# Canaloplasty in One Eye Compared With Viscocanalostomy in the Contralateral Eye in Patients With Bilateral Open-angle Glaucoma

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**Purpose:** To compare the safety and efficacy of canaloplasty with viscocanalostomy when performed in both eyes of patients with bilateral open-angle glaucoma.

**Patients and Methods:** This comparative case series investigated 30 eyes of 15 adult patients with bilateral primary open-angle glaucoma who had canaloplasty performed in one eye and viscocanalostomy performed in the contralateral eye. Qualifying preoperative intraocular pressures (IOP) were at least 18 mm Hg with historical IOPs of at least 21 mm Hg. In canaloplasty, a microcatheter was used to viscodilate the full circumference of Schlemm canal in conjunction with the placement of a trabecular meshwork tensioning suture. Primary outcome measures included IOP, glaucoma medication usage, and adverse events.

**Results:** With a follow-up period of 18 months, both the canaloplasty and viscocanalostomy groups showed statistically significant reductions in mean IOP ($P < 0.01$) and number of supplemental medications ($P < 0.01$) as compared with preoperative values. In the canaloplasty cohort, eyes had a mean IOP of $14.5 \pm 2.6$ mm Hg on $0.3 \pm 0.5$ medications at 18 months postoperatively as compared with preoperative levels of $26.5 \pm 2.7$ mm Hg on $2.1 \pm 1.0$ medications. In the viscocanalostomy cohort, eyes had a mean IOP of $16.1 \pm 3.9$ mm Hg on $0.4 \pm 0.5$ medications at 18 months as compared with preoperative levels of $24.3 \pm 2.8$ mm Hg on $1.9 \pm 0.8$ medications ($P = 0.02$). No patient in either cohort experienced significant complications.

**Conclusions:** Canaloplasty and viscocanalostomy were safe and effective in the surgical management of open-angle glaucoma. Canaloplasty procedures showed superior efficacy to viscocanalostomy in the reduction of IOP ($P = 0.02$) and both procedures demonstrated excellent safety profiles.

**Key Words:** canaloplasty, microcatheter, open-angle glaucoma, Schlemm canal, nonpenetrating glaucoma surgery

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Surgical procedures involving Schlemm canal represent a new frontier in glaucoma surgery[1] which attempt to restore the natural trabeculocanalicular outflow pathway[2,3] while avoiding the complications associated with trabeculectomy.[4–7] Nonpenetrating techniques obviate the need for a subconjunctival filtering bleb which shunts aqueous to nonphysiological routes. Serious postoperative complications are not infrequently associated with penetration of the intraocular space including intraoperative and postoperative bleeding, flat anterior chamber and hypotony caused by overfiltration, choroidal detachment, cataract formation, and bleb-related endophthalmitis.[8–11] Viscocanalostomy was designed to lower the well-documented complication rate associated with trabeculectomy[12,13] by avoiding penetration into the anterior chamber and directing aqueous outflow to Schlemm canal instead of a subconjunctival bleb.

Viscocanalostomy differs from other nonpenetrating surgical procedures in its use of an ophthalmic viscosurgical device to distend Schlemm canal near the surgical margins.[14] The enlargement of Schlemm canal with viscoelastic is designed to enhance aqueous egress through the ostia of Schlemm canal and then out of the eye via aqueous collector channels. Smit and Johnstone[4] showed that injection of high viscosity sodium hyaluronate in the Schlemm canal of the in vivo primate eye not only resulted in a dilated canal and associated collectors, but also in the disruption of the canal walls and the internal structures.

Viscocanalostomy treats a segment of the distal outflow pathway,[15] but recent technological advances have enabled glaucoma surgeons to use a flexible microcatheter to access the lumen of Schlemm canal along its entire length.[16] This treatment approach has led to the development of a nonpenetrating surgical procedure called canaloplasty, which involves catheterization and viscodilation of the full circumference of Schlemm canal. In addition, a suture is placed within the canal to tension the inner wall and the associated trabecular meshwork with the goal of restoring the natural trabeculocanalicular aqueous outflow system. This nonrandomized case series is a retrospective analysis of a prospective study comparing canaloplasty with viscocanalostomy in patients with bilateral open angle glaucoma who had canaloplasty performed in one eye and viscocanalostomy performed in the contralateral eye.

## MATERIALS AND METHODS

### Study Design

Patients who had canaloplasty performed in one eye and viscocanalostomy performed in the contralateral eye were consecutively enrolled. Outcome measures included intraocular pressure (IOP), medication use, and adverse events. Patients received a complete baseline ophthalmic examination within 60 days of surgery, which included a thorough case history, medication usage, IOP by Goldmann applanation tonometry, best corrected Snellen visual acuity (BCVA), biomicroscopy, gonioscopy, and a fundus evaluation. Follow-up examinations performed were at minimum 1 day, 1 week, 6, 12, and 18 months. Postoperative evaluations included IOP measurements, ophthalmic medication usage, BCVA, a slit lamp examination, gonioscopy, and monitoring

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for adverse events. Fundus evaluations were performed at baseline and at 12 months. Reported IOP values were the average of 2 measurements taken within a 60 minute time period where available. If the 2 readings varied by 4 mm Hg or more, a third reading was taken immediately after the second and averaged with the other 2 readings. Safety was evaluated by determining the incidence and severity of intraoperative and postoperative complications.

## Patient Selection

Ethics committee approval was obtained and this research adhered to the tenets set forth in the 1964 Declaration of Helsinki. This study was Health Insurance Portability and Accountability Act compliant and each patient provided written informed consent after the nature of the procedure and options had been fully discussed. All patients were 18 years of age or older at the time of enrollment, able to understand and provide informed consent, and were scheduled for glaucoma surgery. Inclusion criteria for this study consisted of a diagnosis of open-angle glaucoma including pseudoexfoliative and pigmentary glaucoma and a baseline IOP of 18 mm Hg or higher taken at most 60 days before surgery. The glaucoma diagnosis was based on biomicroscopy and gonioscopy observations, optic nerve head cupping, and visual field findings. Exclusion criteria included angle closure or narrow angles, chronic or recurrent uveitis; neovascular ocular disease, angle recession, peripheral anterior synechiae, previous surgery that involved dissection in the area near Schlemm canal or the trabecular meshwork, more than 2 laser trabeculoplasty procedures, and a legally blind eye.

## Treatment

All surgeries in both cohorts were performed by one surgeon (N.K.) experienced in both surgical methods. The most advanced glaucomatous eye was treated first and subsequently the second eye was treated. The patients included in this study received canaloplasty in one eye as part of a multicenter canaloplasty clinical trial[17] and received viscocanalostomy in the contralateral eye owing to the single eye limitation of the canaloplasty study.

### Surgical Technique: Viscocanalostomy

Viscocanalostomy was performed according to Stegmann et al's[15] technique, with the creation of a parabolic 5 × 5 mm limbal-based one-third scleral thickness flap. With the goal of achieving a watertight closure, cautery was avoided and 1:10,000 epinephrine was applied using a Weck-cel to achieve hemostasis. A deep scleral flap was created 0.5 mm inside the superficial flap, dissecting down until the choroid was just visible. Schlemm canal was unroofed and a membrane was cleaved from the cornea, creating a Descemetic window through which aqueous could permeate. The inner, deep scleral flap was then excised, forming the scleral lake. The 2 surgically created ostia of Schlemm canal were injected 6 times with Healon GV (Abbott Medical Optics, Santa Ana, CA) using a 150 μm cannula (Visco Canalostomy Cannula, Grieshaber, Schaffhausen, Switzerland). The superficial flap was sutured tight to achieve internal drainage and prevent bleb formation.

### Surgical Technique: Canaloplasty

Canaloplasty essentially used the same nonpenetrating surgical technique discussed for the viscocanalostomy and has been described in detail in previous reports.[17] After exposing Schlemm canal, a flexible microcatheter (iTrack 250A Canaloplasty Microcatheter, iScience Interventional Corp, Menlo Park, CA) was used to dilate the full circumference of the canal by injecting Healon GV during catheterization. The microcatheter has a 200 μ diameter shaft with an atraumatic distal tip of approximately 250 μ in diameter. The device, which has a lumen through which the viscoelastic is delivered, has an illuminated tip so that the surgeon can observe the location of the beacon tip transsclerally. A 10-0 prolene suture (Ethicon Inc, Somerville, NJ) was tied to the distal tip and the microcatheter was withdrawn, pulling the suture into the canal. After tying the suture in a loop encircling the inner wall of the canal, the suture loop was tightened to distend the trabecular meshwork inward placing the tissues in tension and then locking knots were added. High resolution ultrasound imaging was optionally used to assess Schlemm canal and anterior segment angle morphology, including distension of the trabecular meshwork owing to the tensioning suture (Figs. 1, 2).

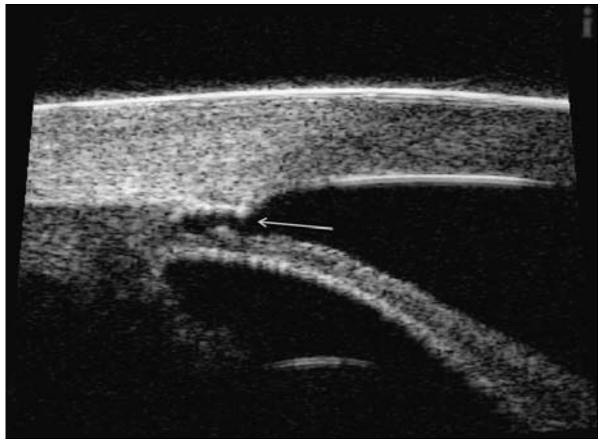

**FIGURE 1.** Ultrasound biomicroscopy of the anterior chamber angle of the inferior quadrant of a patient's right eye. This image was captured 18 months after canaloplasty and shows the suture at anterior edge of Schlemm canal (arrow) with suture distension of the trabecular meshwork.

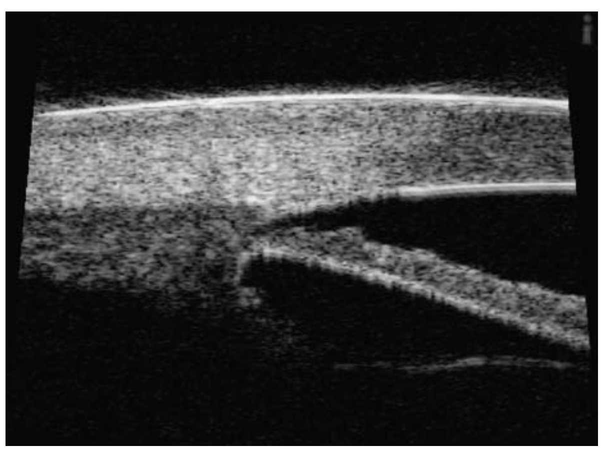

**FIGURE 2.** Ultrasound biomicroscopy of the anterior chamber angle of the inferior quadrant of the contralateral (left) eye of the same patient shown in Figure 1. This image was captured 16 months after viscocanalostomy.

A prophylactic topical antibiotic was prescribed during the first week. Prednisolone acetate 1% (Pred Forte) was prescribed every 2 hours for 1 week and then gradually tapered and discontinued after 1 month for both cohorts. In addition, patients were directed to apply a nonsteroidal anti-inflammatory drug, indomethacine, 4 times a day for 1 month's duration.

## Statistical Methods

Combination glaucoma medications were enumerated according to the number of individual constituent active pharmaceutical agents in the medication. The IOP, antiglaucomatous medication usage, and visual acuity data were compared with baseline values using repeated measures analysis of variance. Parametric analysis (paired *t* test) was applied to compare changes between canaloplasty and viscocanalostomy from baseline through 18 months for both IOP and change in IOP from baseline. The incidence of complications was compared between the 2 study groups by Fisher exact test. Statistical analysis was performed with the SPSS software package (Version 17.0, SPSS Inc, Chicago, IL). Two-tailed values of $P \leq 0.05$ were considered statistically significant.

# RESULTS

Eighteen patients were identified who had bilateral primary open-angle glaucoma and who underwent a canaloplasty in one eye and a viscocanalostomy in the contralateral eye between June 2004 and October 2007. Of these, 15 patients met the inclusion criteria defined above. Three patients were excluded who had combined cataract and glaucoma surgery in at least one eye. In 60.0% of the cases, the canaloplasty was performed first followed by the viscocanalostomy in the second eye.

Table 1 provides a summary of the demographic characteristics of patients at baseline. Both cohorts were closely matched in that both procedures were performed in either eye of the same patient. The patients had the same disease in each eye, similar pathology, and there was no statistically significant difference in regard to the mean number of antiglaucomatous medications and mean BCVA at baseline. However, the mean IOP at baseline was significantly higher in the canaloplasty cohort than in the viscocanalostomy cohort ($P = 0.02$).

## Change in IOP and Antiglaucomatous Drug Usage

Table 2 and Figure 3 present the primary outcomes in both study groups. Both canaloplasty and viscocanalostomy were successful in lowering IOP and medication use compared with baseline at all time points ($P < 0.01$). The decrease in IOP from baseline was significantly greater in the canaloplasty group (approximately 12 mm Hg decrease) as compared with the viscocanalostomy group (approximately 8 mm Hg decrease) at both 12 ($P < 0.01$) and 18 months ($P = 0.02$), respectively. Similarly, the percentage reduction in IOP was higher in the canaloplasty eyes (approximately 44% reduction) as compared with the viscocanalostomy eyes (approximately 33% reduction) at both 12 ($P < 0.01$) and 18 months ($P = 0.04$), respectively. Final absolute IOP was not significantly different, although lower in the canaloplasty group (14.5 mm Hg) as compared with the viscocanalostomy group (16.1 mm Hg) at 18 months ($P = 0.24$).

Success criteria proposed by the World Glaucoma Association[18] are specified below and define a complete success as without antiglaucomatous medication and qualified success as including the use of 1 or 2 medications:

- $\geq 20\%$ IOP reduction and absolute IOP $\leq 21$ mm Hg for mild glaucomatous damage
- $\geq 30\%$ IOP decrease and $\leq 18$ mm Hg for moderate glaucomatous damage
- $\geq 40\%$ and $\leq 15$ mm Hg for advanced damage

Using the second criteria for moderate glaucomatous damage, the percentage of patients achieving a complete success in the canaloplasty cohort was 60.0% with 86.7% achieving a complete or qualified success. In the viscocanalostomy cohort, 35.7% of patients realized a complete success and 50.0% experienced a complete or qualified success.

**TABLE 1.** Demographic Data at Baseline

| | Canaloplasty | Viscocanalostomy |
|---|---|---|
| No. eyes | 15 | 15 |
| Age in years at time of surgery | | |
| Mean ± SD | 66.7 ± 8.8 | 66.8 ± 8.9 |
| Age range (y) | 50-80 | 50-80 |
| Sex | | |
| Male (%) | 6 (40) | |
| Female (%) | 9 (60) | |
| Race | | |
| White (%) | 15 (100) | |
| Glaucoma diagnosis by eye | | |
| Primary open angle (%) | 30 (100) | |
| Previous ocular surgery | | |
| Cataract (%) | 4 (26.7) | 5 (33.3) |
| At least 1 argon laser trabeculoplasty (%) | 4 (26.7) | 4 (26.7) |
| Laser peripheral iridotomy (%) | 1 (6.7) | |
| Trabeculectomy with adjunctive 5-fluorouracil (%) | 1 (6.7) | |

**TABLE 2.** Results

| | Canaloplasty | Visco-canalostomy |
|---|---|---|
| Baseline | | |
| Sample size | 15 | 15 |
| Mean IOP (mm Hg) ± SD | 26.5 ± 2.7 | 24.3 ± 2.8 |
| Mean no. medications ± SD | 2.1 ± 1.0 | 1.9 ± 0.8 |
| Visual acuity (in LogMAR) ± SD | 0.17 ± 0.18 | 0.17 ± 0.16 |
| 6 mo | | |
| Sample size | 15 | 15 |
| Mean IOP (mm Hg) ± SD | 14.3 ± 2.8 | 14.1 ± 3.2 |
| Mean no. medications ± SD | 0.1 ± 0.3 | 0.1 ± 0.3 |
| Visual acuity (in LogMAR) ± SD | 0.05 ± 0.11 | 0.09 ± 0.12 |
| 12 mo | | |
| Sample size | 15 | 15 |
| Mean IOP (mm Hg) ± SD | 14.7 ± 2.4 | 16.3 ± 3.2 |
| Mean no. medications ± SD | 0.1 ± 0.4 | 0.2 ± 0.4 |
| Visual acuity (in LogMAR) ± SD | 0.06 ± 0.12 | 0.05 ± 0.10 |
| 18 mo | | |
| Sample size | 15 | 14 |
| Mean IOP (mm Hg) ± SD | 14.5 ± 2.6 | 16.1 ± 3.9 |
| Mean no. medications ± SD | 0.3 ± 0.5 | 0.4 ± 0.5 |
| Visual acuity (in LogMAR) ± SD | 0.10 ± 0.15 | 0.12 ± 0.15 |

IOP indicates intraocular pressure.

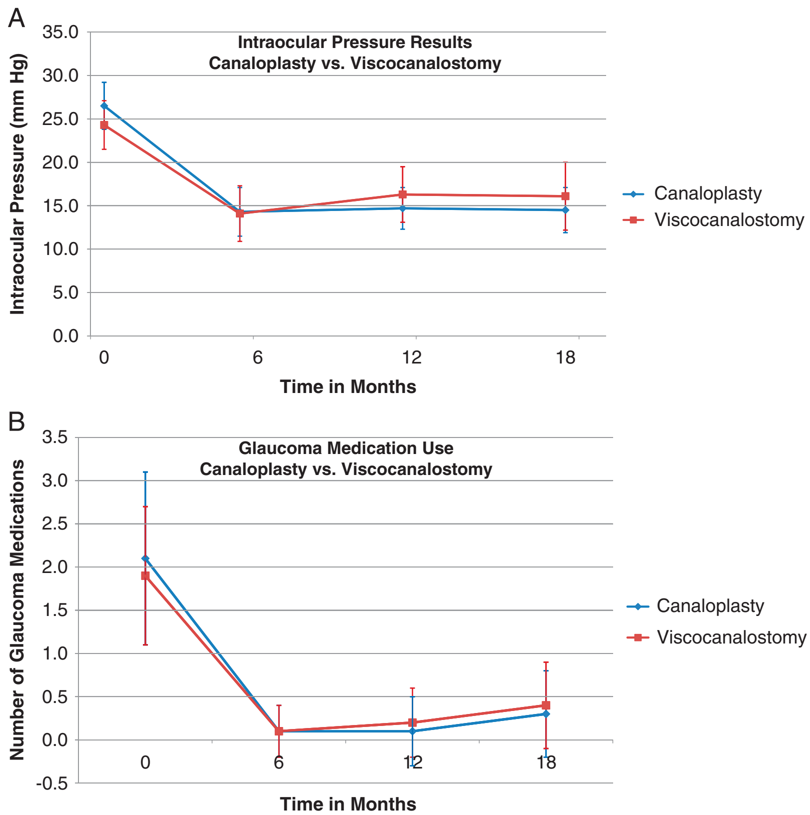


**FIGURE 3.** Graphs comparing efficacy outcomes of the canaloplasty and viscocanalostomy cohorts. A, This graph presents the intraocular pressure results. B, This graph shows the antiglaucomatous medication usage through 18 months. The bars represent one SD.

## Visual Acuity

Best corrected decimal visual acuities were converted to LogMAR values for analysis. Visual acuity results can be found in Table 2. On average there was no loss of visual acuity from either procedure as compared with baseline values at 6, 12, and 18 months postoperatively. For canaloplasty, there was a slight but statistically significant improvement at 6 and 12 months ($P<0.01$) but no significant improvement was shown at 18 months ($P=0.07$). For viscocanalostomy, there was no significant improvement at 6 months ($P=0.07$), a slight improvement at 12 months ($P<0.01$), and no significant improvement at 18 months ($P=0.27$). One eye from each study group (same patient) showed a loss of 0.2 LogMAR at 18 months owing to the progression of preexisting cataracts. Macular findings and perimetry in these patients were stable.

## Safety Analysis and Secondary Interventions

In the canaloplasty group, all patients experienced successful suture placement. At 18 months, biomicroscopy revealed the presence of a flat, diffuse subconjunctival bleb in 2 patients (13.3%) in the canaloplasty and 1 patient (6.7%) in the viscocanalostomy group. No adverse events occurred in any patient in either cohort. Additional interventions or surgical procedures, including goniopuncture, were not required in any eye in either study group.

## DISCUSSION

Owing to the desire to achieve IOP reduction in the safest possible manner, bleb-free procedures involving Schlemm canal are experiencing resurging interest. Bylsma[19] speculated that if the safety of glaucoma surgery could be improved significantly without sacrificing efficacy, surgical intervention might be considered earlier. In canaloplasty, the collector system may have a better chance of survival if intervention is undertaken earlier in the disease process, before the distal collector system collapses or before years of topical therapy create a less favorable environment for procedures that attempt to reestablish natural outflow.[5] In this case series, both the canaloplasty and viscocanalostomy proved effective in reducing IOP, with the canaloplasty showing greater efficacy in conjunction with an outstanding safety profile.

Peckar and Körber[20] conducted a retrospective study in which 97 eyes of 75 patients underwent primary canaloplasty for open-angle glaucoma and were compared with 120 eyes of 92 patients who had undergone primary viscocanalostomy. At 3 years postoperatively, both the canaloplasty and viscocanalostomy groups showed a statistically significant reduction in IOP and number of medications from preoperative levels. There was a statistically significant difference in favor of the canaloplasty group in the reduction of both IOP and number of medications as compared with the viscocanalostomy group (Mann-Whitney $U$ test 3940.5 and 4109.5, $P \leq 0.001$, respectively). In addition, there was a statistically significant difference in favor of the canaloplasty group in the number of patients achieving an IOP of ≤17 mm Hg ($t=2.55$, $P=0.001$) with 83% of patients achieving an IOP of ≤17 mm Hg with no medications and 87% with or without medications.

In this case series, there were no adverse events in either cohort either intraoperatively or postoperatively, although the small sample size limited the occurrence of uncommon events. Lewis et al[17] in the 2-year interim canaloplasty outcomes paper reported intraoperative adverse events in 3 of 127 eyes, including Descemet detachments in 2 eyes (1.6%), a temporary decrease in BCVA in 2 eyes (1.6%), and suture extrusion through a partial segment of the trabecular meshwork in 1 eye (0.8%). All of these adverse events were classified as mild in severity and probably related to the surgical procedure. At 1 day postoperatively, hyphema of 1 mm or greater was observed in 10 of 127 eyes (7.9%). With canaloplasty, it is not uncommon to observe a small amount of blood in the anterior chamber, likely owing to blood reflux into Schlemm canal which filters through the surgically created trabeculo-Descemetic window. In the early 3-month postoperative phase, 10 eyes (7.9%) had elevated, transient IOP ≥ 30 mm Hg. Wishart et al[21] postulated that some cases of early postoperative IOP spikes may be due to a steroid response and reduced the postoperative steroid regimen of patients in their study. One eye (0.8%) in the Lewis et al[17] study had hypotony secondary to a break in the trabeculo-Descemetic window during surgery, which resolved within 1 week. During the late postoperative phase, elevated IOP was reported in 3 eyes and suture erosion at the Descemetic window in 1 eye, which did not require treatment. In contrast, trabeculectomy has a reported incidence of hypotony ranging from 4% to 42%,[12,22–26] hyphema is reported in the range of 8% to 42%,[12,22,24–27] and choroidal detachment has been reported in the range of 1% to 29%.[12,26,27] Furthermore, late hypotony, bleb encapsulation with loss of IOP control, choroidal effusion or detachment, and blebitis/endophthalmitis are persistent concerns after trabeculectomy.[1]

In other studies involving canaloplasty and viscocanalostomy, the learning curve effect may have played a role in outcomes. The incidence of membrane perforations has been recognized as a significant indicator of an individual surgeon's experience in nonpenetrating techniques.[28] Kobayashi et al[13] reported intraoperative microperforation of Descemet membrane in 1 of 25 viscocanalostomy-treated eyes (4%). In this study, the investigator was proficient in both procedures with lengthy experience in identifying Schlemm canal and creating a trabeculo-Descemetic window through more than 600 viscocanalostomy surgeries before adopting canaloplasty. In this study, there were no microperforations or macroperforations. However, should a macroperforation with iris prolapse occur? A canaloplasty can still be performed with the addition of miochol, a peripheral iridectomy, and any additional procedures needed to reverse and prevent a subsequent iris prolapse.

In this study, all patients experienced successful tensioning suture placement in the canaloplasty cohort. Lewis et al[17] reported that successful suture placement was achieved in 85% of patients. The reasons for not achieving successful suture placement in the Lewis et al study were primarily owing to device/anatomical issues such as the microcatheter tip entering a collector channel ostium, an issue with the surgical dissection, or possible scarring in Schlemm canal. Prior argon laser trabeculoplasty, which has been associated with trabecular coagulative changes in eye bank eyes thought to lead to intracanalicular scarring,[29] can potentially render the canal more challenging to catheterize.

Subconjunctival bleb formation has been categorized as a postoperative complication in nonpenetrating glaucoma surgery and has been reported to occur in 5% to 51% of eyes in reports by Stegmann et al,[15] Carassa et al,[30] and Drüsedau et al.[31] In this case series, flat, diffuse blebs were observed in 2 patients in the canaloplasty cohort and 1 patient in the viscocanalostomy cohort at 18 months. Despite this bleb formation, no eyes in either the canaloplasty or viscocanalostomy groups developed hypotony or bleb-related complications. As compared with trabeculectomy, the postoperative management of both canaloplasty and viscocanalostomy was easier and the patient's quality of life less impacted as both procedures avoided bleb-related discomfort and required less postoperative follow-up, observations corroborated by Carassa et al.[30]

This study is unique in that it compares canaloplasty to viscocanalostomy between both eyes within the same patient. Assuming that both eyes of the same patient are fairly similar, patient-specific variables such as Schlemm canal location and morphology, trabecular meshwork morphology, and collector channel location and morphology are effectively similar between the canaloplasty and viscocanalostomy cohorts. In addition, the author's technique for canaloplasty essentially involves the same dissection to Schlemm canal, formation of the scleral lake, and creation of the Descemetic window as in viscocanalostomy. Therefore this study effectively compares the additional effects of the 2 major additional maneuvers associated with canaloplasty: (1) 360 degrees viscodilation of Schlemm canal with canaloplasty as opposed to partial dilation achieved with viscocanalostomy and (2) prolonged opening and tensioning of Schlemm canal with suture placement. The long-term benefits of canaloplasty over viscocanalostomy demonstrated here suggest that circumferential viscodilation and suture tensioning is beneficial to the restoration of aqueous outflow.

The limitations and potential biases of this case series included the lack of randomization and small sample size. In addition, included eyes having a preoperative IOP of ≥ 18 mm Hg may be more likely to benefit from a nonpenetrating procedure. In viscocanalostomy, the IOP showed a gradual increase after 6 months in comparison to canaloplasty where the IOP exhibited greater stability. This finding is substantiated by other studies exploring these procedures[6,7,16,17,32] and is potentially suggestive of a beneficial effect of circumferential treatment of Schlemm canal. This 18-month interim analysis revealed that the absolute postoperative IOP was significantly lower and the percentage reduction in IOP was significantly greater in the canaloplasty group as compared with the viscocanalostomy group. Both procedures proved to have excellent safety profiles and did not demand the close postoperative management generally required with trabeculectomy.

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