MINIMALLY INVASIVE GLAUCOMA SURGERY:

THE KATH EXPERIENCE WITH THE HYDRUS MICROSTENT

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OUTLINE

- INTRODUCTION
- THE HYDRUS MICROSTENT
- RESULTS OF STUDY DONE AT KATH
- CONCLUSION

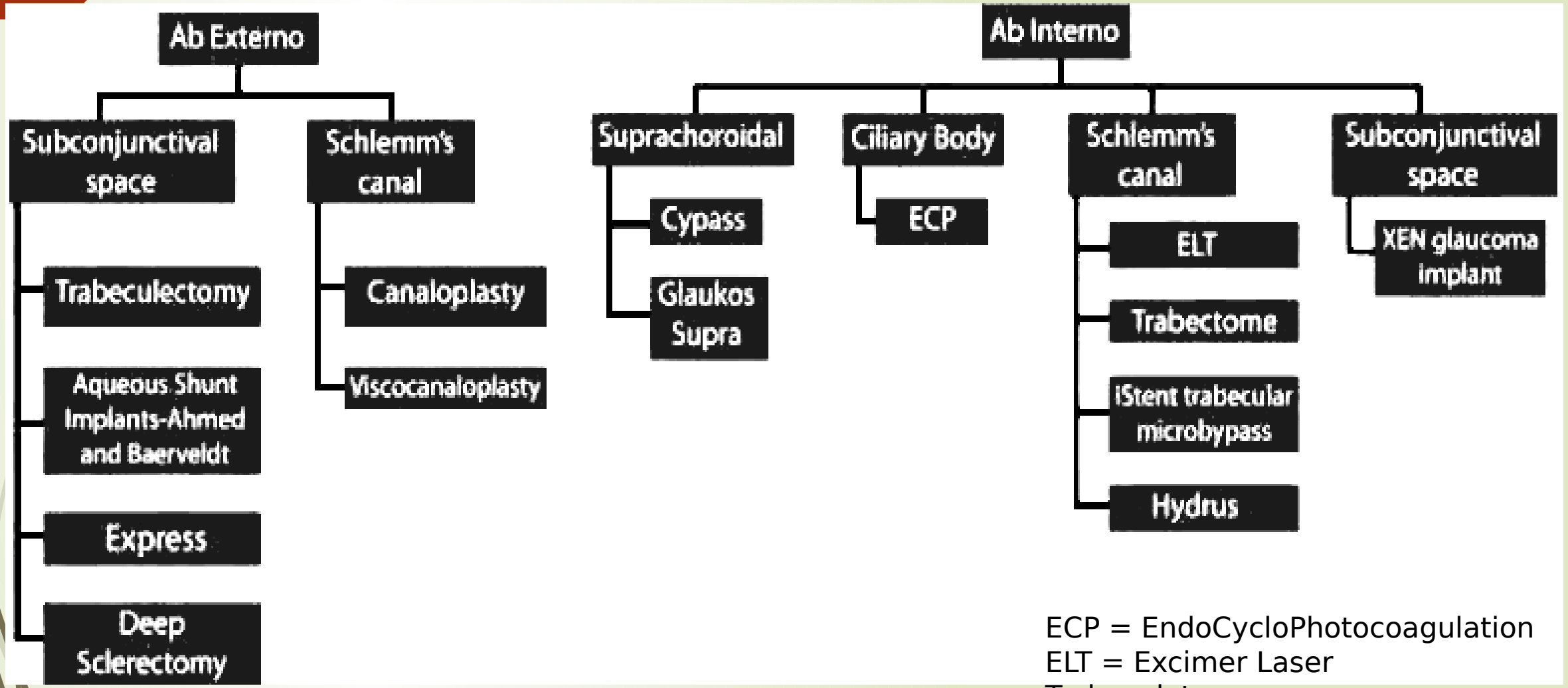
Disclaimer

- The Authors have no financial interests in the product(s) mentioned in this presentation
- The Hydrus Microstent by Ivantis has not been FDA approved for commercial use and is still in the final stages of clinical trials worldwide.

Introduction

- The development of Minimally Invasive Glaucoma Surgery or Micro Incisional Glaucoma Surgery (MIGS) procedures have been born out of and driven by the desire to develop a glaucoma surgical procedure that reduces intraocular pressure effectively and sustainably but avoids the complications and common causes of failure associated with conventional glaucoma filtration procedures.
- MIGS procedures involve:
  - Avoiding extensive conjunctival and Tenon's layer disection
  - The use of small incisions (clear corneal or scleral) to gain access to the anterior chamber angle and trabecular meshwork
  - Bypassing or augmenting the eye's natural drainage systems
  - Combination of MIGS procedures with other procedures e.g. cataract surgery
- Most MIGS procedures are indicated for mild to moderate glaucoma

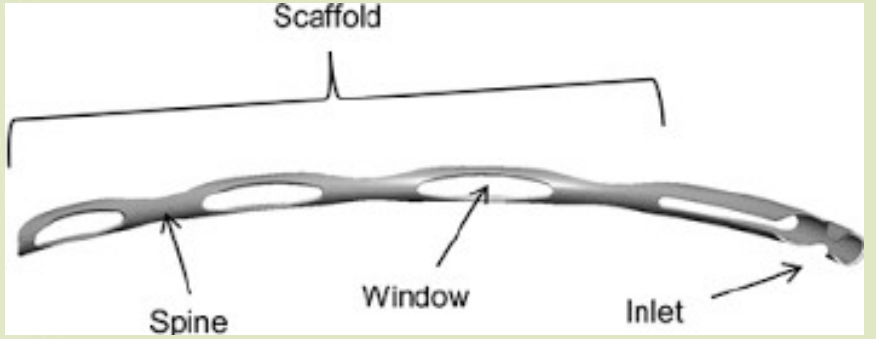
Glaucoma Surgery Examples



ECP = EndoCycloPhotocoagulation
ELT = Excimer Laser Trabeculotomy

Source: ***MIGS Advances in Glaucoma Surgery*** Ed. Malik Y Kahook (2014). Slack Incorporated

Hydrus Microstent[1]

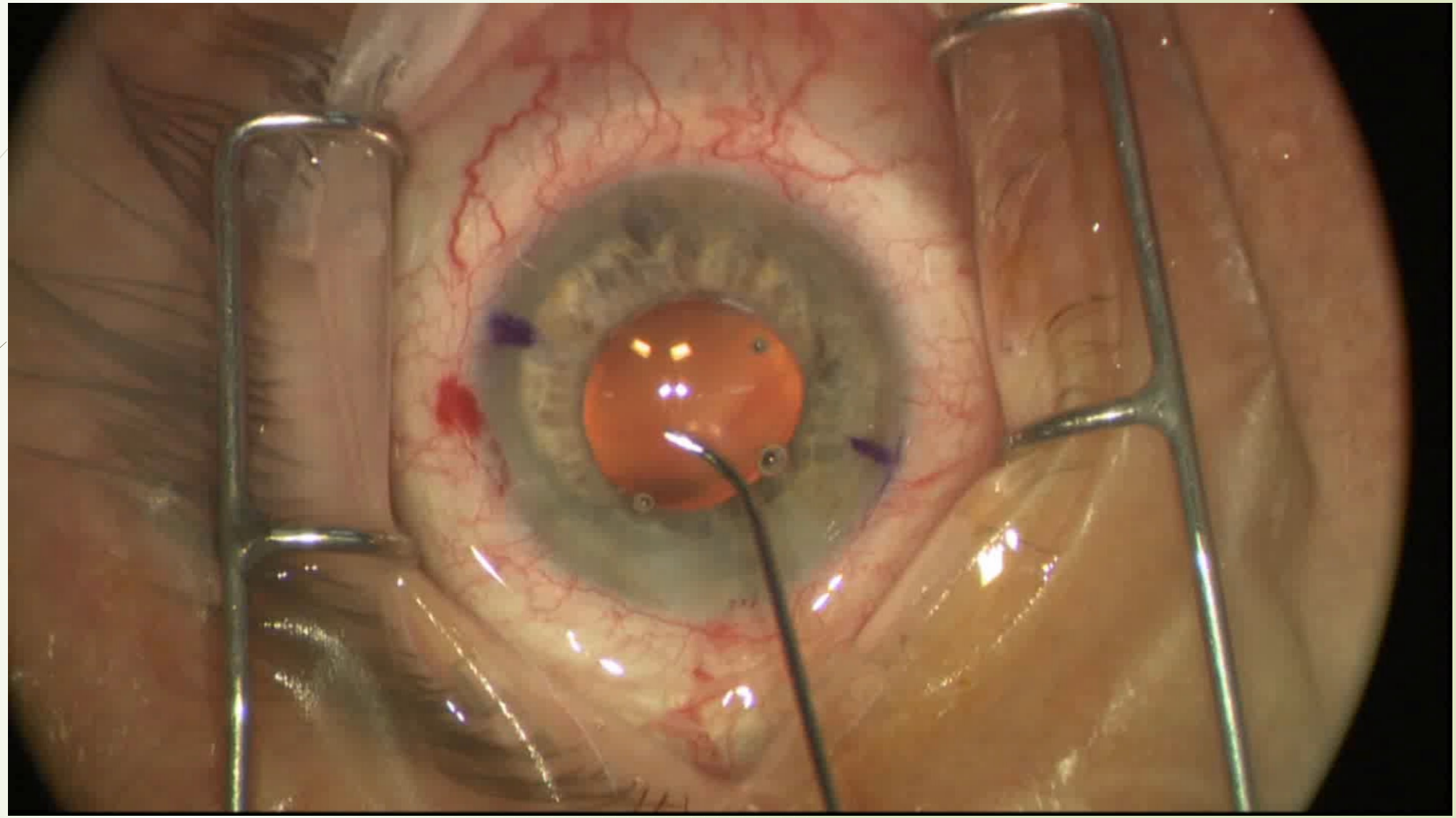


- Developed by Ivantis Inc. (Irvine, CA, USA)
- 8mm long, crescent shaped open structure (tube with fenestrations), curved to match the shape of Schlemm's canal
- Made of Nitinol (Nickel-Titanium Alloy)
  - Inert, elastic, biocompatible material. Also used in cardiovascular and orthopaedic implants
  - Crescent shaped and able to mould its shape to conform to shape of Schlemm's Canal.
- Pre-loaded on an Injector
- Inserted via a clear corneal incision
- SIts within and dilates Schlemm's canal (about 3 clock hours, 4-5 times its natural width))
- Scaffold design minimises tissue contact and prevents it from blocking the collector channel ostia in the posterior part of Schlemm's canal

The Hydrus Microstent (Ivantis)

- Early RCT trials show greater **washed out IOP** reduction in Hydrus + Cataract Surgery combined group as compared to Hydrus alone[2]

Hydrus Microstent Procedure



*Video Curtesy **Dr. Alan Crandall**, Moran Eye Centre, Salt Lake City, Utah*

Hydrus Microstent

- Advantages:
  - Minimally invasive. Micro incision: can be inserted through a 1.5mm clear corneal incision
  - No conjunctival disection. “Saves” conjunctiva for other additional glaucoma procedures (e.g. trabeculectomy) in cases of failure. Can also be used in cases of scarred conjunctiva, where trabeculectomy is likely to fail.
  - Procedure can be stand-alone or in combination with other intraocular surgeries e.g. catarct surgery
- Disadvantages
  - Steep learning curve
  - Needs additional special equipment: microscope with ability to tilt head, goniolens (Volk surgical goniolens)
  - Clinical trials show IOP lowering usually not lower than 15mmHg
  - Cost???

Hydrus Microstent Procedure at KATH

- Device implanted into 22 eyes of 15 patients over a 5 day period
- Preceded by presentation on device as well as “wet lab” practice on model eyes supervised by representatives from Ivantis
- Implantation of the device in patients also supervised and guided by Ivantis representatives
- Patients provided informed consent, were informed it was a new device being tested.
- Inclusion criteria: Open angle glaucoma; uncontrolled on Glaucoma meds; inability to afford/tolerate glaucoma meds
- Exclusion criteria: Closed/Narrow Angles, Angle neovascularisation, Active Inflammation, Less than 18 years, No consent

Hydrus Microstent Procedure

- End points: Intra and post-op safety, Reduction in IOP (measured with Goldman applanation tonometry) compared to baseline, reduction in medications
- Follow-up period 1 day, 1 month, 3 months, 6 months, 9 months, 12 months. Currently, only 3rd month data is complete (Not all patients have reported for 6th month review).
- Data was entered into a portal provided by Ivantis Inc. for automated data analysis and report generation.

Results: Intra- and Post-op complications

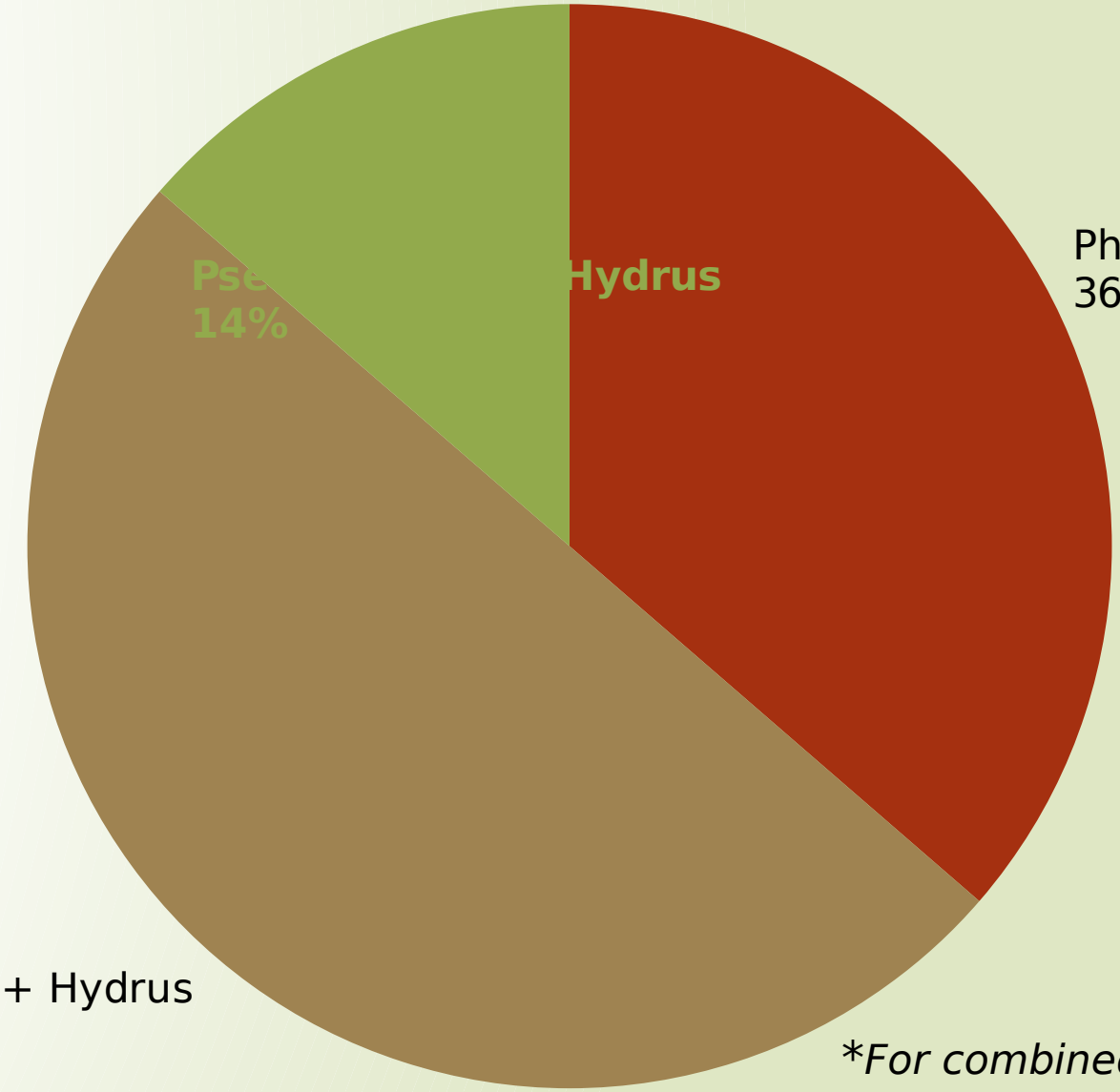
- Intraop complications: Trabecular stripping (1), PC tear during phaco (1), Intraop corneal oedema during phaco (2)
  - Additional Intra-op complications reported by other studies: hyphema, corneal abrasion
- Post -op complications: IOP spikes by >10mmHg above subject's baseline on meds (4 eyes)
  - Additional post-op complications reported by other studies: Peripheral anterior synechiae, vision loss >2 lines,

Results: Patient Demographics

Average Age (years)	63.3 (±15.76)
Female	10 eyes
Male	12 eyes
Number of devices Implanted	22
Right Eyes	14
Left Eyes	8
Mean IOP	28.8 mmHg (Range 17-46 mmHg)
Mean Number of Glaucoma Meds	2 (1-3)
SAP VF mean deviation	-10.3 (±6.39)
SAP Pattern Standard Deviation	6.5 (±2.94)

All patients were Africans (Ghanaians)

Results: Procedure Type

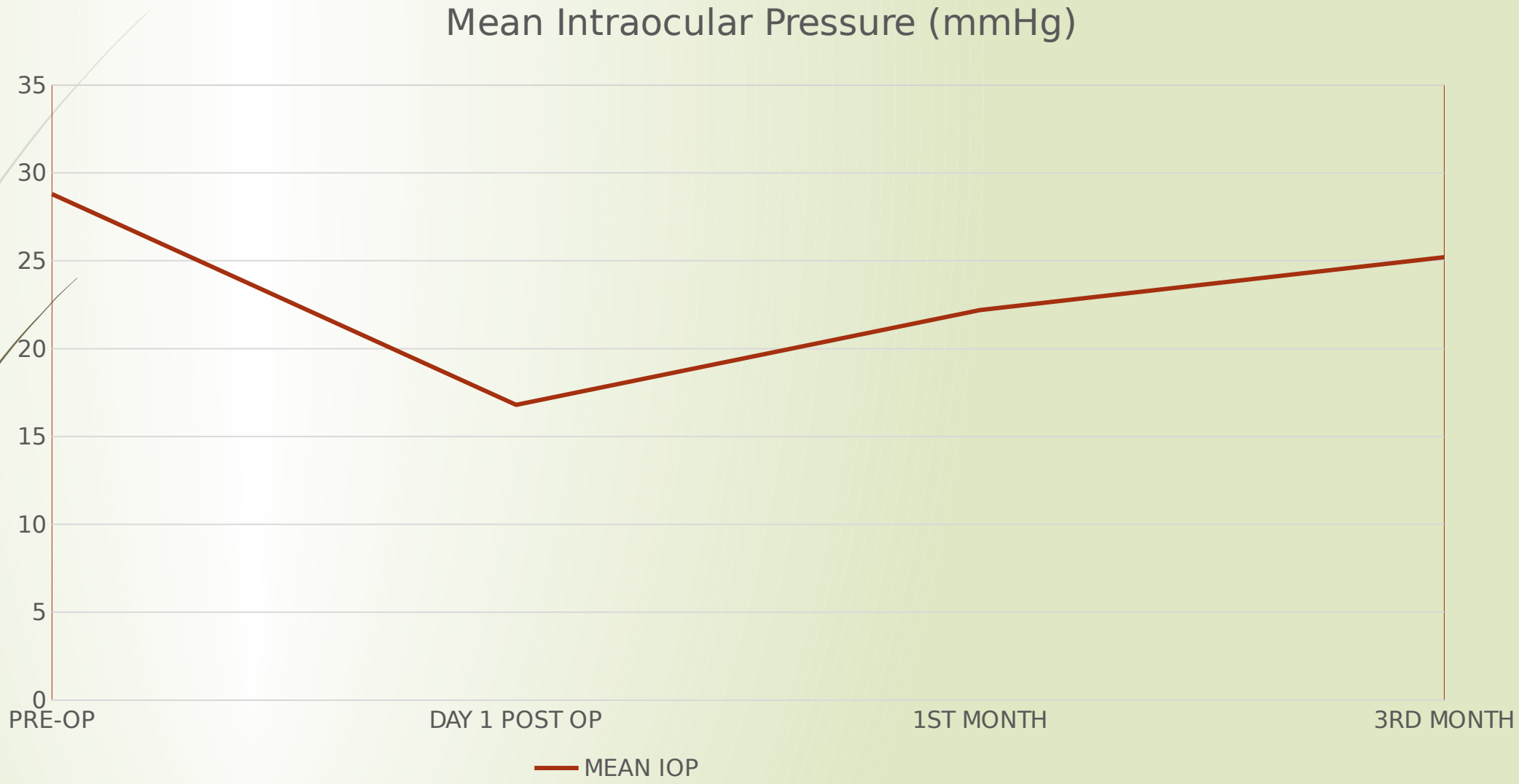


Phakic + Hydrus
36%

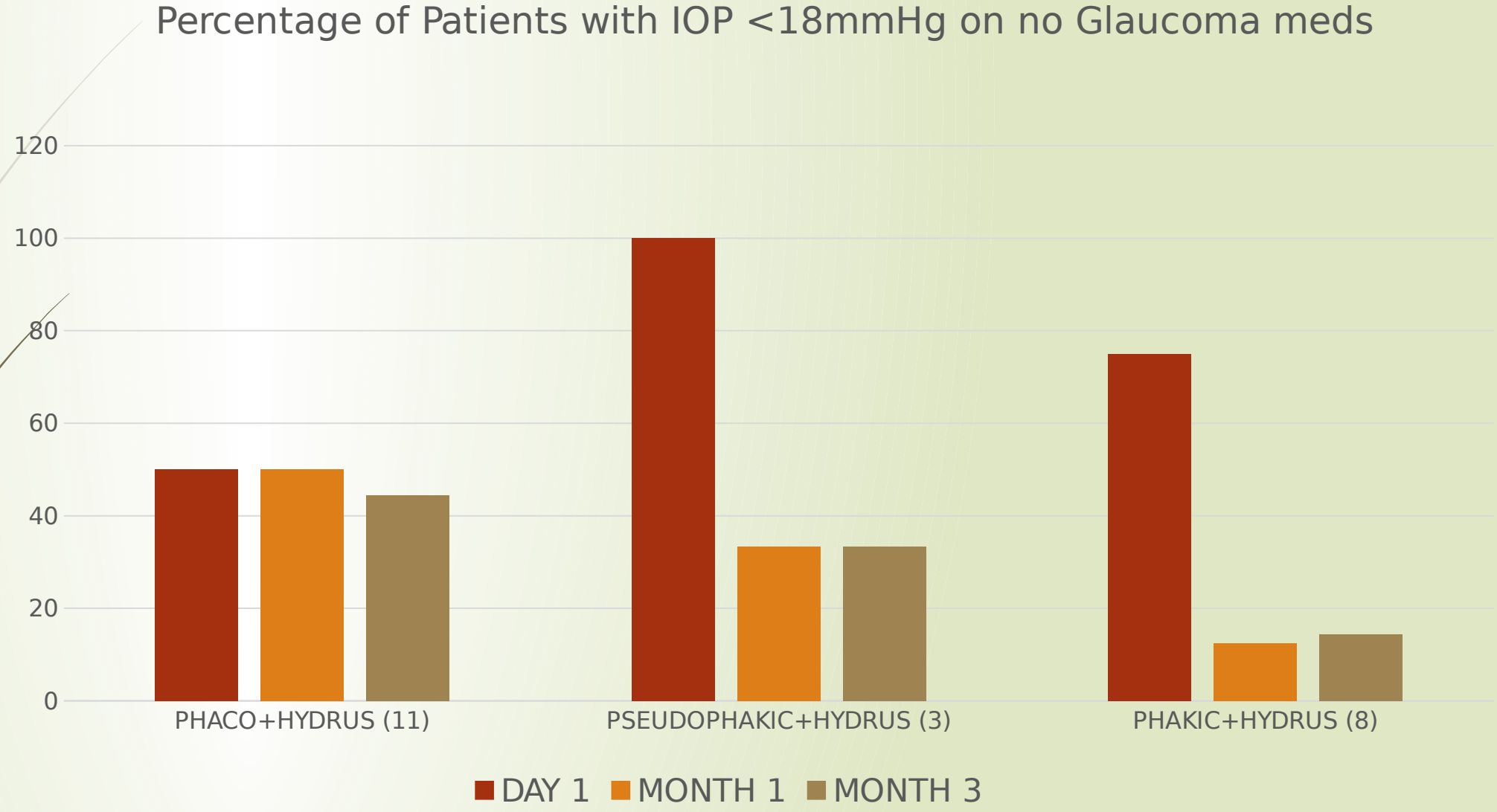
Cataract Surgery (Phaco) + Hydrus
50%

**For combined phaco + hydrus, the hydrus was implanted first*

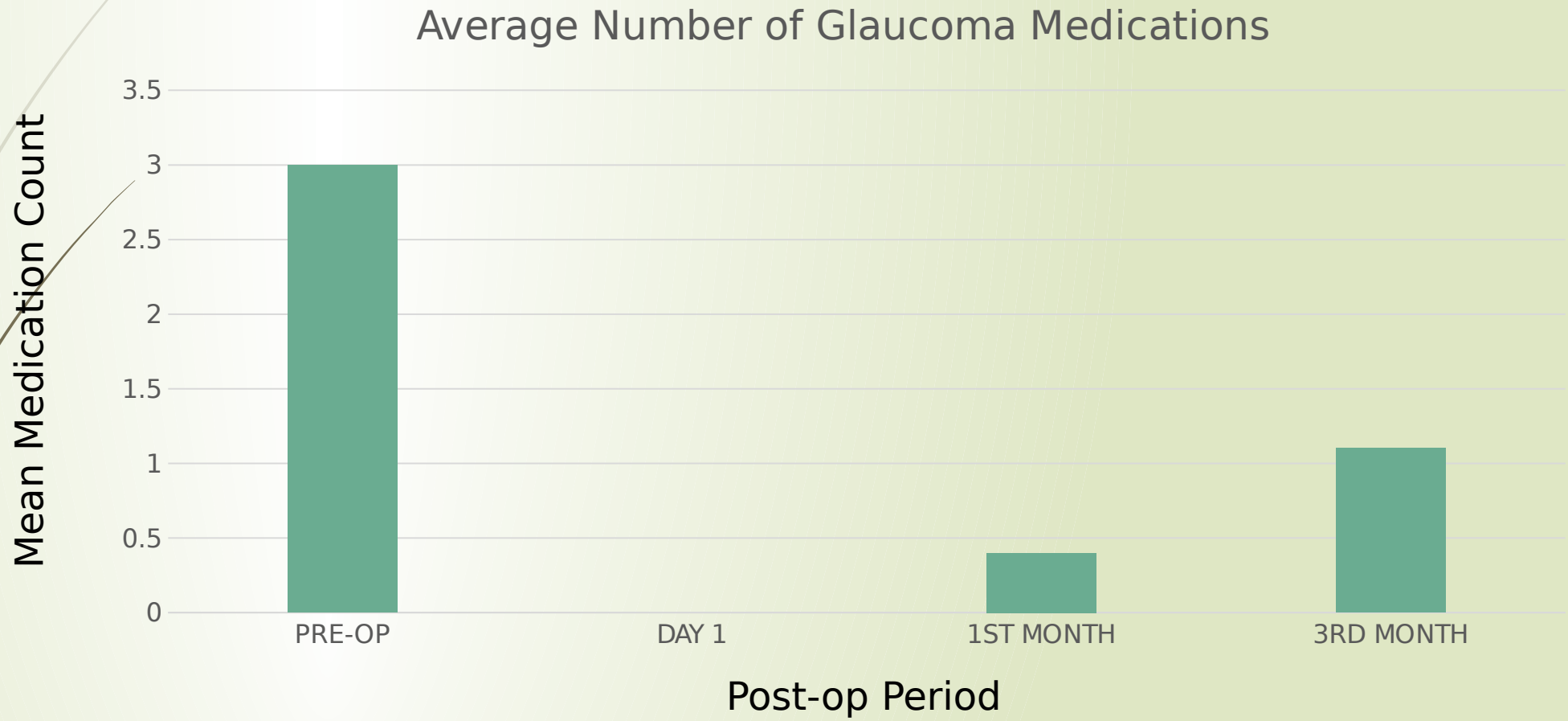
Results: Intraocular Pressure



Results: Intraocular Pressure



Results: Change in Number of Medications



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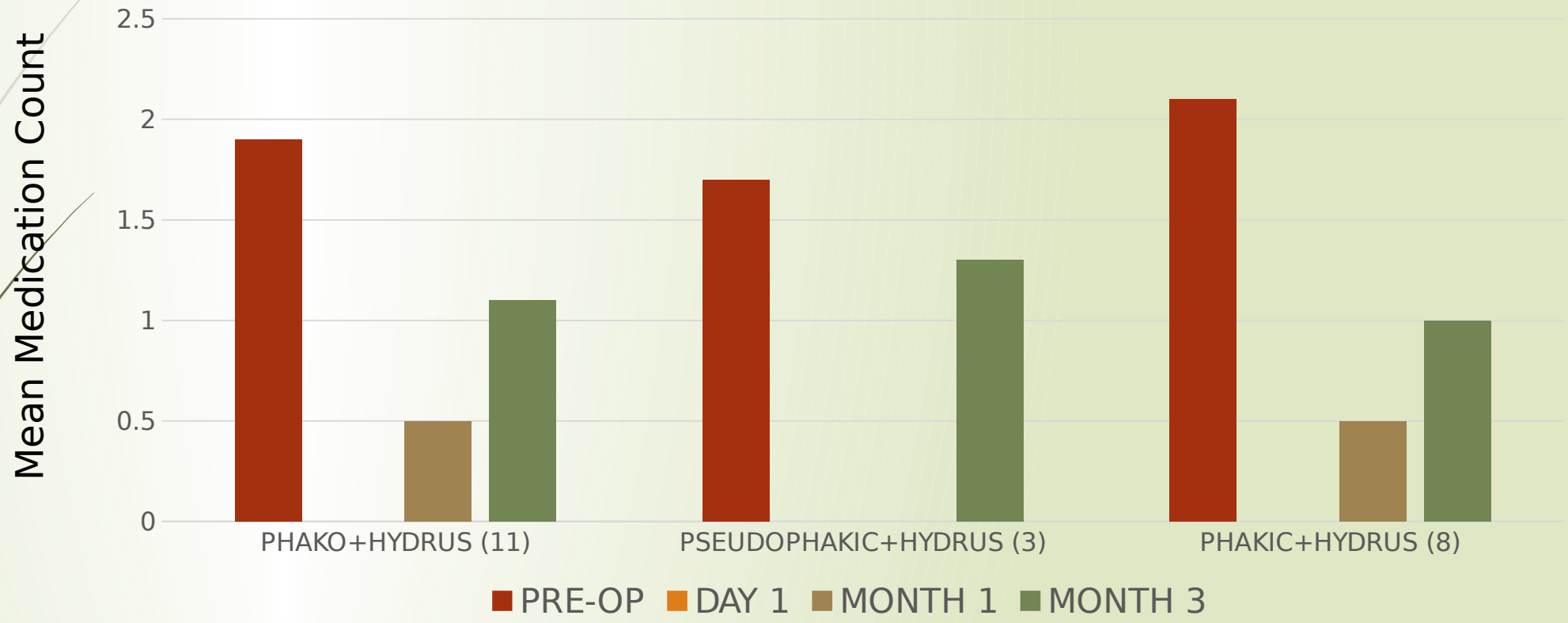

Conclusion

- The procedure is relatively safe, with only one case of trabecular stripping. Main complication was corneal oedema during phacoemulsification in the Phaco+Hydrus group.
- Mean Intraocular pressure dropped initially but has been rising steadily. Long-term follow up is needed to determine whether IOP will continue to rise or will stabilize at a level that is higher or lower than pre-op values.
- Percentage of patients with IOPs less than 18 mmHg on no meds has reduced i.e. more patients have had to be put back on Glaucoma meds to keep their IOPs below 18 mmHg.
  - However, the percentage of patients put back on meds to keep IOPs below 18mmHg has been constant over 3 months in the Phaco+Hydrus group, compared to the other groups where the percentage has been rising steadily. This could suggest that the Hydrus Microstent may be more effective when used in combination with phacoemulsification, as compared to being used as a standalone procedure.

Limitations

- Results are short-term. Longer-term, larger sample results needed to make better informed decisions on efficacy and sustainability of the device in African population
- Limited time was available for preparation for the study. A medication wash-out period was not included to determine baseline IOPs without medications. Therefore, IOP results from this study cannot be compared to similar studies where washed-out baseline IOPs were used.
- Target IOP was the same for all patients and not individualized. Target pressures for each eye should have been used as a reference to make therapeutic decisions i.e. when to restart Glaucoma meds.
- The non-uniform distribution of patients among the 3 surgical groups may have introduced some bias.

References

- 1. Richter GM & Coleman, AL. Minimally invasive glaucoma surgery: Current status and future prospects. *Clinical Ophthalmology* 2016:10 189-206
- 2. Pfeiffer N, Garcia-Feijoo J, Martinez-de-la-Casa JM, *et al*. A randomized trial of a Schlemm's canal microstent with phacoemulsification for reducing intraocular pressure in open-angle glaucoma. *Ophthalmology* 2015; 122: 1283-1293
- 3. Thomas W, Samuelson MD. One-year results of a Schlemm's canal microstent for IOP reduction in open angle glaucoma. Unpublished results. On behalf of the HYDRUS I investigators