

Pupil Size and Quality of Vision after LASIK

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Purpose: To evaluate factors related to the quality of vision after LASIK.

Design: Survey study.

Participants: One hundred consecutive patients.

Intervention: LASIK with a 6.0-mm elliptical ablation pattern without transition zone to treat mild to moderate myopia or astigmatism (preoperative manifest spherical equivalent [MSE], -4.79 ± 1.33 diopters [D]; range, -2.88 to -9.25 D). The second eye was treated 1 month after the first.

Main Outcome Measures: Completed questionnaires assessing night vision problems (glare, haze, and halo symptoms) before surgery and at 1, 3, and 6 months after surgery in 97, 75, 81, and 66 subjects, respectively. Mesopic pupil size and preoperative and postoperative variables were analyzed with questionnaire data using an analysis of variance (ANOVA) and multivariate regression analysis.

Results: Patients with large mesopic pupils had significantly more reports of glare, haze, and halo than did those with smaller pupils in the treated eye at 1 month after surgery ($P=0.02$, $P=0.03$, and $P=0.02$, respectively ANOVA) and of glare at 3 months ($P=0.05$). Significant predictors of symptoms at 6 months, identified through multivariate regression analysis, included preoperative MSE (for glare and haze), preoperative contrast acuity (glare), postoperative uncorrected visual acuity (UCVA; haze), and residual cylinder (haze). Together, these factors accounted for only 19% of the overall variability in glare and 37% of the variability in haze responses. No relationship between pupils and symptoms was noted at 6 months after surgery in either the ANOVA or regression analysis group.

Conclusions: Patients with large pupils had more quality of vision symptoms in the early postoperative period, but no correlation was observed 6 months after surgery. Factors related to long-term symptoms include the level of treatment (preoperative myopia), preoperative contrast acuity, postoperative UCVA, and residual cylinder. Most of the variability in visual quality could not be explained by preoperative or clinical outcome measures, including pupil size. *Ophthalmology* 2003;110:1606–1614 © 2003 by the American Academy of Ophthalmology.

Early excimer laser studies with photorefractive keratectomy (PRK) were conducted with small ablation zones, less than 5.5 mm. However, the severity of quality of vision

complaints, especially at night, led manufacturers to increase the ablation diameter to 6.0 mm and more.¹ Even with larger ablation zones, quality of vision problems have been reported in many clinical studies of PRK and LASIK.^{2–8} Typically, patients report problems with glare or halos at night, or both.

Anecdotal and case series reports as well as ray tracing models have linked the relationship between the ablation zone and low-light (mesopic) pupil size to night vision problems complaint after laser vision correction.^{9–13} Intuitively, the low-light pupil allows light from the untreated cornea to create glare or a halo effect around the viewed image. Many surgeons recommend that LASIK not be performed on patients whose pupil size is larger than the treatment optical zone.¹⁴ However, no careful analysis has been conducted to determine the role of the mesopic pupil on night vision problems occurring after surgery.

The study had three objectives: to assess the time course of night vision problems occurring after LASIK, to determine the relationship between these problems and mesopic pupil size, and to examine other preoperative and postoperative factors that may be related to the problems. The

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Table 1. Subject Demographics

Average age and range (yrs)	36, 23–66
Gender	
Male	82
Female	18
Ethnicity	
White	65
Asian	18
Black	8
Hispanic	6
Not specified	3

study was conducted using a 6.0-mm ablation zone treatment without transition zone. Although larger ablation diameters currently are available, a 6.0-mm treatment may be required because of concern about the amount of corneal tissue remaining after LASIK. An analysis of quality of vision after LASIK using a 6.0-mm ablation zone should represent a “worst case” scenario compared with larger zones.

Subjects and Methods

Subjects

After obtaining informed consent, 100 consecutive subjects underwent LASIK for the correction of myopia or myopia with astigmatism. The protocol was approved by the Institutional Review Board of the Naval Medical Center San Diego. Eligibility requirements included a stable refractive error between -3.0 and -10.0 diopters (D) with up to 4.0 D of astigmatism and normal ocular health. Hard contact lens users were required to remove their lenses for at least 3 weeks (1 week for soft contact lenses) before the preoperative examination. Complete questionnaire data at baseline exist for 97 patients; this is the sample for these analyses. Patient demographics are listed in Table 1. Of the 97, there were 80 males and 17 females, and the average age was 36 years.

Laser Surgery

Three surgeons performed all of the procedures (SCS, DJT, and JT). Each surgeon had similar experience with the operation of the laser and microkeratome. All photoablations were performed on the VISX Star S2 excimer laser system (VISX Inc., Santa Clara, CA). Emmetropia was the goal in all cases. The first eye treated was generally the nondominant eye (96 of 97 subjects), followed 1 month later by the other eye. The microkeratome was the Hansatome (Bausch & Lomb, Irvine, CA) with the 160- μ m plate and the 9.5-mm ring. A new blade was used for each eye. If the astigmatism was 0.50 D or less, the manifest spherical equivalent (MSE) refractive error was treated with a 6.0-mm spherical ablation (110 eyes). The sphere and cylinder components of refraction were both treated if the astigmatism was more than 0.50 D (90 eyes). This resulted in an elliptical ablation profile with a 6.0-mm major axis and a minor axis that varied from 4.5 to 5.8 mm, depending on the magnitude of the sphere and cylinder correction. Of the 90 eyes with an elliptical ablation, 19 had a minor axis of less than 5.0 mm, 54 eyes were between 5.0 and 5.5 mm, and 17 eyes were 5.5 mm or more. There was no transition zone. After the procedure, ciprofloxacin (Ciloxan; Alcon Inc., Fort Worth, TX), flouromethalone (FML; Allergan Pharmaceuticals, Irvine, CA), and tears (Gentel; Ciba Vision, Duluth, GA) were used for 4 days.

Preoperative and Postoperative Testing

Clinical Measures. Preoperative and 1-, 3-, and 6-month postoperative testing consisted of measuring uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometry, and corneal topography and performing a biomicroscopic examination. The Small Letter Contrast Test was used to assess photopic contrast sensitivity. The Small Letter Contrast Test is a front-illuminated chart and is similar to the Pelli-Robson chart, but uses 20/25-size letters.¹⁵

Pupil Size. The pupil diameter was measured under low light conditions (<5 lux) using the Colvard Pupillometer (Oasis, Glendora, CA).¹⁶ Patients were seated and asked to fixate on an object at the opposite end of the room. The pupillometer was placed in front of one eye and adjusted fore and aft until the pupil was in sharp focus through the viewing screen. The operator then aligned the device to read the pupil diameter on the scale to the nearest 0.5 mm. The other eye was measured in a similar fashion.

Questionnaires. A questionnaire was administered to patients at baseline and at 1, 3, and 6 months after surgery that asked them to describe current problems with glare, haze, and halos in seven circumstances. A sample of the preoperative halo survey is shown in Table 2. These questions were derived from a series of focus groups composed of patients who had undergone PRK or LASIK. Patients described the extent to which they were experiencing each problem on a 5-point scale, where 1 represented “no problem” and 5 represented a problem “all the time.” The questions in each set asked patients about problems that occurred at night in general and with oncoming headlights, taillights, brightly illuminated signs, reading signs with headlights, and whether problems driving at night resulted in patients slowing down or feeling unsafe.

At baseline, patients were asked to answer each set of questions when they wore glasses and when they wore contact lenses. One month after LASIK with only one treated eye, patients were asked to answer each set of questions for the treated eye and for the untreated eye. At 3 and 6 months, patients were asked each set of questions once about both eyes.

Analysis

A questionnaire was considered incomplete and not included in the analysis if more than three of the seven questions were not answered within each quality-of-vision category. The seven questions in each category were combined into an index of averaged responses. Both factor analysis and Cronbach's α were used to create the indices and to determine their internal homogeneity and reliability. Cronbach's α for all indices at all time periods was ≥ 0.80 . Individual index scores ranging from 1 (no problem) to 5 (problem all the time) were averaged to create a night problem index. Paired rank-ordered tests (i.e., Wilcoxon matched pairs test) were used to compare the preoperative and postoperative index scores.

Index scores were examined by pupil size category using an analysis of variance (ANOVA). The three pupil size categories were small (5.0 mm or less), medium (5.5 and 6.0 mm), and large (6.5 mm and greater).

Predictors of glare, haze, and halo reports at night were examined using regression analysis. The three subjective indices were the dependent variables in each regression equation, and demographic, treatment, and ophthalmic outcome parameters were the independent predictors as shown in Table 3. Correlation matrices were used to search for potential independent variables. Exploratory (backward stepwise) regressions were used to select the most parsimonious set of predictors for each problem at each postoperative time point (1, 3, and 6 months). Using the reduced list of variables, a forward stepwise regression was performed. Forward

Table 2. Sample Night Halo Questions from Preoperative Questionnaire

People have different experiences with their vision. Some people have problems with halos around lights. How about you? Please indicate whether you are now—that is, within the last 30 days—having problems with halos around lights in any of the following conditions. Please consider your experience when you are wearing glasses and when you are wearing contact lenses

	Never	Occasionally	About Half of the Time	Most of the Time	All of the Time	Does Not Apply
At night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
From oncoming car headlights at night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
From car taillights at night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
Reading a brightly illuminated road sign at night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
Reading a road sign at night using your car headlights						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
To the extent that you slow down when driving at night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6
To the extent that you feel unsafe driving at night						
When wearing glasses	1	2	3	4	5	6
When wearing contact lenses	1	2	3	4	5	6

selection brings the strongest predictor of the dependent variable into the equation first and then examines whether additional predictor variables (starting with the next strongest correlation) increase or add to the amount of residual variance explained in the dependent variable in successive steps, until there are no more significant contributions to explaining the residual variation. Statistica (version 6.0; StatSoft, Inc., 2001) software was used for all analysis.

Results

Clinical Outcomes

The LASIK procedure was successful in reducing myopia and improving UCVA. The preoperative MSE was reduced from a mean of -4.79 ± 1.33 D (-2.88 to -9.25 D) to -0.11 ± 0.60 D (-2.00 to $+1.50$ D) by 6 months, as displayed in Table 4. At 6

months, 78% of subjects achieved at least 20/20 UCVA. No patient had postoperative flap striae or corneal edema.

There were three intraoperative complications in three subjects (3 of 200 flaps; 1.5%): an incomplete flap, an irregular flap, and a displaced flap noted on the first postoperative day. The incomplete and irregular flap cases did not undergo initial excimer laser treatment. Three months after the surgery, both of these subjects had a new flap cut and underwent completion of the LASIK procedure without difficulty. The displaced flap immediately was refloated and repositioned and the patients had an uneventful postoperative course. All three subjects returned to their preoperative BCVA by 1 month after surgery without residual scarring, haze, or topographic irregularity. All three were included in the analysis.

Respondents vs. Nonrespondents

Of the 100 subjects, 97 completed a preoperative questionnaire, and 75, 81, and 66 subjects completed the 1-, 3-, and 6-month questionnaire, respectively. Patients differentially answered questions within each period; this reduced the size of the sample when analyses were performed. Of particular concern were patients lost to follow-up by the 6-month postoperative examination. Some analyses do not include 6-month data because only 40 subjects were examined at every postoperative time interval, that is, at 1, 3, and 6 months after initial treatment, and completed all questionnaires.

An analysis was conducted to determine if there were differences in clinical parameters between those who completed a questionnaire and those who did not. There was less than 0.50 D in preoperative refraction and no difference in acuity between the patients who completed the 6-month questionnaire (66 patients) and those who did not (21 patients), as shown in Table 5. In addition, there was no difference in refraction or acuity at 6 months between those who completed the questionnaire and those who attended the 6-month examination but did not fill out the question-

Table 3. List of Independent Variables Tested for Predicting Quality-of-vision Problem Reports before and after Surgery

Demographics		
Pretreatment	Treatment	Postoperative
Age	Sphere	Sphere
Gender	Cylinder	Cylinder
Ethnicity	MSE	MSE
Pupil diameter	Minor axis of ablation	UCVA
Contrast sensitivity		Contrast sensitivity

MSE = manifest spherical equivalent; UCVA = uncorrected visual acuity.

Treatment and postoperative variables were tested for dominant, non-dominant, and worst uncorrected visual acuity of the two eyes of each subject for the 3- and 6-month analyses.

Table 4. Clinical Outcome

	Preoperative	1 Month	3 Months	6 Months
All subjects	100	99	84	87
Eyes	200	99*	168	174
MSE \pm SD (D)	-4.79 ± 1.33	$+0.08 \pm 0.65$	-0.08 ± 0.63	-0.11 ± 0.60
Range	-9.25 to -2.88	-1.38 to $+2.13$	-2.00 to $+1.88$	-2.00 to $+1.50$
UCVA $\geq 20/20$	0%	81%	75%	78%
UCVA $\geq 20/40$	0%	99%	98%	96%
BCVA (LM)	-0.12 ± 0.06	-0.13 ± 0.08	-0.14 ± 0.08	-0.15 ± 0.07
Range	-0.30 to $+0.06$	-0.30 to $+0.18$	-0.30 to $+0.04$	-0.30 to $+0.10$
Subjects who completed the questionnaire	97	75	81	66
Eyes	194	75*	162	132
MSE \pm SD (D)	-4.76 ± 1.32	$+0.10 \pm 0.62$	-0.08 ± 0.64	-0.12 ± 0.59
Range	-9.25 to -2.88	-1.25 to $+2.13$	-2.00 to $+1.88$	-2.00 to $+1.38$
UCVA $\geq 20/20$	0%	80%	76%	81%
UCVA $\geq 20/40$	0%	99%	98%	96%
BCVA (LM)	-0.12 ± 0.06	-0.14 ± 0.08	-0.14 ± 0.08	-0.15 ± 0.07
Range	-0.30 to $+0.06$	-0.30 to $+0.12$	-0.30 to $+0.04$	-0.30 to $+0.10$

BCVA = best-corrected visual acuity; D = diopters; LM = logarithm of the minimum angle of resolution; MSE = manifest spherical equivalent; SD = standard deviation; UCVA = uncorrected visual acuity.

*Only the first eye treated received a 4-week postoperative examination.

naire completely. This suggests that those who did not answer a postoperative questionnaire did not do so because of a differentially poor or good clinical outcome.

Pupil Size

The distribution of mesopic pupil sizes is shown in Figure 1. The average pupil was 5.7 ± 0.8 mm (range, 4.0–8.0 mm). Thirty-one patients had small (<5.5 mm), 53 had medium (5.5–6.0 mm), and 15 had large (>6.0 mm) mesopic pupils. One subject did not have a pupil measurement. The distribution of preoperative MSE and astigmatism (including minor axis of the ablation) was distributed randomly across the range of mesopic pupil sizes ($r < 0.1$; $P > 0.5$). The delineation of pupil sizes into small, medium, and large did not result in any bias from the preoperative MSE nor from frequency of astigmatic corrections when large pupils were compared with smaller pupil for preoperative, 1-, 3-, or 6-month postoperative symptoms ($\chi^2 < 0.1$; $P > 0.5$, where expected frequency was for small and medium pupils and the observed frequency was for large pupil subjects).

Quality of Vision after LASIK

Figure 2 shows how index responses differed over time (baseline, 1 month, and 3 months after first treatment), condition (glasses and contacts, treated and untreated eye), and quality of vision category (glare, haze, and halo index). This is a coherent dataset of 63 patients who answered at least four of the seven questions in each category at every time period and condition through 3 months after surgery.

The night indexes for glare, haze, and halos in the treated eye at 1 month after surgery are slightly, but significantly, higher than for those for wearing contact lenses at baseline 2.0 vs. 1.5, $P = 0.01$; 1.8 vs. 1.3, $P = 0.01$; 1.6 vs. 1.3, $P < 0.01$; respectively; paired Wilcoxon test). In addition, haze and halo scores were higher in the 1-month postoperative treated eye compared with scores for wearing glasses before surgery (1.8 vs. 1.4, $P = 0.03$; 1.8 vs. 1.5, $P = 0.02$, respectively). Glare, haze, and halo scores also were higher in the 1-month treated eye compared with the untreated eye (2.0 vs. 1.6, $P < 0.001$; 1.8 vs. 1.4, $P < 0.001$; 1.6 vs. 1.4, $P < 0.001$; respectively). At 3 months after surgery, glare and

Table 5. Preoperative and 6-month Postoperative Clinical Outcomes of Those Who Completed the 6-month Questionnaire and Those Who Did Not

	6-month Questionnaire* before surgery	No 6-month Questionnaire	6-month Questionnaire at 6 Months*	No 6-month Questionnaire at 6 Months
Subjects (eyes)	66 (132)	21 (42)	66 (132)	21 (42)
MSE	-4.66 ± 1.13 D	-5.07 ± 1.85 D	-0.12 ± 0.59 D	-0.06 ± 0.65 D
Range	-2.88 to -8.13 D	-3.00 to -9.25 D	-2.00 to $+1.38$ D	-1.33 to $+1.50$ D
UCVA (LM)			-0.03 ± 0.16	0.00 ± 0.14
Range			-0.26 to $+0.60$	-0.20 to $+0.54$
BCVA (LM)	-0.12 ± 0.06	-0.12 ± 0.05	-0.15 ± 0.07	-0.13 ± 0.06
Range	-0.30 to $+0.02$	-0.20 to 0.00	-0.30 to $+0.10$	-0.24 to $+0.02$

BCVA = best-corrected visual acuity; D = diopters; LM = logarithm of the minimum angle of resolution; MSE = manifest spherical equivalent; UCVA = uncorrected visual acuity.

*Those patients who completed the 6-month questionnaire.

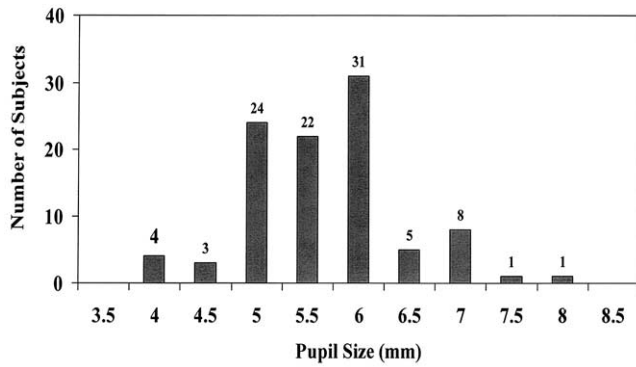


Figure 1. Distribution of mesopic pupil sizes (n = 99).

haze scores were indistinguishable from baseline scores with either glasses or contact lenses. The index for halos remained elevated at 3 months compared with that for wearing contacts lenses before surgery (1.6 vs. 1.3; $P = 0.005$).

Quality of Vision and Pupil Size before and after LASIK

Analysis of the quality-of-vision indices was conducted using a one-way ANOVA (Kruskal-Wallis ANOVA by ranks) and contrasts (Mann-Whitney U test) that compared those with the largest pupils with the other two smaller pupil-size groups combined. Figure 3 shows the relationship between the night index scores and pupil size for glare, haze, and halo reports over time, with complete response from 63 subjects.

Patients with large pupils had significantly more glare, haze, and halo reports at 1 month relative to those with smaller pupils in the treated eye (2.9 large pupil vs. 1.9 medium and 2.0 small pupil, $P = 0.02$; 2.7 vs. 1.7 and 1.5, $P = 0.03$; 2.7 vs. 1.7 and 1.7, $P = 0.02$, respectively). Reports declined at 3 months, with only the

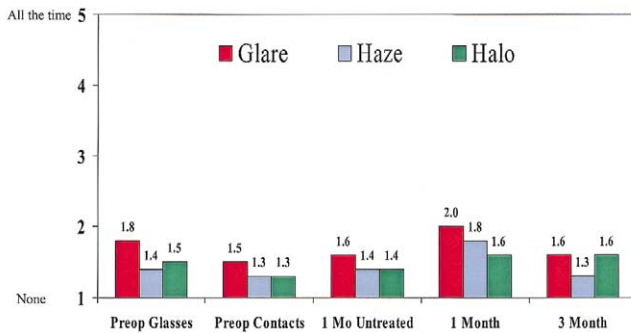
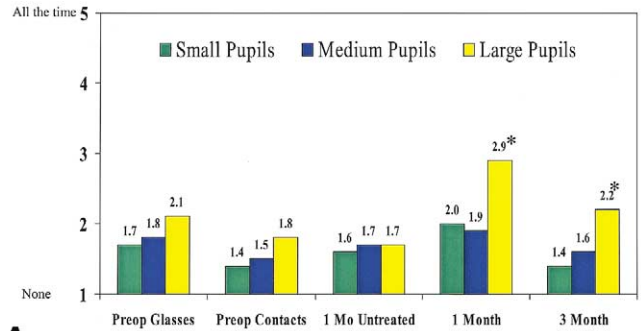
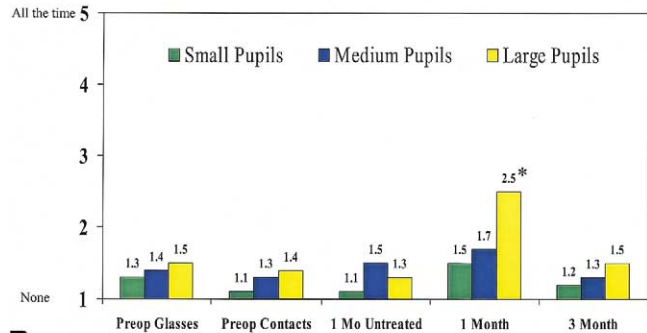


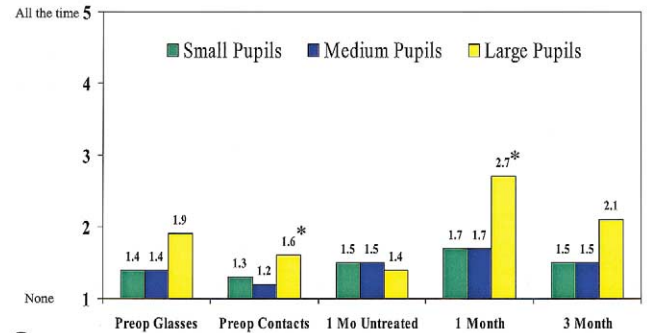
Figure 2. Average quality-of-vision index scores before and after LASIK. Subjects had to answer at least four of seven night questions for every condition during every period through 3 months after surgery for their data to be included (complete dataset, n = 63). Scores for glare, haze, and halos in the treated eye at 1 month after surgery were slightly, but significantly, higher than those for wearing contact lenses at baseline. In addition, haze and halo scores were higher in the 1-month postoperative treated eye compared with those for wearing glasses before surgery. Glare, haze, and halo scores were also higher in the 1-month treated eye compared with the untreated eye. At 3 months after surgery glare and haze scores were indistinguishable from baseline scores with either glasses or contact lenses. The index for halos remained elevated at 3 months compared with wearing contacts lenses before surgery.



A



B



C

Figure 3. Quality-of-vision night index scores for different pupil size categories before and after LASIK. Subjects had to answer at least four of seven night questions for every condition during every period through 3 months after surgery to be included (complete dataset, n = 63). A, Glare at night by pupil size. Patients with large pupils 1 month after surgery had significantly more glare reports than did those with smaller pupils (2.9 glare index for large pupil vs. 1.9 for medium and 2.0 for small pupil; $P = 0.02$, one-way analysis of variance, Kruskal-Wallis statistic). A significant increase was also observed at 3 months, with large pupils having a higher level of problem report ($P = 0.050$). B, Haze at night by pupil size. Patients with large pupils had significantly more haze reports than did smaller pupil size groups in the treated eye at 1 month (2.7 > 1.7 and 1.5; $P = 0.03$, Mann-Whitney U test). No other tests were significant. C, Halos at night by pupil size. Patients with large pupils had significantly more halo reports than did patients with smaller pupils in the treated eye before surgery when wearing contact lenses (1.6 > 1.2 and 1.3; $P = 0.03$ Mann-Whitney U test) and at 1 month (2.7 > 1.7 and 1.7; $P = 0.02$ Mann-Whitney U test). No other tests were significant.

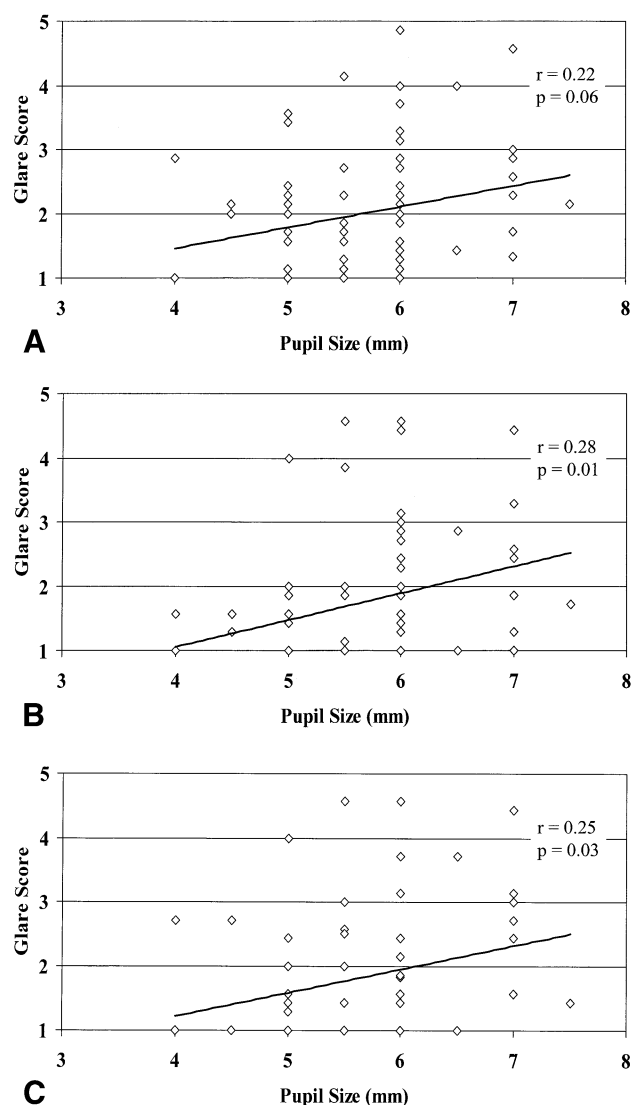


Figure 4. Scatterplot of the night index responses versus pupil size in the treated eye at 1 month after surgery ($n = 74$). The responses of all patients who completed a questionnaire are included. Note the variability of responses among different pupil sizes. **A**, Scatterplot of the glare versus pupil size. The correlation is not significant (Pearson product moment correlation, $r = 0.22$, $P = 0.06$). **B**, Scatterplot of the haze versus pupil size. The correlation is significant ($r = 0.28$, $P = 0.01$). **C**, Scatterplot of the halo versus pupil size. The correlation is significant ($r = 0.25$, $P = 0.03$).

glare index remaining significantly elevated for subjects with larger pupils (2.2 vs. 1.6 and 1.4; $P = 0.046$). Patients with large pupils also tended to have more haze and halo reports, but differences were not statistically significant.

Although significant Pearson product moment correlations exist between pupil size and glare, haze, and halo symptoms after LASIK, there is substantial variability in individual responses. Figure 4 includes scatterplots of pupil size versus the night glare, haze, and halo indices 1 month after surgery in the treated eye. The correlations are significant for glare, haze, and halo reports ($n = 74$; for glare vs. pupil size, $r = 0.22$, $P = 0.06$; for haze vs. pupil size, $r = 0.28$, $P = 0.01$; for halo vs. pupil size, $r = 0.25$, $P = 0.03$); the scatterplots also demonstrate the variability in responses.

Some patients with small pupils have these problems all the time, whereas some patients with large pupils have no problems. This variability in responses is seen for all categories, time periods, and conditions.

To evaluate the relationship between the quality of vision and pupil size at 6 months after surgery, a separate analysis was conducted with a matched set consisting of just the preoperative and 6-month postoperative dataset ($n = 66$; small pupil subjects, $n = 18$; medium pupil subjects, $n = 39$; and large pupil subjects, $n = 8$). The frequency of symptom reports for large pupil subjects was used as an observed distribution and was compared with the expected distribution of such reports by those with smaller pupils. No significant increase in glare, halo, or haze scores among larger pupil-sized subjects was found (Kruskal-Wallis ANOVA, $H < 5$, $P > 0.05$).

Regression Analysis

Night glare, haze, or halo reports at 1, 3, and 6 months after LASIK were predicted using demographic, treatment, and postoperative outcome variables in a forward stepwise regression ($\alpha = 0.05$). Significant predictors were found for glare, haze, and halo reports 1 and 3 months after treatment and for glare and haze reports 6 months after surgery. Uncorrected acuity and mesopic pupil diameter were the independent variables that most consistently demonstrated influence on the level of postoperative symptom reports, as shown in Table 6. Many demographic (age, gender, ethnicity), treatment (cylinder and minor axis of ablation), and outcome characteristics (postoperative contrast sensitivity at 1 and 3 months after LASIK) were not found to influence glare, haze, or halo reports. The level of treatment (MSE) for the eye that had the worse postoperative UCVA was the strongest predictor of postoperative problem reports for night glare 6 months after treatment, accounting for 13% for glare and 8.0% for haze report variability (adjusted partial r^2). Other significant independent predictors at 6 months after surgery were preoperative contrast sensitivity for glare report (6.5% of variability; the worse the preoperative contrast sensitivity, the higher the level of postoperative problem report), UCVA (in the worse UCVA eye at 6 months, 21.0% of variability), and residual cylinder (in the worse UCVA eye at 6 months, 7.8% of variability) for haze reports.

Besides demographic, treatment, and outcome variables, the preoperative level of such reports while using glasses or contact lenses was introduced as another variable. It was assumed that this index would either characterize subjects' propensity to report such problems or indicate their quality of vision problems with glasses or contacts. In only one case was the preoperative report indicative of the postoperative report: the night halo report 1 month after surgery was partially predicted by the preoperative halo report using contact lenses (7.6% of variability explained; Table 6).

Pupil diameter was a persistent but weak predictor of early reports, 1 and 3 months after surgery, accounting for between 3.5% and 8.7% of the variability (Table 6). No correlation between pupil size and such reports was found 6 months after treatment.

Discussion

Optical models, such as point spread function calculations, have been used to predict the quality of vision after refractive surgery. These models suggest that pupil size should be an important determinant in selecting an appropriate ablation zone size for treatment.^{13,17,18} However, visual perception is complicated and optical models cannot account fully for adaptive mechanisms. Some of these adaptive properties

Table 6. Regression Analysis

Postoperative examination	Symptom Report Index	n	R ²	Partial r ² *					
				Pupil Diameter	Preoperative Variables			Postoperative Variables	
					Manifest Spherical Equivalent	Contrast Sensitivity	Contact Lens Index [†]	UCVA [‡]	Cylinder [‡]
1 mo	Glare	73	11.8%	5.0%	—	—	—	6.8%	—
	Haze	72	13.4%	7.9%	—	—	—	5.5%	—
	Halo	74	18.1%	3.5%	—	7.0%	7.6%	—	—
3 mos	Glare	78	42.4%	8.7%	—	8.7%	—	25%	—
	Haze	78	5.5%	—	—	—	—	5.5%	—
	Halo	78	34.9%	4.2%	—	9.5%	—	17%	4.2%
6 mos	Glare	66	19.5%	—	13%	6.5%	—	—	—
	Haze	62	36.8%	—	8.0%	—	—	21%	7.8%
	Halo	66	0	—	—	—	—	—	—

UCVA = uncorrected visual acuity.

*Contribution of each variable on the overall regression.

[†]Preoperative quality-of-vision index using contact lenses.

[‡]In eye with worse uncorrected acuity.

Regression coefficients of determination (R²) and partial r² values (percentage format) for significant variables from forward stepwise regression of demographic, treatment, and postoperative outcome measures to predict postoperative glare, haze, or halo reports. All displayed regressions are significant (P<0.05, analysis of variance). Higher levels of each variable listed increased reports (i.e., larger pupils, higher levels of preoperative myopia, higher levels of symptom reports before surgery when using contact lenses, worse preoperative contrast sensitivity, worse postoperative uncorrected visual acuity).

have been defined, such as the Stiles-Crawford effect, whereas others are less well understood and deal with higher-order image processing. Currently, the best way to understand the quality of vision after refractive surgery is to ask the patient.

A combination of questions, each assessing a somewhat different aspect of the concept being measured, generally provides a much more stable, valid, parsimonious, and reliable measure than does any single question. In the case of the 21 questions in sets of seven developed to assess glare, haze, and halos, both factor analysis and assessment of internal homogeneity and reliability using Cronbach's α indicated that the seven questions within each set could be combined to form a single index about experiences at night. To minimize loss of cases from the sample while maximizing the advantages associated with combining multiple questions into a single measure, patients had to answer at least four of the seven questions about vision at night to form an index of night vision problems. Only 26 of the 1466 indices formed (<2%) were calculated with fewer than all seven questions answered.

This data set is unique in two ways. First, patients were asked about their experiences at baseline with glare, haze, and halos both when wearing glasses and when wearing contact lenses. Second, 1 month after LASIK, patients were asked identical questions about their vision in the first, treated eye, and in the second, untreated eye. This identified problems that occur with glasses and contact lenses in patients who desire refractive surgery. It also provided a comparison between preoperative and postoperative results, something that is not possible with retrospective questionnaires. In addition, a "control" eye at 1 month enabled a unique and direct comparison between the treated and untreated eye.

Previous reports have noted an increase in quality-of-vision problem reports after LASIK, whereas others have

not.^{2,3} In our study, LASIK increased reports of glare, haze, and halos at night during the first month after treatment when compared with experiences with either glasses or contact lenses before LASIK. The level of such reports also was higher in the treated compared with the untreated eye at 1 month. The level of such reports reduced by 3 months after treatment and was indistinguishable from preoperative levels by 6 months. This recovery could be the result of several factors. Higher-order aberrations have been observed to increase after both PRK and LASIK and may be responsible for symptoms.^{17,19-21} Healing or remodeling of the corneal surface months after LASIK may result in a reduction of the previously induced aberrations. Patients also can adapt to visual symptoms in the postoperative period, resulting in a perceived reduction of problem reports. Because there was a delay between treatment of the first and second eye at the 1-month examination, patients had an untreated eye to compare with the visual results of the treated eye. This may have limited their ability to adapt and may have contributed to their reports of such problems, which were at the highest levels 1 month after surgery. This also may explain the elevated reports of haze in the untreated eye at 1 month. By the 3-month exam, both eyes were treated, and adaptive mechanisms to visual symptoms could come into play.

We used a coherent dataset to study many of the effects of LASIK on the time course of quality of vision. The 6-month results were not always included because fewer patients completed the questionnaire. Although this increased the power of analysis through the 3-month postoperative examination, it did limit our ability to analyze longer-term quality-of-vision problems. In this matched dataset, 3-month halo scores were greater than baseline contact lenses, and glare scores in patients with large pupils were greater than those with smaller pupils. A separate analysis was conducted with a matched dataset of preoperative and

6-month data. No significant increase in average glare, halo, or haze scores or increased problems by pupil size were found. This further indicates that quality of symptoms generally improve with time.

Pupil size is a significant predictor of glare, haze, and halo reports after LASIK, especially in the first postoperative month. This was not altogether unexpected. The ablation zone size was 6.0 mm and the minor axis was even smaller when correcting astigmatism. A pupil that dilates larger than the ablation zone could be expected to produce greater visual symptoms, especially halos. In addition, optical aberrations generally increase with increasing pupil size.¹⁷ Aberrations can misdirect light into the eye and can result in symptoms such as glare and haze.²²⁻²⁴ As was the case for average index responses after LASIK, the role of the pupil in predicting quality-of-vision problems diminishes over time. Glare and halo reports at 3 months were only weakly predicted by pupil size, and pupil size was not found to be a significant variable 6 months after treatment (Table 6).

Some patients with pupils larger than the treatment zone had few symptoms and some patients with small pupils had significant symptoms. The variability in responses demonstrated in the plot of 1-month night problem reports as a function of pupil size (Fig 4) means that pupil size only partially explains the differences in reports about quality of vision after LASIK. Our regression analyses demonstrated that several other independent variables also predict quality of vision after surgery, in particular, the level of treatment (MSE), the residual amount of cylinder, and postoperative UCVA. These findings are similar to observations about such quality-of-vision reports after PRK. Haw and Manche²⁵ studied the effect of pupil size on glare, halos, and visual function after PRK in 94 subjects. They found that an increase in postoperative glare symptoms was related to the preoperative MSE. Pupil size was not predictive of long-term glare symptoms.

We found that less than half of the variability in postoperative symptom reports could be explained by variables included in our analyses. Other factors, including adaption, must play a role in explaining such postoperative reports about quality of vision.

What is also interesting are the variables that did not correlate with symptoms, in particular, contrast sensitivity measured during recovery. Patients with poor postoperative contrast sensitivity did not tend to have more quality-of-vision problem reports and patients with better contrast did not have fewer such reports. This lack of correlation erodes the usefulness of contrast testing. However, the chart used in this study (Small Letter Contrast Test) measures contrast threshold at only one frequency and may be insensitive to detecting changes in contrast that produce symptoms.²⁶ In addition, this test was conducted under photopic conditions and without a glare source. Mesopic contrast testing with or without a glare source may be more sensitive to detecting changes that produce symptoms.⁷

A curious but consistent finding in the regression analysis was that patients with reduced preoperative contrast sensitivity had more quality-of-vision problems after surgery. It is not clear why this was the case. Conventional

wisdom would suggest that patients with better contrast sensitivity before surgery would be more likely to note a change after surgery and, hence, voice a higher level of dissatisfaction. Perhaps the surgical expectations of patients with reduced preoperative contrast were higher than those with better contrast sensitivity.

The results of the regression analyses reveal several important aspects of managing patients with quality-of-vision symptoms. Symptoms tend to improve with time. Patience is sometimes the best medicine. Ophthalmologists should not rush into performing additional surgery to correct quality-of-vision problems in an eye with an otherwise satisfactory clinical outcome. Sometimes the best strategy is to wait for healing and adaption to occur, that is, for recovery to be complete. This assumes there are no other sources of symptoms, such as flap striae (none in this study). Uncorrected vision after the surgery consistently was identified as an independent variable in predicting visual symptoms. In addition, postoperative astigmatism was correlated to symptoms in several indices. Both of these terms can be treated successfully with glasses, contact lenses, or additional refractive procedures.

Should patients with pupils larger than the intended optical zone and low to moderate myopia be excluded from surgery? Given important caveats, there is no compelling evidence in this study for such an exclusion. No long-term relationship between pupil size and glare or halo reports was found in our multivariate regression analysis. The relationship at earlier intervals, although significant, was weak and could only explain a small percentage of the overall variability in responses. Even with the 6.0-mm ablation zone treatment used in this study, symptoms decreased with time. However, this study evaluated only mild to moderate myopia with or without low levels of astigmatism. Treatment of higher levels of ametropia may result in more severe symptoms in those patients with large pupils. The lack of a significant relationship between pupil size and quality-of-vision symptoms in the regression analysis at 6 months simply may indicate that a larger sample size is needed. There were only 15 patients with a pupil size greater than 6.0 mm. In addition, when patients had an untreated eye for comparison (1 month after surgery), the increase in quality-of-vision problem reports in patients with large pupils became apparent. At the very least, adequate counseling for quality-of-vision risks should be provided to patients with large pupils that will be treated with a 6.0-mm optical zone.

Should a treatment optical zone diameter be adjusted to be larger than the low-light pupil diameter? The trend in laser ablation profiles has been larger optical zone diameters incorporating even larger transition zones. This study used a 6.0-mm ablation zone without a transition zone, and the minor axis of elliptical ablations to correct myopia with astigmatism was even smaller, as small as 4.5 mm. It is likely that larger ablation zones that are now currently available would reduce further the incidence of quality-of-vision problems in the early postoperative period associated with patients with large pupils. This needs to be balanced by the increased ablation depth for larger diameter treatments.

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