Clear Corneal Trabeculotomy
ASCRS Annual Meeting
April 28, 2014

David Y. Badawi, M.D.
Private Practice, Central Eye Care, LTD.
Chicago, Illinois

Steven R. Sarkisian, M.D.
Glaucoma Fellowship Director
Dean McGee Eye Institute
Clinical Associate Professor
University of Oklahoma

Disclosures: David Badawi, M.D.
• Investment interest in Sight Sciences, Inc.

Disclosures: Steven Sarkisian, M.D.
• Investment interest in Sight Sciences, Inc.

Glaucoma from 20,000 Feet Up
• Leading cause of irreversible global blindness
• 2002: 37 million individuals worldwide
• 2020: Estimated 80 million worldwide
• 2.2 million Americans with the disease
• 120,000 blind from the disease in U.S.
Audience Questions

- Currently, glaucoma is primarily a pharmaceutically-treated disease
- Should it be a surgically-treated disease?
- What if there were better surgical options?
- Would you add glaucoma surgery to your practice?

Glucoma in the Office

- You do not have to be a glaucoma specialist to be seeing a lot of these patients
- Recurrent visits and diagnostic testing
- Our personal experiences with glaucoma
  - Problems with therapy
  - Progression of disease even in seemingly controlled patients

Treatment Options for the Ophthalmologist

- Medical>Laser>Surgery
- Unfortunately, “standard” glaucoma surgery can have a lot of intraoperative and postoperative issues—both short and long term
- Compare this to the evolution of cataract surgery

Different Ways of Viewing Surgery

- Incisional vs Non-incisional
- Implant vs Non-implant
- Bleb vs Bleb-less
- Ab-externo (scleral) vs Ab-interno (corneal)
**Ab Externo**
- Trabeculectomy with MMC in various forms
- Valves
- Cryo
- Cycloidiode
- Trabeculotomy
- More recently, canaloplasty

**Ab Interno**
- **Implant Based Devices**
  - Various stents (trabeculocanalicular, suprachoroidal, and subconjunctival)
- **Non-Implant Based Powered Instruments**
  - Endo Optiks Endocyclophotocoagulation (ECP)
  - NeoMedix Trabectome™
  - iTrack™ Illuminated Microcatheter (GATT)
- **Non-Implant Based Manual Instruments**
  - Manual Goniotomy Knife
  - Sight Sciences Manual Trabeculotome (TRAB™360)

---

**Why talk about clear corneal ab integro glaucoma surgery?**
- No bleb and all of the potential problems
- You can still come back and place filter/bleb later if needed
- Can utilize familiar clear corneal techniques
- Can more efficiently piggy back cataract surgery
- Avoid issues of localizing Schlemm’s canal

---

**Trabeculotomy is not Trabeculectomy**
- Trabeculotomy is the focus of this course
- Definition
- Purpose: To reduce the resistance to aqueous outflow by cutting the trabecular meshwork and inner wall of Schlemm’s canal
- We all know about this for congenital glaucoma, but there are historical data showing that it works in adults as well
- Has been around since 1930’s
Why talk about trabeculotomy?

- Adult data shows the surgery works.
- Sustained effect
- Grant and Rosenquist’s seminal research show the potential for IOP lowering.
- Same literature theorizes why small bypasses whether by stent or laser may not work as well.
- Instruments exist to perform trabeculotomy.

Ab externo Trabeculotomy

- Manual trabeculotome allows access to approximately 120 degrees of canal
- Invasive but well established procedure
- Harms manual trabeculotome

Harms Manual Trabeculotome

Ab externo Trabeculotomy (contd)

- Alternatively, a circumferential technique can be employed.
- Again, a scleral flap cut down is performed and Schlemm’s canal is identified
- A suture or a canaloplasty catheter is then threaded around the canal
- A purse string tension technique is used to disrupt the meshwork
360 Trabeculotomy Ab Externo Using the iTrack™ Microcatheter

Concerns with Ab externo techniques
- Non conjunctival sparing
- Issues finding Schlemm’s canal
- Issues entering AC
- What happens if you cannot circumnavigate the entire canal?

Ab externo Trabeculotomy
- In primary congenital glaucoma, results for manual trabeculotome procedures are similar to the circumferential tensioning procedures - although both are superior to goniotomy
- But, that’s not why we are here. We want adult data.

Trabeculotomy in Adults
Chin Paper, J. Glaucoma 2012
Purpose: To investigate the effects of a modified 360-degree suture trabeculotomy technique for primary and secondary open angle glaucoma (POAG and SOAG).
Various Techniques of \textit{Ab externo} Circumferential Trabeculotomy

From: Chin, J. Glaucoma: Volume 21, Number 6, August 2012

Study Overview (Chin 2012)

- 57 eyes with POAG or SOAG underwent 360 trabeculotomy
- 75\% success of 360...thus 43 eyes
- This all or nothing approach is potentially problematic
- 35 eyes underwent manual ab externo trabeculotomy

Patient Population (Chin 2012)

<table>
<thead>
<tr>
<th></th>
<th>360 Suture Technique</th>
<th>Manual Trabeculotome</th>
</tr>
</thead>
<tbody>
<tr>
<td>POAG</td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>SOAG</td>
<td>18</td>
<td>19</td>
</tr>
</tbody>
</table>

Technique (Chin 2012)
Technique (Chin 2012)

Results (Chin 2012)

<table>
<thead>
<tr>
<th>Month</th>
<th>Eyes</th>
<th>IOP</th>
<th>Meds</th>
<th>Eyes</th>
<th>IOP</th>
<th>Meds</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>43</td>
<td>13.1</td>
<td>.3</td>
<td>35</td>
<td>15.5</td>
<td>.9</td>
</tr>
<tr>
<td>3</td>
<td>43</td>
<td>12.9</td>
<td>.2</td>
<td>35</td>
<td>17.3</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>43</td>
<td>13.2</td>
<td>.3</td>
<td>35</td>
<td>16.7</td>
<td>1.3</td>
</tr>
<tr>
<td>12</td>
<td>43</td>
<td>13.1</td>
<td>.5</td>
<td>35</td>
<td>15.2</td>
<td>1.4</td>
</tr>
<tr>
<td>18</td>
<td>40</td>
<td>12.9</td>
<td>.5</td>
<td>30</td>
<td>14.9</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Ab interno Trabeculotomy

- What drives this?
  - Clear corneal approach and familiarity
  - Potential to piggy-back cataract surgery
  - Conjunctival sparing
  - Efficiency
  - Minimized invasiveness, desire to minimize trauma
  - Grant and Rosenquist data

Trabeculotomy Instruments

- Non-Implant Based Powered Instruments
  - NeoMedix Trabecone™
  - iScience iTrack™ Illuminated microcatheter (GATT)
- Non-Implant Based Manual Instruments
  - B&L Storz Goniotomy Knife
  - Sight Sciences Manual Trabeculotome (TRAB™360)
Trabectome™

- Briefly, electro-cautery or ablation of meshwork
- 90-120 degrees
- Can piggyback cataract surgery
- Requires power unit

Methods (Grover 2014)

- 85 eyes of 85 patients underwent the GATT procedure and were followed for at least 6 months
- Outcome measures: IOP, medications, visual acuity, complications

Gonioscopy-Assisted Transluminal Trabeculotomy (GATT)

- Technique Report and Preliminary Results

GATT Procedure

(Source: Grover. Ophthalmology 2014)
POAG Results (Grover 2014)

- Mean decrease of:
  - 7.7 mm Hg at 6 months
  - 11.1 mm Hg at 12 months
  - 30% IOP lowering at 6 months
  - 39.8% at 12 months
  - 1 less medication
- GATT → GATT+CE → GATT post pseudophakia

Past GATT Results

Clinical Safety and Efficacy of 360-Degree Gonioscopy Assisted Transluminal Trabeculotomy (GATT) for the Treatment of Glaucoma: Interim Outcomes of Primary Glaucomas

DAVID G. GODFREY, Davinder S. Grover, Oluwatosin U. Smith, Ronald L. Fellman.

- 79 eyes with POAG, PXF, Uveitic, pigmentary, and other OAGs
- Pre-Op Mean IOP = 26 mm Hg on 2.9 meds
- At 6 months post-op, mean IOP = 13.7 on 0.7 meds
- Reported transient post-op hyphema 33% of the time

Goniotomy - Manual Ab interno Trabeculotomy

- Decades old ab interno procedure to cut trabecular meshwork using a manual trabeculotome
- Limited to 60-120 degrees of meshwork access
- Difficult to assess cutting given trabeculotome design
- Source: Duane’s Ophthalmology

Sight Sciences TRAB™360: Manual Trabeculotome

- Manual trabeculotomy instrument
- Non-powered cutting instrument
- Single use, disposable
- No capital equipment
TRAB™360

- TRAB™360 is a manual surgical instrument used to mechanically cut trabecular meshwork
- The instrument is NOT indicated for the treatment of glaucoma and it is not a “MIGS” device

Ab interno Trabeculotomy using the Sight Sciences Manual Instrument

Who have we performed Ab interno trabeculotomies on?

- Adults with
  - POAG
  - Pseudoexfoliation
  - Pigmentary glaucoma
Who is contraindicated for *ab interno* trabeculotomy?

- Angle closure
- Angle disruption
- Poor view of angle
- Question of pressure drop required

Informed consent

- Indications
- Risks
- Alternatives
- Benefits

Pre-Op Concerns

- View of Angle
- Angle Anatomy
- Cooperative patient
- Anesthesia

Gonioscopic Considerations

- Need a direct and non-inverted view
- Prism
- Double Mirror
Gonioprism Examples

- Swan Jacob
- Ritch

Considerations with Gonioprisms

- Head tilt
- Scope Tilt
- Field of View
- Magnification

Double Mirror Gonioscopes

- Mori (Ocular Instruments)
- Double Mirror

Performing a Manual *Ab interno* Trabeculotomy
Performing a Manual Ab interno Trabeculotomy
Performing a Manual Ab interno Trabeculotomy

Performing a Manual Ab interno Trabeculotomy
Performing a Manual *Ab interno* Trabeculotomy
Performing a Manual *Ab interno* Trabeculotomy

Video 1: Mori Lens

Video 2: Swan Jacob
Example Post Op Med Regimen

- Pred-Forte 1% QID for 1 month
- Acular 0.4% QID for 1 month
- Polytrim QID for 1 week
- Pilocarpine 1-4% QID for 1 month

Histology - Normal Canal

Histology – After Trabeculotomy

Results Overview with Ab interno Trabeculotomy

- Chin results (Ab externo, manual)
- Trabectome (Ab Interno, powered)
- GATT with iTrack™ (Ab interno, illuminated canaloplasty catheter)
- Our experience with TRAB™360 Manual Trabeculotome
Results Overview-continued

- Pre-Op Dx’s
- Procedures Performed
- Types of cases
- Post-op findings
  - Slit lamp
  - Gonioscopy

Summary of Manual Ab interno Trabeculotomy

- Manual, mechanical cutting of meshwork
- Up to 360 degrees of ab interno meshwork cutting using a single corneal incision
- Not ‘all or none’ 360 degrees required
- Conjunctival Sparing
- No capital equipment

Questions

Thank you.