

# Posterior corneal topographic changes after partial flap during laser in situ keratomileusis

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**Aim:** To study the posterior corneal topographic changes in eyes with partial flaps during laser assisted in situ keratomileusis (LASIK).

**Methods:** Case records of 16 patients, who had partial flap in one eye during LASIK (group 1) and uncomplicated surgery in the other eye (group 2), were studied. Following occurrence of partial flap intraoperatively, laser ablation was abandoned in all the eyes. A 160/180 µm flap was attempted during the initial procedure using the Hansatome microkeratome (Bausch & Lomb Surgical, Munich, Germany). LASIK surgery in all cases was performed using a 180 µm plate, at the mean interval of 4.16 (SD 1.5) months following the initial procedure. None of the eyes had intraoperative complication during LASIK. Relative posterior corneal surface elevation above the best fit sphere (BFS) before the initial procedure, before, and after LASIK were compared using the Orbscan slit scanning corneal topography/pachymetry system.

**Results:** Posterior corneal elevation was comparable in the two groups, both preoperatively (group 1; 16.4 (4.8) µm, group 2; 16.1 (4.8) µm) and after final surgery (group 1; 57.2 (15.6) µm, group 2; 54.3 (13.1) µm). In group 1 after occurrence of partial flap, the posterior corneal elevation was 16.9 (4.4) µm, and this increase was not significant statistically ( $p=0.4$ ). On multiple linear regression analysis, residual bed thickness ( $p<0.001$ ) was independently the significant determinant of final posterior corneal elevation in both groups.

**Conclusion:** The inadvertent occurrence of partial flap during LASIK procedure does not contribute to the increase in posterior corneal elevation.

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iatrogenic posterior corneal ectasia as a potential complication of keratorefractive surgery<sup>1,2</sup> is controversial with regard to its genesis and eventual outcome. Most of the studies suggest that the flap does not contribute to the biomechanical stability of the cornea following laser in situ keratomileusis (LASIK), and residual bed thickness (RBT) following ablation is a crucial factor which determines the postoperative increase in the posterior corneal elevation.<sup>3-5</sup> To segregate the role played by the flap and photoablation, we studied the effect of the flap without ablation on posterior corneal surface topographic changes.<sup>6</sup> Raising a flap alone in the absence of photoablation for the purpose of studying aetiopathogenesis of posterior corneal ectasia may be impractical. However, it is attempted in post-keratoplasty corneas to reduce the surgically induced astigmatism.<sup>7,8</sup> The incidence of flap related complications during LASIK vary from 2.7% to 8.6%.<sup>9-11</sup> At present to the best of our knowledge, there are no studies available regarding the posterior corneal surface topographic changes after the occurrence of a partial flap during LASIK. Hence, we undertook this retrospective study to evaluate the posterior corneal topographic changes in eyes that had inadvertent partial flap intraoperatively in whom the laser ablation was abandoned.

## SUBJECTS AND METHODS

Patient charts for all cases of LASIK procedures for myopia performed between December 1998 and December 2000, at the Rajendra Prasad Centre for Ophthalmic Sciences by experienced surgeons were retrospectively reviewed. A total of 2130 eyes had undergone LASIK for myopia. Eyes with intraoperative partial flaps (0.75%) were identified. Sixteen patients who had partial flap intraoperatively in one of their eye (eight right and eight left eyes) and in whom photoablation was abandoned (group 1,  $n=16$ ) and uncomplicated surgery in the other eye (group 2,  $n=16$ ) were studied. There were 11 females and five male patients with a mean age of 23.4 (SD

3.4) years (range 18–30 years). Inclusion criteria for LASIK at our centre are age >18 years, stable refraction for at least 1 year, and a best corrected visual acuity (BCVA) of 6/9 or better. Patients with keratoconus, active inflammatory disease, ocular surface disease, and previous ocular surgery were excluded. Patients with hard contact lenses discontinued their lenses for 4 weeks and those with soft lenses for 2 weeks before LASIK. Informed written consent was obtained from all the patients.

Preoperatively, two drops of 0.3% ciprofloxacin and 0.5% oxybuprocaine (proparacaine) were instilled before surgery 15 minutes apart. As a routine, simultaneous bilateral LASIK is performed at our centre (right eye followed by the left). In all eyes the Hansatome microkeratome (Bausch & Lomb Surgical, Munich, Germany) with a 160/180 µm plate and a 8.5/9.5 mm suction ring was used to create a superior hinged flap. Following the partial flap, irrigation was done, the flap was repositioned and photoablation was abandoned. No intraoperative pachymetry was attempted. On occurrence of the partial flap in the right eye, the LASIK surgery was deferred in the both eyes for a minimum period of 3 months. Postoperatively, patients received ciprofloxacin 0.3% and fluorometholone 0.1% four times a day for 1 week. Artificial tears were given 6–8 times a day.

Since there were no signs of epithelial ingrowth or subepithelial scarring in any of these eyes, LASIK was performed after a mean interval of 4.16 (1.5) months. However, all fellow eyes had uneventful LASIK. All procedures were performed under 0.5% oxybuprocaine using the Chiron Technolas 217C (Bausch & Lomb Technolas GmbH, Dornach, Germany) LASIK machine. In all eyes, a superior hinged flap was raised with the Hansatome microkeratome using a 180 µm plate and 9.5 mm suction ring. Intraoperatively, the central corneal thickness was measured just before initiating the surgery and then after lifting the flap before laser ablation using the Corneo-gage plus (Sonogage Inc, Cleveland, OH, USA) ultrasonic pachymeter. After stromal ablation, the posterior surface of the flap

**Table 1** Pachymetric and topographical changes in eyes with partial flap (group 1) and in eyes with uneventful LASIK surgery (group 2)

Variables	Group 1	Group 2
Flap thickness ( $\mu\text{m}$ )	124.9 (14.7)	122.4 (11.2)
RBT ( $\mu\text{m}$ )	299.6 (39)	306.2 (31.9)
Posterior corneal elevation ( $\mu\text{m}$ )		
Preoperative	16.4 (4.8)	16.1 (4.8)
After partial flap	16.9 (4.4)	–
After final surgery (flap + RBT)	57.2 (15.6)	54.3 (13.1)
Two way ANOVA/paired <i>t</i> test	F=112.6, $p<0.001$	$t=11.6$ , $p<0.001$
Anterior corneal elevation ( $\mu\text{m}$ )		
Preoperative	13 (2.2)	14.3 (1.5)
After partial flap	13.6 (1.9)	–
After final surgery (flap + RBT)	–14.8 (4.1)	–14.2 (3.6)
Two way ANOVA/paired <i>t</i> test	F=456.7, $p<0.001$	$t=25.5$ , $p<0.001$
Pachymetry ( $\mu\text{m}$ )		
Preoperative	522.6 (19.5)	524.6 (17.2)
After partial flap	523.5 (20)	–
After final surgery (flap + RBT)	421.3 (42.2)	425.4 (38.5)
Two way ANOVA/paired <i>t</i> test	F=167.2, $p<0.001$	$t=13.0$ , $p<0.001$

RBT = residual bed thickness.

was irrigated with the balanced salt solution and the flap was repositioned. An adherence time of 3 minutes was observed. One drop of 0.3% ciprofloxacin eye drops was instilled at the completion of the procedure. The postoperative regimen was identical to that after the occurrence of partial flap.

For each eye included in the study, uncorrected and best corrected visual acuity (UCVA and BCVA) using Snellen's chart, spherical equivalent refraction (SEQ), anterior and posterior corneal topography, and pachymetry with Orbscan slit scanning corneal topography/pachymetry system I (Orbtek Inc, Salt Lake City, UT, USA) were recorded preoperatively, after the partial flap at 3 months, and following subsequent LASIK. Similar parameters were also assessed for the fellow eye and were compared with those eyes that had partial flaps. Any topographic change in the posterior corneal surface was determined by comparing the preoperative and postoperative corneal surface elevation maps, and the highest reading of the relative elevation was noted in the 6 mm central zone.

Residual bed thickness was calculated by subtracting actual flap thickness and attempted ablation depth from preoperative pachymetry. The mean follow up periods for group 1 and group 2 eyes were 18.75 (2.7) months (range 14–24 months) and 19.06 (3.02) months (range 15–26 months) respectively following final LASIK. Follow up periods were comparable between the two groups ( $p = 0.24$ ).

### Statistical analysis

Variables were summarised by mean and standard deviation separately for both complications (group 1) and no complications (group 2) groups. For the eyes in group 1, to compare the mean values at three different time points we used "repeated measures analysis of variance," followed by Bonferroni multiple comparison, if required. For the eyes in group 2 the paired *t* test was used to compare the change in means before and after surgery. Also, we used Student's *t* test to compare the mean values of variables at baseline and following final surgery between two groups. "Analysis of covariance" was used to compute the mean of final posterior corneal elevation in both groups adjusted for preoperative (SEQ, pachymetry and posterior corneal elevation), intraoperative (ablation depth, optic zone diameter, RBT, flap thickness), and postoperative parameters (pachymetry). To find out the determinants of final posterior corneal elevation in both groups, Pearson's correlation coefficient followed by stepwise multiple linear regression analysis was done. For data analysis, STATA 7.0 (intercooled version) and SSPS 8.0 statistical software were used. In this study, all the tests used were two tailed and  $p<0.05$  has been considered as statistically significant.

### RESULTS

In group 1, the mean decimal UCVA preoperatively was 0.09 (0.03) and following partial flap no change was observed. Following LASIK, it significantly increased to 0.9 (0.16) at a minimum follow up of 1 year ( $p<0.001$ ). No loss of BCVA was seen in any of the eyes after partial flap and LASIK. Mean SEQ before the initial procedure in group 1 was  $-6.09$  (2.06) D (range  $-2.50$  to  $-9.50$  D) and after partial flap it was  $-6.29$  (1.99) D (range  $-2.50$  to  $-10.0$  D) ( $p>0.05$ ). This significantly improved to  $-0.08$  (0.25) D (range  $-0.50$  to  $0.50$  D) after LASIK at 1 year of follow up ( $p<0.001$ ). The mean SEQ preoperatively in the group 2 (eyes with uneventful LASIK procedure) was  $-5.8$  (1.8) D (range  $-2.12$  to  $-8.25$  D), which following LASIK significantly decreased to  $-0.1$  (0.4) D (range  $-0.62$  to  $0.5$  D) at a minimum follow up of 1 year ( $p<0.001$ ).

Inadequate suction ( $n = 11$ ), loss of suction ( $n = 3$ ) and interference with the passes of microkeratome by the lids/speculum ( $n = 2$ ) were the causes for intraoperative flap complications in our series. Irregular keratectomy with thin flaps occurred in 10 eyes, incomplete flap with hinge at the pupillary axis occurred in five eyes. In one eye, the hinge was torn radially towards the visual axis.

Orbscan pachymetry reading of central cornea preoperatively and after partial flap were  $522.6$  (19.5)  $\mu\text{m}$  (range 496–560  $\mu\text{m}$ ) and  $523.5$  (20.1)  $\mu\text{m}$  (range 494–562  $\mu\text{m}$ ) respectively in group 1. After LASIK, the pachymetry decreased to  $421.3$  (42.2)  $\mu\text{m}$  (range 360–485  $\mu\text{m}$ ) at 1 year ( $p<0.001$ ). The mean elevation of anterior corneal surface preoperatively and after partial flap was  $13$  (2.2)  $\mu\text{m}$  and  $13.6$  (1.9)  $\mu\text{m}$  respectively ( $p>0.05$ ) in group 1, with no difference before and after the partial flap. After LASIK, it significantly decreased to  $-14.8$  (4.15)  $\mu\text{m}$  ( $p<0.001$ ). In group 2 eyes, pachymetry and anterior corneal elevation were comparable to group 1 eyes preoperatively as well as after LASIK (Table 1). The preoperative keratometry in the group 1 and 2 was  $43.78$  (1.21) D (range 41.5–45.75 D) and  $43.72$  (1.03) D (range 41.75–45.25 D), respectively, with no significant difference among the groups statistically.

The mean elevation of posterior corneal surface preoperatively and after partial flap was  $16.4$  (4.8)  $\mu\text{m}$  and  $16.9$  (4.4)  $\mu\text{m}$  respectively ( $p>0.05$ ) in group 1, with no difference before and after the occurrence of the partial flap. This, however, significantly increased to  $57.2$  (15.6)  $\mu\text{m}$  after LASIK at minimum follow up of 1 year ( $p<0.001$ ). Posterior corneal elevation following LASIK had significant correlation with the attempted correction ( $r = 0.6$ ,  $p=0.01$ ), preoperative pachymetry ( $r = -0.7$ ,  $p=0.004$ ), ablation depth ( $r = 0.6$ ,  $p=0.01$ ),

RBT ( $r = -0.8, p = 0.00003$ ), and the final corneal thickness ( $r = -0.8, p = 0.00003$ ).

In group 2 eyes, posterior corneal elevation preoperatively and after surgery was 16.1 (4.8)  $\mu\text{m}$  and 54.3 (13.1)  $\mu\text{m}$  respectively ( $p < 0.001$ ). Posterior corneal elevation after surgery had significant correlation with preoperative pachymetry ( $r = -0.6, p = 0.02$ ), flap thickness ( $r = 0.5, p = 0.03$ ), ablation depth ( $r = 0.5, p = 0.04$ ), RBT ( $r = -0.8, p = 0.00003$ ), and final corneal thickness ( $r = -0.7, p = 0.0006$ ).

On multivariate linear regression analysis, it was found that RBT was the independent significant determinant of final posterior corneal elevation in both groups. RBT alone accounted for 72% ( $R^2$ ) of total variability in final posterior corneal elevation. An increase of RBT by 1  $\mu\text{m}$  would correspond to a decrease in the final posterior corneal elevation by 0.3  $\mu\text{m}$  ( $p < 0.001$ ).

The mean attempted ablation depth, optic zone diameters, and residual bed thickness during LASIK in group 1 eyes were 98.8 (20.7)  $\mu\text{m}$  (range 58–130), 5.6 (0.46) mm (range 5–6), and 299.6 (39)  $\mu\text{m}$  (range 256–357) and in group 2 eyes were 95.2 (19.7)  $\mu\text{m}$  (range 50–121), 5.6 (0.5)  $\mu\text{m}$  (range 5–6), and 306.2 (31.9)  $\mu\text{m}$  (range 268–355) respectively.

## DISCUSSION

Iatrogenic corneal ectasia is an issue that has been discussed ever since the introduction of keratorefractive surgery.<sup>1,2</sup> An increase in posterior corneal surface elevation following LASIK has been reported<sup>3-5</sup>; however, pathogenesis behind it is poorly understood and is controversial. The Orbscan slit scanning system was used to evaluate the corneal topography in our study. However, the data accumulated by Orbscan may be limited by factors such as the accuracy of the system which is plus or minus 20  $\mu\text{m}$ , the measurement noise which leads to both positive and negative difference in the height of the posterior corneal surface, and the necessity of aligning the posterior surface before and after surgery which may be a source of artefactual ectasia.<sup>12,13</sup> As there are many concerns about the “proper posterior alignment” of the posterior corneal surface while comparing changes of height against best fit sphere in the difference map,<sup>12</sup> we calculated the difference in the posterior corneal surface elevation by subtracting preoperative from postoperative corneal elevation. The Orbscan corneal topography system evaluates corneal thickness across the entire surface and is non-invasive. Yalali and associates<sup>14</sup> reported that the relative accuracy and precision of the Orbscan system is similar to ultrasonic pachymetry, although they found that measurements of the corneal thickness with the Orbscan system were 23–28  $\mu\text{m}$  greater than those obtained by ultrasonic pachymetry. Despite these discrepancies, the Orbscan corneal topography system is a useful tool to evaluate corneal topography and thickness.<sup>15</sup>

The reported factors that determine the increase in the posterior corneal surface elevation after LASIK include preoperative pachymetry,<sup>5</sup> intraocular pressure (IOP),<sup>5</sup> ablation depth,<sup>5</sup> and residual bed thickness (RBT).<sup>3,4</sup> Previous studies have suggested that the flap may not contribute to the biomechanical stability of the cornea following LASIK.<sup>4</sup> Evaluation of the posterior corneal surface topographic changes after partial flaps without ablation may help us to know the contribution of the flap to the corneal elasticity and the increase in posterior corneal elevation following LASIK. In our study, the occurrence of a partial flap did not additionally increase the posterior corneal elevation, as the posterior corneal elevation after uneventful LASIK in fellow eyes was comparable to the eyes in which the LASIK had been undertaken after partial flap during the initial procedure.

The occurrence of a partial flap as a complication does not affect the integrity of the corneal architecture as there was no significant change in pachymetry, or anterior and posterior corneal elevation before and following partial flap. The posterior

corneal elevation increased significantly after LASIK (flap creation + ablation) compared to that after partial flap (without ablation). Hence, residual bed thickness after ablation may be the sole determinant for the increase in posterior corneal elevation following LASIK. Photoablation results in expulsion of tissue fragments from the target site, which occurs within microseconds or less.<sup>16</sup> This process generates reactive forces within the cornea and stress waves of the amplitude up to 100 atm at the level of cornea,<sup>17,18</sup> compromising the structural integrity of cornea. This may possibly increase the posterior corneal elevation following LASIK, which is attributed to the instantaneous biomechanical change in which the IOP pushes against the back surface of a structurally compromised cornea.

The patients in our study achieved comparable visual outcomes after LASIK with and without partial flaps. However, the number of patients in this retrospective case series is small with a short follow up. More patients with a longer follow up are required to assess the long term outcome in eyes with partial flap during LASIK.

In conclusion, the inadvertent occurrence of partial flap during the LASIK procedure does not contribute to the increase in posterior corneal elevation and residual bed thickness is an independent significant determinant of posterior corneal elevation.

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