• Clinical Research •

Early assessment of visual outcomes and corneal stability in eyes with a pre-planned residual stromal thickness of 280 to 300 μm following small incision lenticule extraction

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Abstract

● **AIM:** To assess early visual outcomes and corneal stability following small incision lenticule extraction (SMILE) in eyes with a pre-planned residual stromal thickness (RST) ranging from 280 to 300 μm.

● **METHODS:** This retrospective study was designed to evaluate 82 eyes from 82 patients, all of whom had a pre-planned RST of 280 to 300 μm and normal corneal topography prior to undergoing SMILE surgery. The mean preoperative spherical equivalent (SE) was -4.82±1.30 D. A standard follow-up protocol was conducted between 1 to 6mo postoperatively. Visual outcomes were recorded using uncorrected visual acuity (UCVA) and subjective refraction. The curvature of the anterior and posterior corneal surfaces, as well as the posterior elevation at the thinnest point (PTE) were derived from the Pentacam system.

● **RESULTS:** At the final follow-up, the efficacy index was 1.14±0.15, the safety index was 1.20±0.13. The mean preoperative UDVA was 0.78±0.16 logMAR, which improved significantly to -0.07±0.06 logMAR postoperatively (P<0.001). The preoperative mean SE was -4.82±1.30 D, which decreased to -0.14±0.30 D by the last visit. The curvature of the anterior cornea at the flat meridian (AK1) were 42.62±1.02 D preoperatively, 38.56±1.37 D and 38.59±1.39 D at 1 and 6mo after operation, respectively. Corresponding measurements at the steep meridian (AK2) were 43.55±1.14 D preoperatively, 39.18±1.46 D and 39.22±1.50 D at 1 and 6mo after operation, respectively. Both AK1 and AK2 remained stable at 1 and 6-mo postoperative intervals (P=0.126 and 0.082, respectively). There were no observed changes in the curvature of the posterior cornea at the flat meridian or at the steep meridian, or the PTE before and after surgery.

● **CONCLUSION:** SMILE represents a safe and effective procedure for the correction of myopia and astigmatism in eyes featuring a pre-planned RST ranging from 280 to 300 μm accompanied by normal corneal topography, on the premise of strict control of surgical indications.

● **KEYWORDS:** small incision lenticule extraction; thin cornea; corneal stability

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INTRODUCTION

Over the past decade of clinical application and development, the safety and efficacy of small incision lenticule extraction (SMILE) in correcting myopia and astigmatism have been widely acknowledged[1-4]. The advantages of this surgical method, including the absence of corneal flap creation, excellent biomechanical properties[5-8], and a reduction in dry eye symptoms after surgery[9], have contributed to its robust growth in recent years. In the process of correcting myopia and astigmatism, a small lenticule needs to be created in the central corneal stroma and extracted, which can make the cornea of patients with thin corneas thinner and alter corneal biomechanical properties. In the process of correcting myopia and astigmatism, it is essential to create a small lenticule within the central corneal

stroma and subsequently remove it. This procedure may lead to a thinner cornea in patients who naturally have thin corneas, and it could potentially alter the biomechanical properties of the cornea. As we all know that an excessively thin residual corneal thickness is one of the risk factors for corneal ectasia following SMILE. Previous studies have indicated that photorefractive keratectomy (PRK) or laser-assisted subepithelial keratomileusis (LASEK) are appropriate surgical options for individuals with thin corneas, as they provide an extra 50 to 60 μm of stromal bed for ablation when compared to SMILE[10-12]. This holds particular importance for individuals with thin corneas, particularly those with high myopia. Hwang *et al*[13] reported that SMILE surgery exhibits greater predictability than LASEK in patients with a central corneal thickness of less than 500 μm. Zhao *et al*[14] reported that SMILE demonstrated excellent safety and efficacy in the correction of myopia in patients with thin cornea, with the posterior cornea surface remained stable throughout the 3-year follow-up period. However, Soundarya *et al*[15] demonstrated that a pre-planned residual stromal thickness (RST)<300 μm was one of the risk factors for ectasia development after keratorefractive procedures. It is important to note that there is a scarcity of studies specifically focusing on SMILE surgery for the correction of myopia and astigmatism in eyes with pre-planned RST of 280 to 300 μm post-surgery.

In this study, our objective was to assess the visual outcomes, as well as the safety and efficacy of SMILE with pre-planned RST ranging from 280 to 300 μm over a 6-month postoperative follow-up period.

PARTICIPANTS AND METHODS

Ethical Approval This study followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the General Hospital of Central Theater Command (No.[2024]117-01). All subjects were duly informed and consented to participate in the research.

Participants To assess the visual outcomes, safety and efficacy of SMILE in correcting eyes with pre-planned RST of 280 to 300 μm. A total of 82 eyes from 82 patients (46 females and 36 males) diagnosed with refractive errors at the General Hospital of Central Theater Command between March 2021 to September 2021, were included. The study focused exclusively on the parameters of the right eye. We elucidated the benefits and risks of SMILE to each patient and procured their signed informed consent forms. Furthermore, each patient independently chose their preferred type of surgery.

Inclusion and Exclusion Criteria The inclusion criteria in this study were as follows: 1) age ≥18y; 2) stable refractive status for at least 2y (change ≤0.50 D annually); 3) thinnest corneal thickness ≥480 μm, and pre-planned RST of 280 to 300 μm; 4) corrected distance visual acuity (CDVA) of 20/25 or better; 5) no use of any kind of contact lenses within 2wk before surgery. Patients with ocular pathology, a history of eye surgery or trauma, systemic diseases such as Sjögren syndrome or abnormal corneal topography were excluded.

Methods This study was a retrospective design. Prior to undergoing SMILE, each patient underwent a rigorous assessment. Preoperative examinations revealed no irregular topographical findings. All patients were in good physical and mental health, and were capable of completing regular follow-up appointments. Preoperative examinations were conducted, and follow-ups were completed at 1 and 6mo post-surgery. Detailed information is presented in Table 1. A complete ophthalmic examination encompassed an assessment of uncorrected distance visual acuity (UDVA; International Standard Visual Acuity Chart), CDVA, manifest refraction and cycloplegic refraction (KR-1 Auto Kerato-Refractometer, Topcon, Japan), auto-noncontact tonometry (NIDEK NT-2000, Japan). Curvatures of anterior and posterior cornea, along with posterior elevation at the thinnest point (PTE) were analyzed using the Pentacam system (Oculus GmbH, Wetzlar, Germany). All patients were instructed to blink 2-3 times before each measurement to minimize the impact of tear film on the results. Only the data of Quality Specification (QS) marked with "OK" were analyzed. All measurements were performed by the same operator between 10:00 and 17:00 (Liu Y). The best-fit sphere (BFS) in the central 8.0 mm zone of the preoperative cornea was used as the reference surface for each eye[16]. Alpins method[17-19] for vector analysis was used to characterize the efficacy of SMILE in the correction of astigmatism. Refractive data were converted into three fundamental vectors, which included target-induced astigmatism (TIA), surgically induced astigmatism (SIA), and difference vector (DV). The angle of error (AE) was the angle described by the vector of SIA versus TIA. AE was positive if the achieved correction was on an axis counterclockwise (CCW) to where it was intended and negative if the achieved correction was clockwise (CW) to its intended axis. The correction index (CI) was defined as the SIA divided by the TIA. The value might be preferred, and astigmatism was considered undercorrected if the CI was lower than 1.

Surgical and Postoperative Management All SMILE procedures were conducted by a seasoned physician (Jiang WS). The preoperative treatment included the administration of gatifloxacin eye drops (0.3% Otsuka, China) and artificial tears, both administered four times daily for a duration of 3d. Topical anesthesia consisted of two drops of proparacaine hydrochloride (0.5%; Alcon, USA). SMILE was performed by VisuMax Femtosecond Laser (500 kHz, Carl Zeiss Meditec, AG, Jena, Germany). The spot energy was precisely calibrated to 145 nJ. The treatment was centered on the corneal vertex.

Table 1 Refractive outcomes over the follow-up period mean±SD

Parameters	Preop	1mo postop	6mo postop	*P*1	*P*2
Age (y)	25.15±5.98 (18 to 49)	-	-	-	-
Gender (M/F)	36/46	-	-	-	-
CCT (min, max), μm	505.13±12.05 (480 to 520)	-	-	-	-
UDVA (logMAR), medium (IQR)	0.78±0.16, 0.9 (0.7 to 0.9)	-0.07±0.06, -0.1 (-0.1 to 0)	-0.07±0.06, -0.1 (-0.1 to 0)	<0.001	0.317
CDVA (logMAR), medium (IQR)	-0.00±0.03, 0 (0 to 0)	-0.09±0.05, -0.1 (-0.1 to -0.1)	-0.10±0.05, -0.1 (-0.1 to -0.1)	<0.001	<0.05
Sphere (min, max), D	-4.48±1.34 (-7.5 to -1.5)	0.12±0.36 (-0.75 to +1.00)	-0.01±0.28 (-0.50 to +0.50)	<0.001	<0.001
Cylinder, medium (IQR), D	-0.67±0.41, -0.50 (-1.00 to -0.44)	-0.32±0.11, -0.25 (-0.50 to -0.25)	-0.25±0.16, -0.25 (-0.25 to -0.25)	<0.001	<0.001
SE (min, max), D	-4.82±1.30 (-7.75, -1.75)	-0.04±0.36 (-0.88, 0.88)	-0.14±0.30 (-0.63, 0.5)	<0.001	<0.05

CCT: Central corneal thickness; Preop: Preoperative; Postop: Postoperative; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; D: Diopter; SE: Sphere equivalent. *P*1: Preop to 6mo postop; *P*2: 1 to 6mo postop.

The cap thickness ranged from 110 to 120 μm, with a cap diameter of 7.0 to 7.5 mm, and the lenticule diameter was established at 6.0 to 6.5 mm. At the end of the procedure, the lenticule was carefully extracted through a 2 mm incision located at the 11 o'clock position.

Postoperatively, patients were administered gatifloxacin eyedrops four times daily for 1wk. Additionally, fluorometholone (0.1% Santen, Japan) was gradually tapered from six times daily for a duration of one month.

Non-preserved artificial tears (carboxymethylcellulose sodium eye drops; Allergan, Irvine, California, USA) were employed to alleviate the discomfort associated with dry eye syndrome.

Statistical Analysis Statistical analysis was performed using SPSS software for Windows (version 25.0, IBM Corp., USA). Kolmogorov-Smirnov test was used to test for normality. Normally distributed data were presented as mean±standard deviation (SD) and range, skewed distributed data were presented as mean±SD, medium and interquartile range (IQR). Pared samples *t*-test was applied to analyze normally paired data. Wilcoxon signed-rank test was employed to analyze non-normally paired data. $P<0.05$ was considered statistically significant.

RESULTS

SMILE surgery was conducted on 82 eyes from 82 patients. The average optical zone size (OZ) of 6.27±0.22 mm, the mean lenticule thickness of 97.49±13.67 μm, the mean cap thickness of 118.9±3.1 μm, and the pre-planned RST was 288.62±5.68 μm. The mean value of percentage of tissue altered (PTA) was 42.8%. PTA was described as PTA=(cap thickness+lenticule thickness)/central cornea thickness[20]. The clinical parameters and biometric values of the patients were summarized in Table 1.

Safety and Efficacy At the last follow-up, the safety index was 1.20±0.13, and efficacy index was 1.14±0.15. The mean preoperative UDVA was 0.78±0.16 logMAR, and by the last follow-up, the mean postoperative UDVA had significantly improved to -0.07±0.06 ($P<0.001$). During the final follow-up examination of 82 eyes, UDVA was 20/20 or better in 80 eyes (98%), 20/25 or better in all 82 eyes (100%). UDVA was the same or better than CDVA in 78 eyes (95%). No patient had decreased CDVA, and 68 eyes (83%) gained one or more lines, 9 eyes (11%) gained two or more lines (Figure 1A-1C). All surgical procedures and postoperative follow-up were uneventful, and no significant complications, including keratoconus, infection, diffuse lamellar keratitis, or endophthalmitis, were observed.

Predictability and Stability The scatter plot illustrates the attempted versus achieved SE corrections (Figure 1D). At the final follow-up, 95% and 100% of the subjects had astigmatism within ±0.5 and ±1.0 D, respectively (Figure 1E). The mean SE significantly increased from preoperative -4.82±1.30 to -0.14±0.30 D at the last follow-up ($P<0.001$), and the refraction remained stable from 1 to 6mo (Figure 1F). Regarding the correction of astigmatism, all treated eyes exhibited postoperative astigmatism of less than 0.50 D (Figure 1G). The scatter plot of the TIA *vs* SIA vectors and the distribution of AE are shown in Figure 1H and 1I, respectively. Single-angle polar plots were performed for the TIA, SIA, DV and CI at 6mo postoperatively for 82 eyes with pre-planned RST of 280 to 300 μm following SMILE (Figure 2).

Curvatures and Posterior Elevation at the Thinnest Point of Cornea Table 2 provided a summary of the curvatures and PTE of cornea. The curvature of the anterior cornea's flat meridian (AK1) and the steep meridian (AK2) experienced a significant reduction post-surgery (both $P<0.001$), yet these measurements remained stable from 1 to 6mo following the procedure ($P=0.126$, 0.082). No significant variations were observed in the flat meridian curvature of the posterior cornea (PK1), steep meridian curvature of the posterior cornea (PK2), or PTE between preoperative and postoperative follow-up assessments.

DISCUSSION

This retrospective study demonstrated that SMILE was safe and effective for myopic patients when the pre-planned RST was between 280 to 300 μm. Among all patients, no evidence

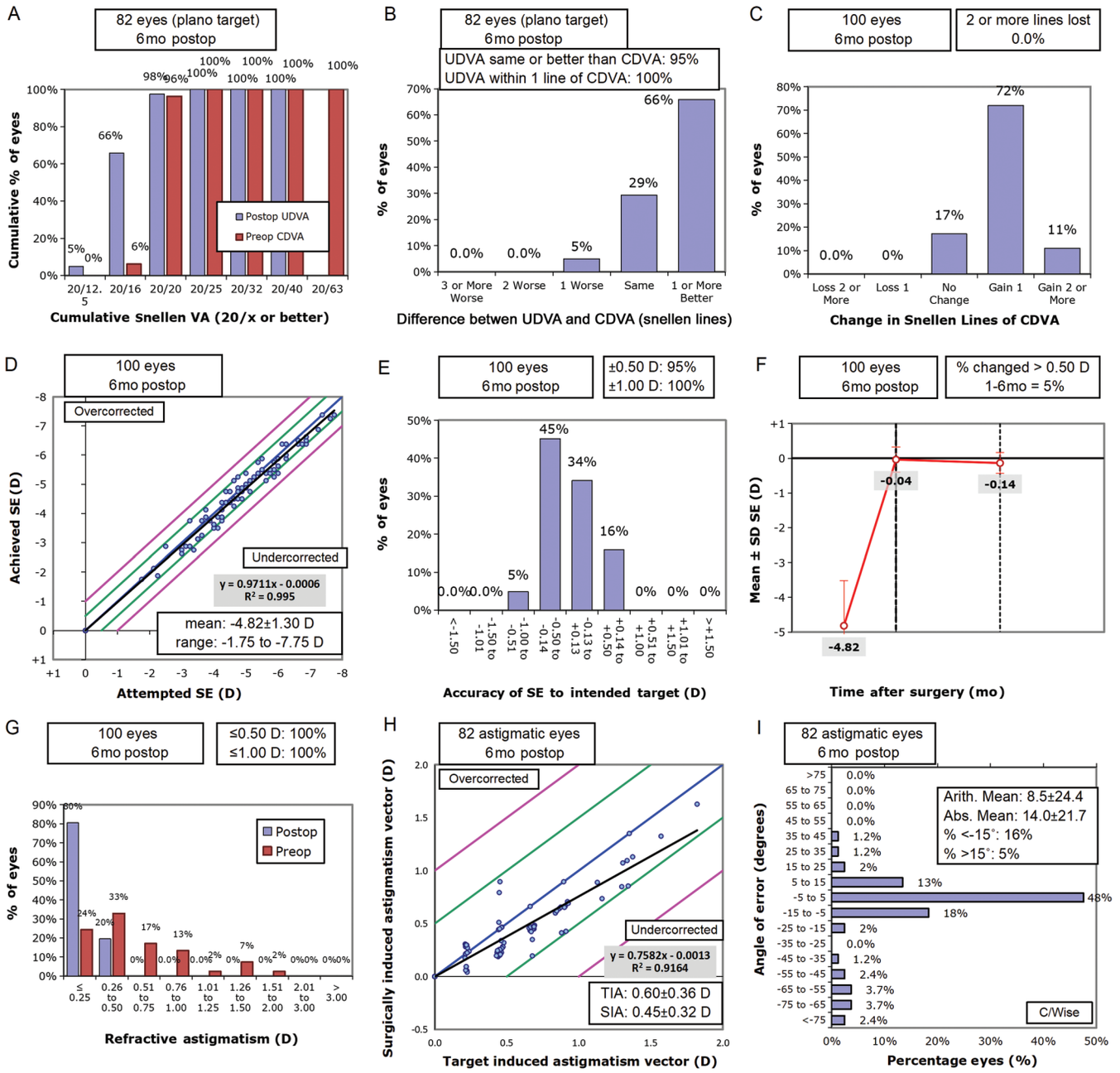

Figure 1 Visual outcomes at 6mo postoperatively for 82 eyes with pre-planned RST of 280 to 300 µm following SMILE A: UDVA; B: UDVA *vs* CDVA; C: Change in CDVA; D: SE refraction attempted *vs* achieved; E: SE refraction accuracy; F: SE refraction stability; G: Refractive astigmatism; H: Target induced astigmatism *vs* surgically induced astigmatism; I: Refractive astigmatism angle of error. RST: Residual stromal thickness; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; D: Diopters; Preop: Preoperative; Postop: Postoperative; SE: Spherical equivalent; TIA: Target induced astigmatism; SIA: Surgically induced astigmatism.

Table 2 Curvatures of cornea and posterior elevation at the thinnest point during the follow-ups mean±SD (min, max)

Parameters	Preoperative	1-month follow-up	6-months follow-up	*P* (Preop to 6mo postop)	*P* (1 to 6mo postop)
AK1 (D)	42.62±1.02 (40.2 to 44.7)	38.56±1.37 (35.0 to 40.9)	38.59±1.39 (35.0 to 40.9)	<0.001	0.126
AK2 (D)	43.55±1.14 (40.8 to 45.6)	39.18±1.46 (35.8 to 42.0)	39.22±1.50 (35.9 to 42.0)	<0.001	0.082
PK1 (D)	-6.10±0.19 (-6.6 to -5.7)	-6.08±0.19 (-6.6 to -5.4)	-6.10±0.17 (-6.5 to -5.7)	0.992	0.187
PK2 (D)	-6.43±0.20 (-6.9 to -6.0)	-6.42±0.19 (-6.9 to -6.0)	-6.42±0.19 (-6.8 to -6.0)	0.223	0.876
PTE (µm)	3.01±3.56 (-3 to 12)	2.62±4.04 (-6 to 12)	2.62±4.26 (-7 to 13)	0.168	0.897

AK1: Flat meridian curvature of anterior cornea; AK2: Steep meridian curvature of anterior cornea; PK1: Flat meridian curvature of posterior cornea; PK2: Steep meridian curvature of posterior cornea; PTE: Posterior elevation at the thinnest point of cornea; D: Diopter; Preop: Preoperative; Postop: Postoperative.

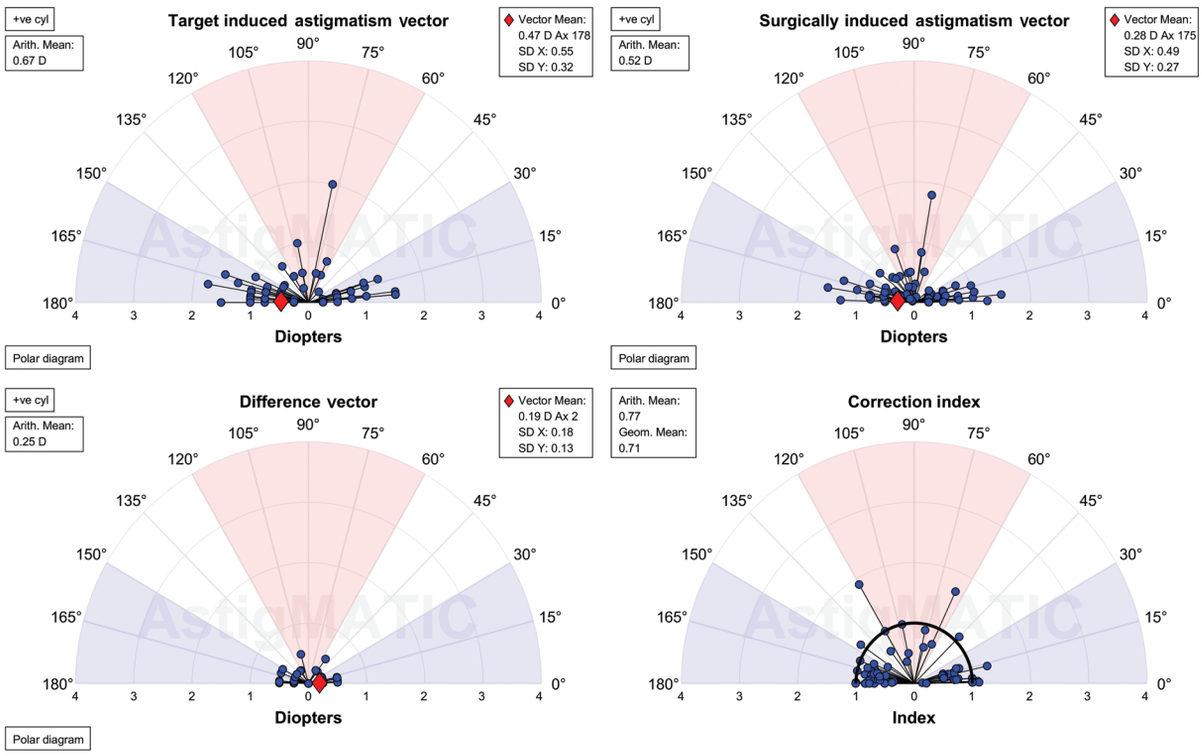

Figure 2 Single-angle polar plots for the TIA, SIA, DV and CI at 6mo postoperatively for 82 eyes with pre-planned RST of 280 to 300 μm following SMILE The vector means are plotted as a red diamond. TIA: Target induced astigmatism; SIA: Surgically induced astigmatism; DV: Difference vector; CI: Correction index; RST: Residual stromal thickness; SMILE: Small incision lenticule extraction.

of corneal ectasia was observed. The preoperative mean central corneal thickness (CCT) and pre-planned RST were recorded as 505.13±12.05 μm and 288.6±5.7 μm, respectively. No abnormalities were detected in the preoperative topographical analysis of any of our patients. At the final follow-up, a remarkable 95% of eyes undergoing SMILE achieved or surpassed their preoperative CDVA, without a single case reporting a decline of one or more lines of vision. Additionally, 95% of these eyes demonstrated SE of ≥-0.50 D, a notable improvement compared to the outcomes of the preceding two studies focused on SMILE[14,21]. This could potentially be linked to our rigorous preoperative evaluation and a comparatively brief follow-up duration.

Previous studies have indicated that thin preoperative CCT, elevated preoperative keratometry, high PTA, and low RST were all identified as risk factors contributing to the development of postoperative ectasia[15,20,22]. Only a limited number of studies have reported ectasia following SMILE surgery, several of which exhibited abnormal preoperative corneal topography and high keratometry readings prior to the procedure[15,23]. Eskina *et al*[24] evaluated the safety and efficacy of SMILE surgery performed on patients with CCT of less than 500 μm in 6mo follow-up period. The mean SE of their study was -4.75±1.93 D, which was comparable to our study's findings of -4.82±1.30 D. In 77% of eyes, a postoperative SE within -0.50 D was observed, whereas our study revealed this phenomenon in an increased proportion of 95% of eyes. We suspect that the reasons for this disparity stem from their thinner preoperative CCT of 488 μm and an advanced age of 31.47±7.21y, in contrast to the thicker CCT of 505.13±12.05 μm and younger age of 25.15±5.98y observed in our study. Moreover, in their study, the optic zone size was deliberately designed to measure 6.11±0.64 mm, whereas in our research, it was determined to be 6.27±0.22 mm. In another long-term research conducted by Kirmaci Kabakci *et al*[21], the myopic patients with thin cornea, who had undergone SMILE with a preoperative CCT of less than 500 μm, exhibited an efficacy index of 0.97±0.15 and a safety index of 1.07±0.15 at the two-year follow-up period. In 84% of eyes, the postoperative SE was found to be within the range of -0.50 D. In the current study, the efficacy index was 1.14±0.15, while the safety index was 1.20±0.13, with a postoperative SE within -0.50 D in 95% of the eyes under observation. These outcomes indicate a slight improvement. The difference may be attributed to their longer follow-up time. Utilizing the identical follow-up duration can potentially facilitate a more comprehensive explanation of the diverse refractive status that emerge subsequent to refractive surgery. Hence, it is imperative that we embark on a long-term observation program for continued observation.

Ambrósio *et al*[25] emphasized that a preoperative CCT of at least 484 μm was crucial to guarantee the safety of LASIK

surgery in patients with myopia exceeding -6 D. In our study, SE of 17 eyes exceeded -6 D, with a mean preoperative CCT of 513.6 μm, ranging from 504 to 520 μm. Six months subsequent to SMILE, the mean SE among all patients approximated -0.14 D, indicating a slight refractive regression when contrasted with the results recorded one-month post-SMILE (-0.04 D; P<0.05). Corneal curvature, CCT, posterior elevation at PTE, and corneal topography represent the most crucial and sensitive markers for diagnosing keratoconus. Currently, Pentacam stands as the most prevalent instrument for accurately and consistently measuring corneal curvature and posterior corneal elevation (PTE), renowned for its precision and reproducibility. Soundarya *et al*[15] reported the occurrence of bilateral ectasia subsequent to SMILE surgery in cases where preoperative keratometry measurements indicated steep corneas, with a maximum keratometry exceeding 49 D. In the current study, the preoperative steep corneal curvature was measured to be 43.55±1.14 D, with a range from 40.8 to 45.6 D. The anterior flat and steep corneal curvatures exhibited a statistically significant decrease after SMILE (both P<0.001), while no notable discrepancy was detected in the measurements taken between 1 and 6mo postoperatively. Furthermore, at no time point were there any alterations observed in the PTE, thereby demonstrating the excellent stability of the surgical procedure.

There are still a few limitations in the current study, particularly in terms of the modest sample size and the relatively brief follow-up duration. Consequently, further validation through studies with larger sample pools and multi-center collaborations is imperative.

In conclusion, the current study demonstrates that SMILE is safe and effective for myopic patients with a pre-planned RST of less than 300 μm, provided that surgical indications are rigorously adhered to and preoperative planning is conducted with meticulous care.

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