The Interventional Glaucoma Revolution

A paradigm shift in how ODs and MDs collaborate in the care of glaucoma patients

Philip S. Garza, MD, MSc
Glaucoma & Cataract Surgeon
October 21, 2023

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1

Disclosures

The presenter does not have any financial disclosures relevant to the topic under discussion.

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2

Philip S. Garza, MD, MSc

Glaucoma & cataract surgeon – Midtown Atlanta & Downtown Decatur

EMORY UNIVERSITY SCHOOL OF MEDICINE

KELLOGG EYE CENTER MICHIGAN MEDICINE

Stanford MEDICINE | Byers Eye Institute *Department of Ophthalmology*

- Born and raised in Miami
- Undergraduate:
  - University of Miami
- Medical School & M.Sc. Clinical Research:
  - Emory University
- Residency:
  - Kellogg Eye Center, University of Michigan
- Fellowship:
  - Byers Eye Institute, Stanford University

3

My Perspective

- Patients with glaucoma deserve access to the **full range** of therapies available at **each stage** of their disease.
  - **Includes trabeculectomy**!
- Treatment strategy should be **individualized** to each patient based on their values, goals, and desires.
- Excellent **communication** and **patient partnership** are key to selecting the optimal treatment strategy at each disease stage.
- Glaucoma is **not an absolute disqualification** for refractive cataract surgery, but **patient selection** and **managing expectations** are key.

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4

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- Glaucoma is **not an absolute disqualification** for refractive cataract surgery, but **patient selection** and **managing expectations** are key.
- **Minimally invasive interventional techniques can be considered for nearly every patient at nearly every stage of their disease**

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5

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6

Outline: Interventional Glaucoma Revolution

I. Introduction 

II. Evolution of the POAG treatment paradigm
III. Evidence for first- or early-line SLT: The LiGHT Trial
IV. Evidence for Durysta: ARTEMIS-I
V. Review of and update on MIGS
   - OMNI viscocanaloplasty / trabeculotomy: The ROMEO Study
VI. Discussion

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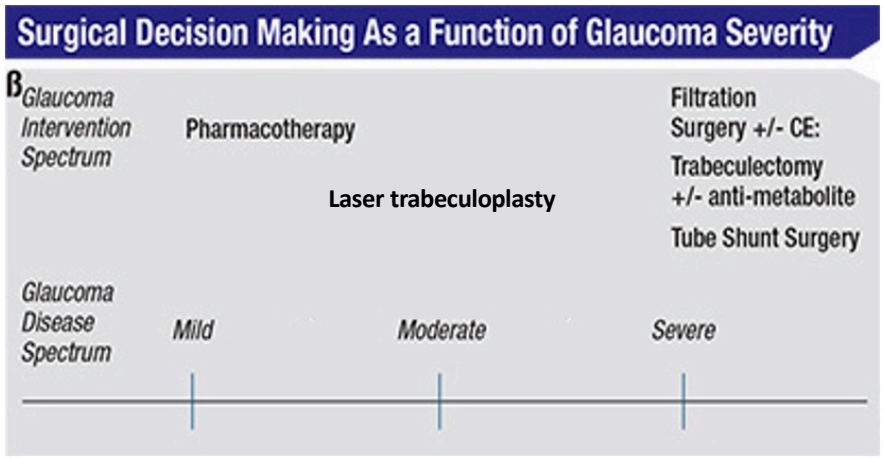
7

Evolution of the POAG treatment paradigm: ≤ 2000s



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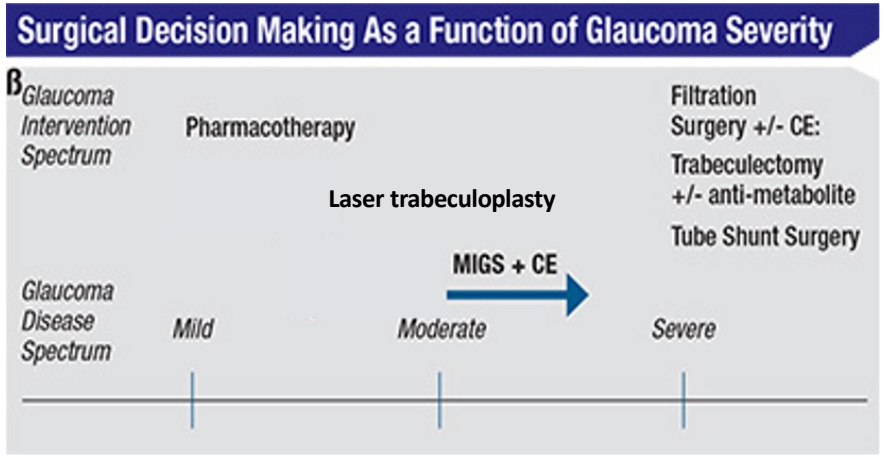
Evolution of the POAG treatment paradigm: 2010s



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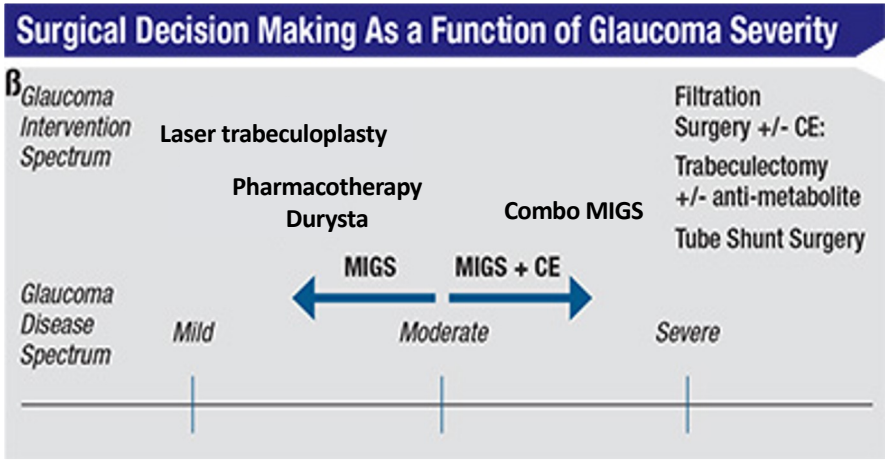
Evolution of the POAG treatment paradigm: 2010s

10

Evolution of the POAG treatment paradigm: *Now*



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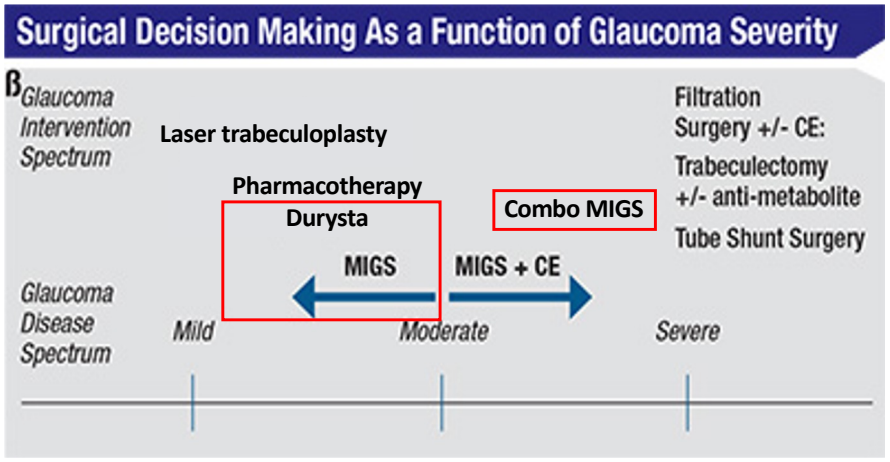
Evolution of the POAG treatment paradigm: *Now*



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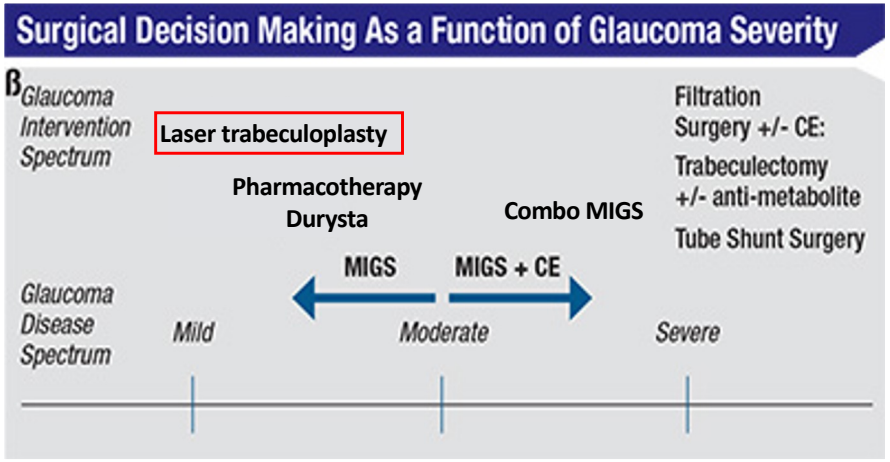
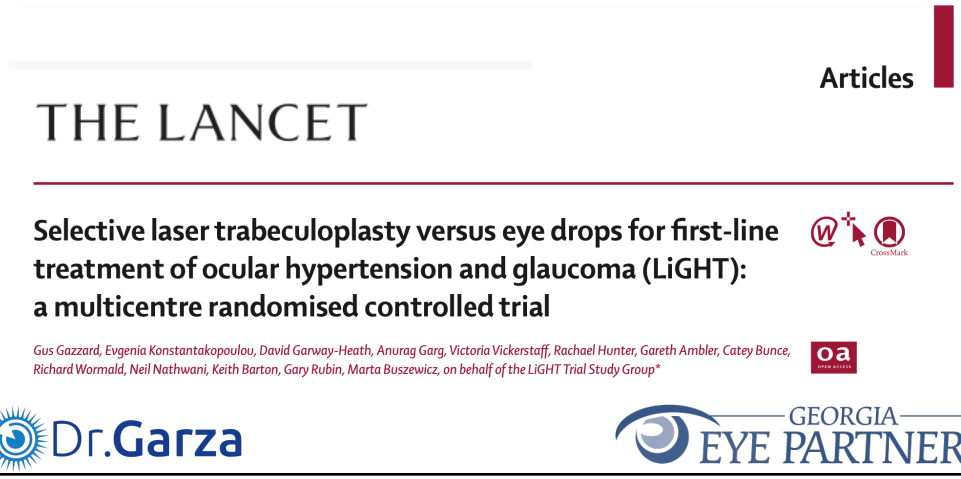
Evolution of the POAG treatment paradigm: *Now*



13

Evidence for first-line SLT: The LiGHT Trial



14

Evidence for first-line SLT: The LiGHT Trial

- LiGHT: Laser in Glaucoma and ocular HyperTension
- Prospective, unmasked multicenter RCT
- 718 patients with treatment-naïve POAG or OHTN
  - 356 SLT → Repeat SLT or Medication PRN → Surgery
  - 362 Medication → More medication → Surgery

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Evidence for first-line SLT: The LiGHT Trial

- Target IOP based on disease severity at recruitment
- Target adjusted / therapy escalated based on software algorithm
- 3 year follow-up (extended for 3 years)
- Primary outcome: Health-related QOL (EQ-5D score)
- Secondary outcomes: Cost-effectiveness, disease-specific QOL, visual function, safety

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LiGHT: Initial results (*Lancet* 2019)

- No difference in EQ-5D
- 74.2% of SLT patients Rx-free at 3 years
- SLT patients at target IOP 93% of the time; 91.3% for medication patients
- 11 medication patients needed surgery; no SLT patients needed surgery
- 97% probability of greater cost-effectiveness in the SLT group
  - Average savings of 451 GBP per patient

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17

LiGHT: Subsequent publications

- Garg et al., *Ophthalmology* 2019
  - IOP lowering effect at two months equal between SLT and medication
  - IOP lowering effect of SLT at two months equal in POAG and OHTN

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18

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- Garg et al., *Ophthalmology* 2019
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- Garg et al., *Ophthalmology* 2020
  - Repeat SLT yielded adequate Rx-free IOP control at 18 months 67% of the time

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19

LiGHT: Subsequent publications

- Garg et al., *Ophthalmology* 2019
  - IOP lowering effect at two months equal between SLT and medication
  - IOP lowering effect of SLT at two months equal in POAG and OHTN
- Garg et al., *Ophthalmology* 2020
  - Repeat SLT yielded adequate Rx-free IOP control at 18 months 67% of the time
- Wright et al., *Ophthalmology* 2020
  - SLT first may delay visual field progression
  - There were differences in progression despite pts being treated to similar IOP targets

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20

Laser Trabeculoplasty …

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21

Laser Trabeculoplasty …

is “Interventional Glaucoma” …

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22

Laser Trabeculoplasty …

is “Interventional Glaucoma” …

And it works …

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23

Laser Trabeculoplasty …

is “Interventional Glaucoma” …

And it works …

<u>As well as or better than drops</u> for first line treatment.

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24

25

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26

Durysta

- Rod-shaped, intracameral implant consisting of biodegradable polymer matrix that continuously releases bimatoprost for 3-4 months
  - Same implant material as Ozurdex, biodegraded to CO_2 and H_2O through hydrolysis and metabolism
  - Single-use, 28-gauge applicator
  - Achieves drug concentration 4400-fold higher than topical 0.03% in iris-ciliary body

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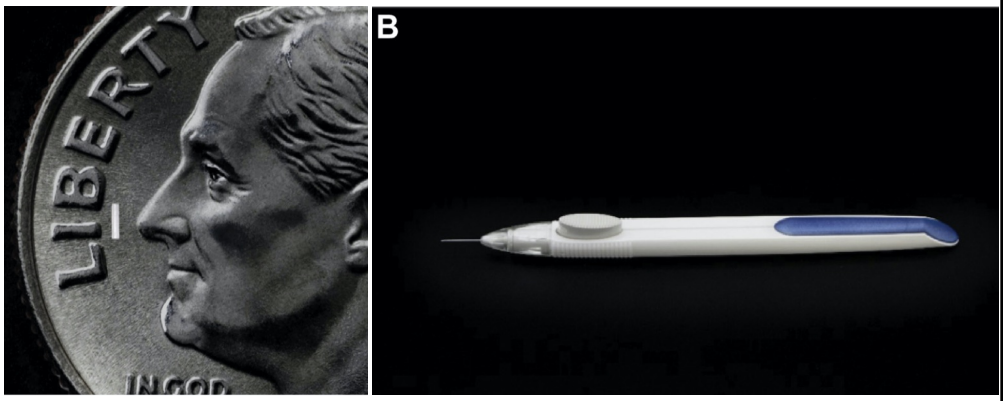
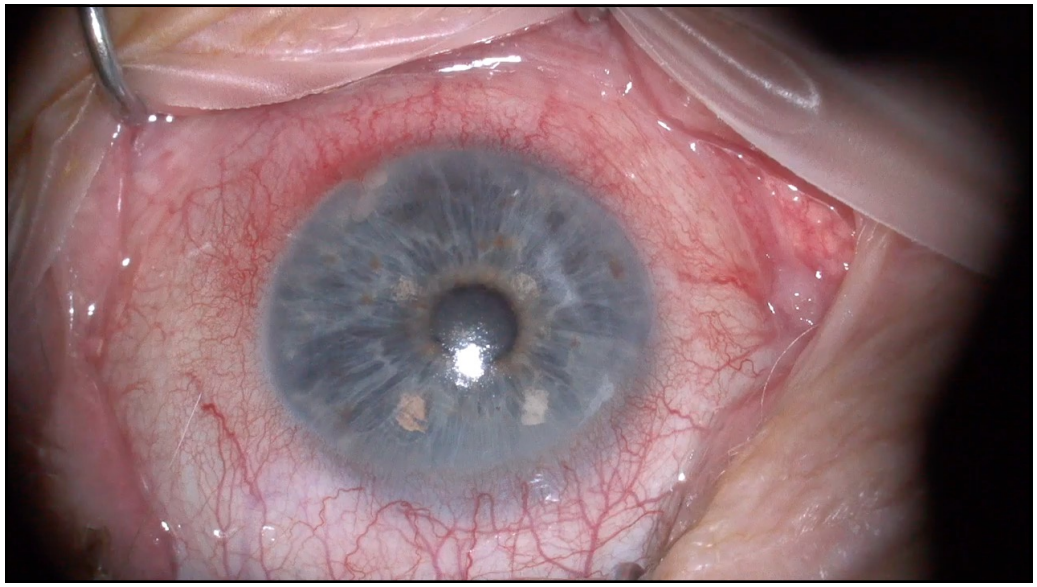
27

Durysta



28



29

Evidence for Durysta: ARTEMIS 1

- Randomized, multicenter, subject- and efficacy-evaluator masked, parallel-group, active-controlled phase 3 clinical trial
  - Efficacy and safety of 10 µg and 15 µg dose strengths after initial and repeated administration
  - Control: Timolol 0.5% BID
  - 20 months: 12 month active treatment period, 8 month extended follow-up

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30

ARTEMIS 1: Results

- Recruitment Dec. 2014 - Sept. 2017, follow-up completed July 2019
- 198 10-µg, 198 15-µg, 198 timolol = 594 subjects
- Mean age 62.5 yrs, 51.5% male
- 63.1% white, 13.8% black, 12.6% Hispanic, 10.5% other
- 78.1% POAG

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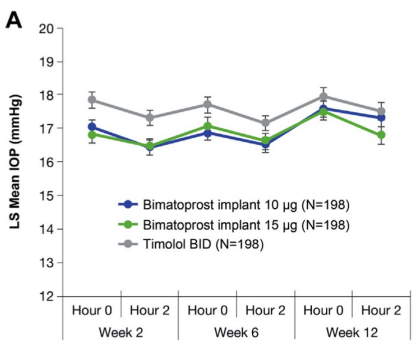
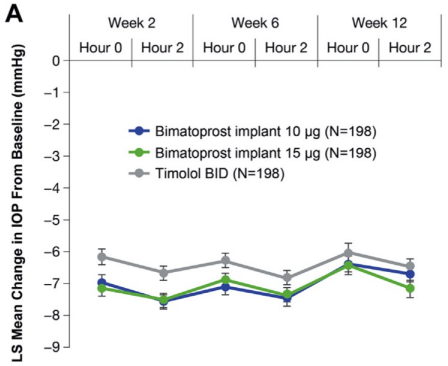
31

ARTEMIS 1: Results





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32

patients with open angle glaucoma or ocular hypertension.

IMPORTANT SAFETY INFORMATION

Contraindications

DURYSTA™ is contraindicated in patients with: active or suspected ocular or periocular infections; corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy); prior corneal transplantation or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial

View Prescribing Information

33

My prognostication: Durysta is just the beginning

34

Currently available MIGS

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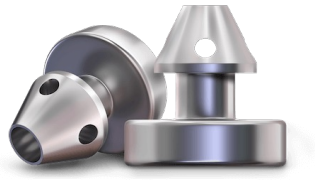
Increase trabecular outflow
- **Bypass trabecular meshwork**
- Excision of trabecular meshwork
- Dilation of trabecular meshwork

Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

iStent *inject* (W)



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35

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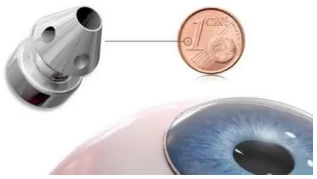

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36

Currently available MIGS

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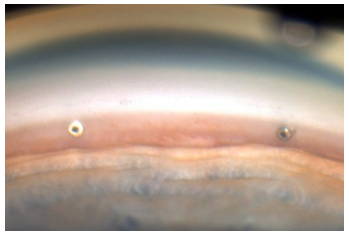

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37

Currently available MIGS

GEORGIA EYE PARTNERS

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Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

iStent *infinite*

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38

Currently available MIGS

GEORGIA EYE PARTNERS

iStent infinite® gives you the versatility to treat a variety of patients who have failed prior medical and surgical intervention, when combined with cataract surgery or in a **standalone surgical setting.**

Failed Medical	Failed Surgical
• Uncontrolled on medication • Non-compliant & non-adherent to treatment • Allergic to glaucoma medication • Intolerant to glaucoma medication due to sequelae (ie, hyperemia, periorbital fat atrophy, hyperchromia, etc) • Patients burdened with underlying ocular surface disease • Failed medical patients who have experienced decreased quality of life	• Failed filtering surgery (ie, trabeculectomy, tube shunts, XEN, etc) • Failed cilioablative surgery • Other failed surgical intervention (upon surgeon discretion) Consider iStent infinite® in place of more invasive procedures, offering intermediate therapy.

39

Currently available MIGS

GEORGIA EYE PARTNERS

Increase trabecular outflow
- **Bypass trabecular meshwork**
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Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Hydrus microstent

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40

Currently available MIGS

GEORGIA EYE PARTNERS

Increase trabecular outflow
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Suprachoroidal space

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Hydrus microstent

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41

Currently available MIGS

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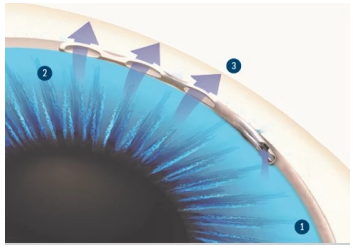

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42

Currently available MIGS

GEORGIA EYE PARTNERS

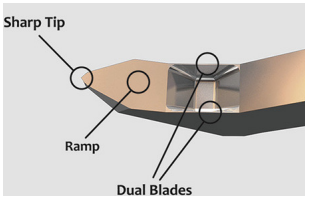
Increase trabecular outflow
- Bypass trabecular meshwork
- **Excision of trabecular meshwork**
- Dilation of trabecular meshwork

Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Kahook dual blade (KDB)



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43

Currently available MIGS

GEORGIA EYE PARTNERS

Increase trabecular outflow
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- Dilation of trabecular meshwork

Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

TrabEx

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44

Currently available MIGS

Increase trabecular outflow
- Bypass trabecular meshwork
- **Excision of trabecular meshwork**
- Dilation of trabecular meshwork

Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

SION

45

Currently available MIGS

Increase trabecular outflow
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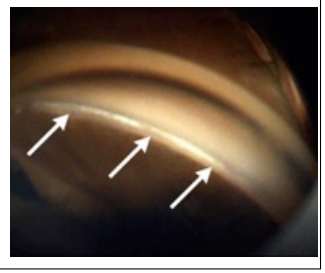
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

KDB, TrabEx, SION



46

Currently available MIGS

Increase trabecular outflow
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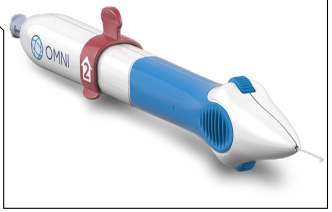
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

OMNI "surgical system"



47

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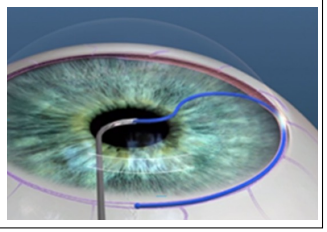

48

Currently available MIGS

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Increase trabecular outflow
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Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Cypass

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49

Currently available MIGS

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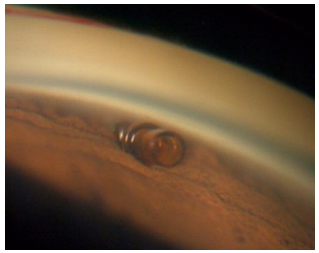
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Cypass



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50

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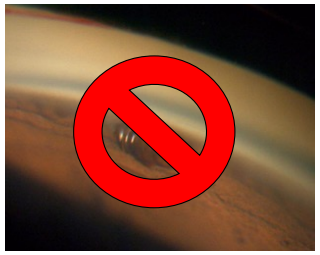

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51

Currently available MIGS

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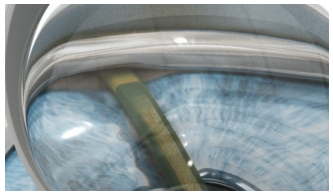
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

iSTAR MINIject*



*Not FDA approved

52

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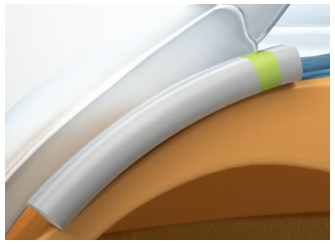

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53

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Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Xen gel stent

54

Currently available MIGS

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Increase trabecular outflow
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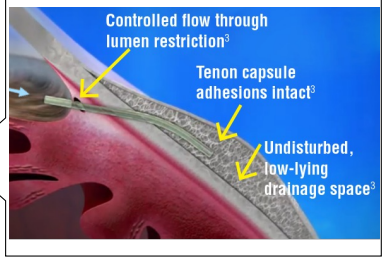
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Xen gel stent



55

Currently available MIGS

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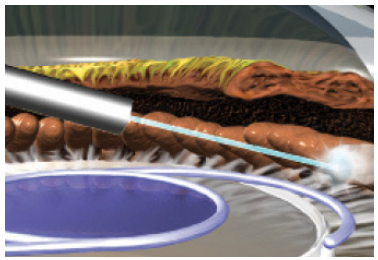
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Endocyclophotocoagulation (ECP)



56

Currently available MIGS

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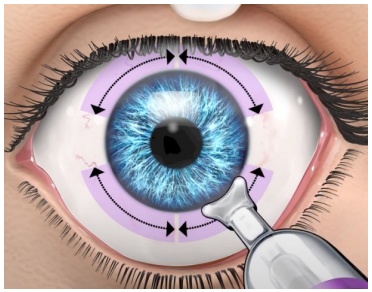
Suprachoroidal space

Subconjunctival filtration

Reduce aqueous production

Micropulse Diode Laser



57

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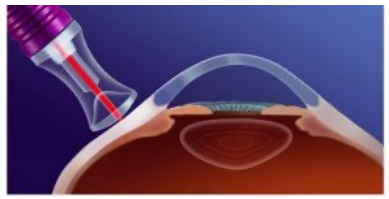
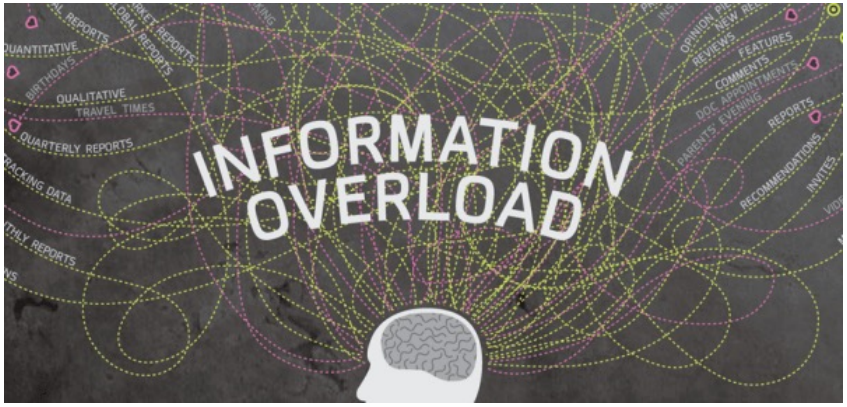
Reduce aqueous production

Micropulse Diode Laser



58

Currently available technologies



59

60

It’s only going to get **more** complicated

61

Let us help

62

Currently available technologies

With versus without cataract extraction

Only **with:**
- iStent *inject*
- Hydrus

Can be **without:**
- iStent *infinite*
- Goniotomy (KDB, TrabEx, SION)
- OMNI (or other viscocanaloplasty/trabeculotomy)
- ECP
- Micropulse
- Xen

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~~Cu~~ COMING SOON ~~ble~~ technologies

~~W~~ versus without cataract extraction

Only **with:**
- iStent *inject*
- Hydrus

Can be ~~**without:**~~
- iStent *infinite*
- ~~Goniotomy~~ (KDB, TrabEx, SION)
- OMNI (or other ~~viscocanaloplasty~~/trabeculotomy)
- ECP
- Micropulse
- Xen

Hopefully:
- **Hydrus**
- **MINIject**

64

65

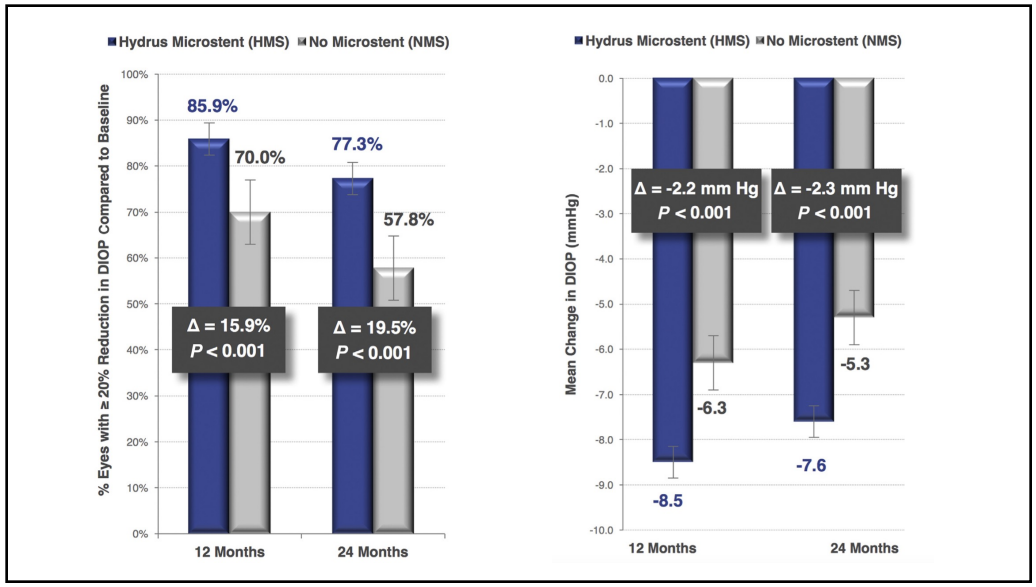
Currently available technologies

An update on the **Hydrus microstent**

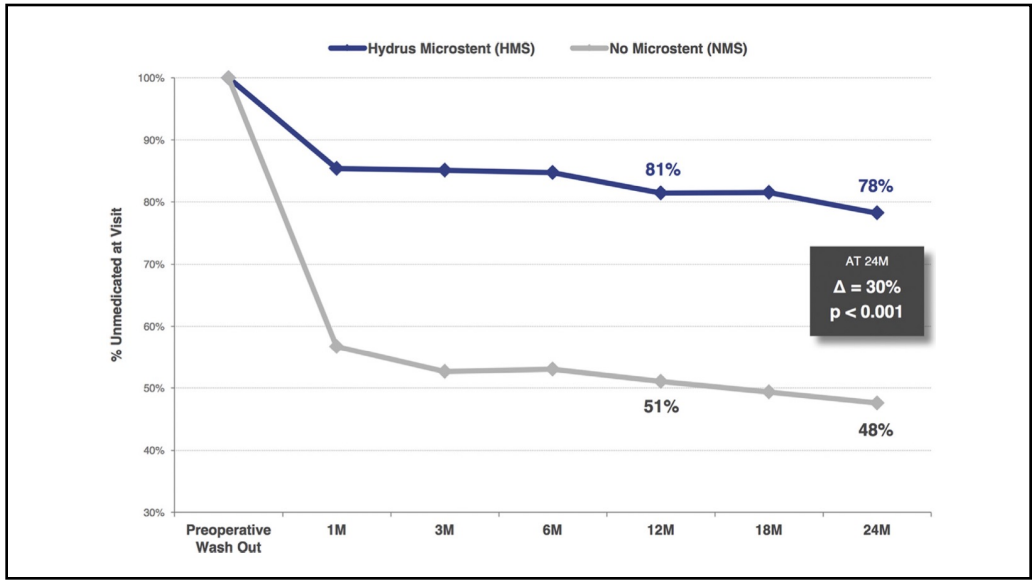
The **HORIZON** Study (Samuelson et al. 2019)

- Prospective, single-masked multicenter RCT
- 369 eyes Phaco+Hydrus, 187 eyes Phaco only
- Mild-moderate OAG on 1+ med with IOP 22-34 after washout
- 1˚ endpoint: ≥20% IOP reduction at 24 months
- 2˚ endpoint: Reduction in IOP at 24 months
- Medication washout at 12 and 24 months

66


Hydrus Microstent (HMS)
No Microstent (NMS)
% Eyes with ≥ 20% Reduction in DIOP Compared to Baseline
85.9%
70.0%
77.3%
57.8%
Δ = 15.9%
P < 0.001
Δ = 19.5%
P < 0.001
12 Months
24 Months
Hydrus Microstent (HMS)
No Microstent (NMS)
Mean Change in DIOP (mmHg)
Δ = -2.2 mm Hg
P < 0.001
Δ = -2.3 mm Hg
P < 0.001
-6.3
-5.3
-8.5
-7.6
12 Months
24 Months

67


Hydrus Microstent (HMS)
No Microstent (NMS)
% Unmedicated at Visit
81%
78%
AT 24M
Δ = 30%
p < 0.001
51%
48%
Preoperative Wash Out
1M
3M
6M
12M
18M
24M

68

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Long-term Outcomes from the HORIZON Randomized Trial for a Schlemm's Canal Microstent in Combination Cataract and Glaucoma Surgery

Iqbal Ike K. Ahmed, MD,[1] Ticiana De Francesco, MD,[1,2] Douglas Rhee, MD,[3] Cathleen McCabe, MD,[4] Brian Flowers, MD,[5] Gus Gazzard, MBBChir, MD,[6] Thomas W. Samuelson, MD,[7] Kuldev Singh, MD, MPH,[8] on behalf of the HORIZON Investigators

Conclusions: The addition of a Schlemm's canal microstent in conjunction with CS was safe, resulted in lowered IOP and medication use, and reduced the need for postoperative incisional glaucoma filtration surgery compared with CS after 5 years. Long-term presence of the implant did not affect the corneal endothelium adversely. *Ophthalmology 2022;129:742-751*

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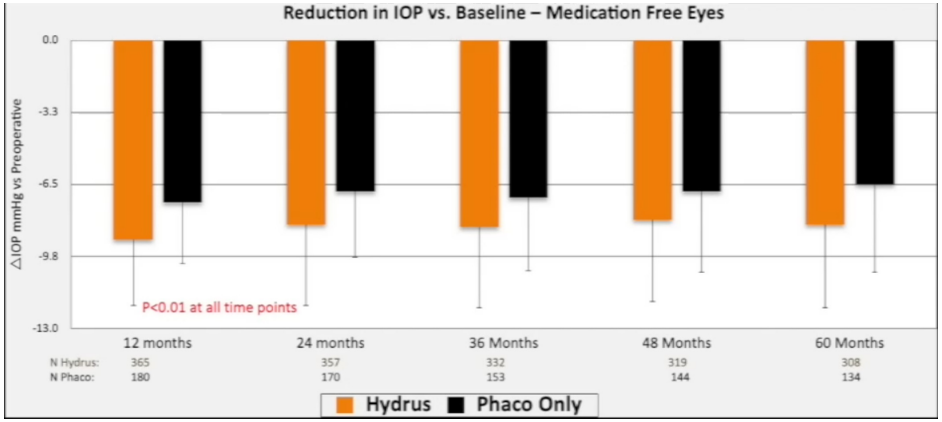
69

Currently available technologies

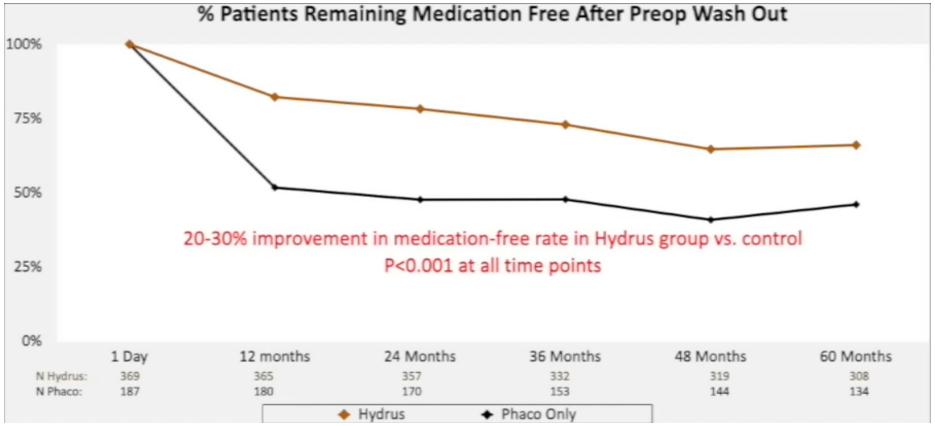
An update on the **Hydrus microstent**



70

Currently available technologies

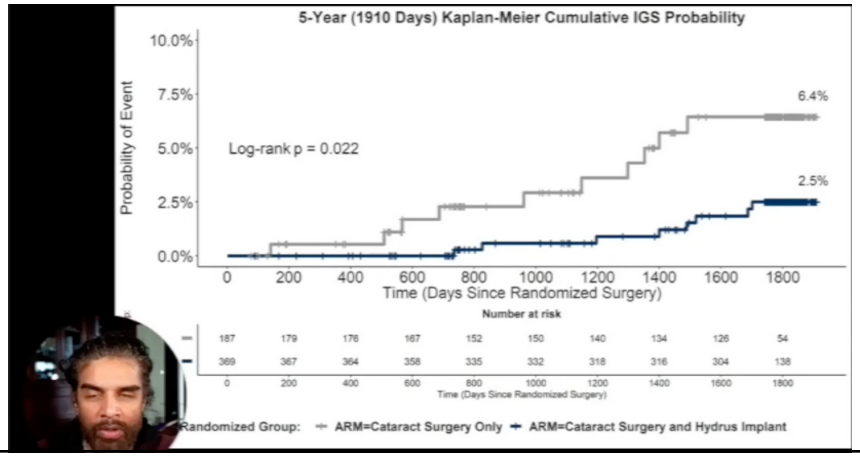
An update on the **Hydrus microstent**



71

Currently available technologies

An update on the **Hydrus microstent**



72

Currently available technologies

An update on the **Hydrus microstent**

Post Operative Adverse Events	Cumulative to 2 Years		Cumulative to 5 Years	
	HYDRUS	CS Only	HYDRUS	CS Only
Device Malposition - postoperative	1.4%	-	1.4%	-
IOP related events – IOP elevation (≥ 10 mmHg, >30D) Hypotony ≤ 6 mmHg ≥ 1 month	0.5% 0	2.7% 0	0.8% 0	2.7% 0
Device Removal	0	-	0	-
Loss of HVF – MD ≥ 2.5 dB	4.3%	5.3%	8.4%	9.6%
Focal PAS – Obstructive Non – obstructive	3.5% 7.3%	- 2.1%	5.4% 8.7%	- 3.7%
Severe Corneal edema ≥ 1 day	0.5%	0.5%	0.5%	0.5%
Persistent inflammation – lasting >3M postop or recurring <3M after cessation of steroids	0.5%	2.1%	0.5%	2.1%

73

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Protecting Sight. Empowering Lives.®

Primary Open-Angle Glaucoma Preferred Practice Pattern®

Sept. 12, 2020

74

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The intracanalicular scaffold, or Hydrus microstent (Ivantis Inc., Irvine, CA), is an 8-mm nitinol implant that is inserted into Schlemm's canal via an ab interno approach using a preloaded injector. Like the iStent, the Hydrus microstent is approved for use in patients with mild to moderate POAG who are undergoing concurrent phacoemulsification. Studies have demonstrated IOP reductions to the midteens, with a decreased need for glaucoma medications after Hydrus microstent implantation combined with cataract surgery compared with cataract surgery alone.[601, 602] At 1 year, stand-alone Hydrus microstent implantation resulted in higher success rates and use of fewer glaucoma medications compared with placement of two iStents in a randomized clinical trial.[603] The Hydrus microstent appears to have excellent safety, with complications largely limited to focal peripheral anterior synechiae. A 2020 Cochrane Systematic Review found moderate evidence that the Hydrus microstent in the short term is more effective when compared to iStent for lowering IOP in patients with OAG.[604] *(I, Moderate Quality, Strong Recommendation)*

75

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I really want standalone Hydrus.

76

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But we can do standalone OMNI & iStent *infinite* today.

77

ARTICLE IN PRESS

AMERICAN ACADEMY OF OPHTHALMOLOGY®

In partnership with the AMERICAN GLAUCOMA SOCIETY

Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study

Steven D. Vold, MD,[1] Blake K. Williamson, MD,[2] Louis Hirsch, MD,[3] Ardalan E. Aminlari, MD,[4] Andrew S. Cho, MD,[5] Cade Nelson, BS,[2] Jaime E. Dickerson, Jr., PhD[6,7]

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ROMEO Background: "OMNI Surgical System"

- Two mechanisms "addresses multiple points of resistance in the conventional outflow pathway"
  - Proximal: Juxtacanalicular and inner wall of Schlemm's canal (trabeculotomy)
  - Distal: Schlemm's canal and collector channels (canaloplasty)

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ROMEO: Methods

- Aim: Report the immediate, post-launch clinical experience of 10 surgeons with up to 12-mo. effectiveness outcomes in pseudophakes
- Multicenter, retrospective, stratified observational study
  - Stratification: Baseline IOP $\leq$ 18 and >18
  - Consecutive enrollment of all eligible patients
- Minimum 180 deg. canaloplasty and 90 deg. trabeculotomy

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ROMEO Methods – Primary Endpoint

- "Success" = proportion of pts with

  ≥ 20% IOP reduction at 12 mos.

  or

  $6 \leq IOP \leq 18$

  - On same or fewer agents
  - No additional IOP lowering surgery or laser

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ROMEO: Results

- *N* = 48
  - 24 eyes baseline IOP > 18
  - 24 eyes baseline IOP ≤ 18
  - Follow-up time 335 +/- 54.8 days
  - Mean age 75 yo.
  - 54% female
  - 79% Caucasian

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ROMEO Results – Primary Endpoint

- "Success" at 12 mos. = 72.9% (95% CI 60.1 – 85.7%)

- Modified criterion for pts with baseline IOP ≤ 18:

  20% IOP reduction or reduction in medications

  - Only one patient removed as "success"
  - "Success" at 12 mos. = 70.8%

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83

ROMEO Takeaways

- OMNI is safe enough to perform standalone procedure, and it accomplishes…
  - IOP lowering for pts with high IOP
  - Medication reduction for pts with lower IOP

- It does this by reducing outflow resistance
  - 75% of resistance from TM and juxtacanalicular tissue
  - Treat canal atrophy by increasing cross-sectional area of Schlemm's canal
  - Open collector channel ostia

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84

Discussion

- The Interventional Glaucoma Revolution is here!
  - Laser trabeculoplasty in the post-LiGHT era
  - Durysta will only get better
  - Standalone OMNI and iStent infinite are here today
  - (Hopefully standalone Hydrus will be here day-after-tomorrow)
  - Even tough disease is amenable to "interim" MIGS management

85

Discussion

- LiGHT and HORIZON are pivotal trials in glaucoma, and we need to treat them as such.
- Together with the evidence for other interventional techniques, these should drive a shift in the glaucoma treatment paradigm.
- Must preserve patient access to the full range of therapies available at each stage of disease by promoting the (correct) **concept of glaucoma as an "interventional disease"**

86

Discussion

- The goal: String together a series of stage-appropriate interventions over the course of the patient's "glaucoma journey"
- Abandon the drops *then* phaco/MIGS *then* filtering paradigm
- Early adoption of interventions that have better diurnal stability and that are less patient dependent WILL save some patients from filtering surgery

87

Discussion

- SLT performs better as early therapy than as adjunctive therapy; the same is probably true for other interventional techniques
- SLT has an excellent safety profile and is better described as a "laser procedure" than "laser surgery"
- Remember that SLT can be repeated

88

Discussion

- Interventional Glaucoma requires surgeons to maximize their impact and reach as many patients as possible
- Leveraging co-management partnerships between optometric physicians and glaucoma specialists will be key to meeting demand
  - Builds on the existing model in the cataract space but requires longitudinal, less episodic partnership
- IG therefore provides a framework for patient-centered collaboration between ODs and MDs

89

Discussion

Glaucoma co-management starts with optometric physicians who:

(1) Are interested in managing ocular disease

(2) Are skilled in and equipped for disease detection and monitoring

(3) Understand the full range of glaucoma therapies and when to refer at each stage of disease (equipped with an understanding of "interventional glaucoma")

90

Discussion

Glaucoma co-management requires co-managing ophthalmologists to be:

(1) Open to the idea of optometrists practicing at ”top of license”

(2) Engaged in their communities and willing to foster partnerships with individual optometrists

(3) Communicative and accessible

(4) Willing to share knowledge to empower optometric partners

91

Dicussion

Glaucoma co-management starts with optometric physicians who:

(1) Are interested in managing ocular disease

(2) Are skilled in and equipped for disease detection and monitoring

(3) **Understand the full range of glaucoma therapies and when to refer** at each stage of disease (equipped with an understanding of “interventional glaucoma”)

92

93

Questions?

Dr.Garza × GEORGIA EYE PARTNERS

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Glaucoma & Cataract Surgeon
Midtown Atlanta & Downtown Decatur

94