



MIGs in the BIGs

A professional level understanding of MIGs

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Financial Disclosures- Ibach

Disclosure Statement:

- Aerie – consultant/speaker
- Allergan – consultant
- Avellino – consultant
- Bausch Health – consultant
- Dorvis – consultant/speaker
- Equinox LLC – shareholder
- Gaukos – consultant/speaker
- Haru – consultant/speaker
- Kala – consultant
- NewWorld Medical – consultant
- Ocular Therapeutix – consultant/speaker
- Oyster Point – consultant/speaker
- Sight Sciences – consultant/speaker
- Sun Pharma – speaker




All relevant relationships have been mitigated

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- Glaucoma is the second leading cause of blindness worldwide
- In the US, there are an estimated 4M cases of OAG, with a significant number of patients going blind every year¹
- ~ 40,000 OD's in US, ~23,000 MD's = 60k ECP's
- Every ECP managed glaucoma - ~ 70 pts

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EOE's Glaucoma Survey

Do you treat Glaucoma?

20.1% No
79.9% Yes

Rank your current knowledge of glaucoma.

7.01 Avg.

Rank your knowledge of MIGS

5.97 Average

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Why MIGs?

Drops - SE's

Drops - convenience

Drops - compliance

Laser - duration

Drug delivery- single use


Tubes/Trabs - risks

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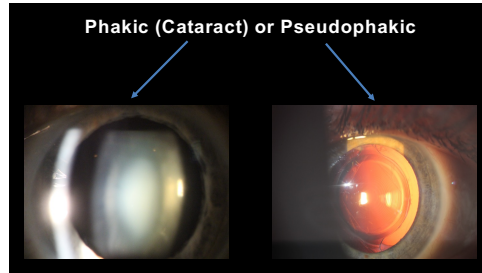
Minimally Invasive Glaucoma Surgery (MIGS)

Procedures that have an ab-interno approach, are minimally traumatic, with at least modest efficacy, extremely high safety and rapid recovery.

Sabib H. Ahmad, BSc. Minimally-invasive glaucoma surgery: current perspectives and future directions. Curr Opin Ophthalmol. 2012;23(2): 96-104.



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MIGs

Trabecular Meshwork / Schlemm's Canal				Suprachoroidal/ Supraciliary	Subconjunctival	Cyclophoto-coagulation
Stents	Ablation	Cutting	Dilation			Endoscopic Transcleral
iStent iStent Inject Hydrus iStent Infinite	Trabectome	Kahook Dual Blade iAccess GATT	ABIC (Ab-Interno Canaloplasty) iPrime OMNI (combo)	Cypass ^{xx} iStent-Supra*	Xen Microshunt*	ECP G6/MP3

http://glaucomanovels.com/2012/08/02/migs-overview.pdf

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iSTENT

- Titanium TM bypass stent
- Creates a patent opening in the trabecular meshwork, the source of 75% of resistance
- Restores natural physiological outflow
- The natural episcleral back pressure of 8 to 11 mm Hg minimizes the risk of hypotony

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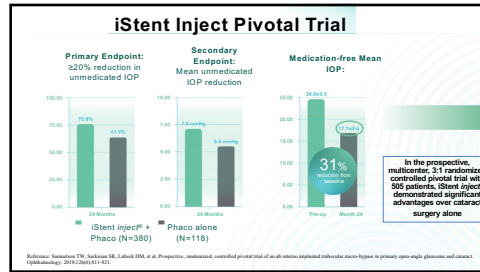
iStent inject W (G2)

Two stents pre-loaded per injector

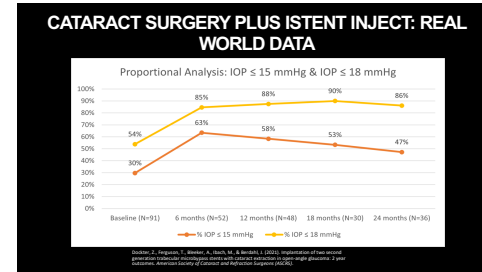
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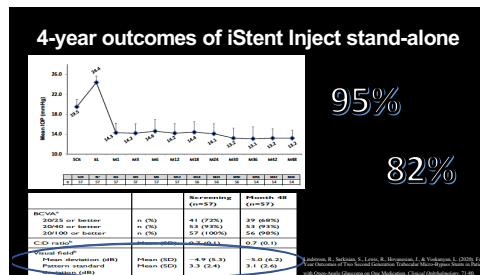
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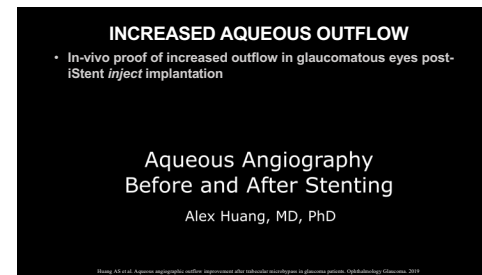
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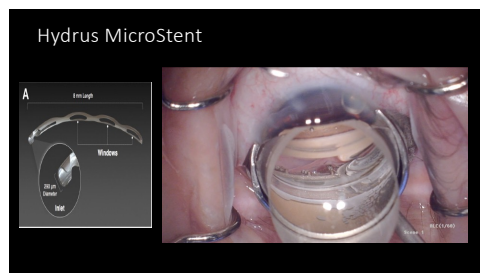
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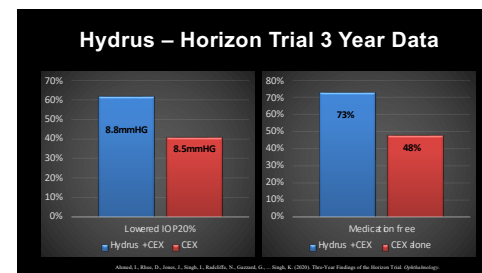
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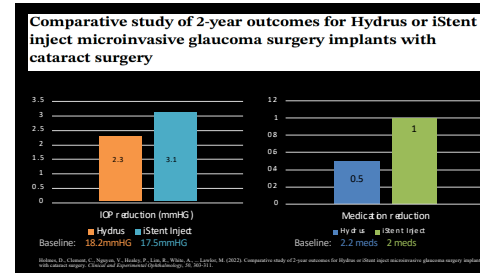
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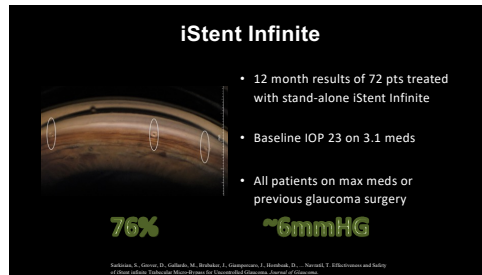
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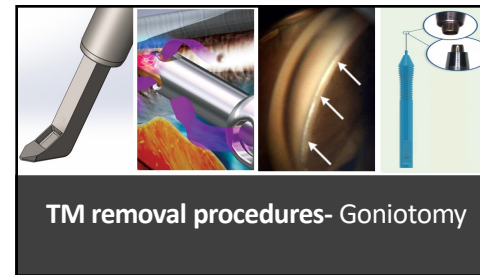
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Combined Phaco+KDB Cohort

	Preoperative	Day 1 (1-3 days) N=60	Week 1 (4-14 days) N=59	Month 1 (15-59 days) N=57	Month 3 (60-120 days) N=52	Month 6 (121-270 days) N=60	Month 12 (271-455 days) N=48
Mean IOP	17.41 5.2*	13.34 3.9	13.44 4.2	13.64 3.4	12.61 2.6	12.74 2.3	12.41 3.4
Mean Difference	Reference	-4.1*	-4.0*	-3.8*	-4.8*	-4.7*	-5.0*
IOP Percent Change	Reference	24%	23%	22%	28%	27%	29%
Mean Meds	1.68 1.3	0.41 0.9	0.74 1.1	0.71 0.9	0.91 1.1	0.91 1.1	0.61 0.8
Mean Difference	Reference	-1.2*	-0.9*	-0.9*	-0.7*	-0.7*	-1.0*
Medi Percent Change	Reference	73%	56%	56%	44%	44%	63%

29% reduction in IOP at month 12 with baseline IOP below 18mmHg

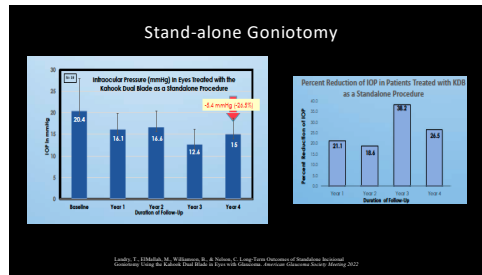
Gonzalez MD, Schulz LL, Baskies NM, Davatz PG, Araf AA, Jankovic-Burton S, Lomax-Greene G, Duffington RL, ANMAH S, Turk MC, Bazzi KA, Baskies LP. Outcomes with a single-step trabeculectomy. *Journal of Glaucoma* 2017;26(11):1071-1076.

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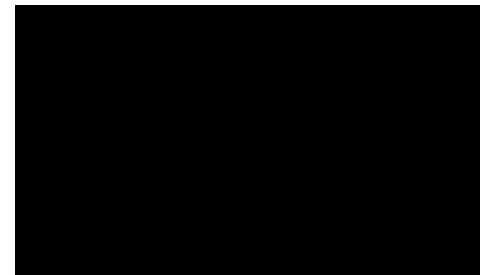
KDB Survey – AE

	Intraoperative N=122	Day 1 (1-3 days) N=108	Week 1 (4-14 days) N=104	Month 1 (15-59 days) N=115	Month 3 (60-120 days) N=111	Month 6 (121-270 days) N=92	Month 12 (271-455 days) N=68
Blood Reflux/Retained Heme	38.5%	10.2%					
Difficulty Removing TM	1.6%	-					
Choroidal/Retinal Ectop	0.8%						
Descemet Tear	0.8%						
Iridodiolysis	0.8%						
Irritation	-	0.9%					
Hypotony	-	0.9%					
Central Edema	-	0.9%					
IAS	-	-					
Reoperation for high IOP	-	-					
IOP Spike	-	-					
Inflammation	-	0.9%					
Choroidal detachment	-	-					
Hazy vision	-	-					
Capillary opacification	-	-					
CME	-	-					
Pain	-	-				1.1%	1.5%
Floater	-	-			2.2%	-	-
Glare	-	-			1.2%	-	-

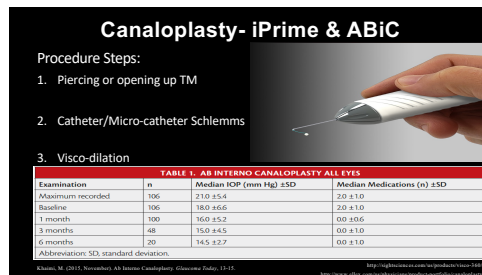
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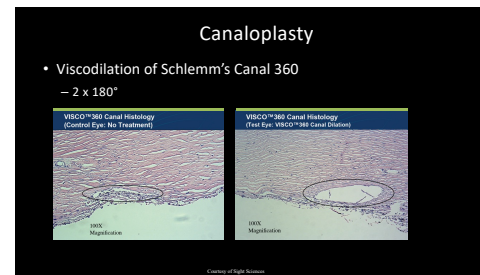
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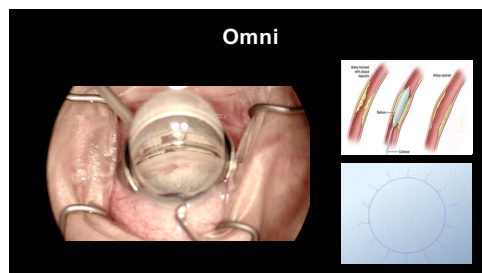
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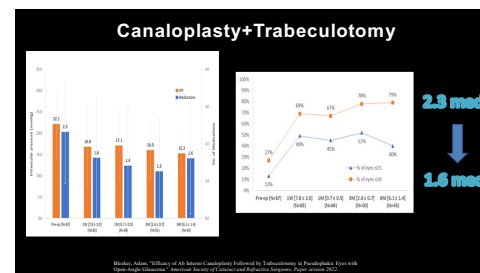
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Suprachoroidal Space

iStent Supra
Currently finishing phase 3 FDA IDE clinical trial

Cypass - voluntarily recalled

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MIGS Considerations: Endothelial Cell Loss Rates

STENT DEVICE	STENT TYPE	VISION OF TIME	VISION OF TIME	% WITH CELL LOSS
CellStent (Lentis)	SL	12 months	12.1% treatment 12.7% control	14.4% treatment 9.5% control
Hydra Microcath (Quanta)	SL	12 months	14.8% treatment 14.8% control	17.8% treatment 17.8% control
Hydra Microcath (Quanta)	SL	36 months	12.0% treatment 12.0% control	14.0% treatment 18.7% control
Hydra Microcath (Quanta)	SL	12 months	No change	No change
Hydra Microcath (Quanta)	SL	12 months	16.4% treatment 17.9% control	17.2% treatment 18.0% control
Hydra Microcath (Quanta)	SL	12 months	No change (<1.5%)	No change (<1.5%)
Hydra Microcath (Quanta)	SL	12 months	No change (<1.5%)	No change (<1.5%)

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Xen-subconjunctival stent

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Xen 45 Gel Stent: US Pivotal Clinical Trial

Visits – IOP and Medications	Mean
Baseline	
Medicated IOP	25.1 (3.7)
Glaucoma Meds	3.5 (1.0)
12 Month	
IOP	15.9 (5.2)
Glaucoma Meds	1.7 (1.5)

76.3% of patients reported a mean diurnal IOP reduction of $\geq 20\%$ from medicated baseline at 12 months

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Postoperative Adverse Events

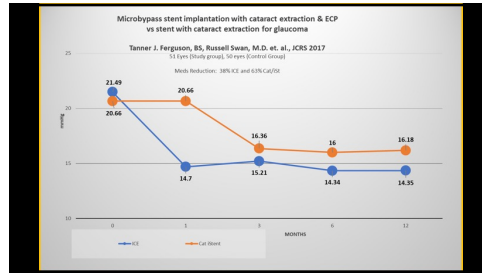
Hypotony (IOP < 6 mmHg at any time)	16 (24.6%)
Anterior chamber shallow with peripheral irido-corneal touch	1 (1.5%)
Anterior chamber fill	1 (1.5%)
Bleb Needling	21 (32.3%)

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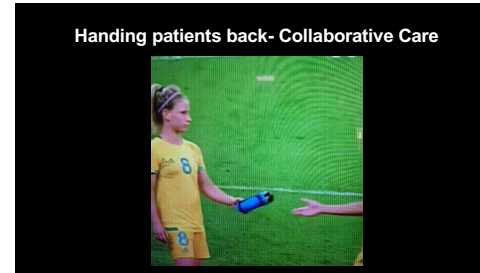
Endocyclophotocoagulation (ECP)

- TREATS INFLOW
- It uses a laser endoscope containing three fiber groupings:
 - a light source (illuminate)
 - an image guide (visualize)
 - diode laser (treat)
- Direct visualization
- Precise delivery to the ciliary processes
- no damage to the underlying ciliary body and surrounding tissue

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Minimally Invasive

Safety First

1. IOP Spikes
2. Microhyphema
3. Hypotony- Can it happen?
4. Endothelial Cell Loss
5. Peripheral Anterior Synechiae

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Following MIGS Further

- Continue monitoring
 - IOP
 - Immediate IOP spike, add med +/- burp para
 - Fluctuates early, +/- steroid effect
 - Slit lamp exam
 - Normal inflammation, hyphema?
 - Gonioscopy
 - 1 time in global period
 - OCT and HVF
 - 3-6 months post-operatively set new baselines.

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How Do You Decide?

- When we want to maximize safety - **Canal**
- When we want to maximize quick visual recovery - **Canal**
- When we need greater efficacy, and are willing to take a bit more risk, but still want greater safety than transcleral - **Supraciliary or combo procedure**
- Quick progressing glaucoma and a need for low IOP - **Transcleral, Trab, or Tube**

Courtesy of Dr. Tom Samuelson

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