

Topography-Guided LASIK: A Prospective Study Evaluating Patient-Reported Outcomes

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Purpose: To evaluate patient-reported outcomes with a validated patient questionnaire following topography-guided LASIK (TG-LASIK).

Methods: Patients undergoing TG-LASIK using Phorcides analytic software were prospectively enrolled to receive an adapted Patient-Reported Outcomes with LASIK Symptoms and Satisfaction (PROWL) questionnaire before and 26-weeks after treatment. The main study outcome was the change in the Global Vision Satisfaction Index from the PROWL questionnaire.

Results: Forty-six patients underwent treatment and completed the modified PROWL questionnaire before and 26-weeks after TG-LASIK. The Global Vision Satisfaction Index from the modified PROWL questionnaire improved from 4.07 (3.87–4.26) to 5.00 (4.81–5.19) after the TG-LASIK treatment ($p < 0.0001$). The study population's binocular uncorrected distance visual acuity was 20/16, 20/12.5, and 20/10 or better in 100%, 87.0%, and 15.2% at 26 weeks post TG-LASIK, respectively.

Conclusion: Patient satisfaction as assessed with the modified PROWL questionnaire is very high after undergoing TG-LASIK using Phorcides analytic software. Patient-reported outcomes add another dimension when assessing treatment efficacy beyond change in visual acuity and corneal architecture, and specialists may consider incorporating such assessments into the consenting process and patient education at large.

Keywords: LASIK, topography-guided, Contoura, PROWL, patient-reported outcomes, Phorcides

Introduction

Wavefront-guided (WG) and wavefront-optimized (WFO) ablations have been among the most popular LASIK techniques performed over the past decade,^{1,2} and conflicting outcomes are reported when the two techniques have been compared.^{3–6} In recent years, topography-guided LASIK (TG-LASIK) has become popular in the United States, and excellent outcomes have been reported.^{7,8} Compared to WG and WFO ablations, TG-LASIK offers the theoretical advantage of improving the cornea's natural shape, thereby enhancing the optics beyond what may be achievable with glasses and/or contact lenses with fewer higher order aberrations.^{9–12}

Researchers have compared various TG-LASIK algorithms for calculating the treatment of astigmatism, focusing mostly on the treatment of manifest refraction versus measured topographic refraction indices with mixed results.^{13–16} More recently, researchers have published outcomes using the Phorcides Analytic Engine software (Phorcides, LLC; MN, USA), a standardized and automated topography analysis algorithm.¹⁷ Better postoperative uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) have been reported when employing the Phorcides analytic software compared to conventional techniques based solely upon manifest refraction.^{18,19}

The medical sciences during the past several years have increasingly recognized the importance of patient-reported outcomes, and the authors agree that such outcomes provide the physician with an opportunity to offer a more holistic approach to the care of their patients.^{20,21} The Patient-Reported Outcomes with LASIK Symptoms and Satisfaction (PROWL) questionnaire are a well-defined and validated survey for assessing patient satisfaction following LASIK.^{22,23} Although reports using the PROWL questionnaire have been published after WG and WFO ablations,²⁴ there are

currently no reports following TG-LASIK. In this study, the authors evaluate patient-reported outcomes with the PROWL questionnaire before and after undergoing TG-LASIK using the Phorcides analytic software.

Methods

The Salus Independent Review Board (IORG0005674-1, Austin, TX, USA) approved this prospective, uncontrolled interventional study of patients who underwent bilateral TG-LASIK from October 2021 through November 2022 at a single private practice institution in Amarillo, TX. All components of this study were in compliance with the tenets of the Declaration of Helsinki and compliant with the Health Insurance Portability and Accountability Act of 1996. Written informed consent was obtained for all participants, and the study was registered on clinicaltrials.gov. prior to subject enrollment (NCT04903301, last accessed on 4–27-23).

The inclusion and exclusion criteria are presented in Table 1. Enrolled subjects underwent bilateral treatment using the Contoura[®] Vision technique (Alcon Vision, LLC; Fort Worth, TX, USA). The TG-LASIK was performed using the Wavelight FS200 and Wavelight EX500 laser platforms (Alcon Vision, LLC; Fort Worth, TX, USA). The flap dimensions were cut to a depth that ranged from 90 to 110 microns and a diameter from 8.8 to 9.0 mm. The excimer laser input parameters were calculated using the Phorcides analytic software with data captured from manifest refraction, Placido disc corneal imaging (Wavelight Vario Topolyzer; Alcon Vision, LLC; Fort Worth, TX, USA), and dual Scheimpflug anterior and posterior corneal imaging from the Galilei G4 Topographer (Ziemer Ophthalmic Systems AG, Alton, IL, USA) as described by previous investigators.²⁵ All treatment calculations were performed by the same examiner (CJP).

The study's baseline was considered the examination in which the patient was assessed for eligibility and consented/enrolled into the study. Data was collected at baseline and then post-treatment at 1 week (± 2 days), 4 weeks (± 1 week), 12 weeks (± 2 weeks), and 26 weeks (± 4 weeks). All the data was stored on a password-protected Microsoft Excel spreadsheet. The preoperative PROWL survey used in this study was adapted from previous studies^{22,23} and is presented in Figure 1. The modification was done to make the survey more concise so that all of the survey items would fit onto one page. The modified postoperative PROWL survey was identical in every way to the preoperative survey with the exception of the first question which substitutes “glasses or contacts on” with “after LASIK”. Visual acuity was measured in ETDRS letters and converted into logMAR for statistical analysis. The Objective Scatter Index analog score of the ocular surface was measured using the Visiometrics HD Analyzer (Keeler, Malvern, PA, USA). Corneal and total higher order aberrations were measured using the Galilei G4 Topographer and the OPD-Scan III Wavefront Analyzer (Marco Ophthalmic, Jacksonville, FL, USA), and additional refractive measurements were calculated using the VX 120+

Table 1 Patient Satisfaction with Topography-Guided LASIK. Eligibility Criteria

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| The age of the patient was 21–44 | Ocular surface disease, which in the opinion of the examiner, was clinically significant |
| Best-corrected visual acuity (Snellen) was 20/20 or better for each eye | Corneal disease (ie keratoconus, dystrophy, scarring, etc.) was clinically-evident |
| Best-corrected visual acuity (Snellen) was within 3 letters among both eyes | Posterior segment disease (ie diabetic retinopathy, glaucoma, etc.) was observed on examination |
| Refractive error was myopia up to -8.00 diopters | History of previous ocular surgery |
| Refractive astigmatism ranged from 0 to 3.00 diopters | |
| Maximum spherical equivalent was -9.00 diopters | |
| Intended target refraction was plano sphere for both eyes | |
| The calculated post-treatment residual stromal bed was >300 microns | |

(Visionix, Bensenville, IL, USA). The modified PROWL questionnaires, visual acuity measurements, and refractions were conducted by the same examiner in all instances (CJP).

Outcomes and Statistical Analysis

The primary outcome of the study was change in the Global Vision Satisfaction Index (visual analog score of 0–5 with 5 being most satisfied) from the adapted PROWL survey from baseline to 26-weeks post-treatment.

The study's power was determined by deriving a standard deviation from the primary outcome for the first 10 enrolled subjects completing the study's follow-up period. The difference to detect was calculated to be 0.5 (50% of the sampling standard deviation), resulting in 43 subjects as the minimum required number to complete follow-up. The data were analyzed using the JMP 11 software (SAS Institute; Cary, NC, USA). Means were compared using Student's *t*-test for numerical values and likelihood ratios for categorical variables. Statistical significance was considered at an alpha level of <0.05.

Results

Fifty-eight consecutive patients meeting eligibility criteria were approached regarding study participation; 49 of the patients elected participation and therefore were enrolled in the study. Forty-six of the 49 enrolled patients were treated and completed the study's 26-week-long study interval (93.9% completion rate). The 3 patients who failed to complete the study interval were lost-to follow-up and could not be brought back for data collection and therefore excluded from data analysis.

The study population's age was 31.1 (\pm 4.5) years with 58.7% female. The Binocular CDVA was -0.11 (\pm 0.06) logMAR with Mean Manifest Refraction Spherical Equivalent of 3.55 (\pm 1.79) diopters and Mean Manifest Refraction Refractive Astigmatism 0.90 (\pm 0.63) diopters. The remainder of the baseline characteristics and demographic features are presented in Table 2. There were no adverse events or intra-operative complications occurring during the treatment session for any of the subjects.

Table 2 Patient Satisfaction with Topography-Guided LASIK. Baseline Characteristics and Demographic Features for the Study Population

| Preoperative Characteristics and Demographics (N = 46) | Means with (Standard Deviations) and Percentages Where Appropriate |
|--|--|
| Age (years) | 31.1 (4.5) |
| | Range = 22 to 41 |
| Gender | Male = 19 (41.3%) |
| | Female = 27 (58.7%) |
| Ethnicity | White = 38 (82.6%) |
| | Hispanic = 6 (13.0%) |
| | Black = 1 (2.2%) |
| | Asian = 1 (2.2%) |
| Contact Lens Wearer | Yes = 33 (71.7%) |
| | No = 13 (28.3%) |
| Binocular CDVA (logMAR) | -0.11 (0.06) |
| | Range = -0.2 to 0 |
| Mean Manifest Refraction Spherical Equivalent (diopters) | -3.55 (1.79) |
| | Range = -7.88 to -0.75 |
| Mean Manifest Refraction Refractive Astigmatism (diopters) | 0.90 (0.63) |
| | Range = 0 to 2.63 |

Primary Outcome

The modified PROWL survey showed significant improvement on the Global Vision Satisfaction Index (analog score from 1 to 5 with 5 being the most satisfied) from 4.1 (3.9–4.3) preoperatively to 5.0 (4.8–5.2) postoperatively ($p < 0.0001$) for which 100% of patients reported maximum score of 5 for overall vision satisfaction postoperatively. Subset analysis from the questionnaire showed statistically significant postoperative improvement in night vision, glares, halos, starbursts, dry eye symptoms, and in the global symptomatology assessment ($p < 0.01$ for all). The only symptom that was not significantly improved was double images ($p = 0.17$). These findings are summarized in [Table 3](#).

Visual Outcomes

These outcomes were previously reported in another study by the authors.²⁶ In summary, the visual outcomes have been displayed in standardized graph format in [Figure 2](#).

Other Outcomes

[Figure 3](#) displays a graphical representation of the change in the Objective Scatter Index and higher order aberrations over time in the study population during the study interval. There was initial worsening for the objective scatter index but no significant change at the final follow-up interval ($p = 0.20$). With regard to the higher order aberrations, there were no significant changes in either the corneal higher order aberrations or the total higher order aberrations at the 4 mm optic zone ($p = 0.80$ and $p = 0.94$, respectively). By contrast, corneal higher order aberrations at the 6 mm optic zone had a significant increase from 0.39 (0.36–0.43) preoperatively to 0.54 (0.51–0.58) at the final visit ($p < 0.0001$). However, there was no significant increase in total higher order aberrations under mesopic pupil conditions (Mean = 5.8 ± 0.9 mm) which showed 0.33 (0.28–0.39) preoperatively versus 0.37 (0.32–0.42) postoperatively ($p = 0.34$).

There were no postoperative complications were identified during the study interval and no patients underwent an enhancement during the 26-week follow-up period.

Table 3 Patient Satisfaction with Topography-Guided LASIK. Pre- and Postoperative Comparative Analysis of the PROWL Survey (N = 46 Patients)

| Survey Question (Visual Analog Score of 1 to 5 with 5 Being the Worst) | Preoperative Means with (95% Confidence Intervals) | Final Postoperative Means at 26 Weeks with (95% Confidence Intervals) | p-value |
|--|--|---|--------------|
| Night Driving | 2.79 (2.52–3.04) | 1.24 (0.98–1.50) | $p < 0.0001$ |
| Double Images | 1.07 (1.00–1.13) | 1.00 (0.93–1.07) | $p = 0.17$ |
| Glares | 1.67 (1.47–1.88) | 1.22 (1.01–1.42) | $p = 0.002$ |
| Halos | 2.59 (2.33–2.84) | 1.48 (1.22–1.73) | $p < 0.0001$ |
| Starbursts | 2.89 (2.60–3.19) | 1.76 (1.47–2.06) | $p < 0.0001$ |
| Dryness | 2.20 (1.95–2.44) | 1.24 (0.99–1.49) | $p < 0.0001$ |
| Dry Eye Subset | | | |
| -Gritty? | Yes = 17.4% No = 82.6% | Yes = 0.0% No = 100.0% | $p = 0.0006$ |
| -Light Sensitive? | Yes = 23.9% No = 76.1% | Yes = 8.7% No = 91.3% | $p = 0.04$ |
| -Sore? | Yes = 4.3% No = 95.7% | Yes = 2.2% No = 97.8% | $p = 0.09$ |
| Global Symptomatology Assessment | 2.89 (2.60–3.18) | 1.13 (0.84–1.42) | $p < 0.0001$ |

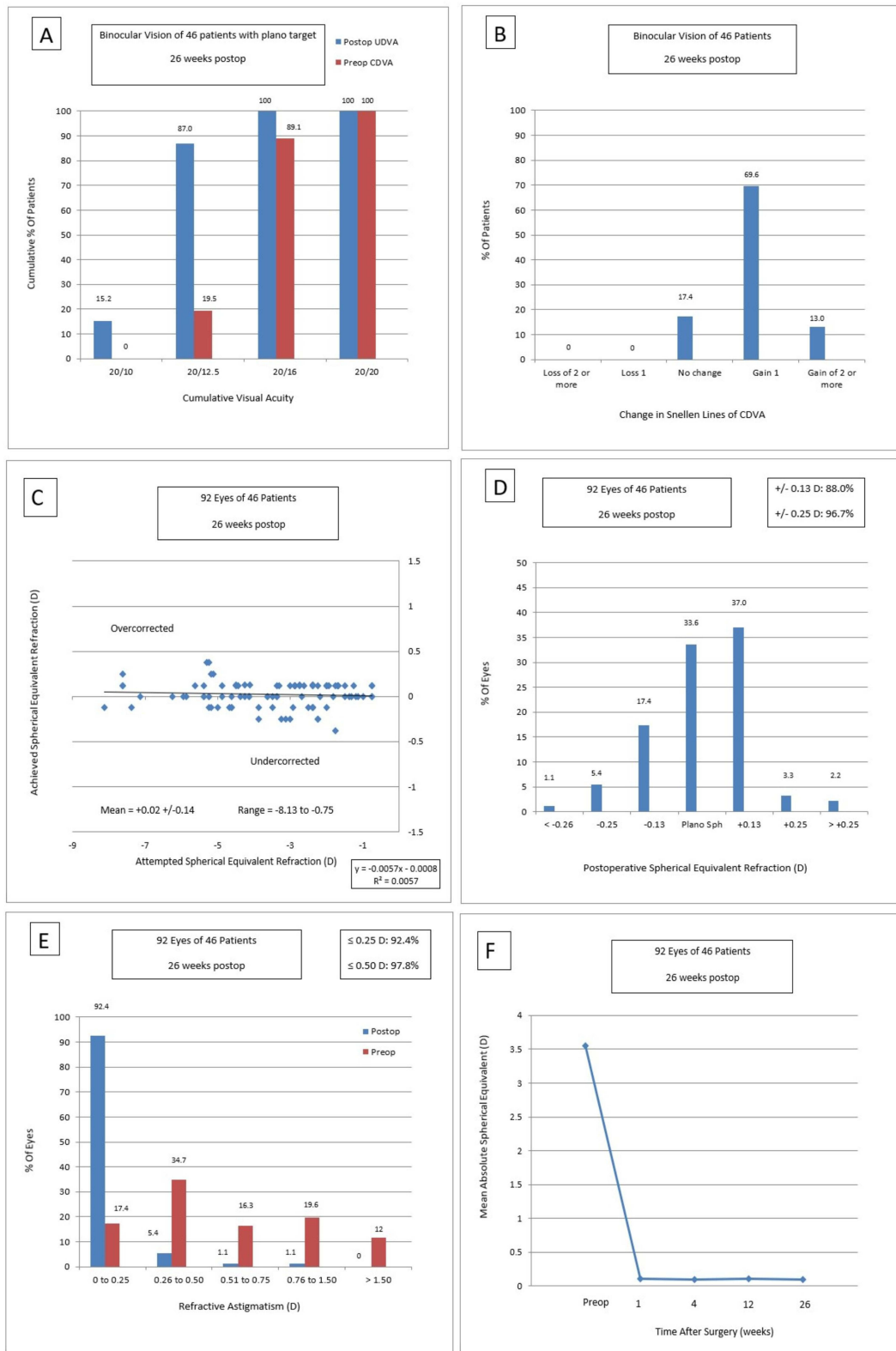


Figure 2 Vision and refractive data in standard graphing format including binocular outcomes. **(A)** Binocular Uncorrected Distance Visual Acuity: The histogram shows cumulative visual acuity binocularly as a percentage of patients reaching a Plano target. **(B)** Binocular Change in Corrected Distance Visual Acuity: The histogram shows change in Snellen lines of corrected distance visual acuity as a percentage of patients. **(C)** Spherical Equivalent Attempted vs Achieved: The scatter plot graph shows spherical equivalent attempted (X) versus spherical equivalent achieved (Y). **(D)** Spherical Equivalent Refractive Accuracy: The histogram shows postoperative spherical equivalent refraction (X) plotted against the percentage of eyes achieving the desired outcome (Y). **(E)** Refractive Astigmatism: The histogram shows refractive astigmatism (X) plotted against the percentage of eyes achieving the desired outcome (Y). **(F)** Stability of Spherical Equivalent Refraction: The line graph plots the mean absolute spherical equivalent (Y) over time (X).

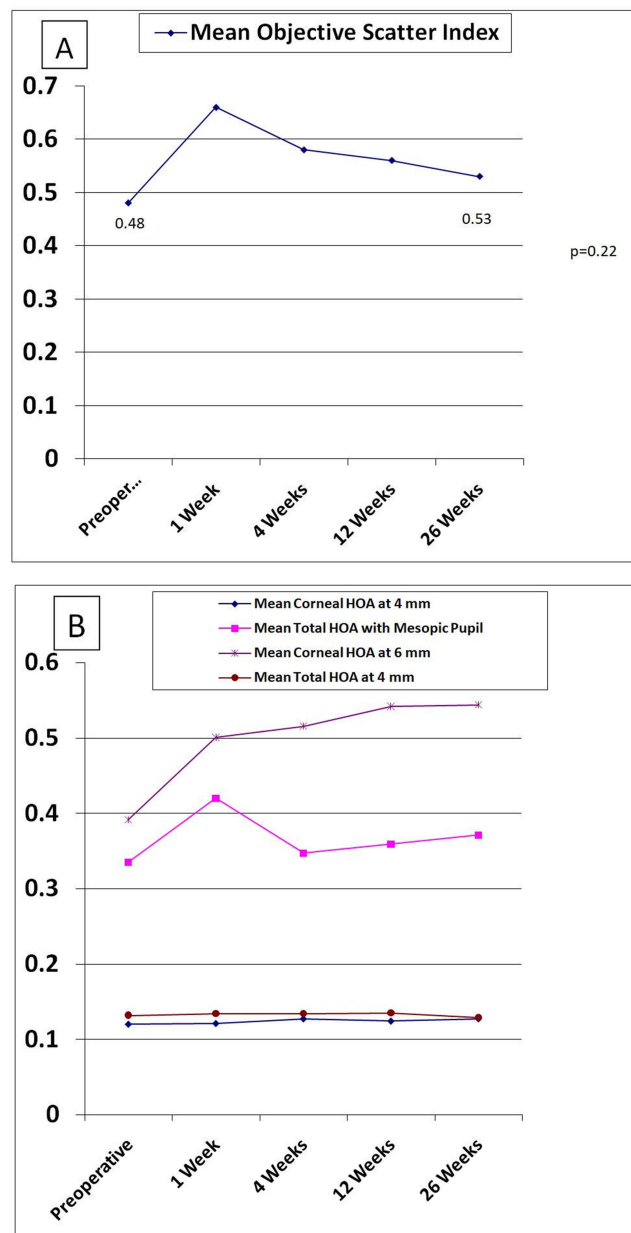


Figure 3 Other study outcome measures. **(A)** Objective Scatter Index. The line graph plots the change in objective scatter indices by analog score (Y) over time (X). **(B)** Higher Order Aberrations change over time. The line graph plots the change in higher order aberration indices in microns (Y) over time (X).

Discussion

To our knowledge, this is the first study to report findings associated with TG-LASIK primarily focused on quality of vision from the patient's perspective. The PROWL questionnaire was originally developed by a joint collaboration among the FDA, Department of Defense, and National Eye Institute in 2009. The PROWL-1 and PROWL-2 studies subsequently validated the first patient reported outcome survey with regard to quality of vision and quality of life after LASIK.^{22,23} These studies were conducted over a decade ago prior to the advent of topography-guided technology without a standardized LASIK technique which used multiple treatment calculation methods and laser platforms. Furthermore, the original PROWL inventory was web-based and included hundreds of questions on dozens of pages. An advantage of our study is that it consolidated key validated survey items from the PROWL questionnaire into a more controlled environment with a consistent survey administration technique and without being overly tedious and

burdensome on the patient to complete. Under these conditions, our findings show that TG-LASIK has a very high patient satisfaction rate. The patient-reported outcomes in this study demonstrate superiority in many aspects when compared to a recent study using WG-LASIK²⁷ in which 25% of those patients reported decreased quality of life relative to our study which had 100% of patients at the maximum level of satisfaction.

In light of the recently expanded FDA patient labeling recommendations for LASIK,²⁸ vision quality measures are paramount when assessing LASIK outcomes and during preoperative counseling with patients. Based upon the findings from this study, the authors believe that, during the informed consent process, surgeons can reasonably include increased difficulty with night vision, glares, halos, starbursts, and dry eye symptoms and the decrease of those same symptoms as both a potential risk and, even more likely, a benefit, respectively, of TG-LASIK. We suspect that many studies that report some of these adverse symptoms after LASIK do not compare these same symptoms to what the patient may have already been experiencing at baseline.²⁹

There is controversy regarding the ideal algorithm for refractive data input into the excimer laser when performing TG-LASIK.^{30–33} Input entirely derived from the surgeon's manifest refraction permits the surgeon a certain level of confidence in their own refraction as the primary source of refractive data in cases where talus is considered to have a negligible impact.¹⁵ By contrast, Phorcides analytic software has the advantage of accounting for the talus vector of astigmatism in all cases in which it is detected on corneal topographic imaging devices, especially in outlier cases where significant discrepancies among the refractive measurements exist.³⁴ The Phorcides algorithm has the additional benefit of objectively determining treatment parameters, thus allowing greater reproducibility among different surgeons. Similar to other studies,³⁵ the Phorcides analytic software employed in this study produced visual acuity outcomes better than 20/20 in many subjects.

Previous studies have reported induced higher order aberrations post-myopic ablation using both WFO-LASIK and TG-LASIK.³⁶ Our study supports that this small increase in higher order aberration is negligible with respect to visual acuity and quality of vision outcomes. Our findings show that the Objective Scatter Index did not increase to a clinically significant level and that there were no significant postoperative increases for either the total or the corneal higher order aberration at the smaller 4 mm optical zone. These findings may help explain the high patient satisfaction seen on the PROWL questionnaire.

The major limitation of this study is its lack of a comparison or control group as well having only a single study site. Strengths of this study include its prospective design using consistent methodology and calculation techniques, its high patient retention rate following enrollment, being sufficiently powered to detect significance, its use of a validated patient-reported outcome measurement tool, and its emphasis on real-world binocular vision with use of an ETDRS vision chart that measures visual acuity all the way down to 20/10 Snellen equivalent. Future investigations are necessary to validate these findings and compare patient-reported quality of vision outcomes with TG-LASIK without Phorcides analytic software and to other techniques, including other excimer laser platforms using wavefront optimized and wavefront-guided procedures as well as with non-excimer refractive treatments using SMILE and intraocular lens-based procedures. In conclusion, patient satisfaction with the PROWL questionnaire employed in this study is very high after undergoing TG-LASIK using Phorcides analytic software. Patient-reported outcomes add another element to help clinicians assess treatment efficacy beyond change in visual acuity and corneal architecture, and clinicians may consider incorporating such assessments into the consenting process as well as patient education at large.

Abbreviations

TG-LASIK, topography-guided laser in situ keratomileusis; WFO-LASIK, wavefront optimized laser in situ keratomileusis; WG-LASIK, wavefront-guided laser in situ keratomileusis; CDVA, best-corrected distance visual acuity; UDVA, uncorrected distance visual acuity; HOA, higher order aberrations; PROWL, patient-reported outcomes with LASIK; OSI, Objective Scatter Index.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Statement

The study was approved by the Salus Independent Review Board (IORG0005674-1, Austin, TX, USA) in accordance with the Ethical Standards laid down in the Declaration of Helsinki.

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This study was presented at the 2023 ASCRS meeting during a paper session.

Author Contributions

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agreed to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this works.

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