

Long-term Functional Outcome after Early Surgery Compared with Laser and Medicine in Open-angle Glaucoma

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Purpose: This randomly allocated prospective clinical study was designed to assess the relative efficacy of laser trabeculoplasty, medical therapy, and trabeculectomy used as the primary treatment in open-angle glaucoma, with particular regard to the level of intraocular pressure control and the amount of visual field decay. No patient had received any antiglaucoma treatment before entry into the trial.

Methods: One hundred sixty-eight patients were entered into the trial and randomly allocated into one of the three treatment groups—laser, medicine, or surgery. Follow-up was for a minimum of 5 years. The patients were monitored in the standard way, including intraocular pressure estimations and visual field tests (initially using the Friedmann analyzer and later including Humphrey automated perimetry).

Results: Despite similar initial composition of the three treatment groups, primary surgery resulted in the lowest mean intraocular pressures. The perimeter Friedmann visual fields were shown to have deteriorated in patients in the medicine-treated group and to a lesser extent in patients in the laser-treated group, but not in patients in the surgery-treated group. Multivariate linear regression analysis showed that the difference in field changes between laser and surgical treatments could be explained entirely by the difference between the intraocular pressure values at 6 months between the two groups. The same was not true for the medicine-treated group.

Conclusion: Primary trabeculectomy appears to have the desired effect in preserving visual function in patients with high-tension glaucoma. This may be related to the pressure-lowering effect. A similar fall in intraocular pressure with medicine and/or laser treatment might be expected to have the same effect.

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In chronic open-angle glaucoma, the intraocular pressure (IOP) is raised above a level compatible with the continued health and function of the eye. Methods of treatment for this condition are aimed at lowering the IOP to preserve visual function, raised IOP being the most significant risk factor predictive of optic disc and

visual field damage from glaucoma.^{1–3} The three methods of treatment in common use are medical treatment in the form of eyedrops and/or tablets, laser trabeculoplasty, and surgery, usually in the form of trabeculectomy. Convention has dictated that medical treatment is the commonly used primary therapy for glaucoma, followed by laser trabeculoplasty if the medical treatment failed, and only ultimately by surgery if necessary. However, there are numerous arguments as to which method of treatment should be the initial therapy.^{4–6} The use of early filtering surgery is supported by several clinical trials carried out in the United Kingdom.^{7–10} Moreover, each of the treatment methods may lower the IOP to a different degree.¹¹

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The Moorfields Primary Therapy Trial commenced in 1983 and the patients were followed for a minimum of 5 years. This report details the results of the three randomly assigned methods of primary therapy (laser, medicine, and surgery) with particular reference to IOP and functional outcome in terms of visual acuity and visual fields.

Materials and Methods

One hundred sixty-eight patients presenting to Moorfields Eye Hospital with untreated chronic open-angle glaucoma were entered into the trial. These patients either received their diagnosis when they attended the Casualty Department for some other disorder, or had been referred by their general practitioner or optician after either a routine screening or the development of visual symptoms.

The minimum criteria necessary for inclusion into the trial were as follows: (1) IOP of at least 24 mmHg on two occasions; (2) cup:disc ratio greater than 0.6, and/or notching, and/or pallor of the neuroretinal rim; (3) glaucomatous field loss using the Friedmann field analyzer (Mark I). The minimal acceptable defect was the loss of at least three adjacent spots at intensities 0.4 log units greater than threshold up to a maximum intensity, and/or one absolute defect; and (4) open drainage angle.

Once the inclusion criteria had been satisfied, the patients were randomly allocated, using computer selection, into one of the three treatment groups. In bilateral asymmetric disease, the "worse" eye was entered into the trial. In symmetric disease, there was random allocation, with conventional glaucoma therapy (i.e., medical treatment initially, followed by laser and/or surgery, if medical treatment failed) being given to the second eye.

The principles of the three methods of therapy were as follows. (1) Patients in the medicine-treated group were treated with pilocarpine, and/or a sympathomimetic, and/or timolol, as the initial therapy, increasing to maximum-tolerated medical therapy, which could, in individual cases, require three topical medications and a carbonic anhydrase inhibitor. (2) Patients in the surgery-treated group underwent a Cairns-type trabeculectomy,¹² using either a fornix- or limbal-based conjunctival flap. The surgery was performed by a consultant, residents, or fellows of the Glaucoma Service at Moorfields. (3) Patients in the laser-treated group underwent two treatments, each consisting of 50 burns over 180° of the anterior trabecular meshwork, separated by an interval of 2 weeks. A spot size of 50 μ m, exposure time of 0.1 seconds, and power of 0.5 to 1.0 W were used. Due to the relatively unproven nature of laser trabeculoplasty at the time the trial was set up, ethical considerations required patients in the laser-treated group to be given eyedrops of 2% pilocarpine four times daily for the first 2 weeks after treatment. If the IOP remained normal, this dosage was tapered. However, eyedrops of 2% pilocarpine four times daily was regarded as permissible adjuvant therapy for those patients in the laser-treated group whose glaucoma was not controlled

by laser alone. Any further requirement to maintain a normal pressure was regarded as a laser failure.

Intraocular pressures were measured with the Goldmann applanation tonometer fitted to the Haag-Streit slit lamp. To avoid bias, at least two separate readings were taken with accurate alignment of the mires. A daytime phasing was carried out annually on each patient, with the IOP measured at 2-hour intervals between 9:30 AM and 3:30 PM.

At the commencement of the trial, the visual fields were charted using the Friedmann field analyzer (Mark I). The first field was used for diagnosis and entry into the trial. Progress was assessed using the initial field as a baseline. Two years after the commencement of the trial, a Humphrey automated perimeter was used in addition to the Friedmann apparatus.

Using the Friedmann apparatus, the threshold was estimated at intensities of 0.4 log units greater than the threshold intensity then at steps of 0.2 log units up to maximal intensity. A field score of the number of spots missed was calculated at each visit for the relative and absolute spots missed, giving two numeric values for each eye at each visit.

The disease in each patient was staged according to the degree of field loss at presentation into early, middle, and late, with respect to the number of absolute defects (early = field score of <2 absolute defects [commonly in the arcuate region]; middle = field score of 2–12 absolute defects; late = >12 absolute defects). Optic discs were photographed annually.

Visual acuities were tested on the Snellen chart with the appropriate refractive correction, where applicable. If a reduction of visual acuity was noted at follow-up, a pinhole aperture was used to ascertain whether this improved the visual acuity to the previous level.

Treatment was considered successful if the IOP had been reduced to 22 mmHg or less by 3 months and maintained below that level. Treatment was considered unsuccessful if the IOP was greater than 22 mmHg on two repeated occasions. The time to failure was noted in months. In the event of a failure, the second line of treatment was undertaken, again randomly allocated by computer selection from the two remaining treatments. Failures in each treatment group were excluded from the calculation of the results from the time of failure.

Statistical Methods

Mean values routinely were compared using the Student's *t* test. Analysis of variance was used to discover the relevance (and significance) of factors where there was more than one variable of interest. The significance of differences showing some effect between two groups was evaluated using Fisher's exact test.¹³ The time-to-failure curves were constructed using the life-table method first described by Kaplan and Meier,¹⁴ with significance between groups being determined using the log-rank test. All *P* values are two-tailed.

Table 1. Initial Composition of the Three Treatment Groups

	Laser*	Medicine*	Surgery*
No. of patients	55	56	57
Mean age (yrs)	64.6	62.4	62.3
Mean starting IOP (mmHg)	35	35	34
SD	8.7	7.9	5.4
SE	1.2	1.1	0.72
Visual field scores			
Threshold†	1.55	1.68	1.67
0.4 > threshold‡	23.6	20.4	20.1
Maximum§	17.6	14.1	13.7
Stage of glaucoma			
Early	13	16	17
Mid	10	10	16
Late	32	30	24

IOP = intraocular pressure; SD = standard deviation; SE = standard error.

* Laser versus Medicine $P = 0.83$; Laser versus Surgery $P = 0.22$; Medicine versus Surgery $P = 0.35$.

† Mean threshold light intensity of the Friedmann field analyzer.

‡ Relative field defect (i.e., number of spots missed at intensities of 0.4 log units greater than threshold to maximum).

§ Maximum light intensity on the Friedmann analyzer.

Multivariate linear regression analysis was used to investigate which factors showed independent predictive capacity for the change in field scores. Seven factors were considered: age, treatment (entered as two variables: medicine versus others, and laser versus others—the effect of surgery versus others therefore being implicitly included), starting IOP, starting visual acuity, starting cup: disc ratio, and starting field score (the mean of the first 3 fields). Changes in the field scores were analyzed by taking the mean of the first three recorded fields and comparing them with the mean of the last three. In this way, the effect of occasional aberrant scores can be minimized.

Results

Initial Composition

The initial composition of the three treatment groups was very similar, with similar mean starting IOPs and no significant differences between the numbers of patients with early-, middle-, and late-stage glaucoma in each treatment group (Table 1). Fifty-six patients received medical treatment, 57 surgery, and 55 laser. Twenty patients in the laser-treated group required adjunctive 2% pilocarpine to control their IOPs.

Intraocular Pressure

The mean IOPs at the 6-month visit were 13.4 mmHg for surgery, 21.1 mmHg for laser, and 20.6 mmHg for

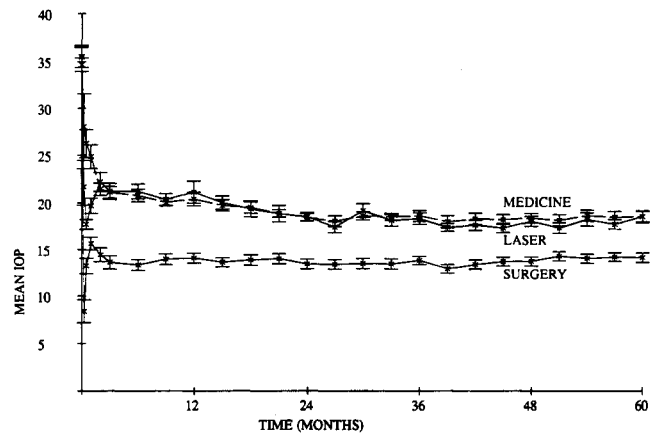


Figure 1. Mean intraocular pressure values by treatment group.

medicine, whereas at 5 years they were 14.1 mmHg for surgery and 18.5 mmHg for both laser and medicine (these figures exclude the failures from their point of failure) (Fig 1). A significant difference existed between surgery and the other two treatment groups throughout the 5-year follow-up period ($P < 0.0001$ at each time point – Mann-Whitney U test).

Calculation of the percentage IOP reduction at 3 years (mean reduction of IOP/starting IOP $\times 100$) was 60% for surgery, 48.5% for medicine, and 47% for laser plus adjunctive 2% pilocarpine compared with 38% for laser alone.

Diurnal variations in pressure (measured annually) also differed among the groups, with the patients in the surgery-treated group having the lowest mean IOPs and with fewer peaks and troughs. The maximum mean phasing IOP was 15.5 mmHg and the minimum mean IOP was 13.1 mmHg for surgery compared with 21.7 mmHg and 16.1 mmHg, respectively, for laser and 22.1 mmHg and 15.9 mmHg, respectively, for medicine. A number of patients exceeded these ranges.

Time to failure in terms of IOP control is shown in the Kaplan-Meier curves (Fig 2), with the percentage of success at 5 years for laser, medicine, and surgery being

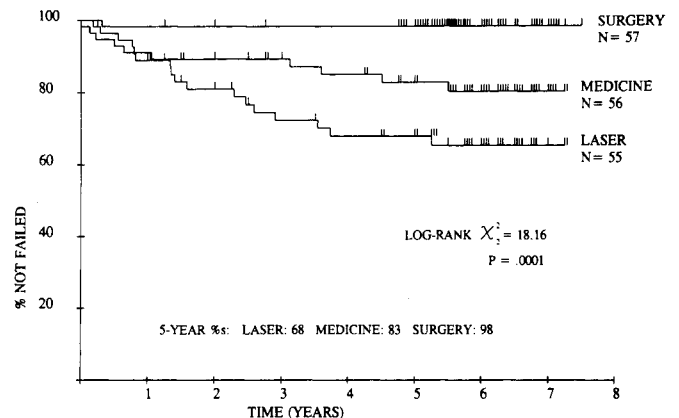


Figure 2. Time to failure by treatment.

68%, 83%, and 98%, respectively. These differences are highly significant (log-rank test heterogeneity chi-square = 18.2, 2 degrees of freedom; $P = 0.0001$).

Visual Fields

Assessment of the Friedmann fields (the number of absolute defects) of the three groups showed significant differences over the 5-year period. The changes over time are shown in Figure 3. Results of examination of differences between the mean of the first three fields and the mean of the last three fields showed significant deteriorations in the medicine- and laser-treated groups ($P = 0.001$ and $P < 0.0001$, respectively), but not in patients in the surgery-treated group ($P = 0.06$ – Wilcoxon signed-rank test). These univariate results are shown graphically in Figure 4.

The apparent improvement in visual fields over the 12 months immediately after treatment in patients in the surgery-treated group (Fig 3) was evaluated by performing a linear regression for each patient's field scores, and examining the slopes of the regression lines produced. The median slope for the surgery-treated group was -1.1 spots per year, and overall there were a significantly higher number of negative slopes compared with positive slopes ($P = 0.003$, Wilcoxon signed-rank test), confirming that this was a real effect. In contrast, the laser-treated group did not show a significant change over the first 12 months ($P = 0.11$), whereas the medicine-treated group showed a significant deterioration ($P = 0.001$).

Multivariate linear regression analysis was used to investigate which of seven factors showed independent predictive capacity for the change in field scores. Note that the R^2 (multiple correlation coefficient) estimates the percentage of the variability in the dependent factor (the change in field scores) explained by the other factors.

The results of the three different regressions are given in Table 2. The first regression included only those factors present at the commencement of treatment. The second regression also included the mean IOP at 6

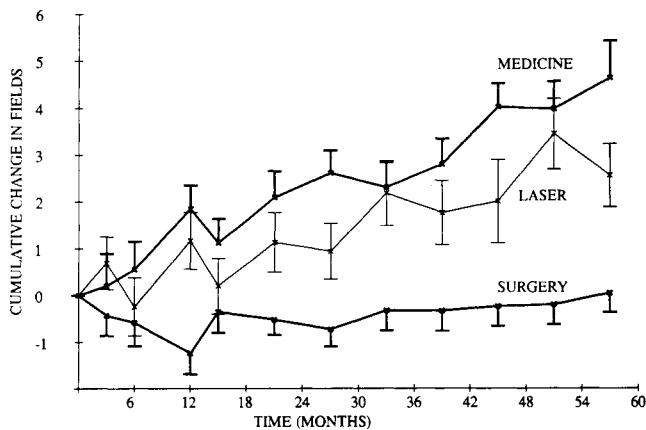


Figure 3. Mean number of absolute defects; laser versus medicine versus surgery (bars are 1 standard error of the mean).

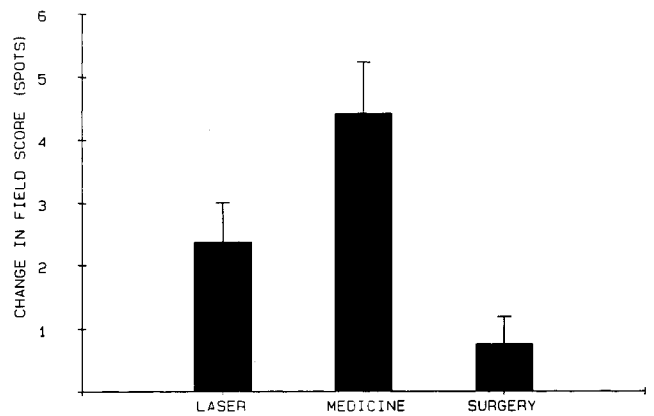


Figure 4. Mean deterioration in field score (no. of spots) by treatment (with standard error of mean).

months (the mean of the first 3 IOP values including and after 6 months). The third regression was limited to the laser and surgery-treated groups only, and also included the mean IOP at 6 months. All three regressions included the time between the first and last field readings as a variable, even though this variable was not significant; this was believed to be important because any change in the field scores might be expected to be greater if there was a longer time in which to observe the effect. The linear nature of this effect was confirmed by examination of a scatter plot of field changes against time between first and last readings.

The first regression showed that the only presentation features predictive for change in field score were treatment (medicine worse than others) and age. The second regression showed that IOP at 6 months was also highly predictive of changes in field scores ($P = 0.001$), in addition to the other two factors. Because treatment (medicine versus others) was still significant in this second regression, medical treatment makes the fields worse in some way beyond its failure to control IOP. There was no significant correlation between stage (i.e., starting field score) and subsequent change in field score.

In a univariate analysis, there was a significantly greater deterioration in field scores in patients in the laser-treated group compared with the surgery-treated group (T ratio = 2.1; $P = 0.04$). To investigate whether this effect also could be explained by a mediating effect of a 6-month IOP, the third regression shown in Table 2 was restricted to the laser and surgery-treated groups only. When treatment (laser versus surgery) was forced into this regression, it was shown not to be predictive (T ratio = 0.6; $P = 0.55$). Thus, the field changes between the laser and surgery-treated groups can be explained entirely by the difference in IOP values at 6 months between these groups.

To examine the effects of medical treatment in more detail, correlations between treatment (medicine versus others) and field changes were examined, allowing and not allowing for the effect of IOP at 6 months. The correlation coefficients were 0.185 ($P = 0.008$) and 0.266 (P

Table 2. Stepwise Linear Regression of Change in Field Scores

Regression No.	Factor*					r ²
	Age	IOP at 6 months	Time between First and Last Fields	Treatment (medicine versus others)	Treatment (laser versus surgery)	
1						
Regression coefficient	0.104	NI	0.033	2.98	NI	
T-ratio	3.06	NI	1.73	3.80	NI	13.0
P	0.003	NI	0.09	0.0002	NI	
2						
Regression coefficient	0.101	0.252	0.028	2.21	NI	
T-ratio	3.05	3.29	1.51	2.77	NI	18.4
P	0.003	0.001	0.13	0.006	NI	
3†						
Regression coefficient	0.062	0.187	0.035	NI	0.57	
T-ratio	1.84	2.15	1.70	NI	0.60	13.7
P	0.07	0.03	0.09	NI	0.55	

IOP = intraocular pressure; NI = factor not included in this regression.

* The following factors also were included but were found not to be significant: starting IOP, starting visual acuity, starting cup:disc ratio, starting field score (the mean of the first 3 fields).

† Patients treated with medicine were excluded from this regression, leaving 112 patients only.

= 0.0002), respectively. These *r*-values produce *R*² of 0.034 and 0.071. Thus, approximately half of the difference between the medicine and the other two treatments can be explained by the difference in the way they control IOP at 6 months. Further quantification of this result showed that there is a mean loss of approximately two spots for the medicine-treated group in addition to the loss caused by inadequate control of IOP. This can be seen to be the approximate difference between the medicine- and laser-treated groups in Figure 3.

Visual Acuity

The starting visual acuities for the three treatment groups were similar and not significant (laser versus medicine, *P* = 0.17; laser versus surgery, *P* = 0.10; medicine versus surgery, *P* = 0.73). Over the follow-up period, there was no significant difference in the mean visual acuity score among the three groups, the difference at 5 years for surgery being less than half a line on the Snellen chart when compared with the laser and medicine treatments.

Discussion

To establish an exact IOP that will ensure preservation of vision is difficult in the individual patient, but it is clear that lowering the IOP often can arrest the progression of visual loss.³

This study concurs with that of other published reports^{10,15} that early surgery in chronic open-angle glau-

coma results in the lowest IOPs, compared with other forms of treatment. In addition, the mean IOPs of the patients in the surgery-treated group remained constant over the 5-year follow-up period, and there were fewer peak pressures on phasing.

The primary treatment trial allowed the use of adjunct pilocarpine for the eyes in the laser-treated group during the first month after treatment. This decision was made on ethical grounds as the maximum IOP lowering would be achieved by that date and the patient should have "protective" treatment until then. After this month, an attempt was made to withdraw the pilocarpine. If withdrawal was followed by a rise in the IOP to a level exceeding 22 mmHg then pilocarpine was continued. No further specific attempt was made to withdraw the drugs. If the IOP exceeded 22 mmHg after this 1-month period despite the use of pilocarpine, then the eye was considered to be a "failure" and was re-randomized to another treatment group.

The criterion for a successful treatment outcome in this study was an IOP of less than 22 mmHg. This report shows that the surgery-treated group achieved a percentage success rate of 98% at 5 years, compared with 83% in patients in the medicine-treated group and only 68% in patients in the laser-treated group. Thus, in terms of IOP, primary surgery would appear to be the most effective form of treatment.

However, IOP is not the only measure of success, and different patients respond differently to IOP levels. It has been postulated that there may be two subgroups in the glaucoma population, those who are pressure-sensitive

and those who are not.¹⁶ Currently, it is not possible to separate these two subgroups accurately.

A common argument against early surgery is the possibility of the inducement of cataract. Cataract is difficult to quantify accurately. However, in terms of visual acuity, there was no significant difference between the three treatment groups, the difference in the mean visual acuity score at 5 years for surgery being less than half a line on the Snellen chart when compared with laser and medicine.¹¹ The Scottish study also found no difference in visual acuity between the medicine- and surgery-treated groups.¹⁷ In two patients who underwent surgery in the Moorfields trial, clinically significant cataracts did develop, but after cataract extraction with intraocular lens implantation, the visual acuities were restored to the pre-trabeculectomy level. In a long-term retrospective study, good IOP reduction did not prevent a gradual decrease in visual acuities and fields over the years in more than half the patients, suggesting that lowering the IOP may only slow the rate of damage, not stop it.¹⁸

The retention of visual function in the form of visual field stability is an important measure of success in the patient with glaucoma who receives treatment. Statistical analysis of the Friedmann field scores in this study showed a difference between the three treatment groups which parallels the differences in IOP. The stepwise regression analysis suggests that the difference between the field changes in laser and surgery are explainable solely by the difference in mean IOP at six months in the laser and surgery-treated groups. Despite similar mean IOP levels for medicine and laser, medical treatment appears to make the fields worse, or allows them to deteriorate faster, in some way beyond its effect on the IOP. The miotic effect of pilocarpine, used in many of the patients, could possibly contribute to this effect.

No attempt was made to accurately assess compliance to medical therapy in this trial. However, at each visit, patients on medical therapy were asked which drops they were taking and at what time the drops had last been instilled. Compliance did appear to be less than ideal, as might be expected, in some patients in the study.

Humphrey fields were only available from about two years after the commencement of this trial. We have previously reported that no differences were elicited in the Humphrey field changes in the three treatment groups,¹⁹ despite a significant difference having been shown between surgery and the other two groups in the first two years using the Friedmann fields.²⁰ The learning effect with regard to Humphrey fields also needs to be taken into account, while the field damage that occurs may develop in the first couple of years, particularly when using laser and medicine treatment where there may be borderline control of IOP before the failure to control the IOP. Similar findings were reported by Jay and Allan.¹⁷

Conclusion

Primary trabeculectomy appears to have the desired effect in preserving visual function in terms of visual field and visual acuity in patients with high-tension glaucoma. This

may be related to the degree of IOP lowering, and a similar fall in IOP with medicine and/or laser treatment might be expected to have the same effect. However, for the patients with glaucoma included in this study, the higher IOP levels achieved with medicine and laser failed to give the same degree of protection.

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Discussion
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The goal of therapy in glaucoma is to prevent visual loss in the lifetime of the patient. The assumption of treatment is that progression of damage can be prevented or at least arrested by lowering intraocular pressure (IOP). The current study is important for several reasons, but most importantly it demonstrates that there is a relation between the degree of lowering of IOP and progression of visual field loss in patients with proven primary open-angle glaucoma. Trabeculectomy lowered IOP to a greater degree than either medicine or primary laser trabeculoplasty, and was associated with less progression of visual field loss. This finding is not new and has been demonstrated previously. For example, a study by Lamping et al¹ demonstrated that full-thickness procedures (posterior lip sclerectomy and trephination) that lowered IOP to a greater degree than trabeculectomy were associated with greater retention of visual field in patients whose glaucoma previously was uncontrolled while receiving medical treatment. With newer techniques, such procedures rarely are currently performed. Nevertheless, when surgical results are evaluated on the basis of IOP, the lower the pressure the better the prognosis for preventing further glaucomatous damage.

There is little argument that in the current study lower IOPs were obtained by primary filtration surgery. The difference in progression of visual field loss, however, could be demonstrated only with the Friedmann field analyzer and only during the first 3 years of the study. No differences could be detected with the use of Humphrey perimetry in subsequent follow-up despite the continued differences in IOP. Most ophthalmologists in the United States are not familiar with the Friedman field analyzer, but have considerable experience with the Humphrey perimeter. While the authors speculate why their findings may have oc-

curred, the inability to detect differences in progression of visual field loss with Humphrey perimetry is disturbing and remains largely unexplained.

From a practical standpoint, one may ask if the findings of this study mean that primary filtration surgery is to be recommended for all patients with glaucoma at the time of diagnosis. Not necessarily. As pointed out by Schumer and Podos,² it has not been shown that there is a benefit to surgical intervention versus medical therapy when the IOP results are equal. If, for example, one could lower IOP medically to the same levels achieved surgically in the current study, might the differences in progression of visual field loss be eliminated? Should we not strive to compare long-term progression rates based on *level of IOP achieved*, whether it be by medical or surgical means? Of course, both surgery and medical therapy have advantages and disadvantages. We make these evaluations whenever we consider therapy in patients with glaucoma. The important thing is that we need to make judgments based on the clinical findings encountered regarding what levels of IOP are likely to be safe in each patient. Having made such an evaluation, the ophthalmologist must then decide whether this degree of pressure lowering is best achieved medically or surgically, weighing the advantages and disadvantages of both.

The authors are to be complimented for demonstrating that surgical treatment of glaucoma is, for most patients at least, a safe and effective therapy.

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