

Conventional versus custom ablation in photorefractive keratectomy: Randomized clinical trial

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PURPOSE: To compare visual outcomes and changes in total higher-order aberrations (HOAs) between conventional photorefractive keratectomy (PRK) and custom PRK

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METHODS: This clinical trial comprised eyes having bilateral myopic PRK with the Technolas 217z excimer machine. One eye had conventional ablation (conventional group) and the other eye, wavefront-guided custom treatment (custom group). Changes in postoperative visual acuity, cycloplegic refraction, contrast sensitivity function, and root mean square higher-order aberrations (RMS HOAs) were compared between the 2 groups.

RESULTS: The mean age of the 28 patients (56 eyes) was 26.7 years. The mean preoperative cycloplegic spherical equivalent refractive error was -4.92 diopters (D) \pm 1.6 (SD) and the mean refractive astigmatism, 0.91 ± 1.0 D. There was no statistically significant difference between the 2 groups in preoperative cycloplegic refractive error, HOAs, or contrast sensitivity function. The mean follow-up was 8.1 ± 3.3 months. The increase in RMS HOAs from preoperatively to postoperatively was statistically significantly higher in the custom group in the 6.0 mm zone ($P = .03$) but not in the 4.0 mm zone ($P = .26$). The decrease in low mesopic contrast sensitivity function was statistically significant in both groups.

CONCLUSIONS: The RMS HOAs significantly increased after PRK with both methods. The results suggest that custom ablation is more sensitive to optical zone (OZ) size and may yield more aberrations with an OZ smaller than 6.0 mm.

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Today, excimer refractive surgery is the treatment of choice for correction of low to moderate myopia.^{1–4} However, irregularities in the optical system after refractive surgery can cause subjective complaints, such as halos and glare, that are attributed to an increase in higher-order aberrations (HOAs).^{5,6} This explains why nearly 30% of patients report night-vision problems after successful laser refractive surgery.^{7,8}

Custom ablation was introduced to better control aberrations caused by refractive surgery.^{9,10} However, the effectiveness of custom ablation has been questioned. Studies comparing custom ablation and conventional treatment^{11–14} report inconsistent results, ranging from a significant reduction in preexisting aberrations to no difference to deterioration in preexisting HOAs in custom-treated eyes.

In this study, we compared changes in HOAs after surface ablation procedures performed using conventional ablation or custom ablation and evaluated the effectiveness of wavefront-guided photorefractive keratectomy (PRK) in controlling postoperative changes in HOAs and consequent alteration of visual function, such as low mesopic contrast sensitivity.

PATIENTS AND METHODS

This double-blind clinical trial comprised patients having bilateral PRK for myopia. The Ethics Committee of the Ophthalmic Research Center approved the study. All patients provided informed consent after receiving a complete explanation of the surgery and the study. A random-number table was used to randomly assign 1 eye of each patient to conventional PRK (conventional group) and the

fellow eye to wavefront-guided custom PRK (custom group).

Preoperatively, all patients were free of ocular pathology except for myopia less than -8.00 diopters (D) and had a corrected distance visual acuity (CDVA) better than 20/20. Exclusion criteria included a history of corneal or intraocular surgery. Soft contact lenses were discontinued 2 weeks and rigid gas-permeable 6 weeks before patients entered the study.

The eye examination included a detailed ocular and systemic case history, Snellen CDVA measurement by a chart projector (Nidek, Inc.), manifest and cycloplegic refractions, slitlamp evaluation of the anterior segment, Goldmann tonometry intraocular pressure, dilated fundus evaluation, horizontal pupil diameter size under photopic and low mesopic illumination, ultrasonic pachymetry (Nidek, Inc.), low mesopic contrast sensitivity function, and ocular wavefront aberrometry. The evaluations were repeated postoperatively.

Pupillometry

After adaptation to a dark environment (0.17 lux), low mesopic pupil diameter was measured with a Colvard pupillometer (Oasis Medical). The pupillometer was also used to measure photopic pupil diameter under photopic conditions (270 lux).

Contrast Sensitivity Measurement

The monocular low mesopic contrast sensitivity function was measured with sine-wave gratings at 6 spatial frequencies (1, 2, 6, 12, 15, and 18 cycles per degree [cpd]) using the Moniteur Ophthalmologique STATphot program (Metrovision). During determination of contrast sensitivity function, patients viewed the chart at 2.0 m with best distance correction spectacles in place. After an initial demonstration of the contrast sensitivity function procedure, the contrast threshold was measured at each spatial frequency. The area under the log contrast sensitivity function (AULCSF) was calculated as described by Applegate et al.¹⁵ Because the contrast sensitivity function was checked with best distance correction with spectacles, the preoperative values were adjusted for the minification effect to make them comparable to those measured postoperatively.^{16,17}

Wavefront Evaluation

After contrast sensitivity function was measured, cycloplegic refraction was determined using tropicamide 0.5%

eyedrops. When the pupil diameter was larger than 6.0 mm, aberrometry was performed with a Zywave II aberrometer (software version 5.2, Bausch & Lomb) in a dark room. The aberrometer was used to calculate HOAs (Zernike polynomials up to 5th order) with a 4.0 mm pupil and a 6.0 mm pupil. At least 3 measurements were taken for each patient; the measurements were averaged after outliers were excluded. The Zernike coefficients were transformed to the standard form recommended by the Optical Society of America.¹⁸ All measurements were performed by an experienced operator using the same machine and procedures.

Surgical Technique

The same surgeon (F.K.) performed all surgeries in a private practice setting using a flying-spot excimer laser (Technolas 217z, Bausch & Lomb) with an emission wavelength of 193 nm, a fixed pulse repetition rate of 100 Hz, and a radiant exposure of 400 mJ. Antisepsis was performed by applying povidone-iodine 10% solution to the skin of the eyelids and periorcular area for 1 minute, after which the eyes were washed out with 20 cc of a balanced salt solution.

After ethyl alcohol 15% was applied in a 7.5 mm well for 20 seconds, the epithelium in the central 7.0 mm area was removed. The first eye was chosen randomly. Photoablation was performed using PlanoScan algorithm software in the conventional group. In the fellow eye (custom group), wavefront-guided custom treatment was performed with an advanced nomogram (as suggested by manufacturer) using aberrometry findings from the Zywave aberrometer (Bausch & Lomb) incorporated into the excimer laser system by Zylink system (version 2.3, Bausch & Lomb). During the custom treatment, iris registration was used to compensate for rotational eye movement. The maximum ablation depth was less than 100 μm and the optical zone (OZ) 5.8 mm or larger (always 1.5 mm larger than the low mesopic pupil). When ablation depth was greater than 70 μm , a sponge soaked with mitomycin-C 0.02% and then dried was placed over the ablated area for 10 to 30 seconds depending on ablation depth. This was followed by copious irrigation with a balanced salt solution and bandage contact lens fitting.

Postoperatively, the patients were given chloramphenicol and betamethasone 0.1% eyedrops every 6 hours for 15 days and then fluorometholone 0.1% eyedrops every 6 hours, gradually tapered over 3 months. After complete reepithelialization (usually between 3 days and 5 days), the bandage contact lens was removed. Postoperative examinations were scheduled for 1, 3, 7, and 30 days and 1, 3, and 6 months.

Statistical Analysis

To measure the surgically induced change in refractive astigmatism, the simple subtraction and vector analysis¹⁹ methods were applied. The efficacy index, defined as the ratio of the postoperative uncorrected distance visual acuity (UDVA) to the preoperative CDVA, was compared between the conventional group and the custom group. To calculate this index, the logMAR of the decimal visual acuity scores was used. The paired *t* test was used to compare preoperative and postoperative values in each group and the independent Student *t* test, to compare the 2 groups. The level of significance was set at 0.05.

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RESULTS

The study comprised 56 eyes of 28 patients (19 women). The mean age of the patients was 26.7 years \pm 6.0 (SD) (range 18 to 43 years). The mean cycloplegic spherical equivalent (SE) refractive error was -4.92 ± 1.6 diopters (D) (range -1.13 to -7.87 D) preoperatively and 0.05 ± 0.60 D (range -1.25 to $+1.38$ D) postoperatively ($P = .002$) and the mean refractive astigmatism, 0.91 ± 1.0 D (range 0 to 4.5 D) and -0.59 ± 0.40 D (range 0 to 1.5 D), respectively ($P = .04$). Table 1 shows the preoperative and operative data by group; there were no statistically significant differences between the conventional group and the custom group. The mean postoperative follow-up was 8.1 ± 3.3 months (range 3.5 to 16.9 months).

Figure 1 shows the preoperative low mesopic contrast sensitivity function; there was no statistically significant difference between the 2 groups at any spatial frequency. Similarly, there was no statistically significant difference between groups in terms of the root mean square (RMS) of coma; trefoil; spherical aberration; or 3rd-, 4th-, or 5th-order aberrations or in individual Zernike coefficients with a 4.0 mm or 6.0 mm pupil (Figure 2).

The mean postoperative UDVA was 0.03 ± 0.09 logMAR (range 0 to 0.3 logMAR) in the conventional group and 0.04 ± 0.09 logMAR (range 0 to 0.3 logMAR) in the custom group ($P = .87$). In both groups, 19 patients (67.9%) had a UDVA of 20/20; none achieved a UDVA better than 20/20 postoperatively. The mean efficacy index was 0.95 ± 0.14 (range 0.5 to 1.0) in the conventional group and 0.94 ± 0.16 (range 0.5 to 1.0) in the custom group ($P = .79$).

The postoperative SE refractive error decreased to -0.09 ± 0.49 D (range -1.25 to $+0.75$ D) in the

conventional group and $+0.19 \pm 0.60$ D (range -0.63 to $+1.38$ D) in the custom group ($P = .60$). The mean reduction in cycloplegic SE refractive error was 4.81 ± 1.45 D and 5.13 ± 1.58 D, respectively ($P = .44$). The mean postoperative refractive astigmatism was 0.62 ± 0.41 D (range 0.0 to 1.5 D) in the conventional group and 0.57 ± 0.40 D (range 0.0 to 1.5 D) in the custom group ($P = .68$). The mean refractive astigmatism measured with the subtraction method decreased by 0.27 D in the conventional group and by 0.36 D in the custom group ($P = .73$) and with the vector analysis method, by 0.83 D and 0.88 D, respectively ($P = .79$). At the final follow-up, 46 eyes (82.1%) in the conventional group and 34 eyes (60.7%) in the custom group had a cycloplegic SE refractive error within ± 0.50 D of emmetropia ($P < .001$); all patients achieved a cycloplegic SE refractive error within ± 1.00 D of emmetropia.

The mean postoperative central corneal thickness was 446.6 ± 37.8 μ m (range 388 to 524 μ m) in the conventional group and 446.2 ± 38.5 μ m (range 338 to 530 μ m) in the custom group. The difference between groups was not statistically significant ($P = .97$).

The low mesopic AULCSF decreased from 2.69 ± 0.04 to 1.69 ± 0.04 (37.2%) in the conventional group and from 2.68 ± 0.06 to 1.69 ± 0.05 (36.9%) in the custom group (both $P < .001$). The difference between the 2 groups was not statistically significant ($P = .82$).

Postoperatively, the mean increase in the RMS of total HOAs with a 4.0 mm pupil was 0.24 ± 0.19 μ m (range 0.13 to 0.59 μ m) in the conventional group and 0.31 ± 0.21 μ m (range 0.31 to 0.90 μ m) in the custom group ($P < .001$). With a 6.0 mm pupil, the increase was 0.34 ± 0.23 μ m (range -0.08 to 0.75 μ m) and 0.52 ± 0.32 μ m (-0.04 to 1.43 μ m), respectively ($P = .03$).

Table 1. Preoperative and operative data.

Parameter	Conventional Group (n = 28)	Custom Group (n = 28)	P Value
Mean scotopic pupil (mm)	6.0 \pm 0.7	5.9 \pm 0.7	.76
Mean photopic pupil (mm)	4.8 \pm 1.4	4.7 \pm 1.5	.87
Mean cycloplegic sphere (D)	$-4.57 \pm .75$	-4.58 ± 1.68	.96
Mean refractive astigmatism (D)	0.88 \pm 0.98	0.93 \pm 1.10	.87
Mean CCT (μ m)	538.6 \pm 28.4	537.5 \pm 39.9	.91
Mean scotopic AULCSF	2.69 \pm 0.04	2.68 \pm 0.06	.74
Mean RMS of HOAs (μ m)			
4.0 mm pupil	0.09 \pm 0.02	0.09 \pm 0.02	.94
6.0 mm pupil	0.34 \pm 0.08	0.33 \pm 0.09	.66
Mean optical zone (mm)	5.90 \pm 0.13	5.90 \pm 0.14	.92
Mean ablation depth (μ m)	75.6 \pm 15.8	79.5 \pm 17.6	.42
MMC application (% of cases)	71.4	75.0	.77
Mean duration of MMC application (s)	28.0 \pm 14.8	28.8 \pm 18.9	.88

AULCSF = area under log of contrast sensitivity function; CCT = central corneal thickness; HOAs = higher-order aberrations; MMC = mitomycin-C; RMS = root mean square

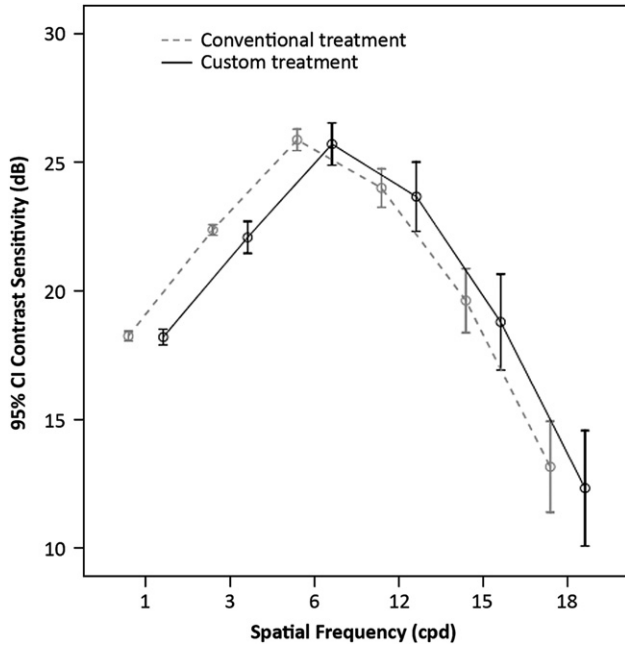


Figure 1. Preoperative low mesopic contrast sensitivity (CI = confidence interval; cpd = cycles per degree).

Table 2 compares the postoperative RMS of different aberrations between the 2 groups. The increase in the RMS HOAs from preoperatively to postoperatively was statistically significantly higher in the custom group than in the conventional group with a 6.0 mm pupil ($P = .03$) but not with a 4.0 mm pupil ($P =$

Table 2. Postoperative RMS of HOAs

RMS	Mean (μm) \pm SD		P Value
	Conventional Group	Custom Group	
Higher order			
4.0 mm pupil	0.54 \pm 0.19	0.60 \pm 0.20	.27
6.0 mm pupil	0.67 \pm 0.23	0.84 \pm 0.32	.04
Spherical			
4.0 mm pupil	0.08 \pm 0.04	0.10 \pm 0.04	.15
6.0 mm pupil	0.41 \pm 0.20	0.50 \pm 0.18	.13
Coma			
4.0 mm pupil	0.14 \pm 0.07	0.16 \pm 0.08	.27
6.0 mm pupil	0.44 \pm 0.22	0.51 \pm 0.22	.30
Trefoil			
4.0 mm pupil	0.14 \pm 0.12	0.15 \pm 0.07	.95
6.0 mm pupil	0.19 \pm 0.12	0.18 \pm 0.09	.94
Third order			
4.0 mm pupil	0.16 \pm 0.07	0.18 \pm 0.07	.37
6.0 mm pupil	0.50 \pm 0.20	0.55 \pm 0.21	.40
Forth order			
4.0 mm pupil	0.09 \pm 0.03	0.11 \pm 0.03	.07
6.0 mm pupil	0.46 \pm 0.17	0.55 \pm 0.17	.08
Fifth order			
4.0 mm pupil	0.01 \pm 0.003	0.01 \pm 0.006	.11
6.0 mm pupil	0.08 \pm 0.03	0.10 \pm 0.05	.10

RMS = root mean square

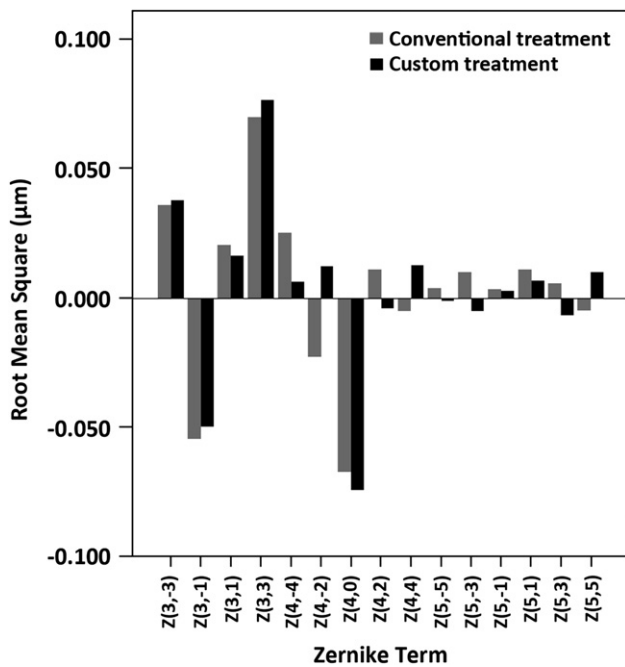


Figure 2. Preoperative Zernike coefficients of HOA up to the 5th order (6.0 mm pupil).

.26). The most prevalent postoperative HOA in both groups was spherical aberration followed by primary vertical coma in the conventional group and primary horizontal coma in the custom group and then primary vertical trefoil in both groups. Figure 3 shows the change in the Zernike coefficients of HOAs.

The conventional group had a statistically significantly higher increase in secondary vertical astigmatism from preoperatively to postoperatively ($P = .02$), while the custom group had a statistically significantly higher increase in secondary horizontal trefoil ($P = .04$) (Figure 4). There was no statistically significant difference between the 2 groups in the postoperative increase in the other Zernike coefficients, including spherical and coma aberrations.

In eyes with a preoperative SE refractive error less than -5.00 D (15 eyes, conventional group; 14 eyes, custom group), the increase in the RMS HOAs with a 6.0 mm pupil was statistically significantly greater in the custom group than in the conventional group ($0.74 \pm 0.36 \mu\text{m}$ and $0.54 \pm 0.18 \mu\text{m}$, respectively) ($P = .04$); however, there was no statistically significant difference between groups with a 4.0 mm pupil. In eyes with a preoperative SE refractive error greater than -5.00 D, there was no statistically significant difference between the conventional group (mean $0.82 \pm$

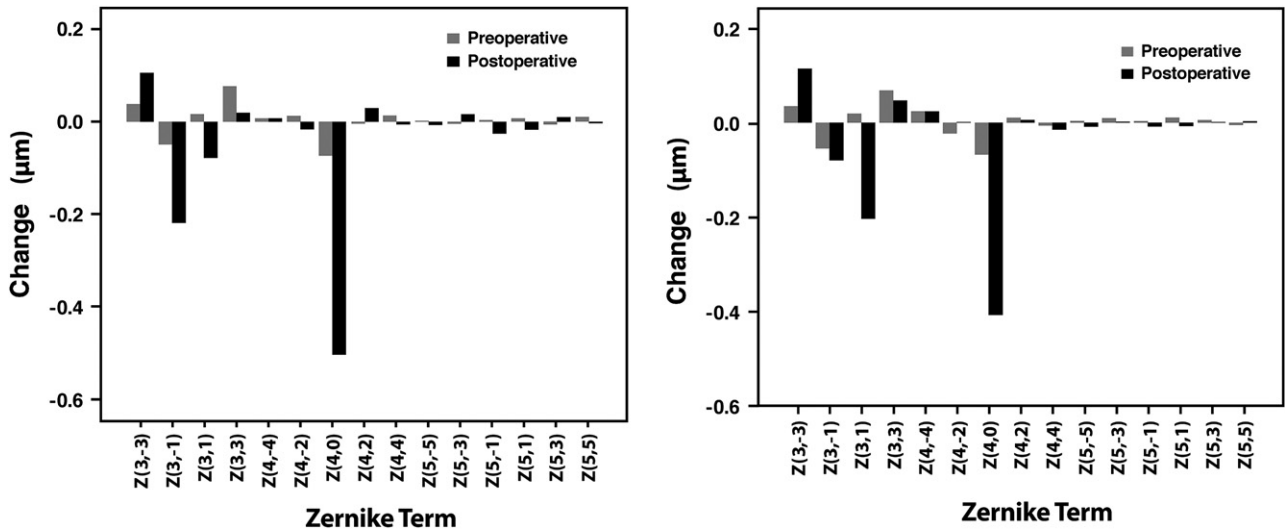


Figure 3. Change in each HOA caused by conventional ablation (left) and custom ablation (right) ablation (6.0 mm pupil).

0.19 µm) and the custom group (mean $0.93 \pm 0.26 \mu\text{m}$) ($P = .22$). There was no significant difference between the 2 groups in SE refractive errors less than -3.00 D and -4.00 D .

Linear regression analysis showed a negative, statistically significant association between RMS HOA and OZ with a 6.0 mm pupil in the custom group ($r^2 = 0.18$, $P = .026$) but not in the conventional group ($r^2 = 0.007$, $P = .68$). With a 4.0 mm pupil, the association was not statistically significant in either group ($r^2 = 0.025$ and $P = .43$, conventional group; $r^2 = 0.12$ and $P = .08$, custom group).

There were no intraoperative or postoperative complications. No eye developed corneal haze formation or required secondary intervention, such as enhancement surgery.

DISCUSSION

Higher-order aberrations are small irregularities or imperfections in the eye that cannot be corrected by simple spherical or astigmatic correction.²⁰ The aberrations affect the quality of the retinal image and often cause visual distortions, in particular in contrast sensitivity and mesopic visual acuity.^{20,21}

It is well known that conventional ablation increases HOAs, especially coma and spherical aberrations,²² which explains why a significant proportion of patients who have refractive surgery report visual symptoms such as glare and halos, despite the apparent success of the surgery.^{7,8} Therefore, custom ablation was introduced to improve the quality of vision.^{9,10}

However, there is no agreement on how effective custom ablation is in reducing postoperative HOA. Although some studies^{11,12} indicate that custom ablation has the potential to reduce or at least cause

deterioration in preexisting HOAs, other studies^{13,14} did not find this to be true. In a study by Vongthongsri et al.,¹³ laser in situ keratomileusis (LASIK) with conventional ablation and with wavefront-guided custom ablation resulted in the same CDVA and HOAs after 1 month. A later study by Phusitphoykai et al.¹⁴ found an increase in HOAs with conventional treatment and custom treatment 3 to 6 months after LASIK; the increase was higher in the conventional group. However, the difference was not statistically significant. Despite high levels of HOAs postoperatively, there was no significant reduction in postoperative contrast sensitivity function in the latter study. The authors did not mention whether they took the minification effect of preoperative correcting spectacles into account when comparing the

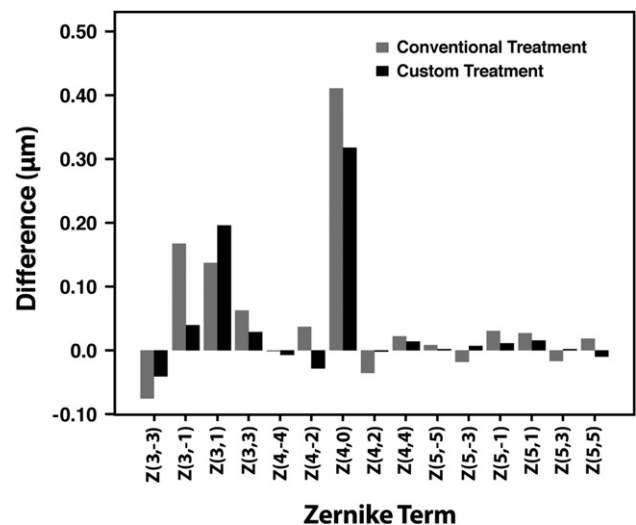


Figure 4. Difference between groups in preoperative and postoperative HOAs (6.0 mm pupil).

preoperative and postoperative contrast sensitivity functions. If they did not, postoperative elimination of the minifying effect of spectacles could offset the negative effect of HOAs on contrast sensitivity function.^{16,17}

Higher-order aberrations increased significantly in our study. The increase was chiefly the result of an increase in coma and spherical aberrations, which had an equal effect on most postoperative HOAs in both groups. The significantly higher HOAs in the custom group were observed when the preoperative SE was less than -5.00 D. In a population with virgin corneas, the value of most HOAs is almost negligible,²³ as was the case in our study when the preoperative HOAs were less than $0.50 \mu\text{m}$. Therefore, a very precise instrument is needed to detect and then correct aberrations in normal eyes with a low refractive error and HOAs. We believe the aberrometer used in our study was not accurate enough to eliminate small HOAs in a population with myopia lower than -5.00 D. Several studies²⁴⁻²⁷ report that although aberrometry was reliable for lower-order aberrations, its repeatability was not satisfactory for HOAs. Mirshahi et al.²⁴ suggest that the repeatability of Hartmann-Shack aberrometry by the aberrometer's wavefront sensor was not satisfactory, particularly for small amounts of HOAs. This confirms that aberrometry measurements should be repeated several times and outliers should be excluded in calculating the means.

Apart from inaccuracy of current aberrometers, HOAs can vary over time. In the short term, the magnitude of optical aberrations varies with blinking and evaporation of the precorneal tear film,⁸ as well as with changes in accommodative status (Tutt RC, et al. IOVS 1997; 38(suppl):ARVO Abstract 746; Hofer HJ, et al. IOVS 1999; 40:ARVO Abstract 1939).²⁹ In the long term, ocular aberrations tend to change moderately with age because of changes in the corneal profile and lens density (Berrio ME, et al. IOVS 2000; 41:ARVO Abstract 545).³⁰ These variations in HOAs may make custom ablation ineffective, or even harmful, after a certain amount of time.

Another explanation for the higher amount of HOAs in our custom group is a relatively small (<6.0 mm) OZ. Regression analysis showed a significant negative correlation in the custom group between postoperative RMS HOAs with a 6.0 mm pupil and OZ; the smaller the OZ, the higher the postoperative HOA RMS. In addition, the significant increase in RMS HOAs in the custom group was observed only with a 6.0 mm pupil, further highlighting the impact of an inadequate OZ on the results of custom ablation. The increase in HOAs has been linked to the size of the effective OZ after surgery.^{31,32} The results in our study imply that custom ablation and the aberrometer we used are more sensitive to the size of the OZ. An OZ

smaller than 6.0 mm can yield more HOAs than conventional treatment. Attempting to use a 6.5 mm OZ may minimize the likelihood of this effect.

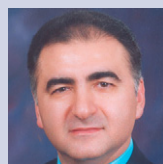
In the current study, contrast sensitivity function deteriorated postoperatively in both groups; however, the deterioration did not parallel the increase in HOAs in each group. Although objective measurements using aberrometry showed a significant difference between the 2 groups, the difference was not reflected in subjective measurements or in contrast sensitivity function. Although HOAs and contrast sensitivity were clearly correlated, HOAs cannot quantitatively predict contrast sensitivity because each Zernike term has a different impact on contrast sensitivity; the more centrally located the aberration, the more deleterious its effect on contrast sensitivity.³³ The increase in centrally located aberrations, such as coma and spherical aberration, was equal in both study groups. The difference between the groups was chiefly the result of an increase in more peripherally located aberrations (ie, secondary vertical astigmatism and secondary horizontal trefoil). This explains why the significantly higher amount of HOAs in the custom group was not reflected in the contrast sensitivity function results.

In summary, wavefront-guided customized ablation did not control the increase in HOAs after surface ablation, especially when the preoperative refractive error was low. However, given the above limitations, it is difficult to draw a definitive conclusion from our study. First, the sample size was not large enough. Second, in retrospect, a relatively small (<6.0 mm) OZ was used in some cases, especially in the custom group. Furthermore, the study evaluated a group with low levels of preoperative HOAs. Therefore, a similar study should be performed using a larger sample with higher levels of preoperative HOAs and using a larger OZ (eg, 6.5 mm). Such a study will increase understanding of the role of custom treatment in refractive surgery.

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