AOI
Advanced Ophthalmic Innovations

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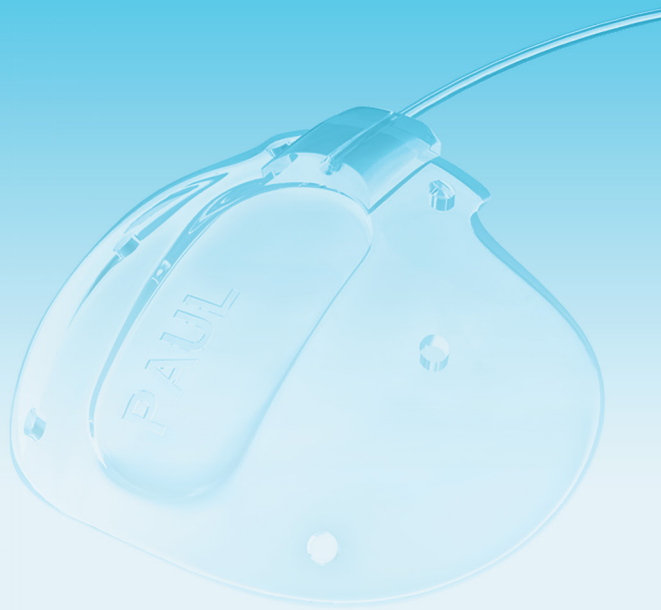
DESIGN ADVANCEMENTS

PERFORMANCE ADVANTAGES

The PAUL® Glaucoma Implant (PAUL®) is a novel glaucoma drainage device. PAUL® has introduced many innovative design features and unified these into one device that delivers both Efficacy and Safety.

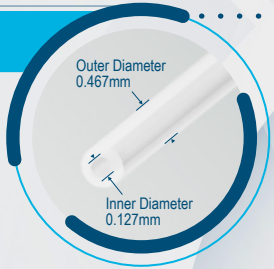


KEY NOVEL FEATURES

PAUL® GLAUCOMA IMPLANT

WHAT MAKES PAUL® DIFFERENT?

Micro-sized Tube



- **Small Internal Calibre:** Creates high flow resistance and safeguards against early hypotony
- **Small External Calibre:** Occupies less space in anterior chamber and minimizes risks of tube erosion and corneal touch

Optimized Endplate Design

- **Optimal Large Plate Surface Area:** More area available for aqueous filtration
- **Ideal Drainage Shape:** Less filtration area covered by recti muscles

Advanced Device Composition

- **Proprietary Medical-grade Silicone:** Creates a device with a new level of flexibility to facilitate the implantation process
- **Flexible Device:** Less rigidity and decreases both micro-abrasion and excessive wound scarring

STUDY RESULTS

PAUL® GLAUCOMA IMPLANT

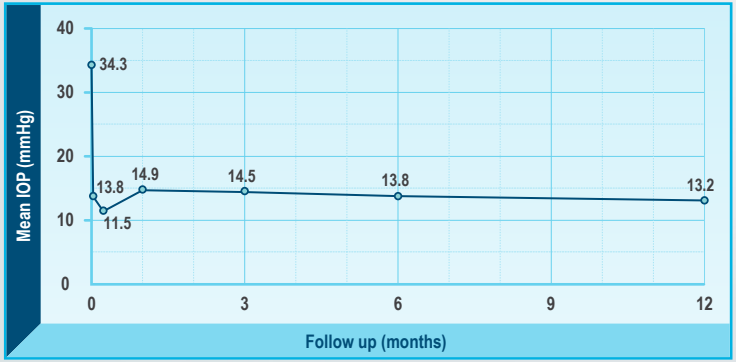
"Treatment Outcomes Using the PAUL® Glaucoma Implant to Control Intraocular Pressure in Eyes with Refractory Glaucoma" concluded that "PAUL® is a novel tube shunt offering some potentially significant advantages over other currently available. This study found comparable prospective safety and efficacy, in a relatively large sample size, as previously published studies of currently available implants 1 year after surgery in eyes with refractory glaucoma".[1]

In this Study, "the primary outcome measure was failure, defined prospectively as IOP of more than 21 mmHg or less than 20% reduction from the preoperative baseline on 2 consecutive visits, 3 months or more after surgery; persistent late hypotony, defined as IOP less than 6 mmHg on 2 consecutive visits after 3 months; additional glaucoma surgery; loss of light perception vision; or removal of the implant for any reason. The complete success was defined as unmedicated IOP of 21 mmHg or less and more than 5 mmHg and reduced by 20% or more from baseline at the 6- and 12-month visits. Qualified success was defined similarly and included eyes receiving medical treatment to lower the IOP".[1] These definitions are consistent with the published World Glaucoma Association Guidelines.[2]

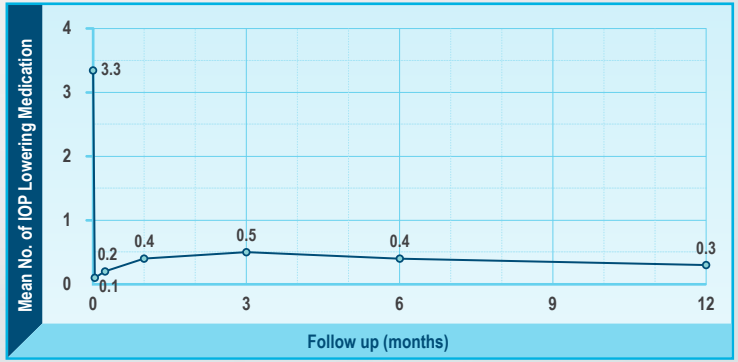
Significant reductions in both IOP and Glaucoma medications used were observed after one year implanting of PAUL®.

The failure rate was 5%, the complete success rate was 69% and the qualified success rate was 93%.

IOP Reduction Post-Operation



Glaucoma Medication Reduction Post-Operation



1 Victor K, Paul C, et al. Treatment Outcomes Using the PAUL® Glaucoma Implant to Control Intraocular Pressure in Eyes with Refractory Glaucoma. *American Academy of Ophthalmology;* 2020. ISSN 2589-4196/20

2 Heuer, DK.; Barton, K.; Grehn, F., et al. Consensus on definitions of success. In: Shaarawy, TM.; Sherwood, MB.; Grehn, F., editors. Guidelines on Design and Reporting of Surgical Trials. Amsterdam, the Netherlands: Kugler: *World Glaucoma Association;* 2008. p. 15-24.

Advanced Ophthalmic Innovations Pte Ltd

101 Cecil Street, #25-04
Tong Eng Building, Singapore 069533

Contact us at info@aoi.sg

WWW.AOI.SG