Comparison of the posterior corneal elevation and biomechanics after SMILE and LASEK for myopia: a short- and long-term observation

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Abstract

Purpose This study compares the posterior corneal elevation and corneal biomechanics after small incision lenticule extraction (SMILE) and laser-assisted subepithelial keratomileusis (LASEK) for myopia correction in a short- and long-term observation. **Methods** This prospective study included 32 patients in the SMILE group and 32 patients in the LASEK group. Corneal posterior central elevation (PCE), posterior mean elevation (PME), corneal back power (Kb), and anterior chamber depth (ACD) were evaluated with Pentacam, and intraocular pressure (IOP), corneal hysteresis (CH), and corneal resistance factor (CRF) were evaluated with the ORA at pre-operation and 3 months and 3 years post-operation.

Results Three months post-operatively, CH, CRF, and IOP decreased significantly and central posterior surface shifted backward in both groups ($p < 0.05$). CH was lower in the LASEK group ($p = 0.03$) and change of CH and CRF per unit corneal tissue removed ($\Delta\text{CH}/\text{ablation depth (AD)}$ and $\Delta\text{CRF}/\text{AD}$) was lower in SMILE than in LASEK ($p = 0.01, 0.03$). Three years post-operatively, the PME shifted more posteriorly in LASEK ($p = 0.04$), but was stable in SMILE ($p = 0.06$). Kb flattened and ACD was shallower in both groups (compared to preoperative data, $p < 0.001$). CH in the LASEK group increased and is comparable to that in the SMILE group at 3 years post-operative.

Conclusion Both SMILE and LASEK can change the posterior surface and corneal biomechanics. SMILE may have less influence on corneal biomechanics than LASEK at an early stage post-operative in terms of per unit corneal tissue removed, but the effect became comparable in a long-term observation.

Keywords Small incision lenticule extraction · Laser-assisted subepithelial keratomileusis · Corneal posterior elevation · Corneal biomechanics

Introduction

Laser refractive surgery corrects a person's refractive error by removing a portion of cornea tissue. The cornea then becomes thinner and weaker and also increases the risk of iatrogenic

keratectasis [1]. Changes in posterior corneal elevation (PCE) as well as biomechanical parameters can represent the shape of the posterior cornea and provide an evaluation of the shape and corneal stability in the post-operative stage [2].

Laser-assisted subepithelial keratomileusis (LASEK) is a type of flapless refractive surgery. Studies have shown a mild but significant forward protrusion of the posterior cornea after FS-LASIK and PRK, but the protrusion was smaller in PRK than in LASIK [3]. However, a study using Pentacam (Oculus, Inc., Wetzlar, Germany) to evaluate the PCE found that there was no significant change after laser surface ablation [4]. As another flapless procedure, small incision lenticule extraction (SMILE) may have biomechanical benefits over FS-LASIK as it leaves the cap overlying the stroma intact. This hypothesis can be confirmed in that posterior corneal elevation change was greater after FS-LASIK than after SMILE [5]. Furthermore, another study demonstrated that PCE decreased over time in moderate and high myopia post-SMILE [6].

The first and second authors contributed equally to this work and should be considered as equal first authors.

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There has been a recent study which showed that change of corneal hysteresis (CH) was less in the early stage after SMILE than after LASEK [7]. However, the corneal biomechanical properties are largely unknown and very complex, and it changed slowly with years; therefore, it is more appropriate to predict the extent of corneal deformation from different aspects and in the long run [8]. In this prospective study, we aim to evaluate corneal structural and biomechanical characteristics in a long term after SMILE and LASEK, by comparing posterior corneal elevation changes and its related factors post-operation.

Patients and methods

Participants

In this prospective, non-randomized study, 64 patients who presented to the Eye and ENT Hospital of Fudan University (Shanghai, P.R. China) between January 2014 and April 2014 for laser refractive surgery were included. Thirty-two patients (32 eyes, 17 male and 15 female) underwent SMILE and 32 patients (32 eyes, 15 male and 17 female) underwent LASEK. Patient inclusion criteria include an age of 18 to 40 years old with a stable refractive error for at least 3 years prior (< -0.25 D change per year), and a minimum estimated residual bed thickness of 280 μm . Patients with a corrected distance visual acuity (CDVA) less than 20/25 or those with systemic or localized ocular disease were excluded.

The institutional review board of The Ethics Committee of the Eye and ENT Hospital approved this study prospectively. Written informed consent was obtained from all patients before surgery. All subjects were treated in accordance with the tenets of the Declaration of Helsinki.

Pre- and post-operative examination

All patients received a routine ophthalmologic examination at baseline, 3 months, and 3 years post-operation. Corneal tomography was performed using Rotating Scheimpflug imaging technology (Pentacam; Oculus, Wetzlar, Germany). Participants were instructed to keep both eyes wide open and look directly at the fixation target when measurements were taken. Data was accepted when the image quality was OK and had at least 10 mm of corneal coverage.

The Ocular Response Analyzer (ORA) (Reichert, Inc., Depew, NY) was used to measure the CH, corneal resistance factor (CRF), corneal compensated intraocular pressure (IOPcc), and Goldmann-correlated IOP (IOPg).

Data collection

The corneal posterior surface elevation data, corneal volume (CV), mean corneal back power (Kb), and anterior chamber depth (ACD) were collected from the Pentacam. The reference best-fit sphere (BFS) was defined from the central 8.0-mm region of the preoperative cornea, which was identical for both the preoperative and post-operative maps. The posterior central elevation (PCE) was set as the posterior elevation at the corneal apex above BFS, and posterior mean elevation (PME) was set as the average value of the posterior elevation above the BFS in the central 4-mm zone. The elevation data of 21 points within the central 4-mm zone were extracted from the Pentacam, and the positions of the points were as follows: the central point; 8 points at 1 mm distance and the other 12 points at 2 mm distance from the center [9]. The average PCE change (ΔPCE) and PME change (ΔPME) were obtained by subtracting preoperative data from post-operative data (difference map). Therefore, a positive number means an ectatic change of the posterior corneal surface, and a negative number means the posterior surface moved posteriorly. The ACD change (ΔACD) was calculated as $\Delta\text{ACD} = \text{ACD}_{\text{post}} - \text{ACD}_{\text{pre}}$, so did the calculation of the CV change and Kb change.

Surgical techniques

A VisuMax femtosecond laser system (Carl Zeiss Meditec, Jena, Germany) was used for SMILE treatments, with a repetition rate of 500 kHz and pulse energy of 130 nJ. The intended cap thickness was 120 μm , with the cap diameter of 7.5 mm, the lenticule diameter of 6.5 mm (no astigmatism) or 6.6 mm (with astigmatism). The refractive lenticule of the stromal corneal tissue was extracted using the surgical forceps through a side cut with a circumferential length of 2.1 mm located at the superior position.

In the LASEK group, a corneal epithelial flap was created with 20% ethanol-aqueous solution for 14 s and was then peeled back with a crescent blade (Model 52424A; 66vision Tech Co., Ltd., Suzhou, China), leaving a 4–6-mm-wide superior hinge. Corneal stromal tissue ablation was performed using the Mel 80 excimer laser (Carl Zeiss Meditec) over an optical diameter ranging from 6.25 to 6.75 mm, surrounded by a 1.5-mm transition zone. The laser parameters included a repetition rate of 250 kHz and pulse energy of 150 nJ. No patient was treated with mitomycin C since the myopia was mild to moderate. The epithelial flap was then repositioned and a bandage contact lens (ACUVE OASYS, Johnson & Johnson, Inc.) was inserted for 7 days.

A standard post-operative topical steroid (Fluorometholone 0.1%; Santen Pharmaceutical Co., Ltd.) tapered over 30 days for SMILE and 60 days for LASEK, topical antibiotic (Tobramycin 0.003%; Alcon Laboratories, Inc.) QID for

7 days, and Tears Naturale (hypromellose 2910, dextran 70, glycerol eye drops; Alcon Laboratories, Inc.) were given.

Statistical analysis

To have an 80% chance of detecting a 1.5- μm difference between SMILE and LASEK with 2- μm standard deviation (SD) in posterior elevation at the $p = 0.05$ level (two-sided), 28 cases were required. Considering the loss of following up, we recruited 32 patients in each group for the study. The data from the right eye of each patient was enrolled for statistical analysis. All statistical analyses were performed using SPSS 20.0 software (SPSS, Inc., Armonk, NY) and reported as mean $\pm$ SD. Kolmogorov-Smirnov normality test was used for all data. Student's t test was used to compare normally distributed data between SMILE and LASEK. The Mann-Whitney rank-sum test was used to analyze non-normally distributed data. Repeated measures ANOVA with Bonferroni post hoc correction was used to compare various parameters at different time points within the group. A p value < 0.05 was considered to indicate a statistically significant difference.

Results

All surgeries were uneventful and there was no specific intra-operative or post-operative complication during the study. All patients completed pre- and post-operative examinations. Pre-operative data were comparable between the two groups, which are summarized and presented as mean standard deviation in Table 1 in detail.

The visual acuity and spherical equivalence at 3 years post-operatively were comparable between the two groups (VA: SMILE (-0.10 ± 0.16) logMAR, LASEK (-0.11 ± 0.09) logMAR, $p = 0.24$; SE: SMILE (-0.30 ± 0.41) D, LASEK (-0.19 ± 0.40) D, $p = 0.73$).

Table 1 Patient demographic information. Data are given as mean $\pm$ standard deviation

	SMILE ($n = 32$)	LASEK ($n = 32$)	t/Z^a	p value
Age (y)	23.4 ± 4.6	25.7 ± 5.7	-1.80	0.08
Male:female	17:15	15:17	-0.50	0.62
SE (D)	-4.1 ± 0.8	-3.7 ± 1.0	-1.58	0.12
CCT (μm)	551.1 ± 23.1	538.3 ± 34.6	1.75	0.09
LT/AD (μm)	92.7 ± 11.7	76.8 ± 16.8	4.43	< 0.001

^a t , Student's t test; Z , Mann-Whitney test

SE spherical equivalent, CCT central corneal thickness, LT lenticule thickness, AD ablation depth

Corneal posterior shape and ACD

Three months post-operation, PCE decreased in the LASEK group ($p = 0.003$), and PCE in SMILE was higher than that in LASEK ($p = 0.04$) (Table 2). However, the ΔPCE after SMILE had no significant difference from LASEK ($p = 0.17$) (Supplementary Data 1). PME had no significant difference between the two groups ($p = 0.55$), but ΔPME in SMILE was greater than that in LASEK ($p = 0.04$). Three years post-operatively, PCE decreased in both groups ($p < 0.001$) and even smaller in the LASEK group ($p = 0.01$), while ΔPCE remained no difference between the two groups ($p = 0.06$), so did PME and ΔPME .

Table 2 Corneal posterior shape parameters and corneal biomechanics data

		SMILE ($n = 32$)	LASEK ($n = 32$)	p value
PME	pre	0.7 ± 0.9	1.0 ± 0.7	0.12
	po3m	1.0 ± 1.3	0.8 ± 1.2	0.55
	po3y	0.4 ± 1.9	0.1 ± 2.0	0.53
PCE	pre	2.4 ± 2.3	1.5 ± 2.1	0.12
	po3m	1.8 ± 3.0	0.3 ± 2.6	0.04^*
	po3y	0.0 ± 3.0	-2.0 ± 2.9	0.01^*
ACD	pre	3.27 ± 0.28	3.26 ± 0.24	0.89
	po3m	3.20 ± 0.29	3.16 ± 0.22	0.51
	po3y	3.16 ± 0.28	3.15 ± 0.23	0.96
CV	pre	61.8 ± 3.2	61.5 ± 3.0	0.61
	po3m	59.6 ± 3.3	59.8 ± 3.1	0.83
	po3y	59.3 ± 3.2	59.4 ± 3.2	0.91
Kb	pre	-6.22 ± 0.23	-6.24 ± 0.19	0.68
	po3m	-6.20 ± 0.22	-6.22 ± 0.21	0.68
	po3y	-6.17 ± 0.24	-6.18 ± 0.18	0.86
IOPcc	pre	17.4 ± 4.6	16.6 ± 2.5	0.39
	po3m	14.0 ± 2.4	15.4 ± 2.0	0.02^*
	po3y	12.5 ± 2.7	12.4 ± 1.4	0.78
IOPg	pre	17.3 ± 3.7	15.8 ± 3.0	0.09
	po3m	10.8 ± 1.9	11.4 ± 2.7	0.31
	po3y	10.9 ± 1.7	10.1 ± 1.8	0.09
CH	pre	10.5 ± 2.1	10.1 ± 1.3	0.36
	po3m	8.4 ± 1.3	7.8 ± 1.1	0.03^*
	po3y	8.7 ± 1.4	8.8 ± 1.5	0.89
CRF	pre	11.1 ± 1.7	10.2 ± 1.6	0.05
	po3m	7.4 ± 0.9	7.0 ± 1.5	0.22
	po3y	7.4 ± 1.1	7.2 ± 1.7	0.63

PME posterior mean elevation, PCE posterior central elevation, ACD anterior chamber depth, CV corneal volume, Kb corneal back power, IOPcc corneal compensated intraocular pressure, IOPg Goldmann-correlated intraocular pressure, CH corneal hysteresis, CRF corneal resistance factor

* $p < 0.05$ = significant difference

The corneal volume (CV) decreased after both treatments as expected ($p < 0.001$), but were not different between the two groups at each time point ($p > 0.5$) (Table 2), while the change of CV was greater in SMILE than in LASEK 3 months and 3 years post-operation ($p < 0.05$) (Supplementary Data 1).

The mean corneal back power had no difference between the two groups pre- and post-operatively (Table 2), and it was stable within 3 months post-operation. However, the posterior cornea flattened at the 3-year follow-up in both groups (SMILE: $p < 0.001$; LASEK: $p < 0.001$).

The ACD was shallower post 3 months in both groups (SMILE: $p = 0.009$, LASEK: $p < 0.001$), and remained until 3 years ($p < 0.001$). Δ ACD in SMILE was less than that in LASEK ($p = 0.03$) at 3 months, while it had no difference between the two groups at 3 years post-operatively (Supplementary Data 1).

The corneal biomechanical parameters

The post-operative IOPg, IOPcc, CH, and CRF were all lower than the preoperative values in both groups ($p < 0.01$) and CH and CRF were stable in the SMILE group from 3 months to 3 years post-operation. IOPcc was lower while CH was higher in SMILE than in the LASEK group 3 months post-operatively (IOPcc: $p = 0.02$; CH: $p = 0.03$). Three years post-operatively, IOPcc decreased while CH increased in the LASEK group (IOPcc: $p < 0.001$; CH: $p = 0.001$).

Standardized corneal biomechanics and posterior elevation data

Considering the lenticule thickness (LT) in SMILE is larger than ablation depth (AD) in LASEK, Δ PME/AD, Δ PCE/AD, Δ CH/AD, and Δ CRF/AD (meaning the change of parameters per 1- μ m corneal tissue removed) were calculated to rule out the effect of different amounts of cornea tissue removed on corneal biomechanics. As a result, Δ CH/AD and Δ CRF/AD were higher in SMILE than in LASEK 3 months post-operation ($p = 0.01$, $p = 0.03$), and Δ PCE/AD in SMILE overtook that in LASEK 3 years after treatment ($p = 0.01$) (Fig. 1).

Discussion

SMILE and LASEK are now commonly used for correcting myopia and astigmatism by removing the corneal tissue, and the two flapless procedures were proven to be safe and effective in previous studies [10, 11]. As the cornea becomes thinner and weaker, the corneal biomechanical stability has become the focus of attention for all surgeons. The change of the corneal posterior surface is of great assistance in predicting early corneal ectasia after ablation, as the posterior elevation is independent of the axis and orientation and not affected by

tear film [12, 13]. In the current study, PCE, PME, and related factors were analyzed to find out whether corneal posterior morphology was stable following SMILE and LASEK.

Previous studies have reported forward shifting of the posterior corneal surface after laser surface ablation for myopia using Orbscan [14, 15]. However, the Orbscan may misevaluate the post-operative posterior surface elevation [13, 16], while Pentacam can acquire accurate corneal posterior elevation and corneal thickness data [17], and the posterior corneal protrusion measured by Pentacam after laser refractive surgery was found to be lower than the measurements obtained using the Orbscan [18]. Ciolino et al. [2] found an average forward protrusion of $0.88 \pm 4.64 \mu\text{m}$ 2 months post PRK with a mean $53.2\text{-}\mu\text{m}$ ablation depth using Pentacam, indicating a greater protrusion of corneal posterior surface in their patients than ours. But considering the short follow-up period and the advancement in laser technology, this difference can be accepted. In 2009, Sun et al. [4] found the mean Δ PCE was $-0.47 \pm 4.23 \mu\text{m}$ following PRK and LASEK, which was lower than our results, and a mean Δ ACD of $0.06 \pm 0.08 \text{ mm}$, which was similar to our results. A long-term result also showed that the Δ PCE was $2.72 \pm 0.46 \mu\text{m}$ 1 year after PRK, a mild but significant forward protrusion [3], which was completely different from the current data.

SMILE is still a relatively new procedure and only a handful of studies have investigated the posterior corneal change after SMILE. Wang et al. [5] demonstrated that Δ PCE was $0.96 \pm 1.18 \mu\text{m}$ and $0.98 \pm 1.32 \mu\text{m}$ at 3 and 12 months post-operation, respectively, which is similar to the findings in this study. Furthermore, they found that Δ PCE was greater in FS-LASIK than in SMILE at 12 months. Zhao et al. [9] found that the PCE and PME were not significantly different after SMILE, regardless of the amount of myopia corrected. These are concurrent with our results, where Δ PCE and Δ PME were $0.69 \pm 3.18 \mu\text{m}$ and $-0.41 \pm 2.22 \mu\text{m}$ at 3 months and $3.30 \pm 3.74 \mu\text{m}$ and $1.25 \pm 3.01 \mu\text{m}$ at 1 year, respectively. In the follow-up study, they observed the similar results at 3 years post-operation [6].

In the current research, PCE decreased significantly 3 years post-operation in both groups, while it changed appreciably within 3 months only after LASEK, which was concordant with the flattened corneal back power and shallower ACD result, indicating that the corneal posterior surface became more flat and shift posteriorly 3 years post-operation. Previous studies have also reported the posterior shift of the cornea early in the post-operative period. The possible reason for this posterior shift may vary, namely, corneal swelling [19], the decrease of the IOP, or fibrotic wound healing after surgery, causing disordered morphology and deflection of the optical paths [20]. Another research in rabbits also reported that the posterior corneal surface shifted backward 3 months post SMILE, but the mechanism remained unclear [21]. The change had little clinical significance as it was so minute and within the manufacturer's reported range of error in the Pentacam ($\pm 5.0 \mu\text{m}$) [19]. Considering the LT in SMILE is larger than AD in LASEK, the

Fig. 1 Plotted with GraphPad Prism 6. Comparison of $\Delta\text{CH}/\text{AD}$ (a), $\Delta\text{CRF}/\text{AD}$ (b), $\Delta\text{PCE}/\text{AD}$ (c), and $\Delta\text{PME}/\text{AD}$ (d) 3 months (3mo) and 3 years (3yr) post-operation between the SMILE and LASEK groups. CH, corneal hysteresis; CRF, corneal resistance factor; PCE, posterior central elevation; PME, posterior mean elevation; AD, ablation depth. Δ = post-operative data – preoperative data

standardized $\Delta\text{PCE}/\text{AD}$ and $\Delta\text{PME}/\text{AD}$ were compared, showing that $\Delta\text{PCE}/\text{AD}$ in the SMILE group was smaller than that in LASEK 3 years post-operation, indicating that the posterior surface was not stable after LASEK as SMILE.

It may be easy to believe that ΔPCE or ΔPME was correlated with residual stromal thickness (RST) or AD, as Zhao et al. [9] reported that RST was correlated with ΔPCE in their high-myopia group post SMILE, while in the current study, neither ΔPCE nor ΔPME had a significant correlation with RST, which is in accordance with previous studies [4, 6, 21–23]. The contradiction may be caused by the different degrees of myopia corrected in surgery.

AD is not the only factor affecting the corneal posterior surface; corneal biomechanical characteristics, such as CH and CRF, can also influence the corneal posterior surface shape. In the current research, post-operative CH and CRF decreased in both groups, but ΔCH and ΔCRF had no significant difference between the two groups, similar with previous studies [7, 24]. However, the standardized CH and CRF, $\Delta\text{CH}/\text{AD}$, and $\Delta\text{CRF}/\text{AD}$ was smaller 3 months after SMILE than after LASEK, indicating that the decrease of corneal biomechanics per unit corneal tissue removed was less in SMILE than in LASEK at an early stage. In a long-term observation, SMILE and LASEK had similar influence on the corneal biomechanics given that $\Delta\text{CH}/\text{AD}$ and $\Delta\text{CRF}/\text{AD}$ had no difference between the two groups 3 years post procedure.

In conclusion, both SMILE and LASEK can change the posterior surface and corneal biomechanics. No subjects developed corneal ectasia during the 3-year follow-up period, suggesting that SMILE and LASEK were both safe procedures. The decrease in CRF and CH per unit of tissue removal

was less in the SMILE group than in the LASEK group at an early stage while similar in a long-term observation. In this regard, SMILE causes less biomechanical changes to the cornea at the beginning of corneal wound healing, which may be due to the preservation of corneal integrity and stiffer anterior stroma; while following years of recovery, the influence of the two procedures were comparable. Further investigations on the mechanisms of the biomechanical changes and wound healing, for example, light or electronic microscopy or molecular detection, are required.

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Compliance with ethical standards

The authors have full control of all primary data and we agree to allow Graefe's Archive for Clinical and Experimental Ophthalmology to review our data upon request. No author has a proprietary or commercial interest in the materials or methods mentioned here.

Conflict of interest The authors declare that they have no conflict of interests.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Disclaimer The sponsor or funding organization had no role in the design or conduct of this research.

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