

Long term changes of posterior corneal elevation after myopic laser *in situ* keratomileusis

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Background: Corneal ectasia is a serious complication after laser *in situ* keratomileusis (LASIK). Ideally, patients at risk of ectasia should be identified prior to laser as unsuitable for LASIK, however, at present, there is no absolute test, system, or marker that can unequivocally identify patients at risk of developing ectasia. It has been suggested that changes in the forward protrusion of the posterior cornea or posterior corneal elevation (PCE) may be a key to the early detection of ectasia after LASIK. The purpose of this study was to examine the long term changes of the PCE after myopic LASIK using the ORBSCAN[®] Iiz (Bausch & Lomb, Rochester, USA) and to evaluate the contributory preoperative factors to PCE changes.

Methods: This was a retrospective longitudinal case series. Forty-two eyes of 23 consecutive myopic patients who underwent uneventful LASIK surgery 6 years ago were recalled for a postoperative follow-up examination using the ORBSCAN[®] Iiz to determine the elevation changes to the posterior corneal surface from the preoperative measurements. A forward shift of the posterior surface was given a negative value. Correlation analyses and forward stepwise regression analyses were performed to evaluate the effect of each of the preoperative parameters on the changes in PCE. Statistical and graphical analyses were performed.

Results: There was no statistical difference between the mean best-fit sphere (BFS) pre-LASIK and 6 years postop ($P=0.25$). Forty-two post-LASIK eyes had a mean posterior displacement of $-9.38\pm 9.84\ \mu\text{m}$ (range, 12 to $-31\ \mu\text{m}$) 6 years after LASIK. Forward stepwise multiple linear regression analysis indicated that the ablation spherical equivalent (ASE) was the only indicator of the forward shift of the posterior cornea after LASIK.

Conclusions: The present study identified a significant forward shift of the posterior cornea 6 years after LASIK. The ASE was the most significant prognostic determinant for forward protrusion of the posterior cornea after LASIK.

Keywords: Posterior corneal elevation (PCE); myopia; laser *in situ* keratomileusis (LASIK); cornea

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Introduction

Laser *in situ* keratomileusis (LASIK) has been a well-recognized procedure for the correction of myopia. However, LASIK can weaken the underlying stroma and may lead to an increased risk for postoperative keratectasia

(1-3). Corneal ectasia is a serious complication after LASIK, resulting in an increase in myopia and astigmatism and the loss of visual acuity due to progressive corneal steepening. The onset of ectasia may be early or delayed of up to more than a year after surgery (2-5). The incidence of keratectasia

Table 1 Characteristics of subjects who attended in comparison to those who were unavailable for the long term postoperative examination

Parameters	Attended (42 eyes)	Unavailable (177 eyes)	P
Age (years)	29.43±6.32	27.19±6.52	0.14
Gender (M:F)	12:11	42:51	0.55
Pre-SE (DS)	-5.37±2.81	-5.05±2.09	0.49
CCT (µm)	545.81±31.71	542.18±35.99	0.55
Pre-PCE (µm)	29.19±6.82	30.08±7.72	0.49
Pre-IOP (mmHg)	15.94±2.50	16.06±2.52	0.78

pre-SE, preoperative spherical equivalent; CCT, central corneal thickness; pre-PCE, preoperative posterior corneal elevation; pre-IOP, preoperative intraocular pressure

after myopic LASIK has been estimated to be 0.04% to 0.6% (2,3,6).

Although posterior corneal elevation (PCE) change consistent with progressive ectasia may be observed as early as 4 to 6 weeks after LASIK, post-LASIK ectasia is usually diagnosed 13 months after surgery (5). Martin *et al.* reported a PCE trend that increased in the first month after LASIK and reduced with time, without any significant differences 1 year after LASIK (7). Few other studies have described the PCE more than 1 year after LASIK, with the longest reported follow-up period of 18 months (8). Longer term results are important, as keratectasia can occur 6 to 20 months after LASIK (1,4,5).

The purpose of this study was to examine the long term changes (6 years postop) of the PCE after myopic LASIK using the ORBSCAN® IIz and to evaluate the contributory preoperative factors to PCE changes.

Methods

This was a retrospective longitudinal case series. Written informed consent was obtained from each participant. The study adhered to the tenets of Declaration of Helsinki, and was approved by the Institutional Review Board of the Joint Shantou International Eye Center (JSIEC). The inclusion criteria were: (I) myopia of ≥ -1.00 DS before LASIK; (II) no contraindications to LASIK (such as Forme Fruste Keratoconus, dry eyes); (III) uneventful LASIK procedures; (IV) a minimum postoperative follow up of 6 years.

One hundred and sixteen consecutive subjects were recalled by phone for a postoperative examination in 2012.

Twenty-three subjects with a total of 42 eyes returned for the visit, while 93 subjects (177 eyes) failed to attend.

There were no marked differences between subjects who attended and those who were unavailable for the follow-up examination with respect to age, gender, preoperative SE, central corneal thickness (CCT), preoperative PCE & preoperative intraocular pressure (IOP) (Table 1).

All LASIK procedures were performed with the Technolas217z100 laser (Bausch & Lomb, Rochester, USA) by four trained ophthalmologists at the JSIEC. All the surgeons adopted the same standard procedure, consisting of the application of a narrow beam, flying-spot excimer laser with eye tracking assistance (Technolas217z100, Bausch & Lomb, USA). The Technolas217z100 laser has an emission wavelength of 193 nm, a fixed pulse repetition rate of 50 Hz and a radiance exposure of 120 mJ/cm². Suction rings of 8.5 or 9.0 mm in diameter were used and LASIK flaps were cut by the Hansatome Microkeratome (Bausch & Lomb, Rochester, USA) with a target thickness of 160 µm.

ORBSCAN® IIz (Bausch & Lomb, Rochester, USA, version 3.12) was used to image the corneas of all the patients preoperatively, 1-month postop and at the 6-year follow-up visits. The system and software were identical. The changes of the posterior corneal surface were determined by the ORBSCAN® IIz posterior best-fit sphere (BFS). The PCE was defined as the value relative to the BFS of a single map and was used to compare the pre-operative and post-operative posterior corneal surface changes (9).

The difference in elevation was considered to be the displacement of the posterior corneal surface. Changes in the posterior surface were determined by subtracting the postoperative elevation data from the preoperative data based on the maximal differences. A forward shift of the posterior surface would result in a negative number.

Corneal thickness was measured by the IOPac® advanced ultrasonic pachymetry (Heidelberg Engineering, Germany), with the lowest CCT reading taken to be the thinnest part of the cornea.

Residual bed thickness (RBT) was calculated by using the thinnest CCT reading and subtracting the non-nomogram-adjusted ablation depth and the flap thickness of 160 mm.

Statistical analysis

All analyses were performed using statistical software (StatLab, SPSS for windows, version 13.0; SPSS, Inc., Chicago, Illinois, USA). Paired-sample t test was used

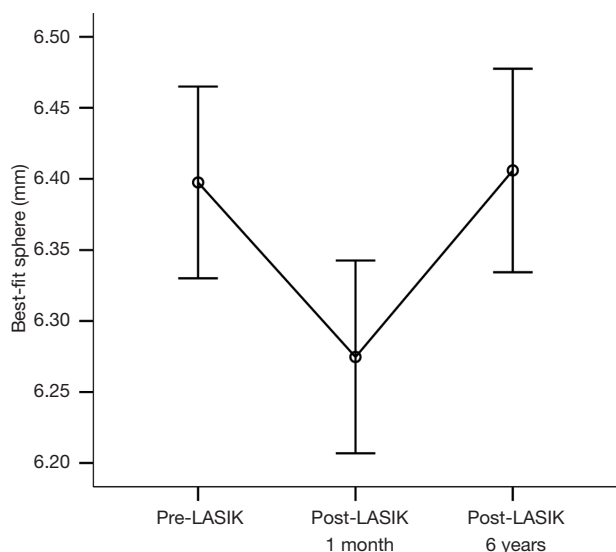


Figure 1 Best-fit sphere evolution at each visit of 32 eyes. Bars represent the 95% confidence interval.

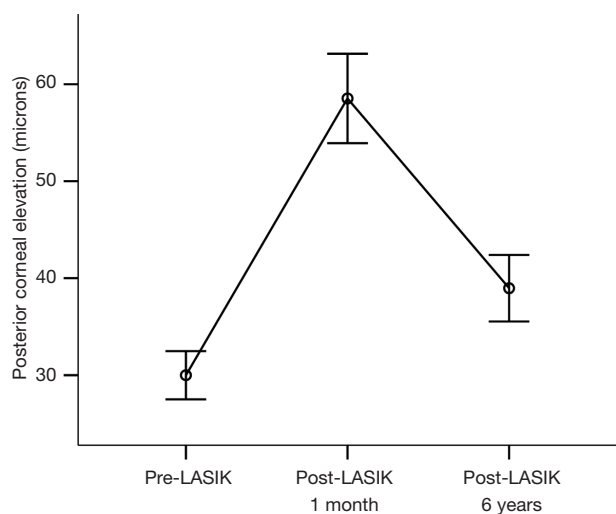


Figure 2 Posterior corneal elevation evolution at each visit of 32 eyes. Bars represent the 95% confidence interval.

for the analysis of PCE and BFS. Pearson correlation analysis was used to assess the effect of each of preoperative parameters on PCE changes. Stepwise forward multivariate linear regression analyses were used to evaluate the contributory preoperative factors to PCE changes. All continuous variables are presented as mean ± standard deviation. A P value of <0.05 was considered as statistically significant.

Table 2 Data at the time of the preoperative examination (n=42 eyes)

Value	Mean ± SD	Median	Range
ASE (D)	-5.70±2.78	-5.15	-2.00 to -12.25
CCT (µm)	545.81±31.71	539.00	498.00 to 655.00
Ablation depth (µm)	104.02±31.18	104.00	48.00 to 168.00
RBT (µm)	281.83±37.03	268.00	245.00 to 384.00

ASE, ablation spherical equivalent; CCT, central corneal thickness; RBT, residual bed thickness.

Results

In 42 eyes, only 32 eyes had 1month postoperative data. The posterior BFS of the 32 eyes for the preoperative, 1-month and 6-year visits were as follows (*Figure 1*): 6.40±0.19 mm (range, 6.09–6.70 mm); 6.27±0.19 mm (range, 5.95–6.74 mm) and 6.41±0.20 mm (range, 6.07–6.68 mm) respectively. The mean differences between the BFS pre-LASIK and 1 month postop were found to be statistically significant (P<0.01). However, there was no statistical difference between the mean BFS pre-LASIK and 6 years postop (P=0.25).

There were statistically significant differences identified in the PCE (P<0.01) between the pre-LASIK, 1-month and 6-year postop visits: at 30.00±6.90 µm (range, 10–45 µm), 58.53±12.79 µm (range, 35–85 µm) and 38.97±9.50 µm (range, 18–60 µm) respectively. *Figure 2* illustrates the PCE evolution of the 32 eyes over the course of time.

Forty-two eyes were examined with the ORBSCAN® IIz for the study. The M:F ratio was 12:11. Four patients had LASIK performed in 1 eye only. The mean age was 29.43±6.32 years (range, 18–39 years). Data at the time of the preoperative examination were showed in *Table 2*.

The minimum RBT was set at 250 µm, but 1 patient in the study ended up with a computed residual thickness of 245 µm. The posterior BFS of the 42 eyes changed from 6.39±0.21 mm (range, 6.09–6.90 mm) before surgery to 6.39±0.23 mm (range, 6.00–6.91 mm) at 6 years postop. The differences were not statistically significant (P=0.64).

The mean PCE in the 42 eyes was 29.19±6.82 µm (10–45 µm) before LASIK and 38.57±9.10 µm (range, 18–60 µm) 6 years after LASIK. The difference was statistically significant (P<0.01). The mean change in PCE 6 years after LASIK was -9.38±9.84 µm (range, 12 to -31 µm).

Pearson correlation analysis for PCE change at 6 years

Table 3 Correlation analysis and stepwise forward regression analysis for preoperative factors on the posterior corneal elevation (PCE) changes 6 years after LASIK

Covariate (preoperative factors)	Pearson correlation analysis		Stepwise forward regression analysis*	
	r	P value	Standardized β	P value
ASE	-0.499	0.001	-0.429	0.005
RBT	0.349	0.024		
pre-SE	-0.493	0.001		
CAD	-0.407	0.007		
IOP	-0.089	0.577		
CCT	-0.014	0.927		

*, adjusted R^2 (the coefficient of multiple determination) =0.184. ASE, ablation spherical equivalent; RBT, residual bed thickness; pre-SE, preoperative spherical equivalent; CAD, central ablation depth; IOP, intraocular pressure; CCT, central corneal thickness; r, Pearson correlation coefficient; β , regression coefficient.

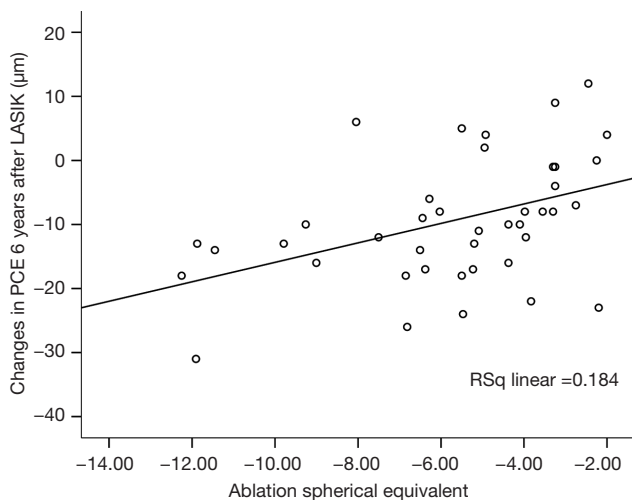


Figure 3 Scatterplot diagram showing the correlation between the ablation spherical equivalent and the posterior corneal elevation changes at 6 years postop. Ablation spherical equivalent values were positively correlated with the PCE changes, suggesting that higher ablation spherical equivalent values were associated with a greater forward shift of posterior corneal elevation. PCE, posterior corneal elevation.

after LASIK is illustrated in *Table 3*.

The preoperative parameters included preoperative SE, ASE, central ablation depth, CCT, IOP and RBT. The

RBT, preoperative SE and ASE were positively correlated with the PCE changes and the central ablation depth was negatively correlated with the PCE changes at 6 years postop. Forward stepwise regression analysis revealed that the ASE was the only contributory preoperative factor ($P=0.005$), suggesting that higher ASE values were associated with a greater forward shift of the PCE (*Figure 3*).

Discussion

Reported risk factors for post LASIK corneal ectasia include high myopia, low residual stromal bed thickness, topographical abnormality such as Forme Fruste Keratoconus, and multiple LASIK procedures (4). Ideally, patients at risk of ectasia should be identified prior to laser as unsuitable for LASIK; however, at present, there is no absolute test, system, or marker that can unequivocally identify patients at risk of developing ectasia. It has been suggested that changes in the forward protrusion of the posterior cornea or PCE may be a key to the early detection of ectasia after LASIK (7). Another advantage of focusing on the posterior surface of the cornea is that the PCE map is not influenced by tear film irregularities or the use of artificial tears (10).

Based on the results identified from the three visits of the 32 eyes, we noted a trend towards PCE that increased in the first month after LASIK and reduced with time, with significant differences present even at 6 years post LASIK. The exact magnitude of displacement predisposing to ectatic changes is however not known. The posterior corneal displacement in the 42 eyes found in this study was $-9.38 \pm 9.84 \mu\text{m}$ (range, +12 to $-31 \mu\text{m}$), which was similar to previously reported studies with the Orbscan (8-14) (*Table 4*). Nobody included in the study had serious corneal ectasia or keratoconus. It suggests that the average elevation change observed here at 6 years means good corneal stability.

Martin *et al.* (7) described that an estimated RBT greater than $300 \mu\text{m}$ will be free from any significant posterior forward shift ($P=0.05$ and $R^2=0.002$, $P<0.86$). Patients with an estimated RBT less than $300 \mu\text{m}$ had a significant posterior forward shift in the first month after LASIK ($P<0.05$), but this difference was not significant at 1 year after surgery ($P>0.05$). Although the RBT has been shown to influence the PCE (14,15), it was not significantly associated with the PCE changes in our long term follow up study. In our study, the mean RBT was $281.83 \pm 37.03 \mu\text{m}$ (range, 245–384 μm), and multivariate linear regression

Table 4 Results of studies evaluating the changes in posterior corneal elevation post LASIK

Study/year published	No. of eyes	Instrument	Follow-up (months)	Posterior corneal forward displacement (µm)	
				Mean ± SD	Range
Baek (11)/2001	196	Orbscan I	1	-40.9±24.8	-25 to -118
Miyata (12)/2004	164	Orbscan II	1	-46.4±27.9	8 to -132
Twa (14)/2005	1,124	Orbscan I	6	-11.1±9.4	-2 to -35
Ciolino (9)/2006	121	Pentacam	1	-2.6±5.0	12 to -14
Ciolino (13)/2007	102	Pentacam	14	-0.5±4.8	7 to -10
Grewal (8)/2011	30	Pentacam	18	-5.8±4.2	12 to -5
Martin (7)/2012	86	Orbscan II	1	-9.4±14.3	80 to -27
Martin (7)/2012	86	Orbscan II	6	-4.0±9.8	24 to -34
Martin (7)/2012	86	Orbscan II	12	-3.1±8.8	21 to -37
Present/2013	42	Orbscan IIz	84	-9.4±9.8	12 to -31

analyses revealed that the ASE was the only indicator of the forward shift of the posterior cornea after LASIK (P=0.001), suggesting that higher ASE values were associated with a greater forward shift of the PCE. Pearson correlation analysis showed that the ablation depth, preoperative SE and RBT were also significantly associated with PCE changes. This may be partially related to the correlation of the ASE with the ablation depth, preoperative SE and RBT (r=0.818, P=0.000; r=0.992, P=0.000, and r=-0.540, P=0.000, respectively). In other words, patients with a higher preoperative SE receive a greater ablation depth, a higher ASE values and a thinner RBT left. This is likely the reason that the forward stepwise regression analysis did not include these covariants in the final models.

In our study, the ORBSCAN® IIz documented larger changes in the PCE after LASIK than the changes reported by Ciolino (13) and Grewal (8) using the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany). One explanation for this observation is the difference in technology used to measure the cornea. Although the ORBSCAN® IIz topographer is better than previous technology used to image the cornea, the use of the Orbscan to assess post-LASIK PCE may still be controversial as the accuracy of the Orbscan in assessing the posterior corneal surface remains a subject of debate (14,16). The Orbscan's mathematical reconstruction of the posterior cornea may lead it an overestimation of the PCE above the BFS (17). Furthermore, Herna'ndez-Quintela (18) and Maloney (19) suggested that the variability between pre-LASIK and post-LASIK PCE Orbscan measurements may be a source of artificially observed ectasia. Different

hypotheses have been proposed to explain the problems with the Orbscan in assessing the posterior corneal curvature after LASIK (20). The effect of eyelids, eyelashes and reflections could provide an incomplete map, especially in the periphery of the cornea. If the peripheral data are missing, the elevation maps could be affected (21).

An alternative corneal imaging modality, the Pentacam (Oculus, Inc.), employs a rotating Scheimpflug camera to directly image the posterior cornea and allows for the calculation of PCE without the need of mathematical reconstruction. The Pentacam's ability to directly image the posterior cornea could be a more accurate representation of the actual posterior corneal topography (17,22). However, we did not identify any significant differences in the changes of the post-LASIK PCE between this study measured with the Orbscan and previous studies reported with the Pentacam (Table 4, Figure 4).

Posterior ectasia typically presents approximately 13 months after LASIK (6), our long term follow-up (6 years) study provides more evidence on the stability of the posterior cornea post LASIK. To the best our knowledge, this is the longest follow up study on the PCE changes after LASIK.

There are several limitations in this study. Although this cohort of patient was retrospectively identified and invited back for an updated examination, there was a high loss to follow-up rate (80%) and we ended up with a relatively small number of patients (only 42 eyes). On the other hand, additional data from the period between 1 month post LASIK to 6 years postop would be highly desirable, thus we would not be able to identify if there were any changes in

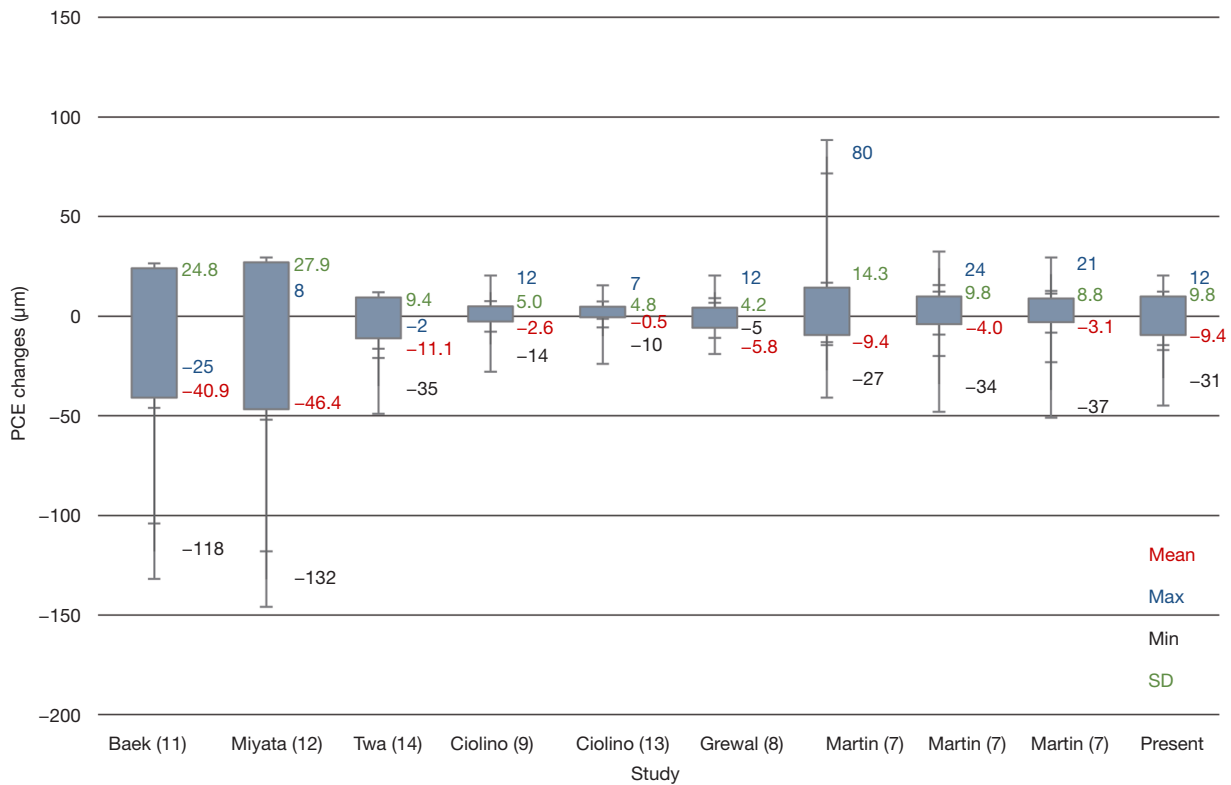


Figure 4 Box-whisker plot shows PCE changes after LASIK in different studies. PCE, posterior corneal elevation; LASIK, laser *in situ* keratomileusis.

between and the time when these changes in the posterior elevation may have taken place or stabilized. The adjusted R^2 value of the final regression model for the changes in PCE was 0.184, indicating a significant degree of variation in the dependent variables of the changes in PCE 6 years post LASIK. Furthermore, the changes in PCE are only one of the outcomes used for assessing keratectasia after LASIK. Another useful parameter would be corneal topography. Other parameters, such as the ablation depth and RBT may also be considered when evaluating keratectasia after LASIK. Therefore, the changes in PCE after LASIK must be interpreted in the light of above variables.

Conclusions

In conclusion, the present study identified a significant change in the PCE 6 years after LASIK using the ORBSCAN® IIz, but the average elevation change observed here at 6 years means good corneal stability. The ASE was the most significant prognostic factor in determining if there will be any changes in the PCE after LASIK.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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