AOI
Advanced Ophthalmic Innovations

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PAUL®

GLAUCOMA IMPLANT

Taking the Lead

bsi ISO 22301 Business Continuity Management CERTIFIED
BCMS 784334

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED
MD 775941

bsi UKAS MANAGEMENT SYSTEMS 0003
UKCA 775935

PAUL® GLAUCOMA IMPLANT KEY NOVEL FEATURES

Micro-sized Tube

- **Small Inner Diameter**
  Balances flow resistance, safeguards against early hypotony
- **Small Outer Diameter**
  Occupies less space in the anterior chamber

Optimized Endplate Design

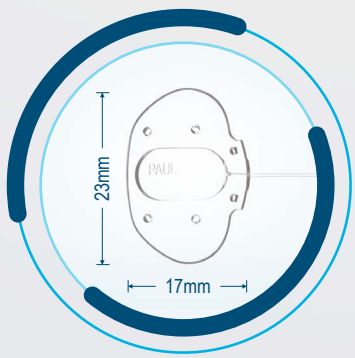
- **Large Plate Surface Area**
  More area available for aqueous drainage for intraocular pressure (IOP) control
- **Ideal Drainage Shape**
  Less device area covered by recti muscles

Advanced Device Composition

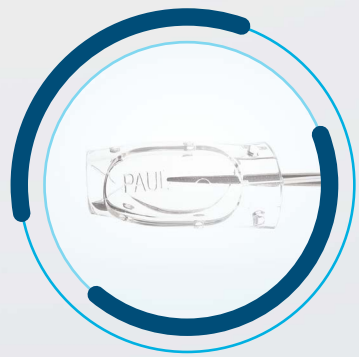
- **Implantable Medical-grade Silicone**
  Certified safe for MRI environment
- **Flexible Device**
  Pliable material facilitates implantation

Key Feature Highlights

Micro-tube Dimensions
(Enlarged 75x approx.)



Actual Plate Size
(Shown Actual Size)



Actual Pliability
(Actual folding of plate)

REDUCING IOP EFFECTIVELY AND SAFELY

Clinical Data

Multiple clinical studies reported that the PAUL® procedure leads to sustained IOP reduction and decreased need for pressure-lowering therapy with lower risk of complications. These outcomes have been observed 1 year after surgery and in the longer-term, including 2- and 3-years post-operatively.

The 1-year study by Koh et al.[1] was the first published outcome of the PAUL® device, reporting a significant IOP reduction 1 year after PAUL® implantation with a corresponding reduction in IOP lowering medication. Figure 1 shows the IOP trend post-operatively up to 1 year. Figure 2 shows the mean number of IOP-lowering medications used after surgery.

At the end of 12 months, among the 74 eyes which completed the study, 93.2% were classified as surgical successes[2], with and without medications, at IOP cutoff of 21 mmHg.

Figure 1. IOP trend before and after surgery up to 1 year

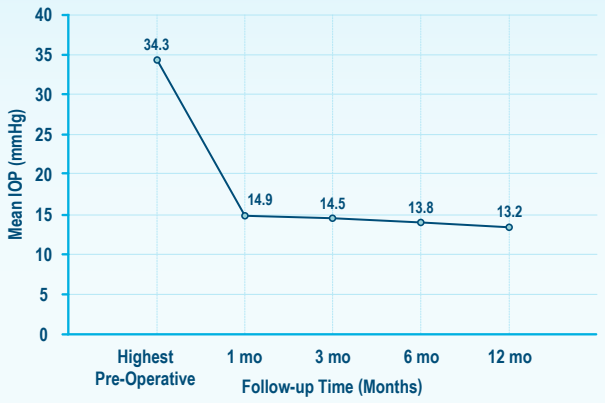
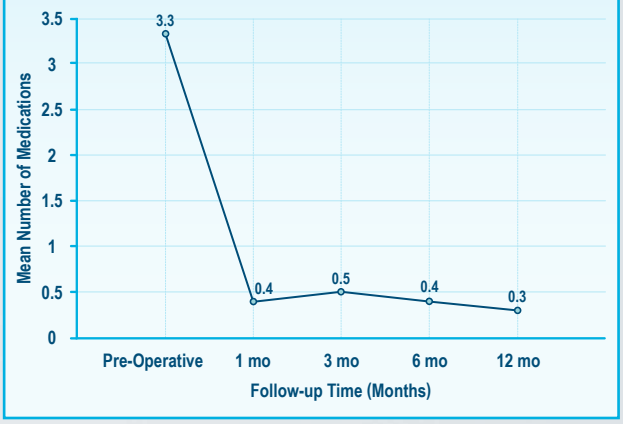


Figure 2. IOP-lowering medications used before and after surgery



Consistency Across Multiple Studies

There were 3 additional clinical studies reporting 1-year outcomes published since Koh et al.[1] They are Vallabh et al.[3] (99 eyes), José et al.[4] (24 eyes) and Weber et al.[5] (45 eyes). The 4 studies were independently conducted by different institutions among varying patient populations. While not directly comparable, results from these studies display certain consistency.

Figure 3 displays PAUL®'s efficacy in lowering IOP reported by each of the 4 studies 1 year after surgery. Figure 4 displays the reduction of the mean number of IOP-lowering medications needed reported by each study for the same period. There was a notable reduction in mean IOP and mean number of medications needed across the 4 independent studies.

Figure 3. IOP trends pre-op and 12 months post-op across 4 studies

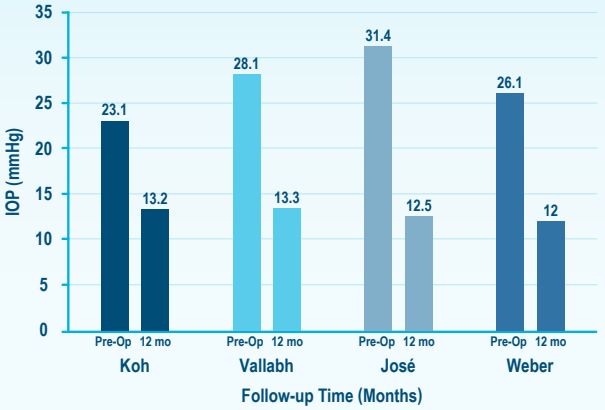
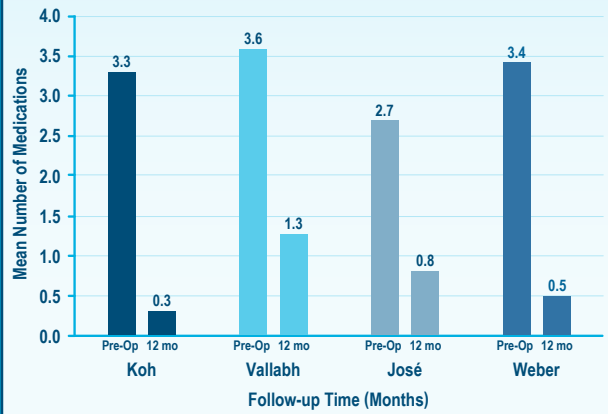


Figure 4. Need for medications pre-op and 12 months post-op across 4 studies



Sustained Effectiveness 1, 2, and 3 years after surgery

The effectiveness of PAUL® in decreasing IOP as well as reducing the need for glaucoma therapy is sustained longer term beyond 12 months.

Weber et al.[6], reported 2-year PAUL® clinical results. Of the 56 eyes included in the study, mean pre-operative IOP was 25.4 mmHg, and all patients used topical IOP-lowering medications with a mean of 3.5 agents. Figure 5 shows a 46.8% reduction in IOP at 12 months and 50.6% reduction after 24 months. The mean number of medications was reduced from 3.5 to 0.45 and 0.46 at 12 and 24 months respectively. Surgical success (with and without medication) rates were 89%, 79%, 64% and 38% using IOP cutoffs of 21 mmHg, 18 mmHg, 15 mmHg and 12 mmHg, respectively, after 24 months.

Tan et al.[7] reported similar results in a 3-year PAUL® study, where 48 eyes completed 36 months follow-up. Reduction of IOP and decreased need for glaucoma therapy were consistent and sustained through the 3 years. IOP reduction was 56%, 56% and 54%, and mean number of meds was 0.06, 0.19, and 0.17 in Year 1, 2 and 3 respectively (Figure 6). 85.4% of patients achieved the surgical success criteria at 3-years (IOP>6 and <18 mmHg, with and without the need for medication).

Additional long-term study results will be posted on **www.aoi.sg** as they are published.

Figure 5. 2-year IOP & medication trends reported by Weber et al.[6]

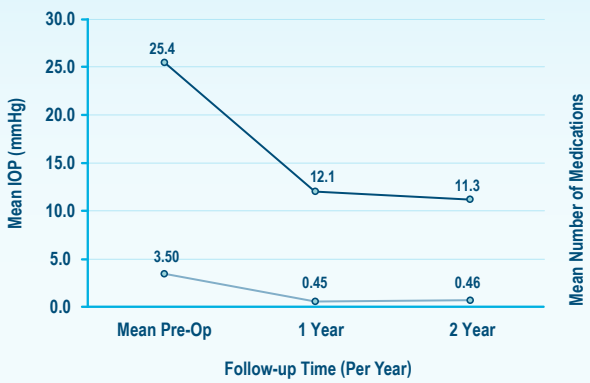
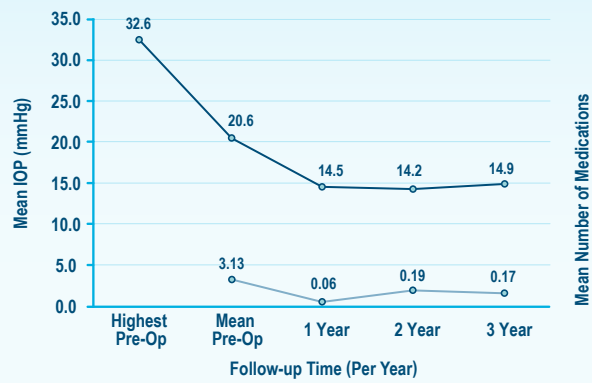


Figure 6. 3-year IOP & medication trends reported by Tan et al.[7]



1. Koh V, Chew P, Triolo G, Lim KS, Barton K. Treatment outcomes using the PAUL® glaucoma implant to control intraocular pressure in eyes with refractory glaucoma. *Ophthalmol Glaucoma*. 2020;3(5): 350-359.
2. Shaarawy TM, Sherwood MB, Grehn F. Guidelines on Design & Reporting Glaucoma Trials. World Glaucoma Association. 2008; 15-24.
3. Vallabh NA, Mason F, Yu JTS, et al. Surgical technique, perioperative management and early outcome data of the PAUL® glaucoma drainage device. *Eye*. 2022;36: 1905-1910.
4. José P, Barao RC, Teixeira FJ, et al. One-year efficacy and safety of the PAUL® glaucoma implant using a standardised surgical protocol. *J Glaucoma*. 2022;31(3): 210-205.
5. Weber C, Hundertmark S, Liegl R, et al. Clinical Outcomes of the PAUL® glaucoma implant: One-year results. *Clin Exp Ophthalmol*. 2023; 51(6): 566-576.
6. Weber C, Hundertmark S, Stasik I, et al. Two-Year Clinical Outcomes of the PAUL® Glaucoma Implant in White Patients with Refractory Glaucoma. *J Glaucoma*. 2024;33(10): 808-814.
7. Tan MCJ, Ong CW, Aquino MC, et al. Three-Year Outcomes of the PAUL® Glaucoma Implant for Treatment of Glaucoma. *J Glaucoma*. 2024;33(7): 478-485.

Sales of the device is restricted by or on order of a physician. Always read the label and follow the instructions for use.

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GD1-3-009-02