MY FIRST SUBCONJUNCTIVAL MIGS CASES

The learning curve, the snags, and the overall experience of adopting a new procedure.

BY INDER PAUL SINGH, MD



I was intrigued by the prospect of a subconjunctival microinvasive glaucoma surgery (MIGS) device with a good adverse event profile that could help reduce or eliminate the burden of medication for patients whose IOP remained uncontrolled on multiple drops.^{1,2} Actually performing a new procedure can be daunting, however, so

I felt both excited and nervous when I started using the Xen45 (Allergan) in February.

For me, the biggest challenge was comfortably manipulating the stent loader with one hand. I had to learn how to hold it and how much forward pressure to apply to the plunger to release the stent into the subconjunctival space. As with any surgical procedure, a muscle memory has to form, and that occurred fairly quickly for me with this MIGS procedure. After a few training sessions, both didactic and wet lab, I had the confidence to move ahead. My first five cases were scheduled for a single day.

MY FIRST CASE

Presentation

My first patient was a 70-year-old diabetic and hypertensive pseudophakic man with advanced open-angle glaucoma and significant optic nerve damage (0.9 cup-to-disc ratio) in his right eye. He had been using four topical antihypertensive medications but had become nonadherent because of side effects and the cost of therapy. The preoperative IOP was in the low 20s on all topical medications.

I recommended the Xen, which has an improved safety profile compared with traditional filtering surgery based on less risk of bleb leakage or infection.3-5

Surgical Course

After marking the planned exit point of the stent (3 mm posterior to the limbus), I injected 0.1 mL of 0.2 mg/mL of mitomycin C (MMC) posteriorly, while making sure to keep the MMC away from the limbus. Next, I made an inferior, temporal, 1.5-mm clear corneal incision into the anterior chamber. I injected preservative-free lidocaine and then viscoelastic to deepen the chamber. I made a superior 11

For me, the biggest challenge was comfortably manipulating the stent loader with one hand."

temporal paracentesis to help stabilize the eye during the stent's insertion.

After double-checking the angle with a gonioprism, I removed the implant's protective cover, tested the loading device, and then introduced it into the eye. I was able to use the gonioprism (without needing to turn the patient's head or the microscope) to ensure that I was engaging the angle just anterior to the trabecular meshwork. Next, I pushed the needle through the sclera (only minimal resistance felt) until I could see the instrument exit into the

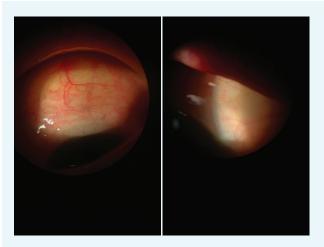


Figure 1. One day after surgery, healthy, diffuse, low blebs are evident, and the conjunctiva is quiet.

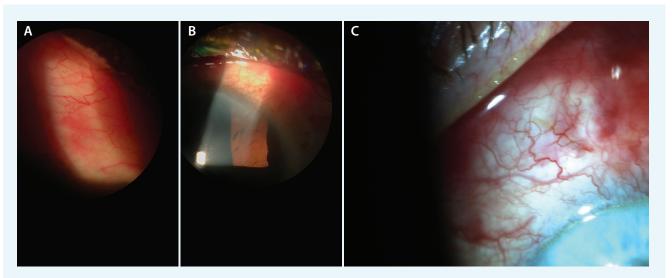


Figure 2. The stent in the subconjunctival space on postoperative day 1 (A and B). Viewed close up (C).

subconjunctival space close to my markings. I then rotated the needle to the 12-o'clock position and slowly pushed the blue lever on the loader forward to release the stent. I made sure to hold the loader in position until I felt confident that the entire implant had been released. Only then did I extract the loading device from the eye.

With manual irrigation and aspiration, I removed the viscoelastic, hydrated the incisions, and observed a low, healthy bleb. I administered topical antibiotic and steroid drops and placed an eye shield.

I was pleased to have properly positioned the stent in the superior nasal quadrant on my first try. The patient had been comfortable throughout the case with minimal intravenous sedation.

Outcome

One day postoperatively, the patient's visual acuity approached baseline (20/30), the IOP measured 7 mm Hg, the anterior chamber was deep and quiet, and there was no retinal edema. The bleb was low and diffuse. Unlike many of my patients after trabeculectomy or the placement of a glaucoma drainage device, this patient had no complaint of foreign body sensation.

One month after surgery, he no longer needed glaucoma medication. The patient was only using artificial tears and a topical steroid. (Steroids are tapered after a few months, depending on aqueous flow and the health of the coniunctiva.)

BUILDING EXPERIENCE

My remaining four cases that day went well but presented a few challenges.

In one case, I pushed the loader too hard, releasing the stent too far into the subconjunctival space. Using forceps on the conjunctiva, I was easily able to draw the implant back into the anterior chamber. In another case, I delivered the stent beautifully, but I pulled back too quickly as I released the loader, thus moving the implant too far into the anterior chamber. I extracted the MIGS device with my forceps, reloaded the stent, and reimplanted it in the eye (see Watch It Now).





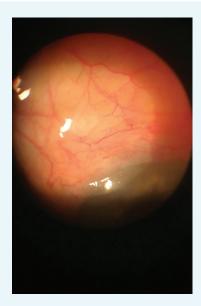


Figure 3. Two months postoperatively, the bleb is diffuse with healthy vessels. The IOP is 10 mm Hg off medication, and the patient is happy.



Figure 4. My only patient who continues to require glaucoma medication after the Xen procedure will undergo bleb needling for more diffuse flow.

To prevent fibrosis, I use an off-label MMC subconjunctival injection technique, which, in one case, caused a subconjunctival hemorrhage. Despite some difficulty visualizing the stent through the hemorrhage, I was able to place the device successfully. In another case, I could not see a bleb form after implanting the MIGS device, likely because of viscoelastic in the stent and/or subconjunctival space. A continuous injection of balanced salt solution into the anterior chamber flushed the viscoelastic out of the anterior chamber and stent, allowing me finally to watch a low, diffuse bleb form.

The postoperative period was fairly uneventful, resembling that of other typical MIGS procedures. A key difference, of course, is the need to manage a bleb, although its morphology is unlike that of standard filtering blebs. I find Xen blebs to have a very low, diffuse appearance (often hard to identify), and the vessels seem to be quiet and to have less avascularity despite the use of MMC (Figures 1 and 2).

I had to perform digital massage on one eye 1 week after surgery because of an IOP increase from 10 mm Hg on postoperative day 1 to 18 mm Hg at week 1. Compared with my other first cases, this eye had a thicker baseline Tenon capsule, and I implanted the stent under the capsule rather than above it. Having now performed 20 cases, I am finding that placing the stent above Tenon capsule—as recommended by Ike Ahmed, MD—produces healthier,

more diffuse blebs with less fibrosis and encapsulation.

One month postoperatively, this patient was doing well with a healthy, low, diffuse bleb and an IOP of 12 mm Hg. He was using a topical steroid four times daily and artificial tears as needed. I should note that digital massage needs to be applied a little longer in Xen patients than after traditional filtering surgery because of the device's small lumen. I usually ask patients to count to 10 as I apply constant pressure from below.

CONCLUSION

The FDA cleared the Xen for the treatment of refractory glaucoma. In my first five cases, postoperative IOP at day 1 ranged from 5 to 13 mm Hg, anterior chambers were formed and quiet, and I observed no choroidals. The IOP has remained stable at follow-up, and more importantly, the patients are happy (Figure 3).

I am now performing two or three Xen procedures a week. Of all my patients so far, only one uses glaucoma drops (Figure 4), and another is being scheduled for bleb nee-

dling. I record the time I spend with patients during followup visits, and those who have undergone subconjunctival MIGS require 40% less time on average than my patients who have traditional trabeculectomy.

Patients' quality of life is a significant consideration for me. Based on my experience, MIGS procedures are an important option for patients who are unable to tolerate, afford, or remember topical glaucoma therapy.

- 1. Eydelman MB. 510(k) Summary: Allergan Xen Glaucoma Treatment System. Silver Spring, MD: Food and Drug Administration; November 21, 2016. https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161457.pdf. Accessed May 9. 2017.
- 2. Pérez-Torregrosa VT, Olate-Pérez Á, Cerdà-Ibáñez M, et al. Combined phacoemulsification and Xen45 surgery from a temporal approach and 2 incisions. Arch Soc Esp Oftalmol. 2016:91(9):415-421.
- 3. Samuelson TW, Katz LJ, Wells JM, et al; US iStent Study Group. Randomized evaluation of the trabecular microbypass stent with phacoemulsification in patients with glaucoma and cataract. *Ophthalmology*. 2011;118(3):459-467. 4. DeBry PW, Perkins TW, Heatley G, et al. Incidence of late-onset bleb-related complications following trabeculectomy with mitomycin. Arch Ophthalmol. 2002;120(3):297-300.
- 5. Edmunds B, Thompson JR, Salmon JF, Wormald RP. The National Survey of Trabeculectomy. III. Early and late complications. Eye (Lond). 2002;16(3):297-303.

Section Editor Richard A. Lewis, MD

- private practice in Sacramento, California
- (916) 649-1515; rlewis@saceye.com

Inder Paul Singh, MD

- practices at The Eye Centers of Racine and Kenosha in Wisconsin
- (262) 637-0500; ipsingh@amazingeye.com
- financial disclosure: consultant to Allergan