

Glaucoma; Less is More? MIGS & SLT

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UKISCRS

IGA

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NHS

UCL

UNIVERSITY OF PLYMOUTH



IGA

The International Glaucoma Association

International Glaucoma Association **iga**

About the IGA

International Glaucoma Association **iga**

- Based in Kent, but working across the UK and beyond
 - Founded in 1974
 - c. 5,000 members
 - 4,000 people with glaucoma
 - 1,000 professionals
 - 15 staff
 - 25 Volunteers
 - Turnover £1.25m
 - Funded entirely through charitable income - donations, legacies & membership income
 - Services are free to all

About the IGA

International Glaucoma Association **iga**

Our vision is that everyone living with glaucoma, and all those at risk, should have the knowledge and access to the care they need to avoid preventable sight loss

To make this a reality we do three things:

IGA - what we do

International Glaucoma Association **iga**

1. **Support research into detection and treatment** - via an annual grant making programme and through our support for the IGA Professor of Glaucoma at UCL
2. **Prevention of needless sight loss** - by running national campaigns to raise awareness and understanding of glaucoma, and reduce needless sight loss by encouraging people to take care of their eyes - especially those most at risk.
3. **Helping people live well with glaucoma** - by providing advice and information on managing the condition, via our telephone helpline, online forum and local patient support groups around the UK.
Publishing and distributing a wide range of booklets and leaflets aimed at patients, carers and professionals. This information is regularly updated and approved by specialists, and is also available via our website.

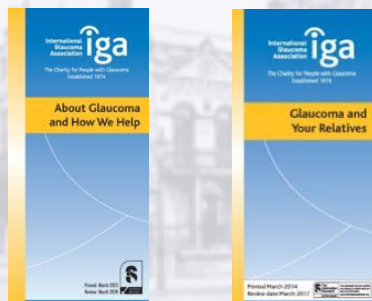
IGA quarterly membership magazine

International Glaucoma Association **iga**



IGA advice & information

International
Glaucoma
Association



IGA campaigns

International
Glaucoma
Association



IGA campaigns

International
Glaucoma
Association



IGA Helpline (*sightline*)

International
Glaucoma
Association

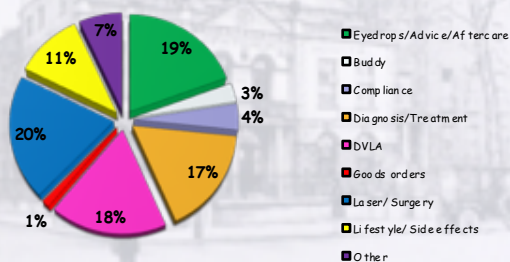
01233 64 81 70



IGA telephone helpline

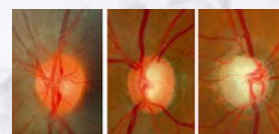
International
Glaucoma
Association

Why do people contact us?



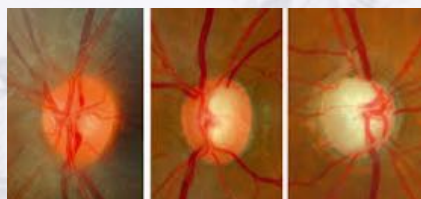
What is Glaucoma?

- A group of diseases
 - Open / closed angle
 - Primary / secondary
 - Childhood / adult
- Common feature is change in optic nerve
 - Thinning of nerve tissue
 - 'Cupping'
- Usually associated with visual field changes
 - Visual fields may be normal in early glaucoma
- Often associated with raised eye pressure (IOP)
 - Not always

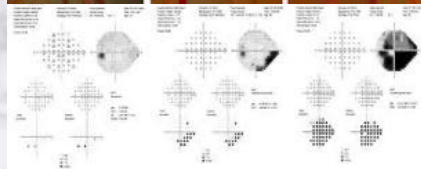


Normal - Early Glaucoma - Advanced Glaucoma

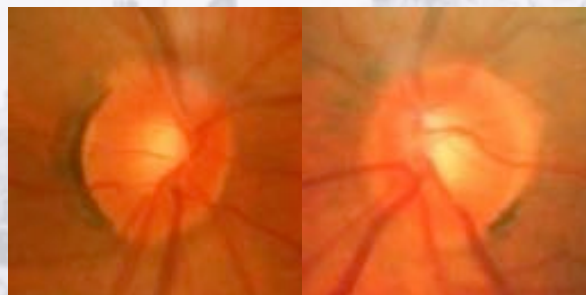
Optic nerve



Visual field



Glaucoma - Progression



Burden of monitoring glaucoma

- UK: One million hospital visits per year



NIHR Health Services and Delivery Research programme

National Institute for Health Research

Frequency of visual field testing when monitoring patients newly diagnosed with glaucoma: mixed methods and modelling

Authors: Crabbe D, Russell R, Malik R, Anand N, Baker H, Brodhurst T, Brorby C, Fung D, Ganley-Heath D, Glen F, Hernandez R, Kirwan J, Lester C, McNaught A, Vignati

Journal: Health Services and Delivery Research Volume: 2 Issue: 27

Publication date: August 2014

DOI: <http://dx.doi.org/10.1016/j.hsr.2014.08.001>

Citation: Crabbe D, Russell R, Malik R, Anand N, Baker H, Brodhurst T, et al. Frequency of visual field testing when monitoring patients newly diagnosed with glaucoma: mixed methods and modelling. Health Serv Res. 2014;27(27):27.

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Related Publications

References

Project Links

Examining Visual Field Loss in Patients in Glaucoma Clinics During Their Predicted Remaining Lifetime

.....enormous variability in progression rates....

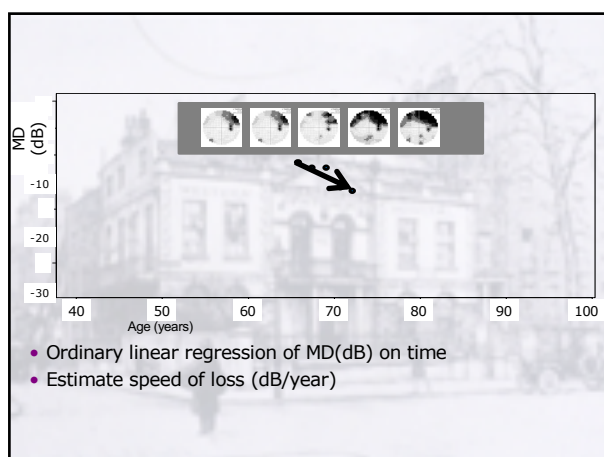
.....most treated patients in clinics are not at high risk of progressing to blindness..

Saunders et al IOVS 2014

'Big' visual field data

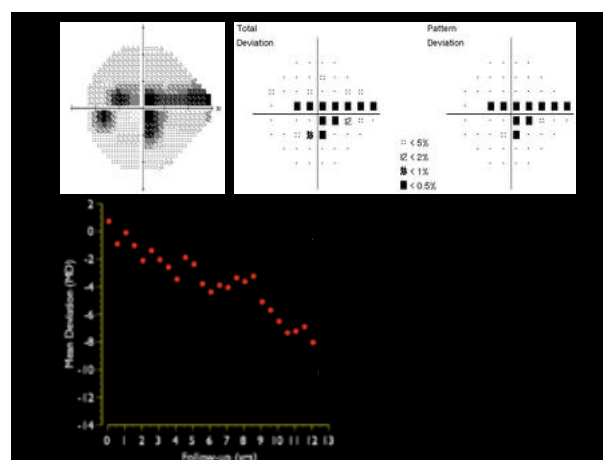
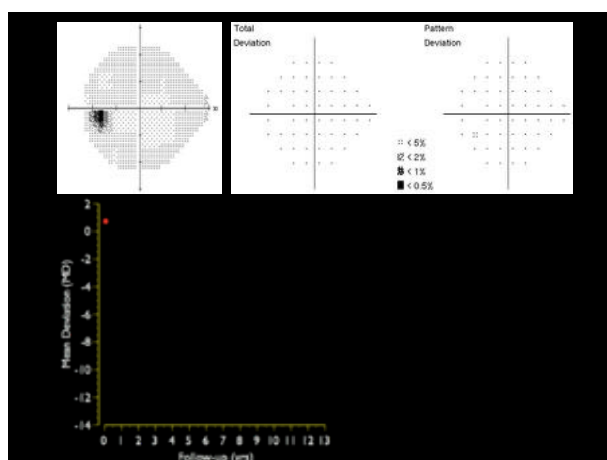
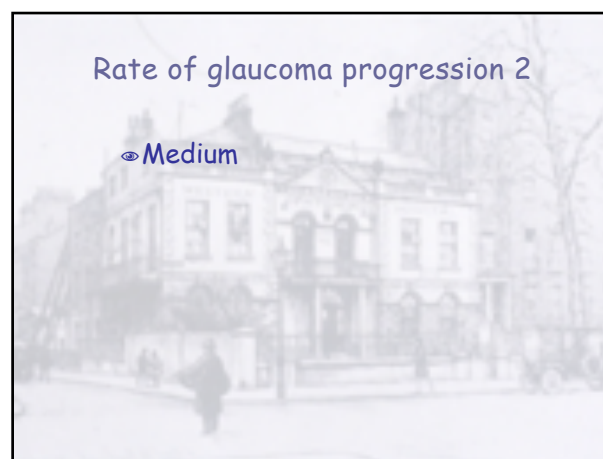
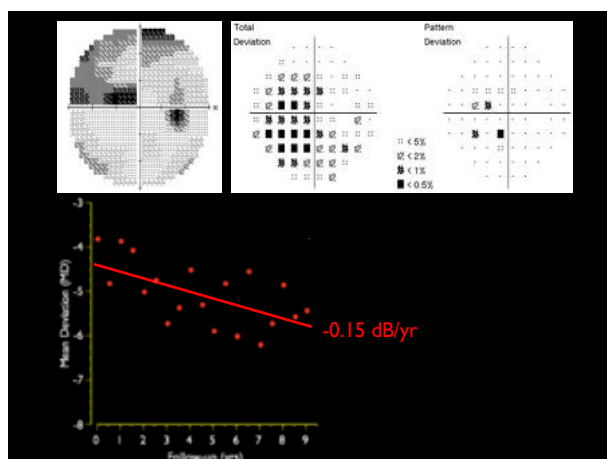
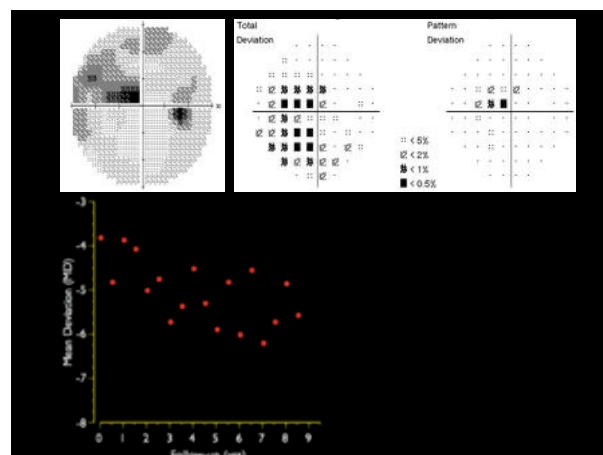
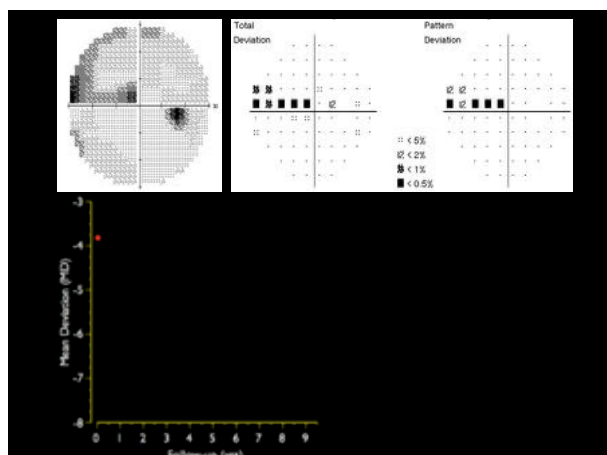
Study	Visual Field Data
Goldman and Humphrey (2002 to 2012)	70,955 VFIs from 13,075 patients
Glaucoma Research (2000 to 2011)	50,144 VFIs from 11,279 patients
Shorland (2000 to 2011)	320,134 VFIs from 55,402 patients
Perkins (1999 to 2011)	11,879 VFIs from 9,086 patients

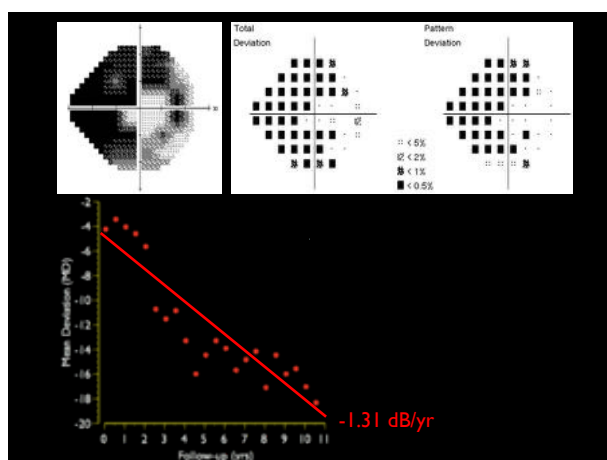
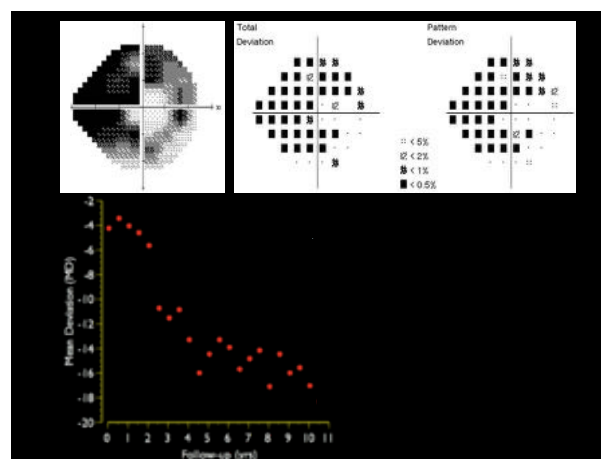
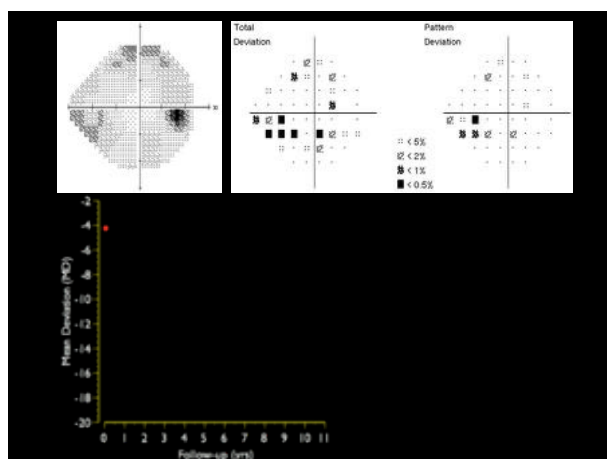
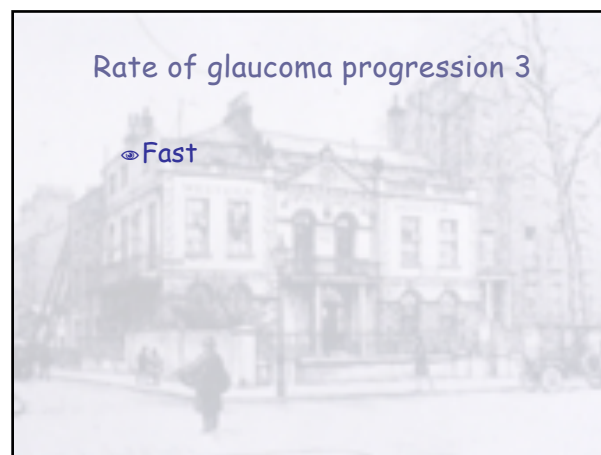
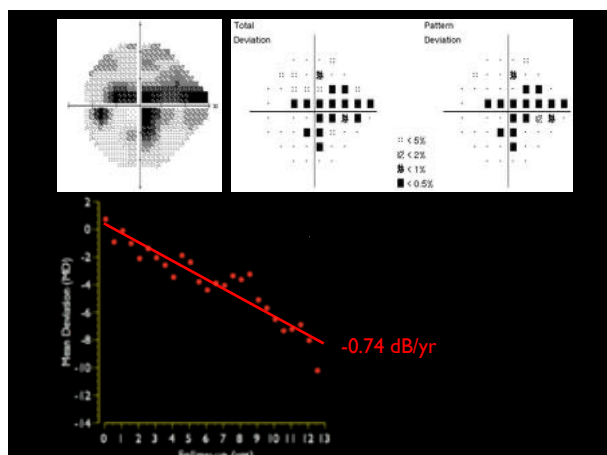
~500K VFIs!!



Rate of glaucoma progression 1

Slow





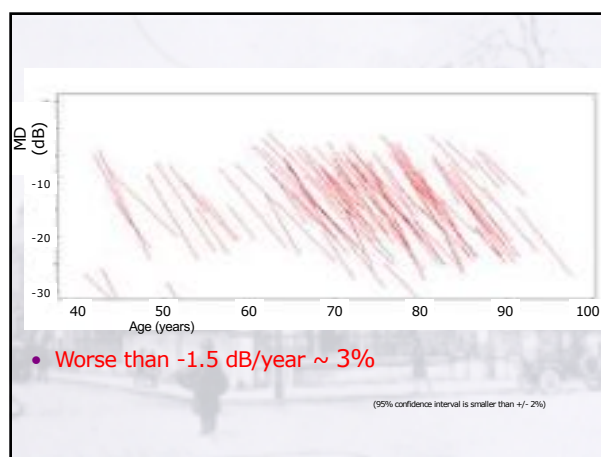
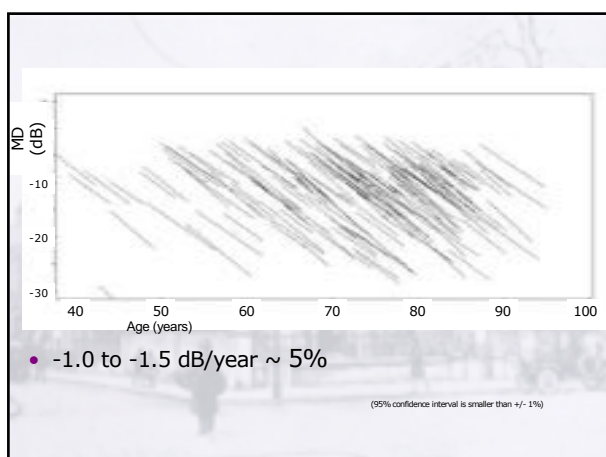
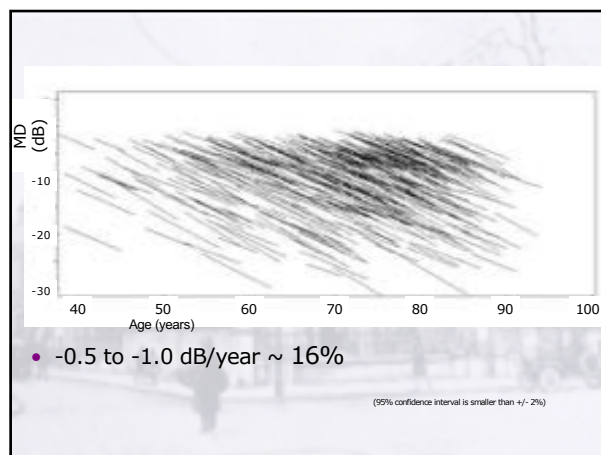
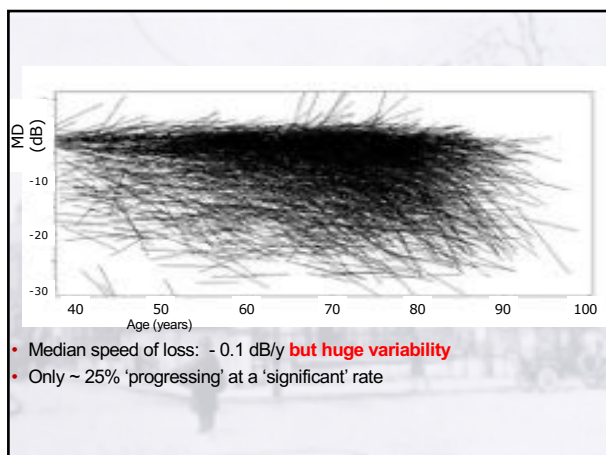
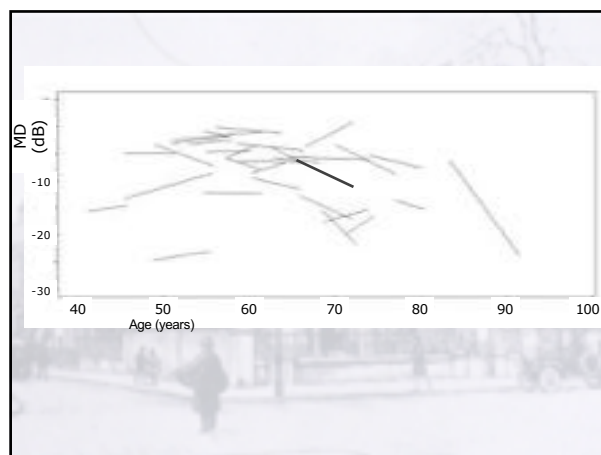
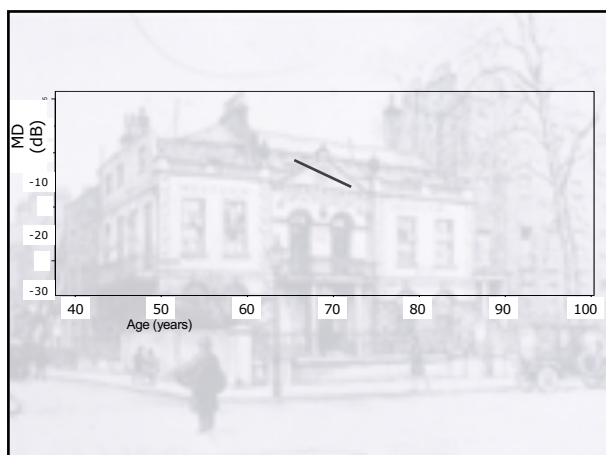
Big data, visual fields and glaucoma

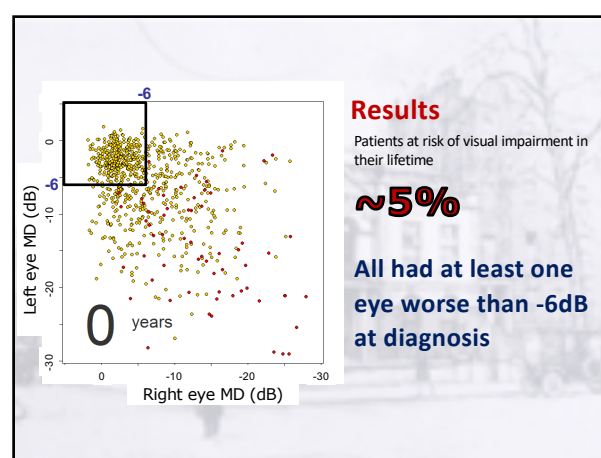
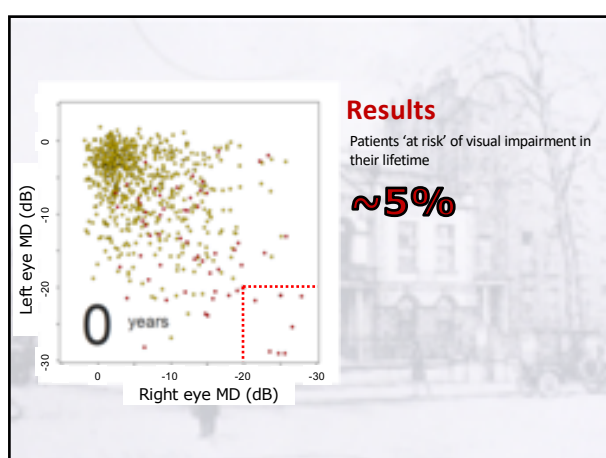
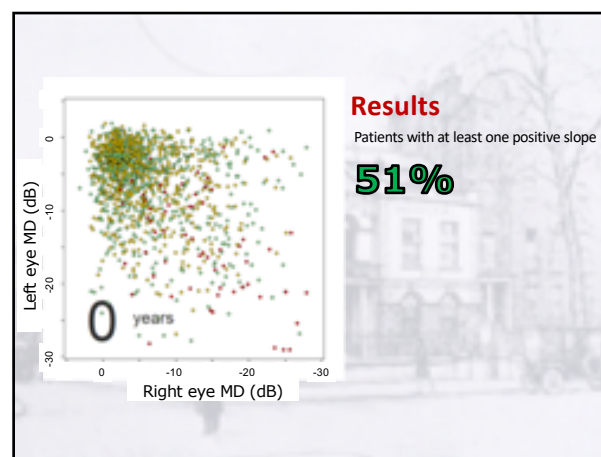
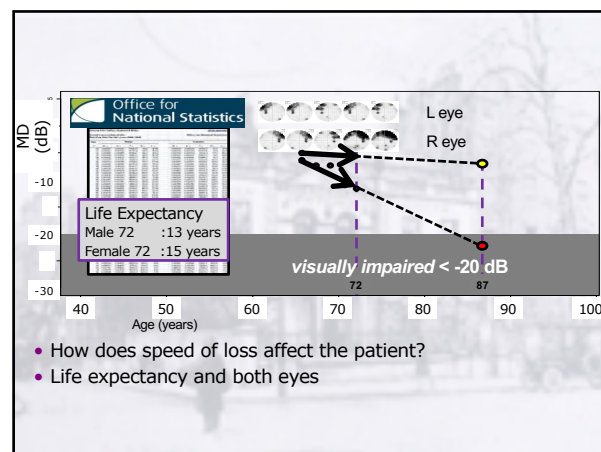
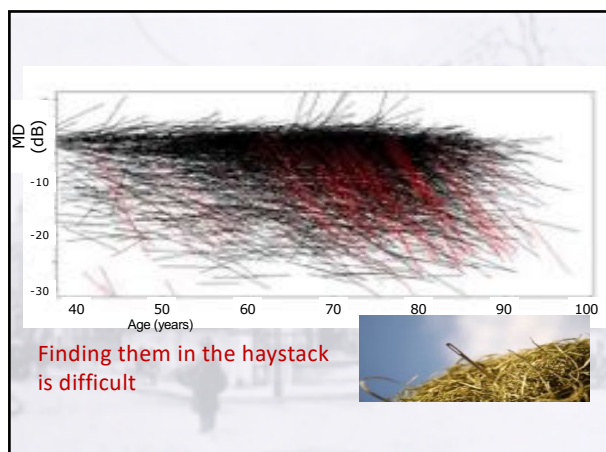
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UNIVERSITY OF LONDON
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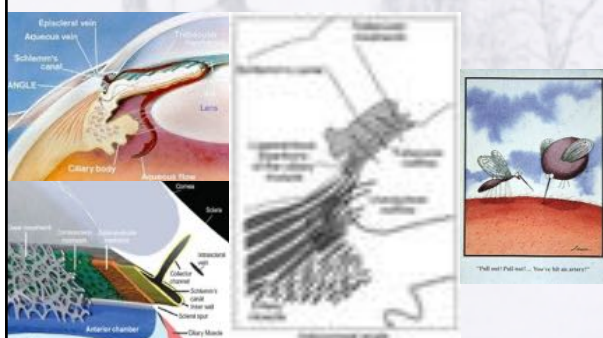
Glaucoma - Eye Pressure

- IOP = Intra-Ocular Pressure
- IOP is often raised in glaucoma
 - But not always
- Not everyone with glaucoma has raised eye pressure
 - Low pressure glaucoma (aka NTG, Normal Tension Glaucoma)
- Not everyone with raised IOP has glaucoma
 - Ocular Hypertension
- Lowering IOP effectively treats glaucoma
 - Even if the IOP was not raised in the first place
- 'Normal' range of IOP *around* 10-24 mmHg
 - Usually 10-21 mmHg is quoted
 - New population studies suggest higher normal upper limit

Glaucoma - Treatment

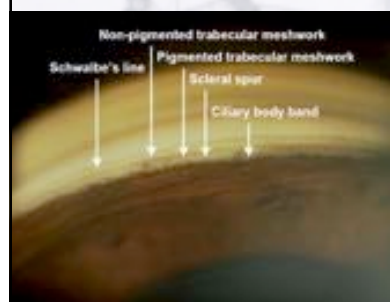
- Medications
 - Drops
 - Tablets
- Laser
 - Iridotomy (PI)
 - Trabeculoplasty (ALT / SLT)
 - Cyclo-photocoagulation ('Cyclodiode' / ECP)
- Surgery
 - Trabeculectomy ('Trab')
 - Glaucoma drainage devices ('Tubes')
 - Cataract surgery ('Phaco')
 - MIGS (with or without phaco cataract surgery)

Outflow & Inflow: 'Plumbing' Anatomy Based Treatment Approaches



Examinations & Investigations: Gonioscopy

Normal Eye Structures



Jain S, South East Asia Glaucoma Interest Group (SEAGIG). www.seagig.org

Laser Treatments

Reduce aqueous production

- TCP/ECP

Relieve obstruction to flow

- PI/ALPI

Increase outflow

- ALT/ SLT

Laser Treatment

Cyclophotocoagulation

- Laser diode cyclophotocoagulation preferable to other forms of ciliary body treatment
- Reduces aqueous production by destruction of ciliary epithelium
- Options:
 - Trans scleral
 - (Neodymium: YAG laser cyclo-photocoagulation [1064 nm])
 - Diode (810 nm) - Cyclodiode
 - (Transpupillary)
 - Endoprobe (ECP, a MIGS procedure)

SLT v ALT: Technique

- ◉ In ALT endpoint - blanching or production of a tiny bubble
- ◉ In SLT there is not endpoint - use microbubbles as guide. The aiming beam is centered over the trabecular meshwork and straddles the entire Trabecular Meshwork



LT Mechanism (ALT / SLT)

- ◉ Potential mechanisms for lowering IOP:
 1. Mechanical effect with focal shrinkage of the anterior meshwork puts the posterior filtering meshwork on stretch
 2. Cellular effect, a diffuse loss of meshwork cells (even in untreated areas between burns)
 3. Biochemical effect causing an alteration in both the rate and composition of the trabecular meshwork's extracellular matrix

SLT - LIGHT study

- ◉ Laser in Glaucoma & Ocular Hypertension
- ◉ Primary treatment - Laser vs Drops
- ◉ Did not show better quality of life
 - They used a very basic questionnaire
- ◉ 75% of SLT patients still off drops at 3 years
- ◉ May change the landscape for initial treatment

Cyclodiode



New Glaucoma Dedicated Laser System: CYCLO G6™

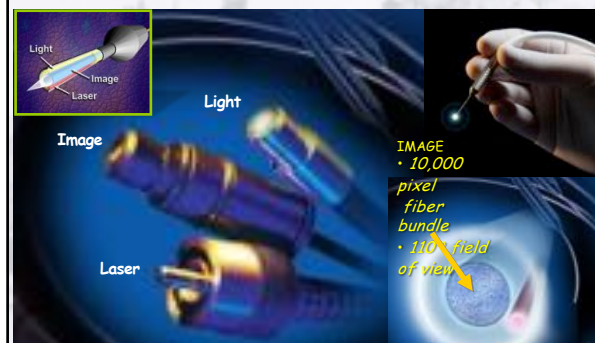


MicroPulse® P3 – Innovative Cyclophotocoagulation with MicroPulse Technology

- Efficient & straightforward for doctor and patient
- Excellent safety profile
- Non-incisional, so can be performed in outpatients or operating theatre
- Predictable
- Minimal inflammation post-op
- Repeatable



ECP Technology The 3 in 1 Micro-Endoscope



ECP (Laser MIGS)

- Localised shrinkage of ciliary processes
- Direct vision - relative tissue sparing
- Observed end point
- Titratable - 90/180/270/360°
- Reduced ciliary body aqueous production
- Reduction in blood flow
- Partial reperfusion - may retreat
- Hypotony (IOP too low) rare
- MIGS
 - Quick
 - Sutureless
 - Ocular surface friendly



Trabeculectomy



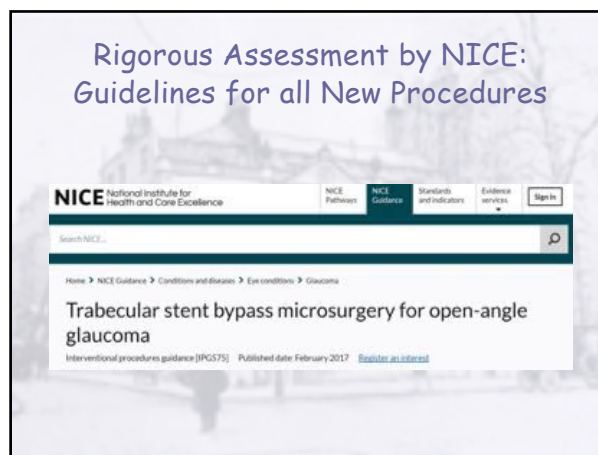
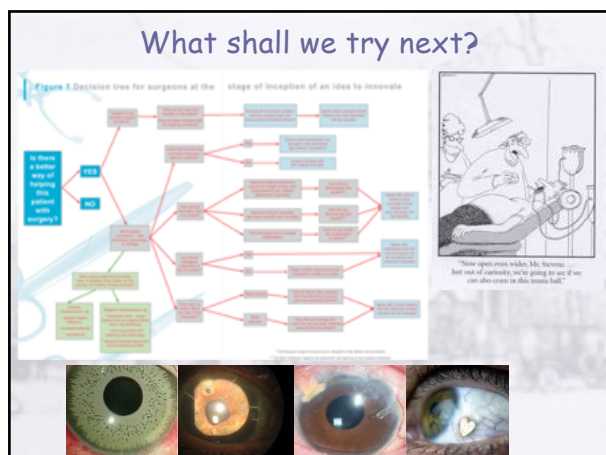
New Surgical Techniques in Glaucoma What are We Looking For?

- Trab replacement?
- Wound healing modulation?
- Medication alternative?
- Adjunct to cataract procedure?
- Blebless?

Stages of surgical innovation

Stage	1. Proof of concept	2. Pre-clinical	3. Clinical	4. Commercial	5. Post-market
Objective	Establish feasibility of the concept	Establish safety and efficacy of the concept	Establish safety and efficacy of the concept	Establish safety and efficacy of the concept	Establish safety and efficacy of the concept
Methods	Pre-clinical studies, animal models, bench tests	Pre-clinical studies, animal models, bench tests	Pre-clinical studies, animal models, bench tests	Pre-clinical studies, animal models, bench tests	Pre-clinical studies, animal models, bench tests
Results	Feasibility of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept
Conclusions	Feasibility of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept	Safety and efficacy of the concept

Surgical Innovation, New Techniques & Technologies
www.rcseng.ac.uk/standardsandguidance



What is MIGS?

(Minimally Invasive Glaucoma Surgery)

focus
Minimally Invasive Glaucoma Surgery: MIGS

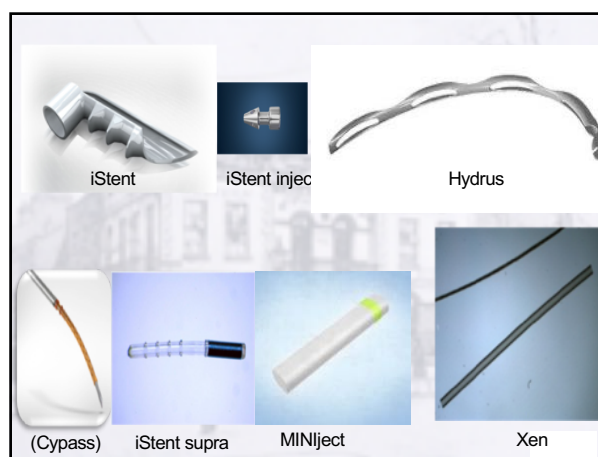
- Ever-expanding plethora of procedures
- Minimally traumatic / invasive
 - Minimal tissue interaction (less effect of wound healing)
- High safety profile
- Rapid recovery
- Frequently combined with cataract extraction
- Provides more modest IOP lowering than trabeculectomy
- Usually via an ab-interno approach
 - Conjunctiva-sparing vs conjunctiva-involving
 - Physiological outflow (Schlemm's canal) vs. non-physiological routes (via the supra-choroidal or sub-conjunctival spaces)
 - Inflow procedures: reduction of aqueous production

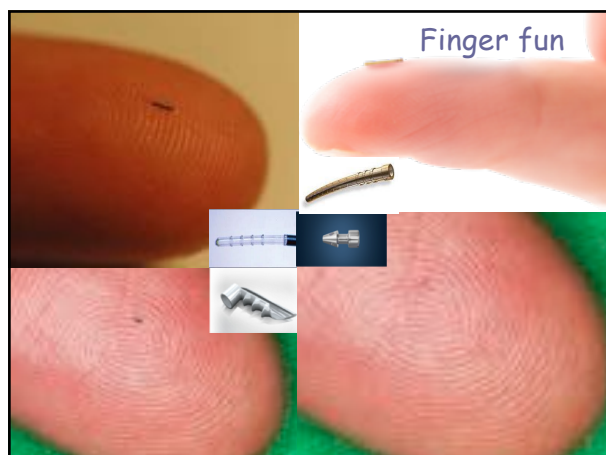
Gazzard G; <https://www.rcophth.ac.uk/wp-content/uploads/2016/05/CN-Focus-Spring-2016.pdf>



Untrabitional Glaucoma Surgery: MIGS

- **Outflow**
 - Conventional sub-conjunctival drainage
 - Trabeculectomy / tube
 - Innfocus
 - MIGS sub-conj drainage
 - Xen (sometimes need revision, incising conjunctiva)
 - MIGS Schlemm's canal surgery
 - iStent, Hydrus
 - MIGS angle surgery
 - Trabectome, Kahook blade
 - MIGS non-conventional outflow
 - Cypass / iStent Supra
- **Inflow**
 - Conventional (trans-conjunctival)
 - Cyclodiode
 - Less invasive (MicroPulse / HiFU)
 - MIGS
 - ECP

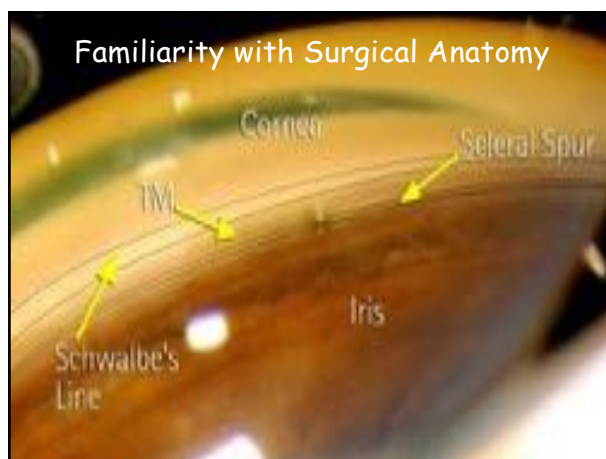




Plethoric MIGS

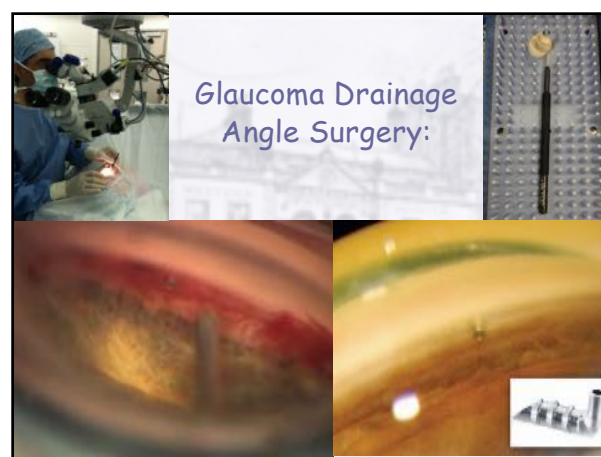
Technique / Device	Drainage Route & Mechanism of IOP Reduction	Conjunctiva Involved?	Published Randomized Controlled Trial Evidence?
Trabectome (Bausch & Lomb)	Via Schlemm's canal incision of trabecular meshwork	No	No
Stent (Allergan)	Via Schlemm's canal incision of trabecular meshwork	No	Yes
Stent Inject (Allergan)	Via Schlemm's canal incision of trabecular meshwork	No	No
Hydrus (Allergan)	Via Schlemm's canal incision of trabecular meshwork	No	Yes
ASL (Allergan)	Via Schlemm's canal incision of trabecular meshwork	No	No
ExPRESS (Allergan)	Via supra-choroidal space	No	No
Stent Supra (Allergan)	Via supra-choroidal space	No	No
Endo-cyclophotocoagulation 'Endo-Stab'	Cyclodestructive	No	No
Microshunt (Allergan)	To sub-tenon / non-conjunctival space	Yes	No
Neo (Allergan / Allergan)	To sub-tenon / non-conjunctival space	Yes	No

Gazzard G. <https://www.rcophth.ac.uk/wp-content/uploads/2016/05/CN-Focus-Spring-2016.pdf>

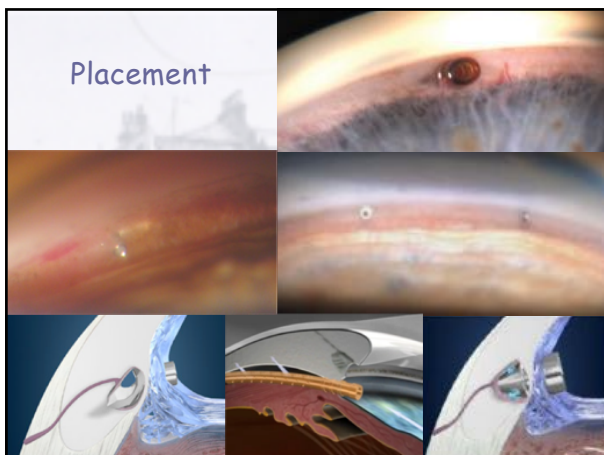


Mechanism: Aqueous Outflow

- Conventional outflow pathway
 - 90% total flow
 - Trabecular meshwork
 - Juxtacanalicular connective tissue
 - Endothelial lining of Schlemm's canal
 - Schlemm's canal
 - Collecting channels and aqueous veins
 - Episcleral veins
 - Blood stream
- Non-conventional pathway
 - 10% total flow
 - Uveo-scleral flow



Placement

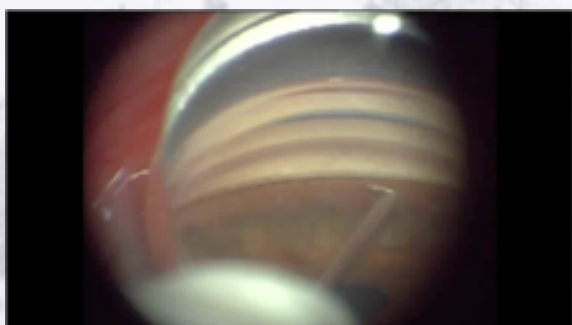


iStent®

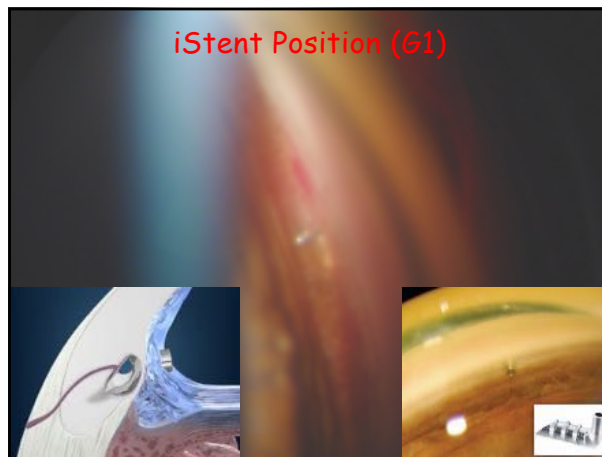
- Inserter held like a pen
- Index finger activates release button in the eye



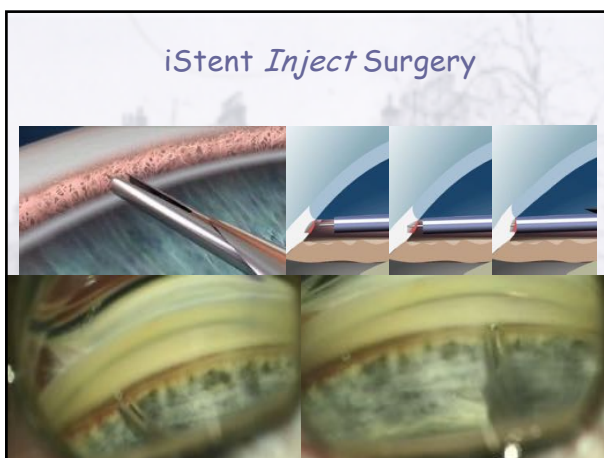
iStent Video (G1)



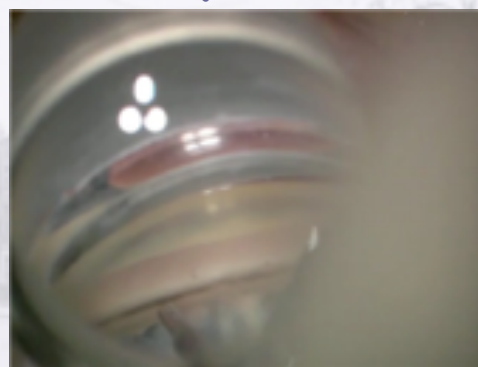
iStent Position (G1)

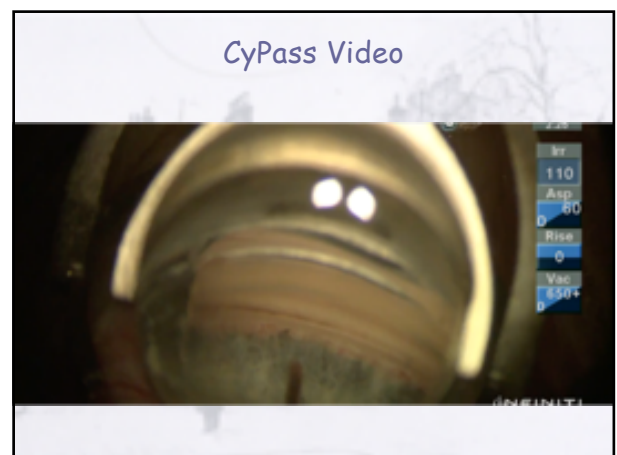
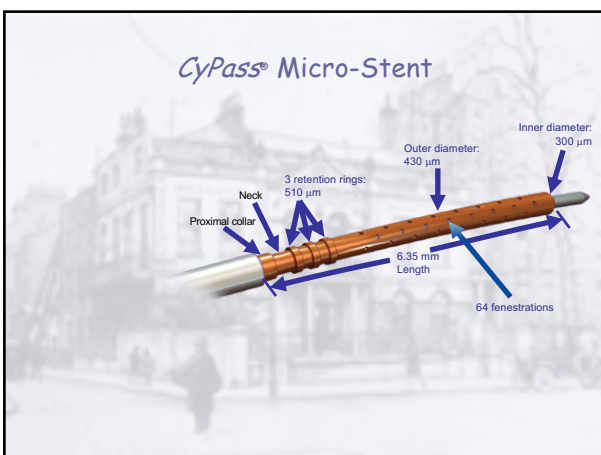
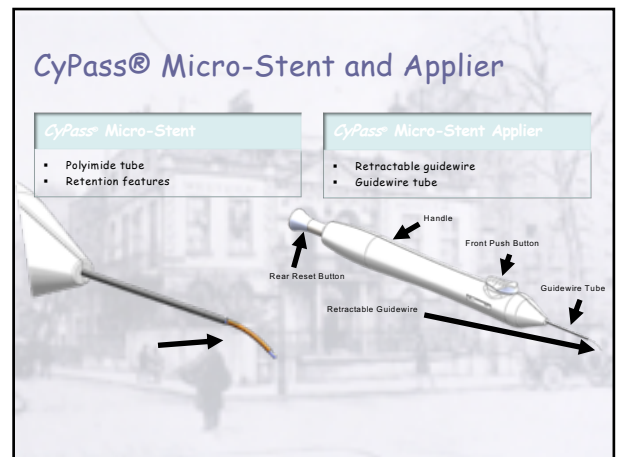
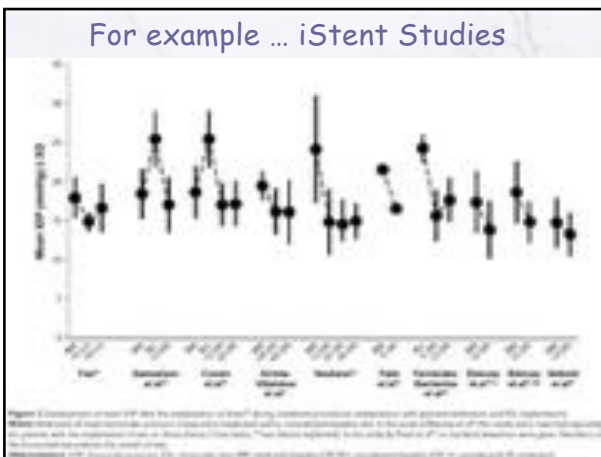
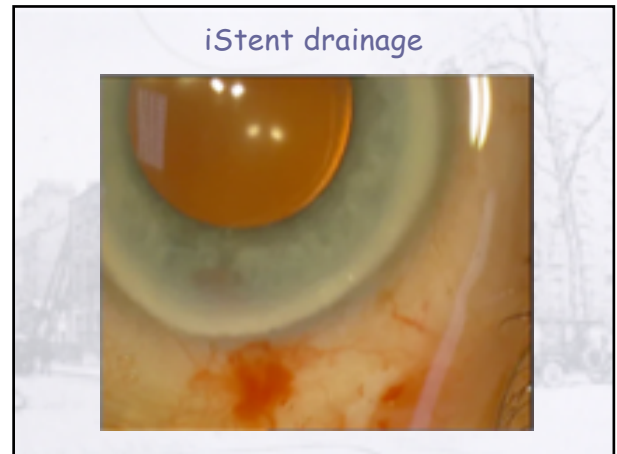
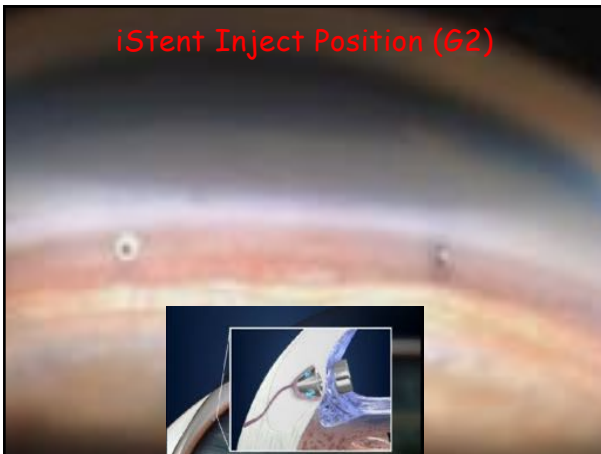


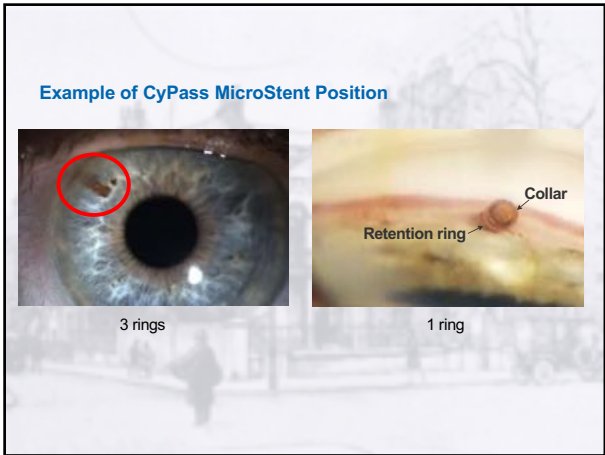
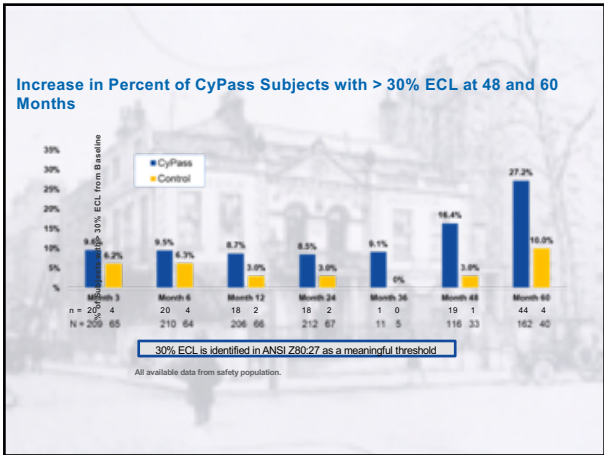
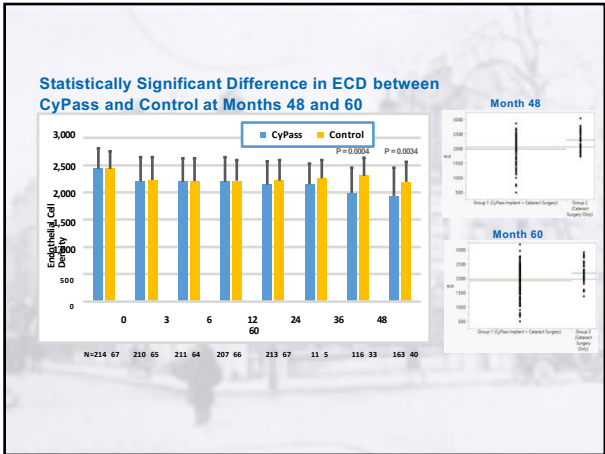
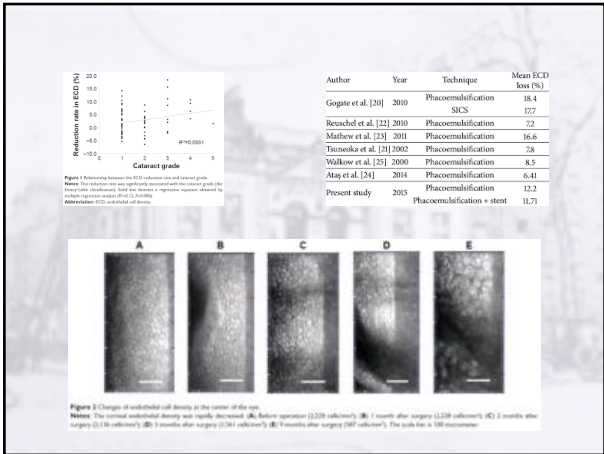
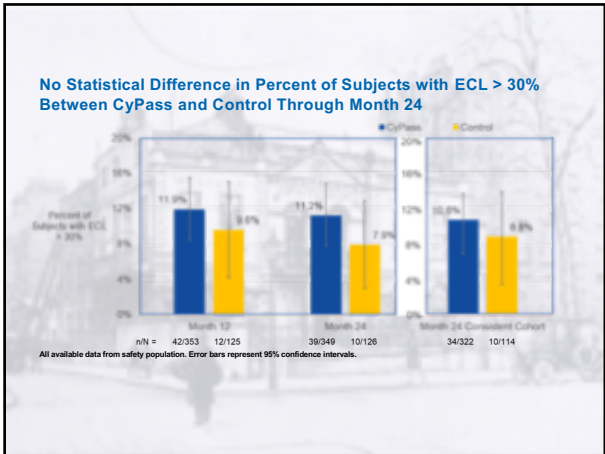
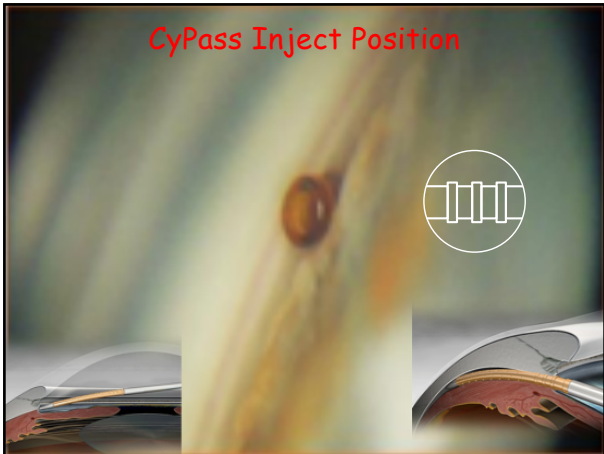
iStent *Inject* Surgery

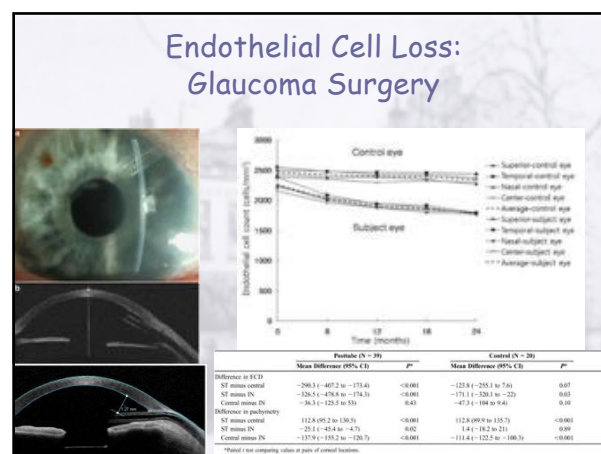
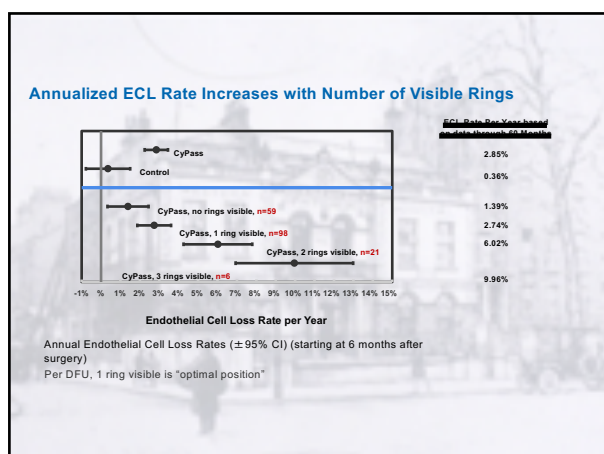


iStent Inject Video (G2)









New treatment paradigms: Wither (sic) MIGS? (after Gazzard)

- Reduced dependence on topical medication
- Stepwise approach for mild to moderate disease
 - Early / primary selective laser trabeculoplasty
 - Preservative-free topical or injectable therapies
 - Ab interno MIGS procedures, with or without lens surgery
 - More invasive conjunctiva-involving stents for more severe disease and / or those who fail initial treatments
- Moderate to advanced disease / low target IOP
 - Traditional MMC or anti-VEGF augmented trabs (follow 10/10/10)
 - Tube surgery - complex, secondary glaucomas and/or failed previous surgery

MIGS: the Good SAFETY

- Complications uncommon
 - Mild
 - Self-limiting
- Haemorrhage
 - Blood in Schlemm's Canal
 - Iris / CB trauma
- IOP spike
 - Manage as normal
- Device occlusion

Risk & Benefit

'Risk of doing something (trab)'

- Complications

'Risk of doing nothing (MIGS)'

- Disease progression
- More sight loss

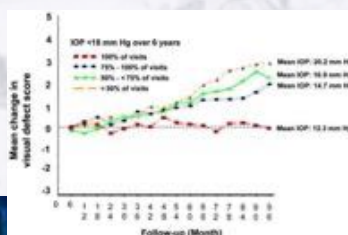
MIGS the bad: EFFICACY

- Schlemm's canal routes seem to have a physiological 'floor' of around 16mmHg due to downstream resistance to flow *
- How much of the effect is due to concurrent cataract surgery?

* Basic science behind trabecular meshwork surgeries. D. Overby Acta Ophthalmologica Vol 91, s252; 2013

What is the answer?

- 42?
- HHGTTG
- 12
- AGIS



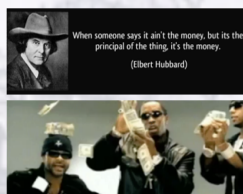
MIGS: the Ugly

- Evidence base
 - (spoiler alert) - not huge
- Cost
 - Complex
- Unexpected consequences
 - The CyPass story
- Regulatory issues



Cost issues are complex

- Theatre time
 - Surgical time
 - Turnaround time
- Equipment / disposable costs
- Device costs
 - Multiple implants
- Follow up costs
- Costs of more surgery
- Economic & human costs of visual loss
- Costs of implementation of new technologies
 - Industry sponsorship and commercial pressures
- New studies should include economic assessment



MIGS guru opines ... (Ike Ahmed)

- "A common misperception of MIGS is that it needs to be compared with the gold standard of MMC-trabeculectomy to show its effectiveness
- This inappropriate interpretation is based on the idea that MIGS procedures are designed to replace conventional filtering surgery
- In fact, MIGS devices are designed to address the treatment gap that exists between medical therapy and more aggressive traditional surgical options"

Ahmed I. MIGS and the FDA: What's in a Name (Editorial)? Ophthalmology Volume 122, Number 9, September 2015

Summary

- MIGS is a useful option
 - To replace drops
 - Before significant functional damage
 - Poor patient compliance
 - Phaco *plus*
 - No free lunches
- MIGS is not a natural comparator for trabeculectomy
 - (But GDDs probably are)
- Trabeculectomy is currently our best option for patients with *proper* glaucoma
- Do not delay surgery ...
- MIGS procedures clearly hold great promise (Gazzard)
 - We have a duty to use them responsibly
 - Objectively investigate risks & benefits
- Less is indeed more

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