MIGS: Will Glaucoma Become a Surgical Disease

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Disclosures

• Aerie
• Allergan
• Alcon
• Aquesys
• AVS
• Glaukos
• Ivantis
Which eye had surgery vs eyedrops?

S/P Glaucoma Surgery

12 mmHg

Medical Rx: 2 Drops

12 mmHg

(Photo from Reay Brown)
Why Should Glaucoma Be a Surgical Disease?

- Simplicity
- Safe and effective surgery avoids...
  - Eye Drops
    - Side effects (esp to ocular surface)
    - Compliance
    - Recurring expense
Selective and Argon Laser Trabeculoplasty

At 1 year, 82% of patients who underwent SLT remained on the same number of medications (2.6)

- 18% required an additional medication
- 100% of patients remained on the same number of medications or increased their medications
- More patients in the ALT group than the SLT group required an additional medication at 1 year

MIGS: A New Perspective

- Who is a candidate?
- What justifies the procedure?
- How to start implanting?
R. Stegmann’s View of the Canal
MIGS: What is it?

- Minimally Invasive Glaucoma Surgery
- Ab interno micro-incision procedures
- Lower risk
- Earlier intervention
- Minimal additional technology
- Does not preclude other glaucoma surgery
MIGS: Mechanism of Action

1. Subconjunctival
   - Aquesys (Xen)

2. Canal
   - Glaukos (iStent)
   - Ivantis (Hydrus)

3. Suprachoroidal
   - Transcend (CyPass)
   - Glaukos (G3)

Trabectome is disruptive to the TM/canal and, thus, not a MIGS procedure
Glaucoma Surgery Profile

MIGS

- Mild to moderate disease
- Open angles
- Modest IOP target (15-16)
- Low risk
- Long term data lacking
# Glaucoma Surgery Profiles

<table>
<thead>
<tr>
<th>MIGS</th>
<th>Trab or Tube</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild to moderate disease</td>
<td>More advanced disease</td>
</tr>
<tr>
<td>Open angles</td>
<td>Open or closed angles</td>
</tr>
<tr>
<td>Modest IOP target (15-16)</td>
<td>Lower IOP target (&lt;13)</td>
</tr>
<tr>
<td>Low risk</td>
<td>Higher risk</td>
</tr>
<tr>
<td>Long term data lacking</td>
<td>Recognized long term effect (s)</td>
</tr>
</tbody>
</table>
Variables to Consider

1. Efficacy
2. Risk/complications
3. Technical ease
4. Duration
5. Cost to physician/ASC/hospital
6. Reimbursement
Canal Surgery Milestones

• 1962: Sinusotomy – Krasnov
• 1968: Trabeculectomy – Cairns/Watson
• 1978: Non perforating trabeculectomy- Zimmerman
• 1982: Deep sclerectomy- Fyodorov
• 1993: Viscocanalostomy – Stegmann
• 2001: Aquaflow Collagen Implant
• 2004: Canaloplasty – Stegmann, Lewis
• 2012: iStent (Trabecular bypass) – Hill
Clinical Development Milestones

1999 – Stegmann: viscocanalostomy

2001 - Ultrasound imaging to localize canal and outflow system

2003 – Development of flexible 250u lumen microcanula

2004-05 - Viscodilation and suture stent passage
    - Canal tensioning or Canaloplasty

Illuminating Tip of Microcannula in Schlemm’s Canal
Canaloplasty: Mechanism of IOP Reduction

1. Aqueous flow through Trabecular Descemet’s membrane (or window)

2. Aqueous re-absorption
   - Subconjunctival filtering bleb
   - Through canal and collectors
Canaloplasty
Canaloplasty – Surgical Site

- Descemet's Window ~0.3 mm deep with FLOW
- Slight inward dimpling of TM from suture
- Clean, open ostia
- ~0.5 mm ledge for outer flap seal
- Clear TM with FLOW
- Choroid visible through remaining sclera
Canaloplasty: Indications

1. Open angle glaucomas including PDS and PXE

2. Expect Trabeculectomy to Fail
   • Failed trabeculectomy or hypotony in fellow eye
   • Significant conjunctival disease

3. Concerned about further loss of vision
   • High myopia and contact lens wearers
   • Immunosuppressive treatments
   • Anti-coagulation
Aussie: Case Report

47 y/o man on 4 meds s/p SLT

- High (-9.0) myope
- Ocular surface disease from long term glaucoma meds
- IOP: 18-20
- Pachy: 490
- Advanced cupping with sup arcuate defect OU
## Canal vs Trab: Ayyala et al

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Canaloplasty IOP (mmHg)</th>
<th>No. of Patients</th>
<th>Trabeculectomy IOP (mmHg)</th>
<th>No. Patients</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td>21.2±6.6</td>
<td>33</td>
<td>23.4±10.4</td>
<td>46</td>
<td>0.28</td>
</tr>
<tr>
<td>1 day</td>
<td>9.3±6.0</td>
<td>33</td>
<td>5.7±3.6</td>
<td>46</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>1 week</td>
<td>13.7±6.4</td>
<td>32</td>
<td>6.8±3.8</td>
<td>45</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>1 month</td>
<td>14.4±5.8</td>
<td>32</td>
<td>8.8±4.5</td>
<td>46</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>3 months</td>
<td>12.6±5.6</td>
<td>32</td>
<td>10.3±3.7</td>
<td>46</td>
<td>0.05*</td>
</tr>
<tr>
<td>6 months</td>
<td>12.1±4.0</td>
<td>32</td>
<td>11.2±4.5</td>
<td>43</td>
<td>0.40</td>
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<tr>
<td>9 months</td>
<td>12.9±5.1</td>
<td>33</td>
<td>11.6±3.4</td>
<td>39</td>
<td>0.18</td>
</tr>
<tr>
<td>12 months</td>
<td>13.8±4.9</td>
<td>33</td>
<td>11.6±4.0</td>
<td>46</td>
<td>0.03*</td>
</tr>
</tbody>
</table>

Ophthalmology 2011
Canal vs Trab: Ayyala et al

![Graph showing comparisons between Canaloplasty and Trabeculectomy for intracocular pressure.](image)

**Table 7. Reoperations**

<table>
<thead>
<tr>
<th>Reoperation Type (n)</th>
<th>No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canaloplasty</td>
<td>5 (15)</td>
</tr>
<tr>
<td>Trabeculectomy</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Trabeculectomy*</td>
<td></td>
</tr>
<tr>
<td>- Bleb revision for leaking cystic bleb (2)</td>
<td></td>
</tr>
<tr>
<td>- Express shunt for failed blebs (2)</td>
<td></td>
</tr>
</tbody>
</table>

*One patient had suprachoroidal hemorrhage drainage.*

Ophthalmology 2011
Canaloplasty: Challenges

1. “Learning curve” - finding the canal
2. Canal access in various glaucomas
3. Magnitude of IOP reduction
4. Long term efficacy
JK: Case Study

- 56 y/o MD with high myopia and glaucoma since 2007, complains of ocular irritation and redness

History:
- High myopia (-18.0) – wears GP CL
- 2006: Glaucoma, initial IOP 23/27
- 2007: Phaco/IOL OS
- 2009: Trab/5FU (post op hypotony)
- 2009: Head MRI, blood studies all WNL

Meds: Azopt OU, Travatan OU, Timolol OU
## JK: Case Study

<table>
<thead>
<tr>
<th>Exam</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acuity</td>
<td>-18.00 CL=20/30</td>
<td>20/20</td>
</tr>
<tr>
<td>SLE</td>
<td>2+ follicles, redness OU</td>
<td></td>
</tr>
<tr>
<td>IOP</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Fundus</td>
<td>0.8 cup</td>
<td>0.9 cup pale</td>
</tr>
<tr>
<td>Pachy</td>
<td>606</td>
<td>590</td>
</tr>
</tbody>
</table>
JK: Case Study

Central 24-2 Threshold Test
Fixation Monitor: Gabor/Min Spot
Fixation Target: Central
Fixation Losses: 0/19 %
False POS Errors: 2 %
False NEG Errors: 0 %
Test Duration: 06:38

Stimulus: White
Background: 51.5 ASB
Visual Acuity:
Rx: +0.75 DS DC X
Age: 56

Field: 35 dB

Total Deviation

Pattern Deviation

*** Low Test Reliability ***

GHT
Outside normal limits

VFI: 51%

MD: -17.83 dB P < 0.5%
PSD: 9.84 dB P < 0.5%

GHT
Outside normal limits

VFI: 17%

MD: -935.66 dB P < 0.5%
PSD: 8.87 dB P < 0.5%

The Permanent Medical Group, Inc.
320 Lennon Lane
Walnut Creek, Ca 94596
Tel: 925-936-2390
Fax: 925-936-2382

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JK: Case Study
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Problem List

- High myopia
- POAG – progression, optimal IOP
- Ocular redness – allergy to meds, CL
Canal-based, non disruptive MIGS Procedures

- Dilates and preserves Schlemm’s canal by channel reconstruction and trabecular meshwork bypass
- Re-establish flow to collector channel system
- May be performed with or without cataract surgery

Options:

1. iStent (Glaukos)
2. Hydrus (Ivantis)
Glaukos iStent
Prevalence of Glaucoma and Cataract

- Of the 3.5 million annual cataract procedures performed in the US, 20.5% of these patients are on a glaucoma medication.

A Large Percentage of your Patient Population fits the Approved Indication

* Medicare data analysis 2003 - 2007
Effect of Cataract Surgery on IOP Reduction

87% of patients who underwent cataract extraction experienced minimal to no reduction in IOP

- 53% had a mean reduction of 1.6 to 2.5 mm Hg
- 34% had an increase of 0.2 mm Hg

From a retrospective chart review of 588 normotensive and OHT patients who underwent cataract surgery

When Should iStent Be Used?

- In any patient with mild-moderate glaucoma undergoing cataract surgery
  - Patients on 1 glaucoma med
    - Goal: getting patient off meds
  - Patients with normal VF
What is Mild to Moderate OAG?

When Should iStent Be Used?

- In **any** patient with mild-moderate glaucoma undergoing cataract surgery
  - Patients on 1 glaucoma med
    - Goal: getting patient off meds
  - Patients with normal VF

- iStent: Option to **treat glaucoma as a surgical disease**
Gonioscopy is back!

- Get comfortable in the office with gonioprism
  - Seldom done yet billable
  - Gonioscopy.org – great source

- Practice **before** a scheduled case
  - Use a gonioprism in one hand and Sinsky hook in the other
Gonio Imaging - Angle Structures

Normal angle - inferior view

- Schwalbe’s Line
- Scleral Spur
- Trabecular Meshwork
- Ciliary Body Band
Gonio Imaging - Angle Structures
79 y/o woman referred for glaucoma

History:
- RK + LASIK OD, RK OS
- Blepharospasm (on Botox)
- Dry eye
- Ocular allergies (to BAK and other preservatives)
- Cataract

Meds: Non-preserved Timolol qd OU
Exam:

- Acuity: +1.75 + 2.50 x 045 = 20/60
  - OS: 0.50 + 1.00 x 128 = 20/80
- SLE: RK scars OU, 2+ NS
- IOP: 14 15
- Fields: Unreliable OU
- Disc: 0.8 cup 0.8 cup
RG: Case Study
RG: Case Study

**Preoperative Data:**

<table>
<thead>
<tr>
<th>AMO Tecno: ZCR90 (UL)</th>
<th>ATRIC SN6ATT</th>
<th>ATRIC SN6WF</th>
<th>ATRIC MA64AC (3-PC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACD Const: 5.78</td>
<td>ACD Const: 5.55</td>
<td>ACD Const: 5.4</td>
<td>ACD Const: 5.23</td>
</tr>
<tr>
<td>A0 Const: -1.47</td>
<td>A0 Const: -0.355</td>
<td>A0 Const: -0.466</td>
<td>A0 Const: 1.532</td>
</tr>
<tr>
<td>A1 Const: 0.174</td>
<td>A1 Const: 0.157</td>
<td>A1 Const: 0.172</td>
<td>A1 Const: 0.017</td>
</tr>
<tr>
<td>A2 Const: 0.246</td>
<td>A2 Const: 0.216</td>
<td>A2 Const: 0.312</td>
<td>A2 Const: 0.145</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IOL (D)</th>
<th>RIF (D)</th>
<th>IOL (D)</th>
<th>RIF (D)</th>
<th>IOL (D)</th>
<th>RIF (D)</th>
<th>IOL (D)</th>
<th>RIF (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.5</td>
<td>-1.48</td>
<td>27.0</td>
<td>-1.23</td>
<td>27.0</td>
<td>-1.52</td>
<td>26.5</td>
<td>-1.19</td>
</tr>
<tr>
<td>27.0</td>
<td>-1.13</td>
<td>26.5</td>
<td>-0.86</td>
<td>26.5</td>
<td>-1.14</td>
<td>26.5</td>
<td>-0.81</td>
</tr>
<tr>
<td>26.5</td>
<td>-0.74</td>
<td>26.0</td>
<td>-0.49</td>
<td>26.0</td>
<td>-0.77</td>
<td>25.5</td>
<td>-0.44</td>
</tr>
<tr>
<td>25.5</td>
<td>-0.38</td>
<td>25.5</td>
<td>-0.13</td>
<td>25.5</td>
<td>-0.40</td>
<td>25.0</td>
<td>-0.08</td>
</tr>
<tr>
<td>25.5</td>
<td>0.02</td>
<td>25.0</td>
<td>0.22</td>
<td>25.0</td>
<td>0.03</td>
<td>24.5</td>
<td>0.28</td>
</tr>
<tr>
<td>25.0</td>
<td>0.33</td>
<td>24.5</td>
<td>0.58</td>
<td>24.5</td>
<td>0.33</td>
<td>24.0</td>
<td>0.64</td>
</tr>
<tr>
<td>24.5</td>
<td>0.68</td>
<td>24.0</td>
<td>0.93</td>
<td>24.0</td>
<td>0.68</td>
<td>23.5</td>
<td>0.99</td>
</tr>
</tbody>
</table>

**Topographic Data:**

<table>
<thead>
<tr>
<th>EyeSys EIRP</th>
<th>Average Central Power*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlas 1mm: 40.66</td>
<td>2mm: 41.19</td>
</tr>
<tr>
<td>Pentacam PWR_SF_40**</td>
<td>CT_MIN**</td>
</tr>
</tbody>
</table>

**Optical (IOLMaster/Lenstar)/Ultrasound Biometric Data:**

<table>
<thead>
<tr>
<th>Lens A-consts (SRKT)</th>
<th>ATRIC MA64AC (3-PC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>119.4 SF (Holladay1)</td>
<td>2.03</td>
</tr>
</tbody>
</table>

*Not Simk values; average central corneal powers from other devices.

**PWR_SF_40 refers to the Pentacam Power Distribution display for the Sagittal Curvature (Front) Mean (Mm) value at a 4.0 mm zone and centered on the pupil. Click on PWR_SF_40 to see this topographic display. CT_MIN is the minimum central corneal thickness in microns as displayed by the Pentacam.

Select the kerometric index (n) of your device. Instruments in North America typically default to 1.3375. Enter the constant available; the other will be calculated. If ultrasound lens is entered, be sure to use your ultrasound lens constants.

---

**OL Powers Calculated Using Double-K Holladay 1 Formula**

<table>
<thead>
<tr>
<th>EyeSys EIRP --</th>
<th>Average Central Power (other) --</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atlas 1-4: 24.08</td>
<td></td>
</tr>
<tr>
<td>Pentacam --</td>
<td>IOL Master/Lenstar: 24.16</td>
</tr>
</tbody>
</table>

Average IOL Power: 24.12

Min: 24.08

Max: 24.16
RG: Case Study

- Underwent uncomplicated phaco/IOL (24D) with iStent

- Results:
  - Discontinued eye drops
  - IOP under control
  - Dry eye symptoms improved
  - Very happy with result
First 50 iStents: IOP

IOP following iStent

Average IOP (mmHg)

Pre-Op  1 day  1 month  2 months  3-4 months

- Pre-Op: 19.729 (N=48)
- 1 day: 17.205 (N=44)
- 1 month: 18.935 (N=31)
- 2 months: 15.625 (N=16)
- 3-4 months: 14.923 (N=13)
First 50 iStents: Number of Eye Drops

Number of Eye Drops after iStent

<table>
<thead>
<tr>
<th>Time</th>
<th>Average Number of Eye Drops</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op</td>
<td>2.245</td>
</tr>
<tr>
<td>1 day</td>
<td>0.020</td>
</tr>
<tr>
<td>1 month</td>
<td>0.082</td>
</tr>
<tr>
<td>2 months</td>
<td>0.417</td>
</tr>
<tr>
<td>3-4 months</td>
<td>0.500</td>
</tr>
</tbody>
</table>
iStent Insertion Tips

1. Head positioning
2. High magnification of microscope
3. Maximize visibility (gonio view)
4. Viscoelastic (just the right amount)
5. Angle tip of injector into TM
6. Press forward while injecting
7. Re-assess after placement
Superficial iStent Placement
Well Placed iStent
Maximizing IOP Reduction with iStent?

- Multiple iStents?
  - 2 iStents achieve lower IOP (Ike Ahmed MD)
  - Subject of continuing studies
  - Not approved for reimbursement in US

- Targeted placement of iStent
  - Near aqueous vein
  - Near pigmented area in meshwork
The Role of Collector Channels in Reducing IOP

- There are numerous collector channels leaving Schlemm’s canal at irregular intervals.
- Bypassing the trabecular meshwork in the inferonasal quadrant is an optimal site to maximize outflow through Schlemm’s canal.
- Increasing outflow through the lower nasal quadrant has a significant impact on increasing outflow and lowering IOP as compared to targeting quadrants with lower collector channel congregations.


Targeted Placement: Pigmented Meshwork

iStent placed in pigmented area of meshwork

Appearance at end of surgery
Targeting Collector Channels

Pigment Suggests Outflow

Less pigment

More pigment

3 months post-op
Targeting Collector Channels

Less pigment

More pigment
Summary

- Large percentage of the patient population presents with mild-to-moderate glaucoma + cataract

- iStent is the first FDA approved device for the treatment of mild-to-moderate open-angle glaucoma in combination with cataract surgery; it will not be the last!

- Get comfortable with the gonioprism!