

First-in-man clinical study on a novel glaucoma drainage implant for refractory glaucoma

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Victor Koh (1,2); Maria Cecilia Aquino (1); Paul Chew (1,2); Keith Barton (3)

(1) Department of Ophthalmology, National University Health System, Singapore; (2) Department of Ophthalmology, Yong Loo Lin School of Medicine, National University of Singapore; (3) Moorfields Eye Hospital

Introduction

Glaucoma is a major blinding disease and lowering intraocular pressure is a mainstay of treatment. Glaucoma tube shunt is a common surgical procedure for refractory eyes.

Aim

To determine the one-year safety and efficacy of the Paul Glaucoma Implant, a novel glaucoma drainage implant in eyes with refractory glaucoma

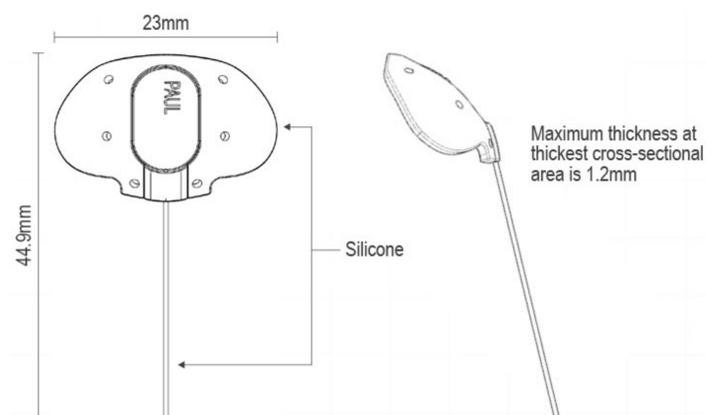
Methods

This is a non-comparative prospective interventional first-in-man study involving six participants with refractory glaucoma, defined as suboptimal intraocular pressure (IOP), despite maximal tolerable medical therapy, in a single centre in Singapore. All subjects underwent successful implantation of the Paul Glaucoma Implant (Advanced Ophthalmic Innovations Pte Ltd, Singapore) which has a reduced tube internal diameter (0.127mm) compared with conventional shunts, but a large plate surface area (342.1mm²) (**Figure 1**). The primary end point included IOP reduction, number of IOP-lowering medicines and complications. All subjects completed one-year of follow-up with fixed follow-up visits (1 day, 1 week, 1 months, 3 months, 6 months and 12 months).

Results

The mean age was 61.3 ± 4.9 years; all were male and included 2 with primary open angle glaucoma, 2 secondary open angle glaucoma, 1 traumatic glaucoma and 1 chronic angle closure glaucoma.

Figure 1. Illustration of the Paul Glaucoma Implant



Results

Compared to the mean highest pre-operative IOP (40.3 ± 11.8 mmHg), there was a statistically significant lower mean post-operative IOP at 1, 3, 6 and 12 months (13.0 ± 7.0 , 11.8 ± 4.0 , 11.8 ± 3.7 and 12.8 ± 3.2 mmHg respectively [$P < 0.001$]) (**Figure 3**). There was a mean 62.9 ± 0.1 % reduction in IOP at one year after surgery. The mean number of IOP-lowering medications before and 1 year after surgery was 2.7 ± 1.0 and 0.33 ± 0.8 respectively ($P = 0.005$).

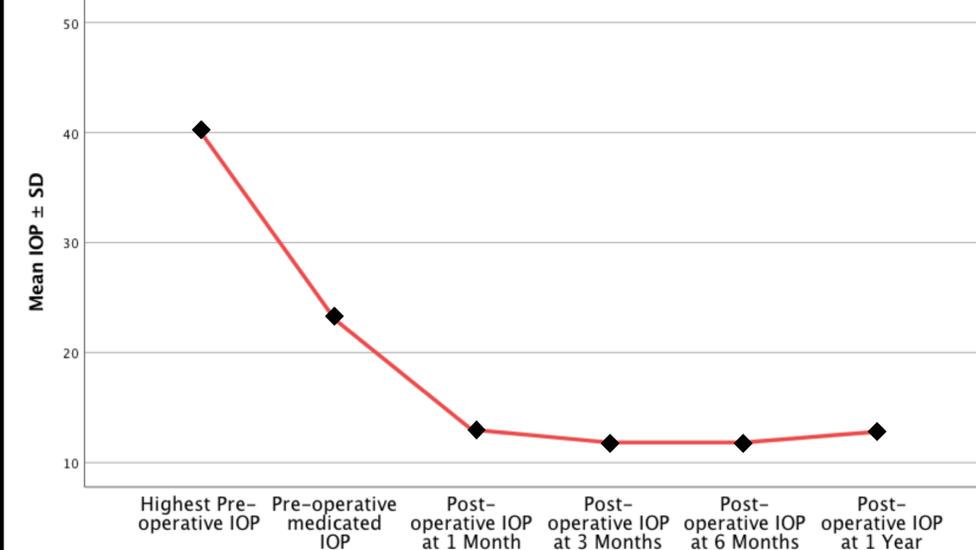
Figure 2. A. Early post-operative period tube position in the mid-anterior chamber (white arrow). B. Tube appearance at 1 year after surgery. C. Smooth diffuse bleb over the plate at 1 year after surgery



Results

There were no intra-operative complications; 1 eye (16.7%) required post-operative laser iridoplasty to release the iris plugging the tube, and 2 eyes (33.3%) had self-limiting shallow anterior chambers, both of which recovered by 1 month after surgery.

Figure 3. Intraocular pressure (IOP) trend before and after surgery



Discussion

In this first-in-man clinical study, the Paul Glaucoma Implant showed a good safety profile and efficacy in IOP reduction and reduction in IOP lowering-medications after 1 year of follow-up.

References

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