

SURGICAL INNOVATIONS IN GLAUCOMA

Is this the end of the trabeculectomy?

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New Mexico Academy of Ophthalmology September 15, 2018

DISCLOSURES

ELLEN: SPEAKER, CONSULTANT AND CLINICAL INVESTIGATOR
GLAUKOS: SPEAKER, CONSULTANT AND CLINICAL INVESTIGATOR
SIGHTSCIENCE: CONSULTANT AND CLINICAL INVESTIGATOR
NEW WORLD MEDICAL: CLINICAL INVESTIGATOR
ALCON: SPEAKER, CONSULTANT AND CLINICAL INVESTIGATOR
IVANTIS: CONSULTANT AND CLINICAL INVESTIGATOR
SENSIMED: CLINICAL INVESTIGATOR
ALLERGAN: SPEAKER AND CLINICAL INVESTIGATOR
ADRIE PHARMACEUTICALS: SPEAKER
VALEANT PHARMACEUTICALS: SPEAKER

CURRENT GOLD STANDARD

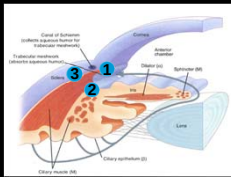


MAXIMIZING OUTFLOW WITH MIGS

A new approach to managing mild to moderate OAG

AREAS OF AQUEOUS OUTFLOW

- MIGS devices can be used to restore outflow through the natural, physiological outflow pathway, the suprachoroidal space or the subconjunctival space.
- SAFETY (Benefit to Risk Ratio) is the ultimate criterion in determining MIGS treatment algorithm



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

THERAPEUTIC OPTIONS

Conventional Outflow

- Trabecular bypass
 - iStent
 - iStent Inject
 - Hydrus
- Trabecular ablative
 - Kahook Dual Blade
 - Trabectome
 - Goniotome
 - Trab360
 - GATT
- Restorative
 - ABIC
 - Visco360

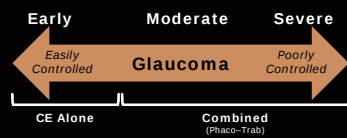
Suprachoroidal

- Supraciliary
 - CyPass
- Suprachoroidal
 - iStent Supra (Phase III)
 - iSTAR

Other

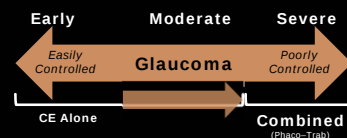
- Cycloablative
 - Irindex MP G6 laser
 - ECP
- Filters (LIGS)
 - Xen45 gel implant
 - InnFocus (Phase III)

CATARACT & GLAUCOMA: EARLY-MID 1990'S



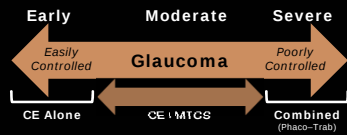
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CATARACT & GLAUCOMA: LATE 1990'S



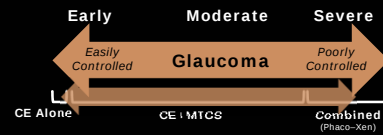
8

CATARACT & GLAUCOMA: 2000'S-PRESENT (FOR MOST PEOPLE)



9

CATARACT & GLAUCOMA: 2000'S-PRESENT (MY APPROACH)

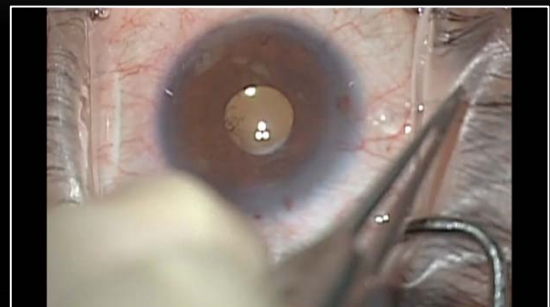


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MIGS AND THE "ENTIRE SYSTEM"

Ab-interno canaloplasty (ABiC)
Visco360

AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)



AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)

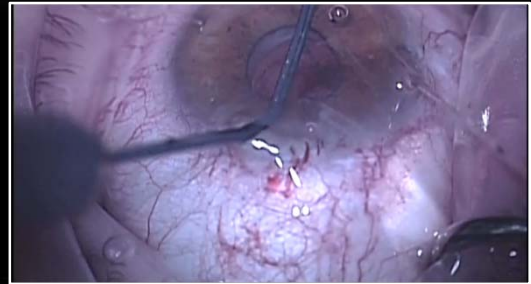
IMMEDIATE PRE-OP



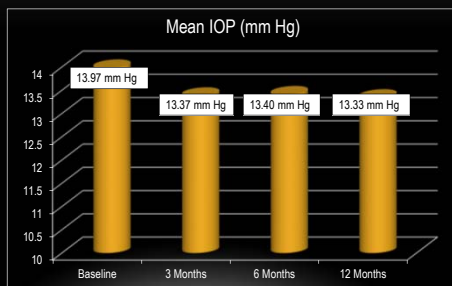
IMMEDIATE POST-OP



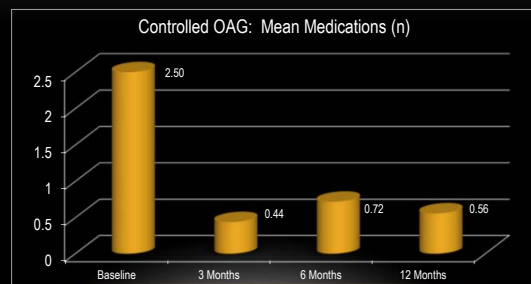
AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)



AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)

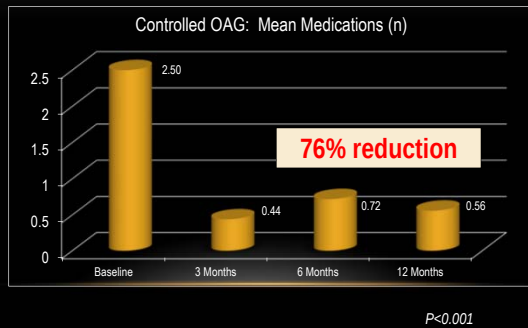


AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)

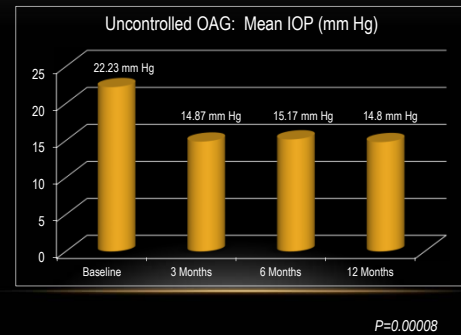


$P < 0.001$

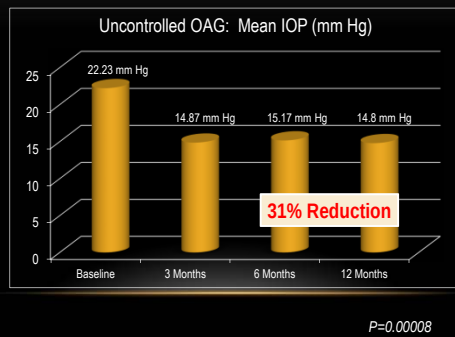
AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)



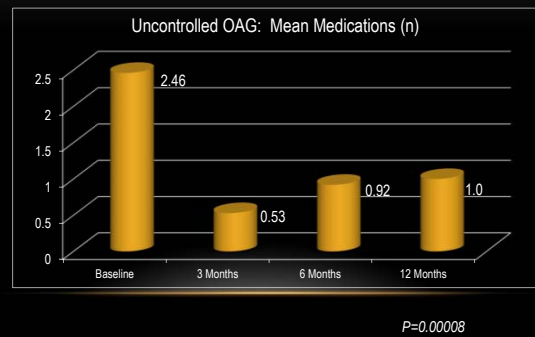
AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)



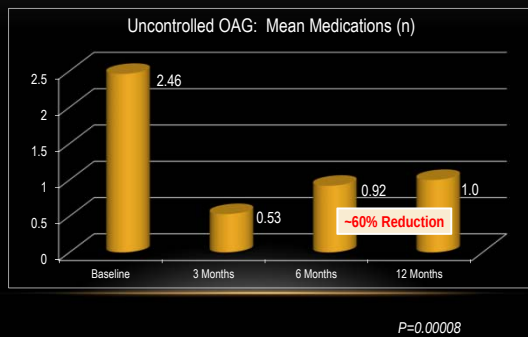
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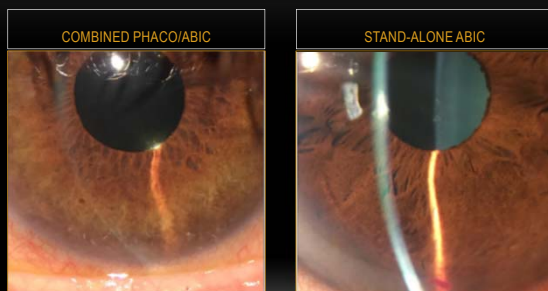


AB-INTERNO CANALOPLASTY (ABiC) (iTRACK™ 250A CANALOPLASTY CATHETER)



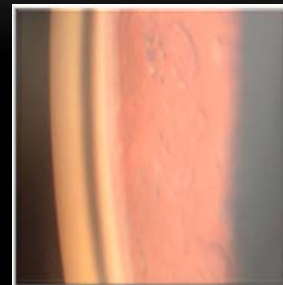
POST-OPERATIVE COURSE
WHAT TO EXPECT

POST-OPERATIVE DAY ONE



Post-Operative Care Same as Phacoemulsification
Quick Steroid Taper

POST-OPERATIVE MONTH ONE



WHO IS A CANDIDATE FOR ABIC

MOST OAG PATIENTS...BUT NOT ALL

Uncontrolled OAG (Mild to Moderate*)
Controlled OAG undergoing cataract surgery
Target IOP Mid to Low Teens
Young Patient
High Risk with Filters
High Myopia
Previous failed filtration surgery
Contact Lens Dependency
Difficult Follow-Up
Monocular Patients
Difficult Patient (squeezers)
Phakic or Pseudophakic

AB-INTERNO CANALOPLASTY (ABIC)

(iTRACK™ 250A CANALOPLASTY CATHETER)



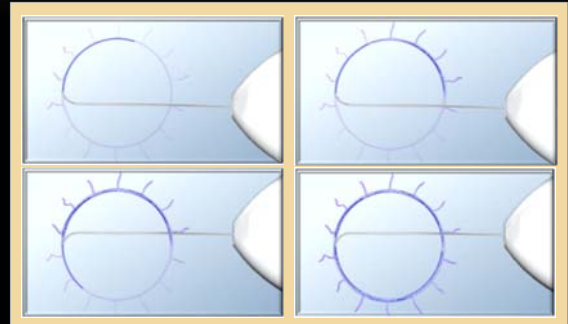
WHAT ELSE EXISTS

THE OTHER MIGS PROCEDURES

VISCO360
(ANOTHER CANALOPLASTY DEVICE)



VISCO360
(ANOTHER CANALOPLASTY DEVICE)



VISCO360
(ANOTHER CANALOPLASTY DEVICE)

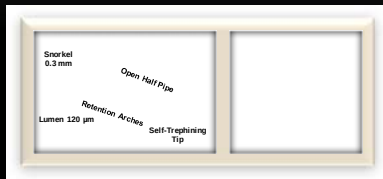


MIGS AND THE TRABECULAR MESHWORK

TRABECULAR BY-PASS

(iStent)
(iStent inject)
(Hydrus)

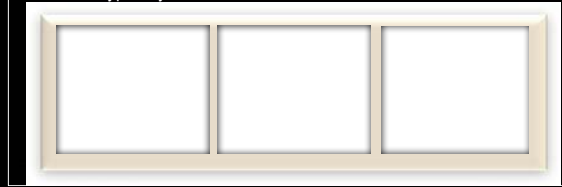
TRABECULAR MICRO-BYPASS (iSTENT®)



- Smallest medical device implanted into the human body
- iStent dimensions are customized for a natural fit within the 270 µm canal space
- Made of surgical-grade nonferromagnetic titanium
- Heparin-coated to promote self-priming

TRABECULAR MICRO-BYPASS (iSTENT®)

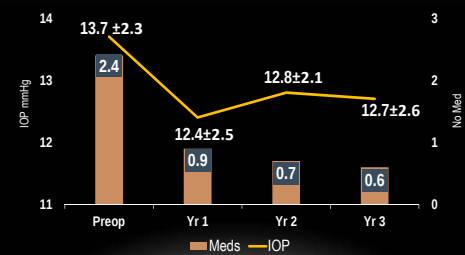
- The iStent® is inserted ab-interno through the clear, cornea phaco-incision and can be performed under topical anesthesia
- The physiological preservation of the trabecular meshwork ensures a natural episcleral back pressure of 8 to 11 mm Hg, with minimal risk for hypotony!

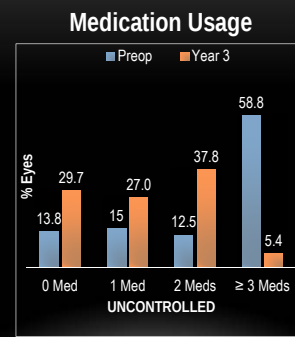
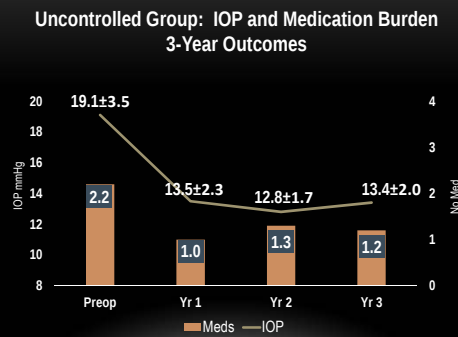
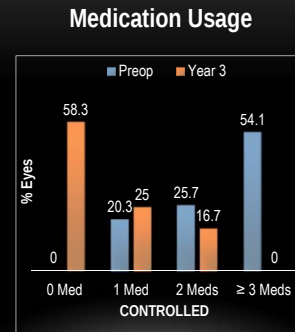
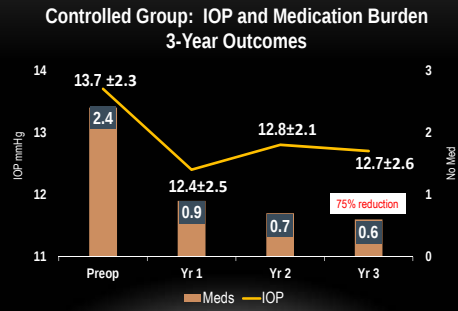


TRABECULAR MICRO-BYPASS (iSTENT®)

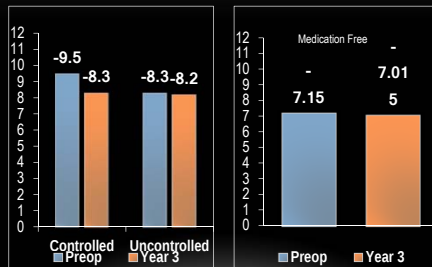


Controlled Group: IOP and Medication Burden 3-Year Outcomes

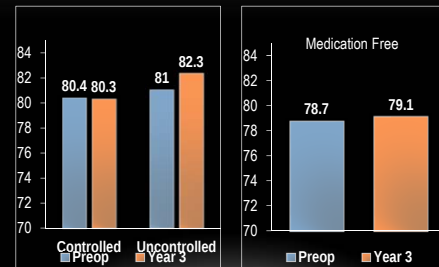




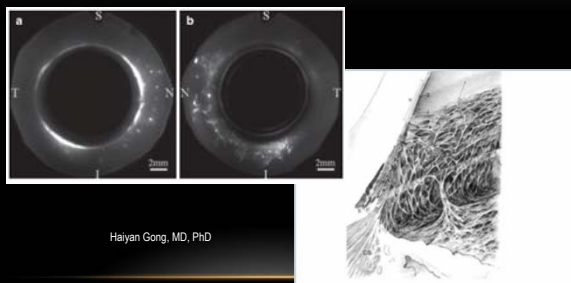
VISUAL FIELD MEAN DEVIATION (dB)



MEAN RETINAL NERVE FIBER LAYER (μM)



TRABECULAR MICRO-BYPASS (iSTENT®) (TARGETED STENT IMPLANTATION—FINDING COLLECTOR CHANNELS)



TRABECULAR MICRO-BYPASS (iSTENT®) TARGETED STENT IMPLANTATION



TRABECULAR MICRO-BYPASS (iSTENT®) TARGETED STENT IMPLANTATION



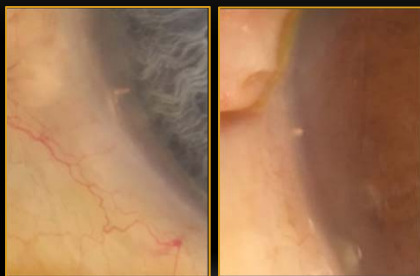
TRABECULAR MICRO-BYPASS (iSTENT®) POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx

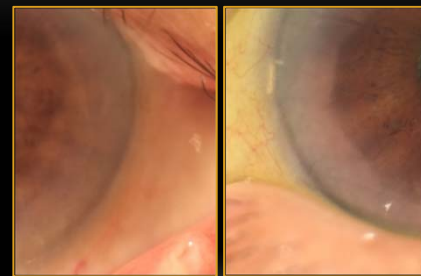
- Topical NSAID
- Topical antibiotic
- Topical steroid****
- May see RBC in anterior chamber
- May see micro-hyphema
- Possible IOP spike



TRABECULAR MICRO-BYPASS (iSTENT®) POST-OPERATIVE APPEARANCE



TRABECULAR MICRO-BYPASS (iSTENT®) POST-OPERATIVE APPEARANCE



TRABECULAR MICRO-BYPASS (iSTENT®)

POST-OPERATIVE APPEARANCE (GONIOSCOPY)

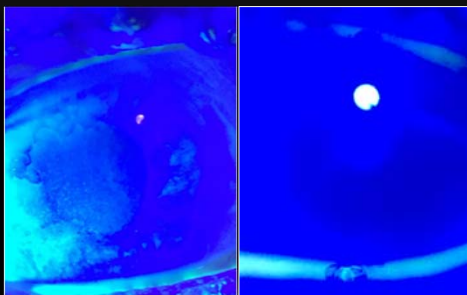


CLINICAL INDICATIONS

Mild to moderate OAG
Concomitant cataract
One one topical medication

TRABECULAR MICRO-BYPASS (iSTENT®)

WHY NOT CONTINUE MEDS?



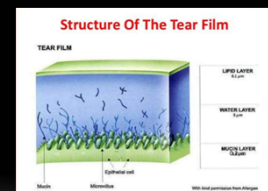
MG1

TOPICAL MEDICATIONS

(ARE THEY REALLY BENIGN?)

Adverse Effects

- Disruption of the preneal tear film
- Epitheliopathy
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells



Slide 52

MG1

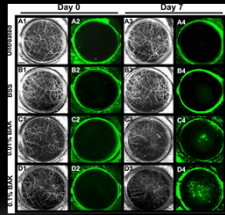
Mark Gallardo, 3/11/2018

MG [21]

TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)

Adverse Effects

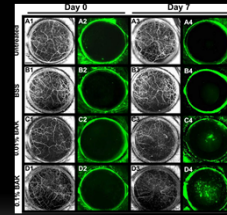
- Disruption of the precorneal tear film
- **Epitheliopathy**
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells



TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)

Adverse Effects

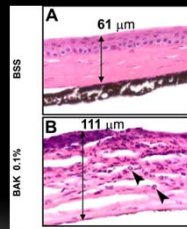
- Disruption of the precorneal tear film
- Epitheliopathy
- **Corneal neurotoxicity**
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells



TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)

Adverse Effects

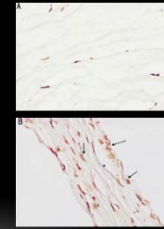
- Disruption of the precorneal tear film
- Epitheliopathy
- Corneal neurotoxicity
- **Corneal and conjunctival inflammation**
- Corneal endothelial cell loss
- Apoptosis of trabecular endothelial cells



TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)

Adverse Effects

- Disruption of the precorneal tear film
- Epitheliopathy
- Corneal neurotoxicity
- Corneal and conjunctival inflammation
- Corneal endothelial cell loss
- **Apoptosis of trabecular endothelial cells**

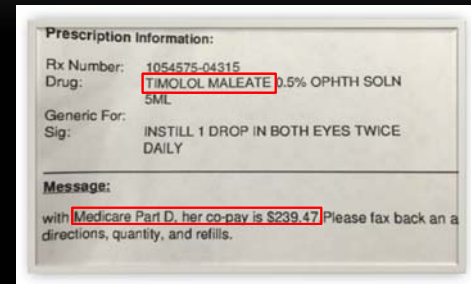


TOPICAL MEDICATIONS (ARE THEY REALLY BENIGN?)



- Periorbital fat atrophy
- Meibomian gland dysfunction

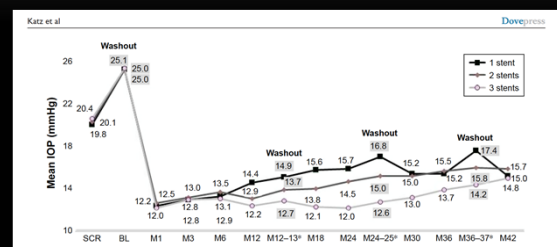
TRABECULAR MICRO-BYPASS (iSTENT®) WHY NOT CONTINUE MEDS?



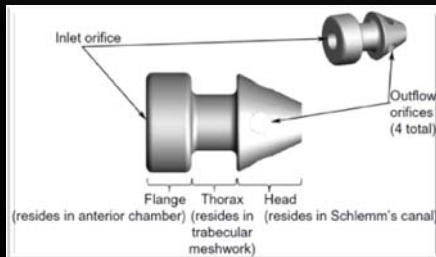
RECENTLY RELEASED

iStent Inject®
Hydrus Microstent®

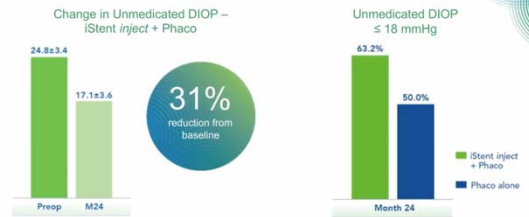
TRABECULAR MICRO-BYPASS (iSTENT®) THE DATA



TRABECULAR MICRO-BYPASS (iSTENT INJECT®)



iStent inject + Phaco Pivotal Study (Samuelson et al, 2018)



Medication reduction is subject to the discretion of the physician.

iStent inject + Phaco (Hengerer, 2018)

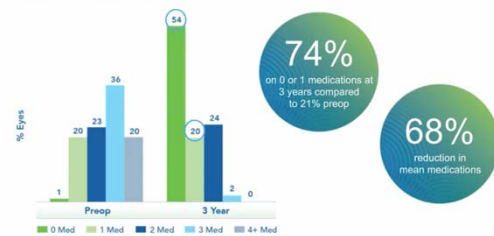
Reduced Intraocular Pressure Over Time



1. Hengerer P. Personal Experiences with Second Generation Trabecular Micro-Bypass Stents in Combination with Cataract Surgery in Patients with Glaucoma: 3 Year Follow-up. ASRS 2018 Presentation.

iStent inject + Phaco (Hengerer, 2018)

Reduced Medication Use Over Time

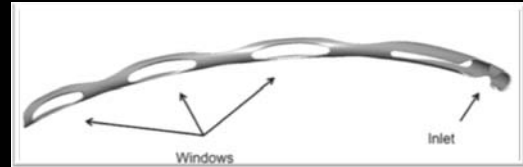


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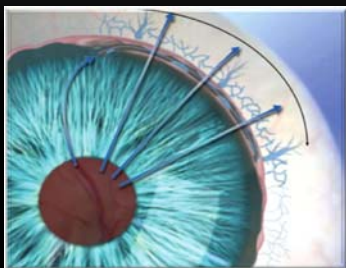
TRABECULAR MICRO-BYPASS

HYDRUS MICROSTENT (IVANTIS)

TRABECULAR MICRO-BYPASS (Hydrus®) (CURRENTLY IN PHASE III CLINICAL TRIALS)



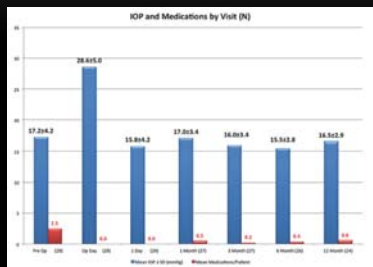
TRABECULAR MICRO-BYPASS (Hydrus®) (CURRENTLY IN PHASE III CLINICAL TRIALS)



TRABECULAR MICRO-BYPASS (Hydrus®) (CURRENTLY IN PHASE III CLINICAL TRIALS)

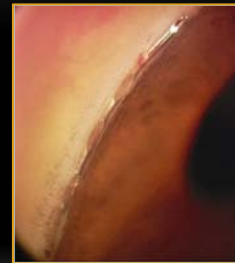


TRABECULAR MICRO-BYPASS (Hydrus®) (THE DATA)



TRABECULAR MICRO-BYPASS (Hydrus®) (POST-OPERATIVE MANAGEMENT)

- Similar to stand-alone cataract sx
- Topical antibiotic
- Topical NSAID
- Topical steroid



MIGS AND THE TRABECULAR MESHWORK

TRABECULAR ABLATION, EXCISION, AND INCISION

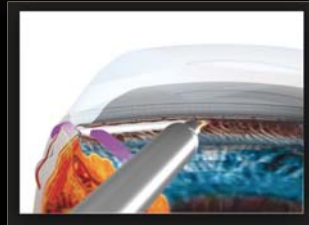
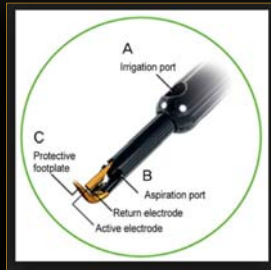
Trabectome, Kahook Dual Blade, GATT Procedure and Trab360

TRABECULOTOMY (TRABECTOME—AB-INTERNO TRABECULECTOMY)



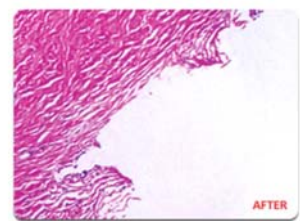
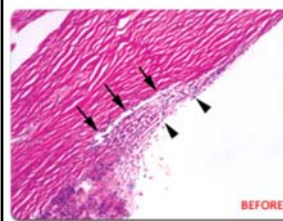
TRABECULOTOMY

(TRABECTOME—AB-INTERNO TRABECULECTOMY)



TRABECULOTOMY

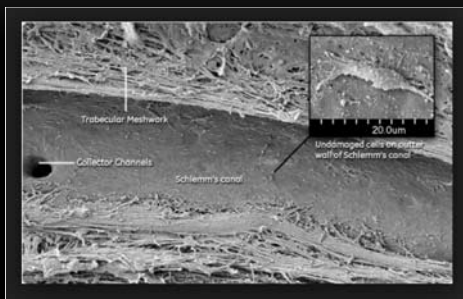
(TRABECTOME—AB-INTERNO TRABECULECTOMY)



Microscopic images of eye drainage tissue before and after Trabectome

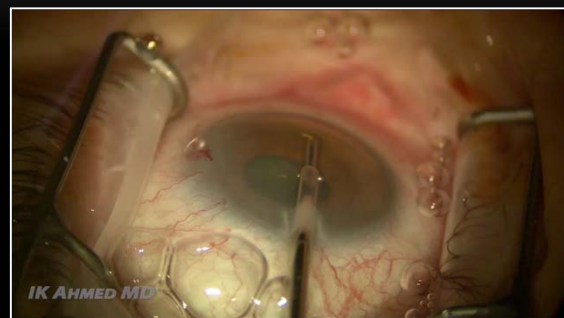
TRABECULOTOMY

(TRABECTOME—AB-INTERNO TRABECULECTOMY)

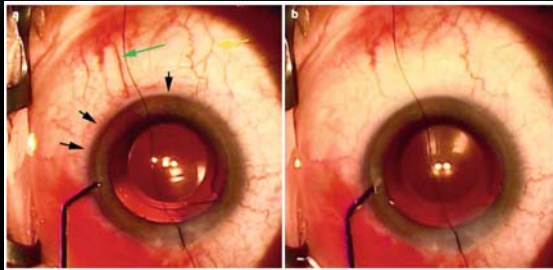


TRABECULOTOMY

(TRABECTOME—AB-INTERNO TRABECULECTOMY)



TRABECULOTOMY (TRABECTOME—AB-INTERNO TRABECULECTOMY)



TRABECTOME (THE DATA)

Table 2. Intraocular pressure preoperatively and postoperatively.

Time	Mean IOP (mm Hg) ± SD	Mean of Differences (% Reduction Postop-Preop)	Eyes, n
Preoperative	20.0 ± 6.3	—	304
Postoperative			
1 d	18.1 ± 9.3	4.1	288
3 mo	14.9 ± 3.7	21.1	193
6 mo	14.8 ± 3.5	22.3	106
12 mo	15.5 ± 2.9	15.6	34
21 mo	16.7 ± 3.5	25.1	7

IOP = intraocular pressure

Table 3. Number of glaucoma medications preoperatively and postoperatively.

Time	Mean Glaucoma Medications (n) ± SD	Mean of Differences (% Reduction Postop-Preop)	Eyes, n
Preoperative	2.65 ± 1.13	—	304
Postoperative			
1 d	1.65 ± 1.58	30.5	288
3 mo	1.77 ± 1.33	32.1	193
6 mo	1.76 ± 1.25	27.3	106
12 mo	1.44 ± 1.29	35.9	34
21 mo	1.43 ± 1.28	32.1	7

Francis et. al. JCRS 2008

TRABECTOME POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx

- Topical NSAID
- Topical antibiotic
- Topical steroid****
- May see RBC in anterior chamber
- More prone to larger hyphemas
- Possible IOP spike
- Reports of recurrent hyphemas

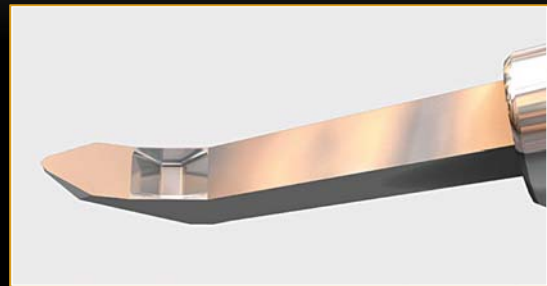


WHO IS A CANDIDATE BEST WITH SECONDARY OAG

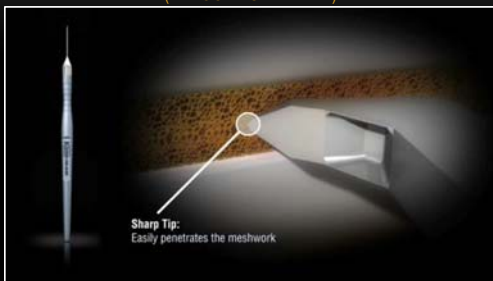
PIGMENTARY GLAUCOMA
PSEUDOEXFOLIATIVE GLAUCOMA
UVEITIC GLAUCOMA

TRABECULAR EXCISION (GONIOTOMY)
KAHOOK DUAL BLADE

GONIOTOMY
(KAHOOK DUAL BLADE)



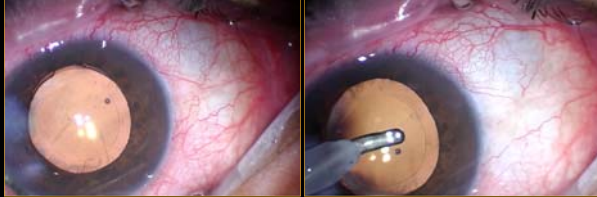
GONIOTOMY
(KAHOOK DUAL BLADE)



GONIOTOMY
(KAHOOK DUAL BLADE)



GONIOTOMY (KAHOOK DUAL BLADE)



GONIOTOMY WITH KDB (POST-OPERATIVE MANAGEMENT)

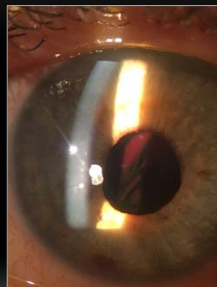
Similar to stand-alone cataract sx

- Topical NSAID
- Topical antibiotic
- Topical steroid****
- May see RBC in anterior chamber
- More prone to larger hyphemas
- Possible IOP spike
- Risk of recurrent hyphemas



GONIOTOMY WITH KDB (POST-OPERATIVE MANAGEMENT)

- Capsular hematoma may appear
- Yag capsulotomy may be needed



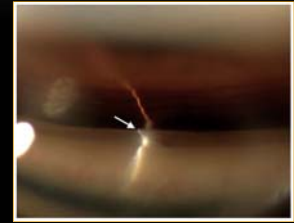
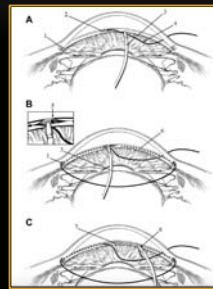
GONIOTOMY WITH KDB (POST-OPERATIVE MANAGEMENT)



TRABECULAR INCISION

GONIOSCOPY ASSISTED TRANSLUMINAL TRABECULOTOMY (GATT)
TRAB360

TRABECULOTOMY GATT PROCEDURE



Davinder Grover, MD

TRABECULOTOMY GATT PROCEDURE



Davinder S. Grover, MD, MPH
Glaucoma Associates of Texas
Dallas, Texas, USA

GATT PROCEDURE THE DATA

POAG

GATT only
Pre-Op: 25.6
Post-Op: 15.7
GATT combined with CE
Pre-Op: 23.9
Post-op: 15.5
GATT with prior CE
Pre-Op: 23.8
Post-Op: 16.2
Med Decrease of 1.1

Other Glaucoma

GATT only
Pre-Op: 31.8
Post-Op: 12.4
GATT combined with CE
Pre-Op: 27.6
Post-op: 13.8
Med Decrease 1.9

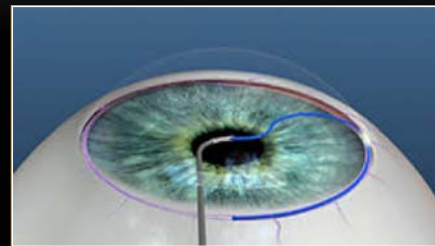
GATT PROCEDURE POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx

- Topical NSAID
- Topical antibiotic
- Topical steroid****
- Pilocarpine or Cyclogel
- May see RBC in anterior chamber
- More prone to larger hyphemas
- Possible IOP spike
- Reports of recurrent hyphemas
- High risk for 8-ball hyphema
- Anti-coagulants contraindicated



TRABECULOTOMY TRAB360



TRABECULAR INCISION TRAB360



TRAB360 POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx

- Topical NSAID
- Topical antibiotic
- Topical steroid****
- Pilocarpine or Cyclogel
- May see RBC in anterior chamber
- More prone to larger hyphemas
- Possible IOP spike
- Requires more frequent follow-up
- Risk of recurrent hyphemas
- Anticoagulants contraindicated



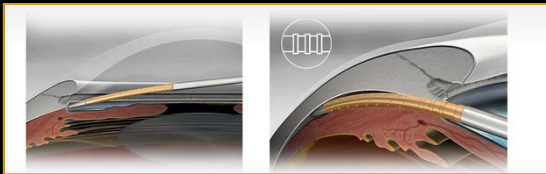
MIGS OF THE SUPRACHOROIDAL SPACE

CyPass® Alcon Laboratories
iStent Supra® Glaukos

CYPASS® SUPRACILIARY SHUNT

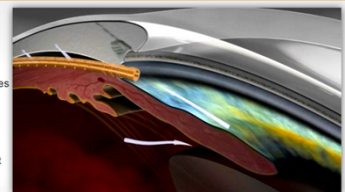


CYPASS® SUPRACILIARY SHUNT



CYPASS® SUPRACILIARY SHUNT

- The supraciliary space has a negative pressure gradient that drives aqueous outflow and reduction of intraocular pressure¹
- The uveoscleral pathway bypasses Schlemm's canal and collector channels, which may be atrophic in glaucoma patients²
- The CyPass® Micro-Stent utilizes the same outflow pathway as first line prostaglandin analogues³



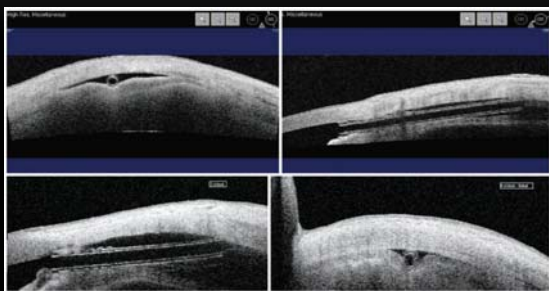
CYPASS®
SUPRACILIARY SHUNT



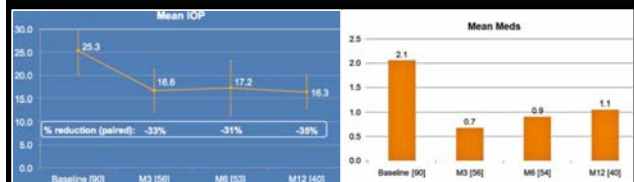
CYPASS®
SUPRACILIARY SHUNT



CYPASS®
SUPRACILIARY SHUNT



CYPASS®
THE DATA



CYPASS® SUPRACILIARY SHUNT POST-OPERATIVE MANAGEMENT

Similar to stand-alone cataract sx

- Topical NSAID
- Topical antibiotic
- Topical steroid****
- MAY NEED CYCLOPLEGIA

- Possible IOP spike

- **RISK FOR HYPOTONY**

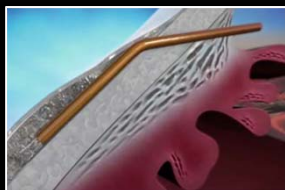


BYPASSING THE NATURAL SYSTEMS XEN 45 GEL IMPLANT

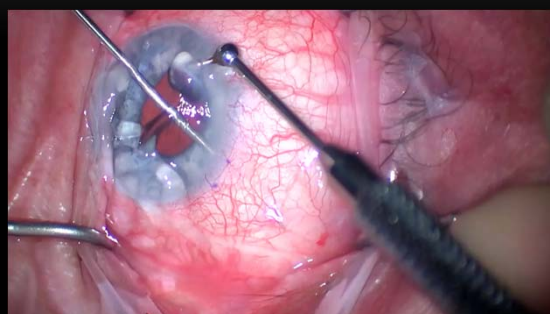
XEN 45 GEL IMPLANT

NOT A MIGS PROCEDURE

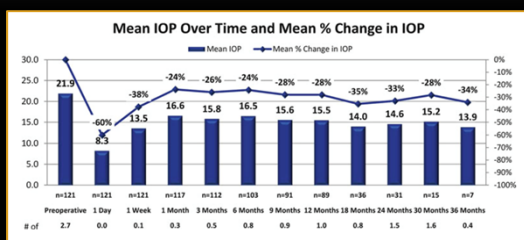
- Less invasive filter
- Bleb dependent procedure
- Same long-term pressure control as a trab
- Quicker post-op vision recovery
- Less risk for hypotony



XEN 45 GEL IMPLANT



XEN 45 GEL IMPLANT THE DATA



XEN 45 GEL IMPLANT POST-OPERATIVE MANAGEMENT

LIKE ALL OTHER BLEB PROCEDURES

- Topical antibiotic
- Topical NSAID
- Topical steroid

- Frequent post-operative visits
- Bleb management
- 5-fluorouracil injections
- Ocular massage
- Needling revisions



FUTURE DIRECTIONS

- SITE SPECIFIC TARGETED TREATMENT
- INTRA-OPERATIVE CANALOGRAM
- HIGH DEFINITION IMAGING OF THE CONVENTIONAL SYSTEM
- COMBINATION OF MIGS PROCEDURES
- COMMUNICATION AND COORDINATION BETWEEN PRIMARY EYE PROVIDER AND SURGEONS

THANK YOU FOR THE INVITATION

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