ARTICLE

Comparison of effective optical zone after small-incision lenticule extraction and femtosecond laser–assisted laser in situ keratomileusis for myopia

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Purpose: To compare the effective optical zone (EOZ) after small-incision lenticule extraction (SMILE) and femtosecond laser–assisted laser in situ keratomileusis (FS-LASIK).

Setting: Jinan Mingshui Eye Hospital, Jinan, China.

Design: Retrospective case series.

Methods: Myopic patients who had small-incision lenticule extraction or FS-LASIK were enrolled in this retrospective study. Effective OZs were measured at 1 week, 1 month, and 3 months postoperatively, using the tangential curvature difference map of the Scheimpflug tomography system. Correlations between the changes in the EOZ and relevant parameters were analyzed 3 months postoperatively.

Results: The study comprised 76 patients (76 eyes). The mean EOZs at 1 week, 1 month, and 3 months postoperatively were 5.39 ± 0.27 mm, 5.33 ± 0.30 mm, and 5.34 ± 0.23 mm in the small-incision lenticule extraction group and 5.06 ± 0.36 mm, 4.98 ± 0.39 mm, and 5.01 ± 0.31 mm in the FS-LASIK group, when the programmed OZ was 6.5 mm. The magnitude of decreases in EOZ was significantly smaller in the small-incision lenticule extraction group than in the FS-LASIK group at all timepoints after surgery ($P < .01$). There were significant correlations between changes in EOZ and corneal asphericity ($P < .01$). Epithelial thickening was positively correlated with EOZ reduction in the small-incision lenticule extraction group ($r = 0.479$, $P < .01$); however, no correlation was found between epithelial thickening and EOZ reduction in the FS-LASIK group ($r = .324$, $P > .05$).

Conclusions: Both small-incision lenticule extraction and FS-LASIK resulted in EOZ reduction during correction of myopia. However, small-incision lenticule extraction resulted in less reduction than FS-LASIK and was associated with corneal asphericity changes and epithelial thickening.

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Small-incision lenticule extraction (SMILE, Carl Zeiss Meditec AG) has been well implemented in Asia, Europe, and America for the correction of myopia, and was approved by the U.S. Food and Drug Administration in 2016. More recent studies have indicated that small-incision lenticule extraction causes smaller changes in higher-order ocular aberrations and biomechanical parameters; in addition, it exhibits better predictability than femtosecond laser–assisted laser in situ keratomileusis (FS-LASIK).[1–3] However, the incidences of night vision complaints, such as glare, halos, and ghosting, have not been eliminated completely. Previous studies of LASIK have shown that the occurrence of these symptoms is directly related to reductions in the effective optical zone (EOZ), relative to the programmed ablation zone, regardless of whether a transition zone existed.[4–6]

The EOZ describes the area of corneal surface with a high level of optical quality and is the portion of the ablation that achieves full correction.[7–10] In recent years, measurement of the EOZ has been of great interest to corneal refractive surgeons; several methods have been used to determine the EOZ.[7–13] Thus far, we are unaware of any studies that have compared the EOZ between small-incision lenticule extraction and FS-LASIK.

In the current study, we compared the EOZs of small-incision lenticule extraction and FS-LASIK using

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topographic methods on the tangential curvature difference map generated by the Scheimpflug tomography system (Pentacam HR, Oculus Optikgeräte GmbH), which measures the corneal curvature before and after surgery.[14] In addition, we determined factors related to changes in the EOZ after surgery.

PATIENTS AND METHODS

Study Group and Protocol

Seventy-six myopic patients (only right eyes) who had either small-incision lenticule extraction or FS-LASIK from January 2016 to October 2016 were enrolled in this retrospective study. Ethics Committee approval was obtained for this study protocol that adhered to the tenets of the Declaration of Helsinki.

Inclusion criteria comprised age of 18 to 40 years, stable refraction for more than 2 years, spherical refraction from −1.00 to −8.00 diopters (D), astigmatism less than −0.25 D, preoperative corneal central thickness (CCT) over 480 μm, and no ocular, corneal, or relevant systemic diseases. All patients had discontinued soft contact lens wear at least 2 weeks before surgery or rigid gas-permeable contact lens wear at least 6 weeks before surgery. Exclusion criteria were active ocular or systemic disease, optical opacities, keratoconus or suspicious corneal topography, and previous ocular trauma or surgery.

All patients had preoperative and postoperative examinations including uncorrected and corrected visual acuities, cycloplegic and subjective refraction, noncontact intraocular pressure, slit-lamp microscopy, and corneal topography via the Scheimpflug tomography system. Corneal parameters, including the mean corneal power (mean keratometry [K]), CCT, and corneal asphericity (Q-value) of the anterior corneal surface within the 6.0 mm corneal diameter were obtained. Patients were followed up at 1 week, 1 month, and 3 months postoperatively.

Surgical Technique

The same surgeon (H.J.) performed all surgeries. Small-incision lenticule extraction treatments and FS-LASIK flap creations were performed using a femtosecond laser (Visumax, Carl Zeiss Meditec AG) with a repetition rate of 500 kHz and pulse energy of 130 nJ.

In the small-incision lenticule extraction group, the cap thickness was 110 μm with an intended diameter of 7.5 mm, whereas the lenticule diameter was 6.5 mm. The incision was located at the 12 o'clock position with a circumferential length of 2.0 mm and a side-cut angle of 90 degrees. After the scanning procedure, the lenticule was dissected and removed through the small incision, using a pair of spatulas.

In the FS-LASIK group, the flap thickness was the same as the cap thickness in the small-incision lenticule extraction group, whereas the flap diameter was 7.9 mm. The hinge of the flap was set superiorly. Excimer laser ablation was performed using the Aberration Smart Ablation profile with a 6.5 mm OZ (Mel-80, software version 3.6, Carl Zeiss Meditec AG), accompanied by a 2.2 mm transition zone provided by the laser. The flap was repositioned after laser ablation and irrigated with a balanced salt solution.

Effective Optical Zone Measurement

Based on previous research,[11,15] the tangential curvature difference map between the preoperative and postoperative value was chosen from the Scheimpflug tomography system. The EOZ was defined as the area outlined by a change of zero diopter on the subtractive map.

In measuring the EOZ, the first step was to move the cursor on the subtraction map from the center to the periphery, along the corneal semi-meridian. The region where the difference was equal to zero was regarded as the cutting boundary. As Figure 1 shows, the coordinate value of this point was recorded as (x, y), whereas the boundary of the other side of the same meridian was recorded as (x', y'). The diameter between these 2 defined confine points was then calculated using the formula $D = \sqrt{x^2 + y^2} + \sqrt{x'^2 + y'^2}$. The EOZ was confirmed as the average value of the diameters that were measured from 6 different corneal meridians at 30-degree intervals. The measurement technique was performed by the same experienced technician, and three measurements were averaged for each result.

Statistical Analysis

Statistical analyses were performed using SPSS software (version 20, IBM Corp.). Data were tested for normality using the Shapiro-Wilk test. The mean and standard deviation were used for descriptive statistics. The repeatability of data was analyzed by intraclass correlation coefficient (ICC) and the Cronbach α coefficient. The Student *t* test was performed to determine differences between small-incision lenticule extraction and FS-LASIK groups; a paired Student *t* test was used for intragroup comparisons. The EOZs at different timepoints and different measurement meridians were compared by repeated-measures analysis of variance. Pearson correlation and simple regression analysis were used to assess correlations between relevant parameters and EOZ. A *P* value less than 0.05 was considered statistically significant.

RESULTS

The study comprised 76 myopic patients (76 right eyes) of whom 46 were men and 30 were women. There were 45 eyes in the small-incision lenticule extraction group and

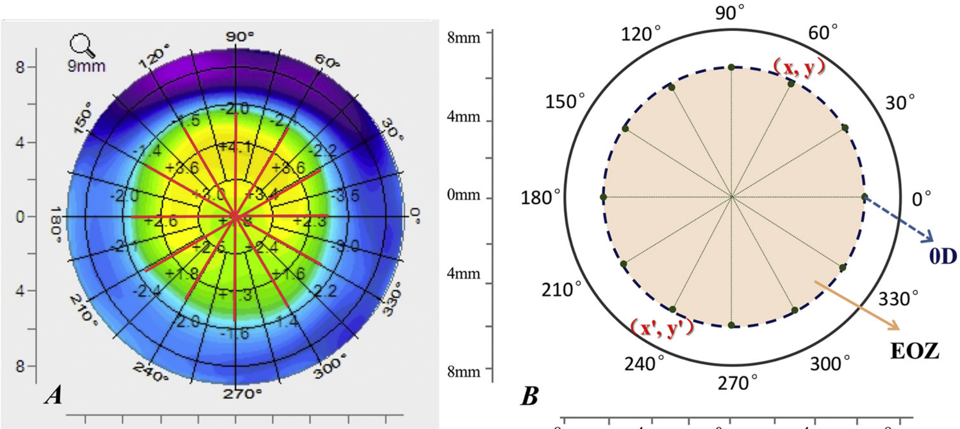

Figure 1. *A*: Effective OZ measurement at different corneal meridians on the tangential curvature difference map generated by the Scheimpflug tomography system. *B*: A conceptual image of the EOZ. The coordinates of (*x*, *y*) represent the region where the curvature difference is equal to zero D (EOZ = effective optical zone).