



HAS A REPLACEMENT FOR TRABECULECTOMY FINALLY ARRIVED?

A new surgical device will substantially reduce the need for this procedure.

BY DAVINDER S. GROVER, MD, MPH



Although most glaucoma subspecialists still consider trabeculectomy to be the gold standard in glaucoma surgery, nearly all of them have been searching for a safer, better, and more predictable method of creating a new outflow pathway in eyes with the disease. My surgical algorithm for glaucoma patients is first to try to open and exploit

the eye's inherent drainage system with an angle-based approach such as gonioscopy-assisted transluminal trabeculectomy, the Kahook Dual Blade (New World Medical), and the iStent Trabecular Micro-Bypass Shunt (Glaukos). When angle-based glaucoma surgery is not successful, then I need to create a new outflow system for the eye. Traditionally, this can only be accomplished by performing either a trabeculectomy or implanting a glaucoma drainage device, but both procedures are fraught with serious complications such as blebitis, tube erosion, double vision, and hypotony.

Although I love caring for glaucoma patients and feel strongly that a significant portion of moderate to advanced glaucoma should be treated surgically, my dream is never to perform another trabeculectomy or tube shunt procedure again. Fortuitously, a golden era of safer glaucoma surgery has dawned, with several techniques and devices approved or in trials that create a new drainage system in the eye. Compared with traditional glaucoma surgery, these novel procedures are less invasive and offer improved safety, predictability, and efficiency. The Xen45 (Allergan), for example, has the potential to revolutionize the way in which glaucoma is treated in the United States.

A PROMISING ADVANCE

Recently approved by the FDA, the Xen is a hydrophilic cylindrical implant of porcine gelatin cross-linked with

(Continued on page 28)

Trabeculectomy remains the gold standard glaucoma surgical procedure.

BY STEVEN J. GEDDE, MD



Despite the recent introduction of several new procedures collectively known as microinvasive glaucoma surgery (MIGS), trabeculectomy remains the most commonly performed incisional glaucoma surgery worldwide. It has been considered the gold standard glaucoma surgical procedure since it was popularized by Cairns

in 1968.¹ Ophthalmologists have gained a wealth of clinical experience with trabeculectomy over the past half-century, and no other procedure has been found more effective at lowering IOP.

The risk of bleb infections, leaks, and dysesthesia associated with trabeculectomy has prompted many surgeons to seek alternative approaches to the surgical management of glaucoma. Advances in surgical technique, however, have reduced the rate of bleb-related complications. The use of a fornix-based conjunctival flap with diffuse mitomycin C application or injection produces blebs that are less prone to problems (Figure).²

A more favorable safety profile is the most attractive feature of MIGS, but at present, improvements in the safety of glaucoma procedures come at the expense of efficacy. It is not surprising that procedures that produce only a modest IOP reduction carry a lower risk of hypotony-related complications. The current treatment of glaucoma, however, is directed entirely toward decreasing IOP. Furthermore, the benefit of pressure reduction appears to be dose dependent, with greater IOP control resulting in lower rates of glaucomatous progression.³

NEW KID ON THE BLOCK

The Xen45 (Allergan) is the latest MIGS device to gain FDA approval. The collagen stent is inserted ab interno

(Continued on page 28)

(Dr. Grover, continued from page 27)

glutaraldehyde (Figure). The stent is designed to treat refractory glaucoma, including eyes in which prior glaucoma surgery failed and various forms of open-angle glaucoma refractory to maximum tolerated medical therapy. The US and European studies demonstrated that the gel stent is as safe and effective for the surgical treatment of refractory glaucoma as currently marketed devices.¹⁻³

To my knowledge, no published research is available comparing the Xen45 to trabeculectomy. The currently available prospective studies on the device demonstrate that it reduces IOP and patients' use of antiglaucoma medication without any serious or unexpected side effects or safety concerns. The results of these trials and of retrospective studies from Canada and the Dominican Republic demonstrate that the implant can be used to effectively manage refractory open-angle glaucoma.

Although the Xen is not without its complications (hyphema, malposition, conjunctival perforation, occlusion, and rarely, erosion), most of these problems can be avoided with proper surgical training and postoperative management. Importantly, although implantation may look easy, the procedure is relatively challenging and can quickly become complicated if not well executed. An attractive and unique aspect of the Xen is the ab interno delivery mechanism, which eliminates the requirement for a conjunctival incision. The implant may be the least invasive and, thus, safest method of creating a new drainage system into the subconjunctival space. Surgery still creates a bleb, but its morphology is characteristically low, posterior, and diffuse, which is highly desirable. That said, when performing this surgery, the ophthalmologist must be comfortable managing a bleb as well as occasionally performing a needling procedure.

LOOKING AHEAD

The big questions about the Xen relate to long-term safety, results outside of clinical trials, outcomes in patients with various subtypes of glaucoma and ethnic backgrounds, cost (which is a major consideration), and long-term integrity in the real world.

(Dr. Gedde, continued from page 27)

through a clear corneal incision, and the device shunts aqueous humor from the anterior chamber to the subconjunctival space. Because aqueous is diverted subconjunctivally, the stent has the potential to reduce IOP to a greater degree than other MIGS devices that enhance outflow through the collector system (eg, iStent Trabecular Micro-Bypass Stent [Glaukos], Trabectome [NeoMedix], Hydrus Microstent [Ivantis], Kahook Dual Blade [New World Medical], and Trab360 [Sight Sciences]). Limited clinical data on the Xen are currently available in the peer-reviewed literature,⁴⁻⁷ but initial results are encouraging. Case series have reported that the IOP decreases to the midteens after the stent's placement without an antifibrotic agent, although needling procedures were required in 32% to 47% of patients.^{4,5}

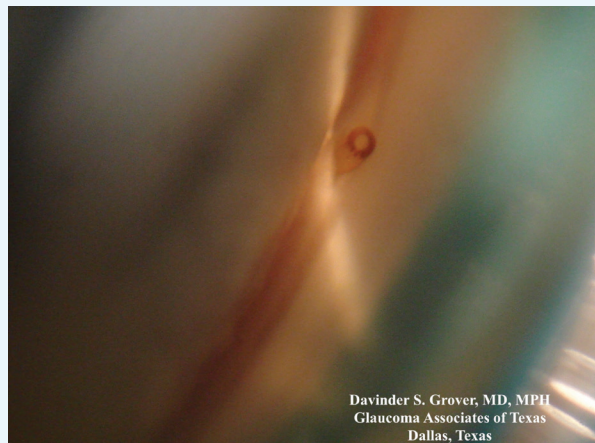


Figure. Gonioscopic view of the Xen45.

I consider the Xen to be an excellent option for surgical glaucoma patients with moderate to advanced disease, because the device allows me to safely, effectively, and predictably create a new drainage system to control IOP. Although the implant may never 100% replace trabeculectomy as a glaucoma surgery, I feel sure that the stent will substantially decrease the number of trabeculectomies and tube shunt procedures that I will have to perform. ■

1. Lewis RA. Ab interno approach to subconjunctival space using a collagen glaucoma stent. *J Cataract Refract Surg*. 2014;40:1301-1306.
2. Sheybani A, Lenzhofer M, Hohensinn M, et al. Phacoemulsification combined with a new ab interno gel stent to treat open-angle glaucoma: pilot study. *J Cataract Refract Surg*. 2015;41(9):1905-1909.
3. Sheybani A, Dick HB, Ahmed II. Early clinical results of a novel ab interno gel stent for the surgical treatment of open-angle glaucoma. *J Glaucoma*. 2016;25(7):e691-696.

Davinder S. Grover, MD, MPH

- attending surgeon and clinician, Glaucoma Associates of Texas, Dallas
- clinical assistant professor, University of Texas, Southwestern Medical School, Dallas
- adjunct assistant professor, University of North Texas, Health Science Center, North Texas Eye Research Institute, Fort Worth
- dgrover@glaucomaassociates.com
- financial disclosure: speaker for and consultant to Allergan and an investigator during US trials of the Xen implant

TITRATION

The ability to titrate IOP postoperatively is a clear advantage of trabeculectomy over all other glaucoma procedures. Surgeons commonly perform laser suture lysis to decrease IOP after trabeculectomy, and this approach is particularly valuable in patients with markedly elevated IOP. Large reductions in IOP have been shown to increase the risk of suprachoroidal hemorrhage,⁸ and a stepwise lowering of IOP with sequential laser suture lysis can ameliorate this risk. Because patients respond differently to glaucoma surgery, the ability to selectively increase filtration when the postoperative IOP is above a desired level is beneficial.

ECONOMICS

Health care is changing rapidly in the United States. It is incumbent on physicians to contain health care costs, and

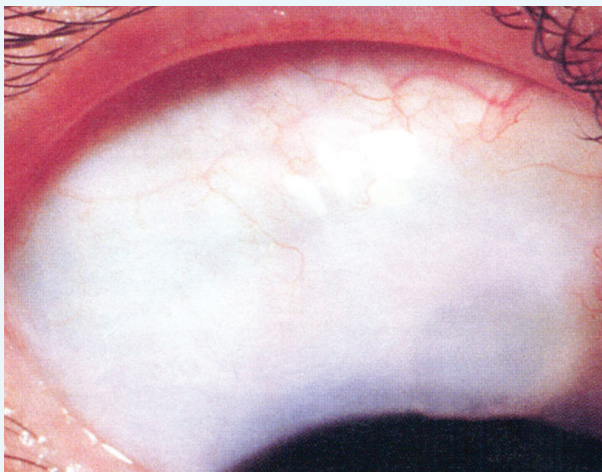


Figure. Filtering bleb after trabeculectomy with mitomycin C.

many of the MIGS devices represent a significant additional expense for patients and insurers. Moreover, physicians will continue to be paid for performance. Reimbursement will be linked to outcomes, including the success of glaucoma surgery. Trabeculectomy is more cost-effective than MIGS, and it is more likely to result in successful IOP control while avoiding glaucoma reoperation.

CONCLUSION

It is an exciting time in glaucoma care. The expansion of surgical options provides an opportunity for ophthalmologists to tailor the selection of a procedure to the individual patient. Long-term data are needed to fully evaluate the safety and efficacy of newer glaucoma procedures. Future surgical innovation in the field should address the trade-off between safety and efficacy that limits current options. It is to be hoped that an operation will become available that offers the efficacy of trabeculectomy and the safety of MIGS. Until then, trabeculectomy will continue to play a prominent role in glaucoma management. ■

1. Cairns JE. Trabeculectomy. Preliminary report of a new method. *Am J Ophthalmol*. 1968;66:673-679.
2. Solus JF, Jampel HD, Tracey PA, et al. Comparison of limbus-based and fornix-based trabeculectomy: success, bleb-related complications, and bleb morphology. *Ophthalmology*. 2012;119:703-711.
3. The AGIS Investigators. The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. *Am J Ophthalmol*. 2000;130:429-440.
4. Sheybani A, Lenzhofer M, Hohensinn M, et al. Phacoemulsification combined with a new ab interno gel implant to treat open-angle glaucoma: a pilot study. *J Cataract Refract Surg*. 2015;41:1905-1909.
5. Sheybani A, Dick B, Ahmed IK. Early clinical results of a novel ab interno gel stent for the surgical treatment of open-angle glaucoma. *J Glaucoma*. 2016;25:e691-e696.
6. Hohberger B, Welge-Luen UC, Lämmer R. ICE-syndrome: a case report of implantation of a microbypass Xen gel stent after DMEK transplantation [published online ahead of print November 10, 2016]. *J Glaucoma*. doi:10.1097/IJG.0000000000000584.
7. Fernandez-Garcia A, Romero C, Garzon N. "Dry lake" technique for the treatment of hypertrophic bleb following Xen gel stent placement. *Arch Soc Esp Ophthalmol*. 2015;90:536-538.
8. The Fluorouracil Filtering Surgery Study Group. Risk factors for suprachoroidal hemorrhage after filtering surgery. *Am J Ophthalmol*. 1992;113:501-507.

Steven J. Gedde, MD

- professor of ophthalmology and John G. Clarkson chair, Bascom Palmer Eye Institute, Miami
- (305) 326-6435; sgedde@med.miami.edu
- financial disclosure: has received research support from AqueSys (acquired by Allergan)