

# Prospective, Randomized, Contralateral Eye Comparison of Functional Optical Zone, and Visual Quality After SMILE and FS-LASIK for High Myopia

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**Purpose:** To compare the functional optical zone (FOZ) and visual quality after small-incision lenticule extraction (SMILE) and femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) in correcting high myopia.

**Methods:** Ninety-two eyes of 46 high myopic patients with the same programmed optical zone (POZ) received SMILE in one eye and FS-LASIK in the contralateral eye. FOZ was calculated using a refractive power method. The decentration, visual outcomes, wavefront aberrations, contrast sensitivity, and quality of vision (QoV) questionnaire were analyzed at 6 months postoperatively.

**Results:** The postoperative visual and refractive outcomes were comparable between SMILE and FS-LASIK. The FOZ for SMILE ( $5.62 \pm 0.31$  mm) was larger than for FS-LASIK ( $5.35 \pm 0.28$  mm;  $P < 0.001$ ). Moreover, the total decentration for SMILE ( $0.29 \pm 0.14$  mm) was greater than in FS-LASIK ( $0.22 \pm 0.11$  mm;  $P < 0.001$ ). The induced change in spherical aberration was less for SMILE than for FS-LASIK ( $P < 0.001$ ). There was better contrast sensitivity under the mesopic condition with glare for SMILE than for FS-LASIK ( $P = 0.024$ ). However, no significant difference was found in QoV scores between the two groups.

**Conclusions:** SMILE created a larger FOZ and greater decentration than FS-LASIK when the same POZ was designed in high myopia. Objective and subjective visual symptoms were comparable between SMILE and FS-LASIK.

**Translational Relevance:** The differences in FOZ and decentration between SMILE and FS-LASIK have little effect on vision outcomes. Surgeons should consider the FOZ and decentration in surgical options in high myopia.

## Introduction

Small-incision lenticule extraction (SMILE) and femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) have become the most commonly

performed laser refractive surgical techniques worldwide in recent decades. Compared with FS-LASIK, SMILE is flapless and requires only a femtosecond laser to create a minor corneal incision, which theoretically causes less damage to the ocular surface and maintains better corneal biomechanics.<sup>1,2</sup> Many

studies have demonstrated that SMILE has better predictability and induces smaller changes in higher order ocular aberrations (HOAs) than FS-LASIK.<sup>3,4</sup> However, most of these studies were conducted on patients with low and moderate myopia.<sup>3,5</sup> Moreover, the corneal thickness of high myopic patients is limited in corneal refractive surgery. Hence, it is difficult for refractive surgeons to select an appropriate surgical technique that suits high myopic patients.

The programmed optical zone (POZ) is a crucial designed parameter that describes the corneal ablation area in corneal refractive surgery. However, the functional optical zone (FOZ), which provides optimal vision for patients postoperatively, often differs from the POZ.<sup>6</sup> A larger FOZ provides better postoperative visual quality and induces fewer HOAs<sup>7</sup>; however, ablation of more corneal tissue is required to achieve this. The diameter of the FOZ is smaller than that of the POZ in both the SMILE and LASIK procedures due to the postoperative changes in the corneal oblate, corneal healing responses, and laser energy losses around the cutting zone.<sup>8-10</sup> In addition, a smaller FOZ could cause several visual quality problems, such as glare, halos, and ghosting, especially in the patients with high myopia requiring greater corneal ablation. Moreover, more corneal stroma must be cut to create a larger OZ. It is unclear whether the greater corneal alteration would cause a further reduction of the FOZ in cases of high myopia.

It is clinically important to clarify the difference in FOZ and the visual quality between SMILE and FS-LASIK in high myopia, which might serve as a vital reference for surgeons when selecting a suitable surgical option. Few studies have compared the FOZ of high myopic eyes treated with SMILE and FS-LASIK. Moreover, a previous study focused on the comparison of different patients,<sup>9</sup> which could be prone to inter-patient variability biases. Therefore, we compared the FOZ and visual quality in the same high myopic patient who underwent SMILE in one eye and FS-LASIK in the contralateral eye in this prospective study. A paired-eye investigation was conducted to eliminate individual bias, as surgical biological responses should be similar in the same individual. FOZ and the subjective and objective postoperative visual quality were evaluated to explore which refractive correction procedure provides greater benefit for patients with high myopia.

## Patients and Methods

### Patients

In this prospective, randomized, paired-eye study, we recruited 92 eyes of 46 patients between

August 2019 and September 2020 at the Zhong Shan Ophthalmic Center, Sun Yat-sen University. Each patient was randomized to undergo SMILE in one eye and FS-LASIK in the contralateral eyes using the coin-flip method. Inclusion criteria were as follows: between 18 and 36 years of age, stable refraction for more than 2 years, corrected distance visual acuity (CDVA)  $\geq$  20/25, myopia greater than  $-6$  diopters (D), differences in spherical equivalent (SE) and cylinder between the paired eyes  $\leq$  1 D, and a minimum theoretical residual stromal thickness exceeding 280  $\mu$ m. Exclusion criteria were as follows: a history of ocular trauma or surgery, active ocular or systemic disease, and keratoconus or suspicious corneal topography.

Preoperative examinations included CDVA and uncorrected distance visual acuity (UDVA), manifest refraction, slit-lamp examination, dilated fundus examination, pupil diameters, central corneal thickness (CCT) using ultrasonic pachymetry (Compact Touch STS; Quantel Medical, Rockwall, TX), and a Scheimpflug camera (Pentacam HR; Oculus Optikgeräte GmbH, Wetzlar, Germany). The patients were followed up at 1 week and at 1, 3, and 6 months after surgery. The study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the ethics board of the Zhongshan Ophthalmic Center of Sun Yat-sen University (2020KYPJ159). Informed written consent was obtained from all participants.

### Surgical Technique

All surgical procedures were performed by an experienced surgeon (KMY) on the same day. The VisuMax 500-kHz femtosecond laser (Carl Zeiss Meditec, Jena, Germany) was used for SMILE treatments and FS-LASIK flap creations. In the SMILE procedure, the intended cap thickness was 110  $\mu$ m, and the cap diameter ranged from 7.0 to 7.7 mm. The lenticule diameter was programmed between 6.0 and 6.8 mm. A transition zone was set at 0.1 mm when correcting the cylinder. Surgical procedures were performed using a coaxially sighted corneal light reflex (CSCLR) centration method. A 2-mm incision was cut at the 130° position for subsequent lenticule dissection and extraction. After the scanning procedure, the lenticule was dissected and removed through the small incision, using a pair of spatulas.

In the FS-LASIK procedure, the intended flap thickness was 95  $\mu$ m and the flap diameter was varied from 8.1 to 8.5 mm with a superior hinge position. Surgical procedures were centered on the CSCLR with pupil tracking enabled. After the flap was lifted, ablation of the stromal bed was performed using the AMARIS 750S excimer laser (Schwind

eye-tech-solutions, Kleinostheim, Germany). Excimer ablation was subsequently performed with the same OZ as the paired eye in the SMILE procedure. The transition zone was set from 1.45 to 2.00 mm. The POZ in both the SMILE and FS-LASIK procedures was designed after considering the pupil diameter and the corneal residual stroma thickness.

The postoperative regimen included the administration of topical 0.5% levofloxacin eyedrops (Tarivid; Santen Pharmaceutical, Osaka, Japan) and 0.25% tobramycin and dexamethasone eyedrops (Maxidex; Alcon Laboratories, Ft. Worth, TX) four times per day for 1 week. Subsequently, 0.1% fluorometholone eyedrops (Tarivid) were given four times per day for 3 weeks. Preservative-free lacrimal substitutes were used as needed.

### Analysis of the FOZ

The FOZ was measured using an Oculus Pentacam HR preoperatively and at 1 week and 1, 3, and 6 months postoperatively. The patient was examined in a dark room. Only readings deemed by the system to be of acceptable quality were used in the analysis. We measured the FOZ based on the corneal vertex and calculated a circular zone where the total corneal refractive power (TCRP) did not exceed at the central 4 mm of the cornea by more than 0.5 D.<sup>6,11</sup> Practically speaking, the functional vision showing visual acuity of 20/32 was usually created by a 0.5-D defocus.<sup>6,12</sup>

### Measurement of Decentration

The tangential curvature difference maps were constructed using an Oculus Pentacam HR preoperatively and 6 months postoperatively. The method used for investigating the accuracy of treatment centration in this study was similar to that used in a previous study.<sup>13</sup> The optical zone was defined on the tangential difference map as the region where the difference was equal to zero, and it was regarded as the cutting boundary. The best-fitting circle was superimposed on the tangential difference map with reference to the corneal vertex. The horizontal and vertical coordinates of the centration offset between the center of the optical zone and the corneal vertex were measured at the minimal unit of increment of 0.05 mm.

### Wavefront Aberrations Measurement

Corneal wavefront aberrations were measured using a Scheimpflug camera (Oculus Pentacam HR) in a dark environment before surgery and at 6 months after surgery. Only readings deemed by the system to be of acceptable quality were used in the analysis. Zernike

polynomials were set to analyze the total cornea with a standardized diameter of 5 mm. The root mean square (RMS) values of the coma and total corneal HOAs were calculated. Four kinds of aberrations were analyzed because of their clinical importance: spherical aberration (SA), vertical coma, horizontal coma, and total HOAs.<sup>14</sup>

### Contrast Sensitivity Measurement

The contrast sensitivities under different lighting conditions (mesopic, mesopic with glare, photopic, and photopic with glare) were measured using a CSV-1000E chart (VectorVision, Greenville, OH) preoperatively and at 6 months postoperatively. Four spatial frequencies (3, 6, 12, and 18 cycles/degree) were measured under the four conditions. Under best spectacle-corrected visual acuity, all patients were asked to indicate for each column whether the top or bottom patch showed grating at a viewing distance of 2.5 meters. The contrast level of the last correct response was used as the contrast threshold in a logarithmic scale. The area under the log contrast sensitivity function (AULCSF) was measured with a method described previously.<sup>15</sup>

### Patient-Reported Quality of Vision

The patients were asked to complete the Quality of Vision (QoV) questionnaire 6 months postoperatively. The questionnaire developed by McAlinden et al.<sup>16</sup> encompasses 10 different categories of visual disturbance: glare, haloes, starbursts, hazy vision, blurred vision, distortion, double or multiple images, vision fluctuation, focusing difficulty, and difficulty judging distance/depth perception. The questionnaire evaluated the patient's QoV in terms of symptom frequency (never, 0; occasionally, 1; quite often, 2; very often, 3), severity (not at all, 0; mild, 1; moderate, 2; severe, 3), and bothersome (not at all, 0; a little, 1; quite, 2; very, 3). The questionnaire was translated into Chinese for better understanding among the participants.

### Sample Size Calculation

The sample size was calculated by PASS 11 (NCSS Statistical Software, Kaysville, UT). As has been done in previous studies,<sup>9,17</sup> the difference in the FOZ between SMILE and FS-LASIK was set to 0.15, the standard deviation was set to 0.3, the power value was set to 0.9, and alpha was set to 0.05. A required sample size of 44 subjects was calculated, and, considering the loss to follow-up rate, this study was designed to include 46 patients.

## Statistical Analysis

All statistical analyses were performed using SPSS Statistics 25.0 (IBM, Armonk, NY) and Prism 7.0 for Windows (GraphPad Software, La Jolla, CA). Mean  $\pm$  standard deviation was used for quantitative variables. Data were tested for normality using the Shapiro–Wilk test. Group comparisons for normally distributed data were made using the paired *t*-test. The Wilcoxon signed-rank tests were used for non-parametric data. Spearman's rank correlation test was used to analyze the relationship between the decentration and the induced changes in aberrations.  $P < 0.05$  was considered statistically significant.

## Results

In this study, 92 high myopic eyes of 46 patients were included. Forty-six eyes were treated with SMILE and

the contralateral eyes were treated with FS-LASIK. The mean age of the patients was  $25.80 \pm 4.67$  years (range, 18–36 years). Twelve patients (26%) were male, and 34 patients (74%) were female. All of the surgeries were performed successfully with no observed complications. The patients' preoperative baseline characteristics are reported in [Table 1](#).

## Visual and Refractive Outcomes

Both high myopic eyes in each participant treated with either SMILE or FS-LASIK achieved satisfactory clinical outcomes. The postoperative visual acuity and refractive correction values are presented in [Table 2](#) and [Figure 1](#). There were no statistically significant differences in the UDVA logMAR ( $P = 0.695$ ) and CDVA logMAR ( $P = 0.381$ ) between the two groups. At 6 months after surgery, 91% of the eyes treated with SMILE and 96% of the eyes treated with FS-LASIK achieved a UDVA of 20/20 or better ([Fig. 1A](#)).

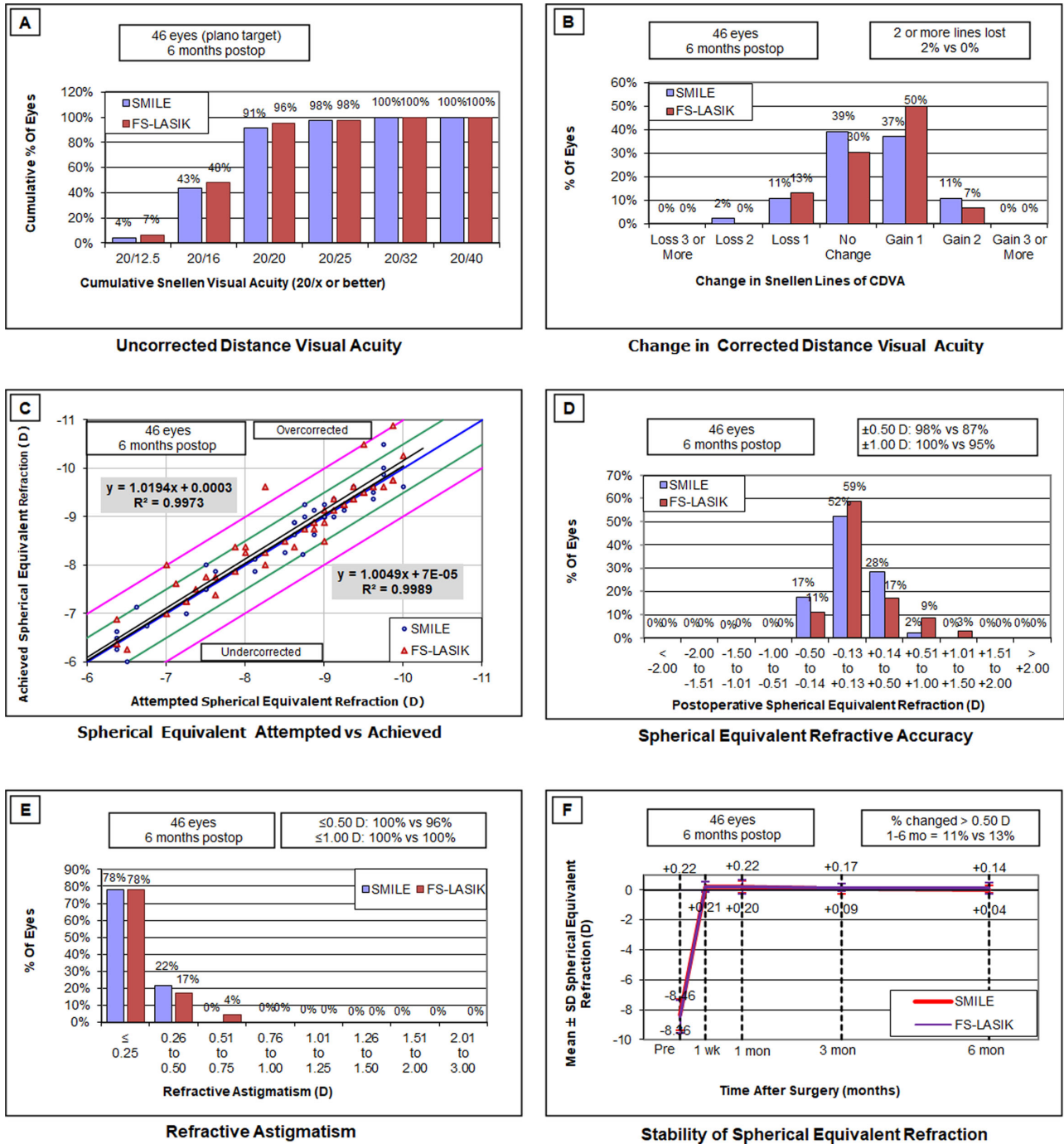
**Table 1.** Preoperative Characteristics of the Participants

Characteristics	SMILE ( $n = 46$ )	FS-LASIK ( $n = 46$ )	<i>P</i>
Age (y), mean $\pm$ SD (range)	25.80 $\pm$ 4.67 (18–36)	25.80 $\pm$ 4.67 (18–36)	—
Sex (male/female), <i>n</i>	12/34	12/34	—
Treatment of right eyes, <i>n</i> (%)	24 (52)	22 (48)	—
CDVA (logMAR), mean $\pm$ SD (range)	−0.02 $\pm$ 0.06 (−0.10 to 0.10)	−0.02 $\pm$ 0.05 (−0.10 to 0.10)	0.180
Sphere (D), mean $\pm$ SD (range)	−7.85 $\pm$ 1.11 (−9.25 to −5.25)	−7.97 $\pm$ 1.21 (−9.75 to −5.50)	0.057
Cylinder (D), mean $\pm$ SD (range)	−1.02 $\pm$ 0.70 (−2.50 to 0.00)	−0.98 $\pm$ 0.68 (−2.25 to 0.00)	0.482
MRSE (D), mean $\pm$ SD (range)	−8.36 $\pm$ 1.04 (−10.00 to −6.38)	−8.46 $\pm$ 1.09 (−10.25 to −6.38)	0.060
Scotopic PD (mm), mean $\pm$ SD (range)	6.63 $\pm$ 0.77 (4.82–7.87)	6.62 $\pm$ 0.80 (4.70–8.17)	0.575
Mesopic PD (mm), mean $\pm$ SD (range)	5.29 $\pm$ 0.73 (3.71–6.49)	5.34 $\pm$ 0.73 (3.84–6.80)	0.467
CCT ( $\mu$ m), mean $\pm$ SD (range)	540.40 $\pm$ 36.95 (486–665)	539.58 $\pm$ 37.56 (486–664)	0.173

MRSE, manifest refraction spherical equivalent; PD, pupil diameter.

**Table 2.** Visual Outcomes and Induced Changes in Aberrations After SMILE and FS-LASIK

Parameter	Mean $\pm$ SD (Range)		<i>P</i>
	SMILE	FS-LASIK	
<b>Visual outcomes</b>			
UVDA (logMAR)	−0.04 $\pm$ 0.08 (−0.20 to 0.20)	−0.04 $\pm$ 0.08 (−0.20 to 0.20)	0.695
CVDA (logMAR)	−0.07 $\pm$ 0.07 (−0.20 to 0.10)	−0.03 $\pm$ 0.23 (−0.20 to 0.10)	0.381
Sphere (D)	0.12 $\pm$ 0.26 (−0.50 to 0.75)	0.23 $\pm$ 0.40 (−0.50 to 1.75)	0.123
Cylinder (D)	−0.15 $\pm$ 0.21 (−0.50 to 0.00)	−0.17 $\pm$ 0.23 (−0.75 to 0.00)	0.609
SE (D)	0.04 $\pm$ 0.26 (−0.50 to 0.75)	0.14 $\pm$ 0.38 (−0.50 to 1.38)	0.150
<b>Changes in aberrations</b>			
Vertical coma ( $\mu$ m)	−0.36 $\pm$ 0.25 (−1.00 to 0.47)	−0.29 $\pm$ 0.23 (−0.91 to 0.20)	0.107
Horizontal coma ( $\mu$ m)	−0.07 $\pm$ 0.22 (−0.47 to 0.45)	−0.02 $\pm$ 0.32 (−0.66 to 0.53)	0.229
RMS coma ( $\mu$ m)	0.37 $\pm$ 0.22 (−0.02 to 1.00)	0.36 $\pm$ 0.20 (−0.05 to 0.90)	0.847
SA ( $\mu$ m)	0.09 $\pm$ 0.08 (−0.04 to 0.29)	0.14 $\pm$ 0.11 (−0.10 to 0.40)	<0.001
Total HOAs ( $\mu$ m)	0.37 $\pm$ 0.19 (−0.01 to 0.98)	0.36 $\pm$ 0.20 (−0.17 to 0.88)	0.909



**Figure 1.** Visual and refractive outcomes at 6 months after SMILE and FS-LASIK. (A) UDVA outcomes. (B) CDVA. (C) SE attempted versus achieved. (D) SE refractive accuracy. (E) Refractive astigmatism. (F) Stability of SE refraction at 6 months postoperatively.

In addition, 87% of eyes treated with both SMILE and FS-LASIK showed an unchanged or better CDVA (Fig. 1B). A scatterplot of the attempted versus the achieved SE correction of SMILE and FS-LASIK is shown in Figure 1C. The surgical predictability (achieved SE of attempted correction) of SMILE and FS-LASIK was 98% versus 87% within  $\pm 0.50$  D; additionally, 100% and 95% of eyes treated with

SMILE and FS-LASIK, respectively, were within  $\pm 1.0$  D (Fig. 1D). As for astigmatism correction, 100% of treated eyes in the SMILE group and 96% of treated eyes in the FS-LASIK group had postoperative astigmatism within  $\pm 0.50$  D cylinder (Fig. 1E). Eleven percent versus 13% of eyes treated with both SMILE and FS-LASIK had a change of  $> 0.50$  D in SE from 1 to 6 months (Fig. 1F).

### Corneal Wavefront Aberrations

The induced changes in the wavefront aberrations after SMILE and FS-LASIK at 6 months postoperatively are shown in Table 2. Among them, at 6 months postoperatively, the induced change in SA was significantly larger in the eyes that underwent FS-LASIK ( $0.14 \pm 0.11$ ) than in those that underwent SMILE ( $0.09 \pm 0.01$ ;  $P < 0.001$ ). However, no statistically significant differences were found in total HOAs, vertical coma, horizontal coma, or RMS coma between SMILE and FS-LASIK (all  $P > 0.05$ ).

### Functional Optical Zone

The parameters of FOZ, POZ, programmed treatment zone (TZ), and CCT for the SMILE and FS-LASIK groups preoperatively and at 6 months postoperatively are summarized in Table 3. The preoperative programmed TZ, including the POZ and a transition OZ, was larger for FS-LASIK than SMILE ( $P < 0.001$ ). However, the FOZ for SMILE ( $5.62 \pm 0.31$  mm) was larger than that for FS-LASIK ( $5.35 \pm 0.28$  mm;  $P < 0.001$ ). The reduction in FOZ (i.e., FOZ minus POZ) was smaller for SMILE ( $-0.51 \pm 0.30$  mm) than for FS-LASIK ( $-0.78 \pm 0.25$  mm;  $P < 0.001$ ). In addition, the CCT for SMILE ( $430.56 \pm 25.66$   $\mu$ m) was greater than for FS-LASIK ( $420.24 \pm 29.43$   $\mu$ m;  $P < 0.001$ ). As shown in Figure 2, there were no significant differences between the four follow-up points of the FOZ after both SMILE and FS-LASIK. Moreover, a significantly larger FOZ was found for SMILE than for FS-LASIK at all of the follow-up points (all  $P < 0.001$ ).

### Contrast Sensitivity

The contrast sensitivity values at different spatial frequencies pre- and postoperatively are shown in Figure 3. No statistically significant differences

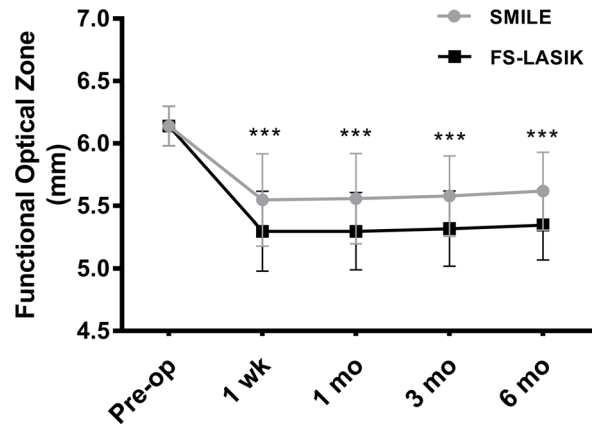


Figure 2. Functional optical zone diameter changes over time in the SMILE and FS-LASIK groups. \*\*\* $P < 0.001$ , statistically significant.

were found in the contrast sensitivity values between SMILE and FS-LASIK preoperatively. The AULCSF of contrast sensitivity under the mesopic condition with glare was significantly larger for SMILE ( $4.39 \pm 0.28$ ) than for FS-LASIK ( $4.17 \pm 0.27$ ;  $P = 0.024$ ). Moreover, the value of contrast sensitivity was greater for SMILE than for FS-LASIK at a lower spatial frequency (3 cycles/degree) under the mesopic condition ( $P = 0.010$ ).

### QoV Scores

The mean QoV scores for visual symptom frequency, severity and bothering effects are shown in Table 4. There were no statistically significant differences in frequency score ( $P = 0.085$ ), severity score ( $P = 0.085$ ), or bothersome score ( $P = 0.058$ ) between SMILE and FS-LASIK. The specific results of all the 10 symptoms for the SMILE and FS-LASIK groups 6 months postoperatively are presented in Figure 4. Difficulty judging distance/depth perception was not reported by any patients pre- or postoperatively. The three most commonly reported visual symptoms were

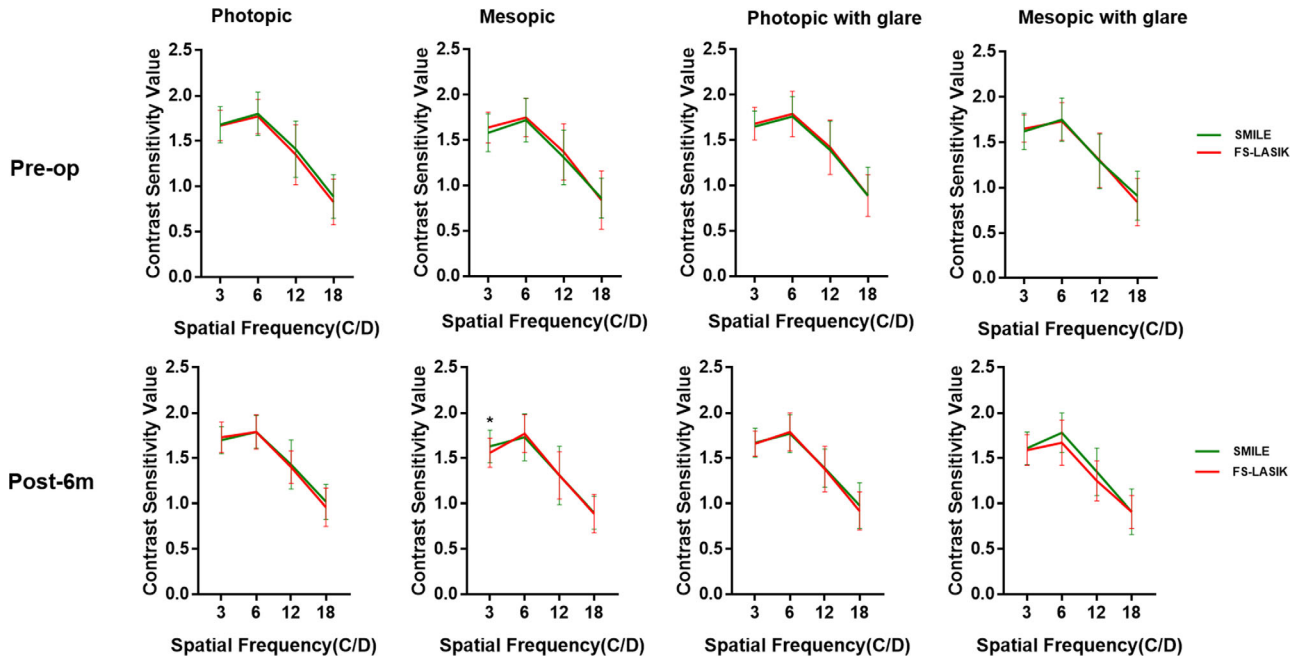
Table 3. Postoperative FOZ and CCT

Parameter	Mean $\pm$ SD (Range)		P
	SMILE	FS-LASIK	
Programmed OZ (mm)	6.14 $\pm$ 0.16 (6.00–6.80)	6.14 $\pm$ 0.16 (6.00–6.80)	—
Programmed TZ (mm) <sup>a</sup>	6.23 $\pm$ 0.16 (6.00–6.90)	7.89 $\pm$ 0.26 (7.45–8.26)	<0.001
FOZ (mm)	5.62 $\pm$ 0.31 (5.00–6.30)	5.35 $\pm$ 0.28 (4.70–6.10)	<0.001
FOZ change (mm) <sup>b</sup>	–0.51 $\pm$ 0.30 (–1.10 to 0.30)	–0.78 $\pm$ 0.25 (–1.30 to –0.10)	<0.001
CCT ( $\mu$ m)	430.56 $\pm$ 25.66 (395.00–543.00)	420.24 $\pm$ 29.43 (385.00–543.00)	<0.001

OZ, optical zone; TZ, treatment zone.

<sup>a</sup>Programmed TZ is the diameter of the programmed OZ plus the transition zone.

<sup>b</sup>FOZ change is the diameter of the FOZ minus the POZ.



**Figure 3.** Contrast sensitivity in SMILE and FS-LASIK pre- and postoperatively. The AULCSFs of contrast sensitivity under the mesopic condition with glare for SMILE and FS-LASIK were  $4.39 \pm 0.28$  and  $4.17 \pm 0.27$ , respectively ( $P = 0.024$ ). \* $P < 0.05$ , statistically significant.

**Table 4.** Postoperative QoV Scores After SMILE and FS-LASIK

QoV Score	SMILE	FS-LASIK	$P^a$
Frequency			0.085
Mean $\pm$ SD	$3.35 \pm 3.09$	$3.67 \pm 3.46$	
Median	3	3	
Range	0–15	0–15	
IQR	1–5	1–5	
Severity			0.085
Mean $\pm$ SD	$2.95 \pm 2.93$	$3.26 \pm 3.25$	
Median	3	3	
Range	0 to 16	0 to 16	
IQR	1–4	1–4	
Bothersome			0.058
Mean $\pm$ SD	$2.60 \pm 3.93$	$2.77 \pm 4.00$	
Median	1	1	
Range	0–20	0–20	
IQR	0–3	0–3	

<sup>a</sup> $P$  values were calculated using the Wilcoxon signed-rank test.

starburst (53% versus 56%), haloes (47% versus 50%), and glare (47% versus 50%) in the SMILE and FS-LASIK groups (Fig. 4A). Likewise, the starburst, haloes, and glare were regarded as the most severe (Fig. 4B) and the most bothersome (Fig. 4C) postoperative visual disturbances.

### Decentration Analysis

The decentration displacement relative to the corneal vertex is summarized in Table 5. The mean total decentration value for SMILE ( $0.29 \pm 0.14$  mm) was greater than for FS-LASIK ( $0.22 \pm 0.11$  mm,  $P = 0.004$ ). Moreover, there was a significant difference in vertical displacement between SMILE and FS-LASIK ( $0.21 \pm 0.22$  mm versus  $0.11 \pm 0.17$  mm,  $P = 0.012$ ). However, no significant difference was found in and the horizontal displacement between SMILE and FS-LASIK ( $0.03 \pm 0.12$  mm versus  $-0.02 \pm 0.14$  mm,  $P = 0.213$ ). The correlation between the induced changes in aberrations and decentration is shown in Table 6. There was a moderately strong and statistically significant correlation between the vertical and total decentration and the vertical coma, RMS coma, and total HOAs for SMILE (all  $P < 0.05$ ), whereas no statistically significant correlation was found for FS-LASIK.

### Discussion

In the present study, to evaluate the difference in FOZ between SMILE and FS-LASIK more accurately, a contralateral-eye comparative study was conducted in high myopic patients who received SMILE in one eye and FS-LASIK in the other eye. Moreover, eyes with similar refraction correction were



Figure 4. Stacked histogram analysis for frequency (A), severity (B), and bothersome (C) of visual symptoms after SMILE and FS-LASIK. Histograms are ranked in the descending order of incidence according to the percentage of visual symptoms.



**Table 5.** Decentration Displacement Relative to the Corneal Vertex After SMILE and FS-LASIK

Decentered Displacement	Mean $\pm$ SD (Range)		<i>P</i>
	SMILE	FS-LASIK	
Preoperative pupillary offset (mm)			
X-axis	0.02 $\pm$ 0.14 (−0.31 to 0.28)	0.00 $\pm$ 0.15 (−0.29 to 0.33)	0.733
Y-axis	0.10 $\pm$ 0.14 (−0.42 to 0.38)	0.12 $\pm$ 0.13 (−0.14 to 0.40)	0.415
Pupillary offset	0.20 $\pm$ 0.10 (0.04–0.47)	0.21 $\pm$ 0.09 (0.04–0.40)	0.278
Decentered displacement (mm)			
Horizontal	0.03 $\pm$ 0.12 (−0.30 to 0.30)	−0.02 $\pm$ 0.14 (−0.30 to 0.30)	0.213
Vertical	0.21 $\pm$ 0.22 (−0.40 to 0.70)	0.11 $\pm$ 0.17 (−0.35 to 0.50)	0.012
Total	0.29 $\pm$ 0.14 (0.07–0.71)	0.22 $\pm$ 0.11 (0.00–0.50)	0.004

**Table 6.** Correlation Between Decentration and Induced Changes in Aberrations Postoperatively

Parameters	SMILE				FS-LASIK			
	Vertical Decentration		Total Decentration		Vertical Decentration		Total Decentration	
	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>
Vertical coma	0.450	0.002	0.475	0.001	0.199	0.196	0.148	0.337
RMS coma	0.497	0.001	0.477	0.001	−0.258	0.091	−0.213	0.165
Total HOAs	0.609	<0.001	0.602	<0.001	0.094	0.546	0.144	0.351

treated with SMILE and FS-LASIK. In addition, the same POZ was designed for both, which minimized interference factors for the FOZ in both groups. To the best of our knowledge, only two previous studies have compared the FOZ between SMILE and FS-LASIK.<sup>9,17</sup> However, they used different calculated measurements and control designs compared to ours. For example, Hou et al.<sup>9</sup> compared the FOZ between SMILE and FS-LASIK in different individuals, whereas Damgaard et al.<sup>17</sup> conducted a paired-eye study to compare the FOZ between SMILE and FS-LASIK without setting a similar POZ. The lack of an appropriate controlled design might compromise the validity of their conclusion. More importantly, none of these studies focused on high myopia.

The FOZ was evaluated using TCRP (calculated by the ray-tracing method) in the present study, which has been recognized as the most realistic estimation of corneal power measurements postoperatively.<sup>18</sup> Our results showed that SMILE created a smaller reduction in FOZ and a larger postoperative FOZ than did FS-LASIK at all follow-up visits. Damgaard et al.<sup>17</sup> measured the FOZ by using a region-growing algorithm and suggested that a larger FOZ was achieved with SMILE than with FS-LASIK. Hou et al.<sup>9</sup> also reported a smaller FOZ reduction for SMILE than for FS-LASIK using a tangential curva-

ture difference map method. Despite the differences in the measurement of FOZ, our observations are mostly consistent with the previous studies.<sup>17</sup> The specific FOZ size could not be directly compared with the previous study because of different calculated measurements. Additionally, no significant differences in the FOZ were observed from 1 week to 6 months postoperatively after SMILE and FS-LASIK, suggesting a stable postoperative FOZ after both SMILE and FS-LASIK surgeries. Moreover, the postoperative CCT for SMILE was greater than that for FS-LASIK, indicating that less corneal tissue was removed during SMILE than during FS-LASIK, which is consistent with a previous study.<sup>4</sup> However, no relationship was found between postoperative CCT and FOZ. Several factors might account for the larger FOZ after SMILE in high myopia. First, there is more energy loss of the excimer laser in the peripheral zone due to the perpendicular ablation during FS-LASIK, which leads to inadequate ablation. Second, a more uniform energy release is produced by the femtosecond laser in the peripheral zone after SMILE. Finally, differences in the wound-healing responses and corneal remodeling after SMILE and FS-LASIK were found.<sup>9</sup>

Moreover, in the present study, greater vertical decentration and total decentration were found for SMILE than for FS-LASIK, consistent with the

previous study.<sup>19</sup> However, other scholars have demonstrated a similar accuracy of centration for SMILE and FS-LASIK.<sup>13,17</sup> In theory, the eye tracker–based centration in FS-LASIK is more accurate than the centration being manually defined in SMILE.<sup>20</sup> Decentration treatment could induce HOAs and lead to vision disturbance, such as halos, glare, and poor visual outcomes.<sup>21,22</sup> Our data showed that vertical decentration had a positive correlation with the induced vertical coma, RMS coma, and total HOAs for SMILE. Chan et al.<sup>23</sup> also reported a significant positive correlation between the decentration distance and the induced total coma and HOAs; however, no correlation was found in FS-LASIK, which might be related to the less vertical and total decentration. Lee et al.<sup>24</sup> suggested that a decentration of greater than 0.30 mm induced more total HOAs and coma than a decentration of less than 0.15 mm, whereas no significant difference was found in aberrations between the two groups when the delimit value was set at 0.20, 0.25, or 0.30 mm. In our study, decentration was concentrated at less than 0.3 mm for both SMILE and FS-LASIK. In addition, no significant difference was found in the induced changes in the HOAs and comas. It could be expected that the relatively greater decentration for SMILE had little effect on vision quality in our study. Thus, the differences in decentration between the two surgeries might not affect the evaluation of FOZ in terms of visual quality.

Furthermore, in the present study, the visual quality in the subjects who received SMILE and FS-LASIK surgeries was evaluated subjectively and objectively. Our data showed that there were no significant differences in coma and total HOAs between SMILE and FS-LASIK. Moreover, SMILE yielded fewer induced changes in SA than did FS-LASIK, which might be related to the larger FOZ achieved by SMILE.<sup>25,26</sup> However, the induction of SA is not devoid of any advantages. The induction of positive SA can extend the depth of focus and improve the intermediate visual acuity to some extent.<sup>27</sup> In our study, only contrast sensitivity under the mesopic condition with glare was better for SMILE than for FS-LASIK, whereas Yang et al.<sup>4</sup> reported that no difference was observed between the two groups. Generally speaking, a smaller FOZ diameter might cause visual complaints, such as glare, haloes, and ghosting.<sup>28</sup> Accordingly, a QoV questionnaire was used to assess the patients' potential postoperative complications. Consistent with what Chiche et al.<sup>29</sup> reported, similar subjective QoV scores were achieved with SMILE and FS-LASIK. A previous paired-eye study also reported no differences between SMILE and LASIK in the visual symptoms by using another questionnaire at 3 months postopera-

tively.<sup>30</sup> Taken together, the objective visual quality and subjective visual symptoms were comparable between SMILE and FS-LASIK.

There are still some limitations in the present study. First, a follow-up of longer duration should be conducted. Second, different POZ sizes should be analyzed to determine the optimal OZ for SMILE and FS-LASIK.

In conclusion, this study, to the best of our knowledge, is the first contralateral eye study to compare the FOZ and vision quality in patients with high myopia. Our results demonstrated a larger postoperative FOZ and greater decentration for SMILE than for FS-LASIK with the same designed POZ in high myopia. The differences in FOZ and decentration between SMILE and FS-LASIK have little effects on vision outcomes. This study could provide evidence for the design of the POZ and the choice of surgery for patients with high myopia.

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