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Glaucoma Today

TARGETING THE TRABECULAR MESHWORK:

The Glaucoma Perspective

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A continuing medical education activity provided by Evolve Medical Education LLC
This activity is supported by an educational grant from New World Medical.

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Trabecular Meshwork: The Glaucoma Perspective

Release Date: May 2020

Expiration: June 2021

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ACTIVITY DESCRIPTION

This supplement, part of a multipart curriculum titled *Targeting the Trabecular Meshwork: Goniotomy Past, Present, and Future*, focuses on the changing treatment of open-angle glaucoma. Trabeculectomy and tube-shunt surgery have for decades been the mainstay of surgical glaucoma therapy, but during the past decade, minimally invasive glaucoma surgeries (MIGS) have offered patients a safe alternative with trabeculectomy-like reductions in IOP. This content focuses on MIGS procedures that target the Schlemm canal.

TARGET AUDIENCE

This educational activity is intended for ophthalmologists involved in the treatment of glaucoma.

LEARNING OBJECTIVES

At the completion of this educational activity, the participating eye care provider will be better able to:

- **Identify and understand** the advantages and disadvantages of trabecular, supraciliary, and subconjunctival MIGS procedures.
- **Describe** the efficacy and safety of trabecular meshwork (TM) and Schlemm canal MIGS procedures.
- **Identify** the patient characteristics that favor the use of TM and Schlemm canal MIGS procedures.
- **Adopt** optimal surgical techniques when performing TM and Schlemm canal MIGS procedures.

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This supplement is part of a multipart curriculum including webinars and supplements, which can be viewed at <https://evolvemed.com/course-group/targeting-the-trabecular-meshwork-goniotomy/>.

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**PLEASE COMPLETE PRIOR TO ACCESSING THE MATERIAL AND
SUBMIT WITH POSTTEST/ACTIVITY EVALUATION/SATISFACTION MEASURES.**

- 1. Please rate your confidence in your understanding of microinvasive glaucoma surgery (MIGS) procedures (based on a scale of 1 to 5, with 1 being not at all confident and 5 being extremely confident).**
 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 2. Please rate how often you use MIGS in your practice (based on a scale of 1 to 5, with 1 being never and 5 being always).**
 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
- 3. Which of the following procedures does NOT involve the Schlemm canal?**
 - a. iStent
 - b. Hydrus Microstent
 - c. OMNI
 - d. XEN Gel Stent
- 4. Which MIGS device is only approved to be performed with cataract surgery?**
 - a. iStent
 - b. MicroShunt
 - c. Trabectome
 - d. XEN Gel Stent
- 5. Which statement is not consistent with the original definition of what constitutes a MIGS procedure?**
 - a. An-interno microincision
 - b. Minimal trauma
 - c. Excellent efficacy
 - d. Rapid Recovery
- 6. What is a differentiating factor between traditional and excisional goniotomy?**
 - a. Can be used to treat pediatric glaucoma
 - b. Used to open an obstructed trabecular meshwork
 - c. Performed under direct gonioscopy to visualize area
 - d. Elevates and excises trabecular meshwork to access multiple collector channels
- 7. Following a MIGS procedure, patients should be advised they may have blurred vision (on average) for how long?**
 - a. 1 to 2 hours
 - b. 1 to 2 days
 - c. 1 to 2 weeks
 - d. 1 to 2 months
- 8. Which of the following describes a patient best suited for a trabecular-based MIGS procedure?**
 - a. Mild to moderate disease
 - b. Able to tolerate some medications
 - c. IOP target of 15 to 18 mm Hg
 - d. All of the above
- 9. Which type of procedure requires a steeper learning curve than others?**
 - a. Supraciliary MIGS
 - b. Subconjunctival MIGS
 - c. TM/Schlemm Canal MIGS
 - d. All of the above
- 10. Which of the following is NOT a relative contraindication for trabecular-based angle surgery?**
 - a. Goal IOP >10 mm Hg
 - b. Patient on maximum medical therapy
 - c. Active uveitic glaucoma
 - d. Chronic angle closure with significant chronic PAS

Targeting the Trabecular Meshwork: The Glaucoma Perspective

This supplement summarizes a webinar available on the Evolve Medical Education website. Click the link to view the full-length webinar featuring glaucoma experts discussing surgical pearls, case studies, and tackling audience questions: <https://evolvemed.com/course-group/targeting-the-trabecular-meshwork-goniotomy/>.

THE IMPACT OF MIGS

BY JASON BACHARACH, MD

Since the FDA approval of the first trabecular bypass device in 2012, there has been an explosion of microinvasive glaucoma surgery (MIGS) options introduced into the marketplace.

The goal has been to increase aqueous humor outflow primarily through the trabecular meshwork (TM) and in Schlemm canal.¹ Newer approaches have looked at shunting aqueous humor into the supraciliary and subconjunctival spaces.²

MIGS has given us the opportunity to intervene earlier to reduce morbidity, possibly to reduce progression of glaucoma and most importantly to reduce the need for more aggressive surgery.^{1,2}

MIGS can be considered for patients with glaucoma who need cataract surgery; the decision to do phacoemulsification alone versus a combined procedure with either a trabeculectomy or tube has been a challenging one. In addition, MIGS is an option for patients who are phakic and who do not require cataract extraction with a lens implantation, or for pseudophakes, who either need lower IOP than medications or lasers can deliver, or for those who have compliance issues.¹

A logical place to start is to improve the outflow in the area of the trabecular meshwork in juxtacanalicular tissue. The TM becomes stiff and there are deposits of glycoproteins and proteoglycans that obstruct

flow in primary open angle glaucoma.³ MIGS can help improve fluid flow through the TM to not only lower the IOP, but also potentially maintain the health of the TM; that is important because the primary way the TM gets its nutrients is through aqueous.⁴

MIGS IDENTITY CRISIS

Several MIGS options now exist, and there are many ways to classify MIGS: (1) the site of drainage; (2) whether or not there is a device implanted; (3) standalone versus combined with phaco; (4) surgical approach; or (5) ab-interno or ab-externo approach. Some of these devices can be implanted with an ab-interno or ab-externo implantation technique (Table).

When choosing which MIGS devices to add to your armamentarium, consider learning a procedure from each of the classes rather than many from one class and learn to do at least one standalone and one that can be combined with cataract surgery.

MIGS has changed since the term was first coined. The original definition of MIGS¹ included five specific criteria: (1) an ab-interno microincision; (2) minimal trauma; (3) modest efficacy; (4) high safety profile; and (5) rapid recuperation of vision. I also believe that any MIGS procedure should also result in minimal induced astigmatism.

Table. Approved MIGS Procedures Targeting the TM / Schlemm Canal

Site of Aqueous Drainage	Procedure	Manufacturer	Device Implanted	Approved for Standalone	Surgical Approach
Trabecular Meshwork/ Schlemm Canal	Trabecular Meshwork/Schlemm Canal	Glaukos	Yes	Yes in Europe, no in US	Ab interno
	Hydrus	Ivantis	Yes	Yes in Europe, no in US	Ab interno
	Excisional Goniotomy with Kahook Dual Blade (KDB)	New World Medical	No	Yes	Ab interno
	Goniotomy with Trabectome	Neomedix	No	Yes	Ab interno
	Gonioscopy-Assisted Transluminal Trabeculotomy (GATT)	--	No	Yes	Ab interno
	Ab Interno Canaloplasty (AbIC)	Ellex	No	Yes	Ab interno
	OMNI (Viscocanalostomy + Goniotomy)	Sight Sciences	No	Yes	Ab interno

Although not officially part of the definition, conjunctival sparing is also part of the criteria for MIGS.¹ That's where some of the newer procedures, depending on the technique, might not fit into the original definition. The available options have expanded since that original definition, but the intent of the procedures remains the same, ie, reduced surgical time, less tissue manipulation, a rapid return to good visual function, and a streamlined postoperative care regimen. We often call these newer options "MIGS plus."

The ab-interno Schlemm canal procedures can blur the lines, as they may have more than one mechanism of action. Some of the procedures might blur the lines, and they may fit into more than one group. We are learning more about this as we become better at assessing outflow with some of our newer techniques. For example, OCT technology may visualize and ensure an appropriate site of incision or placement of an implant within Schlemm canal. This technology may also allow downstream visualization at collector channels and episcleral veins.

Referring to the nonimplant MIGS options, one of the oldest procedures is goniotomy. Traditional goniotomy was primarily used to treat congenital glaucoma, and it had an inability to lift the TM. It was an incisional procedure, and the original blade was used to create leaflets, and often left scarring in the area and a loss of effectiveness over time. The excisional goniotomy using a dual blade, which is the procedure I use in my clinical practice, enables the surgeon to perform this in pediatric or adult patients with any disease severity level. The blade allows you to elevate and excise the TM and access multiple collector channels. You can actually see at the end of the procedure that excised tissue is removed from the eye and the open pathway.

Each of these procedures has advantages and limitations. In my opinion, one of the important advantages is the safety of the TM/Schlemm canal MIGS procedures. There's no hypotony associated with them because there is no bypassing of the episcleral venous bed. One of the limitations may be that it has modest IOP reductions, based on early clinical trials.

Regarding the supraciliary space, there are no available devices in the United States; CyPass was removed from the market in 2018. The advantage of this device is that it utilized a uveoscleral outflow system, an underutilized potential space in the eye. The limitation was the potential for long-term safety concerns through central corneal endothelial cell loss.⁵

Lastly, the subconjunctival area, often referred to as MIGS-plus procedures, bypass the episcleral venous bed and may allow for lower IOPs but the limitation is the creation of a bleb, and use of mitomycin. Anyone performing these procedures should be comfortable with postoperative bleb management, including needling, or have a colleague available who will handle that aspect of patient care.

GONIOTOMY

If choosing to perform a goniotomy, a cooperative patient who will benefit from enhanced trabecular outflow is necessary. You must have a good view of trabecular meshwork on gonioscopy. In nonpigmented trabecular meshwork, you can look for reflux heme

in the Schlemm canal by inducing hypotony intraoperatively.

Goniotomy procedure is useful for any stage or type of glaucoma, including severe stage glaucoma.⁶ However, a Schlemm canal procedure in general appear to be most effective in patient with early to moderate primary or secondary open angle glaucoma.²

The dual-blade excisional goniotomy may also be considered for a patient who has failed a Schlemm canal stent procedure, if the stent is malpositioned, or an insufficient degree of the Schlemm canal is bypassed. However, in patients who failed a canaloplasty or gonioscopy-assisted transluminal trabeculotomy, I probably would not perform another Schlemm canal procedure because several collector channels have most likely been accessed already with those procedures.

The relative contraindications for goniotomy⁷ include (Figure):

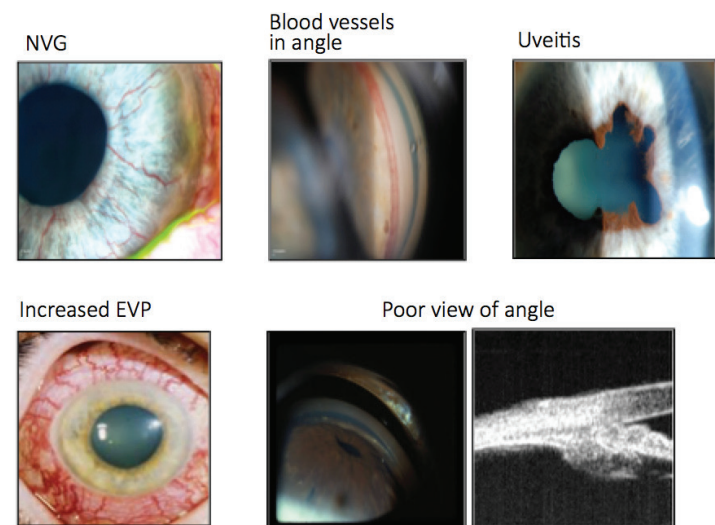
- Active neovascular or uveitic glaucoma
- Elevated episcleral venous pressure
- Poor view of angle
- Goal IOP of less than the mid-teens

PRE- AND INTRAOPERATIVE MEASURES

Patient counseling is important for patients who will have a goniotomy combined with cataract surgery. Explain that visual recovery may take a couple weeks longer than stand-alone cataract surgery due to possible reflux hyphema, and modified hyphema precaution may need to be taken, which consists of elevating head of bed and wearing a shield, and avoiding Valsalva maneuvers or lowering the head below the level of the heart for the first 2 weeks.⁷

Some surgeons will suggest patients cease taking anticoagulants,⁸ but I don't routinely advise this. I may keep the immediate post-procedure IOP in the mid 20s and rarely use a small amount of dispersive viscoelastic in the nasal angle to prevent blood reflux from occurring into the anterior chamber.

When goniotomy is combined with cataract surgery, my



Photos courtesy of Syril Dorairaj, MD (Mayo Clinic – Jacksonville)

Figure. Relative contraindications for goniotomy.

CASE #1: STANDALONE DUAL-BLADE GONIOTOMY by Jella An, MD

An 82-year-old woman presented to our practice with intermittent blurred vision without pain in her only seeing left eye. She was on coumadin for a history of a CVA. She had an axial myopia, with history of complex cataract surgery and retinal detachment in both eyes, unfortunately resulting in no light perception in one eye. She had history of scleral buckles in the affected eye.

On exam, her vision in her "good" eye was counting fingers, and IOP was in mid 20s on four classes of medications. She had diffuse hyphema of the anterior chamber. Her 1pc was found to be in the sulcus. Her posterior view was poor, but prior testing revealed underlying severe glaucoma with dense inferior arcuate defect (Figure).

The diagnosis of active lens-induced uveitis-glaucoma-hyphema syndrome was made, and we planned to proceed with a combined lens exchange, vitrectomy, and a glaucoma valve.

Intraoperatively, I found that her conjunctiva was really friable and there was a lot of scarring from prior encircling buckle surgery. The concern was that further dissections will likely lead to difficult closures

and risk of possible device exposure in the future. Given the chronicity of the problem and advanced baseline glaucoma on maximum tolerated medications, I knew this patient needed something other than just replacing the lens. I decided give angle surgery a try instead.

Her pressure was 6 mm Hg on the day 1 in her left eye off all her glaucoma medications. A single digit low pressure is common after a goniotomy procedure, but one should anticipate this may rise significantly in week 1 or 2 especially when frequent steroid is on board, as it was in her case. Her IOP rose up to mid 20s at week 2, and we decided to ride it out without adding medications or reducing steroid as she was at risk of developing CME.

At month 1 to 2 is when you typically start to see the effects of the procedure as the effect of steroid response wears off. This patient ended up achieving great IOP in mid-teens and the patient was very happy to be off all medications. Once hyphema resolved by month 1, she regained her baseline vision without recurrent hyphema.

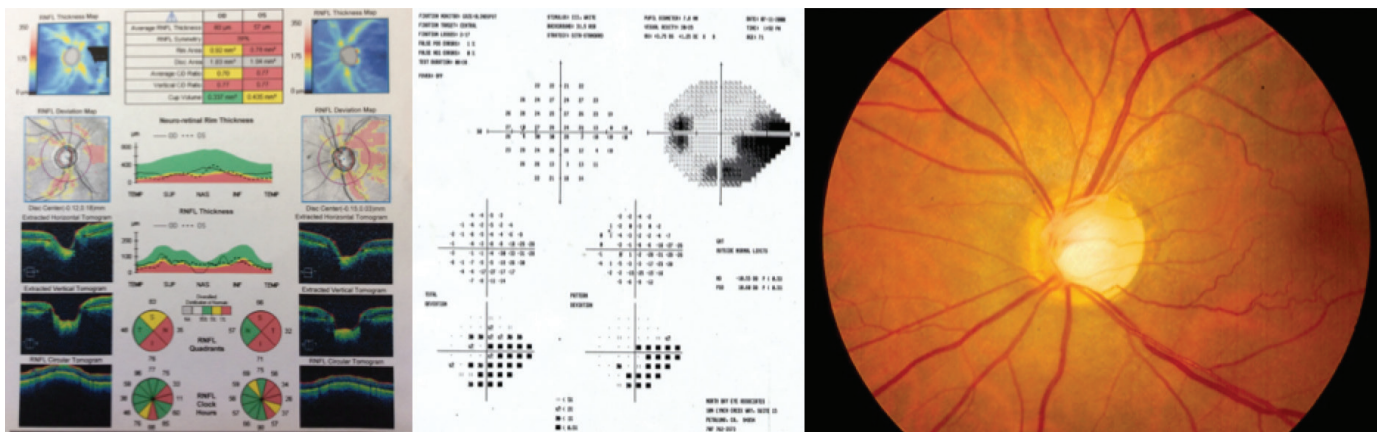


Figure. The patient's posterior view was poor, but prior testing revealed underlying severe glaucoma with dense inferior arcuate defect.

preoperative drop regimen does not differ, and I often start with goniotomy followed by cataract surgery. I use intracameral acetylcholine chloride intraocular solution only for a standalone goniotomy procedure in phakic patients. Note that if you prefer to use a miotic agent in a combined procedure, ensure the viscoelastic is removed from behind the implant before injecting the miotic agent as it's difficult to get behind the IOL to remove the viscoelastic through a small pupil.

I'll also warn the patient preoperatively that I'll be turning their head and moving my microscope so that they anticipate this and not caught off guard.

CONCLUSION

Extreme safety of MIGS and angle surgeries allow us to intervene earlier in patients with mild to moderate glaucoma to reduce IOP and medication burdens, need for more invasive procedures, and

ultimately the risk of disease progression. These procedures can be done alone or combined with the cataract surgery without significant increase in surgical risk. ■

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UNDERSTANDING EACH MIGS PROCEDURE AND THE IMPORTANCE OF PATIENT SELECTION

BY JELLA AN, MD

It is important to understand the limitations of each MIGS category and option. For a Schlemm canal procedure, the main advantage is safety, but the limitation is the modest IOP reduction, usually in mid-teens.^{1,2} Therefore, you should always discuss with the patient the possibility of need for continued medication or further procedures.

Schlemm canal procedures are usually reserved for patients with mild to moderate open angle glaucoma with a modest target IOP in the mid-teens.

A subconjunctival filtering procedure can typically achieve an IOP in the low-teens or even single digit, but it requires more follow-up and activity restrictions of the patient, longer use of steroids, and involves the potential risk of bleb-related or hypotony-induced complications. Therefore, we generally reserve the subconjunctival filtration surgery for patients with advanced disease, who require a low IOP target, or those who cannot tolerate any medications (Figure 1).

CASE SERIES

I want to highlight the 1-year results of a single-surgeon case series looking at goniotomy with a dual blade, presented by Mohammed K. ElMallah, MD, during the 2018 ASCRS Annual Meeting.³ The study included 99 eyes of 83 adult patients with all severities of glaucoma who received either combined and/or standalone dual-blade goniotomies. At 1-year following surgery, he reported about a 20% IOP reduction. However, most patients at baseline had well controlled IOP, an average of 18 mm Hg, which means most patients underwent goniotomy with a goal of medication reduction. There was on average a 50% reduction of medication usage, and less than 5% of patients required additional glaucoma surgery.

At Mason Eye Institute where I practice, we conducted a study to assess the outcome of dual-blade goniotomy in patients with severe open angle glaucoma.⁴ We included 42 patients with primary and secondary open-angle glaucoma, although most patients had

Trabecular-Based MIGS	Subconjunctival Filtration
<ul style="list-style-type: none"> ➤ Mild-moderate disease ➤ Ocular hypertensive ➤ Open-angle ➤ Modest IOP target <li style="padding-left: 20px;">♦ 15 to 18 mm Hg ➤ Able to tolerate some meds if needed 	<ul style="list-style-type: none"> ➤ Advanced disease ➤ Progressive normal-tension ➤ Open or closed angle ➤ Low IOP target <li style="padding-left: 20px;">♦ <15 mm Hg ➤ Intolerant to meds

Different indications and timing

Figure 1. Patient selection criteria for trabecular-based MIGS and subconjunctival-based MIGS procedures.

primary open-angle glaucoma. Severe disease was based on the ICD-10 guideline, and average mean deviation of patients was -13 dB.

We found that no matter how high the preoperative IOP, most patients at 6-month follow-up achieved an IOP in the mid-teens. Similar findings were illustrated in another study by Dorairaj and colleagues⁵ at the Mayo Clinic's location at the University of Florida. The 12-month outcomes for this multicenter, prospective study involving a standalone goniotomy procedure performed in 52 eyes found there was no significant correlation between the baseline IOP and a final postoperative IOP. All of them resulted in the mid-teens.

The patient population in our study had a low baseline IOP and were on multiple medications. The goal of the surgery was to reduce the dependency on the medication. This may explain only modest % IOP reduction seen in our study, with nearly 50% medication reduction.

Sixty-four percent of our patients were able to achieve the target IOP of 15 mm Hg, and half of those patients were also able to discontinue all of their glaucoma medication (Figure 2). Therefore, these results suggest that goniotomy may be an option at the time of cataract surgery in patients with severe open angle glaucoma before we consider any other more invasive surgeries.

SAFETY

The most common adverse event in the early postoperative period was microhyphema, which is almost always expected and most resolve within a week or 2, and very rarely require additional treatment or any intervention. Repeat bleeds are rare after a Schlemm canal procedure but do occur. For example, after a compressive

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Case series: Goniotomy with a dual blade
99 eyes (83 patients), single surgeon
79 concurrent phacoemulsification

1-Year Results
Preoperative IOP: 17.9 +/- 7.0
Postoperative IOP: 14.4 +/- 2.3

Meds (pre): 2/0 +/- 1.1
Meds (12 mos): 0.9 +/- 0.7
4 patients required additional surgery

ElMallah, MC, Session 144A, Presented at: ASCRS, April 14, 2018, Washington, DC.

ON DEMAND WEBINAR: Follow the link to see Drs. An and Bacharach discuss multiple case series: <https://evolvemed.com/course-group/targeting-the-trabecular-meshwork-goniotomy/>.

IOP Goal	% (n)
≤18 mmHg	85.7% (36)
≤18 mmHg + medication reduction	61.9% (26)
≤15 mmHg	64.3% (27)
≤15 mmHg + medication reduction	45.2% (19)
≤15 mmHg + complete medication discontinuation	31.0% (13)

Figure 2. Sixty-four percent of our patients were able to achieve the target IOP of 15 mm Hg, and half of those patients were also able to discontinue all their glaucoma medications.

gonioscopy, blood reflux will appear at the site of the goniotomy. In the same token, if the patient sleeps with their eye compressing the pillow and suddenly decompress the eye upon waking up, they will often report they had blurred vision that lasted for a few hours. Patients should be counselled regarding this risk and advised to avoid directly pressing the operated eye and seek medical attention if blurred vision does not improve within a few hours.

CONCLUSION

If you are just beginning to perform MIGS, we suggest trying to master at least one surgery in each of the categories, whether in Schlemm canal-based surgery, subconjunctival surgery, and in the future when it becomes available, suprachoroidal surgery, and ciliary body ablation.

My preferred angle surgery is the dual-blade excisional goniotomy because, in my opinion, it has several advantages over other Schlemm canal procedures. The main advantage is its ability to access several collector channel entrances with a single procedure. Another advantage of dual-blade goniotomy is its versatility. It can be used as a standalone procedure, and also in patients with all severity levels of glaucoma.⁶ It can also be used in an angle closure patient if it's combined with a cataract surgery, and you can easily do a gentle goniosynechialysis with the same blade.⁷ Because there is no implant option, there's no risk of a lost or malpositioned stent, and it costs less for the patient and the health care system.

It is important to keep in mind the flooring effect with any of the angle procedures. Also, the long-term data is still lacking. Although we have seen good results in our patient populations, our results may not be generalizable.

Most importantly, the safety profile of any angle surgery is very good, especially compared to the subconjunctival procedures or

CASE #2: PHACOEMULSIFICATION + GONIOTOMY WITH A DUAL BLADE

by Jella An, MD

I want to highlight a borderline case involving a patient who normally would be a candidate for a subconjunctival filtering procedure. This is a case of 78-year-old healthy female with advanced open angle glaucoma with poorly controlled IOP in the high 20s, with poor tolerance to her glaucoma medications. Her VF showed evidence of progression at this IOP.

The main decision point here was her social situation. She was still working full-time as a surgery coordinator, she was the sole care provider for her ill husband and couldn't afford any downtime, and she lived three hours away from our center. She needed to be able to drive immediately following a procedure.

Based on these details and discussions with the patient, we chose to perform phacoemulsification plus dual blade goniotomy in both eyes. I explained that she may still need some or all of topical medications or an additional procedure in the future if the IOP lowering was insufficient or if she had an exuberant steroid response.

Thankfully, her postoperative course was rather smooth, and about a month after the second procedure, she achieved 20/20 vision with IOPs in the high-teens—a 35% IOP lowering—but she still required all of her medications, which she was poorly tolerating.

In order to get her off medications, we chose to perform MicroPulse cyclophotocoagulation (MP-CPC). This was a good option for this patient because there is no downtime or activity restrictions required. Within 1 month, she was able to discontinue all of her medications but one class, while maintaining her IOP in mid-teens. She was very happy with the outcome.

ablation procedures. If IOP lowering from the angle surgery is insufficient, subsequent filtering surgeries or cyclophotocoagulations can still be successfully performed.⁸ ■

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