TEMPORAL CORNEAL PHACOEMULSIFICATION IN FILTERED GLAUCOMA PATIENTS*

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ABSTRACT

Purpose: To evaluate the effect of temporal clear corneal phacoemulsification on intraocular pressure (IOP) in eyes that had prior trabeculectomy.

Design: Retrospective case-control study

Patients: Forty consecutive patients (cases; TRAB-PHACO group) who underwent temporal corneal phacoemulsification subsequent to trabeculectomy were identified. Forty patients (controls; TRAB group) who had trabeculectomy alone were matched to the cases for length of follow-up, age, IOP, number of anti-glaucoma medications, number of 5-fluorouracil (5-FU) injections, race, sex and diagnosis.

Main outcome measures: Comparison of IOP before and one year after phacoemulsification in the TRAB-PHACO group, and comparison with the TRAB group. Survival analysis of IOP control after trabeculectomy in the TRAB-PHACO and TRAB groups.

Results: In the TRAB-PHACO group, IOP one year after phacoemulsification was not significantly different from the pre-phacoemulsification IOP value (p=0.65). Kaplan-Meier survival analysis showed that the rates of IOP control at 3, 6 and 9 years after trabeculectomy in the TRAB-PHACO group were 80%, 66% and 44%; in the TRAB group these were 79% , 69% and 55%. These survival curves were not statistically different (p= 0.55).

Conclusions: Cataract surgery by temporal clear corneal phacoemulsification in eyes with filtering blebs after trabeculectomy does not adversely affect long term IOP control.

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INTRODUCTION

Glaucoma patients who undergo trabeculectomy followed by cataract extraction months or years later generally fall into two groups. Some patients with clear lenses require trabeculectomy and then develop significant cataract. Other patients present with a significant cataract and a need for surgical intraocular pressure (IOP) control, but have only trabeculectomy and defer cataract surgery because of the belief that combined procedures do not lower IOP as well as trabeculectomy alone.[1-3] When cataract surgery is contemplated in successfully filtered eyes, there is concern about early postoperative IOP increases as well as long-term maintenance of IOP control.

There have many reports about long-term IOP control after cataract extraction in eyes with functioning filtering blebs, mainly from the era of intracapsular or extracapsular cataract extraction.[4-14] Recent advances in glaucoma filtering surgery, such as the use of 5-fluorouracil (5-FU), mitomycin, and releasable sutures, coupled with recent advances in small incision cataract surgery may change the approach to patients with coexisting glaucoma and cataract.

The purpose of the present study is to determine (1) if temporal corneal phacoemulsification affects the long-term control of IOP as compared with a control group of patients who underwent trabeculectomy but not cataract extraction, (2) if the period of time between the initial trabeculectomy and phacoemulsification influences the survival time in the TRAB-PHACO group, and (3) the early postoperative effect of temporal corneal phacoemulsification on the IOP of eyes that have previously undergone trabeculectomy.

SUBJECTS AND METHODS

We reviewed the charts of 40 consecutive patients (TRAB-PHACO group) who underwent temporal corneal phacoemulsification a minimum of 3 months after conventional superior trabeculectomy with or without low-dose postoperative 5-FU (3 or 4 subconjunctival 5-FU injections of 5 mg each). For a control group, we chose 40 phakic eyes (TRAB group) that had trabeculectomy alone, with or without low-dose 5-FU. The length of follow-up in the 2 groups was matched with respect to the date of trabeculectomy (Fig 1). We also matched the two groups with respect to age, IOP, number of pretrabeculectomy antiglaucoma medications, number of 5-FU injections, race, sex , and diagnosis. Patients with acute angle-closure glaucoma, inflammatory glaucoma, and neovascular glaucoma were excluded. If both eyes were eligible, only the eye with the longer follow-up was included.

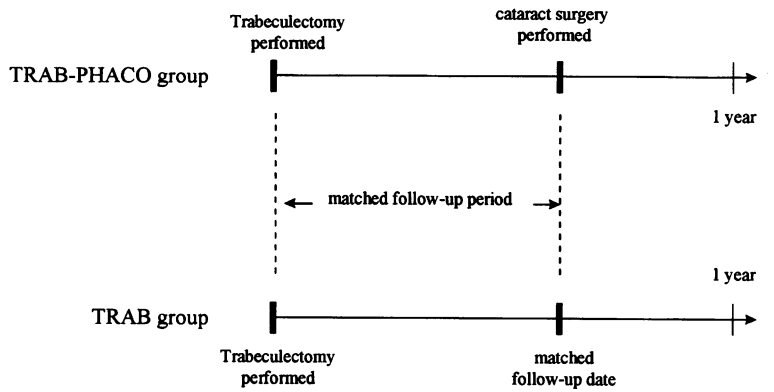

FIGURE 1
Schematic diagram of follow-up intervals. Time period between trabeculectomy and phacoemulsification in TRAB-PHACO group was defined as "matched follow-up period." "Matched follow-up date" in TRAB group was date that corresponded to date of phacoemulsification in TRAB-PHACO group.

In both groups, a standard superior trabeculectomy was performed with a limbus-based conjunctival flap.[15] After trabeculectomy, 18 patients in each group received 3 or 4 subconjunctival 5-FU injections of 5 mg each. The injections were given in the inferior fornix and usually performed on posttrabeculectomy days 1, 4, 8, and 11; all injections were given within the first 2 postoperative weeks. Suture lysis was performed if filtration was insufficient to maintain an acceptable pressure and well-formed bleb in the early posttrabeculectomy period. Posttrabeculectomy medications included a topical corticosteroid used 3 or 4 times daily that was gradually tapered over 6 weeks in both groups. Cycloplegics were usually used only on the first postoperative day. In the TRAB-PHACO group, temporal clear corneal phacoemusification with no manipulation of the conjunctiva was performed a minimum of 3 months after trabeculectomy. The incision size was 3.2 mm. Pupils less than 3 mm in diameter were surgically enlarged with temporal and nasal sphincterotomies. A foldable silicone posterior-chamber intraocular lens was inserted into the capsular bag or ciliary sulcus, according to the status of the capsule. One-piece lenses were used for capsule fixation and three-piece lenses were used for ciliary sulcus fixation. The corneal wound was secured with a single 10-0 nylon suture. At the end of the procedure, intracameral carbachol was injected. Postphacoemulsification medications consisted of a topical antibiotic for the first 4 days and a topical corticosteroid tapered from 4 times daily over approximately 8 weeks. Patients of both groups were fol-

lowed for at least 1 year after phacoemulsification (and after the matched follow-up date in the TRAB group). Visual acuity (VA), IOP, and number of antiglaucoma medications were compared between the prephacoemulsification (the matched follow-up date in the TRAB group) and 1-year follow-up for each group.

Nonparametric statistical methods were used to test for significant differences between groups for all reported measures except for age, which was tested with Student' *t*-test. Pearson's chi-square test was used for race and diagnosis. The Fisher exact test was used to test gender distribution. The longitudinal comparisons of IOP, VA, and number of antiglaucoma medications were tested with Wilcoxon signed rank test except for the IOP comparison within the TRAB-PHACO group, which was done with paired *t*-test. The probability of IOP control after trabeculectomy was estimated by using Kaplan-Meier survival analysis on both groups. Failure after the initial trabeculectomy was defined as (1) an IOP greater than 21 mmHg or less than a 20% reduction compared with the pretrabeculectomy IOP on two consecutive follow-up visits with antiglaucoma medications, (2) a greater number of antiglaucoma medications needed compared with pretrabeculectomy, or (3) additional filtering surgery after the initial trabeculectomy. If an eye fulfilled any of these failure criteria, the failure date was considered the second date of 2 consecutive visits. The distribution of survival rates for the 2 groups were compared with the log-rank test. Cox regression analysis (SPSS Inc., Chicago)[16,17] was used to determine if the period of time between the trabeculectomy and phacoemulsification influenced the survival time in the TRAB-PHACO group.

RESULTS

Patient data before phacoemulsification (and data for the matched follow-up date in the TRAB group) are shown in Table I. Most patients had primary open-angle glaucoma (24/27:TRAB-PHACO group/TRAB group). Pseudoexfoliative glaucoma (6/5), low-tension glaucoma (6/5), chronic angle-closure glaucoma (3/2), and pigmentary glaucoma (1/1) were also diagnosed. Patients in both groups underwent trabeculectomy without intraoperative complications. The mean period between trabeculectomy and phacoemulsification was 37.7 ± 28.6 (range, 5 to 116) months. The "matched follow-up period" of the TRAB group was 33.6 ± 23.2 (range, 6 to 100) months. These were not statistically different ($P = 0.43$). Both groups were clinically and statistically matched for pretrabeculectomy IOP ($P = 0.62$), number of pretrabeculectomy antiglaucoma medications ($P = 0.38$), number of 5-FU injections ($P = 0.07$), and age ($P = 0.29$). In addition, the distributions of sex ($P = 0.62$), race ($P = 0.40$), and diagnosis ($P = 0.97$) were not statistically different.

TABLE I. PATIENT DEMOGRAPHICS

	TRAB-PHACO GROUP	TRAB GROUP
Subjects (with/without 5-FU)	40 eyes (18/22)	40 eyes (18/22)
Sex (female/male)	28/12	30/10
Race (white/black)	36/4	38/2
Age in years (range)	72.7±7.6 (60-91)	70.9 ± 6.9 (58-86)
Diagnosis		
POAG	24	27
PXG	6	5
LTG	6	5
CACG	3	2
PG	1	1
Mean number of 5-FU injections in 18 of 40 eyes on each group (range)	2.5±0.8 (1 - 4)	2.9±0.7 (1 - 4)
Matched follow-up period (range)	37.7±28.6 mo (5.3 - 115.6)	33.6±23.2 mo (6.3 - 99.8)
Pretrabeculectomy IOP (range)	23.6±6.6 mm Hg (14 - 44)	24.4±7.0 mm Hg (15 - 48)
No. of pretrabeculectomy antiglaucoma medications	2.5±0.8	2.3±0.8

TRAB, trabeculectomy; PHACO, phacoemulsification; POAG, primary open angle glaucoma; PXG, pseudoexfoliation glaucoma; LTG, low tension glaucoma; CACG, chronic angle - closure glaucoma; PG, pigmentary glaucoma; 5-FU, 5-fluorouracil. Mean ±SD are given.

During cataract surgery, sphincterotomies were performed in 7 eyes. Three eyes in the TRAB-PHACO group required anterior vitrectomy as a result of vitreous loss during phacoemulsification. The mean follow-up after phacoemulsification was 20.1 ± 8.8 (range, 12.0 to 51.1) months in the TRAB-PHACO group, and the mean follow-up after the matched follow-up date was 18.7 ± 7.1 (range, 11.9 to 52.2) months in the TRAB group. The overall mean follow-up after trabeculectomy was 57.8 ± 27.4 (range, 22.0 to 135.0) months in the TRAB-PHACO group and 52.0 ± 23.4 (range, 19.4 to 115.4) months in the TRAB group. There were no postoperative complications except for 1 case of cystoid macular edema, which occurred 3 months after phacoemulsification in TRAB-PHACO group.

Three eyes in the TRAB-PHACO group and 2 eyes in the TRAB group required additional glaucoma surgery. Two of these 3 eyes in the TRAB-PHACO group underwent additional trabeculectomy within 1 year after phacoemulsification (6.4 and 10.3 months, respectively); these 2 eyes were excluded from the postoperative 1-year data for IOP, VA, and antiglaucoma medications (Tables II through IV). The other eye underwent repeated trabeculectomy 2.4 years after phacoemulsification. In the TRAB group, additional trabeculectomies were performed in 2 eyes, 4.2 years and 7.9 years after the initial trabeculectomy.

The mean ±(SD) IOP at each follow-up interval in both groups is shown in Table II. On the first postoperative day after cataract surgery in the TRAB-PHACO group, the mean (±SD) IOP was 15.5 ± 7.0 mmHg

TABLE II. IOP DATA (MEAN ±SD)

	TRAB-PHACO GROUP (40 EYES)	TRAB GROUP (40 EYES)
Prephacoemulsification (matched follow-up date in TRAB group)	13.5±4.2 mm Hg	14.7±3.5 mm Hg
Postoperative day 1	15.5±7.0	
Postoperative day 10	13.7±3.7	
Postoperative 1 mo	14.8±3.4	
Postoperative 3 mo	13.5±3.9	
Postoperative 6 mo (6 mo after matched follow-up date in TRAB group)	13.4±4.0	15.7±4.0
postoperative 1 yr (1 yr after matched follow-up date in TRAB group)	13.3±4.1(38 eyes°)	15.0±3.8
P value	0.65†	0.74‡

TRAB: trabeculectomy, PHACO: phacoemulsification,
°2 eyes were excluded from 40 eyes, because of additional trabeculectomy within 1 yr of phacoemulsification.
†paired *t*-test between IOP on prephacoemulsification and IOP at postoperative 1 yr in TRAB-PHACO group.
‡ Wilcoxon signed rank test between IOP at matched follow-up date and IOP at 1 yr after matched follow-up date in TRAB group.

TABLE III. MEAN (±SD) NUMBER OF ANTIGLAUCOMA MEDICATIONS

	TRAB-PHACO GROUP (40 EYES)	TRAB GROUP (40 EYES)
Prephacoemulsification (matched follow-up date in TRAB group)	0.7±0.8	0.5±0.8
Postoperative day 1	0.0±0.0	
Postoperative day 10	0.4±0.6	
Postoperative 1 mo	0.4±0.6	
Postoperative 3 mo	0.5±0.6	
Postoperative 6 mo (6 mo after matched follow-up date in TRAB group)	0.5±0.6	0.5±0.8
Postoperative 1 yr (1 yr after matched follow-up date in TRAB group)	0.6±0.7(38 eyes*)	0.7±0.9
P value	0.25†	0.03‡

TRAB, trabeculectomy; PHACO, phacoemulsification.
*2 eyes were excluded from 40 eyes, because of additional trabeculectomy within one year of phacoemulsification.
†Wilcoxon signed rank test between antiglaucoma medications on prephacoemulsification and antiglaucoma medications at postoperative 1 yr in TRAB-PHACO group.
‡ Wilcoxon signed rank test between antiglaucoma medications at matched follow-up date and antiglaucoma medications at 1 yr after matched follow-up date in TRAB group.

TABLE IV. MEAN (±SD) VISUAL ACUITY

	TRAB-PHACO* GROUP (38 EYES)	TRAB GROUP (36 EYES†)
Prephacoemulsification (matched follow-up date in TRAB group)	0.35±0.22	0.62±0.29
Postoperative day 1	0.43±0.26	
Postoperative day 10	0.49±0.27	
Postoperative 1 mo	0.58±0.28	
Postoperative 3 mo	0.65±0.24	
Postoperative 6 mo (6 mo after matched follow-up date in TRAB group)	0.63±0.26	0.53±0.26
Postoperative 1 yr (1 yr after matched follow-up date in TRAB group)	0.61±0.25(36 eyes‡)	0.57±0.27
P value	<0.001§	0.05∏

TRAB, trabeculectomy; PHACO, phacoemulsification.
*40 eyes - 1 eye of ARMD and 1 eye of macular hole.
†40 eyes - 3 eyes of ARMD and 1 eyes of macular hole.
§Wilcoxon signed rank test between visual acuity on prephacoemulsification and visual acuity at postoperative 1 yr in TRAB-PHACO group.
‡2 eyes were excluded from 38 eyes because of additional trabeculectomy within 1 yr of phacoemulsification.
∏ Wilcoxon signed rank test between visual acuity at matched follow-up date and visual acuity at 1 yr after matched follow-up date in TRAB group.

(range, 0 to 30 mmHg). The IOP increased by 2.0 ± 5.4 mmHg (range, -9 to 15 mmHg) relative to prephacoemulsification values. The IOP was lower in 15 eyes (37.5%), and higher in 22 eyes (55%) (Fig 2). Three eyes (7.5%) had an IOP spike greater than 10 mmHg above the prephacoemulsification IOP. No eye had IOP over 30 mmHg on the first postoperative day. At 1 year postoperatively, the average IOP was 13.3 ± 4.1 mmHg in the TRAB-PHACO group. In the TRAB group, the IOP 1 year after the matched follow-up date was 15.0 ± 3.8 mmHg. These IOPs were not statistically different from those of the prephacoemulsification and matched follow-up date values, respectively (P=0.65, 0.74, respectively).

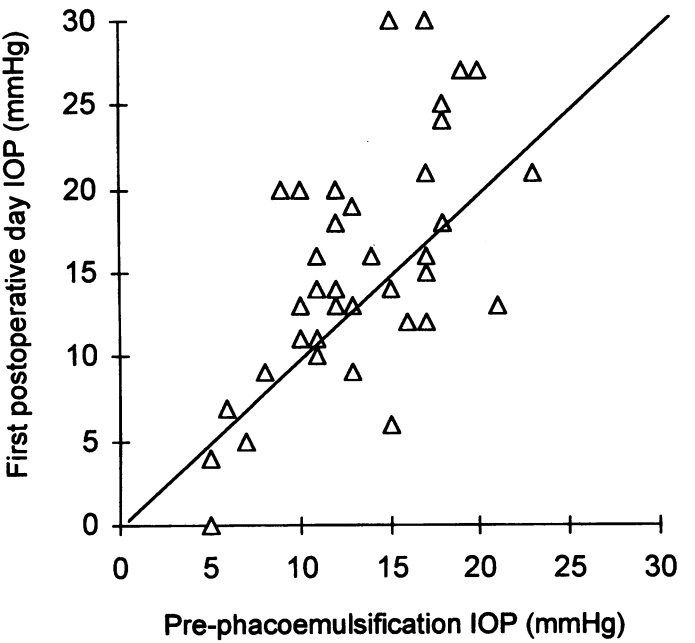

FIGURE 2

Intraocular pressure on first day after phacoemulsification. Values are compared to prephacoemulsification values in TRAB-PHACO group. Three eyes (7.5%) had an IOP spike on first postoperative day of more than 10 mm Hg compared to prephacoemulsification value. No eyes had IOP greater than 30 mm Hg on first postoperative day.

The mean (±SD) number of antiglaucoma medications showed no statistically significant change (P=0.25) over the 1-year follow-up in the TRAB-PHACO group, but there was a statistically significant increase in the TRAB group (P=0.03) (Table III). In the TRAB-PHACO group, 3 eyes (7.5%) required initiation of antiglaucoma medications after phacoemulsification, and 1 eye (2.5%) required one more medication than prephacoemulsification at the 1-year follow-up. In the TRAB group, 4 eyes (10.0%) required initiation of antiglaucoma medications, and 3 eyes (7.5%) required one additional medication during the year after the matched follow-up period.

After excluding 1 case of preexisting age-related macular degeneration and 1 case of preexisting macular hole, the vision of every patient improved 1 year after cataract removal except in 1 eye with significant posterior capsular opacity. The mean (±SD) VA in the TRAB-PHACO group

statistically improved over the first year ($P<0.001$). In the TRAB group (excluding 3 cases of age-related macular degeneration and 1 case of macular hole), VA did not show a statistically significant change after 1 year of follow-up ($P=0.05$) (Table IV).

With our IOP failure criteria, 13 cases in the TRAB-PHACO group and 9 cases in the TRAB group failed. Of the 13 failed cases in the TRAB-PHACO group, 5 cases failed before and 8 cases failed after phacoemulsification. Kaplan-Meier survival analysis showed that the probability of IOP control at 3, 6, and 9 years was 80%, 66%, and 44% in the TRAB-PHACO group and 79% ,69%, and 55% in the TRAB group. Mean survival times after trabeculectomy were 6.8 ± 0.7 years in the TRAB-PHACO group and 7.2 ± 0.7 years in the TRAB group. The distribution of survival times was not statistically different between the 2 groups ($P= 0.55$) (Fig 3). Cox regression analysis showed that the period of time between the initial trabeculectomy and phacoemulsification did not significantly affect survival time in the TRAB-PHACO group ($P=0.27$).

COMMENT

When Kass[18] reported the result of a questionnaire in 1982 about how glaucoma surgeons would remove a cataract in patients with a functioning bleb in the superonasal quadrant, most surgeons answered that they preferred ICCE (86%), no intraocular lens implantation (69%), and lateral limbal (32%) or superior corneal (32%) incision. Innovations in cataract surgery and glaucoma surgery have changed our approach to these patients. There have been many studies concerned with the results of cataract extraction in already filtered eyes,[4-14] along with comparisons of the site of the cataract surgery.[5,7,8] These studies are not easily comparable because of differences in methodology and subjects (Table V). One report showed a higher mean postoperative IOP than before cataract extraction in 9 patients followed for 1 year[10].

In terms of early postoperative IOP control, Murchison and Shields[11] showed that a pressure rise on the first postoperative day occurred in 57% of eyes undergoing the second stage of a two-stage procedure, although the pressure exceeded 30 mmHg in only 3 patients (14%). Despite the resumption of antiglaucoma medications, 50% of patients had an IOP above baseline on the second day after surgery. Brooks and Gillies[12] reported that 13% of the filtered patients had an IOP elevation to 30 mmHg or more on the first and second postoperative days. Recently, Drolsum and Haaskjold[13] and Yamagami and associates[14] reported the rates of 6.3% and 4%, respectively, for pressure spikes over 30 mmHg on the first postoperative day.

With respect to long-term IOP control after cataract extraction, sever-

TABLE V. COMPARISON OF PRESENT STUDY WITH PREVIOUS STUDIES

	PREFILTERED EYES (NO.)	CATARACT EXTRACTION	IOP CHANGE OR CONTROL	COMMENT
Savage (1985)	9	Inferior ECCE	2.1 mm Hg ↑ at last F/U (mean F/U,21.2 mo)	Uncontrolled study
Murchison and Shields (1988)	22	Superior clear cornea ECCE	7.7 mm Hg ↓ t last F/U (mean F/U: 22.3 mo)	Uuncontrolled study
Brooks and Gillies (1992)	43	Clear cornea ECCE	0.8 mm Hg ↓ at 1 yr	Controlled study*
Drolsum and Haaskjold (1994)	32	Clear cornea ECCE	0.2 mm Hg ↑ at 4 mo	Controlled study*
Yamagami et al. (1994)	45	Clear cornea or sclerocorneal ECCE or PE†	56% (2 yr) survival rate after cataract surgery	Controlled study* Kaplan-Meier survival analysis
Current study	40	Temporal clear corneal PE†	0.2 mm Hg ↓ at 1 yr after catract surgery, 80% (3 yr), 66% (6 yr), survival rate after trabeculectomy	Controlled study‡ Kaplan-Meier survival analysis

* Compared with no previous surgery group.
‡ Compared with trabeculectomy group.
† Phacoemulsification.

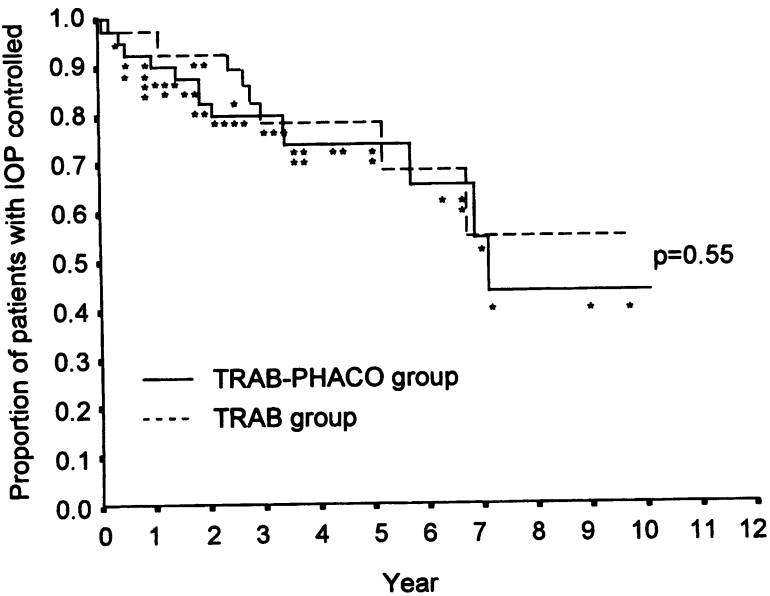

FIGURE 3
Probability of long-term IOP control calculated by Kaplan-Meier survival analysis. Distribution of survival times was not statistically different between two groups (P=0.56). Failure after trabeculectomy was defined as (1) an IOP greater than 21 mm Hg or less than a 20% reduction from pretrabeculectomy IOP on two consecutive follow-up visits with antiglaucoma medications, (2) a greater number of antiglaucoma medications needed than before trabeculectomy, or (3) requirement for additional filtering surgery. Asterisk indicates time of phacoemulsification for eyes in TRAB-PHACO group.

al previous studies reported continuous good control of IOP.[4-9] These studies did not describe the mean change of IOP or use a control group. Oyakawa and Maumenee[9] reported that 20 of 22 glaucomatous eyes had a postoperative increase in IOP in the end. Savage and associates[10] reported that IOP in 6 of 9 cases with follow-up of 1 year was higher than before cataract extraction. Murchison and Shields[11] showed that the pressure rose a mean of 4 mm Hg after cataract extraction at last follow-up, and more medications were required in 5 eyes (22%). Recently, Brooks and Gillies reported a small (0.8-mm Hg) but statistically significant fall in IOP at 1 year.[12] Yamagami and associates[14] showed that the eyes with filtering blebs increased by 2.2 mm Hg, but eyes without filtering blebs decreased by 2.5 mm Hg with a mean follow-up of 18.0 ± 11.9 months.

Survival analysis has been used to predict the long-term success of IOP control after surgery.[14,19,20] Yamagami and associates[14] showed a 56% success rate at 2 years after cataract extraction in filtered eyes. Lamping and colleagues[19] reported 85% and 70% at 2 and 5 years, respectively, in their trabeculectomy group, which included 76 of 252 eyes that underwent subsequent cataract extraction; there was no observable difference in the failure rate of those that had cataract surgery and those that did not. Nouri-Mahdavi and coworkers[20] reported 48% and 40% of IOP control at 3 and 5 years, respectively, with more stringent criteria, and 91% and 81% at 3 and 5 years, respectively, with less stringent criteria (IOP < 21 mm Hg) in their trabeculectomy group.

In our study, the number of antiglaucoma medications was not significantly changed in the TRAB-PHACO group, whereas in the TRAB group it was significantly increased by 0.2 ± 0.6 (P=0.03). The visual acuities improved in almost all patients in the TRAB-PHACO group, but 6 eyes (15.7%) (excluding 1 eye with age-related macular degeneration and 1 eye with a macular hole) did not attain at least 0.5 vision because of impairment of central vision by advanced glaucomatous optic neuropathy.

With respect to early postoperative IOP control, no eyes (0%) had a pressure spike above 30 mmHg, and 6 eyes (15%) had pressures above 21 mm Hg, and 9 eyes (22.5%) had a pressure increase of 7 mm Hg or more on the first postoperative day. This suggests that temporal corneal phacoemulsification, together with intraoperative carbachol, may decrease the risk of early postoperative pressure elevation after cataract surgery in previously filtered patients. The average IOP at 1 year after cataract surgery in the TRAB-PHACO group was not statistically different from the prephacoemulsification value (P=0.65). Considering the IOP course after the matched follow-up period in the TRAB group, phacoemulsification appeared to have no effect on IOP control after trabeculectomy.

In the current study, Kaplan-Meier survival analysis of IOP control took both IOP and number of medications into account. Data were analyzed from the date of trabeculectomy to determine if temporal corneal phacoemulsification affected the survival of trabeculectomy. There was no statistically significant difference in survival rates between 2 groups (P=0.55). The survival analysis from the time of trabeculectomy reinforces the result that the general course of IOP control as a function of filtering surgery seems not to be compromised by cataract extraction performed by temporal corneal phacoemulsification. The time between trabeculectomy and phacoemulsification, when the latter is performed more than 5 months after trabeculectomy, did not appear to influence the survival time in the TRAB-PHACO group.

Recently, we reported that a simultaneous combined procedure with temporal corneal phacoemulsification with low-dose 5-FU trabeculectomy

did not reduce IOP as well as trabeculectomy alone, but may be appropriate in selected patients.[21] We suggested that intraocular factors after cataract surgery other than subconjunctival manipulation might stimulate early postoperative fibroblastic activity at the filtration site. Taken together with the results of the current study, it would appear that temporal corneal phacoemulsification performed once a filtering bleb is well established has little effect on filtration and does not significantly affect IOP.

CONCLUSION

Temporal clear corneal phacoemulsification appears to maintain IOP control well in previously filtered eyes and does not affect the general outcome of trabeculectomy, as suggested by a retrospective, controlled, survival analysis. A prospective, controlled study of IOP control in glaucoma patients after one-stage combined and two-stage cataract and glaucoma surgery will be required to further define the best treatment of patients with coexisting visually significant cataract and glaucoma.

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DISCUSSION

RICHARD K. PARRISH II, MD. I thank Dr Caprioli for kindly forwarding the manuscript for review well in advance of the meeting, I appreciated this very much. I would like to discuss 4 points in reviewing the scientific design and conclusions of this paper.

First, Kaplan-Meier survival curves are used to demonstrate the lack of an apparent effect between intraocular pressure control after phacoemulsification and trabeculectomy versus trabeculectomy alone. It would be helpful to know the extent of confidence intervals at specific postoperative time intervals that are usually considered clinically meaningful, such as 6 months and 1, 3, and 5 years. With only 40 patients in each group, a large difference in failure rates could exist and not be detected.

Second, the matching used in this study appears to be a frequency-matched design, that is to say, control individuals were selected so that their average group characteristics, such as the number of preoperative medications, intraocular pressure control range, age, sex, race, type of glaucoma, and use of postoperative fluorouracil were comparable to those of the patients in the trabeculectomy and phacoemulsification group. If a study design had been chosen in which individual trabeculectomy patients were matched to individual phacoemulsification-trabeculectomy patients on the basis of all these characteristics, rather than a group of characteristics, the analysis could be more sensitive and realize a greater power to detect a difference. From a practical standpoint, given the sample size available, this is virtually impossible. In this frequency-matched model, the means are comparable in the 2 groups, and as such, a consideration for adjusting for these variables should be entertained in the unmatched survival analysis with Cox regression.

Third, the Cox regression model was used to study the effect of the

time of phacoemulsification after trabeculectomy on intraocular pressure control. The authors state that the time between trabeculectomy and phacoemulsification when the latter is performed more than 5 months after trabeculectomy did not appear to significantly influence the survival time in the trabeculectomy-phacoemulsification group; however, no data are provided on how the time interval between trabeculectomy and phacoemulsification correlates with failure rates. Unfortunately, the power to detect statistically meaningful effects given the sample size may be low. Information on confident intervals would also have been useful in interpreting the results. The data presented is consistent with no effect, but it could potentially be consistent with a large effect.

The most important and inescapable conclusion seems to be that neither uncomplicated trabeculectomy alone nor trabeculectomy and subsequent phacoemulsification achieve long-term pressure control in all patients and that eyes in both groups continue to fail at comparable rates. Initial postoperative IOP control with long-term loss of control is somewhat analogous to the relative ease of losing weight but the real difficulty of keeping it off in the long term. This sobering conclusion should compel glaucoma surgeons to develop newer and better surgical methods to achieve intraocular pressure lowering for the purpose of maintaining visual function.

DONALD MINCKLER, M.D. I thank Dr Caprioli for taking on what is a very important clinical problem. This however would seem to be a problem that really is best approached with a randomized prospective study design. First of all, there is incredible variability between eyes in terms of how they react to the surgery and, as was mentioned, the numbers are perhaps not large enough to really deal with all of the vagaries involved.

One specific issue that I do not think was mentioned, is the effect of complications during cataract surgery. Another is what type of bleb existed prior to cataract surgery? We suspect that some blebs are more likely to survive an additional insult, such as surgical trauma, than others.

JOHN T. FLYNN, M.D. I would also like to congratulate Dr Caprioli for tackling a very tough question of the control of intraocular pressure following cataract extraction. My question is a simple one. What happened to the visual fields in these 2 groups? Was there any statistically significant change in one group as opposed to the other? Since survival analysis was carried out in both groups for 3-9 years for IOP, what did their fields do over time? As far as I know, the name of the game is preservation of field, not just intraocular pressure numbers.

ROBERT DREWS, M.D. The important statistical consideration which always comes up in such studies is the rate of lost to follow-up. We have your data on some of these patients, but what percent of the patients were lost to follow-up?

JOSEPH CAPRIOLLI, M.D. Thank you for the remarks. It's always a little dangerous to give a paper on cataracts because so many have clear ideas on how surgery should be performed. Dr Parrish raises 4 points, 1 of which was most important. He spoke to the issue of the statistical power of the study. When one finds that there is no statistically significant difference between 2 groups, one must address the question: what is the power to find the difference? I can tell you that the power to detect a 2 mm difference between the 2 treatment groups after 1 year was 82%. We picked a 2 mm difference to indicate a clinically significant difference. With respect to controls, we did our best to match individual controls; but to match them exactly for every criteria would require a pool of several hundred or perhaps several thousand patients, so we settled for group mean matches. The logistic regression analysis, which was performed to detect whether or not there was a correlation between the time between trabeculectomy and cataract surgery and subsequent failure, did not show any significant correlation. But, because the number of patients that failed in this group was small, I think the power is likely small. We cannot come to any firm conclusion on that point, based on our data in this study.

Another point that Dr Parrish and Dr Minckler mentioned was the rather constant failure rate that we see over these 9 years, whether we do cataract surgery or not. This underscores the limited ability for glaucoma surgery to control patients in the long term. There seems to be a constant failure rate over a long period of time.

With respect to Dr Minckler's points, certainly randomized, prospective design would best answer the questions that are brought up here. This controlled, retrospective study was formed in response to some of the questions we had last year on the subject.

With respect to complications during cataract surgery in the 40 cases, 3 required vitrectomy because of vitreous loss. In each case, a posterior chamber lens was successfully inserted. With regard to possible bias, the appearance of the bleb was not a selection factor, in this case, at least not a conscious one. There is always some potential for bias in studies of this kind because of subconscious selection on the part of the surgeon. I cannot guarantee that did not happen.

Dr Flynn asked the essential question about visual field loss. Glaucoma, fortunately, is a very slow disease and with our follow-up of 1 to 3 years after cataract surgery, we really cannot say much about visual fields. It is also a particularly difficult subject in patients in whom cataract

is removed. The cataract extraction alone would have a significant impact on the visual field and presents a confounding factor.

Dr Drews raised the question of loss to follow-up. We chose 40 consecutive cases and we had a minimum follow-up of 1 year for all those cases. We then matched the controls against these. So, in this controlled study, loss to follow-up is not an issue. What the loss to follow-up is in the "universe of patients" from which these patients were selected, I cannot address.