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by Lynne Peterson

SUMMARY

- There is renewed interest in cyclo-photocoagulation to treat glaucoma.
- Traditionally, endoscopic CPC with **Endo Optiks** laser has been reserved mostly for severe patients and when it can be combined with cataract surgery.
- Transscleral CPC with **Iridex's Ocu-Light SL** laser has expanded use of CPC.
- MicroPulse CPC (MP3-CPC) with **Iridex's Cyclo G6** laser, which uses an intermittent micropulse instead of a continuous wave, is proving to be a kinder, gentler form of CPC, but experts are still figuring out how best to use it. While it may need some tweaking before general glaucoma specialists adopt it, tertiary centers are pleased with the results so far.
- While MP3-CPC may encourage use of CPC for more patients, it will still be a second tier treatment, after drugs and SLT, but it may decrease use of drainage devices.
- Ab-interno canaloplasty with **Ellex's iTrack 250A** microcatheter also is generating interest.

Trends-in-Medicine
Stephen Snyder, *Publisher*
2731 N.E. Pinecrest Lakes Blvd.
Jensen Beach, FL 34957
772-334-7409
Fax 772-334-0856
www.trends-in-medicine.com
TrendsInMedicine@aol.com

GLAUCOMA UPDATE

A lot of drugs are in development to treat glaucoma, which is not surprising since it is a leading cause of blindness in the U.S., particularly among African Americans and Hispanics. But there are two other problems: getting people diagnosed in the first place and figuring out what to do when drugs don't work.

According to the American Academy of Ophthalmology (AAO), ~3 million Americans have primary open-angle glaucoma (POAG), the most common form, but about half do not even know they have it. That is because there usually are no symptoms, so it can silently steal vision.

Six glaucoma specialists and an industry consultant were interviewed to explore therapies for glaucoma when drugs are not enough, with a focus on cyclophotocoagulation.

For most glaucoma patients in the U.S., the first-line treatment is a topical eye drop – most often a prostaglandin (e.g., Pfizer's Xalatan (latanoprost), Allergan's Lumigan (bimatoprost), or Novartis/Alcon's Travatan (travoprost) – or, less commonly, selective laser trabeculoplasty (SLT) or ALT (argon laser trabeculoplasty). If a single eye drop doesn't work, ophthalmologists can add a second or even a third eye drop from another class of drugs (i.e., a beta blocker, an alpha agonist, or a carbonic anhydrase inhibitor), either in a combination medication or separately.

SLT, which stimulates an increase in ***outflow*** of intraocular fluid, can be done either ahead of eye drops or when eye drops don't work well enough or compliance issues arise due to difficulty putting them in, the treatment burden, or cost. SLT, which is much more common today than ALT, uses a cold laser (532 nm) that targets the pigmented trabecular meshwork and does no collateral damage. With a drop of anesthetic, the patient sits in front of the laser, usually in an ophthalmologist's office not a hospital or surgery center.

SLT is very effective in lowering intraocular pressure (IOP), and some doctors are now considering it earlier, rather than maximizing drug therapy, due to compliance issues.

- *Marlene Moster, MD, a glaucoma specialist from Wills Eye Hospital*, said, "It works in ~75% of patients to drop pressure ~20% from baseline. It can be used as a first-line treatment or as an adjunct to medication, which is the current conventional wisdom. Usually, SLT is not done first, though it probably should be. Multiple prospective trials in the U.S. have shown that laser first is at least as effective as medical therapy. Even though everyone accepts this as a wonderful modality with few risks, it has not been accepted as first line by most patients because it is perceived as 'something being done to them.'"

- *Mahmoud Khaimi, MD, a glaucoma specialist from the Dean McGee Eye Institute at the University of Oklahoma College of Medicine*, said that when medications don't work, SLT or minimally-invasive glaucoma surgery is the usual second step. He estimated that 60% of his patients today get SLT and 40% surgery, but he emphasized that a lot of the patients who come to him are already on maximized drug therapy.
- *Thomas Samuelson, MD, a glaucoma specialist from Minnesota Eye Consultants*, said that in most cases, when medications are used, SLT is the next step and vice versa. Exceptions include very high IOP, very severe disease, and cases involving coincident management of cataract.
- *Arindel Maharaj, MD, PhD, a glaucoma specialist from Bascom Palmer Eye Institute*, said most patients in his practice prefer to start with a drop first and <5% start with SLT, "Once patients start drops and realize the inconvenience or toxicity, they are more willing to try SLT…SLT has about the same amount of IOP lowering, 30%-35%, as monotherapy [with drugs]. I explain to a patient that it works in ~75% of patients, and if you are a young patient with many years to live, you may need additional procedures later on. SLT also can be used in combination with other medications, and it offers additional lowering…Almost all glaucoma patients who are progressing or who are on multiple medications who have the appropriate anatomy will, at some point, attempt an SLT…particularly if they can't go to surgery."
- *Andrew Iwach, MD, a San Francisco glaucoma specialist, a clinical spokesperson for the American Academy of Ophthalmology, and board chairman of the Glaucoma Research Foundation*, said, "SLT doesn't always work and doesn't last forever. Beta blockers are well tolerated locally but can have significant systemic side effects. Prostaglandins have great efficacy and a nice systemic profile but can cause local ocular side effects."

When the eye drop and SLT options have been exhausted, the next options are:

- **Trabeculectomy**, a non-laser procedure in which a surgical incision is made into the trabecular meshwork to create new channels for more outflow of aqueous humor.
- **Drainage devices**, such as Glaukos' iStent, New World Medical's Ahmed valve, or Abbott's Baerveldt tube.
- **Cyclophotocoagulation**. Overall, experts estimated that <20% of glaucoma patients will eventually need/get this treatment.
- **Ab-interno canaloplasty (ABiC)**, a minimally-invasive glaucoma surgery that Dr. Khaimi said he developed.

Reimbursement

Reimbursement for glaucoma procedures was reduced this year by the Centers for Medicare and Medicaid Services (CMS), and additional cuts go into effect in 2017. In 2016, Medicare cut trabeculectomy reimbursement by 25%. In 2017:

- Trabeculectomy will go down another
  - 25% when performed in the absence of previous surgery (CPT 66170).
  - 30% if the patient had a previous surgery (CPT 66172).
- Trabeculoplasty by laser (e.g., SLT) will be cut 35% (CPT 65855).
- Cyclophotocoagulation (CPT 66710) does not appear to be facing a cut.

AB-INTERNO CANALOPLASTY (ABIC)

Dr. Khaimi said ABiC "is the procedure that will make a wave in ophthalmology, no question. It is getting a tremendous amount of attention and looks very promising. It is probably as minimally invasive a glaucoma surgery as you can get."

He said ABiC will be positioned before cyclophotocoagulation and could give SLT "a run for its money." He said the only speed bump is convincing patients they need surgery – any glaucoma surgery – "but when you can tell patients that you've got a glaucoma surgery for them that is probably less invasive than cataract surgery, that is very impactful."

ABiC is performed in a temporal approach through a 1.8-mm temporal clear corneal incision, using an illuminated microcatheter (**Ellex's iTrack 250A**) to access, catheterize, and viscodilate sites limiting aqueous outflow, whether it is the trabecular meshwork, Schlemm's canal, or collector channels. It is conjunctiva-sparing and doesn't require placement of a tensioning suture or leaving a device behind.

In Dr. Khaimi's experience, IOP decreases ~30% post-procedure without any medication use. He also claims there have been no significant complications.

CYCLOPHOTOCOAGULATION (CPC)

CPC comes in 3 flavors. All decrease pressure by ablating the ciliary body and decreasing ***inflow*** of ocular fluid, like shutting the water off from the top of the tub:

- Transscleral cyclophotocoagulation (TSCPC).
- Endoscopic cyclophotocoagulation (ECP).
- Micropulse cyclophotocoagulation (MP3-CPC).

Dr. Samuelson said ECP is one of the more commonly performed glaucoma procedures. Micropulse CPC may prove to be popular as well. However, he doesn't foresee its use as a primary therapy. He said he would typically try at least a prostaglandin and a fixed combination before resorting to cyclophotocoagulation. If the patient needs cataract surgery, it can be combined with CPC, but he prefers outflow procedures. For the patient with no cataract or who is already pseudophakic, he prefers a traditional procedure like trabeculectomy or a drainage procedure next.

Dr. Iwach said, "Historically, we tried not to injure the ciliary body. That was historically the last thing to go to…We were one of the first to report an anterior approach to ECP, which is more appealing to anterior segment surgeons. There are reasonable data that you can utilize that at the time of cataract surgery…If you are already opening the eye, the additional incremental risk is reasonable…So, we are doing CPC more frequently because of advances in technology and maximizing the technology to address both glaucoma and cataracts."

Dr. Maharaj said, "More surgeons, including myself, are offering CPC as an alternative to primary surgery. The settings for CPC in this setting is lighter than for blind eyes…I use it in discussions with patients with surgically-untreated glaucoma who, for one reason or another, don't want to undergo invasive, incisional surgery…For example, I had a patient with vision of 20/30 who is an extreme skier and, if he underwent filtration surgery, would have restrictions for several months and precautions for the rest of his life…So, we discussed 180-degree CPC [TSCPC], which would reduce the risk of hypotony and chronic inflammation…He is now doing well… CPC is being more frequently offered as a primary treatment, but you have to warn patients of the risk of hypotony, chronic iritis, and very rare risk of inflammation of the other eye."

Endoscopic Cyclophotocoagulation (ECP)

A diode laser (e.g., **Endo Optiks**) is used, typically for 180 degrees, with the procedure usually done in the operating room (OR). It is either done in patients who already had cataract surgery or, more commonly, in conjunction with phacoemulsification for cataract surgery.

Dr. Moster said, "Multiple studies have shown that, compared to cataract surgery alone, ECP lowers pressure a bit more… You can see an additional 2-3 mmHg drop with ECP than with cataract surgery alone. It can also be used in more severe cases where not only the tips of the ciliary body are targeted, but also the pars plana, which means seriously limiting blood supply to the ciliary processes. This is done through a pars plana approach in vitrectomized eyes. TSCPC, via an external approach, delivers energy, often with a hard knockout of the ciliary processes and the vascular supply, so the pressure comes down dramatically. Typically TSCPC is done in very advanced disease – e.g., patients with multiple failed trabeculectomies or multiple tubes [shunts]. And these are generally pseudophakic patients where the cataract was removed a long time before."

A study of 707 patients in which ECP was combined with cataract surgery found the dual procedure did not cause additional complications and was effective in reducing IOP and sometimes eliminated or reduced the use of glaucoma medications.

Dr. Khaimi said, "A decade ago we used to do cataract surgery plus ECP to bring down pressure. Most of us now use this for recalcitrant patients. It is no longer the go-to with phacoemulsification." He estimated that he does ECP a couple of times a week. He more commonly performs ABiC with cataract surgery.

Dr. Samuelson said, "Across the country, whenever ECP is used, most often it is at the time of cataract surgery, but I don't do that very often…I tend to use MIGS [minimally-invasive glaucoma surgery], like an iStent."

Dr. Maharaj said ECP at time of cataract surgery is "increasing quite markedly," noting that it is often done with cataract surgery with an iStent, referred to as an ICE procedure (iStent cataract extraction and ECP).

Transscleral Cyclophotocoagulation (TSCPC)

A laser probe (e.g., **Iridex's OcuLight SL Infrared 810 nm laser**) is put near the limbus and rotated 360 degrees. It is painful, so it is usually done in the OR, but it can be done in the office with a peribulbar block. The laser uses a continuous wave aimed at the ciliary body. It is usually left for the most advanced cases and is often viewed as an end-of-the-line procedure in patients in whom everything else has been tried. Dr. Moster said, "You can always beat an eye into submission. Transscleral cyclophotocoagulation uses a G-probe with a diode laser and is often reserved as an end-stage procedure…Cyclophotocoagulation works by decreasing inflow, analogous to turning the water off at the faucet. In contrast, filtering surgeries increase the outflow of aqueous fluid through the trabecular meshwork drain."

Dr. Khaimi said, "This is reserved for recalcitrant cases, where a couple of [surgical] procedures have not worked, and the patient is no longer suitable for glaucoma surgery…due to conjunctival scarring, the tissue not able to support more devices, etc." He said that even though TSCPC is done on the surface of the eye and he doesn't actually enter the eye as with ECP, he

still does it in the OR "where I can give patients sedation because it can be painful."

He said he has been doing TSCPC quite a bit more often than in the past, and currently does ~5-10 procedures a week, and he expects that to increase, "TSCPC has a bigger role in my practice [than ECP]…There was bad hype that it was too aggressive a laser, with too much inflammation, that patients could lose vision, and that it was last ditch. But that is simply not the case. I definitely have seen the utility of TSCPC, and I think it is vital…I go to it more often than I was originally trained to do. It is definitely one of those procedures that has saved me multiple times. I never want it to go away."

Dr. Samuelson said TSCPC is "usually reserved for end-of-the-line patients who failed conventional surgery." Dr. Maharaj also saves it for patients who have refractory glaucoma, particularly those who failed filtration surgery or a trabeculectomy, "Many times it is reserved as well for patients with poor visual potential – counting fingers, even no light perception…CPC has been used in patients who are blind but have high pressure that causes a breakdown of the cornea."

Dr. Maharaj does TSCPC with the continuous wave G-Probe diode laser, "My typical treatment for a good visual potential eye is ~15 shots at 180 degrees, avoiding the 9 and 3 positions, typically 1200-1500 mW with a duration of ~4 seconds."

While he said TSCPC can be done in the office, he chooses to do it in the OR, "It is a fairly painful procedure, and we typically give a retrobulbar block and use anesthesia support to provide the patient with brief but heavy sedation. I have done several TSCPCs in the office, including one I did pro bono for a patient who couldn't afford the procedure, but I did it without anesthesia…TSCPC is the only procedure where I prescribe a few days of Percocet [Endo, oxycodone + acetaminophen], expecting significant pain that lasts for several days."

Dave Harmon, founder and president of Market Scope and a laser industry consultant, said, "You can do transscleral procedures with another laser, but it doesn't have a probe…You have to use a goniolens [gonioscope]…It is messy and not very good, and no one does it very often."

MicroPulse (MP3) CPC

This is the newest form of cyclophotocoagulation. Currently, it is only available with **Iridex's Cyclo G6** laser system, which uses an 810 nm laser to deliver a series of short, repetitive bursts instead of a single continuous wave.

Dr. Moster said, "This is a much kinder, gentler photocoagulation that allows for pressure reduction without a slash and burn of the ciliary body. This is really a newer procedure that has given us the ability to treat less severe eyes. It delivers energy from an outside approach…similar to TSCPC. You don't have to enter the eye, and it is non-invasive in that regard. It revolutionizes cyclophotocoagulation because 31.3% of the time the laser is on, and 68.7% of the time it is off. So, you avoid focal heating and burning of the tissue. The idea is to slide the probe 180 degrees slowly over time to totally cover the total ciliary body 360 degrees. Therefore, there is no focal destruction of tissue, which makes for a more gentle and safer procedure."

Dr. Samuelson said, "It seems to be a definite advance…Most [glaucoma experts] are optimistic that it will be an improvement."

Wills Eye Hospital was one of the first centers to get this laser. Dr. Moster said that the first 19 patients for whom they used it had a baseline IOP close to 40 mmHg and multiple prior incisional surgeries. With 2 months of follow-up after MP3-CPC, average IOP dropped 40%, from 37.9 mmHg to 22.7 mmHg. Of those 19 patients, 15% needed a second procedure. The overall success rate was 68% for the initial treatment and 84% when those who needed a second treatment were included.

Dr. Samuelson also called it a "somewhat kinder, gentler" cyclophotocoagulation, saying that it can be used earlier. But he noted that experts are still figuring out how best to use it, "It is new enough that we are still sorting out where it fits in. Where I use it most commonly is for patients who had traditional surgery, such as trabeculectomy or an implant, and the pressure is not low enough…Before using a second drainage implant, I would do [TSCPC]…Some do it before trabeculectomy, and that seems to be gaining some traction…but it is a little early to know how effective it is…It will likely compete the most with patients getting ECP."

Dr. Iwach said MP3-CPC is "a new twist in CPC…We had a basic box in our office the last five years, and we were looking at using the same concept for modified laser trabeculoplasty… But, independent of us, someone found if you used a probe more posterior and broader, there was surprising effectiveness in lowering IOP…Initial reports were quite positive, and that prompted us to get it for our surgical center."

At the Glaucoma 360 Glaucoma Symposium in January 2016 in San Francisco, Dr. Iwach presented preliminary data on his experience with MP3-CPC:

- "We found ~20% of patients with standard treatment did not respond to laser…but some patients ***really*** responded,

with ~50% drop in pressure…This is preliminary and early …but it seems to be working, and now we are trying to figure out why…We feel more comfortable using that laser earlier in the treatment algorithm.

- "With this laser, it may be improving outflow. For years retinal specialists, when they did panretinal photocoagulation, sometimes found that the pressure went down…This has not been proven, but my personal speculation is that MP3-CPC is applying energy in the vicinity of the pars plana and kind of doing what the retinal specialists were doing with energy to the inside of the eye…It raises that question because the energy amount is not nearly as much as what is used with traditional CPC."
- Dr. Iwach said Malvina Eydelman, MD, director of the FDA's Division of Ophthalmic, Neurological, and Ear, Nose, and Throat Devices, Centers for Devices and Radiological Health (CDRH), spoke at the meeting about "a shift at FDA in how they look at approving new technology, not only looking at success and complication rates but also at patient input…And that is really important in a disease like this [glaucoma]…MP3-CPC is finding a niche there."

Dr. Khaimi hasn't tried it yet because Iridex's G-Probe for TSCPC "in my hands works fine…The G6 that just came out is new technology and thought to be less inflammatory than traditional TSCPC, but the jury is still out. It is nothing that we would do now…I'm not sure it is easier [than TSCPC], but perhaps it is less inflammatory. That is where the hype is."

Dr. Maharaj also hasn't tried it yet, "There are several reports comparing MLT [micropulse laser trabeculoplasty] vs. a continuous laser…I reviewed a paper recently in the ***Journal of Clinical & Experimental Ophthalmology*** by a group in Singapore, and they compared micropulse CPC with continuous wave CPC and showed a greater successful primary outcome with micropulse. However, the caveat to the paper was that the patients were refractory glaucoma patients and got a fairly heavy treatment of cyclophotocoagulation, so it is not the same application of CPC we would do on a patient with good visual potential…I have no experience with MP3-CPC."

Harmon said the Iridex system solves some of the problems with diode transscleral photocoagulation, "You take the [Iridex] probe and run it along the edge, and the probe is at an angle and fires into the trabecular meshwork, enough so that you don't have a mess…You just pull it along that space."

Dr. Moster said several things are needed before MP3-CPC is used more widely, though she cautioned it still should be reserved for the "real" glaucoma patient.

1. It has been shown to be clinically **effective** – that bar has been met, and prospective studies are currently in progress.
2. It is truly **repeatable** – that bar also has been met. Dr. Moster said it has to be repeated in ≥15% of patients, but that isn't a problem. Dr. Moster said, "Because the MP3-CPC laser is gentle and may have to be repeated, we tell people this right away." Asked how many times she would repeat it, Dr. Moster said, "I've repeated it three times, and in that patient it worked the third time. Glaucoma doctors never give up."
3. It **does not appear to harm** the patient. Patients are pain-free the next day and only require topical steroids for a month. However, there are still no long-term data on these patients, and the sample size is small. Only time and close follow-up will reveal any late complications.

The procedure

MP3-CPC works differently from SLT. SLT increases outflow by increasing the permeability of the trabecular meshwork – 60% of the resistance in the eye is at the level of the trabecular meshwork, and SLT modifies the permeability of the trabecular meshwork, so the IOP comes down.

SLT is often an adjunct to medication. Dr. Moster explained, "It lowers pressure without causing inflammation. MP3-CPC modifies the ciliary body…The laser targets the ciliary processes to decrease the eye's ability to make aqueous fluid, but you don't want to do this too forcefully or the eye might shut down or become inflamed or hypotonous. This technique is an advance because it is gentle…It decreases aqueous production but does so in a calmer way."

Doctors agreed that this is not a first-line procedure. Dr. Moster said, "If I were to do a procedure on a prostaglandin failure, my first and go-to procedure would be one that improves outflow…With MP3-CPC you are changing the ciliary body…This is a surgical procedure that requires a block or IV sedation. If someone just fails one medication, I am not ready to take them to the OR. It is almost ridiculous to put MP3-CPC up in the realm of SLT, in which the patient walks to the next room, has a quick procedure with a topical anesthetic drop, and goes home…I think of SLT almost as an additional medication that lowers pressure ~20%. The negative aspects of it are almost nil. CPC is the real deal."

They also agreed CPC is not an alternative to SLT. Dr. Iwach said, "Most of us would go to SLT first because it is kinder and gentler." Dr. Moster said, "[CPC] is not done in a user-friendly setting or a patient-friendly way. It requires anesthesia or a block. It hurts. And it is reserved at present for real glaucoma, not 'glaucoma light.' Now that we are seeing it is safer and safer, we are using it earlier in the algorithm, but still these patients are likely to have had at least one prior incisional

surgery. This modality is yet another option to offer people for the real-deal glaucoma." Harmon added, "Iridex claims it is more effective than SLT, but the verdict on that is still out." Dr. Samuelson agreed, "This won't replace SLT anytime soon."

Experts are still experimenting with how best to do MP3-CPC.

- *Dr. Moster:* "We are investigating different timing of the application. Right now, 90 seconds above and below are recommended, and we are looking into delivering the energy for 3 minutes above and below, for 6 minutes total."
- *Dr. Iwach:* "At the University of California, San Francisco, they are also using this laser. The original protocol was 80 seconds for each pulse times two. They found that if they did 4 times 80 seconds, the results were much, much better …We are at the point of titrating it…The initial amount [2 times 80] was not enough, and we upped the ante and did more, 2 times 80 seconds to start, and then another 2 times 80. Some centers are doing 4 times 80 to start. I split the difference, and if 2 is not enough and 4 may be too much, I do 3 times 80 and sometimes 4 times 80. We are in the early empiric phase."

How do users know they are delivering the "right" amount of energy? Dr. Moster said there is no "right" amount of energy. There is only one energy and that is dictated 2000 mJ, which is standard. We are not altering the amount of energy but the amount of time delivered.

The risks with MP3-CPC

What are the risks? Inflammation, hypotony, and perhaps cataracts, but not dry eye. Most experts said risks with MP3-CPC are rare, though follow-up is limited.

- **Hypotony.** Dr. Moster said Wills Eye Hospital had one patient who developed hypotony but recovered over two months. Stanley Braverman, MD, from the Braverman Eye Center in Hallandale Beach FL, said even one case of hypotony in 250 is too much.
- **Inflammation.**
- **Cataracts.** Dr. Moster said, "We don't know whether it will produce a cataract in a phakic eye. Is it possible? We don't know, but trabeculectomy can do that as well." Dr. Braverman also is worried about potential cataracts with MP3-CPC. Dr. Samuelson said, "I'm not sure that has been studied widely, but we tend to use it even if the eye is phakic."

  However, Dr. Iwach said he presented at Glaucoma 360 that MP3-CPC "can have significant complications. We had a case from an outlying office where we are still trying to understand why MP3-CPC treatment ended up inducing significant inflammation and a cataract, and cataract surgery had to be performed relatively soon after. This is the only such case I am aware of."

What is the biggest drawback to this procedure? Probably lack of long-term data.

- *Dr. Moster* said she hasn't found any drawbacks yet, but if it could be done with topical instead of IV anesthesia, it would be a paradigm shift.
- *Dr. Samuelson:* "We generally like to enhance outflow instead of causing tissue destruction and reducing inflow…but, reportedly, this is gentler and doesn't cause as much collateral injury. It is a little new and not proven with a long-term trial, but the initial results are good."
- *Harmon:* "I'm not sure there is one [drawback]. It's kind of like SLT; it either works or not. It doesn't work in every patient."
- *Dr. Iwach:* "We don't know yet how long it lasts…Ultimately you want data for 2-5 years…but because of the [good] risk profile, even if you had to repeat it every few years, [that might not be a problem]…The early results are encouraging, but we need more data."

Where to do it

Where can/should MP3-CPC be done? Though the procedure can, technically, be done in a physician's office, none of the glaucoma specialists questioned do it in their office; all do it only in an OR. Why? Because it is painful.

The anesthesia needed for MP3-CPC is more than for cataract surgery and is a barrier to earlier use. It is possible to do the anesthesia with a retrobulbar block in the office, but none of the experts questioned would do it there or recommend doing it there. To do it in a doctor's office would require a dedicated room for the procedure. Rather, they predicted it will stay in the operating room of a hospital or ambulatory surgery center [ASC]. By comparison, EPC combined with cataract surgery doesn't require additional anesthesia.

Comments included:

- *Dr. Moster:* "I choose to do it in the OR because it hurts. Currently, we do not block. Instead, the anesthesiologist gives a short dose of IV sedation while we are doing the diode laser. The whole procedure takes <6 minutes. So, we are able to avoid a block. Postoperatively, there is no pain, and inflammation is very minimal. Although it is possible to do this in the office, I don't personally want to take the risk of giving an injection behind the eye without any monitoring. Since this is a covered procedure in the OR, having

the laser there and the probes paid for, it totally makes sense to me."

- *Dr. Samuelson:* "I do it at an ASC. It requires either a retrobulbar block or IV sedation. It hurts if you don't have adequate anesthesia…If you feel comfortable doing blocks in the office, you could do it there, but the probe costs money, so typically you need to do it in a facility to be reimbursed for the probe."
- *Dr. Iwach:* "It hurts when you do it…So, you can try to do it in the office, but it doesn't feel good…You could do a block and do it in the office, but it is a magnitude more involved than SLT…Some colleagues tried to do it in the office with blocks, and most found that it was not worth it and decided to just go to the OR."

The candidates

Which patients are the right candidates for MP3-CPC?

- Patients for whom glaucoma specialists would rather not open the eye and do an invasive procedure.
- Patients who have tried multiple medications unsuccessfully.
- Patients who have had multiple surgeries, and their IOP is still not at goal.
- Cataract patients with glaucoma.
- Patients unable to undergo incisional surgery because of the anesthesia risk.
- People with difficulty coming back and forth for removal of sutures (who live far away from the ophthalmologist's office).

Comments included:

- *Dr. Moster:* "This may be, in the future, a go-to procedure for a patient who is getting worse, but right now it still has to be determined who the best target patients are."
- *Dr. Samuelson:* "For a patient who has a cataract that is ready to be operated on, I would do cataract surgery plus an iStent or another canal procedure, but for patients who already had that and failed or who were not indicated for trabeculectomy, I might use MP3-CPC…Or, if the patient had a trabeculectomy and a drainage device and that was not enough, MP3-CPC is a terrific adjunct to that. I don't use it as a primary procedure very often…Usually, only when the more traditional measures fail. We've only had our [Cyclo G6] for four months…As we get more experience with it, we may expand the indications."
- *Dr. Iwach:* "We still reserve this for down the road or maybe during cataract surgery, but this new laser at the moment appears to be finding a home potentially before filtering surgery. Most patients with G6 are happy. They don't seem to have significant symptoms…All of our interventions can take patients without significant symptoms and give them symptoms. If you can find ways to protect the optic nerve adequately and minimize the impact on quality of life in the short term, that is of great interest."

The outlook for MP3-CPC

What percent of glaucoma patients on a prostaglandin will ultimately get to this? Dr. Moster said only 20% of patients require incisional surgery, "I don't know the percent that will need this vs. a more traditional procedure, but maybe a significant percent if we prove that it is not only effective but safe." Dr. Iwach said, "If the early results hold…any day I don't have to do filtering surgery is a good day…If it can delay or avoid the need for those procedures that can so negatively impact quality of life, it is a good day…It appears MP3-CPC ***might*** help us achieve that goal…but it is not without risk, and it doesn't always work."

How often do these experts currently do CPC or MP3-CPC? Dr. Moster said she does ~3 per week, "The longer follow-up I have, the more comfortable I am in doing this." Dr. Iwach said all three of the active glaucoma surgeons in his group are doing MP3-CPC for a total of 5-10 procedures per week, "Over the next year, based on what we know, I think it will increase. We will get more comfortable with it, understand more about the power and exposure time."

Is this laser something all ASCs or hospitals will be getting? Probably, over time, with teaching eye hospitals first.

Will use expand to the average glaucoma doctor? Two ophthalmologists with large, multi-specialty eye clinics aren't doing it yet, and neither is planning to start. Dr. Moster said she thinks it will catch on but warned that may not happen quickly, "There isn't a concern it may move to the average glaucoma doctor too quickly due to the need for anesthesia, explanation, and informed consent…There are risks, and it is not casual. It won't be like an SLT laser that can be done in the office with one drop of topical anesthesia and the patient goes home. Although this is less intense surgery, it nevertheless requires anesthesia."

Dr. Maharaj said, "It is catching on and is becoming more prevalent…I think patients are trying to avoid conjunctival dissecting surgery…and it is a conjunctival-sparing procedure …MP3-CPC may eventually replace diode laser…but I haven't seen a convincing paper that one is better than the other (TSCPC vs. MP3-CPC)."

What will MP3-CPC replace? It may replace or defer the use of large drainage devices, particularly the Baerveldt tube shunt or

the Ahmed valve in patients with a failed trabeculectomy. Dr. Moster said, "In the future, one could consider doing this instead of a trabeculectomy or instead of a more invasive procedure which has more risk…But the data have not yet substantiated this. The jury is still out."

Is reimbursement likely to make this an appealing procedure for glaucoma specialists? Maybe, but while MP3-CPC is seen as affordable technology, it is not viewed as a big money maker. Dr. Iwach said, "When we looked at the numbers, it was affordable [for our ASC]…When we purchased it, our ASC committee felt it was financially viable." Dr. Khaimi said, "I think the reimbursement cuts will promote the community to look at other procedures. It will promote the notion that perhaps we should treat patients earlier on in a more aggressive fashion…We don't think of surgery as aggressive anymore…It will push us to think of treating patients earlier on more aggressively to control the disease earlier, so it may postpone trabeculectomy."

From a business standpoint, Harmon said this is a make or possible break situation for Iridex, "It is a real opportunity for Iridex. What is cool from a business perspective is the probe sells for a couple hundred dollars. In the past, they sold a laser and were done, but with this there is a great revenue stream."

The final word from Dr. Moster: "The caution now is that this is not yet for every glaucoma patient, and longer follow-up is needed before it replaces more standard procedures. Given the steep reimbursement cuts for trabeculectomy, we will see whether this will move up on our surgical list. It will all depend on proving that MP3-CPC is safe, effective, and doesn't cause cataracts."