GLAUCOMA SURGERY: NEW SURGICAL TECHNIQUES

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Financial Disclosure
Ronald L. Gross, MD

I have the following financial interests or relationships to disclose:

- Alcon
- Allergan
- Merck
- Alacrity Biosciences
- Mati Therapeutics

BACKGROUND

- Equipment System & Single Use pack
  - Trabectome System / I/A & Electrosurgery - easily integrated into Phaco unit
  - Special Goniolens
  - Procedure Packs

ANGLE ANATOMY

Trabectome®
Minimally Invasive Surgical management of Glaucoma
ANGLE ANATOMY

Scleral spur

Schwalbe’s line

SCHLEMM’S CHANNEL ~ 350-500µM WIDTH

- Primary resistance to outflow: juxtacanalicular connective tissues & inner wall of Schlemm’s
- ~8 collector channels (aqueous veins) drain directly into episcleral venous plexus, most inferior nasally (Ascher 1942)
- Per Elke Luetjen-Drecoll: The collector channels & aqueous veins have a rich innervation and smooth muscle in their walls as do both surrounding arteries and veins

SCHLEMM’S CHANNEL AND OUTFLOW PATHWAYS

BLOOD REFLUX IN SCHLEMM’S CHANNEL

TRABECTOME SURGICAL SYSTEM

HANDPIECE TIP INSIDE EYE

Image courtesy of Jocson

Image courtesy of Masahiro Maeda, MD

Image courtesy of Atsushi Matsuo, M.D.
**POSITION AND SETUP**

- Similar to Phaco Patient Set-up
- 30° Microscope tilt toward surgeon
- Near axial microscope ocular alignment
- Rotate patient’s head away as needed to maximize gonioscopic view
- Don’t tape patient’s head

**SURGICAL STEPS**

1. 1.7mm Clear Cornea incision
2. Viscoelastic (Occucoat®)
3. Verify Goniolens view
4. Insert Trabectome tip
5. 60°-120° of ablation
6. irrigation, aspiration

**SECTION VIEW**

**SURGICAL VIEW GLOBAL**

**VISCOELASTIC**

- Viscoelastic (Occucoat®):
  - Optional for deepening of the anterior chamber
  - Occucoat® included in the surgical pack
  - Absorbable
  - Easy to remove from anterior chamber
  - Minimizes risk of post-op IOP spikes

**HANDPIECE**

- Surgeon removes cap on the hand piece
- Insert hand piece (parallel to wound) with care to keep the tip directed away from endothelium or iris
- Reacquire gonioscopic view
- Advance the hand piece to the nasal angle
  - Gentle compression of meshwork
  - Rotation toward tip will penetrate compression fold to enter Schlemm’s Channel
  - Continuous irrigation maintains the AC depth (adjust bottle height & magnification to preferences)
ENTERING MESHWORK

• Visual contact with meshwork
• Minimal pressure & gentle compression of meshwork
• Enter Tip into meshwork & Schlemm’s through the wrinkle
• Pull Tip back slightly
• Slow rotation & power adjustment [ 0.8 - 1.1 ] Watts
• Allows ablation without tissue accumulating in the tip

Footplate feeds tissue into ablation gap as tip is rotated

FINAL STEPS

• Irrigate and Aspirate - Simcoe
  • Remove viscoelastic
  • Blood Reflux
• Single 10-0 suture through the incision & re-pressurize globe.
  • Minimize infection risk

TRABECTOME AND CATARACT EXTRACTION

• Easily combined with phacoemulsification
• Appropriate for controlled or uncontrolled glaucoma
• Lowers IOP and reduces glaucoma medications
• Maintains/Re-establishes physiologic aqueous outflow
• Adults with open angle and clear gonioscopic view
• IOP goal range expectation 14 – 17 mmHg
• Safer; simpler follow-up; low complication rates compared to trabeculectomy
• Does not preclude subsequent surgery (spares conjunctiva)

STUDY DESIGN

• Prospective, non-randomized, comparative trial
• Consecutive patients, 1 surgeon
• 2 Groups:
  – Trabectome + PCE (N=89)
  – Trabeculectomy + PCE (N=23)
Experience with Trabectome in Adult Open Angle Glaucoma Patients followed for at Least One Year

Sameh Mosaed, Douglas J. Rhee, Theodoros Filippopoulous, Helen Tseng, Sunil Deokule, and Robert N Weinreb

Clinical & Surgical Ophthalmology 28:8, 2010
TRABECTOME ONLY VS TRABECTOME+PCE SURVIVAL CURVE

<table>
<thead>
<tr>
<th>Survival Time (months)</th>
<th>Trabectome alone</th>
<th>Trabectome+PCE</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>64.9%</td>
<td>86.9%</td>
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<tr>
<td>1</td>
<td>59.8%</td>
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</tr>
<tr>
<td>2</td>
<td>54.7%</td>
<td>79.0%</td>
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<tr>
<td>3</td>
<td>50.5%</td>
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<tr>
<td>4</td>
<td>46.4%</td>
<td>70.3%</td>
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<tr>
<td>5</td>
<td>42.3%</td>
<td>66.0%</td>
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<tr>
<td>6</td>
<td>38.1%</td>
<td>61.7%</td>
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<tr>
<td>7</td>
<td>34.0%</td>
<td>57.4%</td>
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<td>8</td>
<td>30.0%</td>
<td>53.1%</td>
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<tr>
<td>9</td>
<td>26.1%</td>
<td>48.8%</td>
</tr>
<tr>
<td>10</td>
<td>22.0%</td>
<td>44.5%</td>
</tr>
</tbody>
</table>

Success definition: No additional glaucoma surgery and IOP reduction ≥20% from pre-op and IOP <21 mmHg last 2 follow ups, after 3 months post-op

GLAUCOMA OVERVIEW

- Glaucoma is one of the leading causes of blindness and is prevalent in the aging US population.
- Characterized by optic nerve damage and associated visual field loss.
- Primary open-angle glaucoma (POAG) is the most common form of glaucoma.
- Elevated IOP (ocular hypertension) is caused by resistance to aqueous humor outflow in the trabecular meshwork.
- Elevated IOP is the primary risk factor for glaucoma.
- Glaucoma therapy must control both the level and fluctuation of IOP for improved outcomes.
- Surgical intervention in early stage patients may be beneficial in reducing the risk for vision loss due to glaucoma.

CURRENT POAG TREATMENT

Newly Diagnosed POAG Patient

- Prescription Therapy (30 – 90 Days)
- Switch or Add Rx Therapy
- Laser Trabeculoplasty
- Invasive Surgery Trabeculectomy

Drug therapy has been the standard of care in glaucoma for over 30 years. Up to 80% of patients are taking 2 medications increasing the disease management challenges of glaucoma and financial burden to patients and the healthcare system.

AAO Preferred Practice Pattern; Primary Open Angle Glaucoma. AAO committee 2003.


CHANGING POAG TREATMENT

Early Stage POAG Patient

- Prescription Therapy 1 or More Meds
- Combined Cataract POAG Patient

Opportunity to Reduce IOP and Medication Use

- Minimally Invasive Combination Procedure
- Reduce IOP and Medication Use to Sustain Target Pressure

For patients undergoing cataract surgery, minimally invasive combination procedures that lower IOP and reduce medication dependence are practical and sustainable treatments for early disease management.

GLAUCOMA AND CATARACT

Global Incidence of Glaucoma

- Glaucoma will affect more than 60.5 million people by 2030 and nearly 80 million people by 2020.

US Incidence Glaucoma

- An estimated 3 to 6 million people have glaucoma or ocular hypertension.
- Primary open-angle glaucoma (POAG) is the most common form of glaucoma and the 2nd leading cause of blindness.

Combination Cataract and Glaucoma

- Of the 3.3 million annual cataract procedures performed in the US, 20.5% of patients have comorbid glaucoma and/or OHT.
- >650,000 of comorbid cases

AAO Preferred Practice Pattern; Primary Open Angle Glaucoma. AAO committee 2003.

ISTENT® TRABECULAR MICRO-BYPASS

The only currently FDA approved device for the treatment of mild-to-moderate open-angle glaucoma

- Falls into the “MIGS” category
- Improves aqueous outflow through the natural physiologic pathway
- Reduces IOP
- Inserted ab interno through the phaco incision
- Can be performed under topical anesthesia
- Overall safety profile similar to cataract surgery alone
- Spares conjunctival tissue
- Preserves potential for future treatment options

ISTENT® SPECIFICATIONS

iStent is the smallest medical device known to be implanted in the human body and weighs just 60 µg

- iStent dimensions are customized for a natural fit within the 270 µm canal space
- Made of surgical-grade nonferromagnetic titanium
- Heparin-coated to promote self-priming

ISTENT® SYSTEM

iStent is designed for instinctive control

One iStent system is comprised of a preloaded stent in a single-use, sterile inserter with a secure rotatable grip

The inserter has reacquisition capability to facilitate manipulation and placement into Schlemm’s canal

Customized iStent configurations

Two configurations of the iStent are available, one for the right eye (OD) and one for the left eye (OS)

The iStent is inserted ab interno through the phaco incision and can be performed under topical anesthesia

Primary Source of Resistance: Diseased Trabecular Meshwork

- Abnormality of the trabecular meshwork (TM) is the primary source of elevated intraocular pressure (IOP) in open-angle glaucoma
- 50-75% of total resistance to aqueous humor outflow is found in the juxtacanalicular tissue of the TM
- Bypassing the TM allows access to Schlemm’s canal and the distal system in order to improve aqueous outflow through the conventional outflow pathways

ISTENT® MAXIMIZES OUTFLOW THROUGH A SINGLE BYPASS

iStent improves aqueous outflow by creating a patent bypass between the anterior chamber and Schlemm’s canal

ISTENT® PIVOTAL US IDE TRIAL

Prospective, randomized, multi-centered study of POAG patients who underwent iStent + cataract surgery vs. cataract surgery (CE) alone

290 subjects at 29 sites

- 240 randomized subjects with cataract and mild-to-moderate OAG (1:1 randomization)
- 50 additional non-randomized subjects for safety

Patient population

- Mild-to-moderate POAG (also PXE and PDS)
- IOP ≥ 24 mm Hg on 1-3 medications
- Post-medication washout IOP 22 – 36 mm Hg

Efficacy endpoints

- Primary: IOP ≤ 21 mm Hg without medications at month 12
- Secondary: IOP reduction ≥ 20% without medications at month 12

Follow-up through 2 years postoperative
**ISTENT® PIVOTAL US IDE TRIAL - IOP AND MEDICATION REDUCTION**

At 12 months:
- >30% reduction from baseline IOP
- similar outcome validated adherence to the study design (manimize to threshold IOP)
- For iStent subjects, IOP reduction with significantly less (P=0.001) medication:
  - 15% of iStent vs. 35% cataract group on medication

**FREQUENTLY REPORTED ADVERSE EVENTS**

<table>
<thead>
<tr>
<th>Event/_page</th>
<th>iStent® + cataract surgery N=116 n(%)</th>
<th>Cataract surgery only N=117 n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early postoperative corneal edema</td>
<td>9 (8%)</td>
<td>11 (9%)</td>
</tr>
<tr>
<td>Any BCVA loss of at least one line at or after the 3 month visit</td>
<td>8 (7%)</td>
<td>12 (10%)</td>
</tr>
<tr>
<td>Posterior capsular opacification</td>
<td>7 (6%)</td>
<td>12 (10%)</td>
</tr>
<tr>
<td>Stent obstruction</td>
<td>5 (4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Blurry vision or visual disturbance</td>
<td>4 (3%)</td>
<td>8 (7%)</td>
</tr>
<tr>
<td>Elevated IOP</td>
<td>4 (3%)</td>
<td>5 (4%)</td>
</tr>
</tbody>
</table>

Comparable overall safety profile

**PATIENT HEAD & MICROSCOPE**

- Patient head is turned away from you ≥ 35°
- Microscope head is tilted toward you ≥ 35°

**ISTENT® INJECTOR SYSTEM**

The iStent injector is a sterile, single-use system, pre-loaded with one iStent designed to deliver into Schlemm’s canal through the trabecular meshwork

- Disposable
- Re-acquisition capability
- Sterile, Pre-loaded w/iStent®
The iStent® is inserted ab interno through the clear, cornea phaco-incision and can be performed under topical anesthesia.

- The physiological preservation of the trabecular meshwork ensures a natural episcleral back pressure of 8 to 11 mm Hg, ensuring minimal to no risk for hypotony.

ISTENT® SURGICAL PROCEDURE

Cumulative human experience
- Over 4000 subjects have been implanted to date
- Clinical experience in US and OUS studies demonstrate IOP and medication reduction with an overall favorable safety profile

CLINICAL EXPERIENCE
ISTENT

Handling Reminders:
- Do not open the iStent box until cataract surgery is successfully completed AND the Dr. has checked the anterior chamber angle for good visualization.
- After opening the box check to confirm the stent is on the tip of the insertion device.
- Peel back and hold open for scrub to take out by the pinch slots - never drop onto tray – treat the iStent inserter like a diamond blade.
- Squeezing the pinch slots releases tension on the insertion device.

Tray reminders:
- Gonioprism
- Miotic (Miocel/miostat)
- Extra cohesive viscoelastic
- Micro-forceps

SOLX

CANALOPLASTY

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