



Surgical Management of Glaucoma: Evolving Concepts

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Disclosures

Research Funding

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Alcon

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Ad Hoc Consultant

Alcon, Allergan, Iantrek, QLaris



Agenda: Surgery First and Earlier

- **First-line Treatment**
 - **Early-Mild Stage Dz: Selective Laser Trabeculoplasty**
 - **Advanced Stage Dz: Trabeculectomy**
- MIGS: Evidence Based
- What is Disease Progression?

How Have We Initiate Treatment for so many years?

Initiate Topical Medications

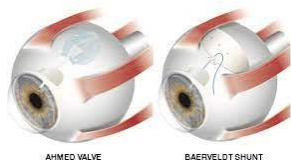
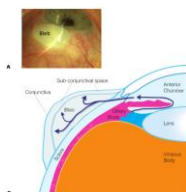


Laser Trabeculoplasty



Incisional Full-Thickness Surgery

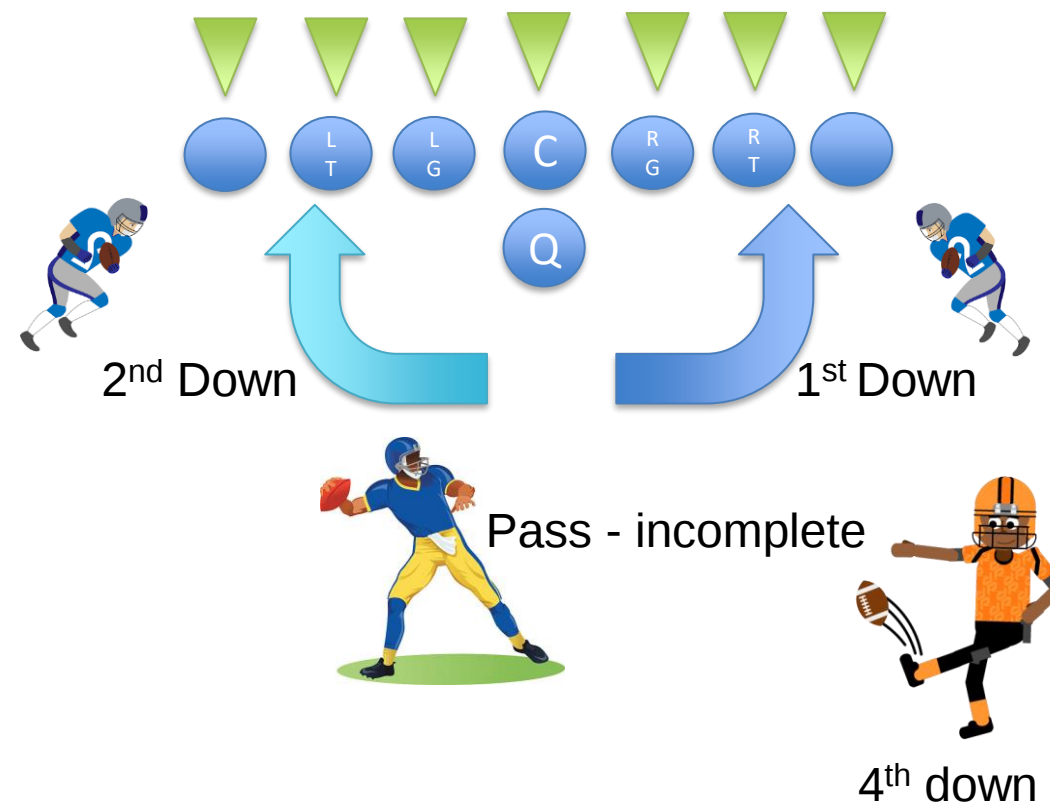
Trab

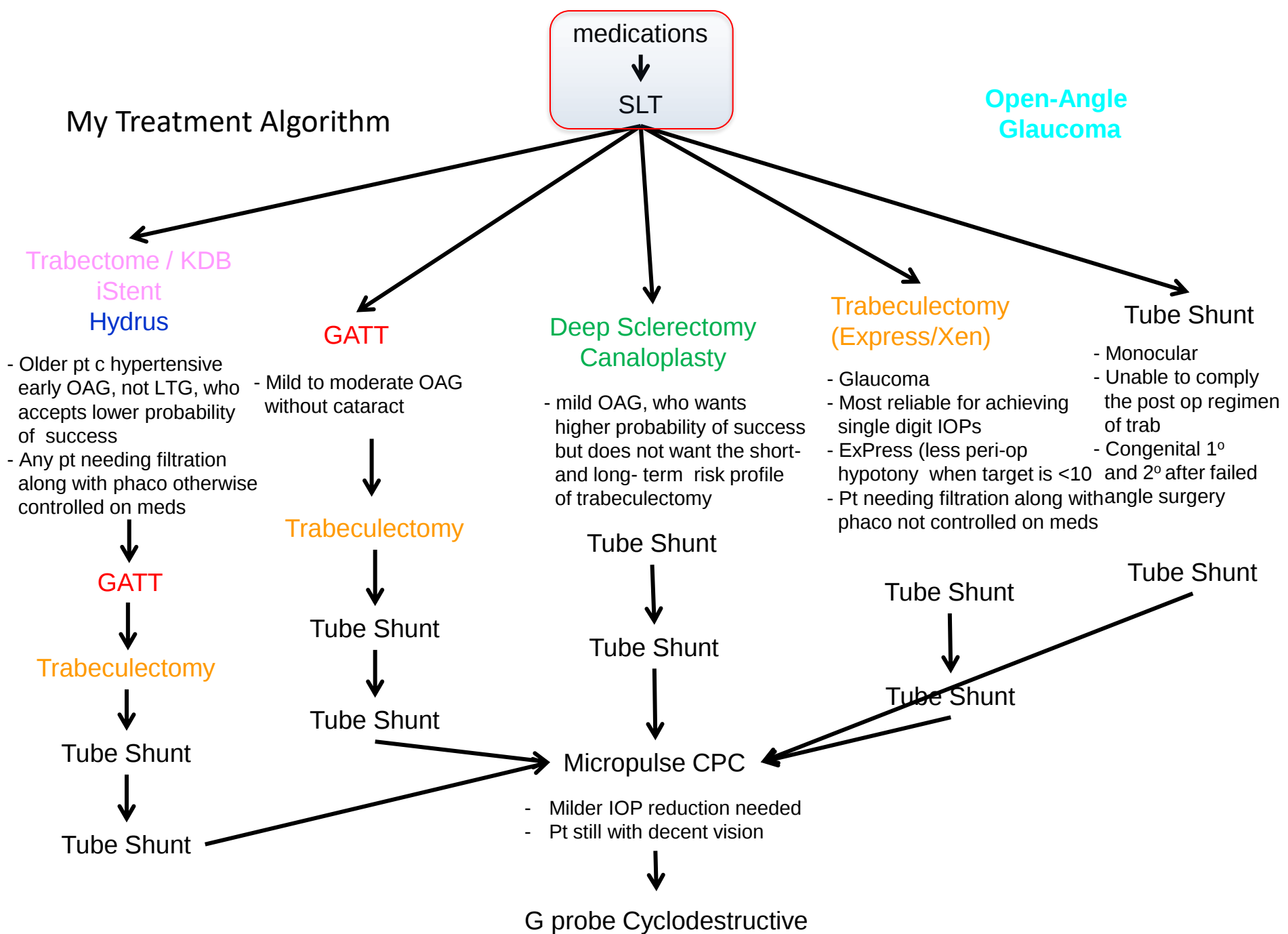


Tube

BIGTEN
CONFERENCE

1990 - 2011





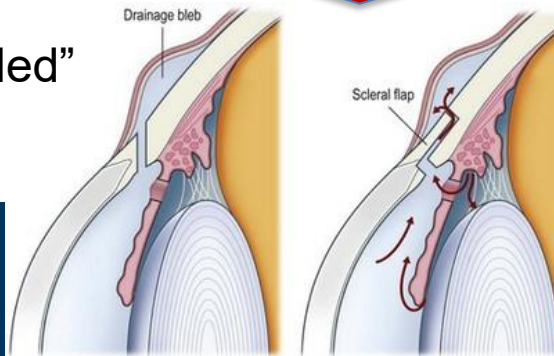
Why Did We Do This?

- In the 1960s through 1995

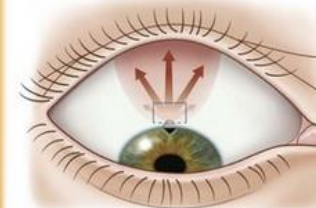


Argon Laser Trabeculoplasty 514 nm

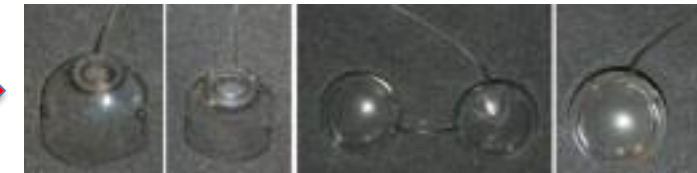
Shea Procedure
“Direct”
“Unguarded”



Trabeculectomy
Guarded

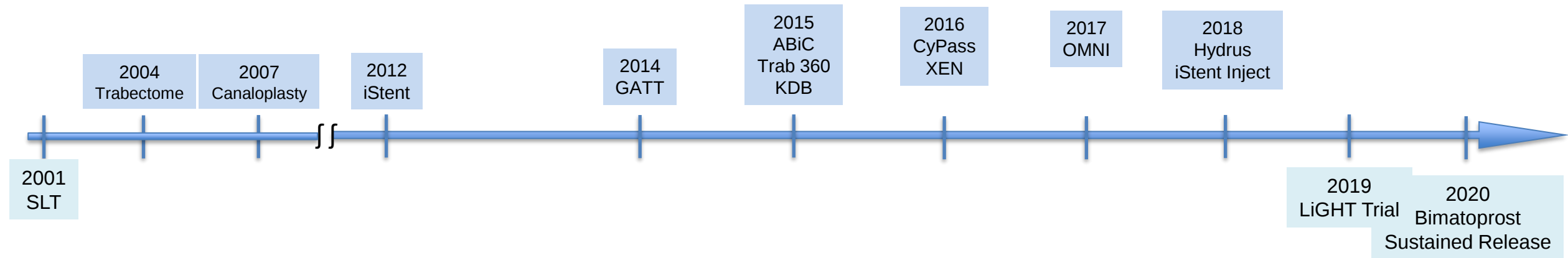


Molteno Implants



Continuing Trend

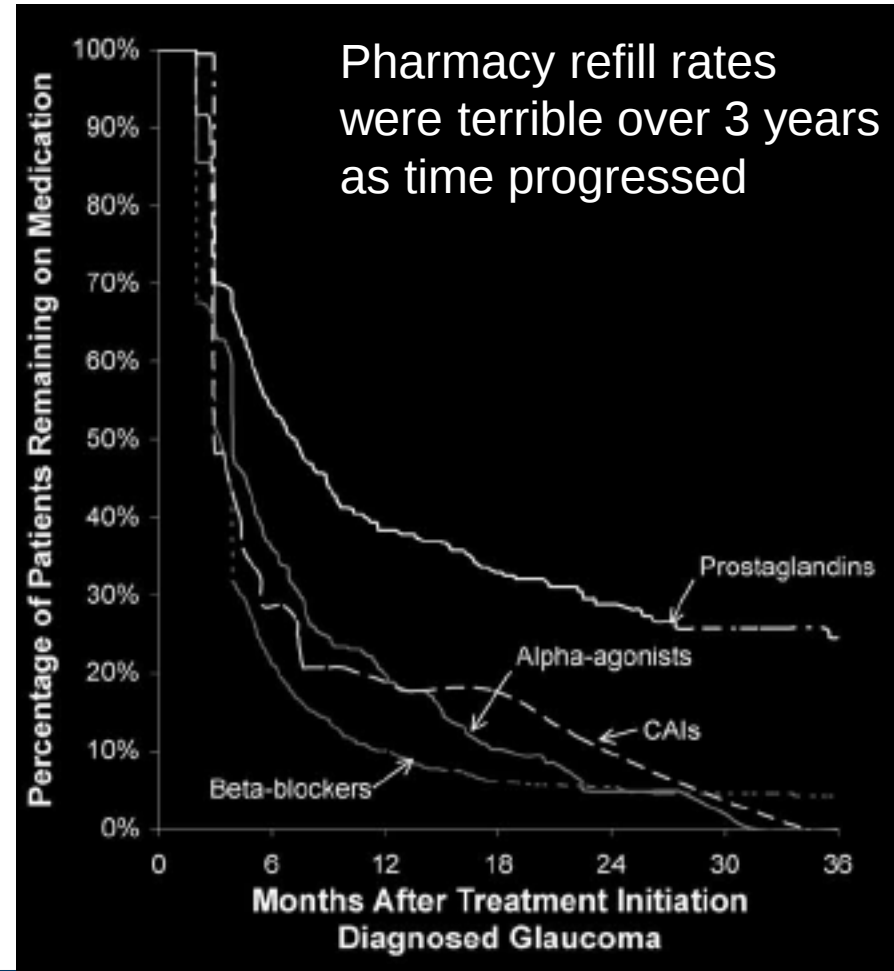
- We always errored towards safety – and meds were much safer than the surgical procedures of the day
- From 2000 until about 2005, medications only became more effective and safer and surgeries didn't really change.



- In 2023, interventions are much safer and we have to question if our traditional paradigm of treatment escalation is still reasonable

Current Paradigm Might Not Be The Best

1. Persistence with medications
decreases dramatically with time



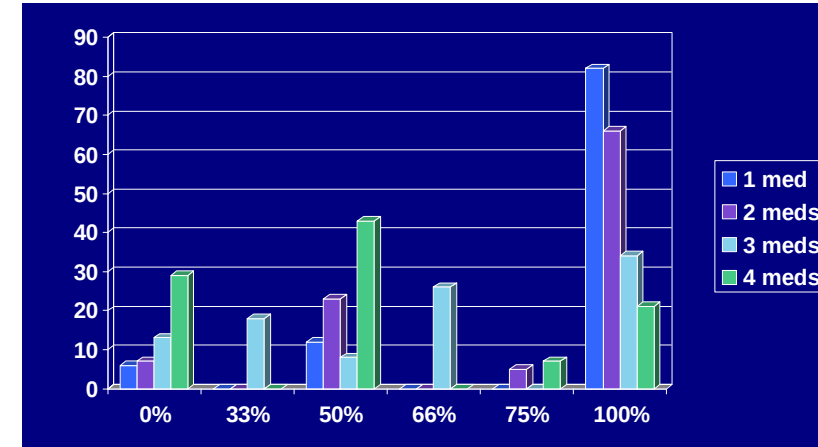
Current Paradigm Might Not Be The Best

1. Persistence with medications decreases dramatically with time
2. More medications patient is on, less compliant / adherent / persistent

Robin AL *et al Ophthalmology* 2005;112:863

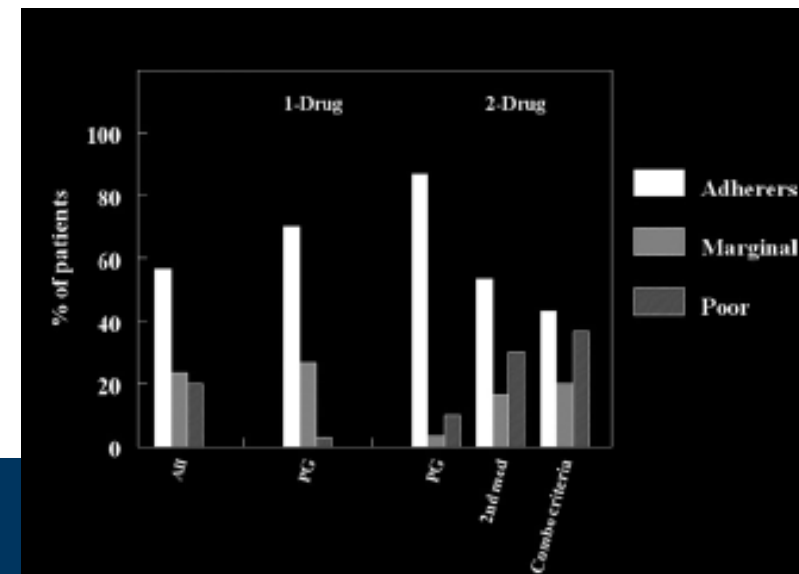
Robin AL *et al AJO* 2007;144:533

Kharod BV, Rhee DJ, *et al J Glaucoma* 2006;15:244



Kharod BV *et al J Glaucoma* 2006;15:244

Robin AL *et al AJO* 2007;144:533



Current Paradigm Might Not Be The Best

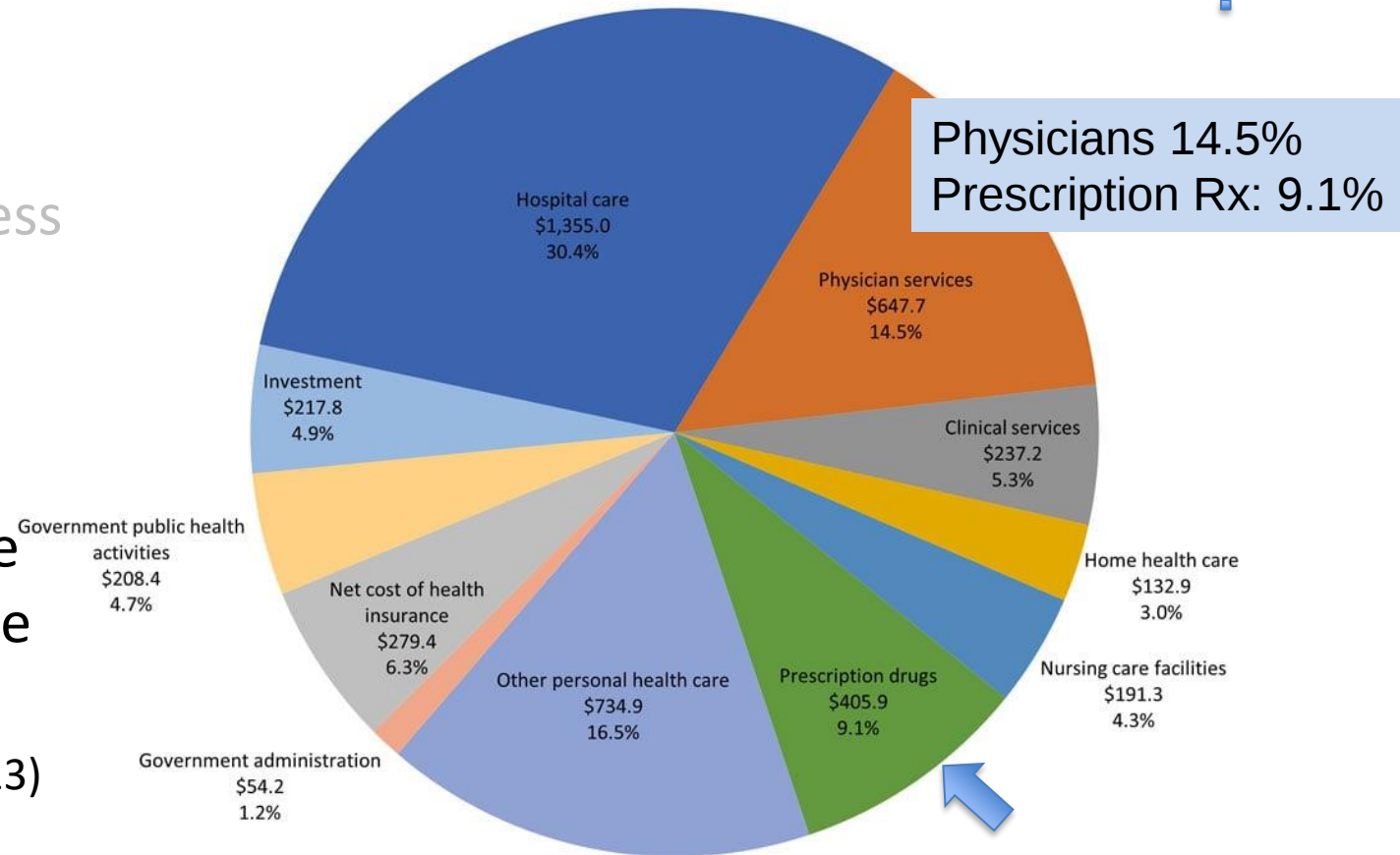
1. Persistence with medications decreases dramatically with time
2. More medications patient is on, less compliant / adherent / persistent
3. We're not getting better with compliance

- **1986** $76 \pm 24\%$ compliance with pilocarpine
Kass MA *et al AJO* 1986;101:515
- **2009** 0.71 ± 0.24 adherence rate
Travatan Dosing Aid Study - Okeke CO *et al Ophthalmology* 2009;116:191

Current Paradigm Might Not Be The Best

The U.S. spent \$4,464.6 billion on health care in 2022
where did it go?

1. Persistence with medications decreases dramatically with time
2. More medications patient is on, less compliant / adherent / persistent
3. We're not getting better with compliance
4. Chronic medication use is expensive over the patient's life time, and we need to be more cost conscious
 - Percent of GDP on healthcare (17.6% in 2023)
 - Within that pool we're spending a lot on pharmaceuticals



Source: [Trends in health care spending](#) | [Healthcare costs in the US](#) | AMA

LTP versus Medications as Initial Therapy

- Glaucoma Laser Treatment (GLT)
- SLT compared to latanoprost
- SLT/Med Study (SLT vs latanoprost)
- LiGHT Trial

LTP versus Medications as Initial Therapy

- **Glaucoma Laser Treatment Trial (GLT)**

Success (defined as < 21mmHg)

- 44% ALT / 30% meds @ 2 yrs (271)
- 20% ALT / 15% meds @ 7 yrs (203 of 271)
- gave ALT **two** sessions for full 360°

ALT vs beta-blocker

At 7 years

- ALT had 1.2 mmHg greater reduction of IOP
- ALT had a 0.6 dB higher mean deviation of visual field

GLT 7. *Am J Ophthalmol* 1995;120:718-731

GLT 2. *Ophthalmology* 1990;97:1403-1413

SLT as INITIAL Treatment for POAG

- 2003 and 2006, Melamed S, et al and McIlrath et al, respectively, performed prospective NON-randomized studies of SLT as initial treatment and found an IOP reduction ~30% and similar to a topical PGA

Melamed S, et al. SLT as primary treatment for open-angle glaucoma: a prospective nonrandomized pilot study. *Arch Ophthalmol*. 2003;121:957-960.

McIlraith L, et al. SLT as initial and adjunctive therapy for open angle glaucoma. *J Glaucoma*. 2006;15:124-130

- Starting in 2005, [Nagar et al](#) and the [SLT-MED trial](#) demonstrated parity of efficacy and safety between SLT (360°) vs topical latanoprost with 1-year follow up

LTP versus Medications as Initial Therapy

- **SLT compared to latanoprost**

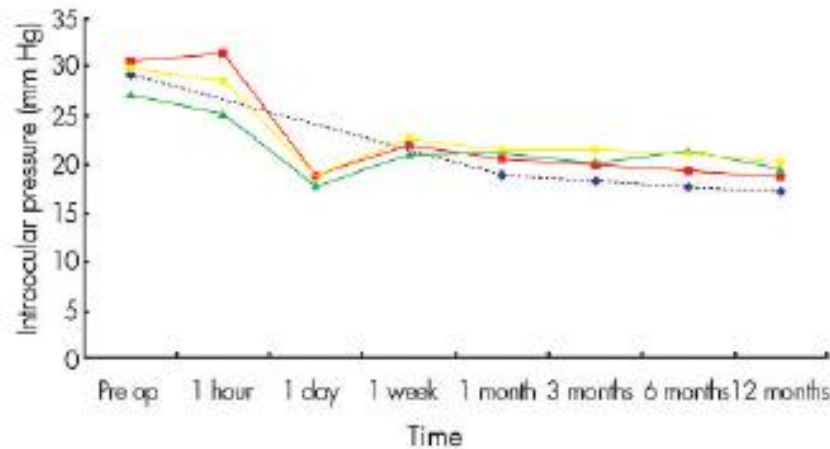


Figure 1 Intraocular pressure over time with treatment with latanoprost (blue diamonds), 90° SLT (green triangles), 180° SLT (yellow squares), and 360° SLT (red squares).

A randomised, prospective study comparing selective laser trabeculoplasty with latanoprost for the control of intraocular pressure in ocular hypertension and open angle glaucoma

M Nagar, A Ogunyomade, D P S O'Brart, F Howes, J Marshall

Nagar M, et al. *Br J Ophthalmol* 2005;89:1413-1417

Success (30% reduction in IOP)

Latanoprost did **better** than 90° or 180° of treatment

Latanoprost = 360° of SLT

- SLT/Med Study

LTP versus Medications as Initial Therapy

- **SLT/Med Study**

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

Katz LJ, et al. *J Glaucoma* 2012;21;460

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

360° SLT versus prostaglandin analogue
11% of eyes received additional SLT
27% of eyes required additional medications

No statistically significant difference

TABLE 3. Overall (Mean of Both Eyes*) Baseline and Follow-up IOP, Changes of IOP and Months of Follow-up

	Baseline	Follow-up 4 to 6 mo	Follow-up 9 to 12 mo
Medicine group	n = 31	n = 31	n = 25
IOP	24.5 (± 2.2)	17.8 (± 3.0)	17.7 (± 2.5)
IOP change	—	6.6 (± 2.8)*	7.0 (± 1.8)*
Months of follow up	—	5.7 (± 1.1)	11.7 (± 0.8)
SLT group	n = 38	n = 38	n = 29
IOP	25.0 (± 2.2)	18.9 (± 2.9)	18.2 (± 2.8)
IOP change	—	6.0 (± 3.1)*	6.3 (± 2.7)*
Months of follow up	—	6.7 (± 1.0)	12.2 (± 1.5)
<i>P</i>		0.13	0.77

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- Starting in 2005, Nagar *et al* and the SLT-MED trial demonstrated parity of efficacy and safety between SLT (360°) vs topical latanoprost with 1-year follow up
- Laser in Glaucoma and Ocular Hypertension (**LiGHT**) trial found superior efficacy of visual field preservation and had a lower incidence of incisional glaucoma surgery and cataract with up to 6 years of follow up.

Laser First-Line

Laser in Glaucoma and Ocular Hypertension (LiGHT) trial

- It is **no** longer appropriate to start a treatment naïve POAG patient with eye drops

Gazzard G., et al *Lancet* 2019;393:1505

Eye receiving SLT were **more likely to have IOP in the target** range 93% vs 91% of visits
Glaucoma surgery in none vs 11 patients

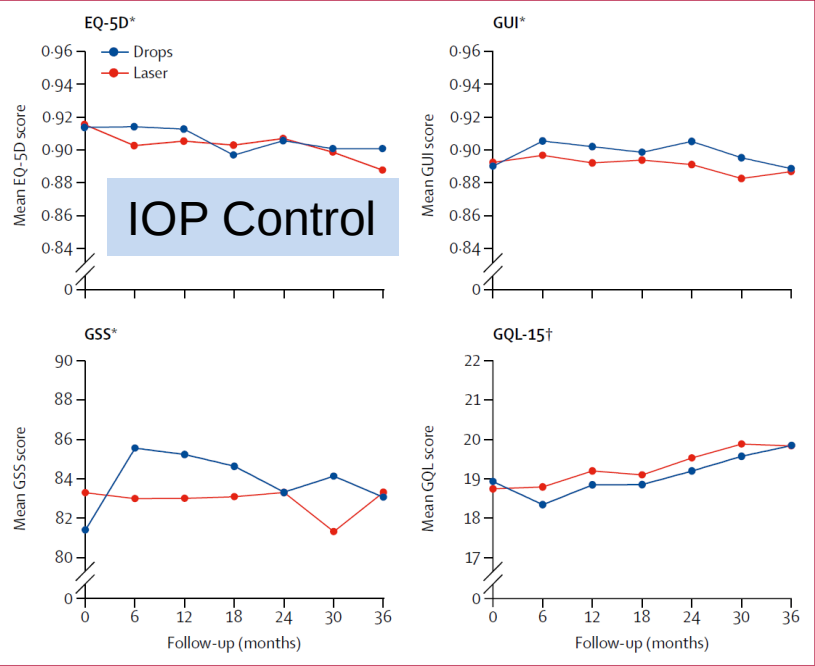
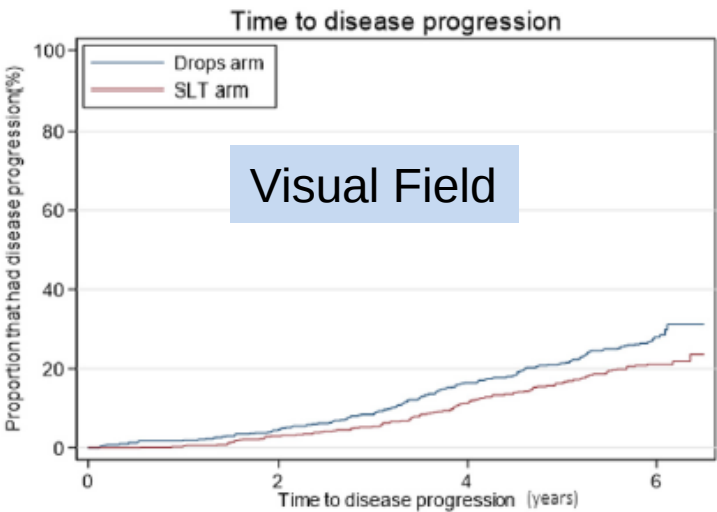


Figure 2: Mean EQ-5D, GUI, GSS, and GQL-15 scores at each time point, across 36 months
Time-point '0' refers to pre-treatment. EQ-5D=EuroQol 5 Dimensions 5 Levels. GUI=Glaucoma Utility Index. GSS=Glaucoma Symptom Scale. GQL-15=Glaucoma Quality of Life-15. *Higher scores indicate better health-related quality of life. †Higher scores indicate worse health-related quality of life.

Wright DM et al *Ophthalmology* 2020;127:1313

A larger proportion of OHTN and POAG pts treated first with medical Rx underwent rapid VF progression

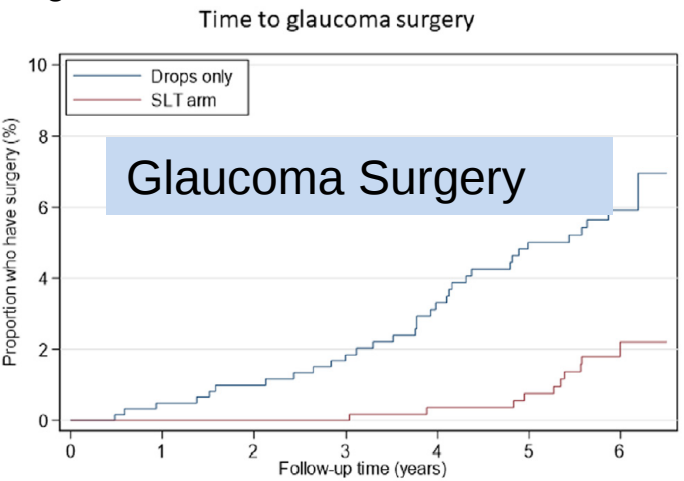


Number of patients at risk / years	0	2	4	6*
Drops arm	361	335	282	235
SLT arm	355	339	287	243

Figure 3. Failure plot indicating time of disease progression from baseline by treatment arm ($P < 0.006$, log-rank test) based on intention-to-treat analysis (the unit of analysis is the eye) for all randomized patients. The number at risk at 6 years includes the patients whose last visit was ± 6 months. SLT = selective laser trabeculoplasty.

Gazzard G et al *Ophthalmology* 2023;130:139

SLT first eyes had fewer incisional glaucoma surgeries



Number of patients at risk / years	0	1	2	3	4	5	6*
Drops arm	361	352	342	334	307	291	266
SLT arm	355	351	345	328	304	287	270

Figure 4. Failure plot indicating time to glaucoma surgery from baseline by treatment arm ($P < 0.001$, log-rank test) based on intention-to-treat analysis (y-axis on a scale of 0–10%; the unit of analyses is the eye). The number at risk at 6 years includes the patients whose last visit was ± 6 months. SLT = selective laser trabeculoplasty.

Selective Laser Trabeculoplasty and Circadian IOP

- Less variation of diurnal IOP with SLT

n=36

Guzey M, Arslan O, Tramcelik N, Satici A. Effects of frequency-doubled Nd:YAG laser trabeculoplasty on diurnal intraocular pressure variations in primary open-angle glaucoma. *Ophthalmologica* 1999;213:214-218

n=5

Kothy P, Toth M, Hollo G. Influence of SLT on 24-hour diurnal IOP fluctuation in POAG: A Pilot Study. *Ophthalmic Surg Lasers Imaging* 2010;41:342-347

- Degree of diurnal variation is roughly equivalent to PGA

Shi Y, Zhang Y, Sun W, Huang AS, Chen S, Zhang L, Wang W, Xie L, Xie X. 24-hour efficacy of single primary SLT versus latanoprost eye drops for naïve POAG and OHTN patients. *Sci Rep* 2023;13:12179

Shi et al n=45

Kiddee W, Atthavuttisilp S. The effects of SLT and travoprost on circadian IOP fluctuations. A randomized clinical trial. *Medicine*. 2017;96:6(e6047)

Kiddee et al n=76

- Degree of diurnal variation is less than latanoprost

n=40

Nagar M, Luhishi E, Shah N. IOP control and fluctuation: the effect of treatment of SLT. *Br. J Ophthalmol* 2009;93:497-201

Potential Complications of LTP

- **Selective Laser Trabeculoplasty**

(Nagar M, et al. Br J Ophthalmol 2004;89:1413-1417)

- IOP >5mmHg 16% after 180 / 27% after 360
- Transient inflammation 50%

Projected cost comparison of selective laser trabeculoplasty versus glaucoma medication in the Ontario Health Insurance Plan

Richard Lee,* BSc; Cindy M.L. Hutnik,† MD, PhD

Can J Ophthalmol 2006;41:449-456

ABSTRACT • RÉSUMÉ

Background: The projected 6-year cost comparison of primary selective laser trabeculoplasty (SLT) versus primary medical therapy in the treatment of open-angle glaucoma for Ontario patients aged 65 years or more is presented. Costs are taken from the perspective of the Ontario Health Insurance Plan at a per-patient level.

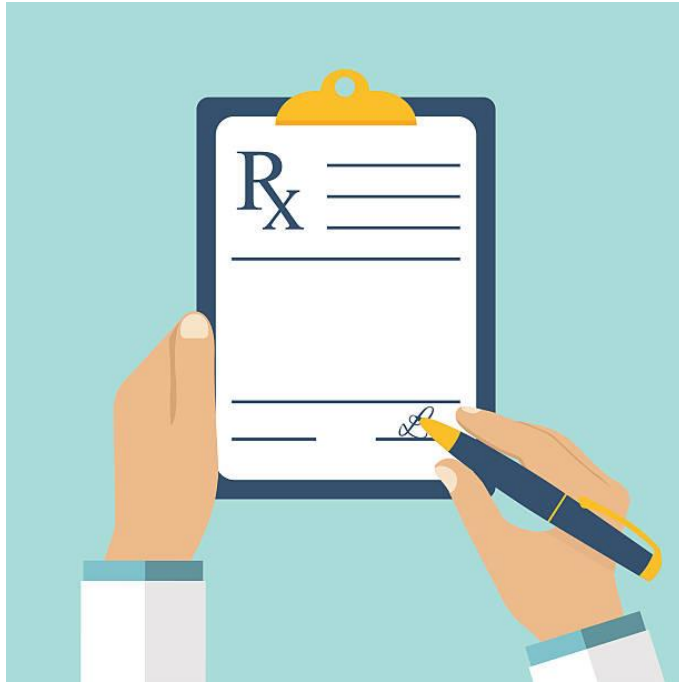
Methods: The cost of each medication was obtained from the 2003 Ontario Drug Benefits formulary. The average annual cost of medications was determined by estimating the provincial prescription rate of glaucoma medications, with reference to both a volume-per-bottle study of these drugs and a study of pharmacy claims reports. A representative provincial prescription rate was calculated by reviewing 707 patient charts selected randomly from 5 ophthalmologic practices across Ontario. Medication therapies were categorized into mono-, bi-, and tri-drug therapy groups. The cost of SLT was analyzed under the following 2 scenarios. SLT rep 2y assumed a duration of 2 years before repeat SLT was necessary. SLT rep 3y assumed a duration of 3 years before repeat SLT was necessary. Bilateral 180° SLT treatment and repeatability of SLT was assumed. The cost of surgery for patients who fail SLT or medical therapy was not accounted for in this study nor was the cost of patients who required medical therapy in conjunction with SLT.

Results: In the SLT rep 2y scenario, the use of primary SLT over mono-, bi-, and tri-drug therapy produced a 6-year cumulative cost savings of \$206.54, \$1668.64, and \$2992.67 per patient, respectively. In the SLT rep 3y scenario, the use of primary SLT over mono-, bi-, and tri-drug therapy produced a 6-year cumulative cost savings of \$580.52, \$2042.82, and \$3366.65 per patient, respectively.

- SLT is cost effective compared to med

Don't Throw Away Your Prescription Pads!!

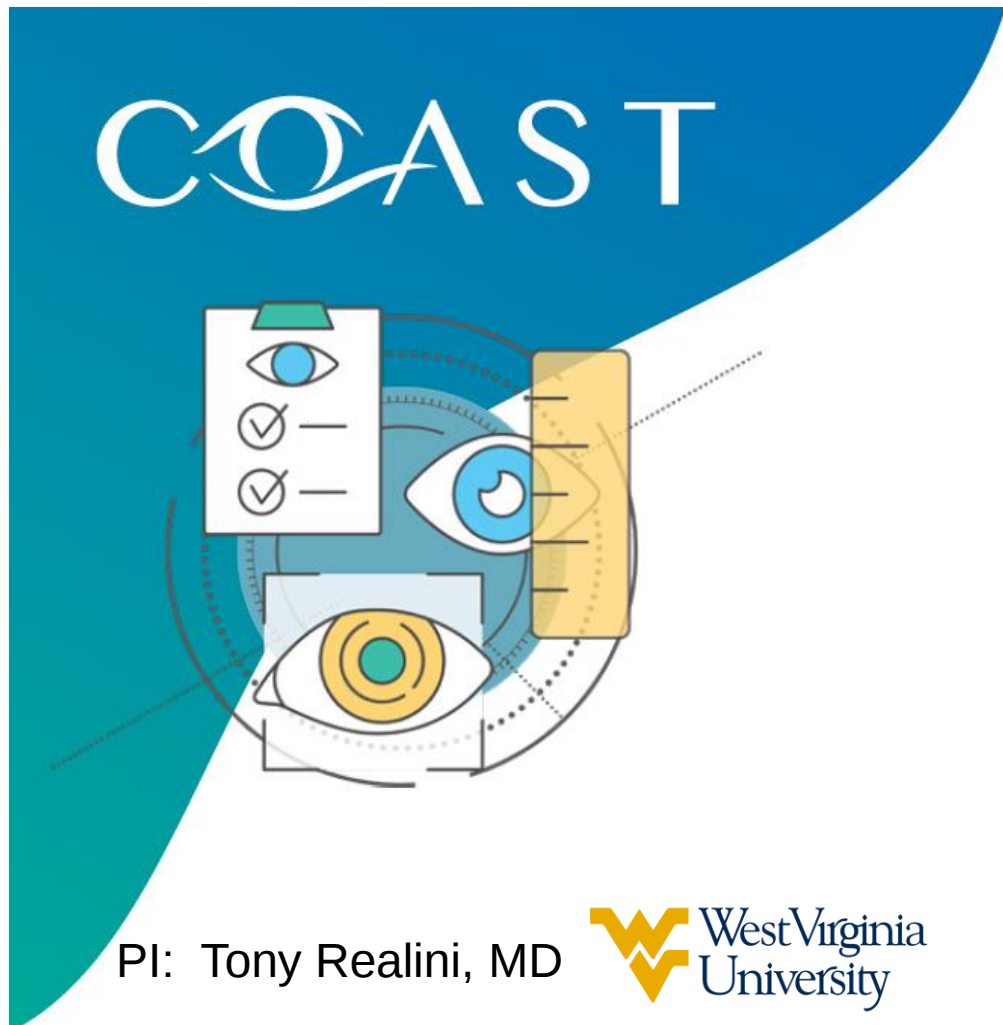
Optometry – Ophthalmology Cooperation Remains Vital



- SLT is not a cure
- Analogous to managing cataract and refractive error
- Following Initial treatment with SLT, patients will still need IOP monitoring, testing, and eventually medications

Clarifying the Optimal Application of SLT Therapy (COAST)

- Intent is to try to get longer duration of efficacy of SLT
- Patients are randomized to standard SLT versus low power SLT



PI: Tony Realini, MD



Yasmin Sozeri, MD



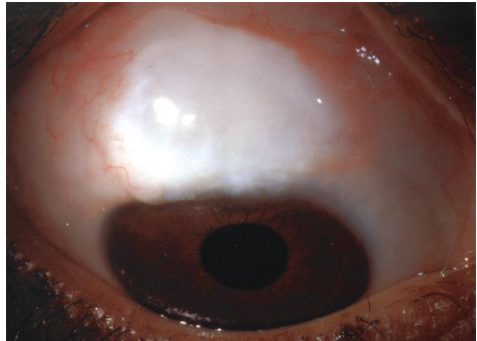
Douglas Rhee, MD

How Many People Present with Advanced Stage POAG

- In the United Kingdom, 25% have advanced glaucoma in at least 1 eye at presentation

Sukumar S, Spencer F, Fenerty C et al. The influence of socioeconomic and clinical factors upon the presenting visual field status of patients with glaucoma. *Eye* 2009;23:1038-1044

Boodhna T, Grabb DP. Disease severity in newly diagnosed glaucoma patients with visual field loss: trends from more than a decade of data. *Ophthalmic Physiol Opt* 2015;35:225-230



Collaborative Initial Glaucoma Treatment Study

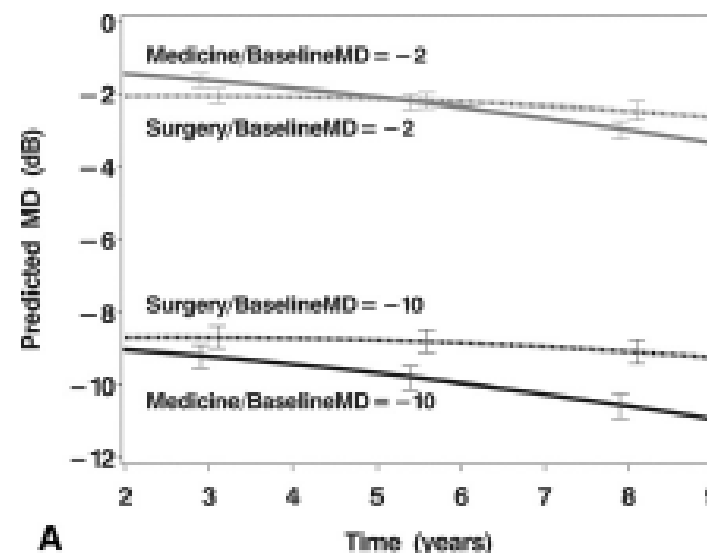
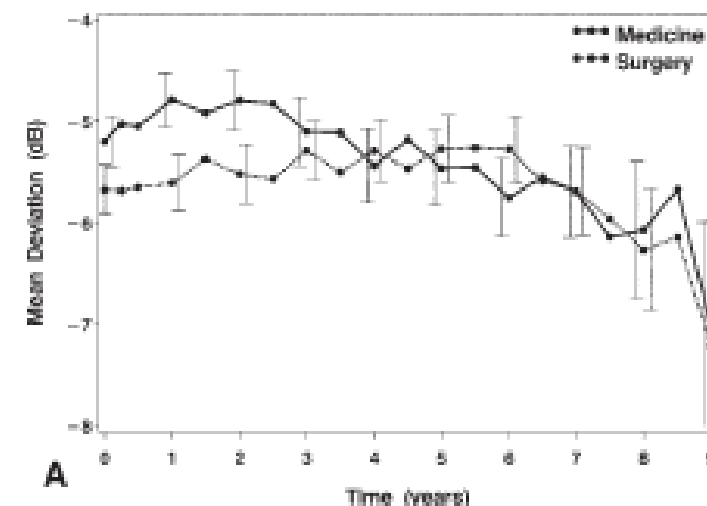
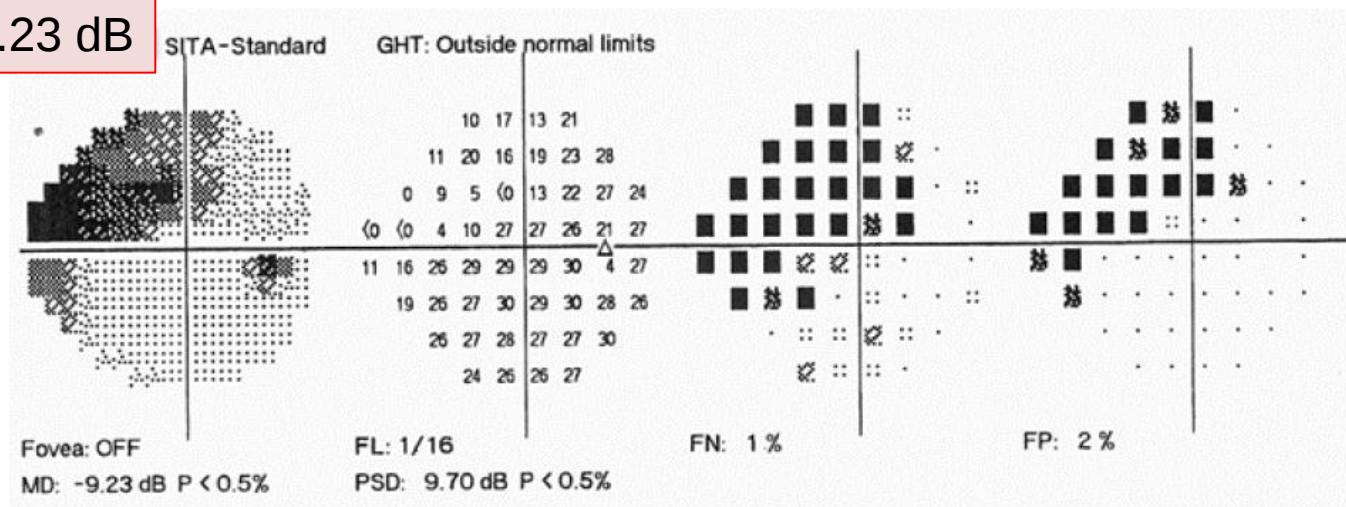
Musch DC, et al., *Ophthalmology* 2009;116:200-207

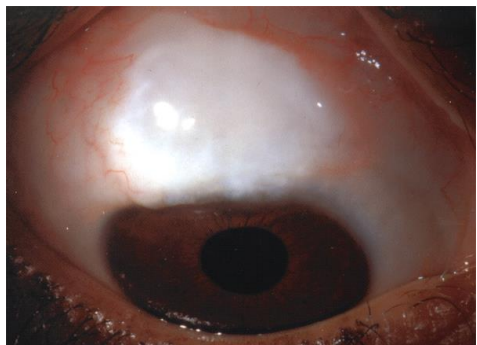
- At 8 years, no difference between surgery versus medication groups with regard to VF progression

Subset analysis

- However, if patient had > -10 dB, patient did **better** if patient had **trabeculectomy** as initial treatment

-9.23 dB



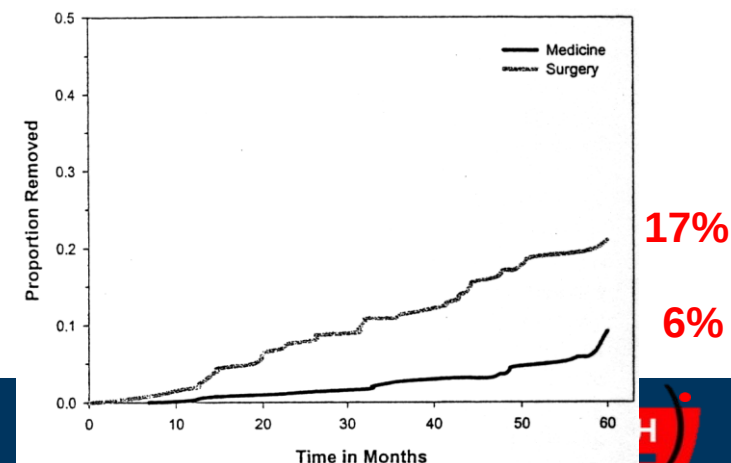
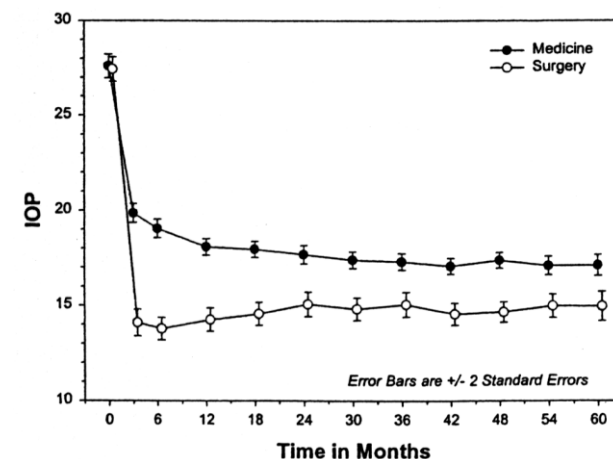


Collaborative Initial Glaucoma Treatment Study

Mean IOP reduction **48% in surgery group**
35% in medication group

- Keep in mind the degree of IOP reduction trabeculectomy achieved i.e. interpret the findings within the context of the population
- **Surgery group had a 3 mmHg lower IOP than medication group,**
- Cataract surgery occurred more frequently in the operated group

Lichter PR, et al. *Ophthalmology* 2001;108:1943-1953
 Musch DC, et al. *Arch Ophthalmol* 2006;124:1694-1700



Treatment of Advanced Glaucoma Study (TAGS)



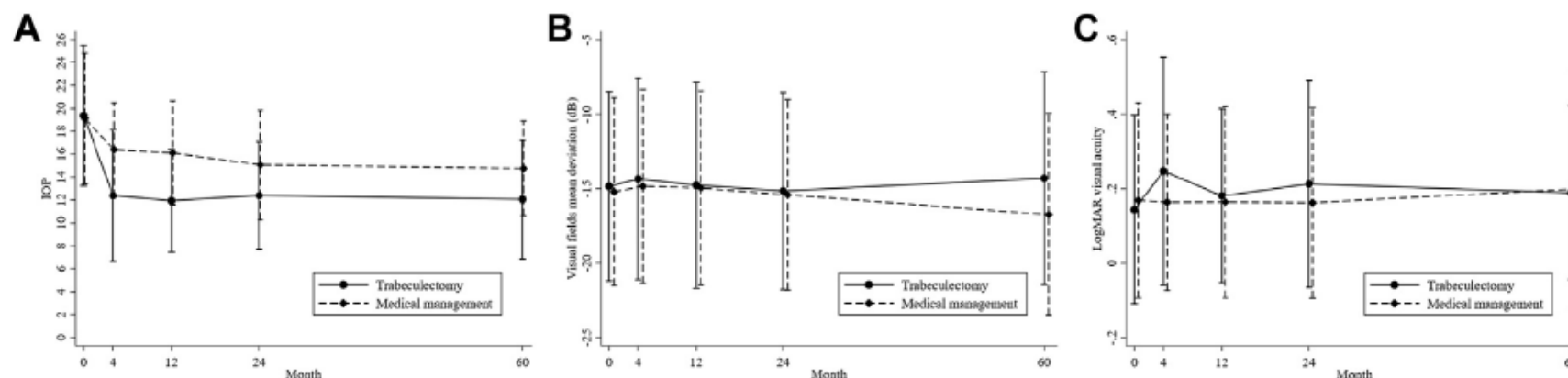
Evaluating Primary Treatment for People with Advanced Glaucoma

Five-Year Results of the Treatment of Advanced Glaucoma Study

Anthony J. King, MD,¹ Jemma Hudson, PhD,² Augusto Azuara-Blanco, PhD,³ Jennifer Burr, MD,⁴ Ashleigh Kernohan, PhD,⁵ Tara Homer, PhD,⁵ Hosein Shabaninejad, PhD,⁵ John M. Sparrow, MD,⁶ David Garway-Heath, MD,⁷ Keith Barton, MD,⁷ John Norrie, PhD,⁸ Tracey Davidson, PhD,² Luke Vale, PhD,⁵ Graeme MacLennan, MSc,² and the TAGS study group

Ophthalmology. 2024;131:759-770

- Between June 2014 – May 2017
- 453 adults newly diagnosed with OAG recruited from 27 sites across the UK randomized to trabeculectomy n=227 or medical Rx n=226
- Reported results at 5 years
- Trab was more successful at lowering IOP and preventing disease progression
- Average MD < -12.00dB



Safety events occurred
52% Trabeculectomy arm
58% Medication arm
p=0.82

Figure 4. A–C, Clinical outcomes up to 5-years for (A) intraocular pressure (IOP), (B) visual field, and (C) logarithm of the minimum angle of resolution (logMAR) visual acuity.



Cost-Effectiveness Trabeculectomy vs Medications

- TAGS study
- “Trabeculectomy was associated with higher costs and slightly greater quality of life outcomes, medication is more likely to be considered cost effective at a 2-year time horizon?”
- Study included not only direct health related expenditures, but travel times, missing work, etc.

Cost-effectiveness of primary surgical versus primary medical management in the treatment of patients presenting with advanced glaucoma

Ashleigh Kernohan ¹, Tara Homer, ¹ Hosein Shabaninejad, ¹ Anthony J King ², Jemma Hudson, ³ Gordon Fernie, ⁴ Augusto Azuara-Blanco ⁵, Jennifer Burr ⁶, John M Sparrow ⁷, David Garway-Heath, ⁸ Keith Barton, ⁸ John Norrie, ⁹ Graeme MacLennan, ⁴ Luke Vale ^{1,10}

Br J Ophthalmol 2023;107:1452-1457

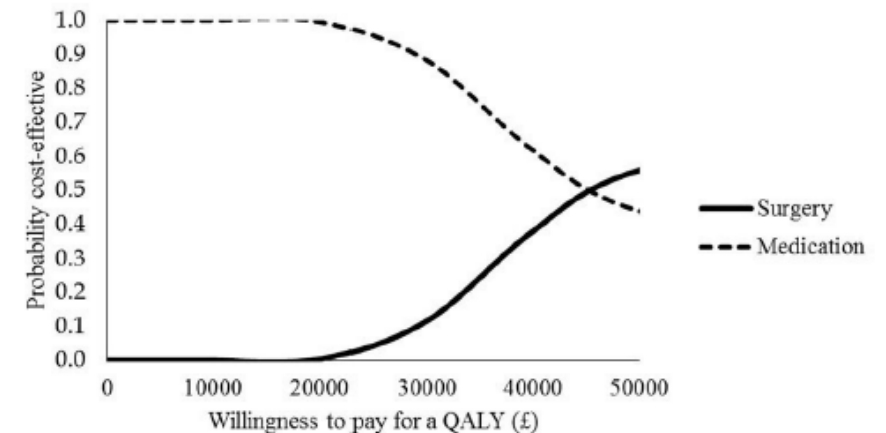


Figure 2 Cost-effectiveness curves for the trabeculectomy and medical management using the results from the EQ-5D-5L using the multiple imputation data. QALY, quality-adjusted life year.

Agenda: Surgery First and Earlier

- First-line Treatment
 - Early-Mild Stage Dz: Selective Laser Trabeculoplasty
 - Advanced Stage Dz: Trabeculectomy
- **MIGS: Evidence Based**
- What is Disease Progression?

Strong Evidence Based Guidelines

PRCTs

Cohort

Proof
of
Concept

Preclinical
Testing
MOA

Novel Idea



Hydrus COMPARE



- 12-Month results from the prospective, multicenter randomized trial comparing single Hydrus Microstent to dual iStent Trabecular Micro-Bypass Devices in Open Angle Glaucoma

Iqbal K Ike Ahmed MD, Antonio Fea MD PhD, Leon Au MBBS, Robert Ang MD, Paul Harasymowycz MD, Thomas W. Samuelson MD, David F. Chang MD, **Douglas J. Rhee, MD**

A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma

The COMPARE Study

Ophthalmology 2020;127:52-61

Strong Evidence Based Guidelines

PRCTs

Cohort

Proof
of
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MOA

Novel Idea



A Prospective Randomized Trial Comparing Hydrus and iStent Microinvasive Glaucoma Surgery Implants for Standalone Treatment of Open-Angle Glaucoma

The COMPARE Study

Iqbal Ike K. Ahmed, MD,¹ Antonio Fea, MD, PhD,² Leon Au, MBBS,³ Robert E. Ang, MD,⁴ Paul Harasymowycz, MD,⁵ Henry Jampel, MD,⁶ Thomas W. Samuelson, MD,⁷ David F. Chang, MD,⁸ Douglas J. Rhee, MD,⁹ on behalf of the COMPARE Investigators

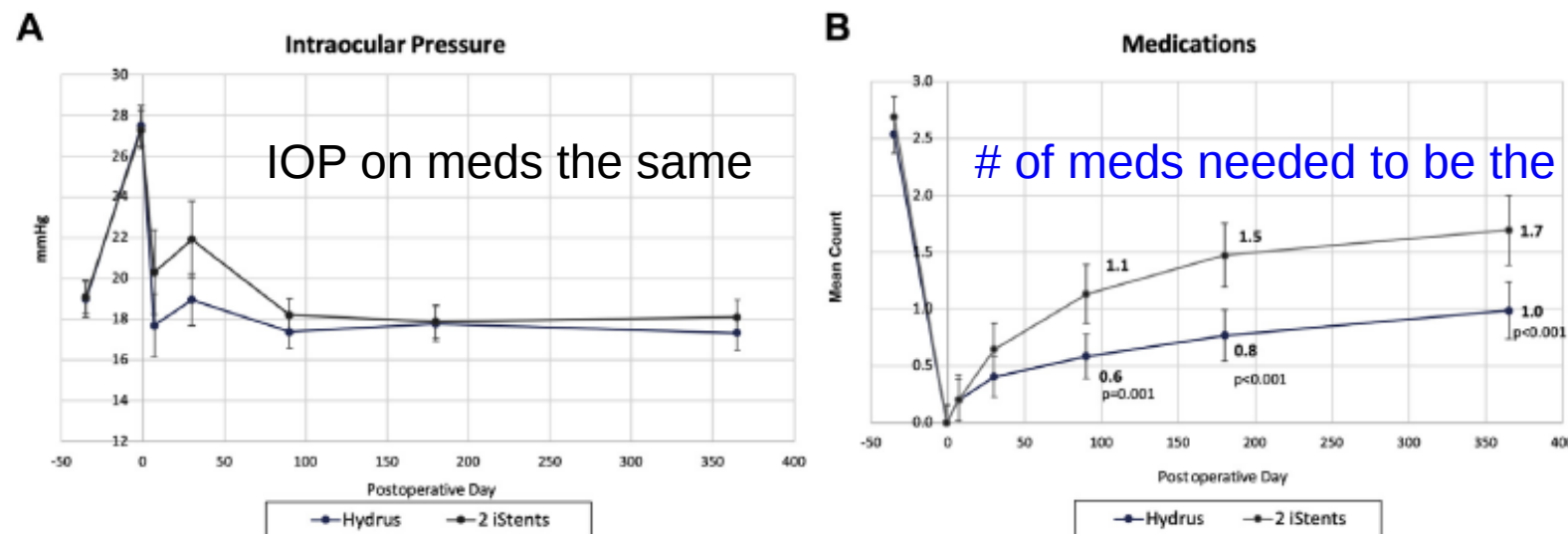


Figure 1. A, Intraocular pressure (IOP). B, Medications. There were no significant differences in IOP between groups at any time point. There was a significant differences in mean medication count at all time points ≥ 90 days. The error bars are 95% confidence intervals.

Ophthalmology 2020;127:52-61

Hydrus versus iStent and iStent inject

- In cadaver eyes, 8 mm hydrus had a greater reduction in outflow facility compared to 2 iStents (n=10 in each group, p=0.4)

Improvement in Outflow Facility by Two Novel Microinvasive Glaucoma Surgery Implants

Cassandra L. Hays,¹ Vikas Gulati,¹ Shan Fan,¹ Thomas W. Samuelson,^{2,3} Iqbal Ike K. Ahmed,⁴ and Carol B. Toris¹

Invest Ophthalmol Vis Sci. 2014;55:1893-1900

- In cadaver eyes, hydrus improved outflow compared to two iStent inject devices. One iStent did better than 2 iStent injects.

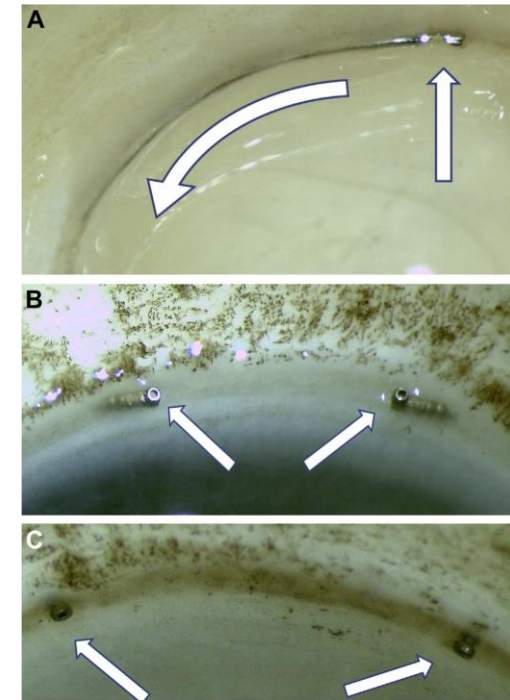
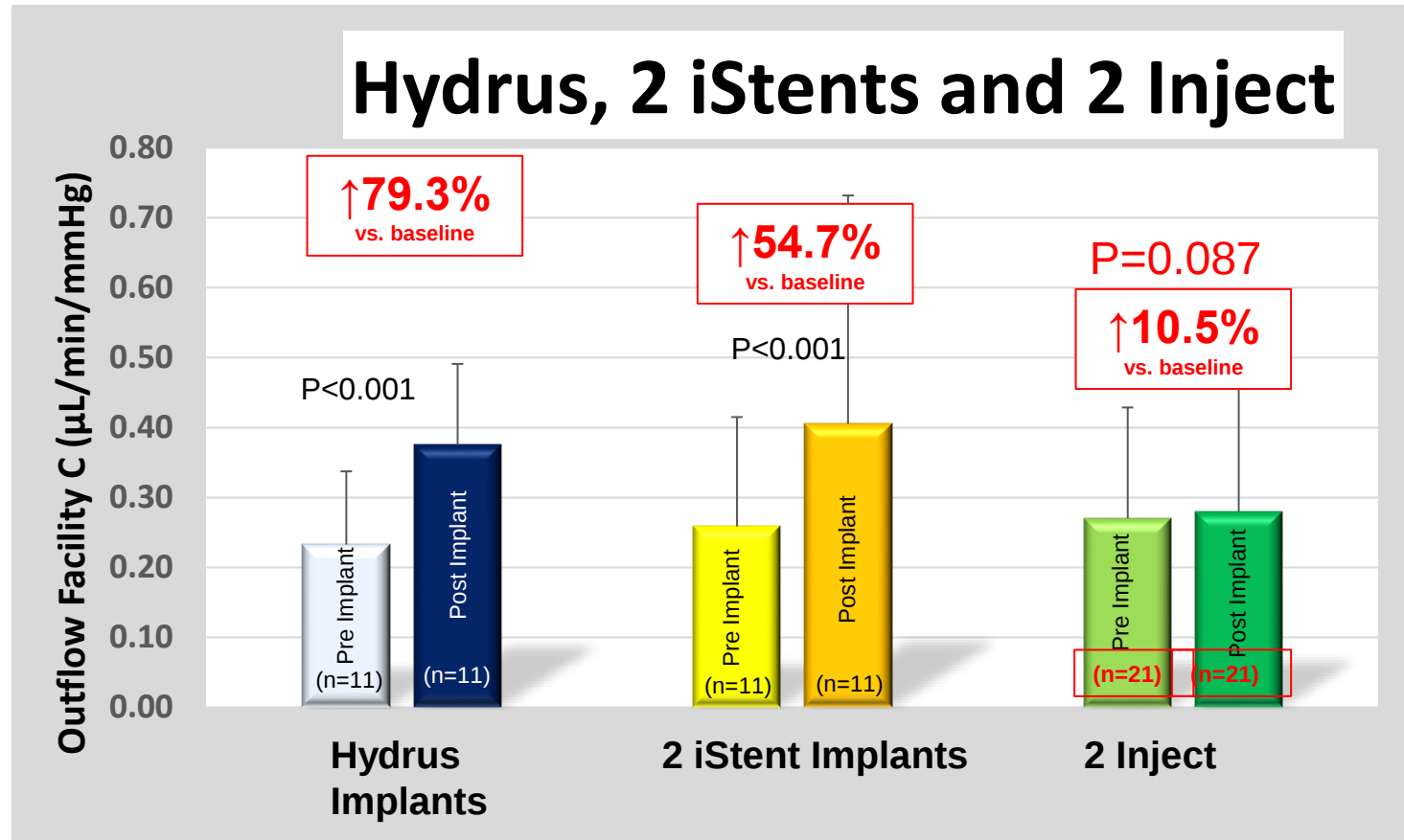
Outflow Facility Effects of 3 Schlemm's Canal Microinvasive Glaucoma Surgery Devices

Carol B. Toris, PhD,^{1,2} Padmanabhan P. Pattabiraman, PhD,³ George Tye, BS,¹ Thomas W. Samuelson, MD,^{4,5} Douglas J. Rhee, MD¹

Ophthalmology Glaucoma 2020;3:114-121

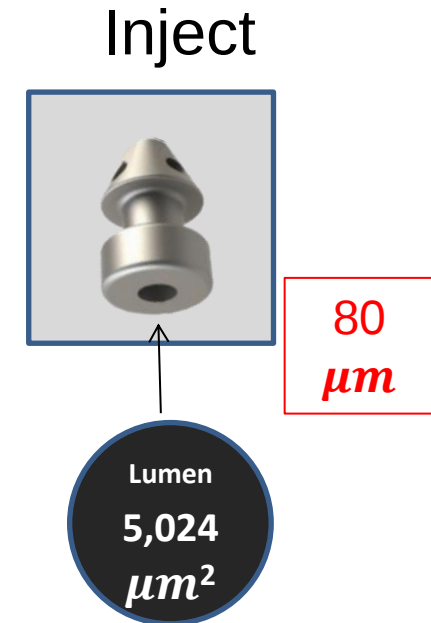
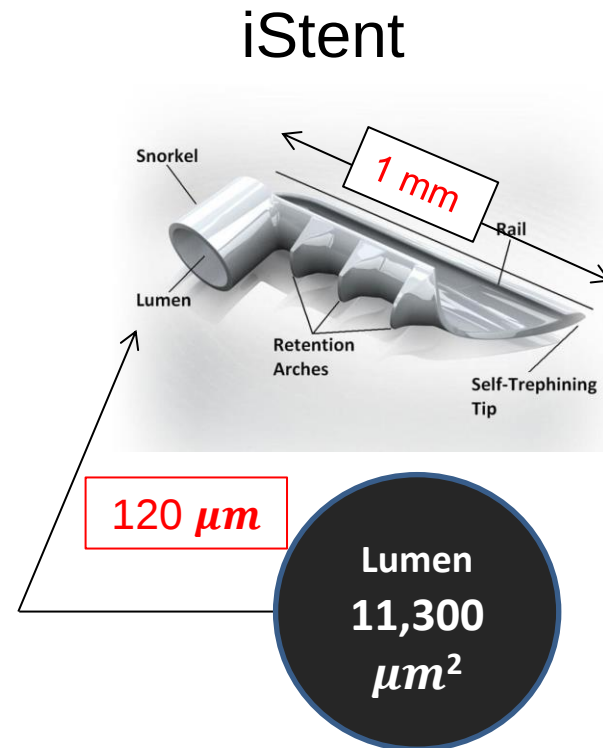
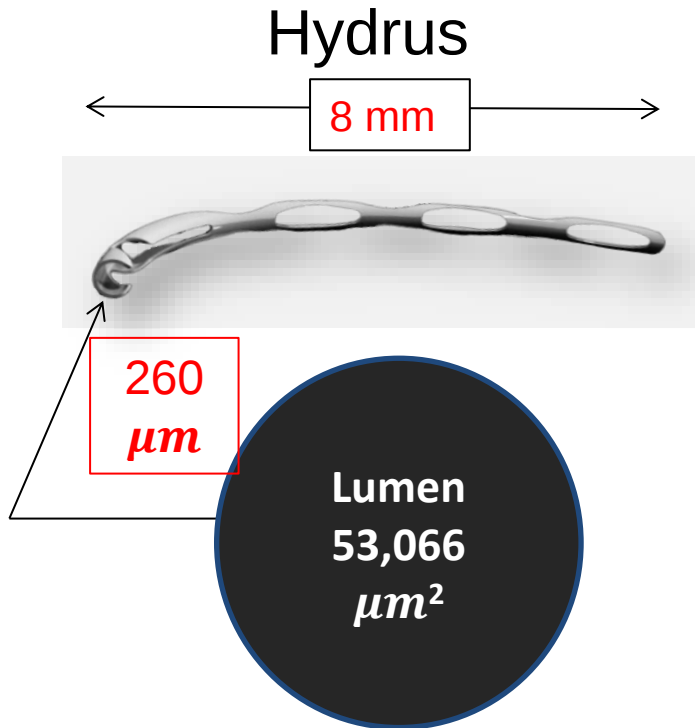
Outflow Facility Change: All Groups

Ophthalmology Glaucoma 2020;3:114-121



Canal Based MIGS Designs

Bigger is Better

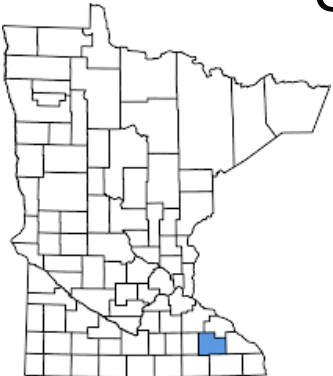


Agenda: Surgery First and Earlier

- First-line Treatment
 - Early-Mild Stage Dz: Selective Laser Trabeculoplasty
 - Advanced Stage Dz: Trabeculectomy
- MIGS: Evidence Based
- **What is Disease Progression?**

The quest for “disease modifying” treatment

- What is “disease modifying?” To directly interrupt the pathophysiology.
- At least most if not **ALL** current treatments that lower IOP are purely palliative.
- Olmsted County, MN

- 
- 1998: legal blindness from open-angle glaucoma (diagnosed 1965 – 1980): 27% over 20 years for one eye (but nearly 50% were blind in 1 eye at diagnosis), 9% for both
 - 2002: legal blindness from open-angle glaucoma (diagnosed 1965 – 1998): 19% over 34 years
 - 2014: legal blindness from OAG (diagnosed between 1965 – 2000): progressing to blindness w/in 10 years
 - 25.8% if diagnosed between 1965-1980
 - 13.5% if diagnosed between 1981-2000

← We’ve gotten better at preventing blindness, but are we stopping the disease?

Hattenhauer MG, Johnson DJ, Ing HH, Herman DC, Hodge DO, Yawn BP, Butterfield LC, Gray DT. The probability of blindness from open-angle glaucoma. *Ophthalmology* 1998;105:2099-2104

Blindness and Glaucoma: A Comparison of Patients Progressing to Blindness From Glaucoma With Patients Maintaining Vision

JESSICA E. OLIVER, MD, MPH, MATTHEW G. HATTENHAUER, MD, DAVID HERMAN, MD, DAVID O. HODGE, MS, ROBERT KENNEDY, MD, PhD, MICHAEL FANG-YEN, MD, AND DOUGLAS H. JOHNSON, MD

Oliver JE, et al Am J Ophthalmol 2002

Long-Term Trends in Glaucoma-Related Blindness in Olmsted County, Minnesota

Mehrdad Malihi, MD¹, Edney R. Moura Filho, MD¹, David O. Hodge, MS², and Arthur J. Sit, SM, MD¹

¹Department of Ophthalmology, Mayo Clinic, Rochester, MN, United States, 55905

²Department of Health Sciences Research, Mayo Clinic, Rochester, MN, United States, 55905

Malihi M, et al., *Ophthalmology* 2014;121:134-141

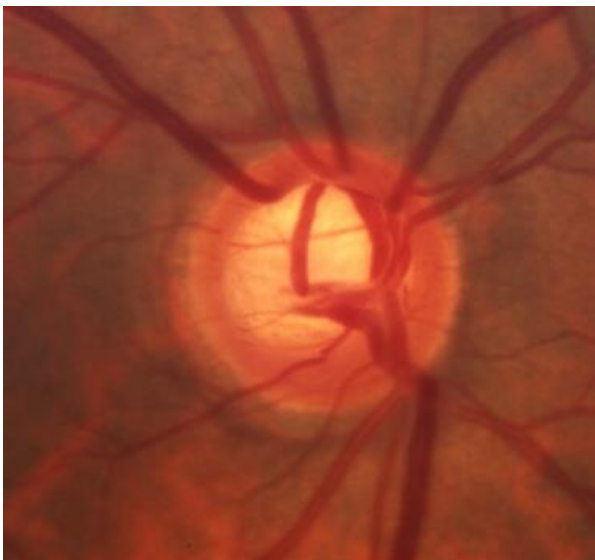
What is Disease Progression

- If you only look at blindness, then you think disease progression is relatively low and we're doing a pretty good job and it is not palliative
- Actually, progression should be thought of as needing to advance treatment
- “I follow you every 3-4 months because we know you are going to get worse, but we just don't know when”

Douglas Rhee in clinic all the time

So What Should Be The New Paradigm?

- If newly diagnosed with Primary Open-Angle Glaucoma (POAG) or high-risk Ocular Hypertension (OHTN), primary Selective Laser Trabeculoplasty (SLT)
- If Mean Deviation on HVF, on presentation, is greater, should consider trabeculectomy first
- Medications should be used afterwards
- MIGS is at the stage where you can begin to use level 1 evidence to decide amongst the myriad of choices
- Progression should be determined by need to advance treatment

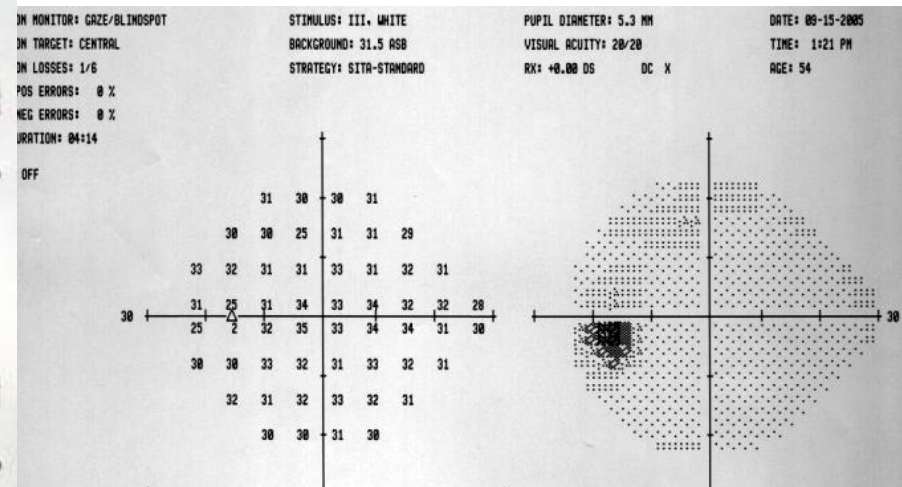
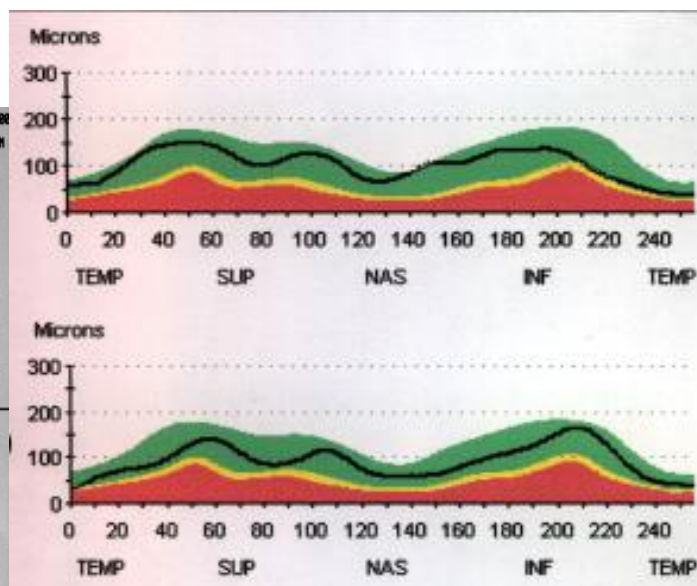
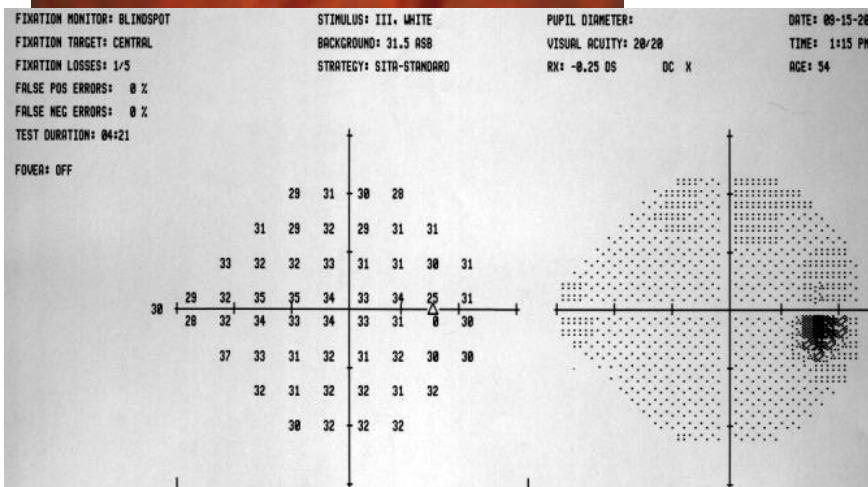


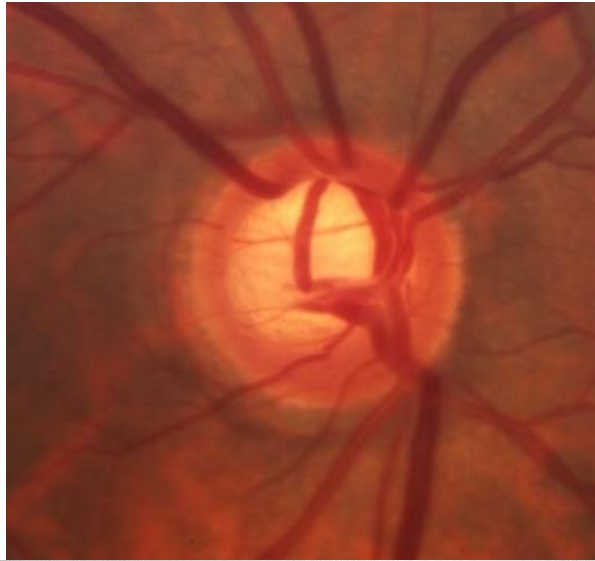
23 mmHg
CCT 590 μm



22 mmHg
CCT 605 μm

64 year old
man
African Ancestry
+ family history



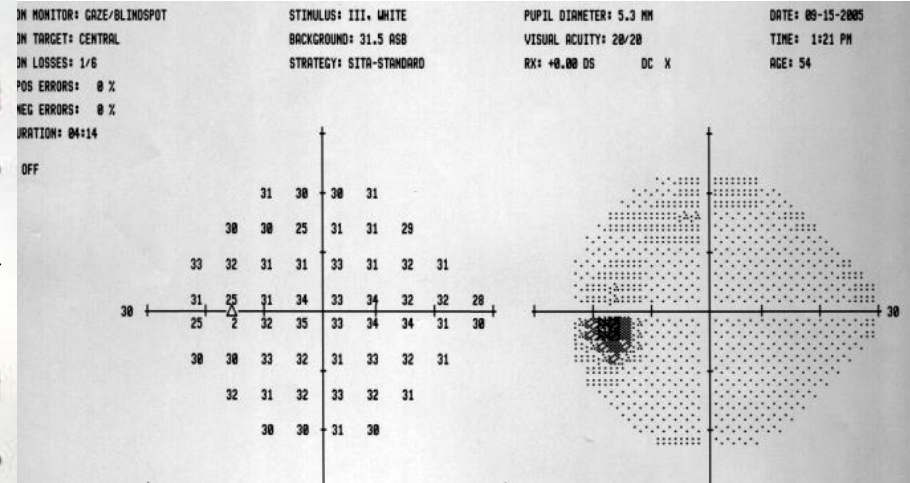
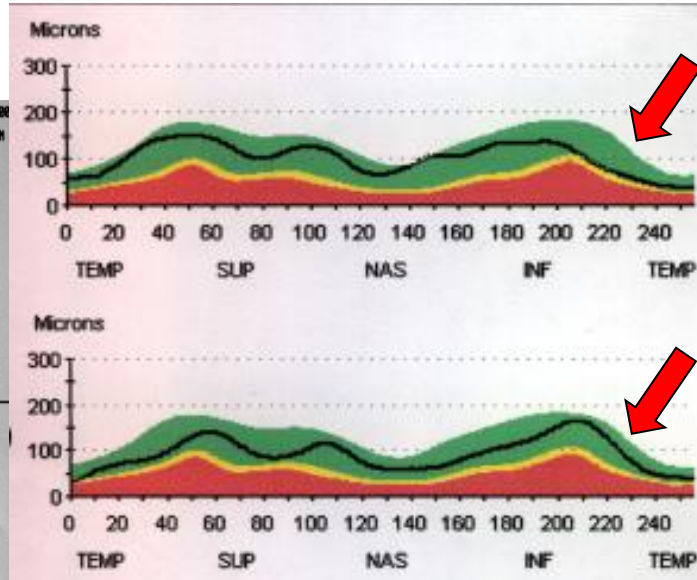
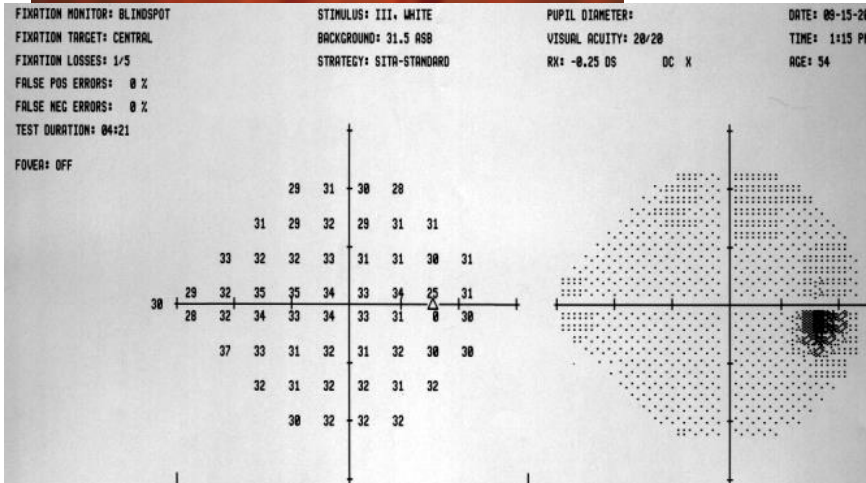


23 mmHg
CCT 590 μm



22 mmHg
CCT 605 μm

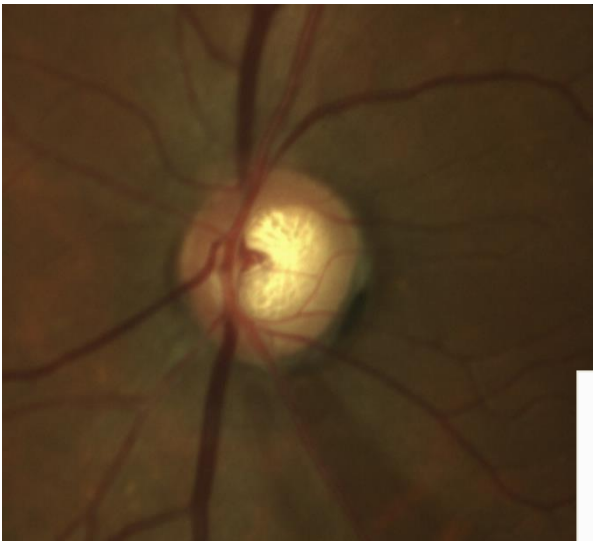
64 year old
man
African Ancestry
+ family history



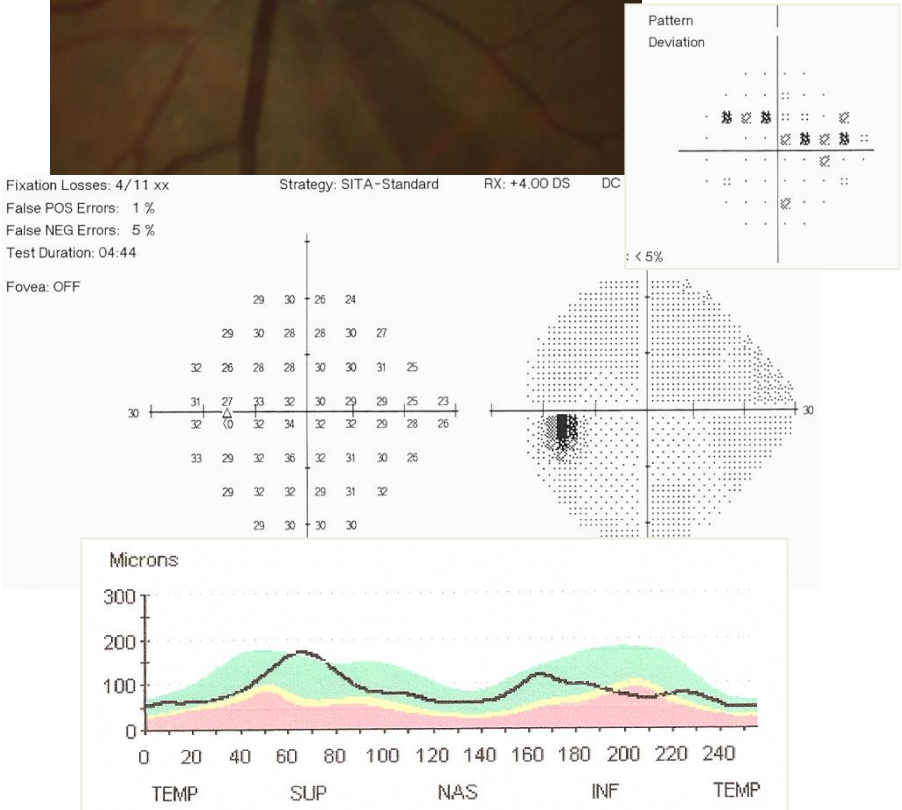
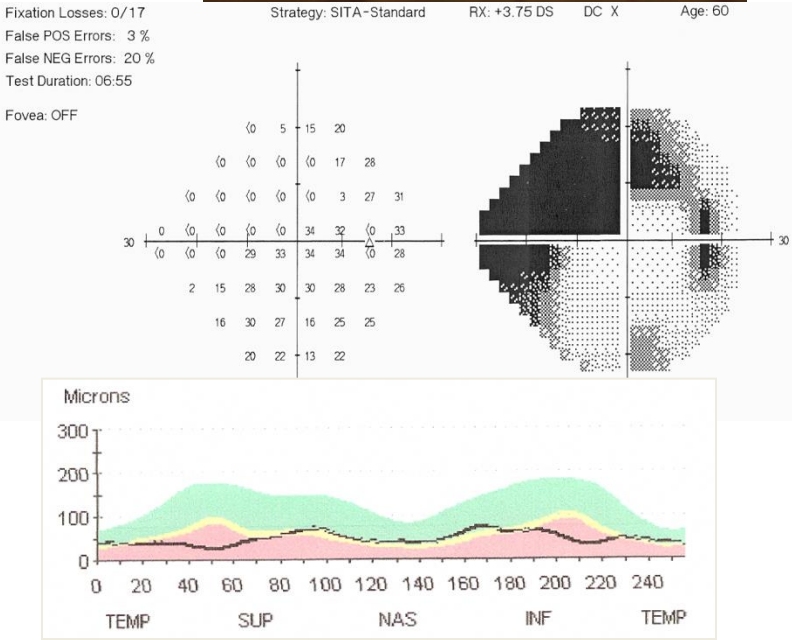
26 mmHg
545 μm



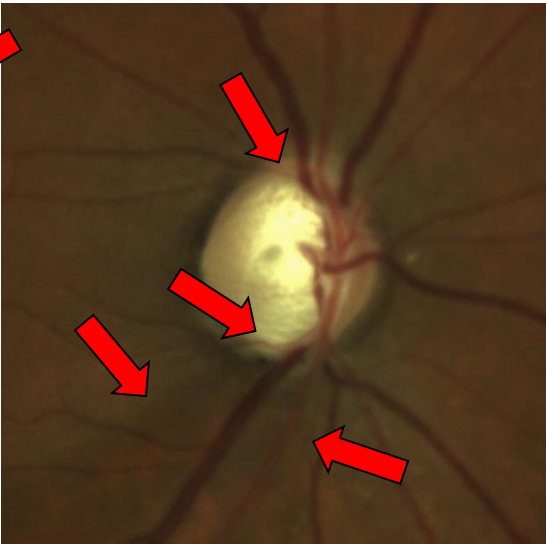
74 year old woman
European Ancestry
+ Family History of Glaucoma



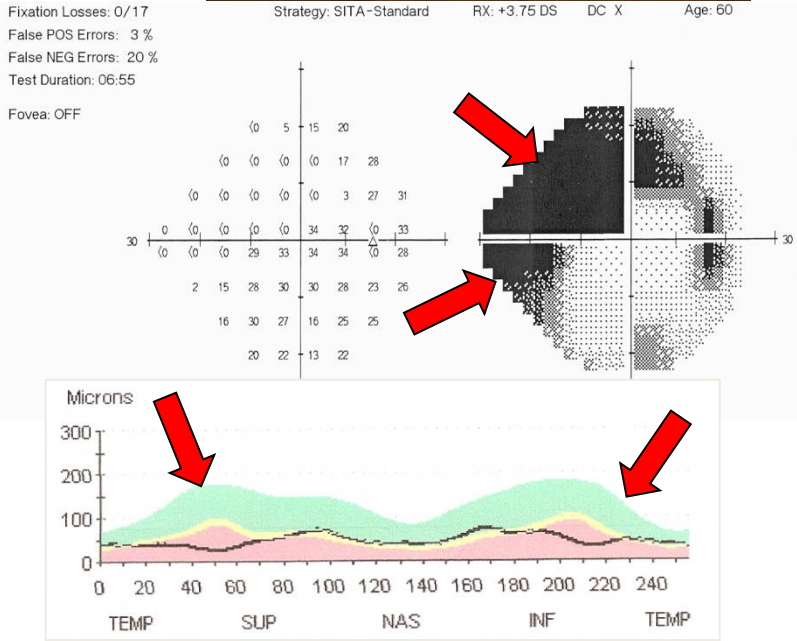
22 mmHg
545 μm



26 mmHg
545 μ m



74 year old woman
European Ancestry
+ Family History of Glaucoma



22 mmHg
545 μ m

