Improving Upon Trabeculectomy With an Innovative Device

Surgeons share their experiences and provide pearls for successful outcomes.

Produced under an educational grant from Alcon Laboratories, Inc.
I began using the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX) in July 2006, after it became popularized as a subscleral flap procedure in response to the work of Eli Dahan, MD, of South Africa.1 I conducted a comparison study of the eyes I implanted with the EX-PRESS device between July 2006 and June 2007 and those I had treated with trabeculectomy between July 2005 and June 2006.2 The 9-month efficacy results showed that IOP was equivalent in both groups (about 11 mm Hg), but there was much less hypotony in the eyes implanted with the EX-PRESS device. I now frequently use the EX-PRESS Glaucoma Filtration Device in many cases in which I would perform a trabeculectomy procedure. Fortunately, insurance coverage of the device has been expanding.

Although I would not call the implantation of the EX-PRESS Glaucoma Filtration Device a simple procedure—it still requires meticulous surgical technique—the learning curve is fairly low. Clearly, this device offers several advantages for which I favor this procedure over trabeculectomy.

This monograph features articles by other respected surgeons who have had a similar experience with the EX-PRESS device. Read on to hear their opinions and learn their implantation techniques and pearls.

— Leon Herndon, MD


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Can glaucoma’s most effective procedure for lowering IOP be improved?

BY GARRY P. CONDON, MD

The Tube Versus Trabeculectomy (TVT) study1 published last year brought glaucoma tube devices back into the forefront of surgical discourse. The well-designed, prospective study conducted by Steve Gedde, MD, and colleagues in Boston randomized 212 glaucomatous patients to receive either a Baerveldt 350-mm glaucoma implant (n=107) or to undergo trabeculectomy with wound management (n=105). The results of this study caused the investigators to conclude that the implant was a more effective procedure than trabeculectomy with a lower incidence of complications in patients who had already undergone some type of previous surgery. These findings raised the question: is trabeculectomy still a viable option, or does the glaucoma implant change our standard of care? Let’s consider the data carefully and then examine the appropriate answer.

TVT TRIAL OUTCOMES

Success and Failure

I believe that glaucoma tubes are valuable for eyes that have undergone previous surgery, but their value may be overstated in terms of a routine glaucoma filtering surgery. The device implant group in the TVT trial experienced a 15% failure rate at 3 years, compared with a 30% failure rate in the trabeculectomy group. However, although most of the eyes in the trabeculectomy group were good candidates for a tube device, the failed trabeculectomy eyes were not ideal candidates for a trabeculectomy. Thus, half of the eyes had already failed one arm of the study prior to surgery. The definition of success in the TVT trial at 3 years was an IOP of less than 21 mm Hg and reduced by 20% with no medications. Forty percent of the trabeculectomy patients met this definition of success, compared with only 28% of the tube device patients. Therefore, medications played a significant role in these patients’ eventual success. The rate of late and serious complications was similar for both groups, but the trabeculectomy procedure was blamed for a greater number of early complications (60 versus 36 in the device group). Twelve of those 60 complications were wound leaks, and eight were hyphemas.

“I is trabeculectomy still a viable option, or does the glaucoma implant change our standard of care?”

The device group experienced three intraoperative scleral perforations—something I do not consider insignificant.

IOP and Visual Acuity

Although both groups in the TVT study experienced significantly reduced IOP, a truly effective reduction of IOP to 14 mm Hg was achieved in only 58% of the trabeculectomy patients and 62% of the tube device patients at 3 years postoperatively. There was no significant difference in the rate of visual loss between the two procedures, but it was concerning that one out of three patients in both groups lost 2 or more lines of Snellen acuity. This result in itself attests to the complexity of treating these challenging cases. In short, the trabeculectomy was effective in 70% of patients and with fewer medications than the tube device group. Furthermore, a recent follow-up study to the TVT trial found new motility problems in 10% of patients in the tube device group (and none in the trabeculectomy group).2

General Issue of Safety With Devices

A study by Kim et al that was presented at ARVO in 2008 examined the loss of endothelial cells in patients who have undergone Ahmed tube device surgery out to 24 months.3 The operated eyes had 15% mean cellular loss at 12 months and 18.3% at 24 months versus 2.8% at 12 months and 4.2% at 24 months in the unoperated eyes. Interestingly, the percentage of cell loss was much greater in the superior temporal zone, where the tubes were placed. These findings are important when considering the long-term safety of glaucoma tubes. We must recognize that some complications can occur beyond 3 years.

In summary, the results of the TVT study cast tube devices in a favorable light in patients who have undergone previous conjunctival surgery. I certainly consider using these devices in eyes that have conjunctival fibrosis or conditions unfavorable for trabeculectomy. The role of

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glaucoma drainage tube devices in clear corneal pseudophakic eyes and primary glaucoma surgery is not at all clear, in my opinion. A primary tube versus trabeculectomy study is currently underway in the hope of clarifying this issue.

CANALOPLASTY
The idea of nonpenetrating canal surgery has received a lot of attention among glaucoma surgeons. The 2-year results from uncontrolled studies conducted by i-Science Interventional (Menlo Park, CA) have now been published.4 The series included 84 patients with 2 years of follow-up, and it found a 30% mean reduction in IOP (from 23.2 to 16.3 mm Hg). This procedure is not always simple or predictable, however, and the surgeons were unable to find the canal or complete the implantation of the microcatheter in 15% of the cases. If we broadly compared the results of the canaloplasty trial with the Collaborative Initial Glaucoma Treatment Study (CIGTS),5 trabeculectomy has an impressive track record (Table 1). It appears that trabeculectomy is still the gold standard for achieving super-low IOP in primary glaucoma surgery.

THE EX-PRESS GLAUCOMA FILTRATION DEVICE
It is important to make the procedure in the OR as smooth, precise, controlled, and predictable as possible, and the idea of standardizing trabeculectomy to achieve this goal has been discussed before. When I first encountered the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX), I wondered how it might help me better manage glaucomatous eyes and if it could give me better control intra- and postoperatively. A retrospective study published by Peter Netland, MD, and his group6 induced me to try the device in surgery. In a routine case with the EX-PRESS Glaucoma Filtration Device, I dissect my scleral flap in the usual manner (Figure 1). Depending on the specific device, I use a 26- or 27-guage needle to create the entry for insertion. Once I insert the device (Figure 2), there is immediately more stability in the anterior chamber, and the surgery feels more controlled. In the OR, this stability makes suturing the flap less hurried. The Netland study included 100 eyes, 50 implanted with the EX-PRESS Glaucoma Filtration Device and 50 without. There was no difference in IOP between the groups, but the eyes implanted with the EX-PRESS device experienced less hypotony and choroidal effusion early in the postoperative period. Also, one of the first things I noticed when I started

| TABLE 1. CANALOPLASTY VERSUS TRABECULECTOMY |
|-----------------|-------|-------|
| Sponsor         | i-Science | CIGTS | NIH |
| Patients (#)    | 84     | 465   |
| F/U (yrs)       | 2      | 9     |
| IOP reduction   | 30%    | 44%   |

Figure 1. The author makes the microscopic, self-sealing entry incision for the EX-PRESS filtration device in the blue/grey zone of the limbus.

Figure 2. The author positions the EX-PRESS Glaucoma Filtration Device in place.

“Once I insert the [EX-PRESS] device, there is immediately more stability in the anterior chamber, and the surgery feels more controlled.”
using this device was the dramatic reduction in early postoperative hyphema, a finding that was also significant in the Netland study.

Another surgical switch I made about a decade ago was to fornix-based flap surgery (see the video, "Closing the Fornix-based Conjunctival Flap" on Eyetube.net) in order to improve on bleb morphology by allowing for more diffuse wound management exposure and a more posterior diffuse bleb (Figure 3). A major criticism with the fornix-based flap approach was a purportedly greater likelihood of wound leaks compared with limbal-based flaps. I did not want to make the change unless I was convinced I could achieve an equally effective wound closure. A review of my results with a fornix-based conjunctival flap approach performed after 2001 versus my limbus-based flaps performed before 2001 revealed no difference in terms of wound leaks requiring repair. Thus, I feel that combining this technique with wound-management application and use of the EX-PRESS Glaucoma Filtration Device gives me reliable control and more reproducible and favorable results in filtering surgery.

Clinically, and in postmortem evaluation, the EX-PRESS device appears to be remarkably biocompatible; it shows minimal evidence of surrounding inflammatory reaction when compared to the Ahmed or Baerveldt plate. A postmortem study conducted by de Feo et al found no difference in the corneal endothelial cell count in the eye that had the EX-PRESS device compared with the unoperated eye. Furthermore, the device has been found safe for MRI procedures.

CONCLUSION

When it comes to complications, any step forward is a step in the right direction. Although I still believe the trabeculectomy is the gold-standard procedure, as glaucoma surgeons, we must continuously raise bar for safer and more effective surgery with new approaches that enhance our current techniques and produce more favorable outcomes. ■

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IMPROVING UPON TRABECULECTOMY WITH AN INNOVATIVE DEVICE

Surgical Technique
With the EX-PRESS Device

Details on how I perform this procedure.

BY IQBAL “IKE” K. AHMED, MD

I have been using the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX) (Figure 1) for more than 4 years now as an advancement over trabeculectomy. Many glaucoma surgeons are already familiar with this device and know that it refines trabeculectomy and promotes consistency. This article describes my step-by-step technique for using this device to the best advantage.

IDENTIFYING LANDMARKS

First, I think it is critical to identify landmarks for placing the EX-PRESS device correctly. Landmarks may not be as critical as in a canaloplasty, but they certainly deserve attention in this procedure. I do this before making any incisions or entering the anterior chamber. I like to assess the important landmarks throughout the case, not just when I have the EX-PRESS glaucoma device in my hand. To help me identify landmarks before I create the scleral flap, I look for a randomized pattern of scleral fibers posteriorly. At the scleral spur, I see a white, glistening band of fibers that crosses the bed of this section. The blue zone is a transition zone to the clear cornea. I want to make sure that I implant the EX-PRESS device in the anterior chamber, just at the level of the scleral spur, but not too far posteriorly (Figure 2). It is important for the device to enter the eye exactly at the anterior aspect of the scleral spur and for it to remain at the iris plane so that it does not point downward toward the iris (Figure 3).

POSITIONING AND SIZING THE SCLERAL FLAP

After I make my conjunctival opening, I create a fornix-based flap. I like to look at the sclera and visualize the location of the blue zone and the scleral spur, estimating where my entry point for the EX-PRESS device will be. My fellows will often place a small ink spot there to remember exactly where to position the implant so that they can build a flap around that area (Figure 4). A trabeculectomy flap can be large or small, but not so small that it does not cover the implant. The external plate of the EX-PRESS device is 1 x 1 mm, so I make these flaps 4 x 3 mm so there is enough tissue to overlap the implant laterally and posteriorly to resist aqueous flow (Figure 5). Personally, I do not like to make the flap overly large; it is unnecessary and may push down onto the external plate of the device excessively. Then, I advance the flap into the clear cornea so there is a small
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The thickness of the scleral flap is just as important with the EX-PRESS Glaucoma Filtration Device as it is during standard trabeculectomy. I prefer to make these flaps 0.50 to 0.75 mm thick. To make the entry point into the anterior chamber, I find both sapphire blades and hypodermic needles useful. I use a 27-gauge needle for the majority of my cases. Again, the entry point should be anterior to the scleral spur. It may take some time to get used to operating with the eye turned down, but this position helps the surgeon enter the sclera perpendicular to the iris; otherwise, the entry point may face the iris. If placed incorrectly, the implant may pinch the iris. Of course, I also make sure to place the EX-PRESS device at a safe distance from the cornea.

It is important to differentiate between the entry point (based on external scleral landmarks) and the entry plane (based on the iris plane).

To insert the EX-PRESS Glaucoma Filtration Device, I rotate it 90° so that it enters the eye with the spur facing the long axis of the entry point (Figure 6). I rotate the device to its final position once it is inside the eye.

Figure 5. A 4x3-mm scleral flap. A 0.50-mm anterior gap prevents excessive compression of the device. Lateral and posterior flap overlap to the EX-PRESS device ensures adequate control of aqueous flow.

Figure 6. Insert the EX-PRESS device on its side, with the tip facing downward slightly. Grasp the sclera or the flap with toothed forceps for countertraction.

Figure 7 shows the perfect positioning of the implant in the anterior chamber, and Figure 8 shows how the external back plate must be flush with the scleral bed before the flap is closed. There have been some issues in the past when the back plate is not placed properly.

Surgeons can use their preferred trabeculectomy technique for the EX-PRESS Glaucoma Filtration Device. I usually administer topical anesthesia (lidocaine). I prefer to use a fornix-based flap, but I leave a conjunctival stump to suture the conjunctiva closed. I use a blunt spread of the conjunctiva and Tenon’s capsule into the quadrant to avoid some of the blood vessels. I like to use diamond blades, although metal blades are certainly a reasonable choice. I personally do not use set-depth blades, however; I prefer to make the cuts freehand so I can visualize their depth. I may advance the blade deeper than I need to posteriorly so I can gauge the sclera’s thickness, and then I will retract the blade slightly to perform the lamellar dissection. I like to use the tunnel technique to make the scleral flap, because I think it leaves the scleral bed smoother.

I do not dissect the scleral flap as anteriorly as I perform a trabeculectomy dissection. It is not necessary to
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Dissect too far into clear cornea, as the device’s entry point will not be in the cornea. Nevertheless, it is important to dissect at least past the area of the blue zone to create enough space to accommodate the implant. Before inserting the EX-PRESS device, I make sure I can visualize the scleral spur and the blue zone. I then apply a wound-management technique before making my entry point.

Although the EX-PRESS procedure is a penetrating procedure, I do not fill the eye with viscoelastic, because it stays quite formed, even after I enter the anterior chamber. I introduce the knife just at the anterior aspect of the scleral spur. Again, it is important to carefully place the device at the iris plane. When the applicator is in place, I simply push down to release the device. The entry point for the device is narrower at the vertical meridian and wider in the horizontal meridian. If necessary, I can turn the implant 90º to position it correctly. Some striation often occurs, but the tissue will push the device in because of the spur. I like a tight fit of the EX-PRESS device into the incision in the eye—large enough to insert with excessive trauma and stretching of tissue, but not so large to cause excessive leakage from around the device. Some egress of aqueous will be visible when the implant is in place.

CLOSING THE SCLERAL FLAP

Although some surgeons do not place any sutures in the scleral flap, I feel more comfortable doing so to create some resistance to flow. I use an intraoperative gono mirror to make sure I have placed the device in the correct plane and position. Sometimes, in eyes with a very deep anterior chamber, such as highly myopic eyes, it can be difficult to see the implant in the peripheral anterior chamber (hence the use of a mirror to identify it). To dynamically check the flow, I continuously inject BSS solution (Alcon Laboratories, Inc.) into the area. I place two standard slipknots that I typically use for trabeculectomy (two single throws in the same direction), which allows me to tighten or loosen the scleral flap after assessing the flow. I may not be as obsessive about the amount of flow as I am with trabeculectomy, but I do want to make sure the chamber is maintained and that there is some resistance to flow. Finally, I lock the sutures so that the flap is closed. I use a running horizontal mattress suture to close the conjunctiva to itself in a watertight fashion.

SUMMARY

The most important steps of implanting the EX-PRESS Glaucoma Filtration Device are to (1) identify the landmarks, (2) size and locate the scleral flap appropriately, (3) make the entry point at the anterior spur and the entry plane at the iris plane, and (4) close the flap to permit some additional resistance. I feel that the EX-PRESS device represents a nice advancement from standard trabeculectomy.

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A New Glaucoma Device With Potential

Why I changed my tune about the EX-PRESS Glaucoma Filtration Device.

BY THOMAS W. SAMUELSON, MD

New options make this an exciting time to be a glaucoma surgeon. This article describes my experience with the EX-PRESS Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX). I refer to the use of this device as the EX-PRESS–assisted guarded filtration procedure, which I believe is more refined and standardized than traditional trabeculectomy. In 2002, when the EX-PRESS Glaucoma Filtration Device first became available as an unguarded subconjunctival procedure, I called it “glaucoma roulette,” because I worried that its lack of a barrier to filtration would induce hypotony. The device’s 50-µm lumen offers some resistance to aqueous flow, but I did not feel it was enough to act as the sole resistor to flow. As such, I did not incorporate the EX-PRESS device into my practice at that time. Once the EX-PRESS device was modified for use under the scleral flap, I decided to try it in my patients, and I have been using the EX-PRESS device–assisted guarded filtration procedure since then with increasing frequency.

MINIMALLY INVASIVE

I currently perform fewer transcleral filtration procedures than I have in the past, due to the fact that I have adopted the less invasive “bleb-less” procedures for patients with early-to-moderate glaucoma. However, I like to use the EX-PRESS glaucoma device in eyes in which it is necessary to abandon the trabecular meshwork and perform a transscleral procedure. I like the EX-PRESS device because it is minimally invasive. It requires a very small point of entry into the anterior chamber (I insert the P-50 model through a 25-gauge needle tract) (Figure 1A and B). Such a minimally invasive approach has many advantages. The device’s placement does not shallow the anterior chamber, and the eye maintains pressures close to physiological throughout the procedure. The P-50 model of the EX-PRESS device has a notch in the back that helps direct aqueous flow posteriorly. The EX-PRESS device–assisted guarded filtration procedure carries no risk of iris prolapse or bleeding from the ciliary body, unlike traditional trabeculectomy. The device also permits a much more elegant and standardized sclerostomy. Some glaucoma surgeons may feel that they do not need help making a hole in the eye, but it is challenging to make a sclerostomy that is the same dimensions every time. The EX-PRESS device does not eliminate or substantially reduce surgical expertise required for the remaining portions of the guarded filtration procedure.

EX-PRESS IMPLANTATION TECHNIQUE

Creating the Scleral Flap

To make the scleral flap, I create a small peritomy at the 12:00 o’clock position and inject lidocaine. I often use epinephrine with the lidocaine (1% or 2%) when injecting anteriorly in order to blanche the blood vessels. I tend to leave a small rim of limbal conjunctiva to assist with the conjunctival closure (although I do not incorporate this rim of tissue into the closure). I then utilize a wound-management
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Figure 2. The EX-PRESS filtration device facilitates placement of the P-50 device through a 2-gauge needle tract.

Having the sutures already in place makes the closing technique in the effort to create a successful bleb. I typically use either a diamond knife or a #75 supersharpe blade to make the 2/3-thickness groove for the scleral flap before completing the flap with a #67 blade. I carefully make sure I am on a smooth plane when dissecting the scleral flap. It is important not to create a multiplane dissection for the EX-PRESS device, because the region within the deeper plane can dehisce under the pressure of the insertion if the bed is too thin. The key to avoiding this error is making the dissection of the plane as smooth as possible. When using the EX-PRESS device, it is important that each component of the dissection (the flap and the bed) are of appropriate thickness. A thin scleral flap may allow the device to erode through the flap, whereas a thin bed may tear during the device’s insertion. The flap should be 1/2 to 2/3 of the scleral thickness. Although some surgeons prefer to use a guarded preset knife, I do not, because I think scleral thickness varies from eye to eye.

Placing the Device

The entry point for the EX-PRESS Glaucoma Filtration Device is critical to success. I place two 10–0 nylon flap sutures (a technique I learned from Garry Condon, MD), which adds control to the procedure without any drawbacks. I then enter the anterior chamber with the 25-gauge needle (Figure 2) and position the tip of the device in the needle tract. Up until this point, my second hand is retracting the scleral flap. While actually inserting the EX-PRESS device, however, I prefer to fixate the eye by grasping the margin of the scleral bed rather than the flap. I fear that the pressure needed to push the spur of the device through the incision may be enough to tear a thin flap if the scleral flap itself is used to stabilize the eye during this step. I gently push the device into place until I feel a pop. I keep my finger on the ridge of the insertion device so I do not have to fumble around to find it when I am ready to release the EX-PRESS device from the inserter.

Suturing the Flap

Having the sutures already in place makes the closing wound much easier. I test the flow of aqueous technique through the device before suturing, but I do not perform titration of flow at this point. I always perform a careful closure of the scleral flap, utilizing at least two sutures. I would caution surgeons not to skip this step. There are no disadvantages to titration of flow with sutures. I either cut the sutures with the laser or use releasable sutures. I advocate using the scleral flap as a resister rather than simply relying on the device to provide all of the resistance to flow.

DISCUSSION

What I really like about the EX-PRESS Glaucoma Filtration Device is its potential to facilitate glaucoma surgery in myriad ways. Andre Mermoud, MD, has described the use of the EX-PRESS device to facilitate a posterior deep sclerectomy. He implants the EX-PRESS device and directs the aqueous flow posteriorly to a deep scleral cut down where the uveal tissue has been exposed. He then closes the scleral flap tightly to encourage subscleral outflow. Unlike the trabeculo-descemet’s window of visco-canalostomy, having an EX-PRESS device in the anterior chamber promotes a predictable flow in such procedures. This novel approach is just one other way that creative surgeons are using the EX-PRESS device to perform less invasive surgery. I am excited to have this device available, and I anticipate that glaucoma surgeons will continue to find additional uses for it. Also, it appears to be safe for MRI scanning, a question that radiologists often ask. The only negative aspect of the EX-PRESS device is that it adds expense to the trabeculectomy procedure.

Finally, surgeons new to the EX-PRESS device may need to slightly alter their postoperative strategy. For example, a filter utilizing the EX-PRESS device is less responsive to focal massage in the early postoperative period. I have to apply diffuse pressure to the globe to increase the IOP and push the fluid through the device. In addition, I tend to cut sutures earlier when I use the EX-PRESS device. I would like to see data that the EX-PRESS device poses no long-term risk for the corneal endothelium. Again, I now implant the EX-PRESS device the majority of the time, rather than perform my standard trabeculectomy procedure, and I get excellent results.

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EX-PRESS® Glaucoma Filtration Device

The EX-PRESS® Glaucoma Filtration Device Preloaded on EDS Versions R-50, P-50, and P-200

INSTRUCTIONS FOR USE

Figure 1: The EX-PRESS® Glaucoma Filtration Device Preloaded on EDS

DESCRIPTION

The EX-PRESS® is a Glaucoma Filtration Device designed to regulate intraocular pressure in eyes suffering from glaucoma. The concept behind the EX-PRESS® Glaucoma Filtration Device is to divide aqueous humor through the implant from the anterior chamber to an intrascleral space - the bleb. The EX-PRESS® Glaucoma Filtration Device is manufactured from implantable stainless steel. It consists of a 2.3mm long and 0.4mm diameter tube, which connects the anterior chamber to the intrascleral space. Despite its miniature size, the EX-PRESS® Glaucoma Filtration Device features several major structural elements:

1. A cannula for draining aqueous humor from the anterior chamber to the intrascleral space.
2. A plate to prevent excessive penetration.
3. A spur to prevent extrusion of the EX-PRESS® Glaucoma Filtration Device from the eye.
4. Reserve orifices near the distal end, which constitute an alternative conduit for aqueous humor drainage in case of occlusion of the primary (axial) opening of the cannula by the iris.

The EX-PRESS® Glaucoma Filtration Device is preloaded on a specially designed disposable introducer, the EX-PRESS® Delivery System (EDS). The EDS is an inserter designed to maintain the correct orientation of the EX-PRESS® Glaucoma Filtration Device throughout the implantation procedure. The EDS allows the surgeon better control of the device as it is released. The EDS enables easy insertion for either right or left handed physicians, using only one finger for simple, consistent device release. The EDS is intended for single use.

The following versions of the EX-PRESS® Glaucoma Filtration Device are commercially available: R-50, P-50 and P-200.

INDICATIONS FOR USE

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

CLINICAL STUDY INFORMATION

A clinical study was performed with the EX-PRESS® Glaucoma Filtration Device R-30 and R-50 versions. As these versions have similar performance to the P models, the results are relevant for these models as well. The study was a prospective, open-label multi-center study conducted at 14 international sites in 8 countries.

There were 113 open angle glaucoma patients enrolled into 3 protocols.

The three protocols included the following:

- STS-97-01 (n=56) - failed medical therapy or laser trabeculoplasty patients
- STS-99-COM (n=36) - failed medical therapy or laser trabeculoplasty patients who underwent a combined procedure of EX-PRESS® Glaucoma Filtration Device implantation and cataract surgery
- STS-99-TRA (n=21) - failed filtering surgery (trabeculectomy) patients

The follow-up period was one year with intermediate scheduled examinations on the 1st and 7th postoperative days and on the 4th, 9th, 13th, 26th, and 39th weeks; the final visit was on the 52nd week. The examinations included tonometry, gonioscopy, and a slit-lamp examination. The clinical study was conducted in accordance with EN 540 Guidelines and the Declarations of Helsinki, and the local laws and regulations of the countries where the study was conducted.

The safety and effectiveness evaluation was done on a total of 113 patients implanted with the R-30 and R-50 versions; 58 consecutive patients completed a one-year follow-up (defined as Per Protocol cohort).

COMPLICATIONS AND ADVERSE EVENTS

Incidence of related Adverse Events stratified by device version (Intent to Treat Cohort) follows:

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<td>%</td>
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<td>%</td>
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<td>6.67</td>
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<tr>
<td>All</td>
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<td>67</td>
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Adverse events reported for other glaucoma penetrating surgical procedures, such as but not limited to, corneal and retinal complications, uveitis, and significant reduction in visual acuity, may occur as well. The safety profile was indistinguishable between the two versions. Reasons for device explantation included flat anterior chamber with hypotony, device exposure from erosion, and poor efficacy.

Efficacy

The cumulative probability of success for this cohort for versions R-30 and R-50 at one year was 75% and 79%, respectively.

SUMMER 2010 | SUPPLEMENT TO GLAUCOMA TODAY | 11
IMPROVING UPON TRABECULECTOMY WITH AN INNOVATIVE DEVICE

GUIDANCE REGARDING THE SELECTION OF THE APPROPRIATE VERSION

The clinical study was 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 implantation of the EX-PRESS® Glaucoma Filtration 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.
- Patient diagnosed with angle closure glaucoma.
- Presence of ocular disease such as uveitis, ocular infection, severe dry eye, severe blepharitis.

HOW SUPPLIED

The EX-PRESS® Glaucoma Filtration Device preloaded on the EDS is supplied sterile in a sealed pouch (Fig. 1). The device and the EDS have been sterilized by gamma irradiation and are intended for single use only.

WARNINGS, PRECAUTIONS

The implanting surgeon should be familiar with the instructions for use. The integrity of the package, the EX-PRESS® Glaucoma Filtration Device and the EDS should be examined. If the package is opened but not used, the implant should be returned to the manufacturer for exchange.

The EX-PRESS® Glaucoma Filtration Device and EDS should not be used if sterility or performance is compromised. The detent button of the EDS should not be pressed until implantation, since it is for single use only. MRI of the head is permitted, however not recommended, in the first two weeks post implantation.

EQUIPMENT REQUIRED

One device loaded on EDS, conventional ophthalmic microsurgical instruments and a surgical microscope. A 25-27G needle is required for performing a pre-incision for the EX-PRESS® Glaucoma Filtration Device.

MODE OF ACTION

The EX-PRESS® Glaucoma Filtration Device is implanted at the limbus after incision under scleral flap (see Figure 2). Its distal tip penetrates into the anterior chamber, while its proximal end is located under the scleral flap. The EX-PRESS® Glaucoma Filtration Device controls intraocular pressure by allowing a limited outflow of aqueous humor into the intrascleral space. The extent of drainage, and thus the intraocular pressure, is controlled by the hydrodynamic structure of the device.

IMPLANTATION PROCEDURE

Local or topical anesthesia is administered and the eye is prepared and covered using conventional sterile procedures. Implantation is performed using a special introducer (EDS), conventional microsurgical instruments and a surgical microscope.

The operation can be performed with viscoelastic material alone or with the use of a mini-A/C maintainer and viscoelastic. The EX-PRESS® Glaucoma Filtration Device, pre-loaded on the EDS, is inserted into the anterior chamber at the limbus through the sclera under the scleral flap.

The implantation procedure may be performed as follows:

EX-PRESS® GLAUCOMA FILTRATION DEVICE IMPLANTATION USING THE EX-PRESS® DELIVERY SYSTEM (EDS)

1. Create a 6mm long fornix-based conjunctival flap in the upper quadrants.
2. Create a limbal-based square (5x5mm) or trapezoidal (5x5x2mm) scleral flap extending into clear cornea. The depth of the flap should be ± 50% of scleral thickness.
3. Application of appropriate wound treating agent onto the sclerectomy bed at the surgeon’s discretion.
4. Penetrate into the anterior chamber, creating a track incision with a 25-27G needle in the grey zone parallel to the iris plane.
5. Loosen and lubricate the EX-PRESS® Glaucoma Filtration Device with BSS® Solution.
6. Implant the EX-PRESS® Glaucoma Filtration Device loaded on the EDS, through that pre-incision.
7. Apply full depression of the EDS detent button, allowing a smooth release of the EX-PRESS® Glaucoma Filtration Device.
8. Release the EDS detent button. The wire is permanently indented and fully retracted (single use only).
9. Withdraw the EDS.
10. Tuck the plate under the scleral flap, and verify its position.
11. Suture the scleral flap in at least 3 or 4 positions.
12. Reposition the conjunctiva with one or two sutures at the limbus.
13. Fill the anterior chamber with viscoelastic material.

After the implantation procedure, antibiotics are administered topically, the eye is covered with a pad and the patient is discharged. Patients must be followed closely during the first year after implantation (at least 4 times), and at least once a year during the device’s lifetime.

See instructions for use
Sterilized by Radiation
Do not Reuse
Federal (USA) law restricts this device for sale by or on the order of a physician

Manufactured by: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX USA
76134-2099
Made in Israel

Figure 2: Implantation of the EX-PRESS® Glaucoma Filtration Device

### Table: Results from clinical studies

<table>
<thead>
<tr>
<th>Criteria/Cohort Per Protocol cohort</th>
<th>Version</th>
<th>R-30</th>
<th>R-50</th>
<th>All (weighted mean)</th>
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<tbody>
<tr>
<td><strong>Number of medications at one year (Mean)</strong></td>
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<tr>
<td>Baseline</td>
<td>1.47</td>
<td>1.65</td>
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<td>One year</td>
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<td>0.38</td>
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<tr>
<td>N</td>
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### Table: % IOP reduction at 12 months

<table>
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<th>R-50</th>
<th>All (weighted mean)</th>
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<tr>
<td><strong>% IOP reduction at 12 months</strong></td>
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<tr>
<td>Per Protocol cohort</td>
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<tr>
<td>Mean</td>
<td>28.68</td>
<td>40.66</td>
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<tr>
<td>N</td>
<td>32</td>
<td>29</td>
<td>36</td>
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### Table: Results from clinical studies

<table>
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<tr>
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<th>R-50</th>
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<tr>
<td><strong>IOP reduction &gt; 20%</strong></td>
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<td>Kaplan-Meier</td>
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<td>95.80%</td>
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### Table: Results from clinical studies

<table>
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<th>R-50</th>
<th>All (weighted mean)</th>
</tr>
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<tbody>
<tr>
<td><strong>IOP &lt; 21 mmHg</strong></td>
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<tr>
<td>Kaplan-Meier</td>
<td>78%</td>
<td>88%</td>
<td>83%</td>
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