

Update on Microinvasive Glaucoma Surgery

A review of the pertinent data on three less invasive glaucoma procedures.

BY MICHAEL STILES, MD



Traditional glaucoma treatments for mild to moderate glaucoma include noninvasive and relatively safe therapies such as medications and laser trabeculoplasty. At the other end of the spectrum, there are effective but invasive and potentially risky treatments for patients with advanced glaucoma including filtering surgery and cyclodestructive procedures. What is missing are therapeutic options for mild to moderate glaucoma for patients who have failed medical therapy or laser therapy but whose disease is not so advanced as to clearly warrant more invasive, risky surgeries. In this installment of "Peer Review," Michael Stiles, MD, reviews the literature on the newer glaucoma surgeries that may fill that niche. Let us see what the data say so far.

—Barbara Smit, MD, PhD, section editor

Since the advent of full-thickness filtration surgery nearly 100 years ago, glaucoma surgeons have been fighting the battle of how to effectively lower IOP and avoid the vision-threatening complications associated with glaucoma surgery. Because many of the glaucoma patients who require surgery have a paucity of symptomatic vision loss, this battle is particularly challenging. Although the Trabectectomy Versus Tube Study demonstrated the efficacy of IOP lowering with both procedures, the study also reported a significant occurrence of vision-threatening complications in both treatment arms.¹ Over the past several years, new procedures have been introduced in an effort to reduce the risk of vision loss not only from the disease but also from surgical intervention. This update reviews the literature on the three currently available microinva-

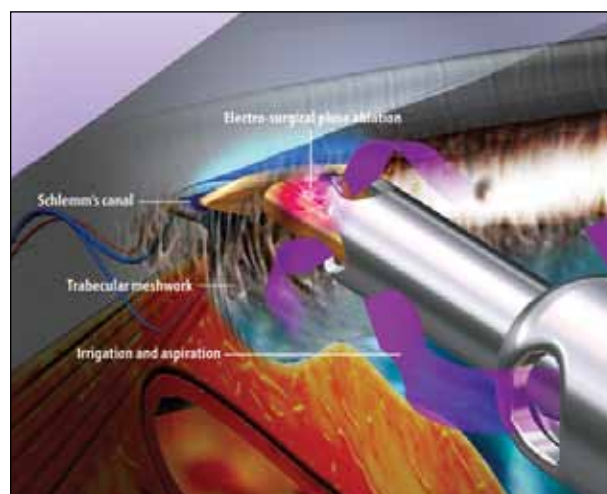


Figure 1. The electrocautery tip of the Trabectome ablates the trabecular meshwork and inner wall of Schlemm canal.

sive glaucoma surgical (MIGS) procedures for the treatment of open-angle glaucoma (OAG): the Trabectome (NeoMedix Corporation), canaloplasty with the iTrack microcatheter (iScience Interventional), and the iStent Trabecular Micro-Bypass Stent (Glaukos Corporation).

THE TRABECTOME

The Trabectome, which received FDA approval in 2004, is an ab interno technique that involves the removal of the nasal 60° to 120° of the trabecular meshwork (TM) and the inner wall of Schlemm canal. This is accomplished under direct gonioscopic view through a 1.8-mm temporal clear corneal incision with a proprietary single-use handpiece (Figure 1). The patient's IOP cannot be reduced



Figure 2. The iLumin Microillumination System and the iTrack Microcather (both by iScience Interventional) are for use during canaloplasty.

below episcleral venous pressure, thus eliminating the complications associated with hypotony.

Initial studies reported both a reduction in IOP and postoperative medications with the Trabectome in adults with OAG. Mosaed and coworkers reported a 31% reduction in IOP (from 26.3 mm Hg $\pm$ 7.7 to 16.6 mm Hg $\pm$ 4) and a 28% reduction in postoperative medications 1 year after surgery in 538 eyes that underwent the Trabectome procedure alone.² When the Trabectome was combined with phacoemulsification ($n = 290$ eyes), the IOP reduction was 18% (from 20.2 mm Hg $\pm$ 6 to 15.6 mm Hg $\pm$ 3.7) with a 33% reduction in postoperative medications. Early hyphema was common but not sustained beyond 5 days postoperatively. Significant vision loss, sustained hypotony, and related complications were not reported in this retrospective series. These results are similar to other reports in which the Trabectome typically yielded a 30% to 40% reduction in IOP with end pressures in the mid-teens, one to two fewer medications postoperatively, and a paucity of vision-threatening complications.³⁻⁵ Surgical intervention for complications from the Trabectome is uncommon, with the most common intervention being trabeculectomy due to failed Trabectome procedures. One retrospective cohort study reported that a previous Trabectome procedure did not reduce the efficacy of trabeculectomy when compared with a control group.⁶

Trabectome Versus Trabeculectomy

Reports from prospective, randomized trials comparing the Trabectome to trabeculectomy are lacking. Jea and coworkers compared the safety and efficacy of the Trabectome to trabeculectomy with mitomycin C.⁷ Both

groups included more than 100 eyes and were followed for approximately 2 years. The trabeculectomy group had a greater reduction in IOP (61.3% vs 43.5%) and better 2-year success (76.1% vs 22.4%). The majority of the Trabectome group failed to meet the success criteria. This was not due to failing the IOP criteria, however, but rather because additional procedures were required postoperatively, with subsequent trabeculectomy being the most common. Hypotony and wound leak occurred in the trabeculectomy group but not in the Trabectome group. The authors concluded that, although the success rate was lower with the Trabectome, the excellent safety profile for the procedure makes it a viable option for glaucomatous eyes with more modest IOP goals or in which the risks of trabeculectomy are of particular concern.

CANALOPLASTY

Canaloplasty is an ab externo technique that combines nonpenetrating deep sclerectomy with dilation of Schlemm canal. Similar to trabeculectomy, conjunctival dissection and formation of a scleral flap are required. The goal of the procedure is to increase conventional outflow by catheterizing and viscodilating Schlemm canal (Figure 2). Placing an intracanalicular tension suture distends the TM and stents the canal open. Additional outflow is created through a surgically created Descemet window into a lake underneath the superficial scleral flap. The flap is secured in a watertight fashion to avoid the formation of a filtering bleb.

Three-year results of a multicenter, prospective, interventional study reported the safety and efficacy of canaloplasty.⁸ Of the 89 procedures performed with successful placement of a suture, there was a 34% mean decrease in IOP from baseline (23.5 mm Hg $\pm$ 4.5 to 15.5 mm Hg $\pm$ 3.5) and a 53% mean reduction in postoperative medications (1.9 $\pm$ 0.8 to 0.9 $\pm$ 0.9). When phacoemulsification was combined with canaloplasty and successful suture placement, 27 eyes had a 42% mean decrease in IOP (23.5 mm Hg $\pm$ 5.2 to 13.6 mm Hg $\pm$ 3.6) and an 80% mean reduction of postoperative medications (1.5 $\pm$ 1 to 0.3 $\pm$ 0.5). Transient hyphema was the most common complication, occurring in 10.2% of eyes. Sustained hypotony and related complications, however, did not occur. Inadvertent filtering blebs occurred in 2.5% of cases, but blebitis and other bleb-related complications were not noted 3 years postoperatively.

When the effect of suture tension on canaloplasty's efficacy 2 years postoperatively was assessed, canal suture placement was unsuccessful in approximately 15% of eyes.⁹ The investigators graded suture tension in the eyes with successful suture placement by observing the amount of canaliculus distension with ultrasound biomicroscopy and



Figure 3. The iStent.

divided the eyes into two groups: those with discernible distention and those without. The mean IOP reduction was greater and statistically significant in the eyes with canalicular distention. These results support the beneficial role of canalicular and TM tension and highlight the importance for surgeons to master this technically complex intraoperative procedure to optimize outcomes.

Canaloplasty Versus Trabeculectomy

Ayyala and colleagues reported a greater mean reduction in IOP with trabeculectomy with mitomycin C ($43\% \pm 28\%$) than with canaloplasty ($32\% \pm 22\%$).¹⁰ Patients in the trabeculectomy group required three fewer medications 12 months postoperatively, whereas patients in the canaloplasty group required two fewer medications. There was no significant difference between the two groups regarding surgical failures, which was defined as any eye requiring reoperation. Transient hyphema was the most common complication in the canaloplasty group, and choroidal effusion was the most common complication in the trabeculectomy group. Hypotony, maculopathy, and suprachoroidal hemorrhage occurred infrequently in the trabeculectomy group and did not occur in the canaloplasty group. The authors concluded that trabeculectomy resulted in lower IOP and less postoperative medications, and canaloplasty resulted in a significant reduction in IOP and postoperative medications without the long-term potential risks of a filtration bleb.

TRABECULAR MICROBYPASS STENT

In 2012, the FDA approved the iStent for use in conjunction with cataract surgery in patients with mild to

moderate OAG (Figure 3). Similar to the Trabectome, implantation of an iStent is an ab interno procedure without the need for conjunctival dissection. The micro-device was developed to bypass the TM and inner wall of Schlemm canal to reestablish outflow. In comparison to cataract surgery alone, combining implantation of an iStent with cataract surgery increased trabecular outflow facility in a fluorophotometric study.¹¹

Craven et al reported the 2-year follow-up of a prospective, randomized, controlled, multicenter trial comparing combined phacoemulsification and iStent implantation to phacoemulsification alone.¹² When the iStent was combined with phacoemulsification, a statistically higher percentage of patients achieved an IOP less than 21 mm Hg without medication versus phacoemulsification alone in patients with mild to moderate glaucoma. The incidence of complications was low in both groups, and no serious adverse complications specifically related to the iStent occurred. In a randomized, prospective clinical trial, the proportion of patients on glaucoma medications 15 months postoperatively was lower for patients who underwent combined iStent implantation and phacoemulsification versus those who underwent phacoemulsification alone.¹³ Both groups had similar safety profiles, and complications commonly associated with filtration surgery such as wound leaks, infection, and hypotony did not occur.

AB INTERNO VERSUS AB EXTERNO

Although no published comparative studies between ab interno and ab externo MIGS procedures have been published, recent studies highlight the comparative pros and cons between the two approaches. Ab interno procedures do not involve conjunctival dissection, thus leaving the superior conjunctiva undisturbed for later filtration surgery, if necessary. Because external dissection is unnecessary, ab interno procedures are shorter in duration and have a minimal learning curve in most surgeons' hands. The iStent, in particular, has the potential flexibility to titrate the amount of IOP reduction by placing multiple stents. Less dependence on medications postoperatively has been reported in eyes with placement of three stents with concomitant cataract surgery versus eyes with two stents.¹⁴ Data on canaloplasty suggest that the postoperative IOP and reduction in medications obtained with this procedure are more in line with those achieved with trabeculectomy than with the ab interno procedures. Comparative studies are needed to elucidate whether or not efficacy and safety differences exist between the two approaches.

CONCLUSION

The ongoing development of MIGS is necessary for advancing the treatment of patients with OAG. The side effects, expense, and relatively poor compliance associated with chronic medical therapy provide inherent limitations to this treatment approach. The short- and long-term complications associated with filtering surgery make this step in our treatment continuum too large to take on behalf of many of our patients. All three of the procedures offer glaucoma surgeons more options for patients with mild to moderate disease and even those with more advanced disease who are at high risk for complications associated with trabeculectomy and glaucoma drainage devices. Much work is underway and is necessary to reveal the longer-term efficacy and safety of these and other MIGS procedures currently under investigation. Such research will provide more clarity about the role of MIGS within our glaucoma treatment armamentarium. ■

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