

# Evaluation of the Relationship Between Ablation Diameter, Pupil Size, and Visual Function With Vision-Specific Quality-of-Life Measures After Laser In Situ Keratomileusis

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**Objective:** To evaluate the relationship between ablation diameter, pupil size, and visual function as measured by a vision-specific quality-of-life instrument after undergoing laser in situ keratomileusis.

**Methods:** Of 300 patients eligible for this study, 97 (32.3%) responded to a mailed study questionnaire, the National Eye Institute Refractive Error Quality of Life (RQL) Instrument. The RQL Instrument was administered in all 97 patients after laser in situ keratomileusis. Spearman correlation coefficients were calculated for the association between RQL subscale scores and characteristics including pupil diameter and uncorrected visual acuity.

**Results:** Positive correlations between larger mesopic and scotopic pupil diameter and higher RQL satisfac-

tion scores (0.12 and 0.19, respectively) were not statistically significant at the  $P=.05$  level. As uncorrected visual acuity in the better eye improved, patients reported significantly less worry ( $-0.22$ ;  $P=.03$ ), more satisfaction ( $-0.25$ ;  $P=.01$ ), clearer vision ( $-0.25$ ;  $P=.01$ ), and better far vision ( $-0.24$ ;  $P=.02$ ).

**Conclusion:** Larger pupil diameter is not significantly associated with postoperative satisfaction and visual function as measured with the RQL. Rather, postoperative uncorrected visual acuity is confirmed as a strong predictor of patient satisfaction after refractive surgery.

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**L**ASER IN SITU KERATOMILEUSIS (LASIK) is effective in treating a wide variety of refractive errors and has become the most commonly performed refractive procedure in the United States. There is, therefore, a need for greater understanding of the factors that directly affect visual function after this procedure. After LASIK, a subset of patients reported nighttime glare, halo, and vision disturbance,<sup>1-5</sup> and these symptoms may be a source of less patient satisfaction.<sup>6</sup>

A difference of opinion exists among refractive surgeons. The role of pupil size in the appropriate selection of patients for refractive surgery insofar as risk of visual disturbances under low-light conditions remains controversial. The effect of increased spherical aberration after LASIK to treat myopia is thought to be partially dependent on pupil size as well as attempted correction. This is supported by clinical findings of increasing incidence of glare, halo, and disturbances in night vision with smaller ablation diameter<sup>7,8</sup> as well as larger pupil size<sup>8,9</sup> and attempted correction.<sup>10</sup>

Seiler et al<sup>11</sup> described an increase in spherical aberration with pupil dilation in corneas that have undergone photorefractive keratectomy but not in healthy corneas, and O'Brart and colleagues<sup>7,12</sup> showed that a pupil diameter greater than 7.0 mm and large corrections are associated with reports of large-diameter halo. Furthermore, Oliver et al<sup>13</sup> calculated modulation transfer functions after photorefractive keratectomy and concluded that the contour change induced substantial optical aberrations, particularly for large-diameter pupils. Several recent articles, however, refute an association between pupil size and night vision disturbances.<sup>14-16</sup> Most of the literature that has attempted to address this relationship has reported no demonstrable association. In a recent study of substantial sample size, not pupil size but attempted degree of spherical correction, optical zone, patient age, and postoperative spherical equivalent were major risk factors for glare and halo symptoms.<sup>14</sup>

It has been difficult to define pupil diameter and treatment zone dimensions that

minimize the risk for subjective visual function compromise after surgery. This can be attributed in part to the difficulty in formally assessing subjective visual function in patients after surgical correction of refractive error. The National Eye Institute (NEI) has recognized the need to "study quality of life and functional status as perceived by the patient . . . to assess the full impact of a treatment or disease process."<sup>17(p331)</sup> Though questionnaires to determine visual acuity have been developed to measure disease-specific<sup>18,19</sup> and generic<sup>20</sup> outcomes, few standardized questionnaires have been designed specifically for preoperative and postoperative use in patients undergoing surgery to correct refractive error. Vitale et al<sup>21</sup> and Schein et al<sup>22</sup> have developed an instrument specific to refractive error and its correction, the Refractive Status and Vision Profile, that enables detection of clinically relevant changes in functional status and quality of life after refractive surgery and shows promise in evaluating interventions for correction of refractive error.

Another such tool that has recently been developed is the NEI Refractive Error Quality of Life (NEI-RQL) Instrument. Like the Refractive Status and Vision Profile, the NEI-RQL has been specifically designed to assess the subjective visual and functional effects of refractive error and its correction, with contact lenses, eyeglasses, or surgery. The NEI-RQL is accurate and sensitive in providing information about patient status that is not reflected by traditional clinical ophthalmic measures.<sup>23,24</sup>

This study retrospectively evaluated the relationship between pupil diameter and excimer laser treatment zone dimension as they relate to subjective outcomes self-reported on the NEI-RQL. We specifically examined the patients' perception of glare and halo symptoms and visual performance after LASIK and report on the relationship between satisfaction scores, performance scores, and pupil size, in an effort to illuminate whether larger pupil size is associated with poor visual function after LASIK.

## METHODS

### STUDY DESIGN

This study was performed under the supervision of the Committee on Human Research at the University of California, San Francisco, from which institutional review board approval was obtained. A retrospective study of 97 patients was performed to assess the relationship between pupil diameter, excimer laser treatment zone size, and visual results, along with patient satisfaction after LASIK for the treatment of myopia. All treatments were performed at the University of California, San Francisco by one of us (S.D.M.), and all patients gave informed consent to the study.

### PATIENT SELECTION

Subjects included adults of either sex who underwent refractive surgery at the University of California, San Francisco between January 1, 1999, and December 31, 2002. All patients enrolled in the study were 23 years or older and had myopia of -1.00 to -11.50 diopters (D) (manifest refraction spherical equivalent). Refractive astigmatism of 3.5 D or less was allowed. In addition, a calculated minimal residual corneal stromal bed thickness greater than 250  $\mu$ m was required. Preop-

eratively, patients gave a complete ophthalmic history and underwent examination including measurement of refractive error, slitlamp examination, Goldmann applanation tonometry, and dilated fundus examination. Pupil size was measured using the Colvard pupilometer (Oasis Medical Inc, Glendora, California) under mesopic and scotopic conditions. Before the preoperative examination, contact lens wear was discontinued for at least 3 weeks in rigid lens wearers and at least 1 week in soft contact lens wearers.

Inclusion criteria were uneventful LASIK for treatment of myopia performed by one of us (S.D.M.). Patients were excluded if both eyes were not operated on using the LASIK procedure (n=8). Patients who underwent monovision treatment or those in whom any surgical or postoperative complication developed that was judged to affect postoperative visual quality were excluded from the study (n=13).

### LASIK PROCEDURE

One of us (G.W.S.) determined which eye was to be treated first. Laser treatments were performed with an excimer laser system (VISX Inc, Santa Clara, California). For procedures performed before June 2001, the VISX Star S2 laser with software version 3.30 was used, and after that, the VISX Star S3 laser with software version 4.52 was used. Before introduction of the 8.0-mm blend zone included in the Star S3 software package, the upper limit of scotopic pupil diameter allowed for treatment with the excimer laser was 6.5 mm. (An EC-5000 excimer laser [Nidek Co Ltd, Gamagori, Japan] that provided enlarged treatment zones was also available in the center.) The default treatment zone on the excimer laser was set at 6.5 mm and, when an attempt was made to limit treatment depth, the treatment zone was not reduced to 6.0 mm unless the scotopic pupil diameter, as measured with the Colvard pupilometer, was 6.0 mm or smaller. After introduction of the blend zone included in the Star S3 software package, the upper limit of scotopic pupil diameter allowed for treatment with the excimer laser was increased to 8.0 mm and a blend zone of 8.0 mm was included in all procedures in which the scotopic pupil diameter was larger than 6.5 mm at Colvard pupilometry.

The Moria Carriazo-Barraquer manual microkeratome was used to prepare a corneal flap with a superiorly located hinge. The flap was then retracted, laser ablation performed, and the flap carefully repositioned and smoothed.

### POSTOPERATIVE MANAGEMENT

After LASIK, a combination of a fluoroquinolone antibiotic and corticosteroid eyedrop were administered 4 times daily, then the treatment was discontinued after 1 to 2 weeks. Patients were followed up postoperatively at 1 day, 1 week, 3 months, and 6 months, and then as needed.

### PATIENT QUESTIONNAIRES

The NEI-RQL Instrument was used to assess patient satisfaction and function after LASIK. Three hundred patients who had undergone LASIK with at least 6 months of follow-up, selected in reverse consecutive order, were asked to complete this self-administered questionnaire. Ninety-seven patients returned questionnaires; a response rate of 32.3%. In general, questionnaires were completed without assistance; however, explanations of questions were given by study personnel if requested by a patient. We performed analyses to determine that those who answered the questionnaire did not differ significantly from those who did not.

## CLINICAL RECORDS DATA ACQUISITION

Along with demographic data, pertinent objective factors including pupil diameter under mesopic and scotopic conditions, preoperative and postoperative uncorrected and best corrected visual acuity, manifest refraction, and ablation data were collected.

### SUBJECTIVE SCORES

Satisfaction with correction, glare, symptoms, clarity of vision, worry, and quality of far vision scores were assessed by and compiled from RQL responses. So that the subscales would operate the same regardless of category, higher scores were assigned to a more favorable outcome (eg, a higher "worry" score to represent a better outcome, or less worry). The RQL is written so that certain questions refer specifically to defined areas including satisfaction with correction, glare, symptoms, clarity of vision, worry, and quality of far vision. The mean of questions 23, 37, 39, and 40 from the NEI-RQL Instrument measure clarity of vision; the mean of questions 21 and 22 assess worry; question 26 measures satisfaction with correction; glare is quantified by responses to questions 17 and 38; symptoms such as pain, itching, dryness, and fatigue are measured by questions 18, 19, 24, 25, 36, 41, and 42; and far vision score is the mean of questions 4, 5, 6, 9, and 10. In examining and evaluating RQL responses in a defined area, study personnel referenced component questions and evaluated the specific scores of the component questions.

### PERFORMANCE SCORES

Three-month, 6-month, and most recent postoperative refractive error and uncorrected visual acuity (UCVA) constituted objective performance scores in this study.

### DATA ANALYSIS

Data were initially entered on an Excel spreadsheet (Microsoft Corp, Redmond, Washington) and were transferred to Stata-View software (SAS Institute Inc, Cary, North Carolina) for statistical analysis. Spearman correlations (rank correlation coefficients) were calculated to evaluate the distribution of values from the norm.

## RESULTS

Of the 300 patients contacted who were eligible for the study, 97 (32.3%) completed a postoperative RQL questionnaire. The baseline characteristics of those completing vs those not completing the RQL were compared. There were no significant between-group differences in scotopic pupil size or preoperative and postoperative refractive error and UCVA. In addition, no demographic differences existed between the groups.

Mean ( $\pm$ SD) patient age was 43.7 ( $\pm$ 9.7) years (age range, 23-67 years). The mean ( $\pm$ SD) preoperative manifest refraction in the right eye was  $-5.15 (\pm 2.24)$  D (range,  $-11.00$  to  $-1.00$  D), and in the left eye was  $-5.13 (\pm 2.35)$  D (range,  $-11.5$  to  $-1.25$  D; **Table 1**). There was a significant percentage of patients with moderate to severe myopia (33.3% with  $-6.0$  to  $-9.9$  D and 1.71% with  $-10.0$  D or higher in the right eye, and 31.6% with  $-6.0$  to  $-9.9$  D and 3.42% with  $-10.0$  D or higher in the left eye). The ab-

**Table 1. Clinical Measures in 97 Patients<sup>a</sup>**

Traditional Measures	Mean $\pm$ SD (Range)
Pupil diameter	
Mesopic	4.67 $\pm$ 0.74 (3.0 to 6.0)
Scotopic	5.82 $\pm$ 0.71 (4.0 to 7.0)
Treatment zone	
Right eye	6.65 $\pm$ 0.54 (6.0 to 8.0)
Left eye	6.67 $\pm$ 0.54 (6.0 to 8.0)
Mesopic pupil diameter-treatment zone	
Right eye	-2.00 $\pm$ 0.74 (-4.5 to -0.5)
Left eye	-2.03 $\pm$ 0.73 (-4.5 to -0.5)
Scotopic pupil diameter-treatment zone	
Right eye	-0.83 $\pm$ 0.60 (-2.5 to -0.5)
Left eye	-0.85 $\pm$ 0.60 (-2.5 to -0.5)
Preoperative refractive error, D	
Right eye	-5.15 $\pm$ 2.24 (-11.0 to -1.0)
Left eye	-5.13 $\pm$ 2.35 (-11.5 to -1.25)
Postoperative refractive error, D	
Right eye <sup>b</sup>	-0.60 $\pm$ 0.55 (-2.75 to 0.75)
Left eye <sup>b</sup>	-0.49 $\pm$ 0.55 (-3.0 to 0.5)

Abbreviation: D, diopters.

<sup>a</sup>Values are given in millimeters unless otherwise indicated.

<sup>b</sup>Values are given for only 82 patients.

**Table 2. Postoperative Refractive Error and UCVA at 3 and 6 Months and Most Recent Measurements After Laser In Situ Keratomileusis<sup>a</sup>**

Variable	Refractive Error		
	3-Month Follow-up	6-Month Follow-up	Most Recent Follow-up
Refractive error, spherical equivalent			
Right eye	<b>n = 82</b>	<b>n = 51</b>	<b>n = 22</b>
Plano	4 (4.9)	2 (3.9)	2 (9.1)
$< \pm 0.50$	37 (45.1)	29 (56.9)	6 (27.3)
$-0.6$ to $-1.0$	20 (24.4)	12 (23.5)	7 (31.8)
$-1.1$ to $-2.0$	18 (22.0)	7 (13.7)	5 (22.7)
$> -2.0$	3 (3.7)	1 (2.0)	2 (9.1)
Left eye	<b>n = 82</b>	<b>n = 58</b>	<b>n = 23</b>
Plano	10 (12.2)	4 (6.9)	1 (4.4)
$< \pm 0.50$	42 (51.2)	31 (53.5)	13 (56.5)
$-0.6$ to $-1.0$	18 (22.0)	13 (22.4)	4 (17.4)
$-1.1$ to $-2.0$	11 (13.4)	9 (15.5)	5 (21.7)
$> -2.0$	1 (1.2)	1 (1.72)	0
Uncorrected visual acuity			
Right eye	<b>n = 96</b>	<b>n = 80</b>	<b>n = 45</b>
$\leq 20/20$	54 (56.3)	50 (62.5)	30 (66.7)
20/25 to 20/40	35 (36.5)	28 (35.0)	10 (22.2)
20/50 to 20/80	5 (5.2)	1 (1.3)	5 (11.1)
20/100 to 20/200	2 (2.1)	1 (1.3)	0
$\geq 20/200$	0	0	0
Left eye	<b>n = 96</b>	<b>n = 78</b>	<b>n = 39</b>
$\leq 20/20$	55 (57.3)	48 (61.5)	23 (59.0)
20/25 to 20/40	37 (38.5)	25 (32.1)	15 (38.5)
20/50 to 20/80	3 (3.1)	5 (6.4)	1 (2.6)
20/100 to 20/200	1 (1.0)	0	0
$\geq 20/200$	0	0	0

<sup>a</sup>Values are given as number (percentage).

lation zone diameter was between 6 and 8 mm in all patients. **Table 2** gives postoperative residual refractive error (spherical equivalent values) and UCVA results in study

**Table 3. Satisfaction With Correction in 97 Patients<sup>a</sup>**

Satisfaction	Responses
Completely satisfied	43 (44.3)
Very satisfied	38 (39.2)
Somewhat satisfied	11 (11.3)
Somewhat dissatisfied	4 (4.1)
Very dissatisfied	1 (1.0)
Completely dissatisfied	0

<sup>a</sup>Values are given as number of patients (percentage).

participants. Three months postoperatively, 95.8% of patients had UCVA of 20/40 or better in their better eye. Three months postoperatively, 74.4% of worse eyes were within  $\pm 1.0$  D of emmetropia and 96.3% were within  $\pm 2.0$  D.

### SATISFACTION

Despite a good outcome reflected by Snellen UCVA, a certain subset of patients indicated occasional untoward symptoms. However, RQL responses demonstrate that 81 patients (83.5%) were either completely or very satisfied with LASIK correction (**Table 3**). One patient (1.0%) was very dissatisfied with correction, primarily because of symptoms of glare, dryness, and blurry vision.

### GLARE

Distortion of vision in the form of glare is a major concern after LASIK and typically is more symptomatic at night, when the pupil dilates. Seventy-six patients (78.4%) reported little or no nighttime glare; 10 patients (10.3%) reported glare some of the time; 5 patients (5.15%) reported nighttime glare most of the time; and 6 patients (6.19%) reported nighttime glare all of the time. In patients who reported nighttime glare, 14 (60.9%) reported the symptom as only a little bothersome.

### OTHER SYMPTOMS AFTER LASIK

Other patient-reported symptoms measured by the NEI-RQL included pain, discomfort, dryness, tearing, itching, soreness, and headaches related to vision. Commonly reported symptoms included eye soreness in 43 patients (44.3%), tearing in 20 (20.8%), itching in 38 (39.6%), and moderate dryness or worse in 28 (20.8%). Most patients indicated pain or discomfort infrequently ( $n=35$  [36.1%]) or never ( $n=46$  [47.4%]). In 5 of these patients (5.21%), pain or discomfort was moderate, and was severe in only 1 patient. Few patients reported headaches related to vision: 71 patients (73.2%) never experienced a headache related to vision and 8 (8.25%) reported only occasional headaches they considered to be related to vision.

### CLARITY OF VISION

Most patients reported excellent clarity of vision postoperatively, with 50 patients (52.1%) reporting perfectly clear vision and 40 (41.7%) indicating nearly clear

vision. Nonetheless, not all patients indicated consistent, perfect clarity of vision, and 24 patients (25%) reported episodes of some degree of distorted vision, 33 (34.4%) indicated episodes of some degree of blurry vision, and 31 (32.3%) reported occasional episodes of some degree of trouble seeing.

### WORRY

A small percentage of patients in this study worry about their postoperative vision. Sixty-eight (70.1%) respondents never or rarely worry about vision, 18 (18.6%) reported occasional worry, 7 (7.22%) indicated some degree of worry, and 4 (4.12%) reported worrying about vision all of the time. The RQL responses to question 22 indicate that 41 patients (43.4%) never or rarely think about their eyesight or vision, 35 (36.1%) occasionally think about their eyesight or vision, 12 (12.8%) sometimes think about eyesight or vision, and 8 (8.3%) think about eyesight or vision all of the time.

### SPEARMAN CORRELATIONS

**Table 4** gives Spearman correlations. Contrary to the notion that larger scotopic and mesopic pupil diameter is correlated with lower satisfaction, the correlations between mesopic and scotopic pupil diameter and the RQL satisfaction score were 0.12 and 0.19, respectively, indicating greater satisfaction with larger pupil diameter; however, neither association was statistically significant at the  $P=.05$  level. With respect to the RQL clarity and far vision scores, the correlations were 0.06 and 0.13, respectively, for mesopic pupil diameter and 0.01 and 0.17, respectively, for scotopic pupil diameter (not statistically significant at the  $P=.05$  level). Therefore, larger pupil diameter is not significantly associated with postoperative satisfaction with vision, clarity of vision, or far vision as measured with the NEI-RQL Instrument.

However, there was a significant association between better eye UCVA and RQL satisfaction scores, which serves to confirm postoperative UCVA as a strong predictor of patient satisfaction after refractive surgery. So that the subscales operated in the same manner (higher scores representing a more favorable outcome), higher worry values indicated a better outcome, or less worry. Therefore, as postoperative UCVA in the better eye improved (with better visual acuity represented by a smaller value), patients reported significantly less worry ( $-0.22$ ;  $P=.03$ ), more satisfaction ( $-0.25$ ;  $P=.01$ ), clearer vision ( $-0.25$ ;  $P=.01$ ), and better far vision ( $-0.24$ ;  $P=.02$ ), according to the respective RQL subscale scores. As UCVA in the worse eye improved, patients reported significantly less worry ( $-0.23$ ;  $P=.02$ ), clearer vision ( $-0.20$ ;  $P=.049$ ), and better far vision ( $-0.24$ ;  $P=.02$ ).

### COMMENT

Although the outcome of LASIK is satisfying for most patients, optical sequelae such as glare, halo, and night vision disturbance are troubling adverse effects in some. The effect of increased spherical aberration after LASIK

**Table 4. Spearman Correlation Coefficients in 97 Patients**

Variable	NEI-RQL Instrument Subscale Score					
	Worry	Satisfaction	Glare	Symptoms	Clarity of Vision	Far Vision
Pupil diameter						
Mesopic	0.10	0.12	0.01	-0.04	0.06	0.13
Scotopic	0.03	0.19	-0.15	-0.06	-0.02	0.17
Zone size						
Right eye	-0.07	0.08	-0.10	-0.09	-0.05	0.19
Left eye	-0.03	0.08	-0.07	-0.07	-0.03	0.27 <sup>a</sup>
Mesopic pupil-zone size						
Right eye	0.11	0.06	0.12	0.09	0.12	0.07
Left eye	0.11	0.10	0.13	0.09	0.13	0.07
Scotopic pupil-zone size						
Right eye	0.06	0.15	-0.01	0.04	0.06	0.12
Left eye	0.07	0.19	-0.01	0.05	0.10	0.13
UCVA						
In better eye <sup>b</sup>	-0.22 <sup>b</sup>	-0.25 <sup>b</sup>	-0.07	0.07	-0.25 <sup>b</sup>	-0.24 <sup>b</sup>
In worse eye <sup>b</sup>	-0.23 <sup>b</sup>	-0.16	-0.14	-0.09	-0.20 <sup>b</sup>	-0.24 <sup>b</sup>
Difference between eyes	0.15	0.01	0.15	0.24 <sup>b</sup>	0.12	0.14

Abbreviations: NEI-RQL, National Eye Institute Refractive Error Quality of Life; UCVA, uncorrected visual acuity.

<sup>a</sup>Correlation coefficient differs significantly from 0 ( $P < .05$ ,  $t$  statistic).

<sup>b</sup>Values are given for only 96 patients.

for treatment of myopia may be partially dependent on pupil size and attempted correction. However, in this study, preoperative scotopic and mesopic pupil diameters were not significantly associated with less postoperative satisfaction and visual function as measured with the NEI-RQL Instrument. We found that a larger scotopic pupil diameter was correlated with higher satisfaction and far vision scores, although statistical significance was not met (Table 4). This study demonstrates that large pupil size, matched to the ablation zones of today's excimer lasers, is not strongly associated with night vision disturbance.

Clinical findings of increasing incidence of glare, halo, and disturbance of night vision with smaller ablation diameter<sup>7,8</sup> and larger pupil diameter<sup>8,9</sup> have implicated pupil size in earlier studies. However, this study and other recent reports<sup>14-16</sup> demonstrate no correlation between larger pupil size and subjective visual outcomes after LASIK. Pop and Payette<sup>14</sup> reported that attempted degree of spherical correction, optical zone, patient age, and postoperative spherical equivalent, and not pupil size, were major risk factors for glare and halo symptoms in their patient population. While these authors obtained responses for a large sample size, their study design is vulnerable in that an unvalidated instrument was used to assess subjective visual disturbances. To our knowledge, our study is the first independent application of the validated NIE-RQL Instrument in evaluating the relationship between pupil size and quality of vision after LASIK.

It must be acknowledged that our study population represents only those who chose to respond to a mailed solicitation for participation (32.3% of the eligible population) and, thus, introduces the confounding element of selection bias. It cannot be predicted whether patients who might be more or less satisfied with their visual outcomes might be more or less inclined to re-

spond to an outcomes questionnaire. However, the demographic and physiologic characteristics were similar between participants and nonparticipants.

Sample size limitations cannot be ruled out as a potential explanation for the lack of statistically significant findings in some measures examined. This study does not confirm previous reports that suggest visual performance may demonstrate a decline in function related to clearance zones compromised by large pupil diameter. A type II error is one of several explanations of why this study did not find a significant result. However, because observed correlations are generally low ( $<0.15$ ), the magnitude of the associations suggests that any true association between larger pupil diameter and postoperative satisfaction scores would be weak at best.

It is important to recognize that in this study, while patients with scotopic pupil diameter up to 7.0 mm were included, routinely patients were selected and ablation zones chosen so that the ablation zone would match or exceed the scotopic pupil diameter as measured with the Colvard pupilometer. Moreover, at the time these procedures were performed, it was the practice of the operating surgeon to discourage surgery if the pupil diameter in daytime ambient light was greater than 6.5 mm. Thus, this study describes the outcomes in a patient cohort in which the pupil diameter in daytime ambient light was consistently 6.5 mm or less and in which the ablation zone diameter including transition zones was chosen to match or exceed the measured scotopic pupil diameter. Results of this study must be interpreted in that context and indicate that in patients in whom scotopic pupil diameter does not exceed treatment zone area including the transition zone, a larger pupil is not more strongly associated with less postoperative satisfaction with visual outcome. It is acknowledged that high degrees of spherical aberration can be introduced by smaller treatment zones in substantially larger pupils, but this

study did not include treatments that fit such a description and, therefore, we cannot comment on the risk of patient dissatisfaction under those circumstances.

With the exponential increase in patients undergoing refractive surgery, an increase in patient dissatisfaction with scotopic or mesopic vision disturbances, regardless of cause, has the potential to become an important public health issue. As new methods and technology continue to advance refractive surgery practice, there is a parallel need to accurately assess such potential complications and to identify appropriate surgical candidates. High-contrast distance visual acuity and decreased residual refractive error are correlated with overall patient visual function and satisfaction after surgery<sup>25</sup>; however, high-contrast visual acuity fails to identify a significant percentage of patients with visual disturbances after LASIK.

Historically, high-contrast distance visual acuity measures (eg, Snellen chart) have been accepted as standards for assessing quality of vision. However, the limits of high-contrast distance visual acuity measures arise when considering the types of complications that occur after refractive surgery. By developing a consistent measure that takes a more nuanced account of various visual functioning (ie, glare disability, contrast sensitivity, and image degradation), we reach a better understanding of specific visual disturbances.

As described herein, the NEI-RQL Instrument seems to be a valuable tool in better assessing subjective visual function. In determining specific factors through a standardized means of measurement, patient characteristics can be categorized, quantified, and, with the aid of instruments such as the NEI-RQL, ultimately analyzed to determine risk factors for poor outcome and design procedures to circumvent these limitations. This study indicates that scotopic pupil diameter (in this case, that does not exceed treatment zone area including the blend zone) does not seem to be a strong risk factor for poor outcome or to be associated with less postoperative satisfaction with visual outcome.

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