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Preoperative refraction, age and optical zone as predictors of optical and visual quality after advanced surface ablation in patients with high myopia: a cross-sectional study

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ABSTRACT

Objective To investigate the factors associated with optical and visual quality of advanced surface ablation in high myopia.

Design A cross-sectional study of high myopic eyes treated with laser epithelial keratomileusis (LASEK)/epipolis laser in situ keratomileusis (Epi-LASIK).

Setting6 Eye and ENT Hospital of Fudan University in Shanghai.

Methods One hundred and thirty-eight high myopic eyes (138 patients) (myopia −6 D or more) were examined more than 12 months after LASEK or Epi-LASIK with advanced surface ablation on the MEL 80 excimer laser (Zeiss AG, Jena, Germany). Refraction, higher order aberrations (HOAs) and contrast sensitivity before and after surgery were evaluated. Factors including preoperative refraction, age, gender, central corneal thickness, pupil size, optical diameter, ablation depth and flap creation method were analysed for association with postoperative high-order aberration, contrast and glare sensitivities, and different analytic diameters.

Results HOAs increased significantly postoperatively ($p<0.05$), with the most significant change found in Z(spherical aberration). At a 5 mm analysis diameter, increased coma was associated with age; increased spherical aberration difference was associated with age, optical zone diameter and method of epithelial flap creation. At a 3 mm analysis diameter, none of the factors contributed to changes in HOAs. Higher preoperative refractive error was associated with decreased contrast and glare sensitivity at each spatial frequency.

Conclusion A larger optical zone diameter design is recommended to achieve better visual quality in advanced surface ablation for high myopia correction. Age and preoperative refraction may help predict postoperative visual quality.

Strengths and limitations of this study

- This present study further analyses the visual quality of patients with high myopia (−6D or more), while previous investigations on visual quality were focused on low and moderate myopia.
- All cases were performed by a single experienced surgeon, removing any confounding effects from intersurgeon variability or training level.
- Participants in this study were recruited only from Shanghai, which may lead to limited external validity.
- The contrast sensitivity measurement range was limited in this study and should be expanded to a larger range of frequencies in future studies.

INTRODUCTION

Corneal refractive surgeries have rapidly evolved in the past 30 years. In 2003, the term 'advanced surface ablation' was coined to reflect the improvements in surface ablation from the early days of photorefractive keratectomy (PRK). Today's advanced surface ablation procedures include numerous techniques, including laser epithelial keratomileusis (LASEK) and epipolis laser in situ keratomileusis (Epi-LASIK).

Visual quality following refractive surgery is a major concern, especially for patients with high myopia. Pupil size, initial refractive error, optical zone size, decentration and residual refractive error are the main factors affecting visual quality after corneal ablation procedures.[1–3] Improved ablation methods such as Q-optimised algorithms may decrease the chances of postoperative visual quality problems in both patients with high myopia and patients with hyperopia.[4 5] Despite abundant literature on visual quality after corneal refractive surgery,[6–8] a multivariate analysis of high myopia, studying preoperative patient data, ablation profile and visual quality in advance surface ablation, has not been conducted. Patients' preoperative data and corneal ablation measurements (optical diameter and ablation depth) have previously been reported; however, do these factors also play important roles in postoperative visual quality in high myopia? And which factors are most significantly related to postoperative visual quality? Furthermore, it is unknown whether the epithelium flap creation method plays a role in postoperative visual quality. Thus, the current study aims to investigate the significant factors influencing visual quality in advanced surface ablations in high myopia.

MATERIALS AND METHODS

Study design

A cross-sectional study was performed to assess the factors influencing advanced surface ablation for the treatment of high myopia with more than 1-year follow-up (average 1.32±0.21 years, range 1~1.6 years). From patients' surgical records, we collected preoperative refraction, pupil size, central corneal thickness, patient age and gender, methods of epithelial flap creation, optical zone diameter and ablation depth. All surgical procedures were performed at the Eye and ENT Hospital of Fudan University, and informed consents were acquired prior to the study. The study followed the tenets of the Declaration of Helsinki.

Patient involving

This study involved 138 consecutive patients with high myopia (−6 D or more with up to −3 D of astigmatism) (68 females and 70 males; mean age: 31.1±9.0 years) who had chosen to undergo surface ablation over intraocular lens implantation. Participants underwent the procedure at the same surgical session.

Measurements

Preoperative examinations included uncorrected visual acuity, best-corrected visual acuity (BCVA), non-cycloplegic manifest refraction, intraocular pressure, corneal topography, corneal pachymetry, contrast sensitivity (CS), wavefront aberrations, slit-lamp examination and dilated fundus examination. Before the preoperative examination, contact lenses were discontinued for at least 3 weeks in rigid lens wearers and for at least 1 week in soft contact lens wearers.

Preoperative and postoperative higher order aberrations (HOAs) were measured with a Hartmann-Shack aberrometer (WASCA, Carl Zeiss Meditec, Jena, Germany) in scotopic conditions after 10 min of dark adaptation. Data were calculated within both 5 mm and 3 mm analysis diameters. CS was measured with a Contrast Glare tester CGT-1000 (Takagi Seiko Corp, Toyama, Japan). The CGT-1000 uses six types of ring-like targets with 12 levels of contrast for measurement. The target sizes are of 6.3°, 4°, 2.5°, 1.6°, 1.0° and 0.7° visual angles, which correspond to 6–12 cycles/degree in spatial frequencies. BCVA was measured first under mesopic conditions, and then under photopic conditions.

Surgical technique

LASEK treatments began with 20% alcohol-assisted epithelial removal, followed by standard excimer laser ablation with a Mel-80 excimer laser (software version: 3.6, Carl Zeiss Meditec AG; tissue-saving ablation profiles; standard nomogram). As the patient focused on a fixation light, the excimer laser energy was delivered to the cornea centred on the optical axis. The epithelium was repositioned after laser ablation, and a bandage contact lens was applied.

During Epi-LASIK, the rotational Epi-LASIK microkeratome (KM-5000D, Wuxi Kangming Medical Device Corp, Wuxi, China) was used to create the epithelial sheet.[9] The remainder of the procedure closely mirrored the LASEK procedure.

Mitomycin C was not used in either LASEK or Epi-LASIK cases. Bandage contact lenses were removed when epithelialisation was complete (usually between postoperative days 3 and 7).

Statistical analysis

One eye of each patient was randomly chosen for analysis. Statistical analysis was performed using SAS software (V.9.2). Continuous variables are expressed as the mean±SD. A normality test and homogeneity test of variance were performed before analysis. Logarithmic transformation was used for variables with skewed distributions. t-Test, repeated measures analysis of variance, multivariate linear regression and multivariate logistic regression were performed in the influencing factors analysis. The χ^2 test and row mean scores difference test was used for analysis of qualitative data. The χ^2 test and one-way ordinal data for mean difference test were used for qualitative data represented in frequencies. The 95% CIs are shown with upper and lower limits. P values less than 0.05 were considered statistically significant.

Patient and public involvement

The role of patients in this study was participants. They were not involved in the development of the research question and outcome measures, the recruitment of subjects and the conduct of the study. They were not involved in the design of this study. Results of the study will be disseminated to all participants by email. No specific patient advisers were involved in the design or conduct of the study.

RESULTS

Patient characteristics

A total of 138 eyes of 138 consecutive patients with high myopia were included (68 females, 70 males). Patient age at the time of refractive surgery was 31.1±9.0 years (range: 19–52 years). The spherical equivalent refraction refractive error was −11.78±1.89 D (range: −8.25 to −17.00). The preoperative central corneal thickness was 513.1±24.1 µm (range: 452–613). The preoperative mesopic pupil size was 6.04±0.83 mm (range: 5.2–7.0). The ablation zone was 5.72±0.23 mm (range: 5.0–6.25). The ablation depth was 139.9±15.6 µm (range: 108–177).

Table 1 Mean higher order aberrations (HOAs) before and 1 year after surgery (mean±SD, μm)

	HOAs	Coma like	Spherical like	spherical aberration
5 mm analysis diameter				
Preoperative	0.19±0.11	0.154±0.098	0.092±0.063	−0.024±0.187
Postoperative	0.11±0.07	0.334±0.131	0.393±0.136	−0.862±0.321
P values	<0.001	<0.001	<0.001	<0.001
3 mm analysis diameter				
Preoperative	0.55±0.13	0.077±0.062	0.059±0.043	0.069±0.090
Postoperative	0.14±0.04	0.110±0.042	0.073±0.024	−0.131±0.061
P values	0.001	<0.001	0.012	<0.001

Wavefront aberration

Mean postoperative root mean square (RMS) wavefront aberration values were significantly greater than those obtained preoperatively under both 5 mm and 3 mm analysis diameters (all p<0.05). Coma-like, spherical-like aberrations and spherical aberration all increased significantly under the analysis diameters of 5 mm and 3 mm (all p<0.05), with greater values observed in the 5 mm analysis diameter (table 1).

Results of multivariate analysis of wavefront aberrations with 5 mm analysis diameter are presented in table 2. Smaller optical zone (β (coefficient value)=−1.17, p=0.037) and younger age (β=−0.07, p<0.001) were found to be associated with higher RMS values of HOAs. Age (β=−0.06, p=0.002) and male gender (β=−0.08, P=0.028) were associated with higher coma-like aberrations. Smaller optical zone (β=−0.38, p<0.001), method of epithelial flap creation (β=−0.07, p=0.01) and younger age (β=−0.06, p<0.001) were associated with increased spherical-like aberration. Although smaller optical zone and younger age were associated with the increase in spherical-like aberrations and decrease in spherical aberration, respectively, under 3 mm of analysis diameter, the coefficient of determination values were very small (all r^2<0.1).

Contrast sensitivity

The CS results are summarised in table 3. CS was significantly lower at all spatial frequencies under mesopic conditions and at all spatial frequencies except 6.3° and 4.0° visual targets under photopic conditions, at 1-year postoperative follow-up.

Three factors, including preoperative refraction, age and optical diameter, were found to be related to the change in CS. At 4.0°, 2.5°, 1.6° and 1.0° visual targets, preoperative refractive error was associated with decreased CS (all p<0.05). Under mesopic conditions, a smaller optical zone was associated with decreased CS at the 6.3° visual target (β=−0.02, p=0.018), and younger age was associated with decreased CS at the 0.7° visual target (β=−0.03, p=0.044); however, the values of the coefficients of determination were too small to confirm these relationships in both cases (r^2<0.1). In the multivariate analysis of CS under photopic conditions (table 4),

Table 2 Multivariate analysis of HOAs (meaningful coefficient value)

	5 mm pupil diameter				3 mm pupil diameter			
	HOAS	CLA	SLA	SA	HOAS	CLA	SLA	SA
Age								
β value	−0.072***	−0.057**	−0.055***	0.084*				
Gender								
β value		−0.079*						0.066**
Methods								
β value			−0.074*					
Optical diameter								
β value	−1.167*		−0.376***	0.729***			−0.061*	
Ablation depth								
β value				−0.005*				

*P<0.05.
**P<0.01.
***P<0.001.
β value, coefficient value; CLA, coma-like aberration; HOAS, higher order aberrations; SAm spherical aberration; SLA, spherical-like aberration.

Table 3 Contrast sensitivity before and after surgery (log unit)

	Target size (°)					
	6.3	4.0	2.5	1.6	1.0	0.7
In mesopic condition						
Preoperative	1.696±0.218	1.676±0.241	1.532±0.228	1.289±0.230	1.003±0.256	0.712±0.281
Postoperative	1.542±0.194	1.514±0.211	1.353±0.240	1.114±0.238	0.849±0.261	0.576±0.206
P values	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
In photopic condition						
Preoperative	1.510±0.246	1.499±0.280	1.331±0.278	1.124±0.265	0.854±0.259	0.635±0.197
Postoperative	1.455±0.247	1.447±0.243	1.269±0.253	1.035±0.248	0.786±0.243	0.548±0.206
P values	0.02	0.03	0.01	<0.001	0.006	0.004

higher preoperative refractive error was associated with decreased CS values at 4.0° (β=–0.003, p=0.001), 2.5° (β=–0.005, p<0.001), 1.6° (β=–0.007, p<0.001) and 1.0° (β=–0.01, p=0.011) visual targets.

Slit-lamp examination

At 1-year postoperative follow-up, 96.38% (133/138) of eyes were clear and 3.62% (5/138) had trace haze. None of the eyes in the study developed corneal haze worse than grade 1, and haze did not affect the visual acuity in any of the operated eyes.

DISCUSSION

Laser refractive surgery increases ocular aberrations in mild, moderate and high myopia.[7 10–13] HOA changes after laser ablations are one of the main factors affecting the visual quality after refractive operations.[12 13]

Spherical-like aberrations can be described as decreased retinal image quality with a mesopic pupil diameter. It is greater when light enters the pupil from the periphery and is not found at the pupil centre. For a large pupil, the effects of aberration are increased approximately 10–20 fold.[10 11 14] In previous studies, Alarcón and colleagues[1] found that retinal image quality was affected by pupil size only when the pupil size was larger than the optical zone. The research of Seo *et al*[8] and Endl *et al*[15] also indicated that wavefront aberrations after refractive surgery with a larger ablation zone are less pronounced and closer to physiological level than those with a regular ablation zone. Consistent with previous studies,[10 15] we also found that a smaller optical zone is associated with greater changes in HOAs. One explanation for these similar results is that light passes through the area connecting the ablation zone and the transition zone under a smaller optical zone and larger pupil diameter, which increases the aberration and reduces the contrast of the retinal image. All of the above may be the causes of glare and halo encountered at night in patients with smaller ablation zones and larger pupil diameters. It is clear that a larger optical zone design prevents a significant increase in HOAs, which would in turn decrease visual quality.

In the present study, younger patients with high myopia were more likely to experience an increase in postoperative HOAs. This correlation has never been reported in previous studies and may be related to the corneal wound

Table 4 Multivariate analysis of contrast sensitivity (meaningful coefficient value

	Mesopic						Photopic					
	6.3	4.0	2.5	1.6	1.0	0.7	6.3	4.0	2.5	1.6	1.0	0.7
Refraction												
β value		–0.003***	–0.005***	–0.007***	–0.010*		–0.004**	–0.005**	–0.007**	–0.010**		
CCT												
β value									0.0005*			
Age												
β value						–0.028*						
Optical diameter												
β value	–0.015*											

*P<0.05.
**P<0.01.
***P<0.001.
β value=coefficient value.
CCT, central corneal thickness.

healing process after surgery. Previous studies showed that corneal wound healing was critical to the success of topography-guided or wavefront-guided excimer laser ablation to optimise visual performance.[16 17] Moreno-Barriuso *et al*'s study[12] reported that the presence of stromal opacities induced by the corneal wound healing process after refractive surgery caused a loss of corneal transparency and an increase of scattering. In addition, histological studies suggested that individual variation in the wound healing process was a major factor affecting refractive surgery outcomes. It is possible that proliferation of corneal stromal cells in young people is more active, which results in elevated degrees of tissue repair. Consequently, younger patients undergoing surface ablation procedures should be informed of the possibility of visual disturbances after surgery and should receive close follow-up postoperatively.

CS is another important indicator of visual quality. Previous studies revealed that in eyes undergoing PRK, CS was reduced at the early postoperative stage but gradually returned to preoperative levels after approximately 6–12 months.[18 19] A study by Ghaith and colleagues[20] showed that PRK significantly reduced CS and induced glare at all spatial frequencies at 1 month postoperatively. These effects seemed to persist over time at lower spatial frequencies, but there was a trend towards recovery at higher spatial frequencies at 6 months. Contrary to their reports, our investigation revealed that CS under both lighting and dim conditions was worse with higher preoperative refractive errors for long-term observation. In particular, the decrease in CS under mesopic conditions was greater than that under photopic conditions. Interestingly, preoperative refractive error was significantly associated with decreased CS values in both photopic and mesopic conditions. One explanation may be that in high myopes, the change in postoperative corneal asphericity resulting in light scattering from the tips of the radial scars and irregular astigmatism in or near the central clear zone may lead to a significant drop in CS function at medium to high spatial frequencies.[2] The present study also reveals that surgical factors, including the method of epithelial flap creation, optical zone and ablation depth, did not affect postoperative CS under either lighting condition. This may be because all selected cases had myopia of −6.00 D or more; the effect of high myopia correction on CS could be a completely distinct relationship. Therefore, further research is needed to verify the association between these surgical factors and CS in patients with differing levels of refractive error.

Increasing HOAs and decreasing CS are associated with poor visual quality in patients with high myopia. In our study, the method of epithelial flap creation had no effect on the HOAs or CS under mesopic and photopic conditions. The most significant factor was the ablation procedure. The relationship between age and HOAs require further study and confirmation. Nonetheless, our results identified the significance of surgical and patient factors on postoperative visual quality; these findings are clinically important for providers and patients alike in choosing the optimal procedure and predicting visual quality outcomes.

A limitation of the study is that the participants were recruited from Shanghai only for the sake of patients' convenience, which might lead to limited external validity. In addition, although the influence of corneal refractive surgery on postoperative CS of patients with high myopia is mostly concentrated in the middle frequency band, a larger range of target frequencies should be evaluated in the future for a more comprehensive assessment.

In conclusion, for patients with high myopia, a larger optical zone diameter design is recommended to achieve better postoperative visual quality in advanced surface ablation. Patient age and preoperative refraction may also predict postoperative visual quality.

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