



# Patient-reported outcomes 5 years after laser in situ keratomileusis

Steven C. Schallhorn, MD, Jan A. Venter, MD, David Teenan, MD, Stephen J. Hannan, OD, Keith A. Hettinger, MS, Martina Pelouskova, MSc, Julie M. Schallhorn, MD

**PURPOSE:** To assess vision-related, quality-of-life outcomes 5 years after laser in situ keratomileusis (LASIK) and determine factors predictive of patient satisfaction.

**SETTING:** Optical Express, Glasgow, Scotland.

**DESIGN:** Retrospective case series.

**METHODS:** Data from patients who had attended a clinical examination 5 years after LASIK were analyzed. All treatments were performed using the Visx Star S4 IR excimer laser. Patient-reported satisfaction, the effect of eyesight on various activities, visual phenomena, and ocular discomfort were evaluated 5 years postoperatively. Multivariate regression analysis was performed to determine factors affecting patient satisfaction.

**RESULTS:** The study comprised 2530 patients (4937 eyes) who had LASIK. The mean age at the time of surgery was 42.4 years  $\pm$  12.5 (SD), and the preoperative manifest spherical equivalent ranged from  $-11.0$  diopters (D) to  $+4.88$  D. Five years postoperatively, 79.3% of eyes were within  $\pm 0.50$  D of emmetropia and 77.7% of eyes achieved monocular uncorrected distance visual acuity (UDVA) and 90.6% of eyes achieved binocular UDVA of 20/20 or better. Of the patients, 91.0% said they were satisfied with their vision and 94.9% did not wear distance correction. Less than 2.0% of patients noticed visual phenomena, even with spectacle correction. Major predictors of patient satisfaction 5 years postoperatively were postoperative binocular UDVA (37.6% variance explained by regression model), visual phenomena (relative contribution of 15.0%), preoperative and postoperative sphere and their interactions (11.6%), and eyesight-related difficulties with various activities such as night driving, outdoor activities, and reading (10.2%).

**CONCLUSION:** Patient-reported quality-of-life and satisfaction rates remained high 5 years after LASIK. Uncorrected vision was the strongest predictor of satisfaction.

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Laser in situ keratomileusis (LASIK) is one of the most commonly performed refractive procedures in the world, and high postoperative satisfaction rates have been documented in numerous studies.<sup>1</sup> Despite the popularity of this surgical technique, relatively few studies of the long-term efficacy and safety of LASIK have been published,<sup>2–7</sup> and most did not report vision-related quality-of-vision and quality-of-life outcomes.

Long-term satisfaction after excimer laser surgery could be different than short-term outcomes for

many reasons. The number of patients attaining emmetropia or 20/20 unaided visual acuity can decrease over time.<sup>2–7</sup> Some regression after excimer ablation is expected because of corneal remodeling and biomechanical changes<sup>8,9</sup>; however, other factors, such as normal age-related physiological changes,<sup>10–12</sup> growth of axial length,<sup>13</sup> or nuclear sclerosis,<sup>9</sup> also affect long-term change in human refractive error.

On the other hand, some symptomatic problems that are related to patient dissatisfaction after LASIK, such as visual phenomena<sup>14,15</sup> or symptoms of ocular

discomfort,<sup>16,17</sup> typically improve with neuroadaptation and corneal healing and positively affect patient satisfaction. However, because of the lack of long-term, large population studies, it is unknown how many patients still experience unwanted side effects years after excimer laser surgery.

This study assessed patient satisfaction and quality-of-life outcomes 5 years after LASIK. To our knowledge, this is the first study evaluating the detailed symptomatic and functional outcomes after excimer laser surgery in a large cohort of patients.

## PATIENTS AND METHODS

This study comprised consecutive patients who had LASIK between October 1, 2007, and September 30, 2008. Patients were recommended to have yearly examinations. Only patients who attended a 5-year postoperative examination and completed a patient-reported outcome questionnaire were evaluated. This study was deemed exempt from full review by the Committee on Human Research, University of California–San Francisco, because it used retrospective deidentified patient data only. All patients provided informed consent to have LASIK.

### Surgical Technique

All patients met the indications for LASIK at the time of surgery. All treatments were performed using the Visx Star S4 IR excimer laser system (Abbott Medical Optics, Inc.) with a conventional or wavefront-guided ablation profile (Advanced Customvue, Abbott Medical Optics, Inc.). Patient choice and preoperative refraction determined the ablation profile. Conventional treatment was only offered for a preoperative sphere between  $-8.0$  diopters (D) and  $+3.0$  D and a cylinder less than  $3.0$  D. For conventional myopic treatments, the optical zone diameter was  $6.5$  mm; for conventional myopic astigmatism, the major axis of the elliptical optical zone was  $6.5$  mm with a minor axis as small as  $5.0$  mm depending on the amount of myopia and astigmatism. The transition zone was  $8.0$  mm unless myopia was less than  $1.0$  D. For wavefront-guided myopia, the optical zone was  $6.0$  mm, and it was also the minor axis of an elliptical ablation. The major axis could be as large as  $7.0$  mm, depending on the patient's refraction. Hyperopic treatments (both conventional and wavefront-guided) used a  $6.0$  mm optical zone and a  $9.0$  mm transition zone. Corneal flaps

were created using a femtosecond laser (Intralase iFS or FS-60, Abbott Medical Optics, Inc.) or a mechanical microkeratome (Moria Evo3 One Use-Plus, Moria SA). Surgeries were performed by 19 surgeons in 33 surgical centers.

### Five-Year Assessment

The 5-year postoperative ophthalmic examination included manifest refraction, monocular uncorrected distance visual acuity (UDVA) and binocular UDVA, corrected distance visual acuity (CDVA) using a calibrated projected eye chart, slitlamp biomicroscopy, and applanation tonometry. In addition, patients were asked to complete a patient-reported outcome questionnaire, which was self-administered and used a password-protected and secure computer terminal in an isolated area of the clinic. The questionnaire was derived from the Joint LASIK Study Task Force<sup>1,18–20</sup> (Figure 1) and assessed patient-reported satisfaction, the effect of their vision on various activities, ocular discomfort, and visual phenomena. All response fields used a Likert scale to obtain the patient's preferences or degree of agreement.

### Enhancements

Indications for enhancement were residual refractive error with the patient noting suboptimum uncorrected vision, a minimum of 1 line improvement between UDVA and CDVA, a stable manifest refraction (determined as no more than a  $0.50$  D change in sphere or cylinder documented over a minimum of 3 months), and otherwise met the criteria for excimer laser treatment.

### Statistical Analysis

Data tabulation and statistical operations were performed with SAS software (version 9.3, SAS Institute, Inc.) and Office Excel software (version 7.0, Microsoft Corp.). Correlation coefficients were calculated to find associations between questionnaire responses and clinical parameters. An unpaired *t* test was used to compare independent groups of patients, and the chi-square test was used to compare percentages. A multivariate regression model was developed in an effort to predict patient-reported satisfaction 5 years postoperatively (Q1 from Figure 1). Descriptive statistics as well as the correlation between variables and analysis of variance were calculated. The covariance between explanatory variables and interaction terms for the model was also examined. A stepwise generalized linear approach to the model creation was used. The patients' demographics, clinical parameters, and other questionnaire responses were considered independent variables in the regression model.

## RESULTS

This study evaluated 2530 (4937 eyes) from the group of 30 905 consecutive patients who had LASIK between October 1, 2007, and September 30, 2008. The study group comprised 1389 men (54.9%) and 1141 women (45.1%). There were 1905 (75.3%) patients with myopia and 625 patients (24.7%) with hyperopia.

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From the Departments of Ophthalmology, University of California (S.C. Schallhorn), San Francisco, and University of Southern California (S.C. Schallhorn, J.M. Schallhorn), Los Angeles, California, USA; Optical Express (S.C. Schallhorn, Venter, Teenan, Hannan, Hettinger, Pelouskova), Glasgow, Scotland.

Corresponding author: Steven C. Schallhorn, MD, 11730 Caminito Prenticia, San Diego, California 92131, USA. E-mail: [scschallhorn@yahoo.com](mailto:scschallhorn@yahoo.com).

<b>Q1. Thinking about your vision during the last week, how satisfied are you with your vision? (without the use of glasses or contact lenses)</b>					
Very Satisfied	Satisfied	Neither	Dissatisfied	Very Dissatisfied	
<b>Q2. Has your overall vision turned out to be:</b>					
Much better than expected	Better than expected	About what expected	Worse than expected	Much worse than expected	
<b>Q3. Thinking about your vision during the last week, if you had to do it over, would you have your procedure again?</b>					
Yes		No			
<b>Q4. Would you recommend this procedure to your friends and relatives?</b>					
Yes		No			
<b>Q5. Has surgery improved your quality of life?</b>					
Yes		No			
<b>Q6. Please check ALL that apply. During a typical day...</b>					
I wear GLASSES to correct my DISTANCE vision	I wear GLASSES to correct my NEAR vision (for example, to read)	I wear CONTACT LENSES to correct my DISTANCE vision	I wear CONTACT LENSES to correct my NEAR vision (for example, to read)	I do NOT wear any corrective lenses	
<b>Impact of eyesight on various activities</b>					
<b>Q7. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer?</b>					
<b>Q8. How much difficulty do you have reading ordinary print in newspapers?</b>					
<b>Q9. How much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms?</b>					
<b>Q10. How much difficulty do you have driving at night?</b>					
<b>Q11. Because of your eyesight, how much difficulty do you have with your daily activities?</b>					
<b>Q12. Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like hiking, swimming, aerobics, team sports, or jogging)?</b>					
<b>Answers (Q7 to Q12):</b>					
No difficulty at all	A little difficulty	Moderate difficulty	A lot of difficulty	Never try to do this because of my vision	Never do this for other reasons
<b>Ocular Discomfort</b>					
<b>Q13. How often do you experience eyes that are sensitive to light?</b>					
<b>Q14. How often do you experience eyes that feel gritty?</b>					
<b>Q15. How often do you experience painful or sore eyes?</b>					
<b>Q16. How often do you experience dry eyes?</b>					
<b>Answers (Q13-Q16):</b>					
None of the time	Some of the time	Half of the time	Most of the time	All of the time	
<b>Q17. How many times a day do you use artificial tears?</b>					
None	One time daily	Two times daily	Three times daily	Four times or more daily	
<b>Visual Phenomena:</b>					
<b>Q18. In the past 4 weeks, have you noticed any glare?</b>					
<b>Q19. In the past 4 weeks, have you noticed any haloes and/or starbursts</b>					
<b>Q20. In the past 4 weeks, have you noticed any double images or ghost images?</b>					
<b>Answers (Q18 to Q20):</b>					
Yes, without glasses or contact lenses	Yes, even with glasses or contact lenses		No, not at all		
<b>If answer to Q17-Q19 was "yes":</b>					
<b>Q21. In the past 4 weeks, how bothersome has the glare been?</b>					
<b>Q22. In the past 4 weeks, how bothersome have the haloes and/or starbursts been?</b>					
<b>Q23. In the past 4 weeks, how bothersome have the double images or ghost images been?</b>					
<b>Answers (Q21 to Q23):</b>					
Not at all bothersome	A little bothersome	Somewhat bothersome	Very bothersome	Extremely bothersome	

Figure 1. Patient satisfaction questionnaire.

**Clinical Outcomes**

Table 1 shows the clinical parameters of the patients included in this study. Monovision was performed in 172 patients (6.8%). Of all eyes targeted for emmetropia, 3779 (79.3%) were within ±0.50 D and 4493 (94.3%) were within ±1.00 D; 3702 eyes (77.7%) achieved monocular UDVA and 2136 patients (90.6%) achieved binocular UDVA of 20/20 or better. Of the eyes, 412 (8.3%) had an enhancement within the first 5 postoperative years. These included 104 eyes (2.1%) that had a previous flap lifted and 308 eyes (6.2%) that had surface ablation performed on top of the flap.

Eyes (3969 [80.4%]) that had wavefront-guided ablation had a higher preoperative sphere than eyes (968 [19.6%]) in which conventional ablation profile was used. The mean preoperative myopic sphere was  $-3.00 \pm 1.87$  D and  $-2.38 \pm 1.46$  D in the wavefront-guided group and in the conventional ablation profile group, respectively ( $P < .01$ ). The same applied for preoperative hyperopic sphere, for which the mean difference was  $+2.22 \pm 1.10$  D in the wavefront-guided group and  $+1.92 \pm 0.71$  D in the conventional ablation profile group ( $P < .01$ ). There was also a statistically significant difference in the

**Table 1.** Clinical parameters in the study group.

Clinical Parameter	Mean $\pm$ SD	Median	Range
Age at surgery (y)	42.4 $\pm$ 12.5	42	18, 70
Age at postop visit (y)	47.1 $\pm$ 12.5	47	23, 75
Preoperative data			
Sphere (D)	-1.64 $\pm$ 2.74	-1.75	-10.50, +5.00
Myopic sphere (D)	-2.89 $\pm$ 1.82	-2.50	-10.50, -0.25
Hyperopic sphere (D)	+2.14 $\pm$ 1.03	+2.00	0.00, +5.00
Cylinder (D)	-0.75 $\pm$ 0.75	-0.50	-5.75, 0.00
MSE (D)	-2.01 $\pm$ 2.76	-2.13	-11.00, +4.88
MSE of eyes with myopic sphere (D)	-3.26 $\pm$ 1.85	-2.75	-11.00, -0.25
MSE of eyes with hyperopic sphere (D)	+1.77 $\pm$ 1.16	+1.75	-2.88, +4.88
CDVA (logMAR)	-0.08 $\pm$ 0.07	-0.10	-0.20, 0.44
Postoperative data			
Sphere (D)	0.10 $\pm$ 0.58	0.00	-4.50, +2.75
Cylinder (D)	-0.32 $\pm$ 0.34	-0.25	-5.00, 0.00
MSE (D)	-0.06 $\pm$ 0.56	0.00	-5.00, +2.38
Monocular UDVA (logMAR)	-0.01 $\pm$ 0.15	-0.08	-0.20, 1.30
Binocular UDVA (logMAR)	-0.08 $\pm$ 0.10	-0.10	-0.20, 0.72
CDVA (logMAR)	-0.09 $\pm$ 0.07	-0.10	-0.2, 1.00

CDVA = corrected distance visual acuity; MSE = manifest spherical equivalent; UDVA = uncorrected distance visual acuity

mean preoperative cylinder ( $-0.79 \pm 0.80$  D in wavefront-guided group and  $-0.60 \pm 0.51$  D in conventional group).

### Patient-Reported Satisfaction and Spectacle Independence

Satisfaction with visual outcomes (Figure 1, Q1) was as follows: 1617 (63.9%) were very satisfied, 686 (27.1%) were satisfied, 100 (4.0%) were neither satisfied nor dissatisfied, 94 (3.7%) were dissatisfied, and 33 (1.3%) were very dissatisfied. In addition, 634 patients (25.1%) indicated that their postoperative vision is what they expected and 1729 patients (68.3%) reported their vision was better or much better than expected (Q2). When asked whether they would have the surgery again if necessary, 2396 patients (94.7%) responded affirmatively (Q3), 2442 patients (96.5%) would recommend the procedure to their family or friends (Q4), and 2410 patients (95.3%) thought the surgery improved the quality of their life (Q5).

The proportion of patients not requiring correction for distance vision was 94.9% (2401 patients). Of all 836 patients (33.0%) who wore spectacles or contact lenses to correct near vision, 813 (97.2%) were in the presbyopic age postoperatively ( $\geq 45$  years). Of all patients who did not wear distance vision correction, 207 (8.6%) had a binocular UDVA 20/25 or worse and 259 (10.8%) had a residual refractive error of  $\pm 0.50$  D in each eye.

### Effect of Eyesight on Quality of Life

Figure 2 shows the eyesight-related degree of difficulty patients experienced with various activities (Q7 to Q12). The questions related with near vision (Q7 to Q9) were significantly correlated with the patient's age (Q7 versus postoperative age:  $r = 0.37$ ,  $P < .01$ ; Q8 versus postoperative age:  $r = 0.43$ ,  $P < 0.01$ ; Q9 versus postoperative age:  $r = 0.51$ ,  $P < .01$ ).

Of all clinical parameters, the strongest correlation for Q10 to Q12 (night driving, daily activities, and outdoor activities) was with postoperative binocular UDVA (Q10 versus binocular UDVA:  $r = 0.22$ ,  $P < .01$ ; Q11 versus binocular UDVA:  $r = 0.23$ ,  $P < .01$ ; Q12 versus binocular UDVA:  $r = 0.18$ ,  $P < .01$ ). As an indication of this relationship, if the postoperative UDVA was 20/20 or better in each eye, only 8 patients (0.5%) had a lot of difficulty with night driving and 2 patients (0.1%) had a lot of difficulty with daily activities or active sports and outdoor activities.

### Ocular Comfort

Figure 3 shows the frequency of ocular discomfort symptoms 5 years postoperatively (Q13 to Q16). In addition, the frequency of artificial-tear use at 5 years (Q17) was as follows: 2091 patients (82.6%) did not use any artificial tears, 237 (9.4%) used 1 drop daily of artificial tears, 107 (4.2%) used 2 drops daily, 45 (1.8%) used 3 drops daily, and 50 (2.0%) used 4 drops or more daily.



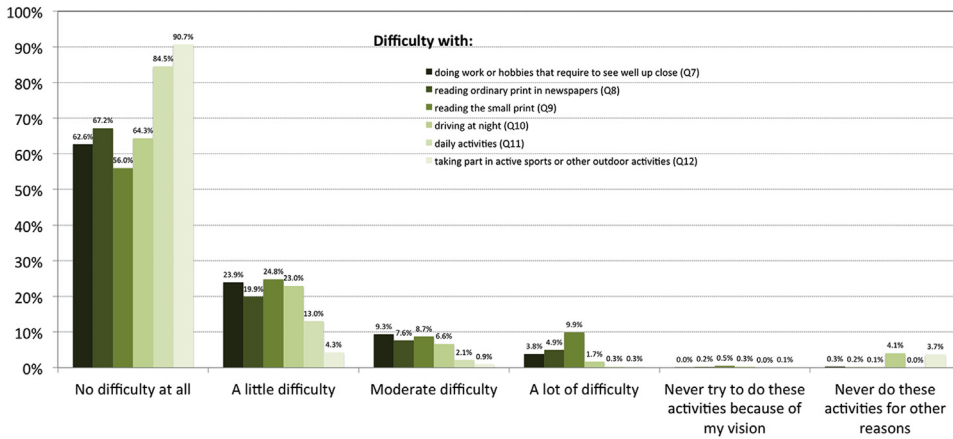


Figure 2. Effect of eyesight on various daily activities. (See Figure 1 for patient satisfaction questions Q7 through Q12.)

Symptoms of ocular discomfort were more prevalent in women than men and in patients who were treated for hyperopia rather than myopia preoperatively. For example, for frequency of dry eyes (Q16), the combined percentage of patients who experienced dry eyes at least half of the time was 9.5% (133 women) and 6.0% (68 men) ( $P < .01$ , chi-square test). The frequency of dry eyes in patients with myopia versus patients with hyperopia was 6.9% (129 patients) versus 11.4% (72 patients) ( $P < .01$ , chi-square test). Older age was only weakly correlated with the increase in frequency of dry-eye symptoms ( $r = 0.04$ ,  $P = .04$ ).

Visual Phenomena

Figure 4 shows the incidence of visual phenomena (Q18 to Q20). Five years postoperative, less than 2% of patients noticed some visual disturbances, even

with the use of spectacles or contact lenses. When asked how bothersome the visual phenomena was (Q21 to Q23, Figure 5), less than 1.0% of the 2530 patients reported that their visual phenomena was very bothersome or extremely bothersome.

The severity of visual phenomena (Q21 to Q23) showed the highest correlation with postoperative binocular UDVA (binocular UDVA versus: glare  $r = 0.12$ ,  $P < .01$ , halo or starburst  $r = 0.11$ ,  $P < .01$ , and ghosting or double vision  $r = 0.17$ ,  $P < .01$ ) and postoperative remaining refractive error (postoperative manifest spherical equivalent versus: glare  $r = 0.07$ ,  $P < .01$ , halo or starburst  $r = .10$ ,  $P < .01$ , and ghosting or double vision  $r = 0.13$ ,  $P < .01$ ). For example, only 0.8% of all patients (20) who achieved a postoperative binocular UDVA of 20/25 or better reported very bothersome or extremely bothersome glare, although only 1 patient (2.7%) had a postoperative binocular UDVA worse than 20/25.

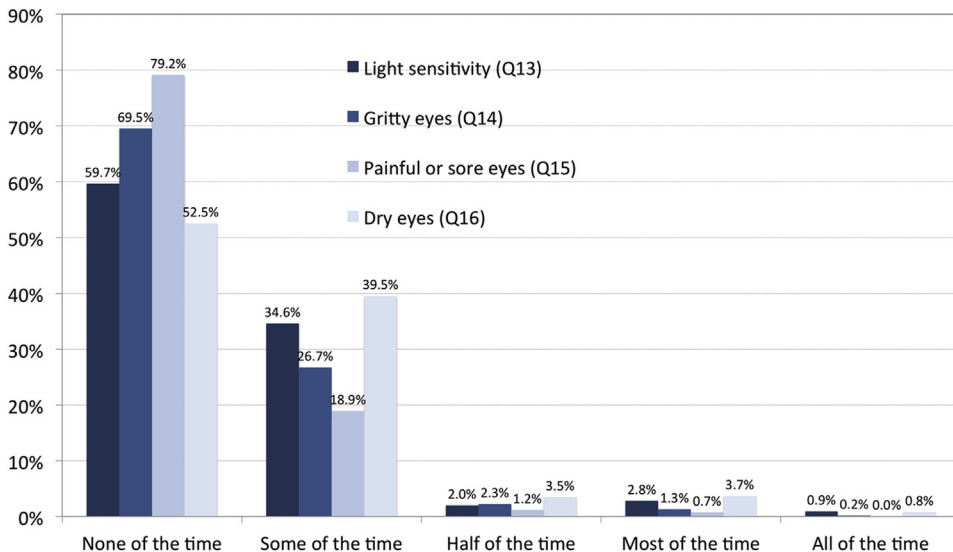
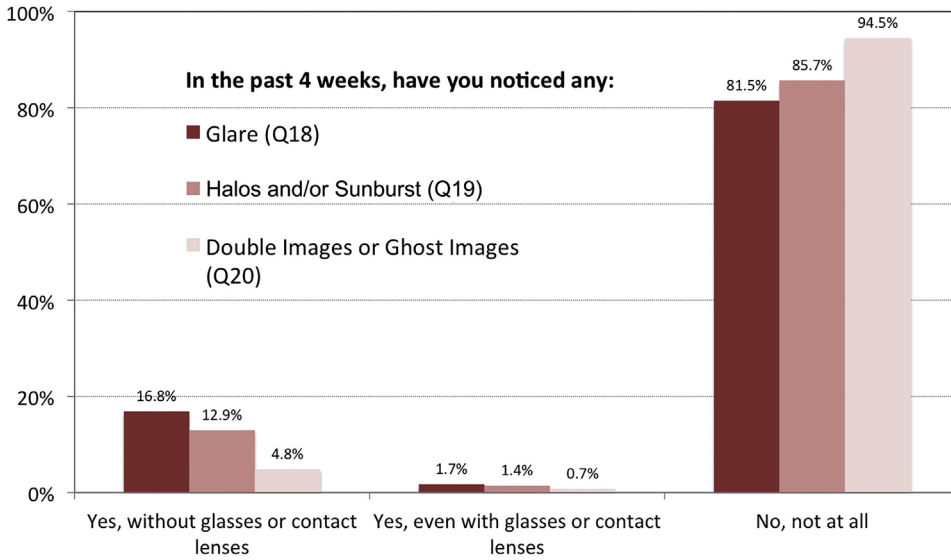


Figure 3. Frequency of symptoms of ocular discomfort. (See Figure 1 for patient satisfaction questions Q13 through Q16.)



**Figure 4.** Incidence of visual phenomena. (See Figure 1 for patient satisfaction questions Q18 through Q20.)

**Regression Analysis**

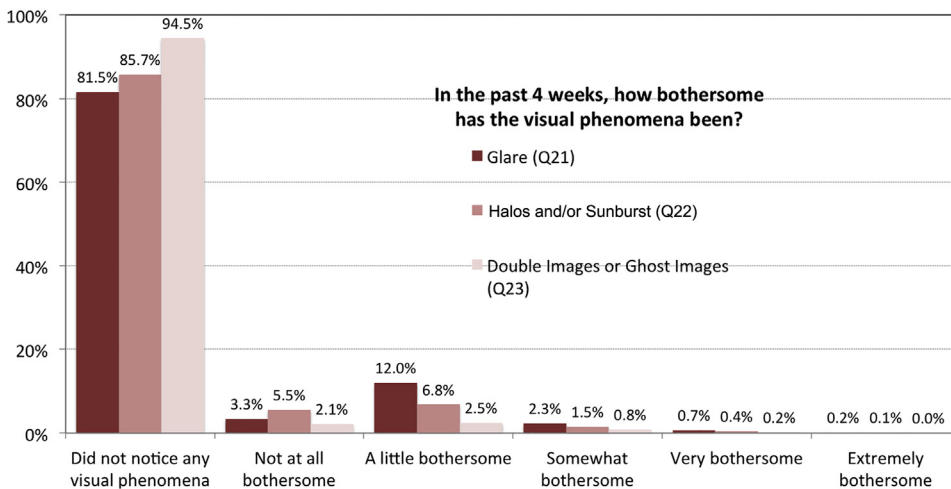
Table 2 shows the clinical parameters and questions from the patient satisfaction questionnaire that were considered for the regression model as well as the results of the univariate and multivariate statistics and the contribution of each variable to the final model predicting patient satisfaction. Overall, 58% of the variance in satisfaction could be explained by this model.

The most significant factor associated with patient satisfaction was postoperative UDVA. Monocular and binocular postoperative UDVA were significantly correlated ( $r = 0.71, P < .01$ ) and binocular UDVA was included in the final model, responsible for 37.6% of variance explained by this model. Of all patients who achieved a binocular UDVA of 20/20 or better, 2136 patients (93.4%) were satisfied with their vision, whereas only 167 patients (69.4%) were

satisfied when their postoperative UDVA was 20/25 or worse. The change between preoperative and postoperative binocular UDVA also had a small, but statistically significant, effect on patient satisfaction (2.7% variance explained by the model).

The effect of eyesight on quality of life (relative contribution to the model 10.2%) as well as the presence and severity of night-vision phenomena (relative contribution 15.0%) were also significant factors in predicting patient satisfaction. For example, 28.9% of patients (24) who found their glare somewhat bothersome, very bothersome, or extremely bothersome were dissatisfied, whereas only 3.7% of patients (77) were dissatisfied in the group that did not experience glare.

The contribution of the frequency of ocular comfort symptoms (light sensitivity, grittiness, sore eyes, or dry eyes) to the satisfaction model was 4.7%. Of all



**Figure 5.** Severity of visual phenomena. (See Figure 1 for patient satisfaction questions Q21 through Q23.)

**Table 2.** Results of multivariate regression analysis predicting 5-year patient satisfaction with vision ( $R^2 = 0.58$ ,  $P < .0001$ ).

Independent Variable	Univariate <i>P</i> Value	Multivariate <i>P</i> Value	Model Contribution (%)
Age at treatment	<.0001*	.0190*	1.2
Sex	>.05	—	—
Pupil diameter	>.05	—	—
Preoperative sphere	.0032*	>.05	—
Preoperative cylinder	>.05	—	—
Postoperative sphere	.0224*	.0089*	2.9
Postoperative cylinder	<.0001*	.0026*	3.8
Preoperative and postoperative sphere interactions	n/a	<.0001*	11.6
Preoperative keratometry	>.05	—	—
Postoperative keratometry	>.05	—	—
Ablation type (wavefront-guided/conventional)	>0.05	—	—
Flap creation type (femtosecond/microkeratome)	>.05	—	—
Postoperative binocular UDVA	<.0001*	<.0001*	37.6
Change in binocular UDVA	<.0001*	.0012*	2.7
Change in CDVA	<.0001*	>.05	—
Number of enhancements	<.0001*	<.0001*	4.2
Surgeon	.0116*	<.0001*	1.1
Surgical center	.0004*	.0032*	0.8
Postsurgery spectacle/contact lens use (Q6) <sup>†</sup>	<.0001*	.0239*	4.2
Impact of eyesight on various activities (Q7–Q12)	<.0001*	.0011*	10.2
Ocular comfort (Q13–Q16)	<.0001*	.0217*	4.7
Visual symptoms (Q18–Q23)	<.0001*	<.0001*	15.0

CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity

\*Statistically significant

<sup>†</sup>See Figure 1 for Q6 through Q23 questions from quality-of-life questionnaire.

patients who experienced dry eye most of the time or all of the time, 18.6% (21) were dissatisfied, whereas only 3.7% (47) who did not have any dry-eye symptoms were dissatisfied.

When evaluating the effect of refractive error on patient satisfaction, the interaction of the preoperative and postoperative sphere had the highest contribution to the model (11.6% variance explained), followed by the main effect contributions of the postoperative cylinder (3.8%) and postoperative sphere (2.9%). In other words, the measured effect of the preoperative sphere on satisfaction was largely variable with respect to the residual level of the postoperative sphere. For example, patients who had a high preoperative refractive error combined with a residual postoperative refractive error were more likely to be dissatisfied than those who had a high preoperative refractive error but were emmetropic postoperatively. Preoperative sphere and cylinder were not independent predictors of satisfaction in the regression model. Postoperative spectacle or contact lens use also had an effect on patient satisfaction, with 4.2% variance explained by the model.

The number of enhancements contributed 4.2% to the regression model. Of the patients who had at least 1 enhancement, 13.2% (38) were dissatisfied, whereas

only 4.5% (89) of patients who had the primary procedure were dissatisfied.

Other significant independent predictors of postoperative satisfaction were age at the time of treatment (1.2%), treating surgeon (1.1%), and surgical location (0.8%). Clinical parameters, such as sex, pupil size, preoperative and postoperative keratometry, ablation type, and flap creation type, were not significant predictors in the regression model.

### Bias Analysis

Preoperative data from the study group were compared with data from other patients who were treated during the same timeframe (October 1, 2007, and September 30, 2008) but did not return for the 5-year follow-up (55 352 eyes of 28 375 patients). Patients who did not return were slightly younger than those in the study group (39.1 years versus 42.4 years;  $P < .01$ ). Also, a slightly higher portion of eyes had preoperative hyperopia (1219 [24.7%]) in the study cohort than the proportion of patients who did not return for the 5-year follow-up (11 181 [20.2%];  $P < .01$ ).

There was no difference in the mean preoperative myopic and hyperopic spheres between the 2 groups.

The study group had a mean myopic preoperative sphere of  $-2.89 \pm 1.82$  D compared with  $-2.92 \pm 1.79$  D for all the other patients ( $P = .34$ ). In patients who were hyperopic preoperatively, the mean sphere was  $+2.14 \pm 1.03$  D in the study group and  $+2.11 \pm 1.26$  D in the group of other patients ( $P = .42$ ). Also, no difference in preoperative cylinder was found between the 2 groups (study group:  $-0.75 \pm 0.75$  D; other patients:  $-0.77 \pm 0.78$  D;  $P = 0.18$ ).

## DISCUSSION

Functional, symptomatic, and quality-of-life related outcomes are some of the most important factors that should be evaluated when reporting results of any refractive surgical procedure. Only a few studies,<sup>2-7</sup> representing a combined total of 210 patients, report on long-term (5 years or more) satisfaction with LASIK, and some of these studies<sup>2,4,5</sup> include patients with extreme refractive errors that many would consider outside the current guidelines for excimer laser surgery.

In this study, we evaluated a cohort of 2530 patients with a wide range of preoperative refractive errors, who were followed for 5 years. Despite the many reasons patients could have residual ametropia, which is expected in a long-term study,<sup>2-7</sup> the number of satisfied patients (91.0%) remained high. The percentages of patients (94.7%) who would have the same procedure again and the patients (96.5%) who would recommend the procedure to their family or friends were similar to results in short-term studies. For example, a study with the same laser platform and same range of preoperative refractions reporting satisfaction scores in 13 655 patients 1-month postoperatively<sup>18</sup> found that exactly the same percentage of patients (96.5%) would recommend the procedure to their friends and family, with only a slightly higher percentage of patients (95%) being satisfied with their vision. One month postoperatively, 93.5% of eyes were within  $\pm 0.50$  D of emmetropia,<sup>18</sup> compared with only 79.3% in the current 5-year study.

There are several reasons long-term satisfaction after LASIK might be high despite a lower percentage of patients achieving emmetropia. Some patients might have adapted to their vision and can tolerate or even appreciate a small refractive error. Of the patients in this study who did not wear distance correction, 10.8% had a residual refractive error outside of  $\pm 0.50$  D in each eye. On the other hand, many patients who were unhappy in the early postoperative period had an enhancement, which improved their satisfaction score. Also, those who became presbyopic and had a slight myopic regression might appreciate a

gain in near vision and prefer to function without correction.

A similar trend was seen in other long-term studies. Satisfaction remained high despite lower predictability. In the 5-year study by O'Doherty et al.,<sup>3</sup> of all levels of preoperative myopia (49 patients presented), only 60% of eyes were within  $\pm 0.50$  D of emmetropia; however, 100% of patients said they would recommend the surgery to a friend, 96% would have LASIK again, and 96% of patients were happy with the quality of their vision. The outcomes were similar in another study of LASIK for myopia (21 patients),<sup>6</sup> in which only 42% of eyes were within  $\pm 0.50$  D 7 years postoperatively; however, 100% of the study population said they would have LASIK again and 89% were satisfied with the surgery. Nineteen patients with moderate to extreme myopia were followed for 6 years in a study by Sekundo et al.<sup>2</sup> Only 46% of eyes were within  $\pm 1.0$  D; however, 71% of patients reported satisfaction with their visual acuity. Kymionis et al.<sup>4</sup> followed 7 patients with extreme myopia for 11 years and found similar results; 55% of patients were within  $\pm 1.0$  D of the attempted correction and 73% said they were happy with their outcomes. However, the attempted correction in these 2 studies<sup>2,4</sup> is not comparable with that in our dataset.

In the current study, lower patient satisfaction was mainly associated with worse postoperative binocular UDVA, the presence and severity of visual symptoms, a higher preoperative and postoperative refractive error, eyesight-related difficulties with performing various activities, a higher frequency of ocular discomfort symptoms, and postoperative spectacle or contact lens use.

As expected, the number of enhancements was also a predictive factor for increased dissatisfaction after LASIK. Many patients might interpret the need for enhancement as a failure of their surgical procedure. Despite this, a significant portion of patients (86.8%) who had an enhancement were still satisfied with their outcomes.

Surprisingly, the contribution of the patient's age in the regression model was minimal, accounting for only 1.2% of variance explained. This contraindicates some previous studies in which older age was one of the most important risk factors for a decrease in patient satisfaction.<sup>1,15</sup> This might reflect the thorough counseling that presbyopic patients receive regarding reading vision and monovision as an alternative (which 6.8% of patients received) as well as the possibility of dry eye and the need for artificial tears in the early postoperative period. The surgeon and surgical center also had an influence on satisfaction, accounting for 1.9% of the explained variance. Thus, despite efforts to standardize the delivery of corporate



eyecare, the surgeon and the surgical environment remain an important element in driving patient satisfaction.

The type of ablation profile did not have an influence on patient satisfaction. This could be because eyes with the wavefront-guided profile had higher preoperative refractions than eyes with the conventional ablation profile. The percentage of eyes (19.6%) with conventional ablation was also much lower, which could be another reason the difference in patient satisfaction between the 2 techniques was not detected in the regression analysis. Pupil size did not affect patient satisfaction, which confirms findings in previous short-term studies.<sup>1,15,19,21</sup>

Our regression model was robust and could explain most (58%), but not all, of the variance in postoperative satisfaction. Other variables that could contribute to satisfaction were not explored in this study. These could be unmet or unknown patient expectations, other patient-related issues (eg, personality traits or depression), other unmeasured clinical parameters (eg, postoperative higher-order aberrations), or issues unrelated to the surgical outcome (eg, clinic wait time or personal-related issues).

An important factor to consider when evaluating the outcomes of LASIK is how the surgery affects the patient's lifestyle. We questioned patients about eyesight-related difficulty with various activities, such as performing hobbies, driving at night, and taking part in active sports or other outdoor activities. Five years postoperatively, 6.6% of patients had moderate difficulty and 1.7% had a lot of difficulty with night driving. Only 0.3% of patients had a lot of difficulty with their daily activities or outdoor activities.

As expected, all questions related to near-vision tasks were strongly correlated with patient age. Most patients who were presbyopic, or soon to be at the time of their procedure, elected to not have monovision. Although they understood the necessity for reading spectacles, they tended to indicate more difficulty with near-vision activities. Difficulty with night driving, daily activities, and active sport and outdoor activities was strongly correlated with the postoperative binocular UDVA. Only a small percentage of patients ( $\leq 0.5\%$ ) had a lot of difficulties with these activities if their postoperative UDVA was 20/20 or better.

Symptoms of ocular discomfort are not uncommon in the immediate period after LASIK. Creation of the corneal flap and ablation of the stroma underneath interrupt corneal nerves, can decrease corneal sensitivity, can reduce blink rates, and can decrease tear production.<sup>16,17</sup> Dry-eye symptoms in the early postoperative stages improve with corneal healing.<sup>16,17</sup> Some studies suggest that 20% to 55% of patients

report dry-eye symptoms at least 6 months after LASIK<sup>16</sup>; however, how many patients have long-term issues with ocular discomfort is not known. It is also important to appreciate that dry-eye syndrome is common and prevalent in the population that has not had LASIK; major epidemiologic studies report the incidence to be between 5% and 34%.<sup>22,23</sup>

Our findings indicate that 5 years postoperatively, 92.1% of patients did not have dry-eye symptoms or had symptoms only some of the time, whereas 7.9% of patients had dry eyes quite frequently (half the time, most of the time, or all the time). In addition, 82.6% of patients did not use artificial tears.

Ocular discomfort occurred with greater frequency in women and in patients with hyperopic ablation. A higher prevalence of dry-eye symptoms in women has been previously reported regardless of whether the women had refractive surgery.<sup>22-24</sup> Unfortunately, there are no published reports of the long-term incidence of dry-eye symptoms, specifically after hyperopic ablation, for comparison with our results. Interestingly, one of the most commonly reported risk factors for dry-eye disease in a normal population, the patient's age,<sup>22,23</sup> showed only a weak correlation with the severity of dry-eye symptoms in this study.

Optical side effects are another common reason for dissatisfaction after LASIK,<sup>14,15</sup> and their presence can be affected by many factors, such as the type of ablation profile, optical zone/treatment zone, attempted correction, or residual refraction.<sup>15,21</sup> Years after refractive surgery, patients have had time to heal; have an enhancement, if required; and neuroadapt. Unwanted symptoms such as glare, halo, or starbursts might become less bothersome as well. On the other hand, the number of patients with postoperative emmetropia might decrease, which can increase night-vision phenomena if patients do not wear correction.

In this study, more than 80% of patients did not report glare, halo, starbursts, ghosting, or double vision 5 years postoperatively. Patients who reported visual phenomena almost always noticed it when not wearing spectacles or contact lenses, strongly suggesting that optical side effects were a direct result of residual refractive error. Less than 2% of patients reported glare, halo, starbursts, ghosting, or double vision, even with spectacles or contact lenses. The rate of night-vision disturbances reported in long-term LASIK studies varies. For example, Sekundo et al.<sup>2</sup> found that up to 75% of patients with moderate to extreme myopia still reported night-vision phenomena almost 7 years after LASIK. Similarly, 82% of patients reported night-vision problems 11 years after LASIK for high myopia in the study by Kymionis et al.<sup>4</sup> On the other hand, Liu et al.<sup>5</sup> found a 3.4% incidence of glare 7 years postoperatively in a similar

cohort of patients (moderate to severe myopia). In another study,<sup>3</sup> 24% of patients reported glare and night-vision problems 5 years after LASIK for all levels of myopia. Zalentein et al.<sup>6</sup> also reported that 39% of patients had visual problems in dim light 7 years after LASIK for myopia. The conventional ablation profile was used in all these studies. To our knowledge, there are no studies evaluating long-term visual phenomena after hyperopic LASIK.

The primary limitations of this study were its retrospective nature and that only 2530 (8.2% of the original cohort) returned for the 5-year follow-up and completed a questionnaire. Patients in the study group were slightly older and more likely to be hyperopic preoperatively. Older age is a reported risk factor for dissatisfaction after refractive surgery.<sup>1,15</sup> Also, the higher relative percentage of hyperopic patients in the study cohort could have had an effect on postoperative predictability. It is also possible that patients who return for long-term follow-ups are more likely to have ongoing visual problems or clinical issues. The absence of a preoperative questionnaire is another limitation of this study. For some questionnaire items, such as ocular comfort or visual phenomena, it would be beneficial to compare preoperative and postoperative scores, which was not possible in this retrospective study. The questionnaire used in this study was based on the study of the Joint LASIK Study Task Force.<sup>1</sup> To date, there is no consensus on which is the best instrument to analyze quality-of-life outcomes in refractive surgery. Rasch analysis has been adopted in many well-known quality-of-life questionnaires.<sup>25</sup> Using probabilistic relationships between questions and responses, Rasch analysis combines concepts into a more global metric. For example, rather than analyzing halos and glare separately, the Rasch system can combine these 2 related concepts into a quality-of-vision metric. This has advantages because it allows similar vision-related issues to be combined, analyzed, and discussed. However, rather than deriving a quality-of-vision metric, we used interval scaling to analyze each visual symptom independently.

In conclusion, in this study, satisfaction with LASIK 5 years after surgery remained high and most patients reported that their quality of life was improved. The frequency of ocular discomfort symptoms was comparable to that in the population of patients who did not have refractive surgery. Few patients have quality-of-vision problems, and the vast majority of them could be alleviated by spectacle correction, which many patients elect not to wear. Success of a refractive procedure cannot be assessed only by clinical parameters such as residual refractive error or achieved visual acuity. It is critically important to evaluate the patient's perception of the surgical outcome, how well it met his

or her expectations, and the effect of the procedure on his or her lifestyle.

#### WHAT WAS KNOWN

- Laser in situ keratomileusis is one of the most commonly performed refractive procedures, with high satisfaction rates.
- Few studies (combining a total of 210 patients) have been published on the long-term satisfaction and quality of life after LASIK.

#### WHAT THIS PAPER ADDS

- Satisfaction 5 years after LASIK remained high.
- The strongest long-term predictive factors of patient satisfaction after LASIK was UDVA.

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First author:

Steven C. Schallhorn, MD

*Department of Ophthalmology,  
University of California, San Francisco,  
California, USA*