Risk Factors for Night Vision Complaints after LASIK for Myopia

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Purpose: To study the preoperative risk factors for night vision complaints (NVCs) after LASIK in a clinical setting.

Design: Retrospective noncomparative case series.

Participants: Seven hundred ninety-five patients (1488 eyes) who underwent LASIK for myopia up to −9.75 diopters (D) (from January 1 to December 31, 1999).

Setting: Private clinic.

Methods: A complete preoperative examination was performed. Patients had bilateral LASIK surgery using the Nidek EC-5000 non–wavefront guided slit-scanning excimer laser and the Moria LSK One microkeratome. Patients were observed postoperatively for 12 months.

Main Outcome Measures: The reported NVCs for each eye were rated on a subjective scale based on functional visual comfort. Clinically important NVC odds ratios (ORs) were calculated.

Results: Reports of NVCs decreased considerably from 25.6% at 1 month to 4.7% at 12 months postoperatively, at which time all patients reported similar NVCs in both eyes. Stratification of risk factors at 12 months postoperatively showed a 2.8-times increase in NVCs for initial myopia of >5 D, a 2.5-times increase for an optical zone of ≤6.0 mm, and a 2.9-times increase for a postoperative spherical equivalent outside ±0.5 D of emmetropia. The role of attempted spherical correction, age of the patient, and postoperative spherical equivalent had significant importance in logistic regression of the OR throughout the first postoperative year. In a stepwise logistic regression using 6- and 12-month data, attempted spherical correction and optical zone were the most predictive factors of NVCs ($P<0.001$). Pupil size at any month postoperatively was not statistically predictive of postoperative NVCs in any differential model involving it.

Conclusions: Attempted degree of spherical correction, age, optical zone, and postoperative spherical equivalent were major risk factors of NVCs throughout the first postoperative year, whereas pupil size was not. Future wavefront studies that characterize higher order aberrations might be helpful for understanding individual visual aberrations while predicting quality of vision. *Ophthalmology 2004;111:3–10 © 2004 by the American Academy of Ophthalmology.*

The potential for excimer laser refractive surgery to induce clinically important night vision complaints (NVCs) was recognized soon after its introduction, when investigators theorized that small optical zones (OZs) would diverge marginal rays and, thereby, might produce visual aberrations in low light illumination.[1,2] In one early clinical study, problems with halos after photorefractive keratectomy (PRK) were reported to be no worse than those associated with myopic spectacle or contact lens wear.[3] However, topographic spherical aberrations were correlated with halos and starbursts,[4] and initial studies using first-generation lasers reported post-PRK NVC rates of 10% to 60%.[5–7] In 1994, some authors reported 51% to 38% NVC rates from 3 to 12 months postoperatively after PRK using an Excimed laser (Summit Technology, Inc., Waltham, MA).[8] In 1998, using the same type of laser, authors reported a 6-year post-PRK complaint rate of 12%.[9] In 2000, a study surveying 690 patients at 4 to 30 months after PRK reported that 31% had increased difficulty with vision at night.[10]

In 1996, concerns were brought forward about potential adverse consequences of excimer laser surgery in eyes with a pupil size larger than 8 mm and for high myopia[11]; surgeons started to evaluate pupil size before refractive surgery. In 1998, based on the observation that postoperative visual aberrations were minimal in daytime illumination, but increased with dim lighting, large 6-mm OZs were suggested to reduce coma and spherical-like aberrations.[12] Because early PRK was performed with an OZ of 3 to 4.5 mm, it was soon found that larger OZs, up to 6 mm, were associated with less NVCs.[13–16]

Some authors proposed that a 1-mm difference between the OZ and pupil size should be maintained to lower the incidence of halos.[17] Optical zone enlargement based on this concept was used successfully to treat halos.[18,19]

Although no clear phenomena have been identified for predicting postoperative NVCs, surgeons use a variety of

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clinical strategies to minimize its risk. Pupil size has been the suspected highlighted variable of NVCs; however, its role remains hypothetically based on optical theory.

The present study, based on 1488 eyes, is an attempt to elucidate risk factors of NVCs in a clinical setting.[20]

Patients and Methods

Patients

All consecutive patients undergoing LASIK between January 1 and December 31, 1999 for treatment of myopia up to –10 diopters (D) were eligible for inclusion in this study. Bilateral surgery was performed on the same day; all patients gave their informed consent.

Refractive Surgery

All LASIK procedures were performed by one surgeon (MP) using a Moria (Antony, France) LSK One microkeratome with the 130-μm thickness plate and the Nidek EC-5000 slit-scanning laser, software version 2.25 (Nidek Co., Tokyo, Japan), without an eyetracker. The excimer laser used non–wavefront guided ablations. The standardized LASIK procedure was identical to the procedure described in a previous study.[21]

Topical anesthesia (proparacaine 0.5% drops [Alcaine, Allergan, Montreal, Canada]) was instilled. The laser was set at 40 Hz, removing 0.6 μm per scan, with a 5.5- to 6.5-mm OZ and a transition zone (TZ) of 6.0 to 8.5 mm. Computed OZs and TZs were programmed into the laser computer by the surgeon; a gradual change in postoperative curve occurred from the limit of OZs to the limit of TZs. Thus, the TZ was a progressive change from the calculated postoperative curvature to the remaining preoperative curvature at the periphery. Calculations were made to leave at least 250 μm or half the total of corneal depth, whichever was greater. A nomogram was used to compensate for the overcorrection known before the study. Although spherical correction symmetrically treated steep and flat meridians of the cornea, astigmatism correction was performed on the steep meridian only.

Postoperative treatment consisted of topical 0.3% ofloxacin (Ocuflox, Allergan) 4 times daily for 1 week and topical 0.1% fluorometholone (FML; Allergan) 4 times daily for 1 week.

Examinations

Patients were evaluated preoperatively and postoperatively at 24 hours and 1, 3, 6, and 12 months after surgery. At all follow-ups, assessments included subjective refraction, Snellen best spectacle-corrected visual acuity (BSCVA) and uncorrected visual acuity (UCVA), corneal topography, and slit-lamp examination. Preoperatively, eye dominance was evaluated and pupil size was measured in scotopic conditions using the Colvard pupillometer (Oasis Medical, Glendora, CA) to the nearest 0.5 mm. Corneal haze and NVCs were evaluated at postoperative visits. All follow-ups were performed at the same location as the surgery by 2 optometrists who were especially trained in post-LASIK examinations.

Subjective Rating of NVCs

Subjective ratings of NVCs were recorded using a subjective scale of *none, mild* (halos, starburst, or acuity distortion noted to affect light sources at night but not interfering with function), *moderate* (halos or starburst noted to affect usual activities, especially while driving or looking at light sources at night), or *disturbing* (halos or starburst forced the patient to restrain from certain activities at night, such as driving or looking at light sources). Patients were first asked by the examining optometrist if they experienced any night vision disturbances. The classification *none* was applied for both eyes if the patient answered no; otherwise, the severity of complaints was determined for each eye separately using the above definitions.

Clinically Important NVCs

Clinically important NVCs were defined as the ones having an impact on important daily visual functional activities. Therefore, we separated absent or mild symptoms from moderate or disturbing NVCs. Using this approach, we investigated NVC risk factors.

Differential Models

Authors have suggested that the difference between the pupil size and the OZ may be relevant to multifocality effects; small differences between pupil size and OZ may help reduce the risks of postoperative halos after LASIK.[17] Using these theories, we calculated for each eye the difference, in millimeters, between the pupil size and the OZ or the TZ: (1) differential OZ = pupil size − OZ size, and (2) differential TZ = pupil size − TZ size.

Statistical Analysis

The Mantel–Haenszel method of data stratification was used to show changes in odds ratios (ORs); stratified data may reveal interactions of variables.

The logistic regression analysis is a robust technique to calculate the probability of odds; in this study, it evaluated the odds of accurately predicting NVCs. In a similar manner, the backward stepwise logistic multiple regression (LMR) used several preoperative factors to determine the best models. To avoid multicolinearity dependence, variables used in modelization were selected on the distinctiveness of their biologic significance: pupil size, OZ size, TZ size, patient age, attempted spherical or cylinder correction, initial mean keratometry, and postoperative spherical equivalent.

Foxpro 2.6 (Microsoft, Redmond, WA) was used for data compilation. SPSS 8 (SPSS Inc., Chicago, IL) was used for analysis of variance, Kruskal–Wallis nonparametrical testing, chi-square tests with Yates correction, logistic regression, and LMR. For the logistic regressions, Hosmer–Lemeshow goodness of fit was tested if expected odds were different then actual data; a P value of ≤ 0.05 was used for variables entry and removal in LMR. Odds ratio confidence intervals were calculated using Epicalc 2000 (Gilman J, Myatt MA, Brixton Health, Llanidloes, United Kingdom).

Results

Refractive Surgery

Laser in situ keratomileusis was performed on 1488 consecutive eyes (757 right, 731 left) in 795 patients (442 women, 353 men) for myopia up to −9.75 D and astigmatism up to −3.75 D. The mean preoperative spherical equivalent was −4.32±1.78 D. Patients' mean age was 36±10 years (range = 18−63). The mean pupil size was 6.6±1.1 mm (range = 3–9). Fifty-seven percent of eyes required no astigmatism correction. Preoperative BSCVA was 20/40 or better in all eyes but one. The latter eye had a BSCVA of 20/50 and was considered fit for surgery, but developed

Table 1. Study Profile

Time Period	No. of Eyes Initial Treatment	No. of Eyes Missing from Last Period	No. of Eyes Re-treated
Preoperative	1488	NA	NA
1 mo	1427	30	31
3 mos	1010	363	54
6 mos	962	18	30
12 mos	752	189	21

NA = not applicable.

a cataract 18 months after LASIK, which was extracted. No infections occurred postoperatively. Seven hundred fifty-two eyes (427 patients) were followed after initial treatment up to 1 year postoperatively (Table 1). One hundred sixty-one eyes (136 patients) were re-treated. At 1 year postoperatively, 600 eyes were lost to follow-up. Including retreatments, 888 eyes (59.7% of the total) were followed up to 1 year postoperatively.

At 12 months after initial LASIK, 78% of eyes were within ±0.5 D of emmetropia and 92% of eyes within ±1 D; 7 eyes (0.8%) were not within ±2 D of emmetropia and had residual myopia up to –3 D. Five of these eyes were targeted for monovision, but resulted in higher residual myopia than predicted; 2 eyes regressed to a lower degree of myopia during the following postoperative year. Eyes lost to follow-up before 12 months postoperatively did not have statistically different proportions of eyes within emmetropia ($P = 0.99$) using last known refraction.

At 12 months postoperatively, 72% of eyes had UCVA of 20/20 or better and 94% had UCVA of 20/40 or better. All eyes had BSCVA of 20/40 or better, and 98% of them had 20/20 or better; before surgery, only 95% of eyes had BSCVA of 20/20 or better. One hundred forty-four eyes (18%) gained 1 line of BSCVA. No eye lost 2 lines of BSCVA after the first postoperative month. Eyes lost to follow-up before 12 months postoperative did not have statistically different proportions of UCVA ($P = 0.35$), using the last known UCVA.

Using the last known postoperative follow-up, 70% of eyes had UCVA of 20/20 or better and 92% had UCVA of 20/40 or better. No eye lost 2 lines of BSCVA. Residual myopic correction was prescribed for 20 patients (2.5%), whereas correction for presbyopia was prescribed for 26 patients (3.3%).

Postoperative NVC Prevalence

Overall NVCs considerably decreased from 25.6% at 1 month to 4.7% at 12 months postoperatively (Table 2). Of eyes that had a retreatment, 6.8% had NVCs at 12 months postoperatively. Only the first postoperative month was found to have significantly more NVCs after a retreatment ($P<0.001$).

Analysis of patients who had bilateral surgery showed that the intensity of reported NVCs was highly symmetrical between the two eyes (Table 3). All patients reported NVC in both eyes at 6 and 12 months postoperatively.

Table 4 summarizes mean values for the preoperative factors based on a 12-month visit after initial surgery. Statistically significant differences were found between NVC and other eyes for attempted spherical correction, age, OZ, and postoperative spherical equivalent at $P<0.05$.

Stratification of NVC Risk Factors at 12 Months Postoperatively

All data after initial surgery were stratified according to preselected factors of risks: pupil size of >7 mm, age over 50 years, attempted spherical myopic correction of >5 D, OZ of ≤6 mm, TZ of ≤7 mm, preoperative mean keratometry of >44 D, achieved

Table 2. Postoperative Night Vision Complaints

Postoperative Month	Initial-Treatment *No. of NVCs*	Initial-Treatment *Total Followed Eyes*	Initial-Treatment *% of Eyes with NVCs*	Re-treated Eyes *No. of NVCs*	Re-treated Eyes *Total Followed Eyes*	Re-treated Eyes *% of Eyes with NVCs*
1	365	1427	25.6	42	103	40.1
3	125	1010	12.4	12	57	21.1
6	68	962	7.1	5	52	9.6
12	35	752	4.7	4	59	6.8

NVCs = clinically important night vision complaints.

Table 3. Symmetry of Bilateral Night Vision Complaints by Patients (Re-treated Patients Excluded)

Postoperative Month	Both Eyes with No NVCs *N*	Both Eyes with No NVCs %*	Both Eyes with NVCs *N*	Both Eyes with NVCs %*	Only One Eye with NVCs *N*	Only One Eye with NVCs %*	Total Patients[†]
1	483	73.7	165	25.2	7	1.1	655
3	402	87.4	55	12.0	3	0.6	460
6	396	92.7	31	7.3	0	0	427
12	309	95.1	16	4.9	0	0	325

NVCs = clinically important night vision complaints.
*Of total patients.
[†] With bilateral surgery.

Table 4. Night Vision Complaint Differences between Factors Using 12-Month Postoperative Data

Factors	NVCs (35 Eyes) [Mean ± SD (Range)]	None (717 Eyes) [Mean ± SD (range)]	*P*
Pupil size	6.3±0.9 (4.0–7.5)	6.6±1.1 (3.0–9.0)	0.18
Age	41.0±8.2 (28–57)	36.6±9.8 (18–46)	0.009*
Attempted spherical correction	−4.54±1.60 (−2.25 to −8.50)	−3.94±1.66 (plano to −9.75)	0.039*
Attempted cylindrical correction	−0.56±0.72 (plano to −2.75)	−0.63±0.73 (plano to −3.50)	0.59
Optical zone	6.1±0.2 (6.0–6.5)	6.2±0.3 (5.5–6.5)	0.017*
Transition zone	7.3±0.2 (7.0–7.5)	7.4±0.3 (6.0–8.5)	0.41
Mean keratometry	43.75±0.92 (42.48–45.50)	43.83±1.30 (39.57–47.79)	0.71
Postoperative SE	−0.56±0.63 (−1.88 to 0.88)	−0.27±0.64 (3.75 to 1.63)	0.012*
Differential OZ	0.2±0.8 (−2.0 to 1.5)	0.3±1.0 (−3.0 to 3.0)	0.44
Differential TZ	−1.0±0.9 (−3.0 to 0.5)	−0.8±1.1 (−4.5 to 1.5)	0.29

NVC = clinically important night vision complaint; OZ = optical zone (mm); SD = standard deviation; SE = spherical equivalent; TZ = transition zone (mm).
*Significant.

postoperative spherical equivalent outside 0.5 D of emmetropia or undercorrection higher than 1 D, differential size of pupil minus OZ greater than 0, and differential size of pupil minus TZ less than or equal to −1 mm (Table 5).

Using 12-month postoperative data, age over 50, attempted spherical correction of >5 D, OZ of ≤6 mm, and postoperative spherical equivalent outside 0.5 D of emmetropia were the main factors that had statistically significant OR without stratification (Table 5). Whenever stratified, ORs of these main factors were not affected by stratification by subfactors. A change in the overall Mantel–Haenszel OR after stratification would have signified an interaction of selected variables within the main factor; because no change was observed, statistically significant ORs of main factors were relatively independent from one another.

Multicolinearity of Variables

Multicolinearity dependency may point to interactions between factors. Attempted spherical and cylindrical correction, OZ and TZ, mean keratometry, pupil size, patient age, and postoperative spherical equivalent were used for logistic regression models. Interestingly, the postoperative spherical equivalent was correlated

Table 5. Stratification of Night Vision Complaint Risk Factors Using 12-Month Postoperative Data (N = 752 eyes)

Factors	Stratification	OR$_{(MH)}$ (95% CI)	*P*
Pupil ≥ 7 mm	None (main factor)	0.92 (0.47–1.82)	0.82
Pupil ≥ 7 mm	Sphere > 5 D*	0.92 (0.46–1.82)	0.94
Pupil ≥ 7 mm	Sphere > 5 D* and OZ ≤ 6 mm	1.26 (0.60–2.64)	0.68
Pupil ≥ 7 mm	Age ≥ 50 yrs	1.03 (0.51–2.06)	0.92
Age ≥ 50 yrs	None (main factor)	2.47 (1.04–5.86)	0.04[†]
Age ≥ 50 yrs	Sphere > 5 D*	2.32 (0.97–5.56)	0.10
Age ≥ 50 yrs	Sphere > 5 D* and OZ ≤ 6 mm	2.30 (0.96–5.47)	0.09
Age ≥ 50 yrs	Pupil ≥ 7 mm	2.48 (1.03–6.02)	0.08
Attempted spherical correction > 5 D	None (main factor)	2.81 (1.41–5.56)	0.002[†]
Attempted spherical correction > 5 D	OZ ≤ 6 mm	2.66 (1.33–5.35)	0.008[†]
Attempted spherical correction > 5 D	Pupil ≥ 7 mm	2.80 (1.40–5.60)	0.005[†]
Attempted cylindrical correction > 1 D	None (main factor)	1.63 (0.48–5.56)	0.43
OZ ≤ 6 mm	None (main factor)	2.51 (1.19–5.31)	0.01[†]
OZ ≤ 6 mm	Sphere > 5 D*	2.41 (1.14–5.11)	0.03[†]
OZ ≤ 6 mm	Pupil ≥ 7 mm	2.92 (1.29–6.61)	0.02[†]
TZ ≤ 7 mm	None (main factor)	1.35 (0.65–2.81)	0.42
K > 44 D	None (main factor)	0.96 (0.49–1.91)	0.92
Postoperative SE <> 0.5 D	None (main factor)	2.85 (1.44–5.64)	0.002[†]
Postoperative SE <> 0.5 D	Sphere > 5 D*	2.48 (1.24–4.96)	0.014[†]
Postoperative SE <> 0.5 D	Pupil ≥ 7 mm	2.97 (1.46–6.02)	0.004[†]
Postoperative SE ≤ −1 D	None (main factor)	1.49 (0.56–3.97)	0.42
Postoperative SE ≤ −1 D	Sphere > 5 D*	1.25 (0.46–3.44)	0.87
Postoperative SE ≤ −1 D	Sphere > 5 D* and OZ ≤ 6 mm	1.09 (0.40–2.99)	0.92
Postoperative SE ≤ −1 D	Pupil ≥ 7 mm	1.46 (0.55–3.86)	0.63
Differential pupil − OZ > 0 mm	None (main factor)	1.06 (0.53–2.11)	0.87
Differential pupil − TZ ≤ 1 mm	None (main factor)	1.03 (0.51–2.08)	0.94

CI = confidence interval; D = diopters; K = keratometry; OR$_{(MH)}$ = odds ratio calculated with the Mantel–Haenszel method for stratification; OZ = optical zone (mm); SE = spherical equivalent; TZ = transition zone (mm).
*Attempted spherical correction.
[†] Significant.

Table 6. Multicolinearity Pearson Correlation Matrix of Factors (Coefficient/Probability)

Factors	Age	Pupil	Sphere*	Cylinder	OZ	TZ	Mean K
Pupil	−0.36						
	<0.001‡						
Sphere*	−0.01	−0.04					
	0.95	0.25					
Cylinder†	−0.03	0.06	−0.01				
	0.36	0.12	0.82				
OZ	−0.03	0.35	−0.01	0.05			
	0.40	<0.001‡	0.88	0.15			
TZ	−0.14	0.28	0.27	0.09	0.12		
	<0.001‡	<0.001‡	<0.001‡	0.02‡	0.001‡		
Mean K	−0.03	−0.1	−0.11	0.04	−0.01	−0.03	
	0.45	0.004‡	0.002‡	0.34	0.79	0.37	
Postoperative SE§	−0.33	0.13	0.16	0.09	0.11	0.14	0.02
	<0.001‡	0.001‡	<0.001‡	0.01‡	0.002‡	<0.001‡	0.68

K = keratometry; OZ = optical zone (mm); TZ = transition zone (mm).
*Attempted spherical correction.
†Attempted cylindrical correction.
‡Significant.
§Last known spherical equivalent.

with all other factors ($P<0.05$), except for preoperative keratometry (Table 6). Pupil size was statistically correlated with age, OZ, TZ, keratometry, and postoperative spherical equivalent ($P<0.05$). Transition zone was associated with OZ, attempted spherical and cylindrical correction, pupil size, and patient age.

Logistic Regression of NVCs

Odds ratios of studied factors were analyzed independently at all postoperative months; Table 7 summarizes the findings from the logistic regression models performed using data from each of the follow-up visits. Attempted spherical correction, age, and postoperative spherical equivalent were predictive of OR at any postoperative period. Other factors, such as attempted cylindrical correction and TZ, showed an erratic pattern and were significant at some specific postoperative months only. Optic zone was predictive of OR only at 6 and 12 months postoperatively.

It has to be noted that the OR for attempted spherical correction was 0.82 at 12 months postoperatively, indicating that low myopia had a protective effect on NVC odds. The opposite was noted for the age of the patient, with an OR of 1.04; older patient age increased the odds of NVCs. As for the OZ, its OR was 0.19 at 12

Table 7. Logistic Regression Models

Models	NVC OR at Postoperative Months			
	1–mo OR (95% CI) (P)	*3-mo OR (95% CI) (P)*	*6-mo OR (95% CI) (P)*	*12-mo OR (95% CI) (P)*
Pupil size	1.03 (0.93–1.15) (0.58)	1.02 (0.87–1.20) (0.80)	0.98 (0.79–1.22) (0.87)	0.81 (0.60–1.10) (0.18)
Age	1.01 (1.00–1.03) (0.04)*	1.02 (1.00–1.04) (0.02)*	1.04 (1.01–1.07) (0.006)*	1.04 (1.01–1.08) (0.01)*
Attempted spherical correction	0.87 (0.82–0.94) (<0.0001)*	0.80 (0.72–0.88) (<0.0001)*	0.76 (0.66–0.87) (<0.0001)*	0.82 (0.66–0.99) (0.04)*
Attempted cylindrical correction	0.93 (0.79–1.10) (0.42)	0.74 (0.58–0.94) (0.01)*	0.81 (0.58–1.11) (0.20)	1.14 (0.70–1.87) (0.59)
OZ	0.94 (0.58–1.51) (0.81)	1.01 (0.48–2.60) (0.98)	0.24 (0.09–0.64) (0.005)*	0.19 (0.05–0.77) (0.02)*
TZ	0.84 (0.59–1.18) (0.32)	0.39 (0.24–0.65) (0.003)*	0.37 (0.21–0.70) (0.002)*	0.66 (0.24–1.78) (0.41)
Initial keratometry	0.96 (0.88–1.05) (0.36)	0.94 (0.81–1.08) (0.38)	1.07 (0.89–1.29) (0.45)	0.95 (0.73–1.23) (0.71)
Postoperative spherical equivalent	0.64 (0.58–0.74) (<0.0001)*	0.70 (0.55–0.90) (0.005)*	0.61 (0.44–0.83) (0.002)*	0.57 (0.37–0.89) (0.01)*
Differential pupil − OZ	1.03 (0.92–1.16) (0.56)	1.0 (0.84–1.19) (0.99)	1.08 (0.85–1.36) (0.52)	0.88 (0.64–1.22) (0.44)
Differential pupil − TZ	1.05 (0.93–1.18) (0.39)	1.11 (0.93–1.32) (0.25)	1.12 (0.89–1.42) (0.34)	0.84 (0.61–1.15) (0.28)
Backward stepwise logistic multiple regression using all factors†	Sphere,‡ 0.92 (0.85–0.99) (<0.0001)*	Sphere,‡ 0.78 (0.69–0.88) (0.0001)*	Sphere,‡ 0.76 (0.66–0.87) (0.001)*	Sphere‡ 0.82 (0.68–1.00) (0.04)*
	SE, 0.67 (0.57–0.78) (0.018)*	Cylinder,§ 0.73 (0.55–0.98) (0.04)*	OZ, 0.23 (0.08–0.64) (0.005)*	OZ, 0.18 (0.04–0.81) (0.02)*

CI = confidence interval; NVC = clinically important night vision complaints; OR = odds ratio; OZ = optical zone (mm); SE = postoperative spherical equivalent; TZ = transition zone (mm).
*Significant at <0.05.
†Factors were pupil size, age, attempted spherical correction, attempted cylindrical correction, OZ, TZ, initial keratometry, and SE.
‡Attempted spherical correction.
§Attempted cylindrical correction.

months postoperatively, demonstrative of a protective effect of larger OZs.

Taken separately, pupil size and keratometry were found not to be good predictors of NVCs at any postoperative months. In the same manner, models involving differential pupil size minus OZ or minus TZ were also not predictive of odds at any postoperative months (Table 7).

Of the preoperative variables included in the LMR (Table 7), attempted spherical correction and OZ were found to be the most significant predictors of NVCs at 6 and 12 months postoperatively after initial LASIK. The LMR model was validated by Hosmer–Lemeshow goodness of fit ($P = 0.20$).

A final statistical analysis was performed with all data using time periods as a covariate factor in the model; the Cox proportional hazard model established time–event risks ratio adjusted with all factors of pooled postoperative data from 1 to 12 months. To distinguish from missing follow-ups, re-treated eyes were also identified and included in the model. Results of the Cox logistic regression showed that attempted spherical correction, postoperative spherical equivalent, age, and retreatment were significant factors in the model ($P<0.001$).

Discussion

NVCs after LASIK in a Clinical Setting

Using a simple scale for evaluation of NVCs and a large number of eyes, the present study attempted to report on the prevalence of NVCs in a clinical setting. Thus, we expect that our findings could be representative of other clinics performing refractive surgery in the same manner using non–wavefront guided ablations.

Our results from follow-up of a large cohort of patients undergoing LASIK for treatment of myopia or myopic astigmatism show that NVCs are present early after surgery for 26% of patients at 1 month postoperatively, but their incidence decreases over time. By 12 months after LASIK, 4.7% of eyes had NVCs. We did not find any differences between NVCs after initial treatment and NVCs 12 months after retreatment. An article on the time-related reduction of glare and halo after LASIK has been published previously.[22]

The difficulty in establishing an objective quantification of NVCs has been recognized.[10] In itself, an NVC may be a subjective experience that cannot easily relate patients, and the present study is limited by such a definition. In selected patients with unilateral LASIK affected by NVCs, an increase in activation of visual cortical areas of the affected LASIK eye was observed by magnetic resonance when compared with the contralateral unoperated eye. No activation was found in the reverse comparison: stimulation of the unaffected eye versus the affected eye.[23] Therefore, although subjective evaluation of NVCs may be biased by an internal scaling factor of visual comfort, we might expect functional disabling complaints to be related to actual individual optical aberrations of each eye. However, consistent with our previous report,[24] we observed considerable symmetry in NVCs between eyes. Thus, the present study cannot conclude that the symmetry of reported NVCs is due to either the symmetry of preoperative risk factors or a cortical interference between eyes while visual function is assessed.

Our analyses indicated that factors such as of pupil size and initial keratometry were not primary factors responsible for NVCs. However, the role of attempted spherical correction, age of the patient, and postoperative spherical equivalent had significant importance in logistic regression of ORs throughout all postoperative periods. When analyzed in a relational model using time periods as a covariate, the Cox logistic regression showed again the importance of these factors throughout the initial postoperative year. Additionally, in a stepwise regression model using 6- and 12-month data, attempted spherical correction and OZ were the most predictive factors of NVCs.

Although extensive statistical analysis of data after initial surgery was performed, projected ORs cannot replace a study where no loss of follow-up may have occurred. However, we believe that the ORs found using the present study methodology are representative of the true OR, for 3 reasons. First, the study is based on at least 752 eyes up to 12 months postoperatively. Second, at least the same 3 factors remained significant throughout all postoperative months when analyzed on a month-by-month basis using logistic regression, or using the Cox proportional analysis with the pooled data from 1 to 12 months postoperatively. Third, the decrease in postoperative prevalence of NVCs over time is similar for eyes with or without retreatments.

Patient age showed significant importance in predicting NVCs. We believe that age may have been a confounding factor that remains to be further studied. Furthermore, we did not evaluate the role of accommodation for younger patients with regard to NVCs.

As pupil size was not a risk factor in NVC odds, neither were the differential models involving it. Even though the OZ proved to be predictive of odds at 6 and 12 months postoperatively, the differential model of pupil size minus OZ was not, again undermining the role of pupil size.

Role of Attempted Correction and OZ

It has been shown that LASIK creates wavefront aberrations, especially from third order and above. As previously reported, attempted correction and amount of tissue removed seem to be related to NVCs.[25–29] In the present study, because NVCs clearly increased for greater amounts of attempted spherical corrections, supplemental studies should specifically target the relation of tissue removal versus wavefront aberrations. Studies on the relation between NVCs and optical aberrations are essential to answer the question of how many and which types of optical aberrations are enough to cause NVCs. The amount of aberrations created by the microkeratome only should also be studied separately.

Previous studies have shown the importance of the OZ in the management of postoperative NVCs.[8,13–16] The present study also confirmed the importance of the OZ in the management of NVCs. For example, the LMR model would predict that an eye with –6 D of myopia would have a 4% chance of having NVCs at 12 months postoperatively using a 6.5-mm OZ, whereas it would be 1.8% using a 7.0-mm

OZ. Mathematically, the importance of the OZ increases for higher myopia. With a maximum tolerance of 1% risk, attempted correction of –3 D limits the OZ to a minimal size of 7.0 mm, although these figures are based on standard excimer laser ablations, not wavefront-guided ablations. While attempting high myopic correction with a small OZ, the risks of obtaining NVCs at 12 months postoperatively increases. This is why surgeons should avoid reducing the OZ for higher myopia to minimize corneal depth ablation. In the case of LASIK for myopia greater than −6 D, if pachymetry is insufficient for a large OZ, corneal refractive surgery should be avoided. Calculation of ablation depth is also dependent on the type of excimer laser used, so the mathematical solutions given in the present study may not be applicable for other types of lasers, though the principle may be the same.

The Pupil Issue

Unexpectedly, pupil size was not found to be among significative variables for accurate prediction of NVC, nor was it part of any significative models predicting NVCs. Some authors have already reported that there was no statistically significant contribution of preoperative pupil size to NVCs[29,30]; pupil size was not significantly correlated with glare or halo symptoms, BSCVA, or contrast sensitivity in post-LASIK patients who had scotopic pupils not larger than 7 mm.[31] Findings from our study concur with these authors. Consequently, some of the patients reporting NVCs in this study had pupil size as low as 4 mm.

We believe the role of pupil size in postoperative NVCs has been overrated. The use of pupil size to predict NVC risks is not justified. Standard pupil measurement can be biased by 0.5 mm between 2 different examiners, and should be improved.[32] However, even if measured more precisely, pupil size may not be the most important clinical predictor of postoperative NVCs, because other variables demonstrated a high degree of statistical significance.

The Future

The understanding of individual interactions of the aberrations in the ocular components of the eye is critical to understanding individual outcomes and NVCs.[33] In the future, we believe that prediction of NVCs will be made by schematic eye models using actual wavefront for simulation of the patient's visual performance,[34] combined with analysis of point spread functions, modular transfer functions,[35] Strehl ratio, and asphericity[36] as variables in this model. In future studies, the effect of pupil size, although not significative as a diagnostic tool for assessing potential risks of NVCs, may redeem its importance in visual function under the presence of high order optical aberrations.[34,35,37]

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