Glaucoma Drainage Device Surgery

Techniques & Decision-Making

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What we’ll cover

• Rationale for using glaucoma drainage devices
• Types of glaucoma drainage devices
• Indications
• Surgical techniques
• Comparative Studies
• Recommendations
Rationale

• Why do trabeculectomies fail early?
  – Internal occlusion by iris, vitreous
  – External fibrosis
    • Scarring of flap
    • Scarring of conjunctiva to sclera

• Why do trabeculectomies fail late?
  – External fibrosis
  – Leaks & infection
Bleb infections
Rationale

• **Risk factors for trabeculectomy failure**
  - Prior trabeculectomy failure
  - Prior conjunctival surgery (e.g. ECCE)
  - Youth
  - Non-use of antimetabolites

• **Risk factors for late failure & complications**
  - Use of antimetabolites $\Rightarrow$ Thin, ischemic blebs $\Rightarrow$ Bleb leaks $\Rightarrow$ bleb infection
  - Poor hygiene, external eye disease
• Glaucoma Drainage Devices are designed to overcome two problems with trabeculectomy:
  – Prevent closure of fistula diverting aqueous out of the eye
    • Silicone tube
  – Prevent failure of bleb due to conjunctival scarring to sclera
    • External plate maintains potential space, capsule
Rationale

- A tube connecting the anterior chamber to the subconjunctival space results in hypotony:
  - Flat chambers, cataract, choroidal effusions & hemorrhages, retinal detachments

- A tube ending in the subconjunctival space will scar shut after a few weeks to months
Rationale

- The key innovation is a tube that diverts aqueous to a potential subconjunctival space maintained by a biocompatible material to prevent scarring.

- Earliest versions included the Molteno and Shocket Implants:
  - The Molteno Implant is purpose-designed for glaucoma surgery.
  - The Shocket Implant uses a combination of silicone tubing and retinal explant material, assembled by surgeon at the time of surgery.
Types of Glaucoma Drainage Devices

Non-Valved Implants

• Molteno implant
  – 1 & 2-plate versions

• Baerveldt Implant
  – 250 & 350 mm² versions

Valved Implants

• Ahmed Glaucoma Valve
Non-valved Glaucoma Drainage Devices

- Require temporary occlusion of tube to prevent early hypotony
  - Ligation of tube with absorbable suture (e.g. 7 or 8-0 Vicryl) which dissolves after 4-6 weeks
  - Internal occlusion of tube with 3-0 nylon or polypropylene suture which is extended subconjunctivally to remote site – removed at slit lamp (“rip-cord” technique)
  - Filling of tube and anterior chamber with Healon 5
Non-valved Implants – Potential Advantages

- Larger surface area in current designs
  - IOP-lowering is roughly proportional to explant surface area

- Bleb not exposed to early postoperative inflammatory mediators
  - Possibly thinner, more permeable blebs

- ? Better long-term IOP lowering
  - Ahmed-Baerveldt Comparison (ABC) Study
  - Ahmed versus Baerveldt (AVB) Study
Ahmed Glaucoma Valve

- Uses a one-way silicone valve that functions on the Venturi principle
  - Claimed to open at $\approx 10$ mmHg \textit{in vivo}
  - Claimed to prevent early postoperative hypotony
Valved Implants – Potential Advantages

- No need for temporary occlusion of device
- Immediate IOP-lowering
- Single-Quadrant implantation
- Faster surgery
Valved Implants – Potential Disadvantages

• Immediate access of capsular tissues to inflamed aqueous
  – ? inflammatory mediators (e.g., TGF$_{\beta}$) may lead to less permeable capsule

• Smaller surface area (than Baerveldt 350)
  – IOP-lowering believed to be roughly proportional to surface area of capsule formed around implant
Indications

- Failed trabeculectomy
- Extensive conjunctival scarring
- Anticipated need for more intraocular surgery
- Prior cataract surgery (esp. ECCE)
- ? primary surgery in selected populations
Implantation Techniques

- Conjunctival Flap
  - Limbal-based or Fornix-based

- Implant preparation
  - Ligation for non-valved implants
  - Flushing of valve for valved implants
Implantation Techniques

- Trimming of tube to appropriate length
- Placement of tube through sclera
  - Under scleral flap
  - Under donor tissue
  - Through long scleral tunnel
Limbal-Based Flap

4 week old infant with bilateral congenital glaucoma of the newborn; failed circumferential trabeculotomy
Flushing a Valved Implant

4 week old infant with bilateral congenital glaucoma of the newborn; failed circumferential trabeculotomy
Baerveldt Implant Insertion
Baerveldt Implant Insertion
Limbus-Based Flaps
Background

• Long history of fornix-based conjunctival incisions for glaucoma drainage devices
  – Shocket surgery was a modification of a scleral buckle
  – Double-plate Molteno Implant required exposure of two adjacent quadrants and isolation of superior rectus muscle
Background

- All currently-popular GDDs require only one quadrant for implantation
- Most US-based glaucoma surgeons use fornix-based flaps (77% in the TVT Study)
- Both Molteno and Baerveldt usually implanted their implants under a limbus-based conjunctival flap
**Limbal-based Conjunctival Flaps**

**Advantages**
- Better exposure posteriorly
- Smaller incision overall
  - Water-tight closure assured
- More comfortable
- Quicker to fit contact lenses
- Spares limbal stem cells

**Disadvantages**
- Requires conjunctival clamp ± really good assistant
- Anterior dissection can challenging when scarring present
- Places area of active wound healing next to bleb
Fornix-based Conjunctival Flaps

**Advantages**

- Better exposure anteriorly
  - Good posterior exposure requires nearly 180° peritomy
- Easier to deal with scarring
- Can do without assistant
- *Limbal wound is far away from posterior bleb*

**Disadvantages**

- Uncomfortable for patients
- Wound is rarely watertight
- Unless incision is large, plate sutures challenging
- Destroys many clock hours of limbal stem cells
Comparative Studies
Retrospective Study (UC Davis)

- Retrospective review of two surgeon’s cases of Baerveldt Implants with ≥ 1 year of followup
  - No difference between limbal-based (N=69) or fornix-based (N=91) conjunctival incisions in:
    - Success
    - IOP
    - Complications
    - Medications

Suhr AW, Lim MC, Brandt JD, Izquierdo JC & Willits N
Outcomes of Fornix-based Versus Limbus-based Conjunctival Incisions for Glaucoma Drainage Device Implant
J Glaucoma 2012;21(8):523-529
**FIGURE 1.** Baseline and follow-up intraocular pressure (mm Hg) for each group. Bars represent the 95% confidence interval. P values describe differences between groups and are adjusted for age.

**FIGURE 2.** Kaplan-Meier analysis of probability of failure for IOP control (failures prior to post operative month 6 omitted).
### Retrospective Study (UC Davis)

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<table>
<thead>
<tr>
<th>Failure Criteria</th>
<th>Limbal-Based (N=69)</th>
<th>Fornix-Based (N=91)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOP &gt; 17 mmHg or not reduced by 20% below baseline IOP</td>
<td>13 (18.8%)</td>
<td>21 (23.1%)</td>
<td>0.52</td>
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<tr>
<td>IOP &gt; 14 mmHg or not reduced by 20% below baseline IOP</td>
<td>13 (18.8%)</td>
<td>22 (24.2%)</td>
<td>0.42</td>
</tr>
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</table>

*Patients with persistent hypotony (IOP <5mm Hg) are classified as failures. Inadequate IOP control criteria must be present on 2 consecutive follow-up visits after 3 months to qualify as failure.*
Limbus-based conjunctival flaps

If there is no difference in IOP-based outcomes, why should you change what you’re already doing?
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The Ocular Surface
Limbal Stem-Cell Deficiency
Fornix-based Conjunctival Flaps

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**Disadvantages**

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  - *Destroys many clock hours of limbal stem cells*
**Limbal-based Conjunctival Flaps**

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- Better exposure posteriorly
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- More comfortable
- Quicker to fit contact lenses
- *Spares limbal stem cells*

**Disadvantages**
- Requires conjunctival clamp ± really good assistant
- Anterior dissection can be challenging when scarring present
- Places area of active wound healing next to bleb
Limbus-based surgery examples
When to consider limbus-based flaps

- Prior MMC trabeculectomy with chronic punctate staining in front of bleb
  - Clinical sign of limbal stem cell deficiency
  - A fornix-based flap *will make this worse*

- Aniridia
  - Stem cell failure is the underlying cause of aniridic keratopathy, vascularization, keratinization
Aniridia
Aniridia
When to consider limbus-based flaps

- Everyone?
  - I use limbal-based conjunctival incisions for most of my GDDs, but I make my final decision on incision location under the microscope based on:
    - Exposure
    - Extent of scarring from prior surgery
      - Injecting saline under the conjunctiva can help demarcate areas of fibrosis
Recommendations

• Examine the ocular surface prior to surgery
  – Look for signs and symptoms of limbal stem cell failure
  – Fornix-based surgery *will* make these patients worse

• Try the limbus-based technique
  – Start with patients with good exposure
Recommendations

• Glaucoma surgeons implanting GDDs should become comfortable with both approaches.

• A limbus-based (limbus-sparing) approach is the preferred technique in patients with aniridia and probably delays the onset of aniridic keratopathy.
Postoperative Care

- Subconjunctival antibiotics & corticosteroid
- Topical steroid q1-2 hrs for first few days, then qid
- Topical antibiotic qid x 7 - 10 days
- Topical steroids continued for at least two months
- Monitor for IOP rise (usually occurs 4 - 6 weeks after tube opens)
  - treat with aggressive aqueous suppression
Comparative Studies

- Many case series in literature
  - Limited by retrospective design, selection bias

- Two major prospective randomized trials
  - Tube versus Trabeculectomy (TVT) Study
  - Primary TVT Study (1 year results announced just 3 weeks ago)
The Tube versus Trabeculectomy Study (TVT)
Tube vs Trabeculectomy Study (TVT)

**Purpose**
- To compare the safety and efficacy of non-valved tube shunt surgery to trabeculectomy with MMC in patients with previous ocular surgery

**Design**
- Prospective, randomized, multi-center clinical trial

**Participants**
- 212 patients at 17 clinical centers

Gedde SJ, Schiffman JC, Feuer WJ et al. for the TVT Study Group (2005)
The Tube versus Trabeculectomy Study: Design and Baseline Characteristics of Study Patients
American Journal of Ophthalmology 140:275-287
Inclusion Criteria

• Age 18 - 85 years
• IOP > 18 mm Hg and < 40 mm Hg on tolerated medical therapy
• Previous cataract extraction with IOL implantation, trabeculectomy, or both

Exclusion Criteria

- Unable or unwilling to give consent
- Pregnant or nursing women
- No light perception vision
- Several secondary glaucomas (neovascular, uveitic, ICE syndrome, fibrous or epithelial downgrowth)
- Unwilling to discontinue contact lens use
- Severe posterior blepharitis
- Aphakia
- Vitreous in anterior chamber
- Prior cyclodestruction, scleral buckling procedure, silicone oil
- Conjunctival scarring
- Need for glaucoma surgery combined with other ocular procedures, or anticipated need for additional ocular surgery

TVT@5: Patient Retention

Treatment Outcomes in the Tube versus Trabeculectomy (TVT) Study after five years of follow-up.
Gedde SJ, Schiffman JC, Feuer WJ et al, for the TVT Study Group (2012)
Treatment Outcomes in the Tube versus Trabeculectomy (TVT) Study after five years of follow-up
TVT@5: Failure Probability

IOP > 21 mm Hg

$P = 0.02$

TVT@5: Failure Probabilities

Gedde SJ, Schiffman JC, Feuer WJ et al, for the TVT Study Group (2012)
Treatment Outcomes in the Tube versus Trabeculectomy (TVT) Study after five years of follow-up
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<th>Trabeculectomy Group (n = 105)</th>
<th>P-value</th>
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<tbody>
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<td>Baseline</td>
<td>212</td>
<td>3.2 ± 1.1</td>
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<td>0.17</td>
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<td>1 year</td>
<td>190</td>
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<td>167</td>
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**TVT@5: Medication Use**

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<tr>
<td>3 years</td>
<td>158</td>
<td>1.3 ± 1.3</td>
<td>1.0 ± 1.5</td>
<td>0.30</td>
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<tr>
<td>5 years</td>
<td>124</td>
<td>1.4 ± 1.3</td>
<td>1.2 ± 1.5</td>
<td>0.23</td>
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• After 5 years, tube surgery was more likely than trabeculectomy to:
  – maintain IOP control
  – avoid persistent hypotony
  – reoperation for glaucoma
  – loss of light perception vision

• Both procedures had similar IOP reduction and use of supplemental medical therapy at 5 years
TVT@5: Conclusions

- No difference in the rate of vision loss following either surgery
- Complications:
  - Early postoperative complications occurred more frequently after trabeculectomy than tube surgery
  - Late postoperative complications and serious complications resulting in vision loss and/or reoperation were similar for both surgical procedures
Conclusions & Recommendations

• Glaucoma drainage devices are an important and proven option for surgical glaucoma management

• The implantation of glaucoma drainage devices requires new surgical skills but these can be learned by most ophthalmic surgeons

• IOP control appears to be similar between trabeculectomy and glaucoma drainage devices
Conclusions & Recommendations

- Trabeculectomy and GDDss each have their own profile of short-term and long-term complications.
- Repeating trabeculectomy over and over again achieves limited returns with increasing complications.
- GDDs may have significant advantages as primary surgery where follow-up is difficult.
Can tubes be used for primary surgery?

I recommend GDDs as primary surgery in several settings:

- When follow-up is anticipated to be poor (long distances, limited social support & transportation)
- Contact lens dependent, frequent water sports
- When IOP-lowering is urgent and further ocular surgery (e.g., PPV, Cataract) is anticipated soon
What do the TVT results mean in my practice?

- Provides the first prospective & randomized comparative evidence demonstrating the utility of glaucoma drainage implants in these settings
  - The TVT results are extremely useful in explaining the pros and cons of the two approaches to patients confronted with this choice
What do the TVT results mean in my practice?

- Significantly lowered my threshold for recommending glaucoma drainage implants in a variety of settings
What do the TVT results mean in my practice?

- Has moved GDDs to the first position for patients in whom follow-up is expected to be poor (long distances, limited transportation)
- Established the scientific and ethical basis for a Primary TVT Study, which is ongoing & reported on its 1 year results just 3 weeks ago at the AAO