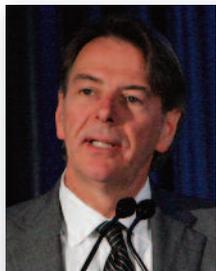


Glaucoma surgery: Advances you & your patients will appreciate



Gary P. Condon, M.D.

“We are still in a mode where we are trying to find something as effective but safer and more predictable than trabeculectomy”



Ike K. Ahmed, M.D.

“In using glaucoma filtration devices, the goal is maintaining or improving efficacy and enhancing surgical procedure safety and predictability”



Malik Y. Kahook, M.D.

“The EX-PRESS device is a single improvement to one step of the gold standard procedure of trabeculectomy”



Richard A. Lewis, M.D.

“Cost has to be a consideration when surgeons think about implementing new procedures, but cost cannot be the driving factor”

This event was sponsored by
Alcon, Fort Worth, Texas.

**Click QR code to
view EX-PRESS
implantation
surgery**

EX-PRESS device is advancing glaucoma surgery to a “new era”

by Garry P. Condon, M.D., and Michelle Dalton, EyeWorld Contributing Editor

We are in a new era of glaucoma surgery. There are so many new innovations and devices we hear about every day. But have we found the Holy Grail? The answer is we are still in a mode where we are trying to find something as effective but safer and more predictable than trabeculectomy. Despite what you hear about the innovations, trabeculectomy is a good procedure because it works. Many people use this technique and will probably continue to do so for years to come.

But can we marry the effectiveness of trabeculectomy and enhance the safety of the type of procedure that it encompasses? The real issue is finding something that works as well as trabeculectomy with increased safety, less tissue trauma, more precision, more predictability, and more control. If we can find that, then we will continue to advance the field of glaucoma surgery.

That's what I think about the EX-PRESS Glaucoma Filtration Device (Alcon, Fort Worth, Texas). It is a starting point. It is a new platform. It is an advance.

We still come back to drainage surgery because we cannot argue with the efficacy. In primary glaucoma filtration, nothing has been proven to be more effective than trabeculectomy. It is that aspect of the surgery that continues to draw us to it. In all of what we have seen, we have seen innovation, and we have seen technology trying to do things better.

The other aspect of this advancement is the idea that glaucoma surgery doesn't always have to be more successful to be better. I like the analogy of phacoemulsification versus extracapsular cataract extraction (ECCE). Phacoemulsification, with a posterior chamber lens implant, is no more effective than—or more successful than—ECCE. But we all agree that phacoemulsification is better. If we threw away evidence-based medicine back in the 1970s, when **Charles Kelman, M.D.**, introduced us to it, who knows what kind of cataract surgery we would be doing today?

The EX-PRESS device procedure has been found to have fewer complications than standard trabeculectomy. Advantages include less

hypotony and choroidal effusions and faster visual recovery.^{1,2} The idea is starting with something better, something safer, something that we have more control over, with more precision, more predictability, less trauma, and if we can do as well in terms of efficacy, then we have a better procedure and we begin to advance.

With the EX-PRESS device procedure, the likelihood of an intraoperative or post-op hyphema in patients taking anticoagulants has been decreased by making a bigger incision in the sclera. I believe the EX-PRESS device procedure gives more control intraoperatively and post-op.

Additionally, wound management is the same in the EX-PRESS device procedure as it is in standard trabeculectomy. Furthermore, the EX-PRESS device procedure is usually performed without viscoelastic, which contributes to its ease. In my opinion, it helps me to better manage these patients with open-angle glaucoma.

Discussants

A participant in this discussion is **Ike K. Ahmed, M.D.**, who is an expert in the OR, a phenomenal innovator, and a tremendous contributor to surgery and ophthalmology in general. Dr. Ahmed discusses his experiences with the EX-PRESS device and will help us to hone in on some of the pearls and aspects of the procedure that he finds useful.

Next, we have **Malik Kahook, M.D.**, who is a rising star in the field of glaucoma surgery, a great investigator and clinician. Dr. Kahook reviews his recently published study, “Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy.”

Richard A. Lewis, M.D., has been a tremendous leader for innovation in glaucoma as a past American Glaucoma Society president and as an advisor to various glaucoma surgery start-up companies. Dr. Lewis's profound influence on new innovations in glaucoma surgery have helped to improve the outcomes of glaucoma surgery. Dr. Lewis will compare trabeculectomy with the

EX-PRESS implantation is “straightforward”

by Ike K. Ahmed, M.D., and Michelle Dalton, EyeWorld Contributing Editor

Trabeculectomy has been a stable procedure for glaucoma surgeons for years, but it is not without its issues. There are a variety of intraoperative issues that the surgeon is challenged with, including intraoperative anterior chamber shallowing, tissue trauma, and bleeding.

Post-op, there are issues related to hypotony, shallowing of the anterior chamber, choroidals, hyphema, and bleb-related issues. Additionally, the surgeon needs to consider the patient's visual recovery and post-op interventions.

Filtration devices have been developed to help overcome some of these challenges. In using glaucoma filtration devices, the goal is maintaining or improving efficacy and enhancing surgical procedure safety and predictability. Implantation of the EX-PRESS Glaucoma Filtration Device (Alcon, Fort Worth, Texas) is straightforward and, with some pearls, easily mastered. In my opinion, it is an advancement over standard trabeculectomy. The step-by-step technique described has been used for more than 5 years.

Device specifics and indications

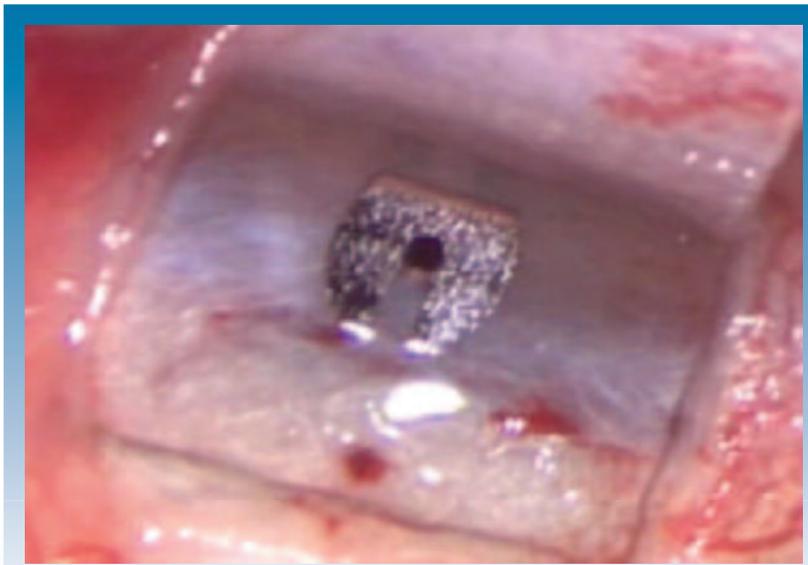
The EX-PRESS Glaucoma Filtration Device is a stainless steel, biocompatible device, about 2.5 mm in length, designed to be placed under a scleral flap. Biocompatibility is not an issue, as the device is made of the same material as cardiac implants. It's been demonstrated as being “MRI safe” up to 3 Tesla. It's available in two lumen sizes, 50 microns and 200 microns. My preference is the 50-micron lumen size as it affords control. The 200-micron version has no resistance to flow but may be less likely to become blocked. Lumen blockage is rare with either lumen size and if it occurs, it can be lasered or managed with intraocular tissue plasminogen activator (TPA).

continued from page 1

EX-PRESS device procedure and comment on several other types of glaucoma surgery.

References

1. Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy. *Am J Ophthalmology*. 2011;151(3):507-513.
2. Maris P, Ishida K, and Netland P. Comparison of trabeculectomy with EX-PRESS miniature glaucoma device implanted under scleral flap. *J Glaucoma*. 2007;16(1):14-19.



The EX-PRESS Glaucoma Filtration Device is a stainless steel, biocompatible device designed to be placed typically under a scleral flap

The EX-PRESS Glaucoma Filtration Device is indicated as a treatment for patients suffering from glaucoma, and for whom there is an indication, according to the physician's judgment, for filtering surgery. For those surgeons just starting out, the ideal patient might be a pseudophakic patient with an open angle, where there is a lot of room to work with and where positioning may be less of an issue.

Surgical technique

First, administer topical lidocaine. During the surgical procedure, the surgeon should look for limbal anatomy, where the scleral fibers can be seen. Then, look for the blue zone and the clear cornea. It is important to position the flap and size it according to where the EX-PRESS device will be implanted. Ensure

that there is a reasonably sized flap around the implant. The thickness will ensure good control of flow post-op. Another pearl is to avoid making a thin flap, as the flap thickness will affect the device's success.

Under the scleral flap, a pilot hole is made with a 26-gauge (if using a hypodermic needle) or 25-gauge EdgePlus Trocar Blade (Alcon) opening into the anterior chamber. This is a critical part of the procedure to ensure adequate positioning of the implant. Enter at the anterior spur at the level of the iris plane, facilitated with the eye pointing down. There is no need to remove a block of sclera or a large piece of tissue as in trabeculectomy—that can create more trauma. Furthermore, the small pilot hole prevents the AC from shallowing during the procedure, which is a concern with trabeculectomy. An iridectomy is also not required with the EX-PRESS device.

Rotate the implant about 90 degrees to place the implant along the long axis of the pilot hole. Rotate the EX-PRESS device to its final position when it is inside the eye. The back plate needs to be flush with the scleral bed. By planning the scleral flap around the point of insertion of the EX-PRESS device, surgeons get good lateral and posterior overlap of the flap after they complete the procedure.

Instrumentation

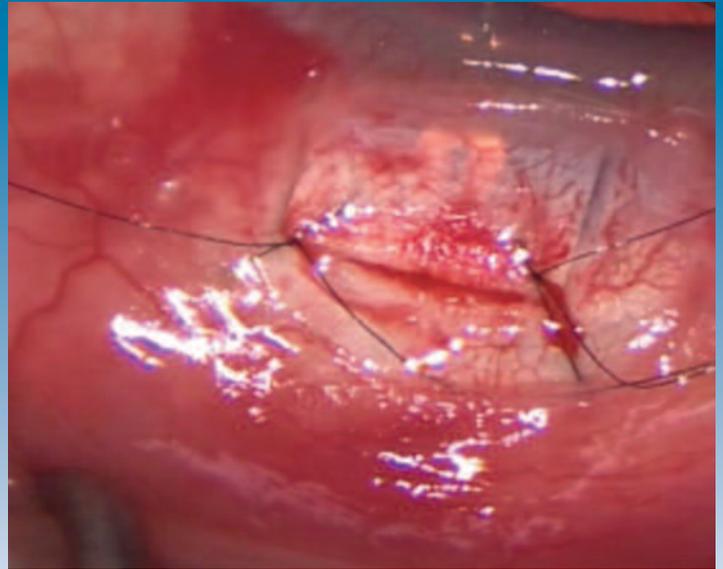
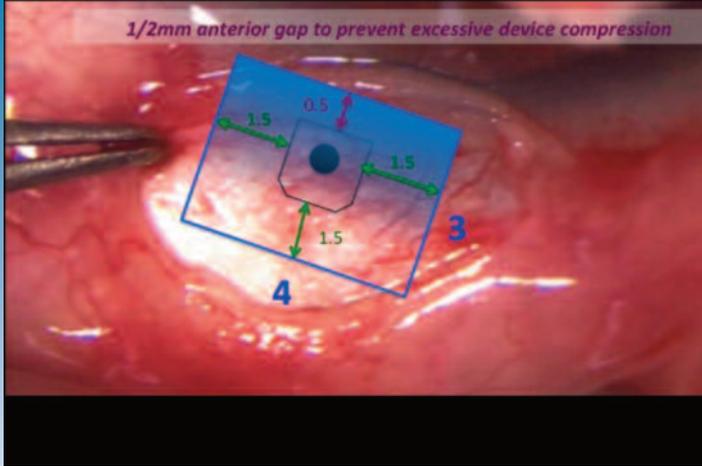
Some of the instruments used to implant the EX-PRESS device include the A-OK Full Handle 15 Degrees (Alcon). The 15-degree blade is useful for the scleral outline, and the

CONTACT INFORMATION

Dr. Condon is chairman, Department of Ophthalmology, Allegheny General Hospital, Pittsburgh; director, Division of Glaucoma Services, Allegheny General Hospital; and clinical associate professor, ophthalmology, Drexel University College of Medicine. He can be contacted at garrycondon@gmail.com.

4x3 mm Scleral Flap

1/2mm anterior gap to prevent excessive device compression



Ensure adequate flap overlap lateral and posterior to the EX-PRESS device to allow control of aqueous flow

Suture tension is important because hypotony can still occur

ClearCut HP Crescent DB (Alcon) is useful for the lamellar dissection of the flap, which is similar to a tunneling technique. The 25-gauge EdgePlus Trocar Blade makes a nice pilot hole for the EX-PRESS device P-50 model.

Intraoperative viscoelastics vs. air bubble

I don't routinely use viscoelastic intraoperatively, unless there is positive pressure. If there is further concern for hypotony (which should be reduced with the device), filling the AC with viscoelastic at the end of the procedure may ease some of the concern.

The type of viscoelastic is also important. The smaller the lumen size, the more likely the viscoelastic used will last longer or won't be as necessary. Post-op, if you do need to refill the anterior chamber, the viscoelastic will tend to stay in the eye longer with an EX-PRESS device in place versus in a trabeculectomy. Thus, less viscoelastic may be required. Alternatively, an air bubble may be placed, which also lasts longer with the EX-PRESS device, again pointing to the added control of the device versus trabeculectomy.

Suturing

Suture tension is another important consideration because hypotony can still occur, although I've found fewer instances of hypotony with the EX-PRESS device than with a trabeculectomy. This could also be a factor for those who are just starting to use the device. The need to do suture lysis may be less frequent with the EX-PRESS device than with trabeculectomy (in my hands).

I recommend using 10-0 nylon sutures for scleral flap sutures and 10-0 vicryl for conjunctival closure in a running horizontal mattress technique, which I think provides a nice closure. This provides a firm conjunctival clo-

sure, prevents leakage early in the procedure, and reduces the amount of tension on the bleb. Anecdotally, this may help with that morphology and can help prevent overriding bleb than can occur in the conjunctiva.

For the scleral flap, two sutures should be placed in each corner, with a slipknot that can be locked. If more control is needed over flow, place additional sutures. Slipknots can help with adjusting the tension accordingly, since they can be easily tightened or loosened. To check the flow, continuously inject balanced salt solution; you can also inject some balanced salt solution into the side port to check on flow.

Wound management

Wound healing modulation is an important part of the success of the EX-PRESS device implantation procedure. Whatever type of wound-healing modulation that one uses or applies during trabeculectomy for controlling fibrosis should be applied for the EX-PRESS device. If a certain agent is appropriate for the particular indication and risk factors for the patient, then the same agent would be applied with the EX-PRESS device. As surgeons become more familiar with the procedure, the device, and the technique, wound management may be less of an issue. Regarding pre- and post-op medications and wound healing management, the surgeon can use the same regimen as for trabeculectomy, being careful during post-op bleb assessment.

Pearls

Blebs sometimes have to be needled. The needling technique we use for blebs is very similar with the EX-PRESS device, although it's not necessary or easy to enter the anterior chamber. Steroids and other wound-healing modalities would be applied here accordingly.

Summary

Anatomical landmarks, flap design and thickness remain important in this procedure. Additionally, entry points for the device are important, as well as the angle entered.

In summary, there are several key steps in implanting the EX-PRESS Glaucoma Filtration Device. First, the surgeon should identify the landmarks. When we look at the sclera first, a white glistening band, this should be the highway you follow and your landmark. The blue zone is next, followed by the clear cornea. Remember those landmarks. The critical point in the technique with the EX-PRESS device is to aim at the anterior aspect of that spur. If you fail to identify this spur and rely on other landmarks, you can get into a little trouble. Finally, be sure to enter at the level of the iris plane.

It's been my experience that it's important to position the flap and size it according to where the implant will go. Approximate the scleral spur so you can plan a flap that will cover the area reasonably well.

Identify the surgical limbus and use that as your entry point. I prefer about 1 mm on either side to ensure adequate flow control. Be sure to secure the flap for additional resistance. We still want to ensure that we have a reasonable size flap around the implant. By planning around the point of insertion, we can ensure we have good lateral and posterior overlap of the flap when we close the procedure.

CONTACT INFORMATION

Dr. Ahmed is assistant professor and research fellowship director, Department of Ophthalmology, and director of the Glaucoma and Advanced Anterior Surgical Fellowship, University of Toronto, and clinical assistant professor, University of Utah. He can be contacted at ike.ahmed@utoronto.ca.

Bleb morphology and post-op outcomes with the EX-PRESS device

by Malik Y. Kahook, M.D., and Michelle Dalton, EyeWorld Contributing Editor

This discussion includes a review of the recently published study, "Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy."¹ This was a retrospective, consecutive, case control series that included 70 patients (35 patients in the EX-PRESS device [Alcon, Fort Worth, Texas] group and 35 patients in the trabeculectomy group). Total follow up was at least 2 years; mean was about 28 months. The EX-PRESS device is "nonvalved and is placed under a partial thickness scleral flap. Similar to trabeculectomy, aqueous humor is allowed to drain and collect into a bleb formed in the sub-Tenon's space."¹ As stated in the publication, the use of the device has steadily increased since it was first introduced, mainly because of perceived improvement in aqueous filtration and the possibility of avoiding an iridectomy.

Implantation

All patients received the EX-PRESS P-50 micron device. During implantation, the plate rests flat against the sclera when it is positioned slightly posterior to the blue line.

Each patient received fornix-based conjunctival incisions; 27-gauge needles were used for all cases to allow for a water-tight fit around the device post-implantation. It takes a little bit of effort to get the device inserted through the needle entry tunnel, so there is a slight learning curve. However, if the surgeon makes a side slit externally with a 27-gauge needle, implantation seems to be a lot easier. In all cases, we made trapezoidal flaps with a 3-mm base.

Viscoelastic may be attached to the 27-gauge needle so the surgeon can deepen the chamber upon entry if needed. In our study,

complete success was defined as IOP ≥ 5 mm Hg and ≤ 18 mm Hg and at least a 30% decrease in IOP. A significant decrease in IOP was needed to call the procedure a complete success. Qualified success was the same definition but with the use of IOP-lowering medication post-op.

Pearl: Despite the flow regulating 50-micron internal lumen on the P-50 device, hypotony is still possible and the scleral flap should be securely sutured with 10-0 nylon as would be done with standard trabeculectomy.

Study results

The Moorfields Bleb Grading System (MBGS) includes three different categories to be examined: bleb area, bleb height, and bleb vascularity. The study found that bleb vascularity for the EX-PRESS device group was less than in the trab group up to 18 months of follow up. At final follow up, the vascularity was similar between the two groups. Additionally, the blebs were more diffuse in the EX-PRESS device group from 3 months to 18 months, after which findings were similar between groups. Bleb height was lower in the EX-PRESS device group up to 3 months of follow up and higher in the EX-PRESS device group from 6 months to 18 months of follow up, but this difference disappeared at the last follow up.

IOP control

There was a statistically significant difference in IOP control at 1 week, 1 year, and at last follow up. The pressure for the EX-PRESS device patients was slightly higher at baseline, but this was not statistically significant. At about 6 months, there was a slight deviation of the pressure between groups, with the EX-PRESS device patients having slightly higher mean pressure at last follow up and 1

year. However, the percent of IOP lowering (45% and 48%) was similar in both groups.

Complete success was achieved in 77% of patients in the EX-PRESS device group and 74% of patients in the trabeculectomy group. There was an additional 5.71% and 8.57% for the EX-PRESS device and trabeculectomy groups, respectively, for qualified success. The P values were not different between the two groups.

Complications

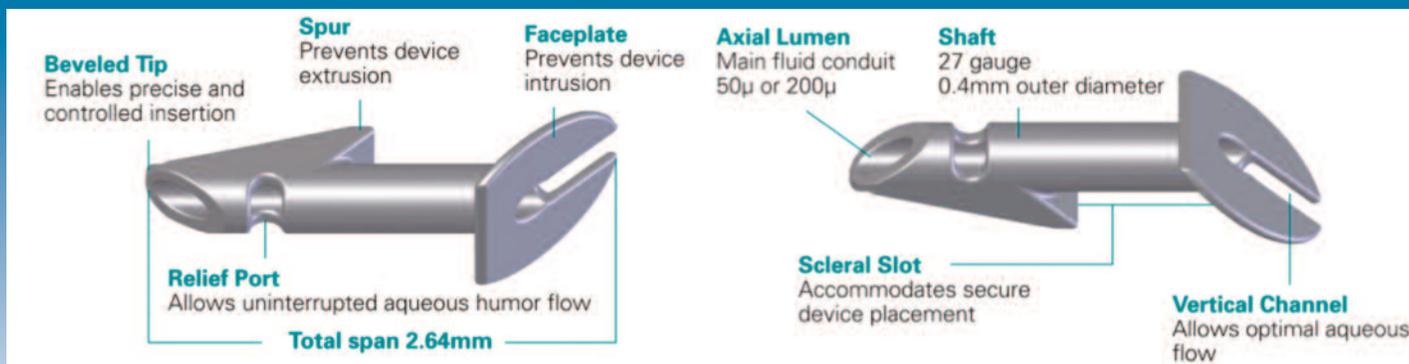
Overall, the complication rates were similar. However, the study found less hypotony in the EX-PRESS device group, 2/35 versus 5/35 in the trabeculectomy group. Incidence of hyphema was also less in the EX-PRESS device group, likely because there is less tissue manipulation. In the EX-PRESS device group, only one patient had micro-hyphema compared with four patients in the trabeculectomy group.

Post-op vision

Additionally, we assessed best corrected visual acuity post-op in patients. The EX-PRESS device group returned to baseline visual acuity after 1 week versus the trabeculectomy patients who took about 1 month to return to baseline visual acuity.

The study also examined the number of post-op visits in the first 3 months after both procedures. Our results found that patients in the EX-PRESS device group were seen by their ophthalmologist on average six times during the first 3 months, whereas the trabeculectomy patients came back an average of eight times. This was statistically significant and seems to validate anecdotal information about quicker recovery times with the EX-PRESS device.

continued on page 5



Specifics of the EX-PRESS P-50 device

Eliminating, reducing complications "open the door to the EX-PRESS device"

by Richard A. Lewis, M.D., and Michelle Dalton, EyeWorld Contributing Editor

The technique of trabeculectomy is pushing the field of glaucoma surgery forward in a way that has not been seen for many years. It is an exciting time. This discussion includes a review of some of the different glaucoma surgical options found to have moderate IOP reduction. A case report on a patient of mine demonstrates this efficacy.

Case report

This patient was first seen in 1993. At that time, he was 46 years old, with a history of glaucoma for 3 years and an IOP of 30 mm Hg. He was taking timolol and dipivefrin twice daily. At his initial examination, he was a moderate myope (-3.75 OU), with IOPs of 25 mm Hg and 22 mm Hg and extensive cupping, considering his age. The visual fields at that time were not bad, although there were some early defects. He was not very compliant, either with his follow-up visits or with medication.

At his next examination in 2001, he said he had undergone a trabeculectomy in the left eye in 1995. He also had undergone bilateral PRK in 1997. At that time, he was taking latanoprost and timolol, although he admittedly noted his own poor compliance. He did not use drops in the left eye (the one that had undergone the trabeculectomy). On examination, his IOP was 22 mm Hg in the right eye (the nonsurgical eye) and 4 mm Hg in the eye

that had surgery. He had extensive cupping, with average-sized corneas.

The eye that had the trabeculectomy remained healthy and looked similar to the 1993 field examination. To me, this case illustrates clearly how trabeculectomy can make a difference in protecting the visual field and preserving vision. Those two goals—protecting the visual field and preserving vision—are why this surgery is performed.

Complications

Trabeculectomy may be one of the most commonly performed procedures, but it is not without its own set of potential complications, such as hypotony, flat ACs, and choroidals. The short-term problems include endophthalmitis, and the long-term problems include blebs and blebitis. The goal of glaucoma specialists is to eliminate or reduce those complications, and that's what opens the door for surgical devices like the EX-PRESS Glaucoma Filtration Device (Alcon, Fort Worth, Texas).

There are alternative concepts being explored to modify the bleb, and additional new procedures that avoid bleb creation altogether are being developed. There is canal surgery, which includes tightening the trabecular meshwork. There are ways to direct flow to the suprachoroidal space, and there are methods being investigated to reduce aqueous flow.

Some may question if one technique will

dominate. In my opinion, that is likely not the case. Unlike another common condition—cataract—glaucoma is a complicated disease. Glaucoma, by diagnosis, encompasses a range of genetic conditions. Again, unlike a patient with a cataract where one procedure (phacoemulsification) can rectify the problem, with glaucoma patients there is not yet one single procedure that can resolve all the potential manifestations of the disease. Each procedure a surgeon performs should be customized to the patient.

Comparisons with trabeculectomy

As I noted earlier, trabeculectomy is a viable surgical option, but is not without its own set of complications; by modifying the procedure we hope to eliminate most of those complications. One of the ways to modify a trabeculectomy is with the EX-PRESS device. In my hands, one of the major advantages to using the EX-PRESS device is the uniformity it creates in the major sclerosis sites. With the EX-PRESS device procedure, there is minimal trauma, minimal inflammation, and minimal involvement of the iris.

For surgeons who are not convinced trabeculectomy should be the surgical standard any longer, there are alternatives. For instance, three different tube shunts have been introduced. I prefer to use tube shunts more for advanced disease. With the three shunts—Ahmed (New World Medical, Rancho Cucu-

continued from page 4

There were no real differences between the number of medications used pre-op or post-op between the two groups.

Conclusions

Results show complete and qualified successes were similar between groups. The percentage of IOP lowering was similar between groups. MBGS initially favored the EX-PRESS device, but then became equivalent the further out from surgery the patient was.

However, we did find quicker visual recovery and fewer post-op visits after the EX-PRESS device.

The EX-PRESS device in practice

With these results in mind, how can the surgeon best use the EX-PRESS device in practice? The EX-PRESS Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed. If a patient is deemed high risk for hypotony, the

EX-PRESS device should be considered as an alternative to traditional trabeculectomy due to the flow regulation that the device provides. If there is a need for quicker visual recovery, as is the case with the monocular patient, I would recommend the EX-PRESS device because the visual recovery is possibly faster than traditional trabeculectomy. In these patients, that 3-week difference is crucial and in my mind justifies the added cost of surgery incurred with use of the EX-PRESS device. I do favor the EX-PRESS device over trabeculectomy in patients who are anticoagulated due to the lower risk of bleeding with the EX-PRESS device.

I also recommend use of the EX-PRESS device for patients undergoing combined cataract extraction and filtration surgery to lessen tissue manipulation and cause less inflammation post-op.

The EX-PRESS device, in my mind, is a single improvement to one step of the gold standard procedure of trabeculectomy. We will still require many more advances such as

wound modulators that enhance success without increasing late complications, as well as sutureless wound closure methods that avoid early bleb leaks. Our approach to filtration surgery continues to evolve and will allow for better outcomes and increased patient satisfaction.

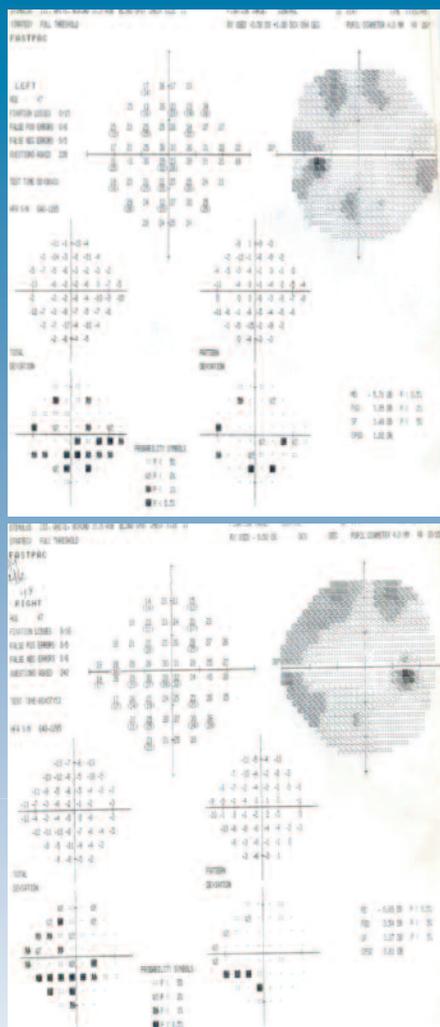
Reference

1. Good TJ, Kahook MY. Assessment of bleb morphologic features and postoperative outcomes after EX-PRESS drainage device implantation versus trabeculectomy. *Am J Ophthalmol.* 2011 Mar;151(3):507-13.e1. Epub 2011 Jan 13.

CONTACT INFORMATION

Dr. Kahook is associate professor of ophthalmology and bioengineering; director, clinical research; and director of the glaucoma service at the University of Colorado Hospital Eye Center. He can be contacted at malik.kahook@gmail.com.

Case report: April 1993



At his initial examination, the patient was a moderate myope, with IOPs of 25 mm Hg and 22 mm Hg and extensive cupping

monga, Calif.), Baerveldt (Abbott Medical Optics, Santa Ana, Calif.), and Molteno (IOP Inc., Costa Mesa, Calif.)—the aqueous flow is distributed back to the equatorial reservoir 8-10 mm from the limbus. The aqueous flow creates a thick bleb wall. Shunts have some advantages in complicated disease because they don't cause scarring as easily.

In the landmark trabeculectomy versus tubes study, results found greater IOP lowering with trabeculectomy.¹ That was an important study and seemed to change the scope of glaucoma surgery. However, anecdotal experience has found fewer long-term complications with tubes. There is also an issue with surgical ease—trabeculectomy is generally considered a fairly simple technique to master, while tube

placement may have a longer learning curve and is generally more difficult.

Considerations

In glaucoma surgery, the surgeon needs to consider the efficacy of the procedure; the risk-complication profile; the technical ease of performing the procedure; how long the procedure takes to perform; what the cost is to the physician, the ASC, and the hospital; and finally, the reimbursement.

In no-bleb glaucoma surgery, the key is to open the site of resistance in the angle at the site of the trabecular meshwork. This is an angled surgery procedure. The classic approach has been trabeculectomy or goniotomy; the latter is usually limited to infants with congenital glaucoma. There are two new approaches—Trabectome (NeoMedix, Tustin, Calif.) and iStent (Glaukos, Laguna Hills, Calif.). The iStent has not yet been approved by the FDA.

The Trabectome is a handpiece that has an infusion and a cutting mode on it. The bipolar electrode thermally ablates the strip of the trabecular meshwork and opens Schlemm's canal to the anterior chamber. The footplate protects collector channels and controls incision depth. A side port paracentesis entry is made into the anterior chamber. Viscoelastic is used to deepen the anterior chamber. This instrument is commonly used in combination with cataract surgery. The Trabectome probe is passed across the anterior chamber. It engages the trabecular meshwork and ablates at about the 4 o'clock position. In those with open-angle glaucoma, this ablation opens the side resistance of the eye; thousands of patients have been followed for up to 3 years. For patients with open-angle glaucoma, it plays an equally important role by potentially dropping average pressures to about 17-18 mm Hg. In early glaucoma, this may be a reasonable option for a select group of patients.

The iStent is one of the smallest medical devices implanted in the human body and is placed directly into the trabecular meshwork. The stent is attached to an inserter, which touches the trabecular meshwork and is then implanted into the canal space. The implant is injected, and the inserters are removed. Anecdotal experience has found that more than one iStent needs to be implanted to get the desired level of pressure reduction.

Canaloplasty is a third procedure and has been approved in the U.S. Canaloplasty is canal surgery with tightening of the trabecular meshwork, in which a 300-micron flexible microcatheter with a lighted beacon tip is passed into the canal space. A superficial flap is created, and a deeper flap is created to pass the catheter into the canal space. The lighted beacon tip shows where it is in the canal

space as it gently passes through. The catheter is passed 360 degrees and comes out the other end. A polypropylene suture is attached to the distal tip, and the catheter is removed. The canal has been dilated with the catheter and the viscoelastic. The canal is tightened with a polypropylene suture, and then the flap is closed. The advantage of this is there is no bleb. This is all done ab-interno. The surgeon is not depending on external drainage, and that makes it safer in the short and long term.

However, there is a learning curve with this technique. It takes some training to identify the canal and feel comfortable working to pass this catheter through. For an experienced surgeon, this procedure will take about 30 minutes. For those who are just beginning to use it, it takes a bit longer.

Results of canaloplasty show that it has great potential for certain types of patients. At 2 years, results average around 15.7 mm Hg in the phakic eye.² This procedure is useful in patients where there might be a complication from trabeculectomy or because a trab failed in the patient's other eye, there was significant conjunctival disease, or the patient is taking anticoagulants.

Conclusion

Cost has to be a consideration when surgeons think about implementing new procedures, but cost cannot be the driving factor—patient outcomes, reduced complications, and surgeon comfort must take precedence. There are numerous procedures we have available to improve outcomes from the standard trabeculectomy. In my opinion, the EX-PRESS device has the advantage of efficacy, reduced complications, and improved predictability compared with trabeculectomy, and it is the most cost-effective option overall.

Editors' note: This discussion includes off-label uses of glaucoma devices.

References

1. Gedde SJ, Schiffman JC, Feuer WJ, et al., for the Tube Versus Trabeculectomy Study Group. Three-year follow-up of the tube versus trabeculectomy study. *Am J Ophthalmol.* 2009;148(5):670-684; Epub Aug 11, 2009.
2. Lewis RA, van Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open angle glaucoma in adults: two year interim clinical study results. *J Cataract Refract Surg.* 2009;35:814-824.

CONTACT INFORMATION

Dr. Lewis is a glaucoma specialist in private practice in Sacramento, Calif. He can be contacted at rlewiseyemd@yahoo.com.

This supplement was produced by EyeWorld based on a corporate event sponsored by Alcon.

Copyright 2011 ASCRS Ophthalmic Corporation. All rights reserved. The views expressed here do not necessarily reflect those of the editor, editorial board, or the publisher and in no way imply endorsement by EyeWorld or ASCRS.

© 2011 Novartis AG 8/11 EXP11647JSEU