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Symptoms and Satisfaction of Patients in the Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) Studies

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IMPORTANCE Patient-reported outcomes should be collected using validated questionnaires prior to and following laser in situ keratomileusis (LASIK) surgery.

OBJECTIVE To report the frequency of patient-reported visual symptoms, dry eye symptoms, satisfaction with vision, and satisfaction with LASIK surgery in the Patient-Reported Outcomes With LASIK (PROWL) studies.

DESIGN, SETTING, AND PARTICIPANTS The PROWL-1 and PROWL-2 studies were prospective, observational studies conducted from September 13, 2011, to June 27, 2014. The PROWL-1 study was a single–military center study of 262 active-duty Navy personnel 21 to 52 years of age. The PROWL-2 study was a study of 312 civilians 21 to 57 years of age conducted at 5 private practice and academic centers. The LASIK surgery and the postoperative care were performed based on the usual practice and clinical judgment at the site. Participants completed a self-administered, web-based questionnaire, preoperatively and postoperatively at 1 and 3 months (the PROWL-1 and -2 studies) and at 6 months (the PROWL-2 study).

EXPOSURES Participants underwent LASIK surgery for myopia, hyperopia, and/or astigmatism.

MAIN OUTCOMES AND MEASURES Visual symptoms (double images, glare, halos, and/or starbursts), dry eye symptoms, participant satisfaction (with vision and LASIK surgery), and clinical measures (visual acuity, refractive error, and slitlamp and posterior segment eye examination findings) were assessed preoperatively and at 1, 3, and 6 months postoperatively.

RESULTS A total of 262 participants were enrolled in the PROWL-1 study (mean [SD] age, 29.1 [6.1] years), and a total of 312 participants were enrolled in the PROWL-2 study (mean [SD] age, 31.5 [7.3] years). Visual symptoms and dissatisfaction with vision were common preoperatively. Overall, the prevalence of visual symptoms and dry eye symptoms decreased, although a substantial percentage of participants reported new visual symptoms after surgery (43% [95% CI, 31%-55%] from the PROWL-1 study and 46% [95% CI, 33%-58%] from the PROWL-2 study at 3 months). The percentages of participants in the PROWL-1 study with normal Ocular Surface Disease Index scores were 55% (95% CI, 48%-61%) at baseline, 66% (95% CI, 59%-72%) at 3 months, and 73% (95% CI, 67%-79%) at 6 months. The percentages of participants in the PROWL-2 study with normal Ocular Surface Disease Index scores were 44% (95% CI, 38%-50%) at baseline and 65% (95% CI, 59%-71%) at 3 months. Of those participants who had normal scores at baseline in both the PROWL-1 and -2 studies, about 28% (95% CI, 19%-37%) had mild, moderate, or severe dry eye symptoms at 3 months. While most participants were satisfied, the rates of dissatisfaction with vision ranged from 1% (95% CI, 0%-4%) to 4% (95% CI, 2%-7%), and the rates of dissatisfaction with surgery ranged from 1% (95% CI, 0%-4%) to 2% (95% CI, 1%-5%).

CONCLUSIONS AND RELEVANCE The systematic administration of a questionnaire to patients who have undergone LASIK surgery is a new approach to assess symptoms and satisfaction. Our findings support the need for adequate counseling about the possibility of developing new symptoms after LASIK surgery.

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Related article

Supplemental content

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The safety and effectiveness of laser in situ keratomileusis (LASIK) has been documented.[1-6] Some patients, however, report dry eye symptoms; problems with vision related to the presence of glare, halos, or starbursts; and dissatisfaction following LASIK surgery.[7-11] An enhanced understanding of the patient's experience following LASIK surgery requires questionnaires designed to assess visual and ocular symptoms and their effect on activities of daily living. Previous studies measuring the association of LASIK with quality of life have not focused on the effect of these symptoms on patients or have been limited by the use of questionnaires with incompletely reported psychometric properties.[10,12-14] Patient satisfaction has been assessed in many studies using only a single question and without examining associations with visual and ocular symptoms.[15-21] The Patient-Reported Outcomes With LASIK (PROWL) studies were conducted with the primary objective to evaluate the measurement properties of the PROWL questionnaire.[22] Exploratory analyses of the prevalence of functional limitations and satisfaction/dissatisfaction with the procedure are reported in this study.

Key Points

Question What are the rates of visual and ocular symptoms and the satisfaction prevalence among civilian and military patients who underwent laser in situ keratomileusis (LASIK) surgery?

Findings In 2 prospective, observational studies of participants undergoing LASIK surgery for myopia, hyperopia, and/or astigmatism, a large proportion reported decreases in visual symptoms, while many participants without visual symptoms at baseline developed symptoms following the procedure; participants were more likely to report visual symptoms on the questionnaire than to their health care professionals. Although visual symptoms were common, few participants reported functionally important limitations due to symptoms.

Meaning These findings suggest that the systematic administration of a valid questionnaire to patients who had undergone LASIK surgery more accurately assesses symptoms and satisfaction.

Methods

The PROWL-1 and -2 studies were prospective, observational cohort studies of participants undergoing LASIK surgery for myopia, hyperopia, and/or astigmatism. The PROWL-1 study was a single-center study of active-duty Navy military personnel; the study protocol was approved by the Naval Medical Center San Diego institutional review board in compliance with all applicable federal regulations governing the protection of human subjects. The PROWL-2 study was conducted at 5 private practice and academic centers. The PROWL-2 study was conducted under the US Food and Drug Administration Research Involving Human Subjects Committee, a central institutional review board for 3 sites, and university institutional review boards for 2 sites (Johns Hopkins University and Stanford University).

Ethics reviews and approvals were conducted and obtained by the institutional review boards of all the participating sites in both studies. All enrolled study participants provided written and oral informed consent. The participants in the PROWL-1 study did not receive any financial compensation per the rules of the military. The participants in the PROWL-2 study were compensated. The PROWL studies, although not clinical trials, are registered at Clinicaltrials.gov (NCT0152629 and NCT01655420 for the PROWL-1 and -2 studies, respectively). Both studies were compliant with the Health Insurance Portability and Accountability Act and adhered to the tenets of the Declaration of Helsinki.[23]

The PROWL-1 and PROWL-2 studies enrolled participants 21 years of age or older who had not had any form of refractive surgery and were determined to be good candidates for LASIK surgery based on each investigator's assessment. Details on enrollment criteria for the studies are summarized elsewhere.[22]

Unlike the experimental study design of clinical trials used to assess the safety and effectiveness of the lasers used in LASIK surgery, this observational study did not specify the care of the participants but limited the enrollment of participants to be consistent with the device label. Data on visual acuity, refractive error, slitlamp observations, dry eye signs, and adverse events were collected. All other surgical and perioperative care was administered according to the surgeon's usual practices. Participants were evaluated at baseline and postoperatively at 1 and 3 months (in the PROWL-1 and -2 studies) and at 6 months (in the PROWL-1 study). The durations of the studies were selected to evaluate the responsiveness of the questionnaire. The LASIK ablation was performed using lasers approved by the US Food and Drug Administration at the investigational site. Participants completed the questionnaires using a secure website. The sites did not have access to any participant's questionnaire data.

Each visual symptom (ie, halos, starbursts, glare, and double images) was accompanied by a definition and illustration showing gradations of symptom severity to use when answering the 8 questions for that symptom. Each item response was transformed linearly to a score with a possible range of 0 to 100 (with a higher score indicating a better condition). A scale score for each of the 4 visual symptoms was created by averaging the responses to the 8 questions.

Satisfaction with vision was assessed using a single item with 6 possible responses, ranging from "completely dissatisfied" to "completely satisfied." Satisfaction with surgery was assessed with 8 items averaged together to produce a scale score from 0 to 100, with a higher score indicating greater satisfaction. The Ocular Surface Disease Index (OSDI) scores, ranging from 0 to 100, were grouped as described by Miller et al[24] and Schiffman et al.[25]

All the participants enrolled in the 2 studies are defined as the *enrolled cohort*. Analyses of clinical measures were performed for those who had LASIK surgery, and these participants were defined as the *surgical cohort*. The *analytical cohort*, which is the term used for all PRO analyses, comprised participants who submitted the preoperative questionnaire and at least 1 postoperative questionnaire. Descriptive and inferential statistics were computed for all the variables using SAS

version 9.3 (SAS Institute). A visual symptom was considered present if the respondent reported it with or without correction. We defined the more problematic visual symptoms as those with responses in the 2 highest categories on items that elicit degree of "bother" and degree of difficulty with activities. All participants who reported being "mildly," "very," or "extremely" dissatisfied with vision were categorized as "dissatisfied with vision." To create a similar grouping for the multiitem satisfaction with surgery scale, we categorized participants with scores of 40 or lower as "dissatisfied with surgery" (at least "mildly dissatisfied" on the vision satisfaction scale) and those with scores of higher than 40 as "satisfied with surgery."

Exploratory analyses assessed the potential influence of various factors on satisfaction and symptoms scores. All correlations were performed using Spearman rank-order correlation coefficients. Correlations between visual symptom scores and the following were estimated: optical aberrations, OSDI scores, preoperative myopic manifest refraction spherical equivalent, and postoperative uncorrected visual acuity (UCVA) and manifest cylinder. Correlations between satisfaction scores and the following were calculated: OSDI scores, visual symptoms scores, and UCVA. (For manifest refraction spherical equivalent, UCVA, and cylinder, we used the eye with the more extreme value.) Correlations of less than 0.3 were considered low. We explored the associations between satisfaction scores of subgroups by calculating *P* values using the Mann-Whitney test. Because all analyses were exploratory, we did not adjust for multiplicity in testing. $P \leq .05$ was considered statistically significant.

Results

A total of 262 participants enrolled in the PROWL-1 study, and a total of 312 participants enrolled into the PROWL-2 study (**Table 1**). Of these, 242 participants in the PROWL-1 study and 292 participants in the PROWL-2 study had LASIK surgery. The percentages of surgically treated participants seen in the clinic were 97%, 93%, and 86% at 1, 3, and 6 months for the PROWL-1 study, respectively, and 97% and 92% at 1 and 3 months for the PROWL-2 study, respectively. The most common reason for loss to follow-up in the PROWL-1 study was deployment or transfer to a new military duty station. In the PROWL-2 study, the reasons for loss to follow-up were rarely provided. Compared with the participants in the PROWL-1 study, the participants in the PROWL-2 study were more often female, white, and, on average, 2 years older. Data on mean refractive error, sex, race, and age were similar in the enrolled, surgical, and analytical cohorts in both studies (Table 1).

A wavefront-guided excimer laser ablation profile was used in 45% of the PROWL-1 procedures and in 33% of the PROWL-2 procedures. A standardized aspheric ablation algorithm was used in 55% of the PROWL-1 procedures and in 64% of the PROWL-2 procedures. A conventional excimer laser ablation profile was used in 3% of the PROWL-2 procedures and in none of the PROWL-1 procedures. Flaps were created by femtosecond laser keratomes in 100% of the PROWL-1 procedures and in 98% of the PROWL-2 procedures.

Adverse events, intraoperative complications, and clinical outcomes are summarized in eTable 1 in the Supplement. The distributions of Oxford grades are shown in eTable 2 in the Supplement.

The percentages of participants in the PROWL-1 study with normal OSDI scores increased postoperatively from baseline (**Table 2**). Of those participants who had normal OSDI scores at baseline, 27% (95% CI, 20%-36%) of the participants in the PROWL-1 study and 28% (95% CI, 19%-37%) of the participants in the PROWL-2 study had dry eye symptoms at 3 months. Of the participants who had mild, moderate, or severe OSDI scores at baseline, 59% (95% CI, 49%-69%) of participants in both studies reported normal OSDI scores at 3 months.

Spearman correlations between OSDI (symptoms) and Oxford scores (signs) preoperatively and postoperatively were not significant except for in the PROWL-2 study at 3 months ($r_s = 0.19$, $P = .004$). Two or fewer participants in each study had Oxford scores greater than 2 at 3 or 6 months postoperatively, making further analyses uninformative.

The rates of visual symptoms reported on self-administered PROWL questionnaires were higher than the rates of visual symptoms reported to the investigators during clinic visits (in the PROWL-1 study, 50% [95% CI, 43%57%] vs 8% [95% CI, 5%-12%] at 3 months and 41% [95% CI, 35%-48%] vs 7% [95% CI, 4%-11%] at 6 months; in the PROWL-2 study, 61% [95% CI, 54%-67%] vs 28% [95% CI, 23%-34%]) (eTable 3 in the Supplement).

The frequency of reporting visual symptoms on the PROWL questionnaire is displayed in **Table 3**. Of those participants who reported no visual symptoms at baseline, 43% (95% CI, 31%-55%) and 46% (95% CI, 33%-58%) of PROWL-1 and PROWL-2 participants, respectively, reported a new visual symptom at 3 months. The most common newly reported symptoms to develop postoperatively were halos and starbursts. Among participants with visual symptoms at baseline, 46% (95% CI, 38%-55%) of participants in the PROWL-1 study and 34% (95% CI, 27%-41%) of participants in the PROWL-2 study reported no visual symptoms at 3 months. Double images were the most common symptoms to resolve in both studies.

Assessing the degree of development of new symptoms or loss of symptoms is difficult because it is affected by regression to the mean. This can be seen with the preoperative test-retest data, where 14% (95% CI, 3%-35%) to 29% (95% CI, 13%-49%) of participants answered that they either did or did not have a symptom on the test and vice versa on the retest (data not shown).

For each type of visual symptom, difficulty performing usual activities due to symptoms was reported by less than 1% of participants in each study. In both studies, very or extremely bothersome symptoms were reported by a smaller percentage of participants at 3 months postoperatively than at baseline (Table 3).

Examining the association of dry eye symptoms with the development of visual symptoms revealed a trend for a greater percentage of participants reporting new visual symptoms to have moderate to severe postoperative OSDI scores than participants who did not report new visual symptoms (in the PROWL-1 study, 6% [95% CI, 1%-21%] vs 2% [95% CI, 0%-12%] at 3 months and 12% [95% CI, 2%-30%] vs 2% [95% CI,

Table 1. Baseline Characteristics and Demographics of Participants

Characteristic	PROWL-1 Study			PROWL-2 Study		
	Enrolled Cohort	Surgical Cohort[a]	Analytical Cohort	Enrolled Cohort	Surgical Cohort[b]	Analytical Cohort
Participants, No.	262	242	240	312	292	271
Age, y						
Mean (SD)	29.1 (6.1)	29.1 (6.2)	29.1 (6.2)	31.5 (7.3)	31.5 (7.3)	31.6 (7.3)
Range	21-52	21-52	21-52	21-57	21-57	21-57
Race, No. (%)						
Non-Hispanic white	143 (54.6)	131 (54.1)	131 (54.6)	245 (78.5)	226 (77.4)	207 (76.4)
Non-Hispanic black	25 (9.5)	23 (9.5)	22 (9.2)	6 (1.9)	5 (1.7)	5 (1.9)
Non-Hispanic Asian	25 (9.5)	22 (9.1)	22 (9.2)	33 (10.6)	33 (11.3)	33 (12.2)
Hispanic	49 (18.7)	48 (19.8)	48 (20.0)	11 (3.5)	11 (3.8)	10 (3.7)
Other	17 (6.5)	15 (6.2)	15 (6.3)	15 (4.8)	15 (5.1)	15 (5.5)
NA	3 (1.2)	3 (1.2)	2 (0.8)	2 (0.6)	2 (0.7)	1 (0.4)
Sex, No. (%)						
Female	53 (20.2)	50 (20.7)	49 (20.4)	168 (53.9)	156 (53.4)	147 (54.2)
Male	209 (79.8)	192 (79.3)	191 (79.6)	144 (46.2)	136 (46.6)	124 (45.8)
Overall MRSE, D						
Eyes, No.	508	484	480	620	584	542
Mean (SD)	−2.7 (1.84)	−2.7 (1.82)	−2.7 (1.8)	−3.9(2.26)	−3.9 (2.26)	−4.0 (2.23)
Range	−8.0 to 3.6	−8.0 to 3.4	−8.0 to 3.4	−11.6 to 4.1	−11.6 to 4.1	−10.3 to 4.1
MRSE in myopia						
Eyes, No.	470	450	446	596	564	524
Mean (SD)	−2.9 (1.65)	−2.9 (1.67)	−2.9 (1.65)	−4.0 (2.05)	−4.1 (2.06)	−4.1 (2.05)
Range	−8.0 to −0.6	−8.0 to −0.6	−8.0 to −0.6	−11.6 to −0.5	−11.6 to −0.5	−10.3 to −0.5
MRSE in hyperopia						
Eyes, No.	10	8	8	14	12	10
Mean (SD)	2.5 (0.81)	2.3 (0.64)	2.3 (0.64)	2.3 (0.93)	2.4 (0.96)	2.3 (0.97)
Range	1.5-3.6	1.5-3.4	1.5-3.4	1.1-4.1	1.1-4.1	1.1-4.1
MRSE in mixed astigmatism						
Eyes, No.	28	26	26	10	8	8
Mean (SD)	−0.5 (0.62)	−0.5 (0.63)	−0.5 (0.63)	−0.7 (0.56)	−0.6 (0.54)	−0.6 (0.54)
Range	−2.4 to 0.3	−2.4 to 0.3	−2.4 to 0.3	−1.4 to 0.1	−1.3 to 0.1	−1.3 to 0.1
Manifest cylinder, mean (range), D	0.9 (0.0-6.0)	0.9 (0.0-6.0)	0.9 (0.0-6.0)	0.8 (0.0-4.3)	0.8 (0.0-4.3)	0.7 (0.0-4.3)
BCVA, % of eyes						
≥20/20	96.9	100.0	100.0	98.2	98.8	99.2
<20/20	0.0	0.0	0.0	1.1	1.2	0.9
NA	3.1	0.0	0.0	0.6	0.0	0.0
Mesopic pupil size, mean (range)	6.3 (1.6-8.1)	6.4 (3.8-8.1)	6.4 (3.8-8.1)	6.4 (3.7-8.8)	6.4 (3.7-8.8)	6.4 (3.7-8.8)
Type of optical correction worn, %						
Contact lenses	49.2	50.4	50.0	66.0	67.1	69.0
Glasses	44.3	45.9	46.3	32.1	31.8	29.9
None	3.4	3.7	3.8	1.0	1.0	1.1
NA	3.1	0.0	0.0	1.0	0.0	0.0

Abbreviations: BCVA, best-corrected visual acuity; D, diopters; LASIK, laser in situ keratomileusis; MRSE, manifest refraction spherical equivalent; NA, not available; PROWL, Patient-Reported Outcomes With LASIK.

[a] Of 20 participants in the PROWL-1 study, 9 decided not to proceed with surgery for various reasons (eg, deployment or change in schedule), 7 switched from LASIK to photorefractive keratectomy, and 4 were determined not to be good candidates for LASIK (eg, metallic foreign body, corneal irregularity, or unstable refraction).

[b] Of 20 participants in the PROWL-2 study, 16 decided not to proceed with surgery for various reasons (eg, cost or scheduling). Of the remaining 4 participants, 2 underwent photorefractive keratectomy per the surgeon's recommendation, 1 had surgery scheduled outside of the appropriate visit window, and 1 had loss of suction during surgery, which prompted the aborting of the procedure.

0%-11%] at 6 months; in the PROWL-2 study, 16% [95% CI, 5%-34%] vs 0% [95% CI, 0%-10%]).

Most visual symptom scores at 3 and 6 months showed moderate correlations with OSDI scores (magnitude ranging

Table 2. OSDI Scores at Baseline and Follow-up for the Analytical Cohorts in the PROWL-1 and -2 Studies

Measure	No./Total No. (%) of Participants				
	Baseline		3 mo		6 mo
	PROWL-1	PROWL-2	PROWL-1	PROWL-2	PROWL-1
Distribution OSDI scores[a]					
Normal	132/240 (55.0)	118/271 (43.5)	148/224 (66.1)	166/256 (64.8)	158/216 (73.1)
Mild	61/240 (25.4)	82/271 (30.3)	56/224 (25.0)	68/256 (26.5)	36/216 (16.7)
Moderate	32/240 (13.3)	38/271 (14.0)	11/224 (4.9)	12/256 (4.7)	14/216 (6.5)
Severe	15/240 (6.3)	33/271 (12.2)	7/224 (3.1)	10/256 (3.9)	7/216 (3.2)
Development of dry eye symptoms[b]					
Total			33/121 (27.3)	30/109 (27.5)	23/118 (19.5)
Mild			28/121 (23.1)	25/109 (22.9)	16/118 (13.6)
Moderate			4/121 (3.3)	2/109 (1.8)	6/118 (5.1)
Severe			1/121 (0.8)	3/109 (2.8)	1/118 (0.8)
Resolution of dry eye symptoms[c]			60/101 (59.4)	87/147 (59.2)	63/97 (64.9)

Abbreviations: OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK.

[a] The OSDI scores were categorized as normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100).[24] The denominator is the number of patients in the analytical cohort who submitted questionnaires.

[b] The denominator is the number of patients with a normal OSDI score at baseline who submitted a questionnaire at the postoperative time point (normal OSDI score at preoperative visit to worse-than-normal score at postoperative visit).

[c] The denominator is the number of patients with a worse-than-normal OSDI score at baseline who submitted a questionnaire at the postoperative time point (worse-than-normal OSDI score at preoperative visit to normal score at postoperative visit).

from 0.30 to 0.45; all $P < .001$). However, the OSDI score correlations with starburst in the PROWL-2 study at 3 months were low (magnitude <0.30). Overall, for each visual symptom, worse visual symptom scores (more severe visual symptoms) were modestly associated with increasing OSDI severity (**Figure 1**).

Visual symptom scores at 3 and 6 months had low correlations (<0.30) with optical aberrations, postoperative UCVA, postoperative cylinder, and magnitude of manifest refraction spherical equivalent in preoperative myopes (data not shown). The distribution of response frequencies to the item "satisfaction with vision" is presented in eTable 4 in the Supplement.

The mean satisfaction with surgery score was 92.9 (95% CI, 91.1-94.7) at 3 months and 93.1 (95% CI, 91.3-95.0) at 6 months in the PROWL-1 study and 90.6 (95% CI, 88.8-92.4) at 3 months in the PROWL-2 study. The rates of dissatisfaction with surgery were 1% (95% CI, 0%-4%) at 3 months and 2% (95% CI, 1%-5%) at 6 months in the PROWL-1 study and 2% (95% CI, 1%-5%) in the PROWL-2 study at 3 months.

Moderate Spearman correlations (ranging from −0.37 to −0.46; all $P < .001$) were observed between satisfaction (both scales) and OSDI at 3 and 6 months, with lower satisfaction associated with greater dry eye symptoms (**Figure 2**). Satisfaction scores at 3 and 6 months generally showed low to moderate correlations (ranging from 0.24 to 0.43) with visual symptoms scores (most $r_s \geq 0.30$; $P < .001$ for all; eTable 5 in the Supplement).

Correlations of logMAR UCVA (poorer eye) with satisfaction scores ranged from −0.24 to −0.29 in both studies at 3 months. This may have been observed because few eyes had UCVA ≤ 20/40 postoperatively. In the PROWL-2 study, eyes with UCVA ≤ 20/40 had significantly lower satisfaction scores than eyes with better acuity (eTable 6 in the Supplement).

Participants using corrective lenses postoperatively reported significantly poorer satisfaction scores than other participants, with the exception of satisfaction with surgery in the PROWL-2 study at 3 months. For adverse events/intraoperative complications, inconsistent and nonsignificant reductions in satisfaction scores were reported (eTable 6 in the Supplement).

Discussion

The reluctance of patients to report "negative" events to their health care professional has been documented.[26,27] The administration of the questionnaires in a private location with the assurance that the health care professional would not see the responses has been reported to increase unbiased reporting by patients.[16,28] In some prior studies, the prevalence of visual symptoms following LASIK surgery was measured by interviewer-administered questionnaires or abstracted information from clinician reports.[29] Our study showed that patients were more likely to report visual and ocular symptoms on an online questionnaire than to their health care professional. Based on our findings, this approach may substantially underestimate the rates of symptoms by a factor of 2 to 4.

To our knowledge, our study is one of the few that have reported the development of new visual symptoms. While the overall prevalence of visual symptoms decreased, a large percentage of participants with no symptoms preoperatively reported new visual symptoms postoperatively. How much of this was regression to the mean and how much a development of new symptoms cannot be determined. Unlike prior studies, we did not observe associations between visual symptoms and optical aberrations, high baseline myopia, poor

Table 3. Visual Symptoms Reported on the Questionnaire by Participants in the Analytical Cohorts in the PROWL-1 and -2 Studies

Data on Symptoms	No./Total No. (%) of Participants[a]				
	Before Surgery		3 mo After Surgery		6 mo After Surgery in PROWL-1
	PROWL-1	PROWL-2	PROWL-1	PROWL-2	
Symptom prevalence[b,c]					
Any type of symptom	161/240 (67.1)	199/271 (73.4)	112/224 (50.0)	154/256 (60.2)	89/216 (41.2)
Double images	72/240 (30.0)	93/271 (34.3)	15/224 (6.7)	15/256 (5.9)	13/216 (6.0)
Glare	95/240 (39.6)	102/271 (37.6)	51/224 (22.8)	68/256 (26.6)	37/216 (17.1)
Halos	99/240 (41.3)	139/271 (51.3)	82/224 (36.6)	118/256 (46.1)	60/216 (27.8)
Starbursts	120/240 (50.0)	152/271 (56.1)	77/224 (34.4)	117/256 (45.7)	68/216 (31.5)
Symptom development[b,d]					
No symptoms of any type to at least 1 symptom			32/75 (42.7)	31/68 (45.6)	26/73 (35.6)
Double images			10/156 (6.4)	5/167 (3.0)	8/153 (5.2)
Glare			23/134 (17.2)	33/159 (20.8)	16/130 (12.3)
Halos			38/127 (29.9)	50/125 (40.0)	33/126 (26.2)
Starbursts			33/114 (28.9)	36/111 (32.4)	33/109 (30.3)
Symptom resolution[b,e]					
Any type of symptom to none at all			69/149 (46.3)	63/186 (33.9)	80/143 (55.9)
Double images			61/66 (92.4)	79/89 (88.8)	57/62 (91.9)
Glare			60/88 (68.2)	60/95 (63.2)	63/84 (75.0)
Halos			48/92 (52.2)	63/131 (48.1)	62/89 (69.7)
Starbursts			62/106 (58.5)	64/145 (44.1)	69/104 (66.3)
Difficulty performing activities due to symptoms[f,g]					
Any type of symptom	18/240 (7.5)	9/271 (3.3)	1/224 (0.4)	2/256 (0.8)	4/216 (1.9)
Double images	2/240 (0.8)	3/271 (1.1)	0/224 (0.0)	0/256 (0.0)	0/216 (0.0)
Glare	7/240 (2.9)	0/271 (0.0)	1/224 (0.4)	0/256 (0.0)	1/216 (0.5)
Halos	7/240 (2.9)	4/271 (1.5)	0/224 (0.0)	1/256 (0.4)	2/216 (0.9)
Starbursts	7/240 (2.9)	6/271 (2.2)	0/224 (0.0)	1/256 (0.4)	1/216 (0.5)
"No difficulty" performing activities due to symptom[f]					
No difficulty due to any symptom	131/240 (54.6)	160/271 (59.0)	149/224 (66.5)	170/256 (66.4)	170/216 (78.7)
Double images	217/240 (90.4)	250/271 (92.3)	210/224 (93.8)	247/256 (96.5)	205/216 (94.9)
Glare	172/240 (71.7)	220/271 (81.2)	186/224 (83.0)	214/256 (83.6)	190/216 (88.0)
Halos	177/240 (73.8)	205/271 (75.6)	175/224 (78.1)	198/256 (77.3)	186/216 (86.1)
Starbursts	163/240 (67.9)	186/271 (68.6)	177/224 (79.0)	206/256 (80.5)	182/216 (84.3)
"Very" or "extremely" bothersome symptoms[f]					
Any type of symptom	26/240 (10.8)	36/271 (13.3)	8/224 (3.6)	13/256 (5.1)	8/216 (3.7)
Double images	5/240 (2.1)	4/271 (1.5)	0/224 (0.0)	2/256 (0.8)	2/216 (0.9)
Glare	11/240 (4.6)	10/271 (3.7)	2/224 (0.9)	2/256 (0.8)	1/216 (0.5)
Halos	10/240 (4.2)	12/271 (4.4)	4/224 (1.8)	2/256 (0.8)	1/216 (0.5)
Starbursts	13/240 (5.4)	29/271 (10.7)	4/224 (1.8)	9/256 (3.5)	5/216 (2.3)

Abbreviation: PROWL, Patient-Reported Outcomes With LASIK.

[a] The percentages may add up to more than 100% because the categories are not mutually exclusive and because the participants may have more than 1 symptom.

[b] The symptom was considered present if it was experienced either with or without optical correction.

[c] The number of patients with a symptom divided by the number of patients who submitted the questionnaire.

[d] Analysis includes only patients with no symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

[e] Analysis includes only patients with a symptom of the relevant type preoperatively who completed the questionnaire at the postoperative visit.

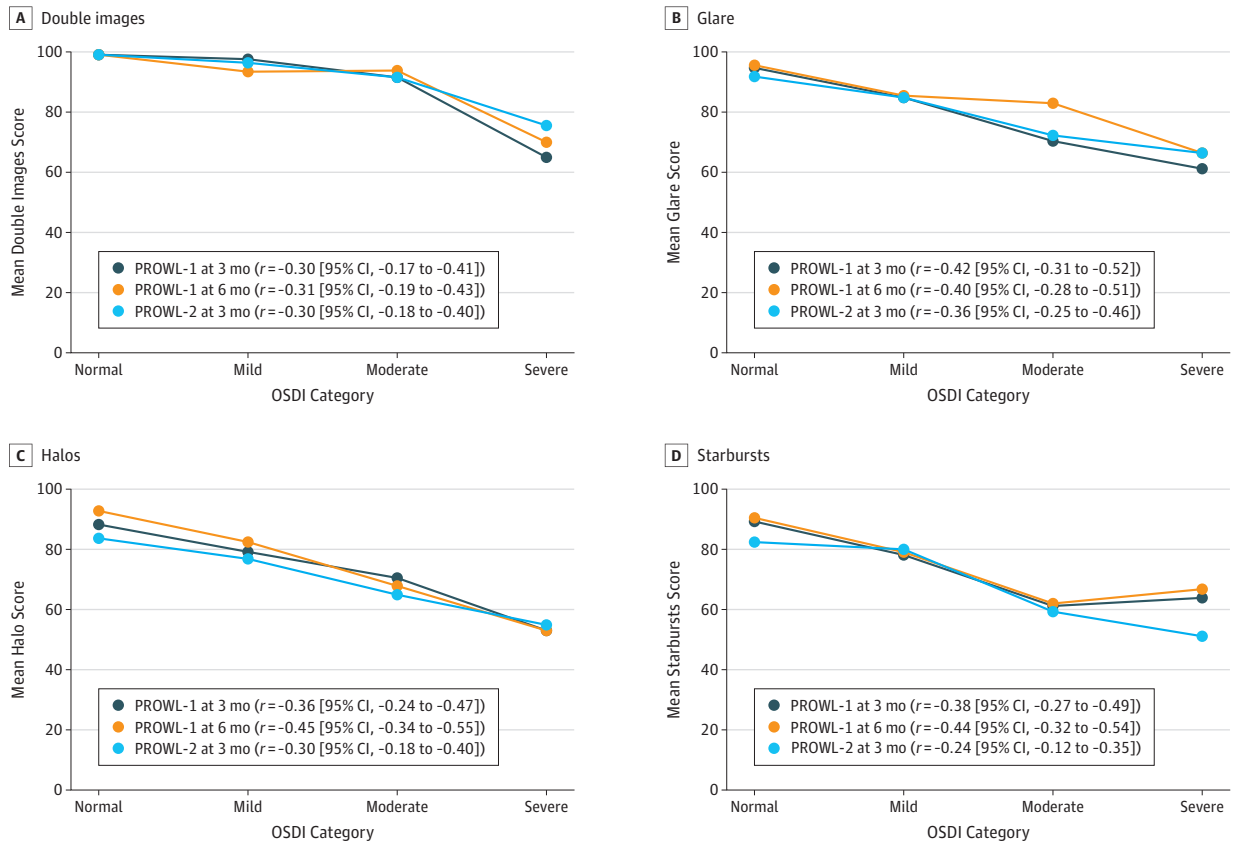
[f] Responses are based on wearing an optical correction preoperatively and wearing no optical correction postoperatively.

[g] Rates based on either of the following responses: "a lot of difficulty" or "so much difficulty that I can no longer do some of my usual activities."

postoperative UCVA, or the use of corrective lenses postoperatively.[15,30-34] Although the magnitude of the development of symptoms is uncertain, patients undergoing LASIK surgery should be adequately counseled about the possibility of developing new visual symptoms after surgery prior to undergoing this elective procedure.

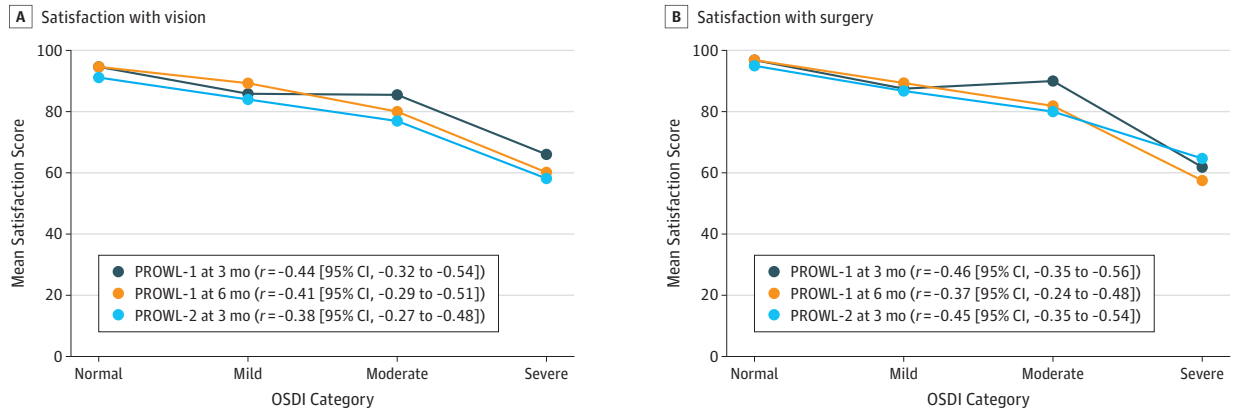
While visual symptoms were common following LASIK surgery in our studies, few participants reported a substantial impact from those symptoms. The small number of reports of the more troublesome symptoms precluded the evaluation of associations with other factors. However, exploratory analyses suggested that dry eye symptoms were associated with visual

Figure 1. Mean Visual Symptom Score vs Ocular Surface Disease Index (OSDI) Category for the Analytical Cohort



All correlations were performed using Spearman rank-order correlation coefficients (visual symptom score vs OSDI score; all $P < .001$). Each panel shows analyses with symptom scores for 1 of 4 types of visual symptoms: double images (A), glare (B), halos (C), and starbursts (D). The OSDI scores were categorized as normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100).[24]

Figure 2. Mean Satisfaction Score vs Ocular Surface Disease Index (OSDI) Category for the Analytical Cohort



All correlations were performed using Spearman rank-order correlation coefficients (satisfaction score vs OSDI Score; all $P < .001$). Each panel shows analyses with satisfaction scores for 1 of 2 types of satisfaction: satisfaction with vision (A) and satisfaction with surgery (B). The OSDI scores were categorized as normal (0-12), mild (13-22), moderate (23-32), and severe dry eye disease (33-100).[24]

symptom scores. Use of this questionnaire in a larger study may provide more information about the factors associated with functional limitations due to visual symptoms.

Dry eye is one of the most common complications reported after LASIK surgery.[7,9,11,35-38] Using the OSDI, with its limitations,[39] our findings for dry eye symptoms were incon-

sistent with prior studies that showed at least temporary worsening after LASIK surgery.[26,27,34] In the PROWL studies, clinicians collected information on clinical signs of dry eyes, possibly leading to greater detection and more aggressive treatment of dry eye problems. In addition, mechanical keratomes were used in less than 3% of cases in the PROWL studies. Some studies suggest that LASIK flaps made with a femtosecond laser are associated with fewer symptoms of dry eye compared with flaps made with mechanical keratomes,[26,40,41] but reports have been inconsistent.[42]

In our studies, 4% (95% CI, 1%-9%) to 6% (95% CI, 2%-12%) of participants with normal OSDI scores at baseline developed moderate or severe OSDI scores postoperatively. Hence, patients should be adequately informed about the potential risk of developing dry eye symptoms, even if they are asymptomatic preoperatively. Consistent with previous literature,[9,11,43-45] dry eye signs did not appear to be correlated with dry eye symptoms. Participants who developed new visual symptoms more frequently had higher rates of moderate-severe OSDI scores than those who did not develop new visual symptoms. Our results highlight the importance of adequately measuring patient-reported dry eye symptoms in clinical trials.

While many studies were not specific about the aspects of satisfaction evaluated (eg, satisfaction with vision or satisfaction with surgery), reported satisfaction rates after LASIK surgery ranged from 82% to 98%.[8,46,47] In the PROWL studies, satisfaction with vision increased from baseline, but 1% (95% CI, 0%-4%) to 4% (95% CI, 2%-7%) of participants had some level of dissatisfaction with vision 3 to 6 months after surgery. The total number of dissatisfied participants in the PROWL studies was too small to assess associations with other factors. Similar to other studies,[9,11,12,21,42,48] we found that lower satisfaction with vision and surgery was often associated with worse dry eye and visual symptom scores and the use of corrective lenses. To better understand which patients are more likely to be dissatisfied postoperatively, a large observational study, including participants with long-term follow-up after LASIK surgery, would be necessary to accurately estimate the prevalence and find useful predictors for these perceptions.

Limitations and Strengths

Our PROWL studies were primarily designed with an adequate sample size to evaluate the questionnaire rather than to report on outcomes. As such, the limitations of the study included a sample that may not generalize to all persons undergoing LASIK surgery, a sample size that was too small for confidence about uncommon events, and short-term follow-up. It is possible that participants were more likely reporting satisfaction in an attempt to be consistent with and justify their choice to have surgery, leading to an underestimation of symptom rates and an overestimation of satisfaction rates. Longer-duration studies need to be performed to evaluate this possibility. Given the main purpose of the PROWL studies, participants were not followed up long enough to obtain long-term data on symptoms and satisfaction. However, the 6-month data from the PROWL-1 study showed a further decrease in the prevalence of visual symptoms compared with the 3-month data. This is consistent with previous reports demonstrating improvement in visual symptoms with time after surgery.[8]

Despite the limitations, the studies had many strengths, including the use of a psychometrically sound questionnaire to assess concepts and the consistency of the findings in a civilian and a military population.[22] By administering the questionnaire preoperatively and at multiple postoperative visits, we were able to measure changes during the perioperative period. In addition, these studies provide demographically diverse participants from different surgical practices.

To mitigate socially desirable reporting of visual symptoms, we included a measure of social desirability, which suggested that this did not impact our findings. In addition, underreporting of subjective symptoms (eg, so as not to displease the physician) was minimized by the systematic separation of the patients' questionnaire responses from the health care professionals (online self-administration of the questionnaire, which would not be available to the health care professional).

By making the PROWL questionnaire publicly available, the ophthalmic community will have a tool to conduct further research on LASIK surgery. Administering the questionnaire to patients preoperatively and postoperatively will allow us to more accurately assesses visual and ocular symptoms and satisfaction in clinical trials. A better understanding of the patients' perceptions following this procedure will lead to better outcomes and will provide better information for informed consent to patients considering LASIK surgery.

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