of hypotony and reversal from a single viscoelastic injection may be due to the smaller internal diameter of the PGI which is more resistant to flow and thus reduces the risk of sustained hypotony.

On the contrary, a smaller lumen theoretically increases the risk of significant tube occlusion. In this study 4 eyes (8.9%) had tube occlusion, 2 by iris, 1 by vitreous, and the last by either fibrin or pigments. The 2 tubes occluded by iris were successfully treated with Argon laser iridoplasty and the tube occluded by vitreous underwent an initial anterior vitrectomy with tube flushing, which was unsuccessful followed by a core vitrectomy with tube flushing

which was successful. The nature of occlusion for the last tube was unclear but it was treated successfully with an anterior chamber washout and tube flushing—we hypothesize that it may have been occluded more distally with fibrin or a pigment clump, thus obscuring the nature of the blockage. Tube occlusion is a known complication in tube shunts and has been shown to be higher in the BGI (5.7%), a nonvalved shunt, compared with the AGV (0.8%).¹³ Being a nonvalved shunt, the PGI is more similar to the BGI in terms of flow behavior as seen in the 4 tube occlusions in our study. Thus, tube positioning in the anterior chamber is important in minimizing occlusion by iris and the optimal position for the PGI would be just slightly above the iris plane. Possible reasons for tube occlusion in the PGI would include a smaller internal diameter, and/or bulk outflow of aqueous causing iris to occlude the lumen. In this series, 1 of the 3 eyes with tube occlusion had an episode of hypotony requiring anterior chamber reformation a month before tube occlusion with vitreous. While the numbers in this study are too small to draw conclusions from, further studies investigating the mechanism of tube occlusion may be warranted.

Our study, being a retrospective case series in a single center, is noncomparative in nature and has a limited number of cases. A majority of patients in this study had concurrent cataract surgery, which could contribute to efficacy results. As this was an observational and non-comparative study, we did not exclude eyes with concurrent cataract surgery to reflect the real-world nature of this study.

The study population is predominantly Asian, with a preponderance of males, which limits generalizability to other populations. Although cost is an important factor in comparing different tube shunts, this study was also not designed nor powered for a cost effectiveness comparison with other glaucoma drainage implants—we believe that future direct comparison studies would be helpful in exploring this.

In conclusion, we found that the PGI was able to achieve sustained IOP reduction with reduction of medications and is comparable to other tube shunts at 2 years postsurgery in patients with advanced glaucoma.

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