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ORIGINAL RESEARCH

Multi-Site Study of Patient Reported Vision Quality and Dry Eye Following LASIK

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Purpose: To assess patient subjective responses regarding satisfaction of vision, visual disturbances, and dry eye symptoms following WaveLight LASIK surgery for myopia or myopic astigmatism.

Methods: This was an ambispective, multicenter, multi-surgeon, single arm, observational study. Subjects were included who had Wavefront Optimized or Phorcidies Planned Contoura LASIK (using the Wavelight EX500 laser) for myopia or myopic astigmatism (targeting bilateral emmetropia) within the last 12 to 15 months. Eligible subjects were identified by retrospective chart review and administered a modified Patient-Reported Outcomes with LASIK (PROWL), Ocular Surface Disease Index (OSDI), and dry eye questionnaires.

Results: A total of 300 subjects completed the study. Postoperatively, all patients were satisfied with their vision, with 95% (285/300) reported being "Completely Satisfied" or "Very Satisfied". In addition, 95% (285/300), 79% (237/300), 78% (234/300), and 70% (210/300) of subjects reported "Never" or "Rarely" experiencing double images, glare, halos, and starbursts, respectively, while 0% (0/300), 2% (6/300), 1% (3/300), and 3% (9/300) of subjects reported that these same visual disturbances were "Extremely" or "Very" bothersome, respectively. Furthermore, 98% (294/300) of patients said they would choose to have the procedure again and 98% (294/300) would recommend it. Mean score on the OSDI questionnaire was 8.7 ± 8.2, with the majority (71%, 213/300) of the subjects being asymptomatic (score < 12). The mean OSDI score was within the range indicative of a normal ocular surface.

Conclusion: The results suggest high patient satisfaction of vision after approximately 12 months following Wavelight LASIK. Visual disturbances were rated low in frequency and in bothersomeness.

Keywords: LASIK, WFO, topography-guided, phorcides, PROWL, patient reported outcomes, OSDI

Introduction

A popular and effective treatment for myopia and myopic astigmatism is laser in situ keratomileusis (LASIK). It has been demonstrated to provide excellent refractive and visual outcomes for patients.[1] However, patients may experience visual disturbances (such as halos and glare) and dry eye following treatment. The Patient-Reported Outcomes with LASIK (PROWL) studies (PROWL-1 and PROWL-2) reported an incidence of any visual disturbance between 50% and 60% at 3 months postoperatively, compared to between 67% and 73% preoperatively.[2] In addition, it has been estimated that 35% of LASIK patients experience dry eye postoperatively compared to 57% preoperatively, and 27% may have their symptoms worsen following treatment.[2–4] Both visual disturbances and dry eye can lead to dissatisifed patients. Indeed, a recent meta-analysis reported that an overall dissatisfaction rate of 2–6% of post-LASIK patients, which was influenced by the type of questionnaire used.[5] Unhappy patients may require additional office visits, and in some cases, further surgical intervention.

Early LASIK treatment plans focused solely on the refractive sphere and cylinder.[6] However, current treatment plans can take into account corneal asphericity, such as with wavefront-optimized LASIK (WFO),[7] and the individualized surface elevation characteristics of the cornea, such as with topography-guided LASIK.[8] In addition, early LASIK also used a microkeratome to create the flap, while currently this can be done using a femtosecond laser. Using a femtosecond

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laser may offer advantages for reducing postoperative dry eye.[9] Many of these advancements were not widespread in use when the PROWL-1 and PROWL-2 studies were completed.

The Wavelight EX500 laser (Alcon Vision, LLC) can perform both WFO and topography-guided LASIK treatments. Excellent visual and refractive outcomes have been reported with both of these treatment plans.[8,10–13] However, to date there are minimal data on the subjective patient reported outcomes for vision quality and dry eye following WFO and topography-guided LASIK, especially beyond 6 months postoperatively. The purpose of this study was to assess patient subjective responses regarding satisfaction of vision, visual disturbances, and dry eye symptoms after 12 to 15 months following WaveLight LASIK surgery for myopia or myopic astigmatism.

Methods

This was a multicenter, multi-surgeon, single arm ambispective study. A central institutional review board (IRB) reviewed and approved the study (Advarra IRB, approval Pro00082114). All participants gave written informed consent. The study was conducted in compliance with Good Clinical Practice, tenets of the Declaration of Helsinki, and International Harmonization Guidelines (ICH), and was registered on clinicaltrials.gov (NCT06668909).

Inclusion criteria were Wavefront Optimized or Phorcidies Planned Contoura LASIK (using the Wavelight EX500 laser) for myopia or myopic astigmatism (targeting bilateral emmetropia) within the last 12 to 15 months, 21 to 35 years of age at the time of surgery, preoperative myopic sphere of −1.00 D to −8.00 and regular astigmatism of 0.00 D to −3.00 D stable refraction preoperatively defined as < 0.5 D of change over at least 1 year. Exclusion criteria were corneal ectatic disorders, residual stromal depth of < 300 um, pre-existing retinal or corneal pathology, irregular astigmatism, autoimmune diseases, dry eye, glaucoma, diabetes, previous corneal surgeries prior to LASIK, or any LASIK enhancements.

Eligible patients were administered a modified Patient-Reported Outcomes with LASIK (PROWL), Ocular Surface Disease Index (OSDI), and dry eye questionnaires. The modified PROWL asked subjects to rate their satisfaction with vision, the frequency, bothersomeness, and difficulty with usual activities of double images, glare, halos, and starbursts, and quality of life. Details are summarized in Supplementary Figure 1. Details on the items from the PROWL-SS questionnaire are available from the American Academy of Ophthalmology Academy (https://www.aao.org/education/prowl-ss). The OSDI questionnaire asked subjects to rate their dry eye symptoms and their visual impact. The dry eye questionnaires asked subjects to describe any artificial tears or prescription dry eye medication that they were currently using. All patient reported outcomes were collected using a software application known as "Sooth" (Lochan, North Oaks, MN, US). Sooth provides HIPPA-secure questionnaires to study patients electronically, and patients can answer the questions from their cell phone or computer.

The primary endpoint of this study was patient satisfaction, specifically the percentage of subjects answering "Completely Satisfied" or "Very Satisfied" on the satisfaction with current vision item of the modified PROWL questionnaire. Other endpoints included responses on the remaining modified PROWL questions, OSDI score, and the percentage of subjects using artificial tears or prescription dry eye medication.

The software R (version 4.4.2; The R Foundation for Statistical Computing, Vienna, Austria) was used for all statistical analyses. We estimated that the study would require a sample size of 300 subjects to characterize patient subjective responses regarding vision, satisfaction of perceived outcomes, and dry eye symptoms following Wavelight LASIK surgery. This sample size was selected to align with the PROWL-1 (n = 262) and PROWL-2 (n = 312) studies.[2] Exploratory analyses included satisfaction correlations to OSDI score, and the frequency of double images, glare, halos, and starbursts. Raw p-values were adjusted using Benjamini–Hochberg, and p-values ≤ 0.05 after adjustment were considered significant.

Results

A total of 300 subjects completed the study. No adverse events were reported during the study. On the modified PROWL satisfaction with current vision item, 95% of subjects reported being "Completely Satisfied" or "Very Satisfied" with their vision, and 5% were "Somewhat Satisfied" with their vision.

Tables 1–3 summarize subject responses regarding dysphotopsias on the modified PROWL. The percentages of subjects "Always" or "Often" experiencing double images, glare, halos, and starbursts were 1% (3/300), 6% (18/300), 4% (12/300), and 11% (33/300), respectively. The percentages of subjects indicating "Extremely" or "Very" bothersome double images, glare, halos, and starbursts were 0% (0/300), 2% (6/300), 1% (3/300), and 3% (9/300), respectively. The percentages of subjects indicating "So Much" or "A Lot of" difficulty with usual activities due to double images, glare, halos, and starbursts were 0% (0/300), 0% (0/300), 1% (3/300), and 1% (3/300), respectively. Furthermore, 94% (282/300) and 54% (162/300) of subjects indicated that they had "No difficulty at all" driving during the day and night, respectively, while 80% (240/300) and 91% (282/300) indicated that they "Never" or "Rarely" worry about their eyesight or are bothered by changes in the clarity of their vision over the course of a day, respectively. In addition, 97% (291/300) of subjects responded that LASIK improved their quality of life, 98% (294/300) would have the procedure again, and 98% (294/300) would recommend to a friend or family member.

Mean postoperative OSDI score was 8.7 ± 8.2 (range 0.0 to 41.7). In addition, 72% (216/300) of patients had a score indicative of being asymptomatic (< 12 on the OSDI questionnaire). The percentage of subjects using artificial tears was 42% (126/300), and of those 71% (90/126) used artificial tears once per day and 18% (23/126) used twice per day. Only 4% (12/300) of subjects indicated that they used prescription dry eye medication.

Table 1 Subject Responses Regarding Dysphotopsia Frequencies on the Modified PROWL Questionnaire

Item	Always	Often	Sometimes	Rarely	Never
Double Image	0	1	3	10	85
Glare	2	4	15	31	48
Halo	2	2	17	25	53
Starburst	4	7	19	23	47

Notes: Data presented as percentages.

Table 2 Subject Responses Regarding Dysphotopsia Bothersomeness on the Modified PROWL Questionnaire

Item	Extremely Bothersome	Very Bothersome	Somewhat Bothersome	A Little Bothersome	Not at All Bothersome
Double Image	0	0	3	4	93
Glare	0	2	8	26	64
Halo	0	1	5	20	73
Starburst	1	2	12	20	65

Notes: Data presented as percentages.

Table 3 Subject Responses Regarding Dysphotopsia Impact on Usual Activities on the Modified PROWL Questionnaire

Item	So Much Difficulty	A Lot of Difficulty	Moderate Difficulty	Very Little Difficulty	No Difficulty at All
Double Image	0	0	1	4	95
Glare	0	0	4	18	78
Halo	0	1	2	15	82
Starburst	0	1	4	21	73

Notes: Data presented as percentages.

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Exploratory Spearman correlation analyses revealed moderate correlations between satisfaction and other patient reported outcomes of OSDI score (rho = 0.42), and the frequency of double images (rho = 0.22), glare (rho = 0.34), halos (rho = 0.39), and starbursts (rho = 0.36). After adjustment, all p-values were statistically significant ($p < 0.001$).

Discussion

This study evaluated patient reported satisfaction, vision quality, and dry eye following WFO or topography-guided LASIK with the Wavelight EX500. Satisfaction was high, with 95% of patients (285/300) reporting being "Completely" or "Very" satisfied on the satisfaction with current vision item of the modified PROWL. Using a modification of the PROWL questionnaire, Rush et al[14] observed that 100% of patients (46/46) reported being "Completely" satisfied with their vision following topography-guided LASIK. In addition, Kanellopoulos et al[15] observed that 97% of subjects (103/106) reporting being "Completely" or "Very" satisfied on the PROWL questionnaire following LASIK using a ray tracing-based treatment algorithm (InnovEyes Sightmap, Alcon Vision, LLC). Differences between our study and others may be due to differences in sample size and the algorithms to generate ablation profile. The results of our study and others suggest high patient statisfaction with modern LASIK platforms.

Subjective patient reported outcomes for vision quality and dry eye are important to understand. In particular, visual disturbances following LASIK can negatively impact patient satisfaction.[16] We found that patients reported a relatively low frequency, bothersomeness, and difficulty with activities from double images, halos, glare, and starbursts. However, starbursts were reported as more frequent, bothersome, and causing more difficulty with activities compared to the other visual disturbances. A few other studies have observed patient reported visual disturbances following LASIK with the Wavelight EX500. The results presented by Ma and Mache[17] following wavefront-guided LASIK are similar to ours, with relatively low reported frequency, bothersomeness, and effect on activities of double images, glare, halos, and starbursts (on the PROWL questionnaire). Rush et al[14] observed a relatively low reported frequency of double images, glare, halos, and starbursts and relatively low reported difficulty driving at night using a modified PROWL questionnaire. Eventhough overall patient satisfaction can be high following LASIK, the reports of visual disturbances highlight the importance of patient counseling.

Dry eye is often considered a side effect of LASIK treatments.[1] We found that there was a low mean OSDI score postoperatively (8.7), which is indicative of normal ocular surface, while 72% of patients (216/300) were asymptomatic (score < 12). In addition, 91% of subjects indicated that they "Never" or "Rarely" are bothered by changes in the clarity of their vision over the course of a day. Ma and Manche[18] reported a mean OSDI score of 8.6 at 12 months post wavefront-guided LASIK, similar to our study. Using a Dry Eye Symptom Index, Rush et al[19] reported subjective dry eye score was relatively low 6 months post topography-guided LASIK and had improved from the preoperative baseline. The results of our study and others suggest that it is uncommon for patients to have clinically significant dry eye symptoms following LASIK.

The primary limitation of this study was a lack of a comparator. This could have been preoperative to postoperative, WFO to topography-guided LASIK, or between different refractive procedures. The purpose of this study was to gather patient reported outcomes from a large sample to understand and describe the subjective patient experience following LASIK. Therefore, the same laser (EX500) was chosen to eliminate confounding factors. Another limitation of the study was the ambispective design. A prospective study could have provided more robust preoperative data, however, the ambispective design limited the burden on patients (as there was no in office visit) and allowed for a large amount of data to be gathered in a relatively short time frame. In addition, our approach can provide data that is closer to real-world conditions.

Conclusions

The results suggest high patient satisfaction of vision approximately 1 year following Wavelight LASIK. Visual disturbances were rated low in frequency and in bothersomeness.

Data Sharing Statement

Data are not available for sharing.

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Disclosure

Brad Hall reports independent contractor fees from Topcon Healthcare Inc. The authors report no other conflicts of interest for this work.

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