Current Advancements in Micro-invasive Glaucoma Surgery (MIGS)

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Course Objectives

- 1) Discuss the current knowledge base and utilization of MIGS procedures in The US and abroad
- 2) Review aqueous outflow pathways to identify mechanisms of action for various MIGS technologies
- 3) Briefly discuss the Glaukos iStent inject study
- 4) Review the literature regarding the next generations of MIGS procedures
Minimally Invasive Glaucoma Surgery

- Improve pressure-dependent aqueous outflow by bypassing or ablating the trabecular meshwork
- OR – create alternative drainage routes to the suprachoroidal or subconjunctival space

- Definitions?
- Goals?
Surgical Outflow Targets
Surgical Outflow Targets

MIGS devices can be used to restore outflow through:

<table>
<thead>
<tr>
<th>Outflow Pathway</th>
<th>Disease State</th>
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<tbody>
<tr>
<td>Trabecular Meshwork</td>
<td>Mild-to-Moderate</td>
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<tr>
<td>Suprachoroidal Space</td>
<td>Progressive</td>
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<tr>
<td>Subconjunctival Space</td>
<td>Refractory</td>
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</tbody>
</table>
MIGS or Not?

**MIGS**
- Schlemm’s canal microstents
- Suprachoroidal microstents
- Subconjunctival microstents
- Ab-interno trabeculectomy
- GATT
- Goniotomy

**Not MIGS?**
- Endocyclophotocoagulation
- Iridex cyclo G6 micropulse laser
- Canaloplasty
- Gold microshunt
- Innfocus microshunt
- ExPress shunt
Patient Selection

Current Patient Profiles

MIGS
- Mild/Moderate Disease
- Hypertensive glaucoma
- Open angle
- Modest IOP target (~15-16 mmHg)
- Able to tolerate meds if needed

MIGS
- Advanced disease
- Progressive normotensive glaucoma
- Open or closed angle
- Low IOP target (<12 mmHg)
- Intolerant to medications
Emergence of MIGS
Schlemm’s Canal

Glaukos iStent®
- Single or multiple stents

US IDE: Single Stent

Primary Endpoint: IOP ≤ 21 mmHg w/o medication (n = 240)*
Secondary Endpoint: IOP Reduction ≥ 20% w/o medication (n = 240)*

23% more iStent® subjects met primary endpoint; Primary endpoint considered to be normal IOP
20% more iStent® subjects met secondary endpoint; Secondary endpoint considered AAO standard of care

Phaco vs Phaco/iStent

  - % IOP reduction
    - 4% for Phaco alone
    - 9% for Phaco + single iStent
    - 27% for Phaco + 2 iStents
  - Weighted mean reduction in # glaucoma medications
    - 1.01 for phacoemulsification alone
    - 1.33 for phaco + single iStent
    - 1.1 for phaco + 2 iStents
  - Significant heterogeneity across studies, but forest plots suggest benefit with Phaco/iStent compared to phacoemulsification alone
Solo iStent


% IOP reduction
- 22% with single iStent (at 18mo)
- 30% with 2 iStents (at 6mo)
- 40% with 3 iStents (at 6mo)

Weighted mean reduction in # glaucoma medications
- 1.2 for single iStent (at 18mo)
- 1.45 for 2 iStents (at 6mo)
- 1 for 3 iStents (at 6mo)
iStent Inject

- 2nd generation device
- 0.4mm by 0.3mm – titanium with heparin coating
iStent video

- https://www.youtube.com/watch?v=ocTZJYifvQ0
- Video courtesy of Ike Ahmed, MD
Clinical Ophthalmology 2014- Italy
- OAG patients randomized to placement of 2 iStent inject devices vs latanoprost/timolol
- ≥20% from baseline IOP at 12 months
  - iStent inject = 94.7% of patients off medication
  - Medication group = 91.8% of patients
- IOP ≤18 mmHg
  - iStent inject = 92.6%
  - Medications = 89.8%
- Mean IOP reduction of 8.1 vs 7.3 mmHg (iStent vs meds)

Multiple iStents – TARGETED DELIVERY – goal to hit aqueous veins
- Aqueous collector veins – drain aqueous fluid at 1uL/min (forms at 2-3 uL/min)
- Targeting 2 should theoretically lower IOP at or near episcleral venous pressure
- Gonio – focal blood reflux OR increased segmental TM pigmentation
GLAUKOS STUDY

**Multicenter Investigation of Trabecular Micro-Bypass Stents vs. Laser Trabeculoplasty**

- Randomized interventional trial evaluating the efficacy and safety of placing 2 iStent inject devices compared to SLT
- Currently recruiting patients:
  - Primary open angle glaucoma
  - Mild to moderate disease on 1-3 topical medications
- Primary outcome: IOP reduction at 24 months
- Secondary outcome: % IOP reduction
Hydrus Microstent (Ivantis, Inc, Irvine, CA)

- Not FDA approved
- Hydrus IV
  - prospective, multicenter, single masked, controlled randomized study in patients with mild to moderate glaucoma undergoing cataract surgery
  - Patients randomized 1:1 to Hydrus Microstent plus cataract surgery or cataract surgery alone
  - Eligible patients had IOP ≤24mmHg on 4 or fewer hypotensive medications, open angles
  - Follow-up evaluations at both the one and two year time points
- Hydrus III – Hydrus vs iStent
- Hydrus V – Hydrus vs 2 iStents
Trabectome

- Ab interno trabeculectomy (AIT)
- 550 kHz bipolar electrode tip – uses ionization and dissipation to remove the TM
- TM can be ablated over 180°
  - Provide access to many more drainage segments compared with bypass stents
Retrospective review of 192 cases of combined phaco + AIT (U of Pittsburgh 2013)
- IOP decreased from 20.1±8.2 mm Hg to 14.5 ±4.5 mm Hg (28% decrease, p<0.05)
- At 2 years, IOP reduction was maintained at 23%
- No mention of # of IOP meds
- Gedde et al - 4 year failure rate of 53%
- Jan 2016 meta-analysis in BJO
  - Analyzed stand-alone AIT and combined with phacoemulsification
  - Weighted mean difference in IOP from baseline
    - AIT = -9.77 mmHg
    - Phaco-AIT = -6.04 mmHg
  - Medication decrease
    - AIT = -1.11
    - Phaco-AIT = -0.73
- Trabectome database (Neomedix)
  - Phaco-AIT = 85% success rate at 5 years
  - AIT = 56% success at 7.5 years
Gonioscopy-Assisted Transluminal Trabeculotomy

GATT
- 1st described in Ophthalmology in 2014
- Conjunctival sparing
- Adult or developmental OAG
GATT
Goniotomy

- Kahook Dual Blade

- Sight Sciences
  - Trab®360

Dual Blades: To excise a strip of meshwork
Goniotomy video

- https://youtu.be/h1EyIDuZD_w
- Video courtesy of Nathan Radcliffe, MD
AqueSys Xen
- Soft collagen tube
- Inner diameter of 65 microns
- Ab interno insertion into subconjunctival space
AqueSys Xen45

JCRS – 2015
- Non-randomized prospective pilot study
- Implantation of two models of a gel stent (Xen140 or Xen63) at the time of cataract surgery
- 37 eyes of 37 patients
  - mean preoperative IOP was 22.4 mm Hg ± 4.2 (SD) on 2.5 ± 1.4 medication classes
- Complete success: IOP <18mmHg AND >20% reduction in IOP without medication
  - Mean IOP 15.4 ± 3.0 mmHg on 0.9 ± 1.0 medication classes
  - Qualified success: 85.3%
  - Complete success: 47.1%
  - No cases classified as failures at 12 months
Aquesys Xen video

- [https://www.youtube.com/watch?v=K9rY7BzwtkA](https://www.youtube.com/watch?v=K9rY7BzwtkA)
- Video courtesy of Ike Ahmed, MD

InnFocus Microshunt

- Poly(styrene-block-isobutylene-block-styrene) “SIBS”
- novel synthetic thermoplastic elastomeric biomaterial
- Resists biodegradation, elicits virtually no Inflammatory reaction in the human eye
  - Manifests as clinically insignificant inflammation and capsule formation
- Tube outer diameter 0.35mm, inner lumen 70 microns
- Adjunct rx with 0.4mg/mL MMC x3 minutes
- 1 year prospective results:
  - 23 patients
  - Baseline IOP $23.8 \pm 5.3$ mmHg on $2.4 \pm 1.0$ medications
  - Post-op IOP $10.7 \pm 2.8$ mmHg on $0.3 \pm 0.8$ medications
  - 100% success rate
Innfocus Microshunt

1) Dissect a fornix-based subconjunctival pouch deep to the equator and 90° to 120° wide. Ensure sclera is white and blood-free.

2) Insert 3 lasik shields soaked in 0.4 mg/mL Mitomycin C, into pouch, contacting all surfaces. Leave for 3 minutes, remove sponges and rinse well with BSS.

3) Mark a spot 3 mm from the limbus using the supplied pen and marker ruler.

4) Cut a shallow pocket with the angled knife just below the surface of the sclera that is 1 mm wide and 1 mm deep.

5) Form a needle tract by advancing a 25G needle through the pocket and under the limbus exiting at the angle.

6) Hold MicroShunt near beveled tip and advance tube through the pocket and needle tract into the anterior chamber.

7) Wedge fins firmly into pocket.

8) Check MicroShunt for flow through lumen.

9) Tuck tail under Tenons.

10) Suture conjunctiva closed with 10-0 Nylon suture.
Suprachoroidal Space

- Cyclodialysis cleft
- Aqueous absorbed through sclera or episcleral veins
- Cypass microshunt
  - Polyamide
  - 6.35mm length
  - 0.51mm largest diameter
- iStent Supra®
CyPass (Transcend Medical)

- J of Glaucoma (January 2016)
  - 1 year data
  - Baseline mean IOP 20.2 +/- 6.0mmHg
  - Mean IOP lowering medications 2.0 ± 1.1
  - Mean IOP at 12mo 15.9 ± 3.1mmHg
    - 14% reduction from baseline
  - Statistically significant decrease in medication usage
  - 2 patients developed transient hyphema
    - 13.8% hypotony in first month
    - No persistent hypotony or prolonged inflammation
CyPass

- Suprachoroidal lake important for IOP control
  - Viscodilation of suprachoroidal space
  - ViscoPass preliminary data (Ahmed IK et al)

![Preliminary Analysis of ViscoPass 1-YR Results](chart.png)
CyPass video

- [https://www.youtube.com/watch?v=YSmELF62CfM](https://www.youtube.com/watch?v=YSmELF62CfM)
  Video courtesy of Ike Ahmed, MD

- [https://www.youtube.com/watch?v=4GF11HV6y5g](https://www.youtube.com/watch?v=4GF11HV6y5g)
  Video courtesy of Lukan Mishev, MD
Conclusions

- Potential for earlier intervention using MIGS procedures
  - Reduce medication burden
  - Reduce morbidity of disease
- Ability to combine MIGS with phacoemulsification
- Three outflow targets to choose from based on potential risks vs benefits
- Continue to work towards reducing the need for more invasive, risky procedures
  - Still a need for trabs and tubes
References