Complications of tube implants and their management

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Purpose of review
The use of glaucoma drainage devices (GDD) in the treatment of glaucoma has become widely accepted for cases of refractory glaucoma. Expansion in the indications for implantation of GDD beyond refractory glaucoma is increasingly common. As such, tube implant complications are reviewed to aid in prevention and improve their management.

Recent Findings
Findings of the Tube Versus Trabeculectomy study resulted in an expanded use of tube implants in cases of refractory glaucoma. As interest in GDD implantation flourished, so too, did investigative comparison between devices; which includes the Ahmed Baerveldt Comparison study and Ahmed Verses Baerveldt study. Comparative analysis of success and complication rates between implantable devices is not only expanding the technology of tube implants, but also building a body of evidence that tube implantation has a strong safety profile and usage among specialists will continue to increase and indications will evolve. Complications resulting from GDD implantation include hypotony, postoperative elevated intraocular pressure, tube erosion, diplopia, motility disturbances, and corneal decompensation.

Summary
Tube implant use is increasing and indications are expanding beyond refractory glaucoma. Understanding differences in GDD, their complications and management will result in improved patient care.

Keywords
complication, glaucoma drainage implants, management, tube shunts

INTRODUCTION

Recent trend analysis demonstrates a growing number of glaucoma specialists are preferentially selecting glaucoma drainage implants for the surgical management of refractory glaucoma. Specifically, Medicare claims data that demonstrated a 43% decrease in the number of trabeculectomy procedures and a concurrent 184% increase in tube-shunt surgery from 1995 to 2004 [1]. Moreover, with thousands of baby boomers joining the ranks of Medicare daily, initiatives aimed to improve healthcare accessibility coupled with participation in quality care measures will only result in increased rates of glaucoma detection and subsequent demand for glaucoma specialists. It is estimated that the incidence of glaucoma in the USA will increase by 50%, from 2.2 to 3.38 million US citizens by 2020 [2]. It is estimated that only half of patients with glaucoma actually know they have the disease process [2]. Efforts to improve patient education and early disease detection will only add to the surge of patients in search of specialized care. The trend in practice patterns toward the use of glaucoma drainage implantation over trabeculectomy [3] makes the review of complications associated with their implantation and their management of timely importance.

EFFICACY OF TUBE IMPLANTS DIRECTS PRACTICE PATTERNS AND GUIDES PROSPECTIVE ANALYSIS

Five-year results on treatment outcomes and complications of the Tube Versus Trabeculectomy study were published in May of 2012. Tube shunt surgery (Baerveldt 350-mm^2, BVT, Abbott Medical Optics,

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KEY POINTS

- The use and indications for the implantation of tube shunts are expanding.
- Recent comparative analysis fails to demonstrate superiority of one glaucoma drainage implant over another.
- Glaucoma drainage implants have a unique set of complications that have been reported and established in the literature.
- New developments in glaucoma drainage implant design should be geared toward minimizing these complications.

Santa Ana, California, USA) had higher success rates when compared with trabeculectomy with mitomycin-C (MMC), although both procedures resulted in similar intraocular pressure (IOP) reduction and use of supplemental medical therapy at a 5-year postoperative interval in patients with prior cataract surgery, prior trabeculectomy or both [4▪]. Additionally, reports of early postoperative complications in the trabeculectomy group were higher than those observed in the Baerveldt series (BVT) cohort, whereas rates of late postoperative complications, reoperations for complications, and cataract extraction were similar in both procedure groups [5▪]. With regards to complications, most were regarded as transient and self-limited [5▪]. Early postoperative BVT complications were considered if occurring at or before the 1-month postoperative date, late complications occurred thereafter. The number of patients captured in the BVT groups was 107, with 22 patients (21%) having early postoperative complications and 36 (34%) having late complications [5▪].

The Primary Tube Versus Trabeculectomy (PTVT) study is a multicenter randomized clinical trial comparing the safety and efficacy of tube shunt surgery (BVT 350-mm^2) with trabeculectomy with MMC in patients at low risk for surgical failure, including eyes without previous ocular surgery (http://clinicaltrials.gov/show/NCT00666237). The results of the PTVT study have the potential to drastically expand the implantation rate of tube shunts and heighten the importance of tube shunt comparative analysis, complication awareness, and management.

Two studies, the Ahmed Verses Baerveldt study (AVB) and the Ahmed Baerveldt Comparison study (ABC), are in the process of comparing the two most commonly used glaucoma drainage devices: the Ahmed glaucoma value implant (model FP7; New World Medical, Rancho Cucamonga, California, USA) and the Baerveldt glaucoma implant (model 101–350; BVT 350-mm^2) [6,7].

Regarding 1-year study results, the ABC study indicated a lower mean IOP in the Baerveldt-350 group when compared with the Ahmed-FP7 (13.2 vs. 15.4 mmHg, respectively, $P = 0.007$), which agreed with results from the AVB study (13.6 vs. 16.5 mmHg, respectively, $P < 0.001$) [6,7]. Additionally, the ABC study found that the adjunct use of medications was similar in both groups; however, the AVB study found that the Baerveldt-350 group required fewer medications than the Ahmed-FP7 group at 1 year (1.2 vs. 1.5 medications, respectively, $P = 0.03$) [6,7]. Probability of failure in the ABC study was not statistically significant between the Ahmed-FP7 and Baerveldt-350 group (16.4 vs. 14.0%, respectively, $P = 0.52$); however, the AVB study found the cumulative probability of failure to be statically significant between the two groups (43% Ahmed-FP7 vs. 25% Baerveldt-350 group, $P = 0.02$) [6,7]. Failure was defined similarly between the two studies with the exception of the upper limit of IOP tolerance to qualify as treatment failure (IOP >21 mmHg in the ABC study vs. IOP > 18 mmHg in the AVB study) [6,7]. One has to wonder whether the cumulative probability of failure would reach statistical significance in the ABC study if the upper limit of IOP was to be adjusted to a more stringent IOP reduction of >18 mmHg. This IOP target may be a more suitable marker for success in patients with advanced or severe glaucoma.

The ABC study showed the Baerveldt-350 group encountered more early (<3 months from surgery) postoperative complications than the Ahmed-FP7 group (58 vs. 43%, respectively, $P = 0.016$) and serious complications like reoperation and/or vision loss of 2 or more Snellen lines of acuity (34 vs. 20%, respectively, $P = 0.014$) [6]. The overall rate of postoperative complications in the AVB study was similar for both implants (54% for the Baerveldt-350 vs. 45% for the Ahmed-FP7, $P = 0.19$) [7]. Additionally, the AVB study demonstrated the Baerveldt-350 group experienced persistent corneal edema more commonly than the Ahmed-FP7 group (12 vs. 2% respectively, $P = 0.004$); however, the Ahmed-FP7 group experienced encapsulation of the bleb at a greater frequency than the Baerveldt-350 group (11 vs. 3%, respectively, $P = 0.011$) [7]. Postoperative interventions were greater in the Baerveldt-350 when compared with the Ahmed-FP7 group (42 vs. 26% respectively, $P = 0.007$) [7] (Table 1) [5▪].

A report from the ABC study at 3 years indicates a similar risk for failure between the Baerveldt-350 mm^2 and Ahmed-FP7 implants [30% at 3 years,

Table 1. Postoperative complication rates following tube shunt surgery in multicenter randomized clinical trials

	TVT study[a] ($n=107$)	ABC Study[b,c] ($n=133$)
Shallow or flat anterior chamber	11%	23%
Persistent corneal edema	16%	12%
Choroidal effusion	16%	11%
Hyphema	2%	18%
Tube obstruction	3%	14%
Persistent diplopia	6%	8%
Cystoid macular edema	5%	5%
Tube erosion	5%	1%
Chronic or recurrent iritis	2%	3%
Vitreous hemorrhage	1%	4%
Suprachoroidal hemorrhage	2%	2%
Hypotonymaculopathy	1%	3%
Endophthalmitis	1%	2%
Retinal detachment	1%	0%
Overall rate[d]/follow-up	21%/1 month 43%/5 years	58%/3 months 69%/1 year

ABC, Ahmed Baerveldt Comparison; TVT, Tube Versus Trabeculectomy.
Adapted with permission from [5▪].
[a]Complication rates reported during 5 years of follow-up.
[b]Complication rates reported during 1 year of follow-up.
[c]Data are presented for patients randomized to receive a Baerveldt glaucoma implant.
[d]Table does not list all complications, only those reported in both studies.

risk ratio, 1.0; $P=0.88$; 95% confidence interval (CI), 0.7–1.6) [8]. Reoperation risk was two times higher in the Ahmed-FP7 group (95% CI, 0.9 to 4.4; $P=0.074$) and the IOP was lower in the Baerveldt-350 group when compared with the Ahmed-FP7 (12.9 vs. 14.3 mmHg, respectively, $P=0.049$) [8]. At 3 years, medication use was similar between groups: 1.5 medications in the Baerveldt-350 mm^2 group compared to 1.9 medications in the Ahmed-FP7 group [8].

Encouragingly, glaucoma specialists have a choice between two tube implants, Baerveldt-350 mm^2 and the Ahmed-FP7, with seemingly similar success rates with our without adjunct medical therapy. Both devices appear to have acceptable rates of self-limiting complications in the immediate and prolonged postoperative period.

CURRENT PERSPECTIVES IN THE MANAGEMENT OF TUBE IMPLANT COMPLICATIONS

Paramount to the management of postoperative complications is proper surgical technique and appropriate patient selection. Minimizing the rates of manageable postoperative complications should parallel the surgeon's emphasis on the appropriate lowering of the intraocular pressure to slow the progression of glaucomatous optic neuropathy.

Hypotony

Initial resistance to aqueous outflow following placement of a GDD is achieved primarily by two means; one is the resistance established by the placement of a ligature suture near the silicone tubing as it approaches the plate or by flow restriction inherent to the device itself.

Nonvalved GDD, such as those in the BVT, require judicious placement of an absorbable polyglactin suture to impede flow from the anterior chamber to the end plate, until such a time that relative encapsulation occurs. Failure to appropriately occlude the silicone tubing, which can be confirmed intraoperatively by testing the restriction of flow through the tubing with a 30-gauge cannula placed in the distal end of the tube, can result in premature and unrestricted flow leading to postoperative hypotony.

Valve GDD, such as those in the Ahmed series (AGV), rely on a flow-restriction mechanism intrinsic to the implant itself. Care must be taken as to not 'over-prime' the implant at the time of confirming patency of the tubing and device. Additionally, manipulation of the valve housing should be avoided, as this can lead to defective performance of the valve mechanism. Reports of postoperative hypotony following placement of the AGV (S2 and FP7) is reported to be less than 3% [9]. Recent publication of a comparative study with the Ahmed Glaucoma Valve iterations (S2, FP7 and M4) did not discover a significant hypotensive phase following implantation of a combined total of 154 implants (76 FP7, 38 S2, and 40 M4) [10▪].

Previously, importance has been placed on the utilization of a 22- or 23-gauge needle when creation of the sclerostomy is undertaken in order to avoid egress of aqueous around the silicone tube. Additionally, at the conclusion of every case, one should examine the eye regarding maintenance of physiologic pressure by observing the anterior chamber depth, assessment of pressure, and fluorescein staining of the conjunctiva for wound leaks.

Recent reporting on the risk of cyclodestruction procedures preceding the implantation of a BVT 250-mm^2 and 350-mm^2 as an independent risk factor for late-onset hypotony and suprachoroidal hemorrhage raises the issue of appropriate patient selection for tube implant consideration [11].

Encapsulation and the hypertensive phase

Long-term success of GDD implantation is dependent on the characteristics of the encapsulation

formed about the end plate in the episcleral space. Previous reports have established plate size, configuration, and composition can be optimized to improve outcome [11].

Innovative design of the newest iteration of the AGV, the M4, incorporates the AVG S2 valve mechanism encased in porous high-density polyethylene allowing for thinner, more vascular capsule formation aimed to reduce outflow resistance when compared with earlier models [10▪]. Comparison of IOP lowering effect between AGV subtypes was carried out and was found to be similar as was cumulative probability of success [10▪]. A mitigation of the early postoperative hypertensive phase was seen with the M4 model in comparison with the FP7 and S2 models [10▪].

Investigative research regarding the factors influencing encapsulation formation [12] and the development of biodegradable drug delivery systems to serve as coatings upon GDD, specifically AGV, are being evaluated in the laboratory and hold promise for improved and prolonged efficacy of GDD owing to a reduction in fibrosis formation around the plate [13].

Another management option for early or late encapsulation following tube implantation includes digital massage [14,15]. Success of AGV implantation has been associated with a thinner encapsulating bleb wall when visualized with Anterior-Segment Optical Coherence Tomography (AS-OCT) [16], perhaps a response to ocular massage may be dependent upon characteristics of the encapsulating bleb and screening for encapsulation characteristics using AS-OCT can aid in selection of patients who may benefit from digital massage.

Tube erosion

Tube erosion is an established complication of GDD implant surgery [5▪,6,7] despite uniformity in technique to secure the tube to the sclera, and utilization of common materials, such as processed pericardium and sclera, in order to reduce the incidence of erosion. When a tube becomes exposed, primary surgical intervention has been to surgically undermine the surrounding conjunctiva, application of absolute alcohol to the wound site, placement of a scleral patch graft, and application of conjunctival and tenons autograft to cover the defect. Huddleston *et al.* [17] established a list of risk factors found to be associated with a recurrence of erosion or persistence of the defect following tube exposure revision. These were black race, diabetes mellitus, a high number of glaucoma medications before shunt implantation, a history of multiple glaucoma laser procedures, and a combination of an initial aqueous shunt implantation with another surgery [17].

Perhaps, forniceal conjunctival pedicle flap and the split-lid techniques described by Grover *et al.* [18] as a treatment option for conjunctival-deficient tube erosions may be a viable treatment in patients indentified by Huddleston *et al.* [17] to be at greater risk for revision failure (Fig. 1) [18].

DIPLOPIA/MOTILITY DISTURBANCES

Diplopia and strabismus are known to occur following tube implant surgery; a review of published studies by the TVT study group [19] demonstrated a range of occurrence from of 1.4–37% and 2.1–77%, respectively. The TVT Baerveldt-350 mm^2 group experienced a 5% rate of diplopia and a 9.9% incidence of strabismus [19]. This is comparable with the 6% rate of diplopia experienced by those undergoing Ahmed-FP7 implantation in the AVB study [7]. Causal relationship is difficult to establish when preoperative documentation of small sensory heterophorias, heterotropias, and measurement of fusional amplitudes is omitted. Rauscher *et al.* [18]

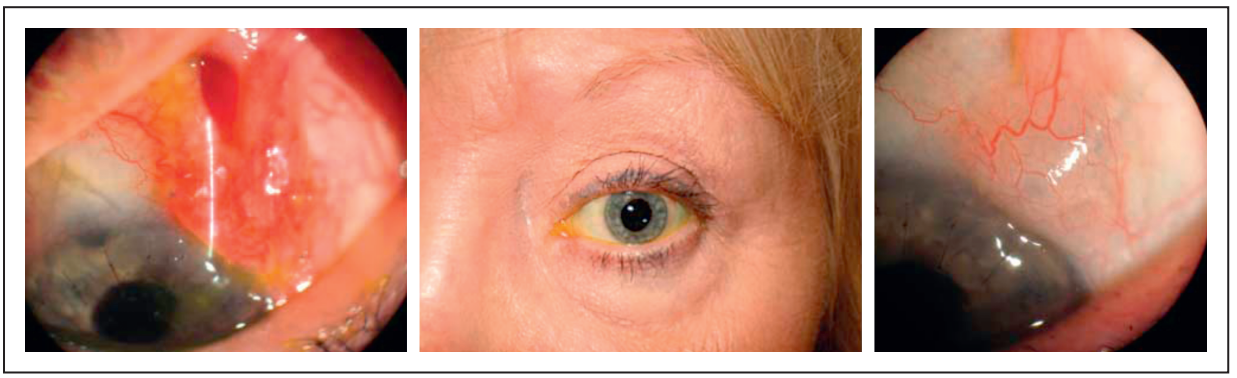

FIGURE 1. One month, 1-year, and external photo following forniceal conjunctival pedicle flap for complex tube erosion (reproduced with permission from [18]).

reported that low visual acuity, less than 20/200, was associated with preoperative tropias. Kim *et al.* [10▪] associated the low profile bleb, characteristic of the Ahmed-M4 iteration, to be the driving factor behind an absence of diplopia in patients undergoing its implantation. Additionally, the TVT study [19] found older age and previous eye surgery to be associated with the increase risk of developing diplopia with placement of the BVT-350 mm^2 implant.

Traditionally, GDD have been primarily implanted in the superior temporal quadrant of the globe in order to avoid oblique muscle fibers and allow for optimal exposure of the surgical field. GDD placement in the superior nasal quadrant is typically avoided because of the increased incidence of diplopia due to restriction of the superior oblique muscle, resulting in a pseudo-Brown's syndrome [20]. When access to the superior temporal quadrant is limited by conjunctival scarring, Martino *et al.* [21] have established that no statistical difference exists regarding surgical success between the superior temporal and inferior nasal quadrant; however, there was a greater incidence of reoperation at 36 months (24.6% superior temporal and 45.5% inferior nasal) and vitreous hemorrhage in the inferior nasal cohort. Additionally, there was no reported manifestation of diplopia or strabismus [21], which is in keeping with results published by Harbick *et al.* [22]. Their study found only three of 182 eyes undergoing inferior nasal BVT implantation resulted in diplopia [22]. In these studies, BVT 250 mm^2 and 350 mm^2 [20] and BVT 250 mm^2, 350 mm^2 and 425 mm^2 [22] were used at the author's discretion.

Treatment of diplopia and strabismus associated with tube implants continues to consist of prism spectacles, extraocular muscle surgery, and explantation of the implant.

CORNEAL ISSUES

Of complications associated with tube implants as they relate to corneal decompensation, it appears that tube-cornea touch is the only modifiable risk factor to corneal decompensation and therefore, care should be taken to avoid contact of the silicone tube with the corneal endothelial surface. Ayuso *et al.* [23] recently demonstrated that AGV placement in uveitic children was independently associated with a decrease in the endothelial cell density (ECD) over time. Additionally, Leiberman *et al.* [24] found pars plana AGV implantation successfully controls IOP in penetrating keratoplasty patients in the short and intermediate terms, but graft clarity and IOP control diminish over time. Both studies, independently, demonstrate an association between tube implantation and long-term survivability of host or donor corneal tissue; therefore, consent for tube implantation needs to include the possibility of corneal decompensation. Fortunately, results from the TVT and ABC studies failed to demonstrate corneal decompensation following tube implantation at 5 and 1 year(s), respectively [5▪,6]. Recall, however, that the AVB study demonstrated the Baerveldt-350 mm^2 group experienced persistent corneal edema more commonly than the Ahmed-FP7 group (12 vs. 2% respectively, $P = 0.004$) [7].

CONCLUSION

The trend for increased acceptance and expansion of the indications for tube implantation is growing. As such, we must remain mindful that no glaucoma surgical intervention is a panacea and patient selection, risk stratification, and consideration of alternative surgical options remains paramount.

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Conflicts of interest

A.K.B. and S.R.S. report no conflicts of interests in the production of this article.

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