Can We Ever Win with a Suprachoroidal Implant?

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Journal of Current Glaucoma Practice (2023): 10.5005/jp-journals-10078-1410

"Scientific breakthroughs are often found on the other side of failure."

—Thomas Edison

Suprachoroidal drainage has long intrigued glaucoma specialists due to its potential to reduce intraocular pressure (IOP) while avoiding subconjunctival filtration blebs and their related complications. Even though the pharmacological manipulation of the uveoscleral outflow is now the first-line therapy for the medical management of glaucoma, the intricacies of its surgical regulation remain elusive.^{1–7}

The profound IOP-lowering effects resulting from traumatic cyclodialysis clefts have long fascinated glaucoma surgeons: the first intentional cyclodialysis cleft was proposed as a surgical treatment for glaucoma by Leopold Heine in 1905.⁸ Over more than a century; thus, glaucoma surgeons have tried to harness the IOP lowering effect of a controlled cyclodialysis. The attempts to surgically navigate the intricacies of suprachoroidal outflow have met with limited success: complications include significant hypotony in the immediate postoperative period, followed by the inevitable cleft closure and high IOP spikes. Various modifications have been proposed,^{9–12} with spacers ranging from autologous scleral tubes to plastic implants and even horse hair! The most promising of these implants are the ones discussed in this article.

SUPRACILIARY GLAUCOMA DEVICES: *AB Externo* Approach

SOLX Gold Micro Shunt

The SOLX gold micro shunt (SOLX Inc. Waltham, Massachusetts, United States of America) was made of industrial grade 24-karat gold and thought to be biocompatible at the time. The T-shaped implant consisted of two leaflets fused together, concealing multiple microchannels that allowed the egress of aqueous into the suprachoroidal space. The device was implanted *ab externo* after a limited conjunctival peritomy, with the smaller front portion in the anterior chamber and the back portion nestled within the suprachoroidal space.¹³ Despite early successes, medium and long-term follow-up results were not encouraging,^{14–17} with complications like poor IOP control, hyphema, hypotony, corneal decompensation, and implant erosion. The primary cause of surgical failure was connective tissue proliferation that obstructed the microchannels. The SOLX gold micro shunt is no longer used in clinical practice.

STARflo

The STARflo device (iSTAR Medical, Isnes, Belgium) was made of a flexible silicone microporous material called "STAR" and was similar in design and surgical technique to the SOLX shunt, except for a longer scleral flap. While initial results were encouraging,¹⁸ Fili et al. reported that the device was not a viable alternative to conventional surgery in patients with refractory glaucoma.¹⁹

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How to cite this article: Au L, Bhartiya S. Can We Ever Win with a Suprachoroidal Implant? J Curr Glaucoma Pract 2023;17(2):55–57.

Source of support: Nil Conflict of interest: None

SUPRACILIARY GLAUCOMA DEVICES: Ab Interno Approach

Cypass Micro Shunt

The Cypass micro shunt (Transcend Medical, United States of America; subsequently acquired by Alcon, United States of America) was the first and arguably the most popular, minimally invasive glaucoma surgical device to target suprachoroidal drainage.

The COMPASS trial (Cypass with phacoemulsification vs phacoemulsification alone) reported effective IOP lowering and a reduced need for medications, with a low rate of complications. The latter included hyphema, transient hypotony, malposition of the micro stent and peripheral anterior synechiae, which could potentially obstruct the device. Garcia-Feijoo et al. reported²⁰⁻²² that as many as 83% of eyes did not require another glaucoma surgery at 12 months following a Cypass implantation. Kerr et al. reported a 33% reduction in IOP and a 56% decrease in medication following Cypass implantation in patients with failed trabeculectomy or tube surgery.²³ Law et al.²⁴ found that CyPass Micro-Stent, along with cataract surgery, decreased both IOP and the number of glaucoma medications significantly, with a success rate ranging from 28 to 42% at 12 months follow-up.

The 5-year postapproval extension of the COMPASS trial, COMPASS-XT, however, reported a significant central endothelial loss (>30%) in the Cypass group (>27%) compared to the control (10%). Also, this loss was found to be associated with device malposition: in patients where two or three retention rings were visible on gonioscopy, the loss was around 10% at the end of 5 years, vs a cell loss of 2% in a correctly implanted device. Even though only 36 out of the original 200 patients were available for review at the end of three years, the Cypass Micro Shunt was withdrawn from the global market in 2018.^{5,16,25}

iStent Supra

The iStent Supra (Glaukos Corporation, Laguna Hills, California, United States of America) is made of biocompatible polyethersulfone

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and titanium with a heparin-coated lumen. The curved device follows the supraciliary contour and has retention ridges along the shaft so that its retention is not limited to the iris root. It is implanted like the Cypass micro shunt. The information on the safety and efficacy of the shunt is promising but is mostly nonpeer reviewed presentations, and therefore to be interpreted with caution.²⁶

MINIject

MINIject (iStar Medical, United States of America), made of the STAR material, features innovative micropores that encourage natural flow speed and decrease fibrosis and the consequent scarring. Denis et al. reported²⁷ that 96% of their first 25 patients achieved an IOP reduction of 20% or more, and 87% did not need IOP-lowering medication at 6 months. Complications like hyphema, IOP spikes and inflammation were transient and resolved without sequelae. At the 2-year follow up.²⁸ All patients were reported to have at least 20% IOP reduction, and almost half the patients were medicationfree. The authors reported no serious complications, endothelial cell loss, or need for additional glaucoma surgery. Feijoó et al. reported that ab interno MINIject DO627 significantly lowered eye pressures by 40% at the 6-month follow-up, with more than half the patients being medication free at 6 months. They also reported transient complications like eye pain, corneal erosion, and chorioretinal folds, all of which resolved without sequelae.²⁹

LEARNINGS SO FAR

- The implant has to be made of biologically inert biomaterials in order to prevent, or at least retard, the formation of a lowpermeability fibrous capsule around the device in order to enable long-term IOP reduction.
- For now, tubes seem to have functioned better than plates, and ab interno procedures have performed better than ab externo suprachoroidal implants. While this is counterintuitive, a possible reason could be the material (newer generation implants are more bioinert) and the microchannels of plates probably get clogged before the larger lumen of the tubes. Also, lumina may just be amenable to pharmacomodulation with heparin/antivascular endothelial growth factor/antimetabolites.
- A device that is anchored not only at the iris root but throughout its contour will be the better option. The greater stability of the device will also ensure fewer chances of erosion and implant migration and less endothelial loss. Also, surface markings on the device to guide its appropriate implantation will also flatten the learning curve for the surgery, resulting in better clinical outcomes.

The surgical manipulation of the suprachoroidal space has been equally fascinating and frustrating for the glaucoma surgeon. In theory, it offers an elegant solution: one that is minimally invasive, bleb free, and effective. The execution yet is to live up to its promise. Each failed implant, however, has set the stage for one that is safer and more effective. The suprachoroidal space may just be the final frontier in our quest for the perfect glaucoma surgery. And the solution, perhaps just around the corner.

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