How to Design Successful Outcomes: Part 3

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DISCLOSURES

- We have no personal conflicts of interest.
- We have no relevant financial relationships.
MIGS
Micro-Invasive Glaucoma Surgery
The challenges of treating glaucoma

- **Medications:**
  - Poor patient compliance
  - Cost of meds, both generics vs. branded
  - Side effects/irritation
  - Refill issues

- **Surgical:**
  - Complications
  - Failure (initial trabeculectomy = 10-20%, 5 year = almost 50%)

- **Testing Variability and Reliability**

- **Asymptomatic Disease**
Most patients with glaucoma are noncompliant

• The majority of patients do not take their glaucoma medications as prescribed

• In a study of over 5,500 managed care patients, 90% were noncompliant and more than 50% of patients failed to refill their initial prescription in the 1st year

Noncompliance is the number one reason for drug therapy failure.

Advantages of MIGS

- Decreased medication load
- Cost savings
- Smoother diurnal curves
- High success rate
- Low complication rate
- Constant coverage despite possible non-compliance
  - “Insurance inside your eye”
By controlling IOP 24 x 7 x 365, MIGS protect your patients’ vision, and make your job easier
The history of surgical options for glaucoma

- Shunt (Molteno, 1966; Baerveldt and Ahmed 1990’s)
- Trabeculectomy (1968)
- Laser Trabeculoplasty (ALT, 1979; SLT, 2001)
- ECP: Endoscopic Cyclophotocoagulation (1992)
- Ex-PRESS shunt (2002)
- Trabectome (2005)
- Canaloplasty (2007)

- MIGS: Micro or Minimally Invasive Glaucoma Surgery (2012)
MIGS defined

• *Ab-interno* approach
  - Clear corneal micro-incision (<2.0mm)
  - Conjunctival sparing
• Minimally traumatic
  - Negligible disruption of normal anatomy/physiology
  - Excellent biocompatibility
• Efficacious
• Extremely high safety profile
• Rapid recovery

Where do MIGS fit in?

Surgical Decision Making As a Function of Glaucoma Severity

- Filtration Surgery +/- CE:
  - Trabeculectomy
  - +/- anti-metabolite
  - Tube Shunt Surgery

<table>
<thead>
<tr>
<th>Glaucoma Intervention Spectrum</th>
<th>Pharmacotherapy</th>
<th>Laser Trabecuoplasty</th>
<th>MIGS</th>
<th>MIGS + CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaucoma Disease Spectrum</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
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</table>

- MIGS (Minimally Invasive Glaucoma Surgery)

Review of Ophthalmology, April 2015
Pre-operative considerations

- Glaucoma workup
  - Visual field – Determination of severity of the glaucoma
  - Optic nerve head imaging/assessment
  - Pachymetry
  - IOPs
  - Gonioscopy – evaluating for synechiae, iris processes, narrow anatomical angles, angle recession or any other abnormalities of the angle structure that may interfere with placement of the micro-stent
  - Anterior segment and dilated fundus examination – rule out significant other ocular pathology
Your role: tell the surgery center...

- If your patient has glaucoma
- Current medications
- Stability vs progression
- Compliance with treatment
- Send recent VFss (within the last year)
Glaucoma stage definitions

Mild or Early Stage Glaucoma
ICD-10 7th digit “1”
- Optic nerve abnormalities consistent with glaucoma
- but NO visual field abnormalities on any visual field test
- OR abnormalities present only on short-wavelength automated perimetry or frequency doubling perimetry
Glaucoma stage definitions

Moderate Stage Glaucoma

ICD-10 7th digit “2”

- Optic nerve abnormalities consistent with glaucoma
- AND glaucomatous visual field abnormalities in ONE hemifield and
- NOT within 5 degrees of fixation (note: 5 degrees = involvement of spots nearest fixation)
Glaucoma stage definitions

**Advanced, Late, Severe Stage**

ICD-10 7th digit “3”

- Optic nerve abnormalities consistent with glaucoma
- AND glaucomatous visual field abnormalities in BOTH hemifields
- AND/OR loss within 5 degrees of fixation in at least one hemifield
SUMMARY:
WHAT YOU MUST TELL THE SURGERY CENTER:

1. Severity
2. Progression
3. Compliance
4. Visual fields
MIGS devices:
iStents, Hydrus, XEN gel, and ABiC

• No surgeon is trained on all MIGS devices
• The best MIGS for your patient is the one with which your surgeon feels confident
TRABECULAR BYPASS MIGS

iStent & Hydrus
Primary source of resistance: diseased trabecular meshwork

- 50-75% of total resistance to aqueous humor outflow is found in the juxtacanalicular tissue of the TM\textsuperscript{1,2,3}

- Bypassing the TM allows improved aqueous outflow to Schlemm’s canal and the distal system

\textsuperscript{1}Grant WM. Further studies on facility of flow through the trabecular meshwork. \textit{Arch Ophthalmol.} 1958;60(4):1:523-33.


Advantages to stenting Schlemm’s canal:

• **Enhancement of natural physiological outflow**
  Lowers IOP and may reduce or eliminate medication burden
  Decrease risk of IOP fluctuations

• **Physiologic floor minimizes risk of hypotony**
  (Natural episcleral venous pressure typically 8-11mm Hg)

• **Lack of bleb or conjunctival manipulation**
  Does not preclude further glaucoma surgery if needed

• **Minimal disruption of angle anatomy**
  Minimize risk related to cell damage, inflammation, fibrosis, PAS
Indications for iStent or Hydrus

- Concomitant cataract & glaucoma
  - Mild to moderate open angle glaucoma
  - Visually significant cataract
- Need to reduce medication burden
- Need for reduction of IOP fluctuations or better IOP control
- Desire for preservation of future surgical options
Contraindications for iStent or Hydrus:

• Closed/narrow angle
• Neovascular
• Angle recession
• Uveitic
• Anatomical variability
  ▪ lack of TM pigment making placement difficult
  ▪ PAS, severe iris processes
The iStent geneology (Glaukos)

- iStent
  Heparin-coated titanium

- iStent Inject
  2 stents in 1 injector

- iStent Infinite (coming soon)
  3 stents in 1 injector
  Stand-alone procedure
Study: iStent family + CE versus CE alone

• iStent with CE versus CE (550 eyes, data at 2 years):
  • 11% more had IOP <21mmHg (61% v. 50%)
  • 9% more achieved 20% IOP reduction (66% v. 48%)
  • 0.3 greater reduction in medications (1.4 avg. reduction v. 1.1)
• iStent Inject versus CE (at 2 years):
  • 14% more achieved 20% IOP reduction (76% v. 62%)
  • 1.2 greater reduction in medications (1.6 avg. reduction v. 0.4)

• Fingeret M, Dickerson JE. The role of minimally invasive glaucoma surgery devices in the management of glaucoma. Optom Vs Sci 2018;95:155–162.
iStent post-op management

- Same as with cataract surgery alone
  - Normal postop schedule (1 day, 1 week, 1 month)
  - Same post op medications
  - Hyphema—blurry vision
  - IOP spike/steroid responder—treated the same
  - Assessment of stent position—1 week gonioscopy
Anatomy of a properly placed iStent
iStent complications

- Microhyphema immediately post-op
- No drop in IOP
- Fibrosis over the lumen
iStent: when to discontinue medications

- Not until post-op medications are finished
- “Final effect” on IOP not until 2-3 months postop
- Typically stop medications after 2-3 months
Hydrus Microstent (Ivantis)

- 8 mm long nitinol alloy
- Placed through trabecular meshwork into Schlemm’s canal
- Acts as a scaffold for 3 clock hours of Schlemm’s canal
- End extends into the AC
- For mild to moderate glaucoma
Hydrus with CE versus CE alone:

- 556 eyes, data at 2 years
- 2.7mmHg greater drop in IOP (avg. 7.9 v. 5.2)
- 24% more achieved 20% IOP reduction (79% v. 55%)
- 40% more medication free (79% v. 39%)
Hydrus vs. iStent head-to-head trial

- Hydrus vs. 2 iStents (152 patients, data at 12 months, standalone procedure):
  - 20% greater reduction in IOP with Hydrus (73% v. 47%)
  - 24% greater reduction in medications with Hydrus (47% v. 24%)
  - 23% more medication-free with Hydrys (47% v. 24%)

Hydrus complications

- 3.8% PAS causing obstruction
- 2.7% IOP elevated significantly
- 1.1% transient hyphema
- No cases of hypotony
Hydrus: when to discontinue medications

- Not until post-op medications are finished
- “Final effect” on IOP not until 2-3 months postop
- Typically stop medications after 2-3 months

- ... same as iStent.
iStent and Hydrus surgery
Anatomic placement & rationale

• Placed in inferonasal locations with high presence of collector channel congregations

• Designed to improve continuous, physiological outflow in the lower nasal quadrants
Why nasal placement of iStent?

Aqueous Angiography
Before and After Stenting

Alex Huang, MD, PhD
Surgical placement of iStent inject
Venous collector channel blanching
XEN gel stent
XEN gel stent (Allergan)

- Bypasses natural drainage pathway by shunting fluid from AC into subconjunctival space
- Potential for lower IOPs like trabs/tube shunts while minimizing hypotony and post op wound leaks
**XEN gel stent**

- Trans-scleral: 1mm in anterior chamber (AC), 3mm in sclera, 2mm in subconjunctival space
- Stent will be visible from the AC, and posteriorly in the superior subconjunctival space with surrounding bleb
- 6mm gelatin tube, lumen diameter 45 µm
XEN gel placement
**Ab-interno vs. ab-externo approach**

- **Ab-interno**: stent inserted via CCI and from the anterior chamber

- **Ab-externo**: stent inserted via injector needle externally, posterior to the limbus

- Mitomycin C (MMC) is used to prevent scarring
Indications for XEN gel stent

- Severe open angle glaucoma, pigmentary glaucoma, pseudoexfoliative glaucoma
- Maximum tolerated medical therapy
Study: XEN gel versus trabeculectomy

- 354 (n =185 Xen, 169 Trab) eyes with no prior filtering surgery
- 35% reduction from pre-surgical medicated IOP
- 80% of patients needed fewer topical medications post-operatively at 1 year.

- **Efficacy, failure rate and safety was equivalent between the 2 groups**

XEN gel post-op care

- Close follow-up is needed. This will likely be done by the surgery center.
- Follow-up timeline is based on IOP and appearance of the bleb.
- Antibiotic drops for 1 week post-op.
- Slow taper of steroid drops needed over the course of a few months to prevent bleb scarring. Initial dose at 1 drop q2h.
- Digital massage is not advised, as stent breakage or exposure can occur.
- If the bleb is scarring, IOP will begin to rise quickly. Bleb needling by the glaucoma surgeon is recommended sooner rather than later.
Bleb Needling

• Up to one third of the patients may need bleb needling.
• Needling be completed at the slit lamp or in the OR.
• Needling is done in conjunction with an anti-fibrotic agent (MMC or 5-FU).
• Corneal epithelial health can be affected upon use of anti-fibrotic agent.
• Open conjunctival bleb revision may be considered if stent is not visible under the conjunctiva.
Potential postoperative complications

- Hypotony
- Choroidal effusion
- Bleb scarring
- XGS migration into AC
- XGS conjunctival exposure
- Hyphema
- Wound leak
AB-iC

Ab-interno Canaloplasty
ABiC: a “comprehensive” MIGS procedure

- Minimally invasive, atraumatic, *restorative*

- A more physiologic procedure that enhances flow through eye’s existing native drainage system vs bypassing it

- Addresses all aspects of potential outflow resistance
  - Accesses, catheterizes, and viscodilates: TM, Schlemm’s canal, collector channels

- Flushes out the natural outflow channels without damaging tissue or leaving behind a stent or shunt
ABiC: a “comprehensive” MIGS procedure

- With cataract surgery
- Standalone
- Subsequent to or following other MIGS
- Subsequent to or following SLT
- Subsequent to or following trab/tube
- Across the entire disease spectrum
## ABiC Patient Selection

<table>
<thead>
<tr>
<th>Cataract surgery patient on topical medications</th>
<th>Pigmentary glaucoma</th>
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<tbody>
<tr>
<td>Open-Angle Glaucoma (OAG) - all stages</td>
<td>Failed trabeculectomy in fellow eye</td>
</tr>
<tr>
<td>First-line option prior to, or after laser surgery</td>
<td>Failing SLT, ALT, ECP</td>
</tr>
<tr>
<td>OAG non-compliant to medications</td>
<td>High-risk patients (high myopes, young AA, elderly with thin conjunctiva)</td>
</tr>
<tr>
<td>OAG intolerant to medications</td>
<td>Monocular patients</td>
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<tr>
<td>Exfoliative glaucoma</td>
<td>Uncontrolled ocular hypertension</td>
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JEC ABiC surgery video
*Ab-interno* vs. *ab-externo*
ABiC efficacy

- 32.2% reduction in mean IOP at 12 mos.
• 60% reduction in medication use at 12 mos
ABiC post-op

- Similar to post cataract surgery
- Antibiotic/NSAID/steroid?
- Stop glaucoma drops
ABiC summary

- Treats the trabecular meshwork, Schlemm’s canal, and the collector channels
  - Treats a greater volume of anatomy than single-point stents
  - Opens the outflow system behind the TM, ensuring better aqueous outflow
- Effective as a stand-alone or adjunct procedure to cataract extraction.
  - ABiC can be used and reimbursed in USA without concurrent cataract surgery
  - Can be performed in phakic and pseudophakic patients.
- Preserves tissue and does not require permanent placement of an implant or stent
  - Atraumatic - does not preclude future treatment options
  - Does not ablate or remove tissue
If you remember nothing else ...

1. For all cataract patients with glaucoma, communicate severity, progression, and compliance.

2. Send visual fields.

3. Know the MIGS devices your surgeon prefers, and your role in their management.