Randomized Comparison of 1-Site and 2-Site Phacotrabeculectomy with 3-Year Follow-up

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Purpose: To compare intraocular pressure (IOP) control and other clinical outcomes after 1-site fornix-based and 2-site limbus-based phacotrabeculectomy.

Design: Prospective randomized controlled trial.

Participants: A total of 90 eyes of 76 patients with cataract and glaucoma were treated.

Methods: Forty-four eyes were assigned randomly to receive a 1-site phacotrabeculectomy with a fornix-based conjunctival flap, and 46 eyes were assigned randomly to receive a 2-site phacotrabeculectomy with a limbus-based conjunctival flap. All operations were performed with mitomycin C.

Main Outcome Measures: Intraocular pressure and number of antiglaucoma medications were recorded at baseline and during a 3-year follow-up period.

Results: Mean preoperative IOP was 20.1±3.8 mmHg in the 1-site group and 19.5±5.3 mmHg in the 2-site group ($P = 0.56$) using a mean of 2.3±0.9 and 2.5±0.9 antiglaucoma medications, respectively ($P = 0.27$). After 3 years of follow-up, the mean IOP was 12.6±4.8 mmHg in the 1-site group and 11.7±4.0 mmHg in the 2-site group ($P = 0.40$), receiving a mean of 0.3±0.7 and 0.4±0.9 medications, respectively ($P = 0.59$). At the end of the study, 73% of 1-site eyes and 78.4% of 2-site eyes had IOPs of less than 18 mmHg while receiving no antiglaucoma medications ($P = 0.59$). Visual acuity was similar for both groups at 3 months after surgery. There were no significant differences in the need for digital pressure, postoperative bleb needling with 5-fluorouracil, or number of postoperative visits. There were 2 major complications in each group during follow-up. Early leaks of the conjunctival wound closure occurred in 6 eyes in the 1-site group and in 0 eyes in the 2-site group ($P = 0.03$). Operating time (in minutes) was less in the 1-site surgery group ($P<0.0001$). Day one postoperative IOP was higher in the 2-site group ($P = 0.0.01$).

Conclusions: One-site fornix-based and 2-site limbus-based phacotrabeculectomy were similarly effective in lowering IOP and reducing the need for antiglaucoma medications over a 3-year follow-up period.
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The care of the patient with coexisting cataract and glaucoma often will include consideration of combined cataract and trabeculectomy surgery. Compared with extracapsular cataract extraction techniques, small-incision cataract surgery by phacoemulsification has improved long-term intraocular pressure (IOP) control in patients undergoing combined procedures.[1–3] In addition, the intraoperative and postoperative use of antimetabolites such as mitomycin C and 5-fluorouracil have been shown convincingly to produce lower IOPs after phacotrabeculectomy.[3–6]

In addition to the decision to use antimetabolites, the surgeon considering phacotrabeculectomy for a patient has 2 major choices to make regarding the surgical strategy. The first is the location of the surgical incision for the cataract extraction, and the second is the location of the conjunctival incision for the trabeculectomy. The earliest clinical studies of phacotrabeculectomy reported surgical results using the same superior scleral incision for both the phacoemulsification and trabeculectomy parts of the operation.[1,2,4–8] This technique is known as a 1-site phacotrabeculectomy. The introduction of the temporal incision for phacoemulsification has allowed surgeons to perform 2-site phacotrabeculectomy, with a second, superior incision created for the trabeculectomy.[9–11] In favor of the latter method, it has been argued that separating the phacoemulsification incision

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from the trabeculectomy incision reduces postoperative scarring of the scleral flap and conjunctiva and improves the results of the filtration surgery.[10–14] Some surgeons also believe that a temporal cataract incision affords better visualization of and surgical access to the eye, especially in patients with difficult orbital anatomic features.[14,15]

At the time this study was conceived, the standard technique for phacotrabeculectomy in the authors' practice was a 1-site procedure with a fornix-based trabeculectomy. They found this to be a fast and effective surgery. However for trabeculectomy alone, their standard operation was a limbus-based approach. To determine whether a 2-site phacotrabeculectomy is better for their patients, they decided to compare the 1-site fornix-based phacotrabeculectomy with a 2-site approach combining temporal phacoemulsification with their preferred limbus-based trabeculectomy procedure. To obtain the most reliable data, they compared and evaluated the clinical results of these 2 techniques in a prospective, randomized trial.

Patients and Methods

The clinical outcomes of 1-site and 2-site phacotrabeculectomy were compared in a 3-year, randomized, controlled clinical trial. Patients were recruited and enrolled at the Ophthalmology Department of the Lahey Clinic. All operations were performed by 2 surgeons (PC or SR) at the Lahey Clinic surgicenter. The protocol was reviewed and approved by the Institutional Review Board of the Lahey Clinic and was conducted according to the Declaration of Helsinki. All patients gave written, informed consent to the study.

Patient Enrollment and Treatment Assignment

Criteria for inclusion in the study were the presence of visually significant cataract and open-angle or combined-mechanism glaucoma in the same eye with inadequate control of IOP or requiring 2 or more antiglaucoma medications. All eyes had to have had an IOP of more than 21 mmHg on at least 1 previous examination. Other exclusion criteria were the presence of neovascularization of the iris or angle, a history of uveitis, phacolytic or phacomorphic glaucoma, steroid-induced glaucoma, traumatic glaucoma, or previous incisional surgery in the same eye. Patients older than 89 years were not included. The authors did not enroll patients with known conditions (e.g., macular degeneration) that would be likely to affect visual acuity. To avoid selection bias, every consecutive patient meeting the inclusion and exclusion criteria was invited to participate throughout the enrollment period. Patients meeting enrollment criteria were assigned to receive either a 1-site or a 2-site phacotrabeculectomy at the beginning of the surgeon's block time on the day of the procedure. The assignment was performed based on simple randomization, and allocation concealment was carried out using numbered opaque envelopes prepared by an independent research monitor. Patients who had both eyes included in the study had their second eye assigned randomly, and it was analyzed separately. Patients could choose to withdraw from the study at any time. If patients were lost to follow-up during the study, data would be included for analysis up to the date of the last visit. All patients signed standard hospital forms consenting to cataract and glaucoma surgery in addition to the research consent forms.

Procedures

All operated eyes received peribulbar anesthesia with 2% lidocaine without epinephrine and 0.75% bupivacaine. Pupils were dilated with topical cyclopentolate 1% and phenylephrine 2.5%. For the 1-site surgery, a 6-0 silk suture was placed under the superior rectus muscle and was used to rotate the globe inferiorly. A superior fornix-based conjunctival flap was made by incising the conjunctiva at the limbus and dissecting posteriorly. This flap was centered at 12 o'clock and was approximately 6 mm in chord length. Electrocautery was used to control episcleral bleeding. A limited tenonectomy was performed in most patients. Beginning with a groove made 2.5 mm posterior to the limbus, a 3.5-mm wide partial thickness scleral tunnel into clear cornea was fashioned using a crescent knife. Radial cuts then were made with scissors at the sides of the tunnel to create a flap. A 4-mm^2 and 0.5-mm thick cellulose sponge was soaked in mitomycin C (MMC; 0.4 mg/ml) and was placed under the scleral flap for 2 minutes. The edge of the conjunctival flap was elevated with forceps to avoid contact with the MMC. After removal of the sponge, the ocular surface was rinsed with balanced salt solution. A paracentesis then was performed, followed by injection of a viscoelastic. A shelved entry into the anterior chamber under the scleral flap was made using a 2.8-mm diamond keratome blade. Phacoemulsification then was performed. When necessary in cases of small pupils, 4 flexible iris retractors were used. After cortical aspiration and reformation of the anterior chamber with viscoelastic, the wound was enlarged slightly with a crescent knife. A 3-piece foldable acrylic intraocular lens was inserted into the capsular bag. After aspiration of all viscoelastic and injection of acetylcholine to constrict the pupil, a Descemet punch was used to create a 1.0-mm diameter sclerostomy under the scleral flap. A small basal iridectomy was performed in all cases. The scleral flap then was closed with 4 interrupted 10-0 nylon sutures with tension adjusted for minimal spontaneous filtration. The conjunctival incision was closed by passing sutures of 10-0 nylon into limbal cornea at 10 o'clock and 2 o'clock. The anterior edge of the conjunctiva was advanced at least 1 mm over the cornea to decrease the risk of leakage. Fluorescein was used to test for wound leaks. A subconjunctival injection of dexamethasone and cefazolin solution (0.5 ml) was performed inferiorly. Drops of apraclonidine 1% and pilocarpine 1% were applied to the cornea before placement of a patch and shield. A single 500-mg dose of oral acetazolamide was given in the recovery room to every patient unless a sulfa allergy was documented.

Two-site surgery began with the surgeon seated temporally. A paracentesis was made, followed by injection of viscoelastic. A temporal clear corneal incision was made with a 2.8-mm diamond keratome. Phacoemulsification and intraocular lens implantation then was performed as described for the 1-site surgery. Although the incisions were self-sealing, a single 10-0 nylon suture was tied across the cataract wound to provide extra security. The surgeon then switched position and was seated superiorly for the trabeculectomy. A 6-0 silk suture was passed through superior corneal tissue to rotate the globe downward and laterally. A limbus-based conjunctival flap was created in the supranasal quadrant starting with an incision 8 mm posterior to the limbus. A limited tenonectomy was performed in most cases. After applying light electrocautery and exposing the conjunctival insertion anteriorly at the limbus, a 2.5×3.5-mm scleral flap was fashioned as described for the 1-site surgery. Mitomycin C application and rinsing was performed in the same manner as for the 1-site phacotrabeculectomy. With a crescent knife under the scleral flap, the dissection then was advanced into clear cornea. The anterior chamber was entered with a diamond knife under the anterior hinge of the scleral flap. The sclerostomy, iridectomy, and scleral flap closure were performed

in the same manner as for the 1-site surgery. The conjunctival wound was closed with 9-0 polygalactin suture on a vascular needle using a running technique. The bleb was elevated with gentle pressure on the scleral flap, and the wound was tested for leakage with fluorescein. Injections and topical medications then were administered as with the 1-site eyes.

The postoperative regimen for both groups of eyes was identical. A topical antibiotic and a topical nonsteroidal antiinflammatory medication were given 4 times daily for 1 week. Topical corticosteroids were used every 2 to 3 hours for the first week and then were tapered slowly, remaining at 4 times daily for the first month, and then reduced gradually and usually discontinued by the end of 4 months. Adjunctive topical and oral antiglaucoma medications were used as needed for the first 1 or 2 weeks, but thereafter typically were discontinued after laser suture lysis and establishment of aqueous filtration. All patients were examined the day after surgery, and then every week up to 1 month. Subsequently, patients were seen as needed up to the 3 month follow-up, generally every 2 to 4 weeks. Thereafter, patients were seen every 3 months for the first year, and then every 3 to 6 months for the last 2 years of follow-up. During follow-up, supplemental antiglaucoma medications were added at the investigator's discretion.

Data Collection

Baseline data were recorded from the last complete examination before surgery. This included IOP by Goldmann applanation tonometry and the number of topical and oral antiglaucoma medications used by the patient. The timolol and dorzolamide combination was considered to be 2 medications. Best-corrected visual acuity was measured by the Snellen method and then was converted to decimal form for analysis. Other information collected before surgery included age, gender, and ethnicity, diagnostic type of glaucoma, and history of previous laser trabeculoplasty or iridotomy. Data collected during surgery included operative time, use of pupil-stretching techniques, and complications. Because of the obvious differences in ocular appearance after the 2 different procedures, it was not possible to mask the clinical observers who obtained follow-up data to the type of surgery performed. Data collected at each postoperative visit included IOP and the number of supplemental antiglaucoma medications. Best-corrected visual acuity, occurrence and nature of any complications, and use of laser suture lysis, adjunctive bleb needling with 5-fluorouracil, and digital massage also were recorded. Information was entered onto standard data collection forms as well as into the hospital medical record. Source data verification was performed by an independent study monitor who copied and collected all patient records from 8 weeks before surgery through the end of the end of the study period, including the operative note.

Statistical Analysis

The study was primarily designed to test for differences in postoperative IOP and number of antiglaucoma medications needed to control IOP between the two surgical procedures. An additional outcome of interest was created for those completing the 36-month follow-up; eyes were categorized into 4 groups: those with IOP less than 13 mmHg while receiving no antiglaucoma medications, those with IOP less than 18 mmHg while receiving no medications, those with IOP less than 21 mmHg while receiving 0 or 1 medications, and those with IOP more than 20 mmHg while receiving 2 or more medications.

The initial power calculations showed that a sample size of 64 eyes per group would detect a 2-mmHg difference between groups, which was judged to be clinically significant. Given the actual sample sizes at 1, 2, and 3 years and an α error of 0.05, the study had 80% power to detect a 2.5-, 2.5-, and 2.7-mmHg difference in mean IOP between groups at 1, 2, and 3 years, respectively.

For comparisons between groups at the patient level, the t test and chi-square test were used for continuous and categorical variables, respectively. For categorical variables, when appropriate the Fisher exact test was used. For comparisons at the eye level, the repeated measures analysis of variance was used for continuous variables, whereas generalized estimating equations were used for categorical (i.e., binary) variables. Generalized estimating equations were used to account for the inclusion of both eyes in some subjects. A P value of less than 0.05 (2 sided) was considered statistically significant.

Results

Ninety-three eyes of 79 patients met the inclusion criteria and were enrolled in the study. Figure 1 (available at http://aaojournal.org) is a flow chart showing the disposition of all study subjects. One patient died before his operative date, and 2 patients decided not to undergo surgery. Seventy-six participants had their eyes randomized to 1 of the 2 procedures and underwent surgery according to the study protocol. Fourteen subjects had both eyes enrolled in the study, which were independently randomized and analyzed. Nine of these patients had different procedures in each eye. Two patients had both eyes randomized to 1-site surgery, and 3 patients had both eyes randomized to 2-site surgery. The treatment was administered according to the random assignment in all eyes: 44 eyes received 1-site surgery and 46 eyes received 2-site surgery. One eye in the 1-site group and 2 eyes in the 2-site group were withdrawn from the study immediately after surgery because the planned procedure could not be completed because of intraoperative complications. In all 3 of these cases, iris retractors had been used because of poorly dilating pupils (2 with pseudoexfoliation and 1 with chronic miotic use), and vitreous loss occurred. In 1 additional eye that was randomized to 2-site surgery, the trabeculectomy was not performed because of patient discomfort. Data from these 4 eyes were not analyzed for this report. After taking into account these exclusions, 43 eyes in each group were used for analysis of preoperative and postoperative data. The baseline characteristics of each group are summarized in Table 1 and confirm that the 2 groups were similar in age, gender, ethnicity, glaucoma diagnosis, history of laser treatment, and visual acuity ($P>0.05$). During the 3-year postoperative observation period, 6 additional eyes in each group were withdrawn from the study. One diabetic patient in the 1-site group was noted to have neovascularization of the iris and angle within 1 month of the phacotrabeculectomy. It was determined that this patient's glaucoma had been classified incorrectly, and the eye was therefore withdrawn from the study. All other dropouts were the result of death or losses to follow-up. Data from these 12 eyes were included in the analyses up to the time of dropout. A total of 74 eyes (37 in each group) completed the full 3 years of planned follow-up.

Figure 2 shows the mean IOPs in the 1-site and 2-site phacotrabeculectomy groups at all time points. Mean preoperative IOPs were similar in both groups ($P = 0.56$), and there were no significant differences between the groups at 3, 6, 12, 18, 24, 30, or 36 months after surgery. Figure 3 shows the mean number of supplemental antiglaucoma medications needed in both groups before surgery and during follow-up. There were no significant differences between groups at any of the time points. Table 2 shows mean IOP, mean number of antiglaucoma medications, and number of eyes receiving antiglaucoma medication for both groups before surgery and at the final 3-year follow-up. Each group had a significant decrease in mean IOP during this interval ($P<0.0001$) and also a significant reduction in the requirement for supplemen-

Table 1. Baseline Characteristics for Groups Treated with 1-Site or 2-Site Phacotrabeculectomy

	1-Site Group (%)	2-Site Group (%)	*P* Value
Patient demographics, no. of patients	41	40	
Age, yrs (mean±SD)	75.1 ± 5.8	75.8 ± 7.5	0.65
Range, yrs	64–88	57–89	
Female gender	28 (68.3)	22 (55.0)	0.26
White race	41 (100)	40 (100)	1.0
Diabetic	8 (19.5)	7 (17.5)	0.79
Ocular characteristics, no. of eyes	43*	43	
Glaucoma diagnosis			0.45
POAG	24 (55.8)	26 (60.5)	
PXFG	14 (32.6)	10 (23.2)	
CMG	4 (9.3)	7 (16.3)	
PG	1 (2.3)	0 (0)	
Previous ALT	12 (27.9)	11 (25.6)	0.94
Previous LI	5 (11.6)	6 (13.9)	0.75

ALT = argon laser photocoagulation; CMG = combined mechanism glaucoma; LI = laser iridotomy; PG = pigmentary glaucoma; POAG = primary open-angle glaucoma; PXFG = pseudoexfoliative glaucoma; SD = standard deviation.
*Values for n differ for patient and ocular data because 2 subjects in the 1-site group and 3 subjects in the 2-site group had both eyes randomized to the same treatment.

tal antiglaucoma medications ($P<0.0001$). There were no differences noted at the final 3-year visit between the 1-site and the 2-site group in mean IOP ($P = 0.40$), in mean number of antiglaucoma medications ($P = 0.59$), or in the percentage of patients requiring such medication ($P = 1.0$). Table 2 also gives the results of the outcome analysis of 74 eyes of the 60 patients that completed 3 years of follow-up. Seventy-three percent of eyes in the 1-site group and 78.4% of eyes in the 2-site group had IOPs of less than 18 mmHg while receiving no antiglaucoma medication ($P = 0.59$). There were also no significant differences noted between the 2 groups in the proportion of eyes with IOPs of less than 13 mmHg while receiving no medications ($P = 0.10$), IOP of less than 21 mmHg while receiving 0 or 1 medication ($P = 0.72$), or IOP of more than 20 mmHg while receiving 2 or more medications ($P = 0.72$).

Table 3 shows the comparison of the secondary outcome measures between groups. Corrected visual acuity improved markedly in both groups after surgery, and 3 months after surgery, there was no statistically significant difference noted between groups (0.70 in 1-site eyes vs. 0.79 in 2-site eyes; $P = 0.09$). Operating time was significantly shorter in the 1-site group (60.1 vs. 83.4 minutes; $P<0.0001$). The IOP on the first postoperative day was significantly higher in the 2-site eyes (23.9 vs. 16.0 mmHg; $P = 0.01$). The number of outpatient visits needed within the first 3 months was similar (9.0 in 1-site eyes vs. 8.8 in 2-site eyes; $P = 0.67$), as were the number of eyes needing laser suture lysis ($P = 0.16$), the number of eyes requiring bleb needling with 5-fluorouracil ($P = 0.61$), and the proportion of eyes needing digital massage ($P = 0.40$).

Table 4 compares the complications observed during the follow-up period in the 2 surgical groups. Two patients in each group returned to the operating room for a major reoperation. In the 1-site group, there was one case of hypotony maculopathy requiring resuturing of the scleral flap and choroidal drainage and 1 eye with a transient shallow anterior chamber in which corneal edema developed and that underwent penetrating keratoplasty. In the 2-site group, 1 patient had a persistent late bleb leak, and a bleb revision was performed 29 months after surgery. A second patient in the 2-site group had a bleb leak and blebitis 33 months after surgery. The infection was successfully treated medically followed by a conjunctival advancement procedure. This was the only case of blebitis seen in the study.

Early conjunctival wound leaks occurred in 6 eyes, all in the 1-site group ($P = 0.03$). Four of these were repaired by bandage contact lens application or by resuturing at the slit lamp, and functional filtering blebs developed in these eyes; the other 2 eyes were resutured in the minor procedure room, and 1 of these blebs failed. There were no late bleb leaks in the 1-site group and 2 late bleb leaks in the 2-site group ($P = 0.49$); these bleb leaks required bleb revision as discussed previously. Early postoperative hypotony was seen in 8 eyes (18.6%) in the 1-site group and in 5 eyes (11.6%) in the 2-site group; late hypotony was noted in 3 eyes (6.9%) in each group. These differences were not significant. A small number of cases of hyphema, choroidal effusion, and Tenon's cysts occurred in both groups.

Discussion

The authors believe this to be the largest prospective, randomized, long-term study comparing 1-site and 2-site phacotrabeculectomy techniques. It is also, to their knowledge, the only study that has compared a 1-site fornix-based procedure with a 2-site limbus-based procedure. Overall, no significant difference was observed in the main outcome measures of IOP and need for supplemental antiglaucoma medications between the 2 groups. Both surgical strategies were effective in reducing IOP, and the mean IOP levels remained stable during the 3 years of follow-up. Both procedures also were able to eliminate the need for antiglaucoma medications in most eyes over the entire study period. These results suggest that bleb function was maintained in a high proportion of all operated eyes. Although the appearance of filtering blebs was not used as an outcome measure, all of the eyes that had an IOP of less than 18 mmHg and were receiving no medications at the 3-year follow-up had visibly elevated blebs.

These data also confirm that phacotrabeculectomy, using either a 1-site or a 2-site technique, is a relatively safe procedure. The numbers of serious intraoperative and postoperative complications were few. The 3 intraoperative complications occurred in higher risk eyes with small pupils or pseudoexfoliation, and only 4.6% of eyes required reoperation during 3 years of follow-up, an equal number in each group. There was 1 case of hypotony maculopathy with persistent loss of visual acuity and 1 case of blebitis that did not progress to endophthalmitis.

Although the 2 procedures seem to be equivalent in terms of the IOP control, reduction in need for antiglaucoma medications, and improvement in visual acuity, there were some significant differences noted between the treatment groups. As would be expected from the need to change surgeon position and to perform the more difficult limbus-based dissection, the 2-site operation took longer to perform than the 1-site procedure. In addition, the 2-site eyes had higher mean IOP on the first postoperative day. The authors postulate that the 1-site incision was manipulated more

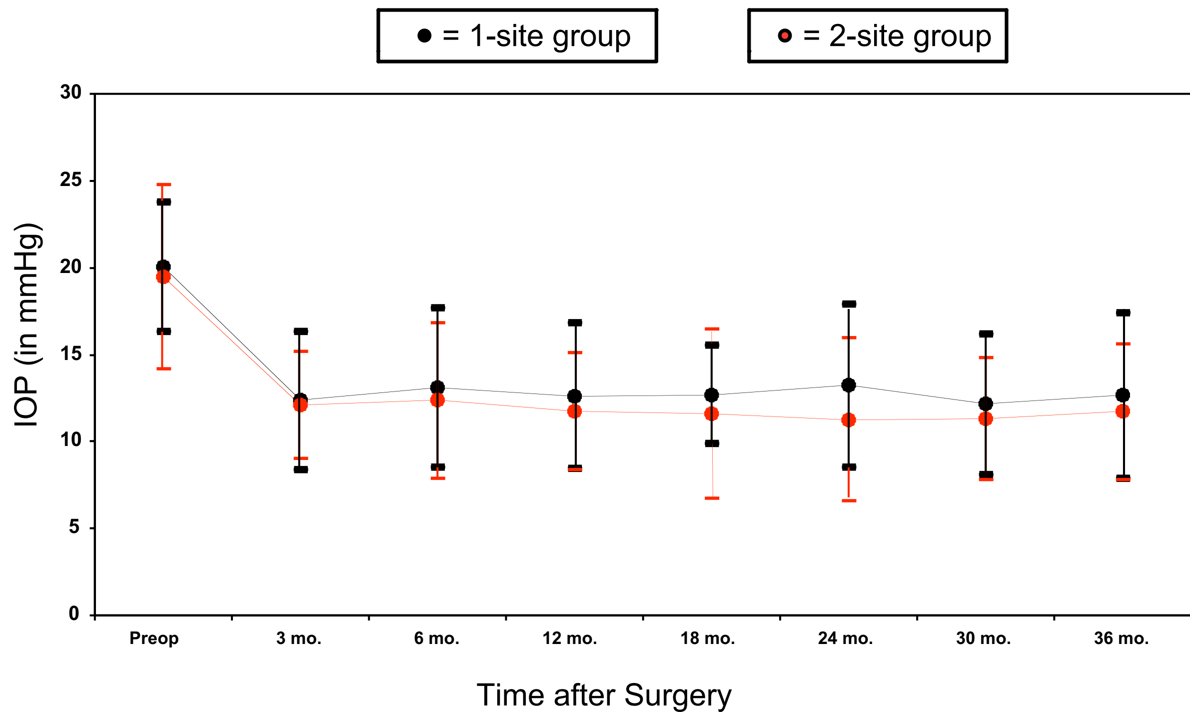

Figure 2. Graph showing the average intraocular pressure (IOP) after 1-site or 2-site phacotrabeculectomy. The mean preoperative IOP of 20.1±3.8 mmHg and 19.5±5.3 mmHg (*P* = 0.56) were reduced to 13.1±4.6 mmHg and 12.4±4.5 mmHg at 6 months after surgery (*P* = 0.50), 12.6±4.2 mmHg and 11.7±3.2 mmHg at 12 months after surgery (*P* = 0.32), 13.2±4.7 mmHg and 11.3±4.2 mmHg at 24 months after surgery (*P* = 0.09), and 12.6±4.8 mmHg and 11.7±4.0 mmHg at 36 months after surgery (*P* = 0.39) in eyes treated with the 1-site and 2-site procedures, respectively. Vertical bars, standard deviation.

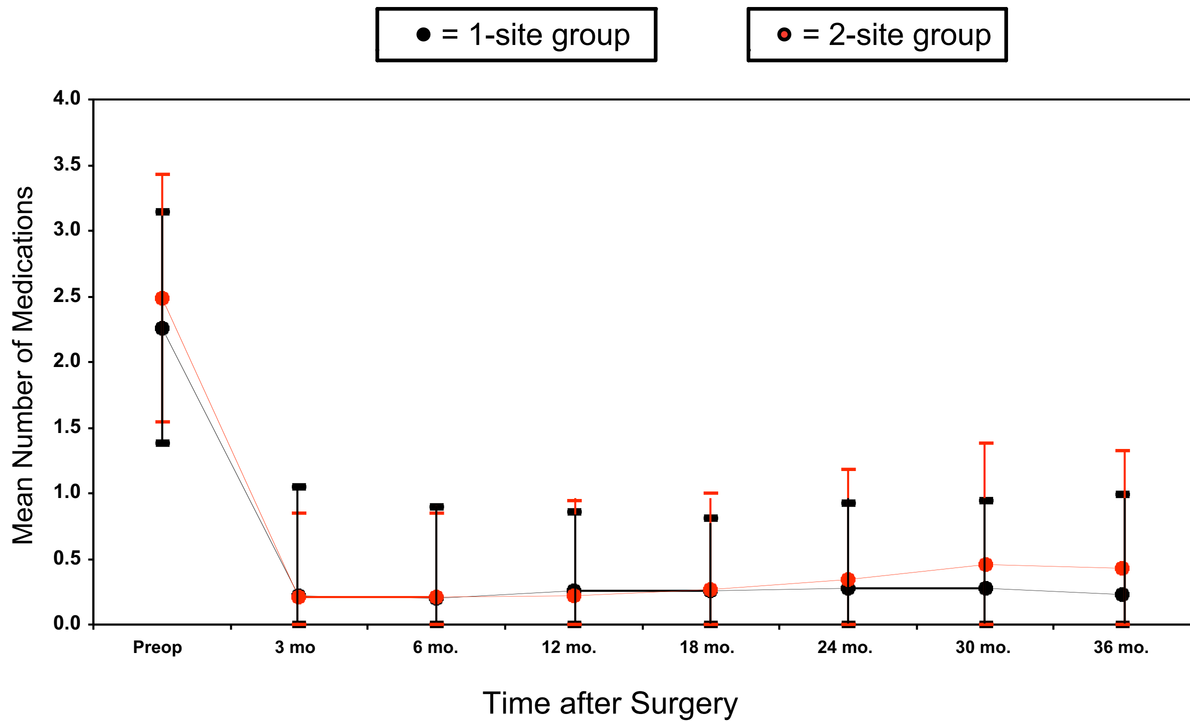

Figure 3. Graph showing the average number of antiglaucoma medications used after 1-site or 2-site phacotrabeculectomy. The mean preoperative medication requirements of 2.3±0.9 and 2.5±0.9 (*P* = 0.29) were reduced to 0.21±0.7 and 0.24±0.6 at 6 months after surgery (*P* = 0.84), 0.30±0.6 and 0.22±0.7 at 12 months after surgery (*P* = 0.59), 0.28±0.7 and 0.34±0.9 at 24 months after surgery (*P* = 0.74), and 0.30±0.7 and 0.41±0.9 at 36 months after surgery (*P* = 0.59) in eyes treated with the 1-site and 2-site procedures, respectively. Vertical bars, standard deviation.

Table 2. Comparison of Preoperative and 3-Year Postoperative Data in Eyes Treated with 1-Site or 2-Site Phacotrabeculectomy

	1-Site	2-Site	*P* Value
Preoperative, no. patients	43	43	
Mean IOP±SD (mmHg)	20.1 ± 3.8	19.5 ± 5.3	0.56
Mean no. of glaucoma medications±SD	2.3 ± 0.9	2.5 ± 0.9	0.27
No. of eyes receiving medication (%)	42 (97.7)	42 (97.7)	1.00
36 months after surgery, no. patients	37	37	
Mean IOP (mmHg)	12.6 ± 4.8	11.7 ± 4.0	0.40
Mean no. glaucoma medications	0.3 ± 0.7	0.4 ± 0.9	0.59
No. of eyes receiving medications	7 (18.9)	7 (18.9)	1.00
No. of eyes with IOP<13 mmHg and receiving no medications	14 (37.8)	21 (56.8)	0.10
No. of eyes with IOP<18 mmHg and receiving no medications	27 (73.0)	29 (78.4)	0.59
No. of eyes with IOP<21 mmHg and receiving 0 or 1 medication	33 (89.2)	32 (86.5)	0.72
No. of eyes with IOP>20 mmHg or receiving 2 or more medications	4 (10.8)	5 (13.6)	0.72

IOP = intraocular pressure; SD = standard deviation.

extensively during surgery and was enlarged to approximately 3 mm to allow for insertion of the intraocular lens; these factors could have caused more aqueous leakage in the immediate postoperative period. Another significant difference between groups was in the higher frequency of early conjunctival leaks at the limbus noted in the 1-site eyes; the authors found, however, that these leaks were repaired readily and resulted in a bleb failure in only 1 case. Other authors have noted the greater likelihood of conjunctival leaks in the fornix-based trabeculectomy technique compared with the limbus-based operation.[16–20] Modification of the conjunctival closure technique for fornix-based trabeculectomy, as recently described, may reduce the frequency of this problem.[21,22]

As noted by Jampel et al[3,23] in their comprehensive reviews of the literature on combined cataract and glaucoma surgery up to 2002, there have been only 3 high-quality randomized studies comparing 1-site and 2-site phacotrabeculectomy techniques. Borggrefe et al[12] compared 1-site and 2-site phacotrabeculectomy in 50 eyes of white patients using a fornix-based conjunctival flap in both groups but no intraoperative antimetabolites. With an average follow-up of 19 months, they reported a mean IOP in the 2-site group of 15.0 mmHg versus 16.8 mmHg in the 1-site eyes but, perhaps because of the small sample size, this difference was not statistically significant. Compared with their study, this study resulted in lower mean postoperative IOPs in both treatment groups, which may be the result of the use of antimetabolites in all cases.

El Sayyad et al[14] compared a fornix-based 1-site phacotrabeculectomy with a fornix-based 2-site phacotrabeculectomy in 76 eyes. In their study, which included a 5-minute intraoperative application of MMC, the 2-site group had a significantly lower mean IOP at 12 months (17.0 vs. 19.1 mmHg for the 1-site eyes; $P = 0.044$). In the present study, the 12-month results revealed a mean IOP of 12.6 and 11.7 mmHg in the 1-site and 2-site groups, respectively, which

Table 3. Comparison of Secondary Outcomes in Eyes Treated with 1-Site or 2-Site Phacotrabeculectomy

Secondary Outcome	1-Site (n = 43)	2-Site (n = 43)	*P* Value
Mean±SD preoperative visual acuity (decimal)	0.35 ± 0.15	0.29 ± 0.14	0.09
Mean±SD 3-month postoperative visual acuity	0.70 ± 0.22	0.79 ± 0.21	0.09
Mean operative time (minutes)	60.1 ± 11.1	83.4 ± 12.9	<0.0001
Mean±SD IOP on first postoperative day	16.3 ± 10.7	23.9 ± 11.9	0.01
Mean no. of postoperative visits (first 3 mos)	9.0 ± 2.4	8.8 ± 2.4	0.67
No. of eyes needing laser suture lysis	37	41	0.16
No. of eyes needing 5-FU needling	11	9	0.61
No. of eyes needing digital massage	6	9	0.40

IOP = intraocular pressure; SD = standard deviation; 5-FU = 5-fluorouracil.

Table 4. Postoperative Complications after 1-Site or 2-Site Phacotrabeculectomy

	1-Site (n = 43)	2-Site (n = 43)	*P* Value
No. of eyes requiring major procedure in operating room (%)	2 (4.6)	2 (4.6)	1.00
Conjunctival bleb leaks			
Early (within 3 mos)	6 (13.9)	0 (0.0)	0.03*
Late (after 3 mos)	0 (0.0)	2 (4.6)	0.49
Hypotony (IOP<6 mmHg)			
Early (within 3 mos)	8 (18.6)	5 (11.6)	0.21
Late (after 3 mos)	3 (6.9)	3 (6.9)	1.00
Hyphema	2 (4.6)	3 (6.9)	0.65
Choroidal effusion	2 (4.6)	4 (9.3)	0.40
Tenon's cyst	3 (6.9)	1 (2.3)	0.33
Bleb infection	0 (0.0)	1 (2.3)	1.00
Hypotony maculopathy	1 (2.3)	0 (0.0)	1.00
Corneal decompensation	1 (2.3)	0 (0.0)	1.00

IOP = intraocular pressure.
*Statistically significant difference between groups.

were not statistically different. In addition to having higher mean postoperative IOP levels when compared with the current data, El Sayyad et al reported a greater mean number of antiglaucoma medications required for each group at 12 months (1.6 for 1-site eyes and 1.9 for 2-site eyes). This may reflect ethnic differences in postoperative fibrosis and bleb function, because their patients were all of Saudi Arabian origin, whereas the present cohort was comprised exclusively of white persons.

Wyse et al[13] compared 1-site and 2-site phacotrabeculectomy in 33 eyes of a primarily white population and used intraoperative MMC for 2 minutes and limbus-based conjunctival incisions for both procedures. With an average follow-up of 16.5 months, they found a lower mean IOP in the 2-site eyes (13.3 vs. 15.3 mmHg) but, perhaps because of the small sample size, this difference was not statistically significant. These authors also reported that a greater mean number of supplemental medications were required to maintain IOP in the 1-site eyes (0.8 medications per eye vs. 0.2 medications per eye; $P = 0.03$).

In contrast with these 3 studies, the authors did not find any significant advantage for a 2-site phacotrabeculectomy technique over a 1-site procedure in either postoperative IOP control or requirement for supplemental antiglaucoma medications. This study is unique in having compared a 1-site fornix-based technique with a 2-site limbus-based technique. The only significant disadvantage of the former was the higher incidence of early leaks at the conjunctival wound closure. The 2-site limbus-based phacotrabeculectomy took longer to perform and was associated with transient postoperative IOP elevations. However, the authors did find the temporal incision easier to use for the phacoemulsification procedure, and for many surgeons, this may be worth the extra time involved in changing position and readjusting the microscope. The authors found no evidence supporting the hypothesis that separating the cataract incision from the trabeculectomy site reduces postoperative fibrosis and bleb failure. Although it is possible that in the current study an advantage for the separation of incisions might have been offset by a disadvantage for the limbus-based conjunctival flap, this is not likely, because several reports comparing limbus- and fornix-based flaps in both trabeculectomy and phacotrabeculectomy have demonstrated either equivalency or a slight advantage for the limbus-based flap.[7,16–19]

It also should be mentioned that the 2 other surgical approaches for phacotrabeculectomy, 1-site, limbus-based and 2-site fornix-based procedures, were not considered in this report. It is possible that either of these techniques may have advantages over the 2 investigated herein.

This study was designed to detect a clinically meaningful (i.e., 2.0-mmHg) difference in postoperative IOP between the treatment groups; however, because of a smaller than expected sample size, as executed the study had sufficient power to detect a difference of approximately 2.5 mmHg. However, the observed differences were, on average, smaller in magnitude than this and were deemed not clinically significant. Other limitations of this investigation might have affected the results. Examiners were not masked to the type of treatment during the postoperative period, and patient adherence to the postoperative care protocol was assessed by interview only; unrecognized bias or poor compliance might have been confounding factors. In addition, the patients studied were exclusively white. Although this did have the advantage of making the 2 treatment groups highly similar at baseline, it does limit the applicability of the findings to other ethnic groups. The authors also analyzed the results for each surgeon (PC or SR) separately and found no significant difference in outcomes (data not shown). Another concern was loss of patients to follow-up. Long-term clinical study of elderly patients, the age group most affected by both cataract and glaucoma, is prone to patient dropout because of death or disability. Of the 85 eyes that were being followed up actively at 6 months, 74 (or 87%) were available for the 3-year follow-up. However, the number of eyes lost to follow-up was the same in both groups, and a review of the data from these cases showed that the main results and conclusions were not affected.

This study indicates that both of these surgical techniques for phacotrabeculectomy are efficacious in white patients and have similar long-term clinical success in controlling IOP and reducing the need for antiglaucoma medications. The authors observed a greater risk of early wound leak in the 1-site fornix-based procedure and a longer operating time and higher immediate postoperative IOP for the 2-site limbus-based procedure. Because these differences did not affect the clinical outcome, the authors conclude that the choice of incision sites for phacotrabeculectomy should remain at the discretion of the surgeon.

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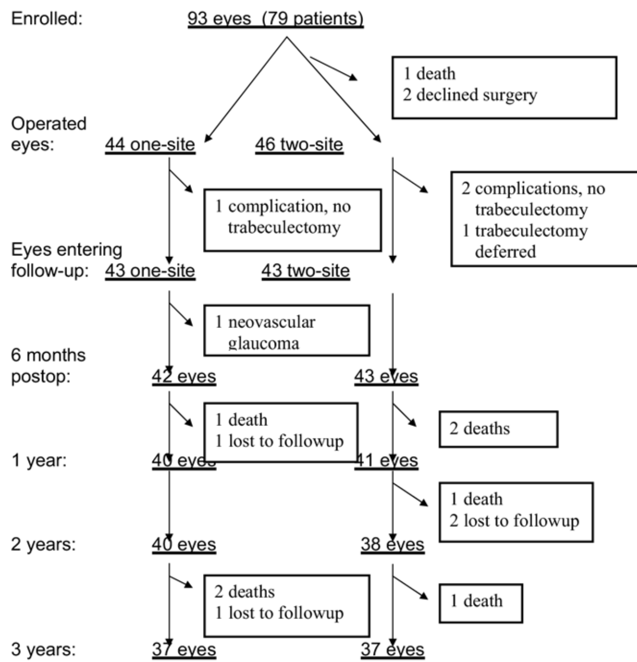

Figure 1. Flow chart showing the total numbers of eyes of patients enrolled, operated on, and observed during the follow-up phase of the study. Eyes exiting the study are indicated with the reason for withdrawal. Details of complications and drop-outs are presented in "Results." Postop = after surgery.