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ORIGINAL RESEARCH

Relationship of Location Between Tear Film Center and Corneal Vertex Following Small-Incision Lenticule Extraction

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ABSTRACT

Introduction: We aimed to measure the relationship of location between the tear film center (TFC) and corneal vertex (CV) following small incision lenticule extraction (SMILE).
Methods: A total of 100 consecutive patients (100 eyes) who underwent the SMILE procedure were included. Screen captures of intraoperative videos and pupillary offset were analyzed. Location was compared using a vector plot for the two reference points.
Results: The arithmetic values for the distance from the pupil center (PC) were almost identical between the TFC and CV ($P = 0.118$). The intraclass correlation coefficient (ICC) for the measures of distance from the CV and TFC to the PC was 0.659. The mean vector and standard deviation ellipse showed similar directional tendencies for both reference points. No significant difference was observed in the arithmetic values of decentration from the TFC and from the CV ($P = 0.056$). The ICC for the measures of decentration from the TFC and from the CV was 0.768. The difference in the distance from the PC was significant for the tear film mark (TFM) decentration group ($P = 0.002$, ICC = .480), while the difference in decentration was significant for the TFM centration group ($P = 0$ .000, ICC = 0.230).
Conclusions: The location of the CV in each eye could be simulated by the TFC. Furthermore, TFM decentered displacement could indicate optical zone decentered displacement.

Keywords: Corneal vertex; Small incision lenticule extraction; Tear film center

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Key Summary Points

Why carry out this study?

To our knowledge, the relationship of the location between the tear film center (TFC) and corneal vertex (CV), the inherent principle of the TFM centration method, has not been investigated.

This study aimed to explain why the tear film mark (TFM) centration method could achieve excellent optical zone decentration following small incision lenticule extraction (SMILE).

What was learned from the study?

The location of the CV in each eye was effectively simulated by the TFC.

TFM decentered displacement could indicate optical zone decentered displacement.

INTRODUCTION

Regarding optical zone centration in myopic small incision lenticule extraction (SMILE), several surgeons believe that the best visual outcomes can be achieved by centering on the corneal vertex (CV) [1–3]. Unfortunately, the CV is an invisible reference when the patient is undergoing laser treatment [4]. Therefore, how best to determine the location of the CV remains unknown.

Several studies have utilized the relative positions of the CV and pupil center (PC) to locate the CV [5, 6]. However, cyclotorsion and instability affect the suitability of the PC as a primary choice for locating the CV [7–9]. Our previous study demonstrated that the tear film mark (TFM) could be used for centering in SMILE surgery [10]. At the moment of contact between the curved contact glass and the maximum elevation point of the cornea, a meniscus tear film mark appears in the position of the CV in the coaxially fixating eye [11]. We suspect that smaller decentration values with TFM centration could be attributed to the tear film center (TFC) simulating the CV. However, the relationship of location between the TFC and CV has not been investigated.

Therefore, we aimed to investigate the location of the CV and to evaluate the relationship between the TFC and CV following SMILE.

METHODS

Patients

This was a retrospective observational case series of consecutive SMILE patients treated between January 2018 and January 2019. This study was approved by the Ethical Committee of the Affiliated Eye Hospital of Nanchang University Review Board (Nanchang, People's Republic of China). All patients signed an informed consent form in accordance with the tenets of the Declaration of Helsinki.

The inclusion criteria were as follows: the presence of stable refraction at least 1 year prior to surgery; age 18 years or older; preoperative corrected distance visual acuity of 20/20 or better; minimum calculated thickness of residual corneal stromal bed of at least 280 μm, and a normal preoperative corneal topography. The exclusion criteria were as follows: concurrent infections of the cornea, concomitant autoimmune diseases, severe dry eye disease, a history of herpetic keratitis, cataract, glaucoma, or vitreoretinal disorders, or current pregnancy or lactation. One eye from each patient was included in the analysis via randomization between the two eyes. Patients were classified into group I (tear film mark centration group) and group II (tear film mark decentration group) based on an intraoperative TFM decentration average of 0.20 mm.

Surgical Techniques

SMILE procedures were performed with the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Germany). Before vacuum

aspiration, the cyclotorsion degree was adjusted by slightly rotating the patient's head so that the horizontal reticule of the microscope overlapped with the cornea reference points (3 and 9 o'clock meridian) [12]. The tear film center was used for centering as described in our previous work [10]. After final confirmation that the green light was coincident with the tear film center (tear film mark was concentric with the margin of the cone), suction was initiated. The intended thickness of the cap was set to 120 μm. The lenticule diameter was 6.3 to 6.8 mm and the cap diameter was 7.5 mm. The incision length was set at 2.0 mm. After laser treatment, the refractive lenticule was dissected and removed manually. All of the surgical procedures were performed by the same surgeon (SL).

Measurements and Location Analysis

With respect to the PC (0, 0), the locations of the CV and TFC were obtained as A (x_1, y_1) and B (x_2, y_2) from the preoperative axis curvature map (Pentacam; Oculus, Wetzlar, Germany) and intraoperative screen captures, respectively (Fig. 1a). The pupil diameter difference was controlled by similar illumination intensity. Subsequently, the PC, CV, and TFC were superimposed on the schematic depicted in Fig. 1b. The distance from the PC was calculated using $d = \sqrt{x^2 + y^2}$. The preoperative and 6-month postoperative ophthalmic examinations included uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), manifest refraction, slit-lamp evaluation, and Scheimpflug imaging. All measurements were performed by a single experienced operator.

Measurement of Decentration

Decentration from the TFC was defined as the distance from the TFC to the green fixation light, as seen on the screen captures (Fig. 1). The screen captures displayed a coordinate (x_3, y_3) in millimeters for the green fixation light relative to the PC (0, 0). Decentration from the TFC was calculated using $d = \sqrt{(x3 - x2)^2 + (y3 - y2)^2}$. The measurement of optical zone decentration was introduced in our recently published study [10]. The tangential curvature difference map

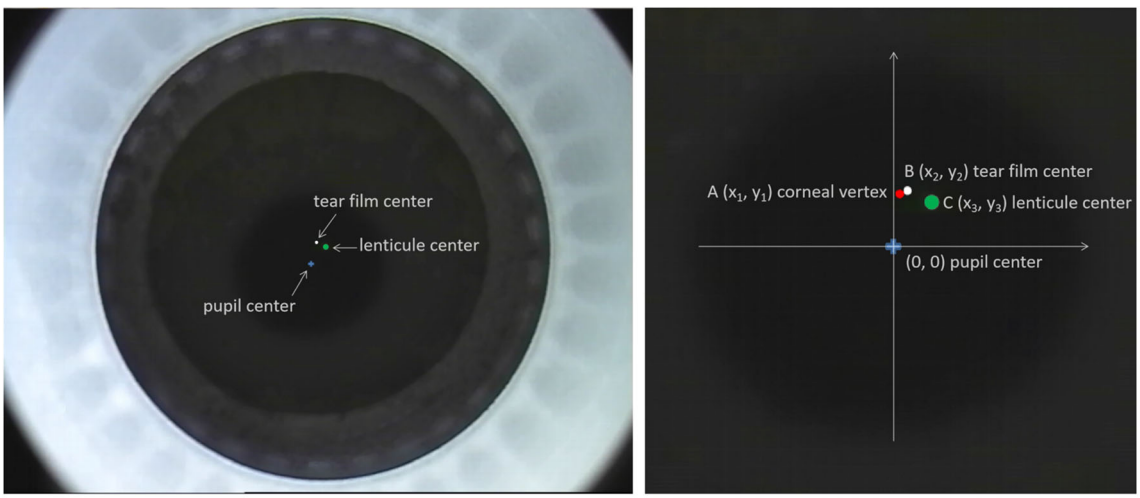


Fig. 1 **a** The locations of pupil center and tear film center in the intraoperative screen captures. **b** A two-dimensional coordinate frame to show the locations of the corneal vertex, pupil center, and tear film center. Green dot = treatment zone center (lenticule center); red dot = corneal vertex derived from Pentacam; white dot = tear film center; blue cross = observed pupil center

displayed the (0, 0) point as the CV and a coordinate (x, y) in millimeters for optical zone centration relative to the (0, 0) point. The x coordinates obtained for left eyes were reflected in the vertical axis (multiplied by −1), so that nasal/temporal characteristics of right and left eyes could be combined. Positive x values indicated nasal decentration, and negative x values indicated temporal decentration.

Statistical Analysis

The Kolmogorov–Smirnov test was used to confirm data normality. Paired t tests were used to evaluate the differences in distance and decentration. An intraclass correlation coefficient (ICC) was used to further assess agreement between the two reference points. ICC estimates and their 95% confidence intervals were calculated using IBM SPSS Statistics 24.0 (IBM Corp., Armonk, NY, USA) based on an absolute-agreement, two-way random model. ICC values of less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent agreement, respectively [13].

Plot diagrams were generated with MATLAB software (version R2018a, MathWorks, Inc.). Principal component analysis was used to calculate the standard deviation ellipse for each reference point by finding the orientation with the most significant standard deviation. The vector difference for each axis was also calculated by subtracting the x- and y-coordinate of the CV from the TFC. All statistical analyses were performed using IBM SPSS Statistics 24.0 (IBM Corp., Armonk, NY, USA). Mean ± SD was used for quantitative variables. Differences were considered statistically significant when the P values were less than 0.05.

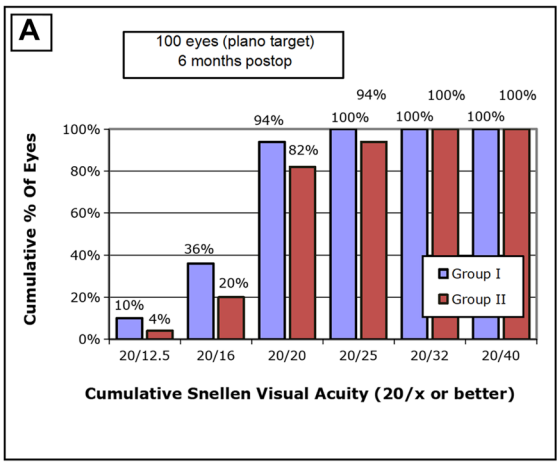
RESULTS

A total of 100 consecutive patients (100 eyes) were included in this retrospective observational study. Patients were classified into group I (tear film mark centration group) or group II (tear film mark decentration group) based on an intraoperative decentration from the TFC

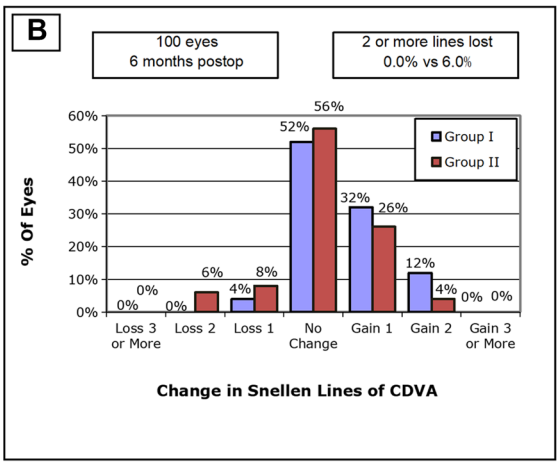
Table 1 The represented demographic data for the patients

Characteristic	Group I	Group II	*P*
Patients (eyes, *n*)	50 (50)	50 (50)	–
Age (years)	22.2 ± 2.8 (18 to 29)	22.8 ± 4.1 (18 to 36)	0.792
Sex (% women)	74%	62%	–
Refractive errors (D)			
Spherical	−5.14 ± 1.47 (−1.25 to −8.75)	−4.72 ± 1.81 (−1.00 to −9.00)	0.124
Cylindrical	−0.67 ± 0.54 (0 to −2..00)	−0.56 ± 0.48 (0 to −1.75)	0.304
MRSE	−5.47 ± 1.48 (−1.63 to −9.00)	−5.00 ± 1.76 (−1.63 to −9.00)	0.151
CCT (μm)	548.2 ± 28.3 (499 to 639)	542.5 ± 28.1 (496 to 607)	0.318
Optical zone (mm)	6.55 ± 0.10 (6.5 to 6.8)	6.54 ± 0.10 (6.3 to 6.8)	0.451
Average keratometry (D)	42.90 ± 1.43 (40.6 to 45.6)	43.08 ± 1.44 (40.1 to 47.4)	0.712
Preoperative pupillary offset (mm)	0.24 ± 0.12 (0.04 to 0.51)	0.23 ± 0.13 (0.03 to 0.51)	0.676
Preoperative pupillary offset (x-axis)	0.05 ± 0.14 (−0.30 to 0.30)	0.06 ± 0.16 (−0.35 to 0.38)	0.866
Preoperative pupillary offset (y-axis)	0.16 ± 0.15 (−0.10 to 0.51)	0.15 ± 0.13 (−0.22 to 0.43)	0.816

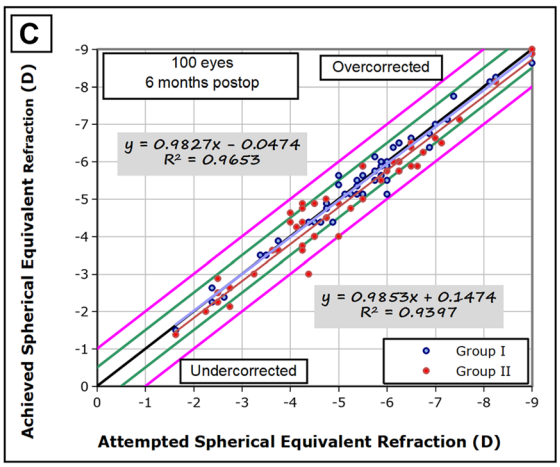
Values presented as means ± standard deviation (range)
D diopters, *MRSE* manifest refraction spherical equivalent, *CCT* central corneal thickness, *Group I* tear film mark centration group, *Group II* tear film mark decentration group



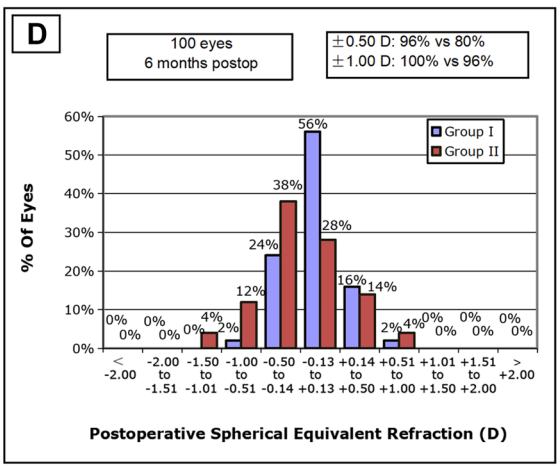
Uncorrected Distance Visual Acuity



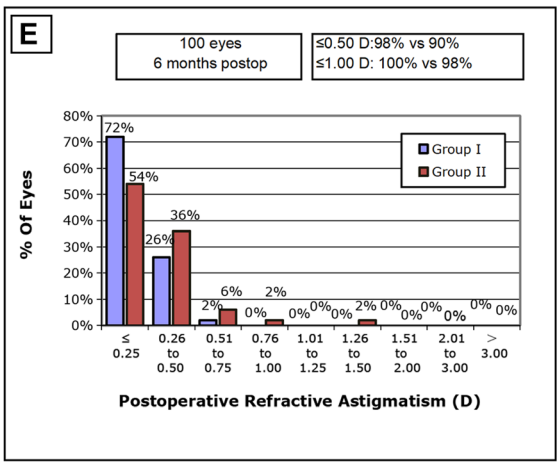
Change in Corrected Distance Visual Acuity



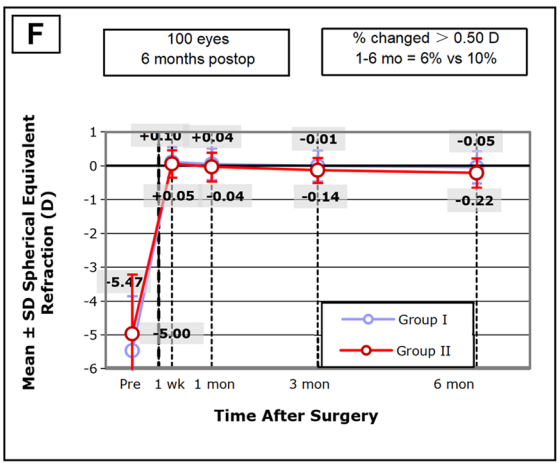
Spherical Equivalent Attempted vs Achieved



Spherical Equivalent Refractive Accuracy



Refractive Astigmatism



Stability of Spherical Equivalent Refraction

◀**Fig. 2** Visual outcomes after small incision lenticule extraction. **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 6 months postoperatively. *D* diopters

Table 2 Comparison of location relative to the pupil center between the corneal vertex and tear film center

Group	Location		
	Horizontal (mm)	Vertical (mm)	Total (mm)
Group I			
CV	−0.05 ± 0.14	−0.16 ± 0.15	0.24 ± 0.12
TFC	−0.05 ± 0.12	−0.15 ± 0.14	0.22 ± 0.10
P	0.789	0.114	0.054
ICC	0.891	0.912	0.86
Group II			
CV	−0.06 ± 0.16	−0.15 ± 0.13	0.23 ± 0.13
TFC	−0.04 ± 0.15	−0.22 ± 0.13	0.28 ± 0.09
P	0.078	0.000*	0.002*
ICC	0.833	0.58	0.48
Total			
CV	−0.05 ± 0.15	−0.16 ± 0.14	0.23 ± 0.12
TFC	−0.04 ± 0.14	−0.18 ± 0.14	0.25 ± 0.10
P	0.177	0.006*	0.118
ICC	0.856	0.752	0.659

Values presented as means ± standard deviation
CV corneal vertex, *TFC* tear film center, *ICC* intraclass correlation coefficient, *Group I* tear film mark centration group, *Group II* tear film mark decentration group
*Significant difference between the CV and TFC locations (*t* test)

average of 0.20 mm [10]. Demographic data are presented in Table 1, and visual outcomes are shown in Fig. 2. All surgeries were uneventful, and no complications occurred in any of the eyes.

As for the distance from the PC, the TFC and CV showed mean magnitudes of 0.25 ± 0.10 mm (range 0.06–0.55 mm) and 0.23 ± 0.12 mm (range 0.03–0.51 mm), respectively (Table 2). No significant difference was observed in the distance from the PC between the two reference points ($P = 0.118$). The ICC for the measures of distance from the CV and TFC to the PC was 0.659 (95% confidence interval 0.533–0.757). The scatter plots of the CV and TFC are shown in Fig. 3a and b, respectively. An inferotemporal tendency of directional location was observed for both reference points, and in 84% (84/100) of eyes, the CV and TFC were located in the same quadrant. In addition, the plots depicting the vector difference of the reference points in each eye showed a convergence, to a certain extent, at the center (Fig. 3c).

The mean decentration from the TFC and the CV was 0.19 ± 0.13 mm and 0.20 ± 0.12 mm, respectively. No significant difference was observed in the arithmetic values of decentration between the two reference points ($P = 0.056$). The ICC for the measures of decentration from the TFC and from the CV was 0.768 (95% confidence interval 0.672–0.838). The horizontal and vertical displacements in decentration are shown in Table 3. From the distributions in Fig. 4, the locations of the treatment zone center tended to be superior on average from both reference points.

The difference in distance from the PC was significant for group II ($P = 0.002$) but not for group I ($P = 0.054$). In group II, a significant difference and a poor ICC were observed in the vertical distance ($P = 0.000$, ICC = 0.580), but not in the horizontal distance ($P = 0.078$, ICC = 0.833), between the two reference points. However, the difference in decentration was significant for group I ($P = 0.000$), but not for group II ($P = 0.968$). Furthermore, the locations of the treatment zone center in group I showed random distribution, whereas group II tended to be superior on average.

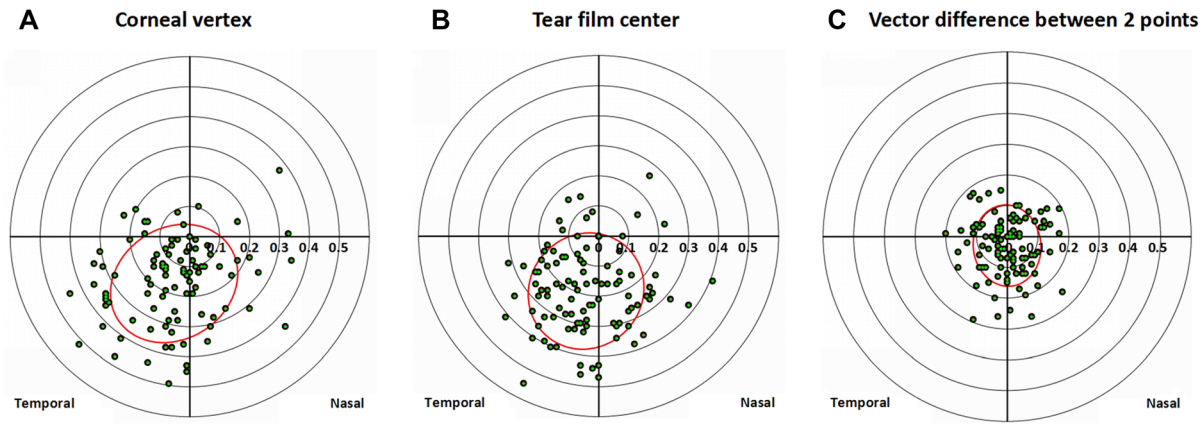


Fig. 3 **a** Scatter plot showing the corneal vertex relative to the pupil center on Scheimpflug tomography. **b** Scatter plot showing the tear film center relative to the pupil center on the screen captures. **c** Vector difference of the location between the corneal vertex and the tear film center. The red ovals represent the standard deviation ellipses

DISCUSSION

The most appropriate method for precisely locating the CV during SMILE has not yet reached a consensus and remains to be studied. In previous studies, greater attention was paid to utilizing the PC to locate the CV, while the TFC was neglected [5, 6]. However, the PC as a primary choice for locating the CV is limited by its instability and cyclotorsion. Therefore, whether the TFC could simulate the location of the CV is worth investigating. In this study, we investigated the interchangeability of the location of the TFC and CV. To eliminate the influence of cyclotorsion in coordinate transformation, we compensated for it by rotating the patient's head [12]. In addition, we believe that the shift of the PC can be ignored because the mean difference in pupil diameter (3.05 ± 0.46 mm from the Pentacam vs. 2.78 ± 0.34 mm from the screen captures) was controlled by similar illumination intensity.

In the current study, the PC, CV, and TFC were superimposed on the schematic depicted in Fig. 1. The results showed that in most (84.0%) cases, the TFC and CV were located in the same quadrant. The mean difference in the distance from the PC between the two reference points was 0.02 mm, and the ICC was 0.659. We conducted a vector analysis in this study because the location of the reference point in SMILE includes both magnitude and direction [14]. The arithmetic values for the magnitude of the distance from the PC were almost identical. The mean vector and standard deviation ellipse showed similar directional tendencies on both reference points. Furthermore, the vector differences for the location between the two reference points showed a convergence, to a certain extent, at the center. Thus, it can be speculated that the location of the CV in each eye could be simulated by the TFC.

In addition, we found that the locations of the TFC and CV were highly consistent in the TFM centration group (ICC was 0.860, 0.891, and 0.912 for total distance, horizontal distance, and vertical distance, respectively) (Fig. 5a, c), but not in the TFM decentration group (ICC was 0.480, 0.833, and 0.580 for total distance, horizontal distance, and vertical distance, respectively). TFM decentration indicated that the pupillary axis and eyepiece

Table 3 Comparison of decentered displacement relative to the tear film center or corneal vertex

Group	Decentered displacement		
	Horizontal (mm)	Vertical (mm)	Total (mm)
Group I			
D_{TFC}	0.04 ± 0.06	−0.01 ± 0.07	0.09 ± 0.04
D_{CV}	0.01 ± 0.09	0.00 ± 0.09	0.12 ± 0.05
P	0.003*	0.304	0.000*
ICC	0.636	0.636	0.23
Group II			
D_{TFC}	0.03 ± 0.15	0.20 ± 0.17	0.29 ± 0.10
D_{CV}	0.04 ± 0.15	0.22 ± 0.15	0.29 ± 0.10
P	0.458	0.318	0.968
ICC	0.897	0.765	0.498
Total			
D_{TFC}	0.03 ± 0.12	0.10 ± 0.17	0.19 ± 0.13
D_{CV}	0.02 ± 0.12	0.11 ± 0.17	0.20 ± 0.12
P	0.091	0.27	0.056
ICC	0.844	0.847	0.768

Values presented as means ± standard deviation

CV corneal vertex, *TFC* tear film center, D_{TFC} Decentration from TFC, D_{CV} Decentration from CV, *ICC* intraclass correlation coefficient, *Group I* tear film mark centration group, *Group II* tear film mark decentration group

*Significant difference between the D_{TFC} and D_{CV} (*t* test)

system were not coaxial in the case of fixation bias or alignment error (Fig. 5d). Since the observed entrance pupil is a deviated virtual image, the difference between the observed PC in non-coaxial eyes and the actual PC in coaxial eyes can influence the PC to a certain degree, resulting in a greater PC-TFC distance (Fig. 5b). Therefore, we attribute the discrepancy, particularly in the vertical direction, to the varied PC image from TFM decentration (non-coaxial eyes), which was also performed in the vertical decentration. Furthermore, caution should be taken, and TFM centration is advised for locating any reference points.

As we know, intraoperative decentration assessment would allow the surgeon to alter the lenticule creation before starting the photodisruption process, which is essential in SMILE [4] In the current study, we investigated the relationship between the decentered distance from the TFC and that from the CV. Our results showed a significant relationship between decentration from the TFC and from the CV (ICC was 0.768, 0.844, and 0.847 for total

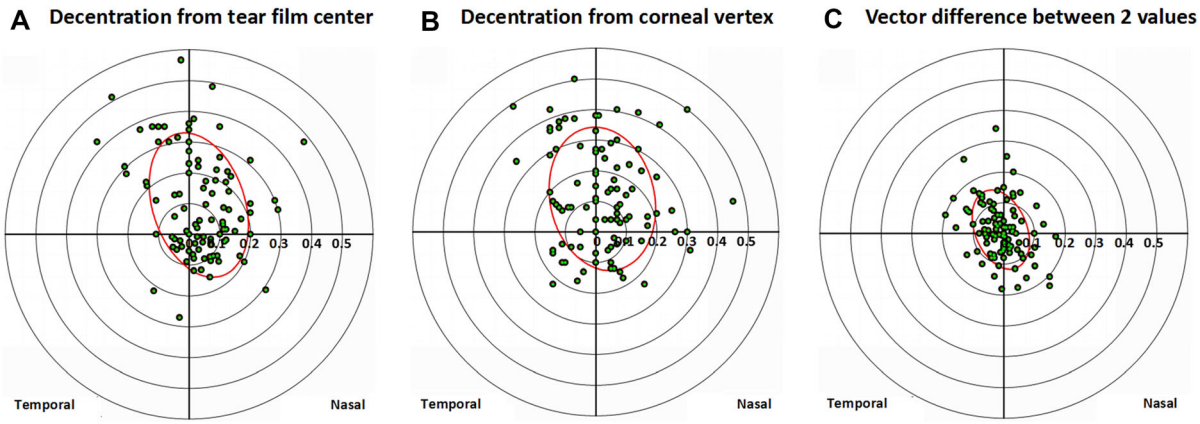


Fig. 4 **a** Scatter plot showing the treatment zone center relative to the tear film center on the screen captures. **b** Scatter plot showing the treatment zone center relative to the corneal vertex on the tangential curvature difference map. **c** Vector difference of the treatment zone center relative to the corneal vertex and the tear film center. The red ovals represent the standard deviation ellipses

decentration, horizontal decentration, and vertical decentration, respectively). In other words, TFM decentered displacement intraoperatively could indicate optical zone decentered displacement postoperatively. The locations of the treatment zone center in group II tended to be superior on average, which related to the superior tendency of decentration from the TFC. Therefore, the surgeon could modify the lenticule centration intraoperatively in real time by observing the dynamic change in TFM.

The limitations of our study include its retrospective design and the need for a more robust analysis method. In addition, analyzing the centration of a three-dimensional mass, such as the refractive lenticule in SMILE, on a two-dimensional screen can yield limited results.

CONCLUSIONS

In conclusion, in this study we found that the TFC could simulate the location of the CV. Furthermore, TFM decentered displacement could indicate optical zone decentered displacement.

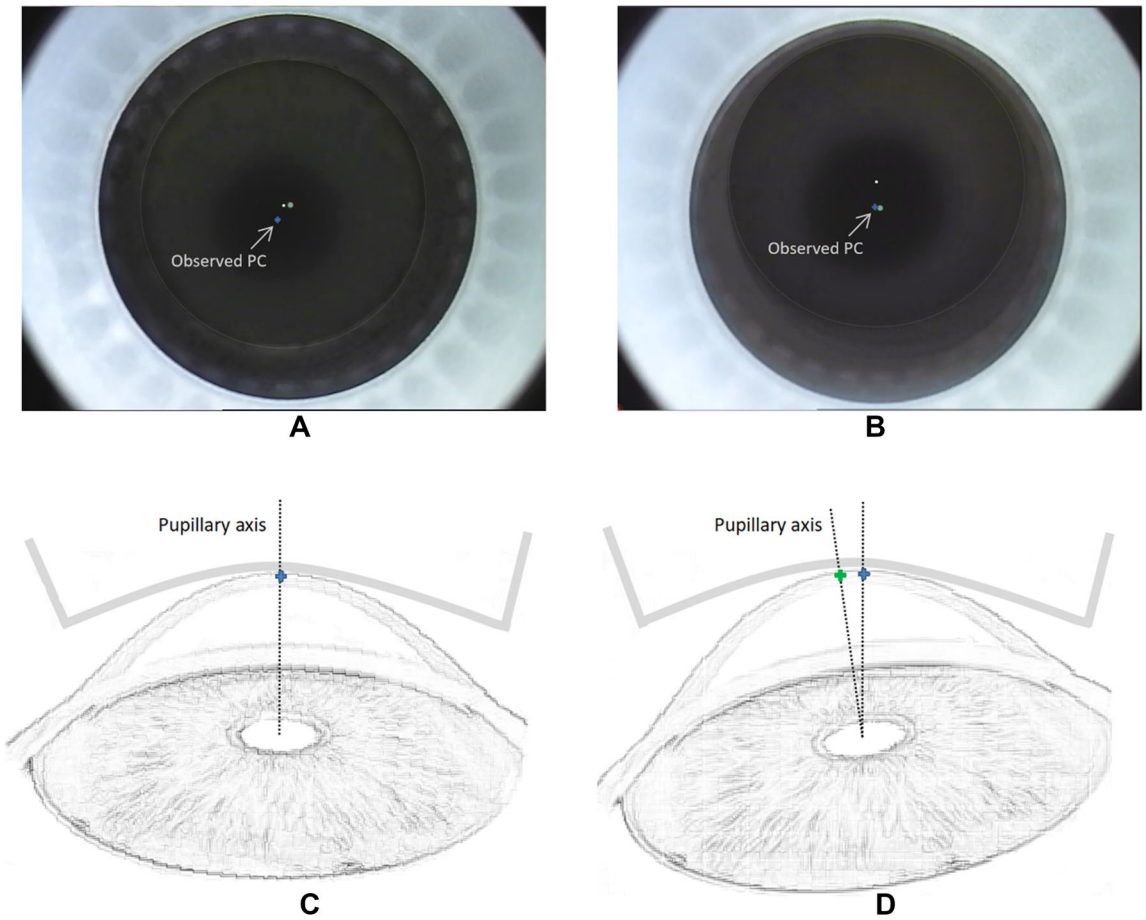


Fig. 5 A calibrated video capture image in the TFM centration (**a**) or TFM decentration group (**b**). The observed PC will overlap or deviate from the actual PC in coaxial (**c**) or non-coaxial eyes (**d**). Green dot = treatment zone center; white dot = tear film center; blue cross = observed pupil center; green cross = actual pupil center

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Author Contributions. Dr Liu had full access to all the data and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: All authors. Acquisition, analysis, or interpretation of data: Drs Liu and Zhang. Drafting of the manuscript: Drs Liu and Zhang. Critical revision of the manuscript for important intellectual content: Drs Liu and Zhou. Statistical analysis: All authors. Obtained funding: Drs Liu and Zhou. Administrative, technical, or material support: Drs Liu and Zhang. Supervision: Dr. Zhou.

Disclosures. Shengtao Liu is currently affiliated with the Eye and ENT Hospital, Fudan University, but was affiliated with the Affiliated Eye Hospital of Nanchang University at the time the study was undertaken. Xiaoxue Zhang, and Xingtao Zhou confirm that they have nothing to disclose.

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 Affiliated Eye Hospital of Nanchang University 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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