



Outcomes of wavefront-guided laser in situ keratomileusis using a new-generation Hartmann-Shack aberrometer in patients with high myopia

Steven C. Schallhorn, MD, Jan A. Venter, MD, Stephen J. Hannan, OD, Keith A. Hettinger, MS

PURPOSE: To evaluate refractive and visual outcomes of wavefront-guided laser in situ keratomileusis (LASIK) to correct high myopia using a new Hartmann-Shack aberrometer.

SETTING: Optical Express, Glasgow, United Kingdom.

DESIGN: Retrospective noncomparative case series.

METHODS: Data of eyes that had wavefront-guided LASIK for high myopia and myopic astigmatism (spherical equivalent [SE] between -6.00 diopters [D] and -10.25 D, up to 5.00 D of cylinder) were analyzed. The treatment profile was derived from a new-generation Hartmann-Shack aberrometer (iDesign Advanced Wavescan). Visual acuities, refractive outcomes, vector analysis of refractive cylinder, and patient satisfaction were assessed. Three-months data are presented.

RESULTS: Data were obtained for 621 eyes. The mean manifest SE reduced from -7.28 D \pm 1.05 (SD) (range -10.25 to -6.00 D) preoperatively to -0.09 \pm 0.44 D (range -2.13 to $+1.38$ D) at 3 months. The mean manifest cylinder changed from -1.02 \pm 0.82 D (range -5.00 to 0.00 D) to -0.27 \pm 0.33 D (range -1.75 to 0.00 D) postoperatively. The percentage of eyes achieving an uncorrected distance visual acuity 20/20 or better was 82.4% monocularly and 92.5% binocularly. The mean correction ratio of refractive cylinder was 1.02 \pm 0.48, and the mean error of angle was -0.29 \pm 14.56 degrees. A postoperative questionnaire revealed high satisfaction with the outcomes of the procedure, with low scores for night-vision phenomena.

CONCLUSION: The results in this study were promising in terms of safety, efficacy, and predictability in eyes with high degrees of myopia.

Financial Disclosure: Dr. Schallhorn is a consultant to Abbott Medical Optics, Inc. No other author has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2015; 41:1810–1819 © 2015 ASCRS and ESCRS

Eyes with high refractive error present a challenging group for keratorefractive procedures. These eyes require deeper ablation, and a greater change in the corneal shape is therefore induced. This results in an increased healing response with a corresponding reduced refractive predictability. Previous studies also found a direct correlation between the magnitude of refractive correction and induced changes in higher-order wavefront aberrations following laser ablation.^{1,2} Specifically, spherical aberration was found to have the highest impact as it systematically increases

with the amount of attempted spherical correction with conventional excimer lasers.³ However, this increase is not unusual, even with the use of wavefront-guided ablation profiles.^{4,5} When treating eyes with high ametropia, the ability to accurately estimate preoperative refractive error, precisely determine the axis of astigmatism, and quantify ocular higher-order aberrations (HOAs) is crucial.

The aim of the current study was to evaluate the visual outcomes, predictability, and accuracy of astigmatic correction of wavefront-guided laser in situ

keratomileusis (LASIK) in patients with high myopia and high myopic astigmatism using an ablation profile derived from a recently developed Hartmann-Shack aberrometer.

PATIENTS AND METHODS

This retrospective noncomparative study evaluated eyes of patients who had LASIK for high myopia. The study was deemed exempt from full review by the Committee on Human Research at the University of California, San Francisco, because it used only retrospective de-identified patient data. Informed consent to have the LASIK procedure was obtained from all patients.

Records of LASIK procedures without patient identifiers were extracted from an electronic database using the following criteria: primary LASIK procedure performed with the Visx Star S4 IR excimer laser (Abbott Medical Optics, Inc.) using a wavefront-guided ablation profile (Advanced Customvue, Abbott Medical Optics, Inc.) derived from a new aberrometer (iDesign) between December 2013 and April 2014, preoperative manifest spherical equivalent (SE) between -6.0 diopters (D) and -12.0 D with no more than 6.0 D of refractive cylinder, postoperative refractive target emmetropia, successful completion of 1- and 3-month postoperative visits, and no prior refractive procedures. The data extraction techniques have been described.⁶

Exclusion criteria for treatment were a corrected distance visual acuity (CDVA) of less than 20/20, age less than 18 years, any active ophthalmic disease, history of ophthalmic disease, concurrent medications or medical conditions that could interfere with corneal healing, abnormal corneal shape, and calculated postoperative corneal stromal bed thickness less than $250\ \mu\text{m}$ in each eye. Soft contact lens wearers were asked to discontinue use at least 1 week prior to the procedure. Hard contact lens users, either poly(methyl methacrylate) or rigid gas permeable, removed their lenses at least 3 weeks prior to baseline measurements and had 2 central keratometry (K) readings and 2 manifest refractions taken at least 1 week apart that did not differ by more than 0.50 D in either meridian.

The baseline examination included manifest and cycloplegic refractions, monocular and binocular uncorrected distance visual acuity (UDVA), CDVA using a calibrated projected eye chart, low-light pupil diameter, slitlamp biomicroscopy, dilated fundus examination, applanation tonometry, corneal topography, ultrasound pachymetry, and wavefront aberration measurement.

Postoperative examinations were conducted at 1 day, 1 week, and 1 and 3 months. On the first postoperative day, a detailed slitlamp examination was performed to evaluate

flap position and the integrity of the cornea. At the subsequent postoperative visits, the same preoperative examination protocol (excluding cycloplegic refraction, pupil diameter, topography, and pachymetry) was used. As part of current practice, all patients were asked to complete a questionnaire during their postoperative visits. It was self-administered by the patient using a password-protected and secure computer terminal in an isolated area of the clinic. The questionnaire responses were stored in the secured Optical Express central database, which is compliant with the International Organization for Standardization 27001 for information security management systems.^A The questionnaire was derived from the Joint LASIK Study Task Force⁷ (Table 1). All response fields used a Likert scale to obtain the patient's preferences or degree of agreement. Night-vision phenomena such as starburst, glare, halo, ghosting, and double vision were rated on the scale from 1 (no difficulty) to 7 (severe difficulty).

Surgical Technique

All LASIK procedures were performed by 21 experienced surgeons certified to use the equipment. Corneal flaps were

Table 1. Patient satisfaction questionnaire (mean follow-up 3.1 ± 1.1 months; $n = 371$ patients).

Questions	Responses
Thinking about your vision during the last week, how satisfied are you with your vision? (without the use of glasses or contact lenses) (%)	
Very satisfied	52.6
Satisfied	38.6
Neither	4.3
Dissatisfied	4.1
Very dissatisfied	0.3
Because of your eyesight, how much difficulty do you have driving at night? (%)	
No difficulty at all	57.0
A little difficulty	25.5
Moderate difficulty	5.0
A lot of difficulty	2.6
I am unable to drive at night because of my vision	1.5
I do not drive at night for other reasons	8.4
Would you recommend vision correction surgery to your friends and relatives? (%)	
Yes	96.4
No	3.6
Night-vision phenomena scores measured on scale from 1 (no difficulty) to 7 (severe difficulty), mean \pm SD (median)	
Visual phenomena	
Starburst	1.93 ± 1.36 (1)
Glare	1.86 ± 1.26 (1)
Halo	1.88 ± 1.29 (1)
Ghosting/double vision	1.42 ± 0.95 (1)

Submitted: November 19, 2014.

Final revision submitted: December 25, 2014.

Accepted: December 31, 2014.

From the Department of Ophthalmology (Schallhorn), University of California, San Francisco, California, USA; Optical Express (Schallhorn, Venter, Hannan, Hettinger), Glasgow, United Kingdom.

Corresponding author: Steven C. Schallhorn, MD, 11730 Caminito Prenticia, San Diego, California 92131, USA. E-mail: scschallhorn@yahoo.com.

Table 2. Nomogram for physician adjustment based on preoperative cylinder values obtained with the aberrometer.

Preoperative Cylinder on Aberrometry (D) (Range)	Physician Adjustment for Sphere (D)
0.00, 0.25	-0.25
0.26, 0.75	-0.13
0.76, 1.00	0.00
1.01, 2.00	0.20
2.01, 3.00	0.40
3.01, 4.00	0.60
4.01, 5.00	0.80
5.01, 6.00	1.00
6.01, 7.00	1.20
7.01, 8.00	1.40

created by a femtosecond laser (iFS, Abbott Medical Optics, Inc.). The diameter of the femtosecond flaps ranged from 8.0 to 9.2 mm, and the programmed depth ranged from 100 to 120 μ m. After the flaps were lifted, the programmed treatment was applied after iris registration was achieved. All surgical procedures were performed under topical anesthesia. Standard postoperative treatment was administered to all patients, consisting of topical levofloxacin 0.5% and topical prednisolone acetate 1.0% 4 times a day for 1 week and preservative-free artificial tear drops as needed.

The ablation profile was derived from the Hartmann-Shack aberrometer (iDesign). This device is based on the Wavescan system (Abbott Medical Optics, Inc.) but has a number of differences in design. The sensor has higher resolution and a larger field of view and uses an enhanced iris-registration algorithm. Unlike its predecessor Wavescan, it does not precompensate for the cylindrical component of the optical path, so the measured cylinder is determined

from the wavefront reconstruction. All the other features of this aberrometer have been previously described.⁸

A nomogram was used to adjust the sphere according to the magnitude of the aberrometer-derived cylinder (Table 2). This is a manufacturer-recommended nomogram intended to reduce apparent sphere overcorrection associated with correcting high cylinder.

Statistical Analysis

Parametric statistics were used to analyze differences between preoperative and postoperative outcomes (paired Student *t* test). The safety index (mean postoperative CDVA/mean preoperative CDVA) and efficacy index (mean postoperative UDVA/mean preoperative CDVA) were calculated. The Pearson correlation coefficient was used to calculate the correlation between continuous variables, and the Spearman correlation coefficient was used to assess correlations of questionnaire responses to other variables. Additionally, vector analysis of the change in refractive cylinder was performed using a previously described technique.⁹ All data were analyzed using Excel 2007 software (Microsoft Corp.) and Statistica (Statsoft, Inc.) on a personal computer. A *P* value equal to 0.5 was considered significant.

RESULTS

This study included 621 eyes of 381 patients who had primary myopic LASIK with an ablation profile derived from the new Hartmann-Shack aberrometer. The mean patient age was 34.0 ± 9.7 years (SD) (range 19 to 63 years). One hundred forty-one patients (37.0%) were men and 240 (63.0%) were women. The mean preoperative mesopic pupil size was 6.5 ± 0.9 mm (range 4 to 9 mm), and the mean K value was 44.0 ± 1.5 D (range 39.75 to 49.00 D).

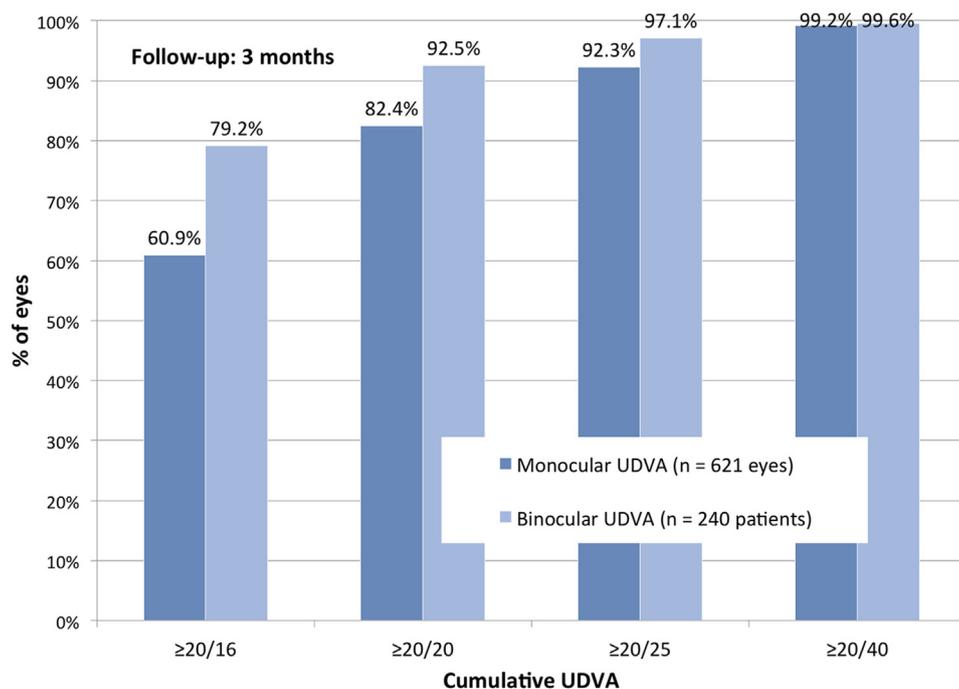


Figure 1. Cumulative monocular and binocular UDVA 3 months postoperatively (UDVA = uncorrected distance visual acuity).

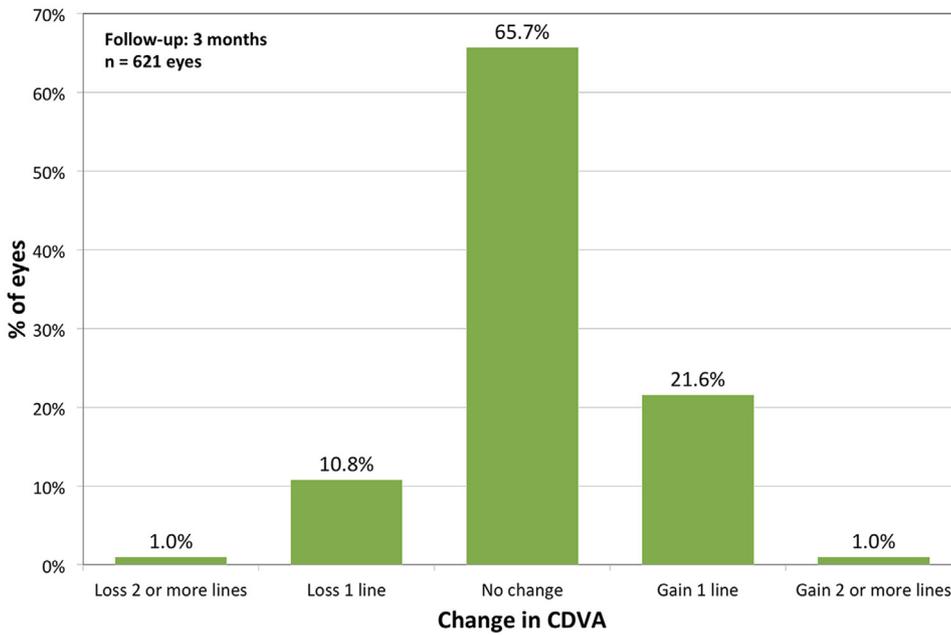


Figure 2. Safety: comparison of preoperative versus postoperative CDVA 3 months postoperatively (CDVA = corrected distance visual acuity).

Visual Acuity

Figure 1 displays the postoperative cumulative UDVA. The percentage of eyes achieving monocular UDVA 20/20 or better at 3 months was 82.4% (512 eyes). In patients who had treatment in both eyes, the percentage of eyes achieving binocular UDVA 20/20 or better was 92.5% (222 of 240 patients). Loss of 2 or more lines of CDVA was recorded in 6 eyes (1.0%), and a gain of 1 or more lines of CDVA was observed in 140 eyes (22.5%). Patients who lost 2 lines of CDVA were diagnosed with superficial punctate keratitis at the time of the 3-month visit, but their issues were resolved at subsequent visits, and the CDVA returned to the preoperative level. Comparison of preoperative and postoperative CDVA is displayed in Figure 2. The efficacy and safety indices at 3 months were 0.92 and 1.02, respectively.

Refractive Outcomes

There was a statistically significant reduction in manifest sphere and cylinder and manifest SE postoperatively (Table 3). At 3 months, 82.6% (513 eyes) and 95.0% (590 eyes) had a manifest SE within ± 0.50 and ± 1.00 D, respectively. Figure 3 shows predictability of the manifest SE (scattergram of attempted versus achieved manifest SE). There was a strong and statistically significant correlation between the attempted and achieved manifest SE ($r = 0.92, P < .01$). A linear regression of the attempted versus achieved manifest SE had a slope of 0.95 and intercept of -0.3 (Figure 3). There was also a statistically significant correlation between the magnitude of the preoperative manifest SE and the magnitude of the residual postoperative SE refraction ($r = 0.17, P < .01$). Figure 4 displays the distribution of postoperative manifest SE.

Table 3. Preoperative and postoperative outcomes (n = 621 eyes).

Parameter	Preoperative		1 Mo Postop		P Value* (Preop to 1 Mo)	3 Mo Postop		P Value* (1 Mo to 3 Mo)
	Mean \pm SD	Range	Mean \pm SD	Range		Mean \pm SD	Range	
Manifest sphere (D)	-6.77 \pm 1.05	-10.25, -4.00	+0.09 \pm 0.40	-1.25, +1.50	<.01	+0.04 \pm 0.44	-1.50, +2.00	<.01
Manifest cylinder (D)	-1.02 \pm 0.82	-5.00, 0.00	-0.27 \pm 0.34	-2.50, 0.00	<.01	-0.27 \pm 0.33	-1.75, 0.00	.85
Manifest SE (D)	-7.28 \pm 1.05	-10.25, -6.00	-0.04 \pm 0.40	-1.50, +1.25	<.01	-0.09 \pm 0.44	-2.13, +1.38	<.01
Monocular UDVA (logMAR)	1.32 \pm 0.14	0.54, 1.60	-0.03 \pm 0.10	-0.18, 0.48	<.01	-0.03 \pm 0.11	-0.18, 0.70	.02
CDVA (logMAR)	-0.06 \pm 0.05	-0.18, 0.00	-0.07 \pm 0.05	-0.18, 0.18	<.01	-0.07 \pm 0.05	-0.18, 0.22	.92

CDVA = corrected distance visual acuity, SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Paired t test

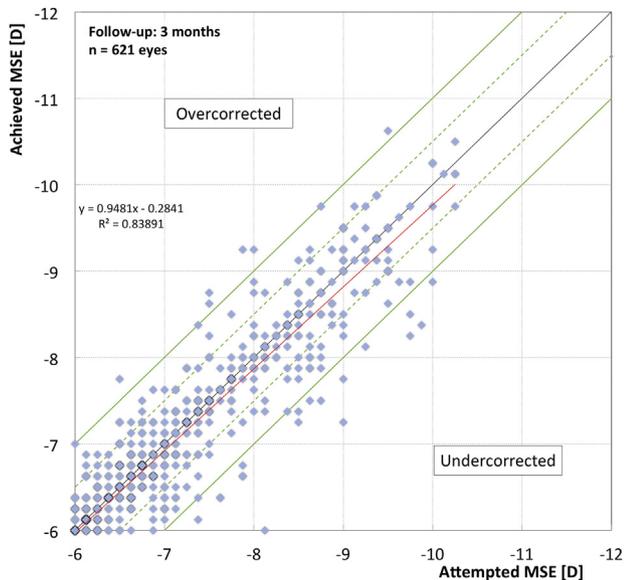


Figure 3. Attempted manifest SE (MSE) correction against achieved correction at 3 months. The solid green line represents manifest SE within 1.00 D. The dashed green line represents manifest SE within 0.50 D of emmetropia. The solid red line is the linear regression.

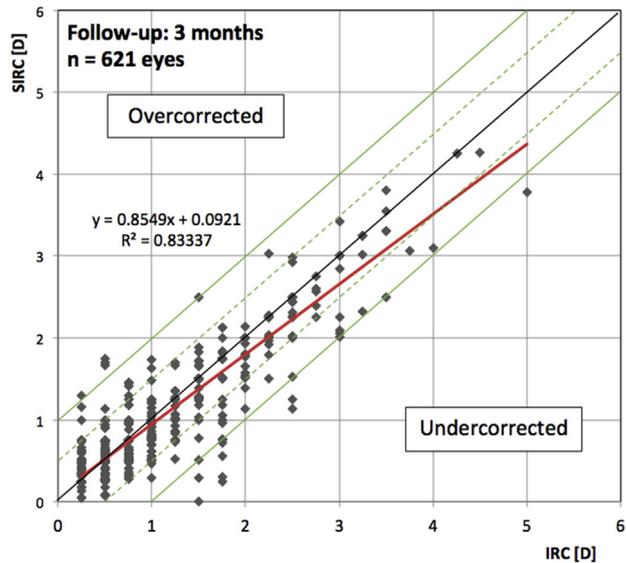


Figure 5. Surgically induced refractive correction (SIRC) plotted against intended refractive correction (IRC). The solid green line represents the error of magnitude within 1.00 D, and the dashed green line represents error of magnitude within 0.50 D of emmetropia. The solid red line is the linear regression.

Vector Analyses of Refractive Astigmatism

Figure 5 plots the surgically induced refractive correction against the intended refractive correction. A strong and statistically significant correlation was found between the 2 variables ($r = 0.91, P < .01$). Table 4 summarizes the mean values for vector analysis of the change in refractive astigmatism. The percentage of eyes with error of magnitude (difference between surgically induced refractive correction and intended refractive correction) within ± 0.25 D and ± 0.50 D was 75.9% (471 eyes) and 91.6% (569 eyes), respectively. A negative correlation was found

between the correction ratio and the magnitude of preoperative cylinder ($r = -0.22, P < .01$), indicating that higher values of preoperative refractive cylinder were undercorrected. Figure 6 depicts the mean correction ratio stratified by the amount of preoperative refractive cylinder. Figure 7 displays the double-angle plot of preoperative and postoperative manifest cylinder. The preoperative centroid of $0.67 \text{ D} \times 94^\circ$ and the shape of the ellipse (standard deviation of x and y datapoints) in Figure 7, A, indicates the predominance of preoperative with-the-rule astigmatism. Postoperatively, the centroid of refractive data shifted closer to

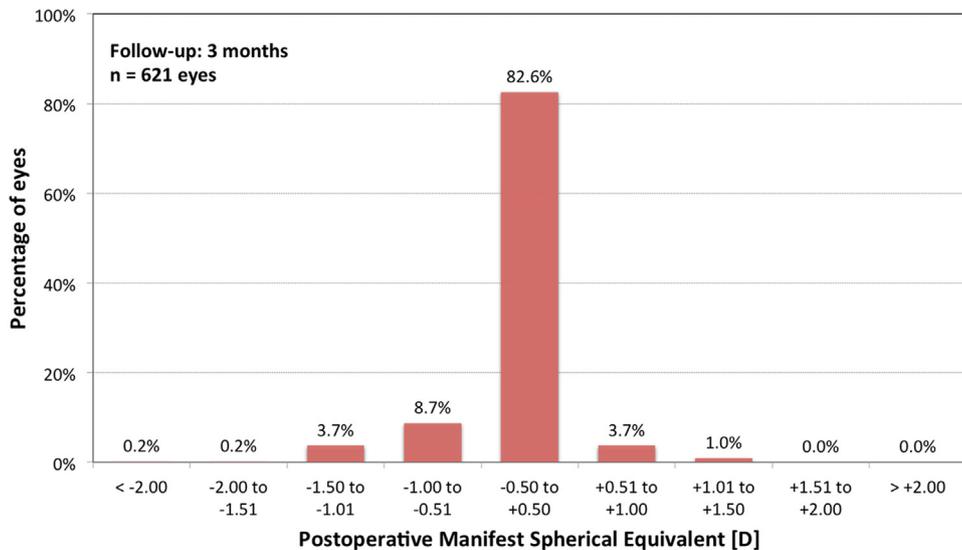


Figure 4. Distribution of manifest SE 3 months postoperatively.

Table 4. Vector analysis of refractive astigmatism changes at 1 and 3 months postoperatively. The mean intended refractive correction was 1.02 ± 0.82 (range 0.00 to 5.00 D).

Vector Parameter	1 Mo (n = 621)		3 Mo (n = 621)		P Value*
	Mean \pm SD	Range	Mean \pm SD	Range	
IRC (D)					—
SIRC (D)	1.06 ± 0.78	0.00, 4.33	1.03 ± 0.75	0.00, 4.26	.005
EV (D)	0.28 ± 0.34	0.00, 2.50	0.27 ± 0.33	0.00, 1.75	.77
EM (D)	$+0.04 \pm 0.32$	-2.01, 1.22	$+0.07 \pm 0.33$	-1.24, 1.50	.005
EA (°)	-0.72 ± 15.38	-80.15, 85.00	-0.29 ± 14.56	-83.35, 88.00	.54
ER	0.41 ± 0.69	0, 7.00	0.37 ± 0.60	0, 5.00	.18
CR	1.05 ± 0.58	0, 7.95	1.02 ± 0.48	0, 5.20	.13

CR = correction ratio; EA = error of angle; EM = error of magnitude; ER = error ratio; EV = error vector; IRC = intended refractive correction; SIRC = surgically induced refractive correction

*Paired t test

the null point ($0.18 \text{ D} \times 98^\circ$), and the size of the ellipse reduced significantly (Figure 7, B).

Patient-Reported Outcomes

The mean follow-up for the patient satisfaction questionnaire was 3.1 ± 1.1 months, with 371 patients (97.4%) participating in the survey (Table 1). The percentage of patients claiming to be very satisfied or satisfied with their vision was 91.2% (338 patients). The mean score for night-vision disturbances was close to 2, indicating only mild night-vision symptoms were present. The numbers of patients scoring 4 or more on the scale for night-vision phenomena (moderate or severe difficulty) were as follows: starburst (n = 62; 16.7%), glare (n = 49; 13.1%), halo (n = 53; 14.2%),

and ghosting/double vision (n = 17; 4.6%). Most of the patients (n = 306; 82.5%) reported having no difficulty or only a little difficulty with nighttime driving. Three hundred fifty-eight patients (96.4%) were willing to recommend the procedure to family and friends.

The satisfaction with postoperative vision was correlated with the postoperative UDVA and the magnitude of postoperative manifest SE (satisfaction: $r = 0.18, P < .01$; manifest SE: $r = 0.19, P < .01$), suggesting that patients with worse postoperative UDVA and an outstanding postoperative refractive error were more likely to be dissatisfied with their outcomes. A weak but statistically significant correlation was also found between the 3-month binocular UDVA and the scores for halo, ghosting/double

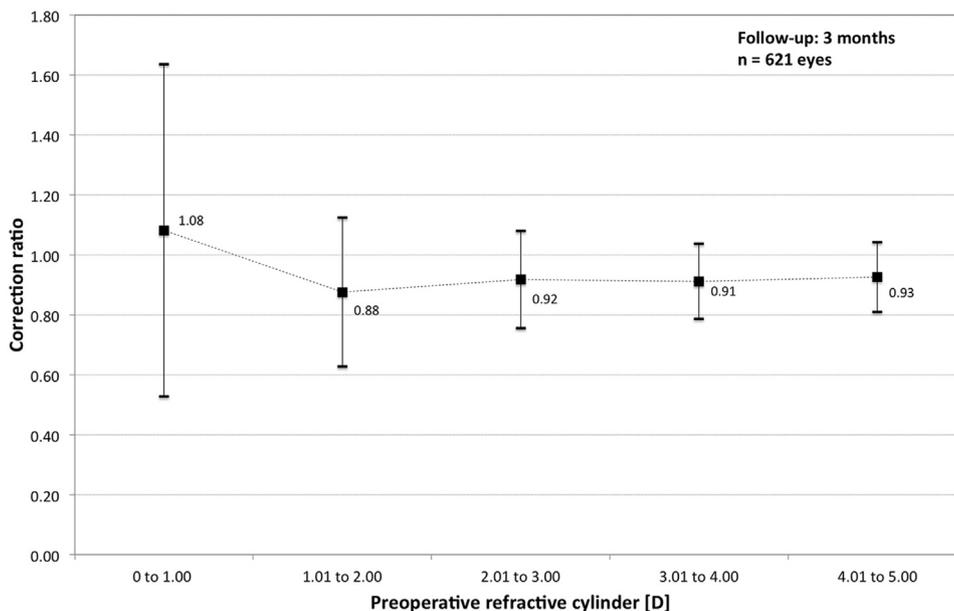


Figure 6. Correction ratio (ratio of the magnitude of surgically induced refractive correction to intended refractive correction) stratified by the amount of preoperative refractive cylinder.

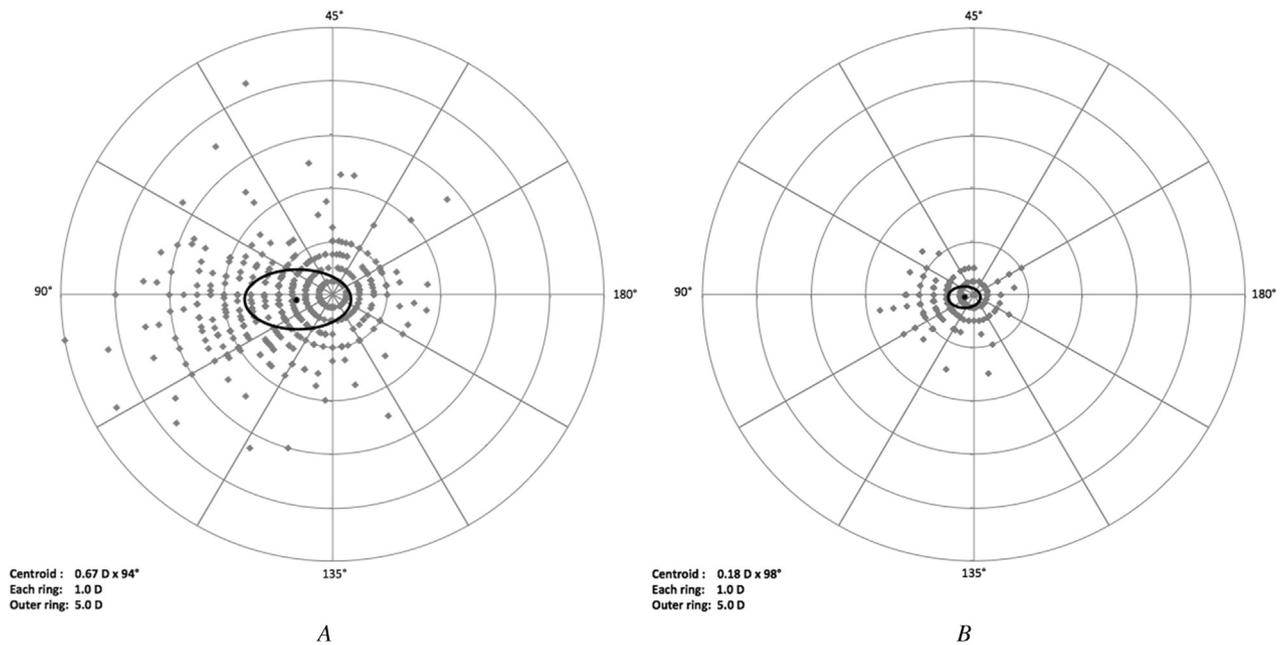


Figure 7. Double-angle polar plot of preoperative (A) and postoperative (B) refractive cylinder in plus cylinder form 3 months postoperatively (n = 621). The centroid is the mean of x and y datapoints, and the axes of each ellipse are twice the standard deviation of the x and y values.

vision, and the difficulties with night driving (halo: $r = 0.09$, $P = .02$; ghosting/double vision: $r = 0.08$, $P = .04$; night driving: $r = 0.16$, $P < .01$).

DISCUSSION

Laser in situ keratomileusis in eyes with high myopia still elicits much discussion. In the early years of LASIK, attempts to treat extreme degrees of myopia often resulted in poor visual outcomes, low predictability, and significant regression.¹⁰⁻¹² Over the past decade, the upper limit of myopia correction has been approximately 12.0 D, with intraocular surgical options considered for higher levels.¹³⁻²⁴

In our study, we achieved favorable results with wavefront-guided LASIK in high myopes. At 3 months, 82.6% of eyes were within ± 0.50 D and 95.0% within ± 1.00 D of emmetropia. Monocular and binocular UDVA of 20/20 or better were 82.4% and 92.5%, respectively. Comparison with other studies is difficult because of variations in the range of preoperative myopia, length of follow-up periods, the use of individual nomograms, and ablation algorithms. Table 5 provides a literature review of LASIK studies for myopia of similar degrees to our study sample.¹³⁻²² This summary combines the outcomes of conventional, wavefront-optimized, and wavefront-guided ablation profiles and demonstrates an increase in the predictability of refractive and visual outcomes of high myopia treatment with

improving technology over the years. The results in our study are comparable with those previously published. Some studies with superior results²⁰ include patients with much lower degrees of preoperative refractive cylinder (up to 2.50 D) or were performed on a small cohort of patients. In our dataset, the slope of the linear regression of attempted versus achieved manifest SE was 0.95 (Figure 3), which indicates an overall undercorrection and that the results could be improved with a nomogram refinement.

We achieved an efficacy index of 0.92 at 3 months. This is comparable with the efficacy index of 0.96 in a large population study²⁵ (32 569 eyes) of wavefront-guided LASIK using the same laser and the previous version of aberrometer of the same manufacturer (Wavescan) in patients with lower degrees of myopia (manifest SE up to 6.0 D). Development of a new nomogram that would account for a slight undercorrection seen in our dataset might increase the efficacy index in the future. A comprehensive report by Yuen et al.²⁶ evaluating outcomes of LASIK performed in 37 932 eyes over a 10-year period found a significant improvement in the efficacy index from 0.78 in patients treated in 1998 to 0.93 in 2007 in a subgroup of patients with myopia slightly lower than that in our study group (-5.0 to -10.0 D). Various lasers and ablation profile algorithms were used in this study.

Although we could not analyze postoperative HOAs in this retrospective study, quality of vision

Table 5. Summary of literature on LASIK in eyes with high myopia.

Author/(Year)	Eyes (n)	Follow-up (Mo)	Excimer Laser (Ablation Profile Algorithm)	Preop Attempted MSE Correction [D] Mean \pm SD (Range)	Postop MSE \pm 0.50 D (%)	Postop MSE \pm 1.00 D (%)	UDVA 20/20 or Better (%)	Loss of 2 Lines CDVA (%)
Zaldivar et al. (1998) ¹³	119	4.5	Nidek EC-5000 (conventional)	-8.62 \pm 1.27 (-5.5, -11.5)	56	83	22	1.20
Kim et al. (2004) ¹⁴	324	12	Nidek EC-5000 (conventional)	-7.91 \pm 1.26 (-6.0, -11.50)	63.3	80.6	71.6	0.6
Gazieva et al. (2011) ¹⁵	326	3	Mel-70 (conventional)	-8.92 \pm 2.08 (-5.50, -11.0)	17*	39*	—	0.60
	354	3	Mel-80 (conventional)	-8.08 \pm 1.85 (-5.50, -11.0)	34*	60*	—	0.60
Kojima et al. (2008) ¹⁶	320	>3	Visx Star S2 and S4 Technolas 217z Ladarvision 4000 (combination of conventional and wavefront-guided)	-7.54 \pm 1.43 (-6.0, -10.0)	56.9	86.1	73.6	1.39
de Benito-Llopis et al. (2008) ¹⁷	114	3	Technolas 217C (not specified)	-8.74 \pm 1.20 D (-7.00, -13.75)	79	94	44.7	6.10
Bababegy et al. (2008) ¹⁸	89	3	Visx Star S4 (wavefront-guided)	-8.10 \pm 0.98 (-6.00, -10.63)	74.2	94.4	—	0
Kulkamthorn et al. (2008) ¹⁹	43	3	Visx Star S4 (wavefront-guided)	-7.38 \pm 1.20 D (-)	82	97.6	58	0
Stonecipher et al. (2010) ²⁰	141	6	Allegretto Wave 200 Hz (wavefront-optimized)	-(-6.0, -12.0)	86	—	77	0
	65	6	Allegretto Wave 400 Hz (wavefront-optimized)	-(-6.0, -12.0)	100	—	92	0
Vega-Estrada et al. (2012) ²¹	29	6	Schwind Amaris (wavefront-optimized)	-8.39 \pm 0.93 (-6.75, -11.25)	—	89.6	—	—
Alio et al. (2011) ²²	51	6	Schwind Amaris (wavefront-optimized)	-8.66 \pm 1.13 (-6.75, -13.00)	84.3	90.2	80.4	0
Current study	621	1	Visx Star S4 (wavefront-guided)	-7.28 \pm 1.05 (-6.0, -10.25)	84.7	96.8	83.6	1.4
		3	Visx Star S4 (wavefront-guided)		82.6	95.0	82.4	1.0

CDVA = corrected distance visual acuity; MSE = manifest spherical equivalent; UDVA = uncorrected distance visual acuity

*Postoperative emmetropia was aimed for in approximately 70% of eyes in this study

could be, to some extent, approximated by the subjective scores for night-vision phenomena such as glare, halo, starburst, and ghosting/double vision. The mean scores for these optical side effects (measured on a scale from 1 = no difficulty to 7 = severe difficulty) were close to 2 (Table 1) with a median of 1, indicating that only mild symptoms were present. Yu et al.²⁷ reported scores for optical side effects after myopic wavefront-guided LASIK for a lower range of myopia (manifest SE \leq -8.0 D and refractive cylinder \leq -3.0 D) using a 10-point scale in reverse order and found mean scores similar to those presented in our study (glare 7.89, halos 8.37, double vision 9.65,

ghost images 9.48). Considering the 6-month results presented in that study,²⁷ our scores might continue to improve beyond the 3-month follow-up. The percentage of patients willing to recommend the procedure to family or friends (96.4%) was similar to the score of 96.5% reported in the study of 13 655 patients who had wavefront-guided laser treatment in a wide range of ametropia (manifest SE between -11.63 D and +6.00 D).²⁸ Patients who reported being dissatisfied or very dissatisfied with the outcomes of the procedure (Table 1) were mainly those with a postoperative refractive error and corresponding reduced UDVA.

Vector analysis was performed to evaluate the change in refractive cylinder. At 3 months, we found a mean error of magnitude of $+0.07 \pm 0.33$ D (arithmetic difference of the magnitudes between surgically induced refractive correction and intended refractive correction) and a minimal mean error of angle of -0.29 ± 14.56 degrees (angular difference between attempted treatment and achieved treatment), indicating that the treatment was aligned correctly. A correction ratio (ratio of the magnitude of surgically induced refractive correction to intended refractive correction) is a numerical expression of the possible overcorrection or undercorrection of refractive cylinder. An ideal correction ratio would be 1, whereas a correction ratio of less than 1 indicates overcorrection and a correction ratio over 1 indicates undercorrection. We achieved the mean correction ratio of 1.02 ± 0.48 . This is consistent with our previous report⁸ in which the correction ratio for a smaller sample of patients ($n = 243$) and wider range of manifest SE (-0.38 to -9.88 D) was 1.02 ± 0.30 . The correction ratio was lower for higher amounts of cylindrical correction (Figure 6). There is a variation in reported correction ratios for treatment of astigmatic error with different lasers and platforms. For example, in U.S. Food and Drug Administration (FDA) preapproval studies,^B the correction ratio varies between 0.88 to 1.42 for all FDA lasers approved in the past 10 years, and the variations can be even higher for subcategories of different magnitudes of preoperative astigmatism. To improve our results further, a slight adjustment to the astigmatic correction nomogram might be necessary, mainly in cases with higher amounts of preoperative refractive cylinder in which undercorrection was obvious (Figure 5). However, a subcategory of patients with high astigmatism was small in this study, and a separate analysis would have to be performed to confirm this.

Despite some limitations of this study, such as its retrospective nature and absence of postoperative HOA measurement, this study demonstrated our experience with the new Hartmann-Shack aberrometer in the treatment planning of high myopia in a large number of cases. Although LASIK enjoys worldwide popularity, studies reporting the results of high myopia treatment in a large cohort of patients are rare. In summary, high efficacy, predictability, and accurate astigmatic correction were achieved in patients with high preoperative ametropia. Further improvement could be expected with nomogram adjustment, and a longer follow-up is needed to evaluate refractive stability.

WHAT WAS KNOWN

- Excimer laser ablation in patients with high myopia is often associated with a reduced refractive predictability and an induction of HOAs.
- The quality of preoperative scanning equipment is crucial in treatment planning in this particular group of patients.

WHAT THIS PAPER ADDS

- The use of a new Hartmann-Shack aberrometer in eyes with high myopia showed promising results with low scores for postoperative night-vision disturbances.
- Predictability of refractive outcomes was comparable with that in other published studies and could be improved further with nomogram refinement.

REFERENCES

1. Oshika T, Miyata K, Tokunaga T, Samejima T, Amano S, Tanaka S, Hirohara Y, Mihashi T, Maeda N, Fujikado T. Higher order wavefront aberrations of cornea and magnitude of refractive correction in laser in situ keratomileusis. *Ophthalmology* 2002; 109:1154–1158
2. Pesudovs K. Wavefront aberration outcomes of LASIK for high myopia and high hyperopia. *J Refract Surg* 2005; 21:S508–S512
3. Moreno-Barriuso E, Merayo Lloves J, Marcos S, Navarro R, Llorente L, Barbero S. Ocular aberrations before and after myopic corneal refractive surgery: LASIK-induced changes measured with laser ray tracing. *Invest Ophthalmol Vis Sci* 2001; 42:1396–1403. Available at: <http://iovs.arvojournals.org/article.aspx?articleid=2162653>. Accessed July 8, 2015
4. Awwad ST, Bowman RW, Cavanagh HD, McCulley JP. Wavefront-guided LASIK for myopia using the LADAR CustomCornea and the VISX CustomVue. *J Refract Surg* 2007; 23:26–38
5. McAlinden C, Moore JE. Comparison of higher order aberrations after LASIK and LASEK for myopia. *J Refract Surg* 2010; 26:45–51
6. Hettinger KA. The role of biostatistics in the quality improvement of refractive surgery. *J Refract Surg* 2009; 25(7 suppl):S651–S654
7. Solomon KD, Fernández de Castro LE, Sandoval HP, Biber JM, Groat B, Neff KD, Ying MS, French JW, Donnenfeld ED, Lindstrom RL; for the Joint LASIK Study Task Force. LASIK world literature review: quality of life and patient satisfaction. *Ophthalmology* 2009; 116:691–701
8. Schallhorn S, Brown M, Venter J, Teenan D, Hettinger K, Yamamoto H. Early clinical outcomes of wavefront-guided myopic LASIK treatments using a new-generation Hartmann-Shack aberrometer. *J Refract Surg* 2014; 30:14–21
9. Eydelman MB, Drum B, Holladay J, Hilmantel G, Kezirian G, Durrie D, Stulting RD, Sanders D, Wong B. Standardized analyses of correction of astigmatism by laser systems that reshape the cornea. *J Refract Surg* 2006; 22:81–95
10. Oruçoğlu F, Kingham JD, Kendüşim M, Ayoğlu B, Toksu B, Göker S. Laser in situ keratomileusis application for myopia over minus 14 diopter with long-term follow-up. *Int Ophthalmol* 2012; 32:435–441

11. Pérez-Santonja JJ, Bellot J, Claramonte P, Ismail MM, Alió JL. Laser in situ keratomileusis to correct high myopia. *J Cataract Refract Surg* 1997; 23:372–385
12. Lyle WA, Jin GJC. Laser in situ keratomileusis with the VISX Star laser for myopia over –10.0 diopters. *J Cataract Refract Surg* 2001; 27:1812–1822
13. Zaldivar R, Davidorf JM, Oscherow S. Laser in situ keratomileusis for myopia from –5.50 to –11.50 diopters with astigmatism. *J Refract Surg* 1998; 14:19–25
14. Kim JK, Kim SS, Lee HK, Lee IS, Seong GJ, Kim EK, Han SH. Laser in situ keratomileusis versus laser-assisted subepithelial keratectomy for the correction of high myopia. *J Cataract Refract Surg* 2004; 30:1405–1411
15. Gazieva L, Beer MH, Nielsen K, Hjortdal J. A retrospective comparison of efficacy and safety of 680 consecutive LASIK treatments for high myopia performed with two generations of flying-spot excimer lasers. *Acta Ophthalmol* 2011; 89:729–733. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1755-3768.2009.01830.x/pdf>. Accessed July 8, 2015
16. Kojima T, Hallak JA, Azar DT. Control-matched analysis of laser in situ keratomileusis outcomes in high myopia. *J Cataract Refract Surg* 2008; 34:544–550
17. de Benito-Llopis L, Teus MA, Sánchez-Pina JM. Comparison between LASEK with mitomycin C and LASIK for the correction of myopia of –7.00 to –13.75 D. *J Refract Surg* 2008; 24:516–523
18. Bababeygy SR, Zoumalan CI, Manche EE. Visual outcomes of wavefront-guided laser in situ keratomileusis in eyes with moderate or high myopia and compound myopic astigmatism. *J Cataract Refract Surg* 2008; 34:21–27
19. Kulkamthorn T, Silao JN, Torres LF, Lim JN, Purcell TL, Tantayakom T, Schanzlin DJ. Wavefront-guided laser in situ keratomileusis in the treatment of high myopia by using the CustomVue wavefront platform. *Cornea* 2008; 27:787–790
20. 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:S814–S818
21. Vega-Estrada A, Alió JL, Arba Mosquera S, Moreno LJ. Corneal higher order aberrations after LASIK for high myopia with a fast repetition rate excimer laser, optimized ablation profile, and femtosecond laser-assisted flap. *J Refract Surg* 2012; 28:689–695
22. Alió JL, Vega-Estrada A, Piñero DP. Laser-assisted in situ keratomileusis in high levels of myopia with the Amaris excimer laser using optimized aspherical profiles. *Am J Ophthalmol* 2011; 152:954–963
23. El Danasoury MA, El Maghraby A, Gamali TO. Comparison of iris-fixed Artisan lens implantation with excimer laser in situ keratomileusis in correcting myopia between –9.00 and –19.50 diopters: a randomized study. *Ophthalmology* 2002; 109:955–964
24. Leaming DV. Practice styles and preferences of ASCRS members—2003 survey. *J Cataract Refract Surg* 2004; 30:892–900
25. Schallhorn SC, Venter JA. One-month outcomes of wavefront-guided LASIK for low to moderate myopia with the VISX STAR S4 laser in 32,569 eyes. *J Refract Surg* 2009; 25:S634–S641
26. Yuen LH, Chan WK, Koh J, Mehta JS, Tan DT; for the SingLasik Research Group. A 10-year prospective audit of LASIK outcomes for myopia in 37,932 eyes at a single institution in Asia. *Ophthalmology* 2010; 117:1236–1244.e1
27. Yu J, Chen H, Wang F. Patient satisfaction and visual symptoms after wavefront-guided and wavefront-optimized LASIK with the WaveLight platform. *J Refract Surg* 2008; 24:477–486
28. Brown MC, Schallhorn SC, Hettinger KA, Malady SE. Satisfaction of 13,655 patients with laser vision correction at 1 month after surgery. *J Refract Surg* 2009; 25:S642–S646

OTHER CITED MATERIAL

- A. International Organization for Standardization. Information Technology – Security Techniques – Information Security Management Systems – Requirements. Geneva, Switzerland, ISO, 2013. (ISO/IEC 27001:2013). Abstract available at: <https://www.iso.org/obp/ui/#iso:std:iso-iec:27001:ed-2:v1:en>. Accessed July 8, 2015
- B. U.S. Food and Drug Administration. Medical Devices. FDA-Approved Lasers for PRK and Other Refractive Surgeries. Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/SurgeryandLifeSupport/LASIK/ucm192110.htm>. Accessed July 8, 2015