EyeWorld CME Supplement™

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Innovating advanced treatments to increase compliance and improve outcomes for glaucoma patients: diagnostics, novel therapies, and surgical options

Customizing treatment strategies

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by Richard A. Lewis, MD

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The ASCRS Clinical Survey is a membership survey designed to assess clinical opinions and practice patterns; in 2014 there were 1,501 unique respondents that helped provide us with 267 data points surrounding the most compelling and controversial issues facing our membership. For instance, in 2014, U.S. respondents said they see more than 400 glaucoma patients yearly, almost twice as much as the non-U.S. respondents.[1] (See Figure 1.)

Overall, the respondents noted fewer than 30% of their patients who are prescribed prostaglandin analog-based therapies for the reduction of intraocular pressure (IOP) are compliant with their prescribed treatment.[1] As a result, we (as clinicians) have little confidence with this traditional therapy that has little to do with the class of medication's efficacy.

In today's real-life clinical settings, medical/topical therapy is likely to remain the first-line choice for the majority of glaucoma specialists, as it is non-invasive and proven efficacious. Unfortunately, one patient may be able to tolerate three medications, but another may only be able to tolerate one, leaving us to choose between combination therapies or surgical interventions early on. Even worse, there are patients who will have loss of visual field despite adequate IOP control.[2] As clinicians, we acknowledge that IOP control is the key to limiting vision loss—it has been generally well accepted for more than a decade that for every 1 mm Hg drop in IOP, the risk of disease progression drops by 10%.[3] Potentially complicating our prescribing habits even further is our underlying belief that brand name glaucoma medications are being substituted with generic pharmaceuticals about half of the time,[1] often by the pharmacist and without our knowledge. These substitutions also may affect patient compliance.

> **"Fewer than 30% of our patients … are compliant with their prescribed treatment."**
>
> **–Richard A. Lewis, MD**

There are new classes of medical treatments on the horizon, including the Rho-kinase (ROCK) inhibitors and adenosine receptor agonists. These target the trabecular meshwork, and the ROCK inhibitor under development (Rhopressa, Aerie Pharmaceuticals) increases fluid outflow through the trabecular meshwork, reduces episcleral venous pressure, and functions as a norepinephrine transporter inhibition. A second ROCK inhibitor combines Rhopressa with latanoprost, and may be commercially available as early as 2018. Trabodenoson

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Educational Objectives
Ophthalmologists who participate in this activity will:

- Describe the issue of treatment compliance in the management of glaucoma and its impact on patient outcomes;
- Identify the latest diagnostics to assist in the diagnosis and detection of progression of glaucoma disease;
- Assess the impact of novel pharmaceutical options—including new combination drugs and drug delivery systems—on treatment compliance among patients with glaucoma and their corresponding effect on treatment outcomes; and
- Identify the latest scientific information on MIGS, both in regard to study results and evolving surgical techniques, to maximize the outcomes in a practice.

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(Inotek) works by enhancing the extracellular matrix turnover in the trabecular meshwork. Latanoprostene bunod (Vesneo, Bausch + Lomb) chemically combines nitric oxide with latanoprost to create the new molecule, a nitric oxide-donating prostaglandin F2-alpha analogue.

Sustained release devices will allow us to use proven prostaglandin analogues, but reduce our reliance upon patient compliance. There are several development programs under way that will (hopefully) demonstrate long-lasting efficacy. Among them: sustained-release travoprost delivered via punctal plug (OTX-TP, Ocular Therapeutix) and a long-lasting bimatoprost implant (bimatoprost SR, Allergan). There are two latanoprost programs in development: one that uses a punctal plug delivery system (Mati Therapeutics) and one that uses a sustained release insert and Durasert technology (pSivida/Pfizer).

With numerous medical therapies and various surgical techniques in our armamentarium, we have little reason not to begin customizing our treatment strategies to best meet our patients' visual goals. The subsequent monograph has been designed to show clinicians how the latest diagnostic tools can make diagnosing disease progression easier, why attention to compliance cannot be underrated, and how to customize surgical approaches by incorporating the latest in microinvasive glaucoma surgery (MIGS) techniques.

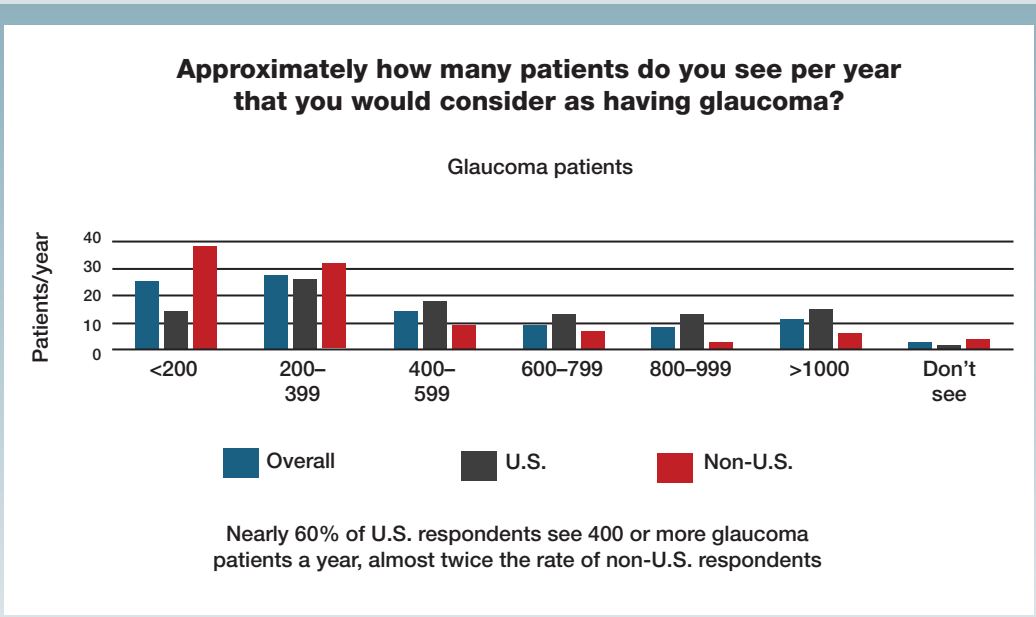

Figure 1. Number of glaucoma patient visits yearly

Source: 2014 ASCRS Clinical Survey

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Panel discussion

Imaging and diagnostics

Rick Lewis, MD: During early diagnosis, where do you put the emphasis?

Douglas J. Rhee, MD: On both optical coherence tomography (OCT) and visual field equally. I diagnose 50% of new onset cases by visual field, the other half by OCT. We look for structural change with OCT—what does everyone else do?

Brian Francis, MD: I use OCT mostly to assess the nerve fiber layer, but also to look at the ganglion cells and the macula. The optic nerve head analysis, in terms of tracking longitudinal changes, is less sensitive than the retinal nerve fiber layer analysis.

Dr. Lewis: Do you use SITA swap?

Dr. Rhee: If the nerve looks very suspicious and I'm quite nervous about it, SITA swap ends up being very reassuring for me. I'm much more dependent on psychophysical testing.

Dr. Lewis: The disadvantage is it takes a little longer to do. So what is your routine visual field test?

Dr. Rhee: I use a 24-2 SITA standard.

Nathan Radcliffe, MD: SITA standard rather than the SITA Fast.

Dr. Lewis: What do you think of the newer diagnostics?

Dr. Rhee: Pattern ERG intrigues me, but I don't think it's mainstream quite yet.

Dr. Radcliffe: Spectral-domain OCT with a good software package is still your best tool; I don't think we're at a point of advocating swept-source OCT.

Dr. Francis: The newer electrophysiology tests and microperimetry are easier to perform in patients, and they may give us information that is psychophysical but not as prone to error as a visual field.

Patient assessment and treatment plans

Dr. Radcliffe: If you're switching from a QD dosing to a BID schedule, make sure the patient's caretaker is a BID caretaker. Otherwise, you're likely to get QD dosing for the BID product.

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Advanced diagnostic measurement for better disease management

by Douglas J. Rhee, MD

Douglas J. Rhee, MD

Diagnosis and detection of glaucomatous progression remains a challenge; detection relies on examination of the structural damage to the optic nerve, combined with measurement of visual function.[1] Unfortunately, changes in structure and function do not always agree in patients,[2] making the diagnosis more difficult. As clinicians, we often concentrate so much on preparametric glaucoma that we forget the first defect is a visual field defect in half our patients. Numerous studies have shown what we note in clinical practice—10% of all patients will become legally blind or lose vision altogether over a 20-year period.[3] Early diagnosis is the only means to prevent this type of glaucoma damage.

We currently have three methods to quantitatively analyze the nerve fiber layer (NFL) thickness, including optical coherence tomography (OCT), Heidelberg Retina Tomograph (HRT), and nerve fiber analyzer (GDx), which uses polarized light to look at the NFL. In the past 10 years, OCT has become a mainstay in our armamentarium.

Spectral-domain OCT (SD-OCT) offers benefits over early generation time-domain OCT because of increased axial resolution, faster scanning speeds, and improved reproducibility but similar diagnostic accuracy,[4] and allows for gaze tracking so the optic nerve remains centered. For clinicians without SD-OCT, time-domain can still be a valuable tool.

> ***"While OCT has vastly improved our ability to diagnose and manage glaucoma, we cannot overlook the importance of visual field testing."***
>
> ***–Douglas J. Rhee, MD***

There are three main reasons to use OCT: to rule out glaucoma and rule out healthy suspects; to understand the areas of abnormality and how intensively to treat; and to determine if treatment needs to be advanced based on disease progression.

Using OCT to rule out healthy patients

In this case, a 64-year-old male of African descent had a family history of glaucoma. In Figure 1, imaging and central thickness are on the borderline stage, as is his IOP.

But Figure 2, a time-domain OCT reading, clearly shows this patient is healthy.

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Dr. Lewis: Is there a difference in the strength of the prostaglandins?

Dr. Radcliffe: There are 20–30 studies that have compared the prostaglandins, and while some have shown similar efficacy between latanoprost, travoprost, and bimatoprost, many have shown travoprost and bimatoprost to have better efficacy than latanoprost. Once you add another medication, you run the risk of diminishing patient compliance, so it might make the most sense to use a more potent prostaglandin analog before adding to latanoprost.

Dr. Lewis: What are the pros/cons to adding a second medication?

Dr. Radcliffe: Beta blockers are (perhaps) our most trusted molecule. We don't have many formulary concerns with beta blockers. Adding them has been shown in studies to reduce the hyperemia rate, lower allergy responses, and enhance tolerability.

Brand name vs. generic

Dr. Radcliffe: The Food and Drug Administration requires the concentration of the active ingredient, and any of the excipients, be the same in the generic as in the name brand. The main difference is human clinical trials on the generic product are not going to show efficacy. That's often where concerns arise.

Dr. Rhee: Generics are often less expensive for the patient, and that can make a difference. But branded products have their role, and if efficacy or side effects are an issue, they may be preferred.

Dr. Francis: Generics have a place because of cost. But there's no control over how the drug is compounded in terms of the order of the ingredients. The manufacturing process and the steps are not necessarily the same as the original drug.

Drug delivery

Dr. Lewis: What are your thoughts about the new drug delivery systems being investigated?

Dr. Rhee: I'm impressed with how much easier patients accept the concept of an implantable drug delivery system. There seems to be a clinical impression that a laser is much more invasive than injecting something into the eye.

Next generation glaucoma therapies and baselines for success

by Nathan Radcliffe, MD

Nathan Radcliffe, MD

From the moment we decide a patient needs to be treated and we write that first prescription, there are numerous incremental steps where something can go wrong: the patient loses the prescription, or the patient's insurance does not cover the prescribed medication and the pharmacist opts to fill the prescription with a generic alternative. Then there's the potential and very real possibility the patient will be unable to successfully apply the drop. The data is grim: Only 10% of patients will have 1 year without a refill gap.[1]

Overcoming compliance issues

The published literature is full of evidence of non-compliance,[2–5] but we've yet to agree on a universal description about how many drops over what course of time defines "non-compliance." Once patients do begin using the medication, however, only 39% of attempted eye drop placement hits the eye, with an average of 1.5 drops delivered per attempt.[6] So their drops are going to run out early. In clinical trials, about 16.5% of patients will have an adverse event and 28% will discontinue therapy.[7] Further, almost 70% of patients who have problems administering eye drops would not tell their doctors, even if directly asked.[8]

It's clear that as clinicians, patient compliance and successful use of topical medication is a difficult hurdle. However, tailoring a dosing regimen around a patient's regular schedule can help—one review article found a 79% compliance rate with QD dosing vs. 51% compliance rate with QID dosing.[9] In my opinion, this is the primary argument for opting to use a powerful prostaglandin analog as your first-line therapy, which may be able to prevent a second adjunctive therapy.

Patient example

Simply put, patients who do not adhere to their treatment regimen have worse visual fields and worse vision compared to those who do comply.

Figure 1 illustrates the case of a young monocular man who had early glaucoma that required 4 topical agents for pressure control. His fellow eye was blind and painful, and he had been prescribed prednisolone and atropine in that eye. One day, he simply switched the drops. Unfortunately, that was also during a 6-month interval where he did not come in for a check-up. He not only stopped his glaucoma medications in his only seeing eye, he also started a topical steroid that induced a steroid-related glaucoma. When he returned for follow-up, he had advanced glaucoma damage in his only seeing eye with an intraocular pressure of 48 mm Hg. All of this occurred in 6 months, simply because he became confused about his eye drop regimen.

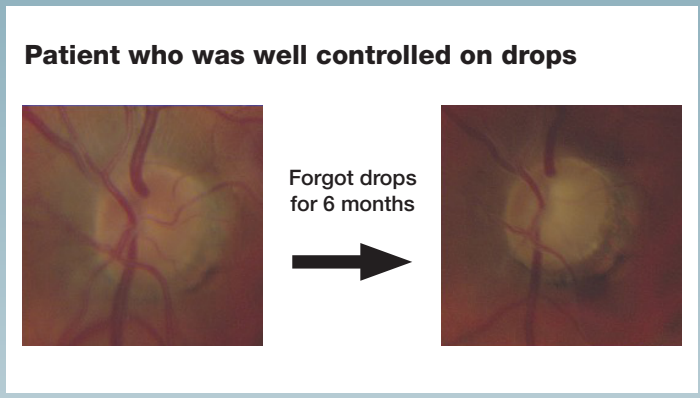

Figure 1. Monocular patient well controlled on drops (left) and 6 months after forgetting to take them (right)

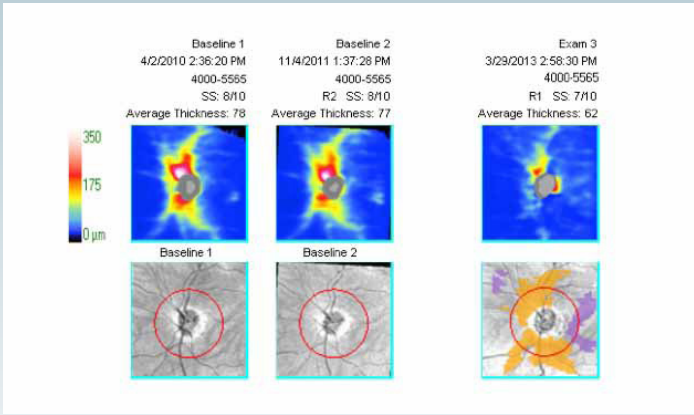

Figure 2. Imaging shows clear disease progression

When the patient did return, his optic nerve had changed dramatically, from a 0.4 to 0.9. Imaging showed dramatic retinal nerve fiber layer loss (see Figure 2).

Improving compliance

Despite these compliance issues, topical medication remains the first-line therapy for many of our patients. Prostaglandin analogs remain our first-line therapy, but we are fortunate to have several different molecules. Generic latanoprost may improve access to patients who have issues with self-pay, or patients who are actually uninsured. Bimatoprost has been reformulated in a lower concentration and altered preservative levels. In one study, patients who were switched from generic latanoprost to bimatoprost 0.01% experienced significant IOP lowering (17–19.9%, or about 4 mm Hg).[10] It's unclear if there were consistency issues with the generic latanoprost that could explain the huge improvement.

Large cohort studies have shown 40% of patients need at

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In this instance, any of the newer technologies would have been helpful, including the HRT and SITA SWAP, both of which confirmed this patient was healthy.

Treatment intensity

The stage of the disease should be the determining factor in how intensively to treat. There does not necessarily need to be the same target pressure for both eyes.

Determine first if there's a change. Figure 3 shows a patient who has an increase in the optic nerve cupping, with an increased corresponding visual field and OCT. This particular patient had time-domain OCT and then we moved to SD-OCT.

The technology behind OCT itself is not patented, so there are numerous manufacturers of OCT machines, among them Heidelberg, Nidek, Optovue, Optos, Topcon, and Carl Zeiss Meditec. Each system has its own benefits and differentiating factors, and each has its own set of enhancements unique to the developer/marketer. Overall, however, OCTs boast progression analysis, structural analysis, ganglion cell analysis, and eye tracking capabilities, and the devices can eliminate static in images to reveal the finer details in the retinal layers.

Visual field testing

While OCT has vastly improved our ability to diagnose and manage glaucoma, we cannot overlook the importance of visual field testing. The published literature supports this—in the randomized, prospective, controlled trials, once there's mild to moderate glaucoma, progression has almost always been detected by visual field changes. The threshold of utility for OCT measurement of retina NFL (RNFL) thickness has been reported to be 75 micromillimeters, and somewhere around 50–55 micromillimeters OCT is no longer able to measure change in RNFL thinning, but visual fields are still useful.[4] In advanced glaucoma, OCT may no longer be helpful; this is typically where clinicians will rely upon visual field testing.

As visual field analyzers continue to improve incrementally, a good diagnostic performance can be obtained with optimized subsets of the standard 24-2 test pattern[5]; once you get to 30 degrees, you'll get more artifactual error that is not glaucoma.

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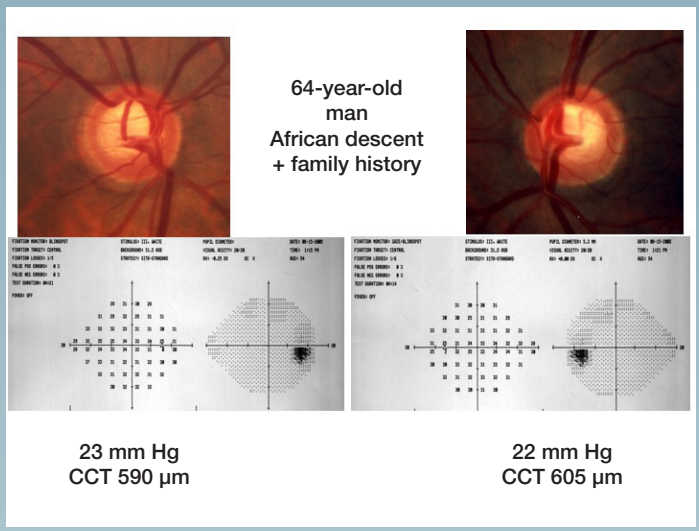

Figure 1. Initial images and visual fields for 64-year-old male of African descent

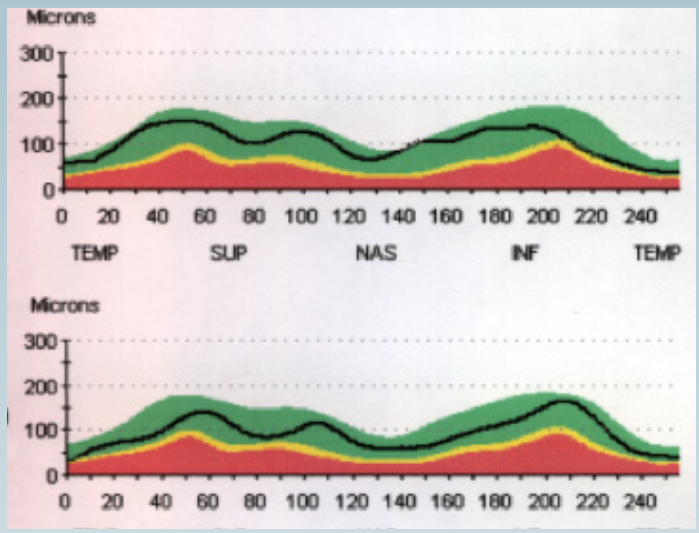

Figure 2. Time-domain optical coherence tomography image of the same patient

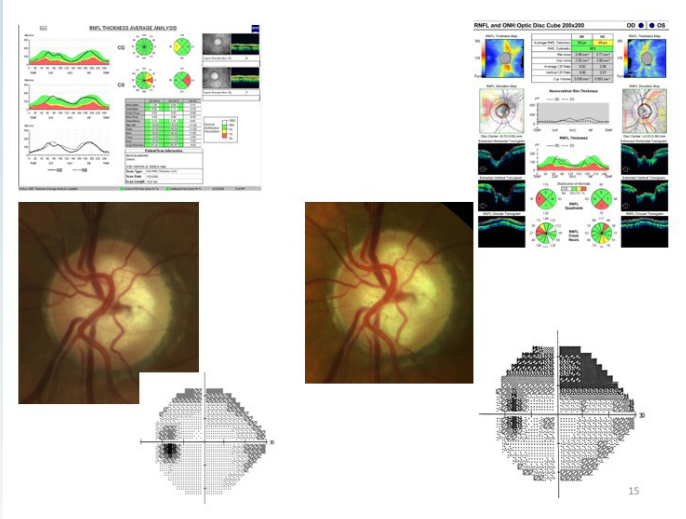

Figure 3. Increasing glaucomatous damage

Individualizing glaucoma surgery

by Brian A. Francis, MD, MS

Brian A. Francis, MD, MS

Virtually every one of our glaucoma patients is a potential surgical candidate at some point in their treatment. There are a multitude of procedures that can benefit our patients—from inflow procedures such as endoscopic cyclophotocoagulation (ECP) to transscleral cyclophotocoagulation, to outflow procedures such as trabeculectomy, shunts and suprachoroidal filtration. The latest approaches include microinvasive glaucoma surgery (MIGS) by internal approach to the trabecular meshwork, filtering surgery by external approach, and suprachoroidal surgeries. We can now individualize our approach, and we should be customizing our treatments. There's no one glaucoma surgery that's appropriate for every patient. The remainder of this article will illustrate different surgical approaches for a variety of patients.

> ***"We should be customizing our [surgical] treatments."***
>
> ***–Brian A. Francis, MD, MS***

Case No. 1: Primary open-angle glaucoma

This patient is an 83-year-old Caucasian female with primary open-angle glaucoma (POAG), with significant optic nerve damage; C:D 0.9. Intraocular pressure (IOP) is 14 mm Hg in the right eye on one med and 23 mm Hg in the left on three meds. She is bilaterally pseudophakic. She had undergone prior Ahmed glaucoma valve in the right eye, but developed strabismus and diplopia postoperatively.

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least 2 medications to reduce pressure by 20% after 5 years.[11] The literature suggests only a modest additional IOP reduction from single-agent adjunct,[12] and there are more than 56,000 potential combinations from which to choose.[13]

Combination therapies simplify treatment. Several are marketed currently; a prostaglandin plus a fixed combination is a realistic maximal therapy for many patients.

> ***"We've yet to agree on a universal description about how many drops over what course of time defines 'non-compliance.'"***
>
> ***–Nathan Radcliffe, MD***

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Even though her pressure OD was acceptable, she wanted to alleviate the strabismus and diplopia. She also had problems with ocular surface disease and sensitivity to medications.

We removed the tube (Figure 1). We could have replaced the tube, but the patient did not want any sort of implant because of the diplopia problems.

We resolved her issue by doing an ab interno trabeculotomy (Trabectome, NeoMedix) and were able to control her IOP, albeit on more medical therapy than she had been previously (two medications vs. one pre-Trabectome). Her diplopia did resolve with removal of the tube shunt.

Case No. 2: Primary open-angle glaucoma

A 68-year-old Indian female is the wife of an ophthalmologist. She has uncontrolled POAG in her left eye (24 mm Hg) and documented visual field progression with significant moderate to severe nerve damage in that eye. She is on four topical medications and a low-dose oral carbonic anhydrase inhibitor. This is clearly a patient on maximal medical therapy.

We elected to perform a trabeculectomy (Figure 2), as a traditional filtering surgery should give her the best possibility of decreasing or eliminating most of those medications and reaching a target IOP in the low teens.

Case No. 3: Exfoliation glaucoma

A 75-year-old Caucasian female with exfoliation glaucoma presented with uncontrolled IOP in the right eye (24 mm Hg), and moderate to severe nerve damage of C:D=0.85. She had failed a previous canaloplasty. Her left eye has had a retinal detachment and a scleral buckle. She is on two glaucoma drops (prostaglandin and a carbonic anhydrase inhibitor) plus oral acetazolamide, which constitutes maximal therapy for her; she has failed the other medical treatments.

This patient was against a filtering surgery and wanted to explore a MIGS-type procedure. We opted for an inflow procedure (ECP) and an outflow procedure (Trabectome). Dr. Radcliffe has previously discussed a combined ECP, iStent (Glaukos), and cataract surgery; combining MIGS procedures is not a novel concept.

Conclusions

Surgery is not going to replace topical medications, and there is room for adjunctive medical therapy. MIGS are not curative and may not reduce the IOP enough. But when the disease cannot be managed medically, adding glaucoma surgery earlier with these newer, less invasive procedures may be able to improve compliance and provide better patient outcomes. For mild glaucoma, I recommend cataract surgery alone or MIGS; for mild to moderate cases, consider the newer procedures, and for severe cases, opt for a combined trab or tube shunt.

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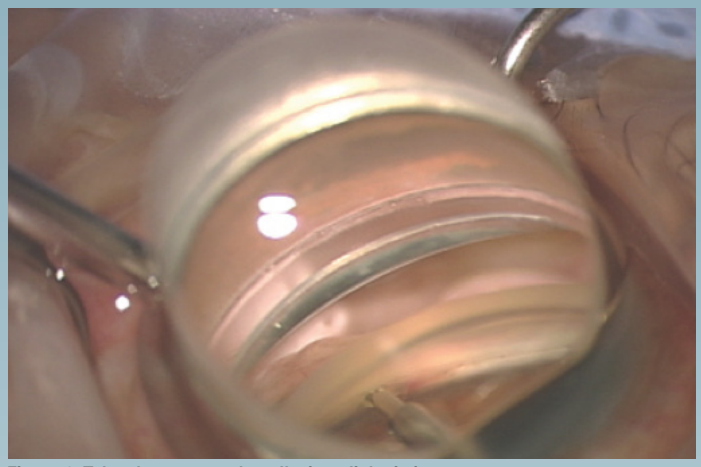

Figure 1. Tube shunt removal to alleviate diplopia issues

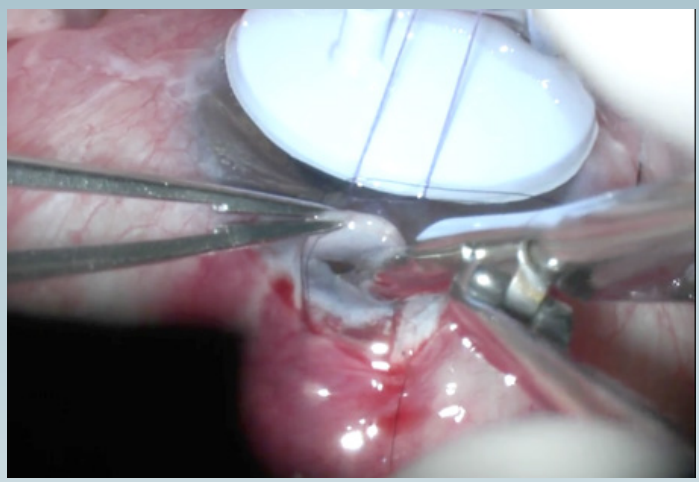

Figure 2. Traditional trabeculectomy to help ensure intraocular pressure lowering

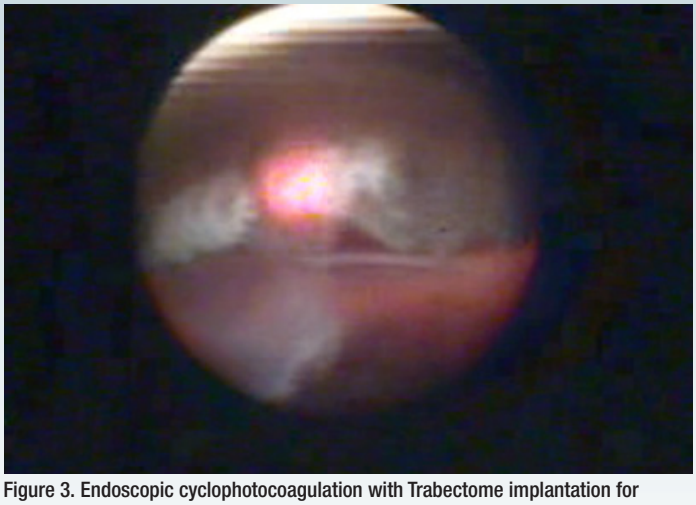

Figure 3. Endoscopic cyclophotocoagulation with Trabectome implantation for exfoliation glaucoma

Source: Brian Francis, MD

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CME questions (circle the correct answer)

1. **In patients with primary open-angle glaucoma, for every 1 mm Hg decrease in intraocular pressure, the risk of diease progression**
   a. Increases 10%
   b. Decreases 10%
   c. Increases by more than 10%
   d. Decreases by more than 10%

2. **According to these presentations, what is NOT a reason to use optical coherence tomography to analyze the nerve fiber layer?**
   a. To rule out glaucoma and glaucoma suspects
   b. To determine how intensively to treat the patient
   c. To determine the type of topical medication to prescribe
   d. To determine if treatment needs to be advanced

3. **True or false: Target pressures should be the same in each eye.**
   a. True
   b. False

4. **According to data from a review article, there is a _____ compliance rate with QD dosing and _____ compliance rate with QID dosing.**
   a. 59%, 62%
   b. 85%, 14%
   c. 21%, 82%
   d. 79%, 51%

5. **Large cohort studies have shown 40% of patients**
   a. Need at least 2 medications to reduce pressure by 20% after 5 years
   b. Need surgery and combination topical therapies to reduce pressure by 40% after 1 year
   c. Need invasive surgery to eliminate medication use
   d. Will continue to be well controlled on one medication only after 5 years

6. **When considering surgery for patients with glaucoma**
   a. Depending on the disease severity, there is only one option
   b. Regardless of disease severity, trabeculectomy should remain the preferred surgical option
   c. Treatments should be customized based on patient and surgeon preferences
   d. Techniques should always be combined with phacoemulsification

7. **What are the clinical differences between brand name and generic glaucoma medications?**
   a. None, they are clinically the same
   b. Differences exist in cost only, and generics are always less expensive
   c. Brand name drugs have to show efficacy in studies; generic equivalent medications do not
   d. Generic medications are not necessarily compounded the same way
   e. B and C
   f. C and D

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