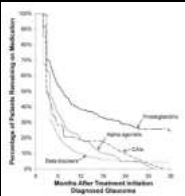




Myth 1 ?


First Line Therapy Is Always A Drop?

4



More than **90%** of patients are nonadherent to their ocular medication dosing regimens, and nearly **50%** discontinue taking their medications before **6 months**!

Nordstrom BL. Persistence and adherence with topical glaucoma therapy. Am J Ophthalmol. 2005;140:598-596



5

Selective Laser Trabeculoplasty Versus Medical Therapy as Initial Treatment of Glaucoma: A Prospective, Randomized Trial

L. Jay Katz, MD, William C. Steinmann, MD,† Azad Kabir, MD,‡ Jeanne Molinenc, COA,* Sheryl S. Wizen, COA,* and George Marcellino, PhD§ the SLT/ Med Study Group*

J Glaucoma • Volume 21, Number 7, September 2012

- SLT Med Study (2012)
 - Dr. Katz @ Wills Eye in Philadelphia
 - J Glaucoma 2012;21:460-468
- SLT (100 applications over 360 degrees of TM) vs. prostaglandin analog
- Primary outcome -> IOP
- Secondary outcome -> # of treatment steps

6

SLT Med Study Treatment Arms



7

SLT vs. Prostaglandins

- SLT Med Study (2012)
- Results:**
- 1. IOP reduction:
 - SLT – 25.7% IOP reduction
 - IOP reduced from 24.5 to 18.2 (6.3 mmHg reduction)
 - Prostaglandin – 28.3% IOP reduction
 - IOP reduced from 24.7 to 17.7 (7.0 mmHg reduction)
- 2. # of treatment steps:
 - SLT group - 11% of eyes required additional SLT
 - Prostaglandin group -> 27% of eyes required additional medication

8

LIGHT trial: 6-year results of primary selective laser trabeculoplasty versus eye drops for the treatment of glaucoma and ocular hypertension

Gus Gazzard, Evgenia Konstantakopoulou, David Garway-Heath, Mariam Adeleke, Victoria Vickerstaff, Gareth Ambler, Rachael Hunter, Catey Bunce, Neil Nathwani, Keith Barton, on behalf of the LIGHT Trial Study Group

Primary Outcome - Quality of Life at 6 years
Secondary Outcome – clinical effectiveness and safety

Conclusions:
No significant difference in QOL
26.8% VS 19.6% progressed drops vs SLT
Trab required in 32 eyes in drops arm compared to 13 eyes in the SLT arm
69.8% of SLT Drop Free @ 6 Years

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Low-Energy SLT Repeated Annually: Rationale for the COAST Trial

Tony Realini, MD, MPH, Gus Gazzard, MD, Mark Latina, MD, Michael Kass, MD

Newly diagnosed POAG treated with:

1. ALT 360 x 1
2. Standard SLT 360 as needed
3. Low-energy SLT 360 repeated annually

10-year Results

Medication Free Rates

1. ALT – 22.6%
2. Standard SLT -25.0%
3. Low-energy SLT – 58.3%

10-year Results

Median Times to Treatment

1. ALT – 2.8 years
2. Standard SLT -3.2 years
3. Low-energy SLT – 6.2 years

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Automated Direct SLT

Automated Direct Selective Laser Trabeculoplasty: First Prospective Clinical Trial

Wordechai Goldenfeld¹, Michael Balkin², Masha Dobkin-Bekman³, Zachary Sacks⁴, Sharon Blum Meirovitch⁵, Nira Geffen⁶, Ari Leibino^{7,8}, and Alon Skaf⁹*



Purpose: Direct selective laser trabeculoplasty (DST) is a rapid, noncontact automated procedure performed directly through the limbus without gonioscopes. In this first nonrandomized clinical trial we assessed its safety and ability to reduce intraocular pressure (IOP).

Methods: Fifteen patients (15 eyes: 10 with open-angle glaucoma (OAG), 4 with ocular hypertension, and 1 with pseudoexfoliation glaucoma), naive or after medication washout, with an IOP ≥ 22 mm Hg, underwent DST by irradiation with 100 or 120 sequential noncontact DST rays. On-attached laser shots (0.8–1.4 mJ) automatically applied during 1.5 or 2.3 seconds on the limbus, guided by image analysis and eye tracking. Results were assessed at 1 and 3 hours, 1 day, 1 week, and 1, 3, and 6 months.

Results: The mean \pm standard deviation baseline IOP (mm Hg) in all eyes was 26.7 \pm 2.3. At 1, 3, and 6 months, this value was significantly reduced to 21.7 \pm 4.2 (by 18.1%), to 20.8 \pm 2.3 (by 37.4%), and to 21.2 \pm 4.1 (by 18.9%), respectively, in the patients treated with 1.4 mJ/shot, the mean IOP at 6 months decreased from 26.7 \pm 2.3 to 19.3 \pm 2.0 (27.1%, $P = 0.03$). There was a significant reduction in hypotensive medications from 1.4 \pm 1.0 to 0.4 \pm 0.7, $P = 0.03$. No serious adverse events occurred.

Conclusions: Automated DST appears to be an effective and safe noncontact, rapid modality for reducing IOP in patients with OAG. Higher energy usage led to better results.

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Iridocorneal Angle

1. Travoprost Intraocular Implant (Glaukos)

Ocular Surface Devices

1. Contact Lenses
2. Microdose latanoprost (EyeNovia)
3. Iontophoresis

Injectable Systems

1. Bimatoprost SR (Abbvie)
2. Travoprost Intracameral Implant (OTX)
3. Travoprost Extended Release Implant (Aerie)

Punctal Plug Devices

1. Latanoprost and Travoprost punctal plug delivery system (Mati)

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Bimatoprost SR (Abbvie)
(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



13

Bimatoprost SR (Abbvie)
(10-microgram bimatoprost sustained-release implant)



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24 Month Phase I/II Clinical Trial

bimatoprost pellet (6, 10, 15, or 20 micrograms)	topical bimatoprost 0.03%
↓	↓
24 months – IOP reduction 7.5, 7.3, 7.3, 8.9 mm Hg	24 months – IOP reduction of 8.2 mm Hg
No Rescue or Retreatment	
68% - 6 mos.	
40% - 12 mos.	
28% - 24 mos.	


Craven ER, Walters T, Christie WC, Day DG, et al. 24-Month Phase I/II Clinical Trial of Bimatoprost Sustained-Release Implant (Bimatoprost SR) in Glaucoma Patients. Drugs. 2020 Feb;80(2): 167-179.

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Travoprost intraocular implant

(Glaukos)

Resides in AC angle, anchored behind TM




- Length: 1.8 mm
- Diameter: 0.5 mm
- Titanium
- Non-ferrous

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Travoprost intraocular implant

(Glaukos)



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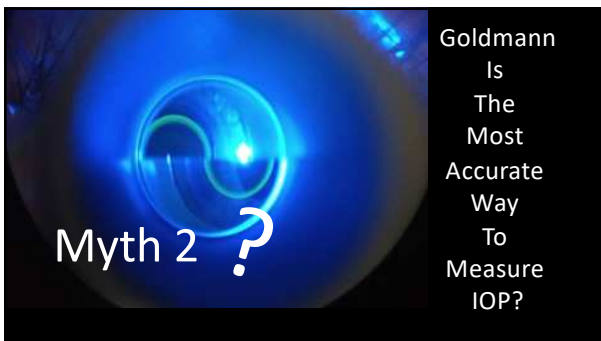
36 Month Update

1. 70% and 68% of subjects in fast and slow-release were well-controlled on fewer or same medications as baseline.
2. Average IOP reductions were 8.3 mmHg and 8.5mmHg in the fast and slow-release arms.

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21



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Limitations of GAT

- 1. Corneal curvature
- 2. Axial Length
- 3. Central corneal thickness
- 4. Tear film biomechanics
- 5. User error
- 6. Patient error



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When gold standards change: time to move on from Goldmann tonometry?

Gus Gazzard,^{1,2} Hari Jayaram ^{2,3} Ana M Roldan ⁴
David S Friedman⁵

Br J Ophthalmol: 10.1136/bjophthalmol-2020-317112 24 September 2020

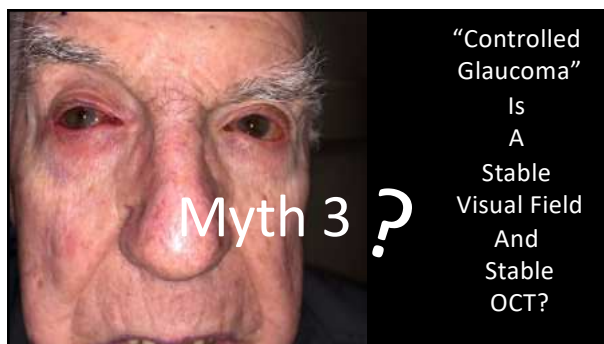
"Why are we persisting in using GAT clinically? The test itself is relatively time consuming, physicians often repeat the measurement because they cannot fully trust a technician, it slows down the clinic requiring technical staff to have slit-lamps and place drops in patient's eyes and worse, it may be giving us a false sense of security."

24

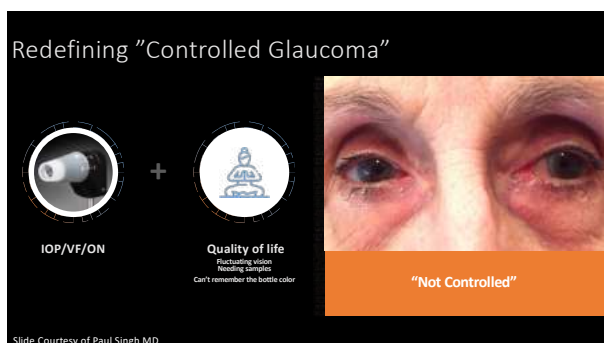
The Correcting Applanation Tonometer Surface (CATS)



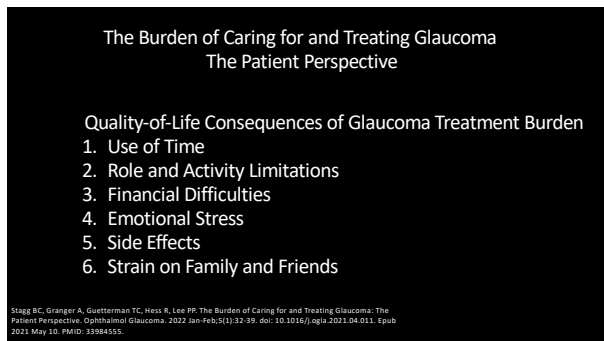
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Solutions?

Preservative-Free Formulations
 SLT
 Glaucoma Drug Delivery
 Minimally Invasive Glaucoma Surgery

35

Preservative-Free Formulations

N=349, Significant improvement in both signs and symptoms of OSD with switch to PF meds

Table 4 Frequency of symptoms and signs at visits 1 and 2 in PF group

	Visit 1 (preserved)		Visit 2 (preservative free)		p-Value
	No*	(%)	No*	(%)	
Patient symptoms					
Discomfort upon instillation	186/245	77.4%	40/243	17.7%	<0.001
Patients presenting with at least one symptom between instillations	283/343	82.2%	123/244	50.8%	<0.001
Ocular signs found at the clinical examination (patients presenting with at least one)					
Pupillary sign (Dysphotopsia)	123/242	51.7%	30/246	14.3%	<0.001
Conjunctival sign	232/238	98.9%	76/238	31.9%	<0.001
Superficial punctate keratitis	43/138	31.4%	18/237	7.6%	<0.001

*Number of patients for which the variable had been recorded

Rosta, P.J., P. Rouiquen, and C. Baudouin. Prevalence of ocular symptoms and signs with preserved and preservative free glaucoma medication

36

Preservative-Free Solutions

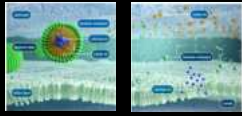
PF-Latanoprost

	Phase 3 (US) Trial (n=325)		Phase 3 (Europe) Trial (n=353)	
	PF-Latanoprost	Xalatan	PF-Latanoprost	Xalatan
Mean baseline IOP ± SD (mmHg)	18.8 ± 2.9	19.2 ± 3.1	24.1 ± 1.8	24.0 ± 1.7
Mean IOP reduction from baseline (mmHg) (range)	2.7 (2.2 - 3.0)	3.4 (2.9 - 3.8)	8.6 (8.3 - 8.8)	8.9 (8.8 - 9.0)

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BAK-Free Latanoprost

- Following instillation, micelles mix with the tear film
- As the micelles migrate toward the ocular surface, they break apart, releasing latanoprost



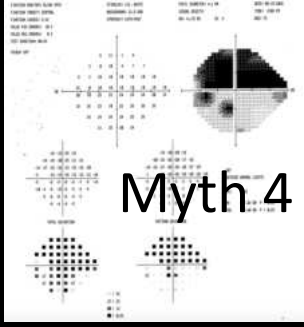
Preservative-Free

Product Name	Preservative
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None
TAZ (latanoprost)	None

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39



Myth 4 ?

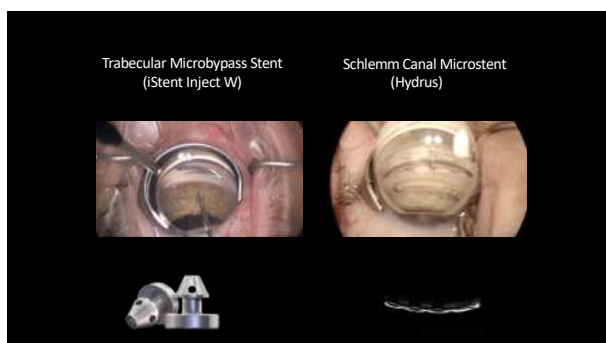
Surgical Intervention Should Be Delayed For As Long As Possible?

40

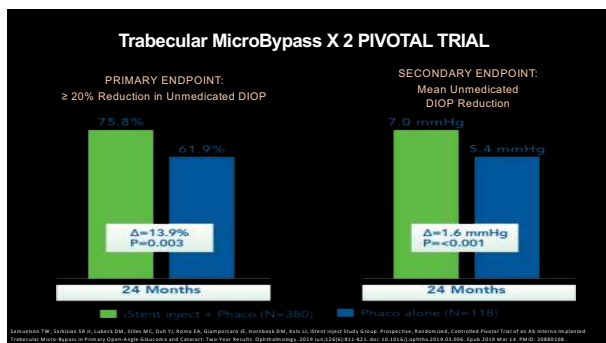
Schlemm's Canal/TM Procedures

	Stents	SC Dilation	TM Cutting
Fibrosis Risk	(-)	(+)/(-)	(+)(+)
Hyphema	(-)	(+)/(-)	(+)(+)
PAS Risk	(-)	(-)	(+)
IOP Lowering	(+)	(+)	(+)(+)
Data	(+)(+)(+)	(+)/(-)	(+)(+)

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HORIZON Trial – 5 Year

	Stent + Cataract (n=369)	Cataract Only (n=187)
Change in diurnal IOP (mean)	-8.3 mm HG (+/-3.8)	-6.5 mm HG (+/-4.0)
60 months medication free	66%	46%
60 months mean IOP (mm Hg)	16.6 (+/-3.2)	17.6 (+/-3.6)
1 preoperative med	52.6%	54%
2 to 4 preoperative med	47.4%	46%

Arnold HK, De Francesco T, Rhee D, McCabe C, Powers R, Gussard S, Sarrafian TW, Singh K. HORIZON investigators. Long-term outcomes from the HORIZON randomized trial for a Schlemm's canal microstent in combination with cataract and glaucoma surgery. *Ophthalmology*. 2022 Feb 23;131(2):422-432.

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Trabecular MicroBypass X 2 PIVOTAL TRIAL¹

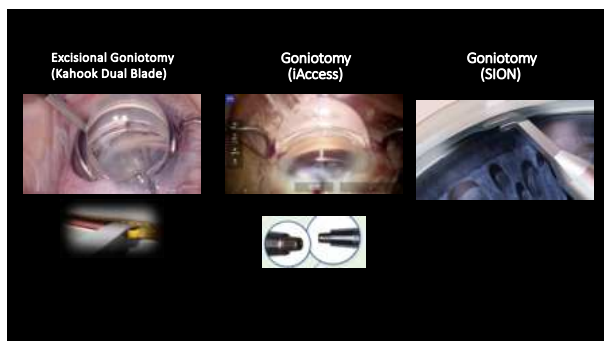
Conclusions: The overall safety profile of the treatment group was favorable and similar to that in the control group throughout the 2-year follow-up.

HORIZON Trial – 5 Year²

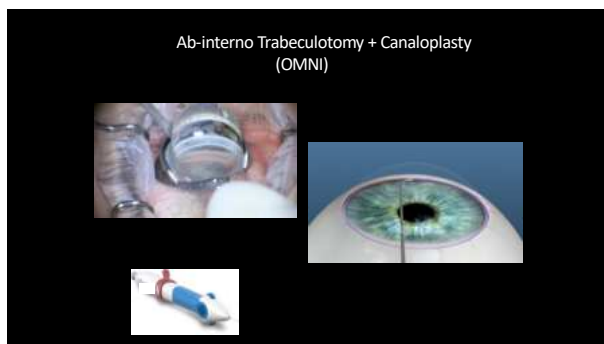
Conclusions: The addition of a Schlemm's canal microstent in conjunction with CS was safe, resulted in lowered IOP and medication use, and reduced the need for postoperative incisional glaucoma filtration surgery compared with CS after 5 years. Long-term presence of the implant did not affect the corneal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

1. Sarrafian TW, Sarkissian SB Jr, Lubner DM, Schar MJ, Doh Y, Rama EA, Gnanapavan R, Warrick DM, Katz LJ. Trabecular MicroBypass X2 Pivotal Trial of an Ab Interno Implanted Trabecular MicroBypass System Using Schlemm's Canal. *Ophthalmology*. 2019 Jun;126(6):1213-1220. Epub 2018 Mar 22. PMID: 29583255
2. Arnold HK, De Francesco T, Rhee D, McCabe C, Powers R, Gussard S, Sarrafian TW, Singh K. HORIZON investigators. Long-term outcomes from the HORIZON randomized trial for a Schlemm's canal microstent in combination cataract and glaucoma surgery. *Ophthalmology*. 2022 Feb 23;131(2):422-432.

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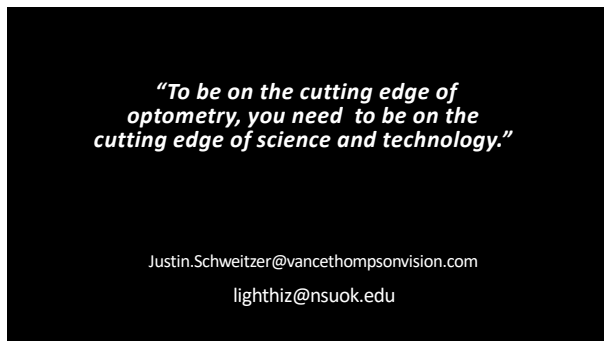
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