GLAUCOMA

Glaucoma Surgeries: Trabectome and Canaloplasty Take the Stage

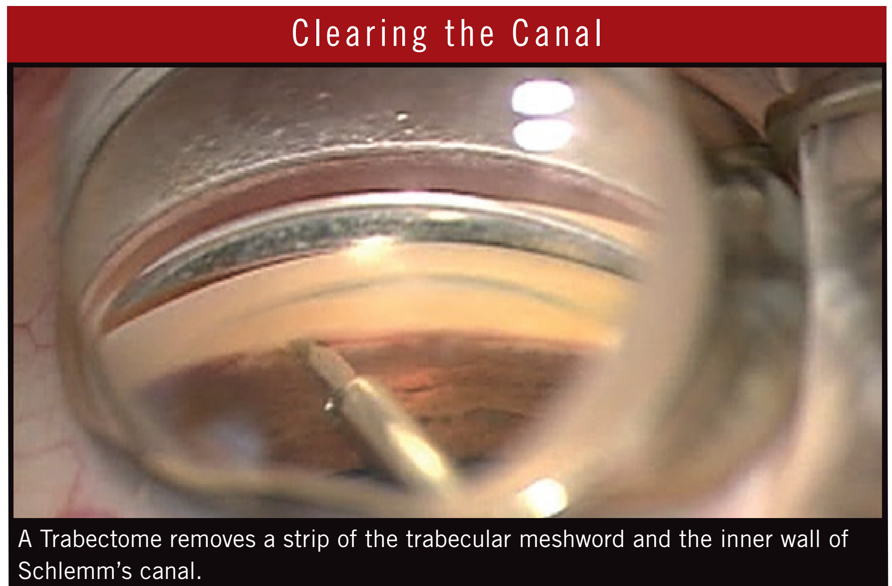
BY MIRIAM KARMEL, CONTRIBUTING WRITER

Engineering, surgical acumen and a better understanding of aqueous outflow is yielding a number of new technologies designed to transform the trabeculectomy for glaucoma patients. "The common feature in some of these new technologies is to reduce the risk profile of trabeculectomy," said Ike K. Ahmed, MD. Most are designed to enhance the physiologic outflow of aqueous. "The goal of these interventions is not to replace trabeculectomy, though that may occur," said Dr. Ahmed, who is assistant professor of ophthalmology at the University of Toronto and director of the glaucoma and advanced anterior surgical fellowship there.

Glaucoma medicine has lagged behind other ophthalmic surgeries, which have enjoyed major advances in recent years. Consider the capsulorhexis: "It's a straightforward, elegant improvement to cataract surgery," said Andrew G. Iwach, MD, who is in private practice in San Francisco. For glaucoma specialists, however, some 40 years after the introduction of trabeculectomy, doctors are still searching for a new gold standard for surgically lowering intraocular pressure. Generally, they're looking for a way to avoid creating the dreaded bleb. "Everyone is trying to do something because we know the standard trabeculectomy has limitations," said Dr. Iwach.

Among the new approaches, two devices for surgeries considered minimally invasive have now been cleared by the FDA for canaloplasty and trabeculotomy ab interno.

Clearing the Canal



A Trabectome removes a strip of the trabecular meshword and the inner wall of Schlemm's canal.

Relative Merits of the New Options

"Anything that keeps us from a bleb is desirable," said David G. Godfrey, MD, who has experience with both canaloplasty and trabeculotomy. But like other glaucoma specialists, he is still doing trabeculectomies. "In my hands, I can get a lower pressure more consistently with a trabeculectomy than with canaloplasty or trabeculotomy," said Dr. Godfrey, who is in private practice in Dallas.

Dr. Iwach agreed. "The data I've looked at suggest they work some of the time. But if you want a pressure of 8 or 10, they may not get you there." On the other hand, if the optic nerve is healthy enough, these newer surgeries may be just what the doctor ordered, he said. "And you can always go back and do a trabeculectomy."

Arthur J. Sit, MD, would agree, at least with regard to trabeculotomy, which he performs as often as trabeculectomy. "Trabeculectomy is in many ways a last resort," said Dr. Sit, who is assistant professor of ophthalmology at Mayo Clinic in Rochester, Minn.

Trabeculotomy

Trabeculotomy ab interno with the Trabectome (NeoMedix) was designed to reestablish access to the eye's natural drainage pathway. The surgery is performed under direct visualization with a gonioscopy lens and removes a 60- to 120-degree strip of the trabecular meshwork and the inner wall of

NeoMedix

Schlemm's canal with electrocautery. The goal is to achieve direct flow of aqueous into the canal and then into the collector channels.

One study reported a 40 percent mean decrease in IOP for all cases over the course of follow-up, including 11 cases at 30 months. Mean preoperative IOP in the initial 101 patients was 27.6 ± 7.2 mmHg. Thirty months out, mean IOP was 16.3 ± 3.3 mmHg.[1]

"It's a good first line for glaucoma surgery," Dr. Godfrey said. Dr. Sit agreed. "The surgery makes sense because you're removing the tissue that's causing the increased flow resistance, that is, the trabecular meshwork and the inner wall of Schlemm's canal." He added, "It makes a lot more physiologic sense than building a whole new pipe," a reference to the new outflow system created by a trabeculectomy.

Caveats and criteria. But, Dr. Godfrey said, the patient must have a fairly healthy optic nerve and be able to tolerate pressure in the midteens. And "You have to visually see the trabecular meshwork while doing the surgery. Then you have to have the ability to perform angle surgery. You have to be able to work across the eye."

Dr. Sit agreed. "Not everyone's a good candidate." He will not perform Trabectome surgery if:

- the patient has advanced disease and needs a target pressure in the low teens or lower,
- the view of the angle is obscured by a cloudy cornea or scarring in the angle, or
- the patient has some type of secondary glaucoma, such as Sturge-Weber syndrome, whereby episcleral venous pressure is elevated.

Dr. Sit's ideal Trabectome patient either has high IOP, open angles and a reasonably healthy optic nerve, or is someone who is going to have cataract surgery and is adequately controlled but on multiple glaucoma medications. "If somebody is well-controlled on two medications but has a cataract, most people would hesitate to perform a trabeculectomy at the same time," he said. "But with a Trabectome, because of the much better safety, I'd feel much more comfortable doing surgery to get the patient off two meds."

Needs some more work. Dr. Sit predicted that Trabectome surgery isn't going to replace medication or trabeculectomy. He wondered, however, whether a redesigned Trabectome, one that would allow removal of a larger arc of tissue, or even the entire trabecular meshwork, might achieve lower pressures. "If you can do that reliably, maybe you could replace the trabeculectomy in most cases."

Canaloplasty

An ophthalmic microcannula (OM), the Interventional Canaloplasty Microcatheter, is now available from iScience Surgical for circumferential viscodilation and tensioning of Schlemm's canal. Canaloplasty refines the older viscocanalostomy by using a microcatheter to clear the entire canal rather than just a segment.

In a canaloplasty, the surgeon inserts the 250-µm fiber-optic OM through a small incision to enlarge the main drainage channel. After 360 degrees of canal cannulation, the OM is then used to insert a 10-0 prolene suture into the entire circumference of the canal. The suture ends are tied together to provide tension to the inner wall of the canal and the associated trabecular meshwork. Once the suture is tied, the tension stretches the trabecular meshwork to facilitate better outflow into the canal, keeping the canal open and preventing its collapse.

"Part of the reason for dilating the canal and creating the suture tension is to allow more fluid to get into the collector channel," Dr. Godfrey explained. But, he added, there is a steep learning curve. "Most people aren't used to working with the canal," Dr. Godfrey said. "You need to learn to look for the landmarks and the anatomy and then understand how to unroof the canal and make the flap and the lake. This is technically more difficult than Trabectome and standard glaucoma surgery," he explained. "But when it works, it works."

Positive results. A report funded by the company last year on the one-year results of a prospective study involving canaloplasty (with cataract removal) in 54 eyes indicated the procedure was safe and effective in lowering IOP. Data from 11 surgeons at nine international study sites showed a reduction from mean baseline IOP of 24.4 mmHg ± 6.1 to 13.7 ± 4.4 mmHg at 12 months. By one year, the mean medication use had also dropped.[2]

Unconvinced. Still, Dr. Sit isn't ready to try it. "It hasn't made physiologic sense to me yet," he said, explaining that Schlemm's canal is probably not the primary source of outflow resistance in glaucoma. It might make more sense, he added, if the pressure got high enough to cause the inner wall of Schlemm's canal to prolapse into the collector channels. If that is what's happening, as has been reported in cadaver models, then canaloplasty may make sense, Dr. Sit said. "But no one's ever shown if it is a cause or consequence of glaucoma." He added that any scarring to the conjunctiva may limit the ability to perform future filtering surgery.

Status Quo: Gray

For now, glaucoma surgeons are left with what Dr. Iwach called "shades of gray." While the armamentarium is fuller, these new approaches still have to stand the test of time. "You need not weeks and months, but years of follow-up," Dr. Iwach said. Until then, as he argues, "Trabeculectomy is king."

Dr. Godfrey predicted that someday multiple techniques will share the stage, and physicians will learn when to use them.

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1 Minckler, D. et al. *Trans Am Ophthalmol Soc* 2006;104:40–50.

2 Shingleton, B. et al. *J Cataract Refract Surg* 2008;34:433–440.

Dr. Ahmed is a consultant for iScience and receives research funding from Alcon, Allergan, Merck and Pfizer. Dr. Godfrey reports no related interests. Dr. Iwach is a past consult for iScience. Dr. Sit reports no interest in the above-mentioned technologies. He has been a consultant for Pfizer and Allergan and receives research funding from Alcon.