

# Real-world three-year comparison of Preserflo Microshunt with Augmented trabeculectomy

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## Introduction

Trabeculectomy is considered the gold standard surgical treatment for glaucoma.<sup>1</sup> Minimally invasive bleb surgery (MIBS), such as the Preserflo Microshunt, have been adopted more recently, with a correspondingly smaller but ever-increasing evidence base. Much of the clinical evidence derives from randomised control trials. As their adoption becomes more widespread, it is critical to examine if these claims translate to real-world benefits.<sup>1</sup>

## Methods

- Retrospective Chart review
- Participant Inclusion criteria:
  - All patients who underwent PreserFlo insertion or Trabeculectomy at the Princess Alexandra Eye Pavilion from 16/05/2022 to 15/05/2023.
- Follow-up period: 24 months
- Primary outcomes – Success Rates:<sup>2</sup>
  - IOP reduction >20% from baseline
  - IOP < 21 mmHg
  - No reoperation required
  - No persistent hypotony (IOP>5)
  - Maintain Light Perception (LP)
- Secondary outcomes:
  - Absolute IOP reduction
  - Relative IOP reduction in percentage
  - Decrease in number of anti-glaucoma medication
  - Number of follow-up visits
  - Complications, including reoperations

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## Results

Tablet 1: Baseline Demographics

|                                       | Trabeculectomy                  | PreserFlo                       | p-values     |
|---------------------------------------|---------------------------------|---------------------------------|--------------|
|                                       | 89 eyes (of 84 unique patients) | 47 (of 41 unique patients)      |              |
| Age                                   | 67.4 ± 12.8                     | 70.3 ± 13.7                     | 0.22         |
| Male Sex (%)                          | 54 (64%)                        | 20 (49%)                        | 0.14         |
| Phakic, n (%)                         | 44 (49%)                        | 17 (36%)                        | 0.19         |
| Glaucoma Duration                     | 10.2 ± 6.7 years                | 9.8 ± 7.6 years                 | 0.75         |
| Baseline Visual Field                 | -13.4 ± 7.9 dB                  | -12.2 ± 9.0 dB                  | 0.44         |
| Baseline IOP                          | 24.8 ± 8.2 mmHg                 | 31.0 ± 8.0 mmHg                 | <0.05        |
| Baseline BCVA (LogMAR)                | 0.13 ± 0.31                     | 0.22 ± 0.36                     | 0.15         |
| Baseline anti-glaucoma meds           | 2.6 ± 0.9                       | 2.5 ± 1.1                       | 0.59         |
| PO acetazolamide                      | 6 (7%)                          | 16 (34%)                        | <0.01        |
| Concurrent cataract surgery           | 1 (1%)                          | 4 (8%)                          | 0.05         |
| Glaucoma types, n (%):                |                                 |                                 |              |
| Primary Open Angle                    | 40 (45%)                        | 22 (47%)                        | 0.98         |
| Normal Tension                        | 31 (35%)                        | 5 (11%)                         | <0.01        |
| Angle-closure                         | 10 (11%)                        | 6 (13%)                         | 0.78         |
| Pseudo-exfoliative                    | 5 (6%)                          | 2(4%)                           | 0.99         |
| Pigment Dispersion                    | 1(1%)                           | 1(2%)                           | 0.99         |
| Uveitic                               | 1 (1%)                          | 8 (17%)                         | <0.01        |
| Medication-induced                    | 1 (1%)                          | 0 (0%)                          | 0.99         |
| Vitrectomy-related                    | 0 (0%)                          | 3 (6%)                          | 0.04         |
| Previous ophthalmic surgeries, n (%): |                                 |                                 |              |
| Prior cataract surgeries              | 45 (50%)                        | 30 (64%)                        | 0.19         |
| Selective Laser Trabeculoplasty       | Once: 16 (18%)<br>Twice: 2 (2%) | Once: 15 (32%)<br>Twice: 2 (4%) | 0.10<br>0.61 |
| Laser Peripheral Iridotomy            | 7 (8%)                          | 6 (13%)                         | 0.37         |
| Prior MIGS                            | 4 (4%)                          | 3 (6%)                          | 0.37         |
| Prior Trabeculectomy                  | 5 (6%)                          | 5 (11%)                         | 0.31         |
| Corneal surgery                       | 2 (2%)                          | 0 (0%)                          | 0.54         |

Figure 1: Success Rates of each procedure (p-value <0.01)

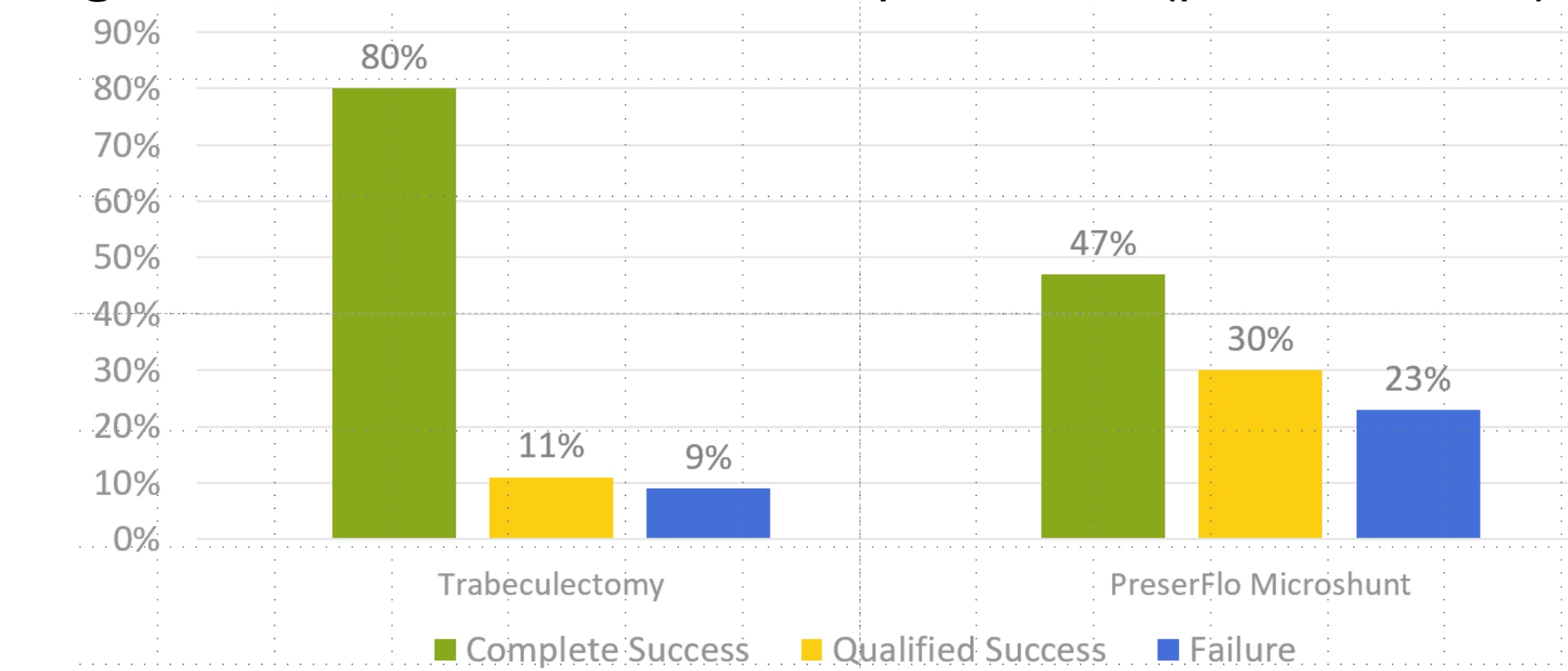


Figure 2: IOP at baseline and at end of Year 2

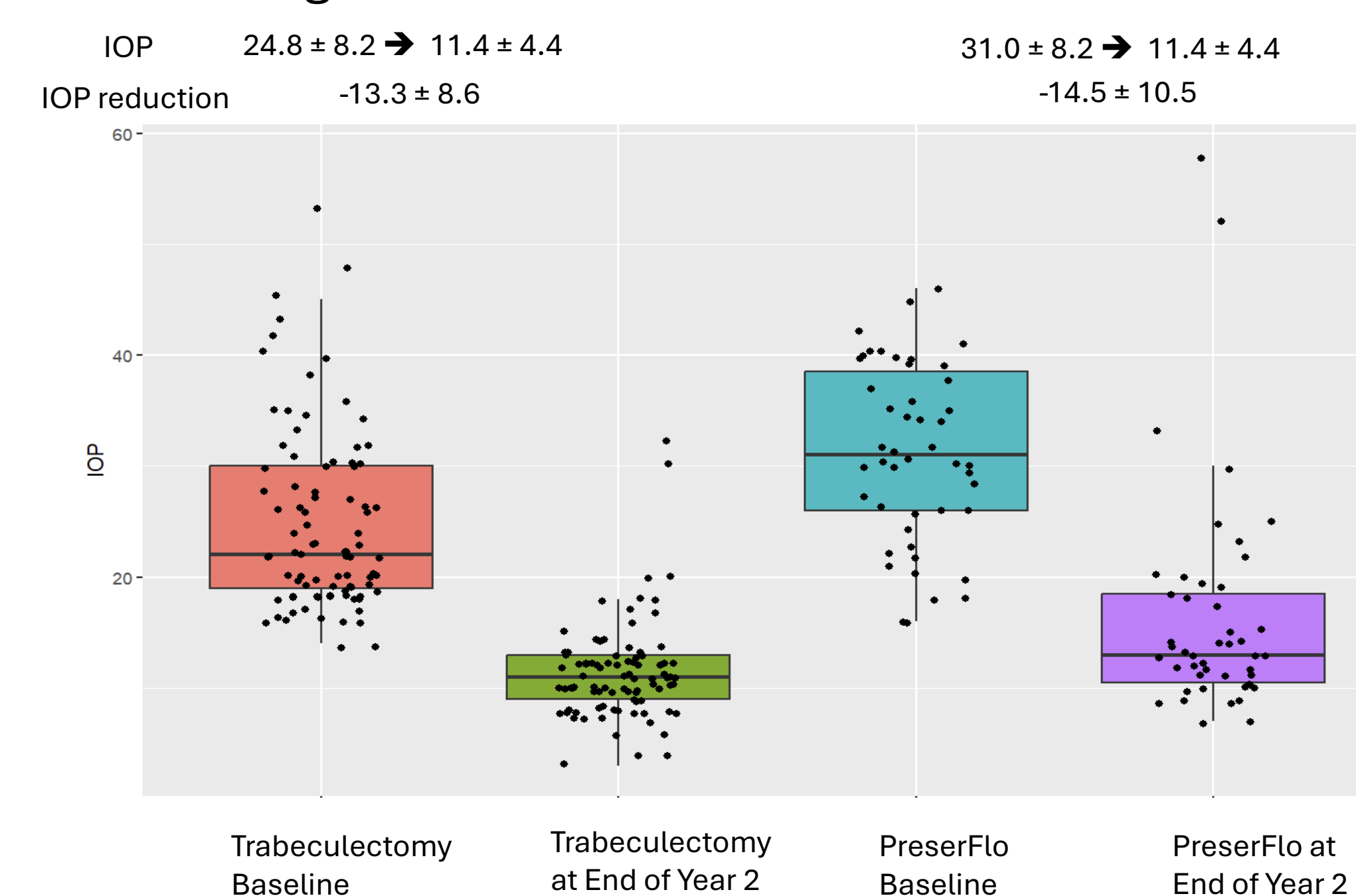


Figure 3: Number of anti-glaucoma medications at baseline and end of Year 2

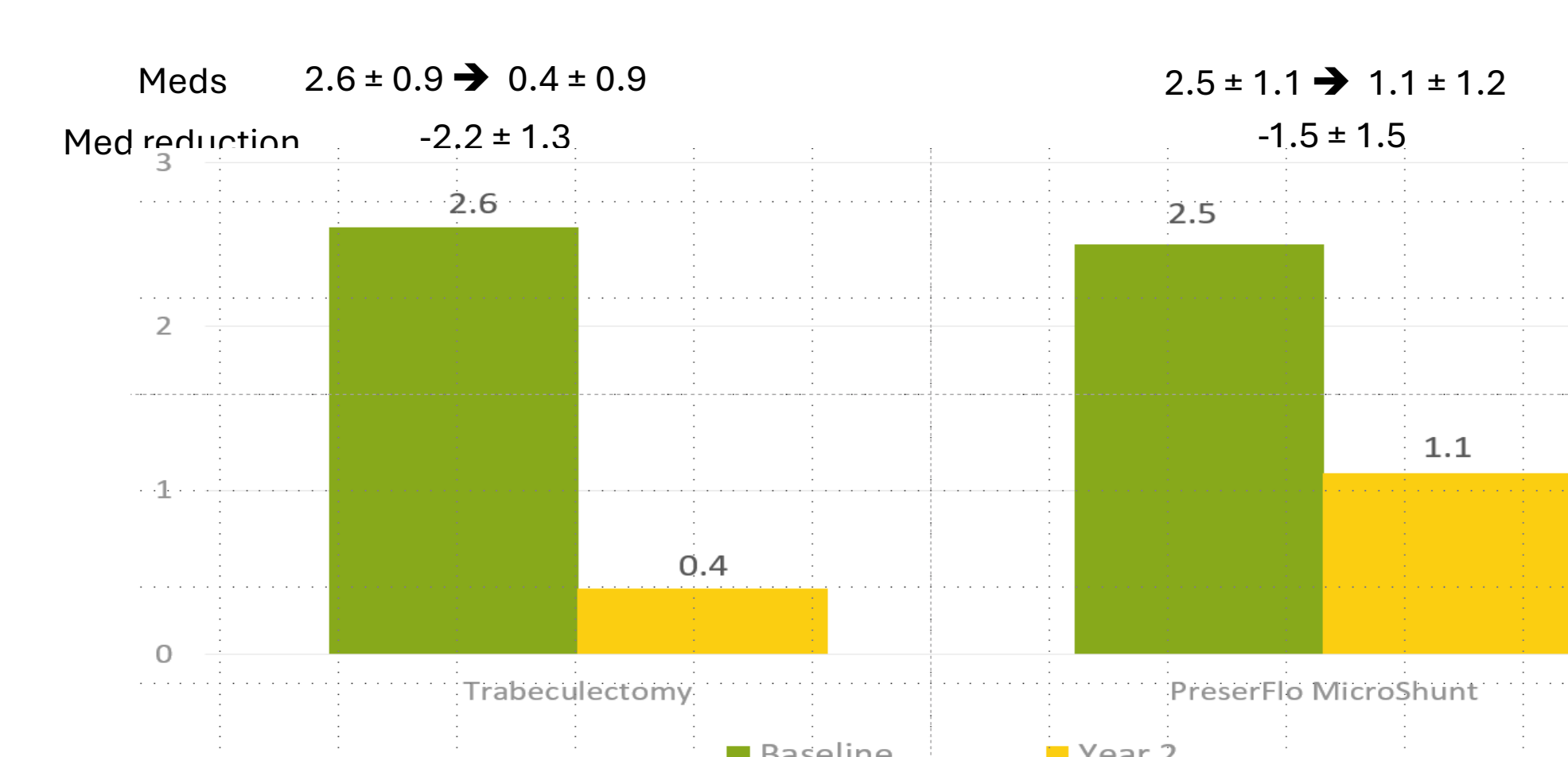


Table 2: Best corrected visual acuity (BCVA) in LogMAR and Visual Field (dB) at Baseline and End of Year 2 Follow-up

|               | Trabeculectomy | PreserFlo   | p-values |
|---------------|----------------|-------------|----------|
| Baseline VA   | 0.13 ± 0.31    | 0.22 ± 0.36 | 0.15     |
| End-of-Year-2 | 0.16 ± 0.38    | 0.19 ± 0.32 | 0.54     |
| Baseline VF   | -13.4 ± 7.9    | -12.2 ± 9.0 | 0.44     |
| End-of-Year-2 | -14.1 ± 8.1    | -13.0 ± 9.4 | 0.62     |

Table 3: Re-operations, Adverse effects and Number of follow-up visits

|                            | Trabeculectomy | PreserFlo | p-values |
|----------------------------|----------------|-----------|----------|
| Hypotony                   | 5 (6%)         | 0 (0%)    | 0.16     |
| Reoperations               | 5 (6%)         | 7 (15%)   | 0.11     |
| Number of follow-up visits | 13.2 ± 4.4     | 8.2 ± 1.9 | <0.05    |

## Discussion

Trabeculectomy is more effective in achieving target IOP with higher percentage of them remaining medication-free, but it has the disadvantages of greater number of follow-up visits and higher percentage of hypotony.

PreserFlo is less effective in achieving target IOP but it requires fewer follow-up visits, has lower rate of complication and lower rate of hypotony. Limitations include retrospective nature of the study, single-centred with predominant Caucasian population and selection bias, based on surgeons' discretion.

## References:

1. Chan PPM, Larson MD, Dickerson JE Jr, Mercieca K, Koh VTC, Lim R, Leung EHY, Samuelson TW, Larsen CL, Harvey A, Töteberg-Harms M, Meier-Gibbons F, Shu-Wen Chan N, Sy JB, Mansouri K, Zhang X, Lam DSC. Minimally Invasive Glaucoma Surgery: Latest Developments and Future Challenges. Asia Pac J Ophthalmol (Phila). 2023 Nov-Dec 01;12(6):537-564. doi: 10.1097/APO.0000000000000646. Epub 2023 Nov 27. PMID: 38079242.
2. Gedde SJ, Feuer WJ, Shi W, Lim KS, Barton K, Goyal S, Ahmed IIK, Brandt J; Primary Tube Versus Trabeculectomy Study Group. Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 1 Year of Follow-up. Ophthalmology. 2018 May;125(5):650-663. doi: 10.1016/j.ophtha.2018.02.003. Epub 2018 Feb 21. PMID: 29477688.