

# Perioperative Complications of Trabeculectomy in the Collaborative Initial Glaucoma Treatment Study (CIGTS)

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- **PURPOSE:** To describe the incidence of, and risk factors for, surgical complications reported during and within the first post-operative month after trabeculectomy in the Collaborative Initial Glaucoma Treatment Study (CIGTS).
- **DESIGN:** Review of prospectively collected data from a multicenter, randomized clinical trial.
- **METHODS:** Complications were tabulated for the 300 CIGTS patients randomized to surgery. Logistic regression analyses were used to identify risk factors for complications.
- **RESULTS:** Among the 300 patients randomized to initial surgery, 465 trabeculectomies were performed. Intraoperative complications were reported in 55 eyes (12%). The most frequent reported complications were anterior chamber bleeding during surgery (37 eyes, 8%) and conjunctival buttonhole (five eyes, 1%). Early post-operative complications were reported in 232 eyes (50%). Complications with a frequency over 10% included shallow or flat anterior chamber (62 eyes, 13%), encapsulated bleb (56 eyes, 12%), ptosis (55 eyes, 12%), serous choroidal detachment (52 eyes, 11%), and anterior chamber bleeding or hyphema (48 eyes, 10%).

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There were three localized suprachoroidal hemorrhages (0.7%) and no cases of endophthalmitis. Older patients were more likely to experience serous choroidal detachment, new anterior or posterior synechiae, and wound leak. Blacks were less likely to experience anterior chamber bleeding, but more likely to experience post-operative ptosis. The number of subjects experiencing bilateral complications was higher than that which would have been predicted by chance alone.

• **CONCLUSIONS:** The incidence of transient and self-limiting complications was high in the perioperative period, but we observed few complications with the potential to cause severe sustained vision loss in this group of previously untreated eyes. (*Am J Ophthalmol* 2005;140:16-22. © 2005 by Elsevier Inc. All rights reserved.)

**T**HE COLLABORATIVE INITIAL GLAUCOMA TREATMENT Study (CIGTS) is a multicenter, randomized, clinical trial comparing trabeculectomy versus topical medications as the initial treatment for glaucoma. Details of the study design and characteristics of the subjects have been previously reported,<sup>1</sup> and interim results from the study regarding visual and quality of life outcomes have been published.<sup>2,3</sup> The interim results suggested that patients initially treated with surgery or medication differed little in terms of visual function or quality of life 3 to 5 years after surgery, but that the patients who underwent surgery first had more ocular symptoms during the first 2 post-operative years.

Given the relative equivalence of treating with medicine or surgery first, the risk/benefit ratio of initial surgery versus initial medications might be largely determined by the incidence and severity of complications after glaucoma surgery. Furthermore, patient and surgeon apprehension about trabeculectomy is in part caused by the fear of sight-threatening surgical complications. The CIGTS

study design allows for the determination of the occurrence of complications in eyes without any previous interventions for glaucoma, and has the advantages of data collection within a carefully monitored randomized clinical trial and some standardization of surgical technique. Therefore, we evaluated the occurrence of intraoperative and early post-operative complications in the CIGTS and explored the relationship between patient demographics and the risk of surgical complications.

## METHODS

BETWEEN OCTOBER 1993 AND APRIL 1997, 607 SUBJECTS entering the CIGTS were randomized to receive either a trabeculectomy or medical therapy. The first eye treated was designated the "study eye." When both eyes of a patient met criteria for treatment, the treating ophthalmologist designated before randomization which eye would be termed the study eye. Surgery on the fellow eye was permitted at a minimum of 4 weeks after the study eye's surgery. The protocol was approved by the Institutional Review Boards at each site and informed written consent obtained from all participants. Investigators comprised 36 surgeons at the 14 clinical centers (center surgeons) as well as participating community ophthalmologists. In an effort to provide some standardization of surgical technique, all surgeons viewed a videotape illustrating critical aspects of trabeculectomy technique, such as careful manipulation of the conjunctiva, control of hemostasis, creation of the trabeculectomy flap and fistula, peripheral iridectomy, and closure of the scleral flap and conjunctiva. An iridectomy was required as part of the protocol. The study protocol allowed for use of adjunctive 5-fluorouracil (5-FU) either intraoperatively and/or post-operatively at the surgeon's discretion, but not use of mitomycin C (MMC) in the initial trabeculectomy, unless the surgery was on the fellow eye of a patient whose study eye had already failed trabeculectomy.

Participating surgeons recorded operative details and intraoperative and post-operative complications at the time of surgery and 1 day, 1 week, and 1 month after surgery on standardized forms. The forms listed a finite number of complications that were designated as present or absent and also included a blank space for writing in complications that did not appear on the list. No attempt was made to standardize the definition of a complication; instead the recording of a complication was left up to the discretion of the surgeon. For the analysis, we did not break down the complications by time of occurrence after surgery, but simply characterized the complication as present or absent during the post-operative period.

• **DATA ANALYSIS:** Descriptive statistics and  $\chi^2$  tests were used for describing the sample and estimating proportions with complications. Logistic regression analyses

**TABLE 1.** Demographic and Medical History of CIGTS Patients Who Underwent Trabeculectomy (n = 291)

Characteristic	
Age, mean y (SD); range, y	59 (11); 29 to 80
Gender	
Male	56% (163)
Female	44% (128)
Race	
White	57% (166)
Black	36% (106)
Other	6% (19)
Education	
<12 y	23% (69)
12 y	26% (78)
13+ y	49% (144)
Marital status	
Never married	9% (27)
Currently married	63% (184)
Divorced/widowed	27% (80)
Hypertension(% Yes)	34% (100)
Diabetes (% Yes)	14% (41)
CIGTS = Collaborative Initial Glaucoma Treatment Study	

with generalized estimation equation adjustment to account for correlation between eyes from the same person were used to identify risk factors for complications. The logistic regression analyses were run with the study center as a fixed effect (combining centers based upon surgical volume) for those complications associated with race. The Proc Genmod statistical procedure from the SAS system was used for these analyses.

Analyses were performed to investigate whether complications tended to cluster in the two eyes of the same person. For each complication, a 2-sided Fisher exact test for independence in a 2 x 2 table of study eye by fellow eye complication occurrence was performed. Additionally, the McNemar test was used to test whether, given discordance in complications between eyes, the study eye (first operated) was more likely than the fellow eye to have experienced the complication. A P value of <.05 was considered to be statistically significant. No adjustments were made for multiple testing.

## RESULTS

THREE HUNDRED SUBJECTS WERE RANDOMIZED TO INITIAL trabeculectomy, and 290 of them underwent surgery in their study eyes and one underwent surgery only in the fellow eye. The 10 subjects who were randomized to initial trabeculectomy but never had trabeculectomy in their study eye included seven patients who refused trabeculectomy for their study eye and were treated with argon laser trabeculoplasty (one of whom later received surgery in the

**TABLE 2. Operative Details of Trabeculectomy in 465 Eyes**

Anesthesia	N (%)
Local	62 (13)
Local with sedation	394 (85)
General	9 (2)
Location of surgery	
Superonasally	231 (50)
Superotemporally	40 (9)
Directly superior	194 (42)
Conjunctival flap	
Limbus-based	410 (88)
Fornix-based	55 (12)
Antifibrosis agent	
None	177 (38)
5-Fluorouracil	266 (57)
Mitomycin C	22 (5)
Viscoelastic	
Yes	116 (25)
No	349 (75)
Tenonectomy	
Yes	68 (15)
No	397 (85)

fellow eye), two who withdrew from the study between randomization and their scheduled surgery, and one who died during the interval between randomization and surgery. One hundred seventy-four subjects underwent trabeculectomies in both eyes, and 117 subjects underwent surgery in one eye only (116 study eyes and one fellow eye), for a total of 465 trabeculectomies.

Information on the 291 patients for whom intraoperative and post-operative complications were assessed is found in Table 1. These patients were very similar in their demographic characteristics and medical history to the 607 CIGTS enrollees.<sup>1</sup> The mean age at the time of trabeculectomy was 59 years (SD, 11 years; range 29 to 80 years). They tended to be men (n = 163, 56%) and white (n = 166, 57%), although a substantial percentage (n = 106, 36%) were blacks. Many of the patients had high blood pressure (n = 100, 34%) and a lesser percentage had diabetes (n = 41, 14%).

The mean number of trabeculectomies performed per center was 33 (range eight to 53). Three hundred and fifty two surgeries (76%) were performed by the 36 clinical center ophthalmologists and 113 by participating community ophthalmologists.

Sixty-two surgeries (13%) were performed under local anesthesia, 393 (85%) under local anesthesia with sedation, and nine (2%) under general anesthesia (Table 2). The surgeon operated superonasally in 231 eyes (50%), superotemporally in 40 eyes (9%), and directly superior in 194 eyes (42%). There were 410 (88%) limbus-based and 55 (12%) fornix-based conjunctival flaps. The surgeon used no antifibrosis agent in 177 (38%), 5-FU in 266

**TABLE 3. Intraoperative and Post-operative Complications After Trabeculectomy in 465 Eyes, n (%)**

Complication	Intraoperative (n = 465)	Post-operative (n = 465)
Conjunctival buttonholes	5 (1.1)	0
Scleral flap problems	3 (0.7)	0
Partial severing of superior rectus tendon	1 (0.2)	0
Orbital bleeding	2 (0.4)	0
Anesthetic or systemic complications	1 (0.2)	0
Wound leak	1 (0.2)	26 (6)
Iris prolapse	1 (0.2)	5 (1.1)
Subconjunctival hemorrhage	2 (0.4)	0
Anterior chamber bleeding	37 (8)	48 (10)
Serous choroidal detachment	2 (0.4)	52 (11)
Suprachoroidal hemorrhage	0	3 (0.7)
Hypotony	0	4 (0.9)
Corneal epithelial defect	0	4 (0.9)
Monocular diplopia	0	1 (0.2)
Cystoid macular edema	0	1 (0.2)
Shallow or flat anterior chamber	0	62 (13)
Aqueous misdirection	0	2 (0.4)
New synechiae or adhesions	0	24 (5)
Encapsulated bleb	0	56 (12)
Dellen	0	18 (4)
Ptosis	0	55 (12)

(57%), and MMC in 22 eyes (5%). Viscoelastic was used in 116 eyes (25%), washed out in 47 (40.5%) and not washed out in 69 (59.5%), and a tenonectomy was performed in 68 eyes (15%).

Intraoperative complications were reported in 55 eyes (12%)(Table 3). The most frequent complication noted was anterior chamber bleeding (37 eyes, 8%), but in no instance did the surgeon perform a post-operative anterior chamber washout. There were two subconjunctival hemorrhages (0.4%). Five conjunctival buttonholes (1.1%) were noted, as well as three scleral flap problems (0.7%), including one buttonhole, one partial amputation at the limbus requiring additional sutures, and one extensive thinning. One wound leak requiring re-suturing was noted, and a partial transection of the superior rectus tendon was repaired intraoperatively. There were two intraoperative serous choroidal detachments (0.4%). Complications associated with anesthesia included two cases of orbital bleeding and one possible systemic reaction (feeling of warmth and shortness of breath) to the local anesthetic.

Four trabeculectomies required what the surgeon deemed additional intraoperative surgery: the scleral flap repair mentioned above, a wound leak requiring re-suturing, a re-attachment of a partially transected superior rectus muscle, and a taking-down of a conjunctival flap and additional suturing of the scleral flap for a shallow anterior chamber noted at the end of surgery.

**TABLE 4. Frequency of Complications By Center**

Center	No. of Surgeries	Intraop AC Bleeding	Post-op Shallow or Flat AC	Post-op Encapsulated Bleb	Post-op Ptosis	Post-op Serous Choroidal Detachment	Post-op AC Bleeding or Hyphema	Post-op Wound Leak	Post-op New Anterior or Posterior Synechiae
01	28	2 (7.1%)	2 (7.1%)	6 (21.4%)	0 (0.0%)	1 (3.6%)	3 (10.7%)	0 (0.0%)	2 (7.1%)
02	43	6 (14.0%)	7 (16.3%)	2 (4.7%)	1 (2.3%)	5 (11.6%)	10 (23.8%)	2 (4.7%)	2 (4.7%)
03	42	4 (9.5%)	11 (26.2%)	15 (35.7%)	12 (28.6%)	16 (38.1%)	5 (11.9%)	6 (14.3%)	7 (16.7%)
04	41	5 (12.2%)	7 (17.1%)	1 (2.4%)	3 (7.3%)	4 (9.8%)	1 (2.4%)	0 (0.0%)	0 (0.0%)
05	31	1 (3.2%)	4 (12.9%)	5 (16.1%)	3 (9.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
06	45	2 (4.4%)	6 (13.3%)	4 (8.9%)	3 (6.7%)	6 (13.3%)	4 (8.9%)	4 (8.9%)	1 (2.2%)
07	30	6 (20.0%)	1 (3.3%)	1 (3.3%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
08	24	2 (8.3%)	1 (4.2%)	2 (8.3%)	5 (20.8%)	0 (0.0%)	1 (4.2%)	3 (12.5%)	0 (0.0%)
09	53	1 (1.9%)	5 (9.4%)	5 (9.4%)	23 (43.4%)	5 (9.4%)	6 (11.3%)	2 (3.8%)	5 (9.4%)
10	50	3 (6.0%)	8 (16.0%)	5 (10.0%)	1 (2.0%)	6 (12.0%)	5 (10.0%)	5 (10.0%)	3 (6.0%)
11	47	3 (6.4%)	9 (19.2%)	10 (21.3%)	3 (6.4%)	8 (17.0%)	11 (23.4%)	3 (6.4%)	4 (8.5%)
12	12	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)
13	8	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)
14	11	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)
Total	465	37 (8.0%)	62 (13.3%)	56 (12.0%)	55 (11.8%)	52 (11.2%)	48 (10.3%)	26 (5.6%)	24 (5.2%)
P-value*		.30	.16	<.0001	<.0001	<.0001	.01	.09	.03

\*Test of the null hypothesis of equality in complication rates across centers (Pearson  $\chi^2$  test).

**TABLE 5. Associations of Intraoperative and Post-operative Complications With Age and Race**

Intraoperative Complication	Age* OR (95% CI); P Value	Race† OR (95% CI); P Value
AC bleeding (n = 37)	1.08 (0.78–1.51); .63	1.95 (0.89–4.27); .10
Any intraoperative complication (n = 58)	1.05 (0.80–1.37); .73	1.76 (0.95–3.28); .07
Post-operative complication		
AC bleeding or hyphema (n = 48)	0.91 (0.69–1.18); .47	1.99 (1.02–3.88); .04
Shallow or flat AC (n = 62)	1.18 (0.91–1.54); .22	0.99 (0.55–1.78); .97
Serous choroidal detachment (n = 52)	1.34 (1.03–1.74); .03	1.56 (0.77–3.17); .22
New anterior or posterior synechiae or (n = 24)	1.48 (1.04–2.12); .03	0.81 (0.33–1.98); .64
Wound leak (n = 26)	1.76 (1.20–2.57); .004	3.07 (0.82–11.56); .10
Ptosis (n = 55)	0.88 (0.65–1.20); .43	0.39 (0.20–0.75); .005
Encapsulated bleb (n = 56)	0.98 (0.76–1.26); .87	1.18 (0.64–2.19); .59
Any post-operative complication (n = 232)	1.01 (0.84–1.22); .88	1.47 (0.96–2.24); .07

AC = anterior chamber; CI = confidence interval; OR = odds ratio.

All statistics were generated from logistic regression models with GEE adjustment for inter-eye dependency, using SAS Genmod. Logistic regression models were performed for complications that had a frequency of n = 20 or more.

\*Age ORs are reported for 10-year increments and are adjusted for gender and race.

†Race ORs are reported for the contrast of whites and others versus blacks and are adjusted for age and gender, and center where surgery was performed.

We had follow-up data for at least 1 month after surgery on 464 of the 465 operated eyes. Early post-operative complications were reported in 232 eyes (50%) (Table 3). Surgeons reported 62 eyes (13%) with shallow or flat anterior chambers. Other commonly recorded post-operative complications included encapsulated blebs (56 eyes, 12%), ptosis (55 eyes, 12%), serous choroidal detachment (52 eyes, 11%), anterior chamber bleeding or hyphema (48 eyes, 10%), wound leak (26 eyes, 6%), and new anterior or posterior synechiae (24

eyes, 5%). There were five instances of iris incarceration in the fistula (1.1%), four eyes (0.9%) with hypotony, four (0.9%) with a corneal epithelial defect, one with monocular diplopia (0.2%), and one (0.2%) with cystoid macular edema. There were three limited suprachoroidal hemorrhages (0.7%), two cases of aqueous misdirection (0.4%), and no cases of endophthalmitis.

Five eyes had two intraoperative complications and no eye had more than two intraoperative complications. The num-

**TABLE 6. Paired Eye Analysis of Trabeculectomy Complications**

Complication	Observed (Expected*) # of Occurrences in:				P-Value†
	Neither Eye	Study Eye Only	Fellow Eye Only	Both Eyes	
Ptosis	143 (133.5)	15 (24.5)	4 (13.5)	12 (2.5)	<.0001
Marked inflammation	167 (165.1)	1 (2.9)	4 (5.9)	2 (0.1)	.003
Serous choroidal detachment	144 (139.9)	12 (16.1)	12 (16.1)	6 (1.9)	.005
Corneal problems (dellen)	163 (161.2)	6 (7.8)	3 (4.8)	2 (0.2)	.017
Shallow or flat anterior chamber	139 (135.4)	16 (19.6)	13 (16.6)	6 (2.4)	.019
Progressive or new lens opacification	170 (169.0)	1 (2.0)	2 (3.0)	1 (0.03)	.034

\*Expected numbers derived from an assumption of independence between eyes within a pair.

†Two-sided P value based on Fisher exact test for independence in a 2 × 2 table.

ber of eyes with one, two, three, four, five, six, and seven post-operative complications was 131, 53, 30, 10, four, three, and one, respectively. We found an association between intraoperative and post-operative anterior chamber bleeding. Of the 69 eyes that experienced anterior chamber bleeding at either time, 16 (23%) had bleeding noted at both times (odds ratio [OR] = 9.4;  $P < .0001$ ,  $\chi^2$  test).

Additional procedures were performed in 15 eyes (3% of all operated eyes) during the first post-operative month for surgical complications. Nine of 64 eyes reported as having a shallow or flat chamber underwent a reformation procedure, five in the operating room, three in the office, and one location unknown. Five of the 25 eyes with wound leaks were re-sutured. One eye underwent a post-operative posterior sclerotomy but the reason was not reported.

The frequency of certain post-operative complications varied by center (Table 4). In particular, the variation was greatest for the reporting of encapsulated bleb, ptosis, and serous choroidal detachment.

The risk of any intraoperative complication occurring was evaluated relative to the patient's age, gender, and race. Logistic regression models were used that included adjustment for intereye dependency. No significant association with any specific intraoperative complication was found.

Associations of post-operative complications with age, gender, and race were also evaluated using logistic regression modeling. Table 5 shows the results of these analyses. Of note is the association of race to the risk of post-operative complications. Whites and others (relative to blacks) were at a significantly increased risk for anterior chamber bleeding or hyphema (OR = 1.99;  $P = .04$ ), after adjustment for age, gender, and center where the surgery was performed. However, whites and others were at a significantly decreased risk of ptosis relative to blacks (OR = 0.39;  $P = .005$ ). Collectively, for the occurrence of any post-operative complication, blacks had a marginally lower risk ( $P = .07$ ). After adjustment for gender and race, older patients were more likely to experience three post-operative complications—serous choroidal detachment (OR = 1.34,  $P = .03$ ), new anterior or posterior synechiae (OR =

1.48,  $P = .03$ ), and wound leak (OR = 1.76,  $P = .004$ ). A patient's gender had no significant association with any post-operative complication.

The results of tests for association of complications in the two eyes of the same person are presented in Table 6. Of 25 complications tested, the six given in Table 5 were found to be statistically significant. The six significant results observed are far more than the one of 25 that would be expected by chance alone, and, therefore, are unlikely to be attributable to type I error.

For each complication, the observed numbers are given as well as the expected numbers of complications assuming independence between eyes. In each case, the numbers observed in the "Neither Eye" and "Both Eye" categories are larger than expected, and the numbers in the "Study Eye Only" and "Fellow Eye Only" are consistently less than or equal to expected. These results show a strong relationship between eyes within the same person to experience (or not) the same complication. Although the numbers of patients experiencing bilateral complications are generally small, they are far greater than that which would be expected by chance alone. The most striking association was seen for ptosis, which was noted by the examining ophthalmologist as a bilateral occurrence after trabeculectomy in 12 (7%) of the 168 patients for whom data were available. If the probability of ptosis were independent between eyes of the same person, we would have expected only 2.5 patients with bilateral ptosis. Additionally, we observed significant asymmetry in occurrence of ptosis between eyes, with the study eye (operated first) exhibiting more ptosis than the fellow eye ( $P = .01$  by McNemar test). Although the five other complications listed in Table 6 had significant bilateral-eye associations, no complication other than ptosis exhibited significant asymmetry between study and fellow eyes.

## DISCUSSION

WE OBSERVED NO CATASTROPHIC COMPLICATIONS THAT would be likely to result in permanent significant vision

loss in this group of previously untreated eyes undergoing initial trabeculectomy. In the three eyes with suprachoroidal hemorrhages, all were peripheral and resolved without surgery. This observation suggests that the performance of surgery initially is not likely to result in important visual loss. This information should be reassuring to physicians and patients contemplating trabeculectomy earlier in the course of the disease. However, although no catastrophic complications occurred, 15 (3%) additional procedures were performed, representing additional risk, costs, anxiety, and inconvenience to the patient.

It is difficult to make meaningful comparisons of the intraoperative and post-operative complications we observed in the CIGTS and the complications reported in other studies of trabeculectomy. To the best of our knowledge, neither of the randomized clinical trials that served as the stimulus for the development of the CIGTS reported early surgical complications in their eyes that underwent trabeculectomy without any prior medical therapy.<sup>4-7</sup>

One can compare our results with those of the Advanced Glaucoma Intervention Trial (AGIS), in which the investigators tabulated the complications they observed in their clinical trial of trabeculectomy versus trabeculoplasty in eyes that had previously failed medical therapy.<sup>8</sup> Of note was a prevalence of 13% for intraoperative anterior chamber bleeding (8% in the CIGTS), and post-operative complication rates of 14% for encapsulated bleb (12% in the CIGTS), 11% for anterior chamber bleeding observed post-operatively (10% in the CIGTS), 15.5% rate of shallow anterior chamber (13% in the CIGTS), 6.5% rate for wound leak (5% in the CIGTS), and 6.3% for anterior synechiae (5% in the CIGTS).<sup>8</sup> Despite the different patient populations, different recording systems for notation of complications, different length of follow-up (1 month for CIGTS, 3 months for AGIS), and absence of use of antifibrosis agents in AGIS, it is striking how close the complication rates are in the two studies. One might tentatively conclude that whether or not an eye has had previously medical treatment for glaucoma has no effect upon early post-operative complications.

An important issue is whether complications either during surgery or during the first month after surgery influence the final outcome. The results of Watson and associates, who reported a 20 year experience of the complications of trabeculectomy are reassuring.<sup>9</sup> In a series of 112 eyes of 92 patients operated between 1985 and 1988 they observed an incidence of 25%, 40%, and 5% for shallow anterior chamber, hyphema, and uveitis, respectively. They also noted six eyes with corneolenticular touch, two suprachoroidal hemorrhages, and no endophthalmitis. Despite these complications, which appear to occur more frequently than in the present study, they did not observe any long-term problems which could be related to any operative or immediately post-operative complications.

We found that race was associated with the occurrence of certain early post-operative complications. Blacks were at decreased risk for anterior chamber bleeding and hyphema. We cannot easily explain the decreased risk of blood in the anterior chamber in black subjects, but perhaps blood was more easily visible in the eye of white subjects, resulting in a greater reporting rate. Conversely, blacks were at increased risk for ptosis. We could not find any reports in the literature on racial differences in ptosis after intraocular surgery, but it is interesting to note that in one study from Korea<sup>10</sup> the rate of ptosis after trabeculectomy (12%) was the same that we observed. Some investigators report that the use of a superior rectus traction suture, as opposed to a corneal traction suture, may predispose to ptosis.<sup>11</sup> However, we did not collect information on the type of traction suture used and, therefore, do not know whether the type of traction suture differed between blacks and whites in our study.

When the CIGTS was started in 1993, there was concern about the safety of using MMC in eyes with no previous eye surgery, and hence the protocol, with few exceptions, did not allow the use of MMC at the time of the initial trabeculectomy. This prohibition on MMC use may have reduced our observed complication rate, especially for hypotony.<sup>12,13</sup>

The shared occurrence of a specific operative or post-operative complication after trabeculectomy in both the study and fellow eyes could be from an examiner bias, skill of the surgeon, or to an elevated risk that is patient specific. Once an examiner makes note of a post-operative complication, when the second eye is operated upon, the examiner undoubtedly has an increased level of attentiveness to the possibility that this complication may occur again. If that lowers the examiner's threshold for recording a complication, such a bias may produce more bilateral occurrences. Although we cannot exclude examiner bias, both surgeon skill and patient-specific elevated risk, particularly for the more objectively rated complications, remain legitimate possibilities. If surgery of the fellow eye is to be done, the surgeon should employ any preventive means available to avoid occurrence of the complication that was experienced in the first eye's surgery. Such attention to surgical detail may have occurred for ptosis, which declined in frequency between the study eye and the fellow eye surgeries.

An important weakness of this study is the lack of standardized definitions of the complications. For instance, the report by a surgeon of anterior chamber bleeding might have meant anything from a minute trickle of blood into the anterior chamber after sclerectomy to a significant hyphema on the first post-operative day. Furthermore, the observation that there were more shallow or flat anterior chambers reported than hypotony could be related to the lack of standardization. This lack of standardization may explain, in part or in full, variations in the rate of reporting of encapsulated bleb, ptosis, and serous choroidal detach-

ment at different clinical centers. Because only complications present at the time of a study visit were recorded, the prevalence of some complications may have been higher than we are reporting if a complication developed and resolved in between study visits.

This manuscript only addresses the intraoperative and perioperative complications of trabeculectomy surgery. Although these are important factors in determining the risk/benefit ratio of trabeculectomy surgery, particularly as a first treatment for glaucoma, there are other important considerations. In particular, over the past several years, there has been an increasing awareness of complications of trabeculectomy surgery that occur much later in the post-operative period. These complications range from visually significant cataract<sup>14</sup> to the constellation of bleb-related complications including bleb leak, hypotony, blebitis, and endophthalmitis.<sup>15</sup> A future manuscript will describe the frequency, treatment, and outcomes of these complications within the CIGTS. Only when we consider both short-term and long-term complications, as well as long-term benefits, of initial trabeculectomy will we be able to make an informed decision about the relative merits of the medical versus the surgical approach.

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