CATARACT EXTRACTION AND LENS IMPLANTATION WITH AND WITHOUT TRABECULECTOMY: AN INTRAPATIENT COMPARISON

BY *James C. Bobrow*, MD

ABSTRACT

Objective: To determine whether cataract extraction and lens implantation combined with trabeculectomy provides better long-term results than cataract extraction and lens implantation alone in a group of patients with primary open-angle glaucoma and cataract randomly selected to receive surgery with trabeculectomy in one eye and without in the other.

Methods: A prospective, randomized clinical trial involving 35 patients with bilateral symmetric primary open-angle glaucoma and visually disabling cataracts with procedures performed by a single surgeon in a private practice setting with follow-up for more than 5 years in all cases.

Results: After an average of 87 months of follow-up, cataract extraction and lens implantation reduced intraocular pressure 4.4 mm Hg, reduced number of medications by 1.28, increased diopter vector of astigmatism by 1.49, and was associated with visual field loss in 6 of 35 eyes. After an average of 80 months of follow-up, cataract extraction, lens implantation, and trabeculectomy reduced intraocular pressure 8.2 mm Hg, reduced number of medications by 1.76, increased diopter vector of astigmatism by 1.14, and was associated with visual field loss in 1 eye. Both groups had similar improvement in visual acuity and perioperative complications.

Conclusions: Extracapsular cataract extraction, lens implantation, and trabeculectomy is a complex procedure that was beneficial in the long-term control of intraocular pressure and in prevention of visual field loss. This procedure should be considered in patients who may not be able to comply with a complex medical regimen, in whom pressure elevation in the immediate postoperative period would be undesirable, or in whom

*Associate Professor of Clinical Ophthalmology, Department of Ophthalmology and Visual Sciences, Washington University School of Medicine, St. Louis, MO. Address reprint requests to Dr. Bobrow at 211 N. Meramec, Suite 304, Clayton, MO 63105.

long-term pressure control at a lower level would be beneficial in preventing further optic nerve damage.

INTRODUCTION

In 1867 DeWecker,[1] recognizing the need for a persistent communication between the anterior chamber and the subconjunctival space to control intraocular pressure, reported on the results of a new operation, which he called an anterior sclerostomy. This procedure was later modified by Bader[2] and Herbert.[3]

It was not until 1906 that the procedures of sclerectomy and iridectomy were combined by LaGrange.[4] He realized that failure of previous filtering procedures was at least in part dependent on interference with the ostomy internally because of incarceration of iris in the wound. LaGrange used a Graefe knife, entering the conjunctiva approximately 1 mm from the limbus temporally.[5] The knife then entered the anterior chamber through sclera and exited symmetrically at the nasal side, creating a 6 to 7 mm chord length opening into the anterior chamber. As the knife was withdrawn toward the surgeon, a semicircular conjunctival flap was created with its apex approximately 3 to 4 mm from the lip of the corneoscleral wound, allowing prolapse of the iris. A peripheral iridectomy was performed. The corneoscleral wound was left open, and the conjunctiva was sutured.

Modifications of this technique were devised by Holth,[6] Griscom,[7] Spratt,[8] and Curdy.[9] Reports of success of these techniques in controlling intraocular pressure without the further use of miotics varied from 50% to 80%. The fact that these procedures did not remain successful is evident from the variety of iridencleisis modifications that were made by Gifford,[10] Holth,[11] and Reese[12] between 1867 and the late 1940s.

Those ophthalmologists who felt that corneoscleral tissue needed to be excised in order for filtration to occur devised trephining operations, which were initially described by D. Argyll Robertson[13] but did not become generally accepted until the work of Elliot.[14] Elliot's initial operation included a semicircular limbus-based conjunctival flap with a 2 mm trephination at the limbus followed by peripheral iridectomy and closure of the conjunctiva. Numerous modifications of the Elliot trephination operation were suggested by Benedict,[15] who recommended that the conjunctival flap begin 8 mm from the limbus and that the limbal conjunctiva be spared. Verhoeff[16] recommended a fornix-based flap, a technique that was amplified by Beard.[17]

As H. Saul Sugar[18] recounted in his discussion of *The Glaucomas*, the complications of filtering operations, with or without trephination, include operative hemorrhage, postoperative hemorrhage, vitreous prolapse,

injury and dislocation of the lens, bulging and prolapse of the ciliary body and processes, incarceration of iris, insufficient opening in the sclera, nonfiltration of the conjunctiva, late leakage through the bleb, late cataract formation, uveitis, late infection, and sympathetic ophthalmia. Aerola[19] found a 1.78% incidence of infections in a group of 5,616 trephining operations. Weeks[20] reported 1.3% late infections in 389 LaGrange-type procedures.

In his discussion of cataract formation after filtering surgery, Sugar[18] suggested that hypotony was to blame in many cases. He emphasized that subsequent cataract surgery be performed in a manner that would not interfere with the filtering cicatrix. He recommended that a corneal section be used anterior to the bleb, although he reported a significant risk of panophthalmitis.

Scheie[21] attempted to synthesize the techniques of sclerostomy and trephination by using cautery to enter the anterior chamber to avoid hemorrhage, shrink rather than remove tissue, and provide a method that could be used by the occasional surgeon with less risk and better visualization. His procedure included a large limbus-based flap and cautery to the sclera 1 mm posterior to the limbus. The area of cautery was then incised with a knife for a distance of 3 to 4 mm parallel to the limbus. The chamber was entered by employing cautery at the base of the incision until aqueous presented. Iris generally prolapsed once the anterior chamber was opened. A peripheral iridectomy was performed. The iris was irrigated gently back into the chamber, and Tenon's and conjunctiva were closed with a single running suture. Among the complications listed for this procedure were: shallow or flat anterior chambers; obstruction of the internal opening by iris, hemorrhage, both suprachoroidal and in the filtration site; wound leaks; infection; rupture of the zonule; and damage to the lens. Berens and King[22] were the first to suggest guarding the wound with a separate flap of Tenon's capsule sewn over the sclerectomy to prevent the bleb from becoming too thin.

THE CONTROVERSY SURROUNDING COMBINED CATARACT EXTRACTION AND TRABECULECTOMY

Up to this point, the assumption shared by almost all specialists in glaucoma was that attention should be paid to uncontrolled intraocular pressure before cataract surgery was considered. In the era from the inception of surgical techniques for the lowering of intraocular pressure until the advent of the surgical microscope, most procedures assumed the presence of the patient's lens. Combined cataract extraction and filtering surgery appeared too dangerous; filtering surgery for aphakic glaucoma failed superiorly because of conjunctival scarring, inferiorly because of hemorrhage and increased risk of infection, and universally because of vitreous

incarceration. Cataract surgery after filtering surgery presented difficulties both in clear cornea and temporally; failure of filtration occurred too frequently.

Becker and Shaffer[23] did not advocate combined cataract and glaucoma surgery in the first edition of their landmark textbook. They noted that "most filtering operations, even when performed as carefully as possible, are followed by a high incidence of progression of lens changes." Even if both conditions coexisted, they insisted that cataract surgery combined with filtering surgery was fraught with problems associated with the enlargement of the wound, prolapse of intraocular contents, persistent flat chambers, and malignant glaucoma. They discussed the complications of cataract surgery after filtration surgery by stating that "no matter how skillfully such surgery is done, because of reaction or postoperative hypotony, some successful filtration areas may close postoperatively." These statements were made at a time when all surgery was performed with loupes, and cataract removal was performed intracapsularly by cryoextraction.

In 1965, Chandler and Grant[24] stated that "the possibility of the development of a cataract is one of the calculated risks of filtering operations." They described combined cataract extraction and cyclodialysis by damning it with faint praise: "The frequency with which open clefts and reduction of the tension have been obtained by cyclodialysis combined with cataract extraction appears to be approximately as high as when cyclodialysis has been done as a separate procedure."

By the time Kolker and Hetherington[25] amended the original Becker-Shaffer text in 1970, they stated the following:

> Combining cataract extraction with filtering surgery may eliminate the need for a second operation to control glaucoma at a later date. It should be emphasized that additional risk is inherent in this surgery. One must also consider that cataract extraction alone may make the glaucoma easier to control postoperatively. Nevertheless, surprisingly few serious complications of the combined procedure have been reported.

Although Wright[26] described a combined cataract extraction, iridectomy, and sclerectomy of the posterior lip of the cataract wound, Maumenee and Wilkinson[27] devised a cataract extraction and glaucoma surgery that combined the elements of the Scheie procedure with a cataract wound. They built on the work of Lee and Weih,[28] who reported 100 cases of cataract and glaucoma surgery and recommended that "in cases of chronic noncongestive glaucoma with the intraocular pressure controlled by miotics, regardless of its original height, the combined cataract extraction should be the initial operation, and is likely to be the only procedure necessary." Other pioneers in combined surgery included Burge,[29] who combined cataract extraction with iridencleisis, and Hughes,[30] who advocated combining sclerectomy and iris inclusion with cataract extraction. In 1963,[31] Hughes reported on a group of 122 eyes followed over a longer

period of time:

> Postoperatively normal tension was restored in all but 9 eyes and drops were unnecessary in 99 of the eyes. It would appear that the combination operation is the operation of choice in cases of glaucoma when it becomes necessary to remove the lens. It is even recommended in cases of uncontrolled glaucoma with minor lens opacities when operation is necessary for the control of the glaucoma since the percentage of glaucoma cures is extremely gratifying.

After Maumenee and Wilkinson's article, posterior lip cautery was frequently combined with cataract extraction in an attempt to control intraocular pressure postoperatively.

ADVENT OF TRABECULECTOMY

The concept of a truly guarded sclerostomy, introduced by Cairns[32] and modified by Watson, allowed control of filtration and offered the promise of reducing many of the complications associated with previous combined procedures. This procedure, although originally trumpeted as at least partially successful because of the openings into Schlemm's canal which improved the egress of fluid from the anatomic outflow system, represented a synthesis of the sclerostomy and trephination with the addition of a protective layer between the anterior chamber and conjunctiva. The procedure has 3 major advantages: (1) maintenance of normal anterior chamber depth in the immediate postoperative period, avoiding the dangers of flat anterior chambers and choroidal separations, (2) production of a diffuse bleb, which protected the eye from the complications seen with cystic blebs, including late infection, and (3) better identification of anatomic landmarks because the scleral flap is dissected into clear cornea, minimizing the risk of excising tissue posterior to the scleral spur.

The advent of microsurgical techniques inspired by the introduction of finer, stronger suture material and swedged-on needles of improved sharpness permitted visualization of many of the anatomic landmarks described in pathologic specimens but not accessible to the naked eye or even to surgical loupes and allowed greater accuracy of wound construction with less inflammation. Controlled entry into the anterior chamber and meticulous closure soon allowed superior outcomes to be reported.

Lamping and associates[33] studied initial filtration surgery on a long-term basis. Eight-five percent (214) of 252 eyes that had initial glaucoma filtering surgery developed successful filtering blebs. Full-thickness procedures appeared to be successful for longer periods of time. At 5 years the probability for success measured by the absence of progressive visual field loss was 94.5% for full-thickness procedures and only 82% for trabeculectomies. Cataract extraction occurred more frequently following full-thickness procedures (34%) than with trabeculectomies (21%). Bleb leaks and infections occurred only in eyes that had full-thickness procedures and resulted in bleb failure and loss of glaucoma control or the need

for reoperation.

The results of primary trabeculectomy followed up for 6 to 12 years were studied by Popovic and Sjostrand.[34] They noted that the percentage of eyes requiring no medication for intraocular pressure control decreased linearly with time, from 90% at 1 year to 60% at 10 years. The prevalence of dense cataract producing severe visual loss at the last visit was 47%; the occurrence of cataract was correlated with the age of the patient at the time of operation.

Watson and his associates[35] revisited their patients who had undergone trabeculectomy beginning in 1968, when the procedure was first introduced by Cairns and himself. Their conclusions include an incidence of cataract formation that they felt to be no greater than normal and no adverse consequences from immediate postoperative shallow anterior chamber, uveitis, or hyphema. However, they also observed an inexplicable reduction in visual acuity and fields in about 33% of patients not related to cataract formation, macular problems, pressure changes, or medications.

Cairns's description of trabeculectomy did not include discussion of combining it with cataract extraction. In 1973, Liaricos and Chilaris[36] reported that 16 of 20 eyes with combined trabeculectomy and cataract extraction had very satisfactory results. They described the now classic benefits of these 2 procedures when combined:

> The corneoscleral wound is sufficiently closed to prevent shallow anterior chambers. The procedure is performed at all stages under the direct visualization and control of the surgeon. The resulting bleb is diffuse, almost flat in many cases, and does not undergo cystic degeneration. The conjunctiva does not come into direct contact with the aqueous escaping because it is protected from the scleral flap.

LENS IMPLANT WITH TRABECULECTOMY

With the advent of lens implantation, the depth of the anterior chamber following surgery became even more critical, because surgeons quickly realized that touch of the intraocular lens to the corneal endothelium spelled death for endothelial cells and an end to corneal clarity. Bourne and Kaufman[37] demonstrated endothelial cells adherent to the polymethylmethacrylate of intraocular lenses as early as 1976. The presence of any part of the pseudophakos anterior to the iris plane increased the risks of endothelial damage. In 1980, Drews[38] emphasized that, in selected patients, "the visual benefits may tempt the use of an intraocular lens in spite of the increased risks of postoperative problems." He cited 19 patients observed for 2½ to 6 years. Seventy-eight percent of his patients were taking the same therapy as, or less therapy than before surgery, at last follow-up; but only 53% achieved visual acuities greater than or equal to 20/40. He stated, "I find that my implantations in patients with preexist-

ing glaucoma present significantly increased surgical and postoperative problems and are relatively contraindicated. This is reflected in my current very low rate of iris-clip lens implantation in patients who have glaucoma."

These cautious comments were echoed by Wiley and colleagues,[39] who studied 22 eyes of 17 patients who had undergone intracapsular cataract extraction, trabeculectomy, and anterior chamber intraocular lens implantation. Although intraocular pressure fell and 73% of patients required no medication at an average follow-up of 1 year, the complications of flat anterior chamber and hyphema were relatively common. Clearly, positioning the intraocular lens in the posterior chamber would overcome a major obstacle. The switch to extracapsular cataract extraction and posterior chamber lenses quickly reversed the reluctance of the majority of surgeons to include an intraocular lens when glaucoma surgery was needed during or after cataract removal.

In the late 1970s and early 1980s, microsurgically controlled extracapsular cataract extraction techniques were widely adopted, and posterior chamber lens implantation became feasible with the implant designs of Shearing,[40] and Clayman and coworkers.[41] These advances led Richardson[42] to declare, "Chronic open angle glaucoma is not an absolute contraindication to implantation of an IOL. Nevertheless it remains a relative one."

The comprehensive article by Shields[43] outlined 3 levels of severity of glaucoma and 3 different approaches to these problems when faced together. He recommended cataract extraction alone in well-controlled patients with minimal damage, a 2-stage procedure of filtering surgery and subsequent cataract extraction when glaucoma was uncontrolled on maximum tolerated medical therapy and posed an immediate threat to vision, and combined surgery when patients were between these two extremes. His rationale for performing glaucoma filtering surgery first in uncontrolled cases was both to protect the eye from immediate postoperative pressure elevations and to achieve the lowest possible pressures for limiting future damage; the irreversible disease was given first priority. He also contrasted the increased rate of complications with combined surgery balanced against the potential for loss of filtration when cataract surgery was performed at a later date.

In an attempt to distinguish the extent of pressure control in patients with primary open-angle glaucoma who had cataract extraction, lens implantation, and trabeculectomy with those who had trabeculectomy alone, Naveh and associates[44] observed patients for an average of 22 months, comparing 40 patients who underwent combined surgery with 38 who underwent trabeculectomy alone. They concluded that in the trabeculectomy group, pressure levels were significantly lower, mean postop-

erative fall in pressure was greater, and fewer medications were required to maintain control of intraocular pressure. The extent to which cataracts formed after trabeculectomy was not noted.

Binkhorst,[45] a pioneer in extracapsular surgery and iris- and capsular-fixated lens implantation, discussed the contrast between prepupillary and retropupillary intraocular lenses. "Posterior chamber lens implantation into cataractous eyes which also suffer from primary glaucoma is then a rewarding experience since postoperative medical management is not impeded and surgical management is not precluded."

Neumann and colleagues[46] compared 23 eyes undergoing cataract extraction and trabeculectomy with a similar group of 23 eyes in whom a posterior chamber lens implant was added. The effect of posterior chamber lens implantation was negligible, and they advocated lens implantation be included in combined cataract and glaucoma surgery in order to provide better rehabilitation of visual function.

EARLY POSTOPERATIVE PRESSURE RISE

Several investigators have attempted to address the problem of early postoperative pressure rise. Vu and Shields[47] studied 25 consecutive cases of extracapsular surgery with posterior chamber lens implantation and 25 cases of intracapsular cataract extraction without intraocular lens implantation. Half of the patients in each group had a pressure rise above 21 mm Hg on the first day postoperatively, and approximately 80% had an intraocular pressure rise during the first postoperative month. The investigators felt that potentially dangerous pressure elevations were frequent enough that patients with moderate to advanced glaucomatous damage should have glaucoma surgery either before or in combination with their cataract operation.

Savage and coworkers[48] reported a large series in which preexisting glaucoma was present in 139 of 296 eyes. They noted intraocular pressure elevations of more than 15 mm Hg above preoperative levels in 23% of patients, whether controlled previously with medications or argon laser trabeculoplasty. They did not note a difference between the groups with posterior chamber intraocular lenses and those without lenses implanted. Ten percent of the patients had worsening of their visual field.

Krupin and associates[49] concentrated on the immediate postoperative period and corroborated the study of Savage, noting that cataract surgery alone was associated with significantly increased intraocular pressure on postoperative day 1 (18.9 mm Hg preoperatively versus 34.2 mm Hg postoperatively). A rise of 10 mm Hg or more occurred in 69% of eyes. In the eyes undergoing combined surgery, an intraocular pressure rise of 10 mm Hg or more was observed in only 14%. The investigators concluded that cataract surgery in eyes with open-angle glaucoma required careful moni-

toring and pressure control in the immediate postoperative period. In addition, Skorpik and colleagues[50] reported that, although postoperative intraocular pressure was reduced to 20 mm Hg or less, in 28% of eyes additional antiglaucomatous medication was required in a follow-up period ranging from 4 to 29 months after combined trabeculectomy, extracapsular cataract extraction, and intraocular lens implantation in patients with glaucoma.

McGuigan and coworkers,[51] in a series of 50 consecutive eyes with glaucoma undergoing extracapsular cataract extraction and intraocular lens implantation, discovered that 62% experienced substantially increased intraocular pressure in the early postoperative period. In a control group of eyes without glaucoma, only 10% experienced substantial elevations in pressure. These problems were avoided in 10 eyes in which trabeculectomy was performed along with cataract surgery. In this series, inadequate intraocular pressure control with maximum medical therapy was considered an indication for combined surgery, whereas in Shields' study only 4 years earlier, the same coincidence of conditions was felt to be a contraindication.

Attempts have been made to utilize argon laser trabeculoplasty prior to cataract extraction to reduce the intraocular pressure rise that is feared in the early postoperative period. Calissendorff and Hamberg-Nystrom[52] observed 74 patients with glaucoma who had extracapsular cataract extraction and posterior chamber lens implantation. Fifty-nine percent of those patients pretreated with an argon laser trabeculoplasty before surgery had a pressure rise of greater than 10 mm Hg the day after surgery. In those patients treated medically, the corresponding percentage was 34%. Of concern, 8 patients who had been treated either with trabeculoplasty or with previous glaucoma filtering surgery to control intraocular pressure had pressure rises that could not be controlled medically and had to undergo repeat trabeculoplasty or secondary filtering surgery. Thus, argon laser trabeculoplasty conferred no protective effect on the early postoperative pressure rise.

When Simmons and associates[53] reported a series of 75 consecutive cases of extracapsular cataract extraction and posterior chamber intraocular lens implantation combined with trabeculectomy, their results were disappointing. They reported that although average intraocular pressure was lower and acuity was better, 36% had a recorded intraocular pressure greater than 30 mm Hg during the first 6 months after surgery and 40% had a pressure 7 mm Hg or higher than preoperative levels in the first 6 months after surgery. Filtering blebs were present in only 12% of patients seen at 1 year. Hyphema occurred in 45% of the cases.

Even in patients who did not have preexisting glaucoma, a retrospective study by Kooner and colleagues[54] demonstrated that a postoperative

pressure rise of 8 mm Hg above baseline or above 23 mm Hg was observed in 149 of 506 eyes (29%) during the immediate postoperative period. Over a follow-up period of 6 years, 24 eyes (4.7%) developed pseudophakic glaucoma. This incidence suggested that although cataract extraction and posterior chamber lens implantation was not associated with the induction of glaucoma in the vast majority of patients, diligence and careful observation are warranted even as far as 6 years beyond surgery.

Worldwide surgical opinion was further confused by the study of Mori and associates,[55] who observed 21 primary open-angle glaucoma and 26 primary angle-closure glaucoma eyes in which intraocular pressures were well controlled on medication. After cataract surgery with lens implantation in the open-angle glaucoma eyes, 24-hour postoperative pressures were significantly higher than baseline levels; in the primary angle-closure eyes, intraocular pressures did not rise significantly. Medications did not differ significantly preoperatively and intraocular pressures were able to be controlled postoperatively. The investigators found that the early postoperative pressure rise did not cause appreciable damage and that medication use was not altered by cataract surgery.

Observation of intraocular pressure measurements after extracapsular cataract extraction and posterior chamber lens implantation in eyes with controlled open-angle glaucoma caused Onali and Raitta[56] to conclude that the critical period postoperatively appeared to be the first 14 days after surgery. They recorded a slight increase in mean intraocular pressure in their primary open-angle glaucoma patients 1 to 2 weeks after surgery. By 2 to 6 weeks, the mean intraocular pressure had returned to preoperative levels, and after 2 years, mean intraocular pressure had declined. In their series, intraocular pressure was controlled without glaucoma medication in 43% of patients.

The indications for combining cataract extraction, lens implantation, and trabeculectomy were expanded by Storr-Paulsen and colleagues,[57] who observed 19 eyes that had undergone this combined procedure for 1 year. They concluded that patients with uncontrolled glaucoma, poor compliance, limited access to medical care, or unacceptable medications should be considered for combined surgery. They also recommended careful monitoring of early postoperative intraocular pressure even if hypotensive agents had been given prophylactically.

FURTHER STUDIES OF COMBINED SURGERY

Several investigators have observed the effects of combining extracapsular cataract extraction, lens implantation, and trabeculectomy. Levine[58] reported in 1986 that the combination of extracapsular cataract extraction, posterior chamber lens implantation, and glaucoma filtering procedure in

a group of patients with marginal pressure control observed for 6 to 24 months produced pressures less than or equal to 21 mm Hg in only 62% of patients; 86% still required medication. In a second group of patients with a functioning filtering bleb before cataract surgery, Levine made his incision through the filtering bleb to remove the cataract and then performed a second filtering operation adjacent to the original one. Pressure control was no worse after the 2 sequential procedures than with the combined procedure.

A comparison of limbus-based and fornix-based conjunctival flaps for trabeculectomy was offered by Murchison and Shields.[59] In a prospective fashion, they evaluated a limbus-based conjunctival flap in 22 and a fornix-based flap in 25 of a consecutive series of 47 patients undergoing cataract extraction, lens implantation, and trabeculectomy observed for a minimum of 6 months. The limbus-based group had significantly better early postoperative intraocular pressure control.

Corroboration was found in the study by McCartney and coworkers,[60] in which 108 consecutive operations for cataract and glaucoma employing extracapsular cataract extraction, posterior chamber lens implantation, and trabeculectomy produced pressure control less than or equal to 21 mm Hg in 92% of eyes, of which 57% required no medications. The investigators noted that posterior capsular rupture and transient hyphema occurred significantly more often than in a comparison group. Visual outcome was satisfactory and engendered the recommendation that combined surgery provided excellent visual rehabilitation and intraocular pressure control.

Two further reports were of significant importance to the design of this study. Obstbaum[61] reported in 1986 on the ability of extracapsular cataract extraction and posterior chamber lens implantation to improve pressure control in patients with glaucoma. He looked at 4 groups of patients, including a group with chronic open-angle glaucoma who had had no previous surgical therapy and whose disease was controlled with topical medication. Intraocular pressure was controlled in all groups at a level approaching the preoperative value. Ninety percent of patients achieved control with equal or less medication than that used preoperatively. Although these patients were observed for a relatively short period, no significant progression of optic nerve cupping or visual field loss occurred.

Handa and associates[62] also performed extracapsular cataract extraction with posterior chamber lens implantation in patients with glaucoma, reporting their results on 43 eyes. They reported decreased dependence on medication for control of intraocular pressure and minimal complications of surgery. They cautioned that:

> Nothing from the above data should be misconstrued to suggest that extracapsular cataract extraction with insertion of a posterior chamber intraocular lens will

> itself lower intraocular pressure. The retrospective nature of this study, lack of a control group, and the unregimented changes in medications postoperatively obviously prevent such conclusions. In addition a longer follow-up period is needed to evaluate the post-operative changes, considering the unknown mechanisms for improved intraocular pressure control. . . a randomized, prospective study using eyes with a wide range of glaucoma control is ultimately needed to evaluate the place of extracapsular cataract extraction with posterior chamber lens implantation in the patient with simultaneous open angle glaucoma and cataract.

All of the previously cited conflicting data were reviewed and summarized in an editorial by Watson[63] in the *British Journal of Ophthalmology* on combined cataract and glaucoma surgery:

> Simply removing the cataract rarely has a lasting effect in controlling the glaucoma. . . The combined operation of cataract extraction and trabeculectomy is successful but is often followed by shallowing of the anterior chamber. . . Techniques change fast, so fast that well controlled studies have become impossible, so it will probably be some time before we have the perfect answer to this difficult problem.

Watson included in his long-term observations a warning concerning the effectiveness of surgical therapy over a longer term:

> The most important finding in this investigation was that whilst some patients have some improvement of vision and field, a long term reduction in visual acuity and visual fields occurred in over half the patients. Even if those with increasing cataract, and overt maculopathy are removed from the calculations there is still a reduction in acuity or in field of at least two grades or more in 30% of patients. . . The reason for reduction of field is *not* clear but is not related to the height of the original intraocular pressure, the amount of fall of intraocular pressure induced by operation, the type of glaucoma for which trabeculectomy was performed or whether the preoperative field was small or large, *nor* is it related to any postoperative or long-term complication or to any specific preoperative medication.

PRELIMINARY STUDY

In an earlier review of long-term results of lens implantation, Bobrow and Drews[64] found that the addition of a lens implant, particularly one which was either fixated to the iris or rested in the anterior chamber angle, had compounded the difficulty of cataract surgery and created a subpopulation of patients who developed secondary glaucoma from complications associated with the lenses themselves. With posterior chamber lens implantation, less interference with trabecular meshwork and irritation of iris occurred; and the isolated effects of separate lens implantation and trabeculectomy compared with combined surgery could be more easily assessed.

Confusion surrounding the conclusions reached as a result of the studies that were available up to 1986 prompted a review of 68 eyes that had glaucoma controlled with maximum tolerated medical therapy. Thirty-four had undergone extracapsular cataract extraction, lens implantation, and trabeculectomy. They were compared with 34 age-matched eyes that had undergone extracapsular cataract extraction

and lens implantation without trabeculectomy. An attempt was made to match severity of glaucoma in the 2 groups, although in a retrospective study, the considerations surrounding the choice of procedure for each patient were unique for each surgery. The demographics of the original 68 eyes are given in Table I. Male-female ratios were identical in both

TABLE I: DEMOGRAPHICS OF PATIENTS: PRELIMINARY STUDY

FACTOR	WITH TRAB	WITHOUT TRAB
Average age (yr)	73.6	71.2
Male: female ratio	11.23	11.23
White: African American	28:6	30:4
Follow-up (mo)	23.4	22.8

groups. The ratio of white to African American patients was reflective of the composition of the practice from which they were drawn. Average follow-up was approximately 2 years for each group. An attempt was also made to find eyes with similar levels of severity of glaucoma for comparative purposes. In addition, an effort was made to match the systemic diagnoses of the 2 groups.

The number of medications being used just prior to surgery in the group having extracapsular cataract extraction, intraocular lens implant, and trabeculectomy was 2.47; in the fellow eye of these patients the number of medications averaged 2.41. In those eyes having extracapsular cataract extraction and intraocular lens implant without trabeculectomy, the average number of medications was 2.14 per eye.

The first significant difference in preoperative and postoperative results was in intraocular pressure. Although preoperative intraocular pressures were comparable at 22.6 mm Hg for the group with trabeculectomy and 22.0 mm Hg for the group without trabeculectomy, at 1 week in the group with trabeculectomy, average intraocular pressure dropped precipitously to 9.5 mm Hg, gradually rising to 13.8 mm Hg at the most recent examination (Fig 1). In contrast, average intraocular pressure in the group without trabeculectomy was 19.6 mm Hg 1 week after surgery and 17.0 mm Hg at the most recent examination.

Visual acuity recorded as the Snellen fraction at each visit was approximately similar in both groups preoperatively (Fig 2). The group with trabeculectomy recovered visual acuity much more gradually, from 20/60 at 1 week to an average level of approximately 20/35 at the most recent examination. The group without trabeculectomy recovered to 20/46 at 1 week with gradual improvement to 20/33 at the most recent examination.

In the group with trabeculectomy, only 13 of 34 eyes required med-

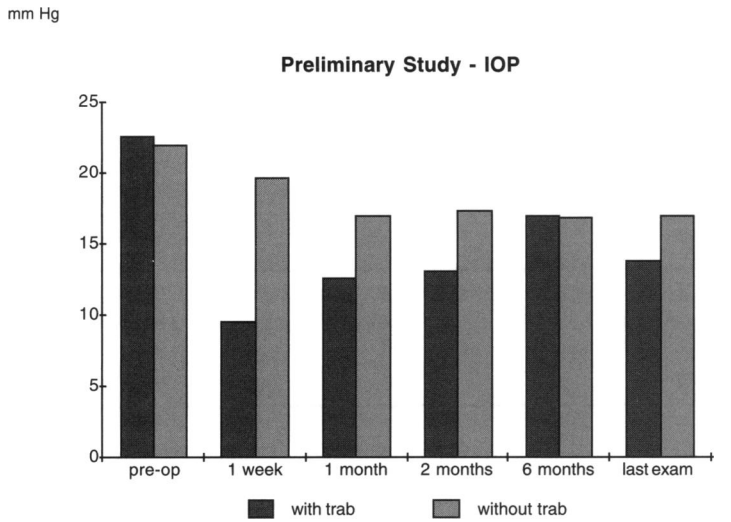

FIGURE 1
Comparison of intraocular pressures in group with trabeculectomy and group without trabeculectomy. Pressure fell to 9.5 mm Hg at 1 week in group with trabeculectomy, then gradually rose to 13.8 mm Hg at last examination. Pressure remained close to preoperative levels initally in group without trabeculectomy, then fell to 17.0 mm Hg at last examination.

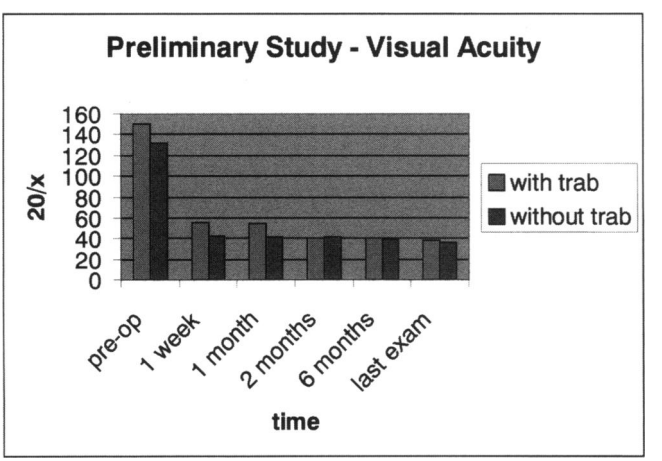

FIGURE 2
Comparison of visual acuity in group with trabeculectomy and group without trabeculectomy. Acuity improved significantly in both groups but recovered more rapidly in group without trabeculectomy.

ication postoperatively. The average number of medications was 0.47 per eye. In the group without trabeculectomy, 28 eyes required medication at 2 years, although the average number had dropped from 2.14 to 1.25 medications per eye.

The results of this study generated the following conclusions: (1) combined surgery was effective in lowering intraocular pressure and improving visual acuity; (2) it decreased the likelihood of increased intraocular pressure in the immediate postoperative period; (3) postoperative pressure could more often be controlled without the use of miotics or systemic carbonic anhydrase inhibitors; and (4) it could be helpful in patients in whom compliance might be a problem.

STUDY DESIGN

Among this preliminary group of 68 eyes were 3 patients who had had extracapsular cataract surgery in both eyes with a trabeculectomy in only one. Intrigued by the concept that this subgroup of patients represented a cohort with each patient serving as his or her own internal control, recruitment began for patients to enter a study in which the decision to perform one or the other technique would be reached on a random basis in patients with bilaterally symmetric disease. Since the dependence on medication had been reduced in both eyes of each of the 3 patients in this small pilot group, it was possible to explain to patients recruited for this study that the long-term benefits of trabeculectomy at the time of cataract surgery were not known; therefore, patients were not being offered a lesser procedure in one eye or a better procedure in the other.

Patients were recruited from a single surgeon's clinical practice. The recruitment period for the 50 patients who ultimately were enrolled in this study lasted from May 1985 to January 1987. Patients were selected according to the following criteria: bilaterally symmetric glaucoma with similar levels of field loss, approximately equal dependence on topical medication, absence of previous laser or incisional surgery, and the presence in at least one eye of a cataract impairing vision to a level that was unacceptable to the patient. Because patients did not always have symmetric cataracts and because in many patients intraocular pressure was satisfactorily controlled with topical medication, intervals between surgery could be as short as 6 months or as long as 5 years.

METHODS

As each patient was recruited for this study, informed consent was obtained individually for each procedure that was being performed. Patients were told that from previous evaluations, no consensus had been established concerning the addition of trabeculectomy to cataract extraction and lens implantation. The patients were told that the consequences

of cataract extraction and lens implant alone were thought to be more rapid visual rehabilitation after surgery, continued dependence on medication for control of intraocular pressure, the possibility that pressure might be more easily controlled after surgery, and some relief from the difficulties associated with miotic pupils because of the stretching of the pupil at the time of surgery.

For the combined procedures, patients were told that, conversely, visual restoration might be attained more slowly, the intraocular pressure spike which might occur when cataract surgery was performed alone might be avoided because of the trabeculectomy, the patient might expect reduced dependence on medications, and that, similarly, miosis might be alleviated by pupil stretching. Since both of these procedures were noninvestigational, no attempt was made to seek the approval of an institutional review board. The procedure to be performed on the first eye was determined by a random-number-generating program: if the random number was odd, trabeculectomy was performed; if the random number was even, no trabeculectomy was performed.

The criteria for diagnosis of primary open angle glaucoma included elevated intraocular pressure, glaucomatous visual field loss, and evidence of optic disc cupping. Patients were taking medication because they had demonstrated progressive visual field loss characteristic of glaucoma on either a Goldmann Perimeter or Humphrey Visual Field Analyzer. Intraocular pressure was measured by Goldmann applanation tonometry. Progression of optic nerve damage was documented by fundus photography, initially with a Kowa Model XV Fundus camera and later with a Nidek stereoscopic fundus camera Model 3-DX. All patients had an ophthalmological examination, recording the history of their ocular problems including declining visual acuity and length of antiglaucoma therapy. General historical information was obtained including all diagnoses, medications, and previous nonocular surgical interventions. Patients were queried concerning family history of glaucoma, cataracts, other ocular diseases, and systemic diseases.

At initial evaluation upon entrance into the study, patients had measurement of best-corrected visual acuity and intraocular pressure, keratometry, slit-lamp biomicroscopy, direct and indirect ophthalmoscopy, gonioscopy, and evaluation of visual fields. At each postoperative examination, the essential information of best-corrected visual acuity, measurement of intraocular pressure, keratometry, slit-lamp biomicroscopy, and ophthalmoscopy were performed. Additional examinations were performed when indicated. All patients had at least annual visual field examinations.

SURGICAL TECHNIQUE

The first patient in the study had cataract extraction, lens implantation, and trabeculectomy in May 1985, and the last patient had surgery in December, 1991. A standardized surgical technique was used. Retrobulbar anesthesia with Marcaine 0.37% and Xylocaine 2% was used, and the patient was prepped and draped in the usual sterile fashion. A 6-0 silk suture (Ethicon 697G) was placed in the superior rectus muscle tendon. For those eyes not having a trabeculectomy, a limbus-based conjunctival flap was made approximately 2 mm from the limbus. A diamond knife was used to make a 10 mm chord length incision at the posterior limbus to approximately 80% depth. Bleeding vessels were lightly cauterized as needed with an Eraser cautery. A mattress suture of 10-0 nylon (Alcon 198001) was preplaced in the groove at the 11 and 1 o'clock positions. The loops were removed from the groove by using a toothed forceps. The chamber was entered at the 12 o'clock position with a diamond knife in a beveled fashion. The chamber was deepened with Healon. In those patients in whom previous miotic therapy necessitated enlarging the pupil, either small sphincterotomies were made in the pupillary border or a radial iridectomy was made at the 12 o'clock position. A 27-gauge cystitome was used to perform a can-opener capsulotomy. The lens was hydrodissected with balanced salt solution. The wound was then opened to 10 mm chord length.

Using an irrigating vectus, the nucleus was delivered from the posterior chamber. The 2 preplaced nylon sutures were then tied in bow knots. A McIntyre apparatus was introduced into the chamber and used to remove cortical material and to polish the posterior lens capsule. The 1 o'clock suture was untied and looped out of the way. A Storz 95UV (single-piece PMMA intraocular lens with 7 mm optic and 13.75 mm total length with an A-constant = 118.0) or a Storz 71 UVNH lens (6 mm PMMA optic without holes, polypropylene J-loops, overall length 13.75 mm and A-constant = 119.0) was introduced into the capsular bag and placed in a horizontal position with the haptics at the 9- and 3-o'clock positions when possible. A cap was placed over the cornea to protect the retina from focused light after the implant was in place. The preplaced sutures were then retied with the knots buried. At the end of the procedure, a 10-0 polypropylene suture on an STC-6 needle (Ethicon 1713) was passed through the open pillars of iris and tied to re-establish a round pupil. Additional 10-0 butterfly sutures were postplaced at 9:30, 10:30, 12:00, 1:30 and 2:30 o'clock to close the wound. The McIntyre apparatus was reintroduced into the chamber to remove as much of the remaining Healon as possible. The conjunctiva was closed by using a running suture of 10-0 Vicryl (Ethicon D-7498). No injectable antibiotics were used at the end of the procedure. Maxitrol ointment was used at the end of the procedure for antibacterial and steroid coverage. No ocular hypotensive

agents were administered topically at the end of the procedure. A splint, patch, and shield were placed over the eye operated on, and the patient was instructed to use prednisolone acetate 1% drops 4 times a day and tobramycin drops 0.3% twice a day. The patient returned for postoperative visits at 1 day, 6 days, 3 weeks, and 6 weeks and at more frequent intervals if needed.

In those patients who had combined cataract extraction, lens implantation, and trabeculectomy, the surgical procedure was modified. Retrobulbar anesthesia was employed by using the same agents. After the lid speculum had been inserted, Xylocaine 2% without epinephrine was injected by using a 30-gauge needle under the conjunctiva superiorly to elevate the conjunctiva and Tenon's from the sclera. A 6-0 silk suture was placed in the superior rectus muscle tendon. A limbus-based flap was made 7 to 8 mm from the limbus for approximately 3 clock hours. Dissection under the flap was carried forward to the limbus. A diamond knife was used to form an equilateral triangular trabeculectomy flap approximately 4 mm on each side. Dissection of a one-third to one-half thickness trabeculectomy flap was accomplished using a No. 69 Beaver blade. The diamond knife was then used to extend the incision along the posterior limbus for a total chord length of approximately 10 mm. A 10-0 nylon mattress suture was placed on either side of the trabeculectomy flap. Loops were removed from the bed with a toothed forceps. A 1x3 mm trabeculectomy bed was then inscribed at the base of the trabeculectomy site with the diamond knife, the surgeon taking care not to enter the anterior chamber. The anterior chamber was then entered along the anterior edge of the trabeculectomy bed with the diamond knife. The chamber was immediately deepened with Healon. A cystotome was used to form a can-opener capsulotomy. If necessary, enlargement of the pupil was accomplished either by radial iridectomy or multiple fine sphincterotomies at the pupil border. The lens was hydrodissected. The wound was then opened to its full extent. The nucleus was expressed using counterpressure and the irrigating vectus. The 2 preplaced sutures were then pulled up and tied in bow knots. A McIntyre apparatus was used to remove the remaining cortical material and to polish the posterior lens capsule. The 10-0 nylon sutures were looped out of the way. Healon was introduced into the chamber to deepen it. The same type of intraocular lens was used for both eyes. The preplaced sutures were then retied and the knots were buried. Two butterfly 10-0 nylon sutures were postplaced on either side of the trabeculectomy site to close the remainder of the wound. The other 3 sides of the trabeculectomy opening were then excised, leaving a clear opening into the anterior chamber over the iris. An iridectomy was performed basally large enough to be sure that iris could not be visualized in the base of the trabeculectomy opening. Bleeding vessels along the posterior lip of

the sclerotomy were cauterized. The trabeculectomy flap was closed using 3 interrupted 10-0 nylon sutures with the knots similarly buried. Filtration was checked by reirrigation at the lateral extent of the wound. Conjunctiva and Tenon's were then closed in a single layer using 10-0 Vicryl on a BV-100 needle (Ethicon D-7498). The Vicryl suture was pulled so that the edges of the conjunctiva were well enough apposed that a fluorescein strip applied to the surface of the conjunctiva revealed no leaks. No injectable antibiotics were used. The cornea was covered with a shield during times when visualization of the anterior chamber was not required. In cases in which the procedure had taken a longer time than usual or in which dissection had been more traumatic because of subconjunctival scarring, dexamethasone (40 mg/mL) 0.3 cc was injected subconjunctivally in the inferior cul de sac. Maxitrol ointment was used for antibiotic and topical steroid coverage. A splint, patch, and shield were placed over the eye operated on, and the patient was instructed to use the same topical regimen reported above in the postoperative period. To promote additional filtration in the early postoperative period, sutures in the trabeculectomy flap were transected as needed using a Hoskins lens and argon laser.

Of 50 patients originally recruited, 35 completed the study by having both eyes operated on and at least a 5-year follow-up for each eye. Eleven patients died either before having their second eye operated on or before follow-up could be completed. Four patients had surgery in 1 eye and then were lost to follow-up before additional data could be collected. Student's *t* test was used for all analyses except as noted.

RESULTS

The demographic data of the 35 patients who completed the study are presented in Table II. Since these patients served as their own controls, their age at entrance into the study is given; some patients have participated in the study for as long as 11 years. Thirty-four percent of the patients were more than 75 years old, consistent with data from large population-based surveys in which the incidence of glaucoma rises with each decade of life.[65,66] Approximately two thirds of the patients were female, again consistent with the average age of the study population. Thirty were white and 5 were African-American, reflecting the composition of the surgeon's office practice.

Preoperative data concerning each group are presented in Table III, as well as the differences between groups. Intraocular pressures were averaged for the last 3 visits prior to surgery for each eye. Although the group that subsequently underwent surgery with trabeculectomy had an average pressure 1.23 mm Hg higher than the group without trabeculectomy, the

TABLE II: DEMOGRAPHICS OF PATIENTS: PRESENT STUDY

Average age (yr)		70.2 ± 10.3
Range (yr)		35 - 82
Male: female ratio		12.23
White: African American		30:5
Right: left (with trab)		17:18
Follow-up:	with trab	80 mo
	without trab	87 mo

TABLE III: PREOPERATIVE DATA FOR STUDY GROUPS

	WITH TRAB	WITHOUT TRAB	*P* VALUE
IOP (mm Hg)	22.0 ± 4.1	20.7 ± 3.4	ns
Visual acuity	20/117 ± 72	20/119 ± 71	ns
Medication	1.94 ± 0.80	2.06 ± 0.84	ns

difference between the 2 groups was not statistically significant. Similarly, visual acuities preoperatively and number of medications used to control intraocular pressure did not differ significantly between groups. Fig 3 shows the number of patients receiving 1, 2, 3, or 4 medications. The frequency distribution appears to be symmetric; the dif-

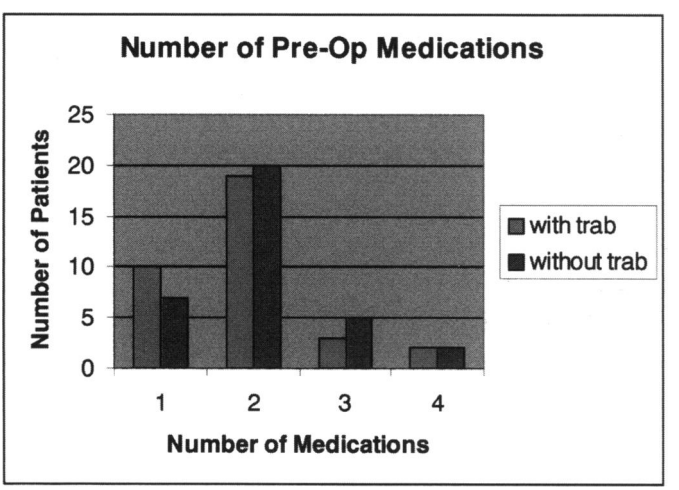

FIGURE 3
Distribution of number of preoperative medications in group with trabeculectomy and group without trabeculectomy.

ference is not statistically significant.

Since this study focuses on the long-term efficacy of combining cataract and glaucoma surgery, the emphasis in the postoperative data has

TABLE IV: POSTOPERATIVE DATA FOR STUDY GROUPS

	WITH TRAB	WITHOUT TRAB	*P* VALUE
IOP (mm Hg)	13.8 ± 2.8	16.4 ± 2.5	.0001
Visual acuity	20/28 ± 10	20/33 ± 17	.038
Medications	0.17± 0.50	0.77 ± 0.70	ns
Follow-up (mo)	80 ± 25	87 ± 22	ns

been placed on findings as long after surgery as possible. As can be seen in Table IV, mean follow-up in the group with trabeculectomy was 80 months and in those without trabeculectomy 87 months. Intraocular pressure was lower in both groups; the absolute pressure in the group with trabeculectomy measured 13.8 mm Hg and in the group without trabeculectomy 16.4 mm Hg. Visual acuities were slightly better in the group with trabeculectomy; importantly, vision did not appear to degrade over time. Reliance on medication was reduced in both groups, although to a greater

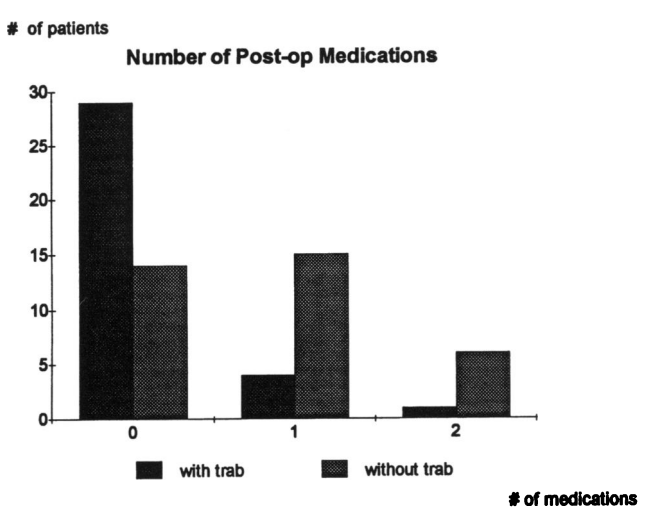

FIGURE 4

Twenty-nine patients who had surgery with trabeculectomy were not using medication at the end of the study, whereas only 14 patients without trabeculectomy were controlled without medications.

TABLE V: PREOPERATIVE AND POSTOPERATIVE DIFFERENCES IN STUDY GROUPS

	WITH TRAB	WITHOUT TRAB	DIFFERENCE	P VALUE
Δ/OP (mm Hg)	-8.2 ± 4.6	-4.4 ± 3.3	-3.8 ± 3.7	0.0001
Δ Visual acuity	-20/89 ± 70	-20/86 ± 69		ns
Δ Astigmatism vector	1.14	1.49	0.34	ns
Δ Medications	-1.76 ± 0.82	-1.28 ± 0.86	-0.47 ± 0.66	0.0002

extent in the group with trabeculectomy. As can be seen in Fig 4, 29 of 35 patients in the group with trabeculectomy were using no medications; 4 patients were using only 1 medication, and only 1 patient was using 2 medications. In the group without trabeculectomy, by contrast, 14 patients were using no medications, 15 patients were using 1 medication, and 6 were using 2 medications.

As can be seen on Table V, the reduction in intraocular pressure in the group with trabeculectomy averaged 8.2 mm Hg and in the group without trabeculectomy 4.4 mm Hg, so that the 3.8 mm Hg difference between these 2 reductions in pressure also was highly statistically significant. Changes in visual acuity in the 2 groups were not significant. The decrease in number of medications in the group with trabeculectomy was 1.76 and

TABLE VI: INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS IN STUDY GROUPS

	WITH TRAB	WITHOUT TRAB
Rupture of posterior lens capsule	1	1
Hyphema	3	0
Persistent inflammation	2	1
Choroidals/hypotony	1	0
YAG capsulotomy	6	9
Progressive field loss	1	6

in the group without trabeculectomy 1.28. The difference between these 2 values was significant with a *P* value of .0002.

Table VI lists the intraoperative and postoperative complications in the 2 groups. Postoperative hyphema was more common in the group with trabeculectomy, but all cases resolved with conservative treatment consisting of dilation, elevation of the head, and restriction of activity. Two patients with trabeculectomy had persistent inflammation, requiring topical steroid therapy. One patient was able to taper off steroid after about 6 months. In the other patient, continued therapy with fluorometholone

0.1% twice daily has been necessary; when all steroids were withdrawn, the patient developed mild cystoid macular edema and reduction in acuity, both of which reversed when therapy was reinstituted.

One eye with trabeculectomy developed a chronic choroidal separation with hypotony. Dexamethasone (80 mg/cc, 0.5 cc) injected in a retrobulbar fashion 6 weeks postoperatively caused resolution of the underlying inflammation with disappearance of the choroidal separation, an increase in intraocular pressure to normal levels, and improvement in acuity from 20/60 to 20/25, where it has remained since that time.

Rupture of the posterior lens capsule occurred intraoperatively in 1 patient in each group. Mechanical anterior vitrectomy was used in both cases. Sufficient lens capsule remnants were preserved to allow placement of a posterior chamber lens in each case. In the patient with trabeculectomy, a bleb has remained elevated with good filtration postoperatively.

More patients in the group without trabeculectomy required YAG laser posterior capsulotomy postoperatively than in the group with trabeculectomy, although the difference was not statistically significant. No

TABLE VII: PROGRESSIVE FIELD LOSS IN STUDY GROUPS*

	WITH TRAB	WITHOUT TRAB
Stable field	34	29
Continued loss	1	6

*P value = .05

patient required additional surgical or laser intervention to control intraocular pressure.

Progressive visual field loss occurred postoperatively in 6 of the patients who had no trabeculectomy performed at the time of surgery; only 1 patient had progressive visual field loss in the group with trabeculectomy. As can be seen from Table VII, a Student's t test performed on these results revealed a p value of 0.05. Of the patients who developed visual field loss in the nontrabeculectomy group, 3 developed visual field loss within 1 year of surgery. An additional 3 eyes have developed visual field loss gradually over the more than 5 years since their procedure. The 1 patient in the group with trabeculectomy who developed further visual field loss did so gradually after surgery. He was the 1 individual who required 2 medications to restore intraocular pressure to adequate levels postoperatively.

Three-dimensional photographic evaluation of the optic nerve was car-

ried out in all patients. In the patients who developed further visual field loss postoperatively, a concomitant change was seen in the cup-disc ratio. In the remaining eyes, evaluation of the optic nerve revealed no significant interval change in cup-disc ratio during the course of the study.

The effect of surgery on astigmatism was compared between groups using the vector method of Cravy.[67] This method compares preoperative and postoperative astigmatism "based upon the dynamics of change in curvature of the cornea as determined by keratometry..in polar coordinate form." The preoperative measurement was taken when the A-scan calculation was performed. The postoperative measurement was taken from the keratometry readings at the last postoperative visit in the study. The change in astigmatism attributable to surgery was then calculated for each eye, and the results were compared. Average change in the astigmatism vector was 1.14 for the group with trabeculectomy and 1.49 for the group without trabeculectomy, with a P value of 0.068 (Table V). Thus, the procedure with trabeculectomy seemed to induce less change in astigmatism than occurred in eyes that did not have trabeculectomy, but the difference was not statistically significant.

DISCUSSION

The results seen in this study are not unexpected, given the population under scrutiny and the improvement in surgical technique over the past 2 decades. Complications were relatively rare, although one should not be lulled into a false sense of security, since consequences like hyphema, suprachoroidal hemorrhage, blebitis, and endophthalmitis occur with unpredictable devastation.

Culling the original 50 patients in this study from a single physician's clinical practice represented a significant effort toward providing results that would turn out to be statistically valid. Most patients had the following: had glaucoma for a number of years; had been determined to have substantially similar levels of intraocular pressure, visual field loss, and cupping of the optic nerve; and, in addition, had a significant cataract limiting vision in at least 1 eye. An implied criterion of good general health was necessitated by the duration of the study; even though the average age at entry into the study was 70.2 years, only 20% of patients died before completion of the 5-year follow-up period. Patients with other ophthalmic problems, including macular degeneration and corneal disease, were excluded because final visual outcomes would be difficult to compare.

Five distinct features separate this study from others that have explored combining cataract and glaucoma surgery. First, each patient served as his or her own control. Second, the length of follow-up has been extended beyond the immediate postoperative period, not only to explore

protection of visual field but also to determine long-term survival of a functioning filtering bleb. Third, this study was limited to patients whose intraocular pressure was well controlled in most cases with topical medical therapy prior to surgery. Fourth, the decision to do surgery was triggered by the advancement of cataract, not by uncontrolled intraocular pressure. Fifth, all cases were operated on and followed throughout the study by the same surgeon.

The advantages of a study of this kind follow from its design. The study population was chosen on a prospective, randomized basis. In addition, variation in surgical technique was limited both by a commitment to uniformity throughout the course of the study and by employment of a single operator. Having the patients serve as their own controls minimized the effect of dependent variables such as compliance, systemic disease, severity of glaucoma, patient reliability, and the physical and physiologic differences that often accompany operations performed on different patients. Demographic data, aside from the age at time of surgery, were identical. Patients were selected because they had roughly symmetric glaucomatous changes.

Evaluation of the preoperative data (Table III) reveals a slight difference in intraocular pressure, with slightly higher pressures in the group that ultimately underwent trabeculectomy at the time of cataract surgery. This difference was not statistically significant (P value = .10) and did not affect outcome, consistent with Watson's observation[63] that "trabeculectomy. . . reduces the intraocular pressure to within the normally accepted limits; the higher the preoperative intraocular pressure the greater the fall." Differences in visual acuity and number of medications were also not statistically significant between groups.

Compliance with the preoperative medical regimen, which might be a confounding error in disparate populations, could be assumed to be comparable if the same patient was applying medication to both eyes. One might argue that, after surgery, when the number of medications in the eye with trabeculectomy decreased in relation to the eye without trabeculectomy, the patient might be tempted to use medications with less consistency; however, all patients were asked at each examination whether they were taking their medications on a regular basis and were monitored to determine whether the number of refilled prescriptions requested appropriately corresponded to the number of drops needed for each postoperative interval.

The pitfalls inherent in a study of shorter duration include inability to monitor attrition in the number of functional blebs, increase in number of postoperative medications, and changes in visual field or optic nerve appearance. For example, when 2-year preliminary results on a smaller cohort of this study were evaluated in 1990, none of the eyes that had

undergone trabeculectomy required topical medication for control of intraocular pressure.[68]

Progression of visual field loss, which occurred in 6 of the 35 eyes that did not have a trabeculectomy and in only 1 of those having a trabeculectomy, may be an indication of increased susceptibility of the optic nerve to damage at lower levels of pressure over time, since pressure control either with or without medication appeared to be adequate postoperatively. These data correlate with those of Kolker,[69] who determined that in patients who had already suffered optic nerve damage secondary to glaucoma, prevention of progression of field loss over a 10-year interval required maintenance of pressures at 18 mm Hg or less.

Since all patients in this study had relatively well-controlled intraocular pressure preoperatively, they only represent a subset of the individuals who might undergo trabeculectomy for control of intraocular pressure. Patients in whom maximum tolerated medical therapy failed to control pressure were excluded from this study even if they already had a cataract significant enough to warrant surgical intervention for the cataract alone. Several studies have addressed this problem. Raitta and Tarkkanen's group of 30 eyes[70] had a mean preoperative intraocular pressure of 31.5 mm Hg on maximum tolerated medical therapy. Severe visual handicap from cataract was also present. Average postoperative pressure was 17.8 mm Hg with significant visual improvement in 24 eyes.

Yu and associates[71] contrasted combined cataract and glaucoma surgery with the results of trabeculectomy alone in patients whose pressures were not well controlled prior to surgery. Both groups had effective control of intraocular pressure postoperatively with a minimum of 12 months' follow-up. Since these investigators noted no difference in complications or failures between the 2 groups, they concluded that if cataract is present, adding cataract surgery to trabeculectomy did not diminish the ability to control intraocular pressure postoperatively. They characterized their patients as "low-risk"; this term belies the fact that "the main limitation of visual improvement was advanced glaucomatous damage that occurred preoperatively. We offered combined surgery to patients with a poor visual prognosis, which is reflected in the relatively poor final visual acuity outcome." In addition, they corroborate the finding that cataract that is present at the time of trabeculectomy advances and reduces visual acuity. Similar results are reported by Kaniasty and colleagues,[72] who encountered increased technical difficulty in performing the procedure in patients with uncontrolled pressure.

The rationale for excluding patients with uncontrolled pressure was that one would compromise the goal of bilaterally symmetric disease, since disease would be addressed first in the eye with greater need. This study did not set out to answer the question of whether one should combine

cataract surgery with trabeculectomy in patients with uncontrolled intraocular pressure; rather, it was designed to elucidate whether patients with well-controlled glaucoma and cataracts should have both diseases attacked surgically or one attacked surgically and the other treated medically. Eyes with uncontrolled pressures and clear lenses require only trabeculectomy.

Since, as is commonly true in clinical practice, surgical intervention was prompted by the cataract, the study also excluded populations in which a trabeculectomy procedure might have caused the cataract to advance. Clarke and coworkers[73] studied 57 patients with primary open-angle glaucoma undergoing trabeculectomy. With use of a Lens Opacity Meter, they observed 35 patients for 6 months and found that none had lost more than one line of Snellen acuity due to lens opacity.

In Popovic and Sjostrand's study,[34] trabeculectomy was performed alone. By the time of the end of the study at 10 years, 47% of patients had visually significant cataracts limiting visual acuity. They note "cataract formation showed no relationship of statistical significance with preoperative treatment, with time since surgery, the magnitude of preoperative IOP, and the reduction of post-operative IOP." The incidence of cataract after trabeculectomy, as described by Watson[63] 20 years after the introduction of this procedure, confirmed that trabeculectomy predictably reduced intraocular pressure but appeared only to speed the advancement of already existing cataracts rather than causing new cataracts to form.

Evidence has also been presented that cataract surgery alone can lower intraocular pressure. In their pioneering study, Bigger and Becker[74] demonstrated that intracapsular cataract surgery alone lowered intraocular pressure in patients with glaucoma. In a more recent contribution, Kusber and Aust[75] reported that 6 to 24 months after extracapsular cataract extraction and lens implantation, 87% of 133 eyes had pressures under 20 mm Hg with 33% using the same number of medications they had used before surgery, 2% more medications, and 64% fewer medications. Fifty-six percent of the eyes did not need any topical therapy at the time of the most recent examination. They concluded that even in cases of poorly controlled glaucoma with cataract-limiting visual acuity, they would perform only an extracapsular cataract extraction and a posterior chamber lens implant without trabeculectomy and would reserve further glaucoma surgery for those patients who could not be controlled medically postoperatively.

Earlier advocates of surgical intervention for cataract alone or trabeculectomy alone have argued that each procedure should be reserved for specific need. The patients included in this study have been chosen for surgical intervention totally on the basis of advancement of the cataract to levels unacceptable to the patient's life-style. In this study, if cataracts had

not developed, the majority of these patients would not have required trabeculectomy for the control of intraocular pressure.

DECISION MAKING

Once the decision to perform cataract surgery is made, several considerations must be taken into account in determining whether to combine surgery with trabeculectomy. First, one must try to determine the patient's ability to comply with the current glaucoma therapy. Kass and others[76,77] have documented problems with patient compliance, especially with a complicated topical or systemic regimen. Prediction of which patients are going to be compliant appears to be impossible without a monitoring device for use of medications.

Second, one must be cognizant of visual acuity in the opposite eye, since in combined surgery, recovery of visual acuity in the operated eye may be delayed. Patients in this study had visual acuity limited by cataract in one eye at a time. Although the extended field loss in some eyes approached fixation, none had lost fixation preoperatively. Since the decision was made to operate on the eye with more advanced cataract first, it was expected that the patient would be able to function visually with the opposite eye until recovery of visual function could be obtained in the eye that had surgery. When the patient's second eye was ready for surgery, the first eye had already recovered maximum potential visual acuity and could be relied on until the second eye also returned to its full level of potential visual function. Patients with other significant ocular diagnoses, such as macular degeneration, were excluded from this study.

Third, patients who might have an adverse reaction to pressure elevation in the immediate postoperative period could benefit significantly from combining cataract surgery with glaucoma surgery. Kolker[69] has documented that in patients with field loss approaching fixation, loss of central acuity can occur if pressure is sustained at higher-than-normal levels even for a short time after surgery. The so-called wipeout syndrome, although rare, devastates both surgeon and patient when it occurs. Visual fields and acuities demonstrated no incidence of loss of fixation secondary to glaucomatous optic atrophy in either group in this study. However, elevation of intraocular pressure in the immediate postoperative period, even when field loss does not impinge on fixation, may damage peripheral nerve fibers and affect visual field. Fortunately, during the course of this study, intraocular pressures measured within 24 hours after surgery did not show evidence of marked elevation in any patient.

Finally, concern regarding unpredictable postoperative astigmatism in combined surgery has been allayed by the technique presented here. Previously, Choplin and Monroe[78] examined the effect of trabeculectomy on astigmatism when combined with their technique of extracapsular

cataract extraction and posterior chamber lens implantation. They showed that surgically induced astigmatism was approximately 1 diopter greater in 19 eyes undergoing combined surgery in comparison to a matched group of controls operated on by the same surgeon. In addition, they found that surgically induced against-the-rule astigmatism was more prevalent in the combined group. By contrast, in this study a 4 mm residual wound opening with secure, well-apposed edges for the remainder of the wound appeared not to generate a markedly different result from the change in the astigmatism that occurs as a result of extracapsular surgery alone. This information coincides with trabeculectomy and phacoemulsification data from Martin and associates,[79] which indicate that a 4 mm opening has a negligible effect on preoperative and postoperative astigmatism. Hugkulstone[80] and Nielson[81] have also attempted to modify the trabeculectomy wound to minimize astigmatism.

From the considerations discussed above, the decision to include trabeculectomy involves the clinical assessment of a multifactorial process. When the threat to central visual acuity or visual field is great, then additional lowering of intraocular pressure, both in the immediate postoperative period and in the long term, greatly outweighs the additional risks of trabeculectomy. As the current study demonstrates, safety, efficacy, and long-term prevention of additional field loss will combine to change the indications for combined surgery as techniques improve.

From an international perspective, this long-term study of extracapsular surgery and trabeculectomy is still important because phacoemulsification is not available universally in the developing world. Considerations regarding compliance with a medical regimen and availability of medications, as well as the presence of cataract in a younger population, combine to make this technique appealing if the procedure can be performed with minimal risks and assurance of improvement both in visual acuity and pressure control. In addition, since long-term results have been demonstrated to be stable, then less intense monitoring may be needed after establishment of a functioning filtering bleb.

LIMITATIONS

In retrospect, the major objection that can be leveled at this study surrounds the problem of observer bias. Although efforts have been made in the earlier part of this thesis to describe the ambiguous nature of the opinions extant at the inception of the study, observer bias in selection and gathering of data could have served to undermine the significance of the results, since the observer could not be masked. Attempts were made to collect data in as objective a fashion as possible. Keratometry readings, tonometry readings, and questions concerning use of medications were obtained by a technician. Visual fields were performed on an automated

perimeter. Refractions were performed before slit-lamp biomicroscopy to avoid determining in advance which eye had trabeculectomy. Finally, surgeries were carried out at varying intervals from one another so that eyes were not being compared at the same postoperative stage at any given examination.

Another criticism that might be leveled at this study is its relevance 10 to 11 years after its inception. Certainly, in the United States, phacoemulsification has superseded extracapsular cataract surgery as the method of choice for cataract extraction, and trabeculectomy combined with phacoemulsification has many advocates.[82-88] In a comparative study of phacoemulsification and extracapsular surgery by Wishart and Austin,[89] 34 eyes were followed prospectively after undergoing phacoemulsification and trabeculectomy. The results of surgery were compared with those in 34 eyes that had undergone extracapsular surgery with trabeculectomy. The groups did not differ preoperatively; but the group with phacoemulsification had earlier visual rehabilitation, less postoperative astigmatism, and improved long-term intraocular pressure control. Early postoperative pressure elevations occurred in 32% of the extracapsular procedures and 23% of the phacoemulsification procedures. They reported that the advantages of phacoemulsification are a smaller wound size, disturbance of a more circumscribed area of conjunctiva and sclera, and the ability to use a foldable lens so that the wound does not need to be enlarged.

Finally, objection can be made to the absence of antimetabolite therapy, the other major advance in trabeculectomy surgery made after the inception of this study. In a poll of clinical glaucoma specialists concerning their use of antimetabolites, 65% of respondents were not using antimetabolite therapy in well-controlled patients.[90] In these patients, it was noted, significant danger of hypotony and flat anterior chambers existed. Only one respondent stated that he used mitomycin C routinely in all patients undergoing trabeculectomy.

Published reports on the effectiveness of antimetabolite therapy have produced differing results. Adjunctive use of 5-fluorouracil conferred no significant advantage.[91-93] The use of mitomycin C has also produced greater lowering of intraocular pressure but a higher incidence of complications, including wound leaks and hypotony maculopathy.[94-96]

FUTURE STUDY

Although a prospective, randomized long-term trial of phacoemulsification, lens implantation, and trabeculectomy may also prove to be out of date in 10 years, the safety and efficacy of this increasingly common procedure would offer a contemporary justification for current practice. The observation that phacoemulsification alone lowers intraocular pressure both in normal controls and in patients with glaucoma has led to specula-

tion that either vibration damage to the ciliary body or a subscleral leak into either the suprachoroidal or subconjunctival space under the flap may be responsible for the chronically low pressures that have occasionally been observed after seemingly routine procedures. Perhaps we have come full circle to an internal iridencleisis on an ultrasonic basis.[97]

Although a Hoskins lens and argon laser were used to transect trabeculectomy flap sutures to increase bleb efficiency, this technique should be compared to releasable sutures. These questions will become of considerable importance when the role of antimetabolite therapy is elucidated; since in order to prevent hypotony, the flap initially needs to be secured more tightly. Thus, additional variables will be introduced, and the study size and numbers within each group will have to be substantial in order to derive statistically significant results.

CONCLUSIONS

This study was designed to determine whether combined cataract extraction, lens implantation, and trabeculectomy or cataract extraction and lens implant alone would be more effective in controlling intraocular pressure, maintaining visual acuity, stabilizing visual field loss, and reducing reliance on medications in eyes that had both glaucoma with intraocular pressure well controlled by medical therapy and cataract-producing visual disability. One may conclude the following from the results presented:

1. Combined cataract extraction, lens implantation, and trabeculectomy is a more demanding procedure and one which requires careful follow-up in the immediate postoperative period.

2. Although pressure elevations do occur in patients who have cataract extraction and lens implantation alone, the short-term elevations in intraocular pressure do not seem to threaten fixation when pressure has been well controlled preoperatively by a stable medical regimen and preoperative visual field damage does not encroach on fixation.

3. Long-term results indicate that pressure can be maintained at a lower level with fewer medications in the group with trabeculectomy.

4. Progression of visual field loss appears more likely if trabeculectomy is not performed.

5. Astigmatism can be well controlled postoperatively with either procedure.

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