POLLING QUESTION

• What is your level of training?
  – 1. Medical student
  – 2. Ophthalmology Resident
  – 3. Ophthalmologist
  – 4. Glaucoma Surgeon
MIGS BACKGROUND
What is/are MIGS?

- Glaucoma surgery with lower risk than trabeculectomy or tube implant
- Often avoid disruption of the conjunctiva
  - Canaloplasty and InnFocus Shunt are exceptions
- Most are designed to restore function to the conventional outflow system
  - Gold Shunt and CyPass are exceptions
So What’s the Big Deal?

- **Efficacy**

  In general, MIGS achieve mid-high teens IOP on average.

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**Clinical Results with the Trabectome for Treatment of Open-Angle Glaucoma**

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**Canaloplasty: Circumferential viscodilation and tensioning of Schlemm’s canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults**

**Two-year interim clinical study results**

Richard A. Lewis, MD, Kurt von Woellen, MD, Matthias Ettin, MD, Norbert Kaufman, MD, John K. Koevary, MD, Bradford J. Shingleton, MD, Thomas W. Summers, MD

*J Glaucoma Refract Surg 2009, 35:914–924*

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**Figure 1.** Group 1 efficacy (all included patients) showing mean IOP (± SD) and mean medications. The dashed line indicates the baseline IOP of 23.6 mm Hg (IOP = intraocular pressure).

**Figure 2.** Group 2 efficacy (canaloplasty alone) showing mean IOP (± SD) and mean medications. The dashed line indicates the baseline IOP of 23.2 mm Hg (IOP = intraocular pressure).

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**Figure 3.** Summary graph illustrating the time course of postoperative intraocular pressure (IOP) results (with standard deviation bars) below baseline mean IOP.

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**Figure 4.** Mean (SD) IOP intracocular pressure over time (12 months) in 38 patients with glaucoma who underwent Gold Micro Shunt implantation. A total of 36 patients (95%) completed the 1-year follow-up.
What Are The Choices?

- Ab Interno Trabeculectomy
- Trabecular Bypass Shunt
- Schlemm Canal Implant
- Tube Shunt
- AC - Suprachiliary Space Bypass
- Endoscopic Laser Cyclophotocoagulation
SCHLEMM CANAL SURGERY
POLLING QUESTION

• I have performed MIGS Schlemm Canal Surgery
  – 1. Yes
  – 2. No
Mechanisms of Action

- **Schlemm canal surgery**: increase aqueous outflow through the conventional pathway, typically through implantation of a drainage device or removal of trabecular tissue.
Schlemm Canal Surgery

**iStent**
- iStent Inject
- Hydrus
- Trabectome
- Kahook Dual Blade
- TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty
Excimer Laser Trabeculotomy
iStent™ Microstent
Glaukos Corporation, Laguna Hills, CA

- Heparin-coated titanium device that enables bypass of the trabecular meshwork, permitting drainage directly to SC
- First MIGS device approved in US (2012)
- Approved for use in combination with CE/IOL in the US and with or without CE/IOL in Europe
- Most common complications are malposition or obstruction (treated with removal and replacement or Nd:YAG laser when intervention is needed) and transient hyphema

http://www.urmc.rochester.edu/news/story/index.cfm?id=3933
iStent™ Microstent
The Evidence: iStent™ Microstent

- One stent doubled the outflow facility in perfused donor eyes and insertion of two stents quadrupled it

Figure 2. (A) Trabecular meshwork and Schlemm's canal (SC) adjacent to location of stent. Note Schlemm's canal is of normal size. Bar = 100 μm. (B) Trabecular meshwork and Schlemm's canal after placement of stent. Stent was removed to allow histologic processing; location of stent is marked in black. Bar = 100 μm.
The Evidence: iStent™ Microstent

• Randomized controlled clinical trial – pivotal phase III study
  – Entry IOP ≥ 22 mm Hg
  – N=240
  – Per protocol, post-operative IOP was maintained below 21 with topical medications in both groups: phaco alone versus phaco + iStent
  – Mean IOP reduction was 1.5 mm Hg in the phaco + iStent group versus 1 mm Hg in the phaco alone group
  – Phaco + iStent group required fewer medications than the phaco alone group
• After 24 months, the IOP decrease was 8% in the phaco + iStent group versus 1% in the phaco group

The Evidence: iStent™ Microstent

• 5-year study of 13 combined phacoemulsification and stent procedures
  – 16% IOP decrease from 19 mm Hg baseline
  – 42% of patients required no further medication¹

• Study of standalone stent implantation (n=10)
  – 27% IOP decrease after 1 year and mean reduction of medications from 2.9 to 1.8²

• Retrospective analysis of standalone stent implantation on pseudophakic patients (n=42)
  – At two years, implantation of one iStent reduced IOP from 20.26 ± 6.00 mm Hg to 13.62 ± 4.55 mm Hg (P<0.01)³

• Prospective series of patients with moderate to severe glaucoma (40% had previous glaucoma
  surgery) at 36 months post-op after iStent with CE/IOL:
  – 36% average reduction of IOP from baseline
  – 86% reduction in number of medication⁴

The Evidence: iStent™ Microstent

- Study that compared two with three stents (combined with phacoemulsification)
  - 30% pressure reduction in both groups after one year
  - Only 46% of the patients with two stents were off medication at one year versus 72% with three stents

- Study that compared one versus two versus three stents (performed as standalone)
  - 89.2% of patients with one stent, 90.2% with two stents, and 92.1% with three stents achieved IOP reduction of at least 20% with an absolute value of ≤18 mm Hg after 18 months without ocular hypotensive medications
  - With each additional stent, there was a significantly greater reduction of mean IOP (P<0.001)

Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome
Kahook Dual Blade
TRAB 360
Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty
Excrimer Laser Trabeculotomy
iStent™ Inject
Glaukos Corporation, Laguna Hills, CA

• Single-piece, heparin-coated, gamma-sterilized titanium device

• Up to two devices can be injected with a single auto-injector device, requiring the surgeon to enter the eye fewer times and thus reducing the risk of complications

• Approved for use in Europe and, as of June 2018, in the United States for patients with mild to moderate glaucoma undergoing cataract surgery

https://www.glaukos.com/healthcare-professionals/istent-inject/
https://www.aao.org/headline/glaukos-istent-inject-finally-wins-fda-approval
The Evidence: iStent™ Inject

• Prospective, unmasked clinical trial in Europe with two stents per patient
  – 66% of patients had IOP ≤18 mm Hg without ocular hypotensive medications
  – 88% of patients had IOP ≤18 mm Hg regardless of ocular hypotensive medication use
  – 71.7% of patients required at least two fewer medications

• Prospective, unmasked clinical trial of two stents versus two ocular hypotensive medications; at 12 months:
  – 94.7% of patients in the study group and 91.8% of patients in the control group had unmedicated IOP reduction of ≥20% compared to a washed-out baseline
  – 53.2% of patients in the study group and 35.7% of patients in the control group had an unmedicated IOP reduction of more than 50% from a washed-out baseline (P=0.02)

The Evidence: iStent™ Inject

• In a study that included patients with POAG and PXG, average IOP decreased by 33% (P<0.001) and 35% (P<0.001) respectively six months post-operatively following placement of two stents
  – In both groups, there were also significant reductions in the number of required medications

• In a comparative study versus the Trabectome, with each patient undergoing CE/IOL + Trabectome in one eye and CE/IOL + two iStent Injects in the contralateral eye, the IOP-lowering effects and safety profiles of both groups were similar

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The Evidence: iStent™ Inject

- Pivotal trial comparing CE/IOL + two iStent Inject versus CE/IOL alone (n=505)
  - At 24 months, 75.3% of patients in the stent group and 61.9% in the control group achieved unmedicated IOP reduction of ≥20% compared to baseline (P=0.004)
  - At 24 months, the mean unmedicated IOP reduction in the stent and control groups were 6.9 mm Hg and 5.4 mm Hg, respectively
  - The groups had similar safety profiles

https://www.glaukos.com/healthcare-professionals/clinical-data/
The Evidence: iStent™ Inject

- Study following the outcomes of patients for 36 months post-operatively following iStent inject implantation (n=81)

Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome
Kahook Dual Blade
TRAB 360
Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty
Excrimer Laser Trabeculotomy
Hydrus™ Microstent
Ivantis Inc., Irvine, CA

- Crescent-shaped device inserted via preloaded handheld injector
- Dilates SC up to three clock hours and bypasses the trabecular meshwork
The Evidence: Hydrus™ Microstent

- Human cadaver eyes (N=21)
- Anterior segment perfusion
- 14 eyes were implanted with an 8mm Hydrus Microstent
- 7 contralateral eyes controls
- The Hydrus microstent significantly increased C and by bypassing the TM and dilating SC, allowing more flow into SC and the episcleral veins
- Implantation did not cause obvious damage to the inner wall of SC beyond the microstent entry point into the TM

The Evidence: Hydrus™ Microstent

• Preliminary data on 28 patients
  – After 6 months, combined phacoemulsification and stent insertion resulted in approximately a 15% decrease in IOP from a baseline of 18 mm Hg, while medications decreased from 2.4 to 0.1
  – Another preliminary study found an approximately 35% decrease in IOP from 25 mm Hg (measured after medication washout) at 12 months
  – The two most common complications were transient hyphema in 15% and PAS formation in 10% of patients

The Evidence: Hydrus™ Microstent

• HYDRUS II randomized controlled trial studied subjects with a combined CE/IOL + Hydrus procedure versus CE/IOL alone over a period of up to two years (n=50)
  – At 24 months, the mean postoperative IOP was significantly lower for the Hydrus group (16.9 mm Hg) than the control group (19.2 mm Hg, P=0.0093)
  – 80% of subjects in the Hydrus group had ≥20% reduction in washed-out diurnal IOP versus 46% in the control group (P=0.0008)\(^1\)

• Non-randomized, prospective case series of patients post-Hydrus implantation (n=31) and post-selective laser trabeculectomy (n=21)
  – The difference in IOP between the groups was not significant, but the Hydrus group had significantly greater medication reduction than the SLT group (-1.4±0.97 versus -0.5±1.05; P=0.001)

• In ≤10% of patients, there is a transient early IOP spike from baseline\(^1,2\)


The Evidence: Hydrus™ Microstent

- Randomized controlled trial of Hydrus Microstent immediately after CE/IOL versus CE/IOL alone; 369 eyes randomized to Hydrus and 187 to control
Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome
Kahook Dual Blade
TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty
Excrimer Laser Trabeculotomy
**Trabectome**

Neomedix Corp, Tustin, CA

- Most commonly used device for ab interno trabeculectomy (AIT)
- Ablates the trabecular meshwork and inner walls of SC to promote greater flow
- Utilizes high-frequency electrocautery energy
- Most common complication is hyphema

http://www.neomedix.net/Learning/Library/Images
Bipolar 550 kHz Ablation of Trabecular Meshwork

- Selective removal of primary pathology
- 200 micron plasma, pico-lightning, no heat transfer, protective footplate
AIT - Loewen
Ab Interno Trabeculectomy: Development of a Novel Device (Trabectome®) and Surgery for Open-Angle Glaucoma

Brian A. Francis, MD,* Robert F. See, MD,† Narsing A. Rao, MD,* Don S. Minckler, MD,* and George Baerveldt, MD;†

J Glaucoma 2006;15:68–73

FIGURE 4. (A) Control specimen. Intact trabecular beams of the TM (arrowheads) are seen overlying Schlemm’s canal (arrows). The peripheral cornea, TM, SC, and surrounding sclera are well preserved (H&E ×40). (B) Simulated goniotomy specimen with overlapping segments of the TM shows a clear space (arrows) between the anterior and posterior flaps of the severed TM; however, the two severed ends have returned to close approximation with one another (H&E ×100). (C) Simulated goniotomy specimen under the confocal microscope shows a 110.73-µm incision into the sclera deep to SC. The confocal microscope was used to precisely measure the structures of the angle as marked by the red lines (H&E ×50). (D) Specimen treated with 2.5W showing removal of a large section of the TM (H&E ×40).
Incision

- Start slightly on the left of insertion axis (better angle to engage TM)
- Distance from limbus 1.5 to 2 mm
- Flare the inner half of incision to extend reach
Engaging the TM

1. Engage pointing up

2. Advance strictly parallel
Keys to Success 2

- Engage slightly on left (better angle)
- Do not push during ablation (catching outer wall, myriad of collector channels)
Know Your Limits: Respect the Outer Wall

- Don’t push outward during ablation, hurting collectors
“Club 180”

90° ablation

Tilt to brow

Rotate gonio in direction of ablation (in iris plane)

90° ablation

Tilt to cheek
Trabectome: the Evidence

• Prospective, randomized clinical trials lacking in this space\(^1\)
• First prospective case series followed patients for one year post-operatively (n=37)
  – Postoperative medicated IOP of 16.3 ± 2.0 mm Hg from baseline post-washout 28.2 ± 4.4 mm Hg
  – Decrease in medication usage from 1.2 ± 0.6 to an average of 0.3 medications\(^2\)
• One large, prospective cohort study found that subjects with exfoliative glaucoma had a more robust response to the Trabectome procedure than those with POAG\(^3\)

Trabectome: the Evidence

Clinical Results with the Trabectome for Treatment of Open-Angle Glaucoma

Don S. Minckler, MD,1 George Baerveldt, MD,2 Marina Ramirez Alfaro, MD,3 Brian A. Francis, MD4

Table 2. Percent Intraocular Pressure (IOP) Reduction and Medication Use by Month

<table>
<thead>
<tr>
<th></th>
<th>IOP (mmHg) (Mean ± SD)</th>
<th>No. of Patients</th>
<th>No. of Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before IOP (no diagnosis)</td>
<td>28.2±4.4</td>
<td>3</td>
<td>0.0</td>
</tr>
<tr>
<td>Before IOP (with diagnosis)</td>
<td>22.6±4.7</td>
<td>34</td>
<td>1.2</td>
</tr>
<tr>
<td>All patients with/without medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Postoperative (1 day)</td>
<td>18.4±10.9</td>
<td>37</td>
<td>0</td>
</tr>
<tr>
<td>Postoperative (1 wk)</td>
<td>17.5±5.9</td>
<td>37</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (2 wks)</td>
<td>16.5±4.5</td>
<td>36</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (1 mo)</td>
<td>17.1±5.4</td>
<td>35</td>
<td>0.3</td>
</tr>
<tr>
<td>Postoperative (2 mo)</td>
<td>17.4±4.6</td>
<td>34</td>
<td>0.3</td>
</tr>
<tr>
<td>Postoperative (3 mo)</td>
<td>17.9±4.1</td>
<td>25</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (4 mo)</td>
<td>16.6±2.4</td>
<td>22</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (5 mo)</td>
<td>16.0±2.4</td>
<td>22</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (6 mo)</td>
<td>17.4±3.5</td>
<td>25</td>
<td>0.4</td>
</tr>
<tr>
<td>Postoperative (7 mo)</td>
<td>17.3±3.5</td>
<td>10</td>
<td>0.5</td>
</tr>
<tr>
<td>Postoperative (8 mo)</td>
<td>16.1±3.1</td>
<td>14</td>
<td>0.2</td>
</tr>
<tr>
<td>Postoperative (9 mo)</td>
<td>15.1±1.7</td>
<td>14</td>
<td>0.6</td>
</tr>
<tr>
<td>Postoperative (10 mo)</td>
<td>15.9±3.6</td>
<td>15</td>
<td>0.1</td>
</tr>
<tr>
<td>Postoperative (11 mo)</td>
<td>15.5±2.1</td>
<td>14</td>
<td>0.1</td>
</tr>
<tr>
<td>Postoperative (12 mo)</td>
<td>16.3±2.0</td>
<td>15</td>
<td>0.1</td>
</tr>
<tr>
<td>Postoperative (13 mo)</td>
<td>15.5±1.6</td>
<td>11</td>
<td>0.1</td>
</tr>
<tr>
<td>Mean±SD</td>
<td>16.7±3.8</td>
<td></td>
<td>0.3</td>
</tr>
</tbody>
</table>

SD = standard deviation.

Figure 3. Summary graph illustrating the time course of postoperative intraocular pressure (IOP) results (with standard deviation bars) below baseline mean IOP.
Trabectome: the Evidence

Kaplan-Meier plot of the probability of Success
Failure = IOP > 21 and not reduced by 20% below baseline (on 2 consecutive visits) after 2 weeks or no repeat surgeries
All subjects

![Graph showing Kaplan-Meier plot of the probability of success](image)

Francis BA, Minckler D, Dustin L, Kawji S, Yeh J, Sit A, Mosaed S, Johnstone M, and Trabectome Study Group. Combined cataract extraction and trabeculotomy by the internal approach for coexisting cataract and open-angle glaucoma: initial results. Journal of Cataract and Refractive Surgery 2008; 34(7):1096-103

Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome

Kahook Dual Blade

TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty
Excrimer Laser Trabeculotomy
Kahook Dual Blade
New World Medical, Rancho Cucamonga, CA

• Alternative method for performing ab interno trabeculectomy
• Elevates the TM prior to removal, enabling cleaner tissue removal and minimizing injury to nearby tissues

Kahook Dual Blade: the Evidence

• No randomized, controlled clinical trials have been published to date

• Preclinical studies utilizing human cadaveric tissue to compare KDB to Trabectome demonstrated more complete removal of trabecular meshwork tissue and lesser injury to surrounding tissues for KDB¹

• A multicenter study following patients who underwent CE/IOL in combination with KDB demonstrated a mean reduction in IOP of 28% at 1 year (P<0.001) and 64% of subjects had reduction of at least one medication (P<0.001)²

Kahook Dual Blade versus iStent: IOP

Figure 1 Mean with 95% confidence interval for IOP at each time point for phaco-goniotomy with KDB and phaco-iStent groups.

Abbreviations: IOP, intraocular pressure; KDB, Kahook Dual Blade; phaco, phacoemulsification; Preop, preoperative.

Figure 2 Proportion of patients with IOP reduction ≥20% from baseline at each time point.

Note: *Significant difference between both groups at an α of 0.05.

Abbreviations: IOP, intraocular pressure; KDB, Kahook Dual Blade; phaco, phacoemulsification.
Kahook Dual Blade versus iStent: Medications

**Figure 3** Mean with 95% confidence interval for IOP-lowering medications at each time point for phaco-goniotomy with KDB and phaco-iStent groups.

**Note:** *Significant difference between both treatment groups at an α of 0.05.

**Abbreviations:** IOP, intraocular pressure; KDB, Kahook Dual Blade; phaco, phacoemulsification; Preop, preoperative.

**Figure 4** Proportion of patients with the number of IOP-lowering medications reduced by ≥1 from baseline.

**Note:** *Significant difference between both groups at an α of 0.05.

**Abbreviations:** IOP, intraocular pressure; KDB, Kahook Dual Blade; phaco, phacoemulsification.
Schlemm Canal Surgery

- iStent
- iStent Inject
- Hydrus
- Trabectome
- Kahook Dual Blade

**TRAB 360**

- Gonioscopy-Assisted Transluminal Trabeculectomy
- Canaloplasty/Ab Interno Canaloplasty
- Excrimer Laser Trabeculotomy
TRAB™ 360
Sight Sciences, Menlo Park, CA

- Alternative method for performing ab interno trabeculectomy
- Designed to enable access to 360° of SC via one clear corneal incision

TRAB™ 360: the Evidence

- No randomized clinical trials to date
- Preliminary study demonstrated improvements following TRAB™ 360 procedure
  - IOP reduction from 19.8±6.4 to 13.5±4.6 mm Hg
  - Reduction in ocular hypotensive medication use from 1.1±1.2 to 0.2±0.5 medications
  - Less than one year post-operatively, 73% of patients required no medications

Schlemm Canal Surgery

- iStent
- iStent Inject
- Hydrus
- Trabectome
- Kahook Dual Blade
- TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy

- Canaloplasty/Ab Interno Canaloplasty
- Excrimer Laser Trabeculotomy
Gonioscopy-Assisted Transluminal Trabeculectomy (GATT, Glaucoma Associates of Texas)

- A method of $360^\circ$ removal of the trabecular meshwork
- A microcatheter or marked 4-0 clear nylon suture is threaded into SC via a goniotomy incision and advanced $360^\circ$
GATT: the Evidence

• No randomized controlled trials
• Preliminary study of 85 patients who underwent GATT by four surgeons
  – Overall decrease in IOP of 39.8% (-11.1±6.1 mm Hg, P<0.001) at 12 months
  – No difference in IOP reduction with or without concurrent or prior CE/IOL
  – Medication reduction of 1.1±1.8 medications at 12 months (P=0.013)¹
• Small retrospective chart review of patients with juvenile open angle glaucoma and primary congenital glaucoma demonstrated promising results in that cohort
  – Average IOP decreased from 27.3 to 14.8 mm Hg over 12 months
  – Average ocular hypotensive medication requirement decreased from 2.6 to 0.86²

Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome
Kahook Dual Blade
TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy

Canaloplasty/Ab Interno Canaloplasty
Excrimer Laser Trabeculotomy
Canaloplasty

A surgical technique that consists of conjunctival and scleral dissection to enable threading of a microcatheter into SC, dilating the canal with OVD, and placing a tensioning suture within the lumen of the canal with the aim of ultimately improving outflow.
Canaloplasty
Canaloplasty: the Evidence

Canaloplasty: Circumferential viscodilation and tensioning of Schlemm canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults

Two-year interim clinical study results

Richard A. Lewis, MD; Scott A. Wolff, MD; Mahadev Tala, MD; Mark J. Eichen, MD; John B. Kerényi, MD; Richard J. Shingleton, MD; Thomas W. Corbett, MD

Table 5A. Results in Group 1 (all included eyes).

<table>
<thead>
<tr>
<th>Exam</th>
<th>n</th>
<th>Mean IOP (mm Hg) ± SD (Range)</th>
<th>Mean Medications (n) ± SD (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>127</td>
<td>23.6 ± 4.8 (16-38)</td>
<td>1.9 ± 0.8 (0-4)</td>
</tr>
<tr>
<td>Postoperative</td>
<td>3 mo</td>
<td>88</td>
<td>15.7 ± 5.3 (7-46)</td>
</tr>
<tr>
<td></td>
<td>6 mo</td>
<td>83</td>
<td>15.6 ± 4.0 (8-28)</td>
</tr>
<tr>
<td></td>
<td>12 mo</td>
<td>101</td>
<td>15.4 ± 4.2 (8-30)</td>
</tr>
<tr>
<td></td>
<td>18 mo</td>
<td>100</td>
<td>16.1 ± 4.1 (7-27)</td>
</tr>
<tr>
<td></td>
<td>24 mo</td>
<td>106</td>
<td>16.0 ± 4.2 (7-35)</td>
</tr>
</tbody>
</table>

Table 5B. Results in Group 2 (canaloplasty alone).

<table>
<thead>
<tr>
<th>Exam</th>
<th>n</th>
<th>Mean IOP (mm Hg) ± SD (Range)</th>
<th>Mean Medications (n) ± SD (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>84</td>
<td>23.2 ± 4.0 (16-38)</td>
<td>2.0 ± 0.8 (0-4)</td>
</tr>
<tr>
<td>Postoperative</td>
<td>3 mo</td>
<td>60</td>
<td>16.5 ± 5.3 (10-46)</td>
</tr>
<tr>
<td></td>
<td>6 mo</td>
<td>53</td>
<td>16.5 ± 3.9 (8-28)</td>
</tr>
<tr>
<td></td>
<td>12 mo</td>
<td>67</td>
<td>15.7 ± 3.9 (10-29)</td>
</tr>
<tr>
<td></td>
<td>18 mo</td>
<td>68</td>
<td>16.2 ± 4.2 (7-27)</td>
</tr>
<tr>
<td></td>
<td>24 mo</td>
<td>72</td>
<td>16.3 ± 5.7 (8-28)</td>
</tr>
</tbody>
</table>

Figure 4. Group 1 efficacy (all included patients) showing mean IOP (±SD) and mean medications. The dashed line indicates the baseline IOP of 23.6 mm Hg (IOP = intraocular pressure).

Figure 5. Group 2 efficacy (canaloplasty alone) showing mean IOP (±SD) and mean medications. The dashed line indicates the baseline IOP of 23.2 mm Hg (IOP = intraocular pressure).
Canaloplasty versus trabeculectomy

- Consecutive case series
- Trabeculectomy with MMC in one eye, canaloplasty in the other
- 30 eyes of 15 patients

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Canaloplasty</th>
<th>Trabeculectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. eyes</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>OD/OS</td>
<td>8/7</td>
<td>7/8</td>
</tr>
<tr>
<td>Sex (n): male/female</td>
<td>5/10</td>
<td>5/10</td>
</tr>
<tr>
<td>Mean age (y) (range)</td>
<td>69.1 (33-86)</td>
<td>66.0 (33-84)</td>
</tr>
<tr>
<td>Preoperative visual acuity (logMAR, SD)</td>
<td>0.06 (± 0.09)</td>
<td>0.28 (± 0.56)</td>
</tr>
<tr>
<td>Postoperative visual acuity (logMAR, SD)</td>
<td>0.08 (± 0.08)</td>
<td>0.32 (± 0.53)</td>
</tr>
</tbody>
</table>

OD/OS indicate oculus dexter/oculus sinister.
Canaloplasty versus trabeculectomy

Ab Interno Canaloplasty

- In contrast to traditional canaloplasty, does not require conjunctival or scleral dissection
- Under gonioscopy, a microcatheter is inserted via an ab interno approach
- No clinical trials published to date

http://new-glaucoma-treatments.com/canaloplasty/introducing-ab-interno-canaloplasty/
Schlemm Canal Surgery

iStent
iStent Inject
Hydrus
Trabectome
Kahook Dual Blade
TRAB 360

Gonioscopy-Assisted Transluminal Trabeculectomy
Canaloplasty/Ab Interno Canaloplasty

Excrimer Laser Trabeculotomy
Excrimer Laser Trabeculotomy (ELT)

- Via an ab interno approach, an endoscopically-guided 308nm xenon chloride excimer laser creates microperforations in the trabecular meshwork
- The laser is guided under direct gonioscopy or with an endoscope
- Complications include transient hyphema and transient IOP spikes in the postoperative period

ELT: the Evidence

- Retrospective review comparing patients post-ELT alone versus ELT+CE/IOL (n=135) found phacoemulsification with ELT to be more effective than ELT alone\(^1\)

- Prospective RCT of 30 eyes comparing ELT to SLT in patients with refractory open-angle glaucoma\(^2\):

\[\text{Graph showing IOP over time for ELT vs SLT with markers indicating statistical significance.} \]

SUPRACHOROIDAL SPACE SURGERY
POLLING QUESTION

• I have performed Suprachoroidal Shunt Surgery
  – 1. Yes
  – 2. No
Suprachoroidal Space Surgery

CyPass

iStent Supra
CyPass™ Micro-stent
Alcon, Forth Worth, TX

- Flexible fenestrated microstent that is threaded through a guidewire to follow the curvature of the sclera, enabling supraciliary bypass
- Inserted via a single corneal incision with dissection under gonioscopic guidance; a cuff maintains the stent’s position in the anterior chamber
- Composed of polyimide material
CyPass™: the Evidence

- Three large clinical trials evaluated CyPass
  - CyPass Clinical Experience (CyCLE)
    - At 6 months, subjects had a 36.9% reduction in IOP; at 12 months, a reduction of 35%
    - At 12 months, 65% of patients were medication-free
    - No sight-threatening complications; most common were implant obstruction, hypotony, subsequent surgery
  - DUETTE
    - Reported IOP decrease of 34.7% and reduction in medication number by 0.8 at 12 months
    - Complications included hyphema, cataract maturation, transient IOP increase, subsequent surgery
  - COMPASS
    - Randomized controlled trial comparing CE/IOL + CyPass implantation (n=374) versus CE/IOL alone (n=131)
    - CyPass group had significantly greater IOP reduction and threefold reduction in medication burden
    - Adverse events were comparable to phacoemulsification alone

1. U.S. National Institutes of Health Clinical Trials. CyPass Clinical Experience (CyCLE) study. NCT01097174
CyPass™ Voluntary Withdrawal from Market

- August 29, 2018: Alcon announced immediate withdrawal from the global market
- September 14, 2018: FDA issued safety communication regarding the risk of damage to corneal endothelial cells following CyPass implantation
- Preliminary results from FDA-mandated 5-year follow-up study were concerning:
  - At 5 years, 27.2% of patients had >30% loss in endothelial cell density
  - From years two to five post-operation, correlation between the length of stent in the anterior chamber (as measured by the number of visible retention rings) and the rate of endothelial cell loss

<table>
<thead>
<tr>
<th>Visible Retention Rings</th>
<th>Mean Loss in Endothelial Cell Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (n=55)</td>
<td>3.1%</td>
</tr>
<tr>
<td>1 (n=65)</td>
<td>8.4%</td>
</tr>
<tr>
<td>2 (n=26)</td>
<td>21.0%</td>
</tr>
<tr>
<td>3 (n=8)</td>
<td>31.4%</td>
</tr>
</tbody>
</table>
Suprachoroidal Space Surgery

CyPass

iStent Supra
iStent™ Supra
Glaukos Corporation, CA, USA

• Investigational device similar to CyPass
• Implanted via ab interno approach
• Composed of polyethersulfone and titanium
• CE-approved but not yet FDA-approved; currently undergoing Phase III clinical trials in the US in combination with CE/IOL
• Preliminary studies show a 98% success rate of achieving IOP reduction ≤20% in combination with post-operative travoprost

Jünemann A. Twelve-month Outcomes Following Ab Interno Implantation of Suprachoroidal Stent and Postoperative Administration of Travoprost to Treat Open Angle Glaucoma. Poster session presented at European Society of Cataract & Refractive Surgeons (ESCRS); Oct 2013; Available at: http://escrs.org/amsterdam2013/programme/posters-details.asp?id=19512
http://eyewiki.aao.org/Suprachoroidal_Devices#iStent_Suprachoroidal_Bypass_System._28iStent_Supra.29
REDUCING AQUEOUS PRODUCTION
Reducing Aqueous Production

Endocyclophotocoagulation
POLLING QUESTION

- I have performed Endocyclophotocoagulation
  - 1. Yes
  - 2. No
Endocyclophothotoacoagulation (ECP)

- FDA-approved procedure consisting of an ab interno approach to diode laser coagulation of the ciliary processes, causing cyclocoagulation and reducing aqueous production
- Laser endoscope probe (Endo Optiks, Little Silver, New Jersey) ablates between 270-360º with a power ranging from 0.25-0.4W
- IOP reduction correlates with clock hours treated
- Useful in both open and narrow angle glaucoma, as the resultant shrinking of tissue can reshape the angle

ECP: the Evidence

- No randomized controlled trials have compared ECP to traditional transscleral cyclophotocoagulation, but complication rates of ECP are lower in observational studies\(^1\).

- Studies comparing ECP to traditional glaucoma surgeries have found that inflammation is relatively lower with ECP+CE/IOL compared to trabeculectomy+CE/IOL\(^2\) and that, compared to a tube shunt procedure, ECP alone has similar outcomes and decreased complications\(^3\).

- Complications of ECP can be more severe than with other MIGS; in a group of 261 eyes, complications included cystoid macular edema (n=4), retinal detachment (n=2), and corneal injury requiring transplant(n=1)\(^4\).

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ECP: the Evidence

- Prospective, non-randomized, case-matched study comparing ECP+CE/IOL versus CE/IOL alone in patients with medically-controlled glaucoma (n=80)
  - Success defined as IOP between 5 and 21 mm Hg and reduction in glaucoma medications without elevation in IOP relative to baseline

ECP: the Evidence

- Retrospective chart review comparing eyes following ECP+CE/IOL versus ECP alone over 36 months
BLEB FORMING SURGERY
POLLING QUESTION

• I have performed Bleb Forming Surgery other than trabeculectomy
  – 1. Yes
  – 2. No
Bleb Forming Surgery

XEN-45 Gel Stent
InnFocus Micro Shunt
XEN-45 Gel Stent
Allergan, Parsippany, NJ

• Hydrophilic collagen tube with a 45-micron lumen, becomes flexible when hydrated. Diameter was selected to minimize risk of hypotony

• Pre-loaded in an injector for ab interno implantation into the subconjunctival space, emerging 3mm from the limbus to create an artificial drainage pathway

• Bleb formation confirmed at the conclusion of surgery

• In contrast to trabeculectomy and tube shunts, avoids conjunctival disruption

• Option to use antimetabolite (e.g., MMC)

https://www.xengelstent.com/XENGelStent
XEN-45 Gel Stent: The Evidence

• Early prospective studies utilized XEN-63 and XEN-140 (lumens of 63 and 140 microns respectively), which are not currently recommended by the manufacturer\(^1,2\)

• Initial study of 31 eyes post-XEN-45 implantation demonstrated promising results and no complications
  – At 12 months, IOP decrease from 20.8 ± 4.6 to 13.1 ± 3.6 (P<0.001)
  – At 12 months, reduction in medications from 2.71±1 to 0.9±1.1 (P<0.001)\(^3\)

• Small prospective nonrandomized case series of 30 subjects with open-angle glaucoma who underwent XEN-45 implantation with MMC + CE/IOL (n=30)
  – At 12 months, IOP decreased from a medicated baseline by 34% with a reduction in medications of nearly 95% and minimal complications\(^4\)

• Additional data is needed to establish the incidence of postoperative encapsulation

## InnFocus MicroShunt: The Evidence

**Table 2. InnFocus MicroShunt**

<table>
<thead>
<tr>
<th>Authors*</th>
<th>Type of study</th>
<th>Potential conflicts of interest</th>
<th>Primary cohort</th>
<th>Comparison cohort</th>
<th>Study duration</th>
<th>Number of eyes</th>
<th>Combined with CEIOL</th>
<th>Mitomycin C application</th>
<th>Preop IOP (mean ± SD)</th>
<th>Preop meds (mean ± SD)</th>
<th>Postop IOP (mean ± SD)</th>
<th>Postop meds (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckers et al. [26]</td>
<td>Retrospective abstract</td>
<td>Disclosures not published in abstract, but several authors with known financial ties to InnFocus from other studies</td>
<td>Primary OAG (France, Dominican Republic, and Netherlands)</td>
<td>None</td>
<td>12 months</td>
<td>91</td>
<td>19.78%</td>
<td>0.2–0.4mg/ml for 2–3 min</td>
<td>24.3 ± 5.9</td>
<td>2.4 ± 1.3</td>
<td>13.3 ± 4.0</td>
<td>0.40 ± 1.0</td>
</tr>
<tr>
<td>Riss et al. [25]**</td>
<td>Retrospective observational pilot study</td>
<td>Several authors with financial ties to InnFocus</td>
<td>Primary OAG (France and Dominican Republic)</td>
<td>None; but compared subgroups based on concentration and location of MMC</td>
<td>12 months</td>
<td>87</td>
<td>24.14%</td>
<td>0.2–0.4mg/ml at limbus or deeper in conjunctival pocket for 2–3 min</td>
<td>25.9 ± 7.0</td>
<td>2.6 ± 1.1</td>
<td>13.5 ± 3.7</td>
<td>0.56 ± 1.1</td>
</tr>
<tr>
<td>Battie et al. [27]**</td>
<td>Prospective, noncomparative</td>
<td>InnFocus sponsored study with several authors having financial ties to InnFocus</td>
<td>Primary OAG (Dominican Republic)</td>
<td>None</td>
<td>36 months</td>
<td>23</td>
<td>39.10%</td>
<td>0.4mg/ml for 3 min</td>
<td>23.8 ± 5.3</td>
<td>2.4 ± 0.9</td>
<td>10.7 ± 2.8</td>
<td>0.7 ± 1.1</td>
</tr>
</tbody>
</table>

Brief summary of published data: CEIOL, cataract extraction with placement of intraocular lens; IOP, intraocular pressure; MMC, mitomycin C; postop, postoperative; prep, preoperative.

*Pinchuk et al. [26] is not included as a separate study as it has 2-year data that is entirely duplicated in the Battie et al. [27]** 3-year results.

**Study includes a subgroup with 1-year data also included in the Battie et al. [27]** 3-year results.

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**Review of the Xen Gel Stent and InnFocus MicroShunt**

Wesley Green, John T. Lind, and Arsham Sheybani
IMPACT
Who is a candidate for MIGS?

- Early to moderate open-angle glaucoma
  - Target IOP in mid- to high-teens
    - iStent
    - iStent Inject
    - Hydrus
    - Trabectome
    - Kahook Dual Blade
    - TRAB 360
    - Gonioscopy-Assisted Transluminal Trabeculectomy
    - Canaloplasty/Ab Interno Canaloplasty
    - Excimer Laser Trabeculotomy
Ab Interno Schlemm Canal Surgeries

- Ab interno Schlemm Canal surgeries offer a controlled means for lowering IOP with less risk than trabeculectomy or glaucoma drainage device implantation.
- The trade-off is somewhat less IOP reduction than more invasive glaucoma procedures.
- The safety of ab interno SC surgery allows implementation of these procedures earlier in the treatment regimen.
- Efficacy issues restrict patient selection for ab interno SC surgery to mild to moderate glaucoma.
Who is a candidate for MIGS?

• Moderate to Advanced Glaucoma
  – Target IOP low- to mid-teens
    • XEN Gel Stent
    • InnFocus MicroShunt
Which MIGS is best for which patient?

This patient – Schlemm Canal based surgery

Bleb Forming Surgery would be the best choice in this patient
THANK YOU