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PAUL Glaucoma Implant: a novel experience at a tertiary institution in Johannesburg, South Africa

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Abstract

Background: Glaucoma drainage implants (GDIs) are frequently used in the management of refractory glaucoma and cases with high risk of failure after a trabeculectomy. The most commonly used GDIs are the Baerveldt glaucoma implant and the Ahmed glaucoma valve.

The PAUL Glaucoma Implant (PGI) is a novel glaucoma device with specific design advantages over these two devices and which has shown comparable efficacy and safety in refractory glaucoma. It can be considered as an alternative approach in the management of these patients.

Results: Our experience with the PGI in a tertiary institution in Johannesburg has been a positive one and we now consider this new device as a feasible option when planning for tube surgery in our patients.

Keywords: glaucoma surgery, PAUL Glaucoma Implant (PGI), glaucoma drainage implants (GDIs), intraocular pressure (IOP), refractory glaucoma

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Introduction

Glaucoma is the commonest cause of irreversible blindness worldwide.[1] Lowering the intraocular pressure (IOP) has been found to be the only proven method to prevent and slow glaucoma progression.[2]

The management of glaucoma has evolved through the years. First-line management options include medical and laser therapy. In recent years, glaucoma drainage implants (GDIs) have been more widely used, especially for the management of secondary and refractory glaucomas.[2] GDI gained popularity after the results of the Tube Versus Trabeculectomy (TVT) study were published, which showed better success rates with Baerveldt tube implantation in patients who had undergone previous surgery.[2]

Pathophysiology of glaucoma drainage implants

GDIs act by creating an alternate pathway for aqueous drainage from the anterior chamber via a tube inserted into the eye to the subconjunctival space in the equatorial region.[3] The GDI is designed to consist of a silicone tube connected to an endplate. Aqueous humour drains from the anterior chamber to a potential space created by the endplate and a fibrous capsule, which develops around the endplate over a period of six weeks. Aqueous then is absorbed into the venous plexus by the periocular capillary and lymphatic system. The capsule that forms around the endplate offers the greatest resistance to aqueous drainage and long-term IOP control.[3]

Indications for GDIs

GDI implantation has been reserved for patients presenting with refractory glaucoma or patients who are unlikely to respond to conventional filtration surgery (e.g., trabeculectomy/deep sclerectomy with adjunctive antifibrotic agents). These include:[3,4]

- Neovascular glaucoma
- Penetrating keratoplasty with glaucoma
- Retinal detachment surgery with glaucoma
- Iridocorneal endothelial syndrome (ICE)

- Traumatic glaucoma
- Uveitic glaucoma
- Open angle glaucoma with previous failed filtration surgery
- Congenital glaucoma
- Contact lens wearers
- Prior conjunctival incisonal surgery and scarring (filtration surgery, cataract extraction, penetrating keratoplasty, scleral buckling surgery)
- Conjunctival cicatricial disease

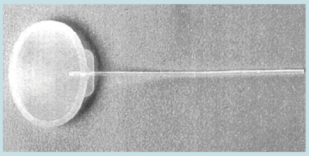
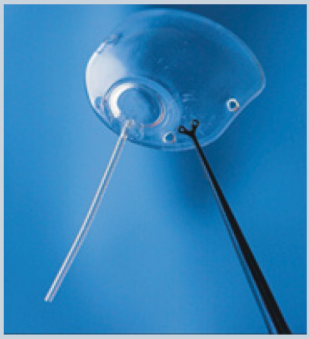
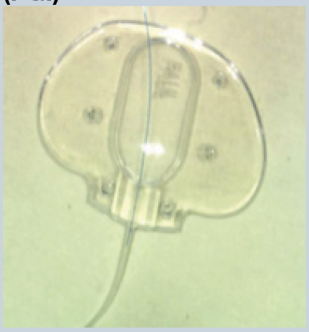
The use of GDIs in patients with previous failed trabeculectomy and/or cataract surgery can be supported following the Tube Versus Trabeculectomy (TVT) study.[4] This study highlighted the benefit of tube shunt surgery with patients having similar IOP reduction (in the low teens) compared to the trabeculectomy group after five years.[5] This differs from the previously held belief that tube shunt surgery resulted in IOP control to the high teens and therefore GDIs could not be used if a lower target pressure was desired.[5] Tube shunt surgery has also gained popularity as the primary glaucoma surgical procedure in patients with low risk of surgical failure. Previously only patients with high risk of surgical failure were chosen to receive GDI; however, in the TVT study, the patient selection included patients with low risk of failure and showed equal success in both groups of patients.[5] The use of GDIs as a primary procedure in low-risk eyes is further supported by the results of the Primary Tube Versus Trabeculectomy (PTVT) study, which showed both tube and trabeculectomy with mitomycin C (MMC) were effective in lowering IOP in patients who had not previously undergone incisional ocular surgery.[6] The rates of early and late postoperative complications were higher in patients with trabeculectomy in the PTVT study.

Absolute and relative contraindications for GDIs[3]

Caution should be exercised when using GDIs in patients with vitreous in the anterior chamber. Vitreous should be cleared appropriately prior to GDI implantation as this can result in tube occlusion. Patients with previous retinal surgery and silicone oil in situ require inferotemporal tube placement to avoid tube occlusion with oil.

GDI implantation should be avoided in patients with severe scleral thinning, extensive fibrosis of the conjunctiva and ciliary block glaucoma.

As seen in *Table I*, GDIs share a common

Table I: Types of GDIs	
Valved GDI	
Ahmed Glaucoma Valve (AGV)[3,4,7] 	• Introduced in 1993 • Available in four different designs • Two models consist of a flexible silicone endplate • Two models consist of a rigid polypropylene plate • Endplate consists of a valved system which restricts aqueous outflow at an IOP below 8–10 mmHg • Silicone tube connected to a silicone sheet valve
Krupin slit valve[4,7] 	• Introduced in 1976 • Silicone endplate with a surface area of 184 mm^2 • Distal portion of the tube contains horizontal and vertical silicone slits • Slits open at an IOP above 11 mmHg and close at an IOP below 9 mmHg • Allows for unidirectional flow of aqueous
Others: Joseph, Optimed	
Non-valved GDI	
Molteno[4,7] 	• Introduced in 1969, with numerous modifications made to the initial design • Seven models available • Two of the models are double plate implants which consists of two separate polypropylene endplates connected by a 10 mm silicone tube – requires placement in two conjunctival quadrants (total surface area of 265 mm^2) • Single plate model is the most recent model and is available in 135 mm^2, 175 mm^2 and 230 mm^2 • Consists of primary and secondary drainage areas within the plate thus allowing for a 'biological' valve which may prevent postoperative hypotony and long-term IOP control
Baerveldt glaucoma implant (BGI)[4,7] 	• Introduced in 1993 • Consists of a silicone tube connected to a barium-impregnated silicone endplate • Three models available with surface areas of 250 mm^2, 350 mm^2 and 500 mm^2 • There is a 350 mm^2 plate connected to a smaller, angled (Hoffman Elbow) by a 7 mm silicone tube; this angulation allows for insertion into the pars plana
Paul Glaucoma Implant (PGI)[8,9] 	• Introduced in 2017 • Novel aqueous shunt • Made from medical grade silicone with a 342 mm^2 endplate • The tube has a smaller internal and external diameter compared to other GDIs (127 µm and 467 µm respectively) • A ripcord 6.0/7.0 polypropylene intraluminal stent allows for less IOP variability in the early postoperative period and helps prevent hypotony
Schocket implant[3]	• Silastic tube which inserts into the anterior chamber while the other end is tucked beneath a retinal encircling band
Ex-Press[3]	• Single piece stainless steel translimbal implant

design but with unique dimensions and materials used which account for differences in postoperative findings. Non-valved shunts require a temporary restriction of flow to prevent postoperative hypotony. This can be done with the use of tube occlusion or ligation allowing the fibrovascular capsule to form around the endplate before flow occurs through the tube.[10,11] Valved shunts have built-in flow restrictors that assist in decreasing the risk of postoperative hypotony prior to fibrous encapsulation and allow for immediate postoperative IOP decrease.[10,11]

Several retrospective and prospective studies have been done over the years to determine which implant offers superiority over the other.[10] Results from these studies have shown that implants with large surface area endplates are associated with a greater IOP reduction and less need for IOP-lowering medication versus smaller endplate sizes. Studies comparing the single and double plate Molteno found lower IOP control with the double plate Molteno.[7] This finding was echoed in the Ahmed Versus Baerveldt (AVB) and the Ahmed Baerveldt Comparison (ABC) studies, where significantly lower IOPs were seen in patients using the Baerveldt glaucoma implant (BGI) versus the Ahmed glaucoma valve (AGV).[12,13] However, there is an upper limit to endplate size where very large endplates do not contribute significantly to IOP reduction. A study comparing the 500 mm^2 BGI to the 350 mm^2 BGI showed less IOP reduction using the larger endplate.

Endplate composition has also been shown to influence IOP reduction.[10] Studies comparing silicone and polypropylene AGV endplate showed a lower mean IOP and higher surgical success using the silicone endplate. Endplate design may also influence postoperative complications.[7] The rigid plates tend to have more micromotion thus allowing low-grade chronic inflammation and greater scarring, whereas fenestrated endplates result in more fibrous tissue anchoring of the endplate and reduced micromotion and scarring.[7]

A study by Choritz *et al.* showed that surface topography of the endplate in GDIs also plays a role in the differences observed with bleb encapsulation between GDIs.[14] This study compared the AGV, BGI and the Molteno demonstrating that early attachment of Tenon fibroblasts to the endplate was greatest in the AGV due to its rough surface. The Molteno and the BGI had smoother endplates which could be a reason for the enhanced success of these devices.

The two most used GDIs are the AGV and the BGI.

Ahmed glaucoma valve versus Baerveld glaucoma implant

The AVB and the ABC study are two multicentre trials comparing the use of these GDIs. Both studies showed the effectiveness of IOP control and decrease in number of glaucoma medications after five years in patients with previous intraocular surgery and refractory glaucoma.[12,13] The BGI showed superiority in long-term IOP control and less need for glaucoma medication. The AGV decreased IOP to a greater degree in the early postoperative period compared to the BGI. These differences can be attributed to the design differences in the BGI and AGV. The AGV, having a smaller surface area versus the BGI, increases the risk of bleb encapsulation and failure. The other reason that the BGI showed lower IOP relates to the exposure of the filtering bleb to postoperative inflammatory aqueous material early in the AGV subgroup.[12] The valved AGV results in immediate flow of aqueous to the bleb; therefore, inflammatory cells from the surgery result in early and more severe scarring in the fibrous capsule surrounding the endplate, thus causing a more encapsulated bleb and less IOP control in the long term. [12] The BGI, which is non-valved, requires occlusion in the early postoperative period which results in the bleb being exposed to less inflammatory material and less aggressive scarring of the fibrous capsule forming around the endplate.

The PAUL Glaucoma Implant (PGI) is a novel device used for glaucoma surgery.

Case series

We had the opportunity to use the novel PGI on two of our patients presenting to the glaucoma clinic at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH).

Patient 1

A 47-year-old female, Ms TN, was seen at the glaucoma clinic with advanced primary open angle glaucoma in September 2018. Her IOPs were 22 and 24 on the right and left eyes respectively with bilateral fully cupped discs. Her visual acuity (VA) at that visit was 6/12 on the right and light perception on the left. She was on maximum medical therapy which included an alpha agonist, beta blocker, prostaglandin and oral carbonic anhydrase inhibitor. At this visit the decision was made that surgery was the next step for her and a deep sclerectomy with mitomycin C (MMC) and avastin was done on the 01/10/2018. Her IOP post operation remained <16 mmHg until June 2019 where it increased to 25. A YAG goniopuncture was performed which decreased her IOP to 15. On the 12/05/2020 her IOP increased to 31 mmHg with a VA of 6/36. She underwent bleb needling with MMC in theatre but her IOP kept creeping up and on the 10/10/2020 she underwent a PGI with MMC, avastin and a corneal patch graft. Her IOP remained between 14 and 20 mmHg for about two months, and in September 2020 the 'ripcord' was removed. Her IOP remained <13 mmHg for two months, and on the 17/11/2020 her IOP was 24 and she was started on two agents of medical therapy. She is, however, happy with the outcome as she is no longer in pain, on fewer topical medications and her VA on the last visit was 6/18.

Patient 2

A 52-year-old male, Mr SM, presented to glaucoma clinic in March 2017 as a right-only eye with a visual acuity (VA) of 6/12 with primary open angle glaucoma. His cup-to-disc ratio was 0.7. His IOP was poorly controlled between 16 and 28 mmHg on maximum medical therapy. He underwent a deep sclerectomy with MMC in January 2018. His IOP remained poorly controlled and fluctuated despite three bleb needlings and two goniopunctures. On the 16/10/2020 he had a PGI inserted. His IOP preoperation was 23 mmHg, his VA had dropped to counting fingers and he was fully cupped. Post PGI his IOP has remained <18 mmHg for one month of medical therapy. His IOP was 24 mmHg on the 17/11/2020 and the 'ripcord' was removed which decreased his IOP to 13 mmHg.

Surgical procedure

The procedure was performed under general anaesthesia (GA) (*Figures 1a–g*):

- 7.0 vicryl corneal stay suture
- Conjunctiva and Tenon's capsule recessed and bleeders cauterised

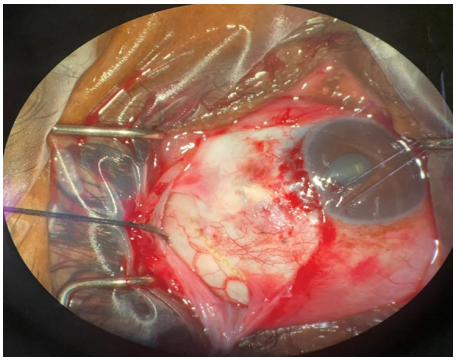


Figure 1a. Corneal stay suture, and conjunctiva and Tenon's recession

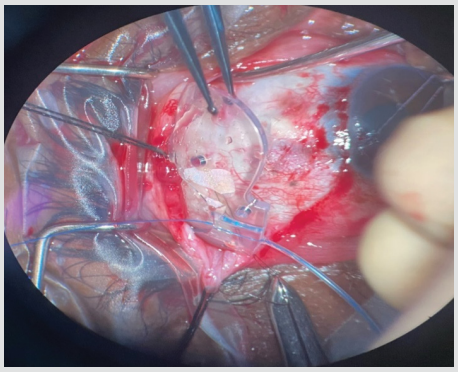


Figure 1b. PAUL Glaucoma Implant placed superotemporally with ripcord in situ

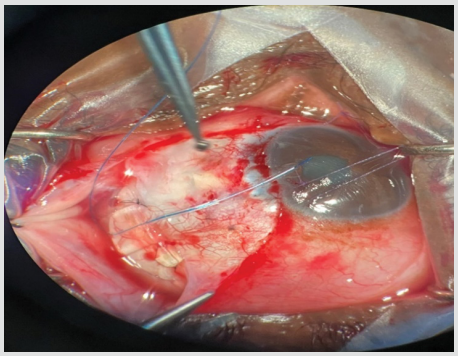


Figure 1e. Tube inserted into the anterior chamber

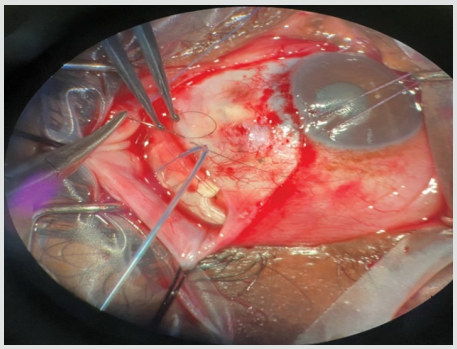


Figure 1c. PGI sutured 10 mm from limbus

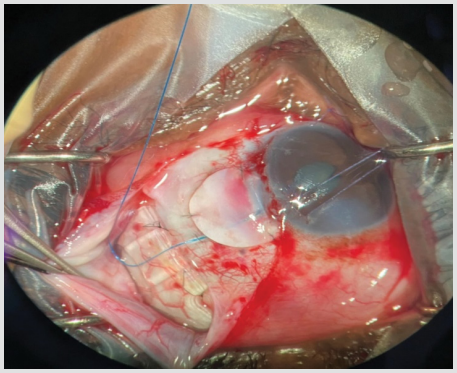


Figure 1f. Tube secured to the sclera using 10.0 nylon sutures and a scleral patch graft to cover the limbal portion of the tube

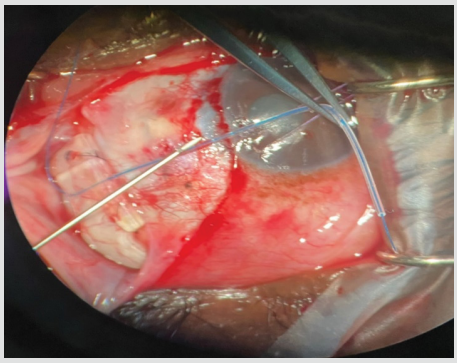


Figure 1d. 26 G needle used to enter the anterior chamber 1 mm post to limbus at iris root

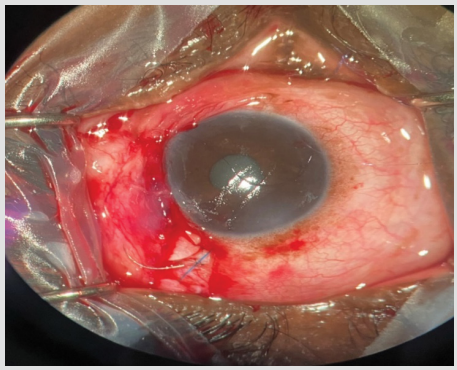


Figure 1g. Conjunctiva sutured with 10.0 vicryl

- Sub-Tenon's macaine and lignocaine given 1:1 as additional local anaesthesia
- A 4.0 silk suture used to retract the Tenon's capsule to allow for maximum exposure
- Paul Tube Implant primed and a 6.0 polypropylene suture inserted into the tube as a 'ripcord'
- Superior rectus and the lateral rectus identified using a squint hook
- MMC (0.04%) used under the sub-Tenon's space for 3 minutes
- Balanced salt solution washout
- Endplate positioned 10 mm posterior from the limbus in the sub-Tenon's space (superotemporally), with the wings under the superior and lateral rectus
- Endplate sutured with 8.0 nylon 10 mm posterior to limbus
- Paracentesis performed temporally
- 26 G needle used to enter the anterior chamber 1 mm post to limbus at iris root
- Tube shortened (bevel up) to sit on iris following the needle track made with the 26 G needle
- Tube secured to the sclera using 10.0 nylon sutures and a scleral patch graft to cover the limbal portion of the tube
- Ripcord polypropylene secured at limbus (to allow for easy visualisation and removal at six weeks depending on the IOP)
- Conjunctiva sutured with 10.0 vicryl

Figures 2 and 3 show Ms TN and Mr SM post PAUL Glaucoma Implant.

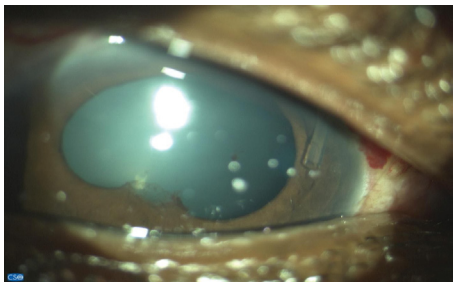


Figure 2. Patient 1, Ms TN, one week post PAUL Glaucoma Implant

PAUL glaucoma implant

GDIs share common design features and the major differences between them occur with respect to their size, material composition of the endplate as well as the presence or absence of a valve.[12] *Table II* shows the important dimensional differences between the PGI and the two most used implants, namely the BGI and the AGV.[8,9] This table highlights that the PGI has a 50% smaller internal diameter and a 30% smaller external diameter than the BGI and AGV, leading some to call it a 'micro-tube'.[8,9] A multicentre trial by Koh *et al.* in 2020 looked at treatment outcomes using the PGI to control IOP in patients with refractory glaucoma.[8] The results of their study showed a significant reduction in IOP and in the number of glaucoma medications used at 12 months.[8] Complications using the PGI were similar to known GDI complications, such as shallow anterior chamber, hypotony, tube shunt occlusion, tube exposure and endophthalmitis.

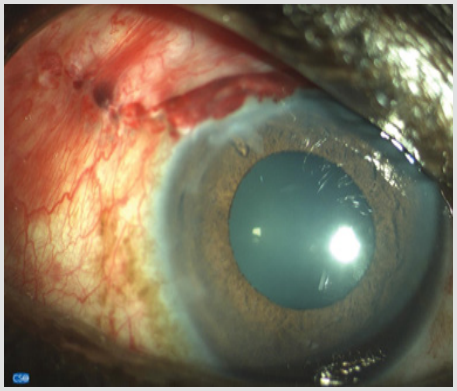


Figure 3a. Patient 2, Mr SM, one day post PAUL Glaucoma Implant

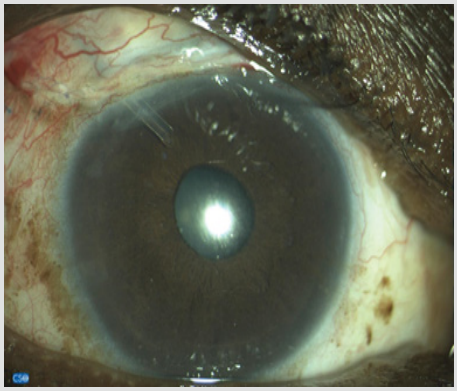


Figure 3b. Patient 2, Mr SM, one month after PAUL Glaucoma Implant

The PGI is closer in design to the BGI compared to the AGV. The design of the PGI took into consideration the advantages and disadvantages of the BGI in order to improve upon its success rate. The larger surface area of the BGI, which increased its success rates in the AVB and ABC studies, is limited to the parts of the plate not covered by the recti muscles.[8] The PGI is designed to have a shorter wingspan and larger extension posteriorly to increase the effective surface area of the device. The use of the ripcord (3.0 nylon/prolene) in the BGI allowed for less aggressive scarring of the fibrous capsule around the endplate; this advantage paved the way for use of a ripcord in PGI. Due to the small calibre of the PGI tube, the device can be inserted mid-anterior chamber occupying less space in the anterior chamber angle and thereby avoiding the iris and the endothelium. This results in less iris occlusion of the device and less endothelial damage.[8]

In the ABC and AVB studies, both the BGI and the AGV failed at the same rate but for different reasons. The AGV failed because of high IOP end points whereas the BGI failed because of safety end points.[12,13] The BGI had greater rates of hypotony due to the lack of a flow restrictor compared to the AGV. As a result of this, many surgeons inserting the BGI will completely prevent flow postoperatively using the ripcord and an absorbable suture to tie the tube off. The disadvantage of this is early postoperative hypertony. Advances in the PGI, such as the smaller internal calibre, allow for the prevention of early postoperative hypotony without having to tie off the tube and with a smaller ripcord compared to the BGI (6.0 vs 3.0). This allows early flow into the bleb (as with the AGV) which allows for early postoperative IOP control. Another feature includes a well at the back end of the PGI endplate; this allows for the rate of aqueous drainage to be visualised, and the ripcord can be adjusted accordingly within the tube to vary the flow rate. This feature helps to decrease the early postoperative IOP variability and decrease the rate of hypotony.[8] The ripcord therefore prevents hypotony early on while still allowing early postoperative IOP control and allows for less scarring around the endplate, therefore allowing good IOP control once the ripcord is removed. These features of the PGI combine the advantageous features of both the BGI and the AGV.[8] In the study by Koh *et al.* using the PGI, the majority of patients had self-limiting anterior chamber shallowing which resolved in two weeks; this is attributed to the small internal calibre of the tube which offers a small degree of resistance and helps prevent hypotony.[8]

Conclusion

The PGI is a novel device showing comparable efficacy with other GDIs in patients with refractory glaucoma. It has unique design features which offer advantages over the BGI and the AGV. With the rise in GDI surgery, the PGI is a feasible and alternate option when deciding on GDI use in patients with refractory glaucoma. Koh *et al.* highlighted the surgical success in patients using the PGI after one-year follow-up, and our own experience using the PGI has been positive.[8] Decisions on which implant to choose depend on surgeon preference and availability.

Table II: Dimensional differences between the Ahmed, Baerveldt and the PAUL Glaucoma Implant

Device/Feature	Ahmed Glaucoma Valve	Baerveldt Glaucoma Implant	Paul Glaucoma Implant	Advantages of the Paul Glaucoma Implant
Plate surface area	184 mm²	350 mm²	342 mm²	Reduces encapsulation
Plate thickness	1.0 mm	0.9 mm	0.95 mm	More IOP control
Plate length (L)	L:13 mm	L:32 mm	L:21.9 mm	Increases effective surface area not covered by recti
Plate width (W)	W:16 mm	W:15 mm	W:16.1 mm	Easier to implant
Fenestration holes	3	4	6	Less micromotion
Reservoir depth	0.5 mm	Nil	0.4 mm	
Tube outer diameter	0.64 mm	0.64 mm	0.467 mm	Less risk of tube erosion and corneal touch
Tube inner diameter	0.3 mm	0.3 mm	0.127 mm	Prevent hypotony

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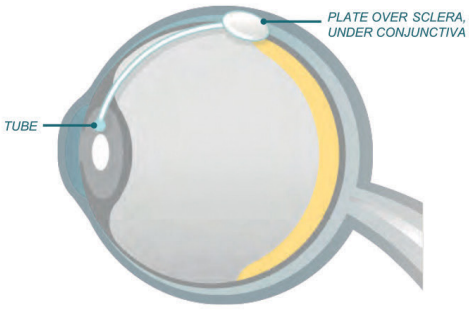
PAUL® GLAUCOMA IMPLANT



PAUL® Glaucoma Implant is a micro-sized tubed aqueous shunt for the PAUL® Stability System which is designed to regulate glaucoma or raised intraocular pressure in the patient's eye.

Drains fluid from the interior of the eye to the exterior of the eye.

Provides a stable & well-formed anterior chamber post-implantation in the immediate post-operation month[1].

Offers effective & safe glaucoma control for the eye; implanted using the PAUL® Stability System[1].

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