

Glaucoma

TODAY

REFINING GLAUCOMA FILTRATION SURGERY

**The EX-PRESS Glaucoma Filtration Device:
Limiting variables to improve outcomes.**

Refining Glaucoma Filtration Surgery

Limiting Variables to Improve Outcomes



The goal of glaucoma surgery is to preserve patients’ visual function by controlling IOP. A second endpoint, as in all surgery, is to avoid intra- and post-operative complications, something we aim to achieve by standardizing as much of the filtration procedure as possible.

Trabeculectomy, which for years has been the gold standard of glaucoma surgery, is difficult to standardize. Over the years, surgeons have tested every aspect of the procedure, from wound size to the use of mitomycin C.

Indicated for IOP reduction after conventional surgical and medical treatments have failed, the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc.) (Figure 1) now has more than 10 years of clinical experience behind it as well as published evidence that its implantation procedure offers a greater level of standardization than trabeculectomy surgery.^{1,2} This monograph, based on a symposium held in San Francisco this past April, reviews the advantages of the EX-PRESS Device for both surgeons and patients. I invite you to read about these colleagues’ experience with the EX-PRESS Device to learn where it may make a sensible addition to the glaucoma armamentarium.

—Richard A. Lewis, MD

Dr. Lewis is a paid consultant for Alcon Laboratories, Inc.



Figure 1. The EX-PRESS Glaucoma Filtration Device.

1. Maris PJ Jr, Ishida K, Netland PA. Comparison of trabeculectomy with Ex-PRESS miniature glaucoma device implanted under scleral flap. *J Glaucoma*. 2007;16(1):14-19.
2. De Feo F, Bagnis A, Bricola G, et al. Efficacy and safety of a steel drainage device implanted under a scleral flap. *Can J Ophthalmol*. 2009;44(4):457-462.

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The EX-PRESS Device: From Skeptic to Believer

One surgeon's journey to adopt micro-shunt technology.

BY ANDREW G. IWACH, MD

The trabeculectomy procedure has evolved over time in many ways, undergoing changes such as the level of anesthesia, the type of traction suture, type of conjunctival flap, the shape of the scleral flap, and the possible use of anti-scarring agents. Also included in the evolution of this procedure is the introduction and utilization of the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc.).

COMMON ELEMENTS OF TRABECULECTOMY

Although every eye is different, there are some common elements to the trabeculectomy procedure, including the fact that many surgeons utilize an 8-0 Vicryl suture (Ethicon, Inc.) with a cutting needle placed intracorneally for traction. Then, we can create scleral flaps of various shapes; personally, I had grown accustomed to creating a triangular-shaped scleral flap (Figure 1). Also, we use cautery as necessary to maintain hemostasis.

Our next step is to remove a block of scleral tissue. Many surgeons now utilize a punch to remove the specimen; however, this still necessitates a surgical iridectomy, which carries inherent risk. Finally, we tack down the scleral flap, typically with a 10-0 nylon suture.



Figure 1. The author creates a triangular-shaped scleral flap in order to access the anterior chamber.

"I consider the EX-PRESS a simple device that can speed visual recovery to preoperative levels, potentially reducing patient anxiety—an important advantage for patients."

Commonly, we use intraoperative anti-scarring agents, such as 5-fluorouracil or mitomycin-C.

The postoperative period for filtration surgery requires careful management, and it may necessitate interventions such as laser suture lysis, additional anti-scarring medications, or possibly even needling procedures or bleb revisions.

WHERE DOES THE EX-PRESS DEVICE FIT IN?

Given the entrenched status of trabeculectomy, where does the EX-PRESS Glaucoma Filtration Device fit in? The US FDA first cleared the EX-PRESS Device in March 2002; it was indicated for IOP reduction after conventional surgical and medical treatments had failed. The

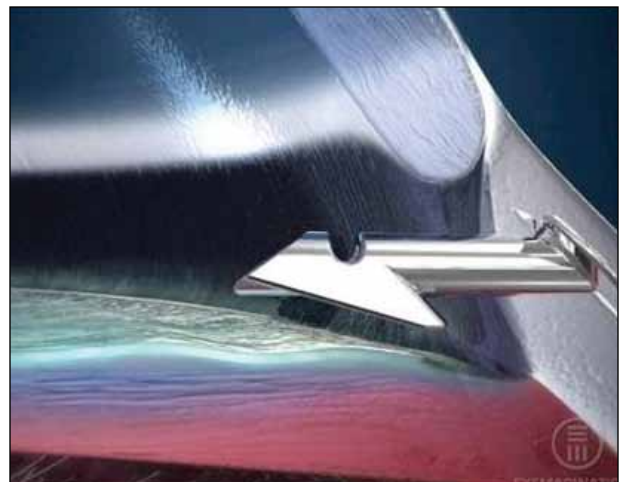


Figure 2. The EX-PRESS Device with a scleral flap.

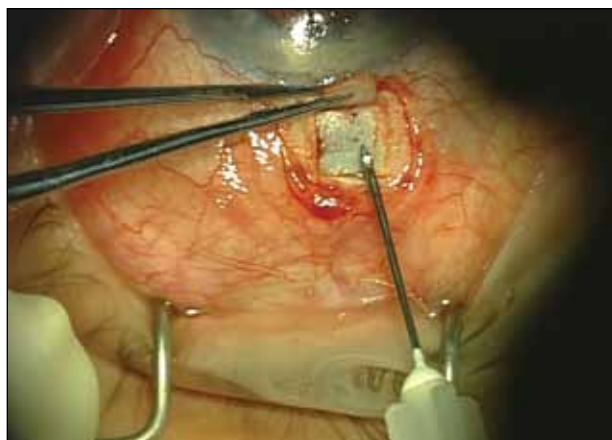


Figure 3. After dissecting a conjunctival flap, the author creates a 3-mm x 3-mm scleral flap.

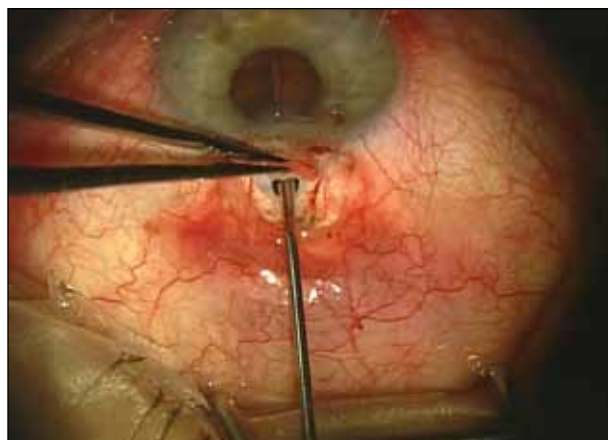


Figure 4. The author uses a preloaded EX-PRESS delivery system to implant an EX-PRESS Device.



Figure 5. The EX-PRESS Device in place.



Figure 6. With the implant in place, the author closes the overlying tissue.

suggestion at the time was to place the EX-PRESS Device subconjunctivally without using a scleral flap. I did not adopt the procedure at that time due to concerns that placing the device in this location could lead to complications such as conjunctival erosion and extrusion of the shunt. However, reports at ophthalmic symposia and in the literature¹ in the mid 2000s indicated improved success in filtering surgery with fewer complications when utilizing an EX-PRESS Device under a scleral flap (Figure 2). With these reports available, I gradually began introducing the EX-PRESS Device in my standard filtering procedures.

The approach of using the EX-PRESS Device under a scleral flap parallels what I had traditionally done with trabeculectomy, except that now instead of making a triangular scleral flap, I make a 3-mm rectangular flap, and I utilize a 25-gauge needle to create a track for placing the EX-PRESS Device. I then introduce the EX-PRESS Device into the anterior chamber through this track (Figures 3–6). Because of its unique design, the EX-PRESS Device eliminates

the need for an iridectomy. The other steps of the procedure are similar to what I have been doing with traditional trabeculectomy.

A GRADUAL TRANSITION

My transition from traditional trabeculectomy to incorporating the EX-PRESS Device was gradual. On the first day that I introduced the EX-PRESS Device into my surgical repertoire, I compared it side-by-side with a standard trabeculectomy I had completed. To give myself the most flexibility intraoperatively, I wrote the consent form to state that a trabeculectomy would be performed with possible implantation of an EX-PRESS Device.

The EX-PRESS Device has changed my practice. In my experience, side-by-side clinical comparisons showed that many patients who received an EX-PRESS Device under the scleral flap experienced satisfaction with their outcomes.

EX-PRESS Device recipients' vision recovered faster, potentially lessening their postoperative anxiety. I was happier because these patients' intraoperative IOPs were

more predictable, and they had fewer complications compared with traditional trabeculectomy. For these reasons, I consider the EX-PRESS a simple device that can speed visual recovery to preoperative levels, potentially reducing patient anxiety—an important advantage for patients.

CONCLUSIONS

Before performing any type of filtering surgery, we surgeons must conduct a careful preoperative examination to understand the nature of the disease and the need and the timing for filtering surgery. Likewise, we need to study the eye's anatomy, particularly the angle structure superiorly, when contemplating placement of the EX-PRESS Device to ensure that the procedure goes as smoothly as possible.

I have utilized an EX-PRESS Device when performing trabeculectomy-type filtering surgery almost exclusively over the past 7 years. There are certain clinical settings in which I consider an EX-PRESS Device the optimal treatment option. For example, when there is a small amount of vitreous in the anterior chamber near the pupillary margin, the device avoids the anterior vitrectomy that a trabeculectomy with iridectomy would necessitate. Similarly, the EX-PRESS Device is advantageous in patients with impaired coagulation, by again negating the need for an iridectomy, which often has associated bleeding. Finally, for patients who have an urgent need for faster visual recovery than trabeculectomy, such as monocular patients or those who will have difficulty getting to the clinic for

postoperative exams, the EX-PRESS Device offers significant advantages.

My own clinical experience has convinced me that recipients of the EX-PRESS Device have a smoother postoperative course, and the long-term results are as good as I have seen with other trabeculectomy procedures. These impressions are consistent with a recent study.² In fact, because the device has reduced the complexity of the postoperative course of trabeculectomy, my threshold for doing filtering surgery is lower, and I find that these patients tolerate the filtering surgery much better.

It is understandable that surgeons are cautious to incorporate new technology into established procedures, as was seen with the transition from extracapsular cataract surgery to phacoemulsification surgery. However, those who made that transition tended to stay with it. I have had the same experience with using the EX-PRESS Device. Once the transition is made, there is really no going back. ■

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1. Maris PJG, Ishida K, Netland PA. Comparison of trabeculectomy with EX-PRESS® miniature glaucoma device implanted under scleral flap. *J Glaucoma*. 2007;16:14-19.

2. Buys YM, Wagschal LD, Jin YP, et al. Prospective randomized study comparing ExPress to trabeculectomy: 1 year results. Paper presented at: The 23rd Annual AGS Meeting; February 28, 2013; San Francisco, CA.

Surgical Options After Failed IOP-Lowering Therapy

The EX-PRESS Device offers similar IOP-lowering efficacy as trabeculectomy with fewer complications.

BY GREGORY KATZ, MD

Ever since its introduction nearly 5 decades ago, trabeculectomy has been the most common procedure for treating glaucoma patients who have failed prior attempts at surgical or medical intervention. As with most incisional approaches to glaucoma treatment, trabeculectomy is often reserved as a last-ditch intervention, or for patients in need of high amounts of IOP reduction.

The procedure, however, presents risks for several intra- and postoperative complications.¹ For this reason, a number of new devices and techniques have been proposed for this category of patients. One such device, the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc.) (Figure 1), can be a viable alternative to trabeculectomy for patients in whom previous medical and surgical intervention is deemed ineffective at controlling IOP.

TRABECULECTOMY: ASSOCIATED COMPLICATIONS

Trabeculectomy was first proposed by H. Saul Sugar in 1961² and was first performed by Cairns in 1968.³ Despite the passage of time, and save for the addition of antimetabolites and some modifications to the suturing techniques, present-day surgeons are still performing the same procedure that was first described over 50 years ago. This is not to say that trabeculectomy is not an effective surgery; in fact, its efficacy is one of the principles reasons it is still one of the most common incisional procedures performed for managing glaucoma. In the intervening period since its introduction, the glaucoma field has witnessed innovations such as microinvasive glaucoma surgery, cyclodestruction, trabectomies, and scores of other procedures. Despite these innovations, many surgeons still turn to the IOP-lowering effects of trabeculectomy.

Trabeculectomy is associated with a number of fairly common complications. Notably, intraoperative bleeding from the sclerotomy site and the iridotomy sites have been reported (Figure 2),¹ and there is a definite



Figure 1. The EX-PRESS Glaucoma Filtration Device is 3 mm in size.



Figure 2. Trabeculectomy is associated with bleeding from the sclerotomy and the iridotomy sites.

risk of suprachoroidal hemorrhage.⁴ Postoperatively, patients are prone to wound leaks, infections, hypotony, occlusion of the ostium, induced astigmatism, ocular discomfort, and a variety of bleb-related complications. Thus, despite its effectiveness for IOP lowering, trabeculectomy's associated safety profile may limit its utility.

Success IOP $\leq$ 21 mm Hg**	Last Examination
EX-PRESS Glaucoma Filtration Device	90%*
Trabeculectomy	92%*
*Not statistically significant **With or without medication	

Figure 3. In a study of the EX-PRESS Device versus trabeculectomy with 50 eyes in each group, there was no statistically significant difference in the rate of success between the two. (Data adapted from: Maris PJG, Ishida K, Netland PA. Comparison of trabeculectomy with EX-PRESS miniature glaucoma device implanted under scleral flap. *J Glaucoma*. 2007;16:14-19.)

AN ALTERNATIVE OPTION

The EX-PRESS Glaucoma Filtration Device offers an alternative in cases where previous medical and surgical intervention has failed. This 3-mm device with a 50- or 200- μ m internal lumen, which is inserted under a scleral flap using a 25- or 26-gauge needle incision, works to restrict aqueous outflow. Due to the fact that the procedure does not require a sclerectomy or iridectomy, it avoids many of the complications associated with classical trabeculectomy.

A number of studies demonstrate the efficacy of this device, as well as its improved safety profile compared with incisional glaucoma procedures. Maris and colleagues reported similar efficacy in 50 eyes implanted with the EX-PRESS Device compared with 50 eyes in which trabeculectomy was performed: 90% and 92% success, respectively

IOP $\leq$ 15 mm Hg	Without IOP Medication		
	EX-PRESS Device (n = 39)	Trabeculectomy (N= 39)	p value
Year 1	80.0 %	51.3 %	0.01
Year 2	71.1 %	48.7 %	0.046
Year 3	66.7 %	38.5 %	0.01
Year 4	61.5 %	46.2 %	0.17
Year 5	59.0 %	46.2 %	0.26
IOP $\leq$ 18 mm Hg	Without IOP Medication		
	EX-PRESS Device (n = 39)	Trabeculectomy (N= 39)	p value
Year 1	86.8 %	61.5 %	0.01
Year 2	76.3 %	51.3 %	0.02
Year 3	66.7 %	41.0 %	0.02
Year 4	64.1 %	46.2 %	0.11
Year 5	59.0 %	46.2 %	0.25

Figure 5. A 5-year study of the EX-PRESS Device versus trabeculectomy demonstrated the IOP success rates at two different IOP thresholds (15 mm Hg and 18 mm Hg).⁷ The number of subjects on postoperative IOP-lowering medication was significantly higher during the first 3 years in patients who had had standard trabeculectomy versus those with an EX-PRESS Device implanted. (Data adapted from: De Jong L, Lafuma A, Aquadé A-S, Berdeaux G. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. *Clin Ophthalmol*. 2011;5:527-533.)

Success of EX-PRESS Device Alone Vs EX-PRESS Combined With Cataract Surgery After 3 Years	
EX-PRESS Device alone	94.8% mean IOP
EX-PRESS Device with cataract surgery	95.6% mean IOP

Figure 4. Surgical success rates 3 years after implantation of the EX-PRESS Device under the scleral flap alone versus combined with cataract surgery (n=345).⁶ Success was defined as IOP between 5 and 21 mm Hg with or without medications. (Data adapted from: Kanner EM, Netland PA, Sarkisian SR Jr, Haiming D. EX-PRESS miniature glaucoma device implanted under a scleral flap alone or combined with phacoemulsification cataract surgery. *J Glaucoma*. 2009;18:488-491.)

(defined as IOP $\leq$ 21 mm Hg) (Figure 3).⁵ Most notably, the rates of hypotony and choroidal effusions were significantly lower in the EX-PRESS Device group. The rate of early postoperative hypotony was 4% in the EX-PRESS Device group versus 32% in the control group ($P < .05$). For choroidal effusions, the EX-PRESS Device group showed a rate of 8% versus 38% in the control group ($P < .05$).

Longer-term data suggest good durability with the EX-PRESS Device. Kanner et al reported a 95% success after 3 years in 345 patients (Figure 4).⁶ De Jong et al conducted a 5-year prospective and randomized trial involving patients with inadequately controlled open-angle glaucoma.⁷ They reported significantly better IOP control in eyes implanted with the EX-PRESS Device compared with trabeculectomy in years 1 to 3, and similar rates between the two in ensuing years.

A reduction in medication requirement in eyes implanted with the EX-PRESS Device versus trabeculectomy was observed in all 5 years of the study (Figure 5).

One of the more interesting findings is with regards to the duration of blurred vision after EX-PRESS Device implantation. Good and Kahook found that the visual acuity of EX-PRESS Device patients returned to baseline by 1 week, while the trabeculectomy patients did not have their visual acuity return to baseline until the 1-month visit (Figure 6).⁸ In addition, they found that patients who underwent the EX-PRESS Device procedure required fewer follow-up visits in the first 3 months compared to trabeculectomy patients (6 visits versus 8, respectively).

The EX-PRESS Device also performs well in more refractory glaucoma. Ates and colleagues investigated the use of the device in eyes with refractory glaucoma

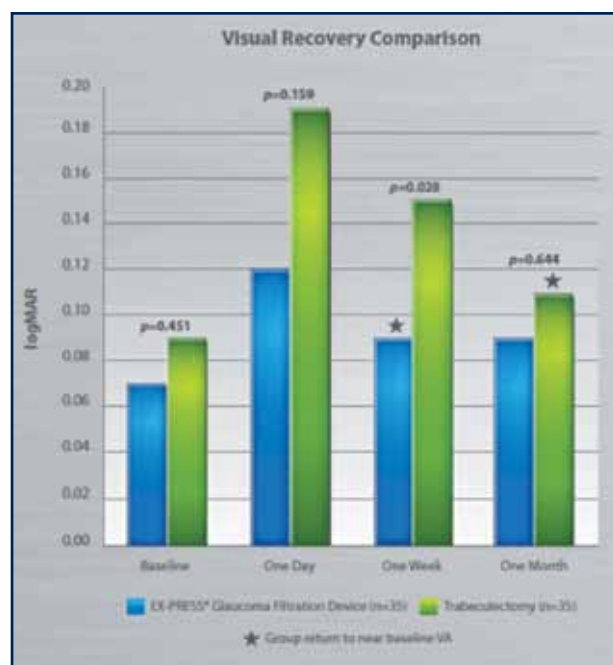


Figure 6. This chart compares the rate of visual recovery between recipients of the EX-PRESS Device and patients who underwent trabeculectomy (n = 35 for each group) using logMAR.⁸ Subjects who received the EX-PRESS Device experienced a faster visual recovery. (Data adapted from: Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy. *Am J Ophthalmol.* 2011;151(3):507-513.

that previously underwent penetrating keratoplasty.⁹ After 1 year of follow up, the subjects' average pressure dropped from 41 to 12 mm Hg, and complete success (IOP lower than 21 mm Hg and no medication) was achieved in 86% of patients. What is interesting to note from this study is that after implantation of the EX-PRESS Device, grafts that were previously deemed clear remained so, and edematous grafts became clearer.

PATIENT SELECTION

In my opinion, the EX-PRESS Glaucoma Filtration Device should be considered for any patient requiring a trabeculectomy, including those with bleeding disorders (because the EX-PRESS Device procedure induces less bleeding), patients with a history of rubeosis, monocular patients or any individuals who need fast recovery of visual acuity, and high myopes or hyperopes who might be at an increased risk for suprachoroidal hemorrhage (as well as patients with very high preoperative pressures).

One case that I think demonstrates some of the benefits of this approach is a hemophiliac patient in whom I implanted the EX-PRESS Device. As I was making my initial conjunctival dissection, the eye started to bleed. I was able to control the conjunctival bleeding, but more bleeding started during the scleral flap dissection. This bleeding was eventually controlled. If this had been a regular trabeculectomy procedure, the extent of bleeding would likely become even more problematic as I moved on to the sclerectomy and iridectomy.

In this case, the EX-PRESS Device was particularly beneficial. After controlling the bleeding, I was able to use a 25-gauge needle to make my opening under the scleral flap, and the anterior chamber remained fully formed. As a result of not performing a sclerectomy and iridectomy in this patient, there was no additional bleeding. The part of the procedure that would have been the most difficult (having the greatest chance of increased bleeding) was actually the easiest.

CONCLUSION

The EX-PRESS Glaucoma Filtration Device has demonstrated a high success rate in numerous clinical trials, with pressure lowering similar to trabeculectomy but with fewer complications. In surgeons' hands, implanting the EX-PRESS Device is a more efficient procedure, because performing a sclerectomy or iridectomy is not required. The EX-PRESS Device procedure delivers predictable flow, and patients may experience faster visual acuity recover with less requirement for follow-up compared with trabeculectomy. ■

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8. Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy. *Am J Ophthalmol.* 2011;151(3):507-513.
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The EX-PRESS Device: Engineered for Better Control

Standardizing the sclerostomy provides surgeons with greater control over surgical outcomes.

BY THOMAS W. SAMUELSON, MD

Achieving repeatability and standardization with surgical maneuvers is something every surgeon strives for. Performing the same steps in precisely the same manner gives the operator better control over the many variables in play when manipulating human tissue, especially when the tissue is as biologically variable as the conjunctiva and sclera. The importance of repeatability lies in the fact that no two human eyes (in the case of ophthalmic surgeons) are exactly the same, and so delivering predictable results is dependent on such standardization.

For glaucomatous eyes, the use of trabeculectomy has been a mainstay of treatment where previous medical and surgical interventions have been unsuccessful at achieving a patient's predetermined target pressure. The surgery has been around for more than 50 years, and the maneuvers used have changed little over time. Yet, despite the refinement of some parts of trabeculectomy (namely, the addition of mitomycin-C and alternations to suturing techniques), there are still several aspects of the procedure that are beyond the surgeon's control. Therefore, trabeculectomy is a surgical procedure that, although highly effective, still delivers sometimes unexpected results, even in the best surgeons' hands.

DESIGN CONSIDERATIONS

The EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc.) is an option in the management of glaucoma for eyes that have failed medical and surgical management. The design and engineering of this device function to standardize important elements of the incisional approach to managing glaucoma (Figure 1); the result is a surgical procedure in which the surgeons' intraoperative maneuvers should have less impact on the final outcome.

Two important variables pertain to the outflow mechanism within a given human eye: the pressure gradient between the anterior chamber and the subconjunctival space and the resistance and size of the opening through which the aqueous will ultimately flow. As to the



Figure 1. Six-point engineering gives the EX-PRESS Device the ability to optimize the dynamics of aqueous flow in ways trabeculectomy cannot.

former, IOP will naturally differ from patient to patient. Therefore, in any procedure that enhances incisional outflow, there is necessarily interpatient variability in this gradient. Although the pressure gradient of flow cannot be standardized, the EX-PRESS Device standardizes the size and inherent resistance of the sclerostomy.

Surgeons may intend to create the same sized sclerostomy each time, and certainly, accuracy should improve as more procedures are performed. Even in the best hands, however, a Kelly punch will open a different sized hole from one case to the next.

The EX-PRESS Device standardizes a critical step in glaucoma filtration surgery—specifically, the sclerostomy—which, along with scleral flap closure, may be the most critical step. Because it comes in two standard sizes (internal lumen dimensions of 50 or 200 μm), aqueous humor outflow is more predictable with the EX-PRESS Device. It eliminates the variability in sizing and shape of the sclerostomy, thus conferring a much more consistent outflow. As a result, surgeons benefit from a greater consistency of outflow volume from one case to the next. Accordingly, the tension of the scleral flap's suturing is more easily standardized as well, because the flow from case to case is less disparate.

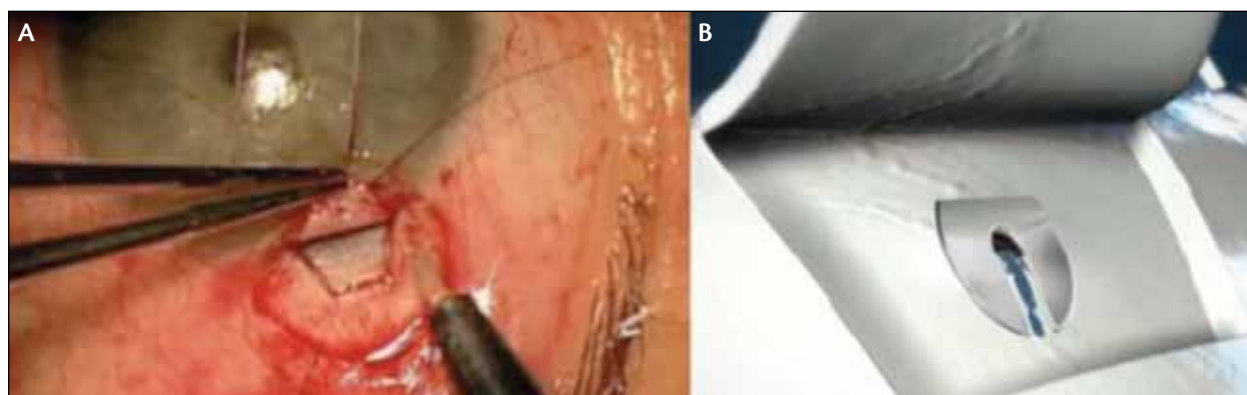


Figure 2. The author creates a partial-thickness, trapezoidal scleral flap, approximately 3.5 mm and based at the limbus (A). The EX-PRESS Glaucoma Filtration Device P-50 has a notch to help aqueous flow posteriorly (B).

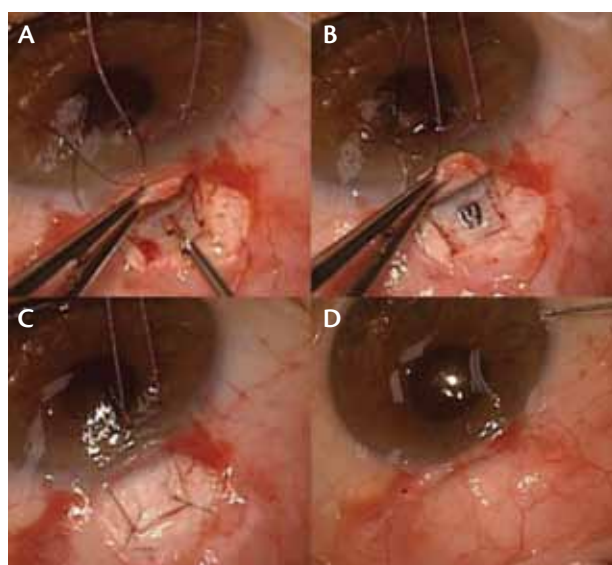


Figure 3. The author's technique for implanting the EX-PRESS Device involves careful placement and suturing (A–D).

MY PREFERRED SURGICAL TECHNIQUE WITH THE EX-PRESS DEVICE

Inserting the EX-PRESS Device and achieving the desired outcome still requires meticulous attention to surgical detail. However, by eliminating some of the variables involved in traditional incisional filtration surgery, the surgeon is afforded greater intraoperative control over the eye. There is virtually no “open eye” experience during which the patient is at risk for iris prolapse or collapse of the anterior chamber. Another benefit of eliminating the sclerotomy is there is no risk of violating the scleral spur, iris, or ciliary process with the punch, which reduces the risk of bleeding.

My preferred technique for using the EX-PRESS Glaucoma Filtration Device is to use a 25-gauge needle to create the opening in a smooth plane. Other than the paracentesis, this is the only opening in the eye, a technique

that should yield less surgically-induced astigmatism because of less scleral displacement.

To insert the EX-PRESS Device, I fixate the eye by grasping the margin of the scleral bed (rather than the flap) while I gently advance the device into place via the inserter (Figure 3A). I know it is in position (Figure 3B) when I feel a gentle “pop.” I then test the aqueous flow through the EX-PRESS Device before closing the eye.

To suture the opening closed, I use two 10–0 nylon sutures that I placed on either side of the scleral flap before I began excising. I use at least two sutures to carefully close the flap (Figure 3C). Finally, if I have not used releasable sutures, I cut the remaining ends for an aesthetically pleasing outcome (Figure 3D).

CONCLUSION

Trabeculectomy is considered the gold standard in incisional glaucoma surgery. It yields unparalleled and expeditious pressure reduction in eyes that have previously failed medical and/or surgical interventions. Yet, the individual steps required for the procedure are not easily repeatable from case to case, which may result in variable effectiveness and risk from one patient to the next. Surgeons seeking better control of intraoperative variables may consider using the EX-PRESS Device. I believe that standardizing the sclerotomy and benefitting from the design considerations of this mini-shunt afford the operating surgeon greater control of pressure regulation, thus improving the safety and precision of this important procedure. ■

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Using the EX-PRESS Device in High-Risk Eyes

BY THOMAS W. SAMUELSON, MD

I recently operated on a 62-year-old woman with exfoliation and elevated IOP. Her glaucoma had been well controlled with prostaglandin therapy and she had undergone a selective laser trabeculoplasty. In the past, the patient's IOP measured in the 20s, with occasional readings around 30 mm Hg; however, her central corneal thickness was 640 μ m, which reassured me that these pressure readings were not overtly troublesome. In addition, her OCT and visual field maps over time yielded nothing that would warrant any additional attention.

In July 2011, I added dorzolamide and timolol to her regimen to address a suspected new afferent pupillary defect (APD). Despite the new APD, her visual field was still quite good, with a positive mean deviation and few false-positive readings (Figure 1). In my experience, visual fields with a positive mean deviation, when associated with a low rate of false-positive responses, indicate a healthy optic nerve.

When I reassessed the patient with OCT in January 2012, the reading was slightly worrisome (Figure 2), and so I instructed her to return for an updated visual field examination. However, this patient canceled one appointment and had to reschedule another, and so I did not see her back in the office until September 2012. At this visit, my examination revealed a degree of visual field progression that I considered worrisome—

there was simply too much progression over such a short period of time for a patient who had been chronically stable (Figures 3 and 4).

Several factors led me to recommend an EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc.) for this patient. Namely, she was phakic with 20/20 vision and no detectable cataract despite a history of some nuclear sclerosis, thus obviating many MIGS approaches. The angle was wide open, and the patient was relatively young. While I might normally consider SLT as a next step, this patient's rapid progression, exfoliation, and family history necessitated a more definitive approach. In cases such as these, however, where I deem there is a high risk of functional impairment, using the EX-PRESS Device has become my procedure of choice. ■

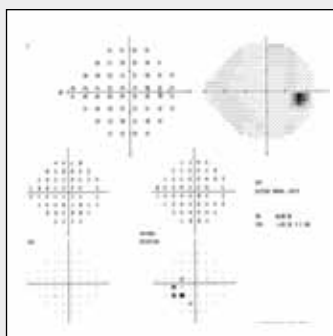


Figure 1. In July 2011, the patient's visual field test looked healthy.

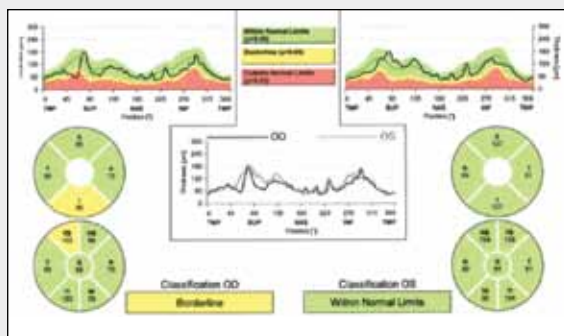


Figure 2. The patient's OCT map in January 2012 showed some areas of concern.

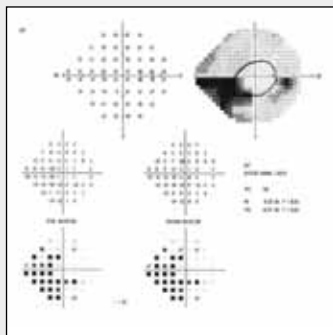


Figure 3. The visual field test in September 2012.

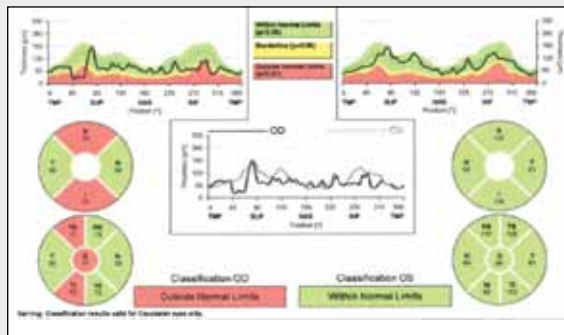


Figure 4. The next OCT reading in September 2012 showed progression of the nerve fiber layer defect.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATION: The EX-PRESS® Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

GUIDANCE REGARDING THE SELECTION OF THE APPROPRIATE VERSION: Prior clinical studies were not designed to compare between the various versions of the EX-PRESS® Glaucoma Filtration Device. The selection of the appropriate version is according to the doctor's discretion.

CONTRAINDICATIONS: The use of this device is contraindicated if one or more of the following conditions exist:

- Presence of ocular disease such as uveitis, ocular infection, severe dry eye, severe blepharitis.
- Pre-existing ocular or systemic pathology that, in the opinion of the surgeon, is likely to cause postoperative complications following implantation of the device.
- Patients diagnosed with angle closure glaucoma.

WARNINGS/PRECAUTIONS:

- The surgeon should be familiar with the instructions for use.
- The integrity of the package should be examined prior to use and the device should not be used if the package is damaged and sterility is compromised.
- This device is for single use only.
- MRI of the head is permitted, however not recommended, in the first two weeks post implantation.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings, precautions, complications and adverse events.

