Changes in Effective Optical Zone After Small-Incision Lenticule Extraction in High Myopia

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Research Article

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Abstract

Purpose: To evaluate the four measurement approaches on the determination of effective optical zone (EOZ) using Scheimpflug tomography after SMILE surgery in eyes with high myopia.

Setting: Corneal refractive surgery conducted in eye hospital in southern China

Design: A retrospective cohort study.

Methods: Total 74 subjects were recruited. EOZ was measured at 3 months postoperatively using Vertex-Based total corneal refraction method (EOZ_V), pupil-based total corneal refraction method (EOZ_P), 4 mm-Ring-Based total corneal refraction method (EOZ_4), and axial curvature difference map (EOZ_D), 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: Mean AD was -6.87 ± 0.75 D, and eccentricity was 0.30 ± 0.17 mm. 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. EOZ_V, EOZ_P, EOZ_4 and EOZ_D were 5.87 ± 0.44 mm, 5.85 ± 0.45 mm, 4.78 ± 0.40 mm, 5.29 ± 0.27 mm respectively, which were significantly smaller than POZ 6.48 ± 0.16 mm. Bland Altman plots showed a good consistency between the four EOZs. The difference between the EOZ_V and EOZ_P was 0.02 mm within the range of clinically acceptable difference. In addition, EOZ_D was positively correlated with AD, and the eccentricity was positively correlated with ΔHOA, ΔComa and ΔSA.

Conclusions: All 4 measurement approaches demonstrated the reduction of EOZs compared to POZ. EOZ_V was the closest to POZ, followed by EOZ_P. ΔEOZs showed no significant difference with eccentricity, AD and corneal aberrations. Our results are useful for the full characterization of corneal treatment profiles after kerato-refractive surgery.

What Was Known

· Effective optical zone (EOZ) describes an ablative area of the cornea with an excellent optical quality, which achieves complete correction and can be used to assess the surgical consequences of refractive surgery.

· Since high myopia patients require larger corneal stroma depth in the refractive surgery, a smaller effective optical zone could be resulted as compared to the planned optical zone.

· There is still no objective and accurate measurement method to measure EOZ after corneal refractive surgery.

What This Paper Adds

· All four measurement approaches of effective optical zone demonstrated the reduction of effective optical zone as compared to the planned optical zone.

· Effective optical zone measured by the Vertex-Based total corneal refraction method showed closest to the planned optical zone, followed by the Pupil-based total corneal refraction method.

· The differences in the effective optical zones showed no significant difference with eccentricity, AD and corneal aberrations.

Introduction

With continual refinements in 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, which achieves complete correction and can be used to assess the surgical consequences of refractive surgery[1,2]. However, patients would complain of blurred vision, ghosting, glare and other symptoms when the postoperative EOZ is smaller than the scotopic pupil. Since high myopia patients require larger corneal stroma depth in the refractive surgery, a smaller EOZ could be resulted as compared to the planned optical zone (POZ)[3]. Previous studies have tried to tackle this concern, including the adjustment of laser beam arrangement, laser energy, ablation area, and corneal biomechanical properties[4–7]. The effects of ablation on corneal structure and function are considered from various aspects [8–10].

Multiple methods could be used to determine EOZ [1,7,11]. Tabernero *et al.*[2] adopted the axial power method, corneal wave-front RMS error and radial modulation transfer function (MTF). The measurement of the axial power method seems to 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. Herein, in this study, we aimed to compare four 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

This retrospective study enrolled 74 (32 male and 42 female) study subjects with high myopia received bilateral SMILE surgery at Joint Shantou International Eye Center of Shantou University and the Chinese University of Hong Kong from January 2017 to March 2019. Only right eyes were included in the analysis of this study. Preoperative and 3-month postoperative data on visual acuity, refractive errors, POZ, ablation degree (AD), intraocular pressure (IOP), eccentricity and aberrations was retrieved from the electronic medical records. The inclusion criteria included: (1) the study subjects requested to stop wearing contact lens for more than 2 weeks; (2) IOP < 21 mmHg (1 mmHg = 0.133 kPa); and (3) the spherical equivalence (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 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, which is in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained from all study subjects after explanation of the nature and possible consequences of the study.

Measurement of corneal topography

Corneal topographic images were acquired with the Scheimpflug device (Pentacam, Oculus, Wetzlar, Germany) by the experienced clinicians. 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 was 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 root mean square (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 (EOZ_V) and Pupil-based total corneal refraction method (EOZ_P). The corneal power data was mechanically measured by Pentacam, which was calculated on an individual ring or circular region (zone) by centering the vertex of cornea (EOZ_V) or the center of pupil (EOZ_P). The corneal power at corneal vertex or pupil center as well as the mean corneal power at the individual rings (from 1 mm 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 (EOZ_4). In the absence of any accommodation, defocusing at -0.50 D reduced the vision to logMAR of 0.2 on average. Therefore, centering on the corneal ring at 4 mm and spacing at 1 mm, the corneal power of EOZ_4 within the range of 0.50 D of corneal refractive power was summarized as a function of simulating pupil size.

Axial curvature difference map (EOZ_D) and eccentricity. The cutting contour displayed by the axial 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 axial 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 EOZ_D, 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 single surgeon (R.Z.). In all cases, 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 consistency of EOZs was compared using the Bland-Altman plots. The difference between EOZs and POZ was analyzed using Spearman correlation with the eccentricity, ablation degree and aberrations. Statistical analyses were calculated using the commercially available software (IBM SPSS Statistics 23; SPSS Inc., Chicago, IL). Significance was defined as $p < 0.05$.

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, $p < 0.01$).

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)	-6.00 ± 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.

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 EOZ_V, EOZ_P, EOZ_4 and EOZ_D 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; Figure 1). The mean ΔEOZ_V, ΔEOZ_P, ΔEOZ_4 and ΔEOZ_D 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_V was the closest to POZ, followed by EOZ_D, ΔEOZ_P and EOZ_4. There was no significant difference between EOZ_V and EOZ_P.

Bland Altman plots showed a good consistency among the four EOZ measurements (Figure 2). The difference between the EOZ_V and EOZ_P was 0.02 mm, which fell within the range of clinically acceptable difference. However, the difference between other methods were higher than 0.5 mm, which were not clinically acceptable.[5,12–14]

For the correlation analysis, the ΔEOZs were independent of eccentricity and Δ aberrations. Instead, the EOZ_D was positively correlated with AD (r = 0.26, $p < 0.05$; Table 2). In addition, the corneal aberrations increased at 3 months after surgery, and the eccentricity was positively correlated with ΔHOA (r = 0.65, $p < 0.01$), ΔComa (r = 0.67, $p < 0.01$) and ΔSA (r = 0.39, $p < 0.01$), but not with ΔTrefoil.

Table 2
Correlation of EOZ reduction with relevant parameters at 3 months after surgery.

Parameters	r					
	ΔHOA	ΔComa	ΔTrefoil	ΔSA	AD	Eccentricity
ΔEOZ_V	0.18	0.19	0.00	0.04	0.11	0.10
ΔEOZ_P	0.16	0.19	-0.04	0.05	0.05	0
ΔEOZ_4	0.15	0.12	0.09	0.04	0.22	0.01
ΔEOZ_D	0.15	0.14	0.19	0.11	0.26*	0.08
Eccentricity	0.65**	0.67**	0.04	0.39**	0.07	/

ΔEOZ_V = POZ - EOZ_V; ΔEOZ_P = POZ - EOZ_P; ΔEOZ_4 = POZ - EOZ_4; ΔEOZ_D = POZ - EOZ_D; ΔHOA = Change of RMS of Higher order aberration; ΔComa = Change of RMS of Coma aberration; ΔTrefoil = Change of RMS of Trefoil aberration; ΔSA = Change of RMS of Spherical aberration; AD = ablation depth; $^*P < 0.05$; $^{**} P < 0.01$.

Discussion

SMILE surgery has been widely implemented for myopia correction. It has been shown that SMILE exhibits better predictability and stability for its smaller changes 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. 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 the corneal topography appears to be the most practical[2,23]. In this study, we adopted the Scheimpflug corneal topography system to measure and compare the EOZ and POZ before and after SMILE surgery by different measurement methods.

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[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 EOZ_V was the closest to the POZ, followed by EOZ_D, EOZ_P and EOZ_4 (Figure 1). There was no significant difference between EOZ_V

and EOZ_P. Since EOZ_V, EOZ_P and EOZ_4 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 are clearly visible, EOZ_D is suitable to measure the eccentricity. In our study, it was noted that the difference between EOZ_P and EOZ_V was 0.02 mm with no statistical difference (Figure 2), which was in the range of clinically acceptable difference. This is likely due to the small differences between the position of corneal apex and pupil center.

In the current study, eccentricity was positively correlated with corneal aberrations, except Trefoil (Table 2). The changes in eccentricity and aberration were independent of EOZ, which was similar to the results from an earlier study[22]. In the eyes undergoing 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 D and -7.50 D. However, no correlation was noted between the change in EOZ and dioptric 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 of EOZ. Moreover, we also found that there was no significant difference between EOZ reduction and aberrations. Likewise, similar to the previous results, Dan *et al*. found that postoperative corneal aberrations changes shows no differences among the 3 EOZ measurement groups[24].

There were few limitations in this study. This study focused on the patients with high myopia. Larger sample size with wide diopter range and higher myopia (> -7.50 D) are warranted in future studies. Many studies showed that the reduction of EOZ was related to the changes of Q values. On the other hand, the EOZ would not necessarily to 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. EOZ_V was the closest to POZ, followed by EOZ_P. The ΔEOZs showed no significant difference with eccentricity, AD and aberrations. Our results are useful for the full characterization of corneal treatment profiles after kerato-refractive surgery.

Declarations

Acknowledgments

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Conflict of interest

The authors declare no potential conflicts of interest.

Funding

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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.

Contributors

L.S. and R.Z.: conception and design; H.N.L. and R.J.: collection and/or assembly of data; H.N.L.: data analysis and interpretation; H.N.L.: manuscript writing. R.Z., V.J. and T.K.N.: critical revision of manuscript.

Data availability statement

Data are available upon request.

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Figures

Figure 1

Comparison of POZ and the 4 EOZ measurements at 3 months after surgery.

EOZ_V = Vertex-Based total corneal refraction method, EOZ_P = Pupil-Based total corneal refraction method, EOZ_4 = 4mm-Ring-Based total corneal refraction method, EOZ_D = axial curvature difference map. POZ = Planned optical zone. $^{*}P < 0.01$.

Figure 2

Bland Altman plots of four EOZ measurements.

A: Bland Altman plots of EOZ_V and EOZ_P. B: Bland Altman plots of EOZ_V and EOZ_4. C: Bland Altman plots of EOZ_V and EOZ_D. D: Bland Altman plots of EOZ_P and EOZ_4. E: Bland Altman plots of EOZ_P and EOZ_D. F: Bland Altman plots of EOZ_4 and EOZ_D.