

Surgical Innovations in glaucoma drainage devices

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ABSTRACT

Although tube shunts have been used for several decades in glaucoma management, new insight into long-term outcomes, comparisons between tube shunts and other procedures, comparisons between different tube shunts, and other ways of improving patient outcomes have emerged. Advancements in glaucoma surgery allow surgeons to provide treatments with less risk.

Keywords: Glaucoma drainage device, Paul glaucoma implant, Surgical innovations.

INTRODUCTION

Glaucoma is still the second leading cause of blindness in Europe. Currently, the only approach proven to be effective in preserving visual function is lowering IOP. Surgery should be considered whenever medical or laser treatment is unlikely to maintain sight in the glaucomatous eye. It should not be left as a last resort. Initial surgery may be considered in patients with advanced visual field loss at presentation.¹

Aqueous humor production begins with the epithelium of the ciliary body behind the iris, travels through the pupillary aperture into the anterior chamber, and exits the eye through the anterior chamber angle. For decades, the primary resistance to aqueous outflow has been thought to reside in the outer one-third of the trabecular meshwork, including the juxtacanalicular connective tissue in continuity with the inner wall of Schlemm's canal. The dysfunction of this portion of the trabecular outflow system is considered the leading cause of open-angle glaucoma (COAG).^{2,3} Overproduction or decrease in egress or filtration results in elevated IOP, commonly leading to optic neuropathy. The delicate regulation of this pathway is responsible for the control of IOP. While surgical approaches directed at decreasing aqueous production involve cyclodestruction via transscleral diode laser, transscleral cryoablation, or

more recently endoscopic diode laser cycloablation, many novel techniques and devices have emerged to enhance outflow. The two physiologic outflow pathways in the normal human eye are the conventional and uveoscleral outflow pathways. The traditional pathway comprises the trabecular meshwork, Schlemm's canal and distal intrascleral and episcleral venous plexi. The uveoscleral outflow pathway consists of the interstitium of the ciliary body, the suprachoroidal space, and ultimately scleral or choroidal vasculature. Alternatively, while subconjunctival filtration is non-physiologic, it remains the most widely utilized means of surgical IOP reduction via trabeculectomy and tube shunt procedures. Current glaucoma surgical options are classified in the flowchart (Figure 1) prepared by the American Glaucoma Society (AGS).⁴

Glaucoma Drainage Devices have been used for several years in glaucoma treatment. New data on long-term outcomes, comparisons between different tube shunts, comparison between tube shunts and other procedures, and other ways of increasing patient outcomes have emerged. In this article we review the current surgical trends in glaucoma drainage devices. Our review also analyzes mechanisms of action, types of aqueous shunts, complications and lastly future directions in tube shunt surgery.

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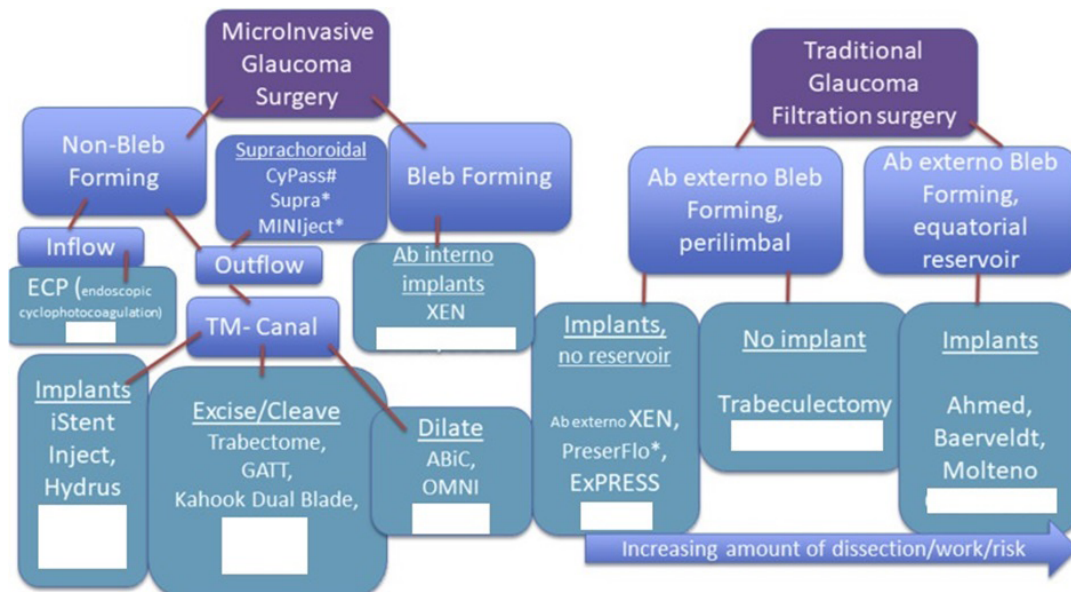


Figure 1: Flowchart showing different types of microinvasive and traditional glaucoma surgical options. #Withdrawn from the market. *Not approved by the United States Food and Drug Administration. ABiC = ab interno canaloplasty; GATT = gonioscopy-assisted transluminal trabeculectomy; TM = trabecular meshwork.

MECHANISMS OF ACTION

Filtration of aqueous humor into the anterior subconjunctival space is achieved by the procedure of trabeculectomy, where a fistula is created from the anterior chamber under a scleral flap to the subconjunctival space to form what is commonly known as a bleb.

The earliest attempts to drain fluid out of the anterior chamber into the subconjunctival space consisted of implanting a variety of foreign objects into the eye extending from the anterior chamber to the subconjunctival space. These early operations failed because of excessive fibrosis over the subconjunctival portion of the implant at the limbus, seton migration, or conjunctival erosion. Dr. Anthony Molteno introduced the concept of draining fluid away from the anterior chamber to a plate posterior to the limbus.⁵ The Molteno implant had an episcleral plate positioned in the equatorial region, which was connected to the anterior chamber by means of an elongated silicone tube. This design allows aqueous humor to egress from the anterior chamber to the posterior subconjunctival space away from the active limbal zone with the potential advantages of less extensive subconjunctival fibrosis, a potentially more significant reservoir for aqueous fluid, and lower incidence of bleb dysesthesia.

Tube shunts, although filtering aqueous posteriorly, share some similar postoperative challenges with trabeculectomy, such as bleb encapsulation and fibrosis. While posterior filtration may be less likely to encounter these issues, as the bleb is further from the metabolically

active limbal zone, tube shunts have their own unique set of postoperative risks. Additional modifications of glaucoma drainage implants have improved the safety and efficacy of the devices.

CLASSIFICATION OF GDDs

Glaucoma drainage implants are devices that allow aqueous outflow by creating communication between the anterior chamber and the sub-Tenon's space. Prior to the advent of trabeculectomy, the first glaucoma drainage device emerged in 1906 with the implantation of horse hair through a corneal paracentesis in a patient with a blind, painful, hypertensive eye. While this had fairly obvious limitations and risks, the first tube and plate device was introduced in the late 1960s by Molteno.^{5,6}

Types of GDD

Various types of GDDs have been used up to date, presenting varied materials and sizes, with or without a flow restriction system. Current glaucoma drainage devices can be classified into two broad categories, valved or nonvalved. Valved implants or flow-restrictive drainage devices resist aqueous flow and prevent hypotony during the early postoperative period. Nonvalved implants or open tube drainage devices provide little resistance to aqueous flow during the early postoperative period until a fibrous capsule forms around the plate. Various techniques and devices have been devised to prevent hypotony associated with open tube implants during the early postoperative

period. Options for future development in glaucoma drainage devices include adjustable valved devices like the eyeWatch (Rheon Medical).⁷

The unique design features of these devices bring up several potential areas of study including the IOP lowering effect of plate surface area, plate surface location, tube diameter, and the different side effect profiles.

Implants with increased surface area have been intended to increase the surface area of the end-plate and lower the intraocular pressure. Thus, double-plate versions of the Molteno implant⁸ and the Ahmed Glaucoma Valve⁹ have been introduced. Also, Dr. George Baerveldt introduced a nonvalved silicone tube attached to a large barium-impregnated silicone plate.¹⁰

Worldwide, commonly used and investigated GDDs are presented.

Aqueous Drainage Devices

Baerveldt Glaucoma Implant (*Johnson & Johnson Vision*)

Ahmed Glaucoma Valve (*New World Medical*)

Ahmed ClearPath (*New World Medical*)

Aurolab (*India*)

Molteno3 (*Nova Eye Medical*)

Calibreye (*Myra Vision*) (INVESTIGATIONAL)

Gore Glaucoma Drainage Implant (*WL Gore & Associates*) (INVESTIGATIONAL)

PAUL Implant (*Advanced Ophthalmic Innovations*) (INVESTIGATIONAL)

eyeWatch (*Rheon Medical*) (INVESTIGATIONAL)

Non-valved GDD (Open tube drainage devices= Valveless)

The tube and plate concept developed by Molteno has mainly been maintained in the design of modern GDDs (Molteno, 1969). In these devices, the aqueous humor is drained from the anterior chamber via a tube and a plate placed in the subconjunctival area on the equatorial part of the eye. Following the Molteno, successive devices made minor changes to the GDD design in an attempt to increase surgical success and prevent failures. Georges Baerveldt invented the Baerveldt GDD in the 1990s.¹⁰ It was made out of a silicone tube linked to a malleable barium impregnated silicone plate that came in various sizes. The main problem, however, with valve-less Molteno and Baerveldt GDDs was hypotony, indicated by excessively low IOP in the early post-operative phase.

The nonvalved GDDs have no unidirectional restrictive mechanism to prevent the retrograde flow of aqueous humor. Baerveldt drainage implant and Molteno drainage implant are two commonly used non-valved GDDs across the globe. The Ahmed ClearPath Glaucoma Drainage Device, the PAUL Glaucoma Implant (PGI), and the Aurolab Aqueous Drainage Implant (AADI) are three valveless glaucoma implants available relatively new to the market for the treatment of glaucoma in pediatric and adult populations. These GDDs do not have a restrictive valve device; hence, they need to be tied off (ripcord suture) at the time of surgery.

India has a cheaper alternative, AADI (Aurolab aqueous drainage implant).¹¹ The Paul Glaucoma Implant (PGI) was created to reduce complications while preserving efficacy. The PGI differs by having a smaller tube diameter—the external tube diameter is 467 μm , and the internal tube diameter is 127 μm . By occupying less space in the anterior chamber and preserving a large endplate surface area for aqueous absorption, damage to the corneal endothelium and risk of tube erosion are theoretically lowered.¹² The smaller tube caliber makes intraoperative surgical occlusion easier.

The Ahmed ClearPath GDD (ACP, New World Medical, Rancho Cucamonga, CA, USA)¹³ was introduced in 2019 as a valveless device, available in both 250 and 350 mm^2 sizes, and with a flexible plate that conforms to the curvature of the globe. Anteriorly located suture fixation points make implantation easier, the posteriorly positioned plate on the 350 models avoids muscle insertions, and an optional pre-threaded 4-0 polypropylene rip cord and a co-packaged 23-gauge needle simplify the creation of a sclerotomy.

Aurolab Aqueous Drainage Implant

The Aurolab Aqueous Drainage Implant (AADI; Aurolab [India]) is a non-valved silicone implant with a 350- mm^2 surface area. Its design is similar to that of the Baerveldt glaucoma implant.

Paul Glaucoma Implant

The Paul Glaucoma Implant (PGI; Advanced Ophthalmic Innovations [Singapore]) is composed of medical-grade silicone, and it drains aqueous over a surface area of 342.1 mm^2 (Figure 2). An important difference between the PGI and aforementioned glaucoma drainage devices is that the internal and external diameters of the tube portion of the PGI are of significantly smaller calibers (0.127 mm and 0.467 mm, respectively) (Figure 2). This decreases the

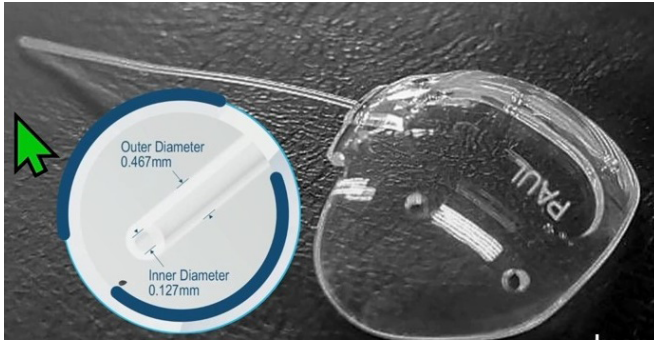


Figure 2: Paul Glaucoma Implant and tube diameters

risks of tube-corneal touch (Figure 3 a-d) and conjunctival erosion.

Koh and colleagues investigated the safety and efficacy of the PGI in 74 eyes of 74 patients after 1 year of follow-up.¹² In the study group, mean baseline medicated IOP decreased from 23.1 +8.2 mm Hg to 13.2 +3.3 mm Hg at 1 year. This corresponded to a decrease in medication use from 3.3 +0.9 medications at baseline to 0.3 +0.6 at 1 year. Importantly, surgeons implanting the PGI (Figure 3 a,c,d) in this study used various techniques to limit immediate postoperative hypotony. These techniques included tube ligation, ripcord

suture (6/0 prolene) (Figure 3 b) placement, and the use of an OVD to fill the anterior chamber. Postoperative complications included self-limited anterior chamber shallowing (14.9%), hypotony requiring an intracameral OVD injection (9.5%), tube shunt occlusion (6.8%), tube exposure (4.1%), and endophthalmitis (1.4%). Longer-term follow-up and experience with the PGI are required to assess better the device's place in the glaucoma treatment armamentarium, but results thus far are encouraging.^{14,15}

The AADI and PGI are novel glaucoma devices that have expanded global access to aqueous shunt surgery. Both devices have attained the CE Mark in Europe but have yet to be approved by the FDA. To date, published data on these devices suggest that their safety and efficacy profiles are similar to those of devices that are commercially available in the United States.

Valved GDD (Flow-restrictive drainage devices)

The main advantage of valved GDD is its safety since the unidirectional outflow of aqueous humor prevents potential blinding complications compared to the non-valved devices.⁽¹⁶⁻³³⁾ Nevertheless, these devices presented earlier encapsulation, resulting in lower long-term

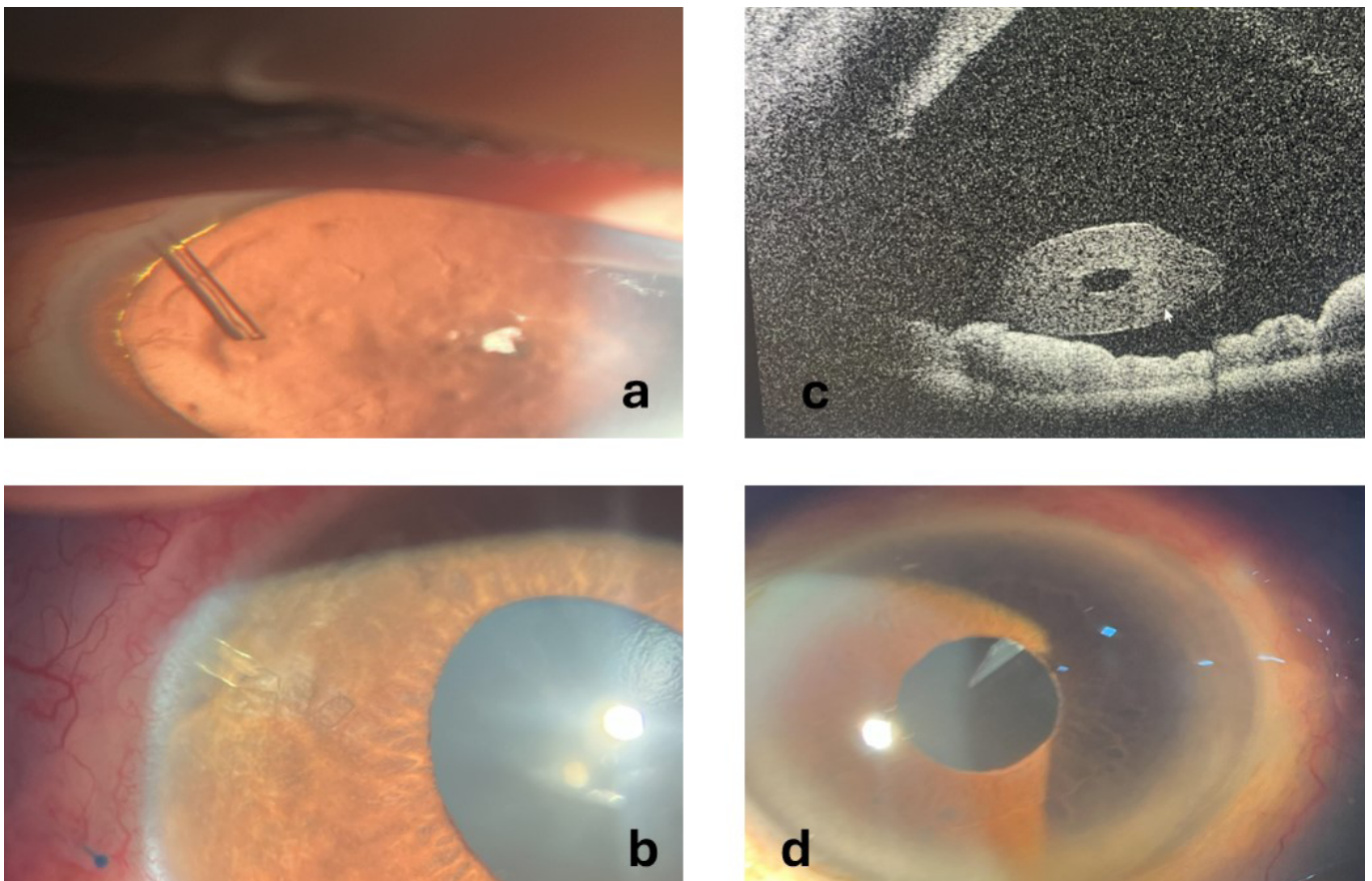


Figure 3: Postoperative photos for Paul Glaucoma implant (PGI); **a.** Anterior segment biomicroscopic photo in an aniridic patient, **b. c.** PGI position and 6/0 subconjunctival prolene suture in the same patient (biomicroscopic and anterior segment OCT photo) **d.** PGI in sulcus (Courtesy of Dr. Serhat İmamoğlu)

success rates than the non-valved GDD.³⁴ Dr. Theodore Krupin developed a pressure-sensitive, slit valve that provided resistance to the flow of aqueous, reducing the occurrence of early postoperative hypotony.³⁵ Dr. Mateen Ahmed introduced the Ahmed Glaucoma Valve, which is a pressure-sensitive glaucoma drainage device with a valve designed to open when the intraocular pressure is approximately 8 mmHg.³⁶

Adjustable Valved GDD

The Ahmed valve became the most used GDD in the world, however, its long-term performance is not optimal because its valve structure adds constant fluidic resistance to flow leading to high IOPs (>21 mmHg) and failures.³⁷ To address the problems in the previous GDDs, the eyeWatch implant (Rheon Medical SA, Lausanne, Switzerland), the world's first commercially available adjustable glaucoma implant, was developed at the laboratory of hemodynamics and cardiovascular technology (LHTC). The eyeWatch implant includes an eccentrically rotatable magnetic disk, which is used to apply variable compression on an internal deformable tube, thereby altering its fluidic resistance to keep the IOP within the clinically desired range (Figure 4).^{38,39} The readout of the magnetic disk rotational position and the rotation of the disk is achieved with the eyeWatch Pen, an external hand-held device that is used as a control unit. It is also important to note that the EyeWatch is an MRI-conditional device. Although it is relatively safe for a patient with the implant (Figure 5) to undergo an MRI, their IOP must be checked after any head scanning because adjustments may be required.

PATIENT SELECTION

Like all glaucoma surgeries, patient selection and clinical examination are crucial in selecting the most appropriate

intervention. GDI surgery is usually indicated in the following settings

1. Patients with failed trabeculectomy/multiple failed glaucoma surgeries
2. Secondary glaucomas uncontrolled on maximal tolerated medical therapy
3. Patients at a high risk of failure of conventional glaucoma filtration surgery

In addition to the usual clinical evaluation for glaucoma patients, preoperative examination should focus on mobility of the conjunctiva, corneal health, presence of neovascularization, anterior chamber depth, gonioscopy with attention to peripheral anterior synechiae, and lens status with phakic eyes being considered for combined cataract surgery, pseudophakic eyes being considered for sulcus tube placement, and vitrectomized eyes being considered for pars plana tube placement.

Several factors should go into consideration when choosing a glaucoma drainage device for a patient. The first decision point is to select a valved or non-valved device. The Ahmed Baerveldt Comparison (ABC) Study and the Ahmed Versus Baerveldt (AVB) Study are two landmark trials that compared the Ahmed FP7 valved implant to the Baerveldt 350 mm² non-valved implant. These studies found the Ahmed FP7 had greater immediate IOP reduction while the Baerveldt implant resulted in lower long-term IOP and medication burden reduction.^{37,40} The Baerveldt implant had a higher rate of serious postoperative complications, including hypotony. Multivariate analysis showed no difference in success rates between devices (AGV, BGI) for neovascular cases. No device conferred an advantage in these patients. As such, patients requiring immediate IOP reduction may be better off with a valved device (AGV),

eyeWatch: Adjustable Flow



Rheon Medical

Figure 4: The EyeWatch device contains a magnetic disc and commercial ruby ball bearings in the center and an attached tube, which is connected to a tube shunt at the time of surgery.

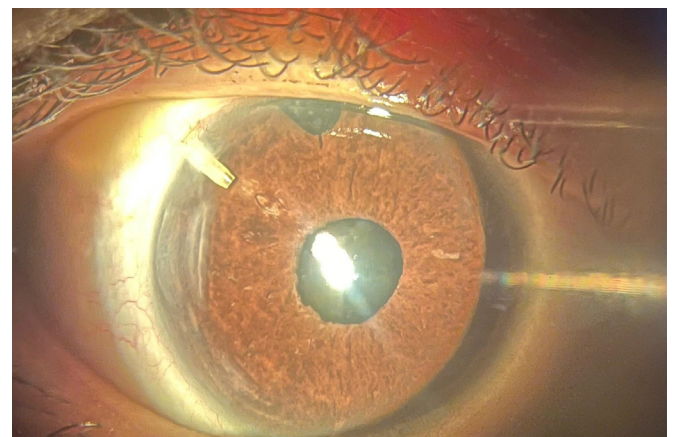


Figure 5: Postoperative anterior segment photo with eyeWatch implant (Courtesy of Dr.Ali Olgun)

while patients requiring lower long-term IOP targets may benefit from a valveless device.³⁷

Valveless devices may require closer initial monitoring, making them less desirable for patients with poor follow-up.

Another factor for consideration is the size of the implant plate. The surface area of the episcleral plate determines the area of encapsulation. Larger plate sizes are thought to correlate with greater IOP reduction⁴⁰ though more recently, several retrospective studies found no difference between the Baerveldt 250–350 mm² implants.^{41–43} In addition, studies comparing 350–500 mm² showed comparable or even greater IOP reduction with the 350 mm² model.^{44,45} Currently, there are no comparative studies investigating the Ahmed ClearPath 250 mm², the Ahmed ClearPath 350 mm², the PAUL glaucoma implant (342.1 mm²), or the Aurolab aqueous drainage implant (350 mm²).

Finally, it is essential to assess the risks of glaucoma drainage implant surgery including hypotony, hyphema, scleral perforation, cataract, corneal decompensation, tube erosion (Figure 6c), endophthalmitis, suprachoroidal

hemorrhage, and strabismus. Notably, there is greater risk of diplopia with manipulation of the rectus muscles and insertion of glaucoma drainage devices with larger episcleral plates and plates with a higher profile.⁴⁶

Common indications of GDI as a primary procedure

Traumatic glaucoma

Neovascular glaucoma

Uveitic glaucoma

Post-penetrating keratoplasty glaucoma

Glaucoma associated with keratoprosthesis

Silicone oil glaucoma

Glaucoma following vitreoretinal surgery

Infantile/juvenile glaucoma

Glaucoma in aphakia/pseudophakia

ICE syndrome with glaucoma

Axenfeld Reiger's syndrome with glaucoma

Glaucoma in Sturge-Weber syndrome

Glaucoma due to epithelial ingrowth

Scleral thinning

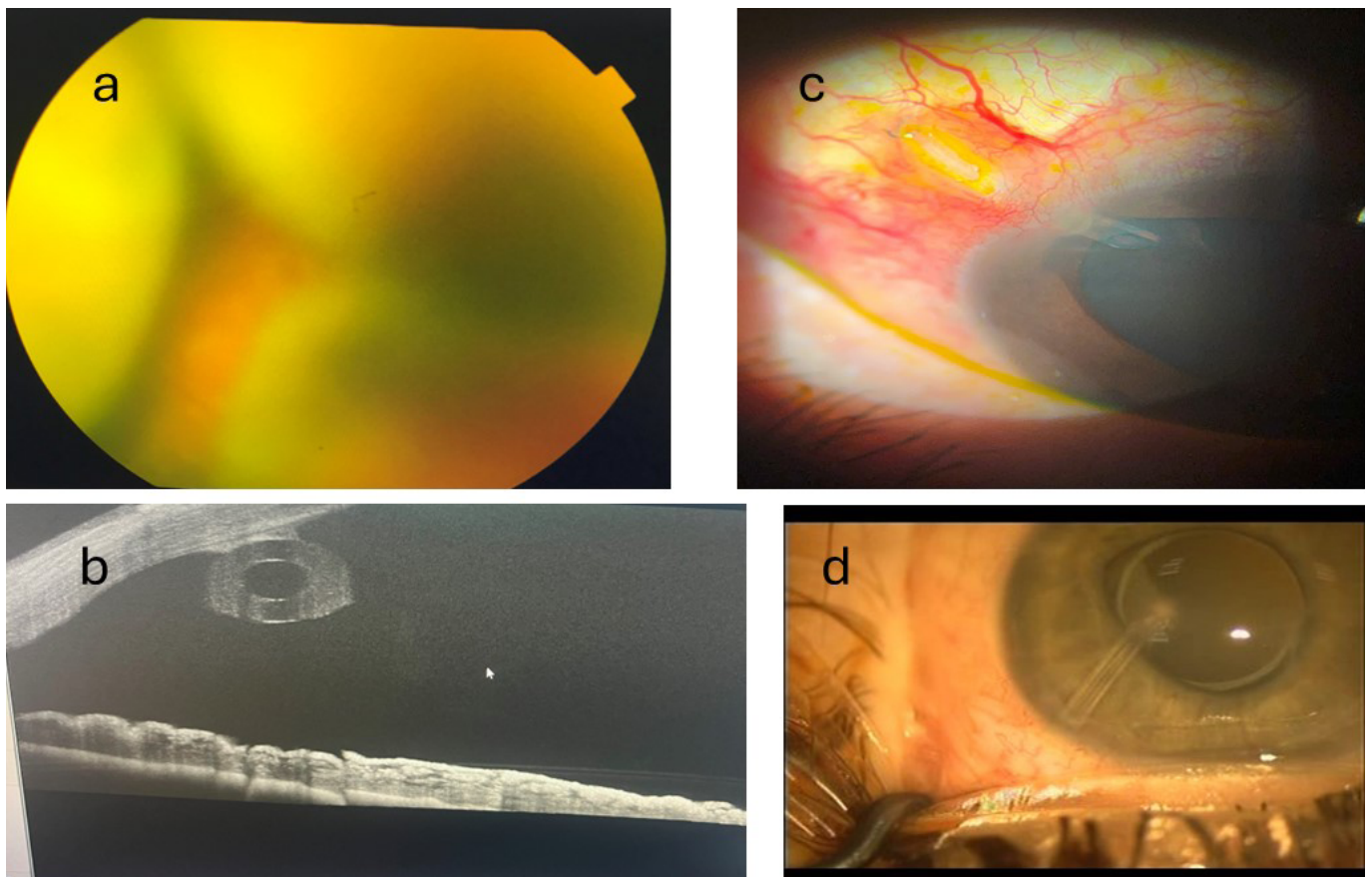


Figure 6: Postoperative complications after AGV, a. kissing choroidal effusion, b. anterior segment OCT photo of corneal endothelial touch, c. tube exposure-erosion, d. tube obstruction with retinal tissue in aphakic pediatric glaucoma patient (Courtesy of Dr. Serhat İmamoğlu)

SURGICAL TECHNIQUE

The preoperative examination should focus on mobility of the conjunctiva, corneal health, presence of neovascularization, anterior chamber depth, gonioscopy with attention to peripheral anterior synechiae, and lens status with phakic eyes being considered for combined cataract surgery, pseudophakic eyes being considered for sulcus tube placement, and vitrectomized eyes being considered for pars plana tube placement.

It's far preferable to place the device in the supratemporal quadrant, which is covered by the eyelid, with the inferonasal quadrant as a second choice.

Depending on the surgeon's preference, a limbus-based or fornix-based conjunctival flap is used. Large plate GDDs is positioned under superior rectus and lateral rectus muscles, to prevent diplopia. The implant is sutured to the sclera with nonabsorbable or absorbable suture (6/0 vicryl) at a measured distance of 10 mm posterior to the limbus, using the two fixation holes in the GDD plate. The valveless tube is completely occluded to temporarily restrict aqueous flow to the plate until it becomes encapsulated to minimize the risk of early postoperative hypotony. Intraluminal stents and occlusion sutures around the tube are frequently used to avoid this complication. The tube is trimmed bevel-up to extend 1 to 2 mm into the anterior chamber. A 23-gauge needle creates a tight entry incision into the anterior chamber at the posterior limbus. The tube is inserted through this entry incision and positioned away from the corneal endothelium, just above the iris. Tube insertion in the vicinity of, or anterior to SL, and short TL were associated with significant ECD loss with time.⁴⁷ Glaucoma drainage tubes may be inserted through a partial-thickness scleral flap or tunnel, or covered with a donor graft patch to prevent tube exposure or tube migration. There is no evidence to suggest that a better long-term survival of GDD surgery depends on the type of graft material or the use of antimetabolites. The conjunctiva is closed using 9-0 or 8-0 polyglactin suture on a tapered needle. Fibrin glue is an alternative to sutures for conjunctival closure.⁴⁸

COMPLICATIONS

Tube shunts have their own challenges and complications. Improvements in surgical technique, in the devices themselves, and new ideas are about to prevent these complications.

According to The Ahmed Versus Baerveldt Study (Five-Year Treatment Outcomes)³⁷ both implants had high

rates of postoperative complications (Table 1), although most were transient or required minimal intervention. The most common early postoperative complication was hypotony, resulting in shallow anterior chambers (Ahmed 15%, Baerveldt 17%) and choroidal effusions (Figure 6 a) (Ahmed 13%, Baerveldt 16%), which resolved over time. Early postoperative IOP spikes requiring paracentesis were more common in the Baerveldt group while the tubes were ligated (Ahmed 4%, Baerveldt 14%, P= 0.007). Tube complications occurred in 14% of the Ahmed group and 17% of the Baerveldt group, with tube obstruction (Figure 6 d) and tube malposition (Figure 6 b) being the most common. Tube interventions were required in 10% of the Ahmed group and 17% of the Baerveldt group (P =0.11), with tube repositioning being the most common. Serious early postoperative complications included suprachoroidal

Table 1: Complications in Five-Year Follow-up³⁷

Complication	Ahmed (n=124)	Baerveldt (n=114)	P Value
Shallow anterior chamber	18 (15%)	19 (17%)	0.65 [†]
Choroidal effusions	16 (13%)	18 (16%)	0.53 [†]
Tube complications	17 (14%)	19 (17%)	0.41 [†]
Tube obstruction	7 (6%)	10 (9%)	0.35 [†]
Tube malposition	8 (6%)	7 (6%)	0.92 [†]
Tube erosion	5 (4%)	2 (2%)	0.45 [‡]
Corneal edema	14 (11%)	14 (12%)	0.81 [†]
Iritis	9 (7%)	14 (12%)	0.19 [†]
Cataract progression	11 (32%)	13 (41%)*	0.49 [†]
Encapsulated blep	14 (11%)	4 (4%)	0.023 [†]
Hyphema	4 (3%)	6 (5%)	0.43 [†]
Motility disorder	6 (5%)	2 (2%)	0.28 [‡]
Aqueous misdirection	2 (2%)	4 (4%)	0.43 [‡]
Suprachoroidal hemorrhage	2 (2%)	3 (3%)	0.67 [‡]
Phthisis bulbi	1 (1%)	2 (2%)	0.61 [‡]
Retinal detachment	1 (1%)	0	1.0 [‡]
Endophthalmitis	1 (1%)	0	1.0 [‡]
Progression to no light perception	7 (6%)	7 (6%)	1.0
Hypotony requiring surgery	1 (1%)	6 (5%)	0.057 [‡]
High IOP requiring de novo surgery	19 (15%)	11 (10%)	0.19 [†]
Other	6 (5%)	7 (6%)	0.66 [†]
Total	78 (63%)	79 (69%)	0.30 [†]

IOP= intraocular pressure, * Corrected for number of phakic patients, † Pearson chi-square test, ‡ Fisher exact test.

hemorrhage, which occurred in 3 patients (3%) in the Baerveldt group, in whom two required drainage. One patient in the Ahmed group had an intraoperative suprachoroidal hemorrhage that required drainage, and one patient had a suprachoroidal hemorrhage after a tube reposition at 18 months.

The most common long-term complication was corneal edema, which affected 11% of the Ahmed group and 12% of the Baerveldt group, of whom 7% of the Ahmed group and 4% of the Baerveldt group required a corneal transplant. Ahmed valve implant may have higher rates of bleb encapsulation than the Baerveldt implant. Ahmed valve implant has early postoperative flow, which may expose the bleb to inflammatory mediators from surgery, stimulating fibrosis. Early aqueous suppressant treatment may improve AGV implantation outcomes regarding IOP reduction, success rate, and hypertensive phase frequency.⁴⁹ High IOP requiring de novo surgery can be seen after failed GDD surgery. Cyclodestructive procedures and additional tube shunts are the most common de novo glaucoma surgeries. Prolonged high IOP within the bleb results in cytokine production by the bleb lining in patients with failed GDD. It is shown that occluding the tube of a failed implant can prevent damage to a new implant in a different eye quadrant.⁵⁰

FUTURE DEVELOPMENTS

Subconjunctival filtration procedures may often result in pressure fluctuations postoperatively. A novel treatment designed to address this challenge is the **Calibreye System**

(Myra Vision; not yet available), a titratable aqueous shunt with valve-controlled channels that can be reversibly and repeatedly opened or closed using an office-based transcorneal laser. The ability to titrate outflow resistance is intended to minimize the risk of early hypotony following surgery and optimize longterm IOP outcomes. The Calibreye System features three flow channels that communicate between the anterior chamber and the subconjunctival space, creating a filtering bleb. These valves can be opened or closed using a slit-lamp-mounted green laser through the peripheral cornea. This design provides reversible, titratable resistance to aqueous humor outflow (Figure 7). By modulating the valves' positions, four device settings can be achieved with decreasing hydrodynamic resistance: baseline (standard channel open), moderate, high, and maximal.

The Calibreye System is implanted through an ab externo approach (Figure 8). The Calibreye System is a promising technology that may safely allow more aggressive IOP reduction for patients with moderate to severe glaucoma. The ability to modulate outflow could enable the delivery of more personalized care while minimizing postoperative complications.⁵¹

One important mechanism of GDI failure is encapsulation or fibrosis over implant plates, which results in decreased bleb permeability and IOP elevation.² Creating a thinner, more permeable GDI bleb without drastically reducing implant surface area requires decoupling this relationship. Preclinical data generated at the Wilmer Eye Institute

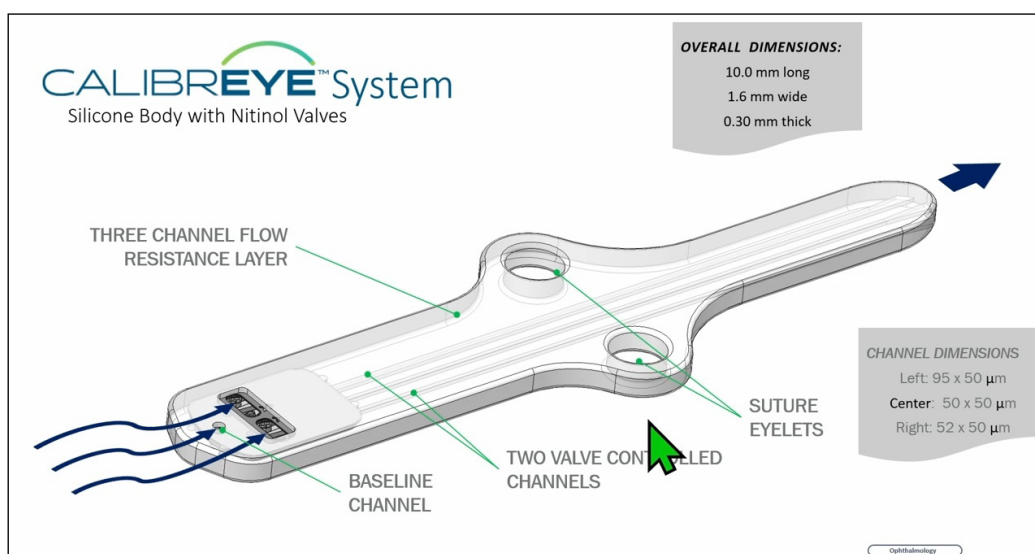


Figure 7: The Calibreye System is a novel titratable aqueous shunt composed of nitinol and silicone. The material, coupled with the low-profile dimension, was selected to conform to the globe and minimize erosion risk.

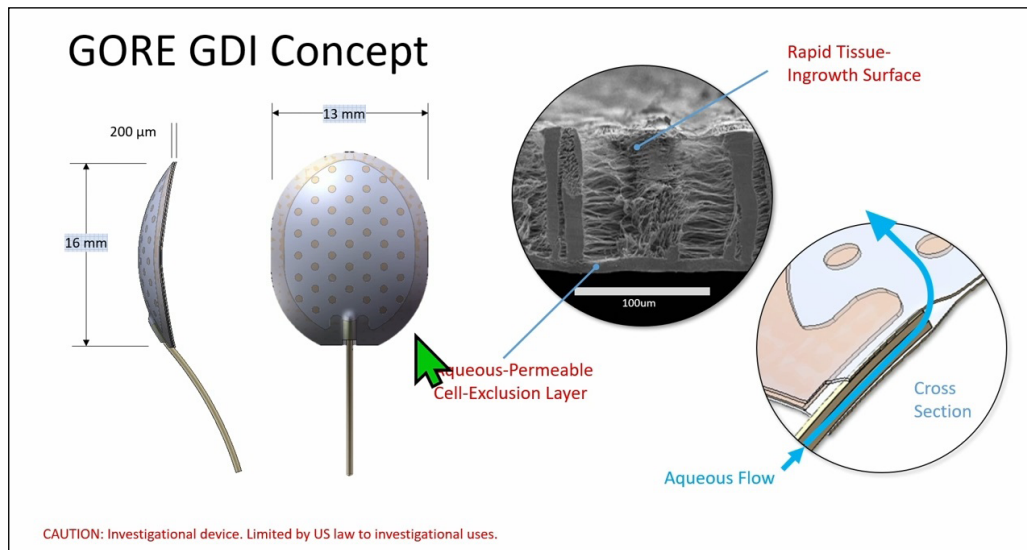


Figure 8: Gore ePTFE. Schematic of the investigational GDI prototype. Scanning electron microscopy of ePTFE. Varying arrangements of dense nodes and thin fibrils allow customization of the ePTFE membranes.

indicate that the team from W.L. Gore & Associates (Gore) has achieved this with a novel, investigational GDI prototype (Figure 8) Gore GDI that will soon be evaluated in a first-in-human (FIH) study.

Expanded polytetrafluoroethylene (ePTFE) is a biocompatible, biostable, highly compliant, and versatile microporous polymer. Because it incorporates well into many tissues, ePTFE is widely used in biomedical implants, including vascular grafts, hernia membranes, and sutures.⁴ By inviting physiologic tissue integration, the ePTFE GDI is intended to promote subconjunctival healing without fibrosis, allowing durable aqueous filtration across the bleb without using antimetabolites. The implant is sized to maximize surface area while avoiding placement on or under muscles or encroachment on the optic nerve. Constraining reservoir inflation to a height of less than 1 mm adds the geometric advantages of a low bleb to the material advantages of ePTFE while minimally increasing resistance, and our tube geometry is designed as a safeguard against hypotony.⁵²

KEY POINTS

- Larger plate sizes are thought to correlate with greater IOP reduction.
- Neovascular glaucoma patients requiring immediate IOP reduction may benefit from valved device (AGV).
- Tube insertion in the vicinity of, or anterior to SL, and short TL were associated with significant ECD loss with time.

- Occluding the tube of a failed implant can prevent damage to a new second implant in a different eye quadrant.
- Early aqueous suppressant treatment may improve AGV implantation outcomes regarding IOP reduction.

CONCLUSION

Finally, prospective comparative trials between these devices and classical devices like the Ahmed glaucoma valve implant and Baerveldt glaucoma implant are needed to help guide ophthalmologists in choosing an implant for their patients. As new design features continue to be discovered and evaluated, glaucoma drainage devices will continue to improve and provide more options for patients with glaucoma.

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