Surgical technique and perioperative management of the PAUL® glaucoma implant

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Introduction

Figure 1. Image of the PAUL® Glaucoma Implant



The PAUL® Glaucoma Implant (PGI) is a new aqueous shunt device, developed with the aim to reduce complications and unpredictability seen with other Glaucoma drainage implants (GDI) whilst maintaining efficacy.

Table 1. GDI characteristics.

	Ahmed Glaucoma valve	Baerveldt Glaucoma Implant	PAUL Glaucoma implant
Valve	Flow restrictor	No	No
Plate surface area (mm^2)	184	350	342
Tube internal diameter (mm)	0.64	0.64	0.467
Tube external diameter (mm)	0.3	0.3	0.127

Methods

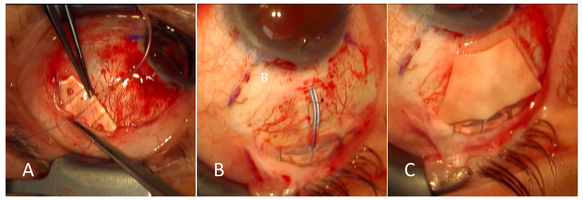
Consecutive cohort study of subjects undergoing PGI at Manchester Royal Eye Hospital, between February 2019 and May 2020 with a minimum of six-months follow-up.

Primary outcomes;
- Failure
  - IOP > 21mmHg
  - Or < 20% reduction from baseline at 3 months
- Removal of the implant
- Further glaucoma intervention
- Visual loss to NPL

Secondary outcomes;
- Mean IOP (mmHg)
- Mean no. medications
- LogMAR visual acuity
- Complications.

Surgical technique & management

Figure 2. Surgical technique for the insertion of the of the PAUL® Glaucoma Implant. A) Insertion of the prolene intraluminal stent. B) Insertion of the tube and fixation with ethilon sutures. C) Placement of the Tutoplast over the tube and fixation with TISSEEL glue.



Our technique for insertion of the PGI involves the use of a 6'0 Prolene® intraluminal stent as standard without the use of viscoelastic over the plate. This allows immediate drainage (unlike surgical techniques that utilise a dissolvable occlusive extraluminal tie to prevent early hypotony) and hence a more predictable early IOP.

The Prolene stent can be removed easily post-operatively at the slit lamp from month 2-3 onwards. In our cohort 56 (56.6%) eyes had the Prolene intraluminal sent removed at a mean of 4.76±2.90 months post-operatively resulting in a mean IOP reduction of 6.2±9.0mmHg.

All glaucoma medications were stopped on the day of surgery.

Results

Table 2. Type of glaucoma.

Diagnosis	n (%)
POAG	38 (38.4)
Uveitic glaucoma	17 (17.2)
Secondary to previous ocular surgery	14 (14.2)
Congenital/Juvenile	7 (7.1)
Primary angle closure glaucoma	2 (2.0)
Other secondary glaucoma (neovascular, traumatic)	12 (12.2)

Results

Table 3. Demographics and baseline characteristics.

Demographic/Characteristic	Data n (%)
No. of Eyes (No. of patients)	99 (97)
Age (yrs) (mean ± SD) (range)	58.7±16.6 (18-86)
Gender	
Male	63 (63.6)
Female	35 (35.4)
Ethnicity	
Caucasian	62 (62.6)
Afrocaribbean	23 (23.2)
Asian	12 (12.1)
Not stated	2 (2.0)
Mean IOP (mmHg), mean ± SD	28.1±9.0
Mean no. of medications ± SD	3.6±1.09
Mean follow-up (months) ± SD	10.7±3.2
Previous glaucoma surgery	
Trabeculectomy	23 (23.2)
Viscocanalostomy/ Deep sclerectomy	5 (5.1)
Baerveldt tube	8 (8.1)
Ahmed valve	1 (1.0)
Minimally invasive glaucoma surgery	14 (14.1)
Selective laser trabeculoplasty	10 (10.1)
Cyclodiode	6 (6.0)

Figure 3. Graph to show mean IOP with 95% confidence intervals prior to and after insertion PGI.

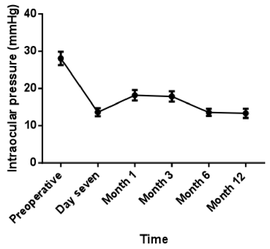


Figure 4. Kaplan-Meier survival curve over the duration of follow-up. Failure is defined as IOP >21mmHg or <20% reduction from baseline (with or without medications) on 2 consecutive visits after 3 months.

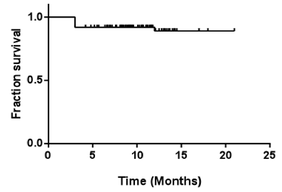


Figure 5. Graph to show mean no. medications with 95% confidence intervals prior to and after insertion PGI.

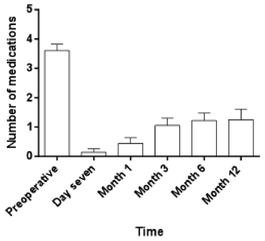


Table 4. Post-operative complications (early < 3 months and late > 3 months).

Early	(n)	Late	(n)
Hypotony	2	Corneal graft failure	2
Conjunctival retraction	1	CMO	1
Hyphaema	4	Vitreous to tube	1
CMO	2	Wound leak	1
Recurrent inflammation	2	Microbial keratitis	1
BRVO	1	Diplopia	2

Conclusions

This method for PGI insertion represents a safe and effective technique with immediate drainage, predictable early IOP and low post-operative maintenance.

The baseline mean IOP was 28.1±9.0mmHg falling to 17.9±6.7 at 3 months, 13.6± at 6 months and 13.3±4.4 at 12 months. The mean reduction in no. medications was 2.38±1.48 (p<0.0001). These outcomes are equivalent to those of the Baerveldt® GDI with a lower rate of hypotony (4% compared with 2%) [2].

References

1. Koh V, Chew P, Triolo G, Lim KS, Barton K. Treatment Outcomes Using the PAUL Glaucoma Implant to Control Intraocular Pressure in Eyes with Refractory Glaucoma. Ophthalmol Glaucoma. 2020;1–10. Available from: https://doi.org/10.1016/j.ogla.2020.05.001.
2. Tsai JC, Budenz DL. Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study. Am J Ophthalmol [Internet]. 2017;176:118–26. Available from: http://dx.doi.org/10.1016/j.ajo.2017.01.003