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• Clinical Research •

Posterior corneal elevation changes after small incision lenticule extraction in patients with thin cornea

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Abstract
● **AIM:** To investigate the changes in posterior corneal elevation within 6mo after small incision lenticule extraction (SMILE) surgery for myopia and myopic astigmatism in patients with thin corneas.

● **METHODS:** A prospective study included patients with thin corneas (preoperative thinnest corneal thickness ranging from 480 to 520 μm) who underwent SMILE for myopia or myopic astigmatism. Corneal topography and posterior corneal elevation were assessed using Pentacam HR at three time points: preoperatively, 1mo, and 6mo postoperatively. The measured parameters included thinnest point elevation (PTE), posterior maximal elevation (PME), posterior central elevation (PCE), and 24 additional reference points.

● **RESULTS:** A total of 106 eyes from 106 patients (age range: 18-34) were included in the study. Uncorrected distance visual acuity (UDVA) improved significantly, with a mean logMAR value of -0.07±0.06 at the final follow-up visit. Measurements of posterior corneal elevation showed no significant changes in most points, hemispheres, and meridians at 6mo postoperatively. Notably, only two points, $\Delta E_{2mm\text{-}45°}$ and $\Delta E_{2mm\text{-}90°}$, exhibited statistically significant elevation changes: the elevation of $\Delta E_{2mm\text{-}45°}$ increased from -2.3±4.99 to -1.0±5.9 μm (P=0.0037), and that of $\Delta E_{2mm\text{-}90°}$ increased from -16±7.53 to -15±7.4 μm (P=0.016). However, these changes were within the measurement error range of the Pentacam HR (±5 μm in a 5 mm area).

● **CONCLUSION:** SMILE surgery is a safe and stable procedure for correcting myopia or myopic astigmatism in patients with thin corneas, as evidenced by the stability of posterior corneal elevation.

● **KEYWORDS:** small incision lenticule extraction; thin cornea; posterior corneal elevation; refractive surgery
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INTRODUCTION

Since the introduction of small incision lenticule extraction (SMILE), the field of corneal refractive surgery has seen significant advancements[1]. SMILE has become one of the most popular refractive surgery techniques, recognized for its precision, safety, and efficacy in correcting refractive errors[2-5]. Compared to laser-assisted *in situ* keratomileusis (LASIK), SMILE does not create a corneal flap, preserving more of the corneal structure and minimizing damage to the Bowman membrane, thereby reducing the occurrence of flap-related complications and impacts on corneal biomechanics[6-7]. Some studies suggested that SMILE surgery had no difference in effectiveness and predictability compared to ICL surgery, but the visual quality was slightly inferior[8]. However, the corneal biological tissue lens provided by SMILE surgery can be applied to the treatment of various corneal diseases and may have important social benefits[9-10].

Ectasia after corneal refractive surgery is a complication associated with changes in corneal biomechanics, and posterior corneal elevation is significant for indicating early ectasia[11-12]. Many studies have shown that posterior corneal elevation remains relatively stable after SMILE surgery[13-16]. However, in patients with thin cornea and an expected thin residual bed thickness (RBT), the surgical indication remains controversial due to relatively insufficient innate corneal conditions.

Therefore, further evaluation of changes in posterior corneal elevation after surgery in these patients is of greater significance for determining the safety of the surgery.

PARTICIPANTS AND METHODS

Ethical Approval The study protocol, adhering to the principles of the Declaration of Helsinki and identified with the reference number [2024]117-01, was approved by the Ethics Committee of the General Hospital of Central Theater Command and Eye and ENT Hospital of Fudan University. All subjects obtained written informed consent and did not derive any benefit from it.

Participants This prospective study aimed to investigate the stability of posterior corneal elevation after SMILE surgery in patients with thin cornea who underwent correction for myopia or myopic astigmatism. A total of 106 right eyes from 106 patients were included in the study.

Inclusion Criteria Myopic patients, with or without astigmatism, with a preoperative best-corrected visual acuity of ≥16/20, corneal thickness between 480 μm and 520 μm, stable refraction within the past 2y, and cessation of soft contact lens wear for 1wk, hard contact lenses for 3wk, and orthokeratology for over 3mo.

Exclusion Criteria Systemic diseases, other ocular diseases aside from refractive errors, history of ocular surgery or trauma, suspected keratoconus or high risk of post-refractive surgery ectasia, and dry eye.

All patients were in good health, able to complete regular follow-ups, and met the surgical conditions. Examinations were conducted preoperatively, and at 1mo and 6mo postoperatively.

Surgical Procedures All surgeries were performed by an experienced surgeon. Topical levofloxacin 0.5% (Cravit; Santen, Osaka, Japan) was applied four times a day for three days prior to surgery. The SMILE procedure was completed using the VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) with a frequency set at 500 kHz and energy set at 130 nJ. The laser scan time during surgery was approximately 35s, with the optical zone diameter set at 6.0-6.5 mm and the corneal cap thickness set at 110-120 μm. The lens was extracted through a 12 o'clock direction incision. Postoperatively, topical levofloxacin 0.5%, fluorometholone solution 0.1%, and non-preserved artificial tears (carboxymethylcellulose sodium eye drops; Allergan, Irvine, California, USA) were applied to the surgical eye.

Examinations Posterior corneal elevation was measured using the Pentacam HR (Oculus GmbH, Wetzlar, Germany). Before each measurement, patients were instructed to blink 2-3 times to minimize the impact of the tear film on the examination results. Only images labeled "OK" and covering a 10.0 mm diameter range with no central dark area were included. All measurements were performed by the same operator (Liu Y) between 10:00 and 17:00.

Routine examinations including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and spherical equivalent (SE) were also followed up.

Data Collection The preoperative best-fit sphere of the central 8 mm of the cornea was taken as the reference plane. Changes in posterior corneal elevation were calculated by subtracting the preoperative posterior elevation from the postoperative posterior elevation. A positive result indicates anterior protrusion of the posterior surface, and vice versa.

In this study, posterior elevation at the thinnest point (PTE), posterior maximal elevation (PME) in relation to preoperative best fit sphere (BFS), posterior central elevation (PCE), and 24 other points (1, 2, and 3 mm from the center, along the 0, 45°, 90°, 135°, 180°, 225°, 270°, and 315° semimeridians) were measured. Among them, PME refers to the highest point of the posterior corneal surface within the central 6 mm, taken from the mouse-over read-out. The average corneal posterior elevation was calculated from PCE and the other 24 points. The average posterior elevation of different diameter concentric circles was recorded as PCE0 (center point), PCE2 (concentric circle with a diameter of 2 mm), PCE4 (concentric circle with a diameter of 4 mm), and PCE6 (concentric circle with a diameter of 6 mm), calculated from the 8 points on the concentric circle (excluding PCE0). The average posterior elevation of different regions was recorded as NPCE (posterior corneal elevation in the nasal hemisphere), TPCE (posterior corneal elevation in the temporal hemisphere), SPCE (posterior corneal elevation in the superior hemisphere), and IPCE (posterior corneal elevation in the inferior hemisphere). The 0 mentioned above is defined as the corneal center pointing towards the temporal direction, and 90° is defined as the corneal center pointing upwards. The temporal side mentioned in this paper does not include the 90°-270° meridian, and other angles and directions are defined accordingly. This is consistent with the methods of the authors' previous studies[10].

Statistical Analysis Data analysis was performed using SAS software (version 9.4, SAS Institute Inc., USA), and the one-sample Kolmogorov-Smirnov test was used for variance homogeneity testing. Normally distributed continuous variables were expressed as mean±standard deviation (SD). Mixed linear models were used to analyze changes in posterior corneal elevation over time and differences between different surgical groups. The average posterior elevation of different hemispheres and meridians was compared using paired *t*-tests. $P<0.05$ was considered statistically significant.

RESULTS

Patients baseline information is presented in Table 1.

Refractive Outcomes The SE results are shown in Figure 1. At 1mo postoperatively, the SE was -0.04±0.36 D, and at

6mo postoperatively, it was -0.14±0.30 D. No statistically significant differences were observed from 1mo to 6mo postoperatively (P=0.736).

Posterior Corneal Elevation The changes in posterior elevation are shown in Table 2. No statistically significant differences were found in the posterior elevation of all different hemispheres and meridians within 6mo postoperatively. Among the different points, except for $\Delta E_{2mm\text{-}45°}$ (changes of the posterior corneal elevation on the 45° meridian at the 2 mm diameter position) and $\Delta E_{2mm\text{-}90°}$ (changes of the posterior corneal elevation on the 90° meridian at the 2 mm diameter position), no parameters were found to change over time. $\Delta E_{2mm\text{-}45°}$ increased at 6mo postoperatively (P=0.0037), but the average value was only from -2.3±4.99 to -1.0±5.90 μm; $\Delta E_{2mm\text{-}90°}$ increased at 1mo postoperatively (P=0.016), with an average value from -16.0±7.53 to -15.0±7.40 μm, and no statistically significant difference was found compared to preoperative values at 6mo postoperatively (P=0.059). At the last follow-up, only one point, $\Delta E_{2mm\text{-}45°}$, showed an increase in elevation compared to preoperative values.

Figure 2 shows the posterior elevation at different points (Figure 2A), hemispheres (Figure 2B), and diameters (Figure 2C). Within the 6-month follow-up period postoperatively, no statistically significant differences were observed in the average posterior elevation at different locations, including PCE, PME, PTE, and different directions and diameters of 2, 4, and 6 mm.

Figure 3 shows the posterior elevation at different diameters and angles. Overall, the distribution of posterior elevation remained consistent over time. From the center to the periphery (fluctuations at 2 mm: 8.13 μm, at 4 mm: 24.55 μm, and at 6 mm: 38.23 μm), the change in posterior corneal elevation gradually increased. In the distribution between the upper and lower, and nasal and temporal directions, a pattern of lower >upper (2 mm, inferior, 2.52±4.38 μm, superior, -1.03±4.45 μm, P<0.001; 4 mm, inferior, 2.53±7.13 μm, superior, -7.01±8.69 μm, P<0.001; 6 mm, inferior, -2.42±11.61 μm, superior, -12.75±13.23 μm, P<0.001) and temporal>nasal (2 mm, temporal, 3.18±4.09 μm, nasal, 1.71±4.37 μm, P<0.001; 4 mm, temporal, 5.12±6.88 μm, nasal, 1.34±6.49 μm, P<0.001; 6 mm, temporal, 4.07±10.66 μm, nasal, -0.01±9.27 μm, P<0.001) was observed.

DISCUSSION

The Pentacam HR is the most widely used instrument for measuring posterior corneal elevation, with good accuracy and repeatability, playing a good role in reflecting posterior corneal elevation[17-18]. In clinical practice, posterior corneal elevation is an important indicator for diagnosing corneal ectatic diseases[19], and the Pentacam HR has high sensitivity and specificity for measuring the posterior corneal elevation in keratoconus, subclinical keratoconus, and normal corneas[20].

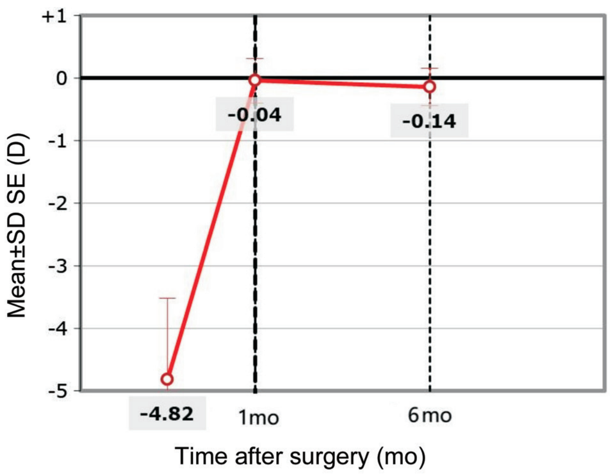

Figure 1 The spherical equivalent results after SMILE SMILE: Small incision lenticule extraction.

Table 1 Patients baseline information

Parameters	Data
Age (y)	25.21±7.06
UDVA (logMAR)	0.81±0.13
CDVA (logMAR)	-0.10±0.05
Sphere (D)	-4.82±1.34
Cylinder (D)	-0.67±0.41
SE (D)	-4.82±1.30
TCT (μm)	504.78±12.97
RBT (μm)	291.9±12.93
Lenticule thickness (μm)	93.87±17.95
IOP (mm Hg)	14.71±2.40

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; TCT: Thinnest corneal thickness; RBT: Residual bed thickness; IOP: Intraocular pressure.

Table 2 Posterior corneal elevations after SMILE

Measuring position	Corneal elevations (μm)			P
	Pre	1mo	6mo	
PCE	1.92±3.24	2.09±3.94	2.06±4.04	0.472
PTE	2.80±3.48	2.54±4.01	2.45±4.05	0.943
PME	1.49±3.00	1.57±3.77	1.91±3.81	0.548
Concentric circle				
2 mm	1.41±4.60	1.48±4.81	1.77±4.64	0.212
4 mm	-0.15±9.38	0.02±9.33	0.35±9.12	0.097
6 mm	-3.66±14.13	-3.63±14.38	-3.59±13.99	0.355
Hemisphere				
NPCE	1.01±6.66	0.85±7.37	1.25±6.77	0.059
TPCE	4.02±7.57	4.14±7.87	4.21±7.78	0.372
SPCE	-7.54±10.68	-6.83±10.62	-6.42±10.56	0.368
IPCE	1.11±8.05	0.71±8.92	0.80±8.75	0.797

PCE: Posterior central elevation; PTE: Point elevation; PME: Posterior maximal elevation; NPCE: Posterior corneal elevation in the nasal hemisphere; TPCE: Posterior corneal elevation in the temporal hemisphere; SPCE: Posterior corneal elevation in the superior hemisphere; IPCE: Posterior corneal elevation in the inferior hemisphere.

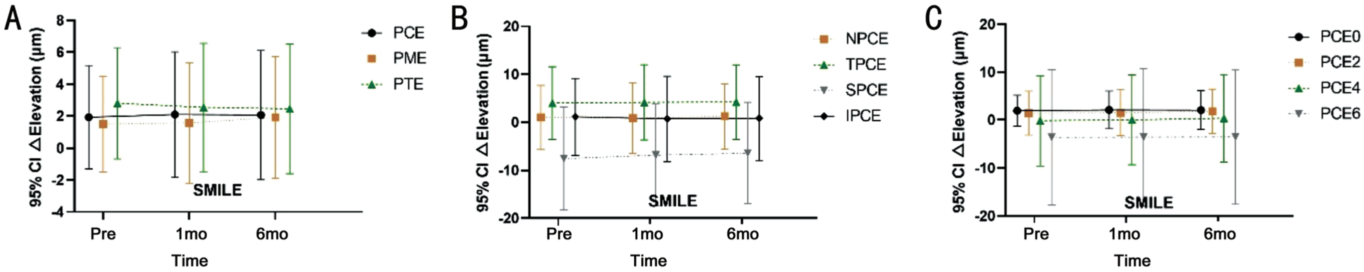

Figure 2 The posterior elevation at different points (A), hemispheres (B), and diameters (C) PCE: Posterior central elevation; PME: Posterior maximal elevation; PTE: Thinnest point elevation; NPCE: Posterior corneal elevation in the nasal hemisphere; TPCE: Posterior corneal elevation in the temporal hemisphere; SPCE: Posterior corneal elevation in the superior hemisphere; IPCE: Posterior corneal elevation in the inferior hemisphere; PCE0: Elevation of center point; PCE2: Average elevation of concentric circle with a diameter of 2 mm; PCE4: Average elevation of concentric circle with a diameter of 4 mm; PCE6: Average elevation of concentric circle with a diameter of 6 mm; SMILE: Small incision lenticule extraction; CI: Confidence interval.

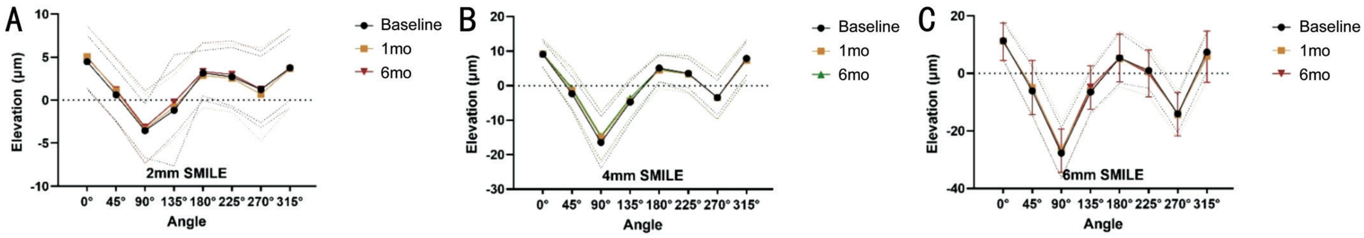

Figure 3 The posterior elevation at different diameters and angles A: Elevation of concentric circle with a diameter of 2 mm; B: Elevation of concentric circle with a diameter of 4 mm; C: Elevation of concentric circle with a diameter of 6 mm. SMILE: Small incision lenticule extraction.

Numerous studies have shown that postoperative coronal elevation remains stable in routine SMILE patients[14,21-22]. However, patients with thin cornea hold a relatively unique position in the field of corneal refractive surgery. Another study conducted by our team on thin corneal patients has confirmed that SMILE surgery can achieve stable visual effects after surgery[23]. The thinner cornea poses potential risks in terms of corneal biomechanics, making the study of surgical safety and efficacy a focal point of interest for scholars. Kirmaci Kabakci *et al*[24] and Eskina *et al*[25] have specifically focused on the postoperative effectiveness in patients with corneal thickness of less than 500 μm. Their studies ultimately demonstrated that the long-term outcomes of SMILE surgery in patients with thin corneas are good and stable. They also pointed out that different surgical parameter calculation methods may be necessary for patients with thin corneas. Sun *et al*[16] also observed the height of the posterior corneal surface after SMILE surgery, and their research confirmed that there were dynamic changes in posterior corneal elevation after SMILE surgery, but no significant anterior convexity was observed within one year after surgery. Cao *et al*[26] showed that eyes with thinner corneas, higher myopia requiring lower RBT exhibited greater predispositions towards posterior protrusion. Ouyang *et al*'s[27] research suggests that the range of 250-310 μm RBT was safe and stable at the early postoperative of SMILE, and the RBT may be positively correlated with the posterior corneal elevation.

In this study, we paid particular attention to the changes in posterior corneal elevation at the central cornea and the thinnest point, which is particularly important for assessing the safety of the surgery. This is because the corneal tissue in these areas is relatively scarce and may be more susceptible to changes postoperatively. The average ΔPCE and ΔPTE 6mo after SMILE correction for thin corneal myopia and astigmatism were -0.34±2.45 and 0.14±2.19 μm, respectively. Most changes in posterior elevation did not show statistical differences, and the points with statistical differences were within the measurement error range of the Pentacam (error of about ±5 μm in a 5 mm area)[17], indicating that the posterior corneal elevation remained stable after SMILE correction for thin corneal myopia and astigmatism.

In the 6-month follow-up, only two points of posterior elevation showed statistically significant increases. The 2 mm diameter 90° point eventually showed no statistically significant difference compared to preoperative results at the last follow-up, and only the 2 mm diameter 45° point showed an increase in posterior elevation at the last follow-up, and all changes were still within the measurement error range of the Pentacam HR. Such changes are similar to our previous studies on the observation of posterior elevation after SMILE and LASIK for high myopia, which again confirms the good safety of SMILE for correcting high myopia and thin corneal patients[15]. This finding is of great significance for alleviating patients' concerns about postoperative corneal expansion.

So far, some studies have explored the pattern of changes in posterior corneal elevation after SMILE surgery. The authors have previously explored the changes in posterior corneal elevation 2y after SMILE correction for high myopia and found that the long-term changes in posterior elevation after SMILE correction for myopia were all within ±5 μm, that is, within the measurement error range of the Pentacam HR[17]. However, there are currently few studies on SMILE correction for thin corneal myopia and astigmatism. The changes in posterior corneal elevation in the long term after SMILE correction for thin corneal myopia and astigmatism are most not statistically significant, which is basically the same as its correction for myopia. Cheng *et al*[13] explored the changes in posterior corneal elevation after SMILE surgery with different optical zones and found that there was no elevation of the posterior corneal surface in the 3-year follow-up, also indicating the stability of posterior corneal elevation. In the study by Zhao *et al*[14], a long-term stability observation of SMILE surgery in thin corneal patients was conducted, and it was found that there was no significant change in the posterior corneal elevation of thin corneal patients within 3y after surgery, which is the same as our research results. In Zhao *et al*'s[14] study, the focus was primarily on the changes in PTE and PME, as well as regional variations. Building on this foundation, we have further expanded the dataset by incorporating a substantial number of additional points and varying meridional data, thereby more accurately capturing the alterations in the entire posterior corneal elevation. We also noted that a study by Yang *et al*[28] showed that the stability of posterior corneal elevation was significantly correlated with the ablation ratio, so preoperative assessment and surgical design are crucial for ensuring postoperative stability. In this study, we also adhered to the same view and performed surgery after a comprehensive assessment of each patient to ensure safety and postoperative stability. In summary, the posterior corneal elevation after SMILE correction for thin corneal myopia and astigmatism is stable.

The relatively small sample size and the specificity of our patient cohort may limit the generalizability of our findings. Additionally, the short-term follow-up period of six months, though sufficient to observe early postoperative changes, does not capture long-term trends that may influence the stability of posterior corneal elevation over time. Future studies with larger cohorts and extended follow-up periods are warranted to confirm these preliminary findings. Another limitation is that this study did not include parameters related to corneal biomechanics. We have noticed that Zhao's[29] research suggests that some biomechanical parameters may affect the changes in PCE after SMILE surgery, which requires further exploration.

Looking ahead, there is a clear need for longitudinal studies that track the long-term stability of posterior corneal elevation following SMILE in thin cornea patients. Such studies will not only provide insights into the durability of the procedure but also inform best practices for postoperative care. Furthermore, the integration of advanced imaging technologies, such as optical coherence tomography (OCT), may offer a more comprehensive assessment of corneal changes post-SMILE.

We have noticed that some scholars have conducted experiments in rabbits to explore the correlation between residual stromal thickness (RST) and SMILE postoperative biomechanical stability, which could provide valuable insights into the safety of performing SMILE with reduced RST values for high myopia correction and guide SMILE procedures[30]. Additionally, there is potential in exploring personalized surgical algorithms that consider the unique corneal biomechanical properties of each patient. Such an approach could further refine the precision and safety of SMILE, particularly in patients with thin corneas where the margin for intervention is narrow.

In conclusion, our study contributes to the growing body of evidence supporting the safety and stability of SMILE in patients with thin corneas. While our findings are encouraging, they also highlight the need for ongoing research to optimize surgical outcomes and enhance our understanding of corneal biomechanics in the context of refractive surgery.

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