OUTLINE

- Review of Anatomy
- Review of devices and various considerations
- Research around the devices and success

WHAT ARE MIGS?

- Minimally invasive glaucoma surgeries (microinvasive ?)

  - Cardinal features as proposed by Saheb and Ahmed in 2012
    - Ab interno, micro-incisional approach (*note: Some use an ab-externo approach.)
    - Minimal trauma/disruption to normal anatomy and physiology
    - Demonstrable/reliable IOP lowering
    - Minimal trauma/disruption to normal anatomy and physiology
    - Extremely high safety profile
    - Rapid post-op recovery, with minimal need for follow-up

  - MIGS typically require shorter operation time and allow for more rapid recovery.
  - MIGS can be combined with/without cataract extraction for patients with mild to moderate glaucoma and cataracts.
  - OAG, or other types like exfoliation and pigment dispersion cases
  - MIGS may be less effective in lowering IOP than traditional glaucoma surgeries.
  - MIGS do fill a gap in the treatment of patients who would benefit from lower IOP but do not warrant the risk of traditional surgery.
  - Decrease medication use
  - Combined with cataract
**WHY MIGS?**

- Increase Trabecular Outflow
  - iStent and iStent inject
  - Trabectome
  - Kahook Blade
  - Hydrus Microstent
- Increase Uveoscleral Outflow
  - Cypass (withdrawn)
  - iStent Supra (not approved)
- Reduce Aqueous Production
  - Endoscopic photocoagulation ECP
- Subconjunctival Filtration
  - Xen Gel Stent
- Ab Externo
  - Inn Focus (not approved)
  - Ahmed Shunt
- Ab interno insertion into Schlemm's canal
- The iStent (or trabecular microbypass stent) direct channel into Schlemm canal and the subsequent collector channels.
- Safe with MRI testing up to 3 tesla

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**ISTENT**

- First implant 2006
- Heparin-coated, non-ferromagnetic titanium stent; 1.0 mm x 0.3 mm.
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**ISTENT – FIRST GENERATION**

- 26-gauge disposable insertion instrument
- right or left-handed model
- The heparin coating helps to prevent blockage or fibrosis
- Three retention arches ensure that the device will be held in place
- It is 1.0 mm in length,
  - 0.33 mm in height,
  - weight of 60 mg.
- The snorkel has a length of 0.25 mm and bore diameter of 120 micro meter.

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**Randomized Evaluation of the Trabecular Micro-Bypass Stent with Phacoemulsification in Patients with Glaucoma and Cataract**

- Primary endpoint unmedicated IOP ≤21 mmHg at 1 year
  - 72% of treatment eyes versus 50% of control eyes
- Secondary endpoint unmedicated 20% reduction in IOP
  - 66% percent of treatment eyes versus 48% of control eyes
- IOP ≤21 mmHg
- IOP ≥20% drop
Meta-analysis of 32 publications
- Sample size 2495
- Phaco vs Phaco with 1 stent vs Phaco with 2 stents
- Percentage reduction in IOP from baseline
- Phaco A 4% IOP reduction (IOPR%)
- Phaco + 1 stent 9%
- Phaco + 2 stents implants 27%


- Significant difference between treatment and control group
- Control group: Phaco only IOP was increased
- Treatment group Stent with Phaco IOP remained stable

Apical head (230 microns in width) connected to a narrow thorax that is attached to a wider flange.
- The head is inserted directly into the canal without the necessity to adjust the angle for implantation.
- It resides within the canal and contains 4 inlets for fluid passage.
- The 23-gauge stainless steel injector contains 2 stents for implantation
- heparin-coated polyethersulfone and a titanium sleeve.
- Ab interno implantation into the suprachoroidal space
- Not available

The device is Crescent-shaped scaffold that is open posteriorly
- "intracanalicular scaffold" for Schlemm’s canal and a bypass of the TM
- nickel-titanium alloy (nitinol)
- Contains three windows along its 8mm length.
- With or without phacoemulsification
- One quadrant of Schlemm’s canal

The device is implanted through the trabecular meshwork using a manual inserter.
- The device is designed for an interno placement through the TM into the Schlemm’s canal.
- The inlet segment of the device resides in the AC, while the remaining length of the stent dilates and scaffolds a quadrant of the Schlemm’s.
- Preclinical studies suggest that Schlemm’s canal scaffolding over a quadrant provides access to multiple collector channels.
A Schlemm Canal Microstent for Intraocular Pressure Reduction in Primary Open-Angle Glaucoma and Cataract

The HORIZON Study

- 1 day, 1 week, and 1, 3, 6, 12, 18, and 24 months postoperatively.
- Primary end point: proportion of subjects demonstrating a ≥20% reduction in unmedicated modified diurnal IOP (MDIOP).
- Secondary endpoint: change in mean MDIOP from baseline at 24 months.

- 388 eyes: Hydrus Micro Stent (HMS) group.
- 183 eyes: control (no stent).

HORIZON RESULTS

- At 12 months and 24 months, unmedicated modified diurnal IOP was reduced by 20%.

- Modified Diurnal Intraocular Pressure.

- 4 ± 2 hours apart between 8AM and 4PM (ANSI Z80.27 guidance for MIGS investigational studies).

HORIZON RESULTS MODIFIED DIURNAL IOP

- The modified diurnal IOP reduction in 24-month unmedicated MDIOP.

HORIZON MEDICATIONS FREE SUBJECTS

A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma

The COMPARE Study

- 114 eyes of 114 individuals
- 1:1 randomization
- Hydrus Versus iStent

THE COMPARE STUDY RESULTS

A. IOP at 12 Months

B. Mediations at 12 Months

Difference in Change

- Normal
- 2 Months
- 1 Month
Failure was defined as any secondary glaucoma surgery, intraocular pressure (IOP) >18 mmHg, or use of hypotensive medications on 2 consecutive visits after the 1-month follow-up visit.

Medication use was reduced by a greater margin or eliminated completely more frequently in the Hydrus group (46.6% vs. 24.0%, \(P=0.006\)). Among eyes without medications, Hydrus achieved an IOP >18 mmHg more often (30.1% vs. 9.3%, \(P<0.001\)).

At 12 months, mean IOP was reduced in the Hydrus group concurrently with elimination of 1.6 medications; in the 2-iStent group IOP was maintained at preoperative levels concurrently with reduction of 1.0 medication.

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TRABECTOME

- The Trabectome removes a strip of trabecular meshwork and inner wall of Schlemm’s canal using high frequency electrosurgery.
- Up to 180 degree
- The 19.5-gauge handpiece incorporates an unraveled footplate that enters Schlemm’s canal through the trabecular meshwork.
- An irrigation port keeps the anterior chamber formed and dissipates heat, and an aspiration port is adjacent to the cautery electrode.

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Prospective randomized controlled trial of phaco-trabectome versus phaco-trabeculectomy in patients with open angle glaucoma

Jessica L.M. Ting, MD, Christopher J. Reddy, MD, MPH, Karen F. Davari, MD, MBA

- Small sample RCT.
TRAB 360 (SIGHTSCIENCES)

- TRAB 360 is a disposable, non-powered device used to perform an ab interno 360° trabeculotomy.
- The TRAB 360 device consists of a cannula, from which a flexible nylon-like trabeculotome is advanced into Schlemm's canal for 180 degrees.
- After the trabeculotomy is created, the trabeculotome can be retracted once and then advanced into the remainder of Schlemm's canal in the opposite direction for up to a total of 360 degrees.

ENDOCYCLOPHOTOCOAGULATION (ECP)

- ECP consists of cyclodestruction of the ciliary body epithelium to reduce aqueous production and therefore IOP.
- The ECP probe is a reusable device, which includes a laser source, camera, and light source.
- The probe directed towards the anterior ciliary processes delivers continuous energy (810 nm wavelength) for successful photocoagulation.
- Localized shrinkage and whitening of the processes
- Through a single corneal incision, approximately 300-500 degrees of the ciliary processes can be treated.
- A single laser treatment is needed for a 360-degree treatment
- As expected, the greater the amount of processes treated, the greater the reduction in IOP and need for glaucoma medications.

XEN GEL STENT

- A glaucoma implant designed to reduce intraocular pressure in eyes suffering from refractory glaucoma.
- 6-mm length, 45-micron inner diameter—about the length of an eyelash.
- Composed of gelatin, cross-linked with glutaraldehyde.
- Creates a permanent channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space.

EXCIMER LASER TRABECULOSTOMY

- Excimer laser trabeculostomy (ELT) creates small holes in the trabecular meshwork and inner wall of Schlemm's canal.
- Energy from a quartz fiberoptic probe connected to a xenon chloride pulsed excimer laser.
- Eight to 10 laser punctures are spaced over 90-degree, with visible whitening of the trabecular meshwork and bubble formation.

AB INTERNO CANALOPLASTY

- Ab interno canaloplasty (ABIC) increases aqueous outflow through cannulation of Schlemm's canal with an illuminated microcatheter (iTrack, Ellex).
- An epithelial microincision device is injected to vesciculate Schlemm's canal and the proximal collector channels.
- It has been theorized that vescication may also create microperforations within the TM to aid in aqueous outflow.
- As the viscoelastic is injected, blanching of episcleral vessels, which is indicative of a patent collecting system, serves as an indirect indicator of success.
- Indications for ABIC include mild to moderate OAG when maximal medical management and laser trabeculoplasty have failed.

CONTRAINDICATIONS

- Required anticoagulation, bleeding diatheses, angle closure, obscured angle structures, severe endothelial compromise, or intraocular lens instability.
- Relative contraindications include previous corneal transplant and an inability to elevate patient's head 30° during the first postoperative week.
The CyPass implant is made of polyamide material.

Inserted ab interno into the suprachoroidal space through a manual inserter.

This RCT demonstrated safe and sustained 2-year reduction in IOP and glaucoma medication use after microinterventional surgical treatment for mild-to-moderate POAG.

505 subjects

131 were randomized to the control

374 were randomized to the microstent group

Decrease 7.4 mmHg for the microstent group versus 5.4 mmHg in controls (P < 0.001), with 85% of microstent subjects not requiring IOP medications at 24 months.

3 year extension trial

Insisted by FDA during approval

282 included 253 completed

Routine gonioscopy is needed

Look for edema or guttata.
CYPASS MICRO-STENT POSITION ADJUSTMENT OR REMOVAL

- “Situations that may merit consideration of CyPass Micro-Stent position adjustment or removal include, but are not limited to: intermittent or persistent contact between the CyPass Micro-Stent and the corneal endothelium; significant decrease in endothelial cell density that appears related to CyPass Micro-Stent positioning or stability; iris-cornea touch; persistent hypotony; persistent uncontrolled uveitis; recurrent or persistent hyphema with IOP elevation above target pressure; or any anatomic or functional clinical sequelae of the anterior or posterior segment that may cause a threat to vision.”

- Minimal trauma, high efficacy, high safety profile, and rapid recovery.
- There is an increasing interest and availability of MIGS procedures.
- Important to have good science and long-term follow-up data.
- MIGS devices may offer benefits to our patients with glaucoma
  - through IOP reduction
  - reduced need for glaucoma medications
  - high safety profile.
- MIGS are here to stay for the foreseeable future and its role increasing.

SUMMARY

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EFFECTIVENESS OF MIGS

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