SURGICAL INNOVATIONS IN GLAUCOMA

Is this the end of the trabeculectomy?

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El Paso Eye Surgeons, P.A.
New Mexico Academy of Ophthalmology September 15, 2018

CURRENT GOLD STANDARD

MAXIMIZING OUTFLOW WITH MIGS

A new approach to managing mild to moderate OAG
AREAS OF AQUEOUS OUTFLOW

- MIGS devices can be used to restore outflow through the natural, physiological outflow pathway, the suprachoroidal space, or the subconjunctival space.
- SAFETY (Benefit to Risk Ratio) is the ultimate criterion in determining MIGS treatment algorithm.

THERAPEUTIC OPTIONS

**Conventional Outflow**
- Trabecular bypass
  - Glaucoma
  - Glaucoma Intraocular Pressure
  - Ahmut
- Trabecular ablative
  - YAG Laser
  - Transcornea
  - Endoablate
  - Trabectome
  - Goniotome
- Restorative
  - ABIC
  - Visco360

**Suprachoroidal**
- Suprachoroidal
  - Giant Supra (Phase III)
  - STAR

**Other**
- Cycloablative
  - YAG Laser
  - ECSP
- Filters (LIGS)
  - Xen Gel Implant
  - InnFocus (Phase II)

CATARACT & GLAUCOMA:

**EARLY-MID 1990'S**

- Early
  - Easily Controlled
- Moderate
  - Poorly Controlled
- Severe
  - Easily Controlled

**LATE 1990'S**

- Early
  - Easily Controlled
- Moderate
  - Poorly Controlled
- Severe
  - Easily Controlled
CATARACT & GLAUCOMA:
2000's–PRESENT (FOR MOST PEOPLE)

- Early
- Moderate
- Severe

Easily Controlled
Poorly Controlled

CE Alone
CE + MIGS

CATARACT & GLAUCOMA:
2000's–PRESENT (MY APPROACH)

- Early
- Moderate
- Severe

Easily Controlled
Poorly Controlled

CE Alone
CE + MIGS

MIGS AND THE “ENTIRE SYSTEM”
Ab-interno canaloplasty (ABiC)
Visco360

AB-INTERNO CANALOPLASTY (ABiC)
( iTracker™ 29GA CANALOPLASTY CATHETER)
AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)

IMMEDIATE PRE-OP
IMMEDIATE POST-OP

Mean IOP (mm Hg)

12.87 mm Hg
12.57 mm Hg
13.45 mm Hg
13.33 mm Hg

Controlled OAG: Mean Medications (n)
P<0.001
### Controlled OAG: Mean Medications (n)

- **Baseline:** 2.50
- **3 Months:** 0.44
- **6 Months:** 0.72
- **12 Months:** 0.56

76% reduction

### Uncontrolled OAG: Mean IOP (mm Hg)

- **Baseline:** 22.23 mm Hg
- **3 Months:** 14.97 mm Hg
- **6 Months:** 15.17 mm Hg
- **12 Months:** 14.8 mm Hg

31% Reduction
AB-INTERNO CANALOPLASTY (ABiC)
(iTRACK™ 250A CANALOPLASTY CATHETER)

Uncontrolled OAG: Mean Medications (n)

<table>
<thead>
<tr>
<th>Time</th>
<th>Medications (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.46</td>
</tr>
<tr>
<td>3 Months</td>
<td>0.53</td>
</tr>
<tr>
<td>6 Months</td>
<td>0.92</td>
</tr>
<tr>
<td>12 Months</td>
<td>1.0</td>
</tr>
</tbody>
</table>

~40% Reduction

P=0.00008

WHAT TO EXPECT

POST-OPERATIVE COURSE

POST-OPERATIVE DAY ONE

COMBINED PHACO/ABiC

STAND-ALONE ABiC

Post-Operative Care Same as Phacoemulsification
Quick Steroid Taper

POST-OPERATIVE MONTH ONE
WHO IS A CANDIDATE FOR ABIC

MOST OAG PATIENTS...BUT NOT ALL

- Uncontrolled OAG (Mild to Moderate*)
- Controlled OAG undergoing cataract surgery
- Target IOP Mid to Low Teens
- Young Patient
- High Risk with Filters
- High Myopia
- Previous failed filtration surgery
- Contact Lens Dependency
- Difficult Follow-Up
- Monocular Patients
- Difficult Patient (squeezers)
- Phakic or Pseudophakic

AB-INTERNO CANALOPLATY (ABIC)

(iTRACK™ 250A CANALOPLASTY CATHETER)

WHAT ELSE EXISTS

THE OTHER MIGS PROCEDURES
VISCO360 (ANOTHER CANALOPLASTY DEVICE)

MIGS AND THE TRABECULAR MESHWORK

TRABECULAR BY-PASS

@Stent
@Stentject
@Myrisol
TRABECULAR MICRO-BYPASS (iSTENT®)

- Smallest medical device implanted into the human body
- 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

TRABECULAR MICRO-BYPASS (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, with minimal risk for hypotony1

Controlled Group: IOP and Medication Burden 3-Year Outcomes

<table>
<thead>
<tr>
<th>Year</th>
<th>IOP (mmHg)</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preop</td>
<td>13.7±2.3</td>
<td>2.4</td>
</tr>
<tr>
<td>Yr 1</td>
<td>12.4±2.5</td>
<td>0.9</td>
</tr>
<tr>
<td>Yr 2</td>
<td>12.8±2.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Yr 3</td>
<td>12.7±2.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>
Controlled Group: IOP and Medication Burden
3-Year Outcomes

Medication Usage

Uncontrolled Group: IOP and Medication Burden
3-Year Outcomes

Medication Usage
### VISUAL FIELD MEAN DEVIATION (dB)

![Graph showing VISUAL FIELD MEAN DEVIATION (dB)](image1)

### MEAN RETINAL NERVE FIBER LAYER (µM)

![Graph showing MEAN RETINAL NERVE FIBER LAYER (µM)](image2)

### TRABECULAR MICRO-BYPASS (iSTENT®)

**TRABECULAR MICRO-BYPASS (iSTENT®)**  
[TARGETED STENT IMPLANTATION—FINDING COLLECTOR CHANNELS]

![Images of trabecular micro-bypass (iSTENT®)](image3)

**Haiyan Gong, MD, PhD**

**TRABECULAR MICRO-BYPASS (iSTENT®)**  
[TARGETED STENT IMPLANTATION]
TRABECULAR MICRO-BYPASS (iSTENT®)
TARGETED STENT IMPLANTATION

TRABECULAR MICRO-BYPASS (iSTENT®)
POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx
- Topical NSAID
- Topical antibiotic
- Topical steroid****
- May see RBC in anterior chamber
- May see micro-hyphema
- Possible IOP spike

TRABECULAR MICRO-BYPASS (iSTENT®)
POST-OPERATIVE APPEARANCE
TRABECULAR MICRO-BYPASS (iSTENT®)

POST-OPERATIVE APPEARANCE (GONIOSCOPY)

CLINICAL INDICATIONS

- Mild to moderate OAG
- Concomitant cataract
- One or more topical medications

WHY NOT CONTINUE MEDS?

- Disruption of the preconal tear film
- Epitheliopathy
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells

TOPOCAL MEDICATIONS

(ARE THEY REALLY BENIGN?)

Potential Effects:

- Disruption of the preconal tear film
- Epitheliopathy
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells
### TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)

#### Adverse Effects

- Disruption of the preconal tear film
- Epitheliopathy
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells

#### References


TOPICAL MEDICATIONS
(ARE THEY REALLY BENIGN?)

- Periorbital fat drophs
- Meibomian gland dysfunction

TRABECULAR MICRO-BYPASS (iSTENT®)

WHY NOT CONTINUE MEDS?

RECENTLY RELEASED

iStent Inject®
Hydrus Microstent®

THE DATA
TRABECULAR MICRO-BYPASS (iSTENT INJECT®)

![Diagram of iStent Inject](image1.png)

iStent inject + Phaco Pivotal Study (Samuelson et al, 2018)

- **Change in Unmedicated IOP**
  - Preop: 20.6 ± 3.6
  - Month 6: 17.1 ± 3.4
  - 31% reduction from baseline

- **Unmedicated IOP ≤ 18 mmHg**
  - 42.2% with iStent inject + Phaco
  - 50.5% with Phaco alone

84% of iStent inject subjects medication-free at 23 months.

Medication reduction is subject to the discretion of the physician.

iStent inject + Phaco (Hengerer, 2018)

- **Reduced Intraocular Pressure Over Time**
  - 37% reduction in mean IOP
  - 100% of patients with IOP ≤ 18 mmHg

- **Reduced Medication Use Over Time**
  - 74% reduction in medications in 1 year compared to 27% in 6 weeks
  - 68% reduction in major medications
TRABECULAR MICRO-BYPASS

HYDRUS MICROSTENT (IVANTI)

TRABECULAR MICRO-BYPASS (Hydrus®)
(CURRENTLY IN PHASE III CLINICAL TRIALS)

TRABECULAR MICRO-BYPASS (Hydrus®)
(CURRENTLY IN PHASE III CLINICAL TRIALS)
TRABECULAR MICRO-BYPASS (Hydrus®)

THE DATA

POST-OPERATIVE MANAGEMENT

- Similar to stand-alone cataract sx
- Topical antibiotic
- Topical NSAID
- Topical steroid

TRABECULAR ABLATION, EXCISION, AND INCISION

Trabectome, Kahook Dual Blade, GATT Procedure and Trab360

MIGS AND THE TRABECULAR MESHWORK

TRABECULOTOMY

TRABECTOME—AB-INTERNO TRABECULLECTOMY
TRABECULOTOMY (TRABECTOME—AB-INTERNO TRABECULECTOMY)

Microscopic images of eye drainage tissue before and after Trabectome.

TRABECULOTOMY (TRABECTOME—AB-INTERNO TRABECULECTOMY)

Microscopic images of eye drainage tissue before and after Trabectome.

TRABECULOTOMY (TRABECTOME—AB-INTERNO TRABECULECTOMY)

Microscopic images of eye drainage tissue before and after Trabectome.

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Microscopic images of eye drainage tissue before and after Trabectome.
TRABECULOTOMY
(TRABECTOME—AB-INTERNO TRABECULECTOMY)

TRABECTOME
(THE DATA)

Francis et. al. JCRS 2008

POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx
• Topical NSAID
• Topical antibiotic
• Topical steroid****
• May see RBC in anterior chamber
• More prone to larger hyphemas
• Possible IOP spike
• Reports of recurrent hyphemas

WHO IS A CANDIDATE
BEST WITH SECONDARY OAG
PIGMENTARY GLAUCOMA
PSEUDOXEFOLIATIVE GLAUCOMA
UVERIC GLAUCOMA
GONIOTOMY
(KAHOOK DUAL BLADE)

GONIOTOMY WITH KDB
(POST-OPERATIVE MANAGEMENT)

Similar to stand-alone cataract sx
• Topical NSAID
• Topical antibiotic
• Topical steroid****
• May see RBC in anterior chamber
• More prone to larger hyphemas
• Possible IOP spike
• Risk of recurrent hyphemas

GONIOTOMY WITH KDB
(POST-OPERATIVE MANAGEMENT)

• Capsular hematoma may appear
• Yag capsulotomy may be needed
TRABECULAR INCISION
GONIOSCOPY ASSISTED TRANSLUMINAL TRABECULOTOMY (GATT) TRAB360

TRABECULOTOMY
GATT PROCEDURE

Davinder Grover, MD

THE DATA

POAG

- GATT only
  - Pre-Op: 25.6
  - Post-Op: 15.7
- GATT combined with CE
  - Pre-Op: 23.9
  - Post-op: 15.5
- GATT with prior CE
  - Pre-Op: 23.8
  - Post-Op: 16.2

Med Decrease of 1.1

Other Glaucoma

- GATT only
  - Pre-Op: 31.8
  - Post-Op: 12.4
- GATT combined with CE
  - Pre-Op: 27.6
  - Post-op: 13.8

Med Decrease 1.9
Similar to stand-alone cataract sx
- Topical NSAID
- Topical antibiotic
- Topical steroid****
- Pilocarpine or Cyclogel
- May see RBC in anterior chamber
- More prone to larger hyphemas
- Possible IOP spike
- Reports of recurrent hyphemas
- High risk for 8-ball hyphema
- Anti-coagulants contraindicated
MIGS OF THE SUPRACHOROIDAL SPACE

CyPass® Alcon Laboratories
iStent Supra® Glaukos

CYPASS® SUPRACILIARY SHUNT

CyPass® Micro-Stent Overview

- The supraciliary space has a negative pressure gradient that drives aqueous humor and results in intrascleral pressure.
- The preexisting pathway provides Schlemm’s canal and collector channels, which may be steeped in glaucoma patients.
- The CyPass Micro-Stent utilizes the same outflow pathway as the line prostaglandine analogues.

CYPASS® SUPRACILIARY SHUNT
CYPASS® SUPRACILIARY SHUNT
POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx
• Topical NSAID
• Topical antibiotic
• Topical steroid
• May need cycloplegia
• Possible IOP spike
• Risk for hypotony

BYPASSING THE NATURAL SYSTEMS
XEN 45 GEL IMPLANT

NOT A MIGS PROCEDURE
• Less invasive filter
• Bleb dependent procedure
• Same long-term pressure control as trab
• Quicker post-op vision recovery
• Less risk for hypotony
XEN 45 GEL IMPLANT
THE DATA

Mean IOP Over Time and Mean % Change in IOP

<table>
<thead>
<tr>
<th>Time</th>
<th>Preoperative</th>
<th>1 Day</th>
<th>1 Week</th>
<th>1 Month</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
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<tbody>
<tr>
<td>IOP</td>
<td>25</td>
<td>24</td>
<td>21</td>
<td>19</td>
<td>17</td>
<td>16</td>
<td>14</td>
</tr>
<tr>
<td>% Change</td>
<td>12%</td>
<td>15%</td>
<td>18%</td>
<td>20%</td>
<td>25%</td>
<td>30%</td>
<td>35%</td>
</tr>
</tbody>
</table>

LIKE ALL OTHER BLEB PROCEDURES
• Topical antibiotics
• Topical NSAID
• Topical steroid
• Frequent post-operative visits
• Bleb management
• 5-fluorouracil injections
• Ocular massage
• Needling revisions

FUTURE DIRECTIONS
• SITE SPECIFIC TARGETED TREATMENT
• INTRA-OPERATIVE CANALGRAM
• HIGH DEFINITION IMAGING OF THE CONVENTIONAL SYSTEM
• COMBINATION OF MIGS PROCEDURES
• COMMUNICATION AND COORDINATION BETWEEN PRIMARY EYE PROVIDER AND SURGEONS

THANK YOU FOR THE INVITATION

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