



Comparison of Predictability in Central Corneal Thickness Reduction After SMILE and FS-LASIK for High Myopia Correction

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ABSTRACT

Introduction: To compare central corneal thickness (CCT) reduction after small incision lenticule extraction (SMILE) and femtosecond laser-assisted in situ keratomileusis (FS-LASIK) in eyes with high myopia.

Methods: In this prospective, consecutive study, 70 eyes with high myopia undergoing SMILE ($n = 35$) or FS-LASIK ($n = 35$) were recruited. Corneal topography images were acquired using the Pentacam HR imaging

system preoperatively and at 1 day, 1 month, and 6 months postoperatively. Predicted CCT reduction was extracted directly from the Visu-Max femtosecond laser system or MEL 80 excimer laser platform. The achieved CCT reduction was determined using corneal thickness difference maps from the Pentacam. Comparative statistics and linear regression analyses were performed to evaluate the predictability in stromal thickness reduction.

Results: The mean predicted CCT reductions were $152.9 \pm 6.7 \mu\text{m}$ and $150.9 \pm 7.3 \mu\text{m}$ in the FS-LASIK and SMILE groups, respectively, with no statistical difference. For each follow-up time, no significant difference was noted in the two groups in the achieved CCT reduction. At 6-month follow-up, the CCT reductions were overestimated to be $23.06 \pm 6.97 \mu\text{m}$ and $28.29 \pm 13.92 \mu\text{m}$ in the SMILE and FS-LASIK groups, respectively ($P = 0.003$), showing statistical difference. Regression analysis revealed that the positive correlation between achieved and predicted CCT reductions was stronger in SMILE ($R^2 = 0.5065$, $P < 0.001$) than in FS-LASIK ($R^2 = 0.2237$, $P = 0.004$). Overestimated CCT reduction was not correlated with predicted CCT reduction in either group.

Conclusions: Systematically overestimated CCT reduction is found after SMILE and FS-LASIK in high myopia correction. Deviations between planned and achieved CCT reductions are more pronounced in FS-LASIK than in SMILE.

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Keywords: Corneal thickness reduction; SMILE; FS-LASIK; High myopia

Key Summary Points

Concerning postoperative stability and to minimize the risk of iatrogenic keratectasia, retaining the corneal residual bed thickness (RBT) to the best extent is always the priority concern for surgeons.

This study aimed to compare central corneal thickness (CCT) reduction after small incision lenticule extraction (SMILE) and femtosecond laser-assisted in situ keratomileusis (FS-LASIK) in eyes with high myopia.

Systematically overestimated CCT reduction is found after SMILE and FS-LASIK in high myopia correction. Deviations between planned and achieved CCT reductions are more pronounced in FS-LASIK than in SMILE.

Clinicians should assess the deviations in CCT reduction using different platforms when screening appropriate candidates for corneal laser surgery and when considering surgical design.

INTRODUCTION

As an efficient alternative treatment for myopia and myopic astigmatism, corneal refractive surgery relies on removing corneal tissue and reshaping anterior corneal surface to free patients from spectacles. Concerning postoperative stability and to minimize the risk of iatrogenic keratectasia, retaining the corneal residual bed thickness (RBT) to the best extent is always the priority concern for surgeons. In clinical practice, the generally accepted method to calculate central corneal thickness (CCT) reduction in surgery is using a formula based on correction of spherical equivalent (SE) and designed optical zone [1, 2]. RBT is subsequently

obtained by subtracting the predicted CCT reduction from the actual CCT. Therefore, accurate prediction of CCT reduction plays a significant role in surgical design and corneal stability [3].

The technique of femtosecond laser has gained an increasingly wide utilization in every profession and in the field of ophthalmology [4]. Recently, femtosecond laser-assisted in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE) have been widely performed. According to several previous studies, in SMILE, corneal reduction has been overestimated using the established formula [5, 6]. However, for FS-LASIK, estimation of corneal reduction has remained a controversial issue, partly because of the different excimer laser platforms used in previous studies [7–9].

High myopia correction requires more corneal removal, which leads to a significant decrease in corneal biomechanical properties, ultimately resulting in higher rate of corneal instability and iatrogenic keratectasia. This highlights significant importance in predicting postoperative RBT with accuracy in high myopia. The comparison of CCT reduction between SMILE and FS-LASIK has been assessed in several previous studies, including in patients with SE more than -9.0 diopters (D) [10–12].

In this study, we prospectively studied the data on CCT reduction and structural changes after SMILE and FS-LASIK for high myopia using an Scheimpflug camera and compared these two methods.

METHODS

Patients

Seventy eyes of 36 patients (11 male, 25 female) who underwent SMILE ($n = 35$) or FS-LASIK ($n = 35$) from April 2015 to April 2016 were recruited in this study. The inclusion criteria were as follows: presence of stable refraction at least 2 years prior to surgery, age > 18 years, sum of sphere and cylinder more than -9.00 D, and calculated RBT > 280 μm . The exclusion criteria were as follows: concurrent infections of the cornea; concomitant autoimmune diseases;

severe dry eye disease; a history of herpetic keratitis, cataract, glaucoma, or vitreoretinal disorders; and current pregnancy or lactation. All patients completed a standard preoperative ophthalmological assessment, including slit-lamp examination, uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) measurement, contrast sensitivity evaluation, wavefront aberration, Pentacam HR imaging, intraocular pressure assessment, and other examinations.

This study followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Fudan University Eye and ENT Hospital Review Board (Shanghai, China, ChiCTR1800017594). All patients signed an informed consent form in accordance with the tenets of the Declaration of Helsinki. Each patient freely selected one of the procedures after receiving a comprehensive explanation on the benefits and risks of both surgeries.

Surgical Techniques

Small Incision Lenticule Extraction

All SMILE procedures were completed by one experienced surgeon (XZ) using the VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Germany). The repetition rate and pulse energy were 500 kHz and 130 nJ, respectively. The intended cap diameter and thickness were 7.5 mm and 110 μm , respectively. The optical zone varied from 5.8 to 6.5 mm according to preoperative thinnest corneal thickness and corrected refractive error. Patients received topical anesthesia and then were positioned under the contact curve glass. After obtaining corneal centration, the surgeon initiated the suction and began femtosecond laser scanning. The whole scanning phase lasted for approximately half a minute, completing the creation of an intrastromal refractive lenticule and a small incision located at 90°. After the completion of laser scanning, the surgeon dissected the lenticule interface and extracted the lenticule manually with precaution.

Femtosecond Laser-Assisted In Situ Keratomileusis

First, corneal flaps, with a super-hinge length of 4.0 mm, located at 12 o'clock, were created using the VisuMax femtosecond laser system. Laser settings were similar to those of SMILE. Once the flap scanning was finished, it was manually lifted using a spatula and gently positioned in the upper cornea. Subsequently, stromal ablation was performed using the MEL 80 excimer laser (Carl Zeiss Meditec AG, Germany) system, with parameters programmed as 500 Hz repetition rate. The diameter and thickness of the flap were 7.5 mm and 110 μm , respectively. The optical zone varied from 5.75 to 6.25 due to the corneal thickness and refractive errors. Bandage soft contact lenses were placed to protect each eye for 1 day and removed at the following day. The same surgeon completed all the procedures uneventfully (XZ).

The postoperative medication regimen included the administration of topical levofloxacin (Santen Pharmaceutical, Osaka, Japan) four times per day for 1 week and then 0.1% fluorometholone eye drops (Santen Pharmaceutical, Osaka, Japan) from eight times to one time per day over 24 days in a sequential decreasing order. Lacrimal substitutes were also used four times per day from 1 to 3 months, as required.

Postoperative Follow-Up Examinations

Follow-up examinations were performed 1 day, 1 month, and 6 months postoperatively. No adverse event was developed through the follow-up periods. At each time, all eyes underwent the Pentacam HR imaging measurements and other routine examinations, such as slit-lamp evaluation and UDVA, CDVA, and intraocular pressure assessment. For the Pentacam imaging (Oculus GmbH, Wetzlar, Germany) system, only images emerged with "OK" in inspection window were accepted and recorded for further statistical analyses. If it was marked yellow or red, duplicated inspections were conducted until the images met the requirements.

Data Collection

Predicted CCT reduction was extracted directly from the VisuMax and MEL 80 excimer platforms. The achieved CCT reduction was determined using corneal thickness difference maps from Pentacam software: “Map A” and “Map B,” which represented the preoperative and postoperative maps, respectively [6, 9]. An “A – B” map displayed the difference in corneal thickness values at each coordinate, which was considered the corneal thickness reduction.

The topographic map displayed the corneal volume (CV) as the point (0, 0) in a 10-mm-diameter region, which was also selected as the location to determine the achieved CCT reduction. The mean K value at the corneal front surface (Kmf), mean K value at the corneal back surface (Kmb), and total corneal refractive power (TCRP) were extracted directly from Pentacam images.

Statistical Analyses

All statistical analyses were performed using IBM SPSS Statistics version 24.0 (SPSS Inc., Chicago, IL). Mean \pm standard deviation was used for quantitative variables. The Kolmogorov–Smirnov test was used to confirm data normality. Independent *t* tests were used to

compare general clinical variables and CCT reduction value. Pearson linear regression analysis was performed, and the coefficient of determination (R^2) was calculated to determine the correlation. Differences were considered statistically significant when the *P* value was less than 0.05.

RESULTS

The current prospective study included 70 eyes from 36 (11 male and 25 female) patients with SE more than -9.00 D. The average preoperative SEs for SMILE and FS-LASIK were -10.51 ± 0.93 D and -11.52 ± 1.20 D, respectively ($P < 0.001$). No statistical difference was observed in preoperative CCT between the two groups. Demographics and clinical characteristics of all patients are shown in Table 1.

Central Corneal Thickness Reduction

The change of CCT in both groups showed fluctuations after procedures: although CCT remained stable at 1 month postoperatively, it thickened slightly after 6 months (Fig. 1). The mean predicted CCT reductions were $152.9 \pm 6.7 \mu\text{m}$ and $150.9 \pm 7.3 \mu\text{m}$ in the FS-LASIK and SMILE groups, respectively, with no statistical difference (Table 2). At each

Table 1 Demographics and clinical characteristics of the patients at baseline

	SMILE	FS-LASIK	<i>P</i>
<i>n</i>	18 (35 eyes)	18 (35 eyes)	
Age (years)	30.0 ± 6.8	29.0 ± 7.1	0.400
Sex (M/F)	6/18	5/18	
Preoperative sphere (D)	-9.89 ± 1.03	-10.72 ± 1.42	0.008
Preoperative cylinder (D)	-1.24 ± 0.86	-1.59 ± 0.98	0.177
Preoperative manifest spherical equivalent (D)	-10.51 ± 0.93	-11.52 ± 1.20	< 0.001
Optical zone (mm)	6.1 ± 0.2	6.0 ± 0.2	0.004
CCT (μm)	555.4 ± 17.5	561.8 ± 18.6	0.149
Predicted CCT reduction (μm)	150.9 ± 7.3	152.9 ± 6.7	0.235

CCT central corneal thickness

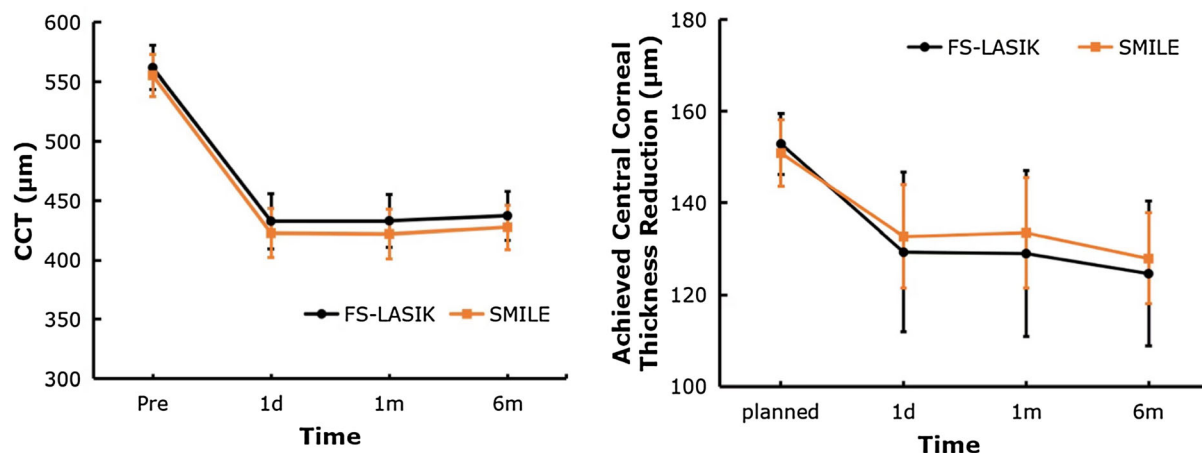


Fig. 1 Time course of central corneal thickness and reduction during the 6-month postoperative period

Table 2 Central corneal thickness and reduction before and after surgery

	Pre	1 day	1 month	6 months	Δ	P
CCT						
FS-LASIK	561.8 ± 18.6	432.6 ± 23.4	432.9 ± 22.1	437.2 ± 20.5	124.6 ± 15.8	0.617
SMILE	555.4 ± 17.5	422.6 ± 20.5	421.9 ± 20.9	427.5 ± 18.5	127.9 ± 9.9	0.445
P	0.149	0.076	0.037	0.042	0.309	
CCT reduction						
FS-LASIK	152.9 ± 6.7	129.3 ± 17.4	129.0 ± 18.1	124.6 ± 15.8	28.3 ± 13.9	0.451
SMILE	150.9 ± 7.3	132.7 ± 11.3	133.5 ± 12.1	127.9 ± 9.9	23.1 ± 7.0	0.077
P	0.235	0.324	0.225	0.309	0.003	

Δ: difference between preoperative and postoperative 6 months

postoperative follow-up time, no statistical difference was noted between SMILE and FS-LASIK in the achieved CCT reduction, with *P* values of 0.324 after 1 day, 0.225 after 1 month, and 0.309 after 6 months. CCT reductions were overestimated to be $23.06 \pm 6.97 \mu\text{m}$ and $28.29 \pm 13.92 \mu\text{m}$ in SMILE and FS-LASIK, respectively, at the final time point (*P* = 0.003).

Pearson regression analysis revealed that the achieved CCT reduction was slightly positively correlated with predicted CCT reduction in FS-LASIK ($R^2 = 0.2237$, *P* = 0.004). For SMILE, a stronger positive statistical correlation was also observed between these two parameters ($R^2 = 0.5065$, *P* < 0.001) (Fig. 2a). The

overestimated CCT reduction was not correlated with predicted CCT reduction in either group ($R^2 = 0.0032$, *P* = 0.977 in FS-LASIK; $R^2 = 0.001$, *P* = 0.858 in SMILE) (Fig. 2b).

Corneal Structural Topography

The Kmf and TCRP significantly decreased postoperatively. Compared to values at 1 day postoperatively, these two metrics exhibited small increasing trends (Fig. 3a, c). Different from the aforementioned metrics, the Kmb was stable from 1 day to 6 months after the surgery (Fig. 3b). No significant difference was observed throughout postsurgery follow-up time in CV in

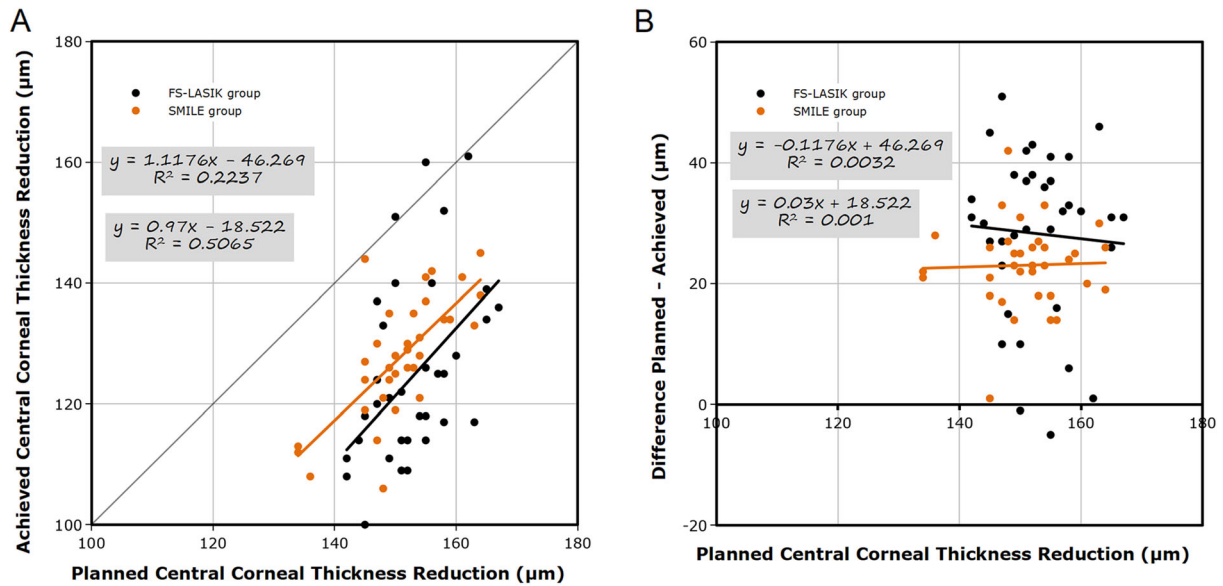


Fig. 2 Correlation between the achieved and planned central corneal thickness reductions

either group (Fig. 3d). Results at different follow-up time periods are summarized in Table 3.

DISCUSSION

In the current study, we investigated the change of CCT reduction after FS-LASIK and SMILE in high myopic eyes using the Pentacam imaging system and examined the association between predicted and measured CCT reduction for both groups.

First, CCT reduction was overestimated at approximately $23 \mu\text{m}$ 6 months after SMILE, which was concordant with the results of previous studies. According to several previous studies, CCT reductions could be overestimated at approximately $15\text{--}18 \mu\text{m}$ when examined by Pentacam imaging and approximately $13\text{--}24 \mu\text{m}$ by optical coherence tomography (OCT) after SMILE [6, 9, 12, 13]. Corneal remodeling pattern was hypothesized as an influencing factor causing the discrepancy between predicted and achieved CCT reductions. Available evidence reported that corneal epithelium and stroma started to remodel from 1 day postoperatively and ended at 3–6 months after SMILE [6, 7, 9]. To better explain the mechanism of corneal remodeling, Reinstein

et al. proposed that after SMILE, central corneal stroma could expand because the tension strength between the corneal cap and residual bed no longer existed [14]. This change in corneal biomechanical characteristics facilitated broken corneal lamellae plate recoil between the removed lenticule interface, leading to the posterior portion of the corneal cap being slightly away from the anterior part of the residual bed. Moreover, as attempted SE correction increased, more corneal stromal tissues were removed, and stronger corneal stromal expansion strength was observed. In a study evaluating the difference in CCT reduction after SMILE in various degrees of myopia, the deviations were $20.08 \pm 6.84 \mu\text{m}$ and $7.20 \pm 10.50 \mu\text{m}$ in the high and low myopia groups, respectively [13]. Notably, our study included eyes with myopia more than -9.0 D , and the deviation was larger than that of the former study, further supporting Reinstein et al.'s hypothesis.

In addition, although SMILE and FS-LASIK overestimated the CCT reduction in myopia more than -9.0 D , no statistical difference was noted among the two groups in different follow-up time periods. Furthermore, the deviation of difference in CCT reduction in FS-LASIK was slightly larger than that in SMILE ($28 \mu\text{m}$ vs.

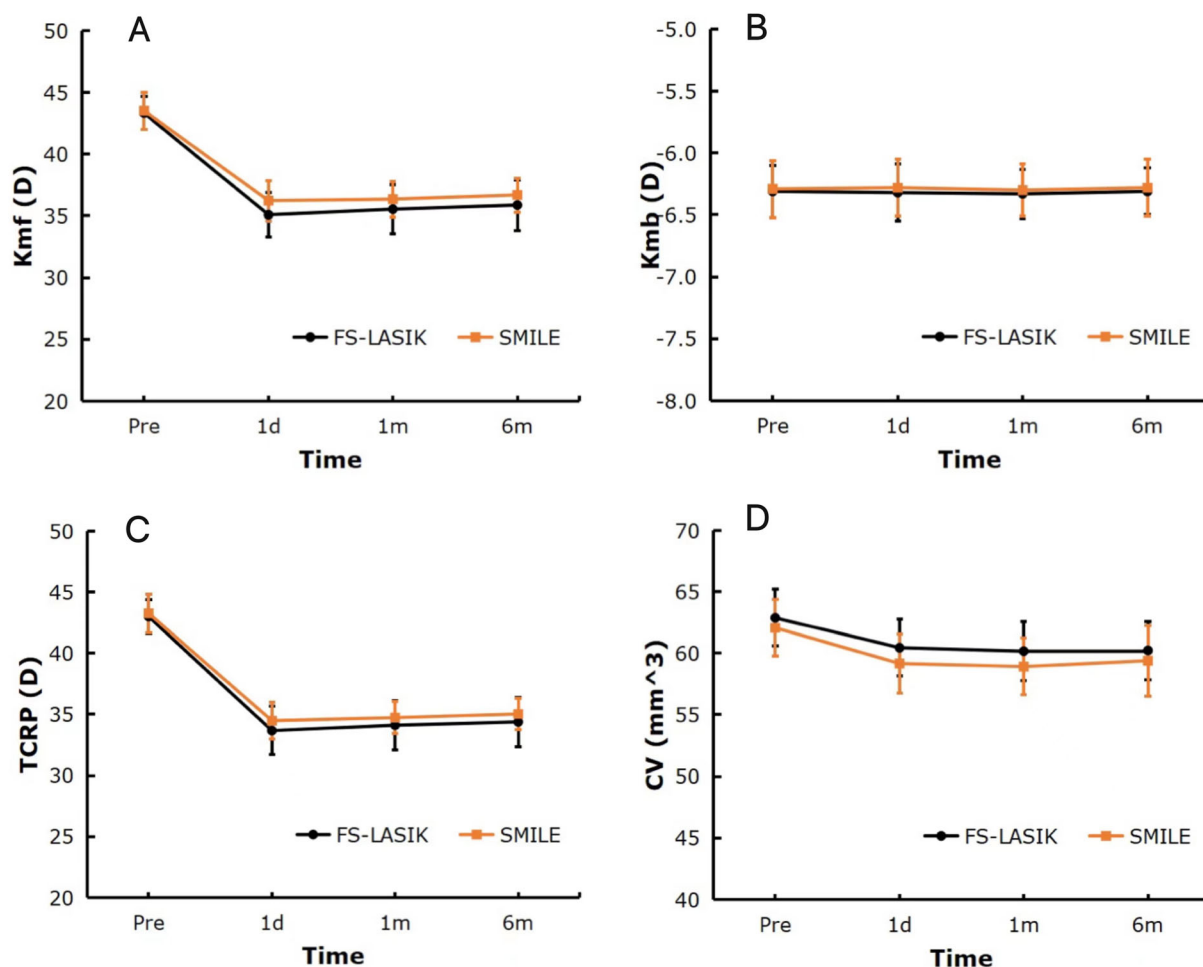


Fig. 3 Corneal front (a) and back (b) keratometric readings, total corneal refractive power (c), and corneal volume (d) before and after surgery

23 μm). Studies comparing deviations of CCT reduction between FS-LASIK and SMILE have inconsistent conclusions. Wu et al. evaluated the agreement between predicted and measured CCT reductions after SMILE and FS-LASIK. They concluded that both procedures overestimated CCT reduction, and that no statistical difference existed between the two procedures ($16.40 \pm 9.35 \mu\text{m}$ for FS-LASIK vs. $14.95 \pm 8.10 \mu\text{m}$ for SMILE) [13]. Lazaridis et al. proposed the higher deviation in CCT reduction after FS-LASIK compared to after SMILE (31 μm vs. 16 μm) [7]. Schuh et al.'s study showed comparable results with Lazaridis et al.'s study [10]. In Kim et al.'s study, the CCT reduction was $20.69 \pm 8.73 \mu\text{m}$ in the SMILE group, which

was higher than that in the FS-LASIK group, which was $8.37 \pm 7.70 \mu\text{m}$ [11]. Other studies comparing CCT reduction between these two procedures showed results in agreement with those of Kim et al., i.e., more overestimated CCT reduction was found after SMILE than after FS-LASIK [8, 9, 12]. Notably, the excimer laser platforms utilized in the aforementioned studies were different, including Amaris 750S [8, 9], EX500 [12], and MEL 80. Further analysis among these studies revealed that Amaris 750S and EX500 had less deviation than MEL 80, which had comparable deviation close to the VisuMax platform.

In the current study, the MEL 80 excimer laser system was applied for corneal ablation in

Table 3 Corneal curvature and volume before and after surgery

	Pre	1 day	1 month	6 months	Δ	<i>P</i>
Kmf						
FS-LASIK	43.34 ± 1.33	35.09 ± 1.79	35.54 ± 1.98	35.87 ± 2.07	7.47 ± 1.24	0.245
SMILE	43.54 ± 1.50	36.23 ± 1.62	36.35 ± 1.43	36.69 ± 1.38	6.85 ± 0.74	0.415
<i>P</i>	0.557	0.007*	0.057	0.057	0.014*	
Kmb						
FS-LASIK	− 6.31 ± 0.21	− 6.32 ± 0.23	− 6.33 ± 0.20	− 6.31 ± 0.19	0.01 ± 0.07	0.92
SMILE	− 6.29 ± 0.23	− 6.28 ± 0.23	− 6.30 ± 0.21	− 6.28 ± 0.23	0.00 ± 0.09	0.924
<i>P</i>	0.915	0.157	0.948	0.803	0.406	
TCRP						
FS-LASIK	42.98 ± 1.38	33.67 ± 1.97	34.11 ± 2.01	34.38 ± 2.01	8.59 ± 1.21	0.323
SMILE	43.27 ± 1.57	34.48 ± 1.48	34.73 ± 1.31	35.03 ± 1.27	8.24 ± 0.82	0.243
<i>P</i>	0.413	0.056	0.129	0.114	0.213	
CV						
FS-LASIK	62.88 ± 2.31	60.45 ± 2.30	60.17 ± 2.41	60.23 ± 2.37	2.64 ± 1.53	0.88
SMILE	62.07 ± 2.29	59.17 ± 2.41	58.92 ± 2.32	59.40 ± 2.88	2.67 ± 2.31	0.737
<i>P</i>	0.144	0.027*	0.030*	0.128	0.208	

Δ : difference among various follow-up time periods after the procedure

*Difference is significant at the 0.05 level

FS-LASIK, and the results indicated that after 6 months postoperatively, CCT reduction was overestimated at approximately 28 μm . A similar trend of overestimating CCT reduction using the identical excimer laser platform was also reported in previous studies. Supporting evidence has reported that the MEL 80 and MEL 90 excimer laser systems tend to overestimate CCT reduction at 8–31 μm [7, 10, 11]. Conversely, contradictory results were observed in investigating the consistency on other excimer laser systems, namely, the Allegretto 200 Hz, Visx Star S2, EX500, and Amaris 750S platforms [8, 9]. Researchers have proposed that these four excimer laser platforms may underestimate the actual corneal reduction [8, 9, 15]. Two main factors should be taken into consideration to analyze the causes: on the one hand, corneal hydration or dehydration affects the accuracy of

excimer laser cutting significantly; on the other hand, complex computational models can be influenced by uncertain factors, such as wavefront aberration and changes of cosine effect. To better achieve surgical efficacy, surgeons should determine the correlation between actual corneal and predicted reductions for different laser platforms [9].

The Pearson linear regression analysis showed that compared to FS-LASIK, SMILE facilitated a better agreement between planned and achieved CCT reductions for high myopia correction. The most reasonable explanation for this is possibly attributed to inherent advantages of SMILE, as an “all-in-one” procedure. Surgical myopia correction only utilizes a femtosecond laser system and can be accomplished in just one step. This avoids energy deficiency and corneal stromal dehydration in the

scanning phase, enhancing surgical accuracy and predictability. Moreover, the incidence of postoperative iatrogenic keratectasia has been reduced owing to the corneal free flap and the most anterior corneal stromal being left intact. However, with FS-LASIK, which requires two steps, consisting of femtosecond laser and excimer laser platforms, its accuracy in excimer laser cutting is vulnerable to interference from more confounding factors, such as humidity, temperature, and corneal hydration. With the increasing refraction correction, higher deviation in laser ablation is induced (especially in high myopia) [16]. Interestingly, no statistical association was observed in the deviation of CCT and planned CCT reductions. This was contrary to some earlier findings in which the discrepancy between the planned and achieved CCT reductions was positively correlated with the refractive correction in SMILE and FS-LASIK [9]. Different from these previous studies, including eyes with a wide range of myopia, we narrowed the study group with an SE from -9.0 to -12.00 D. Thus, the short range of planned CCT reduction in our group, between 140 and 160 μm , can account for these non-significant correlation results.

To state the changes in corneal morphology comprehensively, we compared the CV between these two procedures. It had been proposed that the amount of deviation between planned CCT and actual CCT reductions did not decrease the accuracy of SMILE and FS-LASIK [9]. CV, as an objective index, can represent corneal feature changes more efficiently than subjective manifest refraction. Although the CV in the two groups showed some statistical differences after 1 day and after 1 month postoperatively, no significant difference was found after 6 months. Consistent with our results, Schuh et al. reported statistical difference in a 10-mm-diameter region CV 3 months after LASIK and SMILE and no statistical difference after 12 months [10]. A possible explanation for this phenomenon is as follows: compared to FS-LASIK, SMILE induced more tissue ablation in the corneal periphery region, thus leading to greater alterations of CV at an early stage postoperatively [17].

The current study has some limitations. First, the sample size was relatively small, and both

eyes of each patient were included, which could affect the objectivity of the results. However, some studies have suggested that the results were not affected by including one or both eyes of the individuals [18]. Second, corneal thickness would continue to change after 6 months, which requires longer follow-up time of observations. Additionally, corneal epithelial thickness was not assessed in Pentacam, and our study only analyzed overall corneal thickness changes. It is worth noting that the measurement error in Pentacam (overestimation of CCT reduction following both SMILE and FS-LASIK compared with actual observations) should be taken into consideration, too. Using anterior segment OCT provides more detailed information on corneal thickness changes (e.g., cap, flap, epithelial, stromal, and whole corneal thickness) after corneal laser surgeries.

CONCLUSION

In the current study, systematically overestimated CCT reduction is observed after SMILE and FS-LASIK in high myopia correction. Deviations between planned CCT and achieved CCT reductions are more pronounced in FS-LASIK than in SMILE. Clinicians should assess the deviations in CCT reduction using different platforms when screening appropriate candidates for corneal laser surgery and when considering surgical design.

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Authorship. All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Author Contributions. Study concept and design (SL, YZ, XZ); data collection (SL, YZ); data analysis and interpretation (SL, YZ); drafting of the manuscript (SL, YZ); critical revision of the manuscript (SL, YZ, XZ); supervision (YZ, XZ). All authors read and approved the final manuscript.

Disclosures. Shengtao Liu, Xingtao Zhou, and Yu Zhao have nothing to disclose.

Compliance with Ethics Guidelines. This study was carried out in accordance with the recommendations of tenets of the Declaration of Helsinki with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The Ethics Committee of Fudan University Eye and the ENT Hospital Review Board (Shanghai, China) approved the study protocol. The registration number is ChiCTR1800017594.

Data Availability. The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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