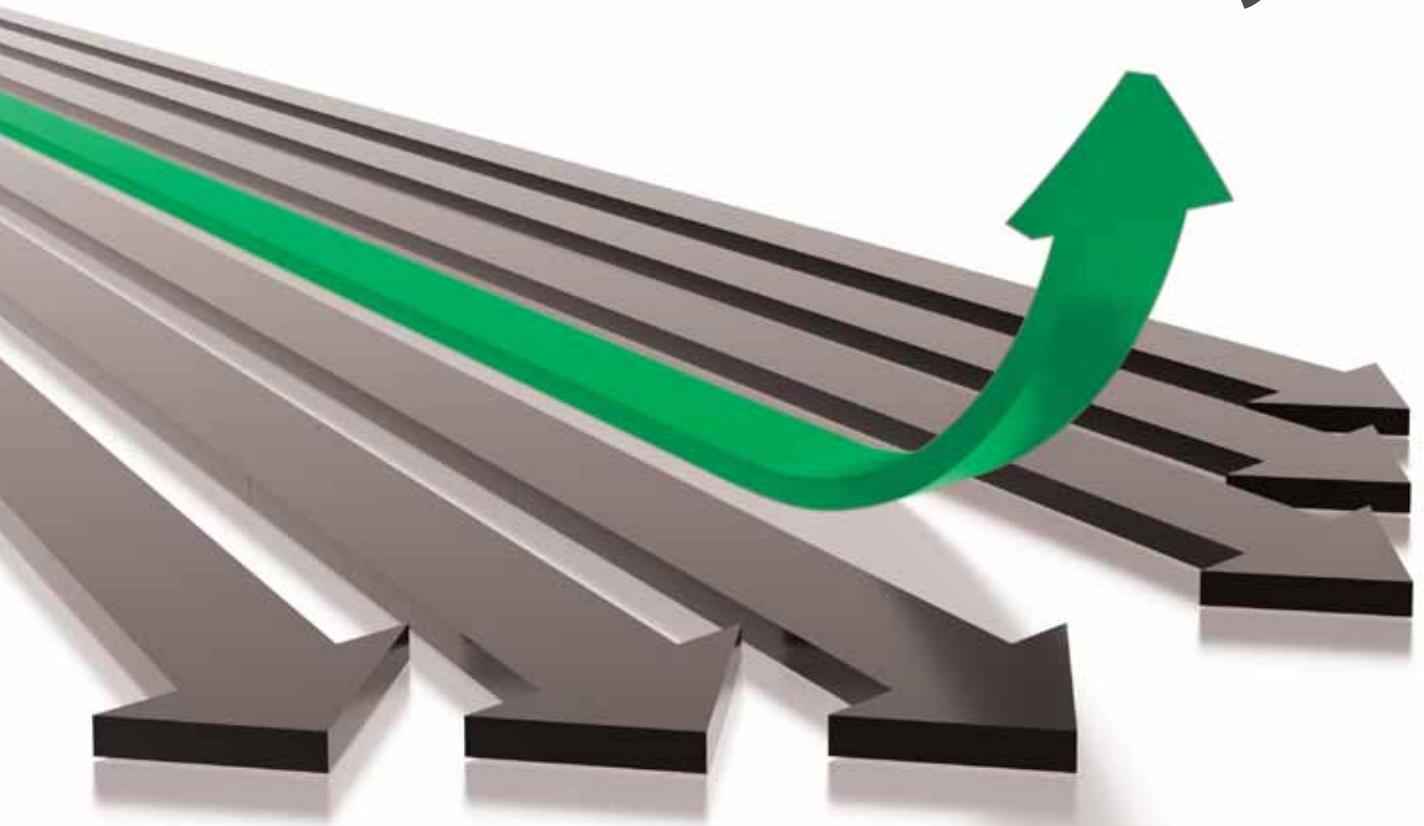


Canaloplasty: Redefining Glaucoma Management for the 21st Century



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Canaloplasty: Redefining Glaucoma Management for the 21st Century

The introduction of canaloplasty into the glaucoma surgical armamentarium was motivated by the desire of clinicians to enhance the quality of patients' glaucoma care. Patients' long-term adherence to topical glaucoma medical therapy is well known to be relatively poor. Laser therapy provides a reduction in IOP that is often short-lived. Traditionally, glaucoma filtration surgery has been reserved for more advanced, uncontrolled glaucoma for obvious reasons. Despite the definite role of standard trabeculectomy in glaucoma care, patients undergoing the procedure are at significant risk for the development of postoperative infection, cataract, hypotony, bleb dysesthesia, astigmatism, and decreased visual acuity. These potential complications have driven surgeons to pursue surgical alternatives.

Canaloplasty is a well-established procedure that has, for the past 3 years, demonstrated impressive efficacy and safety in peer-reviewed prospective studies. Despite growing evidence of its value and increasing performance of the procedure by ophthalmologists all over the world, misconceptions regarding its long-term efficacy as well as challenges in its adoption, surgical technique, and patient selection persist. Several leading surgeons share their experiences and pearls for optimizing success with canaloplasty.

— Steven D. Vold, MD

PANEL

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Please briefly describe your early experience with and approach to adopting canaloplasty.

Dr. Richardson: I was comfortable with the basic elements of the procedure after performing about a 1/2 dozen cases. As with any surgery, however, there are skills that cannot be mastered until the steps become nearly habitual. Essential to the development of any habit or skill is repetition within a short time frame. A key reason I became comfortable with canaloplasty early on is I grouped my first dozen cases over just a few months so I did not have to “relearn” the procedure with each scheduled canaloplasty. Also worth mentioning is the clinical education offered by iScience is unprecedented in terms of the wet lab preparation, in-surgery and in-person support, and the postoperative telephone support. Support from iScience gets you past the initially steep learning curve. After that, it is easy to discuss cases with multiple canaloplasty surgeons around the United States who are all eager to share their experiences. Once you master canaloplasty, you tend to get excited about sharing this procedure, so the support from more experienced surgeons is always readily available.

Dr. Morgan: In order to successfully adopt canaloplasty, I studied the principles of deep sclerectomy very intensely by watching videos and strictly adhering to the following guidelines:

- Find the correct depth at the apex of the deep dissection by cutting right down to the ciliary body. You can do this safely by slowly working your way down with the super-sharp blade until the ciliary body is encountered.
- Once the correct depth has been found, back up a few fibers and advance. This is the correct plane to access Schlemm canal.
- Stay in the same plane, especially when you approach the scleral spur. Avoid the temptation to hasten the process by deepening the plane when you get close to the spur.

Dr. Barnebey: Like with most new procedures, my learning curve did not occur overnight or in a single step. I learned the fundamentals of performing a good trabeculectomy during my fellowship. In the early 1990s, a variation on the trabeculectomy was introduced as a deep sclerectomy and later as a viscocanalostomy. I honed my skills doing these procedures and had respectable results. The introduction of canaloplasty was another building block. Surgically, the introduction of a catheter with 360° viscodilation and placement of a retaining stent was a dramatic step in the advancement of the surgery. The addition of the micro-catheter and stent was an incremental additional step with a relatively brief learning curve.

Dr. Sarkisian: I personally started the canaloplasty adoption process rather slowly. After 10 to 15 cases, I began developing confidence in the procedure. I had been per-

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—Howard Barnebey, MD

forming trabeculectomies on children for some time, so I was already familiar with the canalicular anatomy. However, with the exception of the deep sclerectomy, most of the steps in performing canaloplasty are familiar to any surgeon who has done a trabeculectomy.

Some surgeons have suggested that the learning curve for canaloplasty can be challenging. Would you agree or disagree with this statement?

Dr. Richardson: The steps involved in canaloplasty are new for most surgeons, so of course, there is going to be a learning curve. Does that learning curve compare to the initial curve required to become competent at phacoemulsification? It is not even close. Like phacoemulsification, canaloplasty requires finesse and an understanding of the local anatomy, but there are fewer steps involved (as well as fewer points during which you can get yourself into trouble). Any cataract surgeon who no longer gets nervous making a capsulorhexis or who regularly polishes the capsule can master canaloplasty. Handling Descemet membrane is not so different from dealing with the capsule. That said, I would not recommend canaloplasty to an inexperienced surgeon who is not yet comfortable touching the bare capsule with an instrument.

Dr. Morgan: It is important for the prospective surgeon to realize that the barriers to adoption are largely mental. Most accomplished phaco surgeons already possess the skills necessary to perform the procedure. The techniques are not more difficult than complex, small-pupil phacoemulsification, but because the required surgical maneuvers are new to the surgeon, they are intimidating. This can make surgeons afraid to try the procedure. If they begin with the right patient population, the stress can be greatly minimized.

Dr. Barnebey: Any procedure can be challenging, but the learning curve for a surgeon who understands the anterior segment of the eye is easier than the learning curve for phacoemulsification.

Dr. Sarkisian: The learning curve is challenging but not insurmountable. Trabeculectomy provides the basic skill set

for performing canaloplasty. The main new things are isolating Schlemm canal and fashioning the trabeculo-Desemet window.

Dr. Vold: From my perspective, the challenges associated with canaloplasty are overstated. Experienced surgeons should have little difficulty adopting this procedure. The keys to successfully adopting canaloplasty are being knowledgeable of the angle anatomy and having the ability to fashion quality scleral dissections. Threading the iTrack microcatheter (iScience Interventional, Menlo Park, CA) is relatively easy once Schlemm canal has been isolated. Without question, quality anterior segment surgeons should have little difficulty successfully performing canaloplasty.

What advice would you give to your colleagues to make the learning process easier?

Dr. Richardson: Familiarize yourself with the steps involved in canaloplasty. Read the materials provided by iScience. Do a search on YouTube and watch some of the videos. Then, memorize the steps and mentally perform the surgery before your first case. Many experienced surgeons forget that they must prepare and practice mentally if they are going to succeed physically. Surgeons are no different (or better) than athletes in this manner. Show me a golf professional who has not at least “walked” the course prior to the tournament, and I will show you someone who has no chance of winning the purse.

Dr. Morgan: The key to reducing the initial stress is in choosing the right patients for your early cases. I strongly recommend choosing patients who are undergoing a cataract procedure at the same time and do not desperately need an extremely low IOP. The typical cataract and glaucoma patient on two or more medications is the ideal patient to start on. If the procedure is not successful, the patient will still be happy with the results of the cataract surgery. On the other hand, a successful canaloplasty procedure will further reduce IOP and dependence on medications.

Dr. Barnebey: Deliberate, focused study and practice are necessary. Break the procedure into manageable steps and focus on understanding and mastering each of those steps based on your individual skill set and experience. It is also important to latch onto a mentor who can help guide you through the process.

Dr. Sarkisian: You have to jump in with both feet. Get past the learning curve in the first 2 months. It generally takes 10 to 15 cases. The more canaloplasty cases you perform, the better you get. Just like when learning phacoemulsification for the first time, you soon get more confident and are encouraged by your improved results to press

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—Steven R. Sarkisian Jr, MD

on and perform more cases. You then begin to get more aggressive in finding patients who are good candidates earlier in their treatment algorithm.

Before you started offering canaloplasty to your patients, what was your greatest concern about performing this procedure?

Dr. Richardson: I had two main concerns. First, would I be able to do it? Dissecting the trabeculo-Desemet window sounds nearly impossible to someone who has never done such a thing. Funny, that is probably what I would have thought about polishing the posterior capsule years ago (something I routinely do now). Second, will I harm my patient? I quickly learned that canaloplasty is a very forgiving surgery. It is as near to a “no harm, no foul” glaucoma surgery as I have ever experienced. Is it totally without risk? Of course not, but compared to the bleb-dependent glaucoma surgeries, it is in a league of its own.

Dr. Morgan: I had to come to terms with the fact that I might not succeed. Ophthalmologists are generally very accomplished individuals. They are not comfortable with the prospect of failure. Once I accepted that I might not succeed, I was ready to move forward. It is helpful to have a comfortable backup plan in your mind.

Dr. Sarkisian: My early concern was making a good trabeculo-Desemet window, but the new canaloplasty instrumentation by Mastel Precision, Inc. (Rapid City, SD), makes performing this part of the procedure much easier for surgeons who are new to canaloplasty.

How has canaloplasty influenced your treatment paradigm for glaucoma patients?

Dr. Richardson: I now move directly from maximum tolerated medical therapy to canaloplasty without bothering with laser trabeculoplasty.

Dr. Morgan: Canaloplasty has totally changed how I treat glaucoma patients. I now have a safe and effective glaucoma procedure that I can perform early in the disease process. We know from evidence-based glaucoma studies, such as the Early Manifest Glaucoma Treatment Trial, that earlier intervention is better.¹ The problem we have had in the past is that we did not have a truly safe glaucoma procedure. For this reason, we hesitated to treat patients whom we knew would be better off with a lower IOP. In the past, I intervened surgically only when absolutely necessary. Now, I can confidently treat patients much sooner, and this allows me to provide much better glaucoma care.

Dr. Barnebey: It is always wonderful to have choices, since there is no single procedure that is appropriate for all glaucoma patients. Canaloplasty provides a minimally invasive strategy by which to re-establish aqueous outflow with minimal-to-no violation of the anterior chamber; good, sustained IOP-lowering efficacy; a safer complication profile; and the prospect of avoiding the long-term challenges of a conjunctival bleb.^{2,3}

Dr. Sarkisian: Canaloplasty is now my procedure of choice for baby boomers, monocular glaucoma patients, and patients with split-fixation visual fields at risk for “wipe out” syndrome. It is my experience that young African Americans also respond extremely well to canaloplasty, because one does not have to be concerned with aggressive scarring in this patient population, due to the fact that there is no bleb to maintain. Moreover, I am performing much less cataract surgery combined with endocyclophotocoagulation due to the superb results I am achieving with phacocanaloplasty.

Dr. Vold: Canaloplasty has definitely made me more comfortable intervening surgically in my glaucoma patients. This procedure is an excellent surgical option for patients with uncontrolled mild-to-moderate open-angle glaucoma (OAG). Canaloplasty should also be strongly considered in patients with more advanced OAG who are poor candidates for filtration surgery. Phacocanaloplasty is an outstanding option for patients with medically treated glaucoma and visually significant cataracts.

What type of glaucoma patients benefit the most from canaloplasty?

Dr. Richardson: OAG patients with mild-to-moderate glaucoma that is progressing on topical treatment or who are having difficulty tolerating medical treatment benefit the most from canaloplasty. It is worth mentioning that, when we use the acronym “MTMT,” we should be honest and admit that what this should stand for is minimally tolerated medical therapy. It may actually mean maximum tolerated medical therapy, but I have yet to see a patient on

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—Michael Morgan, MD

two to three different drops who is really “tolerating” the treatment well. With ocular surface issues, systemic side effects, and the cost of treatment, most patients on more than one or two separate drops really need a better alternative therapy.

Dr. Morgan: Canaloplasty has been most effective for me in patients who present with moderately elevated IOPs of around 35 mm Hg without medication. Also, it appears that patients who respond to medications initially, but not enough to eliminate their risk of vision loss, are the best candidates. These patients, I reason, have some trabecular outflow. Patients with very high presenting IOPs and those who did not show a significant response to medications do not seem to do as well in my experience.

Dr. Barnebey: The following three groups of patients may benefit from canaloplasty over traditional trabeculectomy: (1) patients in whom trabeculectomy is expected to fail, (2) patients who have a potential threat of additional irreversible loss of vision, and (3) patients whose jobs and/or lifestyle makes them unable to tolerate the postoperative period of incapacity that often occurs after trabeculectomy.

Given its better safety profile over current incisional glaucoma procedures,² do you perform canaloplasty on glaucoma patients earlier in the disease process?

Dr. Richardson: Absolutely! I now offer canaloplasty to all of my patients scheduled for cataract surgery who have issues with glaucoma medications. Similarly to how I at least discuss the option of advanced IOLs with all of my cataract patients (who are candidates for such IOLs), I now feel that all of my combined cataract and glaucoma patients deserve to be informed about the option of canaloplasty at the time of cataract surgery. I am also now comfortable offering canaloplasty to patients who may only be on one or two topical medications but are poorly tolerating medical therapy. The procedure is also a good choice for patients who have issues with medication and follow-up compliance.

Dr. Morgan: As I become more comfortable with the procedure, I offer it earlier in the disease process. That is not to say I offer it casually. It still is an operation, and it demands careful consideration. However, I am very comfortable offering it to patients to whom I was reluctant to offer traditional glaucoma surgery in the past. Canaloplasty really shines in cataract and glaucoma patients who wish to reduce their dependence on medications.

Dr. Barnebey: I have evolved to a position where a canaloplasty is my initial procedure of choice unless there are circumstances that dictate otherwise.

Dr. Sarkisian: Canaloplasty allows me to provide surgery to patients who previously would have received only topical medication or laser trabeculoplasty. I feel that canaloplasty represents a significant advance in glaucoma surgery by allowing me to treat the earlier phases of glaucoma more aggressively and more definitively.

Dr. Vold: Without question, the impressive safety profile of canaloplasty makes me more comfortable proceeding with glaucoma surgery in my glaucoma patients. Now that I have nearly 4 years of canaloplasty follow-up on some of my patients, I am convinced that the procedure's efficacy persists over time in most patients.

How do you differentiate which patients are candidates for canaloplasty from those who might be better served by standard filtration or tube shunt surgery?

Dr. Richardson: Younger patients, high myopes, and African American patients tend to be better candidates for canaloplasty (as opposed to trabeculectomy).

Dr. Sarkisian: Due to the 3-year canaloplasty data² and my own experience, I am comfortable offering canaloplasty to most of my patients with early OAG who require surgical intervention. In patients with more advanced glaucoma (except monocular patients or those with split fixation as mentioned earlier) or those with narrow-angle glaucoma, neovascular glaucoma, iridocorneal endothelial syndrome, uveitic glaucoma, or other refractory glaucomas, I generally perform filtration surgery using the Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc., Fort Worth, TX). In patients with scarred conjunctiva, when a filter would be less successful, I typically place a conventional tube shunt.

Dr. Vold: Canaloplasty results are best in patients with more mild-to-moderate OAG, but canaloplasty can certainly be effective in more advanced glaucomatous disease. Unfortunately, histological studies show that the collector channel system has more scarring in patients who have been treated with long-term topical glaucoma medication

“We now have a relatively safe surgical option that can address the very source of our glaucoma patients’ suffering.”

—David Richardson, MD

or who have end-stage disease.² Standard filtration surgery should be discussed with patients who have severe glaucoma or who require especially low postoperative IOPs.

On rare occasions, surgeons may be unable to catheterize Schlemm canal for 360° due to scarring within the canal. What recommendations do you have for the intraoperative management of these cases?

Dr. Richardson: It has been mentioned that some surgeons are reluctant to perform canaloplasty on patients earlier in the disease process due to the concern that, if they cannot catheterize 360° of the canal, they will have to convert to a trabeculectomy. These surgeons have been misinformed. In my experience, if a patient has early glaucoma and the surgeon cannot achieve 360° of catheterization, there is still the option of a viscocanalostomy that (when combined with the more extensive viscodilation possible with the iTrack microcatheter) can be nearly as effective as canaloplasty. For a patient with early glaucoma, viscocanalostomy is an appropriate primary surgery in countries outside the United States. As such, it makes a fine “fall back” surgery when catheterization cannot be completed. Most of my patients who required a conversion to viscocanalostomy (modified by the more extensive viscodilation possible with the iTrack microcatheter) have done very well and are within a few IOP points of their fellow canaloplasty eye. After more than 100 canaloplasty cases, I have yet to convert a single canaloplasty procedure to a trabeculectomy.

Dr. Barnebey: If a patient needs glaucoma surgery, most surgeons would select a trabeculectomy. If you are planning on performing canaloplasty and a problem develops, always have two or three backup strategies. For example, if I am unable to completely circumnavigate Schlemm canal for 360°, I will perform viscodilation from both directions and convert to a deep sclerectomy procedure or place an intrascleral collagen implant.

Dr. Sarkisian: Most of the time, if I have an occlusion in the canal, I do not convert to a trabeculectomy. I simply use the catheter to viscodilate as much of the canal as I can, and then I close the flap, which is an excellent alternative for dealing with an occlusion. Performing a trabeculotomy may be another option if I can cannulate enough of the canal to do a cut down and then a purse-string trabeculotomy using

ADOPTING CANALOPLASTY: A NEW CANALOPLASTY SURGEON'S PERSPECTIVE

Shannon Smith, MD, a glaucoma subspecialist and cataract surgeon practicing in Nacogdoches, Texas, recently began the process of adding canaloplasty to her surgical armamentarium. After performing trabeculectomy and tube shunt surgery for 2 decades, she became convinced that canaloplasty offers significant advantages over traditional penetrating surgery. Three-year prospective efficacy and safety data from highly respected colleagues finally encouraged her to begin the process of adopting canaloplasty as a surgical option for her patients with glaucoma.¹

Dr. Smith was fully committed to pushing through the canaloplasty learning process in a timely fashion. She open-mindedly identified candi-

dates as having open-angle glaucoma or ocular hypertension with a high risk of progression and without specific contraindications, ie, angle abnormalities, peripheral anterior synechiae, prior surgical interruption of the canal, etc. She performed 25 canaloplasties within 3 months, shortening and enhancing her learning curve by scheduling multiple consecutive procedures on each surgery day.

She acknowledged that, despite the initial intimidation of deep dissection to the traditionally unfamiliar anatomy of Schlemm canal as well as an incidence of very early postoperative hyphema, blurred vision, and short-term hypotony with inadvertent penetration, she has aggressively and repetitively integrated the procedure and

gained the skills and confidence to add canaloplasty to her surgical repertoire.

"I now consider canaloplasty a viable first surgical option for my patients with open-angle glaucoma," said Dr. Smith in an interview with *Glaucoma Today*. "I am enthusiastic about its potential long-term success rate and limited risk, which will benefit my patients' quality of life."

Shannon Smith, MD, acknowledged no financial interest in iScience Interventional. Dr. Smith may be reached at info@eyesoftexas.us.



1. Lewis R, Von Wolff K, Tetz M, et al. Three-year results of circumferential viscodilatation and tensioning of Schlemm canal using a microcatheter to treat open-angle glaucoma. *J Cataract Refract Surg*. 2011;37(4):682-690.

the catheter. Finally, I may convert to a trabeculectomy if needed.

Dr. Vold: In cases of advanced glaucoma, I tend to convert to trabeculectomy. For more mild glaucomatous disease, viscocanalostomy is certainly a viable surgical alternative. Fortunately, the need to make this type of decision is rare. I encourage surgeons to think through their plan of attack prior to initiating surgery.

Canaloplasty surgeons are generally excited to talk about bleb-free surgery with their patients. Do you include this discussion in your consultations?

Dr. Richardson: Absolutely! This is the defining benefit of canaloplasty. Yes, it is nice that the IOP reduction is on par with trabeculectomy and tubes, but if canaloplasty required a bleb, it would still be a "me too" surgery offering little in terms of what patients are looking for, which is to make their lives easier while protecting their vision.⁴ Patients hate their drops, and most of my patients hate their blebs after trabeculectomy. Blebs are irritating and limiting (in terms of the activities of daily living). Additionally, the reason canaloplasty can be offered earlier in the course of glaucoma is that it has far fewer risks than either trabeculectomy or tube shunt surgery.²

Dr. Barnebey: I do discuss canaloplasty, but I am cautious not to guarantee the absence of a bleb, because one can occur in a small group of patients.²

Dr. Sarkisian: The prevention of bleb formation is clearly a significant advantage of this procedure. As surgeons, we have a responsibility to inform our patients of the clinical implications of long-term blebs.

Dr. Vold: Most patients have no idea how much blebs can affect the quality of their lives postoperatively. I think it is important for us to educate our patients in this regard. I highlight the benefits of canaloplasty such as a faster postoperative recovery of vision, reduced perioperative complications, and fewer postoperative visits when compared with trabeculectomy.² Patients who have undergone canaloplasty commonly have a better overall quality of vision than patients with filtration blebs.² This is due to fewer ocular surface disease problems, less induced astigmatism, and the elimination of fluctuating vision due to postoperative hypotony.²

What advice would you give to a new surgeon recruiting patients for his or her first canaloplasty cases?

Dr. Richardson: I think the ideal patient for a new surgeon to perform canaloplasty on is either (1) a patient with mild-to-moderate glaucoma that is progressing who has side effects from topical medical therapy (such as symptomatic ocular surface disease) or (2) a patient with a cataract and glaucoma on medical therapy who has chosen a standard IOL. In the latter case, since the patient is expecting to

wear glasses (or at least should be if the surgeon has properly managed his or her expectations), there will be time for the eye to properly heal from the combined surgeries before the prescription of new glasses. I would advise against performing phacocanaloplasty on patients with either a multifocal or toric IOL, although this could be done in a staged manner by performing canaloplasty first, followed by cataract surgery with the implantation of an advanced-technology IOL once any induced corneal astigmatism had stabilized.

Dr. Morgan: Focus discussion on the safety of the procedure compared with blebs. Remove the pressure from yourself and offer the procedure to phacoemulsification patients on two or more glaucoma medications. This way, if you do not succeed, the operation will still be a success. Patients burdened by the cost of topical medications or who have medicamentosa are also superb candidates for canaloplasty. These patients will be especially grateful.

Dr. Barnebey: I look at patients who have a deep angle and no previous glaucoma surgery. I also consider those who have significant ocular surface disease or blepharitis where there is an increased risk of bleb-related challenges.

Dr. Sarkisian: Select patients with deep anterior chambers. Younger patients with mild-to-moderate glaucoma and pseudophakes are excellent first cases. Inform patients that you might need to do a trabeculectomy so that they are psychologically prepared for that possibility.

Dr. Vold: Combined procedures are a great place to start. In early cases, I recommend surgeons follow what I call the “5-minute rule” when attempting to cannulate Schlemm canal. If a surgeon spends more than 5 minutes on it, I have found the prognosis for the surgical outcome generally to be more guarded. Failure to cannulate Schlemm canal, however, does not necessarily mean surgical failure.

What advice would you give to surgeons who say they are struggling to find patients for their first canaloplasty cases?

Dr. Richardson: Open your eyes and ears. What I mean by that is take a look at what the topical glaucoma treatments are doing to your patients’ corneal surfaces and conjunctivae. Refractive surgeons have learned the value of a smooth corneal surface in relation to quality of vision. If, after all, our primary goal is to optimize our glaucoma patients’ vision (and not just preserve vision limited by a beat-up corneal surface), then the exacerbation of ocular surface disease by topical medical therapy needs to be recognized and addressed. Also, listen to what your glaucoma patients are saying. What do they complain about the most? I will bet you dollars to doughnuts it is related to (or exacerbated by) the use of their glaucoma drops. Every

“Patients who have undergone canaloplasty commonly have a better overall quality of vision than patients with filtration blebs. This is due to fewer ocular surface disease problems, less induced astigmatism, and the elimination of fluctuating vision due to postoperative hypotony ”

—Steven D. Vold, MD

time a glaucoma patient on topical therapy complains about the cost of his or her drops, the difficulty he or she has remembering to use them (alongside his or her dozen or so other medications), tearing, transient blurring, hyperemia, sore eyes, etc., he or she is pleading with you both to listen and to solve the cause of his or her suffering. We now have a relatively safe surgical option that can address the very source of our glaucoma patients’ suffering. I think we owe it to them to at least consider the possibility that they would be better served by canaloplasty than by our ignoring their complaints and “continuing present management.” I have never had a trabeculectomy patient thank me for recommending surgery. On the other hand, I now have multiple canaloplasty patients who give me a hug every time I see them. That is a difference you will not see in the published literature but should.

Conclusion

Dr. Vold: Canaloplasty is an excellent alternative to standard filtration surgery in the vast majority of OAG patients. Prospective studies demonstrate IOP outcomes comparable to those associated with trabeculectomy.² Skilled anterior segment surgeons can successfully adopt canaloplasty in a timely fashion. With the appropriate selection of patients and proper surgical planning, surgeons should be encouraged by their early results with canaloplasty. More importantly, patients’ surgical care and quality of life should be significantly enhanced. For these reasons, the use of canaloplasty continues to grow among both glaucomatologists and comprehensive ophthalmologists in the United States. Ultimately, patients will be the primary benefactors of this significant change in the glaucoma treatment paradigm. ■

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