Investigating Selected MIGS Approaches


A close examination raises several questions for patients in whom a very low target IOP is needed.

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Glaucoma is the leading cause of irreversible blindness worldwide.[1] Trabeculectomy and tube shunt implantation are the most common surgical procedures for treatment of the disease. Although microinvasive glaucoma surgery (MIGS) procedures are gaining popularity for the treatment of mild to moderate glaucoma, until recently they have not been routinely used in patients with more advanced optic nerve damage who require a very low target IOP.

The Xen45 Gel Stent (Allergan) and InnFocus MicroShunt (Santen) have the potential to combine the safety profile of MIGS with the IOP-lowering ability of traditional glaucoma surgeries. Unlike other MIGS devices, the Xen45 and InnFocus MicroShunt bypass the conventional outflow pathway and shunt aqueous from the anterior chamber to the subconjunctival space, creating a filtering bleb. Both technologies have the ability to provide greater IOP lowering than devices with other outflow targets.

SHUNTING TO THE SUBCONJUNCTIVAL SPACE: THE UNKNOWNS

The Xen45, which is 6 mm in length with a 45-µm lumen, is placed in an ab interno manner. The InnFocus MicroShunt, which measures 8.5 mm in length with a 70-µm lumen, is implanted via an ab externo approach. In the United States, the Xen45 is indicated for patients with open-angle glaucoma who are unresponsive to maximal tolerated medical therapy and for those with refractory glaucoma. The InnFocus MicroShunt is not yet approved for use in the United States, although enrollment in the pivotal trial comparing this device to trabeculectomy was recently completed.

Devices and surgical procedures that target the trabecular meshwork, Schlemm canal, and the suprachoroidal space are rather straightforward in terms of surgical technique. The biggest unanswered question related to these procedures is, "Which one is best?" The answer often depends on proper patient selection. However, when it comes to devices that shunt aqueous to the subconjunctival space, there are many more unknowns.

Although several studies have evaluated the Xen45, many questions regarding how to optimize success with this device remain. Numerous unknowns exist, including:

- How much mitomycin C (MMC) should be used?

AT A GLANCE

- The Xen45 and InnFocus MicroShunt bypass the conventional outflow pathway and shunt aqueous from the anterior chamber to the subconjunctival space, creating a filtering bleb.
- Randomized, prospective trials comparing surgical techniques and outcomes with varying doses of mitomycin C will help optimize results.

"ONCE WE LEARN HOW BEST TO CREATE THESE BLEBS, WE WILL NEED TO DETERMINE HOW BEST TO MANAGE THEM IN THE EARLY AND LATE POSTOPERATIVE PERIODS."

- Should MMC be injected beneath the conjunctiva or directly into the Tenon capsule?
- Should MMC be injected before or after device implantation?
- Can the device be implanted anywhere in the superonasal quadrant, or does the surgeon need to get as close as possible to 12 o'clock to avoid possible erosion?
- How does the surgeon consistently position the distal tip in the subconjunctival space and avoid obstruction by Tenon tissue?

There are also questions about how to troubleshoot commonly encountered intraoperative issues.

A QUESTION OF PLACEMENT

For us, the biggest question that remains unanswered is whether the Xen45 should be placed in the subconjunctival space or beneath the Tenon capsule. Prior studies have evaluated both approaches, but their results cannot be compared because stents of various lumen diameters were used with different concentrations of MMC delivered. The primary advantage of placement in the subconjunctival space is that this method takes full advantage of the ab interno approach. Because no conjunctival incision is needed, tissue disruption is minimal, and quicker visual recovery is anticipated.

In our experience, however, Xen45 placement in the subconjunctival space can be technically challenging, regardless of which method is employed to assist with separating Tenon capsule from the conjunctiva. Additionally, if the stent is malpositioned after being deployed, it cannot be easily manipulated through the overlying conjunctiva. Finally, if the device becomes encased in even a small amount of Tenon membrane, early failure can occur, necessitating needling in the early postoperative course. (Needling on the table is suggested when this problem occurs intraoperatively.)

Placement of the device beneath the Tenon capsule via an ab interno approach requires a conjunctival peritomy (3 mm) with conjunctival dissection. Episcleral vessels can be cauterized to minimize the amount of bleeding when the injector exits the sclera. If the device's location is not ideal, the distal end of the stent can be grasped, and the device can be easily manipulated into the proper position. Flow through the device can be confirmed, and the Tenon/conjunctival layer can be brought over the shunt and up to the limbus and secured with a running polyglactin suture.

Although this approach has its advantages, the question remains whether conjunctival manipulation increases the chance of late device failure from more significant episcleral fibrosis. The pivotal article by Grover et al[3] used this approach and found a high needling rate. However, the concentration and duration of MMC used (0.2 mg/mL on two half-moon soaked pledgets for 2 minutes) was far less than what many surgeons currently use when implanting the device. We inject 40 to 80 µg of MMC 10 mm posterior to the limbus prior to opening the conjunctiva. At these doses, we have been able to achieve successful outcomes, although long-term follow-up is warranted. The procedure does take significantly longer when opening the conjunctiva, but the benefits are what we perceive to be a lower needling rate and less early failure.

Once approved, the InnFocus MicroShunt will be implanted beneath Tenon capsule, although the implant will be placed via an ab externo approach.

Regardless of the technique employed, preliminary data suggest that lower target IOPs can be achieved with these devices than with Schlemm canal-based procedures, which may be more appropriate for patients with an earlier stage of glaucoma.[2-5] The length and luminal diameter of these shunts limit aqueous outflow and minimize the risk of hypotony while producing lower, more diffuse blebs that may be less prone to infection in the long term. Once we learn how best to create these blebs, we will need to determine how best to manage them in the early and late postoperative periods.

CONCLUSION

Randomized, prospective trials comparing these surgical techniques as well as outcomes with varying doses of MMC will help guide the glaucoma surgeon and optimize results. ■

1. Tham YC, Li X, Wong TY, et al. Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. *Ophthalmology*. 2014;121:2081–2090.
2. Sheybani A, Dick B, Ahmed I. Early clinical results of a novel ab interno gel stent for the surgical treatment of open-angle glaucoma. *J Glaucoma*. 2016;25:e691–e696.
3. Grover D, Flynn W, Bashford K, et al. Performance and safety of a new ab interno gelatin stent in refractory glaucoma at 12 months. *Am J Ophthalmol*. 2017;183:25-36.
4. Schlenker MB, Gulamhusein H, Conrad-Hengerer I, et al. Efficacy, safety, and risk factors for failure of standalone ab interno gelatin microstent implantation versus standalone trabeculectomy. *Ophthalmology*. 2017;123:1579–1588.
5. Galal A, Bilgic A, Eltanamly R, et al. Xen glaucoma implant with mitomycin C 1-year follow-up: result and complications. *J Ophthalmol*. 2017;2017:5457246.

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