Higher-order aberrations and visual quality after incision lenticule extraction surgery with intraoperative angle kappa adjustments between small and large kappa patients: A 2-year follow-up

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Purpose: To evaluate the postoperative visual outcomes, that is, corneal higher-order aberrations (HOAs) and visual quality, of patients with an angle kappa greater than 0.30 mm who underwent angle kappa adjustment during small-incision lenticule extraction (SMILE) 2 years after surgery compared to eyes with an angle kappa less than 0.30 mm. Methods: This was a retrospective study and included 12 patients from October 2019 to December 2019 who underwent the SMILE procedure for correction of myopia and myopic astigmatism and had one eye with a large kappa angle and another eye with a small kappa angle. Twenty-four months after surgery, an optical quality analysis system (OQAS II; Visiometrics, Terrassa, Spain) was used to measure the modulation transfer function cutoff frequency (MTF_{cutoff}), Strehl2D ratio, and objective scatter index (OSI). HOAs were measured with a Tracey iTrace Visual Function Analyzer (Tracey version 6.1.0; Tracey Technologies, Houston, TX, USA). Assessment of subjective visual quality was achieved using the quality of vision (QOV) questionnaire. Results: At 24 months postoperatively, the mean spherical equivalent (SE) refraction was -0.32 ± 0.40 and -0.31 ± 0.35 in the S-kappa group (kappa <0.3 mm) and the L-kappa group (kappa ≥ 0.3 mm), respectively (P > 0.05). The mean OSI was 0.73 ± 0.32 and 0.81 ± 0.47 , respectively (P > 0.05). There was no significant difference in MTF_{cutoff} and Strehl2D ratio between the two groups (P > 0.05). Total HOA, coma, spherical, trefoil, and secondary astigmatism were not significantly different (P > 0.05) between the two groups. **Conclusion:** Adjustment of angle kappa during SMILE helps reduce the decentration, results in less HOAs, and promotes visual quality. It provides a reliable method to optimize the treatment concentration in SMILE.



Key words: Ablation center, angle of kappa, HOAs, small-incision lenticule extraction (SMILE), visual quality, wavefront aberration

Femtosecond laser assisted small incision lenticule extraction (SMILE) technique has become a commonly accepted alternative to excimer laser-based techniques, such as femtosecond laser in situ keratomileusis (FS-LASIK) and photorefractive keratectomy (PRK), for the surgical correction of myopia and myopic astigmatism.^[1] It is confirmed that SMILE produces promising refractive outcomes in terms of predictability, efficacy, stability, and safety in the correction of myopia and myopic astigmatism,^[1,2] with high patient satisfaction.^[3] In refractive surgery, the choice of treatment center is very important. Moving the ablation center from the center of the entrance pupil to the center of the visual axis results in less induction of higher-order aberrations (HOAs) and an equal or better visual when compared to laser ablation centered on the entrance pupil.^[4,5] The exact definition of angle kappa is the angular distance between the visual and pupillary axes.^[6] The angle of kappa is a necessary consideration in refractive surgery to avoid eccentricity of the treatment zone and thus obtain a better visual outcome.^[7] SMILE does not have an eye-tracking and positioning system relative to excimer lasers; therefore, an accurate center is

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Received: 15-Nov-2022 Accepted: 09-Jan-2023 Revision: 22-Dec-2022 Published: 17-May-2023 crucial in SMILE, especially in the case of a large angle kappa. SMILE cannot achieve personalized treatment, such as aberration or topographic map guidance, so manual cutting center location is adopted. Compared to SMILE, one potential advantage of excimer laser-based photoablation is the ability to deliberately modulate corneal HOAs. In keratorefractive surgery, an excess of threshold value-inducing HOAs is well known to convey an increased risk for bothersome visual symptoms such as haloes, starburst, and glare.^[1,8] Previous studies have shown that patients with large-angle kappa are more likely to undergo eccentric ablation, resulting in postoperative HOAs and decreased visual quality.^[9-12] Adjustment of the angle kappa during SMILE resulted in fewer HOAs.^[9] Shao et al. described that intraoperative adjustment of kappa angle can reduce postoperative HOA when the kappa angle is 0.19 ± 0.09 mm. However, when the kappa angle is greater than 0.3 mm, it will inevitably bring about a larger displacement from the center of the pupil to the visual axis; so, it is not clear whether

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Figure 1: The method to offset the angle of kappa during SMILE. SMILE = small-incision lenticule extraction

this adjustment is still feasible, as Shao *et al.*^[9] reported. Our retrospective study aimed to analyze whether adjusting the ablation center according to the size and direction of the large kappa angle during SMILE reduces eccentric ablation and the resulting HOAs and poor visual quality.

Methods

The surgical technique was the same following the classic SMILE scanning steps and the lenticule extraction as the VisuMax Femtosecond Laser System (Carl Zeiss, Oberkochen, Germany) required and the literature introduced.^[13] Patients who underwent SMILE surgery, both male and female, aged 18–40 years, with kappa angle <0.3 mm in one eye and ≥0.3 mm in the other eye, and had complete 2-year follow-up data after surgery, were selected for the research. Twelve eligible patients underwent SMILE surgery in both eyes, and both eyes were included in the analysis. All visual data, HOA, and visual quality information were systematically recorded in structured patients' medical records, and all information was comprehensively assessed through electronic records.

Ethics statement

The study protocol was approved by the West China Hospital and was in accordance with the tenets of the Declaration of Helsinki. Informed consent for surgery was obtained before the surgery.

Patient examination

The examinations conducted included slit-lamp microscope, uncorrected distance visual acuity (UDVA), intraocular pressure (IOP), refractions, and corneal topography with the Pentacam tomography system (Oculus Optikgeräte GmbH). We used the Pentacam to measure the displacement of the visual axis from the pupil center (chord distance), which essentially equates the angle kappa, and we used this displacement for the intraoperative angle kappa adjustments. The coefficients of vertical coma, horizontal coma, and spherical aberration were analyzed for a standardized diameter of 3 mm using an iTrace aberrometer because they are clinically significant in visual quality.^[14,15] An optical quality analysis system (OQAS II; Visiometrics, Terrassa, Spain), based on the double-pass technique, was used to measure modulation transfer function $(MTF_{) cutof} f$ frequency $(MT_{Fcutof} f, cycle per f)$ degree [cpd]), Strehl2D ratio (SR), OQAS values (OV) at different contrasts (100%, 20%, and 9%), and the objective scatter index (OSI) of each eye. All measurements were conducted in mesopic conditions with a 4.0-mm artificial pupil. The same experienced optometrists performed these examinations, and the average value from three good-quality images was used for analysis. In addition to objective examination, we assessed patients' subjective visual quality by means of the quality of vision (QOV) questionnaire.^[16] The QOV questionnaire consists of 10 items, including three subscales, and the QOV scores are given according to the symptom frequency, severity, and bothersome. Each item has four self-evaluation options. The first seven items have an associated picture to simulate visual symptoms, which ensures patient understanding. The QOV scores range from 0 to 100; the higher the score, the worse the QOV.^[16,17]All patients were suggested to have a routine ophthalmic examination at 1 day, 1 week, 1 month, 3 months, 6 months, 12 months, and 24 months postoperatively.

Surgical procedure and perioperative medication

The SMILE procedures were completed by an experienced surgeon (DYP), who has more than 10 years of experience in refractive surgery. Briefly, the lenticule was extracted following these steps: fixate the light to centralize the corneal peak, suction on, create the posterior surface, make the border, create the anterior surface, make the incision, suction off, separate the lenticule, and extract it from the incision. The laser scan system (Visumax, Carl Zeiss Meditec AG) was set at a 500 kHz repetition rate. The diameter of the cap was 8 mm, and the thickness ranged from 100 to 110 µm. The thickness and diameter of the lenticules were dependent on pupil diameters, corneal thickness, and equivalent spherical quantity, while the diameter ranged from 6.0 to 6.5 μ m. The incision was 2 mm, located at 11 o'clock in the right eye and 12 o'clock in the left eye to make the operation more convenient. After the lenticule was extracted, the corneal surface around the incision was flushed with a balanced salt solution. It is worth mentioning that the intraoperative adjustment of angle kappa was based on the results of the Pentacam scan, the relative position of the corneal vertex, and the pupil center (angle kappa size) obtained before SMILE surgery. Then, according to the size and direction of the angle kappa, the center of the suction ring was adjusted before suction, similar to excimer laser alignment^[9] [Fig. 1].

Regularly, the operative management included preantibiotic (0.5% levofloxacin; Santen Pharmaceutical Co,Osaka, Japan) and

preservative-free artificial tear drops (0.1% sodium hyaluronate; Ursapharm Arzneimittel GmbH, Saarbrücken, Germany) unsegmenting 12 times in 3 days. Postoperatively, the artificial tear 0.1% sodium hyaluronate was topically used four times daily for 3 months, while the steroid was started four times a day and reduced once weekly until 1 month. Meanwhile, the antibiotics were continued for 1 week, and IOP-lowering drops (0.2% brimonidine tartrate eye drops; Allergan Pharmaceuticals, Dublin, Ireland) was also used after surgery, which was beneficial to the stability of corneal biomechanics.

Statistical analysis

Statistical analysis for visual acuity (VA) was based on the logarithm of the minimum angle of resolution (logMAR) units. Continuous variables are expressed as the mean \pm standard deviation, and categorical variables are expressed as a frequency (percentage). The Kolmogorov–Smirnov test was used to comfirm data normality. Independent *t*-tests were used to compare clinical variables, induced corneal aberration, and visual quality between the two groups. When parameter analysis was not normal, the Wilcoxon test was used. When *P* values were less than 0.05, the difference was considered statistically significant. Data analysis was performed using IBM SPSS 26.0 software (IBM, Inc., Chicago, IL, USA).

Results

Patients

A total of 12 patients (24 eyes) were included in the analyses. The basic patient data are presented in Table 1. All surgical procedures were successful, and no postoperative complications affecting vision were observed throughout the follow-up period. At the postoperative 24-month visit, 100% of treated eyes in the S-kappa (kappa <0.3 mm) and L-kappa (kappa ≥0.3 mm) groups achieved a UDVA of 20/20 or better [Fig. 2a]. Similarly, 58.3% of the S-kappa group and 58.3% of the L-kappa group exhibited unchanged or better corrected distance visual acuity (CDVA) [Fig. 2b]. A scatter plot of the attempted versus the achieved spherical equivalent correction is presented in Fig. 2c. After surgery, the spherical equivalent in 66.7% of handled eyes in the S-kappa group and 66.7% of handled eyes in the L-kappa group were within ±0.50 D. They were 100% and 100%, respectively, within ± 1.0 D [Fig. 2d]. Regarding astigmatism correction, 83.3% of treated eyes in the S-kappa group and 83.3% of treated eyes in the L-kappa group had postoperative astigmatism within ± 0.50 D cylinder, and both groups had postoperative astigmatism within ± 1.0 D [Fig. 2e]. The change in the manifest spherical equivalent is shown in Fig. 2f.

Wavefront aberrations

At 24 months postoperatively, induced changes in total HOA, vertical coma, horizontal coma, spherical aberration, trefoil, and secondary astigmatism were not significantly different between the S-kappa and L-kappa groups (P > 0.05) [Table 2]. At the same time, there were no significant differences in postoperative eccentricity between the two groups (P > 0.05) [Table 2].

Optical quality and intraocular scattering measurement

As shown in Table 3, no significant differences were found in $MTF_{cutoff'}$ SR, OV100%, OV20%, and OV9% between the two groups after 24 months of SMILE.

QOV questionnaire

None of the 24 eyes experienced distortion or depth perception. The most frequent visual symptoms were blurred vision (50%), glare (50%), halo (40.0%), and focusing difficulties (30.0%), and the incidence of other symptoms was less than 30% [Fig. 3]. In all 12 patients with symptoms, severity was assessed as "not at all" or "mild", and bothersome was assessed as "not at all".

Discussion

Previous studies reported that SMILE induced significant amounts of corneal HOAs.[18,19] Decentered photoablation may lead to overcorrection or undercorrection, induction of HOAs, especially coma,^[20] reduced visual acuity (both corrected and uncorrected), induced astigmatism, and reduced contrast sensitivity and night vision disturbances (such as glare).^[21] When laser ablation is performed using existing pupil-tracking systems, any eye with a large angle of kappa, regardless of its refractive status, is more susceptible to eccentric treatment and may face symptomatic eccentricity, unless compensation of angle kappa is considered intraoperatively.^[4] Also, because the Pupil center is dynamic, especially when light conditions change during surgery^{[22];} The results of Okamoto et al.^[23] also suggested that using the pupillary center as the ablation center does not show the best safety, effectiveness, and contrast sensitivity, although some studies have shown that when the pupil is used as the ablation center, satisfactory visual results are obtained.^[24,25] One explanation is that most patients have small kappa angles, thus the average outcome at the center of the incident pupil does not differ much from that of the visual axis center. Wong et al.^[10] confirmed that using the pupil as the ablation center even affected the visual outcomes when the kappa angle was greater than 0.6 mm. Park et al.^[4] also found that the larger the kappa angle, the greater the eccentricity in patients who underwent SMILE with the pupil center as the

Table 1: Basic information of S-kappa groups and L-kappa group of patients					
Characteristic	S-kappa	L-kappa	Р		
Angle of kappa	0.19±0.07 (0.05-0.27)	0.34±0.27 (0.30-0.38)	<0.001		
Sex (% women)	58%	58%	-		
Eyes (n)	12	12	-		
Age (years)	28.9±6.5 (18-39)	28.9±6.5 (18-39)			
Refractive errors (D)					
Spherical	-4.29±1.53 (-7.01.75)	-4.56±1.50 (-6.01.75)	0.667		
Cylindrical	-0.44±0.28 (-0.75-0)	-0.54±0.50 (-1.75-0)	0.536		
MRSE	-4.51±1.55 (-7.122.88)	-4.83±1.50 (-7.382.63)	0.609		

MRSE=Manifest refraction spherical equivalent. Values are presented as the mean±standard deviation (range)



Figure 2: Visual outcomes with angle kappa adjustment during SMILE:(a)Uncorrected distance visual acuity (UDVA) outcomes;(b)change in corrected distance visual acuity (CDVA);(c)distribution of achieved spherical equivalent outcomes;(d)spherical equivalent refractive accuracy;(e) refractive astigmatism, and (f) stability of spherical equivalent refraction at 24 months postoperatively; D = diopters

cutting center. When the kappa angle is large, even a small amount of eccentric ablation can cause glare, which affects visual quality.^[26] In our study, we adjusted the relative position of the corneal surface from the contact ring based on the magnitude and direction of the angle kappa before applying suction, just as Shao *et al.*^[9] did in their study, thereby moving the treatment center closer to the visual axis, which helped in a reduction in the magnitude of induced coma.^[9]

It has been confirmed that the large angle kappa needs to be adjusted to obtain better visual quality. In the case of large angle kappa, eccentric ablation is more likely due to the increased distance between the pupil center and the visual axis. Miao *et al.*^[19] reported that coma is a well-known cause of HOAs and has been shown to be associated with treatment eccentricity.^[14] Eccentric ablation can cause many visual symptoms, including glare, decreased visual acuity, and diplopia. In fact, the small angle kappa in SMILE surgery may not need to be adjusted. When the kappa angle is small, the cutting center centered on the pupil center or the visual axis is not enough to cause significant off-center cutting.^[9,11] Therefore, we assumed that the visual quality and HOA data of patients in the S-kappa group after SMILE without eccentric ablation. Our data showed that there was no significant difference between the two groups in terms of coma, spherical, or total corneal HOAs

Table 2: Aberrations and eccentricity of the cornea postoperatively					
Characteristic	S-kappa	L-kappa	Р		
HOAs	0.113±0.05	0.125±0.09	0.701		
Eccentricity	0.584±0.23	0.625±0.15	0.611		
C6 vertical trefoil (Z ⁻³ ₃)	-0.030±0.05	-0.026±0.04	0.796		
C7 vertical coma (Z ⁻¹ ₃)	-0.035±0.07	-0.044±0.08	0.757		
C8 horizontal coma (Z_{3}^{+1})	0.025±0.07	0.014±0.10	0.759		
C9 horizontal trefoil (Z^{+3}_{3})	-0.000±0.05	-0.001±0.04	0.986		
C11 secondary astigmatism (Z^{-2}_{4})	0.002±0.01	-0.003±0.01	0.799		
C12 spherical aberration (Z_4^0)	0.001±0.02	-0.009±0.03	0.336		
C13 secondary astigmatism (Z_{4}^{+2})	-0.010±0.02	-0.001±0.02	0.308		

HOAs=Higher-order aberrations

Table 3: Visual quality of S-kappa groups and L-kappa group of patients two year after SMILE

Characteristic	S-Kappa	L-Kappa	Р
OSI	0.73±0.32	0.81±0.47	0.569
MTFcutoff	39.41±4.77	37.95±7.06	0.557
SR	0.22±0.04	0.21±0.04	0.910
OV100%	1.32±0.16	1.28±0.23	0.686
OV20%	0.91±0.18	0.92±0.21	0.834
OV9%	0.54±0.14	0.55±0.12	0.878

MTFcutoff=Modulation transfer function cutoff frequency, OSI=Objective scatter index, OV=Optical quality analysis system values, SR=Strehl2D ratio in two dimensions

and also confirmed that there was no eccentric ablation in the L-kappa group. Therefore, it is reasonable to believe that our compensation for the large kappa angle in SMILE is beneficial.

In addition to aberration, the effects of diffraction and scattering should also be taken into account when objectively evaluating the factors affecting the imaging quality of human eyes, which cannot be achieved by ordinary wavefront aberration inspection equipment. The double-pass system objective visual therapy and analysis system OQAS II is based on double-pass technology. By recording the image results formed by the reflection of a point light source projected onto the retina, the visual quality, including HOAs and scattering, can be analyzed.[27,28] Because HOAs and intraocular scattering are two independent factors, both can affect the quality of retinal imaging. It is necessary to consider the effect of intraocular scattering to comprehensively evaluate visual quality after refractive surgery.^[29] MTF refers to the ratio of the contrast between the imaging and the actual object on the retina at different spatial frequencies. The MTF_{cutoff} of OQAS II is the cutoff frequency (cpd) at 1% of the maximum MTF.^[30] The SR is the ratio of the central luminance of the point image of the measured eye to that of the ideal eye without refractive medium problems. The ideal value of 1 represents a perfect system that is only affected by diffraction.[31] The OSI is the ratio of light energy in the periphery to the center of a double-pass image. The OQAS takes the ratio of light energy at 12-20 arcminutes to that at the center 1 arcminute to represent OSI.[32] OV100%, OV20%, and OV9% represent the OQAS values of 100%, 20%, and 9% contrast, respectively, simulating contrast visual acuity values under different illuminations corresponding to day, dusk, and night, respectively. $^{\rm [32]}$ In general, the higher the $\rm MTF_{\rm cutoff'}$ SR, and OV values, the lower the OSI and the better the visual quality. On



Figure 3: Subjective visual quality of patients 2 years after surgery

analyzing the above indices, there was no significant difference between the S-kappa and L-kappa groups, and compared to other studies,^[29] the examination data were also satisfactory.

Visual quality is a subjective entity based on an individual's unique perception of his vision. This perception is multifactorial, including not only visual factors but also psychological factors. Although optical vision is easy to measure, none of these measurements can explain how the patient subjectively perceives his or her vision complexity.^[16] Since this was a retrospective study, only postoperative data were obtained. In terms of visual symptoms, blurred vision and glare had the highest incidence, which is consistent with previous studies because coma was most commonly caused after SMILE.^[20,21] The uncorrected visual acuity of all patients after surgery was not less than 20/20, as for 50% of patients' consciously blurred vision, we suspect that it may be related to dry eye or the deviation caused by the small sample size. Further large sample studies are needed to confirm this. The objective and subjective visual quality data we collected after SMILE showed that the postoperative visual quality of these 12 patients was acceptable; in other words, the method of adjusting the treatment center during SMILE for patients with a large kappa angle can, indeed, reduce eccentric ablation.

Conclusion

In summary, this study showed that the adjustment of angle kappa and making the treatment center near the visual axis during the SMILE procedure will not lead to eccentric ablation in the eyes according to the direction and size of angle kappa. We believe that the current method will help optimize the ablation center and contribute to better visual quality, although in patients with angle kappa >0.3 mm only.

Authors' contributions

Jing T and Yingping Deng conceived and designed the study. Mengzhen Xie, Chengshu Sun, and Leimei Qiu participated in information gathering and editing and they analyzed and interpreted all the data. Mengzhen Xie wrote the manuscript. Jing Tang reviewed and edited the manuscript. All authors read and approved the final manuscript.

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Conflicts of interest

There are no conflicts of interest.

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