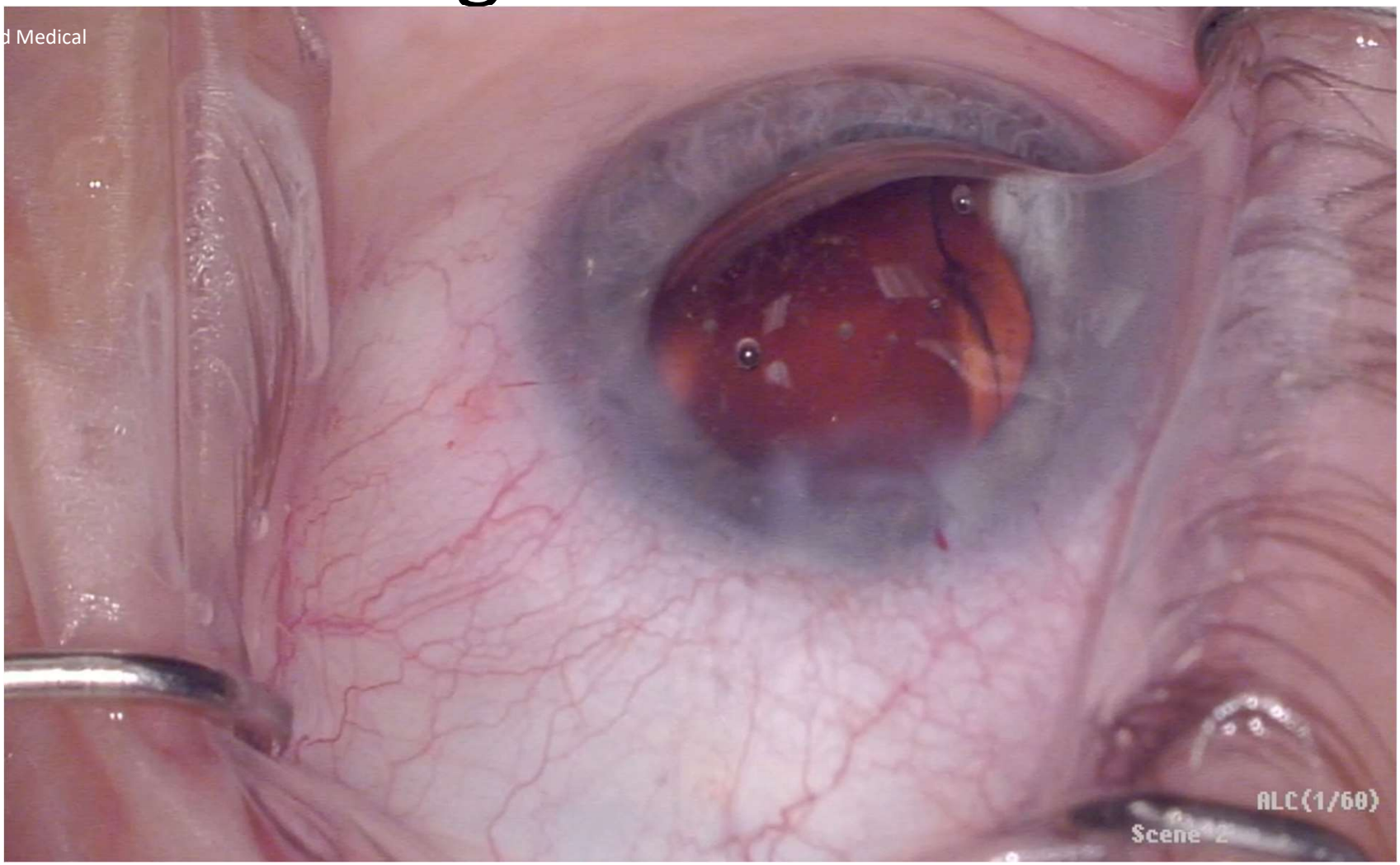
Making Sense of MIGS



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Financial Disclosure

- I have the following financial interests or relationships to disclose:
  - Beaver-Visitec International, Inc.: Consultant/Advisor, Lecture Fees
  - Diopsys, Inc.: Consultant/Advisor, Lecture Fees
  - Endo Optiks, Inc.: Consultant/Advisor, Lecture Fees
  - Ethis Communications: Consultant/Advisor
  - Novartis Pharmaceuticals Corporation: Consultant/Advisor, Lecture Fees
  - Allergan: Consultant/Advisor, Lecture Fees
  - Aquesys: Grant Support
  - Aerie: Consultant/Advisor
  - Ocular Therapeutics: Consultant/Advisor, Equity Owner, Grant Support
  - Polyactiva: Consultant/Advisor
  - Quantel Medical: Lecture Fees
  - Shire: Consultant/Advisor
  - Sun: Consultant/Advisor
  - Glaukos Corporation: Lecture Fees, Grant Support
  - Innfocus: Grant Support
  - Inotek: Consultant/Advisor
  - IRIDEX: Consultant/Advisor, Lecture Fees
  - Katena Products, Inc: Lecture Fees

MIGS or LIGS?

- Trabecular Bypass/Canal Enhancement
  - Istent G1
  - Istent Inject
  - Hydrus
- Goniotomy
  - Trabectome
  - Kahook Dual Blade
  - Omni
  - GATT
- Canal Expansion
  - ABIC
  - Omni
- Suprachoroidal Space
  - None (Cypass)
- Entire Outflow System Bypass
  - Xen
  - Innfocus
- Cycclophotocoagulation
  - ECP
  - TCP

Considerations

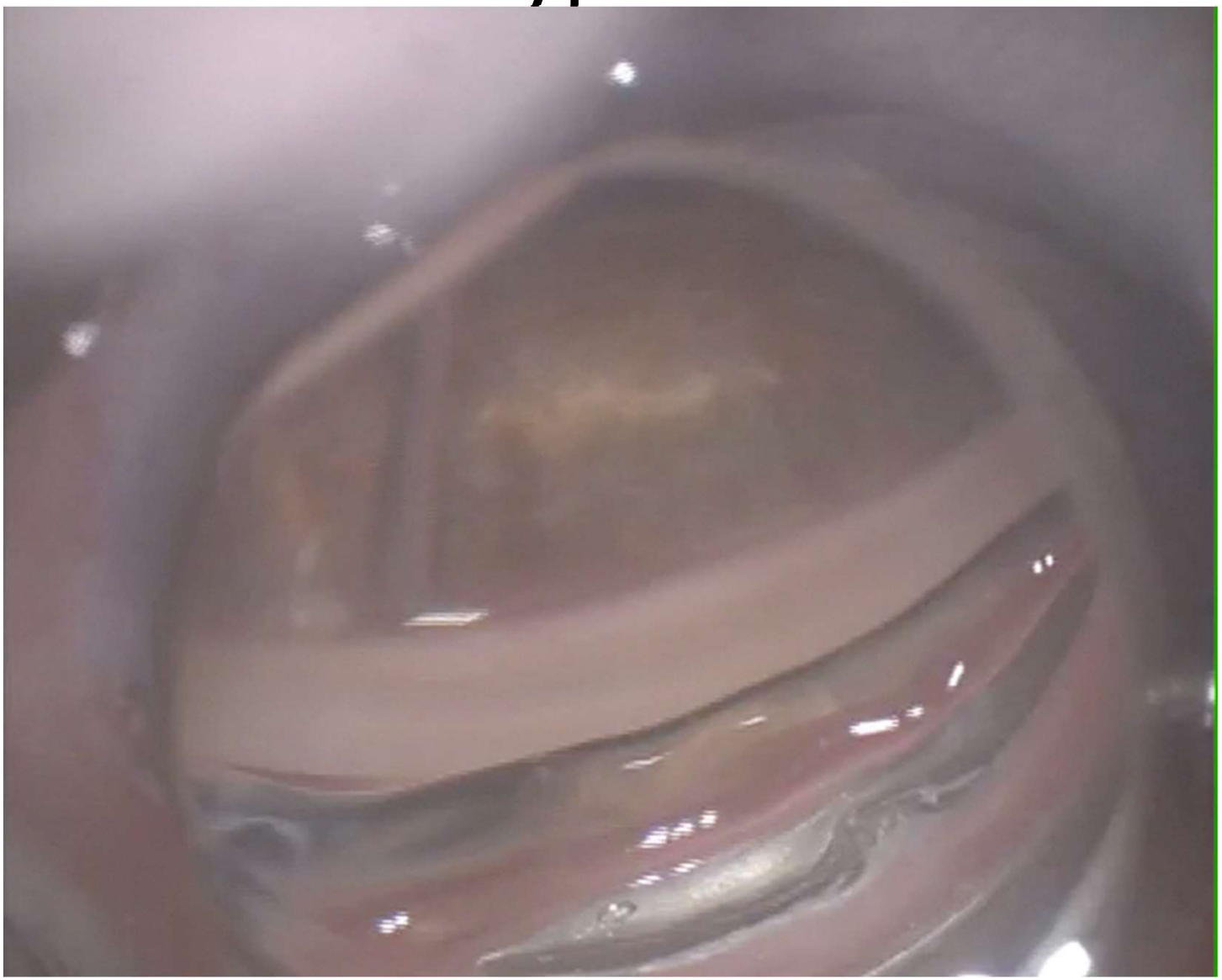
- Lens Status
  - Only opportunity to do (be reimbursed) for iStents or Hydrus - restricted to combination with Cataract Surgery

Case Report

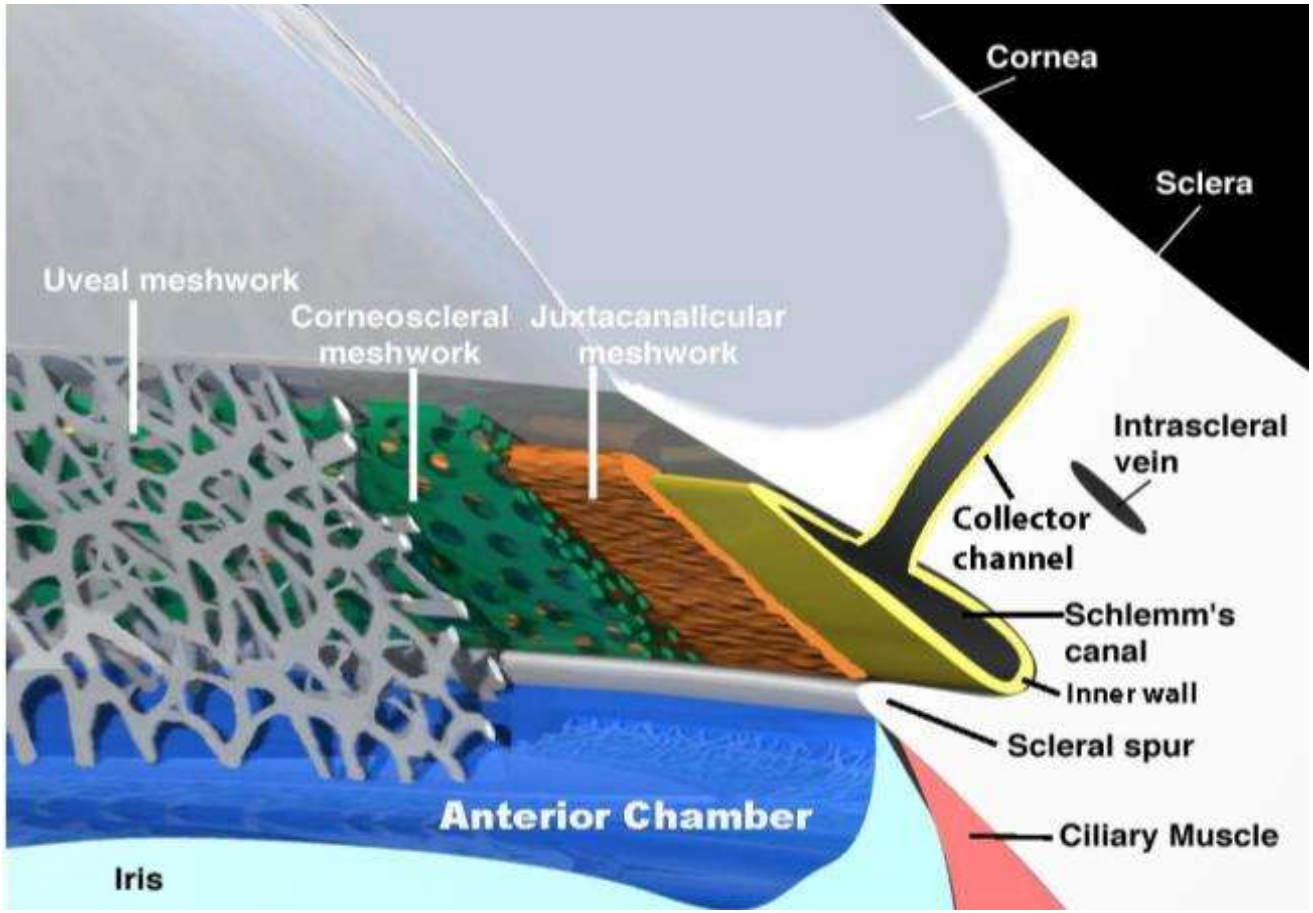
- 65 year old female with mild POAG
- Treated with latanoprost qday x 5 years
- IOP 21/20 Peak IOPs 26/27

- Treated with combined istent/
- IOP 10, no pain no change in vision
- 2 post-op visits – sent back to referring MD

Microbypass Stent



Status of Outflow System

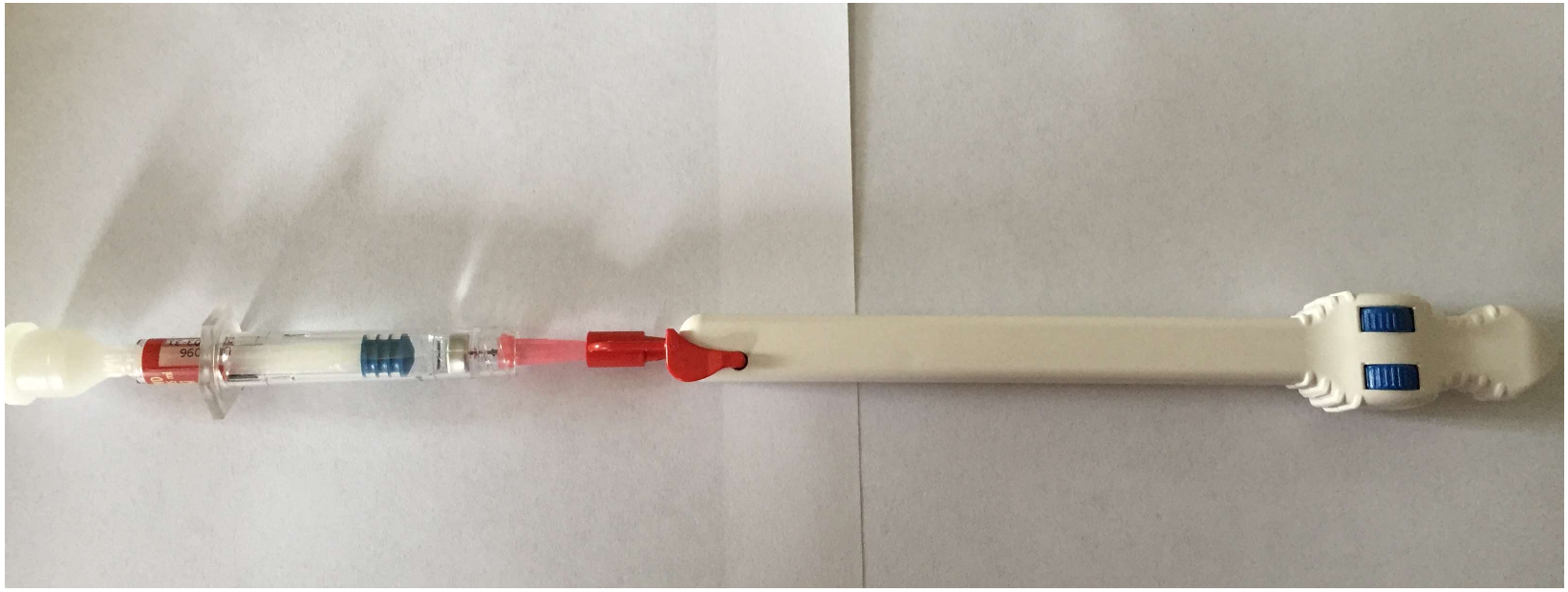


From Figure 2 of Toris CB. Aqueous Humor Dynamics I, Measurement methods and animal studies. The eye's aqueous humor. In Current Topics in Membranes. Mortimer M. Civan, (ed.). Elsevier, Inc. San Diego, 2008.

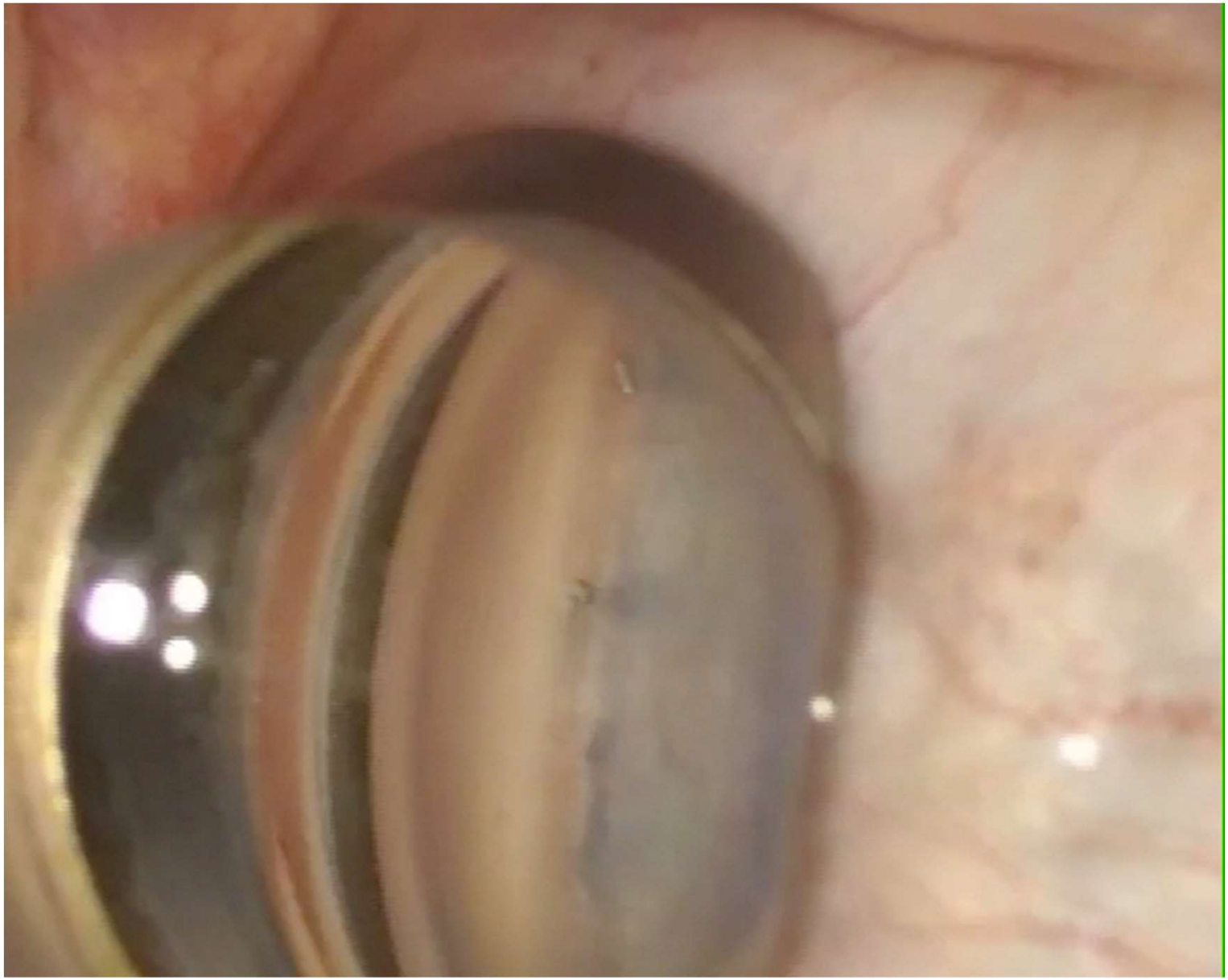
Status of Outflow System

- If viable, the mircobypass, dilation or cutting of canal are viable options

Ab Interno Viscocanalostomy (Visco 360)



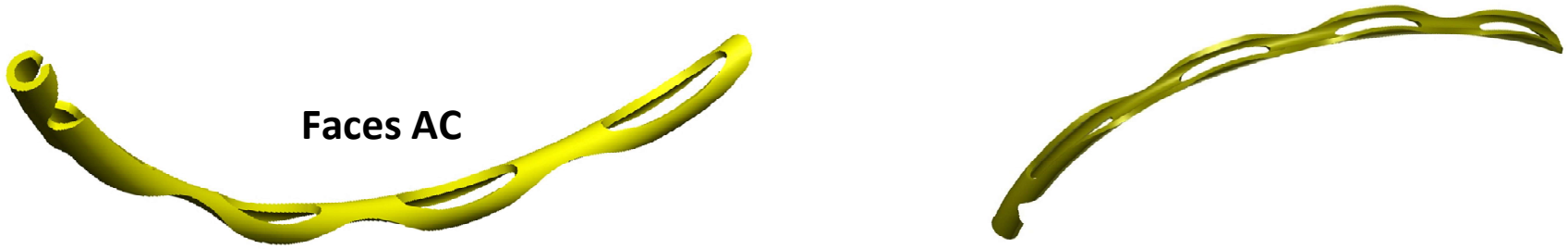
Ab interno Viscocanalostomy



Degree of IOP Lowering Desired

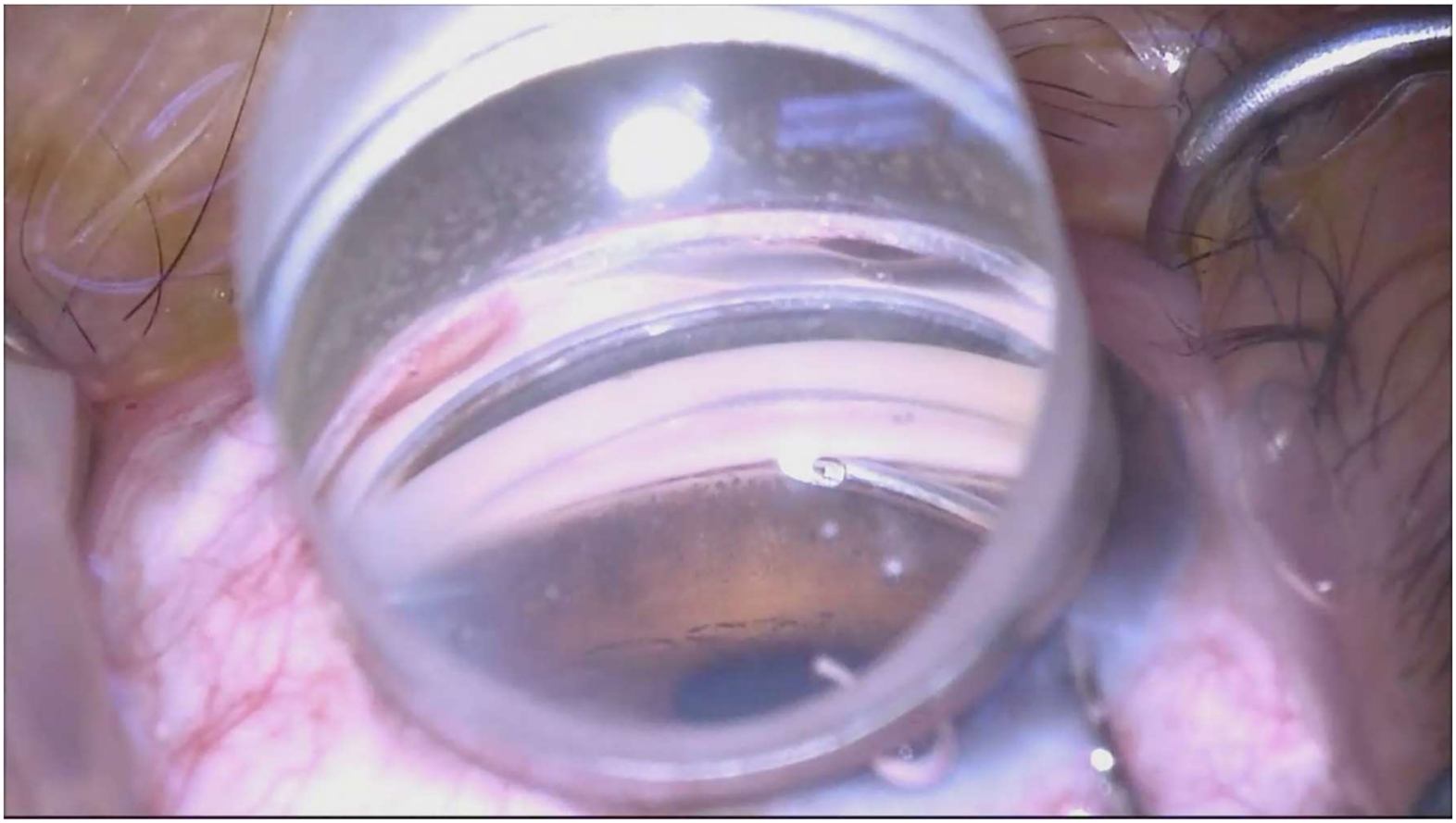
- If need upper teens
  - Trabecular bypass
- If need mid teens
  - Angle procedures
  - Cyclophotocoagulation
- If need low teens
  - Conjunctival procedures

Hydrus™ Aqueous Implant



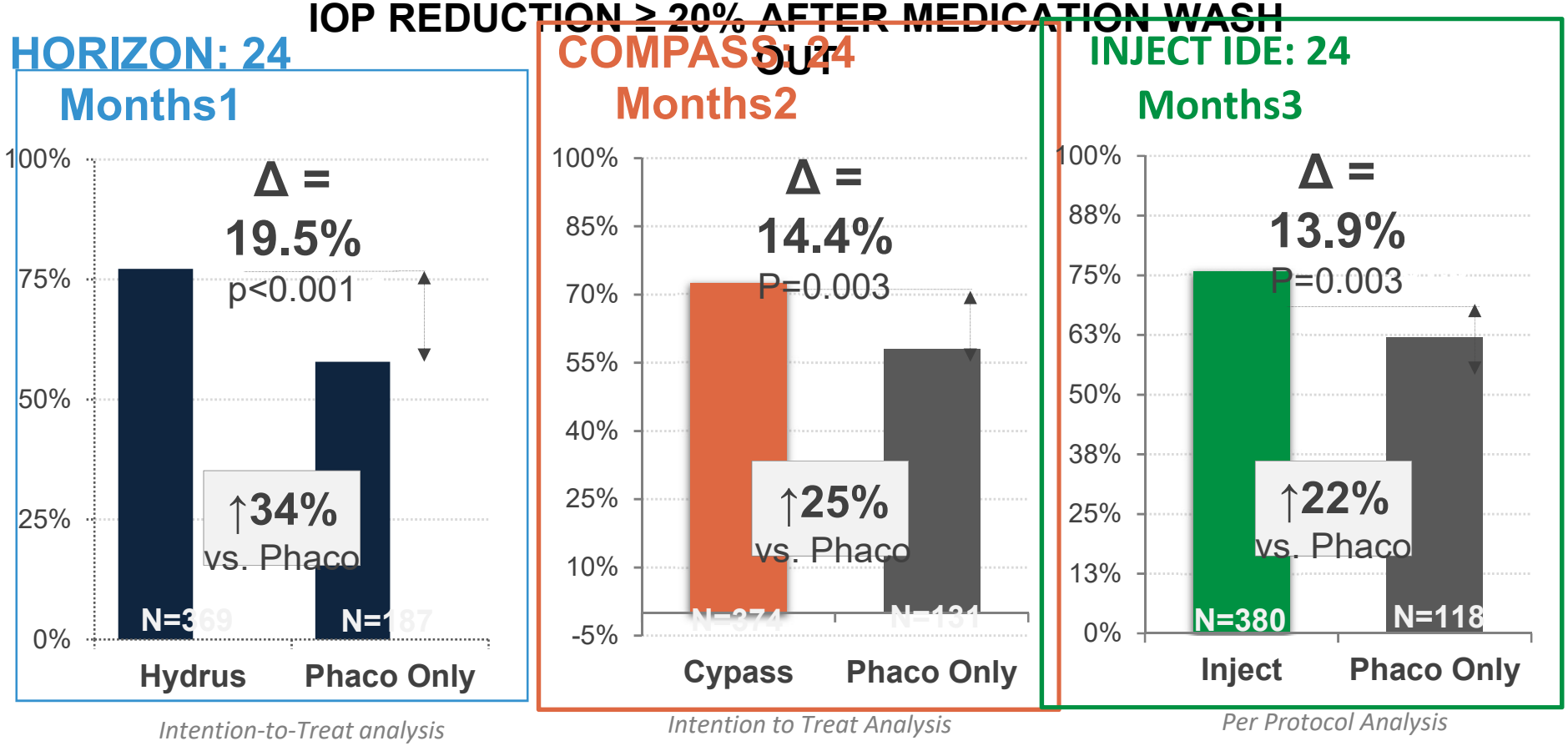
- Flexible canal “scaffold”
- Composed of biocompatible alloy (Nitinol)
- Scalloped and open design allows aqueous flow
- 3 clock-hour length targets multiple collector channels

Hydrus



Primary Endpoint Comparison

IOP REDUCTION ≥ 20% AFTER MEDICATION WASH OUT



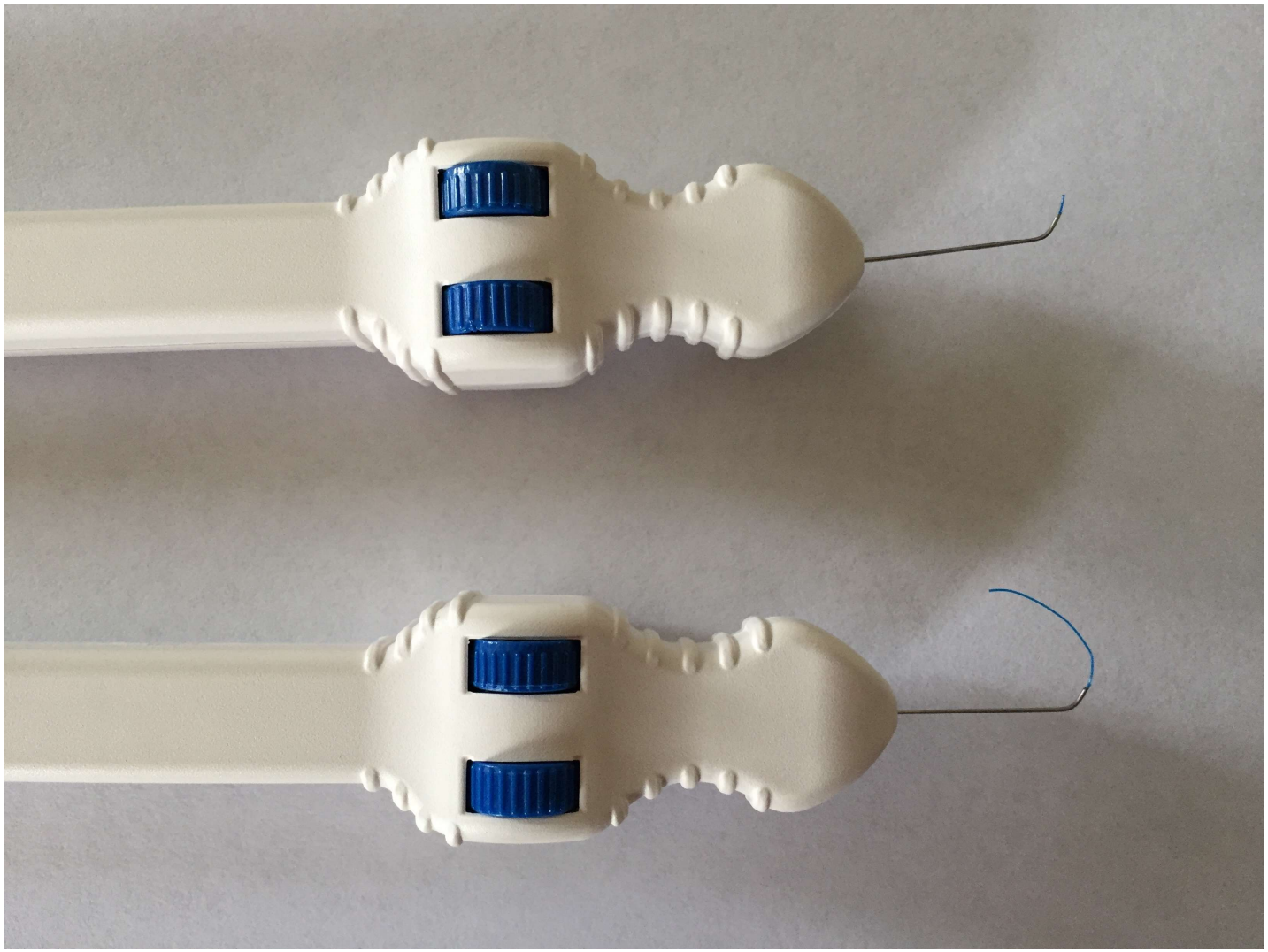
Intention-to-Treat analysis | *Intention to Treat Analysis* | *Per Protocol Analysis*

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.
2. 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/pdf15/P150037B.pdf. Published July 29, 2016..
3. 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/pdf17/P170043b.pdf. Published June 21, 2018.

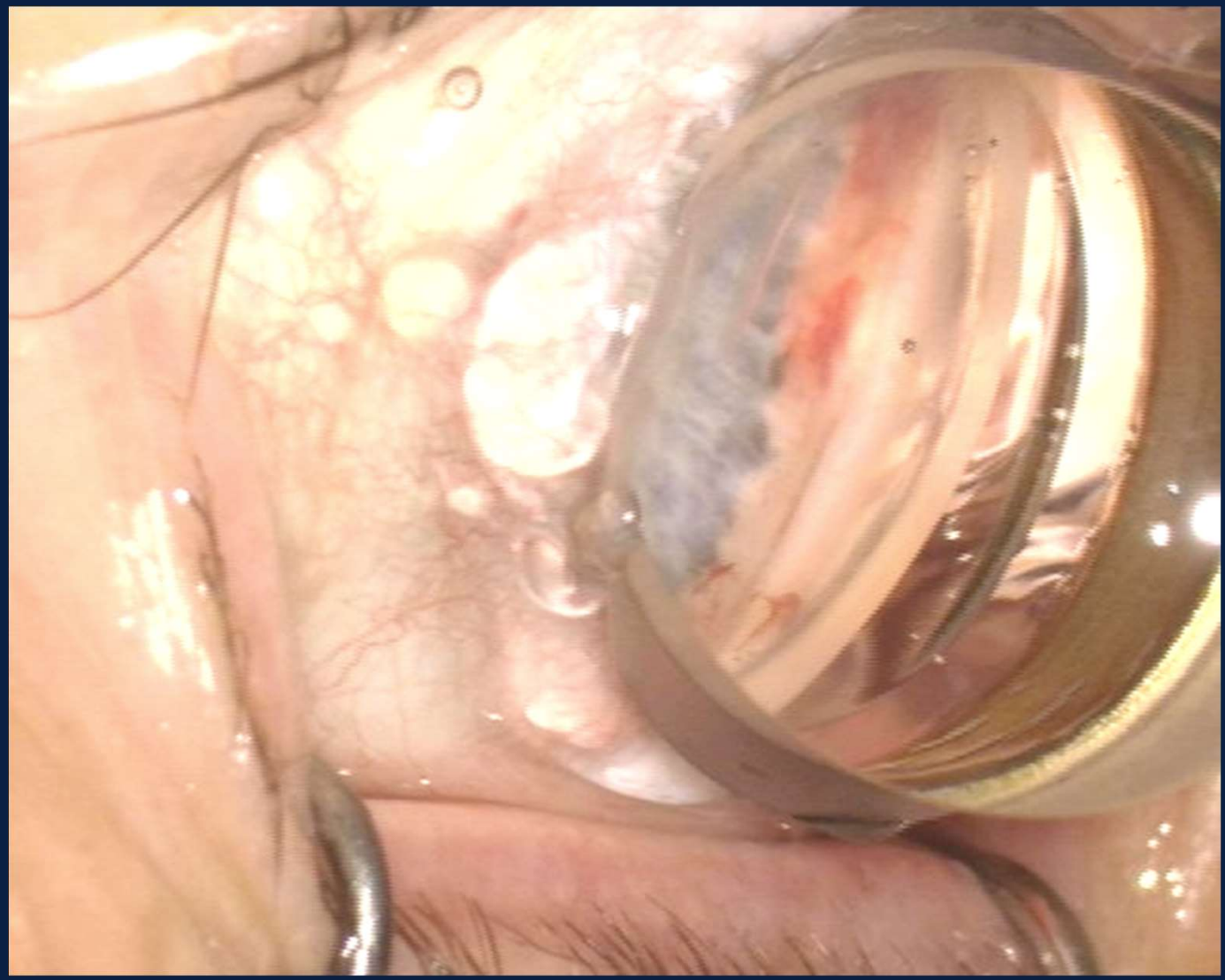
Presense of PAS or synechia

- Possible to place a microbypass but prefer to do can opening procedure to break PAS at same time

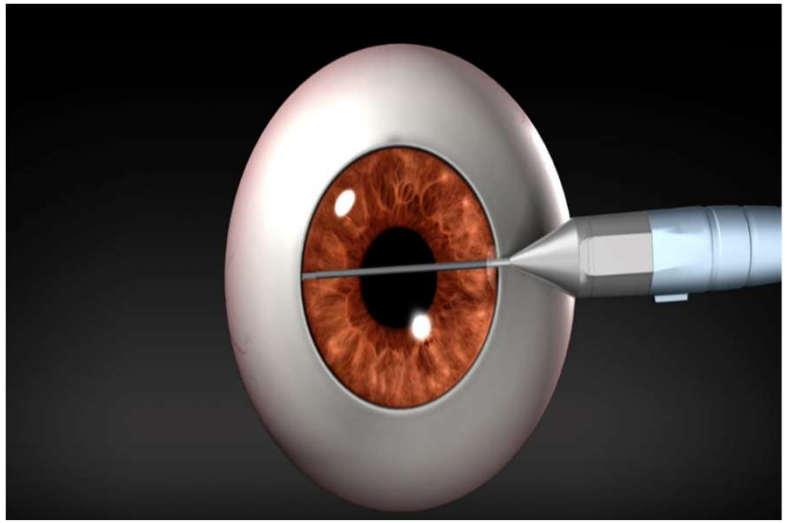
Ab Interno Trabeculotomy (Trab 360)

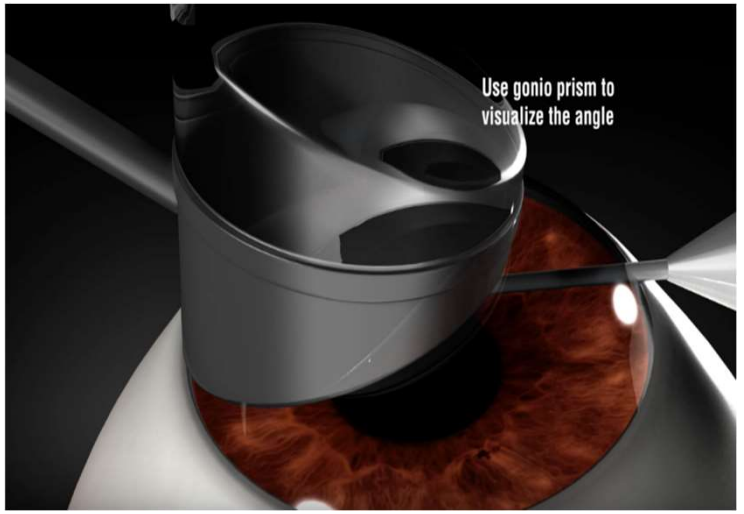


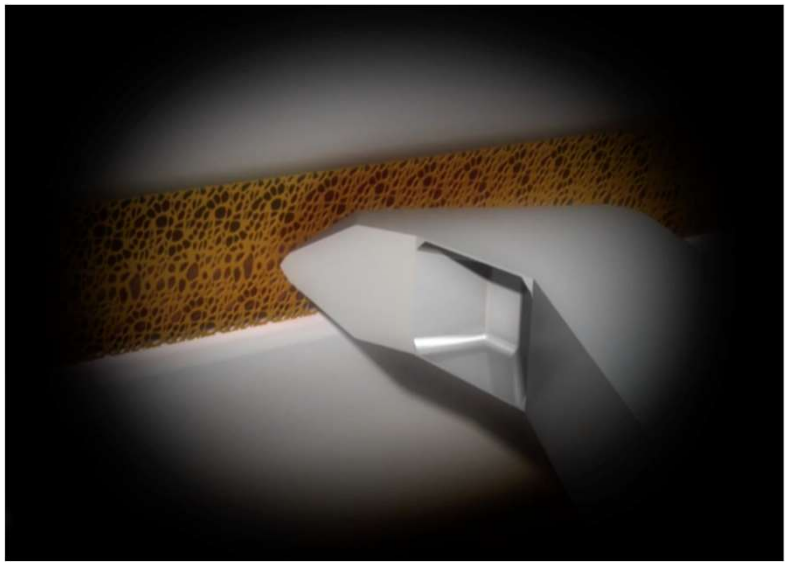
Trab 360

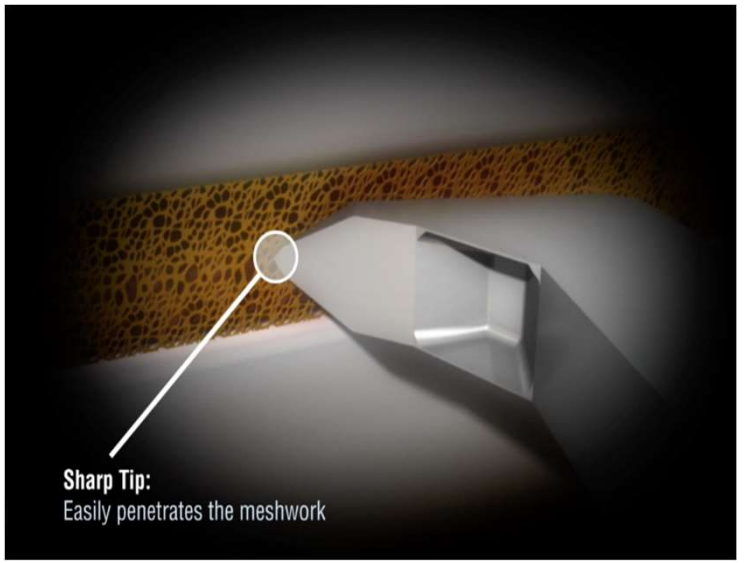


Kahook Dual Blade









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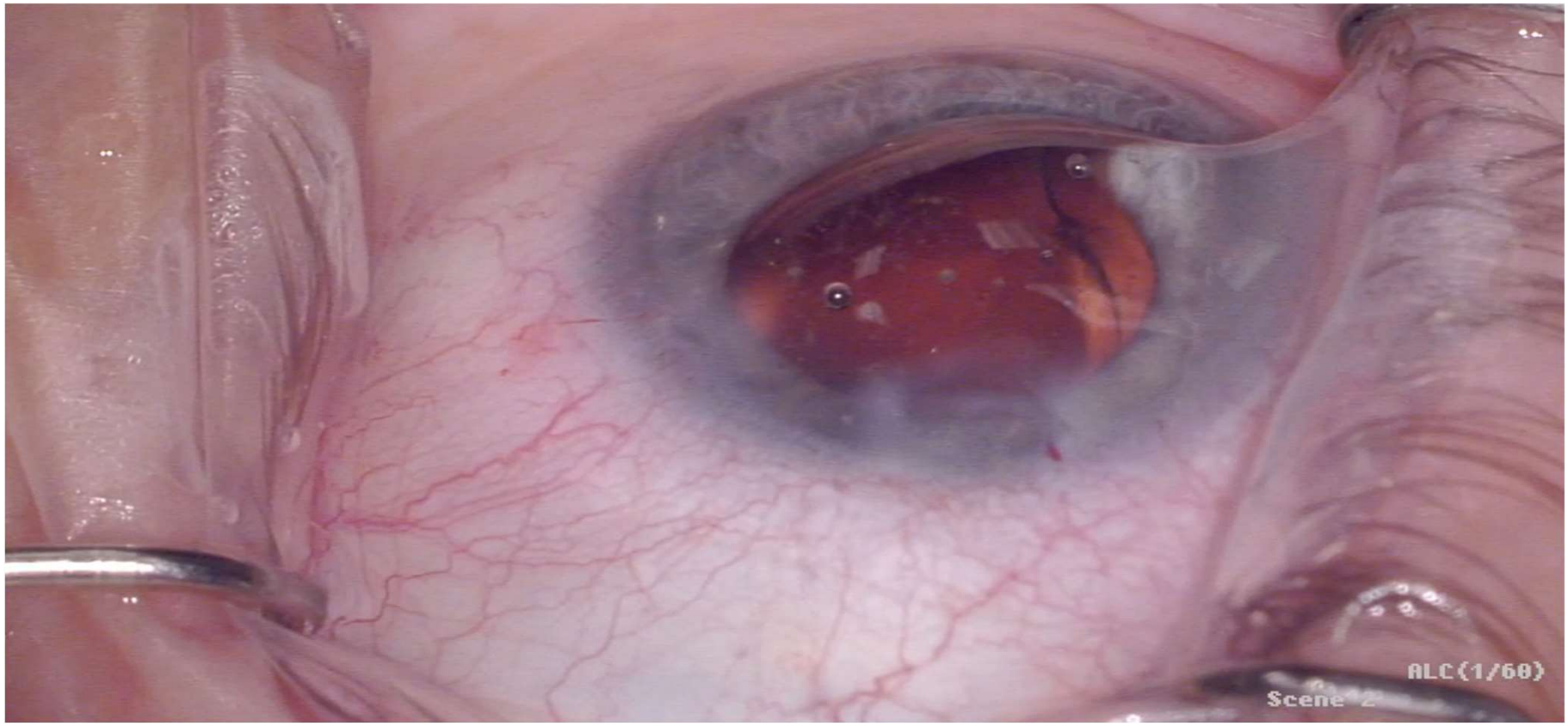


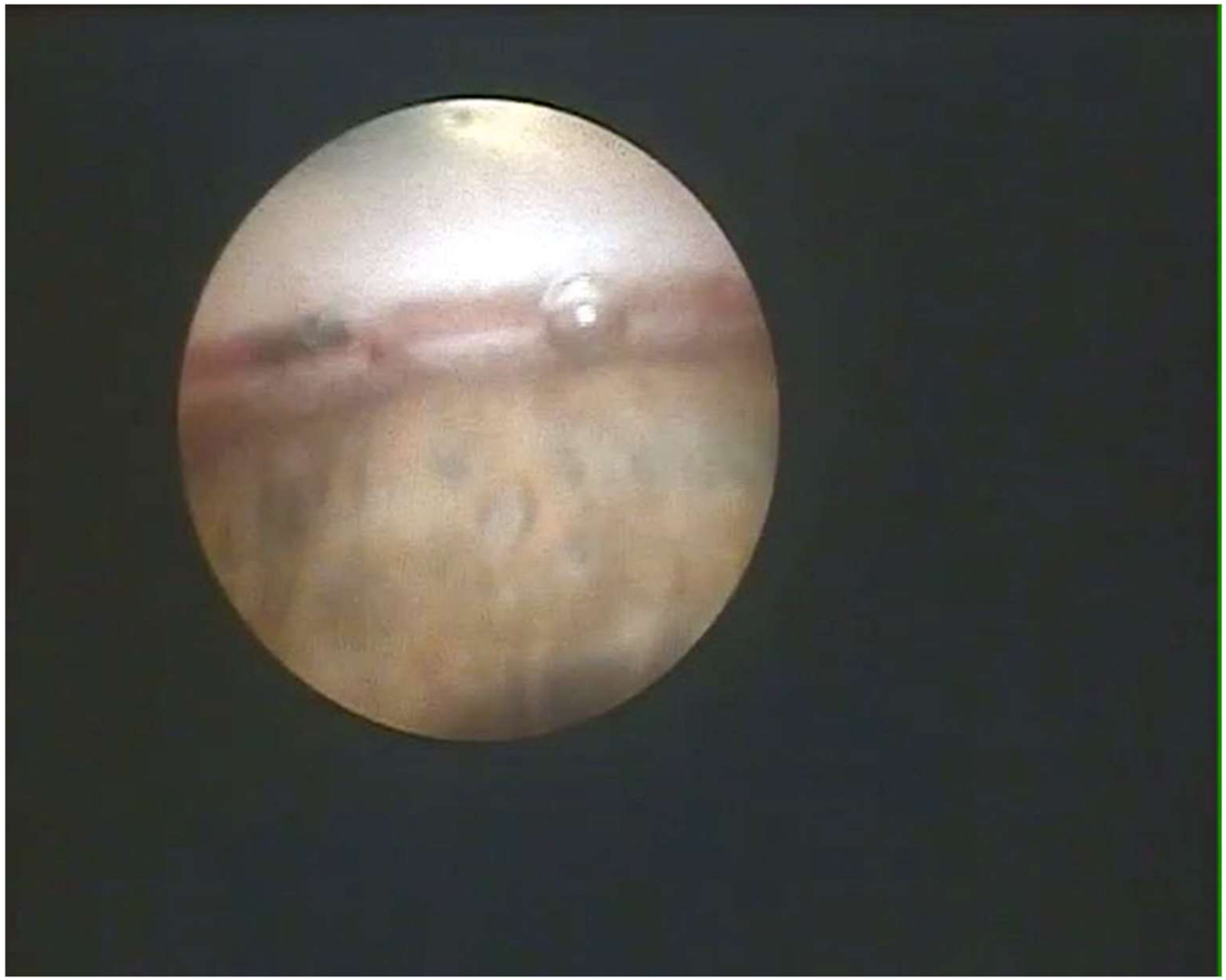
Post – Op Gonio

Courtesy of Leonard K. Seibold, MD

Saftey

- Trabecular microbypass have best safety profile
- Viscodilation tends to be very benign
- Goniotomy procedures tend to bleed but have better IOP lowering
- Cyclophotocoagulation can cause inflammation
- Conjunctival procedures tend to have inflammation and possibility of hypotony

Istent placed



Excellent Safety Profile Through 2 Years*[1,2]

Event	iStent + Cataract Surgery (N=116)	Cataract Surgery Only (N=117)
Any BCVA loss ≥ 1 line ≥ 3 months	7%	10%
Posterior capsular opacification	6%	10%
Elevated IOP	4%	7%
Elevated IOP - other	3%	4%
Elevated IOP req'g treatment with oral or IV meds or with surgical intervention	1%	3%
Stent obstruction	4%	0%
Blurry vision or visual disturbance	3%	7%
Stent malposition	3%	0%
Iritis	1%	5%
Conjunctival irritation due to hypotensive meds	1%	3%
Disc hemorrhage	1%	3%

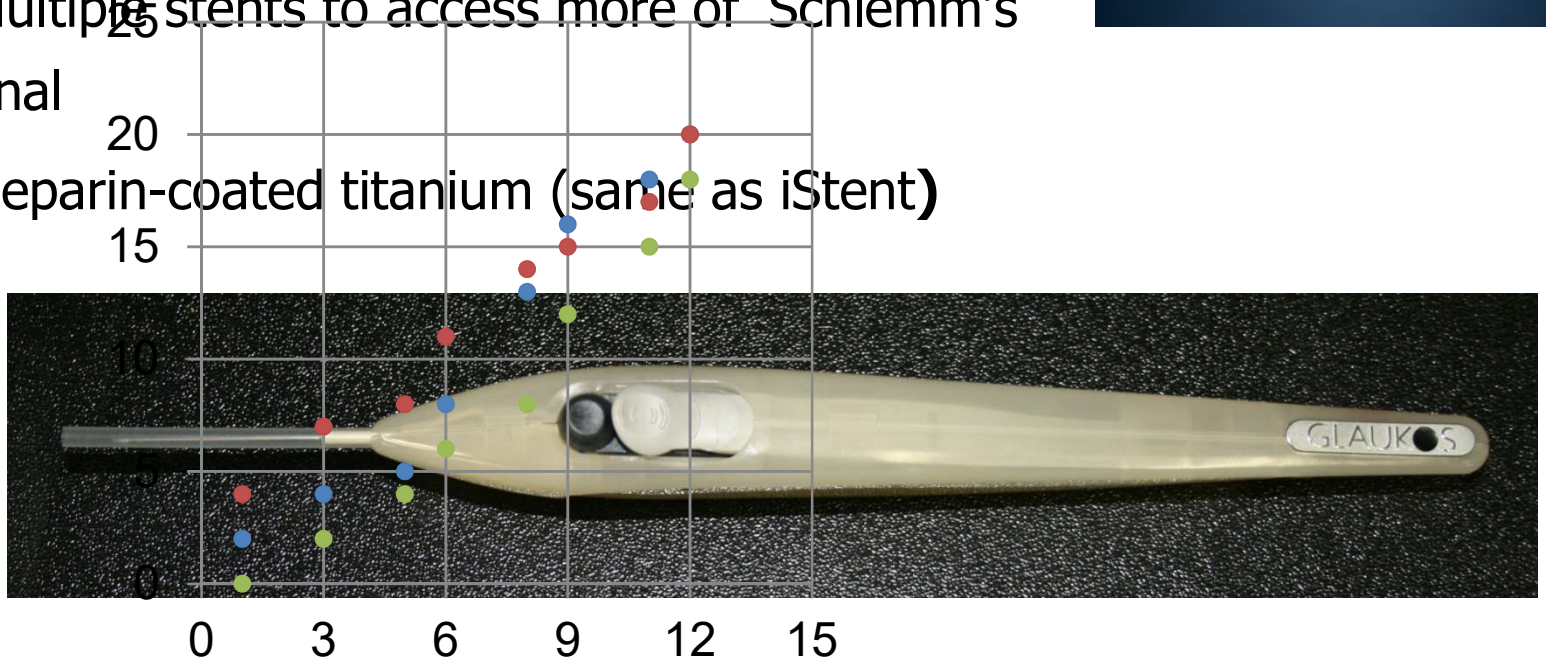
* Postoperative Ocular Adverse Events Occurring ≥ 3 in Either Group

1. Myers, J, et al. 2011 AGS
2. Craven ER, et al. 2011 ASCRS

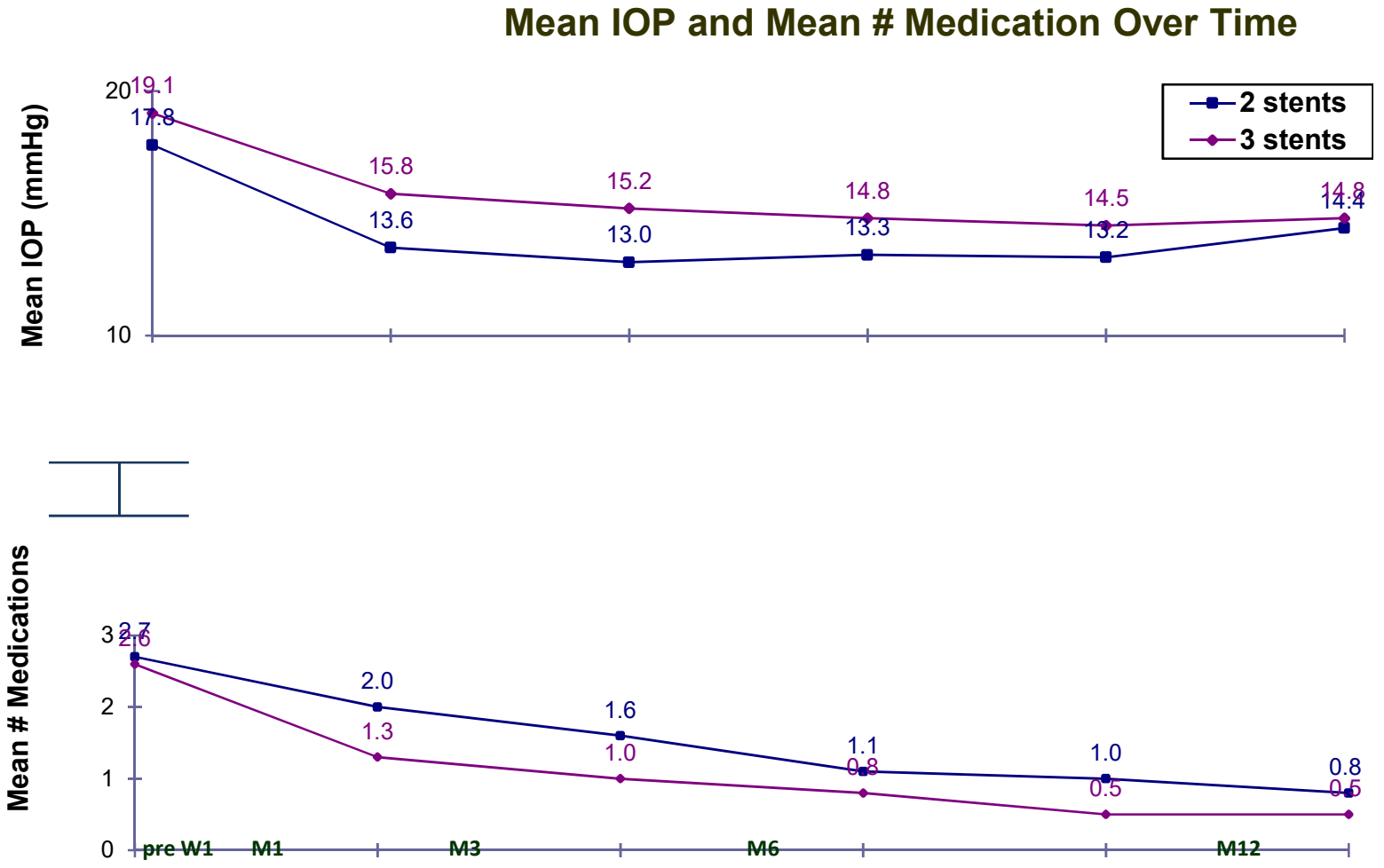
Second Generation Trabecular Microbypass

Second generation product
built on clinical/surgical foundation of
>1500 iStent procedures

- Small incision: minimal trauma
- Multiple stents to access more of Schlemm's canal
- Heparin-coated titanium (same as iStent)



Multiple Trabecular Bypass in Combined Phaco[5]

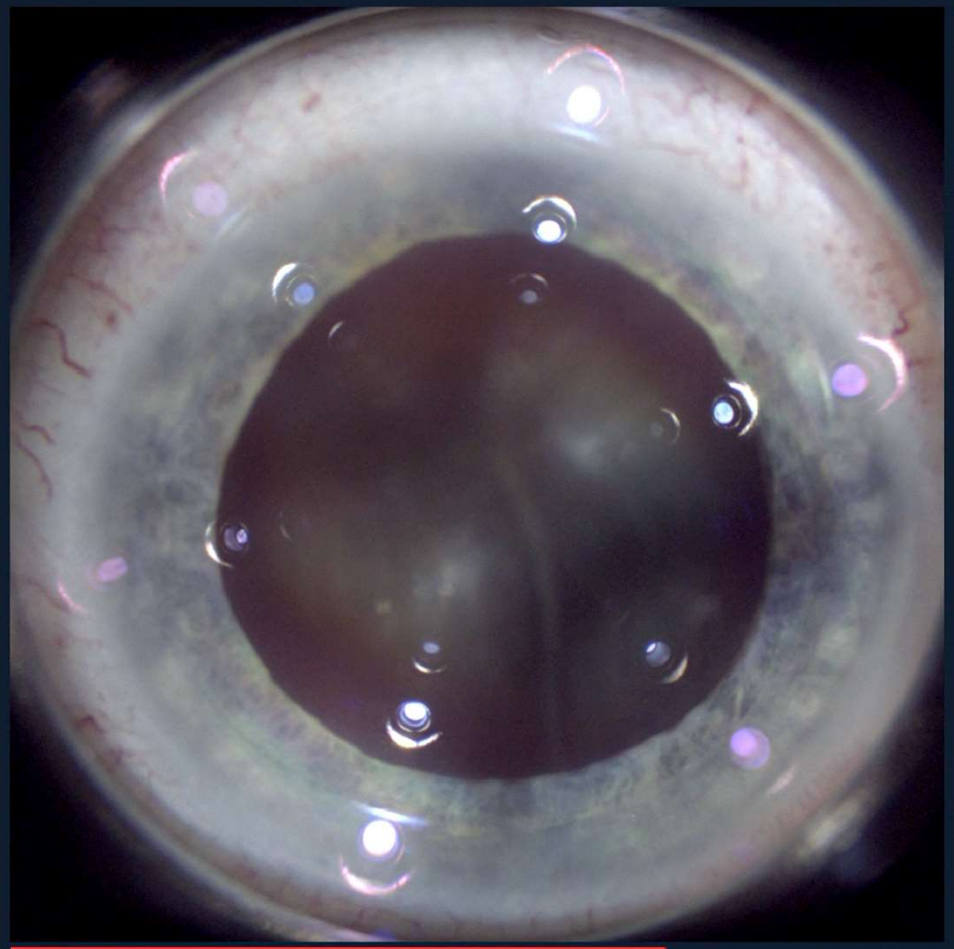


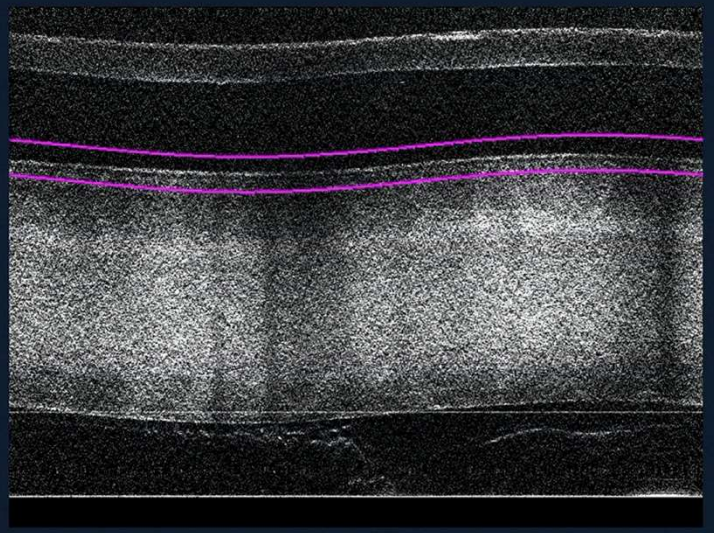
5. Ahmed, et al. AGS 2010

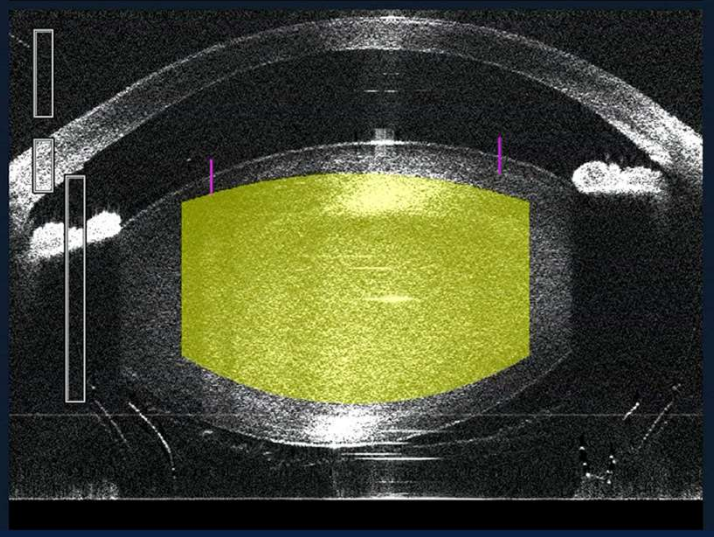
Consider Visual Outcomes

- Combining MIGS with Cataract Surgery

A282 R2.30 01168





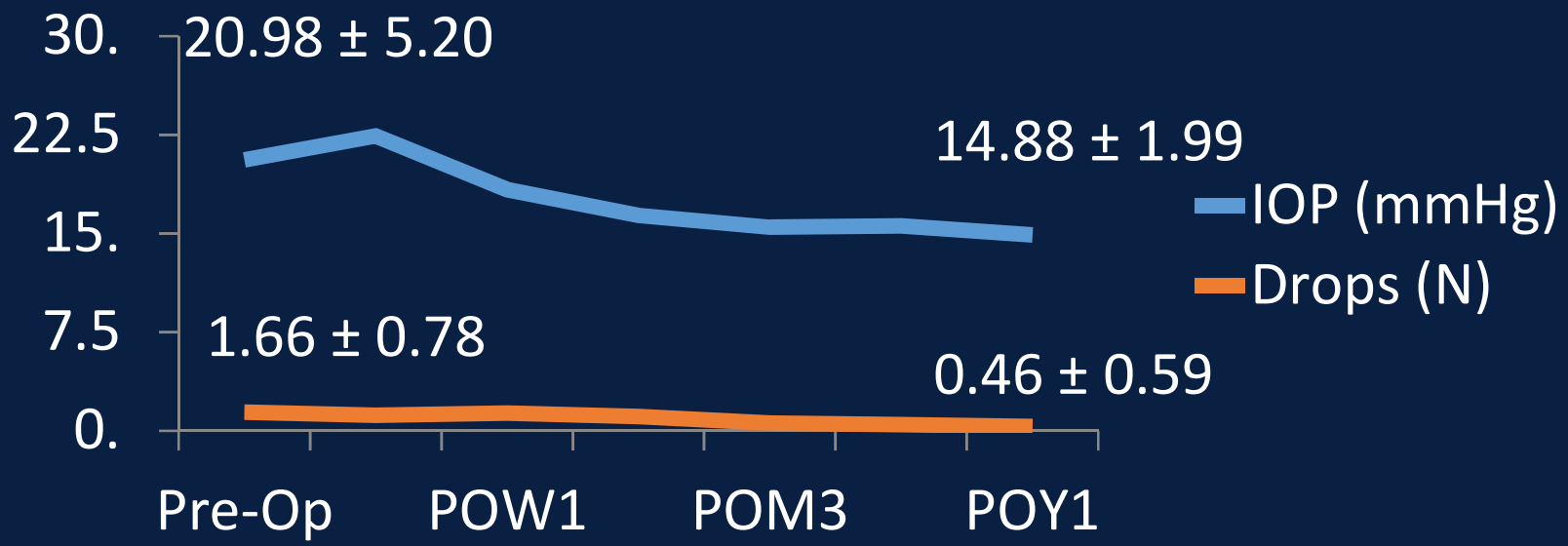


LASER RADIATION

LASER EMISSION

OMNI Femto

- 6.1 mmHg (31.1%) reduction in IOP (p=0.03) and 1.2 med reduction (p<0.001) at 1 year



Yale

No problem with visual outcome of cataract surgery

- Minimal impact on vision and refractive outcome
  - Pre-op LogMAR: 0.33 ± 0.25
  - Post-op LogMAR: 0.12 ± 0.17
  - -0.15 ± 0.7 D difference from predicted
    - IOL Calculation – Spherical Eq.
- Need for more prolonged use of anti-inflammatory medications
  - 4.20 ± 2.58 weeks

OMNI Femto

Complications	N (%)
Hypotony	0
Hyphema	16 (42%)
Choroidal detachment	0
Early Corneal Edema	8 (24%)
Endophthalmitis	0

- There was minimal effect on visual acuity (p=0.37)
  - Pre-op: 0.24 ± 0.18
  - POM 6: 0.19 ± 0.20

Yale

Case Report

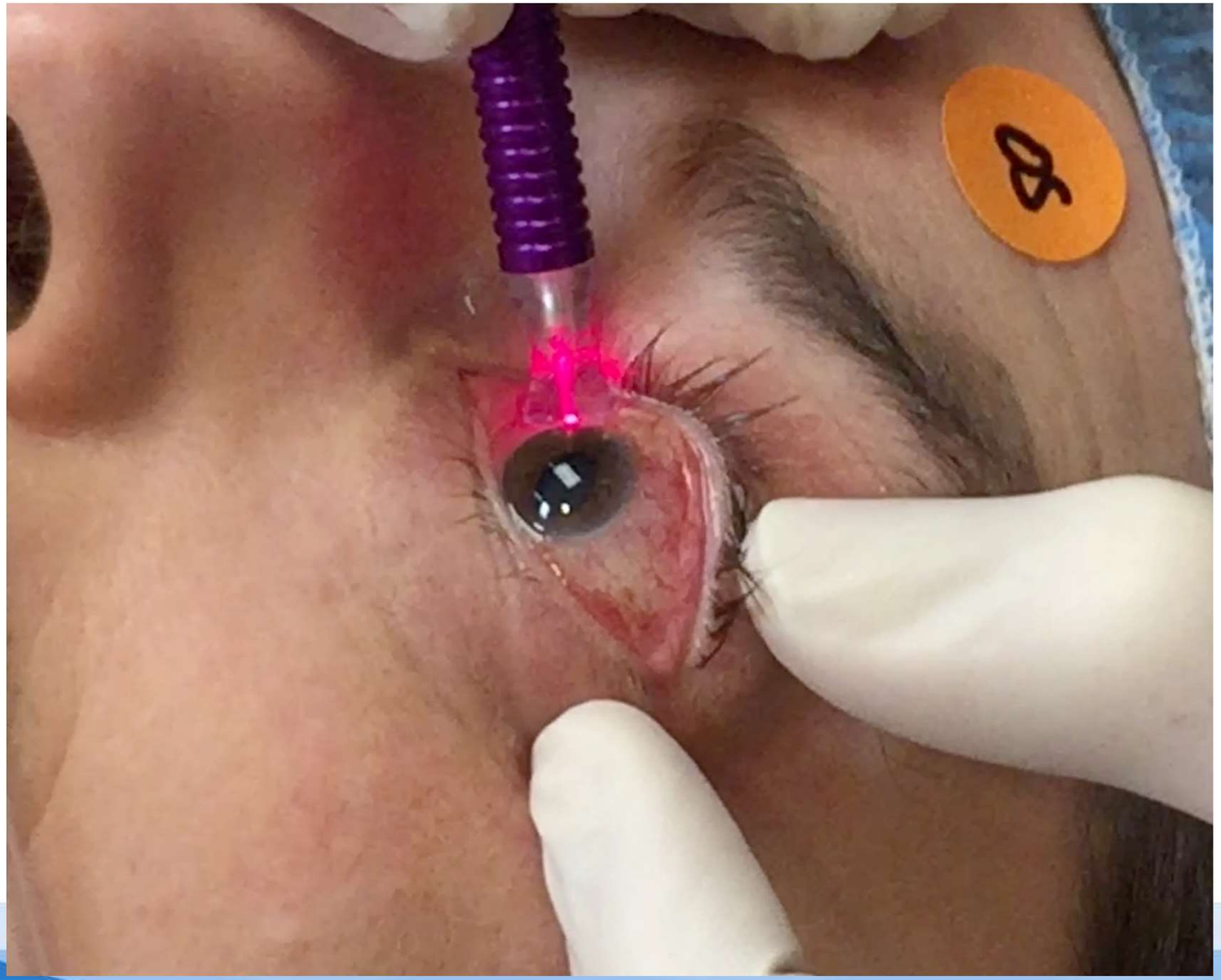
- 65 year old male sp CRVO in right eye.
- Treated by retina with PRP and anti- VEGF
- Va 20/80 right eye, 20/20 left
- IOP 40 right eye on maximal meds including diamox
- Treated with MicroPulse P3 in office (with block)
- IOP 10, no pain no change in vision
- 2 post-op visits – sent back to referring MD

Micropulse treatment

Case 2

- 78 year old woman with PXG right eye
- IOP 38 on 3 meds - recent loss of IOP control
- VA 20/40 right eye with significant visual field loss right eye; VA 20/25 left eye with mild loss
- MicroPulse P3 treatment done in OR with sedation
- Transient low IOP of 6-10 mm Hg for 1-2 weeks; treated with Durezol
- Final IOP at 12 weeks 15 mm Hg on no meds

Micropulse Treatment



Conclusions

- There are many options available now and in the near future for patients needing surgical IOP lowering
- Newer MIGS procedures are aimed at maintaining low risk profiles while providing used friendly techniques that produce good efficacy
- These procedures appear to be reasonable options for patients with earlier and less severe disease

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