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ORIGINAL RESEARCH

Short-Term Impact of Different Corneal Incision Positions on Postoperative Astigmatism and Visual Quality After SMILE Surgery

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ABSTRACT

Introduction: This study aimed to evaluate the short-term impact of different incision positions on astigmatism and visual quality after small incision lenticule extraction (SMILE) surgery.

Methods: This prospective study enrolled patients who decided to have SMILE to correct myopia. Patients were randomly allocated into three groups of different incision positions (group A, B, and C with incision position at 90°, 120°, and 150° respectively). Preoperative and postoperative visual acuity, spherical equivalent, and high-order aberrations (HOAs) were measured and compared among groups. Astigmatism was analyzed with the ASSORT Group Analysis Calculator based on the Alpins method.

Results: A total of 148 eyes were included for analysis (48 eyes in group A, 50 eyes in group B, and 50 eyes in group C). At 1 month postoperatively, the mean uncorrected distance visual acuity (UDVA) logMAR in group A, B, and C was − 0.03, − 0.03, and − 0.04, respectively. The mean corrected distance visual acuity (CDVA) logMAR in group A, B, and C was − 0.03, − 0.04, and − 0.04, respectively ($P > 0.05$). The mean postoperative spherical equivalent (SE) values were − 0.01 ± 0.38, − 0.07 ± 0.39, and − 0.16 ± 0.49 (D) in group A, B, and C, respectively ($P > 0.05$). There was no statistically significant difference in preoperative and postoperative magnitude of astigmatism among different groups ($P > 0.05$). Significant differences were found in the distribution of astigmatism axis among the three groups at 1 day ($P = 0.02$) and 1 week ($P = 0.02$) postoperatively. However, such differences were no longer significant at 1 month after surgery ($P > 0.05$). No significant differences were found in HOAs among different groups 1 month after surgery ($P > 0.05$).

Conclusion: Different incision positions have no effect on postoperative astigmatism and visual quality 1 month after SMILE surgery, though differences were found in the distribution of the astigmatism axis within 1 week after the surgery.

Keywords: Corneal incision; Small incision lenticule extraction; High-order aberration; Surgically induced astigmatism

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Key Summary Points

Small incision lenticule extraction (SMILE) has been widely adopted for treating myopia and myopic astigmatism, and different incision positions might be set during surgery for personal preference.

This prospective study evaluated the influence of incision position on visual quality and astigmatism after SMILE, and the results showed that different incision positions had no effect on postoperative astigmatism and visual quality as early as 1 month after surgery.

The incision position might be individually designed on the basis of the specific situation during SMILE surgery.

INTRODUCTION

Small incision lenticule extraction (SMILE) has been widely accepted in treating myopia with high efficacy and safety [1, 2]. SMILE surgery does not require the creation of a flap, which has several advantages including small incision, more subepithelial nerve retention, biomechanical stability, and fewer postoperative dry eye symptoms [3–5]. However, the small incision during SMILE surgery makes it technically more challenging than flap-based corneal ablation procedures [6, 7].

Standard SMILE procedure involves the creation of intrastromal lenticule using femtosecond laser, and extraction of the refractive lenticule through a peripheral incision of 2–5 mm width. Different surgeons may choose different incision positions through the SMILE platform for personal preference [8, 9]. However, the effect of different incision positions on postoperative visual qualities after SMILE surgery needs to be elucidated. The purpose of this study is to evaluate the short-term influence of incision position on astigmatism and visual quality after SMILE procedure.

METHODS

This prospective study recruited patients who voluntarily accept SMILE surgery for myopia or myopic astigmatism correction between July 2021 and August 2022 in the Department of Ophthalmology, Peking Union Medical College Hospital (PUMCH). The study was approved by the Institutional Ethics Committee of PUMCH (ZS-3516) and registered at chictr.org.cn (Registration number ChiCTR2000039272). The study sample size was based on the postoperative uncorrected distance visual acuity (UCVA). In this study, a UCVA difference of 0.096 logMAR will be considered clinically meaningful and the standard deviation of postoperative UCVA is about 0.12 based on previous studies [10, 11]; thus, a total sample size of 117 eyes (39 eyes per group) will be needed for 5% significance and 80% power. Participants were randomly allocated to groups A–C in a ratio of 1:1:1. The randomization sequence was generated using an internet-based randomization tool provided by the China clinical trial registration center (http://www.medresman.org/login.aspx). The tenets of the Declaration of Helsinki were followed throughout the study and informed consent was obtained from all patients. Preoperative corrected distance visual acuity (CDVA) was 16/20 or better in all eyes, and the target postoperative spherical equivalent (SE) was plano. Patients with myopia SE ≥ -10.00 D and astigmatism ≥ -2.00 D were included in the study.

Surgical Techniques

SMILE procedures were performed by one experienced surgeon using the VisuMax femtosecond laser platform (Carl Zeiss, Meditec, Jena, Germany). Patients were randomly allocated into three groups with different incision positions: group A (90°), group B (120°), and group C (150°). Femtosecond scanning was performed with a repetition rate of 500 kHz and a pulse energy of 130 nJ using 4.5 μm spot/track distance on lenticule and cap, and 2 μm spot/-track distance on lenticule side cut. The intended cap thickness was set to 120 μm, the

diameter of lenticule was set to 6.5 mm, and the cap diameter 7.6 mm in all cases. The width of the incision was set to 2 mm at different positions. The lenticule was subsequently dissected and removed from the microincision. All surgical parameters were identical except the incision position among different groups.

Preoperative and Postoperative Examinations

All patients underwent thorough preoperative and postoperative examinations, including uncorrected distance visual acuity (UDVA), CDVA, subjective refraction, non-contact intraocular pressure, slit-lamp microscopy, central corneal thickness (AL-3000, Tomey, Nagoya, Japan), corneal topography (PentacamHR, Oculus, Germany), and fundus examination. Follow-up examinations were performed at 1 day, 1 week, and 1 month postoperatively. The safety index was defined as CDVA after treatment divided by CDVA before treatment (CDVA post/ CDVA pre). The efficacy index was defined as UCVA after treatment divided by CDVA before treatment (UCVA post/ CDVA pre). Short-term was defined as the period within 1 month after surgery. Visual quality contains subjective and objective visual quality, and only objective visual quality including visual acuity, and higher-order aberrations were evaluated in our study.

Objective visual quality was evaluated by iTrace system (Tracey, USA) preoperatively and 1 month after surgery by the same technician. A pupil diameter of 4.0 mm was set with the iTrace analyzer to get the data of total high-order aberrations (HOAs), corneal HOAs, coma, trefoil, and spherical aberration (SA).

Astigmatic Vector Analysis

Vector analysis of the manifest astigmatism was done with the ASSORT Group Analysis Calculator (ASSORT Pty. Ltd.) based on the Alpins method [12]. The following vectors were calculated: target-induced astigmatism (TIA), which represents the intended change in astigmatism; surgically induced astigmatism (SIA), which represents the actual change achieved in astigmatism; difference vector (DV), which represents the extra change required to achieve the intended target; and correction index (CI), which is the ratio between SIA magnitude and TIA magnitude.

Table 1 Baseline characteristics of different incision position subgroups

Groups	Group A	Group B	Group C	*P* value
N (eyes)	48	50	50	
Age (years)	29.7 ± 9.2	27 ± 4.9	26.2 ± 7.3	0.23
Sex (M/F)	14:10	15:10	15:10	0.99
CCT (μm)	542 ± 27	556 ± 30	542 ± 37	0.10
Kmean (D)	43.1 ± 1.0	43.7 ± 1.2	43.1 ± 1.1	0.07
Pre-SE	− 5.23 ± 1.8	− 5.54 ± 1.6	− 5.47 ± 1.5	0.61
Sphere	− 4.85 ± 1.86	− 5.20 ± 1.58	− 4.98 ± 1.51	0.18
Astigmatism	0.78 ± 0.49	0.76 ± 0.43	0.78 ± 0.55	0.70

Group A, incision position at 90°; group B, incision position at 120°; group C, incision position at 150°
CCT central corneal thickness, *Kmean* mean keratometry, *Pre-SE* preoperative spherical equivalent

Statistical Analysis

Statistical analysis was performed with SPSS for Mac (SPSS 26, IBM Corporation, New York, USA). Differences of visual acuity, central corneal thickness (CCT), keratometry, SE, and HOAs among different groups were compared using a mixed-effects model with eyes as random effects. Chi-squared test was used to test for differences in the distribution of sex and the astigmatism axis. A P value less than 0.05 was considered statistically significant.

RESULTS

A total of 148 eyes of 74 patients with a mean age of 27.6 ± 7.4 years old were included for analysis. Mean preoperative corneal thickness was 547 ± 33 μm (range 481–661 μm), and average keratometry was 43.29 ± 1.14 (D) (range 40.37–46.14 D). The mean preoperative SE was − 5.42 ± 1.64 μm (range − 9.0 to − 1.75 D). The baseline characteristics of different incision position groups are shown in Table 1. There was no statistical difference among those three groups in preoperative corneal thickness, keratometry, SE, CDVA, and total HOAs.

Visual Acuity and Refractive Outcomes

At 1 month after the surgery, the efficacy index was 1.02 ± 0.09, 1.02 ± 0.07, and 1.02 ± 0.14 in group A, B, and C, respectively ($P > 0.05$). The safety index was 1.04 ± 0.11, 1.04 ± 0.08, and 1.04 ± 0.12 in group A, B, and C, respectively ($P > 0.05$). As shown in Fig. 1, no eyes lost two or more lines of CDVA in all groups. All eyes gained 20/25 or more UCVA at 1 month after the surgery. The mean UDVA logMAR in group A, B, and C was − 0.03, − 0.03, and − 0.04, respectively. The mean CDVA logMAR in group A, B, and C was − 0.03, − 0.04, and − 0.04, respectively, at 1 month postoperatively ($P > 0.05$). The mean postoperative SE values were − 0.01 ± 0.38, − 0.07 ± 0.39, and − 0.16 ± 0.49 (D) in group A, B, and C, respectively ($P > 0.05$) (Table 2). No statistically significant difference was found in CDVA among different groups 1 month postoperatively ($P > 0.05$, Fig. 1).

Astigmatism Correction

Figure 2 represents the magnitude and axis of preoperative and postoperative (1 month) astigmatism in different groups using the ASSORT Group Analysis Calculator based on the Alpins method. Mean TIA was 0.48 × 176°, 0.48 × 178°, and 0.58 × 180° in group A, B, and C, respectively ($P > 0.05$). Mean SIA was 0.42 × 177°, 0.38 × 178°, and 0.57 × 2° in group A, B, and C, respectively ($P > 0.05$). No significant difference was found in the mean DV among different groups 1 month postoperatively ($P > 0.05$). Group A and group B showed slightly undercorrected tendency (CI = 0.97 in group A, CI = 0.96 in group B), while group C was slightly overcorrected (CI = 1.01).

As shown in Table 3, there was no statistically significant difference in preoperative and postoperative magnitude of astigmatism among different groups ($P > 0.05$). However, significant differences were found in the distribution of astigmatism axis among the three groups at postoperative day 1 ($P = 0.02$) and week ($P = 0.02$). Specifically, group A had slightly higher proportion of ATR than the other two groups at 1 day and 1 week postoperatively; group B had higher proportion of WTR than the other two groups at 1 day and 1 week; and group C had higher proportion of oblique astigmatism than the other two groups at 1 day and 1 week postoperatively. Such differences were no longer significant at 1 month after the surgery ($P > 0.05$) (Table 3).

Visual Quality Evaluation

Table 4 presents the preoperative and postoperative high-order aberrations among different incision position groups. No significant differences were found in total HOAs, coma, spherical aberrations, or trefoil among different groups before the surgery, as well as 1 month after the surgery (Table 4, all $P > 0.05$).

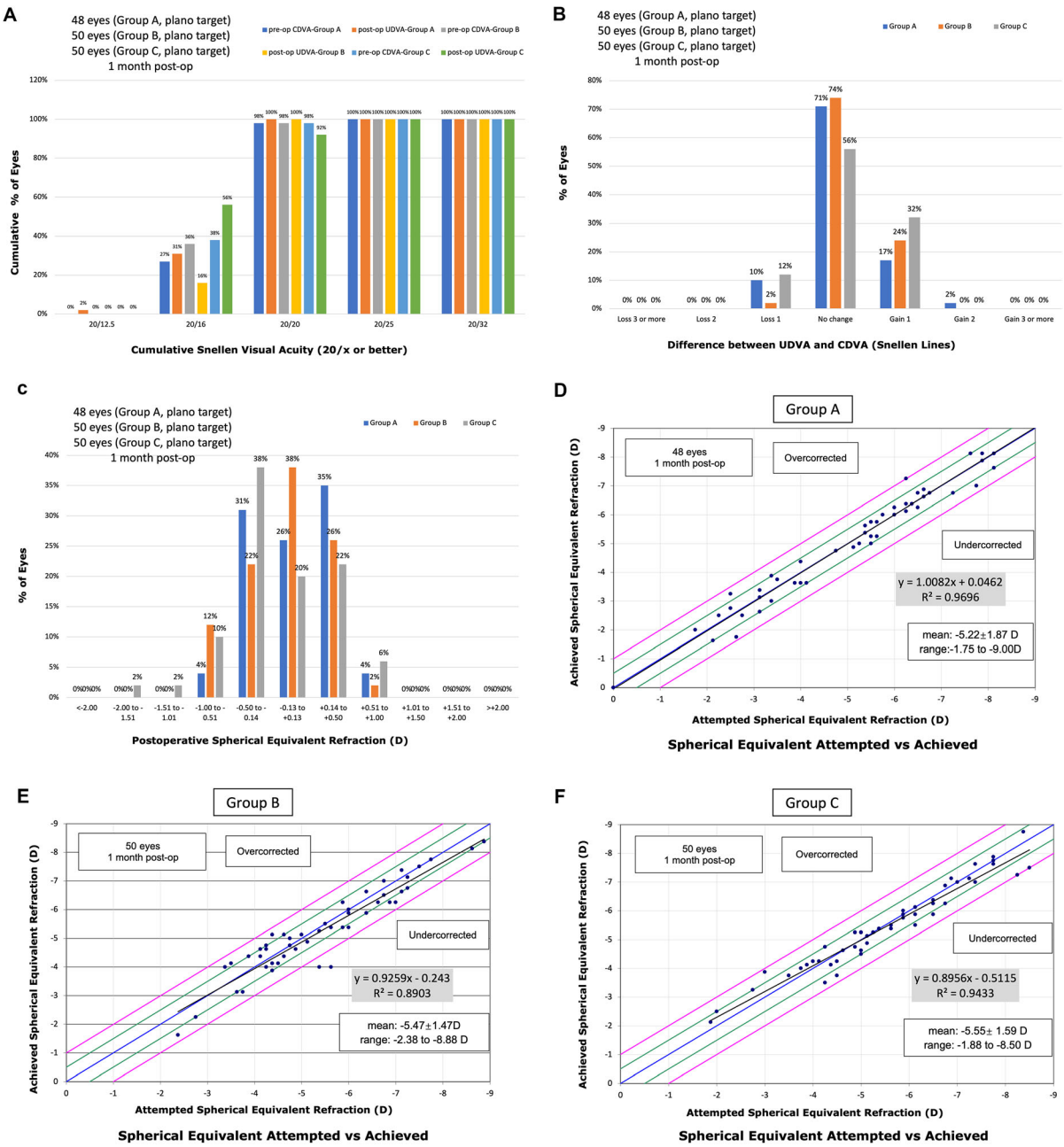


Fig. 1 Visual acuity and refraction outcomes in different groups. **a–c** Visual acuity and spherical equivalent refraction in group A, B, and C. Attempted vs achieved spherical equivalent in **d** group A, **e** group B, and **f** group C. Group A, incision position at 90°; group B, incision position at 120°; group C, incision position at 150°. *CDVA* corrected distance visual acuity, *UDVA* uncorrected distance visual acuity

DISCUSSION

The VisuMax femtosecond laser platform provides surgeons with different incision position options, which could be set individually according to the specific situation. In most cases, the incisions are placed superiorly because the cover of the eyelid can prevent pathogens from entering the stroma pocket through the incision, thus increasing the safety

Table 2 Postoperative visual acuity and spherical equivalent of different incision position subgroups

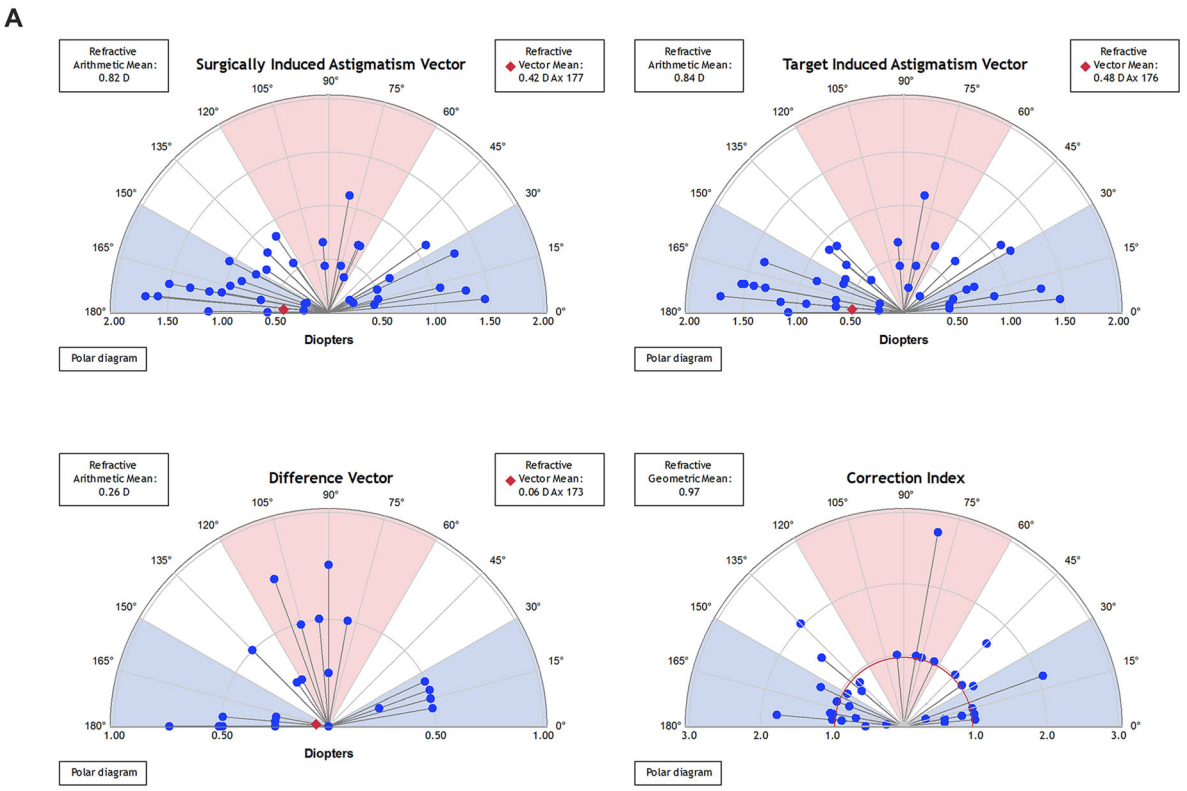
	Follow-up	Group A	Group B	Group C	*p*
UDVA	1 day post operation	− 0.03 ± 0.05	− 0.03 ± 0.05	− 0.03 ± 0.05	0.82
	1 week post operation	− 0.05 ± 0.05	− 0.04 ± 0.05	− 0.03 ± 0.05	0.17
	1 month post operation	− 0.03 ± 0.04	− 0.03 ± 0.04	− 0.04 ± 0.05	0.52
CDVA	1 day post operation	− 0.03 ± 0.04	− 0.04 ± 0.05	− 0.03 ± 0.06	0.66
	1 week post operation	− 0.05 ± 0.05	− 0.04 ± 0.06	− 0.04 ± 0.05	0.45
	1 month post operation	− 0.03 ± 0.05	− 0.04 ± 0.04	− 0.04 ± 0.04	0.40
SE	1 day post operation	− 0.06 ± 0.43	− 0.13 ± 0.44	− 0.27 ± 0.60	0.11
	1 week post operation	− 0.12 ± 0.36	− 0.11 ± 0.37	− 0.22 ± 0.44	0.24
	1 month post operation	− 0.01 ± 0.38	− 0.07 ± 0.38	− 0.16 ± 0.48	0.16

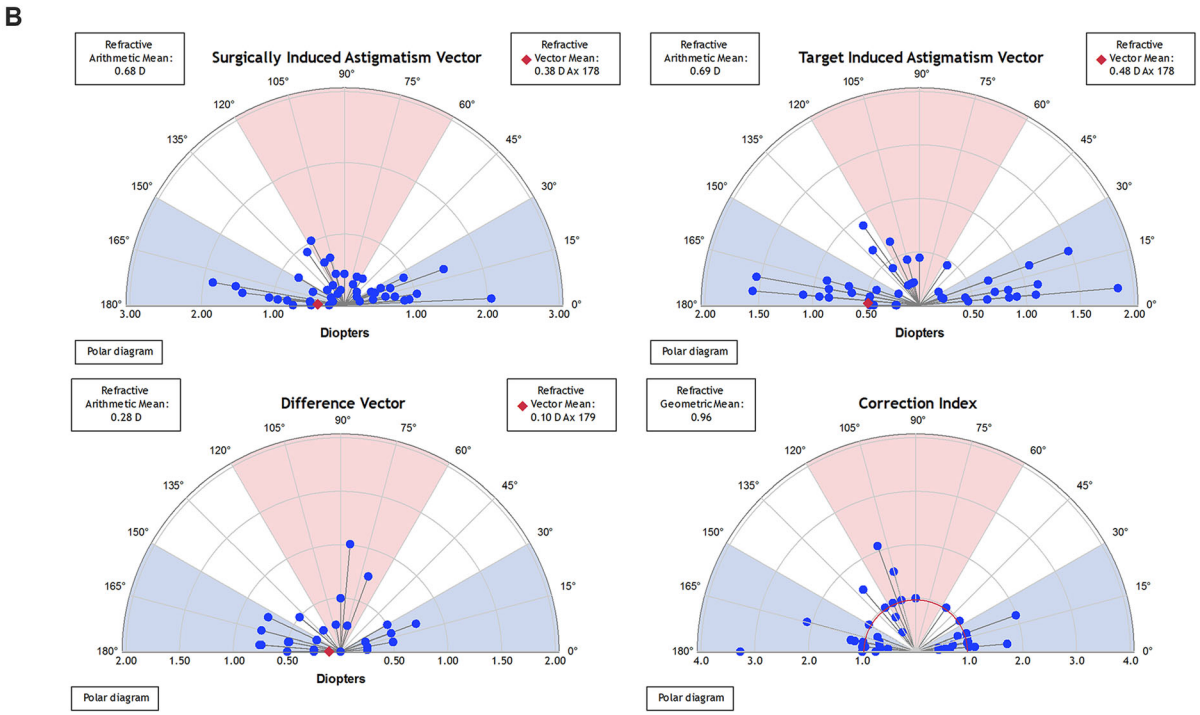
Group A, incision position at 90°; group B, incision position at 120°; group C, incision position at 150°
UDVA uncorrected distance visual acuity, *CDVA* corrected distance visual acuity, *SE* preoperative spherical equivalent

of SMILE surgery. However, for patients who had a high eyebrow arch, superior incision may increase the difficulty of the operation and the incidence of intraoperative complications, such as corneal flap perforation and incision tear. To make the surgery safer and easier to perform, it has been suggested to set the incision position to around 145°, but this may cause concern for surgically induced astigmatism during the corneal incision healing process [13]. Our study found that different incision positions had no effect on postoperative astigmatism and visual quality 1 month after SMILE, suggesting that the position of incision could be individually designed on the basis of patients' characteristics and surgeons' preference.

A considerable amount of literature has been published on evaluating the safety and effectiveness of SMILE in correcting ametropia [14]. In the current study, we also found that SMILE provided good safety and effectiveness in correcting myopia and myopic astigmatism, and there was no statistical difference in postoperative visual acuity and refractions among different side-cut position groups. No intraoperative complications occurred in all groups. Compared to LASIK, the initial learning curve of the SMILE procedure may be more challenging for surgeons; as a result of its flapless nature, lenticule dissection and extraction are the most difficult steps for surgeons, and inappropriate performance may result in complications like side-cut tears, stoma damage, and retained lenticule [15]. Selecting an appropriate incision location according to the characteristics of the patient's eyes may help reduce surgical complications, especially for beginners.

The current study found that different incision positions had no effect on astigmatism magnitude and axis distribution 1 month after SMILE, though significant differences were found in the distribution of astigmatism axis among three groups within 1 week postoperatively. The changes of axis distribution might be caused by the process of corneal wound healing [13]. Different incision positions accompanied by distinct surgical maneuvers might induce uneven distribution of the astigmatism axis shortly after SMILE surgery. However, owing to the microinvasive nature of the incision in SMILE surgery, the difference would become neglectable as early as 1 month postoperatively. Prior reports have shown that clear corneal incision was effective for correcting mild to moderate corneal astigmatism, and the size and location of incision may have an influence on surgically induced astigmatism [16, 17]. This controversy may be explained by the fact that incision depth in SMILE is much shallower than that in the clear corneal incision procedure,


A
Refractive Arithmetic Mean: 0.82 D
Surgically Induced Astigmatism Vector
Refractive Vector Mean: 0.42 D Ax 177
Diopters
Polar diagram
Refractive Arithmetic Mean: 0.84 D
Target Induced Astigmatism Vector
Refractive Vector Mean: 0.48 D Ax 176
Diopters
Polar diagram
Refractive Arithmetic Mean: 0.26 D
Difference Vector
Refractive Vector Mean: 0.06 D Ax 173
Diopters
Polar diagram
Refractive Geometric Mean: 0.97
Correction Index
Diopters
Polar diagram

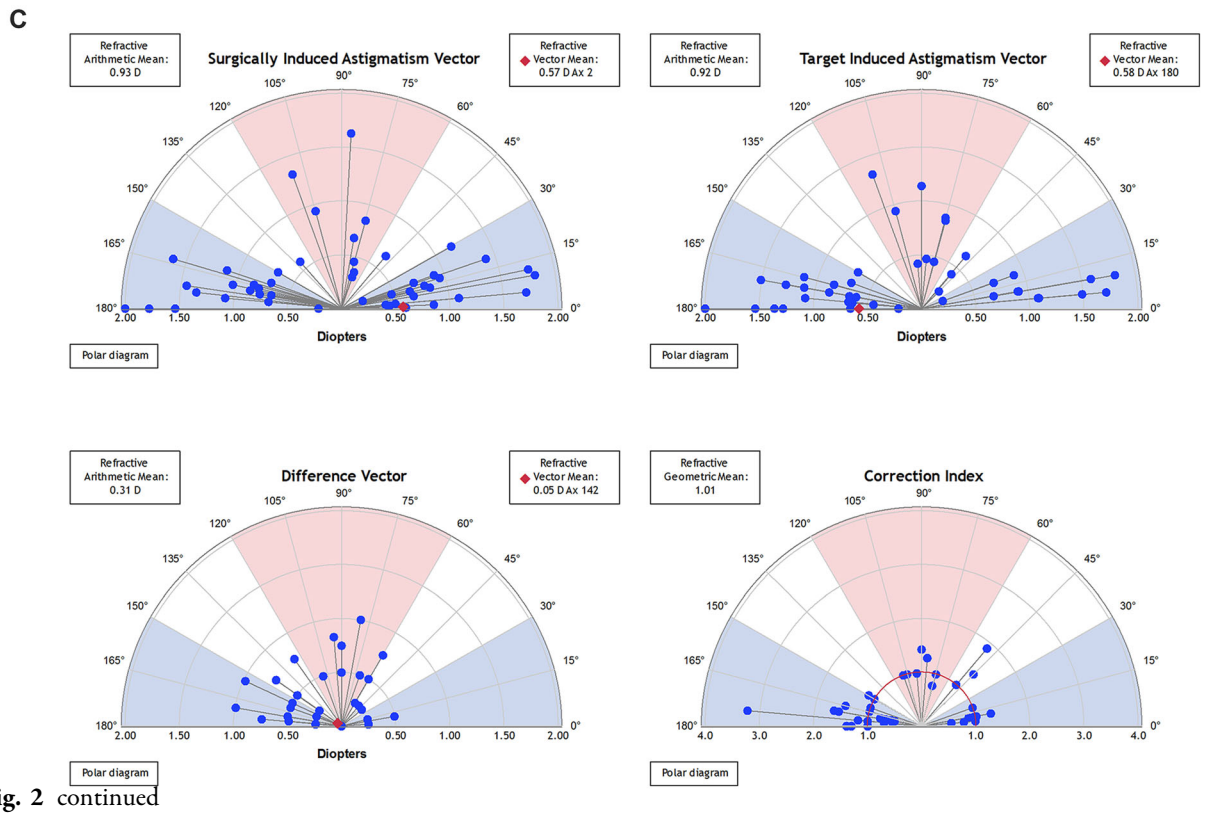

B
Refractive Arithmetic Mean: 0.68 D
Surgically Induced Astigmatism Vector
Refractive Vector Mean: 0.38 D Ax 178
Diopters
Polar diagram
Refractive Arithmetic Mean: 0.69 D
Target Induced Astigmatism Vector
Refractive Vector Mean: 0.48 D Ax 178
Diopters
Polar diagram
Refractive Arithmetic Mean: 0.28 D
Difference Vector
Refractive Vector Mean: 0.10 D Ax 179
Diopters
Polar diagram
Refractive Geometric Mean: 0.96
Correction Index
Diopters
Polar diagram

◀**Fig. 2** Single-angle polar plots for the target-induced astigmatism vector (TIA), surgically induced astigmatism vector (SIA), difference vector (DV), and correction index (CI) in different groups 1 month after surgery. TIA, SIA, DV, and CI in group A (**a**1–4), group B (**b**1–4), and group C (**c**1–4). Group A, incision position at 90°; group B, incision position at 120°; group C, incision position at 150°

which usually reaches the two-thirds of the corneal depth [18]. Another possible explanation is that the wound healing process was different between these two procedures [13]. Compared to the clear corneal incision procedure, laser ablation causes less damage to the corneal epithelium and Bowman layer: this difference leads to less inflammation and corneal scar tissue with SMILE.

In addition, postoperative HOAs were compared to assess the difference in optical performance after SMILE in different incision position groups. The results showed that there were no statistically significant differences in induced HOAs, spherical aberrations, coma, and trefoil at 1 month after surgery among different incision positions. As mentioned in literature reviews, postoperative HOAs increased significantly after the SMILE procedure in patients with high myopia, and the increased HOA was related to preoperative astigmatism [19, 20]. However, for low to moderate myopia, the conclusion was not consistent in different studies [21–23]. This discrepancy could be attributed to the complex influences of wavefront aberrations, such as postoperative follow-up time, corneal irregularity, surgical setting, and wound healing process [24–26].

There are some limitations to this study. The follow-up time was relatively short, and the sample size was relatively small. Besides, the contrast sensitivity was not evaluated. Previous study has shown the corneal wound healing process mainly took place within 28 days after SMILE surgery, with the peak at 7 days. Scar tissue would form at the side-cut incision



◀**Fig. 2** continued

Table 3 Preoperative and postoperative astigmatism in different incision position subgroups

		Group A	Group B	Group C	*P*
Preoperative astigmatism	Magnitude of astigmatism	0.78 ± 0.49	0.76 ± 0.43	0.78 ± 0.55	0.70
	WTR	25 (65.7%)	33 (75.0%)	38 (79.2%)	0.51
	Oblique	7 (18.4%)	5 (11.4%)	3 (6.2%)	
	ATR	6 (15.7%)	6 (13.6%)	7 (14.5%)	
Postoperative astigmatism	Magnitude of astigmatism	0.38 ± 0.42	0.29 ± 0.35	0.30 ± 0.29	0.69
(1 day)	WTR	12 (48.0%)	20 (66.7%)	9 (29.0%)	0.02*
	Oblique	4 (16.0%)	3 (10.0%)	12 (38.7%)	
	ATR	9 (36.0%)	7 (23.3%)	10 (32.3%)	
Postoperative astigmatism	Magnitude of astigmatism	0.38 ± 0.42	0.30 ± 0.35	0.29 ± 0.28	0.38
(1 week)	WTR	12 (44.4%)	23 (71.8%)	10 (34.5%)	0.02*
	Oblique	5 (18.5%)	3 (9.3%)	11 (37.9%)	
	ATR	10 (37.0%)	6 (18.7%)	8 (27.5%)	
Postoperative astigmatism	Magnitude of astigmatism	0.16 ± 0.31	0.25 ± 0.31	0.30 ± 0.32	0.08
(1 month)	WTR	8 (38.1%)	21 (72.4%)	14 (46.7%)	0.66
	Oblique	3 (14.2%)	2 (6.9%)	7 (23.3%)	
	ATR	10 (47.6%)	6 (20.7%)	9 (30.0%)	

Group A, incision position at 90°; group B: incision position at 120°; group C, incision position at 150°
WTR with the rule astigmatism, *ART* against the rule astigmatism
*$P < 0.05$, chi-square test

Table 4 Preoperative and postoperative 1-month HOAs in different incision position groups

	Postoperative HOAs				Postoperative HOAs			
	Group A	Group B	Group C	*P* value	Group A	Group B	Group C	*P* value
N (eyes)	48	50	50		48	50	50	
Total HOAs	0.26 ± 0.12	0.25 ± 0.10	0.23 ± 0.08	0.69	0.21 ± 0.34	0.18 ± 0.05	0.17 ± 0.13	0.31
Coma	0.16 ± 0.13	0.15 ± 0.10	0.11 ± 0.04	0.72	0.11 ± 0.19	0.13 ± 0.04	0.12 ± 0.12	0.36
SA	0.10 ± 0.07	0.12 ± 0.06	0.10 ± 0.06	0.24	0.05 ± 0.09	0.02 ± 0.02	0.03 ± 0.05	0.27
Trefoil	0.13 ± 0.05	0.12 ± 0.05	0.09 ± 0.35	0.30	0.06 ± 0.05	0.04 ± 0.3	0.07 ± 0.04	0.21

Group A, incision position at 90°; group B, incision position at 120°; group C, incision position at 150°
HOAs high-order abberations, *SA* spherical aberration

1 month after surgery [13]. Our study proved that different incision positions had no effect on postoperative visual acuity and astigmatism 1 month after surgery. It is reasonable to suspect that such an effect would last for a longer postoperative period. What is more, patients with astigmatism over 2 D were not enrolled in this study. Although SMILE provides effective and predictable results in correcting astigmatism, evidence reveals a tendency toward undercorrection in the SMILE for treating astigmatism over 2 D [27, 28]. Our study excluded patients with astigmatism over 2 D to minimize the uncertainty of SMILE for high astigmatism.

CONCLUSIONS

Different incision positions have no effect on postoperative astigmatism and visual quality 1 month after SMILE surgery, and the incision position might be individually designed on the basis of the specific situation during SMILE surgery.

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Disclosures. Shan Yang, Tianze Huang, Yuchen Wang, Ken Ning, Qing Long, Zhonghai Wang, Ying Li and Di Chen have nothing to disclose.

Compliance with Ethics Guidelines. The study was approved by the Institutional Ethics Committee of Peking Union Medical College Hospital (ZS-3516) and registered at chictr.org.cn (Registration number ChiCTR2000039272). Informed consent was obtained from all patients (reference to: https://www.chictr.org.cn). The tenets of the Declaration of Helsinki were followed throughout the study.

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

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