PAUL® Glaucoma Implant in the Surgical Management of Refractory Glaucoma: 12-month Safety and Efficacy Outcomes of a Novel Aqueous Shunt Implant

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Purpose

The purpose of this study is to report Paul® Glaucoma Implant (PGI) safety and efficacy preliminary outcomes at 12 months.

Methods

A retrospective, non-comparative, interventional case series of patients undergoing PGI implantation for the treatment of uncontrolled glaucoma despite maximum medical treatment at 6 international centres during a 12-month period from October 2017 to September 2018. Intraocular Pressure (IOP) and number of IOP-lowering medications were noted at baseline, and at 1, 3, 6, and 12 months after surgery. The details of any complications during the follow-up were recorded.

Study Population

Total number of eyes	**74**
Age (years, mean ± SD)	62.3 ± 14.7
Gender	M 74.4%, F 25.6%
Type of glaucoma	
Primary (any type)	61.0%
Secondary (any type)	39.0%
Cup:Disc Ratio (mean ± SD)	0.79 ± 0.14
Lens status	
Phakic	48.7%
Pseudophakic	50.0%
Aphakic	1.3%

Table 1. Enrolled patient demographics and clinical features.

Paul® Glaucoma Implant (PGI)

The PAUL® Glaucoma Implant (PGI) is a novel aqueous shunt that offers an alternative to established shunts in the management of refractory glaucoma. (**Fig. 1A**). Manufactured from medical grade silicone, with a 342mm end-plate, it differentiates itself from other shunts in the small calibre of tube (internal diameter, 127µm, external diameter, 467µm). **Table 2** compares the PGI with some other currently avaiable shunts.

	Device		
Feature	**Ahmed Glaucoma Valve**	**Baerveldt Glaucoma Implant**	**PAUL Glaucoma Implant**
Plate Surface Area	184mm²	350mm²	342mm²
Plate Length	13mm	32mm	21.9mm
Plate Width	16mm	15mm	16.1mm
Tube Outer Diameter	0.64mm	0.64mm	0.467mm
Tube Inner Diameter	0.3mm	0.3mm	0.127mm

Table 2. Dimensions of some currently available aqueous shunts.

Surgical technique

In this study, the PGI was implanted in a manner similar to a Baerveldt Glaucoma Implant.
- Conjunctiva and Tenon's capsule were dissected via a wide peritomy and the shunt end-plate placed in the sub-Tenon's space with the wings under the adjacent rectus muscles.
- The end-plate was sutured to sclera at least 9mm behind the limbus using two non-absorbable sutures.
- The tube was trimmed bevel-up and inserted into the anterior chamber via a 25 gauge needle track (gonioscopic view, **Fig. 1B**).
- To prevent early overdrainage, either: 1. The tube was occluded internally using a 6-0 polypropylene suture (Ethicon US, LLC, Johnson & Johnson) as a "rip-cord" (**Fig. 1A**) or 2. a combination of viscoelastic over the end-plate (Healaflow, Anteis S.A., Geneva, Switzerland) and a pericardial patch (Tutopatch, Tutogen, Germany).
- The tube was secured to sclera with non-absorbable sutures and a donor patch graft of peicardium or fascia lata (Tutoplast or Tutopatch, Tutogen, Germany) was used to cover the limbal portion of the tube before final conjunctival closure **Fig. 1C**.

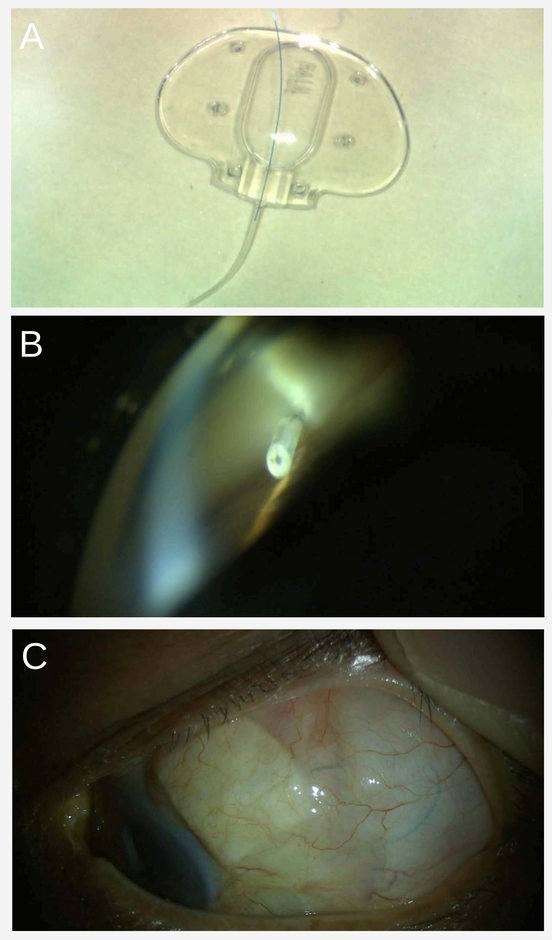

Figure 1. The PGI and its appearance after implantation.

Results

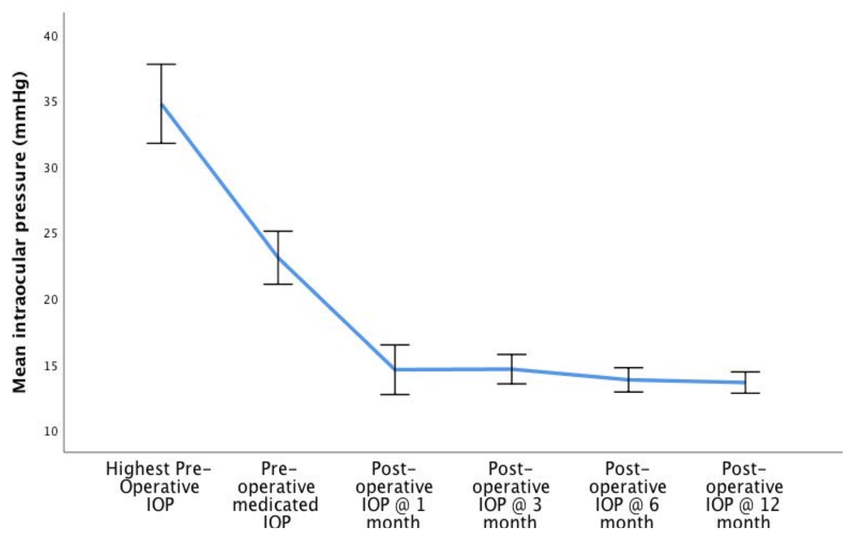

Figure 2. Mean intraocular pressure (IOP, mmHg) before surgery and at postoperative month 1, 3, 6, 12. Error bars: 95% Confidence Interval.

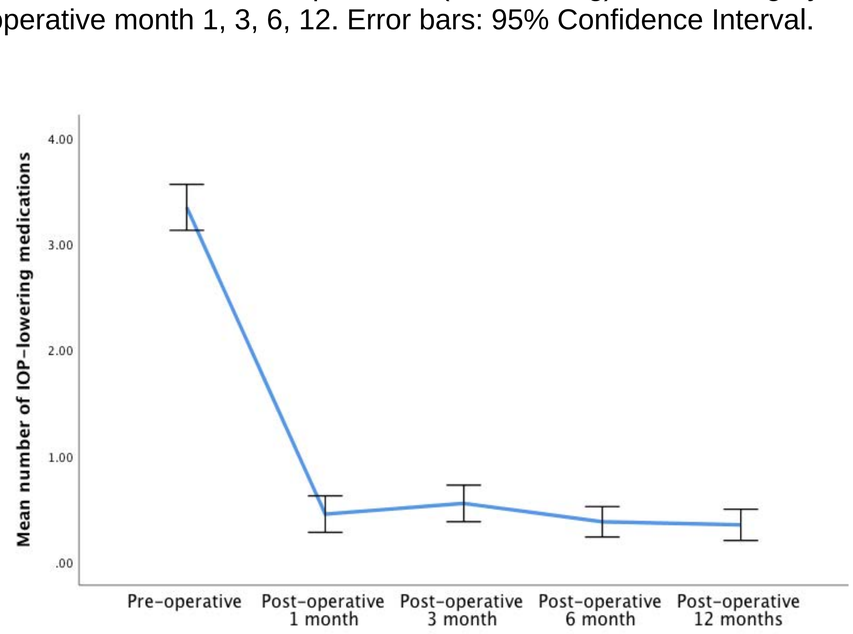

Figure 3. Mean number of IOP-lowering medications before surgery and at postoperative month 1, 3, 6, 12. Error bars: 95% Confidence Interval.

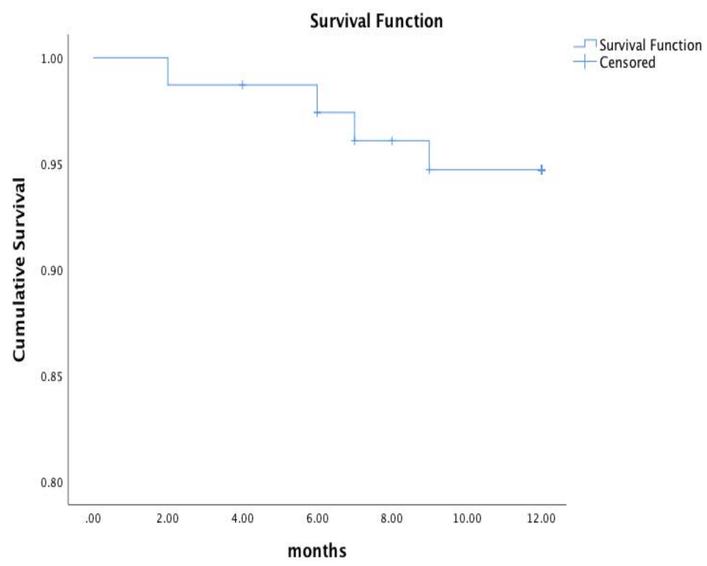

Figure 4. Kaplan-Meier survival analysis for the eyes implanted with PGI over 1 year. After 12-months, 4 (5.4%) were judged to have failed. The reasons for failure were: shunt revision due to IOP<6mmHg (1 eye, 1.35%), or to IOP>21mmHg (1 eye, 1.35%); shunt removal due to exogenous endophthalmitis (1 eye, 1.35%) and recurrent conjunctival erosion over the plate (1 eye, 1.35%).

Complications	**Number of eyes (%)**
Self-limiting shallow anterior chamber	11 (14.9%)
Hyptony requiring intervention	7 (9.5%)
Tube shunt occlusion	5 (6,8%)
Tube exposure	3 (4.1%)
Endophthalmitis leading to vision loss	1 (1.3%)

Table 3. Complication rates (%) of PGI at month 12 post-operatively.
Out of the 5 eyes with tube occlusion, 3 were due to iris plugging the tip of the tube, In all cases, argon laser iridoplasty unblocked the tube successfully. In 1 aphakic eye, the tube was occluded with vitreous. Anterior vitrectomy was performed successfully. In 1 case a sustained high IOP in the first 10 post-operative days in a patient with uveitic glaucoma was remedied by anterior chamber washout and flushing of the shunt in the operating theatre.
Of 7 eyes with hypotony requiring intervention, 6 had intracameral slitlamp viscoelastic injection and 1 returned to the operating theatre for reinsertion of an intraluminal stent via the anterior chamber.

Conclusion

In this study the PAUL® Glaucoma Implant (PGI), with its lower calibre tube, appears to offer a promising alternative to current aqueous shunts (such as the Baerveldt Glaucoma Implant) in terms of safety and efficacy in the treatment of refractory glaucoma.