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April 2024

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Administrative

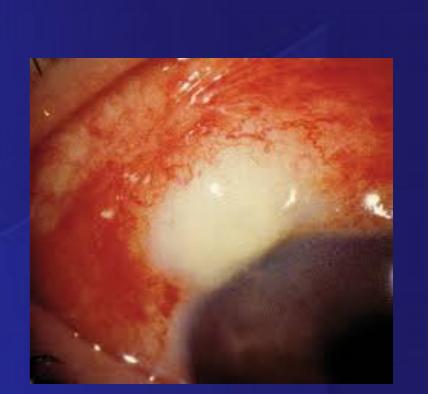
- Financial disclosures: Telasight, inc., Allergan, inc.
- COPE Course ID: 86630-GL

Minimally invasive glaucoma surgery

- Sometimes referred to as "Microinvasive glaucoma surgery"
- Must be safe, low risk for Hypotony, choroidal effusions, infections, phthisis, ect
- Minimal disruption to tissue/normal anatomy
- Must be effective, usually at least 20-30% reduction in IOP
- Fast recovery with minimal downtime/restrictions

Why MIGS?

- Patient noncompliance
- Patient intolerance of topical medications
- Financial burden of drops

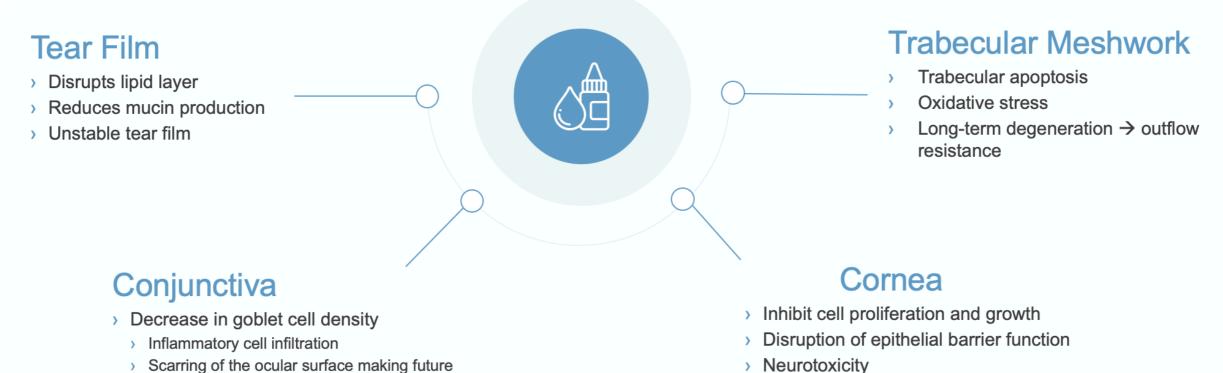


- Physical limitations to self administer eye drops
- Limited duration of laser treatments
- Higher risks and long term complications associated with more invasive glaucoma surgeries
- Early intervention
- Patient desire to reduce treatment burden



Glaucoma and ocular surface disease

Up to 60% of OAG patients have OSD



 Scarring of the ocular surface making future treatments difficult

Glaucoma and ocular surface disease

Ocular Surface Disease Improvement in Eyes Implanted with a MIGS Device

J. Schweitzer, OD, W. Hauser, OD; M. Ibach, OD AAO Poster Session, Orlando, FL 2019

Results

All patients were successfully implanted with either iStent or iStent inject with no remarkable intra- or postoperative complications.

- At 3 months the OSDI results improved from 41.7 ±21.8 (severe) preoperatively to 18.3 ±15.6 (mild). The FTBUT improved from 4.3 ±2.2 seconds to 6.4 ±2.5 seconds.
- Corneal staining based on the Oxford Grading Scale improved from 1.4 ±0.98 to 0.4 ±0.59. The number of glaucoma medications was reduced from 1.5 ±0.83 medications to 0.6 ±0.85 medications.
- The IOP was reduced from 17.2 ±4.3 mm Hg to 14.2 ±3.2 mm Hg

Conclusion

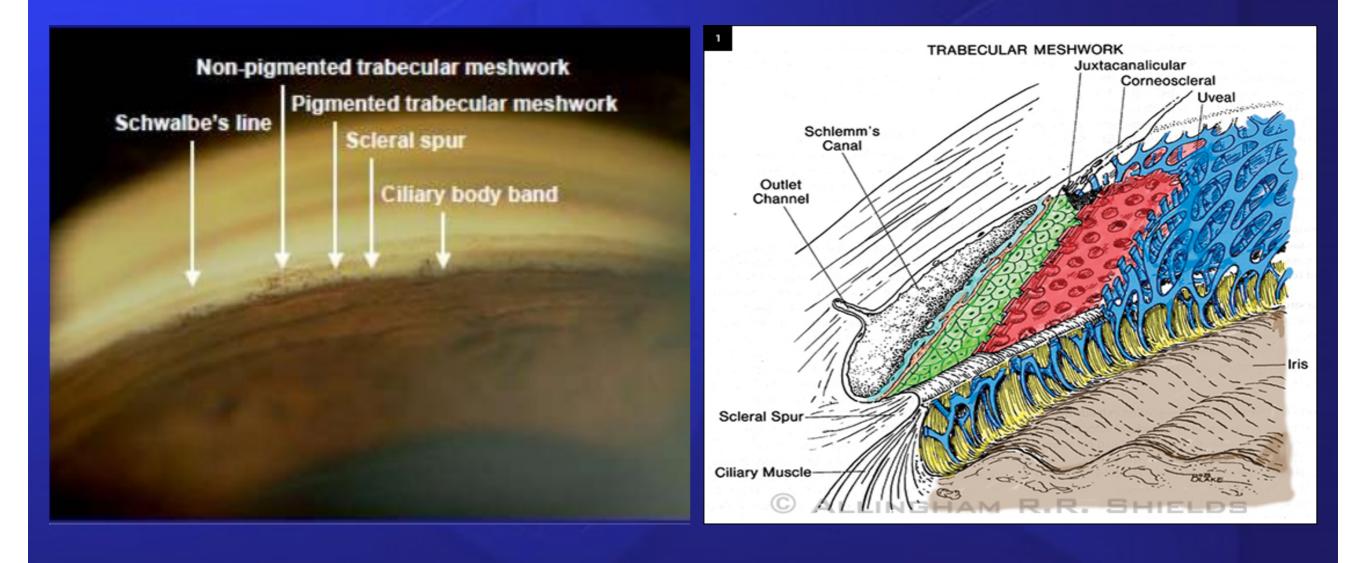
This study provides the first set of evidence showing benefits to ocular surface disease in that patients undergoing cataract surgery in combination with either iStent or iStent inject trabecular meshwork bypass stent(s).

- An improvement in key measures for ocular surface disease such as improved OSDI scores, corneal staining, and FTBUT was demonstrated.
- Additionally, consistent with current literature, a reduction in IOP and medication was shown with iStent and iStent inject.

Anatomy review



Anatomy review



Anatomy review

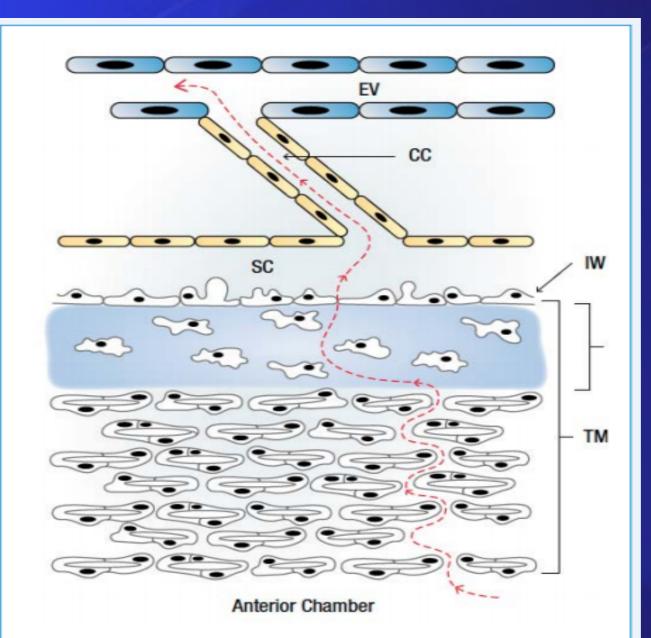


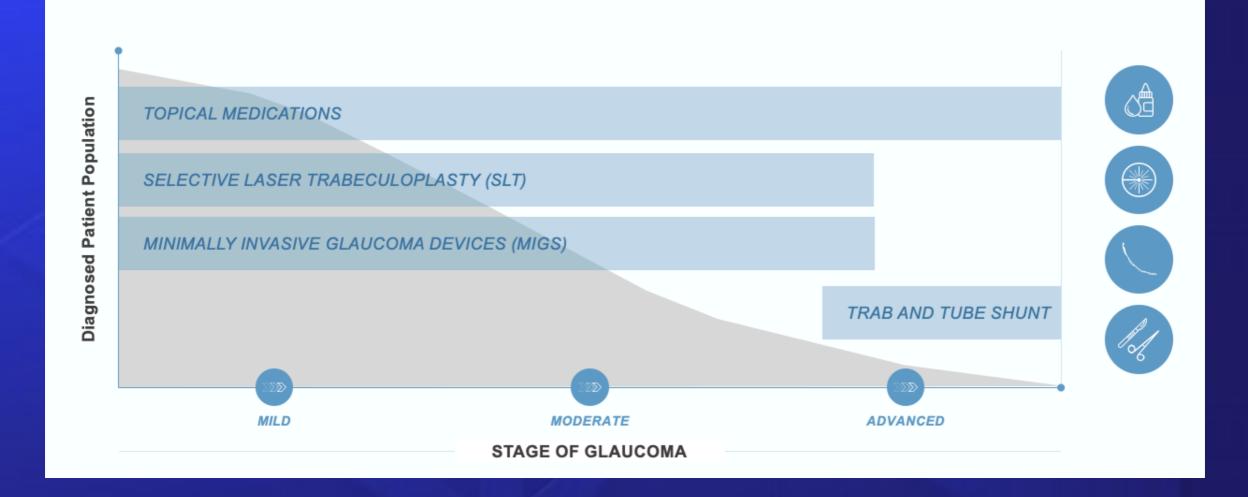
Figure 1: Schematic illustrating the major components of the conventional outflow pathway. Aqueous humor (red dashed line) flows through the initial portion of the trabecular meshwork (TM), juxtacanalicular connective tissue (JCT) region, inner wall of Schlemm canal (IW), Schlemm canal (SC), collector channel (CC), and finally reaches the episcleral vein (EV). Multiple TM cells encase the trabecular beams (tan) within the TM. The JCT is composed of sparse cells and substantial ECM.

Reproduced from J Cataract Refract Surg 2014; 40:1263-1272.

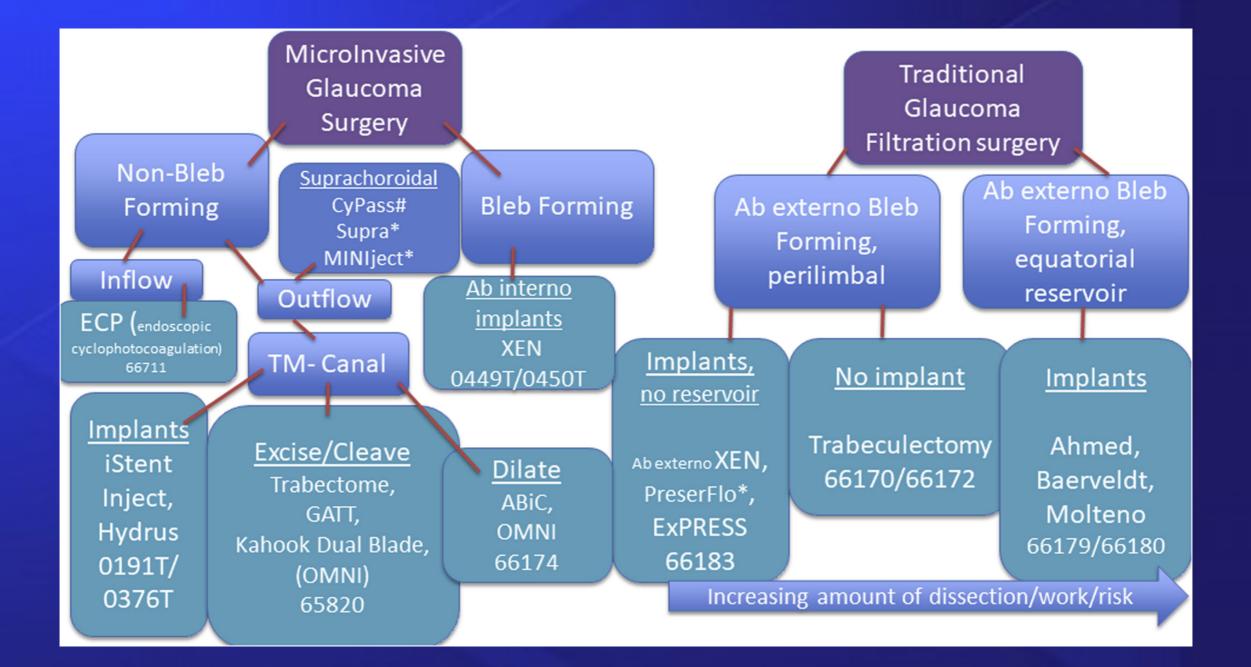
How MIGS work

- Goal is to lower IOP
- Increase aqueous outflow
- Decrease aqueous production

Treatment paradigm



Lots of options!



MIGS in General

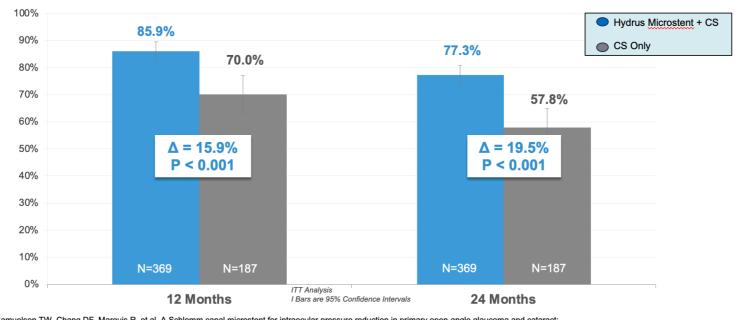
- Mostly for mild to moderate glaucoma, but sometimes appropriate for severe glaucoma
- Usually combined with cataract surgery, but some can be done as stand alone procedures
- ~20% of patients having cataract surgery have a concurrent diagnosis of glaucoma in the United States

Why isn't Cataract surgery on this list?

- Is Cataract surgery alone a MIGS procedure?
- Mechanism?
- ~20% reduction that can last a few years
- Better and longer lasting results with MIGS!

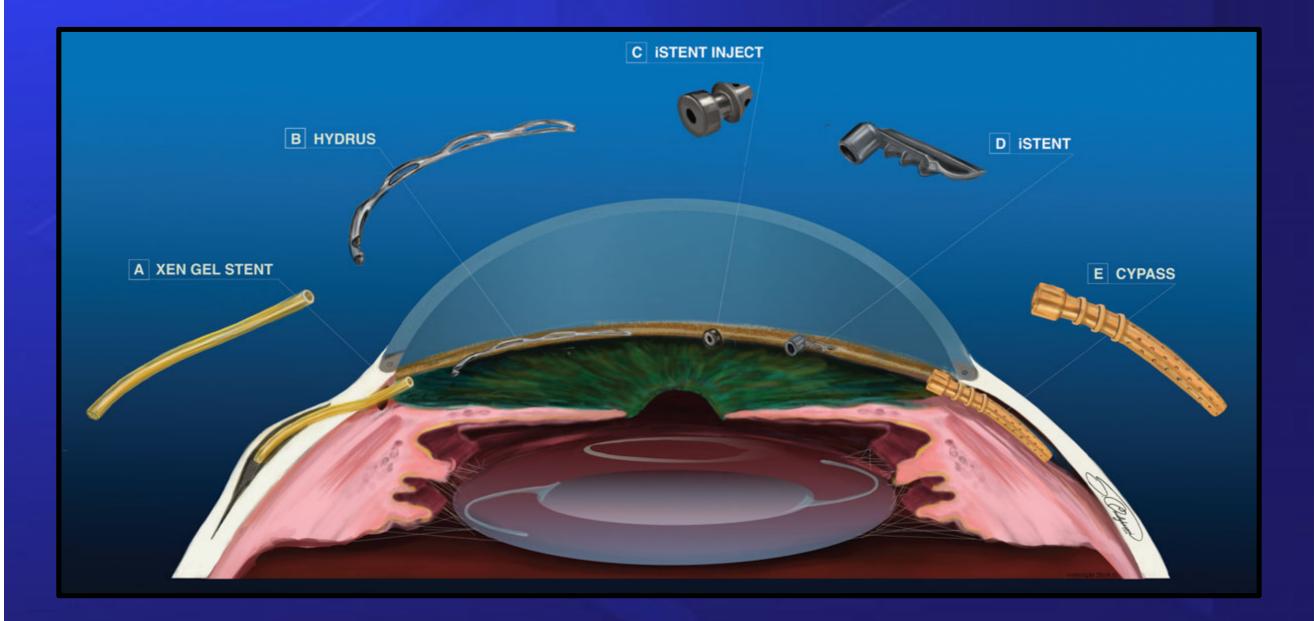
HORIZON: Primary Endpoint¹

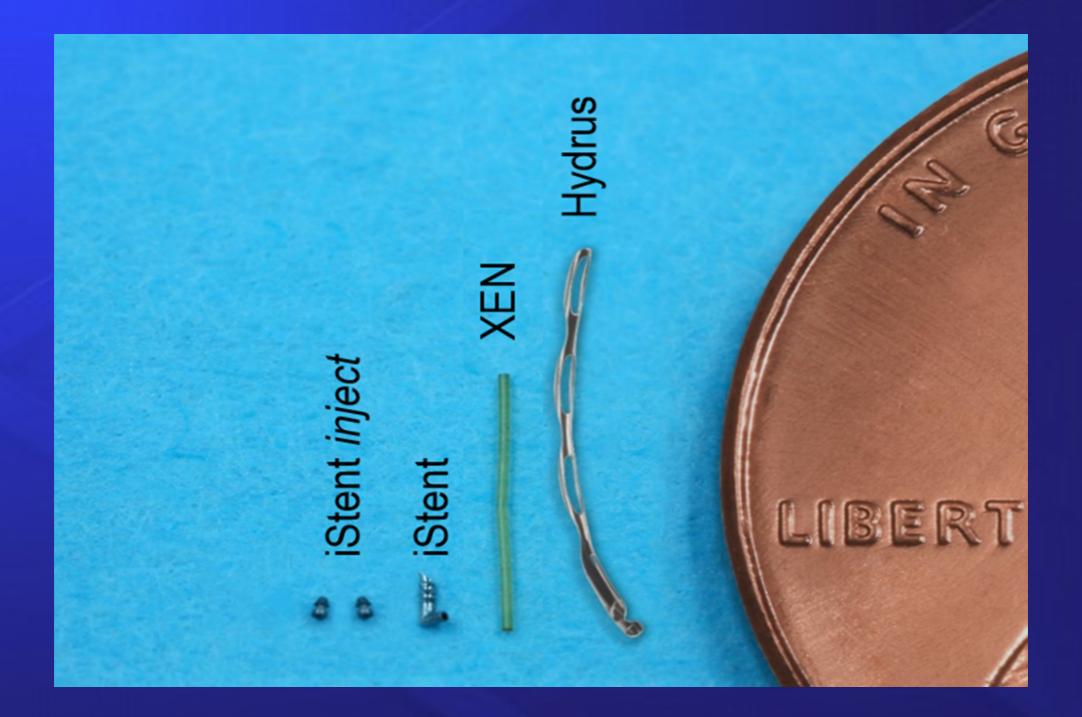
20% REDUCTION IN WASHED OUT DIOP AT 24 MONTHS

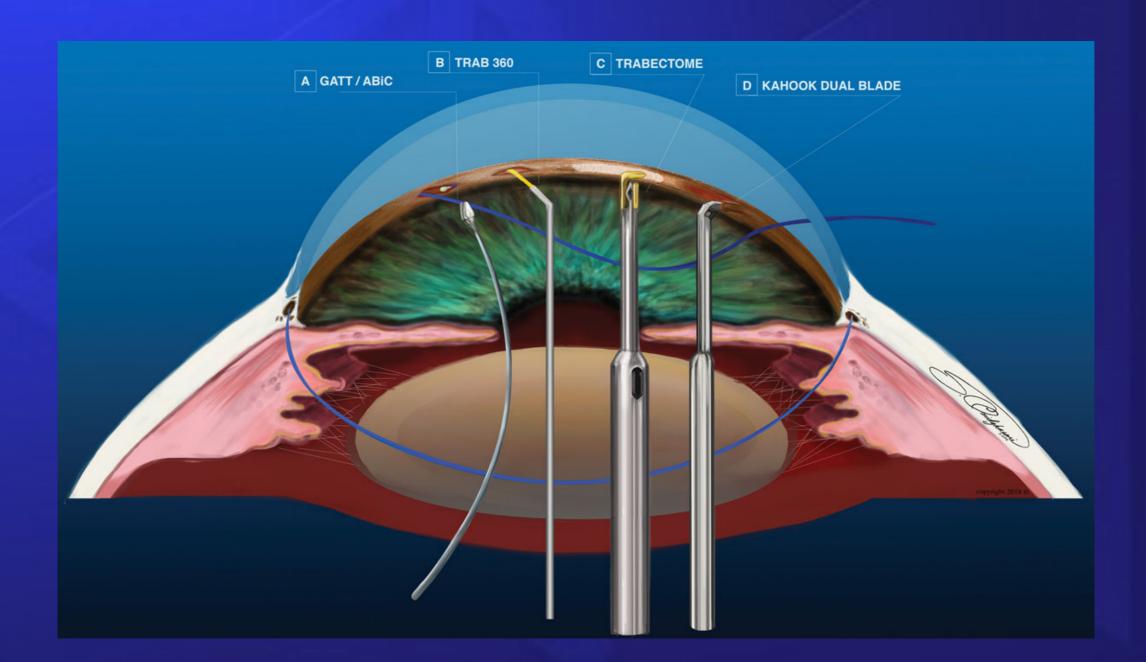


Increasing treatment effect through 24 Months

1. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology 2019;126:29-37.







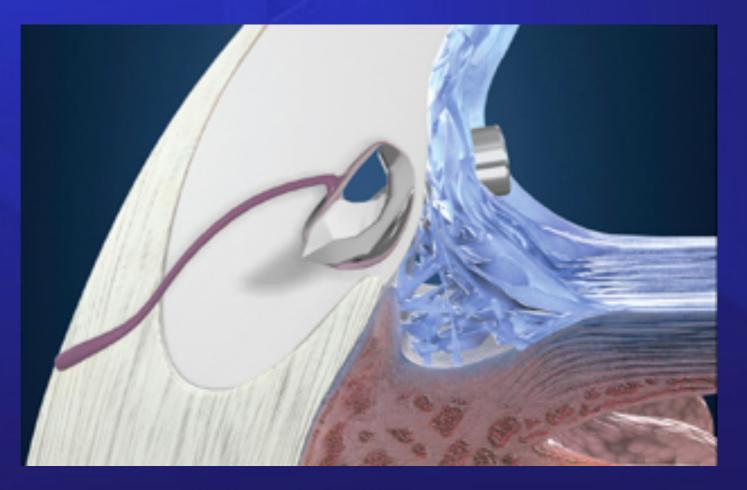
iStent

- Performed only with cataract surgery
- Nonferromagnetic titanium (safe for MRI)
- Insert 1 stent into nasal trabecular meshwork



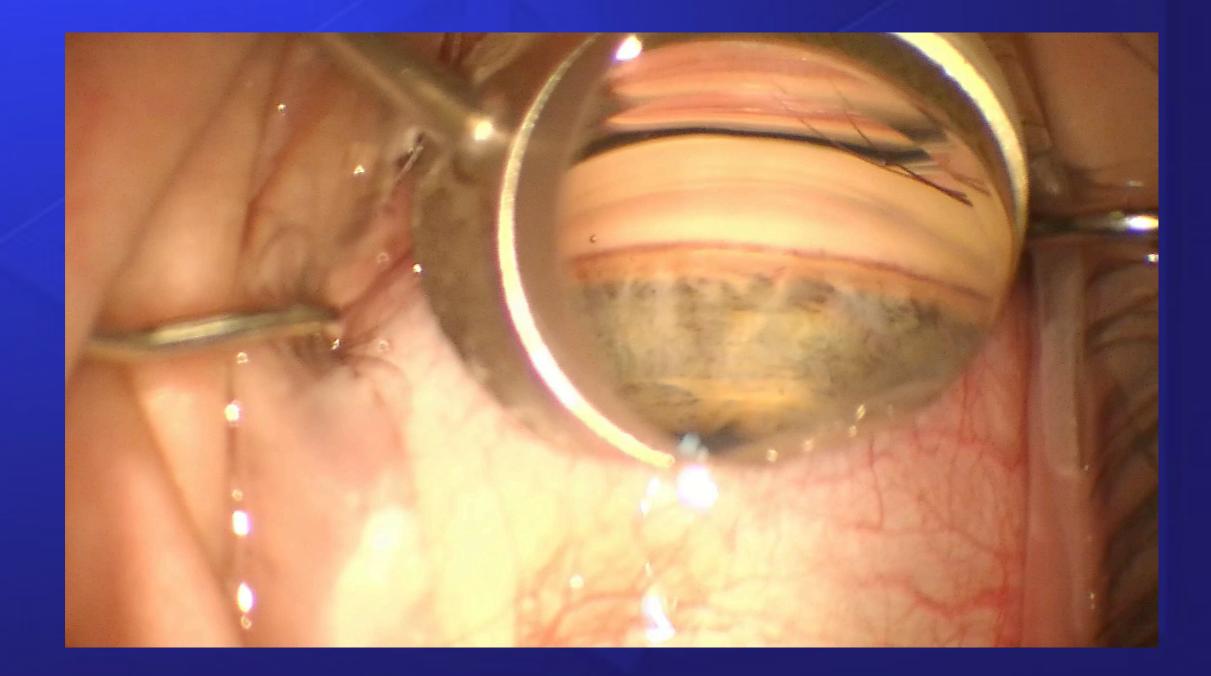
iStent

- MOA: Increases aqueous outflow by directly connecting anterior chamber with Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance



iStent Procedure

• Video:



iStent Good Surgical Candidates

- Must have visually significant cataract (Block anesthesia for cataract surgery)
- Open angle glaucoma (not ocular hypertension!)
- Usually mild to moderate disease, but sometimes severe

iStent Poor Surgical Candidates

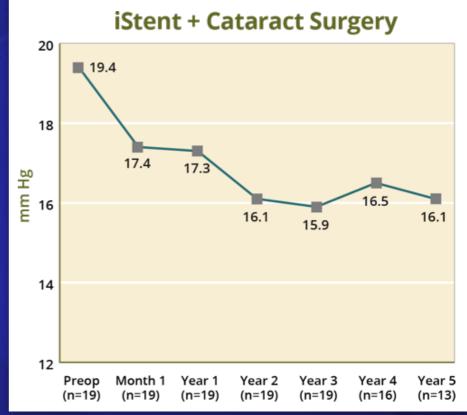
- Iris or angle neovascularization
- Elevated episcleral venous pressure (Retrobulbar tumor, Thyroid eye disease, Sturge-Weber Syndrome)
- Peripheral anterior synechia
- Poor visualization of the angle

iStent Outcomes

- 20-30% IOP reduction
- One stent reduced IOP by ~7 mmHg
- Eliminates on average 1 topical glaucoma drop
- 72% of patients with an istent and cataract surgery achieved an IOP of ≤21 mmHg without ocular hypotensive medications at 12 months, compared to 50% with cataract surgery alone
- 66% of patients with an istent and cataract surgery achieved an IOP reduction of 20% or more without ocular hypotensive medications at 12 months, compared to 48% with cataract surgery alone

iStent Longterm Outcomes

- Retrospective Case Series (Ferguson, Berdahl)
- At 2 years, mean IOP reduction was 22% with a 56% reduction in medications
- Prospective, non-comparative, uncontrolled, non-randomized, interventional case series (Arriola-Villalobos P, et al.)
- At 5 years, 42% of patients were medication free, with mean IOP reduction to 16.1 mm Hg (preoperative medicated IOP was 19.4 mmHg)
- Number of topical medications reduced from 1.3 to 0.8



iStent Complications

Low risk

Hyphema (regurgitation of blood from episcleral venous system possible)

Inflammation

- Peripheral anterior synechia
- Same as cataract surgery (RD, CME, IOP spike, infection)

iStent Post-Op Care

Same as standard cataract surgery (drops or no drops as indicated)

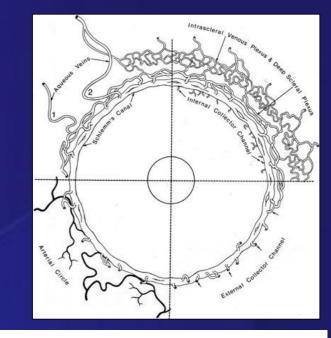
iStent Glaucoma Mangement

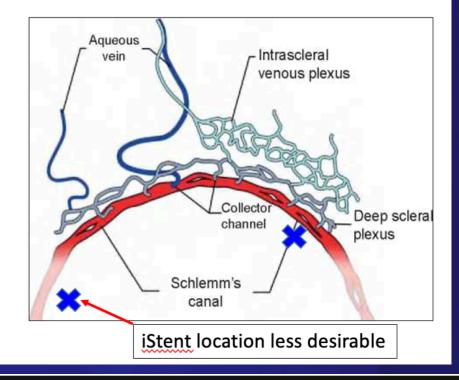
- Continue all glaucoma meds until the 1 month post op visit, then discontinue 1 topical med if trying to reduce drop burden
- Follow up in 1 month to recheck IOP
- Patient still needs monitored long term for glaucoma
- Glaucoma disease (e.g. further TM blockage) can progress leading to increased IOP that the iStent cannot "handle"

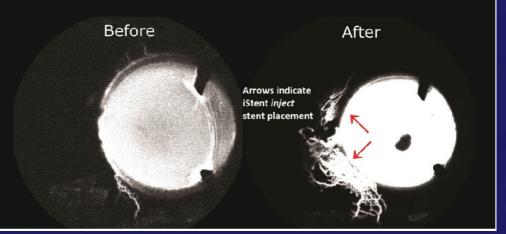
How to improve iStent?

• More stents!

- Single istent inject, increased outflow facility from .16 to .38 µl/min/mmHg, causing a 2-7 mmHg IOP reduction
- Second istent inject, further increased outflow facility to .78 µl/ min/mmHg
- Third istent inject? Unknown
- Why variability? Collector Channels. Anatomic Variants. Not all collector channels are nasally.





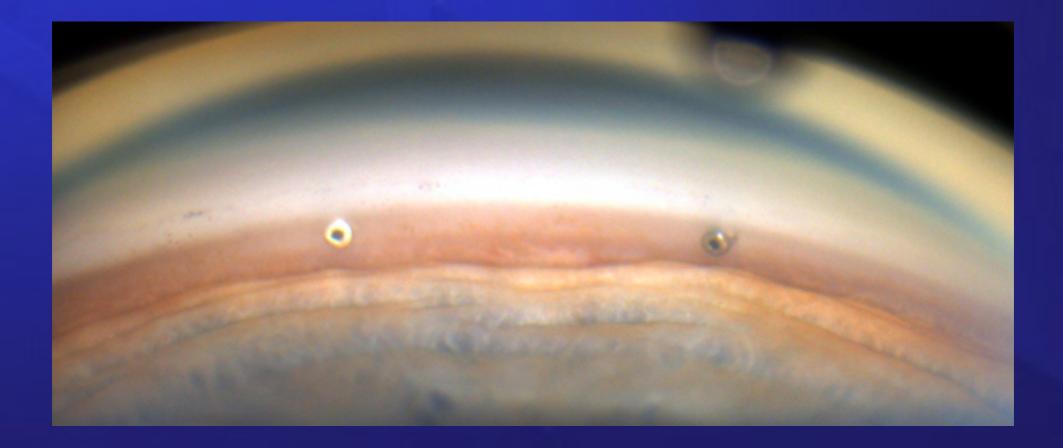


iStent Inject

- Version 2.0
- Performed only with cataract surgery
- Nonferromagnetic titanium (safe for MRI)
- Smallest device to ever be implanted in the human body
- Insert 2 stents, 2 to 3 clock hours apart, into nasal trabecular meshwork (better chance of hitting collector channel!)

iStent Inject

- MOA: Increases aqueous outflow by directly connecting anterior chamber with Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance



iStent Inject Procedure

• Video:



iStent Inject

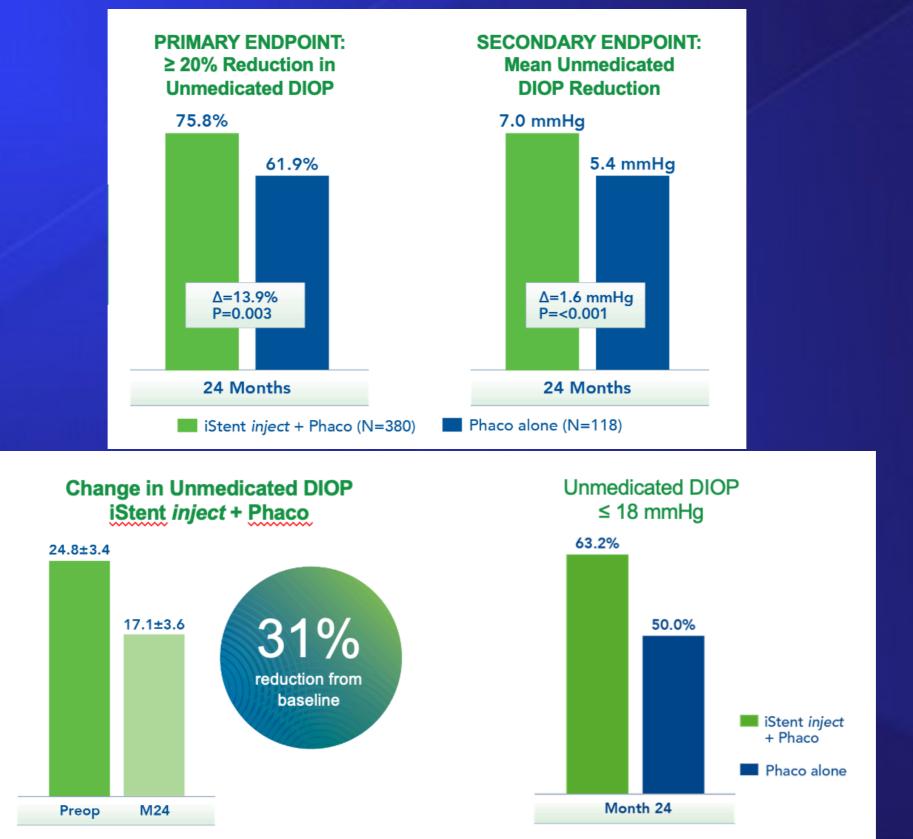
 Surgical candidates, complications, post-op care, and ongoing glaucoma management is the same as the first generation istent



iStent Inject Outcomes

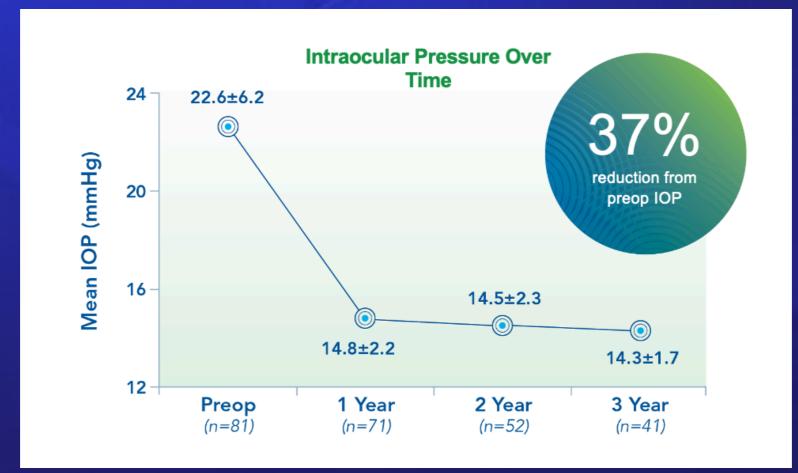
- 20-30% IOP reduction
- 63.2% of patients with an istent inject and cataract surgery achieved an IOP of ≤18 mmHg without ocular hypotensive medications at 24 months, compared to 50% with cataract surgery alone
- 75.8% of patients with an istent inject and cataract surgery achieved an IOP reduction of 20% or more without ocular hypotensive medications at 24 months, compared to 61.9% with cataract surgery alone

iStent Inject Outcomes



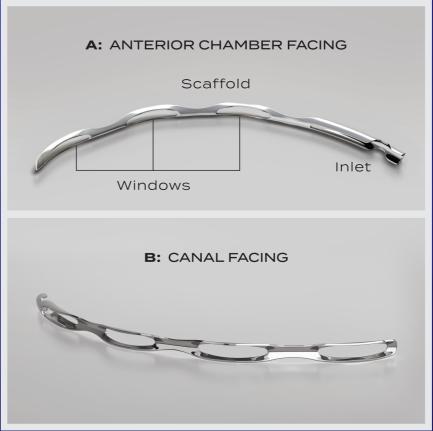
iStent Inject Longterm Outcomes

- Prospective, non-randomized, consecutive cohort (Hengerer)
- At 3 years, 37% reduction from pre-op IOP, mean IOP reduction was 8.3 mmHg



Hydrus Microstent

- Performed only with cataract surgery
- Flexible, biocompatible titanium and nickel alloy (Nitinol, used in cardiac stents, safe for MRI)
- Insert 1 stent into nasal trabecular meshwork, spans 90 degrees



Hydrus Microstent

- MOA: Increases aqueous outflow by directly connecting anterior chamber with Schlemm's canal AND scaffolds/dilates Schlemm's canal to maintain patency.
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance



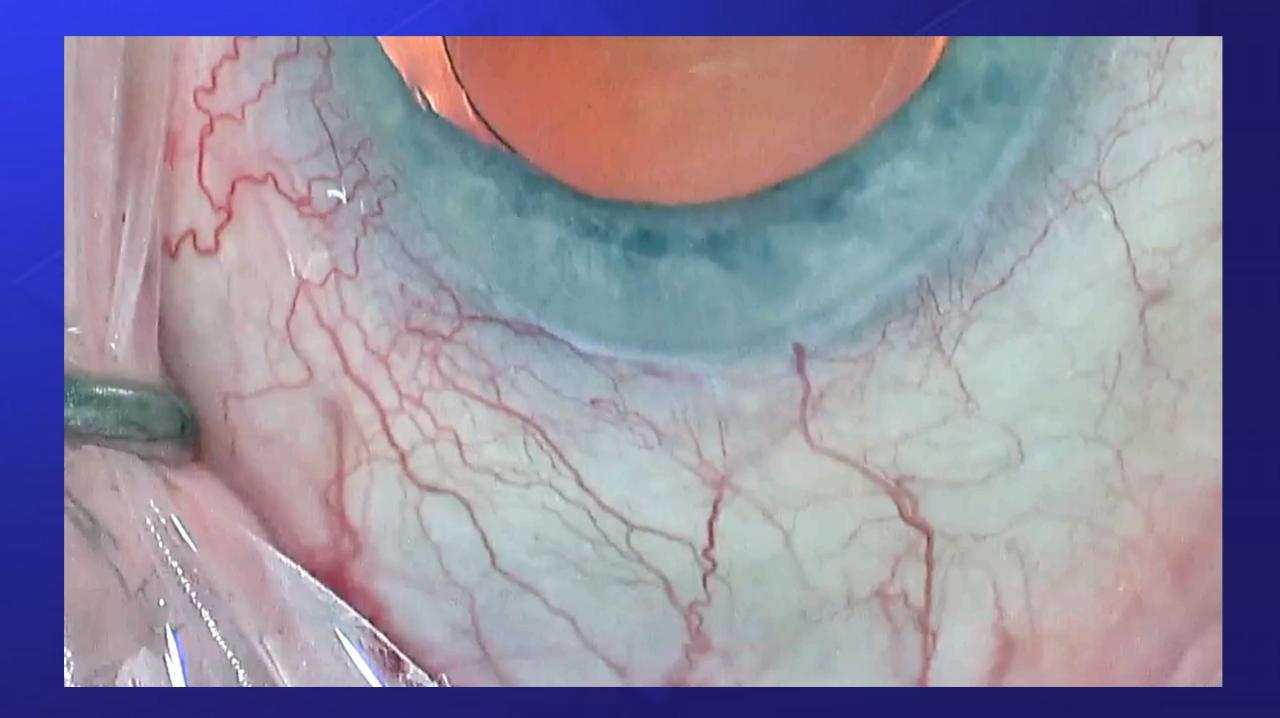
Hydrus Procedure

• Video:



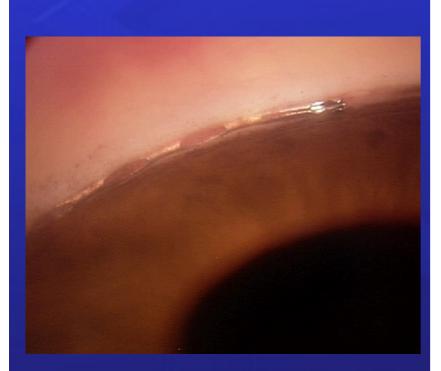
Hydrus Outflow

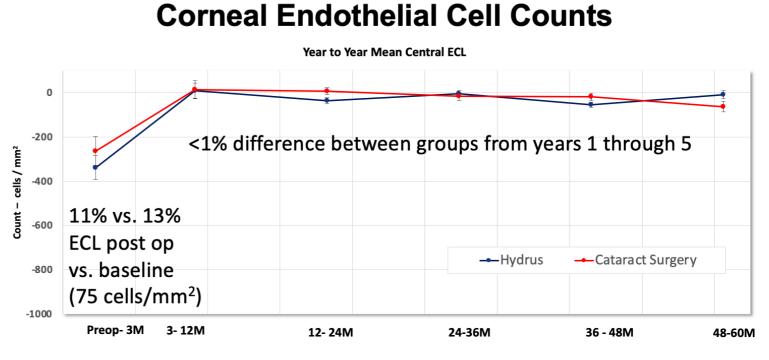
• Video:



Hydrus

 Surgical candidates, complications, post-op care, and ongoing glaucoma management is the same as the first generation istent and istent inject





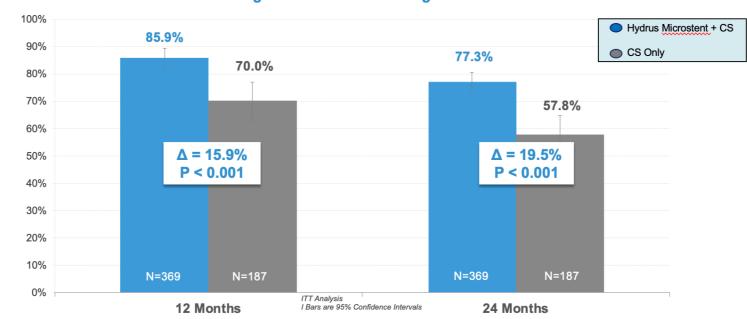
Error bars are 95% Confidence Intervals

Hydrus Outcomes

- 20-30% IOP reduction
- 77.3% of patients with a hydrus and cataract surgery achieved an IOP reduction of 20% or more without ocular hypotensive medications at 24 months, compared to 57.8% with cataract surgery alone
- Patients with a hydrus and cataract surgery achieved a -7.6 mmHg IOP reduction without ocular hypotensive medications at 24 months, compared to -5.3 mmHg IOP reduction with cataract surgery alone
- 78% of all Hydrus patients were medication free at 24 month, compared to 48% with cataract surgery alone

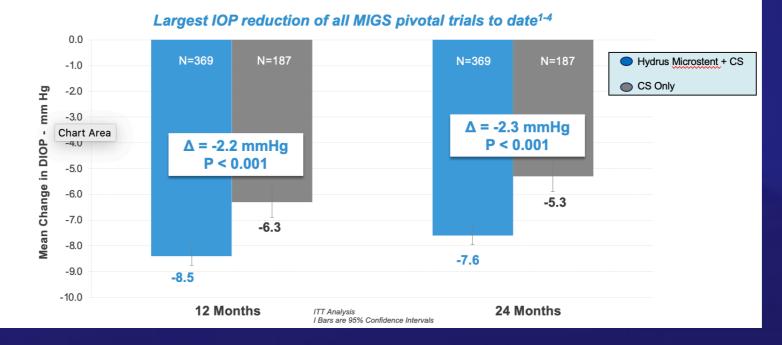
Hydrus Outcomes

HORIZON: Primary Endpoint¹ 20% REDUCTION IN WASHED OUT DIOP AT 24 MONTHS



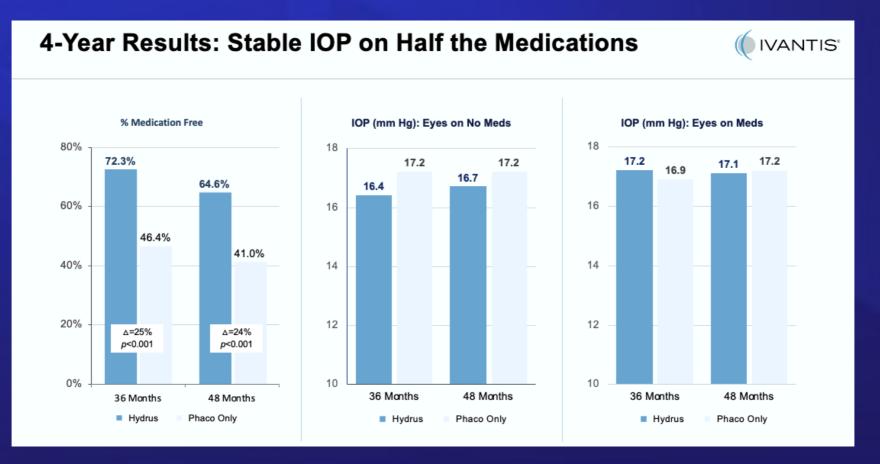
Increasing treatment effect through 24 Months

HORIZON: Secondary Endpoint¹ CHANGE IN WASHED OUT DIOP AT 24 MONTHS



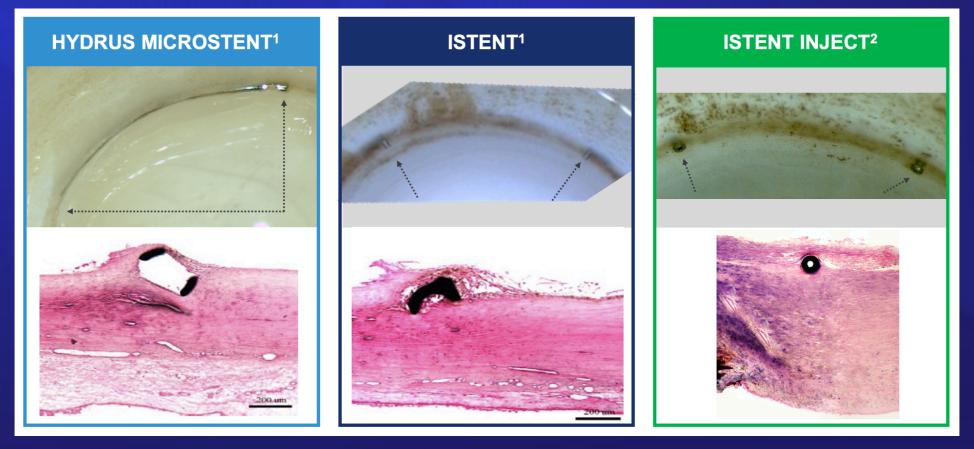
Hydrus Longterm Outcomes

- 65% of all Hydrus patients were medication free at 48 month, compared to 41% with cataract surgery alone
- Hydrus reduces risk of secondary surgical intervention (trab, tube, CPC) from 6% with cataract surgery alone to 2.1% with hydrus and cataract surgery at 4 years.



iStent vs Hydrus?

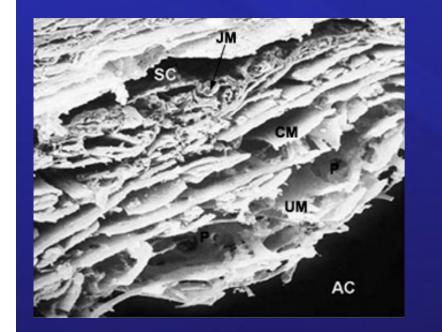
- 79% increase in outflow facility for hydrus compared to 11% increase for istent inject
- 39.7% of patients with a hydrus achieved an IOP reduction of 20% or more without ocular hypotensive medications at 12 months, compared to 13.3% with an istent

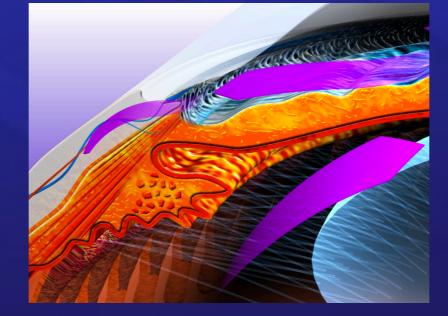


Trabectome

• Goniotomy

- Performed with cataract surgery or as standalone procedure
- Irrigation, electrocautery, and aspiration in sequence
- Ablates 180 degrees of trabecular meshwork

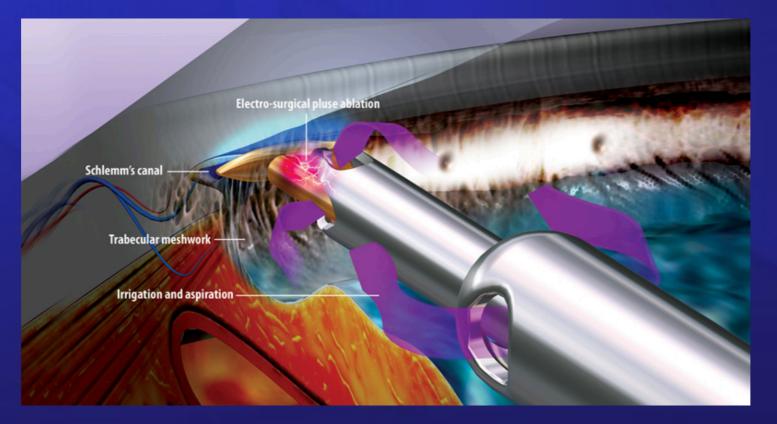






Trabectome

- MOA: Increases aqueous outflow by directly connecting the anterior chamber with Schlemm's canal by removing a strip of trabecular meshwork and the inner wall of Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance

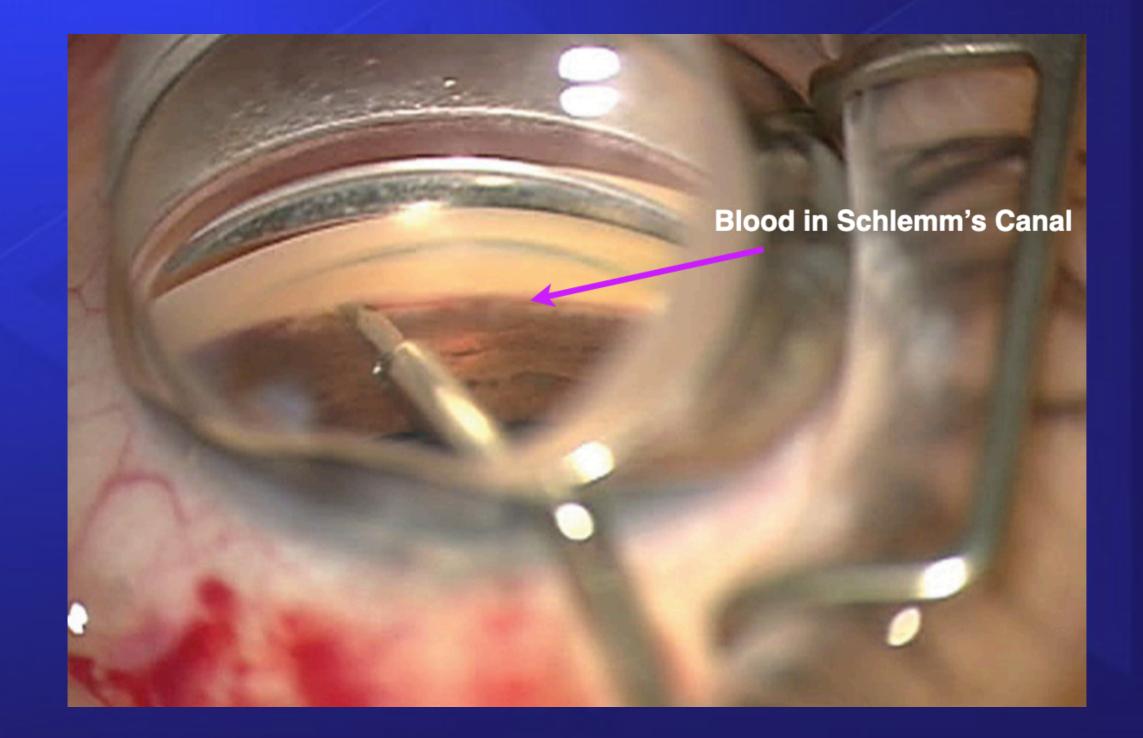


Trabectome Procedure

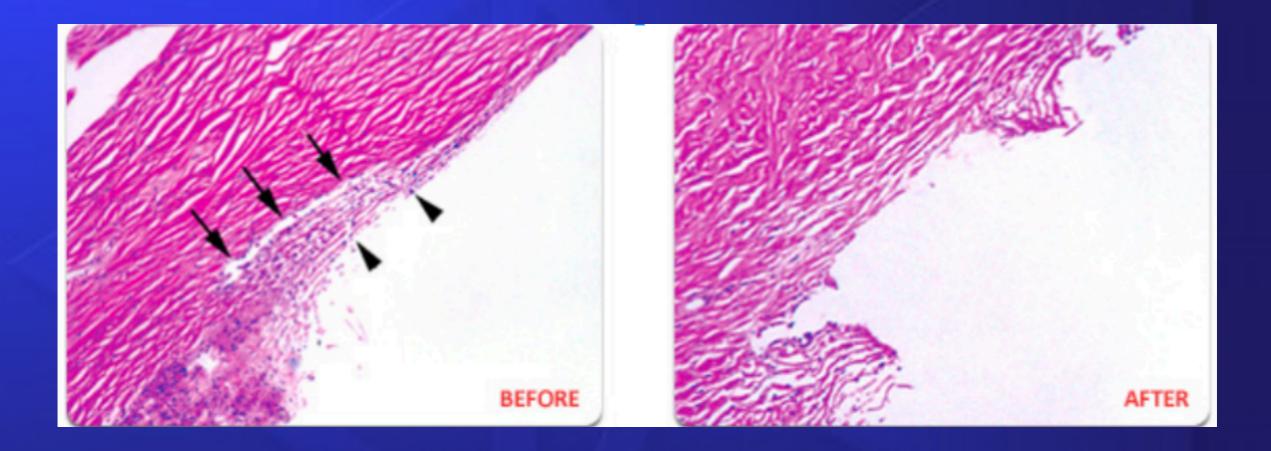
• Video:



Trabectome



Trabectome



Trabectome Good Surgical Candidates

- Phakic, pseudophakic or aphakic patients
- Open angle glaucoma
- Ocular Hypertension
- Some patients with angle closure glaucoma?

Trabectome Poor Surgical Candidates

- Iris or angle neovascularization
- Elevated episcleral venous pressure (Retrobulbar tumor, Thyroid eye disease, Sturge-Weber Syndrome)
- Peripheral anterior synechia
- Poor visualization of the angle

Trabectome Outcomes

- 20-30% IOP reduction
- IOP was reduced from 26.6 to 17.4 mmHg at 6 months
- Average number of medications also decreased from 4.0 to 2.3 at 6 months
- Eliminates on average ~1 topical glaucoma drop
- 84% had an IOP of 21mmHg or less (with or without medication)

Trabectome Complications

- Inflammation
- Hyphema (regurgitation of blood from episcleral venous system possible)
- Peripheral anterior synechia
- Infection

Trabectome Post-Op Care

- Standard cataract surgery antibiotic and NSAID medications
- Durezol 0.05% q2h x 2 weeks, qid x 1 week, tid x 1 week, bid x 1 week, qd x 1 week then stop
- Add Pilocarpine 1%? (Risk of closure from residual TM)

Trabectome Glaucoma Mangement

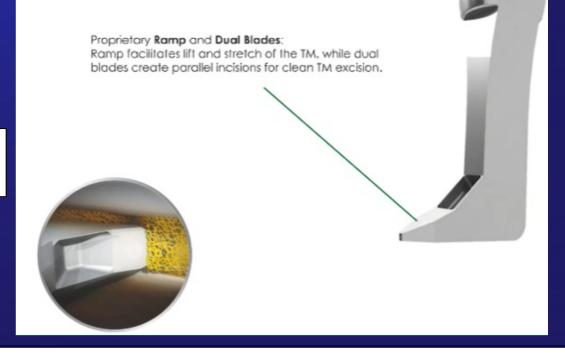
- Continue all glaucoma meds until the 1 month post op visit, then discontinue 1 topical med if trying to reduce drop burden
- Follow up in 1 month to recheck IOP
- Patient still needs monitored long term for glaucoma
- Glaucoma disease (e.g. further TM blockage) can progress leading to increased IOP

Kahook Dual Blade Goniotomy Goniotomy

- Performed with cataract surgery or as standalone procedure
- Sharp tip blade pierces the trabecular meshwork, a small ramp stretches the trabecular meshwork, and then two parallel blades excise the trabecular meshwork thereby minimizing residual tissue

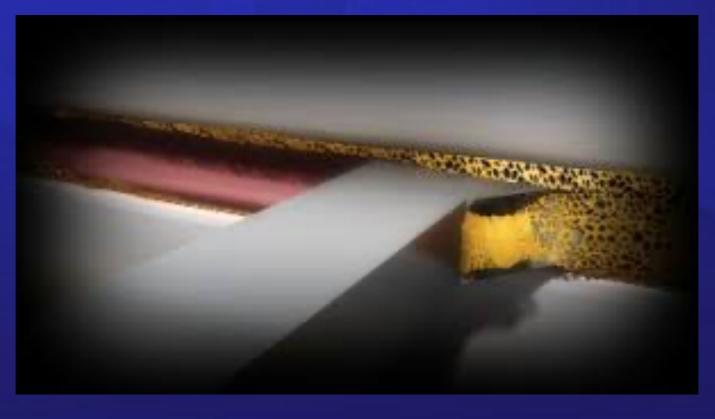


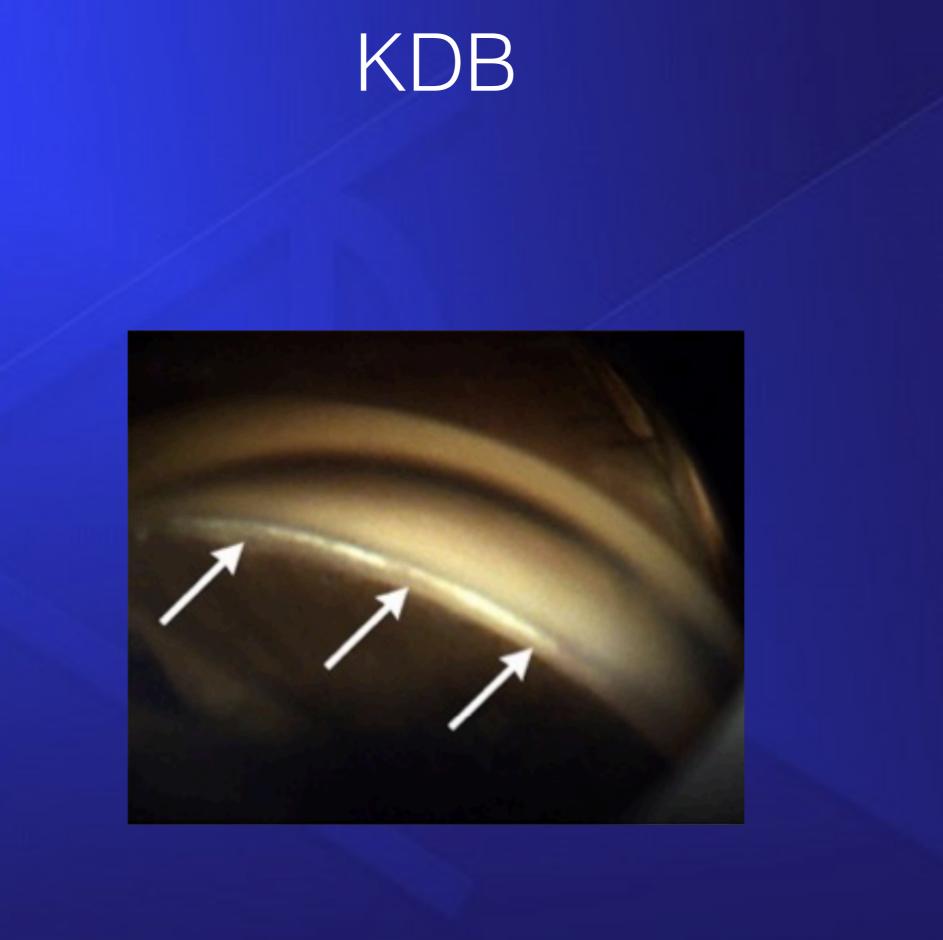
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Kahook Dual Blade Goniotomy

- MOA: Increases aqueous outflow by directly connecting the anterior chamber with Schlemm's canal by removing a strip of trabecular meshwork and the inner wall of Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance





KDB

 Surgical candidates, complications, post-op care, and ongoing glaucoma management is the same as Trabectome

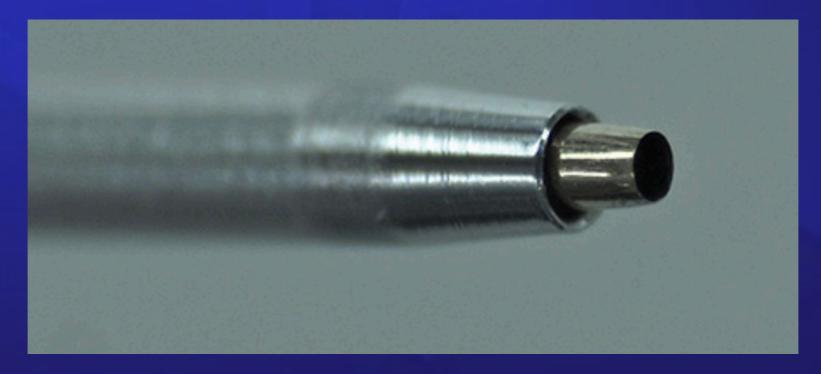
KDB Outcomes

- 20-30% IOP reduction
- 57.7% of patients with a KDB and cataract surgery achieved an IOP reduction of 20% or more at 12 months
- Average number of medications also decreased from 1.6 to 0.8 at 12 months

iAccess Trabecular Trephine

Goniotomy

- Combined with other MIGS (iStent)
- Additional 1-2 mmHg reduction when combined with iStent at 3 months

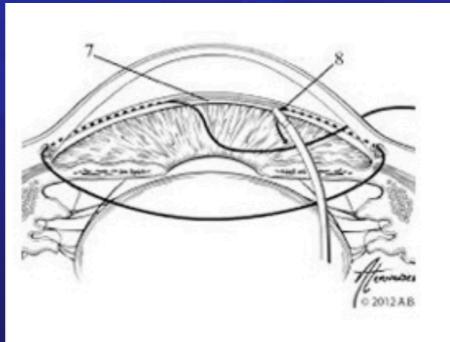


iAccess Trabecular Trephine

- MOA: Increases aqueous outflow by directly connecting the anterior chamber with Schlemm's canal by removing a 220 um segment of the trabecular meshwork and the inner wall of Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance

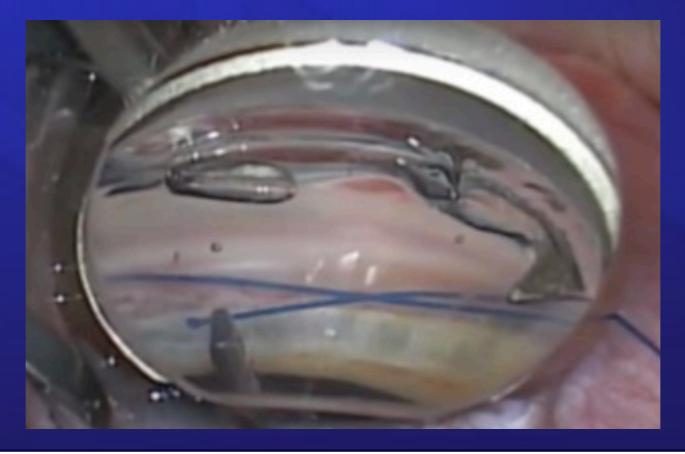
Gonioscopy Assisted Transluminal Trabeculotomy (GATT)

- Nasal goniotomy and then *ab interno* trabeculotomy
- Performed with cataract surgery or as standalone procedure
- 250um iTrack microcatheter advanced 360 degrees through Schlemm's canal
- Shearing of trabecular meshwork 360 degrees



GATT

- MOA: Increases aqueous outflow by directly connecting the anterior chamber with Schlemm's canal by removing the trabecular meshwork and the inner wall of Schlemm's canal
- Bypasses juxtacanalicular meshwork, which accounts for 75% of outflow resistance



GATT

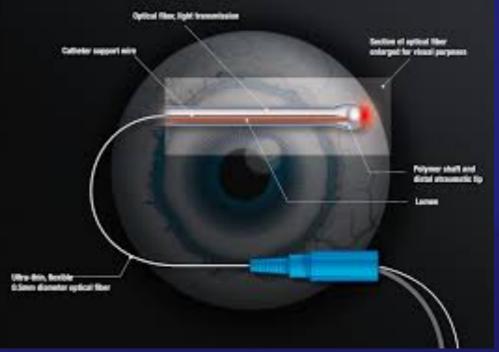
- Good surgical candidates are adult or pediatric patients with open angle glaucoma and a clear cornea
- Complications, post-op care, and ongoing glaucoma management is the same as Trabectome and KDB

GATT Outcomes

- Average IOP decrease of 11.1 mmHg at 12 months
- Average drop reduction by 1.1 drops at 12 months
- 9% of patients had treatment failure and needed further surgical intervention
- Promising results in primary congenital glaucoma and juvenile open angle glaucoma

Ab Interno Canaloplasty (ABiC)

- Nasal goniotomy, catheterization, and viscodilation of Schlemm's canal
- Performed with cataract surgery or as standalone procedure
- 250um iTrack microcatheter with fiber optic light advanced 360 degrees through Schlemm's canal
- Viscoelastic injected into Schlemm's canal and the distal collector channels



Ab Interno Canaloplasty (ABiC)

 MOA: Increases aqueous outflow by dilating Schlemm's canal



CONTROL EYE



TEST EYE 360° Viscodilation of Schlemm's canal*



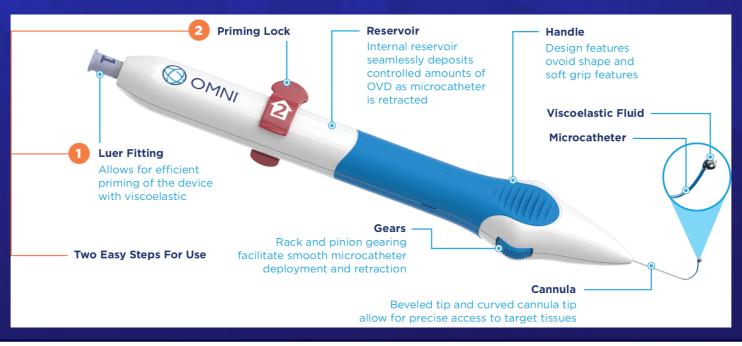
 Surgical candidates, complications, post-op care, and ongoing glaucoma management is the same as GATT

ABiC Outcomes

- 84.9% of patients with ABiC and cataract surgery achieved an IOP reduction of 20% or more at 8 months
- Average number of medications also decreased from 2.8 to 1.1 at 12 months
- 34% reduction in mean IOP at 36 months in patients with ABiC and cataract surgery

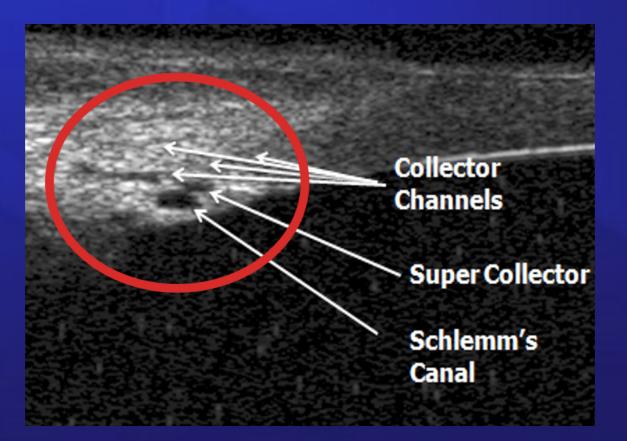
Omni (Trab and Visco 360)

- Catheterization, viscodilation of Schlemm's canal, and titratable trabeculotomy
- Performed with cataract surgery or as standalone procedure
- Microcatheter advanced 180 degrees through Schlemm's canal
- Predetermined amount of viscoelastic injected into Schlemm's canal and the distal collector channels
- Shearing of trabecular meshwork 180 degrees, can be repeated for remaining 180 degrees for full 360 degree treatment



Omni

 MOA: Increases aqueous outflow by dilating Schlemm's canal and/or directly connecting the anterior chamber with Schlemm's canal by removing the trabecular meshwork and the inner wall of Schlemm's canal



Omni Procedure

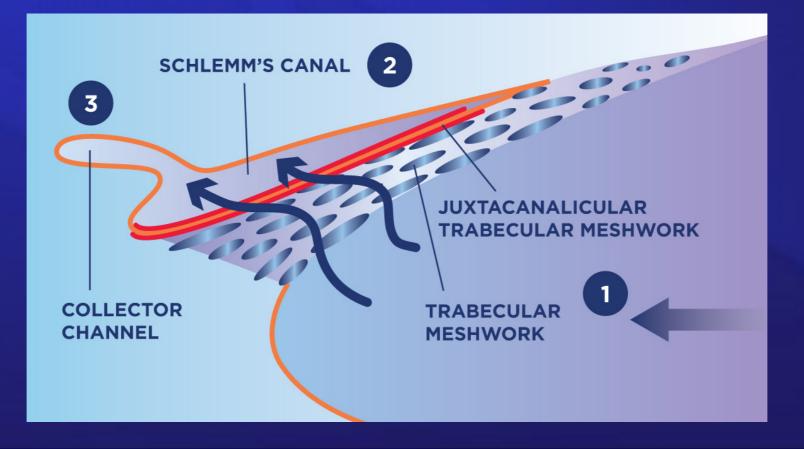
• Video:

Omni

 Surgical candidates, complications, post-op care, and ongoing glaucoma management is the same as GATT and ABiC

Omni Outcomes

- 66% of patients with Omni and cataract surgery achieved an IOP reduction of 20% or more at 8 months
- 39% reduction in mean IOP at 18 months in patients with Omni and cataract surgery



CyPass Micro-Stent

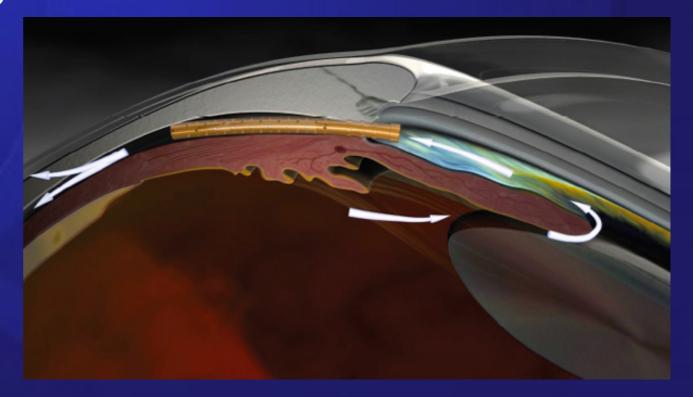
- Pulled from market in August 2018
- Performed only with cataract surgery
- 6.35mm long polymide stent with 300 um inner lumen
- Insert 1 stent into nasal supracilliary space





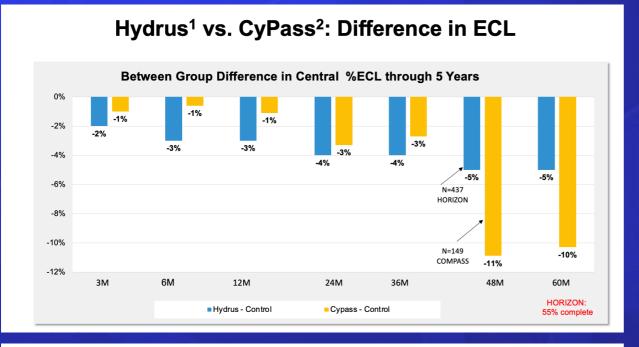
CyPass Micro-Stent

- MOA: Increases aqueous outflow through uveoscleral pathway by creating a microcyclodialysis and directly connecting the anterior chamber with supracilliary/suprachoroidal space
- Not limited by episcleral venous pressure
- 30% reduction in IOP

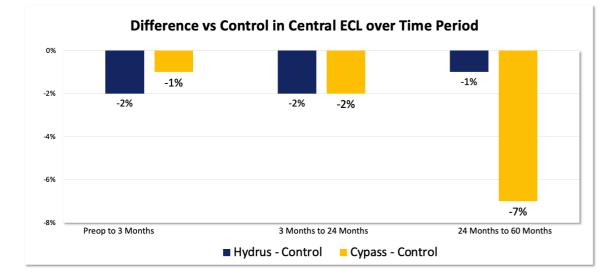


CyPass and Endothelial Cells

 If more than 1 retention ring visible, may need to trim or remove CyPass



ECD Findings: Hydrus vs. CyPass





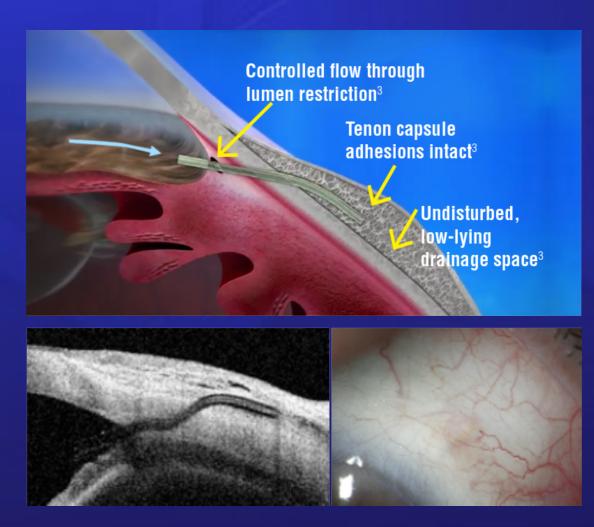
Xen Gel Stent

- Performed with cataract surgery or as standalone procedure
- 6mm long porcine-derived gelatin cross linked with glutaraldehyde stent with 45 um inner lumen
- Insert 1 stent into superior subconjunctival space



Xen Gel Stent

- MOA: Increases aqueous outflow by directly connecting anterior chamber with subconjunctival/subtenons space
- Not limited by episcleral venous pressure



Xen Gel Stent

- Creates a filtering bleb
- More similar to Trabeculectomy or Tube shunt.
- Not really a MIGS in my opinion

EndoCycloPhotocoagulation

- Performed with cataract surgery or as standalone procedure
- Fiber-optic endoscope visualizes the ciliary processes
- 810nm diode laser
- 175 watt xenon light

EndoCycloPhotocoagulation

 MOA: ablates ciliary body to reduce aqueous production and lower IOP



ECP Indications

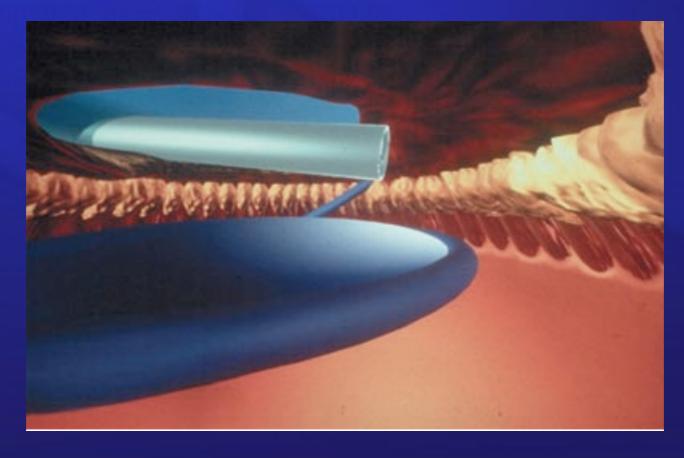
- Phakic, pseudophakic or aphakic patients
- Open angle glaucoma
- Ocular Hypertension

ECP Contraindications

- Uveitis
- Cystoid macular edema
- Iris or angle neovascularization

ECP Procedure

- Initial laser setting, 0.25 W with continuous duration
- Power titrated up until visible whitening of ciliary processes occurs
- 360 degrees of the ciliary body is treated



ECP Procedure

Before:

After: Ciliary processes are treated until there is shrinkage and whitening



ECP Video

Endoscopic Cyclophotocoagulation

Limbal Approach

Aphakic Eye

ECP Outcomes

- Effective in 80% of patients
- 30% IOP reduction
- Eliminates on average 1 topical glaucoma drop
- 30% of patients achieved IOP less than 19mmHg without medication

ECP Complications

- Chronic uveitis
- CME
- Hyphema
- IOP spike

- Choroidal Detachment
- Retinal Detachment
- Endopthalmitis

ECP Post Op

- Durazol 0.05%
 - q2h x 2 weeks
 - qid x 1 week
 - tid x 1 week
 - bid x 1 week
 - qd x 1 week
- Standard cataract surgery antibiotic and NSAID medications

ECP Glaucoma Management

- Continue all glaucoma meds until the 1 month post op visit, then discontinue 1 topical med if trying to reduce drop burden
- Follow up in 1 month to recheck IOP
- Patient still needs monitored long term for glaucoma
- Glaucoma disease (e.g. further TM blockage) can progress leading to increased IOP

Combos

- Cataract surgery with stent and ECP*
- Trabecular Bypass with Rho-Kinase Inhibitor

Quick Generalization

- 20-30% IOP reduction
- Works about 80% of the time
- Minimal risk
- Can be done at the same time as your cataract surgery
- Might get you off 1 drop or prevent you from needing a more invasive surgery in the future
- Educate your patients on their options and what to expect. (Let comangeing doctors know what you want for your patients)

Questions? Thank You.

Special thanks to Michael Chaglasian, O.D. for his contributions to this lecture