

## Advances in Surgical Glaucoma COPE#78911-GL

Walter Whitley, OD, MBA, FAAO  
Director of Professional Relations and Education  
Virginia Eye Consultants  
Regional Medical Director  
Eyecare Partners  
Norfolk, VA

1

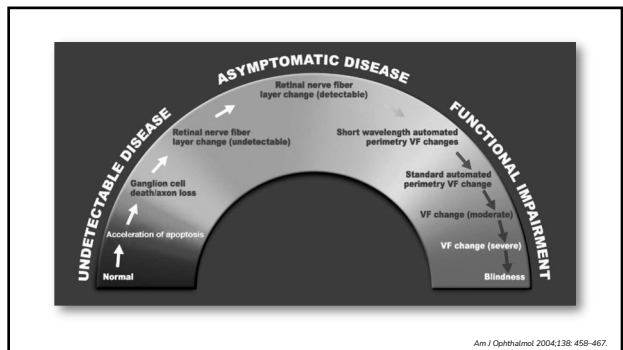
Disclosures - Walter O. Whitley, OD, MBA, FAAO has received consulting fees, honorarium or research funding from:

- Aerie: Advisory Board, Speaker
- Alcon: Advisory Board, Consultant, Speaker
- Allergan: Advisory Board, Consultant, Speaker
- Bausch and Lomb: Advisory Board, Speaker
- Bruder: Advisory Board
- CollaborativeEye – Co-Chief Medical Editor
- Dry Eye Coach – Co-Medical Editor
- Eyeovia: Consultant
- Heru: Consultant, Research
- I-MED Pharma: Advisory Board
- Kala: Advisory Board, Speaker
- Mediprint Pharma: Consultant
- Oyster Point: Advisory Board, Speaker
- Regener-Eyes: Consultant
- Review of Optometry – Contributing Editor
- RVL Pharmaceuticals: Advisory Board, Consultant, Speaker
- Santen: Advisory Board, Consultant
- Science Based Health: Advisory Board
- Sun Pharmaceuticals: Advisory Board
- Tarsus Pharmaceuticals: Advisory Board
- Thea Pharmaceuticals: Consultant
- Visus Pharmaceuticals: Advisory Board

2

The image shows three logos: on the left, a logo for 'Cataracts + Glaucoma @ MGS' with a small image of an eye; in the center, the 'iGlaucoma' logo with the tagline 'GLAUCOMA made EASY for EYECARE PROFESSIONALS'; and on the right, the 'eyetube' logo with the tagline 'Acquainted. Video. Reformed.'

3



4

### 1<sup>st</sup> Line Therapy Considerations

The image shows several different types of eye drop bottles and a close-up photograph of a human eye.

5

### Considerations for Therapy

The collage includes:
 

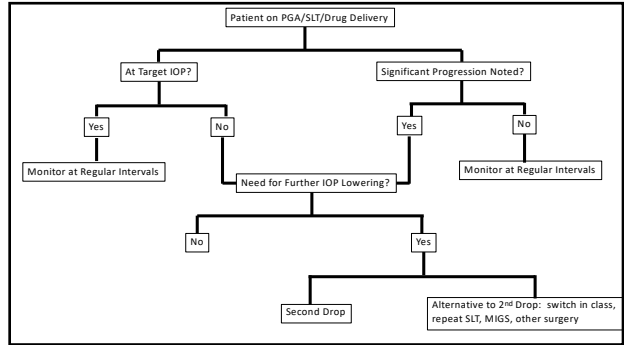
- The word 'MONEY' in large, stylized letters made of dollar bills.
- The word 'easy' in a simple font inside a circular graphic.
- The letters 'IOP' next to a target symbol.
- A close-up of a hand holding a diamond ring.

6

### Target pressure rules of thumb:

- Early POAG and ocular hypertension: Reduction of 25-30% from high IOP reading
  - OHTS, EMGT, CIGTS
- Moderate POAG: 35% or more reduction; no higher than 18 mmHg
  - AGIS, CIGTS
- Severe POAG: no higher than 15 mmHg and optimally 10-12 mmHg
  - AGIS
- Always exceptions! And the target is not set in stone

7



8

### Glaucoma Considerations

- When COMPLIANCE with drops is low
- When MEDICAL THERAPY FAILS
- When the PROGRESSION continues to WORSEN
- Treatment options
  - More medications
  - Laser therapy
  - Surgical intervention

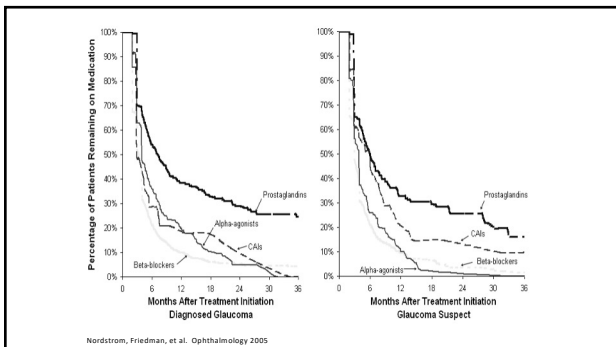
9

### Patient Compliance and Dosing

- Literature review of 76 studies show
  - Compliance increases with decreased dosage regimen and complexity<sup>1</sup>
  - 79% compliance with QD regimen vs 51% for QID regimens (p=0.001)<sup>1</sup>
  - Simpler, less-frequent dosing results in better compliance in a variety of therapeutic classes<sup>1</sup>

1. Claxson et al. Clinical Therapeutics. 2001; 23:1296-1310.

10



11

### Poor Adherence To Glaucoma Therapy

- By one year after first eye drop Rx, less than 50% are still filling prescription
- Among New Jersey Medicaid seniors, 25% never filled the second prescription
- Average number of treated days = 70


Reardon, Schwartz, Mozaffari. Clin Therap 2003;25:1172  
Gurwitz et al. Am J Public Health 1993;83:711-6.

12

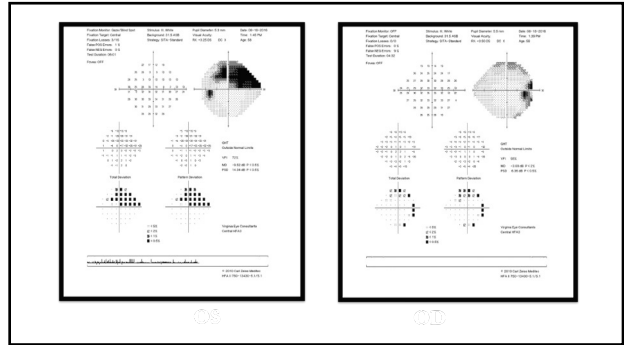


### Case Presentation

- Dilated Fundus Exam:
- Optic Nerve:  
 CDR OD: vert 0.55 horiz 0.5  
 (thin rim infer/sup)  
 CDR OS: vert 0.7 horiz 0.65
- Macula: OU Flat
- Vessels: WNL
- Periphery: WNL



19



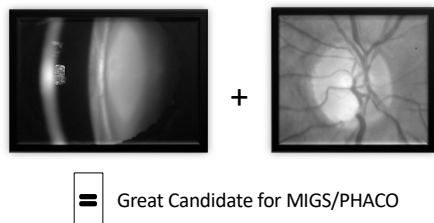
20

### Case Presentation

- Diagnosis: VS Cataract OU, Controlled Glaucoma
- Type of Glaucoma: open angle glaucoma
  - Stage of Glaucoma: **Severe OS>Moderate OD**
  - What is the Tmax? 20/24
  - What is the target pressure? **Low teens OU**
  - Is current treatment adequate? **Yes**

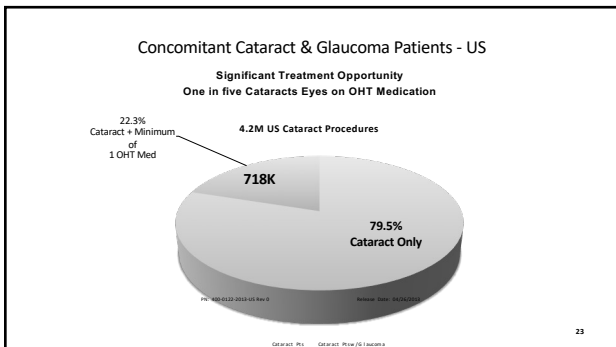
21

### What Do You Get When You Add?



= Great Candidate for MIGS/PHACO

22



23

### How Do Patients Feel about their Drop Usage?


- 68 glaucoma pts
- 54% stated their drops were expensive
- 72% were suffering from side effects
- 91% said medical therapy represented minimal/no inconvenience
- 82% were interested in learning about procedures that could reduce or possible eliminate their need for drops
- 63% would be interested in participating in FDA clinical trials

VEC Internal Survey

24

### QUALITY-OF-LIFE ISSUES

- Improved quality of vision
- Less dependence on glasses / contact lenses
- Patients now
  - More demanding
  - More knowledgeable
  - More sophisticated
  - More informed



*Patients looking for better outcomes and quality of life - your practice can offer this!*

25

### Cataract and Glaucoma


- How to position the cataract operation in the management scheme of the patient's glaucoma condition?
- Is it better to choose one sequence and type of surgery before the other, or to combine two procedures?
- **STRESS the IMPORTANCE** of visual fields **PRIOR** to cataract surgery

26


### IOL Choices in Glaucoma

"Yes – I would like to be free from glasses!"


TORIC



STANDARD




MULTIFOCAL



27

### MINIMALLY INVASIVE GLAUCOMA SURGERY

"The new MIGS procedures are to trabeculectomy what phacoemulsification was to intracapsular cataract extraction or LASIK was to RK."



28

#### Defining MIGS

**MIGS ARE:**

- Minimally invasive procedures that require little to no scleral dissection

**MIGS ARE NOT:**


- Necessarily a stent
- Only limited to the time of cataract surgery
  - Can be performed as a stand-alone procedure
- Only reserved for severe disease
  - May be beneficial for those appropriate patients with milder disease

Blumenfeld et al., Ophthalmol Ther. 2018; 7:202-210. Copyright © 2018. All rights reserved.


29

#### Why MIGS?

To restore the natural outflow of the eye

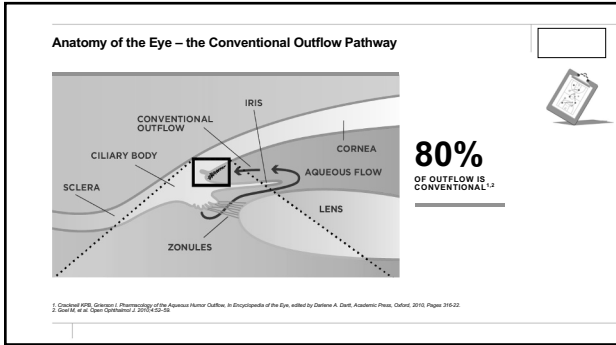


To reduce the burden of medication for patients, caregivers, staff, system, etc.

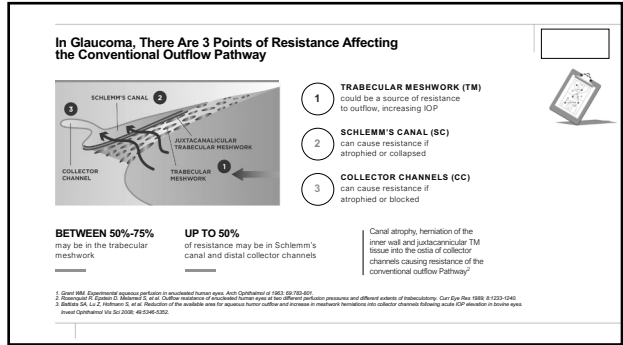


- Decreased compliance with multiple topical medications
- Long-term topical treatment is associated with complications
  - Ocular surface issues associated with BAK - dry eye
  - Increased ipeoscleral/decreased production can collapse Schlemm's canal and make collector channels difficult to open

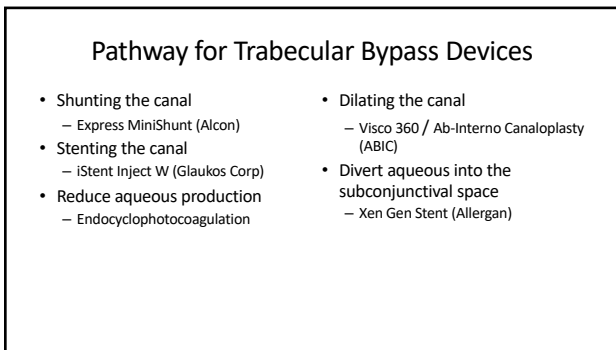
30



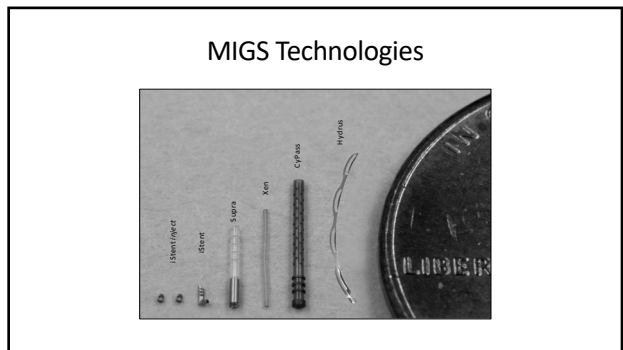
31



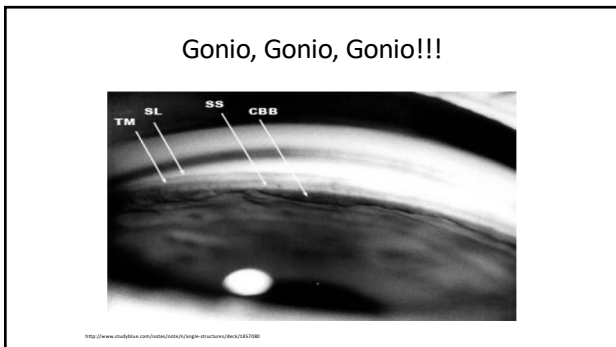
32



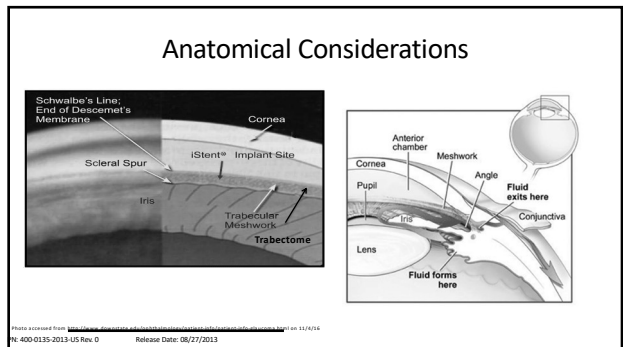
33



34



35



36

### MIGS ADVANTAGES

Safer	Avoids serious complications	
Gentler	Faster recovery	Less OR time
Reduction of IOP	Less glaucoma meds	
Decreased IOP fluctuations		
Combined with cataract sx	No Bleb	
Good for contact lens wearers	Sparses the conjunctiva	
Fewer follow-up appointments		

37

### Are Patients Interested in MIGS?

Interest Level	Percentage
Very Interested	2%
Interested	86%
Not sure	14%

- 28pts
- 79% did not mind instilling drops
- 64% did not mind wearing glasses
- 86% were interested in reducing their need for topical medications

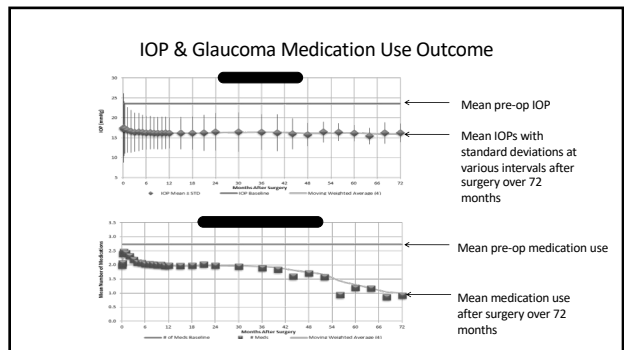
38

### Ab interno trabeculotomy Constance Okeke, MD

**Visualize, Remove or angle Access**  
before application of laser

**Minimally Invasive**  
approach to the trabecular meshwork

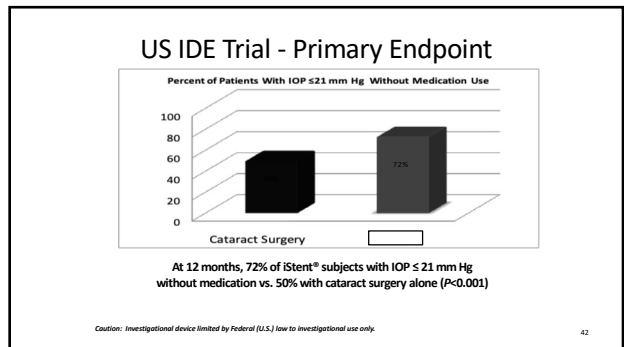
39



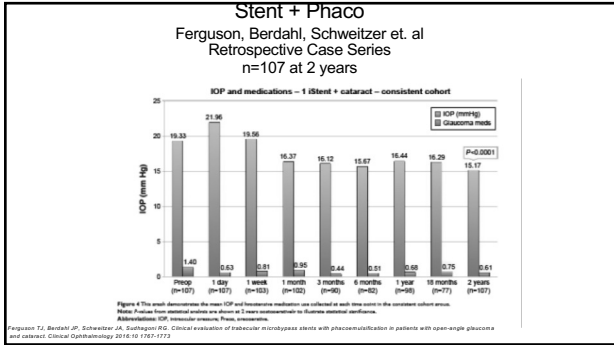
40

### Stent the TM Courtesy of Constance Okeke, MD, MSCE

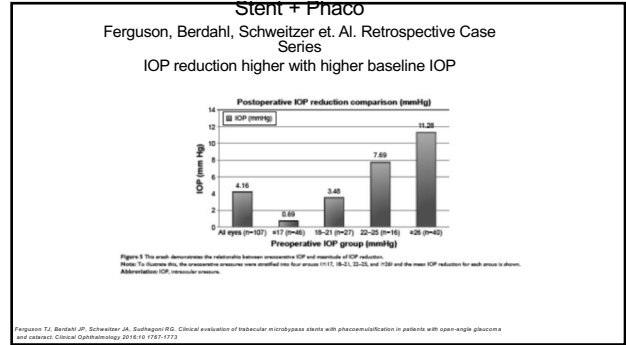
41



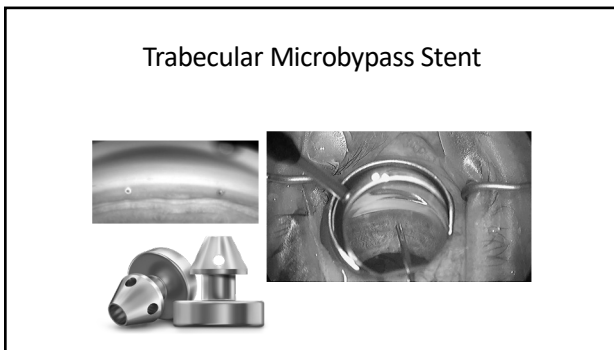
42



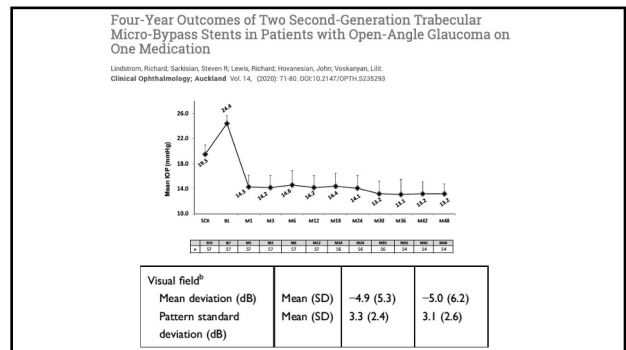
43



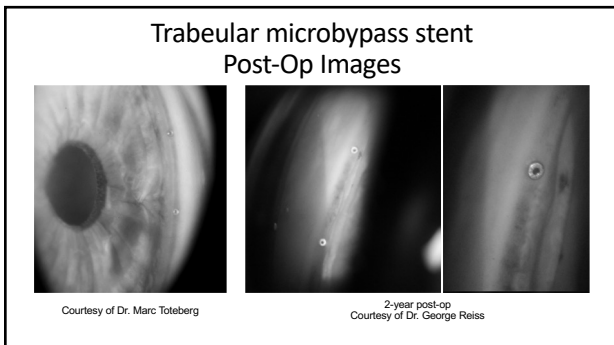
44



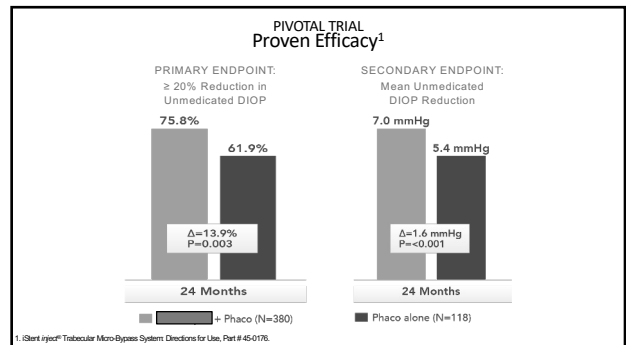
45



46

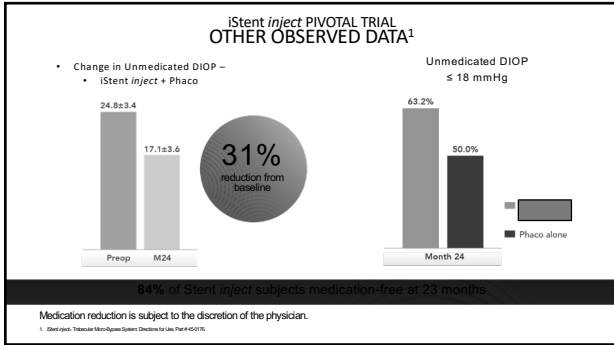


47

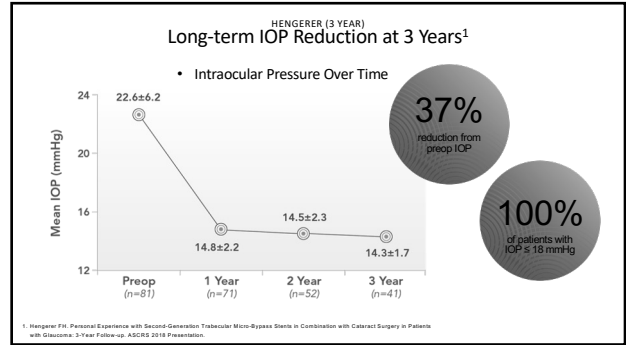


48

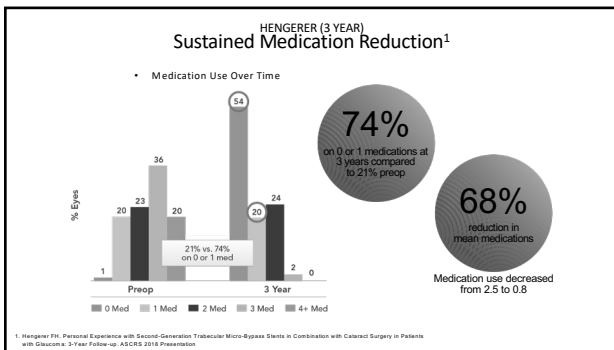




49



50



51

### ICE, ICE Baby

Video Courtesy of John Berdahl, MD and Justin Schweitzer, OD

52

### Ab Interno Canaloplasty

- Provides dilation of:
  - TM
  - Schlemm's Canal
  - Collector channels
- Atraumatic, allows for other future MIGS options and/or SLT
- Combined with phaco or standalone
- 30% reduction in IOP, 50% decrease in medication<sup>1</sup>

53

### Ab interno versus Ab externo Canaloplasty

<p><b>Ab interno</b></p> <ul style="list-style-type: none"> <li>• Clear corneal incision</li> <li>• Small goniotomy to access Schlemm's canal</li> <li>• Viscodilation – no tensioning suture</li> </ul>	<p><b>Ab externo Canaloplasty</b></p> <ul style="list-style-type: none"> <li>• Conjunctival dissection</li> <li>• Scleral flap to access Schlemm's canal</li> <li>• Prolene suture placed to keep Schlemm's canal open</li> </ul>
--	---

54

### Efficacy<sup>1</sup>

- Combined cohort (n = 228)
- Average IOP reduction 30%, average reduction in medication use 50% at 12 months
  - ABiC + phaco (n = 130) – 23% IOP reduction, 50% fewer medications
  - Standalone (n = 98) – 37% IOP reduction, 67% fewer medications
- Results similar to previous canaloplasty studies

1. Ellex Science. Ab-Interno Canaloplasty – The Minimally Invasive Glaucoma Surgery That Keeps Its Promise. White Paper. 2016. <https://www.ellex.com/uploads/Resources/Ellex-ABiC-Whitepaper-12-Months.pdf>

55

- Combination of viscodilation and trabeculotomy up to 360 degrees each

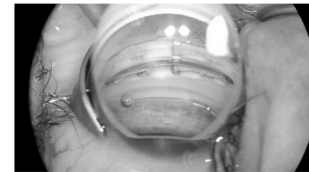
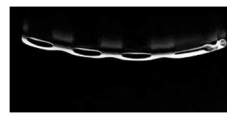


56



57

### Schlemm Canal Microstent



58

### HORIZON Trial – 4 Year Update

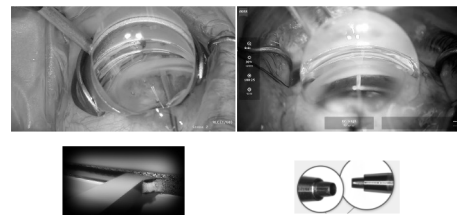
	Stent + Cataract (n=369)	Cataract Only (n=187)
Baseline IOP (mm Hg) after washout	25.5 (+/- 3.0)	25.4 (+/-2.9)
48 months medication free	65%	41%
48 months mean IOP (mm Hg) unmedicated	16.7 (+/-3.1)	17.2 (+/-3.2)
48 months mean IOP (mm Hg)	16.9 (+/-3.3)	17.3 (+/-3.4)
1 preoperative med	52.6%	54%
2 to 4 preoperative med	47.4%	46%

5 Year Update – 66% patient's remain medication-free and 61% reduction in risk to need further surgery

59

### Excisional Goniotomy

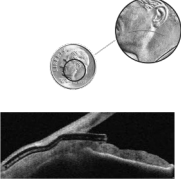
### Goniotomy (iAccess)



60

### Subconjunctival Gel Stent

- A glaucoma implant designed to reduce intraocular pressure in eyes suffering from refractory glaucoma<sup>1</sup>
- 6-mm length, 45-micron inner diameter—about the length of an eyelash<sup>1,2</sup>
- Composed of gelatin, cross-linked with glutaraldehyde<sup>1</sup>

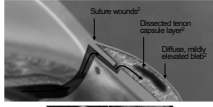


1. XEN® Directions for Use; 2. Vogt et al. In: Blume-Peytavi et al, eds. Hair Growth and Disorders. 2008.

61

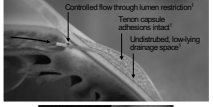
### Procedure Creates a Low-Lying, Ab-interno Bleb in Refractory Glaucoma<sup>1</sup>

**Ab-Externo Bleb**



• Example of elevated, cystic bleb<sup>2</sup>

**Ab-Interno Bleb**

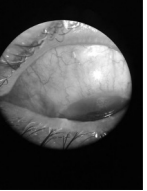
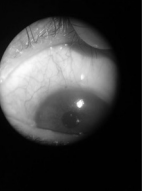
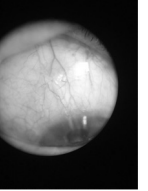


• Low-lying and diffuse<sup>1</sup>

1. Dapena and Ros. Revista Española de Glaucoma e Hipertensión Ocular. 2015; 2. Errico et al. Clin Ophthalmol. 2011.

62

### Ab-interno Bleb Examples

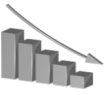




Actual patient. Images courtesy of Francisco Millán, MD, and Vanessa Vera, MD.

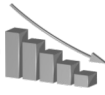
63

### Established Effectiveness at 12 Months

**76.3% of subjects reduced mean diurnal IOP ≥ 20% at 12 months**  
vs baseline on the same or fewer number of medications<sup>1</sup>



**-6.4 mm Hg mean diurnal IOP reduction from baseline at 12 months ± 1.1 mm Hg (SE)<sup>1</sup>**



76.3% (95% CI = 65.8%, 86.8%); using observed data and failures for subjects with glaucoma-related secondary surgical intervention and multiple imputations for missing data (N = 65).<sup>1</sup>

-6.4 ± 1.1 (95% CI = -8.7, -4.2); using observed data and worst within-eye IOP for subjects with glaucoma-related secondary surgical intervention and multiple imputations for missing data (N = 65).<sup>1</sup>

1. XEN® Directions for Use.

64

### Established Effectiveness at 12 Months

<p><b>Mean IOP reduced to 15.9 mm Hg (N = 52) from 25.1 mm Hg at medicated baseline<sup>1</sup></b></p> <p>Baseline 25.1 (± 3.7) mm Hg; 12-month 15.9 (± 5.2) mm Hg.<sup>1</sup></p>	<p><b>Mean IOP-lowering medications reduced to 1.7 (N = 52) from 3.5 at medicated baseline<sup>1</sup></b></p> <p>Baseline 3.5 (± 1.0) medications; 12-month average 1.7 (± 1.5) medications.<sup>1</sup></p>
--	---

1. XEN® Directions for Use.

65

### How To Choose Which Procedure?

- Discuss with your surgeon which procedures they perform
- Based on Stage and Severity
  - Early to Moderate – iStent, ABiC
  - Moderate to advanced cases – Trabectome/Kahook, Xen
  - Omni Surgical System provides combined approach

66

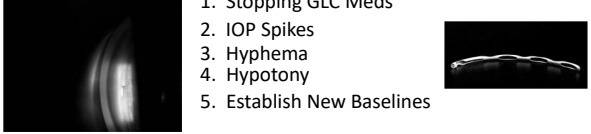
### Post-operative Cataract IOP Spikes in Glaucoma Patients

- Adequate control prior to surgery
  - Additional drops
  - SLT prior
- Consideration of combined glaucoma and cataract procedures
- Aggressive treatment perioperatively
  - Diamox at the end of the case, early post-op
- Closer follow-up post-operatively

67


### Post-operative Considerations with MIGS

1. Stopping GLC Meds
2. IOP Spikes
3. Hyphema
4. Hypotony
5. Establish New Baselines






68

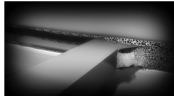
### And There's More



Solix Gold Shunt

- Canaloplasty
- Glaukos Istent Supra
- Allergan Bimatoprost SR
- Ocular Therapeutix SR Travaprost



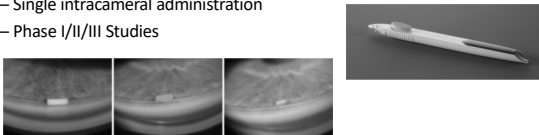
Kahook Dual Blade

69

### Bimatoprost SR (Allergan)

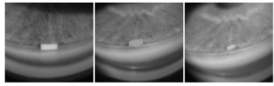
(10-microgram bimatoprost sustained-release implant)

- Biodegradable bimatoprost sustained-release implant
- FDA-approved and indicated to reduce IOP in patients with open angle glaucoma or OHT
- Single intracameral administration
- Phase I/II/III Studies

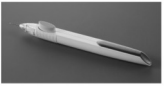


70

### Bimatoprost Sustained Release Implant

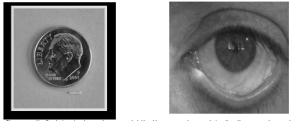


- Phase 2 trial comparable to topical bimatoprost qd dosing (for 4-6 months)
- Inserted into the anterior chamber
- Biodegradable



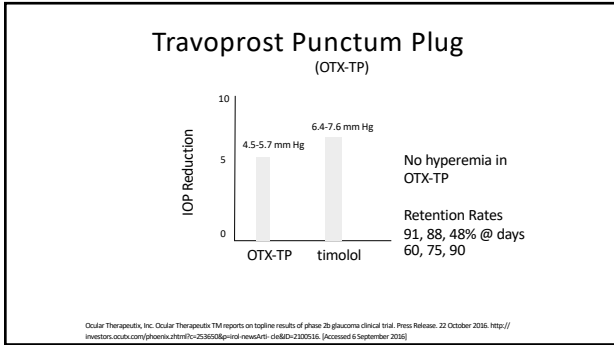
71

- Sustained-release travoprost in an intracanalicular depot composed of polyethylene glycol hydrogel and drug-containing microparticles
  - Drug elutes over 90 day period
  - In Phase 3 Clinical Trials



© 2018 Therapeutic Innovations. All rights reserved. <http://www.oci.com/oculart/oculart-travoprost-oculart.htm>

72



73

- Two formulations have been taken into clinical trials
  - Latanoprost for glaucoma
  - Olopatadine for allergy relief

74

### 24 Month Phase I/II Clinical Trial

75 Patients

Bimatoprost pellet  
(6, 10, 15, or 20 micrograms)

Topical bimatoprost 0.03%

75

### 24 Month Phase I/II Clinical Trial

Bimatoprost pellet (6, 10, 15, or 20 micrograms)      Topical bimatoprost 0.03%

4 months – IOP reduction 7.2, 7.4, 8.1, 9.5 mm Hg 92% of patients      4 months – IOP reduction of 8.4 mm Hg

Sustained at 6 mos. in 71%

76

### Safety

% Conjunctival Hyperemia

Side Effects

52%      30.7%  
Implant group      Topical group

77

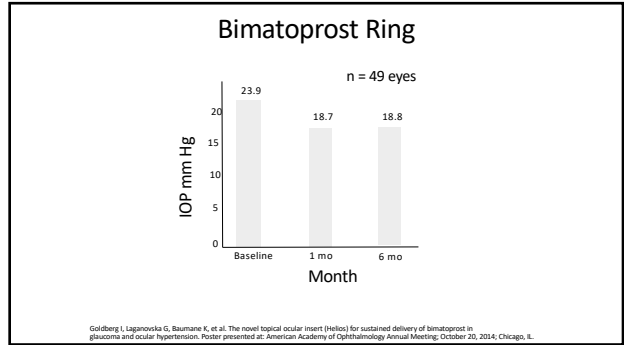
### Travoprost SR Implant

- ENV515 is engineered as a proprietary, fully biodegradable PRINT® (Particle Replication In Non-Wetting Templates) travoprost formulation that could offer sustained reduction in IOP for more than six months after a single dose
- Met Phase 2a primary efficacy endpoint
  - Change in diurnal IOP at Day 25
  - 28-Day dose – Decrease 28%

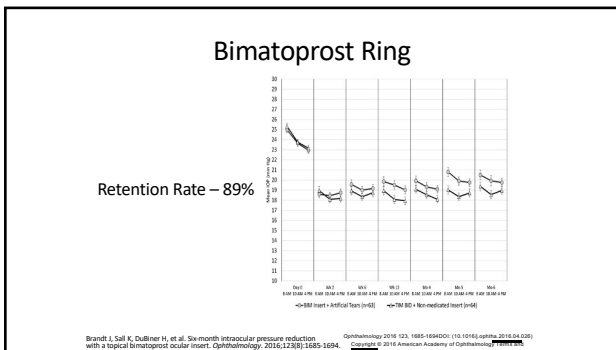
78



79



80



81

### Bimatoprost Ring

	All Patients (n = 130)	Bimatoprost Patients (n = 64)	Timolol Patients (n = 66)
<b>Ocular TEAE</b>			
Patients with any ocular TEAE	52 (40.0)	29 (45.3)	23 (34.8)
<b>Ocular TEAE ≥5%</b>			
Eye discharge	19 (14.6)	10 (15.6)	9 (13.6)
Conjunctival hyperemia	12 (9.2)	9 (14.1)	3 (4.5)
Punctate keratitis	12 (9.2)	8 (12.5)	4 (6.1)
Eye pruritus	9 (6.9)	7 (10.9)	2 (3.0)
Ocular discomfort	6 (4.6)	4 (6.3)	2 (3.0)

Brandt J, Sall K, DuBiner H, et al. Six-month intraocular pressure reduction with a topical Bimatoprost ocular insert. *Ophthalmology*. 2016;123(8):1685-1694. Copyright © 2016 American Academy of Ophthalmology.

82

- ### Summary Points
- Advances in technology have allowed for many good options for our cataract and glaucoma patients
  - When considering cataract surgery in patient with glaucoma, a thorough assessment first of the stage and status of glaucoma is imperative
    - Visual fields should be obtained PRIOR to cataract surgery
  - Establish glaucoma comanagement protocols so everyone is on the same page.

83

**THANK YOU**  
**WOWHITLEY@EYECAREASSOCIATESNV.COM**

84