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Toward Standardization of Trabeculectomy: The EX-PRESS Device in Clinical Practice



Material from the 2011 AGS Symposium in Dana Point, California.

Sponsored by Alcon Laboratories, Inc.

An Advance for Glaucoma Filtration

This monograph is based on a symposium about the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX; Figure 1) that was held during the American Glaucoma Society meeting in Dana Point, California, in March of this year. The purpose of the symposium was to feature advances in glaucoma surgery that may benefit glaucoma patients because, ultimately, what is good for our patients is good for us. I feel that the EX-PRESS device is one of the more exciting of these advances, because it has the potential to standardize filtration in glaucomatous eyes.

Figure 1. The EX-PRESS Glaucoma Filtration Device as seen at the slit lamp after implantation.

The EX-PRESS Glaucoma Filtration Device is indicated to reduce IOP in glaucoma patients where medical and conventional surgical treatments have failed. It is my pleasure to work with Marlene Moster, MD, who participated in the device's clinical trials and has excellent data. I think you will find the information presented herein quite interesting and useful for your practice.

—Robert D. Fechtner, MD
Director of the Glaucoma Division at the
University of Medicine and Dentistry, Newark, New Jersey

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Is Trabeculectomy Still Our Best Surgical Option?

New devices are presenting interesting alternatives.

BY ROBERT D. FECHTNER, MD

I completed my glaucoma fellowship in 1991, and have devoted my academic and clinical career to glaucoma for the past 20 years. These years of experience have led me to ask the question: is the old trabeculectomy procedure I learned as a resident still the glaucoma surgeon's best surgical option? The purpose of glaucoma surgery is to control IOP so that we may preserve patients' visual function and ultimately maintain their quality of life. IOP control is the endpoint by which glaucoma surgery is measured, but it is equally important that the glaucoma surgery not create any avoidable complications. This article reviews the benefits and drawbacks of trabeculectomy versus other procedures to control IOP.

THE PROS AND CONS OF TRABECULECTOMY

Trabeculectomy has not changed much in the past 20 years, although each small change has improved its success or decreased complications. Other than slight differences in flap construction, anti-scarring strategies, or wound closure, the procedure still entails diverting aqueous from the anterior chamber to the subconjunctival space and hoping for sufficient but not excessive resistance to outflow. We continue to perform trabeculectomy because we believe it is effective at lowering IOP, although the Tube Versus Trabeculectomy study[1] suggests that perhaps the procedure is not as effective in the long run as we would like to believe.

The drawbacks of trabeculectomy are that its efficacy is unpredictable, and there are too many complications. Patients' postoperative IOP can be too low or too high. Their wound-healing response can be modulated, but not always sufficiently. Also, the procedure requires intensive postoperative care to achieve a favorable result. I tell my patients that half the work of trabeculectomy is done in the OR, and the other half is done postoperatively, when we identify the pattern of healing and adjust our interventions accordingly. My daily patient schedule is filled with post-trabeculectomy visits. Although we glaucoma surgeons have done our best over the years to modify the technique to minimize complications, I think we have to question the long-term success of this procedure. Only a few studies have looked at the 3- and 5-year success rates of trabeculectomy. The 5-FU Filtering Surgery study[2] showed a 50% rate of failure at 5 years—the same as in the Tube Versus Trabeculectomy study.

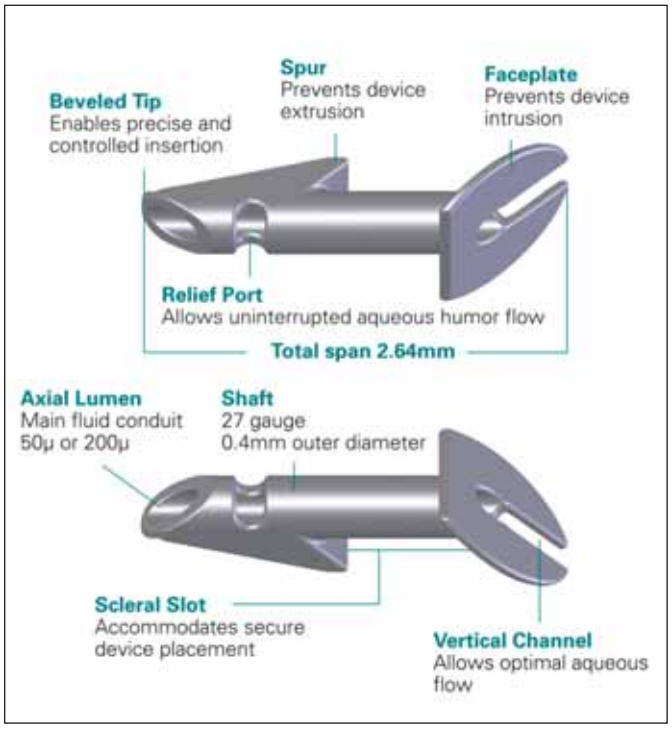


Figure 1. The EX-PRESS Glaucoma Filtration Device.

CONSIDERATIONS FOR TRABECULECTOMY SURGERY

Prior to performing trabeculectomy, we must identify the surgical risk factors and plan our surgical approach in the office, rather than on the table in the OR. Intraoperatively, I feel that certain strategies have significantly improved my surgical efficiency and reduced my intraoperative and early postoperative complications. For example, after I switched to using topical anesthesia, I no longer struggled with bleeding or hydration in the conjunctiva or Tenon's capsule. Switching to an incision at the limbus (fornix-based) improved my exposure and reduced the need for a skilled assistant.

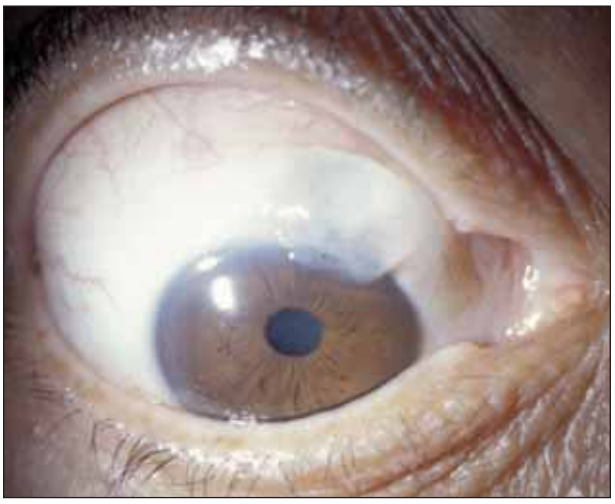


Figure 2. A high bleb migrated under the corneal epithelium and caused a dellen and discomfort. I was forced to reoperate on this thin, avascular bleb. I implanted a tube, and the patient is now comfortable and has controlled IOP.

A modification of the trabeculectomy procedure is to use a short tube under the scleral flap rather than create an ostium in the sclera or peripheral cornea. One such device that can be implanted under a scleral flap is the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX; Figure 1). This device has been available for several years, and we continue to gain experience with it. In one prospective study, de Jong randomized 78 glaucomatous patients to receive either the EX-PRESS device or trabeculectomy.[3] Although the mean IOP was statistically the same between the two groups, there was a greater rate of success (defined as an IOP of less than or equal to 18 mm Hg) in the patients who received the EX-PRESS device at 1 year follow-up.

At best, trabeculectomy results in desired long-term control of IOP, but the patient will have a bleb for the rest of his or her lifetime, which entails a 1% risk per year of endophthalmitis (Figure 2). It is trabeculectomy's unpredictability and the risk of complications and infection that has led practitioners to seek alternative approaches to lowering IOP surgically.

AQUEOUS-DIVERSION STRATEGIES TO CONTROL IOP

Tubes

Aqueous humor serves a purpose in the eye, and the reduction of IOP by aqueous diversion is more physiologic that aqueous suppression. There are only a few convenient spaces to which we can divert aqueous flow: the conventional outflow pathway, the subconjunctival space, and the uveoscleral space. The subconjunctival space can be accessed via trabeculectomy or tubes: long tubes; short, full-thickness, transscleral tubes (no longer advocated); or short tubes under a scleral flap. In my opinion, the biggest advance in our understanding of diverting aqueous to the subconjunctival space was the thoughtful, prospective study of tubes versus trabeculectomy conducted by Stephen Gedde, MD, and colleagues that has reported 3-year results.[1] In the study, more than 200 patients were randomized to undergo either trabeculectomy with mitomycin C or to receive a Baerveldt implant (Abbott Medical Optics Inc., Santa Ana, CA). While there are always limitations to generalizing from clinical trials, these investigators reported that tube shunt surgery had a higher success rate than trabeculectomy with MMC during the first 3 years of follow-up; the failure rate was greater in the trabeculectomy group than in the tube group.

Accessing the Conventional Outflow Pathway

Procedures designed to increase the aqueous' access to the conventional outflow pathways are available. Canaloplasty (iScience Interventional, Menlo Park, CA), as it is now performed by most surgeons, involves passing a device around the full circumference of Schlemm's canal and using it to place a suture within the canal that is then tied under tension. This procedure is performed under a scleral flap. Canaloplasty preserves the trabecular meshwork and works either through improving transmeshwork flow, distal flow, or both. Because canaloplasty has been performed in eyes with and without cataracts, it is somewhat challenging to analyze data on this technique. Although no prospective, randomized studies have examined this procedure, the canaloplasty study for open-angle glaucoma by Lewis et al now has 3-year data,[4] and it reported IOP-lowering efficacy in the study population. Also, some surgeons are taking the approach of converting canaloplasty to a filtering procedure with goniopuncture, either when IOP lowering is not sufficient or as a planned, staged procedure.

Another approach is ablation of the trabecular meshwork (the Trabectome [NeoMedix, Inc., Tustin, CA]), to

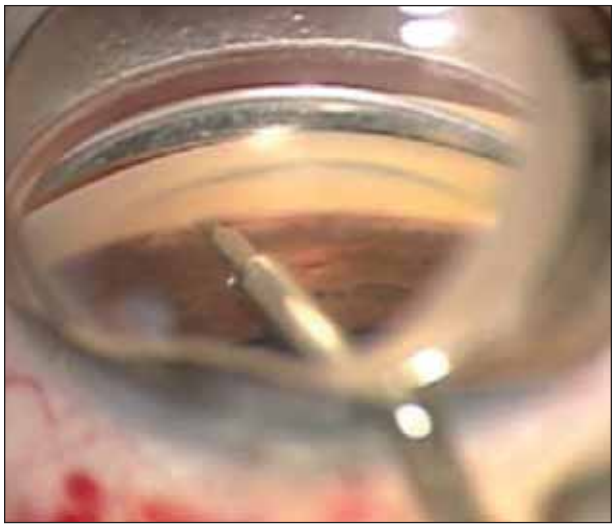


Figure 3. A slit-lamp view of an eye after undergoing the Trabectome procedure.

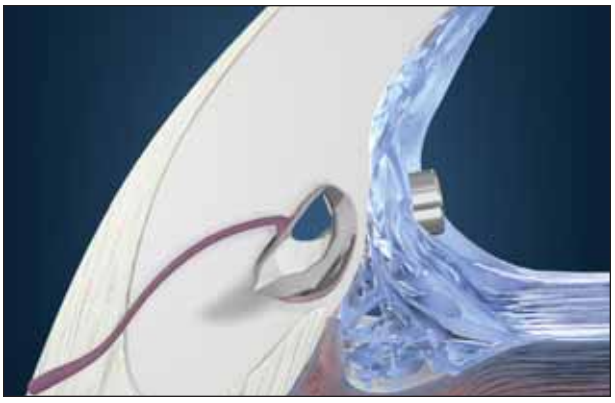
decrease outflow resistance. This is often performed in combination with another procedure such as cataract surgery. The Trabectome (Figure 3) is a new way to achieve anatomically what we do with goniotomy, albeit the former is an advancement in that it incises and also ablates tissue. An informal poll of audience members at the recent AGS meeting in Dana Point, California, found that nearly half had access to this technology.

A similar strategy is to bypass the trabecular meshwork by placing an unrestricted stent (the iStent [Glaukos Corp., Laguna Hills, CA; not available in the United States]) from the anterior chamber through the trabecular meshwork and into Schlemm's canal (Figure 4). Thomas Samuelson, MD, has published the results of a randomized evaluation of the iStent implanted after cataract surgery.[5] He found an incremental improvement in the number of patients who achieved a successful endpoint, although the cataract surgery lowered the IOP in at least 50% of the eyes. Again, it is challenging to judge the effects of procedures that are done in conjunction with other surgeries that also lower IOP.

Uveoscleral outflow is the physiologic diversion of aqueous to the suprachoroidal space. Choroidal detachment is pathologic. However, any physiologic pathway we create should be accessible. In the past, glaucoma surgeons used cyclodialysis, a very effective IOP-lowering procedure, although it was unpredictable and has largely been abandoned. In a proof-of-concept study published in the *Journal of Glaucoma*,[6] some end-stage glaucomatous eyes were implanted with a silicone tube that ran from the anterior chamber into the suprachoroidal space. This procedure effectively lowered IOP and had a fairly low complication rate. Since then, investigational shunts have been developed to access this space, such as the Solx Gold shunt (Solx, Inc., Waltham, MA; not available in the United States) and the CyPass implant (Transcend Medical, Inc., Menlo Park, CA; not available in the United States; Figure 5). Again, these devices do not yet have prospective, randomized studies to support their efficacy, but this area of the eye is interesting to consider as a potential target for aqueous diversion.

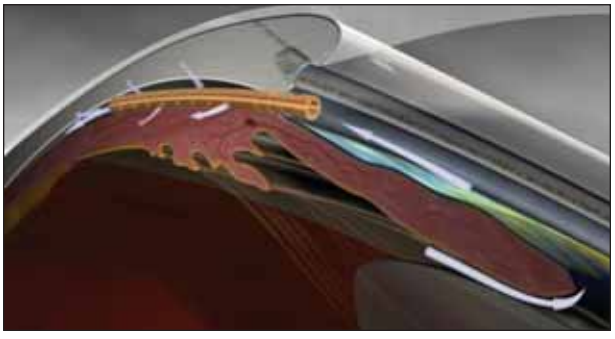
CONCLUSIONS

Is trabeculectomy still our best surgical option? I believe it is for some eyes. Most busy glaucoma surgeons still perform this procedure, although our acceptance of new approaches is growing. As alternatives emerge, we have the option to consider which procedure best fits the clinical situation for each patient. The quality of the study designs and the reporting surrounding these newer procedures varies considerably, however, and we would be well served if surgical clinical trial reports were modeled on the World Glaucoma Association's guidelines on reporting surgical study results.[7] Better-designed studies will help us continue to understand whether alternative surgical methods of controlling IOP are safer and more predictable than trabeculectomy. ■



(Courtesy of Glaukos Corp.)

Figure 4. The iStent trabecular microstent is the fraction of the size of a 1-cent coin.



Courtesy of Transcend Medical, Inc.)

Figure 5. The CyPass supraciliary device targets aqueous outflow through the supraciliary space.

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A Move Toward Standardization

What role the EX-PRESS Device plays in my clinical practice.

BY MARLENE MOSTER, MD, WITH KATHRYN B. FREIDL, MD

For the past 7 years, I have been using the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX). This article describes my clinical experience with the EX-PRESS device in glaucoma management, as well as my recommendations for incorporating it into the glaucoma surgeon's armamentarium.

WHERE THE EX-PRESS DEVICE FITS

Initially, I reserved my use of the EX-PRESS device for eyes with advanced disease. As my comfort with the EX-PRESS device has grown, however, I have expanded my use of it. The EX-PRESS device can be very effective as the first incisional surgery after laser trabeculoplasty and medications, and its ease of insertion also makes it a great surgical option for glaucoma residents.

Figure 1 shows a postoperative bleb after implantation of an EX-PRESS device. It demonstrates the ultimate goal of this implant: a low, diffuse bleb with a low IOP. The EX-PRESS device is designed to direct aqueous flow posteriorly, which may help avoid small cystic blebs that are prone to endophthalmitis-related blebitis (Figure 2).

INCORPORATING THE EX-PRESS DEVICE INTO CLINICAL PRACTICE

Placement

In order to implant the EX-PRESS device, the surgeon creates a partial-thickness (approximately 300-um) scleral flap, located either at the fornix or limbus (I have placed it in both positions with equal success) (Figure 3A). The scleral flap for the device can be triangular-trapezoidal or rectangular, but it must be large enough to cover the plate of the implant. I place the EX-PRESS device exactly at the grey line, parallel to the iris (Figure 3B). Then, I re-secure the scleral flap to the globe, tying it only moderately tightly in order to leave adequate posterior leakage. In the immediate postoperative period, the releasable or laserable sutures placed close to the limbus control the eye's IOP and may be adjusted as necessary. Using these sutures requires their removal at the slit lamp or laser suturelysis in the postoperative period in order to titrate the desired amount of aqueous outflow and IOP.

Patient Candidates

The EX-PRESS Glaucoma Filtration Device is indicated to reduce IOP in glaucomatous patients where medical and conventional surgical treatments have failed. For surgeons first starting to implant the device, I feel that the perfect patients with whom to gain experience are pseudophakes with temporal clear corneal incisions and

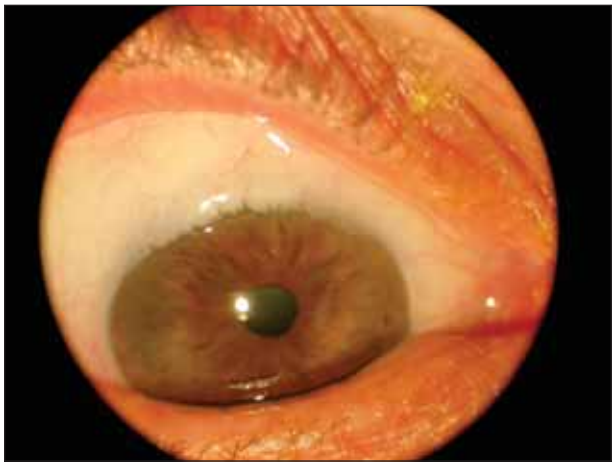

Figure 1. This eye shows the target outcome after implantation with the EX-PRESS device: a low, diffuse postoperative bleb with microcysts at the limbus and a low IOP.

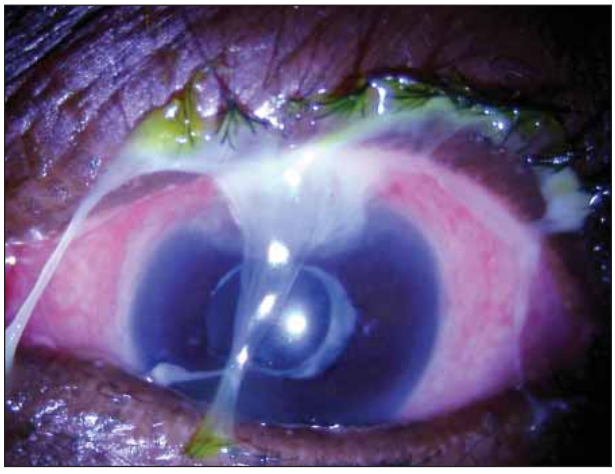

Figure 2. Cystic blebs can be prone to blebitis related to endophthalmitis.

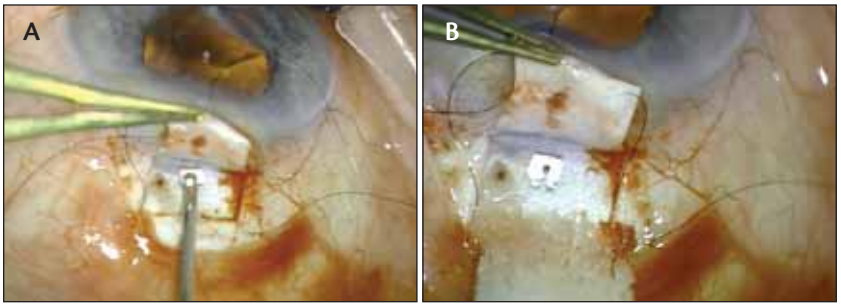

Figure 3. To implant the EX-PRESS device, the author first creates a scleral flap large enough to cover the plate of the implant (A). Then, she positions the EX-PRESS device exactly at the grey line, parallel to the iris (B).

virgin superior conjunctiva. Other appropriate candidates are virgin eyes with deep chambers and open angles that clearly require surgical glaucoma treatment, eyes that have failed a combined phaco/trabeculectomy (ie, "triple") but have enough room temporally for placing the device, and/or eyes in which the surgeon would prefer to place a tube shunt.

The EX-PRESS Device Versus Trabeculectomy

What is the difference between performing trabeculectomy and implanting the EX-PRESS device? Trabeculectomy involves removing a piece of the trabecular meshwork and then performing an iridectomy. It is a difficult procedure to standardize from case to case; the amount of aqueous efflux will vary based on the amount of tissue excised by the surgeon. The tightness of the flap sutures also affords additional variability. Lack of standardization is the main problem with trabeculectomy.

The EX-PRESS Glaucoma Filtration device has a 50-µm lumen that shunts the aqueous from the anterior chamber to underneath Tenon's capsule and conjunctiva. The device is small and takes up very little geography on the globe (Figure 4A-D). The EX-PRESS device provides a more consistent flow of aqueous than trabeculectomy, and the bleb is low and diffuse. The EX-PRESS device is also useful in scarred eyes, because it only needs a small amount of untouched conjunctiva for placement.[1] I consider the EX-PRESS device to be a better alternative than repeating a trabeculectomy where one has already failed. The EX-PRESS device's small size gives the surgeon the flexibility to achieve a low IOP while avoiding the larger tube shunts (although large shunts are still a viable option later, should the EX-PRESS device fail).

INSERTION OF THE EX-PRESS DEVICE

My colleagues and I recently published our intermediate-term results after implanting the EX-PRESS device under a scleral flap in eyes that had undergone a previous operation.[2] The study involved 100 eyes of 100 patients who we observed for more than 2 years. The mean preoperative IOP was 27 ±9.2 mm Hg with the use of 2.73 ±1.1 drugs, and the IOP fell to 14.02 ±5.1 mm Hg with the use of 0.72 ±1.06 drugs at the most recent follow-up visit, $P<.001$ (the mean follow-up period was 27 ±13.2 months). Also, the subjects required significantly less topical glaucoma medication. The rate of complete success (defined as an IOP of 5 to 21 mm Hg without medication or surgical intervention) at 1, 2, and 3 years was 79.8%, 64.4%, and 55.9%, respectively. A subset of patients who had undergone previous cataract surgery achieved a success rate of 59.6% by the third year, and eyes with previous trabeculectomies reached 65.3% success.

The causes of failure (having to repeat the surgery) with the EX-PRESS device included uncontrolled IOP (16%), persistent hypotony (1%), and needling of the bleb (4%). We were able to conclude that the EX-PRESS device implanted under a flap is a safe and effective form of glaucoma surgery in eyes that have prior scarring.

SURGICAL PEARLS

My colleagues and I have used a number of implantation techniques in our study of the EX-PRESS device. For limbus-based flaps, I open the conjunctiva and tenon's approximately 10 mm posterior to the limbus under the "blitz" anesthesia technique (topical Xylocaine jelly [Astrazeneca LP, Wilmington, DE] followed by intracameral 1% lidocaine) (Figure 5). After I make the flap, I fill the anterior chamber

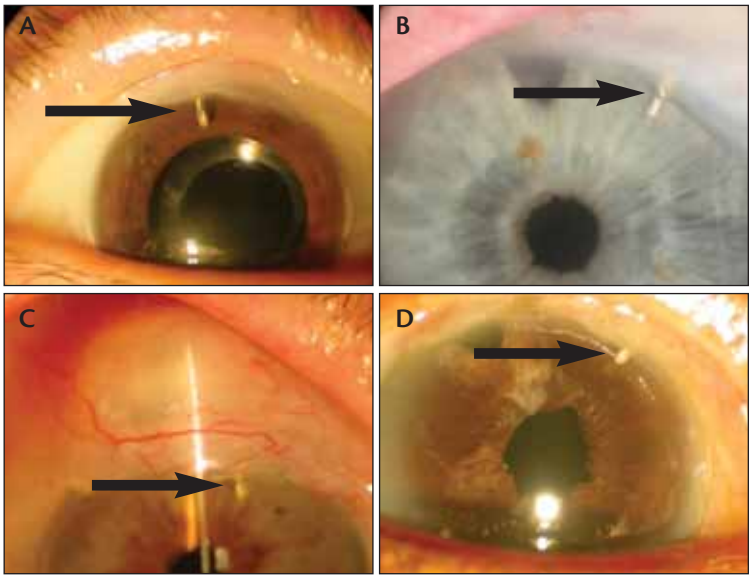

Figure 4. The EX-PRESS device is minimally visible on the globe (A-D).

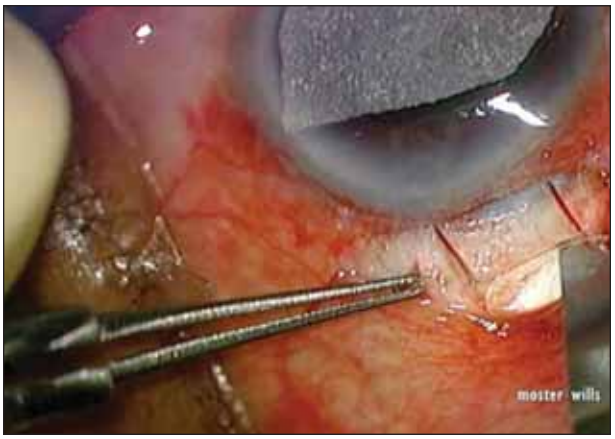

Figure 5. The author cuts a flap for the EX-PRESS device in the conjunctiva and Tenon's approximately 10 mm posterior to the limbus .

with balanced saline solution. It is important to never implant the EX-PRESS device when the chamber is shallow; the pressure should be at least 20 mm Hg.

After suturing the flap over the EX-PRESS device, I assess how much flow there is. Filling the eye to firmness with balanced salt solution should cause leakage around the flap. When the eye is soft (saline can be removed from the eye via pressing on the paracentesis), there should be very little flow. A suture will help control the IOP in the postoperative period and can be released if the IOP appears stable or not low enough. Although I prefer a fornix-based flap for most cases, in patients who are elderly, not careful, or who travel a distance to the surgery center, I often use a limbal-based flap with one releasable suture, because there is only one stitch for the doctor to remove. It does not matter what kind of suture you use, only that the wound is watertight. For my limbal-based flaps, I prefer to lock Tenon's capsule with a continuous running locking suture (8–0 vicryl [Ethicon, Inc., Somerville, NJ]) in one direction that I then exteriorize through the conjunctiva and run in the opposite direction for watertight closure of conjunctiva. For a fornix-based closure, I prefer interrupted 10–0 nylon.

CONCLUSION

It is important to be able to offer glaucoma patients surgical treatment options, especially those who a procedure and medications have already failed. The strategy for managing patients who have experienced a failed trabeculectomy or corneal scarring can be challenging. Do we restart their medications? Repeat the trabeculectomy? Implant a large shunt? Are there other options? The EX-PRESS device offers many solutions: it is stainless steel, inert, and compatible with MRIs. The device stays where it is placed and does not cause inflammation. I have come to rely on the EX-PRESS device as yet another tool to help me manage patients with uncontrolled glaucoma. ■

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