

The Glaucoma Laser Trial (GLT) and Glaucoma Laser Trial Follow-up Study: 7. Results

GLAUCOMA LASER TRIAL RESEARCH GROUP*

• **PURPOSE:** To determine differences between the two treatment groups of the Glaucoma Laser Trial with respect to intraocular pressure, visual fields, optic disk cupping, and therapy for primary open-angle glaucoma.

• **METHODS:** The Glaucoma Laser Trial was a multicenter, randomized clinical trial designed to assess the efficacy and safety of starting treatment for primary open-angle glaucoma with argon laser trabeculoplasty vs starting with topical medication. The Glaucoma Laser Trial Follow-up Study was a follow-up study of 203 of the 271 patients who enrolled in the Glaucoma Laser Trial. By the close of the Glaucoma Laser Trial Follow-up Study, median duration of follow-up since diagnosis of primary open-angle glaucoma was seven years (maximum, nine years).

• **RESULTS:** Over the course of the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study, the eyes treated initially with argon laser trabeculoplasty had lower intraocular pressure and better visual field and optic disk status than their fellow eyes treated initially with topical medication. As compared to eyes initially treated with medication, eyes initially treated with laser trabeculoplasty had 1.2 mm Hg greater reduction in intraocular pressure ($P < .001$) and 0.6 dB greater improvement in the visual field ($P < .001$)

from entry into the Glaucoma Laser Trial. The overall difference between eyes with regard to change in ratio of optic cup area to optic disk area from entry into the Glaucoma Laser Trial was -0.01 ($P = .005$), which indicated slightly more deterioration for eyes initially treated with medication.

• **CONCLUSIONS:** Initial treatment with argon laser trabeculoplasty was at least as efficacious as initial treatment with topical medication.

GLAUCOMA IS A LEADING CAUSE OF LEGAL BLINDNESS in adults age 40 years or older in the United States.¹ The most common form of glaucoma in adults in the United States is primary open-angle glaucoma.² Tielsch and associates³ estimated that 1.6 million Americans age 40 years or older have primary open-angle glaucoma.

Treatment for primary open-angle glaucoma has focused on lowering intraocular pressure. Medicine topically applied to the eye is traditionally the first attempted therapy, followed by systemic carbonic anhydrase inhibitors, and finally by surgical forms of treatment, if necessary, to control intraocular pressure.

Argon laser trabeculoplasty was introduced as a therapy for primary open-angle glaucoma in 1979.⁴ Argon laser trabeculoplasty was first viewed as an alternative to surgery after failure of medications to control progression of primary open-angle glaucoma.⁵⁻⁹ Subsequently, argon laser trabeculoplasty was considered an adjunct or alternative to medication. With confirmation of the pressure-lowering effect of argon laser trabeculoplasty in patients whose intraocular pressure was not controlled by medical therapy, the concept of starting therapy for primary open-angle glaucoma with argon laser trabeculoplasty

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emerged.¹⁰⁻¹³ In 1983, the National Eye Institute began funding the Glaucoma Laser Trial, a multicenter, randomized clinical trial designed to compare the efficacy and safety of argon laser trabeculoplasty to topical medication as a treatment for newly diagnosed primary open-angle glaucoma. One eye of each patient was randomly assigned to argon laser trabeculoplasty as initial treatment. The patient's fellow eye was assigned to 0.5% timolol. Treatment was prescribed subsequently for either eye, if necessary for intraocular pressure control, according to the same stepped medication regimen and the same criteria for assessment of intraocular pressure control in both eyes.

Between 1984 and 1987, a total of 271 patients enrolled in the Glaucoma Laser Trial; follow-up ended in November 1989. Funding was obtained subsequently from the National Eye Institute for the Glaucoma Laser Trial Follow-up Study, to extend follow-up on the patients from the Glaucoma Laser Trial on an observational basis (that is, no managed treatment). Follow-up of the 203 patients from the Glaucoma Laser Trial who enrolled in the Glaucoma Laser Trial Follow-up Study continued from December 1990 through August 1993.

In 1990, the results of the Glaucoma Laser Trial through two years of follow-up were reported. Eyes initially treated with laser trabeculoplasty had mean intraocular pressure approximately 2 mm Hg lower than the eyes initially treated with medication, and fewer eyes initially treated with laser trabeculoplasty than eyes initially treated with medication required simultaneous prescription of two or more medications to control intraocular pressure.¹⁴ Analysis of data through 3.5 years of follow-up indicated that the mean threshold per test location of the visual field for eyes initially treated with laser trabeculoplasty was 0.3 dB greater than for eyes initially treated with medication, averaged over follow-up.¹⁵ Results from the Glaucoma Laser Trial through five years of follow-up and results from the combined Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study through nine years of follow-up are reported.

PATIENTS AND METHODS

THE DESIGN AND METHODS OF THE GLAUCOMA LASER Trial have been described in detail elsewhere.¹⁶⁻¹⁸

Methodologic features of the Glaucoma Laser Trial that are pertinent to this report and the methods of the Glaucoma Laser Trial Follow-up Study are described. The protocol and consent statements for both the Glaucoma Laser Trial and the Glaucoma Laser Trial Follow-up Study were approved by the institutional review board at each center participating in the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study.

Patients were examined before entry into the Glaucoma Laser Trial to determine eligibility and to establish baseline values. Before entry into the Glaucoma Laser Trial, all patients were required to have intraocular pressure of at least 22 mm Hg in each eye on two consecutive examinations. The intereye intraocular pressure ratio had to be at least 0.67 and no greater than 1.50 at both examinations. Patients had to meet at least one of the following criteria: (1) glaucomatous visual field defect in at least one eye, or (2) intraocular pressure of at least 27 mm Hg in one eye and intraocular pressure of at least 31 mm Hg in the other eye and cup/disk ratio disparity (cup/disk ratio of right eye minus cup/disk ratio of left eye) of -0.3 or less or 0.3 or more, or (3) intraocular pressure of at least 31 mm Hg in both eyes and cup/disk ratio of at least 0.8 in at least one eye. Patients with a history of topical or systemic antiglaucoma medication usage within the previous six months, which included treatment for more than two weeks, use of more than one medication, or evaluation of the efficacy of medication, were excluded from enrollment. Patients had to be 35 years of age or older on entry, have consented to enrollment, and be free of conditions precluding the reliable administration or evaluation of medications, laser treatment, tonometry, visual field examinations, or optic disk stereophotography.

Argon laser trabeculoplasty was administered to the eye assigned to initial treatment with laser trabeculoplasty in two sessions, each consisting of 45 to 50 burns placed evenly over 180 degrees of trabecular meshwork and spaced approximately four weeks apart. During each session, the laser was aimed to cause burns straddling the pigmented and nonpigmented bands of the trabecular meshwork. Power intensity was adjusted between 600 and 1,200 mW to achieve blanching at the threshold of bubble formation. The eye initially treated with medication was prescribed

the assigned topical medication (0.5% timolol [Timoptic, Merck, West Point, Pennsylvania], two times daily) on the day of the initial argon laser trabeculoplasty session.

Once argon laser trabeculoplasty was completed, patients were examined three months after enrollment in the Glaucoma Laser Trial and every three months thereafter throughout the Glaucoma Laser Trial. Intraocular pressure and visual acuity were measured at each visit. Visual fields were measured at entry, three months, six months, and every six months thereafter. Optic disk stereophotographs were taken at entry, six months, 12 months, and every 12 months thereafter. From November 1989 until enrollment in the Glaucoma Laser Trial Follow-up Study, patients were examined either by an ophthalmologist in the Glaucoma Laser Trial or by the referring ophthalmologist. Treatment during this period was at the discretion of the treating physician.

The study population of the Glaucoma Laser Trial Follow-up Study consisted of 203 patients from the Glaucoma Laser Trial. Of the 68 patients from the Glaucoma Laser Trial who did not enroll in the Glaucoma Laser Trial Follow-up Study (25% of the Glaucoma Laser Trial population), 18 were deceased (as of Aug. 31, 1991), seven declined to enroll because of illness, 14 were not interested, and 29 could not be located or had moved away from the clinic area. Patients in the Glaucoma Laser Trial Follow-up Study were examined starting in December 1990 and continuing through August 1993 on an annual basis. Refraction, visual acuity measurement, tonometry, visual field measurement, slit-lamp examination, ophthalmoscopy, disk stereophotography, and gonioscopy were performed at each visit according to the methods of the Glaucoma Laser Trial protocol.¹⁶⁻¹⁸ Information on treatment for glaucoma and other medical events since the previous visit was obtained at each visit.

All intraocular pressure measurements were made with a Goldmann applanation tonometer. Two measurements were made for the right eye, followed immediately by two measurements for the left eye. If the two measurements for either eye differed by 4 mm Hg or more, the measurements for both eyes were rejected and repeated. The mean of the last two measurements for an eye was used for analysis.

The visual field was assessed with Program 32 on either the Octopus 201 or 2000 automated perimeter, with a stimulus of size 3. Throughout the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study, patients were examined on the same model Octopus perimeter as used for their initial Glaucoma Laser Trial examination. Pharmacologic dilation of the pupil was required, if necessary, to attain the requisite minimum pupil diameter of 2 mm. The 64 test locations in the central 30-degree field were used to calculate global indices of change in the visual field and to determine whether criteria for localized change had been met.¹⁸

Clinical subjective assessments of the Program 32 output were performed at the Visual Field Reading Center by an experienced clinician who was masked to treatment assignment. The follow-up field for a visit was graded by reviewing all previous visual fields for the eye and making an assessment about the overall change since entry into the Glaucoma Laser Trial; review of all previous fields allowed the clinician to incorporate information on the variability of threshold values in a specific eye into the assessment of change. Each field was characterized as better, worse, unchanged, or questionable. For analysis, fields judged questionable were considered unchanged.

Disk stereophotographs were obtained by using an Allen separator or by taking single-frame photographs on both sides of the visual axis. Photographs were evaluated at the Disc Stereophotography Reading Center by trained graders who were masked to treatment assignment. Each of two graders made a tracing of the cup and rim and centered a diagram of six intersecting line segments on the tracing of the disk. Each grader made one measurement of the cup diameter and two measurements of rim width along each line segment. Tracings from different visits were aligned so that measurements from different visits were comparable.¹⁸ Using the means of corresponding measurements from the two graders and the formula for the area of a circle, the cup and disk areas in each of the 12 sectors formed by the six intersecting line segments were calculated; the sector areas were summed to obtain the total cup and disk areas.

Each grader also provided subjective assessments of change in the disk. These assessments were made by comparing the tracing of the optic disk and cup made

from the follow-up photographs to the tracing made from the entry photographs. Each grader judged whether the disk was better, questionably better, unchanged, questionably worse, or worse as compared to the disk at Glaucoma Laser Trial entry. For analysis, a disk was considered to be better or worse relative to entry if both graders made the same judgment of better or worse; otherwise, the disk was considered to be unchanged.

Visual acuity charts developed for the Early Treatment Diabetic Retinopathy Study^{19,21} were used to measure visual acuity, with the patient wearing the prescription obtained via subjective refraction and standing 10 ft from the chart (5 ft if the initial line could not be read correctly at 10 ft). On these charts, a three-line decrease was equivalent to doubling of the visual angle. Visual acuity was recorded as the number of the last line read completely and correctly and the number of letters read correctly on lower lines. These data were transformed into a score, number of lines read correctly at 10 ft; each letter read correctly counted as 0.2 line.

During the Glaucoma Laser Trial, changes in medication for the eye that received medication first and initiation of or changes in medication for the eye

that received laser trabeculoplasty first could be made on the basis of confirmed increased intraocular pressure, confirmed deterioration in the visual field, clinically detectable deterioration of the optic disk, ocular or systemic adverse effects of medication, or a combination of these factors.^{14,18} Changes in medication were made according to a stepped regimen. Steps subsequent to timolol were as follows: dipivefrin, low-dose pilocarpine, high-dose pilocarpine, timolol with high-dose pilocarpine, and dipivefrin with high-dose pilocarpine. If dipivefrin with high-dose pilocarpine was not sufficient to control intraocular pressure, the ophthalmologists could prescribe treatment according to their discretion. However, prescription of carbonic anhydrase inhibitors was discouraged. Information on the therapy prescribed since the previous visit for eyes treated according to discretion was collected at each visit. During the Glaucoma Laser Trial Follow-up Study, treatment for both eyes of all patients was according to physician discretion. Information on the therapy prescribed for each eye since the previous visit was collected at each visit.

For analysis, each eye of each patient was included in the treatment group to which it was originally assigned, regardless of the course of treatment. All but

TABLE 1

MEAN CHANGE IN INTRAOCULAR PRESSURE FROM ENTRY (MM HG)

TIME (YRS)	GLAUCOMA LASER TRIAL*				GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY†			
	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE
Entry	271	27.2	27.3	-0.1	271	27.2	27.3	-0.1
1	251	-9.6	-8.0	-1.6	251	-9.6	-8.0	-1.6
2	244	-9.8	-8.4	-1.5	244	-9.8	-8.4	-1.5
3	187	-9.3	-8.8	-0.5	187	-9.3	-8.8	-0.5
4	89	-8.1	-8.0	-0.0	123	-8.7	-8.0	-0.7
5	20	-9.1	-8.7	-0.3	130	-10.2	-9.3	-0.9
6	—	—	—	—	162	-9.2	-8.4	-0.8
7	—	—	—	—	133	-8.8	-8.9	-0.0
8	—	—	—	—	71	-7.2	-7.7	0.5
9	—	—	—	—	16	-7.9	-6.4	-1.4
Overall estimate	—	—	—	-1.3	—	—	—	-1.2
Overall P value	—	—	—	<.001	—	—	—	<.001

*Negative change indicates reduction in intraocular pressure since entry; negative difference in change indicates more reduction for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication.

TABLE 2

MEAN CHANGE IN DECIBELS PER TEST LOCATION OF THE VISUAL FIELD FROM ENTRY

TIME (YRS)	GLAUCOMA LASER TRIAL*				GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY**			
	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE
Entry	271	21.0	21.2	-0.1	271	21.0	21.2	-0.1
1	249	1.1	0.6	0.5	249	1.1	0.6	0.5
2	243	1.1	0.6	0.5	243	1.1	0.6	0.5
3	184	0.7	0.1	0.5	184	0.7	0.1	0.5
4	87	0.7	-0.0	0.7	120	0.7	-0.0	0.8
5	19	0.1	-1.9	2.0	126	0.8	-0.4	1.3
6	—	—	—	—	159	0.5	0.0	0.4
7	—	—	—	—	130	0.5	-0.8	1.3
8	—	—	—	—	67	-0.3	-0.4	0.1
9	—	—	—	—	16	-1.5	-2.3	0.8
Overall estimate	—	—	—	0.5	—	—	—	0.6
Overall P value	—	—	—	.001	—	—	—	<.001

*Positive change indicates improvement since entry; positive difference in change indicates more improvement for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication.

three of the 271 patients in the Glaucoma Laser Trial had argon laser trabeculoplasty administered as specified by the Glaucoma Laser Trial protocol.¹⁴

Tables 1 through 8 give the data grouped by follow-up during the Glaucoma Laser Trial and follow-up during the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study. For these latter data, data from the Glaucoma Laser Trial and the Follow-up Study were combined and analyzed as if they had resulted from a continuous data collection effort. The number of days from Glaucoma Laser Trial entry of each Glaucoma Laser Trial Follow-up Study visit was determined, and the Glaucoma Laser Trial Follow-up Study visit was considered to have occurred at the yearly anniversary from Glaucoma Laser Trial enrollment closest in time to the Glaucoma Laser Trial Follow-up Study visit date. In Tables 1 through 6, the data for one, two, and three years in the columns under Glaucoma Laser Trial and the Follow-up Study were collected during the Glaucoma Laser Trial, data for years 4 and 5 are a mix of Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study data (72% Glaucoma Laser Trial at four years and 15% Glaucoma Laser Trial at five years), and data for years 6 and

beyond were collected during the Glaucoma Laser Trial Follow-up Study.

Median duration of follow-up for patients in the Glaucoma Laser Trial was 3.5 years (maximum, 5.5 years). Eighteen patients (7%) died or dropped out before their two-year follow-up visit. Median duration of follow-up of patients in the combined Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study database was seven years (maximum, nine years).

Patients for whom data were missing at entry into the Glaucoma Laser Trial could not be included in analyses of change in a measure from Glaucoma Laser Trial entry; data derived from the stereophotographs are given for the 266 patients whose photographs taken at entry into the Glaucoma Laser Trial could be graded. Patients for whom data were missing for a follow-up examination were excluded from analyses of that follow-up examination but were not excluded from analyses of other follow-up examinations for which data were available. Data are given for yearly anniversaries since Glaucoma Laser Trial randomization, but data from all follow-up examinations available were included in the analyses.

For continuous measures (intraocular pressure, mean dB per test location of the visual field, ratio of cup area to disk area, visual acuity score), change from entry into the Glaucoma Laser Trial to a particular follow-up examination was calculated by subtracting the measurement made at entry from the corresponding measurement made at the follow-up examination. The difference between eyes initially treated with laser trabeculoplasty and those initially treated with medication in change for a measure was calculated by subtracting the change in the eye initially treated with medication from the change in the eye initially treated with laser trabeculoplasty. The size of the difference between eyes in change for a measure was assessed with the generalized estimating equations approach to regression modeling of longitudinal data.²² This approach provides an estimate of the size of the difference that is based on the data from all follow-up times and is corrected for within-patient correlation.

Differences between treatment groups with respect to categorical measures (clinical assessment of the visual field output and subjective assessment of the optic disk tracings) also were evaluated with generalized estimating equation regression models for longi-

tudinal analysis. For analysis, assessments were assigned the following scores: +1 for better, 0 for unchanged or questionable, and -1 for worse. The repeated measures analyzed were the paired differences between eyes in assessment score at each follow-up time.

RESULTS

DATA ON CHANGE IN INTRAOCULAR PRESSURE FROM entry into the Glaucoma Laser Trial, as measured at yearly anniversaries of Glaucoma Laser Trial entry, are given in Table 1. Throughout follow-up in the Glaucoma Laser Trial and the Glaucoma Laser Trial Follow-up Study, the mean change in intraocular pressure from Glaucoma Laser Trial entry for both treatment groups was a reduction; intraocular pressure for eyes initially treated with laser trabeculoplasty was reduced by 7 to 10 mm Hg, and for eyes initially treated with medication, by 6 to 9 mm Hg, on average. Analysis of the difference between eyes in change in intraocular pressure indicated that eyes initially treated with laser trabeculoplasty had 1.2 mm Hg more reduction than eyes initially treated with

TABLE 3

CLINICAL ASSESSMENT OF CHANGE IN THE VISUAL FIELD FROM ENTRY

TIME (yrs)	GLAUCOMA LASER TRIAL					GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY				
	BETTER		WORSE			BETTER		WORSE		
	INITIAL TREATMENT WITH LASER TRABECULO-PLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULO-PLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULO-PLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULO-PLASTY	INITIAL TREATMENT WITH MEDICATION		
	NO.	(NO.) %	(NO.) %	(NO.) %	NO.	(NO.) %	(NO.) %	(NO.) %	(NO.) %	
Entry	271	—	—	—	271	—	—	—	—	
1	249	(56) 22	(49) 20	(23) 9	(30) 12	249	(56) 22	(49) 20	(23) 9	(30) 12
2	243	(54) 22	(53) 22	(22) 9	(32) 13	243	(54) 22	(53) 22	(22) 9	(32) 13
3	184	(42) 23	(35) 19	(19) 10	(25) 14	184	(42) 23	(35) 19	(19) 10	(25) 14
4	87	(24) 28	(21) 24	(11) 13	(20) 23	120	(30) 25	(26) 22	(12) 10	(24) 20
5	19	(3) 16	(1) 5	(2) 11	(8) 42	126	(29) 23	(21) 17	(11) 9	(30) 24
6	0	—	—	—	—	159	(27) 17	(27) 17	(21) 13	(27) 17
7	0	—	—	—	—	130	(30) 23	(24) 18	(17) 13	(33) 25
8	0	—	—	—	—	67	(13) 19	(7) 10	(10) 15	(15) 22
9	0	—	—	—	—	16	(1) 6	(0) 0	(3) 19	(5) 31
Overall P value			.022					.002		

medication, on average over the course of the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study ($P < .001$).

For eyes initially treated with laser trabeculoplasty, mean change in decibels per test location of the visual field from Glaucoma Laser Trial entry ranged from 0.5 to 1.1 dB during the first seven years of follow-up, indicating improvement in the visual field, on average (Table 2). Deterioration in visual fields from entry into the Glaucoma Laser Trial was seen for eyes initially treated with laser trabeculoplasty at eight and nine years after entry (-0.3 and -1.5 dB, respectively). Eyes initially treated with medication showed improvement through three years of follow-up (0.1 to 0.6 dB), with no change or negative mean changes (0.0 to -2.3 dB) observed at subsequent yearly anniversaries from entry into the Glaucoma Laser Trial. Greater improvement was observed for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication, by about 0.6 dB, averaged over all Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study times ($P < .001$). Pupil diameter during visual field examinations

was about 0.2 mm larger for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication, averaged over all follow-up times ($P < .001$).

Visual fields for over 50% of the eyes in both treatment groups were judged to be unchanged from Glaucoma Laser Trial entry throughout the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study, according to the subjective assessments of change (Table 3). The distributions of assessments were different for eyes initially treated with laser trabeculoplasty as compared to eyes initially treated with medication ($P = .022$, Glaucoma Laser Trial; $P = .002$, Glaucoma Laser Trial and the Glaucoma Laser Trial Follow-up Study). The percentage of eyes initially treated with laser trabeculoplasty judged to have improved visual fields relative to entry into the Glaucoma Laser Trial tended to be similar to the percentage of eyes initially treated with medication judged to have improved visual fields relative to entry into the Glaucoma Laser Trial, at each follow-up year. The percentage of eyes initially treated with laser trabeculoplasty judged to have visual fields that

TABLE 4

MEAN CHANGE IN RATIO OF OPTIC DISK CUP AREA TO DISK AREA FROM ENTRY

TIME (yrs)	GLAUCOMA LASER TRIAL*				GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY*			
	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE
Entry	266	0.30	0.29	0.01	266	0.30	0.29	0.01
1	241	-0.00	0.00	-0.01	241	-0.00	0.00	-0.01
2	228	0.00	0.01	-0.01	228	0.00	0.01	-0.01
3	167	0.00	0.02	-0.02	167	0.00	0.02	-0.02
4	82	0.03	0.03	-0.00	113	0.03	0.03	-0.00
5	18	0.02	0.05	-0.03	116	0.04	0.05	-0.02
6	0	—	—	—	145	0.04	0.05	-0.01
7	0	—	—	—	122	0.03	0.06	-0.03
8	0	—	—	—	60	0.04	0.04	0.00
9	0	—	—	—	16	0.02	0.03	-0.01
Overall estimate	—	—	—	-0.01	—	—	—	-0.01
Overall P value	—	—	—	.007	—	—	—	.005

*Positive change indicates deterioration since entry; negative difference in change indicates less deterioration for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication.

TABLE 5

SUBJECTIVE ASSESSMENT OF CHANGE IN THE OPTIC DISK FROM ENTRY

TIME (yrs)	GLAUCOMA LASER TRIAL					GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY				
	NO.	BETTER		WORSE		NO.	BETTER		WORSE	
		INITIAL TREATMENT WITH LASER TRABECULO- PLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULO- PLASTY	INITIAL TREATMENT WITH MEDICATION		INITIAL TREATMENT WITH LASER TRABECULO- PLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULO- PLASTY	INITIAL TREATMENT WITH MEDICATION
		(NO.) %	(NO.) %	(NO.) %	(NO.) %		(NO.) %	(NO.) %	(NO.) %	(NO.) %
Entry	271	—	—	—	—	271	—	—	—	—
1	241	(16) 7	(9) 4	(19) 8	(15) 6	241	(16) 7	(9) 4	(19) 8	(15) 6
2	228	(16) 7	(17) 7	(30) 13	(30) 13	228	(16) 7	(17) 7	(30) 13	(30) 13
3	167	(8) 5	(14) 8	(22) 13	(19) 11	167	(8) 5	(14) 8	(22) 13	(19) 11
4	82	(6) 7	(5) 6	(18) 22	(23) 28	113	(7) 6	(5) 4	(28) 25	(34) 30
5	18	(1) 6	(1) 6	(4) 22	(9) 50	115	(3) 3	(3) 3	(33) 29	(37) 32
6	0	—	—	—	—	146	(3) 2	(1) 1	(34) 23	(32) 22
7	0	—	—	—	—	122	(1) 1	(3) 2	(17) 14	(21) 17
8	0	—	—	—	—	60	(1) 2	(1) 2	(9) 15	(8) 13
9	0	—	—	—	—	16	(1) 6	(0) 0	(2) 13	(1) 6
Overall P value				.441					.535	

worsened tended to be smaller than the corresponding percentage for eyes initially treated with medication.

Eyes in both treatment groups showed slight increases in the mean ratio of cup area to disk area over follow-up (Table 4). The difference between eyes, averaged over all Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study follow-up times, was -0.01 ($P = .005$), indicating slightly more deterioration for eyes initially treated with medication.

The subjective assessments of change in the optic disk, as observed from the tracings of the optic disk and cup, indicate that over half of the eyes in each treatment group were judged to be unchanged from entry into the Glaucoma Laser Trial throughout much of the follow-up period (Table 5). In both treatment groups, more eyes were judged worse relative to entry into the Glaucoma Laser Trial than were judged better. The distribution of assessments was similar in both treatment groups, for both Glaucoma Laser Trial follow-up ($P = .441$) and for Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study follow-up ($P = .535$).

Data relating to visual acuity are given in Table 6. The mean score at entry was 11.4 lines (20/25 Snellen equivalent) for both treatment groups. Eyes in

both treatment groups tended to have decreasing visual acuity scores over follow-up (Table 6), by about 0.2 to one line. Change in visual acuity relative to entry into the Glaucoma Laser Trial was similar for both groups of eyes ($P = .271$, Glaucoma Laser Trial; $P = .276$, Glaucoma Laser Trial and the Glaucoma Laser Trial Follow-up Study).

Data on therapy for primary open-angle glaucoma in the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study are given in Table 7. The first group of data ("Treatment history subsequent to Glaucoma Laser Trial randomization") summarizes the treatment history for both treatment groups during the Glaucoma Laser Trial and during the combined Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study period. As of the last examination in the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study period (which could have occurred in the Glaucoma Laser Trial or Glaucoma Laser Trial Follow-up Study), the only therapy received by 20% (54) of the eyes initially treated with laser trabeculoplasty was the argon laser trabeculoplasty received at Glaucoma Laser Trial randomization; median follow-up time for these 54 eyes was three years (maximum, nine years). Another 20% (54) of the eyes initially treated with laser trabeculo-

plasty had received only timolol in addition to the argon laser trabeculoplasty received at Glaucoma Laser Trial randomization. Thus, the only therapy received by 40% (108) of the eyes initially treated with laser trabeculoplasty was argon laser trabeculoplasty alone or argon laser trabeculoplasty with timolol, as of the last examination in the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study period. Of the eyes initially treated with medication, 15% (40) of eyes had received only timolol. Of the eyes initially treated with laser trabeculoplasty, 17% (45) vs 31% (84) of the eyes initially treated with medication had received other treatment, such as systemic medication, argon laser trabeculoplasty in addition to the argon laser trabeculoplasty received at Glaucoma Laser Trial randomization, or filtering surgery, or a combination.

The second group of data in Table 7 ("Ever administered") displays the percentages of eyes ever receiving the specified types of treatment for primary open-angle glaucoma. By the end of the Glaucoma Laser Trial Follow-up Study, 8% (23) of the eyes initially treated with laser trabeculoplasty had received filtering surgery, and 3% (eight) had received a repeat argon laser trabeculoplasty. Of the eyes initial-

ly treated with medication, 11% (31) had received filtering surgery, and 23% (63) had been administered argon laser trabeculoplasty.

Data on the amount of medication used by eyes in both groups over the course of follow-up are given in Table 8. For this analysis, a medication-day was counted for each day of use of each medication used; the number of doses per day was ignored. The number of medication-days was summed for each eye and for each treatment group, over the course of the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study. By the end of Glaucoma Laser Trial follow-up, the number of medication-days for eyes initially treated with laser trabeculoplasty was 42% of the number of medication-days for eyes initially treated with medication. By the end of Glaucoma Laser Trial Follow-up Study, the number of medication-days for eyes initially treated with laser trabeculoplasty was 62% of the number of medication-days for eyes initially treated with medication.

Data on signs and symptoms severe enough to warrant a change in medication were collected during the Glaucoma Laser Trial (but were not collected during the Glaucoma Laser Trial Follow-up Study); these data are shown in Table 9. The most frequently

TABLE 6

MEAN CHANGE IN BEST-CORRECTED VISUAL ACUITY SCORE FROM ENTRY

TIME (yrs)	GLAUCOMA LASER TRIAL*				GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY*			
	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE	NO.	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE
Entry	271	11.4	11.4	-0.0	271	11.4	11.4	-0.0
1	251	0.14	0.06	0.08	251	0.14	0.06	0.08
2	244	0.06	-0.11	0.17	244	0.06	-0.11	0.17
3	187	-0.10	-0.18	0.09	187	-0.10	-0.18	0.09
4	89	-0.36	-0.61	0.25	122	-0.31	-0.60	0.29
5	20	-0.33	-1.13	0.80	130	-0.06	-0.64	0.58
6	0	—	—	—	162	-0.73	-0.64	-0.09
7	0	—	—	—	133	-0.85	-1.02	0.17
8	0	—	—	—	71	-1.55	-1.37	-0.18
9	0	—	—	—	17	-2.59	-2.26	-0.33
Overall estimate	—	—	—	0.10	—	—	—	0.10
Overall P value	—	—	—	.271	—	—	—	.276

*Negative change indicates deterioration since entry; positive difference indicates less deterioration for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication.

TABLE 7

THERAPY FOR PRIMARY OPEN-ANGLE GLAUCOMA IN THE GLAUCOMA LASER TRIAL AND THE GLAUCOMA LASER TRIAL FOLLOW-UP STUDY

THERAPY	GLAUCOMA LASER TRIAL		GLAUCOMA LASER TRIAL AND THE FOLLOW-UP STUDY	
	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION
	(NO.) %	(NO.) %	(NO.) %	(NO.) %
Treatment history subsequent to Glaucoma Laser Trial randomization				
No treatment	(87) 32	—	(54) 20	—
Timolol only	(62) 23	(53) 20	(54) 20	(40) 15
Topical medications only (additional to or in replacement of timolol)	(102) 38	(165) 61	(118) 44	(147) 54
Other (systemic medication, ¹ argon laser trabeculoplasty subsequent to Glaucoma Laser Trial randomization, filtering surgery)	(20) 7	(53) 20	(45) 17	(84) 31
Total	(271) 100	(271) 100	(271) 100	(271) 100
Ever administered*				
Filtering surgery	(8) 3	(15) 6	(23) 8	(31) 11
Argon laser trabeculoplasty subsequent to Glaucoma Laser Trial randomization	(6) 2	(45) 17	(8) 3	(63) 23
Systemic medication†				
β-blocker	(11) 4	(11) 4	(28) 10	(28) 10
Epinephrine compound	(174) 64	(271) 100	(207) 76	(271) 100
Miotic	(110) 41	(217) 80	(125) 46	(217) 80
No. of eyes	(103) 38	(190) 70	(128) 47	(201) 74
	(271) 100	(271) 100	(271) 100	(271) 100

*Categories are not mutually exclusive.

†Systemic medication is attributed to both eyes.

cited systemic symptom associated with a change in medication was headache. Bradycardia and exacerbation of asthma were each cited four times as the cause for a change in medication, and tachycardia was cited three times. The most frequently cited ocular symptoms associated with a change in medication were pain and blurring of vision.

DISCUSSION

THE GLAUCOMA LASER TRIAL RESULTS THROUGH TWO years of follow-up indicated that initial treatment with argon laser trabeculoplasty was both safe and effective.¹⁴ Mean intraocular pressure was consistently lower, by 1 to 2 mm Hg, for eyes initially treated with laser trabeculoplasty than for eyes initially treated with medication. Eyes initially treated with laser trabeculoplasty generally required less medication for intraocular pressure control than eyes initially treated

with medication. It was noted that neither argon laser trabeculoplasty alone, nor argon laser trabeculoplasty with medications as needed, nor medication alone was a cure-all. Two years after the start of treatment, 56% (137 of 244) of eyes initially treated with laser trabeculoplasty required the addition of one or more medications for control of intraocular pressure, and 70% (171 of 244) of eyes initially treated with timolol required new or additional medication to control intraocular pressure. Analysis of the visual field data through 3.5 years of follow-up indicated that the mean threshold for eyes initially treated with laser trabeculoplasty was 0.3 dB higher (better) than for eyes initially treated with medication, averaged over follow-up.¹⁵

The Glaucoma Laser Trial Follow-up Study data are consistent with the Glaucoma Laser Trial data with respect to intraocular pressure level, visual field results, optic disk status, visual acuity, and medication use. Although none of the treatment group compari-

TABLE 8

TOPICAL MEDICATION-DAYS IN THE GLAUCOMA LASER TRIAL AND GLAUCOMA LASER TRIAL FOLLOW-UP STUDY

	INITIAL TREATMENT WITH LASER TRABECULOPLASTY	INITIAL TREATMENT WITH MEDICATION	DIFFERENCE
No. of eyes	271	271	
Total no. of medication-days			
During the Glaucoma Laser Trial	224,024	477,052	-253,028
During the Glaucoma Laser Trial and the Follow-up Study	538,397	871,339	-332,942

sons (Tables 1-6) indicate large differences between treatment groups, all of the differences suggest that starting treatment with argon laser trabeculoplasty is at least as beneficial as starting with timolol. Although the observed mean differences may not be clinically significant for an individual patient, differences of this sort in relation to group means may have important implications with regard to treatment for primary open-angle glaucoma. Comparison of the two treatment groups with respect to therapy received (Tables 7 and 8) indicates that medication use is less for the eyes initially treated with laser trabeculoplasty than for the eyes initially treated with medication and that similar proportions of eyes initially treated with medication and laser trabeculoplasty were administered filtering surgery (8% [23] of eyes initially treated with laser trabeculoplasty vs 11% [31] of eyes initially treated with medication).

Side effects of argon laser trabeculoplasty observed in the Glaucoma Laser Trial included transient increases in intraocular pressure after argon laser trabeculoplasty treatment and formation of peripheral anterior synechiae.^{14,23} Intraocular pressure increases of greater than 5 mm Hg occurred in 34% (91 of 271) of eyes initially treated with laser trabeculoplasty after one or both argon laser trabeculoplasty sessions; these increases were associated with moderate or heavy pigmentation of the trabecular meshwork.²³ Higher rates of formation of peripheral anterior synechiae were associated with brown iris color and placement of laser burns posterior to the junction of the pigmented and unpigmented anterior trabecular meshwork. The extent of meshwork affected by the peripheral anterior synechiae was 45 degrees or less

for 88% (82) of the 93 eyes that developed peripheral anterior synechiae within three months of initiation of argon laser trabeculoplasty. Throughout follow-up, these 93 eyes had similar or better intraocular pressure reduction, similar visual field status, and similar medical and surgical history as the 171 eyes initially treated with laser trabeculoplasty that were free of peripheral anterior synechiae three months after treatment with argon laser trabeculoplasty.

We do not know whether the effects of having argon laser trabeculoplasty early in the course of treatment for primary open-angle glaucoma are the same as when argon laser trabeculoplasty is administered later. Hence, the benefits of argon laser trabeculoplasty as an initial treatment cannot necessarily be expected to accrue to eyes treated for several years with topical medications and then treated with argon laser trabeculoplasty. Each patient received both treatments, one to each eye, and the treatments may have affected the fellow eye. Although we estimated that the crossover effect of timolol on the fellow eye is approximately 0.5 mm Hg,²⁴ uncertainty remains as to the effects of argon laser trabeculoplasty on intraocular pressure reduction in patients without such treatment in their fellow eye.

There are reasons to be cautious about the Glaucoma Laser Trial Follow-up Study portion of our data. The period of follow-up of the Glaucoma Laser Trial and Glaucoma Laser Trial Follow-up Study (up to nine years) is short in comparison to a lifetime of glaucoma. Second, the 68 patients in the Glaucoma Laser Trial who did not participate in the Glaucoma Laser Trial Follow-up Study may have had different prognoses than the 203 patients who enrolled in the

TABLE 9

SYSTEMIC AND OCULAR SYMPTOMS RESULTING
IN A CHANGE IN MEDICATION IN THE GLAUCOMA
LASER TRIAL

SYMPTOM	NO. OF REPORTS
Systemic	
Headache	12
Fatigue and weakness	9
Anxiety	4
Bradycardia	4
Dizziness	4
Exacerbation of asthma	4
Mental depression	4
Tachycardia	3
Wheezing, shortness of breath	3
Disorientation	2
Memory loss	2
Muscle tremor or weakness	2
Hypotension	1
Other*	13
Ocular	
Pain	27
Blurring of vision	23
Darkening of vision	18
Hyperemia	17
Tearing	13
Itching	6
Periorbital edema	6
Photophobia	1
Other*	15

*Self-reported symptoms.

Follow-up Study. We compared the participants in the Glaucoma Laser Trial Follow-up Study to the nonparticipants, with respect to baseline age, race, gender, and difference between eyes in intraocular pressure and mean decibels per test location of the visual field; no differences were noted. Differences between eyes with respect to change in these ocular characteristics from entry into the Glaucoma Laser Trial were also examined as of the last follow-up examination in the Glaucoma Laser Trial, and again, differences were not observed between the participants and nonparticipants in the Glaucoma Laser Trial Follow-up Study. The design of the Glaucoma Laser Trial assures that the pairing of eyes initially treated with laser trabeculoplasty with eyes initially treated with medication remains intact in the Glau-

coma Laser Trial Follow-up Study, despite the non-participants. Last, from November 1989 onward, the treating physician had complete discretion over the choice, sequence, and timing of therapy for primary open-angle glaucoma.

All of the analyses used to judge efficacy of treatment for primary open-angle glaucoma (change in intraocular pressure level, change in visual field status, change in cup status, change in visual acuity score, use of medications, and amount of surgery received after randomization) indicated that the eyes initially treated with laser trabeculoplasty had a status similar to or better than the eyes initially treated with medication. These analyses suggest that initial treatment with argon laser trabeculoplasty is at least as efficacious as initial treatment with topical medication.

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