MIGS: Changing Paradigm for Glaucoma Management

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**MIGS**: Presentation Topics

- Glaucoma Prevalence and Patient Need
- MIGS Overview, Multiple Devices
- Clinical Data
- Preoperative Considerations
- Postoperative and Co-management

*MInvially Invasive Glaucoma Surgery*

**MIGS**: different target locations

- **Trabecular By-Pass**:
  - iStent (Orig) (Glaukos)
  - iStent Inject (2018)
  - Hydrus (Ivantis)
  - + others

- **Sub-Conjunctival By-Pass**
  - XenGel (Allergan)

**Glaucoma Can Be Devastating**

- Glaucoma is the second leading cause of blindness worldwide
- In the US, there are an estimated 3.7M cases of OAG, growing to more than 4M cases by 2020, with a significant number of patients going blind every year*

**Already Happened:**

- 500,000 New patients with Glaucoma

*Minimally Invasive Glaucoma Surgery

**Consultant:**
- Allergan, Reichert, Carl Zeiss Meditec, Topcon

**Advisory Boards/Speaker:**
- Aerie, Bausch+Lomb, Glaukos, Novartis

**Research Grants:**
- Topcon, Heidelberg, Equinox, Optos
## When to Consider Surgery

- The evolving place of surgery in the glaucoma treatment paradigm
- The role of primary and earlier glaucoma surgery
- Combination cataract & glaucoma surgery

## Challenges
- Long-term exposure to glaucoma medication can cause corneal surface damage
- Non-compliance to medication
- More than 90% of patients are non-adherent, and nearly 50% stop taking their medications before 6 months
- Limited duration of laser treatments
- Risks associated with invasive surgery
- Cost burden to patients & system

## Standard Treatment Options for Glaucoma

### Standard Treatment Options
- Glaucoma Medications
  - Multiple meds
- Laser Trabeculoplasty (SLT)
- Invasive Surgery (bleb forming)
  - Trabeculectomy / Shunt
  - Tube / Shunt Procedures
  - Baerveldt, Ahmed Valve

## What's Driving Shift to Earlier Surgical Intervention

- Desire to decrease risk of IOP fluctuations associated with poor medication compliance or non-adherence to prescribed regimens
- Desire to reduce medications
  - 41% report challenges paying for medications
  - 60% of medically treated glaucoma patients report OSD symptoms
- Quality of life burden

## MIGS Goal

- Intervene earlier in the disease and lower IOP to reduce progression through a procedure that is:
  - Minimally traumatic, tissue sparing
  - Safe and effective
  - Relatively rapid recovery
- Reduce the need for more aggressive surgical options while preserving that option
- Reduce medication burden
- Glaucoma is a chronic disease and may require numerous procedures over a lifetime

## The Opportunity

iStent inject® can help you effectively and comprehensively treat patients with cataracts and glaucoma

- 22.3% of patients with cataracts are also on at least one OHT
- iStent inject is clinically proven to significantly reduce IOP
- May reduce reliance of medications at the discretion of an eye care professional
- Safety profile similar to cataract surgery
MIGS: Changing Paradigm

Concomitant Cataract & Glaucoma Patients – US
Significant treatment opportunity with more than 1 in 5 eyes with cataracts on OHT medication

3.9M US Cataract Procedures
22.3% Cataract + Minimum of 1 OHT Med

Only 1 Opportunity: iStent inject must be performed w/ CE

Mild-to-Moderate Glaucoma Predominates

Mild
52%
Moderate
25%
Advanced
13%
Refractory
10%

Patients with Glaucoma

CASE JB
72 yo female
10+ Year History of OHTN/Early Glaucoma
IOP = 22 OD and 24 OS
Seen at another Chicago Academic Ophthalmology Clinic
Won’t use PGA medication (blue irides), also side effects with Combligan
Struggling to use Azopt TID OU
Cataracts with ~20/30-40 VA OD/OS and night time glare while driving.
Would like second opinion.

OPTIONS?
Change/Add Glaucoma Medications?
(Vyzulta, Rhopressa, Rocklatan)
SLT?
Cataract Surgery alone?
MIGS with Cataract Surgery?

MIGS Classification

- Trabecular Outflow
  - iStent and iStent inject
  - Hydrus microstent
  - Goniotomy (Trabectome, Kahook Dual Blade)
  - Gonioscopy-assisted transluminal trabeculotomy (GATT)
  - Ab interno canaloplasty (ABiC)
- Suprachoroidal Outflow
  - Cypass (recalled)
- Subconjunctival Outflow (“Micro trabeculectomy”)
  - XEN Gel stent

Areas of Aqueous Outflow

MIGS devices can be used to restore outflow through:

Outflow Pathway | Disease State
--- | ---
Trabecular Outflow | Mild-to-Moderate Glaucoma, GATT, and ABiC can be performed in advanced disease
Suprachoroidal Outflow | TID
Subconjunctival Outflow | Refractory
Aqueous Humor Outflow

Conventional Outflow
• The aqueous humor leaves the eye at the anterior chamber angle through the trabecular meshwork, Schlemm’s canal, intrascleral channels, and episcleral and conjunctival veins.
• Trabecular outflow accounts for 70% to 95% of the aqueous outflow.

Unconventional Outflow
• The aqueous humor exits through the root of the iris, between the ciliary muscle bundles, then through the suprachoroidal-scleral tissues.
• 5% to 30% by uveoscleral outflow.

iStent® Original, FDA approved 2012, still in use
• iStent dimensions are customized for a natural fit within the 270 µm canal space
• Made of surgical-grade nonmagnetic titanium
• Heparin-coated to promote self-priming
• The iStent is the smallest medical device known to be implanted in the human body
• Designed to restore natural physiological outflow

Surgical Procedure
For patients with cataracts and glaucoma, iStent inject is:
• FDA approved therapy for the treatment of elevated IOP in adult patients with mild-to-moderate primary open-angle glaucoma (POAG)
• The first available ab interno, micro-bypass system designed to restore natural physiological outflow through two openings through the trabecular meshwork
• In conjunction with cataract surgery

iStent inject
• Creates two patent bypasses through the trabecular meshwork to restore natural outflow
• Significantly and effectively reduces IOP\(^1\)\(^2\)
• Can reduce (or eliminate) the need for glaucoma medications
• Excellent overall safety profile similar to cataract surgery alone\(^3\)

Who is an iStent\(^6\) Candidate?
• Patients undergoing cataract surgery with mild to moderate open-angle glaucoma
• Cataract surgery patients who could benefit from better control of their IOP which may allow for their medications to be reduced
• Patients wanting to decrease risk of IOP fluctuations associated with medication compliance or who are non-adherent to prescribed regimens

74 yo, 8 yrs Hx of POAG, IOP 20 on PGA and SLT OS
PREOPERATIVE CONSIDERATIONS

Diagnostic Testing for MIGS in Cataract Patient

Manifest refraction and brightness acuity testing

Careful slit lamp examination

- Secondary glaucomas such as pseudoexfoliation syndrome and pigment dispersion syndrome?

Glaucoma workup

- Visual field to assess severity of disease
- OCT of NFL, macula
- Pachymetry
- IOP
- Gonioscopy

  - Adequacy of gonioscopic view
  - Angle anatomy: synechia, iris processes, narrow angle, angle recession
- Dilated fundus examination
- Optic nerve head evaluation

iStent inject Surgical Procedure

iStent® inject: Postop Management

- iStent postop not too different than standard cataract
  - Essentially the same schedule and protocol
  - Antibiotics and Steroid schedule usually not different
- Option to Stop or Maintain glaucoma meds:
  - Some may stop some/all meds right after surgery
    - May vary with glaucoma stage and number of meds
  - Some may wait for “Final effect” on IOP (1-3 months Postop)
    - Allow some time for re-establishment of aqueous outflow through collector channels
- Evaluate post-op IOP to “target IOP”

iStent inject PIVOTAL TRIAL Data

PRIMARY ENDPOINT: ≥ 20% Reduction in Unmedicated DIOP

SECONDARY ENDPOINT: Mean Unmedicated DIOP Reduction

Change in Unmedicated DIOP

Unmedicated DIOP ≤ 18 mmHg

Medication reduction is subject to the discretion of the physician.

- 84% of iStent inject subjects medication-free at 23 months
- 31% reduction from baseline
iStent inject PIVOTAL TRIAL

iStent inject demonstrated an overall high safety profile, similar to cataract surgery alone.1

NO REPORTS OF:
• Myopic shift
• Flat AC
• Choroidal hemorrhage or effusion
• Cyclodialysis
• Hyptony ≥ 1 month
• Hyptony maculopathy
• Stent dislocation
• Significant hyphema
• Corneal decompensation

Post-Op Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Stent Inject</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent obstruction</td>
<td>6.2%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Intraocular inflammation</td>
<td>5.7%</td>
<td>4.2%</td>
<td></td>
</tr>
<tr>
<td>BSCVA loss ≥ 2 lines at or after 3 months postoperative</td>
<td>2.6%</td>
<td>4.2%</td>
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<tr>
<td>IOP increase ≥ 10 mmHg</td>
<td>2.1%</td>
<td>0.8%</td>
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</tr>
<tr>
<td>Corneal abrasion</td>
<td>2.1%</td>
<td>3.4%</td>
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</tr>
<tr>
<td>Goniosynechiae</td>
<td>1.8%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>IOP increase requiring oral meds or SSI onset ≥ M1</td>
<td>0.3%</td>
<td>2.5%</td>
<td></td>
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<tr>
<td>Secondary glaucoma surgery</td>
<td>0.5%</td>
<td>2.5%</td>
<td></td>
</tr>
<tr>
<td>Trabeculectomy/Express shunt</td>
<td>1.0%</td>
<td>0.8%</td>
<td></td>
</tr>
</tbody>
</table>

HENGERER (3 YEAR)
Long-term IOP Reduction at 3 Years

1. Hengerer FH. Personal Experience with Second-Generation Trabecular Micro-Bypass Stents in Combination with Cataract Surgery in Patients with Glaucoma: 3-Year Follow-up. ASCRS 2018 Presentation.

Co-Management Considerations

• Establish medical necessity for cataract and glaucoma surgery
• Accurately document all preoperative evaluations or diagnostic tests
• Obtain patient consent to co-management
  – Clearly explain and document patient logistics
  – Financial arrangement disclosures
  – Consent to share information between surgeon and postop care provider
  – Provisions if complications occur
  – Signatures (patient, surgeon, co-managing doctor)

Co-Management Coding

iStent inject implantation is described by CPT® code 0191T and 0376T

• Utilize the following CPT Codes for iStent inject:
  – 0191T AND 0376T
• CPT codes 0191T and 0376T have no assigned Relative Value Units or Global Period
• There is no post-co-management fee for any Category III CPT Code (i.e., T-code)
• Medicare carriers will not recognize modifiers -54 & -55 for 0191T and 0376T

Modifiers -54 & -55 should be appended to CPT code 66984

• Modifier -54: surgical care only
• Modifier -55: all/part of outpatient/postoperative care
• Surgeon MUST initiate the notification to Medicare by using modifier -54 with the claim
• In localities where Medicare has a higher physician payment for 0191T than for 66984 and where 66984 is reduced by 50%, payment for 66984-55 will be reduced by 50%.

Hydrus micro-stent

• The Hydrus Microstent is a tiny scaffold inserted about the size of an eyelash that is inserted into the main drainage channel of the eye to help lower eye pressure and reduce the need for medications
• Nickel/titanium stent scaffolds 90 degrees of trabecular meshwork, holding the canal open
• Mild to moderate POAG
• In conjunction with cataract surgery

Other MIGS Options

All FDA Approved
Kahook Dual Blade (KDB)

- Dual-edge blade used to remove trabecular meshwork strip 2-3 clock hours
- Better aqueous access to the canal
- Numerous types and severity levels of glaucoma
- In conjunction with cataract surgery or standalone

Cypass (Recalled)

- Shunt that connected anterior chamber to suprachoroidal space
- Mild-moderate POAG
- In conjunction with cataract surgery
- FDA Recalled in Fall 2018
  - Noted increased Endothelial Cell Loss

MIGS: Refractory Disease: Subconjunctival Space

Xen Gel Stent:

Labeled for refractory glaucoma:
- Where previous laser/surgical treatment has failed or for patients unresponsive to maximum tolerated medical therapy
- Requires bleb observation/management
- Alternative to a trabeculectomy or tube shunt procedure for refractory patients

XEN Gel Stent

- Gel stent that connects anterior chamber to subtenon space, creating a bleb
- Mitomycin (usually injected)
- For refractory open angle, pigmentary, or pseudoexfoliation glaucoma
- Alternative to conventional trabeculectomy or tube shunt
- In conjunction with cataract surgery or standalone

ABIC™ = Ab-interno Canaloplasty w/ iTrack™

- Microcatheter for viscodilation
- MIGS that flushes out the natural outflow channels without damaging tissue

TM “Cleaning”, Viscodilation +/- Trabeculotomy

The OMNI™ Surgical System is a manually operated device indicated for the delivery of small amounts of viscoelastic fluid during ophthalmic surgery through a custom microcatheter.
- It is also indicated for the cutting of trabecular meshwork when a trabeculotomy is indicated.