Evolution of the Efficient Canaloplasty

The goals of efficient canaloplasty are to offer a procedure that is faster, easier, and more reproducible without any compromise in efficacy and patient safety.

BY STEVEN D. VOLD, MD

In 2004, Robert Stegmann, MD, introduced the concept of canaloplasty to ophthalmic surgeons. He reported canaloplasty's efficacy in lowering intraocular pressure (IOP) with more rapid recovery and reduced complication rates when compared with trabeculectomy. His exquisite surgical videos demonstrated the enhancement of aqueous outflow through the collector system with the creation of a trabeculodescemetic window (TDW) and the utilization of a Prolene suture (Ethicon, Inc.) microstent. The following year, the procedure was initiated in the United States, and a prospective international multicenter clinical trial was begun.

In an attempt to standardize the procedure and help surgeons gain comfort working within Schlemm canal, early on, a 10-step surgical technique was recommended. The published prospective 3-year data validated the potential benefits of canaloplasty and led to the procedure's adoption by nearly 500 surgeons.[1,2] Key elements of the canaloplasty procedure became more clearly defined over time, and surgeons further refined the procedure. In this article, I present the efficient canaloplasty technique as a way to reduce barriers to its adoption and optimize patients' outcomes.

MY CANALOPLASTY JOURNEY

I adopted canaloplasty in February 2008. Around that time, the iTrack 250A Canaloplasty Microcatheter (iScience Interventional) was introduced, and insurance companies began to reimburse for the procedure. As I became comfortable with the technique, I began critically evaluating each of its steps. After examining a fairly extensive number of patients who had undergone previous viscocanalostomy, deep sclerectomy, and canaloplasty procedures with both anterior segment optical coherence tomography and ultrasound, I discovered that scleral lakes were largely nonexistent 1 year following surgery in most patients. I began to question if a full 5-mm pyramidal scleral flap needed to be performed to obtain good postoperative results. Furthermore, the medical economic climate dictated that ambulatory surgery centers examine every surgical procedure in detail to ensure cost effectiveness. I learned that many ambulatory surgery centers refused to perform glaucoma surgeries at their facilities due to high equipment costs and protracted procedure times.

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During my systematic evaluation of more than 300 canaloplasty cases, the concept of a more efficient canaloplasty surgical technique evolved and ultimately was integrated into my practice. The efficient canaloplasty technique seeks to maintain the key elements of the procedure while

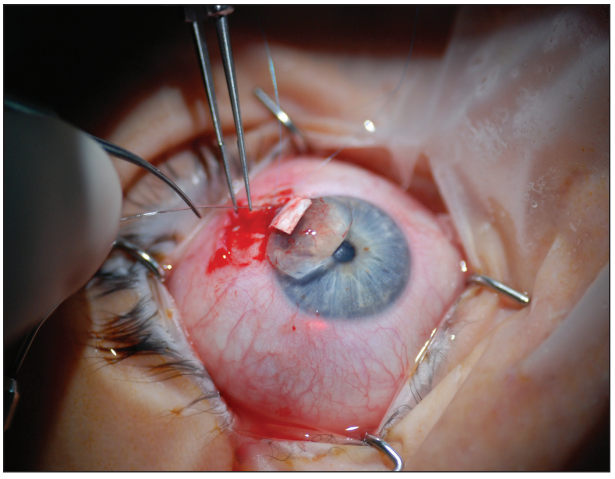

Figure. iTrack Catheter placement.

eliminating nonessential steps in the operation. The goals of efficient canaloplasty are simply to offer a procedure that is faster, easier, and more reproducible without any compromise in efficacy and patient safety.

KEY ELEMENTS OF EFFICIENT CANLOPLASTY

Flap Dissection

Rather than the 5-mm pyramidal scleral flaps advocated early on, I have learned that 3- × 3-mm scleral flaps are more than adequate for most patients. This allows surgeons to reduce the size of conjunctival peritomies significantly and ultimately limit damage to the collector channel system. Scleral flap dissections should enter at least 1 mm into clear cornea and at least 1-mm posterior to the location of Schlemm canal. My outer scleral flap dissection is generally one-half scleral thickness with the inner scleral flap utilized to identify Schlemm canal and establish a 300 to 500 μm^2 TDW. I recommend no sharp instrumentation over the TDW and generally excise the inner scleral flap prior to the catheter's insertion.

Microstent Placement

Once Schlemm canal has been isolated, I secure the iTrack catheter to the patient's forehead over the operative eye at approximately the 12-o'clock position (Figure). This placement allows for the catheter's insertion in either a clockwise or counterclockwise fashion and eases the catheter's manipulation within the surgical field. I hold myself to what I call the "'5-minute rule" when placing the catheter within Schlemm canal. In the vast majority of surgical cases, catheterization of Schlemm canal for 360° should easily be achieved in this amount of time. I have learned that canaloplasty procedures in eyes with significant canal obstruction are sometimes not as efficacious at lowering IOP even when catheterization is successful.

TABLE 1. DEMOGRAPHIC CHARACTERISTICS

	Efficient Canaloplasty Only	Combined Cataract-Canaloplasty
Age at surgery in years		
Mean ± SD	64.1 ± 12.0	70.9 ± 7.5
Range	46 to 83	44 to 92
Gender, n (%)		
Female	11 (50%)	39 (65.0%)
Male	11 (50%)	21 (35.0%)
Race, n (%)		
White	22 (100%)	59 (98.3%)
Hispanic		1 (1.7%)
Eye		
OD	12 (54.5%)	31 (51.7%)
OS	10 (45.5%)	29 (48.3%)
Glaucoma diagnosis, n (%)		
Primary open-angle	21 (95.5%)	57 (95.0%)
Pseudoexfoliative	0	2 (3.3%)
Pigmentary dispersion	1 (4.5%)	1 (1.7%)
Previous ocular surgery, n (%)		
Laser trabeculoplasty	5 (22.7%)	13 (21.7%)
Cataract	9 (40.9%)	N/A
Endocyclophotocoagulation	1 (4.5%)	0

TABLE 2. OUTCOME RESULTS

Examination	All Eyes			Efficient Canaloplasty Only			Combined Cataract-Canaloplasty		
	n	Mean IOP in mm Hg ± SD (Range)	Mean Medications ± SD (Range)	n	Mean IOP in mm Hg ± SD (Range)	Mean Medications ± SD (Range)	n	Mean IOP in mm Hg ± SD (Range)	Mean Medications ± SD (Range)
Baseline	82	19.3 ± 6.5 (10.0 to 48.0)	2.1 ± 1.1 (0 to 5)	22	20.1 ± 4.8 (14.0 to 32.0)	2.4 ± 1.0 (0 to 4)	60	18.9 ± 7.0 (10.0 to 48.0)	1.9 ± 1.2 (0 to 5)
1 mo	79	15.6 ± 6.5 (5.0 to 49.0)	0.7 ± 1.1 (0 to 3)	21	17.5 ± 5.5 (10.0 to 27.0)	0.9 ± 1.1 (0 to 3)	58	14.9 ± 6.7 (5.0 to 49.0)	0.6 ± 1.0 (0 to 3)
3 mo	69	14.3 ± 7.3 (5.0 to 47.0)	0.6 ± 1.0 (0 to 4)	15	15.5 ± 6.4 (5.0 to 27.0)	1.0 ± 1.3 (0 to 4)	54	13.9 ± 7.6 (6.0 to 47.0)	0.5 ± 0.8 (0 to 3)
6 mo	56	14.8 ± 5.3 (6.0 to 36.0)	0.8 ± 1.1 (0 to 4)	11	17.6 ± 8.5 (7.0 to 36.0)	1.4 ± 1.1 (0 to 3)	45	14.2 ± 4.0 (6.0 to 25.0)	0.7 ± 1.0 (0 to 4)
12 mo	43	14.9 ± 5.2 (6.0 to 32.0)	1.0 ± 1.2 (0 to 4)	8	14.3 ± 3.6 (9.0 to 20.0)	1.1 ± 1.4 (0 to 4)	35	15.0 ± 5.6 (6.0 to 32.0)	1.0 ± 1.2 (0 to 3)
24 mo	19	14.8 ± 4.7 (8.0 to 28.0)	1.0 ± 1.4 (0 to 4)	6	14.8 ± 4.9 (8.0 to 21.0)	1.0 ± 1.3 (0 to 3)	13	14.8 ± 4.8 (8.0 to 28.0)	1.0 ± 1.6 (0 to 4)

TABLE 3. VISUAL ACUITY

	LogMAR Units ± Standard Deviation	
Visit	Efficient Canaloplasty Only	Combined Cataract-Canaloplasty
Baseline	0.2 ± 0.2	0.3 ± 0.3
Postoperative	0.2 ± 0.3	0.2 ± 0.2

TABLE 4. OCULAR-RELATED SURGICAL AND POSTSURGICAL COMPLICATIONS OF EFFICIENT CANALOPLASTY

Surgical/Early Postoperative Complications (< 90 d postoperatively)	Efficient Canaloplasty Only[a] (N = 22) Number (%)	Combined Cataract-Canaloplasty[b] (N = 60) Number (%)
Hyphema (freely circulating or layered red blood cells)	nine (40.9%)	12 (20.0%)
Hypotony: IOP ≤ 5 mm Hg	nine (40.9%)	12 (20.0%)
Elevated IOP (≥ 30 mm Hg)	two (9.1%)	six (10.0%)
Hypotony: IOP ≤ 5 mm Hg with shallow anterior chamber	none	none
Late postoperative implications (≥ 90 days postoperatively)		
Decreased vision (≥ 2 Snellen lines from baseline)	one (4.5%)	five (8.3%)
Elevated IOP (≥ 30 mm Hg)	one (4.5%)	three (5.0%)

[a]In the canaloplasty-only group, seven eyes with early hypotony had IOPs ≤ 5 mm Hg on day 1 postop with six recovering within 1 week and one recovering within 1 month. Two eyes were hypotonous at 1 week, both recovering within 1 month.
[b]In the combined surgery group, eight eyes with early hypotony had IOPs ≤ 5 mm Hg on day 1 postop, with seven recovering within 1 week and one recovering within 1 month. Two eyes were hypotonous at 1 week with both recovering within 1 month. Two eyes were hypotonous at 1 month with both recovering within 3 months.

TABLE 5. POSTOPERATIVE INTERVENTIONS		
	Number (%)	
	Efficient Canaloplasty Only (N = 22) Number (%)	Combined Cataract-Canaloplasty (N = 60) Number (%)
Reoperation for Complications		
Trabeculectomy	two (9.1%)	three (5.0%)
Tube shunt	none	one (1.7%)
Other Procedures		
Trabeculotomy	four (18.2%)	one (1.7%)
Nd:YAG goniopuncture	two (9.1%)	one (1.7%)
Diode cyclophotocoagulation	none	two (3.3%)
Laser peripheral iridotomy	none	one (1.7%)
Selective laser trabeculoplasty	none	one (1.7%)
Pars plana vitrectomy	none	one (1.7%)

TABLE 6. REFRACTIVE CYLINDER		
	Magnitude in D of Cylinder	
Visit	Efficient Canaloplasty Only	Combined Cataract-Canaloplasty
Baseline	0.9 ±0.7	0.8 ±0.6
Postoperatively	1.3 ±0.9	0.9 ±0.7

Pearls for facilitating the catheter's placement that have been beneficial to me include: (1) injecting viscoelastic into Schlemm canal to expedite the catheter's insertion; (2) attempting both clockwise and counterclockwise insertions when necessary; (3) gently depressing the sclera just proximal to the catheter along the corneal limbus; and (4) kinking the distal end of the catheter to facilitate catheter placement as a last resort. After tying the 10–0 or 9–0 Prolene suture to the catheter, I gently inject viscoelastic every 1- to 2-clock hours while retracting the catheter from the eye. A slipknot technique potentially enhances my ability to achieve proper suture tension.

Incision Closure

For the vast majority of patients, scleral flap sutures are unnecessary. With high-quality scleral dissections, the outer scleral flap lies neatly within the scleral bed. Postoperative astigmatism has not been problematic in these patients. In fact, I feel quite comfortable offering both accommodative and toric IOLs to most patients undergoing phacocanaloplasty.

In eyes with thin or myopic sclera or a perforation sustained in the TDW, I encourage scleral flap suture placement. This prevents potential bleb formation, shallow anterior chambers, hyphema, hypotony, and astigmatism postoperatively. For conjunctival closure, surgeons may utilize bipolar cautery, tissue glue, or sutures. By limiting the number of surgical steps and instruments used in the operating field, surgical efficiency is greatly enhanced.

POSTOPERATIVE CARE

Following surgery, patients commonly achieve a visual acuity of 20/40 or better on postoperative day 1, especially in combined phacocanaloplasty cases. My perioperative topical medication regimen includes topical antibiotic and loteprednol 0.5% (Lotemax, Bausch + Lomb) four times per day. I anticipate discontinuing all topical medication within 3 to 4 weeks after surgery and instruct patients to resume normal activities within 2 weeks of surgery.

SURGICAL OUTCOMES

In an effort to validate the efficacy and safety of the efficient canaloplasty, my colleagues and I performed a retrospective analysis of 82 consecutive cases in my clinic. The demographic data regarding these patients is seen in Table 1. Despite operating on patients with generally more advanced disease than those included in other published peer-reviewed studies, our efficient canaloplasty outcomes remained quite comparable to currently published findings (Table 2). Visual acuities were

"Efficient canaloplasty easily combines with cataract surgery."

stable postoperatively in efficient canaloplasty-alone cases, while expected improvements in visual acuity were observed after phacocanaloplasty (Table 3).

With efficient canaloplasty, early postoperative IOPs trend toward being lower during the first week postoperatively, but this resolved quickly (Table 4). Early postoperative hypotony may result in small hyphemas that generally resolve within 1 to 2 weeks. Complications following efficient canaloplasty mirrored those found with the original canaloplasty technique including the procedure's failure, Descemet detachment, and hyphema. No bleb-related complications were encountered. Fortunately, the rate of surgical intervention postoperatively remained low following this procedure (Table 5). Lastly, the efficient canaloplasty yielded only minimal changes in postoperative astigmatism (Table 6).

CONCLUSIONS

Canaloplasty remains a viable and potentially the preferred glaucoma procedure for patients with mild, moderate, and even select eyes with advanced open-angle glaucoma. Its sustained efficacy and excellent safety profile are currently unmatched when compared with more established glaucoma surgical procedures. With recent efforts to make the procedure faster, easier, and more reproducible while maintaining outstanding postoperative outcomes, the appeal of this procedure continues to grow among both glaucoma subspecialists and comprehensive ophthalmologists. Efficient canaloplasty easily combines with cataract surgery and provides competent surgeons with a procedure that can be consistently performed in times comparable to those of cataract surgery alone. ■

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2. Tam D, Calafati J, Ahmed I. Nonpenetrating Schlemm's canaloplasty versus trabeculectomy. Paper presented at: The American Society of Cataract and Refractive Surgery Annual Meeting; April 6, 2009; San Francisco, CA.