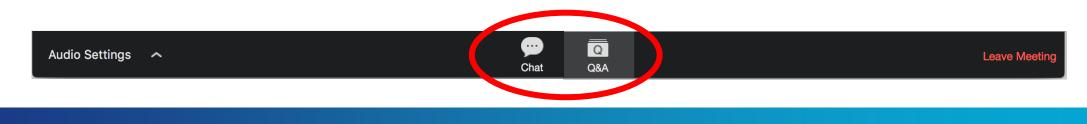


Glaucoma Surgical Treatment: Minimally Invasive Glaucoma Surgery

Tigran Kostanyan, MD Glaucoma and Cataract Specialist Wellish Vision Institute May 6 2021

This event is supported with an unrestricted educational grant from Ivantis

- For a 1-hour webinar attendees must be online for a minimum of 50 minutes
- For a COPE certificate, please fill out the survey link in the chat. Also, the survey link will appear when the webinar ends.
- CE certificates will be delivered by email and sent to ARBO with OE tracker numbers
- For the best audio experience, close all unnecessary windows on your computer
- Ask questions using the zoom on-screen floating panel



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Tigran Kostanyan, MD

Education

- Fellowship Glaucoma, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
- Residency University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
- Medical School Yerevan State Medical University, Yerevan, Armenia

Bio

Dr. Kostanyan was born in Armenia. He graduated from Yerevan State Medical University with honors at age 21. He completed his ophthalmology residency at the Malayan Eye Center in Yerevan. While in residency Dr. Kostanyan worked at the Armenian Eye Care Project, a nonprofit organization providing medical and surgical eye care in underserved areas of the country. After moving to United States he joined Ophthalmic Imaging Research Laboratory and worked with world-renowned glaucoma specialist and one of the inventors of optical coherence tomography Dr. Joel Schuman. Dr. Kostanyan has since completed his second ophthalmology residency and prestigious glaucoma and anterior segment fellowship at the University of Pittsburgh Medical Center.

Dr. Kostanyan specializes in cataract and medical, laser and surgical treatments of glaucoma. Having in his armamentarium both traditional and newer microincisional glaucoma surgeries (MIGS) he is able to personalize a surgical approach for his patients.



Glaucoma Surgical Treatment: Minimally Invasive Glaucoma Surgery

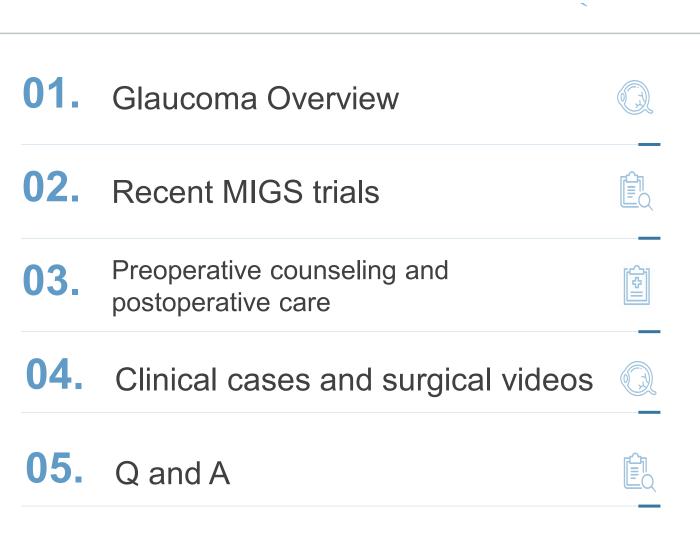
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Financial Disclosures

- Ivantis: Consultant
- ImprimisRx: Consultant

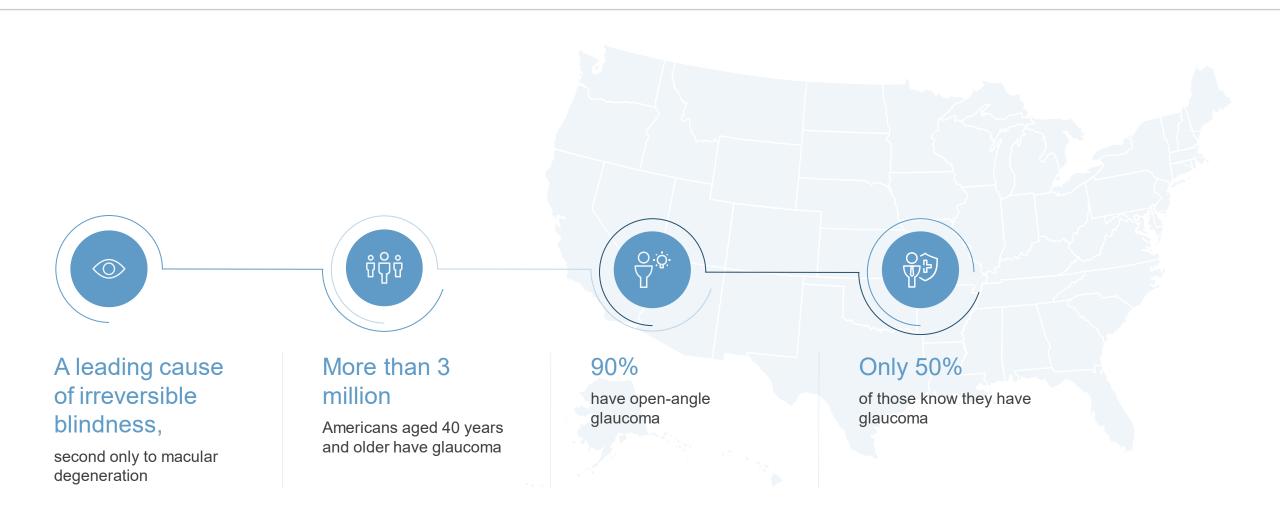
Contents



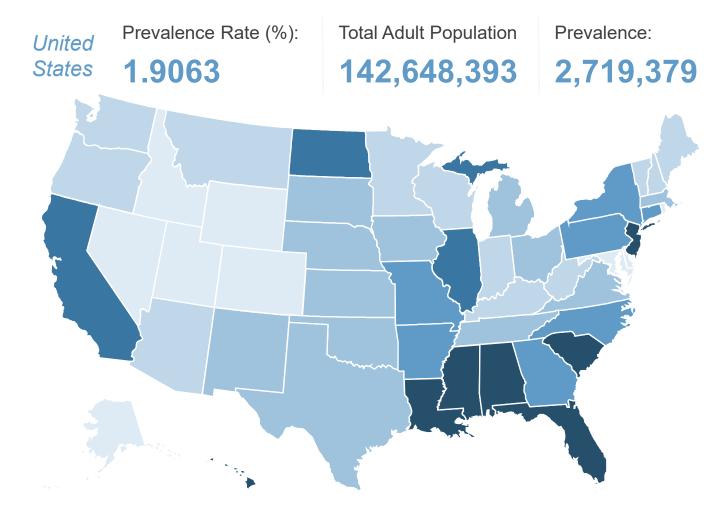




The Current Prevalence of Glaucoma in US

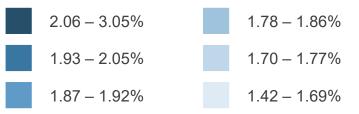


The Prevalence of Glaucoma in the US by State

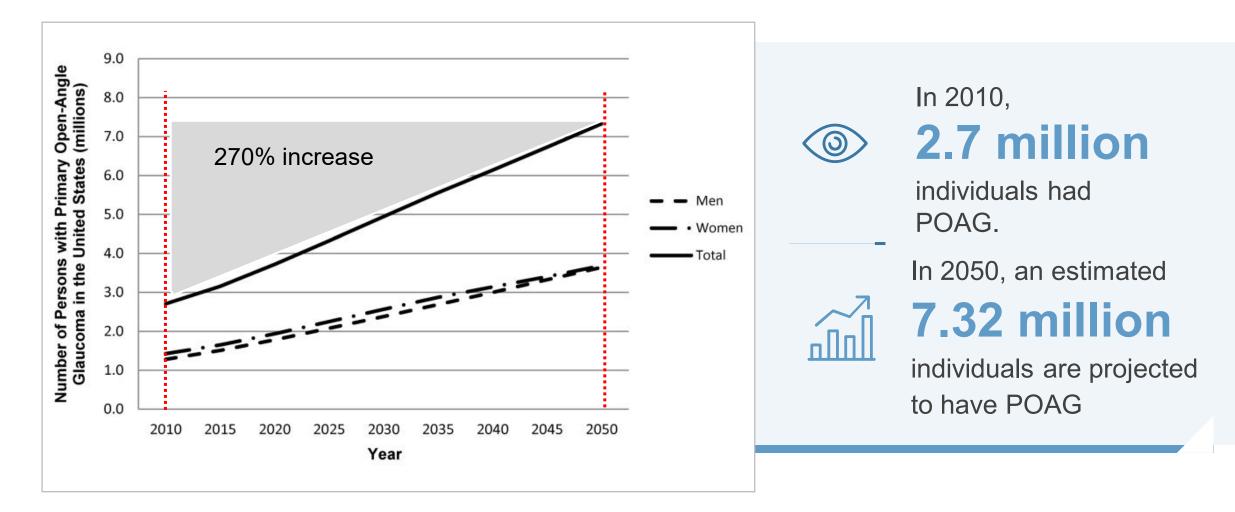


The map above reflects estimated state-by-state prevalence rates of glaucoma. The overall national rate is 1.9% for the U.S. population age 40 and older, indicating that more than 2.7 million older Americans have primary open-angle glaucoma.

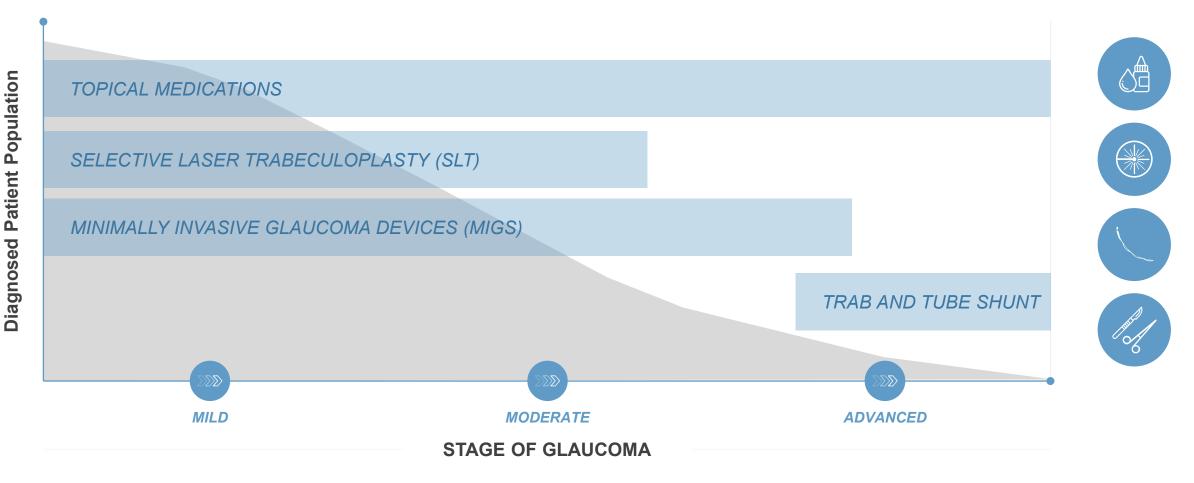
State Prevalence Rate



Projected Growth of Glaucoma Diagnosed in the US by 2050

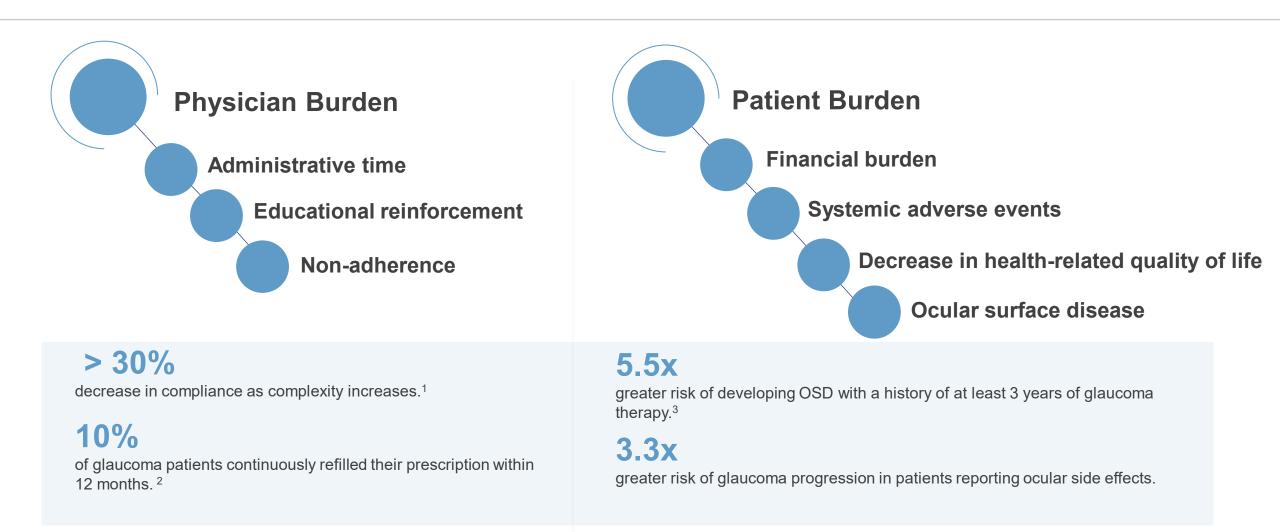


Glaucoma Treatment Options



*Market Scope 2017 Glaucoma Surgical Device Report

Drawbacks to Topical Medications

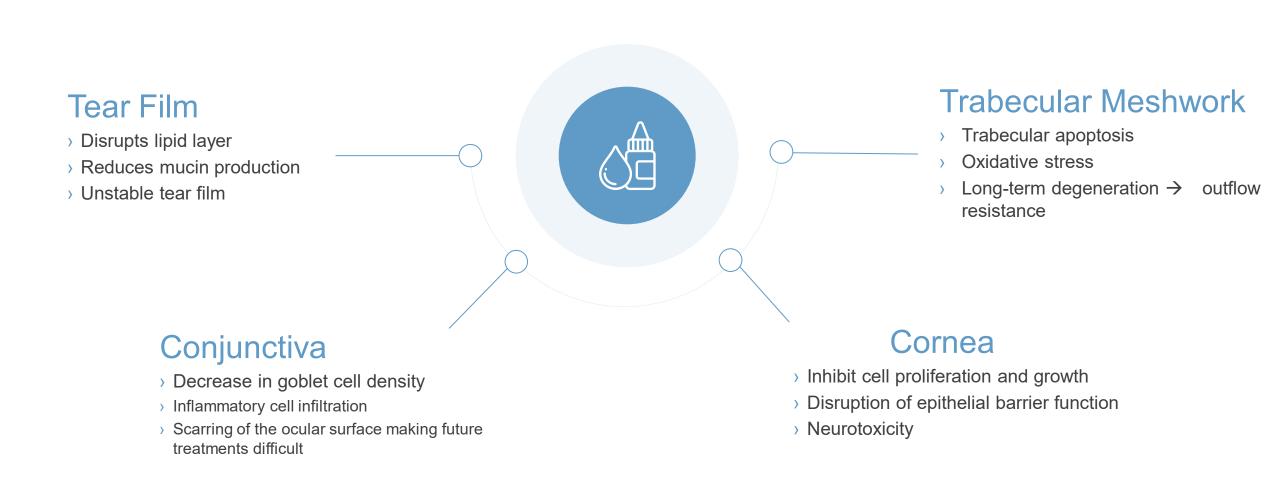


1. Reardon G1, Kotak S, Schwartz GF. Objective assessment of compliance and persistence among patients treated for glaucoma and ocular hypertension: a systematic review. Patient Prefer Adherence. 2011;5:441-63. doi:0.2147/PPA.S23780. Epub 2011 Sep 23.

2. Friedman DS, Quigley HA, Gelb L. Using pharmacy claims data to study adherence to glaucoma medications: methodology and findings of the Glaucoma Adherence and Persistency Group (GAPS). Invest Ophthalmol. Vis Sci. 2007;48:5052–5057

3. Rossi GC1, Pasinetti GM, Scudeller L. Risk factors to develop ocular surface disease in treated glaucoma or ocular hypertension patients. Eur J Ophthalmol. 2013 May-Jun;23(3):296-302.

Tissue Sequelae of Chronic Topical Preservatives









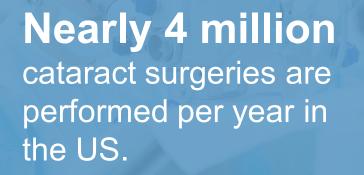








Can We Reduce the Burden



Up to 20% of patients undergoing cataract surgery have a concurrent diagnosis of glaucoma, according to US studies.¹ *Potentially 800,000 patients.*

Cataract surgery is estimated to increase at a rate of 3.1% each year.² *Potentially 124,000 additional cataract patients each year.*

1. Tseng, Victoria I. et al. Risk of Fractures Following Cataract Surgery in Medicare Beneficiaries.JAMA. Vol 308, No 5. August 1,2012 2. MarketScope Report: 2017 Cataract Surgical Equipment Report. A Global Market Analysis For 2016 To 2022.

Optometrists are at the frontline to recommend treatment for cataract and glaucoma patients.



Established relationships with patients

- > Ability to inform patients of the best technologies available
- > Needs, wants, expectations, and lifestyle

Reduce patient and physician burden

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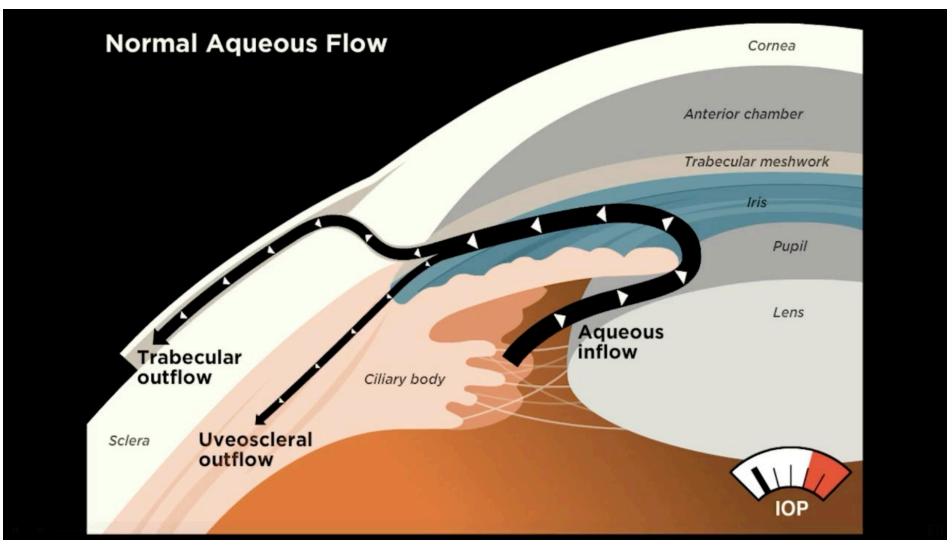
- Cost/pharmacy visits and prior authorizations
- Ocular surface disease and potential effects on visual acuity

Ability to impact patients' post-operative lifestyle

 ONE TIME opportunity during cataract surgery to address a patient's cataract, refractive needs (astigmatism and presbyopia) as well as their glaucoma



Aqueous Outflow Pathways



Source: https://www.aao.org/basic-skills/animation-of-aqueous-flow

Resistance Within The Conventional Outflow Pathway

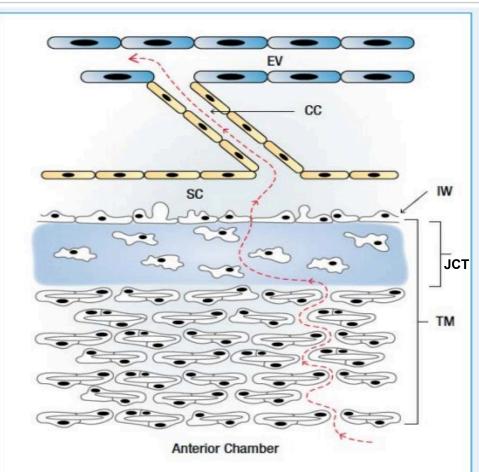


Figure 1: Schematic illustrating the major components of the conventional outflow pathway. Aqueous humor (red dashed line) flows through the initial portion of the trabecular meshwork (TM), juxtacanalicular connective tissue (JCT) region, inner wall of Schlemm canal (IW), Schlemm canal (SC), collector 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.

Collector Channels

- > Possible age-related reduction in CC.
- > TM can herniate into CC ostia causing blockage.

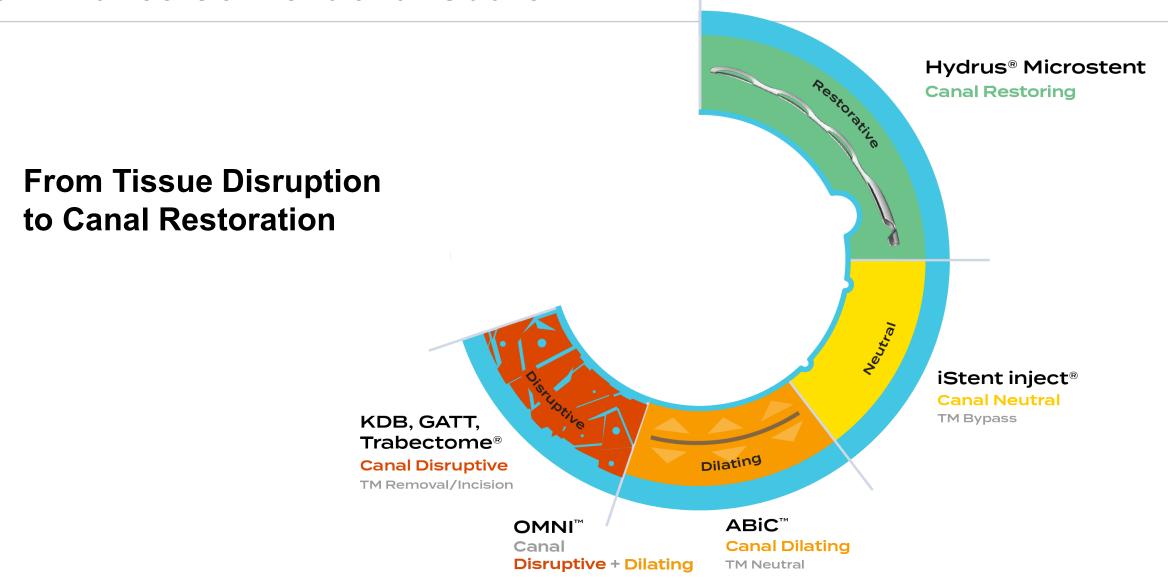
Schlemm's Canal

As IOP increases, TM is forced toward SC resulting in collapse of canal.

Trabecular Meshwork

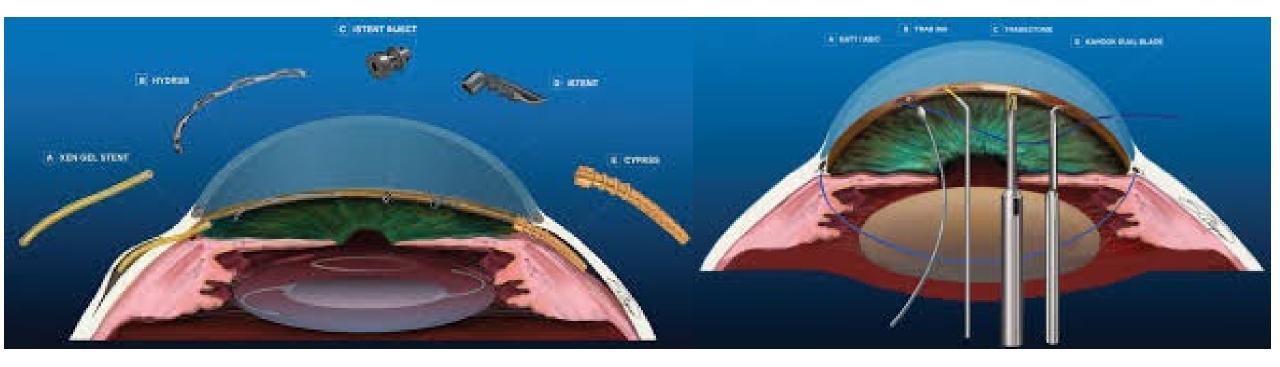
- Loss and compaction of cells causes reduced permeability.
- Accumulation of extracellular matrix and plaque materials.
- > Reduced size/number of vacuoles in JCT.

Current MIGS Mechanisms to Enhance Conventional Outflow



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Current MIGS options



~

Increase trabecular outflow

- Removing tissue
- Canaloplasty
- Bypass stent

Increase Uveoscleral / Suprachoroidal/ Supraciliary Outflow

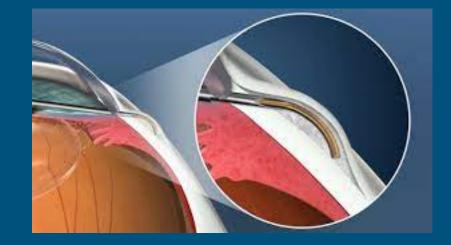
- CyPass *
- iStent Supra **
- * Recalled from market
- ** Pending FDA approval

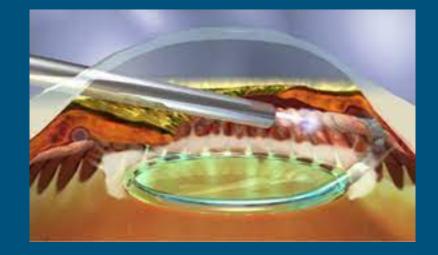
Increase Subconjunctival Outflow

- XEN gel stent

• Decrease aqueous production

- Endocyclophotocoagulation



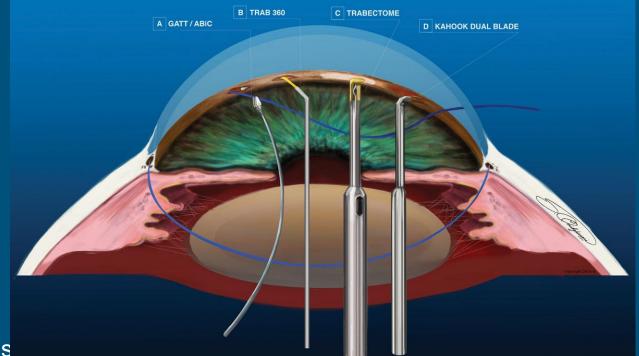


Increase trabecular outflow

- Removing tissue

Kahook Dual Blade Trabectome GATT with suture, iTrack, OMNI

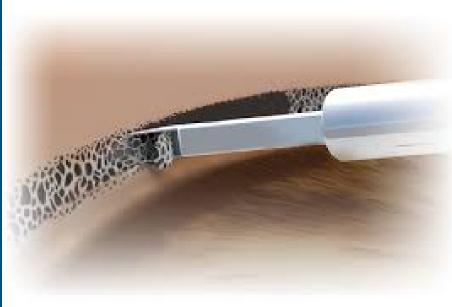
Can be done combined with cataract surgery and s



Increase trabecular outflow

Kahook Dual Blade

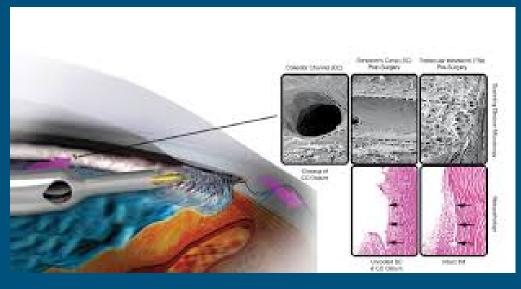




Increase trabecular outflow

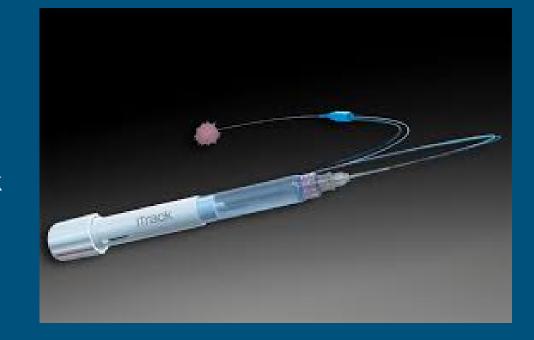
Trabectome





Increase trabecular outflow

iTrack



GATT with suture, iTrack, OMNI



Increase trabecular outflow

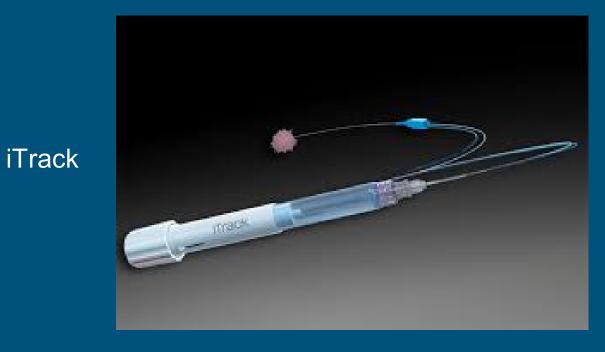
- Canaloplasty

iTrack

OMNI

Can be done combined with cataract surgery and

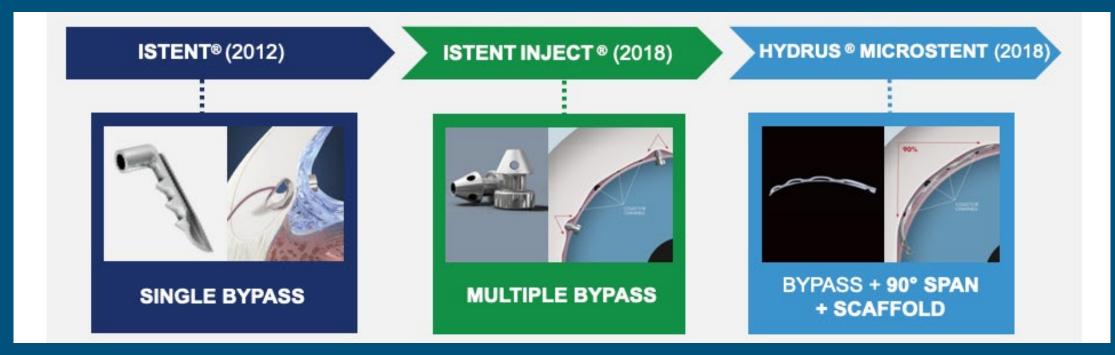
OMNI







- Increase trabecular outflow
- Bypass stent



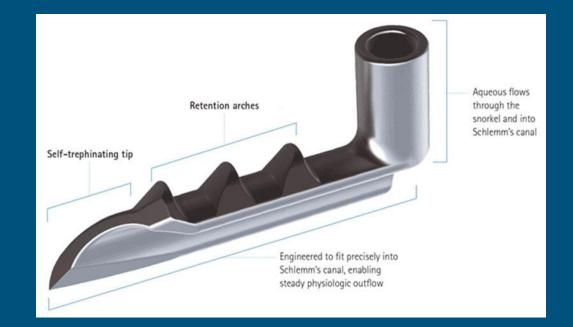
Only combined with cataract surgery

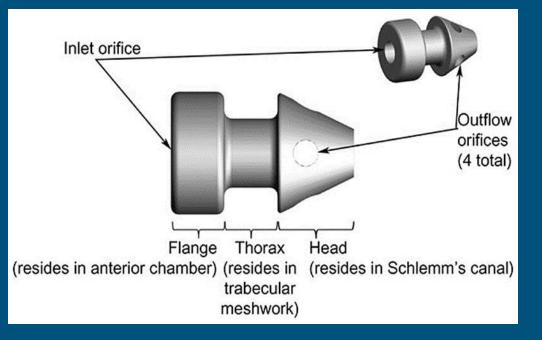
Increase trabecular outflow

- Bypass stent

iStent

iStent inject



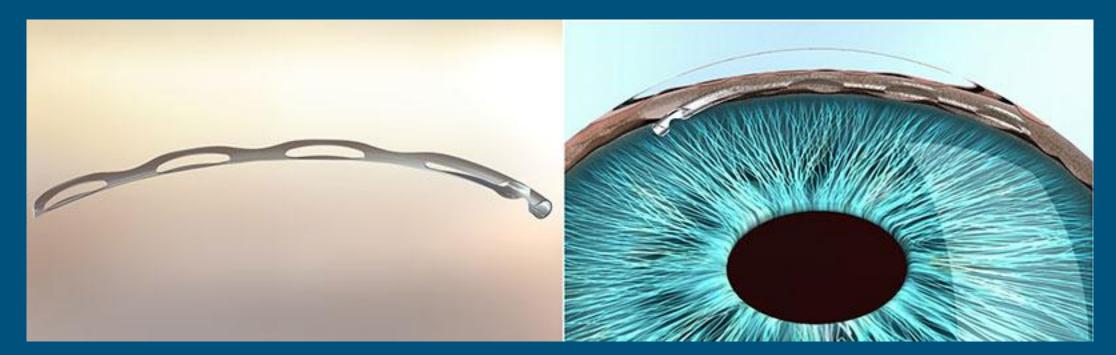




Increase trabecular outflow

- Bypass stent

Hydrus Microstent

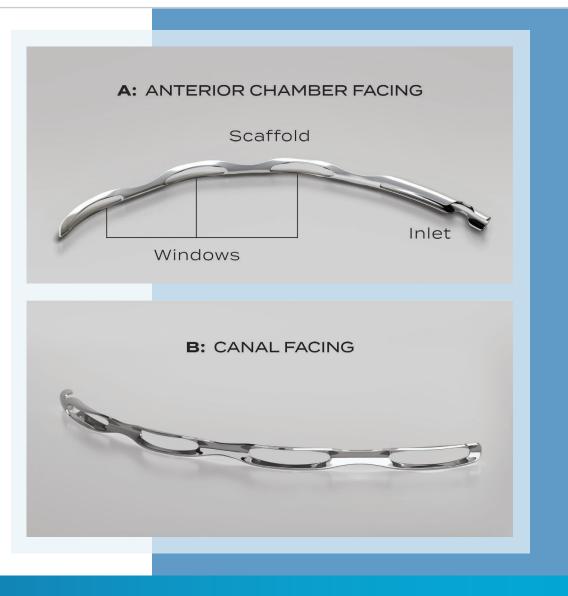


MIGS Procedure	Decrease in IOP	Decrease in Medi-	Study Type
		cations	
iStent Micro-Bypass*	8.4 mmHg @ 2 years	0.8 @ 2 years	Randomized controlled trial
iStent Inject	8.1 mmHg @ 1 year	Not available	Prospective, randomized trial
Gonioscopy-assisted transluminal trabeculotomy	8.4 mmHg @ 1 year	1.9 @ 1 year	Retrospective review
(GATT)*			
Trabectome*	6.2 mmHg @ 2 years	0.76 @ 2 years	Meta-analysis
TRAB 360 Trabeculotomy	6.3 mmHg @ 131.5	0.9 @ 131.5 days**	Retrospective review
	days**		
Ab interno canaloplasty*	4.0 mmHg @ 1 year	1.0 @ 1 year	Case-series review

9.4 mmHg @ 2 years	1.5 @ 2 years	Randomized controlled trial
7.4 mmHg @ 2 years	1.2 @ 2 years	Randomized controlled trial
7.8 mmHg @ 2 years	Not available	Prospective, single arm clinica
		trial
9.2 mmHg @ 1 year	1.8 @ 1 year	Prospective, single arm clinica
		trial
16.2 mmHg @ 3 years	1.6 @ 3 years	Prospective, single arm clinica
		trial
2.1 mmHg @ 2 years	1.1 @ 2 years	Prospective case-control study
	7.4 mmHg @ 2 years7.8 mmHg @ 2 years9.2 mmHg @ 1 year16.2 mmHg @ 3 years	7.4 mmHg @ 2 years1.2 @ 2 years7.8 mmHg @ 2 yearsNot available9.2 mmHg @ 1 year1.8 @ 1 year16.2 mmHg @ 3 years1.6 @ 3 years

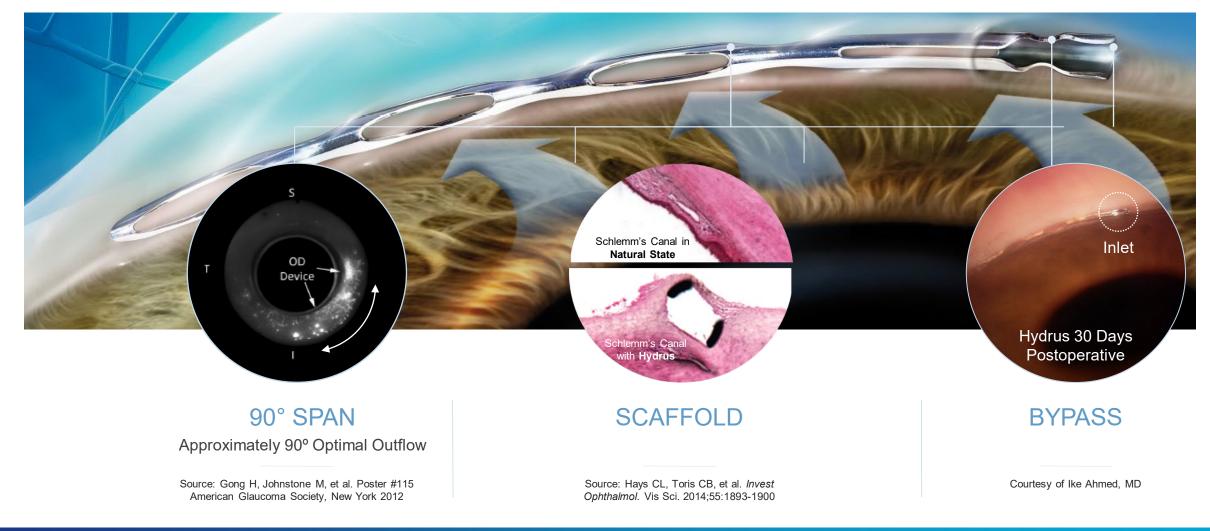
Hydrus[®] Microstent

Flexible, biocompatible 8 mm long microstent
Comprised of nitinol with an electropolished surface
Contoured to match canal curvature
Three open windows face the anterior chamber
The canal-facing surface is completely open for unobstructed collector channel access

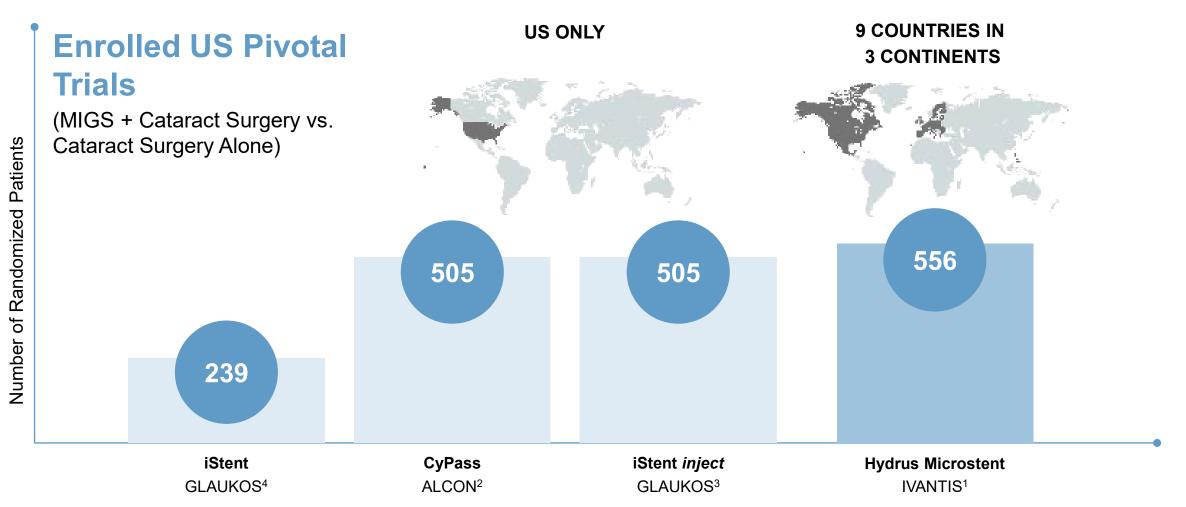


Hydrus Microstent: Ab interno Canal-based MIGS

Tri-Modal® Mechanism of Action



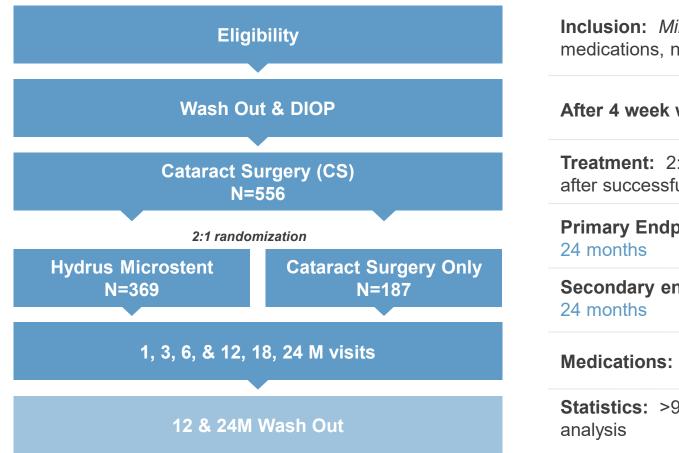
HORIZON is the Largest Ever MIGS Pivotal Trial



US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Ivantis Hydrus® Microstent. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170034B.pdf. Published August 10, 2018.
 US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): CyPass® System (Model 241-S). US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170034B.pdf. Published August 10, 2018.
 US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): iStent inject® Trabecular Micro-Bypass System. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150037B.pdf. Published July 29, 2016..
 US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): iStent inject® Trabecular Micro-Bypass System. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150037B.pdf. Published July 29, 2016..

4. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Glaukos iStent® Trabecular Micro-Bypass Stent. US Food and Drug Administration website. <u>https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030B.pdf</u>. Published June 25, 2012)

HORIZON Trial: Study Design¹



Inclusion: *Mild/moderate* POAG (VF MD >-12dB), cataract, 1-4 medications, no prior glaucoma surgery, ±prior SLT

After 4 week wash out: Mean diurnal IOP 22-34 mmHg

Treatment: 2:1 randomization in the OR to Hydrus or phaco only after successful PC IOL

Primary Endpoint: 20% reduction in washed out diurnal IOP at 24 months

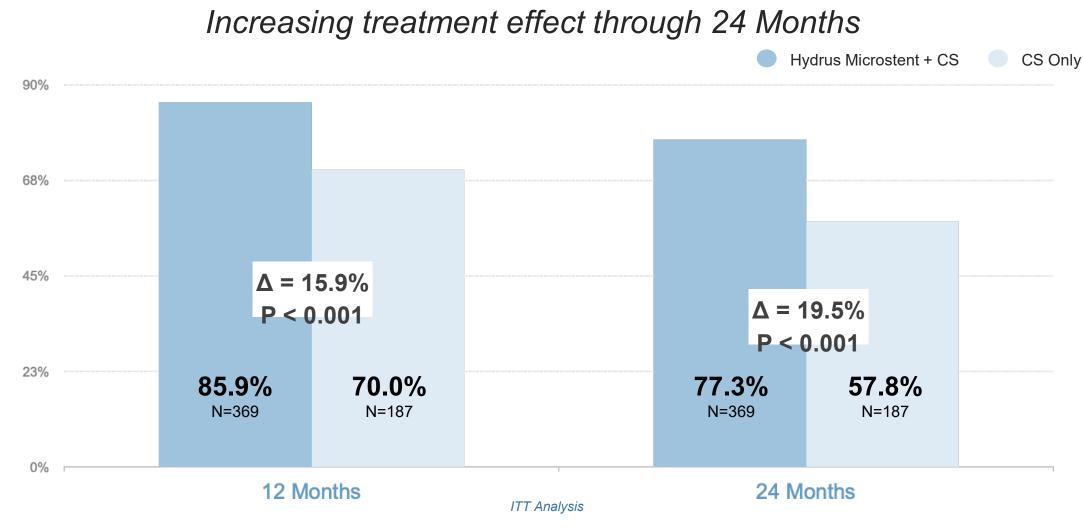
Secondary endpoint: Change in mean washed out diurnal IOP at 24 months

Medications: mean and counts at each visit

Statistics: >90% power for primary endpoint; Intention-to-treat analysis

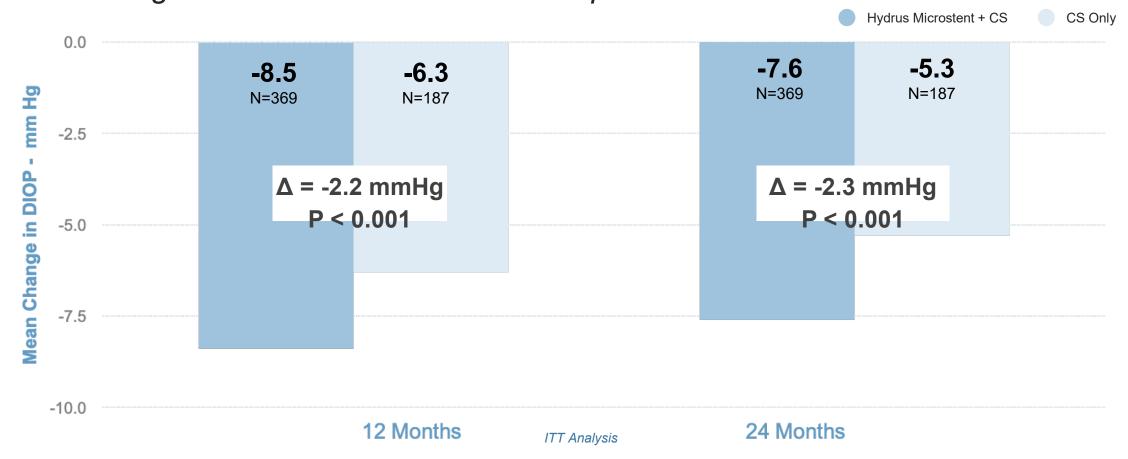
1. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology 2019;126:29-37.

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



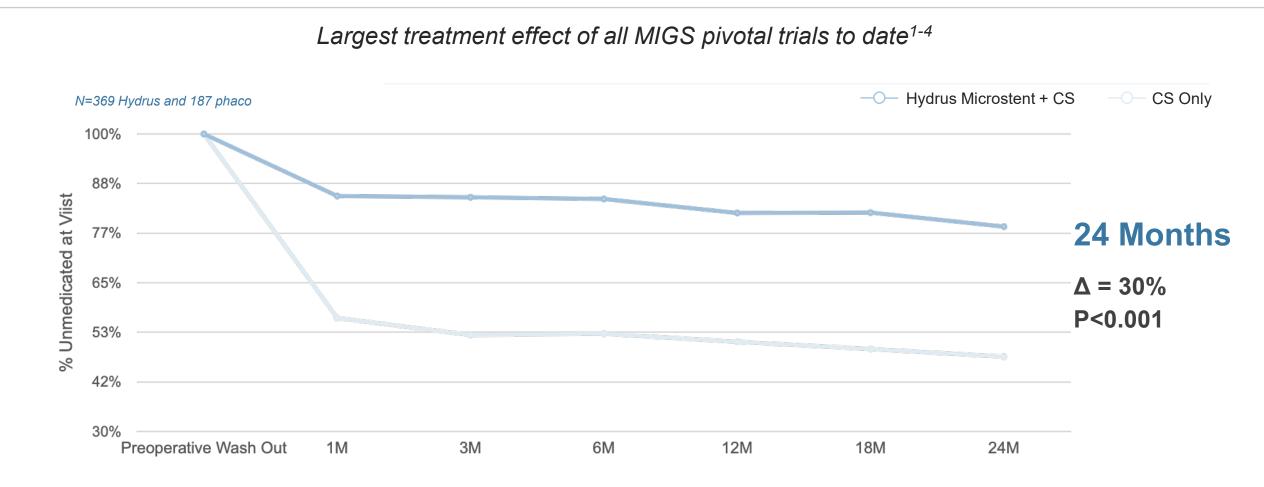
1. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology 2019;126:29-37.

HORIZON Secondary Endpoint¹ CHANGE IN WASHED OUT DIOP AT 24 MONTHS Largest IOP reduction of all MIGS pivotal trials to date¹⁻⁴



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. 2. Vold S, Ahmed II, Craven ER, et al; CyPass Study Group. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. Ophthalmology. 2016;123(10):2103-2112. 3. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Glaukos istent® Trabecular Micro-Bypass Stent. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030B.pdf. Published June 25, 2012. 4. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): iStent inject® Trabecular Micro-Bypass System. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030B.pdf. Published June 21, 2018.

HORIZON Medication Free¹



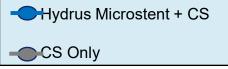
1. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology 2019;126:29-37. 2. Vold S, Ahmed II, Craven ER, et al; CyPass Study Group. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. Ophthalmology. 2016;123(10):2103-2112.

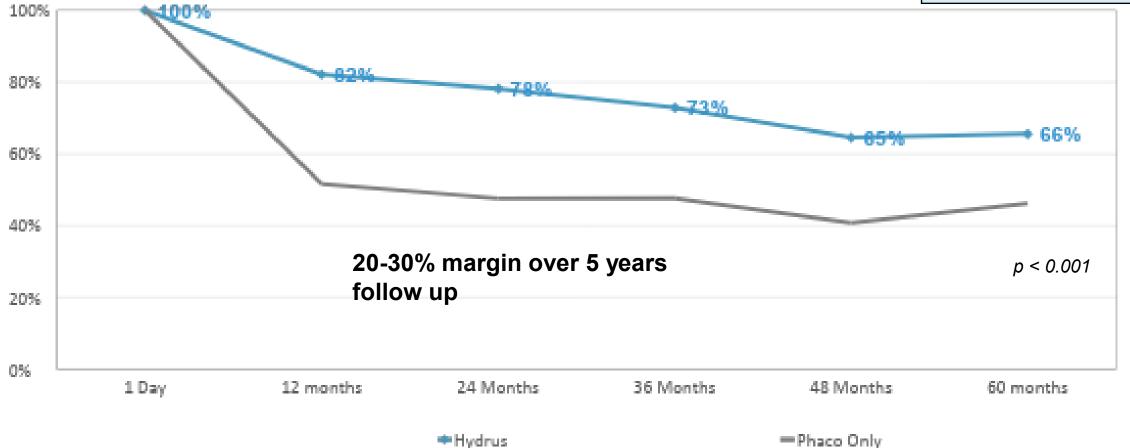
3. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Glaukos iStent® Trabecular Micro-Bypass Stent. US Food and Drug Administration website. <u>https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080030B.pdf.</u>Published June 25, 2012. 4. US Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): iStent inject® Trabecular Micro-Bypass System. US Food and Drug Administration website. <u>https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170043b.pdf.</u>Published June 21, 2018.

HORIZON: Medication Free¹

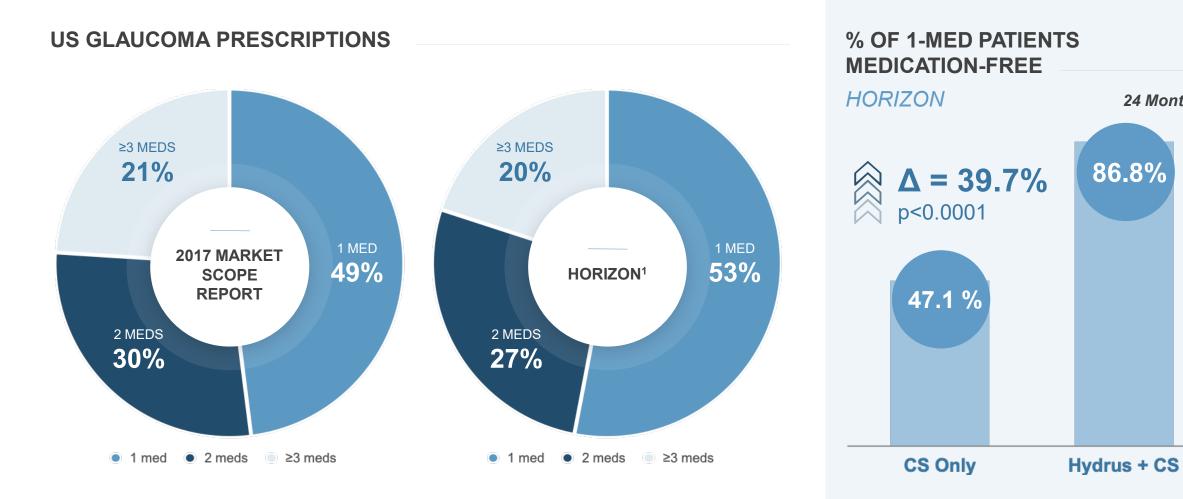
MEDICATION FREE 0-60 MONTHS







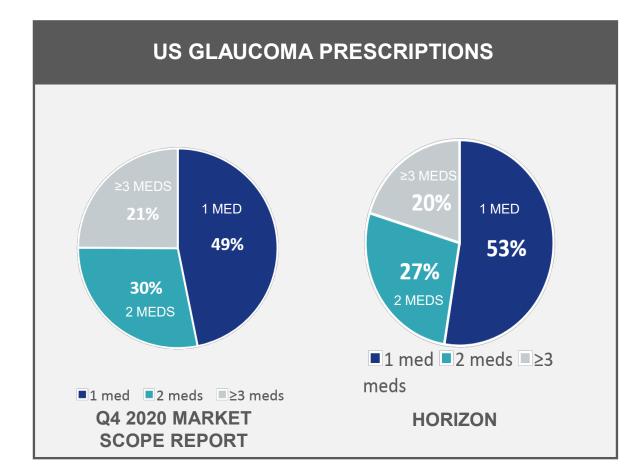
Hydrus in the 1-Med Patient

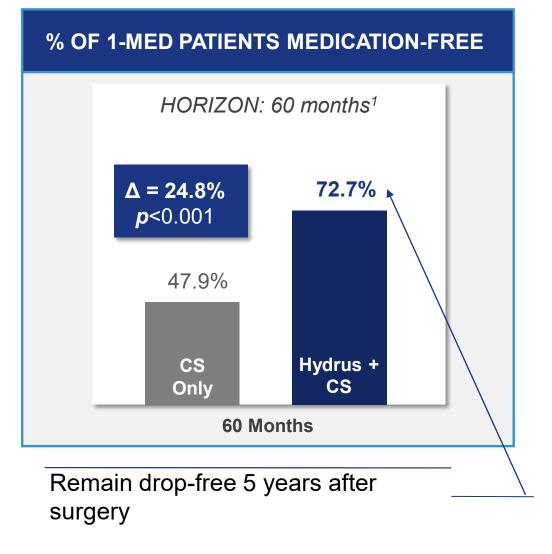


24 Months

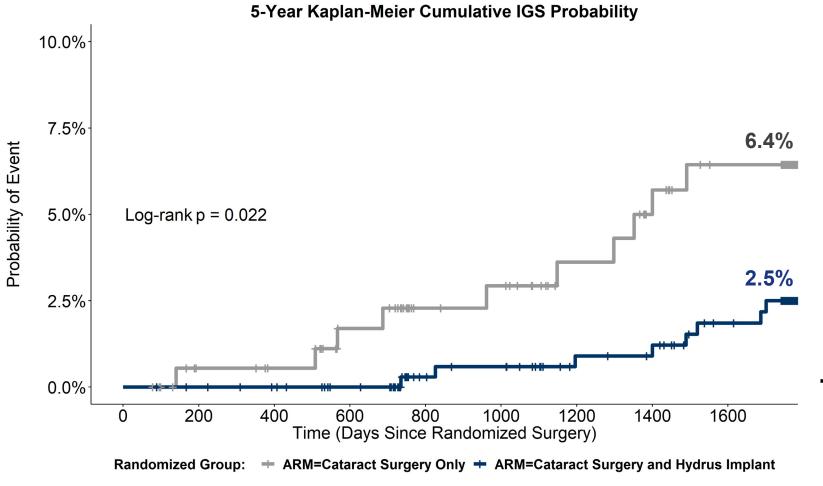
1. Samuelson TW, Chang DF, Marquis R, et al. A Schlemm canal microstent for intraocular pressure reduction in primary open-angle glaucoma and cataract: The HORIZON Study. Ophthalmology 2019;126:29-37.

Drop Elimination in the 1 Med Patient





Key Finding: Reduced Risk of Reoperation¹



Incisional Glaucoma Surgery:

- Trabeculectomy,
- Tube shunt,
- Cilioablative
 procedure

<u>61% Reduction</u> in Risk of SSIs in eyes treated with Hydrus

Two-thirds of the patients who had an IGS were mild at baseline

(Visual Field MD better than -6 dB) Patient Selection & Postoperative Findings and Observations



3

Who is an Ideal Hydrus[®] Microstent Candidate?



The Hydrus Microstent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).



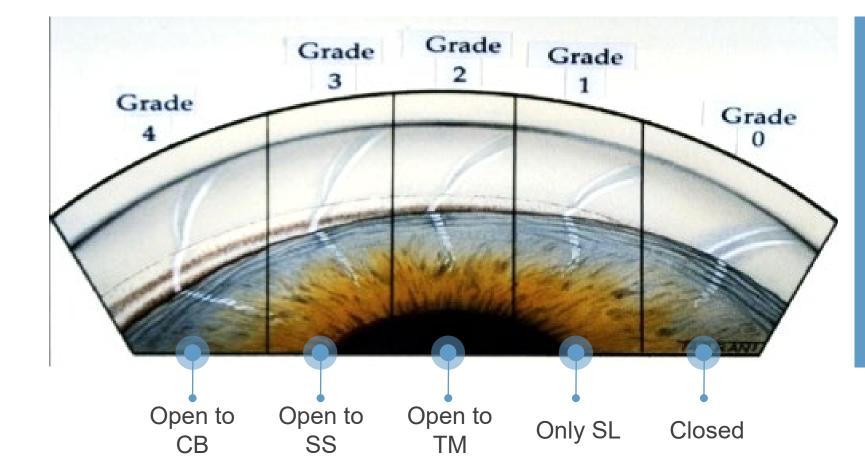
Normal angle anatomy ➤Shaffer Grade 3 & 4

Up to 4 glaucoma medication ➤May include prior history of SLT

Clear media for adequate visualization

The Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications.

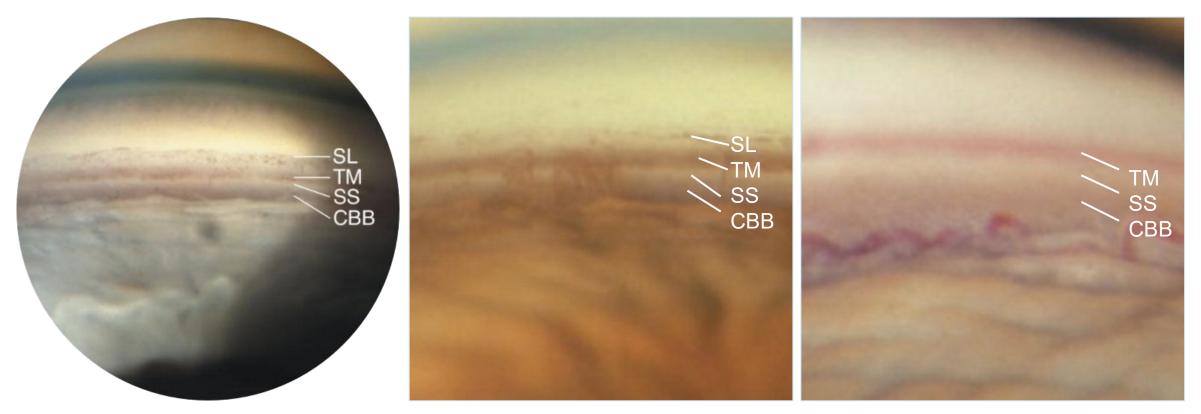
Angle Grading – Shaffer Classification





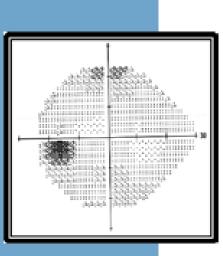
Confirm Shaffer grade 3 or 4 for Hydrus candidacy

Recognizing Variations in Relevant Anatomy



SL - Schwalbe's Line TM - trabecular meshwork SS - scleral spur CBB - ciliary body band

Source: Alward WLM. Color Atlas of Gonioscopy. Barcelona: Wolfe; 1994.

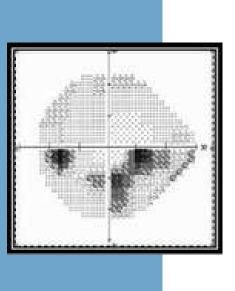


Optic nerve abnormalities associated with glaucoma But NO visual field abnormalities on any visual field test OR abnormalities present only on shortwave- length automated perimetry or frequency doubling perimetry

Current ICD-10 Glaucoma Reference Guide

Source: American Academy of Ophthalmology American Glaucoma Society

Moderate Stage Glaucoma

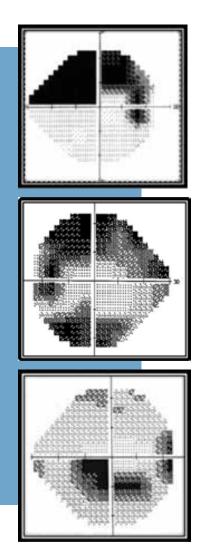


Optic nerve abnormalities consistent with glaucoma AND glaucomatous visual field abnormalities in ONE hemifield and NOT within 5 degrees of fixation

Current ICD-10 Glaucoma Reference Guide

Source: American Academy of Ophthalmology American Glaucoma Society

Advanced, Late, Severe Stage Glaucoma



Optic nerve abnormalities consistent with glaucoma AND glaucomatous visual field abnormalities in BOTH hemifields

AND/OR loss within 5 degrees of fixation in at least one hemifield

Current ICD-10 Glaucoma Reference Guide

Source: American Academy of Ophthalmology American Glaucoma Society

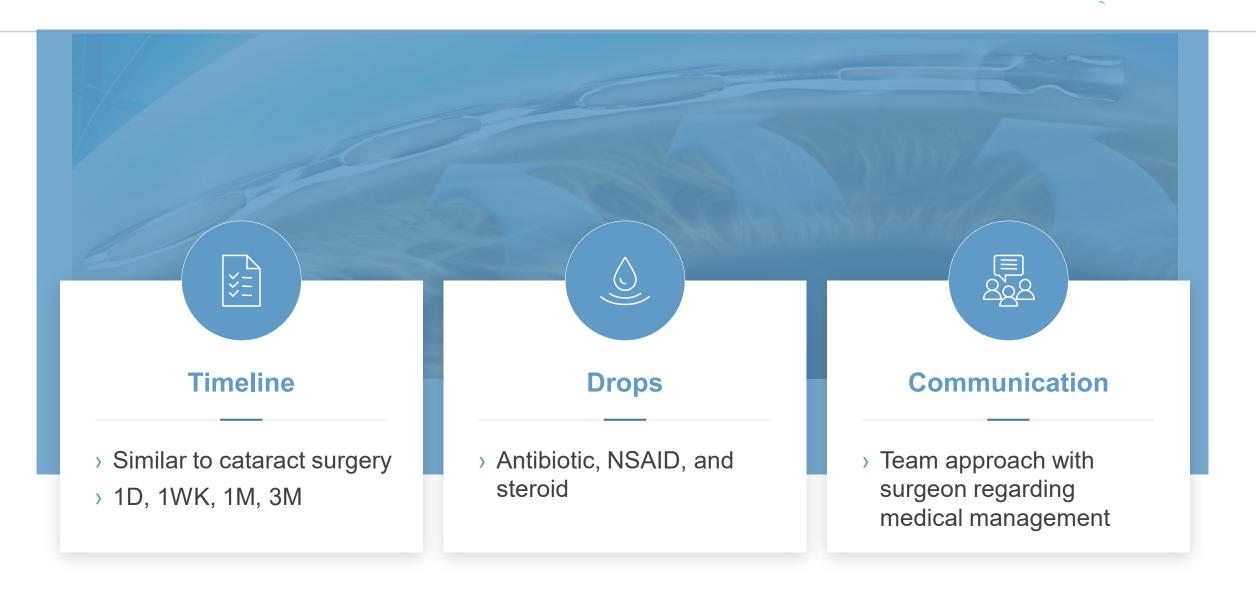
Contraindications

The Hydrus® Microstent is contraindicated under the following circumstances or conditions:

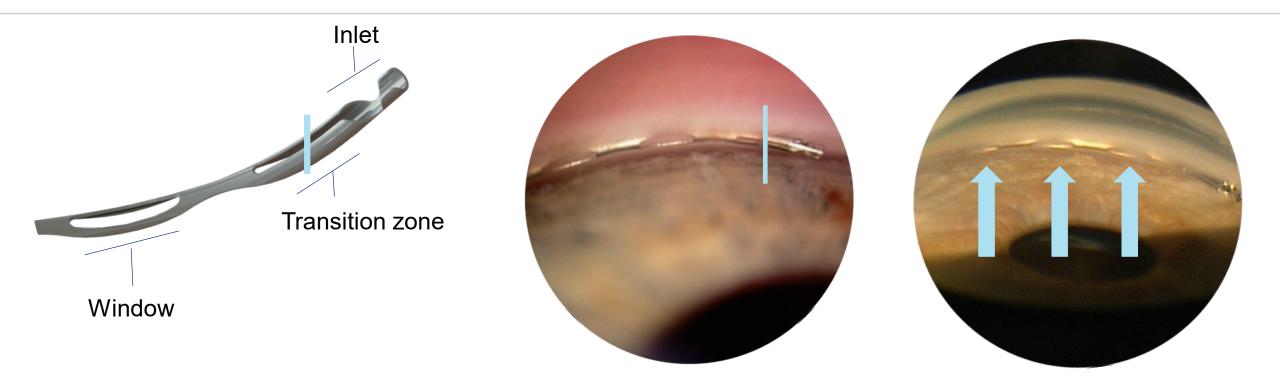
In eyes with angle closure glaucoma

In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle

Postoperative Evaluation



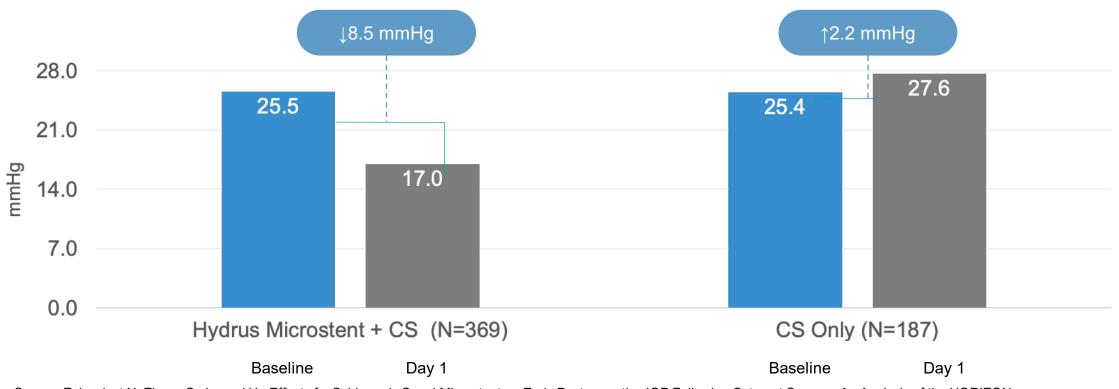
Confirmation of Proper Placement



Appreciate the trabecular meshwork covering 50% – 75% of the Hydrus transition zone Approximately 1mm of the stent will be in the anterior chamber

Appreciate Hydrus windows behind the trabecular meshwork Hydrus will appear dull positioned in Schlemm's canal behind the trabecular meshwork

IOP Change Post Operative Day 1

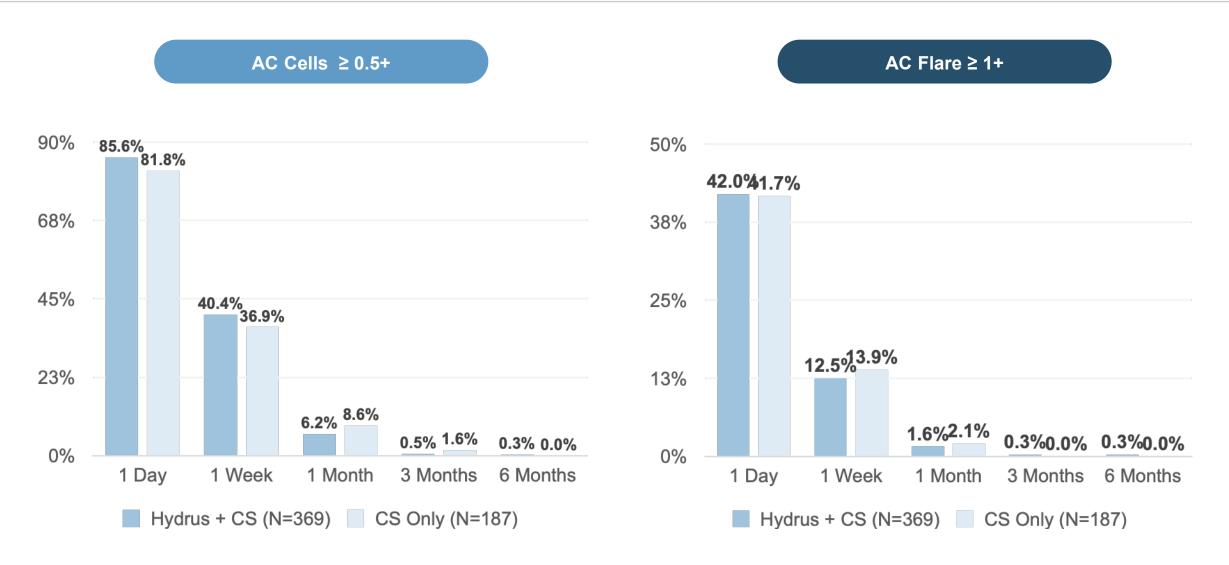


Source: Zebardast N, Zheng C, Jampel H. Effect of a Schlemm's Canal Microstent on Early Post-operative IOP Following Cataract Surgery: An Analysis of the HORIZON randomized controlled trial. Ophthalmology 2020 (in press). doi: https://doi.org/10.1016/j.ophtha.2020.01.025

	HYDRUS	PHACO ONLY	RESOLUTION
Hyphema 1 day → 7 days Micro or layered < 1mm Layered ≥ 1mm	$10.6\% \rightarrow 3.8\%$ $2.7\% \rightarrow 0.8\%$	0% 0%	100% resolved by 1M without intervention
Corneal Edema 1 day → 7 days ≥ 2+ stromal edema ≥ 2+ endothelial folds	11.1% → 0.8% 7.6% → 0.3%	$9.1\% \rightarrow 0\%$ $4.3\% \rightarrow 0\%$	>99% edema/folds resolved by 1M without intervention
Cell and Flare 1 day → 7 days ≥ 1+ cells ≥ 2+ flare	62.9% → 15.2% 14.9% → 1.4%	$52.4\% \to 10.2\%$ $9.6\% \to 0.5\%$	98% of cell and flare resolved by 1M without intervention
Persistent inflammation	0.5%	2.1%	Extended steroids >1M
Rebound inflammation	5.1%	1.6%	New course of steroids

Slit Lamp Findings – Cell and Flare*

Postoperative Inflammation comparable to Cataract Surgery



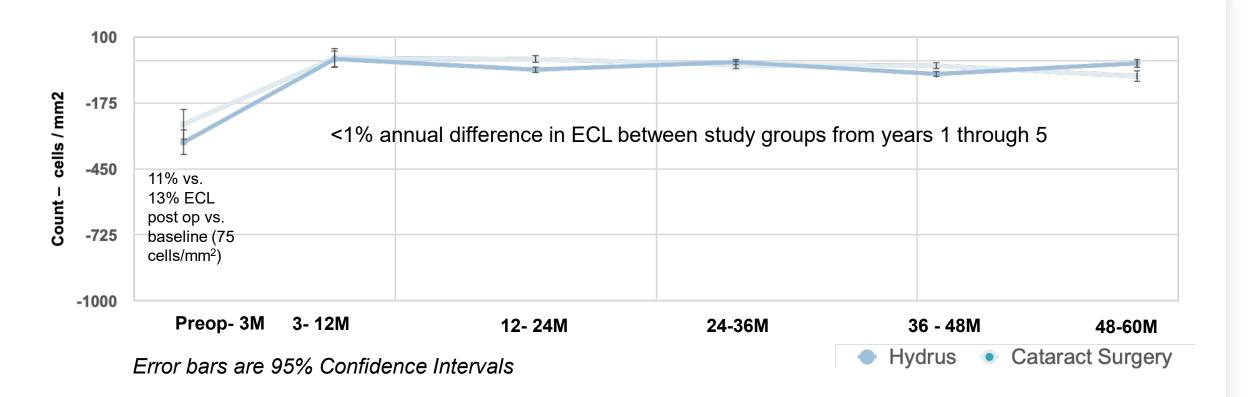
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	Cumulative – 2 Years ¹		Cumulative – 4 Years ²	
Post Operative Events	HYDRUS MS (N=369)	CS Only (N=187)	HYDRUS MS (N=369)	CS Only (N=187)
IOP elevation	0.5%	2.7%	0.8%	2.7%
Hypotony	0	0	0	0
Loss of BCVA ≥ 2 lines after 3 months	1.4%	1.6%	1.9%	2.1%
Loss of VF (MD \geq 2.5 dB)	4.3%	5.3%	7.3%	9.1%
Nickel/allergic reaction	0	-	0	-
Focal PAS -				
 Inlet visually obscured – "Obstructive" Inlet visible "Non-obstructive" 	3.5% 7.3%	0 2.1%	4.3% 8.7%	0 3.2%
Corneal Edema	0.5%	0.5%	0.5%	0.5%

Note: PAS observation based on gonioscopic appearance not IOP

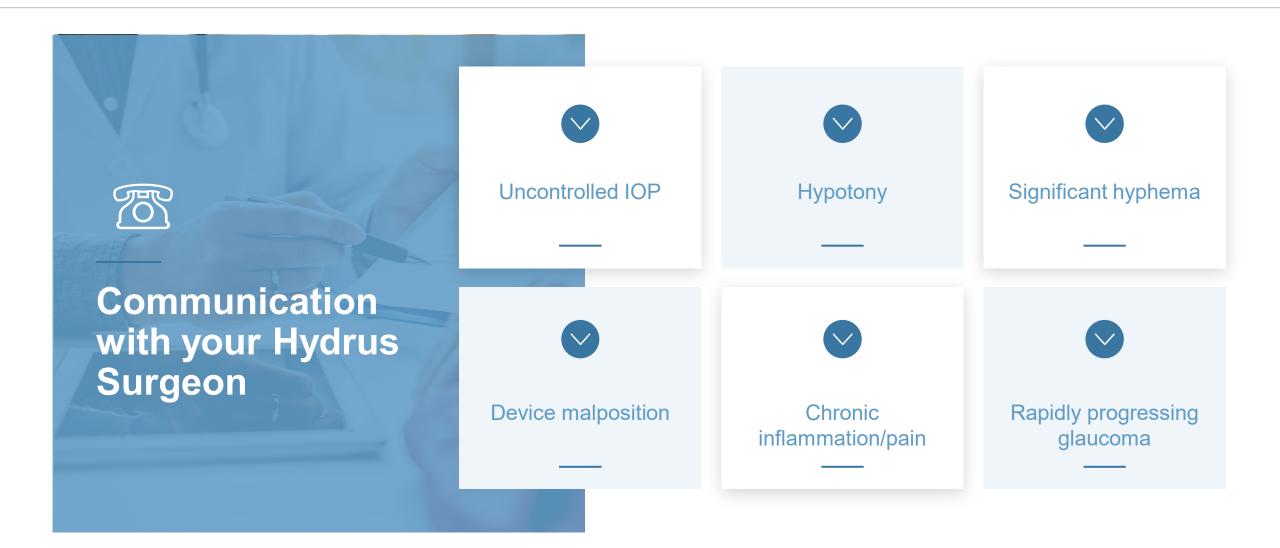
Corneal Endothelial Cell Counts

Year to Year Change in Mean Central ECL



Rhee DJ. 4 Year Findings from the HORIZON Trial AGS 2020, Washington DC





62 3/20/2021



Make an Impact With Your Recommendation



Evidence-based Support for Your Recommendation



Lifetime diseases deserve durable solutions ... Hydrus Microstent!





Increasing prevalence of cataracts and glaucoma

Hydrus Tri-Modal mechanism of action



Horizon data

- 2.3mmHg reduction over phaco alone
- 30% medication free over phaco alone
- 65% reduction in SSI

Case 1

•67 yo AA F referred for cataract and glaucoma evaluation

•C/o blurry vision, glare
•BCVa 20/40 OU
•Ta 24/25 mmHg
•Pachy 512/516

On exam •2+ NS OU •C/D 0.8 OU •OCT ONH inferior NFL/GCC thinning OU •Normal VF OU Options

1. CEIOL + glaucoma drop

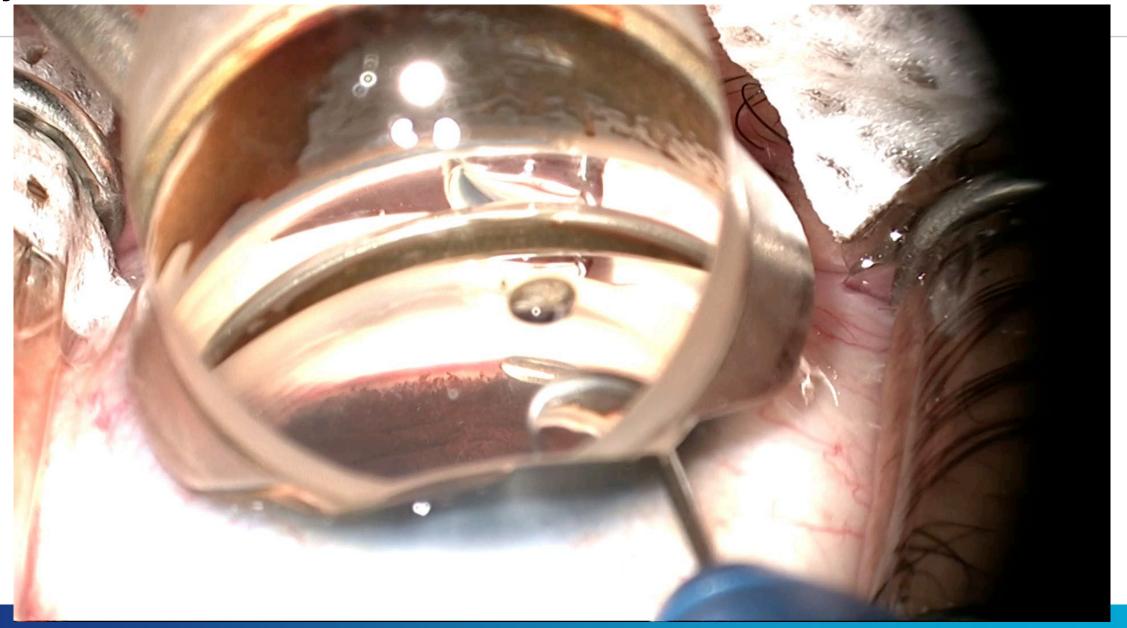
2. CEIOL + SLT

3.CEIOL + TM stent

Patient had CEIOL/Hydrus OD then OS

4 months post-op: Va 20/20, Ta 17/18

Hydrus Microstent



•52 yo caucasian M

•POHx:

°OD VS NS, severe POAG, s/p SLT x 3

 OS corneal edema, mature cataract, severe POAG, s/p GDI x 2, s/p tube erosion x 2, endophthalmitis, s/p PPV

•C/o gradual vision decline OD

•BCVa OD 20/80, OS LP

•Ta 32/4 on 3 classes of glaucoma meds OD

On exam

•OD 2+ NS, C/D 0.95, severe superior NFL/GCC thinning, VF inferior arcuate scotoma approaching fixation

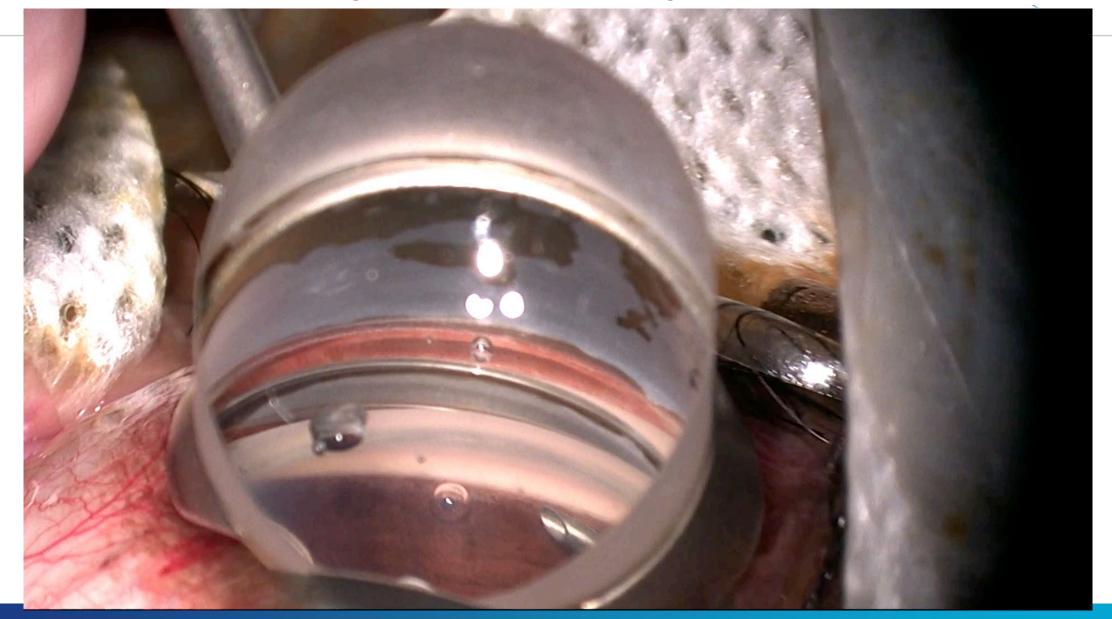
Options

- 1.CEIOL + glaucoma drops (issues with compliance)
- 2.CEIOL + SLT (will be his 4th SLT)
- 3.CEIOL + GDI
- 4.CEIOL + combined MIGS

Patient had CEIOL/ab interno canaloplasty/Hydrus

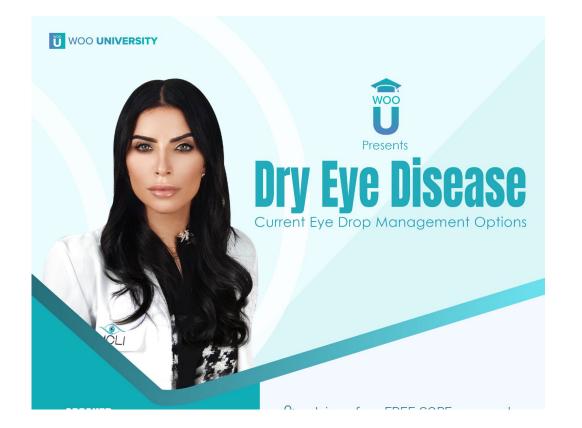
5 months post-op: Va 20/40, Ta 17 on PGA at bedtime

Ab interno Canaloplasty with OMNI plus Hydrus Microstent





Thank you! Please join us for our next COPE event



Date: May 13. 2021 Time: 5:00 pm PST Speaker: Dr. Elise Kramer Topic: Dry Eye Disease – Current Eye Drop Options COPE: One hour live CE



Scan QR code to register Open OE tracker app and scan QR code to receive COPE CE credit instantly!

ARBO QR Code

COPE Course 71848-GL COPE Event

