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Corneal aberrations after small-incision lenticule extraction versus *Q* value-guided laser-assisted in situ keratomileusis

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Abstract

Previous studies compared ocular aberration and visual quality after small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK), but anterior corneal surface aberration properties are poorly known. This study aimed to compare the changes in anterior corneal surface aberration after SMILE versus Q-FS-LASIK.

This was a prospective, observational cohort study. Patients with myopia and myopic astigmatism underwent SMILE or Q-FS-LASIK at Hangzhou MSK Eye Hospital between January 2015 and November 2015. High order aberration (HOA), primary spherical aberration (PSA), primary coma aberration (PCA), primary vertical coma aberration (PVCA), and primary horizontal coma aberration (PHCA) were assessed using pre- and postoperative Sirius scanning.

Both surgery were associated with significant increases in postoperative HOA, PSA, and PCA (both groups $P < .01$). In the SMILE group ($n = 51$), the variations in HOA, PSA, and PCA were no longer significant after postoperative week 2 ($P > .05$). In the Q-FS-LASIK group ($n = 73$), the variations in HOA and PCA were no longer significant after postoperative day 1 ($P > .05$). In the SMILE group, the 3-month changes in PCA were not correlated with spherical, spherical equivalent (SE), and spherical plus cylinder measurements. Cylinder measurements were not correlated with HOA, PSA, and PCA. In the Q-FS-LASIK group, the 3-month changes in PCA correlated with spherical, SE, and spherical plus cylinder measurements.

Both SMILE and Q-FS-LASIK resulted in an increase in HOA, PSA, and PCA at postoperative day 1, but Q-FS-LASIK introduced lower HOA and showed better stability. Spherical measurement was related to PSA.

Abbreviations: ANOVA = analysis of variance, HOA = high order aberration, LogMAR = logarithms of the minimum angles of resolution, PCA = primary coma aberration, PHCA = primary horizontal coma aberration, PSA = primary spherical aberration, PVCA = primary vertical coma aberration, Q-FS-LASIK = *Q* value-guided femtosecond laser-assisted in situ keratomileusis, SD = standard deviation, SE = spherical equivalent, SMILE = small-incision lenticule extraction.

Keywords: anterior corneal surface aberration, femtosecond laser-assisted in situ keratomileusis, *Q* value, small-incision lenticule extraction

What Was Known/What This Paper Adds

What Was Known

- Small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK) are used for visual corrections, but anterior corneal surface aberration properties are poorly known.

What This Paper Adds

- No previous study examined the anterior corneal surface aberration properties after SMILE or Q-FS-LASIK.
- The results showed that both methods increased high order aberration, primary spherical aberration, and primary coma aberration, but high order aberration was lower with Q-FS-LASIK and stability was better.

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Statement of ethics: The study was approved by the ethics committee of Hangzhou MSK Eye Hospital. All participants were informed about the risks and benefits of both procedures and provided written informed consent.

The authors declare that they have no conflict of interest.

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1. Introduction

With the rapid and extensive development of modern corneal refractive surgery, new surgical procedures are being developed. *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK) is a safe and popular surgical procedure in which lower spherical aberration is introduced.[1–4] Changing the *Q* value of the corneal anterior surface will result in a significant change in spherical aberration,[5] which will further affect visual quality.[6] Therefore, it is hopeful to reshape the anterior surface of the cornea to solve the problem of low-order refraction and at the same time reduce the spherical aberration of the cornea and the whole eye, improving visual quality.[7] Many factors (such as uneven ablation, eccentric ablation, biased replacement of corneal flap, and uneven corneal tissue healing) can affect the actual corneal *Q* value after corneal refractive surgery. Therefore, using the

Q value to guide LASIK treatment is of clinical value.[1–4] Nevertheless, some complications may occur, mainly related to the corneal flap and tissue ablation. These complications may include high order aberrations (HOA), dry eyes, halos, and flap complications (such as displaced flap, folds in the flap, slipped flap, and flap interface particles).[8–11]

Small-incision lenticular extraction (SMILE) is a new flapless surgical procedure that avoids flap-related complications.[12,13] Although similar to Q-FS-LASIK, SMILE uses a single femtosecond laser referenced to the corneal surface to create the lenticule, which will be removed manually.[14–17] The advantages are minimal invasiveness and minimal collateral tissue damage. Data about corneal wound healing and inflammatory response after SMILE are limited, but a 5-year follow-up study suggests long-term stable outcomes.[18]

Both procedures have performed well in studies in all measures of safety, efficacy, and predictability.[13,19–22] Although some previous studies have compared ocular aberration and visual quality after SMILE and LASIK, anterior corneal surface aberration properties can evaluate the effect of refractive surgery on corneal morphology more accurately and more intuitively and then reflect the influence of refractive surgery on visual quality.

Therefore, the aim of this study was to increase anterior corneal surface aberration parameters to provide a better frame of reference. In addition, and different from earlier research, we used Q-FS-LASIK.

2. Subjects and methods

2.1. Study design and patients

This was a prospective, observational cohort study (ChiCTR-ORN-17012819). Consecutive patients who met the eligibility criteria and had myopia or myopia astigmatism underwent either SMILE or Q-FS-LASIK at Hangzhou MSK Eye Hospital between January 2015 and November 2015.

The inclusion criteria were:

(1) myopia (sphere plus cylinder measurement of <–10.00 D);
(2) myopia astigmatism (cylinder measurement of <–5.00 D with or without astigmatism –5.00 D to 0 D).

The exclusion criteria were:

(1) history of corneal refractory surgery;
(2) with nebula, macula, leukoma, or other corneal opacities;
(3) with significantly irregular astigmatism of the cornea; or
(4) with contraindications to corneal refractive surgery.

The study was approved by the ethics committee of Hangzhou MSK Eye Hospital. All participants were informed about the risks and benefits of both procedures and provided written informed consent.

2.2. Preoperative assessments

Preoperative assessments included a complete medical and ophthalmological history and a thorough ocular examination, including measurements of uncorrected visual acuity, manifest refraction, best corrected visual acuity, cycloplegic refraction, slit-lamp examination, axial length, gonioscopy, funduscopy, and intraocular pressure. In addition, corneal topography was obtained using a tomography instrument (Sirius; CSO, Florence, Italy).

2.3. Measurement of anterior corneal surface aberration

HOA, primary spherical aberration (PSA), primary coma aberration (PCA), primary vertical coma aberration (PVCA), and primary horizontal coma aberration (PHCA)[23] of the central 5-mm region of the anterior corneal surface were determined using the Sirius tomography instrument. The aberration values with high quality, high repeatability, and high centrality was used for statistical analysis. High quality was defined as a device signal classification based on the composite index of Scheimpflug and keratoscopy images and fixation states. High repeatability was defined as a tangential anterior corneal curvature difference <0.5 D, and anterior and posterior elevate difference <5 μm. High centrality was defined as a device signal percentage, based on keratoscopy image, of >90%. The evaluators were blind to grouping.

2.4. Surgical procedures

The patients selected either SMILE or Q-FS-LASIK after thorough discussion with the ophthalmologist. All surgical procedures were performed in the supine position by the same surgeon with 23 years of experiences in corneal refractive surgery. Routine disinfection and surface anesthesia were performed before surgery.

For the SMILE group, during the procedure, a cap of 120 μm, a single side-cut incision with a circumferential length of 2.0 mm at the 120° position, a side-cut angle of 90°, a 3 × 3-μm point spacing of the lens surface, a 2.5 × 2.5-μm point spacing of the lens side, and a 2 × 2-μm point spacing of the side cut were created. After a femtosecond laser scan (VisuMax; Carl Zeiss, Oberkochen, Germany) with a frequency of 500 kHz, both the front and back lens surfaces were separated using a micro-separator. The free lens was then removed using micro-forceps.

Q-FS-LASIK was performed using FS200 femtosecond and EX500 excimer lasers (both from Alcon, Fort Worth, TX). During flap creation, settings were adjusted to achieve a thickness of 100 μm, side-cut angle of 90°, 8 × 8-μm point spacing of the flap, and 5 × 3-μm point spacing of the side cut. After a femtosecond laser scan, the corneal stroma was ablated with a 0.2 negative adjustment of the *Q* value (6 mm).

2.5. Postoperative care and follow-up

After surgery, fluorometholone 0.1% and bromfenac sodium 0.1% were immediately administered topically. Levofloxacin 0.3% (Cravit; Santen, Osaka, Japan) was administered topically four times a day for 1 week. Fluorometholone 0.1% was administered topically six times a day for 3 weeks, after which the frequency was steadily tapered. Patients were followed, and measurements using the Sirius system were repeated 1 day, 2 weeks, 1 month, and 3 months after surgery.

2.6. Statistical analysis

Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were expressed as frequency (percentage). The Student *t* test was used to compare baseline characteristics between the two groups. For the purpose of statistical comparisons, visual acuity measurements were converted to logarithms of the minimum angles of resolution (LogMAR) units. Bivariate repeated measures analysis of variance (ANOVA) was used to assess corneal aberration parameters at different examination points within and between each group. Pre- and post-operative corneal aberration parameters were confirmed to not meet the Mauchly's test of sphericity (Greenhouse-Geisser <0.7); therefore, the Bonferroni test was used for multivariate statistical analysis and comparisons between each group, after degree of freedom Greenhouse-Geisser correction. Pearson correlation coefficients were calculated to evaluate correlations between 3-month changes in corneal aberration parameters and multiple variables, including spherical, cylinder, spherical equivalent (SE), and spherical plus cylinder measurements. All statistical analyses were performed using SPSS 19.0 (IBM, Armonk, NY). Two-sided P values of <.05 were considered statistically significant.

3. Results

3.1. Baseline and clinical characteristics

The study enrolled 124 patients (240 eyes); there were 51 patients in the SMILE group and 73 in the Q-FS-LASIK group. No patient was lost to follow-up and no data was missing for the 3-month postoperative period. Baseline characteristics are summarized in Table 1, with no significant differences (all $P<.05$). All operations were successful and no serious complications or iatrogenic corneal ectasia were seen during the 3-month postoperative period. There were 16 eyes in the SMILE group and 25 eyes in the Q-FS-LASIK group with symptoms of dry eye. All cases were successfully managed using artificial tears. There were 18 eyes in the SMILE group and 30 eyes in the Q-FS-LASIK group with symptoms of glare, which relieved by themselves with time.

3.2. Corneal aberration

The corneal aberration parameters are summarized in Table 2. The changes in HOA, PSA, PC, PVCA, and PHCA following SMILE and Q-FS-LASIK are shown in Figures 1–5, respectively.

Table 1

Baseline characteristics.

Variable	SMILE (n=51)	Q-FS-LASIK (n=73)	P
Age (years)	24.26±6.14	26.42±7.32	.287
Male, *n* (%)	21 (41.2)	31 (42.5)	.886
Axial length (mm)	25.92±0.90	25.70±0.97	.352
Intraocular pressure (mm Hg)	15.00±2.27	15.47±2.64	.067
Spherical (D)	−5.18±1.90	−5.68±2.29	.099
Cylinder (D)	−0.86±0.69	−1.10±0.87	.382
Best corrected visual acuity (LogMAR)	−0.05±0.05	−0.04±0.05	.452
Uncorrected visual acuity (LogMAR)	1.29±0.30	1.35±0.27	.849
Corneal thickness (μm)	551.68±26.01	537.22±26.88	.432
Optical zone (mm)	6.40±0.16	6.38±0.15	.496

LogMAR=logarithms of the minimum angles of resolution, Q-FS-LASIK=*Q* value-guided femtosecond laser-assisted in situ keratomileusis, SMILE=small-incision lenticule extraction.

In the SMILE group, variations in HOA, PSA, and the PCA were statistically significant (all $P<.001$). HOA, PSA, and PCA at each postoperative time point were statistically significantly higher than the preoperative values (all $P<.001$), but after the 2-week postoperative time point, the differences between each postoperative time point were not significant.

In the Q-FS-LASIK group, the variations in HOA, PSA, and PCA were statistically significant (all $P<.001$). HOA, PSA, and PCA at each postoperative time point were statistically significantly higher than the preoperative value ($P<.001$), but after the first postoperative day, HOA and PCA differences between each postoperative time point was not significant. PSA was statistically significant between postoperative day 1 and postoperative months 1 and 3. There were no statistically significant differences between the other postoperative time points.

The differences in HOA and PSA between the SMILE and Q-FS-LASIK groups were statistically significant ($P=.043$ and $P<.001$, respectively). The differences in PCA, PVCA, and PHCA between the SMILE and Q-FS-LASIK groups were not statistically significant ($P=.201$, $P=.097$, and $P=.736$, respectively).

Table 2

Corneal aberration parameters.

Parameter	Preoperative	Postoperative 1 day	Postoperative 2 weeks	Postoperative 1 month	Postoperative 3 months	P
HOA (μm)						
SMILE	0.24±0.06	0.39±0.23*	0.44±0.15*	0.44±0.17*	0.46±0.18*,#	<.001
Q-FS-LASIK	0.25±0.08	0.35±0.13*	0.38±0.13*	0.38±0.11*	0.41±0.25*	<.001
PSA (μm)						
SMILE	0.10±0.04	0.19±0.10*	0.21±0.09*	0.22±0.09*	0.22±0.08*,#	<.001
Q-FS-LASIK	0.09±0.04	0.12±0.12	0.16±0.10*,#	0.15±0.09*,#	0.15±0.13*	<.001
PCA (μm)						
SMILE	0.14±0.06	0.17±0.09*	0.21±0.09*,#	0.24±0.11*,#,&	0.25±0.11*,#,&	<.001
Q-FS-LASIK	0.12±0.07	0.18±0.11*	0.20±0.10*	0.21±0.09*	0.23±0.19*	<.001
PVCA (μm)						
SMILE	0.03±0.11	−0.06±0.14*	−0.12±0.15*,#	−0.14±0.17*,#	−0.14±0.17*,#	<.001
Q-FS-LASIK	0.04±0.10	−0.02±0.15*	−0.08±0.14*,#	−0.07±0.14*,#	−0.12±0.48*	.004
PHCA (μm)						
SMILE	0.01±0.09	0.00±0.12	0.00±0.14	−0.01±0.16	0.00±0.16	.895
Q-FS-LASIK	0.00±0.07	−0.02±0.10	0.01±0.12	0.02±0.13#	0.01±0.13	.012

HOA=high order aberration, PCA=primary coma aberration, PHCA=primary horizontal coma aberration, PSA=primary spherical aberration, PVCA=primary vertical coma aberration, Q-FS-LASIK=*Q* value-guided femtosecond laser-assisted in situ keratomileusis, SMILE=small-incision lenticule extraction.

* $P<.05$ vs preoperative.

\# $P<.05$ vs postoperative 1 day.

& $P<.05$ vs postoperative 2 weeks.

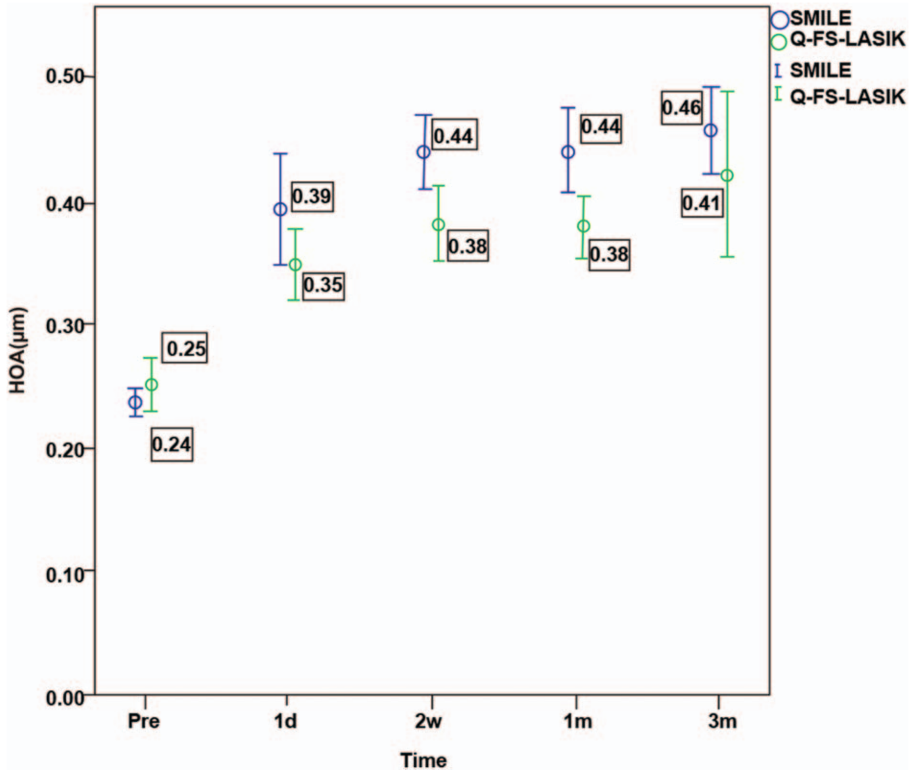

Figure 1. High order aberration (HOA) changes following small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK). Bars represent standard deviations. The differences in HOA between the SMILE and Q-FS-LASIK groups were statistically significant ($P = .043$).

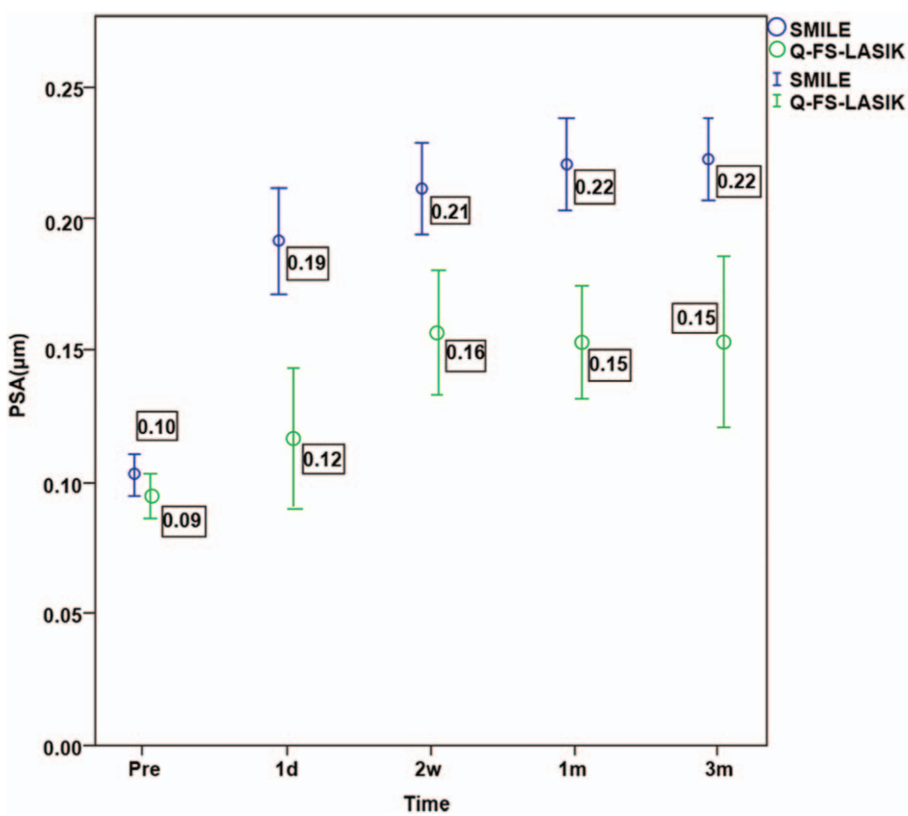

Figure 2. Primary spherical aberration (PSA) changes following small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK). Bars represent standard deviations. The differences in PSA between the SMILE and Q-FS-LASIK groups were statistically significant ($P < .001$).

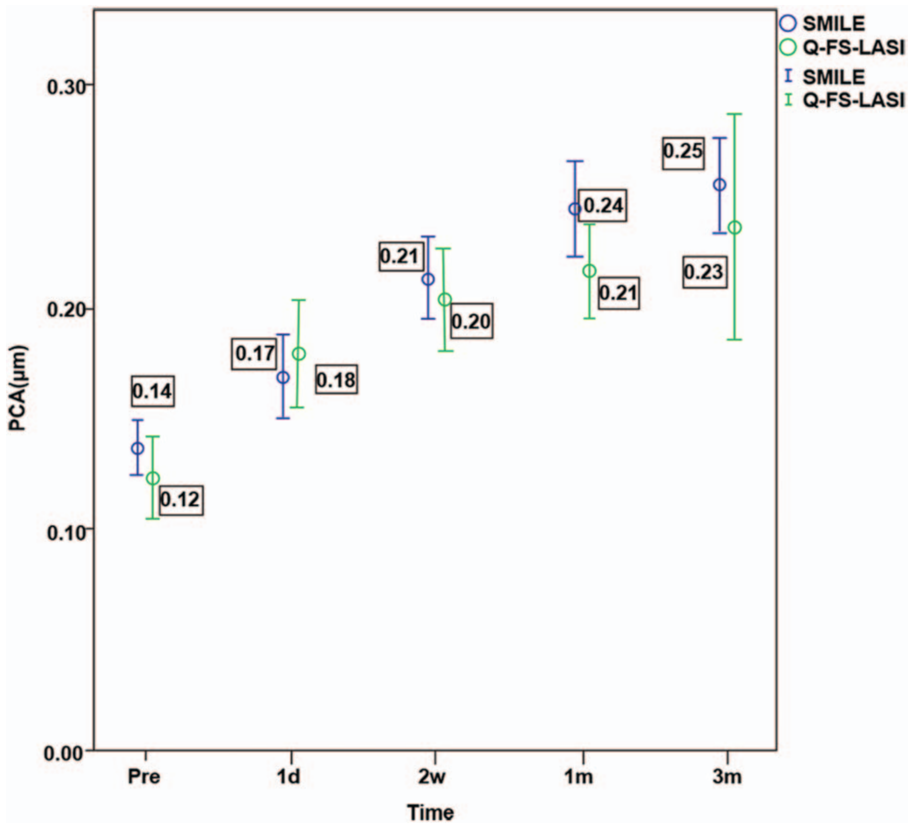

Figure 3. Primary coma aberration (PCA) changes following small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK). Bars represent standard deviations. The differences in PCA between the SMILE and Q-FS-LASIK groups were not statistically significant ($P > .05$).

3.3. Correlations

In both groups, the 3-month changes in HOA and PSA correlated with spherical, SE, and spherical plus cylinder measurements. In the SMILE group, the 3-month changes in PCA were not correlated with spherical, SE, and spherical plus cylinder measurements. Cylinder measurements were not correlated with HOA, PSA, and PCA. In the Q-FS-LASIK group, the 3-month changes in PCA correlated with spherical, SE, and spherical plus cylinder measurements. Cylinder measurements correlated with PSA (Table 3).

4. Discussion

Although some previous studies have compared ocular aberration and visual quality after SMILE and Q-FS-LASIK,[12,13,19,20] anterior corneal surface aberration properties are poorly known. Therefore, the present study aimed to compare the changes in anterior corneal surface aberration after SMILE versus Q-FS-LASIK. The results showed that both SMILE and Q-FS-LASIK resulted in an increase in HOA, PSA, and PCA at postoperative day 1, but Q-FS-LASIK introduced lower HOA and showed better stability. Spherical measurement was related to PSA.

A perfect refractive system is one through which parallel light can pass and in which a wavefront will become an ideal spherical wavefront. The human eye is not a perfect refractive system; therefore, differences between actual and ideal wavefronts will appear. This difference is called the wavefront aberration[24] and is an important index used to evaluate irregular corneal morphology and visual quality.[25] There are two main sources of wavefront aberrations in human eyes: the cornea and the lens.[26] During the design of the present study, several reasons led us to choose corneal anterior surface aberrations to evaluate the effect of refractive surgery on corneal morphology and visual quality. First, corneal anterior surface aberrations account for nearly 80% of all aberrations of the eye and significantly influence visual quality.[26,27] Second, corneal refractive surgery mainly modifies the corneal anterior surface shape and does not modify the lens shape. Third, compared with total aberration of the eye, corneal anterior surface aberrations are less disturbed by tears, pupil size, pupillary center position, and kappa angle.[28] Therefore, corneal anterior surface aberrations have better repeatability and accuracy. Fourth, although low order aberrations have greater impact, they can be adjusted and eliminated with a nomogram, according to surgeon's experience. Therefore, the reference value of low order aberrations is not high, and does not match the statistical analyses. Finally, in the Zernike high order aberration chart, relatively low order primary coma and relatively central axial position primary spherical aberrations have the most obvious influence on visual quality.[29,30] Therefore, by analyzing the changes in HOA, PSA, PCA, PVCA, and PHCA of the corneal anterior surface, the effects of refractive surgery on corneal morphology and visual quality can be more accurately and intuitively evaluated.

The results of this study suggest that high order wavefront aberrations were increased by postoperative day 1 following

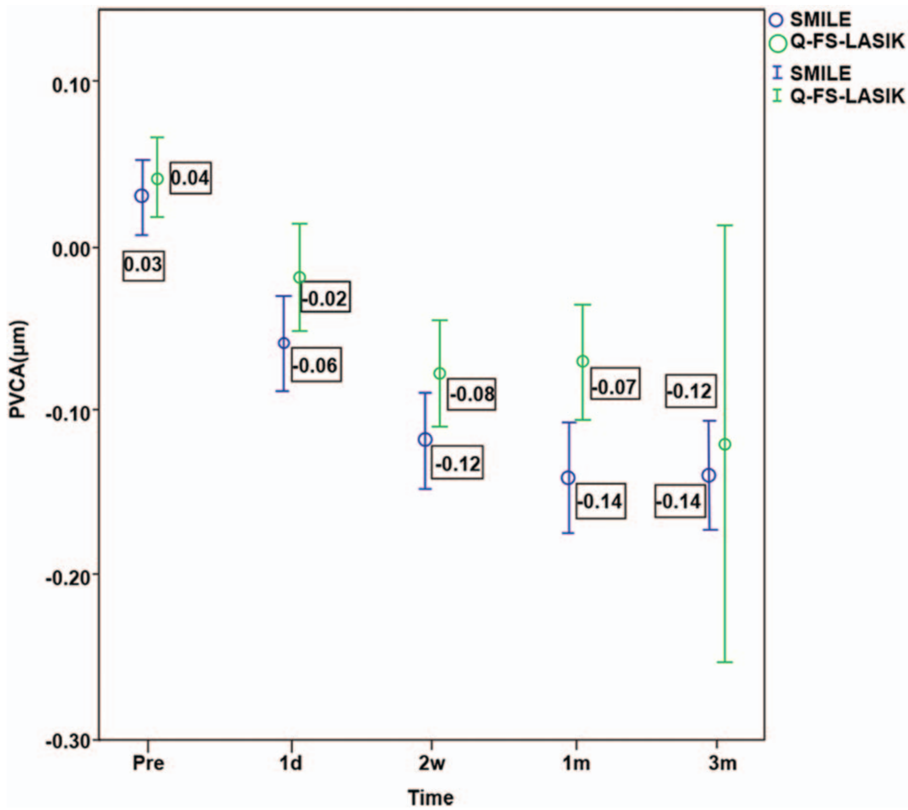

Figure 4. Primary vertical coma aberration (PVCA) changes following small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK). Bars represent standard deviations. The differences in PVCA between the SMILE and Q-FS-LASIK groups were not statistically significant ($P > .05$).

either SMILE or Q-FS-LASIK. This shows that both procedures affected regular corneal morphology and visual quality, especially in highly spherical patients, as previously observed.[31] Consistent with other studies, greater high order wavefront aberrations increased the relative risk of symptoms.[32,33] A previous study by our group showed that the SMILE and Q-FS-LASIK resulted in similar eye biomechanics.[34] Therefore, eventual differences between the two methods are more likely due to differences in aberrations and eye inflammation. Nevertheless, a previous study showed that preoperatively screening for high order aberrations could help patient management.[35] Additional studies are necessary to optimize patient management.

In the present study, we also found that high order wavefront aberrations were very stable after 2 weeks following either SMILE or Q-FS-LASIK. Furthermore, Q-FS-LASIK achieved stability earlier and introduced less high order wavefront aberration. This suggests that Q-FS-LASIK leads to better stability and better visual quality. Compared with the one-step separation of corneal stroma using Q-FS-LASIK, the two-step corneal stroma separation using SMILE causes more obvious corneal irritation symptoms.[19] Therefore, the cornea needs a relatively longer time to completely heal and to allow edema to subside. During SMILE surgery, removal of the lens results in negative capsular pressure on which additional traction on the anterior and posterior stroma surfaces may affect the primary lamellar structure of the cornea. If only the size of the side cut is considered, Q-FS-LASIK's larger side cut may introduce higher wavefront high order aberrations, but after removing a large number of corneal stroma, compared to corneal cap of SMILE, the corneal flap of Q-FS-LASIK should have a better fit with the remaining corneal stroma. Compared to the femtosecond laser, the ablation done by the excimer laser can yield a smoother surface, which needs a relatively shorter repair time.[36] Finally, under the same diopter, SMILE consumes more corneal tissue, which makes the change of corneal shape more obvious because SMILE needs to remove a layer of ineffective stroma. A previous study showed that compared with Q-FS-LASIK, SMILE induced less total HOA, but induced more horizontal and vertical coma.[37]

Our study had several limitations. First, the sample size was relatively small, from a single center, and the patients were selected based on specific criteria, introducing some selection and information biases. Second, other surgical procedures were not considered as independent factors or control groups. Third, a selection bias was at least partially offset by having each patient select the surgical procedure, however it could not be completely ruled out. In addition, only one surgeon performed all procedures, which is a selection bias. Finally, the study follow-up was limited to 3 months, which does not rule out the possibility of subsequent regression. Further studies are needed to elucidate long-term aberration changes.

In conclusion, both SMILE and Q-FS-LASIK were associated with increases in wavefront high order aberrations. Q-FS-LASIK introduced lower high order aberrations, maintained better visual stability, and achieved better visual quality.

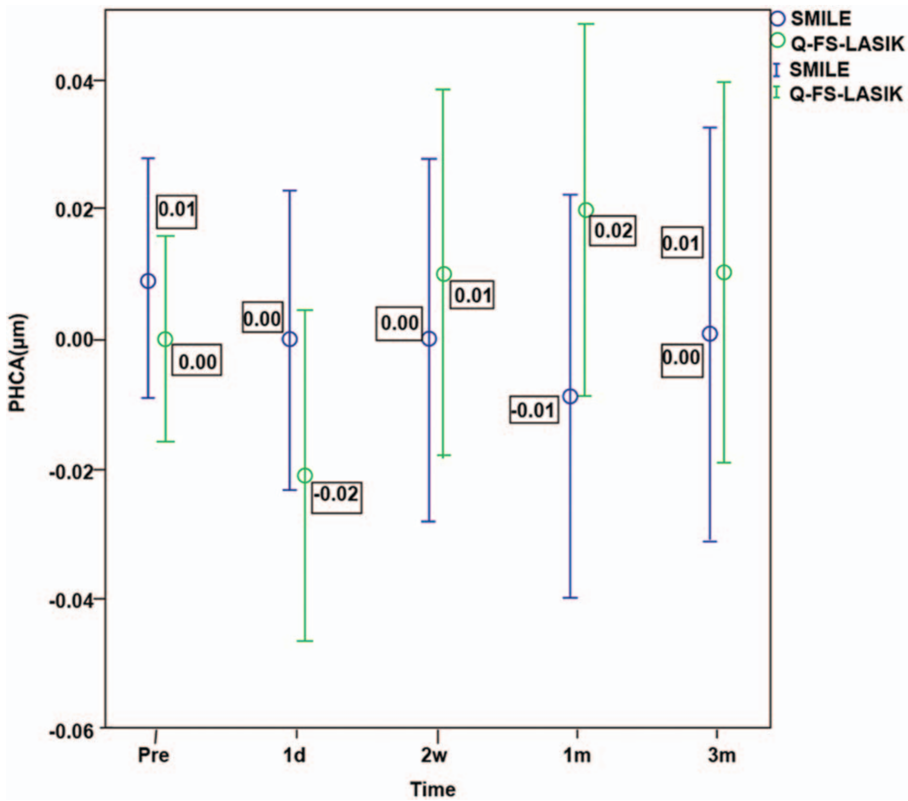

Figure 5. Primary horizontal coma aberration (PHCA) changes following small-incision lenticule extraction (SMILE) and *Q* value-guided femtosecond laser-assisted in situ keratomileusis (Q-FS-LASIK). Bars represent standard deviations. The differences in PHCA between the SMILE and Q-FS-LASIK groups were not statistically significant ($P > .05$).

Table 3

Correlation analysis.

Parameters	Spherical		Cylinder		Spherical equivalent		Spherical plus cylinder	
	R	*P*	*R*	*P*	*R*	*P*	*R*	*P*
SMILE								
High order aberration	−0.340	.001	−0.049	.625	−0.337	.001	−0.326	.001
Primary spherical aberration	−0.463	<.001	−0.051	.616	−0.457	<.001	−0.438	<.001
Primary coma aberration	−0.324	.001	−0.233	.020	−0.354	<.001	−0.372	<.001
Primary vertical coma aberration	0.285	.004	0.290	.003	0.326	.001	0.355	<.001
Primary horizontal coma aberration	−0.030	.766	−0.180	.073	−0.061	.549	−0.087	.390
Q-FS-LASIK								
High order aberration	−0.357	<.001	0.130	.126	−0.325	<.001	−0.285	.001
Primary spherical aberration	−0.420	<.001	0.140	.098	−0.384	<.001	−0.339	<.001
Primary coma aberration	−0.216	.010	0.150	.076	−0.183	.031	−0.147	.084
Primary vertical coma aberration	0.024	.782	−0.020	.816	0.019	.822	0.015	.862
Primary horizontal coma aberration	−0.008	.927	0.011	.899	−0.006	.948	−0.003	.968

SMILE = small-incision lenticule extraction, Q-FS-LASIK = *Q* value-guided femtosecond laser-assisted in situ keratomileusis.

Author contributions

Conceptualization: Jun Zhang.
Data curation: Li Zheng, Xia Zhao, Yi Sun.
Formal analysis: Xia Zhao, Yi Sun.
Writing – original draft: Jun Zhang, Li Zheng, Wei Feng, Minhui Yuan.
Writing – review & editing: Wei Feng, Minhui Yuan.

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