Changes in effective optical zone after small-incision lenticule extraction in high myopia

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Abstract
Purpose To evaluate the four measurement approaches on the determination of effective optical zone (EOZ) using Scheimpflug tomography after small-incision lenticule extraction surgery in eyes with high myopia.

Setting Corneal refractive surgery conducted in an eye hospital in southern China.

Design This is a retrospective cohort study.

Methods In total, 74 subjects were recruited. EOZ was measured at 3 months postoperatively using vertex-based (EOZv), pupil-based (EOZp), 4 mm-ring-based total corneal refraction method (EOZ4) and tangential curvature difference map method (EOZD), and their consistencies were compared. EOZs and planned optical zone (POZ) were compared and analyzed with eccentricity, ablation degree (AD) and total corneal aberrations.

Results At 3 months after surgery, the mean root mean square of ΔHOA, ΔComa, ΔTrefoil and ΔSA were 0.53 ± 0.27 μm, 0.36 ± 0.20 μm, 0.01 ± 0.84 μm and 0.16 ± 0.14 μm, respectively. EOZv, EOZp, EOZ4 and EOZD were 5.87 ± 0.44 mm, 5.85 ± 0.45 mm, 4.78 ± 0.40 mm and 5.29 ± 0.27 mm, respectively, which were significantly smaller than POZ 6.48 ± 0.16 mm. Bland–Altman plots showed a good consistency among the four EOZs. The difference between the EOZv and EOZp was 0.02 mm within the range of clinically acceptable difference. In addition, the eccentricity was positively correlated with ΔHOA, ΔComa and ΔSA.
Conclusions  All 4 measurement approaches demonstrated the reduction of EOZs compared to POZ. The EOZ_v was the closest to POZ, followed by EOZ_p. The ΔEOZs showed no significant difference with eccentricity, AD and corneal aberrations.

Keywords  Corneal topography · Effective optical zone · High myopia · Eccentricity · Aberration · Small-incision lenticule extraction

Introduction

With continual refinements on corneal refractive surgery, it is important to evaluate if surgical results could correspond to the intended correction. Effective optical region (EOZ) describes an ablative area of the cornea with an excellent optical quality (Fig. 1), which achieves complete correction and can be used to assess the surgical consequences of refractive surgery [1, 2]. However, the patients would complain of blurred vision, ghosting, glare and other symptoms when the postoperative EOZ is smaller than the scotopic pupil. Since more ablation is required in corneal stroma for high myopia patients in the refractive

Fig. 1 Four EOZ measurement methods by the Scheimpflug tomography system. a Vertex-based total corneal refraction method (EOZ_v). b Pupil-based total corneal refraction method (EOZ_p). c 4 mm-ring-based total corneal refraction method (EOZ4). d tangential curvature difference map (EOZ_d)
surgery, EOZ would be smaller as compared to the planned optical zone (POZ) [3]. Adjustment of laser beam arrangement, laser energy, ablation area and corneal biomechanical properties have been adopted to tackle this concern [4–7]. The ablation could alter the corneal structure and corneal function as well as the corneal aberration and corneal biomechanics [8–10].

Multiple methods could be used to determine EOZ, including region-growing algorithms, ray-tracing analysis, pure tangential curvature topographic map, the tangential curvature difference topographic map and the postoperative front elevation map [1, 7, 11]. Tabernero et al. [2] adopted the axial power method, corneal wave-front root mean square (RMS) error and radial MTF method, and proposed that the measurement of the axial power method should be the most effective as it is easy to implement and corresponds to the corneal topography. At present, there is still no objective and accurate measurement method to measure EOZ after corneal refractive surgery, especially in patients with high myopia (spherical equivalent (SE) ≤ −6.00 diopters (D)). Herein, in this study, we aimed to compare four commonly used measurement approaches of EOZ using Scheimpflug tomography after small-incision lenticule extraction (SMILE) surgery in eyes with high myopia. In addition, the factors influencing the changes in EOZ after SMILE were also determined, which would be of clinical important to fully characterize the corneal treatment profiles after kerato-refractive surgery.

Methods

Study subjects

In total, 74 study subjects with high myopia received bilateral SMILE surgery were recruited at Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong from January 2017 to March 2019. Written informed consent was obtained from all study subjects before surgery after explanation of the inclusion of data for the research study. Only right eyes were included in the statistical analysis to avoid the potential bias of the data of both eyes from the same patient. Preoperative and 3-month postoperative data on visual acuity, refractive errors, POZ, ablation degree (AD), intraocular pressure (IOP), eccentricity and aberrations were retrieved from the electronic medical records. The inclusion criteria included: (1) study subjects requested to stop wearing contact lens for more than 2 weeks prior to the surgery; (2) intraocular pressure (IOP) < 21 mmHg (1 mmHg = 0.133 kPa); and (3) SE ≤ −6.00 D. The exclusion criteria included: (1) any history of ocular surgery; (2) history of other ocular diseases, including keratoconus, cataract and glaucoma; (3) history of systemic diseases, including hypertension and diabetes; and (4) postoperative complications, including incision tear, lens residue and severe eccentricity.

The data retrieval for this retrospective study was approved by the Ethics Committee for Human Medical Research at the Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong (approval number: EC20190306(1)P19; issued on March 6th 2019), which is in accordance with the tenets of the Declaration of Helsinki.

Measurement of corneal topography

Corneal topographic images were acquired with single Scheimpflug device (Pentacam, Oculus, Wetzlar, Germany) by the experienced clinicians following same protocol, but without blinding. The study subjects with scotopic pupil were asked to keep their eyes open while resting their chins on the stand. Image acquisition was performed on an automatic mode. A total of 3 images were obtained for each eye, and total corneal aberration data with 6 mm diameter were obtained. Images with >8 mm diameter data and quality marked as ‘OK’ were selected for data processing. Higher-order aberration (HOA), coma aberration (Coma), trefoil aberration (Trefoil) and spherical aberration (SA) were analyzed by the RMS (μm).

Measurement of effective optical region

Four different strategies were applied to estimate EOZ. Four EOZ measurement strategies shared one dataset from corneal topography (Pentacam), and all results were shown by equivalent diameter in millimeters (mm).
Vertex-based total corneal refraction method (EOZV) and pupil-based total corneal refraction method (EOZP)

The corneal power data were mechanically measured by Pentacam, which was calculated on an individual ring or circular region (zone) by centering the vertex of cornea (EOZV) or the center of pupil (EOZP). The corneal power at corneal vertex or pupil center as well as the mean corneal power at individual rings (from 1 to 8 mm) were calculated for the analysis. The EOZ was defined as the maximum ring diameter when the mean corneal power was 1.50 D or less different from the central of the pupil or the apex of the cornea.

4-mm-ring-based total corneal refraction method (EOZ4)

In the absence of any accommodation, defocusing at −0.50 D reduced the vision to the logarithm of the minimum angle of resolution (logMAR) VA 0.2 on average. Therefore, centering on the corneal ring at 4 mm and spacing at 0.1 mm, the corneal power of EOZ4 within the range of 0.50 D of corneal refractive power was summarized as a function of simulating pupil size.

Tangential curvature difference map (EOZD) and eccentricity

The cutting contour displayed by the tangential curvature difference map of corneal topography before and at 3 months after operation was used as the EOZ. The area with zero curvature difference was the cutting boundary, which was shown by the boundary of blue and green marker circle. The tangential curvature difference map was analyzed by ImageJ software (version 1.47; National Institute of Health, Bethesda, MD). A circle was drawn simulating the boundary. The diameter of the circle was considered as EOZD, and the distance between the center of the circle and the corneal apex was labeled as the eccentricity.

Small-incision lenticule extraction surgery

All SMILE surgeries were performed with a 500-kHz VisuMax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) with a pulse energy of 130 nJ. All operations were performed by a single surgeon (R.Z.).

For all study subjects, the intended cap thickness were 120 microns thick and intended cap diameters were usually adjusted to 1 mm larger than the optical zone, which was larger than the diameter of the refractive lenticule (range: 6.3–6.8 mm). Throughout the process, the study subjects were required to keep their eyes on a flashing green light, avoiding the increasing decentration.

Statistical analysis

The comparisons of EOZs and POZ were performed using one-way analysis of variance with repeated measurement, and the Bland–Altman plots were used to compare the consistency of different measurement methods on EOZ. The difference between EOZs and POZ was analyzed by Pearson correlation with the eccentricity, ablation degree and aberrations. Statistical analyses were calculated using a commercially available software (IBM SPSS Statistics 23; SPSS Inc., Chicago, IL). Significance was defined as

Results

This study included 74 patients (32 males and 42 females) with an average age of 24.85 ± 5.31 years and scotopic pupil of 6.47 ± 0.76 mm. The mean spherical and cylindrical corrections were −6.39 ± 0.82 D and −0.96 ± 0.65 D, respectively, before surgery, and the mean spherical equivalent (SE) was −6.87 ± 0.77 D (Table 1). The mean ablation degree (AD) was −6.87 ± 0.75 D. The eccentricity was 0.30 ± 0.17 mm. Uncorrected visual acuity was significantly improved at 3 months after surgery (1.09 ± 0.18, p < 0.01).

Comparing the measurements before and at 3 months after surgery, the mean ΔHOA, ΔComa, ΔTrefoil and ΔSA were 0.53 ± 0.27 μm (p < 0.01), 0.36 ± 0.20 μm (p < 0.01), 0.01 ± 0.84 μm (p > 0.05) and 0.16 ± 0.14 μm (p < 0.01), respectively (Table 1). The EOZV, EOZP, EOZ4 and EOZD were 5.87 ± 0.44 mm, 5.85 ± 0.45 mm, 4.78 ± 0.40 mm and 5.29 ± 0.27 mm, respectively, which were significantly smaller than the POZ (6.48 ± 0.16 mm; Fig. 2). The mean ΔEOZV, ΔEOZP, ΔEOZ4 and ΔEOZD was 0.61 ± 0.05 mm (p < 0.01), 0.63 ± 0.06 mm (p < 0.01), 1.70 ± 0.05 mm (p < 0.01) and 1.19 ± 0.03 mm (p < 0.01), respectively. Among the four EOZ
measurement methods, EOZ\text{V} was the closest to POZ, followed by EOZ\text{P}, ΔEOZ\text{D} and EOZ\text{4}. There was no significant difference between EOZ\text{V} and EOZ\text{P}.

Bland–Altman plots showed a good consistency among the four EOZ measurements (Fig. 3). The difference between the EOZ\text{V} and EOZ\text{P} was 0.02 mm, which fell within the range of clinically acceptable difference. However, the differences for other methods were higher than 0.5 mm, which were not clinically acceptable. [5, 12–14].

Table 1 Ophthalmic examination measurements before and at 3 months after surgery

| Parameters | Pre-operation | 3 months post-operation | Δ | p |
|------------|---------------|------------------------|---|---|
| UCVA       | 0.05 ± 0.04   | 1.09 ± 0.18            | 1.04 ± 0.18 | <0.01 |
| BCVA       | 1.07 ± 0.12   | 1.05 ± 0.14            | 0.01 ± 0.15 | >0.05 |
| S (D)      | −6.39 ± 0.82  | 0.00 ± 0.21            | 6.39 ± 0.80 | <0.01 |
| C (D)      | −0.96 ± 0.65  | −0.07 ± 0.18           | 0.89 ± 0.65 | <0.01 |
| SE (D)     | −6.87 ± 0.77  | −0.04 ± 0.22           | 6.83 ± 0.74 | <0.01 |
| HOA (μm)   | 0.38 ± 0.09   | 0.90 ± 0.27            | 0.53 ± 0.27 | <0.01 |
| Coma (μm)  | 0.14 ± 0.08   | 0.50 ± 0.22            | 0.36 ± 0.20 | <0.01 |
| Trefoil (μm)| 0.10 ± 0.06  | 0.11 ± 0.07            | 0.01 ± 0.08 | >0.05 |
| SA (μm)    | 0.18 ± 0.08   | 0.34 ± 0.14            | 0.16 ± 0.14 | <0.01 |

UCVA = Uncorrected visual acuity; BCVA = best-corrected visual acuity; S = spherical correction; C = cylinder; SE = spherical equivalent refraction; HOA = Higher-order aberration; Coma = coma aberration; Trefoil = trefoil aberration; SA = spherical aberration; Δ = the changes before and at 3 months after surgery

Fig. 2 Comparison of POZ and the 4 EOZ measurements at 3 months after surgery. EOZ\text{V} = Vertex-based total corneal refraction method, EOZ\text{P} = Pupil-based total corneal refraction method, EOZ\text{4} = 4 mm-ring-based total corneal refraction method, EOZ\text{D} = tangential curvature difference map. POZ = planned optical zone. *P < 0.01

For the correlation analysis, the ΔEOZs were independent of eccentricity, AD and aberrations (Table 2). In addition, the corneal aberrations increased at 3 months after surgery, and the eccentricity was positively correlated with ΔHOA (r = 0.66, p < 0.01), ΔComa (r = 0.66, p < 0.01) and ΔSA (r = 0.35, p < 0.01), but not with ΔTrefoil.
Discussion

Results from this study showed that: (1) the 4 EOZ measurements (EOZ\text{V}, EOZ\text{P}, EOZ\text{4} and EOZ\text{D}) were significantly smaller than POZ; (2) the four EOZs should good consistency; (3) the difference between the EOZ\text{V} and EOZ\text{P} was within the range of clinically acceptable difference; and (4) the EOZ\text{V} was the closest to POZ, followed by EOZ\text{P}. Collectively, our results indicate that eccentricity was positively correlated with ΔHOA, ΔComa and ΔSA. And ΔEOZs showed no significant difference with eccentricity, AD and corneal aberrations.

The SMILE surgery has been widely implemented for myopia correction. It has been shown that SMILE exhibits better predictability and stability than femtosecond laser–assisted laser in situ keratomileusis (LASIK) [15–17], including smaller aberrations and
better biomechanics. However, there are still complaints of problems with night vision-like ghosting and glare [18]. Previous studies suggested that the appearance of these symptoms is directly related to the reductions in the EOZ [2, 18, 19]. At present, EOZ has been evaluated by multiple methods, including region-growing algorithms [20], ray-tracing analysis [21], corneal power distribution analysis [22] and modulation transfer function method [2]. These methods have different measurement principles. However, the method performed by corneal topography appears to be the most practical [2, 23]. Critically, there is no objective and accurate EOZ measurement method for high myopic eyes after corneal refractive surgery. In this study, we, for the first time, adopted the Scheimpflug corneal topography system to measure and compare the EOZ and POZ in high myopic eyes before and after SMILE surgery by different measurement methods.

The EOZ was defined as the diameter of the largest ring that the corneal refractive power difference between the ring and the pupil center was smaller than 1.50 D (Fig. 1) [22]. In our study, four measurement methods showed that EOZs were significantly reduced in eyes with high myopia as compared to the POZ at 3 months after SMILE surgery (Table 1), which is consistent with the findings in other reported studies [2, 3, 11, 19, 24]. This reduction could be attributed to the postoperative corneal oblate changes [15] and the corneal healing responses, including the increased epithelial thickness [25], the loss of laser energy around the cutting zone and the changes in biomechanical properties after surgery [8, 26]. We observed that EOZV was the closest to the POZ, followed by EOZD, EOZP and EOZ4 (Fig. 2). There was no significant difference between EOZV and EOZP. Since EOZV, EOZP and EOZ4 are easy to be determined, they could be measured in patients even with preoperative data loss. On the other hand, since both preoperative and postoperative data were clearly visible, EOZD would be suitable for eccentricity measurement. In our study, it was noted that the difference between EOZp and EOZv was 0.02 mm with no statistically significant difference (Fig. 3), which is within the range of clinically acceptable difference. This could be likely due to the small differences between the position of corneal apex and pupil center.

In the current study, the patients with eccentricity greater than 1 mm were excluded [27], and we found that the eccentricity was positively correlated with corneal aberrations, except Trefoil (Table 2), and the changes in ablation degree, eccentricity and aberration were independent of EOZ, which is similar to the results from an earlier study [22]. In the eyes received SMILE surgery, Qian et al. found that there was no correlation between the size of EOZ between high and low myopia, but the EOZ in myopic eyes with less than − 7.50 D was significantly smaller as compared to those between − 6.00 and − 7.50 D [22]. However, no correlation was noted between the change in EOZ and dioptic power. Hou et al. [15] found that there was no significant correlation relationship between the attempted refractive correction and the reduction of EOZ. For the LASIK patients with myopic spherical equivalent less than − 10.00 D, Nepomuceno et al. [21] showed that increase in the attempted refractive correction leads to further reduction in EOZ myopia. In our study, patients with myopic mean ablation degree (AD) were − 6.87 ± 0.75 D, which may account for the independence of EOZ, further studies are required to characterize these differences. Moreover, we also found that there was no significant difference between EOZ reduction and aberrations. Similar to the previous report, Dan et al. [24] found that postoperative corneal aberrations changes show no differences among the three EOZ measurements.

There were few limitations in this study. First, this study only focused on the patients with high myopia. Larger sample sizes with wide diopter ranges and more severe myopia (< −7.50 D) are warranted in future studies, which could correlate the EOZ based on the level of dioptries among high myopes. Second, this study did not include the analysis of the corneal mean keratometry, corneal central thickness and gender effect. Third, the EOZ would not necessarily be round, but oval in most cases. Our study did not analyze the transverse and vertical diameters of the EOZ, which could make further improvements in the measurement.

Conclusions

Results from this study on 4 EOZ measurement methods revealed that EOZs was significantly reduced as compared to POZ. EOZv was the closest to POZ, followed by EOZp. The ΔEOZs showed no significant difference with eccentricity, AD and aberrations.
Vertex-based total corneal refraction method would be useful for full characterization of corneal treatment profiles in high myopia individuals after keratorefractive surgery.

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**Author contributions**  L.S. and R.Z. conceived and designed the study; H.N.L. and R.J. collected and/or assembled the data; H.N.L. analyzed and interpreted the data and wrote the manuscript; and R.Z., V.J. and T.K.N. critically revised the manuscript.

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**Data availability statement**  Data could be available upon request to the corresponding author.

**Declarations**

**Conflict of interest**  The authors declare no potential conflicts of interest.

**Ethical approval**  The study protocol was approved by the Ethics Committee for Human Medical Research at the Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong.

**Informed consent**  Informed consent was obtained from all participants in the study.

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