Combined Cataract Surgery and MIGS: Which Procedures Will Be a Match Made in Heaven?

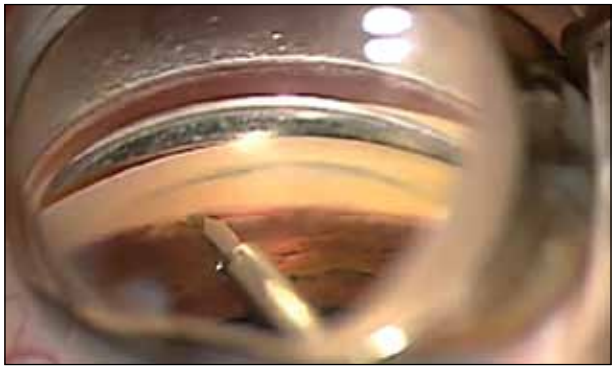
Technologies for microinvasive glaucoma surgery will have an increasing role in managing patients with mild to moderate glaucoma and cataracts.

BY QUANG H. NGUYEN, MD

Glaucoma is a progressive disease that affects the retinal ganglion cells, and increased IOP is associated with irreversible damage to the optic nerve. Cataracts and glaucoma are the two most common ocular diseases in the United States and frequently coexist, as the prevalence of each disease increases with age.[1,2] Cataract surgery alone has been suggested as a treatment for managing IOP in patients with mild to moderate glaucoma.[3-7] In a recent study, a 20% IOP reduction was achieved and sustained for many months in 39.7% of patients who underwent cataract surgery alone.[8] The challenge to this approach, however, is that a consistent and sustained IOP reduction is not observed in all patients. Moreover, there is mounting evidence that a greater reduction in IOP is seen in patients with higher preoperative IOPs, which may further confound the result.[9]

In recent years, emerging technologies for microinvasive glaucoma surgery (MIGS) have set the stage for a revolutionary surgical approach that targets mild to moderate glaucoma in patients with visually significant cataracts. The goal of combined glaucoma and cataract surgery is to achieve a sustained IOP reduction in glaucoma patients undergoing cataract surgery, as well as a reduction in ocular hypotensive medications.

For patients undergoing cataract surgery, the current MIGS procedures being investigated include the Trabectome (NeoMedix Corporation), the iStent Trabecular Micro-Bypass Stent and iStent Supra (both from Glaukos Corporation), the Hydrus Microstent (Ivantis, Inc.), the AqueSys Implant (AqueSys, Inc.), and the CyPass Micro-Stent (Transcend Medical, Inc.). With these technologies, the trabecular meshwork is bypassed, or a suprachoroidal approach is undertaken.



(Courtesy of Neomedix, Inc.)

Figure 1. The Trabectome probe through a clear corneal incision (ab interno approach) shows ablation of the trabecular meshwork using a goniolens for visualization.

TRABECULAR MESHWORK BYPASS

Trabectome

The Trabectome, which received FDA approval in 2004, is an ab interno technique that involves the removal of the nasal 60° to 100° of the trabecular meshwork, leaving the inner wall of Schlemm canal intact to preserve collector channel drainage. The Trabectome offers surgeons the opportunity to combine surgical cataract and glaucoma

(Courtesy of Glaukos Corporation.)

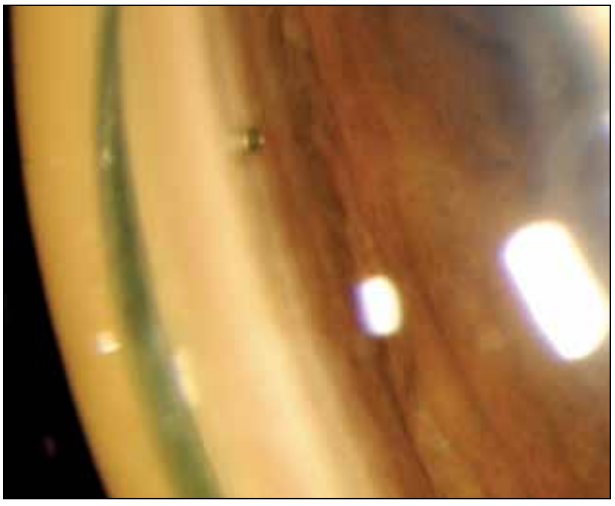


Figure 2. The iStent implanted in Schlemm canal via an ab interno approach through a clear corneal incision using a goniolens for visualization.

treatment with relatively favorable risk profiles while sparing the conjunctiva (Figure 1). Using similar success criteria as the Tube Versus Trabeculectomy (TVT) Study, Francis reported an 80% survival rate 24 months postoperatively in combined Trabectome and cataract extraction compared with a survival rate of 45% for cataract extraction alone.[10] Furthermore, there was a 40% reduction of medications from baseline 2 years postoperatively. Although this was a prospective, controlled surgical trial, it was nonrandomized, and biases could have been introduced. Another limitation of the study was that the baseline IOP between the groups was not the same. In another study, when combined with cataract surgery, the Trabectome had an 86.9% success rate with an 18% reduction in IOP and a 33% decrease in medication usage 1 year postoperatively.[11]

iStent Trabecular Micro-Bypass Stent

Similar to the Trabectome, implantation of an iStent is an ab interno procedure that eliminates the need for conjunctival dissection. The microdevice was developed to bypass the trabecular meshwork and inner wall of Schlemm canal to reestablish outflow. Samuelson and colleagues published 1-year results of a prospective trial of 240 eyes with mild to moderate glaucoma randomly assigned to cataract surgery and iStent implantation (stent group) or cataract surgery alone (control group; Figure 2).[12] A significantly higher proportion of patients in the stent group (72% vs 50%) achieved a primary efficacy endpoint of an IOP less than 21 mm Hg without medication. The mean reduction in IOP at 12 months versus the preoperative IOP was lower (1.5 mm Hg ±3 in the stent group vs 1.0 mm Hg ±3.3 in the control group).

Craven and colleagues published 2-year safety and efficacy data from the same study showing similarly favorable results.[13] The proportional analysis of an IOP of 21 mm Hg or lower without the use of ocular hypotensive medications showed a significant difference in favor of the stent group at 2 years (61% vs 50%). The pitfall of the Craven report, however, is that it was not designed with or statistically powered for 2-year endpoints. Moreover, the studies by Samuelson et al and Craven et al failed to include a medication washout period before assessing endpoints.

The iStent received FDA approval in 2012. Glaukos is currently conducting clinical trials in the United States of the iStent Plug to test if implanting two devices will sustain a reduction in IOP when combined with cataract surgery.

The Hydrus Microstent

The Hydrus is an intracanalicular device. Presently, a 2-year prospective, randomized, controlled trial is underway in the United States to determine the safety and efficacy of the Hydrus implanted in conjunction with phacoemulsification. More than 500 patients at more than 30 sites are expected to participate in the study.

The primary endpoint will be a reduction in IOP of at least 20% after medication washout, with results measured at the 2-year postoperative time point. The secondary endpoint will be the difference in IOP reduction between the Hydrus and control groups. Safety outcomes will include vision loss, changes found during a slit-lamp examination, endothelial cell loss, and any other complications or adverse events.

AqueSys Implant

The AqueSys Implant is made of a collagen-derived gelatin. Upon implantation, the device is designed to create a diffuse outflow of aqueous from the anterior chamber into the nondissected tissue of the subconjunctival space. Several multicenter studies are underway in the United States, Canada, Europe, Asia, Australia, and South America. AqueSys was granted CE Mark approval in Europe in 2011 for a broad treatment range for patients with mild, moderate, and refractory glaucoma. The company is currently enrolling subjects under an approved investigational device exemption for its first indication in the United States, with an estimated clearance in 2014.

SUPRACHOROIDAL APPROACHES

CyPass Micro-Stent

The CyPass Micro-Stent is implanted in the supraciliary space to establish a permanent conduit for aqueous filtration via uveoscleral outflow. An initial pilot study of the CyPass showed a favorable sustained reduction of IOP when implanted at the time of cataract surgery (Figure 3) and a significant reduction in medication usage.[14]

(Courtesy of Transcend Medical, Inc.)

Figure 3. The CyPass implanted via an ab interno approach through a clear corneal incision using a goniolens for visualization.

The COMPASS Clinical Trial is studying the safety and effectiveness of the CyPass in combination with cataract surgery compared to cataract surgery alone (control group) in the United States. In this randomized, controlled study, 505 patients are randomized either to undergo implantation of the CyPass combined with phacoemulsification or to have phacoemulsification alone. Diurnal IOP measurements will be taken at baseline, 1 year, and 2 years, all with medication washouts. The investigation will be fully enrolled in the next several months, again with follow-up for 2 subsequent years. At the conclusion of the trial, unequivocal scientific data will be available to demonstrate the safety and efficacy of the CyPass implant and elucidate the IOP-lowering effect of cataract surgery alone in patients with mild to moderate glaucoma.

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iStent Supra

Glaukos Corporation has initiated clinical trials to develop a suprachoroidal device (the iStent Supra) that will allow surgeons to lower IOP by enhancing uveoscleral or conventional outflow, both via an ab interno approach, in patients undergoing combined cataract and glaucoma procedures.

CONCLUSION

Although traditional filtering or glaucoma drainage devices remain the surgery of choice for patients with advanced glaucoma, there exists an unmet need for surgical intervention for mild to moderate glaucoma patients with coexisting cataract. MIGS combined with cataract surgery will have an increasing role in managing these patients. The safety profile of MIGS has resurrected and stimulated surgeons' interest in combined procedures. It is unclear, however, which technology is best suited for implantation in combination with cataract surgery. Furthermore, a subgroup of patients may have better outcomes with one technology versus another. Ultimately, if a particular MIGS procedure in combination with cataract surgery can demonstrate a sustained IOP reduction better than cataract surgery alone in the majority of patients, is relatively safe and easy to implant, and reduces the burden of medication usage, then it will become the procedure of choice. ■

Weigh in on this topic now!

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1. **Would you consider MIGS for patients with ocular hypertension?**
   - ☐ Yes
   - ☐ No
   - ☐ Undecided. More data are needed.
2. **For patients on medical therapy, would you consider MIGS to potentially reduce or eliminate the need for eye drops?**
   - ☐ Yes
   - ☐ No
   - ☐ Undecided. More data are needed.

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