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Assessment of the Psychometric Properties of a Questionnaire Assessing Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL)

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IMPORTANCE Patient-reported outcome (PRO) measures for laser in situ keratomileusis (LASIK) are needed.

OBJECTIVE To develop PRO measures to assess satisfaction, eye-related symptoms, and their effect on functioning and well-being following LASIK based on patient and expert input.

DESIGN, SETTING, AND PARTICIPANTS The Patient-Reported Outcomes With LASIK (PROWL) studies were prospective observational studies of patients undergoing LASIK surgery for myopia, hyperopia, or astigmatism. PROWL-1 was a single-center study of active-duty US Navy personnel and PROWL-2 was a 5-center study of civilians. PROWL-1 enrolled 262 active-duty service personnel and PROWL-2 enrolled 312 civilians 21 years or older who spoke English; 241 individuals in PROWL-1 and 280 in PROWL-2 completed a baseline questionnaire before surgery. The analytic sample included those also completing 1 or more follow-up questionnaires: 240 (99.6%) of those in PROWL-1 and 271 (94.4%) of those in PROWL-2. Questionnaires were self-administered through the internet preoperatively and at 1 and 3 months postoperatively in both studies and at 6 months postoperatively in PROWL-1. PROWL-1 began in August 2011 and was completed May 30, 2014; PROWL-2 began in July 2012 and was completed June 27, 2014. Data were analyzed from June 28, 2014, to October 24, 2016.

MAIN OUTCOMES AND MEASURES Scales assessing visual symptoms (double images, glare, halos, and starbursts), dry eye symptoms, satisfaction with vision, and satisfaction with LASIK surgery. Items from the National Eye Institute (NEI) Refractive Error Quality of Life Instrument (NEI-RQL-42), NEI Visual Function Questionnaire (NEI-VFQ), and the Ocular Surface Disease Index (OSDI) were included. All scales are scored on a 0 to 100 possible range. Construct validity and responsiveness to change were evaluated (comparing scores before and after surgery).

RESULTS The median age of the 240-person PROWL-1 analytic sample was 27 years (range, 21-52 years); 49 were women (20.4%). The median age of the 271-person PROWL-2 analytic sample was 30 years (range, 21-57 years); 147 were women (54.2%). Internal consistency reliabilities for the 4 visual symptom scales ranged from 0.96 to 0.98 in PROWL-1 and from 0.95 to 0.97 in PROWL-2. The median (interquartile range) test-retest intraclass correlation was 0.69 (0.57-0.79) and 0.76 (0.68-0.84) in PROWL-1 and PROWL-2, respectively. Product-moment correlations of satisfaction with surgery with visual symptom scales at follow-up evaluations ranged from $r = 0.24$ to $r = 0.49$. Measures improved from baseline to follow-up, with effect sizes of 0.14 to 1.98, but scores on the NEI-RQL-42 glare scale worsened at the 1-month follow-up. Hours of work did not change significantly from baseline to 1-month follow-up, with the mean number (mean [SD] difference) in PROWL-1 of 41.7 vs 40.9 hours (−0.8 [18.7]) and in PROWL-2 of 38.8 vs 38.2 hours (−0.6 [17.1]).

CONCLUSIONS AND RELEVANCE The results of these studies support the reliability and validity of visual symptom scales to evaluate the effects of LASIK surgery in future studies.

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Related article

Supplemental content

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Laser in situ keratomileusis (LASIK) is a refractive corneal surgical procedure for reducing or eliminating myopia, hyperopia, and astigmatism.[1,2] The US Food and Drug Administration evaluates the safety and effectiveness of LASIK devices before approving them for use in the US market.[3] Dry eye symptoms, dissatisfaction with visual outcomes, and burdensome visual symptoms have been reported following LASIK.[4,5] Given the high volume of surgery performed and patient concerns voiced at a public meeting, it is important to evaluate the effect of surgically induced changes on patient-reported outcomes (PROs) of LASIK: eye-related symptoms, daily functioning and well-being (health-related quality of life [HRQOL]), and patient satisfaction.[6-8] A better understanding of PROs after LASIK may allow eye care professionals and patients to make more educated decisions. Thus, a reliable and valid PRO instrument is needed to evaluate the effects of this intervention.[9]

The Patient-Reported Outcomes With LASIK (PROWL) project team developed a questionnaire to evaluate PROs for persons undergoing LASIK for myopia, hyperopia, or astigmatism, incorporating existing HRQOL measures and developing new items. This article summarizes the psychometric performance of the instrument in 2 studies of participants undergoing LASIK surgery.

Key Points

Question What are the psychometric properties of a patient-reported outcome instrument to assess eye-related symptoms and their effect on functioning and well-being following laser in situ keratomileusis (LASIK)?

Findings The Patient-Reported Outcomes With LASIK (PROWL) studies (PROWL-1 and PROWL-2) were prospective observational studies evaluating a total of 574 patients undergoing LASIK surgery for myopia, hyperopia, or astigmatism. The study results support the reliability and validity of these patient-reported outcome measures for use in evaluating LASIK surgery.

Meaning These studies yield support for use of the PROWL survey in future studies to assess the effects of LASIK surgery on functioning and well-being.

Methods

Study Design

We conducted a literature search and obtained input from an expert panel of ophthalmologists, optometrists, psychometricians, and clinical researchers. Draft items were revised based on input from patients who underwent LASIK and another group of experts. In addition, 9 individuals contemplating LASIK surgery and 9 who had LASIK surgery performed between 6 months and 2 years ago participated in interviews in Los Angeles, California, and Washington, DC. Four of the post-LASIK participants were satisfied and 4 were dissatisfied with the results of LASIK surgery (1 unknown). These interviews were used to assess item redundancy, content coverage, recall period, instructions, and format, and to revise items for the PROWL studies.

The PROWL-1 study protocol was approved by the Naval Medical Center San Diego Institutional Review Board (IRB) in compliance with all applicable federal regulations governing the protection of human participants. The PROWL-2 study was conducted under the US Food and Drug Administration Research Involving Human Subjects Committee, a central IRB for 3 sites (20/20 Institute, Indianapolis, Indiana; Durrrie Vision, Overland Park, Kansas; and Vance Thompson Vision, Sioux Falls, South Dakota), and university IRBs for 2 sites (The Johns Hopkins University, Baltimore, Maryland; and Stanford University, Stanford, California). All participants provided written as well as oral informed consent. There was no financial compensation in PROWL-1; PROWL-2 participants received compensation. The PROWL studies are registered at Clinicaltrials.gov (NCT0152629 and NCT01655420 for PROWL-1 and PROWL-2, respectively). Both studies were compliant with the Health Insurance Portability and Accountability Act and complied with the tenets of the Declaration of Helsinki.[10]

PROWL-1 and PROWL-2 were prospective observational studies. Both enrolled patients planning to undergo LASIK surgery for myopia, hyperopia, or astigmatism. Investigators screened, enrolled, and treated study participants with LASIK surgery and followed up participants postoperatively according to their usual clinical practice. PROWL-1 was a single-center study of active-duty Navy military personnel; PROWL-2 was a 5-center study of civilians. Participants completed the questionnaires preoperatively and at 1 and 3 months after surgery using a secure website accessed from any computer. PROWL-1 had an additional 6-month postoperative visit with questionnaire administration. PROWL-1 began in August 2011 and was completed May 30, 2014; PROWL-2 began in July 2012 and was completed June 27, 2014. Data were analyzed from June 28, 2014, to October 24, 2016.

Participant Selection

Participants were 21 years or older, spoke and read English fluently, had not previously received any form of refractive surgery, and were determined to be good candidates for LASIK based on the surgeon's assessment of medical and ophthalmic health, cognitive function, and physical and social limitations. A random subsample completed the questionnaire twice before surgery within a 3- to 14-day interval.

PROWL-1

PROWL-1 enrolled active-duty service naval personnel with a target refraction of bilateral emmetropia or slight hyperopia (+0.25 diopters [D]). Each participant had access to internet service and received their commanding officer's permission to participate.

PROWL-2

PROWL-2 enrolled patients with a targeted refraction of bilateral emmetropia. To obtain a sample that reflected the refractive range of the LASIK-treated population, each site oversampled participants with higher refractive errors, including hyperopic participants with a spherical equivalent of equal to or greater than +1.50 D and myopic participants with a spherical equivalent more myopic than −7.00 D. Three strata were

created based on spherical equivalent: more hyperopic than +1.50 D, between +1.50 D and −7.00 D, and more myopic than −7.00 D. Site enrollment was capped at 45 individuals with spherical equivalents between −7.00 D and +1.50 D until either 18 participants had enrolled in the other 2 strata or 105 days of enrollment had passed. After 105 days, enrollment was opened without restriction by strata.

Clinical Procedures and Measures

Centers performed the LASIK procedure and postoperative care based on the clinical judgment of the surgeons. The protocol did not dictate the care of participants, but it specified the collection of medical, ophthalmic, and surgical history; visual acuity, slitlamp, and posterior segment ocular examination findings; surgical factors; and postoperative clinical assessments.

Questionnaire

The questionnaire included new items to assess satisfaction with current vision (1 item), satisfaction with LASIK surgery (8 items), and the existence, bothersomeness, and effect on usual activities in the past 7 days of 4 key visual symptoms using polytomous response options: double images (8 items), glare (8 items), halos (8 items), and starbursts (8 items). We used a written definition of the symptom and images to illustrate symptom severity levels.

The questionnaire also included items from the National Eye Institute (NEI) Refractive Error Quality of Life Instrument with 42 items (NEI-RQL-42),[11,12] the NEI Visual Function Questionnaire with 25 items (NEI-VFQ-25),[13,14] and the Ocular Surface Disease Index (OSDI).[15] All scales are scored on a 0 to 100 possible range. NEI-RQL-42 scales, NEI-VFQ driving scale, visual symptoms scales, and satisfaction with vision are scored such that a higher score is better; OSDI is scored such that a higher score is worse. Potential threats to the validity of the HRQOL measures were evaluated by assessing optimism (Life Orientation Test-Revised),[16] health proneness (Brien Holden Vision Institute Quality of Life Scale for Myopia),[17] anxiety and depressive symptoms (Patient Health Questionnaire-4),[18] socially desirable response set,[19] and expectations about spectacle use and vision after surgery (6 items). The questions and rationale for their selection are available in eMethods and eTables 1-11 in the Supplement.

The PROWL-1 preoperative (baseline) version of the questionnaire included 161 items and the postoperative version contained 129 items. The PROWL-2 baseline questionnaire had 154 items and the postoperative questionnaire included 112 items.

Statistical Analysis

The analytic sample comprised individuals who completed a baseline and at least 1 follow-up questionnaire. Correlations of items with the scale that they represented were estimated and compared with correlations of items with other scales.[20] For these item-scale correlations, we imputed missing item responses using maximum likelihood estimates of the covariance matrix via the expectation-maximization algorithm in SAS, version 9.4.[21] We evaluated multi-item scales, including the OSDI dry eye symptoms and environmental triggers (8 items), NEI-RQL-42 clarity of vision (4 items), NEI-RQL-42 near vision (4 items), NEI-RQL-42 far vision (5 items), NEI-RQL-42 glare (2 items), NEI-RQL-42 diurnal vision (2 items), NEI-RQL-42 activity limitations (4 items), NEI-RQL-42 worry (2 items), new items for satisfaction with surgery (8 items), and new symptom items developed for the study: glare (8 items), starbursts (8 items), halos (8 items), and double images (8 items).

We estimated descriptive statistics and internal consistency reliability (coefficient α) for multi-item scales. The subsample with repeated questionnaire administrations within 14 days was used to estimate test-retest correlations (product-moment and intraclass). Reliability coefficients of 0.70 or above were considered adequate for group-level comparisons.[22]

We evaluated construct validity, using product-moment correlations of vision symptom scores with the satisfaction with LASIK surgery scale (hypothesizing statistically significant, positive associations) and expectations about spectacle use and vision after surgery, optimism, health proneness, depression and anxiety symptoms, and socially desirable responses (hypothesizing nonsignificant correlations). Responsiveness to change was assessed by computing change scores, effect size (change in scores divided by SD at baseline), and 2-tailed, paired *t* tests of the significance of change. We hypothesized that changes over time would be statistically significant and represent improvement in HRQOL (except for possibly worsening glare and dry eye symptoms). Results were considered statistically significant if the probability was $P \leq .05$. Because the number of significant effects is inflated by change, we interpreted our results with this in mind.

Results

Participant Characteristics

Table 1 summarizes baseline characteristics of enrolled participants (262 in PROWL-1 and 312 in PROWL-2) and the analytic sample (240 [99.6% response rate] in PROWL-1 and 271 [94.4% response rate] in PROWL-2 among those eligible for the study). The most common reason participants were not included in the analytic sample was not having LASIK surgery (eFigure in the Supplement).

The median age of the 240 PROWL-1 respondents was 27 years (range, 21-52 years). Most participants were non-Hispanic white (54.6%), with 20.0% Hispanic, 9.2% non-Hispanic black, 9.2% non-Hispanic Asian, and 6.3% who self-identified as being other race/ethnicity; 20.4% were women. PROWL-2 did not include participants in the analytic sample if they did not complete the preoperative questionnaire (n = 5) or did not complete a postoperative questionnaire (n = 16). The median age of the 271 PROWL-2 respondents was 30 years (range, 21-57 years). Most participants were non-Hispanic white (76.4%), with 3.7% Hispanic, 1.8% non-Hispanic black, 12.2% non-Hispanic Asian, and 5.5% who self-identified as other; 54.2% were women.

Questionnaire Completion Time

The median (interquartile range) self-reported time for questionnaire completion at baseline was 25.00 (20.00-35.00) and

Table 1. Baseline Characteristics of PROWL Participants

Characteristic	No. (%) Analytic Sample	Enrolled
PROWL-1		
No. of participants	240	262
Race/ethnicity		
Non-Hispanic white	131 (54.6)	143 (54.6)
Non-Hispanic black	22 (9.2)	25 (9.5)
Non-Hispanic Asian	22 (9.2)	25 (9.5)
Hispanic	48 (20.0)	49 (18.7)
Other	15 (6.3)	17 (6.5)
Not reported	2 (0.83)	3 (1.1)
Women	49 (20.4)	53 (20.2)
Condition treated by LASIK		
Left eye		
Myopia	223 (92.9)	235 (89.7)
Hyperopia	4 (1.7)	5 (1.9)
Mixed astigmatism	13 (5.4)	14 (5.3)
Missing	0	8 (3.1)
Right eye		
Myopia	223 (92.9)	235 (89.7)
Hyperopia	4 (1.7)	5 (1.9)
Mixed astigmatism	13 (5.4)	14 (5.3)
Missing	0	8 (3.1)
Current correction method		
Daily-wear soft contact lens	110 (45.8)	119 (45.4)
Extended-wear soft contact lens	10 (4.2)	10 (3.8)
Rigid gas-permeable contact lens	0	0
Eyeglasses	111 (46.3)	116 (44.3)
No correction	9 (3.8)	9 (3.4)
Missing	0	8 (3)
Ocular history		
Any prior ocular history	6 (2.5)	6 (2.3)
Dry eye syndrome	0	0
Corneal scarring	0	0
Diabetic retinopathy	0	0
Cataract	0	0
Glaucoma	0	0
Myopic degeneration	0	0
Other ocular disease	1 (0.4)	1 (0.4)
OSDI overall by category (%)		
Normal (0-12)	132 (55.0)	141 (53.8)
Mild (>12-22)	61 (25.4)	64 (24.4)
Moderate (>22-32)	32 (13.3)	33 (12.6)
Severe (>32-100)	15 (6.3)	15 (5.7)
Missing	0	9 (3.4)
PROWL-2		
No. of participants	271	312
Race/ethnicity		
Non-Hispanic white	207 (76.4)	245 (78.5)
Non-Hispanic black	5 (1.8)	6 (1.9)
Non-Hispanic Asian	33 (12.2)	33 (10.6)
Hispanic	10 (3.7)	11 (3.5)
Other	15 (5.5)	15 (4.8)
Not reported	1 (0.4)	2 (0.6)
Women	147 (54.2)	168 (53.8)
Condition treated by LASIK		
Left eye		
Myopia	261 (96.3)	297 (95.2)
Hyperopia	5 (1.8)	7 (2.2)
Mixed astigmatism	5 (1.8)	6 (1.9)
Missing	0	2 (0.6)
Right eye		
Myopia	263 (96.3)	299 (95.8)
Hyperopia	5 (1.8)	7 (2.2)
Mixed astigmatism	3 (1.1)	4 (1.3)
Missing	0	2 (0.6)
Current correction method		
Daily-wear soft contact lens	128 (47.2)	142 (45.5)
Extended-wear soft contacts	58 (21.4)	63 (20.2)
Rigid gas permeable contacts	1 (0.37)	1 (0.3)
Glasses	81 (29.9)	100 (32.1)
No correction	3 (1.1)	3 (1.0)
Missing	0	3 (1.0)
Ocular history		
Any prior ocular history	37 (13.7)	46 (14.7)
Dry eye syndrome	9 (3.3)	11 (3.5)
Corneal scarring	9 (3.3)	11 (3.5)
Diabetic retinopathy	0	0
Cataract	2 (0.7)	3 (9.1)
Glaucoma	0	0
Macular degeneration	0	0
Other ocular disease	14 (5.2)	18 (5.8)
OSDI overall by category (%)		
Normal (0-12)	118 (43.5)	129 (41.3)
Mild (>12-22)	82 (30.3)	89 (28.5)
Moderate (>22 -32)	38 (14.0)	40 (12.8)
Severe (>32-100)	33 (12.2)	36 (11.5)
Missing	0	18 (5.8)
Spherical equivalent		
≥+1.50 D	5 (1.8)	6 (1.9)
Worse than −7.00 D	26 (9.6)	28 (9.0)
Between and including −7.00 D through +1.25 D	240 (88.6)	278 (89.1)

Abbreviations: D, diopters; LASIK, laser in situ keratomileusis; OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK.

20.00 (15.00-25.00) minutes, respectively, in PROWL-1 and PROWL-2; the median (range) internet-recorded time was 22.42 (17.17-28.69) and 17.91 (14.63-22.51) minutes, respectively, in PROWL-1 and PROWL-2. The product-moment correlation between self-reported and recorded time was 0.49 in PROWL-1 and 0.58 in PROWL-2. Most study participants reported that completing the questionnaire by computer was easier than it would have been by paper (54.4% in PROWL-1 and 69.4% in PROWL-2). The mean (SD) number of days between test and retest was 10.74 (3.94) days (range, 5-23 days) in 50 PROWL-1 participants and 6.34 (3.04) days (range, 4-20 days) in 68 PROWL-2 participants.

Table 2. Baseline Scale Descriptive Statistics and Reliability Estimates in PROWL[a]

Scale[b]	Median/ Mean (SD)	Floor/ Ceiling, %	Cronbach Coefficient α	Test-Retest Intraclass (Product-Moment) Correlation[c]
NEI-RQL-42				
Clarity of vision, 4 items				
PROWL-1	92/83 (19)	0/20	0.67	0.79 (0.80)
PROWL-2	92/80 (21)	0/21	0.71	0.77 (0.77)
Near vision, 4 items				
PROWL-1	85/80 (16)	0/12	0.74	0.61 (0.61)
PROWL-2	92/87 (14)	0/31	0.76	0.85 (0.85)
Far vision, 5 items				
PROWL-1	77/76 (18)	0/15	0.79	0.79 (0.79)
PROWL-2	88/83 (16)	0/18	0.78	0.93 (0.93)
Glare, 2 items				
PROWL-1	88/79 (24)	0/35	0.55	0.47 (0.48)
PROWL-2	88/77 (26)	1/34	0.65	0.69 (0.69)
Diurnal vision, 2 items				
PROWL-1	88/82 (22)	1/46	0.89	0.77 (0.77)
PROWL-2	88/81 (22)	0/42	0.86	0.74 (0.74)
Activity limitations, 4 items				
PROWL-1	56/60 (27)	1/9	0.76	0.80 (0.80)
PROWL-2	81/73 (24)	0/17	0.71	0.89 (0.90)
Worry, 2 items				
PROWL-1	38/36 (27)	20/2	0.83	0.67 (0.68)
PROWL-2	38/34 (24)	18/1	0.82	0.69 (0.69)
NEI-VFQ-25				
Driving, 3 items				
PROWL-1	83/77 (21)	0.4/25	0.85	0.68 (0.69)
PROWL-2	83/85 (15)	0/33	0.74	0.82 (0.82)
Hours worked[d]				
PROWL-1	43/42 (16)	6/18	NA	0.33 (0.34)
PROWL-2	40/39 (14)	4/10	NA	0.54 (0.54)
OSDI				
Symptoms, 5 items				
PROWL-1	10/14 (14)	26/0	0.61	0.76 (0.76)
PROWL-2	15/18 (17)	14/0	0.72	0.82 (0.82)
Environment, 3 items				
PROWL-1	8/10 (14)	49/0.4	0.67	0.53 (0.55)
PROWL-2	8/15 (18)	35/0	0.74	0.80 (0.80)
Visual Symptoms				
Glare, 8 items				
PROWL-1	100/80 (26)	0/60	0.98	0.60 (0.60)
PROWL-2	100/81 (25)	0/62	0.97	0.66 (0.66)
Starbursts, 8 items				
PROWL-1	79/74 (28)	0/50	0.97	0.80 (0.80)
PROWL-2	64/70 (29)	0.4/44	0.97	0.66 (0.66)
Halos, 8 items				
PROWL-1	100/79 (26)	0/59	0.97	0.78 (0.78)
PROWL-2	76/74 (28)	0/49	0.97	0.75 (0.76)
Double images, 8 items				
PROWL-1	100/87 (20)	0/70	0.96	0.49 (0.49)
PROWL-2	100/86 (21)	0/66	0.95	0.88 (0.89)
Satisfaction With Vision				
PROWL-1	40/36 (25)	14/2	NA	0.69 (0.70)
PROWL-2	40/45 (26)	8/2	NA	0.67 (0.67)

Abbreviations: NA, not applicable for single-item measure; NEI-RQL-42, National Eye Institute Refractive Error Quality of Life Instrument, 42 items; NEI-VFQ-25, National Eye Institute Visual Functioning Questionnaire, 25 items; OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK (laser in situ keratomileusis).

[a] PROWL-1, 240 participants; PROWL-2, 271 participants.

[b] All scales are scored on a 0 to 100 possible range. NEI-RQL-42 scales, NEI-VFQ driving scale, visual symptoms scales, and satisfaction with vision are scored such that a higher score is better. OSDI is scored such that a higher score is worse.

[c] The mean (SD) number of days between test and retest was 10.74 (3.94) days (range, 5-23 days) in 50 PROWL-1 participants and 6.34 (3.04) days (range, 4-20 days) in 68 PROWL-2 participants.

[d] Truncated at 60 hours.

Scale Descriptive Statistics and Reliability Estimates

Table 2 provides baseline scale descriptive statistics and reliability estimates. For most scales, a higher score indicated better HRQOL. Exceptions were the OSDI symptom and environment scales, where higher scores indicated worse symptoms. Ceiling effects (indicating healthiest possible responses) were noteworthy (≥40%) for the NEI-RQL-42 diurnal vision scale and for the visual symptoms scales (double images, glare, halos, and starbursts).

Reliabilities (Cronbach coefficient α) ranged from 0.55 (NEI-RQL-42 glare scale) to 0.98 (new visual symptoms glare scale) in PROWL-1 and 0.65 (NEI-RQL-42 glare scale) to 0.97 (new visual symptoms glare, starbursts, and halos scales) in PROWL-2. The α values for other multi-item scales were as follows in PROWL-1 and PROWL-2, respectively: expectations about spectacle independence and vision clarity (6 items: 0.61 and 0.63), optimism (6 items: 0.77 and 0.81), health proneness (10 items: 0.85 and 0.84), Patient Health Questionnaire-4 (4 items: 0.80 and 0.81), and socially desirable response set (2 items: 0.56 and 0.51). At the 1-month postoperative assessment, α levels for satisfaction with surgery (8 items) were 0.90 for PROWL-1 and 0.91 for PROWL-2. Test-retest product-moment correlations over a mean interval of 10.74 (3.94) days in PROWL-1 ranged from 0.33 (hours worked) to 0.80 (NEI-RQL-42 clarity of vision and activity limitations) and, over a mean (SD) interval of 6.34 (3.04) days in PROWL-2 ranged from 0.54 (hours worked) to 0.93 (NEI-RQL-42 far vision). The median (interquartile range) test-retest intraclass correlation was 0.69 (0.57-0.79) in PROWL-1 and 0.76 (0.68-0.84) in PROWL-2.

Table 3. Baseline and 1-Month Postoperative Scale Means and Differences in PROWL

Scale[a]	Preoperative Mean	1-mo Postoperative Mean	Difference, Mean (SD)	*t* Statistic	*P* Value
NEI-RQL-42					
Clarity of vision					
PROWL-1 (n = 232)	83.1	87.4	4.3 (26.3)	2.52	.01
PROWL-2 (n = 262)	80.0	83.7	3.7 (26.9)	2.21	.03
Near vision					
PROWL-1 (n = 232)	80.3	93.9	13.6 (17.7)	11.67	<.001
PROWL-2 (n = 262)	86.7	93.6	6.9 (14.2)	7.87	<.001
Far vision					
PROWL-1 (n = 232)	76.3	89.3	13.0 (18.7)	10.60	<.001
PROWL-2 (n = 262)	83.1	90.7	7.6 (15.6)	7.92	<.001
Glare					
PROWL-1 (n = 232)	79.6	70.7	−8.9 (30.1)	−4.52	<.001
PROWL-2 (n = 262)	76.5	68.2	−8.3 (33.0)	−4.07	<.001
Diurnal vision					
PROWL-1 (n = 232)	82.2	88.0	5.8 (25.6)	3.45	<.001
PROWL-2 (n = 262)	80.5	84.1	3.6 (25.1)	2.36	.02
Activity limitations					
PROWL-1 (n = 232)	60.2	91.9	31.7 (29.2)	16.51	<.001
PROWL-2 (n = 262)	72.8	93.5	20.7 (25.4)	13.18	<.001
Worry					
PROWL-1 (n = 232)	35.7	53.6	17.9 (33.4)	8.18	<.001
PROWL-2 (n = 262)	33.9	56.2	22.3 (25.9)	13.92	<.001
NEI-VFQ-25 Driving					
PROWL-1 (n = 227)	77.8	89.2	11.4 (23.0)	7.47	<.001
PROWL-2 (n = 256)	84.7	90.4	5.7 (17.2)	5.28	<.001
Hours Worked[b]					
PROWL-1 (n = 224)	41.7	40.9	−0.8 (18.7)	−0.61	.54
PROWL-2 (n = 226)	38.8	38.2	−0.6 (17.1)	−0.52	.60
OSDI					
Symptoms					
PROWL-1 (n = 232)	14.2	11.8	−2.4 (16.8)	−2.19	.03
PROWL-2 (n = 262)	18.3	13.4	−4.9 (18.5)	−4.28	<.001
Environment					
PROWL-1 (n = 232)	10.1	12.3	2.2 (17.4)	1.88	.06
PROWL-2 (n = 262)	15.2	13.9	−1.3 (21.3)	−0.97	.33
Visual Symptoms					
Glare					
PROWL-1 (n = 230)	80.7	83.9	3.2 (29.7)	1.65	.10
PROWL-2 (n = 261)	81.2	86.2	5.0 (28.4)	2.85	<.005
Starbursts					
PROWL-1 (n = 229)	74.5	78.6	4.1 (32.9)	1.90	.06
PROWL-2 (n = 261)	69.9	72.7	2.8 (33.6)	1.35	.18
Halos					
PROWL-1 (n = 230)	79.0	76.3	−2.7 (32.3)	−1.28	.20
PROWL-2 (n = 261)	73.9	69.9	−4.0 (33.9)	−1.93	.05
Double images					
PROWL-1 (n = 229)	87.3	96.3	9.0 (23.3)	5.82	<.001
PROWL-2 (n = 262)	85.3	95.0	9.7 (24.0)	6.55	<.001
Satisfaction With Vision					
PROWL-1 (n = 232)	36.2	89.1	52.9 (28.4)	28.36	<.001
PROWL-2 (n = 262)	44.4	84.7	40.3 (32.3)	20.18	<.001

Abbreviations: NEI-RQL-42, National Eye Institute Refractive Error Quality of Life Instrument, 42 items; NEI-VFQ-25, National Eye Institute Visual Functioning Questionnaire, 25 items; OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK (laser in situ keratomileusis).

[a] All scales are scored on a 0 to 100 possible range. NEI-RQL-42 scales, NEI-VFQ driving scale, visual symptoms scales, and satisfaction with vision are scored such that a higher score is better. OSDI is scored such that a higher score is worse.

[b] Truncated at 60 hours.

The 2 largest correlations among scales at baseline (eTable 3 in the Supplement) were between the NEI-RQL-42 far vision and the NEI-VFQ-25 driving scales (PROWL-1, $r = 0.81$; PROWL-2, $r = 0.85$) and between the visual symptoms scales of starbursts and halos ($r = 0.63$ and $r = 0.70$, respectively).

Construct Validity

Correlations of the new visual symptom measures with satisfaction with surgery were statistically significant in the hypothesized direction: glare ($r = 0.34$ at 1 month, $r = 0.36$ at 3 months, and $r = 0.43$ at 6 months in PROWL-1; $r = 0.40$ at 1 month and $r = 0.33$ at 3 months in PROWL-2), starbursts ($r = 0.27$ at 1 month, $r = 0.24$ at 3 months, and $r = 0.32$ at 6 months in PROWL-1; $r = 0.36$ at 1 month and $r = 0.36$ at 3 months in PROWL-2), halos ($r = 0.37$ at 1 month, $r = 0.34$ at 3 months, and $r = 0.49$ at 6 months in PROWL-1; $r = 0.38$ at 1 month and $r = 0.33$ at 3 months in PROWL-2), and double images ($r = 0.43$ at 1 month, $r = 0.37$ at 3 months, and $r = 0.39$ at 6 months in PROWL-1; $r = 0.29$ at 1 month and $r = 0.48$ at 3 months in PROWL-2).

Correlations between baseline expectations of spectacle use and vision with satisfaction with surgery at 1 and 3 months in both studies and at 6 months in PROWL-1 were not significant. The correlation of baseline health proneness with satisfaction with surgery at 3 months was statistically significant but small in magnitude ($r = 0.14$, $P = .04$ in PROWL-1 and $r = 0.13$, $P = .04$ in PROWL-2). The Patient Health Questionnaire-4 depressive/anxiety score at baseline was significantly associated with satisfaction with surgery at 6 months in PROWL-2, but was small in magnitude ($r = -0.19$, $P = .004$). The correlations of satisfaction with surgery with socially desirable response set were small in PROWL-1 ($r = 0.13$, $P = .47$ at 1 month and $r = 0.15$, $P = .29$ at 3 months) and not significant in PROWL-2 ($r = 0.08$, $P = .17$ at 1 month and $r = 0.05$, $P = .46$ at 3 months).

Change From Baseline to Follow-up

Changes from baseline to 1 month (**Table 3**), 3 months (**Table 4**), and 6 months (**Table 5**) postoperatively are reported. As hypothesized, most of the measures improved significantly in both studies from baseline to the 1-month follow-up, but hours worked, OSDI environment scale, and 2 visual symptoms (starbursts and halos) did not change in either study and the new visual symptoms glare scale did not change in PROWL-1. The NEI-RQL-42 glare scale score significantly worsened from baseline to 1 month postoperatively in both studies.

At the 3-month follow-up, every measure improved significantly except that there was no change from baseline for the NEI-RQL-42 glare scale and hours worked in both studies and for the OSDI environment scale in PROWL-1. At the 6-month follow-up (PROWL-1), all measures improved significantly from baseline with 2 exceptions: hours worked and the OSDI environment scale.

The magnitude of change in PROWL-1 ranged from 0.14 baseline SD (OSDI symptom scale) to 1.86 SD (satisfaction with vision) at 1 month, 0.17 SD (halos symptom scale) to 1.95 SD (satisfaction with vision) at 3 months, and 0.20 SD (NEI-RQL-42 glare scale) to 1.98 SD (satisfaction with vision) at 6 months. Magnitude of change in PROWL-2 ranged from 0.14 SD (NEI-RQL-42 clarity of vision) to 1.25 SD (satisfaction with vision) at 1 month and 0.19 SD (halos scale) to 1.34 SD (satisfaction with vision) at 3 months. Repeated-measures analyses that included baseline and all follow-up data in a single model produced results similar to those reported here.

Discussion

This study provides support for the reliability and validity of the HRQOL instrument administered in the PROWL studies for patients undergoing LASIK surgery. Content validity was enhanced by input from patients who underwent LASIK and clinicians during development of the new items.[23] Item-scale correlations indicated that the items were almost always more highly correlated with the scale they were intended to represent than with other scales. Reliability estimates exceeded the 0.70 threshold for adequate reliability for most of the measures. In addition, correlations among the scales indicated that they yield distinct information about HRQOL. Moreover, the HRQOL measures were significantly positively correlated with patient satisfaction with LASIK surgery, consistent with a previous study.[24] The measures were uncorrelated or weakly associated with socially desirable response set, health proneness (coping), optimism, depressive and/or anxiety symptoms, and expectations of spectacle use and vision.

Responsiveness to change was supported by improvements in almost every HRQOL measure from baseline to follow-up. The NEI-RQL-42 glare scale showed increases in glare at 1 month in both PROWL-1 and PROWL-2 and reduction in glare at 6 months in PROWL-1. Differences from baseline for all other follow-up times were not found. A previous evaluation of 185 patients before and 4 months after surgical correction of myopic or hyperopic refractive error found increases in glare among myopes.[12] Unlike the NEI-RQL-42, the new glare items included a definition that focused solely on glare, as well as an image showing graded severity. We found significant improvements (less glare) on the new visual symptoms glare scale at 1 month in PROWL-2, 3 months in PROWL-1 and PROWL-2, and 6 months in PROWL-1.

Limitations and Strengths

Inferences about the prevalence of the symptoms are limited by oversampling of high myopes and hyperopes. In addition, whether the changes observed persist beyond the time intervals studied is unknown. Furthermore, PROWL studies were limited to English-language participants. Administering the questionnaire to people whose English differs from US English or whose primary language is not English would require translation and assessment of the linguistic and cultural equivalence relative to the original English-language questionnaire. Moreover, associations of the PROs with visual acuity were small or not significant and using acuity as a clinical and/or was not supported. Finally, caution in drawing conclusions is warranted because of the multiple statistical tests performed.

Despite these limitations, most eligible patients were included in the analysis (99.6% in PROWL-1 and 95% in

Table 4. Baseline and 3-Month Postoperative Scale Means and Differences in PROWL

Scale[a]	Preoperative Mean	3-mo Postoperative Mean	Difference, Mean (SD)	*t* Statistic	*P* Value
NEI-RQL-42					
Clarity of vision					
PROWL-1 (n = 223)	82.8	90.0	7.2 (25.5)	4.23	<.001
PROWL-2 (n = 256)	80.0	89.7	9.7 (24.9)	6.22	<.001
Near vision					
PROWL-1 (n = 223)	80.6	96.5	15.9 (15.7)	15.08	<.001
PROWL-2 (n = 256)	86.9	95.1	8.2 (14.2)	9.20	<.001
Far vision					
PROWL-1 (n = 223)	76.6	92.4	15.8 (18.4)	12.78	<.001
PROWL-2 (n = 256)	82.9	92.1	9.2 (15.8)	9.38	<.001
Glare					
PROWL-1 (n = 222)	79.5	81.4	1.9 (29.1)	0.98	.33
PROWL-2 (n = 256)	77.1	77.3	0.2 (30.9)	0.13	.90
Diurnal vision					
PROWL-1 (n = 222)	82.8	90.7	7.9 (24.7)	4.72	<.001
PROWL-2 (n = 256)	80.0	88.1	8.1 (24.4)	5.30	<.001
Activity limitations					
PROWL-1 (n = 223)	60.8	96.2	35.4 (28.1)	18.79	<.001
PROWL-2 (n = 256)	72.3	97.4	25.1 (24.9)	16.15	<.001
Worry					
PROWL-1 (n = 224)	36.2	68.2	32.0 (32.3)	14.83	<.001
PROWL-2 (n = 256)	34.4	66.6	32.2 (29.9)	17.17	<.001
NEI-VFQ-25 Driving					
PROWL-1 (n = 220)	77.8	92.7	14.9 (22.7)	9.68	<.001
PROWL-2 (n = 252)	84.7	91.7	7.0 (16.5)	6.65	<.001
Hours Worked[b]					
PROWL-1 (n = 215)	41.3	40.3	−1.0 (21.3)	−0.69	.90
PROWL-2 (n = 215)	38.9	39.6	0.7 (16.6)	0.57	.57
OSDI					
Symptoms					
PROWL-1 (n = 222)	14.4	9.1	−5.3 (15.8)	−4.96	<.001
PROWL-2 (n = 256)	18.4	9.6	−8.8 (16.7)	−8.47	<.001
Environment					
PROWL-1 (n = 221)	10.2	8.7	−1.5 (17.8)	−1.23	.22
PROWL-2 (n = 256)	15.4	9.2	−6.2 (20.6)	−4.75	<.001
Visual Symptoms					
Glare					
PROWL-1 (n = 222)	80.5	90.0	9.5 (28.9)	4.86	<.001
PROWL-2 (n = 254)	81.4	88.6	7.2 (28.1)	4.07	<.001
Starbursts					
PROWL-1 (n = 220)	75.1	84.3	9.2 (31.8)	4.28	<.001
PROWL-2 (n = 256)	69.4	79.6	10.2 (33.5)	4.90	<.001
Halos					
PROWL-1 (n = 219)	79.0	84.3	5.3 (30.3)	2.58	.01
PROWL-2 (n = 256)	73.7	80.0	6.3 (33.1)	3.03	<.003
Double images					
PROWL-1 (n = 222)	87.7	97.2	9.5 (22.3)	6.37	<.001
PROWL-2 (n = 256)	85.6	97.4	11.8 (21.3)	8.91	<.001
Satisfaction With Vision					
PROWL-1 (n = 222)	36.0	90.9	54.9 (28.2)	28.96	<.001
PROWL-2 (n = 256)	44.5	87.3	42.8 (31.9)	21.50	<.001

Abbreviations: NA, not applicable for single item measure; NEI-RQL-42, National Eye Institute Refractive Error Quality of Life Instrument, 42 items; NEI-VFQ-25, National Eye Institute Visual Functioning Questionnaire, 25 items; OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK (laser in situ keratomileusis).

[a] All scales are scored on a 0 to 100 possible range. NEI-RQL-42 scales, NEI-VFQ driving scale, visual symptoms scales, and satisfaction with vision are scored such that a higher score is better. OSDI is scored such that a higher score is worse.

[b] Truncated at 60 hours.

Table 5. Baseline and 6-Month Postoperative Scale Means and Differences in PROWL-1

Scale[a]	Preoperative Mean	6-mo Postoperative Mean	Difference, Mean (SD)	*t* Statistic	*P* Value
NEI-RQL-42					
Clarity of vision (n = 215)	83.2	90.7	7.4 (23.9)	4.58	<.001
Near vision (n = 215)	80.6	96.5	15.8 (16.1)	14.46	<.001
Far vision (n = 215)	77.4	93.1	15.7 (18.2)	12.63	<.001
Glare (n = 215)	79.2	85.0	5.8 (28.5)	2.97	<.004
Diurnal vision (n = 215)	83.1	90.3	7.2 (23.4)	4.49	<.001
Activity limitations (n = 215)	61.4	96.7	35.3 (28.2)	18.37	<.001
Worry (n = 215)	36.5	71.9	35.3 (31.8)	16.30	<.001
NEI-VFQ driving (n = 214)	78.3	92.4	14.2 (22.8)	9.10	<.001
Hours worked (n = 206)[b]	41.3	40.0	−1.2 (22.8)	−0.78	.43
OSDI (n = 215)					
Symptoms (5 items)	14.2	8.1	−6.1 (15.3)	−5.85	<.001
Environment (3 items)	10.1	8.0	−2.1 (18.2)	−1.71	.09
Visual symptoms					
Glare (n = 214)	80.6	92.7	12.1 (28.2)	6.28	<.001
Starbursts (n = 213)	74.7	86.3	11.6 (32.8)	5.15	<.001
Halos (n = 215)	79.1	88.1	9.0 (31.7)	4.14	<.001
Double images (n = 215)	87.9	97.2	9.3 (22.3)	6.13	<.001
Satisfaction with vision (n = 215)	36.6	91.5	55.0 (27.8)	28.96	<.001

Abbreviations: NEI-RQL-42, National Eye Institute Refractive Error Quality of Life Instrument, 42 items; NEI-VFQ-25, National Eye Institute Visual Functioning Questionnaire, 25 items; OSDI, Ocular Surface Disease Index; PROWL, Patient-Reported Outcomes With LASIK (laser in situ keratomileusis).

[a] All scales are scored on a 0 to 100 possible range. NEI-RQL-42 scales, NEI-VFQ driving scale, visual symptoms scales, and satisfaction with vision are scored such that a higher score is better. OSDI is scored such that a higher score is worse.

[b] Truncated at 60 hours.

PROWL-2), which is notably better than most surveys.[25] The results of PROWL-1 and PROWL-2 were consistent. The new visual symptom items provide a potentially valuable approach that couples images with definitions and facilitates reports about the impact of surgery. Eight questions for each symptom were used to assess frequency, bother, and difficulty doing usual activities when and when not wearing vision correction. Estimates of the minimally important difference of mean scores are reported in eTable 9 in the Supplement. Supplementary Rasch-model analyses were consistent with the reported results (eTables 10 and 11 in the Supplement).

The web-based administration of questionnaires, which allowed for questionnaire completion outside of the clinical visit, facilitated the conduct of the clinical studies by removing 1 level of data entry and potentially provided the participants more anonymity in their responses. Most study participants reported that completing the questions by computer was easier than it would have been to do so by paper.[26]

Conclusions

The PROWL studies provided support for the reliability and validity of most scales included in the questionnaire for evaluating the effect of LASIK surgery. The newly created measures to assess satisfaction with LASIK surgery and double images, glare, halos, and starbursts supplement the existing OSDI symptoms scale, NEI-RQL-42 scales (clarity of vision, near vision, far vision, diurnal vision, activity limitation, and worry), and the NEI-VFQ-25 driving scale. This collection of measures can be used to help provide estimates of the prevalence of symptoms, functioning, and well-being in future studies evaluating LASIK devices. We recommend use of the new visual symptoms scales, the satisfaction with LASIK surgery scale, and the satisfaction with vision item in future studies. These newly created scales in the PROWL questionnaire could be used to measure important visual symptoms that occur following LASIK.

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