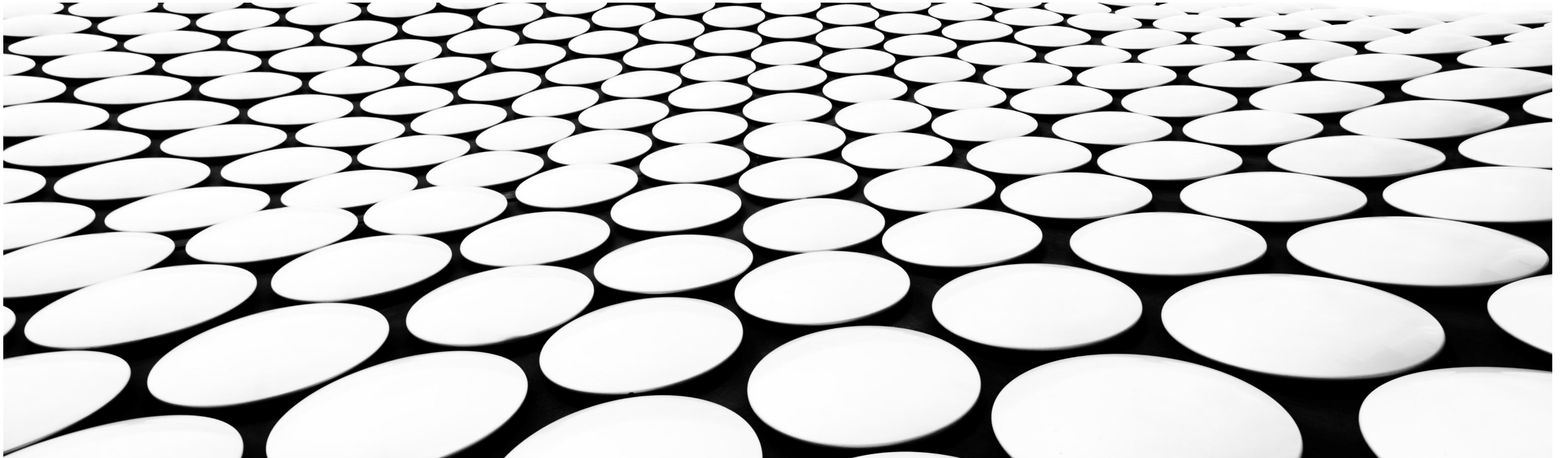


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# REVIEW OF MINIMALLY INVASIVE GLAUCOMA SURGICAL TECHNIQUES

CHRISTINE FUNKE MD





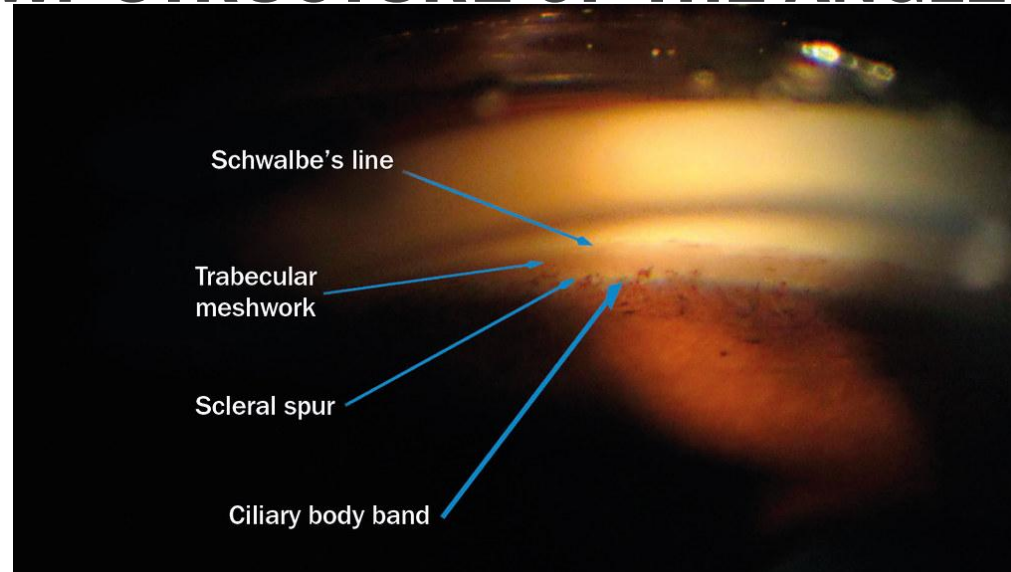
# DISCLOSURES

Alcon – Consultant, Key Opinion Leader, Research, National Speaker

Sight Sciences – Consultant, Key Opinion Leader, National Speaker

Glaucos - Consultant

## ANATOMY REVIEW: STRUCTURE OF THE ANGLE



Schwalbe's Line: Delineates outer limit of corneal endothelium

Trabecular Meshwork: Responsible for draining aqueous humor

Scleral Spur: Inner aspect of the anterior portion of sclera

Ciliary Body Band: Represents the longitudinal fibers of the ciliary muscle



# MINIMALLY INVASIVE GLAUCOMA SURGERY (MIGS)

- Device that lowers IOP by improving outflow
- Can be done ab interno or ab externo
- Limited surgical manipulation of the sclera
- Limited manipulation of the conjunctiva



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## MIGS SAFETY

- Touted as safer than traditional trabeculectomy or tube shunt surgery
- Long term data is not readily available
- No randomized trials comparing MIGS with trabeculectomy



## **MIGS: SURGICAL TIME AND IOP EFFECT**

- Shorter times can lead to safety
- Not as effective at lower IOP as traditional glaucoma surgery

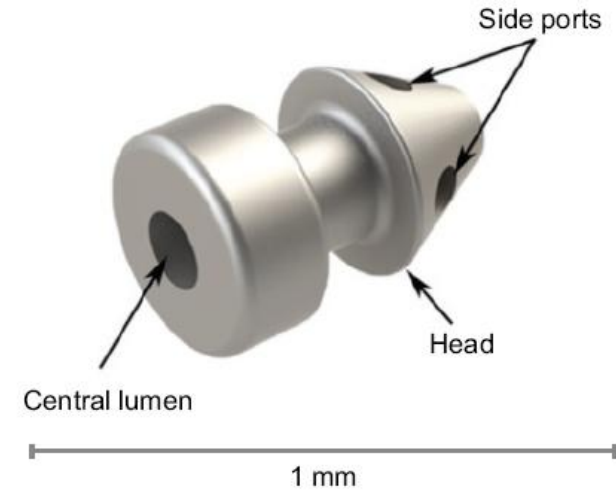
<b>Table 1. Summary and Results of Select MIGS Studies</b>										
<b>Procedure</b>	<b>Stent</b>	<b>w/cataract surgery or stand-alone</b>	<b>Target structure</b>	<b>Pre-op IOP +/- SD</b>	<b>Post-op IOP +/- SD</b>	<b>IOP reduction</b>	<b>Pre-op meds +/- SD</b>	<b>Post-op meds +/- SD</b>	<b>Total medication reduction</b>	<b>Post-op period</b>
iStent <sup>4</sup>	Yes	Combined	TM/Schlemm's canal	18.6 +/-3.4	17.1 +/-2.9	8.1%	1.6 +/-0.8	0.3 +/-0.6	1.3	Two years
iStent inject <sup>7</sup>	Yes (2)	Combined	TM/Schlemm's canal	20.0 +/-3.7	17.0 +/-2.3	15%	1.3 +/-0.7	0.5 +/-0.6	0.83	Two years
Hydrus <sup>8</sup>	Yes	Combined	TM/Schlemm's canal	18.9 +/-3.3	16.5 +/-2.9	12.7%	2.0 +/-1.0	0.5 +/-1.0	1.5	Two years
Trabectome <sup>10*</sup>	No	Either	TM/Schlemm's canal	27.6 +/-7.2**	15.2 +/-2.4	44.9%	Not reported			Two years
Kahook <sup>12</sup>	No	Either	TM/Schlemm's canal	17.4 +/-5.2	12.8 +/-2.6	26.4%	1.6 +/-1.3	0.9 +/- 1.0	0.7	Six months
GATT <sup>13*</sup>	No	Either	TM/Schlemm's canal	25.6 +/-6.1	15.7 +/-4.5	38.7%	3.2 +/-0.9	1.5 +/-1.2	1.7	One year
Trab360 <sup>14</sup>	No	Either	TM/Schlemm's canal	19.8 +/-6.4	13.5 +/-4.0	31.8%	1.1 +/-1.2	0.2 +/-0.5	0.9	One year
ABiC <sup>16</sup>	No	Either	TM/Schlemm's canal/collector channels	28.6 +/-5.9	13.8 +/-3.2	51.7%	1.9 +/-1.2	0.5 +/-0.8	1.4	One year
CyPass <sup>18</sup>	Yes	Combined	Suprachoroidal space	24.5 +/-3.0	17.1 +/-3.4	30.2%	1.4 +/-0.9	0.2 +/-0.6	1.2	Two years
iStent Supra <sup>19</sup>	Yes	Combined	Suprachoroidal space	20.4 +/-2.4	11.9	41.6%	2	1	1	Two years
Solx gold shunt <sup>20</sup>	Yes	Either	Suprachoroidal space	30.8 +/-8.8	13.7 +/-3.0	55.5%	2.8 +/-1.1	1.5 +/-0.8	1.3	Two years
Xen <sup>21</sup>	Yes	Either	Subconjunctival	22.5 +/-3.7	13.1 +/-2.4	41.8%	2.5 +/-0.09	0.4 +/-0.8	2.1	One year
InnFocus Microshunt <sup>23</sup>	Yes	Either	Subconjunctival	23.8 +/-5.3	10.7 +/-3.5	55%	2.4 +/-0.9	0.7 +/-1.1	1.7	Three years
ECP <sup>26</sup>	No	Either	Anterior ciliary processes	18.1 +/-3.0	16.0 +/-3.3	11.6%	1.5 +/-0.8	0.4 +/-0.7	1.1	Two years

\* reported results for stand-alone procedure, \*\* non-medicated IOP



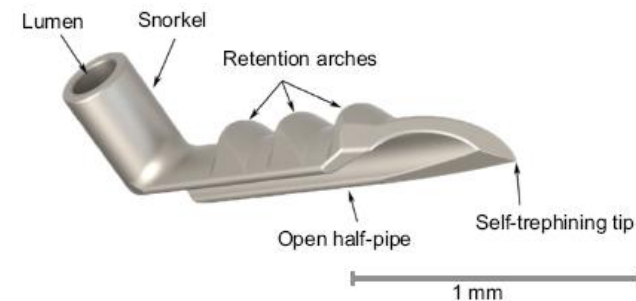
## ISTENT AND ISTENT INJECT

- In combination with cataract only
- Indicated for mild to moderate open angle glaucoma
- 68% of glaucoma patients who received iStent were medication free 12 months after surgery (IOP <21 mmHg) vs. 50% of cataract surgery alone
- Contraindications:
  - Angle closure glaucoma
  - Neovascular glaucoma
  - Retrobulbar tumor
  - TED or any condition with my increase EVP
- Adverse Events:
  - PO K edema (8%)
  - BCVA loss > or equal to 1 line after 3 mts (7%)
  - PCO (6%)
  - Stent obstruction (4%)
  - A/C cell (3%)
  - K abrasion (3%)



**Figure 4** Second-generation iStent inject.

**Notes:** Copyright © 2014. Dove Medical Press. Adapted from Hunter KS, Fjield T, Heitzmann H, Shandas R, Kahook MY. Characterization of micro-invasive trabecular bypass stents by ex vivo perfusion and computational flow modeling. *Clin Ophthalmol.* 2014;8:499–506.<sup>14</sup>

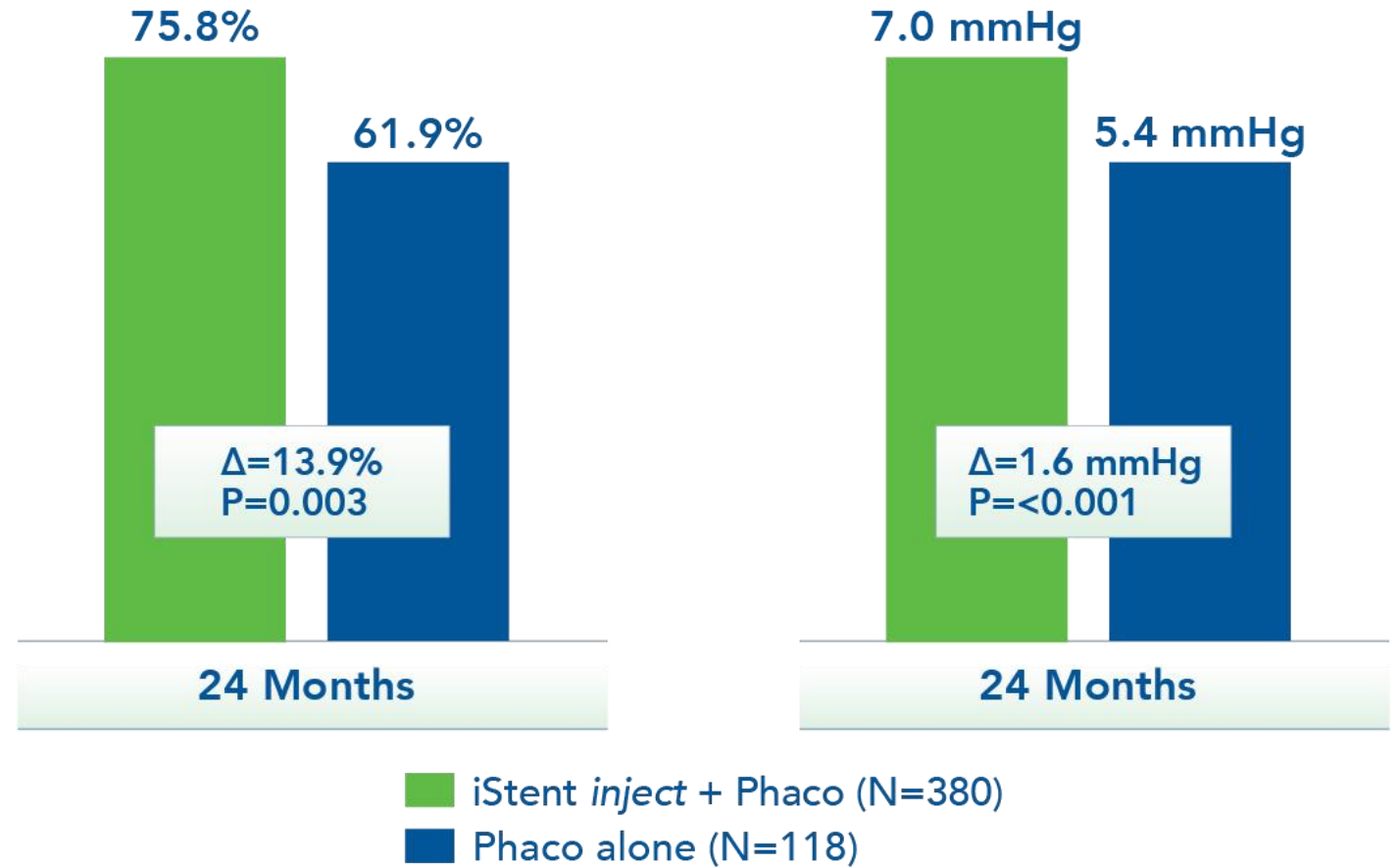


**Figure 1** First-generation iStent.

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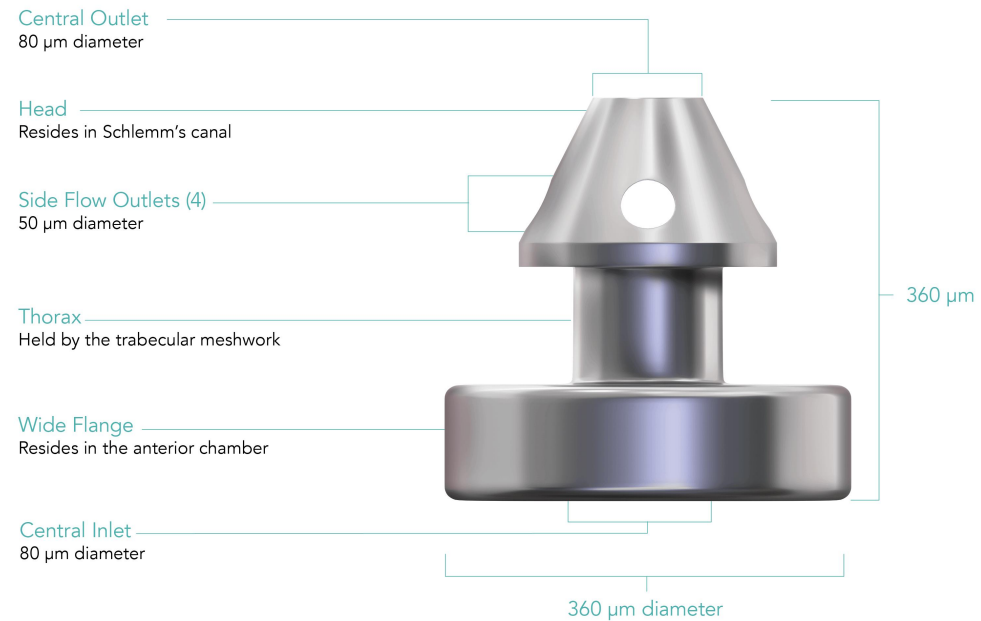
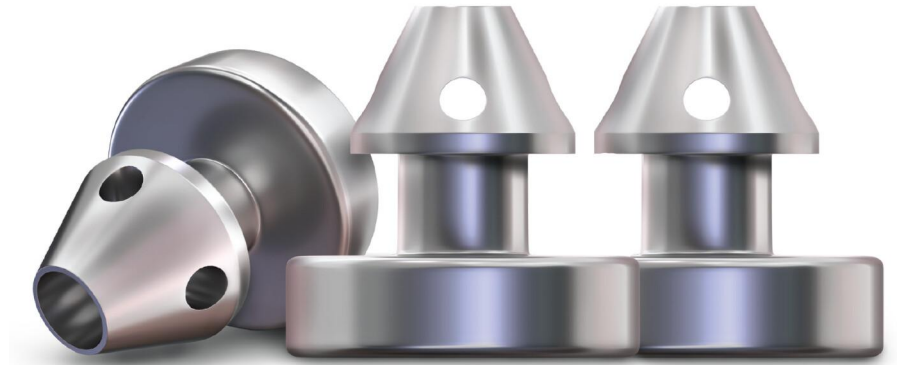
# iSTENT INJECT Trial<sup>1</sup>

- 17.1 mm Hg mean med free IOP at 24 months
- Mean of 0.4 meds at 23 months, down from preop mean of 1.6 in treatment arm



# ISTENT INFINITE

First FDA approved micro-invasive standalone trabecular bypass implant



# ISTENT INFINITE

iStent infinite<sup>®</sup> gives you the versatility to treat a variety of patients who have failed prior medical and surgical intervention, when combined with cataract surgery or in a **standalone surgical setting**.

Failed Medical	Failed Surgical
<ul style="list-style-type: none"><li>• Uncontrolled on medication</li><li>• Non-compliant &amp; non-adherent to treatment</li><li>• Allergic to glaucoma medication</li><li>• Intolerant to glaucoma medication due to sequelae (ie, hyperemia, periorbital fat atrophy, hyperchromia, etc)</li><li>• Patients burdened with underlying ocular surface disease</li><li>• Failed medical patients who have experienced decreased quality of life</li></ul>	<ul style="list-style-type: none"><li>• Failed filtering surgery (ie, trabeculectomy, tube shunts, XEN, etc)</li><li>• Failed cilioablative surgery</li><li>• Other failed surgical intervention (upon surgeon discretion)</li></ul> <hr/> <p>Consider iStent infinite<sup>®</sup> in place of more invasive procedures, offering intermediate therapy.</p>

<https://www.glaukos.com/glaucoma/products/istent-infinite/>



## ISTENT INFINITE CLINICAL DATA

- 73.4% of patients with  $\geq$  20% reduction of IOP (on same or fewer meds at 12 months)
- 47.3% of patients with  $\geq$  30% reduction in IOP
- 16.9 mmHg was mean diurnal IOP (pts without IOP-related SSI); mean reduction of 6.5 mmHg (27.7%)
- Only 4.9% of eyes needed a secondary surgical intervention by 12 months after implantation

## HYDRUS

- Small scaffold inserted into Schlemm's canal
- Made of nickel and titanium alloy
- Indications: Mild to Moderate glaucoma in conjunction with cataract surgery
- Risks: Bleeding, blockage or malposition



# HYDRUS WITH OR WITHOUT CATARACT SURGERY

- Horizon Study – 2 year prospective, multicenter, randomized controlled single-masked clinical trial (556 eyes) – 369 Cat/Hydrus and 187 Cat alone
- Results: 77.3% Hydrus pts greater than 20% unmedicated mean IOP vs 57.8% Cat alone
  - Hydrus had greater reduction of mean unmedicated IOP (-7.6 vs -5.3 mm Hg)
  - Average meds before surgery was 1.7; Hydrus 0.3 and Cat alone 0.7
  - 78% med free with Hydrus and 48% with Cat alone

# HYDRUS VS. ISTENT

- Prospective Randomized trial
- Standalone Treatment: 1 Hydrus Microstent or 2 iStent Trabecular Bypass devices
- Results: At 12 months, Hydrus had greater surgical success, reduced medication use (difference -0.6 meds), more pts who are med free (difference 22.6%). Secondary glc surgery in 2 istent patients and no hydrus patients
- 2 eyes in Hydrus and 1 in iStent group had BCVA loss of  $\geq 2$  lines



## HYDRUS VS SLT

- 12 month, prospective, non-randomized uncontrolled mild to moderate POAG – 25 pt SLT and 31 Hydrus
- 90% Hydrus and 88% SLT had greater than 20% IOP reduction
- Drug Reduction:  $-1.4 \pm 0.97$  Hydrus vs.  $-0.5 \pm$  SLT
- Drug Free: 47% Hydrus and 4% SLT



## 5 YEAR DATA FOR HYDRUS (HORIZON)

- 47% reduction in visual field loss vs cataract surgery alone
- 73% of “mild” (one med) patients remained medication free at 5 years (cataract surgery alone 48%)
- 2.5% rate of secondary invasive glaucoma surgery (6.4% with cataract surgery alone)

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## AB INTERNO CANALOPLASTY

- Three options: ABiC, Stre or OMNI devices
- Internally canalizing Schlemm's canal and injecting viscoelastic for dilation, can perform GATT at some time
- Surgical candidates: Mild to Moderate glaucoma, CL wearers, high risk for bleeding or infection
- Complications: Descemet's detachment, bleeding

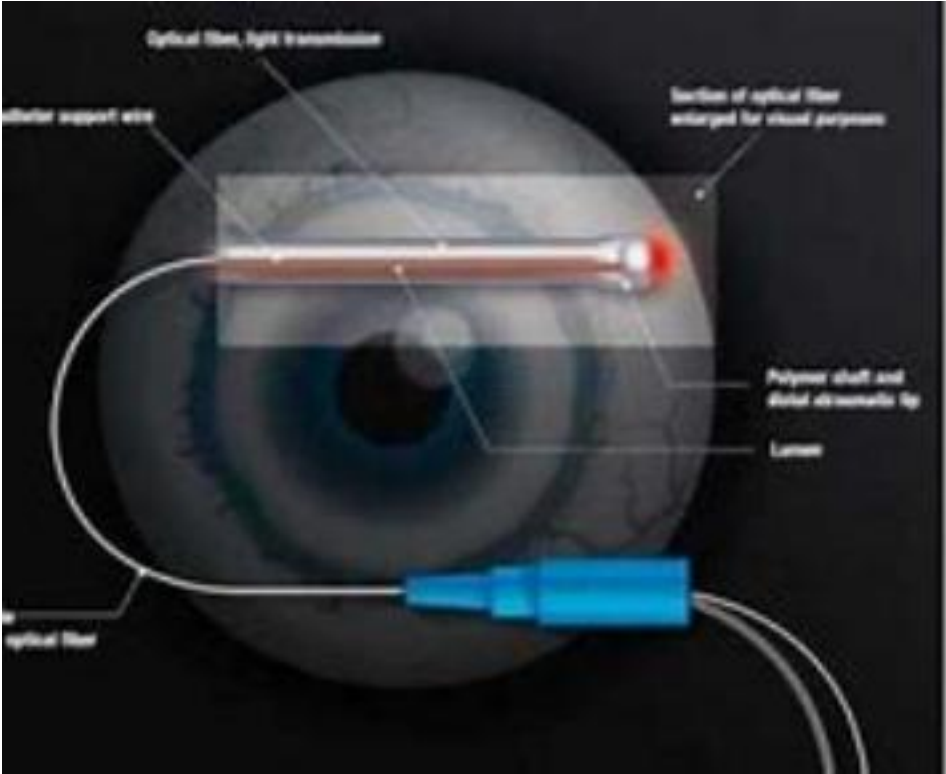
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## OMNI 36 MONTH STUDY DATA

- Mean reduction in IOP of at least 20% for all 38 eyes
- Mean number of IOP lowering meds was reduced by 0.5-0.7 at 36 months



# ABIC



# STREAMLINE



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## WHAT IS CANALOPLASTY VS GONIOTOMY?

- Canaloplasty – cleaning and dilating Schlemm’s Canal
- Goniotomy – unroofing the trabecular meshwork from Schlemm’s Canal

# KAHOOK BLADE/SION/GATT

- Kahook Dual Blade and Sion: remove a strip of trabecular meshwork (similar to Trabectome without cautery)
- GATT: placing a suture then performing trabeculotomy
- Complications: bleeding, scarring





# XEN GEL STENT

- Moves aqueous humor from the anterior chamber to a created subconjunctival space
  - Designed to prevent hypotony (via the lumen size of 45  $\mu\text{m}$ )
- Complications: scarring and failure, high needling rate for ab interno, bleeding, exposure
- 2 Methods:
  - Ab Interno – from inside the eye out – avoiding open conjunctiva – higher failure rate
  - Ab Externo – traditional conjunctival opening with placing stent from outside in





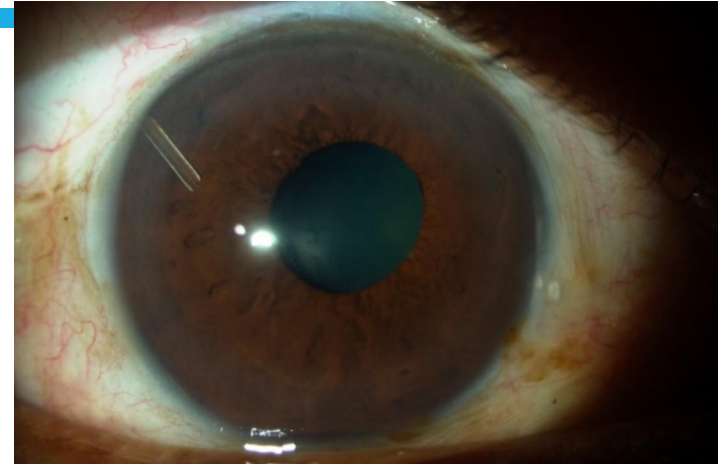
## WHO IS A CANDIDATE

- Good Candidate: uncontrolled glaucoma, POAG, PXG, Pigmentary dispersion on maximally tolerated topical treatment
- Contraindications: Angle closure glaucoma, previous shunt or conjunctival scarring in the superior quadrant, neovascularization, active inflammation, A/C IOL, silicone oil, Vitreous in A/C, impaired episleral venous flow (nanophthalmos)

# XEN GEL STENT VS TRABECULECTOMY

- International multicenter retrospective study – 354 eyes with uncontrolled glaucoma and no prior filtration surgery (185 Xen and 169 Trab)
- Median preop IOP of 24 mmHg on 3 meds – Decreased to 13 on zero meds for Xen45 and Trab groups
- Both groups had 75% survival of ~ 10 months without meds and 2 years with meds
- Trab group had more post op interventions (suture lysis) and complications (leak or dehiscence)
- Bleb needling was higher in Xen Gel group (not statistically significant)

# INNOFOCUS MICROSHUNT



- An 8 mm long tube, non-metallic
- Candidates: Uncontrolled POAG, more effective than iStent, Hydrus or Cypass; moderate to advanced patients
- Less invasive and fewer post ops than traditional trabeculectomy
- Not commercially available