

Achieving Success in Today's World of Glaucoma Surgery

Ahmad A. Aref, MD, MBA

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Illinois Eye
AND EAR INFIRMARY



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Disclosures

New World Medical, C

Aerie Pharmaceuticals, S



Disease
Stage?

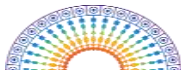
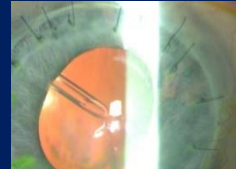
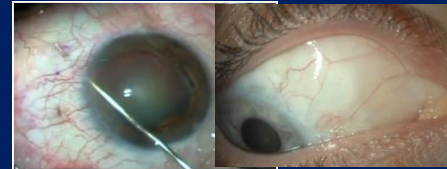
POAG?

Filtration
Surgery

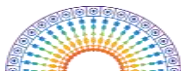
Assess Risk for Subconjunctival
Fibrosis

HIGH

ECP



Trabeculectomy



MMC Sponge Application versus Injection



Treatment Outcomes of Mitomycin C-Augmented Trabeculectomy, Sub-Tenon Injection versus Soaked Sponges, after 3 Years of Follow-up

A Randomized Clinical Trial

Hamed Esfandiari, MD,^{1,2} Mohammad Pakravan, MD,³ Shahin Yazdani, MD,⁴ Azadeh Doozandeh, MD,¹ Mehdi Yaseri, PhD,⁵ Ian P. Conner, MD, PhD²

- 82 consecutive patients randomized to MMC injection vs. sponges and followed for 3 years post-operatively
- Primary Outcome
 - Surgical Success = IOP > 5 and < 21 mm Hg, IOP reduction $\geq 20\%$, no loss of NLP, no re-op
- Secondary Outcomes
 - IOP, # gtts, BCVA, Complications, Endothelial Cell Count Changes, Bleb Appearance

Esfandiari H, et al. *Ophthalmology Glaucoma* 2018;1:66-74.



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- Similar cumulative probabilities of success at 3-years (72.2% vs. 65.1% in injection versus sponge groups, $P=.30$)
- Similar post-op IOPs (15.3 ± 3.7 vs. 16.4 ± 3.5 , respectively, $P=0.54$)
- More diffuse, less vascularized, and more shallow blebs in injection group

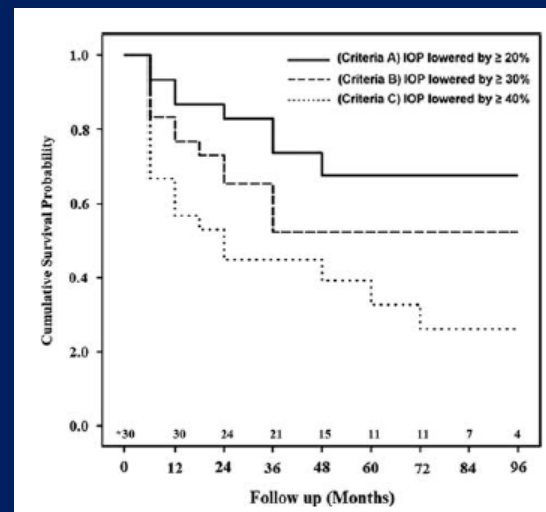
Esfandiari H, et al. *Ophthalmology Glaucoma* 2018;1:66-74.



Safety And Efficacy Of Achieving Single-Digit Intraocular Pressure Targets With Filtration Surgery In Eyes With Progressive Normal-Tension Glaucoma

*Scott K. Schultz, MD, Shawn M. Iverson, DO, Wei Shi, MS,
and David S. Greenfield, MD*

- Retrospective review of 30 eyes of 28 NTG patients with follow-up of 50.3 ± 30.8 mos after trabeculectomy
- Mean pre-op IOP = 13.3 ± 1.4 mmHg
- Mean post-op IOP = 8.6 ± 2.9 mmHg

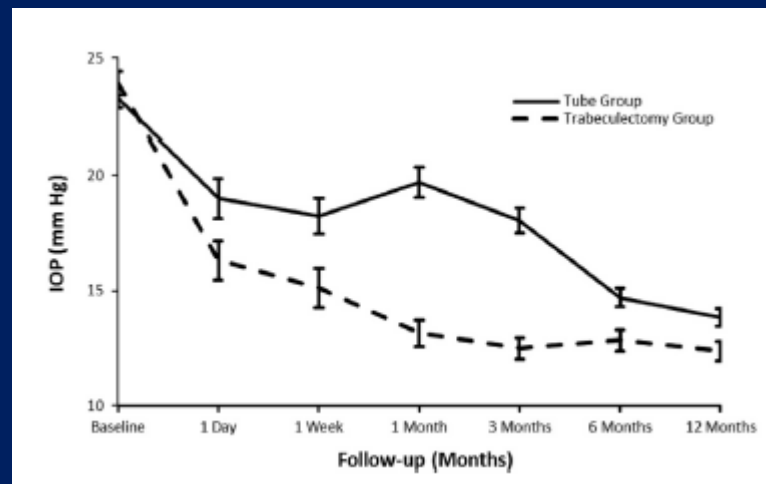
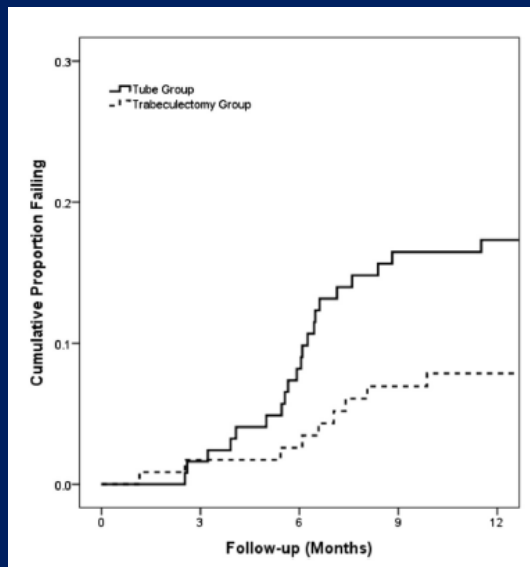


Schultz SK, et al. J Glaucoma 2016; 25:217-222.

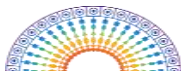


Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 1 Year of Follow-up

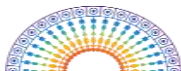
Steven J. Gedde, MD,¹ William J. Feuer, MS,¹ Wei Shi, MS,¹ Kin Sheng Lim, MD,² Keith Barton, MD,³ Saurabh Goyal, MD,⁴ Iqbal I.K. Ahmed, MD,⁵ James Brandt, MD,⁶ for the Primary Tube Versus Trabeculectomy Study Group*



Gedde SJ, et al. Ophthalmology 2018;125:650-663.



Aqueous Shunts

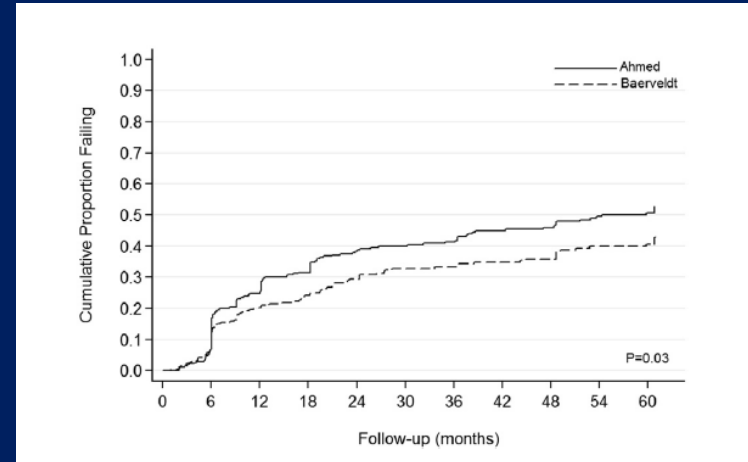


Five-Year Pooled Data Analysis of the Ahmed Baerveldt Comparison Study and the Ahmed Versus Baerveldt Study



PANOS G. CHRISTAKIS, DONGYU ZHANG, DONALD L. BUDENZ, KEITH BARTON, JAMES C. TSAI, AND
IQBAL I.K. AHMED, FOR THE ABC-AVB STUDY GROUPS

- Cumulative proportion failing, $p=.01$
 - AGV \rightarrow 49%
 - BGI \rightarrow 37%



Christakis PG, et al. Am J Ophthalmol 2017;
176:118-126.



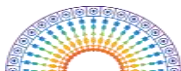
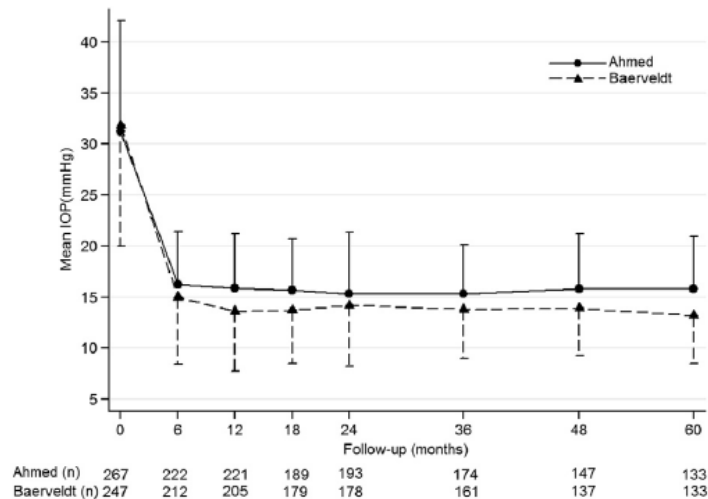
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Pooled AVB-ABC Study, IOP Results

- Mean IOPs, $p < .001$
 - AGV: $31.2 \pm 10.9 \rightarrow 15.8 \pm 5.2$
 - BGI: $31.8 \pm 11.8 \rightarrow 13.2 \pm 4.8$



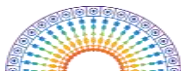
Pooled AVB-ABC Study, Reasons for Failure

TABLE 4. Ahmed Baerveldt Comparison Study and Ahmed Versus Baerveldt Study: Failure Analysis

	Ahmed (N = 267)	Baerveldt (N = 247)	P Value
Overall outcome			
Success	137 (51%)	156 (63%)	.007 ^a
Failure	130 (49%)	91 (37%)	
Reasons for failure			
Hypotony	1 (0.4%)	11 (4%)	.002 ^b
High intraocular pressure	112 (42%)	56 (23%)	<.001 ^a
Severe vision loss	13 (4.9%)	18 (7%)	.25 ^a
Explantation	4 (2%)	6 (2%)	.53 ^b



Risk-Reward



Effect of Early Treatment with Aqueous Suppressants on Ahmed Glaucoma Valve Implantation Outcomes

Mohammad Pakravan, MD,¹ Shahram Salehi Rad, MD,¹ Shahin Yazdani, MD,¹ Elaham Ghahari, MD,¹ Mehdi Yaseri, PhD²

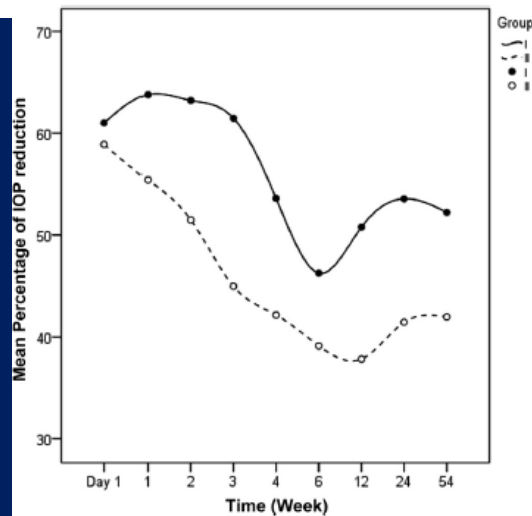
- 47 cases tx'd with timolol/dorzolamide once IOP > 10mm Hg (group 1) vs. 47 cases tx'd with stepwise gtt therapy once IOP > goal (group 2)
- 63.2% vs. 33.3% success rates, respectively, P=0.008, at 1-year

Pakravan M, et al. Ophthalmology 2014; 121:1693-1698.



Effect of Early Treatment with Aqueous Suppressants on Ahmed Glaucoma Valve Implantation Outcomes

Mohammad Pakravan, MD,¹ Shahram Salehi Rad, MD,¹ Shahin Yazdani, MD,¹ Elaham Ghahari, MD,¹ Mehdi Yaseri, PhD²



Pakravan M, et al. Ophthalmology 2014; 121:1693-1698.



MicroInvasive Glaucoma Surgery



MIGS Definition



Micro-invasive glaucoma surgery: current perspectives and future directions

Hady Saheb^{a,b} and Iqbal Ike K. Ahmed^{a,c}

Ab interno microincision

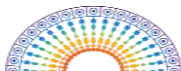
Minimal trauma

Modest Efficacy

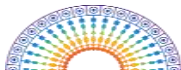
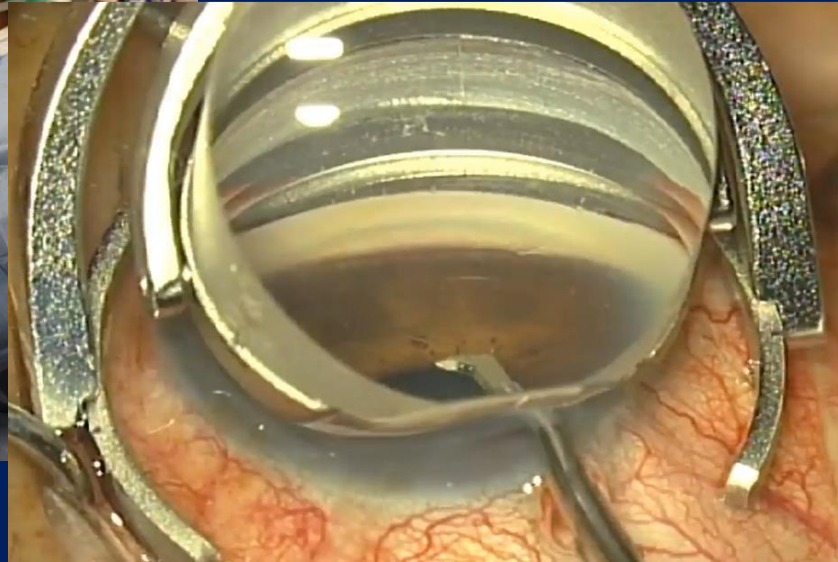
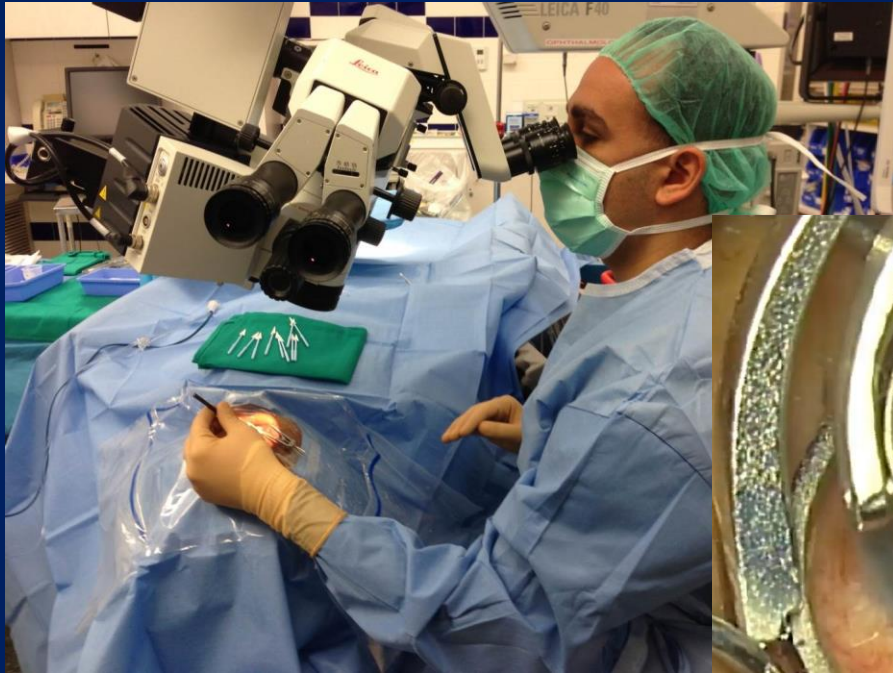
High Safety Profile

Rapid Recovery

Saheb H, Ahmed II. Curr Opin Ophthalmol 2012;23:96-104.

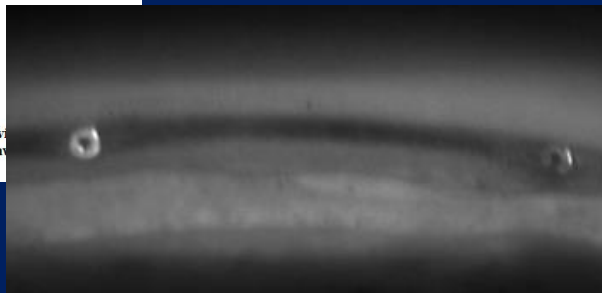
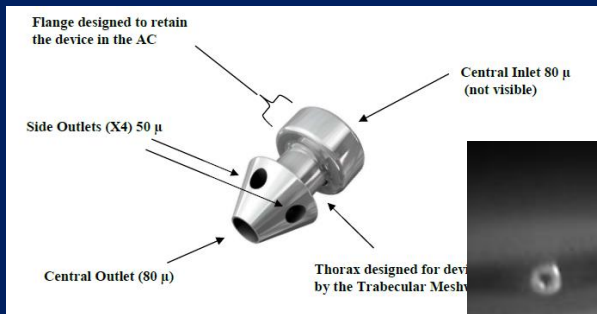


Visualization is Key!



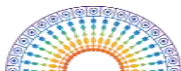
iStent Inject

- FDA approved for combination with cataract surgery in mild to moderate stages of primary open-angle glaucoma in June 2018

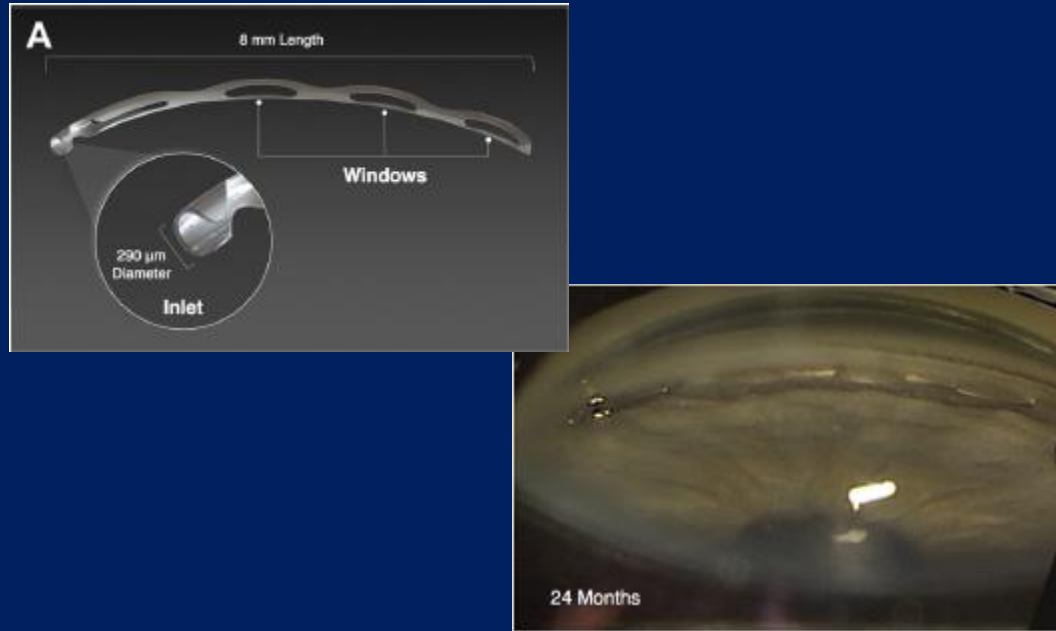


SSED, available at [FDA.gov](https://www.fda.gov).

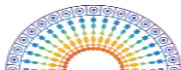
Larsen CL, et al. Surv Ophthalmol 2017; 706-711.



Hydrus Microstent



Samuelson TW, et al. Ophthalmology 2018. Epub Ahead of Print.



For Old Time's Sake



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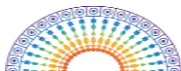
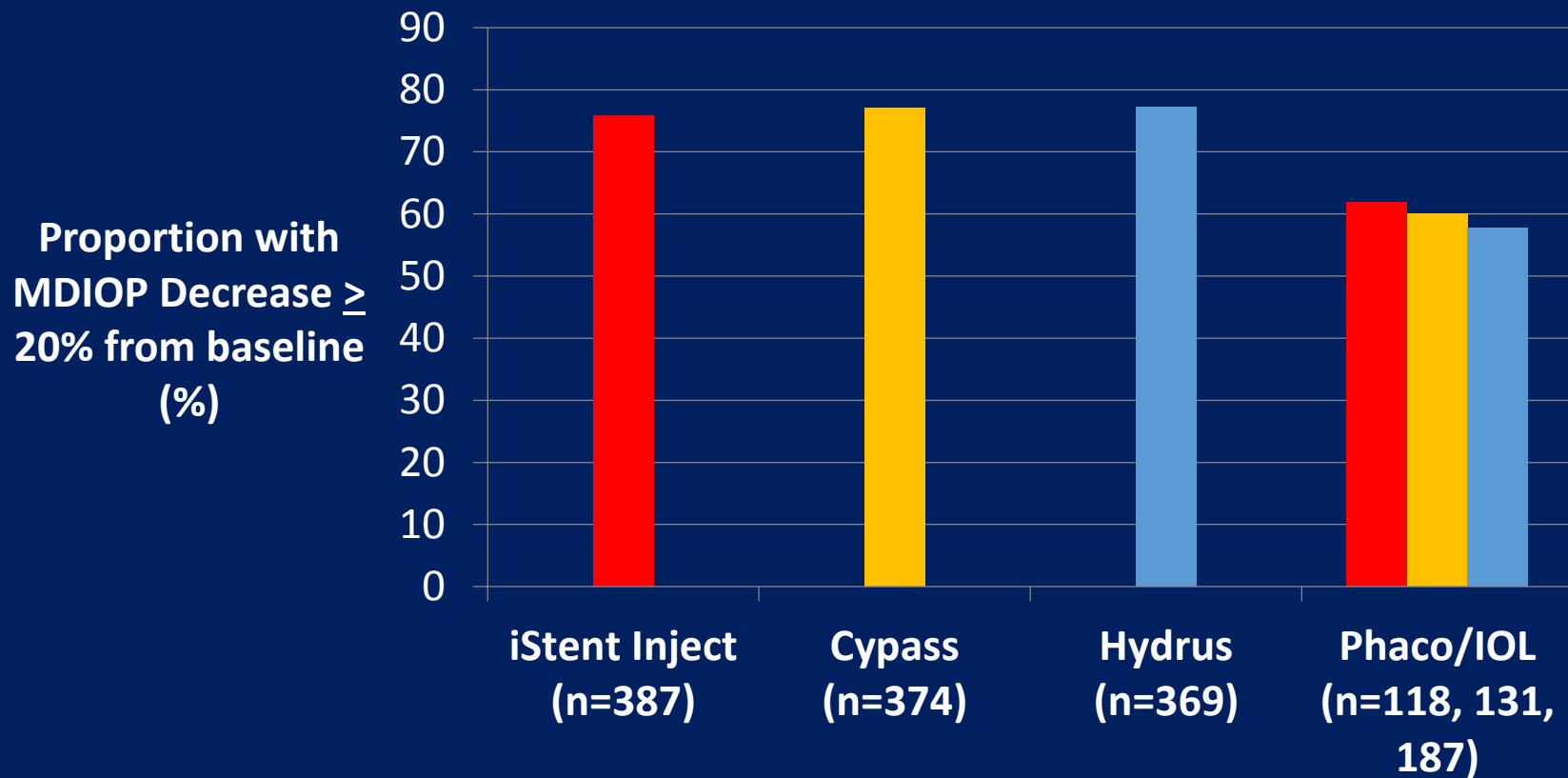
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MIGS Efficacy Outcome Measures

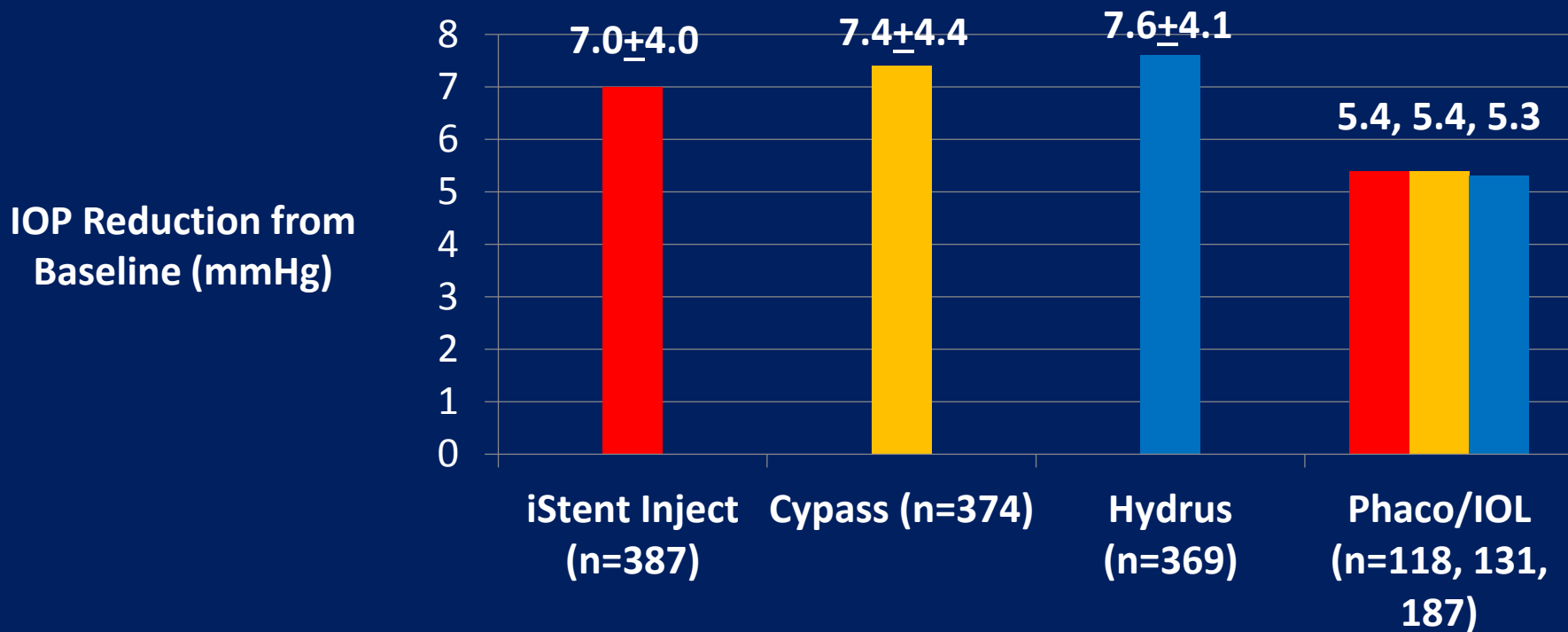
- 1) Percentage of subjects achieving $\geq 20\%$ reduction in unmedicated mean diurnal IOP (MDIOP) versus baseline
 - Medication washout at baseline AND at 2-year follow-up visit
- 2) Mean unmedicated IOP reduction



MIGS Efficacy Summary – Outcome 1, 24 mo

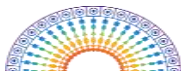
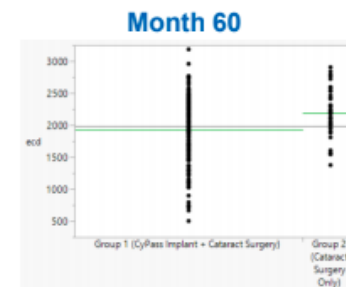
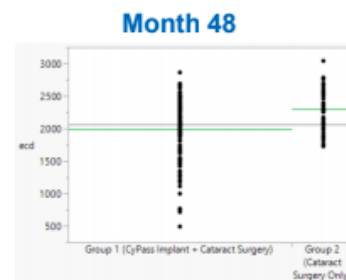
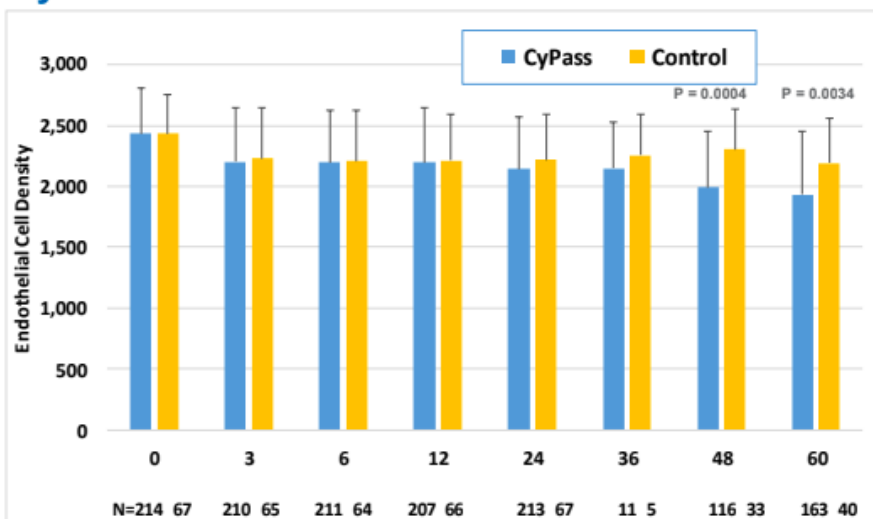


MIGS Efficacy Summary – Outcome 2, 24mo



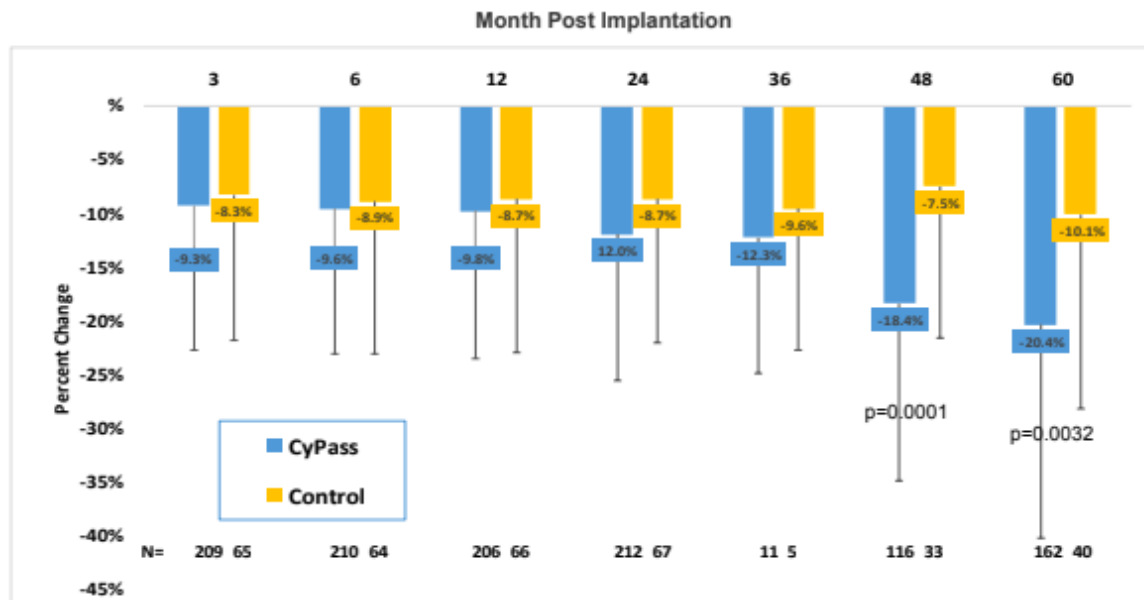
Cypass & Endothelial Health

Statistically Significant Difference in ECD between CyPass and Control at Months 48 and 60



Cypass & Endothelial Health

Statistically Significant Difference in ECL between CyPass and Control at Months 48 and 60



Cypass Device Recall

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2999

Alcon Novartis

August 29, 2018

Dear Colleagues,

Today, Alcon announced an immediate, voluntary market withdrawal of all versions of the CyPass® Micro-Stent from the global market.

This market action is not related to a manufacturing or quality issue. Rather, we are undertaking this action based on an analysis of the completed dataset from the COMPASS-XT long-term safety study. That analysis showed that, over time, the CyPass® Micro-Stent group experienced statistically significant endothelial cell loss (ECL) compared to the group who underwent cataract surgery alone.

By way of background, the two-year COMPASS study that served as a basis for FDA approval of the CyPass® Micro-Stent included an evaluation of ECL. As noted in the COMPASS-XT long-term safety study, there was little difference in ECL between the CyPass® Micro-Stent and cataract surgery-only groups (ECL) compared to the group who underwent cataract surgery alone.

The COMPASS-XT study was designed to collect safety data on the subjects who participated in the COMPASS study for an additional three years, with analysis of the completed dataset at five years post-surgery. At five years, the CyPass® Micro-Stent group experienced statistically significant ECL compared to the group who underwent cataract surgery alone. Specifically, ECL increased in relation to the number of retention rings noted on clinical examination with gonioscopy, particularly when two or more retention rings were visible.

Based on this new information, we are advising surgeons to immediately cease further implants with the CyPass® Micro-Stent and to return any unused devices to Alcon. Our Quality group will be communicating directly with CyPass® Micro-Stent implanters with instructions for returning unused devices, and recommendations for evaluating and managing those patients who have already received a CyPass® Micro-Stent.

Although we are removing the product from the market now or caution, we intend to partner with the FDA and other regulatory agencies to support the reintroduction of the CyPass® Micro-Stent.

We recognize the inconvenience this causes you, your staff and changes that would support the reintroduction of the CyPass® Micro-Stent.

Please contact the following Alcon departments if you have questions about this communication, or if you would like to report product complaints or adverse events:

Customer Service	1-800-862-5266	for assistance with product returns
Medical Information	1-800-757-9765	for medical information on the CyPass® Micro-Stent
Medical Safety	1-800-757-9765	to report product complaints or adverse events

Kind regards,

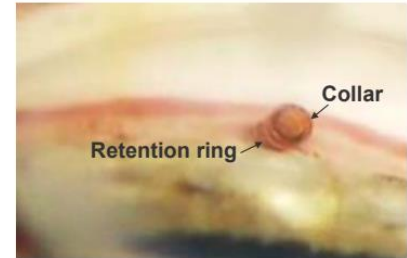
Stephen S. Lane, MD

Stephen S. Lane, MD
Chief Medical Officer

Example of CyPass MicroStent Position



3 rings



1 ring



Recommendations

- If more than 1 ring visible and corneal decompensation → trim proximal end
- Do not attempt removal/repositioning
- If no clinical sequelae to > 1 ring → monitor

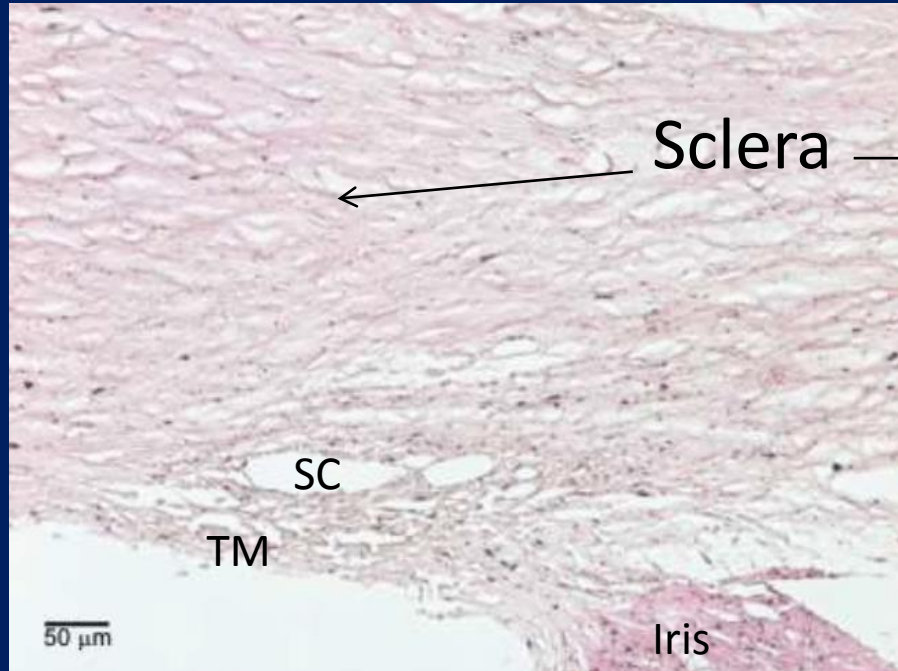


Kahook Dual Blade

Courtesy of Leo Seibold, MD
University of Colorado



Control

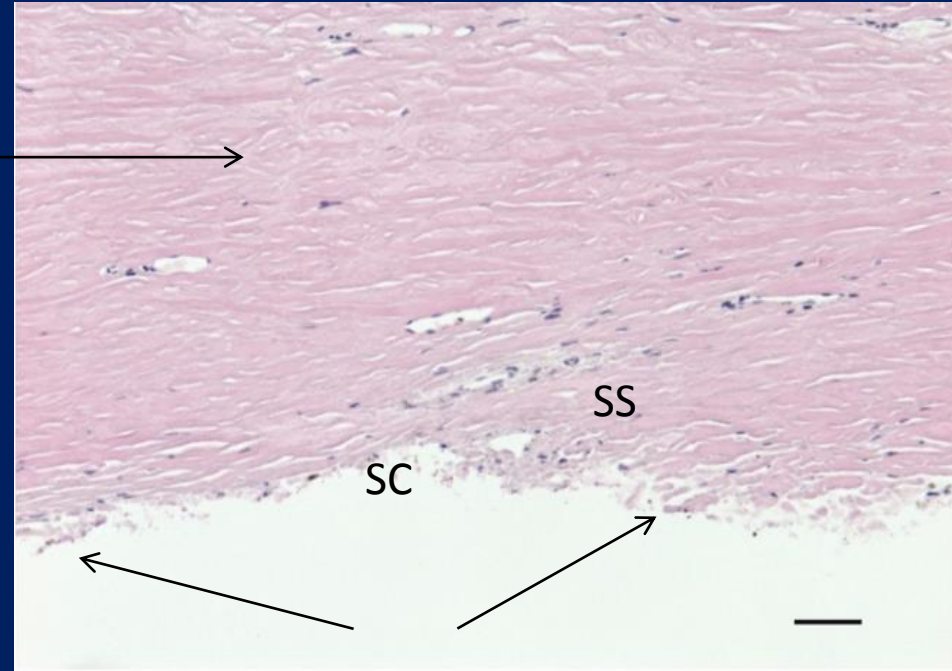


SC = Canal of Schlemm

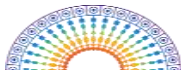
TM = Trabecular Meshwork

SS = Scleral Spur

KDB



Source: NWM Sponsored Study at Univ. of Colorado



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Outcomes of Kahook Dual Blade Goniotomy with and without Phacoemulsification Cataract Extraction

Erin G. Sieck, MD,¹ Rebecca S. Epstein, MD,¹ Jeffrey B. Kennedy, MD,¹ Jeffrey R. SooHoo, MD,¹ Mina B. Pantcheva, MD,¹ Jennifer L. Patnaik, PhD,¹ Brandie D. Wagner, PhD,^{1,2} Anne M. Lynch, MD,¹ Malik Y. Kahook, MD,¹ Leonard K. Seibold, MD¹

- Retrospective Review of standalone KDB goniotomy (n=32) vs. KDB/Phaco (n=165)
- Success = IOP reduction $\geq 20\%$ and/or reduction of 1 gtt
- At 12 mo
 - 68.8% and 71.8% success rates (84.6% in PXF)
 - IOP/gtt reductions
 - 20.4 ± 1.3 on $3.1 \pm .2$ gtts $\rightarrow 14.1 \pm .9$ on $2.3 \pm .4$ gtts ($p \leq .01$)
 - 16.7 ± 0.4 on $1.9 \pm .1$ gtts $\rightarrow 13.8 \pm .4$ on $1.5 \pm .1$ gtts ($p \leq .01$)

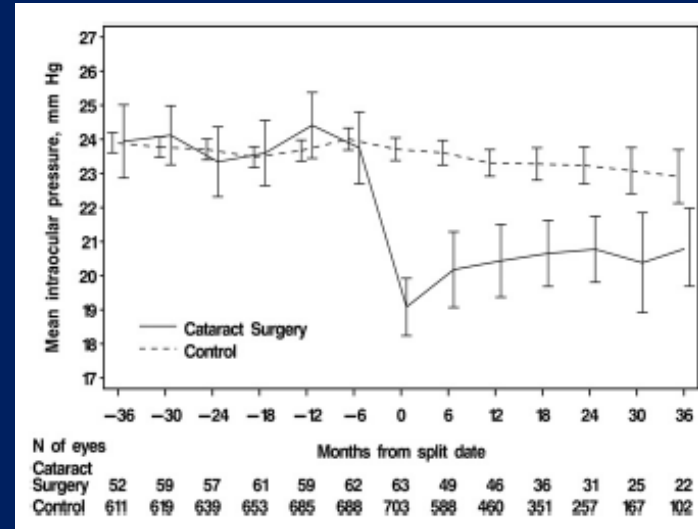
Sieck EG, et al. Ophthalmology Glaucoma 2018; 1:75-81.



Reduction in Intraocular Pressure after Cataract Extraction: The Ocular Hypertension Treatment Study

Steven L. Mansberger, MD, MPH,¹ Mae O. Gordon, PhD,² Henry Jampel, MD, MHS,³ Anjali Bhorade, MD,² James D. Brandt, MD,⁴ Brad Wilson, PhD,³ Michael A. Kass, MD,² for the Ocular Hypertension Treatment Study Group*

- Average 16.5% IOP reduction
- 39.7% with postoperative IOP reduction >20%



GATT Video



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Gonioscopy-assisted Transluminal Trabeculotomy: An Ab Interno Circumferential Trabeculotomy: 24 Months Follow-up

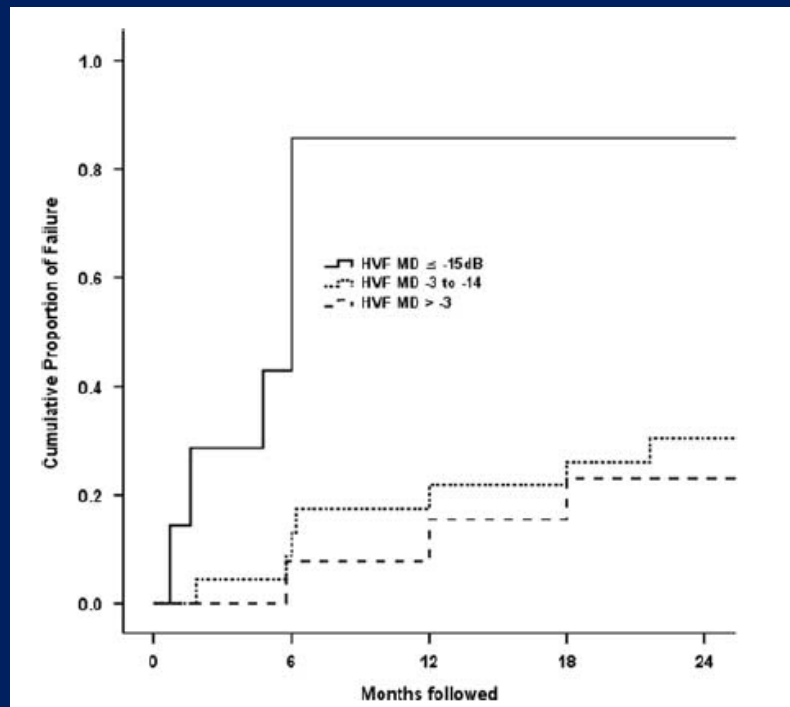
Davinder S. Grover, MD, MPH, Oluwatosin Smith, MD,*
Ronald L. Fellman, MD,* David G. Godfrey, MD,* Aditi Gupta, MD,*
Ildamaris Montes de Oca, MD,† and William J. Feuer, MS‡*

- Retrospective review of 198 adult patients with ≥ 18 months follow-up
- POAG
 - Mean IOP decrease = 9.2 mm Hg (37.3%) at 24 months
- SOAG
 - Mean IOP decrease = 14.1 mm Hg (49.8%) at 24 months
- 9-13% incidence of hyphema

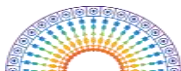
Grover DS, et al. J Glaucoma 2018; 27:393-401.



GATT Results – Advanced Disease



Grover DS, et al. J Glaucoma 2018; 27:393-401.

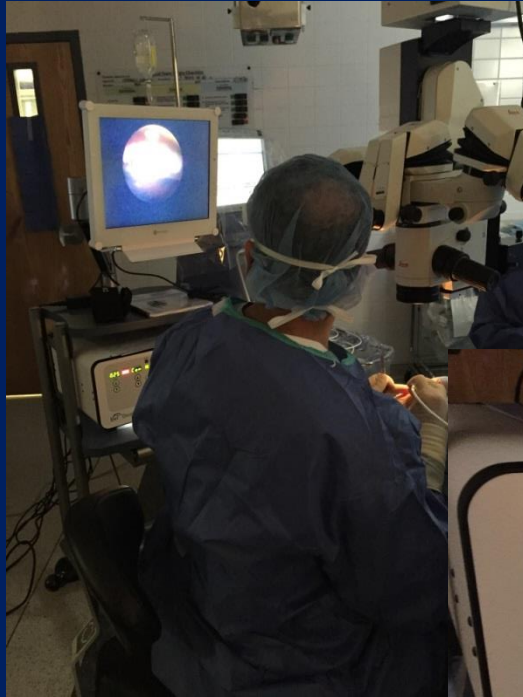


Endoscopic Cyclophotocoagulation

- Endoscopically-guided ablation of ciliary processes
- 810nm diode laser probe combined with video camera and light source
- Developed in 1992 by Uram



Operating Room Logistics



ECP Technique



One-site Versus Two-site Endoscopic Cyclophotocoagulation

Malik Y. Kahook, MD, Kira L. Lathrop, MAMS, and Robert J. Noecker, MD

- 1-Site ECP (n=15)
 - $23.6 \pm 3.89 \rightarrow 16.00 \pm 2.77$ mmHg at 6mo
- 2-Site ECP (n=25)
 - $24.48 \pm 8.99 \rightarrow 13.00 \pm 3.09$ mmHg at 6mo
- $P=0.03$ for IOP difference between 1-site and 2-site ECP

Kahook MY, et al. J Glaucoma 2007; 16:527-530.



ECP Complications

- 5824 eyes, 5.2 years follow-up
 - Cataract (24.5%)
 - Post-operative IOP spike (14.5%)
 - Intraocular hemorrhage (3.8%)
 - CME with vision loss (1.0%)
 - Serous choroidal effusion (0.4%)
 - Retinal detachment (0.3%)
 - Hypotony/phthisis (0.1%)
 - Choroidal hemorrhage (0.1%)

Noecker RJ. Complications of endoscopic cyclophotocoagulation: ECP Collaborative Study Group. ASCRS, 2007, San Diego



Xen Gel Stent



Performance and Safety of a New Ab Interno Gelatin Stent in Refractory Glaucoma at 12 Months



DAVINDER S. GROVER, WILLIAM J. FLYNN, KENT P. BASHFORD, RICHARD A. LEWIS, YI-JING DUH, RUPALI S. NANGIA, AND BARBARA NIKSCH

- 76.3% (n=65) with $\geq 20\%$ IOP lowering from baseline on same or fewer medications
- Mean diurnal IOP reduction = 6.4 ± 1.1 mm Hg
- Efficacy independent of age, ethnicity, gender, and baseline IOP
- AEs through month 12 classified as mild/moderate and self-resolved
- 32.3% required needling within 12 months

Grover DS, et al. Am J Ophthalmol 2017; 183:25-36.



Future Questions to Consider

- Preferential Bleb Morphology with MMC injection associated with better long-term outcomes?
- Differential MIGS Efficacy Based on:
 - Age? Duration of Disease? Topical Meds?
- Will suprachoroidal devices make a comeback?



Thank you

aaref@uic.edu

