

## Glaucoma Drainage Implants

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### Abstract

#### Purpose of review

The purpose of this review is to critically compare the various glaucoma drainage implants in popular use.

#### Recent findings

Glaucoma drainage implants are being increasingly utilized in the surgical management of glaucoma. Comparisons between the various drainage implants are difficult because most clinical data are derived from retrospective studies with different study populations, follow-up periods, and criteria defining success. The type of glaucoma under treatment is a major factor influencing surgical outcomes. The resistance to aqueous flow through glaucoma drainage implants occurs across the fibrous capsule around the end plate, and the major determinants of the final intraocular pressure are capsular thickness and filtration surface area. The use of antifibrotic agents as adjuncts to drainage implant surgery has not proven effective in modulating capsular thickness. Valved implants appear to reduce, but do not eliminate, the risk of hypotony. Bleb encapsulation is more frequently seen with the Ahmed valve implant than other drainage implants. Diplopia was a common complication with the Baerveldt glaucoma implant after its introduction, but design modifications have markedly reduced the incidence of this complication.

#### Summary

There are several glaucoma drainage implants that are currently available, and all have been shown to be safe and effective in reducing intraocular pressure. Greater pressure reduction may be achieved with implants with larger end plates, and valved implants appear to reduce the risk of postoperative hypotony.

#### Keywords

Antifibrotic, drainage implants, glaucoma, intraocular pressure, surgical

#### Introduction

The use of glaucoma drainage implants has increased in recent years, especially relative to other surgical glaucoma procedures such as trabeculectomy [1,2]. The increased utilization of drainage implants is related to a greater experience and appreciation of the efficacy of aqueous shunts, and a growing concern about late complications associated with standard filtering surgery [3].

Only a handful of glaucoma drainage implant types are commercially available and in common use. Comparisons between the various implant types are, however, difficult because most clinical data are derived from retrospective studies with different study populations, small sample size, limited follow-up, and varied criteria for defining successful outcomes. In addition, the types of glaucoma for which drainage implants are being used has expanded to include eyes with major retinal or corneal surgery and glaucomas associated with pseudophakia, aphakia, uveitis, trauma, epithelial and fibrous downgrowth, aniridia, and microcorneal endothelial syndrome.

These refractory glaucoma types can be effectively managed with glaucoma drainage implants, albeit with differing levels of success that affect comparative efficacy results between the varying types of glaucoma drainage implants.

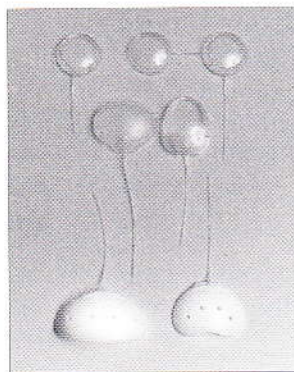
**Current glaucoma drainage implants**

All modern glaucoma drainage implants consist of a tube that shunts aqueous humor to an end plate (or explant) located in the equatorial region of the globe. Drainage implants differ in their design with respect to the size, shape, and material from which the end plate is constructed. They may be further subdivided into valved and nonvalved implants, depending on whether or not a valve mechanism is present that limits flow through the tube to the plate if the intraocular pressure (IOP) becomes too low. The implants currently in common use include the Ahmed glaucoma valve (New World Medical, Rancho Cucamonga, California, USA), the Baerveldt glaucoma implant (Advanced Medical Optics, Santa Ana, California, USA), the Krupin slit valve (Hood Laboratories, Pembroke, Massachusetts, USA), and the Molteno implant (Molteno Ophthalmic Limited, Dunedin, New Zealand). Fig. 1 shows these popular glaucoma drainage implants, and Table 1 reviews the major design features for each implant.

**Ahmed glaucoma valve**

The Ahmed glaucoma valve has a scarab-shaped end plate made of polypropylene (models S2, S3, and B1)

Figure 1 Glaucoma drainage implants in common use



Single-plate and double-plate Molteno implants (top row). Krupin slit valve and Ahmed glaucoma valve (middle row). 350-mm2 and 250-mm2 Baerveldt glaucoma implants (bottom row).

**Table 1 Design features of current glaucoma drainage implants**

Implant type	Size	Material	Valved/ nonvalved
Ahmed glaucoma valve	96 mm <sup>2</sup> (S3)	Polypropylene	Valved
	184 mm <sup>2</sup> (S2)		
	364 mm <sup>2</sup> (B1)	Silicone	
	96 mm <sup>2</sup> (FP8)		
	184 mm <sup>2</sup> (FP7)		
364 mm <sup>2</sup> (FX1)			
Baerveldt glaucoma implant	250 mm <sup>2</sup> 350 mm <sup>2</sup>	Silicone	Nonvalved
Krupin slit valve Molteno implant	183 mm <sup>2</sup>		
	134 mm <sup>2</sup> (single -plate)		
	268 mm <sup>2</sup> (double -plate)		

or silicone (models FP7, FP8, and FX1). Fenestrations have been added to the plate of the silicone models. Different sizes of the Ahmed valve are available, including those with a surface area of 96 mm<sup>2</sup> (S3 and FP8) or 184 mm<sup>2</sup> (S2 and FP7). A double-plate version has a surface area of 364 mm<sup>2</sup> (B1 and FX1). Aqueous humor passes from the anterior chamber tube through two thin membrane-like elastomer sheets that theoretically restrict flow until a pressure of greater than 8–12 mmHg is exerted upon them.

### **Baerveldt glaucoma implant**

The Baerveldt glaucoma implant is a nonvalved implant. The end plate is made of barium impregnated, rounded silicone with surface areas of 250- or 350-mm<sup>2</sup>. The plate has fenestrations, which allow fibrous bands to develop that reduce the profile of the bleb. Krupin slit valve The Krupin slit valve consists of an anterior chamber tube connected to an oval silastic disc with a surface area of 183 mm<sup>2</sup>. Alternatively, the tube end may be connected to a #220 silastic band. The distal end of the tube contains horizontal and vertical slits that function as a unidirectional and pressure-sensitive valve.

### **Molteno implant**

The Molteno implant has a round polypropylene end plate with a surface area of 134 mm<sup>2</sup> for the singleplate implant and 268 mm<sup>2</sup> for the double-plate implant. The plates of the double-plate implant are connected by a 10 mm silicone tube.

### **Surgical results**

Attempts at comparing the surgical results achieved with the various glaucoma drainage implants are made difficult because of differences in study populations, followup period, and criteria by which success is defined. Case series studying glaucoma drainage implants have reported success rates ranging from 22% to 78% for neovascular glaucoma [4–16], 75% to 100% for uveitic glaucoma [9–11,17,18,19], 44% to 100% for developmental glaucoma [4,5,8–11,20–32, 33], 50% to 88% for eyes that have undergone cataract surgery [4,5,8,10,11,14,15,34,35], and 44% to 88% for eyes with failed glaucoma filtering surgery [4,5,8,11,15, 35]. The poorest surgical results are observed in neovascular glaucoma. As with trabeculectomy, attrition over time results in a trend toward lower success rates among studies with longer follow-up periods.

### **Pathophysiology**

Following implantation of a glaucoma drainage device, a fibrous capsule forms around the end plate over a period of several weeks. A feature common to all glaucoma drainage implants is construction of the plate from materials to which fibroblasts cannot adhere. Aqueous humor pools in the potential space between the end plate and surrounding, nonadherent fibrous capsule when flow occurs through the anterior chamber tube. Aqueous then passes through the capsule via the process of passive diffusion and is absorbed by periorbital capillaries and lymphatics. It is the fibrous capsule around the end plate that offers the major resistance to aqueous flow with drainage implants. Therefore, the degree of IOP reduction observed following glaucoma drainage implant surgery is dependent on capsular thickness and the total surface area of encapsulation. Lower postoperative IOP is expected with a thinner capsule and larger surface area of encapsulation.



**Table 2 Surgical result with glaucoma drainage implant in eyes with neovascular glaucoma**

Author	Procedure	Success rate	IOP Success (mmHg)	Follow-up (months)	
				Mean	Range
Hodkin et al. (4)	Baerveldt	43%	<21	18.3	
Minckler et al (5)	SP Molteno	47%	≤21	20.2	
Krupin et al (6)	Krupin long valve	77%	≤21	20.2	12-36
Ancker and Molteno(7)	SP Molteno	67%	<20	18	6-55
Lloyd et al (8)	SP Molteno	22%	≤21 and >5	33.8	7-70
Seigner (9)	Baerveldt	71%	≤21 and >5	13.6	4-37
Freedom and Rubin(10)	SP Molteno	76%	≤21	35	6-88.9
Mills(11)	SP/DP Molteno	50%	≤22	24	6-66
Sidoti(12)	Baerveldt	61%	≤22 and >5	15.7	6-28
Mastropasqua(13)	Baerveldt	36%	≤22 and >5	58.4	10-108
Huang(14)	Ahmed	68%	≤22 and >5	13.4	4-44
Broadway(15)	SP Molteno	53%	≤22 and >5	28	
Krishna(16)	Baerveldt	78%	≤22 and 30% reduction	24	

DP;double-plate;IOP;intraocular pressure;SP;single- plate

**Table 3 Surgical result with glaucoma drainage implants in eyes with glaucoma**

Author	Procedure	Success rate	IOP Success criteria (mmHg)	Follow-up (months)	
				Mean	Range
Seigner (9)	Baerveldt	91%	≤21 and >5	13.6	4-37
Freedom and Rubin(10)	SP Molteno	80%	≤21	48	0.5-13.9
Mills(11)	SP/DP Molteno	75%	≤22	69	42-96
Damata(17)	Ahmed	100%	≤21	24.5	
Molteno(18)	SP Molteno	83%	≤21 and >6	85.2	20-240
Ceballos(19)	Baerveldt	92%	≤21 and >5	20.8	

DP;double-plate;IOP;intraocular pressure;SP;single- plate

Table 4 Surgical result with glaucoma drainage implants in eyes with developmental glaucoma

Author	Implant	Age (years)	Success rate	IOP Success criteria (mmHg)	Follow-up (months)	
					Mean	Range
Moltino (20)	SP Molteno	≤36	95%	<20	66	12-114
Goldberg(21)	DP Molteno	<13	100%	<20	18.4	6-24
Minckler(5)	SP Molteno		54%	≤21	22.8	
Billson(20)	DP Molteno	<21	78%	<21	41.3	12-84
Hill(23)	SP/DP Molteno		62%	<22 and >5	22.7	6-59
Freedom and Rubin(10)	SP Molteno		50%	≤21	37	16-51
Munoz(24)	SP Molteno	<12	68%	≤21	18	6-36
Nesher(25)	SP/DP Molteno	≤13	59%	≤21	20	6-36
Lloyd(8)	SP/DP Molteno	<13	44%	<21 and >5	49.1	7-76
Netland and Walton(26)	Molteno , Baeveldt	≤10	80%	≤21	25	8-41
Hodkin(4)	Baeveldt	<13	100%	≤21	19.2	
Seigner(9)	Baeveldt		80%	<21 and >5	13.6	4-37
Fellenbaum(27)	Baeveldt	<21	83%	<21 and >6	15	6-25
Mills(11)	SP/DP Molteno	<18	50%	≤22	36	10-99
Coleman(28)	Ahmed	<18	71%	<22 or 20% reduction	16.3	
Eid(29)	SP/DP Molteno, Schocket, Baeveldt		44%	<21 and >5	47.3	14-80
Englert(30)	Ahmed	<18	85%	≤21	12.6	3-31
Djodeyre(31)	Ahmed	<15	69%	≤22	12.6	0-37.9
Pereira(32)	SP/DP Molteno, Schocket, Baeveldt	≤3	60%	≤22	50	
Budenz(33)	Baeveldt	<18	71%	<22 and ≥5	23.4	1-106

DP;double-plate;IOP;intraocular pressure;SP;single- plate



Table 5 Surgical result with glaucoma drainage implants in aphakic/pseudophakic eyes

Authors	Implant	Eyes	Success rate	IOP	Follow-up (months)	
					Mean	Range
Minckler et al (5)	SPMolteno	A/P	63%	≤21	16.2	7-30
Freedom and Rubin (10)	SPMolteno	A/P	83%	≤21	22	8.1-53.3
Lloyd et al (8)	SP/DPMolteno	A/P	56%	≤21- >5	48.6	7-78
Heuer(34)	SP/DPMolteno	A/P	50/75%	≤21- >6	14.9	6-29
Hodkin(4)	Baeveldt	A/P	74%	≤21	16.4	7-30
Mills(11)	SP/DPMolteno	A/P	58%	≤22	16.3	6.1-26.1
Huang(14)	Ahmed	A	88%	≤22-	45	6-107
		P	70%	>5	13.4	
Broadway(15)	SP/DPMolteno	A	70%	≤21-	43	4-44
		P	66%	>5		
Roy et al(35)	Baeveldt	A	75%	≤21- >6	37.6	12-68

DP;double-plate;IOP;intraocular pressure;SP;single- plate

Table 6 Surgical result with glaucoma drainage implants in eyes with failed filters

Author	Implant	Success rate	IOP Success creiteria (mmHg)	Follow-up (months)	
				Mean	Range
Minckler et al (5)	SP Molteno	70%	≤21	12.3	6-25
Lloyd et al (8)	SP/DP Molteno	75%	<21 and ≥5	41.4	15-64
Hodkin et al. (4)	Baerveldt	75%	≤21	16.1	7.1-26.1
Mills(11)	SP/DP Molteno	44%	≤22	42	8-78
Broadway(15)	SP/DP Molteno	58%	<22 and ≥5	43	
Roy et al(35)	Baerveldt	89%	<21 and ≥6	37.6	12-68

DP;double-plate;IOP;intraocular pressure;SP;single- plate

### Implant size and intraocular pressure reduction

The surface area of encapsulation around a glaucoma drainage implant is directly proportional to the end-plate size. Therefore, the degree of IOP reduction achieved postoperatively is also directly proportional to implant size. In other words, glaucoma drainage implants with large plates produce a larger surface area of encapsulation and greater degree of pressure reduction. There is good clinical evidence to support this premise. In a prospective randomized clinical trial comparing single-plate and double-plate Molteno implants, Heuer and colleagues found a higher success rate and greater IOP reduction with the double-plate implant presumably because of its larger surface area [34].

There appears to be an upper limit to plate size beyond which an increase in surface area may not improve pressure control, and may even detrimentally affect surgical outcome. In a prospective study comparing the 350-mm<sup>2</sup> and 500-mm<sup>2</sup> Baerveldt glaucoma implants, Lloyd et al. found no significant difference in surgical success and visual outcomes between the different implant sizes [36]. With longer follow-up, Britt et al. reported lower success with the 500-mm<sup>2</sup> Baerveldt compared to the 350-mm<sup>2</sup> implant [37]. Adjunctive use of antifibrotic agents Surgeons have attempted to modulate capsular thickness with the various glaucoma drainage implants by applying antifibrotic agents intraoperatively in much the same manner as with standard filtering surgery. Perkins et al. compared 21 patients who received adjunctive mitomycin C (MMC) at the time of Molteno implantation with 18 patients who received buffered saline solution [38]. After 3 years follow-up, 35% of MMC-treated patients were considered successes versus 17% of the non-MMC-treated group. Cantor et al. randomized 25 consecutive patients to receive either MMC or balanced saline solution during placement of a Molteno implant. No significant IOP difference was noted between the two groups [39]. Costa et al. prospectively randomized 60 eyes with refractory glaucoma to receive intraoperative MMC or buffered saline and found no effect of the MMC on IOP lowering at 18 months [40]. No clear benefit of antifibrotic agents as adjuncts to glaucoma implant surgery has been observed, and a higher incidence of hypotony, flat anterior chambers, choroidal effusions, and conjunctival melts has been reported with their use [38,41,42].

### Studies comparing different implant types

Prospective randomized clinical trials comparing glaucoma drainage implants of differing size, but of the same type (that is, double-plate versus single-plate Molteno implants [34] and 350-mm<sup>2</sup> versus 500-mm<sup>2</sup> Baerveldt implant [36,37]) have offered important insight into the role of implant plate surface area and IOP lowering. Unfortunately, no prospective studies comparing different implant types have been reported. Current data regarding the role and efficacy of different glaucoma drainage implant designs are limited to retrospective case series, which have selection bias inherent to any retrospective study design. Differences in the familiarity of surgeons with each of the implants (that is, the number of each type used in the study), differences in the glaucoma type (that is, neovascular, uveitic, postkeratoplasty, etc.), follow-up periods, and other factors make direct comparisons in these retrospective studies difficult. In addition, some of these comparative study results for the Ahmed valve may not be valid to current practice with the change from the polypropylene to the silicone Ahmed implant by many surgeons. The results of a recently initiated prospective study comparing the new silicone Ahmed to the Baerveldt [the Ahmed Baerveldt Comparison (ABC) study] glaucoma drainage implant will provide important clinical insight into the comparative efficacy of these two widely used glaucoma drainage devices (D. Budenz, personal communication).

### Baerveldt versus Ahmed

Retrospective comparative studies between the Ahmed and the Baerveldt glaucoma drainage implants demonstrate similar good IOP lowering capacity with high success rates. At 1 year follow-up, the Ahmed and Baerveldt implants had relatively similar rates for IOP control and success end points [43,44].

Similar results were observed in an Asian population with a shorter mean follow-up period [45]. Several differences are notable with regard to the Ahmed implant, however, which had a higher hypertensive phase rate with increased IOP typically 1–2 months after implantation and a higher rate of bleb encapsulation [43,44]. With regard to hypotony and choroidal effusions, our experience has been that the Baerveldt implant has a higher risk of these complications after the ligature dissolves 4–6 weeks after shunt implantation, whereas the Ahmed implant has a higher risk in the first week after shunt implantation, probably due to poor valve function. Syed et al., however, found a higher hypotony rate for Baerveldt glaucoma drainage implants within the first 2 days of implantation [44], which may reflect their greater experience with Ahmed compared to Baerveldt glaucoma drainage implants.

**Baerveldt versus double-plate Molteno**

Smith et al. retrospectively compared 18 eyes that underwent implantation of a 350-mm<sup>2</sup> Baerveldt implant to 19 eyes that received a double-plate Molteno [46]. The double-plate Molteno and the 350-mm<sup>2</sup> Baerveldt glaucoma drainage implants had relatively similar reduction in IOP (greater than 44%), success rates, and visual outcomes with almost 1 year of follow-up. Whereas the Baerveldt had a slightly higher risk of anterior chamber shallowing, the Molteno was associated with a higher corneal graft failure rate, although the study numbers were small.

**Ahmed versus double-plate**

Molteno In a retrospective study, 30 patients implanted with the Ahmed device were compared to 30 patients who received the double-plate Molteno implant [47]. The double-plate Molteno produced a statistically significant lower IOP at 12 and 18 months compared to the Ahmed. The Ahmed had a significantly greater risk of developing a hypertensive phase (83.5%) compared with the double-plate Molteno (43.5%), albeit with ultimate success rates that were similar (approximately 50%) at 24 months.

**Ahmed versus Krupin eye valve with disk versus double-plate Molteno**

Taglia et al. performed a nonrandomized retrospective review of 27 patients who received a double-plate Molteno implant, 13 patients who had a Krupin eye valve with disk, and 13 patients who underwent placement of an Ahmed glaucoma valve, with adjunctive MMC [48]. The double-plate Molteno was more likely to produce a lower IOP, but it also had a higher rate of hypotony.

**Complications**

Comparison of the various glaucoma drainage implants requires not only an assessment of their efficacy, but also an evaluation of their surgical complications. Drainage implants have similar operative and postoperative complications as encountered with trabeculectomy, but there are other unique complications associated with their use. Differences exist in the incidence of hypotony, diplopia, and bleb encapsulation with the glaucoma drainage implants in current use.

**Hypotony**

Nonvalved implants initially had a relatively high rate of postoperative hypotony until techniques were developed to temporarily restrict aqueous flow through the device until encapsulation of the end plate occurred. Methods for flow restriction with single-stage implantation include tube ligation with a polyglactin (Vicryl; Ethicon, Somerville, New Jersey, USA) or prolene suture, or tube obstruction with a collagen plug or luminal suture. Additionally, a two-stage implantation technique may be used in which the implant is attached to sclera in the first stage of the procedure, and the tube is later inserted into the anterior chamber after a period of several weeks during the second stage.



Temporary restriction of aqueous flow makes the implant nonfunctional in the immediate postoperative period. Reinstitution of medical therapy frequently provides adequate pressure reduction until the tube opens and the implant becomes functional. Tube fenestration may also be performed intraoperatively, and this technique has been shown to effectively decrease IOP in the early postoperative period with nonvalved implants [49,50]. We prefer to fenestrate the tube with a TG-140 or TG-160 needle (Ethicon) anterior to a Vicryl ligature near the tube-plate junction, and 1-3 fenestrations are placed along the tube depending on the preoperative IOP level. Alternatively, an orphan trabeculectomy may be performed in conjunction with glaucoma drainage implant placement for early postoperative pressure control.

### Diplopia

Transient diplopia is not uncommon following glaucoma drainage implant surgery, but it generally resolves as the postoperative periocular edema improves. Persistent restrictive strabismus may occur because of scarring between the rectus or oblique muscles and the implant [51], or due to a crowding effect from a large bleb with limitation of extraocular motility [52,53]. Although diplopia may occur with any of the drainage implants, it was particularly common following the introduction of the Baerveldt glaucoma implant [54]. The manufacturer of the Baerveldt implant subsequently discontinued the 500-mm<sup>2</sup> size implant and included fenestrations in the end plate, which allows the growth of fibrous bands through the plate to reduce bleb height. These design modifications have markedly reduced the incidence of diplopia with the Baerveldt glaucoma implant.

### Bleb encapsulation

Failure to control IOP after glaucoma drainage implant surgery may occur secondary to encapsulation of the bleb around the end plate. This complication is analogous to an encapsulated bleb that develops after trabeculectomy, and it is generally treated in a similar fashion with antiglaucoma medications. The incidence of bleb encapsulation has been estimated to be between 40% and 80% with the Ahmed glaucoma valve, and between 20% and 30% with the Baerveldt and double-plate Molteno glaucoma implants [55]. Several possible explanations have been offered for the higher incidence of bleb encapsulation with the Ahmed glaucoma valve compared with other implants. Some authors have suggested that immediate aqueous filtration with inflammatory factors may stimulate a fibrotic response in the subconjunctival space when the Ahmed implant is used, and delayed flow with a ligated, nonvalved implant may elicit a less fibrous reaction [43]. Others have speculated that differences in the rate of bleb encapsulation may be related to the biomaterial, shape, and consistency of the end plate [56,57].

### Future glaucoma drainage implants

Several glaucoma implants are in development, and early clinical use shows variable levels of promise. These new glaucoma implants have a similar goal of shunting aqueous fluid out of the anterior chamber and bypassing the trabecular meshwork to increase outflow and lower the IOP.

MIGS has been defined as IOP-lowering surgery with the following characteristics that distinguish it from traditional glaucoma surgery:

- Minimally traumatic
- Via an ab-interno conjunctiva-preserving approach
- High safety profile
- Rapid recovery

Frequently combined with cataract extraction

Provides more modest IOP lowering than trabeculectomy

It is generally accepted that MIGS uses an ab-interno approach that leaves the conjunctiva intact for potential later trabeculectomy or non-penetrating surgery. MIGS procedures form a heterogeneous group of techniques: they may bypass trabecular meshwork (TM) resistance to aqueous flow with stents into Schlemm's canal (iStent, Hydrus), via drainage into the suprachoroidal space (Cypass, iStent Supra) or by excision of TM itself (Trabectome).

### Conclusion

Several different types of glaucoma drainage implants are currently available, and all have been shown to be safe and effective in reducing IOP in glaucoma patients. A paucity of studies exists which compare different glaucoma drainage implant types, and these are all limited to retrospective case studies. The Ahmed Baerveldt Comparison (ABC) study is the first multicenter randomized clinical trial comparing different implant types and promises to yield valuable information that will guide surgical decision-making (D. Budenz, personal communication). We generally prefer the Baerveldt glaucoma implant because it optimizes surface area and ease of implantation as a single-plate implant. A Vicryl suture is used to ligate the tube at the time of implantation, and we routinely fenestrate the tube for early pressure control. We use valved implants in the rare situations where aqueous hyposecretion may be present with uncontrolled glaucoma, such as uveitic glaucoma or eyes with prior cyclodestruction. In these settings, the valve mechanism should serve to minimize the risk of postoperative hypotony.

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