

STANDALONE MIGS

Weighing the benefits and risks of surgical approaches.

BY NATHAN M. RADCLIFFE, MD, AND ANONYMOUS

READY

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When considering the future standards of care for glaucoma, it is helpful to take inventory of the treatment options

available. Although the most common first-line approach, topical therapy is far from ideal. Glaucoma drops increase the risk of cataract development,^{1,2} and patients have trouble adhering to their prescribed regimens.³ Drops also have inherent limitations, including challenges with IOP fluctuation, side effects, insurance coverage, preservative toxicity, and instillation. Over time, most patients treated with topical therapy experience local side effects, especially ocular surface disease. Some patients, however, prefer drops because they give them a sense of control or accomplishment in managing a complex disease.

GOALS OF GLAUCOMA TREATMENT

The goals of glaucoma treatment are to lower IOP, preserve vision, and prevent incisional surgery. I discuss these objectives with patients at their first visit. Efforts are also made to preserve

or improve the patient's quality of life. To achieve these goals, ophthalmologists must take a proactive approach to glaucoma care. With a reactive approach, intervention typically occurs too late, after significant vision loss has occurred; then, to slow glaucomatous progression, a more invasive surgery is performed that could make the patient's vision worse.

DISRUPTING DROPS

Topical glaucoma therapy has never shown stellar outcomes compared with interventional glaucoma procedures. Even back in 1990, the Glaucoma Laser Trial (GLT) showed that visual fields worsened by 31% in patients treated with medications and by 21% in patients treated with argon laser trabeculoplasty ($P = .02$).⁴ Although the GLT investigators concluded that there were no major differences between the two treatment approaches, laser therapy certainly outperformed drops in slowing glaucomatous progression.

More recently, the HORIZON study compared phacoemulsification plus Hydrus Microstent (Alcon) implantation with phacoemulsification alone; both groups were supplemented with medication. Roughly equivalent IOPs were achieved by each arm, but the

group that did not receive a MIGS implant had a higher rate of secondary surgical intervention (6.4% in the phacoemulsification only group vs 2.5% in the phacoemulsification plus MIGS group) and a higher rate of glaucomatous progression (-0.49 dB/y in the phacoemulsification only group vs -0.26 in the phacoemulsification plus MIGS group).^{5,6}

In the Laser in Glaucoma and Ocular Hypertension (LIGHT) study comparing selective laser trabeculoplasty (SLT) with drops, the rate of secondary surgical intervention at 6 years was 12.2% in patients who underwent trabeculectomy with drops compared with 4.9% in patients who underwent SLT.⁷ More eyes in the drop arm exhibited disease progression compared to those in the SLT arm (26.8% vs 19.6%; $P = .006$). Even when topical therapy demonstrates similar IOP-lowering efficacy, it does not stand up to MIGS.

OPTIONS FOR STANDALONE MIGS

The iStent infinite trabecular microbypass system (Glaukos) is a standalone procedure indicated for the treatment of refractory glaucoma. In a prospective study, implantation of the iStent infinite (three trabecular meshwork bypass stents) was performed as a standalone surgical procedure

in eyes with open-angle glaucoma uncontrolled by prior incisional or cilioablative surgeries or maximum tolerated medical therapy.⁸ Mean IOP was reduced from 23.4 mm Hg preoperatively to 17.5 mm Hg postoperatively. No serious complications were reported. Approximately 5% of patients required subsequent incisional glaucoma surgery.

Several other standalone MIGS procedures have shown similar IOP-lowering efficacy, significant medication reductions, and excellent safety profiles. Treatment options include stenting, canaloplasty, goniotomy, and a combination of these methods. Biointerventional glaucoma surgery is evolving in the suprachoroidal space. Options targeting the ciliary body, such as endoscopic cyclophotocoagulation and micropulse transscleral cyclophotocoagulation, fit well within the standalone paradigm, as do transconjunctival procedures such as implantation of a Xen Gel Stent (AbbVie). Sustained drug

delivery is likely to be an increasingly popular option in the standalone space.

MAKING STANDALONE MIGS WORK WELL

To make standalone MIGS work well, ophthalmologists must accept and believe that standalone interventions are a better option than drops. Insecurity limits adoption. SLT should be performed as a first-line treatment to reduce patients' medication burden. Once SLT has run its course or adjunctive therapy is required, ophthalmologists must consider the next best step. Staying ahead of this complex disease requires a robust, efficacious approach that starts with laser treatment and continues along that interventional path, with drops used as a bridge therapy between interventions.

Patient education should evolve to include a detailed and honest discussion of eye drops' side effects. Ophthalmologists must demonstrate confidence in standalone interventions without promising a particular

outcome (as is done with topical therapy). For standalone MIGS, the surgeon should follow the best recommendation for the individual patient and deliver a similar message to that delivered for refractive cataract surgery: "I will use the best technology to deliver the best outcome possible, but I cannot promise perfect results."

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OR NOT?

ANONYMOUS



Standalone MIGS is not ready for widespread use, as evidenced by a particular case

scenario I see commonly in my clinic.

A 64-year-old White woman presents with an IOP of 36 mm Hg OS and a severe allergy to all topical drops. Humphrey visual field testing (Carl Zeiss Meditec) is normal. She is pseudophakic and has previously undergone SLT twice. OCT shows superior thinning of the retinal nerve fiber layer in the left eye. This patient experienced progression from ocular hypertension to early glaucoma with a superior defect. How would you proceed? Would your first approach be standalone angle surgery? What

about tube shunt surgery or Xen Gel Stent implantation?

This discussion focuses on standalone angle-based procedures and bleb-based surgeries. The former category includes gonioscopy-assisted transluminal trabeculotomy, goniotomy, canaloplasty, and iStent infinite, which are approved for standalone use, and the latter includes tube shunt surgery and trabeculectomy. This article does not include the Xen because I routinely use this device as a standalone treatment, and, for this case, that approach may not be debatable.

CONCERNS WITH A STANDALONE MIGS APPROACH

In my experience, there are several concerns with taking a standalone angle-based surgical approach to cases like this one.

Modest IOP Lowering

Standalone angle-based surgery provides only modest IOP lowering. I

question whether this approach could lower the patient's IOP of 36 mm Hg to where it needs to be.

In 2022, Dr. Radcliffe published a review to "present evidence supporting early standalone surgery in the era of [MIGS]."¹ The article describes the efficacy of GATT, Trabectome (MST), excisional goniotomy with the Kahook Dual Blade (New World Medical), ab interno canaloplasty, and combined canaloplasty and trabeculotomy using the Omni Surgical System (Sight Sciences). Although these procedures provided meaningful reductions in IOP, they also demonstrated variability in IOP lowering. Patients treated with the Kahook Dual Blade, for example, experienced IOP reductions ranging from 15% to 36%. With a 15% reduction, my patient's IOP would still be 30 mm Hg. With standalone angle-based surgery, it is difficult to predict where the postoperative IOP might be.

Limited Long-Term Data

Long-term prospective, randomized controlled trial data for standalone angle-based MIGS are limited. The onus is on the glaucoma community to initiate a non–industry-sponsored, independent trial that can serve as a landmark study to support the efficacy of this approach.

Lack of Coverage

Say I had planned to use the iStent infinite for my patient because this device is approved for standalone use and has strong pivotal trial data. Unfortunately, payers do not always cover standalone MIGS. Even if covered, there is a huge cost difference between using one or two MIGS devices and performing a trabeculectomy or tube shunt surgery.

Risk of Complications

Potential complications of standalone angle-based MIGS include hyphema, inflammation, and

IOP spikes. These events can be managed and are temporary. With longer visual recovery, however, are these procedures actually less invasive than incisional surgery?

Potential Need for Drops or Reintervention

The unpredictable outcomes of standalone angle-based MIGS introduce the potential need for drops or reintervention. It is impossible to know whether these approaches will be sufficiently effective in each patient; opening the angle via traditional surgery, however, is guaranteed to work. Wouldn't it better to perform a procedure that is more likely to get achieve the patient's target IOP with fewer visits to the OR?

SUMMARY

Standalone MIGS provides modest IOP lowering and variable efficacy among patients. Long-term data are limited. There is the potential for a patient who undergoes standalone angle-based surgery to require the same

number of medications postoperatively, and there is a potential need for reintervention. Complications include hyphema, inflammation, and IOP spikes. Insurance coverage is always an issue. Above all, IOP reductions with standalone MIGS are unpredictable, so this approach may not always be best. ■

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Editor's note: The glaucoma specialist who authored this side of the debate chose to remain anonymous.

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