

Rate of ectasia and incidence of irregular topography in patients with unidentified preoperative risk factors undergoing femtosecond laser-assisted LASIK

Majid Moshirfar¹
Jared G Smedley²
Valliammai Muthappan¹
Allison Jarsted³
Erik M Ostler¹

¹John A Moran Eye Center, University of Utah, Salt Lake City, UT, USA;

²College of Human Medicine, Michigan State University, Lansing, MI, USA;

³Department of Ophthalmology, State University of New York Upstate Medical University, Syracuse, NY, USA

Purpose: To report the rate of postoperative ectasia after laser-assisted in situ keratomileusis (LASIK) with femtosecond laser-assisted flap creation, in a population of patients with no identified preoperative risk factors.

Methods: A retrospective case review of 1,992 eyes (1,364 patients) treated between March 2007 and January 2009 was conducted, with a follow up of over 4 years. After identifying cases of ectasia, all the patient charts were examined retrospectively for preoperative findings suggestive of forme fruste keratoconus (FFKC).

Results: Five eyes of four patients with post-LASIK ectasia were identified. All eyes passed preoperative screening and received bilateral LASIK. One of the five patients developed ectasia in both eyes. Three patients retrospectively revealed preoperative topography suggestive of FFKC, while one patient had no identifiable preoperative risk factors. Upon review of all the charts, a total 69 eyes, including four of the five eyes with ectasia, were retrospectively found to have topographies suggestive of FFKC.

Conclusion: We identified four cases of post-LASIK ectasia that had risk factors for FFKC on reexamination of the chart and one case of post-LASIK ectasia with no identifiable preoperative risk factors. The most conservative screening recommendations would not have precluded this patient from LASIK. The rate of purely iatrogenic post-LASIK ectasia at our center was 0.05% (1/1,992), and the total rate of post-LASIK ectasia for our entire study was 0.25% (1/398). The rate of eyes with unrecognized preoperative FFKC that developed post-LASIK ectasia was 5.8% (1/17).

Keywords: LASIK, ectasia, visual acuity, forme fruste keratoconus, topography

Introduction

Laser in situ keratomileusis (LASIK) has long been well established as a safe and effective corrective procedure for patients with refractive error. Complications are rare but can be visually devastating, particularly in the case of iatrogenic keratectasia. Postoperative ectasia results in severe, progressive myopic astigmatism that is traditionally considered to be irreversible. The development of postoperative ectasia varies between LASIK centers and depends on the screening tools used to screen candidates, the experience and technical skill of the surgeon, and the tools used during the surgery. Risk factors for the development of post-LASIK ectasia include a personal or family history of keratoconus, forme fruste keratoconus (FFKC), high myopia, low-residual stromal bed (RSB),^{1,2} and deep primary keratotomy resulting in a thick flap.³ Patients who develop ectasia will

Correspondence: Majid Moshirfar
John A Moran Eye Center, Old Mill
Medical Center, 6360 South 3000 East,
Suite 200, Salt Lake City,
Utah 84121, USA
Tel +1 801 585 3937
Fax +1 801 947 9286
Email majid.moshirfar@hsc.utah.edu

often show one or more of these risk factors upon review; however, patients with no risk factors have also developed ectasia following LASIK.^{4,5}

As recently as 2007, over half of the surgical centers surveyed in the United States were using the traditional mechanical microkeratome for LASIK flap creation, which has been shown to produce unpredictable cut depths and variable flap thickness.^{6–8} In the last half decade, there has been a shift towards femtosecond laser-assisted flap creation, which provides a more predictable flap profile.^{9,10} In this study, we examined the rate of ectasia in patients undergoing femtosecond laser-assisted LASIK as well as the incidence of abnormal topography, in patients who were identified as having no preoperative risk factors.

Methods and patients

A retrospective chart analysis was performed at the John A Moran Eye Center (Department of Ophthalmology and Visual Science, University of Utah), identifying 1,992 eyes of 1,364 patients who underwent femtosecond laser-assisted LASIK from March 11, 2007 to January 19, 2009, a time period of approximately 22.5 months. Patient data was examined, and follow up was assessed over a period of 4 years. The population consisted of 1,115 eyes from females (56%) and 877 eyes from males (44%), with an average patient age of 39 ± 5.17 years (range 21–52 years). Prior to surgery, all eyes were screened for keratoconus and the presence of associated risk factors, using slit-lamp examination, retinoscopy, topography, and Rabinowitz criteria.^{11–13} All patients were asked about a family history of keratoconus, and topographic analysis was done, using the Orbscan® IIz (Bausch and Lomb, Inc, Rochester, NY, USA), to screen all eyes for asymmetry, nonorthogonal bowties, or skewed radial axes. Corneal keratometry values were measured using an Atlas™ 9000 Corneal Topographer (Carl Zeiss Meditec Inc, Jena, Germany). All surgeries were performed by creation of a corneal flap with the IntraLase™ FS femtosecond laser (Abbott Medical Optics, Inc, Santa Ana, CA, USA) and with stromal ablation by the Visx Star S4 IR™ excimer laser (Abbott Medical Optics, Inc). In all cases, the right eye was operated on first, followed by the left eye. Intraoperative ultrasound pachymetry was not performed.

In this study, all of the patient charts were scrutinized postoperatively for evidence of preoperative risk factors, such as a family history of keratoconus, abnormal slit-lamp examinations, suspicious inferior steepening, and findings suggestive of FFKC as defined by Rabinowitz and McDonnell (central corneal power >47.2 D or inferosuperior asymmetry

value >1.4 D).^{12–14} In a manner similar to Randleman et al,¹ we defined postoperative ectasia as an inferior topographic steepening of 5 D or more compared with immediate postoperative topographies, along with a decrease in uncorrected visual acuity (UCVA) of two or more lines on the Snellen chart. We defined rate as the number of occurrences of ectasia at any time following LASIK surgery per number of eyes.

Case reviews

Case 1 (eye 1)

A 20-year-old woman underwent bilateral LASIK in July 2007. By 21 months postop, the patient began to experience blurred vision OD, with UCVA of 20/30 in the right eye (OD) and 20/20 in the left eye (OS); the best corrected visual acuity (BCVA) was 20/20 OD and 20/15 OS, and corneal topography showed inferonasal steepening OD (Figure 1), with a normal post-LASIK appearance OS. At the most recent follow up, the UCVA was 20/50 OD and BCVA was 20/25. Topography demonstrated inferonasal corneal ectasia OD, with simulated keratometry (SimK) measurements of 42.12/48.75 and Orbscan pachymetry thickness of 392 mm OD at the tip of the cone. The postoperative course of her left eye remained uncomplicated. The patient currently wears a rigid gas permeable lens in her right eye.

The postoperative retrospective chart review revealed FFKC bilaterally, with an acceptable central corneal power (<47.2 D) and an inferosuperior asymmetry value of 3.0 D in the affected eye (Figure 2). There was no noted family history of keratoconus.

Case 2 (eye 2)

A 39-year-old woman underwent bilateral LASIK in January 2008. At 44 months after surgery, the patient complained of decreased vision in her right eye. At that time, the patient

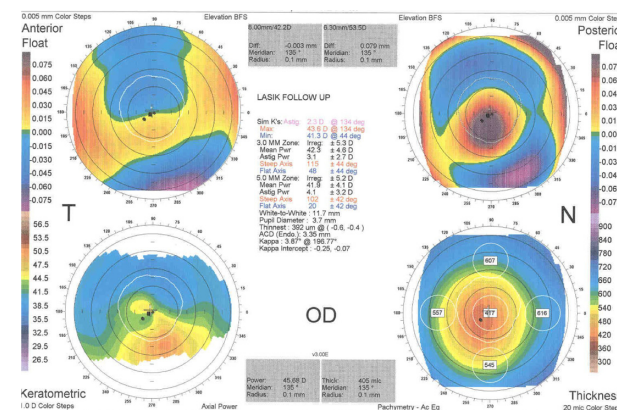


Figure 1 Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) image of patient 1, showing inferior ectasia in the right eye 21 months postoperatively.

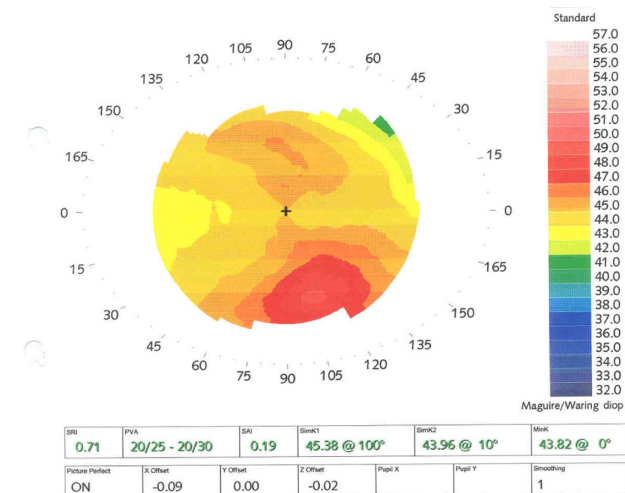


Figure 2 Preoperative Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) topography of patient 1, demonstrating inferior steepening of right eye.

had UCVA of 20/30 in each eye and BCVA of 20/30 OD and 20/20 OS. The result of the Orbscan study showed signs of inferior steepening OD (Figure 3) and a normal post-LASIK central flattening OS. The most recent postoperative evaluation showed UCVA of 20/30 OD and 20/25 OS. The keratometry measured 40.90/43.80 OD and 41.80/43.10 OS, with Orbscan pachymetries of 421 μm OD and 407 μm OS. She currently wears spectacles to achieve BCVA.

The postoperative retrospective chart review revealed inferior steepening in the right eye (Figure 4) as well as a preoperative pachymetry measurement of 458 μm and a RSB of 254 μm in this eye, which suggests a previously unrecognized FFKC. There was no noted family history of keratoconus.

Case 3 (eyes 3 and 4)

A 34-year-old female underwent bilateral LASIK in December 2008. At 12 months postop, the patient complained

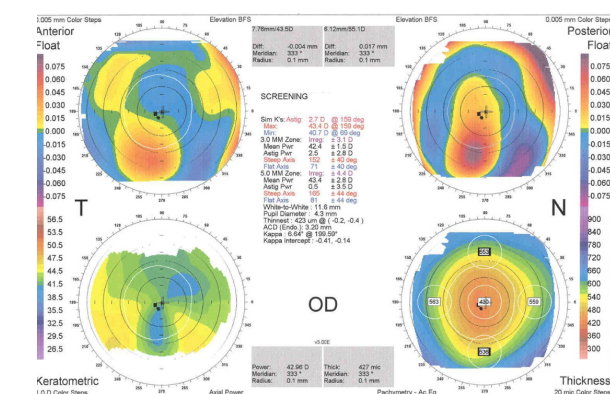


Figure 3 Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) image demonstrating inferior ectasia in the right eye at postoperative month 44 in patient 2.

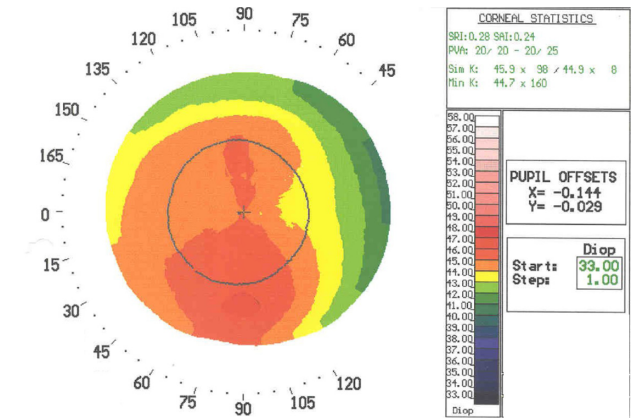


Figure 4 Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) topography demonstrating right eye inferior steepening preoperatively in patient 2.

of progressive blurring in both eyes. The UCVA was 20/50 OD and 20/80 OS, and the BCVA was 20/20 OD and 20/25 OS. The Orbscan revealed inferior steepening bilaterally (Figure 5). The UCVA at the most recent follow up, at 32 months postop, was 20/60 in both eyes (OU). Keratometry at this visit measured 40.60/42.00 OD and 41.20/42.80 OS (Figure 6), with Orbscan pachymetry of 479 μ m OD and 462 μ m OS. The patient currently has a spectacle-corrected BCVA of 20/25 OD and 20/15 OS.

As in cases 1 and 2, a retrospective review of the preoperative corneal topography demonstrated inferior steepening bilaterally (Figures 7 and 8). There was no noted family history of keratoconus.

Case 4 (eye 5): unilateral corneal ectasia with no identifiable preoperative risk factors

A 30-year-old male underwent bilateral LASIK in June 2007. At 20 months postprocedure, the patient experienced progressive blurring in his left eye. The UCVA was 20/25 OD and 20/150 OS, with a BCVA of 20/20 OU, corresponding

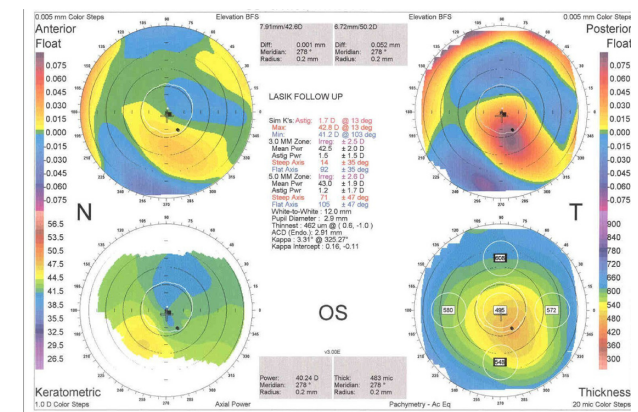


Figure 5 Orbiscan® (Bausch and Lomb, Inc, Rochester, NY, USA) image demonstrating inferior steepening of the left eye at 12 months postoperatively in patient 3.

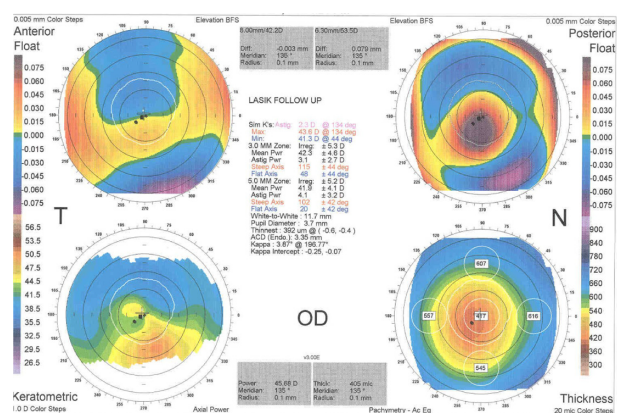


Figure 6 Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) demonstrating inferior ectasia in the right eye at 32 months postoperatively in patient 3.

to a manifest refraction of $-0.50 +0.75 \times 153$ OD and $-4.50 +3.25 \times 030$ OS.

By 22 months he complained of progressive blurring of his left eye. The UCVA was 20/200 OS and BCVA was 20/25, with an increase in average keratometry from 40.30 D to 42.37 D. Corneal topography showed significant inferior ectasia (Figure 9), and Orbscan pachymetry measured 523 μ m. The patient currently wears rigid gas permeable contact lenses to achieve a BCVA of 20/20 OS.

The retrospective review of the preoperative data showed relatively normal topography with no clear indication of keratoconus and no other risk factors for the development of postoperative ectasia (Figure 10). There was no noted family history of keratoconus.

Results

Over a period of 10.5 months, 1,992 femtosecond assisted LASIK procedures were performed at our institution. No intraoperative complications occurred during the time

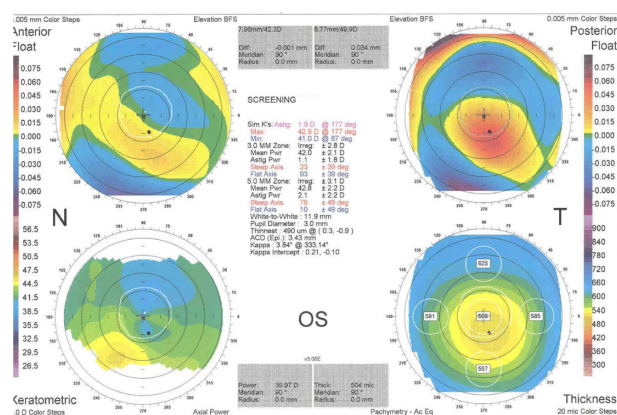


Figure 7 Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) showing inferior steepening preoperatively in the left eye of patient 3.

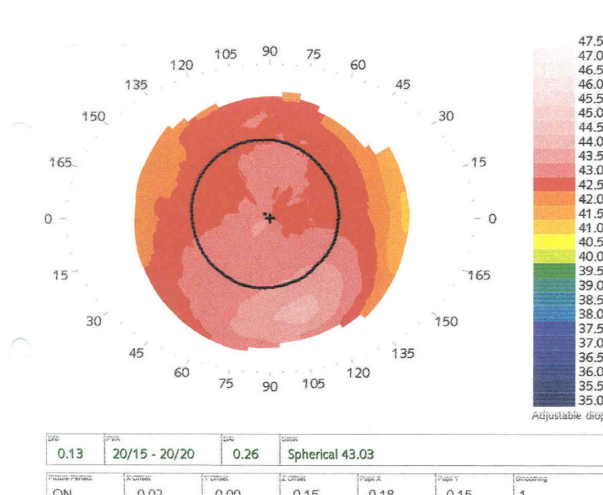


Figure 8 Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) topography showing inferior steepening preoperatively in the right eye of patient 3.

period of the study. The chart and topography review of all 1,992 eyes revealed that five eyes of four patients developed postprocedure ectasia. Based on the preoperative topographical review, it was determined that four of the five eyes with ectasia had topographical shifts suggestive of FFKC that passed initial screening, while one eye showed no clearly identifiable preoperative risk factors. In addition, 69 eyes, including four eyes with post-LASIK ectasia, were also found to have abnormal topographies suggestive of FFKC. Of these 69 eyes, there were 43 eyes from females (62%) and 26 eyes from males (38%), with an average patient age of 38 ± 4.50 years (range 21–48 years). The preoperative characteristics can be seen in Table 1.

In our study, the rate of post-LASIK ectasia in patients with no identifiable risk factors was one case of ectasia per 1,922 eyes, or 0.05% (69 eyes were subtracted from the total

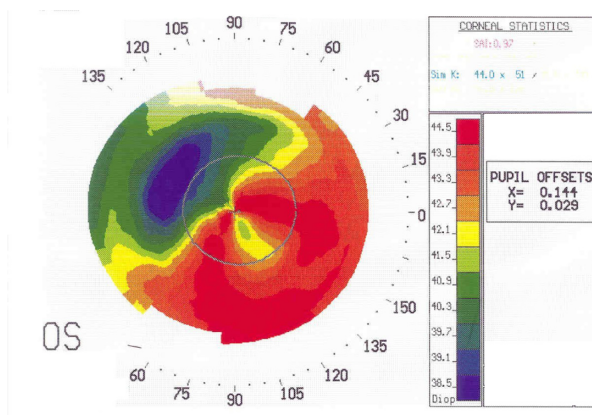


Figure 9 Inferior ectasia seen in patient 4's left eye 22 months postoperatively, by Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) topography scan.

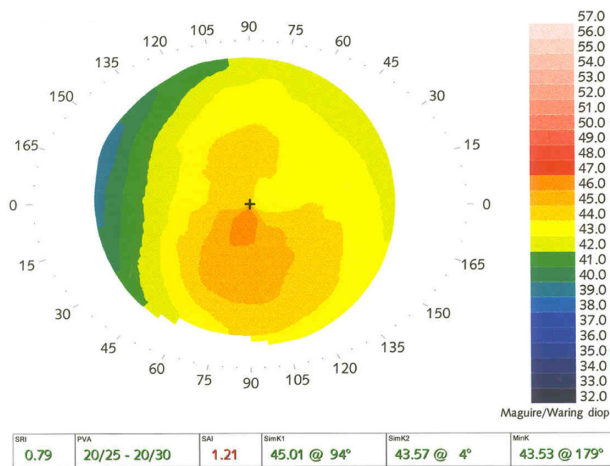


Figure 10 Normal preoperative topography of patient 4's left eye as seen on Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) topography scan.

due to identified preoperative risk of abnormal topography). Retrospectively, 69 eyes (3.5%) had preoperative topographies that were suggestive of FFKC. Four of these 69 eyes developed postoperative corneal ectasia, with a rate of one case of ectasia per 17 eyes (5.8%) in patients with unrecognized FFKC preoperatively. The rate of post-LASIK ectasia in eyes due to all causes was one case of ectasia per 398 eyes (0.25%). The average time to detection of post-LASIK ectasia in our study was 18.8 ± 6.51 months after surgery (range 5 to 44 months). The postoperative visual outcomes are seen in Table 2.

Discussion

The development of corneal ectasia is a well-known and visually devastating complication of LASIK surgery.^{4,12,15–24} In our study, we evaluated the rate of this complication after the implementation of the femtosecond laser for the creation of the LASIK flap. Abnormal topography was the most common risk factor, with four of the five eyes displaying this on the retrospective review of their charts. This has been reported in up to 50% of patients with iatrogenic ectasia.^{25,26}

Thinning of the cornea is one of the initial changes in ectasia and keratoconus.²⁷ Of the four eyes with postoperatively identified abnormal topography, two eyes also had preoperative ultrasound pachymetry measurements just below the recommended value of 500 μm . According to the Randleman criteria,¹ these two patients (three eyes) had two risk factors for developing ectasia: FFKC and reduced corneal thickness. The common methods for measuring central corneal thickness include ultrasound pachymetry, optical coherence tomography (OCT), and scheimpflug imaging Pentacam® (Oculus Optikgeräte GmbH, Wetzlar, Germany);

Table 1 Clinical data from preoperative LASIK consultations

Case (age/sex)	Eye	BCVA	Preoperative refraction	Keratometry (diopters)	Average Keratometry (diopters)	Ultrasound pachymetry (μm)	Target flap thickness (μm)	Calculated residual stromal bed (μm)	Attempted correction (spherical equivalent) (diopters)
Patient 1 (20/F)	OD*	20/20	-6.00+0.25x084	43.96/45.38@100	44.7	494	120	277	-5.9
	OS	20/20	-6.00+0.25x113	43.17/44.42@094	43.7	510	120	293	-5.9
Patient 2 (39/F)	OD*	20/15	-4.50+0.75x090	44.70/46.30@093	45.5	505	120	318	-4.1
	OS	20/15	-6.00+1.00x105	43.40/46.70@094	45.1	458	120	254	-5.1
Patient 3 (34/F)	OD*	20/20	-2.00+0.50x010	41.80/42.80@097	42.3	493	120	347	-1.6
	OS*	20/20	-1.75+1.00x150	42.20/43.00@085	42.6	489	120	353	-1.0
Patient 4 (30/M)	OD	20/20	-4.50+0.50x080	43.87/45.41@096	44.6	507	120	317	-4.3
	OS*	20/20	-4.50+0.50x105	43.57/45.01@096	44.3	523	120	333	-4.3

Notes: Calculations and data were based on the available Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) or Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) topography scans, manifest refraction, corneal pachymetry, and desired spherical equivalent correction as determined in the preoperative consultation for LASIK. *Eyes that developed ectasia following LASIK.

Abbreviations: BCVA, best corrected visual acuity; F, female; LASIK, laser-assisted in situ keratomileusis; M, male; OD, right eye; OS, left eye.

Table 2 Postoperative clinical data at 3 months post-LASIK and at the most recent follow up on record

Cases (age/ sex)	Eye	3-month post-LASIK follow-up visit			Most recent follow-up visit				
		Manifest refraction	Keratometry (diopters)	Average keratometry (diopters)	UCVA	BCVA	Manifest refraction	Keratometry (diopters)	Average keratometry (diopters)
Patient 1 (20/F)	OD*	-0.75 DS	38.73/39.63@108	39.2	20/50	20/25	-1.75 +3.50 ×157	42.12/48.75@070	45.4
	OS	plano	38.76/39.68@069	39.2	20/25	20/15	-1.00 DS	38.12/39.50@074	38.8
Patient 2 (39/F)	OD*	plano +0.50 ×110	41.10/42.10@100	41.6	20/30	20/20	-0.25 +0.75 ×133	40.90/43.80@157	42.4
	OS	plano +0.75 ×110	40.20/42.10@110	41.1	20/25	20/20	-0.75 +0.75 ×070	41.80/43.10@071	42.5
Patient 3 (34/F)	OD*	plano +0.50 ×015	40.30/41.10@150	40.9	20/60	20/20	-0.75 +2.25 ×170	40.60/42.00@168	41.3
	OS*	-1.75 +1.75 ×152	41.10/42.10@003	41.6	20/60	20/20	-1.25 +2.50 ×163	41.20/42.80@013	42.0
Patient 4 (30/M)	OD	-0.25 DS	40.15/41.21@105	40.6	20/25	20/20	-0.25 +1.00 ×140	38.75/41.75@122	40.3
	OS*	plano	39.88/40.70@072	40.3	20/200	20/25	-3.75 +2.75 ×045	39.50/45.25@045	42.4

Notes: The examination data and topography was collected at follow up 3 months post-LASIK. The final examination data and keratometry readings were determined by the most recent (or current) follow-up data on record after the diagnosis of ectasia. The examinations included visual acuities, refractions, and topographies performed with either an Atlas™ (Carl Zeiss Meditec Inc, Jena, Germany) or Orbscan® (Bausch and Lomb, Inc, Rochester, NY, USA) device. *Eyes that developed ectasia following LASIK. Similar to Randleman,¹ we defined postoperative ectasia as an inferior topographic steepening of 5 D or more compared with immediate postoperative topographies, along with a decrease in uncorrected visual acuity of two or more lines on the Snellen chart.

Abbreviations: BCVA, best corrected visual acuity; F, female; LASIK, laser-assisted in situ keratomileusis; M, male; OD, right eye; OS, left eye; UCVA, uncorrected visual acuity.

significant variations in accuracy and reproducibility have been seen between these different modalities and within the same modality, in repeated measurements. Thus it is difficult to define hard screening criteria for central corneal thickness.²⁸

When retrospectively applying the Randleman criteria to our study, four ectatic eyes were established to be high risk, while one eye with ectasia showed little to no preoperative risk. Intraoperatively, flap thickness and RSB thickness were not measured for these patients. RSB and flap thickness are known risk factors for the development of ectasia, with^{23,24} thicker flaps reducing the amount of tissue available for excimer ablation and final RSB thickness.^{25,28–30} Until recently, mechanical microkeratome was the primary method for flap creation, and flap thickness has varied greatly depending on the brand and plate size of the microkeratome.^{31–33} Despite improvements in consistency, there has still been significant variability in both the mean and range of flap thickness.^{6–8,34,35} One report attributed a case of post LASIK ectasia to a microkeratome-created flap with thickness of 225 µm that was intended to be 160 µm. It may be beneficial to measure flap thickness and RSB intraoperatively, to identify cases that may be at risk for postoperative ectasia despite a lack of risk on preoperative evaluation. The femtosecond laser has more reliability than the microkeratome in creating flaps of consistent

thickness; however, it is not unfailing, and some cases of ectasia may be due to a thicker-than-intended flap, even with laser-assisted flap creation.

Since 2008, the femtosecond laser has become the primary method for flap creation in the US,³⁶ with improved consistency of flap size, depth, and circularity. This reliability is particularly valuable for thin flap LASIK (90–120 micron thickness) techniques, which have been shown to limit the reduction in corneal tensile strength.^{9,37} The overall rate of ectasia has anecdotally been on the decline; however, due to the rarity of cases, the evidence of an overall trend is lacking. Klein et al have estimated a rate of 0.04%, or one in 2,500 cases, for microkeratome-assisted LASIK,³⁸ and other reports show rates of ectasia up to 0.9%.^{26,38–42} There are often limitations to the interpretations of the reported data, such as inadequate follow up or poor generalizability.⁴² A strength of our study is the wide variety of preoperative refractive error in our patients, the high rate of follow up over 4 years, and the consistency of all procedures (that were performed in a single facility, using the same IntraLase femtosecond laser for flap creation).

Regarding low-risk patients with ectasia, a prior study has suggested that approximately one out of every 1,000 patients (0.1%) who have undergone LASIK with microkeratome flap may later be identified as developing ectasia despite little to no identifiable preoperative risk.³⁹ In our study, approximately

one out of every 2,000 patients (0.05%) who underwent LASIK with femtosecond laser-assisted flap may be identified as developing ectasia with little to no preoperative risk. This represents a 50% rate reduction.

Interestingly, 69 eyes with abnormal topography underwent LASIK at our center, even after undergoing the rigorous preoperative screening. All of these cases were retrospectively identified as high risk, with a Randleman score of 4, excluding any other coexisting risk factors. However, only four of these eyes developed ectasia. This suggests that 94.2% of patients excluded from LASIK based on topography alone would not develop ectasia for 4 years. It is possible that these patients have not yet developed ectasia, and longer follow up of this group is warranted. Additionally, this highlights the need for more sensitive and specific tests to detect ectasia risk.

This study sought to determine the rate of iatrogenic ectasia in patients undergoing LASIK with femtosecond laser-assisted flap formation. The most significant limitation to this study was the lack of adequate date-matched studies addressing the rate of ectasia among cases of LASIK with mechanical microkeratome flap creation versus femtosecond laser-assisted LASIK. The best comparable study we found displays a cohort that underwent LASIK a minimum of 4 years before LASIK was performed in our population.⁴⁰ This study showed twice the rate of ectasia formation; however, one limitation to this interpretation is that changes in surgical techniques, heightened awareness and vigilance for risk factors, and general advances in other technologies over time, may have played a significant role in the difference in rate between the two studies. For example, newer screening modalities, using instruments such as the Pentacam or Visante OCT (Carl Zeiss Meditec, Inc), have proven better reproducibility of central corneal thickness measurements over ultrasound pachymetry. Additionally, we are comparing studies of procedures performed at one facility to those performed at another facility; each of these facilities may treat a special patient population that may not be entirely representative of the general population. All studies on iatrogenic ectasia suffer from the rarity of such cases and a delayed time to presentation complicated by a short follow up, leading to an underreporting of cases. Our study is stronger than most in this regard, due to the 4 years of follow up but still suffers from the small number of cases diagnosed with postprocedure ectasia.

A multicenter prospective longitudinal study of LASIK performed with mechanical microkeratome versus femtosecond laser would be most effective in comparing real-world

outcomes among LASIK patients but may be unrealistic due to the increased popularity of femtosecond lasers and the general belief that they are safer than microkeratomes. We propose that in addition to its other benefits, femtosecond-assisted laser also decreases the incidence of iatrogenic keratectasia, when compared with microkeratome-assisted procedures.

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Disclosure

The authors report no conflicts of interest in this work.

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