

# Visual outcome after correcting the refractive error of large pupil patients with wavefront-guided ablation

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**Purpose:** To investigate the efficacy and predictability of wavefront-guided laser in situ keratomileusis (LASIK) treatments using the iris registration (IR) technology for the correction of refractive errors in patients with large pupils.

**Setting:** Horus Vision Correction Center, Alexandria, Egypt.

**Methods:** Prospective noncomparative study including a total of 52 eyes of 30 consecutive laser refractive correction candidates with large mesopic pupil diameters and myopia or myopic astigmatism. Wavefront-guided LASIK was performed in all cases using the VISX STAR S4 IR excimer laser platform. Visual, refractive, aberrometric and mesopic contrast sensitivity (CS) outcomes were evaluated during a 6-month follow-up.

**Results:** Mean mesopic pupil diameter ranged from 8.0 mm to 9.4 mm. A significant improvement in uncorrected distance visual acuity (UCDVA) ( $P < 0.01$ ) was found postoperatively, which was consistent with a significant refractive correction ( $P < 0.01$ ). No significant change was detected in corrected distance visual acuity (CDVA) ( $P = 0.11$ ). Efficacy index (the ratio of postoperative UCDVA to preoperative CDVA) and safety index (the ratio of postoperative CDVA to preoperative CDVA) were calculated. Mean efficacy and safety indices were  $1.06 \pm 0.33$  and  $1.05 \pm 0.18$ , respectively, and 92.31% of eyes had a postoperative spherical equivalent within  $\pm 0.50$  diopters (D). Manifest refractive spherical equivalent improved significantly ( $P < 0.05$ ) from a preoperative level of  $-3.1 \pm 1.6$  D (range  $-6.6$  to  $0$  D) to  $-0.1 \pm 0.2$  D (range  $-1.3$  to  $0.1$  D) at 6 months postoperative. No significant changes were found in mesopic CS ( $P \geq 0.08$ ), except CS for three cycles/degree, which improved significantly ( $P = 0.02$ ). Magnitudes of primary coma and trefoil did not change significantly ( $P \geq 0.34$ ), with a small but statistically significant increase in primary spherical aberration.

**Conclusion:** Wavefront-guided LASIK provides an effective correction of low to moderate myopia or myopic astigmatism in large pupil patients without deterioration of visual quality.

**Keywords:** large pupil, wavefront, LASIK

## Introduction

Laser corneal refractive surgery has been shown to be a safe and reliable option for the correction of refractive errors.<sup>1</sup> However, the induction of significant amounts of higher order aberrations (HOA) that may lead to a postoperative limitation of the visual quality (mainly primary coma and spherical aberration) has been described as a potential side effect of this surgical option.<sup>2-11</sup> This aberrometric phenomenon has been associated with several factors, such as the use of inappropriate ablation algorithms, corneal biomechanical changes, flap creation in laser assisted in situ keratomileusis (LASIK) surgery, decentration of the ablation, or the effectivity loss of the peripheral laser rays coming into contact with the cornea in a nonorthogonal way

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with no energy compensation.<sup>12-17</sup> Visual discomfort and night vision disturbances after keratorefractive surgery have been related to the magnitude of these induced HOAs.<sup>4,18,19</sup> These aberration-related symptoms are pupil-dependent. It should be noted that the larger the pupil diameter, the higher the magnitude of HOA. This is the reason for considering the presence of a large mesopic pupil size as a potential risk factor for night vision complaints after refractive surgery.<sup>20</sup>

The introduction of wavefront-guided laser technology into the field of refractive surgery in 1999 represented a significant advancement in ophthalmology, allowing an optimized correction not only of spherocylindrical errors but also of HOA.<sup>21,22</sup> Specifically, ocular or total wavefront-guided ablations have been shown to be effective in minimizing aberrations in eyes without previous unsuccessful or nonoptimized refractive surgeries.<sup>23-33</sup> Patients with large mesopic pupil sizes seem to be ideal candidates for this type of procedure considering the commonly increased aberrometric profile in these type of eyes, and the potential of night vision disturbances after surgery.<sup>20</sup> However, the larger the pupil, the higher the possibility of a significant pupil center displacement from mesopic conditions maintained during aberrometric measurements to photopic conditions during laser treatment. The recently developed iris registration (IR) technology compensates for such shift by means of axial registration considering the iris periphery as a reference for centration. IR also uses torsional registration based on identification of the individual iris details to compensate for torsional changes that might occur when patient's position changes from sitting during aberrometric measurement to supine position during laser treatment. IR provides better axial and torsional registration, and this may be especially useful in eyes with large pupils.<sup>34</sup>

The aim of this prospective noncomparative study was to investigate the efficacy and predictability of wavefront-guided LASIK treatments using the IR technology for the correction of refractive errors in patients with large pupils.

## Patients and methods

This prospective, noncomparative study included a total of 52 eyes from 30 consecutive laser refractive correction candidates at the Horus Vision Correction Center ([HVCC] Alexandria, Egypt). In all cases, wavefront-guided LASIK was indicated and performed due to the presence of a preoperative large pupil size by using the VISX STAR S4 IR excimer laser platform (Abbott Medical Optics Inc, Santa Ana, CA). This study was reviewed and approved by the Institutional Review Board at HVCC in Alexandria, Egypt.

Written informed consent was obtained from all subjects before their participation in the study.

## Inclusion and exclusion criteria

Inclusion criteria consisted of preoperative refractive errors ranging from +4.0 diopters (D) to -7.0 D of the spherical equivalent of myopia or hyperopia with astigmatism of up to 5.0 D at the spectacle plane, and pupil diameter of 8.0 mm or larger at 3 cd/m<sup>2</sup> of illumination (mesopic),<sup>35</sup> age of 18 years old or older, and stable refraction, which was defined as a change in the spherical equivalent within  $\pm 0.5$  D over the last 12 months. Exclusion criteria were dry eye syndrome, irregular corneal topography patterns compatible with corneal ectatic disease, corneal scarring, history of herpetic eye disease, significant anterior and posterior segment pathologies, previous ocular surgeries, autoimmune disease, and any active ocular disease. Contact lens wearers were asked to discontinue the use of contacts at least 1 week for soft lenses and 3 weeks for hard or gas permeable lenses prior to the preoperative examination. If topographic features of contact lens warpage or unstable tear film were detected after that period, the patients were asked to discontinue wearing contact lenses for 1 or 2 additional weeks while using preservative-free artificial tear drops.

## Preoperative evaluation and surgical planning

The preoperative evaluation included examining patients' ocular and medical history with special attention to the above mentioned exclusion criteria, manifest and cycloplegic refraction measurements, uncorrected (UDVA) and best corrected distance visual acuity (CDVA) testing, pupil diameter under both photopic and mesopic conditions using the Colvard pupillometer<sup>35</sup> (OASIS Medical, Inc, Glendora, CA), mesopic contrast sensitivity (CS) testing using the CVS-1000 chart (Vector-Vision Inc, Greenville, OH), corneal topography, anterior segment imaging using the Pentacam-HR system (Oculus Inc, Wetzlar, Germany), ultrasound pachymetry using the Nidek UP-1000 US pachymeter (Nidek Co, Ltd, Gamagori, Japan), slit-lamp examination, and applanation tonometry. Regarding the aberrometric analysis, the following parameters were analyzed and recorded: higher order root mean square (RMS), primary coma RMS (computed for the Zernike terms  $Z_3^{\pm 1}$ ), trefoil RMS, and the Zernike term corresponding to the primary spherical aberration ( $Z_4^0$ ) with its sign.

The WaveScan aberrometer (Hartmann-Shack wavefront sensor; Abbott Medical Optics Inc) was used for the

preoperative measurement of wavefront aberrations as well as for the planning of the most optimum ablation profile in each case (wavefront-guided ablation profile). Target postoperative refraction was emmetropia in all eyes. The wavefront-guided customized ablation was designed and calculated using the commercially available software CustomVue™ from Abbott Medical Optics Inc. For this purpose, the aberrometric data as well as the manifest refraction, central corneal thickness, and intended flap pachymetry were introduced in the software. In all cases, the optical zone was set to 6.5 mm and the transition zone to 8.5 mm.

## Surgical procedure

All surgical procedures were performed by the same surgeon at HVCC. The designed treatment with the CustomVue™ software was first loaded to the excimer laser computer and reviewed by the surgeon to confirm the data. The VISX STAR S4 IR excimer laser platform (0.65 mm spot size combined with the ActiveTrak 3D eye tracker; Abbott Medical Optics Inc) was used to perform all the LASIK treatments. After ablation pattern confirmation, a corneal flap was created by means of the mechanical microkeratome Moria M2 (Moria SA, Antony, France) and lifted prior to corneal laser ablation. The microkeratome rings were selected according to the preoperative k-reading for each individual eye (manufacturer's recommendations) to create superior hinge flaps at a diameter of 9.0 mm. After this, the programmed treatment was applied on the stroma. All surgeries were performed under topical anesthesia. Regular topical postoperative treatment was administered to all patients in the form of topical antibiotics, topical steroids, and topical preservative-free artificial tears drops. No retreatments were performed in any case during the postoperative follow-up.

## Postoperative follow-up

Patients were examined the day after surgery and were then scheduled to come back to the hospital after 1 week, as well as 1, 3, and 6 months postoperatively. Since then, regular examinations were recommended every year. On the first postoperative day, a detailed slit-lamp examination was performed to evaluate the flap position and the integrity of the cornea. UDVA and CDVA assessment, manifest refraction, and biomicroscopic examination were performed in the remaining visits. Likewise, mesopic CS and ocular wavefront aberrations were evaluated at the last follow-up visit. Efficacy and safety indexes were calculated using the visual acuities in decimal notation. The efficacy index was calculated as the ratio of the postoperative UDVA to the

preoperative CDVA, whereas the safety index was calculated as the ratio of the postoperative CDVA to the preoperative CDVA. Furthermore, the magnitude of decentration was evaluated at the end of the follow up. The method of evaluating the ablation centration has been described.<sup>36</sup> Briefly, on the preoperative map, the cursor was placed at the detected pupil center and the distance from the corneal vertex to the pupil center was recorded directly from the legend in both millimeters and the angle of semimeridians. On the difference map, between preoperative and 6 months postoperative, the cursor was placed in the center of the confluent blue zone, which represents the ablation center. The distance from the corneal vertex to the ablation center was recorded directly from the legend. The distance from the pupil center to the ablation center (amount of decentration) was calculated by vector analysis from the above data (ie, distance from the corneal vertex to the pupil center and from the corneal vertex to the ablation zone; Figure 1).

## Refraction notation

The spherocylindrical refractions obtained before and after surgery were converted to vectorial notations using the power vector method described by Thibos and Horner.<sup>37</sup> Using this procedure, any spherocylindrical refractive errors can be expressed by three dioptric powers:  $M$ ,  $J_0$ , and  $J_{45}$ , with  $M$  being a spherical lens equal to the spherical equivalent of the given refractive error, and  $J_0$  and  $J_{45}$  are two Jackson crossed cylinders equivalent to the conventional cylinder. These numbers are the coordinates of a point in a three-dimensional dioptric space ( $M$ ,  $J_0$ ,  $J_{45}$ ). The length of this vector is a measure of the overall blurring strength  $B$  of a spherocylindrical refractive error.

According to the power vector method, manifest refractions in conventional script notation ( $S$  [sphere],  $C$  [cylinder]  $\times \phi$  [axis]) were converted to power vector coordinates and overall blurring strength ( $B$ ) by the following formulas:

$$M = S + C/2 \quad (1)$$

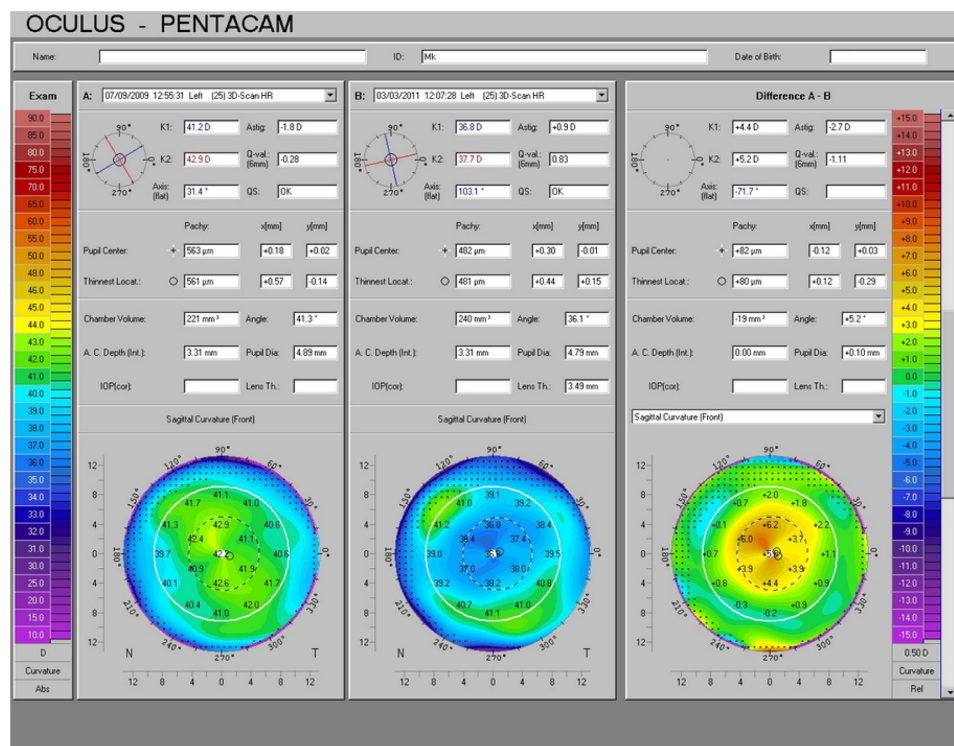
$$J_0 = (-C/2) \cos(2\phi) \quad (2)$$

$$J_{45} = (-C/2) \sin(2\phi) \quad (3)$$

$$B = (M^2 + J_0^2 + J_{45}^2)^{1/2} \quad (4)$$

## Statistical analysis

Data analysis was performed using the Statistical Package for the Social Sciences software for Windows, version 15.0



**Figure 1** Pentacam (Oculus Inc, Wetzlar, Germany) axial curvature difference map comparing pre- and postoperative curvature to assess treatment centration.

(IBM Corporation, Armonk, NY). Normality of the data samples was evaluated by means of the Kolmogorov–Smirnov and Shapiro–Wilk tests. When parametric analysis was possible, the Student's *t*-test for paired data was used for comparisons between the preoperative and postoperative data, whereas the Wilcoxon rank sum test was applied to assess the significance of such differences when parametric analysis was not possible. Differences were considered to be statistically significant when the associated *P*-value was  $<0.05$ . Correlation coefficients (Pearson or Spearman, depending if normality condition could be assumed) were used to assess the correlation between different variables. Furthermore, the standard graphs for reporting the outcomes in refractive surgery according to the Waring protocol<sup>38</sup> were used for displaying and summarizing the main outcomes of this study.

## Results

Mean patient age of the analyzed sample was 27.4 (standard deviation [SD]  $\pm 3.1$ ) years (range 19 to 32 years). Nine patients were males and 21 were females. Mean mesopic pupil diameter ranged from 8.0 mm to 9.4 mm, with a mean value of 8.6 (SD  $\pm 0.41$ ) mm. IR was enabled in 86% of cases during laser treatment. Table 1 summarizes the preoperative and postoperative visual, refractive, and aberrometric outcomes.

## Visual outcomes

As shown in Table 1, a significant improvement in LogMAR UDVA was found postoperatively (Wilcoxon test,  $P < 0.01$ ); however, no significant changes were detected in LogMAR CDVA (Wilcoxon test,  $P = 0.11$ ). Postoperative LogMAR UDVA was 0.1 (about 20/25) or better in all cases (100%), and 0.0 (about 20/20) or better in 44 eyes (84.62%) (Figure 2). Postoperative LogMAR CDVA was 0.1 (about 20/25) or better in all cases (100%), and 0.0 (about 20/20) or better in 48 eyes (92.31%).

The overall efficacy and safety indices were 1.06 (SD  $\pm 0.33$ ) and 1.05 (SD  $\pm 0.18$ ), respectively. Postoperatively, losses of lines of CDVA were only observed in two eyes (3.85%) (Figure 3). In contrast, gains of lines of CDVA were detected in a total of seven eyes (13.46%) (Figure 3).

## Refractive outcomes

As shown in Table 1, statistically significant reductions in B and M values were found postoperatively (Wilcoxon test,  $P < 0.01$ ). Almost all eyes (50 eyes, 96.15%) had a postoperative value of M within  $\pm 1.00$  D of emmetropia (Figure 4), and 48 eyes (92.31%) had a postoperative M value within  $\pm 0.50$  D of emmetropia (Figures 4 and 5). Figure 4 shows the achieved spherical equivalent correction plotted against the intended correction. A strong and

**Table 1** Summary of the visual, refractive, and aberrometric outcomes in the current series during the complete follow-up

Outcome	Preoperative Mean (SD) Median (range)	Postoperative Mean (SD) Median (range)	P-value (Wilcoxon test)
LogMAR UDVA	0.41 (0.18) 0.40 (0.05 to 0.70)	0.01 (0.05) 0.00 (-0.08 to 0.10)	<0.01
Manifest sphere (D)	-2.65 (1.67) -3.00 (-6.25 to 1.00)	-0.07 (0.25) 0.00 (-1.00 to 0.25)	<0.01
Manifest cylinder (D)	-1.02 (0.71) -1.00 (-2.25 to 0.00)	-0.19 (0.20) -0.25 (-0.75 to 0.00)	<0.01
$J_0$ (D)	0.32 (0.39) 0.35 (-0.81 to 1.11)	0.07 (0.10) 0.01 (-0.11 to 0.34)	<0.01
$J_{45}$ (D)	0.06 (0.36) 0.03 (-0.77 to 1.11)	0.003 (0.075) 0.000 (-0.20 to 0.22)	0.20
B (D)	3.25 (1.57) 3.68 (0.00 to 6.64)	0.23 (0.27) 0.18 (0.00 to 1.43)	<0.01
MRSE (D)	-3.15 (1.64) -3.63 (-6.63 to 0.00)	-0.17 (0.28) -0.13 (-1.38 to 0.13)	<0.01
LogMAR CDVA	0.02 (0.11) 0.00 (-0.08 to 0.40)	-0.002 (0.060) 0.000 (-0.08 to 0.15)	0.11
Primary coma RMS ( $\mu\text{m}$ )	0.27 (0.14) 0.23 (0.10 to 0.75)	0.25 (0.16) 0.24 (0.05 to 0.63)	0.64
Primary trefoil RMS ( $\mu\text{m}$ )	0.24 (0.15) 0.18 (0.05 to 0.65)	0.24 (0.18) 0.18 (0.08 to 0.77)	0.35
Primary spherical aberration ( $\mu\text{m}$ )	-0.02 (0.17) 0.01 (-0.45 to 0.38)	0.16 (0.23) 0.20 (-0.45 to 0.62)	<0.01

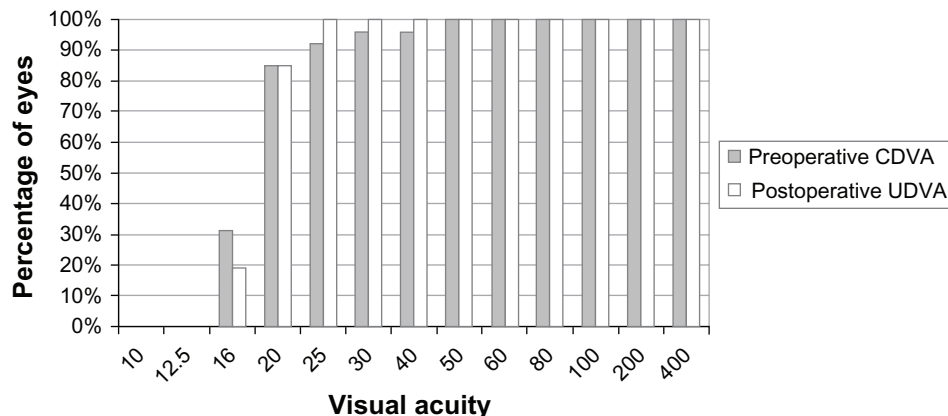
**Abbreviations:** SD, standard deviation; UDVA, uncorrected distance visual acuity;  $J_0$  and  $J_{45}$ , power vector components of manifest cylinder; MRSE, spherical equivalent; B, overall blurring strength of the manifest spherocylindrical error; CDVA, corrected distance visual acuity; RMS, root mean square; D, diopters.

statistically significant correlation was found among the achieved and the intended corrections ( $r = 0.97$ ,  $P < 0.01$ ). Regarding the astigmatic outcomes (Table 1), a statistically significant reduction was only detected postoperatively in the power vector component  $J_0$  (Wilcoxon test,  $P < 0.01$ ).

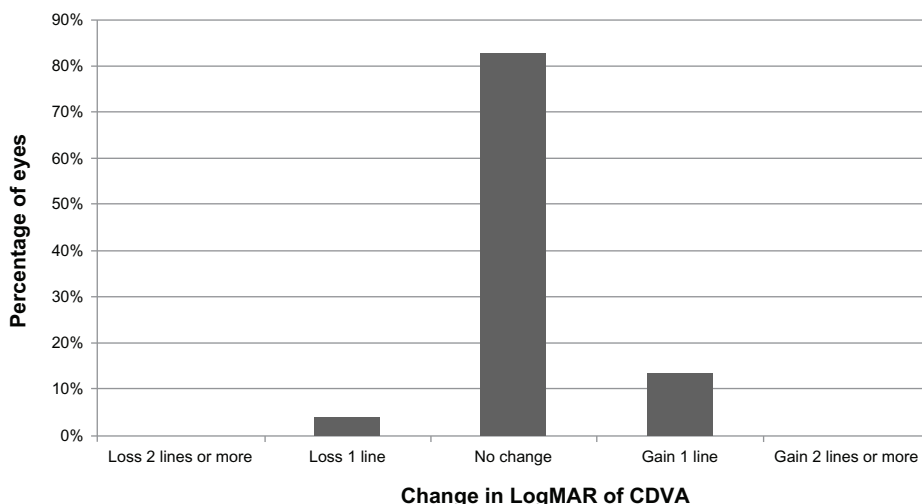
### Contrast sensitivity outcomes

Figure 6 summarizes the monocular CS outcomes obtained in the analyzed sample under mesopic conditions preoperatively and postoperatively. No statistically significant changes were

observed after surgery in the CS corresponding to the spatial frequencies of six ( $P = 0.68$ , Wilcoxon test), 12 ( $P = 0.08$ , Wilcoxon test), and 18 cycles/degree ( $P = 0.47$ , Wilcoxon test). Only a minimal but statistically significant improvement was observed for the lowest spatial frequency evaluated, three cycles/degree ( $P = 0.02$ , Wilcoxon test). Mesopic pupil diameter did not correlate with CS for any of the spatial frequencies analyzed (three cycles/degree,  $r = -0.15$ ,  $P = 0.32$ ; six cycles/degree,  $r = -0.11$ ,  $P = 0.47$ ; 12 cycles/degree,  $r = -0.19$ ,  $P = 0.20$ ; 18 cycles/degree,  $r = -0.21$ ,  $P = 0.16$ ).

**Figure 2** Comparative distribution of the preoperative CDVA and the UDVA at the end of the follow-up.

**Abbreviations:** CDVA, corrected distance visual acuity; UDVA, uncorrected distance visual acuity.



**Figure 3** Distribution of changes in postoperative CDVA during follow-up. **Abbreviation:** CDVA, corrected distance visual acuity.

### Ocular aberrometric outcomes

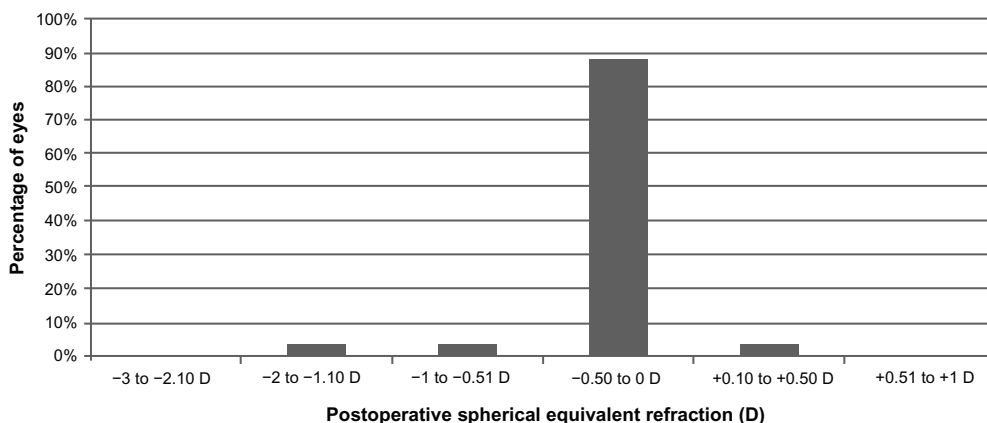
No statistically significant changes were observed in primary coma ( $P = 0.64$ , Wilcoxon test) and trefoil RMS ( $P = 0.34$ , Wilcoxon test) (Table 1). However, a small but statistically significant change in the magnitude of primary spherical aberration toward a more positive value was found postoperatively ( $P < 0.01$ , Wilcoxon test) (Table 1). Specifically, the mean change in this aberrometric parameter was  $0.18 \mu\text{m}$ .

A weak but statistically significant correlation between postoperative primary coma RMS and CDVA was observed ( $r = 0.31$ ,  $P = 0.03$ ). However, no significant correlations of postoperative CDVA with postoperative trefoil RMS ( $r = 0.17$ ,  $P = 0.24$ ) and  $Z_4^0$  ( $r = -0.17$ ,  $P = 0.26$ ) were detected. Mesopic pupil size did not correlate with the magnitude of the postoperative HOA analyzed: primary coma

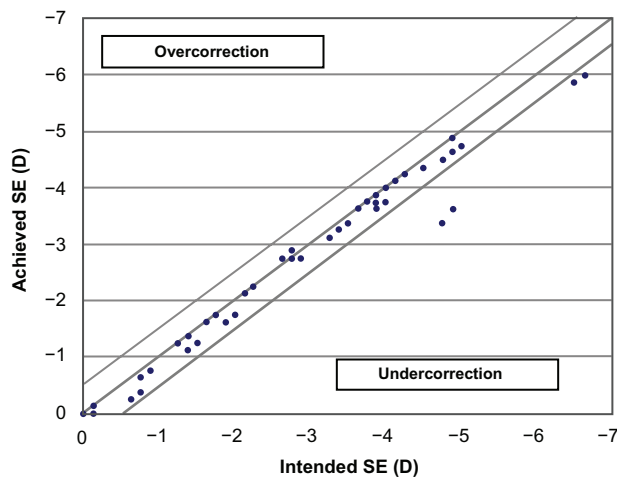
( $r = 0.16$ ,  $P = 0.29$ ), trefoil ( $r = 0.25$ ,  $P = 0.10$ ), and primary spherical aberration ( $r = 0.11$ ,  $P = 0.47$ ). Furthermore, no significant correlations were detected between postoperative CS and the magnitude of the HOA analyzed ( $-0.21 \leq r \leq 0.21$ ,  $P \geq 0.15$ ). The change in M was also found to be significantly correlated with the change in magnitude of primary spherical aberration with surgery ( $r = -0.51$ ,  $P < 0.01$ ) (Figure 7). Figure 8 shows the aberrometric outcomes in one patient that presented an improvement or maintenance of HOA.

### Complications

No intraoperative complications occurred. Retreatment was not necessary during the follow-up period in any cases from the current series. Decentration analysis by means of corneal topography revealed the absence of decentrations.



**Figure 4** Distribution of the postoperative spherical equivalent during the whole follow-up. **Abbreviation:** D, diopters.

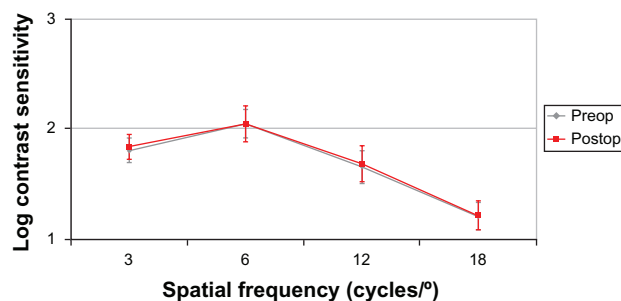


**Figure 5** Scattergram showing the relationship between the achieved postoperative spherical equivalent correction and the intended.

**Abbreviations:** SE, spherical equivalent; D, diopters.

## Discussion

Excimer laser wavefront-guided ablations were developed and introduced in clinical practice with the aim of optimizing the outcomes obtained with keratorefractive procedures. Several studies have shown that this type of procedure is effective in correcting the spherocylindrical error and minimizing HOA in eyes without previous refractive surgeries.<sup>23–33</sup> Therefore, this surgical procedure has the potential to reduce post-LASIK night vision problems, and may even result in improved post-LASIK vision. These types of treatments seem to be especially useful in patients with large pupil diameters who are more likely to suffer from HOA and related night vision disturbances after LASIK.<sup>20</sup> Indeed, Chan and Manche<sup>39</sup> found that large pupil size does not positively correlate with any postoperative visual symptoms 12 months after wavefront-guided LASIK surgery. One potential limitation for the aberrometric minimization programmed with the ablation profile is the cyclotorsion in the supine position that can lead even to the induction of aberrations.<sup>40</sup> The IR technology has been recently developed

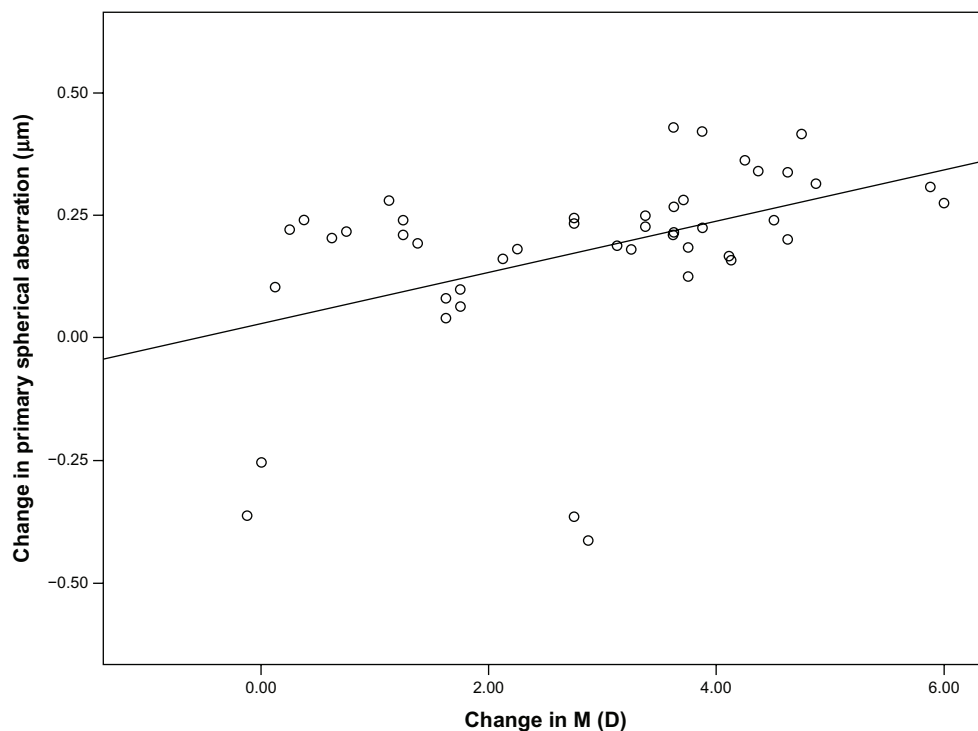


**Figure 6** Mean monocular contrast sensitivity function measured under mesopic conditions preoperatively (gray line) and postoperatively (red line).

with the aim of compensating for these cyclotorsional movements during surgery by means of axial registration, while considering the iris periphery as a reference for centration. The aim of the current study was to investigate the efficacy of wavefront-guided LASIK treatments using the IR technology for the correction of refractive errors in patients with large pupils.

In the current series, a significant improvement in UDVA was found, which was consistent with a significant reduction of the spherocylindrical error. The efficacy index was of 1.06, an excellent value comparable to or even better than those reported by other authors with other wavefront-guided platforms.<sup>23–33</sup> In addition, no significant changes in CDVA were observed. This reveals that an optimum visual quality was maintained after surgery. Indeed, the mean safety index was 1.05, with only losses of lines of CDVA observed in two eyes (3.85%). These results are also consistent with those reported in other previous series evaluating wavefront-guided LASIK procedures.<sup>23–33</sup> Gains of lines of CDVA were detected in a total of seven eyes (13.46%). It should be noted that the improvement in CDVA should not be the main goal of the wavefront-guided procedures considering the neural limitations as well as other optical limitations, such as scattering, that cannot be controlled with the surgical procedure.<sup>41</sup> The predictability of refractive correction was excellent, with 96.15% and 92.31% of eyes having a spherical equivalent within  $\pm 1.00$  D and within  $\pm 0.50$  D of emmetropia, respectively. These outcomes were similar and even better than those reported by other authors using other wavefront-guided platforms.<sup>23–33</sup>

Mesopic CS was maintained after surgery for the highest spatial frequencies evaluated, with a minimal but statistically significant improvement for three cycles/degree. This confirms that no deterioration of visual quality was induced with the surgery. Some contradictory findings have been reported in the peer reviewed literature concerning this issue. Some authors have found improvements in CS after wavefront-guided LASIK,<sup>26</sup> whereas others have found no change,<sup>24,29</sup> or even a small worsening.<sup>42</sup> Several factors may have accounted for this significant variability among studies, such as the laser platform or the microkeratome used, the clinical procedure used for testing the CS, the optical zone programmed, and the specific clinical characteristics of the samples evaluated in each study. Furthermore, no significant correlations between postoperative CS and mesopic pupil diameter were found in our series. This reveals that pupil size did not compromise the postoperative visual quality. A similar finding was reported by Tuan and Liang<sup>43</sup> in a study evaluating



**Figure 7** Scattergram showing the relationship between the change with surgery in spherical equivalent ( $\Delta M$ ) and the associated change in the magnitude of the Zernike coefficient corresponding to the primary spherical aberration ( $\Delta Z_4^0$ ).

**Note:** The adjusting line to the data obtained by means of the least-squares fit is shown ( $R^2: 0.20$ ):  $\Delta Z_4^0 = 0.030 - 0.052 \times \Delta M$ .

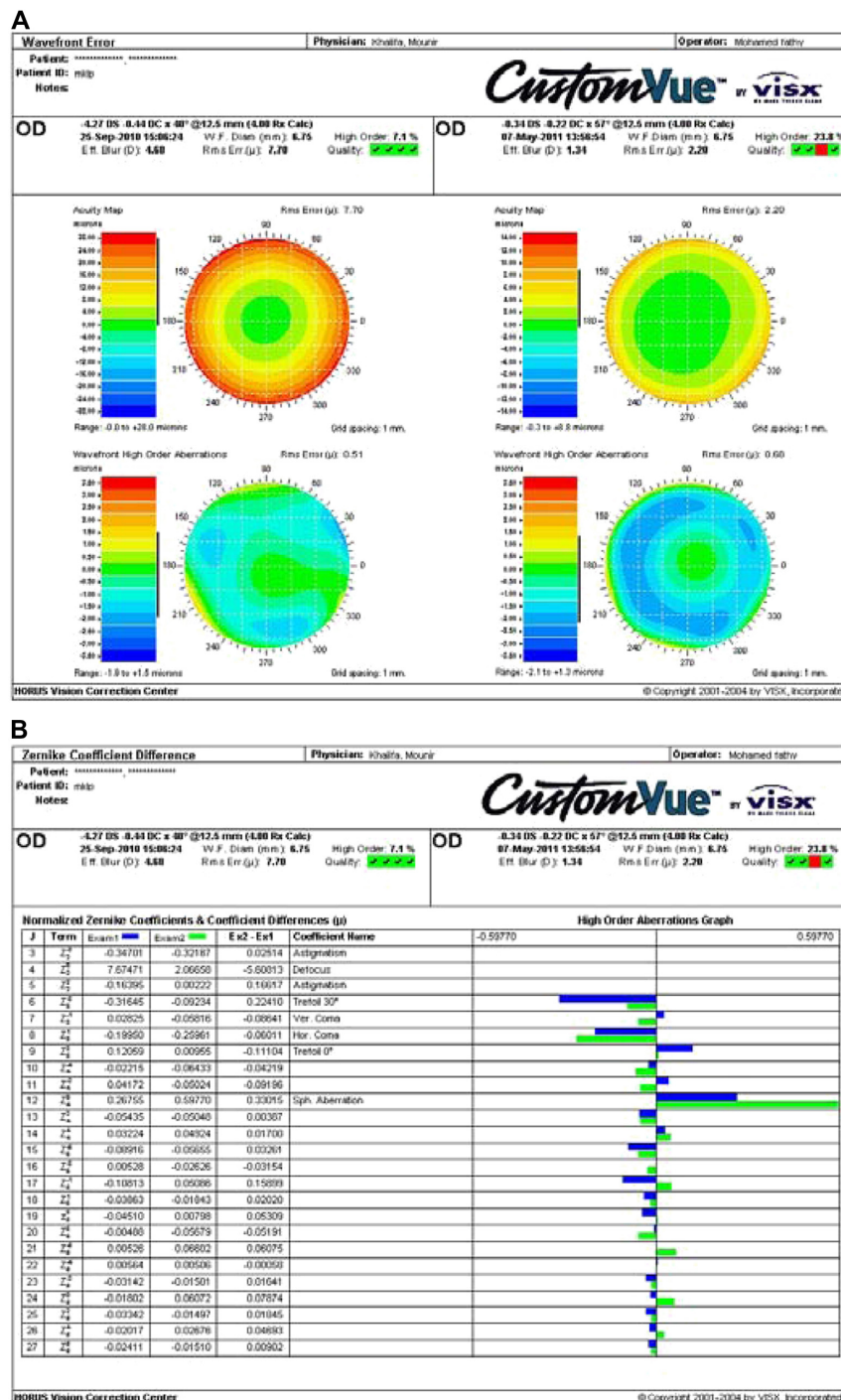
**Abbreviation:** D, diopters.

the CS outcomes after wavefront-guided procedures using the WaveScan aberrometer (Abbott Medical Optics Inc) and the Star S4 excimer laser system (Abbott Medical Optics Inc) in a sample of 274 myopic astigmatic eyes.

Regarding HOA, no significant changes were detected in the magnitude of primary coma and trefoil; however, a mean change of  $0.18 \mu\text{m}$  in primary spherical aberration was found, which was statistically significant. Therefore, the wavefront-guided ablation pattern was able to prevent the induction of some kind of aberration except the primary spherical aberration. It should be considered that a myopic ablation of 2 D or higher was programmed in 71% of eyes, and a correlation between the change in M and the change in primary spherical aberration was present. Specifically, the more negative the value of M, the more positive the postoperative spherical aberration. In any case, the levels of this aberration were within the normal range as defined for the healthy population.<sup>44</sup> In addition, the magnitude of this induction was of small magnitude and was also much lower than those induced by standard ablation profiles.<sup>2-11</sup> For this reason, no significant correlations were found between the postoperative magnitude of this aberration and CDVA or CS.

It should be mentioned that lower levels of the induction of primary spherical aberration have been reported with

optimized non-wavefront guided ablation profiles (aspheric) for similar amounts of myopia corrections.<sup>45-47</sup> One factor that may have accounted for this fact is the selection of a smaller optical zone than the scotopic pupil size.<sup>48</sup> Roberts and Koester<sup>49</sup> estimated the effect of the optical zone for entrance pupils in the range between 2 mm and 8 mm using an optical analysis computer program. These authors concluded that the optical zone diameter in corneal refractive surgery must be at least as large as the entrance pupil diameter to preclude glare at the fovea, and larger than the entrance pupil to preclude parafoveal glare. A similar conclusion was reached by Klonos et al<sup>50</sup> using a computer model. However, when scotopic pupil size is larger than 7 mm, the ablation diameter often cannot be as large as the pupil size, as recommended by Roberts and Koester<sup>49</sup> and Klonos et al<sup>50</sup> due to pachymetric limitations. In the current study, we used an optical zone of 6.5 mm and a total ablation zone of 8.5 mm in all cases. These diameters, as well as the customized blend zone, were thought to be enough to avoid the potential night vision disturbances after LASIK in these patients with large pupil sizes. Macsai et al<sup>51</sup> found that the use of a peripheral transition zone 1.0 mm larger than the pupil diameter under scotopic conditions resulted in a low incidence of glare and halos postoperatively, and did not adversely affect the



**Figure 8** CustomVue™ software (Abbott Medical Optics Inc, Santa Ana, CA) showing the aberrometric outcomes in one patient that presented an improvement/maintenance of HOA. (A) Shows wave-front maps, and (B) shows Zernike polynomials differences.

**Note:** Images used with permission of Abbott Medical Optics Inc, Santa Ana, CA.

**Abbreviation:** HOA, higher order aberrations.

visual acuity. In our study, there was no negative effect of the selected optical zone on CDVA or CS. In addition, no significant correlations were detected between postoperative CS and the magnitude of the HOA analyzed.

This study has limitations such as that we fixed the optical and transition zones, and did not change them

according to the mesopic pupil diameter. This was due to the limitations of the measured wavefront diameter with the used aberrometer which could not reach >8.0 mm. Also, the study did not include a comparison to the conventional ablation of Munnerlyn’s formula. Conventional ablation is comprehensively studied and has been proven to be

unsatisfactory, so we felt no need to compare this in cases with large pupils.

In summary, ocular wavefront-guided LASIK using the VISX STAR S4 IR excimer laser platform is an effective and predictable procedure for the correction of low to moderate myopia and/or myopic astigmatism in large pupil patients, maintaining an excellent level of visual quality. Future studies with longer follow-ups are necessary to confirm the stability of the outcomes reported here. In addition, other potentially influencing factors on the postoperative visual quality in these types of patients after wavefront-guided LASIK procedures, such as the creation of the flap or the ablation pattern design, should be investigated further.

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## Disclosure

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