Astigmatism correction and corneal aberrations variability between two locations of cap side-cut after small incision lenticule extraction: a randomized study

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Abstract

Purpose To investigate astigmatism correction and the effect on corneal aberrations between two locations of the cap side-cut (CSC) after small incision lenticule extraction (SMILE) surgery.

Methods In this randomized, prospective research, 91 eyes of 49 patients were investigated after SMILE. The eyes were randomized into two groups with different CSC locations. The location was set at 120° for group 1 and 90° for group 2. Uncorrected distant vision acuity (UDVA) and corrected distant vision acuity measurements, manifest refraction, and imaging were performed before and after surgery.

Results At the 3-month follow-up, all eyes in both groups had a postoperative UDVA $\geq 20/20$. There was no significant difference in the refraction data nor in the safety and efficacy indices between the two groups ($P=0.343$ and $P=0.738$, separately). The effects on corneal astigmatism, corneal root mean square high-order aberration, corneal spherical aberration, and corneal coma aberration at 0° and 90° showed no difference between the two groups.

Conclusions Astigmatic correction was not influenced by two locations of the CSC in SMILE surgery. No significant difference was found in visual and corneal optical quality results with two different CSCs in SMILE surgery.

Introduction

More than 90% of refractive surgeries are performed on the cornea. Of these, the small-incision lenticule extraction (SMILE) surgery is a popular one. A femtosecond laser is utilized to scan the lenticule in the corneal stroma, and the lenticule is taken out through a miniature incision; the entire operation process is in a closed mode. Milder postoperative reactions¹, less nerve damage, quicker nerve recovery^{2,3} and milder dry eye symptoms⁴ greatly improve the safety and comfort of SMILE surgery.

The location of the cap side-cut (CSC) through which the lenticule is extracted can be determined individually^{5,6}. Most investigations revealed a cap thickness of 100–150 microns and CSC length of 2–5 millimeter in the 90° and 120° directions^{7,8}. Whether the direction of the CSC influences astigmatism correction or anterior corneal high-order aberration (HOA) requires verification. As far as we know, studies^{9–11} have reported the refractive and keratometric outcomes of limbal relaxing incisions during cataract surgery, whereas few studies have investigated the influence of the location of the CSC on the refractive and optical outcomes after SMILE. We directed this randomized review to analyze the refractive and corneal optical quality results between two CSCs in SMILE surgery.

Methods

Patients

In this prospective, randomized research, 91 eyes of 49 patients (mean age of 22.73 ± 5.36 years) with myopic astigmatism were randomly assigned to two CSC groups by flipping a coin. Group 1 included 49 eyes (CSC on 120°) and group 2 included 42 eyes (CSC on 90°). All patients underwent routine preoperative examinations and SMILE surgery between July 2021 and August 2021 at the Third People's Hospital of Chengdu.

Inclusion criteria were listed as following: age between 18–45 years; ≤ 0.50 D increase in refraction in the past two years; abandoned soft contact lens use for 2 weeks), and no rigid contact lens use (≥ 3 months). Exclusion criteria were as following: severe corneal opacity or cataract; ocular surface inflammation; uncontrolled glaucoma and fundus disease; corneal thickness no more than 500 μm ; abnormal corneal topography, and uncontrolled systemic diseases.

The investigation was approved by the Ethics Committee of the Third People's Hospital of Chengdu(No.2021-S-92)and was carried out conforming to the tenets of the Declaration of Helsinki. Informed consent was signed by every patient prior to the procedures.

Examinations

Preoperatively and 3 months postoperatively, routine ocular examinations, including slit-lamp biomicroscopy, manifest refraction, high-resolution Scheimpflug tomography, and intraocular pressure, uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA) measurements, were performed by the same experienced optometrist. The following ophthalmological parameters were assessed: (1) UDVA, CDVA, manifest refraction; (2) vector analysis of astigmatism correction: target-induced astigmatism vector (TIA), surgically induced astigmatism vector (SIA), correction index (CI), index of success (IOS), magnitude of error (MofE), and angle of error (AofE); and (3) anterior corneal astigmatism, corneal root mean square high-order aberration (RMS HOA), and corneal coma aberration (CA) at 0° and 90° , determined using tomography on Pentacam tomography.

Operation procedure

All surgeries were accomplished by the same surgeon (W.Y.). After topical anesthesia, the surgeon performed SMILE utilizing the 500-kHz VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany). The treatment parameters were as follows: with a cap diameter of 7.5 millimeter; with a cap thickness of 120 microns; with a lenticule diameter of 6.5 millimeter (with a transition zone of 0.1 mm); CSC was performed at 90° (12 o'clock) or 120° (11 o'clock) with a 2 mm length. After femto-second laser scanning, the lamellar lenticule was carefully isolated with a slight obtuse spatula and grasped with a couple of forceps through the 2 mm CSC. Postoperatively, the patient was prescribed an antibiotic and steroid eye drop to use four times a day for 14 days.

Statistical analysis

Data were analyzed by utilising the Statistical Package for the Social Sciences (SPSS version 23.0, IBM). Values were totally expressed as mean $\pm$ standard deviation(SD). Astigmatism correction was analyzed by vector analysis according to the Alpins method¹². The Shapiro-Wilk test was utilized to test if the

values follow a normal distribution. Normally distributed variables were tested by the Welch t-test, and non-normally distributed variables were detected by the Mann-Whitney U test. P-value < 0.05 was viewed as statistically significant.

Results

In total, 91 eyes of 49 patients were investigated in this research. The CSC was performed at 120° peripherally in group 1 and 90° in group 2. All eyes underwent an uneventful SMILE without any complication. No significant difference were revealed in the clinical and optical parameters before and 3 months after SMILE between the two groups (Table 1).

Table 1
The clinic parameters between two groups before and 3 months after surgery

	Pre-op			3 months Post-op		
	Group 1	Group 2	P Value	Group 1	Group 2	P Value
UDVA	1.13 ± 0.178	1.140 ± 0.205	0.927	-0.092 ± 0.049	-0.083 ± 0.054	0.532
CDVA	-0.096 ± 0.041	-0.079 ± 0.047	0.150	-0.102 ± 0.038	-0.098 ± 0.047	0.593
Sphere	-4.760 ± 1.338	-4.970 ± 1.257	0.443	-0.112 ± 0.275	-0.101 ± 0.265	0.464
Cylinder	-0.898 ± 0.582	-0.86 ± 0.446	0.747	-0.209 ± 0.299	-0.25 ± 0.297	0.557
SE	-5.209 ± 1.430	-5.40 ± 1.269	0.498	-0.008 ± 0.286	-0.024 ± 0.301	0.488
Pre-op: Pre operation, Post-op: Post operation, UDVA: Uncorrected Distance Visual Acuity, CDVA: Corrected Distance Visual Acuity,						
SE: Spherical Equivalent						
*P < 0.05 = statistically significant						

Safety and efficacy

At the 3-month follow-up visit, the efficacy and safety indices were 1.00 ± 0.08 and 1.01 ± 0.06 in group 1 and 1.02 ± 0.14 and 1.04 ± 0.14 in group 2, respectively. We detected no significant differences in the safety and efficacy indices between the two groups ($P = 0.343$ and $P = 0.738$, respectively). A decline in CDVA was showed in six eyes, whereas all eyes had a UDVA $\geq 20/20$ after the surgery. Furthermore, 88% of the eyes (80 eyes) had better follow-up UDVA than preoperative CDVA, and 14 eyes gained at least one line.

Vector analysis

The vector analysis of astigmatism correction in the two groups are recorded in Table 2. The CI was 1.028 ± 0.384 in group 1 and 1.043 ± 0.516 in group 2. The MofE was -0.045 ± 0.245 and -0.018 ± 0.262 in groups 1 and 2, respectively. The AofE was -0.630 ± 9.639 in group 1 and -2.710 ± 13.994 in group 2, and the values within -15 to 15° were 85.71% and 83.33% in the eyes of group 1 and group 2, separately. No significant differences were detected between the two groups. The IOS in group 1 was lower than that in group 2, however, no significant difference was detected ($P = 0.09$). Single-angle plots introducing the comparison of the TIA, SIA, DV and CI for astigmatism correction between the two groups are shown in Fig. 1. The DV in Group 2 (0.327 ± 0.161) was higher than that in Group 1 (0.255 ± 0.188). However, no significant difference was detected ($P = 0.105$), no significant difference were observed between the two groups in TIA, SIA and CI neither ($P = 0.820, 0.839, 0.971$). The Scatterplots and the linear regression analysis between the SIA and TIA after SMILE surgery in group 1 and group 2 are shown in Fig. 2. The predictability of cylinder correction was excellent, 95% of eyes were within ± 0.50 D, whereas all eyes were within ± 1.00 D of astigmatism correction. The predictability was slightly better in the Group 2 (average deviation: -0.02 D) versus the Group 1 (average deviation: -0.04 D), However, no significant difference was observed ($P = 0.538$).

Table 2
Vector parameters of refraction astigmatism between two groups

	Group 1	Group 2	P Value
TIA	0.785 ± 0.493	0.756 ± 0.391	0.820
SIA	0.740 ± 0.442	0.738 ± 0.385	0.839
DV	0.255 ± 0.188	0.327 ± 0.161	0.105
AofE	-0.630 ± 0.639	-0.700 ± 0.493	0.914
MofE	-0.045 ± 0.245	-0.018 ± 0.161	0.447
CI	1.028 ± 0.384	1.043 ± 0.516	0.971
IOS	0.365 ± 0.311	0.548 ± 0.403	0.09
COA	1.099 ± 0.380	1.172 ± 0.520	0.978
FI	0.974 ± 0.372	0.970 ± 0.530	0.965
TIA = target-induced astigmatism; SIA = surgically induced astigmatism; DV = difference vector; AofE = angle of error; MofE = magnitude of error CI = correction index; IOS = index of success; COA = coefficient of adjustment; FI = flattening index;			
*P < 0.05 = statistically significant			

Corneal aberrations

The values of anterior corneal astigmatism (ACA) and CA before the surgery and 3 months postoperatively are shown in Table 3. No statistically significant difference was found in the preoperative and postoperative ACA between the group 1 and group 2; furthermore, the changes in ACA in the group 1 and group 2 had no significant difference ($P = 0.747$, 0.930 , and 0.768 , respectively). There was significant increase in RMS HOA, spherical aberration (SA), and coma in both groups after SMILE surgery ($P < 0.05$). Although the induced vertical coma (VC) was higher than the induced horizontal coma (HC) in both groups, no significant differences were found between the two groups. Moreover, no significant difference was found in surgically induced RMS HOA ($P = 0.688$), SA ($P = 0.497$), HC ($P = 0.570$), or VC ($P = 0.732$).

Table 3

Comparisons of anterior corneal astigmatism and corneal wavefront aberrations between two groups

		Preop	Postop	Induced
Group 1 (n = 49)	ACA	1.186 ± 0.569	0.598 ± 0.350	0.588 ± 0.537
	RMS HOA	0.351 ± 0.090	0.734 ± 0.256	0.383 ± 0.281
	SA	0.187 ± 0.073	0.349 ± 0.189	0.162 ± 0.162
	HC	0.033 ± 0.112	0.137 ± 0.278	0.105 ± 0.256
	VC	-0.031 ± 0.174	-0.430 ± 0.307	-0.398 ± 0.290
Group 2 (n = 42)	ACA	1.124 ± 0.565	0.604 ± 0.331	0.520 ± 0.497
	RMS HOA	0.352 ± 0.073	0.739 ± 0.187	0.387 ± 0.199
	SA	0.191 ± 0.082	0.357 ± 0.105	0.166 ± 0.102
	HC	0.019 ± 0.121	0.066 ± 0.149	0.048 ± 0.141
	VC	-0.03 ± 0.168	-0.424 ± 0.341	-0.394 ± 0.313
P Value (Group 1 vs Group 2)	ACA	0.747	0.930	0.768
	RMS HOA	0.978	0.799	0.688
	SA	0.956	0.504	0.497
	HC	0.469	0.162	0.570
	VC	0.943	0.880	0.732
ACA = anterior corneal astigmatism, RMS HOA = Root mean square high order abberation, SA = spherical abberation, HC = horizontal coma, VC = vertical coma				

Discussion

To date, studies on SMILE have not determined the standard size or location for CSCs. Most studies^{13–15} have determined a 90° direction for CSCs of 1.95 mm length. For patients with superior corneal pannus or extremely deep sockets, the surgeon may adjust the CSC direction to 120° to avoid hemorrhage or ease the procedure. Dan *et al.* reported the design of two CSCs in the superior nasal and superior temporal directions in SMILE surgery for low myopia¹⁶. We performed this research to investigate the effects of the two CSC types on astigmatism correction and visual performance.

In this study, all eyes in both the two groups had a postoperative UDVA $\geq 20/20$ at the 3-month visit. The safety and efficacy index were 1.01 ± 0.06 and 1.00 ± 0.08 in group 1 and 1.04 ± 0.14 and 1.02 ± 0.14 in group 2, respectively. The safety index was close to that reported in previous studies^{17,18}, which reported a median safety index of 1 and 1.1, respectively, at the 3-month follow-up after SMILE surgery. Another study¹⁹ reported an efficacy index of 1.18 ± 0.21 , with a mean preoperative astigmatism of -0.68 ± 0.46 D, which was -0.82 ± 0.52 D in the current study. There were no differences in UDVA, CDVA, SE, safety, or efficacy index between the two groups. Our findings showed no difference in refraction outcomes between the two CSC groups.

Vector analysis revealed an average CI of 1.028 and 1.043 in groups 1 and 2, respectively ($P = 0.971$), which indicated a slight overcorrection of astigmatism in both groups. The average CI in a previous study²⁰ showed a similar value of 1.05 using SMILE surgery and 0.95 using laser epithelial keratomileusis. Although a lower IOS was found in group 1 (0.365 vs. 0.548, $P = 0.09$), the difference was not significant, and the difference in ME between the two groups was not statistically significant ($P = 0.447$), indicating no difference in residual astigmatism between the two groups. Chan *et al.* also concluded that there was no difference in astigmatism correction between two opening incisions²¹. In addition to the magnitude, it is important to correct astigmatism with a precise axis. Alpíns noted that the deficiency of the correction effect is 13.4% when treatment is skewed by 15° and is almost 50% when treatment is skewed by 30°²². Xia *et al.* conducted that 77% of the eyes had AE values between -15° and 15° ²³. In this study, 85.71% and 83.33% of the eyes in group 1 and group 2, separately, had AE values between -15 and 15° , which showed a slightly more accurate correction of astigmatism in group 1; however, no statistical significance was found between the two groups. The AE in group 1 was -0.630 ± 9.64 and in group 2 was -2.710 ± 13.99 ; the less favorable range (9.64° and 13.94°) occurred in both groups, suggesting some variable factors, such as healing or alignment, which require further investigation. No significant difference was detected in other variables by using vector analysis.

Corneal anterior surface aberrations account for 80% of aberrations in the eye and are the main factors influencing visual quality^{24,25}. In the Zernike HOA chart, SA and coma are the most common parameters used to analyze the impact on visual quality²⁶. Corneal anterior astigmatism and aberration variability were used in the present study. The change in corneal anterior astigmatism was greater in group 1 (0.588) than in group 2 (0.520), but the difference was not statistically significant. Corneal aberrations, including RMS HOA, SA, HC, and VC increased after SMILE surgery. Several studies^{27–29} have reported increased HOA in both SMILE and laser-assisted in situ keratomileusis (LASIK). The induced VC was

considerably higher than the induced HC in both groups ($P = 0.447$), and Chalita *et al.* reported that increased HC after LASIK surgery was correlated with double vision but not with increased VC³⁰. No significant difference was discovered in the induced RMS HOA, SA, HC, or VC between the two groups.

A limitation of our investigation is that the 3-month follow-up may be not adequate to evaluate astigmatic correction and vision quality in the two different directions of CSCs. Studies with longer follow-up durations and more directions of CSCs are needed to confirm the results of the present study.

Conclusions

we found no significant differences in visual and corneal optical quality results in two different directions of CSC during SMILE surgery. Surgeons can choose either of the two directions of CSC individually during SMILE surgery without affecting the visual outcome.

Declarations

Acknowledgements

No author reports any financial interest relevant to this study.

Author contribution

(I) Conception and design: M Zhang, W Yang, J, Yang; (II) Administrative support: M Zhang; (III) Provision of study materials or patients: M Zhang; (IV) Collection and assembly of data: W Yang; Z Shu (V) Data analysis and interpretation: W Yang, J Guo, Z Shu, L Song, L Chen, Y Jiang; (VI) Manuscript writing: All authors; (VI) Final approval of manuscript: All authors.

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Data Availability statement

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Conflict of interest

The authors declare no competing interests.

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Figures

Figure 1

Single-angle polar plots depicting TIA, DV, CI and SIA of eyes in the two group. SIA, surgically induced astigmatism; TIA, target-induced astigmatism; CI, correction index; DV, difference vector.

Figure 2

Surgically induced astigmatism vector versus target induced astigmatism vector in diopters (D) after small-incision lenticule extraction with a 120 °(Group 1) and 90 ° (Group 2) cap side-cut. Above the blue line in the middle is overcorrection and below is undercorrection. The black line indicates the outcome of linear regression analysis.