GLAUCOMA

Alternatives to trabeculectomy

by Faith A. Hayden EyeWorld Staff Writer

An overview of what's available

It's no secret that trabeculectomy, the so-called "gold standard" of glaucoma surgery, has been called some pretty nasty things of late by glaucoma surgeons. Everyone, it seems, is desperate for an alternative to the procedure, which was first considered contemporary when Lyndon B. Johnson was in office. It may be the most effective glaucoma surgery for lowering intraocular pressure, but it also comes with the highest risk of complications. So what are the alternatives? And can any usurp trabeculectomy from its battered and beleaguered throne? EyeWorld spoke to experts on the Trabectome, canaloplasty, endoscopic cyclophotocoagulation (ECP), the EX-PRESS, and the iStent to garner a closer look at what makes each alternative tick, as well as some of the scientific data backing up their efficacy.

Trabectome

The Trabectome procedure (NeoMedix, Tustin, Calif.) gained FDA approval in 2004 for the treatment of open-angle glaucoma, and it's best suited for mild to moderate cases. According to a comprehensive article on Trabectome by Steven D. Vold, M.D., founder and chief executive officer, VoldVision, Springdale, Ariz., the procedure has a number of safety advantages over trabeculectomy, such as no bleb creation, which eliminates blebitis and other related complications; no requirement for using mitomycin-C or 5-fluorouracil; and it does not require the dissection of the conjunctiva or sclera, leaving the door open for future glaucoma surgeries (International Ophthalmology Clinics, 51:65-81). During the operation, a surgeon makes a 1.6-1.7 mm temporal clear corneal incision with a keratome. Dr. Vold suggested injecting viscoelastic to help stabilize the anterior chamber. The surgeon then ablates the trabecular meshwork and Schlemm's canal, while maintaining irrigation throughout the ablation process, thus minimizing the risk of thermal damage to surrounding tissues. "Failure is probably the first complication you need to talk about," said Dr. Vold. "It doesn't work in everyone. Hyphema has to be minimized. There's talk of if we should use anticoagulants or not. I personally think that in this procedure it's best to stop anticoagulants if possible for a small period of time, just to prevent a large hyphema at the time of surgery. Some people use viscoelastic to tamponade the surgery to minimize blood. That's a reasonable option. I think pressurizing the eye at the conclusion of the case is an important thing."

Although there haven't been many peer-reviewed, prospective, randomized trials of the Trabectome, case study data has been encouraging thus far. A pilot study, for example, involved 37 patients who had the procedure at CODET Eye Institute, Tijuana, Mexico (Ophthalmology, 2005; 112:962-967). After the surgery, patients had a 40% drop in IOP levels overall. Mean IOP declined from pre-op levels of 28.2±4.4 to 16.3±2.0 mm Hg (n=15) at 12 months post-op, and medication use decreased from 1.2±0.6 (n=34) to 0.4±0.6 at 6 months post-op (n=25). "All hyphemata cleared within 6.4±4.1 days," stated Dr. Vold's paper. "Other complications included peripheral anterior synechiae (24.3%), corneal injury (16.2%), focal iris adhesion to spur or posterior meshwork (13.5%), and pressure spike (post-op IOP >5 mm Hg above baseline) (5.4%). Vision loss did not exceed 2 Snellen lines in any patient. No serious, vision-threatening complications were observed." The two biggest benefits of the Trabectome, said Dr. Vold, are its safety profile and the fact that the procedure spares the conjunctiva. Furthermore, it does not negatively impact the results of a future
trabeculectomy, should the Trabectome fail. "It's a growing procedure," he said. "It's picking up some steam in the U.S. I think the whole space of minimally invasive glaucoma surgeries, where we're doing conjunctive sparing surgeries, is an area that's about to explode. Moving from filtration surgery to surgeries that do not create a bleb is going to be the wave of the future."

**Canaloplasty**

Canaloplasty is a non-penetrating and minimally invasive procedure for open-angle glaucoma that works by dilating and stenting Schlemm's canal, stretching the trabecular meshwork, and opening up Descemet's membrane, allowing fluid to flow through the window out. The procedure will not work on patients with angle-closure glaucoma and is best suited for open-angle patients who need a pressure in the mid- to high teens. "If patients are losing vision with a pressure of 40, canaloplasty works well," said Richard A. Lewis, M.D., cataract surgeon and glaucoma specialist, Sacramento, Calif. "If they're losing vision with a pressure of 18, then you might not get as much pressure reduction as you would with a trabeculectomy. Our studies show that the average pressure ends up around 15. If you want the pressure down to 12, it's hard to do that predictably with this procedure." Dr. Lewis and colleagues published 3-year follow-up results on the procedure in the April 2011 issue of the Journal of Cataract & Refractive Surgery (2011; 37:682-690). "Canaloplasty led to a significant and sustained IOP reduction in adult patients with open-angle glaucoma and had an excellent short- and long-term postoperative safety profile," it stated. Early complications included a 12.1% incidence of microhyphema and a 0.6% incidence of hypotony. No patients had flat/shallow anterior chambers or choroidal detachment. Late complications were infrequent and included four observed blebs at 36 months with no long-term bleb-related issues. According to Dr. Lewis, naysayers criticize the procedure as being too difficult to do. "They think it's too hard and are skeptical of the way it works," he explained. "It's not that hard, but the perception is that it is. It takes some practice getting the skill set. We have to put the catheter stent in the canal, and many we are critical have not taken the course. Buy to do it." Dr. Lewis is impressed with the 3-year results he and his colleagues recently published. "It's held up pretty well," he said. "Every glaucoma procedure presents problems in long-term follow-up—all of them. That's the nature of this disease. I don't think we've hit the nail on the head in terms of a perfect surgery. Until that time, canaloplasty is a great way to avoid complications."

**ECP**

ECP is a surgical glaucoma procedure typically used in conjunction with cataract surgery for glaucoma patients with controlled IOP. However, in recent years it's also been safely done as a standalone procedure in combination with a pars plana vitrectomy. If a patient has already been implanted with a tube or had a failed ECP Plus is an option. "There's a paper by Brian Francis, M.D., that looked at patients who had a barbell tube and questioned if we want a second tube or an ECP," said Robert Noecker, M.D., vice chair, ophthalmology department, University of Pittsburgh Medical Center Eye Center. "What he showed was that ECP was a good alternative to doing a second tube in those patients who failed one tube already." The paper, published in the October/November 2011 issue of the Journal of Glaucoma (20:523–527), reported the results of a prospective, non-randomized clinical trial that included 25 eyes of 25 consecutive glaucoma patients with a previous tube shunt and uncontrolled IOP. Patients had a pre-op IOP greater than 21 mm Hg. "At 12 months, the mean IOP dropped from 24.02 to 15.36 mm Hg," the report stated. "The mean of the differences was −7.77 mm Hg (−30.8%). The mean number of medications was 3.2 before laser and 1.5 at 12 months (P<0.001). The success rate at 12 months (n=18) was 88% and remained at that level until the end of the follow-up period of 2 years (n=11, P<0.00005). There were no serious complications."

"The results were excellent, with about 80% success at 1 year and beyond," said Dr. Francis. "With this procedure we avoid the possible complications of a second tube such as strabismus (with a superior nasal tube) or erosion (with an inferior tube)." Dr. Francis walked away with some other pearls from the study. "Be prepared to cause and treat inflammation," he said. "We use IV steroids, intracameral preservative-free steroids, as well as frequent topical and sometimes PO steroids. Some patients have very disrupted anatomy with limited access to the ciliary processes, especially via a standard anterior approach. For some, we recommend a pars plana approach combined with complete or partial vitrectomy."

Finally, he said, "Use caution when treating NVG or uveitic glaucoma. Some of these patients get inflammation that is chronic and may get hypotony."

According to Dr. Noecker, the great thing about the ECP/cataract surgery combination is that the cataract incision is already made and the ECP probe simply goes into that incision. "What we do is try to ablate the ciliary body as much as we can from the front side," he said. "The good and bad thing about that approach is the most we can treat is about 50% of the ciliary body. We can't over treat because we can't get to it all. The only thing worse than high pressure is low pressure. At the same time, it's limited. The best you can do is get a pressure into the mid- and upper teens."

For patients with mild glaucoma, that pressure reduction may be enough. Furthermore, for patients who are on multiple glaucoma medications, it's realistic to expect that ECP will get them off the medication. There is a learning curve to the procedure, however, which may frustrate and deter some surgeons. "Most of the problems come from overtreating and inexperienced in recognizing it," said Dr. Noecker. "If you overtreat, what happens is you basically cause too much heating in one area and you get an explosion. That will cause inflammation."

Experienced surgeons will do more of a painting and continuously move across the ciliary body. That way they aren't in one spot too long, causing a burn. What a surgeon should be doing is treating the whole area, but that comes with experience. "Some people get frustrated because they undertreat and don't get enough IOP lowering, so it's not effective," he said. "Then they've overtreat and get these explosions. In the past, the procedure has been oversold as really easy, but to get the optimum results, it takes some finesse."
The EX-PRESS Glaucoma Filtration Device

The EX-PRESS Glaucoma Filtration Device (Alcon, Fort Worth, Texas) is a biocompatible, stainless steel, non-valved device placed under a partial thickness scleral flap to drain the aqueous humor from the anterior chamber to the subconjunctival space. It forms a traditional filtration bleb after a standard trabeculectomy. The IOP control with this device is reported to be comparable to that of a standard trabeculectomy. The major difference though, said Sarwat Salim, M.D., associate professor of ophthalmology, and director of the glaucoma service, University of Tennessee, Memphis, is the complication rates. Post-op complications from the EX-PRESS are similar to that of a trabeculectomy and include hyphema, hypotony, shallow or flat anterior chamber, choroidal effusions, and on rare occasions, suprachoroidal hemorrhage, but are much less overall. "Fewer complications with the EX-PRESS device are attributed to more controlled aqueous humor flow through a consistent lumen size unlike trabeculectomy where sclerotomies made with a punch or scissors may be of different sizes and translate into unpredictable aqueous flow and outcomes," wrote Dr. Salim in her article "EX-PRESS Glaucoma Filtration Device Surgical Technique and Outcomes" (Int Ophthalmol Clin 2011 Summer; 51:83-94). Complications unique to the device include erosion and extrusion, which have been minimized but not eliminated by placing the EX-PRESS under a partial thickness scleral flap. "From my clinical experience I have noticed thinning of the sclera over the device in some cases," said Dr. Salim. "There is a possibility that these cases may erode with time, and a longer follow-up will help us better understand this potential complication."

The most common device-related complication in one large retrospective study was occlusion of the lumen, which was not visible on clinical exam. "When you examine the tip of the device in the anterior chamber during the slit lamp exam, you don't see the blockage," she said. "But the reason you know it's blocked is because the bleb is flat and IOP is high." To alleviate the obstruction, Dr. Salim suggested liberating the fibrinous particles or debris with a Nd:YAG laser, which restores aqueous outflow through the device and results in an elevation of bleb height and a lowering of IOP. Benefits of the EX-PRESS include a rapid learning curve, less inflammation since there is no tissue removal, predictable outcomes related to consistent lumen size and controlled flow, lower intraocular pressures post-op, and fewer post-op complications. "Although the current literature reports favorable outcomes, the long-term safety and efficacy of this device have yet to be determined," wrote Dr. Salim in her paper. "The ongoing prospective, randomized clinical trial, XVT, will elucidate additional information comparing this latest modification to the standard trabeculectomy."

iStent

The iStent Trabecular Micro-Bypass (Glaukos, Laguna Hills, Calif.) is the first ab interno micro-bypass implant for the treatment of glaucoma. It's currently CE marked and available for use in select countries in Europe and was approved for use in Canada. However, the device is still awaiting FDA approval in the U.S. and has been for some time.

"In ocular devices nothing is approved quickly," said L. Jay Katz, M.D., Wills Eye Hospital, Philadelphia, on the FDA process. "Everything is kind of on a slow path. [Glaukos has] one last hurdle apparently and one last question the FDA wants resolved, and that's been resubmitted. If that's resolved I think they are home free."

Thomas W. Samuelsen, M.D., Minnesota Eye Consultants, Minneapolis, published a study in March 2011 in Ophthalmology (118:459-467) assessing the safety and efficacy of the device in combination with cataract surgery in 240 eyes with mild to moderate open-angle glaucoma. Patients had an IOP of ≤24 mm Hg controlled on one to three medications and were randomized for cataract surgery with iStent implantation or cataract surgery only. Success was defined as unmedicated IOP ≤21 mm Hg at 1 year. A secondary success measure was unmedicated IOP reduction ≥20% at 1 year. "In this study of the iStent, when used in conjunction with cataract surgery in subjects with mild to moderate open-angle glaucoma, we found a statistically and clinically significant treatment effect in favor of the iStent in reducing IOP with less medication use compared with cataract surgery alone," the authors concluded. "At 12 months after implantation, there was a 22% treatment difference (72% vs. 50%) in favor of the iStent in the proportion of patients with IOP 21 mm Hg without ocular hypotensive medications at 12 months."

In terms of complications, Dr. Katz pointed out that hyphema in the anterior chamber is pretty common. A rare complication is the misplacement of the device altogether. "The FDA is always concerned when we're putting devices in the eye, what happens to the cornea, but looking at the parameters we've had in the studies, there's no evidence of increased corneal injury related to having a stent inside the eye," he said. If a patient needs a lower IOP than a single stent implant will achieve, surgeons can insert multiple stents into a single eye. Using multiple stents, said Dr. Katz, does not appear to increase complication rates. "We're trying to create a bridge somewhere between failure with medications and the other surgeries like trabeculectomy and tube shunt," said Dr. Katz. "I think the iStent is a procedure that offers something that might be effective but is safer than going to the big guns. If it doesn't work by the nature of what type of surgery it is, meaning it doesn't involve cutting into the conjunctiva, then we haven't jeopardized the success of the big gun surgeries like trabeculectomy and tube shunts down the road."

Editors' note: Dr. Francis has financial interests with Endo Optiks (Little Silver, N.J.). Dr. Katz has financial interests with Glaukos. Dr. Lewis has no financial interests related to this article. Dr. Noecker has financial interests with Endo Optiks. Dr. Salim has financial interests with Alcon. Dr. Vold is founder and chief executive officer of NeoMedix.
Contact information

Francis: BFrancis@doheny.org
Katz: ljaykatz@gmail.com
Lewis: rlewiseyemd@yahoo.com
Noecker: noeckerrj@gmail.com
Salim: sarwat_salim@yahoo.com
Vold: svold@cox.net

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