



## Comparison of the change in posterior corneal elevation and corneal biomechanical parameters after small incision lenticule extraction and femtosecond laser-assisted LASIK for high myopia correction



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### ABSTRACT

**Purpose:** To compare posterior corneal elevation (PCE) changes and corneal biomechanical changes post femtosecond laser-assisted laser in situ keratomileusis (FS-LASIK) and small incision lenticule extraction (SMILE) procedures using the Pentacam system and the Ocular Response Analyzer (ORA).

**Design:** Retrospective observational case series study.

**Method:** 106 patients with bilateral myopia who underwent either FS-LASIK (56 patients) or SMILE (50 patients) were reviewed, only the right eye was used in the analysis. Inclusion criteria include a spherical equivalent of  $-6.00$ DS and completion of 12 months follow up. The main outcome evaluated was change in PCE at 3 months, 6 months and 12 months post-operation using the Pentacam system. Corneal biomechanical parameters were evaluated at 6 and 12 months with the ORA.

**Results:** PCE change at 3 and 6 months were not significantly different between the two procedures ( $p=0.064$ ,  $p=0.109$  respectively). At 12 months, PCE change was greater in FS-LASIK than SMILE ( $p=0.048$ ). One-way ANOVA showed that for either procedure, the change in PCE did not differ at 3, 6 or 12 months post operation. CH and CRF values were reduced after both procedures, with FS-LASIK demonstrating a greater reduction in CRF than SMILE at 6 and 12 months ( $p=0.037$  and  $p=0.001$ ). Both CH and CRF reduction correlated with PCE increase at 6 and 12 months.

**Conclusion:** FS-LASIK demonstrated a greater increase in PCE than SMILE only at 12 months, as well as a greater reduction of CRF than SMILE. There were no significant differences in PCE change over time within either group.

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Laser in situ keratomileusis (LASIK), in which a corneal flap was initially created by a mechanical microkeratome but is now being increasingly replaced by the femtosecond laser, has gained worldwide popularity for myopia correction. Although the clinical results are accordingly enhanced, postoperative complications, amongst which LASIK-inflicted ectasia is the foremost concern, still occur. As most complications are believed to be associated with the corneal flap, people have been engaging in developing a new procedure that could avoid the flap creation. Recently, small-incision lenticule extraction (SMILE) has been established as a

'flapless' procedure in which an intrastromal lenticule is cut by a femtosecond laser and manually extracted through a peripheral corneal tunnel incision [1,2]. The refractive predictability, safety, and patient satisfaction of SMILE are comparable to femtosecond laser-assisted LASIK (FS-LASIK) [3–5]. SMILE may also have biomechanical benefits over LASIK in that it leaves the stroma overlying the lenticule intact. However, corneal hysteresis and corneal resistance factor, which are two metrics used to describe the biomechanical properties of the cornea, have been shown to have no significant difference between SMILE and FS-LASIK treatments in postoperative values [6]. Because corneal biomechanical properties are largely unknown, it is not possible to theoretically predict the extent of the potential corneal deformation after refractive surgery [7]. Posterior corneal changes are of great assistance in predicting the response of the cornea to

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ablation, with posterior elevation being the most effective parameter in the diagnosis of ectatic disorder, as demonstrated by Mihaltz [8]. In this retrospective study, we aim to evaluate the corneal structural and biomechanical characteristics by comparing the changes in posterior corneal elevation (PCE) as well as corneal hysteresis (CH) and corneal resistance factor (CRF), after SMILE and FS-LASIK for high myopia correction, which is regarded as one of the risk factors for developing post-LASIK ectasia.

## 1. Patients and methods

### 1.1. Patients

The records of patients who were referred to the Shanghai Eye & ENT Hospital for myopia correction between January 2012 and January 2014, were reviewed. For the present study, only patients who received FS-LASIK or SMILE for their high myopia corrections (pre-operative spherical equivalent (SE) more than  $-6.00$  diopters (D)) and who completed 12 months of postoperative follow-up were included.

In all cases, data was collected from the first eye (right eye) on which the procedure was performed. There were 106 patients (106 eyes) meeting these criteria.

Of the 106 patients, 50 eyes underwent SMILE procedures (SMILE Group) while 56 eyes underwent FS-LASIK procedures (FS-LASIK Group). Minimum stromal residual bed thickness was  $250\ \mu\text{m}$  in both groups.

Spherical equivalent, intraocular pressure (IOP), central corneal thickness (CCT), and posterior corneal elevation (PCE) in all patients pre-operation and 12 months post operation were retrieved. IOP was determined by a non-contact toniometer (Topcon, Japan) and CCT and PCE were determined with a Pentacam system (Typ70700; Oculus; Wetzlar, Germany), which measures the anterior and posterior corneal surfaces using a rotating Scheimpflug camera. The Ocular Response Analyzer (ORA) (Reichert, Inc., Depew, NY) was used to measure the CH as well as CRF. An average of 4 measurements was used. Residual bed thickness (RBT) was estimated using the thinnest CCT reading and subtracting the non-nomogram-adjusted ablation depth and the flap thickness of  $95\ \mu\text{m}$  in FS-LASIK or the cap thickness of  $100\text{--}120\ \mu\text{m}$  in SMILE. Changes in PCE was obtained from the difference map and was determined by subtracting the postoperative elevation data from the preoperative elevation data based on the maximum difference in the central  $4.0\ \text{mm}$  zone. The reference best-fit sphere (BFS) was determined by the central  $8.0\ \text{mm}$  zone of

**Table 1**

Clinical characteristics of the patients included in this study.

	Mean $\pm$ standard deviation		
	SMILE (n = 50)	FS-LASIK (n = 56)	P Value
Age (y)	25.26 $\pm$ 6.64	24.75 $\pm$ 6.24	0.684
Gender(F/M)	27/23	30/26	0.157
Preop SE(D)	$-7.60 \pm 1.12$	$-7.68 \pm 1.19$	0.713
Preop CCT( $\mu\text{m}$ )	542.96 $\pm$ 23.34	548.00 $\pm$ 23.97	0.276
Preop IOP(mmHg)	14.68 $\pm$ 2.65	14.94 $\pm$ 2.36	0.609

SE = spherical equivalent, CCT = central corneal thickness, IOP = intraocular pressure.

the preoperative cornea, which was identical for both the preoperative and postoperative maps.

### 1.2. Surgical procedures

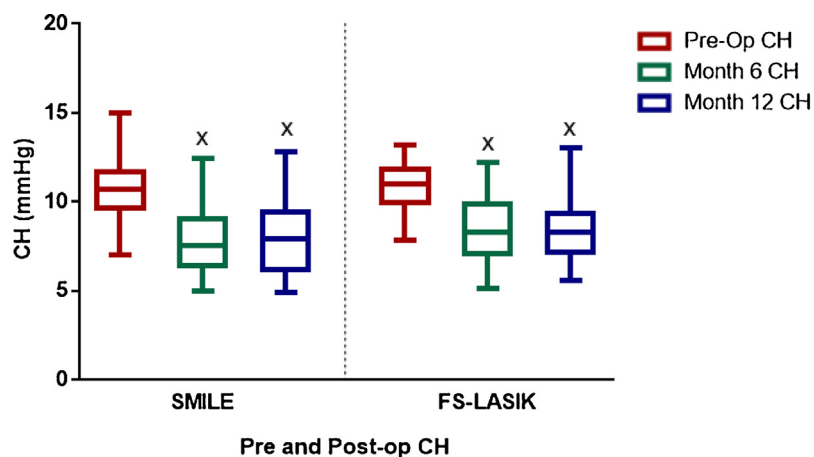
SMILE was performed using the VisuMax femtosecond laser system (Carl Zeiss Meditec) with a repetition rate of  $500\ \text{kHz}$ , pulse energy of  $185\text{--}190\ \text{nj}$ , intended cap thickness of  $100\text{--}120\ \mu\text{m}$ , cap diameter of  $7.5\ \text{mm}$ , lenticule diameter of  $6.1\ \text{to}\ 6.6\ \text{mm}$  (depending on the refractive error), and a  $90^\circ$ -angle side cut with a circumferential length of  $2.1\ \text{mm}$  at the superior position.

FS-LASIK was performed with the VisuMax system for flap creation followed by Mel 80 excimer laser (Carl Zeiss Meditec) for stromal ablation, with an intended flap thickness of  $95\ \mu\text{m}$ , optical zone size of  $5.75\text{--}6.50\ \text{mm}$  and pulse energy of  $185\ \text{nj}$ . The hinge was located at the superior position. All procedures were performed by one surgeon experienced in both types of procedures. (H.Z).

A standard postoperative topical steroid (Fluometholone 0.1%) tapered over 30 days (or longer if deemed necessary), and topical antibiotic (Tobramycin 0.003%) QID for 7 days was given.

### 1.3. Statistical analysis

All statistical analyses were performed with a statistics program (SPSS 19.0 IBM Corp., Armonk, NY, USA). Independent-samples *t*-test was used to compare the differences between groups. One way repeated measures ANOVA test with the Bonferroni correction was used to compare PCE, CH and CRF change within groups at different postoperative time points. Pearson's correlation test was used to evaluate the relationship between variables.  $p < 0.05$  was considered significant.



**Fig. 1.** Pre and Postop Corneal Hysteresis between SMILE and FS-LASIK. "x" statistically significantly less than preop values.

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