Aus der Augenklinik und Poliklinik

der Universitätsmedizin der Johannes Gutenberg-Universität Mainz

One-Year Efficacy and Safety Outcomes of the Paul Glaucoma Drainage Implant Compared to the Ahmed Glaucoma Valve Implant in a Retrospective Cohort at the University Medical Centre Mainz

1-Jahres-Wirksamkeits- und Sicherheitsbewertung des Paul-Glaukomimplantats im Vergleich zum Ahmed-Glaukomventil: Eine retrospektive Kohortenstudie an der Augenklinik und Poliklinik der Universitätsmedizin Mainz

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Dedication

To Tanyi and Ramiro, my parents, to whom I owe every achievement in my life. They have taught me that sacrifice and perseverance lead to accomplishing goals.

To Madelyn and Kevin, my siblings and best friends.

Zusammenfassung

Diese Studie verglich die Einjahres-Ergebnisse von Implantationen des Ahmed-Glaukomventils (AGV) und des Paul-Glaukomimplantats (PGI) in einer Kohorte von respektiv 24 und 28 Glaukompatienten. Beide Gruppen wiesen ähnliche präoperative intraokuläre Druckwerte (IOD) auf und verwendeten eine vergleichbare Anzahl an drucksenkenden Medikamentengruppen. Die häufigste Diagnose war ein sekundäres Glaukom und die Mehrheit der Patienten war voroperiert sowie pseudophak.

Die primären Endpunkte der Studie waren die Reduktion des Augeninnendrucks und der Anzahl der drucksenkenden Medikamentengruppen. Sekundäre Endpunkte umfassten den chirurgischen Erfolg bei drei verschiedenen Zieldruckdefinitionen in Kombination mit einer dazugehörigen festgelegten prozentualen Reduktion (IOD ≥6 mmHg und ≤21 mmHg mit einer Reduktion von ≥25 %; IOD ≥6 mmHg und ≤18 mmHg mit einer Reduktion von ≥30 %; IOD ≥6 mmHg und ≤15 mmHg mit einer Reduktion von ≥40 %), Visus sowie Komplikations- und Interventionsraten.

Der mittlere präoperative IOD sank von 34,0 ± 9,4 mmHg auf 16,5 ± 6,3 mmHg in der AGV-Gruppe und von 32,8 ± 9,0 mmHg auf 14,8 ± 3,35 mmHg in der PGI-Gruppe nach einem Jahr. Die mediane (IQR) Anzahl der drucksenkenden Medikamentengruppen verringerte sich von 3,5 (1,0) auf 0 (2) in der AGV-Gruppe und von 3,0 (2,0) auf 0 (1) in der PGI-Gruppe.

Komplette Erfolgsraten (IOD ≥6 mmHg und ≤21 mmHg mit einer Reduktion von ≥25 %) betrugen 33,3 % für AGV und 53,6 % für PGI, mit qualifizierten Erfolgsraten von 62,5 % bzw. 75,0 %. Bei einem IOD ≥6 mmHg und ≤18 mmHg mit einer Reduktion von ≥30 % lagen die kompletten und qualifizierten Erfolgsraten bei 33,3 % und 54,2 % für AGV sowie 50 % und 71 % für PGI. Bei einem IOD ≥6 mmHg und ≤15 mmHg mit einer Reduktion von ≥40 % betrugen die kompletten und qualifizierten Erfolgsraten 20,8 % und 29,2 % für AGV sowie 28,6 % und 32,1 % für PGI. Es gab zu keinem Zeitpunkt und bei keinem Erfolgskriterium statistisch signifikante Unterschiede zwischen den Gruppen.

Sowohl das Ahmed-Glaukomventil als auch das Paul-Glaukomimplantat senken den Augeninnendruck und die Anzahl der Antiglaukommedikamente nach einem Jahr effektiv. Das PGI neigt dazu, weniger Misserfolge und einen höheren Anteil an Patienten mit chirurgischem Erfolg zu erzielen als das AGV, obwohl diese Unterschiede nicht statistisch signifikant waren. Beide Glaukomdrainagen haben vergleichbare Sicherheitsprofile, wobei das AGV mit mehr verkapselten Sickerkissen und das PGI mit mehr konjunktivale Durchwanderung assoziiert wird.

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List of abbreviations

ABC……Ahmed Baerveldt Comparison Study

AGV……Ahmed glaucoma Valve

ALT……Argon laser trabeculoplasty

AVB……..……Ahmed Versus Baerverdlt Study

BGI…..……..Baerveldt glaucoma implant

BVCA.……Best corrected visual acuity

COPD……Chronic obstructive pulmonary disease

DMEK…….…… Descemet Membrane Endothelial Keratoplasty

EGS……European Glaucoma Society

GDD……Glaucoma drainage device

GFCS……Glaucoma following congenital cataract surgery

IDDM……Insulin dependent Diabetes Mellitus

IOP……..Intraocular pressure

MD ……..mean deviation or mean defect

MMC……..…Mitomycin C

PCG……Primary congenital glaucoma

PGI……...Paul Glaucoma Implant

PTVT……...Primary Tube Versus Trabeculectomy

SLT……Selective laser trabeculoplasty

VF…….visual field

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1 Introduction

Glaucoma drainage devices (GDD) are widely employed for managing intraocular pressure, especially in refractory glaucoma (2). However, in the last years it has been suggested as a viable option in patients diagnosed with glaucoma without previous surgery (3). It has been demonstrated that although trabeculectomy produces a greater decrease in intraocular pressure (IOP) during the first and third postoperative years, it has more early postoperative complications in the first year and greater rates of failure at higher levels of preoperative IOP than tube shunt implantation (3).

After the introduction of the nonvalved Molteno implant in the 1970s, the most popular GDDs, namely the Ahmed Glaucoma Valve (AGV) and the Baerveldt glaucoma implant (BGI), emerged in the early 1990s (4). The AGV (New World Medical Inc., Rancho Cucamonga, California, USA) is a glaucoma valve equipped with a silicone elastomer membrane within the tube to mitigate postoperative hypotony (2,5). The tube has an inner diameter of 0.305mm and received FDA approval in 1993 (2,5,6). Long-term results indicate a success rate of 78.7% at the 7-year follow-up(2). The BGI (Johnson & Johnson Vision, Santa Ana, CA, USA) has an inner diameter of 0.320mm but no resistance to flow (3,6). Long-term success rate is approximately 63-78% (7–10). Although both BGI and AGV are effective in controlling the IOP in the long-term, BGI shows less tendency to failure. However, it has more postoperative complications, above all hypotony compared to AGV (11–13). Moreover, it appears that GDD do not significantly reduce intraocular pressure (IOP) in patients whose preoperative IOP is less than 19 mmHg (14). Postoperative complications of both implants include hypotony and its associated consequences, diplopia, device exposure, corneal endothelial failure, bleb encapsulation, among others (2–4).

With the advancement in knowledge and better understanding about fluid dynamics in intraocular surgery, new implants have emerged (4,6,15). One of them is the Paul Glaucoma implant (PGI). The PGI (Advanced ophthalmic innovations PTE. LTD. Singapore) received Conformité Europeenne (CE) mark in Europe in 2018 (16,17). The tube has an inner diameter of 0.127mm, which is approximately half that of the BGI, while maintaining the same plate area (4,6,17). It is designed to reduce hypotony, tube exposure, and endothelial cell loss compared to other tube implants (6). The intraluminal 6-0 Prolene suture prevents hypotony in the early postoperative period and allows for subsequent intraocular pressure (IOP) control through extraction during postoperative weeks 8-12 (15–19). The 3-year results of the PGI studies showed a good postoperative control with a good safety profile (15).

Although clinical trials showed that the BGI demonstrated lower IOP compared to the AGV (11,12,20), the AGV was the preferred glaucoma drainage device at University Medical Centre Mainz. This preference was due to the hypertensive phase associated with the BGI in the initial months, which is caused by lumen obstruction and tube ligature used to prevent hypotony until the bleb completes the remodelling phase. This necessitates frequent patient monitoring. Additionally, once the ripcord or sutures are removed, there is a renewed risk of hypotony.

The goal of this thesis is to compare the one-year efficacy and safety profile between the Ahmed Valve and the Paul glaucoma implant on patients that underwent tube implant in the University Medical Centre Mainz from 2019 to 2023. It is retrospective, single-center and comparative study. There is a limited number of studies comparing both procedures. A retrospective study conducted on patients with silicone oil glaucoma revealed that both procedures demonstrated comparable surgical success (19). Nevertheless, PGI tended to have less postoperative complications (19). As the Paul Glaucoma Implant (PGI) is a relatively novel device, it is crucial to persist in collecting data regarding its safety, intraocular pressure control, and conduct a long-term follow-up on patients who have undergone this surgery. It is not uncommon for approved devices to be withdrawn from the market due to adverse events

identified during long-term follow-ups. Continued monitoring and analysis of outcomes are essential to ensure the device's sustained efficacy and safety.

2 Literature discussion

2.1 **Glaucoma definition**

Glaucoma comprises a group of intraocular diseases that share a common pattern of optic nerve damage along with corresponding defects in the visual field (1). The high intraocular pressure in one of the risk factors but no the only for the development und progression of the glaucoma (1,21).

2.2 **Glaucoma classification**

The most used classification systems are according to the aetiology and to the mechanism (1).

The etiology refers to the underlying disorder that causes alterations in the dynamics of aqueous humor or loss of retinal ganglion cells (1). Glaucoma can be classified into primary and secondary forms, depending on whether the initial events are confined to the anterior chamber angle or conventional flow, with no influence from other ocular or systemic diseases or not (1). However, this division in the events of the current knowledge about the glaucoma physiopathology is becoming obsolete (1). A new schema consisting in five stages was proposed by Allingham et al. (1) This schema classifies glaucoma according to the initiating events and attempts to fill more gaps than the traditional classification does. See figure 1.

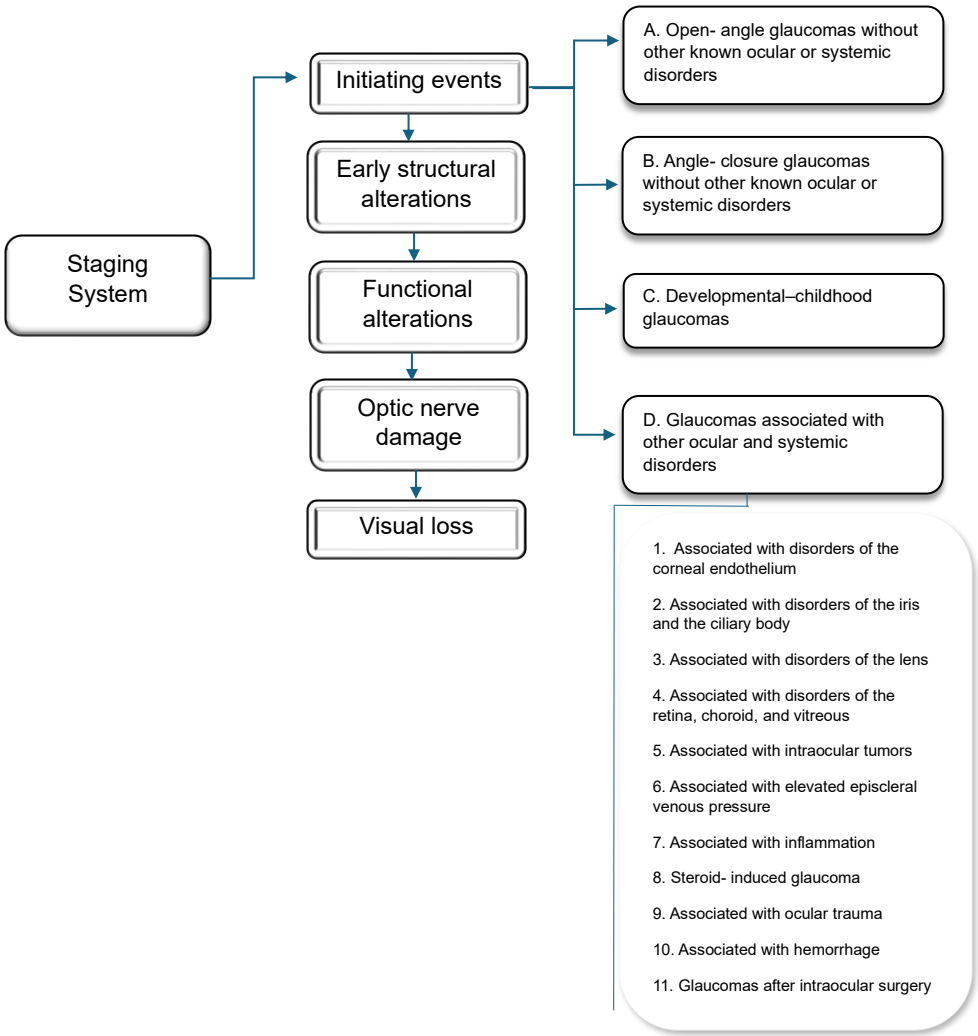

Figure 1. Classification based on the etiology proposed by Allingham et al.(1)

The mechanism refers to structural alterations in the anterior chamber, causing a rise in intraocular pressure due to the obstruction of aqueous humor outflow (19). The shortcomings of this classification include its failure to consider other mechanisms unrelated to intraocular pressure and the complexity of certain forms of glaucoma, which may involve multiple mechanisms (19). The advantage lies in the current understanding of structural changes leading to elevated intraocular pressure (IOP), surpassing the understanding of initial events (19). Additionally, current glaucoma therapy continues to focus on reducing IOP (19). According to the mechanism, glaucoma can be classified into open-angle glaucoma, angle-closure glaucoma, and developmental anomalies of the anterior chamber angle (19). See figure 2.

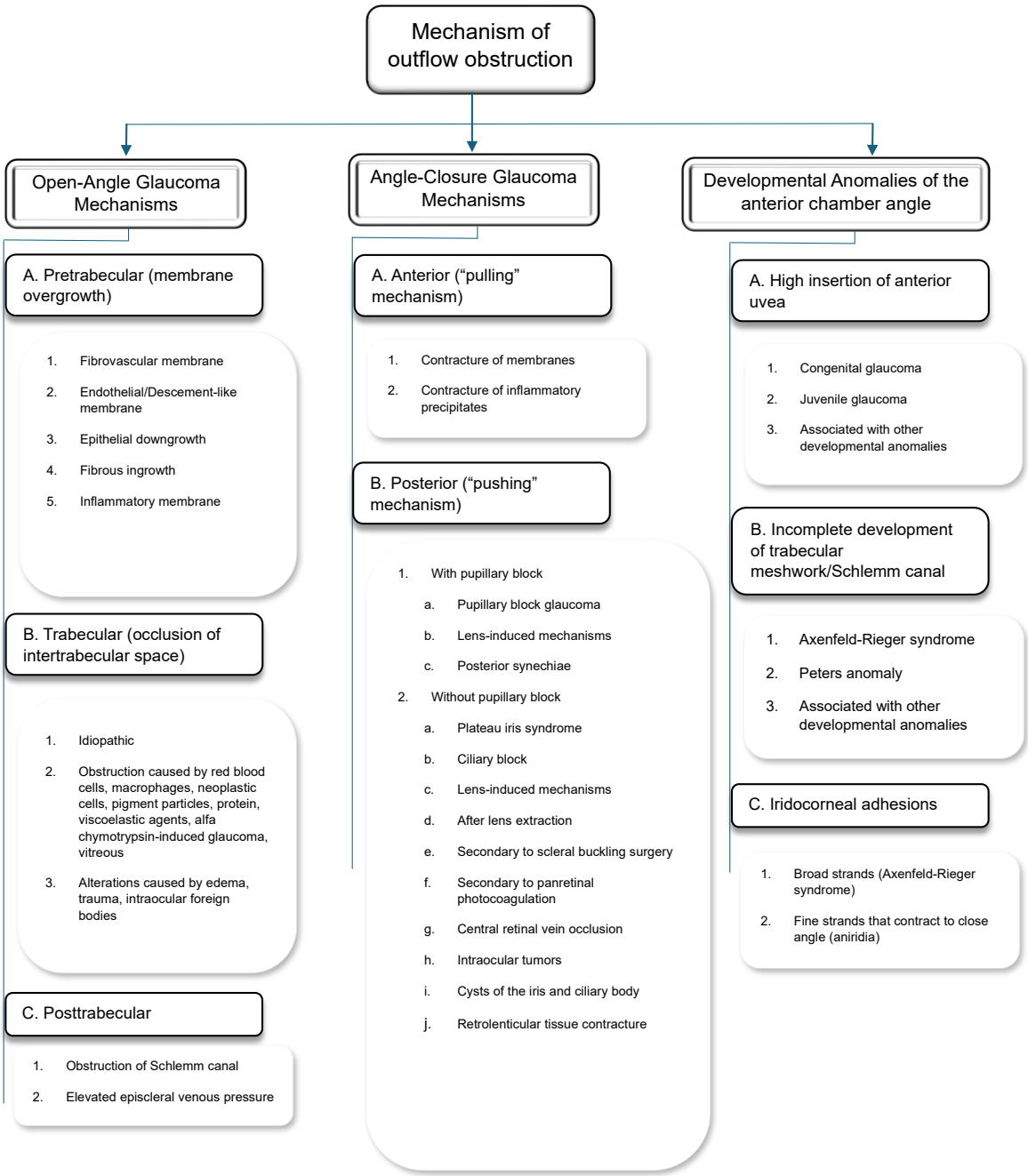

Figure 2. Classification based on the mechanism modified from Allingham et al.(1)

2.3 **Glaucoma therapy**

The therapy for glaucoma aims to achieve an intraocular pressure (IOP) target that reduces or stops disease progression with minimal adverse effects an promote quality of life within a sustainable health care system (20). t should be individualized for each patient. In newly diagnosed patients, the target is determined by the disease stage and baseline IOP (20). In early glaucoma, characterized by a mean deviation (MD) of ≤ 6 dB in the visual field (VF), an IOP of 18 to 20 mmHg with a reduction of at least 20% may be sufficient; for moderate glaucoma, with an MD in the VF of 6 to 12 dB, an IOP of 15 to 17 with a reduction of at least 30% is recommended, while for advanced glaucoma, with an MD in the VF of >12 dB, a lower IOP target with a reduction of 40% may be necessary (20,21). At follow-up, if the disease is progressing, the target IOP should be further reduced (20). If the disease is not progressing but the target IOP has not been reached, it could be considered to accept a higher target IOP (20). The initial therapy in most case is topical medications, but it could be laser or surgery depending on the severity or on the mechanism (21).

2.3.1 Medication

Prostaglandin and Prostamide Analogs

They reduce IOP by enhancing uveoscleral outflow and are usually the first-line therapy due to their minimal systemic side effects (1,21). The IOP reduction typically ranges from 25-35% and are dosed once daily (21). Local side effects may include conjunctival hyperemia, burning sensation, stinging, foreign body sensation, itching, increased pigmentation of periocular skin, periorbital fat atrophy, eyelash changes, increased iris pigmentation, and cystoid macular edema in patients with risk factors, as well as the reactivation of herpes keratitis, and uveitis, among others. The first drug to be released was Latanoprost. Other drugs in this group include Unoprostone, Travoprost, Tafluprost, Latanoprostene, and Bimatoprost ((1,21,22). Bimatoprost and Travoprost are also available as intracameral implants (21). In 2022, Omidenepag isopropyl was approved by the FDA; it is an EP2 receptor agonist that has shown non-inferiority to latanoprost and decreased uveoscleral and trabecular meshwork outflow resistance (22).

β-receptor Antagonists

They lower IOP by reducing aqueous humor production and are dosed once or twice daily (1). The nonselective antagonists Timolol, Levobunolol, Metipranolol, and Carteolol block β1 and β2 receptors, resulting in a reduction of IOP by 20-25% (1,21). The selective agents primarily block β1 receptors, leading to fewer pulmonary and cardiovascular side effects but reducing IOP by only approximately 20% (1,21). They are contraindicated in asthma, chronic obstructive pulmonary disease (COPD), sinus bradycardia, heart block, or cardiac failure (21). Local side effects include conjunctival hyperemia, superficial punctate keratitis, dry eye, corneal anesthesia, and allergic blepharoconjunctivitis. Systemic adverse effects may include bradycardia, arrhythmia, heart failure, syncope, bronchospasm, airway obstruction, distal edema, hypotension, masked hypoglycemia in patients with insulin-dependent Diabetes Mellitus (IDDM), nocturnal systemic hypotension, depression, and erectile dysfunction (21).

Carbonic anhydrase inhibitors

The topical inhibitors brinzolamide and dorzolamide typically reduce IOP by 20% and are commonly administered two to three times daily (1,21). However, their effect is negligible at night (23). Their mechanism of action involves decreasing aqueous humor production (1,21). They are contraindicated in patients with a low corneal endothelial cell count (21). Local side effects may include burning, stinging, bitter taste, superficial punctate keratitis, and tearing (21). Systemic side effects may manifest as headache, urticaria, angioedema, pruritus, asthenia, dizziness, paresthesia, and transient myopia (21).

Acetazolamide, a systemic inhibitor, lowers IOP by 30-40% but is contraindicated in patients with low sodium or potassium blood levels, kidney and liver disease, suprarenal gland failure, hyperchloremic acidosis, or allergy to sulfamides (21). Systemic side effects of acetazolamide may include paresthesia, hearing dysfunction, tinnitus, loss of appetite, taste alteration, nausea, vomiting, diarrhea, depression, decreased libido, kidney stones, blood dyscrasias, metabolic acidosis, and hypokalemia (1,21).

Adrenergic agonists

Nowadays, only α2 agonists are utilized in the treatment of glaucoma (1,21). Apraclonidine decreases IOP by 25-35% through the reduction of aqueous humor production, while Brimonidine decreases IOP by 18-25% and additionally enhances uveoscleral outflow (21). They are contraindicated in individuals using oral monoamine oxidase inhibitors, adults with very low body weight, children under 3 years old, and should be administered with caution in older children (21,24). Local side effects may include lid retraction, allergic blepharoconjunctivitis, periocular contact dermatitis, and allergies (21). Systemic effects such as dry mouth, nasal dryness, fatigue, and drowsiness have been reported (21). Brimonidine can induce respiratory depression in infants (1,24).

Rho kinase inhibitors

They reduce IOP by 20-25% by increasing trabecular outflow (21). Netarsudil is a prodrug and additionally reduces episcleral venous pressure (21,25). It is administered once a day (21,25). Ripasudil is administered twice daily (21,25). Reported adverse effects include non-inflammatory conjunctival hyperemia, blepharitis, conjunctivitis, transient reduction in corneal epithelial thickness, and corneal verticillata. Systemic adverse effects such as headache, rhinitis, gastrointestinal discomfort, nasal congestion, and petechiae may occur (21)

Cholinergic Agonists (Miotics)

Pilocarpine is the oldest glaucoma medication, functioning by reducing IOP through the facilitation of aqueous humor outflow (1,21). This occurs via the contraction of the ciliary muscle, tension on the scleral spur, and traction on the trabecular meshwork (21). The decrease in IOP typically ranges from 20-25% (21). Pilocarpine is contraindicated in patients with postoperative ocular inflammation, uveitis, neovascular glaucoma, those at risk of retinal detachment, epilepsy, and Parkinson's disease (21). It may precipitate angle closure, reduced vision due to accommodative-induced myopia and miosis, iris cysts, bronchospasms, headaches, intestinal cramps, among other potential side effects (21).

Osmotics

They act by dehydrating the vitreous volume, resulting in the posterior displacement of the iris-lens plane and deepening of the anterior chamber (21). This mechanism contributes to a reduction in IOP by 15-30% (21). Glycerol and Isosorbide are available in oral form, while Mannitol is administered via intravenous injection (21). They are contraindicated in patients with renal or cardiac failure (21). Common side effects may include nausea, hyponatremia, lethargy, increased diuresis, renal failure, among others(21).

2.3.2 Laser trabeculoplasty

Argon laser trabeculoplasty (ALT) enhances the outflow of aqueous humor through the initial mechanical injury caused by the laser (26). This triggers cellular responses that lead to the remodeling of the trabecular meshwork (26). The settings typically involve a 0.1-second duration exposure, a 50µm beam diameter, and power levels ranging between 700 – 1500 mW, adjusted to produce either a depigmentation spot or a small gas bubble at the treatment site (1).

Selective laser trabeculoplasty (SLT) produces less damage compared to argon laser trabeculoplasty (ALT) (27). The laser energy is selectively absorbed by the pigmented

trabecular meshwork cells and can induce an increase in matrix metalloproteinase production(28). Although no standardized protocol has been established, it is suggested that utilizing fixed high-energy SLT (1.2 mJ without titration of laser energy in 360º degrees) produces greater IOP reduction without compromising safety (27). SLT sustains a 20% reduction in IOP in up to 76% of patients at a 10-year follow-up. However, more than half of the patients require retreatment in such cases (29).

2.3.3 Canaloplasty

The outer wall of the Schlemm canal is opened, and a viscoelastic agent is inserted with the help of a flexible microcatheter to dilate the Schlemm canal (1). Subsequently, a 10-0 or 9-0 Prolene suture is tied under tension within the Schlemm canal (1). As a standalone procedure, canaloplasty decreases the IOP by approximately 30% from a preoperative value of 23 mmHg (30).

2.3.4 Microinvasive glaucoma surgery (MIGS)

These devices are characterized by an ab interno approach through a clear corneal incision or an ab externo approach with minimal scleral dissection, resulting in minimal trauma to the target tissue (31,32). Additionally, they exhibit a moderate IOP-lowering efficacy, a high safety profile, and promote rapid recovery with minimal impact on the patient's quality of life (31,32). They are designed to address mild to moderate glaucoma. Some, such as the iStent, iStent inject, and Hydrus microstent, bypass the trabecular meshwork via stent placement (33). Others, like Kahook Dual Blade Goniotomy, Trabectome, Gonioscopy Assisted Transluminal Trabeculotomy (GATT), and TRAB 360/OMNI, achieve bypass by tissue excision (31–34). Visco 360/OMNI, ab Interno Canaloplasty (ABiC), and the STREAMLINE Surgical System enhance aqueous outflow through Schlemm’s canal (31–34). The MINIject Supraciliary Implant reduced IOP by 39.3% from baseline, with 37.9% of patients medication-free at 2 years, showing a good safety profile (35). The XEN Gel Stent and PRESERFLO MicroShunt bypass aqueous outflow into the subconjunctival space (33). The IOP reduction achieved by MIGS varies from 10% to 55%, with the PRESERFLO demonstrating the highest reduction (33).

2.3.5 Cyclodestruction

Those techniques aim to reduce aqueous humor production by damaging the ciliary body (36). Initially developed to treat eyes with refractory glaucoma and poor visual potential due to the risk of inflammation, ineffective treatment, and potential complications such as hypotony and phthisis bulbi, safer and less destructive procedures have gained traction over the past decade (36). These alternatives are now being considered even for less severe glaucoma cases with good visual potential (36). Cyclocryotherapy, trans-scleral laser cycloablation, micropulse diode cyclophotocoagulation, endoscopic cyclophotocoagulation, and ultrasound cyclodestruction are among the employed cycloablation techniques.

2.3.6 Trabeculectomy

The principal mechanism of IOP reduction is the external filtration around the margins of the scleral flap (1). Other possible routes include aqueous flow into the cut ends of Schlemm's canal (rare), cyclodialysis (if tissue is dissected posterior to the scleral spur), filtration through outlet channels in the scleral flap, and filtration through the connective tissue substance of the scleral flap (1). Our results at 6 years showed 73% and 69% qualified and complete surgical success, respectively, with an IOP between 5 mm Hg and 18 mm Hg (37).The survival rate of trabeculectomy reported at the 20-year follow-up is approximately 60% without the use of antiglaucoma medication and approximately 90% with its addition (38). Complications such as blebitis, corneal dellen, decompression retinopathy, dysesthesia, iris atrophy, leakage, ptosis, haemorrhage, hypotony, endophthalmitis, cataract progression, choroidal detachment, anterior chamber reduction, aqueous misdirection, among others may occur (37–39).

2.4 **Glaucoma drainage devices**

These implants essentially consist of a tube that connects either the anterior chamber or the vitreous to a plate positioned beneath the conjunctiva and Tenon capsule (1). This plate boasts large surface areas that promote the posterior formation of a filtering bleb, located nearly at the level of the equator (1). The morphology of the bleb differs from that of a trabeculectomy bleb (1). One month post-insertion, a thin collagenous capsule surrounded by a granulomatous reaction develops (1). This granulomatous reaction typically resolves within 4 months, while the capsule thickness remains relatively stable (1). This reaction translates into a hypertensive phase in patients with a GDD (1). Over time, the collagen stroma within the capsule becomes less compact. In rabbit eyes, the fibrous capsule tends to thin out after 6 months (1). The material used for the external portion of the GDD significantly influences the level of inflammation in the surrounding tissue (1). Polypropylene and rigid plates typically induce more inflammation compared to silicone(1). Studies in rabbits have demonstrated a direct correlation between the surface area of the implants and the filtering capacity of the surrounding capsule (40).

Table 1. Characteristics of Glaucoma Drainage Devices

DEVICE	**Molteno implant**	**Baerveldt glaucoma implant**	**Ahmed glaucoma valve**	**Ahmed ClearPath**	**Paul glaucoma implant**	**The eyeWatch System**
Regulatory status	CE mark, FDA approval	CE mark, FDA approval	CE mark, FDA approval	CE mark, FDA approval	CE mark	CE mark
Manufacturer, Country	Molteno Ophthalmic Limited, Dudein, New Zeland	Abbott Medical Optics Inc., USA	New World Medical Inc., Rancho Cucamonga	New World Medical Inc., Rancho Cucamonga	Advanced ophthalmic innovations PTE. LTD. Singapore	RheonMedical, Lausanne, Switzerland
Tube material	Silicone	Silicone	Silicone	Barium impregnated medical-grade silicone	Silicone	Silicone
Plate material	Polypropylene	Silicone impregnated with barium	Silicone, Polypropylene; Porous polyethylene	Barium impregnated medical-grade silicone	Silicone	PEEK (Polyetheretherketone, Victrex) eW implant Silicone
Tube diameter	0,60 mm external 0.30 mm internal	0,64 mm external 0,32 mm internal	0,635 mm external 0,305 mm internal	0,635 mm external 0,305 mm internal	0,467 mm external 0,127 mm internal	eW implant 0.20 mm internal eyePlate: 0.63mm external 0.30mm internal
Tube length	-	32 mm	25 mm	32 mm	29 mm	32 mm eW implant 28 mm eyePlate
Surface area	135 mm^2 175 mm^2 230 mm^2	250 mm^2 350 mm^2	96 mm^2 - 364 mm^2	250 mm^2 350 mm^2	342 mm^2	200 mm^2 300 mm^2

2.4.1 Open-Tube Drainage Devices

2.4.1.1 Molteno implant

It is the prototype of GDD, introduced in 1969 (1,6). Some surgeons still use the revised model (6). The original model consisted of a plate made of acrylic (1,6). This design underwent various modifications to increase success and reduce the complications of the first model (1). The success rate of a double plate Molteno device is nearly double that of a single plate Molteno device; however, it was associated with more complications due to hypotony(41). The

success rate of the Molteno device is 74% with a mean follow-up of 18 months, but it decreases to 57% with a mean follow-up of 44 months (42).

2.4.1.2 Baerveldt implant

It is typically implanted beneath the rectus muscles in the superotemporal quadrant (1). The plate features fenestrations, facilitating a reduction in the height of the bleb by enabling the growth of fibrous tissue through it (1). The fibrous capsule typically forms between 3 to 6 weeks postoperatively (1).

The Tube Versus Trabeculectomy (TVT) study compared the efficacy of a 350-mm^2 Baerveldt glaucoma implant with trabeculectomy using MMC 0.4% for 4 minutes in eyes with previous failed trabeculectomy and/or cataract surgery (43). The study revealed a higher success rate in the tube arm, with the cumulative probability of failure over 5 years of follow-up being 29.8% in the tube group compared to 46.9% in the trabeculectomy group (43). Additionally, tube-shunt surgery initially resulted in greater medication use during the first 2 years, but medication usage became similar between the groups after this period (43). Adverse events were comparable in both groups, while the reintervention rate was higher in the trabeculectomy arm, with 29% requiring a reoperation, compared to 9% in the tube arm (43).

The Primary Tube Versus Trabeculectomy (PTVT) Study compared the safety and efficacy of the Baerveldt glaucoma implant with trabeculectomy + MMC 0.4% in eyes with no previous transscleral procedures and found that, although the mean IOP was statistically significantly lower in the first year postoperative, there was no difference in the third and fifth year (3). The majority of patients at the end of the follow-up had an IOP ≤ 14 mmHg (3).

2.4.1.3 Ahmed ClearPath 250 and 350

The device does not include a valve and was approved by the FDA in 2019 (6). It has a thinner profile than the BGI, facilitating the formation of a lower and more diffuse bleb (4,6). It is supposed to cause less inflammation and diplopia than the BGI (4,6). The design allows for limited muscle manipulation during surgery and eliminates the need for extensive posterior dissection because the fixation eyelets are positioned more anteriorly (4,6). It comes with a preloaded polypropylene ripcord in the lumen to reduce the rate of early hypotony (4,6). A retrospective study with a 24-month follow-up on 12 eyes demonstrated a significant reduction in IOP, from 29.0 mmHg to 12.2 mmHg, with minimal postoperative complications (44). A retrospective noninferiority comparative study between the Ahmed ClearPath and the BGI demonstrated similar outcomes in both groups regarding final IOP, BCVA, and complication rates. However, the Ahmed ClearPath group required fewer medications (45).

2.4.1.4 Paul glaucoma implant

The Paul glaucoma implant obtained the Conformité Européenne (CE) mark in Europe in 2018 but is still awaiting FDA approval (6). With a tube boasting an inner diameter of 0.127mm, it is designed to minimize hypotony, tube exposure, and endothelial cell loss compared to alternative tube implants(6). The intraluminal 6-0 Prolene suture effectively prevents hypotony during the early postoperative phase and facilitates controlled intraocular pressure (IOP) management through extraction between postoperative weeks 8 and 12. (15,16,18). The three-year clinical outcomes demonstrated a failure rate of 14.6%, with a mean intraocular pressure (IOP) of approximately 15 mmHg, down from a preoperative value of 20.6 mmHg. The incidence of hypotony in this study was 35.4%, which was self-limiting in most cases (15). A study comparing the PGI to the BGI showed lower IOP in the BGI group (46). The preoperative IOP was 23.7±6.9 mmHg in the PGI group, decreasing to 13.1±2.9 mmHg, whereas in the BGI group, it dropped from 26±7.3 mmHg to 10.3±4.9 mmHg at one-year follow-up (46). Additionally, the BGI group required fewer antiglaucoma medications at the end of the follow-up (46). The incidence of complications was similar between the two groups (46).

2.4.2 Flow-Restricted Drainage Devices

The incorporation of a valve mechanism provides resistance to the flow and thus reduces the incidence of hypotony until the plate becomes encapsulated (1). The critical site for pressure drop, however, is at the capsule surrounding the glaucoma implants (47).

2.4.2.1 Ahmed Glaucoma valve

It is one of the most commonly used implants (1). A silicone tube is connected to a silicone sheet valve, which is held in a polypropylene body (1). The bodies of the S2 and FP-7 models have a surface area of 184 mm^2, and the reservoir plates are made from polymethylmethacrylate and silicone, respectively (1). In a retrospective study, the FP-7 model showed lower IOP at one year compared to the S2 model (48). The valve mechanism aims to maintain the IOP between 8 and 10 mmHg in the early postoperative period (1). The pediatric size of 96 mm^2 is available in silicone in the FP-8 model or polypropylene in the S3 model (1). The device needs to be primed before insertion to ensure that the valve opens adequately (1). The AGV also has a transient hypertensive phase at 4 to 8 weeks postoperatively due to the low capsule permeability during this period (1). The ABC and AVB studies compared the BGI to the AGV and showed that the BGI produces lower IOP with fewer medications but has higher rates of hypotony and hypotony-related complications (12,20). The pooled analysis indicates that the BGI reduces the IOP to 13.2 ± 4.7 mmHg, compared to 15.8 ± 5.2 mmHg in the AGV, with a failure rate at 5 years of 37% versus 49%, respectively (8).

2.4.2.2 The eyeWatch system

The system consists of two implants: the eyeWatch implant and the eyePlate (6,49). The eyePlate is inserted under the muscle insertions, and then the eyeWatch implant is attached to it (6,49). The eyeWatch implant features a magnetic disk that allows selective opening or closing of an internal deformable tube. This adjustment can be performed using an external tool called the eyeWatch Pen, which includes a compass and an external magnet (6,49). At the 2-year follow-up, results demonstrated a 47% reduction in intraocular pressure (IOP) from a mean baseline of 23 mm Hg (49). Complications occurred in 9% of patients during both the early and late periods (49).

2.5 **Postoperative complications of the glaucoma drainage devices**

2.5.1 Hypotony

It primarily occurs with open-tube drainage devices because they offer no resistance to the outflow until the fibrous capsule forms around the plate (1). To prevent early hypotony, the lumen of non-valvular devices needs to be obstructed (1). With the PGI, this is achieved by temporarily occluding the tube lumen using a stent with 6-0 Prolene (1). Other techniques, such as suture ligation of the tube or two-stage implantation, have been described with other GDDs (1). If early postoperative hypotony occurs in combination with a flat anterior chamber or choroidal detachment, injecting cohesive viscoelastic into the anterior chamber and close observation may be helpful (1). For refractory hypotony, removal of the tube from the anterior chamber is recommended to prevent corneal decompensation, with tube reinsertion in the following days (1). Late hypotony from GDD implantation is usually treated with permanent occlusion of the proximal tube or removal of the tube from the anterior chamber (1).

2.5.2 Peak intraocular pressure

The GDD can result in both early and late elevated intraocular pressure (IOP) (1). Non-valved devices typically exhibit elevated IOP until the ligature suture dissolves or the intraluminal ripcord is removed (1). The tube can also become obstructed in any GDD during the early postoperative period by fibrin, blood, iris, neovascular membrane, vitreous, or silicone oil (1). In cases of neovascular glaucoma, using an anti-VEGF agent in combination with panretinal

photocoagulation seems to help control IOP (50). Other techniques to manage obstructions include irrigating the tube with a balanced salt solution using a 30-gauge cannula through a paracentesis incision and employing Nd or neodymium-doped yttrium lithium fluoride lasers to open occluded tubes (1). The hypertensive phase can be managed medically, or in refractory cases, with fenestrations in the tube or a trabeculectomy (1). The intraluminal ripcord should not be removed until 8 weeks after surgery (1).

The hypertensive phase in GDD occurs after the capsule forms around the plate, with IOP usually stabilizing 3-6 months post-surgery (1). This phase is directly associated with a poor prognosis for IOP control (1). Using aqueous suppressants early postoperatively, if the IOP is higher than 10 mmHg, can improve IOP control (1). If elevated IOP occurs in the late postoperative period, it is usually due to a thickened capsule, requiring needling or revision with partial removal of the capsule (1). However, up to 30% of bleb encapsulations recur, and a new GDD in another quadrant may be needed (1).

2.5.3 Migration

If the tube is not correctly fixed to the sclera, it can migrate posteriorly out of the anterior chamber (1). Anterior migration typically occurs due to dislocation from the external plate (1). In pediatric patients, as the eye grows, the tube can lose its original position (1). The treatment involves surgically repositioning the tube, or if it is too short, using an extension tube (1).

2.5.4 Extrusion, and Erosion

Erosion of the silicone tube through the overlying conjunctiva is a recognized complication of glaucoma drainage device implantation (1). To prevent this, the tube should be covered by a scleral flap, scleral tunnel, preserved sclera, dura, fascia lata, or pericardium (51,52). Younger age and inflammatory-type glaucoma have been identified as factors associated with a higher risk for tube erosion (51,52).

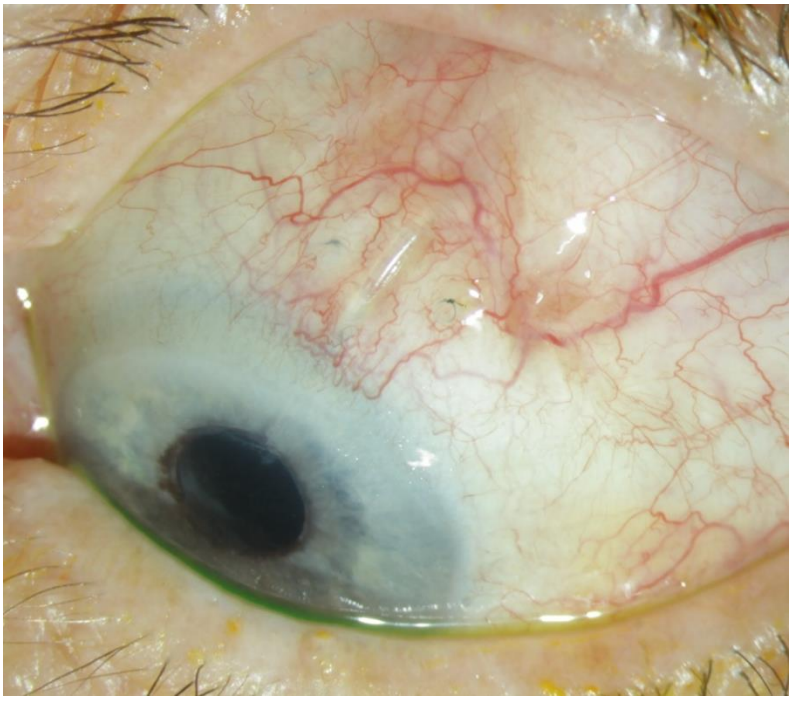

Figure 3. Tube Extrusion in a patient at University Medical Centre Mainz

2.5.5 Endophthalmitis

If an infection occurs, removal of the drainage device is necessary, along with antibiotic therapy and surgical management of the infection (1). Exposure of the tube is a major risk factor for infection (1).

2.5.6 Visual loss

There are multiple causes of visual loss, which can range from mild to severe. These include hypotony, elevated intraocular pressure, retinal detachment, vitreous haemorrhage, cystoid macular edema, and operating microscope–induced retinal phototoxicity.

2.5.7 Corneal decompensation and graft failure

The rate of corneal decompensation or graft failure is higher than with trabeculectomy (1). Multiple factors contribute to corneal decompensation in eyes with a tube implant. In many cases, corneal decompensation is already present before tube surgery. Factors such as the use of mitomycin in prior glaucoma surgeries, the number of previous intraocular surgeries, and the severity and duration of elevated intraocular pressure all play a significant role in the progression of corneal disease (53,54). Tube-cornea touch and retrograde flow from the encapsulated reservoir to the anterior chamber are causes of endothelial cell loss (1). Although there is no difference in tube-cornea touch between the AGV and the BGI, the rates of corneal decompensation and the need for corneal grafts are higher with the BGI (54). When tube-cornea contact is observed, it may be necessary to remove the tube from the anterior chamber, shorten it, and then reinsert it, or to trim it in situ within the anterior chamber (1).

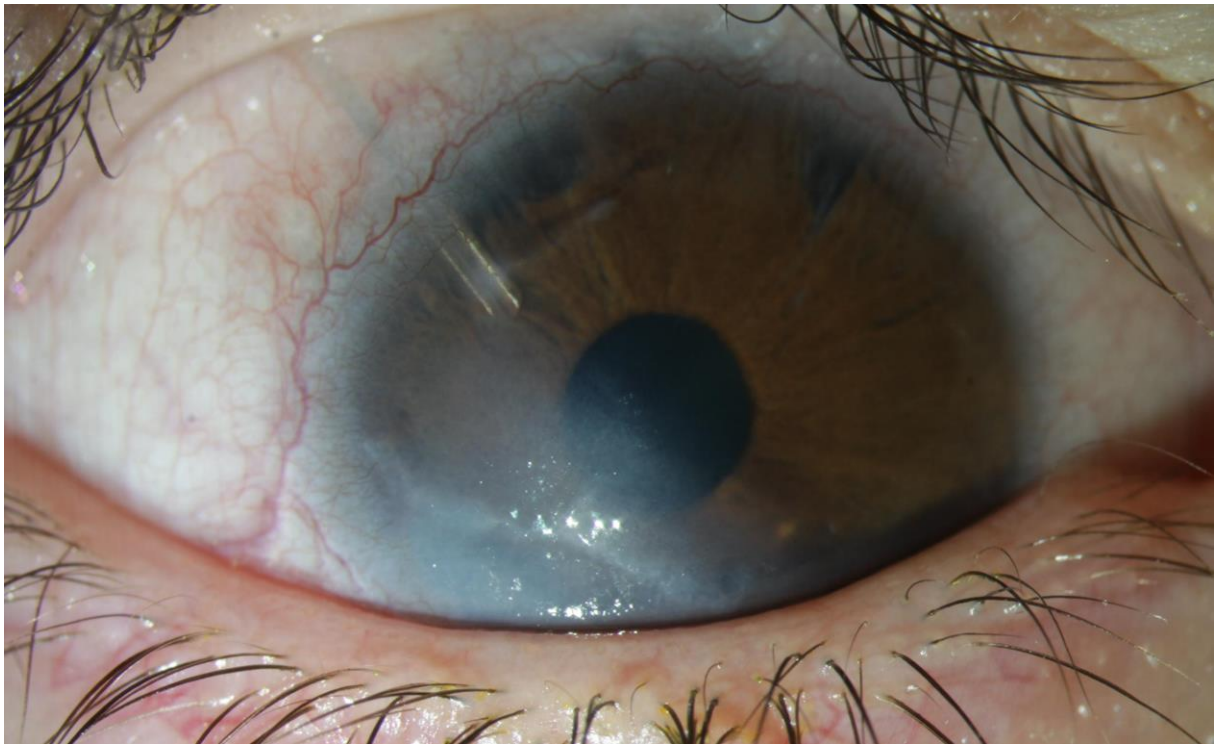

Figure 4. Corneal decompensation on the side of the Paul-Glaucoma-Implant in a patient at University Medical Centre Mainz

2.5.8 Diplopia

Diplopia occurs more frequently with devices that have larger plates and when they are implanted in the superonasal quadrant (1). The height of the bleb could also play a role. Diplopia may resolve spontaneously over time, but surgical intervention, including relocation of the device or exchange for a new device with a smaller plate, may be necessary (1).

2.5.9 Epithelial and fibrous downgrowth

This complication is very rare and occurs mostly in tubes implanted at the limbus (1). Epithelial downgrowth is characterized by the invasion of surface epithelial cells into the anterior chamber, potentially causing angle obstruction and elevated intraocular pressure that is

difficult to control. In contrast, fibrous downgrowth is usually less aggressive, involving the invasion of fibrovascular connective tissue into the eye.

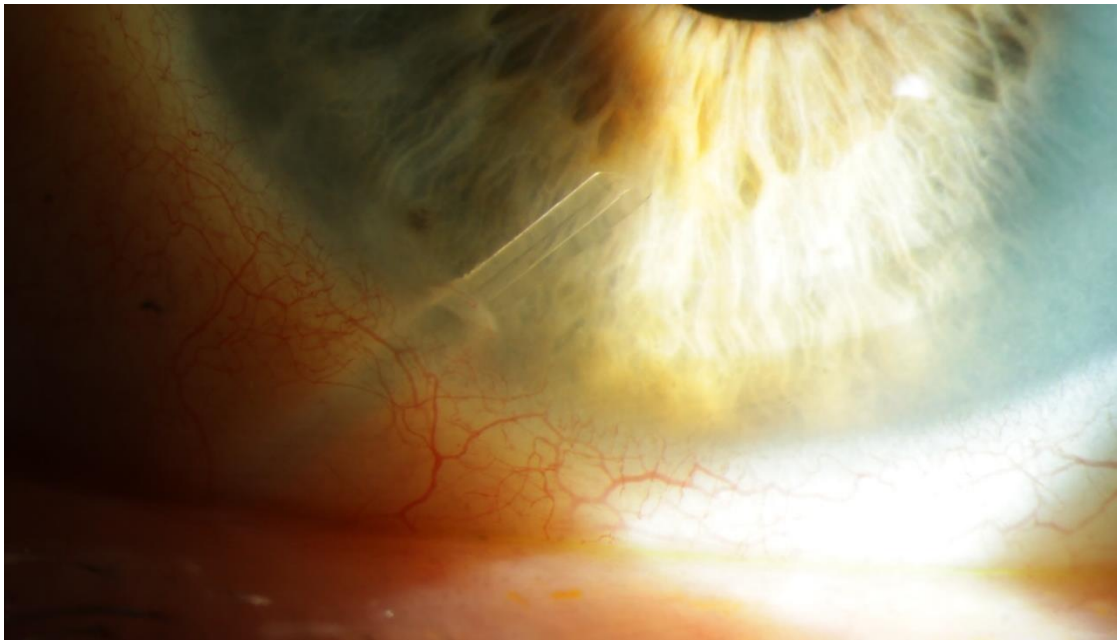

Figure 5. Fibrous downgrowth around the entry point of the tube in the anterior chamber in a patient at University Medical Centre Mainz

2.5.10 Iris atrophy and pupil deformity

Contact between the tube and the iris, or the adherence of the iris root to the tube insertion, can cause iris atrophy or corectopia (1,39). However, these issues typically do not represent a significant ocular problem (1). It is more important to ensure that the tube remains distant from the endothelium (1).

2.5.11 Retinal complications

Retinal detachment, suprachoroidal haemorrhage, choroidal effusions, and vitreous haemorrhages have been described (1,39).

3 Materials and Methods

3.1 **Patient eligibility**

3.1.1 Inclusion criteria

Patients aged 18 and older who underwent standalone Paul Glaucoma Implant surgery with at least 12 months of follow-up were compared with the most recent patients who received a standalone Ahmed Glaucoma Valve and had a 12-month follow-up at the University Medical Center of Mainz from 2019 until 2023.

3.1.2 Exclusion criteria

Patients younger than 18 years, who underwent a combined procedure, or did not have a minimum of 12 months follow-up.

3.2 **Surgical techniques**

3.2.1 Ahmed Glaucoma Valve

Disinfection of the eye to be operated on with povidone-iodine, looping of the cornea with 7.0 silk. Creation of a limbal-based conjunctival flap involved making an incision of the conjunctiva approximately 10 mm posteriorly from its insertion at the limbus. The quadrant for the incision was selected based on the available space and the quality of the conjunctiva and sclera observed intraoperatively by the surgeon. Priming of the Ahmed implant, and insertion of the implant body. Application of MMC 0.2 mg/ml in the posterior Tenon space over the Ahmed plate using an 8x8 mm sponge, application duration 1-5 minutes, rinsing with 30 ml BSS. Creating a half-thickness scleral flap. Fixation of the Ahmed plate with a 6.0 prolene suture. Trimming the tube. Paracentesis at 10 o'clock with insertion of Healon. Marking the entry point for the tube on the sclera 2 mm behind the limbus with a blue pencil under the flap. Puncturing into the anterior chamber with a 14-gauge cannula, followed by inserting the trimmed tube into the anterior chamber. Closure of the scleral flap with four 10/0 nylon sutures, tightening the entry point with 10/0 nylon for sealing. Closure of Tenon's capsule with 8/0 Vicryl in interrupted sutures and closure of the conjunctiva (continuous) with 8/0 Vicryl. Adjusting the anterior chamber form and pressure with balanced salt solution. Closure of the paracenteses. Verifying the eye pressure by palpating the cornea with a cannula. Removal of the traction suture. Some viscoelastic is left in the anterior chamber. Subconjunctival injection of 4 mg Dexamethasone, application of ofloxacin ointment, bandage.

If Tutoplast® Fascia lata or Tutopatch® Bovine Pericardium were used, no scleral flap was created. The entry point for the tube was marked directly on the sclera, 2 mm behind the limbus. Placing the mesh material (Tutopatch® or Tutoplast®) on the tube and fixing it with 10.0 nylon were done after the trimmed tube was inserted into the anterior chamber.

3.2.2 Paul Glaucoma Implant

Disinfection of the eye to be operated on with povidone-iodine, looping of the cornea with 7.0 silk. Creation of a limbal-based conjunctival flap involved making an incision of the conjunctiva approximately 10 mm posteriorly from its insertion at the limbus. The quadrant for the incision was selected based on the available space and the quality of the conjunctiva and sclera observed intraoperatively by the surgeon. Blunt dissection forward and backward with scissors, and further to the limbus with a crescent knife. Cauterization. Placement of one Merocel sponge soaked with MMC 0.02%. Duration: 3 minutes. Irrigation with 30 ml NaCl. Insertion of an intraluminal 6.0. Prolene suture into the tube. Paracentesis and insertion of cohesive viscoelastic are performed until the intraocular pressure, assessed by palpation, reaches approximately 20-25 mmHg. Insertion of the Paul implant with looping of the adjacent rectus muscles. Fixation with 8.0 Prolene anteriorly. Subsequent trimming of the tube and puncture with a 26-G needle parallel to the sclera to prepare a tunnel. Inserting trimmed tube into the anterior chamber through the created tunnel. Adjusting the anterior chamber form and pressure with balanced salt solution. Closure of the paracenteses. Placing a 3x2 mm mesh material (Tutopatch® or Tutoplast®) on the tube, fixation with 10.0 nylon. Closure of Tenon's capsule and conjunctiva (continuous) with 8/0 Vicryl. Verifying the eye pressure by palpating the cornea with a cannula. Removal of the traction suture. Some viscoelastic is left in the anterior chamber. Subconjunctival injection of 4 mg Dexamethasone, application of ofloxacin ointment, bandage.

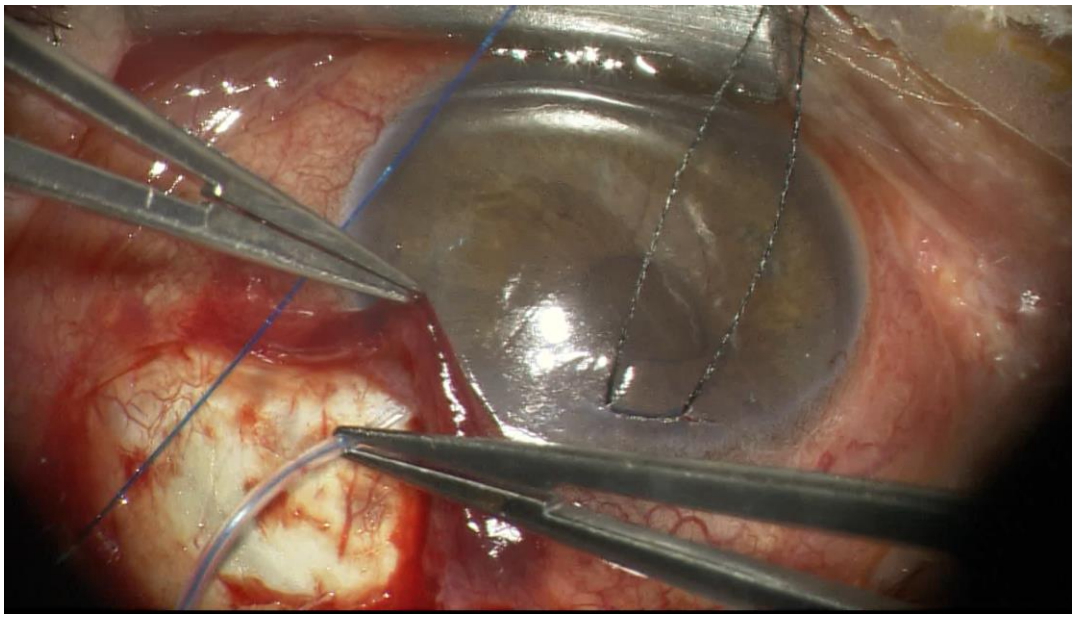

Figure 6. Insertion of the trimmed tube into the anterior chamber through the created tunnel.

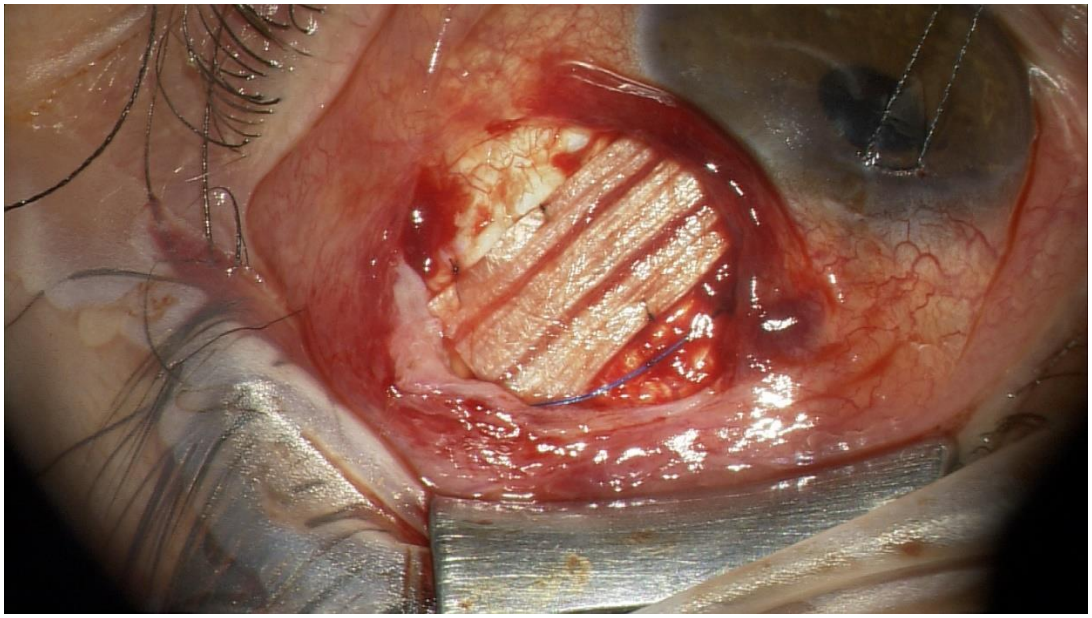

Figure 7. Tube covered by a Tutoplast® fascia lata

If a scleral flap was used, after trimming the tube, a half-thickness scleral flap and a scleral tunnel between the plate and the scleral flap were created. The trimmed tube was then inserted into the scleral tunnel, followed by the use of a 25-gauge needle to enter the anterior chamber. The tube was inserted through this puncture into the anterior chamber. The scleral flap was closed with two 10.0 nylon sutures. The anterior chamber form and pressure were adjusted with balanced salt solution, and the paracenteses were closed. Tenon's capsule and the conjunctiva were closed continuously with 8.0 Vicryl. The eye pressure was verified by palpating the cornea with a cannula. The traction suture was removed, and some viscoelastic was left in the anterior chamber. A subconjunctival injection of 4 mg Dexamethasone was administered, followed by the application of ofloxacin ointment and a bandage.

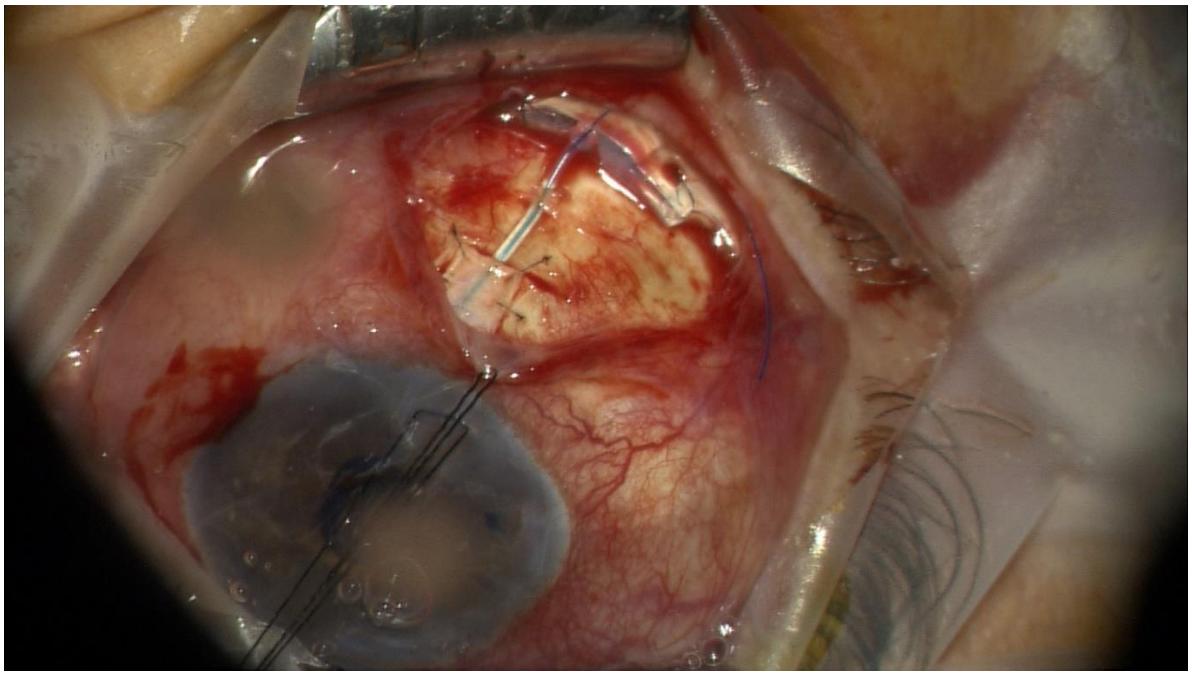

Figure 8. Tube covered by a scleral flap and fixed in a scleral tunnel.

3.3 **Study measurements**

Patient identification was conducted chronologically using an electronic surgical case register, with subsequent verification through manual chart review. To ensure patient data protection, all data were pseudonymized prior to access. Post-operative data were collected at specific time points: day 1, month 1 (± 1 week), months 3 and 6 (± 2 weeks), month 12 (± 1 month). The collected post-operative data encompassed measurements of intraocular pressure (IOP), changes in the number of prescribed antiglaucoma medications, and the occurrence of adverse events.

- Age: Age in years at the time of surgery.
- Sex: Male, female, or diverse, according to the electronic register.
- Ethnicity: Cultural or descent background as recorded in the electronic register.
- Diabetes: Presence or absence of the disease. The type of diabetes was not specified.
- Type of Glaucoma
- Tonometry: The intraocular pressure was measured with an applanation tonometer at the University of Mainz. If this is not possible, other techniques like iCare or palpation were used. The specific measurement technique was not recorded at each time point because the majority of cases were done with an applanation tonometer, and this would not affect the statistical calculations.
- Preoperative and postoperative medication: The number of the active substances.
- Use of acetazolamide systemically.
- Lens status: pseudophakic, phakic, aphakic at the time of the surgery
- Number and type of previous glaucoma surgeries
- Type of previous intraocular surgeries (except glaucoma and cataract)
- Preoperative and postoperative visual acuity: Visual acuity was recorded on a decimal scale using the standardized Snellen method, as is customary for all patients at Hospital Mainz. The records were converted into the Logarithm of the Minimum Angle of Resolution (logMAR) using the formula -log10 (decimal visual acuity). The following low vision transformations into logMAR were used: finger count = 2.0, hand motion = 2.7 logMAR, light perception = 3.7 logMAR, and no light perception = 4.7 logMAR (55).

3.4 **Outcome measurements**

The results were presented according to the last guideline of the EGS (39).

3.4.1 Primary outcome measurements

3.4.1.1 Intraocular pressure reduction

Mean/median absolute postoperative IOP at one-year follow-up for AGV and PGI

Mean/median postoperative IOP change at one-year follow-up for AGV and PGI

Mean/median percentage postoperative IOP change at one-year follow-up for AGV and PGI

3.4.1.2 IOP-lowering medication reduction

Mean/median number of postoperative medications at one-year follow-up for AGV and PGI

Mean/median number of postoperative medications change at one-year follow-up for AGV and PGI

3.4.2 Secondary outcome measurements

3.4.2.1 IOP trend over duration of follow-up

Mean/median absolute postoperative IOP at each follow-up time point

3.4.2.2 IOP-lowering medication use trend over duration of follow-up

Mean/median number of postoperative medications at each follow-up time point

3.4.2.3 Failure

Failure was considered if the IOP was greater than 21 mmHg or less than 6 mmHg at the one year follow-up, removal of the implant or in cases of loss of light perception vision or the need for further surgical intervention to control the IOP.

3.4.2.4 Surgical success

Proportion of patients at postoperative IOP targets at one-year follow-up:

- IOP1, defined as ≤21 mmHg with a percentage reduction of ≥ 25% from the baseline
- IOP2, defined as ≤18 mmHg with a percentage reduction of ≥ 30% from the baseline
- IOP3, defined as ≤15 mmHg with a percentage reduction of ≥ 40% from the baseline

Complete success was achieved for each IOP target if the final IOP was attained without treatment, while qualified success was achieved if the target IOP was reached with the inclusion of treatment.

3.4.2.5 Postoperative visual acuity

Mean/median absolute postoperative visual acuity and mean/median postoperative change measured in logMAR at one-year follow-up for AGV and PGI

3.4.2.6 Intraoperative and postoperative complications

Numerical hypotony (IOP <6 mmHg with no associated complications) clinical hypotony (IOP <6 mmHg associated with choroidal detachment and/or anterior chamber depth reduction), choroidal detachment, severe anterior chamber shallowing (with iris-corneal touch), hyphema, endophthalmitis, IOP spike (elevation of 10 mmHg from preoperative IOP), corneal decompensation (corneal edema persisting for over 4 weeks), persistent uveitis (SUN grade >1+cell in the anterior chamber persisting for 6 weeks), no light perception, leak, ptosis,

diplopia, corneal Dellen, dysesthesia, iridodialysis, iris atrophy, device obstruction, device malposition, fibrous/epithelial ingrowth, device migration, and device exposure. An early postoperative complication was defined as one that occurred within the first 3 months after surgery. The need for ripcord removal in the PGI group was analysed; however, it was not considered a criterion for surgical failure.

3.5 **Statistical Analysis**

The statistical analysis was performed using IBM SPSS Statistics version 23 (IBM Corp, New York, USA). Statistical significance was defined by a p-value less than 0.05. Data were tested for normal distribution using Kolmogorov-Smirnov and Shapiro-Wilk test and were expressed as number (percentage %), mean (standard deviation or 95% confidence interval) or median (interquartile range). The Chi-squared test was used to analyse the relationship between categorical variables if less than 20% of the cells had an expected count of less than 5. If this assumption was violated, Fisher's Exact Test was used for binary variables, and the Likelihood Ratio Test was used for variables with more than two categories. The Mann–Whitney U test was used to analyse intergroup differences when the distribution was non-parametric, while the Wilcoxon signed-rank test was utilized to assess intragroup differences. The paired Student t-test was employed to evaluate both intra- and inter-group changes when the distribution was parametric. Patients who underwent additional glaucoma surgery, had the implant removed, or experienced a loss of light perception during follow-up were censored from analysis for the mean/median intraocular pressure and number of glaucoma medications after the time of those events.

3.6 **Ethical aspects**

The retrospective nature of this study exempts it from Ethics Committee approval. The collection and analysis of existing internal routine clinical data were performed in accordance with the ethical standards set forth in the Declaration of Helsinki of 1964 and Good Clinical Practice guidelines.

4 Results

4.1 **Baseline Characteristics of Study Population**

The characteristics of the study population are summarized in Table 2. A total of 24 patients underwent standalone AGV implantation, while 28 patients underwent standalone PGI implantation. The mean age (±SD) was 48.3±17.7 years in the AGV group and 47.6±16.8 years in the PGI group. The mean preoperative IOP was 34.0±4.1 mmHg in the AGV group and 32.8±9.0 mmHg in the PGI group. The median (IQR) number of classes of intraocular pressure-lowering medications was 3.5 (0-4) in the AGV group and 3.0 (0-5) in the PGI group.

Table 2. Baseline demographic and clinic characteristics of the study population according to the surgical procedure.

	AGV (n=24)	PGI (n=28)	p-value
Age, years Mean (SD)	48.3 (17.7)	47.6 (16.8)	0.88[a]
Gender, n (%) Male Female	12 (50.0) 12 (50.0)	17 (60.7) 11 (39.3)	0.44[b]
Ethnicity, n (%) North European African South Asian	12 (50.0) 1 (4.2) 1 (4.2)	21 (75.0) 3 (10.7) 1 (3.6)	<0.01[c]

Middle East South European Non available	2 (8.3) 0 (0.0) 8 (33.3)	1 (3.6) 2 (7.1) 0 (0.0)	
Laterality, n (%) Right Left	 7 (29.2) 17 (70.8)	 13 (46.4) 15 (53.6)	0.20[b]
Diabetes, n (%) Yes No	 4 (16.7) 20 (83.3)	 3 (10.7) 25 (89.3)	0.69[d]
Diagnosis, n (%) Primary open angle glaucoma Secondary open angle glaucoma Neovascular glaucoma Anterior segment developmental anomaly glaucoma Primary angles closure glaucoma	 2 (8.3) 13 (54.2) 5 (20.8) 3 (12.5) 1 (4.2)	 5 (17.9) 17 (60.7) 2 (7.1) 4 (14.3) 0 (0.0)	0.35[c]
Lens status, n (%) Pseudophakia Phakia Aphakia	 17 (70.8) 4 (16.4) 3 (12.5)	 17 (60.7) 10 (35.7) 1 (3.6)	0.18[c]
Previous intraocular surgery (other than cataract surgery and glaucoma surgery, n (%) No Pars plana Vitrectomy Penetrating Keratoplasty Descemet Membrane Endothelial Keratoplasty Laser-in-situ-Keratomileusis	 14 (58.3) 8 (33.3) 2 (8.4) 0 (0.0) 0 (0.0)	 18 (64.3) 5 (17.9) 3 (10.7) 1 (3.6) 1 (3.6)	0.30[c]
Previous glaucoma laser, n (%) Yes No	 4 (16.7) 20 (83.3)	 1 (3.7) 26 (96.3)	0.18[d]
Previous glaucoma surgery, n (%) Yes No	 22 (91.7) 2 (8.3)	 21 (75.0) 7 (25.0)	0.15[d]
Previous cyclodestructive procedure, n (%) Yes No	 17 (70.8) 7 (29.2)	 14 (50.0) 14 (50.0)	0.18[b]
Number of previous glaucoma surgeries Mean (SD) Median (IQR)	 2.6 (1.9) 2.0 (2.0)	 1.9 (1.6) 2.0 (3.0)	0.27[e]
Visual acuity, logMAR Mean (SD) Median (IQR)	 0.9 (1.5) 0.9 (1.7)	 0.9 (0.9) 0.56 (1.35)	0.38[e]
Preoperative IOP, mm Hg Mean (SD)	 34.0 (9.4)	 32.8 (9.0)	0.63[a]
Number of classes of intraocular pressure-lowering medications Mean (SD) Median (IQR)	 3.2 (1.1) 3.5 (1.0)	 3.0 (1.0) 3.0 (2.0)	0.40[e]
Oral Acetazolamide, n (%) Yes No	 15 (62.5) 9 (37.5)	 16 (57.1) 12 (42.9)	0.70[b]

[a] T-test. [b] Chi-squared test. [c] Likelihood Ratio. [d] Fisher's Exact Test. [e] Mann-Whitney test

There were no statistically significant differences between the two populations, except for ethnicity. Ethnicity information was available for only 16 patients in the AGV group. However, in both groups, the predominant ethnicity was Caucasian. Most patients had a diagnosis of secondary glaucoma in both groups (54.2% in the AGV group and 60.7% in the PGI group). Primary open-angle glaucoma was present in 8.3% of the AGV group and 17.9% of the PGI group. The majority of patients in both groups were pseudophakic and had no previous intraocular surgeries other than cataract or glaucoma surgery.

In the AGV group, 16% of the patients had received glaucoma laser treatment: one patient underwent SLT, one patient underwent ALT, and two patients had iridotomies. In comparison, one patient in the PGI group (3.7%) had received ALT as prior glaucoma laser treatment. Previous glaucoma surgery had been performed in 91.7% of the AGV group and 75% of the PGI group. Charts 1 and 2 show the frequency of previous glaucoma surgeries performed in both groups. The most common surgery in the AGV group was cyclocryocoagulation, followed by trabeculectomy, while in the PGI group, it was trabeculectomy, followed by cyclocryocoagulation and controlled cyclophotocoagulation.

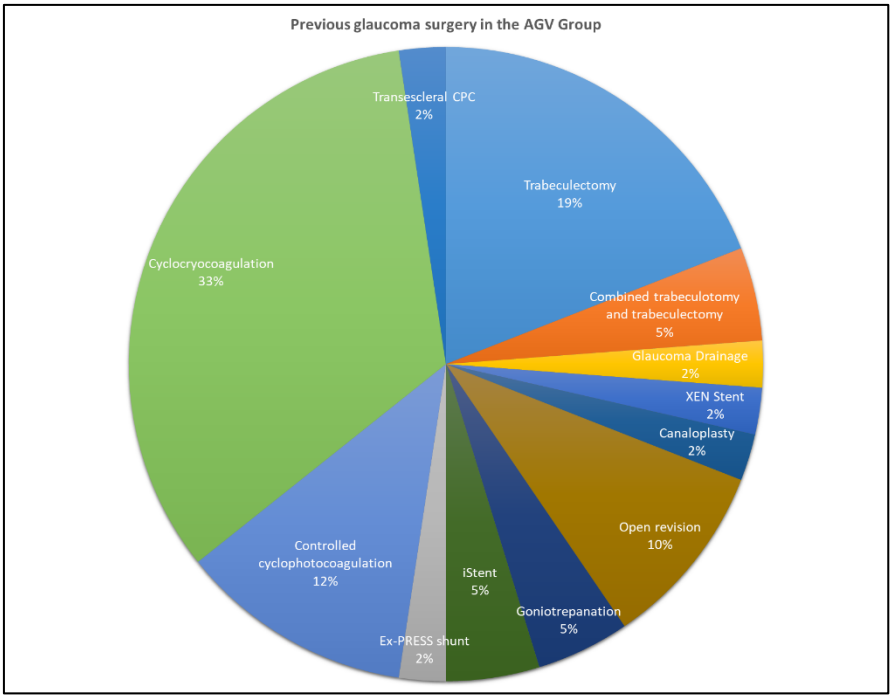

Chart 1. Previous glaucoma surgeries in the Ahmed-Glaucoma-Valve group.

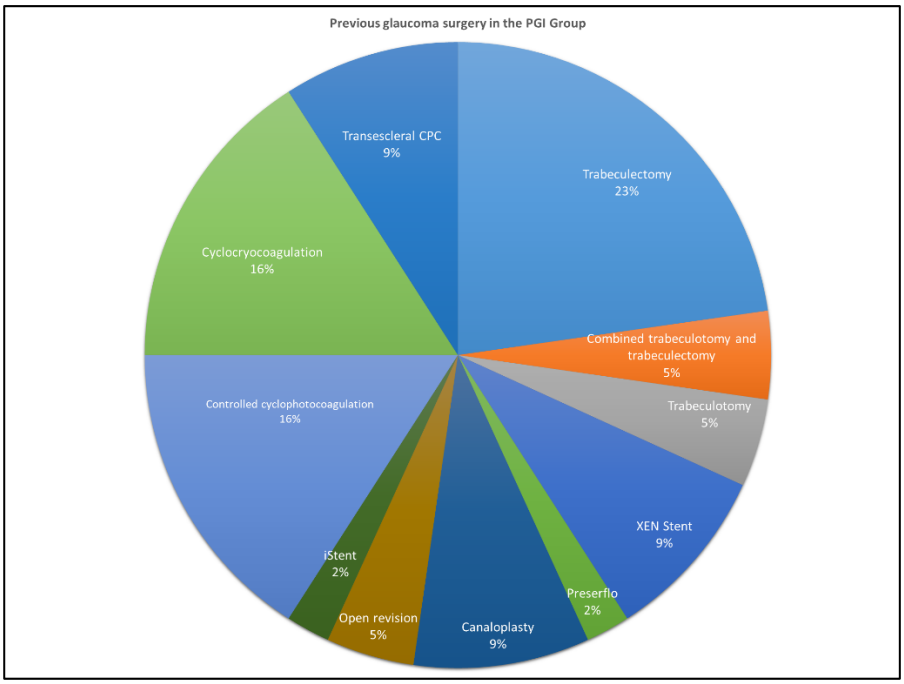

Chart 2. Previous glaucoma surgeries in the Paul-Glaucoma-Implant group.

4.2 **Intraoperative characteristics**

	AGV (n=24)	PGI (n=28)	p-value
Patch, n (%)			
Tutopatch® bovine pericardium	3 (12.5)	17 (60.7)	<0.01[a]
Tutoplast® Fascia lata	3 (12.5)	2 (7.1)	
Scleral flap	18 (75.0)	8 (28.6)	
Only scleral tunnel	0 (0)	1 (3.6)	
Mitomycin, n (%)			
0.02%	24 (100.0)	27 (96.4)	1.00[b]
None	0 (0)	1 (3.6)	
Place, n (%)			
Nasal superior	5 (20.8)	3 (10.3)	0.62[a]
Temporal superior	16 (66.7)	23 (82.1)	
Temporal inferior	2 (8.3)	1 (3.6)	
Nasal inferior	1 (4.2)	1 (3.6)	
Surgical time			
Mean (SD)	1h11 (0h29)	1h13 (0h21)	0.80[c]

[a] Likelihood Ratio. [b] Fisher's Exact Test. [c] T-test.

There was a statistically significant difference in the methods used to cover the tube. In the AGV group, most patients received a scleral flap, whereas in the PGI group, most patients were treated with a Tutopatch® bovine pericardium. The majority of patients in both groups received intraoperative mitomycin, and the glaucoma drainage device (GDD) was typically placed in the superior temporal quadrant. There was no significant difference in surgical time between the two groups.

4.3 **Primary outcomes**

4.3.1 Intraocular pressure reduction

The median preoperative IOP (IQR) decreased from 29.5 (21-42) to 16.0 (7-37) at the one-year follow-up in the AGV group (p<0.01, Wilcoxon signed-rank test). In the PGI group, it

decreased from 34.0 (13-56) to 16.0 (7-21) (p<0.01, Wilcoxon signed-rank test). The mean postoperative IOP change ±SD at the one-year follow-up was -15.7 ± 11.1 mmHg for the AGV group and -18.0 ± 9.9 mmHg for the PGI group. The mean percentage reduction in postoperative IOP at the one-year follow-up was 44.7 ± 33.4% for the AGV group and 50.6 ± 19.9% for the PGI group. Chart 3 represents the change in IOP from the preoperative value to the one-year follow-up. Three cases stand out in the chart. The first patient, who had uveitic glaucoma and underwent PGI implantation, had a preoperative IOP of 13 mmHg while on three glaucoma medications and had a history of LASIK. One year postoperatively, the IOP was 12 mmHg with only one medication. The surgery was indicated due to visual field progression. The second patient, also with uveitic glaucoma and who received a PGI, had a preoperative IOP of 20 mmHg despite being on three antiglaucoma medication classes and systemic acetazolamide. One year after surgery, the IOP remained at 20 mmHg, but the patient was only on one antiglaucoma medication class. The third patient, diagnosed with secondary glaucoma due to iridocorneal syndrome, received an AGV. Their preoperative IOP was 21 mmHg with three antiglaucoma medication classes. At the one-year follow-up, the IOP had increased to 37 mmHg without any medication. New medications were initiated, and in the following months, the IOP stabilized at 15 mmHg with two antiglaucoma medication classes.

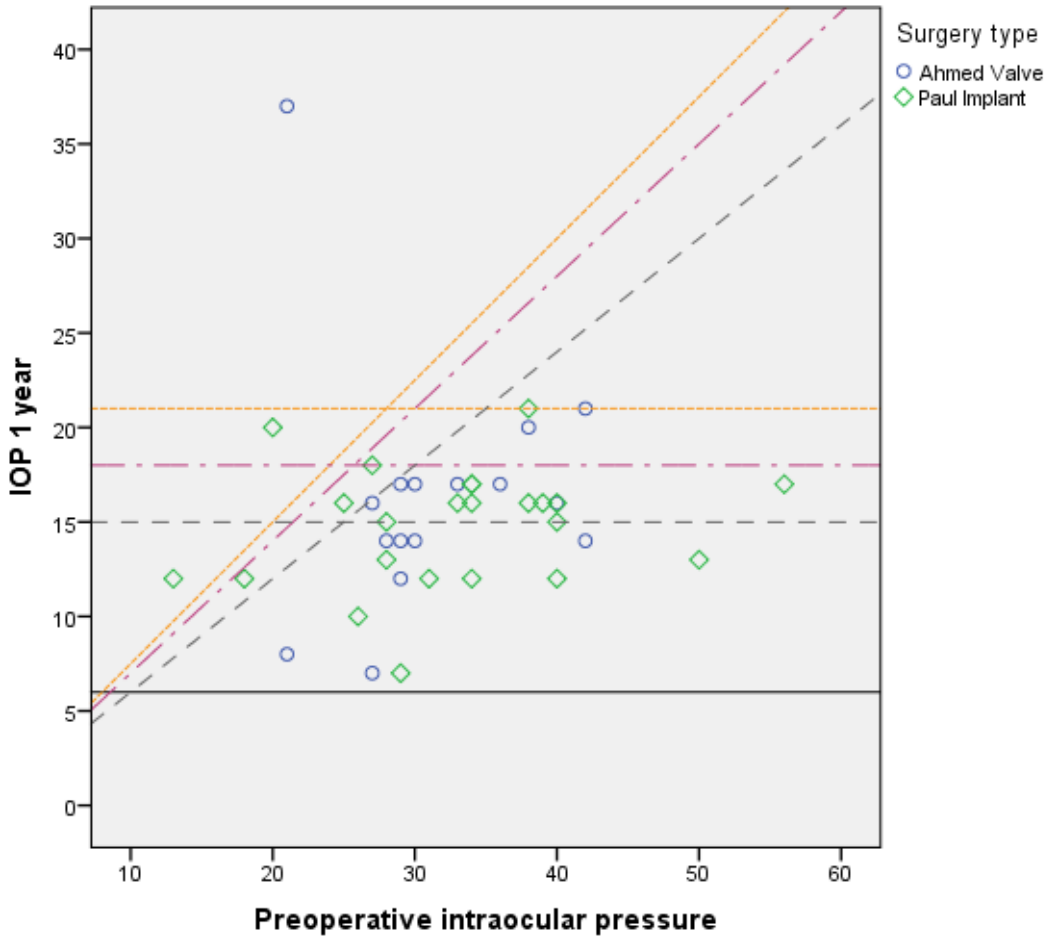

Chart 3. Intraocular pressure preoperative and at one-year follow-up. Combined success criteria of ≤21 mmHg, ≤18 mmHg, and ≤15 mmHg (horizontal lines) and ≥25%, ≥30%, and ≥40% lowering of IOP (oblique lines) are represented in orange, purple, and grey, respectively. The inferior horizontal line represents the lower limit of 6 mmHg IOP.

4.3.2 IOP-lowering medication reduction

The median (IQR) number of classes of intraocular pressure-lowering medications was 3.5 (0-4) in the AGV group and 3.0 (0-5) in the PGI group, and it decreased to 0 (0-3) ($p<0.01$, Wilcoxon signed-rank test) and 0 (0-4) ($p<0.01$, Wilcoxon signed-rank test), respectively. The mean change ±SD in the number of postoperative medications at the one-year follow-up was -1.9 ±1.9 for the AGV group and -2.7 (±1.0) for the PGI group. There were no statistically significant between the two groups (p-values=0.33, Mann-Whitney Test). See Chart 4. The use of oral acetazolamide was reduced from 15 out of 24 patients (62.5%) to 1 out of 18 patients (5.6%) in the AGV group, and from 16 out of 28 patients (57.1%) to 0 out of 22 patients (0%) in the PGI group.

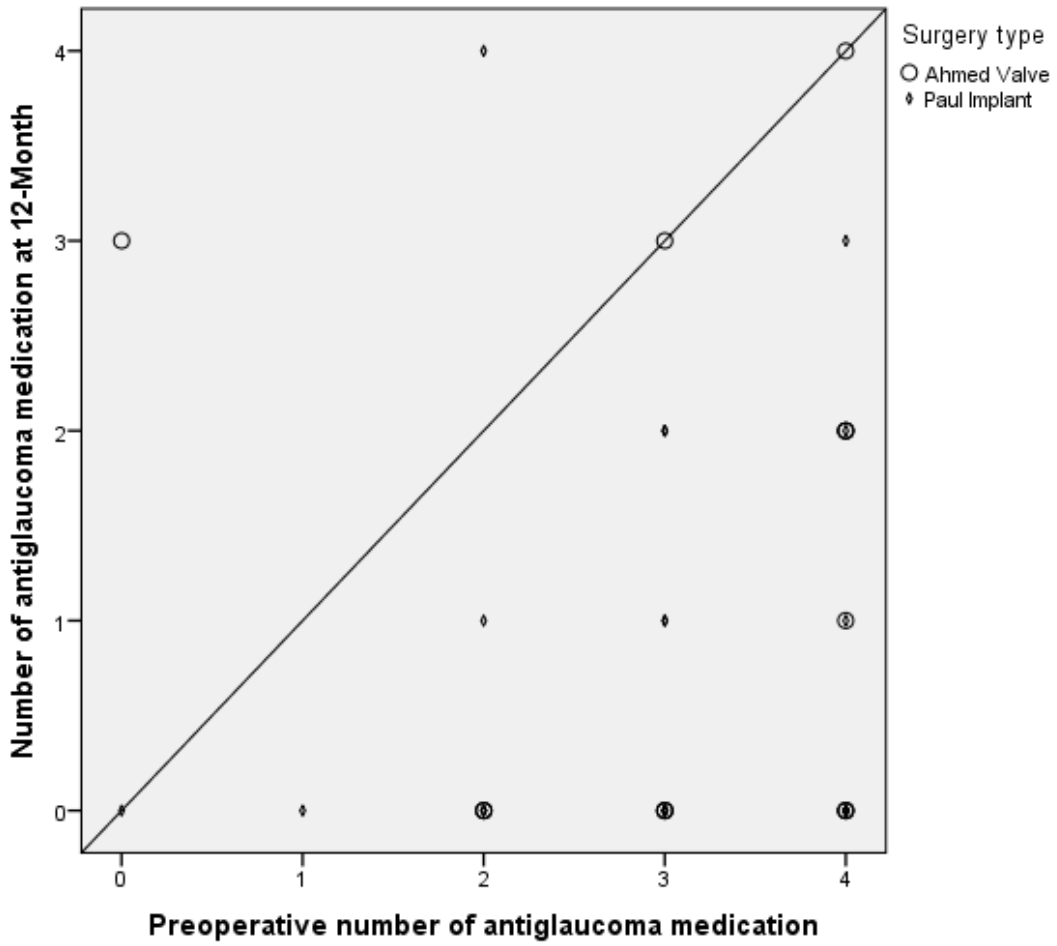

Chart 4. Number of antiglaucoma medications preoperative and at one-year follow-up. The oblique line represents no change from the preoperative value.

4.4 **Secondary outcomes**

4.4.1 IOP trend over duration of follow-up

There were no statistically significant differences between the two groups at any time point (p-values: 0.30, 0.37, 0.69, 0.09, 0.35, 0.39 at 24 hours, 1 week, 1 month, 3 months, 6 months, and 1 year postoperatively, respectively; Mann-Whitney Test). Chart 5 describes the evolution of the IOP. On the first postoperative day, the median intraocular pressure (IOP) was 14 mmHg (IQR: 9) in the AGV group and 11 mmHg (IQR: 7) in the PGI group. In the AGV group, the IOP increased from one month postoperatively, peaked at three months (median: 19 mmHg, IQR: 10), and decreased again at six months. This trend aligns with the known postoperative peak

in glaucoma drainage. In contrast, the PGI group showed its highest median IOP at one month (median: 17 mmHg, IQR: 8).

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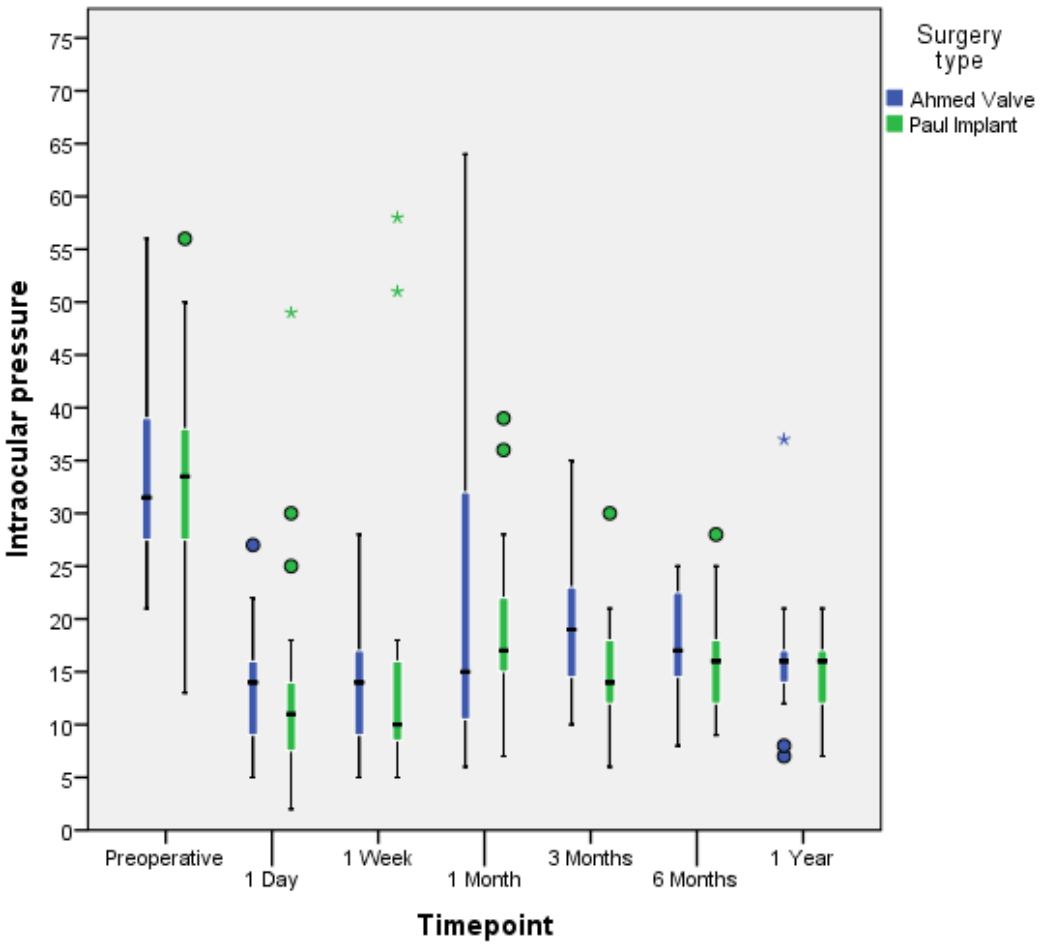

Chart 5. Median IOP values (horizontal black line) and percentiles (boxes-quartiles = 25/75; whiskers = 5/95) given preoperatively and for a follow-up of 1 year. Single outliers are shown by circles and extreme outliers by asterisks.

4.4.2 IOP-lowering medication use trend over duration of follow-up

There were no statistically significant differences in the number of glaucoma medications between the two groups at any time point (p-values: 1.00, 0.83, 0.09, 0.27, 0.06, 0.33 at 24 hours, 1 week, 1 month, 3 months, 6 months, and 1 year postoperatively, respectively; Mann-Whitney Test). Refer to Chart 6 for details. The greatest difference between the two groups occurred at 6 months, with the median number of medications being 2 (IQR: 4) in the AGV group and 0 (IQR: 2) in the PGI group. There is a trend towards increased use of glaucoma medications around the third month, coinciding with the hypertensive phase of the drainage devices, followed by a decrease towards one year as remodelling is completed.

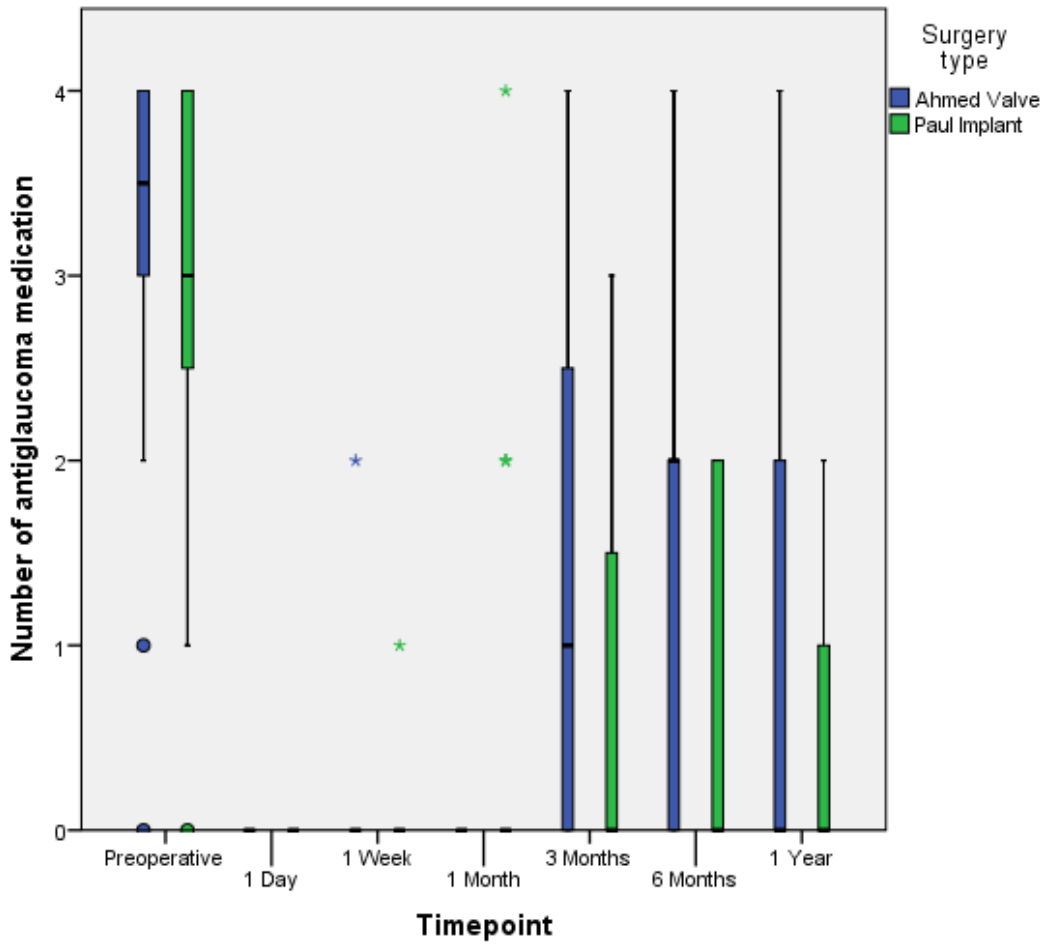

Chart 6. Median number of glaucoma medications (horizontal black line) and percentiles (boxes-quartiles = 25/75; whiskers = 5/95) given preoperatively and for a follow-up of 1 year. Single outliers are shown by circles and extreme outliers by asterisks.

4.4.3 Failure

Chart 8 shows the Kaplan-Meier survival curve over the 1-year duration of follow-up. In the AGV group, 9 out of 24 patients (37.5%) experienced failure, compared to 5 out of 28 patients (17.9%) in the PGI group. The 1-year Kaplan-Meier survival was 62.5% in the AGV group and 82.1% in the PGI group without reaching the statistical significance (p=0.11, Log Rank Mantel-Cox).

Reasons for failure in the AGV group included 8 open revisions due to uncontrolled intraocular pressure (IOP) and one patient whose IOP was 37 mmHg but could be managed medically in the following month.

In the PGI group, one patient with open-angle glaucoma required anterior chamber washing two days post-surgery due to an IOP of 49 mmHg, up from a preoperative value of 33 mmHg, which could not be controlled medically. Another patient with active uveitic glaucoma experienced an IOP peak of 58 mmHg in the first week, up from a preoperative value of 36 mmHg, which was medically managed down to 26 mmHg but had recurrent episodes of hyphema and vitreous haemorrhage requiring open revision. Additionally, a patient with neovascular glaucoma had an IOP peak of 51 mmHg in the first week that did not respond to medical therapy, necessitating cyclocryocoagulation. The other two patients in the PGI group had encapsulated devices requiring open revision.

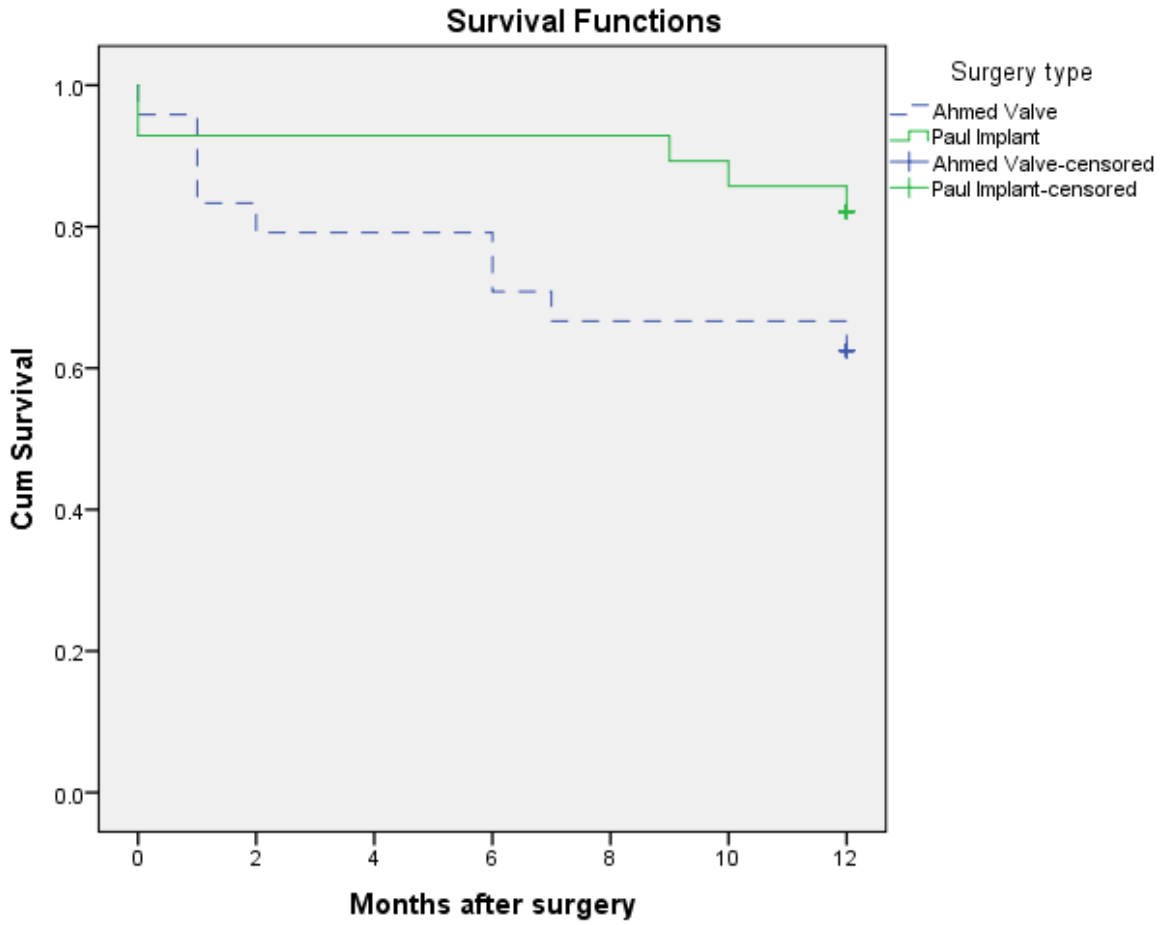

Chart 8. Kaplan-Meier Survival Curve over 1-year post-operatively

4.4.4 Surgical success

Chart 3 and Table 3 represent the percentage of patients who achieved surgical success at different IOP targets in each group. There was no significant difference between the groups at any IOP target.

In addition to the patients who experienced surgical failure, two patients in the PGI group did not achieve a minimum 25% reduction in IOP. Both patients had uveitic glaucoma. The first patient had a preoperative IOP of 13 mmHg with three glaucoma medications and a history of LASIK. At one year postoperatively, the IOP was 12 mmHg with one medication. The surgery was indicated due to progression in the visual field. The second patient had a preoperative IOP of 20 mmHg while on oral acetazolamide and three glaucoma medications. Postoperatively, the IOP was controlled without oral acetazolamide and with just one medication.

Table 3. Complete and Qualified Surgical Success for Different Intraocular Pressure Targets.

	Complete success, n(%)			Qualified success, n(%)		
Target	AGV	PGI	p-value	AGV	PGI	p-value
IOP ≥6mmHg ≤21 mmHg and a percentage reduction of ≥ 25%	8/24 (33.3)	15/28 (53.6)	0.14[a]	15/24 (62.5)	21/28 (75.0)	0.33[a]
IOP ≥6mmHg ≤18 mmHg and a percentage reduction of ≥ 30%	8/24 (33.3)	14/28 (50.0)	0.26[a]	12/24 (50.0)	21/28 (75.0)	0.09[a]
IOP ≥6mmHg ≤15 mmHg and a percentage reduction of ≥ 40%	5/24 (20.8)	8/28 (28.6)	0.52[a]	7/24 (29.2)	9/28 (32.1)	0.82[a]

[a] Chi-squared test.

4.4.5 Postoperative visual acuity

The median preoperative visual acuity (IQR) remained stable from 0.95 (1.70) to 1.0 (2.1) at the one-year follow-up in the AGV group (p=0.149, Wilcoxon signed-rank test) and from 0.56 (1.35) to 0.55 (2.08) in the PGI group (p=0.782, Wilcoxon signed-rank test). Although there was no statistically significant difference in the preoperative values between the two groups (p=0.376, Mann-Whitney test), the PGI group showed better visual acuity at the one-year follow-up (p=0.043, Mann-Whitney test). However, since the preoperative to postoperative change within each group did not reach statistical significance, the observed difference at the one-year follow-up might be due to inherent preoperative group characteristics. Chart 3 represents the change in IOP from the preoperative value to the one-year follow-up.

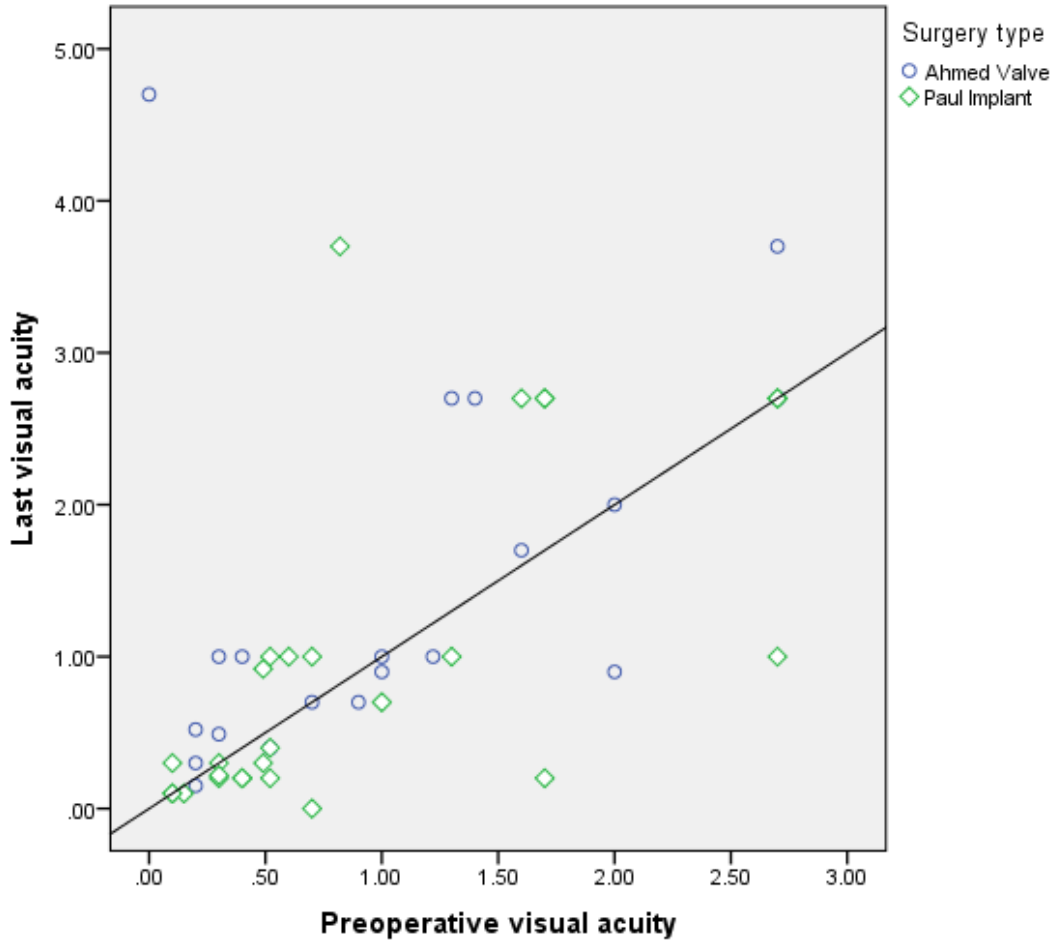

Chart 7. Visual acuity in logMAR preoperatively and at one-year follow-up. The oblique line represents no change from the preoperative value.

4.4.6 Intraoperative and postoperative complications

The incidence of intraoperative and postoperative complications are shown in Table 4. Scleral damage was reported in one case with a PGI and another with an AGV. In both instances, the sclera was sutured without any postoperative complications. Additionally, one AGV patient experienced accidental muscle damage, which was reattached and sutured in its original position. No diplopia was reported during the postoperative period.

Table 4. Adverse events.

	AGV n (%)	PGI n (%)	p-value

Intraoperative complications Scleral Damage Muscle Damage Hyphema Conjunctival Tear	4/24 (16.7) 1/4 1/4 1/4 1/4	1/28 (3.6) 1/1	0.17[a]
Postoperative complications	17/24 (70.8)	17/28 (60.7)	0.56[b]
Early complications[1]	13/24 (54.2)	11/28 (50.0)	0.28[b]
Late complications[2]	11/24 (45.8)	14/28 (50.0)	0.76[b]
Numerical Hypotony (IOP <6mmHg) Early Late	 3/24 (12.5) 1/24 (4.2)	 4/28 (14.3) 2/28 (7.1)	 0.87[a]
Choroidal detachment Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 0.26[a]
Severe anterior chamber shallowing Early Late	 1/24 (4.2) 0/24 (0)	 0/28 (0) 0/28 (0)	 0.21[a]
Visible Hyphema Early Late	 2/24 (8.3) 0/24 (0)	 2/28 (7.1) 0/28 (0)	 0.87[a]
IOP Peak Early Late	 1/24 (4.2) 1/24 (4.2)	 4/28 (14.3) 2/28 (7.1)	 0.38[a]
Cataract progression Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 0.26[a]
Persistent corneal erosion Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 0.26[a]
Corneal decompensation Early Late	 2/24 (8.3) 1/24 (4.2)	 1/28 (3.6) 3/28 (10.7)	 0.53[a]
Persistent uveitis	2/24 (8.3)	2/28 (7.1)	1.00[a]
Blinding visual acuity loss Early Late	 1/24 (4.2) 0/24 (0)	 0/28 (0) 0/28 (0)	 0.46[a]
Choroidal Haemorrhage Early Late	 1/24 (4.2) 0/24 (0)	 0/28 (0) 0/28 (0)	 0.46[a]
Macular oedema Early Late	 2/24 (8.3) 0/24 (0)	 3/28 (10.7) 0/28 (0)	 1.00[a]
Retinal detachment Early Late	 1/24 (4.2) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 1.00[a]
Vitreous Haemorrhage Early Late	 2/24 (8.3) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 0.59[a]
Diplopia Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 1.00[a]
Device obstruction Early Late	 6/24(25.0) 2/24 (8.3)	 0/28 (0) 2/28 (7.1)	 0.01[a]
Device migration Early	 1/24 (4.2)	 0/28 (0)	 0.46[a]

Late	0/24 (0)	0/28 (0)	
Device malposition Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 1.00[a]
Fibrous ingrowth Early Late	 0/24 (0) 0/24 (0)	 1/28 (3.6) 0/28 (0)	 1.00[a]
Device exposure Early Late	 1/24(4.2) 0/24 (0)	 0/28 (0) 4/28 (14.3)	 0.04[a]
Need of reintervention	10/24 (41.7)	9/28 (32.1)	0.57[a]

[a] Fisher's Exact Test. [b] Chi-squared test. [c] Likelihood Ratio

There was no statistically significant difference in intraoperative and postoperative complications between the two groups, except for device obstruction and device exposure. Device obstruction was more frequent in the AGV group (p=0.005, Likelihood Ratio), while device exposure was more frequent in the PGI group (p=0.036, Likelihood Ratio). Logistic regression analysis between the use of tutopatch and the occurrence of device exposure revealed no statistically significant difference (p=0.312, Wald test).

Regarding the patients with corneal decompensation, in the AGV group, one had a history of penetrating keratoplasty, another had a history of ICE Syndrome, and a third had a diagnosis of congenital glaucoma with seven previous glaucoma surgeries. In the PGI group, one patient had a diagnosis of congenital glaucoma with four previous glaucoma surgeries, another had uveitic glaucoma with a history of two previous cyclodestructive procedures, one had a previous Descemet Membrane Endothelial Keratoplasty (DMEK), and another had a history of penetrating keratoplasty.

No cases of endophthalmitis were observed in this cohort. In the AGV group, reintervention was required for 8 cases due to uncontrolled intraocular pressure, for 1 case due to tube exposure through the conjunctiva, and for 1 case involving an injection of Healon into the anterior chamber because of choroidal detachment with an intraocular pressure of 10 mmHg. In the PGI group, four patients required reintervention due to tube exposure. Additionally, one patient needed cyclocryocoagulation, three patients required open revisions due to elevated intraocular pressure, and one patient needed tube shortening in the anterior chamber following an episode of vasculitis and uveitis with iris bombe, which caused the tube to be in direct contact with the iris.

The ripcord (Prolene 6-0) was removed in 12 patients (42.9%). The mean intraocular pressure prior to extraction was 31.1 mmHg (SD ±7.44), and the mean time to extraction was 253.1 days (SD ±149.4) after surgery.

5 Discussion

This study analysed one-year outcomes for 24 and 28 adult patients, predominantly diagnosed with secondary glaucoma, who received either an Ahmed Glaucoma Valve or a Paul Glaucoma Implant at the University Centre of Mainz. At the time of this analysis, only one study had been published comparing these two glaucoma drainage devices (19).

Our study demonstrated that the AGV group experienced a reduction in median preoperative IOP (IQR) decreased from 29.5mmHg (21-42) to 16.0 mmHg (7-37) at the one-year follow-up ($p<0.01$, Wilcoxon signed-rank test). Similarly, the PGI group showed a decrease from 34.0 mmHg (13-56) to 16.0 mmHg (7-21) ($p<0.01$, Wilcoxon signed-rank test). The median number of postoperative medications decreased from 3.5 (IQR: 0-4) to 0 (IQR: 0-4) in the AGV group

and from 3.0 (IQR:0-5) to 0 (0-3) in the PGI group. There were no statistically significant differences between the two groups as observed by the study published by Karapapak et al(19). However, a trend was seen in favour of the PGI in terms of IOP and medication reduction.

The decrease in IOP observed by Karapapak et al. at the one-year follow-up was slightly greater than in our study (19). However, the mean number of glaucoma medications used in their study was higher, which could contribute to the observed difference. Karapapak et al. compared the results of AGV and PGI in 18 patients per group, all diagnosed with secondary glaucoma due to silicone oil (19). In their study, AGV reduced the IOP from 39.3 ± 10 mmHg to 14.9 ± 4.2 mmHg, while PGI reduced the mean IOP from 40 ± 13 mmHg to 13.5 ± 2.2 mmHg (19). Additionally, AGV decreased the mean number of medications from 4 ± 0 to 1.9 ± 1.8, and PGI from 3.8 ± 0.4 to 1.7 ± 1.3. They also found no statistically significant differences between the two groups (19).

The criteria used by Karapapak et al. for surgical success at the end of the 12-month follow-up period included patients with IOP ≤21 mmHg or ≥6 mmHg and no loss of light perception (19). They did not consider a percentage reduction in IOP as necessary for surgical success, nor did they count additional surgical procedures due to elevated IOP as failures (19). In fact, six patients in the AGV group required additional surgery, and the final reported surgical success was 16/18 (89%) in the AGV group and 17/18 (94%) in the PGI group (19). If we also include patients who required surgery to control IOP in our analysis, our surgical success rate would increase from 62.5% to 83.3% in the AGV group and from 75.0% to 92.9% in the PGI group.

Kurapapak et al. reported complications in 44.4% of AGV patients and 22.2% of PGI patients, with no statistically significant difference between the groups (19). Our complication rate was higher, at 70% in the AGV group and 60.7% in the PGI group, but also showed no significant difference between the groups. Our cohort includes various types of secondary glaucoma, such as neovascular glaucoma and adult congenital glaucoma, both of which are well-known for their challenging management and high rates of postoperative complications. Kurapapak et al. reported hyphema in three PGI patients (compared to our two patients) and one case of pupillary membrane; in the AGV group, they found hyphema in two patients (compared to our two patients) and six cases of acute hypotony (compared to our four patients) (19). They did not report any incidence of hypotony in the PGI group, while we reported six cases (19). Additionally, they did not observe any tube exposure cases, despite using a pericardium patch in every patient, as we did (19). They also found more bleb encapsulation in the AGV group compared to the PGI group (19). They removed the ripcord in 14 out of 18 patients (77.8%) with a mean time of 30.1 ± 14.8 days, compared to our 12 out of 28 patients (42.9%) with a mean extraction time of 253.1 ± 149.4 days (19). No patients in their PGI group required additional surgery, whereas nine patients in our cohort did. Additionally, six patients in their AGV group required further surgery, compared to ten patients in our cohort (19).

A potential explanation for these differences is the duration of glaucoma evolution. Patients in Karapapak's study were diagnosed with glaucoma secondary to silicone oil, and those with a history of glaucoma prior to vitreoretinal surgery were excluded (19). This suggests a shorter disease duration in their cohort compared to ours, and possibly fewer prior glaucoma procedures than our patients. Although Karapapak et al. did not report the mean number of glaucoma surgeries per group, they noted that all 18 patients in the PGI group had undergone at least one glaucoma surgery, compared to 13 out of 18 patients in the AGV group (19). In our study, 22 out of 24 patients (91.7%) in the AGV group and 21 out of 28 patients (75.0%) in the PGI group had undergone previous glaucoma surgery. Our mean number of previous glaucoma surgeries was 2.6 ± 1.9 in the AGV group and 1.9 ± 1.6 in the PGI group

Berteloot et al. conducted a comparative study of PGI and BGI at the one-year mark, excluding patients with neovascular glaucoma (46). In their study, 43% of the patients in the PGI group had POAG, compared to 33% in the BGI group (46). In contrast, our cohort had POAG in 8.3%

of the patients in the AGV group and 17.9% in the PGI group. Beteloot et al. reported results for 23 patients with PGI and 27 patients with BGI, finding that the BGI group had a statistically significant lower IOP at the 12-month follow-up (46). The IOP decreased from 23.7±6.9 to 13.1±2.9 mmHg in the PGI group, and from 26±7.3 to 10.4±4.9 mmHg in the BGI group (46). The percentage reduction in IOP for the PGI group was 44.6%, closely matching our result of 44.7% (46). Both groups showed no difference in terms of medication use at the 12-month follow-up, with the PGI group reducing medication from 2.7±1.1 to 1.41±1.4, though this end value was greater than ours (46). Their success rates, defined as an IOP between 6 and 18 mmHg and at least a 20% reduction from baseline, were similar for both groups: 91% for the PGI and 89% for the BGI. In the PGI group, two cases were considered failures: one due to severe hypotony on day 3 requiring intervention, and another with late hypotony after ripcord removal (46). In the BGI group, three cases were deemed failures: one requiring tube revision due to posterior displacement, another needing tube flushing and needling, and a third presenting with loss of light perception after ripcord removal due to vitreous bleeding and corneal staining (46). There were no significant differences in complication rates between the two groups (46). The PGI group experienced early complications in 21.7% of cases and late complications in 65.2%, but they did not record the number of patients with numerical hypotony (46). No tube exposure was observed in the PGI group, although three patients developed encapsulated blebs (46). Ripcord removal occurred in 29 of the 23 PGI patients (87.0%), approximately double the proportion in our cohort, which may explain the lower IOP observed compared to our results (46).

Despite the similarities between the PGI and BGI, such as their valveless systems and endplate surface areas, the IOP results for the PGI tend to fall between those achieved by the BGI and the AGV. The reason the PGI produces similar results to the Ahmed Glaucoma Valve and higher intraocular pressure than the BGI may lie in the exposure of the bleb to aqueous humor during the early phases of bleb formation. Aqueous humor contains various growth factors that induce fibroblasts to synthesize collagen and transform into myofibroblasts (56). Reduced exposure of the bleb to aqueous humor may decrease the fibrosis of the capsule (56). This could also explain why the Ahmed Glaucoma Valve produces more encapsulated blebs that require surgical intervention, as the bleb in this case is more exposed to aqueous humor from the beginning of wound healing. Additionally, the surface of the implant itself could contribute to the formation of encapsulation. We did not find a significant percentage of patients with peak intraocular pressure or hypotony with these devices.

Our results align with those reported in non-comparative studies of PGI in adults (15–19,46,57–60) and fall within the range of IOP reduction published in comparative studies with the AGV (11,12,20,61). In other studies, the mean preoperative IOP for PGI ranged from 20 to 40 mmHg, with a 12-month follow-up IOP range of 12 to 14.8 mmHg (15–19,46,57–60). Most studies of PGI showed a predominance of primary open-angle glaucoma compared to secondary glaucoma, which contrasts with our study where secondary glaucoma was more prevalent (15–19,46,57–60). The upper limit of the 12-month IOP range was noted in Olgun's study, which focused on patients with PEX-glaucoma compared to those with primary open-angle glaucoma (59). Few studies have assessed PGI outcomes beyond one year, with the mean IOP reported as approximately 11.3 to 14.2 mmHg, and 14.9 mmHg at three years (15,17,57). The PGI also reduces the number of antiglaucoma medications from a mean/median preoperative value of approximately 3 to 0-1 one year postoperatively (15,17,18,57,58,60).

The heterogeneity in the definitions of surgical success makes comparing studies very challenging. The EGS recommends using both upper and lower limits of IOP in conjunction with a percentage reduction in IOP, but even this combination varies across studies (39). Studies that employ only one of the criteria tend to report higher rates of success. For example, Koh et al. reported their surgical success without including a percentage reduction in IOP, defining failure as an IOP >21 mmHg or <6 mmHg on two consecutive visits after three months,

reoperation for IOP-related indications, explantation of the implant, or loss of light perception vision (16). They observed a 5.4% failure rate, 68.9% complete success, and 93.2% qualified success at one year. Weber et al. used three target IOP levels but without a percentage reduction, reporting for an IOP ≤21 mmHg a complete success rate of 73.3% and a qualified success rate of 95.6% at one year (18). Vallahb defined failure as an IOP >21 mmHg or not reduced by 20% below baseline, resulting in a 9.3% failure rate, 38.4% complete success, and 90.1% qualified success (58). Tan et al. defined failure without including a percentage reduction, as an IOP ≥18 mmHg or ≤6 mmHg on two consecutive visits after three months, reoperation for IOP-related indications, explantation of the implant, or loss of light perception. They reported a 14.6% failure rate, 75% complete success, and 85.4% qualified success at three years (15). José et al. defined success as an IOP ≤18 mmHg with at least a 30% reduction and higher than 5 mmHg, reporting a 75% qualified success rate and 33% complete success rate at one year (15,17,58). Using the same target IOP, we reported a 71.4% qualified success rate and a 50% complete success rate. Our definition of success is strict, yet our success rates align closely with those reported in other studies. Moreover, patients requiring a GDD typically suffer from more aggressive forms of glaucoma and have often undergone multiple prior surgeries. As a result, achieving strict success in these cases is more challenging than in patients with primary open-angle glaucoma or those without previous surgical interventions.

The rates of ripcord removal range from 42% to 87% within 1 to 5 months after surgery (19,46,57–59). Not all surgeons used an intraluminal stent to prevent hypotony with PGI. Tan et al. described a "stability system" involving a pericardial patch graft placed between the subconjunctival space and the PGI plate, with cross-linked viscoelastic injected beneath the patch graft to fill the plate's reservoir (15). They reported an incidence of 35.7% hypotony with an IOP of 14.5 ±3.6 mmHg at 12 months. José et al. used a single 7-0 vicryl ligature instead of an intraluminal stent (60). They reported an 8% incidence of choroidal detachment and no cases requiring intervention for postoperative hypotony, with a final IOP of 12.5 ± 3.6 mmHg at 12 months. Koh et al. reported an incidence of 14.9% with self-limiting shallow anterior chamber and a 9.5% rate of hypotony requiring intervention (16). They used an intraluminal stent in 14.9% of cases. Studies using an intraluminal ripcord reported varying incidences of hypotony ranging from 0% to 17.1% (19,46,57–59), though they considered hypotony only when accompanied by clinical signs. We followed EGS guidelines and recorded numerical hypotony as a complication (39). Although we observed a numerical hypotony incidence in 6 out of 28 patients (21.42%), only one patient (3.6%) showed choroidal detachment as a clinical sign of hypotony, which resolved spontaneously. None of the patients in our PGI group required intervention due to hypotony. The small diameter of the PGI tube is believed to help prevent post-operative hypotony (16).

Regarding tube exposure, while Weber et al. (57)suggested a potential association with the pericardial patch, our logistic regression analysis found no statistically significant correlation between the incidence of exposure and the type of patch, regardless of the GDD used. However, there was a trend indicating higher exposure rates with pericardium grafts compared to fascia lata or scleral flaps. In our study, most AGV devices were covered by scleral flaps, whereas pericardium patches were used for the PGI. Studies using pericardium grafts in PGI reported exposure incidences ranging from 0% to 16.1% (15,19,46,57,59,60)

In terms of visual acuity, studies on the PGI show no statistically significant changes from preoperative values (15,16,58). Given the progressive nature of glaucoma, it is crucial for new surgical procedures to avoid causing any damage to the visual function, as the damage caused by glaucoma is irreversible.

Our study has several limitations. The small sample size restricts the scope for comprehensive comparative analysis, and its retrospective nature carries a risk of bias. As a well-recognized glaucoma center in Germany, our hospital attracts patients from various regions who come for surgery and then return to their local ophthalmologists. This introduces potential bias, as we may primarily report data from patients who return due to surgical complications. Patients who do not return might have either good IOP control or dissatisfaction leading them to seek care elsewhere. Additionally, our study had a limited follow-up period of 12 months and included a heterogeneous patient population in terms of ethnicity. Longer-term studies with larger sample sizes and prospective designs are needed to demonstrate the superiority or equivalence of these two procedures. The AGV has an established track record and a proven safety profile. The PGI offers similar efficacy and safety, with few complications, most of which are minor.

6 Conclusion

This study compares the one-year outcomes of Ahmed Glaucoma Valve (AGV) implantation and Paul Glaucoma Implant (PGI) in a cohort of 24 and 28 adult patients, respectively. Both groups had similar preoperative intraocular pressure (IOP) and used a comparable number of antiglaucoma medications. The predominant diagnosis was secondary glaucoma, and the majority of patients had undergone previous glaucoma surgery and were pseudophakic.

The primary endpoints were the reduction of IOP and the number of glaucoma medications. Secondary endpoints included surgical success using three IOP targets combined with percentage reductions (IOP ≥6 mmHg and ≤21 mmHg with a reduction of ≥25%; IOP ≥6 mmHg and ≤18 mmHg with a reduction of ≥30%; IOP ≥6 mmHg and ≤15 mmHg with a reduction of ≥40%), visual acuity, and complication and intervention rates.

The mean preoperative IOP decreased from 34.0 ± 9.4 mmHg to 16.5 ± 6.3 mmHg in the AGV group, and from 32.8 ± 9.0 mmHg to 14.8 ± 3.35 mmHg in the PGI group at the one-year follow-up. The median (IQR) number of classes of IOP-lowering medications reduced from 3.5 (1.0) to 0 (2) in the AGV group, and from 3.0 (2.0) to 0 (1) in the PGI group.

Complete success rates (IOP ≥6 mmHg and ≤21 mmHg with a reduction of ≥25%) were 33.3% for AGV and 53.6% for PGI, with qualified success rates of 62.5% and 75.0%, respectively. For IOP ≥6 mmHg and ≤18 mmHg with a reduction of ≥30%, complete and qualified success rates were 33.3% and 54.2% for AGV, and 50% and 71% for PGI. For IOP ≥6 mmHg and ≤15 mmHg with a reduction of ≥40%, complete and qualified success rates were 20.8% and 29.2% for AGV, and 28.6% and 32.1% for PGI. There were no statistically significant differences between the groups at any time point or for any success criteria.

Both the Ahmed Glaucoma Valve and the Paul Glaucoma Implant effectively reduce IOP and the number of antiglaucoma medications at one year. The PGI tends to result in fewer failures and a higher proportion of patients achieving surgical success compared to the AGV, although these differences did not reach statistical significance. Both glaucoma drainage devices have comparable safety profiles, with the AGV being associated with more encapsulated blebs and the PGI with more tube exposures.

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9 Curriculum Vitae

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Ophthalmologist, FEBO, FICO

Birthday:	Am 03.12.1992 in Rocafuerte, Ecuador
Nationality:	Ecuadorian

Clinical Experience

1.1.2025 – present	Junior Consultant Universitätsmedizin, Mainz, Deutschland
1.10.2023 - 30.9.2024	European Glaucoma Society Fellowship Universitätsmedizin, Mainz, Deutschland
1.8.2023 - 31.8.2023	EBO Residency Exchange Grant Holder Glaucoma Department Universitätsklinikum Bonn, Bonn, Deutschland
7.6.2019 - 7.6.2023	Ophthalmology resident Hospital Universitario Dr. Balmis, Alicante, Spanien
1.7.2018 - 31.7.2018	Hospitantin St Josefs Krankenhaus, Dortmund, Deutschland
1.5.2018 - 31.5.2018	Hospitantin Paulinen Krankenhaus, Berlin, Deutschland
1.1.2017- 31.12.2017	Social Service in General Medicine Centro de Salud Fajardo, Quito, Ecuador
1.8.2015- 31.08.2016	Practical Year Hospital Vozandes, Quito, Ecuador Areas of Focus: Internal Medicine, General Surgery, Gynecology and Pediatrics
1.10.2012-28.02.2013	Student Assistant Institute of Physiology, Faculty of Medicine Universidad Central del Ecuador, Quito, Ecuador

Education

09.2010 – 09.2016	Medicine Universidad Central del Ecuador, Quito, Ecuador Final grade: 1.4

Training

05.3.2024	Grundlagenkurs für Hauptprüfer / Prüfer und Mitglieder eines Prüfungsteams / einer Prüfgruppe bei klinischen Prüfungen nach der Verordnung (EU) Nr. 536/2014 (Humanarzneimittel). Interdisziplinäres Zentrum Klinische Studien (IZKS) der Universitätsmedizin Mainz
06.2023	Ophthalmologist Ministerio de Sanidad, Spain

05.2023	Formación para cirugía trabecular de micro bypass coniStent inject® W [iStent inject®W trabecular micro-bypass implantation training]
	GLAUKOS, Spain
01.2023	Curso Avanzado de Cirugía de Catarata - Wetlab [Advanced Cataract Surgery Course]
	Alcon und Clinic Eye Training Center del Hospital Clínic Barcelona
09.2022	EBO Examination
	European Board of Ophthalmology
10.2021	The ICO Advanced Examination
	International Council of Ophthalmology
03.2021	The Clinical Ophthalmology Examination, ICO Part C
	International Council of Ophthalmology
10.2020	The Optics, Refractions and Instruments Examination in Ophthalmology, ICO Part B
	International Council of Ophthalmology
07.2020	The Visual Sciences Examination in Ophthalmology,
	ICO Part A
	International Council of Ophthalmology
05.2019	Approbation als Ärztin
	LaGeSo, Berlin, Deutschland

Membership

European Glaucoma Society

Deutsche Ophthalmologische Gesellschaft

Languages

Spanish	Mother tongue
German	C1
English	B2
Portuguese	A1

Publications

Wagner FM, Oster P, Stingl JV, Schuster AK, Rezapour J, Mendoza-Moreira AL, Fieß A, Messerschmidt-Roth A, Grehn F, Pfeiffer N, Hoffmann EM. Rigid Probe Trabeculotomy Versus 360-Degree Catheter Trabeculotomy in Childhood Glaucoma. J Clin Med. 2024 Dec 2;13(23):7341. doi: 10.3390/jcm13237341. PMID: 39685798; PMCID: PMC11642443.

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