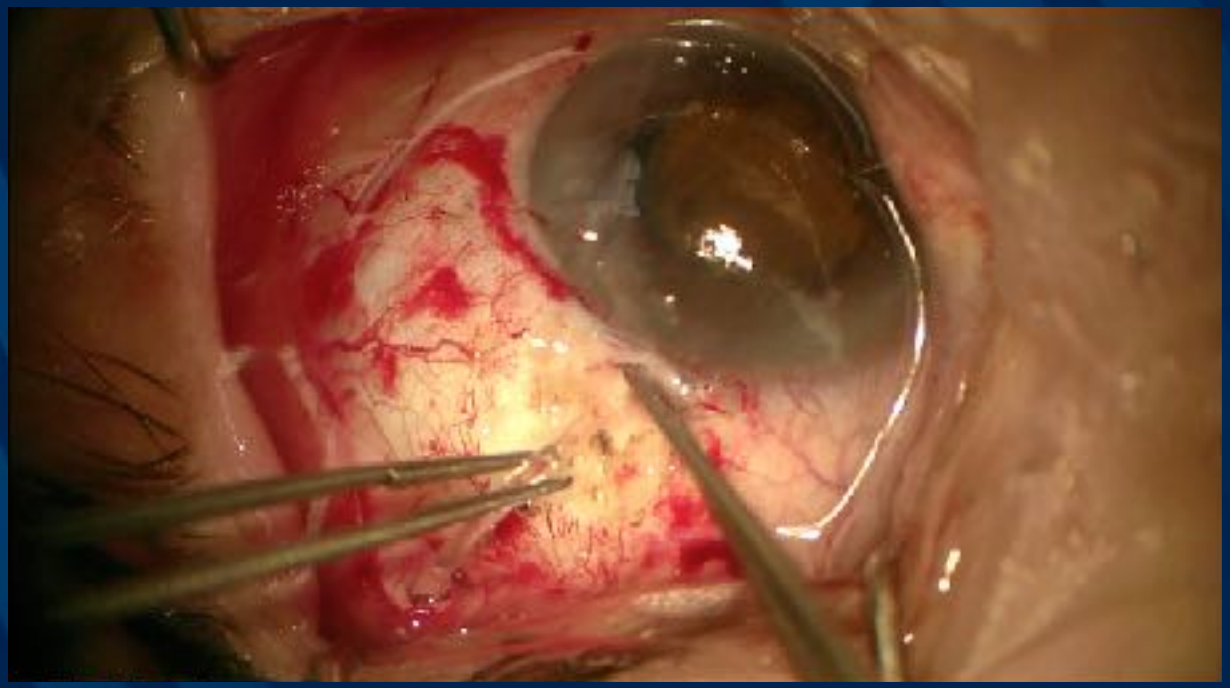
Patient Selection for Glaucoma Interventions: Lasers to MIGS and Blebs to Tubes



Brian McMillan, MD

WVAEPS

April 27, 2018

Disclosures

- Consultant-
  - Aerie Pharmaceuticals
  - No disclosures related to this talk

Outline

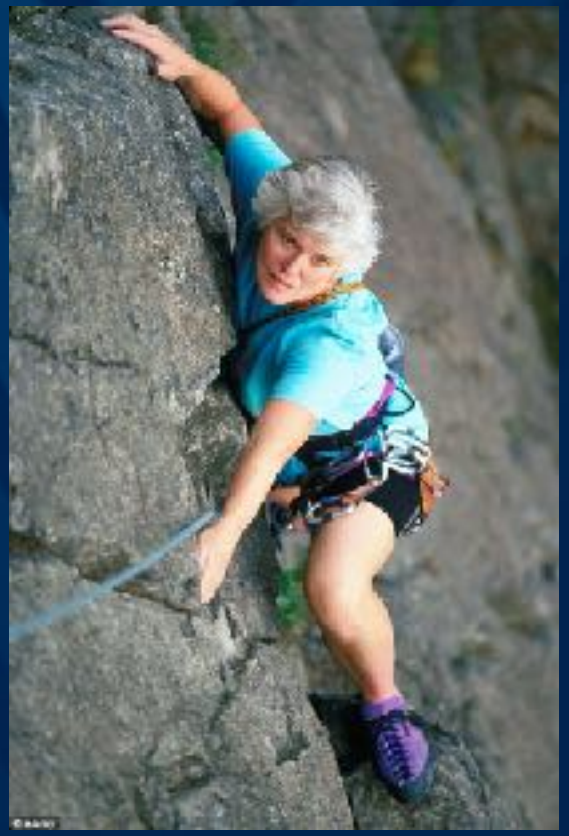
- Goals of Treatment
- Laser Interventions
- Surgical Interventions
  - Cataract Surgery
  - Minimally Invasive Glaucoma Surgery (MIGS)
  - OR Lasers
  - Traditional
- Patient cases

Goal of Treatment: Lower IOP

- Lowering IOP decreases the rate and likelihood of glaucoma progression
- Large Multicenter Trials help to guide treatment
  - Ocular Hypertension Treatment Study (OHTS)
    - 20% IOP reduction
  - Collaborative Normal Treatment Study
    - 30% reduction
  - Early Manifest Glaucoma Treatment Study
    - 1 mmHg reduction = 10% reduction in risk of progression

Goal of Treatment- MIGS Era

- Lower IOP
- Maintain Quality of Life
  - Medication free
  - Medication reduction
  - Fewer complications
  - Shorter recovery period
  - Delay higher risk procedures
- Patient expectations of care

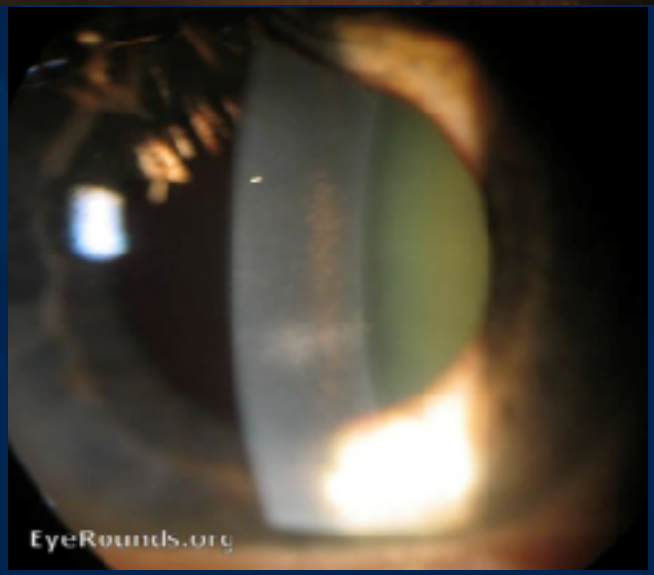


Treatment Options & Patient Selection

- Laser peripheral Iridotomy or phacoemusification
- Medications or laser – First line treatment
- Mini-MIGS-
  - Phaco, Phaco + Trabecular Microbypass (Istent)
- Mod- MIGS-
  - Goniotomy- (KDB, Trabectome, GATT, ECP, Cypass, Micropulse)
- Mega- MIGS-
  - Ab interno filtration- (XEN), 360 Trabeculotomy (GATT, Trab 360)
- Trabeculectomy and Tube shunt
- Diode CPC- (G-probe)

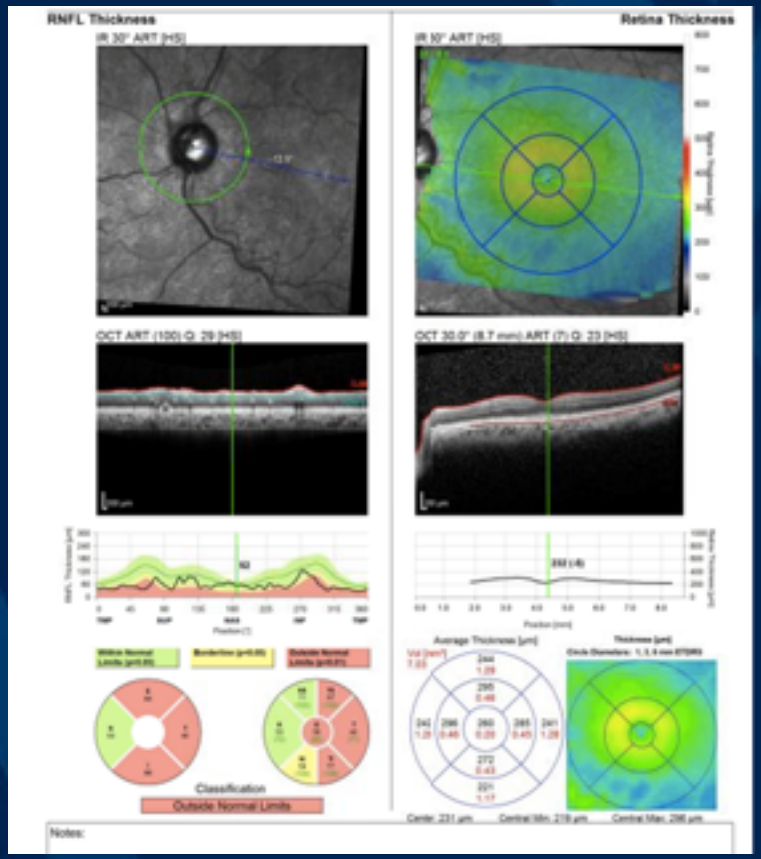
Evaluation

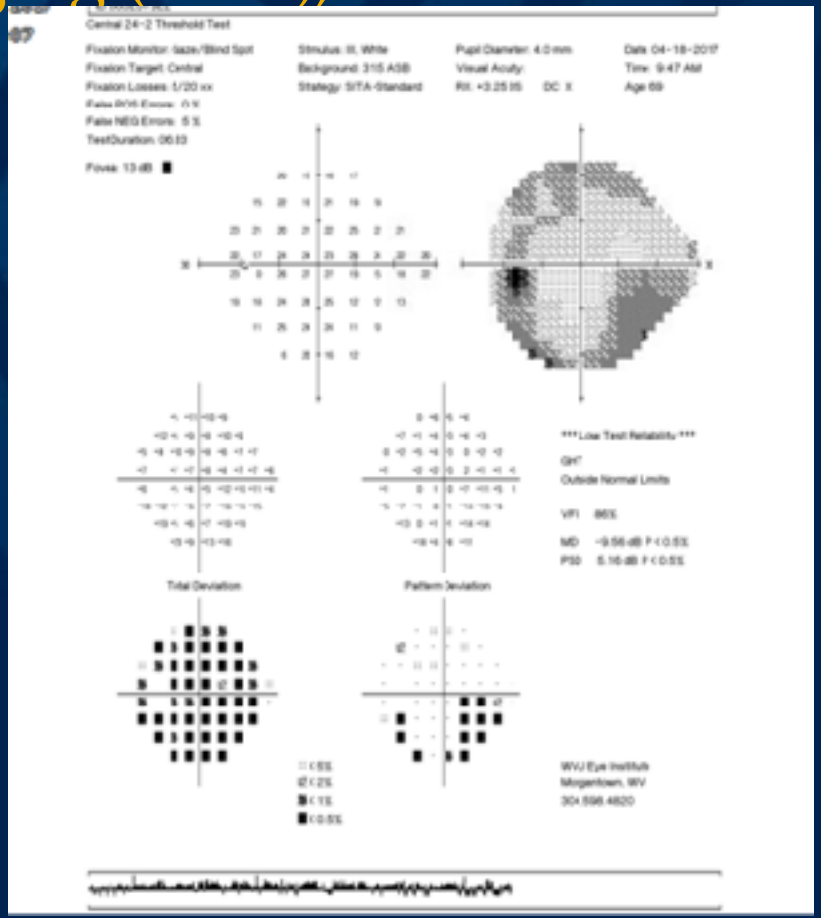
- Slit- lamp biomicrosopy
  - Secondary glaucomas-
    - (PXF, Pigmentary, NVG, ICE, etc)
  - Gonioscopy-
    - angle classification
  - Lens status
  - Nerve assessment-
    - focal or concentric loss
  - Co-existent ophthalmic disease



Evaluation- testing

- Fundus photo, Nerve imaging (OCT), Visual Field





EAGLE Study

- Lancet 2016
- Clear lens extraction for the treatment of primary angle-closure glaucoma
- 419 patients 155 primary angle closure 263 primary angle-closure glaucoma
- 30 sites, 5 countries
- Clear-lens extraction vs Standard care (Laser iridotomy)

Effectiveness of early lens extraction for the treatment of primary angle-closure glaucoma (EAGLE): a randomised controlled trial

Augusto Azuara-Blanco, Jennifer Burr, Craig Ramsay, David Cooper, Paul J Foster, David S Friedman, Graham Scotland, Mehdi Javanbakht, Claire Cochrane, John Norrie, for the EAGLE study group

Study design

- ≥50 years old, phakic
- Primary angle closure with IOP 30mmHg or greater
- Iridotrabecular contact 180° on gonioscopy
- Primary angle closure glaucoma (field, nerve or both)

Exclusion Criteria

- Symptomatic cataract
- Advanced glaucoma
- Prior acute angle-closure attack
- Prior laser or ocular surgery

Outcomes

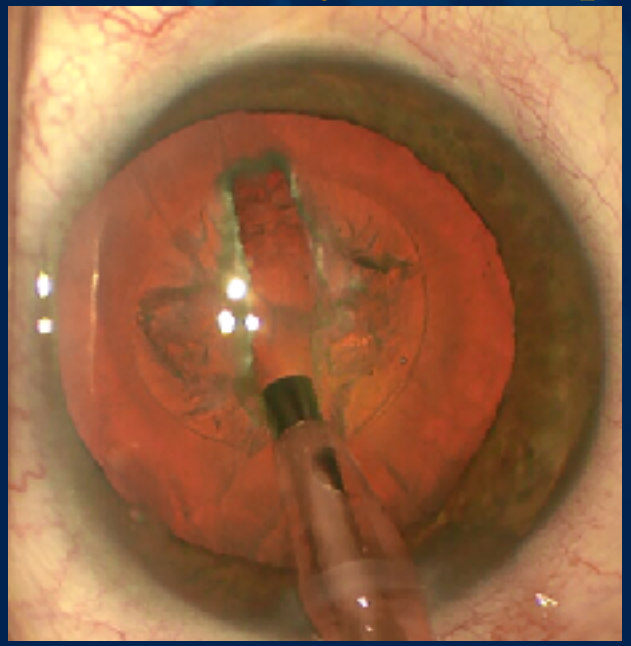
- Clear lens extraction was superior to laser + topical
- Visual acuity 3 EDTRS letters better
- IOP 1 mmHg lower
- 21% required further treatment compared to 61%
- Further glaucoma surgery 1 vs 24
- Increased quality of life

SLT- Selective Laser Trabeculoplasty

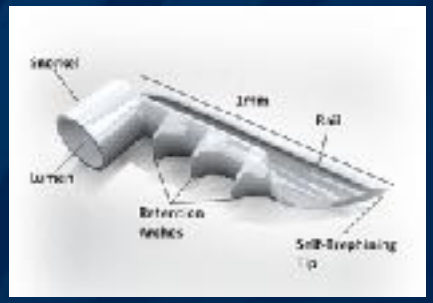
- Efficacy similar to PGA
  - Katz et al. Selective laser trabeculoplasty versus medical therapy as initial treatment of glaucoma: a prospective, randomized trial. J Glaucoma. 2012;21:460–8.
- Meta-analysis
  - Li et al. Meta-analysis of selective laser trabeculoplasty versus topical medication in the treatment of open-angle glaucoma. BMC Ophthalmology 2015. 15:107

Mini-MIGS

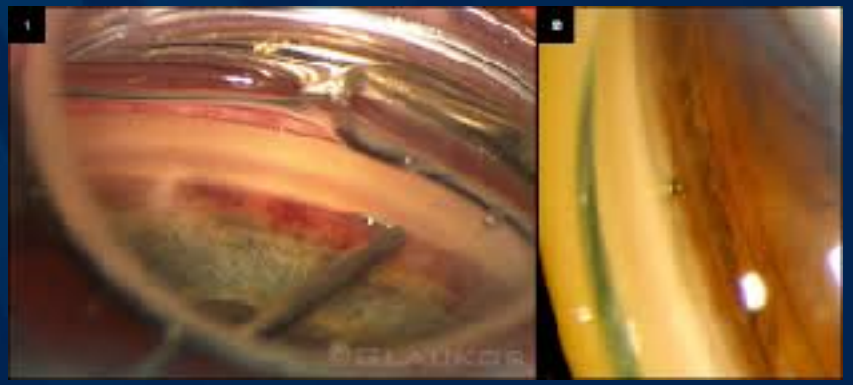
- Phacoemulsification alone
  - Control group
    - 48% IOP ≥20% reduction 1 year (istent trial)
    - 66% IOP ≥20% reduction 1 year (compass trial)



Trabecular microbypass (iStent)



- 240 eyes mild to moderate glaucoma
- Cataract + istent vs cataract alone
- Outcome #1 unmedicated IOP ≤21 1 year
- Outcome #2 unmedicated IOP ≥20% reduction 1 year
- #1 72% tx eyes, 50% control
- #2 66% tx eyes,48% control
- Adverse events similar



Randomized Evaluation of the Trabecular Micro-Bypass Stent with Phacoemulsification in Patients with Glaucoma and Cataract

*Thomas W. Samuelson, MD,1 L. Jay Katz, MD,2 Jeffrey M. Wells, PharmD,3 Yi-Jing Duh, PhD,4 Jane Ellen Giamporcaro, BS,3 for the US iStent Study Group**

Table 3. Frequently Reported Postoperative Ocular Complications (≥2%) through Month 12

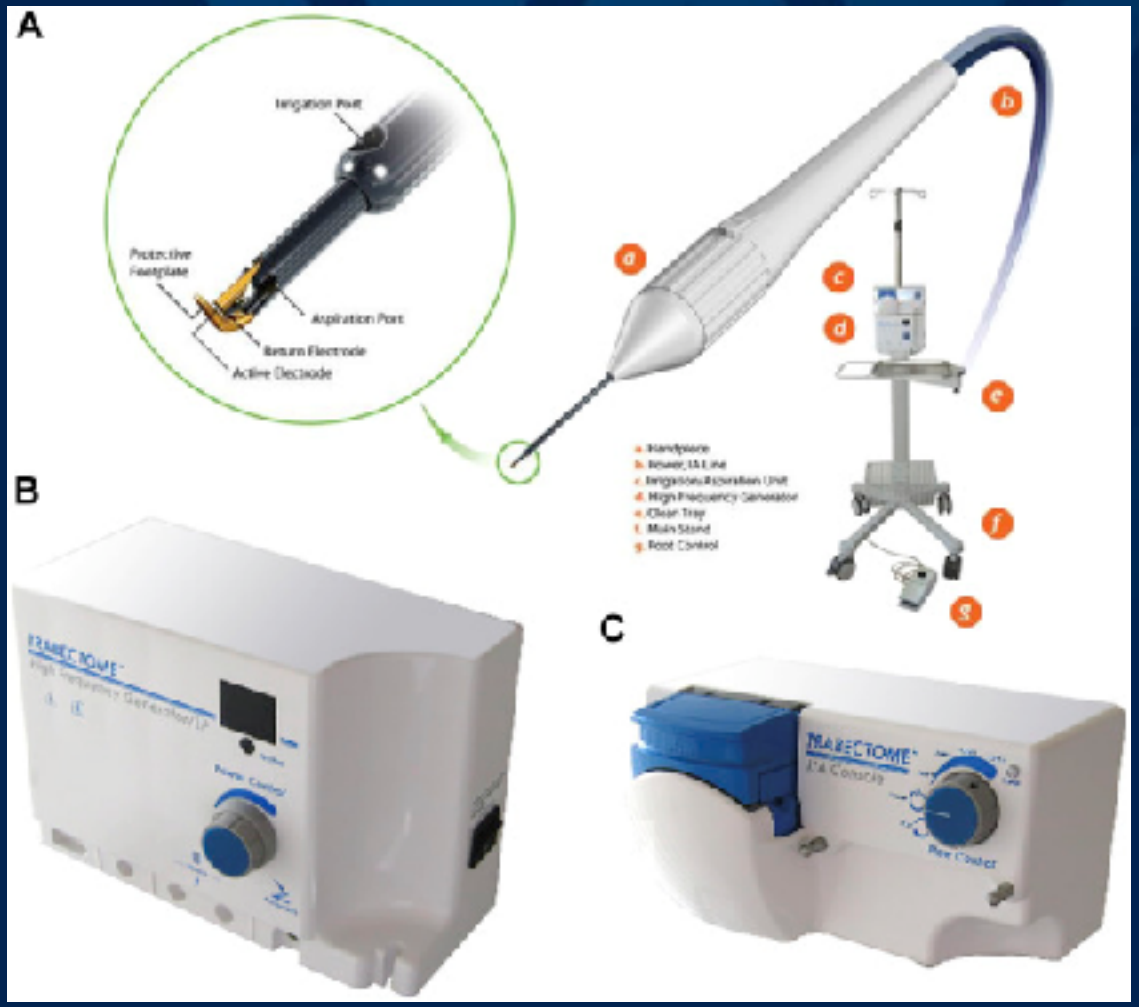
Complication	iStent with Cataract Surgery N = 111	Cataract Surgery Only N = 122
Anticipated early postoperative event	14 (13%)	15 (12%)
Stent obstruction by iris, vitreous, fibrous overgrowth, fibrin, blood, and so forth	4 (4%)	0 (0%)
Posterior capsular opacification	3 (3%)	8 (7%)
Stent malposition	3 (3%)	0 (0%)
Subconjunctival hemorrhage	2 (2%)	2 (2%)
Elevated IOP, other	2 (2%)	1 (1%)
Epiretinal membrane	2 (2%)	1 (1%)
Iris atrophy	2 (2%)	0 (0%)
Blurry vision or visual disturbance	1 (1%)	6 (5%)
Iritis	1 (1%)	6 (5%)
Dry eye	1 (1%)	2 (2%)
Elevated IOP requiring treatment with oral or intravenous medications or with surgical intervention	1 (1%)	2 (2%)
Macular edema	1 (1%)	2 (2%)
Foreign body sensation	0 (0%)	3 (2%)
Allergic conjunctivitis	0 (0%)	2 (2%)
Mild pain	0 (0%)	2 (2%)
Rebound inflammation from tapering steroids	0 (0%)	2 (2%)

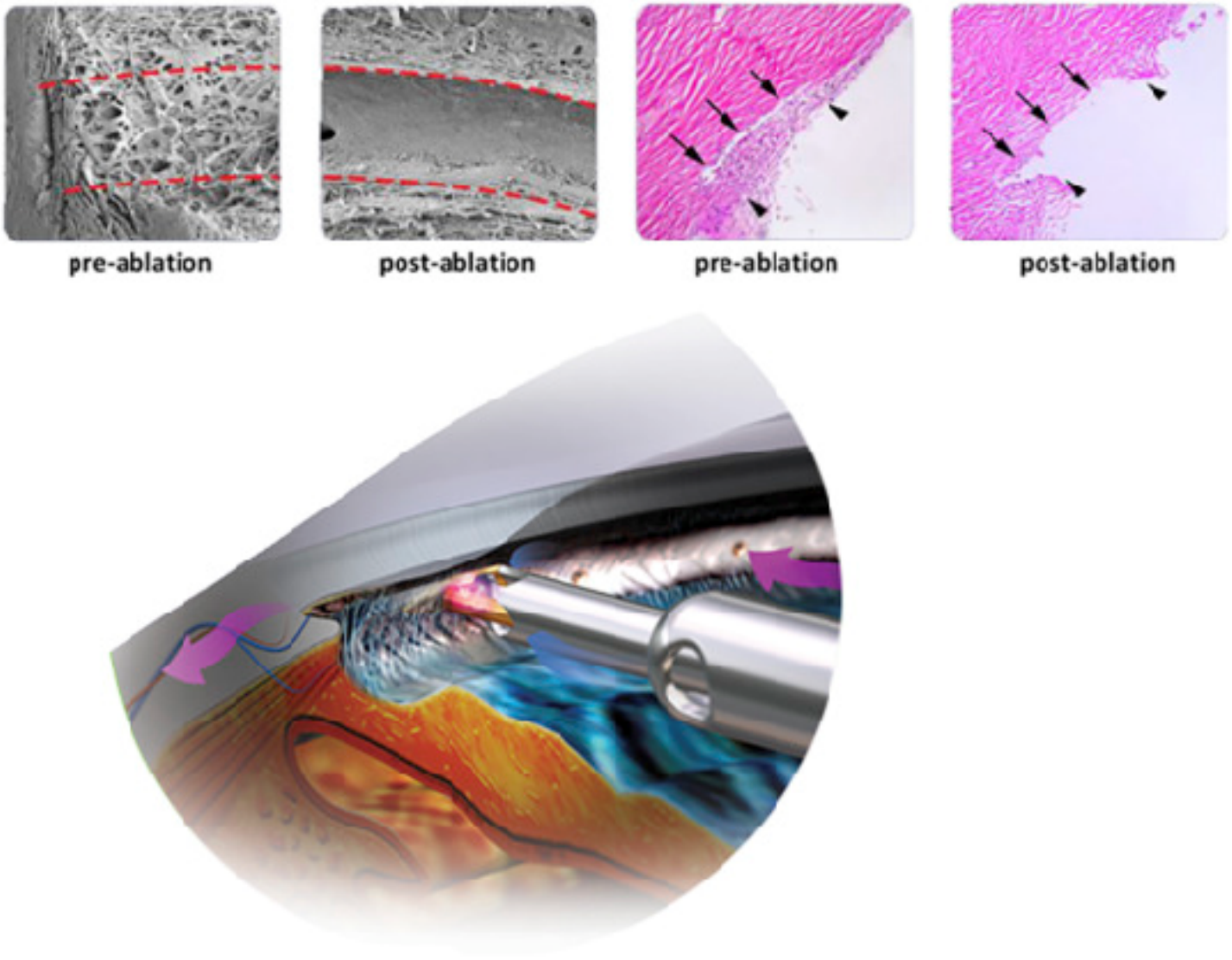
IOP = intraocular pressure.
"Anticipated, early postoperative events" included transient events such as corneal edema, trace folds, trace striae, transient hypotony at 5–7 hrs, inflammation, epithelial defect, and discomfort as expected after cataract surgery.

Moderate- MIGS

- Goniotomy-
  - Trabectome
  - Kahook Dual Blade (KDB)
  - Gonioscopy Assisted Transluminal Trabeculotomy (GATT)
- Titratable cyclophotocoagulation
  - Endocyclophotocoagulation (ECP)
  - Micropulse cyclophotocoagulation (mCPC)
- Suprachoroidal space
  - Cypass shunt

Trabectome

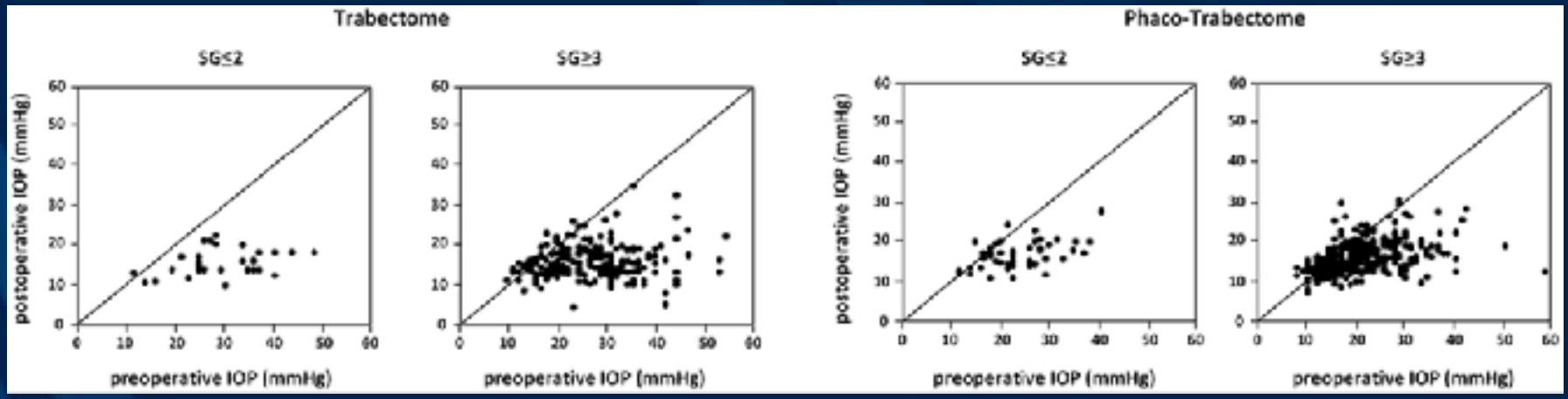

A
Irrigation Port
Protective Faceplate
Aspiration Port
Return Electrode
Active Electrode
a
b
c
d
e
f
g
B
C



https://www.youtube.com/watch?v=Jwd6rDNqMgM

Outcomes

- Reported as independent of preoperative IOP
- Limited by downstream resistance (collector channels, ESVP)
- Avg IOP reduction 30-40%
- Post op IOP <21 or >20% decrease in IOP 60-85%



Complications

- Early Hyphema- (100%) generally resolves within days
- Delayed hyphema onset is rare
- 3.5 % early IOP spike
- 0.9% cyclodialysis cleft

Combined phacoemulsification and trabectome for treatment of glaucoma
Julia K. Polat, MD, Nils A. Loewen, MD, PhD*
Survey of Ophthalmology 2016

Kahook Dual Blade

A Novel Dual Blade Device For Goniotomy: 12 Month Follow Up

Nathan M. Radcliffe[1], Suhail Abdulhak[2], Mark C. Jasek[3], Jesús Jiménez Rosario[4], Leonard K. Seibold[5], Gabriel S. Lazcano[6], Jason K. Darlington[6], Syril K. Dorairaj[7], Ahmad A. Aref[8], Khaled A. Bahjri[9], John P. Dunkelt[9]
1. New York Eye Surgery Center, New York, NY 2. New World Medical, Inc., Rancho Cucamonga, CA 3. B Through C, LLC, Bradenton, TX 4. APEC, Mexico City Mexico, 5. University of Colorado, Denver, CO
6. The Eye Institute, Melbourne, FL 7. Mayo Clinic, Jacksonville, FL 8. University of Illinois, Chicago, IL 9. Vance Thompson Vision, Sioux Falls, SD

Figure 3. The anterior wall of Schlemm's Canal is visible after TM excision with the KDB (Source: Dr. Seibold)

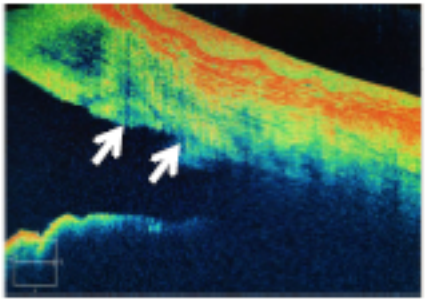


Figure 4: AS OCT image after KDB treatment. Arrows indicate area of TM removal revealing minimal residual leaflets. (Source: Dr. Radcliffe)

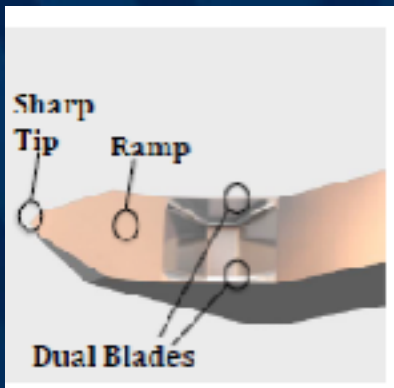


Figure 1: KDB Design Features

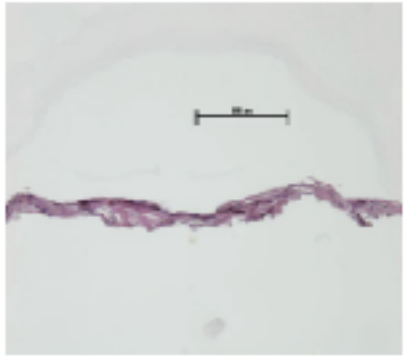


Figure 2: H&E-stained TM strip harvested after a KDB procedure (Source. Dr. Seibold)

Table 2: Treatment results for eyes post Phaco+KDB

	Pre-Op N=71	Day 1 (1-3 days) N=60	Week 1 (4-14 days) N=59	Month 1 (15-59 days) N=67	Month 3 (60-120 days) N=56	Month 6 (121-270 days) N=60	Month 12 (271-455 days) N=48
Mean IOP	17.4± 5.2	13.3± 3.9	13.4± 4.8	13.6± 3.4	12.6± 2.6	12.7± 2.3	12.4± 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	1.6± 1.3	0.4± 0.9	0.7± 1.1	0.7± 0.9	0.9± 1.1	0.9± 1.1	0.6± 0.8
Mean Difference	Reference	-1.2*	-0.9*	-0.9*	-0.7*	-0.7*	-1.0*

Gonioscopy-Assisted Transluminal Trabeculotomy: GATT

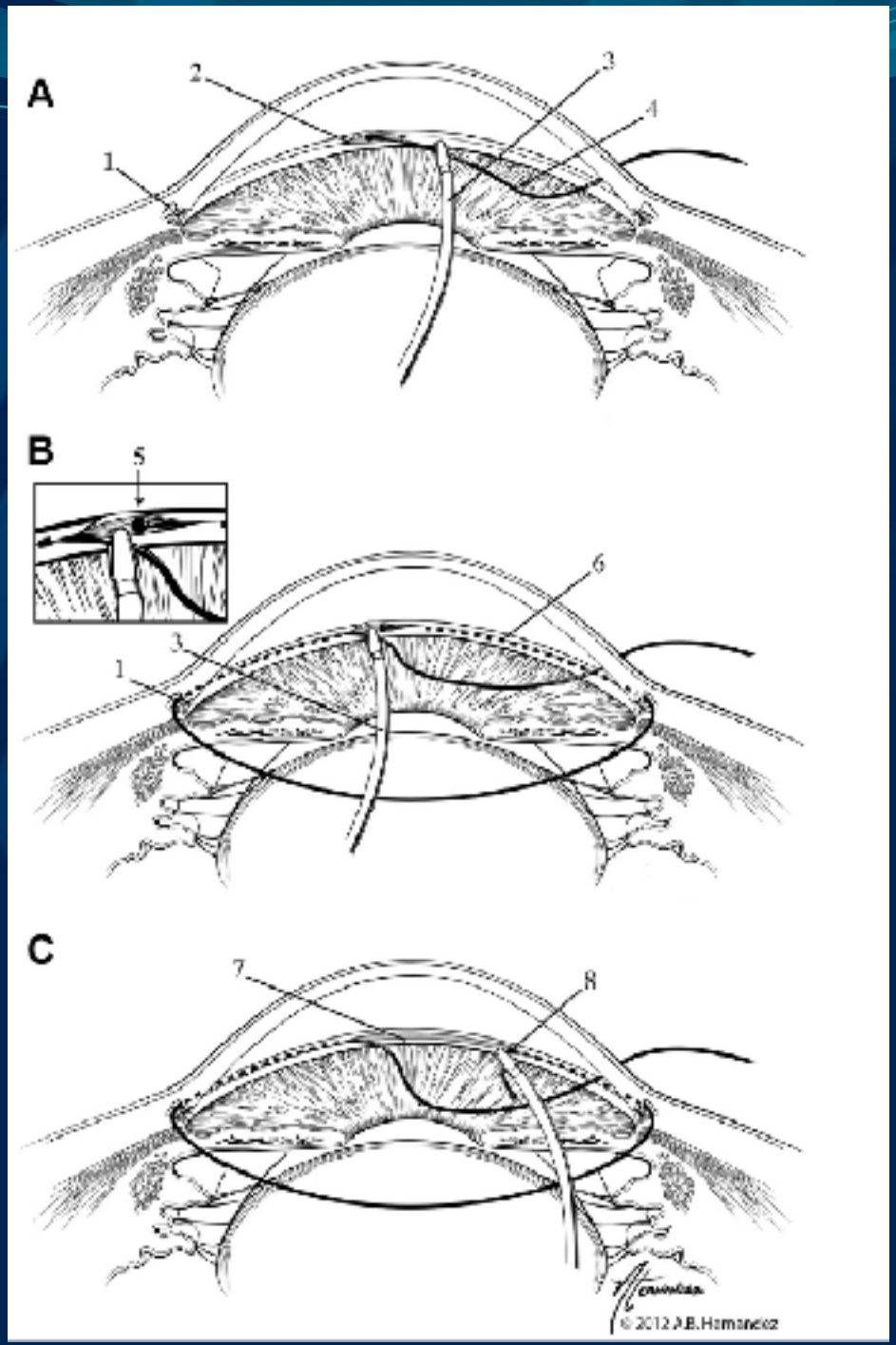
Gonioscopy-Assisted Transluminal Trabeculotomy, Ab Interno Trabeculotomy

Technique Report and Preliminary Results

Davinder S. Grover, MD, MPH,[1] David G. Godfrey, MD,[1] Oluwatosin Smith, MD,[1] William J. Feuer, MS,[2] Ildamaris Montes de Oca, MD,[3] Ronald L. Fellman, MD[1]

- 6 Months: 7.7mmHg IOP decrease, 30% reduction, 0.9 med reduction
- 12 Months: 11.1mmHg IOP decrease, 39.8% reduction, 1.1 med reduction

Procedure



Complications

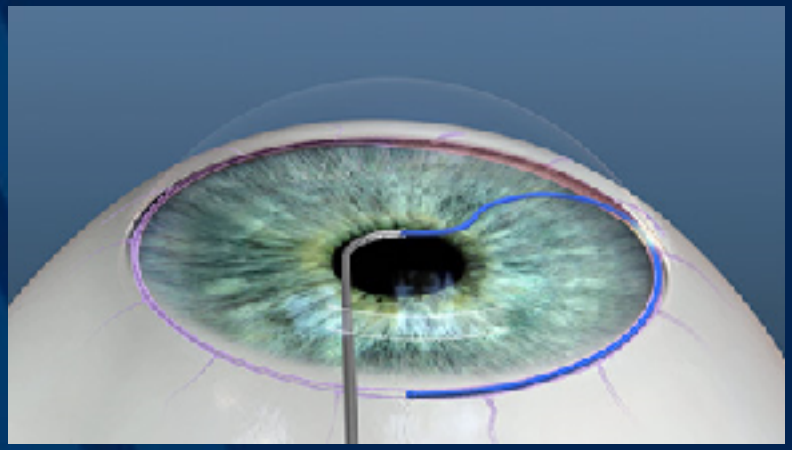
Table 3. Intraoperative and Postoperative Complications, Separated by Group

	Primary Open-Angle Glaucoma			Other Glaucoma	
	Gonioscopy-Assisted Transluminal Trabeculotomy Only	*Gonioscopy-Assisted Transluminal Trabeculotomy plus Cataract Extraction with Intraocular Lens Implantation*	*Prior Cataract Extraction with Intraocular Lens Implantation, Gonioscopy-Assisted Transluminal Trabeculotomy Only*	*Gonioscopy-Assisted Transluminal Trabeculotomy Only*	*Gonioscopy-Assisted Transluminal Trabeculotomy plus Cataract Extraction with Intraocular Lens Implantation*
Intraoperative complications	None	None	None	None	1 bag dehiscence/AV
Hyphema, no. (%)					
Week 1	7 (23)	6 (29)	5 (29)	7 (37)	5 (33)
Month 1	1 (3)	0	1 (6)	1 (5)	0
Month 3	1 (3)	0	0	0	0
Month 6	0	1 (5)	0	0	0
Other week-1 complications	1 choroidal folds	0	0	2 IOP spike	0
Other month-1 complications	2 steroid-induced IOP spikes	0	2 steroid-induced IOP spikes	1 steroid-induced spike, 1 shallow AC	0
Other month-3 complications	0	0	0	0	1 CME

AC = anterior chamber; AV = anterior vitrectomy; CME = cystoid macular edema; IOP = intraocular pressure.

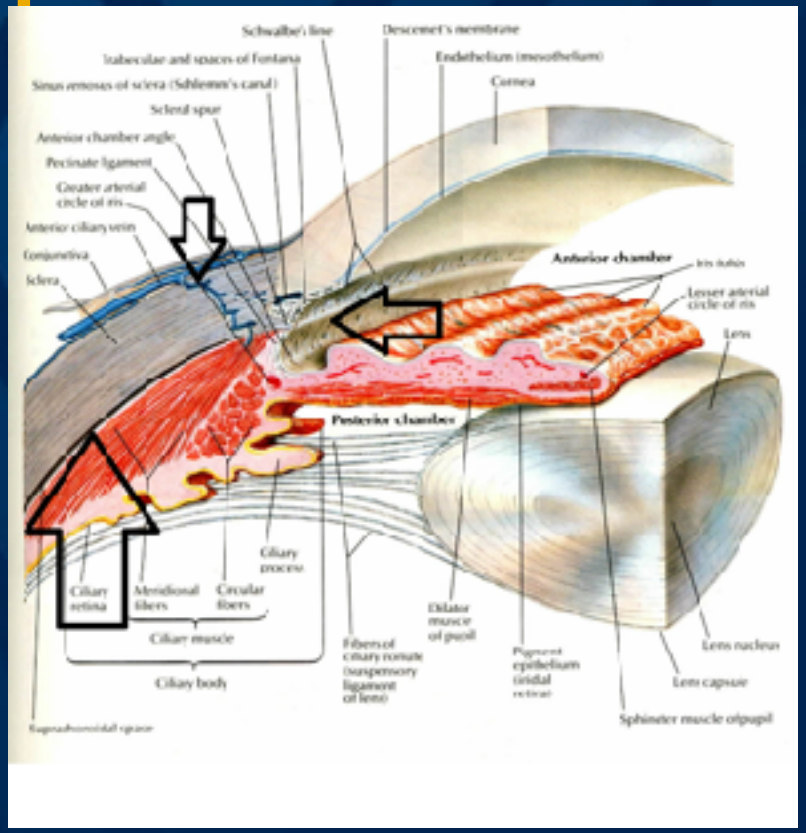
Trab 360 & Visco 360

https://www.youtube.com/watch?v=SEt6ujl6Jpg

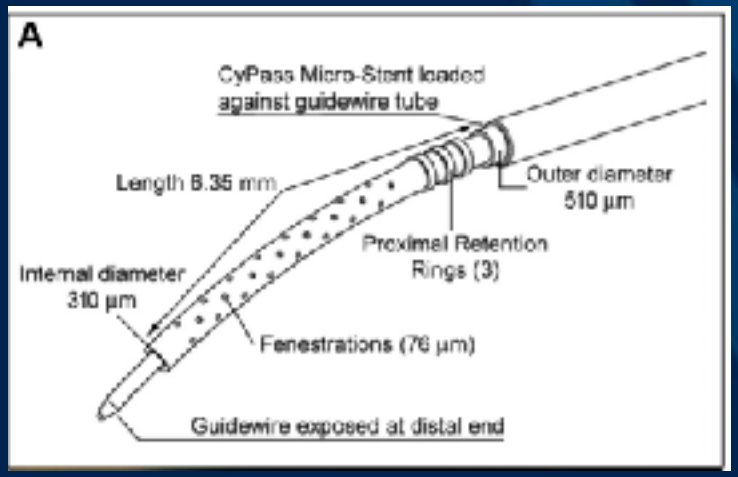


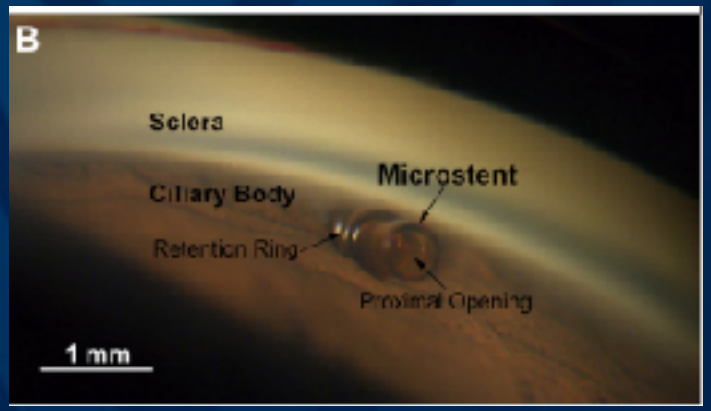
Suprachoriodal Space

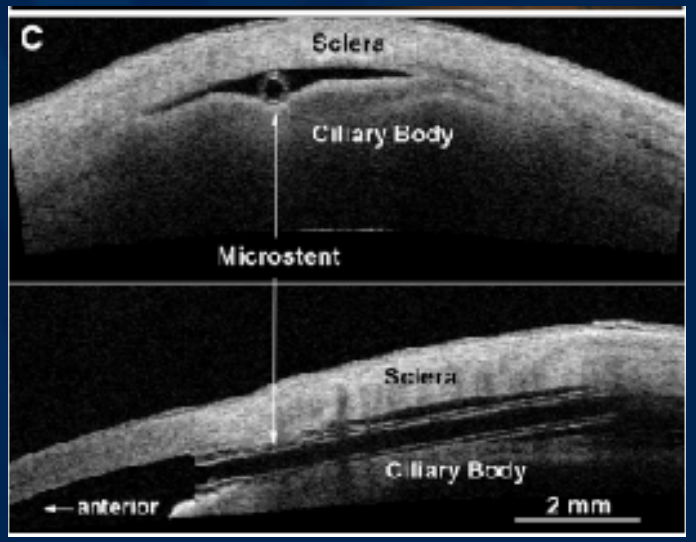
- Ab Externo cyclodialysis – 1905
- Abandoned- Complications- Trabeculectomy, Tubes
- Ab Interno approach



Cypass micro stent





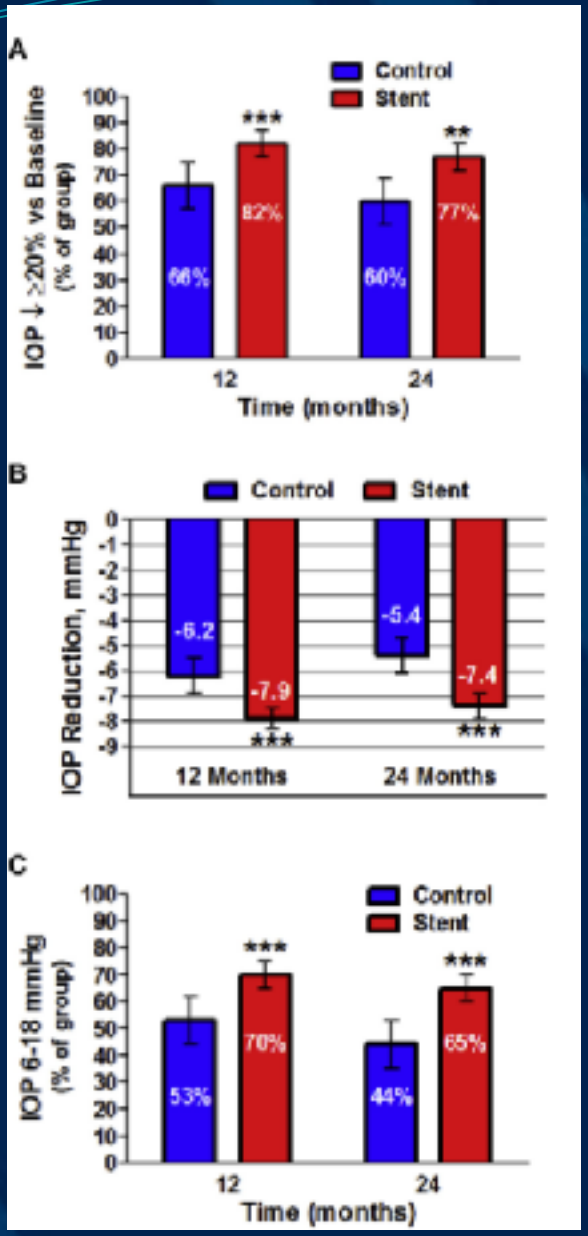


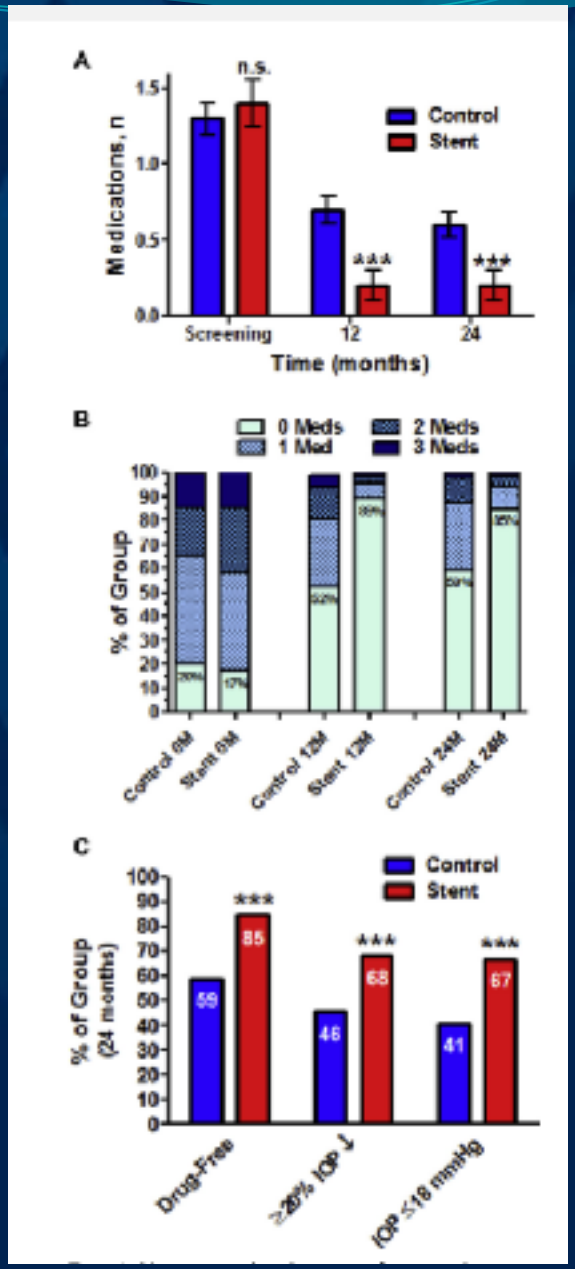
Cypass micro stent

AMERICAN ACADEMY™
OF OPHTHALMOLOGY

Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts

*Steven Vold, MD,[1] Iqbal Ike K. Ahmed, MD,[2] E. Randy Craven, MD,[3,4] Cynthia Mattox, MD,[5] Robert Stamper, MD,[6] Mark Packer, MD,[7] Rexy H. Brown, MD,[8] Tsontcho Ianchulev, MD, MPH,[9,10] for the CyPass Study Group**


A
Control
Stent
IOP ↓ ≥20% vs Baseline (% of group)
66%
82%
60%
77%
***
**
12
24
Time (months)
B
Control
Stent
IOP Reduction, mmHg
-6.2
-7.9
-5.4
-7.4
***
***
12 Months
24 Months
C
Control
Stent
IOP 6-18 mmHg (% of group)
53%
70%
44%
65%
***
***
12
24
Time (months)


A
n.s.
Control
Stent
Medications, n
Screening
12
24
Time (months)
B
0 Meds
1 Med
2 Meds
3 Meds
% of Group
Control 6M
Stent 6M
Control 12M
Stent 12M
Control 24M
Stent 24M
C
Control
Stent
% of Group (24 months)
59
85
46
68
41
67
Drug-Free
≥20% IOP ↓
IOP ≤18 mmHg

Complications

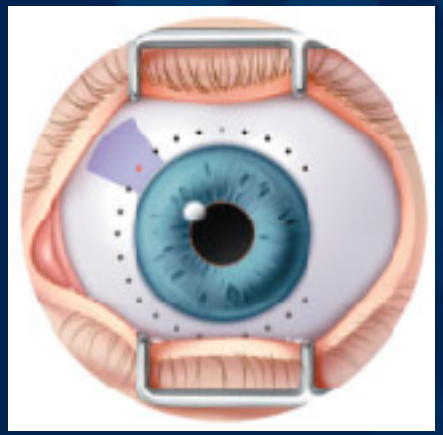
Table 2. Ocular Adverse Events through 24 Months of Follow-up

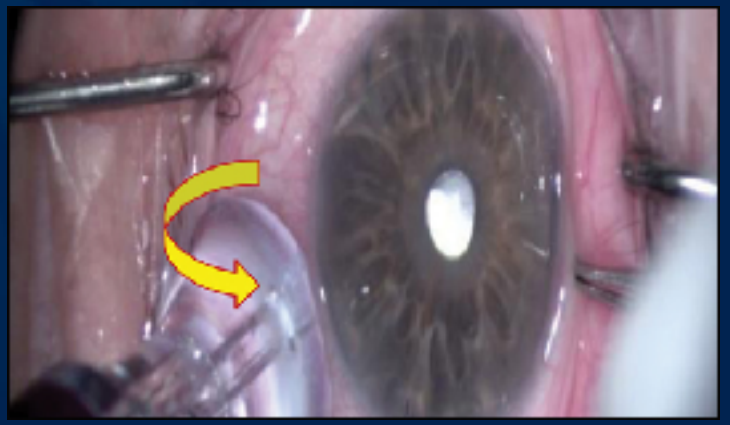
AE	Stent (n = 374)	Control (n = 131)	P Value*
BCVA loss ≥10 letters	33 (8.8%)	20 (15.3%)	0.0466
Corneal abrasion	7 (1.9%)	2 (1.5%)	0.9999
Corneal edema	13 (3.5%)	2 (1.5%)	0.3741
Conjunctivitis	4 (1.0%)	3 (2.3%)	0.3828
Cyclodialysis cleft >2-mm circumference	7 (1.9%)	0 (0.0%)	0.1985
Hyphema, transient intraoperative	10 (2.7%)	0 (0.0%)	0.0706
Iritis	32 (8.6%)	5 (3.8%)	0.0809
Hypotony (IOP <6 mmHg)	11 (2.9%)	0 (0%)	0.0744
IOP ≥10 mmHg over baseline	16 (4.3%)	3 (2.3%)	0.4263
Maculopathy, cystoid edema	6 (1.3%)	1 (0.8%)	0.6829
Stent obstruction	8 (2.1%)	N/A	N/A
Subconjunctival hemorrhage	6 (1.6%)	1 (0.8%)	0.6829
Secondary ocular surgical intervention	20 (5.5%)	7 (5.3%)	0.9999
Visual field loss progression, confirmed	25 (6.7%)	13 (9.9%)	0.2488

AE = adverse event; BCVA = best-corrected visual acuity; IOP = intraocular pressure; N/A = not applicable.
Shown are any ocular AE that occurred in at least 1% subjects in either experimental group, either intraoperatively or through 24 postoperative months.
Data are n (%) unless otherwise indicated.
*P values calculated by the Fisher exact test using 2×2 contingency tables.

Ciliary Body

- External Diode
  - G-probe and Micropulse

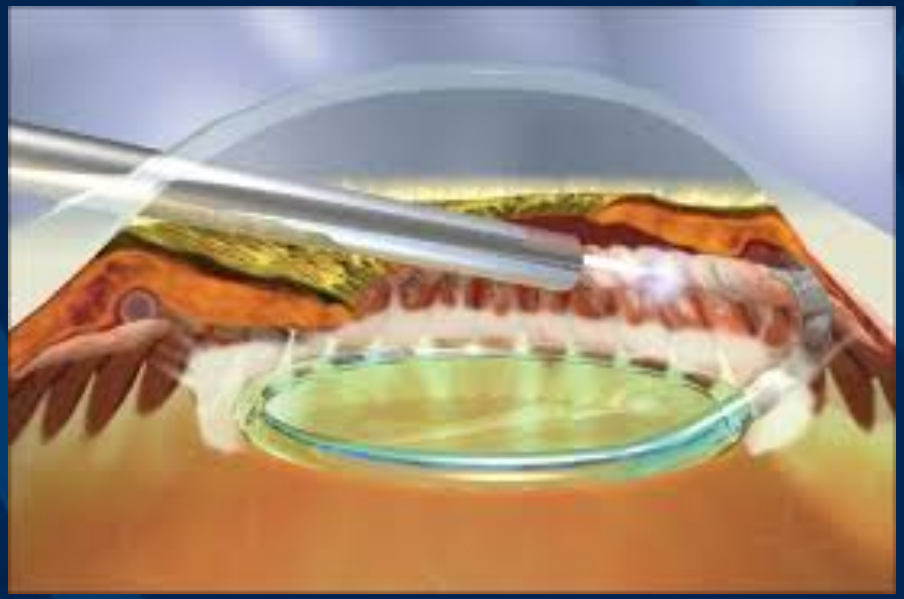




Safety and Efficacy- Micropulse

- 79 Patients, 7.8 month post op
- 51% IOP reduction, ~ 1 less med
- Success (IOP 6-21mmHg or 20% IOP reduction
  - 75% 3 months 67% at last follow up
- Complications
  - Hypotony 8.8%, - 2 lines + BCVA 17%
  - 26% prolonged inflammation
  - 5% macular edema
- Williams AL, Moster MR et al. Clinical and Efficacy and Saftery profile of micropulse transscleral cyclophotocoagulation in refratory glaucoma. J Glaucoma 2018 Mar. epub.

Internal- Endocyclophotocoagulation- ECP



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J Cataract Refract Surg. 2014 Aug;40(8):1313-21. doi: 10.1016/j.jcrs.2014.06.021.

Endoscopic cyclophotocoagulation combined with phacoemulsification versus phacoemulsification alone in medically controlled glaucoma.

Francis BA[1], Berke SJ[2], Dustin L[2], Noecker R[2].

Table 2A. Between-group comparison of preoperative and postoperative IOP.

Parameter	Study Group	Control Group	*P* Value Between Groups†
IOP (mm Hg)			
Preop			
Mean ± SD	18.1 ± 3.0	18.1 ± 3.0	1.00
Eyes (*n*)	80	80	
Postop			
6 mo			
Mean ± SD	15.6 ± 2.5	17.9 ± 3.5	<.001
Eyes (*n*)	78	80	
12 mo			
Mean ± SD	16.0 ± 2.8	17.5 ± 3.6	.004
Eyes (*n*)	79	80	
24 mo			
Mean ± SD	16.0 ± 3.3	17.3 ± 3.2	
Eyes (*n*)	80	80	.01
36 mo			
Mean ± SD	15.4 ± 2.5	17.2 ± 3.0	.003
Eyes (*n*)	45	43	
Postop decrease (%)			
6 mo			
Mean ± SD	12.4 ± 16.7	0.7 ± 13.1	<.001
P value (from baseline)*	<.001	NS	
12 mo			
Mean ± SD	10.2 ± 17.1	2.7 ± 16.2	.005
P value (from baseline)*	<.001	NS	
24 mo			
Mean ± SD	10.1 ± 18.7	0.8 ± 12	.02
P value (from baseline)*	<.001	NS	
36 mo			
Mean ± SD	13.6 ± 15.1	5.1 ± 10.4	.003
P value (from baseline)*	<.001	.01	

IOP = intraocular pressure; NS = not significant
*Paired *t* test
†Independent-samples *t* test

Table 2B. Between-group comparison of preoperative and postoperative glaucoma medications.

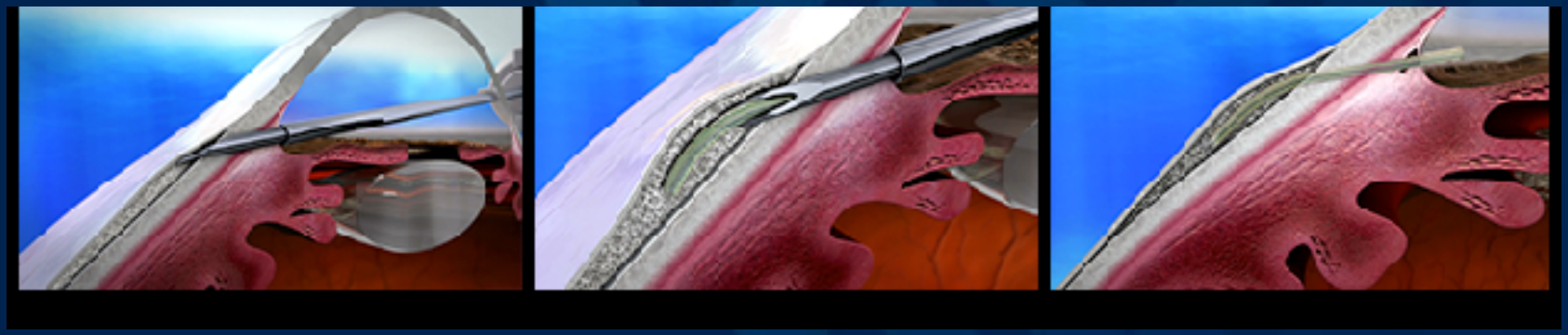
Parameter	Study Group	Control Group	*P* Value Between Groups
Medications (n)			
Preop			
Mean ± SD	1.5 ± 0.8	2.4 ± 1.0	<.001
Median	1	2	
Postop			
6 mo			
Mean ± SD	0.3 ± 0.7	1.3 ± 1.2	<.001
Median	0	1	
12 mo			
Mean ± SD	0.4 ± 0.7	1.8 ± 1.2	<.001
Median	0	2	
24 mo			
Mean ± SD	0.4 ± 0.7	2.0 ± 1.0	
Median	0	2	<.001
36 mo			
Mean ± SD	0.4 ± 0.7	2.3 ± 1.0	<.001
Median	0	2	
Last			
Mean ± SD	0.5 ± 0.7	2.2 ± 1.1	<.001
Median	0	2	
Postop change (n)			
6 mo			
Mean ± SD	−1.1 ± 0.8	−0.9 ± 1.2	.24
P value (from baseline)*	<.001	<.001	
12 mo			
Mean ± SD	−1.0 ± 0.9	−0.6 ± 0.5	.006
P value (from baseline)*	<.001	<.001	
24 mo			
Mean ± SD	−1.1 ± 0.9	−0.4 ± 0.8	<.001
P value (from baseline)*	<.001	<.001	
36 mo			
Mean ± SD	−1.0 ± 0.9	−0.1 ± 0.8	<.001
P value (from baseline)*	<.001	NS	
Last			
Mean ± SD	−1.0 ± 0.9	−0.2 ± 0.8	<.001
P value (from baseline)*	<.001	NS	

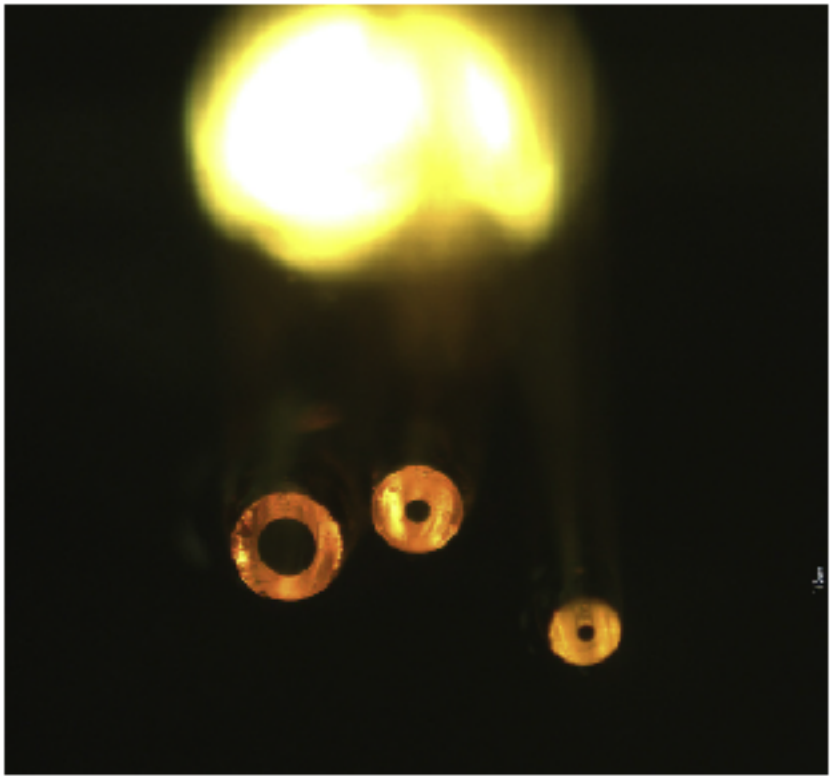
IOP = intraocular pressure; NS = not significant
*Paired *t* test
†Wilcoxon rank-sum test

Complications

- 2 (2.5%) – Anterior chamber hemorrhage
- 2(2.5%) significant inflammation
- 3 (3.8%) CME
- 1 (1.3%) hemorrhage

Ab Interno Bleb creating stents- Xen-gel stent





A

B

https://www.youtube.com/watch?v=gjVI1RDNWog

ORIGINAL STUDY

Early Clinical Results of a Novel Ab Interno Gel Stent for the Surgical Treatment of Open-angle Glaucoma

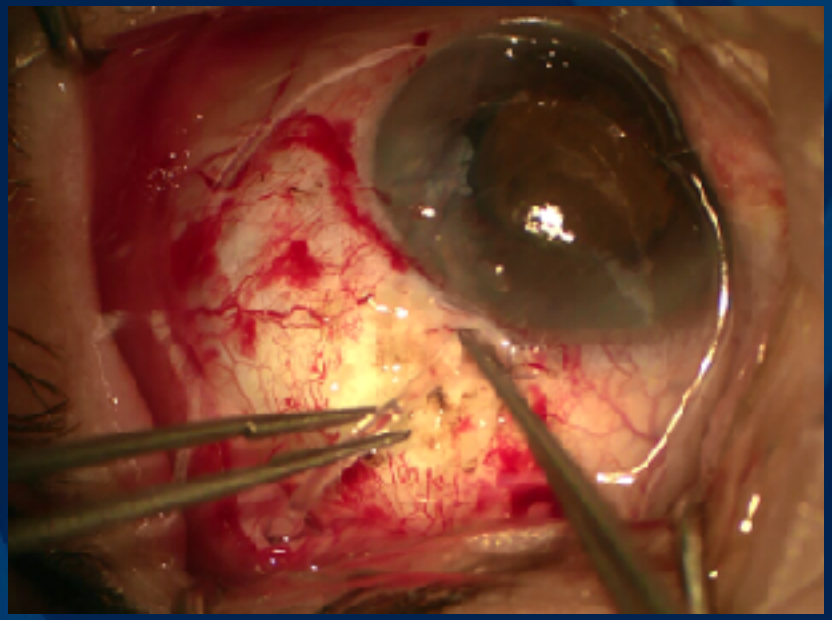
Arsham Sheybani, MD, Burkhard Dick, MD, PhD,† and Iqbal I. K. Ahmed, MD‡§‖*

- 49 eyes
- Complete success IOP≤18mmHg with ≥20% reduction in IOP
- 12 Months
  - IOP 23.1 +/-4.1 decrease to 14.7 +/-3.7
  - 36.4% reduction
  - Success 89%
  - Complete success 40%

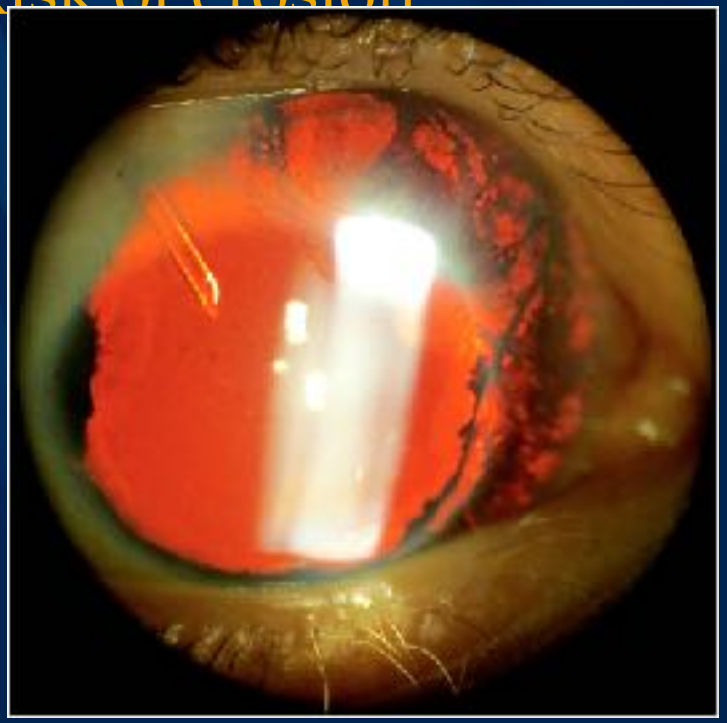
Trabeculectomy

- Remains Gold standard for Advanced Uncontrolled Glaucoma
- Greatest IOP reduction
- Lowest absolute IOP
- Takes time- surgically, and Clinically
- Laser Suture Lysis post op

Tube Shunt

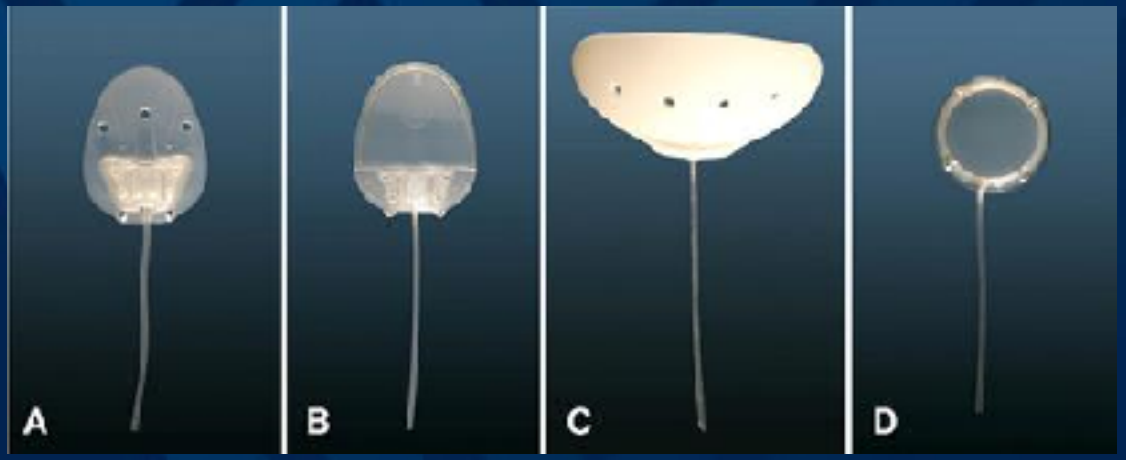


- Failed Trabeculectomy or Some secondary glaucomas
- Less post operative management
- Risk of erosion



Tube Types

- Baerveldt 350
- Baerveldt 250
- Ahmed Valve
- Molteno

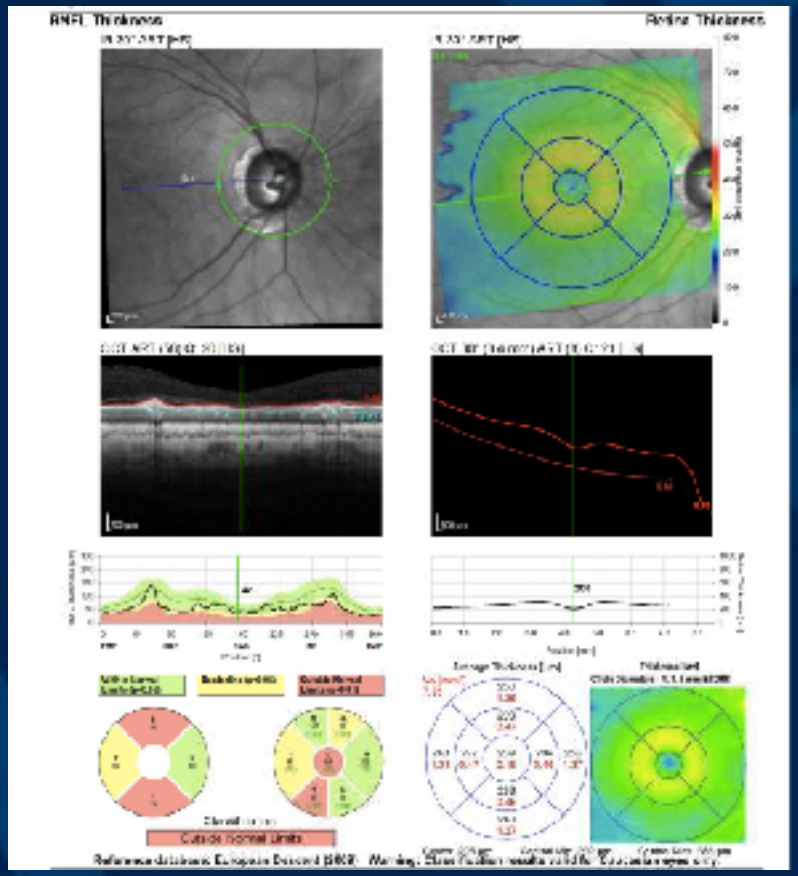


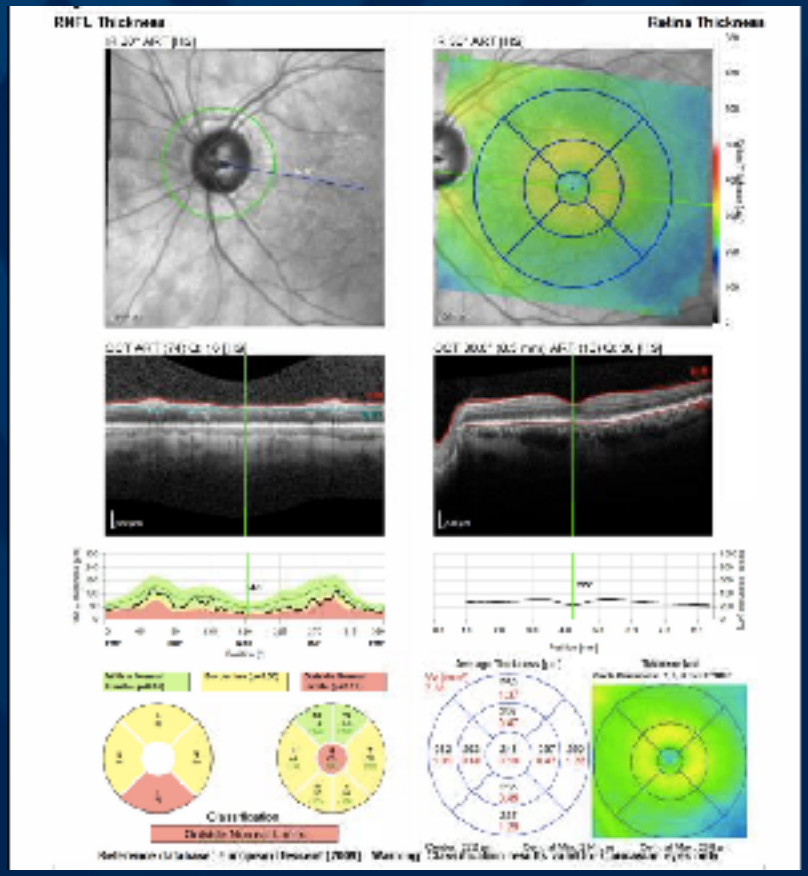
Cases – Patient 1

- 73 yo F with moderate POAG on Latanoprost

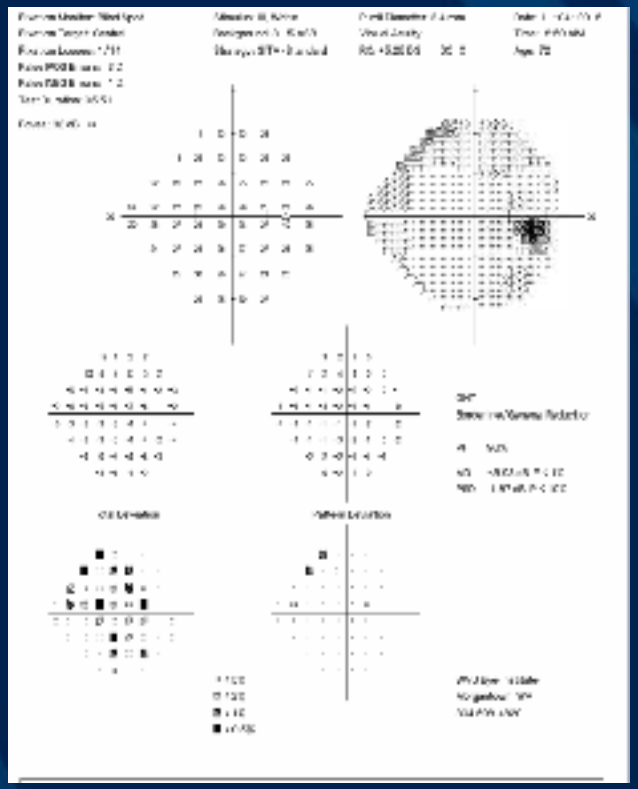
- Pre op
  - OD: +1.75 +1.00 x 084 → 20/30; glare 20/100 IOP 20
  - OS: +1.25 +0.75 x 063 → 20/30; glare 20/400 IOP 19
  - 2+ NSC OU with cortical spokes OS>OD

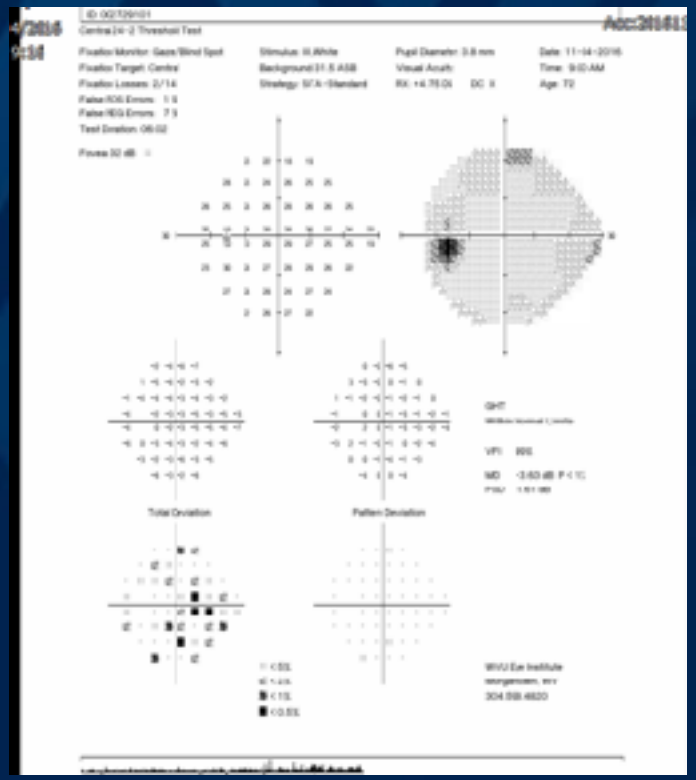
Patient 1


RNFL Thickness
Retina Thickness
Outside normal limits


RNFL Thickness
Retina Thickness
Classification

Patient 1





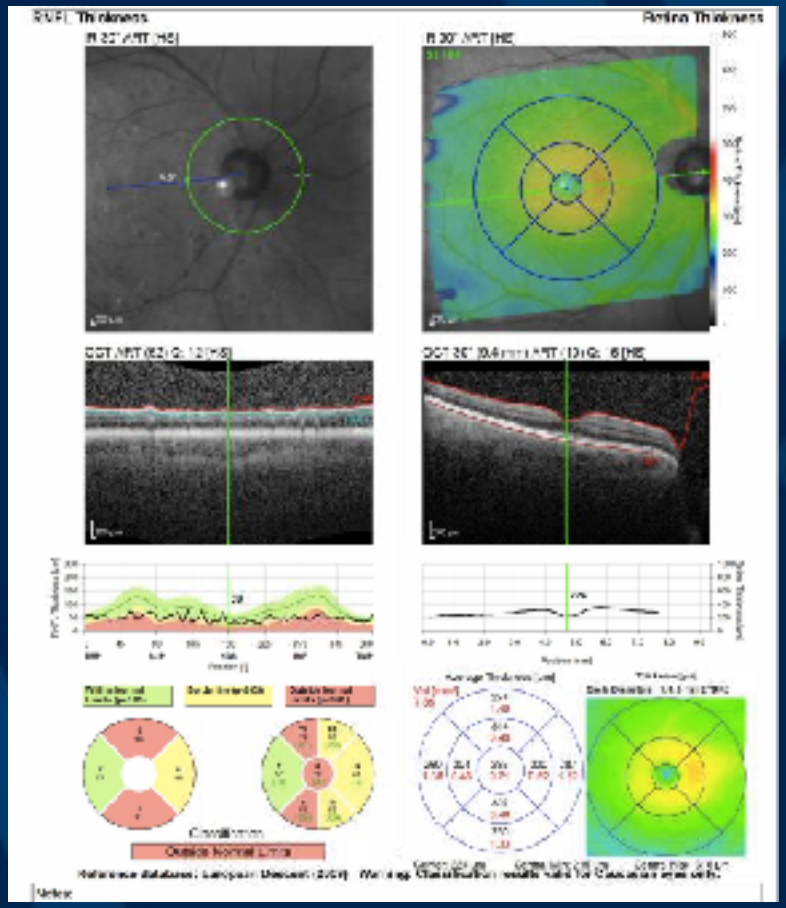
Mini-MIGS

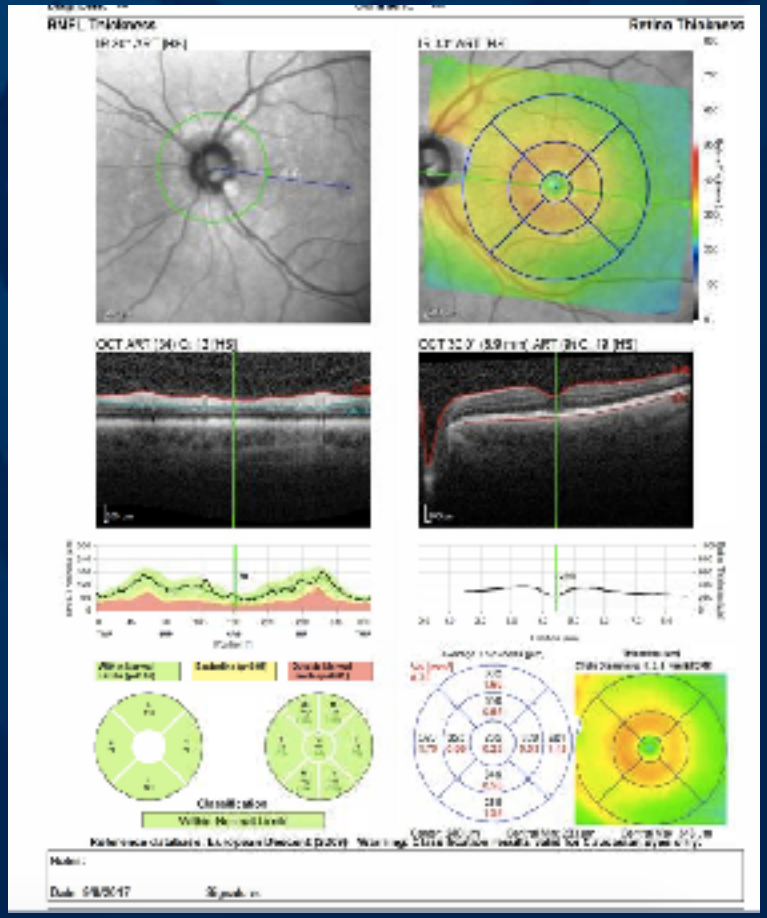
- Phaco or Phaco + istent

Patient 2

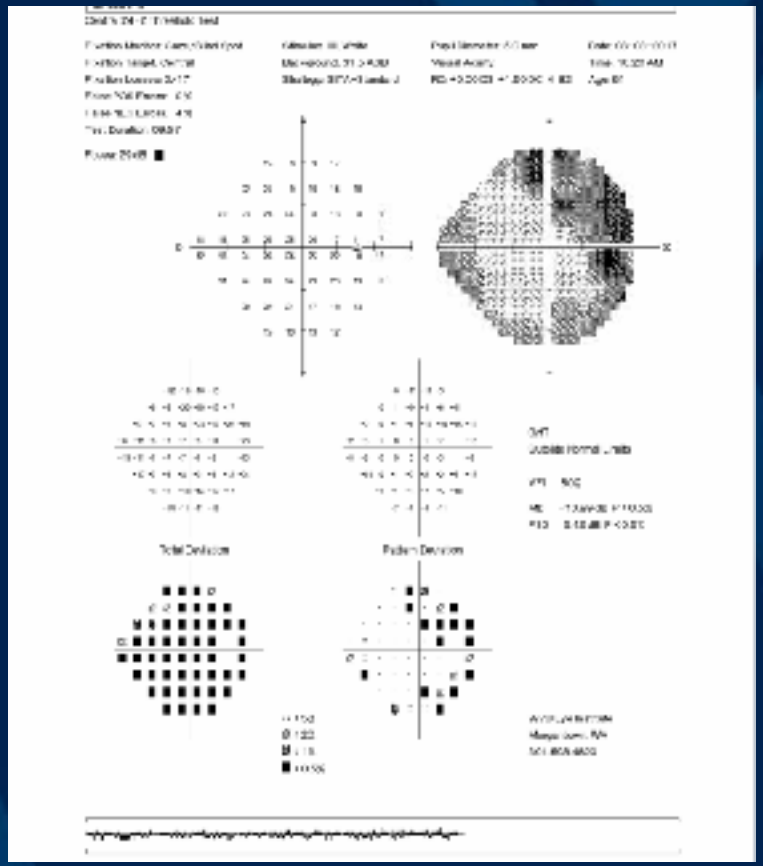
- 62 yo F
- Hx of PXF glaucoma, moderate stage OD
- On max medical therapy and s/p SLT in 2016
- 2+ NSC, 3+ PSC, PXF on anterior lens capsule
- Pre-op
  - MRx: -4.50 +2.00 x 075 → 20/50
  - IOP 22

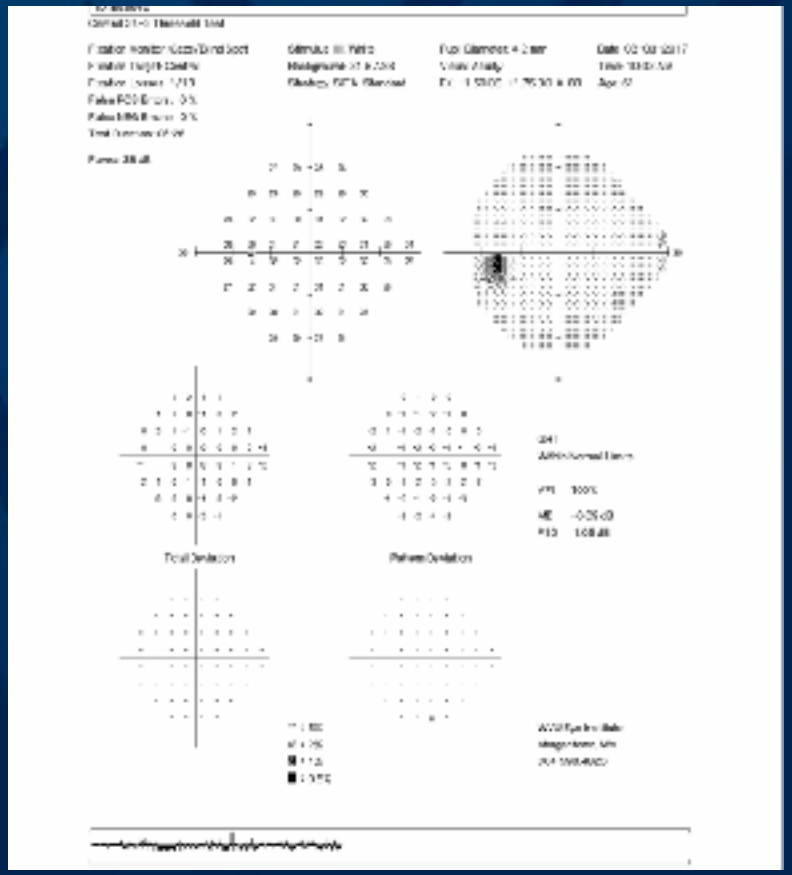
Patient 2


RNFL Thickness
Retina Thickness


RNFL Thickness
Retina Thickness

Patient 2





Patient 2

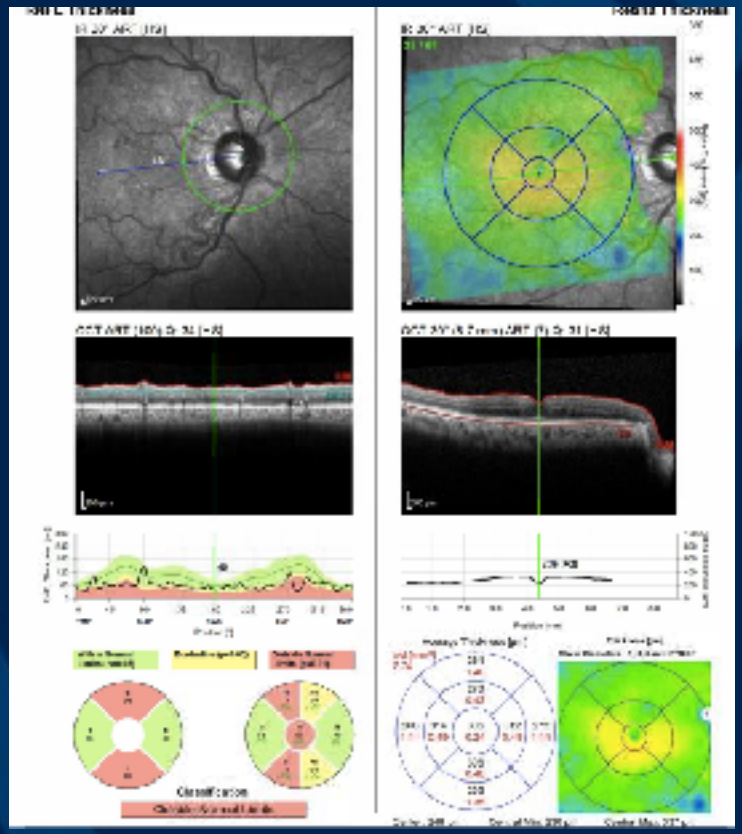
- Significant Glaucoma
- Stable
- Significant Medication burden
- Moderate MIGS – Goniotomy, Suprachoroidal, ECP?

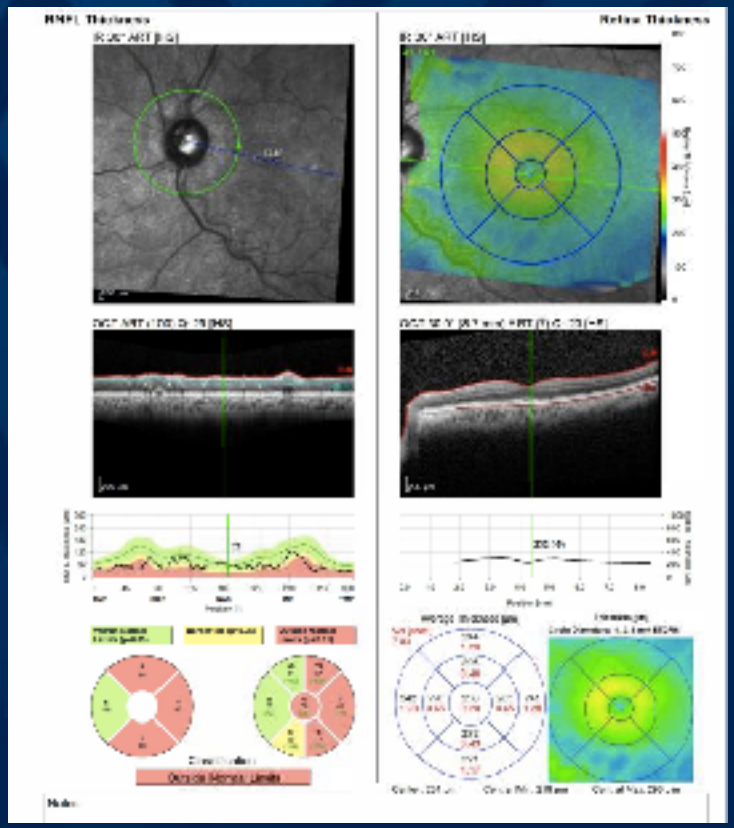
- If progressive, uncontrolled
  - MEGA – MIGS or Trabeculectomy

Patient 3

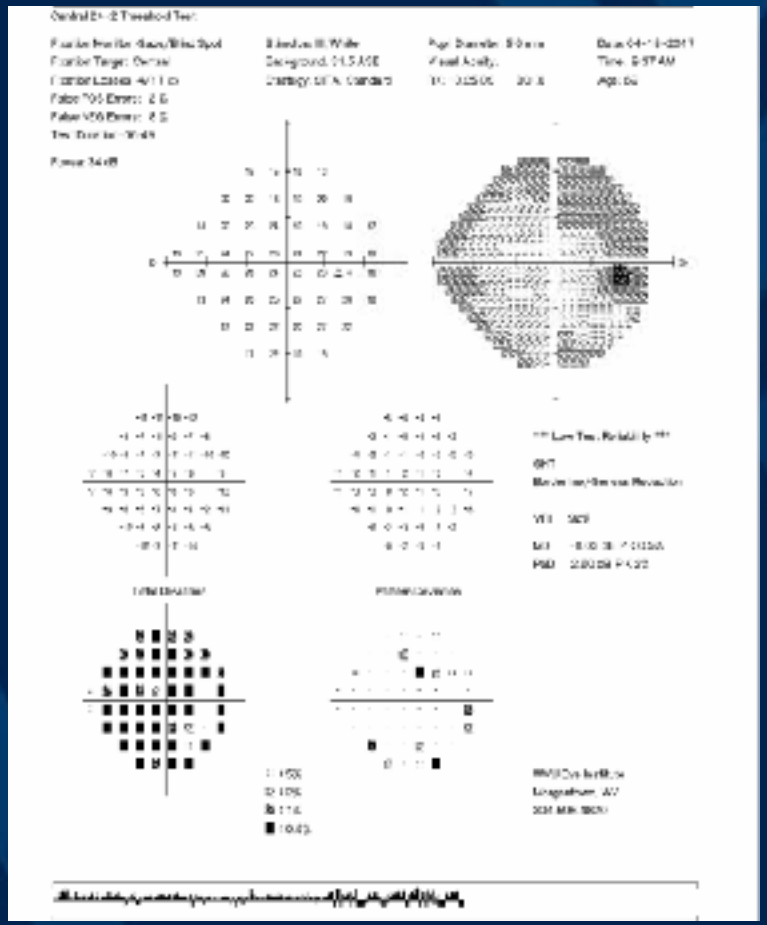
- 70 yo M
- Low – Tension Glaucoma OU
  - Latanoprost, Dorzolamide, Timolol
  - IOP: 16

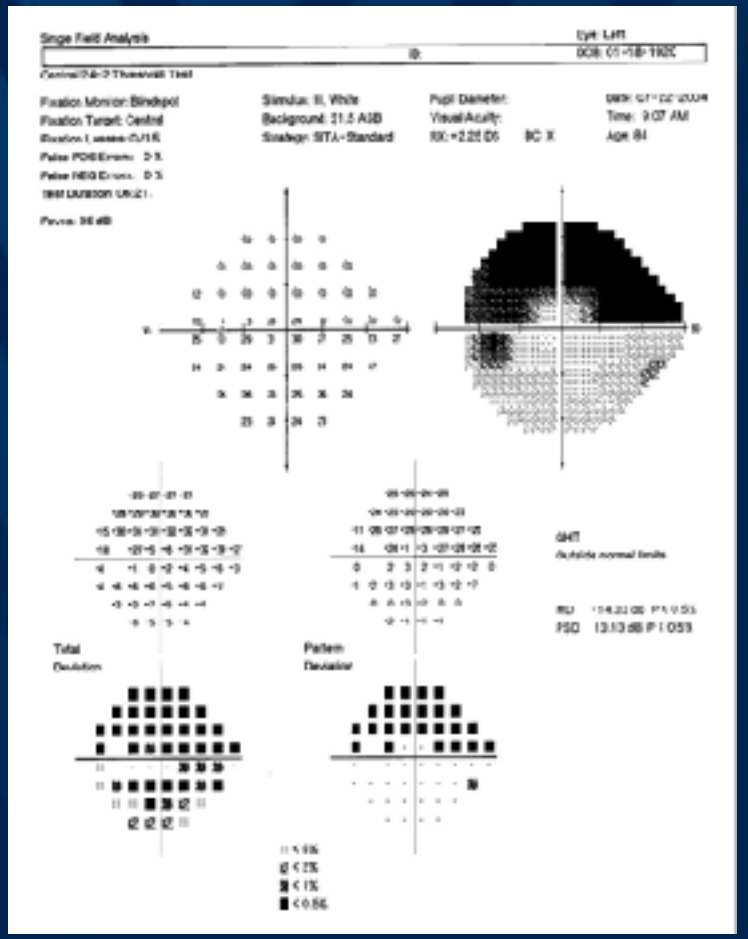
Patient 3





Patient 3





Patient 3

- Trabeculectomy- Lowest IOP, Greatest IOP reduction

Keys to Glaucoma Management

- Lower Intraocular Pressure (IOP) to a level the minimizes or prevents progression with the least amount of risk.
- Drops
- SLT
- Mini - MIGS
- Moderate – MIGS
- MEGA - MIGS
- Traditional
- ASSISTS- Second Tube vs Diode CPC- Enrolling

Photograph by Tom Samuelson, My Shot https://www.nationalgeographic.com/photography/photo-of-the-day/2013/4/gray-owl-mouse/