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Treatment Outcomes Comparing the Paul and Baerveldt Glaucoma Implants After One Year of Follow-Up

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Précis: In reducing intraocular pressure (IOP), Paul (PGI) and Baerveldt (BGI) glaucoma implants are safe and effective in patients with glaucoma.

Objective: To compare efficacy and safety profiles of the PGI and BGI in the treatment of medically uncontrolled glaucoma at 1 year of follow-up.

Methods: Retrospective analysis of patients implanted with a PGI or BGI with a minimum of 12 months follow-up. The primary outcome was surgical success defined as IOP ≥ 6 and ≤ 18 mm Hg and at least 20% IOP reduction from baseline. Secondary outcomes included IOP measurements, number of medications, and complications.

Results: Twenty-three patients implanted with PGI and 27 with BGI were included. At last visit (12 mo), mean IOP had decreased from 23.7 ± 6.9 to 0.1 ± 2.9 mm Hg in the PGI group versus 26 ± 7.3 to 10.4 ± 4.9 mm Hg with the BGI ($P < 0.001$ for both comparisons). Overall qualified success rates were similar between groups (PGI 91% vs BGI 89%, $P = 0.784$). IOP was significantly lower in the PGI at week 1 and month 1 of follow-up versus the BGI (13.6 ± 6.1 vs 20.1 ± 7.4; 14.6 ± 3.8 vs 21.2 ± 5.8 mm Hg; $P < 0.002$ for both) with a lower number of medications (1.57 ± 1.47 vs 2.52 ± 1.16 at mo 1, $P = 0.015$). Most complications were minor and similar in both groups.

Conclusion: Both PGI and BGI are safe and effective in reducing IOP in patients with glaucoma, with similar success rates.

Key Words: aqueous shunt, long tube, glaucoma implant, hypotony

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Glaucoma is the leading cause of irreversible blindness worldwide.[1,2] Although trabeculectomy is considered the gold standard and the most widely used surgical option for medically uncontrolled glaucoma, the use of glaucoma drainage devices (GDDs) has gained popularity among glaucoma surgeons.[3–7] Moreover, the tube versus trabeculectomy (TVT) and primary TVT trials showed comparable results between both trabeculectomy and the Baerveldt glaucoma implant (BGI), further establishing GDDs as a valuable alternative to trabeculectomy, particularly in cases of refractory glaucoma or patients with high risk of surgical failure.[8,9] The most commonly used and most extensively studied GDDs are the Ahmed glaucoma valve and the BGI.[10–12] Both share common features such as the presence of a hollow silicone tube with a luminal diameter of 300 μm which drains aqueous humor from the AC to an external endplate implanted in the subconjunctival space, where the aqueous humor can be resorbed. Whereas the Ahmed glaucoma valve has a Venturi-based valve to prevent early hypotony, the BGI is unvalved, requiring an intraluminal stent and/or external ligature to prevent hypotony.[13] Moreover, the BGI has a larger endplate surface area (350 vs 184 mm^2), which has been associated with improved intraocular pressure (IOP) control.[14–17] The Paul glaucoma implant (PGI) is a newer nonvalved implant, similar in that respect to the BGI and with a comparable large endplate surface area (342 mm^2). However, it has a reduced tube lumen diameter (127 μm) aimed at preventing early hypotony. Early positive results have been reported with the PGI device but no study comparing it to other GDDs has been published so far.[18–21] The purpose of this study is to report mid-term efficacy and safety results of the PGI compared with the BGI device in glaucoma patients.

METHODS

This is a retrospective comparative analysis of consecutive glaucoma patients implanted with a PGI or a BGI device from January 2015 to September 2020 in University Hospitals Leuven. Clinical data were retrieved from patient medical records. This study adhered to tenets of the Declaration of Helsinki and approval from the UZ/KU Leuven Ethics Committee was obtained (S62970). All patients provided written informed consent for data collection and publication. Patients and data collected Exclusion criteria for analysis included combination with cataract surgery, history of another ocular disease other than refractive error or lens opacification, neovascular glaucoma, absence of light perception vision at baseline, and follow-up inferior to 12 months. The clinical indication for both implants was glaucoma refractory to medication. Of note, most patients underwent failed glaucoma surgery (eg, trabeculectomy) before tube implantation. Before the introduction of the PGI in the study center in 2019, the BGI

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TABLE 1. Baseline Demographic and Clinical Patient Characteristics

	PGI (n = 23)	BGI (n = 27)	*P*
Age, mean ± SD	60 ± 17	54 ± 16	0.152*
Right eye, N (%)†	13 (57)	15 (56)	> 0.999‡
Sex (M), N (%)	17 (74)	14 (52)	0.190§
White, N (%)	22 (96)	25 (93)	> 0.999‡
Diabetes mellitus, N (%)	5 (22)	4 (15)	0.790§
Arterial hypertension, N (%)	10 (43)	8 (30)	0.471§
IOP (mm Hg), mean ± SD	23.7 ± 6.9	26 ± 7.3	0.267*
Glaucoma medications			
Patients on medication, N (%)	21 (91)	24 (89)	0.601‡
No. medications, mean ± SD	2.74 ± 1.01	2.81 ± 1.11	0.517*
Patients on oral CAI, N (%)	8 (35)	9 (33)	> 0.999‡
Diagnosis, N (%)			
POAG	10 (43)	9 (33)	0.657§
SOAG	10 (43)	14 (52)	0.759§
PXFG	1 (4)	0	0.935§
PG	2 (9)	4 (15)	0.820§
Uveitic	2 (9)	0	0.401§
Other	5 (22)	10 (37)	0.386§
CACG	2 (9)	0	0.401§
JOAG	0	1 (4)	0.935§
PCG	1 (4)	3 (11)	0.722§
Lens status, N (%)			
Phakic	6 (26)	2 (7)	0.159§
Pseudophakic	14 (61)	19 (70)	0.684§
Aphakic	3 (13)	6 (22)	0.636§
Previous glaucoma surgery, N (%)	21 (91)	24 (89)	> 0.999‡
Bleb-forming surgery‖	16 (70)	15 (56)	0.387‡
Revision or needling procedures	12 (52)	12 (44)	0.777‡
Other IOP-lowering surgery¶	7 (30)	15 (56)	0.093‡
Visual acuity (logMAR), mean (IQR: 25–77)	0.6 (0.3–1.3)	0.5 (0.25–0.8)	0.604*
Tube placement, N (%)			
AC	15 (65)	19 (70)	0.932§
Sulcus	7 (30)	7 (26)	0.970§
Pars plana	1 (4)	1 (4)	0.543§

Data are presented as the number of complications as some patients experienced more than one complication.
*$\chi 2$ test or Fischer exact test.
†Early is considered as < 1 month postoperative, late > 1 month postoperative.
‡Optical coherence tomography was performed if there were a clinical suspicion of macular edema.
§Dilated examination and/or B scan ultrasound was conducted only when patients reported reduced vision or during follow-up of a diagnosed complication.
‖Only cases not classified as corneal decompensation at baseline or cases of new onset painful bullous keratopathy.
¶Positive Seidel test on biomicroscopy within the first month postoperative performed standard.
AC indicates anterior chamber; BGI, Baerveldt glaucoma implant; CACG, chronic angle closure glaucoma; CAI, carbonic anhydrase inhibitor; IOP, intraocular pressure; IQR, interquartile range; JOAG, juvenile open angle glaucoma; logMAR, logarithm of the minimum angle of resolution; PCG, primary congenital glaucoma; PG, pigmentary glaucoma; PGI, Paul glaucoma implant; POAG, primary open angle glaucoma; PXFG, pseudoexfoliation glaucoma; SOAG, secondary open angle glaucoma.

was the main tube of choice. With the advent of the PGI, this implant has been used in parallel with the BGI, for similar indications. Data collected from patients selected for analysis included demographic characteristics, ocular and medical history, glaucoma subtype diagnosis, Goldmann applanation tonometry measurement of IOP, logarithm of the minimum angle of resolution visual acuities, and glaucoma medication at baseline, day 1, day 7, months 1, 3, 6, and 12, and subsequent surgical interventions. In patients with bilateral GDD implantation, only 1 eye was considered for analysis.

Surgical Technique

In summary, both GDD types were implanted in the superior temporal quadrant, with the tube inserted into the AC, the sulcus, or the vitreous cavity. The BGI tube was stented with a 3-0 Supramid (B. Braun Medical) suture and ligated with two 10-0 nylon ligatures as an additional hypotony prevention measure, whereas the PGI tube was only stented with a 6-0 polypropylene suture. Full surgical descriptions are available elsewhere.[13,18]

Outcomes

Primary outcome measure was a surgical success, defined as IOP ≥ 6 and ≤ 18 mm Hg and at least 20% reduction of IOP from baseline. Failure to meet these criteria on 2 consecutive visits after 3 months of follow-up, need for additional glaucoma surgery, or loss of light perception at any time point was considered a failure. Interventions performed at the slit-lamp, such as needling procedures, AC refill, laser suture lysis, shortening, or removal of tube stent were not considered glaucoma reoperations. Cases were further described as absolute success if unmedicated, or qualified success regardless of medication. Secondary outcome measures included IOP measurements, IOP reduction, number of IOP-lowering medications used, early complications (within the first month of the postoperative period), and late complications

(after 1 mo). Persistent hypotony was defined as IOP <6 mm Hg for more than 2 weeks and/or requiring intervention, with or without associated findings such as choroidal effusion. Secondary outcome data generated by patients who underwent additional glaucoma surgery during the follow-up period was excluded from the time of reoperation.

Statistical Analyses

This study was powered to detect a clinically relevant difference in IOP reduction. With a 2-sided significance level of 0.05, a sample size of 21 patients in each treatment group would be required to detect an IOP reduction of 3 mm Hg with 0.80 power assuming a SD of 5.5 mm Hg, as reported in previous studies.[10,22] Demographics and clinical characteristics of patients were described using the mean ± SD and frequencies for categorical variables. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess distribution normality. The χ^2 test was used to compare categorical variables and proportions, whereas Student *t* and Kolmogorov-Smirnov tests were used for parametric and nonparametric quantitative data analysis, respectively. For comparisons between multiple variables, analysis of variance and Kruskal-Wallis tests were performed according to normality. Kaplan-Meier survival curves were used to assess cumulative survival probability. Survival analysis also included the Manthel-Cox log-rank test to compare survival probability. Statistical analysis was performed with SPSS (version 26.0) and a *P* value <0.05 was used for statistical significance.

RESULTS

A total of 50 eyes from 50 patients were included in this analysis. Twenty-three were implanted with a PGI and 27 with a BGI, all surgeries were performed as solo procedures. There were no statistically significant differences in demographics or ocular findings at baseline between both treatment groups, including preoperative IOP, baseline glaucoma medication, age at the time of surgery, glaucoma diagnosis, ocular history, lens status, or visual acuity (Table 1).

Primary Outcomes

Cumulative probability of qualified success was similar between the PGI and BGI groups (91% and 89% respectively; $P = 0.784$) at 12 months, as were absolute success rates (44% for the PGI and 48% with the BGI; $P = 0.812$). Figure 1 displays Kaplan-Meier survival curves for both groups. There were 2 failed cases in the PGI group: (1) one patient required a tube revision on day 3 due to severe hypotony (leakage from prior trabeculectomy site) and (2) another also required tube revision 3 months postoperatively due to hypotony after stent removal. In the BGI group, we recorded 3 failures, 2 of which also needed tube revision (1 tube repositioning due to posterior displacement of the tube, and 1 tube flushing and needling) within the first 3 months, and 1 patient who suffered from secondary loss of light perception due to intravitreal bleeding and consequent corneal staining the day after stent removal.

Secondary Outcomes

Intraocular Pressure

IOP was significantly reduced at 12 months in both groups, from a preoperative measurement of 23.7 ± 6.9 mm Hg in the PGI group to 13.1 ± 2.9 mm Hg and 26 ± 7.3 mm Hg to 10.3 ± 4.9 in the BGI ($P < 0.001$ for both comparisons). This amounts to a relative reduction in IOP from baseline of 44.6% and 61% and the BGI, respectively. Comparing both groups at multiple time points, the PGI group showed lower IOP measurements at 1 week (13.6 ± 6.1 vs 20.1 ± 7.4 mm Hg, $P = 0.002$) and at 1 month (14.6 ± 3.8 vs 21.2 ± 5.8 mm Hg, $P < 0.001$). No difference was observed for the remainder of the follow-up period until month 12, when a significantly lower IOP was recorded with the BGI (10.4 ± 4.9 vs 13.1 ± 2.9 mm Hg, $P = 0.024$). Figure 2 shows a bar graph of IOP measurements for both groups during follow-up visits with IOP and medication comparisons at each time point. Figure 3 displays a scatterplot comparing the baseline IOP with the IOP at 12 months postoperatively for the PGI and the BGI group, which shows most patients achieved IOP criteria for success.

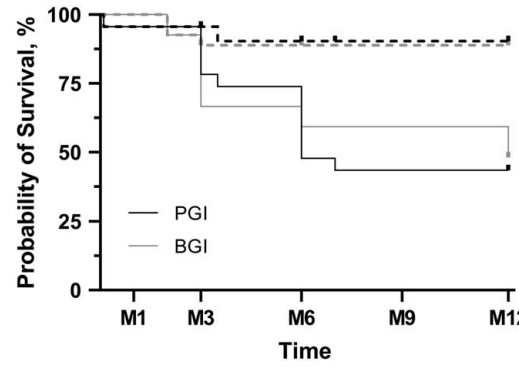


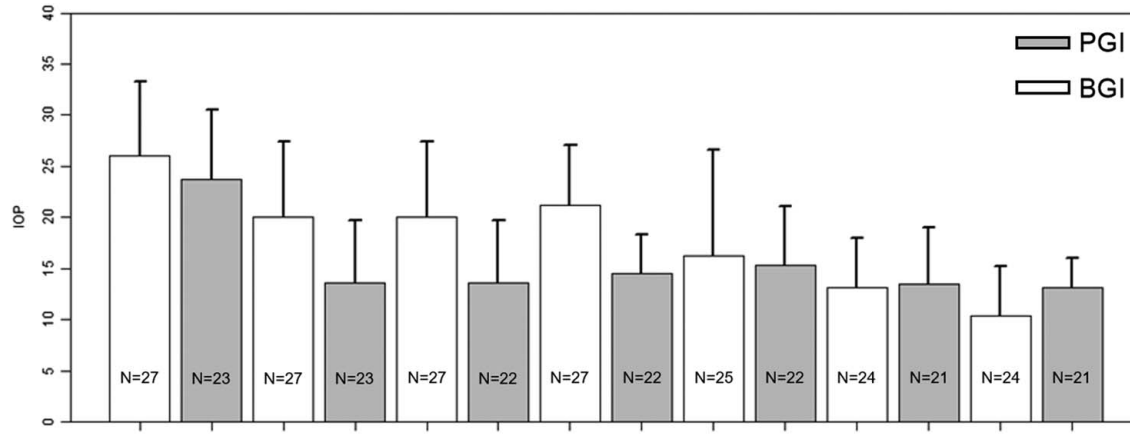
FIGURE 1. Kaplan-Meier survival curves for PGI and BGI groups. Absolute success curves are shown as solid lines, whereas qualified is represented by dashed lines. BGI indicates Baerveldt glaucoma implant; PGI, Paul glaucoma implant.

Glaucoma Medications

Both PGI and BGI were effective in reducing the need for glaucoma medications. The mean number of medications was 2.74 ± 1.01 at baseline in the PGI group which decreased to 1.41 ± 1.40 at 12 months postoperatively, and in the BGI group medication was reduced from 2.81 ± 1.11 to 1.20 ± 1.35 ($P < 0.001$ for both comparisons). At month 1, patients with PGI were under a significantly lower number of topical medications versus patients with BGI (1.57 ± 1.47 vs 2.52 ± 1.16; $P = 0.015$) and oral acetazolamide (n = 2, 8.7% vs n = 9, 33%, respectively; $P = 0.046$; Fig. 2 for further details).

Visual Outcomes

There was no statistically significant decrease in visual acuity between baseline and 1 year postoperative in the PGI (0.86 ± 0.75 vs 0.88 ± 0.72; $P = 0.943$) or the BGI group (0.77 ± 0.70 vs 0.91 ± 0.84; $P = 0.872$), nor was there a statistically significant difference between groups ($P = 0.604$ for baseline measurement and $P = 0.706$ at 1 y). Five patients in the PGI (22%) and 5 patients in the BGI group (19%) did show a clinically, although not statistically significant, vision change from baseline, defined as a loss of more than 2 Snellen lines. Reasons identified for this decrease in the PGI were macular disease (2 patients; central retinal venous occlusion and epiretinal fibrosis) and corneal decompensation (3 patients). In the BGI group, the vision



Timepoint	Pre-operative	Day 1	Day 7	Month 1	Month 3	Month 6	Month 12
IOP, mmHg	26±7.3 | 23.7±6.9	17.2±7.6 | 13.7±6.2	20.1±7.4 | 13.6±6.1	21.2±5.8 | 14.6±3.8	16.2±10.5 | 15.3±5.7	13.1±4.9 | 13.3±5.7	10.4±4.9 | 13.1±2.9
p-value	0.267	**0.088**	**0.002**	**<0.001**	0.746	0.916	**0.024**
Medication, mean±SD	2.81±1.11 | 2.74±1.01	0 | 0	2.11±1.38 | 1.56±1.38	2.52±1.16 | 1.57±1.47	1.00±1.47 | 0.68±1.13	1.20±1.38 | 1.45±1.26	1.20±1.35 | 1.41 ±1.4
p-value	0.517	>0.999	0.128	**0.015**	0.459	0.547	0.594
Oral CAI, N	8 | 8	0 | 0	8 | 1	9 | 2	1 | 1	0 | 0	0 | 0
p-value	>0.999	>0.999	**0.028**	**0.046**	>0.999	>0.999	>0.999

FIGURE 2. Bar graph displaying IOP measurements for both groups during follow-up with IOP and medication comparisons at each time point. BGI indicates Baerveldt glaucoma implant; CAI, carbonic anhydrase inhibitor; IOP, intraocular pressure; PGI, Paul glaucoma implant.

loss was related to glaucoma progression (2 patients), persistent hypotony (1 patient) which resolved spontaneously, corneal decompensation (2 patients, one of which was the one with intravitreal bleeding), and intraocular lens subluxation (1 patient).

Interventions at the Slit-Lamp

Intraluminal stents were removed at the slit-lamp in 20 (out of 23) patients with PGI and 24 (out of 27) in the BGI group according to IOP control during follow-up. The mean time from surgery to stent removal was 95 ± 48 days for the PGI and 88 ± 70 days for the BGI ($P = 0.690$). Suture lysis was performed in 22 patients with BGI (out of 27) to loosen the nylon ligatures as needed. No suture lysis was needed in the PGI group given the surgical technique used for this group.

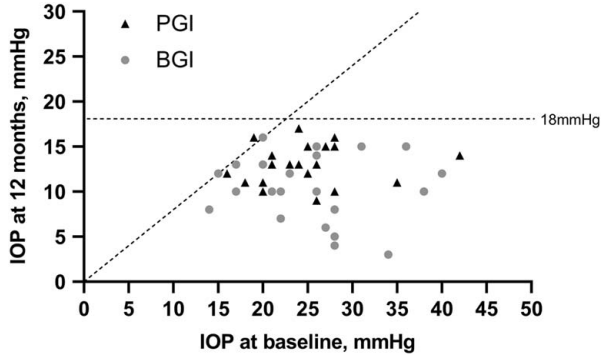


FIGURE 3. Scatterplot comparing preoperative and 12-month IOP measurements for each eye. The horizontal line represents the 18 mm Hg threshold. A line of identity was drawn to represent a threshold of 20% reduction in IOP from baseline. Failures due to reoperation were censored. BGI indicates Baerveldt glaucoma implant; IOP, intraocular pressure; PGI, Paul glaucoma implant.

Complications

Surgical complications were defined according to "Guidelines on Design and Reporting of Glaucoma Surgical Trials" by the World Glaucoma Association.[23] During the 12-month follow-up period, patients from both groups suffered from similar complications, the most common being hyphema, choroidal effusion, corneal decompensation, and encapsulated bleb (Table 2 for further details). There was no significant difference between groups regarding the number of intraoperative, early postoperative, or late postoperative complications.

DISCUSSION

This study aimed at comparing the success and safety profiles of the PGI and BGI tubes. Our results suggest a similar efficacy of both GDDs with similar success rates (91% and 89%) and medication reduction (mean number of medications at 12 mo of 1.41 ± 1.4 and 1.2 ± 1.35, $P = 0.594$). Despite similar success rates, we did find lower IOP measurements in the BGI group at 12 months (10.4 ± 4.9 vs 13.1 ± 2.9 mm Hg; $P = 0.024$). These results are comparable with previously published reports on both devices, although direct comparisons are difficult to establish due to variability in success criteria.[10–12,18–21] Absolute success rate was 48% for both groups owing to a high number of patients requiring medication to achieve adequate IOP control. This is also in line with published studies, which have shown that patients with GDDs require a greater number of medications than patients undergone trabeculectomy.[9] This may be partly explained by a predictably higher IOP within the first month of surgery compared with patients undergone trabeculectomy due to the fact that nonvalved GDDs are stented to prevent hypotony, therefore, commonly requiring IOP-lowering medication in the early postoperative period. The common features shared by both PGI and BGI devices (valveless system, endplate surface area) may explain similar success

TABLE 2. List of Recorded Surgical Complications

	PGI (n = 23)	BGI (n = 27)	P*
Intraoperative complications	1	1	> 0.999
Severing of extraocular muscle tendon	0	0	NA
AC bleeding	0	1	NA
Scleral perforation	1	0	NA
Vitreous prolapse	0	0	NA
Early postoperative complications†	5	11	0.225
Shallow or flat AC	1	0	NA
Choroidal effusion‡	1	3	NA
Hypotony maculopathy§	0	0	NA
Malignant glaucoma	0	0	NA
Macular edema#§	0	0	NA
Disc swelling§	0	0	NA
Hyphema	1	3	NA
Vitreous cavity bleeding	0	2	NA
Increased lens opacity	0	0	NA
Cataract extraction during follow-up period	0	0	NA
New onset corneal decompensation‖	0	1	NA
Tube occlusion	0	0	NA
Tube retraction	0	0	NA
Tube exposure (transconjunctival)	0	0	NA
Stent exposure (transconjunctival)	0	1	NA
Tube corneal touch	0	0	NA
Tube lenticular touch	0	0	NA
Encapsulated bleb	0	0	NA
Wound leak¶	2	1	NA
Diplopia	0	0	NA
Retinal disease (vascular occlusion, retinal tear, etc)**	0	0	NA
Late postoperative complications†	15	19	0.767
Shallow or flat AC	1	1	NA
Choroidal effusion‡	1	3	NA
Hypotony maculopathy§	0	2	NA
Malignant glaucoma	1	0	NA
Macular edema#§	0	0	NA
Disc swelling§	0	0	NA
Hyphema	0	3	NA
Vitreous cavity bleeding	0	1	NA
Increased lens opacity	1	1	NA
Cataract extraction during follow-up period	2	0	NA
New onset corneal decompensation‖	3	2	NA
Requiring corneal surgery during follow-up	2	1	NA
Tube occlusion	0	0	NA
Tube retraction	0	0	NA
Tube exposure (transconjunctival)	0	0	NA
Stent exposure (transconjunctival)	0	1	NA
Tube corneal touch	0	0	NA
Tube lenticular touch	0	0	NA
Encapsulated bleb	3	3	NA
Bleb leak#	0	0	NA
Diplopia	1	1	NA
Retinal disease**	0	0	NA
Total no. of postoperative complications	21	31	0.177

*Student *t* test with SD or Shapiro-Wilk test with interquartile range (IQR: 25-77).
†Percentages are rounded to units.
‡$\chi 2$ test with Yates correction.
§Fisher exact test.
‖Bleb-forming surgery includes trabeculectomy, deep sclerectomy, Express shunt, glaucoma drainage device, XEN gel stent, Preserflo Microshunt.
¶Other surgeries include diode cyclophotocoagulation, ultrasound cyclocoagulation, trabeculotomy/goniotomy.
#Positive Seidel test after 1 month postoperative was categorized as a bleb leak. After 1 month postoperative, the Seidel test was only performed in selected cases based on clinical suspicion.
**Includes occurrences within 3 months of surgery (otherwise not attributable to the glaucoma surgery).
AC indicates anterior chamber; BGI, Baerveldt glaucoma implant; NA, not applicable; PGI, Paul glaucoma implant.

outcomes. However, some differences in secondary outcomes are worth noting. Despite better final IOP control with the BGI devices, the PGI group had lower IOPs in the early postoperative period (up to 1 mo). This may be because, unlike the PGI tubes, the BGI tubes were ligated with 10-0 nylon sutures as an added hypotony prevention measure. This more aggressive flow restriction in the BGI group would account for higher early IOPs and a higher need for IOP-lowering medication, as shown in Figure 2. Interestingly, the smaller diameter of the PGI tube is hypothesized to be protective against postoperative hypotony compared with wider tubes such as the BGI, which are known to carry an added hypotony risk versus valved Ahmed tube shunts.[12] Indeed, we observed only one case of early hypotony with the PGI despite the absence of restrictive ligatures in addition to the stent (a case with early hypotony due to leakage in a previous trabeculectomy site). Moreover, although our small sample size only allows for limited exploratory comparative analysis, we observed 5 patients with hypotony-related complications beyond the first postoperative month in the BGI group (vs 2 in the PGI group), one of which had a substantial visual loss at 1 year. Early outcome studies with the PGI device also report lower hypotony rates than those associated with the BGI, suggesting that its reduced lumen may indeed be protective against this complication.[18–21] In summary, we observed better early postoperative IOP control with the PGI with a lessened risk of hypotony-related complications compared with the BGI, which may have important clinical implications. Although not statistically significant, the 1-year IOP results were slightly better in the BGI group, reaching numbers in the low teens.

Most recorded complications were minor and did not require intervention. There was no significant difference in complication rates (overall, early, and late) between groups. However, we observed a trend toward a higher number of complications with the BGI device. Among early complications with the BGI, hypotony-related complications [choroidal effusion, hypotony maculopathy, and flat anterior chamber (AC)] and hyphema were the most frequent. The latter may be related to the wider needle tract which is required to fit in the larger tube lumen of the BGI. Moreover, the BGI group recorded a higher number of postoperative interventions at the slit-lamp, owing mainly to suture lysis of nylon ligatures, which were not present in the PGI group. Corneal edema remains an important and feared long-term complication related to tube implants. Our study shows similar rates of corneal decompensation and corneal surgery during follow-up for both implants and overlapping existing data from TVT and primary TVT studies.[8,9] However, these data should be interpreted carefully due to the relatively short follow-up time. Moreover, it may be difficult to extrapolate the causes for corneal decompensation in our sample, as tube patients often have a higher number of prior complex surgeries (likely the reason they were tube candidates in the first place). It is therefore possible that low(er) endothelial cell counts existed before tube shunt surgery. Whether or not the differences in tube diameter would have made a difference in corneal survival in naïve eyes remains to be determined. Nevertheless, it has been suggested that the smaller PGI tube may reduce the incidence of this complication compared with larger tubes.[20] Some limitations of this study should be addressed. Our sample was calculated to effectively show significant IOP differences between groups. However, the sample size is insufficient to draw conclusions regarding other exploratory analyses such as complications occurring in small numbers. The fact that the study population was mainly white further limits this extrapolation. Its retrospective nature also limits our findings. Moreover, it should be considered that many patients had a history of prior trabeculectomy, thus limiting our results regarding the role of these drainage devices as primary surgical procedures. Furthermore, small differences between both samples, although statistically insignificant, may be clinically relevant, such as IOP, age, or number of specific glaucoma diagnoses, which may make it difficult to generalize our conclusions. Finally, the PGI is a newer device and thus a learning curve effect should be considered in this group. This is the first study reporting outcomes with the PGI compared with another GDD.

CONCLUSION

We report similar overall efficacy and safety profiles of both PGI and BGI devices. Although BGI provided lower IOP at 1 year of follow-up, PGI provided better IOP control in the early postoperative period, which may be an important clinical consideration for some patients.

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