




A Systematic Review of the PAUL Glaucoma Implant

Nicholas Tan , Steven Summers, Saif Aldeen Alryalat, Jennifer L Patnaik , Gabriel S Lazcano-Gomez , Leonard K Seibold, Malik Y Kahook

Department of Ophthalmology, The University of Colorado, Aurora, CO, USA

Correspondence: Malik Y Kahook, Department of Ophthalmology, The University of Colorado, 1675 Aurora Ct, Aurora, CO, 80045, USA, Tel +1 720 848-2500, Fax +1 720 848-5079, Email malik.kahook@cuanschutz.edu

Abstract: The PAUL Glaucoma Implant (PGI) is a novel, valveless glaucoma drainage device that is distinguished from prevailing tube shunts by its compact plate and small lumen. However, clinical consensus is lacking on its real-world advantages. Thus, we conducted a systematic review to assess PGI surgical approaches, safety, and efficacy. A comprehensive literature search was performed using PubMed, Embase, Web of Science, and ClinicalTrials.gov. Single case reports were excluded. Twenty-six studies comprising 1143 eyes were included. The most common duration of follow-up was one year, and five studies were prospective. Median IOP reduction by last follow-up was 53.4% (range 27.7–66.2%), and glaucoma medication use decreased by 71.8% (42.3–94.6%). At an intraocular pressure (IOP) upper threshold of 21 mmHg, the median qualified success rate was 92.0% (80.0–100.0%), and complete success was 48.0% (24.0–73.3%); though criteria varied between studies. The most frequently reported complications were hyphema (10.0%), numerical hypotony (9.7%), and shallow anterior chamber (5.9%). Tube erosion occurred in 5.0% of cases overall, and in 9.8% of eyes in prospective studies. A single randomized controlled trial comparing the PGI to the Ahmed Glaucoma Valve in pediatric patients found noninferiority at 12 months, but was limited by sample size and generalizability. Four additional retrospective comparative studies (three versus Baerveldt, one versus Ahmed) showed no consistent advantages of the PGI. Substantial variation was also reported in PGI surgical techniques, including ripcord use, graft material, and adjunctive antifibrotics. While the PGI appears effective in lowering IOP and medication burden, current evidence is limited by retrospective designs, small cohorts, heterogeneous protocols, and short follow-up. Tube erosions were reported more often than historically seen with Baerveldt and Ahmed devices. Higher-quality, prospective comparative studies are needed to determine the long-term safety, efficacy, and optimal surgical approach for the PGI.

Keywords: glaucoma drainage device, tube shunt, safety, efficacy, outcomes

Introduction

Glaucoma is a progressive optic neuropathy with an increasing global burden. For primary open-angle glaucoma (POAG) alone, the number of affected patients is projected to climb to 79.8 million by 2040 compared to 52.7 million in 2020.¹ Intraocular pressure (IOP) reduction constitutes the principal approach to treatment. In cases of advanced disease, maximal reduction in IOP can be achieved through a trabeculectomy or glaucoma drainage device (GDD) implantation.² The most commonly used GDDs are the Ahmed and Baerveldt tube shunts.³ The Ahmed Glaucoma Valve (AGV, New World Medical, Rancho Cucamonga, CA, USA) utilizes a valved system to reduce the flow of aqueous humor when IOP is low, reducing the risk of hypotony. Frequently used models of the AGV include the FP7 (endplate surface area of 184 mm²) and FP8 (102 mm²). The Baerveldt Glaucoma Implant (BGI, Abbott Medical Optics, Santa Ana, CA, USA) differs in that it features both a wider endplate (250 or 350 mm²) and a valveless reservoir to allow for maximum IOP reduction. In multicenter randomized controlled trials (RCTs), the BGI was found to have greater success rates, while the AGV demonstrated fewer side-effects, particularly in the early postoperative period.^{4–6}

Though both tube shunts possess advantages, there has been interest in developing GDDs that may improve upon their designs. One such example is the valveless Ahmed ClearPath (ACP, New World Medical, Rancho Cucamonga, CA, USA).

Like the BGI, it exists in 250 mm² and 350 mm² plate sizes. Its key differences include an alternatively contoured plate and more anteriorly positioned eyelets.⁷ The compact ACP 250 endplate allows it to be implanted without manipulating extraocular muscles.⁸ The PAUL Glaucoma Implant (PGI, Advanced Ophthalmic Innovations, Singapore) is another valveless GDD that incorporates some aspects of the Baerveldt implant. By using a 342.1 mm² endplate with compact wings, it can more easily be tucked between the recti.⁹ The smaller profile is hypothesized to reduce device interference with motility in a manner similar to the ACP. It further differs from the BGI by including a smaller diameter tube, theoretically reducing flow rate without requiring a valve. Combined, these features aim to achieve sustained IOP reduction with fewer hypotony-associated complications.⁹

Though the United States Food and Drug Administration (FDA) approved the ACP in 2019, the PGI has not yet gained equivalent status. Most American glaucoma specialists have not trialed the PGI, and there is growing anecdotal interest in its effects. No systematic review of the PGI has been published at the time of writing. Therefore, we sought to review the existing retrospective and prospective literature on PGI clinical outcomes. It was our aim to provide a comprehensive assessment of current PGI findings in order to better inform tube shunt surgeons.

Methods

PRISMA 2020 guidelines were followed.¹⁰ Pubmed, Embase, Web of Science, and clinicaltrials.gov were each queried with the search terms “PAUL Glaucoma Implant.” The period of extraction was from 4/1/2025 – 4/7/2025. Prospective studies and retrospective case series that examined primary clinical outcomes of the PAUL Glaucoma Implant were included. The following publication types were excluded: reviews, commentaries, replies, individual case reports, imaging or histologic studies, abstracts with data published in a separate paper, and articles lacking an English full text.

After initial identification from the aforementioned databases and register, Microsoft EndNote was used to remove duplicate records. The remaining records were then screened by abstract. At this stage, records were excluded for having no data or being unrelated to the PGI. The subsequent reports were then sought for full text retrieval with the remaining exclusion criteria applied to determine the final studies.

Data from the final selected studies were compiled onto Excel spreadsheets. Data entries were recorded and cross-verified by three authors (NT, SS, SAA). Three sheets were assembled: 1) baseline and outcomes; 2) surgical techniques; and 3) complications. Demographics data included country or countries of study, retrospective or prospective study design, PGI sample size, mean duration of follow-up, surgical comparison group (if any), sample size of comparison group, mean age, % female, racial/ethnic breakdown of PGI sample, % with prior glaucoma surgery, glaucoma types, mean baseline IOP, and mean baseline glaucoma medications. Outcome measures recorded included mean final IOP, mean final medications, % reduction in IOP and medications from baseline to last follow-up, definitions of success, and qualified and complete success rates. For surgical techniques, patch graft type, ripcord suture use, mitomycin-C use, 5-fluorouracil use, and combination with cataract surgery were evaluated. Lastly, for complications, the full list was based off those reported in the Ahmed Baerveldt Comparison (ABC) and Ahmed Versus Baerveldt (AVB) studies.^{11,12}

Sample sizes were enumerated using the eye as the unit of measurement. In cases where descriptive statistics were extracted, the native measures of dispersion (eg standard deviation, range) were reported without conversion. In cases where two comparison groups were involved and both groups received the PGI implant, study values were computed for the combined sample. Summative metrics were pooled accordingly between groups. For studies that reported multiple success rates, percentages of qualified successes at a given IOP target were counted inclusive of the complete successes. The central tendency and dispersion of study-level means were described using the median and range. Percentage reduction metrics were averaged across all studies. Complications were tallied across all studies and assigned a cumulative percentage. Per study, a complication was coded as zero percent when the authors indicated that the complication was monitored for and did not occur. Otherwise, if a complication was not reported in a study, that complication was assigned a null value to avoid underestimation.

Results

Demographics and Baseline Characteristics

The PRISMA diagram for this review is shown in [Figure 1](#). At the completion of screening, 26 studies were selected for full analysis ([Table 1](#)). Five were prospective,^{9,13–16} of which one was a randomized controlled trial.¹³ All others were

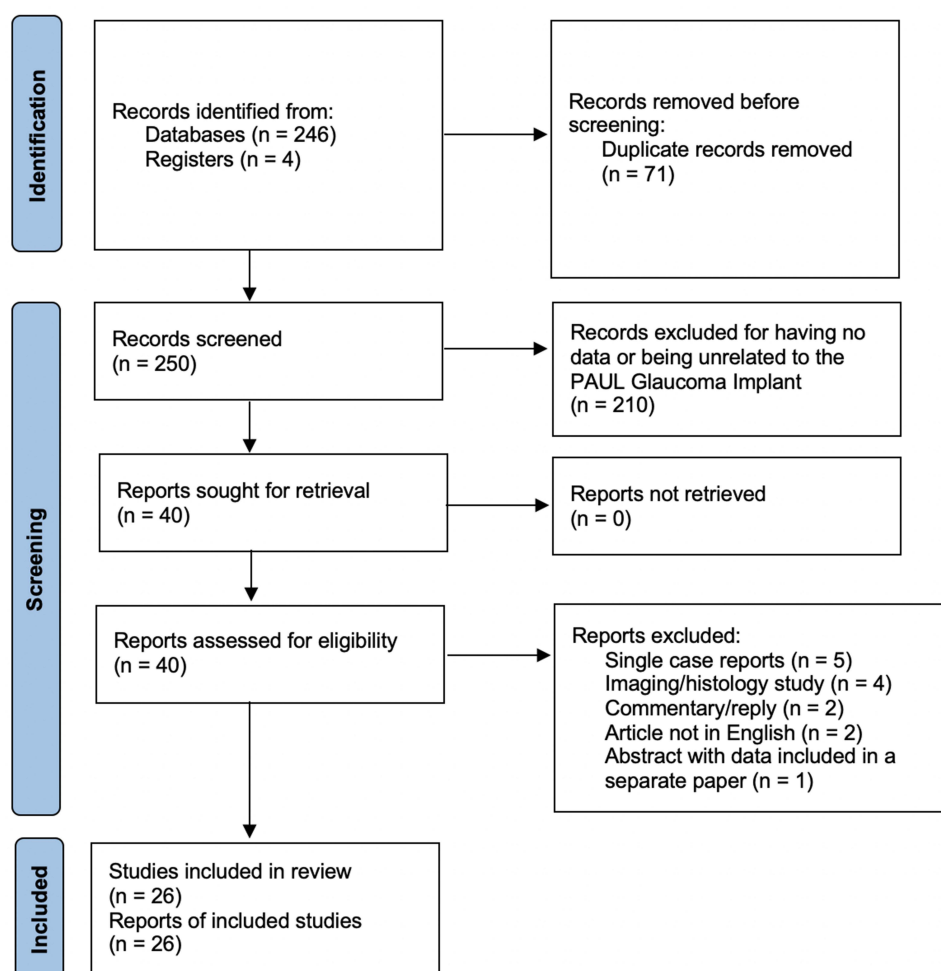


Figure 1 PRISMA Diagram for PAUL Glaucoma Implant Studies.

Notes: PRISMA figure adapted from Page MJ, McKenzie JE, Bossuyt PM et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.¹⁰

retrospective. Comparison groups with differing surgical techniques were included in 6 studies.^{13,17–21,22} Second arms included the AGV (N = 2), BGI (N = 3), and PGI with mitomycin-C (MMC; N = 1). Mean follow-up for all studies ranged from 2 months to 35.8 months. Twelve studies had mean follow-up between 11 and 13 months, and five studies followed patients for 2–3 years. Eighteen studies were based solely in Europe, most commonly Germany (N = 5).^{14–31} Three publications were specific to Asian nations.^{32–34} Two studies were performed exclusively in the United Arab Emirates (UAE).^{35,36} Two studies involved sites in two nations, while a third publication described international collaborations across five nations.^{9,13,37} No patients were recruited from the United States.

There were four first authors and one pair of authors who contributed multiple PGI publications. Marcus Tan, Abdelrahman Elhousseiny, and Neeru Vallabh each published two studies as first authors, and Constance Weber published four studies.^{13,15,16,23,24,29,30,32,33,35} The duo of Ali Olgun and Murat Karapapak published four studies.^{19,21,22,37} In total, 14/26 (53.8%) of the reviewed publications had Tan, Elhousseiny, Vallabh, Weber, or Olgun plus Karapapak listed.

Per-study sample sizes of PGI recipients ranged from 3 to 99. The median N was 39, and the total number of PAUL device implantations across all reviewed publications was 1143. The median age across studies was 59.8 years, with reported mean ages ranging from 7.5 to 67.8 years. Five protocols examined PGI use specifically in pediatric patients.^{13,25,29,35,37} Twelve studies were comprised of a 60% or greater proportion of white patients, while four had 65% or greater Asian representation. The remaining ten publications did not report race or ethnicity.^{18–22,26,30,31,35,37} Six studies specified PGI use for only a single classification of glaucoma; all others that described the glaucoma subtypes of their samples included multiple classes (Table 2). Previous glaucoma surgeries, where reported, were relatively common (522/901, 57.9%).

Table 1 Baseline Data in Studies of the PAUL Glaucoma Implant

Study	Country	Study Design	Mean f/u (months)	PGI Sample	Comparison Group	Comparison Sample	Mean Age (years)	% Female	Racial or Ethnic Distribution
Berteloot et al 2024 ¹⁷	Belgium and Portugal	Retrospective	12	23	BGI	27	60.0 ± 17.0 (SD)	26.1%	White 96%, Other 4%
Elhusseiny et al 2023 ³⁵	UAE	Retrospective	6	3	None	N/A	9.3 (range 6–15)	66.7%	NR
Elhusseiny et al 2025 ¹³	Egypt, UAE	Prospective RCT	12	25	AGV FP7	19	7.5 ± 5.0 (SD)	60.0%	White 100%
José et al 2022 ³¹	Portugal	Retrospective	12	24	None	N/A	42.0 ± 26.0 (SD)	45.8%	NR
Karapapak and Olgun 2024 ³⁷	Turkey, Iraq	Retrospective	12	30	None	N/A	7.7 ± 4.4 (SD)	47.1%	NR
Karapapak and Olgun 2024 ¹⁹	Turkey	Retrospective	12	18	AGV FP7	18	56.9 ± 16.4 (SD)	44.4%	NR
Khodeiry et al 2025 ³⁶	UAE	Retrospective	14.6 ± 2.1 (SD)	30	None	N/A	58.3 ± 7.4 (SD)	23.3%	White 76.7%, Asian 23.3%
Koh et al 2020 ⁹	Singapore, UK, Thailand, Malaysia, HK	Prospective	12	74	None	N/A	62.3 ± 14.7 (SD)	27.0%	Asian 64.9%, White 18.9%, Afro-Caribbean 16.2%
Labay-Tejado et al 2024 ²⁷	Spain	Retrospective	6	16	None	N/A	67.8 ± 17.6 (SD)	56.3%	European 87.5%, Hispanic/Latino 12.5%
Lechanteur et al 2023 ²⁶	Netherlands	Retrospective	6	92	None	N/A	NR	NR	NR
Mendoza-Moreira et al 2024 ²⁵	Germany	Retrospective	7.7 ± 4.2 (SD)	10	None	N/A	13.1 ± 3.64 (SD)	30.0%	Northern European 50%, Southern European 30%, South Asian 10%, Middle Eastern 10%
Olgun and Karapapak 2024 ²²	Turkey	Retrospective	12	68	None	N/A	62.4 ± 12.4 (SD)	48.5%	NR
Olgun and Karapapak 2025 ²¹	Turkey	Retrospective	15.0 ± 3.9 (SD)	81	PGI w/o MMC vs with	40 w/o MMC vs 41 with	62.8 ± 11.9 (SD)	49.4%	NR
Oliver-Gutiérrez et al 2025 ¹⁸	Spain	Retrospective	11.8 ± 4.2 (SD)	27	BGI 350	29	64.9 ± 19.4 (SD)	48.1%	NR
Richardson et al 2024 ²⁸	UK	Retrospective	35.8 ± 9.8 (SD)	50	None	N/A	45.8 ± 19.8 (SD)	48.0%	White 60%, Asian 18%, Afro-Caribbean 16%, Mixed/Other 6%
Rusmayani et al 2023 ³⁴	Indonesia	Retrospective	2–6 months ^a	22	None	N/A	47.3 ± 17.3 (SD)	43.0%	Malay 90%, Chinese 5%, Indian 5%
Scheres et al 2023 ²⁰	Netherlands	Retrospective	12	90	BGI	89	NR	NR	NR
Studsgaard et al 2025 ¹⁴	Denmark	Prospective	12	49	None	N/A	66.5 ± 16.9 (SD)	22.4%	White 90%, Middle Eastern 8%, South Asian 2%

(Continued)

Table 1 (Continued).

Study	Country	Study Design	Mean f/u (months)	PGI Sample	Comparison Group	Comparison Sample	Mean Age (years)	% Female	Racial or Ethnic Distribution
Tan et al 2022 ²²	Singapore	Retrospective	24.9 ± 2.0 (SD)	45	None	N/A	64.3 ± 12.2 (SD)	20.0%	Chinese 75.5%, Malay 15.6%, Indian 4.4%, Other 4.4%
Tan et al 2024 ³³	Singapore	Retrospective	35.6 ± 2.33 (SD)	48	None	N/A	64.4 ± 11.6 (SD)	18.8%	Chinese 70.8%, Malay 18.8%, Indian 4.2%, Other 6.3%
Vallabh et al 2022 ³⁰	UK	Retrospective	10.7 ± 3.2 (SD)	99	None	N/A	58.7 ± 16.6 (SD)	35.4%	White 62.6%, Afro-Caribbean 23.2%, Asian 12.1%, Unknown 2.0%
Vallabh et al 2023 ²⁹	UK	Retrospective	23.8 ± 4.3 (SD)	25	None	N/A	8.3 ± 4.8 (SD)	71.4%	White 61.9%, Afro-Caribbean 4.8%, Asian 33.3%
Weber et al 2022 ¹⁵	Germany	Prospective	8 (range 1–13)	60	None	N/A	NR	NR	NR
Weber et al 2023 ²⁴	Germany	Retrospective	13.0 (range 11–15)	45	None	N/A	66.4 (range 18–89)	NR	White 97.8%, Southeast Asian 2.2%
Weber et al 2024 ¹⁶	Germany	Prospective	24	56	None	N/A	64.9 (range 14–83)	46.4%	White 98.1%, Other 1.9%
Weber et al 2025 ²³	Germany	Retrospective	12	33	None	N/A	59.8 (range 16–81)	36.4%	White 100%

Note: ^aRusmayani et al 2023 only reported a range of follow-up, not mean follow-up.

Abbreviations: AGV, Ahmed Glaucoma Valve; BGI, Baerveldt Glaucoma Implant; F/U, follow-up; HK, Hong Kong; MMC, Mitomycin-C; NR, Not reported; PGI, PAUL Glaucoma Implant; RCT, randomized controlled trial; SD, standard deviation; UAE, United Arab Emirates; UK, United Kingdom.

Table 2 Types of Glaucoma Included in Studies of the PAUL Glaucoma Implant

Study	Types of Glaucoma
Berteloot et al 2024 ¹⁷	POAG (43%), PXG (4%), PG (9%), uveitic (9%), CACG (9%), PCG (4%), other (22%)
Elhusseiny et al 2023 ³⁵	GFCS (33.3%), PCG (33.3%), Mixed PCG+trauma (33.3%)
Elhusseiny et al 2025 ¹³	PCG (60%), GFCS (12%), JOAG (4%), glaucoma associated with nonacquired ocular conditions (8%), glaucoma associated with nonacquired systemic conditions (4%), glaucoma associated with acquired conditions (12%)
José et al 2022 ³¹	POAG (12.5%), congenital/juvenile (25%), aphakic (4.2%), NVG (12.5%), uveitic (16.6%), PXG (8.4%), GFCS (12.5%), FAP (8.4%)
Karapapak and Olgun 2024 ³⁷	PCG (100%)
Karapapak and Olgun 2024 ¹⁹	SOI (100%)
Khodeiry et al 2025 ³⁶	NVG (30%), SOI (30%), PXG (16.7%), post-keratoplasty (10%), traumatic (6.7), uveitic (3.3), lens-induced (3.3)
Koh et al 2020 ⁹	POAG (47.3%), PACG (16.2%), NVG (8.1%), uveitic (8.1%), traumatic (5.4%), other (14.9%)
Labay-Tejado et al 2024 ²⁷	PXG (43.6%), POAG (25.0%), uveitic (12.5%), congenital (6.3%), steroid-induced (6.3%), NVG (6.3%)
Lechanteur et al 2023 ²⁶	NR

(Continued)

Table 2 (Continued).

Study	Types of Glaucoma
Mendoza-Moreira et al 2024 ²⁵	GFCS (100%)
Olgun and Karapapak 2024 ²²	PXG (57.4%), POAG (42.6%)
Olgun and Karapapak 2025 ²¹	NVG (100%)
Oliver-Gutiérrez et al 2025 ¹⁸	Failed filtering procedure ^a (63%), juvenile/congenital (3.7%), aphakia/pseudophakia (7.4%), uveitis (3.7%), other (22.2%)
Richardson et al 2024 ²⁸	Uveitic (100%)
Rusmayani et al 2023 ³⁴	POAG (20%), Juvenile (5%), Congenital (5%), NVG (27%), uveitic (14%), SOI (14%), post-keratoplasty (5%), aphakic (5%), traumatic (5%)
Scheres et al 2023 ²⁰	NR
Studsgaard et al 2025 ¹⁴	POAG (30%), PACG (2%), SOI (27%), uveitic (8%), NVG (16%), PXG (4%), post-keratoplasty (4%), lens-induced (2%), syndromic (6%)
Tan et al 2022 ³²	POAG (42.2%), PACG (24.4%), NVG (8.9%), other (24.4%)
Tan et al 2024 ³³	POAG (39.6%), PACG (25.0%), NVG (10.4%), other (25.0%)
Vallabh et al 2022 ³⁰	POAG (38.4%), uveitic (17.2%), congenital/juvenile (7.1%), PACG (2.0%), NVG (8.1%), traumatic (2.0%), post-corneal surgery (9.1%), post-vitreoretinal surgery (5.1%), other (11.1%)
Vallabh et al 2023 ²⁹	PCG (20%), JOAG (12%), aphakic (16%), uveitic (28%), Axenfeld–Rieger (4%), Sturge–Weber (8%), secondary (12%)
Weber et al 2022 ¹⁵	NR
Weber et al 2023 ²⁴	POAG (46.7%), PXG (20.0%), narrow angle (2.2%), secondary (24.4%), other (6.7%)
Weber et al 2024 ¹⁶	POAG (46.4%), PXG (16.1%), narrow angle (1.8%), secondary (26.8%), other (8.9%)
Weber et al 2025 ²³	Secondary glaucoma after vitreoretinal surgery (100%)

Note: ^aThe types of glaucoma with failed filtering procedures were not specified in the text.

Abbreviations: CACG, chronic angle-closure glaucoma; GFCS, glaucoma following cataract surgery; JOAG, juvenile open-angle glaucoma; PACG, Primary angle-closure glaucoma; PCG, primary congenital glaucoma; POAG, primary open-angle glaucoma; PXG, pseudoexfoliative glaucoma; SOI, silicone-oil induced glaucoma; NVG, neovascular glaucoma; NR, not reported.

Surgical Technique

Koh et al 2020 were the first to describe a PGI surgical technique.⁹ Conjunctiva and Tenon's fascia are dissected in the quadrant of choice, with the end plate of the device tucked between the adjacent recti muscles and sutured 9–10 mm posterior to the limbus. A tract into the anterior chamber, parallel to iris, is then made using a 25- or 27-gauge needle. The tube is then trimmed, tunneled into the AC, and covered with a donor patch graft. Beyond these general steps, several factors were left to surgeon discretion in Koh et al's protocol. Patch graft type, ligation sutures, suture tube occlusion ("ripcord"), viscoelastic filling, use of mitomycin-C (MMC), and extent of postoperative topical antibiotics and steroids were all operator-dependent.

This variability in surgical approach extended to subsequent studies (Table 3). Twenty papers (76.9%) described use of a 6–0 polypropylene ripcord suture threaded into the PGI lumen. The principle is that the suture obstructs some outflow in the early postoperative period to limit hypotony, whilst allowing for later removal to facilitate further IOP reduction. Criteria designating when the polypropylene stent would be removed were not uniform across studies, and often not specified. Rates of retained versus extracted ripcords accordingly varied. Furthermore, the ripcord was

Table 3 PAUL Glaucoma Implant Surgical Data

Study	Prior Glaucoma Surgery (%)	Patch Graft Type	Use of Ripcord	Use of Mitomycin-C	Use Of 5-Fluorouracil	Combination with Cataract Surgery
Berteloot et al 2024 ¹⁷	91.0%	Pericardium	Yes	No	No	No
Elhusseiny et al 2023 ³⁵	100.0%	Corneal	Yes	No	No	No
Elhusseiny et al 2025 ¹³	88.0%	Scleral or corneal	Yes	No	No	No
José et al 2022 ³¹	41.6%	Pericardium or corneal	No	Yes	No	No
Karapapak and Olgun 2024 ³⁷	100.0%	Pericardium	Yes	No	No	No
Karapapak and Olgun 2024 ¹⁹	100.0%	Pericardium	Yes	No	No	No
Khodeiry et al 2025 ³⁶	10.0%	Corneal	Yes	No	No	No
Koh et al 2020 ⁹	32.4%	Pericardium, corneal, scleral, fascia lata	Yes	Yes	No	26 cases (35.1%)
Labay-Tejado et al 2024 ²⁷	93.8%	Pericardium	Yes	No	Yes	No
Lechanteur et al 2023 ²⁶	NR	Not specified	No	No	No	No
Mendoza-Moreira et al 2024 ²⁵	80.0%	Pericardium or fascia lata	Yes	Yes	No	No
Olgun and Karapapak 2024 ²²	100.0%	Pericardium	Yes	No	No	No
Olgun and Karapapak 2025 ²¹	61.7%	Pericardium	Yes	Yes	No	No
Oliver-Gutiérrez et al 2025 ¹⁸	63.0%	Scleral	Yes	Yes	Yes	No
Richardson et al 2024 ²⁸	32.0%	Pericardium	Yes	Yes	Yes	No
Rusmayani et al 2023 ³⁴	18.0%	Scleral	Yes	No	No	No
Scheres et al 2023 ²⁰	NR	Not specified	No	No	No	No
Studsgaard et al 2025 ¹⁴	47.0%	Corneal	Yes	Yes	No	No
Tan et al 2022 ³²	24.4%	Pericardium	No	No	No	28 cases (62.2%)
Tan et al 2024 ³³	37.5%	Pericardium	No	No	No	29 cases (60.4%)
Vallabh et al 2022 ³⁰	67.7%	Pericardium	Yes	Yes	Yes	No
Vallabh et al 2023 ²⁹	44.0%	Pericardium	Yes	Yes	Yes	No
Weber et al 2022 ¹⁵	NR	Not specified	No	No	No	No
Weber et al 2023 ²⁴	64.4%	Pericardium	Yes	Yes	No	No
Weber et al 2024 ¹⁶	67.9%	Pericardium then fascia lata after high exposure rate	Yes	No	No	No
Weber et al 2025 ²³	39.4%	Pericardium or fascia lata	Yes	Yes	No	No

Abbreviation: NR, not reported.

reported to cause a few cases of conjunctival erosion.¹⁴ Where specified, pericardial patch grafts were most commonly employed to reduce tube erosion risk (17/26 studies, 65.4%). Three studies used exclusively corneal grafts.^{14,35,36} Six studies utilized a mix of grafts, including various combinations of pericardium, cornea, sclera and fascia lata (Table 3).

In terms of antifibrotics, 12 studies (46.2%) used MMC and/or 5-Fluorouracil (5-FU) with the goal of reducing bleb fibrosis rates. MMC was more frequently employed (N = 11). One study by Olgun and Karapapak 2025 retrospectively compared the PGI with MMC (N = 41) to no MMC (N = 40) in neovascular glaucoma patients through a year of follow-up.²¹ At baseline, the MMC arm had numerically more prior trabeculectomies (70.7% MMC (+) vs 52.5% MMC (-); $p = 0.09$). At postop month 1, IOP was lower in the MMC group (20.2 ± 7.7 MMC (-) vs 15.0 ± 3.7 mmHg MMC (+); $p < 0.001$). Regarding postoperative glaucoma medications, means were lower at every timepoint in the MMC group ($p < 0.05$ for all). The non-MMC group required significantly more cycloablative procedures in the follow-up period (25.0% (-) MMC vs 2.4% (+) MMC; $p = 0.003$). There were no statistically significant differences in success rates, month 12 IOP, vision changes, or complications. Mean time to ripcord suture removal was earlier in the non-MMC group (43.1 ± 44.1 days (-) MMC vs 158.4 ± 102.3 days (+) MMC; $p < 0.001$).

Three studies included patients who received concurrent cataract surgery.^{9,32,33} Of those, only Tan et al 2024 compared phaco (+) and phaco (-), finding no differences in rates of hypotony.³³ Moreover, the two publications by Tan and et al described a unique approach to shielding the plate. An additional pericardial patch graft, undermined by viscoelastic, was placed between the plate and the subconjunctival space.^{32,33}

Efficacy and Safety Outcomes

Twenty-two publications (84.6%) described surgical success as an endpoint (Table 4). Certain criteria for success were shared across many studies: an IOP 6 or above, no loss of light perception, no reoperation for glaucoma, and no explantation. The most commonly used IOP maximum threshold was ≤ 21 mmHg, followed by ≤ 18 mmHg. Minimum expected reduction from preop IOP was usually 20%, with a few protocols citing higher targets. Ten out of 22 studies

Table 4 PAUL Glaucoma Implant Success Criteria by Study

Study	Definition of Success
Berteloot et al 2024 ¹⁷	Qualified: IOP ≥ 6 and ≤ 18 mmHg and $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no loss of light perception, with or without meds; Complete: same criteria without meds.
Elhusseiny et al 2023 ³⁵	Not defined.
Elhusseiny et al 2025 ¹³	Qualified: IOP 6–21 mmHg, no reoperation for glaucoma, no vision threatening complications, no oral glaucoma meds, and no disease progression with or without topical meds; Complete: same criteria without topical meds.
José et al 2022 ³¹	Qualified: IOP 6–18 mmHg with $\geq 30\%$ reduction at 12 months with or without meds, no reoperation for glaucoma, no explantation, no loss of 2 Snellen lines or more, and no loss of light perception; Absolute: same criteria without meds.
Karapapak and Olgun 2024 ³⁷	IOP 6–21 mmHg and $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no severe vision loss attributable to surgery, no loss of light perception, and no implant removal.
Karapapak and Olgun 2024 ¹⁹	IOP 6–21 mmHg without light perception loss.
Khodeiry et al 2025 ³⁶	IOP 6–21 mmHg with $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no explantation, no loss of light perception, and no vision-threatening complications.
Koh et al 2020 ⁹	Qualified: IOP 6–21 mmHg with $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no loss of light perception, and no explantation, with or without meds; Complete: same criteria without meds. Additional thresholds analyzed at 18 and 15 mmHg.

(Continued)

Table 4 (Continued).

Study	Definition of Success
Labay-Tejado et al 2024 ²⁷	Criterion A: IOP 6–18 mmHg and $\geq 30\%$ reduction (failed if out of range at 2 consecutive visits after week 1), no reoperation for glaucoma, no explantation, and no vision-threatening complications; Criterion B: same except upper IOP limit of 15 and $\geq 40\%$ reduction. Complete = no meds, Qualified = with meds.
Lechanteur et al 2023 ²⁶	Not defined.
Mendoza-Moreira et al 2024 ²⁵	Qualified: IOP ≤ 21 , 18, or 15 mmHg with $\geq 25\%$, 30%, or 40% reduction, respectively, with or without meds, no severe vision loss, no reoperation for glaucoma; Complete: same criteria without meds
Olgun and Karapapak 2024 ²²	Qualified: IOP 6–21 mmHg, no reoperation for glaucoma, no revision surgery, and no loss of light perception, with or without meds; Complete: same criteria without meds
Olgun and Karapapak 2025 ²¹	IOP 6–21 mmHg, no additional surgery after 3 months, no loss of light perception
Oliver-Gutiérrez et al 2025 ¹⁸	Qualified: IOP ≥ 6 and ≤ 21 , 18, or 15 with $\geq 20\%$ reduction, no loss of light perception, and no reoperation, with or without meds; Complete: same criteria without meds.
Richardson et al 2024 ²⁸	Qualified: IOP 6–21 mmHg with $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no explantation, no loss of light perception, no severe vision loss from complications, and no increase in glaucoma medications from preop; Complete: same criteria without meds.
Rusmayani et al 2023 ³⁴	IOP < 21 mmHg or $\geq 20\%$ or more reduction for 2 consecutive visits, without further glaucoma surgery or explantation.
Scheres et al 2023 ²⁰	Not defined.
Studsgaard et al 2025 ¹⁴	Qualified: IOP ≤ 21 , 18, 15, or 12 mmHg with or without meds; complete: same thresholds with meds.
Tan et al 2022 ³²	Qualified: IOP 6–18 mmHg with or without meds (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no loss of light perception, and no explantation; Complete: same criteria without meds. Alternative success also defined at ≤ 15 mmHg.
Tan et al 2024 ³³	Qualified: IOP 6–18 mmHg with or without meds (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no loss of light perception, no explantation; Complete: same criteria without meds. Alternative success also defined at ≤ 15 mmHg.
Vallabh et al 2022 ³⁰	Qualified: IOP 6–21 mmHg with $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no severe vision loss from complications, no loss of light perception, and no explantation, with or without meds; Complete: same criteria without meds.
Vallabh et al 2023 ²⁹	Qualified: IOP 6–21 mmHg and $\geq 20\%$ reduction (failed if out of range at 2 consecutive visits after 3 months), no reoperation for glaucoma, no severe vision loss from complications, no loss of light perception, and no explantation, with or without meds; Complete: same criteria without meds.
Weber et al 2022 ¹⁵	Not defined.
Weber et al 2023 ²⁴	Qualified: IOP ≤ 21 , 18, 15, or 12 mmHg, no persistent IOP < 6 mmHg, no reoperation for glaucoma, no explantation, and no loss of light perception, with or without meds; Complete: same criteria without meds.
Weber et al 2024 ¹⁶	Qualified: IOP ≤ 21 , 18, 15, or 12 mmHg, no persistent IOP < 6 mmHg, no reoperation for glaucoma, no explantation, and no loss of light perception, with or without meds; Complete: same criteria without meds.
Weber et al 2025 ²³	Qualified: IOP ≤ 21 , 18, 15, or 12 mmHg, no persistent IOP < 6 mmHg, no reoperation for glaucoma, no explantation, and no loss of light perception, with or without meds; Complete: same criteria without meds.

(45.5%) did not include any percentage reduction requirement (Table 4). Most also distinguished between “complete” and “qualified” success. The former excluded postoperative ocular hypotensive use. At an IOP limit of 21 mmHg, the median qualified success rate was 92.0% (range 80.0–100.0%) and the median complete success rate was 48.0% (range

24.0–73.3%) (Table 5). At a limit of 18 mmHg, the median rates were 83.3% (75.0–94.0%) and 46.0% (30.0–75.0%), respectively.

From a median baseline IOP of 29.5 mmHg (range 19.8–43.0 mmHg), median IOP at last follow-up was 13.4 (range 10.8–25.2 mmHg) (Table 5). Median percentage IOP reduction was 53.4% (range 27.7–66.2%). From a median baseline 3.5 glaucoma medications (range 2.6–4.3), median meds at last follow-up was decreased to 1.0 (range 0.2–2.0). Median percentage reduction in medications was 71.8% (range 42.3–94.6%).

Complications for the PGI summed across all reporting studies are shown in Table 6. Though each publication reported individual complications, only eight studies specified the cumulative percentage of the sample with any complications.^{13,16,18,19,21,23–25} The summed complication rate across those eight papers was 28.8% (85/295 eyes). The most common individual complication was hyphema, occurring in 10.0% (76/759) of implantations. Numerical hypotony (IOP < 6 for at least one follow-up visit), where reported, occurred for 9.7% (68/701) of eyes. In terms of hypotony-related issues, maculopathy occurred at a rate of 1.8% (10/545), shallow anterior chamber at 5.9% (38/646), and choroidal effusions at 3.4% (27/805). Corneal decompensation occurred in 3.0% (7/230) of cases. Tube/plate issues varied; erosions were documented in 5.0% (45/900) of eyes, obstructions in 4.5% (27/599), tube-corneal touch in 2.3% (8/349), diplopia in 3.1% (16/523), and encapsulated blebs in 3.6% (7/196). Of note, tube erosion was reported more frequently in prospective studies (9.8%, 20/204 eyes prospective vs 3.6%, 25/696 eyes retrospective). A single case of endophthalmitis was reported (0.2%, 1/469). Complication-related reoperation rate was 8.3% (75/908).

Comparative Studies Against the AGV and BGI

The sole RCT reviewed, the PAUL Ahmed Comparison study (PAC), compared 25 pediatric patients who received the PGI to 19 pediatric patients who received the AGV FP7.¹³ Antifibrotic agents were not used. Participants were followed for a year at sites in Egypt and the UAE. The study followed a per-protocol approach, with the two eyes that dropped out in the AGV group being excluded from analysis. At baseline, none of the metrics compared between groups were significantly different. The AGV group contained numerically more patients with glaucoma following cataract surgery (3 PGI vs 7 AGV), while the PGI group contained more patients who had glaucoma associated with ocular, systemic, or acquired conditions (6 PGI vs 0 AGV). IOPs were averaged from three rebound measurements. Mean IOP at postop month 1 was 5.6 mmHg greater in the PGI group compared to the AGV group ($p = 0.003$). At months 3, 6, and 12, there were no statistically significant differences in IOP, and the PGI group met prespecified noninferiority criteria. There were no statistically significant differences in medications or success rates at any time point. Complication rates were 12.0% in the PGI cohort and 15.7% for the AGV. The three complications for the PGI were tube extrusion, tube exposure, and flat anterior chamber. The three AGV complications included two cases of hypotony requiring AC reformation, and one event of endophthalmitis.

An additional four studies that compared the PGI to another tube were all retrospective. Karapapak and Olgun 2024 compared outcomes of the PGI ($N = 18$) to the AGV FP7 ($N = 18$) for silicone oil glaucoma.¹⁹ Antifibrotics were not used and baseline characteristics were similar. Success rates, IOP, and medication endpoints were similar between groups through one year of follow-up. Though the complication rate was higher for the AGV (44.4%) compared to the PGI (22.2%), this difference did not achieve statistical significance ($p > 0.05$).

The remaining three studies used the BGI as the second arm. Oliver-Gutierrez et al 2025 compared 27 PGI eyes to 29 BGI eyes, both implanted using MMC sponges and topical 5-FU, followed for an average period of 15.3 months.¹⁸ Two statistically significant baseline differences were noted: the PGI group more frequently had failed previous filtering surgery (63.0% PGI vs 31.0% BGI; $p = 0.04$) and more frequently had the tube placed in the anterior chamber (81.5% PGI vs 24.1% BGI; $p < 0.01$). No statistically significant differences were found for IOP at 1 year, medications at 1 year, success rates, complication rates, or vision changes. However, complete success rates at 12 months with an upper IOP threshold of 21 mmHg were lower for the PGI group (32.0% PGI vs 56.0% BGI, $p = 0.22$) and complication rates were higher (48.2% PGI vs 31% BGI, $p = 0.15$), but neither difference was significant. In the conference abstract from Scheres et al 2023, 90 PGI eyes were compared to 89 BGI eyes and followed for 1 year.²⁰ At baseline, the BGI group had a higher mean IOP ($p = 0.003$) and a greater proportion of eyes with uveitic glaucoma ($p = 0.02$). Day 1 and week 1 IOPs were lower in the PGI group compared to the BGI (10.5 ± 8.7 and 11.7 ± 6.2 mmHg PGI vs 16.8 ± 12.5 and $13.7 \pm$

Table 5 Outcomes of the PAUL Glaucoma Implant

Study	BL Mean IOP (mmHg)	BL Mean Glaucoma Meds	% IOP Reduction	% Meds Reduction	Final Mean IOP	Final Mean Meds	QS at 21 mmHg	CS at 21 mmHg	QS at 18 mmHg	CS at 18 mmHg
Berteloot et al 2024 ¹⁷	23.7 ± 6.9 (SD)	2.7 ± 1.0 (SD)	44.7%	48.5%	13.1 ± 2.9 (SD)	1.41 ± 1.4 (SD)	NR	NR	91.0%	44.0%
Elhusseiny et al 2023 ³⁵	32.7 (range 24–46)	4.3 (range 4–5)	60.2%	83.7%	13.0 (range 10–18)	0.7 (range 0–2)	NR	NR	NR	NR
Elhusseiny et al 2025 ¹³	32.6 ± 6.1 (SD)	3.6 ± 0.6 (SD)	54.3%	69.4%	14.9 ± 4.1 (SD) ^a	1.1 ± 1.0 (SD)	80.0%	24.0%	NR	NR
José et al 2022 ³¹	31.4 ± 10.0 (SD)	3.0 (IQR 2–4)	60.2%	70.0%	12.5 ± 4.3 (SD)	0.9 ^d	NR	NR	75.0%	33.0%
Karapapak and Olgun 2024 ³⁷	38.8 ± 9.2 (SD)	3.6 ± 0.5 (SD)	58.5%	75.0%	16.1 ± 3.3 (SD)	0.9 ± 1.2 (SD)	86.6%	NR	NR	NR
Karapapak and Olgun 2024 ¹⁹	40.0 ± 13.0 (SD)	3.8 ± 0.4 (SD)	66.2%	55.3%	13.5 ± 2.2 (SD)	1.7 ± 1.3 (SD)	94.0%	NR	NR	NR
Khodeiry et al 2025 ³⁶	32.6 ± 10.0 (SD)	4.0 ± 0.9 (SD)	53.4%	77.5%	15.2 ± 4.6 (SD)	0.9 ± 1.2 (SD)	93.3%	NR	NR	NR
Koh et al 2020 ⁹	23.1 ± 8.2 (SD)	3.3 ± 0.9 (SD)	42.9%	90.9%	13.2 ± 3.3 (SD)	0.3 ± 0.6 (SD)	93.2%	68.9%	85.1%	60.8%
Labay-Tejado et al 2024 ²⁷	26.6 ± 6.2 (SD)	2.6 ± 1.0 (SD)	42.5%	42.3%	15.3 ± 4.6 (SD)	1.3 ± 1.2 (SD)	NR	NR	75.0%	43.8%
Lechanteur et al 2023 ²⁶	26.7 ^d	3.0 ± 1.1 (SD)	46.8%	70.0%	14.2	0.9 ± 1.1 (SD)	NR	NR	NR	NR
Mendoza-Moreira et al 2024 ²⁵	29.5 ± 9.5 (SD)	3.5 (median; IQR = 1)	50.2%	42.9%	14.7 ± 4.0 (SD)	2.0 (median; IQR = 2)	90.0%	30.0%	80.0%	30.0%
Olgun and Karapapak 2024 ²²	33.4 ± 7.6 (SD)	Median 4 (PXG) and 3 (POAG) ^b	57.5%	NR	14.2 ± 2.9 (SD)	NR	92.6%	60.3%	NR	NR
Olgun and Karapapak 2025 ²¹	35.8 ± 12.4 (SD)	3.0 ± 0.11 (SD)	59.4%	59.0%	14.5 ± 3.2 (SD)	1.2 ± 1.4 (SD)	86.4%	NR	NR	NR
Oliver-Gutiérrez et al 2025 ¹⁸	23.9 ± 8.0 (SD)	3.0 ± 1.0 (SD)	45.0%	66.7%	11.2 ± 6.0 (SD)	1.0 ± 1.0 (SD)	82.0%	32.0%	82.0%	32.0%

(Continued)

Table 5 (Continued).

Study	BL Mean IOP (mmHg)	BL Mean Glaucoma Meds	% IOP Reduction	% Meds Reduction	Final Mean IOP	Final Mean Meds	QS at 21 mmHg	CS at 21 mmHg	QS at 18 mmHg	CS at 18 mmHg
Richardson et al 2024 ²⁸	30.6 ± 9.8 (SD)	3.9 ± 0.9 (SD)	60.1%	71.8%	12.2 ± 4.4 (SD)	1.1 ± 1.3 (SD)	92.0%	48.0%	NR	NR
Rusmayani et al 2023 ³⁴	43.0 ± 13.9 (SD)	3.7 ± 0.5 (SD)	52.4%	71.4%	25.2 ± 21.4 (SD)	1.1 ± 1.4 (SD)	100.0%	59.0%	NR	NR
Scheres et al 2023 ²⁰	NR	NR	NR	NR	10.8 ± 2.9 (SD)	1.5 ± 1.2 (SD)	NR	NR	NR	NR
Studsgaard et al 2025 ¹⁴	29.9 ± 8.6 (SD)	3.4 ± 0.8 (SD)	61.9%	73.5%	11.4 ± 3.1 (SD)	0.9 ± 0.9 (SD)	96.0%	43.0%	94.0%	43.0%
Tan et al 2022 ³²	19.8 ± 6.3 (SD)	3.2 ± 0.8 (SD)	29.8%	90.9%	13.9 ± 3.7 (SD)	0.3 ± 0.7 (SD)	NR	NR	82.2%	71.1%
Tan et al 2024 ³³	20.6 ± 6.13 (SD)	3.1 ± 1.0 (SD)	27.7%	94.6%	14.9 ± 4.1 (SD)	0.2 ± 0.5 (SD)	NR	NR	85.4%	75.0%
Vallabh et al 2022 ³⁰	28.1 ± 9.0 (SD)	3.6 ± 1.1 (SD)	53.7%	66.2%	13.0 ± 3.8 (SD)	1.2 ± 1.2 (SD)	90.1%	38.4%	NR	NR
Vallabh et al 2023 ²⁹	30.9 ± 5.9 (SD)	3.8 ± 0.7 (SD)	57.3%	73.7%	13.2 ± 4.9 (SD)	1.0 ± 1.3 (SD)	84.0%	48.0%	NR	NR
Weber et al 2022 ¹⁵	26.0	NR	64.0%	NR	12.0	NR	NR	NR	NR	NR
Weber et al 2023 ²⁴	26.1 (range 7–48)	3.4 (range 1–5)	48.8%	85.3%	12.0 (range 3–24)	0.5 (range 0–3)	95.6%	73.3%	84.4%	74.4% ^c
Weber et al 2024 ¹⁶	25.4 (range 7–48)	3.5 (range 1–5)	50.6%	86.9%	11.3 (range 3–20)	0.5 (range 0–3)	89.0%	52.0%	79.0%	48.0%
Weber et al 2025 ²³	25.6 (range 14–49)	3.2 (range 1–5)	46.9%	88.2%	13.6 (range 8–20)	0.4 (range 0–3)	97.0%	69.7%	87.9%	66.7%

Note: ^aIn Elhusseiny et al 2025, the main text reports a different final mean IOP than the corresponding table; 14.9 ± 4.1 versus 13.2 ± 3.0, respectively ^bUnable to calculate a cumulative median with information in Olgun and Karapapak 2024 ^cWeber et al 2023 reported a higher complete success rate at an IOP target of 18 mmHg compared to 21 mmHg, which should be impossible ^dNo measure of dispersion found in text.

Abbreviations: BL, baseline; CS, complete success; f/u, follow-up; IOP, intraocular pressure; IQR, interquartile range; NR, not reported; POAG, primary open-angle glaucoma; PXG, pseudoexfoliative glaucoma; QS, qualified success; SD, standard deviation.

Table 6 PAUL Glaucoma Implant Complications ^aOnly Including Studies That Explicitly Delineated Total Eyes with Complications

PAUL Glaucoma Implant complication	Tallied rates across reporting studies
Numerical hypotony	68/701 (9.7%)
Choroidal effusion	27/805 (3.4%)
Suprachoroidal hemorrhage	1/363 (0.3%)
Endophthalmitis	1/469 (0.2%)
Cystoid macular edema	13/469 (2.8%)
Shallow anterior chamber	38/646 (5.9%)
Hypotony maculopathy	10/545 (1.8%)
Diplopia or ocular motility disorder	16/523 (3.1%)
Corneal edema without decompensation	7/230 (3.0%)
Corneal decompensation	20/484 (4.1%)
Encapsulated bleb	7/196 (3.6%)
Tube–corneal touch or malposition	8/349 (2.3%)
Tube obstruction or occlusion	27/599 (4.5%)
Tube erosion, conjunctival exposure, or bleb leak	45/900 (5.0%)
Hyphema	76/759 (10.0%)
Vitreous hemorrhage	3/148 (2.0%)
Retinal detachment	8/311 (2.6%)
Vision loss of 2 Snellen lines or no light perception	19/384 (4.9%)
Iritis	4/208 (1.9%)
Malignant glaucoma	4/151 (2.6%)
Cataract progression	15/315 (4.8%)
Reoperation for complications	75/908 (8.3%)
Total eyes with any complication ^a	85/295 (28.8%)

Note: ^aOnly including studies that explicitly delineated total eyes with complications.

6.8 mmHg BGI; $p < 0.05$), however there were no significant differences in IOP at year one ($p = 0.92$). Numbers of medications and complications were similar. Berteloot et al 2024 examined 23 PGI eyes and 27 BGI eyes with 1 year of follow up.¹⁷ No statistically significant differences were noted in baseline characteristics, year 1 meds, success rates, vision changes, slit lamp interventions, or complications. The PGI group had lower IOP at week 1 (13.6 ± 6.1 PGI vs 20.1 ± 7.4 mmHg BGI, $p = 0.002$) and month 1 (14.6 ± 3.8 PGI vs 21.2 ± 5.8 mmHg BGI, $p < 0.001$), and furthermore required fewer medications at month 1 (1.6 ± 1.5 PGI vs 2.5 ± 1.2 BGI; $p = 0.02$). However, at 1 year the IOP trend reversed, with the BGI group having lower IOP (13.1 ± 2.9 PGI vs 10.4 ± 4.9 mmHg BGI; $p = 0.02$).

Discussion

In this review of 26 studies containing 1143 PGI implantations, efficacy outcomes were generally positive. Median complete and qualified success rates at an IOP upper limit of 21 were 48.0% and 92.0%, respectively; at a limit of 18 mmHg, they were 46.0% and 83.3%. Median reductions in IOP and glaucoma medications were 53.4% and 71.8%,

respectively. Given that the most frequent length of PGI follow-up was a year, one can compare against the ABC and AVB studies at 1 year.^{11,12} The ABC study targeted a 21 mmHg upper threshold for success, while the AVB set a more aggressive 18 mmHg goal; other criteria were largely shared. The ABC study's AGV group had a 19% complete success rate and an 84% qualified success rate. The BGI group had a 31% complete success rate and an 86% qualified rate. By comparison, the AVB study reported complete and qualified success for the AGV at 8% and 57%, respectively, while for the BGI rates were 17% and 72%.

Though it appears that the PGI success rates compare reasonably well to the BGI data from the ABC and AVB trials, such comparisons should be viewed with caution. Definitions of success across reviewed studies varied and in several instances were less stringent than the seminal tube trials (Table 4). For instance, only 54.5% (12/22) of PGI studies with success criteria required a reduction in IOP of 20% or more, and the number of visits during which IOP needed to remain within range was only occasionally specified. In both the ABC and AVB studies, success required two consecutive visits at or after 6 months with IOP in range. The AVB study had especially demanding complete criteria: not only no meds, but also a lack of vision loss of 2 Snellen lines or more and IOP targets met at every study visit from 3 months onwards. No PGI study replicated this full standard. Furthermore, four PGI studies that reported success had follow-up of less than a year, possibly contributing to inflated success rates.^{25,27,30,34}

Regarding safety, the cumulative PGI complication rate across reporting studies was 28.8%. The most frequent individual complications were hyphema (10.0%), numeric hypotony (9.7%), shallow anterior chamber (5.9%), and tube erosion (5.0%). Hypotony-related sequelae such as maculopathy (1.8%), choroidal effusion (3.4%), and suprachoroidal hemorrhage (0.3%) were rare. Vision loss of two Snellen lines or more occurred in 4.9% of eyes in reporting studies. Only a single eye (0.2%) experienced endophthalmitis. Reoperation rate for complications was 8.3%. In the ABC study's 1-year findings, overall complication rates were 43% for the AGV and 58% for the BGI.¹² In the AVB study, rates were 45% for the AGV and 54% for the BGI.¹¹ For most individual complications, the reported PGI data appears to compare favorably to both the AGV and BGI. A key exception is tube erosions. Overall tube erosion rates in both the ABC and AVB studies were 1% and 2%, respectively.^{11,12} In contrast, rates for the PGI were higher, particularly among prospective studies (9.8%). This difference may be reflective of the greater tendency to utilize MMC in PGI implantation (no tubes in the ABC or AVB studies received MMC) and/or differences in plate design.

However, just as with success rates, comparing complication rates has its limitations. For the current review, complications were tallied from a source only when the study at least alluded to monitoring the complications in question. This rule was used to avoid underestimation. Regardless, certain complications may still have been under-represented. For instance, corneal changes were typically only reported when there was decompensation, not edema. Vision in the postop period was often reported as average or median changes rather than tallied into eyes that lost 2 lines or more. Most studies failed to disclose reoperation and overall complication rates. On the other hand, certain other complications may have been overestimated by the current study's methodology. Serious adverse events, such as endophthalmitis, would presumably be monitored for in any study even if not made explicit.

It would thus be more optimal to have high-quality, prospective comparative studies of the PGI. At the time of writing, there has been just a single RCT of the PGI published, the PAC study.¹³ Though the PAC study found noninferiority for the PGI arm, it had several limitations: small sample size, just one year of follow-up, a purely pediatric sample recruited from Egypt and the UAE, per-protocol design, baseline differences in glaucoma types that approached statistical significance, and IOP levels that were only averaged from three rebound measurements. Aside from that RCT, the four studies that directly compared the PGI to an AGV or BGI were each retrospective and in adult populations. The one comparison of the PGI and AGV occurred in the very specific clinical circumstance of silicone oil glaucoma, with a trend towards fewer complications in the PGI arm that did not reach statistical significance.¹⁹ For the three PGI vs BGI studies, few meaningful differences in outcomes were seen between groups. However, two of the three retrospective studies had significant differences in baseline characteristics between treatment arms, with clinical implications for the outcome measures.^{18,20} Thus, for surgeons weighing the PGI against the current standard of care, the utility of the few comparative studies is limited. At best, they point to no definitive benefits of the PGI.

PGI surgical techniques varied widely, with 76.9% of studies using a ripcord technique (with minimal uniformity in the timing of removal), 65.4% using pericardial patch grafts, and 46.2% employing antifibrotic agents. Each of these

variations could have affected rates of events such as hypotonous sequelae and tube exposure. Weber et al 2024 remarked that after an inordinately high exposure rate with pericardium, their practice switched to facia lata grafts with improvement in outcomes.¹⁶ No other study remarked on similar adjustments. As for antifibrotics, the one retrospective study comparing MMC to no MMC use in neovascular glaucoma patients found generally better outcomes for the MMC group.²¹ Better IOP control overall likely was reflected in the lower medication use, later removal of the ripcord, and less need for follow-up cycloablation. However, the MMC group did have more tube exposure events (9.8% vs 0.0%), possibly reflecting increased conjunctival thinning from the antifibrotic. There has been some interest in using MMC to reduce the rates of the hypertensive phase in AGV surgeries, so further research into its use in PGIs may be beneficial.³⁸

In sum, the reviewed studies were heterogenous with several limitations. Over half of the reviewed studies listed one of six researchers (Tan, Elhousseiny, Vallabh, Weber, Olgun, or Karapapak) as a first author. With multiple studies from the same clinicians, risks of bias and sample overlap are increased. No study contained more than 99 eyes that received the PGI. The median number of PGI surgeries was only 39. Merely five studies were prospective, with the remainder suffering from retrospective bias risks. The most common follow-up duration was just one year, with the longest period of follow-up being a single study at 3 years. Most studies looked at implantations in a potpourri of glaucoma subtypes, without sufficient power to determine which subtypes the device may be most efficacious for. Five studies focused on purely pediatric patients, whereas the ABC and AVB studies each excluded pediatric patients. Patient populations were predominantly White or Asian, limiting applicability to other groups. Significant heterogeneity of included studies and lack of robust comparative evidence limit the utility of this article for guiding clinical practice. As for the current review's methodology, it is principally limited by a lack of rigorous meta-analysis and a lack of formal bias assessment. Querying additional databases may have yielded further studies. And for any large-scale data extraction, risks for coding errors exist, even with multiple reviewers.

Conclusion

The PGI was conceptualized in part to combine the strengths of two popular tube shunts. In an ideal scenario, it would provide efficacy at or above the level of the BGI, whilst offering a safety profile comparable or even favorable to the AGV. On one hand, the PGI's reported success rates were high, and complications in general appeared relatively infrequent. On the other, with the many methodologic limitations of the currently published data that bias towards pro-PGI outcomes, it is difficult to reliably assess how the novel device compares to the current standard of care. The sole RCT available has poor generalizability and certain protocol challenges. The remaining retrospective comparative studies provide minimal compelling evidence to choose the PGI over other tubes. Moreover, a possible safety signal was seen in prospective PGI studies that reported high tube erosion rates, which may relate to antifibrotic use. Overall, there is need for high-quality RCTs in adults that compare the PGI against mainstream tubes and that compare different PGI surgical approaches.

Disclosure

Malik Kahook and Leonard K. Seibold are consultants to New World Medical, which produces the Ahmed Glaucoma Valve. Also, Leonard K. Seibold is a consultant to Abbvie and Thea. The other authors have no relevant conflicts of interest to declare.

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