

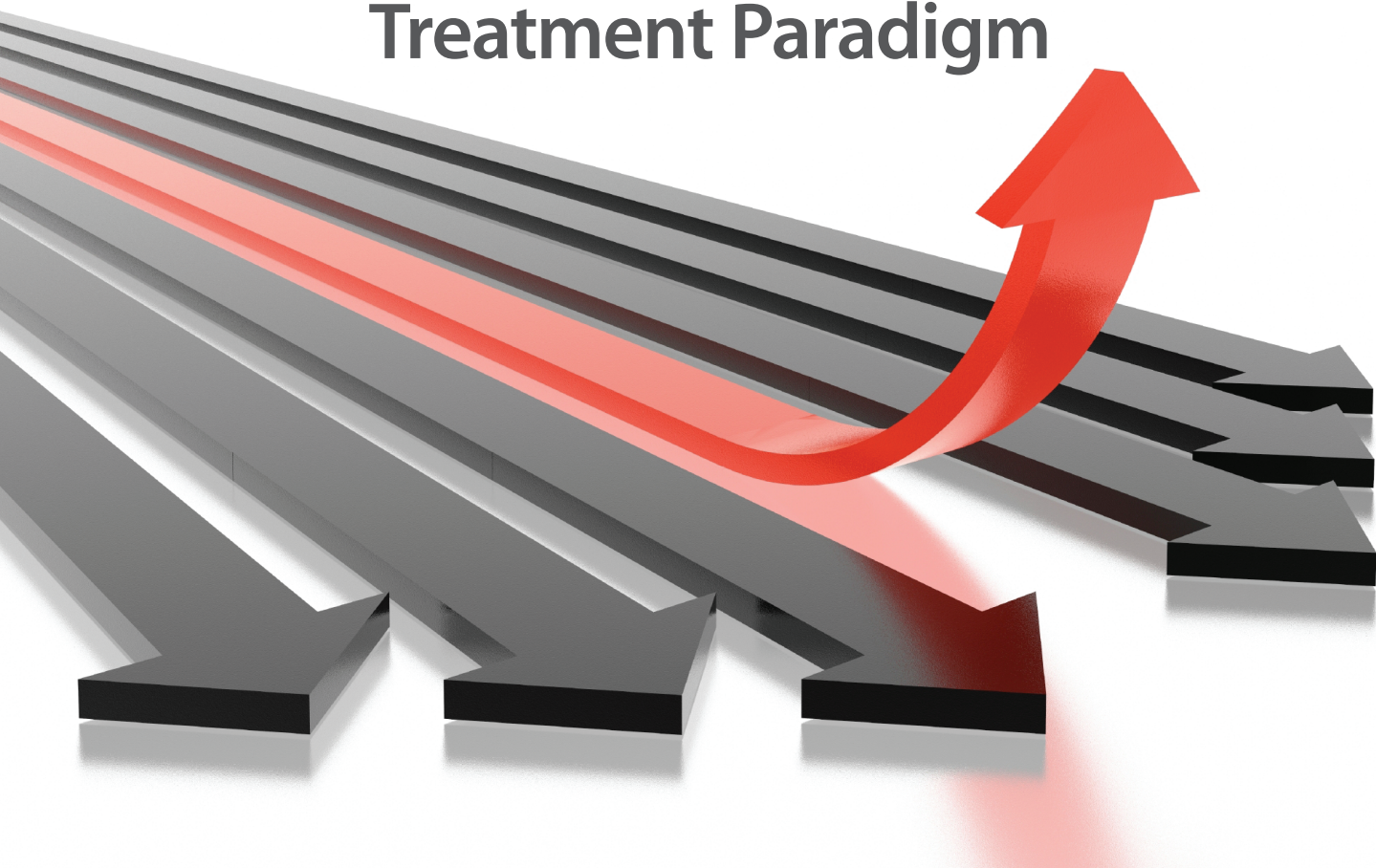
Glaucoma

TODAY

Winter 2011

Canaloplasty

Changing the Glaucoma
Treatment Paradigm



**Have you taken the
canaloplasty challenge?**

Canaloplasty: Changing the Glaucoma Treatment Paradigm

Have you taken the canaloplasty challenge?

PANEL



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Canaloplasty is a recent advance in glaucoma surgery that has been shown to be extremely successful in consistently lowering IOP in patients with open-angle glaucoma. Prospective 3-year data show that the IOP-lowering effect of canaloplasty is comparable to trabeculectomy and persists over time. The safety profile thus far has been very impressive, with complications of surgery much more rare than those found with traditional filtration surgery. Canaloplasty adoption among ophthalmic surgeons has grown dramatically in recent years. With the adoption of a new CPT code in 2011 and now widespread insurance coverage, canaloplasty has become a viable alternative to trabeculectomy in many patients. In this article, surgeons will discuss their experience and the keys to successful adoption of this significant step forward in glaucoma surgery.

— Steven D. Vold, MD

Dr. Vold: What was your motivation for adopting canaloplasty in your practice?

Dr. Sarkisian: Canaloplasty seemed especially appealing to me for younger patients with earlier forms of glaucoma. It is also ideal for monocular patients or patients with split-fixation visual fields in whom I wanted to be compulsive about avoiding hypotony and the dreaded "wipe out" syndrome, which occurs when a patient loses fixation entirely during a postoperative period of hypotony.

Dr. Chu: The first motivation was a need in my practice for a safe, effective treatment for patients with cataract and glaucoma.

Dr. Morgan: My goal was to be able to provide a safe, effective glaucoma surgery for my patients.

Dr. Nichamin: Cataract surgeons have come to appreciate that modern phacoemulsification surgery alone lowers IOP, but in many patients, it is not enough. Having a handy procedure like canaloplasty is a step forward in glaucoma management. Canaloplasty affords us the advantage of minimizing many of the complexities that traditional filtering surgery engenders.

Dr. Vold: What are the advantages of canaloplasty over traditional incisional glaucoma surgery from the patient's and surgeon's perspectives?

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Dr. Sarkisian: Canaloplasty restores the natural outflow. Conventional surgery essentially gives up on the natural outflow system.

Dr. Chu: There are significant advantages of canaloplasty over traditional penetrating glaucoma surgery, whether it is tube placement or trabeculectomy. Canaloplasty is a painless procedure with a quick postoperative recovery. Usually within a few weeks, the patients have excellent vision that occurs earlier on after surgery compared to penetrating procedures.

Dr. Morgan: The complication rate of trabeculectomy makes it unpredictable and can create a very rocky postoperative course. The real joy of canaloplasty is that the patients are seeing well so quickly. I get a wonderful effect without placing the patient at risk for vision-threatening complications.

Dr. Nichamin: Canaloplasty is not, in general, associated with significant complications, such as hypotony, choroidal detachment, cystoid macular edema, or other bleb-related complications, including late sight-threatening infection.

Dr. Vold: Which patients benefit most from canaloplasty?

Dr. Sarkisian: Patients need to have open-angle glaucoma. In fact, if the patient has a history of a peripheral iridotomy or shallow anterior chamber, I tend to shy away from canaloplasty. I also consider previous argon laser trabeculoplasty to be a relative contraindication to this procedure. However, selective laser trabeculoplasty is not a contraindication. Interestingly, I have been using the iScience catheters to perform 360° trabeculotomies on children with congenital glaucoma.¹

Dr. Chu: I have found that patient selection is not very difficult at all. I think the main criterion is that they cannot have had argon laser trabeculoplasty. You are looking for people who have moderate open-angle glaucoma who are on a couple of medications that you know would benefit from an IOP-reducing surgical procedure.

Dr. Morgan: Patients who seem to respond best to canaloplasty in my experience are patients who have some evidence of trabecular outflow. I seem to get the best results in patients who run IOPs without medications in the 30s or so. I have had some excellent results in patients who ran IOPs in the 40s and up without medications, but the procedure seems to be less predictable in that patient population. Canaloplasty really shines in

monocular patients and those with moderate glaucoma due to its safety.

Dr. Nichamin: I am not particularly selective when it comes to contraindications. Essentially, if the patient has a relatively normal angle and does not require an extremely low final IOP, and stand-alone cataract surgery is not likely to yield an adequate tension, then I give canaloplasty serious consideration. I do like to have adequate, mobile conjunctiva in the unlikely event that conversion to a trabeculectomy is required.

Dr. Vold: As a stand-alone procedure, patients with mild-to-moderate open-angle glaucoma do best in my experience. In more severe open-angle glaucoma, canaloplasty can be effective, but results will be more mixed. I relate this to the fact that the outflow system is likely more compromised in eyes with more advanced glaucoma and that are on topical glaucoma medication long-term. In patients with visually significant cataract and open-angle glaucoma, canaloplasty is a wonderful adjunct to cataract surgery. Many of these patients will have their IOP well controlled off all topical medications following surgery.

“Canaloplasty restores the natural outflow. Conventional surgery essentially gives up on the natural outflow system.”

—Dr. Sarkisian

Dr. Vold: What kind of surgical outcomes can surgeons reliably expect from canaloplasty?

Dr. Sarkisian: Richard Lewis, MD, has presented thorough data with canaloplasty revealing his IOPs with canaloplasty alone are in the midteens, whereas canaloplasty combined with phacoemulsification had results in the low teens. My experience has mirrored his results.²

Dr. Chu: The data have shown that the surgical outcomes with canaloplasty are really close to those that can be achieved with traditional trabeculectomy combined with phacoemulsification.³

Dr. Vold: Which eye surgeons are best suited to adopting canaloplasty?

Dr. Sarkisian: I think that, first and foremost, surgeons who do a lot of glaucoma surgery, particularly glaucoma filtration surgery, with either trabeculectomy or the Ex-

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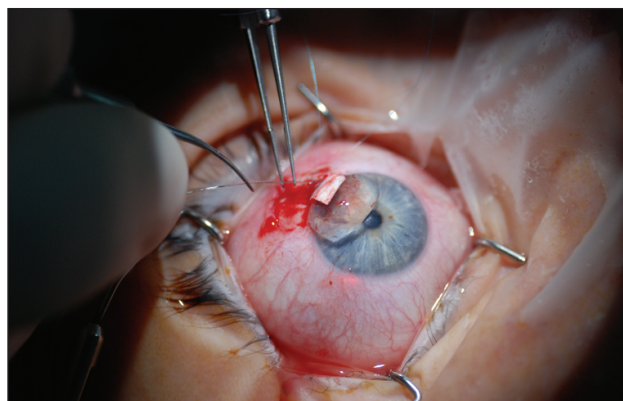


Figure 1. The iTrack 250A Microcatheter and light beacon (iScience Interventional, Menlo Park, CA) serve as a guide for placing the polypropylene suture in Schlemm's canal.

Press mini glaucoma shunt (Alcon Laboratories, Inc., Fort Worth, TX) should be able to do canaloplasty because it involves the creation of a scleral flap. For most people, the learning curve is involved with doing the deep sclerectomy. However, if I think back to my early days doing phacoemulsification as a resident, I would say that learning how to do a deep sclerectomy was far easier than learning how to do phacoemulsification.

Dr. Chu: I think one of the reasons cataract surgeons have been reluctant to perform a lot of glaucoma surgery in the past has been mostly the postoperative management. With canaloplasty, the surgical technique is easily mastered within a few cases, and I think it is well within the skill set of an anterior segment surgeon or a cataract surgeon. Also, the postoperative care now has been simplified because of the nonpenetrating nature of the procedure.

"Canaloplasty is a surgical technique that falls well within the purview of nearly all modern phacoemulsification surgeons."

—Dr. Nichamin

Dr. Morgan: I recommend surgeons ask themselves how many times a day they encounter a patient who would benefit from a safe, effective glaucoma procedure. If they find that it is a high number, they will benefit from adding canaloplasty to their surgical regimen.

Dr. Nichamin: I do not think one needs to be a glaucoma fellowship-trained surgeon to become proficient with this procedure and obtain excellent outcomes for patients. It is a procedure for surgeons who enjoy oper-

TABLE 1. THREE-YEAR RESULTS OF PATIENTS WHO UNDERWENT CANALOPLASTY ALONE VERSUS PHACOCANALOPLASTY.

	Baseline	6 Month	12 Month	24 Month	36 Month
Group 1: Canaloplasty Alone With Suture Placement					
N	103	86	91	89	89
Mean IOP	23.5 ±4.5	16.1 ±3.4	16.1 ±3.9	16.1 ±4.0	15.5 ±3.5
Mean Medications	1.9 ±0.8	0.4 ±0.7	0.6 ±0.8	0.6 ±0.8	0.9 ±0.9
Group 2: Phacocanaloplasty					
N	30	25	27	25	27
Mean IOP	23.5 ±5.2	12.8 ±2.9	13.6 ±4.1	13.4 ±3.2	13.6 ±3.6
Mean Medications	1.5 ±1.0	0.1 ±0.3	0.1 ±0.4	0.2 ±0.4	0.3 ±0.5

ating and learning a new microincisional technique (Figure 1). In fact, once familiar with the anatomy and deep dissection, most find it to be a satisfying and enjoyable procedure. If the surgeon is simply looking to press a button and treat as with a simple laser, then he or she will find canaloplasty to be more than that. Canaloplasty is a surgical technique that falls well within the purview of nearly all modern phacoemulsification surgeons.

Dr. Vold: What kind of commitment and learning curve should surgeons expect to successfully incorporate canaloplasty into surgical practice?

Dr. Sarkisian: I was very skeptical in the beginning and very resistant to trying it for a variety of reasons. I was very encouraged by Dr. Lewis' data and several other surgeons who had experience with canaloplasty, however, so I decided to proceed (Table 1). Once people get over their initial skepticism, they will find the surgery to be very rewarding. I believe that, once you do about 10 to 15 cases, you definitely have the confidence to continue because your surgical times decrease significantly.

Dr. Chu: It starts with the surgeon's educating him- or herself about the procedure. I think the learning curve is approximately three to five cases and mainly requires a change of flow during the surgery day initially. It is a change of gears, but once this is incorporated and once the staff and the surgeon get their flow, like with any procedure, it can be easily incorporated.

Dr. Morgan: When you start doing canaloplasty, it can be a somewhat intimidating task. You will be doing things that you have not done before. On the other hand, I think it is important to understand that you can get results on your first series of patients. That gave me

Canaloplasty: Perspective of an Ophthalmology Pioneer and Patient

An ophthalmology legend chooses canaloplasty.

BY ROBERT M. SINSKEY, MD

The decision to proceed with any surgical procedure is, for a patient, no small decision. A great deal of thought and research is required to make the correct choice. Dr. Sinskey explains why, for him, that choice was canaloplasty.

In the year 2000, I was on a cruise to Alaska with my family when I noticed that my contrast sensitivity was different between my two eyes. Upon returning home, I had my eyes checked in my practice. My IOP measured 26 mm Hg in my left eye and 17 mm Hg in my right. A slit-lamp examination showed that I had an exfoliation type of glaucoma. I started treatment with a single topical medication. Shortly thereafter, I underwent selective laser trabeculoplasty in my left eye.

"I think it behooves any ophthalmologist who treats glaucoma to add canaloplasty to his or her surgical armamentarium."

After several years of selective laser trabeculoplasty efficacy, my IOP gradually increased, and I was placed on latanoprost (Xalatan; Pfizer Inc). At that point, I underwent argon laser trabeculoplasty in my left eye that decreased my IOP into the midteens. After about a year, my IOP began increasing again. I was treated with almost every class of glaucoma medication without much success. After consulting multiple glaucomatologists, it became clear to me that surgical intervention would be required to control my glaucoma.

During my surgical career, I performed and managed a large number of filtration procedures. After witnessing the numerous complications and often long, difficult postoperative courses involved with trabeculectomy, I wanted to avoid a bleb at all costs. After thoroughly exploring my options, I finally decided to proceed with canaloplasty.

I selected Richard Lewis, MD, to perform my surgery. After

discussing the risks and benefits of canaloplasty with him, I underwent the procedure on July 28, 2010. On postoperative day 1, I had almost completely regained all of my vision and was able to conduct my normal activities of daily living; my IOP was 8 mm Hg but increased to 26 mm Hg over a 2-month period. At my 2-month postoperative visit, Dr. Lewis used a laser to open a hole in my Descemet's window. My IOP dropped to 10 mm Hg and has been stable off all topical medication since that time. Patients should be reassured constantly that it may take 2 to 3 months for the pressure to stabilize at a lower point after canaloplasty. Looking back, I cannot tell you how pleased I am with my postoperative outcome. Prior to canaloplasty, I was taking seven drops a day in my left eye. Eye drops were extremely irritating to my eye and completely occupied my life. Canaloplasty has significantly improved my quality of life.

After taking care of glaucoma patients for 45 years before I retired, experiencing glaucoma from a patient's perspective, doing the research on canaloplasty, and finally undergoing the procedure, I am certain that canaloplasty represents a major advance in glaucoma surgery. I think it behooves all ophthalmologists who treat glaucoma to add canaloplasty to their surgical armamentarium. ■

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the momentum that I needed to keep going. It is not something you can do once or twice and decide if it is right for you. I felt comfortable that I was going to get results fairly early on, but it seemed that, after about the 15th case, I became comfortable with the procedure.

Dr. Nichamin: iScience has done an extraordinarily good job of educating new surgeons. The company has a won-

derful technical field team that comes into the OR and trains both surgeons and their staff. I found that my results became quite consistent, and the procedure became quite enjoyable after about four to six cases. In general, it comes down to familiarizing oneself with the anatomy involved.

Dr. Vold: How quickly do your canaloplasty patients regain vision following surgery?

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Dr. Sarkisian: Most of them regain visual acuity almost immediately. Typically, the vision at day 1 is somewhere between 20/25 and 20/70, and it improves very quickly. I have been very happy with the postoperative visual results with canaloplasty compared to filtering surgery.

Dr. Chu: I think patients regain visual acuity remarkably quickly. Visual recovery is significantly faster in my experience with canaloplasty compared to other glaucoma surgical procedures. I think the pleasant thing for me is that postoperative management has been incredibly straightforward and simple with canaloplasty patients.

Dr. Morgan: Recently, we had a series of bleb-forming surgeries, and it took up to 3 months for the patients' vision to return to baseline. Conversely, many canaloplasty patients see well on postoperative day 1.

Dr. Nichamin: After the surgeon gets the first few cases under his or her belt, he or she will find that the visual recovery is very similar to stand-alone phacoemulsification cases. Certainly, it is much more rapid than what is typically seen with trabeculectomy or other more complex glaucoma surgeries.

Dr. Vold: All procedures have potential complications. What complications are most commonly observed with canaloplasty?

Dr. Sarkisian: Hyphema tends to be the most significant complication. However, with every patient I have had with a hyphema after canaloplasty, it has resolved spontaneously within 1 to 5 weeks. To reduce the incidence of hyphema, I have altered one thing in my technique. At the end of the surgery, I tend to inflate the

Canaloplasty: Perspective of a Referring Doctor

A top optometrist shares his perspective on canaloplasty.

BY MICHAEL R. MCFARLAND, OD

In my experience, the main benefit of canaloplasty is the IOP-lowering effect combined with the less-invasive approach. Patients have been so happy with it. All of my patients have done extremely well postoperatively. Additional benefits to the procedure are that there is no bleb or negligible ocular surface irritation, and postoperative recovery of vision is much more rapid than after standard trabeculectomy.

Canaloplasty's effect on IOP has been excellent in my patients. I have witnessed about a 30% to 40% reduction in IOP. All the patients I have referred to Steven Vold, MD, have had moderate-to-advanced glaucoma and were on at least two or three medications. Dr. Vold has combined most of the canaloplasties with a cataract extraction as well. As a result, my patients come back to me about 4 to 6 weeks postoperatively with the benefit of not only getting off their glaucoma medications but also seeing better.

I have seen no complications and no IOP spikes or hypotony with this procedure. For my patients that are 12 to 18 months out, there has been no long-term IOP drift, and IOP has been maintained off medication. I am more apt to refer people for canaloplasty more quickly, just because the results have been better than with standard incisional glaucoma surgery. In the past, I was always slightly hesitant to refer someone for trabeculectomy.

Most optometrists would be more comfortable observing patients with canaloplasty over a trabeculectomy, just

"I am more apt to refer people for canaloplasty sooner, just because the results have been better than with standard incisional glaucoma surgery."

because there are fewer complications. A key to my success with this procedure is that Dr. Vold and I work very closely together on the management of these patients. Communication is critical, as his practice is more than an hour's drive from my office. He manages the early postoperative care and returns my patients to me once their examination stabilizes. I have observed the surgery and understand how the surgery uses the natural anatomy of the eye to allow the drainage pathway to function more efficiently. ■

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anterior chamber through a paracentesis with balanced salt solution using a 27- or 30-gauge anterior chamber cannula. Bringing the pressure up somewhere in the high teens causes Schlemm's canal to be somewhat compressed during the initial postoperative period, which prevents a reflux of blood in the scleral lake and the canal and thus a reflux of blood into the anterior chamber.

"Visual recovery is significantly faster in my experience with canaloplasty compared to other glaucoma surgical procedures."

—Dr. Chu

Dr. Morgan: I try to avoid operating on patients who are on anticoagulants, such as Coumadin and Plavix (both from Bristol Myers Squibb Company) or aspirin. I stop these medications whenever possible preoperatively.

Dr. Vold: In nonpenetrating procedures, I have found steroid-related IOP spikes are more common than with traditional filtration surgery. To avoid this problem, I tend to use Lotemax (Bausch + Lomb) on a q.i.d dosing basis in the early postoperative period. By using this medication, I have virtually eliminated steroid-induced IOP rises. An alternative would be to taper prednisolone acetate 1% more rapidly. In stand-alone canaloplasty cases, I often have my patients off all topical medications within 2 to 3 weeks.

Dr. Morgan: Be aware of the possibility of a Descemet's detachment. When withdrawing the catheter and injecting the viscoelastic, if the catheter is not moving quickly enough, or if the viscoelastic is injected too close together in the process, you can cause this complication. Other complications that are typical in bleb-forming surgeries (such as wound leaks, prolonged hypotony, maculopathy, flat chambers, prolonged visual recovery, and others) just do not occur with canaloplasty.

Dr. Vold: Where does canaloplasty fit into your glaucoma treatment paradigm?

Dr. Morgan: Canaloplasty has become my procedure of choice for glaucoma patients. Although I still perform trabeculotomy and other bleb-forming procedures, most patients who need glaucoma surgery fit well into the parameters for canaloplasty.

Dr. Nichamin: It is filling a distinct void that we have seen between the patients who have very mild glaucoma, who are going to adequately benefit from cataract surgery alone,

to the other extreme where one is faced with aggressive disease that requires a trabeculectomy. As such, there is this big hump in the center of the bell curve where we are increasingly utilizing newer procedures such as canaloplasty.

Dr. Sarkisian: My patients' profiles tend to fall primarily into two groups. The first is patients between the ages of 40 and 60 who have never had surgery before and have minimal glaucomatous damage. The second group really has a very broad age range, anywhere from the 40s to even patients in their 90s, who have very advanced glaucoma where there is split fixation. In these cases, the referring surgeon is very concerned about preventing wipe-out syndrome.

Dr. Chu: It definitely fits in before penetrating surgery such as trabeculectomy or tube shunts. Some patients prefer canaloplasty to selective laser trabeculoplasty.

Dr. Vold: What impact has canaloplasty had on your overall clinical practice?

Dr. Nichamin: As the owner of an ambulatory surgery center, I have been pleasantly satisfied with the remuneration for this procedure. Fortunately, both surgeon and facility payments have been established. Our staff has enjoyed adopting this new technology and has found working with the iScience field support team to be very easy. We are also attracted to canaloplasty from the standpoint of postoperative management. Unlike trabeculectomy, managing canaloplasty postoperatively is less eventful. It has been a real boon to a practice such as ours, including considerations from a comanagement perspective.

"Complications that are typical in bleb-forming surgeries . . . just do not occur with canaloplasty."

—Dr. Morgan

Dr. Sarkisian: Since I have become more experienced with the procedure, canaloplasty can efficiently be placed within a busy OR day in which I am doing a variety of different things. It has expanded my surgical treatment of glaucoma and increased the types of referrals I have been receiving.

Dr. Chu: It is a fun procedure to learn for the cataract surgeon. I think modern cataract surgery has become a very elegant and efficient procedure. I feel canaloplasty allows cataract surgeons to stretch their surgical skills in a very safe and effective way for these patients. Integrating it

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into the practice has been economically viable and helpful to our patients. It has really helped grow our practice.

Dr. Morgan: Canaloplasty affects clinical practice in several ways. Once you become comfortable with canaloplasty, you actually feel good about recommending this glaucoma procedure. This is a tremendous contrast to how you feel when you recommend that a patient undergo a bleb-forming procedure. This is directly due to canaloplasty's inherent safety. The other thing that canaloplasty does for you is it actually creates a lot of interest in the community with what you are doing, and it ends up helping you build a larger practice.

"Preparation, patient selection, and the surgeon's commitment to the procedure are critical to success."

—Dr. Vold

Dr. Vold: Canaloplasty has been a game changer in my practice. Now that canaloplasty is covered by almost all insurance carriers and the new category 1 CPT 66175 code is in place, this procedure is without question a financially viable option. With experience, canaloplasty can be performed in an acceptable amount of time in the ambulatory surgery center setting. The rapid visual recovery following canaloplasty makes for extremely happy patients and referring doctors. Without question, canaloplasty has grown both my cataract and glaucoma practices significantly.

Dr. Vold: What do you perceive to be the keys to the successful adoption of canaloplasty into a surgical practice?

Dr. Sarkisian: It is always difficult for a surgeon to perform procedures that he or she did not learn as a resident, so you really need to have a combination of courage and humility and always be willing to try new things for the benefit of patient care. Be patient and persistent. I think that it is not very productive if a surgeon does one or two cases and then observes those patients for 6 months before doing another case. I think that you really need to try to get that learning curve done within a few months. I would strongly encourage surgeons to try to get through those 10 or 15 cases in a 2- to 3-month period.

Dr. Chu: If there is a significant need, then make the commitment to trying canaloplasty and stay with it at least through the learning curve of at least five or 10 cases. Then, make sure that you take the time to educate your

staff about the procedure. Really, education and commitment, for me, have been the keys to making this successful.

Dr. Morgan: You need the patient population to justify the effort and the desire to learn a new procedure. The mistake a lot of folks make is they bring in patients who are end stage, who have already failed other types of glaucoma procedures, and who are really high risk. That just is not the ideal patient population to start on.

Dr. Nichamin: It is the same type of commitment that surgeons need to put forth as when adopting any type of technique—be it a new corneal, lens-based, or refractive procedure—but the magnitude of that commitment is reasonable. Surgeons need to share their enthusiasm with other team members. Involving the staff in the adoption of such a procedure is critical to its ultimate success. The fact is that these patients are abundant in most practices, but they are probably not being adequately treated. We now have an emerging array of new procedures like canaloplasty that can preserve their vision.

Dr. Vold: Preparation, patient selection, and the surgeon's commitment to the procedure are critical to success. With early success, my staff became big proponents of this procedure. This gives patients confidence that they are making a good surgical decision. Once surgeons get past the initial learning curve, I think they will find this to be one of the most enjoyable and successful procedures they have performed during their medical careers. Newer instrumentation has also improved the safety of the procedure and made the surgery easier to perform.

Surgeons across the world are finding canaloplasty to be a significant advance in surgical glaucoma therapy. Canaloplasty appears to demonstrate efficacy similar to trabeculectomy with more rapid recovery for patients and an avoidance of complications traditionally associated with glaucoma surgery. This allows surgeons to intervene earlier in glaucomatous disease and allows patients a viable alternative to long-term medicinal therapy. For surgeons skeptical of the efficacy of the procedure or concerned about the learning curve, we encourage you to evaluate canaloplasty for yourself and compare your results and experience with canaloplasty versus trabeculectomy. Are you ready to take the canaloplasty challenge? □

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