The Role of Suprachoroidal Stents

Where will they fit in the glaucoma treatment paradigm?

BY BRIAN FLOWERS, MD

A concerted effort is underway to develop glaucoma surgical interventions that approximate modern cataract surgery with regard to safety, efficacy, and the experience of patients. A therapeutic gap exists between relatively benign medical treatment and laser surgery at one end of the spectrum and invasive filtration surgery at the other. There will long remain a role for trabeculectomy and glaucoma drainage devices, because there will always be patients who require very low IOPs or whose options for treatment are limited. Unfortunately, these individuals are at significant risk of serious complications, including a loss of BCVA and a need for additional surgery. Additionally, I believe that the characterization of these filtering procedures as definitive solutions is overstated. The published failure rates of trabeculectomy and glaucoma drainage devices are much higher than glaucoma specialists care to admit.[1]

Awareness of the aforementioned therapeutic gap has led to the development of several devices for microinvasive glaucoma surgery. The goal of these procedures is to reduce IOP meaningfully but also to offer a stronger safety profile and a vastly improved experience for patients compared with filtration surgery. Various approaches to microinvasive glaucoma surgery have been put forth, including trabecular implants (iStent Trabecular Micro-Bypass Stent [Glaukos], Hydrus [Ivantis; not available in the United States]) and trabecular ablation techniques (Trabectome [NeoMedix]). This article focuses on the place of suprachoroidal devices in modern glaucoma surgery.

> "A therapeutic gap exists between relatively benign medical treatment and laser surgery at one end of the spectrum and invasive filtration surgery at the other."

WHY THE SUPRACHOROIDAL SPACE?

The suprachoroidal space is an attractive target for several reasons. First, there is a large surface area and a negative pressure gradient, which provides a great driving force for aqueous outflow. In addition, clinical experience has shown the significant effect a cyclodialysis can have on IOP.

Attempts to use the suprachoroidal space to lower IOP in glaucoma patients date back nearly 100 years. Investigators have placed horse hair, platinum wires, magnesium strips, and various plastics into the suprachoroidal space to maintain a functioning cyclodialysis.[2,3] None of these materials proved successful owing to significant complications or poor long-term efficacy. Of late, there has been a renewed interest in using the suprachoroidal space to treat glaucoma.

SUPRACHOROIDAL DEVICES

The CyPass Micro-Stent

The CyPass Micro-Stent (Transcend Medical) is a biocompatible polyimide stent meant to provide a permanent conduit from the anterior chamber to the suprachoroidal space. The device measures 6.35 mm in length, with

Weigh in on this topic now!

Direct link: https://www.surveymonkey.com/s/GT18

How interested are you in the development of surgical interventions that target the suprachoroidal space?

- ☐ Very
- ☐ Somewhat
- ☐ Not at all

a 300-µm lumen and 76-µm fenestrations along its distal end. The stent is placed ab interno via a clear corneal incision while loaded on a guidewire. Retention rings help ensure its stability.

This device is the subject of three major European studies and a phase 3 investigational device exemption study in the United States. The US study completed enrollment more than 1 year ago. It enrolled 505 patients who are to be observed for 2 years. Data from the European studies have been presented in a variety of forums. In one prospective, single-armed study, the CyPass was placed in 65 patients whose glaucoma was refractory to medical therapy. Their IOP was reduced from a mean of 24.5 mm Hg pretreatment to 16.8 mm Hg at 1 year (P = .0001). Their use of medication decreased from a mean of 2.2 to 1.5 at 1 year (P = .008). There were no significant complications. Nine patients required additional glaucoma surgery.[4]

In a study with 2 years' follow-up, investigators examined patients' responses to phacoemulsification combined with implantation of the CyPass. Subjects were divided into two cohorts. Cohort 1 consisted of 51 patients who had a baseline IOP greater than 21 mm Hg. Cohort 2 consisted of 85 patients who had a baseline IOP less than 21 mm Hg. In cohort 1, the mean IOP decreased from 25.5 to 15.8 mm Hg (P = .0001), and mean medication use dropped from 2.2 to 1.0 at 2 years (P = .0265). In cohort 2, the mean IOP was reduced slightly from 16.4 to 16.1 mm Hg, and the mean medication use decreased from 2.0 to 1.1 at 2 years (P = .0001). There were no major complications. Seven patients required additional glaucoma surgery.[5]

The iStent Supra

The iStent Supra (Glaukos) is a suprachoroidal stent made from a heparin-coated combination of polyethersulfone and medical-grade titanium. The device is 4 mm long and has a 165-µm lumen. It is placed ab interno via a clear corneal incision and has retention rings to help ensure its stability.

There are trials in Europe, and a US phase 3 investigational device exemption study is currently enrolling patients. Very little has been published on this device thus far. In one European report, 42 subjects were monitored for 1 year after receiving an iStent Supra and beginning therapy with travoprost ophthalmic solution 0.004% (Travatan; Alcon). The pretreatment unmedicated IOP was 24.8 mm Hg and 20.4 mm Hg on Travatan. The investigators reported that 98% of patients met the primary endpoint, which was a decrease in IOP greater than 20% and a reduction of at least one medication.[6]

CONCLUSION

I am pleased by the continuing interest in the suprachoroidal space. There is likely a greater potential to lower IOP via the suprachoroidal space than by means of the trabecular meshwork or Schlemm canal. The impediment to long-term success has been cellular proliferation and fibrosis.[7] It is to be hoped that these newer devices can overcome this obstacle. In my experience, the implantation of devices in Schlemm canal is virtually unnoticed by the patient. Thus far, the IOP response has been reasonable but less than ideal. The newer suprachoroidal devices have a greater impact on the experience of patients than the Schlemm canal implants, but few patients have any symptoms beyond 1 week. The suprachoroidal stents appear to have the potential to lower IOP satisfactorily and, importantly, have not been plagued with hypotony. The forthcoming results of the US trials will be welcome. ■

Brian Flowers, MD, is a glaucoma specialist at Ophthalmology Associates in Fort Worth, Texas. He is a consultant to Alcon, Glaukos, Ivantis, and Transcend Medical. Dr. Flowers may be reached at (817) 332-2020; bflowers@oafw2020.com.

1. Gedde SJ, Schiffman JC, Feuer WJ, et al, on behalf of the Tube Versus Trabeculectomy Study Group. Three-year follow-up of the Tube Versus Trabeculectomy Study. *Am J Ophthalmol*. 2009;148:670-684.
2. Troncoso MU. Cyclodialysis with the insertion of a metal implant in the treatment of glaucoma: a preliminary report. *Arch Ophthalmol*. 1940;23:270.
3. Lee KY, et al. Magnetic resonance imaging of the aqueous flow in eyes implanted with the trabeculo-suprachoroidal glaucoma seton. *Invest Ophthalmol Vis Sci*. 1992;33(suppl):948.
4. Nardi M, Gargia-Feijoo J, Rau M, et al. Safety and efficacy of stand-alone CyPass Micro-Stent implantation in patients refractory to topical glaucoma therapy (Duette Study): 1 year results. Presented at: The European Society of Cataract and Refractive Surgeons; 2013; Amsterdam, the Netherlands.
5. Flowers BE, Vold S, Hoh H, et al. Two-year clinical experience after combined cataract surgery and supraciliary microstent implantation to treat glaucoma. Poster presented at: The American Academy of Ophthalmology Annual Meeting; 2013; New Orleans, LA.
6. Junemann J. Twelve month outcomes following ab interno implantation of a suprachoroidal stent and postoperative administration of travoprost to treat open angle glaucoma. Presented at: The European Society of Cataract and Refractive Surgeons; 2013; Amsterdam, the Netherlands.
7. Reas M, Pawlik B, Grala B, Kozłowski W. Clinical and morphological evaluation of gold micro shunt after unsuccessful surgical treatment of patients with primary open-angle glaucoma. *Eye (Lond)*. 2013;27(10):1214-1217.