

## Original Article

# Effect of a 2-mm incision on keratometry and visual quality after small-incision lenticule extraction

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**Abstract:** Objectives: To analyze the effects of corneal changes on astigmatism and keratometry (including cylinder power and corneal axis), and to evaluate the effect of a 2-mm corneal incision in small-incision lenticule extraction (SMILE) surgery by comparing visual quality parameters before and 1 year after SMILE. Methods: A total of 40 myopic eyes underwent myopia correction with SMILE. The axis of corneal curvature and the axes of flat (k1) and steep keratometric power (k2) were assessed preoperatively and 1 year postoperatively in different scan areas (3 mm, 5 mm, and 7 mm). Optical quality parameters were analyzed simultaneously. A paired *t*-test was used to compare preoperative and postoperative results, and a *P*-value < 0.05 was considered significant. Results: Corneal astigmatism, including the cylinder power and the corneal axis, did not change significantly (*P* > 0.05). Both k1 and k2 decreased after surgery. The k1 and k2 axes showed slight deflection, and the results in the 5-mm scan area were significantly different (k1: *P* = 0.045; k2: *P* = 0.000). The gap between k1 and k2 (k1-k2) showed significant change only in the 5-mm optical zone (*P* = 0.031). High-order aberrations significantly increased postoperatively in each scan area (*P* < 0.05), while coma and spherical aberration significantly changed in the larger optical zone. The point spread function changed significantly in the 7-mm optical zone after surgery (*P* = 0.011). Conclusion: A 2-mm incision is an appropriate technique in SMILE surgery that provides an ideal optical result in the central optical zone; however, it causes axial dispersion of keratometry and a decrease of visual quality. Hence, the flat k1 location is suggested for the SMILE incision.

**Keywords:** Corneal incision, SMILE, corneal astigmatism, keratometry, visual quality

## Introduction

Today, the femtosecond laser is widely used in refractive surgeries including small-incision lenticule extraction (SMILE), a flapless, minimally invasive, refractive procedure that has become a common treatment for myopia correction. Many studies have indicated that SMILE is a safe, predictable, and effective surgery [1-7], and it has been reported to result in fewer dry-eye symptoms and higher corneal sensitivity than alternative procedures [1, 8]. In addition, the corneal cap predictably demonstrated great regularity, reproducibility, and uniformity, and had only a small effect on refractive outcomes in the early phase [9]. The SMILE procedure causes slight loss of corneal sensitivity, minor effects on biomechanical properties, insignificant corneal deformation, and heals rapidly. These advantages have made it more appealing than LASIK surgery [10-13].

However, the cause of the SMILE advantages remains unknown. The key difference is a decrease in the incision length (2-4 mm), which is much smaller than the incisions used for previous LASIK surgery or femtosecond LASIK. We wondered if the differences were due to the smaller corneal incision. If the minimum 2-mm incision is appropriate, it should not affect corneal-related astigmatism or optical quality as a round, uniform lenticule is extracted from the cornea; thus, the corneal-related astigmatism should change only slightly after surgery. An obvious change in astigmatism after SMILE, regardless of the magnitude or axis, indicates that additional methods could be applied to improve upon the smaller incision and improve surgical outcomes. However, corneal curvature (k-value) should decrease after surgery because the cornea should be flatter after lenticule extraction, but the gap between k1 and k2 should not change with the k-value; axis mea-

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**Table 1.** Basic characteristic

Parameter	Before surgery		After surgery	
	Mean $\pm$ SD	Range	Mean $\pm$ SD	Range
UCVA	1/20	2/200~12/20	> 20/20	20/20~30/20
IOP	16.10 $\pm$ 2.73	9~20	10.45 $\pm$ 2.39	7~17
SE (D)	-4.96 $\pm$ 1.66		-0.23 $\pm$ 0.54	
BCVA	> 20/20	20/20~30/20		
CCT (um)	543.23 $\pm$ 18.52	507~583	459.00 $\pm$ 29.13	411~521

UCVA: uncorrected distance visual acuity. IOP: intraocular pressure. D: diopter. SE: Manifest spherical equivalent. BCVA: best corrected distance visual acuity. SD: standard deviation. CCT: Central corneal thickness.

surement would be required for verification. The aim of this study was to analyze these data and evaluate the effect of a 2-mm corneal incision in SMILE surgery.

### Methods

This retrospective study was approved by the West China Hospital of Sichuan University and conducted in accordance with the principles of the Declaration of Helsinki. Ethical permission was obtained from the Chinese Clinical Trial Registry: ChiCTR-ORh-17011030. Forty eligible patients who underwent SMILE to correct myopia between January 2014 and December 2014 at our refractive surgery center were included in this study. All patients were between 18 and 45 years of age, had only spherical refractive error (without astigmatism), and had undergone corneal topography preoperatively and 1 year postoperatively. Patients were included irrespective of sex. All surgical procedures were performed by the same surgeon (DYP).

All patients underwent SMILE procedures, and only myopic eyes were selected for analysis. If two eyes were treated, both eyes were included in the analysis. If one eye was treated for myopia and the other eye had a myopic astigmatism, only the myopic eye was included in the analysis.

The VisuMax Femtosecond Laser System (Carl Zeiss, Oberkochen, Germany) was used to perform SMILE surgery with a repetition rate of 500 kHz and pulse energy of 130 nJ. The surgical procedure was previously described by Sekundo et al. [1]. The optic area was 6.5 mm, and the lenticule diameter was 7.5 mm. The incision length was 2 mm and located at the 120° axis position.

The visual quality could be evaluated by point spread function (PSF), high-order aberrations (HOAs), spherical aberration, or coma. Corneal topography was measured by a rotating Scheimpflug camera (Sirius, Costruzione Strumenti Oftalmici, Italy) that had been verified as consistent with the keratometer [14]. Values for

k1 and k2 in optical zones of 3 mm, 5 mm, and 7 mm were obtained using the rotating camera. Any cornea-related astigmatism was evaluated by cylinder power in diopters and corneal axis.

Statistical analysis was performed using SPSS Statistics for Windows, Version 19.0 (IBM, Corp., Armonk, NY, USA). A paired *t*-test was used to compare preoperative and postoperative results. Scatter plots showed the distribution of *k*-values (including *k*1 and *k*2 values) and were created using Origin (OriginLab Corporation, Northampton, MA, USA). All values are presented as mean  $\pm$  standard deviation. A *P*-value < 0.05 was considered significant.

### Results

#### Study population

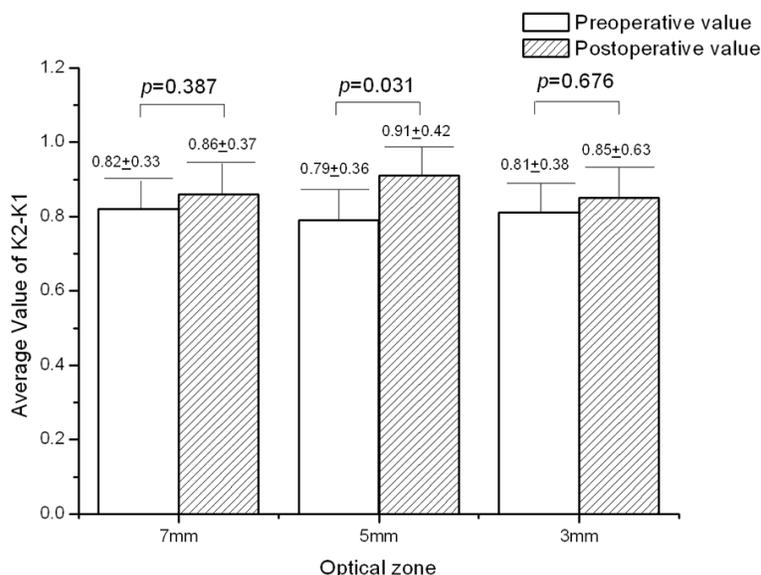
This study included 40 eyes from 31 patients (17 male and 14 female patients). Both eyes of nine patients and one eye of 22 patients were included. The mean age was 24.13  $\pm$  7.17 years (range, 18-48 years). **Table 1** shows the preoperative and postoperative patient characteristics. All patients had only spherical corneas preoperatively (without astigmatism), and the target refractive station for all patients was emmetropia. Additional parameters are shown in **Table 1**.

All of the treated eyes achieved an uncorrected visual acuity (UCVA) of 20/20, and corneal curvatures had decreased 1 year postoperatively, which demonstrated that visual acuity was stable over a long observation period. All eyes had a best corrected visual acuity (BCVA) of 20/20 or better preoperatively and a UCVA of 20/20 or better 1 year postoperatively (**Table 1**).

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**Table 2.** Description of corneal astigmatism in the measuring optical diameter of 3 mm, 5 mm and 7 mm

	Zone	Preoperative value	Postoperative value	Difference	t	P
Cylinder diopter (D)	3 mm	-0.7640 ± 0.5120	-0.7910 ± 0.4873	0.0270 ± 0.4815	0.355	0.725
	5 mm	-0.8787 ± 0.3540	-0.7982 ± 0.4551	-0.0805 ± 0.3510	-1.432	0.160
	7 mm	-0.8650 ± 0.7252	-0.9028 ± 0.3665	0.3775 ± 0.6691	0.357	0.723
Axis	3 mm	98.4250 ± 80.3770	92.2000 ± 79.2203	6.2250 ± 60.0002	0.725	0.516
	5 mm	99.8462 ± 81.3244	109.5897 ± 78.6678	-9.7436 ± 59.8320	-1.130	0.265
	7 mm	114.6695 ± 80.1612	108.5000 ± 80.2943	6.1695 ± 61.7102	0.723	0.531



**Figure 1.** Evaluation of average value of difference between k1 and k2 in preoperative and postoperative time.

### The corneal astigmatism and the corneal axis

There are mild variations in corneal-related astigmatism at different optical diameters (Table 2). The results showed no significant differences between preoperative and postoperative values, as the axis of astigmatism is not significantly deflected. These data were collected using the Sirius camera, which revealed that a 2-mm SMILE incision did not increase corneal-related astigmatism or alter light reflection from the cornea.

The postoperative k1-k2 gap increased slightly compared to the preoperative value, but there was no significant change in the 3- to 7-mm zone (Figure 1).

The scatter plots depicted in Figure 2A show the distribution of the preoperative (blank) and postoperative (black) axis degree of k1 and k2

values in the 3-mm optic area. The scatter plots in Figure 2B provide the preoperative and postoperative distribution in the 5-mm optic area. Figure 2C gives the preoperative and postoperative distribution in the 7-mm optic area.

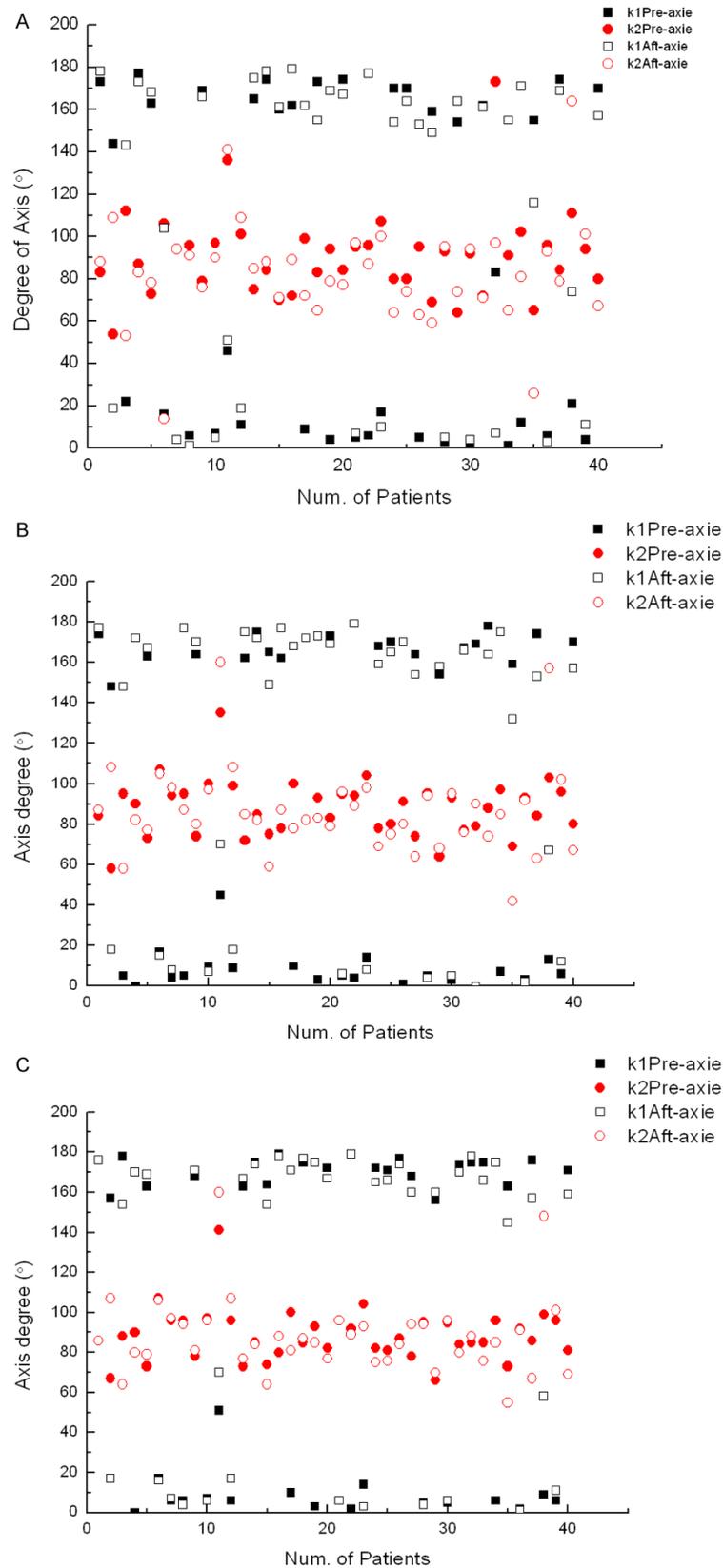
The scatter plot suggested that k1 was distributed horizontally and k2 was distributed vertically. The overall trend of the keratometric location did not definitively change after surgery.

In the 7-mm optical area, the k1-k2 value increased from  $0.82 \pm 0.33$  before surgery to  $0.86 \pm 0.37$  after surgery. The difference was not significant ( $t = -0.876$ ;  $P = 0.387$ ).

In the 5-mm optical area, the k1-k2 value increased from  $0.79 \pm 0.36$  to  $0.91 \pm 0.42$  after surgery; the difference was significant ( $t = -2.233$ ;  $P = 0.031^*$ ). The k1-k2 value in the 3-mm optical area increased from  $0.81 \pm 0.38$  before surgery to  $0.85 \pm 0.63$  after surgery; the difference was not significant ( $t = -0.422$ ,  $P = 0.676$ ) (Figure 1; Table 3).

In the 7-mm optical area, the preoperative k1 axis was  $97.73 \pm 81.82$ ; it increased to  $114.58 \pm 74.49$  after surgery, but the difference was not significant ( $t = -1.677$ ,  $P = 0.101$ ). In the 5-mm optical area, the preoperative axis was  $87.50 \pm 80.51$ , which significantly increased to  $113.45 \pm 73.29$  after surgery ( $t = -2.068$ ,  $P = 0.045^*$ ). In the 3-mm optic area, the axis was  $85.95 \pm 78.20$  before surgery and significantly increased to  $109.70 \pm 72.29$  after surgery ( $t = -2.223$ ,  $P = 0.032^*$ ). Two results of the kerato-

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**Figure 2.** Distribution of the axis degree of k1 and k2 in different optical zone. A: 3 mm; B: 5 mm; C: 7 mm.

metric axis showed significant changes. For the k2 value, the axis was  $88.50 \pm 13.00$  pre-operatively and  $88.18 \pm 19.51$  postoperatively in the 7-mm optical area ( $t = 0.149$ ,  $P = 0.882$ ),  $43.74 \pm 1.40$  and  $40.13 \pm 1.77$  in the 5-mm optical area ( $t = 20.767$ ,  $P = 0.000^*$ ), and  $90.45 \pm 20.46$  and  $82.58 \pm 25.24$  in the 3-mm area ( $t = 1.872$ ,  $P = 0.069$ ). No result showed significant changes in the corneal astigmatism axis (**Figure 3**).

### Visual quality

**Table 4** shows corneal-related optical quality parameters. The comparison results reflect parameters of preoperative and postoperative visual quality, including coma, spherical aberration, HOAs, and PSF. There was no significant difference in preoperative and postoperative corneal cylinder power or corneal axis in any of the optical areas measured ( $P > 0.05$ ). HOAs and the coma and spherical aberration values in the 5-mm and 7-mm optical areas increased significantly after SMILE ( $P < 0.05$ ), while the central 3-mm optical area value did not ( $P > 0.05$ ). PSF increased after the optical area was enlarged, but the difference was only significant in the 7-mm optical area ( $P = 0.011$ ).

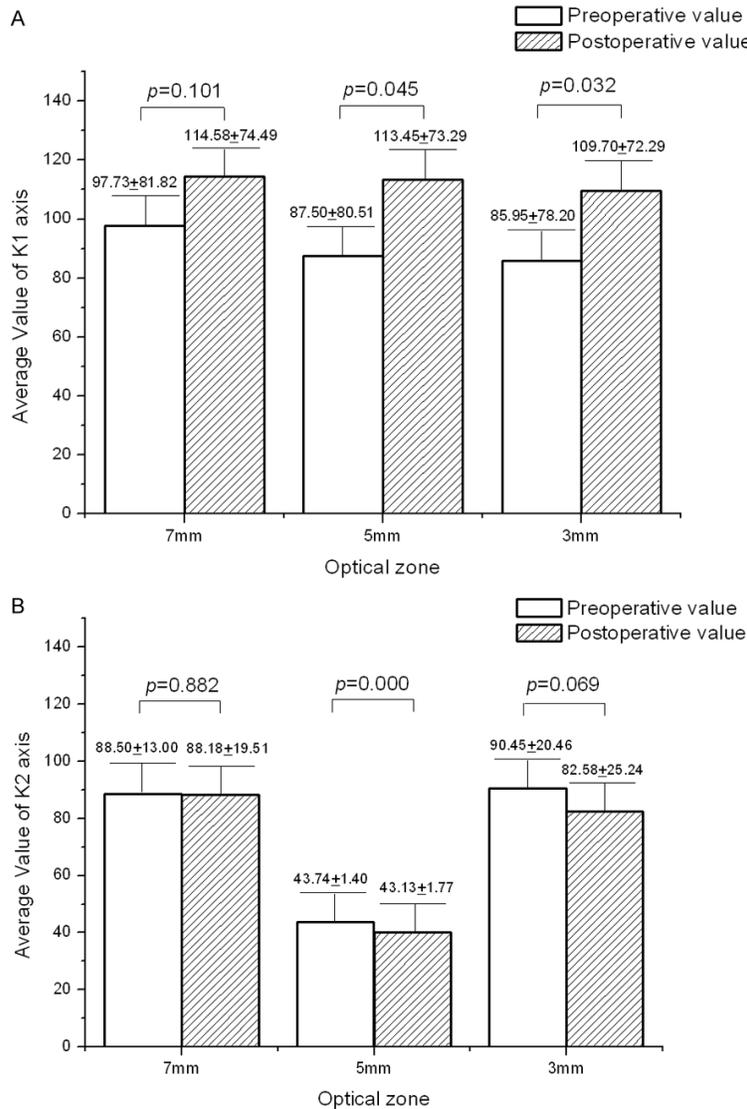
### Discussion

In the current study, we evaluated the incision of SMILE for keratometry and optical quality in different optical areas. We found that the keratometry changed in the 5-mm optical area and the optical quality in larger scan areas decreased. Recent developments in laser platforms and surgical

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**Table 3.** Description of k1 and k2, and their axis location preoperatively and one year postoperatively

	Preoperative k value			Postoperative k value		
	k2-k1	k1	k2	k2-k1	k1	k2
	value	axis	axis	value	axis	axis
7 mm	0.82 ± 0.33	97.73 ± 81.82	88.50 ± 13.00	0.86 ± 0.37	114.58 ± 74.49	88.18 ± 19.51
5 mm	0.79 ± 0.36	87.50 ± 80.51	43.74 ± 1.40	0.91 ± 0.42	113.45 ± 73.29	40.13 ± 1.77
3 mm	0.81 ± 0.38	85.95 ± 78.20	90.45 ± 20.46	0.85 ± 0.63	109.70 ± 72.29	82.58 ± 25.24



**Figure 3.** A: Shows the difference of preoperative and postoperative k1 value axis. B: Shows the difference of preoperative and postoperative k2 value axis.

techniques have made SMILE a revolutionary corneal refractive surgery [15-17]. In this study, basic visual parameters including UCVA, BCVA, and intraocular pressure were described before and after 2 mm-incision SMILE surgery, and

postoperative vision was significantly improved. These results agree with many other studies [3, 5, 6]. We included patients with myopia without ocular astigmatism in order to extract a positive circular lenticule from the corneal stroma, so the disparity between the corneal axes should not have changed. Corneal astigmatism and keratometry were used to determine the results. Measurements were acquired using the Sirius camera and showed good repeatability in the anterior segment measurements for both normal eyes and post-surgical eyes [18-20]. To our knowledge, this is the first extended observation for myopic SMILE surgery (without astigmatism) and a comparative, deep analysis of keratometry of different scan areas that were used to evaluate the SMILE incisions.

Topographic cylindrical value, as one of corneal topographical parameters, reflects the astigmatism of the cornea and can be measured using a rotating camera [21]. In this study, the variation of the cylinder power measured in 3-mm, 5-mm, and 7-mm scan areas was less than 0.1 diopter, which indicates that corneal astigmatism changed slightly. The results suggest that a 2-mm SMILE incision does not increase total corneal astigmatism, and this surgery may be used to create a lenticule with a high degree of homogeneity. In addition, the k1-k2 gap showed a difference

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**Table 4.** Shows corneal related optical quality parameters in different optical area from Sirius

		Preoperative value	Postoperative value	Difference	t	P
HOAs	3 mm	0.0615 ± 0.0322	0.0865 ± 0.0409	-0.0250 ± 0.0473	-3.340	0.002
	5 mm	0.2275 ± 0.0688	0.3553 ± 0.3496	-0.1278 ± 0.3564	-2.267	0.029
	7 mm	0.7078 ± 0.2756	1.1915 ± 0.3589	-0.4837 ± 0.4735	-6.461	0.000
SA	3 mm	0.0153 ± 0.0157	0.0155 ± 0.0200	-0.0003 ± 0.0220	-0.072	0.943
	5 mm	-0.1303 ± 0.0457	-0.1738 ± 0.0877	-0.0435 ± 0.1022	2.692	0.010
	7 mm	-0.4230 ± 0.1446	-0.9170 ± 0.3236	0.4940 ± 0.3619	8.633	0.000
coma	3 mm	0.0258 ± 0.1693	0.0318 ± 0.0242	-0.0060 ± 0.0277	-0.072	0.943
	5 mm	0.1220 ± 0.0654	0.1790 ± 0.0997	-0.0570 ± 0.1109	-3.250	0.002
	7 mm	0.3903 ± 0.1873	0.6663 ± 0.4274	-0.2760 ± 0.4392	-3.974	0.000
PSF	3 mm	0.3640 ± 0.1526	0.3231 ± 0.1734	0.3231 ± 0.1734	1.311	0.197
	5 mm	0.4907 ± 0.1526	0.4800 ± 0.2795	0.1066 ± 0.1446	0.461	0.648
	7 mm	1.0895 ± 0.7075	1.3225 ± 0.7484	-0.2330 ± 0.5488	-2.685	0.011

HOAs: high-order aberration SA: spherical aberration.

between the steepest axis and flattest axis, reflecting the degree of corneal irregularity. A significant difference occurred only in the 5-mm scan area, because corneal power increased from the pupil center to the periphery when the ring size was greater than 4 mm. In SMILE surgery with a 6.5-mm lenticule, the postoperative corneal power of the individual ring was higher when the ring size was greater than 5 mm. However, Qian et al. [22] provided only the total k-value from a Pantacam. Similarly, Hary et al. [23] evaluated the k-value accuracy after myopia LASIK at 1, 2, 3, 4, and 4.5 mm using a Pantacam and suggested use of a 4-mm equivalent k reading before cataract surgery, but the exact role of the k-value reported by the Sirius camera was not properly evaluated. In the present study, the difference between k1 and k2 was small, and only the value of the 5-mm optical zone showed a significant difference. However, as it showed an insignificant difference between the 3-mm and 7-mm optical zones, it did not affect the central 3-mm area or general astigmatism. It also suggested yet again that the corneal-related astigmatism should not significantly change compared to the preoperative value.

On the astigmatism axis, the counterclockwise rotation of the k1 axis and the average k1 axis from approximately 90° to approximately 110° revealed that it was near the incision axis (120°), even when k1 was distributed horizontally. We speculate that this is related to incision healing after surgery. Even when the width of the incision was only 2 mm, it affected the

cylinder location along the flat axis. The k2 axis was located at approximate positions that remained stable before and 1 year after SMILE surgery. The complete change trends were not significant in the 7-mm optical zone. The central variation of k2 was not significant in the 3-mm optical zone. Therefore, we determined that the location of the SMILE incision might have affected the axial dispersion of the corneal curvature after refractive surgery using a 2-mm incision. If the incision was made on the k1 axis, the postoperative keratometry would be closer to the preoperative value. It is suggested that the surgical incision design should refer to the parameters of the k1 value.

Several indexes were used to demonstrate visual quality, including HOAs, spherical aberration, coma, and PSF. Visual quality decreased as the HOAs increased after SMILE surgery; as the measuring diameter expanded, the variation became more obvious. Therefore, central optical imaging is superior to peripheral imaging. The same results were obtained through variation of spherical aberration and coma. Objective visual quality could be comprehensively demonstrated using PSF, including wave front aberration and diffraction [24]. PSF reflected a poor result in the large optical zone, while the PSF Strehl ratio increased by  $0.2330 \pm 0.5488$ , and the result revealed a significant difference between preoperative and postoperative PSF (Table 4). All of these results may cause night vision blurring, halo, or other visual dissatisfaction for patients with large pupils according to the HOA change. The previous

study reported that SMILE anticipated slow visual recovery after surgery [8], which agrees with our previous study [25] and is related to incision characteristics according to the present study.

After SMILE surgery, the corneal stroma in the central optical region was usually uniform and smooth. The corneal curvature during SMILE decreased on each axis; hence, the corneal astigmatism did not significantly change. In addition, in a larger optical area, the total variety of the ectomy result was not significantly different after surgery. It is important that the corneal astigmatism and its axis did not significantly change, which reflects good regularity of the cornea and the lenticule during surgery. SMILE with a 2-mm incision provided ideal central vision. The visual quality of the total optical zone decreased, which may have resulted from imbalanced corneal healing of the incision and lenticule edge [26], but it did not significantly affect central visual quality.

We discovered that a 2-mm incision enables formation of a comparative uniform lenticule during SMILE surgery and prevents central visual quality decrease, but axial dispersion of flat keratometry and visual quality decreased on peripheral area and affected postoperative outcomes. This study enrolled 40 subjects and observed them for 1 year. Future studies with a larger sample size are needed to determine the correlation between corneal incision and surgical outcome. Our results show for the first time that the k1 axis is closely rotated to the incision location; placement of the incision at the flat k axis could be considered for future SMILE surgeries. Moreover, we cannot exclude the possibility of smaller incisions or new revolutions in refractive surgery. Additional studies may explain why the general optical quality and central 3-mm optical quality did not change even though the postoperative astigmatism axis was deflected.

In summary, a standard incision in SMILE can help avoid increased total corneal astigmatism and produces ideal central optical quality after surgery. However, the results of this study strongly indicate that 120° is inappropriate for the SMILE incision; the location should be adjusted to a location near the k1 axis.

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### Disclosure of conflict of interest

None.

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