



Functional Optical Zone and Visual Quality After Small-Incision Lenticule Extraction for High Myopic Astigmatism

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ABSTRACT

Introduction: The aim of this study was to compare the functional optical zone (FOZ) after correction of high myopic astigmatism and low myopic astigmatism by small-incision lenticule extraction (SMILE).

Methods: In this prospective study, 30 patients who received SMILE for high myopic astigmatism correction (cylindrical diopters ≤ -2.0 D) were enrolled in the high astigmatism group (HA). The control group comprised 40 patients who underwent SMILE for low myopic astigmatism correction (LA; cylindrical diopters ≥ -0.5 D). FOZ was delineated as the area outlined by a change of 0.5D relative to the power at the corneal vertex on the total corneal refractive power map. An ellipse-fitting program (MatLab) was used to calculate some parameters of the FOZ. Visual quality evaluations were also conducted, including evaluations of wavefront aberrations, optical quality, and intraocular scattering, and completion of a quality of life questionnaire. All of the right eyes were analyzed in the study.

Results: The preoperative average treatment spherical equivalent (-5.77 ± 1.86 D vs. -6.49 ± 1.49 D; $P = 0.074$), lenticule thickness ($120.87 \pm 23.27 \mu\text{m}$ vs. $118.53 \pm 21.66 \mu\text{m}$; $P = 0.666$), and programmed optical zone ($6.58 \pm 0.17 \text{ mm}$ vs. $6.65 \pm 0.18 \text{ mm}$; $P = 0.104$) were comparable between the HA and LA groups. The long axes ($6.99 \pm 1.14 \text{ mm}$ vs. $5.32 \pm 0.61 \text{ mm}$; $P < 0.001$), short axes ($4.66 \pm 0.96 \text{ mm}$ vs. $4.23 \pm 0.64 \text{ mm}$; $P = 0.047$), and area ($25.90 \pm 8.03 \text{ mm}^2$ vs. $17.92 \pm 4.36 \text{ mm}^2$; $P < 0.001$) of the FOZ were significantly larger in the HA group than in the LA group. The centration of the FOZ were comparable between the two groups ($0.62 \pm 0.25 \text{ mm}$ vs. $0.70 \pm 0.25 \text{ mm}$; $P = 0.194$). Postoperative spherical aberration was lower in the HA group than in the LA group ($0.07 \pm 0.05 \mu\text{m}$ vs. $0.14 \pm 0.10 \mu\text{m}$; $P = 0.001$). There was no significant difference in the ocular scatter index (0.80 ± 0.46 vs. 0.73 ± 0.46 ; $P = 0.447$), modulated transfer function (MTF)_{cutoff} ($37.89 \pm 9.79 \text{ cpd}$ vs. $39.78 \pm 7.45 \text{ cpd}$; $P = 0.363$), and Strehl in two dimensions (Strehl2D) ratio (0.20 ± 0.04 vs. 0.20 ± 0.04 ; $P = 0.363$) between the HA group and the LA group. There were no significant differences in the scores on quality of life between the HA and LA groups (45.88 ± 2.15 vs. 45.64 ± 1.84 ; $P = 0.423$). Correlation analysis revealed that increase in the spherical aberration was significantly correlated with the long axes, short axes and area in the FOZ in both groups.

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Conclusion: With a comparable optical design and attempted correction in SMILE, the eyes with higher myopic astigmatism correction achieved larger FOZ than the eyes with lower myopic astigmatism correction. Consequently, less spherical aberration induction was created after higher myopic astigmatism correction. This result may be associated with less corneal volume sculpted by laser for the higher astigmatism treatment, leading to fewer biochemical responses and less change in corneal asphericity. Good retinal image quality and satisfied quality of life were achieved at a comparable level in both study groups.

Keywords: Astigmatism; Functional optical zone; Small-incision lenticule extraction; Visual quality

Key Summary Points

Why carry out this study?

To our knowledge, there is no published report on functional optical zone (FOZ) features after high myopic astigmatism correction.

The aim of this study was to compare the FOZ after correction of high myopic astigmatism and low myopic astigmatism by small-incision lenticule extraction (SMILE).

What was learned from the study?

With comparable optical design and attempted correction in SMILE, the eyes with higher myopic astigmatism correction achieved a larger FOZ and less spherical aberration induction than eyes with lower myopic astigmatism.

Subjective visual quality indicators, such as optical quality and intraocular scattering, and assessments of the quality of life were comparable in the two groups.

DIGITAL FEATURES

This article is published with digital features, including a summary slide, to facilitate understanding of the article. To view digital features for this article go to <https://doi.org/10.6084/m9.figshare.13547000>.

INTRODUCTION

Small-incision lenticule extraction (SMILE) is a minimally invasive type of laser refractive corneal surgery that which achieves refractive correction by creating a lenticule with a femtosecond laser and then extracting the lenticule through a small peripheral incision. SMILE is associated with high efficacy, predictability, stability, and safety for the correction of myopia and myopic astigmatism, with postoperative visual outcomes and vision related quality of life comparable to that achieved with femtosecond laser-assisted in situ keratomileusis (FS-LASIK) [1–3]. Due to the corneal flapless design, SMILE has two main advantages over FS-LASIK: lower odds of iatrogenic dry eye and fewer induced higher order aberrations (HOAs) [4]. However, the lack of cyclotorsion control with the VisuMax femtosecond laser increases the difficulty in achieving treatment centration, leading to incorrect correction of the moderate or high myopic astigmatism [5].

The optical zone (OZ) is the corneal area is the target in refractive surgery, with complete refractive correction achieved by changing the corneal curvature. No matter which type of corneal refractive surgery is performed, this area is essentially associated with postoperative visual outcomes. The functional optical zone (FOZ) is defined as the corneal surface region which achieves full refractive correction after the treatment [6]. It is a theoretical indicator that reflects visual acuity on the basis of data obtained from corneal topography examinations [7]. The FOZs of SMILE and FS-LASIK are known from previous studies, and a consensus

has been reached that the postoperative FOZs of both SMILE and FS-LASIK are smaller than their preoperative programmed OZ and that SMILE creates a larger FOZ than FS-LASIK in myopic correction [8, 9]. The discrepancy between the FOZ and the programmed OZ increases with attempts of greater myopic correction in SMILE and FS-LASIK [10]. Compared with FS-LASIK, SMILE provides less satisfaction in terms of astigmatism correction due to the lack of automated cyclotorsion control [11, 12].

In the study reported here, we have evaluated features of the FOZ and analyze its potential pattern, which may act as a guidance for centration adjustment and programmed parameters of high myopic astigmatism correction. Our aim was to compare the 6-month postoperative FOZ following high myopic astigmatism and low myopic astigmatism correction by SMILE and to analyze the correlation between FOZ parameters and ocular wavefront aberrations.

METHODS

General Data

This was a prospective, non-randomized cohort study that enrolled 70 patients (right eyes only) between December 2018 and May 2019 at the Refractive Center of The Eye and ENT Hospital of Fudan University. The study followed the requirements of medical ethics, and all patients provided written informed consent before surgery. All subjects were treated in accordance with the tenets of the Declaration of Helsinki. The Ethical Committee of the Fudan University EENT Hospital Review Board approved the study protocol. Patients with myopic astigmatism of $\leq -2.0D$ were included in the high astigmatism (HA) group, and patients with myopic astigmatism of $\geq -0.5D$ and comparable programmed OZ diameter and lenticule thickness to those in the HA group served as the control group (LA) in the current study. Other inclusion criteria included a minimum age of 18 years; stable refractive error for 2 years before surgery; and best-corrected distance visual acuity (DVA) $\geq 20/20$. Exclusion criteria were a

history of systemic or other ocular conditions, with the exception of myopia and myopic astigmatism; ocular surgeries and trauma history; active ocular inflammation and infection; calculated postoperative residual stromal bed thickness of $< 250 \mu\text{m}$; and suspicion of keratoconus.

All patients underwent routine ophthalmic evaluation procedures preoperatively that included slit-lamp examination, fundus examination, uncorrected DVA (UDVA), corrected DVA (CDVA), objective (ARK-510A autorefractor keratometer; NIDEK, Tokyo, Japan) and manifest refraction (RT-5100 automatic phoropter; NIDEK) in microcoria and in a cycloplegic state, corneal topography (Pentacam HR®, OCULUS Optikgeräte GmbH, Wetzlar, Germany), intraocular pressure measurement (TX-20 tonometer; Canon, Tokyo, Japan), axial length measurement (IOLMaster optical biometer; Carl Zeiss Meditec AG, Jena, Germany), and wavefront aberration (WASCA aberrometer; Meditec Carl Zeiss).

Small-Incision Lenticule Extraction Procedure

All of the SMILE procedures were performed using the VisuMax femtosecond laser (Carl Zeiss Meditec AG), with the following parameters: pulse energy, 130 nJ; cap diameter, 7.5 mm; cap thickness, 110–120 μm ; programmed optical zone, 6.0–6.8 mm with a transition zone of 0.1 mm for astigmatism correction; side-cut angle, 90° at the superior position. The target spherical correction was set to 0 to + 0.75 D on the basis of age and preoperative refractive power.

The patient was required to stare at the fixation light throughout the operation. The surgeon centered the corneal vertex by observing through the microscope and moving the joystick. Suction was activated when the watermark exceeded 80% of the cone; then the eyeball was fixed and photo disruption was created to generate the posterior and anterior surfaces of the refractive lenticule, followed by a single side-cut incision. The lenticule was then dissected through the side-cut incision and

removed manually using microforceps. All procedures were uneventful and no postoperative complication was observed.

Postoperative Treatment and Follow-Up

Postoperatively, 0.5% ofloxacin eye drops (Santen Pharmaceutical Co., Ltd., Osaka, Japan) were applied 4 times a day for 1 week, 0.1% fluorometholone eye drops (Santen Pharmaceutical Co., Ltd.) were applied 4 times daily for 1 month, and 0.3% sodium hyaluronate eye drops (Santen, Pharmaceutical Co., Ltd.) were used 4 times daily for 2–3 months.

Follow-up visits were scheduled on postoperative day 1 and months 1, 3, and 6. UDVA, CDVA, objective and manifested refractions, intraocular pressure, and a slit-lamp examination were included in every follow-up visit. High-resolution tomography (Pentacam HR system), aberrometry (WASCA aberrometer), and overall eye quality measurements using the OQASII system (Visiomereics SL, Barcelona, Spain) were also performed at each postoperative visit with the exception of day 1 after surgery.

Functional Optical Zone Measurements

In the present study, the achieved functional optical zone was defined as the area outlined by a change of 0.5D relative to the power at the corneal vertex on the total corneal refractive power map. We chose 0.5D as a threshold value because a $-0.5D$ defocus generally induces a UDVA of 20/32, which is the limit of acceptable vision for daily activities [13, 14]. The FOZ was measured by Pentacam HR tomography. All examinations were performed by the same experienced examiner (LW) in the same room under the same illumination conditions. Only images with 'OK' quality were included in the analysis. The total corneal refractive power map of the Pentacam HR system was chosen to delineate the FOZ outline. The measurements steps are: first, use the cursor on the computer screen to find the points whose power diopters reach to the corneal apex refractive power diopters $+0.5D$ and record the coordinates (at

least 12 points); second, import these coordinates to the ellipse fitting program using MatLab (MathWorks, Natick, MA, USA) to obtain the FOZ center coordinates, long and short axes, and the area of the ellipse.

To confirm the current study's results, we also measured the FOZ using the method of Hou et al. [9] who defined the FOZ as the area outlined by a change of zero diopter on the tangential curvature difference map (preoperative value $-$ postoperative value). The steps calculated by these authors are similar to those described above, and the area was named the effective optical zone (EOZ) in order to distinguish it from the FOZ. (Fig. 1).

Wavefront Aberrations Measurements

Ocular wavefront aberrations were measured on the WASCA Wave-front Analyzer (Carl Zeiss Meditec AG) and analyzed for a pupil diameter

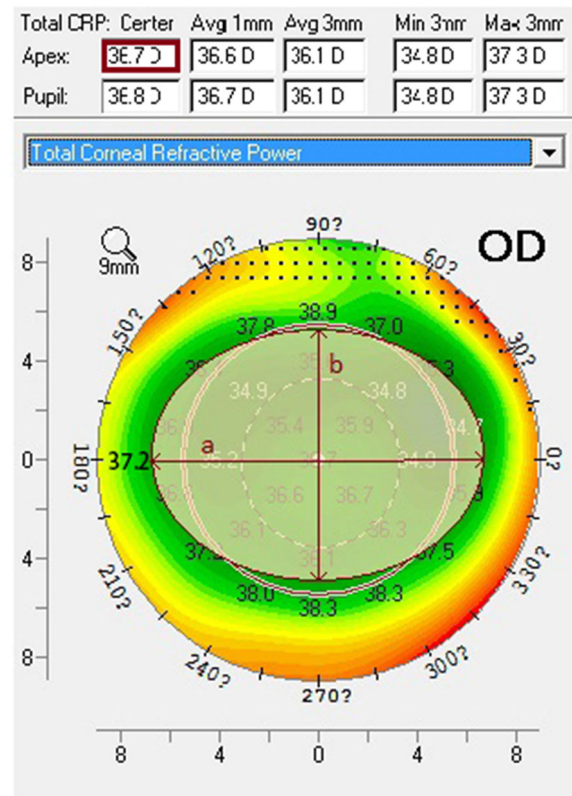


Fig. 1 Illustration of the postoperative functional optical zone measurements

Table 1 Preoperative characteristics by patient group

Characteristic	High Astigmatism group (<i>n</i> = 30)	Low Astigmatism group (<i>n</i> = 40)	<i>P</i> value
Age (years)	27.47 ± 5.71 (19–39)	27.90 ± 4.29 (19–36)	0.718
Gender (male/female)	13/17	16/24	–
Central corneal thickness (μm)	544.27 ± 28.24 (506–605)	540.95 ± 27.71 (498–598)	0.625
Intraocular pressure (mmHg)	16.51 ± 2.17 (9.10–20.40)	16.10 ± 2.69 (12.50–20.60)	0.497
Mean curvature (anterior surface) (D)	43.67 ± 1.09 (41.80–46.60)	43.34 ± 1.28 (40.70–45.60)	0.259
Treatment sphere (D)	– 4.48 ± 2.02 (– 7.75 to – 0.50)	– 6.34 ± 1.48 (– 9.00 to – 3.25)	< 0.001
Treatment cylinder (D)	– 2.58 ± 0.60 (– 4.00 to – 2.00)	– 0.30 ± 0.20 (– 0.50 to 0.00)	< 0.001 ^a
Treatment spherical equivalent (D)	– 5.77 ± 1.86 (– 8.88 to – 2.38)	– 6.49 ± 1.49 (– 9.25 to – 3.50)	0.074
Lenticule thickness (μm)	120.87 ± 23.27 (76–157)	118.53 ± 21.66 (77–156)	0.666

Values in table are presented as the mean ± standard deviation (SD) with the range given in parentheses

D Diopter

^a M-U test for non-normally distributed data

of 5 mm. Zernike coefficients were fitted up to the sixth order using the standards recommended by the Optical Society of America (OSA). The root mean square of total HOAs, coma, spherical aberrations, and trefoil were calculated.

Optical Quality and Intraocular Scattering Measurements

Optical quality and intraocular scattering were quantitatively evaluated by the OQASII double-pass optical quality analysis system (Visiometrics, Barcelona, Spain) with an artificial pupil diameter of 4.0 mm in the same dark condition. The examiner repeated each intraocular scattering and optical quality measurement three times. Intraocular scattering was measured using an objective scatter index (OSI). For the evaluation of optical quality, a two-dimension modulated transfer function (MTF) profile was calculated from the retinal image through Fourier transformation [15]. We analyzed the OSI, MTF cutoff frequency (MTF_{cutoff}), and Strehl in two dimensions (Strehl2D) ratio.

Quality of Life by the Refractive Correction Questionnaire

Patients in both groups were asked to rate their feelings using the Chinese version of the Quality of Life by the Refractive Correction (QIRC) questionnaire at 6 months after the surgery. This version was completed by Xu et al. [16]. The QIRC questionnaire consists of 20 items, including visual function, symptoms, convenience, concerns, and emotional well-being, and provides a good coverage of the quality of life domains [17]. It is a highly recommended questionnaire to assess quality of life and has been proven responsive as an assessment tool for different refractive surgery procedures, including LASIK and SMILE [18]

Statistical Analysis

Data before and 6 months after the surgery were collected and analyzed. All statistical tests were done using PASW software V.25.0 (SPSS/IBM Corp., Armonk, NY, USA). Data were tested for normality using the Kolmogorov–Smirnov test. The Student's *t* test was used to compare

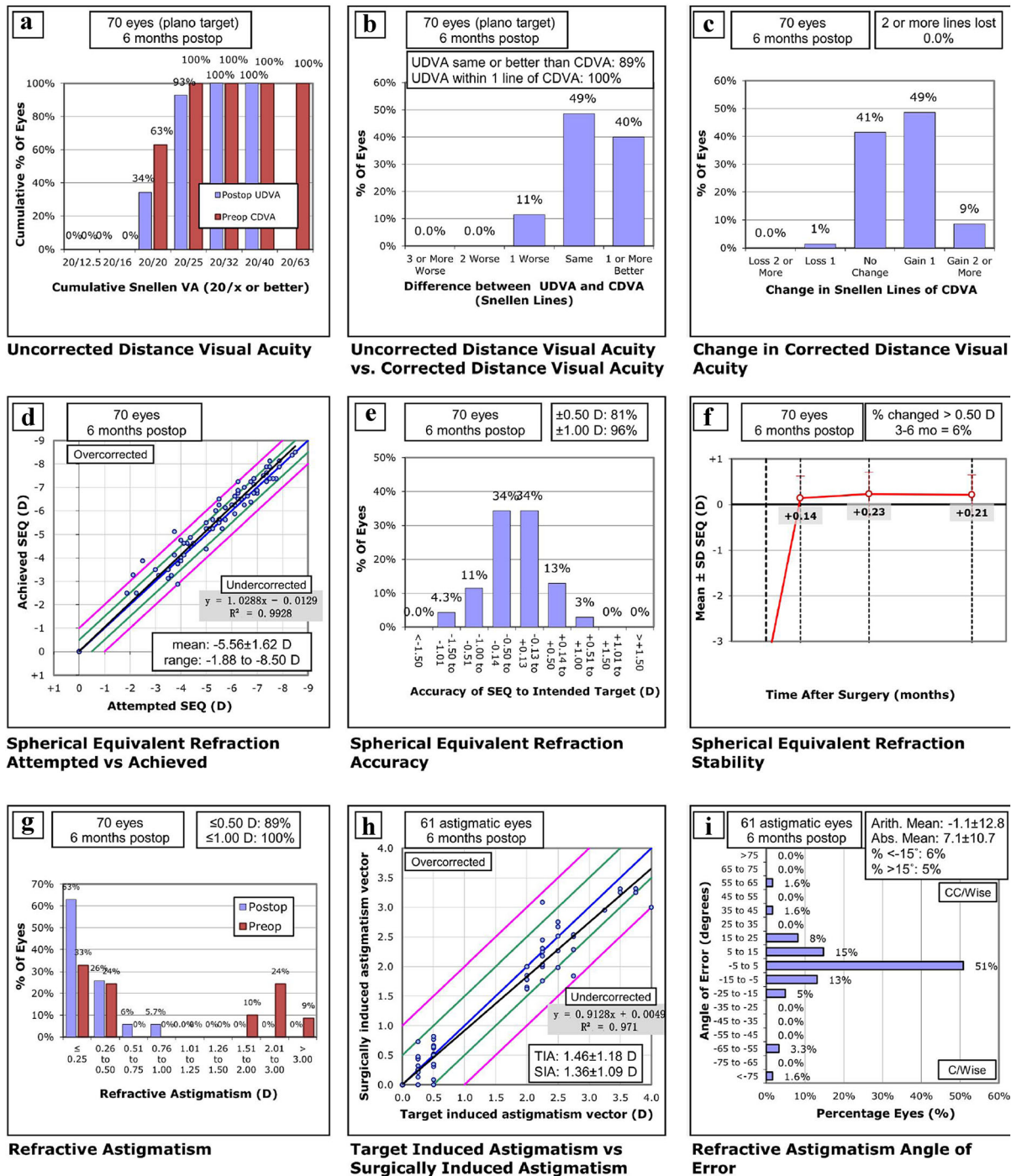


Fig. 2 Refractive outcomes. *CDVA* Corrected distance visual acuity, *UDVA* uncorrected visual acuity, *SEQ* spherical equivalent refraction

normally distributed variables between groups, and the paired *t* test was used for comparison within a group. The Mann–Whitney test was

used to compare non-normally distributed data. Pearson’s and Spearman’s correlation tests were used to assess the correlation between the FOZ

Table 2 Visual outcomes at 6 months after the small-incision lenticule extraction procedure by group

Parameter	High astigmatism group	Low astigmatism group	<i>P</i> value
UDVA (logMAR)	- 0.07 ± 0.05 (- 0.20 to 0.00)	- 0.08 ± 0.06 (- 0.20 to 0.00)	0.817
CDVA (logMAR)	- 0.10 ± 0.32 (- 0.20 to 0.00)	- 0.11 ± 0.05 (- 0.20 to 0.00)	0.313
Sphere (D)	0.35 ± 0.62 (- 1.50 to 1.50)	0.33 ± 0.32 (- 0.25 to 1.25)	0.452
Cylinder (D)	- 0.40 ± 0.29 (- 1.00 to 0.00)	- 0.27 ± 0.24 (- 1.00 to 0.00)	0.083
Spherical equivalent (D)	0.15 ± 0.63 (- 1.75 to 1.38)	0.19 ± 0.34 (- 0.38 to 1.00)	0.986
OSI	0.80 ± 0.46 (0.30–1.90)	0.73 ± 0.46 (0.23–2.30)	0.447
MTF _{cutoff} (cpd)	37.89 ± 9.79 (17.41–52.92)	39.78 ± 7.45 (20.77–51.38)	0.363
SR	0.20 ± 0.04 (0.12–0.27)	0.20 ± 0.04 (0.12–0.27)	0.172

Values in table are presented as the mean ± SD with the range given in parentheses

CDVA Corrected distance visual acuity, cpd cycles per degree, MTF_{cutoff} modulated transfer function cutoff frequency, OSI objective scatter index, SR Strehl2D ratio, UDVA uncorrected distance visual acuity

parameters and introduction of HOAs after SMILE. A probability of < 5% ($P < 0.05$) was considered to be statistically significant.

RESULTS

General Data

A total of 70 right eyes were included in the study, with 30 eyes in the high astigmatism group and 40 eyes in the low astigmatism group. Preoperative characteristics of the patients are shown in Table 1. There were no significant differences in all of the listed variables between two groups, with the exception of treatment sphere ($P < 0.001$) and treatment cylinder ($P < 0.001$). Suction loss occurred in one patient's left eye during the side-cut incision; the surgeon then made the side cut using a needle. No postoperative corneal complication was observed in any patient. All data shown in the tables and figures are presented as mean and standard deviation.

Six-Month Postoperative Visual Outcomes by Group

Refractive outcomes are shown in Fig. 2. All patients had a UDVA of > 20/20 at the 6-month

follow-up visit, and no significant differences were observed in visual acuity ($P = 0.817$ for UDVA; $P = 0.313$ for CDVA) at this time-point. Postoperative manifest sphere ($P = 0.452$), manifest cylinder ($P = 0.083$), and manifest spherical equivalent ($P = 0.986$) were not significantly different between the two groups (Table 2). In addition, the OSI ($P = 0.447$), MTF_{cutoff} ($P = 0.363$), and Strehl2D ratio ($P = 0.172$) were comparable between the two groups. Overall, there were no statistically significant differences in the total QIRC scores and the scores for all 20 responses (Table 3).

Programmed Optical Zone, Achieved Functional Optical Zones and Effective Optical Zones

The programmed optical zone (POZ), programmed treatment zone (PTZ), FOZ, and EOZ are summarized in Table 4. The programmed treatment zone was defined by the sum of the POZ and the transition zone. The diameter and area of the POZ ($P_d = 0.104$; $P_s^2 = 0.100$) and PTZ ($P_d = 0.281$; $P_s^2 = 0.273$) were noted not to be significantly different between the two groups. Postoperatively, the long axes ($P < 0.001$), the short axes ($P = 0.047$), and the area ($P < 0.001$) of FOZ in the HA group was significantly larger than those in the LA group.

Table 3 Differences in responses to items in the Quality of Life by the Refractive Correction questionnaire between the two study groups

Questionnaire item	High astigmatism group				Low astigmatism group				P value
	Mean	SD	Median	Interquartile range	Mean	SD	Median	Interquartile range	
Total QIRC questionnaire score in each group	45.88	2.15	46.08	44.33–47.58	45.64	1.84	45.65	44.43–47.34	0.423
1. How much difficulty do you have driving in glare conditions	47.12	7.84	45.06	45.06–45.06	51.63	7.73	45.06	45.06–60.51	0.225
2. During the past month, how often have you experienced your eyes feeling tired or strained?	54.30	10.85	49.66	49.66–65.11	50.43	9.22	49.66	49.66–49.66	0.091
3. How much trouble is not being able to use off-the-shelf (nonprescription) sunglasses?	43.84	7.12	41.26	41.26–41.26	47.83	7.73	41.26	41.26–56.71	0.282
4. How much trouble is having to think about your spectacles or contact lenses or your eyes after refractive surgery before doing things; e.g., traveling, sport, going swimming?	54.16	9.72	61.37	45.92–61.37	54.42	7.78	61.37	45.92–61.37	0.869
5. How much trouble is not being able to see when you wake up; e.g., to go to the bathroom, look after a baby, see alarm clock?	44.39	7.57	43.87	43.87–43.87	42.71	6.44	43.87	43.87–43.87	0.363
6. How much trouble is not being able to see when you are on the beach or swimming in the sea or pool, because you do these activities without spectacles or contact lenses?	62.38	4.71	63.92	63.92–63.92	61.99	5.17	63.92	63.92–63.92	0.747

Table 3 continued

Questionnaire item	High astigmatism group				Low astigmatism group				<i>P</i> value
	Mean	SD	Median	Interquartile range	Mean	SD	Median	Interquartile range	
7. How much trouble is your spectacles or contact lenses when you wear them when using a gym/doing keep-fit classes/circuit training, etc.?	53.63	4.71	55.17	55.17–55.17	53.24	5.17	55.17	55.17–55.17	0.747
8. How concerned are you about the initial and ongoing cost to buy your current spectacles/contact lenses/refractive surgery?	35.77	5.34	33.71	33.71–33.71	36.41	5.95	33.71	33.71–33.71	0.638
9. How concerned are you about the cost of unscheduled maintenance of your spectacles/contact lenses/refractive surgery; e.g., breakage, loss, new eye problems?	43.63	7.42	45.18	45.18–45.18	44.02	5.41	45.18	45.18–45.18	0.765
10. How concerned are you about having to increasingly rely on your spectacles or contact lenses since you started to wear them?	43.32	7.79	50.01	34.56–50.01	44.60	7.46	50.01	34.56–50.01	0.482
11. How concerned are you about your vision not being as good as it could be?	47.68	5.36	49.69	49.69–49.69	46.21	6.53	49.69	49.69–49.69	0.850
12. How concerned are you about medical complications from your choice of optical correction (spectacles, contact lenses and/or refractive surgery)?	30.65	5.34	28.59	28.59–28.59	32.07	6.53	28.59	28.59–28.59	0.333

Table 3 continued

Questionnaire item	High astigmatism group				Low astigmatism group				<i>P</i> value
	Mean	SD	Median	Interquartile range	Mean	SD	Median	Interquartile range	
13. How concerned are you about eye protection from ultraviolet (UV) radiation?	38.81	7.48	35.72	35.72–35.72	37.65	6.53	35.72	35.72–35.72	0.420
14. During the past month, how much of the time have you felt that you have looked your best?	48.07	5.79	45.52	45.52–45.52	47.05	4.64	45.52	45.52–45.52	0.413
15. During the past month, how much of the time have you felt that you think others see you the way you would like them to (e.g., intelligent, sophisticated, successful, cool, etc.)?	49.43	5.11	48.99	48.99–48.99	50.14	4.07	48.99	48.99–48.99	0.565
16. During the past month, how much of the time have you felt complimented/flattered?	49.37	8.05	54.55	37.28–54.55	50.23	7.57	54.55	41.60–54.55	0.644
17. During the past month, how much of the time have you felt confident?	48.31	13.85	57.94	38.35–57.94	43.40	15.54	50.31	25.40–57.94	0.191
18. During the past month, how much of the time have you felt happy?	47.69	8.92	54.88	39.61–54.88	47.15	9.41	54.88	39.61–54.88	0.849
19. During the past month, how much of the time have you felt able to do the things you want to do?	33.43	10.11	31.66	31.66–46.92	32.12	9.67	31.66	31.66–31.66	0.561

Table 3 continued

Questionnaire item	High astigmatism group				Low astigmatism group				<i>P</i> value
	Mean	SD	Median	Interquartile range	Mean	SD	Median	Interquartile range	
20. During the past month, how much of the time have you felt eager to try new things?	44.21	7.57	41.22	41.22–45.04	43.41	7.63	41.22	41.22–41.22	0.647

QIRC Quality of Life by the Refractive Correction

The centration of FOZ was calculated as the linear distance between the FOZ centroid and the corneal apex by the distance formula. The centration of FOZ was similar in the HA group and LA group ($P = 0.194$). Similarly, the long axes ($P < 0.001$) and the area ($P < 0.001$) of EOZ were significantly larger in the HA group than in the LA group. There were no statistically significant differences in the short axes ($P = 0.965$) and centration ($P = 0.909$) of the EOZ between the two groups.

Wavefront Aberrations

The preoperative and postoperative ocular wavefront aberrations of the two groups are presented in Fig. 3. Preoperative HOAs ($P = 0.234$), spherical aberrations ($P = 0.729$), and trefoil ($P = 0.419$) were similar in the two groups; in contrast, preoperative coma were significantly higher in the HA group than in the LA group ($P = 0.037$). After surgery, all aberrations analyzed was significantly increased in the LA group (all $P < 0.001$), with the exception of trefoil ($P = 0.777$), whereas only HOAs ($P = 0.018$) and coma ($P = 0.003$) were significantly increased postoperatively in the HA group, with no significant change in spherical aberrations ($P = 0.443$) and trefoil ($P = 0.184$) from before to after surgery. Postoperative spherical aberrations were significantly higher in the LA group as compared with the HA group. There were no significant differences noticed in postoperative HOAs ($P = 0.869$),

coma ($P = 0.900$), and trefoil ($P = 0.096$) between the HA and LA groups.

Correlation Analysis

The r values and associated P values for the relationship between the FOZ parameters and the calculated change in the ocular wavefront aberrations are shown in Table 5. The correlation test revealed that the increase in the spherical aberrations in the HA group correlated with the long axes ($r = -0.456$, $P = 0.013$), short axes ($r = -0.434$, $P = 0.019$), and area ($r = -0.523$, $P = 0.004$) in the HA group. Similarly, in the LA group, the spherical aberrations were also found to be correlated with the long axes ($r = -0.661$, $P < 0.001$), short axes ($r = -0.415$, $P = 0.010$), and area ($r = -0.602$, $P < 0.001$). In addition, there was a correlation between the increase in coma and FOZ centration in the LA group ($r = 0.393$, $P = 0.015$). No correlation was observed between the increase in coma and the long axes, the short axes and the area of FOZs in both groups. The increase in HOAs showed no significant correlation with all four FOZ parameters in both groups, similar to trefoil.

DISCUSSION

The concept of FOZ was summarized by Taber-nero, who described the FOZ as the area of the corneal surface that provides reasonable quality vision after laser sculpting [6]. The FOZ can

Table 4 Preoperative and postoperative optical zone

Optical zone	High astigmatism group	Low astigmatism group	<i>P</i> value
Programmed optical zone ^a			
Diameter (mm)	6.58 ± 0.17 (6.20–6.80)	6.65 ± 0.18 (6.20–6.80)	0.104 ^c
Area (mm ²)	34.06 ± 1.77 (30.19–36.32)	34.78 ± 1.80 (30.19–34.78)	0.100 ^c
Programmed treatment zone ^b			
Diameter (mm)	6.68 ± 0.17 (6.30–6.90)	6.73 ± 0.18 (6.30–6.90)	0.281 ^c
Area (mm ²) ^c	35.10 ± 1.80 (31.17–37.39)	35.60 ± 1.89 (31.17–37.39)	0.273 ^c
Achieved functional optical zone			
Long axis (mm)	6.99 ± 1.14 (4.89–9.27)	5.32 ± 0.61 (3.77–6.68)	< 0.001
Short axis (mm)	4.66 ± 0.96 (2.36–6.47)	4.23 ± 0.64 (2.90–5.99)	0.047 ^c
Area (mm ²)	25.90 ± 8.03 (13.29–25.90)	17.92 ± 4.36 (9.88–31.43)	< 0.001
Centration (mm) ^d	0.62 ± 0.25 (0.07–1.05)	0.70 ± 0.25 (0.30–1.24)	0.194
Effective optical zone			
Long axis (mm)	6.25 ± 0.59 (5.04–7.30)	5.48 ± 0.28 (4.94–5.96)	< 0.001
Short axis (mm)	5.16 ± 0.41 (4.30–6.29)	5.17 ± 0.27 (4.56–5.62)	0.965
Area (mm ²)	25.43 ± 3.86 (17.82–33.50)	22.29 ± 2.16 (17.95–25.89)	< 0.001
Centration (mm) ^d	0.30 ± 0.23 (0.02–1.01)	0.30 ± 0.15 (0.05–0.62)	0.909

Values in table are presented as the mean ± SD with the range given in parentheses

^a Programmed optical zone area is the circular area with a diameter corresponding to the programmed optical zone;

^b Programmed treatment zone is the diameter of the programmed optical zone + transition zone

^c Programmed treatment area is the circular area with a diameter corresponding to the programmed treatment zone

^d Centration is the distance from the corneal vertex to the centroid of functional optical zone

^e M-U test for non-normally distributed data

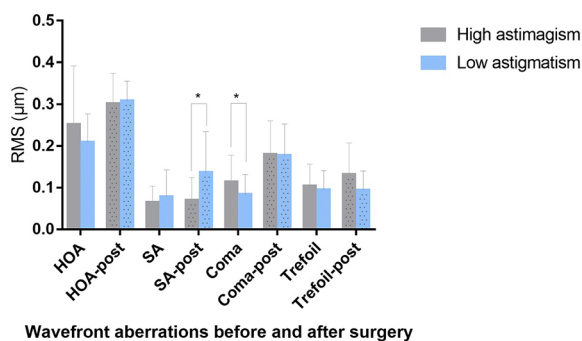


Fig. 3 Wavefront aberrations before and after surgery. *HOA* Higher order aberrations, *RMS* root mean square, *SA* spherical aberrations

vividly reflect how closely the corneal refractive surgical result corresponds to the intended correction. Previous studies have used a variety of methods to evaluate the FOZ, such as region-growing algorithms, ray-tracing analysis, and corneal power distribution analysis. Some of these assume the FOZ to be a circular area with optimal correction [7, 10]; however, the FOZ may not be circular, especially when cylinder correction increases. In this study, we delineated the FOZ outline as an elliptical shape and compared the parameters of the FOZs, including shape (long axis and short axis), area, and centration, between the HA group and the LA group at 6 months after SMILE. Additionally, we

Table 5 The correlation between the FOZ parameters and calculated changes of the higher order aberrations after surgery. [R value (P value)]

	AFOZ in High astigmatism group				AFOZ in Low astigmatism group			
	Long axis, mm	Short axis, mm	Area, mm ²	Centration, mm	Long axis, mm	Short axis, mm	Area, mm ²	Centration, mm
ΔHOAs (μm)	- 0.015 (0.938)	- 0.300 (0.113)	- 0.143 (0.458)	0.211 (0.272)	- 0.235 (0.246)	- 0.208 (0.211)	- 0.274 (0.096)	0.118 (0.482)
ΔSA (μm)	- 0.456 (0.013)*	- 0.434 (0.019)*	- 0.523 (0.004)*	0.303 (0.111)	- 0.661 (< 0.001)*	- 0.415 (0.010)*	- 0.602 (< 0.001)*	- 0.142 (0.393)
ΔComa (μm)	- 0.089 (0.645)	- 0.101 (0.602)	- 0.119 (0.537)	0.272 (0.154)	- 0.042 (0.800)	- 0.021 (0.901)	- 0.080 (0.633)	0.393 (0.015)*
ΔTrefoil (μm)	0.151 (0.433)	0.017 (0.928)	0.065 (0.739)	0.102 (0.599)	0.114 (0.497)	0.181 (0.277)	0.190 (0.253)	0.027 (0.874)

Δ = change from preoperative to postoperative; HOA = Higher order aberrations; SA = Spherical aberration

observed the subjective visual quality (refractive outcomes, aberrations, optical quality, and intraocular scattering) and quality of life in the two groups.

A consensus was reached in previous studies that the shrinking FOZ corresponds to the POZ [7, 9, 10, 13, 14, 19]. Thus, in some studies, the focus was on measuring the FOZ after different types of surgery. Hou et al. defined the FOZ as the area outlined by a change of zero diopter on the tangential curvature difference map of the Scheimpflug tomography system [9]. Likewise, Damgaard et al. located the FOZ using the refractive power map of the Pentacam (OCULUS Optikgeräte GmbH) by a region-growing algorithm [8]. The authors of both studies concluded that SMILE and FS-LASIK resulted in FOZ reduction, compared with POZ, and that SMILE created a larger FOZ than FS-LASIK. Other studies reported the FOZ after different attempts at correction by SMILE and LASIK. Several studies demonstrated that attempted myopic and hyperopic correction was negatively correlated with the FOZ after LASIK [7, 13, 14, 19]. Fu et al. drew a similar conclusion, reporting that the discrepancy between the FOZ and POZ increased with greater myopic attempted correction after SMILE [10].

In the current study, we observed that the FOZs were larger and more oblate in shape in the HA group than in the LA group, despite both groups having comparable average POZ and lenticule thickness. Almost all of the long axes observed in the study were horizontal axes, with the exception of two patients with 90° cylinder axis correction in the HA group. This finding is consistent with results from a previous study [9]. For astigmatism correction, the Visumax software (Carl Zeiss Meditec) adds a transition zone to convert the elliptical lenticule into a circle. However, the lenticule still has an oval posterior surface, which results in a smaller diameter of the cleavage plane along its steep axis than its flat axis [20]. Hou et al. speculated that local curvature changes and wound healing caused by the superior incision location may be related to the asymmetric change in horizontal and vertical orientation [9]. We calculated the change of corneal volume in the two groups and found that the corneal volume

decreases in the HA group were significantly smaller than those in the LA group ($2.36 \pm 1.21 \text{ mm}^3$ vs. $2.93 \pm 1.11 \text{ mm}^3$, $P = 0.048$). Although lenticule thickness, which is defined as the greatest thickness in the lenticule in the SMILE nomogram, was comparable in two groups, lenticule shape in the LA group was more regular with less difference between the steep and flat axes. Dupps and Roberts demonstrated a change in corneal topography after anterior lamellar disruption on intact donor eyes, reporting found an acute biomechanical expansion of the peripheral stromal matrix [21] that results in the peripheral stromal matrix collagen relaxing towards the limbal base, causing a central hyperopic shift. This peripheral response may decrease the area of the actual optimal correction, also referred to as the FOZ. The amount of sculpting volume determines just how great the corneal biomechanical change in the peripheral corneal stroma will be. We also evaluated the change in asphericity in the HA and LA groups before and after surgery and found that the ΔQ -value was positively correlated with the long axes ($r = 0.582$, $P < 0.001$) and area ($r = 0.406$, $P < 0.001$) of the FOZ. Holladay and Janes observed that an oblate shape of the cornea after excimer laser myopic correction results in a smaller FOZ than does an prolate shape [22]. Hou et al. also found a significantly positive correlation between the change in Q-value and EOZ in the SMILE and FS-LASIK groups [9]. Therefore, a smaller change in corneal contour, similar to a smaller change in corneal volume, may lead to the larger FOZ in the HA group.

Pupil diameter plays an important role in the visual quality, especially night vision. Boxer et al. demonstrated that greater aberrations presented when the pupil diameter exceeds the FOZ diameter [14], possibly explaining many patients' complaints of increased halos, glare, and burring in scotopic vision. In order to explore whether the visual quality outcomes were consistent with the FOZ, we measured wavefront aberrations, optical quality, and intraocular scattering. Only the increase in spherical aberrations was found to be associated with FOZ size. The increase in coma was

positively correlated with FOZ centration, which is in agreement with the results of Li et al. [23].

Intraocular scattering, which are independent of aberrations, also play an important role in retinal image quality, especially in patients who have undergone refractive surgery [24, 25]. Previous studies have found that although there is a transient decrease in intraocular scattering and optical quality in the early period after femtosecond lenticule extraction (FLEX) and SMILE, these negative changes gradually recover and are maintained at a stable level [25–27]. Jin et al. compared the optical quality between SMILE and FS-LASIK in which they analyzed the MTF curve and SR using the SIRIUS corneal topography system (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany) and concluded that while both two refractive procedures showed a comparable great improvement in optical quality at 3 mm pupil diameter, but better optical quality was observed at larger pupil diameter (6 mm) in the SMILE group, which might be beneficial for night vision [28]. In the current study, optical quality and intraocular scattering data were measured by a double-pass system at 6 months postoperatively. This study showed satisfied optical quality and intraocular scattering results in both groups; these results are consistent with those reported in the studies mentioned above,

The QIRC questionnaire was adopted for assessing the functional and emotional change in patients after surgery. It was used for patients with refractive correction by spectacles, contact lenses, and refractive surgery. Han et al. measured differences between patients with correction by spectacles and SMILE and concluded that patients who underwent SMILE had a better quality of life than individuals who wore spectacles [29]. Ang et al. evaluated vision-related quality of life (VRQoL) after SMILE and LASIK and found that VRQoL scores through the QIRC questionnaire were comparable after 3 months between patients who underwent SMILE and FS-LASIK, respectively. Our results also showed good results for the quality of life of the patients, with no difference found for patients with high astigmatism correction.

A limitation of this study is the relatively small sample size, which might influence the precision of the results. Future studies should include more groups with different classifications in terms of cylindrical diopters and axis. Corneal biomechanical properties should also be investigated to improve our understanding of the reason for FOZ change.

CONCLUSIONS

In conclusion, with a comparable optical design and attempted correction by SMILE, eyes with higher myopic astigmatism correction achieved larger FOZ and less spherical aberration induction than the eyes with lower myopic astigmatism. Subjective visual quality indicators, such as optical quality and intraocular scattering, and the quality of life were comparable in the two groups.

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Compliance with Ethics Guidelines. The study followed the requirements of medical ethics and all the patients provided written informed consent before surgery. All subjects were treated in accordance with the tenets of the Declaration of Helsinki. The Ethical

Committee of the Fudan University EENT Hospital Review Board approved the study protocol.

Data Availability. The datasets generated during and analyzed during the current study are available from the corresponding author on reasonable request.

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