Commentary

Commentary: the CyPass, a novel supraciliary implant for open-angle glaucoma

Yalong Dang, Nils A. Loewen

Department of Ophthalmology, University of Pittsburgh, Pittsburgh, PA 15213, USA

Correspondence to: Nils A. Loewen, MD, PhD. Department of Ophthalmology, University of Pittsburgh, Pittsburgh, PA 15213, USA. Email: loewen.nils@gmail.com.

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Comment on: Vold S, Ahmed II, Craven ER, *et al*. Two-Year COMPASS Trial Results: Supraciliary Microstenting with Phacoemulsification in Patients with Open-Angle Glaucoma and Cataracts. Ophthalmology 2016;123:2103-12.

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Traditional glaucoma surgeries are effective at lowering the intraocular pressure (IOP) but with a relatively high incidence of complications, that can amount to 77% (early and late) (1). In contrast, microincisional glaucoma surgeries (MIGS) have a complication rate that is 10 to 20 fold lower (2) but were only in less advanced glaucoma until recently (3-5). Although often advertised as new, procedures that qualify as MIGS have been performed for more than a century: for instance, Tailor performed angle surgery in 1891 and Heine introduced suprachoroidal drainage procedures in 1900 (6). Many more MIGS types are now available, including trabecular meshwork (TM) bypass stents (iStent G1 and iStent G2 Inject, Glaukos, Laguna Hills, CA; Hydrus, Ivantis, Irvine, CA, USA), TM ablation (Kahook Dual Blade, New World Medical, Rancho Cucamonga, CA, USA; Trabectome, Neomedix Inc, Tustin, CA, USA) or disruption (Trab360, Sight Sciences, Menlo Park, CA, USA) devices. There are subconjunctival (XEN, AqueSys, Irvine, CA, USA) or suprachoroidal shunts (Gold Shunt, SOLX, Waltham, MA, USA; CyPass, Transcend Medical, Menlo Park, CA, USA; iStent G3 Supra, Glaukos, Laguna Hills, CA, USA), and endocyclophotocoagulation (Endo Optiks, Little Silver, NJ, USA). The CyPass is implanted via an interno approach which is less invasive than ab externo as necessary with the older SOLX Gold Shunt or the Aquashunt (Opko Health, Miami, FL, USA) (7). Although both used inert and biocompatible materials (gold and polypropylene), a high rate of fibrosis can be seen even when combined with antifibrotics (8-10). This is not surprising as the same fibroblasts are present in the suprachoroidal space as in the sub-tenon space that epibulbar devices face.

Although vessels can be encountered in the suprachoroidal space, an earlier study with the very similar Glaukos iStent Supra indicated that no serious complication are normally seen (11). Despite being in direct contact with the choroid, no progressive thinning has been reported as seen with epibulbar devices. The newer CyPass microstent is now FDA approved, and presents as a tubular polyimide implant with a 310 μm internal diameter and many smaller openings of 76 μm at the distal end. This material is a synthetic resin in which the polymer units are linked by imide groups, as used chiefly for heat-resistant films and coatings but also applied to neuroelectrodes because it allows conductivity.

The results from the Two-Year COMPASS Trial (12) have now become available (12) and confirm the safety and efficiency of the CyPass. Vold *et al*. assessed this device for mild-to-moderate primary open angle glaucoma patients undergoing phacoemulsification. This study was well designed, and the manuscript is well written. It provides a convincing and in-depth assessment of methods and results by detailing power calculations, statistics, and group compositions. The authors used an image that we published in 2013 (13) to highlight the device's features but mislabeled it as ocular coherence tomography (OCT) while this transscleral imaging requires ultrasound

biomicroscopy (UBM).

A total of 505 patients were enrolled and randomized into phacoemulsification alone group (n=131) and compared to a combined surgery group (CyPass microstent plus phacoemulsification, n=374) at a ratio of 1:3. The baseline IOPs and numbers of medication were the similar in both groups (24.5±3.0 *vs*. 24.4±2.8 mmHg, 1.3±1.0 and 1.4±0.9, P>0.05, respectively). At 24 months postoperatively, 21% of IOP reduction in phacoemulsification alone group and 30% of IOP reduction in the combined surgery group were achieved respectively (P<0.01). The 77% of patients from the combined surgery group obtaining over 20% of IOP reduction, compared with 60% in phacoemulsification alone group (P=0.001), suggesting an additional IOP lowering effect exists by CyPass microstent implantation. A slightly lower number of glaucoma drops were needed in the study group (0.2±0.6 *vs*. 0.6±0.8, P<0.001) at the 24 months. In total, 84.8% of combined surgery patients were medication free compared to 59.1%. No vision-threatening complication was encountered. BCVA loss ≥2 lines, visual field loss progression, iritis, corneal edema, hyphema, stent obstruction, cyclodialysis cleft, postoperative ocular hypertension, and hypotony were recorded, but most of them were transient. About 5% of patients in the both groups needed a secondary glaucoma surgery. All ab interno MIGS procedures, including this one, are not affected by conjunctival scar formation (5) and can be performed as secondary procedures as long as the angle can be visualized, a requirement that is not necessary with ECP or secondary tubes or trabeculectomies. It is surprising that a cyclodialysis forming procedure like the CyPass produces an IOP of around 16.5 mmHg, very similar to the other MIGS that are limited by the episcleral venous pressure (2) which may not be low enough for advanced glaucoma. Cleft forming procedures that are device free (14) can, in theory, achieve much lower pressures and are a major cause of hypotony unless the flow is restricted by fibrosis or tissue juxtaposition.

As seen in several publications and consistent with this paper, the Cypass has a favorable safety profile (12,15-18). The incidence of stent obstruction was 2.1% (12) to 8.8% (15), mainly due to synechiae formation (16), too deep insertion into the supraciliary space (16) and overgrowth of iris cells (18). Transient hypotony was more common [from 2.9% (12) to 15.8% (18)] than ocular hypertension [3% (16) to 10.8% (17)]. Transient hyphema occurred between 1.2% (16) and 6.2% (17). Repositioning and explantation sometimes were necessary (16,18) due to the dislocation of the implant. A few patients had endothelial contact with the stent (16,18) a potentially serious issue which can lead to corneal decompensation.

In conclusion, this publication shows that the CyPass holds promise as a new route to lowering IOP with relative ease and safety. As with many new glaucoma surgeries, surgeons have to take into consideration that the sample size and follow-up is still relatively limited and no direct comparison to other glaucoma surgeries exist (12,15-18). It would be remarkable if the material used here, polyimide, is so fundamentally different from prior used ones that it allows a sustained, fibrosis free function.

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Footnote

Conflicts of Interest: NA Loewen obtained wetlab and lecture honoraria from Neomedix Inc.

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