Efficacy and safety of the PAUL glaucoma implant: systematic review and meta-analysis

Health New Zealand
Te Whatu Ora

Chuen Yen, Hong
Health New Zealand Southern, Dunedin, New Zealand

Introduction

The PAUL® Glaucoma Implant (PGI) is a novel non-valved glaucoma drainage device constructed from medical implantable grade silicon. The PGI was designed to have a smaller internal and overall tube calibre compared to currently available glaucoma drainage devices with the aim to reduce post-operative complications such as postoperative hypotony, conjunctival erosion, tube-endothelium contact and damage.

This systematic review aim to summarise the efficacy and safety of the PGI.

PRISMA flow chart

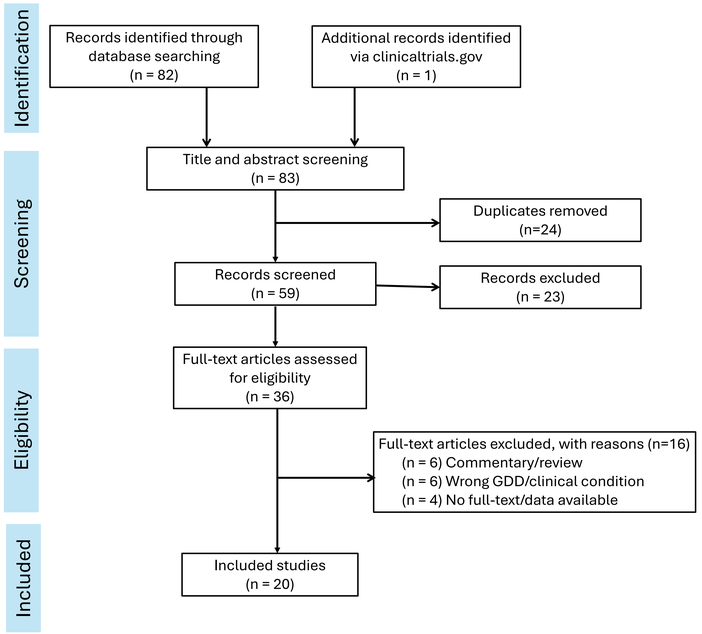


Figure 1: Flowchart of literature search.

Results

Adults

Post-operative IOP reduction

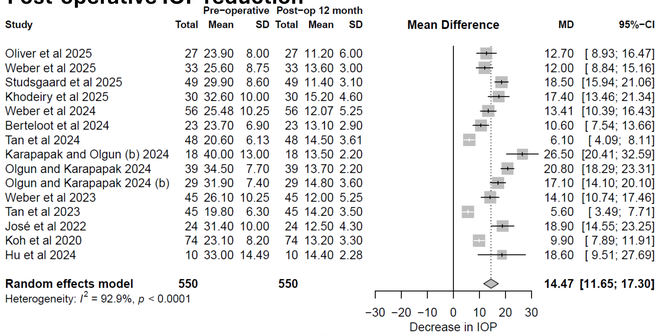


Figure 2: Meta-analysis for mean reduction in IOP at 12 months.

Post-operative IOL-lowering medication reduction

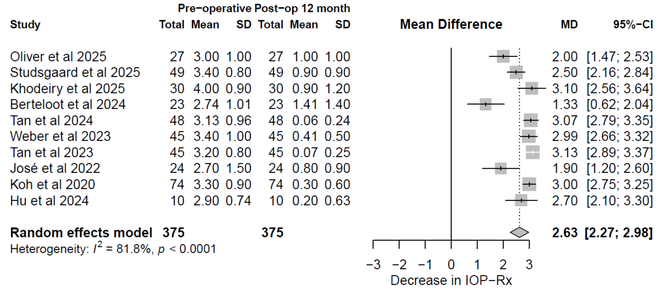


Figure 3: Meta-analysis for mean reduction in IOP-lowering medications.

Summary

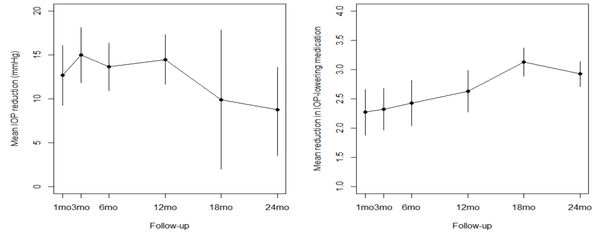


Figure 4: Mean reduction in postoperative IOP and number of IOP-lowering medications.

Results

Paediatrics

Post-operative IOP reduction

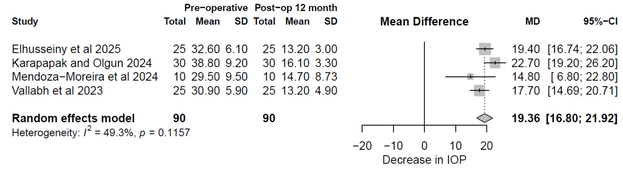


Figure 5: Meta-analysis for mean reduction in IOP at 12 months.

Post-operative IOL-lowering medication reduction

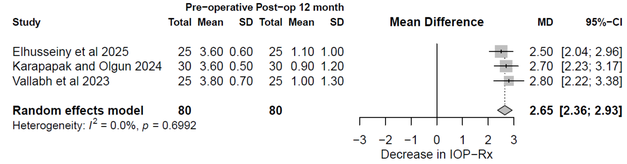


Figure 6: Meta-analysis for mean reduction in IOP-lowering medications.

Conclusion

There was a significant reduction in mean IOP at 1 month post-operative mark, with the effect persistent over the 24 months follow-up period. For adults, the mean IOP reduction at 12 months was 14.5mmHg (11.7 – 17.3). For the paediatric population, the mean IOP reduction at 12 months was 19.4mmHg (16.8 – 21.9). This is comparable to other glaucoma drainage devices. The number of IOL-reducing medications continued to drop over the follow-up period, indicating good IOP control without needing to re-start anti-glaucoma eye drops.

The most common adverse events reported by the studies were hypotony (8.7%), shallow or flat anterior chamber (8.4%), hyphema (7.9%), stent exposure (7.2%), loss of 2 rows or more in best-corrected visual acuity (6.6%), choroidal haemorrhage/effusion/detachment (5.8%), tube occlusion (4.8%), corneal decompensation (3.9%), diplopia (3.5%), and high IOP post-operatively (2.6%). Rates of hypotony was higher compared to Ahmed glaucoma valve and similar to Baerveldt glaucoma implant.

This meta-analysis gives an overview of the efficacy and safety of the PAUL glaucoma implant. Limitations include short follow-up period and lack of studies comparing PGI with other glaucoma drainage devices. As more studies become available in the literature, an updated systematic review will better inform clinicians of the relative benefits and caveats of using PGI over other implants.