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Original Article

Assessing the Efficacy of the PAUL Glaucoma Implant in Pseudoexfoliative Glaucoma

Ali Olgun,[1] Murat Karapapak[2]

[1]West Eye Hospital, Erbil, Iraq
[2]Department of Ophthalmology, University of Health Sciences, Basaksehir Cam and Sakura City Hospital, Istanbul, Türkiye

Abstract

Objectives: The aim of the study was to evaluate the outcomes and complications associated with PAUL glaucoma implant (PGI) surgery in pseudoexfoliation glaucoma (PXG) patients, comparing them with a primary open-angle glaucoma (POAG) control group.

Methods: A retrospective analysis included 39 PXG and 29 POAG eyes undergoing PGI surgery between January 2020 and December 2022. Surgical success was defined as intraocular pressure (IOP) between ≤21 and ≥6 mmHg at 12 months and no loss of light perception. Demographic data, ocular examinations, and complications were recorded.

Results: PXG patients (68.5±9.9 years) differed significantly in age from POAG patients (54.1±10.6 years) ($p<0.05$). Surgical success rates at 12 months were 97.4% (PXG) and 86.2% (POAG). No significant inter-group differences in gender, laterality, lens status, vertical cup/disc ratio, or pre-operative best-corrected visual acuity were observed. Mean IOP comparisons showed significant differences within both groups ($p<0.001$). Ripcord suture removal occurred at mean 30.3±7.43 days (PXG) and 30.6±9.89 days (POAG). Median pre-operative AGM use was 4 (PXG) and 3 (POAG). No significant differences were noted postoperatively.

Conclusion: To the best of our knowledge, this is the first study to evaluate the results of PGI in PXG and POAG, demonstrating a remarkable success rate and limited complications. Encouragingly, PXG patients with a history of unsuccessful filtration surgery demonstrated positive outcomes. The findings affirm PGI as a promising surgical intervention for PXG and POAG, exhibiting high success rates and manageable complications.

Keywords: Glaucoma drainage devices, PAUL glaucoma implant, primary open-angle glaucoma, pseudoexfoliation glaucoma, surgical outcomes

Introduction

Pseudoexfoliation syndrome emerges as the foremost identified cause of open-angle glaucoma, standing as an independent risk factor for this condition. The imperative lies in the accurate differentiation between pseudoexfoliation glaucoma (PXG) and primary open-angle glaucoma (POAG). PXG, characterized by its severity, presents an elevated risk of vision impairment, distinctly higher maximum and mean intraocular pressure (IOP) at the time of diagnosis, and a broader spectrum of IOP fluctuation when juxtaposed with POAG. Recognizing these distinctions is pivotal for effective clinical management and tailored thera-

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Address for correspondence: Murat Karapapak, MD. Department of Ophthalmology, University of Health Sciences, Basaksehir Cam and Sakura City Hospital, Istanbul, Turkey
Phone: +90 545 214 12 03 **E-mail:** mrtkarapapak@gmail.com

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peutic interventions in the realm of glaucomatous pathologies (1). PXG is postulated to arise from the obstruction of the trabecular meshwork by exfoliation material, leading to an elevation of IOP. Additionally, anomalies in the lamina cribrosa, particularly those associated with elastic tissue, may contribute to the development of glaucoma (2,3). PXG poses distinct challenges in comparison to POAG, demonstrating greater resistance to medical therapy and displaying a more transient response (4). The propensity for surgical interventions is markedly higher in PXG cases than in those of POAG, suggesting a distinctive clinical trajectory for these patients (5).

Eyes afflicted with PXG typically necessitate surgical intervention due to the progressive and severe nature of its clinical course (6). Surgical management becomes a requisite when there is evidence of glaucomatous progression or when IOP reaches a level at which progression is anticipated, despite adequate attempts at medical therapy or laser treatment. The implantation of a glaucoma drainage device (GDD) emerges as a surgical recourse in cases of medically uncontrolled IOP. The outcomes of this surgical intervention exhibit variations contingent on the specific type of device employed and the diverse etiologies of glaucoma being addressed. GDDs particularly manifest their utility in eyes that have previously undergone unsuccessful surgical interventions. The PAUL glaucoma implant (PGI) represents a recent addition to the array of GDDs, distinguished by its composition of silicone and unique structural features. Notably, the PGI sets itself apart by incorporating a smaller outer tube diameter of 467 µm and a reduced inner diameter of 127 µm compared to other available GDDs (7). Featuring an end plate with an expansive surface area measuring 342 mm^2 for aqueous absorption, the PGI occupies minimal space in the angle, while simultaneously demonstrating a lower redundant flow capacity in comparison with other valveless GDDs. Despite previous studies investigating GDD implantation for PXG, (8) there are no studies reporting outcomes and complications of PGI surgery.

This study aims to evaluate the outcomes and complications associated with PGI surgery in PXG patients and compare them with those of POAG patients as a control group.

Methods

This retrospective study was undertaken to investigate patients diagnosed with PXG or POAG who underwent PGI (Fig. 1) surgery performed by a single surgeon (A.O), during the period spanning from January 2020 to December 2022. Approval for the study was obtained from the Institutional Review Board of the local Ethical Committee, ensuring

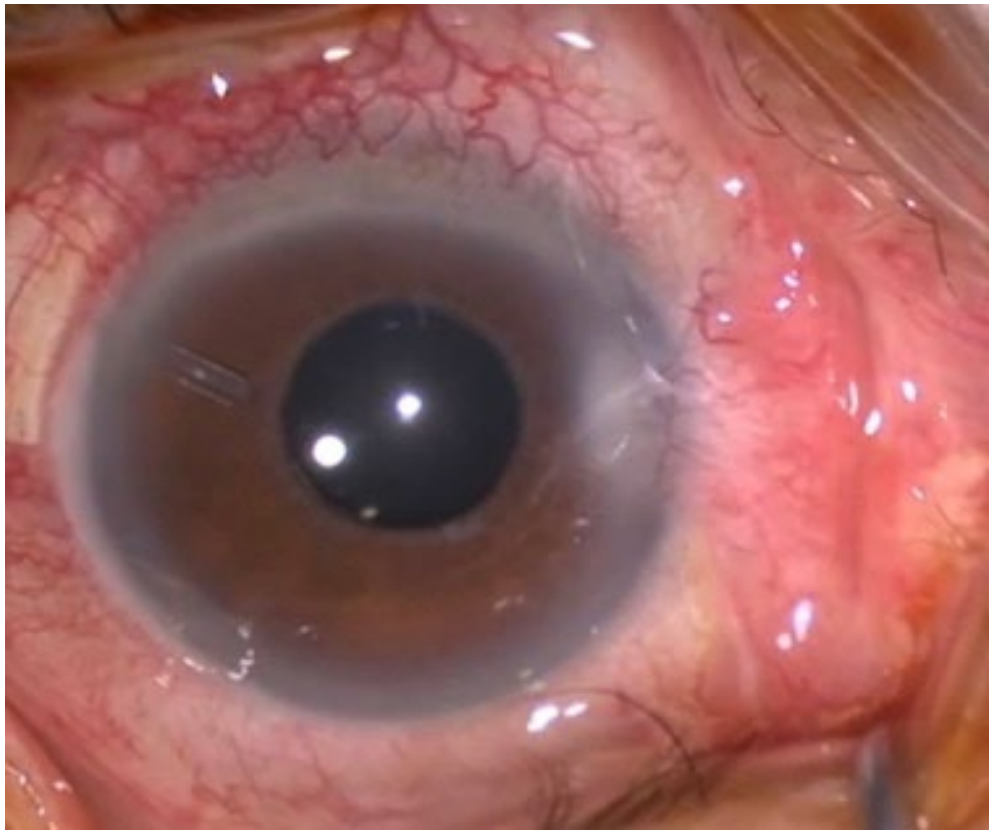

Figure 1. Clinical photograph showing the PAUL glaucoma implant inside the anterior chamber

compliance with the ethical standards outlined in the Declaration of Helsinki. Thirty-nine eyes from 39 consecutive patients diagnosed with PXG were included in the study, alongside 29 control eyes from 29 patients diagnosed with POAG. The control group was matched based on criteria such as age, sex, and history of previous cataract surgery. In instances where both eyes of a patient underwent PGI surgery, only the eye treated first was considered for enrollment in the study.

Due to the retrospective design of this study, surgical indications were determined by considering the target IOP and the benefit-to-risk ratio for each individual glaucoma patient. Specifically, inclusion criteria comprised patients with refractory PXG who exhibited inadequate responses to prior glaucoma surgical interventions. Exclusion criteria for this study encompassed eyes with a narrow-angle, the presence of a coexisting neurological disease, or severe retinal disease. Patients with a post-operative follow-up period of fewer than 12 months in both groups and those with no light perception before surgery were excluded from the study. The primary outcome of our study hinges on evaluating the surgical success rate, with a classification into complete success, and qualified success. Each category is delineated based on specific criteria aimed at comprehensively characterizing the efficacy of the surgical procedure. Complete Success Criteria: A surgical intervention qualifies as a complete success when it satisfies the following conditions: IOP remains at or below 21 mmHg and is maintained at a minimum of 6 mmHg; the procedure avoids instances of failure, such as the need for revision surgery; loss of light perception is prevented; the patient does not require supplementary medical therapy to regulate IOP. Qualified Success Criteria: The category of qualified success encompasses cases where post-operative pharmaceutical intervention is necessitated for achieving satisfactory IOP reduction (IOP≤21 and ≥6 mmHg). However, these cases are distinctively characterized by the absence of additional surgical procedures.

A comprehensive ocular examination, inclusive of best-corrected visual acuity (BCVA), IOP measurement using Goldmann applanation tonometry, slit lamp examination, gonioscopy, and assessment of postoperative complications, was conducted both preoperatively and postoperatively. The follow-up schedule included assessments at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months after surgery. All patients in both groups underwent examinations and surgical procedures performed by a single glaucoma specialist. Additional, more frequent examinations were conducted for certain patients as deemed necessary. The removal date of the ripcord suture was recorded for all patients. In cases where IOP elevation necessitated intervention, medical treatment was administered for both groups.

Surgical Procedure

The PGI (Advanced Opht. Ino., Singapore) procedure was carried out under general anesthesia for all patients. In the majority of cases, placement occurred in the superior temporal quadrant, while in some instances, it was positioned in the superior nasal quadrant. Following adequate dissection of the conjunctiva and Tenon's capsule, the PGI endplate was positioned beneath the rectus muscles. The endplate was then sutured to the sclera using 7/0 prolene, approximately 10 mm posterior to the limbus. A segment of the 6/0 prolene suture was introduced into the PGI tube. Subsequently, the tube was trimmed within the anterior chamber to a size of a few millimeters, with the bevel oriented upwards. The entry point into the anterior chamber was established using a 25-gauge needle through the limbus, parallel to the plane of the iris. The prolene suture within the tube was anchored in place at the tube's end. The tube was then inserted into the anterior chamber through the needle pathway, positioned just above the iris, and carefully situated away from the corneal endothelium. Pericardium was used to cover the length of the tube, securing it to the sclera with 8/0 vicryl. The conjunctiva was closed by suturing with 8/0 vicryl. All patients undergoing PGI surgery were subjected to routine topical treatment with prednisolone and moxifloxacin for 8 weeks. If deemed necessary, ripcord sutures were extracted from the anterior chamber during the post-operative period using microforceps.

Statistical Analysis

In the study, continuous variables were presented using both mean±standard deviation and median (min-max) values, while categorical variables were expressed as numbers and percentages. The normal distribution of numerical data was assessed using the Shapiro–Wilk test. For comparing differences between groups, either an independent groups t-test or Mann–Whitney U test was applied based on the distribution structure. Friedman's test was employed for comparisons involving three or more matched groups. Pairwise comparisons before and after the procedure were conducted using Wilcoxon's test, considering the distribution structure, and Bonferroni correction was applied. The association between categorical variables was assessed using Pearson's Chi-square test and Fisher's exact Chi-square test. Spearman's correlation coefficient was employed to analyze relationships between variables. To estimate the success rate over time, Kaplan–Meier analysis was performed. All statistical analyses were conducted using the IBM SPSS Statistics program (Version 28). The significance level was set at 95%, and results were deemed statistically significant for $p<0.05$.

Results

In this study, a total of 39 patients diagnosed with PXG and 29 patients with POAG who underwent surgery of PGI were included for analysis. The PXG group exhibited an age range of 46–87 years, while the POAG patient group ranged from 36 to 74 years. A statistically significant difference in age was observed between the two groups ($p<0.05$). Gender distribution, laterality, lens status, vertical cup/disc ratio, and preoperative BCVA were comparable between the groups ($p>0.05$). Detailed demographic information and ocular examination findings are presented in Table 1.

All participants in both PXG and POAG groups had undergone at least one prior glaucoma procedure. Table 2 illustrates a comparison of mean IOP among patients, both within and between the groups, at various time points preoperatively and postoperatively. No statistically significant differences were found in mean IOP between PXG and POAG patients ($p>0.05$) during different follow-up periods. Pairwise comparisons revealed a statistically significant difference between pre-operative IOP and all subsequent post-operative IOP averages in both groups ($p<0.001$), while no differences were found between post-operative IOPs ($p>0.05$). The pairwise comparison results are summarized in Table 3.

Ripcord sutures were removed at a mean of 30.3±7.43 days for PXG patients and 30.6±9.89 days for POAG patients, with no significant difference between the groups regarding the day of cord suture removal. In terms of medication use, the median number of anti-glaucoma medications (AGM) used by PXG and POAG patients preoperatively was 4 and 3, respectively. There were no significant differences in the number of AGMs used during various follow-up periods within each group ($p>0.05$).

The study found that complete surgical success was attained in 53.8% of PXG patients and 68.9% of POAG patients. Qualified surgical success was achieved in 97.4% of PXG patients and 86.2% of POAG patients. Kaplan–Meier analysis, depicted in Figure 2, illustrates similar post-operative success rate. There was no statistically significant difference between the two groups in terms of complications ($p>0.05$) (Table 4).

Table 2. Intraocular pressures in pre-operative and post-operative periods

IOP-mmHg	PSG Mean±SD	POAG Mean±SD	p
Pre-operative	34.5±7.7	31.9±7.4	0.622[a]
Post-operative (1 day)	13.7±3.5	13.1±2.2	0.404[b]
Post-operative (1 week)	15.3±6.9	14.8±4.6	0.253[b]
Post-operative (1 month)	15.4±4.6	15.9±6.3	0.420[b]
Post-operative (3 months)	13.8±1.7	13.9±3.2	0.408[b]
Post-operative (6 months)	13.4±1.9	14.5±3.2	0.250[a]
Post-operative (12 months)	13.7±2.2	14.8±3.6	0.419[a]
	<0.001*[c]	<0.001*[c]	

[a]Independent Samples t test; [b]Mann–Whitney U, [c]Friedman test, *P<0.05. SD: Standard deviation.

Table 1. Demographics and clinical characteristics of participants

	PSG	POAG	p
Age	68.5±9.9/(46–87)	54.1±10.6/(36–74)	<0.05[a,*]
Sex			
Female	22 (56.4)	11 (37.9)	0.132[b]
Male	17 (43.6)	18 (62.1)	
Laterality			
Right	17 (43.6)	12 (41.4)	0.855[b]
Left	22 (56.4)	17 (58.6)	
Lens Status			
Phakia	4 (10.3)	5 (17.2)	0.404[c]
Pseudophakia	34 (89.7)	24 (82.8)	
Vertical Cup/ Disc Ratio	0.8±0.08/(0.7–1)	0.8±0.1/(0.6–1)	0.945[a]
Preoperative BCVA (LogMAR)	0.4±0.5/(0–1.3)	0.47±0.5/(0–1.3)	0.379[a]

[a]Mann–Whitney U; [b]Chi-square test, [c]Fisher's exact test *P<0.05, Continuous variables are presented as the mean±standard deviation/median (min-max). Categorical variables are presented as number (%).

Table 3. Pairwise comparisons for intraocular pressure

IOP-mmHg	PSG	POAG
Pre-operative × Post-operative (1 day)	<0.001*	<0.001*
Pre-operative × Post-operative (1 week)	<0.001*	<0.001*
Pre-operative × Post-operative (1 month)	<0.001*	<0.001*
Pre-operative × Post-operative (3 months)	<0.001*	<0.001*
Pre-operative × Post-operative (6 months)	<0.001*	<0.001*
Pre-operative × Post-operative (12 months)	<0.001*	<0.001*

*P<0.002 (Bonferroni correction (P=0.05/6)).

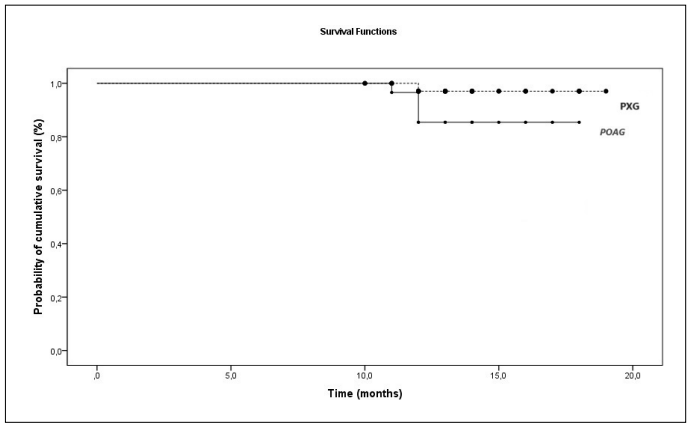

Figure 2. Kaplan–Meier survival analysis graph.

Discussion

The present investigation sought to assess the efficacy of a PGI in the treatment of PXG and POAG. The results demonstrated a noteworthy cumulative probability of successful outcomes, reaching 97.4% in the PXG group and 86.2% in the POAG group at the 12-month follow-up. Following implantation, occurrences of hyphema were noted in only five eyes and pupillary membrane formation in one eye within the PXG group. In the POAG group, hyphema was observed in four eyes. Importantly, no late complications were reported in any patient. These findings underscore the potential efficacy of PGI as a viable therapeutic option for managing PXG and POAG patients.

PXG is commonly perceived as a more severe form of glaucoma compared to POAG. This perception arises from several factors, including wider IOP fluctuations, greater optic disc damage, more extensive visual field loss at the time of detection, a tendency for rapid progression, a shorter duration from diagnosis to surgery, and an increased demand for surgical intervention (1,9). Consequently, in cases where achieving a low target pressure is imperative, glaucoma surgery is often considered the preferred treatment option for PXG (10). Patients with PXG may be more susceptible

Table 4. Post-operative complications according to type of glaucoma

	PSG (n=39) Number (%)	POAG (n=29) Number (%)	p
Hyphema	5 (12.8)	4 (13.7)	0.435
Acute hypotonia	5 (12.8)	4 (13.7)	0.435
Pupillary membrane	1 (2.5)	0	0.917

Fisher's exact test.

to postoperative complications due to heightened inflammatory responses, compromised trabecular outflow, and blood-ocular barrier dysfunction associated with the disease (11). Despite this understanding, there is a paucity of studies comparing the outcomes of GDDs in patients with PXG (12). To the best of our knowledge, this is the first study to compare the surgical outcomes of PXG and POAG specifically for PGI procedures.

Traditional surgical and laser interventions utilized for the management of PXG encompass laser trabeculoplasty, trabeculectomy, and GDD surgery. Trabeculectomy, having shown comparable safety and efficacy to POAG, remains the most frequently performed surgery for PXG due to its established track record. However, contemporary trends in developed nations indicate a notable shift toward GDD surgery, emerging as the preferred procedure for PXG in many cases. This shift is indicative of evolving practices in glaucoma management, likely influenced by advancements in surgical techniques and the increasing recognition of the effectiveness of GDDs in PXG (13). The implantation of GDDs has emerged as a preferred procedure for refractory glaucoma cases, demonstrating success rates that are comparable or even higher than those achieved with conventional trabeculectomy (14-16). The effectiveness and safety of GDD implantation, however, exhibit variability depending on the specific GDD model used and the underlying etiologies of glaucoma. This variability highlights the importance of considering the diversity of glaucoma types and selecting an appropriate GDD model based on individual patient characteristics and clinical requirements. The PGI represents a novel GDD designed to mitigate post-operative complications associated with existing GDDs (17). Successfully employed in shunt surgery for glaucoma, the PGI is characterized as a valveless aqueous shunt. In comparison with the Baerveldt glaucoma implant (BGI) and Ahmed glaucoma valve (AGV), the PGI exhibits distinctive features. Notably, the PGI possesses an external caliber that is more than 30% smaller and an internal caliber that is over 50% smaller than both the BGI and AGV. Extrapolating from experimental flow studies, utilizing an internal diameter of 127 mm and a 10mm length, the PGI

is anticipated to have a simulated IOP ranging between 6 and 12 mmHg (18). This is attributed to flow restriction resulting from the smaller internal caliber of the PGI. Plate dimensions play a crucial role in the success rates of glaucoma implants. Previous studies have linked the superior performance of the BGI to its larger plate surface area and flatter plate profile, which reduces the risk of encapsulation (19). In addressing this consideration, the PGI adopts a unique design strategy. It features a shorter wingspan but compensates with a longer posterior plate extension, effectively increasing the implant's surface area. These theoretical advantages in the design of the PGI have been postulated to explain its performance relative to the AGV and BGI, albeit over a relatively short observational period of one year (18).

The Ahmed-Baerveldt Comparison and the Ahmed versus Baerveldt studies, two randomized controlled trials, undertook a comparative analysis of the AGV, a valved implant, and the BGI, a non-valved implant, across various types of glaucoma (20,21). Both trials reported that the BGI achieved a more substantial reduction in IOP compared to the AGV. However, this advantage in IOP reduction was accompanied by a higher incidence of complications associated with the BGI. Notably, the specific number of cases with PXG was not specified in either study, and a subset analysis based on the type of glaucoma was not included in the reported results. Despite this limitation, the authors of this review emphasize their positive experiences with the BGI in PXG cases. They highlight commendable success rates and a favorable safety profile associated with the BGI, leading to its current status as their preferred surgical procedure for patients diagnosed with PXG. In our study, the success rates at the 12-month follow-up were notably high, with a recorded rate of 97.4% in the PXG group and 86.2% in the POAG group. These results underscore the favorable outcomes associated with the use of the PGI in the management of PXG and POAG patients. The study findings present a notable and somewhat unexpected result, as cases with unsuccessful previous filtration surgery, are generally associated with poor outcomes in subsequent surgeries (22). Despite this expectation, the PGI group in this study demonstrated successful surgical outcomes, even though it included a significantly higher proportion of patients with a history of filtration surgery. This positive outcome challenges the conventional notion and suggests that PGI surgery may be a viable and effective option for patients with a history of unsuccessful filtration surgery.

The status of the lens, whether it is a result of cataract surgery or its inherent condition, can have a significant impact on IOP and the progression of glaucoma (23,24). To minimize the potential impact on IOP of lens status resulting from cataract surgery or the native state of the lens itself, a similar number of pseudophakic patients were included in our study. Naumann and Schlötzer-Schrehardt (25) reported the association between exfoliation keratopathy and an elevated risk of corneal endothelial decompensation, potentially culminating in irreversible corneal edema necessitating penetrating keratoplasty. Although the incidence of corneal decompensation was not specifically evaluated in the groups examined in our study, a comprehensive preoperative clinical examination focusing on endothelial status is warranted. In our study, five patients in the PXG group manifested hyphema, while pupillary membrane development occurred in one patient. These occurrences were effectively managed through the administration of medical therapy. Likewise, hyphema manifested in four patients within the POAG group, and medical treatment successfully mitigated this complication. Notably, neither group necessitated additional surgical interventions. Postoperative hypotony was observed in five PXG patients and acute hypotonia in four POAG patients. Our analysis suggests a potential association between the use of Ripcord suture and the relatively small lumen diameter of the PGI with the occurrence of acute hypotony in a limited number of patients.

The present study has several limitations that need to be considered. These include the retrospective design, a relatively small number of patients, a limited follow-up period of 12 months, and the inclusion of patients with a history of different glaucoma surgeries. Preoperative corneal endothelial density was not assessed. To fully evaluate the enduring effects of PGI on PXG patients, long-term studies with larger surgical series are warranted.

Conclusion

In this study, we have demonstrated the surgical safety and efficacy of PGI in patients with PXG, but it is essential to acknowledge the need for longer-term studies with a more extensive sample size to establish the superiority or equivalence of PGI procedure over other GDDs. Our current findings suggest that PGI offers predictable and immediate drainage, exhibiting a high success rate and fewer complications. While these results are promising, further investigation through well-designed randomized controlled trials is crucial for comparing PGI with other glaucoma surgical interventions and other GDDs. Such comparative studies will contribute to a more comprehensive understanding of the relative effectiveness and safety of PGI in the context of diverse glaucoma indications.

Disclosures

Ethics Committee Approval: Approval for the study was obtained from the Institutional Review Board of the local Ethical Committee, ensuring compliance with the ethical standards outlined in the Declaration of Helsinki.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – A.O., M.K.; Design – A.O., M.K.; Supervision – A.O., M.K.; Resource – A.O., M.K.; Materials – A.O., M.K.; Data Collection and/or Processing – A.O., M.K.; Analysis and/or Interpretation – A.O., M.K.; Literature Search – A.O., M.K.; Writing – A.O., M.K.; Critical Reviews – A.O., M.K.

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