Early Flap Displacement after LASIK

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Purpose: To evaluate the risks of flap displacement after LASIK.

Design: Retrospective case series.

Participants: We included 41 845 consecutive adults who underwent LASIK surgery at Optical Express in the United Kingdom, including 81 238 eyes, of which 14 555 were hyperopic and 66 681 myopic or mixed astigmatic. We treated 57 241 eyes with the IntraLase FS-60 femtosecond laser and 23 997 with the Moria S.A. ONE Use-Plus automated microkeratome.

Methods: We calculated the incidence of all flap displacements in the study population during an observational time period of ≥12 months after surgery. Independent variables were entered into logistic regression models to identify risk factors. Postoperative outcomes were assessed.

Main Outcome Measures: The incidence and odds ratios (OR) of flap displacement in the study population and in categories of refractive error and flap surgery technique.

Results: The incidence of flap displacements was 10 in 81 238 LASIK procedures (0.012%), including 8 hyperopic eyes (0.055%) and 2 myopic eyes (0.003%). All flap displacements occurred within 48 hours of surgery and none were preceded by ocular trauma. They were classified as "early flap displacements" (EFD). The incidence of EFD after microkeratome surgery was 0.033% (n = 8), and after femtosecond laser it was 0.003% (n = 2). In hyperopic eyes having microkeratome surgery, the incidence was 0.179% (n = 7). In a logistic regression model, the strongest predictor of EFD after LASIK was hyperopia, recording an OR of 19.29 ($P<0.001$). The OR of developing an EFD after microkeratomy was 10.53 times higher than after femtosecond laser ($P<0.005$). In hyperopes, the OR of an EFD was 18.87 times higher after microkeratomy than after femtosecond treatment. Four of 10 displaced flaps needed secondary surgery, and 1 eye lost 2 lines of best-corrected visual acuity.

Conclusions: The incidence of flap displacements during a 12-month period after LASIK was extremely low (0.012%). Although the small number of displacements with the femtosecond laser limits conclusions, the risk of EFD was higher after microkeratome surgery than femtosecond laser.

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Flap displacement is considered a highly undesirable complication of LASIK, and flap stability is a key safety concern in occupational groups such as the emergency services and the military.[1] In an unpublished series of 29 patients who had traumatic flap dislocations, the highest number occurred in the first month after surgery, tapering thereafter, suggesting that the flap was most vulnerable early on in the postoperative course (Schallhorn SC. Refractive Surgery in Naval Aviation. Paper presented at: AsMA Annual Meeting, May 14, 2006; Orlando, FL).

Flap displacement has been reported in the early postoperative time period after LASIK.[2,3] In contrast with traumatic dislocation, which can be caused by an injury many years after LASIK,[4] displacements occurring early on in the postoperative course usually have no obvious precipitating event. We conducted a large, retrospective, consecutive, case series of patients undergoing LASIK at Optical Express in the United Kingdom. An analysis of flap displacements that occurred during the first 12 months after LASIK revealed that all known dislocations occurred in the early postoperative period and that there was no identifiable antecedent trauma. We defined these dislocations as "early flap displacements" (EFD) because they have distinct etiological risk factors to traumatic dislocations. We assessed the exposure of operated eyes to a number of categorical and continuous variables, including refractive error and flap surgery (femtosecond laser and microkeratomy) to evaluate the incidence and risk factors of these flap displacements. Postoperative outcomes of these eyes were also assessed. The incidence of either early or traumatic flap displacements over the 12-month period after surgery has never been reported previously.

Patients and Methods

Study Population

Ethics committee approval was obtained for this study and all patients were properly consented for surgery. With patient identifiers removed, the demographic details, preoperative measurements and visual outcomes of 81 238 consecutive eyes of 41 845 patients who underwent LASIK were analyzed.

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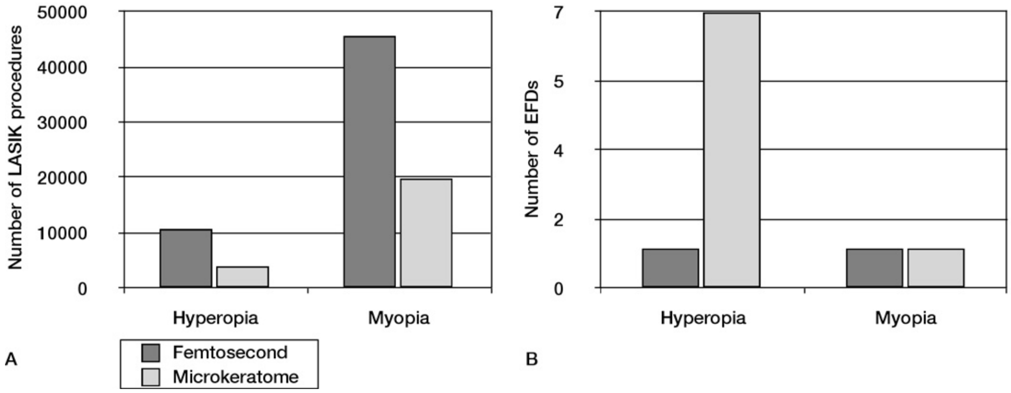

Figure 1. Numbers of femtosecond and microkeratome LASIK procedures (**A**) and early flap displacements (EFDs; **B**) in hyperopic and myopic eyes.

Operative Technique

LASIK surgery was performed by 23 surgeons working at Optical Express outlets in the United Kingdom. The Moria ONE Use-Plus automated microkeratome (Moria S.A., Antony, France) was used with a 130-μm standard head (or a Large-Cut head for some hyperopic eyes) and a suction ring with adjustable stops chosen by the surgeon on the basis of the keratometry readings, to create nasally hinged flaps. The IntraLase FS-60 laser (Abbott Medical Optics, AMO, Abbott Park, IL) created femtosecond flaps with diameter ranging from 8.2 to 9.2 mm and programmed depth from 100 to 120 μm. All femtosecond flaps were created with the hinge placed superiorly. Patient and surgeon preference determined the choice of procedure. Excimer laser was performed on a Star S4IR platform (AMO). After excimer laser, the stromal bed was irrigated and the flap was repositioned with a Weck-cell sponge. Postoperatively, patients were prescribed a third-generation fluoroquinolone and 1% prednisolone acetate, each 4 times a day for 1 week, and instructed to use an artificial tear solution ≥4 times a day for a month.

Data Collection

Patients were instructed to return to the provider in the event of symptoms such as loss of vision and discomfort. All postoperative checks were carried out by refractive optometrists who ensured that all cases of flap displacement were properly recorded. Clinical data were entered by the surgeon, optometric, technical, and nursing staff, and included preoperative monocular and binocular uncorrected (UCVA) and best spectacle-corrected visual acuities, manifest sphere, cylinder and axis, keratometry readings (Nidek Tonoref II, Nidek ARK 510, Gamagori, Japan), ultrasonic pachymetry readings (Pachmate DGH55, DGH Technology, Inc., Exton, PA) and operative details (ablation depth, procedure choice, ablation parameters). The manifest refraction of each eye was measured using a "push plus" technique at each visit. Visual acuities were measured using logarithmically sized letters and recorded as the logarithm of minimum angle of resolution. Data were recorded onto computer terminals at peripheral outlets and stored automatically on the Optical Express central database. For uncomplicated procedures, patients were instructed to attend follow-up at 1 day, 1 week, 1 month, 3 months, 6 months, and then annually after LASIK. Anonymized files of all patients with flap displacements in the first 12 months after LASIK surgery were retrieved for analysis from the Optical Express electronic medical records system. The documented postoperative findings in these files included symptoms, treatments, and final visual and refractive outcomes.

Statistical Analysis

Statistical analysis was performed with Predictive Analytical Software Statistics 18.0 (SPSS Inc., an IBM Company, Chicago, IL). This included descriptive statistics and logistic regression analyses based on a number of categorical and continuous variables, performed on the control population as a whole and by category of ametropia.

Results

Incidence and Logistic Regression Analysis

LASIK was performed on 81 238 consecutive eyes of 41 845 patients. The average age was 39.2 years (standard deviation [SD], 12.1; range, 18–70). Of these patients, 46.9% were male and 53.1% female. Microkeratome surgery was performed on 23 997 eyes (29.5%), and femtosecond laser surgery on 57 241 eyes (70.5%). Standard treatment was performed in 16 390 eyes (20.2%), whereas 64 848 (79.8%) had customized ablation. The spherical equivalent (SE) treatment range (computed from manifest refraction data) was −12.625 to +7.75 diopters (D).

Patients were further divided according to their preoperative sphere and flap operative procedure (Fig 1). There were 14 555 eyes treated for hyperopia (17.9% of total; mean SE, +1.99; SD, 0.84). The mean age was 53.3 years (SD 8.9). Of these eyes, 3914 (26.9%) had microkeratome surgery and 10 641 (73.1%) had femtosecond laser. Treatments for myopia numbered 65 312 (80.4% of total; mean SE, −3.27 D; SD, 1.85; mean age, 36.0 years; SD, 10.3). Of the myopic eyes, 19 766 (30.3%) underwent microkeratome surgery and 45 546 (69.7%) femtosecond treatment. Of 1369 eyes treated for mixed astigmatism (1.7%; mean SE, −0.62; SD, 0.5; mean age, 40.1 years; SD, 10.9), none had a displaced flap.

Ten eyes of 9 patients (6 male, 3 female) were diagnosed with flap displacements. There was no history of trauma in any case and all flap displacements occurred within the first 48 hours after LASIK. Therefore, all the cases were classified as EFDs. The cases included 8 hyperopic and 2 myopic eyes (Table 1). Microkeratome surgery was performed in 8 eyes (7 hyperopic and 1 myopic), and femtosecond laser surgery in 2 (1 hyperopic and 1 myopic). One male subject with bilateral hyperopia had an EFD in each eye. Among the hyperopic eyes with EFD, the mean SE was +1.92 (SD, 0.66; range, +0.75 to +2.75) and the mean age was 57.3 years (SD, 7.83; range, 44–68). The 2 myopes had SEs of −2.50 and −9.38, and were 32 and 24 years old, respectively. Five cases were operated on by 1 surgeon and 3 by another.

The total incidence of flap displacements was 10 in 81 238 LASIK procedures (0.012%). The incidence in hyperopic eyes was

Table 1. Preoperative Details and Procedure in Eyes Diagnosed with Early Flap Displacement

Eye	Side	Age	Gender	SE	BCVA	Flap Procedure	Ablation	Surgeon
1	L	50	F	+2.38	−0.1	Microkeratome	Wavefront	D
2	R	56	M	+2.75	0.0	Intralase	Wavefront	A
3	L	60	F	+2.38	−0.1	Microkeratome	Standard	A
4	R	66	M	+2.25	−0.1	Microkeratome	Wavefront	B
5	L	68	M	+2.00	−0.1	Microkeratome	Wavefront	C
6	R	57	M	+1.50	−0.1	Microkeratome	Standard	B
7	L	57	M	+1.38	−0.1	Microkeratome	Standard	B
8	L	44	F	+0.75	0.0	Microkeratome	Standard	B
9	R	32	M	−2.50	−0.1	Microkeratome	Wavefront	B
10	L	24	M	−9.38	0.0	Intralase	Wavefront	A

BCVA = best corrected visual acuity; F = female; L = left; M = male; R = right; SE = spherical equivalent.

8 in 14 555 (0.055%), compared with 2 in 65 312 myopic eyes (0.003%). The incidence was higher after microkeratome surgery (8 in 23 997; 0.033%) than femtosecond surgery (2 in 57 241; 0.003%). The incidence in hyperopic eyes after microkeratome surgery was 7 in 3914 eyes (0.179%), compared with 1 in 10 641 after femtosecond treatment (0.009%). In myopic eyes treated with microkeratome surgery, the incidence was 1 in 19 766 (0.005%), compared with 1 in 45 546 having femtosecond laser (0.002%).

Direct logistic regression was carried out to assess the impact of a number of factors on the likelihood of developing an EFD after LASIK in the entire test population of 81 238 eyes. A high bivariate correlation (0.908) was found on standard linear regression between age and mean SE in the hyperopic category, precluding their inclusion in the same analysis. Multicollinearity with other variables was low. The factors analyzed included 5 independent categorical variables (gender, laterality, standard vs customized ablation, hyperopia vs. nonhyperopia, and procedure). There was incomplete data for 7 eyes. The model was significant: Chi square (3; n = 81 231) = 32.542 ($P<0.001$). The Hosmer-Lemeshow goodness-of-fit test chi square value was 5.890 with a significance level of 0.436, indicating support for the model. Between 0% (Cox and Snell R^2) and 16.3% (Nagelkerke R^2) of the variability in outcome could be explained by the variables listed. Of the independent variables studied, 2—hyperopia and procedure—made a significant contribution to the model. The strongest predictor of EFD was hyperopia, recording an OR of 19.29 ($P<0.001$). The OR of developing an EFD after mechanical microkeratomy was 10.53 times higher than after femtosecond laser treatment ($P<0.005$).

When the study population was categorized by refractive error, the model remained statistically significant for the hyperopic group only, chi square (2, n = 14 544) = 13.541 ($P<0.005$). The OR indicated that, in hyperopic eyes, EFD was 18.87 times more likely with microkeratomy than laser. The contribution of age did not have a significant impact on the model. Further analyses assessed the impact of other variables including gender, age, ablation depth, and keratometry. In the hyperopic category, the omnibus test of model coefficient significance level was 0.314 (>0.05, indicating poor fit). For myopia, the significance level of the model as a whole was 0.019, but the goodness of fit chi-square value was 0.132, indicating that the null hypothesis could not be rejected with confidence. Therefore, neither model was used.

Postoperative Outcomes

Flap displacements were diagnosed within 1 hour in 1 case, within 24 hours in 8 cases, and within 48 hours in 1 case. All but 1 flap displacements were initially treated by flap lift, irrigation, realignment, and bandage contact lens (Table 2). In 1 case, the displace-

Table 2. Postoperative Complications, Treatments and Final Visual Outcomes of Eyes with Early Flap Displacement (EFD)

Eye	Hours to EFD	Primary Treatment	Secondary Complications	Secondary Surgical Treatment	Follow-up Visits	Final SE	Final UCVA
1	<24	Flap lift, BCL	Epithelial ingrowth+, DLK+		15	+0.62	>0.1
2	<48	Flap lift, BCL	Epithelial ingrowth++, DLK++, infiltrate+	Flap lift, removal of ingrowth, Tisseel glue	37	+0.50	0
3	<24	Removal of epithelium, flap lift + BCL	DLK+		9	0	−0.1
4	<24	Flap lift, BCL	Secondary displacement after 15 minutes	Flap lift, sutures	12	+0.12	0.1
5	<24	Flap lift, BCL			6	+0.12	0.1
6	<24	Flap lift, suture + BCL	DLK+		20	−0.12	−0.1
7	<24	Flap lift, BCL	Epithelial ingrowth +, DLK+		20	−0.25	−0.1
8	<24	Flap lift, suture + BCL	Macrostriae, epithelial ingrowth +++	Removal of epithelium, flap lift, removal of ingrowth, Tisseel glue	16	+0.12	0.1
9	<1	Flap lift, BCL	Secondary displacement after 30 minutes	Flap lift, sutures	6	0	−0.1
10	<24	BCL			4	+0.50	0

BCL = bandage contact lens; DLK = diffuse lamellar keratitis; SE = spherical equivalent; UCVA = uncorrected visual acuity.

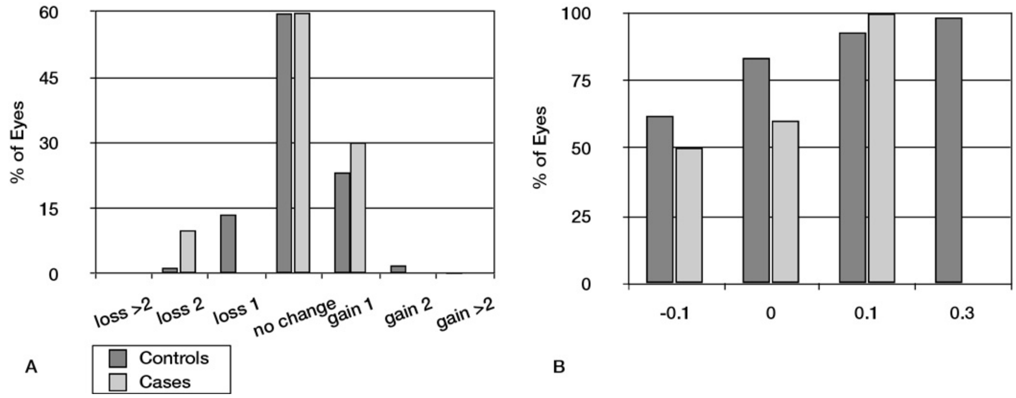

Figure 2. Change in lines of best corrected visual acuity (**A**) and cumulative final visual acuity (logarithm of minimum angle of resolution equivalent; **B**) for control and case populations.

ment was minimal and was treated with a bandage contact lens alone. Sutures were added as a precaution in 2 eyes. Secondary complications included immediate secondary displacement in 2 eyes, diffuse lamellar keratitis in 5 eyes and epithelial ingrowth in 4 eyes. For secondary displacement and severe epithelial ingrowth, the flap was re-lifted. Epithelial ingrowth was removed mechanically, and the flaps were glued with Tisseel fibrin glue. Secondary displacements were sutured. After surgery, patients with EFD had on average >14 postoperative visits (range, 4–37) over a course of 213 days (range, 20–523). One patient with EFD lost 2 lines of BCVA (from −0.1 to 0.1), compared with 2.5% of the study population at 1 month after LASIK (Fig 2A). A greater proportion of unaffected eyes achieved postoperative UCVA of −0.1 and 0 than eyes diagnosed with EFD (61.80% vs 50% and 83.20% vs 60%, respectively; Fig 2B). Mean final UCVA in eyes with EFD was −0.01 (SD 0.10), which compares with the study population UCVA of −0.04 1 month after LASIK (SD 0.13). The mean postoperative SE in eyes with EFD was +0.16 D (SD, 0.28; range, −0.25 to +0.62), whereas the study population mean SE was −0.07 D (SD, 0.41; Fig 3).

Discussion

In our study, 9 patients in 41 845 having LASIK surgery had a displaced flap, with 1 patient suffering bilateral displacements. The overall incidence of flap displacements during the 12-month observational time period was 0.012%, much lower than that found in previous studies (Table 3). All displacements occurred shortly after surgery, with no accompanying history of trauma, and were therefore classified as EFDs. This suggests that either the incidence of late flap displacements is exceedingly low or that patients with a late dislocation sought care from a different provider. Mitigating against the possibility of underreporting flap displacements, Optical Express has numerous clinics (>200) strategically placed throughout the United Kingdom. Patients are given a 24-hour hotline phone number to call in case of any problem. It is likely that they would attempt to contact Optical Express if they spontaneously experienced a sudden loss of vision owing to a flap displacement (i.e., nontraumatic). For an isolated traumatic displacement, care could have been provided through emergency services and the patient referred back to Optical Express or to a different provider.

In this small set of EFDs, the ratio of hyperopic to myopic eyes was 4:1. The incidence of EFD was highest after microkeratome surgery for hyperopia (0.179%), and was lowest in mixed astigmatic and myopic eyes which underwent femtosecond surgery (0.002%), a difference of

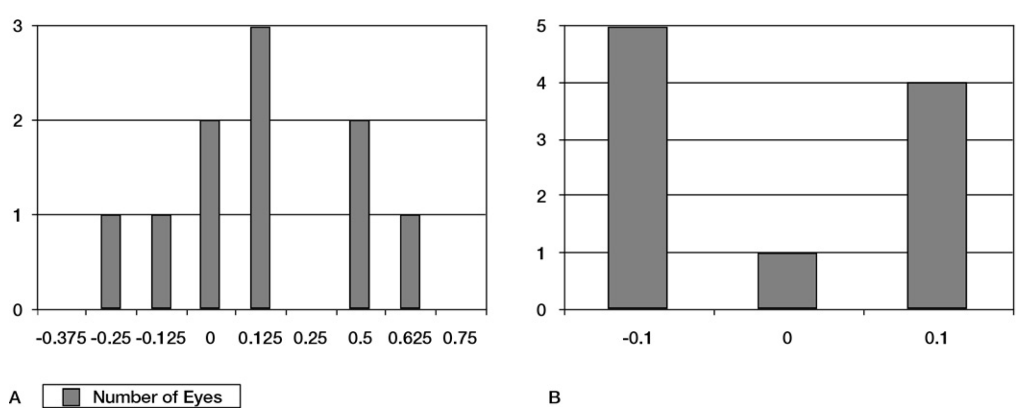

Figure 3. Postoperative mean spherical equivalent in diopters (**A**) and final uncorrected visual acuity (logarithm of minimum angle of resolution; **B**) in eyes with early flap displacement.

Table 3. Studies Reporting the Incidence of Early Flap Displacements after LASIK

Authors	Year	Keratome	No. of Eyes	Incidence of EFD (%)
Lin and Maloney[5]	1999	Automated corneal shaper (Chiron)	1019	2.0
Stulting et al[6]	1999	Automated corneal shaper (Chiron)	1345	1.0
Recep et al[7]	2000	Moria	1481	1.4
Lui et al[8]	2003	Moria Carriazo Barraquer	580	2.0

>80-fold. Because the case population is small and the study not randomized, conclusions about the overall risk to hyperopes should be viewed with caution. Moreover, success is determined by many outcome measures besides flap displacement rates. Nonetheless, the increased incidence of EFD in hyperopia in this study may be significant.

The extent of the contribution of individual surgeons was beyond the scope of this study. The apparent excess of cases of EFD after surgery by individual surgeons may reflect individual surgical experience. However, if surgical experience alone were responsible for EFD, myopes and hyperopes would be affected equally, and EFDs would be distributed equally between microkeratome and femtosecond procedures, yet the incidence of flap displacement in myopia and after femtosecond treatment was extremely low in this series (0.003% each).

Lin and Maloney[5] reported 20 eyes with displaced flaps out of 1019 eyes (2.0%), speculating that these were caused by a failure to expel fluid from the interface after keratomileusis. In a prospective study, Stulting et al[6] noted 13 flap dislocations within 2 days of surgery in a series of 1345 LASIK procedures for myopia, an incidence of <1%. Recep et al[7] described 21 early postoperative displacements out of 1481 eyes that underwent LASIK with a Moria keratome (1.4%). More recently, Lui et al[8] reported an incidence of 2.0% of flap dislocations or striae needing repositioning after LASIK with the Moria-Carriazo-Barraquer microkeratome.[8] These case series may not reflect modern practice, because technological innovations have resulted in improvements in microkeratome designs. None of these studies used femtosecond laser, and an association between hyperopia and EFD was not reported. In our study population as a whole, the likelihood of EFD was >10 times higher after microkeratomy with the Moria ONE Use-Plus than with the IntraLase FS-60 laser, and hyperopic eyes were almost 20 times more likely to develop an EFD than myopic and mixed astigmatic eyes together. The OR of EFD in hyperopic eyes was almost 20 times higher after microkeratomy than after femtosecond laser.

A recent review of large studies of microkeratome complications found that different microkeratomes had different complication rates, indicating that small differences in flap shape and size are clinically relevant.[9] Complications included numerous partial, irregular, and free flaps and buttonholes. Risk factors for epithelial defects with the Hansatome microkeratome included preoperative hyperopia,[10] suggesting that corneal factors may influence the development of complications. This idea is supported by a study linking flat keratometry readings with free and incomplete flaps.[11] In our study, the association between EFD and hyperopia was highly significant, although no association was found between EFD and keratometry measurements.

The apparent increased risk of EFD in microkeratome-created flaps, especially in hyperopes, may reflect the characteristics of the flap. The increased microkeratome flap thickness and hyperopic flap diameter result in a heavier flap, increasing the rotational forces about the horizontal axis. This would explain the observation that microkeratome-induced flap displacements tend to cause folds at the nasal hinge.[12] In contrast, the superiorly placed femtosecond laser hinge protects the flap against vertical movement. The angular, planar shape of the IntraLase flap may make it less prone to microdisplacement than meniscus-shaped microkeratome flaps. High-speed optical coherence tomography studies found the variability in peripheral thickness of Zyoptix XP microkeratome flaps to be significantly higher than in the center, whereas IntraLase flaps were significantly more uniform.[13] Moreover, ultrasound pachymetry studies found central flap thickness to be more reproducible with the IntraLase FS than with 2 Moria microkeratomes.[14] Potentially important variables such as hinge localization and true flap thickness were not addressed in our study. For this reason, the 2 techniques are not compared directly.

Two rabbit model studies have compared the force required to dislodge LASIK corneal flaps, at 1 and 3 months[15] and at 75 days.[16] In both studies, femtosecond flaps were significantly stronger than their microkeratome counterparts. Conversely, the force of ejection from a cockpit ejection seat simulator was found to be insufficient to dislodge microkeratome LASIK flaps 1 month after surgery in a rabbit model,[17] and a study subjecting rabbit eyes to high-speed wind trauma as early as 24 hours after LASIK found the microkeratome flaps to be stable, probably as a result of epithelial bridging across the edge of the flap and the osmotic gradient across the interface.[18]

Our case population was predominantly hyperopic, and extremely small next to the mostly myopic study population 1 month after surgery, making a direct comparison of final visual outcomes difficult. However, 1 eye with EFD lost 2 lines of BCVA, and the mean final SE in eyes with EFD was 0.23 D more hyperopic than the study population at 1 month. Clinically significant complications included epithelial ingrowth in 40% of eyes and secondary displacement in 20%. Four eyes required further operative management, greatly prolonging the usual follow-up time and the number of appointments. Of 4 cases reported by Lam et al,[12] 2 required flap amputation (1 for epithelial ingrowth and stromal melt and the other to achieve correct positioning). Final UCVAs were 20/40 and 20/60 respectively. Thus, active management of EFDs is necessary to avoid further complications and visual loss.[19]

Our ongoing study supports the IntraLase FS-60 laser over the Moria ONE Use-Plus automated microkeratome in terms of flap stability, and it also highlights the possibility of a higher incidence of EFD in hyperopic eyes. It remains to be seen whether these findings are reproduced for other brands of microkeratome and femtosecond laser.

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