Efficacy and Safety of Surgically Managed Late Traumatic LASIK Flap Displacements in a Study of 66 Cases

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ABSTRACT

PURPOSE: To evaluate safety and efficacy in the management of flap displacement after laser in situ keratomileusis (LASIK) and subsequent complications.

METHODS: This was a retrospective study performed using data recorded at the center's database from October 2002 to August 2021. Efficacy and safety were both converted to binary outcomes (loss of one or more lines and no change or gain in lines of visual acuity). The effects of time from surgery to complication and from complication to repair were assessed and the odds ratios and probabilities were calculated. The same procedure was applied to investigate the effect of these temporal variables on complications.

RESULTS: A total of 66 eyes with late traumatic LASIK flap displacements were studied. Efficacy remained unchanged in 48 patients (64 eyes, 75%), and safety remained unchanged in 53 patients (59 eyes, 90%). Sixty-six patients (64 eyes, 100%) achieved visual acuity values of 20/40 and 45 patients (64 eyes, 70.3%) achieved values of 20/20. The flap displacement was resolved in the first 24 hours (SD ± 0.1 days). Surgery was performed in 58 patients (65 eyes, 90%). Epithelial ingrowth was the most frequent complication. Patients who underwent surgery tended not to lose lines ($P = .05$). The risk of developing epithelial ingrowth increases with time after LASIK surgery until traumatic flap displacement (odds ratio: 1.001; $P < .001$). The prevalence of dislocation during the study period was 0.012%.

CONCLUSIONS: Visual safety values were favorable after resolution of the flap complication. Immediate surgical management leads to better visual efficacy, and the time between LASIK and trauma increases the risk of epithelial ingrowth after flap displacement.

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Although laser in situ keratomileusis (LASIK) has a good long-term safety profile, complications such as corneal flap displacement and epithelial ingrowth may occur, even many years after the initial surgery. Postoperative LASIK flap dislocations occur most commonly in the first 24 hours after surgery in approximately 1% to 2% of patients, mainly due to eye rubbing or eyelid motion such as squeezing and blinking.[1-4] Late flap displacement (> 1 week after surgery) is much rarer and has generally been described in single case reports and small case series.[5]

We analyzed the visual consequences of late-onset traumatic corneal flap displacement between 9 days and 13 years after LASIK.

PATIENTS AND METHODS

We performed a retrospective study based on data from our center from October 2002 to August 2021. The sample comprised 66 eyes from 66 patients with late traumatic LASIK flap displacements. The term "late" was defined as postoperative week 1 or later.[5]

The data collected included age, sex, type of eye injury, surgery/conservative treatment, visual acuity,

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preoperative refractive and keratometry parameters, and postoperative visual, refractive, and keratometry data at the last available visit. The intraoperative data on the refractive surgical procedure included pachymetry, depth of laser ablation, and patient collaboration (with 2 indicating poor collaboration and 5 indicating excellent collaboration). We also recorded postoperative flap complications such as epithelial ingrowth, flap-folds, haze, leucoma, diffuse lamellar keratitis (DLK), flap tears, part loss or amputation, and melting.

For the statistical analysis of visual data, Snellen visual acuity was converted to logMAR visual acuity. Efficacy was defined as logMAR (corrected distance visual acuity [CDVA] preoperative) – logMAR (uncorrected distance visual acuity [UDVA] posttreatment flap dislocation). Safety was defined as logMAR (CDVA preoperative) – logMAR (CDVA posttreatment flap dislocation). The onset of the traumatic dislocation after refractive surgery and the time between the complication and the surgical repair were also measured and correlated with the complications, final visual acuity, and loss of efficacy and safety.

Statistical Analysis

Efficacy and safety were both transformed to binary outcomes (loss of one or more lines and no change or gain in lines of visual acuity). Each binary outcome was entered as a dependent variable in a logistic regression analysis. The effects of time from surgery to complication and from complication to surgical repair were estimated, and the odds ratios (ORs) and probabilities were calculated. The same procedure was applied to investigate the effect of these variables on complications. The paired *t* test was used for the analysis of refractive, keratometric, and surgical data before and after the flap complication.

All analyses were performed using R Core Team software (R Foundation for Statistical Computing).

The study conformed to the tenets of the Declaration of Helsinki.

RESULTS

The prevalence of dislocation between 2003 and the end of 2020 was 66 of 541,263 LASIK procedures (0.0122%; 95% CI: 0.0094% to 0.0155%).

Table 1 shows demographic parameters, refractive surgery data, and mechanism of trauma. Blunt trauma was the most frequent mechanism involved.

The study of refractive, keratometric, and visual data before refractive LASIK surgery and at the last follow-up visit after resolution of the traumatic dislocation revealed statistically significant differences for all of the parameters as a result of the procedure.

TABLE 1
Demographics and Study Data (N = 66)

Characteristic	Value
Sex	
Female	26 (39.4%)
Male	40 (60.6%)
Age (years)	
Mean ± SD	35 ± 9
Range	20 to 68
Patient collaboration	
Poor	22 (33.3%)
Good	44 (66.7%)
Flap (µm)	
Mean ± SD	91 ± 21
Range	50 to 180
Median (Q1, Q3)	90 (80, 100)
Laser ablation (µm)	
Mean ± SD	70 ± 25
Range	29 to 126
Median (Q1, Q3)	68 (49, 86)
Pachymetry (µm)	
Mean ± SD	553 ± 29
Range	492 to 620
Median (Q1, Q3)	550 (535, 570)
Mechanism of trauma	
Trauma with sharp object	41.5%
Blunt trauma	58.5%

SD = standard deviation; Q1 = first quartile; Q3 = third quartile

Statistically significant differences were not observed for CDVA (Snellen scale and logMAR scale) (**Table 2**).

Figure 1 shows the analysis of visual acuity, efficacy, and safety, as well as the distribution of the cumulative percentage of eyes by amount of CDVA before LASIK and UDVA after the complication had been treated. The final spherical equivalent after flap displacement resolved was compared with the desired correction, as was the distribution of patients in terms of emmetropia as the outcome.

The median time from surgery to flap displacement was 92 days (range: 9 to 4,662 days), and the median time from complication to surgery was 0 days, because the displacement was resolved in the first 24 hours (standard deviation [SD] ± 0.1 days; range: 0 to 31 days). In 58 patients (65 eyes, 90%), the dislocated flap was repositioned using surgery; in the remaining 8 cases, treatment was conservative. Epithelial ingrowth was the most frequent complication after repositioning.

TABLE 2

Changes in Refractive and Visual Data Before and After Late Traumatic Dislocation

Parameter	Preoperative Refractive Surgery (N = 66)	After Resolution of Flap Dislocation (N = 66)	*P*[a]
Sphere (D)			< .001
Mean ± SD	-2.20 ± 2.93	0.06 ± 0.68	
Range	-9.00 to 5.00	-1.75 to 2.25	
Median (Q1, Q3)	-2.25 (-3.88, -1.06)	0.00 (-0.25, 0.25)	
Cylinder (D)			< .001
Mean ± SD	-1.15 ± 1.08	-0.60 ± 0.74	
Range	-5.00 to 0.00	-3.50 to 0.00	
Median (Q1, Q3)	-0.75 (-1.50, -0.50)	-0.25 (-1.00, 0.00)	
Spherical equivalent (D)			< .001
Mean ± SD	-2.44 ± 3.15	-0.24 ± 0.61	
Range	-9.25 to 4.50	-2.12 to 1.12	
Median (Q1, Q3)	-2.94 (-4.00, -1.53)	0.00 (-0.50, 0.00)	
Mean keratometry (D)			< .001
Mean ± SD	43.55 ± 1.34	41.29 ± 2.61	
Range	40.00 to 47.50	35.75 to 49.75	
Median (Q1, Q3)	43.50 (42.75, 44.25)	40.50 (39.75, 42.38)	
Mean astigmatism (D)			.13
Mean ± SD	-1.18 ± 0.77	-1.00 ± 0.65	
Range	-3.50 to 0.00	-3.25 to 0.25	
Median (Q1, Q3)	-1.00 (-1.34, -0.75)	-0.75 (-1.25, -0.50)	
UDVA (Snellen)			< .001
Mean ± SD	0.17 ± 0.23	0.84 ± 0.21	
Range	0.00 to 0.90	0.20 to 0.10	
Median (Q1, Q3)	0.10 (0.00, 0.30)	0.93 (0.74, 1.00)	
UDVA (logMAR)			< .001
Mean ± SD	1.60 ± 1.08	0.09 ± 0.15	
Range	0.05 to 2.70	-0.04 to 0.70	
Median (Q1, Q3)	1.00 (0.52, 2.70)	0.03 (-0.00, 0.13)	
CDVA (Snellen)			.72
Mean ± SD	0.95 ± 0.08	0.94 ± 0.13	
Range	0.60 to 1.00	0.30 to 1.20	
Median (Q1, Q3)	0.98 (0.90, 1.00)	1.00 (0.90, 1.00)	
CDVA (logMAR)			.55
Mean ± SD	0.02 ± 0.04	0.03 ± 0.08	
Range	-0.00 to 0.22	-0.08 to 0.52	
Median (Q1, Q3)	0.01 (-0.00, 0.05)	-0.00 (-0.00, 0.05)	

D = diopters; SD = standard deviation; Q1 = first quartile; Q3 = third quartile; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity
[a]*Paired* t *test.*

Complications included 26 (39.4%) patients with epithelial ingrowth, 22 (33.3%) patients with flap-folds, 8 (12.1%) patients with DLK, 3 (4.5%) patients with corneal leucoma, 3 (4.5%) patients with flap tear and part loss, and 2 (3.0%) patients with corneal melting.

Patients who underwent surgery tended not to present loss of efficacy ($P = .05$). No significant differences in efficacy or safety were observed between the various types of complication (epithelial ingrowth, flap-folds, haze, leucoma, DLK, flap tears, part loss or amputa-

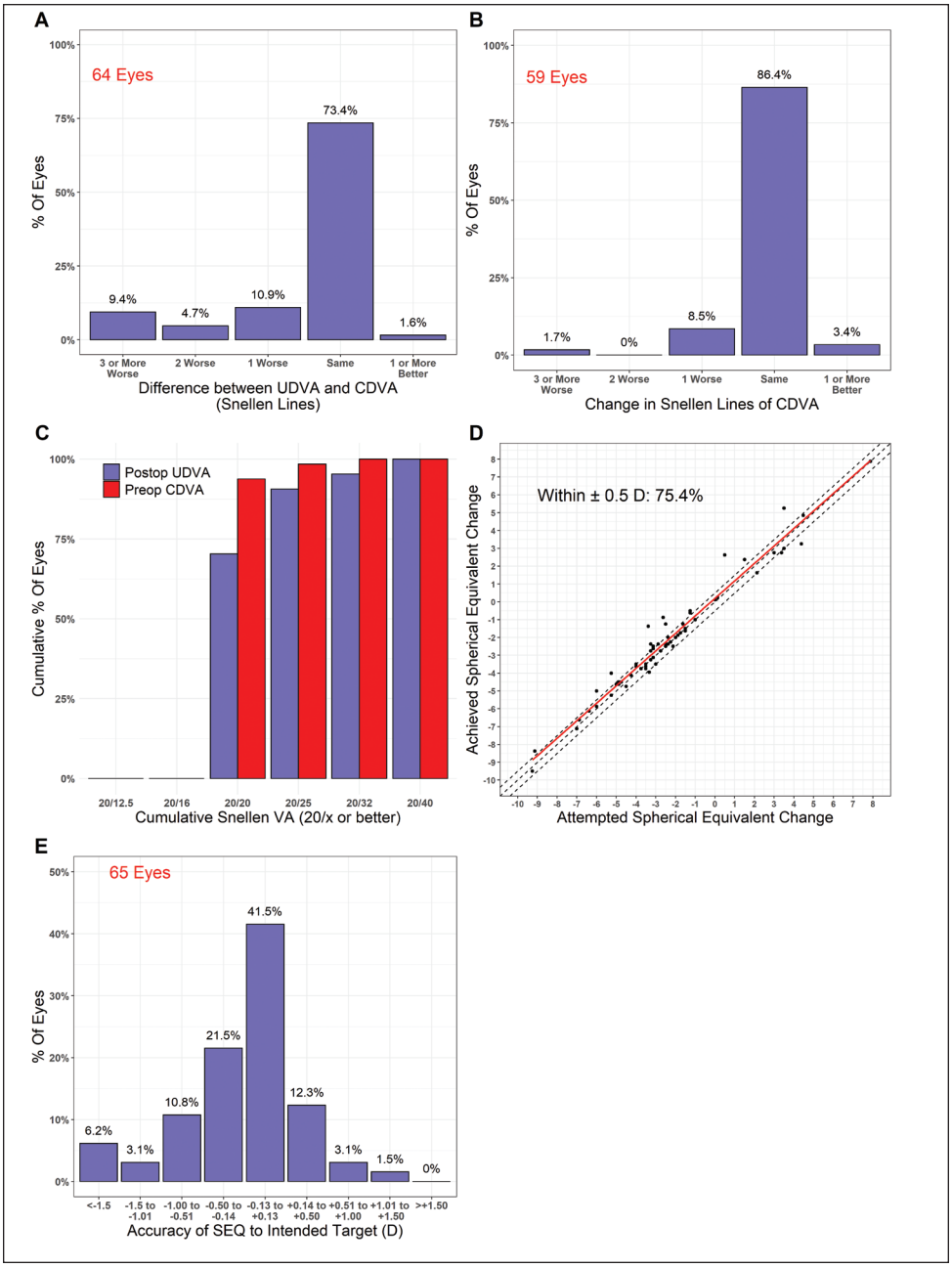

Figure 1. Analysis of visual acuity in terms of efficacy and safety after late traumatic dislocation of the corneal flap. (A) Distribution of patients based on efficacy after complication. (B) Distribution of patients according to safety. (C) Comparison of cumulative percentage of eyes based on preoperative uncorrected distance visual acuity (UDVA) and postoperative corrected distance visual acuity (CDVA). (D) Difference between attempted spherical equivalent (SEQ) refraction versus achieved spherical equivalent refraction. (E) Distribution of postoperative spherical equivalent refraction accuracy. D = diopters

tion, and melting) after resolution of the displacement (**Figure 2**).

A logistic regression model was applied to study the possible relationship between flap complications and interval between refractive surgery and trauma, and between traumatic dislocation and resolution. The risk of developing epithelial ingrowth increased with the time between LASIK and traumatic flap displacement (odds ratio [OR]: 1.001, $P < .001$). A tendency ($P > .10$) to develop epithelial ingrowth (OR: 1.12) and flap-folds (OR: 1.1) was observed when the interval between dislocation and surgery was long (**Figure 3**).

DISCUSSION

The frequency of flap complications is low compared with the number of LASIK procedures performed. Corneal flap dislocation was the most frequent complication after eye injury in patients who underwent LASIK in the largest case series published to date.[6] We observed that late dislocation of the corneal flap due to trauma has a prevalence of 0.0122% (95% CI: 0.0094% to 0.0155%). In their study of ocular trauma in military patients, Xiao et al[6] reported 550 cases of late traumatic flap complications after LASIK between the years 1998 and 2011 and recommended surface ablation in this professional group.

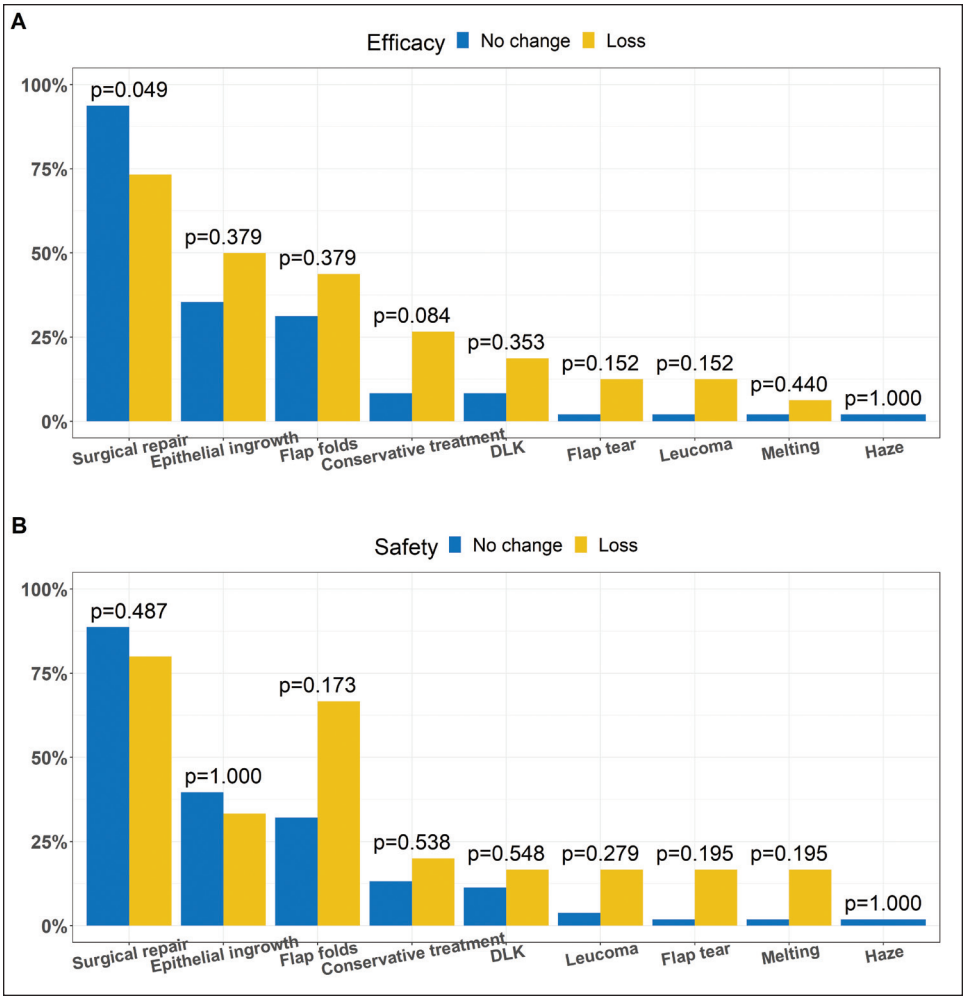

Figure 2. Relationship between (A) efficacy and (B) safety and the different variables studied after resolution of the traumatic flap dislocation. DLK = diffuse lamellar keratitis

Visual outcomes following surgical repair of a flap dislocation after LASIK are generally good. In this study, efficacy remained unchanged in 75% and safety remained unchanged in 90%. Postoperative UDVA of 20/40 was reached by 100% of patients and 20/20 by 70.3%. These results are similar to those published in the literature.[7-9]

Surgical resolution of traumatic flap dislocation maintained efficacy. The literature considers LASIK flap dislocations an emergency that is best managed by immediate surgery in the form of repositioning to prevent flap complications and preserve UDVA.[5] Because our clinic specializes in refractive surgery, traumatic late dislocation after LASIK surgery was resolved by surgical repositioning of the flap in 90% of patients in less than 24 hours. The rapid surgical response was associated with favorable visual outcomes. Six patients lost lines of safety and 16 patients lost lines of efficacy. In addition, the accuracy of the spherical equivalent with respect to the intended target was between -1.00 and +1.00 diopters in 86.4% of patients. Residual refractive astigmatism was -0.60 ± 0.74 diopters, and corneal astigmatism was -1.00 ± 0.65 diopters.

Furthermore, recovery of corneal sensation does not appear to be affected after traumatic flap dislocation. Published studies show that corneal sensitivity, noninvasive tear break-up time, and height of the meniscus tear in the injured eye can recover within 12 months after surgery. However, the discrepancy in the interocular ocular surface disease index, which reflects resolution of symptoms, required longer to resolve.[10]

The risk of epithelial ingrowth following LASIK is reportedly low, estimated at approximately 0% to 1%. However, this risk is increased when the flap is dislocated or lifted for re-treatment, especially 3 or more years after the initial LASIK procedure. Therefore, the risk of epithelial ingrowth increases with time after refractive surgery. In contrast with other case series, we did not find a relationship between the presence of flap complications and the loss of safety and efficacy. Late-onset epithelial ingrowth in patients with previous LASIK should raise the suspicion of occult flap displacement.[11]

We found that delayed action after traumatic flap dislocation tended to favor the development of flap-folds. Previous studies indicate that the risk of postoperative

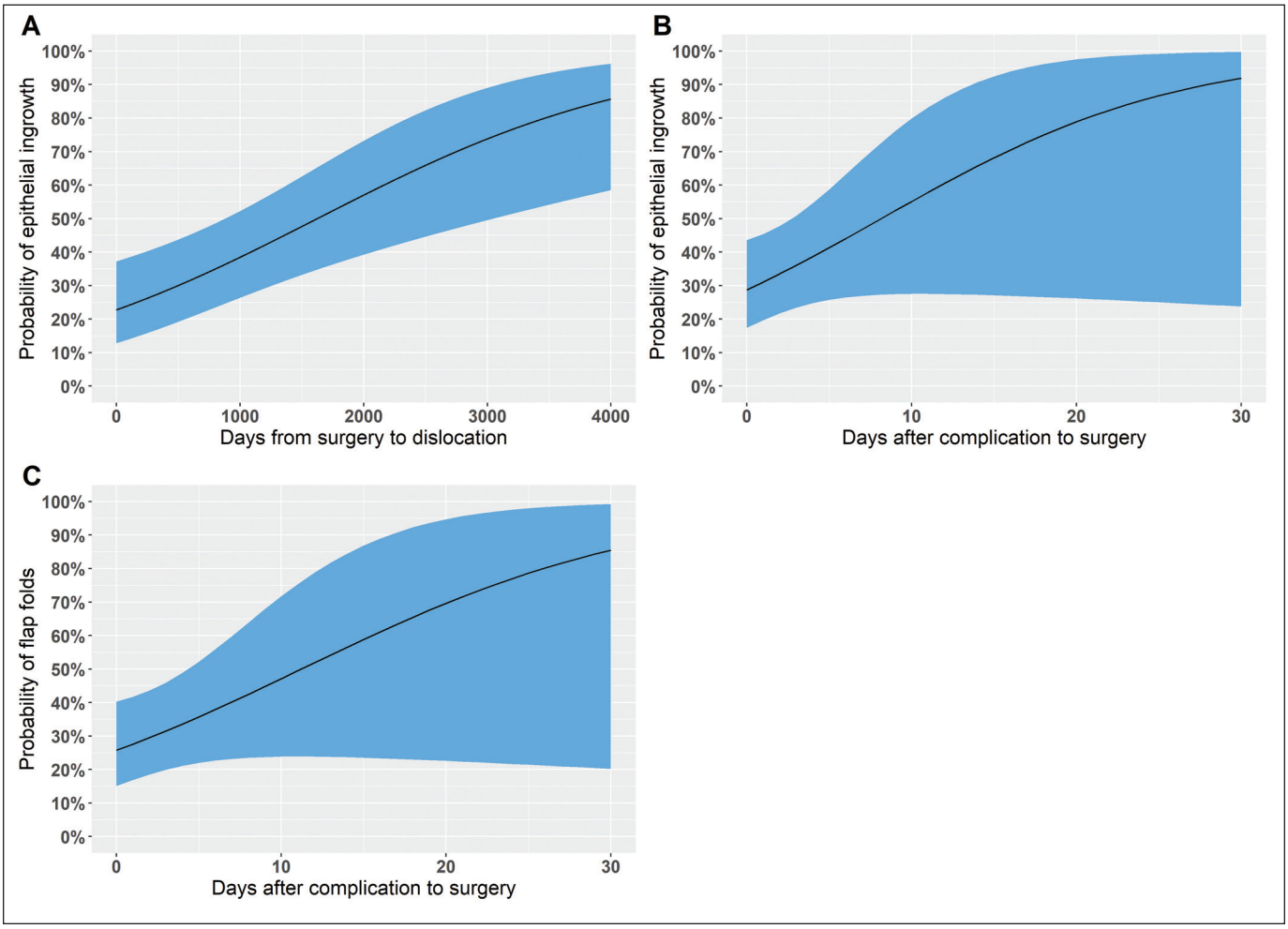

Figure 3. Effect of time as a variable in flap complications: (A) probability of epithelial growth in the flap as a function of time from refractive surgery to traumatic dislocation, (B) probability of epithelial growth in the flap as a function of time elapsed until resolution of the traumatic dislocation, and (C) probability of developing flap-folds in the flap as a function of time elapsed until resolution of the traumatic dislocation.

striae was affected by the duration of the displaced flap, probably because the longer duration of the injury results in greater adhesion/fibrosis within the striae, thus limiting complete smoothing of the flap during the operation. Therefore, prompt surgical repositioning reduces the risk of these postoperative complications.[11]

Surgical management of traumatic dislocation begins by lifting the dislocated flap for repositioning. Generally, the flap margin is easily identified owing to the presence of edema and/or epithelial ingrowth. Epithelial ingrowth and flap-folds must be resolved. Epithelial ingrowth can be treated by mechanical debridement, with or without other measures, including ethanol, suture, fibrin glue, or YAG laser treatment. Flap amputation is also considered a viable option in patients with recalcitrant epithelial ingrowth or significant flap injury.[12] In our sample, amputation of an unviable flap was necessary in 1 case, in which trauma with a tree branch caused infectious keratitis and lack of response to antibiotics. After amputation, decimal UDVA was 0.6, decimal CDVA was 0.7, and residual refraction was -1.00 -2.50 × 180°. Treatment was with topography-guided photorefractive keratectomy. After 1 year of follow-up, decimal UDVA was 0.9 and decimal CDVA was 0.94, with refraction of +0.75 -0.50 × 5°.

The use of alcohol in epithelial ingrowth remains controversial, and the literature shows various effective concentrations; however, high-concentration alcohol has been associated with flap melting. Given that a 25% concentration is considered the threshold for epithelial survival, 30% alcohol is recommended for removal of epithelial ingrowth. The use of higher concentrations does not seem to provide an additional benefit over simple mechanical scraping for removal and prevention of recurrence of epithelial ingrowth after LASIK.[13]

Flap-folds are treated by hydrating the flap, which, after being repositioned, is pressed with rotational movements of the barrel of a syringe as if it were a roller. Some authors advise removing the epithelium that covers the area of the flap-folds to release traction. Because the epithelial defect increases the risk of DLK and stromal haze, others reserve abrasion for mature or refractory striae or epithelial ingrowth. The use of phototherapeutic keratectomy involves similar considerations. Once repositioned, the flap can be ironed and sutured.[13,14] Given that the use of hypotonic solutions to hydrate the flap is controversial, some authors advocate hypotonic irrigation and hydration, whereas others caution that the risk of keratocyte lysis may outweigh the benefits of a more hydrating osmotic gradient.[14] Finally, we suggest removing the epithelium from the corneal periphery and using bandage contact lenses or sutures to ensure flap adherence and thus promote epithelial healing without ingrowth into the interface.[12,13]

New technologies for the creation of the corneal flap, namely, femtosecond laser treatment and small incision lenticule extraction, do not seem to eradicate this posttraumatic complication, and the behavior of the flap anatomy created by the small incision lenticule extraction technique after traumatic corneal impact is currently unknown.[6,15]

Our findings are subject to three limitations: few patients lost efficacy and safety, and the number of repositioned flaps with postoperative complications was low, thus making it difficult to assess the existing relationship with the variable time after LASIK surgery and after surgical resolution of the traumatic complication. Another limitation is that some patients who may have had traumatic flap dislocations may have sought care at alternative sites. Finally, our results may not reflect those observed in general ophthalmology hospitals.

Consistent with other authors, we observed that ophthalmological training programs do not incorporate refractive surgery, thus hampering identification and management of complications related to this clinical practice, with the subsequent repercussions for visual outcomes.

Late displaced corneal flap secondary to trauma after LASIK has a prevalence of 0.01%. Visual safety was good after resolution of the flap complication, and immediate surgical management led to better visual efficacy. The time from LASIK to injury increases the risk of developing epithelial ingrowth after a dislocation. Because there are no uniform criteria for management of flap complications, each case should be managed individually.

AUTHOR CONTRIBUTIONS

Study concept and design (YF-B, JO-U); data collection (YF-B, JB-S); analysis and interpretation of data (YF-B, JB-S, VD, JLR-N, JLG-G-C); writing the manuscript (YF-B); critical revision of the manuscript (JO-U, JB-S, VD, JLR-N, JLG-G-C); statistical expertise (VD); supervision (JO-U, JB-S)

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