Original Article

# Paul versus Baerveldt 350 glaucoma drainage implants: One-year comparative analysis

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**Purpose:** This study aimed to evaluate and compare the effectiveness and safety of Paul glaucoma implant (PGI) and Baerveldt 350 glaucoma implant (BGI) over a 1-year follow-up period. **Methods:** This retrospective study was conducted in a private clinic. It compared 27 patients consecutively treated with the PGI to a historical cohort of 29 eyes that received the BGI prior to the introduction of the PGI between 2018 and 2023. Intervention: A new drainage device, the Paul implant, was placed in the anterior or posterior chamber of eyes with uncontrolled intraocular pressure (IOP). **Main Outcome Measures:** The main outcome measures were success rate, final mean IOP, IOP reduction percentage, medication reduction, and complications. Statistical analyses, including adjustments for confounders, were used to compare the performance of PGI and BGI over at least a 12-month period. **Results:** Significant reductions in IOP were observed in both groups ($P < 0.001$). At 1 year, no significant differences were found in mean IOP (BGI: 12.0 mmHg, SD 2.9; PGI: 11.2 mmHg, SD 6.0) or medication usage ($P > 0.05$). The failure rates were 7% for BGI and 18% for PGI, with complete success rates of 56% for BGI and 32% for PGI. Hypertensive phases occurred in 32% of the BGI cases and in 19% of the PGI cases. No significant differences in the complication rates or postoperative visual acuity were observed between the groups. **Conclusion:** PGI and BGI exhibited comparable efficacy and safety profiles after 1 year.

**Key words:** Baerveldt glaucoma implant, glaucoma drainage implants, Paul glaucoma implant, refractory glaucoma, tube surgery

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Over the past few decades, changes and improvements have been introduced in glaucoma drainage implants (GDIs) to enhance the efficacy and safety of the procedure. The most notable changes have been the introduction of more biocompatible materials, plates of different sizes and designs, and flow control devices that allow pressure control during the early postoperative period.[1–8]

All designs share a common principle: A silicone tube with an external diameter of 0.63 microns is placed inside the eyeball and attached to a plate located in the subconjunctival space. Encapsulation that forms around the endplate during the initial postoperative weeks regulates the outflow in the long run.[9]

In the initial description of the surgical technique, the intraocular end of the tube was placed inside the anterior chamber (AC).[10,11] Subsequently, the decision was made to place it in either the posterior[12–14] or vitreous chamber[15,16] to avoid contact with the cornea and prevent long-term endothelial damage and corneal decompensation, which has emerged as a long-term complication, particularly in implants positioned in the AC.[17] Although placement away from the AC has proven to be effective, the surgery is more complex, requiring a peripheral iridectomy in the case of posterior chamber (PC) placement or a complete vitrectomy with thorough peeling of the vitreous base to prevent tube obstruction by a vitreous strand when vitreous cavity placement has been chosen.

The introduction of a new drainage implant to the market, the Paul glaucoma implant (PGI), featuring an outer a tube diameter of 0.47 microns, aims to enhance endothelial safety. The presence of a tube that fits more easily into the angle due to its smaller diameter should not necessarily diminish the long-term efficacy of the device, as supported by studies conducted to date.[18–22]

However, its efficacy must be compared with the gold standard implant, the Baerveldt 350. In this study, we aimed to compare the efficacy of the Paul implant with that of the gold standard Baerveldt 350 implant at a 1-year follow-up.

## Methods

This retrospective study included all patients who were consecutively treated with Paul implants and compared them

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against a historical database of patients who had consecutively received Baerveldt glaucoma implant (BGI) treatment before the marketing of PGI from 2018 to 2023. The study was performed in a private clinic setting and adhered to the tenets of the Declaration of Helsinki of 1975, as revised in 2000, and Institutional Review Board approval (ref# HCB.2023.0218 23[SD1] /03/2023).

Surgical Technique: Baerveldt 350 devices were implanted under peribulbar anesthesia and sedation. Topical 5-fluorouracil (5FU), 50 mg/mL, or Mitomycin C (MMC) 0.2 mg/ml was applied in all cases by soaking a sponge and placing it on the scleral surface for 3 minutes. The entry was made with a 23- or 25-gauge needle into the anterior, posterior, or vitreous chamber based on the surgeon's discretion. A Prolene 3/0 stent was inserted into the lumen before applying a 6-7/0 polyglactin ligature. An alcohol-preserved donor scleral graft is used to cover the extraocular portion of the tube. In cases where the intraocular pressure (IOP) was excessively high, slits were made in the tube between the ligature and the entry into the AC, or a previously closed trabeculectomy was reopened where no antimetabolites were applied, nor was it manipulated postoperatively to maintain filtration. The same surgical technique was used for PGI implantation, and the tube was placed in the anterior or posterior chamber, according to the surgeon's discretion. Prolene® 6/0 was used as a stent in the ripcord technique, followed by a 7/0 polyglactin ligature, except in cases where the IOP was high. Fifty eyes were operated by SD, and six cases were operated by CA and EA. Postoperative treatment included Tobradex® (3 mg/mL tobramycin + 1 mg/mL dexamethasone, Novartis, Barcelona, Spain) and dexamethasone® (1 mg/mL, Novartis) drops administered three times daily, along with aqueous secretion inhibitors. The rip cord stent was withdrawn at the surgeon's discretion before or after release of the absorbable ligature. The "Molteno cocktail" (Prednisone 2.5 mg tid, Diclofenac 25 mg tid, and Colchicine 0.25 mg tid) was prescribed based on the surgeon's discretion. The hypertensive phase (HP) was managed with topical and subconjunctival steroids, aqueous suppressants, and as needed, along with the Molteno cocktail.

### Primary and secondary outcomes

The primary outcomes included failure criteria, IOP reduction, percentage IOP reduction (IOPR%), mean final IOP, and glaucoma medication use. The failure criteria were as follows: IOP >21 mmHg, less than 20% IOP reduction, sustained IOP <6 mmHg affecting vision, loss of light perception, or need for additional glaucoma surgery or implant removal. Success was defined as IOP 6–21 mmHg and 20% reduction without loss of light perception or additional glaucoma surgery, including GDI removal. Partial Success (PS) criteria were met with the need for glaucoma medication, whereas complete success (CS) criteria were not. HP was defined as an increase in IOP greater than 21 mmHg (with or without medications) during the 6-month postoperative period, which was not attributable to tube obstruction, retraction, or malfunction.

### Statistical analyses

The analysis was conducted using STATA 17.0. Groups were compared using Student's *t*-test for continuous variables and the Chi-square or Fisher's test for categorical variables. The IOP, IOPR%, and number of medications were compared at each follow-up point using multivariate logistic regression to control for potential confounders. Paired t-tests were used to compare pre- and postoperative data. Statistical significance was set at $P < 0.05$.

## Results

In this study, we evaluated 56 eyes over an average follow-up period of 15.3 months (6.4). The BGI group included 29 eyes with a mean 18.0-month follow-up (6.4), with 28 eyes completing a 1-year follow-up. The PGI group consisted of 27 eyes with an 11.8-month follow-up (4.2), with 22 eyes reaching the 1-year mark.

Demographically, both groups were comparable in age, sex, preoperative best-corrected visual acuity (BCVA), and glaucoma medication use. The BGI group presented a higher baseline IOP under a greater number of glaucoma medications than the PGI group, although these differences were not statistically significant ($P = 0.07$ and $P = 0.57$, respectively). Significant disparities were observed in the types of glaucoma, particularly with a higher prevalence of patients undergoing tube surgery due to previously failed filtering surgery in the PGI group ($P = 0.03$), as shown in Table 1.

The BGI was implanted in the AC in eight cases, PC in 18 cases, and vitreous chamber in three cases. All cases received topical per-operative 5FU (50 mg/ml for 3 minutes with no BSS rinse). The PGI was primarily implanted in the AC, involving 21 eyes, compared to eight eyes in the PC. MMC (0.2 mg/ml applied for 3.5 minutes with BSS rinse) was always used prior to tube entry through scleral tunneling. In the BGI group, seven eyes had slits considered, and one case required reopening of a previously failed trabeculectomy to avoid postoperative ocular hypertension. This reopened trabeculectomy closed before the dissolution of the ligature. The Paul implant group did not use ligature in seven cases to avoid postoperative hypertension.

Comparative analyses between baseline IOP and follow-up measurements at 1, 3, 6, and 12 months revealed statistically significant reductions in IOP ($P < 0.001$) in both cohorts. When adjustments were made for baseline IOP, age, sex, and the reason for tube surgery, no significant differences were observed between the groups in terms of IOP, IOPR%, or medication use at any time point [Table 2 and Figs. 1 and 2].

After 12 months, 88% of all eyes met success criteria. CS was noted in 45% of the cases, with a partial success (PS) of 43%. As the success criteria narrowed to an IOP range of 6–18 mmHg, PS and CS remained unchanged. With further restriction of success to an IOP range of 6-15mmHg, success decreased to 74%. The Baerveldt group attained higher CS across all IOP thresholds than the Paul group: 56% vs 32% for the 6–21 and 6–18 mmHg success criteria and 52% vs 27% for the 6–15 mmHg success criteria, although these differences were not statistically significant [Table 3].

BCVA did not change significantly postoperatively, and no significant differences were found between the groups throughout the follow-up period ($P > 0.05$) [Table 4].

The incidence of HP was 32% (9 cases) in the BGI and 19% (5 cases) in the PGI ($P = 0.36$).

In the BGI group, nine cases showed HP. One case resulted from a failed previous filtering surgery, while eight were linked to ocular anatomical issues that precluded standard filtering surgery, such as penetrating keratoplasty and complex

**Table 1: Comparative demographic and clinical characteristics of patients receiving Baerveldt and Paul implants**

| | BGI | PGI | *P* |
|---|---|---|---|
| N | 29 | 27 | |
| Age | 63.4 (18.3) | 64.9 (19.4) | 0.77 |
| Sex (Female) | 11 (37.9%) | 13 (48.15%) | 0.60 |
| Preoperative visual acuity (LogMAR) | 0.58 (0.65) | 0.76 (0.85) | 0.39 |
| Preoperative IOP | 28.2 (9.4) | 23.9 (8.0) | 0.07 |
| Preoperative number of medications | 3.17 (1.3) | 3.0 (1.0) | 0.58 |
| Number of previous IOP lowering interventions | 1.11 (1.0) | 1.22 (1.1) | 0.68 |
| Pseudophakia | 21 (81%) | 20 (74%) | 0.37 |
| Reason for tube surgery: | | | 0.04* |
| Neovascular Glaucoma | 0 (0.0%) | 0 (0.0%) | |
| Juvenile, congenital, and syndromes | 5 (17.2%) | 1 (3.7%) | |
| Aphakia, pseudophakia and AC IOL | 0 (0%) | 2 (7.4%) | |
| Failed previous filtering surgery | 9 (31.0%) | 17 (63.0%) | |
| Ocular anatomy that precludes standard filtering surgery such as Penetrating keratoplasty, complicated intraocular surgery, nanophthalmos. | 11 (37.9%) | 6 (22.2%) | |
| Uveitis | 4 (13.8%) | 1 (3.7%) | |
| Tube location | | | <0.01* |
| Anterior chamber | 7 (24.1%) | 22 (81.5%) | |
| Posterior chamber | 19 (65.5%) | 5 (18.5%) | |
| Vitreosus cavity | 3 (10.3.0%) | 0 (0.0[SD1] %) | |

**Table 2: Timewise comparison of IOP, IOP reduction percentage, and medication usage between BGI and PGI groups (adjusted for age, baseline IOP, sex, and reason for tube surgery)**

| Time | N | | IOP (mmHg) | | | IOPR% | | | Number of Glaucoma drugs | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | BGI | PGI | BGI | PGI | *P* | BGI | PGI | *P* | BGI | PGI | *P* |
| Pre-op | 29 | 27 | 28.2 (9.4) | 23.9 (8.0) | 0.19 | - | - | | 3.2 (1.3) | 3.0 (1.0) | 0.85 |
| 1 mo | 26* | 27 | 16.5 (9.6) | 14.9 (4.8) | 0.74 | 39.1 (36.9) | 31.0 (33.4) | 0.92 | 1.0 (1.3) | 1.2 (1.4) | 0.84 |
| 3 mo | 25* | 27 | 15.0 (6.5) | 14.7 (4.5) | 0.22 | 45.4 (23.9) | 34.4 (24.4) | 0.18 | 0.89 (1.0) | 0.89 (1.1) | 0.87 |
| 6 mo | 26* | 27 | 13.9 (4.2) | 14.7 (5.0) | 0.31 | 46.4 (20.4) | 33.3 (30.0) | 0.22 | 0.96 (1.2) | 1.0 (1.0) | 0.73 |
| 12 mo | 27 | 22 | 12.0 (2.9) | 11.2 (6.0) | 0.7 | 52.6 (20.3) | 45.0 (22.2) | 0.61 | 0.58 (0.8) | 1.0 (1.0) | 0.23 |

*Remote patients were overseen by their ophthalmologists, but we only used data verified in our clinic to ensure accuracy. IOPR=Rate of IOP reduction

**Table 3: Success rates at 6 months and 1 year for success criteria of 6-21mmHg, 6-18mmHg and 6-15mmHg**

| months | GDI | 6-21 mmHg | | | | 6-18 mmHg | | | | 6-15 mmHg | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Failure | PS | CS | *P* | Failure | PS | CS | *P* | Failure | PS | CS | *P* |
| 6 | BGI *n*=27 | 4 (15%) | 12 (46%) | 10 (38%) | 0.64 | 6 (23%) | 11 (42%) | 9 (35%) | 0.38 | 13 (50%) | 7 (27%) | 6 (23%) | 0.82 |
| | PGI *n*=27 | 7 (26%) | 12 (44%) | 8 (30%) | | 11 (41%) | 9 (33%) | 7 (26%) | | 15 (56%) | 8 (30%) | 4 (15%) | |
| | Total | 11 (21%) | 24 (45%) | 18 (34%) | | 17 (32%) | 20 (38%) | 16 (31%) | | 28 (53%) | 15 (28%) | 10 (19%) | |
| 12 | BGI *n*=27 | 2 (7%) | 10 (37%) | 15 (56%) | 0.22 | 2 (7%) | 10 (37%) | 15 (56%) | 0.22 | 8 (27%) | 5 (19%) | 14 (52%) | 0.06 |
| | PGI *n*=22 | 4 (18%) | 11 (50%) | 7 (32%) | | 4 (18%) | 11 (50%) | 7 (32%) | | 5 (23%) | 11 (50%) | 6 (27%) | |
| | Total | 6 (12%) | 21 (43%) | 22 (45%) | | 6 (12%) | 21 (43%) | 22 (45%) | | 13 (26%) | 16 (33%) | 20 (41%) | |

intraocular surgeries. In the PGI group, five cases exhibited HP. One required tube surgery due to aphakia, pseudophakia, and AC IOL. One was due to anatomical challenges including penetrating keratoplasty, complex intraocular surgery, and nanophthalmos; three followed failed previous surgeries. Regarding the intraocular placement of the tube in eyes that exhibited HP: In the PGI group, all tubes were positioned in the AC, except for one in the PC. In the BGI group, one eye had the tube in the vitreous chamber, two eyes in the AC, and six eyes in the PC.

Complications are listed in Table 5. BGI had 31% complications, and PGI had 48.2% ($P = 0.15$). Late complications after the third month were observed just in two eyes with BGI with silk suture extrusion and the need for tube repositioning in one case. Some eyes experienced more than one complication, so both BGI and PGI group had five patients with complications.

## Discussion

**Salient observations:** At 1-year follow-up, the PGI and the BGI demonstrated a significant reduction in IOP ($P < 0.001$), with no significant differences in final IOP between groups (BGI: 12.0 mmHg; PGI: 11.2 mmHg, $P > 0.05$). Complete success was achieved in 56% of BGI cases and 32% of PGI cases, with failure rates of 7% for BGI and 18% for PGI. The incidence of the hypertensive phase (HP) was 32% for BGI and 19% for PGI, and the overall complication rate was 48% for PGI and 31% for BGI, with no significant difference ($P = 0.15$). Visual acuity remained stable in both groups.

The introduction of the Paul implant, which has a smaller diameter and occupies less space at the anterior angle, suggests that it may be safer when placed in the AC.[21] However, the effectiveness of this device must be understood not only in isolation but also in comparison with the gold standard, the Baerveldt implant. PGI efficacy studies to date, with 1- and 2-year follow-ups, have shown mixed results, potentially due to different surgical techniques, flow restriction methods, or the use of antifibrotics.[18–22]

Analyzing the individual outcomes of the Paul implant, a 1-year study of 74 eyes conducted by the prospective study group[21] reported a PGI failure of 5.4% and a CS of 25.7%, with a final average IOP of 13.8 mmHg while on 0.3 glaucoma medications. Using stricter criteria and per-operative MMC in all cases, José *et al*.'s retrospective study[22] reported 25% failure and 75% fulfilled the surgical success criteria, 8 (33%) of which did not require any IOP-lowering medication, with a final IOP of 12.5 mmHg on 0.8 glaucoma medications of 1 year.

Another retrospective study with a 2-year follow-up using success criteria of 6–18 mmHg noted a 17.8% failure rate and an 11.1% of CS, with a final IOP of 14.2 (±3.5) mmHg at 12 months and 13.9 (±3.7) mmHg at 24 months. Patients were on 0.1 (±0.4) and 0.2 (±0.6) hypotensive medications, respectively at these time points.[19] There was almost no difference in IOP control between the first and second years of FU, suggesting the sustained hypotensive efficacy of PGI.[19]

Our results showed 18% failure at 1 year using the 6-21 and 6-18 mmHg criteria and 23% failure under the strictest criterion (IOP between 6 and 15 mmHg). This is likely due to the lower target pressure selected by the surgeon, which aims to consistently achieve pressures below 18 mm Hg. By the end of the first year, the mean IOP was 11.2 mmHg, reflecting a 45% IOPR. Notably, 77% of the eyes achieved an IOP below 15 mmHg, a significant achievement, as GDIs often struggle to maintain low IOP. Our findings are in close

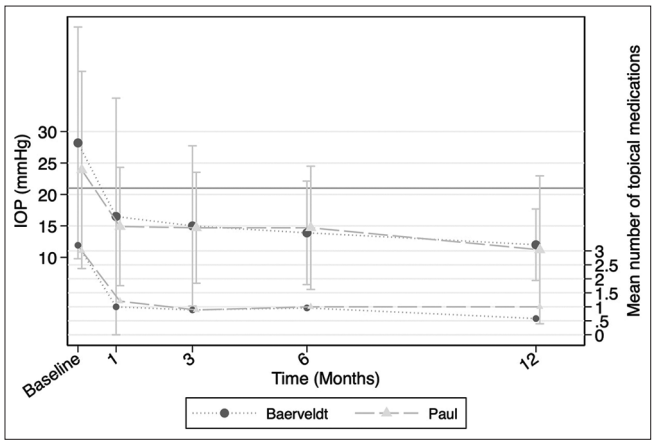


**Figure 1:** Longitudinal trends of IOP (left) and the mean number of topical medications (right) for BGI and PGI groups over 12 months (adjusted for age, baseline IOP, sex, and reason for tube surgery)

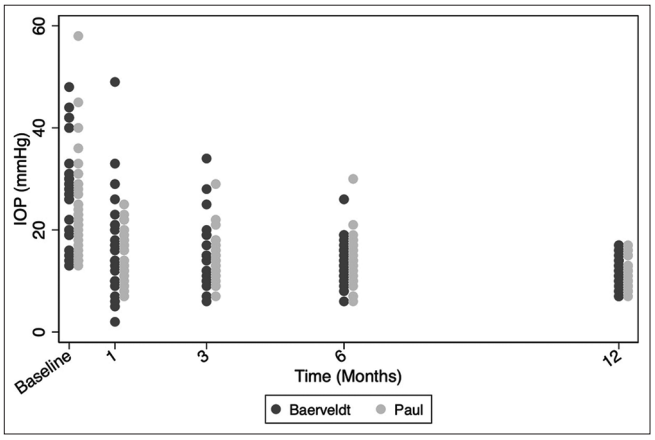


**Figure 2:** Scatterplot with preoperative and postoperative IOP at the last follow-up visit

**Table 4: Mean differences in BCVA, IOP, IOPR%, and antiglaucoma medication between BGI and PGI groups**

| F/U | Visual acuity (LogMAR) | IOP (mmHg) | IOPR% | Glaucoma drugs |
|---|---|---|---|---|
| 1 mo | -0.26 (-0.73 to 0.22; *P*=0.28) | -3.2 (-8.8 to 2.5; *P*=0.27) | -8.0% (-27.4 to 11.3; *P*=0.41) | -0.18 (-1.1 to 0.76; *P*=0.70) |
| 3 mo | 0.08 (-0.44 to 0.60; *P*=0.75) | -4.8 (-9.9 to 0.28; *P*=0.03) | -11.0% (-24.5 to 2.5; *P*=0.11) | -0.05 (-0.87 to 0.77; *P*=0.91) |
| 6 mo | -0.07 (-0.41 to 0.27; *P*=0.69) | -4.7 (-9.4 to 0.09; *P*=0.05) | -13.1% (-27.3 to 1.1%; *P*=0.07) | -0.20 (-0.98 to 0.57; *P*=0.60) |
| 12 mo | -0.22 (-0.59 to 0.15; *P*=0.24) | -5.1 (-10.1 to -0.01; *P*=0.049) | -7.6% (-19.8 to 4.7; *P*=0.22) | -0.66 (-1.48 to 0.15; *P*=0.11) |

* Values represent the mean difference having Baerveldt group as reference

| F/U | Visual acuity (LogMAR) | IOP (mmHg) | IOPR% | Glaucoma drugs |
|---|---|---|---|---|
| 1 mo | -0.30 (-0.8 to 0.2; *P*=0.27) | 1.03 (-3.5 to 5.6; *P*=0.65) | 0.6% (-18.2 to 19.5; *P*=0.95) | 0.24 (-0.9 to 1.3; *P*=0.66) |
| 3 mo | -0.04 (-0.6 to 0.6; *P*=0.91) | -2.0 (-5.3 to 1.3; *P*=0.22) | -8.8% (-21.8 to 4.2; *P*=0.18) | 0.11 (-0.8 to 1.1; *P*=0.81) |
| 6 mo | -0.07 (-0.4 to 0.3; *P*=0.71) | -1.5 (-4.4 to 1.3; *P*=0.29) | -8.5% (-22.0 to 5.0%; *P*=0.21) | 0.19 (-0.6 to 1.0; *P*=0.63) |
| 12 mo | -0.18 (-0.6 to 0.2; *P*=0.39) | -0.64 (-2.3 to 1.15; *P*=0.47) | -3.7% (-12.9 to 5.5; *P*=0.42) | -0.38 (-1.3 to 0.5; *P*=0.41) |

* Values[SD1] represent the mean difference having BGI group as reference and adjusted for age, baseline IOP, sex, and reason for tube surgery with a 95% confidence interval and *p*-value

**Table 5: Complications**

| Types of complications | BGI *n*=29 | | PGI=27 | | Fisher's Exact test |
|---|---|---|---|---|---|
| | Percentage | Number | Percentage | Number | |
| Transient symptomatic hypotony | 3.5% | 1 | 3.7% | 1 | 0.74 |
| Choroidal Effusion | 3.5% | 1 | 3.7% | 1 | 0.74 |
| Hyphema | 3.5% | 1 | | | 0.52 |
| Diplopia | | | 3.7% | 1 | 0.48 |
| Flat Anterior Chamber | | | 3.7% | 1 | 0.48 |
| Tube Occlusion (YAG§ laser required) | | | 3.7% | 1 | 0.48 |
| Malignant Glaucoma | | | 3.7% | 1 | 0.48 |
| Tube Repositioning | 3.5% | 1 | | | 0.52 |
| Wound Dehiscence* | | | 3.7% | 1 | 0.48 |
| Vitreous Hemorrhage | | | 3.7% | 1 | 0.48 |
| Acute angle-closure glaucoma | 3.5% | 1 | | | 0.52 |
| Suture extrussion | 6.9% | 2 | | | 0.26 |
| Choroidal Hemorrhage | 3.5% | 1† | 3.7% | 1‡ | 0.74 |
| Total number of complications | 27.6% | 8 | 37.0% | 10 | 0.32 |
| Number of eyes with complications | 17.2% | 5 | 18.5% | 5 | 0.59 |

*The patient experienced suture dehiscence and a leak which required three separate surgical interventions for resolution. † Delayed choroidal hemorrhage occurred following the removal of the prolene® stent. ‡ Serohemorrhagic choroidal detachment choroidal with retiral detachment in high miopic eye after capsule puncturing in HP. § Yittrium aluminum garnet

agreement with the PGI efficacy reported in Weber's study,[20] a retrospective analysis of 45 consecutive Caucasian children eyes, which documented a mean IOP of 12.0 mmHg at 1 year (48.8% IOPR%) and failure of 5%, 15.4%, and 37.8% with IOP success criteria set below 21, 18, and 15 mmHg, respectively, alongside an average use of glaucoma medications of 0.5 per patient. Compared with this population, PGI success in the present study was also higher for IOP criteria of <15 mmHg.

Weber *et al*.[20] reported a relatively high exposure rate in children despite the use of double-layered pericardial patch grafts, which may be related to the use of per-operative MMC. In our study, all PGIs were inserted via tunneling, in addition to donor scleral coverage. Tunneling provides extra protection against exposure and permits re-entry into the sclera if the intraocular position is inaccurate without the need for suturing.[23]

Initial evidence showed no significant differences in outcomes when using MMC in drainage implants, although a higher incidence of complications was observed. Subsequent studies by Cui *et al*.[24] and Alvarado *et al*.[25] indicated better results with higher doses of antimetabolites. Consequently, the use of MMC has become standard practice in GDI surgeries. Given the variations in dosage and application, it is crucial to analyze the use of antimetabolites when comparing outcomes across different reports. In studies of PGI, MMC was used at 0.4 mg/ml for 1.5 minutes,[22] at 0.5 mg/ml for 2 minutes,[20] and in our study at 0.2 mg/ml for 3 minutes. Other studies, such as those by Koh *et al*., used MMC at the surgeon's discretion, while Tan *et al*.[21] conducted studies without antimetabolites, achieving the best results, with failure rates of 5.4% at 1 year and 17.8% at 2 years, respectively. Hence, the use of MMC does not appear to be crucial for the success of the technique.

The comparatively lower success rate observed in José's study, in contrast to others, even though the use of high dose of MMC, could be attributed to the flow restriction technique utilized, which was not employed in other studies: an absorbable ligature without a ripcord stent. This method may cause an abrupt initiation of flow, leading to transient hypotension and potentially triggering capsular inflammation.[26] Consequently, this might explain the high incidence of HP observed in 42% of eyes, which is associated with decreased long-term hypotensive efficacy.[27,28]

Regarding BGI efficacy, the pooled data reported an average IOP of 13.6 mmHg (SD ±5.9) on 1.4 (SD ±1.4) medications at 1 year,[29] which is comparable to our results of a mean IOP of 12.0 mmHg (SD ±2.9) on 0.6 (SD ±0.8) medications.

When comparing the outcomes of BGI and PGI, both employing a similar flow-restriction strategy, this study observed no significant year-long differences in the mean final IOP ($P$ = 0.47), IOPR% ($P$ = 0.42), anti-glaucoma medication usage ($P$ = 0.28), or HP ($P$ = 0.34). Another factor to consider is that, despite no epidemiological differences between the groups, the BGI group began with slightly but no significant higher pressures (28.3 vs 23.9 mmHg, $P$ = 0.07), a known risk factor for reduced success in GDI surgery.[30] In addition, a higher proportion of patients in the PGI group (63% vs 31%) underwent GDI implantation because of previous filtering surgery failure, which is considered to have a higher risk of HP and subsequent poorer long-term IOP control.[27,28] Despite these differences, when adjusting for age, baseline IOP, sex, and reason for tube surgery, differences in average IOP reduction, IOP values, and use of hypotensive medication were not significant at any of the study time points.

Insufficient cases with HP were detected in this study to establish a relationship with the etiology or the intraocular location of the tube. However, tubes placed in the PC cause more inflammation due to surgical manipulation, which could contribute to a higher incidence of HP.[27] Paul's implant was predominantly placed in the AC, while in the BGI group, it was predominantly in the PC to avoid endothelial contact.

Furthermore, there were no significant differences in failure, PS, and CS between BGI and PGI across the studied success thresholds of 6–21 mmHg, 6–18 mmHg, and 6–15 mmHg, with *P* values of 0.22, 0.22, and 0.06, respectively [Table 3].

Recently, the results of a retrospective study comparing Baerveldt and Paul have been published. At 1 year, there were no significant differences between the two implants, with a failure rate of 9% for PGI and 11% for BGI with pressures at 1 year slightly lower than that of BGI, similar to what we found in the present study.[31]

While IOP values and percentage reductions slightly favored the BGI group, it is possible that PGI outcomes were influenced by a learning curve, given the extensive experience with the Baerveldt implant. Inexperience with the Paul implant may have led to more complications, despite its smaller size and AC placement. Symptomatic hypotony and choroidal detachment were comparable across implants, a surprising finding given the smaller diameter of the PGI and its presumed safety. Postoperative hypotony depends on the hermetic sealing of the tube entrance and the restrictive technique employed. In some cases, peritubular leakage cannot be prevented, and in others, hyperfiltration may result from the absence of an absorbable ligature, leading to excessive outflow. All eyes with a PGI had a 6-0 stent introduced approximately 5 mm into the lumen, but in cases with high preoperative IOP despite medical treatment, no ligature was added around the tube. In these cases, aqueous outflow is not consistent due to the variable length of the stent introduced into the lumen and the manufacturing imprecision in the sizes of tubes and suture gauges.[32,33] This can lead to hyperfiltration observed in the early days after surgery. This phenomenon could also occur with the 0.63 mm GBU tube; however, in these instances, there is always a ligature that consistently collapsed the outflow, effectively preventing hypotony. The reliance on just an intraluminal stent, in cases where hypotony poses a risk to the eye, suggests that surgeons should ensure additional safety measures, such as the use of the resorbable peritubular ligature. Furthermore, each group reported one case of delayed choroidal hemorrhage: one in an anticoagulated elderly patient with a BGI following stent removal and another in a PGI case with congenital glaucoma and high myopia during capsule puncture in the HP.

The BGI group required repositioning in one case due to an endothelial threat, and in two other cases, the suture securing the plates extruded and needed removal without further consequences. A new complication emerged in a BGI eye with a narrow angle that developed immediate postoperative acute angle-closure glaucoma, necessitating the repositioning of the iris and removal of air bubbles from the AC.

The PGI group experienced complications such as conjunctival dehiscence and diplopia, which were unrelated to the tube size but rather to the dimensions of the plate and the intrinsic high scarring characteristics of the eye.[2,30,34,35] The presence of malignant glaucoma in this group does not seem to be related to the type of implant but to the dynamic of a nanophthalmic eye. The occlusion of the Paul tube by iris was resolved with YAG laser impacts and later by shortening the tube. From a personal perspective, it appears to us that the smaller diameter of the PGI increases its susceptibility to obstruction and makes repermeabilization more challenging.

Except for the two cases of choroidal hemorrhage, changes in BCVA were minimal, starting from baseline LogMAR values of 0.65 and 0.85, respectively. At 3 months, there were no differences between the groups ($P > 0.05$), nor were there any changes from the baseline values at 3, 6, and 12 months ($P > 0.05$). This indicates the safety of the surgical technique in this patient group.

The potential advantage of the Paul implant over the BGI may lie in its greater long-term safety regarding endothelial damage, a complication that requires more extended monitoring, as seen in other studies, which needed more than 2 years to detect changes in endothelial density.[36,37] This is something that our current study cannot provide.

This study compared a recent cohort of patients who received a Paul implant with a historical cohort who received a Baerveldt 350 implant. Although the surgeon and technique were consistent, the follow-up duration varied between groups. The significant differences between the two groups in terms of surgical rationale and tube location complicate direct comparisons. The limited sample sizes of 27 and 22 cases arriving at 12 months may restrict the statistical power of the study, and the absence of a randomized design could introduce potential biases. These limitations do not invalidate the findings but should be considered when interpreting the results. In summary, GDI surgery appears to be effective in improving IOP control and reducing the need for postoperative medication. The implants studied, Baerveldt-350 and Paul, showed no significant differences in their hypotensive efficacy, with both techniques being effective at 1-year follow-up.

The lack of differences between the two groups could be attributed to the limited number of cases and the relatively short follow-up period. An extension of the follow-up duration and an increase in the number of cases are needed to corroborate these results with stronger evidence. Given the intent of PGI to be safer in terms of corneal survival by occupying less space in the AC, studying the endothelial changes in both populations is of great interest. However, a longer follow-up period is necessary to identify these differences between implants.

## Conclusion

This study aimed to assess the efficacy and safety of the PGI and the BGI over 1 year. Our findings reveal that both implants effectively reduce IOP, with no significant differences between them, corroborating existing research on their efficacy. Notably, the PGI's design, which potentially reduces endothelial damage, requires further long-term studies to confirm these benefits.

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