Original Article



# Comparison of posterior corneal elevation after SMILE and FS-LASIK in correcting myopia over –9.0 diopters

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**Background:** To compare the changes in posterior corneal elevation after small incision lenticule extraction (SMILE) and femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) in correcting myopia over –9 diopters (D).

**Methods:** In this prospective comparative study, 82 eyes of 82 patients scheduled for refractive correction were recruited. Eyes were randomly assigned to the SMILE group (45 eyes, –10.43±0.92 D) or FS-LASIK group (37 eyes, –10.97±1.37 D). The posterior corneal surface was measured using a Scheimpflug camera (Pentacam, Oculus, Germany) preoperatively and at 1 day, 1 month, and 6 months after surgery. Posterior corneal elevation in the central point and central 4-mm area, and in various optical zones above the best-fit sphere, was analyzed. A P value of less than 0.05 was considered statistically significant.

**Results:** All surgeries were completed successfully. The safety index and efficacy index were 1.20 and 1.00, respectively, in the SMILE group, and was 1.10 and 0.90, respectively, in the FS-LASIK group. No significant difference existed in all analyzed data before and at 6 months after surgery in both the SMILE group and the FS-LASIK group. Changes in posterior corneal elevation after FS-LASIK were greater than after SMILE, with no statistical significance (P≥0.07). In the SMILE group, residual bed thickness was found to be moderately negatively correlated with changes in the elevation in the central area (P≤0.045); whereas it was positively correlated in the peripheral area (P=0.002).

**Conclusions:** SMILE and FS-LASIK presented stable posterior corneal surface in correction of myopia over –9.0 D at the follow-up visit of 6 months.

**Keywords:** Posterior corneal elevation; high myopia; small incision lenticule extraction (SMILE); femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK)

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## Introduction

Safety and stability have always been a major concern in evaluating corneal refractive surgery, especially in patients with high myopia. Researchers have demonstrated that iatrogenic keratectasis is prone to occur in patients with high myopia, as they require deeper ablation, and that the initial sign of keratectasis is protrusion of the posterior corneal surface (1). According to published studies, investigating posterior corneal elevation has proven to be an

effective way to evaluate posterior corneal stability (2).

Corneal surgical correction for high myopia provides distinctive advantages over phakic intraocular lens (IOL) implantation; for instance, simple postoperative administration and low incidence of complications associated with intraocular surgery (3). Lindbohm evaluated a 2- to 5-year result of patients who underwent laser *in situ* keratomileusis (LASIK) with at least -9 diopters (D) preoperatively (4). The author proposed that LASIK is a safe alternative for the treatment of super high myopia with safety precautions and careful patient selection. Additionally, Alió conducted a longer follow-up (10-year) study of LASIK for correction of myopia up to –10 D, and demonstrated that LASIK was an effective and predictable procedure resulting in slight regression (5).

Recently, femtosecond lasers have been widely applied in the field of ophthalmology, especially in refractive surgery. It was initially used for the creation of corneal flaps in LASIK, followed by corneal stroma ablation by an excimer laser. The technology combining the excimer laser and femtosecond laser is known as femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) (6). Small incision lenticule extraction (SMILE), solely utilizing the femtosecond laser, is a new type of corneal refractive surgery free of the creation of a flap (7). Reinstein performed a retrospective study of high myopic FS-LASIK eyes between –8.00 and –14.25 D, and demonstrated that FS-LASIK could achieve high efficacy and safety for these patients (8). Moreover, in our previous study, SMILE was shown to be as safe and effective as FS-LASIK in the treatment of myopia over –10.00 D (9).

The aim of the current study was to evaluate posterior corneal stability both after SMILE and FS-LASIK at a 6-month follow-up, and to compare the two different procedures.

We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/atm-20-5165).

## Methods

### *Patients*

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Fudan University Eye and ENT Hospital Review Board (Shanghai, China, No. KJ2008-10), and informed consent was obtained from all the patients.

In this prospective comparative study, 82 eyes of 82 patients who were scheduled for refractive correction from June 2015 to June 2016 at the Department of Ophthalmology, Eye and ENT Hospital of Fudan University (Shanghai, China) were recruited. Eyes were randomly assigned to the SMILE group (45 eyes) or FS-LASIK group (37 eyes). The patients had no ocular disease other than refractive error and met the inclusion criteria. Subjects participating in the study were 18 to 45 years of age with a preoperative manifest spherical equivalent over –9.00 D.

The mean preoperative manifest spherical equivalent was –10.43±0.92 D (range: –9.00 to –13.00 D) in the SMILE group and –10.97±1.37 D (range: –9.00 to –13.25 D) in the FS-LASIK group. All patients underwent a comprehensive preoperative ophthalmologic examination, including Pentacam HR imaging, slit-lamp examination, measurement of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), intraocular pressure, and other examinations. The detailed data are shown in *Table 1*.

### *Surgical procedure*

#### Small incision lenticule extraction

The VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Germany) was used to perform all of the surgeries. After topical anesthesia, the patient was positioned under the curved contact glass and instructed to focus on the internal target light. The surgeon then achieved correct corneal centration and initiated suction, followed by femtosecond laser scanning. Once the laser scanning was completed, the surgeon inserted a spatula into the cornea, dissecting the lenticule interface, and manually extracted the lenticule. The femtosecond laser settings were as follows: repetition rate of 500 kHz, 110 μm intended cap thickness, 5.8 to 6.5 mm optical zone (lenticule diameter), 7.3 to 7.5 mm cap diameter, and a 2-mm side cut at the 12 o'clock point. The same experienced surgeon performed all procedures (XZ).

#### Femotosecond-assisted laser *in situ* keratomileusis

The same experienced surgeon performed all of the procedures. All flaps, created using the same VisuMax femtosecond laser system, had a superior hinge. After the flap was scanned, a spatula was inserted to lift it. Stromal ablation was performed with a Mel-80 excimer laser system (Carl Zeiss Meditec AG, Germany). The flap diameter

was set at 7.5 mm, and 110 μm for the flap thickness. The optical zone varied between 5.75 and 6.25 mm according to the refractive errors and corneal thickness. A bandage contact lens was applied to protect the eye, which was removed the next day.

### Pentacam Scheimpflug imaging

All eyes were examined using the Pentacam imaging system (Oculus GmbH, Wetzlar, Germany). The patient was instructed to position their head on the headrest and fixate the target light. After attaining alignment, the device captured 25 images and recorded 12,500 elevation points automatically within 2 seconds. To avoid miscalculations of poor imaging, the quality of each measurement was shown in the specification window, and only results with "OK" statements were accepted. The examination was duplicated if the statement did not meet the requirement (marked yellow or red). Only maps with at least 10 mm of corneal coverage and no deduced data in the central 9-mm zone were accepted.

### Postoperative examination

Follow-up appointments were scheduled at 1 day, 1 month, and 6 months after surgery (eyes undergoing FS-LASIK were followed at 1 day and 6 months postoperatively). Postoperative examinations included Pentacam imaging examinations, slit-lamp examination, measurement of UDVA, CDVA, spherical equivalent refraction, and intraocular pressure.

### Data collection

Elevation data of the posterior corneal surfaces were obtained using Pentacam software. The reference best-fit sphere (BFS) was defined in the center 8.0-mm region of the cornea and determined by the preoperative data, so it was the same across all images. For points above the reference, values were positive; for points below the reference, values were negative. Calculated values were obtained from 27 points in the central 6-mm zone as follows: 1 point at the center, 4 points at 1 mm distance from the center along 45°, 135°, 225°, and 315° meridians (0°, defined as the horizontal semi-meridian on the right, and rotating counterclockwise in both eyes), 8 points at 2 mm distance from the center at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, and the other 14 points at 3 mm distance from the center along 15°, 45°, 75°, 90°, 105°, 135°, 165°, 195°, 225°, 255°, 270°, 285°, 315°, and 345°. Posterior corneal elevation in the central 4mm area and in various optical zones (2-, 4-, and 6-mm diameter) was calculated as the mean value from determined points in the corresponding area. Changes in the posterior elevation were found by subtracting preoperative data from postoperative data (difference elevation map). The change in elevation was the shift of the posterior corneal surface, with a positive number indicating ectatic change. Elevation data were recorded in an Excel Spreadsheet (Microsoft Corp, Redmond, WA, USA) for further analysis.

**Table 1** Patient demographic information of SMILE and FS-LASIK groups

| Variable | SMILE | FS-LASIK |
|---|---|---|
| Age | | |
| Mean ± SD | 27.51±7.26 | 29.05±7.07 |
| Range | 18, 38 | 20, 40 |
| Preoperative SE (D) | | |
| Mean ± SD | −10.43±0.92 | −10.97±1.37 |
| Range | −13.00, −9.00 | −13.25, −9.00 |
| Preoperative TCT (μm) | | |
| Mean ± SD | 543.76±21.84 | 557.68±24.10 |
| Range | 503, 590 | 518, 614 |
| AD (μm) | | |
| Mean ± SD | 149.80±8.06 | 153.68±6.88 |
| Range | 128, 164 | 142, 172 |
| RBT (μm) | | |
| Mean ± SD | 283.96±18.53 | 294.00±24.45 |
| Range | 257, 323 | 258, 357 |

SE, spherical equivalent; D, diopters; TCT, thinnest corneal thickness; AD, ablation depth; RBT, residual bed thickness.

### *Statistical analysis*

The descriptive results contained the mean and the standard deviation. The Kolmogorov-Smirnov normality test and test for homogeneity of variances were performed for all data. The analysis of variance (ANOVA) for repeated measures with the Bonferroni correction was employed to compare pre- and postoperative values. If the data were not suitable for ANOVA analysis, we used the Friedman's rank test for k correlated samples. Bivariate normal analysis was performed before the correlation test. The Pearson or Spearman correlation test was applied subsequently to determine the association between the change in posterior

corneal surface 6 months after surgery and residual bed thickness (RBT). Statistical analyses were performed using SPSS ver. 20.0 (SPSS Inc., Chicago, IL, USA). A P value <0.05 was considered a statistically significant difference.

### *Patient and public involvement*

The role of the patients in this study was participants. They were not involved in the development of the research question and outcome measures, the recruitment of subjects, and the conduct of the study. They were not involved in the design of this study. The results of the study will be disseminated to all participants by email. No specific patient advisers were involved in the design or conduct of the study.

## Results

### *Visual outcomes*

All surgeries were completed successfully. The safety index and efficacy index were 1.20 and 1.00, respectively, in the SMILE group, and 1.10 and 0.90, respectively, in the FS-LASIK group. At the last follow-up, 80% (36/45) of eyes in the SMILE group and 65% (24/37) in the FS-LASIK group were within ±1.00 D; a best corrected distance visual acuity (BDVA) of 0.8 or better was achieved in 100% of eyes.

### *Small incision lenticule extraction*

The posterior corneal elevation of all points in various annulus of the cornea is shown in *Figure 1*. As seen in *Table 2*, the mean values of central posterior corneal elevation at different follow-ups were similar to each other, and no notable difference was observed between the times. The same results were also found for the 2-mm areas, as no statistical difference existed among different times. A significant statistical difference was revealed between pre- and postoperative 1 day in the 6-mm area. No significant difference existed among measurements at different times for the central 4-mm optical zone.

### *Femotosecond-assisted laser in situ keratomileusis*

Changes in posterior corneal elevation in eyes that underwent FS-LASIK had some differences when compared to those who underwent SMILE. The posterior corneal elevation at the central point, various corneal rings, and the central 4-mm area showed a slight forward displacement but no statistical significance (*Figure 1*, *Table 2*). Changes in posterior corneal elevation after FS-LASIK were greater than after SMILE, with no statistical significance (P≥0.07) (*Table 3*).

### *Correlations*

In the FS-LASIK group, RBT was significantly positively correlated with changes in posterior corneal elevation in the 3-mm radius of the corneal annulus. For eyes that underwent SMILE, RBT was positively correlated with changes in the 3-mm radius corneal ring. As for the central corneal area in the SMILE group, including the posterior corneal elevation in the center, the 1-mm radius corneal circle, and the central 4-mm optical zone, RBT was significantly negatively related to changes in the values (*Figure 2*, *Table 3*).

## Discussion

It has been theoretically proven that the greater the myopia is, the thicker the corneal ablation required, which may result in less corneal thickness with loss of corneal biomechanical stability leading to corneal protrusion after the procedure (10). Therefore, we studied the changes in the posterior corneal surface after FS-LASIK and SMILE in super high myopia.

First, no statistical significant difference was noted between the 6-month postoperative and baseline values when analyzing values in various zones. The results indicated that the posterior corneal surface remained stable after FS-LASIK and SMILE with no corneal forward displacement in super high myopia. In our previous study, we analyzed the changes in posterior corneal elevation in high myopia. The results revealed that the posterior corneal surface remained stable after SMILE (11). Considering patients who underwent FS-LASIK, Grewal evaluated the posterior corneal stability in the central 5-mm zone postoperatively and demonstrated no significant changes following the procedure (12). Cagini also observed that the posterior corneal surface did not have a forward displacement after FS-LASIK during follow-up (13). The results in the current study are in good agreement with those of the above studies. However, changes of posterior corneal elevation in longer periods for correction of myopia over –9.0 D is still unknown and worthwhile investigated.

Although no statistical significance existed when

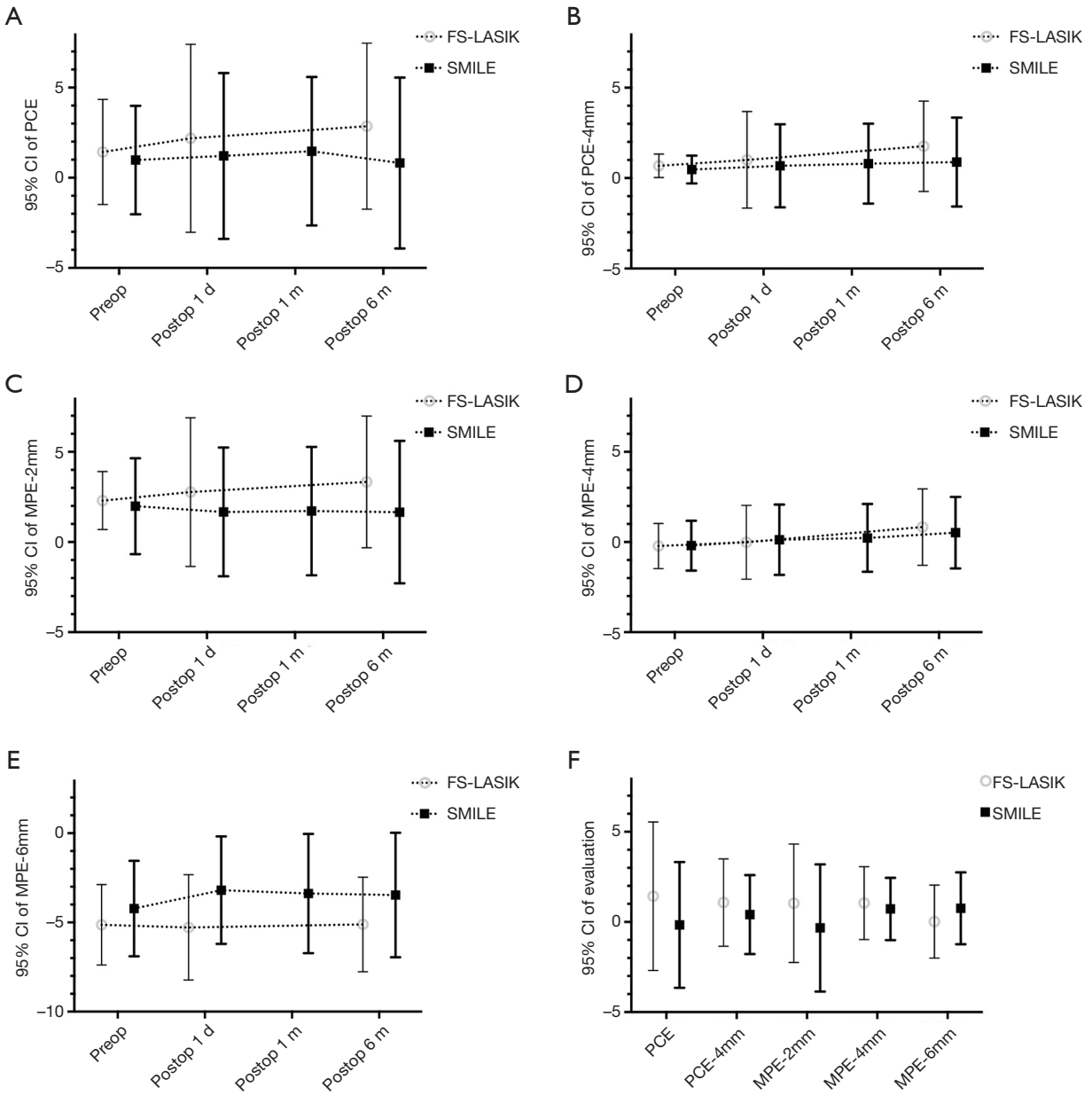


**Figure 1** (A,B,C,D,E) Mean and standard deviation of posterior corneal elevation at different follow-up times in the SMILE group and FS-LASIK group (A: PCE, B: PCE-4mm, C: MPE-2mm, D: MPE-4mm, E: MPE-6mm). (F) Mean change and standard deviation in PCE, PCE-4mm, MPE-2mm, MPE-4mm, MPE-6mm at 6 months after surgery, respectively. Square, SMILE; circle, FS-LASIK; SMILE, small incision lenticule extraction; FS-LASIK, femtosecond laser-assisted laser *in situ* keratomileusis; MPE, mean posterior corneal elevation.

comparing the changes in posterior corneal elevation after 6 months between the two groups, there were still some differences that should not be ignored. The mean changes in posterior corneal elevation in various areas after SMILE were less pronounced within 1 μm; however, greater changes after FS-LASIK were shown as the values were around 1 μm in almost all regions. A previous study also found that the change in posterior corneal elevation after FS-LASIK was greater than that after SMILE (14). The discrepancy in the wound healing response and biomechanical properties postoperatively may account for this finding. Dong has conducted a comparative study to evaluate corneal

**Table 2** Posterior corneal elevation before and after SMILE and FS-LASIK

| Variable | Time point | | | | P value | | | |
|---|---|---|---|---|---|---|---|---|
| | Preop | Postop 1 day | Postop 1 month | Postop 6 months | All times | Preop-1d | Preop-1m | Preop-6m |
| SMILE | | | | | | | | |
| PCE | 0.98±3.01 | 1.21±4.60 | 1.475±4.12 | 0.82±4.74 | 0.773[a] | 1.000 | 1.000 | 1.000 |
| PCE-4mm | 0.48±0.77 | 0.68±2.30 | 0.80±2.21 | 0.89±2.46 | 0.543[b] | | | |
| MPE-2mm | 1.99±2.66 | 1.67±3.57 | 1.72±3.56 | 1.66±3.95 | 0.821[a] | 1.000 | 1.000 | 1.000 |
| MPE-4mm | −0.20±1.38 | 0.125±1.95 | 0.23±1.88 | 0.52±1.98 | 0.050[a] | 1.000 | 1.000 | 0.050 |
| MPE-6mm | −4.22±2.68 | −3.19±3.01 | −3.38±3.34 | −3.46±3.49 | 0.001[a] | 0.002 | 0.177 | 0.458 |
| FS-LASIK | | | | | | | | |
| PCE | 1.43±2.91 | 2.19±5.21 | | 2.86±4.60 | 0.444[b] | | | |
| PCE-4mm | 0.68±0.65 | 1.01±2.67 | | 1.76±2.50 | 0.843[b] | | | |
| MPE-2mm | 2.30±1.61 | 2.77±4.12 | | 3.34±3.65 | 0.536[b] | | | |
| MPE-4mm | −0.22±1.25 | −0.01±2.05 | | 0.83±2.12 | 0.238[b] | | | |
| MPE-6mm | −5.13±2.25 | −5.28±2.95 | | −5.11±2.65 | 0.777[a] | 1.000 | | 1.000 |

[a], the analysis of variance for repeated measures (ANOVA) with the Bonferroni correction; [b], the Friedman's Rank test for k correlated samples. SMILE, small incision lenticule extraction; FS-LASIK, femtosecond laser-assisted laser in situ keratomileusis; preop, preoperative; postop, postoperative; PCE, posterior central elevation; PCE-4mm, mean posterior corneal elevation in the central 4-mm zone of 13 points; MPE-2mm, mean posterior corneal elevation in the 2-mm optical zone as a function of the meridian of 4 points; MPE-4mm, mean posterior corneal elevation in the 4-mm optical zone as a function of the meridian of 8 points; MPE-6mm, mean posterior corneal elevation in the 6-mm optical zone as a function of the meridian of 14 points.

wound healing and inflammatory course after these two surgeries, and found that SMILE resulted in less keratocyte apoptosis, proliferation, and inflammation compared with FS-LASIK (15). SMILE may result in a lower wound healing response, which can lead to more stable posterior corneal elevation due to the following reasons. On one hand, compared with the excimer laser, which uses ultraviolet light to break molecular bonds in the corneal stroma, the femtosecond laser produces ultrashort light pulses of high frequencies with a lower energy level, permitting photo-disruption of the corneal tissue at a precise depth (16). On the other hand, SMILE possesses distinct advantages over FS-LASIK for a 2-mm small incision and is free of lifting the cap, leaving most of the anterior stromal lamellae intact postoperatively (17). Reinstein developed a mathematical model to calculate the total stromal tensile strength following photorefractive keratectomy (PRK), LASIK, and SMILE, and concluded that SMILE possesses the greatest tensile strength (18). Based on another comparison experiment, Sinha Roy inferred that SMILE could theoretically afford less biomechanical risk than LASIK (19).

In the SMILE group, changes in the posterior corneal elevation in the central area were found to be moderately negatively correlated with RBT, whereas changes in the peripheral area were positively correlated with RBT. Similar results in the peripheral zone were also noted in the FS-LASIK group. The correlation between changes in posterior corneal elevation and RBT remains controversial. Grewal *et al.* revealed no correlation between change in posterior corneal elevation and RBT in either of three corneal refractive surgery groups (FS-LASIK, LASIK, and LASEK) (12). Sun also demonstrated that the RBT had no correlation with the amount of forward displacement (20). In contrast, another study reported that eyes with a thinner RBT were more susceptible to show a greater positive change in posterior corneal elevation in the central area after SMILE, which is consistent with our results (14). It is rational to infer that several factors may lead to different results: with a longer follow-up period, smaller sample size, and larger analyzed zone (especially for data covering both

 

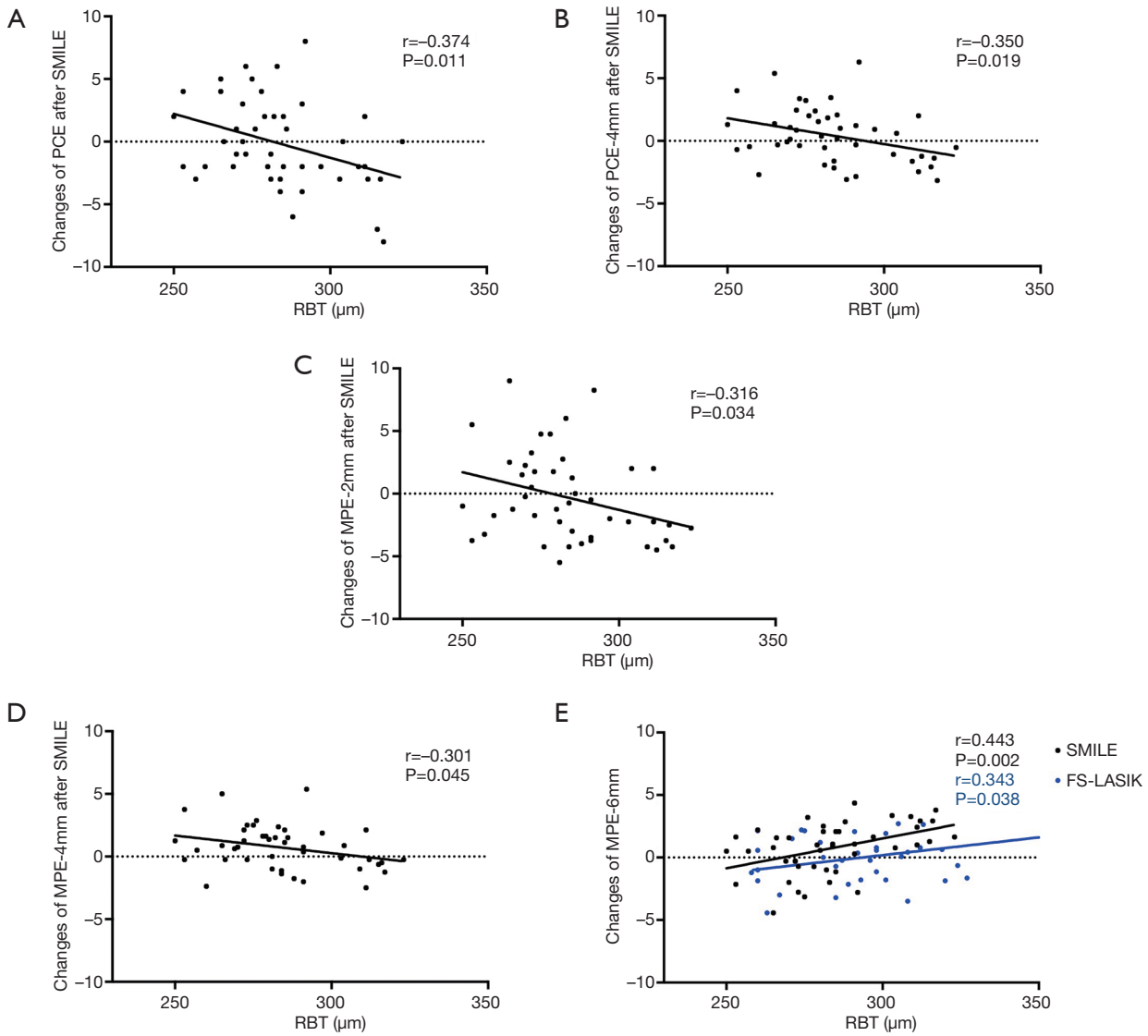


**Figure 2** (A,B,C,D) A significant correlation was found between RBT and the change of PCE (A), PCE-4mm (B), MPE-2mm (C), and MPE-4mm (D) at 6 months after SMILE. (E) A significant correlation was found between RBT and the change of MPE-6mm at 6 months after SMILE and FS-LASIK. Black, SMILE; blue, FS-LASIK; SMILE, small incision lenticule extraction; FS-LASIK, femtosecond laser-assisted laser *in situ* keratomileusis; preop, preoperative; postop, postoperative; PCE, posterior central elevation; PCE-4mm, mean posterior corneal elevation in the central 4-mm zone of 13 points; MPE-2mm, mean posterior corneal elevation in the 2-mm optical zone as a function of the meridian of 4 points; MPE-4mm, mean posterior corneal elevation in the 4-mm optical zone as a function of the meridian of 8 points; MPE-6mm, mean posterior corneal elevation in the 6-mm optical zone as a function of the meridian of 14 points; RBT, residual bed thickness.

the central and peripheral areas at the same count), the correlation was weaker or even not statistically significant.

There are limitations to our study: the sample size was small and the observation time was short. Future studies will include a lager sample size and a longer follow-up, which will provide more information on the posterior corneal surface changes after these two surgeries.

In the current study, our results demonstrated that both SMILE and FS-LASIK present a promising advance in the correction of myopic over –9.0 D. At the final follow-up

**Table 3** Change of posterior corneal elevation after SMILE and FS-LASIK and its correlation with RBT

| Variable | Change of evaluation after SMILE | Correlation with RBT | | Comparison between groups (P) | Change of evaluation after FS-LASIK | Correlation with RBT | |
|---|---|---|---|---|---|---|---|
| | | r | P | | | r | P |
| PCE | −0.16±3.49 | −0.374 | 0.011[b] | 0.070[c] | 1.43±4.12 | −0.273 | 0.102[a] |
| PCE-4mm | 0.41±2.19 | −0.305 | 0.041[a] | 0.201[d] | 1.08±2.42 | −0.183 | 0.279[a] |
| MPE-2mm | −0.33±3.53 | −0.316 | 0.034[a] | 0.078[d] | 1.04±3.28 | −0.271 | 0.105[a] |
| MPE-4mm | 0.72±1.73 | −0.301 | 0.045[a] | 0.436[d] | 1.05±2.02 | −0.067 | 0.695[a] |
| MPE-6mm | 0.76±1.99 | 0.443 | 0.002[a] | 0.103[d] | 0.02±2.03 | 0.343 | 0.038[a] |

[a], the Pearson correlation test; [b], the spearman correlation test; [c], the Mann-Whitney U test; [d], the analysis of variance (ANOVA). SMILE, small incision lenticule extraction; FS-LASIK, femtosecond laser-assisted laser *in situ* keratomileusis; RBT, residual bed thickness; PCE, posterior central elevation; PCE-4mm, mean posterior corneal elevation in the central 4-mm zone of 13 points; MPE-2mm, mean posterior corneal elevation in the 2-mm optical zone as a function of the meridian of 4 points; MPE-4mm, mean posterior corneal elevation in the 4-mm optical zone as a function of the meridian of 8 points; MPE-6mm, mean posterior corneal elevation in the 6-mm optical zone as a function of the meridian of 14 points.

visit of 6 months, all recruits in the two groups exhibited a stable posterior corneal surface.

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## Footnote

*Reporting Checklist:* The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/atm-20-5165

*Data Sharing Statement:* Available at http://dx.doi.org/10.21037/atm-20-5165

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/atm-20-5165). The authors have no conflicts of interest to declare.

*Ethics Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Fudan University Eye and ENT Hospital Review Board (Shanghai, China, No. KJ2008-10) and informed consent was taken from all the patients.



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