

17TH INTERNATIONAL CONFERENCE OF THE
RESEARCH INSTITUTE OF OPHTHALMOLOGY

RIO 2025

*Anterior Segment Eye Diseases
Current Status & Future Directions*

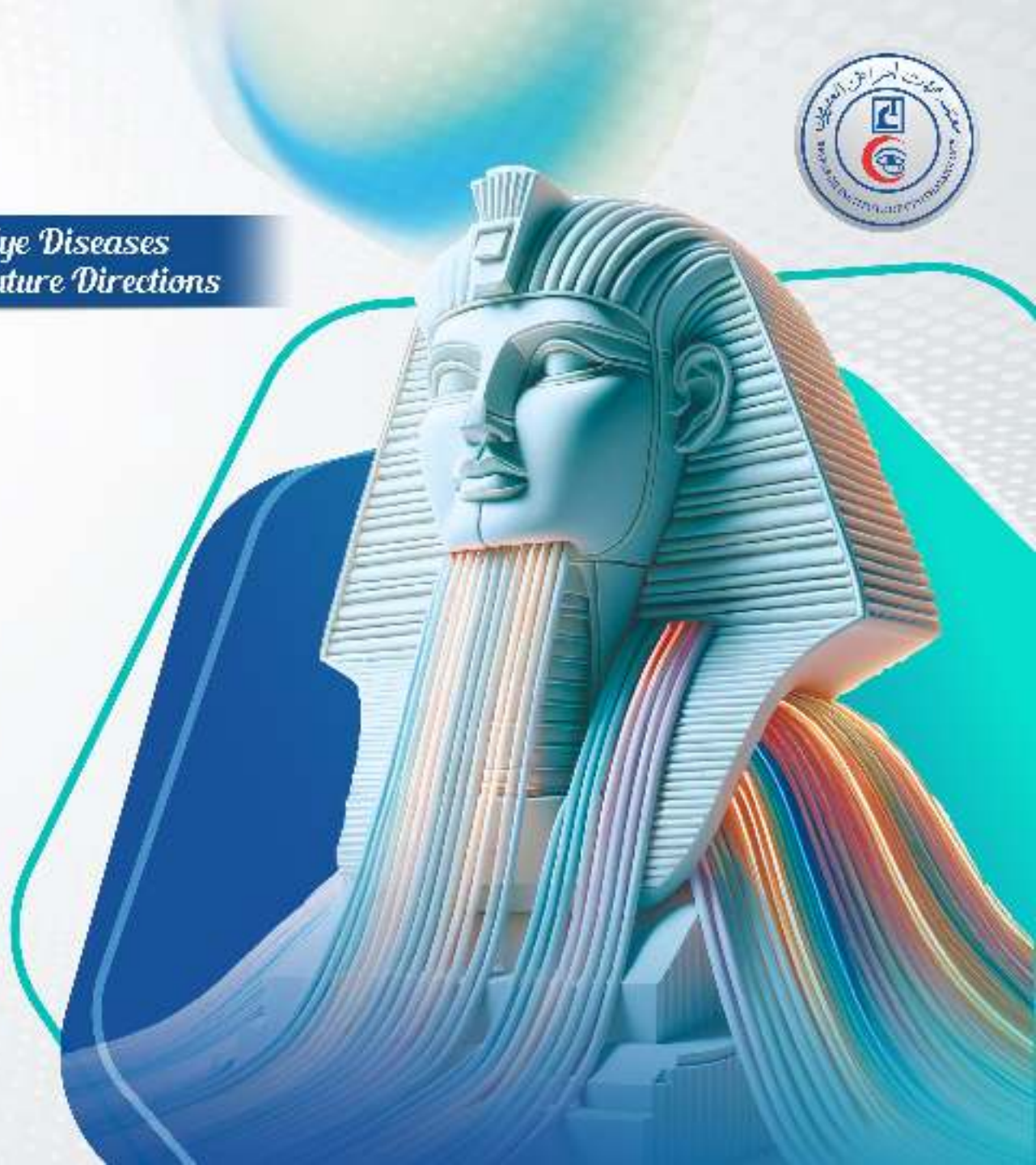


Changing Paradigm in Glaucoma Surgery

Sheng Lim

MD MBChB FRCOphth

Professor of Glaucoma Studies





**Kersley Eye
Clinic**



**King's College
London &**



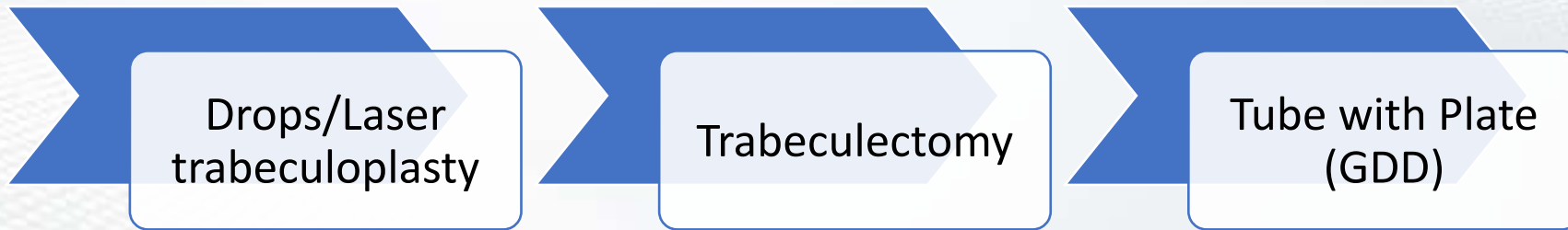
**St Thomas'
Hospital**





Company	Device	Funding
New World Medical	Kahook DB	Research Grant Advisory Board
EyeTechCare	HIFU	Research Grant
BVI Medical	ECP	Research Grant Advisory Board
Iridex	Micropulse	Research Grant Advisory Board
Ivantis	Hydrus	Investigator Consultant
Glaukos	iStent	Travel Grant Advisory Board
AbbVie (Allergan)	Xen	Investigator Lecture
iSTAR Medical	STARFlo	Scientific Advisor Medical Monitor
RheonMedical	EyeWatch	Investigator
Ellex	SLT	Research Grant Lecture
Santen	PreserFlo	Consultant Lecture Research grants

Treatment Paradigm for POAG



PTVT

 AMERICAN ACADEMY OF OPHTHALMOLOGY

Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 3 Years of Follow-up

Steven J. Gedde, MD,¹ William F. Fawc, MS,² Xin Sheng Liu, MD,² Kath Byron, MD,² Sandra Goyal, MD,^{2,3} Igbal I. Ahmed, MD,² James D. Brant, MD,² for the Primary Tube Versus Trabeculectomy Study Group

Purpose: To report 3-year results of the Primary Tube Versus Trabeculectomy (PTVT) Study.
Design: Multicenter randomized clinical trial.
Participants: Two hundred fifty-two eyes of 125 patients with medically uncontrolled glaucoma and no previous ocular surgery, including 125 in the tube group and 117 in the trabeculectomy group.
Methods: Patients were enrolled at 16 clinical centers and were assigned randomly to treatment with a tube shunt (820 mm² Baerveldt glaucoma implant) or trabeculectomy with mitomycin C (MMC; 0.4 mg/mL for 2 minutes).

Main Outcome Measures: The primary outcome measure was the rate of surgical failure, defined as intraocular pressure (IOP) greater than 21 mmHg or need for more than 20% from baseline IOP at 5 mmHg or less, reoperation for glaucoma, or loss of light perception vision. Secondary outcome measures included IOP, glaucoma medical therapy, visual acuity, and adverse complications.

Results: The cumulative probability of failure after 3 years of follow-up was 33% in the tube group and 28% in the trabeculectomy group ($P = 0.14$; hazard ratio, 1.39; 95% confidence interval, 0.7–2.2). Mean standardized deviation IOP was -14.0 ± 2 mmHg in the tube group and -12.1 ± 3 mmHg in the trabeculectomy group at 3 years ($P = 0.02$), and the number of glaucoma medications was 2.1 ± 1.4 in the tube group and 1.2 ± 1.5 in the trabeculectomy group ($P < 0.001$). Serious complications requiring reoperation or enucleation occurred in 2 or more eyes and developed in 3 patients (12%) in the tube group and 3 patients (15%) in the trabeculectomy group ($P = 0.11$).

Conclusions: There was no significant difference in the rate of surgical failure between the 2 surgical procedures at 3 years. Trabeculectomy with MMC achieved lower IOP with use of fewer glaucoma medications compared with tube shunt surgery after 3 years of follow-up in the PTVT Study. Serious complications requiring reoperation or enucleation occurred with similar frequency after both surgical procedures. (Ophthalmology 2020;127:337–347. © 2019 by the American Academy of Ophthalmology)

 Supplemental material available at www.aaojournal.org.

 AMERICAN ACADEMY OF OPHTHALMOLOGY

Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 5 Years of Follow-up

Steven J. Gedde, MD,¹ William F. Fawc, MS,² Xin Sheng Liu, MD,² Kath Byron, MD,² Sandra Goyal, MD,^{2,3} Igbal I. Ahmed, MD,² James D. Brant, MD,² for the Primary Tube Versus Trabeculectomy Study Group

Purpose: To report 5-year treatment outcomes in the Primary Tube Versus Trabeculectomy (PTVT) Study.
Design: Multicenter randomized clinical trial.

Participants: A total of 242 eyes of 242 patients with medically uncontrolled glaucoma and no previous ocular surgery, including 125 patients in the tube group and 117 patients in the trabeculectomy group.

Methods: Patients were enrolled at 16 clinical centers and randomly assigned to treatment with a tube shunt (820 mm² Baerveldt glaucoma implant) or trabeculectomy with mitomycin C (MMC; 0.4 mg/mL for 2 minutes).

Main Outcome Measures: The primary outcome measure was the rate of surgical failure, defined as intraocular pressure (IOP) > 21 mmHg or reduced $> 20\%$ from baseline IOP ≤ 5 mmHg, reoperation for glaucoma, or loss of light perception. Secondary outcome measures included IOP, glaucoma medical therapy, and visual acuity.

Results: The cumulative probability of failure after 5 years of follow-up was 48% in the tube group and 36% in the trabeculectomy group ($P = 0.21$; hazard ratio = 1.31–85% confidence interval = 0.76–2.01). At 5 years, IOP (mean $\pm$ standard deviation) was 13.4 ± 3.5 mmHg in the tube group and 13.0 ± 3.2 mmHg in the trabeculectomy group ($P = 0.57$), and the number of glaucoma medications (mean $\pm$ standard deviation) was 2.2 ± 1.3 in the tube group and 1.5 ± 1.4 in the trabeculectomy group ($P < 0.001$).

Conclusions: Trabeculectomy with MMC and tube shunt surgery produced similar IOPs after 5 years of follow-up in the PTVT Study, but fewer glaucoma medications were required after trabeculectomy. No significant difference in the rate of surgical failure was observed between the 2 surgical procedures at 5 years. (Ophthalmology 2020;128:1344–1358. © 2020 by the American Academy of Ophthalmology)

 Supplemental material available at www.aaojournal.org.

 AMERICAN ACADEMY OF OPHTHALMOLOGY

Postoperative Complications in the Primary Tube Versus Trabeculectomy Study During 5 Years of Follow-up

Steven J. Gedde, MD,¹ William F. Fawc, MS,² Xin Sheng Liu, MD,² Kath Byron, MD,² Sandra Goyal, MD,^{2,3} Igbal I. Ahmed, MD,² James D. Brant, MD,² for the Primary Tube Versus Trabeculectomy Study Group

Purpose: To describe postoperative complications encountered in the Primary Tube Versus Trabeculectomy (PTVT) Study during 5 years of follow-up.
Design: Multicenter randomized clinical trial.

Participants: A total of 242 eyes of 242 patients with medically uncontrolled glaucoma and no previous ocular surgery, including 125 patients in the tube group and 117 patients in the trabeculectomy group.

Methods: Patients were enrolled at 16 clinical centers and randomly assigned to treatment with a tube shunt (820 mm² Baerveldt glaucoma implant) or trabeculectomy with mitomycin C (MMC; 0.4 mg/mL for 2 minutes).

Main Outcome Measures: Surgical complications, reoperations for complications, visual acuity, and patient progression.

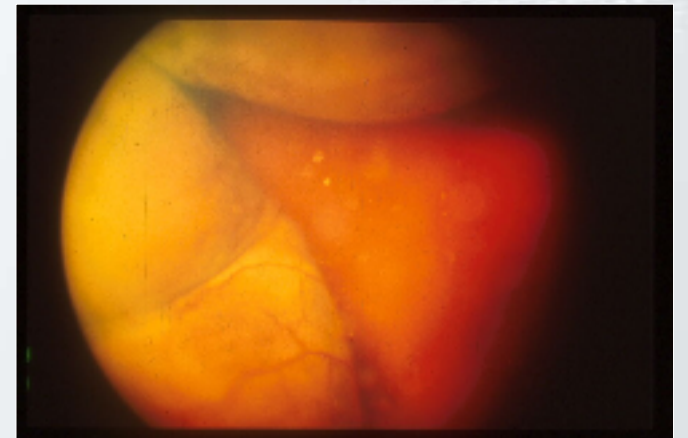
Results: Early postoperative complications occurred in 24 patients (19%) in the tube group and 40 patients (34%) in the trabeculectomy group ($P = 0.013$). Late postoperative complications developed in 27 patients (23%) in the tube group and 32 patients (27%) in the trabeculectomy group ($P = 0.87$). Serious complications producing vision loss and/or requiring reoperation were observed in 3 patients (2%) in the tube group and 8 patients (7%) in the trabeculectomy group ($P = 0.11$). Patient progression was seen in 66 patients (52%) in the tube group and 52 patients (44%) in the trabeculectomy group ($P = 0.32$). Surgical complications were not associated with a higher rate of treatment failure ($P = 0.65$), vision loss ($P = 1.00$), or patient progression ($P = 0.77$).

Conclusions: A large number of surgical complications were observed in the PTVT Study, but most were transient and self-limited. The rate of late postoperative complications was higher following trabeculectomy with MMC than with tube shunt surgery. The rates of late postoperative complications, serious complications, and patient progression were similar in both surgical procedures after 5 years of follow-up. Surgical complications did not increase the risk of treatment failure, vision loss, or patient progression. (Ophthalmology 2020;128:1357–1367. © 2020 by the American Academy of Ophthalmology)

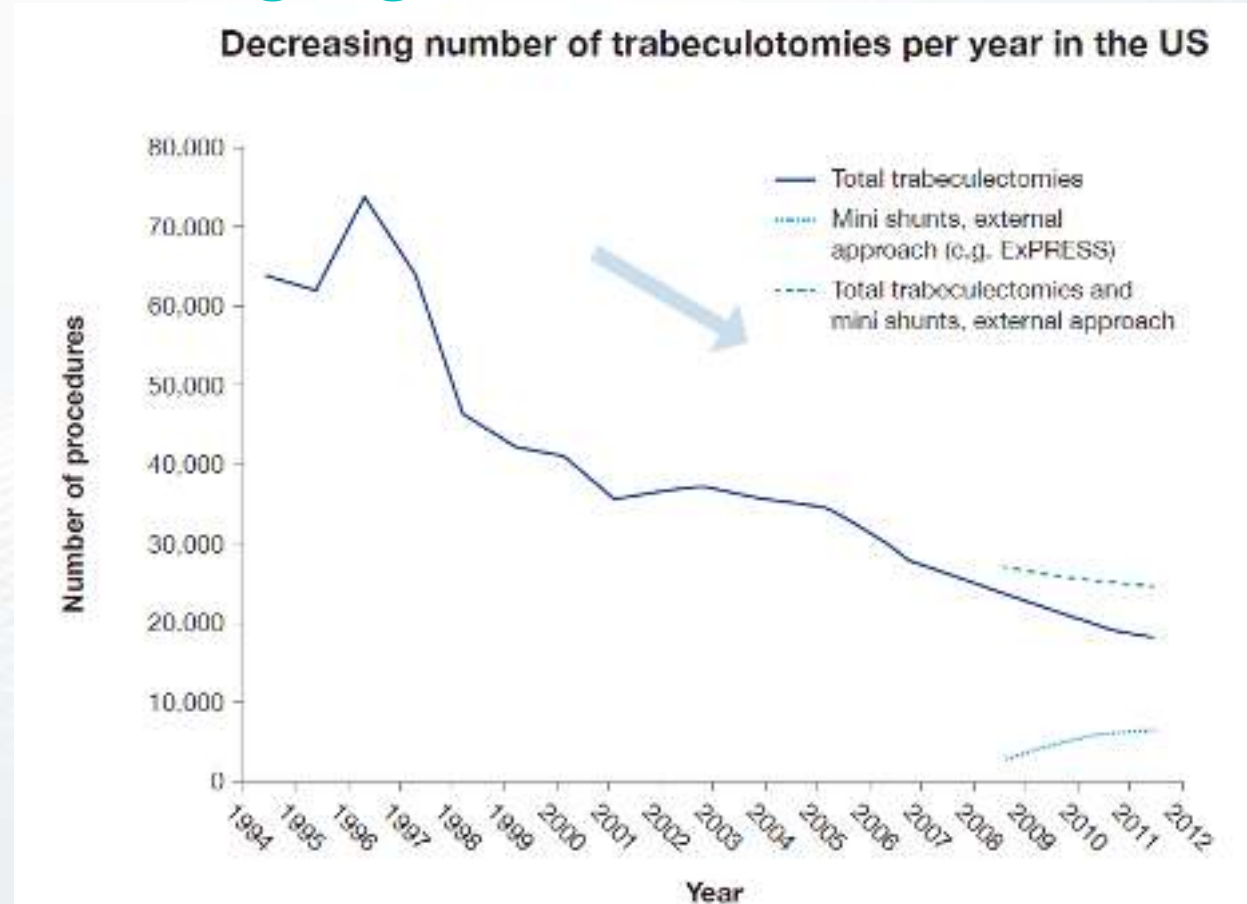
 Supplemental material available at www.aaojournal.org.

Complications - Trabeculectomy

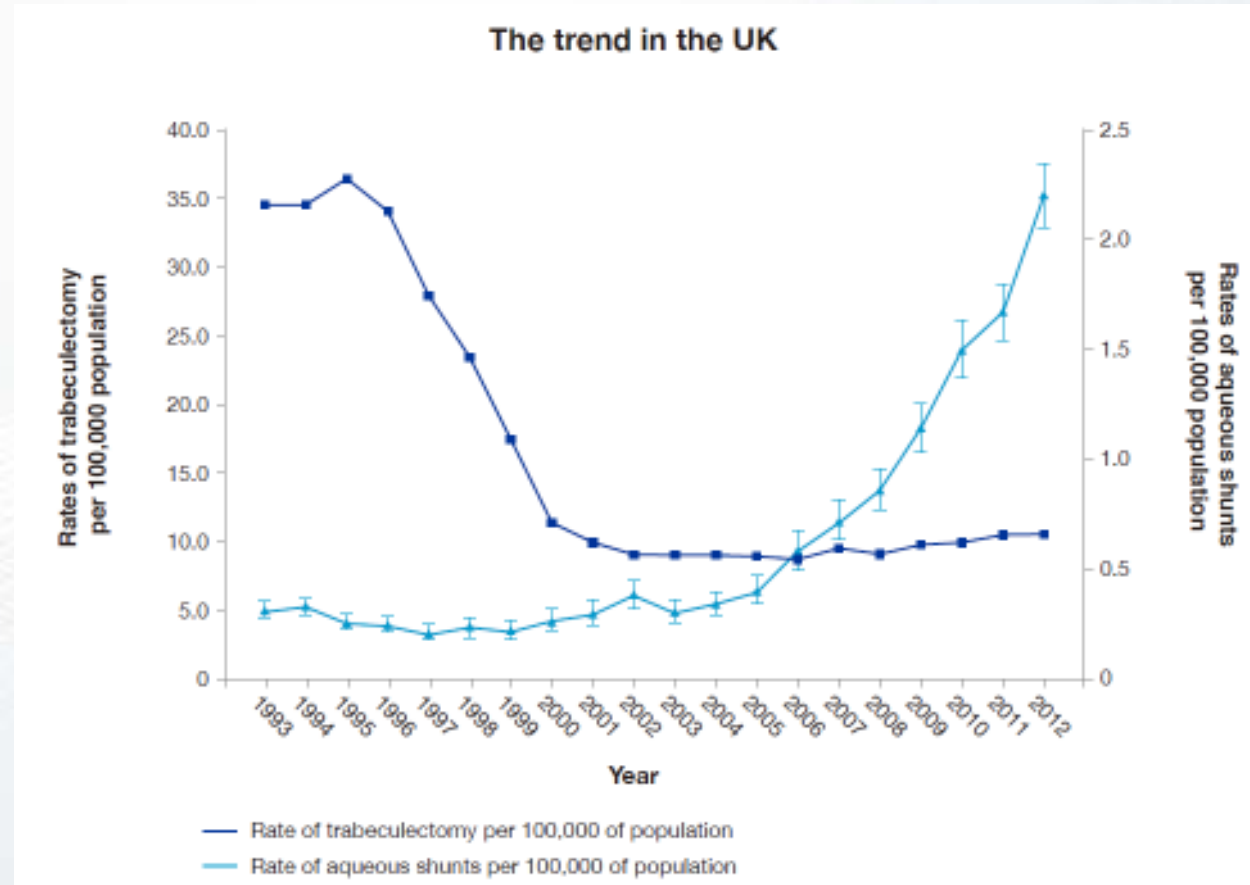
- Hypotony (early & late)
- bleb leak
- Avascular bleb
- Infection



The changing trends for trabeculotomies



Trabeculectomy trends in UK



Does tube need to have plate to be successful?

Br J Ophthalmol 1998;82:1083-1089

1089

PERSPECTIVE

Glaucoma drainage devices; past, present, and future

KS Lim, B D S Allan, A W Lloyd, A Moor, P T Khaw

Glaucoma filtration surgery (GFS) has been shown to be more effective at preventing disease progression than other primary treatment modalities in open angle glaucoma.^{1,2} If it were possible to avoid complications associated with near filter control, primary GFS would probably be offered

implants in short aqueous to a variety of anatomical sites, including the vortex veins³ and the nasolacrimal duct,⁴ have since been reported. Results were generally unfavourable or too poorly documented to evaluate, and attention has therefore been directed towards revision filtration

<i>Year</i>	<i>Investigator</i>	<i>Type</i>	<i>Material</i>
1907	Rollet ⁴	seton	Horse hair
1912	Zorab ⁷	seton	Silk thread
1925	Stefansson ⁸	seton/tube	Gold
1934	Row ¹¹	seton	Platinum
1940	Troncoso ¹²	seton	Magnesium
1942	Gibson ¹³	tube	Lacrimal canal
1949	Bick ⁹	seton/tube	Tantalum
1951	Muldoon ¹⁰	seton	Platinum
1952	Losche ¹⁴	tube	Supramid
1955	Bietti ¹⁵	tube	Polyethylene

Does tube need to have plate to be successful?

Br J Ophthalmol 1998;82:1083-1089

1083

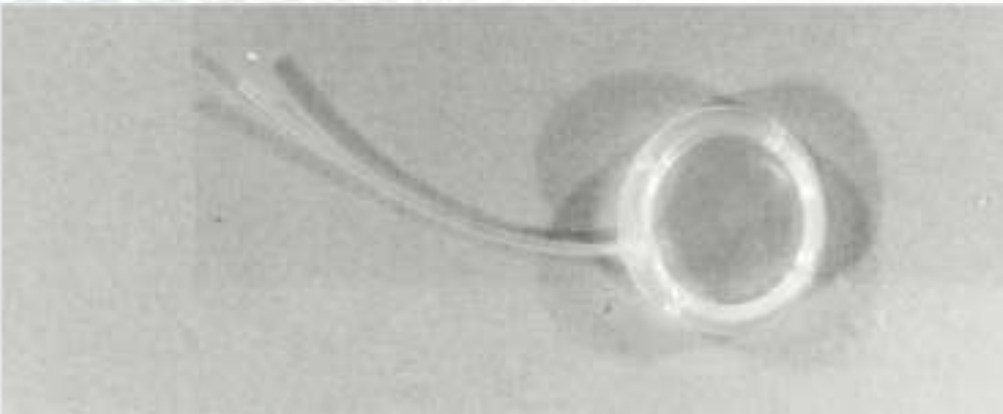
PERSPECTIVE

Glaucoma drainage devices; past, present, and future

KS Lim, BD S Allan, A W Lloyd, A Muir, P T Khaw

Glaucoma filtration surgery (GFS) has been shown to be more efficacious in preventing disease progression than other primary treatment modalities in open angle glaucoma.¹⁻³ If it were possible to avoid complications associated with aqueous flow control, primary GFS would probably be offered

empirically to some patients as a variety of unconventional sites, including the vortex veins⁴ and the nasolacrimal duct,⁵ have since been reported. Results were generally unfavourable or too poorly documented to evaluate, and attention has focused on devices channeling aqueous fluid to



<i>Year</i>	<i>Investigator</i>	<i>Type</i>	<i>Material</i>
1907	Rollet ⁴	seton	Horse hair
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1955	Bietti ¹⁵	tube	Polyethylene
1958	La Rocca ¹⁶	tube	Polyvinyl
1960	Ellis ¹⁷	tube	Silicone
1967	Mascati ⁶	tube	Plastic
1969	Molteno ¹⁸	tube and plate	Acrylic

Does tube need to have plate to be successful?

Does tube need to have plate to be successful?

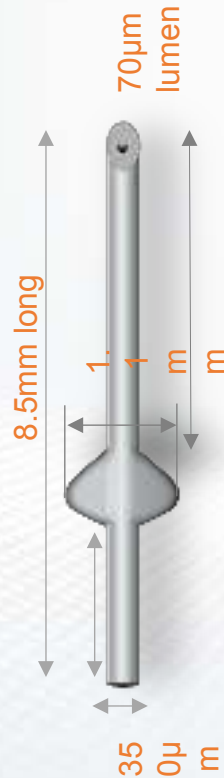
- Long tube with posterior flow

Does tube need to have plate to be successful?

- Long tube with posterior flow
- Mitomycin – C (Chen 1983)

Design Principles of Minimally Invasive Bleb Surgery (MIBS)

- Poiseuille's Law

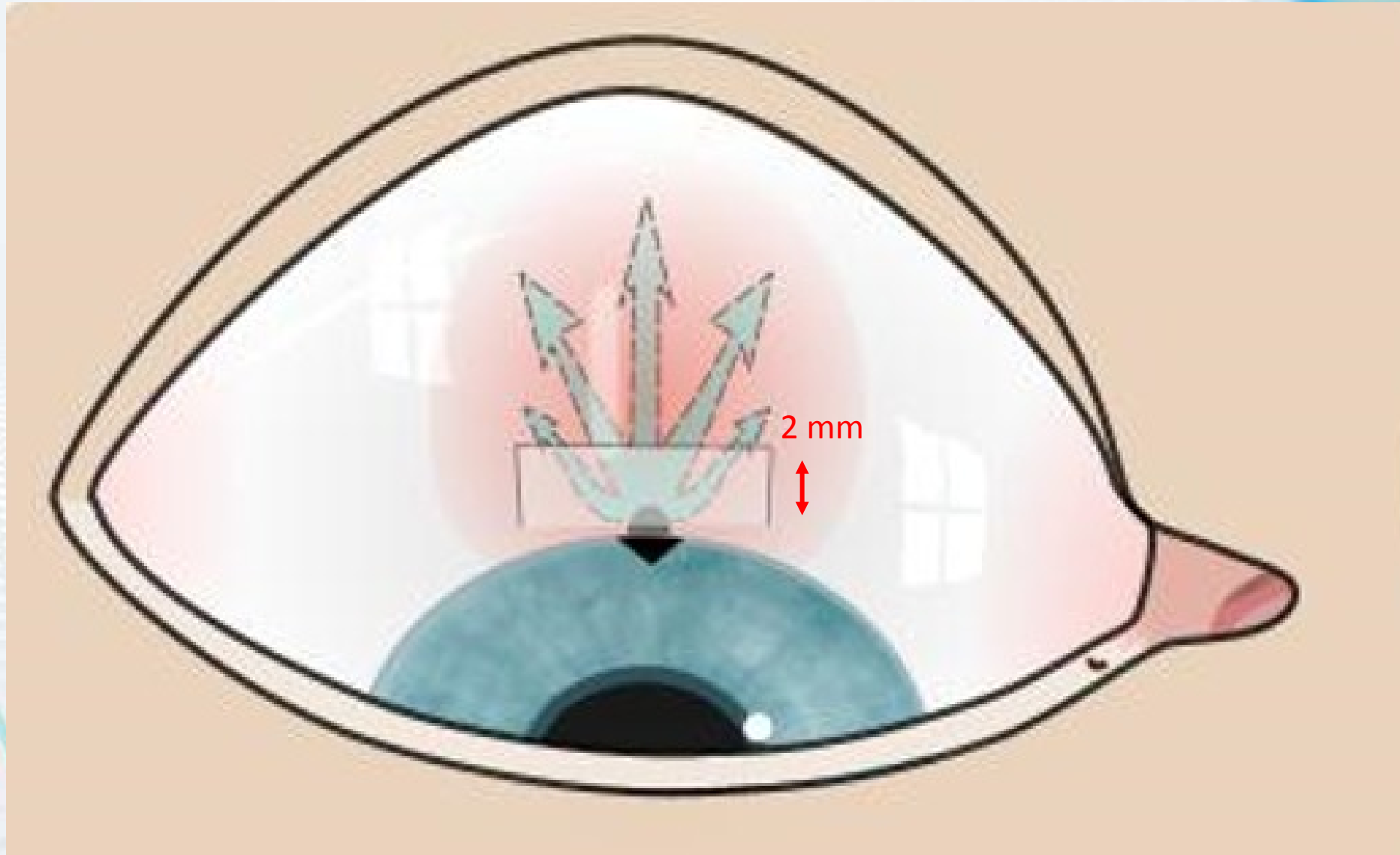


PRESERFLO
8.5mm length
70µm lumen
350µm EXTERNAL diameter



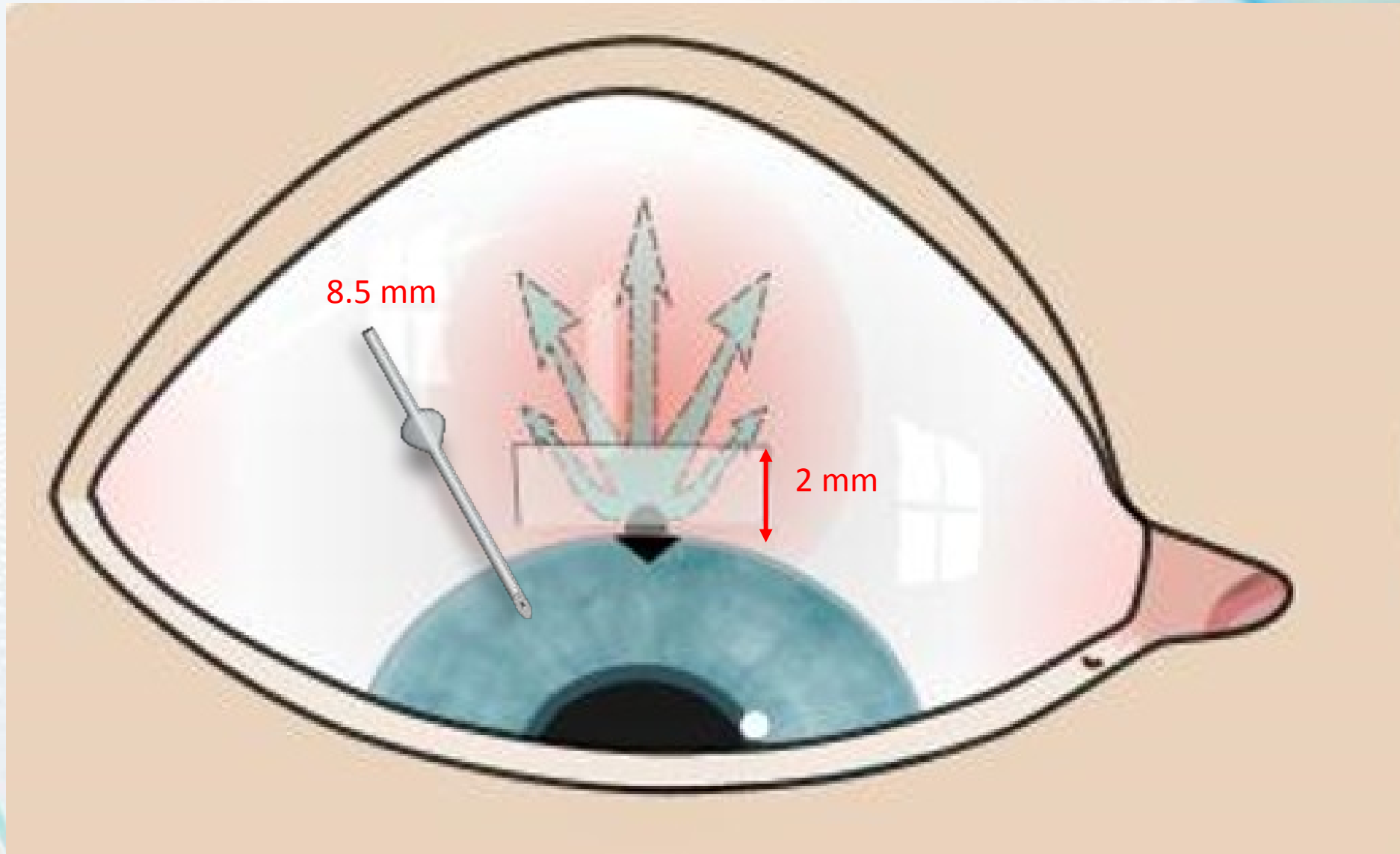
XEN
6 mm length
45µm lumen
210µm EXTERNAL diameter

posterior flow



Original drawing from K. Barton

posterior flow

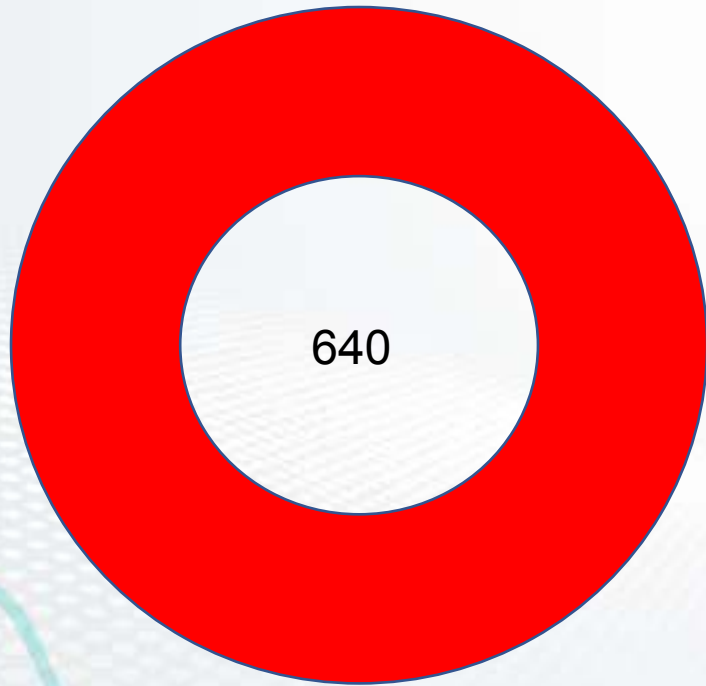


Original drawing from K. Barton

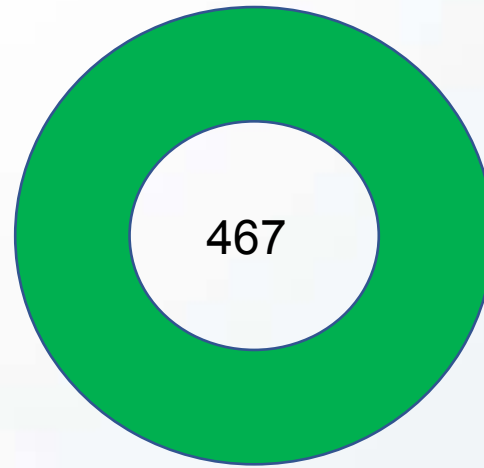
PRESERFLOW – Design principles

- Long tube (8.5 mm)
- Flow control (70 μ m lumen)
- Small tube in AC (350 μ m diameter)

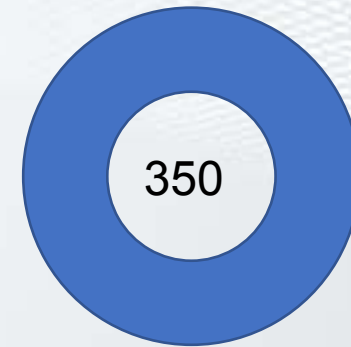
Size of different tubes (external diameter μm)



Baerveldt



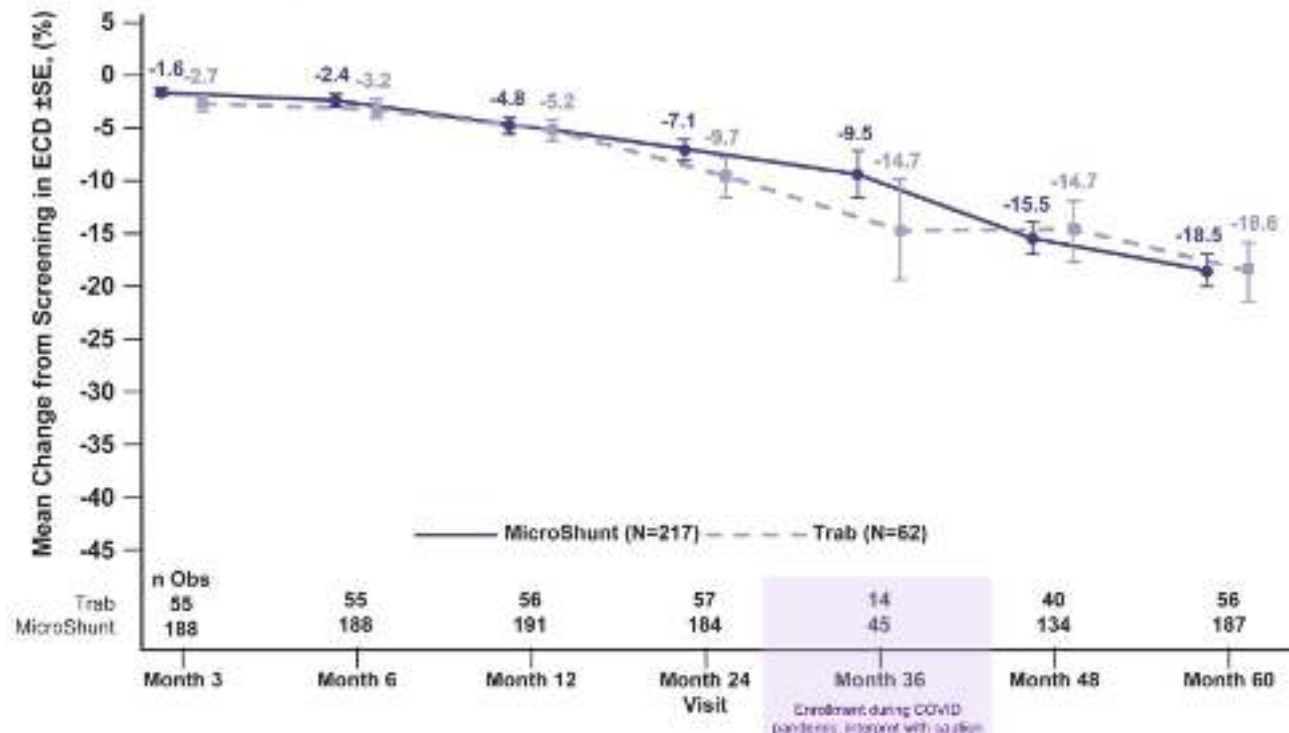
Paul's Glaucoma Implant



PRESERFLO

Long-term ECC PRESERFLO

Percent Change from Screening in Corneal Endothelial Cell Density
Enrolled Population



**What are the clinical trial data
supporting the use of
the PRESERFLO[®] MicroShunt?**

***Ab-externo* MicroShunt versus trabeculectomy in primary open-angle glaucoma: 2-year results from a randomised, multicenter study**

Panarelli JF et al. *Ophthalmology* 2023; doi:
10.1016/j.opthta.2023.09.023

Comparison of the efficacy and safety of the PRESERFLO[®] MicroShunt versus trabeculectomy in patients with mild-to-severe POAG (1/2)

- INN-005 was a 2-year, prospective, randomised, head-to-head study comparing the efficacy and safety of the PRESERFLO[®] MicroShunt versus trabeculectomy in patients with mild-to-severe POAG (N=527), conducted across 29 sites in the USA and Europe¹
- Year 1 results were published by Baker ND et al., 2021.² Year 2 results were published by Panarelli JF et al., 2023.¹ Year 4 safety data from the open-label extension study have been reported³

SURGICAL PROCEDURE^{1,2} were decided at the discretion of each surgeon

- Patients randomised 3:1 to undergo standalone PRESERFLO[®] MicroShunt implantation or trabeculectomy
- Adjunctive MMC (0.2 mg/mL) was applied for 2 minutes for both procedures
- Anaesthesia type (excluding general anaesthesia), traction suture type and conjunctival flap closure technique (including type of suture material and needle)

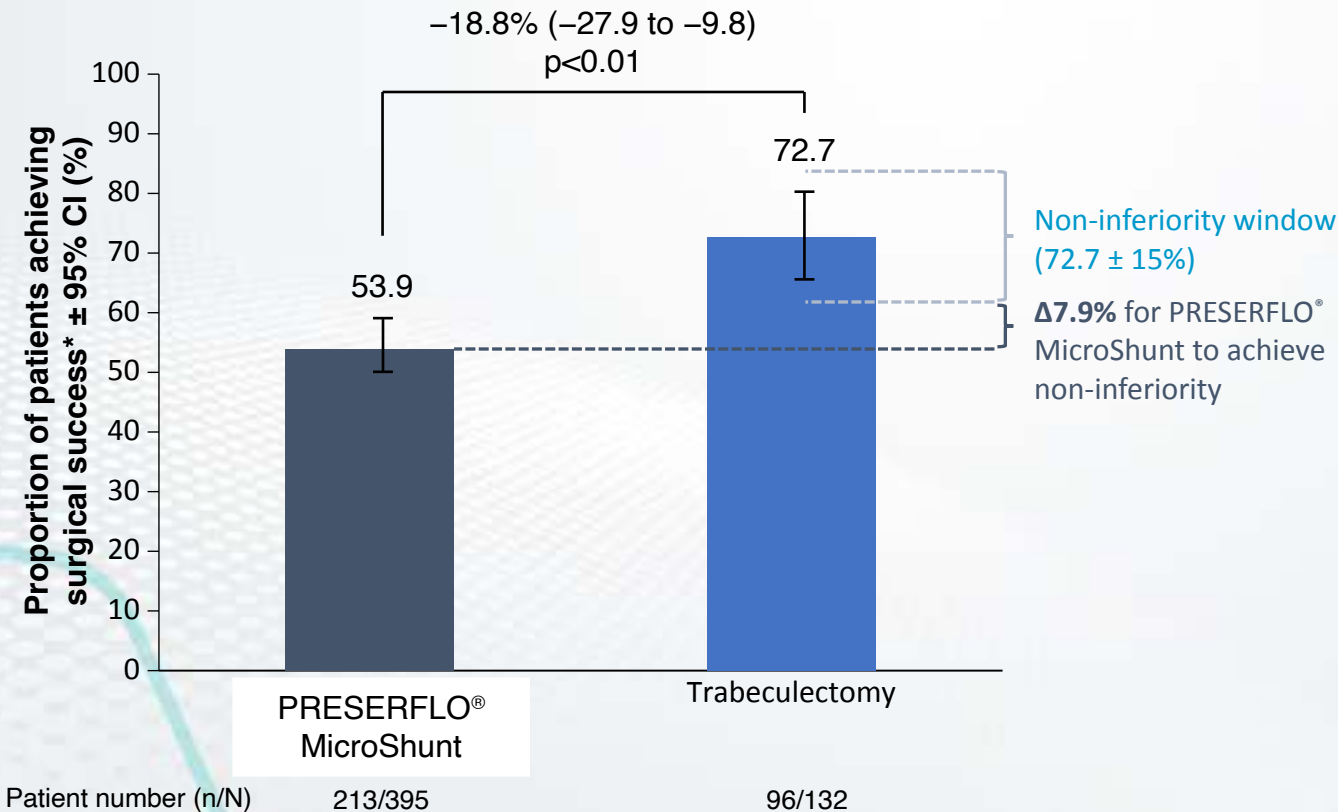
MMC, mitomycin C; POAG, primary open-angle glaucoma.

1. Panarelli JF et al. *Ophthalmology* 2023; doi: [10.1016/j.ophtha.2023.09.023](https://doi.org/10.1016/j.ophtha.2023.09.023) [Epub ahead of print]; 2. Baker ND et al. *Ophthalmology* 2021;128:1710–1721; 3. García-

Feijó J. Presented at WGC 2023. ePoster P-437.

PRESERFLO® inferior to trabeculectomy

Overall surgical success* rate at Year 1



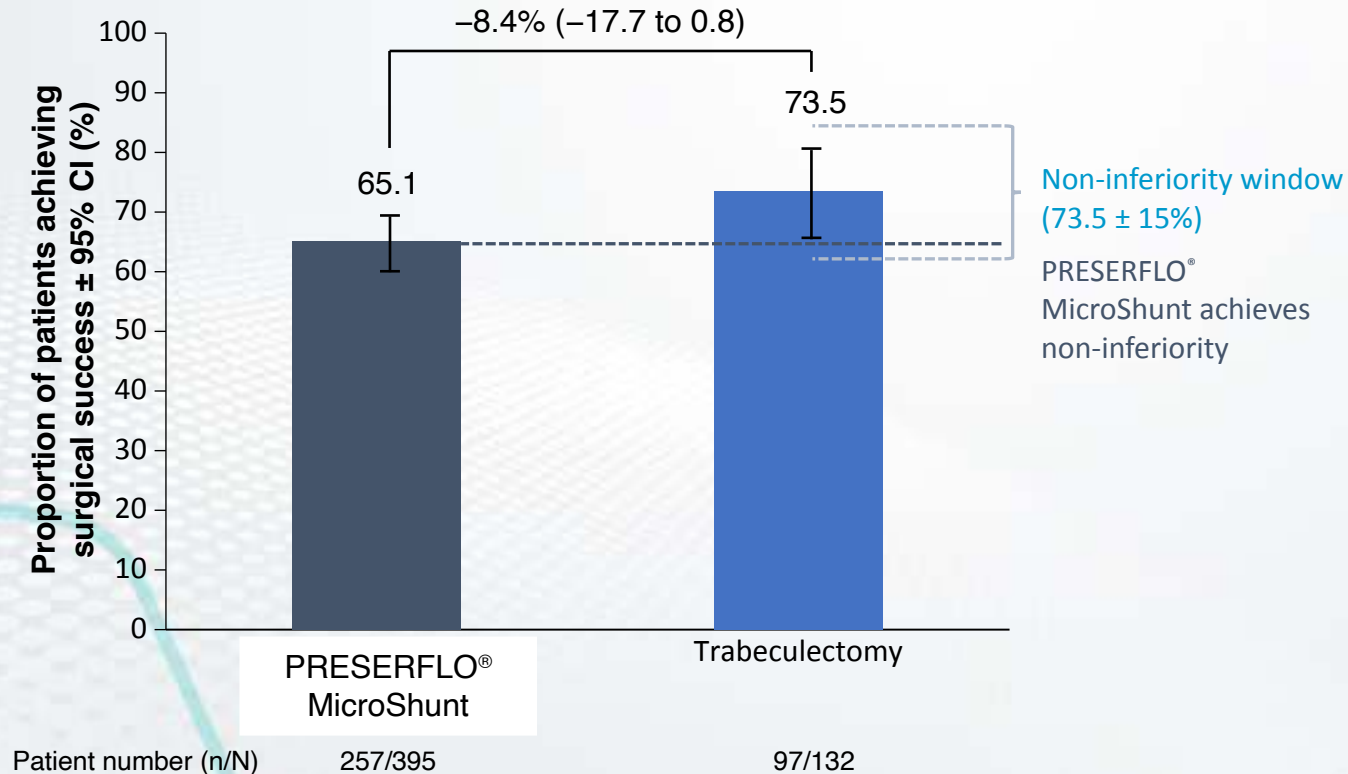
53.9% of patients receiving PRESERFLO® MicroShunt experienced surgical success*

72.7% of patients treated with trabeculectomy experienced surgical success*

The mean surgical success* rate with PRESERFLO® MicroShunt was 7.9% lower than the trabeculectomy non-inferiority margin

*Defined as a ≥20% reduction in mean diurnal IOP from baseline at Year 1, without increasing the number of glaucoma medications. CI, confidence interval; IOP, intraocular pressure; POAG, primary open-angle glaucoma. Baker ND et al. *Ophthalmology* 2021;128:1710–1721.

Overall surgical success rate at Year 1 according to WGA definition



WGA defines surgical success as IOP ≥ 6 mmHg to ≤ 21 mmHg and a $\geq 20\%$ reduction in IOP from baseline on two consecutive follow-up visits after Month 3, with or without glaucoma medications

When the definition of surgical success was based on the WGA guidelines, the responder rates increased to **65.1%** for the PRESERFLO® MicroShunt versus **73.5%** for trabeculectomy, thereby achieving **non-inferiority**

Comparison of the efficacy and safety of the PRESERFLO® MicroShunt versus trabeculectomy in patients with mild-to-severe POAG (1/2)

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FDA

The only formulation of
ophthalmic MMC approved
by the FDA



of each surgeon

) was applied for 2 minutes

What are the current real-world data supporting the use of the PRESERFLO[®] MicroShunt?

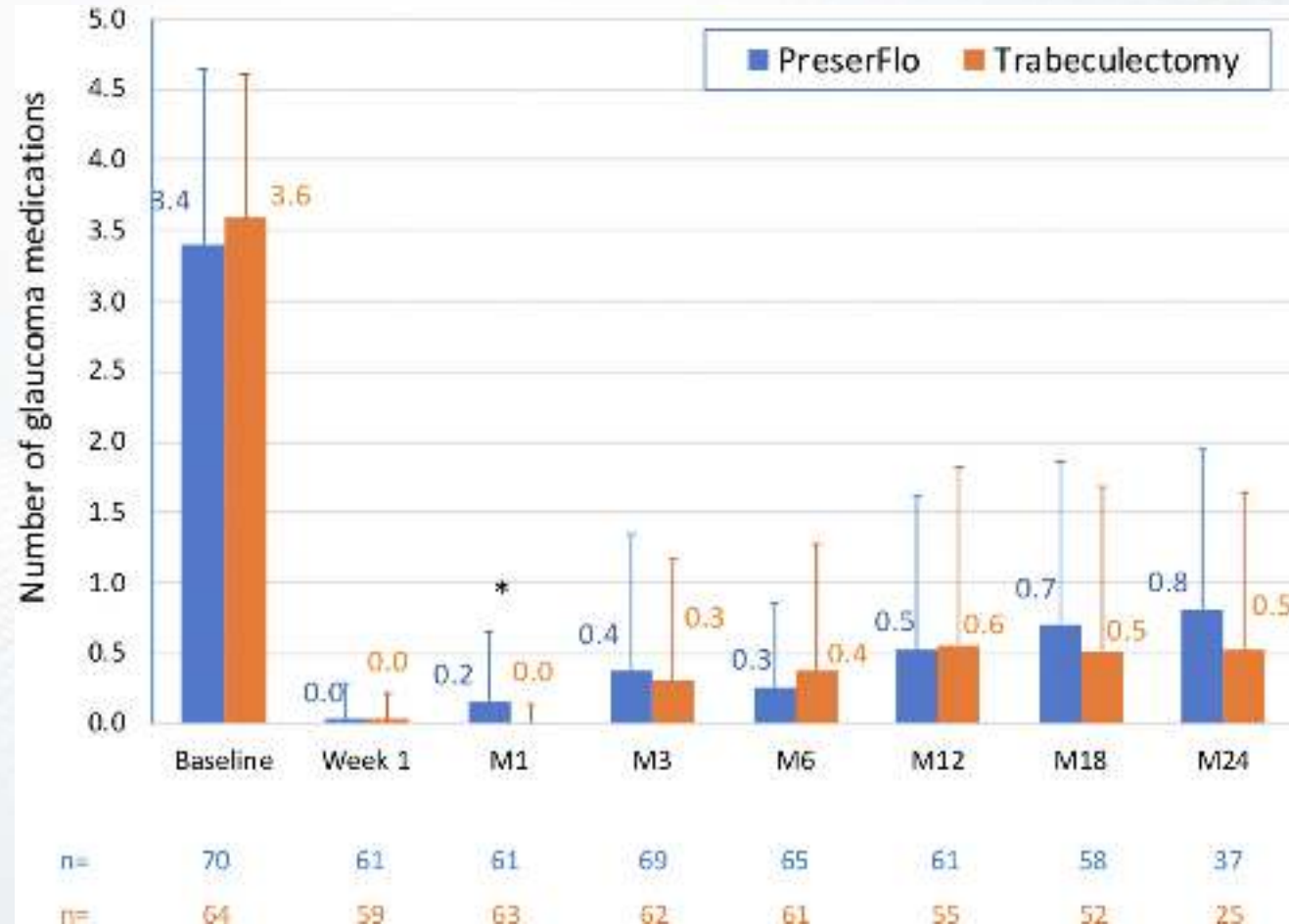
Clinical Outcomes and Cost Analysis of PreserFlo versus Trabeculectomy for Glaucoma Management in the United Kingdom

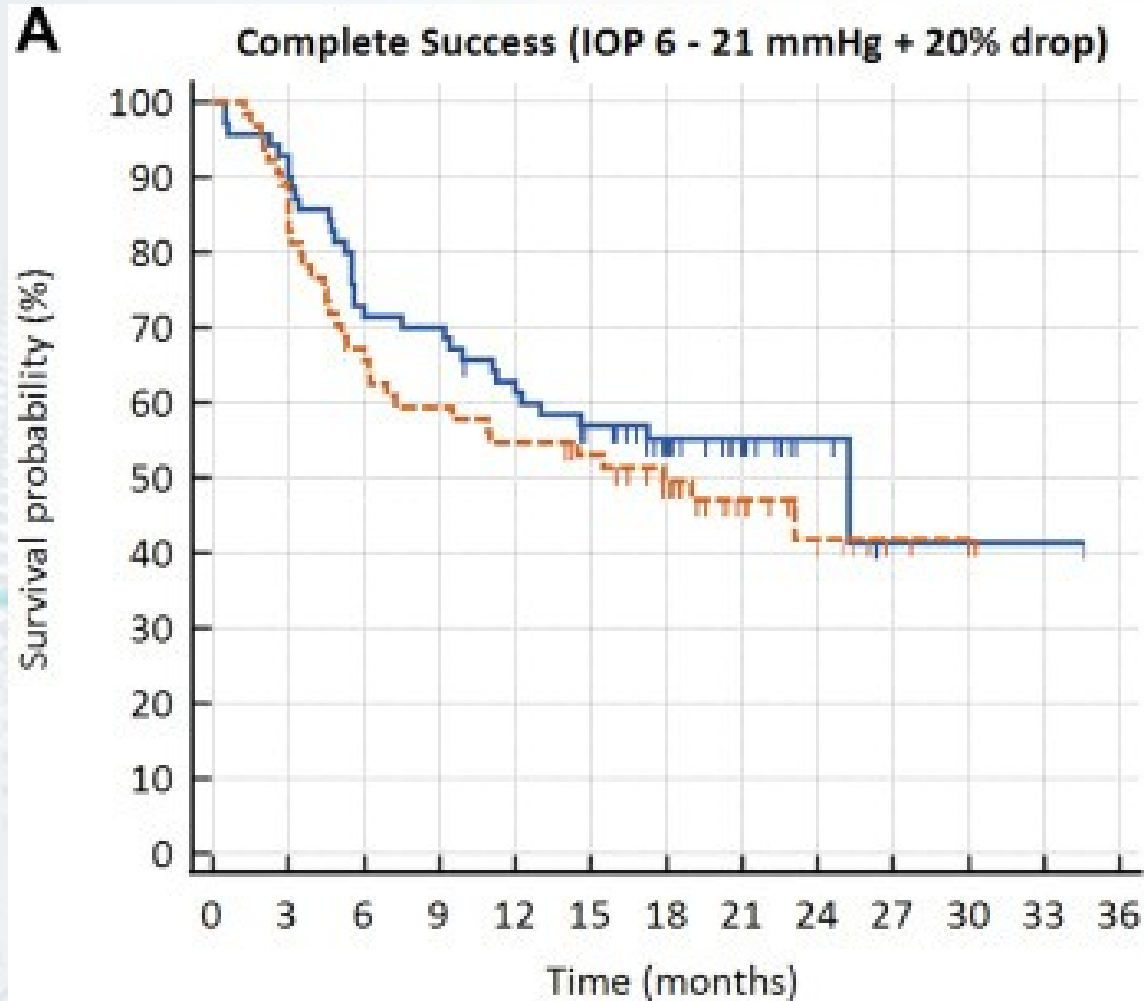
Lauren Van Lancker, MRCP, FRCOphth,¹ Anrita Saravanan, MBBS,¹ Mohammed Abu-Bakra, FRCOphth,¹ Kyle Reid, BSc,¹ Claudia Quijano, PHEC, MD,² Saurabh Goyal, MS, FRCOphth,² Ian Rodriguez, FRCOphth,² Gerassimos Lascaratos, PhD, FRCOphth,² Sameer Trikha, MBA, FRCOphth,¹ Caroline Barwood, MSc,² Emily Combe, BSc,² Avinash Kulkarni, FRCOphth,¹ Kin Sheng Lim, MD, FRCOphth,² Sancy Low, PhD, FRCOphth²

Van Lancker, et.al. Ophthalmology Glaucoma. 2023
Jul-Aug;6(4):342-357

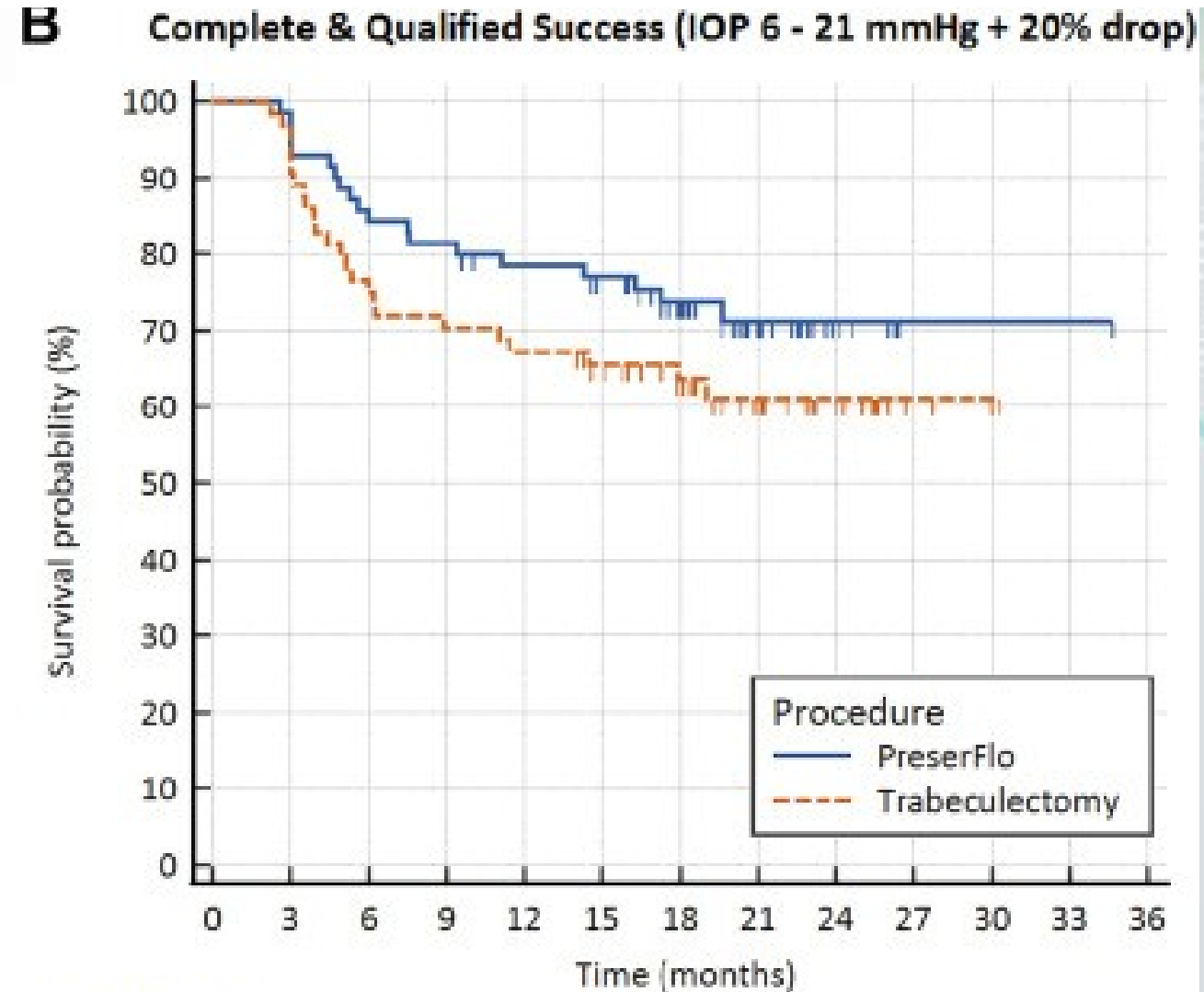


Mean Number of Medications





Number at risk



Number at risk

Complications



Early < 1 month



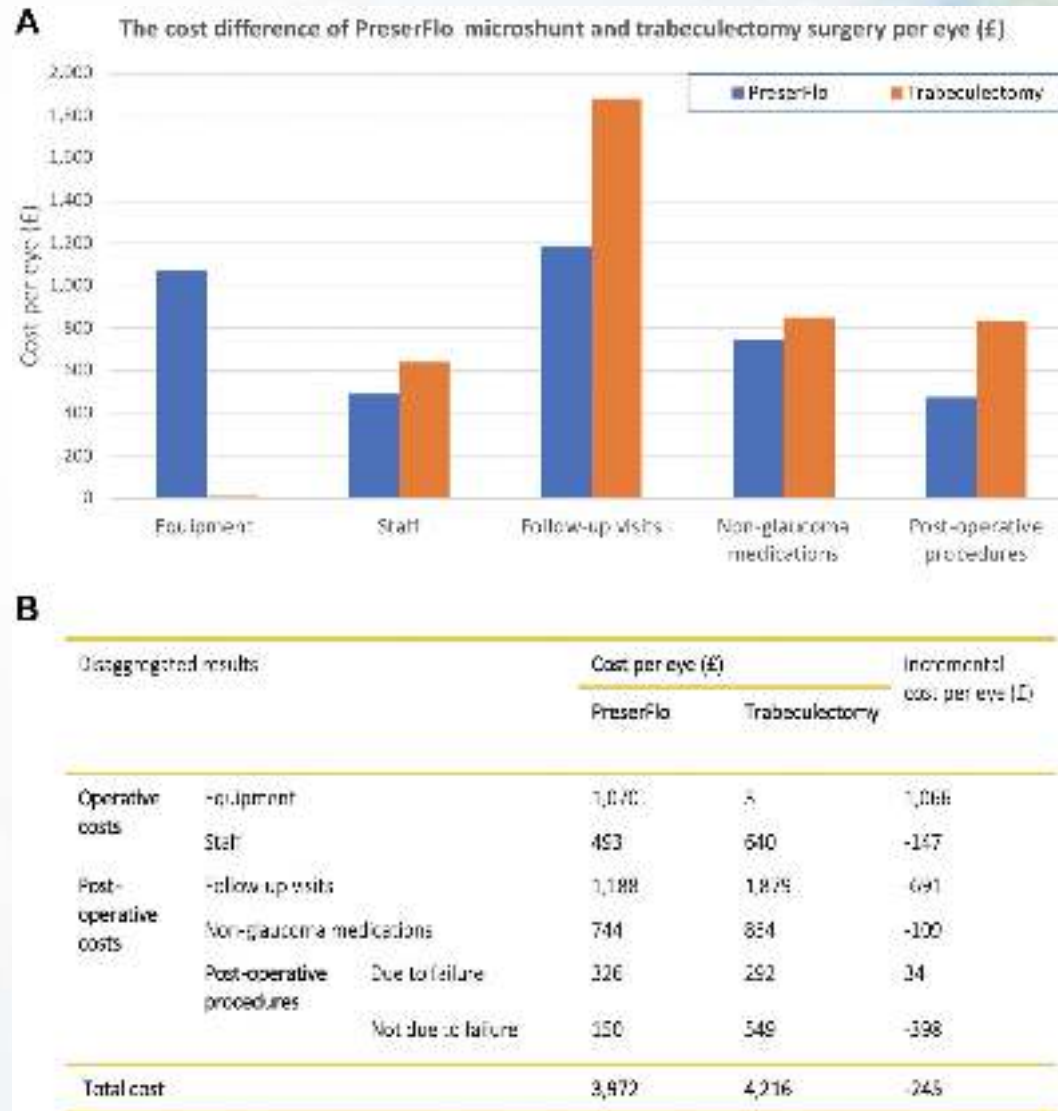
Late > 1 month

Van Lancker, et.al. Ophthalmology Glaucoma. 2023
Jul-Aug;6(4):342-357

	PreserFlo Group, n = 70 (%)	Trabeculectomy Group, n = 64 (%)	PreserFlo Group, n = 70 (%)	Trabeculectomy Group, n = 64 (%)
Intraoperative				
Hyphema	5 (7)	0		
Conjunctival buttonhole	2 (3)	1 (2)		
Conjunctival tear	1 (1)	1 (2)		
Scleral perforation	0	1 (2)		
Postoperative				
	Early < 1 mos		Late > 1 mos	
Shallow/flat AC	2 (3)	9 (14)	0	0
Bleb leak	3 (4)	5 (8)	0	2 (3)
Choroidal effusion	2 (3)	8 (13)	0	2 (3)
Hyphema	3 (4)	8 (13)	0	1 (2)
Hypotony maculopathy	1 (1)	4 (6)	0	1 (2)
CME	1 (1)	0	2 (3)	5 (8)
Keratitis	1 (1)	0	0	0
Retinal tear	0	1 (2)	0	0
Overfiltering bleb	0	2 (3)	0	0
Vitreous hemorrhage	0	1 (2)	0	0
Encapsulated bleb	0	0	1 (1)	3 (5)
Iritis	0	0	0	4 (6)
Persistent corneal edema	0	0	1 (1)	0
Surgical Success				
	n		n	
Total	13	38	8	27
Success	(19%)	(59%)	(11%)	(42%)
Success		*		*
enc				
Ret				
Ptc				
VMT/ERM	0	0	2 (3)	3 (5)
Total	13 (19%)	38 (59%)	8 (11%)	27 (42%)

Cost Analysis

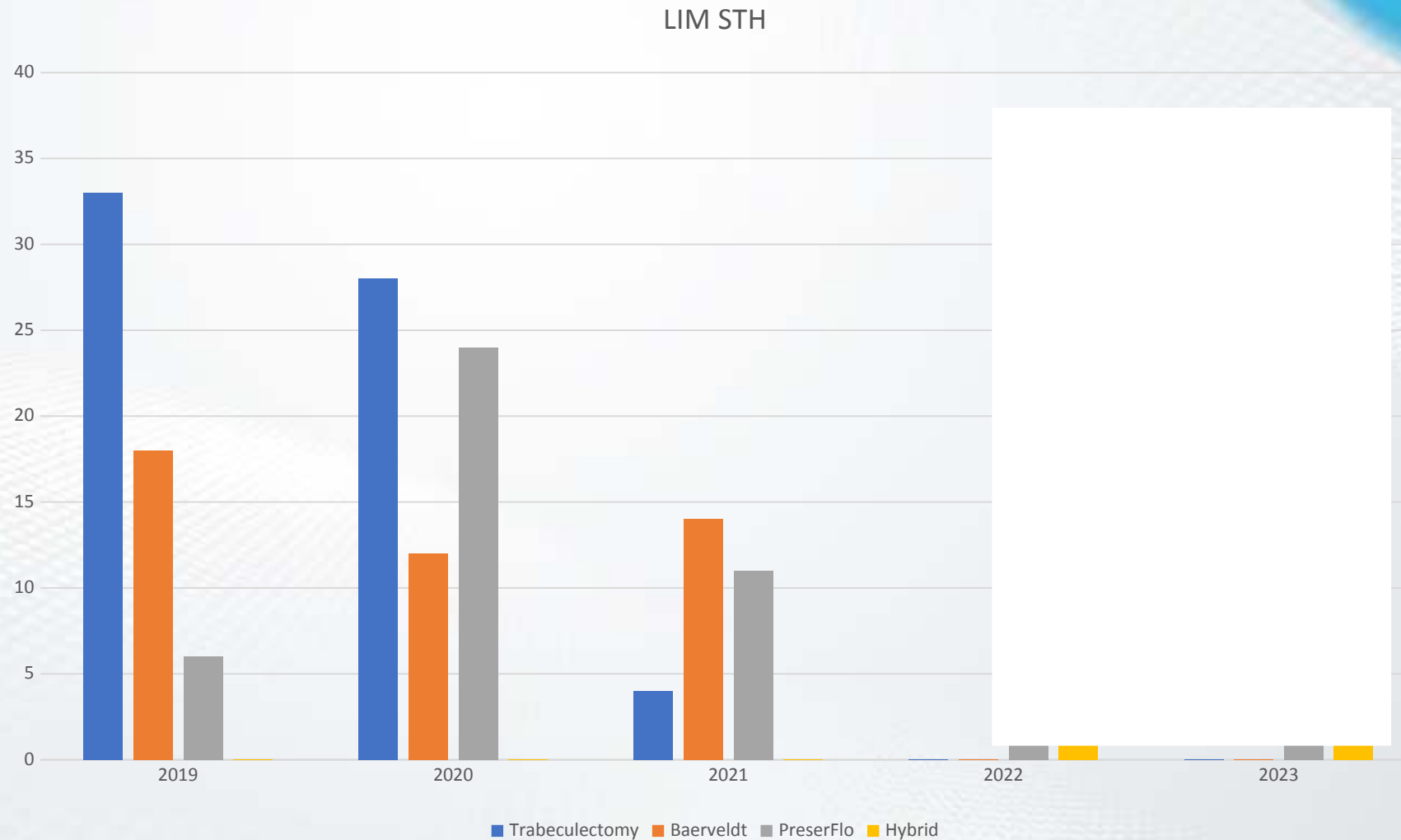
Total savings of UK£245 per case



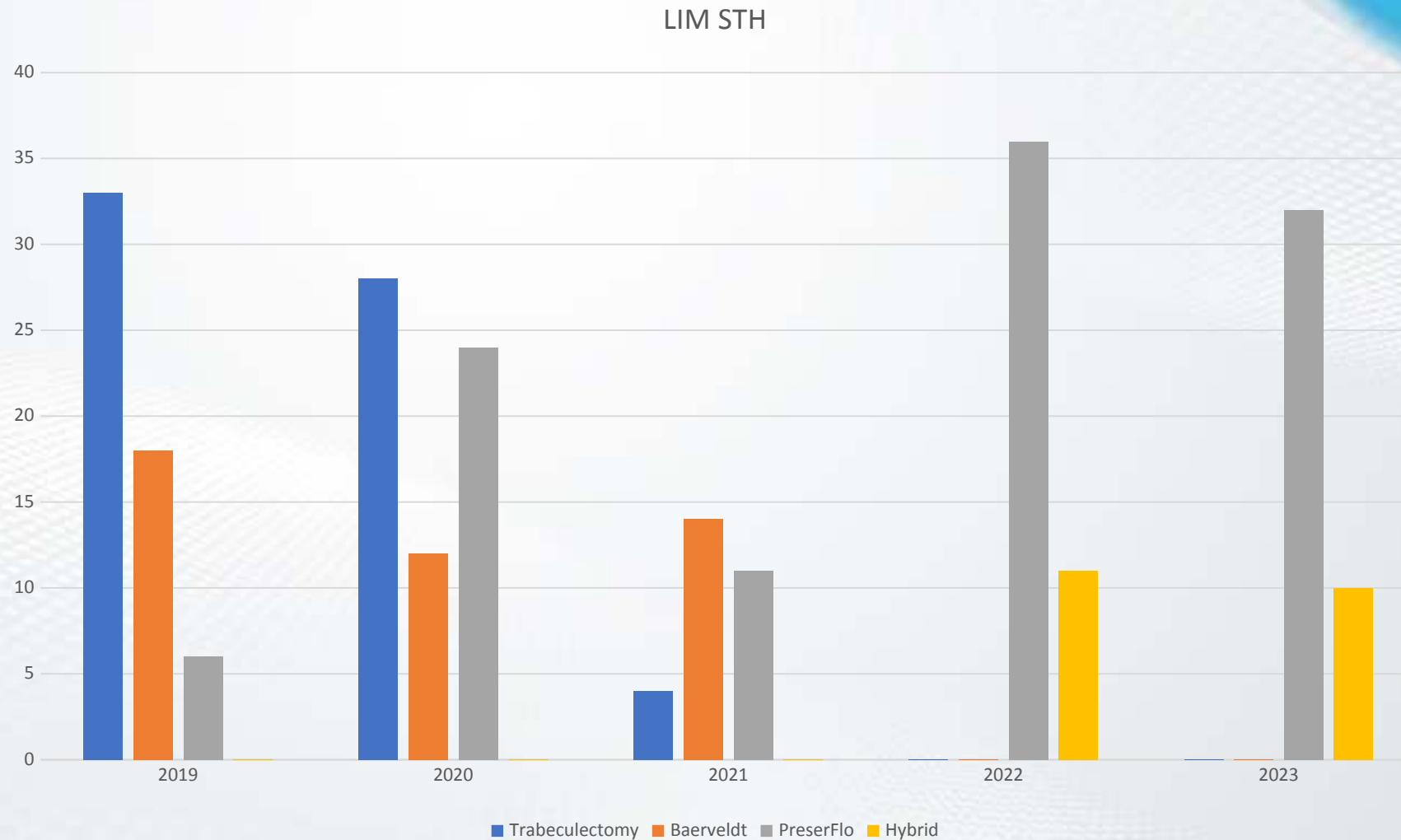
Summary

- Innovative designs of PRESERFLO
 - Posterior flow (long tube)
 - Flow resistance (small lumen)
 - Likely less endothelial attrition (small tube in AC)
- Higher dose of MMC is needed due to the presence of an intrinsic flow resistance
- Lower risk of post-op complications
- Cheaper overall cost in the NHS compared to Trabeculectomy (likely)

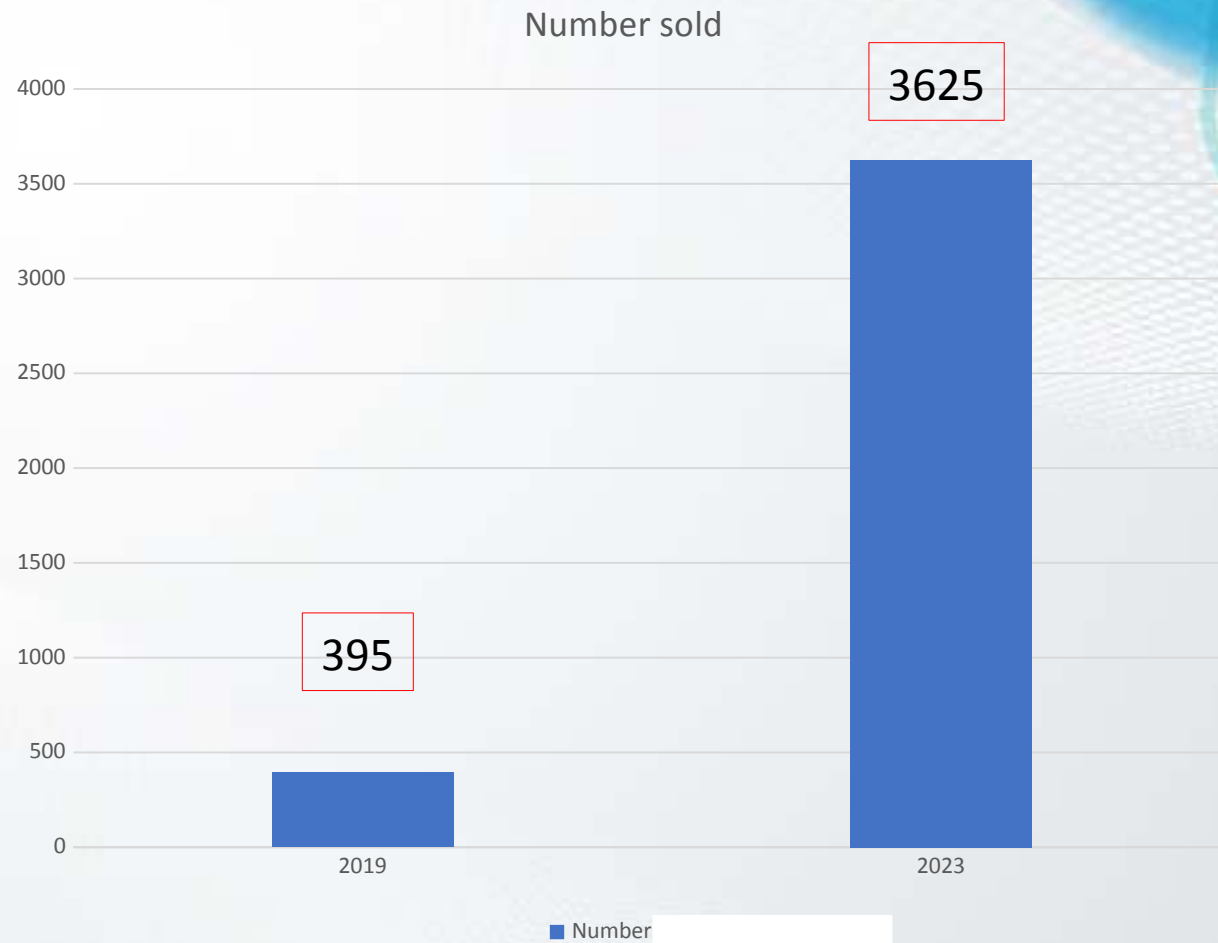
Changing pattern of glaucoma filtering surgeries



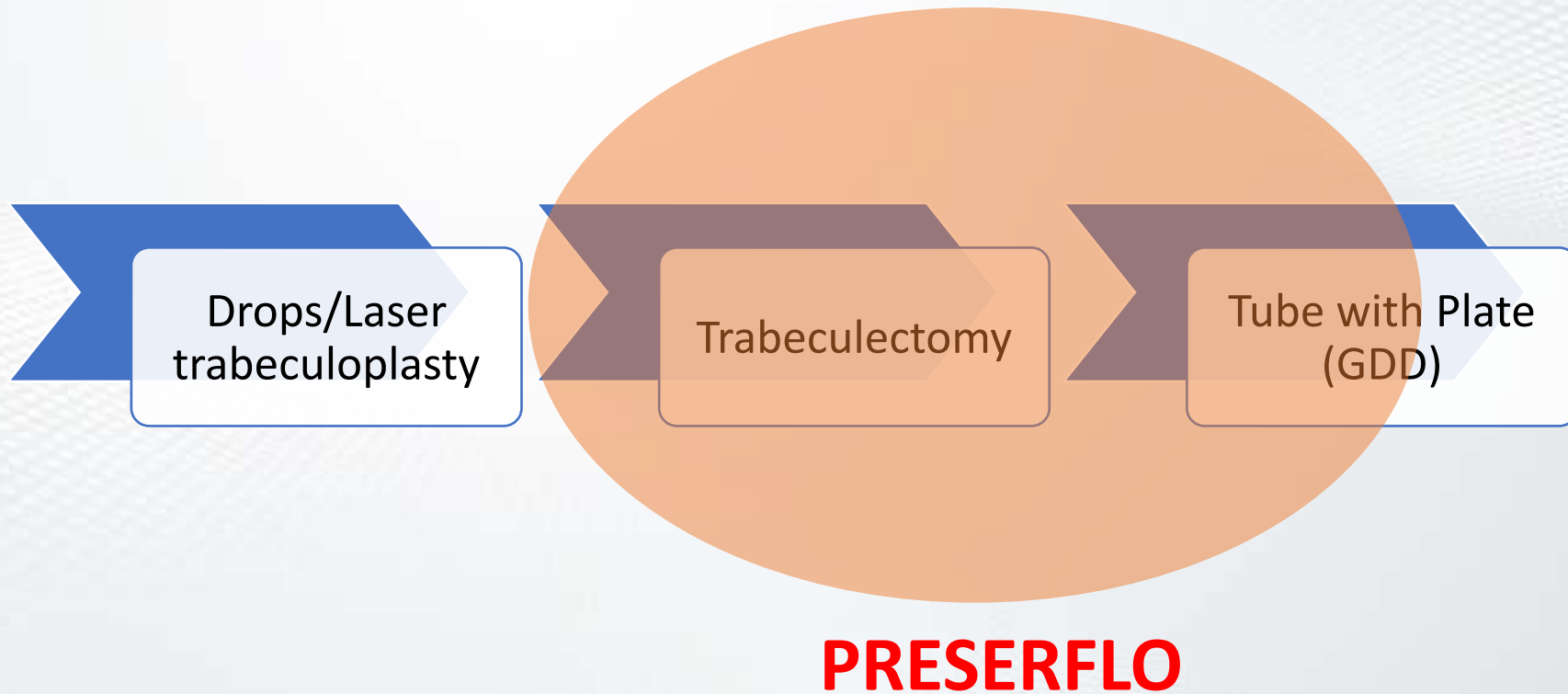
Changing pattern of glaucoma filtering surgeries



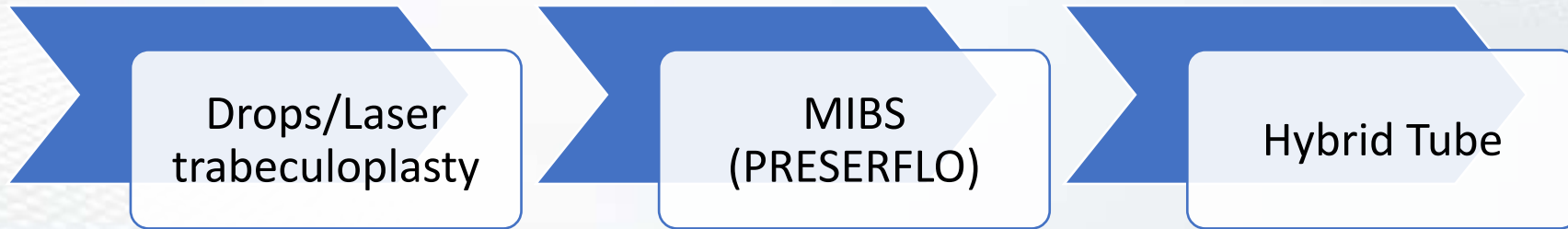
UK PRESERFLO PRESERFLO sale figures



Treatment Paradigm for POAG



NEW Treatment Paradigm for POAG



Thank You