ARTICLE

Clinically significant laser in situ keratomileusis flap striae

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Purpose: To describe the incidence, risk factors, and outcomes before and after irrigation of clinically significant laser in situ keratomileusis (LASIK) flap striae.

Setting: Multisurgeon multicenter standardized protocol practice.

Design: Retrospective case-control series.

Methods: Eyes with striae necessitating flap relift and irrigation were identified. Preoperative, intraoperative, and postoperative variables were collected. Incidence, risk factors, and outcomes were assessed.

Results: Of the 109 403 eyes that had LASIK, the incidence of striae-treated eyes was 0.79% (n = 875), with 8.7% irrigated the first hour after surgery. The preoperative spherical equivalent (SE) and ablation depth exponentially increased the striae risk (R^2 = 0.9674; P < .001). Striae induced a small hyperopic shift that reversed after the relift (mean 0.22 diopter [D] ± 0.52 [SD] versus −0.02 ± 0.45 D) (P < .001). After relifting, 68.0%, 87.0%, and 96.0% of eyes had an uncorrected distance visual acuity (UDVA) of 20/20, 20/25, 20/40 or better versus 25.0%, 55.0%, and 84.0%, respectively, before the relift (P < .001). Thirteen percent fewer striae-treated eyes achieved a UDVA of 20/20. Before relifting, 51.0% of striae eyes lost 1 or more lines of corrected distance visual acuity, with a safety index reverting to control values (0.99 versus 1.00) (P > .05) after the relift. A laser refractive enhancement was performed in 6.28% of relifted striae eyes versus 3.04% in nonstriae control eyes.

Conclusions: Flap striae requiring surgeon intervention occurred in 0.79% of eyes. Higher preoperative SE values were associated with an exponential increase risk for striae. Treatment by lifting and irrigation significantly improved the accuracy, efficacy, and safety to a level close to that of contralateral control eyes, although striae-treated eyes were more likely to need excimer laser retreatment.

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Having one of the lowest complication rates for an elective surgical procedure, laser in situ keratomileusis (LASIK) has gained broad acceptance and commands high patient expectations. Most significant complications occur intraoperatively during flap creation, but they can also occur postoperatively. Flap striae, or (micro and macro) folds, represent wrinkling of the flap tissue that can be seen on slitlamp biomicroscopy. Striae are one of the more common post-LASIK complications,[1–3] with an incidence reported to range between 0.033% and 3.5% in previous studies of more than 1000 eyes.[1–3] Without an optically smooth corneal surface, LASIK visual outcomes are compromised. Striae can induce corneal irregularity, resulting in decreased quality of vision, optical aberrations, a change in manifest refraction, monocular diplopia, loss of contrast sensitivity, loss of uncorrected (UDVA) and corrected (CDVA) distance visual acuities, as well as symptoms of glare, halos, ghosting, and foreign-body sensation.[2–9] Striae are also a cause of prolonged visual recovery and patient dissatisfaction and can present significant treatment challenges, especially if not treated adequately early.[2,9–15] Lifting the flap followed by hydrating, stretching, and repositioning is the most common treatment modality used.[9,16,17]

This study reviewed a large population of LASIK patients (109 403 eyes) who had microkeratome LASIK surgery in a multisurgeon multicenter corporate laser vision correction (LVC) setting using standardized protocol and operating technique. The purpose of this study was to accurately determine the incidence of and the risk factors for clinically significant post-LASIK flap striae requiring flap irrigation and to report striae outcomes before and after flap

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irrigation compared with those in contralateral eyes without striae.

PATIENTS AND METHODS

Selection of Patients

A review of an internally developed electronic medical record (EMR) database comprising consecutive eyes that had a primary microkeratome LASIK procedure between November 2012 and November 2014 at 25 Canadian LVC centers was performed. Post-LASIK eyes deemed to have clinically significant striae that had intervention with flap relift and irrigation were retrospectively identified. Eyes that had a history of post-LASIK trauma with flap displacement causing striae were excluded, thus reporting only eyes with spontaneously occurring striae. A subset of the study population comprising normal control eyes in which all preoperative variables were available was used for comparative purposes and termed the large-volume cohort.

This study was approved by the institutional ethics review board. Patient identifiers were fully removed from the database files. All procedures performed fulfilled the principles of the tenets of the Declaration of Helsinki, and all patients provided written consent for surgery and potential use of data for research.

Standardized Identification of Clinically Significant Striae

All surgeons used the same standardized criteria to identify striae that required intervention as follows: striae in proximity to the visual axis or within the pupil diameter causing a decrease in UDVA and/or CDVA or affecting quality of vision as subjectively described by the patient as causing halos, glare, ghosting, shadowing, or monocular diplopia. To further help delineate symptoms, patients were asked to look at a point source of light in a dark room and describe the image they saw, comparing it to the contralateral eye, in essence checking for a Maddox rod effect.[18] Before striae removal, a subset of patients had a preoperative examination including UDVA, CDVA, manifest refraction, and a slitlamp examination.

Surgeon Training

All 48 surgeons received identical training before performing their first case at their LVC clinic. One (or more) of 5 medical directors, each having performed more than 30 000 LVC procedures, provided the teaching. The training consisted of an observership and proctorship and required reading of laser refractive surgery proprietary manuals. Teaching included best practices of flap alignment, including ink-marking of the cornea, minimal irrigation for flap repositioning, meticulous flap positioning, flap distension, and detailed observation postoperatively to look for striae. Surgeons also attended a yearly didactic teaching conference and had access to expert opinion through an online surgeon's consultation group where these principles were reemphasized.

Surgical Technique

Laser In Situ Keratomileusis The LASIK procedures were performed with a standardized technique on identical equipment at all clinic locations. The cornea was marked with 2 asymmetrically overlapping circles using a Bores optic zone marker and inkpad (both Ambler Surgical). Hansatome microkeratomes (Z16 or Z18 head, Bausch & Lomb, Inc.) were used in combination with 8.5 or 9.5 mm suction rings to create corneal flaps. All surgeons followed a standardized protocol for microkeratome ring and head selection. The same microkeratome blade (Bausch & Lomb, Inc.) was used in both eyes. The Technolas Z100 laser (Bausch & Lomb, Inc.) with plano scan or Zyoptix software, Wavelight Allegretto 400 Hz laser (Alcon Laboratories, Inc.), or Wavelight EX-500 laser (Alcon Laboratories, Inc.) with Wavefront Optimized or FCAT software (Custom-Q), was used for excimer ablation. Surgery was performed first in the right eye and then in the left eye. Surgical tape was used to hold the right upper lid closed while surgery was performed in the left eye. Flaps were checked at the slitlamp immediately after surgery, and an additional flap check was performed 1 hour after the LASIK procedure.

Topical artificial tears (Refresh, Allergan, Inc.), gatifloxacin 0.3% (Zymar), and prednisolone acetate 1.0% (Pred Forte) were started right after surgery completion. All patients received education regarding proper drop instillation. Artificial tears were then given every half hour for the first day, hourly the second day, and then 4 times a day for 5 days. Gatifloxacin 0.3% was given 4 times a day for 5 days and prednisolone acetate 1.0% 4 times a day for 5 days. Patients were also instructed to avoid rubbing their eyes or squeezing their eyelids tight and wore protective sunglasses for 48 hours.

Striae Removal The striae removal technique was standardized per the surgeon training course and proprietary teaching manuals. All work was performed at the slitlamp, where patients first received 4 sets of proparacaine hydrochloride 0.5% eyedrops (Alcaine) and/or a proparacaine hydrochloride 0.5%–soaked pledget. After a small wire speculum (Ambler Surgical) was inserted, a 27-gauge cannula (Bausch & Lomb, Inc.) attached to a 5.0 mm syringe with a balanced salt solution was used for under-flap irrigation at the slitlamp. If the intervention was the same day, the flap edge was opened with the irrigating cannula. For interventions occurring after 24 hours, a Machat spreader (Ambler Surgical) or a spud-tip spreader (Instrumentarium) was used to open anywhere from 2 clock hours up to the entire flap edge with careful attention not to disrupt the epithelium. The amount of circumferential flap opening was dictated by the clinical situation. Before irrigation, any exposed stromal bed was cleaned of epithelium with a dry polyvinyl alcohol sponge (Merocel, Nu-Life Medical & Surgical Supplies, Inc.). Irrigation underneath allowed for swelling of the flap to remove striae and proper flap repositioning if needed. The cannula was then used to smooth the flap surface in the direction perpendicular to the striae axis and distend it. After irrigation, the flap edge was meticulously examined for gutter asymmetry, epithelial tags, and flap-edge inversion, which was then removed or rectified. After 1 hour, patients were reexamined at the slitlamp. If the appearance of striae was not significantly diminished, the procedure was repeated and the patient rechecked 1 hour later.

Post-Striae Removal Regimen

All patients received topical artificial tears, gatifloxacin 0.3%, and prednisolone acetate 1.0% identical to the protocol after uneventful LASIK procedures. Some patients received a bandage contact lens that was removed the next day at the discretion of the surgeon, depending on the surface epithelial status. In some cases, the involved eye was taped closed for 1 hour after relifting if the striae were severe or if poor endothelial function was thought to have played a role. All patients were told to keep their eyes closed between drops for the first hour after surgery. Patients were examined the next day, 1 week, and 1 month after the procedure. If the postoperative examinations were stable, patients were followed on an annual basis.

Data and Statistical Analysis

The incidence of visually significant striae needing flap relift and irrigation was calculated and time to diagnosis recorded. The pre-LASIK manifest refraction, UDVA, CDVA, pachymetry, maximum and minimum keratometry, and intraoperative laser treatment, ablation depth, optical zone, microkeratome head, and suction ring diameter were recorded to determine potential risk factors. Risk factors were assessed by comparing preoperative variables and intraoperative variables in eyes with striae that had a relift eyes with those in the large-volume cohort of eyes that had microkeratome surgery with the identical protocol and equipment. For eyes with a follow-up of more than 3 months after the

relift procedure, the pre-LASIK, pre-relift, and post-relift manifest refraction, UDVA, and CDVA were obtained to report standard refractive surgery accuracy, efficacy, astigmatism vector analysis, safety, and stability and to compare outcomes against contralateral, nonstriae, control, LASIK eyes. Postoperative data obtained before subsequent excimer enhancement (laser retreatment) were used.

All statistical analyses were performed using Matlab R2016B software (Mathworks, Inc.). The nonparametric Wilcoxon rank-sum test for independent samples was used to compare eyes with striae that had a relift with the eyes in the large-volume cohort and to compare eyes with striae that had a relift with the contralateral control eyes without striae. The 1-sample t test and the 2-sample chi-square test were used to compare between proportions. Statistical significance was set at a P value of less than 0.05. All data are reported as the mean $\pm$ SD.

RESULTS

Out of 109 403 LASIK procedures, post-LASIK striae requiring flap relift and irrigation occurred in 875 eyes, resulting in an overall incidence of 0.79%. The mean age of the patients with striae was 35.7 $\pm$ 10.4 years.

Table 1 shows the demographics of the striae cases as well as the time of the diagnosis of the striae. There was no statistically significant difference in the incidence of striae between men and women ($P = .16$) or between hyperopic eyes and myopic eyes ($P = .18$). Striae intervention occurred more often in left eyes than right eyes, and the difference was statistically significant ($P < .001$). Fifty-seven treated eyes (6.5%) required a second relift and irrigation on a separate day. At the time of intervention, 26 eyes (3.0%) had co-occurring under-flap debris. Diffuse lamellar keratitis was found in 20 eyes (2.3%), 12 eyes (1.4%) had an epithelial defect, and the other 817 eyes were unremarkable. The mean time to flap relift was 2.36 $\pm$ 4.22 days after LASIK. Of the 875 eyes with striae, 738 (84.3%) were detected and treated within day 1 after LASIK and 810 eyes (92.6%) were detected within 1 week. A same-day slitlamp examination after intervention showed that the striae resolved completely in 700 eyes (80.0%) and that 175 eyes (20.0%) still had some visible residual striae, but with significant improvements. Follow-up data for more than 3 months were available for 459 eyes that had a relift and 328 contralateral control eyes that did not have a relift.

Table 1. Demographic data and time to relift in 875 eyes with striae.

Parameter	Value
Eyes requiring 2nd relift, n (%)	57 (6.51)
Myopic eyes, n (%)	828 (0.81)
Hyperopic eyes, n (%)	47 (0.66)
Affected eye, n (%)	
Right	294 (33.6)
Left	375 (42.9)
Both	206 (23.5)
Sex, n (%)	
Male	423 (48.3)
Female	452 (51.7)
Age (y)	
Median $\pm$ SD	33 $\pm$ 10.4
Range	18, 70
Months of follow-up	
Median $\pm$ SD	7 $\pm$ 4.7
Range	3, 26
Post-LASIK time to relift (d)	
Median $\pm$ SD	1.00 $\pm$ 4.22
Range	0, 35
Number (%) eyes diagnosed within	
Same day	76 (8.7)
Day 1	662 (75.7)
48 hours–1 week	72 (8.2)
1 week–1 month	61 (7.0)
>1 month	4 (0.4)

LASIK = laser in situ keratomileusis

Risk Factors

Table 2 compares the preoperative and the intraoperative characteristics between the eyes with striae that had a relift and eyes in the large-volume cohort of 79 944 eyes. The pre-LASIK UDVA, manifest refraction sphere, cylinder, and spherical equivalent (SE) were significantly higher in striae eyes than in eyes in the large-volume cohort ($P < .0001$). The total ablation depth and the percentage of corneal tissue ablated were also significantly higher in the eyes with striae ($P < .0001$). The Z values in Table 2 show that the most significant difference between the eyes with striae and eyes in the large-volume cohort was in the preoperative SE. A greater percentage of eyes with striae had a preoperative SE value greater than 4.00 D than eyes in the large cohort of normal eyes (Figure 1, *A*). The probability density ratio showed an exponential risk for developing striae necessitating a relift with increasing preoperative SE values ($R^2 = 0.9674$, $P < .0001$) (Figure 1, *B*). Nearly identical probability density patterns were obtained for preoperative sphere and cylinder, total ablation depth, and percentage of corneal tissue ablated (not reported). In contrast, the CDVA, central corneal thickness, maximum and minimum keratometry, and optical zone were not associated with an increased striae risk (all $P > .05$).

Table 3 shows the incidence of microkeratome head and ring size use. The proportions were nearly identical between eyes having a relift and eyes in the large-volume cohort (all $P > .05$). Last, the striae incidence rate per month was similar ($P = .89$), indicating that the incidence of striae did not vary by season across the calendar year.

Vision Efficacy

Table 4 compares the changes in refraction and visual acuity between the eyes with striae that had a relift and eyes in the large-volume cohort. Before treatment, LASIK flap striae significantly worsened vision, reducing the UDVA and CDVA logarithm of the minimum angle of resolution values; the difference between the 2 groups was statistically significant (both $P < .001$). There was also a large decrease in the percentage of pre-relift striae eyes achieving a

Table 2. Comparison of preoperative and intraoperative characteristics between relifted eyes and large-volume cohort.

Parameter	Relift		Large Cohort		*P* Value	Z Value
	Mean ± SD	Range	Mean ± SD	Range		
Visual acuity (logMAR)						
UDVA	1.47 ± 0.60	0.00, −2.00	1.32 ± 0.61	−0.12, −2.00	<.0001	7.00
CDVA	−0.03 ± 0.06	−0.12, 0.40	−0.03 ± 0.06	−0.12, 0.88	.27	1.08
Manifest refraction (D)						
Sphere	−3.85 ± 2.47	−10.5, +4.50	−2.79 ± 2.27	−12.5, +5.75	<.0001	12.50
Cylinder	−0.90 ± 0.85	−5.00, −0.00	−0.82 ± 0.81	−7.25, 0.00	<.0001	3.12
SE	−4.30 ± 2.46	−11.25, +4.25	−3.20 ± 2.23	−13.00, +5.38	<.0001	13.50
Topography* variables						
CCT (um)	562 ± 32	449, 647	562.7 ± 37.30	439, 688	.89	0.13
Kmax (D)	44.42 ± 1.62	40.6, 50.0	44.39 ± 1.89	39.4, 50.5	.82	0.22
Kmin (D)	43.35 ± 1.56	39.0, 49.0	43.33 ± 1.41	37.3, 48.4	.97	0.04
Laser treatment						
Total ablation (μm)	76.1 ± 29.8	11.9, 165	62.76 ± 25.8	11.7, 165.4	<.0001	13.40
Tissue ablated (%)	13.33 ± 5.36	2.8, 26.3	11.17 ± 4.49	1.9, 28.91	<.0001	9.52
Optical zone (mm)	6.48 ± 0.20	5.7, 7.2	6.48 ± 0.19	5.5, 7.3	.75	0.32

CCT = central corneal thickness; CDVA = corrected distance visual acuity; Kmax = maximum keratometry; Kmin = minimum keratometry; SE = spherical equivalent; UDVA = uncorrected distance visual acuity
*Orbscan (Bausch & Lomb)

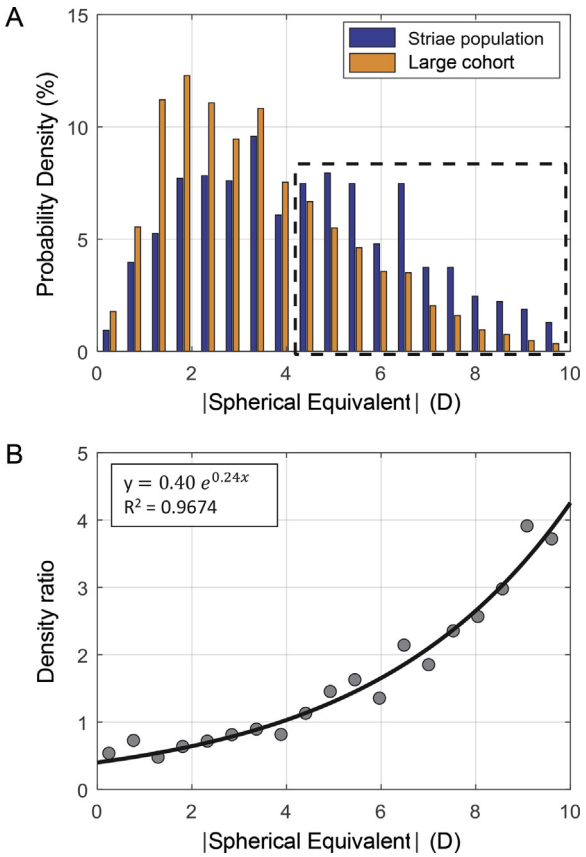


Figure 1. *A*: Distribution of the absolute SE variable in the striae population and general large-volume cohort. The population histograms are reported as normalized probability density histograms to account for the sample-size differences in the 2 study populations. The dashed-line rectangle highlights the region with increased likelihood of striae. *B*: Probability density ratios (also termed relative risk) obtained at each SE value (*gray circles*) obtained by dividing the probability density in the striae population (*in panel A*) by that of the general large-volume cohort (*in panel A*).

cumulative Snellen UDVA of 20/20, 20/25, 20/30, and 20/40 compared with contralateral control eyes ($P < .001$) (Figure 2, *A*). Flap relifting and irrigation significantly improved vision, increasing the UDVA and CDVA (both $P < .001$). Fewer post-relift eyes than control eyes achieved a UDVA of 20/20 (Figure 2, *A*), resulting in post-relift UDVA that was slightly, but statistically significantly, below control levels ($P < .001$). The striae-induced UDVA decrease was also apparent when comparing the difference in Snellen lines of pre-LASIK CDVA and the pre-relift UDVA ($P < .001$) (Figure 2, *B*). After relift, the pre-LASIK CDVA to post-relift UDVA was significantly improved to near control levels ($P < .001$) (Figure 2, *B*). Finally, although striae resulted in a significantly decreased LASIK efficacy index of 0.73 ± 0.25 (pre-relift) compared with control values (0.96 ± 0.12) ($P < .001$), the index significantly improved to near control levels after relifting (0.91 ± 0.17) ($P < .001$).

Refractive Accuracy

Untreated LASIK flap striae induced a small, but statistically significant, hyperopic shift in the manifest refraction

Table 3. Incidence of microkeratome head and ring size.

Parameter	Number (%)		*P* Value
	Relift	Large Cohort	
MK head			
Z16	708 (80.89)	62 620 (78.33)	.6477
Z18	167 (19.11)	17 324 (21.67)	.9686
Ring size (mm)			
8.5	188 (21.49)	16 157 (20.21)	.7078
9.5	687 (78.51)	63 787 (79.79)	.7078

MK = microkeratome

Table 4. Changes in refraction and visual acuity in striae-treated eyes.

Parameter	Pre-Relift		Post-Relift		*P* Value	Control		*P* Value	
	Mean ± SD	Range	Mean ± SD	Range		Mean ± SD	Range	Pre-Relift	Post-Relift
Manifest refraction (D)									
Sphere	0.30 ± 0.56	−1.50, +4.25	0.11 ± 0.43	−1.75, +1.75	<.001	0.05 ± 0.32	−1.00, +1.50	<.001	.089
Cylinder	−0.17 ± 0.39	−0.17 ± 0.39	−0.25 ± 0.34	−0.25 ± 0.34	.0195	−0.16 ± 0.24	−1.25, 0.00	.7243	.004
SE	0.22 ± 0.52	−1.50, +3.50	−0.25 ± 0.34	−2.00, +1.25	<.001	−0.03 ± 0.34	−1.13, +1.38	<.001	.637
Visual acuity (logMAR)									
UDVA	0.20 ± 0.20	−0.12, 1.30	0.07 ± 0.13	−0.12, 1.00	<.001	0.04 ± 0.09	−0.12, 1.00	<.001	<.001
CDVA	0.10 ± 0.10	−0.12, 0.88	0.01 ± 0.04	−0.12, 0.40	<.001	0.01 ± 0.04	−0.12, 0.30	<.001	.022

CDVA = corrected distance visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity

SE compared with control eyes ($P < .001$) (Table 4). This refractive worsening was more pronounced for the manifest refraction sphere ($P < .001$) than for the manifest refraction cylinder ($P = .72$). There was no significant difference in the attempted versus the achieved SE accuracy between post-relift treated striae eyes and control eyes ($R^2 = 0.9856$ and 0.9868, respectively) (Figure 3, *A*). After relifting, 448 eyes (97.5%) and 389 eyes (84.7%) were within ±1.00 D and ±0.50 D of the intended correction, respectively, compared with 324 (98.9%) and 306 (93.3%) control eyes, respectively (Figure 3, *B*). There was a significant improvement in SE from before relifting to after relifting ($P < .001$) (Table 4). The sphere also improved significantly ($P < .001$), while cylinder was slightly enhanced ($P = .02$). Figure 3, *C*, shows the percentage of eyes within ±0.25 D, ±0.50 D, and ±1.00 D of the intended plano cylinder after relift compared with the percentage of control eyes; the difference was significant ($P = .004$). There was a clinically minor, but statistically significant, increase in cylinder magnitude after relift compared with controls ($P = .004$).

Cylinder Vector Analysis

The target induced astigmatism (TIA) versus surgically induced astigmatism (SIA) vector scattergram showed no significant differences between post-relift eyes and control eyes ($R^2 = 0.8741$ and 0.9172, respectively; $P = .13$) (Figure 3, *D*). The SIA and TIA vectors showed similar vector means in the post-relift Alpins' standard graphs (Figure 4). Table 5 shows the cylinder vector analysis results. After relift, the mean correction index was close to that in the control eyes ($P = .9935$). In post-relift eyes and control eyes, the angle of error was within −15 degrees and +15 degrees in most eyes. A minor, yet statistically significant, decrease was noted in the difference vectors ($P = .002$) and index of success ($P = .0024$) between post-relift eyes and contralateral control eyes. There were no significant differences in other vector analysis parameters.

Safety

Figure 5, *A*, shows the lines of Snellen CDVA lost and gained before and after the relift and irrigation and in the control eyes. Compared with control eyes, the safety index was significantly reduced before relift (0.86 ± 0.09 versus 1.00 ± 0.06) ($P < .001$). The relift intervention significantly improved safety, with most eyes having no change. As a result, the post-relift CDVA (Figure 5, *B*) and safety index (0.99 ± 0.07) were significantly improved to control levels ($P < .001$).

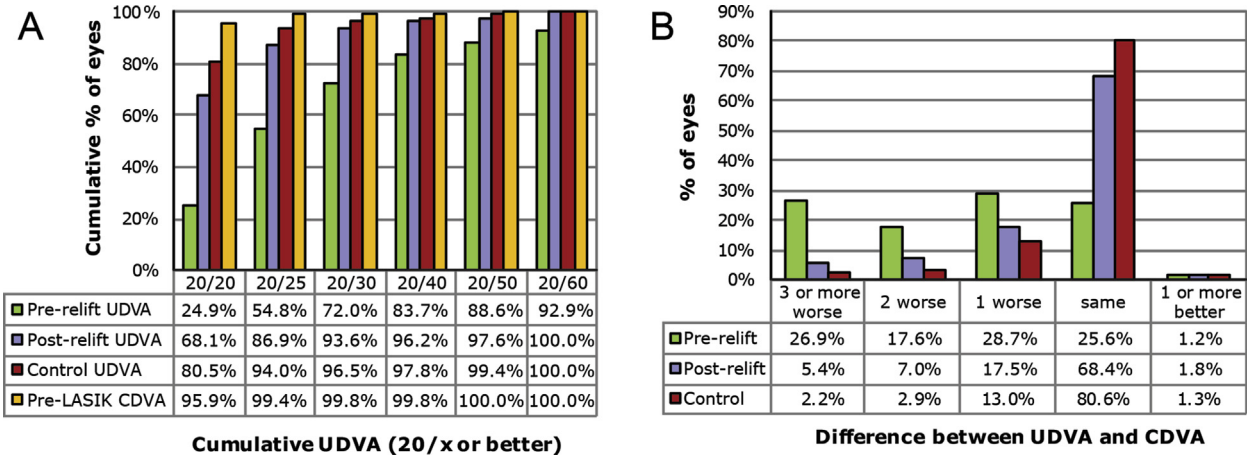
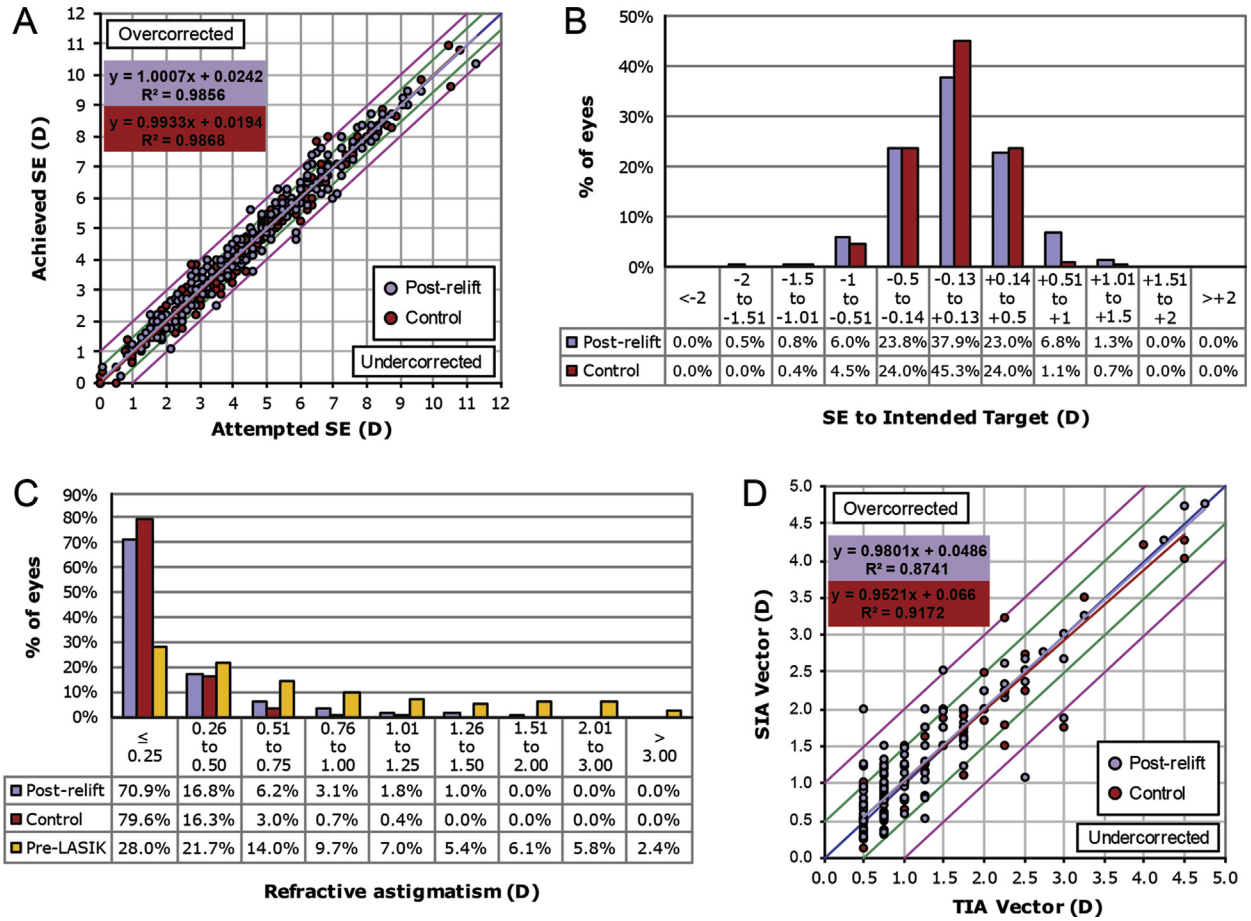


Figure 2. *A*: Cumulative Snellen UDVA before and after relift and in contralateral control eyes compared with pre-LASIK CDVA. *B*: Difference in Snellen lines of UDVA before and after relift and in contralateral control eyes compared with pre-LASIK CDVA (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).



	<-2	-2 to -1.51	-1.5 to -1.01	-1 to -0.51	-0.5 to -0.14	-0.13 to +0.13	+0.14 to +0.5	+0.51 to +1	+1.01 to +1.5	+1.51 to +2	>+2
Post-relift	0.0%	0.5%	0.8%	6.0%	23.8%	37.9%	23.0%	6.8%	1.3%	0.0%	0.0%
Control	0.0%	0.0%	0.4%	4.5%	24.0%	45.3%	24.0%	1.1%	0.7%	0.0%	0.0%

	≤ 0.25	0.26 to 0.50	0.51 to 0.75	0.76 to 1.00	1.01 to 1.25	1.26 to 1.50	1.51 to 2.00	2.01 to 3.00	> 3.00
Post-relift	70.9%	16.8%	6.2%	3.1%	1.8%	1.0%	0.0%	0.0%	0.0%
Control	79.6%	16.3%	3.0%	0.7%	0.4%	0.0%	0.0%	0.0%	0.0%
Pre-LASIK	28.0%	21.7%	14.0%	9.7%	7.0%	5.4%	6.1%	5.8%	2.4%

Figure 3. *A*: Attempted versus achieved SE in post-relift and contralateral control eyes. Blue line indicates attempted = achieved. Green lines indicate ±0.50 D. Pink lines indicate ±1.00 D. *B*: Intended target post-relift compared with contralateral control eyes. *C*: Refractive astigmatism accuracy in post-relift and contralateral control eyes compared with pre-LASIK. *D*: Pre-LASIK TIA vector versus SIA vector for post-relift and contralateral control eyes. Blue line indicates TIA = SIA, green lines indicate ±0.50 D, pink lines indicate ±1.00 D (SE = spherical equivalent; SIA = surgically induced astigmatism; TIA = target induced astigmatism).

Stability

At all timepoints (pre-LASIK, 1 month, 3 months, and >3 months), the post-relift SE was not significantly different from that in contralateral control eyes ($P = .637$) (Figure 6). The 2 groups had identical stability profiles. Fifty-five relifted eyes (6.28%) had a laser refractive enhancement between 2 years and 4 years after LASIK. In contrast, 20 (3.04%) of the control eyes had an enhancement during the same period.

Complications

Six eyes (0.69%) eventually required sutures for flap stretching after an unsuccessful second relift and irrigation. Nine eyes (1.03%) were treated for epithelial ingrowth with removal.

DISCUSSION

Flap striae are thought to be the most common complication after LASIK surgery, with the literature quoting rates between 0% and 12.8%[2,9–15] and between 0.033% and 3.5% in previous studies of more than 1000 eyes.[1–3] We believe that there are no published reports comparable to the current study's sample size. Our large retrospective review of 109 403 consecutive eyes within a corporate multisurgeon multicenter standardized technique practice, showed an incidence of 0.79%, or 1 in 125 eyes requiring post-LASIK intervention. This compares similarly to Krueger et al.'s unpublished retrospective review[A] of a high-volume expert surgeon group in Japan in which 0.85% of eyes with striae had an intervention. Because not all striae require treatment, the true incidence of striae in the current study population is higher because cases that did not affect vision and did not receive a relift are not reported in this paper.

Bilateral striae accounted for 23.5% of eyes needing intervention. Given that the preoperative and intraoperative variables were not significantly different from those in unilateral cases, these bilateral cases might suggest an anatomic or physiologic predisposition as a cause in certain patients. A weaker corneal endothelial pump with resultant diminished flap adherence might be one example. Bilateral striae could also occur in "hard blinkers" with more forceful contraction of their lids (ie, squeezing) or tighter lid apposition, leading to increased friction and flap movement causing striae.[7] Dry ocular surface conditions and adhesion of the flap

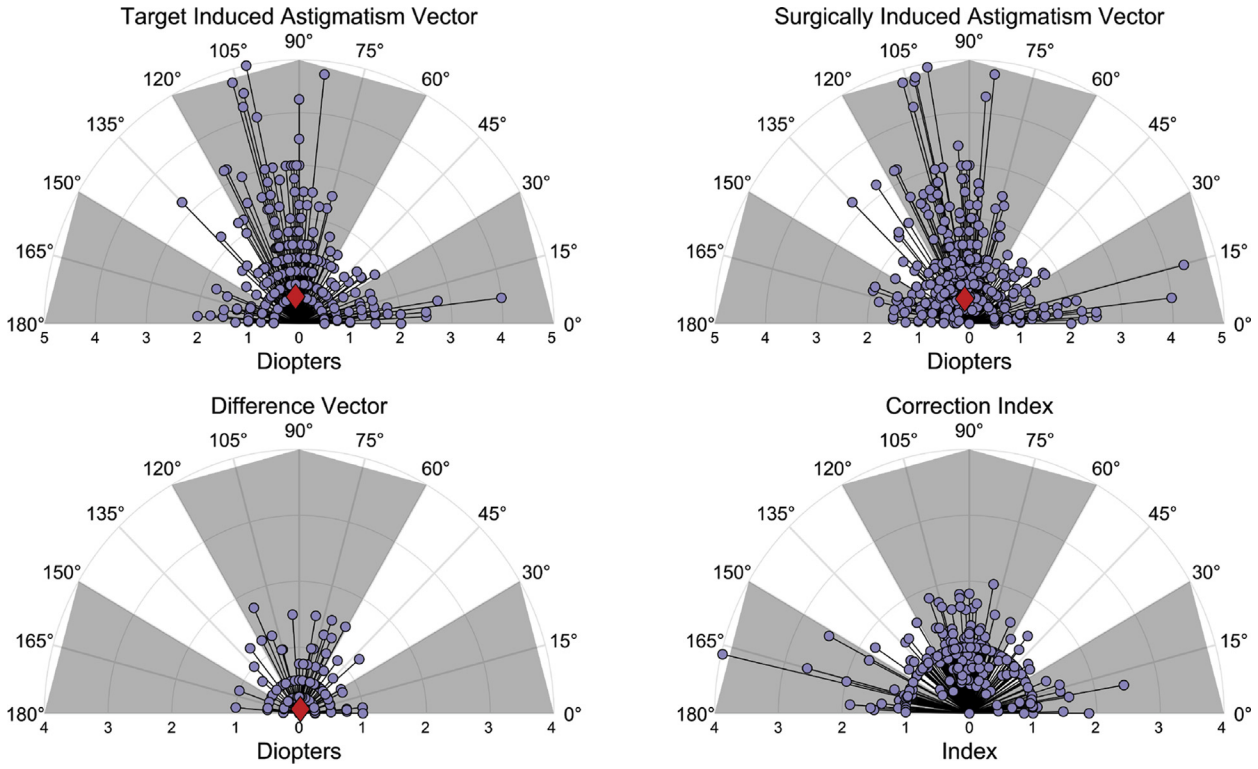


Figure 4. Post-relift single-sided polar plots for the TIA vector, the SIA vector, the difference vector, and the correction index. The vector means are plotted as a red diamond.

to the tarsal conjunctiva might also be causative.[19] Decreased tear breakup time has been reported as a risk.[15] Although this study did not assess dry eye as a variable, patients who presented with a poor ocular surface preoperatively were aggressively treated before surgery according to protocol, whereas a postoperative standardized dry-eye regimen of lubrication, punctual plugs, topical steroids, and cyclosporine 0.05% (Restasis) was used when indicated. Although eyes with known trauma were excluded, this study did not ask patients about eye rubbing and thus we cannot comment on this factor as being causative.[7]

A greater percentage of left eyes (42.9%) than right eyes (33.6%) had striae ($P < .001$), and this difference was the same for both microkeratome heads. Because the same keratome blade was used in second (left) eyes, left-eye flaps were cut thinner for both microkeratome heads, as previously reported in the literature[20] and validated here (Table 6). Although left-eye flaps were thinner and left eyes had a greater incidence of striae, one cannot simply assume a causal relationship between thinner flaps and striae.

Intraoperative pachymetry showed that left eyes in which the Z16 microkeratome head was used had the

Table 5. Cylinder vector analysis.

Variable	Post-Relift	Control	*P* Value
Preop cylinder >0.50 D (n)	343	234	—
Mean TIA ± SD	1.23 ± 0.83	1.14 ± 0.75	.0874
Mean SIA ± SD	1.27 ± 0.86	1.15 ± 0.74	.0761
Mean DV ± SD	0.23 ± 0.35	0.13 ± 0.23	.0021
Mean CI ± SD	1.05 ± 0.33	1.03 ± 0.23	.9935
Mean IoS ± SD	0.24 ± 0.41	0.14 ± 0.27	.0024
Mean ME ± SD	−0.04 ± 0.30	−0.01 ± 0.21	.9844
Mean AE ± SD	−0.33 ± 12.39	−0.10 ± 6.17	.4556
ME within ±1.00 D (%)	98.25	99.57	—
ME within ±0.50 D (%)	93.00	97.44	—
AE within ±15 degrees (%)	92.42	97.01	—
AE >15 degrees (%)	3.50	1.71	—
AE <−15 degrees (%)	4.08	1.28	—

AE = angle of error; CI = correction index; DV = difference vector; IoS = index of success; ME = magnitude of error; n = eyes; SIA = surgically induced astigmatism vector; TIA = target induced astigmatism vector

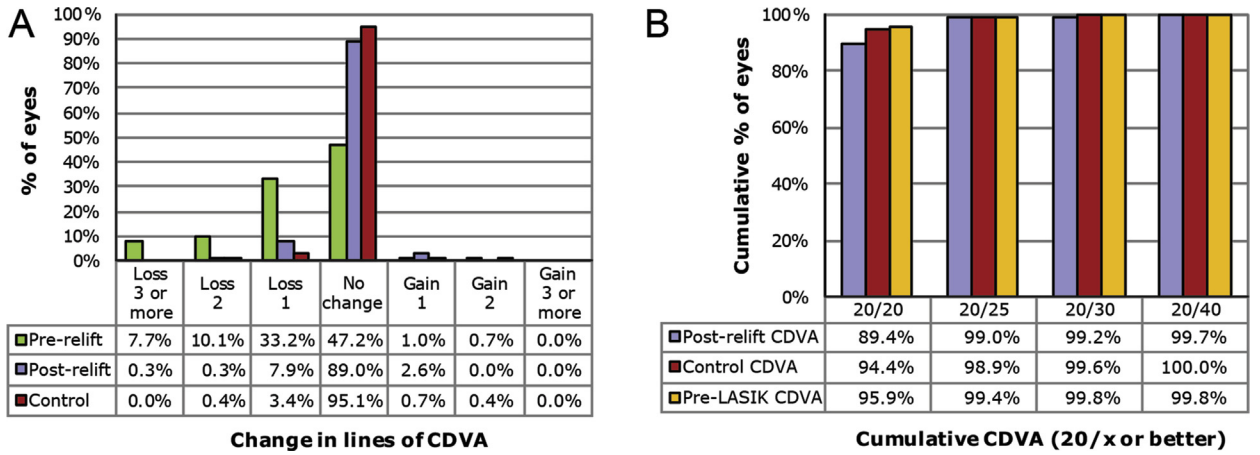


Figure 5. *A*: Change in Snellen lines of CDVA before and after relift and in contralateral control eyes compared with pre-LASIK CDVA. *B*: Cumulative Snellen CDVA in post-relift and contralateral control eyes compared with pre-LASIK CDVA (CDVA = corrected distance visual acuity).

thinnest flaps at 109.9 μm (mean) but did not have a higher striae rate than thicker left eyes in which the Z18 microkeratome head was used ($P = .63$) (Table 6). Right-eye (first surgery and thicker) flaps in which the Z16 head was used were on average 127.45 μm, and left-eye (second surgery and thinner) flaps in which the Z18 head was used were on average 126.95 μm. Although right eyes in which the Z16 head was used and left eyes in which the Z18 head was used had similar flap thicknesses ($P = .56$), the left eyes still had a significantly greater incidence of striae ($P < .001$). This would suggest that flap thickness was not a risk factor for striae but rather something related to left eyes was potentially responsible. Although it has been reported that thinner flaps might increase the rate of flap striae with microkeratomes,[9,15,19,21] our findings do not support that thesis. One explanation for the difference in striae rates between the 2 eyes is that right eyes were taped closed for 3 to 5 minutes during the left-eye procedure, while left eyes did not receive this treatment. Taping the right eyelid closed immediately after flap replacement could confer a protective effect against developing striae. It may be the reason left eyes had a greater striae incidence in the current study and why thinner flaps appear to have greater striae risk in previous studies. Taping both eyes closed for a period after surgery might be warranted to reduce the likelihood of striae. Further studies with direct comparison of right and left eyelid taping would be needed to definitively confirm such a conclusion.

Studies[9,21] have shown a higher incidence of flap striae in eyes with high myopia. Similarly, in our study, the preoperative SE and the total ablation depth (directly correlated) were found to be the most significant striae risk factors, exponentially increasing the likelihood of striae (Figure 1). Our exponential model, defined as $y = 0.4e^{0.24x}$, can be used to derive the relative risk (y variable) for developing striae as a function of absolute preoperative SE (x variable). For example, a patient treated for 10.0 diopters (D) of myopia would be 6.82 times more likely to develop striae than a patient treated for 2.0 D of myopia. Increasing ablation depth leading to a greater mismatch of flap tissue to the underlying stromal bed might be the cause of the increased risk for striae with increasing SE and has been described in myopia.[9,17] The flap has its own tissue rigidity and might have to adapt itself by deforming or folding over the new central flatter shape of the ablated stromal surface. This is the theory of resulting flap redundancy and the tenting effect.[9,17] In our observations, the clinical appearance of striae in high myopia tends to be fine, paracentral, and often radially oriented microstriae, seated over the central depression, which would be in line with the above mismatch

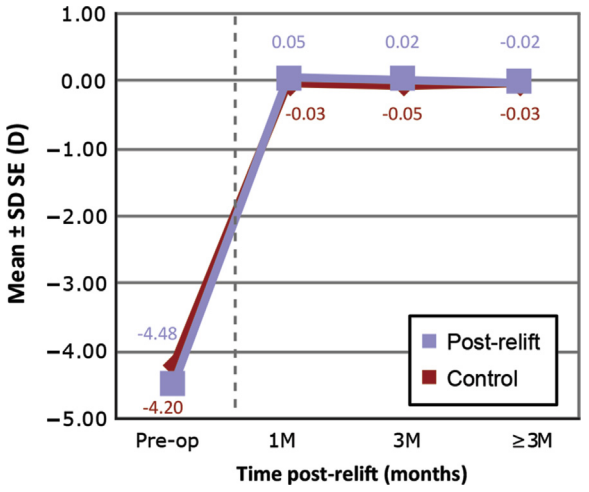


Figure 6. Spherical equivalent stability from before LASIK to over 3 months after LASIK in post-relift and contralateral control eyes (SE = spherical equivalent).

Table 6. Flap thickness by microkeratome head size.

MK Head	Mean Thickness (μm) ± SD		*P* Value
	Right Eye	Left Eye	
Z16	127.45 ± 21.81	109.9 ± 19.31	<.001
Z18	146.95 ± 23.36	126.95 ± 22.25	<.001

MK = microkeratome

theory. Given the above, we believe that the main risk factor for striae is the total ablation depth. Inadequate surgeon distention of the flap on repositioning might also contribute, and surgeons should spend extra time to properly distend flaps in eyes with higher ablations.

The incidence of striae was not statistically different between hyperopic and myopic patients (0.66% versus 0.81%; $P = .18$). Similar to patients with high myopia, those with higher hyperopia (eg, +2.25 to +4.00 D) were also more likely to develop striae than those with lower hyperopia (eg, +0.25 to +2.00 D). However, considering that the ablation depth was 4-fold greater in myopia than hyperopia, there might be additive mechanisms for striae development in hyperopic eyes. An increased incidence of early flap displacement, but not an increase in clinically significant striae, was previously reported in a small number of hyperopic eyes.[22] Additional study is required to draw definitive conclusions in hyperopic eyes.

Detection and treatment at the 1-hour postoperative check accounted for 8.7% of eyes (76 eyes) with striae, and 84% of eyes with striae (738 eyes) were treated within the first postoperative day. Many spontaneously occurring striae develop in the initial hours after surgery before the flap strongly adheres to the stromal bed. Keeping patients in the clinic for an hour rather than immediately letting them go home allows early treatment of eyes in which striae develop right after surgery. Regarding seasonality, the relative percentages of striae cases per month were identical to the relative percentages of surgeries performed in those months, suggesting that outside weather and seasonality do not affect the likelihood of striae.

Laser in situ keratomileusis flap striae induced a clinically small (~0.25 D) but statistically significant hyperopic shift in outcomes ($P < .001$), as documented elsewhere.[15,19,21] Although the optical reasons for this shift remain to be elucidated, we postulate that flap striae undulations cause slight flap elevation with resultant localized steepening near the visual axis, giving a mild hyperopic effect. The effect is variable as to the location and severity of striae. Although striae were also shown to induce astigmatism in a series of 91 eyes,[15] this study of 459 eyes with striae found that a majority of the eyes (77.3%) did not have induced cylinder measured on refraction. This finding might also be explained by the variation in striae severity and location. Mild striae likely induce higher-order aberrations (HOAs) that are visually significant without a change in lower-order astigmatism, while striae that are more pronounced might induce measurable cylinder. It is also possible that new cylinder is induced by flap movement only. Differentiating between true corrugations that are in the stroma deep to Bowman layer and caused by flap displacement or misalignment (macrostriae) versus simply grooves in Bowman layer that are true microstriae would be useful to correlate to induced new cylinder. Further analysis with wavefront measurements and clinical correlation to severity and location could also be useful.

The accuracy of the attempted correction improved significantly in eyes with striae that were treated ($P < .001$), with just a slightly higher cylinder magnitude after the relift (−0.25 ± 0.34 D) compared with control eyes (−0.16 ± 0.24 D) ($P < .001$). The efficacy index improved by 25% (0.73 to 0.91), also nearing levels in control eyes without striae. Despite the marked improvement, fewer eyes with striae than contralateral control eyes achieved 20/20 UDVA (68% versus 81%), more eyes with striae had a difference of 1 line or more between UDVA and CDVA (29.4% worse) compared with control eyes (18.1% worse), and the vector analysis index of success was higher (0.24 ± 0.41 versus 0.14 ± 0.27) ($P < .005$). This might explain why eyes treated for striae were twice as likely to need an excimer enhancement than eyes without striae (6.28% versus 3.04%), although the overall rate of retreatment was clinically low. Although striae caused a considerable loss of CDVA, with 51% of eyes with striae losing 1 to 3 lines of vision, the safety index returned to control values (0.99 versus 1.00; $P > .05$) and the loss of lines was reversed after a relifting procedure.

The authors believe that the positive outcomes obtained in this study are likely attributed to early intervention postoperatively when the striae were deemed to be visually significant, to meticulous technique of swelling the flap and repositioning it when necessary, and to repeating the intervention if the striae did not resolve. Surgeons must determine at the slitlamp whether the etiology of striae is from flap-bed mismatch, partial flap movement, or an entire flap misalignment. The clinical situation should dictate how many clock hours of the flap to open or whether the entire flap has to be refloated. Opening only a few clock hours in cases of flap bed mismatch or localized movement has the advantage of creating a pocket that can be filled with fluid and allows one to achieve maximum localized flap edema to distend the striae. One also avoids opening larger areas that can lead to unwanted epithelial ingrowth. The need for ingrowth removal after relift for striae removal was low at approximately 1.0%.

Irrigation as a technique for striae removal works by repositioning the flap displacement and by swelling the flap stroma to cause stretching of Bowman layer and overlying epithelium. Although the appearance of striae markedly improved right after irrigation, they did not resolve completely in all cases. This is likely explained by the elastic nature and memory of Bowman layer as well as potential early epithelial remodeling. Optical coherence tomography epithelial imaging at different healing stages before and after relifting and irrigation could prove useful to elucidate the role of epithelial remodeling in outcomes. Removing the epithelium overlying chronic striae has been described as a treatment option,[13,23–26] although it was not used in this study. In the authors' experience, it induces significant edema with a potential risk for DLK and a long visual recovery. Temporary interrupted sutures were used in the chronic cases that did not respond to repeated relifting and irrigation.

Of interest is the small rate of under-flap epithelial ingrowth requiring removal (1.0%), less than reported in flap relift excimer enhancements for microkeratome-assisted LASIK.[27–29] This is likely because care was taken not to introduce epithelium with the relift technique and because the intervention was performed early, before flap edge scarring began. Flap-edge adherence would have been strong with striae that had a relift, without an increased chance of delayed flap adherence creating a portal for epithelium from peripheral flap-edge fibrosis.

In this high-volume multicenter multisurgeon corporate refractive surgery practice with standardized technique, all 48 surgeons received the same training course consisting of an observership and proctorship and attended a yearly didactic teaching conference. All surgeons had proprietary teaching manuals readily available to review electronically as well as a peer consult group to communicate with on an as needed basis regarding patient care issues. Surgeons followed the same standardized LASIK surgical procedure and used the same indications to treat striae with the same relift and irrigation technique, all using identical equipment. It is this unique environment with medical infrastructure and oversight that enabled standardized technique and process with optimized quality control and assurance. To our knowledge, this is the first study to examine the outcomes of a treated LASIK complication with a standardized surgical intervention for which the medical protocol and process were controlled. This is also the first report of detailed refractive surgery outcomes comparing before and after striae flap relifting and irrigation with a comparison to contralateral eyes with no striae from a large EMR database.

Study limitations were that vision was not measured to better than 20/20 Snellen acuity in this busy large-volume setting and that neither contrast sensitivity nor HOAs were examined. Although measuring to 20/20 is adequate to draw results and conclusions, performing more detailed acuity and quality-of-vision assessments might have shown worse outcomes in treated eyes with striae.

In conclusion, in a large multicenter multisurgeon practice with a standardized process and protocol, the incidence of LASIK flap striae was 0.79% (1 in 125 eyes). The total ablation depth was the main risk factor for striae development. Reexamining 1 hour after surgery allowed for identification and timely intervention in almost 9.0% of striae cases. Early detection and treatment by flap lifting and irrigation reversed loss of lines of CDVA and significantly improved safety, equivalent to that in eyes with no striae and with minimal complications. Accuracy and efficacy after striae removal approached those for contralateral control eyes, with 13% less eyes achieving 20/20 UDVA and an excimer enhancement rate of 6%, double that of eyes without striae. Taping the eyelids closed immediately after LASIK flap repositioning might provide protection against developing clinically significant striae.

WHAT WAS KNOWN

- The development of flap striae is one of the more common post-LASIK complications and induces changes in manifest refraction and loss of UDVA and CDVA.
- Flap relifting and irrigation improve outcomes in eyes with striae.

WHAT THIS ARTICLE ADDS

- The incidence of flap striae requiring relift and irrigation was 0.79% but exponentially rose with increasing SE refraction, with nearly 9% of clinically significant striae occurring in the first hour after surgery.
- Fifty-one percent of all eyes with striae lost 1 to 3 lines of CDVA, with treatment reversing the loss and improving the efficacy index to near normal.
- Thirteen percent fewer striae-treated eyes achieved 20/20 UDVA and were twice as likely to need future excimer enhancement (6%) compared with controls (3%).

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