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Repeatability and reproducibility of a new method for centration analysis via optical zone tangent points after corneal refractive surgery

Xuejuan Wu¹, Jing Wu¹, Chuanwei Zhang¹, Yan Xu², Qian Chen², Qing Chen¹ and Kai Li^{1*}

Abstract

Purpose To investigate the repeatability and reproducibility of a new method for centration analysis after small incision lenticule extraction (SMILE) and femtosecond laser-assisted LASIK (FS-LASIK).

Methods This study comprised 29 eyes treated with SMILE and 24 with FS-LASIK. Decentrations were analyzed using tangential and pachymetry difference maps respectively. Both difference maps were generated with a Scheimpflug tomographer (Pentacam) for each eye, using preoperative and 3-month postoperative scans. Repeatability and reproducibility were evaluated by calculating the intraclass correlation coefficient (ICC), within-subject standard deviation (Sw), and coefficient of repeatability (CR).

Results ICC, Sw, and CR showed good to excellent repeatability in locating the coordinates of the optical zone (OZ) center on both maps, with values ranging from 0.84 to 0.96, 0.03 to 0.13, and 0.08 to 0.36 respectively. The repeatability of the total decentration from the preoperative corneal vertex on the tangential curvature difference maps (d_{TC}) and the pachymetry difference maps (d_{PC}) were moderate and good, respectively. The ICC, Sw, and CR of d_{TC} were 0.63, 0.09, and 0.25, respectively. The ICC, Sw, and CR of d_{PC} were 0.77, 0.10, and 0.28, respectively. The reproducibility of the OZ center measurements was excellent for the tangential difference maps ($ICC \geq 0.97$) and good for the pachymetry difference maps ($ICC \geq 0.86$). ICC, Sw, and CR showed excellent reproducibility of d_{TC} , with values of 0.95, 0.03, and 0.08, respectively. ICC, Sw, and CR showed good reproducibility of d_{PC} , with values of 0.89, 0.06, and 0.17, respectively.

Conclusion The centration analysis method used in this study showed good to excellent repeatability and reproducibility in locating the coordinates of the center of the OZ on the tangential and pachymetry difference maps.

Keywords Centration analysis, Decentration, Corneal refractive surgery, Repeatability, Reproducibility

Introduction

Accurate centration of the ablation zone during corneal refractive surgery plays a significant role in achieving good visual outcomes. Decentral ablation may lead

to under-correction and other undesirable side effects, such as diplopia, decreased contrast sensitivity, and night vision disturbances [1, 2]. Compared to small incision lenticule extraction (SMILE), although eye tracking systems have advantages in reducing the incidence of decentered treatments, they have not completely eliminated topographic decentration in laser in situ keratomileusis (LASIK) [3–5].

In previous studies, the overlay grid method was widely used for the centration analysis. In this method, a sheet of transparent film was placed on a computer

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screen to point to the apparent center of the optical zone (COZ) on the difference maps [6, 7]. The technical assessment of decentration is often based on an ablation profile analysis in a tangential or a pachymetry difference map. The edge of the ablation area is highlighted in the tangential maps. Centration analysis using a tangential difference map is less influenced by the gaze, anterior cornea surface modification-related misalignment, and non-centered references [8]. However, when the optical area is not a regular circle or ellipse, it is challenging to locate the OZ center. Some researchers reported that pachymetry difference maps could provide a good depiction of the treatment zone [9]. The optical zone center was the point of maximum pachymetry difference located on each pachymetry difference map. Accurately positioning the COZ remains a challenge due to the presence of multiple points corresponding to the maximum pachymetric difference. Based on the above, the current study proposed a new method for measuring COZ.

It is well known that the repeatability of methods is closely related to the accuracy of the experimental results and the comparability of the results among different studies. To our knowledge, studies that have focused on the repeatability of methods for analyzing decentration are scarce. Therefore, this study aimed to investigate the repeatability and reproducibility of the novel methods for the centration analysis after small incision lenticule extraction (SMILE) and femtosecond laser-assisted LASIK (FS-LASIK).

Patients and methods

Patients

This study was a retrospective analysis. Fifty-three consecutive patients with myopia and myopic astigmatism were recruited for this study and treated with SMILE (29) or FS-LASIK (24) at the Affiliated Hospital of Nanjing University of TCM, Nan Jing, China. The ethics approval was not required due to the retrospective nature of reviewing the data. The study adhered to the tenets of the Declaration of Helsinki and followed good clinical practice. Only the right eye of each patient was included.

The enrolling criteria for the patients included in the study groups were stable refraction more than one year prior to surgery and a normal preoperative corneal topography. Patients were excluded if they had any optical opacities or pathology on slit-lamp examination, previous corneal surgeries, ocular trauma, or intraocular surgery, severe dry eye, corneal disease, ocular infection, or collagen vascular/autoimmune diseases.

Surgical techniques

All SMILE treatments were performed using the 500-kHz VisuMax femtosecond laser (software version 2.4.0; Carl Zeiss Meditec, Jena, Germany) by the same surgeon (Kai Li). The intended depth of the superior cap was set to 120 μm , and the length of the incision was set to 2.0 mm at 110 degrees in both eyes. The diameter of the optical zone (OZ) ranged from 6.4 to 7.0 mm, and the cap diameter ranged from 7.4 to 7.9 mm. The center of the OZ was set to be the coaxially sighted corneal light reflex. During the procedure, the patient is raised to the contact glass of the femtosecond laser. When a meniscus tear film appears, the patient is able to see the fixation target clearly because the vergence of the fixation beam is adjusted according to the individual eye's refraction. At this point, the surgeon instructed the patient to keep on looking at the green light and continued to adjust the position until a satisfactory centration of the docking was achieved. Then the corneal suction ports are activated to fixate the eye in this position. After successful femtosecond laser cutting, the refractive lenticule of the intrastromal corneal tissue was dissected and extracted through a 2-mm incision using forceps.

FS-LASIK procedures were performed by the VisuMax femtosecond laser system (Carl Zeiss, Meditec AG, Jena, Germany) with a repetition rate of 500 kHz and a pulse energy of 150 nj, for the flap creation. Ablation was performed with the MEL90 excimer laser (Carl Zeiss, Meditec AG, Jena, Germany). The flap diameter was 8.1 mm, and the thickness was 90 to 100 μm , with a 2.5 mm wide hinge immediately above. The diameters of the optical zone were set at 6.5 mm to 7.0 mm. The coaxially sighted corneal light reflex was used as the best approximation of the intersection of the visual axis with the cornea [10], and the intraoperative alignment of the photoablation was controlled by the eye tracker.

Postoperative evaluation

Patients in both groups were medicated with topical 0.5% levofloxacin eye drops four times daily for 1 week. (0.1%) fluorometholone was applied six times daily for SMILE and four times daily for FS-LASIK in the first week, after which it was tapered over 30 days. Artificial tears were used for 1-3 months or as needed. Patients were observed at 1 day, 1 month, and 3 months. Corneal tomography was performed at the 3-month visit.

Centration analysis

The centration of the OZ after SMILE and FS-LASIK was evaluated on the Pentacam tangential difference maps and corneal thickness differential maps respectively. A single experienced operator measured all corneal

tomographies. Both difference maps were generated with the Scheimpflug tomography system (Pentacam; OCULUS Optikgeräte GmbH, Wetzlar, Germany), using preoperative and 3-month postoperative scans. The (0, 0) point in each topographic graph was displayed as the corneal vertex (CV), and a coordinate (x, y) in millimeters was used for any point relative to the (0, 0) point. The OZ is shown as an area with warm colors (yellow to red) and is outlined by a change of zero diopter in the tangential difference maps [11]. The center of the OZ (COZ) was defined as the geometric center of a square (if the OZ is elliptical, the center is still calculated from four tangent points, with the difference that the square of tangents becomes a rectangle) generated by four hypothetical tangents along the edge of the OZ (the left panel of Fig. 1). The steps of the coordinates of each tangent point obtained from the difference maps were 0.01 mm and the coordinates of the COZ were measured to the nearest 0.005 mm.

Located the tangent points on the farthest edges of the OZ at the temple (X_{TT}, Y_{TT}), nasal (X_{TN}, Y_{TN}), superior (X_{TS}, Y_{TS}), and inferior (X_{TI}, Y_{TI}) regions (Fig. 2)). The coordinates of the COZ (X_{TC}, Y_{TC}) in the tangential difference maps were calculated using the following formulas,

$$\begin{aligned} X_{TC} &= \frac{1}{2}(X_{TN} + X_{TT}), \\ Y_{TC} &= \frac{1}{2}(Y_{TS} + Y_{TI}). \end{aligned} \tag{1}$$

The centration analysis on the pachymetry difference maps was conducted similarly. The OZs in the pachymetry

difference maps resemble the shape of concentric circles. The coordinates of the four tangent points were located on the smallest circle encompassing the maximum pachymetrical difference (Fig. 3). The coordinates of the COZ (X_{PC}, Y_{PC}) in pachymetry difference maps were calculated by the following formula,

$$\begin{aligned} X_{PC} &= \frac{1}{2}(X_{PN} + X_{PT}), \\ Y_{PC} &= \frac{1}{2}(Y_{PS} + Y_{PI}). \end{aligned} \tag{2}$$

The coordinates of ($\Delta X, \Delta Y$) refer to the displacement of the decenter relative to the preoperative CV. $\Delta X(\Delta Y)$ was also equivalent to the horizontal(vertical) decentration [12]. As previously described, the decentration in the tangential curvature difference map was calculated as,

$$\begin{aligned} \Delta X_{TC} &= X_{P1} - X_{P2} + X_{TC}, \\ \Delta Y_{TC} &= Y_{P1} - Y_{P2} + Y_{TC}, \end{aligned} \tag{3}$$

where X_{P1} and Y_{P1} are the preoperative pupil center coordinates, and X_{P2} and Y_{P2} are the postoperative pupil center coordinates [12]. In the pachymetry difference map, the values of X_{PC} and Y_{PC} were used to calculate the parameters of ΔX_{PC} and ΔY_{PC} .

The magnitude of total decentration in each difference map was calculated as follows,

$$\begin{aligned} d_{TC} &= \sqrt{\Delta X_{TC}^2 + \Delta Y_{TC}^2}, \\ d_{PC} &= \sqrt{\Delta X_{PC}^2 + \Delta Y_{PC}^2}. \end{aligned} \tag{4}$$

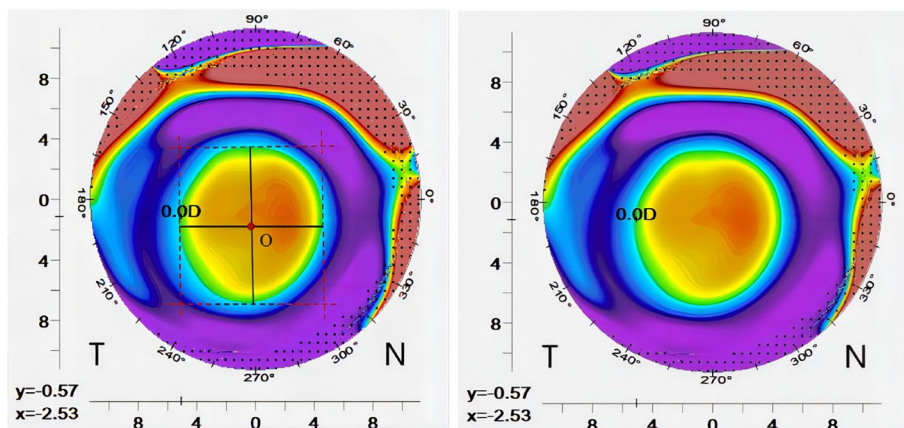


Fig. 1 The left panel is a composite picture using the square method to measure the COZ on the Pentacam tangential difference map. A rectangle is formed by hypothetical tangents (red dashed lines) in four directions: superior, inferior, nasal, and temporal to the optical zone. Point O is the geometric center of the rectangle, i.e., the center of the optical zone. In the right panel, the point of the farthest edges of OZ at the temple is located on the Pentacam tangential difference map. The diopter of this point is 0.0D and the coordinates of this point (-2.53 mm, -0.57 mm) are directly shown on the map. Examiners could judge the location of the tangent point by moving the mouse and observing the changes in the values of the coordinates and diopters during the measurement process

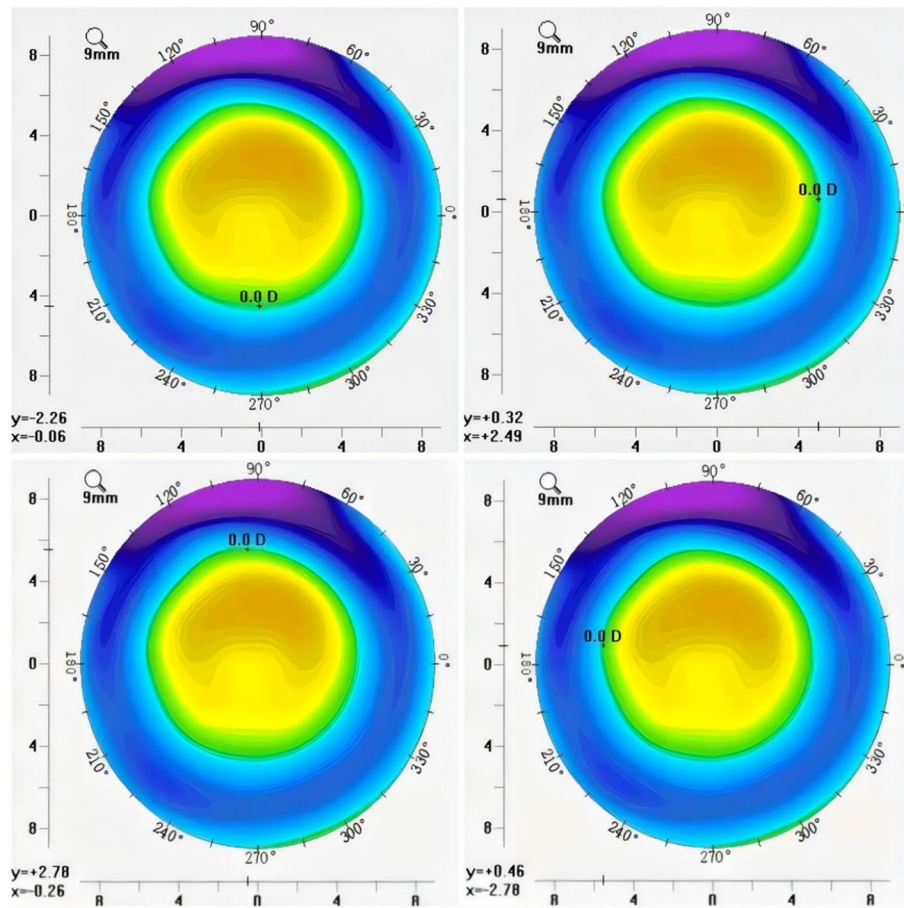


Fig. 2 On the tangential difference maps, the tangent point is depicted with a black cross, which also indicates the position of the mouse cursor during the measurement. The left aspect of the image represents the temporal side. The coordinates of the tangent point are displayed directly in the lower left corner of each panel. For the right eye, the positive x values indicated nasal decentration and negative x values indicated temporal decentration

We take the coordinates of four tangential points in Fig. 2 as an example to show how to calculate the value of the d_{TC} . The coordinates of (X_{TT}, Y_{TT}) , (X_{TN}, Y_{TN}) , (X_{TS}, Y_{TS}) , and (X_{TL}, Y_{TL}) were $(-2.78 \text{ mm}, +0.46 \text{ mm})$, $(+2.49 \text{ mm}, +0.32 \text{ mm})$, $(-0.26 \text{ mm}, +2.78 \text{ mm})$, and $(-0.06 \text{ mm}, -2.26 \text{ mm})$, respectively. Bringing the above coordinates into Eq. (1), X_{TC} and Y_{TC} were calculated to be -0.15 mm and 0.26 mm , respectively. The coordinates of the pupil center were shown directly on the Pentacam. Here, the preoperative pupil center coordinates (X_{P1}, Y_{P1}) was $(+0.05 \text{ mm}, -0.05 \text{ mm})$; the postoperative pupil center coordinates (X_{P2}, Y_{P2}) was $(-0.07 \text{ mm}, +0.11 \text{ mm})$. By bringing them into Eq. (3), it can be calculated that the $(\Delta X, \Delta Y)$ was $(-0.03 \text{ mm}, 0.10 \text{ mm})$. Finally, the value of the d_{TC} was calculated from Eq. (4) as 0.10 mm .

Repeatability and reproducibility

All patients underwent one pre-operative examination and three repeated post-operative examinations

by one experienced examiner. This allowed us to obtain three tangential curvature difference maps and three pachymetry difference maps for each patient. The coordinates of the COZ in each difference map were also measured by this examiner. The repeatability of the three measurements in each difference map was assessed. Patients were repositioned before the measurements to ensure the correct alignment of the eye with the optical axis of the measuring device. There was no extra lighting in the examination room to ensure that all measurements were made under constant dim lighting.

The centration analysis of each difference map measured for the first time was also conducted by two other new operators. The three examiners were blinded to each other's results during the measurements. The parameters of the first difference map measured by the three examiners were evaluated to assess the reproducibility of this method.

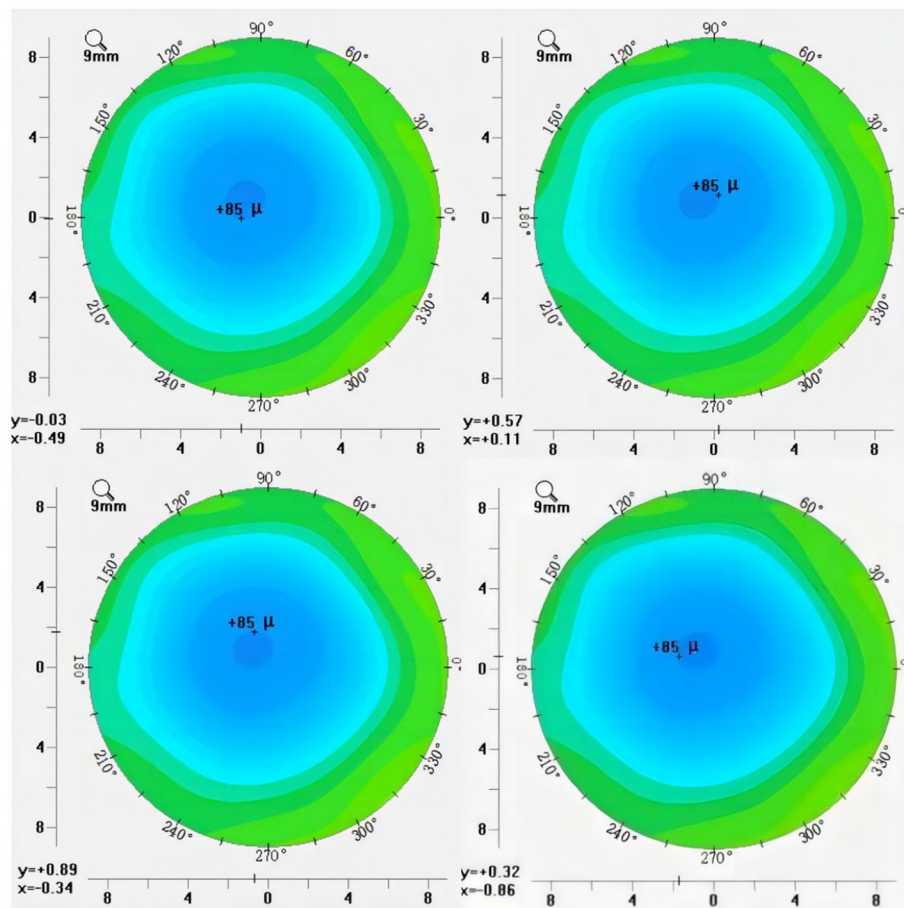


Fig. 3 On the pachymetry difference map, the positions of four tangential points marked with a black cross are located on the smallest circle containing the maximum pachymetric difference. Examiners could also judge the location of the tangential point by moving the mouse and observing the changes in the values of the coordinates and thickness during the measurement process. The 85u represents the magnitude of the pachymetric difference at the tangential point is 85um. The coordinates of the tangential point are also displayed directly in the lower left corner of each panel

Statistical analysis

Statistical analysis was performed using SPSS statistical package version 24 (IBM Corp., Armonk, N.Y., USA). The sample size was estimated by the number of repeated measures and the level of confidence [13]. We set the confidence level at 0.15 and calculated a total sample size of 43. The normality for variables was checked using the Quantile-quantile Plot. Results are shown as the mean \pm standard deviation (SD). Repeatability and reproducibility were assessed through the intraclass correlation coefficients (ICC), within-subject standard deviation (Sw), and coefficient of repeatability (CR). The ICC was calculated based on the form of two-way random effect, absolute agreement, and single measurement. The range of the ICC was from 0 to 1. The closer the ICC is to 1, the better the consistency of the measurement, indicating that the total variation in the measurements is solely due to the variability in the

parameter being measured [14]. ICC values below 0.5 can indicate poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values above 0.90 indicate excellent reliability [15]. Sw equals the square root of the mean square within groups calculated through one-way ANOVA [14, 16], and CR was defined as $2.77 \times Sw$ [17]. Sw and CR denote good repeatability when their values are near zero [18]. Three measurements were recorded for each eye and the mean values of the magnitude of the total, horizontal, and vertical decentrations were calculated and used for the analysis. The difference between the parameters measured on the two difference maps was analyzed by paired t-tests when the data were normally distributed. The independent t-test was used to analyze the difference in the mean values of decentrations between SMILE and FS-LASIK. $P < 0.05$ was considered statistically significant.

Results

Fifty-three eyes of 53 patients (16 men and 37 women; SMILE 29 and FS-LASIK 24) were enrolled. The population demographics are reported in Table 1.

Optical zone decentration

The average d_{PC} measured three times was 0.38 ± 0.18 mm, which was greater than that of d_{TC} (0.28 ± 0.14 mm), $t = 4.23, P < 0.01$. Figure 4 shows the distribution of the mean decentration values. The magnitude of the average d_{TC} was within ± 0.30 mm in 32 (60.38%) of the 53 eyes. On the pachymetry difference maps, the magnitudes of the average total decentration were within ± 0.30 mm in 17 eyes (32.08%). The mean of the average values of X_{TC} and Y_{TC} was 0.00 ± 0.14 mm and 0.06 ± 0.27 mm, respectively

($t = -1.34, P = 0.19$). The mean of the average values of X_{PC} and Y_{PC} was 0.03 ± 0.23 mm and 0.12 ± 0.32 mm, respectively ($t = -1.51, P = 0.14$).

The average d_{TC} of three repeated measurements was 0.29 ± 0.15 mm (range: 0.09 to 0.67 mm) for the SMILE group and 0.27 ± 0.12 mm (range: 0.10 to 0.60 mm) for the FS-LASIK group, with no statistically significant difference between them ($t = 0.60, P = 0.55$). The average d_{PC} was 0.40 ± 0.17 mm (range: 0.07 to 0.72 mm) for the SMILE group and 0.37 ± 0.20 mm (range: 0.11 to 0.83 mm) for the FS-LASIK group. The results also revealed no statistically significant differences between groups in the average d_{PC} of three repeated measurements ($t = 0.58, P = 0.57$).

Repeatability

The repeatability of the eccentricity-related parameters on the tangential difference maps and the pachymetry difference maps are shown in Tables 2 and 3, respectively. The ICC values of X_{TC} and ΔX_{TC} were greater than those of Y_{TC} and ΔY_{TC} , indicating excellent repeatability. The ICC of d_{PC} was 0.77, which indicated good reliability. The ICC of d_{TC} was slightly lower than that of d_{PC} , although the Sw and CR were still good.

We also divided the patients into two groups based on the diameter of the analyzed areas on the Pentacam. In group 1 (34 eyes), the diameters reached 8 mm in all of the measurements before and after surgery. In group 2 (19 eyes), the diameters did not reach 8 mm at least once in the three repeated measurements. The ICC of Y_{TC} and ΔY_{TC} of group 1 were 0.93 and 0.89 respectively, which were greater than those of group 2 (Table 4). The ICC of d_{TC} in group 1 was also greater than that in group 2.

Table 1 Preoperative parameters of the patients

| Parameter | Mean \pm SD (Range) | | |
|-------------|--------------------------------------|--------------------------------------|--------------------------------------|
| | SMILE(n=29) | FS-LASIK(n=24) | TOTAL(n=53) |
| Age(range) | 26.66 \pm 6.53 (18 to 41) | 24.96 \pm 6.24 (18 to 46) | 25.77 \pm 6.46 (18 to 46) |
| Sphere(D) | -4.29 \pm 1.03 (-2.50 to -5.75) | -6.55 \pm 1.02 (-4.25 to -9.00) | -5.44 \pm 1.58 (-2.50 to -9.00) |
| Cylinder(D) | -0.83 \pm 0.74 (-0.25 to -3.00) | -0.74 \pm 0.35 (-0.25 to -1.75) | -0.78 \pm 0.57 (-0.25 to -3.00) |
| C/S | 0.19 \pm 0.20 (0.00 to 0.71) | 0.10 \pm 0.12 (0.03 to 0.62) | 0.16 \pm 0.16 (0.00 to 0.71) |
| OZ size(mm) | 6.87 \pm 0.19 (6.50 to 7.00) | 6.78 \pm 0.20 (6.50 to 7.00) | 6.83 \pm 0.20 (6.50 to 7.00) |

C/S the ratio of the cylinder to the sphere

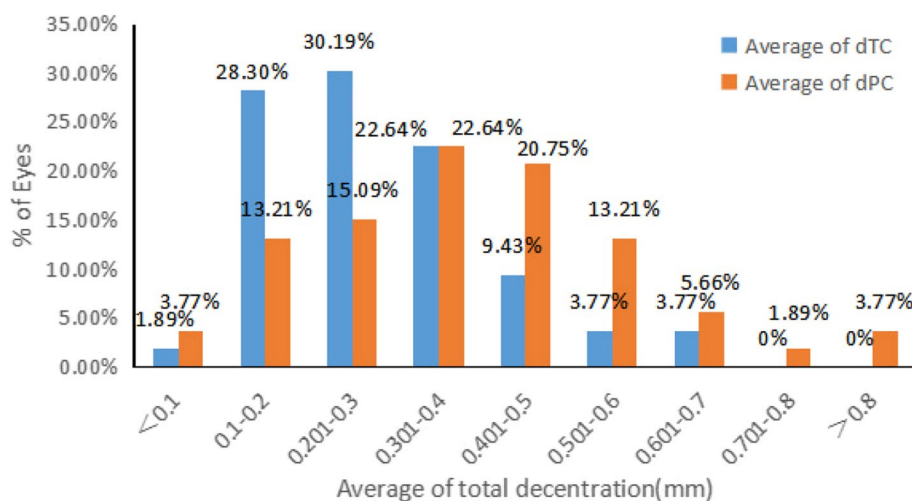


Fig. 4 Distribution of the average of total decentration values on the tangential curvature topography difference maps and the pachymetry difference maps

Table 2 Repeatability of parameters related to decentration on tangential difference maps

| | Mean±SD for each measurement | | | ICC | 95% CI for ICC | Sw | CR |
|----------------------|------------------------------|-------------|-------------|------|----------------|------|------|
| | 1 | 2 | 3 | | | | |
| X_{TC} (mm) | 0.01 ± 0.17 | 0.01 ± 0.17 | 0.03 ± 0.17 | 0.96 | 0.94-0.98 | 0.03 | 0.08 |
| Y_{TC} (mm) | 0.09 ± 0.33 | 0.08 ± 0.35 | 0.08 ± 0.32 | 0.84 | 0.76-0.90 | 0.13 | 0.36 |
| ΔX_{TC} (mm) | 0.00 ± 0.14 | 0.00 ± 0.15 | 0.00 ± 0.15 | 0.90 | 0.86-0.94 | 0.04 | 0.11 |
| ΔY_{TC} (mm) | 0.06 ± 0.29 | 0.06 ± 0.30 | 0.06 ± 0.26 | 0.82 | 0.73-0.88 | 0.12 | 0.33 |
| d_{TC} (mm) | 0.29 ± 0.16 | 0.29 ± 0.17 | 0.27 ± 0.15 | 0.63 | 0.49-0.75 | 0.09 | 0.25 |

ICC Intraclass correlation coefficient, Sw within-subject SD, CR Coefficient of repeatability; 95% CI 95% confidence interval, X_{TC} the x coordinate of the COZ on the tangential difference map, Y_{TC} the y coordinate of the COZ on the tangential difference map, ΔX_{TC} horizontal decentration from preoperative CV on the tangential difference map, ΔY_{TC} vertical decentration from preoperative CV on the tangential difference map, d_{TC} total decentration from the preoperative CV on the tangential difference map

Table 3 Repeatability of parameters related to decentration on pachymetry difference maps

| | Mean±SD for each measurement | | | ICC | 95% CI for ICC | Sw | CR |
|----------------------|------------------------------|-------------|-------------|------|----------------|------|------|
| | 1 | 2 | 3 | | | | |
| X_{PC} (mm) | 0.03 ± 0.28 | 0.05 ± 0.30 | 0.04 ± 0.29 | 0.85 | 0.77-0.90 | 0.11 | 0.30 |
| Y_{PC} (mm) | 0.14 ± 0.40 | 0.17 ± 0.38 | 0.14 ± 0.04 | 0.93 | 0.89-0.96 | 0.11 | 0.30 |
| ΔX_{PC} (mm) | 0.02 ± 0.24 | 0.04 ± 0.24 | 0.02 ± 0.25 | 0.80 | 0.71-0.87 | 0.11 | 0.30 |
| ΔY_{PC} (mm) | 0.11 ± 0.33 | 0.15 ± 0.33 | 0.11 ± 0.34 | 0.89 | 0.83-0.93 | 0.11 | 0.30 |
| d_{PC} (mm) | 0.37 ± 0.19 | 0.39 ± 0.21 | 0.39 ± 0.20 | 0.77 | 0.67-0.85 | 0.10 | 0.28 |

X_{PC} the x coordinate of the COZ on the pachymetry difference map, Y_{PC} the y coordinate of the COZ on the pachymetry difference map, ΔX_{PC} horizontal decentration from preoperative CV on the pachymetry difference map, ΔY_{PC} vertical decentration from preoperative CV on the pachymetry difference map, d_{PC} total decentration from the preoperative CV on the pachymetry difference map

Table 4 The ICC values of parameters related to decentration in the two groups

| | Group 1 | | Group 2 | |
|----------------------|---------|----------------|---------|----------------|
| | ICC | 95% CI for ICC | ICC | 95% CI for ICC |
| X_{TC} (mm) | 0.96 | 0.92-0.98 | 0.96 | 0.92-0.98 |
| Y_{TC} (mm) | 0.93 | 0.88-0.96 | 0.78 | 0.59-0.90 |
| ΔX_{TC} (mm) | 0.91 | 0.84-0.95 | 0.90 | 0.80-0.96 |
| ΔY_{TC} (mm) | 0.89 | 0.81-0.94 | 0.76 | 0.57-0.89 |
| d_{TC} (mm) | 0.76 | 0.62-0.86 | 0.50 | 0.22-0.74 |
| X_{PC} (mm) | 0.84 | 0.73-0.91 | 0.87 | 0.75-0.94 |
| Y_{PC} (mm) | 0.91 | 0.84-0.95 | 0.96 | 0.91-0.98 |
| ΔX_{PC} (mm) | 0.79 | 0.67-0.88 | 0.83 | 0.67-0.92 |
| ΔY_{PC} (mm) | 0.87 | 0.78-0.93 | 0.91 | 0.83-0.96 |
| d_{PC} (mm) | 0.72 | 0.56-0.83 | 0.82 | 0.66-0.92 |

However, the ICCs of X_{TC} and ΔX_{TC} in both groups were quite similar, indicating excellent repeatability.

Reproducibility

Table 5 shows the results of the reproducibility analyzed on the tangential difference maps. The level of reproducibility considering ICC, Sw, and CR can be regarded as

excellent for all of the measurements on the tangential difference maps (Table 5). Most of the ICCs of repeated measurements of centration shift were greater than 0.9 on the pachymetry difference maps (Table 6). The reproducibility of the Y_{PC} and ΔY_{PC} was better than that of X_{PC} and ΔX_{PC} on the pachymetry difference maps (Table 6).

Discussion

Accurate alignment of corneal ablation is crucial in corneal refractive surgeries to optimize visual outcomes. The pupil center shifts with changes in pupil size under different lighting conditions [19]. The corneal vertex is a stable reference for the cornea and has been recommended as the central alignment point for corneal laser refractive surgery [20]. It has also been shown to be closest to the corneal intersection of the visual axis [20, 21]. To date, there is no specific standard for determining the center of the optical zone, and few studies have investigated and compared methods used for assessing decentration after corneal refractive surgery.

This new method used to analyze decentration in our study was named as square method. The measurement approach reported by Lin's group is similar but not identical to ours [22, 23]. They also marked the maximum edges of the ablation on the x and y axes, but the center of the

Table 5 Reproducibility of the parameters related to the decentration on tangential difference maps

| | Mean±SD for each examiner | | | ICC | 95% CI for ICC | Sw | CR |
|----------------------|---------------------------|-------------|-------------|------|-------------------|------|------|
| | 1 | 2 | 3 | | | | |
| X_{TC} (mm) | 0.01 ± 0.17 | 0.00 ± 0.17 | 0.01 ± 0.97 | 0.97 | 0.80-0.98 | 0.03 | 0.08 |
| Y_{TC} (mm) | 0.09 ± 0.33 | 0.10 ± 0.32 | 0.10 ± 0.34 | 0.98 | 0.97-0.99 | 0.04 | 0.11 |
| ΔX_{TC} (mm) | 0.00 ± 0.14 | 0.01 ± 0.14 | 0.00 ± 0.14 | 0.96 | 0.93-0.97 | 0.03 | 0.08 |
| ΔY_{TC} (mm) | 0.06 ± 0.29 | 0.06 ± 0.28 | 0.68 ± 0.30 | 0.97 | 0.96-0.98 | 0.04 | 0.11 |
| d_{TC} (mm) | 0.28 ± 0.16 | 0.28 ± 0.16 | 0.28 ± 0.16 | 0.95 | 0.92-0.97 | 0.03 | 0.08 |

Table 6 Reproducibility of parameters related to decentration on pachymetry difference maps

| | Mean±SD for each examiner | | | ICC | 95% CI for ICC | Sw | CR |
|----------------------|---------------------------|-------------|-------------|------|-------------------|------|------|
| | 1 | 2 | 3 | | | | |
| X_{PC} (mm) | 0.04 ± 0.29 | 0.09 ± 0.32 | 0.05 ± 0.31 | 0.86 | 0.79-0.91 | 0.11 | 0.31 |
| Y_{PC} (mm) | 0.14 ± 0.40 | 0.16 ± 0.38 | 0.13 ± 0.39 | 0.97 | 0.96-0.98 | 0.06 | 0.17 |
| ΔX_{PC} (mm) | 0.03 ± 0.24 | 0.08 ± 0.26 | 0.04 ± 0.26 | 0.80 | 0.71-0.87 | 0.11 | 0.31 |
| ΔY_{PC} (mm) | 0.11 ± 0.33 | 0.13 ± 0.32 | 0.10 ± 0.32 | 0.96 | 0.94-0.98 | 0.06 | 0.17 |
| d_{PC} (mm) | 0.37 ± 0.19 | 0.39 ± 0.21 | 0.37 ± 0.20 | 0.89 | 0.83-0.93 | 0.06 | 0.17 |

ablation was estimated as the intersection of these four points [22, 23]. When the shape of the OZ is irregular, the center of the OZ obtained directly from the intersection of the four points may exaggerate the degree of decentration. In the overlay grid method the lines of the grid were distributed equally with 0.1 mm steps and the concentric circles had radii increasing in 0.1 mm steps [11]. The x and y coordinates of the centration offset between the center of the optical zone and the corneal vertex were measured to the nearest 0.05 mm [11]. In our method, the steps of the coordinates of each tangent point obtained from the difference maps were 0.01 mm and the coordinates of COZ were measured to the nearest 0.005 mm. As the overlay grid method does not have a clear criterion for selecting the best-fitting circle of the OZ, it is possible to introduce more human error when it is oval or irregular. Compared to this approach, the coordinates used to calculate the center of the OZ in our study were obtained directly on the Pentacam difference maps without any additional grid. The shape of the OZ has no significant effect on the location of the four tangent points and therefore has less effect on the location of the COZ. Theoretically, when the shape of the OZ is a regular circle, the location of the OZ center obtained by the method of this study should be consistent with the results of the overlay grid method. The ratio of the cylinder to the sphere may affect the shape of the OZ. In our study, this ratio is 0.16 ± 0.16 (0.00 to 0.71) and this does not significantly affect our results.

A deviation of the center of the lens from the corneal vertex of more than 0.3mm may lead to a decrease in

postoperative refractive results [19]. The magnitude of the average d_{TC} was within ± 0.30 mm in 32 (60.38%) of the 53 eyes, while the magnitude of the average d_{PC} was within ± 0.30 mm in 17 eyes (32.08%). The mean value of d_{PC} for three repeated measurements was greater than that of d_{TC} . This could be explained by the fact that the alteration of the anterior corneal shape after refractive surgery may lead to changes in the direction where the corneal thickness was measured, resulting in possible misalignment of the tomography pachymetry difference map [24]. In addition, the shifts in pupil offset from pre- to post-operative can cause serious artifacts in the subtraction of the pachymetry maps [25]. Therefore, it would not be appropriate to compare the decentration reported by different studies without taking into account the differences in analytical methods [7]. Previous studies also found that the decentration was predominantly along the vertical meridian [21]. In our study, the mean values of vertical decentration were larger than those of horizontal decentration, whether for tangential difference maps or pachymetry difference maps. However, there was no statistically significant difference between them.

In the current study, the mean values of d_{TC} were 0.29 ± 0.15 mm (range: 0.09 to 0.67 mm) for the SMILE group and 0.27 ± 0.12 mm (range: 0.10 to 0.60 mm) for the FS-LASIK group. Consistent with the results of the previous studies, there is no statistically significant difference between the two groups [11, 26]. In a previous study, Dan Z. Reinstein et al. reported a centration offset of 0.20 ± 0.11 mm (range: 0.00 to 0.50 mm) for the SMILE

group and 0.17 ± 0.10 mm (range: 0.00 to 0.53 mm) for the FS-LASIK group [11], which were lower than those reported in the present study. However, it was worth noting that the results of a recently published study were comparable to ours. In their study, the mean optical zone decentration was 0.33 ± 0.12 mm (range: 0.06 to 0.58 mm) and 0.27 ± 0.15 mm (range: 0.06 to 0.65 mm) for the SMILE and FS-LASIK groups, respectively [26]. Their method was similar to the overlay grid method, where a best-fitting circle was superimposed on a tangential difference map. However, they used a software program to accurately distinguish the boundary of the OZ [27]. Perhaps this is why their decentration values are larger than those reported by Dan Z. Reinstein et al. The mean values of decentration measured on the pachymetry difference map were 0.40 ± 0.17 mm (0.07 to 0.72 mm) for the SMILE group and 0.37 ± 0.20 mm (0.11 to 0.83 mm) for the FS-LASIK group, with no statistically significant difference between them. This differs from the results of a previous study where the decentration was greater with FS-LASIK than with SMILE [9]. The main reason for this discrepancy may be that in their study, centration in FS-LASIK is targeted to the entrance pupil center.

The precision of a measurement can be described by 2 terms, repeatability and reproducibility. As few researchers have addressed the problem of the repeatability and reproducibility of OZ center measurements, we were incapable of comparing the differences in repeatability and reproducibility between this measurement method and others. The results obtained in this study showed good repeatability for COZ coordination measurements on both difference maps. In contrast to the measurements on the pachymetry difference maps, the ICC of the X_{TC} and ΔX_{TC} were better than those of the Y_{TC} and ΔY_{TC} . This may be partly due to the different locations of the tangential points measured on the two types of maps. On the tangential difference maps, the four tangential points used to calculate the coordinates of the OZ center were located on the outlines of the OZ (Fig. 1); on the pachymetry difference maps, the tangent points were located on the boundary of the innermost circle (Fig. 3). The diameter of the analyzed area of the Pentacam can be affected by factors such as eyelashes and the size of the interpalpebral zone, particularly in the vertical direction. Therefore, the vertical parameters of the OZ center are more susceptible to measurement errors, especially on tangential difference maps. Our experimental results confirmed that the repeatability of the parameters for Y_{TC} , ΔY_{TC} , and d_{TC} in group 1 was better than that in group 2 (Table 4). This may also be the reason why the ICC of d_{TC} in group 1 is superior to the ICC of d_{TC} obtained based on the overall data.

Centration analysis typically requires subjective visual estimates by an observer, making it susceptible to human error [7]. In this study, reproducibility was used to assess the consistency of the parameters measured by examiners with different levels of experience. The reproducibility of the parameters related to the OZ centration accuracy was good or very good, indicating that the human error involved was acceptable. It is interesting to note that the reproducibility of the parameters was better when measured with tangential difference maps than with pachymetry difference maps. The pachymetry difference map has been reported to provide a good depiction of the treatment zone [10], but sometimes the difference in corneal thickness between the central ring and the adjacent ring is small, making it difficult to locate the boundary contour. On the tangential difference maps, myopic ablation results in a focal peripheral steepening at the edge of the centrally flattened optical zone, and this transition is very evident on the tangential curvature difference maps [9]. The ICC of d_{TC} in Group1 is higher than that of d_{PC} also confirmed this i.e. excluding the effect of the analysed area, the tangential difference maps showed better repeatability. Furthermore, tangential difference maps provide high sensitivity for the location of the treatment zone, as the diopter change is zero only on the contour of the OZ, but the point of maximum pachymetry difference is not only at the edge of the OZ on the pachymetry difference map. We also noticed that the reproducibility of the parameters measured on the pachymetry difference map was better in the vertical direction than in the horizontal direction. We cannot draw firm conclusions about this finding, but one possible interpretation is that the shapes of the measurement areas on some pachymetry difference maps tend to be transverse ellipses. As the top and bottom curvatures of the contour were flatter, a horizontal bias in the location of the tangent point on the vertical side may not cause a significant difference in the vertical coordinates.

Angle kappa is the angle between the visual axis and the pupillary axis of the eye [25]. A previous study indicated that the differences in the angle κ may lead to both translation and rotation of the eye in the post-operative measurement relative to the preoperative measurement, creating artifacts in the subtraction of a measurement normal to the surface [24]. The repeatability and reproducibility of the data obtained in this study, after accounting for differences in pupil offset, did not improve and tended to decrease, which was different from our previous expectations. Since the entrance pupil we see is a virtual image of the real one, the change in corneal refraction after corneal refractive surgery may cause a change in the position of the entrance pupil, even though the visual axis may not have changed during the

measurement. As a limitation of this study, we have not yet been able to determine from which side the changes in the offset values are coming. Therefore, whether the differences in pupil offset values should be directly substituted for calculating the OZ center coordinates needs to be discussed in a future study. From the results of our study and theoretically, the repeatability and reproducibility would be better if the coordinates of the entrance pupil center and the corneal apex on the differential maps were the same as those on the preoperative maps.

Conclusion

In our study, the coordinates of the OZ center could be located on the tangential and pachymetry difference maps without the aid of other additional measurement tools. The square method showed good to excellent repeatability in measuring the coordinates of COZs on both kinds of difference maps. This method also showed good to excellent reproducibility in calculating the values of decentration on both difference maps. The diameter of the analysed area of the Pentacam may affect the repeatability of the measurements on the tangential difference map. Overall, the square method provides a new option for centration analysis after corneal refractive surgery.

Abbreviations

| | |
|-----------------|--|
| SMILE | Small incision lenticule extraction |
| FS-LASIK | Femtosecond laser-assisted LASIK |
| ICC | Intraclass correlation coefficient |
| Sw | Within-subject standard deviation |
| CR | Coefficient of repeatability |
| OZ | Optical zone |
| COZ | Center of the optical zone |
| CV | Corneal vertex |
| C/S | The ratio of the cylinder to the sphere |
| d_{TC} | The total decentration from the preoperative corneal vertex on the tangential curvature difference map |
| d_{PC} | The total decentration from the preoperative corneal vertex on the pachymetry difference map |
| X_{PC} | The x coordinate of the COZ on the pachymetry difference map |
| Y_{PC} | The y coordinate of the COZ on the pachymetry difference map |
| ΔX_{PC} | The horizontal decentration from the preoperative CV on the pachymetry difference map |
| ΔY_{PC} | The vertical decentration from the preoperative CV on the pachymetry difference map |
| X_{TC} | The x coordinate of COZ on the tangential difference map |
| Y_{TC} | The y coordinate of COZ on the tangential difference map |
| ΔX_{TC} | The horizontal decentration from the preoperative CV on the tangential difference map |
| ΔY_{TC} | The vertical decentration from the preoperative CV on the tangential difference map |

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Authors' contributions

Study concept and design (Xuejuan Wu, Kai Li); data collection (Jing Wu, Yan Xu, Qian Chen); analysis and interpretation of data (Chuanwei Zhang, Yan Xu); writing of the manuscript (Xuejuan Wu); critical revision of the manuscript (Kai Li, Xuejuan Wu); statistical expertise (Xuejuan Wu, Kai Li, Chuanwei Zhang); administrative, technical, or material support (Jing Wu, Qing Chen); supervision (Xuejuan Wu, Kai Li).

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Availability of data and materials

The data used and analyzed in this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

In this paper ethics approval was not required due to the retrospective nature of reviewing the data. The requirement for consent was waived by the Institutional Review Board of the Affiliated Hospital of Nanjing University of TCM.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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