

The Role of the Mesopic Pupil on Patient-Reported Outcomes in Young Patients With Myopia 1 Month After Wavefront-Guided LASIK

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ABSTRACT

PURPOSE: To determine the relationship between low-light pupil size and patient-reported outcomes 1 month after wavefront-guided LASIK in young patients with myopia.

METHODS: Retrospective case series of 10,944 eyes of 5,563 young patients with myopia who underwent wavefront-guided LASIK (6.0-mm optical zone). Preoperative pupil size was measured under low-light conditions with an infrared pupillometer. Visual and refractive outcomes were evaluated at 1 month postoperatively. A questionnaire was administered to assess patient-reported outcomes including satisfaction with the procedure, night driving, and glare and halo visual symptoms.

RESULTS: The average patient age was 29.8 years (range: 18 to 40 years). The mean preoperative manifest spherical equivalent of -3.49 diopters (D) (range: -0.50 to -11.75 D) was reduced to -0.04 ± 0.29 D at 1 month, with 94% of eyes achieving an uncorrected distance visual acuity of 20/20 or better. The mean low-light pupil diameter was 6.6 mm (range: 4 to 9 mm) and 1,514 patients (27.2%) had a diameter of 8 mm or larger. No correlation between pupil diameter and patient-reported outcomes was found (r range: -0.02 to 0.07). Logistic regression analysis identified postoperative uncorrected distance visual acuity and postoperative manifest refraction as significant predictors of night halo complaints after wavefront-guided LASIK ($P < .01$).

CONCLUSIONS: In this large series of young patients with myopia treated with wavefront-guided LASIK, low-light pupil diameter was not predictive of surgery satisfaction, ability to perform activities, or visual symptoms at 1 month postoperatively.

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There is continued controversy regarding the relationship between low-light pupil diameter and night visual disturbances after LASIK.¹⁻³ A direct relationship between a large pupil and visual disturbances after LASIK seems plausible if there is an untreated area between the pupillary margin and ablation zone.⁴ Optical modeling, editorials, and a single clinical trial concluded that a large mesopic pupil, or a pupil larger than the laser ablation (or optical) zone, is directly associated with significant night visual symptoms after LASIK.^{1,5-13} However, there are other compensatory mechanisms, such as the Stiles-Crawford effect, that may mitigate symptoms for those with large pupils.¹⁴ In fact, every clinical trial that has studied the role of the pupil in visual symptoms after LASIK has not demonstrated a relationship.¹⁵⁻²⁰

The low-light pupil controversy continues to impact patient care. Some surgeons discourage LASIK for patients with pupil sizes larger than the optical zone. Others increase the optical zone to as large as the pupil diameter, but, in doing so, more stromal tissue is removed. Other surgeons provide additional counseling to patients, stating that they are at higher risk for visual symptoms. Yet others restrict treatment to patients with smaller pupils.

This study was conducted to further explore the relationship between low-light pupil size and patient-reported outcomes after LASIK in a large patient sample. Young patients with myopia were chosen because they may represent a population at risk of having large pupils and developing visual symptoms.

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PATIENTS AND METHODS

This study was deemed exempt from full review by the Committee on Human Research at the University of California–San Francisco because it used only de-identified patient data. All patients provided informed consent to undergo LASIK.

All LASIK records without patient identifiers were extracted from the Optical Express electronic medical record system using the following criteria: wavefront-guided LASIK (with use of a femtosecond laser to create the flap) performed between 2008 and 2010; refractive target was emmetropia; patient age at time of treatment was 40 years or younger; preoperative manifest sphere of 0.50 diopters (D) or greater of myopia; no prior refractive procedures; attended the 1-month postoperative examination; and completed the 1-month postoperative questionnaire.

All treatments were performed using the STAR S4 IR excimer laser system (Abbott Medical Optics, Santa Ana, CA) with a wavefront-guided ablation profile (Advanced CustomVue; Abbott Medical Optics). For all treatments, the optical zone diameter was 6.0 mm with an 8.0-mm transition zone. For patients with astigmatism, the minor axis of the elliptical ablation was 6.0 mm. Corneal flaps were created using a femtosecond laser (IntraLase iFS or FS-60; Abbott Medical Optics). Patients were instructed to instill a topical steroid (1% prednisolone acetate) and a third- or fourth-generation fluoroquinolone four times a day for 1 week postoperatively. In addition, patients were encouraged to use artificial tears at least four times a day for 1 month postoperatively.

Patients underwent a complete preoperative examination and the results were directly recorded in an electronic medical record. The low-light pupil was measured with the Colvard infrared pupillometer (Oasis Medical, Glendora, CA). Lighting in every examination room was standardized and calibrated with a photometer (Model LS-100; Konica Minolta, Ramsey, NJ) so that luminance at the patient's eye when measuring the pupil diameter would be 1 to 2 cd/m². One eye at a time was measured and the patient was instructed to view a distant target with the eye not being measured. When the observed pupil reached its maximum dilation, the pupil diameter was recorded and rounded to the nearest millimeter. No additional counseling was provided to patients with large pupils (> 6 mm). Specifically, they were not told that they were at an increased risk for night vision problems (eg, glare and halos) because of their pupil size. If anisocoria was present, the largest pupil diameter was used for analysis.

All patients were asked to complete a questionnaire after the 1-month postoperative examination; it 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 and assessed patient-reported outcomes including surgery satisfaction, the ability to perform activities, and visual and ocular symptoms.²¹ A list of the four questions analyzed in this study are included in **Appendix A** (available in the online version of this article). Response scaling had equidistant intervals and, when applicable, there was a neutral response with equidistant intervals above or below this level. Questions were analyzed individually as ordered-categorical data without summing or creating quantitative variables. This approach has been deemed acceptable by other studies.²²

Questionnaire outcome predictors were examined using logistic regression analysis. Responses constituted the dependent variables in each regression analysis. Demographics (age and gender), date and location of surgery, surgeon, preoperative and postoperative refraction, type of flap creation, postoperative uncorrected distance visual acuity, and low-light pupil diameter were the independent variables analyzed.

Data tabulation and statistical operations were performed with SAS 9.1 (SAS Institute, Inc., Cary, NC) and Microsoft Office Excel 7.0 (Microsoft Corporation, Redmond, WA) software. Parametric statistics were used to analyze differences between both preoperative and postoperative outcomes (paired Student's *t* test) and groups of eyes (unpaired Student's *t* test). The chi-square test was used to assess the statistical significance of differences in percentages. Forward stepwise logistic multi-regression analysis was used to identify significant predictors of symptoms and adjusted odds ratios were computed.

RESULTS

There were 5,563 patients (10,944 treated eyes) who met the inclusion criteria of this study and were treated by 30 surgeons at 41 Optical Express centers. Their demographics and preoperative and postoperative results are displayed in **Table 1**. The mean age was 29.8 years (range: 18 to 40 years). There was no anisocoria in most patients (91.5%) and the difference in low-light pupil diameter between the left and right eye was 1.0 mm or less in most (99.7%). There were 1,514 patients with a pupil diameter of 8 mm or larger (**Figure 1**). At 1 month postoperatively, 94% of eyes achieved 20/20 or better uncorrected distance visual acuity. Forty-three eyes of 35 patients had intraoperative complications or developed complications within 1 month postoperatively (incidence: 0.39%). Most complications were minor, resulted in no vision loss, and included mild diffuse

TABLE 1
Demographic Data and 1-Month Postoperative Results

Variables	Attended 1-Month Exam, Questionnaire	Consecutive Treatments	Did Not Attend 1-Month Exam	Attended 1-Month Exam, No Questionnaire
No. of patients (eyes)	5,563 (10,944)	13,481 (26,446)	2,789 (5,459)	5,129 (10,043)
% of total	41.3	100	20.7	38.0
% of attending 1 month	52.0	79.3	–	48.0
Age (y)	29.8	29.8	29.2	30.1
Gender (M/F) (%)	45.7 / 54.3	45.7 / 54.3	51.1 / 48.9	42.9 / 57.1
Mean preop MSE (D) (range)	-3.49 (-0.50 to -11.75)	-3.47 (-0.38 to -12.5)	-3.34 (-0.38 to -11.75)	-3.52 (-0.50 to -12.5)
Mean pupil diameter (mm) (range)	6.59 (4.0 to 9.0)	6.59 (4.0 to 9.0)	6.57 (4.0 to 9.0)	6.59 (4.0 to 9.0)
Mean 1-month MSE ± SD	-0.04 ± 0.29	-0.04 ± 0.30	–	-0.05 ± 0.30
% 20/20 UDVA at 1 month	94.0	93.2	–	92.4

preop = preoperative; MSE = mean spherical equivalent; D = diopters; SD = standard deviation; UDVA = uncorrected distance visual acuity

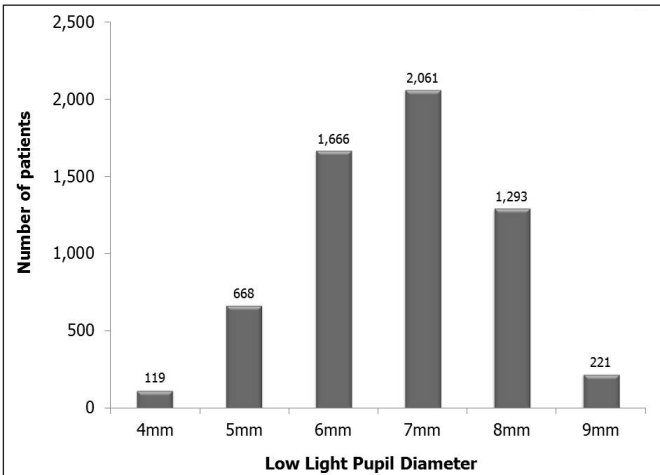


Figure 1. Distribution of low-light pupils.

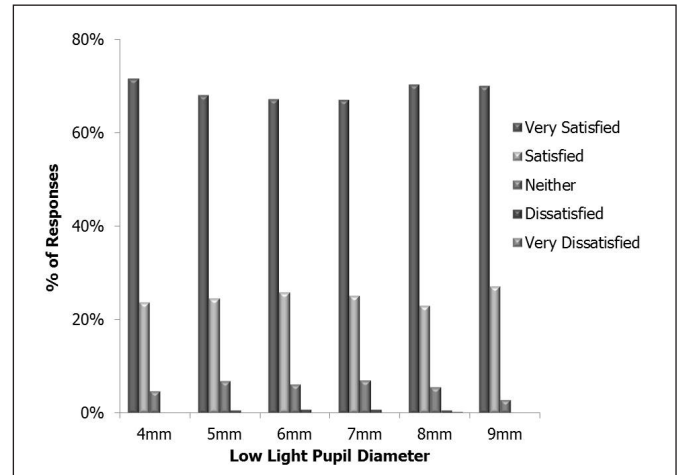


Figure 2. Satisfaction with the procedure stratified by pupil diameter.

lamellar keratitis (18 eyes) and corneal epithelial abrasion at the time of surgery (7 eyes). One eye developed a presumed microbial keratitis, which was treated with intense topical antibiotics; the patient recovered 20/16 uncorrected distance visual acuity. The mean low-light pupil diameter of patients who had complications was similar to those who did not (6.82 vs 6.59 mm).

SATISFACTION

Ninety-three percent of patients reported satisfaction with the surgery (satisfied or very satisfied), 6.2% indicated neither satisfied nor dissatisfied, and 0.7% reported dissatisfaction (dissatisfied or very

dissatisfied). Patients with 8- and 9-mm low-light pupils had similar satisfaction (93.1% and 97.1%, respectively) as the rest of the cohort and without an increase in dissatisfaction (Figure 2).

VISUAL SYMPTOMS

The response distribution to glare and halo symptoms for different pupil sizes is demonstrated in Figures 3-4. Most patients reported mild or no symptoms of glare (93.8%) and halos (91.2%), which was similar to patients with 8- and 9-mm pupils (glare: 94.5% and 97.2%, respectively; halo: 90.7% and 91.2%, respectively). Severe glare and halo symptoms were reported

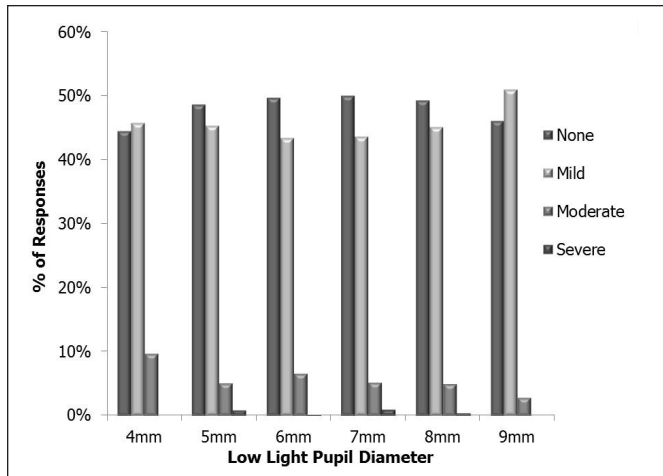


Figure 3. Glare responses stratified by pupil diameter.

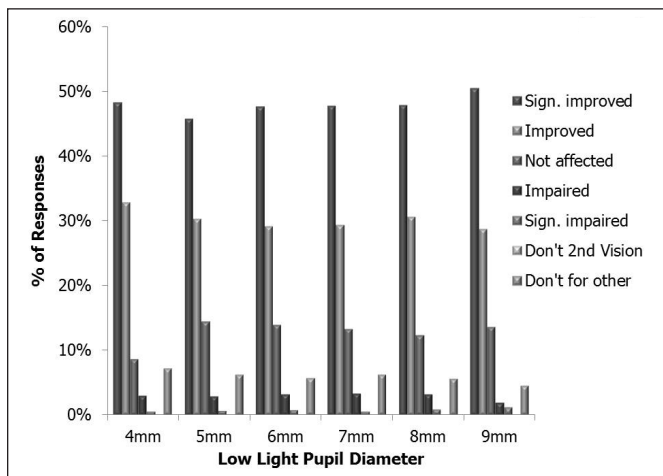


Figure 5. Ability to drive at night responses stratified by pupil diameter.

by 0.6% and 0.8% of patients, respectively. This was similar to patients with 8- and 9-mm pupils reporting severe symptoms (glare: 0.5% and 0.0%, respectively; halo: 0.9% and 0.8%, respectively). There was no difference in glare or halo symptoms due to pupil size ($P = .08$ and $.26$, respectively; chi-square test).

NIGHT DRIVING

No patients indicated that they could not drive after surgery because of their vision, but 5.8% indicated that they did not drive at night for reasons other than vision (Figure 5). Of patients who drove postoperatively, most (82.1%) indicated that their night driving improved; 14% reported that their night driving was not affected and 3.8% reported worse or significantly worse night driving. There was no increase in difficulty of night driving for patients with 8- or 9-mm pupils (with 3.8% and 2.9% indicating impairment, respectively). No differences in reported night-driving ability were observed due to pupil size ($P = .13$; chi-square test).

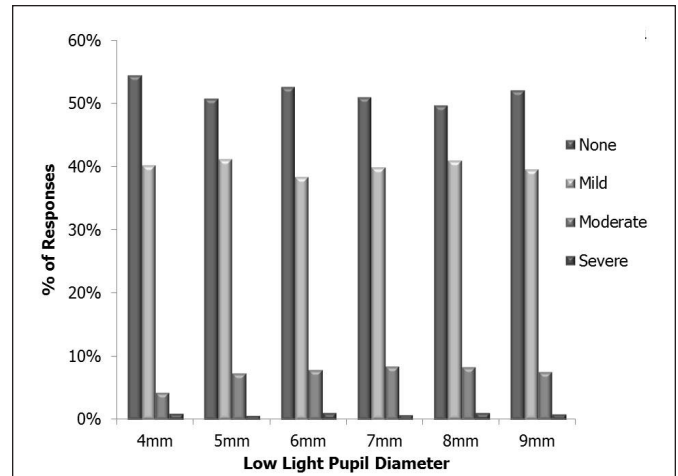


Figure 4. Halo or starburst responses stratified by pupil diameter.

CORRELATION AND LOGISTIC REGRESSION ANALYSIS

Surgery dissatisfaction and halo symptoms were significantly correlated to postoperative uncorrected distance visual acuity (Satisfaction $r = 0.19$, $P < .01$; Halo $r = 0.09$, $P < .01$) (Figures 6-7). Patients with worse postoperative uncorrected distance visual acuity were more likely to report glare and halo symptoms. A total of 7.8% of patients were not satisfied with the surgery when postoperative uncorrected distance visual acuity was worse than 20/25 (compared to 0.3% for those who achieved 20/12.5).

Forward stepwise logistic multi-regression analysis identified significant, independent predictors of dissatisfaction, halo symptoms, and night-driving ability after LASIK. No significant predictors were found for glare or daily activities. Dissatisfaction predictors were postoperative uncorrected distance visual acuity and postoperative cylinder. Specifically, for every diopter increase in postoperative cylinder (in absolute terms), the odds of reporting dissatisfaction after surgery increased by a factor of 1.48 (95% confidence interval [CI]: 1.21 to 1.79). Likewise, for every line decrease of uncorrected distance visual acuity (ie, 20/20 compared to 20/16), the odds of reporting dissatisfaction increased by a factor of 140 (95% CI: 83.4 to 236.0). For halo symptoms, the predictors were postoperative uncorrected distance visual acuity (odds ratio: 3.11; 95% CI: 2.08 to 4.63), preoperative sphere (odds ratio: 1.12; 95% CI: 1.09 to 1.14), and preoperative cylinder (odds ratio: 1.09; 95% CI: 1.03 to 1.14). Regression analysis identified postoperative uncorrected distance visual acuity and postoperative sphere and cylinder as predictors for patient-reported, impaired night driving postoperatively. For every diopter of postoperative sphere disparity from emmetropia, the odds ratio of reporting night-driving problems after surgery increased by a factor of 1.48 (95% CI: 1.19 to 1.76). Likewise, for every diopter increase in postoperative cylinder (in

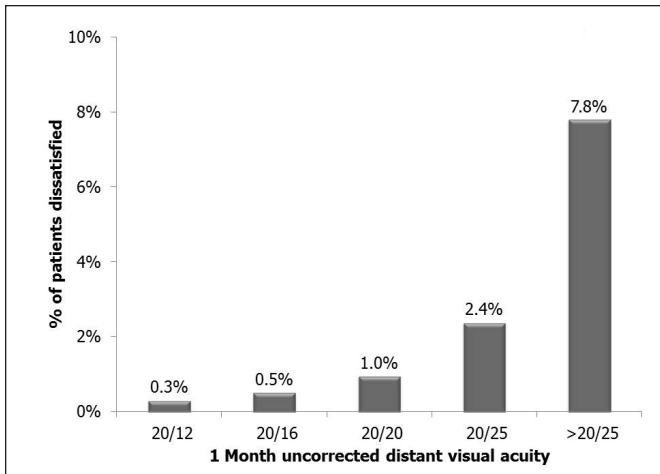


Figure 6. Surgery dissatisfaction (“dissatisfied” or “very dissatisfied”) stratified by postoperative uncorrected distance visual acuity.

absolute terms), the odds ratio of reporting night-driving problems after surgery increased by a factor of 1.80 (95% CI: 1.44 to 2.24). For every line decrease of uncorrected distance visual acuity (ie, 20/20 compared to 20/16), the odds ratio of reporting night-driving problems increased by a factor of 2.36 (95% CI: 1.28 to 4.36).

BIAS ANALYSIS

An analysis was conducted between the study group and all other patients treated during the same time period who met the inclusion criteria. Specifically, these other patients either did not attend the 1-month postoperative examination or attended the examination but did not complete the questionnaire. There was no difference in distribution of low-light pupil diameter between the study cohort and other patients ($P = .08$; unpaired Student's t test) (Table 1). Compared to the study population, patients who did not attend the 1-month visit were slightly younger (29.2 years), had a lower mean preoperative manifest spherical equivalent (-3.34 D), and were more likely to be males. Patients who attended the 1-month examination but did not complete the questionnaire had similar age and preoperative and postoperative manifest spherical equivalent as the study cohort but were more likely to be female and have slightly worse uncorrected distance visual acuity (92.4% vs 94.0% achieving 20/20 uncorrected distance visual acuity).

DISCUSSION

This study was designed to analyze the relationship between visual symptoms and low-light pupil diameters after wavefront-guided LASIK in a large sample size. A younger population was used because they tend to have larger pupils. Myopic treatments were selected because reports have associated quality of vision problems with patients who have large pupils after myopic

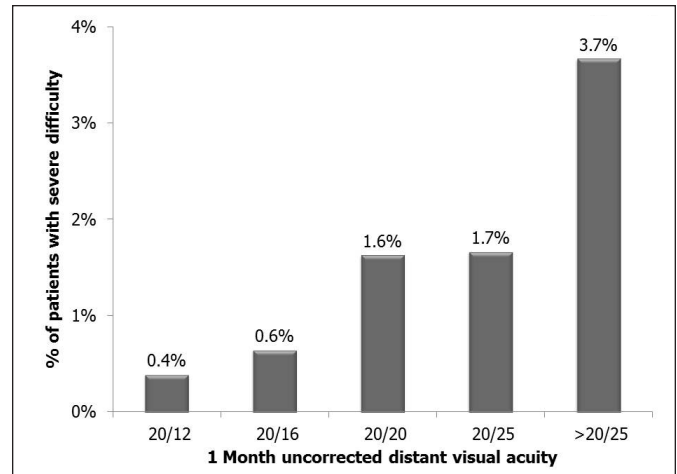


Figure 7. Severe halo or starburst difficulty stratified by postoperative uncorrected distance visual acuity.

LASIK.^{1,8-13} Thus, young patients with myopia were considered an ideal study population that may be at risk for quality of vision problems after LASIK.

The role of the low-light pupil on visual symptoms after LASIK has been controversial. Increasing higher-order aberrations with larger pupil sizes and optical modeling suggest there should be a correlation.^{7,23,24} A treatment where the excimer optical zone is smaller than the low-light pupil provided a stronger correlation. Several anecdotal reports suggest a relationship exists.^{4,8,13,25} Excimer laser companies have warnings in their product labeling stating patients with large pupils may be at higher risk for visual symptoms; such a warning is currently on the U.S. Food and Drug Administration web site (<http://www.fda.gov/>). Helgesen et al. reported on 46 patients treated with the Mel-70 excimer laser (Carl Zeiss Meditec, Inc., Jena, Germany) and found a positive correlation between large pupils and night visual disturbances at 3 months postoperatively.¹⁰ However, this remains the only published clinical study that has found such a relationship beyond 1 month postoperatively.

Other published clinical studies have not shown a relationship, as shown in Table A (available in the online version of this article).^{1,15-20,26-28} In 2001, Haw and Manche found no association between low-light pupil size and postoperative visual symptoms in a series of 93 patients who underwent PRK and 24 months of follow-up.¹ Schallhorn et al. described 100 patients who underwent LASIK using a standard ablation profile and found that the pupil was weakly correlated to visual symptoms 1 month postoperatively, but found no relationship at 3 and 6 months postoperatively.¹⁹ In a study of 32 patients 6 months after LASIK, Lee et al. reported that postoperative parameters (eg, spherical equivalent) correlated to the presence of glare symptoms but the pupil size did not.²⁰ Pop and

Payette analyzed 795 eyes for risk factors for night vision problems after LASIK.¹⁸ One year after surgery, various preoperative and postoperative parameters were found to be risk factors, whereas pupil size was not.¹⁸ Recent studies have also concluded that pupil size does not significantly correlate with postoperative symptoms.^{16,17}

There are several differences between this study and previous reports (the most important being sample size). The number of participants in this study was twice that in all previous reports. A total of 3,575 patients had a pupil diameter of 7 mm or greater and 1,293 and 221 patients had 8- and 9-mm pupils, respectively. The ablation profile used in this study was wavefront-guided as opposed to the standard profile used in previous studies. A wavefront-guided treatment is derived from an aberrometer and has been shown to induce fewer higher-order aberrations than the standard profile.²⁹ In addition, the nomenclature of the optical zone diameter for the excimer laser used in this study is also different. A 6.0-mm optical zone with wavefront-guided treatment with this laser signifies the minor axis of an elliptical ablation for myopic/astigmatic correction, whereas a 6.0-mm optical zone standard treatment (nonwavefront-guided) signifies the major axis of an elliptical ablation.

Previous studies reported that patient dissatisfaction and low-light visual phenomena are associated with residual refractive errors.^{16,26} This study agrees with this finding. We found that the postoperative uncorrected distance visual acuity and postoperative refractive error were correlated to halo responses in the logistic regression analysis. This is because patients do not typically wear glasses or contact lenses after LASIK, including those who may not achieve 20/20 uncorrected distance visual acuity. Uncorrected lower-order aberrations (sphere and cylinder) can increase patient dissatisfaction and cause visual symptoms, as observed in the logistic regression model for patient dissatisfaction.^{30,31}

Two important limitations of this study were it being retrospective and having many patients who did not complete the 1-month questionnaire. Patients were asked to complete the postoperative questionnaire as part of the Optical Express standard of care, but their participation was voluntary. Patients not included in the study either did not attend the 1-month visit or attended but elected not to complete the questionnaire. Bias could be introduced if these patients were selectively more or less likely to have symptoms relating to the surgery. Several elements of the study design were used to counter this potential bias. First, consecutive patients who underwent LASIK within defined treatment dates

were included. The inclusion criteria were well defined and straightforward, such as primary wavefront-guided procedures with emmetropia as the surgical goal. This helped reduce patient-selection bias. Second, to reduce observer bias, the questionnaire was self-administered in a private area of the clinic and no clinic personnel had access to the results. Third, the sample size was very large (5,563 patients) and resulted in having patients within each pupil size category, reducing the effect of individual variability. It also enabled a robust analysis of those who did not complete a questionnaire. Most importantly, there was no difference in distribution of low-light pupil size between those who did not attend the postoperative examination, those who did not complete the questionnaire, and those in the study. Patients with large pupils were neither more nor less likely to decline answering the questionnaire than those who completed it. Although the study objective was to evaluate patient-reported quality of vision symptoms, an additional limitation was that, other than high contrast visual acuity, no other objective testing was conducted to evaluate visual quality (eg, contrast sensitivity).

This study only analyzed 1-month outcomes. However, many reports have demonstrated that visual symptoms improve with time.^{19,32,33} Thus, if the pupil is not predictive of visual symptoms at 1 month postoperatively, it is not anticipated that it would be predictive in later postoperative time periods.

Low-light pupil diameter was not found to be predictive of 1-month, patient-reported outcomes in a large sample of young patients with myopia treated with femtosecond flap, wavefront-guided LASIK. Postoperative refraction and uncorrected distance visual acuity were correlated to patient satisfaction and visual symptoms. This study supports the results of other studies regarding the absence of a relationship between pupil size and quality of vision symptoms after laser vision correction.

AUTHOR CONTRIBUTIONS

Design and concept of the study (SS); data collection (KH, MB, SH, SS, JV); analysis and interpretation of the data (MB, SH, SS); writing the manuscript (SH, SS); critical revision of the manuscript (JV, KH, MB, SS); statistical expertise (KH); administrative, technical, or material support (MB, SH)

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TABLE A
Studies Evaluating the Relationship Between Low-light Pupil Diameter and Quality of Vision After Laser Vision Correction

Study	Procedure	Patients	Follow-up (mo)	Result
Haw and Manche ¹ (2001)	PRK	56	12	No correlation
Schallhorn et al. ¹⁸ (2003)	LASIK	100	6	No correlation ^a
Lee et al. ⁴ (2003)	LASIK	32	6	No correlation
Bailey et al. ²⁸ (2003)	LASIK	604	6	No correlation
Pop and Payette ¹⁷ (2004)	LASIK	795	12	No correlation
Tahzib et al. ²⁹ (2004)	LASIK	142	4–36	No correlation
Helgesen et al. ⁹ (2004)	LASIK	46	3	Positive
Tuan ²⁷ (2006)	LASIK	274	6	No correlation
Schmidt et al. ¹⁵ (2007)	LASIK	97	6	No correlation
Villa et al. ¹⁶ (2007)	LASIK	55	3–6	No correlation
Chan and Manche ¹⁴ (2011)	LASIK	51	12	No correlation

PRK = photorefractive keratectomy

^aA weak correlation was found at 1 month postoperatively but not at 3, 6, or 12 months.

APPENDIX A

1-Month Patient Questionnaire

Parameter

How satisfied are you with the outcome of your refractive procedure?

- Very satisfied
- Satisfied
- Neither satisfied nor dissatisfied
- Dissatisfied
- Very dissatisfied

During the last week, how much difficulty do you now have with your vision at night because of glare around bright lights (as you normally function at night either wearing spectacles, contact lenses, or no correction)?

- No difficulty
- A little difficulty
- Moderate difficulty
- Severe difficulty

During the last week, how much difficulty do you now have with your vision at night because of starburst or halos around bright lights (as you normally function at night either wearing spectacles, contact lenses, or no correction)?

- No difficulty
- A little difficulty
- Moderate difficulty
- Severe difficulty

How has your procedure affected your ability to drive at night (as you normally drive either wearing spectacles, contact lenses, or no correction)?

- Significantly improved
- Improved
- Not affected
- Impaired
- Significantly impaired
- I don't drive because of my vision
- I don't driver for other reasons