

On behalf of Vision Expo, we sincerely thank you for being with us this year.

Vision Expo Has Gone Green!

We have eliminated all paper session evaluation forms. Please be sure to complete your electronic session evaluations online when you login to request your CE letter for each course you attended! Your feedback is important to us as our Education Planning Committee considers content and speakers for future meetings to provide you with the best education possible.

1

Innovations in Glaucoma

Next Generation Technology, Medications, and Delivery

Justin Schweitzer, OD, FAAO

Vance Thompson Vision, Sioux Falls, South Dakota

Optometric Externship Director

Associate Director Residency Program

2

Financial Disclosure – Justin Schweitzer, OD, FAAO

- Acetate - C/I
- Alcon - C/I
- Allergan - C/I
- Bausch + Lomb - C/I
- Ocular Therapeutics - C
- EyePoint - C
- Sight Sciences - C/I
- Dura - C
- Zeiss - C/I
- Vitus - C
- Science Based Health - C
- Kala - C
- RVL - C

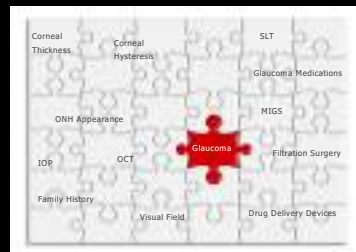
- Sun - C/I
- Equinox - I
- Reichert - C
- J&J - C/I
- Glaukos - C/I
- Horizon - C
- Quidel - C
- MedPointe - C
- LAC - C/I
- Avellino - C
- Novartis - C
- Inverto Bio - C
- Occhipore - C

3

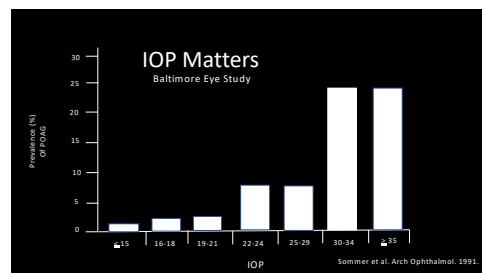
Today's Optometrists

"To be on the cutting edge of optometry, you need to be on the cutting edge of science and technology."

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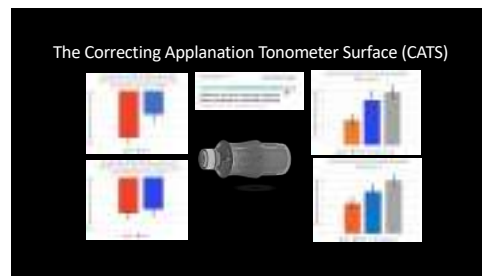
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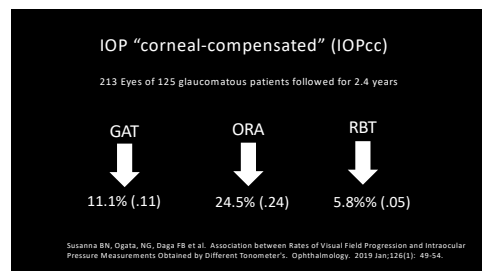
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14



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Corneal Hysteresis, IOP, CCT



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Corneal Hysteresis

Corneal Hysteresis reflects the ability of the corneal tissue to dissipate energy¹
Function of viscoelastic damping²

Two predictive functions

1. Which glaucomatous eyes are most susceptible to visual field loss progression and risk of rate of progression?
2. Which eyes are susceptible to glaucoma?

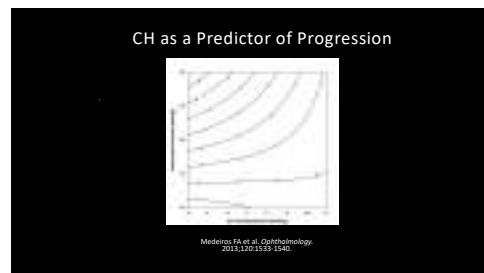
1. Linn BH, J. Glaucoma's Refract Surg. 2006;11:156-162.
2. Dapkin NG, R. J. Glaucoma's Refract Surg. 2007;11:1499-1505.

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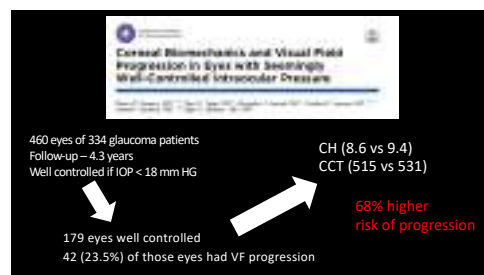
Average CH in Normal Subjects

	N	CH
Brazil	105	10.1 +/- 1.8
UK	272	10.2 +/- 1.2
China	125	10.9 +/- 1.5
Japan	204	10.2 +/- 1.3
Spain	88	10.8 +/- 1.5
USA	44	10.5 +/- 1.2

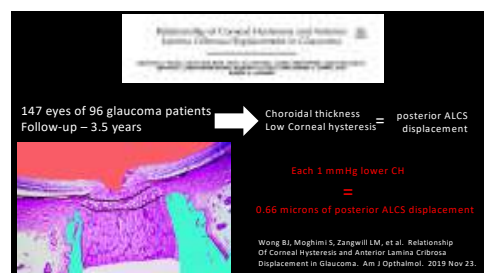
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Home IOP Monitoring

A device is intended as an adjunct for monitoring IOP of adult patients (self-use). The HOME tonometer is designed for use at home or on the go.



Time	IOP	Time	IOP
12:00	12.0	12:00	12.0
12:05	12.5	12:05	12.5
12:10	13.0	12:10	13.0
12:15	13.5	12:15	13.5
12:20	14.0	12:20	14.0
12:25	14.5	12:25	14.5
12:30	15.0	12:30	15.0
12:35	15.5	12:35	15.5
12:40	16.0	12:40	16.0
12:45	16.5	12:45	16.5
12:50	17.0	12:50	17.0
12:55	17.5	12:55	17.5
13:00	18.0	13:00	18.0
13:05	18.5	13:05	18.5
13:10	19.0	13:10	19.0
13:15	19.5	13:15	19.5
13:20	20.0	13:20	20.0
13:25	20.5	13:25	20.5
13:30	21.0	13:30	21.0
13:35	21.5	13:35	21.5
13:40	22.0	13:40	22.0
13:45	22.5	13:45	22.5
13:50	23.0	13:50	23.0
13:55	23.5	13:55	23.5
14:00	24.0	14:00	24.0
14:05	24.5	14:05	24.5
14:10	25.0	14:10	25.0
14:15	25.5	14:15	25.5
14:20	26.0	14:20	26.0
14:25	26.5	14:25	26.5
14:30	27.0	14:30	27.0
14:35	27.5	14:35	27.5
14:40	28.0	14:40	28.0
14:45	28.5	14:45	28.5
14:50	29.0	14:50	29.0
14:55	29.5	14:55	29.5
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15:45	34.5	15:45	34.5
15:50	35.0	15:50	35.0
15:55	35.5	15:55	35.5
16:00	36.0	16:00	36.0
16:05	36.5	16:05	36.5
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16:15	37.5	16:15	37.5
16:20	38.0	16:20	38.0
16:25	38.5	16:25	38.5
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16:55	41.5	16:55	41.5
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17:15	43.5	17:15	43.5
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17:25	44.5	17:25	44.5
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17:35	45.5	17:35	45.5
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10:55	149.5	10:55	149.5
11:00	150.0	11:00	150.0

ARGOS-02 Trial: 1 year results

- 22 Patients
- Major Design Changes:
 - 0.9 to 0.5mm thickness with 0.1mm rounded tapering
 - 4 haptics to prevent ciliary sulcus rotation
- IOP Concordance:
 - D30:
 - Eyemate: 22.2 ± 0.2 mmHg
 - GRT: 19.5 ± 0.8 mmHg
 - D360:
 - Eyemate: 15.7 ± 3.8 mmHg
 - GRT: 14.1 ± 2.2 mmHg

Avastar Journal of Ophthalmology (2023) 1(1) 1010, pp. 2019-2021





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Sensors on the horizon...

LaunchPoint Technologies (Goleta, CA)

- Sensor attached to IOL or injected into vitreous



Intelligence Research Center, LaunchPoint Technologies, Avastar (2023) 1(1) 1010, pp. 2019-2021

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Sensors on the horizon...

- AcuMEMS (Menlo Park, CA)
 - Series system implantable sensor
- Glaukos (San Clemente, CA)
 - DQSC Medical IOP Sensor
- Implantsdata Ophthalmic Products GmbH
 - Suprachoroidal IOP sensor
- Injectsense Inc (Emeryville, CA)
 - Configurable on-demand sensor
- LaunchPoint Technologies (Goleta, CA)
 - Sensor attached to IOL or injected into vitreous
- Solk (Waltham, MA)
 - wireless intraocular sensor



Intelligence Research Center, LaunchPoint Technologies, Avastar (2023) 1(1) 1010, pp. 2019-2021

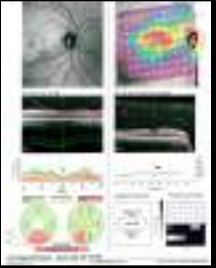
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OCT

Pay attention to TSNIT curve.

Pay attention to the actual numbers in the segmentation plot

Pay attention to the numbers between eyes in the segmentation plot



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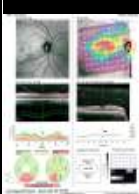
comprehensive provision of retinal nerve fiber layer and macular thickness asymmetry parameters for identifying early primary open-angle glaucoma

Inter-eye (OD/OS) macular thickness asymmetry 5 microns

Intra-eye (sup/inf of same eye) macular thickness 9 microns

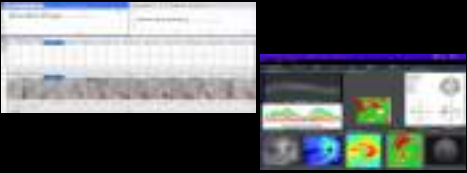
Inter-eye (OD/OS) average RNFL thickness 9 microns

Total RNFL thickness 78 microns or less

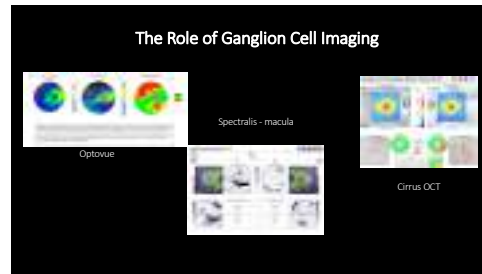


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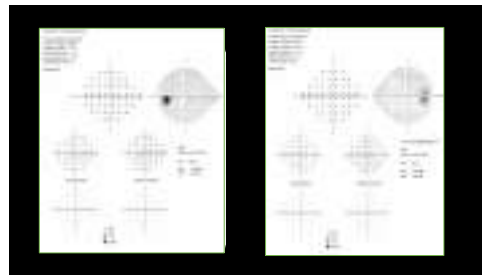
OCT Technology – Matching Structure and Function



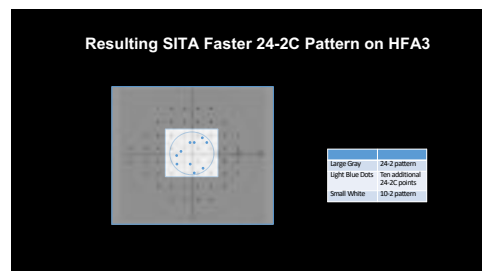
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A New SITA Perimetry Threshold Testing Algorithm: COAT (Cognitive and Objective Threshold)
Clinical Study

Study	Results
Study 1	30.4% shorter than SITA Fast
Study 2	53.5% shorter than SITA Standard

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Objective Visual Field Testing

FDA 510(K) Cleared
Tests OU simultaneously in 7 minutes
Measures the response of the pupils to a stimulus

objectiveFIELD

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The Future of Visual Field Testing?

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OCT Angiography: the Next Chapter?

- Images retinal microvasculature without dye injection
- Displays structure and function from a single imaging system



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Trend Analysis

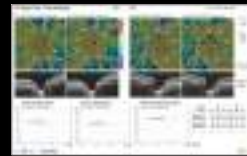


Image courtesy of Eric D. Hollerman, MD and Michael H. Goldbaum, MD of Biologics Research Institute, University of California at San Diego, La Jolla, CA

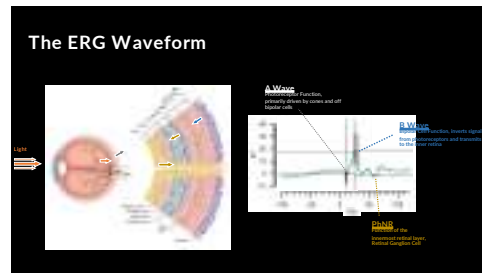
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Electroretinography

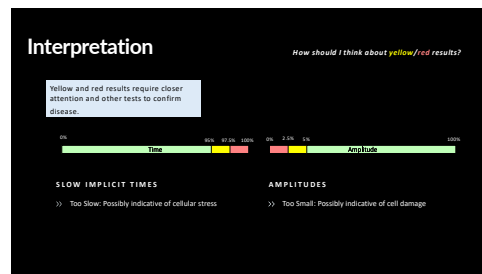
Measures the electrical responses of various cell types in the retina, including the photoreceptors (rods and cones), inner retinal cells (bipolar and amacrine cells), and the ganglion cells in response to a stimulus.



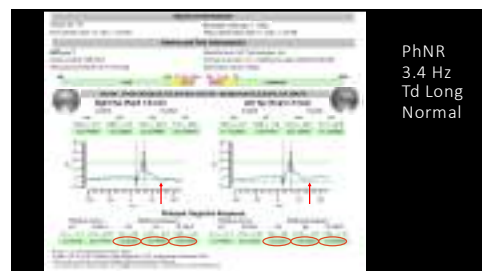
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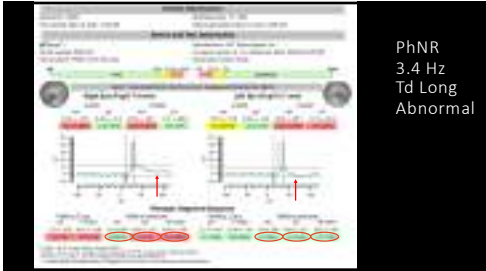
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Evaluation of an AI system for the automated detection of glaucoma from stereoscopic optic disc photographs: the European Optic Disc Assessment Study

- Objectives - To evaluate the performance of a deep learning based Artificial Intelligence (AI) software for detection of glaucoma from stereoscopic optic disc photographs, and to compare this performance to the performance of a large cohort of ophthalmologists and optometrists.
- Results
 - Pegasus was able to detect glaucomatous optic neuropathy with an accuracy of 83.4% (95% CI: 77.5–89.2)
 - This is comparable to an average ophthalmologist / optometrist accuracy of 80.5% / 80% respectively (95% CI: 67.2–93.8) / (85% CI: 67–95) on the same images.
 - There was no statistically significant difference between the performance of the deep learning system and ophthalmologists or optometrists.

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Genetics of Glaucoma

Key Points

- Ultimately, it allows for a more personalized patient management treatment algorithm
- Understanding the genetic basis of various forms of POAG glaucoma provides an opportunity for targeting specific genes or biological pathways for disease.
- By genetic testing it may be possible in the future to provide personalized therapeutic plans for a given patient based on knowledge of their specific gene mutations and the molecular pathways they impact
- Patients with gene variants in mitochondrial genes may benefit from antioxidant therapies, whereas patients with mutations in lipid metabolism genes may benefit from cholesterol lowering medications. JAMA Ophthalmol. 2019;137(7):756-765. doi:10.1001/jamaophthalmol.2019.0900

Avellino's test will have Monogenic & Polygenic POAG forms

Early Onset monogenic forms:

- Juvenile open angle glaucoma
- Congenital glaucoma
- Anterior segment developmental syndrome

Adult Onset polygenic forms:

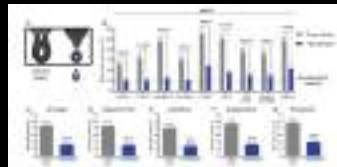
- Primary open angle glaucoma (POAG)
- Angle closure glaucoma (ACG)
- Low tension glaucoma (LTG)
- Exfoliation glaucoma

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Treatment

53

Delivering Treatment



54

latanoprostene bunod 0.024% (Vyzulta)



55


Nitric Oxide

Endogenous in the human body

Causes alterations in the cytoskeletal network

Reduced NO in TM, Schlemm's canal, and ciliary muscle

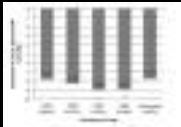
Nathanson JA et al. Alterations of ocular nitric oxide synthase in human glaucoma. Invest Ophthalmol Vis Sci. 1999;40(12):3111-3118.



56

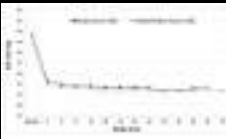
VOYAGER Study

latanoprostene bunod 0.024% (Vyzulta)



JUPITER Study


latanoprostene bunod 0.024% (Vyzulta)



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Association of Dietary Nitrate Intake With Primary Open-Angle Glaucoma: A Prospective Longitudinal Study

the Nurses' Health Study and Health Professionals Follow-Up Study



•63,893 women from Nurses' Health Study

•41,094 men from Health Professionals Follow-Up Study

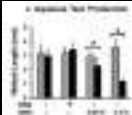

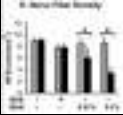
Findings:

- Compared with the lowest quintile of dietary nitrate intake (appx 80mg/day), the highest quintile (appx 240mg/day) was associated with:
- 21% lower risk of all POAG
- 44% lower risk of POAG with early paracentral visual field loss

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Neurotoxicity of BAK

- Exposure to BAK (0.01% or 0.1%) QD x 7 days:
 - Decrease NFD ($p=0.02$ & 0.001)
 - Decrease aqueous production (phenol red)




Invest Ophthalmol Vis Sci. 2012 Apr; 53(4): 1792-1802

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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



60

netarsudil 0.02% (Rhopressa)

MOAs

- ↓ aqueous humor production
- ↑ trabecular outflow
- ↓ episcleral venous pressure

ROCK inhibitors

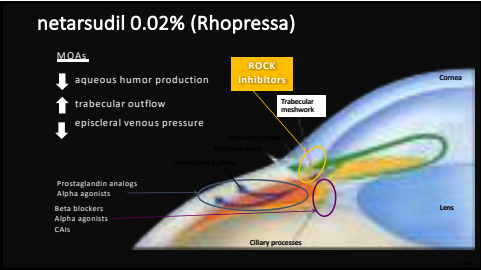
Trabecular meshwork

Ciliary processes

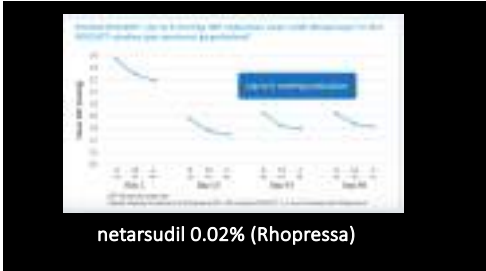
Coma

Lens

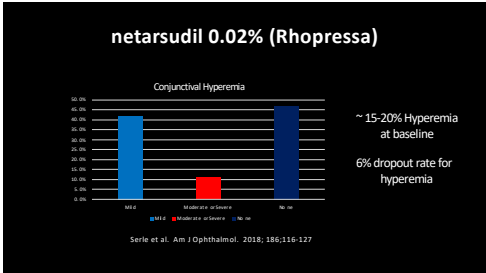
Prostaglandin analogs
Alpha agonists
Beta blockers
Alpha agonists
CAIs



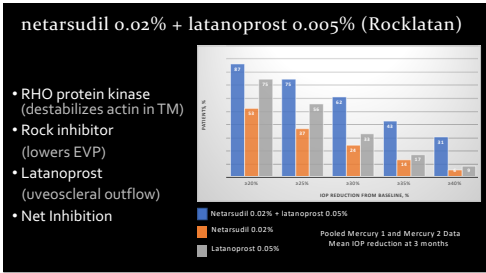
61



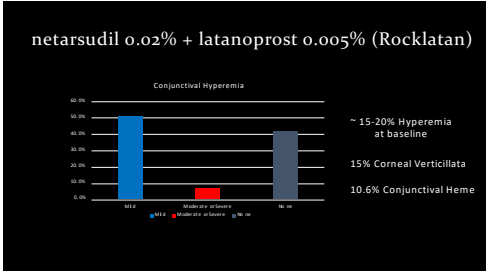
62



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Omidenepag Isopropyl (OMDI)

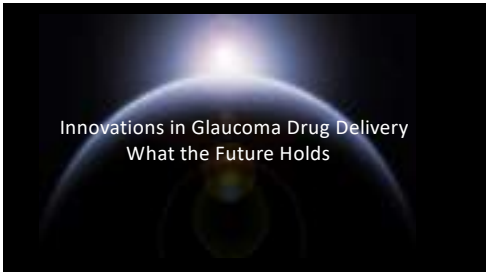
Selective, non-prostaglandin, prostanoid EP2 receptor agonist
Mechanism of Action: Increase outflow via both conventional and uveoscleral

Phase 3 AYAME Study

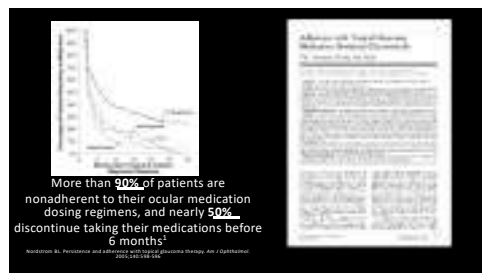
OMDI 0.002% vs latanoprost 0.005%
qd dosing x 4 weeks
Baseline IOP ~ 24 mm Hg

OMDI = 25.1% reduction (17.81 mm Hg)
Conjunctival hyperemia = 24.5%

66



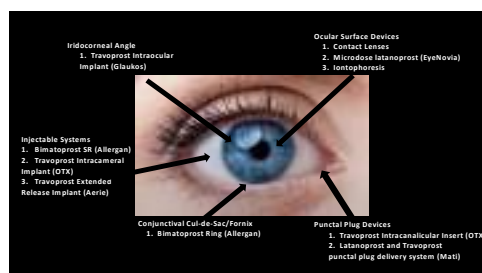
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Patients Attitudes Towards Drug Delivery

- Triple Combination Eye Drop – 85%
- Microdose Eye Spray – 54%
- Drug-eluting Contact Lens – 31%
- Drug-eluting Periocular Ring Insert – 43%
- Injectable Subconjunctival Drug Insert- 32%
- Injectable Anterior Chamber Implant – 30%

attitude is everything

Wang BB, Lin MM, Nguyen T, et al. Patient attitudes towards novel glaucoma drug delivery approaches. *Digit J Ophthalmol*. 2018; 24(3): 18-23

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Microdose latanoprost (EyeNovia)

Delivers microdoses of latanoprost with Optejet delivery

Advantages: 75% less drug and preservative
88% of the time got to target

Achieved 29% IOP lowering from baseline in Phase 2 study




Pasquale LA, Shan L, Weisrath RN, et al. Latanoprost with high precision, Pico-print microdose delivery for IOP lowering: clinical results of the P021 study of 0.4 micrograms daily microdose.

73

Drug-Eluting Contact Lens

Attractive option secondary to large residence time in the eye and upward of 50% bioavailability in comparison with eye drop formulations.



Li CC, Chauhan A. Modeling ophthalmic drug delivery by soaked contact lenses. *Ind Eng Chem Res* 2006; 45: 3716-3734.

Peng C-C, Kim J, Chauhan A. Extended delivery of hydrophilic drugs from silicone hydrogel contact lenses containing Vitamin E diffusion barriers. *Biomaterials* 2010; 31: 4032-4047.

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Drug-Eluting Contact Lens

- Diophter Corporation
 - Uses an approved contact lens with approved drugs
 - Vitamin E Nano-barriers to extend drug release
- Phase I
 - Subject wore contact lens for 2 day dosing period
 - IOP reduction was observed over 9 days after the lens was removed
- Phase Ib and Phase 2 are planned for 2nd and 3rd quarter of 2021

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Drug-Eluting Contact Lens

- MediPrint Ophthalmics
 - LLT-BMT1 – drug eluting contact lens - bimatoprost
- Phase I – SIGHT-1
 - 5 Subjects wore the lens for 7 days continuously
 - Demonstrated 100% tolerability and no adverse events
 - IOP efficacy was noted
- SIGHT-2 – Phase 2b dose-ranging clinical study is underway

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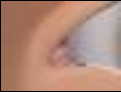

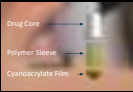
Punctal Plug Delivery System

(Mati Therapeutics)

Latanoprost and Travoprost designs

U.S. Phase II Multi-center Trials (Lower Puncta)
Glau 12 (n=92) – 96% retention rate
Glau 13 (n=87) – 92% retention rate

Phase II Clinical Study
L-Evolute - 5.5 mmHg IOP lowering over 12 weeks study



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Travoprost Intracanalicular Insert


(Ocular Therapeutic)

Bioresorbable sustained-release intracanalicular insert

Designed for continuous steady release of travoprost to the ocular surface for up to 90 days

Preservative free

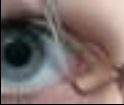
Allows visualization




Low Ocular Adverse Events:

Dacryocanalculitis - 8.3%

Lacrimal structure disorder - 6.6%




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Travoprost Intracanalicular Insert

(Ocular Therapeutic)



Phase III randomized, double-blind, placebo-controlled clinical trial

Diurnal Time Points	2 Week		Reduction in IOP		12 Week	
	mm Hg		mmHg		mmHg	
	OTX-TP	Vehicle	OTX-TP	Vehicle	OTX-TP	Vehicle
8:00 AM	-5.72	-3.88	-4.81	-4.01	-3.91	-3.52
10:00 AM	-4.92	-3.16	-4.63	-3.23	-3.34	-2.63
4:00 PM	-5.22	-3.18	-4.16	-3.14	-3.27	-2.60

n=334 OTX-TP

n=211 Vehicle

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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



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Bimatoprost SR (Allergan)

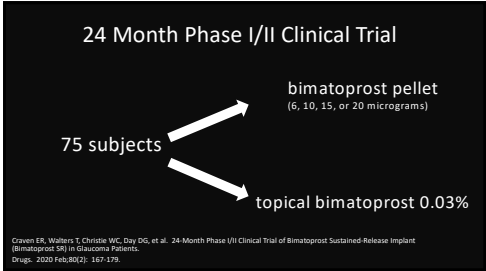
(10-microgram bimatoprost sustained-release implant)



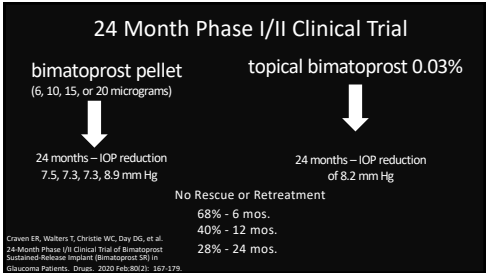
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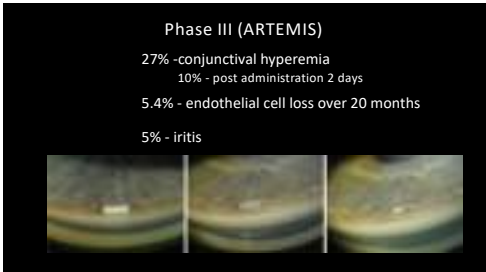
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Travoprost Intracameral Implant

(Ocular Therapeutic)

Bioresorbable sustained-release implant injected into the AC


Goal: Steady release of travoprost with target duration from 4 to 6 months



Precinical Models (beagle dogs)

Steady state release through 4 months

IDP lowering of 25-30% through 4 months



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Travoprost Intracameral Implant

(Ocular Therapeutic)

Phase 1, prospective, multi-center, open label

Cohort 1 n=5
(15 micrograms)


Cohort 2 n=4
(26 micrograms)

Cohort 3 n=4
(15 micrograms
Fast Degrading)

Day 28 - 9.1 mm Hg (n=5)
Mo. 4 - 7.6 mm Hg (n=4)
Mo. 6 - 7.5 mm Hg (n=3)
*Mo. 21 - 9.3 (n=1)

Day 28 - 6.0 mm Hg (n=4)
Mo. 4 - 6.8 mm Hg (n=4)
Mo. 6 - 6.1 mm Hg (n=3)
*Mo. 9 - 5.9 (n=2)

Day 28 - 11.3 mm Hg (n=3)
Mo. 4 - 13.8 mm Hg (n=2)
*Mo. 6 - 12.5 (n=1)




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Travoprost intraocular implant

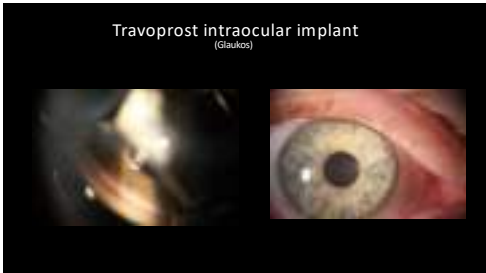
(Glaukos)

Resides in AC angle, anchored behind TM



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

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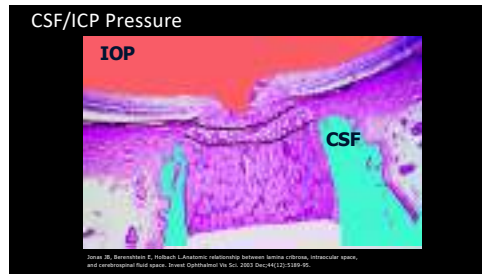
90



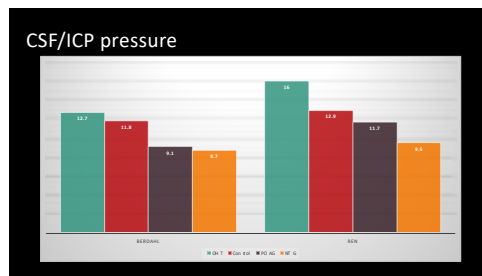
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92



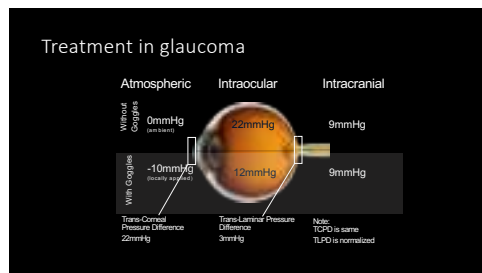
93



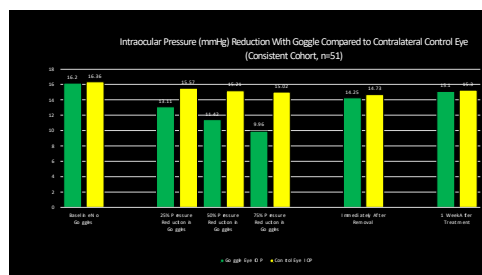
94



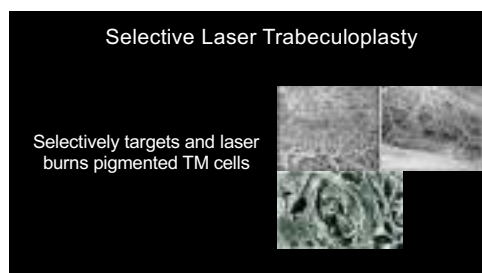
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Selective Laser Trabeculoplasty Versus Medical Therapy as Initial Treatment of Glaucoma: A Prospective, Randomized Trial


Dr. Katz @ Wills Eye in Philadelphia

J Glaucoma 2012;21:460-468

- 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

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SLT Med Study Treatment Arms



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SLT vs. Prostaglandins

SLT Med Study (2012)

Results:

1. IOP reduction:
 - SLT - 25.7% IOP reduction
 - IOP reduced from 24.8 to 18.7 (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

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SLT, which is a laser procedure, is a minimally-invasive procedure that is performed in the office. It is a safe and effective treatment for glaucoma. SLT is a non-invasive procedure that is performed in the office. It is a safe and effective treatment for glaucoma. SLT is a non-invasive procedure that is performed in the office. It is a safe and effective treatment for glaucoma.

Primary Outcome - Quality of Life at 3 years
Secondary Outcome – Cost, cost-effectiveness, clinical effectiveness, and safety

Conclusions:
No significant difference in QOL
97% probability of SLT as 1st treatment being more cost-effective
SLT at target IOP 93% of visits vs 91.3% at target for meds
78.2% of SLT Drop Free @ 3 Years

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Steroid After Laser Trabeculoplasty (SALT)

Steroid	NSAID
• IOP Pre-Op: 23.3 mm Hg	• IOP Pre-Op: 23.3 mm Hg
• 12 week IOP check	• 12 week IOP check
• IOP lowering of 5.2±2.7 mmHg	• IOP lowering of 6.2±3.1 mmHg
Saline Tears IOP lowering of 3.4±3.3 mmHg	
• Steady state IOP ~ 6 weeks (new baseline)	

Graph et al. Steroids After Laser Trabeculoplasty (SALT) Trial: Impact of Short-term Anti-inflammatory Treatment on SLT Efficacy. Ophthalmology June 1, 2018

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What
About
MIGS

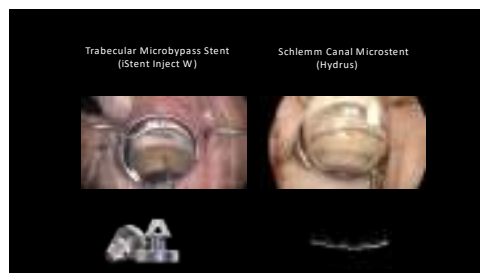
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**US Multicenter Pivotal Trial:
Trabecular Microbypass Stent x 3
(iStent infinite)**

Three-stent, standalone procedure

- Three wide flange stents preloaded in injector system, to facilitate placement across ~6 clock hrs. of Schlemm's canal



Trial enrolled patients with open angle glaucoma with uncontrolled IOP:

- Unresponsive to maximum tolerated medical therapy O₃
- Uncontrolled by medical therapy and have failed ≥ 1 conventional incisional intraocular glaucoma or ciliabative procedure

Enrollment completed Oct 2019

- US IDE open label, prospective, single-arm pivotal study
- 72 subjects across 15 investigational sites
- 12-month follow-up

Not approved by the FDA

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**Excisional Goniotomy
(Kahook Dual Blade)**

**Goniotomy
(Access)**





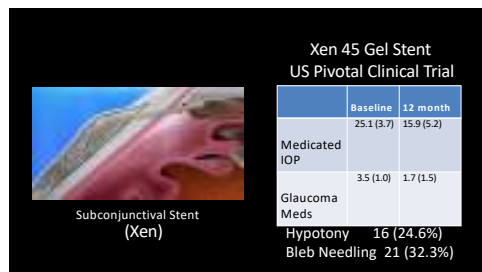

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**Ab-interno Trabeculotomy + Canaloplasty
(OMNI)**





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Technology is nothing.
 What's important is that you have a faith in people, that they're basically good and smart, and if you give them tools, they'll do wonderful things with them.

justin.schweitzer@vancethompsonvision.com

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