Safety and Effectiveness of Laser In Situ Keratomileusis Using the Teneo 317 Model 2 for Correcting Myopia and Myopic Astigmatism: Results of the U.S. FDA Clinical Trial

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ABSTRACT

PURPOSE: To evaluate the safety and effectiveness of a new aspheric ablation profile for correcting myopia and myopic astigmatism.

METHODS: This prospective, multicenter study included patients who underwent laser in situ keratomileusis (LASIK) using a new aspheric ablation profile of the Technolas Teneo 317 (Model 2) excimer laser (version 1.28 US SW) by Technolas Perfect Vision, Bausch+Lomb, Inc. No nomogram adjustments were made, and the patient's manifest refraction was entered into the laser (for treatment). Postoperative assessments included visual and refractive outcomes. Patients were asked to complete the Patient-Reported Outcomes With LASIK (PROWL) questionnaire preoperatively and postoperatively.

RESULTS: A total of 333 eyes from 168 patients with a mean age of 33 ± 7 years were included. At postoperative 9 months, uncorrected and corrected distance visual acuities of 20/25 or better were seen in 97.8% and 100% of eyes, respectively. None of the eyes lost two or more lines of corrected distance visual acuity. The mean manifest spherical refraction improved from -5.67 ± 2.52 diopters (D) preoperatively to -0.04 ± 0.32 D postoperatively, with 92.7% of eyes achieving residual refractive error within ±0.50 D. Residual refractive cylinder within ±0.50 and ±1.00 D was seen in 93% and 99.4% eyes, respectively. The refractive outcomes were stable throughout the follow-up of 9 months. The proportion of patients satisfied with their vision rose from 27.7% preoperatively to 98.1% postoperatively.

CONCLUSIONS: LASIK performed using a new aspheric ablation profile of the Technolas Teneo 317 (Model 2) excimer laser is safe and effective for correcting myopia and myopic astigmatism, yielding excellent visual and refractive outcomes that were stable over 9 months.

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From the approval of the excimer laser for reshaping the cornea (photorefractive keratectomy) to the development of laser in situ keratomileusis (LASIK) for refractive correction in the 1990s,[1,2] technological advancements in the past two decades have made laser vision correction one of the most commonly performed elective procedures.[3-5] Modern laser systems are much more sophisticated and offer submicron precision to safely and effectively correct refractive errors in patients seeking spectacle independence.[6]

Although excimer lasers from different manufacturers use similar principles for excimer ablation, many technical differences exist among excimer laser platforms. These variations in technology may include but are not limited to ablation algorithms, pulse frequency of laser ablation, amount of corneal tissue ablated, treatment duration, accuracy, and precision of eye trackers.[7-10] Ablation profiles designed to account for radial ablation efficiency can reduce the induction of spherical aberration by adjusting for reflection losses due to non-normal incidence of the excimer laser beam and have been associated with favorable outcomes.[2,11,12] Accurate and high-speed eye trackers reduce the rate of decentered ablations and help reduce the chances of dysphotopsias and reduction in contrast sensitivity.[13]

The Technolas Teneo 317 (Model 2) excimer laser by Technolas Perfect Vision, Bausch+Lomb, Inc, is an advanced version of the Technolas 217z excimer laser and employs a high pulse frequency of 500 Hz, a beam fluence of 200 mJ/cm^2, a small laser spot (1-mm diameter), and a laser pulse duration of 8 ± 3 ns. Other features include an optimized plume evacuator, a high-speed eye tracker that operates at 1,740 Hz, and contrast-optimized infrared illumination, allowing accurate and real-time compensation for X and Y and dynamic cyclotorsion and Z tracking. The aspheric ablation algorithm (PROSCAN version 1.28) calculates the expected amount of surgically induced spherical aberration for the intended ablation and compensates for it, which aims to maintain the natural aspheric shape of the cornea. The optimized pulse sorting algorithm in the Technolas Teneo 317 Model 2 excimer laser minimizes temporal or spatial overlapping of laser pulses to avoid unnecessary local thermal load during high repetition rate corneal laser surgery. The advanced algorithm ensures that the spots overlap only once every six pulses and optimizes the spatial-temporal distribution of laser pulses on the cornea.

The purpose of the current pivotal trial was to evaluate the safety and effectiveness of excimer laser surgery performed with the Technolas Teneo 317 (Model 2) using the new aspheric ablation algorithm (PROSCAN 1.28 SW) for the correction of myopia and myopic astigmatism. No nomogram adjustments were made, and the patient's manifest refraction was used for entry into the laser (for the intended emmetropic refractive target).

PATIENTS AND METHODS

This prospective, multicenter, open-label, nonrandomized, single-arm study was conducted at 10 clinical sites in the United States (ClinicalTrials.gov Identifier: NCT04111757) (Gregg Feinerman, MD, Feinerman Vision Center, Newport Beach, CA; Michael Endl, MD, Fichte, Endl & Elmer Eyecare, Amherst, NY; George O. Waring IV, MD, Waring Vision Institute, Mt. Pleasant, SC; Karl Stonecipher, MD, Physicians Protocol, Greensboro, NC; Vincent Restivo, MD, Hill Country Eye Center, Cedar Park, TX; N. Timothy Peters, MD, Clear Advantage Vision Correction Center, Portsmouth, NH; Y. Ralph Chu, MD, Chu Vision Institute, Bloomington, MN; Ronald Krueger, MD, UNMC Truhlsen Eye Institute, Omaha, NE; Vance Thompson, MD, Vance Thompson Vision, Sioux Falls, SD; Mark Lobanoff, MD, North Suburban Eye Specialists, Coon Rapids, MN). Written informed consent was obtained from all patients. The study was approved by the Advarra Institutional Review Board and followed the tenets of the Declaration of Helsinki.

Inclusion Criteria

The study included patients aged 22 years or older seeking unilateral or bilateral LASIK surgery with a refractive goal of emmetropia; manifest refraction spherical equivalent (MRSE) between -1.00 and -11.50 D with or without astigmatism (sphere between -1.00 and -10.00 D, cylinder between 0.00 and -3.00 D) demonstrating stable refraction (a change of 0.50 D or less in sphere and cylinder) for a minimum of 12 months prior to surgery; uncorrected distance visual acuity (UDVA) of 20/40 or worse; corrected distance visual acuity (CDVA) of 20/25 or better; 0.50 D or less difference between the cycloplegic and manifest refraction at the preoperative visit; normal corneal topography as determined by the investigator; and willingness to comply with the schedule for all postoperative follow-up visits.

Contact lens users were instructed to discontinue contact lens use for at least 2 weeks (for hard or toric lenses) or 3 days (for soft contact lenses) prior to the preoperative examination and through the day of surgery. In addition, they needed to demonstrate stable computed corneal topography and stable refraction (within ±0.50 D) as determined by MRSE on two consecutive examinations at least 1 week apart in the study eye and an axis of the cylinder not differing by more than 15 degrees.

Exclusion Criteria

Exclusion criteria were history or evidence of retinal vascular disease, corneal disease, keratoconus (manifest or forme fruste), glaucoma or glaucoma suspect, central corneal scars affecting visual acuity, systemic disease that may affect wound healing (eg, autoimmune disease, systemic connective tissue disease, diabetes, or severe atopic disease), acute or chronic disease or illness (eg, immunocompromised, rheumatoid arthritis, clinically significant atopic disease, or acne rosacea) that would increase operative risk or may confound the results of the study.

Individuals were also excluded if they had previous intraocular or corneal surgery or demonstrated unstable keratometry with irregular mires, irregular astigmatism, visually significant or progressive cataract, ocular muscle disorder (including strabismus or nystagmus, or another disorder affecting fixation), or mesopic pupil size greater than 7 mm. Eyes with an estimated residual corneal bed thickness of less than 250 µm or Schirmer's preoperative test score less than 4 mm/5 minutes without anesthesia were also excluded. Additional exclusion criteria included known sensitivity to any study medication, use of chronic medications (including those known to affect wound healing, such as corticosteroids or antimetabolites), and use of medications such as isotretinoin (Accutane; Wyeth Pharms, Inc) or amiodarone hydrochloride (Cordarone; Wyeth Pharms, Inc) that may increase the risk to the participant or confound the study outcomes. In addition, patients participating in any other ophthalmic clinical trial within 30 days of screening or during this clinical trial, and those who were pregnant, lactating, or planning to become pregnant during the study were excluded.

Preoperative and Postoperative Examinations

Preoperative evaluation included assessment of the patient's ocular and medical history, UDVA, CDVA, cycloplegic and manifest refraction, pachymetry, keratometry, corneal topography or tomography, slit-lamp examination, dilated fundus examination, intraocular pressure (IOP), and pupil size.

Postoperatively, patients were assessed at 1, 3, 6, and 9 months for UDVA, CDVA, manifest refraction, corneal topography, slit-lamp examination, dilated fundus examination, IOP, pupil size, complications, and adverse events. Patients were asked to self-administer the Patient-Reported Outcomes With LASIK (PROWL) questionnaire preoperatively and postoperatively at 9 months to assess patient-reported outcomes.

A sub-study conducted at four clinical sites also evaluated the mean preoperative and 6-month postoperative endothelial cell density (ECD) measurements using a non-contact specular microscope (Konan NSP-9900; Konan Medical, Inc) and contrast sensitivity (Clinical Trial Suite-1000; M&S Technologies) changes under mesopic conditions.

Study Endpoints

The effectiveness endpoints were the percentage of eyes that achieved predictability of MRSE within ±0.50 and ±1.00 D and the percentage of eyes targeted for emmetropia that achieved a UDVA of 20/40 (0.3 logMAR) or better.

Safety was assessed by evaluating the change in lines of CDVA postoperatively compared to preoperative CDVA. The incidence of adverse events, complications, and results from the PROWL questionnaire were also reported. Other safety parameters evaluated as a part of the sub-study included preoperative and 6-month postoperative ECD measurements and contrast sensitivity changes under mesopic conditions for both eyes at four clinical sites by specular microscopy.

Surgical Procedure

All surgeries were performed under topical anesthesia by experienced LASIK surgeons. Corneal lamellar flaps were created using the commercially available femtosecond laser of the investigator's choice prior to performing LASIK. LASIK was performed using a new aspheric ablation algorithm (version 1.28 US SW) with the Technolas Teneo 317 (Model 2) excimer laser workstation (Technolas Perfect Vision, Bausch+Lomb, Inc) on one or both eyes per its Instructions for Use. The patient's manifest refraction values were entered into the laser, and no nomogram adjustments were made. The excimer laser treatment was performed using default parameters (K = 43.3, Q = -0.2). The optical zone diameter (OZ) was 6.4 mm (range: 5.4 to 6.6 mm). Static cyclotorsion compensation was not performed.

Statistical Analysis

Up to 334 eyes meeting the study eligibility criteria were planned to be recruited, yielding a sample size of 300 evaluable eyes at the final visit after a 10% dropout rate. The primary effectiveness endpoints were analyzed for the observed data. Summaries for continuous and ordinal variables included the number of observations (n), arithmetic mean, and standard deviation. Summaries for discrete variables included counts and percentages.

The normality of the scale data was checked using the Kolmogorov-Smirnov test. For normally distributed scale data, the preoperative and postoperative data were compared using paired *t*-tests. For the data that were not normally distributed, a non-parametric Wilcoxon signed-rank test was used. For the statistical analysis of

categorical data, McNemar's test was used. Eyes were treated as independent sampling units, ignoring any correlation between the 2 eyes of each patient, as is customary for LASIK clinical trials. A *P* value less than .05 was considered statistically significant.

RESULTS

A total of 333 eyes from 168 patients were enrolled and treated, including 51 eyes treated for spherical myopia and 282 eyes for astigmatic myopia. The mean age of all 168 patients was 33 ± 7 years (range: 22 to 50 years), and the majority of patients were White (83.3%). More than half of the patients were women (60.1%). Of the 168 patients, 165 underwent bilateral surgery and 3 underwent unilateral treatment. Seventeen of 333 eyes discontinued the study, leaving 316 eyes available for analysis at postoperative 9 months. The preoperative patient characteristics are summarized in **Table 1**.

Visual Outcomes

All eyes were targeted for emmetropia. At postoperative 9 months, 97.8% of eyes demonstrated a UDVA of 20/25 or better and 99.7% had a UDVA of 20/40 or better (**Figure 1A**). When stratified by the type of refractive treatment, 100.0% of eyes treated for spherical myopia and 99.6% of eyes treated for astigmatic myopia had a UDVA of 20/40 or better at the 9-month visit. At postoperative 9 months, UDVA was within one line of preoperative CDVA in 92.1% of the eyes (**Figure 1B**). At postoperative 9 months, all eyes had CDVA of 20/25 or better; 4.4% of eyes gained two or more lines of CDVA and none of the eyes lost two or more lines of CDVA at 9 months postoperatively (**Figure 2**).

Refractive Outcomes

Figure 3A represents attempted versus achieved refraction; 92.7% of eyes achieved residual refractive error within ±0.50 D and 99.1% achieved refractive error within ±1.00 D (**Figure 3B**). The corresponding percentages for eyes treated for spherical myopia were 96.1% and 100%, respectively. Among eyes treated for astigmatic myopia, 92.1% of eyes were within ±0.50 D and 98.9% were within ±1.00 D. The mean MRSE improved from -5.67 ± 2.52 D preoperatively to -0.04 ± 0.32 D at postoperative 9 months. In eyes treated for spherical myopia, the mean preoperative MRSE improved from -5.22 ± 2.23 to -0.09 ± 0.28 D at postoperative 9 months. In eyes treated for astigmatic myopia, it improved from -5.75 ± 2.57 to -0.03 ± 0.33 D (**Figure 4**). Refractive results were stable, with 96.2% (1 to 3 months), 95.3% (3 to 6 months), and 93.9% (6 to 9 months) showing a change in MRSE of 0.50 D or less.

TABLE 1
Patient Characteristics and Preoperative Manifest Sphere and Cylinder (168 Patients, 333 Eyes)

Characteristic	Value
Age (years), mean ± SD	32.5 ± 6.6
Sex, n (%)	
Male	67 (39.9)
Female	101 (60.1)
Ethnicity, n (%)	
Hispanic or Latino	19 (11.3)
Not Hispanic or Latino	149 (88.7)
Race, n (%)	
American Indian or Alaska Native	1 (0.6)
Asian	18 (10.7)
Black/African American	3 (1.8)
Native Hawaiian or Other Pacific Islander	0
White	140 (83.3)
Multi-racial	3 (1.8)
Unknown	3 (1.8)
Sphere (D) , n (%)	
-1.00 to -2.00	49 (14.7)
-2.01 to -3.00	34 (10.2)
-3.01 to -4.00	40 (12.0)
-4.01 to -5.00	43 (12.9)
-5.01 to -6.00	35 (10.5)
-6.01 to -7.00	39 (11.7)
-7.01 to -8.00	43 (12.9)
-8.01 to -9.00	26 (7.8)
-9.01 to 10.00	24 (7.2)
Cylinder (in minus notation) (D) , n (%)	
0.00	51 (15.3)
-0.25 to -0.50	107 (32.1)
-0.51 to -1.00	77 (23.1)
-1.01 to -2.00	74 (22.2)
-2.01 to -3.00	24 (7.2)

D = diopters; SD = standard deviation

Of the 316 eyes, 73.1% showed improvement in astigmatism from preoperatively to postoperatively. There was no change in astigmatism (from preoperatively to postoperatively) in 18% of eyes. None of the eyes showed an increase in refractive astigmatism of greater than 0.75 D from preoperatively to postoperatively. The percentage of eyes with a residual refractive cylinder of 0.50 D or less and 1.00 D or less was 93% and 99.4%, respectively,

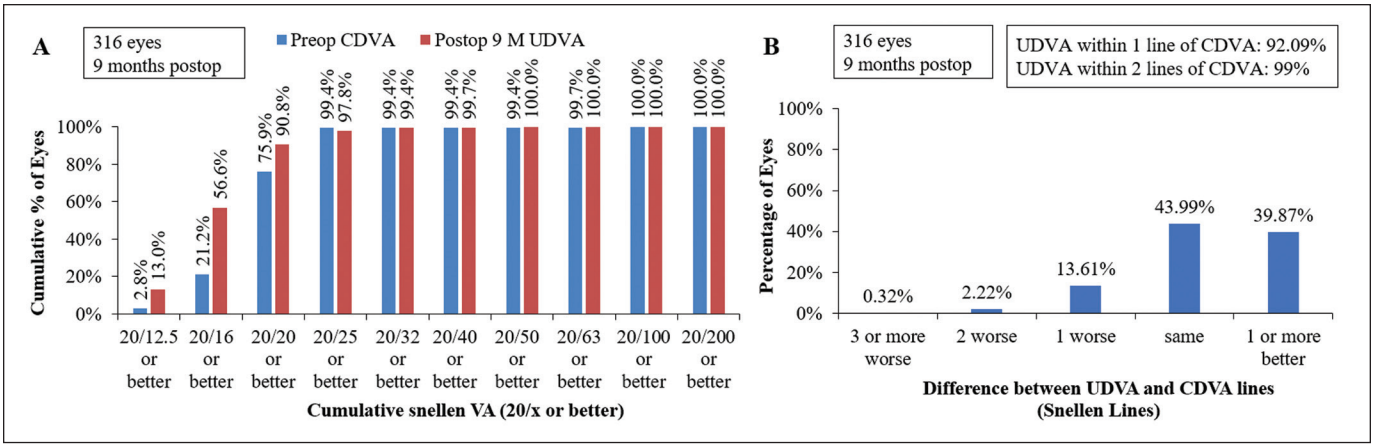

Figure 1. (A) Efficacy chart comparing the postoperative cumulative uncorrected distance visual acuity (UDVA) and preoperative corrected distance visual acuity (CDVA); (B) Efficacy chart showing differences in the number of lines between postoperative UDVA and preoperative CDVA.

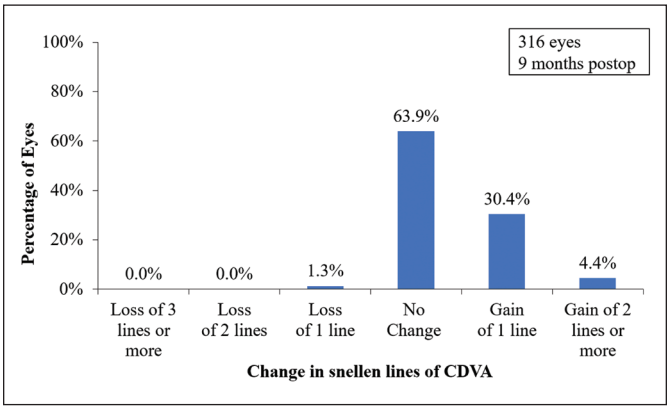

Figure 2. Safety chart depicting the change in the lines of corrected distance visual acuity (CDVA) from preoperatively to postoperatively.

at postoperative 9 months (**Figure 5A**). The Alpins method of astigmatism analysis was used to evaluate results in 265 eyes with preoperative refractive astigmatism of 0.25 D or greater. **Figure 5B** shows target induced astigmatism against surgically induced astigmatism at 9 months postoperatively. The mean postoperative angle of error was 1.9 ± 14.4 degrees (**Figure 5C**). Visual, refractive, and astigmatic data obtained at different time points from months 1 to 9 are summarized in **Table 2**.

ECD and Contrast Sensitivity

The ECD sub-study included 124 eyes with a mean preoperative ECD of 2,803.24 ± 315.57 cells/mm^2 and a 6-month postoperative ECD of 2,811.76 ± 297.64 cells/mm^2. The contrast sensitivity sub-study included 47 patients. The mean postoperative mesopic contrast sensitivity without glare measured in cycles per degree (cpd) was similar to or better than the preoperative mean contrast sensitivity, with statistically significant improvement (from preoperatively to postoperatively) observed for 6 and 12 cpd. A similar trend was observed for the mesopic contrast sensitivity with glare. The mean postoperative contrast sensitivity values were either similar to or better than the mean preoperative contrast sensitivity at all cpd levels, with statistically significant improvement observed at 3, 6, and 12 cpd (**Figure 6**).

Patient-Reported Outcomes

The proportion of patients reporting "no or little difficulty" in performing daily activities improved postoperatively, with statistically significant improvement in driving at night or in difficult conditions and performing outdoor activities. Similarly, the incidence of visual phenomena also reduced postoperatively, with a higher proportion of patients documenting no starbursts, glare, or distorted/blurry vision postoperatively. The symptoms of ocular discomfort also improved postoperatively (**Table 3**). Postoperatively, there was a statistically significant improvement in the proportion of patients reporting being "somewhat to very satisfied" with their vision compared to preoperatively (98.1% vs 27.7%; $P < .001$).

DISCUSSION

This pivotal study was undertaken to determine the safety and efficacy of LASIK performed with the Technolas Teneo 317 (Model 2) excimer laser to correct myopia and myopic astigmatism. The new aspheric ablation profile used in the study yielded excellent postoperative visual and refractive outcomes with high patient satisfaction. These results obtained in the current study are encouraging, given that no nomogram adjustments were made and the patient's manifest refraction was used for entry into the laser in all cases.

The refractive outcomes remained stable with a mean change of -0.03 D (range: -0.01 ± 0.31 to -0.04 ±

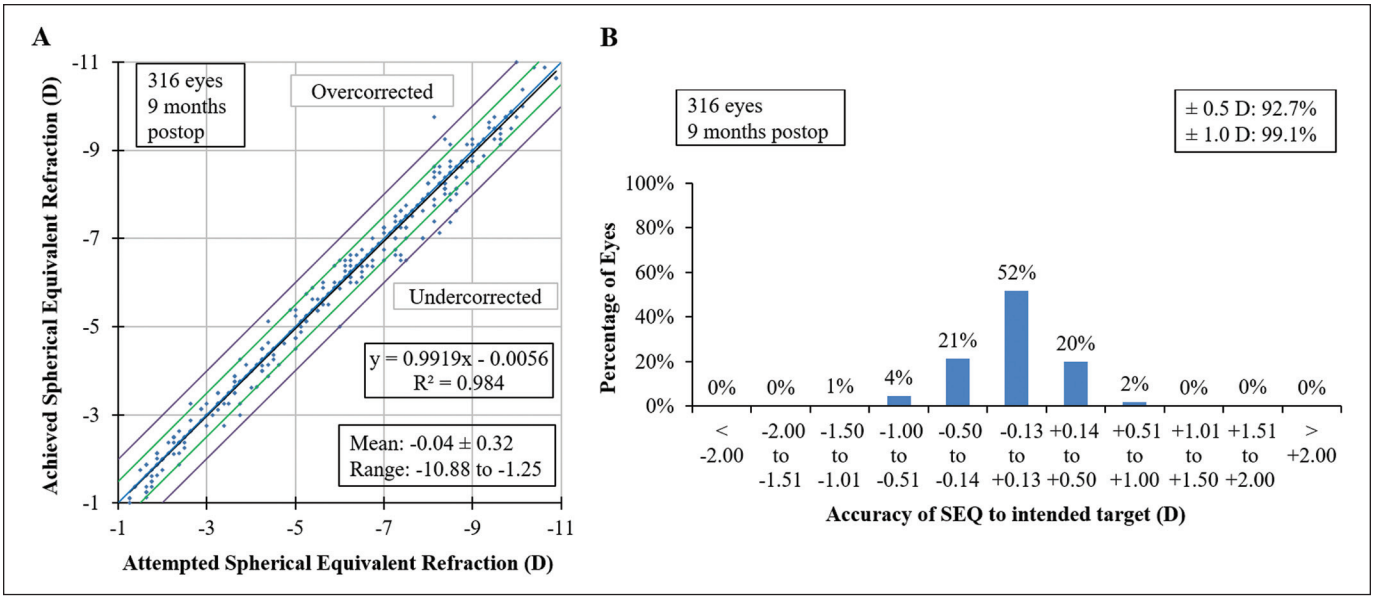

Figure 3. (A) Scatterplot of the attempted versus achieved refraction. (B) Accuracy of achieved manifest refraction spherical equivalent (SEQ). D = diopters

0.32 D) in postoperative refraction from 1 to 9 months. The refractive stability (±0.50 D) achieved in the current study at 1 to 3 months, 3 to 6 months, and 6 to 9 months was comparable to the pivotal trial of the U.S. Food and Drug Administration (FDA)–approved topography-guided LASIK.[14]

The mean postoperative manifest refraction depicts the accuracy of refractive outcomes, and the standard deviation of postoperative refractive outcomes aids in evaluating the precision of a laser system. A lower value of standard deviation denotes that the values are closer to the mean, indicating less spread of data and greater reliability of refractive results. In the current study, the small magnitude of mean postoperative MRSE (-0.04 D) and a low standard deviation of 0.32 D at 9 months are consistent with the overall positive clinical outcomes. Furthermore, the accuracy and precision of the outcomes achieved with the Technolas Teneo 317 Model 2 excimer laser were found to be comparable to or better than the topography-guided and wavefront-guided LASIK with FDA-approved laser systems.[14,15] For example, the accuracy (-0.06 and -0.04 D at 6 and 9 months) achieved in the current study was similar to the accuracy achieved with topography-guided LASIK (0.0 and 0.01 D at 6 to 12 months) and better than that reported for wavefront-guided LASIK (-0.46 to -0.49 D at 6-12 months).[14,15] Similarly, the precision of the laser system (0.31 to 0.32 D at 6 and 9 months, respectively) in the current study was comparable to the precision achieved with topography-guided LASIK (0.27 and 0.35 D at 6 to 12 months) and better than that achieved with wavefront-guided LASIK (0.40 to 0.45 D) at 6 to 12 months.[14,15]

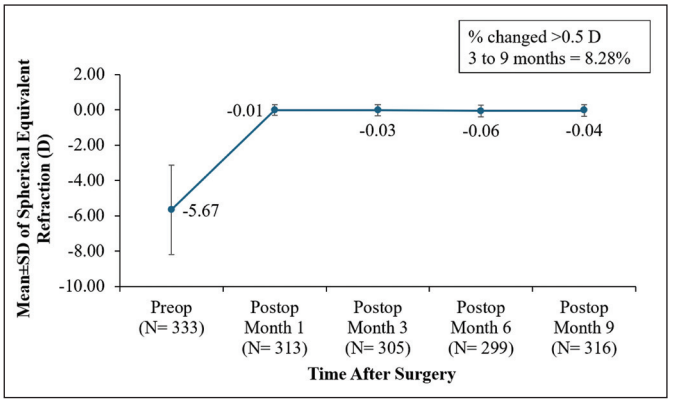

Figure 4. Stability of manifest refraction spherical equivalent (MRSE) over time. D = diopters

The findings achieved in the current study are comparable to the previously reported findings of topography-guided or wavefront-guided LASIK in terms of efficacy, spherical equivalent refractive predictability, astigmatism accuracy, and safety.[14,15] The percentage of eyes with postoperative UDVA of 20/20 or better was 90.8% in the current study, which is comparable to the values reported in the pivotal trial of topography-guided LASIK (92.6%) and better than those of wavefront-guided LASIK (83.8%).[14,15] When considering refractive accuracy, the current study showed 92.7% of eyes achieving MRSE within ±0.50 D, which was better than that reported in the pivotal trial of wavefront-guided LASIK (65.9%) and similar to that reported in the pivotal trial of topography-guided LASIK (94.8%).[14,15]

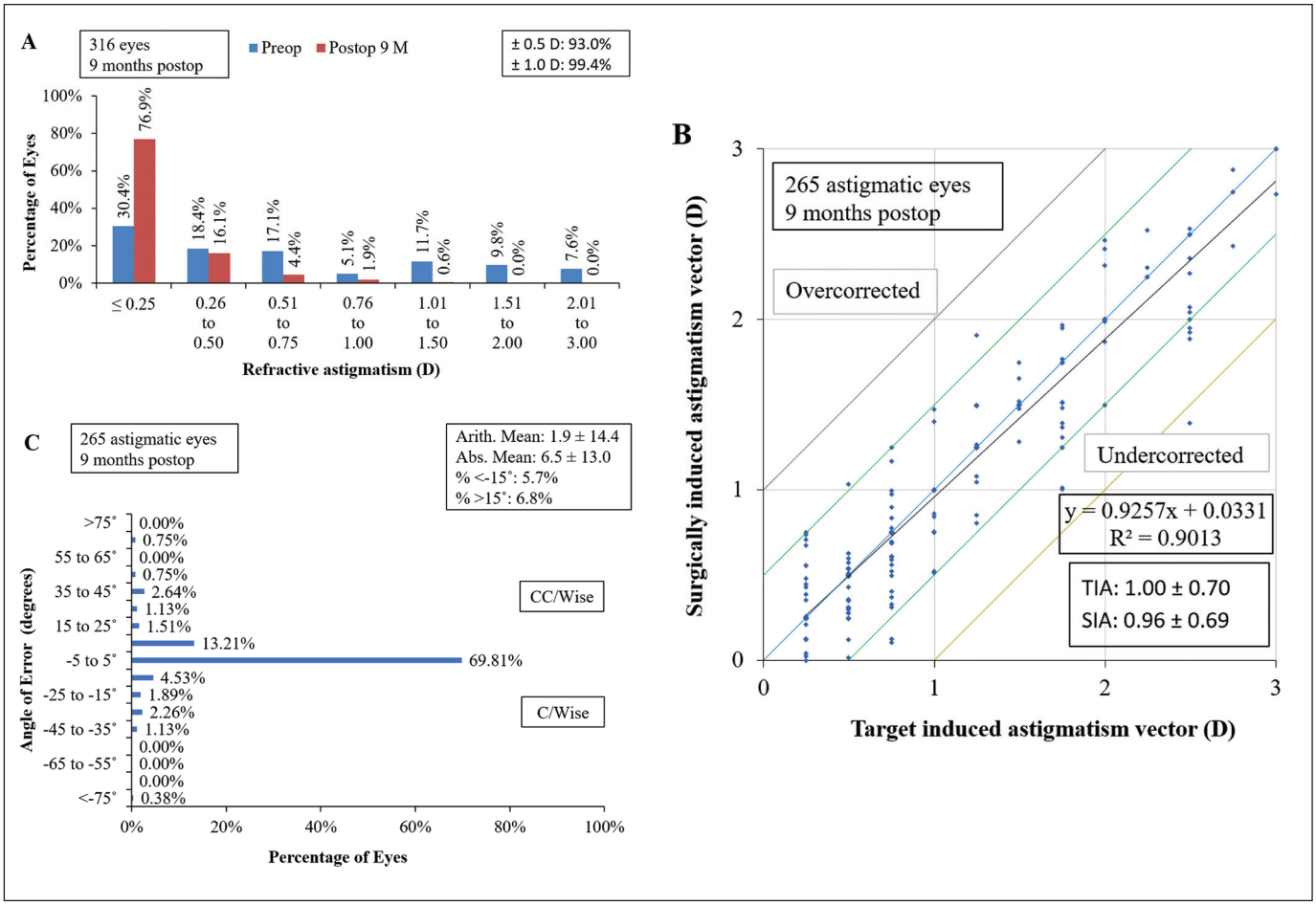

Figure 5. (A) Comparison of the preoperative and postoperative refractive astigmatism accuracy. (B) Scatterplot of target-induced astigmatism (TIA) versus surgically induced astigmatism (SIA). (C) The angle of error graph. D = diopters

Likewise, the proportion of eyes (93%) with cylinder within ±0.50 D was comparable to that reported in the pivotal trial of topography-guided LASIK (90%).[14] Vector analysis showed a small mean magnitude of error (-0.04 D) and angle of error (1.92°), verifying the current study's excellent correction and alignment of the astigmatic treatment. It is to be noted that these outcomes were achieved without compensating for static cyclotorsion. In the authors' experience, cyclotorsion compensation may help further improve the astigmatic outcomes. None of the eyes showed clinically meaningful loss (2 or more) in lines of CDVA. These findings also corroborate the published findings for wavefront-guided (0.0%) and topography-guided (0.4%) LASIK.[14,15]

Contrast sensitivity is an important parameter for assessing visual function after laser refractive surgery. It has been documented to initially decrease (compared to preoperative levels) and then recover to near-normal levels in the first few months.[16,17] Studies comparing the changes in contrast sensitivity with various ablation profiles (wavefront-guided, wavefront-optimized, and topography-guided) showed variable outcomes. Although one study found a slight increase in mesopic contrast sensitivity following topography-guided LASIK and a slight decrease following wavefront-optimized LASIK (both statistically not significant),[18] a different study found mesopic contrast sensitivity to be comparable at lower cpd levels (1.5, 3, and 6 cpd) and deteriorate significantly at higher cpd levels (12 and 18 cpd) following both topography-guided and wavefront-optimized LASIK.[19] A comparison of contrast sensitivity outcomes following wavefront-guided and wavefront-optimized LASIK documented significant improvement at all spatial frequencies following wavefront-optimized LASIK and no significant changes in contrast sensitivity (from preoperatively to 6 months postoperatively) following wavefront-guided LASIK.[20] Alternatively, the other study showed that wavefront-guided LASIK resulted in better contrast sensitivity outcomes than wavefront-optimized LASIK.[21]

Because low light conditions have more influence on contrast sensitivity, the current study evaluated

TABLE 2

Visual, Refractive, and Astigmatic Data at Different Postoperative Time Points From Month 1 to 9

Parameter	1 Month (n = 313)	3 Months (n = 305)	6 Months (n = 299)	9 Months (n = 316)
Visual outcomes (efficacy) (logMAR)				
UDVA 20/20 or better	86.3%[a]	89.8%	85.6%	90.8%
UDVA 20/25 or better	94.9%[a]	97.4%	97.0%	97.8%
UDVA 20/32 or better	99.0%[a]	99.3%	99.3%	99.4%
Visual outcomes (safety) (logMAR)				
No change in the lines of CDVA	67.1%	62.0%	66.2%	63.9%
Gain of 1 line	26.5%	33.1%	29.4%	30.4%
Gain of ≥ 2 lines	3.2%	3.3%	3.7%	4.4%
Loss of 2 lines	0.0%	0.0%	0.0%	0.0%
Loss of ≥ 2 lines	0.0%	0.0%	0.0%	0.0%
Refractive outcomes (D)				
Mean MRSE	-0.01 ± 0.31	-0.03 ± 0.31	-0.06 ± 0.33	-0.04 ± 0.32
% eyes within ±0.50 D	94.2%	94.1%	92.0%	92.7%
% eyes within ±1.00 D	98.7%	99.0%	98.3%	99.1%
Astigmatic outcomes (D)				
Mean refractive cylinder	-0.15 ± 0.28	-0.18 ± 0.30	-0.19 ± 0.31	-0.13 ± 0.29
% eyes within ±0.50 D	93.3%	90.8%	91.0%	93.0%
% eyes within ±1.00 D	99.4%	99.0%	99.0%	99.4%

CDVA = corrected distance visual acuity; D = diopters; MRSE = manifest spherical equivalent; UDVA = uncorrected distance visual acuity
[a]Percentages based on N = 315. For two eyes (1 patient), UDVA data were available, but manifest refraction and CDVA data were not available.

changes in mesopic contrast sensitivity with and without glare.[22] In the current study, the 6-month mesopic contrast sensitivity improved from baseline across all cpd levels (1.5, 3, 6, and 12 cpd), with statistically significant improvement observed at 3, 6, and 12 cpd with glare and at 6 and 12 cpd without glare. Factors such as maintenance of corneal asphericity (Q value), less induction of higher order aberrations, use of the larger optical zone, absence of microfolds or other flap-related optical imperfections, irregular collagen deposition, and interface debris may play a role.[23-31]

To evaluate patient-reported outcomes, self-administered validated questionnaires are preferred over physician-administered ones, because the latter are considered more prone to bias.[32] In the current study, the self-administered PROWL questionnaire was used preoperatively and postoperatively. Following surgery, the frequency of visual phenomena reduced, and the patients experienced less difficulty driving at night or during difficult conditions. A higher proportion of patients could actively participate in sports or other outdoor activities with no or little difficulty. Overall, the proportion of patients who were somewhat to very satisfied with their vision improved from 27.7% preoperatively to 98.1% postoperatively.

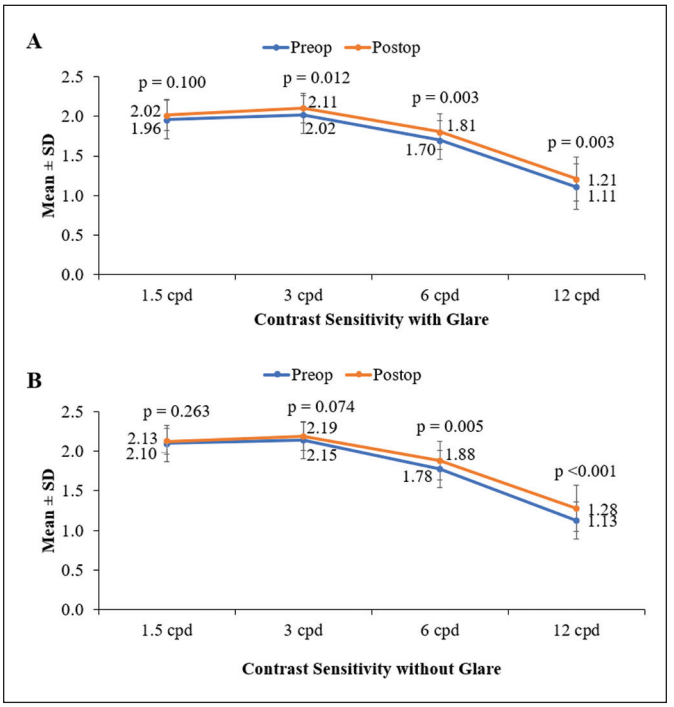

Figure 6. Preoperative and postoperative mesopic contrast sensitivity with and without glare at 1.5, 3, 6, and 12 cycles per degree (cpd) spatial frequencies. SD = standard deviation

TABLE 3

Preoperative and Postoperative Patient-Reported Outcomes Assessed Using the PROWL Questionnaire

Outcome	Percentage of Patients		*P*
	Preoperative	Postoperative	
No/little difficulty performing daily activities			
Driving during daytime	98.1%	98.7%	1.000
Driving at night	83.0%	98.7%	< .001
Driving in difficult conditions	87.4%	98.7%	< .001
Active sports or other outdoor activities	81.1%	100.0%	< .001
Activities requiring near vision	96.9%	98.7%	.453
Reading ordinary print in newspaper	97.5%	98.1%	1.000
Reading small print in a telephone book, on a medicine bottle, or on legal forms	93.7%	96.2%	.424
No incidence of visual phenomena in the previous 7 days			
Starbursts or halos	76.1%	85.5%	.040
Glare	76.1%	79.9%	.451
Distorted vision	91.8%	95.0%	.302
Blurry vision	81.8%	90.6%	.013
Frequency of symptoms of ocular discomfort (none/some of the time)			
Light sensitivity	93.7%	95.6%	.629
Gritty eyes	99.4%	99.4%	1.000
Painful or sore eyes	98.7%	100.0%	.500
Satisfaction with the present vision			
Somewhat to very satisfied	27.7%	98.1%	< .001

PROWL = Patient-Reported Outcomes With Laser in situ keratomileusis

The current study had a few limitations. Preoperative higher order aberrations were not measured, so the change in higher order aberrations induced by surgery could not be determined. Although the refractive outcomes were found to be stable throughout the follow-up at 9 months and are expected to remain stable over longer follow-up time points, further studies with longer follow-up periods can provide more insights regarding the safety and efficacy of the laser.

This study demonstrates that LASIK surgery performed with a new aspheric ablation algorithm of the Technolas Teneo 317 (Model 2) excimer laser using the patient's manifest refraction is safe and effective for correcting myopia and myopic astigmatism. The refractive outcomes were stable throughout the follow-up of 9 months. The mesopic contrast sensitivity values trended to improve postoperatively compared to the preoperative values, with statistically significant improvement observed at 3, 6, and 12 cpd (with glare) and at 6 and 12 cpd (without glare). The outcomes of the PROWL questionnaire also suggest improved quality of vision in eyes with moderate to high myopia.

AUTHOR CONTRIBUTIONS

Study concept and design (GOW, KS, YRC, LOH, NK); data collection (GOW, KS, ML, YRC, ME, GF, NK); analysis and interpretation of data (GOW, KS, YRC, GF, ME, LOH); writing the manuscript (KS, YRC); critical revision of the manuscript (GOW, KS, ML, YRC, ME, GF, LOH, NK); administrative, technical, or material support (ML, ME, LOH, NK); supervision (KS, LOH, NK)

REFERENCES

1. Krueger RR, Rabinowitz YS, Binder PS. The 25th anniversary of excimer lasers in refractive surgery: historical review. *J Refract Surg*. 2010;26(10):749-760. https://doi.org/10.3928/1081597X-20100921-01 PMID:20954683
2. Pidro A, Biscevic A, Pjano MA, Mravicic I, Bejdic N, Bohac M. Excimer lasers in refractive surgery. *Acta Inform Med*. 2019;27(4):278-283. https://doi.org/10.5455/aim.2019.27.278-283 PMID:32055096
3. Waring GO III, Stulting RD, Wiley WM, Garr JD, Thompson KP. Abstracts-LASIK in 3946 eyes with the Nidek EC-5000 excimer Laser. *J Refract Surg*. 2001;17(2):S277.
4. Brint SF, Ostrick DM, Fisher C, et al. Six-month results of the multicenter phase I study of excimer laser myopic keratomileusis. *J Cataract Refract Surg*. 1994;20(6):610-615. https://doi.org/10.1016/S0886-3350(13)80648-7 PMID:7837070

5. Kezirian G, Casebeer JC. The CRS LASIK study. In: Machat JJ, Slade SG, Probst LE, eds. *The Art of LASIK*. SLACK Incorporated; 1999:293-302.

6. Arba-Mosquera S, Vinciguerra P, Verma S. Review of technological advancements in calibration systems for laser vision correction. *J Biomed Opt*. 2018;23(2):1-8. https://doi.org/10.1117/1.JBO.23.2.020901 PMID:29411563

7. Stonecipher KG, Kezirian GM. Wavefront-optimized versus wavefront-guided LASIK for myopic astigmatism with the ALLEGRETTO WAVE: three-month results of a prospective FDA trial. *J Refract Surg*. 2008;24(4):S424-S430. PMID:18500097

8. Kezirian GM, Moore CR, Stonecipher KG; SurgiVision Consultants Inc WaveLight Investigator Group. Four-year postoperative results of the US ALLEGRETTO WAVE clinical trial for the treatment of hyperopia. *J Refract Surg*. 2008;24(4):S431-S438. PMID:18500098

9. Stonecipher KG, Kezirian GM, Stonecipher M. LASIK for -6.00 to -12.00 D of myopia with up to 3.00 D of cylinder using the ALLEGRETTO WAVE: 3- and 6-month results with the 200- and 400-Hz platforms. *J Refract Surg*. 2010;26(10):S814-S818. https://doi.org/10.3928/1081597X-20100921-08 PMID:20954676

10. Stonecipher KG, Kezirian GM, Stonecipher K. LASIK for mixed astigmatism using the ALLEGRETTO WAVE: 3- and 6-month results with the 200- and 400-Hz platforms. *J Refract Surg*. 2010;26(10):S819-S823. https://doi.org/10.3928/1081597X-20100921-09 PMID:20954677

11. Schallhorn SC, Farjo AA, Huang D, et al; American Academy of Ophthalmology. Wavefront-guided LASIK for the correction of primary myopia and astigmatism a report by the American Academy of Ophthalmology. *Ophthalmology*. 2008;115(7):1249-1261. https://doi.org/10.1016/j.ophtha.2008.04.010 PMID:18598819

12. Stonecipher KG, Potvin R, Meyer JJ, Durrie D, Stonecipher K. Refractive surgery outcomes comparison—All wavefront-guided versus a decision tree for selecting wavefront-guided or wavefront-optimized. *US Ophthalmic Rev*. 2012;5(1):14-17. https://doi.org/10.17925/USOR.2012.05.01.14

13. Schulze S, Nietgen G, Sekundo W. [Reduction of decentration after LASIK using a modified eye tracker ring for the MEL-70 excimer laser]. *Klin Monbl Augenheilkd*. 2004;221(7):546-549. https://doi.org/10.1055/s-2004-813270 PMID:15273907

14. Stulting RD, Fant BS, Bond W, et al; T-CAT Study Group. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. *J Cataract Refract Surg*. 2016;42(1):11-18. https://doi.org/10.1016/j.jcrs.2015.08.016 PMID:26948773

15. Abbott Medical Optics Inc. *Advanced CustomVue Myopia Treatment Professional Use Manual*. Abbott Medical Optics Inc, 2015. Accessed June 15, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf/P930016S044c.pdf

16. Yamane N, Miyata K, Samejima T, et al. Ocular higher-order aberrations and contrast sensitivity after conventional laser in situ keratomileusis. *Invest Ophthalmol Vis Sci*. 2004;45(11):3986-3990. https://doi.org/10.1167/iovs.04-0629 PMID:15505046

17. Holladay JT, Dudeja DR, Chang J. Functional vision and corneal changes after laser in situ keratomileusis determined by contrast sensitivity, glare testing, and corneal topography. *J Cataract Refract Surg*. 1999;25(5):663-669. https://doi.org/10.1016/S0886-3350(99)00011-5 PMID:10330642

18. Mai EL, Chang CK, Lee CY, Lian IB, Chao CC. Higher-order aberrations of topography-guided LASIK and wavefront-optimized LASIK in high- and low-myopic eyes: a non-randomized controlled trial. *J Pers Med*. 2023;13(3):399. https://doi.org/10.3390/jpm13030399 PMID:36983581

19. Jain AK, Malhotra C, Pasari A, Kumar P, Moshirfar M. Outcomes of topography-guided versus wavefront-optimized laser in situ keratomileusis for myopia in virgin eyes. *J Cataract Refract Surg*. 2016;42(9):1302-1311. https://doi.org/10.1016/j.jcrs.2016.06.035 PMID:27697248

20. Goyal JL, Garg A, Arora R, Jain P, Goel Y. Comparative evaluation of higher-order aberrations and corneal asphericity between wavefront-guided and aspheric LASIK for myopia. *J Refract Surg*. 2014;30(11):777-784. https://doi.org/10.3928/1081597X-20141021-10 PMID:25375851

21. Ghoneim A, Wasfy T, Abass S, et al. Comparative analysis of outcomes after wavefront-guided and wavefront-optimized laser in-situ keratomileusis in high myopic eyes. *Egypt J Cataract Refract*. 2018;24(1):1. https://doi.org/10.4103/JCRS.JCRS_16_17

22. Hieda O, Nakamura Y, Wakimasu K, Yamamura K, Kinoshita S, Sotozono C. Long-term course of contrast sensitivity in eyes after laser-assisted in-situ keratomileusis for myopia. *Indian J Ophthalmol*. 2020;68(12):2981-2984. https://doi.org/10.4103/ijo.IJO_1916_19 PMID:33229681

23. Melki SA, Azar DT. LASIK complications: etiology, management, and prevention. *Surv Ophthalmol*. 2001;46(2):95-116. https://doi.org/10.1016/S0039-6257(01)00254-5 PMID:11578645

24. Mimouni M, Vainer I, Assad N, et al. Incidence, indications, and outcomes of eyes needing early flap lifting after LASIK. *Cornea*. 2018;37(9):1118-1123. https://doi.org/10.1097/ICO.0000000000001617 PMID:29672432

25. Özülken K, Kaderli A. The effect of different optical zone diameters on the results of high-order aberrations in femto-laser-assisted in situ keratomileusis. *Eur J Ophthalmol*. 2020;30(6):1272-1277. https://doi.org/10.1177/1120672119865688 PMID:31353955

26. Sridhar MS, Rao SK, Vajpayee RB, Aasuri MK, Hannush S, Sinha R. Complications of laser-in-situ-keratomileusis. *Indian J Ophthalmol*. 2002;50(4):265-282. PMID:12532491

27. Wallerstein A, Gauvin M, Adiguzel E, et al. Clinically significant laser in situ keratomileusis flap striae. *J Cataract Refract Surg*. 2017;43(12):1523-1533. https://doi.org/10.1016/j.jcrs.2017.09.023 PMID:29335096

28. Wu Y, Wang S, Wang G, Zhao S, Wei R, Huang Y. Corneal asphericity and higher-order aberrations after FS-LASIK and trans-PRK for myopia. *J Ophthalmol*. 2021;2021:3765046. https://doi.org/10.1155/2021/3765046 PMID:34912576

29. Karabela Y, Muftuoglu O, Gulkilik IG, Kocabora MS, Ozsutcu M. Intraoperative and early postoperative flap-related complications of laser in situ keratomileusis using two types of Moria microkeratomes. *Int Ophthalmol*. 2014;34(5):1107-1114. https://doi.org/10.1007/s10792-014-9919-7 PMID:24531872

30. Murueta-Goyena A, Cañadas P. Visual outcomes and management after corneal refractive surgery: A review. *J Optom*. 2018;11(2):121-129. https://doi.org/10.1016/j.optom.2017.09.002 PMID:29183707

31. Wilson SE. Corneal myofibroblast biology and pathobiology: generation, persistence, and transparency. *Exp Eye Res*. 2012;99(1):78-88. https://doi.org/10.1016/j.exer.2012.03.018 PMID:22542905

32. Edwards P. Questionnaires in clinical trials: guidelines for optimal design and administration. *Trials*. 2010;11(1):2. https://doi.org/10.1186/1745-6215-11-2 PMID:20064225