Microinvasive Glaucoma Surgery (MIGS)

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New York University
New York Eye Surgical Center
WAEPS April 1, 2016
## Financial Disclosures

<table>
<thead>
<tr>
<th>Commercial Interest</th>
<th>Nature of Relevant Financial Relationship (Include all those that apply)</th>
<th>What was received?</th>
<th>For what role?</th>
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<td>Example: Company ‘X’</td>
<td>Honorarium, salary, etc.</td>
<td>Speaker, consulting, etc.</td>
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<td>Allergan, Iridex, Alimera,</td>
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<td>Year</td>
<td>Name</td>
<td>Procedure</td>
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<tr>
<td>1867</td>
<td>de Wecker</td>
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<td>Iridencleisis</td>
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<td>1906</td>
<td>Heine</td>
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<td>Horse hair shunt</td>
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<td>Latina</td>
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<td>Canaloplasty</td>
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<td>2005</td>
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<td>Ex-Press Glaucoma Filtration Device (under scleral flap; Alcon Laboratories, Inc.)</td>
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<td>Solx Gold Shunt (suprachoroidal; Solx, Inc.)</td>
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# Glaucoma Surgery Trends 1994-2012

<table>
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<tr>
<th>Surgery</th>
<th>1994</th>
<th>2012</th>
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<tr>
<td>Trabeculectomy</td>
<td>54,000</td>
<td>12,000</td>
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<tr>
<td>Ex-Press®</td>
<td>0</td>
<td>5,870</td>
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<tr>
<td>Tubes</td>
<td>2,400</td>
<td>12,000</td>
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<td>Cyclophotocoag</td>
<td>5,383</td>
<td>10,728</td>
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<td>iStent®</td>
<td>0</td>
<td>?36,000 (2014)</td>
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<tr>
<td>Trabeculoplasties</td>
<td>150,000</td>
<td>142,682</td>
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Problems With Traditional Glaucoma Surgery
Blebitis
Overhanging/Painful Bleb
Clogged Tube
What About Mild Glaucoma?

IOP 21 mm Hg OU, down to 16 mm Hg on latanoprost
Ideal Glaucoma Surgery?

- As effective as trabeculectomy, with better safety
- Reproducible/predictable
- Avoid a bleb/infection
- Easy to perform
- Less post-op time & effort
- Rapid visual recovery
- Cost effective
Microinvasive Glaucoma Surgery (MIGS)

- Ab-interno microincisional approach
- Minimally traumatic to the target tissue
- Safe and efficacious (at least modest) IOP reduction
- Rapid recovery with minimal impact on the patient’s quality of life
- Typically indicated for mild to moderate POAG
- iStent® FDA approved 2012

The Outflow Pathway
iStent® Trabecular Micro-Bypass Stent

- FDA approved 2012 (Glaukos Corporation, Laguna Hills, CA)
- Made of nonferromagnetic titanium
- Length: 1 mm; Height: 0.33 mm
- Snorkel: 0.25 mm x 120 µm (bore diameter); 60 µg in weight
- Heparin-coated to promote self-priming and to facilitate flow
iStent® (Glaukos, Inc.)
At 12 months, 68% of iStent® + cataract patients with IOP ≤ 21 mm Hg without medication vs 50% with cataract surgery alone (P = 0.004)
At 12 months, 15% of iStent® vs 35% of cataract group on medication ($P = 0.001$)
iStent® Video
Ab-interno Viscocanalostomy

- The Sight Sciences VISCO360 Viscosurgical System is indicated for the delivery of small amounts of viscoelastic fluid.

- The instrument features:
  - A curved cannula
  - A soft and flexible injection tube/filament
  - A handle with an internal infusion pump and viscoelastic reservoir
  - A control wheel that advances and retracts the flexible injection tube
Viscocanalostomy
(Visco360, Sight Sciences)
Ab-interno Trabeculotomy

- Gonioscopy-assisted transilluminated trabeculotomoy (GATT) uses a flexible microcatheter (iTrack® 250A, Ellex) from an ab-interno approach to enter and open the circumference of the canal.

- The TRAB360 surgical instrument (Sight Sciences) is a “trabeculotome,” a non-powered instrument intended for the manual cutting of the trabecular meshwork, or trabeculotomy.

- TRAB360 can be used to mechanically cut up to 360 degrees of trabecular meshwork.
360° Trabeculotomy
(Trab360, Sight Sciences)
GATT Procedure
Gonioscopy-assisted Transilluminated Trabeculotomy (GATT)

- Ab-interno circumferential 360-degree trabeculotomy performed with the Ellex illuminated microcatheter
  - FDA cleared in 2008

- Grover and colleagues performed GATT on 57 patients and saw 7.7 mm Hg (30%) IOP reduction with 0.9 fewer medications at 6 months
  - Additional glaucoma surgery was needed in 9% of patients
  - 30% of patients had a hyphema at 1 week

1. iScience 510(K) Summary. Available at: ihttp://www.accessdata.fda.gov/cdrh_docs/pdf8/K080067.pdf.;
Ab-interno Trabeculotomy

- Ab-interno trabeculotomy performed with a dual-bladed instrument—Kahook Dual Blade™ (New World Medical)
- The instrument is designed to excise (not just incise) a strip of TM and Schlemm’s canal outer wall
- Potential advantages include potentially lower rate of fibrosis due to lack of TM leaflets left behind, potentially lower costs

Goniotomy
(Kahook Dual Blade™, NWM)
Trabectome® (Neomedix)

- **Trabectome® (NeoMedix)**—Trabectome ablates and removes a strip of trabecular meshwork and re-establishes access to the eye’s primary outflow pathway.
Ab Interno Trabeculectomy Versus Trabeculectomy for Open-Angle Glaucoma

Seung Youn Jea, MD, PhD,1 Brian A. Francis, MD, MS,2 Ghazal Vakili, MD,2 Theodoros Filippopoulos, MD,1 Douglas J. Rhee, MD1

• Review of 115 patients who underwent ab-interno trabeculectomy (Trabectome®; NeoMedix, Inc., Tustin, CA) compared with 102 patients who underwent trabeculectomy MMC
• The success rates (IOP < 21 mm Hg or > 20% reduction) at 2 years were 22.4% for Trabectome® and 76.1% for trabeculectomy (P = 0.001)
• Trabectome® had 100% hyphema POD #1, plus 4.3% other complications, compared to 35.3% complication rate for trabeculectomy (P = .001)

Endocyclophotocoagulation (ECP)

- ECP is the selective ablation of aqueous producing ciliary processes via an ab-interno approach
- Inhibits aqueous production, therefore reducing IOP and medication use
- ECP has been performed globally for over 12 years
- More than 50,000 patients treated to date
Aquesys Xen™ Implant
Xen gel stent maintains reduced IOP at 1 year

September 8, 2015

BARCELONA — Reduced IOP and reduced need for medications was maintained at 1 year after implantation of the Xen gel stent, according to a speaker here.

“"We like to call the AqueSys Xen gel stent a hybrid system," Ingeborg Stalmans, MD, PhD, said at the European Society of Cataract and Refractive Surgeons meeting. The ab interno glaucoma device is less invasive than trabeculectomy, but also targets the subconjunctival space as trabeculectomy does.

"AqueSys attempted to combine the best of both worlds and design a stent that gives you a less invasive surgery and maintains the efficacy," she said.

Stalmans shared results from a prospective, nonrandomized, multicenter study, which included 63 patients with primary open angle glaucoma, pigmentary glaucoma or pseudoexfoliative glaucoma who were implanted with the gel stent.

Mean IOP preoperatively was 22.1 mm Hg. Mean IOP postoperatively 1 year was 12.9 mm Hg. Mean number of medications preoperatively was 2.8. Mean number of medications postoperatively 1 year was 1.1.

See Also
AqueSys completes enrollment for clinical trial of Xen 45 gel ...
Xen 45 gel stent with MMC may be combined with cataract ...
Ab interno collagen stent offers minimally invasive aqueous ...
A recent appreciation for the risks and complications associated with traditional glaucoma surgery has ignited the ab-interno revolution.

We now have several ab-interno options for both outflow and inflow treatments.

Overall a generally favorable safety profile with moderate efficacy.

Traditional glaucoma surgery still has a role in advanced glaucoma.
Thank You!