Circumferential viscodilation and tensioning of Schlemm canal (canaloplasty) with temporal clear corneal phacoemulsification cataract surgery for open-angle glaucoma and visually significant cataract

One-year results

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PURPOSE: To evaluate the safety and efficacy of circumferential viscodilation and tensioning of the inner wall of Schlemm canal, a new nonpenetrating surgical procedure (canaloplasty) to treat open-angle glaucoma (OAG), combined with clear corneal phacoemulsification and posterior chamber intraocular lens (IOL) implantation.

SETTING: Multicenter surgical sites.

METHODS: This international multicenter prospective study comprised adult patients with OAG having combined glaucoma and cataract surgery. Patients with qualifying treated preoperative intraocular pressure (IOP) of at least 21 mm Hg or higher and open angles were eligible. Evaluation was performed at baseline and 1 day, 1 week, and 1, 3, 6, and 12 months postoperatively. Intraoperative and postoperative high-resolution ultrasound imaging was used to assess Schlemm canal and anterior segment angle morphology, including distension of the trabecular meshwork due to the tensioning suture.

RESULTS: Data from 54 eyes that had combined glaucoma and cataract surgery performed by 11 surgeons at 9 study sites were analyzed for this interim analysis. The mean baseline IOP was 24.4 mm Hg $\pm$ 6.1 (SD) with a mean of 1.5 $\pm$ 1.0 medications per eye. In all eyes, the mean postoperative IOP was 13.6 $\pm$ 3.8 mm Hg at 1 month, 14.2 $\pm$ 3.6 mm Hg at 3 months, 13.0 $\pm$ 2.9 mm Hg at 6 months, and 13.7 $\pm$ 4.4 mm Hg at 12 months. Medication use dropped to a mean of 0.2 $\pm$ 0.4 per patient at 12 months. Surgical complications were reported in 5 eyes (9.3%) and included hyphema (n = 3, 5.6%), Descemet tear (n = 1, 1.9%), and iris prolapse (n = 1, 1.9%). Transient IOP elevation of more than 30 mm Hg was observed in 4 eyes (7.3%) 1 day postoperatively.

CONCLUSION: Circumferential viscodilation and tensioning of Schlemm canal combined with clear corneal phacoemulsification and posterior chamber IOL implantation was a safe and effective procedure to reduce IOP in adult patients with OAG.

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Combined surgery to treat both glaucoma and cataract has historically been of interest due to the frequent coincidence of the 2 conditions in older patients. The reduction in surgical trauma from 2 separate surgical procedures and the high incidence of cataract development after glaucoma surgery[1–3] are factors supporting the application of a combined procedure in appropriate patients.

Of particular interest is the combination of a nonpenetrating glaucoma surgical procedure with clear corneal cataract surgery. Typically, nonpenetrating glaucoma surgical methods have a lower postsurgical

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complication rate than trabeculectomy[4–10] and may complement the minimal complications and rapid visual recovery after clear corneal phacoemulsification and posterior chamber intraocular lens (IOL) implantation. A new nonpenetrating surgical approach involving microcatheter dilation of the entire circumference of Schlemm canal, in conjunction with placement of a trabecular tensioning suture in a procedure called canaloplasty, is being evaluated in adult patients with open-angle glaucoma (OAG).[11] The present analysis evaluated eyes treated by combined canaloplasty and clear corneal cataract surgery performed by 11 surgeons at 9 surgical sites, with postsurgical results up to 1 year.

PATIENTS AND METHODS

Design

This is an interim report of an ongoing international multicenter prospective open-label surgical study of canaloplasty at 14 clinical sites in the United States and Germany, with 16 surgeon–investigators, performed in accordance with the principles set forth in the Declaration of Helsinki. Combined canaloplasty and cataract surgery had been performed by 11 surgeons at 9 of the study sites. The study was designed to evaluate the safety and efficacy of using a microcatheter to dilate the entire length of Schlemm canal and to place a circumferential suture to tension the inner wall of the canal and associated trabecular meshwork to reduce intraocular pressure (IOP) in nonpenetrating surgery for open-angle glaucoma. The protocol was approved for each study site by the appropriate institutional review board or ethics committee. All patients (or their legal representative) read, signed, and dated a consent form before having a screening examination and participating in the study.

All enrollees had a single complete baseline ophthalmic examination within 60 days of surgery that included history of glaucoma, medication use, IOP, best corrected visual acuity (BCVA), gonioscopy, and slitlamp and fundus evaluations. At minimum, postoperative follow-up examinations were at 1 day, 1 week, and 1, 3, 6, and 12 months. Postoperative evaluations included IOP measurement, BCVA measurement, slitlamp examination, gonioscopy, ophthalmic medication reporting, and adverse event reporting. Reported IOP values are the mean of 2 measurements taken within a 60-minute period, when available. If the difference between the 2 readings was 4 mm Hg or greater, a third reading was taken. The presurgical and postsurgical medication regimen was investigator specific and recorded at each patient visit.

High-resolution ultrasound biomicroscopic (UBM) images were obtained using an 85 MHz center frequency system (iUltrasound, iScience Interventional) designed for intraoperative and office-based anterior segment imaging to characterize anterior angle morphology presurgery and postsurgery. At least 1 postoperative UBM examination was scheduled for each patient during the follow-up period to assess the role of anterior angle morphology on surgical outcomes.

Patient Inclusion and Exclusion Criteria

The study protocol was designed to allow flexibility in patient selection and treatment options to reflect the investigator's current practice of glaucoma surgery. Specifically, previous surgeries that would not interfere with complete circumferential catheterization of Schlemm canal were allowed. All patient enrollment and baseline examination case report forms were verified against the patient medical records by study monitors during the course of the study. Eyes that did not meet enrollment criteria during this verification were excluded from this analysis but were examined by the respective investigators for postoperative complications.

All patients were 18 years old or older at the time of enrollment, able to understand and provide informed consent, and scheduled for combined cataract and glaucoma surgery. Inclusion criteria in this study included a glaucoma diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, exfoliation glaucoma, or POAG with narrow but not occludable angles after laser iridectomy; a treated IOP of 16 mm Hg or higher taken at most 60 days before surgery (baseline); and a historical untreated IOP of 21 mm Hg or higher. For many patients on maximum tolerated medical therapy, the protocol was designed to allow them with need to withdraw from medications due to intolerance or poor compliance, provided they demonstrated historically recorded maximum IOP of 21 mm Hg or greater. Patients with more than 2 laser trabeculoplasty procedures, chronic uveitis, peripheral anterior synechias, or a history of angle closure were excluded. Only 1 eye per patient was eligible for inclusion in the study.

The primary endpoints included mean IOP and mean number of glaucoma medications at the 3-, 6-, and 12-month follow-up visits. Secondary endpoints included the use of glaucoma medications and visual acuity.

Surgical Technique

Temporal clear corneal phacoemulsification with posterior chamber IOL implantation was performed before the glaucoma procedure or after dissection of the sclera to access Schlemm canal. The surgeons followed traditional viscocanalostomy and deep sclerectomy methods for surgical access to the canal, with the additional use of the microcatheter to dilate Schlemm canal and install a trabecular tensioning 10-0 polypropylene suture (Prolene) (Figure 1). A Descemet window was formed at the surgical site, followed by excision of the deep flap and watertight closure of the superficial tissues to prevent bleb formation. Details of the surgical procedure and catheterization of the Schlemm canal have been described.[11]

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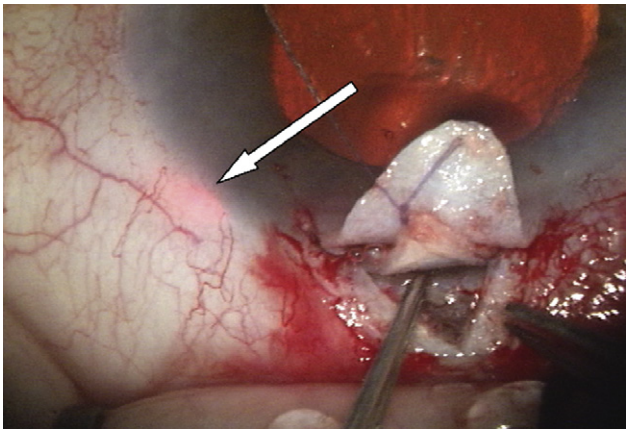

Figure 1. Catheterization of Schlemm canal with beacon tip visible through sclera (*arrow*).

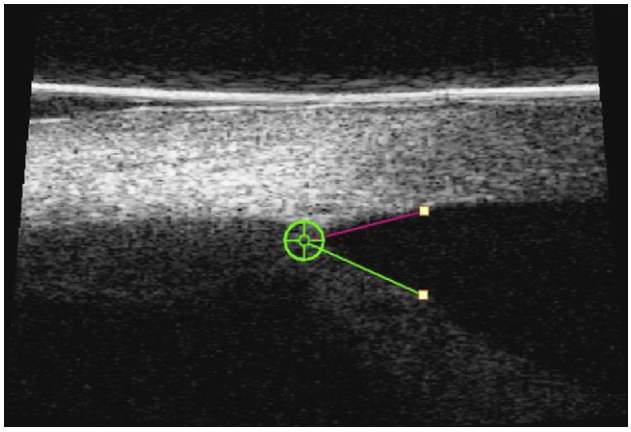

Figure 2. High-resolution UBM images of anterior chamber angle with protractor tool for measurement of angle width.

Intraocular Pressure Analysis

The IOP results were analyzed based on patients meeting the protocol inclusion/exclusion criteria and having combined canaloplasty and cataract surgery. Additional subgroups were analyzed to evaluate the results based on the presence of the tensioning suture, blebs, and the relationship of trabecular meshwork distension to IOP.

Ultrasound Biomicroscopic Imaging

Preoperative, intraoperative, and postoperative high-resolution UBM images of the anterior chamber angle and Schlemm canal were obtained from a nonrandom selection of patients and reviewed based on availability of the UBM systems. Images were collected for all 4 quadrants of the operative eye to assess viscodilation of Schlemm canal and distension of the trabecular meshwork from the tensioning suture (Figure 2). A mean distension score from 4 quadrants was calculated. The postsurgical images of the anterior segment angle were also evaluated for general angle morphology (Figure 3). Longitudinal follow-up by UBM assessing for change in suture position or movement was not conducted. The IOP results based on the placement of a trabecular tensioning suture were reviewed.

A previous analysis of eyes with the canaloplasty glaucoma procedure alone[11] found the acquired UBM images to be useful in analyzing whether there is correlation between the trabecular meshwork distension and IOP results. A semiquantitative grading scale of 0 to 3 based on exemplary images was used to evaluate the role of distension of the trabecular meshwork due to the tensioning suture.

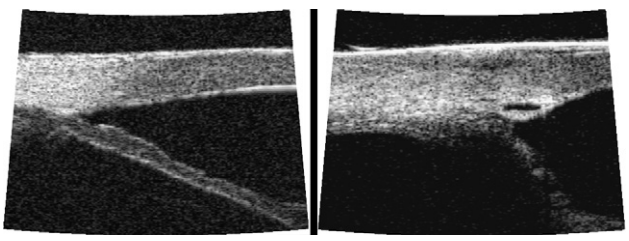

Figure 3. High-resolution UBM images of anterior chamber angle before and after canaloplasty showing dilation of Schlemm canal and location of tension suture.

Data Analysis

One-way analysis of variance (ANOVA) was performed on IOP and glaucoma medication results at all postoperative time points compared with baseline values. Comparison of the means for all pairs of the follow-up times was performed using the Tukey-Kramer correction adjusted for multiple comparisons. Individual pair-wise comparison of group means using the Student *t* test was performed for trabecular distension partitioned results and angle width obtained from UBM imaging.

RESULTS

Table 1 shows the patients' demographics. Of the 54 patients enrolled, 50 (93%) were white, 3 (6%) were of African descent, and 1 (2%) was Hispanic. In the 2 eyes (4) reported to have POAG with a narrow angle, the trabecular meshwork was visible on gonioscopy after laser iridectomy.

Successful circumferential catheterization of the canal was achieved in 44 eyes (81%), and tension sutures were successfully placed in 40 eyes (74%). No case of suture erosion through trabecular meshwork or sclera was noted during the follow-up. Although canaloplasty intends to yield a blebless procedure, 3 eyes (12%) had low subconjunctival blebs at 12 months.

In 1 case (26%), sutures were not placed. The reasons for not inserting a suture in Schlemm canal were divided into several categories. Most cases had device/anatomical issues such as the microcatheter tip entering a large collector channel or meeting other unknown factors for resistance during catheterization. No serious device-related adverse events were reported due to these occurrences. The procedural learning curve also contributed to the suture

Table 1. Patient characteristics.

Parameter	Value
Demographic	
Enrollees, n	54
Eyes, n	54
Sex, n (%)	
Female	32 (59)
Male	22 (41)
Mean age (y) ± SD	75.8 ± 10.0
White race, n (%)	51 (93)
Early termination, n (%)	2 (4)
Diagnosis, n (%)	
POAG	45 (83)
Pseudoexfoliation	7 (13)
POAG with narrow angle (not occludable)	2 (4)
Baseline	
IOP (mm Hg)	
Mean ± SD	24.4 ± 6.1
Range	16–38
Mean medications per pt ± SD	1.5 ± 1.0
Previous laser trabeculoplasty, n (%)	
Argon	5 (9)
Selective	5 (9)
Unspecified	1 (2)
Previous laser peripheral iridotomy	5 (9)

IOP = intraocular pressure; POAG = primary open-angle glaucoma; pt = patient

Table 2. Intraocular pressure results.

Exam	Mean IOP (mm Hg) ± SD (Range)	*P* Value*
Baseline (n = 54)	24.4 ± 6.1 (16–8)	—
Postoperative		
1 mo (n = 40)	13.6 ± 3.8 (6–22)	<.001†
3 mo (n = 41)	14.2 ± 3.6 (7–23)	<.001†
6 mo (n = 42)	13.0 ± 2.9 (8–21)	<.001†
12 mo (n = 25)	13.7 ± 4.4 (8–21)	<.001†

IOP = intraocular pressure
*Versus baseline
†Statistically significant at 0.05 level

placement success rate, and successful circumferential catheterization and suture placement increased with surgeon experience.

Two patients (4%) were lost to follow-up during the postoperative period. Due to technical difficulties, 1 eye (2%) was converted to trabeculectomy during the surgical procedure and 1 eye (2%) failed to complete the procedure. These 2 eyes were treated as early terminations. No eye received postoperative goniopuncture.

All enrolled eyes, including the 2 patients lost to follow-up, completed the 1-day, 1-week, and 1-month follow-up examinations. For the 3-month examination, 85% of eyes were examined and case report forms received for analysis. Due to the length of the patient enrollment period, not all eyes were due for examination at 6 and 12 months, resulting in 89% of eyes due for examination reported at 6 months and 74% of eyes reported at 12 months.

Intraocular Pressure Lowering

Table 2 shows the IOP results. The mean IOP decreased by 44% from baseline to 12 months postoperatively (Figure 4).

One-way ANOVA confirmed there was a statistically significant difference in IOP between baseline and the follow-up visits ($P<.0001$). Comparison of the means for all pairs of follow-up times using the Tukey-Kramer correction for multiple comparisons showed that the baseline was statistically different at the 0.05 significance level from each follow-up visit, including the 1-year follow-up.

Antiglaucoma Medication Results

The use of IOP-lowering medications was not discontinued before study enrollment. Of the 54 enrolled patients meeting inclusion/exclusion criteria, 10 (19%) were on 3 or more medications at baseline. At the 1-, 3-, 6-, and 12-month time points, no patient remained on glaucoma medical therapy of 3 or more medications (Table 3).

One-way ANOVA showed that differences in medication use were highly statistically significant from baseline ($P<.0001$). Comparison of the means for all pairs of follow-up times using the Tukey-Kramer correction for multiple comparisons showed that the baseline was statistically different at the 0.05 significance level from each follow-up visit, including the 1-year follow-up.

Ultrasound Biomicroscopic Imaging

High-resolution UBM images of the anterior angle and Schlemm canal were obtained and reviewed from 35 (88%) of 40 patients with sutures placed. Eyes with a tensioning suture within Schlemm canal had a lower mean IOP at 6 months (n = 31) and 12 months (n = 22) than eyes without a tensioning suture (n = 11 and n = 3, respectively). The differences were not statistically significant, however, possibly due to the lack of sufficient eyes for comparison. The 24 eyes with a tensioning suture and imaged trabecular

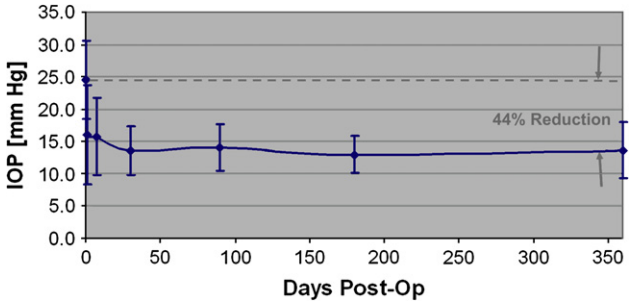

Figure 4. The IOP results (mean preoperative IOP of 24.4 mm Hg denoted by dashed line).

distension (distension grade ≥0.5) had a lower mean IOP and reduced medication use at 12 months than the 11 eyes with a tensioning suture and no imaged trabecular distension (grade <0.5). The reduced medication use was statistically significant ($P = .006$, t test); however, the difference in IOP was not statistically significant.

The mean angle width after combined surgery measured from UBM images was 29.4 degrees ± 14.0 (SD) (n = 23). For comparison, evaluation of available postoperative images of eyes in the noncombined surgery arm of the study showed a mean angle width of 14.4 ± 9.5 degrees (n = 8), a statistically significant difference ($P = .009$, t test).

Visual Acuity

The BCVA was reduced by 0.3 logMAR units or more from preoperative levels in 3 (7.7%) of 39 eyes at 1 month and in 0 of 25 eyes at 12 months (Table 4 and Figure 5). Overall, a mean improvement in BCVA of 0.21 logMAR was observed after 12 months.

Surgical and Postsurgical Complications

Table 5 shows the surgical and postoperative complications. Six surgical complications were reported in 5 (9.3%) of 54 eyes. One eye (1.9%) had a Descemet detachment that was related to the surgical procedure. The eye had a transient reduction in BCVA of 0.6 logMAR 1 day postoperatively; BCVA subsequently recovered to the baseline value by 1 month postoperatively. No hyphema or hypotony was associated with the detachment. No eye had hypotony. Microhyphema without layering of blood was observed in 15 (28.8%) of 52 eyes at the 1-day follow-up, which decreased to 2 (4.3%) of 47 eyes by 1 week and resolved in all eyes by 1 month.

The transient IOP elevation of more than 30 mm Hg in 4 eyes at 1 day was possibly related to clearance of the ophthalmic viscosurgical device (OVD) used surgically. The IOP elevation was resolved in all eyes by the 1-month examination. All nonocular adverse events were determined to be not related to the canaloplasty and cataract surgical procedures.

Table 3. Antiglaucoma medications required.

Exam	Mean Medications (n) ± SD	*P* Value*
Baseline (n = 54)	1.5 ± 1.0	—
Postoperative		
1 mo (n = 40)	0.1 ± 0.4	<.001†
3 mo (n = 41)	0.1 ± 0.3	<.001†
6 mo (n = 42)	0.1 ± 0.4	<.001†
12 mo (n = 25)	0.2 ± 0.4	<.001†

IOP = intraocular pressure
*Versus baseline
†Statistically significant at 0.05 level

Table 4. Visual acuity results.

Postop Exam	Mean BCVA (LogMAR) ± SD	Eyes with BCVA ≥0.3 LogMAR, n (%)
1 d (n = 49)	0.92 ± 0.88	23 (47.9)
1 wk (n = 47)	0.46 ± 0.39	12 (26.1)
1 mo (n = 39)	0.30 ± 0.41	3 (7.7)
3 mo (n = 40)	0.22 ± 0.36	2 (5.0)
6 mo (n = 42)	0.21 ± 0.37	2 (4.8)
12 mo (n = 25)	0.21 ± 0.41	0

BCVA = best corrected visual acuity

DISCUSSION

Canaloplasty is a new surgical procedure that attempts to lower IOP with few surgical complications using a nonpenetrating approach to restoring more natural aqueous outflow pathways. Canaloplasty is performed with the intent of increasing the flow of aqueous humor from the anterior chamber, through the trabecular meshwork and a Descemet window, into and around Schlemm canal and out through the

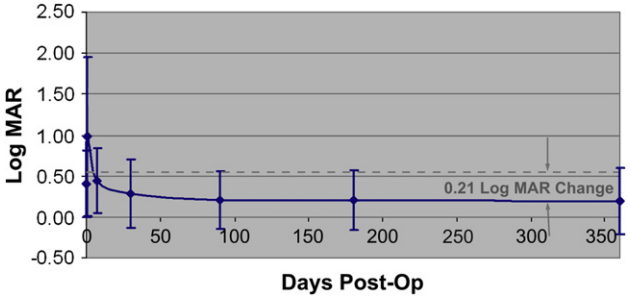

Figure 5. Visual acuity results (mean preoperative visual acuity of 0.42 logMAR equivalent denoted by dashed line).

Table 5. Surgical and postsurgical ocular-related complications.

Complication	Number of Eyes (%)
Gross hyphema	3 (5.6)
Microhyphema*	15 (28.0)
Descemet membrane detachment	1 (1.9)
Hypotony	0
Corneal edema	0
Iris prolapse	1 (1.9)
Wound hemorrhage	1 (1.9)

*n = 52

collector channels, thereby reducing IOP by restoring the trabeculocanalicular outflow pathway.

Our population had a mean preoperative IOP of 24.4 ± 6.1 mm Hg requiring a mean of 1.5 ± 1.0 glaucoma medications. Patients with advanced glaucoma and a need for extremely low postoperative IOP were not included in this study. Although it is difficult to compare absolute postoperative IOP levels in different studies that may have different patient populations and study methods, the IOP reduction after combined canaloplasty and cataract surgery 1 year postoperatively compares favorably with that reported for cataract surgery combined with other forms of glaucoma surgery. Comparative phacotrabeculectomy studies report 1-year postoperative IOP ranging from 11.0 to 15.5 mm Hg.[12–17] Combined deep sclerectomy and cataract studies report 1-year postoperative IOP in the range of 13.1 to 15.8 mm Hg,[18–20] and combined viscocanalostomy and cataract studies report 1-year postoperative IOP in the range of 15.0 to 15.9 mm Hg.[21–23]

Although the study investigators were new to Schlemm canal catheterization, dilation, and suture tensioning, surgical complications were limited and most resolved within 2 months of surgery. Microhyphema was an early transient finding, and gross hyphema was less common. It became apparent during the trial that avoiding profound hypotony during surgery was helpful in reducing the incidence of blood in the anterior chamber. After combined canaloplasty and cataract surgery, no eye had poor IOP control that required goniopuncture or subsequent conversion to trabeculectomy. Previous studies of trabeculectomy report rates for reoperation or additional procedures due to postoperative complications ranging from 3% in the first postoperative month[24] to 5% in the first year.[25]

A major advantage of a nonpenetrating surgical approach over trabeculectomy is the potential for fewer postoperative complications. As success in controlling IOP in canaloplasty is not believed to be dependent on formation of a bleb, immediate postoperative care does not require bleb massage or management of sutures to enhance flow. The incidence of hypotony after trabeculectomy is reported to be between 10% and 37%.[25–27] Hyphema as a postoperative complication in trabeculectomy is reported in the range of 8% to 42%.[24–27] The adverse events rate in the study eyes having combined canaloplasty and cataract surgery compares favorably with a 0% incidence rate of hypotony and 5.5% incidence of gross hyphema. However, 4 eyes (8.0%) had a transient spike in IOP to more than 30 mm Hg on postoperative day 1, possibly related to clearance of OVD from the anterior chamber. From the data available and presented here, the canaloplasty procedure appears to present a low surgical complication rate similar to that of the nonpenetrating glaucoma surgical procedures of deep sclerectomy and viscocanalostomy.[5,6,8–10,19,28,29] Although eyes having canaloplasty had a low occurrence of subconjunctival blebs and would therefore not be subjected to bleb-related late complications, it is not known whether other forms of late complications may occur after canaloplasty.

Combined trabeculectomy and cataract surgery has been extensively studied. Of most relevance are studies incorporating modern cataract surgery using phacoemulsification and small incisions through clear cornea. Studies of phacotrabeculectomy have demonstrated long-term benefit with IOP reduction.[12,13,30,31] However, some comparative studies of phacotrabeculectomy and trabeculectomy found greater IOP reduction with the noncombined procedure.[14,31–35] In contrast, nonpenetrating glaucoma surgery studies show a trend toward greater IOP reduction when combined with phacoemulsification cataract surgery. Randomized comparative studies[18,19] found deep sclerectomy combined with phacoemulsification cataract surgery led to lower IOP than deep sclerectomy alone. A nonrandomized study[36] found viscocanalostomy combined with phacoemulsification cataract surgery resulted in a trend of lower IOP but a similar percentage of IOP reduction.

The current clinical study of canaloplasty combined with phacoemulsification cataract surgery found a significantly greater IOP reduction in combined surgical cases than in cases of canaloplasty alone.[11] It has been well established that cataract surgery alone produces a postoperative reduction in IOP that ranges from approximately 1 to 5 mm Hg.[37–44] The IOP reduction appears to be sustained, with a recent study reporting an IOP reduction of 1.8 mm Hg in glaucomatous eyes 5 years after phacoemulsification and IOL implantation.[39] The mechanism of IOP reduction after cataract surgery has been postulated to be associated with increased outflow facility due to tensioning of the trabecular meshwork, reduced aqueous

production due to increased traction on the ciliary body by the zonular fibers, or alterations in the blood–aqueous barrier.[38–46] It is interesting that previously reported data on canaloplasty performed in phakic eyes showed a significantly greater reduction in IOP with observed distension of the trabecular meshwork from the intracanalicular tensioning suture.[11] The evaluation of a smaller sample of canaloplasty eyes that had combined cataract surgery lacked sufficient statistical power to examine for a difference in IOP reduction due to suture distension through 1-year follow-up. Although a significant reduction in medications was found at 12 months by the *t* test on the small data set, greater statistical power will be needed to elucidate the role of intracanalicular suture tension in combined cataract surgery.

There are several limitations to this study. First, although prospective, the study was not randomized with a control group present. Second, the learning curve inherent in any new surgical procedure plays a key role in the clinical outcomes. Sites with larger number of enrolled patients had greater success in identifying the canal, placing the tensioning suture, and providing sufficient trabecular tension to achieve the best results. Many questions remain regarding the proper degree of tension of the suture, long-term effect of the suture in the canal, and resultant microscopic changes in the outflow system morphology. The study design includes 5-year follow-up and further reporting with more extensive subgroup analysis was anticipated during the study. Additional studies to evaluate this new technique in relation to existing treatments as well as other types of glaucoma are recommended.

In conclusion, canaloplasty is a nonpenetrating glaucoma surgery that attempts to restore more natural outflow of aqueous within the eye. Interim analysis of a prospective clinical study indicates that the surgical procedure in combination with phacoemulsification and IOL implantation effectively lowers IOP with few complications and with continued control of IOP in patients followed up to 12 months. The use of a microcatheter in the procedure to access the entire circumference of Schlemm canal facilitates treatment of the trabeculocanalicular outflow system.

APPENDIX

Canaloplasty Clinical Investigators and Centers

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