Glaucoma Tube Shunt Implantation Through the Ciliary Sulcus in Pseudophakic Eyes With High Risk of Corneal Decompensation

Asher Weiner, MD,* † Aaron D. Cohn, MD,* Mamtah Balasubramaniam, MS,§ and Adam J. Weiner∥

Purpose: To summarize our clinical experience with implanting Baerveldt glaucoma tube shunts through the ciliary sulcus in eyes with a posterior chamber intraocular lens and shallow anterior chambers, corneal transplants, guttata or edema.

Patients and Methods: A retrospective interventional nonrandomized noncomparative case series. Main outcome measure was postoperative corneal status. Secondary outcome measures included postoperative intraocular pressure (IOP), visual acuity and complications.

Results: Thirty-six eyes of 32 patients were identified through chart review. Follow-up period was 21.8 ± 16.6 months (mean ± standard deviation, range: 4.0 to 58.5 mo). At final visit, all 23 preoperative clear native corneas and 6 of 7 corneal transplants remained clear. Thus, of the 30 preoperative clear corneas, only 1 decompensated. Preoperative IOP was 27.9 ± 11.5 mm Hg (range: 12 to 59 mm Hg), reduced postoperatively to 10.1 ± 3.9 mm Hg (range: 2 to 21 mm Hg, \( P = 0.0001 \)), a reduction of 58.2% ± 19.3% (range: 5.0% to 95.4%). Final IOP was ≤ 5 and ≤ 21 mm Hg in 33 of 36 eyes (91.7%). It was lowered by 30% or more in 34 of 36 eyes (94.4%).

Conclusions: Although previously published studies demonstrated a significant risk of corneal decompensation after tube shunt implantation through the irido-corneal angle1–7 (Fig. 1) and a risk of both corneal decompensation and significant posterior segment complications after implantation through the pars plana,1,5,8–11 Tube insertion through the ciliary sulcus has previously been advocated to protect corneal transplants after tube implantation in 2 studies.12,13 In these studies combined, 6 corneal transplants remained clear during a 16 to 36 month follow-up period. Eight eyes with no corneal transplants were also described,12,14,15 bringing the total number of eyes detailed in the literature with ciliary tube insertion to 14.

We have been inserting tubes through the ciliary sulcus since 2002 in an attempt to protect the corneal endothelium in eyes with a posterior chamber intraocular lens (PCIOL) with shallow anterior chambers, corneal transplants, corneal guttata or corneal edema. This paper is a summary of our clinical experience with this procedure.

Key Words: tube shunt implantation, ciliary sulcus, corneal decompensation, glaucoma surgery, intraocular pressure (J Glaucoma 2010;19:405–411)

Tube shunt implantation is an effective means to reduce intraocular pressure (IOP) in eyes with uncontrolled glaucoma. However, previous studies demonstrated a significant risk of corneal decompensation after tube shunt implantation through the irido-corneal angle1–7 (Fig. 1) and a risk of both corneal decompensation and significant posterior segment complications after implantation through the pars plana.1,5,8–11 Tube insertion through the ciliary sulcus has previously been advocated to protect corneal transplants after tube implantation in 2 studies.12,13 In these studies combined, 6 corneal transplants remained clear during a 16 to 36 month follow-up period. Eight eyes with no corneal transplants were also described,12,14,15 bringing the total number of eyes detailed in the literature with ciliary tube insertion to 14.

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FIGURE 1. Localized corneal edema in the area of a tube shunt (T; black arrow) implanted through the anterior chamber angle, too close to the cornea.
of our clinical experience in such eyes and it is the largest series with the longest follow-up published to date.

PATIENTS AND METHODS

The Human Investigation Committee, William Beaumont Hospital, Royal Oak, Michigan approved this study. We retrospectively identified 36 high-risk eyes of 32 patients (Table 1) in a private glaucoma and retina referral practice through a chart review of all tube shunt surgeries we performed during the years from 2002 to 2007. We considered these eyes to be of high-risk for corneal decompensation after tube shunt implantation through the anterior chamber angle if the tube would end up in close proximity to the cornea in a shallow anterior chamber, if the cornea demonstrated guttata or edema preoperatively, or if the eye already had a corneal transplant.2–7,16 Inclusion criteria to our study included a tube implanted through the ciliary sulcus, a PCIOL, and one or more of the following: shallow anterior chamber, corneal transplant, corneal guttata or corneal edema. Exclusion criteria included a tube implanted through the anterior chamber angle or the pars plana, phakia, aphakia, an anterior chamber intraocular lens (ACIOL), or a normal native cornea with none of the risk factors detailed above. In the 36 eyes identified, to avoid postoperative corneal decompensation and significant posterior segment complications, the tube was inserted through the ciliary sulcus to rest between the iris and the PCIOL, instead of through the anterior chamber angle or the pars plana. Consequently, the cornea was shielded from the tube by the iris with only the distal end of the tube emerging from behind the iris at the pupil margin (Fig. 2), resting as far as possible from the cornea (Fig. 3). All tube shunts were implanted by a single surgeon (A. W.) in eyes with uncontrolled glaucoma refractory to medical therapy, most of which had previous failed glaucoma procedures (Table 2).

Surgical Procedure and Postoperative Care

In all cases, steroid and antibiotic eye drops were used 4 times daily starting 3 days before surgery. Peribulbar anesthesia was used and supplemental intraoperative subtenon anesthesia was added as needed. The superotemporal quadrant was used in 32 of 36 eyes (89%), the superonasal quadrant in 2 eyes (5.5%), and the inferotemporal quadrant in the remaining 2 eyes (5.5%).

A single-stage procedure was performed. A conjunctival and tenon’s capsule incision was made between corresponding recti muscles, 7-8 mm from the limbus. A Baerveldt-350 tube shunt (Advanced Medical Optics, Santa Ana, CA) was implanted in all eyes, with a “rip-cord” valve consisting of intraluminal 5-0 nylon suture (Ethicon, Piscataway, NJ), and a 6-0 Vicryl suture (Ethicon, Piscataway, NJ) tied tightly around the tube 1 mm from the plate, thereby occluding the tube to prevent early postoperative hypotony. The 5-0 nylon suture was left lying under the conjunctiva and Tenon’s capsule extending to the inferior limbal area for future removal in the office. The shunt plate was placed under the corresponding recti muscles and

![FIGURE 2. Tube shunt (T; white arrow) implanted through the ciliary sulcus, mostly shielded from the cornea by the iris, in an eye with a corneal transplant. The anterior chamber was too shallow (double-headed arrow) to allow for cornea-safe implantation of a tube through the angle.](image1)

![FIGURE 3. Ultrasound biomicroscopy of a tube shunt (T; white arrow) implanted through the ciliary sulcus, seen between the iris (I; white arrow) and the posterior chamber IOL, as far as possible from the cornea (C; white arrow). A/C indicates anterior chamber; IOL, intraocular lens.](image2)
TABLE 2: Eye Characteristics

Preoperative Eye Characteristics (36 Eyes)

<table>
<thead>
<tr>
<th>Glaucoma type</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic angle closure</td>
<td>17 (47.2)</td>
</tr>
<tr>
<td>Primary open angle</td>
<td>10 (27.8)</td>
</tr>
<tr>
<td>Uveitic</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Neovascular</td>
<td>3 (8.3)</td>
</tr>
<tr>
<td>Pseudoxfoliative</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>Pigmentary</td>
<td>1 (2.8)</td>
</tr>
<tr>
<td>Right eye</td>
<td>13 (36.1)</td>
</tr>
<tr>
<td>Shallow anterior chamber</td>
<td>25 (69.4)</td>
</tr>
<tr>
<td>Corneal guttata</td>
<td>12 (33.3)</td>
</tr>
<tr>
<td>Corneal transplant (all clear)</td>
<td>7 (19.4)</td>
</tr>
<tr>
<td>Edematous native cornea</td>
<td>6 (16.7)</td>
</tr>
<tr>
<td>Previous trabeculectomy</td>
<td>24 (66.7)</td>
</tr>
<tr>
<td>Previous laser trabeculoplasty</td>
<td>25 (69.4)</td>
</tr>
<tr>
<td>Previous cyclophotocoagulation</td>
<td>5 (13.9)</td>
</tr>
</tbody>
</table>

IOP (mm Hg) Mean ± SD, range, n

- 27.9 ± 11.8, 12-59, 36
- 10.1 ± 3.9, 2-21, 36
- 1.9 ± 1.7, 0-5, 36

Postoperative complications Mean ± SD, range, n

- Early hyphema 10/36 (27.8)
- Flat anterior chamber* 3/36 (8.3)
- Serous choroidal detachment 7/36 (19.4)
- Corneal failure† 1/30 (3.3)

*Requiring viscoelastic injection into the anterior chamber.
†Defined as decompensation of a cornea, native or transplant, that was clear preoperatively.
IOP indicates intraocular pressure.

Postoperative therapy included antibiotic eye drops 4 times daily, steroid drops 4 to 6 times daily with a slow taper, and a combination antibiotic-steroid ointment administered nightly with a shield. This regimen was continued until the surgical wound appeared well closed and vascularized, usually within 4 to 6 weeks. The intraluminal 5-0 nylon suture was removed at the slit lamp usually within 4 to 8 weeks postoperatively by pulling it through a 1 mm conjunctival incision performed at the location of the tip of the 5-0 nylon suture. IOP lowering medications were used postoperatively as needed, and the final desired IOP was usually achieved and maintained within the first 6 weeks postoperatively, with or without medications.

Fixed to bare sclera, 9 mm from the limbus, with 2 interrupted 8-0 nylon sutures (Ethicon, Piscataway, NJ).

A 15-degree supersharp knife (Alcon Laboratories, Inc, Fort Worth, TX) was used to create a limbal inferotemporal paracentesis, through which Viscoat (Alcon Laboratories, Inc, Fort Worth, TX) was injected into the anterior chamber, with care to maintain low normal IOP throughout the procedure. All tubes were then trimmed to appropriate length with an anterior facing bevel.

Additional Viscoat was injected between the iris and the PCIOL in the location chosen for tube insertion. A 23-gauge needle, mounted onto the Viscoat syringe, was used to create a shelved scleral tunnel, beginning 1.5 mm to 2 mm from the limbus, directed to enter the space between the iris and the PCIOL. During needle insertion, small amounts of Viscoat were injected to identify the location of the needle tip behind the iris and to help keep the tip clear of the iris, lens capsule, and the IOL. The tube was then inserted through the scleral tunnel and advanced until its tip emerged from behind the iris, clearing the nondilated pupil margin to prevent later occlusion by iris tissue (Fig. 3). In eyes with a small pupil, a small sector iridectomy (Fig. 4) was performed at the tube location with fine long-blade capsular scissors (Katena Products, Inc, Denville, NJ) inserted through the limbal paracentesis. The small sector iridectomy was performed to allow keeping the tube away from the center of a small pupil where it could interfere with retinal evaluations and photoocoagulation, yet allowing it to clear iris tissue. Only 5 patients (5 eyes) in our current series underwent sector iridectomy.

The tubes were fixated to sclera 1 mm from their scleral entry with a triple-loop 10-0 nylon suture (Ethicon, Piscataway, NJ) and a single loop 10-0 nylon suture several millimeters more posteriorly. Two to three 1 mm fenestrations were made into the side of the tube using a 15-degree supersharp knife (Alcon Laboratories, Inc, Fort Worth, TX) to allow for early postoperative IOP control. Aqueous humor was observed to slowly egress through these fenestrations. All tubes were covered by a 5 × 8 mm Tuto-plast scleral graft (IOP Inc, Costa Mesa, CA), first soaked in gentamycin solution, then trimmed to appropriate size and fixated to sclera with 2 interrupted 10-0 nylon sutures with the knots buried under the patch.

The initial conjunctival and Tenon’s incision was then closed in 2 layers using an 8-0 Vicryl suture (Ethicon, Piscataway, NJ), closing Tenon’s capsule in a running-locking fashion and the conjunctiva in a running-nonlocking watertight fashion. Viscoat was then irrigated out of the anterior chamber through the paracentesis using balanced salt solution (Alcon Laboratories, Inc, Fort Worth, TX), maintaining a deep anterior chamber and a low normal IOP. Then, a 1 mL of an antibiotic and steroid mixture was injected into the inferior fornix, a combination antibiotic-steroid ointment was instilled onto the cornea, and the eye was double-patched and shielded.

FIGURE 4. Tube shunt (T; white arrow) implanted through the ciliary sulcus, mostly shielded from the cornea by the iris, with only its distal end visible through a small sector iridectomy (SI; double white arrow).
Corneal Status Definitions

We defined a native cornea as a natural cornea without any past corneal procedure. Corneal transplant refers in our study only to a full thickness transplant. We defined corneal decompensation as a thickened cornea with endothelial striae and stromal opacification sufficient to obscure some or all details of the anterior chamber structures. Corneal edema was defined as a thickened cornea with endothelial striae but with a clear view of the anterior chamber structures and no stromal opacification.

Surgical Success

The primary definition of surgical success in our study was lack of postoperative corneal edema or decompensation, as defined above, in a preoperative clear cornea, native or transplant.

The main secondary measure of surgical success was postoperative IOP control. This was defined as final visit IOP ≥ 5 mm Hg and ≤ 21 mm Hg, and reduced by at least 30% compared with preoperative IOP, with or without IOP-lowering medications.

Statistical Methods

Paired t-test was used to compare parameters such as preoperative and postoperative IOP. Cox proportional hazards regression, with results based on the Wald χ² test, was used to assess potential predictors for surgical failure. Kaplan-Meier actuarial rates of survival were determined to assess time to failure. Only 1 eye of each patient was used in the Cox proportional hazard regression and the Kaplan-Meier survival analyses. P-values less than an α of 0.05 (Probability of Type I Error) were considered statistically significant. Statistical analysis was performed using the SAS System for Windows version 9.1.3, Service Pack 2.

RESULTS

Thirty-six eyes of 32 patients were identified. Follow-up period was 21.8 ± 16.6 months (mean ± SD, range, 4.0 to 58.5 mo). Tables 1 and 2 show pertinent patient and eye characteristics.

Surgical Results

Postoperative Corneal Decompensation (Table 3)

At final visit, all 23 preoperative clear native corneas, and 6 of 7 preoperative clear corneal transplants remained clear. Thus, of the 30 preoperative clear corneas, only 1 decompensated postoperatively and thus met the criteria of surgical failure because of corneal status. On the basis of Kaplan-Meier survival analysis, the corresponding actuarial success rate was 0.9643 (only 1 failure) with a length of follow-up of 5.2 months to failure (Fig. 5). Of the 6 preoperative edematous corneas, 2 cleared, 1 decompen- sated, and 3 remained unchanged (Table 3).

Postoperative-IOP Control

Preoperative IOP was 27.9 ± 11.8 mm Hg (mean ± SD, range: 12 to 59 mm Hg). It was significantly reduced to final visit IOP of 10.1 ± 3.9 mm Hg (mean ± SD, range: 2 to 21 mm Hg, P = 0.0001), a reduction of 58.2% ± 19.3%, (mean ± SD, range: 5.0% to 95.4%). Final visit IOP was ≥ 5 and ≤ 21 mm Hg in 33 of 36 eyes (91.7%), and it was lowered by 30% or more in 34 of 36 eyes (94.4%). Five eyes met the criteria of surgical failure because of the postoperative-IOP control. At final visit, 3 of them had IOP below 5 mm Hg, and the 2 additional failures had an IOP reduction of less than 30%. On the basis of Kaplan-Meier survival analysis, the corresponding Kaplan-Meier actuarial success rate was 0.66 with a length of follow-up to failure of 38.49 ± 3.04 months (mean ± SD, Fig. 6).

On the basis of Cox proportional hazard regression analysis there was no significant difference in time to failure due to any of the variables studied such as age, sex, ethnicity, and systemic or ocular conditions, shown in Tables 1 and 2.

The number of IOP lowering medications (36 eyes) was significantly reduced from 4.1 ± 1.1 (mean ± SD, range: 2 to 6) to 1.9 ± 1.7 (mean ± SD, range: 0 to 5, P = 0.0001) postoperatively. Nine (25.0%) of the 36 eyes required no IOP lowering medications at final visit whereas 8 (22.2%), 7 (19.4%), 6 (16.7%), 2 (5.6%), and 4 (11.1%) eyes required 1, 2, 3, 4, and 5 medications, respectively.

Visual Acuity

For the purpose of visual acuity calculation, count finger vision equivalent was 20/800, hand motion equivalent was 20/1600, and light perception equivalent was
with PCIOLs lowers the risk of both corneal decompensation and significant posterior segment complications. Despite the fact that our tubes were implanted in eyes with high risk of corneal decompensation, only 1 preoperative clear cornea decompensated postoperatively (Fig. 5). This cornea was a second corneal transplant in an eye with a history of severe trauma, several surgeries, and a previously failed corneal transplant that was replaced before the tube shunt implantation. The other 2 corneal failures in our study were already partially decompensated before the tube implantation. Interestingly, 2 other eyes with preoperative corneal edema cleared after tube insertion through the sulcus, most likely secondary to the postoperative reduction in IOP. All other preoperative clear corneas, native or transplant, remained clear postoperatively.

Our results support those of 2 previous smaller studies suggesting that tube insertion through the sulcus is safe, effective, and lowers the risk of corneal decompensation. Our study nearly quadruples the number of such eyes described in the literature, and doubles the number of similar eyes with corneal transplants. It also expands their follow-up period to up to 53.7 months. Thus, it further strengthens the impression that tube insertion through the ciliary sulcus may be safer than through the anterior chamber angle or the pars plana in eyes with PCIOLs.

Several mechanisms for corneal damage after tube shunt implantation may be considered. Continuous corneal endothelial damage may occur because of a constant cornea-tube touch such as when the tube is implanted through the angle too close to the cornea. In such eyes, we have first observed the development of local corneal edema around the tube (Fig. 1), followed even years later by diffuse corneal edema and decompensation. Intermittent corneal endothelial damage may also occur when the tube is implanted through the angle. In such cases the tube, although not continuously touching the cornea, is positioned close enough to the cornea to allow for intermittent cornea-tube touch during eye rubbing, squeezing, and perhaps even blinking. In contrast, when implanting a tube through the ciliary sulcus to rest between the iris and the PCIOL, the cornea is shielded from the tube which lies against the PCIOL as far away from the cornea as possible (Fig. 3). This most likely prevents cornea-tube touch under any normal circumstances.

However, corneal decompensation may also occur without any cornea-tube touch by several mechanisms. Periods of increased IOP before and after tube implantation may lead to an accelerated rate of corneal endothelial cell loss. The chronic use of topical glaucoma medications before and after tube implantation may be a significant risk factor for corneal graft failure by rejection, endothelial decompensation without rejection, and ocular surface disease. In fact, the chronic use of topical glaucoma medications alone, even with no tube shunt implantation, was demonstrated to triple the rate of corneal transplant failure, up to 47.1%. Other mechanisms are the continued decline in endothelial cell count of corneal grafts in eyes with no tubes and the additional age-related normal decline in corneal endothelial cell count. The previous use of Mitomycin C in trabeculectomy surgery may be another risk factor for corneal endothelial damage. Many eyes undergoing tube shunt implantation have already had several surgeries including trabeculectomy with Mitomycin C. Yet another mechanism is the known accelerated rate of corneal endothelial cell loss after any ocular surgery.
The additional surgical trauma from the vitrectomy procedure, in addition to that from the tube implantation, may be the underlying cause of the significant rate of corneal failure after pars plana tube insertion. In conclusion, in view of all these possible contributing mechanisms, corneal decompensation after tube shunt implantation cannot be attributed exclusively to the mere presence of a tube in the eye, whether anterior or posterior to the iris.

Further, whereas insertion of tube shunts through the pars plana has been advocated as a means to reduce the frequency of corneal decompensation after tube shunt implantation, not only does this method of tube insertion not seem to reduce the rate of corneal failure, it is also costly and often carries the risk of significant posterior segment complications. It often necessitates posterior vitrectomy in cooperation with a retinal surgeon resulting in significant costs and logistics, and it can lead to tube blockage by residual vitreous in 3% to 15.4% of the eyes, epiretinal membrane formation in 9%, retinal detachment in 6% to 20%, and even blindness in as many as 15% of the eyes. In contrast, the only posterior segment complication in our study was a self-limited serous choroidal detachment. Similarly, significant posterior segment complications were not reported in the previous studies on sulcus inserted tubes. Thus, it appears that tube shunt implantation through the ciliary sulcus may help avoid significant posterior segment complications compared with pars plana insertion.

In addition to its apparent safety, our study demonstrates that sulcus tube implantation is also effective in controlling IOP. Postoperative final IOP was reduced by 30% or more in 34 of 36 eyes (94.4%); the remaining 2 eyes were considered surgical failures (Fig. 6). Final IOP was between 5 and 21 mm Hg in 33 of 36 eyes (91.7%). The other 3 eyes were considered surgical failures since their final IOP was below 5 mm Hg. One was a case of severe ocular ischemia with neovascular glaucoma secondary to a familial hypercoagulative condition and later ciliary body shut down; IOP remained very low even after the tube was eventually removed. The other 2 eyes had end-stage glaucoma where a very low IOP was targeted and did not affect visual acuity. Further, the number of IOP lowering medications in our study was significantly reduced postoperatively, with 9 eyes (25%) requiring no IOP lowering medications at the end of follow-up.

We have observed several complications during the postoperative period (Table 2). Ten eyes (27.8%) had early postoperative small (0.5 mm to 2.0 mm) hyphema that cleared within 1 to 2 weeks except for 1 eye with neovascular glaucoma and extensive iris rubeosis that required anterior chamber washout. This rate of hyphema was higher than that reported in studies of tubes inserted through the angle or the pars plana (8% to 16.9%). However, none of these cases in our study resulted in tube blockage or long-term complications. Sector iridectomy did not seem to be a major cause of hyphema as the latter was present in only 2 of the 5 eyes that underwent sector iridectomy and 8 of the 10 eyes with hyphema did not have sector iridectomy. Self-limited serous choroidal detachment occurred in 7 eyes (19.4%) in our study; this rate was not different than that reported in studies of angle or pars plana inserted tube shunts (7% to 23%). None of these or other complications listed in Table 2 were of any long-term consequence. Furthermore, with our described technique of tube insertion through the sulcus, we have not observed any cases of IOL dislocation, pigment dispersion, tube blockage by iris, or significant visual loss.

Our study is limited by several factors. It is a retrospective chart review and a summary of our clinical experience rather than a randomized controlled prospective study, and the number of eyes studied was relatively small, particularly the number of eyes with neocorneal transplants. Also, only some types of glaucoma were represented in our study (Table 2); thus, the safety of tube implantation through the sulcus was not evaluated in all types of glaucoma. In addition, half of our patients were diabetic (Table 2). This is most likely the result of the relatively high proportion of patients with diabetes in our private glaucoma and retina referral practice. It is our speculation that this bias has not affected our results.

Despite our study limitations, we believe that our clinical experience further supports the notion that tube implantation through the ciliary sulcus in eyes with PCIOls is a safe and effective procedure, and may be the preferred mode of tube implantation in such eyes, especially in those with high risk of corneal decompensation.

REFERENCES