





Minimally Invasive Glaucoma Surgery (MIGS) John Kung, MD



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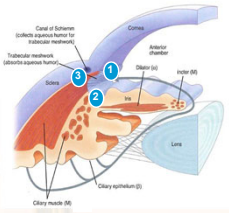



Minimally Invasive Glaucoma Surgery

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






Surgical Outflow Targets





MIGS devices can be used to restore outflow through:

Outflow Pathway	Disease State
Trabecular Meshwork	Mild-to-Moderate
Suprachoroidal Space	Progressive
Subconjunctival Space	Refractory

MIGS or Not?



<p>MIGS</p> <ul style="list-style-type: none"> ▪ Schlemm's canal microstents (iStent, Hydrus) ▪ Suprachoroidal microstents (Cypass) ▪ Subconjunctival microstents (Xen) ▪ Canaloplasty (OMNI, Streamline) ▪ Goniotomy (Kahook, MST) ▪ AbiC (Ab-interno Canaloplasty) 	<p>Not MIGS?</p> <ul style="list-style-type: none"> ▪ Endocyclophotocoagulation ▪ Iridex cyclo G6 micropulse laser (CPC) ▪ Ex-Press shunt ▪ Innfocus microshunt, now Preserflo ▪ Gold micro shunt (Solx)
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Patient Selection

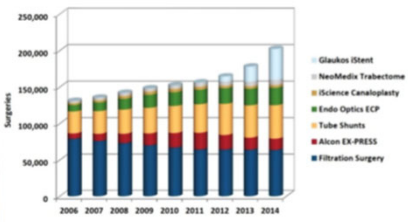
Current Patient Profiles



<p><u>MIGS</u></p> <ul style="list-style-type: none"> ▪ Mild/Moderate Disease ▪ Hypertensive glaucoma ▪ Open angle ▪ Modest IOP target (~15-16 mmHg) ▪ Able to tolerate meds if needed 	<p><u>Trabeculectomy</u></p> <ul style="list-style-type: none"> ▪ Advanced disease ▪ Progressive normotensive glaucoma ▪ Open or closed angle ▪ Low IOP target (<12 mmHg) ▪ Intolerant to medications
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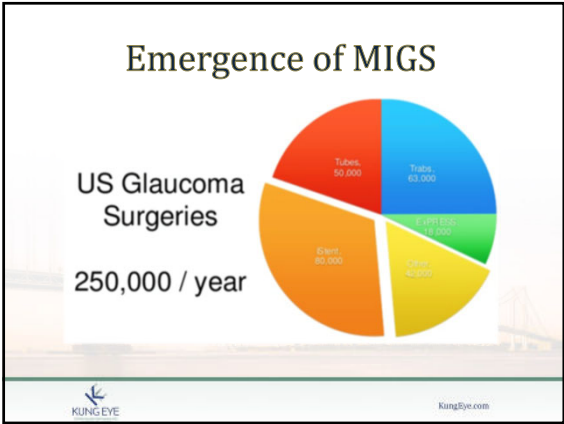



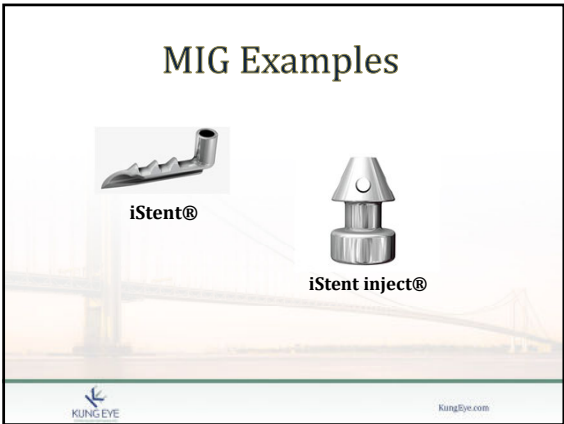
Emergence of MIGS

Figure 5: US Glaucoma Surgery Treatment Mix—Historical Perspective







Glaucoma Micro-Surgical Devices

Introducing a NEW Category of MIGS designed to Address the Range of Glaucoma Progression

<p>iStent</p> <p>Approved 2012</p> <p>Trabeculectomy alternative injection</p> <p>Combo-Catheter</p>	<p>iStent inject</p> <p>Approved 2018</p> <p>2 multi-directional trabeculectomy alternative injection</p> <p>Combo-Catheter</p>	<p>iStent SA</p> <p>Approval Target 2021</p> <p>2 multi-directional trabeculectomy alternative injection</p> <p>Combo-Catheter</p>	<p>iStent inflex</p> <p>Approval Target 2021</p> <p>3 multi-directional trabeculectomy alternative injection</p> <p>Combo-Catheter</p>	<p>PRESEFLO</p> <p>Approval Target 2021</p> <p>4th generation trabeculectomy alternative injection</p> <p>Combo-Catheter</p>
Mild to Moderate			Advanced to Refractory	

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Categories

MIGS can be thought of in a few broad categories, either enhancing fluid outflow using the eye's inherent drainage system (GATT, Goniotomy, Trabectome, iStent, Hydrus, Omni Canaloplasty), shunting fluid to the outside of the eye (XEN Gel Stent, ExPress Shunt) or decreasing production of fluid within the eye (ECP, Iridex G6 CPC).



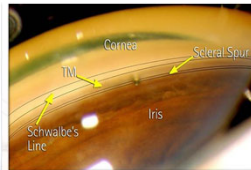
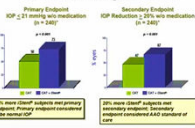
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Schlemm's Canal

Glaukos iStent®

Single or multiple stents

US IDE: Single Stent



Samuelson et al., Ophthalmology 2011; Crowell et al., JCRS 2012; K. Ahmad MD



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Phaco vs Phaco/iStent inject®







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Phaco vs Phaco/iStent inject®

84%

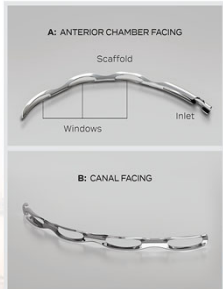
iStent *inject* subjects medication-free at 23 months

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Hydrus® Microstent

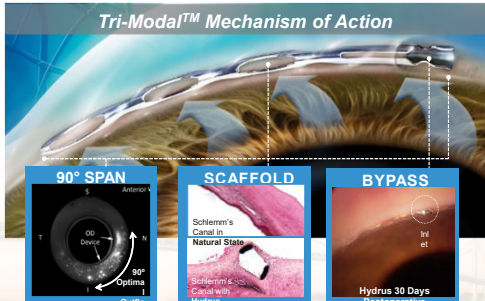


- Flexible, biocompatible 8 mm length microstent
- Made out of nitinol (highly biocompatible material used in cardiovascular stents)
- Contoured to match canal curvature

Hydrus is a registered trademark of Ivantis, Inc. KING EYE KingEye.com 16

Tri-Modal® Mechanism of Action

Tri-Modal™ Mechanism of Action



90° SPAN

Anterior Chamber
Optima
Inlet

Source: Gong H, Johnson M, et al. Poster #115 American Glaucoma Society, New York 2012

SCAFFOLD

Schlemm's Canal in Natural State
Schlemm's Canal with Hydrus

Source: Rays CL, Tello CB, et al. Invest Ophthalmol Vis Sci. 2014;55(10):3959-3960

BYPASS

Inlet

Hydrus 30 Days Postoperative


Courtesy of Ike Ahmed, MD

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Hydrus® Microstent

- FDA Approved Aug 2018
- Designed to treat patients with mild to moderate primary open-angle glaucoma in conjunction with cataract surgery.

According to the trial results, more than 77% of patients who received the microstent experienced a statistically significant decrease in unmedicated IOP at 24 months postoperatively compared with 57.8% of patients who underwent cataract surgery alone.



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Hydrus®

- Using a gonioprism, the Hydrus® Microstent is **inserted through a clear corneal incision** and guided through the trabecular meshwork into Schlemm's canal.



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Hydrus®

- Once in position, the Hydrus® Microstent is advanced until the device has scaffolded **90° of the canal**, ensuring consistent access to collector channels.



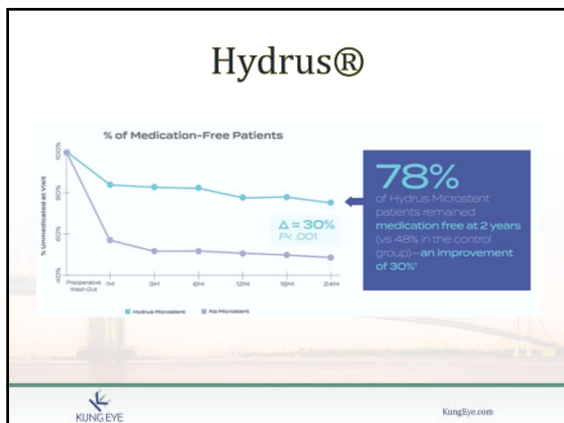
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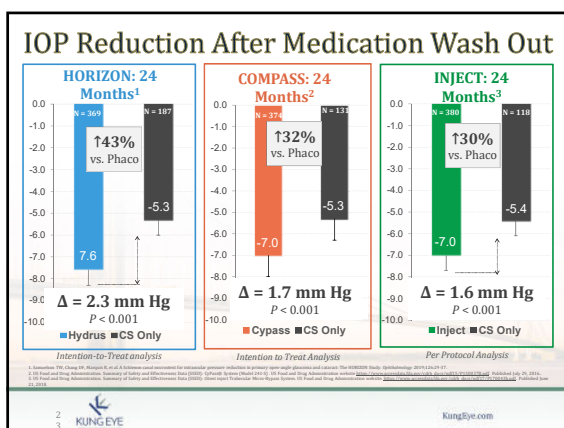
Real-time Confirmation of Accurate Delivery

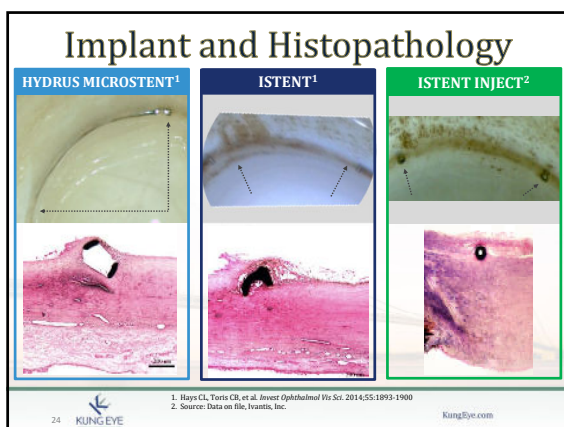


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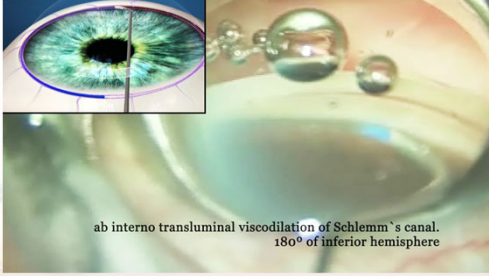
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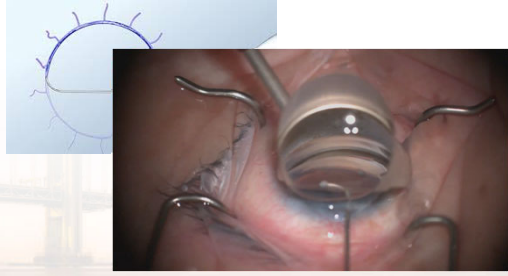
Transluminal Viscodilation



ab interno transluminal viscodilation of Schlemm's canal.
180° of inferior hemisphere

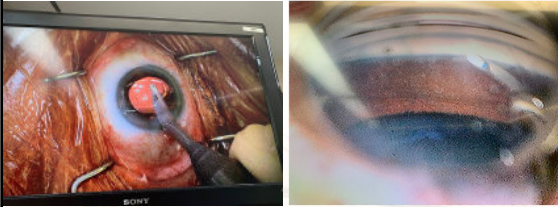
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OMNI



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OMNI



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360° Ab-interno Schlemm's Canal Viscodilation (Ondrejka et al. 1-year Results)¹⁴

PURPOSE:
Safety and effectiveness of ab-interno viscodilation and combination of trabeculectomy with, with or without cataract surgery

RESULTS:
BASELINE IOP 23.6 mmHg (n=72)

14. Ondrejka S, Gierke R. 360° ab-interno Schlemm's canal viscodilation in primary open-angle glaucoma. *Clinical Ophthalmol*. 2019; 13:1235-1246.

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360° Ab-interno Trabeculotomy (TRAB360) in Refractory POAG (Sarkisian, et al. 1-year Results)¹⁵

PURPOSE:
To evaluate IOP and medication reduction out to 1 year with TRAB360 as a stand-alone procedure in patients with refractory glaucoma and moderate-to-severe OAG.

RESULTS AT 1 YEAR:
ALL PATIENTS (N=62)

COMPLICATIONS:
• 1 total cataract AE was mild, transient (glare)
(5.2% eyes)
• 30 (48%) eyes required reinterventions within the first year

CONCLUSIONS:
• Trabeculectomy using TRAB360 resulted in significant IOP reductions up to 1 year with a favorable safety profile.

15. Sarkisian, et al., 360° ab-interno trabeculotomy in refractory primary open-angle glaucoma. *Clinical Ophthalmology* 2019; 13:161-168

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Trabeculectomy Combined with Viscodilation of Schlemm's Canal for Reducing IOP in Mild to Moderate and More Advanced Open Angle Glaucoma (Brown et al. 8-month Results)

41 EYES, COMBINED WITH CATARACT SURGERY

RESULTS:

COMPLICATIONS:
• No complications related to cataract surgery
• Hypotonia observed in 2 eyes (4%). Cleared by 1 week
• No eyes have undergone secondary glaucoma surgery

33 EYES, STANDALONE PROCEDURE IN PSEUDOPHAKIC EYES

RESULTS:

CONCLUSIONS:
• Effect: • Greater ability to lower IOP. Magnitude of IOP reduction highly correlated with pre-OP IOP.
• Patients with highest pre-OP IOP a greatest post-OP IOP reduction.
• 81% stand-alone lowers IOP 40%.

17. Brown, Bayo R, Pagan, Solomon, Dharmaraja, Kesava "Viscodilation of Schlemm's canal and trabeculectomy combined with cataract surgery for reducing intraocular pressure in open-angle glaucoma" *Journal of Cataract and Refractive Surgery*, 46(4):648-648, April 2020.
18. Brown R, Pagan R, Kesava R, Dharmaraja R. Trabeculectomy combined with Viscodilation of Schlemm's canal for Reducing IOP in Open Angle Glaucoma. AAOCS presentation, May 2017 (submitted to JCRS)

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OMNI® Surgical System in open-angle glaucoma treatment: an 18-month follow-up¹⁹

OMNI W/ CATARACT SURGERY (N=10)

Timepoint	Mean IOP (mmHg)
Baseline	18.7
18-month follow-up	11.4
Reduction	39%

OMNI STANDALONE PROCEDURE (N=14)

Timepoint	Mean IOP (mmHg)
Baseline	25.4
18-month follow-up	14.0
Reduction	40%

COMPLICATIONS:

- IOP spikes (3 eyes)
- Hyphemas (0 eyes)
- Intraocular infection (0 cases) that resolved in the first week after surgery

CONCLUSION:

- OMNI® Surgical System is a promising approach for the treatment of high-severity OAG
- The procedure achieves reduction of the IOP and the number of glaucoma medications.
- It also demonstrates good safety profile.
- Further studies are needed.

¹⁹ Grabacka-Liberek L, Majczyk-Iwanicz L, Duda P, et al. OMNI in open-angle glaucoma treatment: an 18-month follow-up. ESCRS 2019, Presented Poster Session: Glaucoma II [https://www.esrs.org/paris2019/programme/poster-village-detail.aspx?id=33863&day=4].

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Kahook Dual Blade (Goniotomy)

Footplate width = 230 microns
Schlemm's canal width = 248 microns

Patented clamp to lift and stretch trabecular meshwork for a clear excision

Smooth blades for precise excision of trabecular meshwork

Preop **Day 1 (1-3 days)** **Week 1 (4-14 days)** **Month 1 (15-59 days)** **Month 2 (60-120 days)** **Month 3 (121-270 days)**

Timepoint	Phaco-goniotomy with KDB (mmHg)	Phaco-Gonio (mmHg)
Preop	17.9	15.7
Day 1 (1-3 days)	15.8	14.4
Week 1 (4-14 days)	15.3	14.8
Month 1 (15-59 days)	15.0	14.6
Month 2 (60-120 days)	14.8	13.6
Month 3 (121-270 days)	14.7	13.6

Intraoperative view of eye's drainage system as a goniotomy is being performed.

Goniotomy: removal of the surface layer of the drusen.

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Streamline

Outer Sleeve
Micro-channel for irrigation

Inner Canula
Tubular canula

Bottom left insert shows retracted outer sleeve and creation of goniotomy by inner canula. Main photo shows delivery of viscoelastic aliquot.

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Streamline

In a study¹ of 20 patients with glaucoma who underwent goniotomy and viscodilation with the STREAMLINE surgical system, 89.5% experienced at least a 20% reduction in IOP and no increase in medication use. The average IOP decreased from 23.5 mmHg to 14.7 mmHg after 6 months, and the average number of medications decreased from 2.0 at screening to 1.1.



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Conclusion

- MIGS is providing an exciting resurgence of novel glaucoma surgeries
- This will minimize the need for trabs and tubes and allow for earlier intervention before vision loss
- Risk profile makes procedures ideal during cataract surgery



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Cyclophotocoagulation



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RETHINKING YOUR PATIENTS' GLAUCOMA CARE

PATIENTS TO CONSIDER

- Maximum tolerated medical therapy and compliance issues
- Pre trabeculectomy, stent or filter
- Failed trabeculectomy, stent or filter
- Eyes with compromised ocular surface

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One laser, one probe, multiple patient types

THE EQUIPMENT

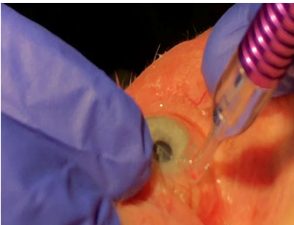
MICROPULSE® P3 PROBE **CYCLO G6® LASER**

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How is it Performed?

- Diode cyclophotocoagulation is an outpatient procedure. The patient receives a peribulbar block prior to the laser. The procedure takes 5 minutes and will require use of postoperative drops to decrease inflammation in the eye. Most patients have minimal postoperative pain.

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KEY ELEMENTS OF THE PROCEDURE

- Viscous interface
- Probe orientation and placement
- Probe angle and pressure
- 300-degree treatment
- Appropriate dose (exposure and power)

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SCIENTIFIC RATIONALE

Early work demonstrates that shrinking ciliary tissue may create a supraciliary space thereby increasing uveoscleral outflow.¹⁶⁻¹⁸

MECHANISM OF ACTION

The presumed mechanism of action of MicroPulse TLT is dominated by heat-induced changes in ciliary body morphology resulting in increased uveoscleral outflow.¹⁸

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CONSIDER MICROPULSE TLT FOR MODERATE-STAGE* GLAUCOMA PATIENTS BECAUSE IT IS SAFE & EFFECTIVE

Recent research** using MicroPulse TLT in patients with 20/50 or better VA on ≥ 2 topical medications show high success rates of IOP reduction and an excellent safety profile. ^{3,7,8,18,20}	83% Success rate post ≥1 MicroPulse TLT sessions
	35% Reduction in IOP
	33% Reduction in topical drug burden
	76% Reduction in oral medication burden
	Safety Minimal adverse events or complications

*Defined as ≥2 medications, maximum tolerated medical therapy, pre-incisional surgery or post-incisional surgery.
**Based on 448 eyes with ≥2 medications, VA 20/50 or better (range 20/20 to 20/400) with 6 to 25 months follow-up.^{3,7,8,18,20} Percentages are based on weighted averages.

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Iridex G6 Probe



XEN

