MIGS: Will Glaucoma Become a Surgical Disease

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Disclosures

- Aerie
- Allergan
- Alcon
- Aquesys
- AVS
- Glaukos
- Ivantis

Which eye had surgery vs eyedrops?

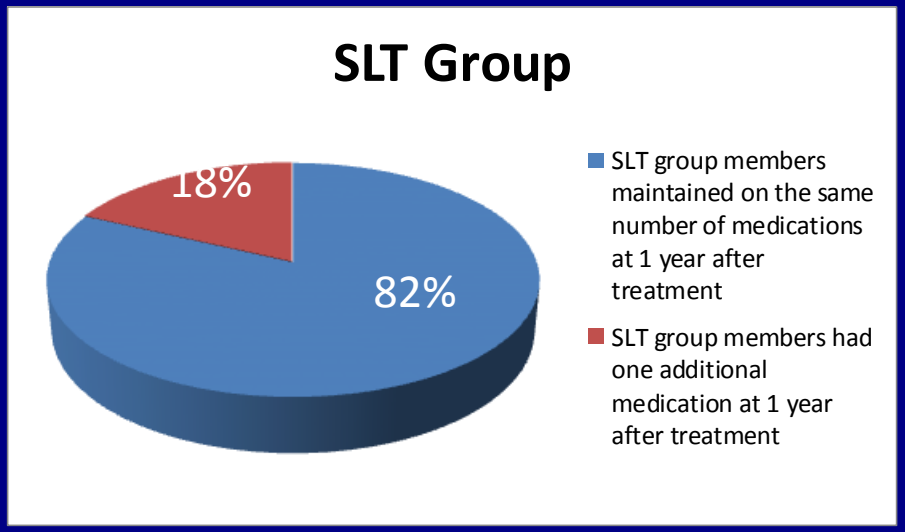
Why Should Glaucoma Be a Surgical Disease?

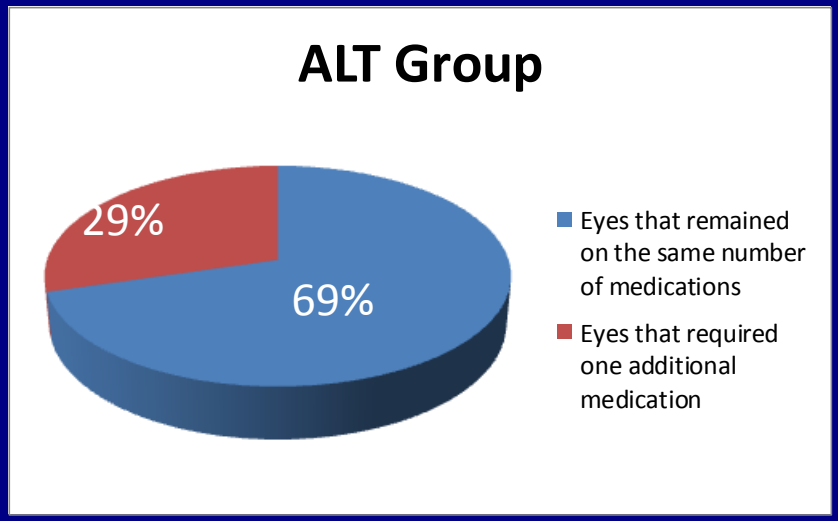
- Simplicity
- Safe and effective surgery avoids…
  - Eye Drops
    - Side effects (esp to ocular surface)
    - Compliance
    - Recurring expense

Selective and Argon Laser Trabeculoplasty

At 1 year, 82% of patients who underwent SLT remained on the same number of medications (2.6)

- 18% required an *additional* medication
- 100% of patients remained on the same number of medications or increased their medications
- More patients in the ALT group than the SLT group required an additional medication at 1 year

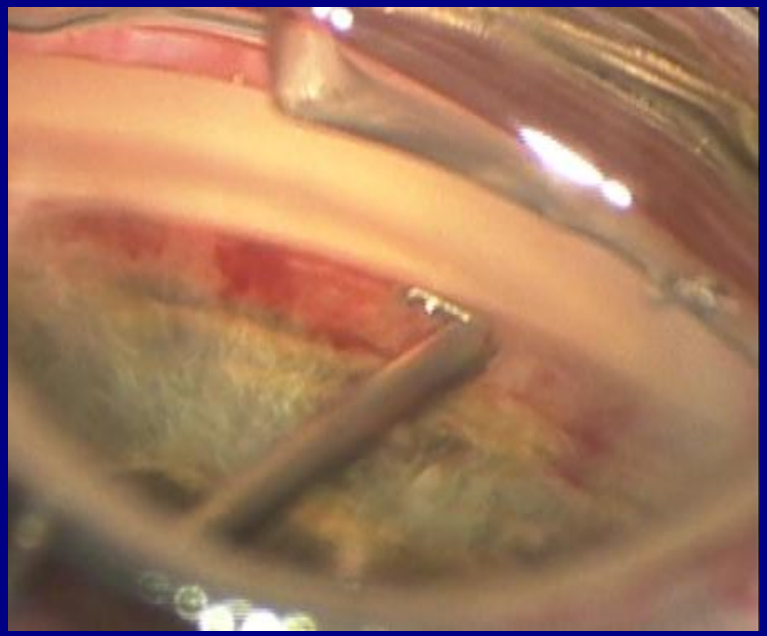




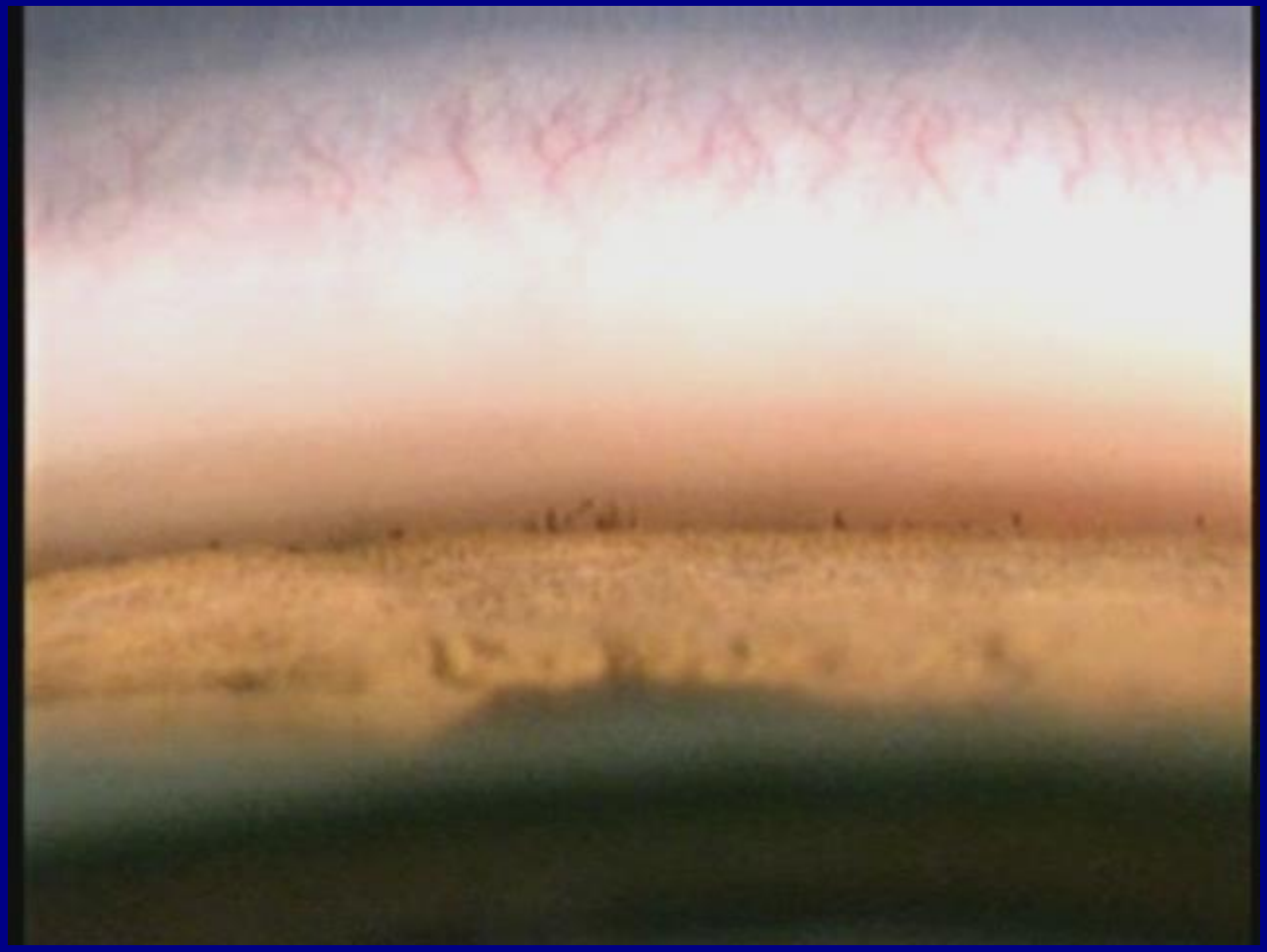
Cantor, L. B., L. J. Katz, et al. Economic evaluation of medication, laser trabeculoplasty and filtering surgeries in treating patients with glaucoma in the US. *Curr Med Res Opin* . 2008;24(10): 2905-18.

MIGS: A New Perspective

- Who is a candidate?
- What justifies the procedure?
- How to start implanting?



R. Stegmann's View of the Canal



MIGS: What is it?

- **Minimally Invasive Glaucoma Surgery**
- **Ab interno micro-incision procedures**
- **Lower risk**
- **Earlier intervention**
- **Minimal additional technology**
- **Does not preclude other glaucoma surgery**

MIGS: Mechanism of Action

1. Subconjunctival
   - Aquesys (Xen)
2. Canal
   - Glaukos (iStent)
   - Ivantis (Hydrus)
3. Suprachoroidal
   - Transcend (CyPass)
   - Glaukos (G3)

Trabectome is disruptive to the TM/canal and, thus, not a MIGS procedure

Glaucoma Surgery Profile

MIGS

- Mild to moderate disease
- Open angles
- Modest IOP target (15-16)
- Low risk
- Long term data lacking

Glaucoma Surgery Profiles

MIGS

- Mild to moderate disease
- Open angles
- Modest IOP target (15-16)
- Low risk
- Long term data lacking

Trab or Tube

- More advanced disease
- Open or closed angles
- Lower IOP target (<13)
- Higher risk
- Recognized long term effect (s)

Variables to Consider

1. Efficacy
2. Risk/complications
3. Technical ease
4. Duration
5. Cost to physician/ASC/hospital
6. Reimbursement

Canal Surgery Milestones

- 1962: Sinusotomy – Krasnov
- 1968: Trabeculectomy – Cairns/Watson
- 1978: Non perforating trabeculectomy- Zimmerman
- 1982: Deep sclerectomy- Fyodorov
- 1993: Viscocanalostomy – Stegmann
- 2001: Aquaflow Collagen Implant
- 2004: Canaloplasty – Stegmann, Lewis
- 2012: iStent (Trabecular bypass) – Hill

Clinical Development Milestones

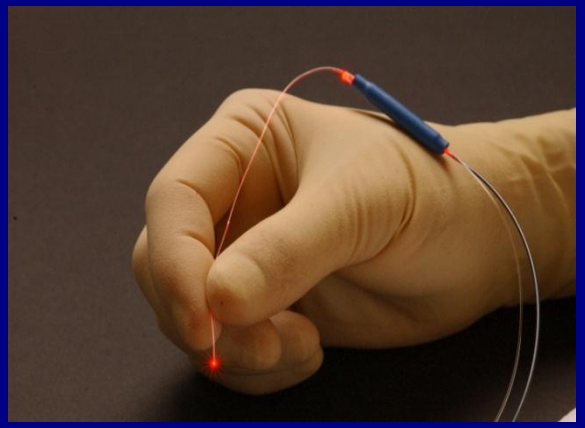
1999 – Stegmann: viscocanalostomy

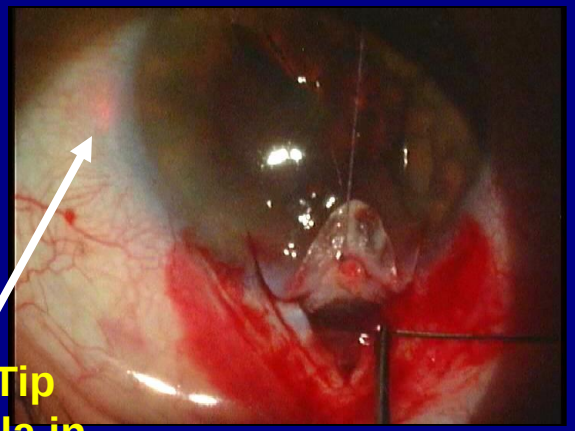
2001 - Ultrasound imaging to localize canal and outflow system

2003 – Development of flexible 250u lumen microcanula

2004-05 -Viscodilation and suture stent passage

- Canal tensioning or Canaloplasty





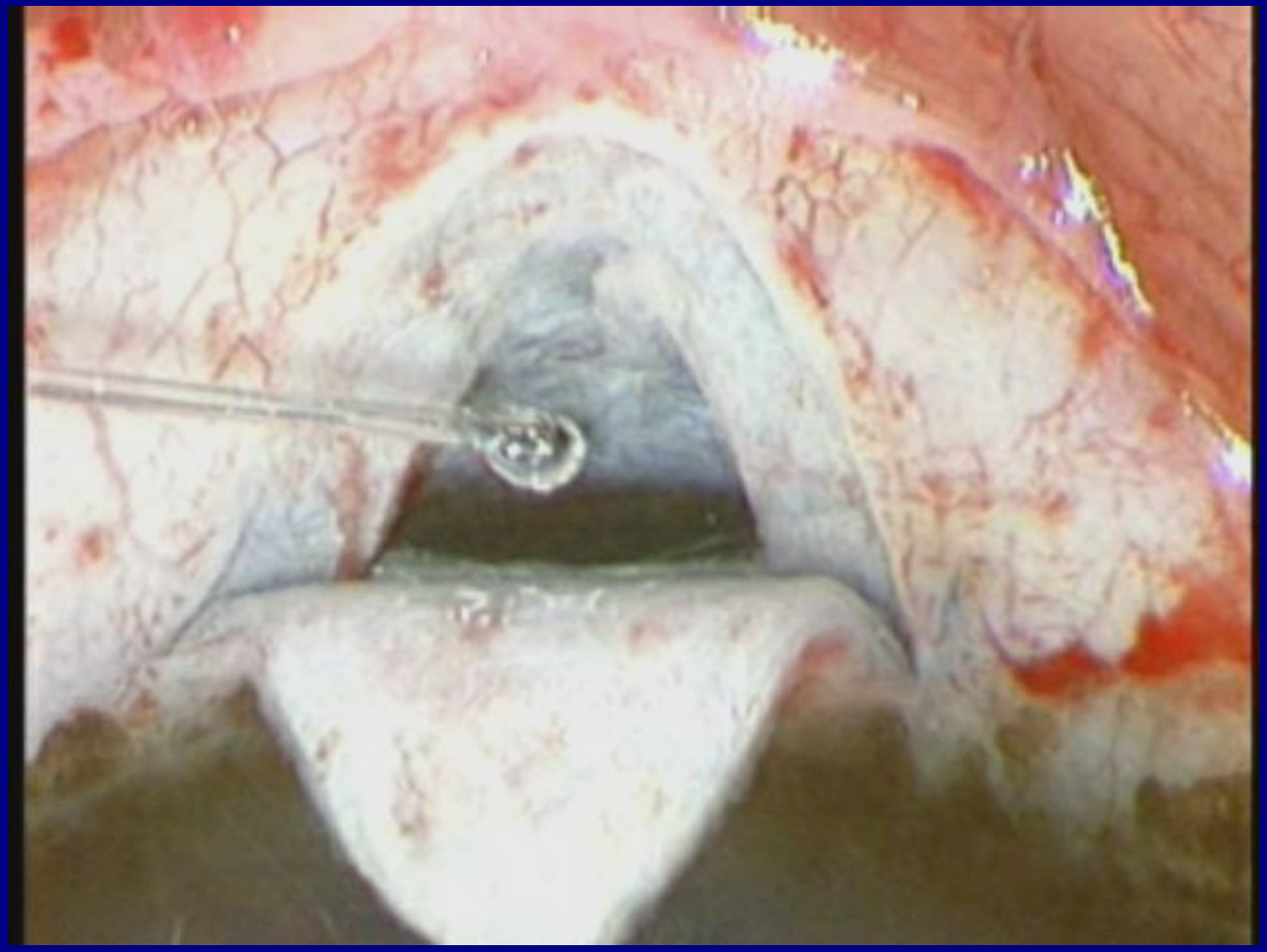
Illuminating Tip of Microcannula in Schlemm's Canal

Canaloplasty: Mechanism of IOP Reduction

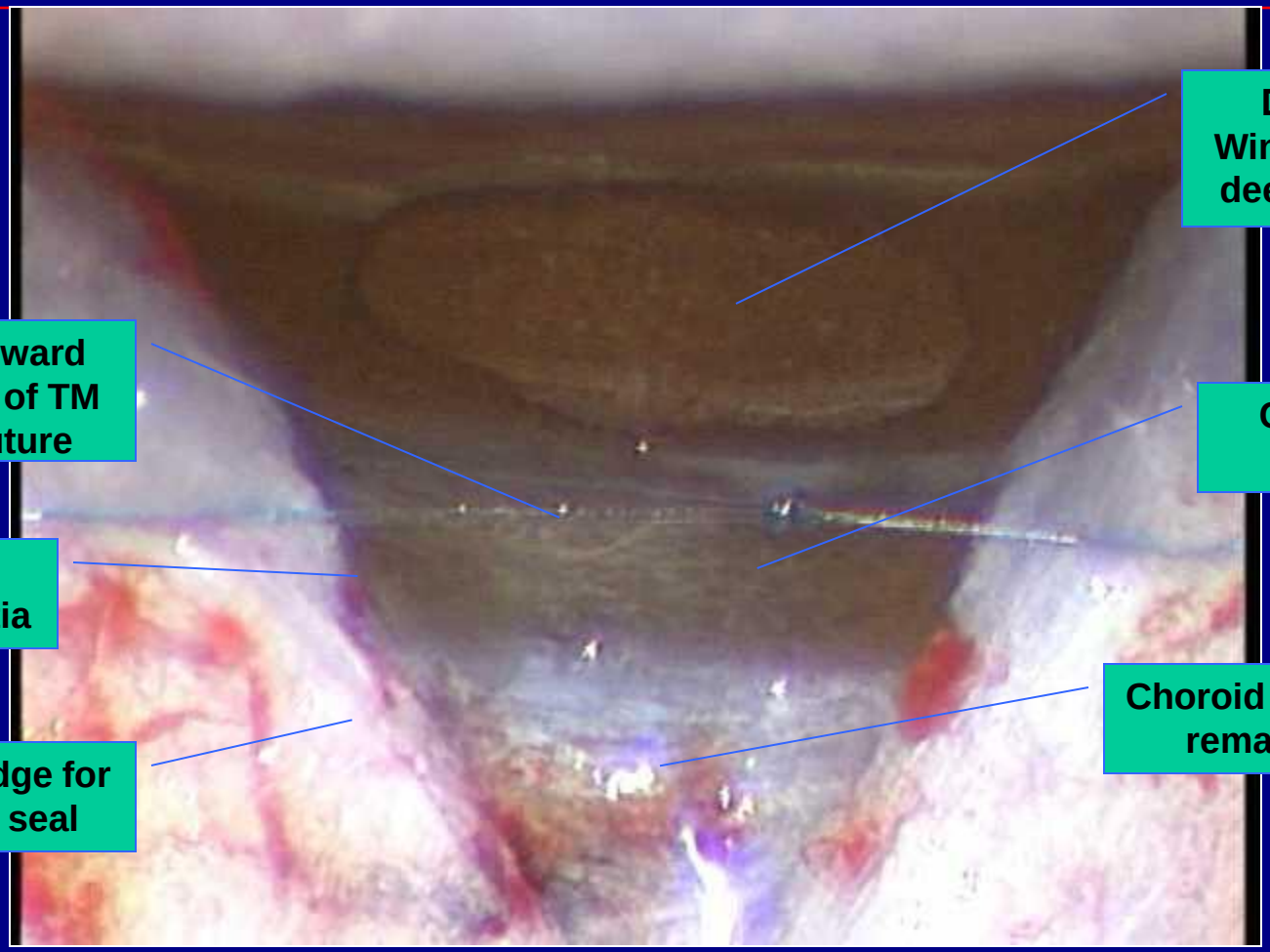
1. Aqueous flow through Trabecular Descemet's membrane (or window)

2. Aqueous re-absorption
   - Subconjunctival filtering bleb
   - Through canal and collectors

Canaloplasty



Canaloplasty – Surgical Site



Canaloplasty: Indications

1. Open angle glaucomas including PDS and PXE

2. Expect Trabeculectomy to Fail
   - Failed trabeculectomy or hypotony in fellow eye
   - Significant conjunctival disease

3. Concerned about further loss of vision
   - High myopia and contact lens wearers
   - Immunosuppressive treatments
   - Anti-coagulation

Aussie: Case Report

47 y/o man on 4 meds s/p SLT

- High (-9.0) myope
- Ocular surface disease from long term glaucoma meds
- IOP: 18-20
- Pachy: 490
- Advanced cupping with sup arcuate defect OU

Canal vs Trab: Ayyala et al

Time Point	Canaloplasty IOP (mmHg)	No. of Patients	Trabeculectomy IOP (mmHg)	No. Patients	*P* Value
Preoperatively	21.2±6.6	33	23.4±10.4	46	0.28
1 day	9.3±6.0	33	5.7±3.6	46	<0.01*
1 week	13.7±6.4	32	6.8±3.8	45	<0.001*
1 month	14.4±5.8	32	8.8±4.5	46	<0.001*
3 months	12.6±5.6	32	10.3±3.7	46	0.05*
6 months	12.1±4.0	32	11.2±4.5	43	0.40
9 months	12.9±5.1	33	11.6±3.4	39	0.18
12 months	13.8±4.9	33	11.6±4.0	46	0.03*

Ophthalmology 2011

Canal vs Trab: Ayyala et al

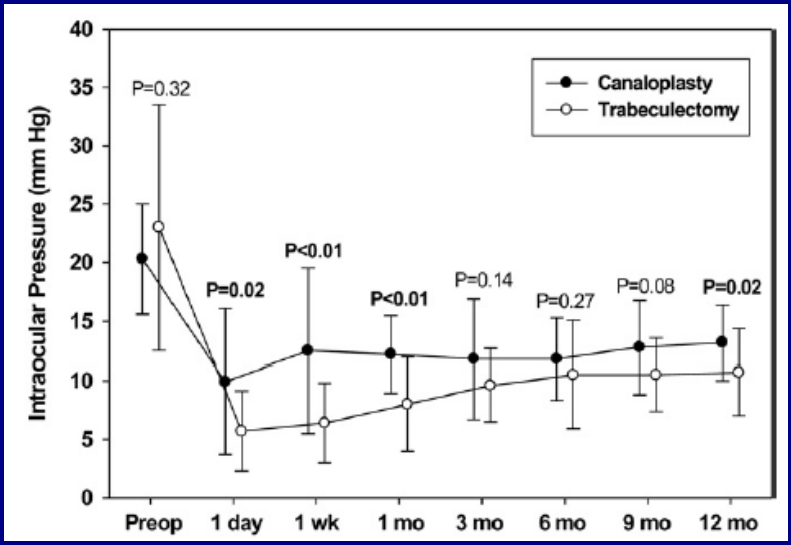


Table 7. Reoperations

	Reoperation Type (n)	No. of Patients (%)
Canaloplasty	Trabeculectomy (1) Express shunt (1) Ahmed glaucoma valve (3)	5 (15)
Trabeculectomy*	Bleb revision for leaking cystic bleb (2) Express shunt for failed blebs (2)	4 (9)

*One patient had suprachoroidal hemorrhage drainage.

Ophthalmology 2011

Canaloplasty: Challenges

1. “Learning curve” - finding the canal
2. Canal access in various glaucomas
3. Magnitude of IOP reduction
4. Long term efficacy

JK: Case Study

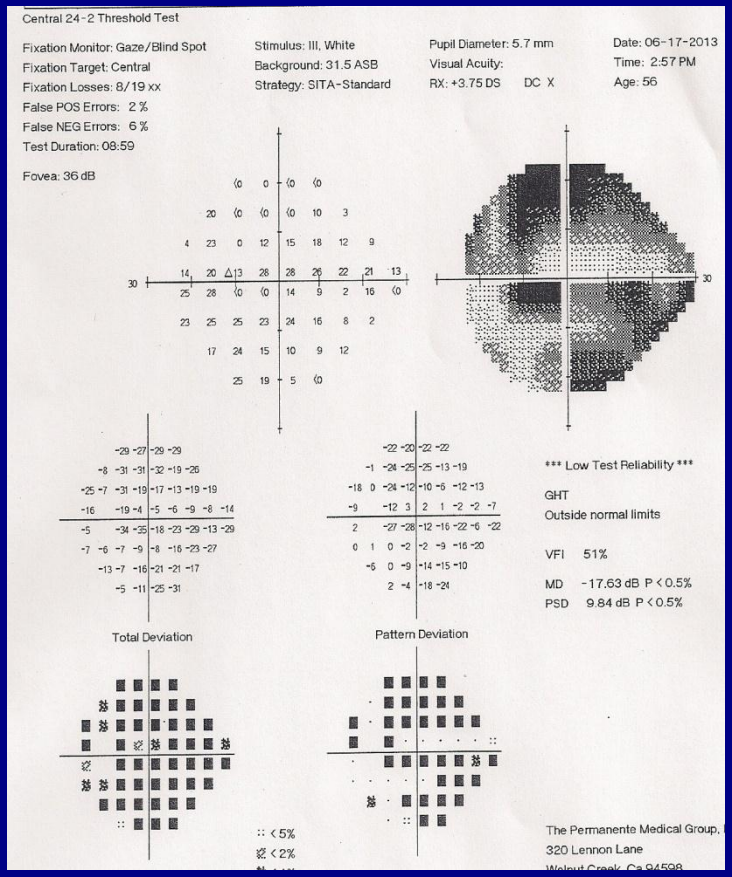
- 56 y/o MD with high myopia and glaucoma since 2007, complains of ocular irritation and redness
- History:
  - High myopia (-18.0) – wears GP CL
  - 2006: Glaucoma, initial IOP 23/27
  - 2007: Phaco/IOL OS
  - 2009: Trab/5FU (post op hypotony)
  - 2009: Head MRI, blood studies all WNL
- Meds: Azopt OU, Travatan OU, Timolol OU

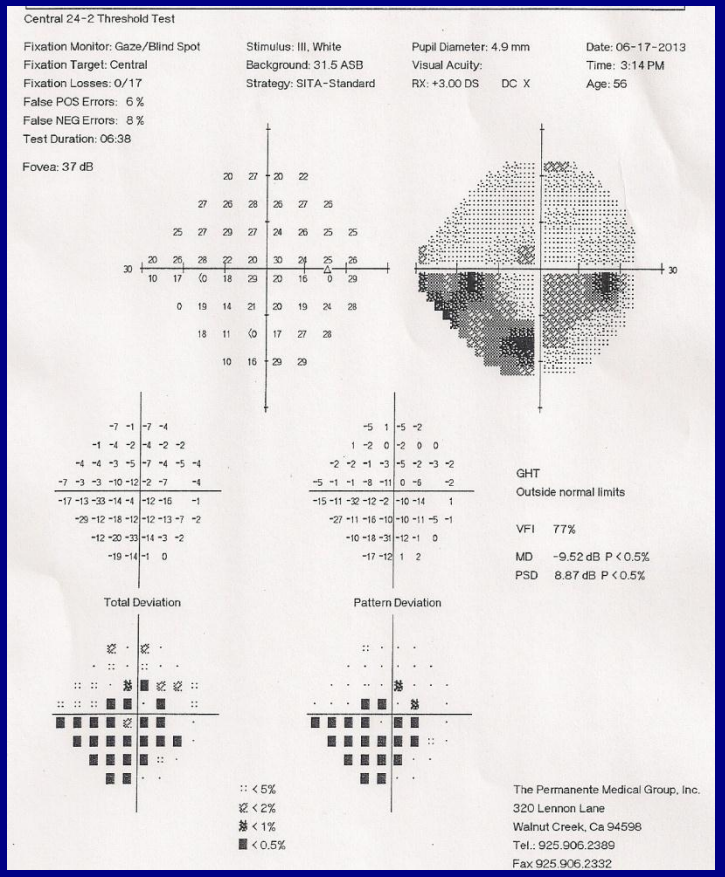
JK: Case Study

- Exam:

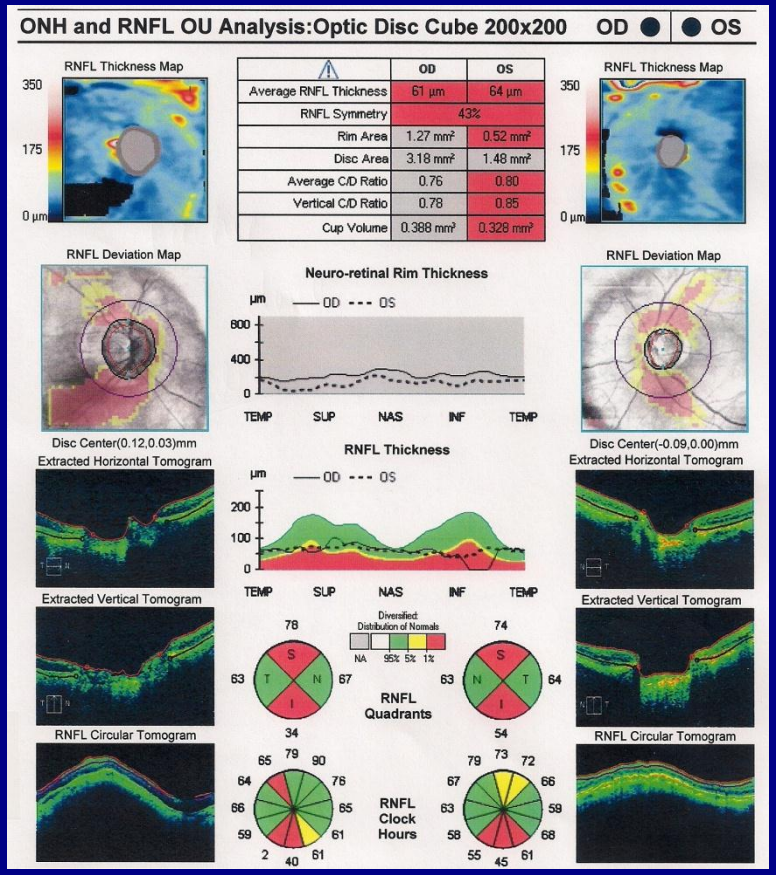
	OD	OS
– Acuity	-18.00CL=20/30	20/20
– SLE	2+ follicles, redness OU	
–	2+ NS, PSC	PC IOL
– IOP	11	11
– Fundus	0.8 cup	0.9 cup pale
– Pachy	606	590

JK: Case Study





JK: Case Study

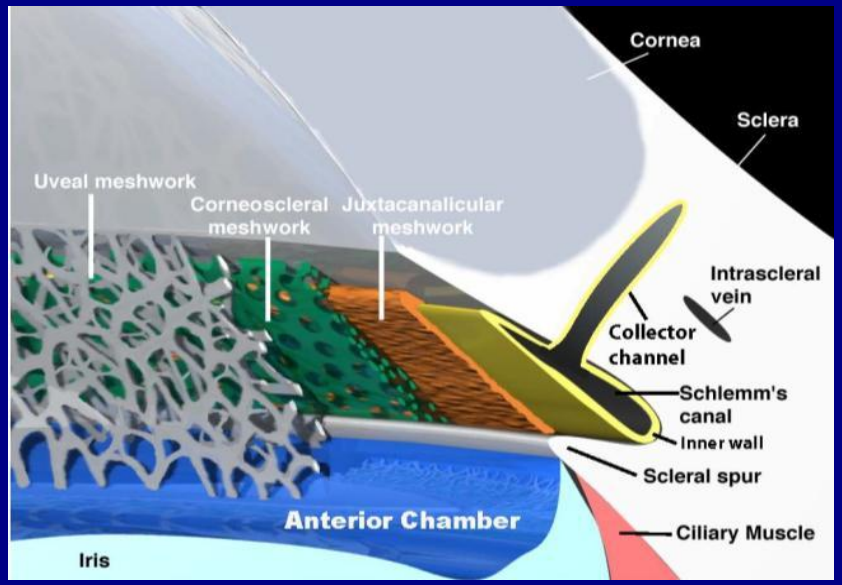


JK: Case Study

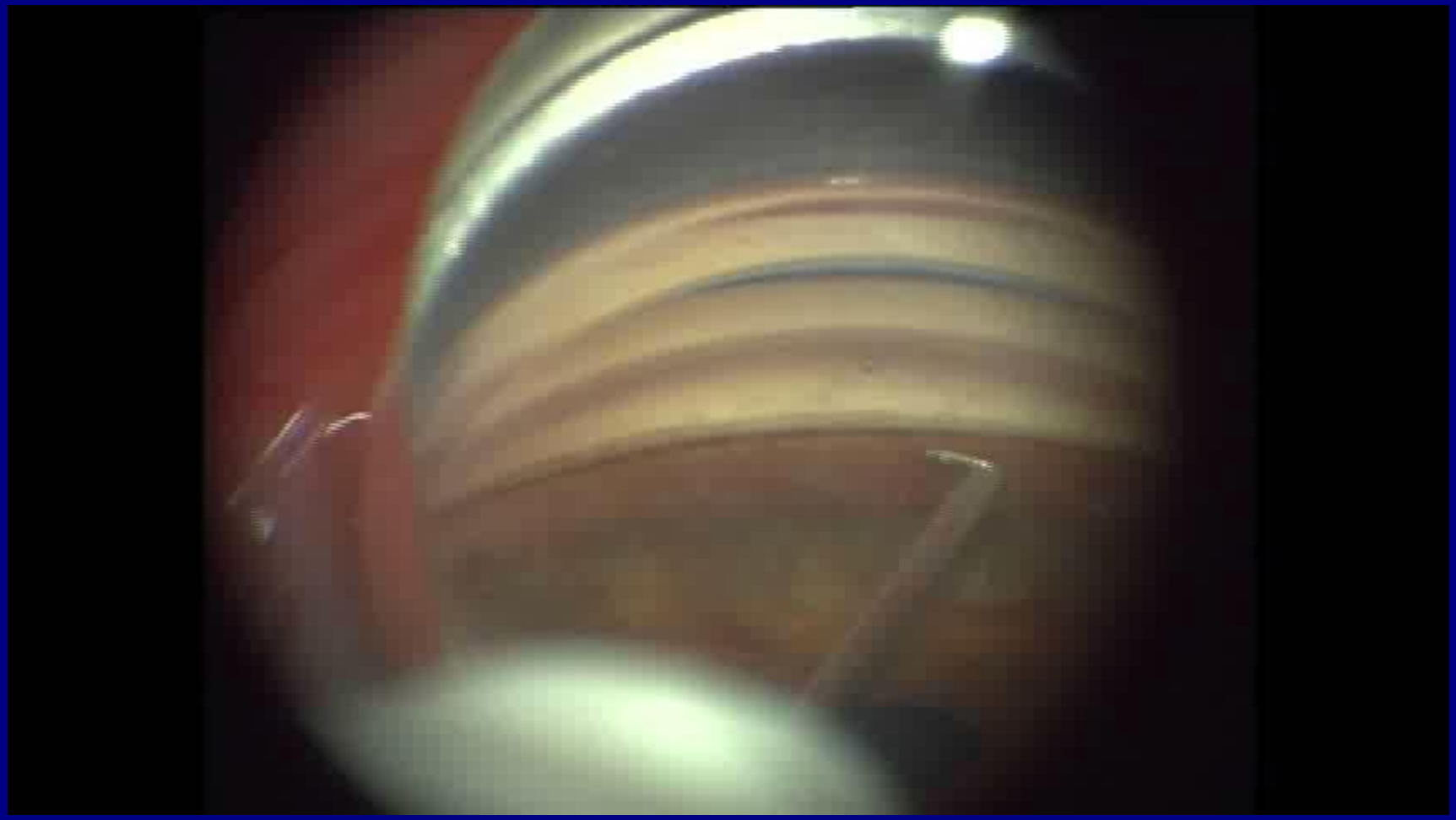
- Problem List
  - High myopia
  - POAG – progression, optimal IOP
  - Ocular redness – allergy to meds, CL

Canal-based, non disruptive MIGS Procedures

- Dilates and preserves Schlemm's canal by channel reconstruction and trabecular meshwork bypass
- Re-establish flow to collector channel system
- May be performed with or without cataract surgery
- Options:
  1. iStent (Glaukos)
  2. Hydrus (Ivantis)

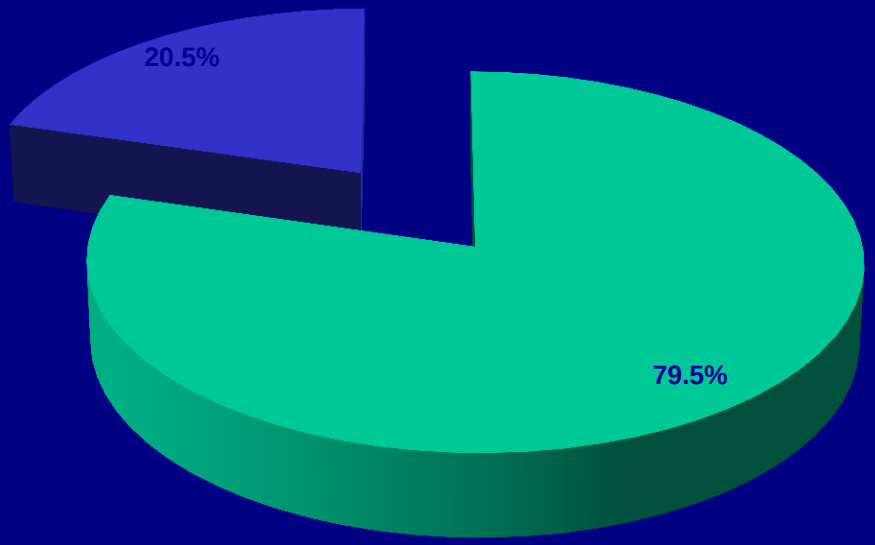


Glaukos iStent



Prevalence of Glaucoma and Cataract

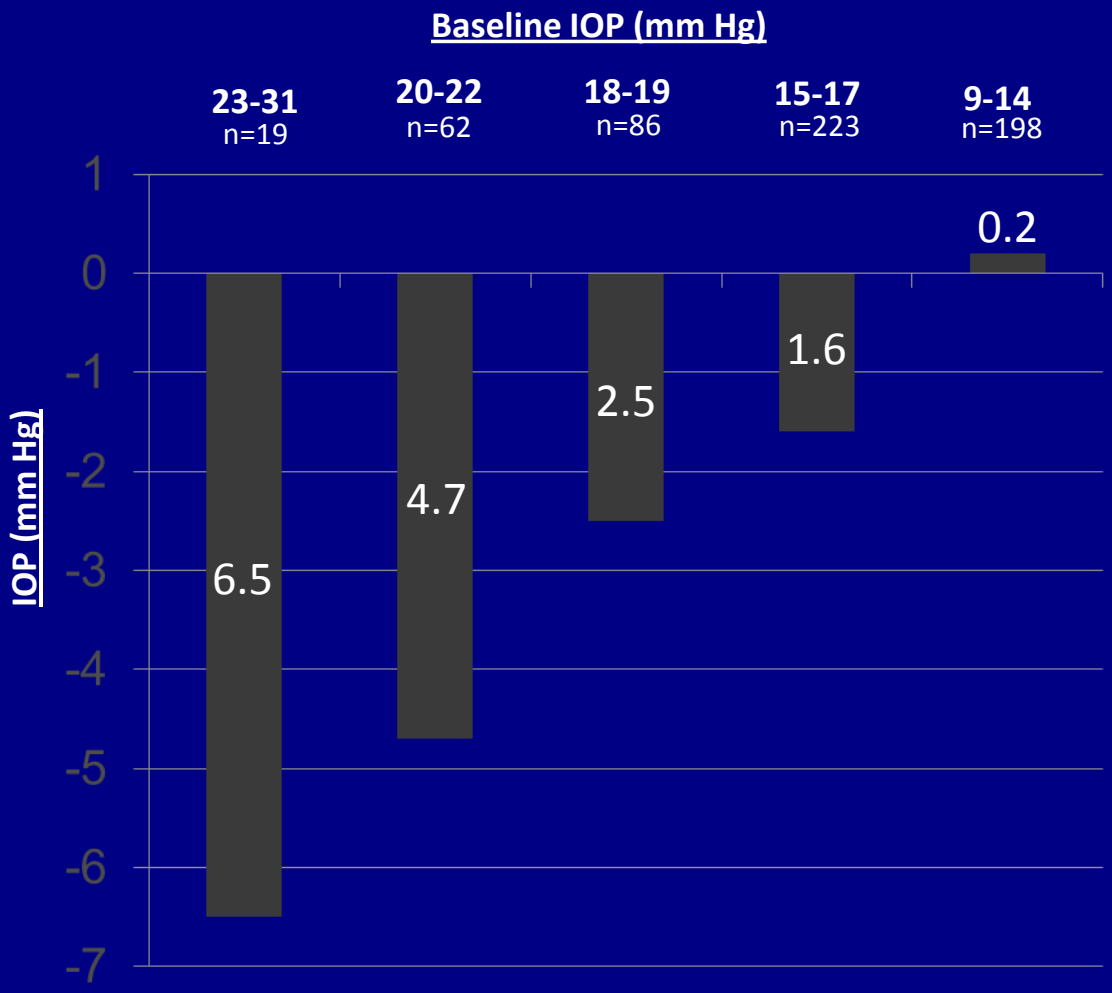
- **Of the 3.5 million annual cataract procedures performed in the US, 20.5% *of these patients are on a glaucoma medication**



A Large Percentage of your Patient Population fits the Approved Indication

*** Medicare data analysis 2003 - 2007**

Effect of Cataract Surgery on IOP Reduction



87% of patients who underwent cataract extraction experienced minimal to no reduction in IOP

- **53% had a mean reduction of 1.6 to 2.5 mm Hg**
- **34% had an increase of 0.2 mm Hg**

From a retrospective chart review of 588 normotensive and OHT patients who underwent cataract surgery

Poley BJ, Lindstrom RL, et al. Long-term effects of phacoemulsification with intraocular lens implantation in normotensive and ocular hypertensive eyes. J *Cataract Refract Surg* .2008;34(5):735-42.

When Should iStent Be Used?

- In any patient with mild-moderate glaucoma undergoing cataract surgery
  - Patients on 1 glaucoma med
    - Goal: getting patient off meds
  - Patients with normal VF

What is Mild to Moderate OAG?

1. American Academy of Ophthalmology Glaucoma Panel. Preferred Practice Pattern. *Primary Open-Angle Glaucoma Report 2010*

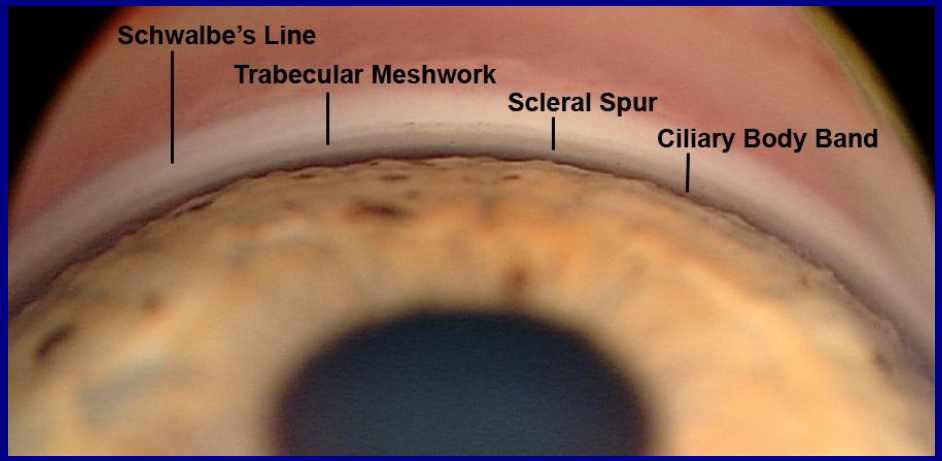
When Should iStent Be Used?

- In any patient with mild-moderate glaucoma undergoing cataract surgery
  - Patients on 1 glaucoma med
    - Goal: getting patient off meds
  - Patients with normal VF

- iStent: Option to treat glaucoma as a surgical disease

Gonioscopy is back!

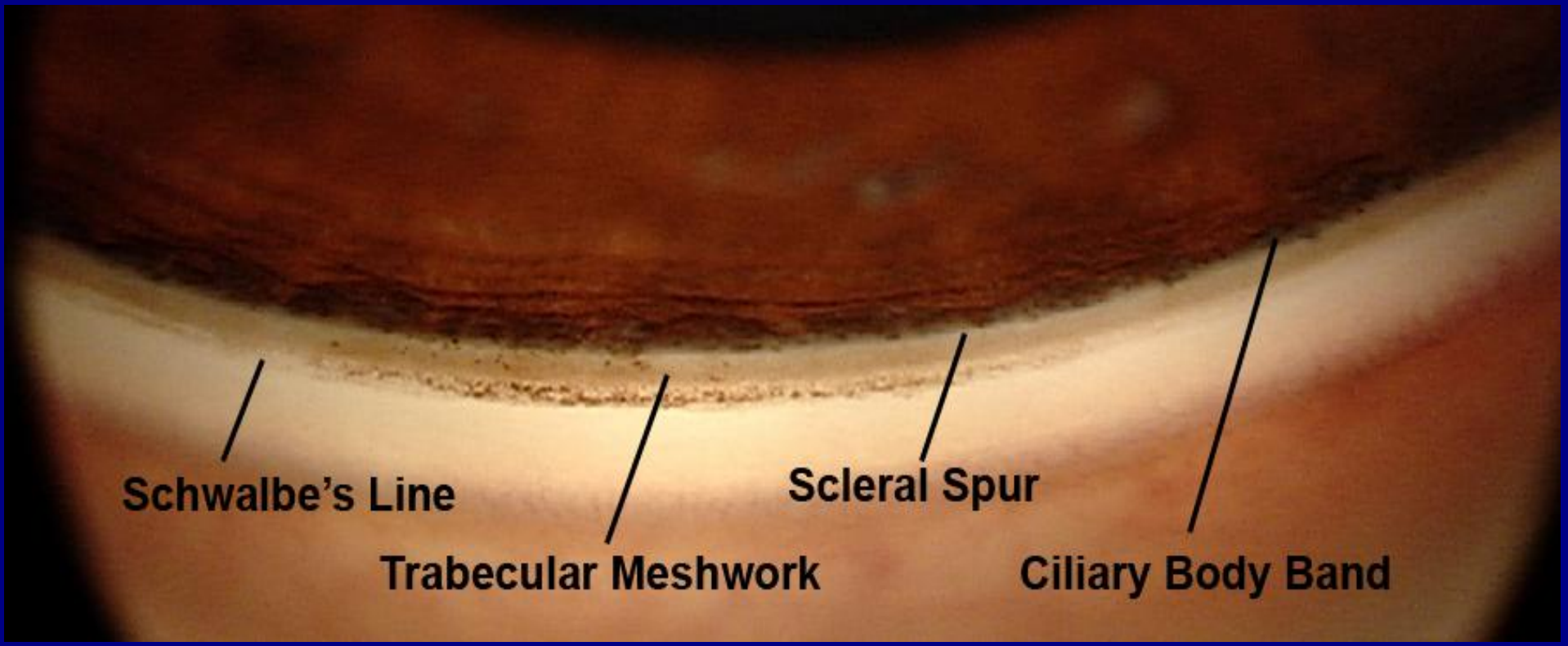
- Get comfortable in the office with gonioprism
  - Seldom done yet billable
  - Gonioscopy.org – great source



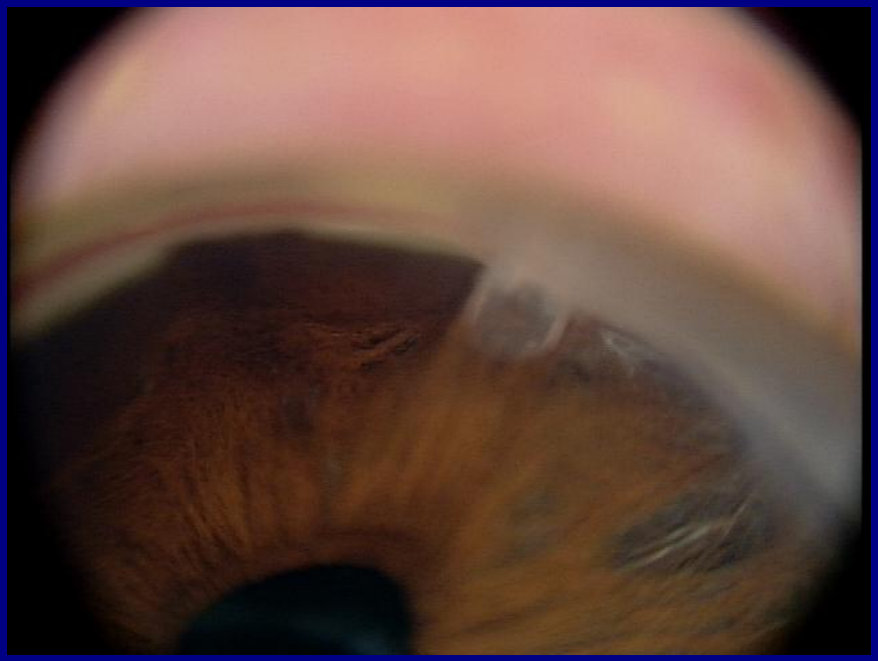
- Practice before a scheduled case
  - Use a gonioprism in one hand and Sinsky hook in the other

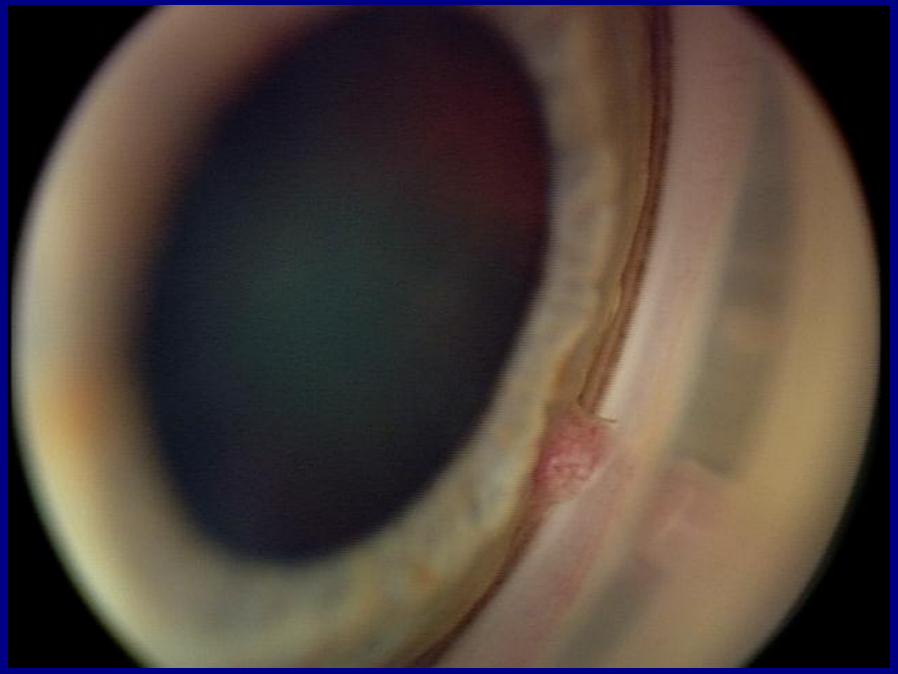
Gonio Imaging - Angle Structures

Normal angle - inferior view



Gonio Imaging - Angle Structures





RG: Case Study

- 79 y/o woman referred for glaucoma
- History:
  - RK + LASIK OD, RK OS
  - Blepharospasm (on Botox)
  - Dry eye
  - Ocular allergies (to BAK and other preservatives)
  - Cataract
- Meds: Non-preserved Timolol qd OU

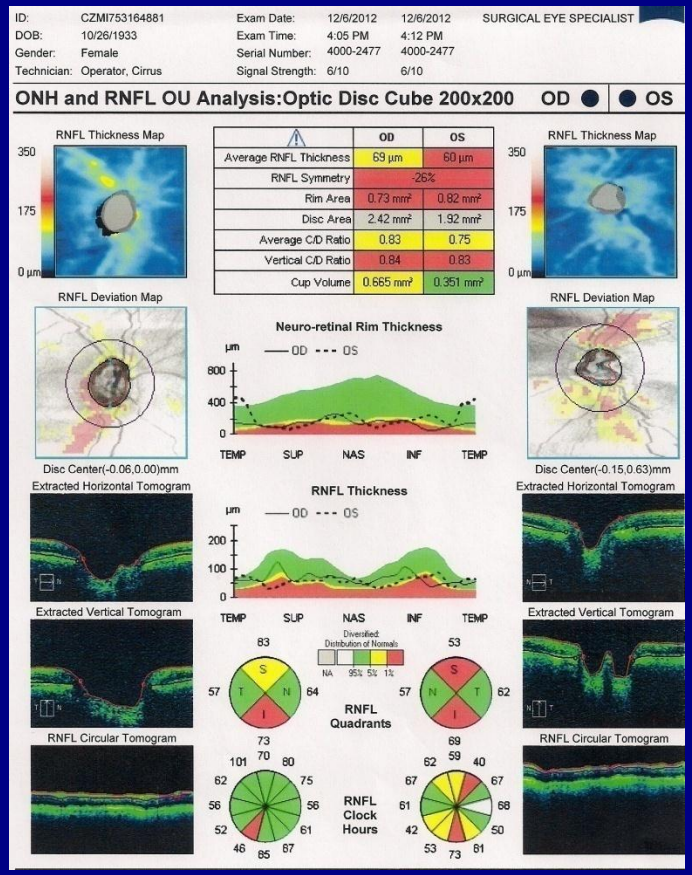
RG: Case Study

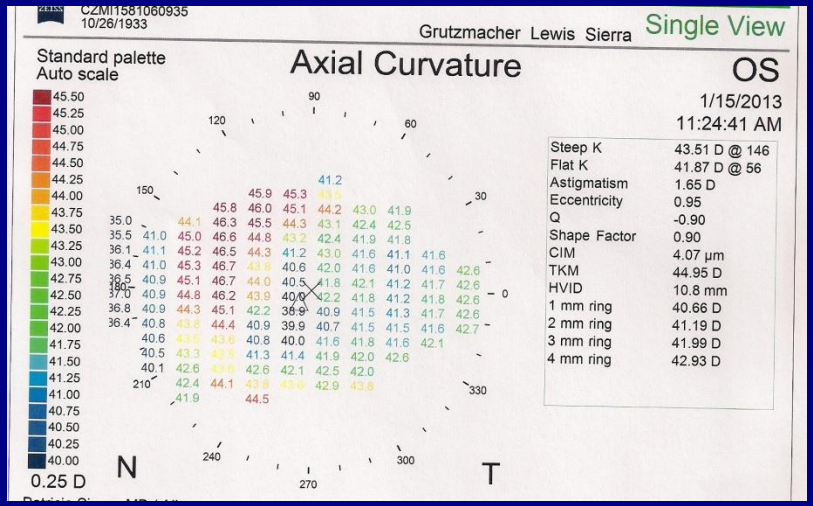
RG: Case Study

- **Exam:**

	OD	OS
– Acuity	+1.75+2.50x045=20/60	0.50+1.00x128=20/80
– SLE	RK scars OU, 2+ NS	
– IOP	14	15
– Fields	Unreliable OU	
– Disc	0.8 cup	0.8 cup

RG: Case Study





RG: Case Study

ID:
Date of Birth: **10/26/1933**
Exam Date: **12/06/2012**

Formula: **Haigis**
n: **1.3375**

ZEISS

Preoperative Data:

AL: **23.67 mm (SD = 0.03 mm, SNR = 85.9)**
K1: **39.73 D / 8.49 mm (*)**
K2: **41.18 D / 8.20 mm (*)**
SE: **40.45 D (*)**
Cyl.: **1.45 D (*)**
R: **8.35 mm (*)**

Target Ref.: **-0.25 D**
opt. ACD: **2.75 mm**
Visual Acuity:
Refraction:
Eye Status: **phakic**

OD
right

AMO Tecnis ZCB00 (ULIE		Alcon A-TORIC SN6ATT		Alcon SN60WF		Alcon MA60AC (3 PC)	
ACD Const:	5.78	ACD Const:	5.55	ACD Const:	5.4	ACD Const:	5.21
A0 Const:	-1.047	A0 Const:	-0.355	A0 Const:	-0.466	A0 Const:	1.532
A1 Const:	0.174	A1 Const:	0.157	A1 Const:	0.172	A1 Const:	0.012
A2 Const:	0.246	A2 Const:	0.216	A2 Const:	0.212	A2 Const:	0.145
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
27.5	-1.48	27.0	-1.23	27.0	-1.52	26.5	-1.19
27.0	-1.11	26.5	-0.86	26.5	-1.14	26.0	-0.81
26.5	-0.74	26.0	-0.49	26.0	-0.77	25.5	-0.44
26.0	**-0.38**	**25.5**	**-0.13**	**25.5**	**-0.40**	**25.0**	**-0.08**
25.5	-0.02	25.0	0.23	25.0	-0.03	24.5	0.28
25.0	0.33	24.5	0.58	24.5	0.33	24.0	0.64
24.5	0.68	24.0	0.93	24.0	0.68	23.5	0.99

Preoperative Data:

AL: **23.75 mm (SD = 0.03 mm, SNR = 44.5)**
K1: **40.71 D / 8.29 mm @ 65°**
K2: **42.56 D / 7.93 mm @ 155°**
SE: **41.64 D**
Cyl.: **1.85 D @ 155°**
R: **8.11 mm (SD = 0.00 mm)**

Target Ref.: **-0.25 D**
opt. ACD: **2.98 mm**
Visual Acuity:
Refraction:
Eye Status: **phakic**

OS
left

AMO Tecnis ZCB00 (ULIE		Alcon A-TORIC SN6ATT		Alcon SN60WF		Alcon MA60AC (3 PC)	
ACD Const:	5.78	ACD Const:	5.55	ACD Const:	5.4	ACD Const:	5.21
A0 Const:	-1.047	A0 Const:	-0.355	A0 Const:	-0.466	A0 Const:	1.532
A1 Const:	0.174	A1 Const:	0.157	A1 Const:	0.172	A1 Const:	0.012
A2 Const:	0.246	A2 Const:	0.216	A2 Const:	0.212	A2 Const:	0.145
IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)	IOL (D)	REF (D)
25.5	-1.32	25.5	-1.44	25.0	-1.34	25.0	-1.45
25.0	-0.96	25.0	-1.07	24.5	-0.97	24.5	-1.08
24.5	-0.60	24.5	-0.71	24.0	-0.60	24.0	-0.71
24.0	**-0.24**	**24.0**	**-0.35**	**23.5**	**-0.24**	**23.5**	**-0.35**
23.5	0.11	23.5	0.00	23.0	0.12	23.0	0.01
23.0	0.46	23.0	0.35	22.5	0.47	22.5	0.37
22.5	0.80	22.5	0.70	22.0	0.82	22.0	0.72

(* = Changed manually, ' = Borderline Value)

Topographic Data:

EyeSys EffRP — Average Central Power*

Atlas 1mm 40.66 — 2mm 41.19 — 3mm 41.99 — 4mm 42.93

Pentacam PWR_SF_40** — CT_MIN**

Optical (IOLMaster/Lenstar)/Ultrasound Biometric Data:

Ks — K1(D) 40.71 — K2(D) 42.56 — Keratometric Index (n)*** 1.3375 1.332 Other

AL(mm) 23.75 — Target Ref(D) -0.25

Lens Constants**** — A-cons (SRK/T) 119.4 — SF (Holladay1) 2.03

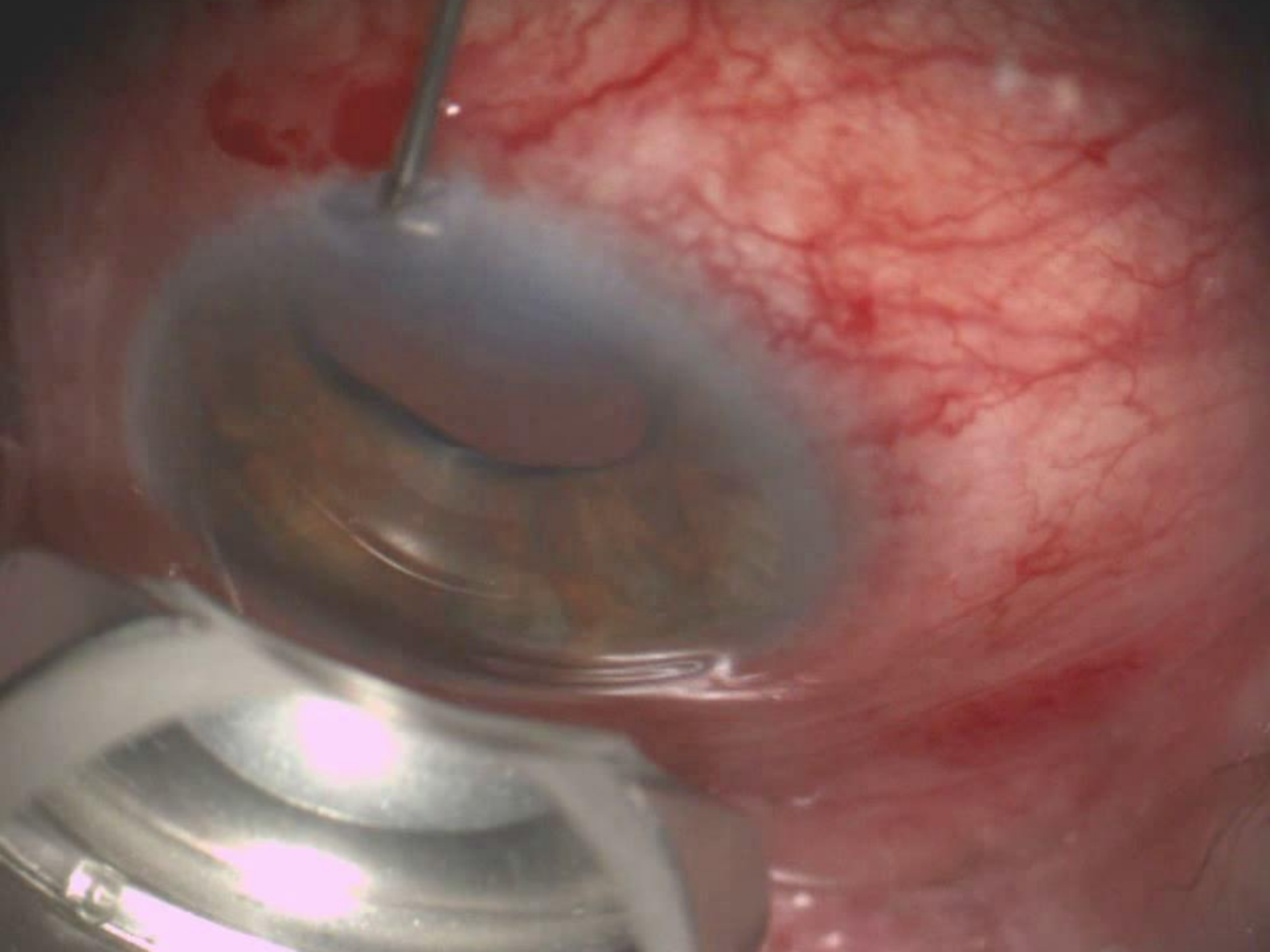
*Not SimK values; average central corneal powers from other devices.
**PWR_SF_40 refers to the Pentacam Power Distribution display for the Sagittal Curvature (Front) Mean (Km) value at a 4.0 mm zone and centered on the pupil. Click on PWR_SF_40 to see this topographic display.
CT_MIN is the minimum central corneal thickness in microns as displayed by the Pentacam.
***Select the keratometric index (n) of your device. Instruments in North America typically default to 1.3375.
****Enter the constant available; the other will be calculated. If ultrasonic AL is entered, be sure to use your ultrasound lens constants.

Calculate — Reset Form

IOL Powers Calculated Using Double-K Holladay 1 Formula

EyeSys EffRP --
Average Central Power (other) --
Atlas 1-4 **24.08**
Pentacam --
IOLMaster/Lenstar **24.16**

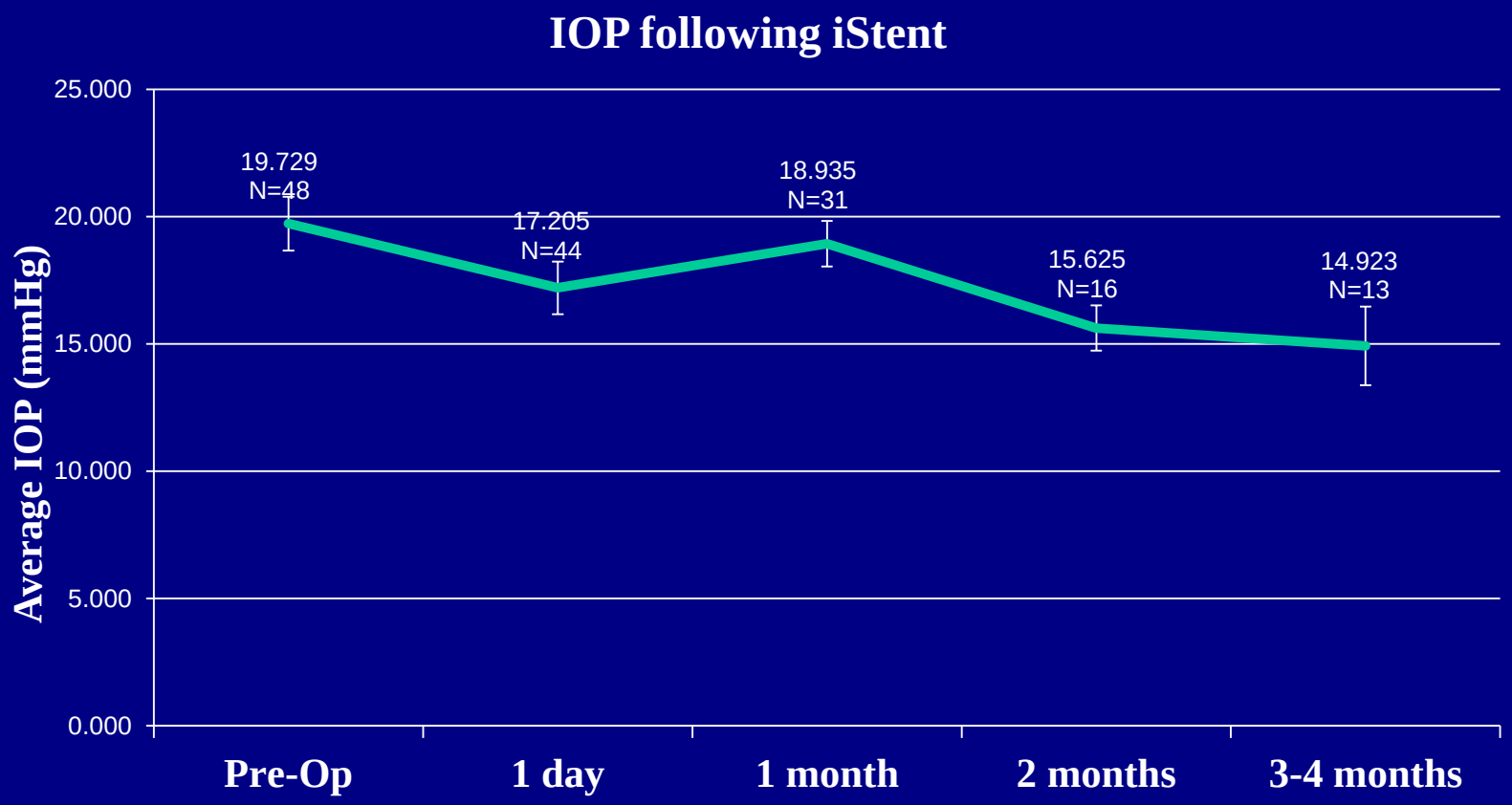
Average IOL Power: 24.12
Min: 24.08
Max: 24.16



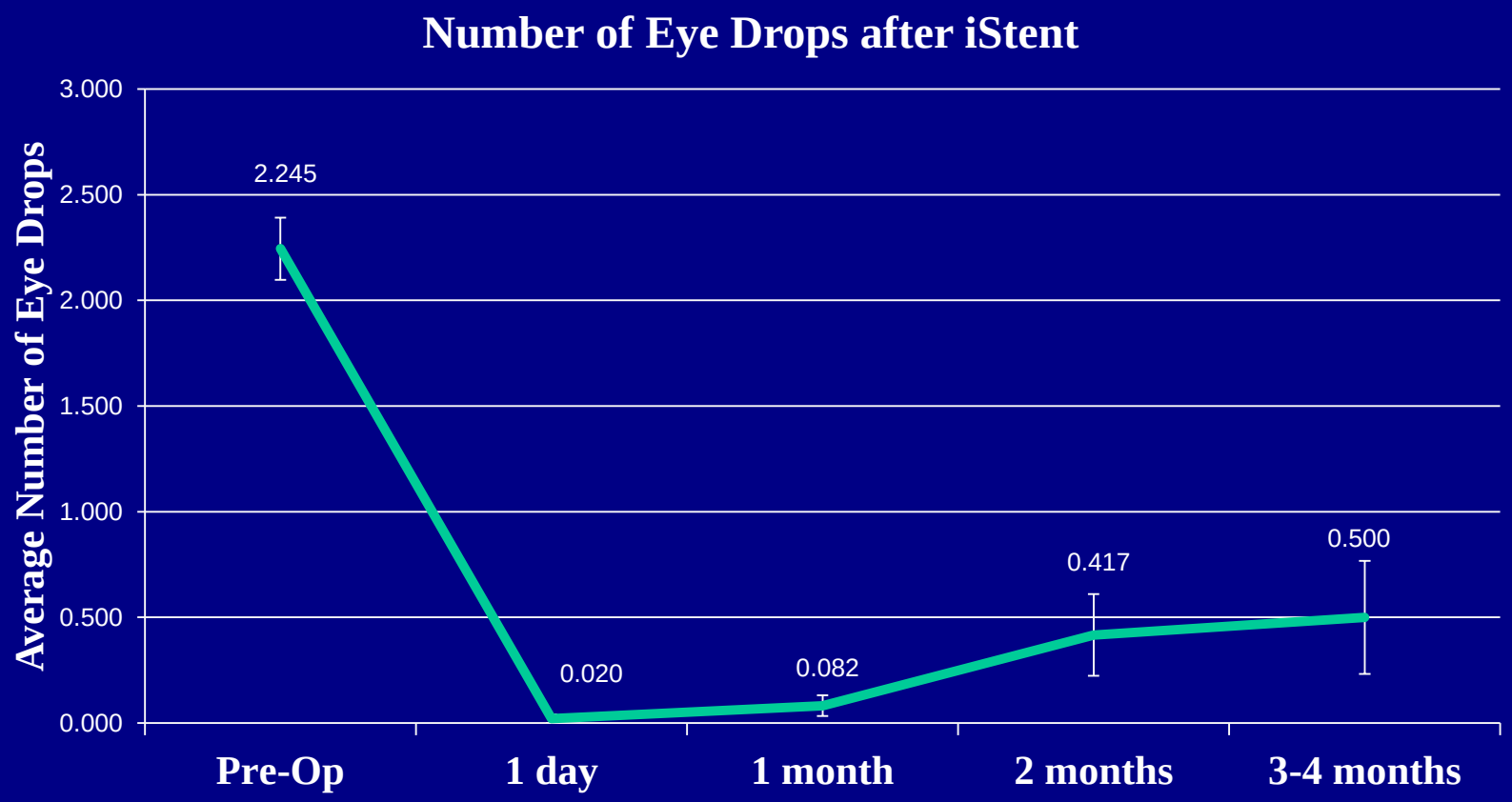
RG: Case Study

- Underwent uncomplicated phaco/IOL (24D) with iStent
- Results:
  - Discontinued eye drops
  - IOP under control
  - Dry eye symptoms improved
  - Very happy with result

First 50 iStents: IOP



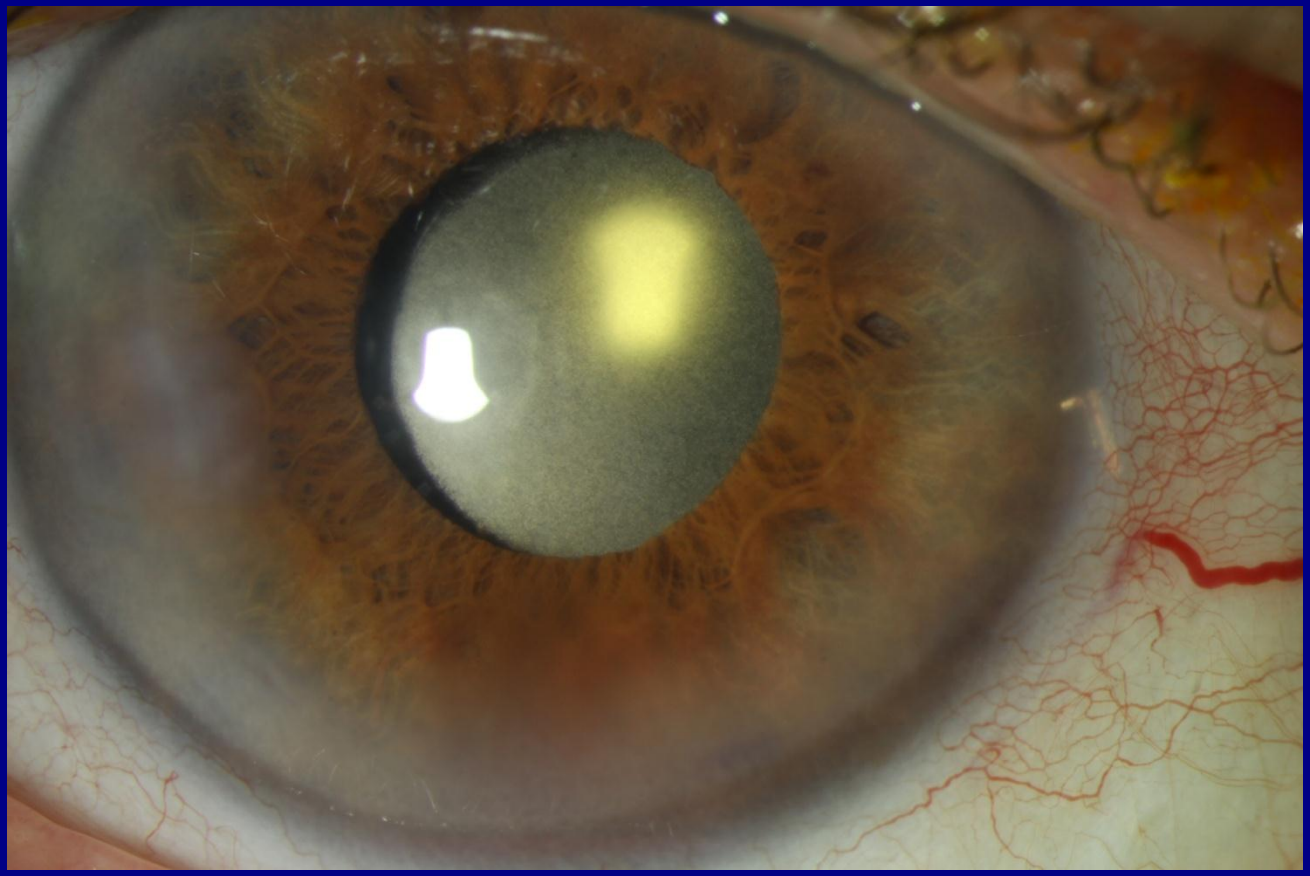
First 50 iStents: Number of Eye Drops



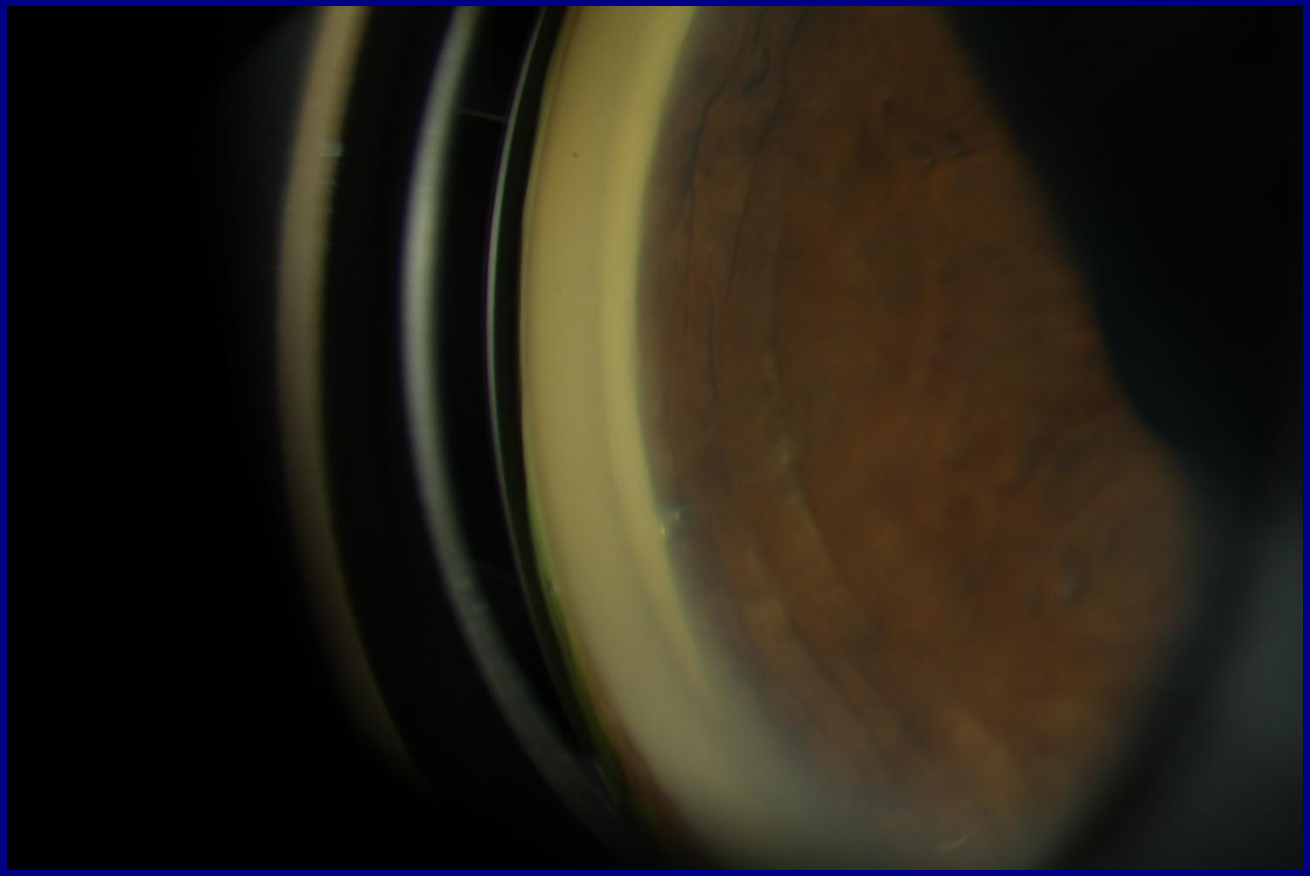
iStent Insertion Tips

1. Head positioning
2. High magnification of microscope
3. Maximize visibility (gonio view)
4. Viscoelastic (just the right amount)
5. Angle tip of injector into TM
6. Press forward while injecting
7. Re-assess after placement

Superficial iStent Placement



Well Placed iStent

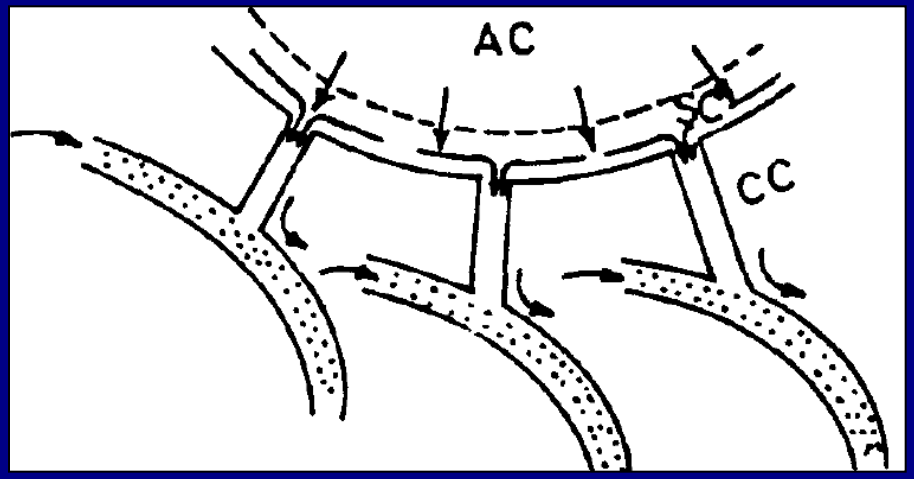


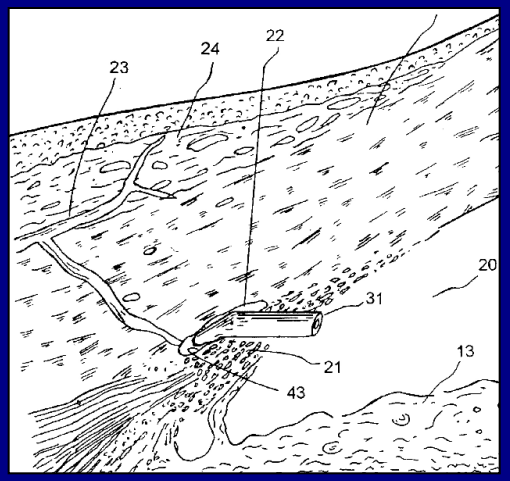
Maximizing IOP Reduction with iStent?

- Multiple iStents?
  - 2 iStents achieve lower IOP (Ike Ahmed MD)
  - Subject of continuing studies
  - Not approved for reimbursement in US
- Targeted placement of iStent
  - Near aqueous vein
  - Near pigmented area in meshwork

The Role of Collector Channels in Reducing IOP

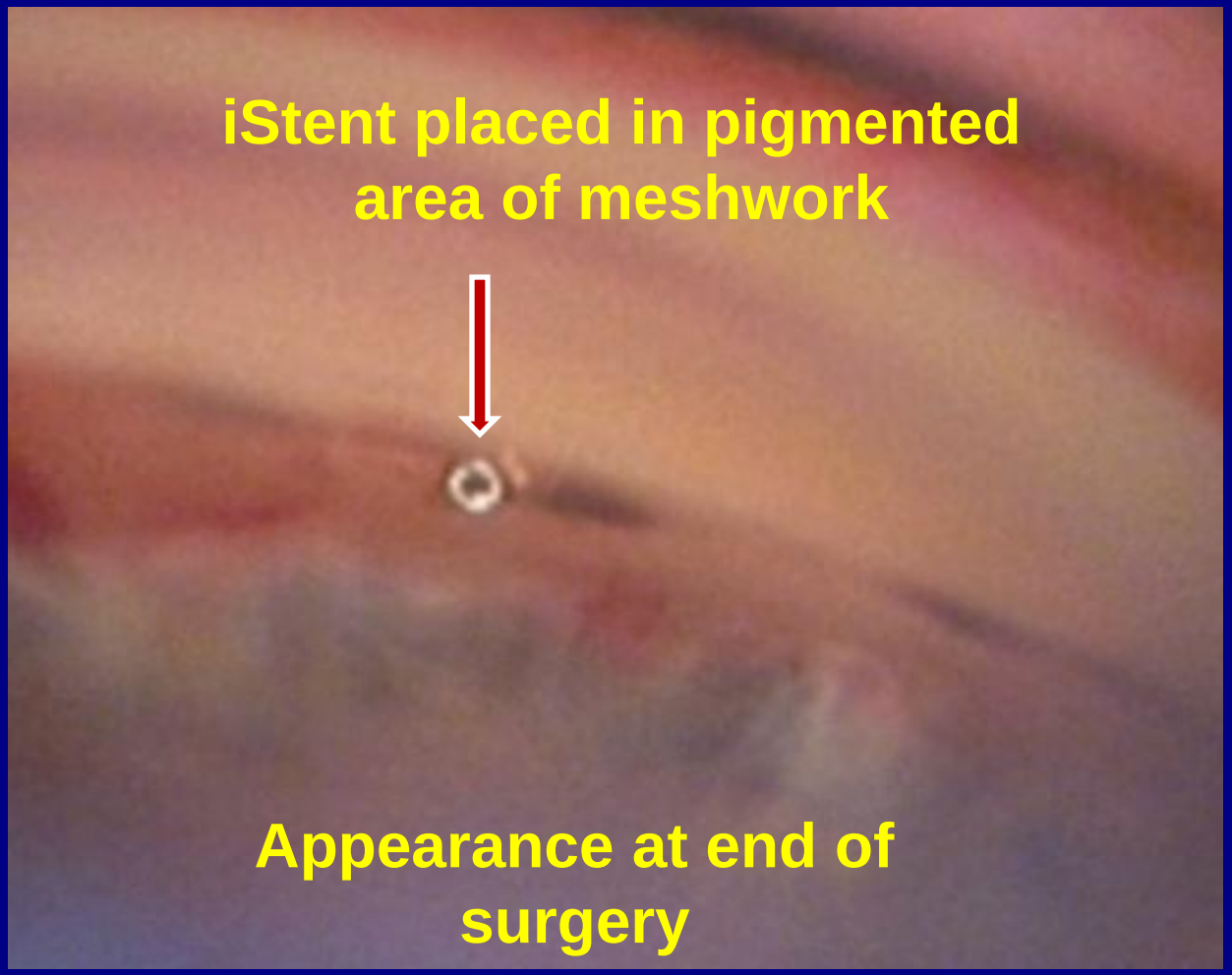
- There are numerous collector channels leaving Schlemm's canal at irregular intervals
- Bypassing the trabecular meshwork in the inferonasal quadrant is an optimal site to maximize outflow through Schlemm's canal
- Increasing outflow through the lower nasal quadrant has a significant impact on increasing outflow and lowering IOP as compared to targeting quadrants with lower collector channel congregations





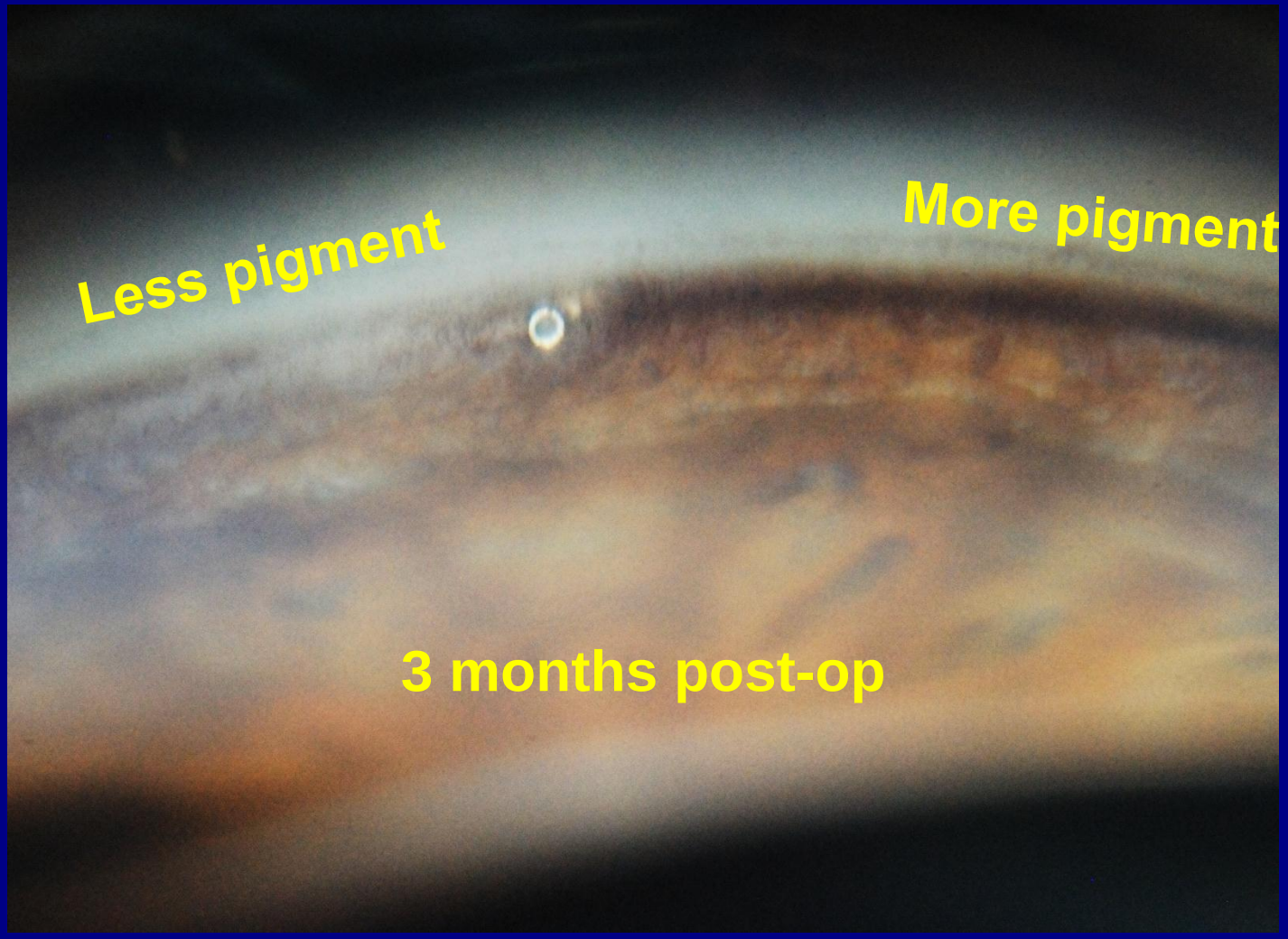
Dvorak-Theobald G. Schlemm's Canal: Its Anastomoses and Anatomic Relations. Trans Am Ophthalmol Soc. 1934;32:574-95.
Zhou J, Smedley GT. Trabecular bypass: effect of schlemm canal and collector channel dilation. *J Glaucoma*. 2006;15(5):446-55.

Targeted Placement: Pigmented Meshwork

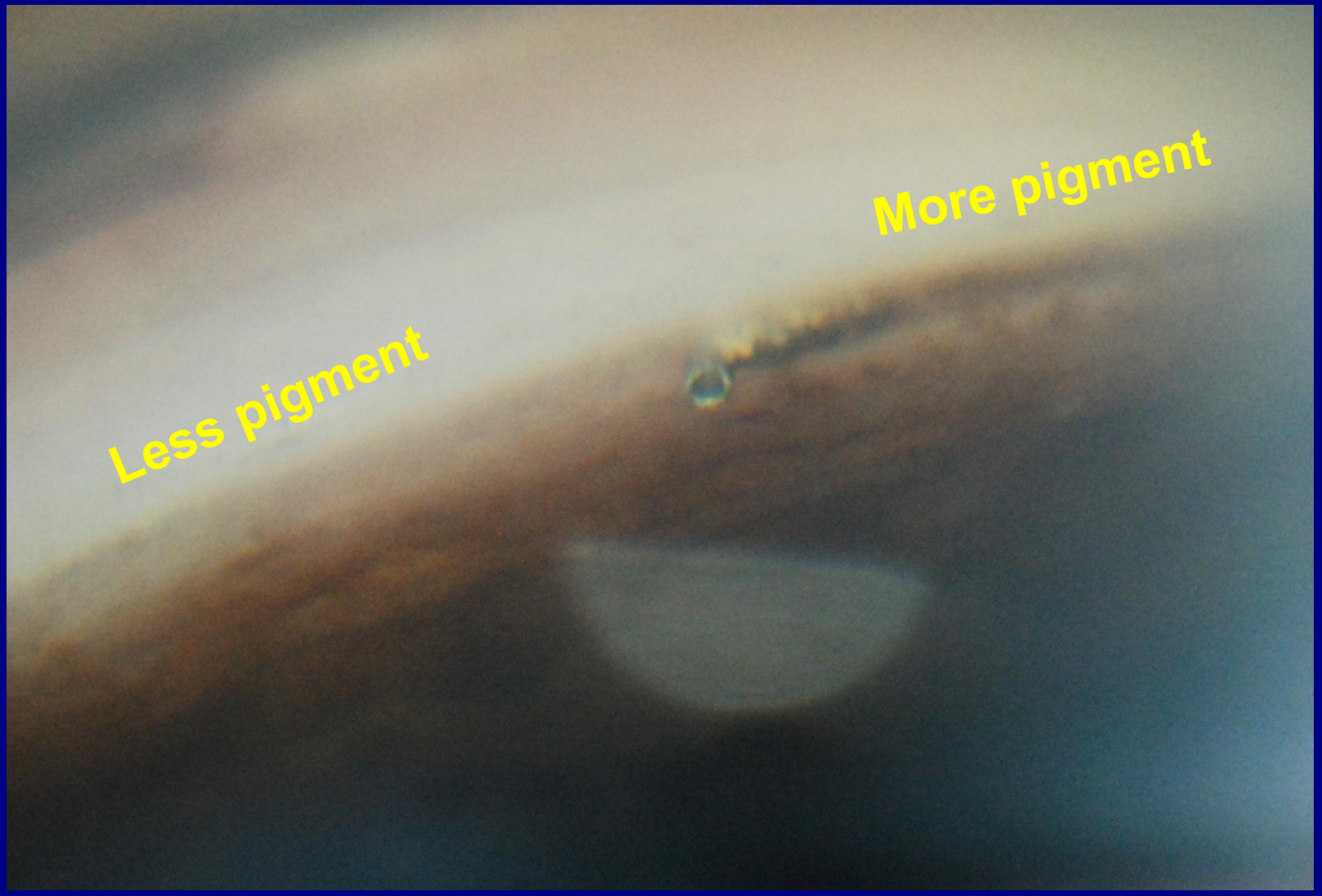


Targeting Collector Channels

Pigment Suggests Outflow



Targeting Collector Channels



Summary

- Large percentage of the patient population presents with mild-to-moderate glaucoma + cataract
- iStent is the first FDA approved device for the treatment of mild-to-moderate open-angle glaucoma in combination with cataract surgery; it will not be the last!
- Get comfortable with the gonioprism!