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Aqueous shunt implantation in glaucoma

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Abstract:

Aqueous shunts or glaucoma drainage devices are increasingly utilized in the management of refractory glaucoma. The general design of the most commonly-used shunts is based on the principles of the Molteno implant: ie. a permanent sclerostomy (tube), a predetermined bleb area (plate) and diversion of aqueous humour to the equatorial region and away from the limbal subconjunctival space. These three factors make aqueous shunts more resistant to scarring as compared to trabeculectomy. The two most commonly used shunts are the Ahmed Glaucoma Valve, which contains a flow-restrictor, and the non-valved Baerveldt Glaucoma Implant. While the valved implants have a lower tendency to hypotony and related complications, the non-valved implants with larger, more-biocompatible end plate design, achieve lower intraocular pressures with less encapsulation. Non-valved implants require additional suturing techniques to prevent early hypotony and a number of these methods will be described. Although serious shunt-related infection is rare, corneal decompensation and diplopia are small but significant risks.

Keywords:

Aqueous shunts, glaucoma drainage devices, glaucoma surgery, glaucoma tube shunts

Introduction

Aqueous shunts or glaucoma drainage devices (GDD) are artificial filtering devices which lower the intraocular pressure (IOP) by draining aqueous humor to the external subconjunctival space. The shunts commonly used in clinical practice are based on the design of the original Molteno implant, i.e., a silicone tube draining aqueous from inside the eye to an end plate of variable size placed on the sclera. The silicone tube may be inserted into the anterior chamber, ciliary sulcus, or vitreous cavity through the pars plana. The plate is placed over equatorial sclera, usually in the superotemporal quadrant (STQ). The advantages of a GDD over the traditional trabeculectomy include the presence of:

1. A permanent sclerostomy (the tube)
2. Aqueous drainage to the equatorial region where the potential for conjunctival scarring is less than with anterior conjunctiva at the limbus

3. A predetermined bleb area (the plate).

The use of GDD in glaucoma management has become increasingly popular. The number of GDD implantations increased 231% between 1994 and 2003 in the United States alone.^[1] Today, a large proportion of glaucoma specialists routinely perform aqueous shunt surgery in managing refractory glaucoma. This review discusses the indication, surgical techniques, and complications of aqueous shunt implantation.

Aqueous Shunts Overview

Aqueous shunts differ in plate surface area, shape, thickness, material, and the presence of a flow restrictor [Table 1]. Regardless of the type of shunt, the tube part is made of silicone and of a similar size. The inner lumen of the tube is typically 0.30 mm in diameter with an outer diameter of around 0.64 mm. The Molteno implant was the first commercially available GDD, and much of our experience with aqueous shunt surgery is based on the earlier Molteno implants. Although the original is still available,

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Table 1: Common valved and nonvalved glaucoma drainage devices

	Year	Model	Plate material	Plate size (mm ²)	Plate thickness (mm)	Opening IOP and comments
Valved GDD						
Ahmed glaucoma implants	1993	S2	Polypropylene	184	1.6	Closes below 8 mmHg
		S3	Polypropylene	85	1.6	
		B1	Polypropylene (double plate)	364	1.6	
		Pars plana		184	1.6	
		PS2	Polypropylene	85	1.6	
		PS3	Polypropylene	184	2.1	
		FP7	Silicone	102	2.1	
		FP8	Silicone	364	2.1	
		FX1	Silicone (double plate)	184	2.1	
		Pars plana		102	2.1	
Krupin eye valve	1976	PC7	Silicone	184	1.75	Opens above 10 mmHg Closes below 8 mmHg
		PC8	Silicone			
Nonvalved GDD						
Molteno	1973	Molteno				
	2004	S1 (single plate)	Polypropylene	133	1.65	-
	2012	D1 (single plate with ridge)	Polypropylene	133	1.65	Ridge valve on the plate
		L2, R2 (double plate - left; right)	Polypropylene	266	1.65	-
		DL2, DR2 (double plate with ridge - left; right)	Polypropylene	266	1.65	Ridge valve on the plate
		P1 (microphthalmic)	Silicone	175	0.4-1.15	Ridge valve on the plate
		Molteno 3 GS	Silicone	230	0.4-1.15	Ridge valve on the plate
		Molteno 3 GL		185	0.4-0.95	
		Molteno3 S series		245	0.4-0.95	
		M3-185 (SS)				
	M3-245 (SL)					
Baerveldt	1992	101-250	Silicone	250	0.95	Barium-impregnated silicone plate, therefore radiopaque
		101-350	Silicone	350	0.95	
		Pars plana	Silicone	350	0.95	
		103-350				

GDD = Glaucoma drainage devices, IOP = Intraocular pressure

its use has been largely superseded by newer shunts. Currently, the Ahmed glaucoma valve (AGV, New World Medical Inc., Rancho Cucamonga, CA, USA) and Baerveldt glaucoma implant (BGI, Abbott Medical Optics, Abbott Park, IL, USA) are the most commonly used implants [Figure 1].

Plate size and material are two factors that determine the long-term IOP outcome. As aqueous drains to the shunt end plate, flow is eventually restricted by a capsule around the plate. Plate size predetermines the size of the capsule (bleb), and this is one of the factors that predicts the final IOP.

In an earlier study, Heuer *et al.* reported that 2 years after surgery, the success rate in controlling the IOP was greater with the double than single-plate Molteno (71% vs. 46%) as was the degree of IOP reduction (46% ± 33% vs. 25% ± 43%).^[2] However, hypotony-related complications such as flat anterior chamber, choroidal hemorrhage, and phthisis were

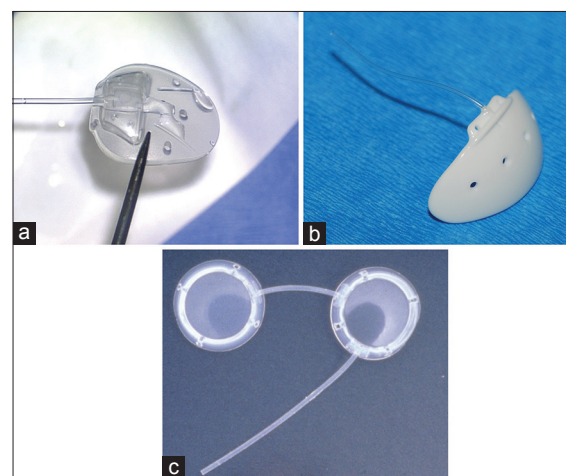


Figure 1: The most commonly used implants: (a) Ahmed glaucoma valve model FP7. (b) Baerveldt glaucoma implant 101-350. (c) Double-plate Molteno

higher with the double-plate implants. Britt *et al.* compared 350 mm² BGI implants to 500 mm² BGI implants and reported that the 500 mm² BGI achieved

lower IOP, but sight-threatening hypotony-related complications were more common leading to a lower overall success with the larger plate.^[3] This study was the first to demonstrate that aqueous shunts could achieve low mean IOP levels with little supplemental glaucoma medication, 5 years after implantation. In a smaller nonrandomized series, Molteno also reported that IOP control with two plates was significantly better than with one.^[4] In addition, the IOP control with a four-plate implant was only marginally better but at the cost of severe hypotony. In summary, larger plate size results in lower IOP. The ideal plate size should provide a balance between a safe low IOP without a significant risk of long-term hypotony.

While plate size is important, other factors including plate material, profile, and surface characteristics also influence capsule formation and long-term IOP control. Plates are commonly made from polypropylene or silicone. Silicone implants are more flexible, easier to handle, and more biocompatible due to their flexibility. Ayyala *et al.* reported that silicone plates cause less inflammatory response than more rigid polypropylene plates in rabbits.^[5] In clinical studies comparing the polypropylene with silicone AGV, most observed lower IOP levels with less supplemental glaucoma medication and longer survival with the silicone version.^[6,7] However, GDD plates differ in other factors such as shape, profile, surface texture, contact area with adjacent tissues, flexibility, and micro-motion, all of which might influence the degree of encapsulation, so the observed effect is likely to result from a combination of factors.

One important feature of an aqueous shunt is the presence or absence of a fixed flow restrictor or valve. Technically, a valved device should allow only unidirectional flow with a minimum opening pressure, whereas nonvalved devices are passive and incapable of influencing either anterograde or retrograde flow. The only valved device in current use is the AGV. The Molteno and BGI are nonvalved and therefore provide no resistance to aqueous outflow in the early postoperative period before the bleb capsule develops. The only resistance to flow with nonvalved GDD is the capsule that develops over the plate around 3–6 weeks after surgery. When implanting one of these devices, the surgeon must use some form of suture to occlude the tube portion, otherwise severe early postoperative hypotony is almost inevitable.

While the valved GDD offers the advantage of avoiding immediate hypotony without surgical manipulation, many believe aqueous flow to be a disadvantage during the early postoperative period. The reason is two-fold. First, tissue contact with aqueous containing elevated transforming growth factor-beta may stimulate a greater

healing response over the plate.^[8] Second, mechanical stretching of fibroblasts by the presence of fluid in the subconjunctival space may also stimulate fibroblast contraction and healing. Paradoxically, nonvalved devices largely avoid these effects because they are occluded in the early postoperative period.

The current clinical consensus is that valved GDD have a higher frequency of a hypertensive phase than nonvalved GDD.^[9] The hypertensive phase typically starts after 4–6 weeks and has been reported in 30%–80% of patients with AGV.^[10] Clinically, a thick capsule forms around the plate preventing aqueous absorption into the venous system. Such thick capsule formation seems to be less common with the BGI.^[11]

The question of whether nonvalved GDDs achieve a better long-term IOP control is addressed in two randomized controlled trials which compared the AGV model FP7 and the BGI model 101-350: the Ahmed versus Baerveldt Comparative (ABC) study and the Ahmed versus Baerveldt (AVB) study [Table 2].^[12,13] The definition of failure is slightly different between the two trials, rendering the percentage of surgical failure slightly higher in the AVB trial. After 3 years, the AVB study reported slightly less surgical failure, lower IOP, and less medication in the BGI group than the AGV group.^[14] The ABC study reported no significant difference in surgical failure in the two groups at 3 and 5 years after surgery.^[15,16] However, the BGI group required less medication after 3 years and had a lower IOP after 5 years. Both ABC and AVB studies reported more hypotony-related complications in the BGI groups, whereas the AGV groups more often required surgery for uncontrolled IOP.^[14,17] Complications in the BGI groups were more serious: persistent hypotony, explantation of the shunt, or loss of light perception. In summary, in both studies, the BGI group achieved a lower IOP on

Table 2: Results of Ahmed versus Baerveldt Comparison study and Ahmed versus Baerveldt study

	1 year	3 year	5 year
AVB study			
IOP - Baerveldt	13.6±4.8**	14.4±5.1	NA
IOP - Ahmed	16.5±5.3**	15.7±4.8	NA
Medication - Baerveldt	1.2±1.3*	1.1±1.3*	NA
Medication - Ahmed	1.6±1.3*	1.8±1.4*	NA
ABC study			
IOP - Baerveldt	13.2±6.8*	13.1±4.5	12.7±4.5*
IOP - Ahmed	15.4±5.5*	14.3±4.7	14.7±4.4*
Medication - Baerveldt	1.5±1.4	1.5±1.4*	1.8±1.5
Medication - Ahmed	1.8±1.3	2.0±1.4*	2.2±1.4

**Difference between the two groups reached statistical significance level at $P < 0.001$. *Difference between the two groups reached statistical significance level at $P < 0.05$. ABC = Ahmed versus Baerveldt Comparison, AVB = Ahmed versus Baerveldt, IOP = Intraocular pressure, NA = Not available

fewer glaucoma medications but at the cost of a higher rate of serious hypotony-related complications. This emphasizes the importance of preventing early hypotony in nonvalved aqueous shunts.

Indications

Aqueous shunts are preferred in cases where trabeculectomies are likely to fail or might be hazardous, such as in neovascular glaucoma, iridocorneal endothelial syndrome, aphakic glaucoma, Sturge–Weber syndrome, glaucoma after vitreoretinal surgery or keratoplasty, and many uveitic glaucomas. Aqueous shunts are commonly used in pediatric glaucoma because the risk of infection and the requirement for postoperative manipulation is lower than with trabeculectomy. Whether aqueous shunts are more effective than trabeculectomy in the management of primary open-angle glaucoma was addressed in the Tube versus Trabeculectomy (TVT) study. This study compared the BGI 101-350 to trabeculectomy with mitomycin-C (MMC) in patients with previously failed trabeculectomy or with previous cataract surgery over 5 years of follow-up.^[18] The more recent Primary Trabeculectomy versus Tube study will compare the efficacy and safety of BGI model 101-350 and trabeculectomy in phakic patients with no previous cataract or glaucoma surgery.

The TVT study compared the efficacy of BGI model 101-350 without antimetabolite to trabeculectomy with MMC 0.4 mg/ml for 4 min. Although 80% of participants were pseudophakic, 44% had undergone cataract surgery without a previous trabeculectomy, a third of whom had undergone cataract surgery through a scleral tunnel approach.^[18] After 1, 3, and 5 years, the BGI group had higher rates of success than the trabeculectomy group even though the mean IOP levels were similar.^[19-21] The rate of BGI failure averaged 5%/year compared with 9%/year for trabeculectomy. The trabeculectomy group required less medication after 1 year than the tube group, but this difference was lost after further follow-up. The complication rates were similar in the two study groups.

Surgical Technique

GDD surgery can be performed under local or general anesthesia. Retro- or peri-bulbar block with mixed bupivacaine and lidocaine will achieve adequate anesthesia and akinesia during the procedure. A clear cornea traction suture is placed and the globe is rotated away from the area where the GDD will be placed. With the AGV, “priming” of the tube is essential to open and wet the valve leaflets. Priming is achieved by injecting balanced salt solution (BSS) through the tube lumen using a 30-gauge cannula. Flow of BSS should be observed emerging from the end plate.

Plate Placement

A 3–4 clock hour peritomy with radial relaxing incisions provides good access. A limbus-based conjunctival flap (fornix-based conjunctival incision) is an alternative but has the limitation that it restricts access when inserting the tube into the anterior chamber. In addition, the presence of a wound over the tube or plate can potentially lead to dehiscence or erosion and exposure. A limbal peritomy can lead to tube exposure through conjunctival retraction, but this can be avoided by tightly securing conjunctiva at the limbus.

The GDD plate is most often placed in the STQ between the lateral and superior rectus muscles. The STQ provides the easiest access and does not contain any oblique muscle fiber. In eyes with a preexisting tube or previous surgical scar precluding STQ placement, both inferonasal quadrant and superonasal quadrant (SNQ) are alternatives. Inferiorly placed tubes have a higher exposure rate, but the SNQ placement carries a higher risk of vertical diplopia from restricting the superior oblique muscle, i.e., a pseudo-Brown’s restrictive strabismus syndrome.^[22,23] In addition, aqueous shunts with a longer anteroposterior length, such as AGV, may encroach on the optic nerve when placed in the SNQ resulting in a significant injury response.^[24-26]

The ideal plate position is at least 8 mm from the limbus. The plate should be tightly secured with a nonabsorbable suture (e.g., 8-0 or 9-0 nylon or polypropylene) to prevent migration and to reduce plate micromovement which can stimulate a greater fibroblastic response and capsule formation.

While there have been a number of studies investigating the use of adjunctive antimetabolites, there is currently no evidence to support increased efficacy. Two randomized controlled trials examined the use of MMC in Molteno and AGV implants.^[27,28] Neither study found a lower IOP or higher success rate in the MMC group compared to the no MMC group. The use of MMC in AGV did not reduce the rate of the hypertensive phase. Interestingly, neither study reported a higher hypotony rate in the MMC group.

Tube Insertion

The tube is trimmed so that it is beveled anteriorly for anterior chamber placement and posteriorly for sulcus placement to prevent iris occluding the tip. Anterior chamber positioning allows direct visualization of the tube to detect tube blockage by iris or tube retraction. The tube should be short and posteriorly placed to avoid touching the cornea as corneal decompensation is a common long-term complication of poorly positioned

aqueous shunts. Pars plana and sulcus placement minimize corneal endothelium damage but compromise visualization of the tube.^[29] Pars plana placement requires careful vitrectomy with shaving of the vitreous base close to the tube to prevent obstruction with vitreous.^[30,31]

A 23- or 25-gauge needle is used to create a short tunnel for insertion posterior to the surgical limbus: 1.5–2 mm from the limbus for anterior chamber and sulcus insertion or 3.5–4 mm for pars plana insertion. Both AGV and BGI offer a pars plana adaptation in the form of an elbow. The AGV pars plana clip and the BGI Hoffman elbow have a small plate at the pars plana entry site. In practice, the pars plana models are not frequently used as they are associated with a high rate of erosion, and conventional tubes without the elbow are relatively easy to insert in the pars plana.

Tubes must be covered at the limbus to prevent conjunctival erosion. Human donor sclera, cornea, or pericardium can all be used.^[32] An alternative long intrascleral tunnel technique without patch has been described with good midterm results.^[33]

Nonvalved aqueous shunts - intraoperative techniques to prevent hypotony

In nonvalved GDD, few techniques have been described to prevent early hypotony. The simplest is to place an external ligature such as an absorbable 7-0 polyglactin (Vicryl™) suture around the tube.^[34] The ligation should completely occlude the tube lumen, so no aqueous flow occurs until the suture absorbs after 5–6 weeks when a capsule has formed around the plate and provided some resistance to outflow. The first problem with a complete ligation of the tube is the high IOP during the first 6 weeks. To counteract this, many surgeons will additionally fenestrate the tube proximal to the ligature (Sherwood slit).^[35] Some even perform a trabeculectomy concomitantly with the tube implantation that is intended to mitigate against an initial high IOP and fail around the time the ligature dissolves.^[36] The second disadvantage of using a single external ligation is the sudden IOP drop when the tube opens. Even if sufficient encapsulation has developed, the precipitous drop in eyes with larger implants may be sufficient to cause a choroidal hemorrhage in a predisposed individual.

A technique used successfully by one of the authors (KB) is an adjustable intraluminal occluding suture enhanced by a variable number of external ligatures [Figure 2].^[35] A 3-0 nylon (Supramid Extra; S. Jackson Inc., Alexandria, VA, USA) suture is introduced internally along most of the length of the tube but not into the anterior chamber. Aqueous flow is tested at the tube aperture over the plate after insertion of the suture and the length adjusted, so only very slow flow is visible [Figure 2]. One or more 10-0 nylon

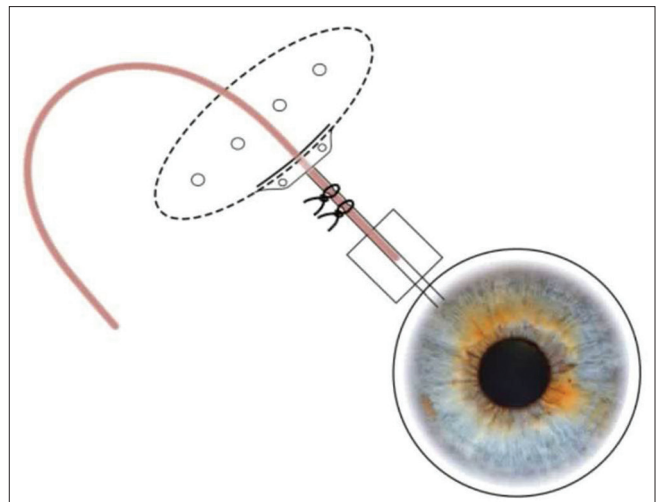


Figure 2: Schematic illustration of stepwise occlusion method where tube is partially occluded with intraluminal 3-0 nylon Supramid Extra suture and the remaining flow is just eliminated using one or more 10-0 nylon ligatures around the stented portion of the tube. The 10-0 nylon ligature can be lasered relatively early in the postoperative period permitting some flow

ligatures are then tied around the tube over the Supramid suture to just eliminate flow completely [Figures 3 and 4]. These adjunctive ligatures can be lasered electively at the slit lamp after approximately 2–3 weeks, avoiding the risk of a sudden precipitous pressure drop. If after 3 months, the pressure is still not adequately controlled, the intraluminal suture can be withdrawn at the slit lamp through a small conjunctival entry [Figure 5]. This can also be performed in stages, again avoiding sudden decompression. The rationale of this technique is a stepwise reduction in IOP instead of a sudden drop. The disadvantage is more manipulation and more intensive follow-up than the solo ligature technique.

Complications and Management

Complications associated with GDD surgery may be classified as intraoperative, early (<3 months), and late. Intraoperative complications are infrequent. About 4%–8% of patients experienced intraoperative complications in the AVB, ABC, and TVT studies. The single most common complication is hyphema during tube insertion.^[12] Other intraoperative complications include leakage such as inadvertent opening of a preexisting trabeculectomy bleb or persistent leakage at the insertion site. Intraoperative leakage should be addressed at the time of surgery because of the high risk of hypotony. A leaking entry site can be very difficult to suture closed but can alternatively be plugged with a small piece of tenons, pericardium, or sclera. Inadvertent opening of a bleb may require closure with a scleral or pericardial patch.

Hypotony, shallow anterior chamber, tube-corneal touch, corneal edema, uncontrolled high pressure, ptosis,

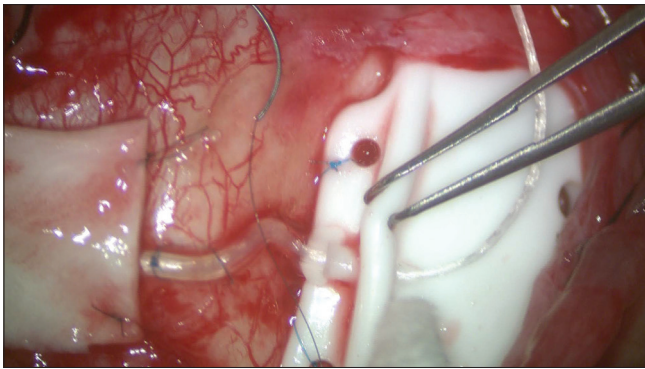


Figure 3: After insertion of the Supramid suture (white), slow flow can be observed at the back of the plate (arrow)

and diplopia may occur in the early postoperative period. Most complications are hypotony related and may occur with valved and nonvalved shunts. In the TVT study, the BGI group had fewer early complications than the trabeculectomy group (21% vs. 37%; $P = 0.012$) although this difference is mostly due to conjunctival leakage. The incidence of severe hypotony was similar between the BGI and trabeculectomy groups.^[37] Although valved aqueous shunts are designed to prevent hypotony, hypotony may still occur if the valve fails or the entry site leaks. With a valved GDD, a small amount of viscoelastic is often left in the anterior chamber at the end of surgery, whereas with a nonvalved GDD, a tight external ligature and/or intraluminal occluding suture should be enough to prevent hypotony. A less commonly used alternative is a two-stage procedure during which the plate is implanted and the tube tucked under conjunctiva without inserting the tube into the eye.^[38] The second stage of tube insertion is usually performed 6 weeks later when the capsule has formed. If early hypotony occurs despite intraoperative precautions, sequelae from hypotony can usually be prevented in the short term by small volume anterior chamber viscoelastic injections at the slit lamp. If hypotony persists despite numerous injections, the patient needs to return to the operating room for further tube ligation.

Early ptosis and motility disturbance can be simply due to surgical manipulation and inflammation. It is advisable to wait and watch and to only intervene if the signs and symptoms persist beyond 6 months.

While short-term complications may result from surgical technique, late complications are less predictable. They include corneal edema, erosion, persistent motility disturbance, chronic iritis, tube obstruction, failure of intraocular pressure control, and rarely endophthalmitis. The TVT study found similar rates of long-term complications in the BGI and trabeculectomy groups at 5 years. Although the BGI group had a higher rate of corneal edema (16% vs. 9%) and diplopia (6% vs. 2%), the

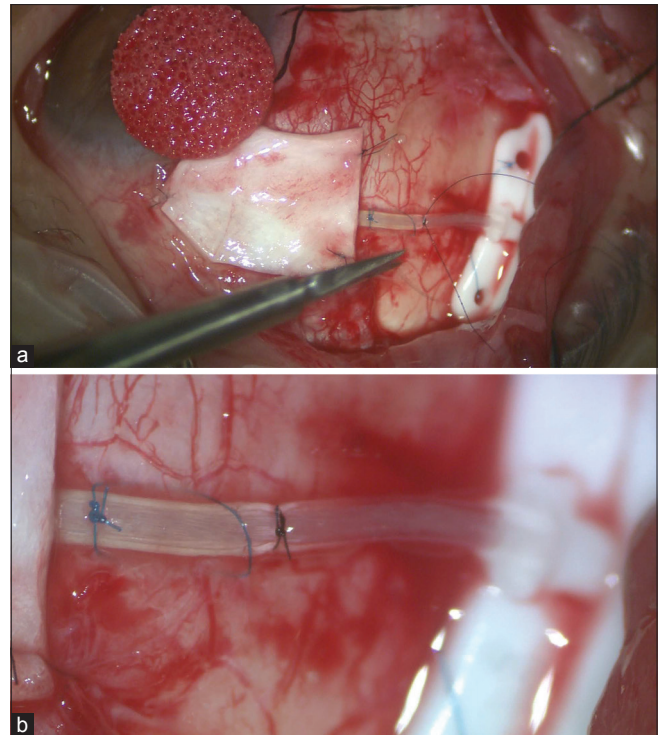


Figure 4: Occlusion of the tube portion of the Baerveldt glaucoma implant with a 10-0 nylon ligature (black) around the stented portion (a) and in higher magnification (b), just eliminating the remaining flow after the tube is stented

difference did not reach statistical significance.^[37] The rate of subsequent keratoplasty was similar between the two groups. In the ABC study, the corneal decompensation rate after 5 years of follow-up was similar between the AGV and BGI groups: about 20% in each group.^[17] In the TVT study, 6% of patients receiving BGI had persistent diplopia after 3 years. Some surgeons argue that proper placement of the BGI plate under the muscles will prevent diplopia. However, the ABC investigators did not observe a higher rate of diplopia in the BGI than the AGV group (11.8% vs. 12.7%; $P = 0.81$). Bleb height is a likely reason for diplopia. Fortunately, diplopia was rarely experienced in the primary position of gaze. The incidence of tube erosion was 1%–3% in the AGV and BGI groups, respectively ($P = 0.04$).^[17]

Endophthalmitis related to aqueous shunts is rare and much less common than after trabeculectomy. The single risk factor for GDD-related endophthalmitis is tube exposure.^[39] Therefore, exposed tubes should be revised urgently.

Suprachoroidal hemorrhage (SCH) was reported in 6% of patients in Molteno's earlier studies. In the TVT, ABC, and AVB studies, the rate of SCH was lower and varied between 0% and 3%. The rate of SCH was similar in the tube group compared to the trabeculectomy group in the TVT study. Most of SCH occurs postoperatively instead of intraoperatively. SCH is likely to occur in



Figure 5: External view of the Baerveldt glaucoma implant *in situ* with the external portion of the Supramid Extra stent suture visible under conjunctiva (a and b). The bleb over the back of the plate is often shallow and very diffuse with the Baerveldt implant (a), though usually in the early postoperative period, there is no visible bleb when the tube is occluded (b)

eyes that experience a precipitous drop in IOP and aphakia.^[40]

Conclusions

Aqueous shunt implantation is an indispensable tool in the management of glaucoma, particularly in secondary glaucoma and after trabeculectomy failure. Aqueous shunts appear to have similar efficacy to trabeculectomy in lowering the IOP but require less intensive postoperative follow-up. The predictability of aqueous shunt surgery is still, at best, moderate, though probably greater than after trabeculectomy. Hypotony is always a risk but can be more predictably prevented. The factors that result in long-term corneal endothelial loss in patients implanted with aqueous shunts still remains to be clarified.

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Conflicts of interest

There are no conflicts of interest.

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